Bedside glucose testing systems

Glucose analyzers 2002— sweeter than ever

Raymond D. Aller, MD

Profiled on pages 64–72 are 15 models of handheld/point-of-care glucose meters, manufactured by nine vendors. In many cases, these devices represent decades of refinement of engineering and human interface designs. They are far more reliable and accurate and less susceptible to user variability than were the four meters my pathology group purchased in 1982.

We were convinced then that point-of-care testing for glucose would represent a revolution in diabetic care (as it has), but we were anxious about this new technology being employed properly to yield results as accurate as feasible. We donated these meters to the hospital nursing staff with the stipulation that a rigorous quality control mechanism be established. We asked the manufacturer for QC protocols, but it had not established protocols using whole blood. Therefore, in cooperation with the nursing educator, we created a system (*Nursing.* 1985[May];15[5]:569) whereby the fingerstick glucose would be compared with a laboratory glucose value on a venous sample drawn within a few minutes of the fingerstick. Of course, today a variety of QC materials and protocols are available, and meters can be programmed to require that QC is run, and is within expected limits, before patient specimens are tested. Nevertheless, most hospitals continue to experience difficulties in enforcing that QC protocols are performed and documented.

Anecdotal evidence suggests that hypoxia (such as is seen at elevated altitudes or in capillary samples from neonates or critically ill adults) may interfere with accurate reading on meters that rely on the glucose oxidase enzyme. However, coverage of this topic is sparse in the indexed literature. If you know of well-controlled studies that have documented and quantitated the altitude sensitivity of meters depending on various enzyme systems (for example, how do meters behave in a ski resort at 9,000 feet?), or correlated meter-lab discrepancies with arterial, capillary, or venous oxygen tension, please let me know (raller@earthlink.net).

I am pleased to see that at least one manufacturer is using a more definitive glucose method (GC-MS) as a standard of comparison, rather than simply comparing one enzymatic method—the meter—with another—such as the YSI glucose meter, or a hexokinase method on a chemistry analyzer.

This year, as in recent years, much of the advance in technology is in the meters' data-management capabilities and accompanying management systems. We asked the vendors a series of questions to elucidate these capabilities, but we urge the reader, as you examine alternative devices, to concentrate on data-management features. We hope to see vendors provide devices soon that support the recently adopted Connectivity Industry Consortium/NCCLS Standard POCT1-A, for communication between POC testing devices and laboratory information systems.

Electronic validation of the patient's identification is one feature that should become standard on all POC testing devices used in the hospital, clinic, or any other setting outside the home, whenever more than one patient might be tested in the environment. Although it might appear to be the easiest portion of the testing event, proper identification of the patient continues to be a source of some of the most egregious errors in laboratory medicine. A decade ago, only a few hospitals in the United States had applied machine-readable identification bracelets (for example, bar-coded wristbands) to all inpatients. Today, it is more prevalent, and I hope it will soon be considered the standard of community hospital practice. It is hard to justify or condone reliance on human memory, which is error-prone, to check the wristband when automated systems are readily available to ensure, to greater than six-sigma accuracy, that the right patient is being drawn and tested.   □

Dr. Aller is based in Vista, Calif., and can be reached at raller@earthlink.net.

Part 1 of 8	Abbott Diagnostics Medisense Products Jim Gibbons jim.gibbons@abbott.com 4A Crosby Dr. Bedford, MA 01730 (781) 276-7774 abbottlaboratories.com
Name of instrument/first year sold	Precision PCx/1998
Professional or home use	professional & home use
Units sold in U.S./outside U.S.	15,000+
Part of series of similar/related models	—
Dimensions (H x W x D)/weight	7.7 x 3 x 2 in/10 oz (including batteries)
Analytical method/technology/enzyme system used	glucose oxidase, 3 electrode biosensor technology
List price	$995
Price per disposable reagent system unit	$70.50 per box 100 test strips
No. of dispos. reag. system units per basic package	100 per box
No. of times analyses performed using 1 reag. system unit	1
Dispos. units shelf life/reag. unit storage requirements	18 mo (room temp.)/no (room temp.)
Digital readout size/keypad input capability	font size 24 pt/menu selection, numeric
How results are displayed	true values
Specimen types/sampling techniques	whole blood/drop, wipe, capillary transfer
Suitable for samples from well/sick neonates	yes/yes
Time from sample intro. to result availability	20 sec
Batteries used/number used/avg. life of 1 set	AA or rechargeable batt. pk./2 AA, 1 pk/~30 days (based on 30 tests/day)
Avg. expected life of device/mean time between failures	—
Device warranty/service options	24-h replacement upon failure
Loaners provided	24-h replacement upon failure
User list or user group	yes
Toll-free No. for customer questions	24 h, 7 d
Training and certif. program/No. training days provided	yes/depends on No. of operators
Avg. time for lab to complete maintenance	none
Special cleansing procedures	no
Internal QC recommended or required	none
Between instrument CV (based on PT) at these levels:	
• <50 mg/dL	12.2
• 100–200 mg/dL	8.3
• >400 mg/dL	—
• Program name, year/challenge No./level of mean glucose challenge sample	CAP, WBG A/A/42,226
Accuracy/compared to what reference method or device	capillary sample vs. plasma—slope 0.922, 0.984, intercept 11.1 mg/dL/YSI
Precision/compared to what reference method or device	CV 2.1%–5.6% across a range of samples (40–478 mg/dL)/within run precision
Linear range	20–600 mg/dL
Suggested dynamic/measurement range	20–600 mg/dL
Contraindications	severely dehydrated or severely hypotensive patients, patients in shock or in hyperglycemic state
Known interferences/high altitude interference	none/no
Restrictions based on hematocrit	yes, 20%–70% Hct range
Electronic, optical function checks	battery, bar-code scanner, database, and temperature check performed during power up of meter
Sample quantity checks	test will not start until sufficient sample detected
When auto lock or shutdown occurs	user ID failure, QC failure, when meter is not docked in a specified amount of time
User defines QC lockout intervals/lockout can be circumvented	yes/no
What device supports bar-code scanning of	operator & patient identifiers, reag. lot No., both control vials and strips (individually wrapped and bar-coded)
Method of analyst ID/ID required	bar-code scan or keypad entry/yes
Internal memory size/max. No. patient results stored	4,000 patient results, 1,000 QC results, 4,000 operators/4,000
What meters connect to	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 identifier, operator ID, patient ID, result, QC identifier
Hardware/software for data mgmt. system	Precision Net System
No. of different mgmt. reports system can produce	25 standard reports with custom options
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, patient IDs, result, time, date, physicians
System connected (live installations) to which LISs/HISs:	
• 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 (Neon Tools)
Distinguishing features	• direct bidirectional interface using HL7 protocol • automated downloading • automated sample detection before test starts

