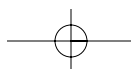
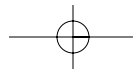


## Bedside glucose testing systems

<b>Part 1 of 6</b>	Abbott Diabetes Care 1360 Harbor Bay Parkway Alameda, CA 94502 800-323-9100 www.abbottdiabetescare.com	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com
<i>Please see accompanying article on page 22</i>		
<b>Name of instrument/First year sold</b>	Precision PCx/1998	Assure Pro/2006
<b>Professional or home use</b>	professional use	professional use
<b>List price</b>	—	free with competitive trade out
<b>Units sold in U.S./Outside U.S./In 2006</b>	40,707/15,000/—	n/a/n/a/n/a
<b>Part of series of similar or related models</b>	yes, i-Stat 1	yes
<b>Dimensions (H x W x D)/Weight</b>	7.7 x 2.95 x 5.1 in/10 oz	4.1 x 2.4 x 1 in/2.5 oz without battery
<b>Analytical method/Technology/Enzyme system used</b>	amperometric/glucose oxidase with Precision PCx strips/glucose dehydrogenase with PCx Plus test strips	glucose oxidase
<b>Price per disposable reagent system unit</b>	—	contact sales representative
<b>No. of dispos. reagent system units per basic package</b>	100 per box	50, 100
<b>No. of times analyses performed using 1 reagent system unit</b>	1	1
<b>Dispos. units shelf life/Reagent unit storage requirements</b>	12–18 months (room temperature)/39°–86°F	18 months/room temperature
<b>Digital readout size/Keypad input capability</b>	font size 24 points/menu selection, numeric	—/—
<b>How results are displayed</b>	true values	true values
<b>Specimen types/Sampling techniques</b>	whole blood/drop, can apply blood directly to test strip	whole blood/capillary transfer
<b>Minimum specimen volume required</b>	3.5 µL with PCx, 2.5 µL with PCx Plus	1 µL
<b>Suitable for samples from well/Sick neonates</b>	yes/yes	no/no
<b>Time from sample intro. to result availability</b>	20 seconds	10 seconds
<b>Batteries used/No. used/Avg. life of 1 set</b>	AA/2/~60 days (based on 30 tests/day)	1.5V alkaline AAA/2/up to 5,000 tests
<b>Avg. expected life of device/Mean time between failures</b>	24 months/24 months	—/—
<b>Device warranty/Service options</b>	1-year warranty, lifetime replacement with reagent contact/24-hour replacement	5-year warranty/—
<b>Loaners provided</b>	yes	yes
<b>User list or user group</b>	yes	no
<b>Toll-free No. for customer questions/Hours</b>	800-323-9100/24 hours, 7 days	800-818-8877/24 hours, 7 days
<b>Training and certif. program/No. training days provided</b>	yes/depends on No. of operators	yes/as needed
<b>Avg. time for lab to complete maintenance</b>	none	weekly: 5 minutes
<b>Special cleansing procedures</b>	no	no
<b>Internal QC recommended or required</b>	as required by facility or institutional policy or when glucose results are questioned or when new lot No. is received	as specified by accreditation
<b>Between instrument CV (based on PT) at these levels:</b>		
• <50 mg/dL	—	n/a
• 100–200 mg/dL	71.9 mg/dL, CV=4.1%; 192.3 mg/dL, CV=5.5%	n/a
• >400 mg/dL	400.7 mg/dL, CV=6.9%	n/a
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP Whole Blood Glucose Survey, 2003/Set B	n/a
<b>Accuracy/Compared to what reference method or device</b>	capillary blood: $y=0.91x + 0.91$ , $r=0.98$ /YSI	slope=0.91, $r=0.96$ /YSI glucose analyzer
<b>Precision/Compared to what reference method or device</b>	blood samples: CV 2.9% to 5.1%/YSI	4.5%/n/a
<b>Linear range</b>	20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx	20–600 mg/dL
<b>Suggested dynamic, measurement range</b>	20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx	20–600 mg/dL
<b>Contraindications</b>	per labeling	yes
<b>Known interferences/High-altitude interference</b>	per labeling/none up to 7,200 feet	per labeling/no, tested up to 10,000 feet
<b>Restrictions based on hematocrit</b>	yes, glucose <300 mg/dL, 20–70%; glucose ≥300 mg/dL, 20–60%	yes, 30%–55%
<b>Electronic, optical function checks</b>	battery, bar-code scanner, database, and temperature checks performed during power up of meter	automatic electronic
<b>Sample quantity checks</b>	a fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected	—
<b>When auto lock or shutdown occurs</b>	user ID failure, QC failure, download time if selected	—
<b>User defines QC lockout intervals/Lockout can be circumvented</b>	yes/no	no/—
<b>Device supports bar-code scanning of</b>	operator & patient identifiers, reagent lot Nos., comment codes, control & linearity lot Nos.	no bar-code scanner
<b>Method of analyst ID/ID required</b>	manual or bar-code ID entry/operator ID lockout optional	n/a/—
<b>Internal memory size/Max. No. patient results stored</b>	4,000 patient results, 1,000 controls, 1,000 operators/—	250 tests with time & date stamp/250 test results
<b>Information transfer capability:</b>		
• 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/50+; modem dial-in/100+; hospital network/800+	—
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., test dates & times, comment codes	—
<b>Hardware/software for data mgmt. system</b>	Enterprise multi-user Web-based system running on highly redundant Dell server	n/a
<b>No. of different mgmt. reports system can produce</b>	25	n/a
<b>Contents downloaded from DMS to meter</b>	strip lot Nos., valid control values, valid operator IDs, QC lockout & upload lockout parameters	n/a
<b>System connected (live installations) to which LISs/HISs:</b>		
• using screen animation/screen scraping	Misys, Cerner, Meditech, Soft Lab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab	n/a
• using standard HL7 interface	Cerner, Misys, PerSe, Meditech, Soft Lab	n/a
• using proprietary protocol interface	none	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Sybase	no
<b>Distinguishing features (provided by vendors)</b>	<ul style="list-style-type: none"> <li>• positive reagent ID</li> <li>• positive calibration ID—no need to visually verify code key against test strip vial</li> <li>• ability to reapply blood within 30 seconds to same strip</li> </ul>	<ul style="list-style-type: none"> <li>• 24-hour optional control solution reminder</li> <li>• top-of-meter strip insertion</li> <li>• strip release button</li> <li>• backlight display</li> </ul>

