Survey of Instruments

All the basics on 11 bedside glucose testing systems

Anne Ford

The push for tight glycemic control means hospitals must perform ever more glucose testing on their patients. But just because you have more information, says Steve Sabicer, Medtronic communications senior manager, doesn't mean you know how to use it. "The technology is moving in a direction that is giving physicians significantly more data regarding diabetes management," he says. "The challenge will be to develop products that can utilize this data for better diabetes management outcomes."

Many of the vendors in this month's instrumentation survey, which addresses bedside glucose testing, offer, or will soon offer, ways for their customers to not only collect but also manage glucose-related data.

Case in point: Roche Diagnostics, through a partnership with Medical Automation Systems, offers IT solutions such as the soon-to-be-available Rals-TGCM, an informatics module of the Rals-Plus information management system. Company representative Sonia Terrell says the Rals-TGCM "allows institutions to effectively monitor their implemented glycemic control programs." In addition, she says, "the Accu-Chek Inform system functionality of Enhanced Patient ID, intended to help hospitals comply with JCAHO National Patient Safety Goals, is now enabled through the Roche Diagnostics release of the MAS Rals-Plus v1.3. This system provides regulatory and operator-level certification benefits in addition to the Enhanced Patient ID function, bringing operational efficiency, economic value, and better patient care to our customers."

Also new from Roche Diagnostics: the Accu-Chek Convenience Bleach wipe, which, product marketer Mary Catherine Coyle says, has been made available to "select, direct customers along with a written procedure for disinfecting the Accu-Chek Inform meter." The company plans to expand the wipe's distribution in the last quarter of this year.

At International Technidyne Corp., glucose data collection takes the shape of the IRMA TruPoint, a portable blood analyzer designed for bedside use that can also measure blood gases, hematocrit, electrolytes, creatinine, and other chemistries. "For glucose testing, TruPoint's versatility provides the ability to measure glucose in whole blood enzymatically using a single-use cartridge and/or the LifeScan SureStep Strip technology," says Bruce Toben, RRT, manager of clinical applications. "This can be important in a situation where peripheral perfusion is significantly impaired." In these cases, he says, glucose measured from a finger stick may not accurately reflect concentrations measured systemically by whole blood analysis. "The results of these tests, although analytically accurate, can misrepresent metabolism, leading to erroneous interventions. Having both whole blood and glucose strip technologies available at the bedside, the clinician can choose the point-of-care tool most appropriate to a specific patient's condition."

Once the test results have been gathered, the user can upload them into the company's IDMS data-management system. Toben says the TruPoint allows POC coordinators to limit user testing privileges: "So, for example, a glucose strip user would only be able to perform and recall glucose strips . . . and have limited access to select analyzer set-up functions."

While Medtronic does not manufacture a bedside glucose testing system for hospitals per se, it continues to offer the CGMS System Gold, a continuous glucose monitoring system designed for clinician use. Sabicer says Medtronic is developing a second-generation system for outpatient use, "as well as a sensor-augmented pump that combines the 'smart pump' technology of our Paradigm insulin pumps with the real-time glucose monitoring of our Guardian products." The Guardian RT system, he adds, "is the only FDA-approved continuous glucose monitor that measures glucose levels around the clock, even while a patient sleeps. It also provides trend reports that can be viewed after information is downloaded to a computer." The Guardian RT system is available in seven cities on a limited launch.

Finally, forthcoming from HemoCue in May: the Glucose 201 RT system. "This new platform brings the same accuracy and precision of the existing Glucose 201 platform with the added benefit of room temperature cuvettes, increased measuring range, and longer shelf-life," says national marketing manager Lily Sunkin. "The HemoCue glucose systems are ideal for critical care settings. There is no lot-to-lot variation between different cuvette batches, and all instruments are factory-calibrated. In addition, the HemoCue glucose systems are not subject to common interferences affecting glucose strip/meter systems. These include extreme hematocrit levels, PO_2, pH, or various drug interferences."

