April 2005

For glucose systems, greater accuracy and safety

Anne Ford

he new emphasis on tight glycemic control in critical care units has proved to be a boon to manufacturers of bedside glucose testing systems, who find their products in greater demand than ever. With this shift in practice comes heightened awareness of the need for accuracy and patient safety. "The FDA has reported that 75 percent of all blood glucose errors can be traced to user errors," says Peter Karkantis, director of marketing for Abbott Point of Care. In response to that sobering statistic, many companies are updating existing products or releasing new ones with an eye to improved accuracy and safety.

Roche Diagnostics, for example,

in troduced firmware for its Accu-Chek Inform meter last year; the new firmware allows operators to use a password in addition to an operator ID number. "The unique password discourages nurses from borrowing name badges or ID codes since the password will also be required," says Mary Catherine Coyle, Roche manager of marketing for hospital glucose meters and ancillary products.

But "probably the most exciting feature," Coyle adds, is the firmware's enhanced patient identification function. The enhanced function meets the new JCAHO patient safety goals, which require that two distinct identifiers for patients be used at all stages of analysis. With the Inform meter, the operator scans or keys in the patient identification number. "The meter finds the matching ID and displays the patient identification number as well as the patient name," Coyle says. "These two components appear on the meter screen for confirmation during the sample application, during the test sequence, and at result display. This feature truly is in line with a hospital's commitment to error reduction."

Just a few months ago, meanwhile, HemoCue introduced its 201 DM systems, which include the HemoCue Glucose 201 DM system. Company re presentative Lily Sunkin calls the glucose system "particularly suitable for critical care settings such as NICU and ICU"—the former, she says, because "results are not affected by hematocrit." In addition, "the system is less susceptible to interferences than some glucose strip/meter systems and is suitable for ICU/CCU patients who might be taking many different medications," Sunkin says. To eliminate the risk of transcription error, when placed in its docking station the DM analyzer automatically transfers its results to a network PC.

On a similar technological note, ITC recently updated the automatic electronic QC capabilities of its IRMA Trupoint analyzer. The update included extending the number of characters available for patient and user identification. Company representative Beth O'Connell says ITC plans to introduce creatinine and lactate on the instrument early next year.

At Abbott Point of Care, says Karkantis, patient safety concerns are reflected in innovations such as the company's new Nurse Competency Trainer, a Web-based training tool that "helps ensure opera*continued on page 46*

Meters connect to

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tor competence and certification while reducing the workload on nurse educators and POC coordinators." He also cites Abbott's Precision Plus test strips (used with the PCx and iStat1 point-of-care diagnostic systems) as a tool in the battle against error; the strips feature a fill trigger electrode and glucose-specific chemistry that, he says, "virtually eliminate short-sampling errors and interferences from substances common to other glucose strips." In addition, this year Abbott Point of Care plans to introduce a POC glucose-testing technology known as Coulometry, which will reduce blood sample size by 90 percent, reduce test time by 50 percent, minimize the effects of hematocrit and oxygen on results, and, Karkantis says, "set the standard for POC glucose monitoring performance, accuracy, reliability, and ease."

Medtronic MiniMed, meanwhile, continues to offer its CGMS System Gold, a continuous glucose monitoring system that allows physicians to track patients' glycemic excursions over a three-day period. "The company is looking to bring its glucose-sensing technology to the hospital market for use in critical care patients," says company representative Deanne McLaughlin.

Finally, LifeScan offers the Sure-StepFlexx and DataLink Glucose Management System, a portable blood glucose testing system for multipatient settings that features a unique off meter dosing blood application to promote infection control. "Patient and operator safety are a key component to the LifeScan system," says Paul Hausman, marketing manager for institutional products. The SureStepFlexx is now available with a software enhancement that provides the option to force bar-code scanning of patient and operator badges, which helps hospitals comply with safety standards.

Hospital IT departments are playing a larger role in point-of-care, Hausman says. DataLink is now delivered on a CD, making it possible for POC managers to load the system manager on a hospital-provided PC. IT managers can load service packs and antivirus software in accordance with their policies. LifeScan also plans to launch a wireless telemetry unit for the system later this year. CAP TODAY's survey of bedside glucose testing systems includes products from the manufacturers cited above and from Hypoguard. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. \Box

Part 1 of 7	Abbott Point-of-Care
	Ken Stoner ken.stoner@abbott.com
	104 Windsor Center Dr., East Windsor, NJ 08520
	009-443-4820
See accompanying article on page 44	
Name of instrument/First year sold	Precision PCx/1998
Professional or home use	professional use
Units sold in U.S./Uutside U.S. Part of sories of similar or related medals	40,707/15,000 voc. iStat 1
Dimensions (H x W x D)/Weight	7.7 x 2.95 x 5.1 in/10 oz
Analytical method/technology/Enzyme system used	amperometric/glucose oxidase with Precision PCx strips/glucose
	dehydrogenase with PCx Plus test strips
List price	\$995
Price per disposable reagent system unit	\$71.50 per box 100 test strips
No. of dispos. reag. system units per basic package	100 per box
No. or unles analyses performed using 1 reag. system unit Dispos, units shelf life/Reag, unit storage requirements	l 12_18 months /room temn)/30°_96°E
טופעטים. עוווגס שופון ווופירופמע. עוווג טוטו מער ופעעוו פווופווגט	12-10 monuts (100m temp.//33 -00 F
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, can apply blood directly to test strip
Minimum specimen volume required	אווטיס שיטטע עוסף, טעון עאריז אווטטע עווכטעץ נט נכצו צעוף
Suitable for samples from well/Sick neonates	3.5 µL with PCx, 2.5 µL with PCx Plus
Time from sample intro. to result availability	yes/yes
Batteries used/No. used/Avg. life of 1 set	20 sec
Ava expected life of device/Mean time between failures	AA/2/~60 days (based on 30 tests/day) 24 months/24 months
Device warranty/Service options	1-vr warranty, lifetime replacement with reagent contact/24-h
	replacement
Loaners provided	yes
User list or user group	Ves
Toll-free No. for customer questions	24 h, 7 days
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	as required by facility or institutional policy or when glucose results
Between instrument CV (based on PT) at these levels:	
• <50 mg/dL	-
• 100–200 mg/dL	71.9 mg/dL, CV=4.1%; 192.3 mg/dL, CV=5.5%
• >400 mg/dL	400.7 mg/dL, CV=6.9%
• Program name, year/chailenge No./Level of mean glucose challenge sample	CAP whole blood Glucose Survey, 2003/Set B
Accuracy/compared to what reference method as device	conillory bloods y=0.01x + 0.01 = 0.00/VCl
	Gapinary Dioou: y=0.91x + 0.91, r=0.98/151
Precision/compared to what reference method or device	blood samples: CV 2.9% to 5.1%
Linear range	20-500 mg/dL PCx Plus; 20-600 mg/dL for PCx
Suggested dynamic, measurement range	20-500 mg/dL PCx Plus; 20-600 mg/dL for PCx
Contraindications	per labelling
Known Interferences/High-altitude interference	per labeling/none up to 7,200 ft
NESUIGUOIIS DASEU OII HEIHATOCHT	yes, giucose <300 mg/aL, 20-70%; giucose 2300 mg/aL, 20-60%
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks
Sample quantity checks	performed during power up of meter
Sample qualitity clicches	a minunger electrone on each test surp specifically designed to start the test when sufficient sample is detected
When auto lock or shutdown occurs	user ID failure, QC failure, download time if selected
User defines QC lockout intervals/Lockout can	yes/no
Device supports bar-code scanning of	operator & patient identifiers, reag. lot Nos., comment codes, control &
	linearity lot Nos.
Method of analyst ID/ID required	manual or bar-code ID entry/operator ID lockout optional
Internal memory size/Max. No. of patient results stored	4.000 natient results 1.000 controls 1.000 operators/—