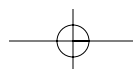


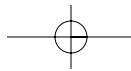


## Bedside glucose testing systems

<b>Part 2 of 6</b>	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com
<i>Please see accompanying article on page 22</i>		
<b>Name of instrument/First year sold</b>	Assure 3/2003	Glucose 201 DM Analyzer/2005
<b>Professional or home use</b>	professional & home use	professional use
<b>List price</b>	free with competitive trade out	—
<b>Units sold in U.S./Outside U.S./In 2006</b>	—/—/37,900	—/—/—
<b>Part of series of similar or related models</b>	yes	yes
<b>Dimensions (H x W x D)/Weight</b>	4 x 2 1/4 x 3/4 in/2.2 oz with battery	6.7 x 3.7 x 2 in/0.77 lb
<b>Analytical method/Technology/Enzyme system used</b>	glucose oxidase	absorbance photometry/glucose dehydrogenase
<b>Price per disposable reagent system unit</b>	contact sales representative	—/—
<b>No. of dispos. reagent system units per basic package</b>	50, 100	25 in vial/box; 4 vials/boxes per package
<b>No. of times analyses performed using 1 reagent system unit</b>	1	1
<b>Dispos. units shelf life/Reagent unit storage requirements</b>	18 months/room temperature	9 months from manufacture date/refrigeration
<b>Digital readout size/Keypad input capability</b>	5 mm (w) x 10 mm (h)/none	varies from 8 to 28 points/menu selection, numeric, alphabetic
<b>How results are displayed</b>	true values	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)
<b>Specimen types/Sampling techniques</b>	whole blood/capillary transfer	whole blood (capillary, venous, arterial)/exact amount of blood drawn into cuvette by capillary force
<b>Minimum specimen volume required</b>	3 µL	5 µL
<b>Suitable for samples from well/Sick neonates</b>	no/no	—/—
<b>Time from sample intro. to result availability</b>	10 seconds	40–240 seconds
<b>Batteries used/No. used/Avg. life of 1 set</b>	3 V lithium/1/1,000 tests	rechargeable lithium ion supplied by HemoCue/several years
<b>Avg. expected life of device/Mean time between failures</b>	20,000 tests/—	7 years/>5 years
<b>Device warranty/Service options</b>	5-year warranty/—	2 years at no additional cost/replacement of defective analyzer
<b>Loaners provided</b>	yes	yes
<b>User list or user group</b>	no	no
<b>Toll-free No. for customer questions/Hours</b>	800-818-8877/24 hours, 7 days	6 AM–5 PM PST, 800-323-1674
<b>Training and certif. program/No. training days provided</b>	yes/as needed	yes/–1 hour per device purchased
<b>Avg. time for lab to complete maintenance</b>	weekly: 3 minutes	daily: ≤5 minutes
<b>Special cleansing procedures</b>	no	no
<b>Internal QC recommended or required</b>	as specified by accreditation	one level of controls prior to patient testing, each day of testing
<b>Between instrument CV (based on PT) at these levels:</b>		
• <50 mg/dL	n/a	not available
• 100–200 mg/dL	n/a	3.8
• >400 mg/dL	n/a	≥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
<b>Accuracy/Compared to what reference method or device</b>	slope=0.93, r=0.976/YSI glucose analyzer	±10% or ±6% mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS
<b>Precision/Compared to what reference method or device</b>	within-run: 3.4%; between run: 3.1%/—	within run CV 1.9% (108 mg/dL)/—
<b>Linear range</b>	30–550 mg/dL	0–444 mg/dL
<b>Suggested dynamic, measurement range</b>	30–550 mg/dL	0–444 mg/dL
<b>Contraindications</b>	no	no
<b>Known interferences/High-altitude interference</b>	L-dopa and dopamine/yes, 7,000 feet	grossly lipemic samples, methemoglobin, glucosamine/no
<b>Restrictions based on hematocrit</b>	yes, 30%–55%	no
<b>Electronic, optical function checks</b>	sumcheck functions for electronics and software, no optics	internal electronic self-test automatically checks that the instrument's optronic unit is working properly
<b>Sample quantity checks</b>	one drop (≥3µL)	visual inspection
<b>When auto lock or shutdown occurs</b>	1-minute time-out	user ID failure if configured to require operator ID; QC failure if configured to require quality control; number of device errors
<b>User defines QC lockout intervals/Lockout can be circumvented</b>	no/—	yes/no (stat testing may be allowed; 1–100 tests after QC interval)
<b>Device supports bar-code scanning of</b>	no bar-code scanner	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID
<b>Method of analyst ID/ID required</b>	%	alpha-numeric manual entry or bar-code scan entry/optional
<b>Internal memory size/Max. No. patient results stored</b>	10-test memory/10	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000
<b>Information transfer capability:</b>		
• Meters connect to	n/a	analyzer connects to 201 DM docking stations (data management system, which can further transmit data)
• How meters are connected to external system to upload results/No. installations	n/a	direct USB/hospital network
• Info. contained in transmission to external system	n/a	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags
<b>Hardware/software for data mgmt. system</b>	n/a	PC/server/HemoCue 201 DM PC software
<b>No. of different mgmt. reports system can produce</b>	n/a	15 different templates, custom reports based on templates, multiple export formats
<b>Contents downloaded from DMS to meter</b>	n/a	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration
<b>System connected (live installations) to which LISs/HISs:</b>		
• using screen animation/screen scraping	n/a	—
• using standard HL7 interface	n/a	—
• using proprietary protocol interface	n/a	—
<b>Use 3rd-party interfacing tool/engine for LIS/HIS interfaces</b>	n/a	TELCOR QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator
<b>Distinguishing features (provided by vendors)</b>	<ul style="list-style-type: none"> <li>• wick in test strip, ergonomically formed, large handle</li> <li>• fast test time—10 seconds</li> <li>• extremely easy to use, low maintenance</li> </ul>	<ul style="list-style-type: none"> <li>• POCT-1A compliant</li> <li>• indicated for diagnosis of diabetes mellitus</li> <li>• not hematocrit dependent</li> </ul>