CAP TODAY's survey of bedside glucose testing systems includes products from the aforementioned manufacturers and from Abbott, Hypoguard, and LifeScan. Vendors supplied the information listed. Readers interested in a particular product should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

SURVEY OF INSTRUMENTS

Bedside glucose testing systems

Part 1 of 6

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	Abbott Point-of-Care	HemoCue Inc.
	Ken Stoner ken.stoner@abbott.com	40 Empire Dr.
	104 Windsor Center Dr., East Windsor, NJ 08520	Lake Forest, CA 92630-2244
	609-469-0322	800-323-1034
	www.abbottdiabetescare.com	www.hemocue.com
Name of instrument/First year sold	Precision PCx/1998	Glucose 201 DM Analyzer/2005
Professional or home use	professional use	professional use
List price	$995	—
Units sold in U.S./Outside U.S./In 2005	40,707/15,000/—	—/—/—
Part of series of similar/Related models	yes, i-Stat 1	yes
Dimensions (H x W x D)/Weight	7.7 x 2.95 x 5.1 in/10 oz	6.7 x 3.7 x 2 in/0.77 lb
Analytical method/Technology/Enzyme system used	amperometric/glucose oxidase with Precision PCx strips/glucose dehydrogenase with PCx Plus test strips	absorbance photometry/glucose dehydrogenase
Price per disposable reagent system unit	$71.50 per box 100 test strips	—/—
No. of dispos. reag. system units per basic package	100 per box	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	12–18 months (room temp.)/39°–86°F	9 months from manufacture date/refrigeration
Digital readout size/Keypad input capability	font size 24 pt/menu selection, numeric	varies from 8 to 28 points/menu selection, numeric, alphabetic
How results are displayed	true values	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)
Specimen types/Sampling techniques	whole blood/drop, can apply blood directly to test strip	whole blood (capillary, venous, arterial)/exact amount of blood drawn into cuvette by capillary force
Minimum specimen volume required	3.5 µL with PCx, 2.5 µL with PCx Plus	5 µL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	20 sec	40–240 sec
Batteries used/No. used/Avg. life of 1 set	AA/2/~60 days (based on 30 tests/day)	rechargeable lithium ion supplied by HemoCue/several years
Avg. expected life of device/Mean time between failures	24 months/24 months	7 yr/>5 yr
Device warranty/Service options	1-yr warranty, lifetime replacement with reagent contact/24-h replacement	2 yr at no additional cost/replacement of defective analyzer
Loaners provided	yes	yes
User list or user group	yes	no
Toll-free No. for customer questions	24 h, 7 days	6 AM–5 PM PST, 800-323-1674
Training and certif. program/No. training days provided	yes/depends on No. of operators	yes/~1 hr per device purchased
Avg. time for lab to complete maintenance	none	daily: ≤5 min
Special cleansing procedures	no	no
Internal QC recommended or required	as required by facility or institutional policy or when glucose results are questioned or when new lot No. is received	one level of controls prior to patient testing, each day of testing
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	not available
• 100–200 mg/dL	71.9 mg/dL, CV=4.1%; 192.3 mg/dL, CV=5.5%	3.8
• >400 mg/dL	400.7 mg/dL, CV=6.9%	≥272 mg/dL=2.9
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP Whole Blood Glucose Survey, 2003/Set B	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL; 120 mg/dL
Accuracy/Compared to what reference method or device	capillary blood: y=0.91x + 0.91, r=0.98/YSI	±10% or ±6% mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS
Precision/Compared to what reference method or device	blood samples: CV 2.9% to 5.1%/YSI	within run CV 1.9% (108 mg/dL)/—
Linear range	20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx	0–444 mg/dL
Suggested dynamic, measurement range	20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx	0–444 mg/dL
Contraindications	per labeling	no
Known interferences/High-altitude interference	per labeling/none up to 7,200 ft	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, glucose <300 mg/dL, 20–70%; glucose ≥300 mg/dL, 20–60%	no
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks performed during power up of meter	internal electronic self-test automatically checks that the instrument's optronic unit is working properly
Sample quantity checks	a fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected	visual inspection
When auto lock or shutdown occurs	user ID failure, QC failure, download time if selected	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/Lockout can be circumvented	yes/no	yes/no (stat testing may be allowed; 1–100 tests after QC interval)
Device supports bar-code scanning of	operator & patient identifiers, reag. lot Nos., comment codes, control & linearity lot Nos.	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID
Method of analyst ID/ID required	manual or bar-code ID entry/operator ID lockout optional	alpha-numeric manual entry or bar-code scan entry/optional
Internal memory size/Max. No. patient results stored	4,000 patient results, 1,000 controls, 1,000 operators/—	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000
Information transfer capability:		
• Meters connect to	Precision Web data management system, which in turn connects to LIS/HIS	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	direct serial/50+; modem dial-in/100+; hospital network/800+	direct USB/hospital network
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., test dates & times, comment codes	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server	PC/server/HemoCue 201 DM PC software
No. of different mgmt. reports system can produce	25	15 different templates, custom reports based on templates, multiple export formats
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, QC lockout & upload lockout parameters	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	Misys, Cerner, Meditech, Soft Lab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab	—
• using standard HL7 interface	Cerner, Misys, PerSe, Meditech, Soft Lab	—
• using proprietary protocol interface	none	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Sybase	TELCOR QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator
Distinguishing features (provided by vendors)	• positive reagent ID • positive calibration ID—no need to visually verify code key against test strip vial • ability to reapply blood within 30 seconds to same strip	• POCT-1A compliant • indicated for diagnosis of diabetes mellitus • not hematocrit dependent

