Bedside glucose testing systems

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	Abbott Diabetes Care 1420 Harbor Bay Parkway Alameda, CA 94502 510-749-5400 www.abbottdiabetescare.com	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com
Name of instrument/First year sold	Precision Xceed Pro Point of Care System/2007	Assure Pro/2006
Professional or home use	professional use	professional use
List price	—	free with competitive trade out
Units sold in U.S./Outside U.S./In 2007	—/—/—	n/a/n/a/n/a
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	19.7 cm (7.7 in) × 7.5 cm (2.96 in) × 5.33 cm (2.1 in)/256 g (9 oz)	4.1 × 2.4 × 1 in/2.5 oz without battery
Analytical method/Technology/Enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference	glucose oxidase
Price per disposable reagent system unit	—	contact sales representative
No. of dispos. reag. system units per basic package	100	50 or 100
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	15–18 months/4°–30°C	18 months/room temperature
Digital readout size/Keypad input capability	3.06 mm (normal), 8.16 mm (results)/menu selection, numeric, alphabetic	—/—
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable test strips	whole blood/capillary transfer
Minimum specimen volume required	2.5 µL with PCx Plus test strips	1 µL
Suitable for samples from well/Sick neonates	yes/yes	no/no
Time from sample intro. to result availability	20 seconds	10 seconds
Batteries used/No. used/Avg. life of one set	AA or NiMH rechargeable/2/—	1.5 V alkaline AAA/2/up to 5,000 tests
Avg. expected life of device/Mean time between failures	—/—	—/—
Device warranty/Service options	1 year, lifetime replacement with reagent contact/24-hour replacement	5 years/—
Loaners provided	yes	yes
User list or user group	yes, list available upon request	no
Toll-free No. for customer questions/Hours	877-529-7185/24 hours, 7 days	800-818-8877/24 hours, 7 days
Training and certif. program/No. training days provided	yes/depends on number of operators	yes/as needed
Avg. time for lab to complete maintenance	none	weekly: 5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	as defined by facility or institutional policy	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	92.0 mg/dL, CV=5.1% (3,215 labs)	n/a
• 100–200 mg/dL	205.3 mg/dL, CV=4.5% (6,612 labs)	n/a
• >400 mg/dL	387.4 mg/dL, CV=4.7% (3,167 labs)	n/a
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP Whole Blood Glucose Survey, WBG-C, 2007/—/—	n/a
Accuracy/Compared to what reference method or device	capillary blood: y=0.91x + 0.91, r=0.98/YSI	slope=0.91, r=0.96/YSI glucose analyzer
Precision/Compared to what reference method or device	blood samples: CV 2.9% to 5.1%/YSI	4.5%/—
Linear range	20–500 mg/dL	20–600 mg/dL
Suggested dynamic, measurement range	20–500 mg/dL	20–600 mg/dL
Contraindications	per labeling	yes
Known interferences/High-altitude interference	per labeling/none up to 7,200 feet	per labeling/no, tested up to 10,000 feet
Restrictions based on hematocrit	yes, glucose <300 mg/dL, 20–70%; glucose ≥300 mg/dL, 20–60%	yes, 30%–55%
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks performed during power-up of meter	automatic electronic
Sample quantity checks	fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected	—
When auto lock or shutdown occurs	user ID failure, QC failure	—
User defines QC lockout intervals/Lockout can be circumvented	yes/no	no/—
Device supports bar-code scanning of	operator & patient identifiers, reag. lot Nos., comment codes, control and linearity lot Nos.	no bar-code scanner
Method of analyst ID/ID required	bar-code or manual ID entry/analyst ID optional	—/—
Internal memory size/Max. No. patient results stored	1,000 control test results, 6,000 operators, 6,000 patient IDs, 2,500 patient test results, 18 glucose test strip lots, 20 proficiency test results, 20 glucose linearity test results (1 panel, 5 levels, 4 replicates per level)/2,500	250 tests with time & date stamp/250 test results
Information transfer capability:		
• Meters connect to	Precision Web data management system, which in turn connects to LIS/HIS	—
• How meters are connected to external system to upload results/No. installations	direct serial, modem dial-in, hospital network/—	—
• Info. contained in transmission to external system	device unique identifiers, operator and patient IDs, results, QC identifiers, strip lots, comment codes, test dates & times	—
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server	—
No. of different mgmt. reports system can produce	25	—
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, patient list, QC lockout and upload lockout parameters	—
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	Cerner, Misys, PerSe, Meditech, SoftLab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab	—
• using standard HL7 interface	Cerner, Misys, PerSe, Meditech, SoftLab	—
• using proprietary protocol interface	none	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes/Sybase	no
Distinguishing features (provided by vendors)	• TrueID: technology to ID patients by name, gender, date of birth, alphanumeric data entry • TrueMeasure: test strip technology detects adequate sample and minimizes chemical interference • TrueAccess: notification and lock-out technology helps ensure compliance with procedures	• 24-hour optional control solution reminder • top-of-meter strip insertion • strip release button • backlight display