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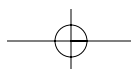




## Bedside glucose testing systems

<b>Part 3 of 6</b>	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
<i>Please see accompanying article on page 22</i>		
<b>Name of instrument/First year sold</b>	Glucose 201 Analyzer/2002	IRMA TRUpoint (glucose module)
<b>Professional or home use</b>	professional use	professional use
<b>List price</b>	—	\$350
<b>Units sold in U.S./Outside U.S./In 2006</b>	—/—/—	—/—/1,207
<b>Part of series of similar or related models</b>	yes	no
<b>Dimensions (H x W x D)/Weight</b>	6.3 x 3.4 x 1.7 in/0.77 lb	5 x 9.5 x 13.5 in/6 lb (IRMA TRUpoint)
<b>Analytical method/Technology/Enzyme system used</b>	absorbance photometry/glucose dehydrogenase	glucose only: reflectance photometry, glucose oxidase
<b>Price per disposable reagent system unit</b>	—/—	consult SureStep Pro representative
<b>No. of dispos. reagent system units per basic package</b>	25 in vial/box; 4 vials/boxes per package	50 strips
<b>No. of times analyses performed using 1 reagent system unit</b>	1	1
<b>Dispos. units shelf life/Reagent unit storage requirements</b>	9 months from manufacture date/refrigeration	strip: 18 months/room temperature
<b>Digital readout size/Keypad input capability</b>	1/2 inch/none	4.5 x 2.5 in/menu selection, numeric, alphabetic
<b>How results are displayed</b>	plasma equivalent values	true values
<b>Specimen types/Sampling techniques</b>	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood/drop, capillary transfer, touchable strip
<b>Minimum specimen volume required</b>	5 µL	1 drop
<b>Suitable for samples from well/Sick neonates</b>	—/—	yes/yes
<b>Time from sample intro. to result availability</b>	40–240 seconds	<45 seconds
<b>Batteries used/No. used/Avg. life of 1 set</b>	AA/4/150 hours	rechargeable NIMH battery/1/3 years
<b>Avg. expected life of device/Mean time between failures</b>	7 years/>5 years	>5 years/<3% warranty return rate
<b>Device warranty/Service options</b>	2 years at no extra cost/—	24-hour replacement upon failure
<b>Loaners provided</b>	yes	24-hour replacement upon failure
<b>User list or user group</b>	—	yes
<b>Toll-free No. for customer questions/Hours</b>	6 AM–5 PM PST, 800-323-1674	800-631-5945/24 hours, 7 days
<b>Training and certifi. program/No. training days provided</b>	yes/as needed	yes/depends on No. of operators
<b>Avg. time for lab to complete maintenance</b>	daily: ≤5 minutes	clean glucose module as needed, 2 minutes
<b>Special cleansing procedures</b>	no	no
<b>Internal QC recommended or required</b>	system must be verified on testing days using commercially available controls	based on hospital-specific policy
<b>Between instrument CV (based on PT) at these levels:</b>		
• <50 mg/dL	not available	4.39%
• 100–200 mg/dL	3.8	3.44%
• >400 mg/dL	≥272 mg/dL=2.9	4.97%
• Program name, year/Challenge No./Level of mean glucose challenge sample	Equalis (Swedish PT program), 2003/2003-03; 2003-07/272 mg/dL; 120 mg/dL	data from 2000 AACC poster
<b>Accuracy/Compared to what reference method or device</b>	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	r >0.98/YSI
<b>Precision/Compared to what reference method or device</b>	within run CV 1.9% (108 mg/dL)/—	3.44–4.97 CV across runs/—
<b>Linear range</b>	0–444 mg/dL	0–500 mg/dL
<b>Suggested dynamic, measurement range</b>	0–444 mg/dL	0–500 mg/dL
<b>Contraindications</b>	no	excessive H <sub>2</sub> O loss or dehydration
<b>Known interferences/High-altitude interference</b>	grossly lipemic samples, methemoglobin, glucosamine/no	sodium fluoride/no
<b>Restrictions based on hematocrit</b>	no	yes, <25% high results, >60% low results
<b>Electronic, optical function checks</b>	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test
<b>Sample quantity checks</b>	visual inspection	uses LED to determine sufficient quantity
<b>When auto lock or shutdown occurs</b>	n/a	user ID failure, QC failure, lockout if reagent expired or if control lot & reagent not entered
<b>User defines QC lockout intervals/Lockout can be circumvented</b>	no/no	yes/no
<b>Device supports bar-code scanning of</b>	no bar-code scanner	bar-code scanner available
<b>Method of analyst ID/ID required</b>	n/a	touchscreen/optional or required, QA user setup
<b>Internal memory size/Max. No. patient results stored</b>	n/a/n/a	4 MB RAM, 4 MB ROM, 256 KB nonvolatile/200 patient results
<b>Information transfer capability:</b>		
• Meters connect to	n/a	data management system, which connects to LIS/HIS; also directly to LIS/HIS
• How meters are connected to external system to upload results/No. installations	n/a	direct serial/—, modem dial-in/—, Ethernet/—
• Info. contained in transmission to external system	n/a	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
<b>Hardware/software for data mgmt. system</b>	—	nondedicated IBM compatible PC, IDMS (Integrated Data Management System)
<b>No. of different mgmt. reports system can produce</b>	—	6
<b>Contents downloaded from DMS to meter</b>	—	strip lot Nos., valid control values, valid operator IDs
<b>System connected (live installations) to which LISs/HISs:</b>		
• using screen animation/screen scraping	—	major vendors
• using standard HL7 interface	—	major vendors
• using proprietary protocol interface	—	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	yes, through laboratory data systems
<b>Distinguishing features (provided by vendors)</b>	<ul style="list-style-type: none"> <li>• CLIA waived</li> <li>• indicated for diagnosis of diabetes mellitus</li> <li>• not hematocrit dependent</li> <li>• lab verification of patient home meter</li> </ul>	<ul style="list-style-type: none"> <li>• integrated workstation with IRMA TRUpoint (blood gas, electrolytes, BUN, creatinine, lactate, cartridge glucose test, Hct)</li> <li>• 1 user interface, 1 in-service program, 1 data management system</li> </ul>

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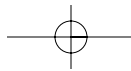


