

tech guide

Lab and point-of-care glucose monitors

1. What is the brand name and model of your company's lab or POC glucose monitor?
2. What is the latest version of your named monitor; what year was this version first released to market?
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.
4. What are the dimensions of the named product; if the device is portable, what is its weight?
5. What type of sample does the product employ?
6. What does the product measure?
7. Under ideal conditions, what is the time to first result; how are the test results made available?
8. How many test results is the device able to store?
9. Briefly describe any automation or connectivity features or options.
10. How is the device powered; if a battery is required, what is the average battery life?
11. What capabilities, features, or accessories distinguish this product from others on the market?

Arkray USA Inc
 Minneapolis
 (800) 818-8877
 www.arkrayusa.com

Arkray USA Inc
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 (800) 818-8877
 www.arkrayusa.com

Dexcom
 San Diego
 (888) 738-3646
 www.dexcom.com

ReliOn Premier BLU blood glucose monitoring system	ReliOn Premier Voice blood glucose monitoring system	Dexcom G5 mobile continuous glucose monitoring system
ReliOn Premier BLU blood glucose monitoring system, 2018.	ReliOn Premier Voice blood glucose monitoring system, 2017.	Dexcom G5 continuous glucose monitoring system, 2015.
FDA 510(k), 2017.	FDA CLIA waiver, 2017.	CE mark, 2015; FDA PMA, 2015.
4.06 inches x 2.23 inches x 0.67 inches; 2.53 ounces with batteries.	3.90 inches x 2.21 inches x 0.75 inches; 2.47 ounces with batteries.	Transmitter with sensor pod: 1.5 inches x 0.9 inches x 0.5 inches; G5 mobile receiver: 4.2 inches x 2.5 inches x 0.55 inches.
Capillary whole blood.	Capillary whole blood.	Interstitial fluid.
Glucose.	Glucose.	Glucose levels.
Test results appear 5 seconds after the meter recognizes the blood sample. The test result will appear on the screen of the blood glucose meter. Results are stored in the meter's memory and can be uploaded via Bluetooth to the ReliOn Life app.	Test results appear 5 seconds after the meter recognizes the blood sample. The test result will appear on the screen of the blood glucose meter. Results are stored in the meter's memory and can be manually entered into the ReliOn Life app.	A glucose reading is sent via Bluetooth to a receiver or smart device every 5 minutes. The first sensor requires a 2-hour warm-up period.
1,000	500	The G5 Mobile app and receiver can store 30 days' worth of glucose data (8,640 estimated glucose values; 288 per day).
An auto-code feature eliminates the need to enter strip codes manually. The Bluetooth feature provides connectivity to the ReliOn Life mobile application. ReliOn Life is available for iOS and Android enabled smartphones.	An auto-code feature eliminates the need to enter strip codes manually. Premier Voice is compatible with the ReliOn Life mobile app with manual data entry. ReliOn Life is available for iOS and Android enabled smartphones.	With the Dexcom G5 Mobile app, users can view real-time glucose data and trends on their smart device and share data. The Dexcom Share feature is built into the G5 Mobile app; loved ones and caregivers can remotely monitor by using the Dexcom Follow app.
Two 3.0V lithium batteries (disposable type CR2032); battery life, 1,000 test results.	Two alkaline AAA batteries; battery life, 1,000 test results.	The receiver is rechargeable; its battery takes 3 hours for a full charge, and with average use will last for 2 days.
Full-feature blood glucose monitoring system features Bluetooth technology; wireless Bluetooth technology can be downloaded onto smartphones; the ReliOn Life app makes test results available at any time on an iOS or Android compatible phone; eliminates the need for paper logbooks.	Bilingual-speaking (English and Spanish) blood glucose monitoring system; features up to 29 different voice prompts to guide users through meter setup, testing, and review of test results; voice guidance may be turned on or off based on user preferences.	A continuous glucose monitor that sends glucose readings to an Apple or Android smart device (phone or watch) every 5 minutes; the first continuous glucose monitor approved by FDA to make diabetes treatment decisions without a confirmatory fingerstick; approved for Medicare reimbursement; approved for children ages 2 years and up.