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Survey editor: Raymond Aller, MD

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	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com
Name of instrument/First year sold	Assure 3/2003	Assure 4/2007
Professional or home use	professional and home use	professional and home use
List price	free with competitive trade out	free with competitive trade out
Units sold in U.S./Outside U.S./In 2007	—/—/37,900	—/—/—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	4 × 2.25 × .75 in/2.2 oz with battery	3.9 × 2.3 × 1.0 in/2.5 oz without batteries
Analytical method/Technology/Enzyme system used	glucose oxidase	glucose oxidase
Price per disposable reagent system unit	contact sales representative	contact sales representative
No. of dispos. reag. system units per basic package	50 or 100	50 or 100
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	18 months/room temperature	18 months/room temperature
Digital readout size/Keypad input capability	5 mm (w) x 10 mm (h)/none	—/none
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood/capillary transfer
Minimum specimen volume required	3 µL	1.5 µL
Suitable for samples from well/Sick neonates	no/no	no/no
Time from sample intro. to result availability	10 seconds	10 seconds
Batteries used/No. used/Avg. life of one set	3 V lithium/1/1,000 tests	1.5 V alkaline AAA/2/3,000 tests
Avg. expected life of device/Mean time between failures	20,000 tests/—	—/—
Device warranty/Service options	5 years/—	5 years/—
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions/Hours	800-818-8877/24 hours, 7 days	800-818-8877/24 hours, 7 days
Training and certif. program/No. training days provided	yes/as needed	yes/as needed
Avg. time for lab to complete maintenance	weekly: 3 minutes	weekly: 5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	as specified by accreditation	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	n/a	—
• 100–200 mg/dL	n/a	—
• >400 mg/dL	n/a	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—/—/—	—/—/—
Accuracy/Compared to what reference method or device	slope=0.93, r=0.976/YSI glucose analyzer	slope=1.010/r=0.993/ YSI glucose analyzer
Precision/Compared to what reference method or device	within-run: 3.4%; between run: 3.1%/—	4.1%/—
Linear range	30–550 mg/dL	30–550 mg/dL
Suggested dynamic, measurement range	30–550 mg/dL	30–550 mg/dL
Contraindications	no	no
Known interferences/High-altitude interference	L-dopa and dopamine/yes, 7,000 feet	per labeling/no (tested up to 7,000 feet)
Restrictions based on hematocrit	yes, 30%–55%	yes, 30%–55%
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	sumcheck functions for electronics and software, no optics
Sample quantity checks	one drop (≥ 3 µL)	—
When auto lock or shutdown occurs	1-minute time-out	—
User defines QC lockout intervals/Lockout can be circumvented	no/—	no/—
Device supports bar-code scanning of	no bar-code scanner	no bar-code scanner
Method of analyst ID/ID required	%	—
Internal memory size/Max. No. patient results stored	10-test memory/10	50-test memory/50
Information transfer capability:		
• Meters connect to	n/a	—
• How meters are connected to external system to upload results/No. installations	n/a	—
• Info. contained in transmission to external system	n/a	—
Hardware/software for data mgmt. system	n/a	—
No. of different mgmt. reports system can produce	n/a	—
Contents downloaded from DMS to meter	n/a	—
System connected (live installations) to which LISs/HISs:		—
• using screen animation/screen scraping	n/a	—
• using standard HL7 interface	n/a	—
• using proprietary protocol interface	n/a	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	n/a	—
Distinguishing features (provided by vendors)	• wick in test strip, ergonomically formed, large handle • fast test time—10 seconds • easy to use, low maintenance	• small sample size: 1.5 µL • fast test time: 10 seconds

