26 / CAP TODAY

March 2001

Bedside glucose testing systems

POC glucose instruments

Raymond Aller, MD

See pages 26-34 for CAP TODAY's annual lineup of bedside glucose testing systems. Nine vendors market 14 systems for professional (and, in a few cases, home) use.

The data displayed—on everything from list price and loaners to linear range and lockout—were supplied by the vendors in answer to CAP TODAY questions. We urge you to confirm that the device your hospital may be considering has the stated features and capabilities.

New to the lineup this year is MiniMed's system, which was launched one year ago. With this device, a patient's glucose values are recorded continuously, typically over two to three days. Also in the lineup of instruments for the first time is Roche Diagnostics' Accu-Chek Inform, which the Food and Drug Administration has not yet cleared.

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Part 1 of 7	Abbott Diagnostics Medisense Products Jim Gibbons (jim.gibbons@abbott.com) 4A Crosby Dr., Bedford, MA 01730 781-276-7774 abbottlaboratories.com	Agilent Technologies 3000 Minuteman Rd. Andover, MA 01810 978-659-7396 agilent.com/healthcare/pocd (manufactured by Diametrics Medical Inc.)
Name of instrument/first year sold	Precision PCx/1998	IRMA SL with SureStep Pro Blood Glucose Module/1998
Professional or home use Units sold in U.S./outside U.S. Part of series of similar/related models Dimensions (H x W x D)/weight Analytical method/technology/enzyme system used List price Price per disposable reagent system unit	Professional & home use 15,000+ 7.7 x 3 x 2 in./10 oz. (including batteries) Glucose oxidase, 3 electrode biosensor technology \$995 \$70.50 per box 100 test strips	Professional use 15,000+ No 5 x 9.5 x 13.5 in. (IRMA with SureStep Pro)/6 lbs. (IRMA SL with SureStep Pro Blood Glucose Module) Glucose only: reflectance photometry, glucose oxidase \$1,116 Consult RNA Medical
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No. of dispos. reagent 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 18 mo. (room temp.)/no (room temp.)	50 strips 1 Strip: 24 mo./room temp.
Digital readout size/keypad input capability How results are displayed Specimen types/sampling techniques Suitable for samples from well/sick neonates Time from sample intro. to result availability Batteries used/number used/avg. life of 1 set Avg. expected life of device/mean time between failures	Font size 24 pt./menu selection, numeric True values Whole blood/drop, wipe, capillary transfer Yes/yes 20 sec. AA or rechargeable batt. pk./2 AA, 1 pk/~30 days (based on 30 tests/day)	4.5 x 2.5 in./menu selection, numeric, alphabetic True values Whole blood/drop, capillary transfer Yes/yes <45 sec. NiMH/1/3.2 h per battery >5 yrs./<3% warranty return rate
Device warranty/service options Loaners provided	24-h replacement upon failure 24-h replacement upon failure	24-h replacement upon failure 24-h replacement upon failure
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 d Yes/depends on No. of operators None No	Yes 24 h, 7 d Yes/depends on No. of operators Clean glucose module as needed, 15 min. No
Internal QC recommended or required Between instrument CV (based on PT) at these levels:	None	Hospital-specific procedures
• <50 mg/dL • 100–200 mg/dL	12.2 8.3	4.39% 3.44%
>400 mg/dL Program name, year/challenge No./level of mean glucose challenge sample		4.97% CAP
Accuracy/compared to what reference method or device	Capillary sample vs. plasma—slope 0.922, 0.984, intercept 11.1 mg/dL/YSI	r >0.98/YSI
Precision/compared to what reference method or device	CV 2.1–5.6% across a range of samples (40–478 mg/dL)/within run precision	3.44–4.97 CV across runs/YSI
Linear range Suggested dynamic/measurement range Contraindications	20–600 mg/dL 20–600 mg/dL Severely dehydrated or severely hypotensive	0–500 mg/dL 0–500 mg/dL No
Known interferences/high altitude interference Restrictions based on hematocrit Electronic, optical function checks	patients, patients in shock or in hyperglycemic state None/no Yes. 20–70% Hct range Battery, bar-code scanner, database, and temperature check performed during power up of	Sodium fluoride/no Yes. <25% high results, >60% low results Optical self-zeroing. Has LED to detect errors & internal check strip that is part of strip holder,
Sample quantity checks When auto lock or shutdown occurs User defines QC lockout intervals/lockout can	meter Test will not start until sufficient sample detected User ID failure, QC failure, when meter is not docked in a specified amount of time Yes/no	automatically done with every test Uses LED to determine sufficient quantity User ID failure, QC failure, lockout if reag. expired or if control lot & reag. not entered Yes/no
be circumvented What device supports bar-code scanning of	Operator & patient identifiers, reag. lot No., both control vials and strips (individually wrapped and	Bar-code scanner available
Method of analyst ID/ID required Internal memory size/max. No. patient results stored	bar-coded) Bar-code scan or keypad entry/yes 4,000 patient results, 1,000 QC results, 4,000 operators/4,000	Touchscreen/optional or required, QA user setup 4 Mb RAM, 4 Mb ROM, 256 KB nonvolatile/200 patient results
What meters connect to	Data management system, which in turn connects to LIS/HIS	Data management system, which in turn connects to LIS/HIS; also directly to LIS/HIS
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 identifier, operator ID, patient ID, result, QC identifier	Direct serial/—, modem dial-in/—, Ethernet/— Device unique identifier, operator & patient ID, result, QC identifier, result date & time, strip/material lot, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample type
Hardware/software for data management system	Precision Net System	Nondedicated IBM compatible PC with Pentium processor/Windows 95 & IDMS
No. of different mgmt. reports system can produce Contents downloaded from DMS to meter	25 standard reports with custom options Strip lot Nos., valid control values, valid operator IDs, patient IDs, result, time, date, physicians	6 Strip lot Nos., valid control values, valid operator IDs
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	Major vendors Major vendors None	Major vendors Major vendors None Yes. Product used depends on host system emulation requirements
Distinguishing features	Direct bi-directional interface using HL7 protocol Automated downloading Automated sample detection before test starts	Integrated workstation with IRMA (blood gas, electrolytes, Hct) 1 user interface, 1 in-service program, 1 data management system