Precision Web data management system, which in turn connects to LIS/HIS

Anne Ford is a writer in Chicago.

How meters are connected to external system to upload results/No. of installations Info. contained in transmission to external system	direct serial/50+; modem dial-in/100+; hospital network/800+ device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., test dates & times, comment codes
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server
No. of different mgmt. reports system can produce	25
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, QC lockout & upload lockout parameters
System connected (live installations) to which LISs/HISs:	
using screen animation/screen scraping	Mysis, Cerner, Meditech, Soft Lab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab
 using standard HL7 interface 	Cerner, Misys, PerSe, Meditech, Soft Lab
using proprietary protocol interface	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Sybase
Distinguishing features (provided by vendor)	 positive reagent ID positive calibration ID—no need to visually verify code key against test strip vial ability to reapply blood within 30 seconds to same strip

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Survey editor: Raymond Aller, MD

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	Badeida alucaea tastina	evetome
_	beusiue giucose testing	Systems
Part 2 of 7	HemoCue Inc.	HemoCue Inc.
	40 Empire Dr.	40 Empire Dr.
	Lake Forest, CA 92630	Lake Forest, CA 92630
	800-323-1674	800-323-1674
See accompanying article on page 44	Chicago 201 DM Applyzer/2005	Chucono 201 Applyzor/2002
Name of instrument/First year solu	Giucose 201 Divi Alialyzer/2005	
Professional or home use	professional use /	professional use
Part of series of similar or related models	ves	ves
Dimensions (H x W x D)/Weight	6.7 x 3.7 x 2 in/0.77 lb	6.3 x 3.4 x 1.7 in/0.77 lb
Analytical method/technology/Enzyme system used	absorbance photometry/glucose dehydrogenase	absorbance photometry/glucose dehydrogenase
List price	\$1,200	\$600
Price per disposable reagent system unit	\$1.20 per test if in vial; \$1.25 per test if individually packaged	\$1.20 per test if in vial; \$1.25 per test if individually packa
No. of dispos. reag. system units per basic package	25 in vial/box; 4 vials/boxes per package	25 in vial/box; 4 vials/boxes per package
No. of times analyses performed using 1 reag. system unit Dispos units shelf life/Reag. unit storage requirements	1 9 months from manufacture date/refrigeration	1 9 months from manufacture date/refrigeration
Dispus, units shen me/neay, unit storaye requirements	ש אישראיש אישרא	o monulo nom manulaciule uale/reirigefation
Digital readout size/Keypad input capability	varies from 8 to 28 points/menu selection, numeric, alphabetic	¹ /2 in/none
now results are displayed	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)	piasma equivalent values
Specimen types/Sampling techniques	whole blood (capillary, venous, arterial)/exact amount of blood drawn into	whole blood, venous, capillary, or arterial/exact amount o
	cuvette by capillary force	into the cuvette by capillary force
Minimum specimen volume required	5 µL	5 μL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	40–240 sec	40-240 sec
batteries used/No. used/Avg. life of 1 set	rechargeable lithium ion supplied by HemoGue/several years	АА/4/150 П 7. vr /> 5. vr
wy, expected me of device/mean time between failures Device warranty/Service ontions	/ yr/20 yr 2 yr at no additional cost/replacement of defective analyzer	י און י>ט או 2 vr at no extra cost/—
Loaners provided	- y, as no additional observe placement of defective analyzer Ves	Ves
llear liet ar usar group	no.	
user list of user group Toll-free No. for customer questions	11U 6 AM-5 PM PST 800-322-1674	
Training and certif program/No. training days provided	ves/~1 hr ner device nurchased	0 AM-3 FM F31, 000-323-1074 ves/as needed
Avg. time for lab to complete maintenance	daily: 5 min	daily: 5 min
Special cleansing procedures	no	no
Internal QC recommended or required	one level of controls prior to patient testing, each day of testing	system must be verified on testina davs usina commercia
		controls
Between instrument CV (based on PT) at these levels: • <50 mg/dl	not available	not available
• 100–200 ma/dL	3.8	3.8
• >400 mg/dL	272 mg/dL=2.9	272 mg/dL = 2.9
Program name, year/Challenge No./Level	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL;	Equalis (Swedish PT program), 2003/2003-03; 2003-07/27
of mean glucose challenge sample	120 mg/dL	120 mg/dL
Accuracy/compared to what reference method or device	$\pm 10\%$ or $\pm 6\%$ mg/dL; corr=0.994/wet chemical glucose dehydrogenase,	$\pm 10\%$ or ± 6 mg/dL; corr = 0.994/wet chemical glucose d
	ID-GCMS	ID-GCMS
Precision/compared to what reference method or device	within run CV 1.9% (108 mg/dL)/—	within run CV 1.9% (108 mg/dL)/—
Linear range	U–444 mg/dL	U–444 mg/dL
Suggested dynamic, measurement range	U-444 Mg/QL	v–444 mg/aL
GUIN ANNUGAUUIS		10
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	grossly lipemic samples, methemoglobin, glucosamine/ne
Restrictions based on hematocrit	no	no
Electronic, optical function checks	internal electronic self-test automatically checks that the instrument's	internal electronic self-test automatically checks that the
	optronic unit is working properly	optronic unit is working properly
Sample quantity checks	visual inspection	visual inspection
When auto lock or shutdown occurs	user ID failure if configured to require operator ID: OC failure if configured	n/a
	to require quality control; number of device errors	
User defines QC lockout intervals/Lockout can	yes/no (stat testing may be allowed; 1-100 tests after QC interval)	no/no
be circumvented		
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID	no bar-code scanner
	alpha-numeric manual entry or har-ondo coan entry/entional	n/a
Method of analyst ID/ID required	מוקוומ-וועוווכווט וומוועמו כווע א טו שמו-טטער געמון כוועא/טשנוטוומו	li/d