## Bedside glucose testing systems

Part 4 of 6	LifeScan Inc., a Johnson & Johnson company Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com	LifeScan Inc., a Johnson & Johnson company Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com
<i>Please see accompanying article on page 22</i>		
Name of instrument/First year sold	SureStepPro/1997	OneTouchFlexx*/2000
Professional or home use List price	professional use \$2,000 per bedside unit	professional use \$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 2006 Part of series of similar or related models Dimensions (H x W x D)/Weight Analytical method/Technology/Enzyme system used Price per disposable reagent system unit	>20,000/n/a/— yes 7.4 x 3.5 x 2.6 in/1.2 lb reflectance photometry/glucose oxidase by contract, volume	>30,000/>3,000/— yes 6.34 x 3.55 x 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without) reflectance photometry/glucose oxidase by contract, volume
No. of dispos. reagent system units per basic package No. of times analyses performed using 1 reagent system unit Dispos. units shelf life/Reagent unit storage requirements	2 25-strip vials (50 strips per box) 1 18 months unopened/<30°C (86°F); away from heat, direct sunlight	2 25-strip vials (50 strips per box) 1 18 months unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/Keypad input capability How results are displayed Specimen types/Sampling techniques Minimum specimen volume required Suitable for samples from well/Sick neonates Time from sample intro. to result availability Batteries used/No. used/Avg. life of 1 set Avg. expected life of device/Mean time between failures Device warranty/Service options Loaners provided	18-point font/menu selection, numeric, alphabetic, bar-code scan built-in true values whole blood/drop, capillary transfer, touchable test strip 5 µL, maximum 30 µL yes/yes 15-second minimum C 1.5 V/2/approximately 1,000 tests >5 years/<3% warranty return rate 1-year warranty/extended service agreements available 24-hour replacement with new device	18-point font (16-pixels high, 8-pixels wide)/menu select., numeric, alphabetic true values whole blood/drop, capillary transfer, touchable test strip 5 µL, maximum 30 µL yes/yes 15-second minimum AA/3/1,000 test minimum 5-year minimum/<3% warranty return rate 1-year warranty/extended service agreements available 24-hour replacement with new device
User list or user group Toll-free No. for customer questions/Hours Training and cert. program/No. training days provided Avg. time for lab to complete maintenance Special cleansing procedures	yes (contact SureStepPro product manager) 800-524-7226/24 hours, 7 days, multiple languages yes/as negotiated none no	yes (contact OneTouchFlexx product manager) 800-524-7226/24 hours, 7 days, multiple languages yes/as negotiated none no
Internal QC recommended or required Between instrument CV (based on PT) at these levels: • <50 mg/dL • 100–200 mg/dL • >400 mg/dL • Program name, year/Challenge No./Level of mean glucose challenge sample	as defined by hospital policy 4.39% 3.44% 4.97% data from 2000 AACC poster	as defined by hospital policy 2.5% 2.9% 2.4% data from 2000 & 2001 AACC posters
Accuracy/Compared to what reference method or device Precision/Compared to what reference method or device	>0.98/YSI 3.44–4.97 CV across runs/YSI	>0.98/YSI 3.44–4.97/YSI
Linear range Suggested dynamic, measurement range Contraindications Known interferences/High-altitude interference	0–500 mg/dL 0–500 mg/dL excessive water loss or dehydration sodium fluoride/no	0–500 mg/dL 0–500 mg/dL excessive water loss or dehydration sodium fluoride/no
Restrictions based on hematocrit	adult: 25%–60% RBC; neonates: 25%–65% RBC	adults: 25%–60% RBC; neonates: 25%–65% RBC
Electronic, optical function checks	automatic electronic and optical checks with each test	automatic electronic and optical checks with each test