Nova Biomedical

Waltham, Mass
 (781) 894-0800
 www.novabiomedical.com

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Oak Tree Health

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StatStrip glucose hospital meter system	StatStrip Xpress 2 glucose hospital meter system	EasyMax	Fortiscare
StatStrip glucose hospital meter system v1.86, 2015.	StatStrip Xpress 2 glucose hospital meter system, 2016	EasyMax EMMU/Long Term Care, 2013.	Fortiscare EM66, 2016.
FDA 510(k), 2006.	FDA 510(k), 2016.	CE mark, 2012; FDA PMA, 2012.	CE mark 2013; FDA PMA, 2014.
5.8 inches x 3.0 inches x 1.18 inches; 0.49 pounds.	3.9 inches x 2.4 inches x 0.9 inches; 2.77 ounces.	3.8 inches x 2 inches x 0.6 inches; 1.37 ounces.	3.29 inches x 2.01 inches x 0.9 inches; 1.41 ounces.
Whole blood.	Whole blood.	Capillary and venous whole blood.	Capillary and venous whole blood.
Glucose.	Glucose.	Blood glucose.	Blood glucose.
6 seconds.	6 seconds.	5 second results; test results made available on liquid-crystal display screen.	5 second results; test results made available on liquid-crystal display screen.
1,000 patient tests, 200 quality control tests.	400 tests total (first in, first out).	480	480
Interfaces with laboratory information systems and hospital information systems via included NovaNet application or through commonly available middleware.	The StatStrip Xpress 2 professional meter is designed for applications that do not need data interface/connectivity capability.	Users can download the results from their meters to their computers using a micro USB.	Users can download the results from their meters to their computers using a micro USB.
3.7V Li polymer rechargeable battery.	Two AAA batteries, minimum 600 tests.	Two AAA batteries, sufficient to perform 2,000 tests.	Two AAA batteries, sufficient to perform 1,000 tests.
FDA-cleared for use with critically ill patients, single-use glucose biosensors; 1.2 µL whole blood sample; results in 6 seconds; no known interferences; lab-like accuracy validated in more than 170 clinical studies worldwide.	FDA-cleared for use with critically ill patients, single-use glucose biosensors; 1.2 µL whole blood sample; results in 6 seconds; no known interferences; lab-like accuracy validated in more than 170 clinical studies worldwide.	Glucose dehydrogenase flavin adenine dinucleotide technology is FDA approved and meets FDA requirements.	Glucose dehydrogenase flavin adenine dinucleotide technology is FDA approved and meets FDA requirements.

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Roche Diagnostics Corp

Indianapolis
(800) 440-3638
usdiagnostics.roche.com

Accu-Chek Inform II blood glucose system

Accu-Chek Inform II blood glucose system, 2012.

FDA 510(k), 2012.

1.73 inches x 3.74 inches x 7.60 inches

Whole blood.

The Accu-Chek Inform II system quantitatively measures glucose as an aid in monitoring the effectiveness of glucose control.

Blood glucose results are displayed on the meter's touchscreen within 5 seconds after the addition of a blood sample to the test strip.

Accu-Chek Inform II system provides an accurate result in 5 seconds using a whole blood sample size of 0.6 mL.

The Cobas IT 1000 application is designed to provide users with complete management of point-of-care testing—including remote configuration and control of devices, user management, and laboratory and hospital information system interfaces—from a single point of control.

Powered by a rechargeable battery; battery life is dependent on usage, and the intended battery life is 5 years.

Each sample undergoes 150 quality checks; patented AC/DC technology checks range of variables including compensation for hematocrit; meter-level wireless for real-time data transfer without need to dock the meter; extensive studies prove system performance in presence of more than 190 potential interferences, following Clinical and Laboratory Standards Institute guidelines; live 24/7/365 customer support.

Siemens Healthineers

Norwood, Mass
(781) 269-3000
usa.healthcare.siemens.com

DCA Vantage analyzer

DCA Vantage analyzer, 2006.

CE mark, 2006; FDA 510(k), 2007.

9.0 inches x 11.5 inches x 10.5 inches; 9.0 pounds

HbA1c, 1 µL whole blood; urine.

Albumin, creatinine, A:C ratio (urine); HbA1c (whole blood).

HbA1c, 6 minutes; albumin, creatinine, and A:C ratio in urine, 7 minutes; onboard printed results and/or automatically uploaded to a laboratory information system (LIS) or health information system (HIS), or other data manager.

Stores 4,000 patient or control records, and up to 1,000 operator IDs.

POCT1-A2 communication protocol simplifies connectivity to data managers; automatically uploads results to an LIS/HIS or other data manager; results can also be uploaded to a PC via a USB flash drive.

100 to 240 VAC; 50/60 Hz.

Quantitative HbA1c in whole blood in 6 minutes; albumin, creatinine, and A:C ratio in urine in 7 minutes; highlighted in more than 100 clinical articles; flexible patient data management; onboard printer; connectivity to electronic medical records and laboratory information systems; customizable quality control lockout capability; authorized operator management; heparinized capillary allows for 5-minute sample hold time.

UPCOMING TECH GUIDES

Each month, *CLP* invites IVD manufacturers and clinical laboratory suppliers to complete a standardized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future print issues of *CLP*.

March

Laboratory software and information technologies

April/May

Microbiology systems and tools

June

Anatomic and digital pathology instruments and tools

Urinalysis assays and instruments

July

Clinical chemistry and integrated analyzers

Hematology assays and instruments

To be considered for inclusion, contact associate editor Elaine Sanchez Wilson at ewilson@medqor.com.

