Bedside glucose testing systemsCAP TODAY's annual lineup of bedside glucose

CAP TODAY's annual lineup of bedside glucose testing systems—14 systems in all—begins on page 24. We list the systems' distinguishing features, mean time between failures, memory size, and much more. The data we display are the seven vendors' answers to CAP TODAY's questions. Please verify that any system you're considering has the stated features and capabilities.

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Bedside glucose testing systems

Abbott Diagnostics Medisense Products
Steven Pemberton steven.pemberton@abbott.com
4A Crosby Dr., Bedford, MA 01730
781-276-4797

HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630 949-859-2630/800-323-1674

itures and capabilities.	781-276-4797 www.abbott.com	949-859-2630/800-323-1674 www.hemocue.com
Name of instrument/First year sold	Precision PCx/1998	Blood Glucose Analyzer/1992
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	professional use 40,707/15,000 yes, i-Stat 1 7.7 x 2.95 x 5.1 in/10 oz amperometric/glucose oxidase with Precision PCx strips/glucose dehydrogenase with PCx Plus test strips \$995	professional use >20,000 worldwide yes 6 ¹ /4 x 8 ¹ /4 x 3 ¹ /2 in/2 lb dehydrogenase, absorbance photometry \$800 classic, \$950 for data management model
Price per disposable reagent system unit	\$70.50 per box 100 test strips	\$1.20 per test
No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements	100 per box 1 12–18 months (room temp.)/39°–86°F	25 cuvettes per vial; 4 vials in box 1 9 months/refrig. or 3 d room temp.
Digital readout size/Keypad input capability How results are displayed Specimen types/Sampling techniques	font size 24 pt/menu selection, numeric true values whole blood/drop, can apply blood directly to test strip	1.25 cm/menu selection, numeric true values whole blood, venous, capillary, or arterial/exact amount of blood drawn into cuvette by capillary force
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	3.5 µL with PCx, 2.5 µL with PCx Plus yes/yes 20 sec AA/2/~60 days (based on 30 tests/day)	5 μL yes/yes 40–240 sec AA/5/5 cycles (150 h)
Avg. expected life of device/Mean time between failures Device warranty/Service options Loaners provided	24 months/24 months 1-yr warranty, lifetime replacement with reagent contact/24-h replacement	7 yr/>5 yr 1 yr, \$125 each additional yr/24-h loaner program
	yes	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 none no	no 7 AM-5 PM PST, 800-323-1674 yes/as needed from vendor office weekly: 5 min no
Internal QC recommended or required	as required by facility or institutional policy or when glucose results	quality control cuvette daily
Between instrument CV (based on PT) at these levels:	are questioned or when new lot No. is received	
• <50 mg/dL • 100–200 mg/dL	— 71.9 mg/dL, CV=4.1%; 192.3 mg/dL, CV=5.5%	7.5% (XQ-01) 6.6% (XQ-03)
• >400 mg/dL	400.7 mg/dL, CV=6.9%	4.4% (XQ-04 >350)
 Program name, year/Challenge No./Level of mean glucose challenge sample 	CAP Whole Blood Glucose Survey, 2003/Set B	CAP EXCEL, 1997/—/—
Accuracy/compared to what reference method or device	capillary blood: y=0.91x + 0.91, r=0.98/YSI	0.994/GC-MS
Precision/compared to what reference method or device	blood samples: CV 2.9% to 5.1%	within run CV 2.6% (138 mg/dL)/GC-MS
Linear range Suggested dynamic, measurement range Contraindications	20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx 20–500 mg/dL PCx Plus; 20–600 mg/dL for PCx per labeling	0–400 mg/dL 0–400 mg/dL no
Known interferences/High-altitude interference Restrictions based on hematocrit	per labeling/none up to 7,200 ft yes, glucose <300 mg/dL, 20–70%; glucose ≥300 mg/dL, 20–60%	methemoglobin, glucosamine/no no
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks	control cuvette (an interface filter) verifies photometer calib.