Tabulation does not represent an endorsement by the College of American Pathologists   Survey editor: Raymond Aller, MD

Bedside glucose testing systems

Part 2 of 8	Bayer Diagnostics Sales and Marketing Support P.O. Box 2001 Mishawaka, IN 46544 (800) 445-5901 www.bayerdiag.com	GDS Technology, a Division of Stanbio Laboratory 25235 Leer Dr. Elkhart, IN 46514 (800) 545-4437 www.statsite.com
Name of instrument/first year sold	Glucometer Encore QA+ Professional System Model 5856/1998	Stat-Site/1991
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	700/100	—
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	4 $^{11}/_{16}$ x 12 $^{7}/_{16}$ x 12 $^{9}/_{16}$ in/5 lbs (including batteries)	7 x 4.75 x 1.75 in/16 oz
Analytical method/technology/enzyme system used	hexokinase	reflectance photometry, glucose oxidase and peroxidase
List price	$850	$990
Price per disposable reagent system unit	$0.79 per strip	$1 per test
No. of dispos. reag. system units per basic package	50 strips	100
No. of times analyses performed using 1 reag. system unit	once per strip	1
Dispos. units shelf life/reag. unit storage requirements	18 mo/59–86˚ F (do not freeze)	18 mo/2–4˚C (30 d at room temp.)
Digital readout size/keypad input capability	4 mm/menu selection, numeric, alphabetic	2 $^{5}/_{16}$ x $^{5}/_{8}$ in/menu selection
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/drop	whole blood/1st drop
Suitable for samples from well/sick neonates	yes/yes	no/no
Time from sample intro. to result availability	15–60 sec	2 min
Batteries used/number used/avg. life of 1 set	C 1.5 v alk./6/5,100 cycles	9 v alk./2/4 h
Avg. expected life of device/mean time between failures	20,000 tests/6.7 yrs	<1% failure rate/6 yrs
Device warranty/service options	replace or repair at no additional cost for 2 yrs/lifetime replace-repair program, 24-h turnaround; spares kept on-site	1-yr parts, labor/1-yr extension $250
Loaners provided	yes	yes
User list or user group	yes (available upon request)	yes (call home office)
Toll-free No. for customer questions	24 h, 7d	8 AM–5 PM EST
Training and certif. program/No. training days provided	yes/depends on number of staff to be trained	yes/1 d on-site
Avg. time for lab to complete maintenance	daily: 5 min, weekly: 5 min, monthly: 10 min	n/a (sealed system)
Special cleansing procedures	no	no
Internal QC recommended or required	one or more control tests daily before patient testing begins and again if problems suspected with system	controls–check cards
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	9.1%	not available
• 100–200 mg/dL	7.4%	not available
• >400 mg/dL	7.0%	not available
• Program name, year/challenge No./level of mean glucose challenge sample	Whole Blood Glucose Multiple Site–Series 1, 1998/WBG-C & B/52.2 mg/dL, 108.9 mg/dL, 333.4 mg/dL	n/a
Accuracy/compared to what reference method or device	y=0.96 x -4.1/Dupont Dimension AR analyzer (hexokinase chem. method)	1.008/YSI 2300 Stat Plus
Precision/compared to what reference method or device	within run CV 6.5% (34 mg/dL), 4.3% (97 mg/dL), 4.0% (474 mg/dL)/n/a—aqueous controls	mean: 99, SD: 5.3, CV: 5.3; mean: 222, SD: 6.8, CV: 3.1; mean: 350, SD: 1.7, CV: 3.9/Whole Blood YSI 2300 Stat Plus
Linear range	10–600 mg/dL	50–500 mg/dL
Suggested dynamic/measurement range	10–600 mg/dL	50–500 mg/dL
Contraindications	capillary blood glucose testing may not be clinically appropriate when peripheral blood flow is decreased	no
Known interferences/high altitude interference	none/no (fluoride and iodoacetic acid collection tubes not recommended)	evaluated ascorbic acid levels/no
Restrictions based on hematocrit	yes, blood Hct 20%–70% do not significantly affect results at glucose levels ≤120 mg/dL; combination of high glucose (300 mg/dL) and high Hct (60%) can lower results by as much as 10%	no
Electronic, optical function checks	series of checks run to ensure integrity of electronics, memory, batteries, optical systems	check card 1 & 2, reflectance values, calib. module (lot specific)
Sample quantity checks	checks for insufficient sample by using second wavelength	hanging drop approximately 25 µL; "insufficient sample" will appear if significantly <25 µL
When auto lock or shutdown occurs	user ID failure, operator-meter lockout, insufficient sample	QC failure
User defines QC lockout intervals/lockout can be circumvented	yes/no	no/n/a
What device supports bar-code scanning of	operator & patient identifiers, reagent lot No. & exp., control lot No., exp., & ranges	reagent lot No., exp., test
Method of analyst ID/ID required	bar-code scanner or alphanumeric keyboard/yes	manual/no
Internal memory size/max. No. patient results stored	4,800 patient & control results/4,800 results	1 KB/1 last result
What meters connect to	data management system, which in turn connects to LIS/HIS	data management system, which cannot further transmit data
How meters are connected to external system to upload results/No. installations	modem dial-in/7	direct serial/—
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, reag. lot info., linearity results, comment codes	device unique identifier, operator & patient ID, result, QC identifier, date, time, test
Hardware/software for data mgmt. system	Windows 95/NT 4.0, 486/66 MHz, 16/24 Mb RAM	n/a
No. of different mgmt. reports system can produce	14	n/a
Contents downloaded from DMS to meter	none	n/a
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	Dynamic, Cerner, SCC, Sunquest	n/a
• using standard HL7 interface	none	n/a
• using proprietary protocol interface	none	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes (Data Innovations/Instrument Manager)	n/a
Distinguishing features	• off-meter inoculation—easier application, lessens infectious disease issues because only disposable strip enters patient room • hexokinase reagent chem.—standard method in labs • individually foil-wrapped strips—less waste • capillary, venous, arterial, and neonatal samples can be used	• multiple tests from one meter • true plasma results • sealed optics • expired reagent lockout