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Survey editor: Raymond Aller, MD

Bedside glucose testing systems

Part 2 of 6

Please see accompanying article on page 26

	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com	Hypoguard USA 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.hypoguard.com
Name of instrument/First year sold	Glucose 201 Analyzer/2002	Assure II/2001
Professional or home use	professional use	professional & home use
List price	—	free with competitive trade out
Units sold in U.S./Outside U.S./In 2005	—/—/—	10,000/—/3,403
Part of series of similar/Related models	yes	yes
Dimensions (H x W x D)/Weight	6.3 x 3.4 x 1.7 in/0.77 lb	4 x 2 1/4 x 3/4 in/2.2 oz with battery
Analytical method/Technology/Enzyme system used	absorbance photometry/glucose dehydrogenase	glucose oxidase
Price per disposable reagent system unit	—/—	$0.47
No. of dispos. reag. system units per basic package	25 in vial/box; 4 vials/boxes per package	50, 100
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	18 months/room temp.
Digital readout size/Keypad input capability	1/2 in/none	5 mm (w) x 10 mm (h)/none
How results are displayed	plasma equivalent values	true values
Specimen types/Sampling techniques	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood/capillary transfer
Minimum specimen volume required	5 µL	3 µL
Suitable for samples from well/Sick neonates	yes/yes	no/no
Time from sample intro. to result availability	40–240 sec	30 sec
Batteries used/No. used/Avg. life of 1 set	AA/4/150 h	3 V lithium/1/1,000 cycles
Avg. expected life of device/Mean time between failures	7 yr/>5 yr	20,000 tests/—
Device warranty/Service options	2 yr at no extra cost/—	5-yr warranty/—
Loaners provided	yes	yes
User list or user group	—	no
Toll-free No. for customer questions	6 AM–5 PM PST, 800-323-1674	24 h, 7 days, 800-818-8877
Training and certif. program/No. training days provided	yes/as needed	yes/as needed
Avg. time for lab to complete maintenance	daily: ≤5 min	weekly: 5 min
Special cleansing procedures	no	no
Internal QC recommended or required	system must be verified on testing days using commercially available controls	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	not available	n/a
• 100–200 mg/dL	3.8	n/a
• >400 mg/dL	≥272 mg/dL=2.9	n/a
• 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	n/a
Accuracy/Compared to what reference method or device	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	slope=0.93, r=0.976/YSI glucose analyzer
Precision/Compared to what reference method or device	within run CV 1.9% (108 mg/dL)/—	within-run: 3.4%; between run: 3.1%
Linear range	0–444 mg/dL	30–550 mg/dL
Suggested dynamic, measurement range	0–444 mg/dL	30–550 mg/dL
Contraindications	no	no
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	L-dopa and dopamine/yes, tested up to 7,000 ft
Restrictions based on hematocrit	no	yes, 30%–55%
Electronic, optical function checks	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	sumcheck functions for electronics and software, no optics
Sample quantity checks	visual inspection	only one drop (≥3µL) sample required
When auto lock or shutdown occurs	n/a	1 min
User defines QC lockout intervals/Lockout can be circumvented	no/no	no/—
Device supports bar-code scanning of	no bar-code scanner	no bar-code scanner
Method of analyst ID/ID required	n/a	—/—
Internal memory size/Max. No. patient results stored	n/a/n/a	10-test memory/10
Information transfer capability:		
• Meters connect to	n/a	n/a
• How meters are connected to external system to upload results/No. installations	n/a	n/a
• Info. contained in transmission to external system	n/a	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)	• CLIA waived • indicated for diagnosis of diabetes mellitus • not hematocrit dependent • lab verification of patient home meter	• Guide-Me Curve test strip wicks in sample for easy use