Sample quantity checks	performed during power up of meter a fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected	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, download time if selected	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	operator & patient identifiers, reag. lot Nos., comment codes, control & linearity lot Nos.	operator & patient identifiers, controls, reagent
Method of analyst ID/ID required Internal memory size/Max. No. of patient results stored	manual or bar-code ID entry/operator ID lockout optional 4,000 patient results, 1,000 controls, 1,000 operators/—	manual or bar code/optional 1,000 records/approximately 1,000 results dependent on configuration
Meters connect to How meters are connected to external system to upload results/No. of installations	Precision Web data management system, which in turn connects to LIS/HIS direct serial/50+; modem dial-in/100+; hospital network/800+	HemoCue data management system, which cannot further transmit data direct serial/—
Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., test dates & times, comment codes	device unique identifiers, operator & patient IDs, results, QC identifiers, pass/fail, dates, times, comment codes, analyte unit of measurement type
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server	PC or laptop/HemoCue DM software
No. of different mgmt. reports system can produce Contents downloaded from DMS to meter	redundant Dell server 25 strip lot Nos., valid control values, valid operator IDs, QC lockout & upload lockout parameters	customizable —
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	none
using standard HL7 interface using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Cerner, Misys, PerSe, Meditech, Soft Lab none Sybase/Neon	none Misys in progress
Distinguishing features (provided by vendor)	 positive reagent ID positive calibration ID—no need to visually verify code key against 	indicated for diabetes mellitus not hematocrit dependent

• ability to reapply blood within 30 seconds to same strip

not hematocrit dependentno known interferences

CLIA waived

• perfect for meter verification

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	Part 2 of 7	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
ŀ	Name of instrument/First year sold	Glucose 201 Analyzer/2002	Supreme II Blood Glucose Meter/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	professional use —/— yes 3.35 x 6.3 x 1.69 in/0.77 lb	professional & home use —/— yes 4 ³ / ₄ x 2 ¹ / ₂ x 1 ¹ / ₄ in/4.7 oz
	Analytical method/technology/Enzyme system used List price Price per disposable reagent system unit	dehydrogenase, absorbance photometry \$600 \$1.20 per test	glucose oxidase \$50 \$0.40
	No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements	25 in vial; 4 vials in box 1 9 months from manufacture date/refrigeration	50 1 18 months/ambient temp.
	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	¹ / ₂ in/none calculated values (plasma equivalent values) whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force 5 μL yes/yes 40–240 sec AA/4/150 h 7 yr/>5 yr 2 yr at no extra cost/— yes	¹ / ₄ x ¹ / ₂ in/none true & calculated values; reports true results in whole blood values, serum/plasma value calculated (whole blood x 1.12) whole blood/drop 9 μL no/no 50 sec J cell/1/700 cycles 20,000 tests/not available 3 yr/none 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	— 7 AM-5 PM PST, 800-323-1674 yes/as needed weekly: 5 min no	no 24 h, 7 days 800-818-8877 yes/as needed weekly: 10 min no
	Internal QC recommended or required Between instrument CV (based on PT) at these levels: • <50 mg/dL • 100-200 mg/dL • >400 mg/dL • Program name, year/Challenge No./Level of mean glucose challenge sample	system must be verified on testing days using commercially available controls recommended by HemoCue not available 3.8 ≥272 mg/dL = 2.9 Equalis (Swedish PT program), 2003/2003-03; 2003-07/272 mg/dL; 120 mg/dL	as specified by accreditation not available not available not available n/a
	Accuracy/compared to what reference method or device Precision/compared to what reference method or device Linear range Suggested dynamic, measurement range	$\pm 10\%$ or ± 6 mg/dL; corr = 0.994/wet chemical glucose dehydrogenase, ID-GCMS within run CV 1.9% (108 mg/dL)/— 0-444 mg/dL 0-444 mg/dL	y=0.99 x + 3, r=0.983, n=113/YSI 2300 within-run: 3.9%, between-run: 4.0%/YSI 2300 30–600 mg/dL 30–600 mg/dL
	Contraindications Known interferences/High-altitude interference	no methemoglobin, glucosamine/no	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, standard 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 Device supports bar-code scanning of	no/no no bar-code scanner	no/yes no bar-code scanner
	Method of analyst ID/ID required Internal memory size/Max. No. of patient results stored	n/a n/a/n/a	none/n/a 100 tests/100 tests
ŀ	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 Contents downloaded from DMS to meter	Ξ	n/a n/a
	System connected (live installations) to which LISs/HISs: • using screen animation/screen scraping • using standard HL7 interface	<u> </u>	n/a n/a
	• using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Ξ	n/a n/a
	Distinguishing features (provided by vendor)	CLIA waived indicated for diabetes mellitus not hematocrit dependent lab verification of patient home meter	• blood can be applied to test strips inside <i>or</i> outside of meter

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7 4.12 67 7	7301 Ohms Lane	7301 Ohms Lane
	Edina, MN 55439 800-818-8877	Edina, MN 55439 800-818-8877
	www.hypoguard.com	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. Part of series of similar or related models	8,000/— yes	10,000/— 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 \$50	glucose oxidase
List price Price per disposable reagent system unit	\$0.35	free with competitive trade out \$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
Dispos. units shelf life/Reag. unit storage requirements	18 months/ambient temp.	18 months/room temp.