to unload results/No. of installations		
Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags	n/a
Hardware/software for data mgmt. system	PC/server/HemoCue 201 DM PC software	_
No. of different mgmt. reports system can produce	15 different templates, custom reports based on templates, multiple export formats	_
Contents downloaded from DMS to meter	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration	—
System connected (live installations) to which LISs/HISs:		
using screen animation/screen scraping	_	_
using standard HL7 interface	_	_
using proprietary protocol interface	_	_
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Telcor QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator	_
Distinguishing features (provided by vendor)	 POCT-1A compliant indicated for diagnosis of diabetes mellitus not hematocrit dependent 	 CLIA waived indicated for diagnosis of diabetes mellitus not hematocrit dependent lab verification of patient home meter

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Part 3	пf

Part 3 of 7 Hy Part 3 of 7 Hy See accompanying article on page 44 See accompanying article on page 44 Name of instrument/First year sold Su Professional or home use pr Units sold in U.S./Outside U.S. - Part of series of similar or related models ye Dimensions (H x W x D)/Weight 4 if Analytical method/technology/Enzyme system used gli List price \$55 Price per disposable reagent system unit \$00 No. of dispos. reag. system units per basic package \$00 No. of dispos. reag. system units torage requirements 11 Digital readout size/Keypad input capability 1/4 How results are displayed true Specimen types/Sampling techniques with Minimum specimen volume required 9 I Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Device warranty/Service options 3 is Loaners provided ye User list or user group no Toll-free No. for customer questions 24	Pypoguard USA 301 Ohms Lane dina, MN 55439 00-818-8877 www.hypoguard.com supreme II Blood Glucose Meter/1997 rofessional & home use -/ es 3 ³ /4 x 2 ¹ /2 x 1 ¹ /4 in/4.7 oz Juccose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop µL	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.com Assure Blood Glucose Meter/1998 professional & home use 8,000/ yes 4 ³ /8 x 2 ³ /8 x ¹³ /32 in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
Part 3 of 7 Hy See accompanying article on page 44 Name of instrument/First year sold Su Professional or home use pr Units sold in U.S./Outside U.S.	Avpoguard USA 301 Ohms Lane idina, MN 55439 300-818-8877 www.hypoguard.com Supreme II Blood Glucose Meter/1997 rofessional & home use -/ es 3/4 x 2 ¹ /2 x 1 ¹ /4 in/4.7 oz lucose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop µL	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.com Assure Blood Glucose Meter/1998 professional & home use 8,000/ yes 4 ³ / ₈ x 2 ³ / ₈ x ¹³ / ₃₂ in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
Part 3 of 7 Hy 73 Fd 80 See accompanying article on page 44 Name of instrument/First year sold Su Professional or home use pr Units sold in U.S./Outside U.S. — Part of series of similar or related models ye Dimensions (H x W x D)/Weight 4 if Analytical method/technology/Enzyme system used gli List price \$55 Price per disposable reagent system unit \$0 No. of dispos. reag. system units per basic package \$0 No. of dispos. reag. system units per basic package \$0 No. of times analyses performed using 1 reag. system unit 1 Digital readout size/Keypad input capability 1/4 How results are displayed \$0 Specimen types/Sampling techniques \$0 Minimum specimen volume required \$9 Suitable for samples from well/Sick neonates \$0 Device warranty/Service options 3 y Loaners provided ye User list or user group \$0 Toll-free No. for customer questions 24 Training and certif. pr	lypoguard USA 301 Ohms Lane idina, MN 55439 300-818-8877 www.hypoguard.com interpret II Blood Glucose Meter/1997 rofessional & home use -/ es 3 ³ /4 x 2 ¹ / ₂ x 1 ¹ / ₄ in/4.7 oz lucose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹ / ₂ in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop µL	Hypoguard USA 7301 Ohms Lane Edina, MN 55439 800-818-8877 www.hypoguard.com Assure Blood Glucose Meter/1998 professional & home use 8,000/ yes 4 ³ /8 x 2 ³ /8 x ¹³ /32 in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
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Name of instrument/First year sold Su Professional or home use pr Units sold in U.S./Outside U.S.	Supreme II Blood Glucose Meter/1997 rofessional & home use -/	Assure Blood Glucose Meter/1998 professional & home use 8,000/
Professional or home use pr Units sold in U.S./Outside U.S.	rofessional & home use -/ es ³ / ₄ x 2 ¹ / ₂ x 1 ¹ / ₄ in/4.7 oz lucose oxidase 50 00.40 0 8 months/ambient temp. /4 x ¹ / ₂ in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop μL	professional & home use 8,000/
Units sold in U.S./Outside U.S.	-/ es ³ /4 x 2 ¹ / ₂ x 1 ¹ / ₄ in/4.7 oz lucose oxidase 50 00.40 0 8 months/ambient temp. /4 x ¹ / ₂ in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	8,000/ yes 4 ³ / ₈ x 2 ³ / ₈ x ¹³ / ₃₂ in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ / ₄ x ¹ / ₂ in/menu selection true values whole blood/drop
Part of series of similar or related models ye Dimensions (H x W x D)/Weight 4 Analytical method/technology/Enzyme system used glit List price \$5 Price per disposable reagent system unit \$0 No. of dispos. reag. system units per basic package \$0 No. of dispos. reag. system units per basic package \$0 No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed tru Specimen types/Sampling techniques wd Minimum specimen volume required 9 µ Suitable for sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye Wser list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance wd <	es ³ /4 x 2 ¹ /2 x 1 ¹ /4 in/4.7 oz jlucose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	yes 4 ³ / ₈ x 2 ³ / ₈ x ¹³ / ₃₂ in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ / ₄ x ¹ / ₂ in/menu selection true values whole blood/drop
Dimensions (H x W x D)/Weight 4 * Analytical method/technology/Enzyme system used gli List price \$5 Price per disposable reagent system unit \$0 No. of dispos. reag. system units per basic package \$0 No. of dispos. reag. system units per basic package \$0 No. of dispos. reag. system units per basic package \$0 No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed tru Specimen types/Sampling techniques wd Minimum specimen volume required 9 µ Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye Wser list or user group no Toll-free No. for customer questions 24 Training and certif, program/No. training days provided ye </td <td> 3/4 x 2 ¹/₂ x 1 ¹/₄ in/4.7 oz lucose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹/₂ in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) yhole blood/drop µL </td> <td>4 ³/₈ x 2 ³/₈ x ¹/₃₂ in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹/₄ x ¹/₂ in/menu selection true values whole blood/drop</td>	 3/4 x 2 ¹/₂ x 1 ¹/₄ in/4.7 oz lucose oxidase 50 0.40 0 8 months/ambient temp. /4 x ¹/₂ in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) yhole blood/drop µL 	4 ³ / ₈ x 2 ³ / ₈ x ¹ / ₃₂ in/5.3 oz glucose oxidase \$50 \$0.35 50, 100 1 18 months/ambient temp. ¹ / ₄ x ¹ / ₂ in/menu selection true values whole blood/drop
Analytical method/technology/Enzyme system used git List price \$5 Price per disposable reagent system unit \$0 No. of dispos. reag. system units per basic package \$0 No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed tru Specimen types/Sampling techniques will Minimum specimen volume required 9 I Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif, program/No. training days provided ye Avg. time for lab to complete maintenance wo Special cleansing procedures no	1/4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) vhole blood/drop	\$50 \$0.35 50, 100 1 18 months/ambient temp.
