Bedside glucose testing systems

The sweet smell of safety

Anne Ford

No one doubts that point-of-care glucose meters have brought efficiency to bedside glucose testing. But Peter Karkantis, director for point-of-care marketing at Abbott Laboratories, hopes hospital staff won't sacrifice safety for speed. "When you have 4,000 humans doing a test," he says, "you're going to make mistakes."

With the products in this year's lineup of glucose meters—some with new features, some with tried-and-true capabilities—manufacturers aim to minimize those inevitable mistakes while taking advantage of the expedience and productivity that make handheld meters a boon to the industry.

Safety and accuracy drive Abbott's Precision PCx meter, Karkantis says. The PCx, first introduced in 1999, uses glucose strips that are individually packaged and bar-coded, so the administering nurse can use the meter to scan the bar code and encode the key calibration information and expiration date for that particular strip lot directly into the meter, rather than relying on a visual check.

One feature of the PCx meter is designed to guard against sampling error. "We have the only test that will not start until you have enough blood on the strip," Karkantis says.

LifeScan's SureStepPro and SureStepFlexx meters, on the market since 1997 and 2000 respectively, address another key aspect of POC glucose testing: the risk of patient infection. With the SureStepPro, the user applies the blood sample to the test strip up to two minutes before inserting the strip into the meter—requiring only the strip itself, instead of the entire meter, to be taken to the patient's bedside. Lorna Wood, LifeScan senior marketing manager, says SureStepPro technology is "ideal for not exposing patients to the meter—which was just in close proximity to another patient and possibly contaminated." It's useful for testing in "isolation units, neonates in isolettes that make maneuvering a meter with the strip already inserted difficult, and in testing combative or uncooperative patients," she says.

HemoCue's Glucose 201 analyzer, released in April 2002, similarly aims to minimize the risk of contamination by reducing health care workers' exposure to blood. Marketing communications specialist Diep Tatch explains that the handheld analyzer uses a disposable microcuvette to contain the freeze-dried reagent. Capillary action draws the blood sample into the microcuvette, where it mixes with the reagent.

Tatch emphasizes the Glucose 201's accuracy as well as its safety. While it's the size of a meter, she says, "it's actually a professional analyzer, a professional instrument as accurate as any lab."

Diametrics Medical's IRMA SL blood analysis system, introduced in 1994, isn't a meter either, says worldwide marketing communications specialist Dawn Larson. "It's a portable, single-use, cartridge-based blood gas, electrolyte, and chemistry blood analysis system that can use LifeScan's SureStepPro test strips through an optional SureStepPro glucose module attachment. Its primary benefit is its flexibility to perform both cartridge and glucose strip testing on a single device."

Meanwhile, Roche Diagnostics plans to increase the capability of its Inform meter later this year. "We'll be introducing the ability for the Inform to record other tests that are traditionally manually recorded in a patient's chart," says Mary Catherine Coyle, manager of marketing for hospital glucose meters. "Once the meter is docked, that information will automatically file into the patient's chart and be available for billing."

While technological advances are making bedside glucose testing easier and safer than ever, a new device for patient home use is due out this year. In January, Medtronic MiniMed and BD announced an alliance to co-develop and co-market new diabetes products. The companies' first co-branded product, the Logic meter, provides glucose readings in five seconds. This year, a next-generation Logic meter, which will automatically send glucose values to an insulin pump using radio frequency, will be available. Based on the glucose value, the pump will estimate the amount of insulin a patient must deliver, which may eliminate calculation mistakes for many patients. "Automating glucose monitoring with insulin delivery is a giant leap forward for people with diabetes," says Deanne McLaughlin, communications manager at Medtronic MiniMed. "We are combining our insulin pumps with a continuous glucose monitoring system and look to introduce an artificial pancreas in about four years." ☐

Anne Ford is CAP TODAY *senior editor.*

Part 1 of 8	Abbott Diagnostics Medisense Products Steven Pemberton steven.pemberton@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
Minimum specimen volume required	3.5 µL, FDA cleared for now, 2.5 µL strip config. to be released March 2003
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
Device supports bar-code scanning of	operator & patient identifiers, reag. lot No., both control vials and strips (individually wrapped and bar code)
Method of analyst ID/ID required	bar-code scan or keypad entry/yes
Internal memory size/max. No. of patient results stored	4,000 patient results, 1,000 QC results, 4,000 operators/4,000
Meters connect to	data management system, which in turn connects to LIS/HIS
How meters are connected to external system to upload results/No. of 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