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	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com
Name of instrument/First year sold	Glucose 201 DM Analyzer/2005	Glucose 201 Analyzer/2002
Professional or home use	professional use	professional use
List price	—	—
Units sold in U.S./Outside U.S./In 2007	—/—/—	—/—/—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	6.7 × 3.7 × 2 in/0.77 lb	6.3 × 3.4 × 1.7 in/0.77 lb
Analytical method/Technology/Enzyme system used	absorbance photometry/glucose dehydrogenase	absorbance photometry/glucose dehydrogenase
Price per disposable reagent system unit	—/—	—/—
No. of dispos. reag. system units per basic package	25 in vial/box; 4 vials/boxes per package	25 in vial/box; 4 vials/boxes per package
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	9 months from manufacture date/refrigeration	9 months from manufacture date/refrigeration
Digital readout size/Keypad input capability	varies from 8 to 28 points/menu selection, numeric, alphabetic	0.5 in/none
How results are displayed	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)	plasma equivalent values
Specimen types/Sampling techniques	whole blood (capillary, venous, arterial)/exact amount of blood drawn into 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	5 µL	5 µL
Suitable for samples from well/Sick neonates	—/—	—/—
Time from sample intro. to result availability	40–240 seconds	40–240 seconds
Batteries used/No. used/Avg. life of one set	rechargeable lithium ion supplied by HemoCue/—/several years	AA/4/150 hours
Avg. expected life of device/Mean time between failures	7 years/>5 years	7 years/>5 years
Device warranty/Service options	2 years at no additional cost/replacement of defective analyzer	2 years at no extra cost/—
Loaners provided	yes	yes
User list or user group	no	—
Toll-free No. for customer questions/Hours	800-323-1674, 6 AM–5 PM PST	800-323-1674, 6 AM–5 PM PST
Training and certif. program/No. training days provided	yes/~1 hour per device purchased	yes/as needed
Avg. time for lab to complete maintenance	daily: ≤5 minutes	daily: ≥5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	one level of controls prior to patient testing, each day of testing	system must be verified on testing days using commercially available controls
Between instrument CV (based on PT) at these 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), 2003/2003–03; 2003–07/272 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	±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	within run CV 1.9% (108 mg/dL)/—	within run CV 1.9% (108 mg/dL)/—
Linear range	0–444 mg/dL	0–444 mg/dL
Suggested dynamic, measurement range	0–444 mg/dL	0–444 mg/dL
Contraindications	no	no
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	no	no
Electronic, optical function checks	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	n/a
User defines QC lockout intervals/Lockout can be circumvented	yes/no (stat testing may be allowed; 1–100 tests after QC interval)	no/no
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID	no bar-code scanner
Method of analyst ID/ID required	alpha-numeric manual entry or bar-code scan entry/optional	n/a
Internal memory size/Max. No. patient results stored	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000	n/a/n/a
Information transfer capability:		
• Meters connect to	analyzer connects to 201 DM docking stations (data management system, which can further transmit data)	n/a
• How meters are connected to external system to upload results/No. installations	direct USB/hospital network	n/a
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags	n/a
Hardware/software for data mgmt. system	PC/server/HemoCue 201 DM PC software	—
No. of different mgmt. reports system can produce	15 different templates, custom reports based on templates, multiple export formats	—
Contents downloaded from DMS to meter	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration	—
System connected (live installations) to which LISs/HISs:		—
• using screen animation/screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Telcor QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator	—
Distinguishing features (provided by vendors)	• POCT-1A compliant • indicated for diagnosis of diabetes mellitus • not hematocrit dependent	• CLIA waived • indicated for diagnosis of diabetes mellitus • not hematocrit dependent • lab verification of patient home meter