Sample quantity checks	test strip color confirmation dot when adequate sample applied, bedside unit error messages	test strip color confirmation dot when adequate sample applied; meter error messages
When auto lock or shutdown occurs	user ID failure, QC failure, data upload lockout option	user ID failure, QC failure, failure to transfer data
User defines QC lockout intervals/Lockout can be circumvented Device supports bar-code scanning of	yes/no operator & patient identifiers, reagent (strip) lot Nos., bedside unit serial Nos., control solution lot Nos.	yes/yes, automatic meter unlock feature requires no user intervention operator & patient identifiers, reagent (strip) lot Nos., control solution lot Nos., meter serial Nos.
Method of analyst ID/ID required	bedside unit custom programmed for manual or bar-code entry/required or optional	unique alphanumeric ID/optional (defined by location)
Internal memory size/Max. No. patient results stored	2,500 patient & QC tests plus 50 test strip lots and QC lots	256k/1,500 patient +QC tests, 50-test strip lots and 50 QC lots
Information transfer capability: • Meters connect to • How meters are connected to external system to upload results/No. installations • Info. contained in transmission to external system	DataLink Data Management System via network or modem connectivity solutions: DataLink Data can be interfaced to LIS/HIS (script & EDI) DataLink Connect connectivity solutions; modem, network/ >250 hospital sites, DataLink interface >350 device unique identifiers, operator & patient IDs, results, QC identifiers, flags, comments	DataLink Data Management System via network and/or modem connectivity solutions: DataLink can be interfaced to LIS/HIS (script & EDI) DataLink Connect connectivity solutions; modem, network/wireless connectivity >1,400 hospital sites, DataLink interface >350 device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site
Hardware/software for data mgmt. system 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	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML 17 reports plus export function for customized reports strip lot Nos., valid control values, valid operator IDs, all configurations: expiration, time, lockouts DHCP-VA System, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy), SCC, SoftLab, DHT, Dynacor Premier Cerner Millennium & Pathnet (legacy), Misys Flexilab, Meditech Magic & client/server none yes (Telcor, Quick-Linc POC interface engine)	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML; DataLink Web 12 standard, unlimited customized reports strip lot Nos., valid control values, valid operator IDs, critical value ranges, comment codes DHCP-VA system, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier Cerner Millennium & Pathnet (legacy); Misys Flexilab; Meditech Magic & client/server none yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features (provided by vendors)	<ul style="list-style-type: none"> <li>unique test strip technology: off-meter sample application, sample volume confirmation</li> <li>bedside unit with alphanumeric touchscreen and built-in bar-code scanner</li> <li>infrared bidirectional interface between bedside unit and workstation with the widest array of DataLink Connectivity solutions: direct, modem, network, scripted interface, EDI, POC multi-analyte data management systems: QML</li> </ul>	<ul style="list-style-type: none"> <li>configurable bar-code scanning options—allows truncation of leading and trailing characters</li> <li>bar-code scan required feature</li> <li>unique meter unlock</li> <li>hardware independent DataLink software</li> <li>compatible with Telcor's QML</li> <li>flexible database options</li> <li>wireless connectivity</li> </ul>