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

March 2001 CAP TODAY / 29

Part 3 of 7	HemoCue	Hypoguard USA Inc. (formerly MEDgenesis)
	Customer Service	Customer Service (jordanc@hypoguard.com)
	23263 Madero #A, Mission Viejo, CA 92691 949-859-2630/800-323-1674	10900 Red Circle Dr., Minnetonka, MN 55343 800-888-5957
	www.hemocue.com	www.hypoguard.com
lame of instrument/first year sold	HemoCue Glucose Analyzer/1992	Supreme II Blood Glucose Meter/1997
Professional or home use	Professional use	Professional & home use
Inits sold in U.S./outside U.S.	>20,000 worldwide	—/—
Part of series of similar/related models	Yes 6 ¹ / ₄ x 8 ¹ / ₄ x 3 ¹ / ₂ in./2 lbs.	Yes 4 ³ /4 x 2 ¹ / ₂ x 1 ¹ / ₄ in./4.7 oz.
Dimensions (H x W x D)/weight	6 74 X 8 74 X 3 72 III./2 IDS.	4 ~/4 x 2 ·/2 x 1 ·/4 III./4.7 OZ.
Analytical method/technology/enzyme system used	Dehydrogenase, absorbance photometry	Glucose oxidase
.ist price Price per disposable reagent system unit	\$600 classic, \$825 for data management model \$0.93 per test	\$50 \$0.35
	OF annualization	05 ev 50
lo. of dispos. reagent system units per basic package lo. of times analyses performed using 1 reag. system unit	25 cuvettes per vial 1	25 or 50 1
Dispos. units shelf life/reag. unit storage requirements	9 mo./refrig. or 3 d room temp.	17 mo./ambient temp.
Digital readout size/keypad input capability	1.05 cm/many calcution numeric	¹ /4 x ¹ /2 in./none
low results are displayed	1.25 cm/menu selection, numeric True values	True & calculated values. Reports true results in whole blood values,
Specimen types/sampling techniques	Whole blood/venous, capillary, or arterial	serum/plasma value calculated (whole blood x 1.12) Whole blood/drop
Guitable for samples from well/sick neonates	Yes/yes	No/no
ime from sample intro. to result availability	15–240 sec.	50 sec.
latteries used/number used/avg. life of 1 set lvg. expected life of device/mean time between failures	AA/5/5 cycles (150 h) 7 yrs./>5 yrs.	J cell/1/700 cycles 20,000 tests/not available
evice warranty/service options	1 yr., \$125 each additional yr./24-h loaner program	3 yrs./none
oaners provided	Yes	Yes
lser list or user group	No	No
Foll-free No. for customer questions Fraining and certif. program/No. training days provided	7 AM-5 PM PST, 800-881-1611 Yes/as needed from vendor office	7 AM-6 PM CST Yes/as needed
Avg. time for lab to complete maintenance	Weekly: 5 min.	Weekly: 10 min.
Special cleansing procedures	No	No
nternal QC recommended or required	Quality control cuvette daily	Customer established
Between instrument CV (based on PT) at these levels:		
<50 mg/dL	7.5% (XQ-01)	Not available
> 100–200 mg/dL > >400 mg/dL	6.6% (XQ-03) 4.4% (XQ-04 >350)	Not available Not available
Program name, year/challenge No./level	CAP EXCEL, 1997/—/—	n/a
of mean glucose challenge sample		
Accuracy/compared to what reference method or device	0.994/GC-MS	y=0.99 x + 3, r=0.983, n=113/YSI 2300
Precision/compared to what reference method or device	1.44%/GC-MS	Within-run: 3.9%, between-run: 4.0%/YSI 2300
Linear range	0–400 mg/dL	30–600 mg/dL
Suggested dynamic/measurement range	0–400 mg/dL	30–600 mg/dL
Contraindications	No	No
Known interferences/high altitude interference Restrictions based on hematocrit	None/no No	Dopamine ≥10 mg/dL, ascorbate ≥4 mg/dL/no Yes. 28%–65%
Electronic, optical function checks	Control cuvette (an interface filter) verifies photometer calib.	Internal sumcheck functions for electronics, internal optics standardization, std. strip
Sample quantity checks	Sample quantity always 5 µL due to cuvette technique & design. Cuvette automatically draws (by capillary action) exact amount of blood	Only 1 drop (≥9 μL) sample required
When auto lock or shutdown occurs	QC failure, control or reagent past exp., QC length	No auto lock or shutdown
Jser defines QC lockout intervals/lockout can be circumvented	Yes/optional	No/yes
What device supports bar-code scanning of	Operator & patient identifiers, controls, reagent	No bar-code scanner
Method of analyst ID/ID required	Manual or bar code/optional	None/n/a
nternal memory size/max. No. patient results stored	1,000 records/approximately 1,000 results dependent on configuration	100 tests/100 tests
Vhat meters connect to	Hemocue data management system, which cannot further transmit data	n/a
low meters are connected to external system	Direct serial/—	n/a
to upload results/No. of installations		
nfo. contained in transmission to external system	Device unique identifier, operator & patient ID, result, QC identifier, pass/fail, date, time, comment code, analyte unit of measurement type	n/a
lardware/software for data management system	PC or laptop/HemoCue DM software	n/a
No. of different mgmt. reports system can produce	Customizable	n/a
oo. of afferent fight. reports system can produce Contents downloaded from DMS to meter	—	n/a n/a
System connected (live installations) to which LISs/HISs:		
using screen animation/screen scraping	None	n/a
· ·	None Sunquest	n/a n/a
using standard HL7 interface		
· ·		n/a
using standard HL7 interface using proprietary protocol interface Jse 3rd-party interfacing tool/engine for LIS/HIS interfaces	In progress	
using standard HL7 interface using proprietary protocol interface	In progress Indicated for diabetes mellitus Not hematocrit dependent	Blood can be applied to test strips inside <i>or</i> outside of meter
using standard HL7 interface using proprietary protocol interface Jse 3rd-party interfacing tool/engine for LIS/HIS interfaces	In progress • Indicated for diabetes mellitus	