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	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com	LifeScan Inc. Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com
Name of instrument/First year sold	IRMA TRUpoint (glucose module)	OneTouchFlexx*/2000
Professional or home use	professional use	professional use
List price	$350	$1,200 with bar-code scanner/$1,300 with bar-code scanner, meter unlock, and bar-code scan required features/$850 without bar-code scanner
Units sold in U.S./Outside U.S./In 2007	—/—/—	>41,000/>3,500/—
Part of series of similar or related models	no	yes
Dimensions (H x W x D)/Weight	5 × 9.5 × 13.5 in/6 lb (IRMA TRUpoint)	6.34 × 3.55 × 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without)
Analytical method/Technology/Enzyme system used	glucose only: reflectance photometry, glucose oxidase	reflectance photometry/glucose oxidase
Price per disposable reagent system unit	—	by contract, volume
No. of dispos. reag. system units per basic package	50 strips	Two 25-strip vials (50 strips per box)
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	strip: 18 months/room temperature	18 months unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/Keypad input capability	4.5 x 2.5 in/menu selection, numeric, alphabetic	18-point font (16 pixels high, 8 pixels wide)/menu select., numeric, alphabetic
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable strip	whole blood/drop, capillary, venous, arterial, neonatal blood samples, touchable strip
Minimum specimen volume required	1 drop	5 µL, maximum 30 µL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	<45 seconds	15-second minimum
Batteries used/No. used/Avg. life of one set	rechargeable NIMH battery/1/3 years	AA/3/1,000 test minimum
Avg. expected life of device/Mean time between failures	>5 years/<3% warranty return rate	5-year minimum/<3% warranty return rate
Device warranty/Service options	1 year/extended warranty service available	1 year/extended service agreements available
Loaners provided	24-hour replacement upon request	24-hour replacement with new device
User list or user group	yes	yes (contact OneTouchFlexx product manager)
Toll-free No. for customer questions/Hours	800-631-5945/24 hours, 7 days	800-524-7226/24 hours, 7 days, multiple languages
Training and certif. program/No. training days provided	yes/depends on No. of operators	yes/as negotiated
Avg. time for lab to complete maintenance	clean glucose module as needed, 2 minutes	none
Special cleansing procedures	no	no
Internal QC recommended or required	based on hospital-specific policy	as defined by hospital policy
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	4.39%	2.5%
• 100–200 mg/dL	3.44%	2.9%
• >400 mg/dL	4.97%	2.4%
• Program name, year/Challenge No./Level of mean glucose challenge sample	data from 2000 AACC poster	data from 2000 & 2001 AACC posters
Accuracy/Compared to what reference method or device	r >0.98/YSI	>0.98/YSI
Precision/Compared to what reference method or device	3.44–4.97 CV across runs/—	3.44–4.97/YSI
Linear range	0–500 mg/dL	0–500 mg/dL
Suggested dynamic, measurement range	0–500 mg/dL	0–500 mg/dL
Contraindications	excessive H_2O loss or dehydration	excessive water loss or dehydration
Known interferences/High-altitude interference	sodium fluoride/no	sodium fluoride/no