\*SureStepFlexx has now become the OneTouchFlexx

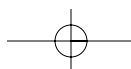
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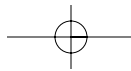


## Bedside glucose testing systems

<b>Part 5 of 6</b>	<b>Medtronic MiniMed Inc.</b> 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com	<b>Nova Biomedical</b> sales department info@novabio.com 200 Prospect St. Waltham, MA 02454 781-894-0800 or 800-458-5813 www.novabiomedical.com
<i>Please see accompanying article on page 22</i>		
<b>Name of instrument/First year sold</b>	<b>Medtronic MiniMed CGMS System Gold/2003</b>	<b>StatStrip Glucose Monitoring System/2006</b>
<b>Professional or home use</b>	professional use	Professional use
<b>List price</b>	\$35 per unit for glucose sensor; \$1,995 for CGMS System Gold	\$ 1,500, includes bar-code reader, spare battery, quick reference guide
<b>Units sold in U.S./Outside U.S./In 2006</b>	>1,000/>1,000/—	n/a/n/a/n/a
<b>Part of series of similar or related models</b>	no	yes
<b>Dimensions (H x W x D)/Weight</b>	2.8 x 0.9 x 3.6 in/4 oz	6.0 x 3.25 x 1.8 in/0.8 lb
<b>Analytical method/Technology/Enzyme system used</b>	glucose oxidase	electrochemistry
<b>Price per disposable reagent system unit</b>	\$1,995/monitor, \$35/unit (disposable)	pricing based on volume
<b>No. of dispos. reagent system units per basic package</b>	10/box	25 strips per vial and 50 per box
<b>No. of times analyses performed using 1 reagent system unit</b>	1 sensor lasts 72 hours	1
<b>Dispos. units shelf life/Reagent unit storage requirements</b>	6 months/refrigeration 2°C–24°C	24 months from date of manufacture/none
<b>Digital readout size/Keypad input capability</b>	—/menu selection	varies and is defined by the particular field/numeric, alphabetic
<b>How results are displayed</b>	at time of monitor download, system can display 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	true values
<b>Specimen types/Sampling techniques</b>	continuous monitoring and sampling of interstitial fluid glucose levels	whole blood/drop
<b>Minimum specimen volume required</b>	n/a	1.2 µL
<b>Suitable for samples from well/Sick neonates</b>	no/yes (with diabetes)	yes/yes
<b>Time from sample intro. to result availability</b>	retrospective analysis after disconnection	6 seconds
<b>Batteries used/No. used/Avg. life of 1 set</b>	AAA alkaline batteries/2/~2 months	3.7 Li Polymer (rechargeable/replaceable)/1/8 hours
<b>Avg. expected life of device/Mean time between failures</b>	~3 years/—	n/a/n/a
<b>Device warranty/Service options</b>	1-year warranty for monitor, no warranty on disposable/none	2 years (extended 5-year warranty at additional cost)/meter replacement
<b>Loaners provided</b>	no	yes
<b>User list or user group</b>	no	no
<b>Toll-free No. for customer questions/Hours</b>	800-646-4633/—	800-458-5813/24 hours, 7 days, all year
<b>Training and cert. program/No. training days provided</b>	yes (training only)/~1 day	yes/defined during implementation planning
<b>Avg. time for lab to complete maintenance</b>	none	no user maintenance
<b>Special cleansing procedures</b>	no	no
<b>Internal QC recommended or required</b>	none	CLIA requirements 2 levels per day
<b>Between instrument CV (based on PT) at these levels:</b>		
• <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, 1998–99	—
<b>Accuracy/Compared to what reference method or device</b>	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements	R <sup>2</sup> =0.9978, slope=1.0127–2.0975/YSI 2300