Price per disposable reagent system unit \$0 Price per disposable reagent system unit \$0 No. of dispos. reag. system units per basic package 50 No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed trues with Specimen types/Sampling techniques with Minimum specimen volume required 9 µ Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance with Special cleansing procedures no	0.40 0 8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	\$0.35 50, 100 1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
No. of dispos. reag. system units per basic package 50 No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed true Specimen types/Sampling techniques withinimum specimen volume required Minimum specimen volume required 9 [Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye Wser list or user group no Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance we Special cleansing procedures no	0 8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	50, 100 1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
No. of times analyses performed using 1 reag. system unit 1 Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability How results are displayed How results are displayed Specimen types/Sampling techniques Minimum specimen volume required Suitable for samples from well/Sick neonates Time from sample intro. to result availability Batteries used/No. used/Avg. life of 1 set Ayg. expected life of device/Mean time between failures Device warranty/Service options Loaners provided User list or user group Toll-free No. for customer questions Z4 Training and certif. program/No. training days provided Avg. time for lab to complete maintenance Special cleansing procedures	8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	1 18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
Dispos. units shelf life/Reag. unit storage requirements 18 Digital readout size/Keypad input capability 1/4 How results are displayed tru Specimen types/Sampling techniques will Minimum specimen volume required 9 (Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J (Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 (Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance wide Special cleansing procedures no Internal QC recommended or required as	8 months/ambient temp. /4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) whole blood/drop	18 months/ambient temp. ¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
Digital readout size/Keypad input capability 1/4 How results are displayed tru Specimen types/Sampling techniques will Minimum specimen volume required 9 I Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J (Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as	/4 x ¹ /2 in/none rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) vhole blood/drop µL	¹ /4 x ¹ /2 in/menu selection true values whole blood/drop
Bightan readult size/Reppad input capability 74 How results are displayed tru Specimen types/Sampling techniques will Minimum specimen volume required 9 i Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 i Loaners provided ye User list or user group no Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance wide Special cleansing procedures no	rue & calculated values; reports true results in whole blood values, erum/plasma value calculated (whole blood x 1.12) vhole blood/drop μL	vhole blood/drop
Specimen types/Sampling techniques se Specimen types/Sampling techniques wil Minimum specimen volume required 9 j Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J (Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as	erum/plasma value calculated (whole blood x 1.12) vhole blood/drop μL	whole blood/drop
Specimen types/Sampling techniques widhight with widhight with widhight widhight with widhight widhis widhight widhight widhight widhight widhight widhight	vhole blood/drop μL	whole blood/drop
Minimum specimen volume required 9 j Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J (Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as	μL	
Minimum specimen volume required 9 Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as	μL	
Suitable for samples from well/Sick neonates no Time from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J of Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 n Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as		10 µL
The from sample intro. to result availability 50 Batteries used/No. used/Avg. life of 1 set J (Avg. expected life of device/Mean time between failures 20 Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal OC recommended or required as	0/n0	no/no
Device varianty/Service options 31 Device warranty/Service options 31 Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Special cleansing procedures no Internal QC recommended or required ast	U SEC cell/1/700 cycles	33 SEC cell/1/1 000 cycles
Device warranty/Service options 3 y Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance wo Special cleansing procedures no	0.000 tests/not available	20.000 tests/not available
Loaners provided ye User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance we Special cleansing procedures no	yr/none	3-yr warranty/none
User list or user group no Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance we Special cleansing procedures no Internal OC recommended or required as	es	yes
Toll-free No. for customer questions 24 Training and certif. program/No. training days provided ye Avg. time for lab to complete maintenance we Special cleansing procedures no Internal OC recommended or required as	0	no
Training and certif, program/No. training days provided ye Avg. time for lab to complete maintenance we Special cleansing procedures no	4 h, 7 days 800-818-8877	24 h, 800-818-8877
Avg. time for rab to complete maintenance with a special cleansing procedures no	es/as needed	yes/as needed
Internal OC recommended or required as	veekiy: 10 min 10	no
	s specified by accreditation	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL no	ot available	not available
• 100–200 mg/dL no	ot available	not available
• >400 mg/dL no	ot available	not available
• Program name, year/challenge No./Level n/- of mean glucose challenge sample	/a	n/a
Accuracy/compared to what reference method or device y=	=0.99 <i>x</i> + 3, r=0.983, n=113/YSI 2300	y=0.98 <i>x</i> + 8, r=0.976, n=109/YSI 2300
Precision/compared to what reference method or device wi	vithin-run: 3.9%, between-run: 4.0%/YSI 2300	within-run: 4.7%, between-run: 3.7%/YSI 2300
Linear range 30	0–600 mg/dL	30–550 mg/dL
Suggested dynamic, measurement range 30	0–600 mg/dL	30–550 mg/dL
Contraindications no	0	no
Known interferences/High-altitude interference do	lopamine 10 mg/dL, ascorbate 4 mg/dL/no	L-dopa and dopamine (10 mg/dL)/no
Restrictions based on hematocrit ye	es, 28%–65%	yes, 20%–60%
Electronic, optical function checks int sta	nternal sumcheck functions for electronics, internal optics tandardization, standard strip	sumcheck functions for electronics and software, no op
Sample quantity checks on	nly 1 drop (9 µL) sample required	only 1 drop (10 μ L) sample required
When auto lock or shutdown occurs no	o auto lock or shutdown	no auto lock or shutdown
User defines QC lockout intervals/Lockout can no	io/yes	no/yes
be circumvented Device supports bar-code scanning of no	o bar-code scanner	no bar-code scanner