Restrictions based on hematocrit	yes, <25% high results, >60% low results	adults: 25%–60% RBC; neonates: 25%–65% RBC
Electronic, optical function checks	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test	automatic electronic and optical checks with each test
Sample quantity checks	uses LED to determine sufficient quantity	test strip color confirmation dot when adequate sample applied; meter error messages
When auto lock or shutdown occurs	user ID failure, QC failure, lockout if reagent expired or if control lot & reagent not entered	user ID failure, QC failure, failure to transfer data
User defines QC lockout intervals/Lockout can be circumvented	yes/no	yes/yes, automatic meter unlock feature requires no user intervention
Device supports bar-code scanning of	bar-code scanner available	operator & patient identifiers, reagent (strip) lot Nos., control solution lot Nos., meter serial Nos.
Method of analyst ID/ID required	touchscreen/optional or required, QA user setup	unique alphanumeric ID/optional (defined by location)
Internal memory size/Max. No. patient results stored	4 MB RAM, 4 MB ROM, 256 KB nonvolatile/200 patient results	256 KB/1,500 patient +QC tests, 50-test strip lots and 50 QC lots
Information transfer capability:		
• Meters connect to	data management system, which connects to LIS/HIS; also directly to LIS/HIS	DataLink Data Management System via network and/or modem connectivity solutions: DataLink can be interfaced to LIS/HIS (script & EDI)
• How meters are connected to external system to upload results/No. installations	direct serial/—, modem dial-in/—, Ethernet/—	DataLink Connect connectivity solutions; modem, network/wireless connectivity >1,250 hospital sites, DataLink interface >440
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, results dates & times, strip/material lots, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample types	device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site
Hardware/software for data mgmt. system	nondedicated IBM compatible PC, Integrated Data Management System	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML; DataLink Web
No. of different mgmt. reports system can produce	6	12 standard, unlimited customized reports, TGC advisor
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs	strip lot Nos., valid control values, valid operator IDs, critical value ranges, comment codes
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	major vendors	DHCP-VA system, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier
• using standard HL7 interface	major vendors	Cerner Millennium & Pathnet (legacy); Misys Flexilab; Meditech Magic & client/server
• using proprietary protocol interface	none	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, through laboratory data systems	yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features (provided by vendors)	• integrated workstation with IRMA TRUpoint (blood gas, electrolytes, BUN, creatinine, lactate, cartridge glucose test, Hct) • 1 user interface, 1 in-service program, 1 data management system	• accurate results in the presence of maltose, xylose, or galactose • configurable bar-code scanning options—allows truncation of leading and trailing characters • bar-code scan required feature • unique meter unlock • hardware independent DataLink software • compatible with Telcor's QML • flexible database options • wireless connectivity

