Part 1 of 3

For additional information about bedside glucose testing systems, see www.greenarrowdx.com

	Abbott Diabetes Care **Alameda, CA** **877-643-2098** www.myfreestyle.com/fspp	**Abbott Diabetes Care** **Alameda, CA** **877-643-2098**	**Arkray** **Edina, MN** **800-818-8877** www.arkrayusa.com
Name of instrument/First year sold	Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System/2013	Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System/2008	Assure Platinum/2010
Professional or home use	professional	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2021	—	—	—
Dimensions (H × W × D)/Weight	length: 7.85 in. ±.08; width: 2.93 in. ±.08; thickness: 1.92 in. ±.08/10.58 oz. ±.51	7.7 × 2.96 × 1.2 in./9 oz.	4.5 × 2.5 × 1.2 in./2.8 oz.
Analytical method or technology or enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; β-hydroxybutyrate, the predominant blood ketone associated with DKA	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; β-hydroxybutyrate, the predominant blood ketone associated with DKA	glucose oxidase
No. of disposable reagent system units per basic package	glucose: 100 individually wrapped strips; ketone: 50 individually wrapped strips	glucose: 100 individually wrapped strips; ketone: 50 individually wrapped strips	50 or 100
Disposable units shelf life	18 months	18 months	18 months
Reagent unit storage requirements	39°–86°F (4°–30°C)	39°–86°F (4°–30°C)	39°–86°F
Digital readout character size/Keypad input capability	variable/alphanumeric keypad	variable/alphanumeric keypad	—
How results are displayed	plasma equivalent glucose values	plasma equivalent glucose values	true values
Specimen types	glucose and ketone: fresh capillary, venous, arterial, or neonatal whole blood	glucose and ketone: fresh capillary, venous, arterial, or neonatal whole blood	whole blood
Sampling techniques	top-fill or end-fill sample application	top-fill or end-fill sample application	drop
Minimum specimen volume required	glucose: 0.6 µL; ketone: 1.5 µL	glucose: 0.6 µL; ketone: 1.5 µL	0.5 µL
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes	no/no
Time from sample introduction to result availability	glucose: 5 seconds; ketone: 10 seconds	glucose: 20 seconds; ketone: 10 seconds	7 seconds
Batteries used/No. used/Average life of one set of batteries	AA alkaline, lithium, nickel cadmium, or NiMH rechargeable/depends on type/depends on use	AA alkaline or NiMH rechargeable/depends on type/depends on use	AAA/2/5,000 tests with 4 tests per day
Average expected life of device	—	—	5 years
Device warranty	1 year or contract term	1 year or contract term	5 years
Service options/Loaners provided	replacement/no	replacement/no	—/yes
User list or user group	—	—	no
Toll-free No. for customer questions/Hours of operation	877-529-7185/24 hours, 7 days, all year	877-529-7185/24 hours, 7 days, all year	800-818-8877/24 hours, 7 days
Training and certification program/No. of training days provided	yes/based on implementation plan	yes/based on implementation plan	yes/one on site
Internal QC recommended or required	as defined by facility or institutional policy	as defined by facility or institutional policy	control solution testing
Accuracy	capillary blood glucose results: 100% within ±15 mg/dL or ±15%; 95.1% within ±10 mg/dL or ±10%	capillary blood glucose results: 97% within ±15 mg/dL or ±20%	slope=1.0, y-inter.= -2.33, r=0.99
• Compared with what reference method or device	YSI glucose analyzer	YSI glucose analyzer	YSI model 2300 glucose analyzer
Precision	repeatability: pooled whole blood SD 2.8 mg/dL at concentrations <75 mg/dL and <3.6% CV for concentrations ≥75 mg/dL; intermediate precision: pooled whole blood SD 2.8 mg/dL at concentrations <75 mg/dL and <5.0% for concentrations ≥75 mg/dL	repeatability: CV ranges from 3.0% to 4.9% across AMR	results for glucose concentration ≥75 mg/dL: 100% within ±20%; 96% within ±15%; 79% within ±10%; 53% within ±5%; results for glucose concentration <75 mg/dL: 100% within ±15 mg/dL; 100% within ±10 mg/dL; 88% within ±5 mg/dL
• Compared with what reference method or device	—	—	YSI model 2300 glucose analyzer
Linear range	glucose: 20–500 mg/dL; ketone: 0–8 mmol/L	glucose: 20–500 mg/dL; ketone: 0–8 mmol/L	20–600 mg/dL