Part 4 of 7	Hypoguard USA Inc. (formerly MEDgenesis) Customer Service (jordanc@hypoguard.com) 10900 Red Circle Dr., Minnetonka, MN 55343 800-888-5957 www.hypoguard.com	LifeScan Inc., a Johnson & Johnson Company Lorna Wood (Iwood2@Ifsus.jnj.com) 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com
Name of instrument/first year sold	Assure Blood Glucose Meter/1998	OT II Hospital first sold in 1992, Data Dock in 1996
Professional or home use Units sold in U.S./outside U.S. Part of series of similar/related models Dimensions (H x W x D)/weight Analytical method/technology/enzyme system used List price Price per disposable reagent system unit	Professional & home use —/— No 4 ³ / ₈ x 2 ³ / ₈ x ¹³ / ₃₂ in./5.3 oz. Glucose oxidase \$50 \$0.35	Professional use (CLIA waived) 4,000 shipped annually/n/a Yes Data Dock: 8 x 3.62 x 3.25 in., meter: 4.7 x 2.4 x 1.1 in./1 lb. (1.5 lb. meter + dock) Glucose oxidase, reflectance photometry Contracted Contracted
No. of dispos. reagent system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/reag. unit storage requirements	25, 50, 100 1 18 mo./ambient temp.	50 test strips per box (2 vials of 25 strips) 1 Strips: 18 mo. or 4 mo. after opening; controls: 18 mo. or 3 mo. after opening/room temp.
Digital readout size/keypad input capability How results are displayed Specimen types/sampling techniques Suitable for samples from well/sick neonates Time from sample intro. to result availability Batteries used/number used/avg. life of 1 set Avg. expected life of device/mean time between failures Device warranty/service options	1/4 x 1/2 in./menu selection True values Whole blood/drop No/no 35 sec. J cell/1/1,000 cycles 20,000 tests/not available 3 yrs./none	2 x 0.5 in./menu selection, numeric, alphabetic True values Whole blood/drop-hanging, cap. transfer, fine tip transfer pipette, syringe Yes/yes <45 sec. AA/2 for Dock & J 6 v/1 for meter/1,000 tests >5 yrs./not available No charge replacement for life of contract/24-h replacement policy
User list or user group Toll-free No. for customer questions Training and certif. program/No. training days provided Avg. time for lab to complete maintenance Special cleansing procedures	No 7 AM-6 PM CST Yes/as needed Weekly: 10 min. No	No 24 h, 7 d Yes/as needed on site Daily: <1 min. Standard biohazard disinfection procedures
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	Customer established Not available Not available Not available n/a	As specified by accreditation 3.1% 3.4% <4.0% Internal testing & clinical studies
Accuracy/compared to what reference method or device	y=0.98 x + 8, r=0.976, n=109/YSI 2300	Slope 1.0, r=0.98/YSI 2700
Precision/compared to what reference method or device	Within-run: 4.7%, between-run: 3.7%/YSI 2300	3–4%/YSI 2700
Linear range Suggested dynamic/measurement range	30–550 mg/dL 30–550 mg/dL	0–600 mg/dL 0–600 mg/dL
Contraindications Known interferences/high altitude interference	No L-dopa and dopamine (≥10 mg/dL)/no	No Sodium fluoride (black/gray top tube preservative)/no
Restrictions based on hematocrit	Yes. 20%–60%	Yes. Neonatal 25–76%, glucose <150 mg/dL; adult 25–60%
Electronic, optical function checks	Sumcheck functions for electronics and software, no optics	Internal system checks upon power up; checkstrip
Sample quantity checks	Only 1 drop (≥7 µL) sample required	User alerted if insufficient sample
When auto lock or shutdown occurs User defines QC lockout intervals/lockout can	No auto lock or shutdown No/yes	User ID failure, QC failure (optional), QC not performed within required tim alerts insufficient specimen, cannot test blood in QC mode, alerts battery low, memory almost full Yes/no
be circumvented What device supports bar-code scanning of	No bar-code scanner	Operator & patient identifiers, reag. lot No. (optional bar-code wand)
Method of analyst ID/ID required	None/n/a	Alphanumeric entry/optional
Internal memory size/max. No. patient results stored	180 tests/180 tests	128k/1,200 results
What meters connect to	n/a	Data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interface)
How meters are connected to external system to upload results/No. of installations	n/a	DataLink Connect (modem & network)/newly available, 22 installations; DataLink Interface (script & EDI to LIS)/1
Info. contained in transmission to external system	n/a	Device unique identifier, operator & patient ID, result, QC identifier, flags 8 comments
Hardware/software for data management system	Yes	Desktop Windows NT & proprietary software
No. of different mgmt. reports system can produce Contents downloaded from DMS to meter	4 n/a	9 Strip lot Nos., valid control lot Nos., unique meter loc. ID, unique event codes (QC), unique critical ranges, unique lockout parameters
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	n/a n/a n/a n/a	None None None n/a
Distinguishing features	Touchscreen display	Ability to detect blood vs. control solution—"true" QC lockout Alphanumeric keypad entry Simplest to use, chosen by thousands of hospitals/clinicians