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 3 of 8	HemoCue Inc. Customer Service 23263 Madero Mission Viejo, CA 92691 (949) 859-2630/(800) 323-1674 www.hemocue.com	Hypoguard USA Jelica Danilovic danilovicj@hypoguard.com 7301 Ohms Lane Edina, MN 55439 (800) 818-8877 www.hypoguard.com
Name of instrument/first year sold	HemoCue Blood Glucose Analyzer/1992	Supreme II Blood Glucose Meter/1997
Professional or home use	professional use	professional & home use
Units sold in U.S./outside U.S.	>20,000 worldwide	—/—
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	6 $\frac{1}{4}$ x 8 $\frac{1}{4}$ x 3 $\frac{1}{2}$ in/2 lbs	4 $\frac{3}{4}$ x 2 $\frac{1}{2}$ x 1 $\frac{1}{4}$ in/4.7 oz
Analytical method/technology/enzyme system used	dehydrogenase, absorbance photometry	glucose oxidase
List price	$650 classic, $850 for data management model	$50
Price per disposable reagent system unit	$0.98 per test	$0.35
No. of dispos. reag. system units per basic package	25 cuvettes per vial	25 or 50
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/reag. unit storage requirements	9 mo/refrig. or 3 d room temp.	18 mo/ambient temp.
Digital readout size/keypad input capability	1.25 cm/menu selection, numeric	$\frac{1}{4}$ x $\frac{1}{2}$ in/none
How results are displayed	true values	true & calculated values; reports true results in whole blood values, serum/plasma value calculated (whole blood x 1.12)
Specimen types/sampling techniques	whole blood/venous, capillary, or arterial	whole blood/drop
Suitable for samples from well/sick neonates	yes/yes	no/no
Time from sample intro. to result availability	15–240 sec	50 sec
Batteries used/number used/avg. life of 1 set	AA/5/5 cycles (150 h)	J cell/1/700 cycles
Avg. expected life of device/mean time between failures	7 yrs/>5 yrs	20,000 tests/not available
Device warranty/service options	1 yr, $125 each additional yr/24-h loaner program	3 yrs/none
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions	7 AM–5 PM PST, (800) 323-1674	24h, 7d (800) 818-8877
Training and certif. program/No. training days provided	yes/as needed from vendor office	yes/as needed
Avg. time for lab to complete maintenance	weekly: 5 min	weekly: 10 min
Special cleansing procedures	no	no
Internal QC recommended or required	quality control cuvette daily	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	7.5% (XQ-01)	not available
• 100–200 mg/dL	6.6% (XQ-03)	not available
• >400 mg/dL	4.4% (XQ-04 >350)	not available
• Program name, year/challenge No./level of mean glucose challenge sample	CAP EXCEL, 1997/—/—	n/a
Accuracy/compared to what reference method or device	0.994/GC-MS	y=0.99 x + 3, r=0.983, n=113/YSI 2300
Precision/compared to what reference method or device	1.44%/GC-MS	within-run: 3.9%, between-run: 4.0%/YSI 2300
Linear range	0–400 mg/dL	30–600 mg/dL
Suggested dynamic/measurement range	0–400 mg/dL	30–600 mg/dL
Contraindications	no	no
Known interferences/high altitude interference	none/no	dopamine ≥10 mg/dL, ascorbate ≥4 mg/dL/no
Restrictions based on hematocrit	no	yes, 28%–65%
Electronic, optical function checks	control cuvette (an interface filter) verifies photometer calib.	internal sumcheck functions for electronics, internal optics standardization, std. strip
Sample quantity checks	sample quantity always 5 µL due to cuvette technique & design; cuvette automatically draws (by capillary action) exact amount of blood	only 1 drop (≥9 µL) sample required
When auto lock or shutdown occurs	QC failure, control or reagent past exp., QC length	no auto lock or shutdown
User defines QC lockout intervals/lockout can be circumvented	yes/optional	no/yes
What device supports bar-code scanning of	operator & patient identifiers, controls, reagent	no bar-code scanner
Method of analyst ID/ID required	manual or bar code/optional	none/n/a
Internal memory size/max. No. patient results stored	1,000 records/approximately 1,000 results dependent on configuration	100 tests/100 tests
What meters connect to	HemoCue data management system, which cannot further transmit data	n/a
How meters are connected to external system to upload results/No. installations	direct serial/—	n/a
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, pass/fail, date, time, comment code, analyte unit of measurement type	n/a
Hardware/software for data mgmt. system	PC or laptop/HemoCue DM software	n/a
No. of different mgmt. reports system can produce	customizable	n/a
Contents downloaded from DMS to meter	—	n/a
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	none	n/a
• using standard HL7 interface	none	n/a
• using proprietary protocol interface	Sunquest	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	in progress	n/a
Distinguishing features	• indicated for diabetes mellitus • not hematocrit dependent • no known interferences • perfect for meter verification • CLIA waived	• blood can be applied to test strips inside *or* outside of meter