Digital readout size/Keypad input capability How results are displayed	1/4 x 1/2 in/menu selection true values	5 mm (w) x 10 mm (h)/none 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 Time from sample intro. to result availability	no/no	no/no
Batteries used/No. used/Avg. life of 1 set	35 sec J cell/1/1,000 cycles	30 sec 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 Loaners provided	3-yr warranty/none	3-yr warranty/—
	yes	yes
User list or user group Toll-free No. for customer questions	no 24 h, 800-818-8877	no 24 h, 800-818-8877
Training and certif. program/No. training days provided	24 n, 800-818-8877 yes/as needed	24 n, 800-818-8877 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/dLProgram name, year/Challenge No./Level	not available n/a	n/a n/a
of mean glucose challenge sample	11/4	104
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
when auto lock of Shutuown occurs	no auto lock of Shutdown	1 111111
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	n/a n/a	_
to upload results/No. of installations	-la	
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:	-1-	
 using screen animation/screen scraping using standard HL7 interface 	n/a n/a	
 using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces 	n/a n/a	Ξ
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Distinguishing features (provided by vendor)	touchscreen display	
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	7301 Ohms Lane	8 Olsen Ave.
	Edina, MN 55439	Edison, NJ 08820
	800-818-8877	800-631-5945
	www.hypoguard.com	www.itcmed.com
Name of instrument/First year sold	Assure 3/2003	IRMA Trupoint
,		
Professional or home use	professional & home use	professional use
Units sold in U.S./Outside U.S.	_/_ 	_
Part of series of similar or related models Dimensions (H x W x D)/Weight	yes 4 x 2 ¹ /4 x ³ /4 in/ 2.2 oz with battery	no 5 x 9.5 x 13.5 in/6 lb (IRMA Trupoint)
Analytical method/technology/Enzyme system used	qlucose oxidase	glucose only: reflectance photometry, glucose oxidase
	free with competitive trade out	\$350
Price per disposable reagent system unit	\$0.47	consult SureStep Pro representative
	50, 100	50 strips
No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements	18 months/room temp.	strip: 24 months/room temp.
Dispos. units shell interneag. unit storage requirements	To months/room temp.	Surp. 24 months/100m temp.
	5 mm (w) x 10 mm (h)/none	4.5 x 2.5 in/menu selection, numeric, alphabetic
How results are displayed	true values	true values
	whole blood/capillary transfer	whole blood/drop, capillary transfer
Minimum specimen volume required Suitable for samples from well/Sick neonates	3 µL no/no	1 drop yes/yes
Time from sample intro. to result availability	10 sec	<45 sec
	3 V lithium/1/1,000 tests	rechargeable NIMH battery/1/3 yr
Avg. expected life of device/Mean time between failures	20,000 tests/—	>5 yr/<3% warranty return rate
Device warranty/Service options	3-yr warranty/—	24-h replacement upon failure
Lagrage provided	1100	24 h voulocoment unes failure
Loaners provided	yes	24-h replacement upon failure
User list or user group	no	yes
	24 h, 7 days, 800-818-8877	24 h, 7 days
Training and certif. program/No. training days provided	yes/as needed	yes/depends on No. of operators
Avg. time for lab to complete maintenance	weekly: 10 min	clean glucose module as needed, 2 min
Special cleansing procedures	no	no
Internal OC recommended or required	as specified by accreditation	hased on hospital-specific policy
Internal QC recommended or required Between instrument CV (based on PT) at these levels:	as specifically accreditation	based on hospital-specific policy
• <50 mg/dL	_	4.39%
• 100–200 mg/dL	_	3.44%
• >400 mg/dL	_	4.97%
Program name, year/Challenge No./Level	—/—/—	CAP
of mean glucose challenge sample		
Accuracy/compared to what reference method or device	slope=0.93, r=0.976/YSI glucose analyzer	r >0.98/YSI
	within-run: 3.4%; between run: 3.1%/—	3.44–4.97 CV across runs/—
	30–550 mg/dL	0–500 mg/dL
	30–550 mg/dL	0–500 mg/dL
Contraindications	no no	no
Known interferences/High-altitude interference	L-dopa and dopamine/yes, 7,000 ft	sodium fluoride/no
• • • • • • • • • • • • • • • • • • • •		
Restrictions based on hematocrit	yes, 30%–55%	yes, <25% high results, >60% low results
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test
		part of Surp holder, automatically dolle with every test
Sample quantity checks	one drop (≥3μL)	uses LED to determine sufficient quantity
,	,	• •
When auto lock or shutdown occurs	1 min time out	user ID failure, QC failure, lockout if reag. expired or if control lot & reag.