*SureStepFlexx has become the OneTouchFlexx

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	Medtronic MiniMed Inc. 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	**CGMS iPro Recorder/2008**	**StatStrip Glucose Monitoring System/2006**
Professional or home use	professional use	professional use
List price	$35 per unit for glucose sensor; $1,299 for CGMS iPro starter kit	$ 1,500, includes bar-code reader, spare battery, quick reference guide
Units sold in U.S./Outside U.S./In 2007	—/—/—	n/a/n/a/n/a
Part of series of similar or related models	yes (third-generation professional CGM system)	yes
Dimensions (H × W × D)/Weight	—/<5 grams	6.0 × 3.25 × 1.8 in/0.8 lb
Analytical method/Technology/Enzyme system used	glucose oxidase	electrochemistry
Price per disposable reagent system unit	$35 unit glucose sensor (disposable)	pricing based on volume
No. of dispos. reag. system units per basic package	10 per box	25 strips per vial and 50 per box
No. of times analyses performed using 1 reag. system unit	1 sensor lasts 72 hours	1
Dispos. units shelf life/Reag. unit storage requirements	6 months/non-refrigeration 36°–80°F (2°–27°C)	24 months from date of manufacture/none
Digital readout size/Keypad input capability	no patient monitor interface/blinded glucose values, retrospective data at time of iPro recorder download, system displays retrospective only/numerical agreement; avg. difference between glucose sensor and glucose meter of –5.4 mg/dL, daily median correlation coefficient of 0.92, calibration using blood glucose meters daily	varies and is defined by the particular field/numeric, alphabetic
How results are displayed		true values
Specimen types/Sampling techniques	continuous monitoring and sampling of interstitial fluid glucose levels	whole blood/drop (arterial, venous, capillary, neonatal)
Minimum specimen volume required	n/a	1.2 µL
Suitable for samples from well/Sick neonates	no/yes (with diabetes)	yes/yes
Time from sample intro. to result availability	retrospective analysis after disconnection	6 seconds
Batteries used/No. used/Avg. life of one set	rechargeable battery, CGMS iPro charger, AAA/1/—	3.7 Li Polymer (rechargeable/replaceable)/1/8 hours
Avg. expected life of device/Mean time between failures	1 year/—	n/a/n/a
Device warranty/Service options	6 months for iPro Recorder/no warranty on disposables	2 years (extended 5-year warranty at additional cost)/meter replacement
Loaners provided	no	yes
User list or user group	no	no
Toll-free No. for customer questions/Hours	800-646-4633/—	800-458-5813/24 hours, 7 days, all year
Training and certif. program/No. training days provided	yes (training only)/~1 day	yes/defined during implementation planning
Avg. time for lab to complete maintenance	none	no user maintenance
Special cleansing procedures	no	no
Internal QC recommended or required	none	CLIA requirements 2 levels per day
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	n/a
• 100–200 mg/dL	5% (40–400 mg/dL) in vitro	n/a
• >400 mg/dL	—	n/a
• Program name, year/Challenge No./Level of mean glucose challenge sample	CGMS 1999, CGMS Gold 2003, CGMS iPro 2008	—
Accuracy/Compared to what reference method or device	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements	R2=0.9978, slope=1.0127–2.0975/YSI 2300
Precision/Compared to what reference method or device	—/glucose meters, HemoCue, YSI (any and all)	within run (whole blood=1.9%–3.6%) & (day to day=3.4%–4.7%) linearity standards/—
Linear range	—	10–600 mg/dL
Suggested dynamic, measurement range	40–400 mg/dL	10–600 mg/dL
Contraindications	not recommended for use by those with impaired vision or hearing	—
Known interferences/High-altitude interference	possibly MRI/no	none/no, operates at altitudes up to 15,000 feet
Restrictions based on hematocrit	no	none (no Hct interference)
Electronic, optical function checks	test plug, 24–29nA	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results
Sample quantity checks	none	RapidFill sampling electronically checks for correct strip dosing
When auto lock or shutdown occurs	none	options include user ID failure, QC failure, required docking for data transfer
User defines QC lockout intervals/Lockout can be circumvented	no/no	yes/no, not if configured
Device supports bar-code scanning of	no bar-code scanner	operator & patient identifiers, reagent, lot No., QC lots
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/Max. No. 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
Information transfer capability:		
• Meters connect to	ComLink for CGMS iPro	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/No. installations	serial port/—	hospital network/n/a
• Info. contained in transmission to external system	patient IDs, results	device unique identifier, operator & patient IDs, results, QC identifiers
Hardware/software for data mgmt. system	ComLink for CGMS iPro and Solutions Software	connects to Telcor QML and Laboratory Data Systems AegisPOC
No. of different mgmt. reports system can produce	7 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
System connected (live installations) to which LISs/HISs:	does not interface LIS or HIS, a report from software–nontransferable	available through Telcor & Laboratory Data Systems
• using screen animation/screen scraping	no	available through Telcor & Laboratory Data Systems
• using standard HL7 interface	no	yes
• using proprietary protocol interface	no	no
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	no	yes, Telcor QML/Quick-Linc, Laboratory Data Systems AegisPOC
Distinguishing features (provided by vendors)	• continuous glucose values collected (every 5 minutes) • up to 14 days of data • blood glucose values from bg meter and events (meals, insulin, exercise) downloaded into Solution Software	• measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose • no calibration codes required • results reported in 6 seconds using 1.2 µL of sample

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Bedside glucose testing systems