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Bedside glucose testing systems

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	Diametrics Medical Inc. 2658 Patton Rd. St. Paul, MN 55113 651-638-1099 www.diametrics.com	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630 949-859-2630/800-323-1674 www.hemocue.com
Name of instrument/first year sold	IRMA SL with SureStep Pro Blood Glucose Module/1998	HemoCue Blood Glucose Analyzer/1992
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	—	>20,000 worldwide
Part of series of similar/related models	no	yes
Dimensions (H x W x D)/weight	5 x 9.5 x 13.5 in/6 lb (IRMA SL with SureStep Pro Blood Glucose Module)	6 $^1/_4$ x 8 $^1/_4$ x 3 $^1/_2$ in/2 lb
Analytical method/technology/enzyme system used	glucose only: reflectance photometry, glucose oxidase	dehydrogenase, absorbance photometry
List price	$350	$800 classic, $950 for data management model
Price per disposable reagent system unit	consult SureStep Pro representative	$0.98 per test
No. of dispos. reag. system units per basic package	50 strips	25 cuvettes per vial; 4 vials in box
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.	9 mo/refrig. or 3 d room temp.
Digital readout size/keypad input capability	4.5 x 2.5 in/menu selection, numeric, alphabetic	1.25 cm/menu selection, numeric
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/drop, capillary transfer	5 µL
Minimum specimen volume required	1 drop	whole blood/venous, capillary, or arterial
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	<45 sec	15–240 sec
Batteries used/number used/avg. life of 1 set	rechargeable NIMH battery/1/3 yr	AA/5/5 cycles (150 h)
Avg. expected life of device/mean time between failures	>5 yr/<3% warranty return rate	7 yr/>5 yr
Device warranty/service options	24-h replacement upon failure	1 yr, $125 each additional yr/24-h loaner program
Loaners provided	24-h replacement upon failure	yes
User list or user group	yes	no
Toll-free No. for customer questions	24 h, 7 d	7 AM–5 PM PST, 800-323-1674
Training and certif. program/No. training days provided	yes/depends on No. of operators	yes/as needed from vendor office
Avg. time for lab to complete maintenance	clean glucose module as needed, 2 min	weekly: 5 min
Special cleansing procedures	no	no
Internal QC recommended or required	based on hospital-specific policy	quality control cuvette daily
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	4.39%	7.5% (XQ-01)
• 100–200 mg/dL	3.44%	6.6% (XQ-03)
• >400 mg/dL	4.97%	4.4% (XQ-04 >350)
• Program name, year/challenge No./level of mean glucose challenge sample	CAP	CAP EXCEL, 1997/—/—
Accuracy/compared to what reference method or device	r >0.98/YSI	0.994/GC-MS
Precision/compared to what reference method or device	3.44–4.97 CV across runs/—	1.44%/GC-MS
Linear range	0–500 mg/dL	0–400 mg/dL
Suggested dynamic/measurement range	0–500 mg/dL	0–400 mg/dL
Contraindications	no	no
Known interferences/high altitude interference	sodium fluoride/no	none/no
Restrictions based on hematocrit	yes, <25% high results, >60% low results	no
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	control cuvette (an interface filter) verifies photometer calib.
Sample quantity checks	uses LED to determine sufficient quantity	sample quantity always 5 µL due to cuvette technique & design; cuvette automatically draws (by capillary action) exact amount of blood
When auto lock or shutdown occurs	user ID failure, QC failure, lockout if reag. expired or if control lot & reag. not entered	QC failure, control or reagent past exp., QC length
User defines QC lockout intervals/lockout can be circumvented	yes/no	yes/optional
Device supports bar-code scanning of	bar-code scanner available	operator & patient identifiers, controls, reagent
Method of analyst ID/ID required	touchscreen/optional or required, QA user setup	manual or bar code/optional
Internal memory size/max. No. of patient results stored	4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results	1,000 records/approximately 1,000 results dependent on configuration
Meters connect to	data management system, which connects to LIS/HIS; also directly to LIS/HIS	HemoCue data management system, which cannot further transmit data
How meters are connected to external system to upload results/No. of installations	direct serial/—, modem dial-in/—, Ethernet/—	direct serial/—
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, QC identifier, pass/fail, date, time, comment code, analyte unit of measurement type
Hardware/software for data mgmt. system	nondedicated IBM compatible PC, idms (Integrated Data Management System)	PC or laptop/HemoCue DM software
No. of different mgmt. reports system can produce	6	customizable
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs	—
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	major vendors	none
• using standard HL7 interface	major vendors	none
• using proprietary protocol interface	none	Misys
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, product used depends on host system emulation requirements	in progress
Distinguishing features	• integrated workstation with IRMA (blood gas, electrolytes, BUN, cartridge glucose test, Hct) • 1 user interface, 1 in-service program, 1 data management system	• indicated for diabetes mellitus • not hematocrit dependent • no known interferences • perfect for meter verification • CLIA waived