Suggested dynamic or measurement range	glucose: 20–500 mg/dL; ketone: 0–8 mmol/L	glucose: 20–500 mg/dL; ketone: 0–8 mmol/L	20–600 mg/dL
Contraindications	yes (per labeling)	yes (per labeling)	yes (per labeling)
Known interferences	yes (per labeling)	yes (per labeling)	yes
High-altitude interference	none (tested up to 7,200 feet)	none (tested up to 7,200 feet)	none, up to 10,000 feet
Restrictions based on hematocrit	yes, hematocrit range: 15–65%	yes, hematocrit range: 20–70%	yes, hematocrit range: 30–55%
Electronic and optical function checks	battery, barcode scanner, database, and temperature checks performed during power-up	battery, barcode scanner, database, and temperature checks performed during power-up	battery, test strip, temperature, EEPROM, measurement, self-check, transmission, and thermistor errors
Sample quantity checks	test strip contains fill-trigger electrode designed to start the test when sufficient sample is detected	test strip contains fill-trigger electrode designed to start the test when sufficient sample is detected	fill-trigger electrode on each test strip designed to start the test when sufficient sample is detected
When auto lock or shutdown occurs	configurable lockout for operator certification, strip lot, upload, and QC requirements	configurable lockout for operator certification, strip lot, upload, and QC requirements	—
User can define QC lockout intervals/QC lockout can be circumvented	yes/no	yes/no	yes/yes
Information for which device supports barcode scanning	operator ID, patient ID, strip lot, QC, comment code, and free text field data	operator ID, patient ID, strip lot, QC, comment code, and free text field data	—
Method of analyst ID/ID required	scan or manual entry/required	scan or manual entry/required	—
Internal memory size	patient test results: 2,500; control test results: 1,000; patient IDs: 6,000; operator IDs: 6,000; test strip lots: 36 (18 glucose, 18 ketone)	patient test results: 2,500; control test results: 1,000; patient IDs: 6,000; operator IDs: 6,000; test strip lots: 36 (18 glucose, 18 ketone)	500 tests
Maximum No. of patient results stored	same as internal memory size	same as internal memory size	500 tests
Meter connections for information transfer	data-management system, which connects to LIS/HIS	data-management system, which connects to LIS/HIS	—
How meters are connected to external system to upload results	real-time wireless data transfer via meter or through docking station connected to ethernet	data transfer via docking station connected to ethernet or wireless workstation	—
Information contained in transmission to external system	device unique identifier, operator ID, patient ID, reagent and QC lot numbers, test results, comment codes, and free text entry	device unique identifier, operator ID, patient ID, reagent and QC lot numbers, test results, comment codes, and free text entry	—
Hardware and software for data-management system	compatible with data-management systems from Abbott, Orchard, Siemens, and Telcor	compatible with data-management systems from Abbott, Orchard, Siemens, and Telcor	—
Information downloaded from DMS to meter	operator list, patient list, strip lot list, adjusted QC ranges, and meter configuration settings	operator list, patient list, strip lot list, adjusted QC ranges, and meter configuration settings	—
LISs/HISs to which system is connected (live installs) using:			
• Screen animation/Screen scraping	—	—	—
• Standard HL7 interface	—	—	—
• Proprietary protocol interface	—	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	yes, via Abbott, Orchard, Siemens, or Telcor	yes, via Abbott, Orchard, Siemens, or Telcor	—
LOINC can be used to identify tests when communicating with LIS	yes	yes	—