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SURVEY OF INSTRUMENTS

Bedside glucose testing systems

Part 3 of 6

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	Hypoguard USA 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.hypoguard.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
Name of instrument/First year sold	Assure 3/2003	IRMA TRUpoint (glucose module)
Professional or home use	professional & home use	professional use
List price	free with competitive trade out	$350
Units sold in U.S./Outside U.S./In 2005	—/—/35,779	—/—/1,207
Part of series of similar/Related models	yes	no
Dimensions (H x W x D)/Weight	4 x 2 1/4 x 3/4 in/2.2 oz with battery	5 x 9.5 x 13.5 in/6 lb (IRMA TRUpoint)
Analytical method/Technology/Enzyme system used	glucose oxidase	glucose only: reflectance photometry, glucose oxidase
Price per disposable reagent system unit	$0.47	consult SureStep Pro representative
No. of dispos. reag. system units per basic package	50, 100	50 strips
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	18 months/room temp.	strip: 18 months/room temp.
Digital readout size/Keypad input capability	5 mm (w) x 10 mm (h)/none	4.5 x 2.5 in/menu selection, numeric, alphabetic
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood/drop, capillary transfer, touchable strip
Minimum specimen volume required	3 µL	1 drop
Suitable for samples from well/Sick neonates	no/no	yes/yes
Time from sample intro. to result availability	10 sec	<45 sec
Batteries used/No. used/Avg. life of 1 set	3 V lithium/1/1,000 tests	rechargeable NIMH battery/1/3 yr
Avg. expected life of device/Mean time between failures	20,000 tests/—	>5 yr/<3% warranty return rate
Device warranty/Service options	5-yr warranty/—	24-h replacement upon failure
Loaners provided	yes	24-h replacement upon failure
User list or user group	no	yes
Toll-free No. for customer questions	24 h, 7 days, 800-818-8877	24 h, 7 days
Training and certif. program/No. training days provided	yes/as needed	yes/depends on No. of operators
Avg. time for lab to complete maintenance	weekly: 3 min	clean glucose module as needed, 2 min
Special cleansing procedures	no	no
Internal QC recommended or required	as specified by accreditation	based on hospital-specific policy
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	n/a	4.39%
• 100–200 mg/dL	n/a	3.44%
• >400 mg/dL	n/a	4.97%
• Program name, year/Challenge No./Level of mean glucose challenge sample	—/—/—	data from 2000 AACC poster
Accuracy/Compared to what reference method or device	slope=0.93, r=0.976/YSI glucose analyzer	r >0.98/YSI
Precision/Compared to what reference method or device	within-run: 3.4%; between run: 3.1%/—	3.44–4.97 CV across runs/—
Linear range	30–550 mg/dL	0–500 mg/dL
Suggested dynamic, measurement range	30–550 mg/dL	0–500 mg/dL
Contraindications	no	excessive $H_2$0 loss or dehydration
Known interferences/High-altitude interference	L-dopa and dopamine/yes, 7,000 ft	sodium fluoride/no
Restrictions based on hematocrit	yes, 30%–55%	yes, <25% high results, >60% low results
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test
Sample quantity checks	one drop (≥3µL)	uses LED to determine sufficient quantity
When auto lock or shutdown occurs	1 min time out	user ID failure, QC failure, lockout if reag. expired or if control lot & reag. not entered
User defines QC lockout intervals/Lockout can be circumvented	no/—	yes/no
Device supports bar-code scanning of	no bar-code scanner	bar-code scanner available
Method of analyst ID/ID required	%	touchscreen/optional or required, QA user setup
Internal memory size/Max. No. patient results stored	10-test memory/10	4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results
Information transfer capability:		
• 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
Hardware/software for data mgmt. system	n/a	nondedicated IBM compatible PC, IDMS (Integrated Data Management System)
No. of different mgmt. reports system can produce	n/a	6
Contents downloaded from DMS to meter	n/a	strip lot Nos., valid control values, valid operator IDs
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	n/a	major vendors
• using standard HL7 interface	n/a	major vendors
• using proprietary protocol interface	n/a	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	n/a	yes, through laboratory data systems
Distinguishing features (provided by vendors)	• wick in test strip, ergonomically formed, large handle • fast test time—10 sec • extremely easy to use, low maintenance	• integrated workstation with IRMA TRUpoint (blood gas, electrolytes, BUN, cartridge glucose test, Hct) • 1 user interface, 1 in-service program, 1 data management system