Heavidefines 00 Indicate the U.S.		not entered
User defines QC lockout intervals/Lockout can be circumvented	no/—	yes/no
Device supports bar-code scanning of	no bar-code scanner	bar-code scanner available
20-100 capporte sur coue comming of	22. Oodo oodiiiioi	5540 common aradabio
Method of analyst ID/ID required	%	touchscreen/optional or required, QA user setup
Internal memory size/Max. No. of patient results stored	10 test memory/10	4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results
Meters connect to	n/a	data management system, which connects to LIS/HIS; also directly to
		LIS/HIS
How meters are connected to external system	n/a	direct serial/—, modem dial-in/—, Ethernet/—
to upload results/No. of installations		
Info. contained in transmission to external system	n/a	device unique identifiers, operator & patient IDs, results, QC identifiers,
		results dates & times, strip/material lots, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample types
		Todat nago, rotoronoo rango qo minto, sortware revision, sampie types
Hardware/software for data mgmt. system	_	nondedicated IBM compatible PC, IDMS (Integrated Data Management
		System)
No. of different mgmt. reports system can produce	_	6
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
• using standard HL7 interface	_	major vendors
J		
using proprietary protocol interface	_	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	_	yes, product used depends on host system emulation requirements
Distinguishing features (provided by vendor)	wick in tast strin arganomically formed large handle	integrated workstation with IRMA (blood gas, electrolytes, BUN,
bisanguising reatures (provided by vendOf)	 wick in test strip, ergonomically formed, large handle fast test time—10 sec 	• Integrated workstation with IRMA (blood gas, electrolytes, Bon, cartridge glucose test, Hct)
	extremely easy to use, low maintenance	• 1 user interface, 1 in-service program, 1 data management system
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Bedside glucose testing systems

Part 5 of 7 LifeScan Inc., a Johnson & Johnson company LifeScan Inc., a Johnson & Johnson company **Healthcare Professional Line Healthcare Professional Line** 1000 Gibraltar Dr., Milpitas, CA 95035-6312 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 800-524-7226 www.lifescan.com www.lifescan.com Name of instrument/First year sold SureStepPro/1997 SureStepFlexx/2000 Professional or home use professional use professional use Units sold in U.S./Outside U.S. >20,000/n/a >10,000/>3,000 Part of series of similar or related models Dimensions (H x W x D)/Weight 7.4 x 3.5 x 2.6 in/1.2 lb 6.34 x 3.55 x 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without) reflectance photometry/glucose oxidase Analytical method/technology/Enzyme system used reflectance photometry/glucose oxidase \$1,200 with bar-code scanner, \$850 without bar-code scanner List price \$2,000 per bedside unit Price per disposable reagent system unit by contract, volume by contract, volume 2 25-strip vials (50 strips per box) 2 25-strip vials (50 strips per box) No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements 18 months unopened/<30°C (86°F); away from heat, direct sunlight 18 months unopened/<30°C (86°F); away from heat, direct sunlight Digital readout size/Keypad input capability 18 pt. font/menu selection, numeric, alphabetic, bar-code scan built-in 18 pt. font (16-pixels high, 8-pixels wide)/menu select., numeric, alphabetic How results are displayed true values true values Specimen types/Sampling techniques whole blood/drop, capillary transfer, touchable test strip whole blood/drop, capillary transfer, touchable test strip Minimum specimen volume required 5 μL, maximum 30 μL 5 μL, maximum 30 μL Suitable for samples from well/Sick neonates yes/yes yes/yes Time from sample intro. to result availability 15 sec minimum 15 sec minimum Batteries used/No. used/Avg. life of 1 set C 1.5 V/2/approximately 1,000 tests AA/3/1,000 test minimum Avg. expected life of device/Mean time between failures >5 yr/<3% warranty return rate 5-yr minimum/<3% warranty return rate life of contract for defects 1-yr warranty/extended service agreements available **Device warranty/Service options** Loaners provided yes (contact SureStepPro product manager) yes (contact SureStepFlexx product manager) User list or user group Toll-free No. for customer questions 24 h, 7 days, multiple languages 24 h, 7 days, multiple languages Training and certif. program/No. training days provided ves/as negotiated yes/as negotiated