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Bedside glucose testing systems

Part 3 of 8	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630 949-859-2630/800-323-1674 www.hemocue.com	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.com
Name of instrument/first year sold	Glucose 201 Analyzer/2002	Supreme II Blood Glucose Meter/1997
Professional or home use	professional use	professional & home use
Units sold in U.S./outside U.S.	—/—	—/—
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	3.35 x 6.3 x 1.69 in/0.77 lb	4 $^3/_4$ x 2 $^1/_2$ x 1 $^1/_4$ in/4.7 oz
Analytical method/technology/enzyme system used	dehydrogenase, absorbance photometry	glucose oxidase
List price	$600	$50
Price per disposable reagent system unit	$0.98	$0.40
No. of dispos. reag. system units per basic package	25 in vial; 4 vials in box	50
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/reag. unit storage requirements	9 mo from manufacture date/refrigeration	18 mo/ambient temp.
Digital readout size/keypad input capability	$^1/_2$ in/none	$^1/_4$ x $^1/_2$ in/none
How results are displayed	calculated values (plasma equivalent 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/exact amount of blood is drawn into the cuvette by capillary force	whole blood/drop
Minimum specimen volume required	5 µL	9 µL
Suitable for samples from well/sick neonates	yes/yes	no/no
Time from sample intro. to result availability	40–240 sec	50 sec
Batteries used/number used/avg. life of 1 set	AA/4/150 h	J cell/1/700 cycles
Avg. expected life of device/mean time between failures	7 yr/>5 yr	20,000 tests/not available
Device warranty/service options	2 yr at no extra cost/—	3 yr/none
Loaners provided	yes	yes
User list or user group	—	no
Toll-free No. for customer questions	7 AM–5 PM PST, 800-323-1674	24 h, 7 d 800-818-8877
Training and certif. program/No. training days provided	yes/as needed	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	system must be verified on testing days using commercially available controls recommended by HemoCue	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	not available	not available
• 100–200 mg/dL	3.8	not available
• >400 mg/dL	≥272 mg/dL = 2.9	not available
• 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	y=0.99 x + 3, r=0.983, n=113/YSI 2300
Precision/compared to what reference method or device	within run CV 1.9% (108 mg/dL)/—	within-run: 3.9%, between-run: 4.0%/YSI 2300
Linear range	0–444 mg/dL	30–600 mg/dL
Suggested dynamic/measurement range	0–444 mg/dL	30–600 mg/dL
Contraindications	no	no
Known interferences/high altitude interference	methemoglobin, glucosamine/no	dopamine ≥10 mg/dL, ascorbate ≥4 mg/dL/no
Restrictions based on hematocrit	no	yes, 28%–65%
Electronic, optical function checks	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	internal sumcheck functions for electronics, internal optics standardization, std. strip
Sample quantity checks	visual inspection	only 1 drop (≥9 µL) sample required
When auto lock or shutdown occurs	n/a	no auto lock or shutdown
User defines QC lockout intervals/lockout can be circumvented	no/no	no/yes
Device supports bar-code scanning of	no bar-code scanner	no bar-code scanner
Method of analyst ID/ID required	n/a	none/n/a
Internal memory size/max. No. of patient results stored	n/a/n/a	100 tests/100 tests
Meters connect to	n/a	n/a
How meters are connected to external system to upload results/No. of 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	• CLIA waived • indicated for diabetes mellitus • not hematocrit dependent • lab verification of patient home meter	• blood can be applied to test strips inside *or* outside of meter