Distinguishing features (supplied by company)	• individually foil-wrapped test strips support a no-touch procedure and vial-free solution, which assists in complying with CDC and CLSI recommendations for bedside testing supplies • 1D/2D barcode reader; real-time dual band wireless data transmission; TrueID technology with active patient ID confirmation, which assists in complying with the Joint Commission's NPSG.01.01.01 • hematocrit compensation algorithm • replaceable strip port module	• individually foil-wrapped test strips support a no-touch procedure and vial-free solution, which assists in complying with CDC and CLSI recommendations for bedside testing supplies • TrueID technology with active patient ID confirmation, which assists in complying with the Joint Commission's NPSG.01.01.01 • replaceable strip port module	• hypoglycemic alert: audio alert is designed to improve resident safety • qcProGuard: control solution test notifications provide additional quality control • ProGrip: rubberized case design for secure handling • other features: auto coding, LCD backlit display, and test strip ejector

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

BEDSIDE GLUCOSE TESTING SYSTEMS

Part 2 of 3 **For additional information about bedside glucose testing systems, see** www.greenarrowdx.com	**Arkray** **Edina, MN** **800-818-8877** www.arkrayusa.com	**Nova Biomedical** **Nova Sales** info@novabio.com **Waltham, MA** **781-894-0800 or 800-458-5813** www.novabiomedical.com	**Nova Biomedical** **Nova Sales** info@novabio.com **Waltham, MA** **781-894-0800 or 800-458-5813** www.novabiomedical.com
Name of instrument/First year sold	Assure Prism multi/2015	StatStrip Xpress2 Glucose Hospital Meter System/2016	StatStrip Glucose Hospital Monitoring System/2006
Professional or home use	professional	professional	professional
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2021	—	—	—
Dimensions (H × W × D)/Weight	3.66 × 2.2 × 0.83 in./2.1 oz.	3.9 × 2.4 × 0.9 in./2.77 oz. (78.5 g)	5.8 × 3.1 × 1.18 in./0.49 lb. (220 g)
Analytical method or technology or enzyme system used	glucose oxidase	electrochemical	electrochemical
No. of disposable reagent system units per basic package	50 or 100	50 test strips per vial	50 test strips per vial
Disposable units shelf life	18 months	24 months from date of manufacture	24 months from date of manufacture
Reagent unit storage requirements	34°–86°F	room temperature	room temperature
Digital readout character size/Keypad input capability	—	variable (defined by the particular field or menu)/menu selection	variable (defined by the particular field or menu)/menu selection, numeric, alphabetic
How results are displayed	true values	plasma equivalent values	plasma equivalent values
Specimen types	whole blood	whole blood	whole blood
Sampling techniques	drop	drop, capillary transfer	drop
Minimum specimen volume required	0.5 µL	1.2 µL	1.2 µL
Suitable for samples from well neonates/Sick neonates	no/no	yes/yes	yes/yes
Time from sample introduction to result availability	5 seconds	6 seconds	6 seconds
Batteries used/No. used/Average life of one set of batteries	3v lithium (disposable, type CR2032)/2/1,000 tests	AAA/2/minimum 600 tests	3.7v Li-polymer (rechargeable, replaceable)/1/24–36 months
Average expected life of device	3 years	>5 years	>5 years
Device warranty	3 years	2 years (optional 5-year extended warranty)	2 years (optional 5-year extended warranty)
Service options/Loaners provided	—/yes	meter replacement/yes	meter replacement/yes
User list or user group	no	no	no
Toll-free No. for customer questions/Hours of operation	800-818-8877/24 hours, 7 days	800-458-5813/24 hours, 7 days, all year	800-458-5813/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/one on site	yes/defined during implementation planning	yes/defined during implementation planning
Internal QC recommended or required	control solution testing	CLIA requirements, two levels per day or per hospital policy	CLIA requirements, two levels per day or per hospital policy
Accuracy	slope=1.0, y-inter.= –7.39 mg/dL, r=0.99	>97% versus IDMS-traceable laboratory reference method	>97% versus IDMS-traceable laboratory reference method
• Compared with what reference method or device	YSI model 2300 glucose analyzer	tested to CLSI POCT 12-A3 criteria (r2=0.994)	tested to CLSI POCT 12-A3 criteria (r2=0.994)
Precision	results for glucose concentration ≥75 mg/dL: 100% within ±20%; 98% within ±15%; 80% within ±10%; 42% within ±5%; results for glucose concentration <75 mg/dL: 100% within ±15%; 100% within ±10%; 100% within ±5%	within run=1.9–3.6% (whole blood) and day to day=3.4–4.7% (linearity standards)	within run=1.9–3.6% (whole blood) and day to day=3.4–4.7% (linearity standards)