Avg. time for lab to complete maintenance none none Special cleansing procedures Internal QC recommended or required as defined by hospital policy as defined by hospital policy Between instrument CV (based on PT) at these levels: 4.39% 2.5% • <50 mg/dL • 100-200 mg/dL 3.44% 2.9% • >400 mg/dL 4.97% 2.4% • Program name, year/Challenge No./Level data from 2000 AACC poster data from 2000 & 2001 AACC posters of mean glucose challenge sample Accuracy/compared to what reference method or device >0.98/YSI >0.98/YSI 3.44-4.97 CV across runs/YSI 3.44-4.97/YSI Precision/compared to what reference method or device 0-500 mg/dL 0-500 mg/dL Linear range Suggested dynamic, measurement range 0-500 ma/dL 0-500 ma/dL **Contraindications** excessive water loss or dehydration excessive water loss or dehydration Known interferences/High-altitude interference sodium fluoride/no sodium fluoride/no Restrictions based on hematocrit adult: 25%-60% RBC; neonates: 25%-65% RBC adults: 25%-60% RBC; neonates: 25%-65% RBC **Electronic, optical function checks** automatic electronic and optical checks with each test automatic electronic and optical checks with each test Sample quantity checks test strip color confirmation dot when adequate sample applied, bedside test strip color confirmation dot when adequate sample applied; meter unit error messages error messages When auto lock or shutdown occurs user ID failure, QC failure, data upload lockout option user ID failure, QC failure, failure to transfer data User defines QC lockout intervals/Lockout can yes/no be circumvented Device supports bar-code scanning of operator & patient identifiers, reagent (strip) lot Nos., bedside unit serial operator & patient identifiers, reagent (strip) lot Nos., control solution lot Nos., control solution lot Nos. Nos., meter serial Nos bedside unit custom programmed for manual or bar-code entry/ Method of analyst ID/ID required unique alphanumeric ID/optional (defined by location) required or optional 256k/1,500 patient +QC tests, 50 test strip lots and 50 QC lots Internal memory size/Max. No. of patient results stored 2,500 patient & QC tests plus 50 test strip lots and QC lots Meters connect to data management system, which in turn connects to LIS/HIS (scripted data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interfaces) interface & electronic data interfaces) DataLink Connect, >950 hospital sites; DataLink Interface, >150 sites DataLink Connect, >950 hospital sites; DataLink Interface, >150 sites How meters are connected to external system to upload results/No. of installations device unique identifiers, operator & patient IDs, results, QC identifiers, Info. contained in transmission to external system device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site flags, comments desktop, Windows NT & 2000, Microsoft SQL server, proprietary DataLink Hardware/software for data mgmt. system desktop or laptop, Windows NT & 2000, proprietary DataLink Data Management System; QML; RALS-Plus Data Management System; QML; RALS-Plus No. of different mgmt. reports system can produce 17 reports plus export function for customized reports 12 standard, unlimited customized reports Contents downloaded from DMS to meter strip lot Nos., valid control values, valid operator IDs, all configurations: strip lot Nos., valid control values, valid operator IDs, critical value ranges, expiration, time, lockouts comment codes System connected (live installations) to which LISs/HISs: • using screen animation/screen scraping DHCP-VA System, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner DHCP-VA system, McKesson PathLab 3, Star, ALG; Misys Flexilab, Cerner Pathnet (legacy), SCC, SoftLab, DHT, Dynacor Premier Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier Cerner Pathnet (legacy), Misys Flexilab, Meditech Magic & client/server Cerner Pathnet (legacy); Sunquest Flexilab; Meditech Magic & client/server • using standard HL7 interface • using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces yes (Telcor, exclusive contract; Reflections WRQ software) yes (Telcor, exclusive contract; Reflections WRQ software) • exception reporting and database tracking—customized QC compliance Distinguishing features (provided by vendor) unique test strip technology: off-meter sample application, sample volrules—patented February 2003 ume confirmation • multiple levels of security-nonvalidated operator, noncertified operator, • bedside unit with alphanumeric touchscreen and built-in bar-code scanner • infrared bidirectional interface between bedside unit and workstation warn and lockout, QC lockout with the widest array of DataLink Connectivity solutions: direct, modem, · true off-meter sample application; unique test strip technologynetwork, scripted interface, EDI, POC multi-analyte data management touchable, absorbent test strip systems: QML & RALS-Plus • 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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	Part 6 of 7	Medtronic MiniMed Inc. 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com	Roche Diagnostics Accu-Chek Customer Care 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us