Part 5 of 7	LifeScan, a Johnson & Johnson Company Lorne Wood (lwood2@lfsus.jnj.com) 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com	Lifescan, Inc., a Johnson & Johnson Company Lorna Wood (lwood2@lfsus.jnj.com) or Diane Snoey (dsnoey@lfsus.jnj.com) 1000 Gibraltar Dr., 10A, Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com
Name of instrument/first year sold	SureStep Pro/1997	SureStep FLEXX/2000
Professional or home use Units sold in U.S./outside U.S. Part of series of similar/related models Dimensions (H x W x D)/weight Analytical method/technology/enzyme system used List price Price per disposable reagent system unit	Professional use >20,000/n/a Yes 7.4 x 3.5 x 2.6 in./1.2 lbs. Glucose oxidase, reflectance photometry \$1,200 per bedside unit Contracted	Professional use n/a Yes 6.34 x 3.55 x 1.63 in./12.5 oz. (with bar-code scanner), 12.1 oz. (without) Reflectance photometry/glucose oxidase \$1,200 with bar-code scanner, \$850 without bar-code scanner By contract, volume
No. of dispos. reagent system units per basic package No. of times analyses performed using 1 reag. system unit Dispos. units shelf life/reag. unit storage requirements	2 25-strip vials (50 strips per box) 1 18 mo. unopened/<30°C (86°F); away from heat, direct sunlight	2 25-strip vials (50 strips per box) 1 18 mo. unopened/<30°C (86°F); away from heat, direct sunlight
Digital readout size/keypad input capability How results are displayed Specimen types/sampling techniques Suitable for samples from well/sick neonates Time from sample intro. to result availability Batteries used/number used/avg. life of 1 set Avg. expected life of device/mean time between failures Device warranty/service options	18 pt. font/menu selection, numeric, alphabetic, bar-code scan built-in True values Whole blood/drop, wipe, capillary transfer, touchable test strip Yes/yes 15–45 sec. C 1.5v/2/approximately 1,000 tests >5 yrs./<3% warranty return rate Life of contract for defects/Gold Service Program option	18 pt. font (16-pixels high, 8-pixels wide)/menu select., numeric, alphabetic True values Whole blood/drop, wipe, capillary transfer, touchable test strip Yes/yes 15 sec. minimum AA/3/1,000 test minimum 5 yr. minimum (15 tests per day)/not yet determined 1-year warranty/extended service agreements available
Loaners provided	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 (contact SureStep Pro product manager) 24 h, 7 d, multiple languages Yes/as negotiated None No	Yes (contact SureStep FLEXX product manager) 24 h, 7 d, 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	As defined by hospital policy 4.39% 3.44% 4.97% Data from 2000 AACC poster #20 and #63	As defined by hospital policy 2.5% 2.9% 2.4% Data from 2000 AACC poster #20
of mean glucose challenge sample		
Accuracy/compared to what reference method or device	>0.98/YSI	>0.98/YSI
Precision/compared to what reference method or device Linear range Suggested dynamic/measurement range Contraindications Known interferences/high altitude interference	3.44–4.97 CV across runs/YSI 0–500 mg/dL 0–500 mg/dL Excessive water loss or dehydration Sodium fluoride/no	3.44–4.97/YSI 0–500 mg/dL 0–500 mg/dL Excessive water loss or dehydration Sodium fluoride/no
Restrictions based on hematocrit Electronic, optical function checks	Yes. Adult: 25–60% RBC; neonates: 25–65% RBC Automatic electronic and optical checks with each test	Yes. Adults: 25–60% RBC; neonates: 25–65% RBC Automatic electronic and optical checks with each test
Sample quantity checks When auto lock or shutdown occurs User defines QC lockout intervals/lockout can be circumvented	Test strip color confirmation dot when adequate sample applied, bedside unit error messages User ID failure, QC failure, data upload lockout option Yes/no (2.0 software version)	Test strip color confirmation dot when adequate sample applied; meter error messages User ID failure, QC failure, failure to transfer data Yes/no
What device supports bar-code scanning of Method of analyst ID/ID required	Operator & patient identifiers, reagent (strip) lot No., bedside unit serial Nos. Bedside unit custom programmed for manual or bar-code entry/required or	Operator & patient identifier, reagent (strip) lot No., control solution lot No., meter serial No. Unique alphanumeric ID/optional (defined by location)
Internal memory size/max. No. patient results stored	optional 2,500 patient & QC tests plus 50 test strip lots and QC lots	256k/1,500 patient +QC tests, 50 test strip lots and 50 QC lots
What meters connect to	Data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interfaces)	Data management system, which in turn connects to LIS/HIS (scripted interface & electronic data interfaces)
How meters are connected to external system to upload results/No. of installations	Datalink Connect (modem + network): 376 sites; Datalink Interface (script + EDI + LIS): 75 sites; infrared port used to transfer results by modem or network to workstation	Datalink Connect (modem + network): 376 sites; Datalink Interface (script + EDI + LIS): 75 sites; infrared port used to transfer results by modem or network to workstation
Info. contained in transmission to external system	Device unique identifier, operator & patient ID, result, QC identifier, flags, comments	Device unique identifier, operator & patient ID, result, QC identifier, result flags, location/site
Hardware/software for data management system	Desktop or laptop, Windows NT, proprietary software	Desktop or laptop, Windows NT, Microsoft SQL server, proprietary DataLink
No. of different mgmt. reports system can produce Contents downloaded from DMS to meter	17 reports plus export funtion for customized reports Strip lot Nos., valid control values, valid operator IDs, all configurations: expiration, time, lockouts	Data Management System 3.0 12 standard, unlimited customized reports Strip lot No., valid control values, valid operator IDs, critical value ranges, comment codes
System connected (live installations) to which LISs/HISs: • using screen animation/screen scraping	DHCP-VA System, HBOC Pathlab3, Star, ALG, Sunquest Flexilab, Cerner Pathnet (legacy), SCC, Softlab, DHT, Dynacor Premier	DHCP-VA system, HBOC PathLab 3, Star, ALG; Sunquest Flexilab, Cerner Pathnet (legacy); SCC SoftLab, DHT Dynacor Premier
using standard HL7 interface using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Cerner Pathnet (legacy), Sunquest Flexilab, MEDITECH Magic & client/server None Yes (Telcor, exclusive contract; Reflections WRQ software)	Cerner Pathnet (legacy); Sunquest Flexilab; MEDITECH Magic & Client/Server None Yes (Telcor, exclusive contract; Reflections WRQ software)
Distinguishing features	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	Exception reporting and database tracking—customized QC compliance rules Multiple levels of security—nonvalidated operator, noncertified operator, warn and lockout True off-meter sample application; unique test strip technology—touchable, absorbent test strip