• Compared with what reference method or device	YSI model 2300 glucose analyzer	—	—
Linear range	20–600 mg/dL	10–600 mg/dL (0.5–33.3 mmol/L)	10–600 mg/dL (0.5–33.3 mmol/L)
Suggested dynamic or measurement range	20–600 mg/dL	10–600 mg/dL (0.5–33.3 mmol/L)	10–600 mg/dL (0.5–33.3 mmol/L)
Contraindications	yes (per labeling)	none	none
Known interferences	yes (per labeling)	none	none
High-altitude interference	none, up to 10,000 feet	none, up to 15,000 feet	none, up to 15,000 feet
Restrictions based on hematocrit	yes, hematocrit range: 20–60%	no	no
Electronic and optical function checks	battery, test strip, temperature, system, and sample errors	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results
Sample quantity checks	fill-trigger electrode on each test strip designed to start the test when sufficient sample is detected	RapidFill sampling electronically checks for correct strip dosing	RapidFill sampling electronically checks for correct strip dosing
When auto lock or shutdown occurs	user flags control solution tests when conducted	—	user ID failure, QC failure, required docking for data transfer (if configured)
User can define QC lockout intervals/QC lockout can be circumvented	no/no	no/—	yes/no
Information for which device supports barcode scanning	no barcode scanner	no barcode scanner	operator ID, patient ID, reagent lot No., QC lots
Method of analyst ID/ID required	—	none/—	barcode scan or virtual keypad input/yes
Internal memory size	500 tests	400 tests total (FIFO)	1,000 patient samples, 200 QC samples, 8,000 operators
Maximum No. of patient results stored	500 tests	400 tests total (FIFO) patient and QC tests	1,000 patient samples
Meter connections for information transfer	—	—	NovaNet data-management system, which in turn connects to LIS/HIS
How meters are connected to external system to upload results	—	—	hospital network, real-time wireless (RF Nova)
Information contained in transmission to external system	—	—	device unique identifier, operator ID, patient ID, result, QC identifier
Hardware and software for data-management system	—	none	connects to Telcor QML, RALS Web 3, Orchard Trellis, UniPOC, POCellerator, Aqure, BioConnect, Qvera, others
Information downloaded from DMS to meter	—	—	strip lot numbers, valid control values, valid operator IDs, patient demographics (with ADT interface), configuration files, physician ID, diagnostic codes, physician notes
LISs/HISs to which system is connected (live installs) using:			
• Screen animation/Screen scraping	—	—	—
• Standard HL7 interface	—	—	Meditech, Cerner, Orchard, others
• Proprietary protocol interface	—	—	Meditech, Cerner, Orchard, others
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	—	yes, Telcor QML, RALS Web 3, UniPOC, POCellerator, Aqure, BioConnect, Qvera, others
LOINC can be used to identify tests when communicating with LIS	—	—	yes
Distinguishing features (supplied by company)	• optimized readout display: large, thick numbers are intended to improve readability • compact design: small, lightweight design provides better portability • ProGrip: rubberized case design for secure handling • other features: auto coding, LCD backlit display, and test strip ejector	• only meter FDA cleared for use with all sample types, including capillary, in critically ill patients • measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose; unlimited manual test entry • only meter CLIA waived for use with all patients, in all departments, on all sample types	• only meter FDA cleared for use with all sample types, including capillary, in critically ill patients • measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose; unlimited manual test entry • only meter CLIA waived for use with all patients, in all departments, on all sample types

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BEDSIDE GLUCOSE TESTING SYSTEMS

Part 3 of 3 **For additional information about bedside glucose testing systems, see** www.greenarrowdx.com	**Roche Diagnostics Corp.** **Roche Customer Support Center** **Indianapolis, IN** **800-440-3638** http://go.roche.com/informii
Name of instrument/First year sold	Accu-Chek Inform II/2012
Professional or home use	professional