Meters connect to How meters are connected to external system	n/a n/a	data management system, PC direct serial
to upload results/No. of installations Info. contained in transmission to external system	n/a	meter results, date, time
Hardware/software for data mgmt. system	n/a	yes
No. of different mgmt. reports system can produce	n/a	4
Contents downloaded from DMS to meter	n/a	n/a
System connected (live installations) to which LISs/HISs:		
 using screen animation/screen scraping 	n/a	n/a
 using standard HL7 interface 	n/a	n/a
 using proprietary protocol interface 	n/a	n/a
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	s n/a	n/a
Distinguishing features (provided by vendor)	blood can be applied to test strips inside or outside of meter	• touchscreen display

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Bedside glucose testing systems

ril 2004		CAP TODAY / 51
Bec	lside glucose testing sy	stems
art 4 of 7	Hypoguard USA	Hypoguard USA
	7301 Ohms Lane	7301 Ohms Lane
	Edina, MN 55439 800-818-8877	Edina, MN 55439 800-818-8877
	www.hypoguard.com	www.hypoguard.com
e accompanying article on page 44		
me of instrument/First year sold	Assure II/2001	Assure 3/2003
ofessional or home use	professional & home use	professional & home use
its sold in U.S./Outside U.S.	10,000/—	_/_
rt of series of similar or related models	yes	yes
mensions (H x W x D)/Weight	$4 \times 2^{1/4} \times {}^{3/4}$ in/ 2.2 oz with battery	4 x 2 ¹ /4 x ³ /4 in/ 2.2 oz with battery
alytical method/technology/Enzyme system used	glucose oxidase	glucose oxidase free with competitive trade out
ce per disposable reagent system unit	\$0.47	\$0.47
of dispos. reag. system units per basic package	50, 100	50, 100
). of times analyses performed using 1 reag. system unit	1 18 months/room temp	1 18 months/room temp
spos, units shen merkeag, unit storage requirements	ro monuis/room temp.	ro monuis/room temp.
nital readout size/Kevnad innut canability	5 mm (w) x 10 mm (b)/none	5 mm (w) x 10 mm (h)/none
w results are displayed	true values	true values
ecimen types/Sampling techniques	whole blood/capillary transfer	whole blood/capillary transfer
nimum specimen volume required	3 µL	3 µL
itable for samples from well/Sick neonates	no/no	no/no
ne from sample intro. to result availability	30 sec	10 sec
tteries usea/No. usea/Avg. lite of 1 set a. expected life of device/Mean time between failures	3 V IIIIIIIII/1/1,000 Cycles	3 V IIIIIIII/1/1,000 TESTS 20 000 tests/
y connected the of device/mean time between failures vice warranty/Service options	3-yr warranty/—	3-yr warranty/—
aners provided	yes	yes
ser list or user aroun	no	10
III-free No, for customer questions	24 h. 800-818-8877	24 h. 7 davs. 800-818-8877
aining and certif. program/No. training days provided	yes/as needed	yes/as needed
g. time for lab to complete maintenance	weekly: 5 min	weekly: 3 min
ecial cleansing procedures	no	no
ternal QC recommended or required	as specified by accreditation	as specified by accreditation
etween instrument CV (based on PT) at these levels:	n/a	n/a
-00 mg/ac 100-200 mg/dL	n/a	n/a
>400 mg/dL	n/a	n/a
Program name, year/Challenge No./Level	n/a	<i>— — </i> —
of mean glucose challenge sample		
curacy/compared to what reference method or device	slope=0.93, r=0.976/YSI glucose analyzer within-run: 3.4%: between run: 3.1%	slope=0.93, r=0.976/YSI glucose analyzer within-run: 3.4%; between run: 3.1%/
near range	30–550 mg/dL	30–550 mg/dL
ggested dynamic, measurement range ntraindications	งบ–๖วบ mg/aL ทด	3U-35U mg/aL
own interferences/High-altitude interference	L-dopa and dopamine/ves. tested up to 7.000 ft	L-dopa and dopamine/ves. 7.000 ft
strictions based on hematocrit	ves. 30%–55%	ves. 30%–55%
ectronic, optical function cnecks	sumcneck functions for electronics and software, no optics	sumcneck functions for electronics and software, no optics
mple quantity checks	only one drop (3µL) sample required	one drop (3µL)
hen auto lock or shutdown occurs	1 min	1 min time out
er defines QC lockout intervals/Lockout can	no/—	no/—
be circumvented vice supports bar-code scanning of	no bar-code scanner	no bar-code scanner
	, , , , , , , , , , , , , , , , , , ,	
etnod of analyst ID/ID required	—/—	%
ternal memory size/Max. No. of patient results stored	10-test memory/10	10-test memory/10
eters 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	_	_
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	s —	_
Distinguishing features (provided by vendor)		 wick in test strip, ergonomically formed, large handle fast test time—10 sec extremely easy to use, low maintenance