	Name of instrument/First year sold	Medtronic MiniMed CGMS Gold/2003	Accu-Chek HQ/1999
	Part of series of similar or related models Dimensions (H x W x D)/Weight Analytical method/technology/Enzyme system used List price	professional use >1,000/>1,000 no 2.8 x 0.9 x 3.6 in/4 oz glucose oxidase \$1,995/monitor, \$35/sensor (disposable) \$35 per sensor	professional use 7,500/none yes 2.9 x 4.2 x 9.4 in/3.5 lbs biosensor–glucose dehydrogenase \$1,495 contingent on contract price
ŀ	The per disposable reagent system unit	ψου μετ συτίσοι	contingent on contract price
	No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements	10/box 1 sensor lasts ~36–72 h 6 months/refrigeration 2°C–24°C	50 test strips 1 18–24 months, stable until exp. on vial/room temp., <90°F, do not freeze
		—/menu selection 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	7 lines x 30 characters/menu selection, numeric, alphabetic true values
	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	continuous monitoring and sampling of interstitial fluid glucose levels n/a no/yes (with diabetes) retrospective analysis after disconnection AAA alkaline batteries/2/~2 months ~3 yr/— 1-yr warranty for monitor, no warranty on disposable/none	whole blood/arterial, venous, capillary, neonate (including cord blood) 4 µL yes/yes 26 sec 3 V lithium/2/700 tests 5 yr/828,000 tests all-inclusive warranty through life of Accu-Chek HQ system at no additional cost/24 h, 365 days/yr customer care with overnight replacement if needed replaced under warranty
		no yes, 800-646-4633 yes (training only)/~1 day none no	yes (contact local account manager) yes (24 h, 365 days per yr) yes/site-specific according to quantity of personnel 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	none 5% (40–400 mg/dL) in vitro CGMS, 1998–99	daily, 2 level 53.8 mg/dL SD=4.1 (6,088 labs) 191.4 mg/dL CV=4.7% (3,096 labs) 228.5 mg/dL CV=4.6% (6,099 labs) CAP, 2001/WBG-C/see above
	Precision/compared to what reference method or device Linear range Suggested dynamic, measurement range	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements —/glucose meters, HemoCue, YSI (any and all) — 40–400 mg/dL not recommended for use by persons with impaired vision or hearing possibly MRI/no no	y=0.991 x + 8.4, r=0.980/glucose hexokinase—Hitachi controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase 10–600 mg/dL 10–600 mg/dL per labeling per labeling/none up to 10,150 ft yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
	Electronic, optical function checks Sample quantity checks	test plug, 24–29nA	meter cradle communication with the Advantage meter, meter cradle with code key, battery voltage test, internal database memory check, internal configuration check built-in electronic strip check, visual confirmation of sample volume
	When auto lock or shutdown occurs User defines QC lockout intervals/Lockout can be circumvented Device supports bar-code scanning of	no/no no bar-code scanner	user ID failure (valid op.), QC failure, patient ID length, reagent & QC lots, comment codes, incorrect code key, incorrect Advantage meter yes/yes (information management system identifies operators who violate hospital policy) operator & patient identifiers
	Method of analyst ID/ID required Internal memory size/Max. No. of patient results stored	at time of monitor download/optional	alphanumeric/yes 2,000 records/2,000 records
-	Meters connect to	up to 14 days continuous data/288 readings per day Com-Station for download to computer & software	data management system, which in turn connects to LIS/HIS
		direct serial/—	
	How meters are connected to external system to upload results/No. of installations Info. contained in transmission to external system	patient IDs, results	direct serial/—, modem dial-in/—, hospital network/— device unique identifiers, operator & patient IDs, results, strip lot Nos., QC identifiers, proficiency & linearity samples, comments, meter loc., download loc.