<b>Precision/Compared to what reference method or device</b>	—/glucose meters, HemoCue, YSI (any and all)	within run (whole blood=1.9%–3.6%) & (day to day=3.4%–4.7%) linearity standards/—
<b>Linear range</b>	—	10–600 mg/dL
<b>Suggested dynamic, measurement range</b>	40–400 mg/dL	10–600 mg/dL
<b>Contraindications</b>	not recommended for use by persons with impaired vision or hearing	—
<b>Known interferences/High-altitude interference</b>	possibly MRI/no	none/no, operates at altitudes up to 15,000 feet
<b>Restrictions based on hematocrit</b>	no	no
<b>Electronic, optical function checks</b>	test plug, 24–29nA	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results
<b>Sample quantity checks</b>	none	AccuFil sampling electronically checks for correct strip dosing
<b>When auto lock or shutdown occurs</b>	none	options include user ID failure, QC failure, required docking for data transfer
<b>User defines QC lockout intervals/Lockout can be circumvented</b>	no/no	yes/no, not if configured
<b>Device supports bar-code scanning of</b>	no bar-code scanner	operator & patient identifiers, reagent, lot No., QC lots
<b>Method of analyst ID/ID required</b>	at time of monitor download/optional	medical record ID No., medical billing ID No., Accession ID No./ID required
<b>Internal memory size/Max. No. patient results stored</b>	up to 14 days continuous data/288 readings per day	1,000 patient samples, 200 QC samples, 4,000 operators/1,000 tests
<b>Information transfer capability:</b>		
• Meters connect to	Com-Station for download to computer & software	Instrument Manager (NovaNet or Laboratory Data Systems AegisPOC) to Data Manager (TELCOR QML/Quick-Linc or AegisPOC) then to LIS if required hospital network/n/a
• How meters are connected to external system to upload results/No. installations	direct serial/—	
• Info. contained in transmission to external system	patient IDs, results	device unique identifier, operator & patient IDs, results, QC identifiers
<b>Hardware/software for data mgmt. system</b>	Com-Station (docking unit that transmits data from CGMS to computer) and software	connects to TELCOR QML and Laboratory Data Systems AegisPOC
<b>No. of different mgmt. reports system can produce</b>	7 standard unlimited customized reports	provided by TELCOR and Laboratory Data Systems
<b>Contents downloaded from DMS to meter</b>	—	strip lot numbers, valid control values, valid operator IDs, patient demographics, configuration files, physician IDs, diagnostic codes available through TELCOR & Laboratory Data Systems
<b>System connected (live installations) to which LISs/HISs:</b>	does not interface LIS or HIS, a report from software—nontransferable	available through TELCOR & Laboratory Data Systems
• using screen animation/screen scraping	no	
• using standard HL7 interface	no	n/a
• using proprietary protocol interface	no	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	no	yes, TELCOR QML/Quick-Linc, Laboratory Data Systems AegisPOC
<b>Distinguishing features (provided by vendors)</b>	<ul style="list-style-type: none"> <li>• continuous glucose values collected (every 5 minutes)</li> <li>• up to 14 days of data</li> <li>• ability to enter in events (insulin, food, exercise, etc.) to compare against glucose values upon review of data</li> </ul>	<ul style="list-style-type: none"> <li>• measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose</li> <li>• no calibration codes required</li> <li>• results reported in 6 seconds using only 1.2 µL of sample</li> </ul>

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## Bedside glucose testing systems