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Bedside glucose testing systems

ME	Bedside glucose testing	systems
Part 5 of 7	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945	LifeScan Inc., a Johnson & Johnson company Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226
See accompanying article on page 44	www.tonou.com	www.meddan.com
Name of instrument/First year sold	IRMA Trupoint	SureStepPro/1997
Professional or home use Units sold in U.S./Outside U.S. Part of series of similar or related models Dimensions (H x W x D)/Weight Analytical method/technology/Enzyme system used List price Price per disposable reagent system unit	professional use — no 5 x 9.5 x 13.5 in/6 lb (IRMA Trupoint) glucose only: reflectance photometry, glucose oxidase \$350 consult SureStep Pro representative	professional use >20,000/n/a yes 7.4 x 3.5 x 2.6 in/1.2 lb reflectance photometry/glucose oxidase \$2,000 per bedside unit by contract, volume
No. of dispos. reag. system units per basic package	50 strips	2 25-strip vials (50 strips per box)
No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements	1 strip: 24 months/room temp.	1 18 months unopened/<30°C (86°F); away from heat, dire
Digital readout size/Keypad input capability How results are displayed Specimen types/Sampling techniques Minimum specimen volume required Suitable for samples from well/Sick neonates Time from sample intro. to result availability Batteries used/No. used/Avg. life of 1 set Avg. expected life of device/Mean time between failures Device warranty/Service options Loaners provided	4.5 x 2.5 in/menu selection, numeric, alphabetic true values whole blood/drop, capillary transfer 1 drop yes/yes <45 sec rechargeable NIMH battery/1/3 yr >5 yr/<3% warranty return rate 24-h replacement upon failure 24-h replacement upon failure	18 pt. font/menu selection, numeric, alphabetic, bar-code true values whole blood/drop, capillary transfer, touchable test strip 5 μL, maximum 30 μL yes/yes 15 sec minimum C 1.5 V/2/approximately 1,000 tests >5 yr/<3% warranty return rate 1 yr warranty/extended service agreements available 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	yes 24 h, 7 days yes/depends on No. of operators clean glucose module as needed, 2 min no	yes (contact SureStepPro product manager) 24 h, 7 days, multiple languages yes/as negotiated none no
Internal QC recommended or required Between instrument CV (based on PT) at these levels: • <50 mg/dL • 100–200 mg/dL • >400 mg/dL • Program name, year/Challenge No./Level of mean glucose challenge sample	based on hospital-specific policy 4.39% 3.44% 4.97% CAP	as defined by hospital policy 4.39% 3.44% 4.97% data from 2000 AACC poster
Accuracy/compared to what reference method or device	r >0.98/YSI 3 44-4 97 GV across runs/	>0.98/YSI 3 44-4 97 CV across runs/YSI
Linear range Suggested dynamic, measurement range Contraindications Known interferences/High-altitude interference	0–500 mg/dL 0–500 mg/dL no sodium fluoride/no	0-500 mg/dL 0-500 mg/dL excessive water loss or dehydration sodium fluoride/no
Restrictions based on hematocrit	yes, <25% high results, >60% low results	adult: 25%-60% RBC; neonates: 25%-65% RBC
Electronic, optical function checks	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test	automatic electronic and optical checks with each test
Sample quantity checks	uses LED to determine sufficient quantity	test strip color confirmation dot when adequate sample a unit error messages
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, QC failure, data upload lockout option
User defines QC lockout intervals/Lockout can be circumvented	yes/no	yes/no
Device supports bar-code scanning of	bar-code scanner available	operator & patient identifiers, reagent (strip) lot Nos., bed Nos., control solution lot Nos.
Method of analyst ID/ID required	touchscreen/optional or required, QA user setup	bedside unit custom programmed for manual or bar-cod required or optional
Internal memory size/Max. No. of patient results stored	4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results	2,500 patient & QC tests plus 50 test strip lots and QC lo
Meters connect to How meters are connected to external system to upload results/No. of installations	data management system, which connects to LIS/HIS; also directly to LIS/HIS direct serial/—, modem dial-in/—, Ethernet/— device unique identifiers, operator & patient IDs, results, OC identifiers	DataLink Data Management System via network or mode solutions: DataLink Data can be interfaced to LIS/HIS (sc DataLink Connect connectivity solutions; modem, networ Connect >1,100 hospital sites, DataLink interface >250 douice unique identificate concreter & patient log regular

	result flags, reference range/QC limits, software revision, sample types	
Hardware/software for data mgmt. system	nondedicated IBM compatible PC, IDMS (Integrated Data Management System)	hardware independent/DataLink Data Management System installation CD for Windows XP Pro & 2000 Pro; QML; RALS-Plus
No. of different mgmt. reports system can produce	6	17 reports plus export function for customized reports
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs	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 	major vendors	DHCP-VA System, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Millennium & Pathnet (legacy), SCC, SoftLab, DHT, Dynacor Premier
• using standard HL7 interface	major vendors	Cerner Millennium & Pathnet (legacy), Misys Flexilab, Meditech Magic & client/server
 using proprietary protocol interface 	none	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, product used depends on host system emulation requirements	yes (Telcor, Quick-Linc POC interface engine)
Distinguishing features (provided by vendor)	 integrated workstation with IRMA (blood gas, electrolytes, BUN, cartridge glucose test, Hct) 1 user interface, 1 in-service program, 1 data management system 	 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