-	Hardware/software for data mgmt. system No. of different mgmt. reports system can produce Contents downloaded from DMS to meter	Com-Station (docking unit that transmits data from CGMS to computer) and software 7 standard unlimited customized reports —	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook*, DataCare POC with Telcor Quick-Linc interface, Accu-Chek HDM unlimited (customer defined) strip & QC lot Nos., valid control values, valid operator IDs, meter configuration, message of the day, linearity values, critical ranges comments
	System connected (live installations) to which LISs/HISs: • using screen animation/screen scraping • using standard HL7 interface	does not interface LIS or HIS, a report from software–nontransferable no	all major LIS vendors including Cerner, Misys, DHCP, McKesson, Phamis, Meditech, SoftLab Cerner, Misys, Meditech, McKesson
	using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	no no	none through Telcor as well as interfacing through the MAS continuum
		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	uses the Accu-Chek Comfort Curve Test Strip; oxygen independent chemistry with reliable results at varying hematocrit levels hand-free communication with LIS/HIS alphanumeric touchscreen proven bidirectional network connection from Accu-Chek HQ to LIS/HIS ADT data interface with RALS-Plus/DataCare POC with Telcor Quick-Linc interface *Roche exclusive*
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Dort 7 of 7	Roche Diagnostics	Roche Diagnostics
Part 7 of 7	Accu-Chek Customer Care	Accu-Chek Customer Care
	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
lame of instrument/First year sold	AccuData GTS, 1994; AccuData GTS Plus, 2000	Accu-Chek Inform System/2001
rofessional or home use	professional use	professional use
Inits sold in U.S./Outside U.S. Part of series of similar or related models	40,000*/5,000 ves	28,500/1,500 yes
Dimensions (H x W x D)/Weight	11 x 8.75 x 4 in/5 lbs	1.4 x 3.8 x 7.6 in/12 oz
Analytical method/technology/Enzyme system used	biosensor-glucose dehydrogenase	biosensor—glucose dehydrogenase
.ist price Price per disposable reagent system unit	\$550 contingent on contract price	\$1,200 contingent on contract price
lo. of dispos. reag. system units per basic package	50 strips per vial	50 test strips
lo. of times analyses performed using 1 reag. system unit Dispos. units shelf life/Reag. unit storage requirements		1 18–24 months, stable until expir. date on vial/room temp., less than 90° do not freeze
Digital readout size/Keypad input capability	4 lines x 20 characters LCD/menu selection, numeric	font size varies/menu selection, numeric, alphabetic
low results are displayed	true values	true values
Specimen types/Sampling techniques Minimum specimen volume required	whole blood/arterial, venous, capillary, neonate (including cord blood) 4 μL	whole blood/arterial, venous, capillary, neonate (including cord blood) $4 \mu L$
uitable for samples from well/Sick neonates	yes/yes	yes/yes
ime from sample intro. to result availability	26 sec	26 sec
atteries used/No. used/Avg. life of 1 set vg. expected life of device/Mean time between failures	3 V lithium/2/~700 tests 5 yr/10,000 tests	3.7 V rechargeable lithium ion/1/testing in progress 5 yr/542,000 tests
Device warranty/Service options	all-inclusive warranty through life of AccuData GTS/GTS Plus at no addition-	all-inclusive warranty through life of Accu-Chek Inform System at no a
	al cost/24 h, 365 days customer care w/ overnight replacement if needed	tional cost/customer care is available 24 h, 365 days per yr with overni
oaners provided	replaced under warranty	replacement if needed replaced under warranty
ser list or user group	yes (contact local account manager)	yes (contact local account manager)
Oll-free No. for customer questions	yes (24 h, 365 days per yr)	yes (24 h, 365 days per yr)
Training and certif. program/No. training days provided	yes/site-specific according to No. of employees	yes/site-specific according to No. of employees
lvg. time for lab to complete maintenance special cleansing procedures	none no	none no
nternal QC recommended or required	daily, 2 level	daily, 2 levels of glucose control solutions
etween instrument CV (based on PT) at these levels:	53.8 mg/dl SD=4.1 (6.098 labe)	53 8 ma/dl SD=4 1 (6 088 Jahe)
<50 mg/dL 100–200 mg/dL	53.8 mg/dL SD=4.1 (6,088 labs) 191.4 mg/dL CV=4.7% (3,096 labs)	53.8 mg/dL SD=4.1 (6,088 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	CAP, 2001/WBG-C/see above	CAP, 2001/WBG-C/see above
of mean glucose challenge sample		