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Bedside glucose testing systems

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	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
Name of instrument/First year sold	SureStepPro/1997	SureStepFlexx/2000
Professional or home use	professional use	professional use
List price	$2,000 per bedside unit	$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 2005	>20,000/n/a/—	>30,000/>3,000/—
Part of series of similar/Related models	yes	yes
Dimensions (H x W x D)/Weight	7.4 x 3.5 x 2.6 in/1.2 lb	6.34 x 3.55 x 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without)
Analytical method/Technology/Enzyme system used	reflectance photometry/glucose oxidase	reflectance photometry/glucose oxidase
Price per disposable reagent system unit	by contract, volume	by contract, volume
No. of dispos. reag. system units per basic package	2 25-strip vials (50 strips per box)	2 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	18 months unopened/<30°C (86°F); away from heat, direct sunlight	18 months unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/Keypad input capability	18 pt. font/menu selection, numeric, alphabetic, bar-code scan built-in	18 pt. 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 test strip	whole blood/drop, capillary transfer, touchable test strip
Minimum specimen volume required	5 µL, maximum 30 µL	5 µL, maximum 30 µL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	15 sec minimum	15 sec minimum
Batteries used/No. used/Avg. life of 1 set	C 1.5 V/2/approximately 1,000 tests	AA/3/1,000 test minimum
Avg. expected life of device/Mean time between failures	>5 yr/<3% warranty return rate	5-yr minimum/<3% warranty return rate
Device warranty/Service options	1-yr warranty/extended service agreements available	1-yr warranty/extended service agreements available
Loaners provided	24-h replacement with new device	24-h replacement with new device
User list or user group	yes (contact SureStepPro product manager)	yes (contact SureStepFlexx product manager)
Toll-free No. for customer questions	24 h, 7 days, multiple languages	24 h, 7 days, multiple languages
Training and certif. program/No. training days provided	yes/as negotiated	yes/as negotiated
Avg. time for lab to complete maintenance	none	none
Special cleansing procedures	no	no
Internal QC recommended or required	as defined by hospital 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	>0.98/YSI	>0.98/YSI
Precision/Compared to what reference method or device	3.44–4.97 CV across runs/YSI	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 water loss or dehydration	excessive water loss or dehydration
Known interferences/High-altitude interference	sodium fluoride/no	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	yes/no	yes/yes, automatic meter unlock feature requires no user intervention
Device supports bar-code scanning of	operator & patient identifiers, reagent (strip) lot Nos., bedside unit serial Nos., control solution lot Nos.	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	DataLink Data Management System via network or modem connectivity solutions: DataLink Data can be interfaced to LIS/HIS (script & EDI)	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	DataLink Connect connectivity solutions; modem, network/DataLink Connect >1,100 hospital sites, DataLink interface >250	DataLink Connect connectivity solutions; modem, network/DataLink Connect >1,300 hospital sites, DataLink interface >350
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, flags, comments	device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site
Hardware/software for data mgmt. system	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML; RALS-Plus	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML; RALS-Plus, DataLink Web
No. of different mgmt. reports system can produce	17 reports plus export function for customized reports	12 standard, unlimited customized reports
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, all configurations: expiration, time, lockouts	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	DHCP-VA System, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy), SCC, SoftLab, DHT, Dynacor Premier	DHCP-VA system, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier
• using standard HL7 interface	Cerner Millennium & Pathnet (legacy), Misys Flexilab, Meditech Magic & client/server	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 (Telcor, Quick-Linc POC interface engine)	yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features (provided by vendors)	• unique test strip technology: off-meter sample application, sample volume confirmation • bedside unit with alphanumeric touchscreen and built-in bar-code scanner • 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 & RALS-Plus	• configurable bar-code scanning options—allows truncation of leading and trailing characters • bar-code scan required feature • unique meter unlock • hardware independent DataLink software • open architecture—compatible with QML and RALS-Plus • hardware independent DataLink software • flexible database options