March 2001 CAP TODAY / 33

Part 6 of 7	MiniMed Inc.	Roche Diagnostics
	Leslie Wright (leslie.wright@minimed.com) 18000 Devonshire St., Northridge, CA 91325	Accu-Chek Customer Care 9115 Hague Rd., Indianapolis, IN 46256
	800-999-9859	800-440-3638
	minimed.com	www.roche.com
Name of instrument/first year sold	MiniMed Continuous Glucose Monitoring System (CGMS)/2000	Accu-Chek HQ/1999
•		
Professional or home use Units sold in U.S./outside U.S.	Professional use >1.000/>600	Professional use 7,500/none
Part of series of similar/related models	No	Yes
Dimensions (H x W x D)/weight	2.8 x 0.9 x 3.6 in./4 oz.	2.9 x 4.2 x 9.4 in./3.5 lbs.
Analytical method/technology/enzyme system used	Glucose oxidase	Biosensor-glucose dehydrogenase
List price Price per disposable reagent system unit	\$1,995/monitor, \$30/sensor (disposable) \$30 per sensor	\$1,495 Contingent on contract price
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No. of dispos. reagent system units per basic package No. of times analyses performed using 1 reag. system unit	10/box 1 sensor lasts ~36–72 h	50 test strips
Dispos. units shelf life/reag. unit storage requirements	6 mo./refridgeration 2°C–24°C	18–24 mo., stable until exp. on vial/room temp., <90°F, do not freeze
Digital readout size/keypad input capability	—/menu selection	7 lines x 30 characters/menu selection, numeric, alphabetic
How results are displayed	At time of monitor download, system can display retrospective	True values
	only/numerical agreement. Avg. difference between glucose sensor and	
	glucose meter of -5.4 mg/dL, daily median correlation coefficient of 0.92,	
Specimen types/sampling techniques	calibration using blood glucose meters daily. Continuous monitoring and sampling of interstitial fluid glucose levels	Arterial, venous, capillary, neonate (including cord blood)
		The contract of the contract o
Suitable for samples from well/sick neonates	No/yes (with diabetes)	Yes/yes
Time from sample intro. to result availability Batteries used/number used/avg. life of 1 set	Retrospective analysis after disconnection AAA alkaline batteries/2/~2 mo.	40 sec. (soon to be 25 sec.) 3v lithium/2/700 tests
Avg. expected life of device/mean time between failures	~3 yrs./—	5 yrs./828,000 tests
Device warranty/service options	1 yr. warranty for monitor, no warranty on disposable/none	All-inclusive warranty through life of Accu-Chek HQ system at no additional
Loaners provided	No	cost/24 h, 7 d customer care with overnight replacement if needed Yes
Loaners provided		
User list or user group	No Yes	Yes (contact local account manager)
Toll-free No. for customer questions Training and certif. program/No. training days provided	Yes (training only)/~1 day	24 h, 7 d Yes/site-specific according to quantity of personnel
Avg. time for lab to complete maintenance	Monthly: 10–15 min	None
Special cleansing procedures	No	No
Internal QC recommended or required	None	Daily, 2 level
Between instrument CV (based on PT) at these levels:		,
• <50 mg/dL		50.0 SD=4.2 (6,593 labs)
• 100–200 mg/dL	5% (40–400 mg/dL)	167.9 CV=4.5 (6,619 labs)
 >400 mg/dL Program name, year/challenge No./level 		203.3 CV=4.3 (13,382 labs) CAP, 2000/WBG-C/see above
of mean glucose challenge sample		
Accuracy/compared to what reference method or device	Coefficient of variation (CV) of 5%/fingerstick blood glucose measurements	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi
Precision/compared to what reference method or device	—/glucose meters, Hemocue, YSI (any and all)	Controls: low SD=1.9 mg/dL, mid CV=2.6%, high CV=1.8%; Blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/qlucose hexokinase