 $\label{eq:constraint} \ensuremath{\mathsf{Tabulation}}\xspace{0.5ex} \ensuremath{\mathsf{obs}}\xspace{0.5ex} \ensurema$

Bedside glucose testing systems

1		
	Part 6 of 7	

Intr	Bedside glucose testing	systems
Part 6 of 7	LifeScan Inc., a Johnson & Johnson company	Medtronic MiniMed Inc.
	1000 Gibraltar Dr., Milpitas, CA 95035-6312	Northridge, CA 91325
See accompanying article on page 44	800-524-7226 www.lifescan.com	800-646-4633 www.minimed.com
Name of instrument/First year sold	SureStepFlexx/2000	Medtronic MiniMed CGMS Gold/2003
Professional or home use	professional use	professional use
Units sold in U.S./Outside U.S. Part of series of similar or related models	>10,000/>3,000 ves	>1,000/>1,000 no
Dimensions (H x W x D)/Weight Analytical method/technology/Enzyme system used	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 ducose ovidase
List price	\$1,200 with bar-code scanner, \$850 without bar-code scanner by contract volume	\$1,995/monitor, \$35/sensor (disposable) \$25 ner censor
No. of dispos read, system units per basic package	2 25-strin vials (50 strins ner hox)	10/hox
No. of times analyses performed using 1 reag. system unit Disoos. units shelf life/Reag. unit storage requirements	1 18 months unopened/<30°C (86°F): away from heat, direct sunlight	1 sensor lasts ~36–72 h 6 months/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 retrospectiv
		glucose meter of -5.4 mg/dL, daily median correlation coeffic
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable test strip	calibration using blood glucose meters daily continuous monitoring and sampling of interstitial fluid gluco
Minimum specimen volume required	5 μL, maximum 30 μL ves/ves	n/a
Time from sample intro. to result availability	15 sec minimum	retrospective analysis after disconnection
Batteries used/No. used/Avg. life of 1 set Avg. expected life of device/Mean time between failures	AA/3/1,000 test minimum 5-vr minimum/<3% warranty return rate	AAA alkaline batteries/2/~2 months ~3 vr/—
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 Toll-free No. for customer questions	yes (contact SureStepFlexx product manager) 24 h. 7 days, multiple languages	no ves. 800-646-4633
Training and certif. program/No. training days provided	yes/as negotiated	yes (training only)/~1 day
Special cleansing procedures	none	none no
Internal QC recommended or required	as defined by hospital policy	none
• <50 mg/dL	2.5%	_
• 100–200 mg/dL • >400 mg/dL	2.9% 2.4%	5% (40–400 mg/dL) in vitro —
 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 n
Precision/compared to what reference method or device Linear range	3.44–4.97/YSI 0–500 ma/dL	—/glucose meters, HemoCue, YSI (any and all) —
Suggested dynamic, measurement range	0-500 mg/dL	40–400 mg/dL
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 identifiers, reagent (strip) lot Nos., control solution lot Nos., meter serial Nos.	no bar-code scanner
Method of analyst ID/ID required Internal memory size/Max. No. of patient results stored	unique alphanumeric ID/optional (defined by location) 256k/1,500 patient +QC tests, 50 test strip lots and 50 QC lots	at time of monitor download/optional up to 14 days continuous data/288 readings per day
Meters connect to	DataLink Data Management System via network or modem connectivity	Com-Station for download to computer & software
How meters are connected to external system	DataLink Connect connectivity solutions; modem, network/DataLink	direct serial/—
to upload results/No. of installations Info. contained in transmission to external system	Connect >1,100 hospital sites, DataLink Interface >250 device unique identifiers, operator & patient IDs, results, QC identifiers,	patient IDs, results
Hardware/software for data mumt_system	hardware independent/DataLink Data Management System installation CD	Com-Station (docking unit that transmits data from CGMS to
	for Windows XP Pro & 2000 Pro; QML; RALS-Plus	and software
NO. OT DITTETENT MGMT. REPORTS SYSTEM CAN PRODUCE Contents downloaded from DMS to meter	12 standard, unlimited customized reports strip lot Nos., valid control values, valid operator IDs, critical value ranges, commont codes	/ standard unlimited customized reports —
System connected (live installations) to which LISs/HISs:	Comment Cours	does not interface LIS or HIS, a report from software-nontran
 using screen animation/screen scraping 	Millennium & Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier	10
• using standard HL7 interface	Cerner Millennium & Pathnet (legacy); Sunquest Flexilab; Meditech Magic & client/server	no
• using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	none s yes (Telcor, exclusive contract; Reflections WRQ software)	no no
Distinguishing features (provided by vendor)	• configurable bar-code scanning options—allows truncation of leading	
	and trailing characters • bar-code scan required feature	 continuous glucose values collected (every 5 min) up to 72 h of data
	unique MeterUnlock bedrugen indexed at Data Link (frame)	• ability to enter in events (insulin, food, excercise, etc.) to consist alugar
	naroware independent DataLink software open architecture—compatible with QML and RALS-Plus	against glucose values upon review of data
	hardware independent Datal ink software	

 $\label{eq:constraint} \ensuremath{\mathsf{Tabulation}}\xspace{0.5ex} \ensuremath{\mathsf{obs}}\xspace{0.5ex} \ensurema$