Part 6 of 7	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
Name of instrument/First year sold	AccuData GTS, 1994; AccuData GTS Plus, 2000	Accu-Chek Inform System/2001
Professional or home use	professional use	professional use
List price	$550	$1,200
Units sold in U.S./Outside U.S./In 2007	40,000*/5,000/—	55,000/10,000/—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	11 × 8.75 × 4 in/5 lb	1.4 × 3.8 × 7.6 in/12 oz
Analytical method/Technology/Enzyme system used	biosensor–glucose dehydrogenase	biosensor—glucose dehydrogenase
Price per disposable reagent system unit	contingent on contract price	contingent on contract price
No. of dispos. reag. system units per basic package	50 strips per vial	50 test strips
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. 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 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/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	26 seconds	26 seconds
Batteries used/No. used/Avg. life of one set	3 V lithium/2/~700 tests	3.7 V rechargeable lithium ion/1/testing in progress
Avg. expected life of device/Mean time between failures	5 years/10,000 tests	5 years/542,000 tests
Device warranty/Service options	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	Accu-Chek Inform System will be free from defects in materials & workmanship through life of the Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7, 365 days per year
Loaners provided	replaced under warranty	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	800-440-3638/24 hours, 365 days per year	800-440-3638/24 hours, 365 days per year
Training and certif. program/No. training days provided	yes/site-specific according to No. of employees	yes/site-specific according to No. of employees
Avg. time for lab to complete maintenance	none	none
Special cleansing procedures	no	acceptable active ingredients: water, soap, 70% (or less) isopropyl alcohol, 1:10 dilution of sodium hydrochlorite
Internal QC recommended or required	daily, 2 levels	daily, 2 levels of glucose control solutions
Between instrument CV (based on PT) at these 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
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
Linear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic, measurement range	10–600 mg/dL	10–600 mg/dL
Contraindications	per labeling	yes, per labeling
Known interferences/High-altitude interference	per labeling/none up to 10,150 feet	per labeling/none up to 10,150 ft
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, 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 op.), QC failure, patient ID length, incorrect code key, incorrect Advantage meter	user ID failure (valid op.), QC failure, download interval lockout, patient ID length, reagent editing, mandatory comments, incorrect/missing code key, time, and data editing
User defines QC lockout intervals/Lockout can be circumvented	yes/yes (information management system identifies operators who violate hospital policy)	yes/no (optional QC pass/fail feature)
Device supports bar-code scanning of	operator & patient identifiers, comment codes	operator & 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/Max. No. patient results stored	1,000 total patient, control, linearity, proficiency tests/1,000	4,000 results/4,000 tests
Information transfer capability:		
• Meters connect to	information management system, which in turn connects to LIS/HIS	information management system, which in turn connects to LIS/HIS
• How meters are connected to external system to upload results/No. installations	direct serial/—, modem dial-in/—, hospital network/—	direct serial/—, modem dial-in/—, hospital network/—
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., download location, comment codes, proficiency & linearity samples	device unique identifiers, operator & patient IDs, results, strip lot Nos., QC identifiers, proficiency & linearity samples, comments, meter location, download location
Hardware/software for data mgmt. system	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook†, and MAS RALS-Web
No. of different mgmt. reports system can produce	varies by Data Manager (customer defined)	varies by Data Manager (customer defined)
Contents downloaded from DMS to meter	strip & QC lot Nos., valid operator IDs, valid control values, linearity values	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot Nos. & values, comments
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	all major LIS vendors including Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, Opus, others**	all major LIS vendors including Cerner, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, SIA Molis, Opus, others**
• using standard HL7 interface	—	yes
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	MAS	MAS
Distinguishing features (provided by vendors)	• 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 the Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry with reliable results at varying hematocrit levels • offers alphanumeric touchscreen, onboard bar-code ID, plus connectivity, including ADT feed provides two patient identifiers for confirmation • extends the quality of blood glucose programs to six other point-of-care tests by allowing the entry and transfer of manual test information

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

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

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Bedside glucose testing systems