Linear range	_	10–600 mg/dL
Suggested dynamic/measurement range	40–400 mg/dL	10–600 mg/dL
Contraindications	Not recommended for use by persons with impaired vision or hearing	Per labeling
Known interferences/high altitude interference	Possibly MRI/no	Per labeling/none up to 10,150 feet
Restrictions based on hematocrit	No	Yes. Glucose <200 mg/dL, 20-65%; glucose >200, 20-55%
Electronic, optical function checks	None	Meter cradle communication with the Advantage meter, meter cradle with
		code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	None	Built-in electronic fail safe check, visual confirmation of sample volume
When auto lock or shutdown occurs	None	User ID failure (valid op.), QC failure, patient ID length, reagent & QC lots,
		comment codes, incorrect code key, incorrect Advantage meter
User defines QC lockout intervals/lockout can	No/no	Yes/yes. (RALS-G information management system identifies operators
be circumvented	No house de communication of the communication of t	who violate hospital policy)
What device supports bar-code scanning of Method of analyst ID/ID required	No bar-code scanner At time of monitor download/optional	Operator & patient identifiers Alphanumeric/yes
Internal memory size/max. No. patient results stored	Up to 14 days continuous data/288 readings per day	2,000 records/2,000 records
What meters connect to	Com-Station for download to computer & software	Data management system, which in turn connects to LIS/HIS
How meters are connected to external system	Direct serial/—	Direct serial/50, modem dial-in/5, hospital network/50
to upload results/No. of installations	Deticat ID vesselt	Device unique identification and the second
Info. contained in transmission to external system	Patient ID, result	Device unique identifier, operator & patient ID, result, QC identifier, proficiency & linearity samples, comment codes, meter loc., download loc.
Hardward for the second	0 01	
Hardware/software for data management system	Com-Station (docking unit that transmits data from CGMS to computer) and software	Software: Accu-Chek HDM, RALS-Link, RALS-G, RALS Plus, DataCare POC
No. of different mgmt. reports system can produce	3	Unlimited (customer defined)
Contents downloaded from DMS to meter	-	Strip & QC lot Nos., valid control values, valid operator IDs, meter
		configuration, message of the day, linearity values, critical ranges comments
System connected (live installations) to which LISs/HISs:	Does not interface LIS or HIS, a report from software–nontransferable	
using screen animation/screen scraping	No	Cerner, Sunquest, DHCP, HBOC, Phamis, MEDITECH, SoftLAB
using standard HL7 interface using approximate and interface	No No	Cerner, Sunquest, MEDITECH, HBOC
using proprietary protocol interface Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	No No	None Roche offers DataCare POC as well as interfacing through the MAS
ood ord party interracing tool/engine for Lio/filo interraces		continuum
Distinguishing feetures	a Continuous diverse values callested (sugar, 5)	a Cupariar atrip technology, always debudes and a
Distinguishing features	Continuous glucose values collected (every 5 min) Up to 72 h of data	Superior strip technology: glucose dehydrogenase & comfort curve design
	Ability to enter in events (insulin, food, excercise, etc.) to compare	Hand-free communication with LIS/HIS
	against glucose values upon review of data	Alphanumeric touchscreen
		Proven bidirectional network connection from Accu-Chek HQ to LIS/HIS ADT data interface with PALS C/PALS Blue/Data Care POC
		ADT data interface with RALS-G/RALS Plus/DataCare POC