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Bedside glucose testing systems

Part 4 of 8	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.com	Hypoguard USA 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	professional & home use	professional & home use
Units sold in U.S./outside U.S.	8,000/—	10,000/—
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	$4\,^3/_8$ x $2\,^3/_8$ x $^{13}/_{32}$ in/5.3 oz	4 x $2\,^1/_4$ x $^3/_4$ in/ 2.2 oz with battery
Analytical method/technology/enzyme system used	glucose oxidase	glucose oxidase
List price	$50	free with competitive tradeout
Price per disposable reagent system unit	$0.35	$0.47
No. of dispos. reag. system units per basic package	25, 50, 100	50, 100
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/reag. unit storage requirements	18 mo/ambient temp.	18 mo/room temp.
Digital readout size/keypad input capability	$^1/_4$ x $^1/_2$ in/menu selection	5 mm (w) x 10 mm (h)/none
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/drop	whole blood/capillary transfer
Minimum specimen volume required	—	3 µL
Suitable for samples from well/sick neonates	no/no	no/no
Time from sample intro. to result availability	35 sec	30 sec
Batteries used/number used/avg. life of 1 set	J cell/1/1,000 cycles	3 v lithium/1/1,000 cycles
Avg. expected life of device/mean time between failures	20,000 tests/not available	20,000 tests/—
Device warranty/service options	3 yr/none	3-yr warranty/—
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions	24 h, 800-818-8877	24 h, 800-818-8877
Training and certif. program/No. training days provided	yes/as needed	yes/as needed
Avg. time for lab to complete maintenance	weekly: 10 min	weekly: 10 min
Special cleansing procedures	no	no
Internal QC recommended or required	as specified by accreditation	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	not available	n/a
• 100–200 mg/dL	not available	n/a
• >400 mg/dL	not available	n/a
• Program name, year/challenge No./level of mean glucose challenge sample	n/a	n/a
Accuracy/compared to what reference method or device	y=0.98 *x* + 8, r=0.976, n=109/YSI 2300	slope=0.93, r=0.976/YSI glucose analyzer
Precision/compared to what reference method or device	within-run: 4.7%, between-run: 3.7%/YSI 2300	within-run: 3.4%; between run: 3.1%
Linear range	30–550 mg/dL	30–550 mg/dL
Suggested dynamic/measurement range	30–550 mg/dL	30–550 mg/dL
Contraindications	no	no
Known interferences/high altitude interference	L-dopa and dopamine (≥10 mg/dL)/no	L-dopa and dopamine/yes, tested up to 7,000 ft
Restrictions based on hematocrit	yes, 20%–60%	yes, 30%–55%
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	sumcheck functions for electronics and software, no optics
Sample quantity checks	only 1 drop (≥7 µL) sample required	only one drop (≥3µL) sample required
When auto lock or shutdown occurs	no auto lock or shutdown	1 min
User defines QC lockout intervals/lockout can be circumvented	no/yes	no/—
Device supports bar-code scanning of	no bar-code scanner	no bar-code scanner
Method of analyst ID/ID required	none/n/a	—/—
Internal memory size/max. No. of patient results stored	180 tests/180 tests	—/10
Meters connect to	n/a	—
How meters are connected to external system to upload results/No. of installations	n/a	—
Info. contained in transmission to external system	n/a	—
Hardware/software for data mgmt. system	yes	—
No. of different mgmt. reports system can produce	4	—
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	• touchscreen display	

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Bedside glucose testing systems