Total units sold in U.S./Total units sold outside U.S.	—
No. of contracts for product signed in 2021	—
Dimensions (H × W × D)/Weight	1.85 × 3.62 × 7.48 in./12.24 oz. (347 g)
Analytical method or technology or enzyme system used	electrochemical (AC/DC), mutant variant quinoprotein glucose dehydrogenase
No. of disposable reagent system units per basic package	50 strips per vial
Disposable units shelf life	18 months
Reagent unit storage requirements	39°–86°F (4°–30°C)
Digital readout character size/Keypad input capability	test results are 48-point font/menu selection, numeric, alphabetic
How results are displayed	true values
Specimen types	whole blood
Sampling techniques	drop
Minimum specimen volume required	0.6 µL
Suitable for samples from well neonates/Sick neonates	yes/yes
Time from sample introduction to result availability	5 seconds
Batteries used/No. used/Average life of one set of batteries	3.7v Li-polymer (rechargeable)/1/5 years
Average expected life of device	5 years
Device warranty	1 year or contract term
Service options/Loaners provided	—/no
User list or user group	no
Toll-free No. for customer questions/Hours of operation	800-440-3638/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/defined during implementation planning
Internal QC recommended or required	—
Accuracy	capillary: r=0.993; venous: r=0.995; arterial: r=0.990; neonatal: r=0.976
• Compared with what reference method or device	hexokinase method traceable to NIST
Precision	controls: low SD=1.2 mg/dL, mid SD=2.2, high SD=4.6; low CV=2.6%, mid CV=1.9%, high CV=1.5%; blood: 1 SD=1.2 mg/dL, 3 SD=4.2 mg/dL, 5 SD=9.5 mg/dL; 1 CV=3.3%, 3 CV=3.4%, 5 CV=3.0%
• Compared with what reference method or device	hexokinase method traceable to NIST
Linear range	10–600 mg/dL
Suggested dynamic or measurement range	10–600 mg/dL
Contraindications	yes (per labeling)
Known interferences	yes (per labeling)
High-altitude interference	none, up to 10,000 feet
Restrictions based on hematocrit	yes, hematocrit range: 10–65%
Electronic and optical function checks	150 integrity checks, including variation in hematocrit, temperature, and humidity
Sample quantity checks	sampling checked electronically for complete sample dosing
When auto lock or shutdown occurs	user ID failure, QC failure, download interval lockout (all configurable)
User can define QC lockout intervals/QC lockout can be circumvented	yes/no
Information for which device supports barcode scanning	operator ID, patient ID, reagent lot No.
Method of analyst ID/ID required	alphanumeric or barcode scan/yes
Internal memory size	1,000 results, 5,000 operator IDs, 4,000 patient IDs, 300 predefined comments
Maximum No. of patient results stored	—
Meter connections for information transfer	data-management system, which connects to LIS/HIS
How meters are connected to external system to upload results	hospital network, real-time wireless
Information contained in transmission to external system	device unique identifier, operator ID, patient ID, result, QC identifier, strip lot numbers, proficiency and linearity samples, comments
Hardware and software for data-management system	Roche cobas infinity POC application for connection to third-party DMS, including Telcor QML, Abbott RALS
Information downloaded from DMS to meter	strip lot numbers, valid control values, valid operator IDs, patient IDs, meter configuration, linearity lot numbers and values, comments
LISs/HISs to which system is connected (live installs) using:	
• Screen animation/Screen scraping	—
• Standard HL7 interface	—
• Proprietary protocol interface	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	yes, Telcor QML or Abbott RALS
LOINC can be used to identify tests when communicating with LIS	yes
Distinguishing features (supplied by company)	• 150 individual quality checks are conducted prior to measuring the glucose concentration • patented dual-current AC/DC meter technology checks a range of variables including compensation for hematocrit • adjustable workflow option for isolation patients; live 24/7/365 customer care service and support
Note: a dash in lieu of an answer means company did not answer question or question is not applicable	

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