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 4 of 8	Hypoguard USA Jelica Danilovic danilovicj@hypoguard.com 7301 Ohms Lane Edina, MN 55439 (800) 818-8877 www.hypoguard.com	Hypoguard USA Jelica Danilovic danilovicj@hypoguard.com 7301 Ohms Lane Edina, MN 55439 (800) 818-8877 www.hypoguard.com
Name of instrument/first year sold	Assure Blood Glucose Meter/1998	Assure II/2001
Professional or home use Units sold in U.S./outside U.S. Part of series of similar/related models Dimensions (H x W x D)/weight Analytical method/technology/enzyme system used List price Price per disposable reagent system unit	professional & home use 8,000/— yes 4 $\frac{3}{8}$ x 2 $\frac{3}{8}$ x $\frac{13}{32}$ in/5.3 oz glucose oxidase $50 $0.35	professional & home use 10,000/— yes 4 x 2 $\frac{1}{4}$ x $\frac{3}{4}$ in/ 2.2 oz with battery glucose oxidase free with competitive tradeout $0.35
No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/reag. unit storage requirements	25, 50, 100 1 18 mo/ambient temp.	25, 50, 100 1 18 mo/room temp.
Digital readout size/keypad input capability How results are displayed Specimen types/sampling techniques Suitable for samples from well/sick neonates Time from sample intro. to result availability Batteries used/number used/avg. life of 1 set Avg. expected life of device/mean time between failures Device warranty/service options Loaners provided	$\frac{1}{4}$ x $\frac{1}{2}$ in/menu selection true values whole blood/drop no/no 35 sec J cell/1/1,000 cycles 20,000 tests/not available 3 yrs/none yes	5 mm (w) x 10 mm (h)/none true values whole blood/capillary transfer no/no 30 sec 3 v lithium/1/1,000 cycles 20,000 tests/— 3-yr warranty/— yes
User list or user group Toll-free No. for customer questions Training and certif. program/No. training days provided Avg. time for lab to complete maintenance Special cleansing procedures	no 24 h (800) 818-8877 yes/as needed weekly: 10 min no	no 24 h (800) 818-8877 yes/as needed weekly: 10 min 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 specified by accreditation not available not available not available n/a	as specified by accreditation n/a n/a n/a n/a
Accuracy/compared to what reference method or device Precision/compared to what reference method or device Linear range Suggested dynamic/measurement range Contraindications Known interferences/high altitude interference Restrictions based on hematocrit Electronic, optical function checks Sample quantity checks When auto lock or shutdown occurs User defines QC lockout intervals/lockout can be circumvented What device supports bar-code scanning of Method of analyst ID/ID required Internal memory size/max. No. patient results stored	y=0.98 x + 8, r=0.976, n=109/YSI 2300 within-run: 4.7%, between-run: 3.7%/YSI 2300 30–550 mg/dL 30–550 mg/dL no L-dopa and dopamine (≥10 mg/dL)/no yes, 20%–60% sumcheck functions for electronics and software, no optics only 1 drop (≥7 µL) sample required no auto lock or shutdown no/yes no bar-code scanner none/n/a 180 tests/180 tests	slope=0.93, r=0.976/YSI glucose analyzer within-run: 3.4%; between run: 3.1% 30-550 mg/dL 30-550 mg/dL no L-dopa and dopamine/yes, tested up to 7,000 ft yes, 30%–55% sumcheck functions for electronics and software, no optics only one drop (≥3µL) sample required 1 min no/— no bar-code scanner —/— —/10
What meters connect to How meters are connected to external system to upload results/No. installations Info. contained in transmission to external system	n/a n/a n/a	— — —
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	yes 4 n/a n/a n/a n/a n/a	— — — — — — —
Distinguishing features	• touchscreen display	