Part 5 of 8	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.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	Assure 3/2003	SureStepPro/1997
Professional or home use	professional & home use	professional use
Units sold in U.S./outside U.S.	—/—	>20,000/n/a
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	4 x 2 $^1/_4$ x $^3/_4$ in/ 2.2 oz with battery	7.4 x 3.5 x 2.6 in/1.2 lb
Analytical method/technology/enzyme system used	glucose oxidase	glucose oxidase, reflectance photometry
List price	free with competitive trade out	$1,200 per bedside unit
Price per disposable reagent system unit	$0.47	contracted
No. of dispos. reag. system units per basic package	50, 100	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 mo/room temp.	18 mo unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/keypad input capability	5 mm (w) x 10 mm (h)/none	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/capillary transfer	whole blood/drop, wipe, capillary transfer, touchable test strip
Minimum specimen volume required	3 µL	5 µL, maximum 30 µL
Suitable for samples from well/sick neonates	no/no	yes/yes
Time from sample intro. to result availability	10 sec	15 sec minimum
Batteries used/number used/avg. life of 1 set	3 v lithium/1/1,000 tests	C 1.5 v/2/approximately 1,000 tests
Avg. expected life of device/mean time between failures	20,000 tests/—	>5 yr/<3% warranty return rate
Device warranty/service options	3-yr warranty/—	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, 800-818-8877	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	weekly: 10 min	none
Special cleansing procedures	no	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	—	4.39%
• 100–200 mg/dL	—	3.44%
• >400 mg/dL	—	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	>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/YSI
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 water 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%	adult: 25%–60% RBC; neonates: 25%–65% RBC
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	automatic electronic and optical checks with each test
Sample quantity checks	one drop (≥3µL)	test strip color confirmation dot when adequate sample applied, bedside unit error messages
When auto lock or shutdown occurs	1 min time out	user ID failure, QC failure, data upload lockout option
User defines QC lockout intervals/lockout can be circumvented	no/—	yes/no
Device supports bar-code scanning of	no bar-code scanner	operator & patient identifiers, reagent (strip) lot No., bedside unit serial Nos., control solution lot Nos.
Method of analyst ID/ID required	%	bedside unit custom programmed for manual or bar-code entry/required or optional
Internal memory size/max. No. of patient results stored	10 test memory/10	2,500 patient & QC tests plus 50 test strip lots and QC lots
Meters connect to	n/a	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. of installations	n/a	DataLink Connect, >950 hospital sites; DataLink Interface, >150 sites
Info. contained in transmission to external system	n/a	device unique identifier, operator & patient ID, result, QC identifier, flags, comments
Hardware/software for data mgmt. system	—	desktop or laptop, Windows NT, proprietary DataLink Data Management System; QML; RALS-Plus
No. of different mgmt. reports system can produce	—	17 reports plus export function for customized reports
Contents downloaded from DMS to meter	—	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	—	DHCP-VA System, McKesson Pathlab3, Star, ALG, Misys Flexilab, Cerner Pathnet (legacy), SCC, Softlab, DHT, Dynacor Premier
• using standard HL7 interface	—	Cerner Pathnet (legacy), Misys Flexilab, Meditech Magic & client/server
• using proprietary protocol interface	—	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features	• wick in test strip, ergonomically formed, large handle • fast test time—10 sec • extremely easy to use, low maintenance	• 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

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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	Medtronic MiniMed Inc. 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com
Name of instrument/first year sold	SureStepFlexx/2000	Medtronic 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/>1,000
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
Minimum specimen volume required	5 µL, maximum 30 µL	n/a
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 yr/—
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, 800-826-2099
Training and certif. program/No. training days provided	yes/as negotiated	yes (training only)/~1 d
Avg. time for lab to complete maintenance	none	none
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) in vitro
• >400 mg/dL	2.4%	—
• Program name, year/challenge No./level of mean glucose challenge sample	data from 2000 & 2001 AACC posters	CGMS, 1998–99
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	test plug, 24–29nA
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
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. of 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
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. of installations	DataLink Connect, >950 hospital sites; DataLink Interface, >150 sites	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 & 2000, 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	7 standard unlimited customized reports
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, McKesson PathLab 3, Star, ALG; Misys 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—patented February 2003 • 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 • 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	• 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

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Bedside glucose testing systems