Part 7 of 7	Roche Diagnostics Accu-Chek Customer Care	Roche Diagnostics Local account manager
	9115 Hague Rd., Indianapolis, IN 46256 800-440-3638	9115 Hague Rd., Indianapolis, IN 46256 800-428-5074
	www.roche.com	www.roche.com
Name of instrument/first year sold	AccuData GTS Plus System/2000	Accu-Chek Inform/FDA CLEARANCE PENDING
•		
Professional or home use Units sold in U.S./outside U.S.	Professional use 40,000*/5,000	Professional use n/a
Part of series of similar/related models	Yes	Yes
Dimensions (H x W x D)/weight Analytical method/technology/enzyme system used	11 x 8.75 x 4 in./5 lbs. Biosensor-glucose dehydrogenase	1.4 x 3.8 x 7.6 in/12 oz. Biosensor—glucose dehydrogenase
List price	\$550	TBD
Price per disposable reagent system unit	Contingent on contract price	Contingent on contract price
No. of dispos. reag. system units per basic package No. of times analyses performed using 1 reag. system unit	50 strips per vial	50 test strips
Dispos. units shelf life/reag. unit storage requirements	18-24 mo., stable until exp. on vial/<90°F, do not freeze	18–24 mo., stable until expir. date on vial/room temp., less than 90°F, do
		not freeze
Digital readout size/keypad input capability How results are displayed	4 lines x 20 characters LCD/menu selection, numeric True values	Font size varies/menu selection, numeric, alphabetic True values
Specimen types/sampling techniques	Arterial, venous, capillary, neonate (including cord blood)	Whole blood/drop
Suitable for samples from well/sick neonates Time from sample intro. to result availability	Yes/yes 40 sec. (soon to be 25 sec.)	Yes/yes 40 sec. (shorter test time will be introduced in 2001)
Batteries used/number used/avg. life of 1 set	3v lithium/2/~700 tests	3.7 v rechargeable lithium ion/1/testing in progress
Avg. expected life of device/mean time between failures Device warranty/service options	5 yrs./10,000 tests All-inclusive warranty through life of AccuData GTS Plus at no additional	5 yrs./testing in progress All-inclusive warranty through life of Accu-Chek Inform System at no
	cost/24 h, 7 d customer care with overnight replacement if needed	additional cost/customer care is available 24 hrs/365 days per year with
Loaners provided	n/a	overnight replacement if needed Yes
User list or user group	Yes (contact local account manager)	Yes (contact local account manager)
Toll-free No. for customer questions	24 h, 7 d	Yes (24 h, 7d/365 d per yr.)
Training and certif. program/No. training days provided Avg. time for lab to complete maintenance	Yes/site-specific according to quantity of personnel None	Yes/site specific according to quantity of personnel None
Special cleansing procedures	No	No
Internal QC recommended or required	Daily, 2 level	Daily, 2 levels of glucose control solutions
Between instrument CV (based on PT) at these levels: • <50 mg/dL	50.0 SD=4.2 (6,593 labs)	
• 100–200 mg/dL	167.9 CV=4.5 (6,619 labs)	n/a
 >400 mg/dL Program name, year/challenge No./level 	203.3 CV=4.3 (13,382 labs) CAP, 2000/WBG-C/see above	n/a n/a
of mean glucose challenge sample		_
Accuracy/compared to what reference method or device	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi	y=0.991 x + 8.4, r=0.980/glucose hexokinase—Hitachi
Precision/compared to what reference method or device	Controls: low SD=1.9 mg/dL, mid CV=2.6%, high CV=1.8%; Blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase	Controls: low SD=1.9 mg/dL, mid CV=2.6%, high CV=1.8%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase
Linear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic/measurement range 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%