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 5 of 8	LifeScan Inc., a Johnson & Johnson Company Healthcare Professional Line 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 (800) 524-7226 www.lifescan.com	LifeScan Inc., a Johnson & Johnson Company Healthcare Professional Line 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 (800) 524-7226 www.lifescan.com
Name of instrument/first year sold	OT II Hospital first sold in 1992, Data Dock in 1996	SureStepPro/1997
Professional or home use	professional use (CLIA waived)	professional use
Units sold in U.S./outside U.S.	>4,000 shipped annually/n/a	>20,000/n/a
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	Data Dock: 8 x 3.62 x 3.25 in, meter: 4.7 x 2.4 x 1.1 in/1 lb (1.5 lb meter + dock)	7.4 x 3.5 x 2.6 in/1.2 lbs
Analytical method/technology/enzyme system used	glucose oxidase, reflectance photometry	glucose oxidase, reflectance photometry
List price	contracted	$1,200 per bedside unit
Price per disposable reagent system unit	contracted	contracted
No. of dispos. reag. system units per basic package	50 test strips per box (2 vials of 25 strips)	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	Strips: 18 mo or 4 mo after opening; controls: 18 mo or 3 mo after opening/room temp.	18 mo unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/keypad input capability	2 x 0.5 in/menu selection, numeric, alphabetic	18 pt. font/menu selection, numeric, alphabetic, bar-code scan built-in
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/drop–hanging, cap. transfer, fine tip transfer pipette, syringe	whole blood/drop, wipe, capillary transfer, touchable test strip
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	<45 sec	15 sec minimum
Batteries used/number used/avg. life of 1 set	AA/2 for Dock & J 6 v/1 for meter/1,000 tests	C 1.5 v/2/approximately 1,000 tests
Avg. expected life of device/mean time between failures	>5 yrs/not available	>5 yrs/<3% warranty return rate
Device warranty/service options	no charge replacement for life of service contract/24-h replacement policy	life of contract for defects
Loaners provided	yes	yes
User list or user group	no	yes (contact SureStepPro product manager)
Toll-free No. for customer questions	24 h, 7 d	24 h, 7 d, multiple languages
Training and certif. program/No. training days provided	yes/as needed	yes/as negotiated
Avg. time for lab to complete maintenance	daily: <1 min.	none
Special cleansing procedures	standard biohazard disinfection procedures	no
Internal QC recommended or required	as specified by accreditation	as defined by hospital policy
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	3.1%	4.39%
• 100–200 mg/dL	3.4%	3.44%
• >400 mg/dL	<4.0%	4.97%
• Program name, year/challenge No./level of mean glucose challenge sample	internal testing & clinical studies	data from 2000 AACC poster
Accuracy/compared to what reference method or device	slope 1.0, r=0.98/YSI 2700	>0.98/YSI
Precision/compared to what reference method or device	3%–4%/YSI 2700	3.44–4.97 CV across runs/YSI
Linear range	0–600 mg/dL	0–500 mg/dL
Suggested dynamic/measurement range	0–600 mg/dL	0–500 mg/dL
Contraindications	no	excessive water loss or dehydration
Known interferences/high altitude interference	sodium fluoride (black/gray top tube preservative)/no	sodium fluoride/no
Restrictions based on hematocrit	yes, neonatal 25%–76%, glucose <150 mg/dL; adult 25%–60%	adult: 25%–60% RBC; neonates: 25%–65% RBC
Electronic, optical function checks	internal system checks upon power up; checkstrip	automatic electronic and optical checks with each test
Sample quantity checks	user alerted if insufficient sample	test strip color confirmation dot when adequate sample applied, bedside unit error messages
When auto lock or shutdown occurs	user ID failure, QC failure (optional), QC not performed within required time, alerts insufficient specimen, cannot test blood in QC mode, alerts battery low, memory almost full	user ID failure, QC failure, data upload lockout option
User defines QC lockout intervals/lockout can be circumvented	yes/no	yes/no
What device supports bar-code scanning of	operator & patient identifiers, reag. lot No.	operator & patient identifiers, reagent (strip) lot No., bedside unit serial Nos., control solution lot Nos.
Method of analyst ID/ID required	alphanumeric entry/optional	bedside unit custom programmed for manual or bar-code entry/required or optional
Internal memory size/max. No. patient results stored	128k/1,200 results	2,500 patient & QC tests plus 50 test strip lots and QC lots
What meters connect to	data management system	data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interfaces)
How meters are connected to external system to upload results/No. installations	DataLink Connect (modem & network)/newly available, 22 installations; DataLink Interface (script & EDI to LIS)/1	DataLink Connect (modem + network + direct serial via PC): >575 hospital sites; DataLink Interface (script + EDI + LIS): infrared port used to transfer results by modem or network to workstation
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, flags & comments	device unique identifier, operator & patient ID, result, QC identifier, flags, comments
Hardware/software for data mgmt. system	desktop Windows NT & proprietary software	desktop or laptop, Windows NT, proprietary DataLink Data Management System; QML; RALS-Plus
No. of different mgmt. reports system can produce	9	17 reports plus export function for customized reports
Contents downloaded from DMS to meter	strip lot Nos., valid control lot Nos., unique meter loc. ID, unique event codes (QC), unique critical ranges, unique lockout parameters	strip lot Nos., valid control values, valid operator IDs, all configurations: expiration, time, lockouts
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	none	DHCP-VA System, HBOC Pathlab3, Star, ALG, Sunquest Flexilab, Cerner Pathnet (legacy), SCC, Softlab, DHT, Dynacor Premier
• using standard HL7 interface	none	Cerner Pathnet (legacy), Sunquest Flexilab, Meditech Magic & client/server
• using proprietary protocol interface	none	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	n/a	yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features	• ability to detect blood vs. control solution—"true" QC lockout • alphanumeric keypad entry • simplest to use, chosen by thousands of hospitals/clinicians	• 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