Bedside glucose testing systems

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Bedside glucose testing systems		
Part 7 of 7	Roche Diagnostics	Roche Diagnostics
	9115 Hague Rd., Indianapolis, IN 46256	9115 Hague Rd., Indianapolis, IN 46256
	800-440-3638 www.roche-diagnostics.us	800-440-3638 www.roche-diagnostics.us
e accompanying article on page 44	Accultata GTS 1004: Accultata GTS Plus 2000	ACCIL-CHEK Inform System/2001
	nreferesional use	
nits sold in U.S./Outside U.S.	40,000*/5,000	40,000/5,000
art of series of similar or related models	yes 11 x 9 75 x 4 in/5 lbs	yes 1.4 x 2.9 x 7.6 in/12 oz
nalytical method/technology/Enzyme system used	biosensor–glucose dehydrogenase	biosensor—glucose dehydrogenase
st price ice per disposable reagent system unit	\$550 contingent on contract price	\$1,200 contingent on contract price
p. of dispos, read, system units per basic package	50 strips per vial	50 test strips
). of times analyses performed using 1 reag. system unit	1 1 20 Od mantha adalla militarining an sigl(2005 de astériors	
ispos. units sneit lite/keag. unit storage requirements	18–24 months, stable until expiration on viai/<90°F, do not freeze	18-24 months, stable until expiration date on vial/room temp., less than 90°F, do not freeze
jital readout size/Keypad input capability	4 lines by 20 characters LCD/menu selection, numeric	font size varies/menu selection, numeric, alphabetic
ow results are alsplayed pecimen types/Sampling techniques	u ue values whole blood/arterial, venous, capillary, neonate (including cord blood)	uue values whole blood/arterial, venous, capillary, neonate (including cord blood)
inimum specimen volume required	4 µL	4 μL
litable for samples from well/Sick neonates me from sample intro, to result availability	yes/yes 26 sec	yes/yes 26 sec
atteries used/No. used/Avg. life of 1 set	3 V lithium/2/~700 tests	3.7 V rechargeable lithium ion/1/testing in progress
rg. expected life of device/Mean time between failures evice warranty/Service options	5 yr/10,000 tests warranty through life of ACCII-CHEK Comfort Curve test strip at no additional	5 yr/542,000 tests warranty through life of ACCU-CHEK Comfort Curve test strip at no
	cost/24 h, 365 days customer care with overnight replacement if needed	additional cost/24 h, 365 days customer care with overnight replacement
paners provided	replaced under warranty	replaced under warranty
ser list or user group hll-free No. for customer succtions	yes (contact local account manager)	yes (contact local account manager)
aining and certif. program/No. training days provided	yes (24 ii, 305 days per yr) yes/site-specific according to No. of employees	yes (24 ii, 305 days per yr) yes/site-specific according to No. of employees
/g. time for lab to complete maintenance secial cleansing procedures	none no	none no
ternal QC recommended or required	daily, 2 levels	daily, 2 levels of glucose control solutions
etween instrument CV (based on PT) at these levels:	52.8 mn/dl SD-/ 1 /6 098 Jahe)	53.8 mg/dl SD-11 /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)
of mean glucose challenge sample	uar, 2001/WDQ-0/See 200Ve	UAF, 2001/WDU-0/588 20088
curacy/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
ecision/compared to what reference method or device	controls: low SD=2.83 mg/aL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/alucose hexokinase	controls: low SD=2.83 mg/aL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/alucose hexokinase
iear range	10–600 mg/dL	10–600 mg/dL
iggested dynamic, measurement range intraindications	10–600 mg/dL per labeling	10–600 mg/dL ves. per labeling
	por reboining	Joo, por fusioning
10wn interferences/High-altitude interference estrictions based on bematocrit	per labeling/none up to 10,150 feet ves_alucase <200 ma/dl_20%_65%; alucase >200_20%_55%	per labeling/none up to 10,150 ft ves_alucase <200 ma/dl_20%_65%; alucase >200 ma/dl_20%_55%
ectronic, optical function checks	meter cradle communication with Advantage meter, GTS with code key,	meter with code key, battery voltage test, internal database memory
	battery voltage test, internal database memory check, internal configura-	check, internal configuration check
ample quantity checks	built-in electronic strip check, visual confirmation of sample volume	built-in electronic strip check, visible verification of sample volume
hen auto lock or shutdown occurs	user ID failure (valid op.), QC failure, patient ID length, incorrect code key,	user ID failure (valid op.), QC failure, download interval lockout, patient ID
	nicon cor Auranauge Illeter	time, and data editing
ser 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)
evice supports bar-code scanning of	operator & patient identifiers, comment codes	operator & patient identifiers, reagent lot Nos.
ethod of analyst ID/ID required	numeric input or bar-code wand scan/yes	alphanumeric or bar-code scan/yes 4.000 results/4.000 tests
aters connect to	information management evetors which in turn connects to LIC/UIC	information management eveters which in two connects to LIC/UIC
nw meters are connected to external system	direct serial/— modem dial.in/— bosnital network/	direct serial/— modem dial.in/— beenital network/_
to upload results/No. of installations ifo, contained in transmission to external system	device unique identifiers operator & nationt IDs results OC identifiers	device unique identifiers operator & nationt IDs results strin lot Nos
	strip lot Nos., download loc., comment codes, proficiency & linearity samples	QC identifiers, proficiency & linearity samples, comments, meter location, download location
ardware/software for data mgmt. system	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†, DataCare POC,	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook*, DataCare POC
a of different mant reports sustan aan produce	ACCU-CHEK HDM	unlimited (user defined)
ontents downloaded from DMS to meter	strip & QC lot Nos., valid operator IDs, valid control values, linearity values	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter
stem connected (live installations) to which LISs/HISs:		oomiyuraann, micariy in 1005. & Values, Cullinelits
using screen animation/screen scraping	all major LIS vendors including Cerner, Misys, McKesson, Meditech, Softlab, Siemens, SIA Molis, Onus, others**	all major LIS vendors including Cerner, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, SIA Molis, Onus, others**
using standard HL7 interface	Cerner, Misys, Meditech, McKesson	oreniens, monossun, sin muns, upus, uners
using proprietary protocol interface se 3rd-party interfacing tool/engine for LIS/HIS interfaces	— MAS	— MAS
stinguishing features (provided by vendor)	• proven bidirectional network connection from AccuData GTS/GTS Plus to	uses the ACCU-CHEK Comfort Curve test strip; universal sampling due to
		oxygen independent chemistry with reliable results at varying hematocrit
	 AD L GATA INTERTACE WITH KALS-PIUS/DATAGARE PUC uses the ACCU-CHEK Comfort Curve test strip: universal sampling due to 	 offers alphanumeric touchscreen, onboard bar-code ID, plus connectivi-
	oxygen independent chemistry with reliable results at varying hematocrit	ty, including ADT feed provides two patient identifiers for confirmation
	evers * combined AccuData GTS and AccuData GTS Plus sales	 extends the quality of blood glucose programs to six other point-of-care tests by allowing the entry and transfer of manual test information
	t Dooho ovaluaiva	* Roche exclusive

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