Electronic, optical function checks	Meter cradle communication with Advantage meter, GTS with code key,	Meter with code key, battery voltage test, internal database memory check,
Liectionic, optical function checks	battery voltage test, internal database memory check, internal configuration check	internal configuration check
Sample quantity checks	Built-in electronic fail-safe check, visual confirmation of sample volume	Built-in electronic fail safe check, visible verification of sample volume
When auto lock or shutdown occurs	User ID failure (valid op.), QC failure, patient ID length, incorrect code key,	User ID failure, QC failure, download interval lockout, patient ID length,
User defines QC lockout intervals/lockout can	incorrect Advantage meter Yes/yes (RALS-G information management system identifies operators who	reagent editing, mandatory comments, incorrect/missing code key Yes/no (optional QC pass/fail feature)
be circumvented	violate hospital policy)	, , , , , , , , , , , , , , , , , , ,
What device supports bar-code scanning of	Operator & patient identifiers	Operator & patient identifiers (reagent lot number to be introduced in 2001)
Method of analyst ID/ID required	Numeric input or bar-code wand scan/yes	Alphanumeric/yes
Internal memory size/max. No. patient results stored	1,000 total patient, control, linearity, proficiency tests/1,000 (stores 2,000 valid operator IDs)	4,000 results/4,000 tests
What meters connect to How meters are connected to external system	Data management system, which in turn connects to LIS/HIS Direct serial/50, modem dial-in/5, hospital network/50	Data management system, which in turn connects to LIS/HIS Direct serial/—, modem dial-in/—, hospital network/—
to upload results/No. installations Info. contained in transmission to external system	Device unique identifier, operator & patient ID, result, QC identifier,	Device unique identifier, operator & patient IDs, result, QC identifier,
contained in transmission to external system	download loc., comment codes, proficiency & linearity samples	proficiency and linearity samples, comments, meter location, download location
Hardware/software for data mgmt. system	Software: Accu-Chek HDM, RALS-Link, RALS-G, RALS Plus, DataCare POC	DataCare POC, RALS Plus
No. of different mgmt. reports system can produce	Unlimited (customer defined)	Unlimited (user defined)
Contents downloaded from DMS to meter	Strip & QC lot Nos., valid operator ID, valid control values, linearity values	Strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot numbers and values, comments
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	Cerner, Sunquest, DHCP, HBOC, Phamis, MEDITECH, SoftLAB	Limited scripting on a system-by-system basis
using standard HL7 interface	Cerner, Sunquest, MEDITECH, HBOC	Cerner, MEDITECH, Sunquest, CPSI, CompuCare, Antrim, Softlab, SMS, HBOC, CHC, TDS, Dawning Tech., Cloverleaf, Data Innovations
• using proprietary protocol interface	None	
use 3rd-party interfacing tool/engine for LIS/HIS interfaces	Roche offers DataCare POC as well as interfacing through the MAS continuum	No
Distinguishing features	Superior strip technology: glucose dehydrogenase & comfort curve	Superior strip technology, glucose dehydrogenase, wide hematocrit range
	design • Proven bidirectional network connection from AccuData GTS Plus to	and comfort curve design • Hands-free, bidirectional communication with LIS/HIS
	LIS/HIS	Palm-powered alphanumeric touchscreen (based on Palm OS)
	ADT data interface with RALS-G/RALS Plus/DataCare POC *Combined AccuData GTS and AccuData GTS Plus sales	
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