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 6 of 8	Lifescan Inc., a Johnson & Johnson Company Healthcare Professional Line 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 (800) 524-7226 www.lifescan.com	MiniMed Inc. Leslie Wright leslie.wright@minimed.com 18000 Devonshire St., Northridge, CA 91325 (800) 999-9859 minimed.com
Name of instrument/first year sold	SureStepFlexx/2000	MiniMed Continuous Glucose Monitoring System (CGMS)/2000
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	>10,000/>3,000	>1,000/>600
Part of series of similar/related models	yes	no
Dimensions (H x W x D)/weight	6.34 x 3.55 x 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without)	2.8 x 0.9 x 3.6 in/4 oz
Analytical method/technology/enzyme system used	reflectance photometry/glucose oxidase	glucose oxidase
List price	$1,200 with bar-code scanner, $850 without bar-code scanner	$1,995/monitor, $30/sensor (disposable)
Price per disposable reagent system unit	by contract, volume	$30 per sensor
No. of dispos. reag. system units per basic package	2 25-strip vials (50 strips per box)	10/box
No. of times analyses performed using 1 reag. system unit	1	1 sensor lasts ~36–72 h
Dispos. units shelf life/reag. unit storage requirements	18 mo unopened/<30°C (86°F); away from heat, direct sunlight	6 mo/refrigeration 2°C–24°C
Digital readout size/keypad input capability	18 pt. font (16-pixels high, 8-pixels wide)/menu select., numeric, alphabetic	—/menu selection
How results are displayed	true values	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
Specimen types/sampling techniques	whole blood/drop, wipe, capillary transfer, touchable test strip	continuous monitoring and sampling of interstitial fluid glucose levels
Suitable for samples from well/sick neonates	yes/yes	no/yes (with diabetes)
Time from sample intro. to result availability	15 sec minimum	retrospective analysis after disconnection
Batteries used/number used/avg. life of 1 set	AA/3/1,000 test minimum	AAA alkaline batteries/2/~2 mo
Avg. expected life of device/mean time between failures	5 yr minimum/<3% warranty return rate	~3 yrs/—
Device warranty/service options	1-yr warranty/extended service agreements available	1-yr warranty for monitor, no warranty on disposable/none
Loaners provided	yes	no
User list or user group	yes (contact SureStepFlexx product manager)	no
Toll-free No. for customer questions	24 h, 7 d, multiple languages	yes
Training and certif. program/No. training days provided	yes/as negotiated	yes (training only)/~1 d
Avg. time for lab to complete maintenance	none	monthly: 10–15 min
Special cleansing procedures	no	no
Internal QC recommended or required	as defined by hospital policy	none
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	2.5%	—
• 100–200 mg/dL	2.9%	5% (40–400 mg/dL)
• >400 mg/dL	2.4%	—
• Program name, year/challenge No./level of mean glucose challenge sample	data from 2000 & 2001 AACC posters	CGMS 1999–98/—/—
Accuracy/compared to what reference method or device	>0.98/YSI	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements
Precision/compared to what reference method or device	3.44–4.97/YSI	—/glucose meters, Hemocue, YSI (any and all)
Linear range	0–500 mg/dL	—
Suggested dynamic/measurement range	0–500 mg/dL	40–400 mg/dL
Contraindications	excessive water loss or dehydration	not recommended for use by persons with impaired vision or hearing
Known interferences/high altitude interference	sodium fluoride/no	possibly MRI/no
Restrictions based on hematocrit	adults: 25%–60% RBC; neonates: 25%–65% RBC	no
Electronic, optical function checks	automatic electronic and optical checks with each test	none
Sample quantity checks	test strip color confirmation dot when adequate sample applied; meter error messages	none
When auto lock or shutdown occurs	user ID failure, QC failure, failure to transfer data	none
User defines QC lockout intervals/lockout can be circumvented	yes/no	no/no
What device supports bar-code scanning of	operator & patient identifier, reagent (strip) lot No., control solution lot No., meter serial No.	no bar-code scanner
Method of analyst ID/ID required	unique alphanumeric ID/optional (defined by location)	at time of monitor download/optional
Internal memory size/max. No. patient results stored	256k/1,500 patient +QC tests, 50 test strip lots and 50 QC lots	up to 14 days continuous data/288 readings per day
What meters connect to	data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interfaces)	Com-Station for download to computer & software
How meters are connected to external system to upload results/No. installations	DataLink Connect (modem + network + direct serial via PC): >575 hospital sites; DataLink Interface (script + EDI + LIS): infrared port used to transfer results by modem or network to workstation	direct serial/—
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, result flags, location/site	patient ID, result
Hardware/software for data mgmt. system	desktop or laptop, Windows NT, Microsoft SQL server, proprietary DataLink Data Management System; QML; RALS-Plus	Com-Station (docking unit that transmits data from CGMS to computer) and software
No. of different mgmt. reports system can produce	12 standard, unlimited customized reports	3
Contents downloaded from DMS to meter	strip lot No., valid control values, valid operator IDs, critical value ranges, comment codes	—
System connected (live installations) to which LISs/HISs:		does not interface LIS or HIS, a report from software–nontransferable
• using screen animation/screen scraping	DHCP-VA system, HBOC PathLab 3, Star, ALG; Sunquest Flexilab, Cerner Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier	no
• using standard HL7 interface	Cerner Pathnet (legacy); Sunquest Flexilab; Meditech Magic & client/server	no
• using proprietary protocol interface	none	no
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes (Telcor, exclusive contract; Reflections WRQ software)	no
Distinguishing features	• exception reporting and database tracking—customized QC compliance rules • multiple levels of security—nonvalidated operator, noncertified operator, warn and lockout, QC lockout • true off-meter sample application; unique test strip technology—touchable, absorbent test strip	• 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