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Bedside glucose testing systems

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	Medtronic MiniMed Inc. 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com	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	Medtronic MiniMed CGMS Gold/2003	AccuData GTS, 1994; AccuData GTS Plus, 2000
Professional or home use	professional use	professional use
List price	$40 per unit	$550
Units sold in U.S./Outside U.S./In 2005	>1,000/>1,000/—	40,000*/5,000/—
Part of series of similar/Related models	no	yes
Dimensions (H x W x D)/Weight	2.8 x 0.9 x 3.6 in/4 oz	11 x 8.75 x 4 in/5 lbs
Analytical method/Technology/Enzyme system used	glucose oxidase	biosensor–glucose dehydrogenase
Price per disposable reagent system unit	$1,995/monitor, $40/unit (disposable)	contingent on contract price
No. of dispos. reag. system units per basic package	10/box	50 strips per vial
No. of times analyses performed using 1 reag. system unit	1 sensor lasts 72 h	1
Dispos. units shelf life/Reag. unit storage requirements	6 months/refrigeration 2°C–24°C	18–24 months, stable until expiration on vial/<90°F, do not freeze
Digital readout size/Keypad input capability	—/menu selection	4 lines by 20 characters LCD/menu selection, numeric
How results are displayed	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
Specimen types/Sampling techniques	continuous monitoring and sampling of interstitial fluid glucose levels	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	n/a	4 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	26 sec
Batteries used/No. used/Avg. life of 1 set	AAA alkaline batteries/2/~2 months	3 V lithium/2/~700 tests
Avg. expected life of device/Mean time between failures	~3 yr/—	5 yr/10,000 tests
Device warranty/Service options	1-yr warranty for monitor, no warranty on disposable/none	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
Loaners provided	no	replaced under warranty
User list or user group	no	yes (contact local account manager)
Toll-free No. for customer questions	yes, 800-646-4633	yes (24 h, 365 days per yr)
Training and certif. program/No. training days provided	yes (training only)/~1 day	yes/site-specific according to No. of employees
Avg. time for lab to complete maintenance	none	none
Special cleansing procedures	no	no
Internal QC recommended or required	none	daily, 2 levels
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	53.8 mg/dL SD=4.1 (6,088 labs)
• 100–200 mg/dL	5% (40–400 mg/dL) in vitro	191.4 mg/dL CV=4.7% (3,096 labs)
• >400 mg/dL	—	228.5 mg/dL CV=4.6% (6,099 labs)
• Program name, year/Challenge No./Level of mean glucose challenge sample	CGMS, 1998–99	CAP, 2001/WBG-C/see above
Accuracy/Compared to what reference method or device	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements	y=0.991 *x* + 8.4, r=0.980/glucose hexokinase-Hitachi
Precision/Compared to what reference method or device	—/glucose meters, HemoCue, YSI (any and all)	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
Suggested dynamic, measurement range	40–400 mg/dL	10–600 mg/dL
Contraindications	not recommended for use by persons with impaired vision or hearing	per labeling
Known interferences/High-altitude interference	possibly MRI/no	per labeling/none up to 10,150 feet
Restrictions based on hematocrit	no	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
Electronic, optical function checks	test plug, 24–29nA	meter cradle communication with Advantage meter, GTS with code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	none	built-in electronic strip check, visual confirmation of sample volume
When auto lock or shutdown occurs	none	user ID failure (valid op.), QC failure, patient ID length, incorrect code key, incorrect Advantage meter
User defines QC lockout intervals/Lockout can be circumvented	no/no	yes/yes (information management system identifies operators who violate hospital policy)
Device supports bar-code scanning of	no bar-code scanner	operator & patient identifiers, comment codes
Method of analyst ID/ID required	at time of monitor download/optional	numeric input or bar-code wand scan/yes
Internal memory size/Max. No. patient results stored	up to 14 days continuous data/288 readings per day	1,000 total patient, control, linearity, proficiency tests/1,000
Information transfer capability:		
• Meters connect to	Com-Station for download to computer & software	information management system, which in turn connects to LIS/HIS
• How meters are connected to external system to upload results/No. installations	direct serial/—	direct serial/—, modem dial-in/—, hospital network/—
• Info. contained in transmission to external system	patient IDs, results	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., download loc., comment codes, proficiency & linearity samples
Hardware/software for data mgmt. system	Com-Station (docking unit that transmits data from CGMS to computer) and software	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†, DataCare POC, ACCU-CHEK HDM
No. of different mgmt. reports system can produce	7 standard unlimited customized reports	varies by Data Manager (customer defined)
Contents downloaded from DMS to meter	—	strip & QC lot Nos., valid operator IDs, valid control values, linearity values
System connected (live installations) to which LISs/HISs:	does not interface LIS or HIS, a report from software–nontransferable	
• using screen animation/screen scraping	no	all major LIS vendors including Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, Opus, others**
• using standard HL7 interface	no	—
• using proprietary protocol interface	no	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	no	MAS
Distinguishing features (provided by vendors)	• continuous glucose values collected (every 5 min) • up to 72 h of data • ability to enter in events (insulin, food, excercise, etc.) to compare against glucose values upon review of data	• proven bidirectional 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 ** combined AccuData GTS and AccuData GTS Plus sales* *† Roche exclusive* *** both scripted/HL7 are available*