Part 7 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	Accu-Chek HQ/1999	AccuData GTS, 1994; AccuData GTS Plus, 2000
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	7,500/none	40,000*/5,000
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	2.9 x 4.2 x 9.4 in/3.5 lbs	11 x 8.75 x 4 in/5 lbs
Analytical method/technology/enzyme system used	biosensor–glucose dehydrogenase	biosensor–glucose dehydrogenase
List price	$1,495	$550
Price per disposable reagent system unit	contingent on contract price	contingent on contract price
No. of dispos. reag. system units per basic package	50 test strips	50 strips per vial
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/room temp., <90°F, do not freeze	18–24 mo, stable until exp. on vial/<90°F, do not freeze
Digital readout size/keypad input capability	7 lines x 30 characters/menu selection, numeric, alphabetic	4 lines x 20 characters LCD/menu selection, numeric
How results are displayed	true values	true values
Specimen types/sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	4 µL	4 µL
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	26 sec	26 sec
Batteries used/number used/avg. life of 1 set	3 v lithium/2/700 tests	3 v lithium/2/~700 tests
Avg. expected life of device/mean time between failures	5 yr/828,000 tests	5 yr/10,000 tests
Device warranty/service options	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	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
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	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 level
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	per labeling
Known interferences/high altitude interference	per labeling/none up to 10,150 ft	per labeling/none up to 10,150 feet
Restrictions based on hematocrit	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
Electronic, optical function checks	meter cradle communication with the Advantage meter, meter cradle with code key, battery voltage test, internal database memory check, internal configuration check	meter cradle communication with Advantage meter, GTS 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, visual confirmation of sample volume
When auto lock or shutdown occurs	user ID failure (valid op.), QC failure, patient ID length, reagent & QC lots, comment codes, incorrect code key, incorrect Advantage meter	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	yes/yes (information management system identifies operators who violate hospital policy)	yes/yes (information management system identifies operators who violate hospital policy)
Device supports bar-code scanning of	operator & patient identifiers	operator & patient identifiers, comment codes
Method of analyst ID/ID required	alphanumeric/yes	numeric input or bar-code wand scan/yes
Internal memory size/max. No. of patient results stored	2,000 records/2,000 records	1,000 total patient, control, linearity, proficiency tests/1,000
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. of installations	direct serial/—, modem dial-in/—, hospital network/—	direct serial/—, modem dial-in/—, hospital network/—
Info. contained in transmission to external system	device unique identifier, operator & patient ID, result, strip lot No., QC identifier, proficiency & linearity samples, comments, meter loc., download loc.	device unique identifier, operator & patient ID, result, QC identifier, strip lot No., download loc., comment codes, proficiency & linearity samples
Hardware/software for data mgmt. system	software: Accu-Chek HDM, DataCare POC, DataCare GM, RALS-Link, RALS-G, RALS Plus, RALS Lite,* RALS Notebook*	software: Accu-Chek HDM, DataCare POC, DataCare GM, RALS-Link, RALS-G, RALS Plus, RALS Lite,† RALS Notebook†
No. of different mgmt. reports system can produce	unlimited (customer defined)	unlimited (customer defined)
Contents downloaded from DMS to meter	strip & QC lot Nos., valid control values, valid operator IDs, meter configuration, message of the day, linearity values, critical ranges comments	strip & QC lot Nos., valid operator ID, valid control values, linearity values
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	all major LIS vendors including Cerner, Misys, DHCP, McKesson, Phamis, Meditech, SoftLab	all major LIS vendors including Cerner, Misys, DHCP, McKesson, Phamis, Meditech, SoftLab
• using standard HL7 interface	Cerner, Misys, Meditech, McKesson	Cerner, Misys, Meditech, McKesson
• using proprietary protocol interface	none	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	through Telcor as well as interfacing through the MAS continuum	through Telcor as well as interfacing through the MAS continuum
Distinguishing features	• 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 * Roche exclusive	• 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 † Roche exclusive