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 7 of 8	Philips Medical Systems (manufactured by Diametrics Medical) Sales Department 3000 Minuteman Rd., Andover, MA 01810 (978) 659-7396 www.medical.philips.com	Roche Diagnostics Accu-Chek Customer Care 9115 Hague Rd., Indianapolis, IN 46256 (800) 440-3638 www.roche.com
Name of instrument/first year sold	IRMA SL with SureStepPro Blood Glucose Module/1998	Accu-Chek HQ/1999
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	—	7,500/none
Part of series of similar/related models	no	yes
Dimensions (H x W x D)/weight	5 x 9.5 x 13.5 in (IRMA with SureStep Pro)/6 lbs (IRMA SL with SureStepPro Blood Glucose Module)	2.9 x 4.2 x 9.4 in/3.5 lbs
Analytical method/technology/enzyme system used	glucose only: reflectance photometry, glucose oxidase	biosensor–glucose dehydrogenase
List price	$1,116	$1,495
Price per disposable reagent system unit	consult SureStepPro representative	contingent on contract price
No. of dispos. reag. system units per basic package	50 strips	50 test strips
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/reag. unit storage requirements	strip: 24 mo/room temp.	18–24 mo, stable until exp. on vial/room temp., <90°F, do not freeze
Digital readout size/keypad input capability	4.5 x 2.5 in/menu selection, numeric, alphabetic	7 lines x 30 characters/menu selection, numeric, alphabetic
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/drop, capillary transfer	whole blood/arterial, venous, capillary, neonate (including cord blood)
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	<45 sec	26 sec
Batteries used/number used/avg. life of 1 set	NiMH/1/3.2 h per battery	3 v lithium/2/700 tests
Avg. expected life of device/mean time between failures	>5 yrs/<3% warranty return rate	5 yrs/828,000 tests
Device warranty/service options	24-h replacement upon failure	all-inclusive warranty through life of Accu-Chek HQ system at no additional cost/24 h, 365 d/yr customer care with overnight replacement if needed
Loaners provided	24-h replacement upon failure	yes
User list or user group	yes	yes (contact local account manager)
Toll-free No. for customer questions	24 h, 7 d	24 h/365 d per yr
Training and certif. program/No. training days provided	yes/depends on No. of operators	yes/site-specific according to quantity of personnel
Avg. time for lab to complete maintenance	clean glucose module as needed, 2 min	none
Special cleansing procedures	no	no
Internal QC recommended or required	based on hospital-specific policy	daily, 2 level
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	4.39%	53.8 mg/dL SD=4.1 (6,088 labs)
• 100–200 mg/dL	3.44%	191.4 mg/dL CV=4.7% (3,096 labs)
• >400 mg/dL	4.97%	228.5 mg/dL CV=4.6% (6,099 labs)
• Program name, year/challenge No./level of mean glucose challenge sample	CAP	CAP, 2001/WBG-C/see above
Accuracy/compared to what reference method or device	r >0.98/YSI	y=0.991 x + 8.4, r=0.980/glucose hexokinase–Hitachi
Precision/compared to what reference method or device	3.44–4.97 CV across runs/—	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	0–500 mg/dL	10–600 mg/dL
Suggested dynamic/measurement range	0–500 mg/dL	10–600 mg/dL
Contraindications	no	per labeling
Known interferences/high altitude interference	sodium fluoride/no	per labeling/none up to 10,150 ft
Restrictions based on hematocrit	yes, <25% high results, >60% low results	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
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	meter cradle communication with the Advantage meter, meter cradle with code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	uses LED to determine sufficient quantity	built-in electronic fail safe check, visual confirmation of sample volume
When auto lock or shutdown occurs	user ID failure, QC failure, lockout if reag. expired or if control lot & reag. not entered	user ID failure (valid op.), QC failure, patient ID length, reagent & QC lots, comment codes, incorrect code key, incorrect Advantage meter
User defines QC lockout intervals/lockout can be circumvented	yes/no	yes/yes (information management system identifies operators who violate hospital policy)
What device supports bar-code scanning of	bar-code scanner available	operator & patient identifiers
Method of analyst ID/ID required	touchscreen/optional or required, QA user setup	alphanumeric/yes
Internal memory size/max. No. patient results stored	4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results	2,000 records/2,000 records
What meters connect to	data management system, which connects to LIS/HIS; also directly to LIS/HIS	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/—, Ethernet/—	direct serial/10, modem dial-in/5, hospital network/90
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, result date & time, strip/material lot, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample type	device unique identifier, operator & patient ID, result, strip lot No., QC identifier, proficiency & linearity samples, comments, meter loc., download loc.
Hardware/software for data mgmt. system	nondedicated IBM compatible PC, IDMS (IRMA Data Management System)	software: Accu-Chek HDM, DataCare POC, DataCare GM, RALS-Link, RALS-G, RALS Plus
No. of different mgmt. reports system can produce	6	unlimited (customer defined)
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs	strip & QC lot Nos., valid control values, valid operator IDs, meter configuration, message of the day, linearity values, critical ranges comments
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	major vendors	Cerner, Sunquest, DHCP, HBOC, Phamis, Meditech, SoftLAB
• using standard HL7 interface	major vendors	Cerner, Sunquest, Meditech, HBOC
• using proprietary protocol interface	none	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, product used depends on host system emulation requirements	Roche offers DataCare POC and DataCare GM as well as interfacing through the MAS continuum
Distinguishing features	• integrated workstation with IRMA (blood gas, electrolytes, Hct) • 1 user interface, 1 in-service program, 1 data management system	• superior strip technology: glucose dehydrogenase, reliable results at varying hematocrit levels, comfort curve design • hand-free communication with LIS/HIS • alphanumeric touchscreen • proven bidirectional network connection from Accu-Chek HQ to LIS/HIS • ADT data interface with DataCare POC, DataCare GM, RALS-G/RALS Plus