Part 7 of 7	YSI Life Sciences Jamie Lussier jlussier@ysi.com 1725 Brannum Lane, Yellow Springs, OH 45387 800 659-8895 www.ysilifesciences.com
Name of instrument/First year sold	YSI 2300 STAT Plus Glucose & Lactate Analyzer/1989
Professional or home use	professional use
List price	$10,600
Units sold in U.S./Outside U.S./In 2007	—/—/—
Part of series of similar or related models	yes
Dimensions (H x W x D)/Weight	35.6 × 35.6 × 25.4 cm/25 lbs. (11.4 kg)
Analytical method/Technology/Enzyme system used	enzyme electrode, hydrogen peroxide, glucose oxidase
Price per disposable reagent system unit	$15 per membrane sensor (cost per test: $0.14 @ 2,000 patient samples)
No. of dispos. reag. system units per basic package	4 membranes per package
No. of times analyses performed using 1 reag. system unit	time based 3 weeks, 1000+ patient samples
Dispos. units shelf life/Reag. unit storage requirements	1 year/liquid reagents: room temp.; membrane sensor: 4°C refrigerated
Digital readout size/Keypad input capability	font hgt: 0.2 in., 2 x 40 alphanumeric LCD/menu selection, numeric
How results are displayed	true and calculated values
Specimen types/Sampling techniques	plasma, serum, whole blood/probe aspirated 25 µL
Minimum specimen volume required	35–50 µL, dependent upon tube style
Suitable for samples from well/Sick neonates	yes/yes
Time from sample intro. to result availability	65 seconds
Batteries used/No. used/Avg. life of one set	AC line power/—/—
Avg. expected life of device/Mean time between failures	non-specified, 10 years+/unknown
Device warranty/Service options	1 year/on all parts and labor/on-site service, dealer service centers, manufacturer service center in Ohio
Loaners provided	yes
User list or user group	no (YSI 2300 is a reference blood instrument)
Toll-free No. for customer questions/Hours	yes/8 AM-5 PM EST USA
Training and certif. program/No. training days provided	yes/onsite: 1 day; vendor office: negotiable
Avg. time for lab to complete maintenance	daily: 15 min (calibration and check solution sample); weekly: 30 min (buffer solution change); monthly: 30 min (calibration solution and buffer solution change)
Special cleansing procedures	no
Internal QC recommended or required	run a daily third-party control, such as a serum control
Between instrument CV (based on PT) at these levels:	
• <50 mg/dL	2.5 mg/dL*
• 100–200 mg/dL	2%*
• >400 mg/dL	2%*
• Program name, year/Challenge No./Level of mean glucose challenge sample	—/—/—
Accuracy/Compared to what reference method or device	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	hexokinase/UV spectrophotometric compared to plasma
Linear range	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Suggested dynamic, measurement range	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Contraindications	no
Known interferences/High-altitude interference	none that are biological in nature/no
Restrictions based on hematocrit	no
Electronic, optical function checks	— (sensor technology is amperometric, not optically based)
Sample quantity checks	—
When auto lock or shutdown occurs	calibration instability, low reagent levels, various electromechanical checks related to moving parts
User defines QC lockout intervals/Lockout can be circumvented	—/—
Device supports bar-code scanning of	no bar-code scanner
Method of analyst ID/ID required	numeric identifier optional/optional
Internal memory size/Max. No. patient results stored	—/last 32 results stored in internal buffer accessible by serial port
Information transfer capability:	
• Meters connect to	— (requires customized software for LIS/HIS interface)
• How meters are connected to external system to upload results/No. installations	—/—
• Info. contained in transmission to external system	—
Hardware/software for data mgmt. system	through custom software, patient ID and results may be retrieved
No. of different mgmt. reports system can produce	—
Contents downloaded from DMS to meter	—
System connected (live installations) to which LISs/HISs:	
• using screen animation/screen scraping	—
• using standard HL7 interface	—
• using proprietary protocol interface	
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—
Distinguishing features (provided by vendors)	• commonly used reference method for glucometers • ideal for hospital diabetes evaluation testing, e.g. clamp studies • accurate stat whole blood glucose 1 minute result

*based on YSI proof of claims testing

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