<b>Part 6 of 6</b>	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
<i>Please see accompanying article on page 22</i>		
<b>Name of instrument/First year sold</b>	AccuData GTS, 1994; AccuData GTS Plus, 2000	ACCU-CHEK Inform System/2001
<b>Professional or home use</b>	professional use	professional use
<b>List price</b>	\$550	\$1,200
<b>Units sold in U.S./Outside U.S./In 2006</b>	40,000*/5,000/—	55,000/10,000/—
<b>Part of series of similar or related models</b>	yes	yes
<b>Dimensions (H x W x D)/Weight</b>	11 x 8.75 x 4 in/5 lb	1.4 x 3.8 x 7.6 in/12 oz
<b>Analytical method/Technology/Enzyme system used</b>	biosensor—glucose dehydrogenase	biosensor—glucose dehydrogenase
<b>Price per disposable reagent system unit</b>	contingent on contract price	contingent on contract price
<b>No. of dispos. reagent system units per basic package</b>	50 strips per vial	50 test strips
<b>No. of times analyses performed using 1 reagent system unit</b>	1	1
<b>Dispos. units shelf life/Reagent unit storage requirements</b>	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
<b>Digital readout size/Keypad input capability</b>	4 lines by 20 characters LCD/menu selection, numeric true values	font size varies/menu selection, numeric, alphabetic true values
<b>How results are displayed</b>	whole blood/arterial, venous, capillary, neonate (including cord blood)	whole blood/arterial, venous, capillary, neonate (including cord blood)
<b>Specimen types/Sampling techniques</b>	4 µL	4 µL
<b>Minimum specimen volume required</b>	yes/yes	yes/yes
<b>Suitable for samples from well/Sick neonates</b>	26 seconds	26 seconds
<b>Time from sample intro. to result availability</b>	3 V lithium/2/~700 tests	3.7 V rechargeable lithium ion/1/testing in progress
<b>Batteries used/No. used/Avg. life of 1 set</b>	5 years/10,000 tests	5 years/542,000 tests
<b>Avg. expected life of device/Mean time between failures</b>	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	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 replaced under warranty
<b>Device warranty/Service options</b>		
<b>Loaners provided</b>		
<b>User list or user group</b>	yes (contact local account manager)	yes (contact local account manager)
<b>Toll-free No. for customer questions/Hours</b>	800-440-3638/24 hours, 365 days per year	800-440-3638/24 hours, 365 days per year
<b>Training and cert. program/No. training days provided</b>	yes/site-specific according to No. of employees	yes/site-specific according to No. of employees
<b>Avg. time for lab to complete maintenance</b>	none	none
<b>Special cleansing procedures</b>	no	acceptable active ingredients: water, soap, 70% (or less) isopropyl alcohol, 1:10 dilution of sodium hydrochlorite
<b>Internal QC recommended or required</b>	daily, 2 levels	daily, 2 levels of glucose control solutions
<b>Between instrument CV (based on PT) at these levels:</b>		
• <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
<b>Accuracy/Compared to what reference method or device</b>	$y=0.991x + 8.4$ , $r=0.980$ /glucose hexokinase—Hitachi 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	$y=0.991x + 8.4$ , $r=0.980$ /glucose hexokinase—Hitachi 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
<b>Precision/Compared to what reference method or device</b>		
<b>Linear range</b>	10–600 mg/dL	10–600 mg/dL
<b>Suggested dynamic, measurement range</b>	10–600 mg/dL	10–600 mg/dL
<b>Contraindications</b>	per labeling	yes, per labeling
<b>Known interferences/High-altitude interference</b>	per labeling/none up to 10,150 feet	per labeling/none up to 10,150 ft
<b>Restrictions based on hematocrit</b>	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%	yes, glucose <200 mg/dL 20%–65%; glucose >200 mg/dL 20%–55%
<b>Electronic, optical function checks</b>	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
<b>Sample quantity checks</b>	built-in electronic strip check, visual confirmation of sample volume	built-in electronic strip check, visible verification of sample volume
<b>When auto lock or shutdown occurs</b>	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
<b>User defines QC lockout intervals/Lockout can be circumvented</b>	yes/yes (information management system identifies operators who violate hospital policy)	yes/no (optional QC pass/fail feature)
<b>Device supports bar-code scanning of</b>	operator & patient identifiers, comment codes	operator & patient identifiers, reagent lot Nos.
<b>Method of analyst ID/ID required</b>	numeric input or bar-code wand scan/yes	alphanumeric or bar-code scan/yes
<b>Internal memory size/Max. No. patient results stored</b>	1,000 total patient, control, linearity, proficiency tests/1,000	4,000 results/4,000 tests
<b>Information transfer capability:</b>		
• 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
<b>Hardware/software for data mgmt. system</b>	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook†
<b>No. of different mgmt. reports system can produce</b>	varies by Data Manager (customer defined)	varies by Data Manager (customer defined)
<b>Contents downloaded from DMS to meter</b>	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
<b>System connected (live installations) to which LISs/HISs:</b>		
• 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	—	—
• using proprietary protocol interface	—	—
<b>Use 3rd-party interfacing tool/engine for LIS/HIS interfaces</b>	MAS	MAS
<b>Distinguishing features (provided by vendors)</b>	<ul style="list-style-type: none"> <li>proven bidirectional network connection from AccuData GTS/GTS Plus to LIS/HIS</li> <li>ADT data interface with RALS-Plus/DataCare POC</li> <li>uses the ACCU-CHEK Comfort Curve test strip; universal sampling due to oxygen independent chemistry with reliable results at varying hematocrit levels</li> </ul> <p>* combined AccuData GTS and AccuData GTS Plus sales † Roche exclusive ** both scripted/HL7 are available</p>	<ul style="list-style-type: none"> <li>uses the ACCU-CHEK Comfort Curve test strip; universal sampling due to oxygen independent chemistry with reliable results at varying hematocrit levels</li> <li>offers alphanumeric touchscreen, onboard bar-code ID, plus connectivity, including ADT feed provides two patient identifiers for confirmation</li> <li>extends the quality of blood glucose programs to six other point-of-care tests by allowing the entry and transfer of manual test information</li> </ul> <p>† Roche exclusive ** both scripted/HL7 are available depending on LIS version</p>

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