accuracy/compared to what reference method or device recision/compared to what reference method or device	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: lo
recision/compared to what reference method of device	SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase	SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase
inear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic, measurement range Contraindications	10-600 mg/dL per labeling	10-600 mg/dL yes, per labeling
Known interferences/High-altitude interference	per labeling/none up to 10,150 feet	per labeling/none up to 10,150 ft
Restrictions based on hematocrit	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%	yes, glucose <200 mg/dL 20%-65%; glucose >200 mg/dL 20%-55%
lectronic, 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- tion check	check, internal configuration check
Sample quantity checks	built-in electronic strip check, visual confirmation of sample volume	built-in electronic strip check, visible verification of sample volume
When auto lock or shutdown occurs	user ID failure (valid op.), QC failure, patient ID length, incorrect code key,	user ID failure (valid op.), QC failure, download interval lockout, patien
	incorrect Advantage meter	length, reagent editing, mandatory comments, incorrect/missing code time & data editing
Jser defines QC lockout intervals/Lockout can	yes/yes (information management system identifies operators who	yes/no (optional QC pass/fail feature)
be circumvented	violate hospital policy)	
Device supports bar-code scanning of	operator & patient identifiers, comment codes	operator & patient identifiers, reagent lot Nos.
Method of analyst ID/ID required nternal memory size/Max. No. of patient results stored	numeric input or bar-code wand scan/yes 1,000 total patient, control, linearity, proficiency tests/1,000	alphanumeric or bar-code scan/yes 4,000 results/4,000 tests
Meters connect to	data management system, which in turn connects to LIS/HIS	data management system, which in turn connects to LIS/HIS
low meters are connected to external system	direct serial/—, modem dial-in/—, hospital network/—	direct serial/—, modem dial-in/—, hospital network/—
to upload results/No. of installations	device unique identification and the control of the	dada mimi idanis
nfo. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., download loc., comment codes, proficiency & linearity samples	device unique identifiers, operator & patient IDs, result, strip lot Nos., QC identifiers, proficiency & linearity samples, comments, meter locati download location
lardware/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
lo of different manuta annuta annuta annuta	with Telcor Quick-Linc interface, Accu-Chek HDM	with Telcor Quick-Linc interface
lo. of different mgmt. reports system can produce contents downloaded from DMS to meter	unlimited (customer defined) strip & QC lot Nos., valid operator IDs, valid control values, linearity values	unlimited (user defined) QC & strip lot Nos., valid control values, valid operator & patient IDs, m
system connected (live installations) to which LISs/HISs:		configuration, linearity lot Nos. & values, comments
vising screen animation/screen scraping	all major LIS vendors including Cerner, Misys, DHCP, McKesson, Phamis,	all major LIS vendors including Cerner, Meditech, Misys, CPSI, Comput
	Meditech, SoftLab	Antrim, SoftLab, Siemens, McKesson, CHC, TDS, Dawning Tech., Clover
• using standard HL7 interface • using proprietary protocol interface	Cerner, Misys, Meditech, McKesson none	Data Innovations —
• • • • • • • • • • • • • • • • • • • •	through Telcor as well as interfacing through the MAS continuum	through Telcor as well as through MAS continuum
istinguishing features (provided by vendor)	• proven bidirectional network connection from AccuData GTS/GTS Plus to	• uses the Accu-Chek Comfort Curve Test Strip; oxygen independent
	LIS/HIS	chemistry with reliable results at varying hematocrit levels
	 ADT data interface with RALS-Plus/DataCare POC with Telcor Quick-Linc interface 	 offers alphanumeric touchscreen, onboard bar-code ID, plus connecincluding ADT feed provides two patient identifiers for confirmation
	• uses the Accu-Chek Comfort Curve Test Strip; oxygen independent	 extends the quality of blood glucose programs to six other point-of-
	chemistry with reliable results at varying hematocrit levels	tests by allowing the entry and transfer of manual test information
	* combined AccuData GTS and AccuData GTS Plus sales	* Roche exclusive
	† Roche exclusive	