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Bedside glucose testing systems

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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	ACCU-CHEK Inform System/2001
Professional or home use	professional use
List price	$1,200
Units sold in U.S./Outside U.S./In 2005	40,000/8,500/>8,000
Part of series of similar/Related models	yes
Dimensions (H x W x D)/Weight	1.4 x 3.8 x 7.6 in/12 oz
Analytical method/Technology/Enzyme system used	biosensor—glucose dehydrogenase
Price per disposable reagent system unit	contingent on contract price
No. of dispos. reag. system units per basic package	50 test strips
No. of times analyses performed using 1 reag. system unit	1
Dispos. units shelf life/Reag. unit storage requirements	18–24 months, stable until expiration date on vial/room temp., less than 90°F, do not freeze
Digital readout size/Keypad input capability	font size varies/menu selection, numeric, alphabetic
How results are displayed	true values
Specimen types/Sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	4 µL
Suitable for samples from well/Sick neonates	yes/yes
Time from sample intro. to result availability	26 sec
Batteries used/No. used/Avg. life of 1 set	3.7 V rechargeable lithium ion/1/testing in progress
Avg. expected life of device/Mean time between failures	5 yr/542,000 tests
Device warranty/Service options	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
User list or user group	yes (contact local account manager)
Toll-free No. for customer questions	yes (24 h, 365 days per yr)
Training and certif. program/No. training days provided	yes/site-specific according to No. of employees
Avg. time for lab to complete maintenance	none
Special cleansing procedures	no
Internal QC recommended or required	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)
• 100–200 mg/dL	191.4 mg/dL CV=4.7% (3,096 labs)
• >400 mg/dL	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
Accuracy/Compared to what reference method or device	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
Linear range	10–600 mg/dL
Suggested dynamic, measurement range	10–600 mg/dL
Contraindications	yes, per labeling
Known interferences/High-altitude interference	per labeling/none up to 10,150 ft
Restrictions based on hematocrit	yes, glucose <200 mg/dL 20%–65%; glucose >200 mg/dL 20%–55%
Electronic, optical function checks	meter with code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	built-in electronic strip check, visible verification of sample volume
When auto lock or shutdown occurs	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/no (optional QC pass/fail feature)
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos.
Method of analyst ID/ID required	alphanumeric or bar-code scan/yes
Internal memory size/Max. No. patient results stored	4,000 results/4,000 tests
Information transfer capability:	
• Meters connect to	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/—
• Info. contained in transmission to external system	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*, DataCare POC
No. of different mgmt. reports system can produce	varies by Data Manager (customer defined)
Contents downloaded from DMS to meter	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, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, SIA Molis, Opus, others**
• using standard HL7 interface	—
• using proprietary protocol interface	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	MAS
Distinguishing features (provided by vendors)	• 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 ** Roche exclusive* *** both scripted/HL7 are available depending on LIS version*

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