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SURVEY OF INSTRUMENTS

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	Stanbio Laboratory 1261 N. Main St. Boerne, TX 78006 800-782-6246 www.stanbio.com
Name of instrument/first year sold	Accu-Chek Inform/2001	Stat-Site/1991
Professional or home use	professional use	professional use
Units sold in U.S./outside U.S.	19,000/300	—
Part of series of similar/related models	yes	yes
Dimensions (H x W x D)/weight	1.4 x 3.8 x 7.6 in/12 oz	7 x 4.75 x 1.75 in/16 oz
Analytical method/technology/enzyme system used	biosensor—glucose dehydrogenase	reflectance photometry, glucose oxidase & peroxidase
List price	$1,200	$1,135
Price per disposable reagent system unit	contingent on contract price	$1.20 per test
No. of dispos. reag. system units per basic package	50 test strips	100
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 expir. date on vial/room temp., less than 90°F, do not freeze	18 mo/2–4°C (30 d at room temp.)
Digital readout size/keypad input capability	font size varies/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/arterial, venous, capillary, neonate (including cord blood)	whole blood/1st drop
Minimum specimen volume required	4 µL	25 µL
Suitable for samples from well/sick neonates	yes/yes	no/no
Time from sample intro. to result availability	26 sec	2 min
Batteries used/number used/avg. life of 1 set	3.7 v rechargeable lithium ion/1/testing in progress	9 v alk./2/4 h
Avg. expected life of device/mean time between failures	5 yr/testing in progress	<1% failure rate/6 yr
Device warranty/service options	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	1 yr parts, labor/1 yr extension $250
Loaners provided	yes	yes
User list or user group	yes (contact local account manager)	yes (available upon request)
Toll-free No. for customer questions	yes (24 h, 365 d per yr)	8 AM–5 PM EST
Training and certif. program/No. training days provided	yes/site-specific according to quantity of personnel	yes/none
Avg. time for lab to complete maintenance	none	n/a (sealed system)
Special cleansing procedures	no	no
Internal QC recommended or required	daily, 2 levels of glucose control solutions	controls–check cards
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	53.8 mg/dL SD=4.1 (6,088 labs)	not available
• 100–200 mg/dL	191.4 mg/dL CV=4.7% (3,096 labs)	not available
• >400 mg/dL	228.5 mg/dL CV=4.6% (6,099 labs)	not available
• Program name, year/challenge No./level of mean glucose challenge sample	CAP, 2001/WBG-C/see above	n/a
Accuracy/compared to what reference method or device	y=0.991 x + 8.4, r=0.980/glucose hexokinase–Hitachi	1.008/YSI 2300 Stat Plus
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	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	yes, per labeling	no
Known interferences/high altitude interference	per labeling/none up to 10,150 ft	elevated ascorbic acid levels/no
Restrictions based on hematocrit	yes, glucose <200 mg/dL 20%–65%; glucose >200 mg/dL 20%–55%	no
Electronic, optical function checks	meter with code key, battery voltage test, internal database memory check, internal configuration check	check card 1 & 2, reflectance values, calib. module (lot specific)
Sample quantity checks	built-in electronic fail-safe check, visible verification of sample volume	hanging drop approximately 25 µL; "insufficient sample" will appear if significantly <25 µL
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 & data editing	QC failure
User defines QC lockout intervals/lockout can be circumvented	yes/no (optional QC pass/fail feature)	no/n/a
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos.	reagent lot No., exp., test
Method of analyst ID/ID required	alphanumeric or bar-code scan/yes	manual/no
Internal memory size/max. No. of patient results stored	4,000 results/4,000 tests	1 KB/1 last result
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. of installations	direct serial/—, modem dial-in/—, hospital network/—	direct serial/—
Info. contained in transmission to external system	device unique identifier, operator & patient IDs, result, strip lot No., QC identifier, proficiency & linearity samples, comments, meter location, download location	device unique identifier, operator & patient ID, result, QC identifier, date, time, test
Hardware/software for data mgmt. system	DataCare POC, DataCare GM, RALS Plus, RALS Lite,* RALS Notebook*	n/a
No. of different mgmt. reports system can produce	unlimited (user defined)	n/a
Contents downloaded from DMS to meter	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot Nos. & values, comments	n/a
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	all major LIS vendors including Cerner, Meditech, Misys, CPSI, CompuCare, Antrim, SoftLab, Siemens, McKesson, CHC, TDS, Dawning Tech., Cloverleaf, Data Innovations	n/a
• using standard HL7 interface		n/a
• using proprietary protocol interface	—	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	through Telcor as well as through MAS continuum	n/a
Distinguishing features	• 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 *Roche exclusive*	• multiple tests from one meter—glucose, cholesterol, ketone (blood) • true plasma results • sealed optics • expired reagent lockout

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