Tabulation does not represent an endorsement by the College of American Pathologists

Bedside glucose testing systems

Part 8 of 8	Roche Diagnostics Accu-Chek Customer Care 9115 Hague Rd., Indianapolis, IN 46256 (800) 440-3638 www.roche.com	Roche Diagnostics Accu-Chek Customer Care 9115 Hague Rd., Indianapolis, IN 46256 (800) 440-3638 www.roche.com
Name of instrument/first year sold	AccuData GTS, 1994; AccuData GTS Plus, 2000	Accu-Chek Inform/2001
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	40,000*/5,000	6,500/300
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	11 x 8.75 x 4 in/5 lbs	1.4 x 3.8 x 7.6 in/12 oz
Analytical method/technology/enzyme system used	biosensor–glucose dehydrogenase	biosensor—glucose dehydrogenase
List price	$550	$1,200
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	18–24 mo, stable until exp. on vial/<90°F, do not freeze	18–24 mo, stable until expir. date on vial/room temp., less than 90°F, do not freeze
Digital readout size/keypad input capability	4 lines x 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)
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	26 sec	26 sec
Batteries used/number used/avg. life of 1 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 yrs/10,000 tests	5 yrs/testing in progress
Device warranty/service options	all-inclusive warranty through life of AccuData GTS/GTS Plus at no additional cost/24 h, 365 d customer care w/ overnight replacement if needed	all-inclusive warranty through life of Accu-Chek Inform System at no additional cost/customer care is available 24 h, 365 d per yr with overnight replacement if needed
Loaners provided	yes	yes
User list or user group	yes (contact local account manager)	yes (contact local account manager)
Toll-free No. for customer questions	24 h, 365 d per yr	yes (24 h, 365 d per yr)
Training and certif. program/No. training days provided	yes/site-specific according to quantity of personnel	yes/site-specific according to quantity of personnel
Avg. time for lab to complete maintenance	none	none
Special cleansing procedures	no	no
Internal QC recommended or required	daily, 2 level	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 fail-safe check, visual confirmation of sample volume	built-in electronic fail-safe 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 & 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)
What 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/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
What meters connect to	data management system, which in turn connects to LIS/HIS	data management system, which in turn connects to LIS/HIS
How meters are connected to external system to upload results/No. installations	direct serial/1,000, modem dial-in/5, hospital network/100	direct serial/47, modem dial-in/3, hospital network/82
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, QC identifier, strip lot No., download loc., comment codes, proficiency & linearity samples	device unique identifier, operator & patient IDs, result, strip lot No., QC identifier, proficiency and linearity samples, comments, meter location, download location
Hardware/software for data mgmt. system	software: Accu-Chek HDM, DataCare GM, DataCare POC, RALS-Link, RALS-G, RALS Plus	DataCare POC, DataCare GM, RALS Plus
No. of different mgmt. reports system can produce	unlimited (customer defined)	unlimited (user defined)
Contents downloaded from DMS to meter	strip & QC lot Nos., valid operator ID, valid control values, linearity values	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot numbers and values, comments
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	Cerner, Sunquest, DHCP, HBOC, Phamis, Meditech, SoftLab	Cerner, Meditech, Sunquest, CPSI, CompuCare, Antrim, SoftLab, SMS, HBOC, CHC, TDS, Dawning Tech., Cloverleaf, Data Innovations
• using standard HL7 interface	Cerner, Sunquest, Meditech, HBOC	
• using proprietary protocol interface	none	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Roche offers DataCare POC and DataCare GM as well as interfacing through the MAS continuum	proprietary DataCare Interface Manager
Distinguishing features	• superior strip technology: glucose dehydrogenase, reliable results at varying hematocrit levels, and comfort curve design • proven bidirectional network connection from AccuData GTS/GTS Plus to LIS/HIS • ADT data interface with DataCare POC, DataCare GM, RALS-G/RALS Plus *combined AccuData GTS and AccuData GTS Plus sales*	• superior strip technology, glucose dehydrogenase, reliable results at varying hematocrit levels, and comfort curve design • hands-free, bidirectional communication with LIS/HIS • palm-powered alphanumeric touchscreen (based on Palm OS) • ADT data interface with DataCare POC, DataCare GM, RALS Plus

Tabulation does not represent an endorsement by the College of American Pathologists