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DIABETES PRODUCT PROFILE

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HemoCue Diabetes Product Portfolio



**HemoCue®
Glucose 201
System**



**HemoCue®
Glucose 201 DM
System**



**HemoCue®
Albumin 201
System**

The HemoCue Diabetes Systems put lab-quality answers in clinician's hands when they are needed most, at the point-of-care.

The HemoCue glucose portfolio includes the basic HemoCue Glucose 201 System and the HemoCue® Glucose 201 DM System. The CLIA-waived HemoCue® Glucose Systems results supplement the clinical evidence in the diagnosis and treatment of patients with diabetes. The HemoCue® Albumin 201 System is a CLIA-waived and quantitative Albumin test for diagnosing and monitoring albuminuria at the point-of-care.

HemoCue® Glucose 201 System

The “Intended Use” of any medical device may be found in the system’s “Package Insert”. The package insert for the HemoCue® Glucose 201 System is included with each new box of microcuvettes.

The purpose of the package insert is to detail the specific approved uses of the product based on its FDA submission and clearance. It is important to note that no claims about product use can be made that are not indicated in the product’s package insert. Be sure to read and understand the information contained in each HemoCue product package insert.

For the HemoCue® Glucose 201 System, our intended use is unique and compelling. The intended use states:

The quantitative determination of the instant blood glucose concentration in circulation to supplement the clinical evidence in the diagnosis and treatment of patients with diabetes as well as monitoring of neonatal blood glucose levels.

Two unique statements about our glucose systems should be observed from the intended use:

- The HemoCue® Glucose 201 System can be used for aiding in diagnostic testing to supplement clinical evidence
- The HemoCue® Glucose 201 System can be used to monitor neonatal blood glucose levels

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HemoCue® Glucose 201 System



The test system consists of two primary components, the HemoCue® Glucose 201 Analyzer, which is a dual-wavelength spectrophotometer, and the HemoCue® Glucose 201 Microcuvette. Used together, the photometer and microcuvette test the amount of glucose in the sample.

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HemoCue® Glucose 201 System Methodology



There are three basic steps to the HemoCue glucose test:

1. The microcuvette automatically collects a precise amount of blood.
2. The microcuvette is placed in the analyzer for testing no later than 40 seconds after sampling. The blood reacts with the reagents in the cuvette. These reagents convert the glucose in the sample into a form that can be measured. This process is called enzymatic conversion.
3. The result is displayed once the conversion is complete and has been measured in the analyzer.

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HemoCue® Glucose 201 System Specifications*

Specimen requirement: 5 uL capillary, venous or arterial whole blood sample.

Results: Displayed in mg/dL within 40 to 240 seconds.

Measuring Range:

0-444 mg/dL

0-24.6 mmol/L (SI units)

Quality Control: Instrument has an internal self-test that verifies the analyzer each time the analyzer is turned on and every second hour thereafter.

One level of control is required per day of use. Contact HemoCue America for recommended control.

*HemoCue® Glucose 201 System Package Insert 150702 180514

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Unique Microcuvette Technology



Ready to Use: Each HemoCue microcuvette contains reagents for each test. No additional components needed.

Convenient Packaging: Microcuvettes are available in individually wrapped and multi-pack vial formats, offering flexibility to optimize shelf life.

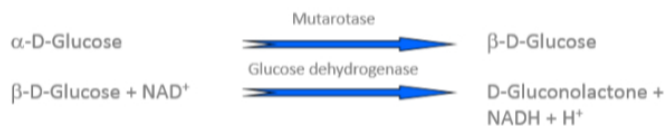
Simple Microcuvette Placement: HemoCue microcuvettes are easy to handle and cannot be inserted improperly into the analyzer.

Secure Sample Environment: Unique HemoCue microcuvette technology draws sample into the inner cavity by capillary action.

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Reactions in the Microcuvette

- Hemolysis of red blood cells by saponin
- Enzymatic conversion



- Color reaction



The chemical reaction in the microcuvette cavity has two phases: hemolysis and the glucose reaction. Hemolysis, the disintegration of the erythrocyte membranes, is brought about using saponin.

The glucose enzymatic reaction is a modified glucose dehydrogenase method in which a tetrazolium salt is used to obtain a quantification of glucose in visible light. In other words, the whole process turns glucose in the sample into a form that can be measured using spectrophotometry.

In very simple terms, there are three types of enzymatic glucose tests available in laboratory testing: Oxidase, Dehydrogenase, and Hexokinase. Our system uses the Dehydrogenase method. The cuvette simply provides the chemicals and process to allow for glucose to be changed into glucose dehydrogenase for measurement. We then measure the glucose in dehydrogenase form using a spectrophotometer.

When explaining this methodology to customers, keep it simple! The above paragraph is more than sufficient on how to explain our test method.

Reference:

HemoCue® Glucose 201 System Package Insert #150702 180514


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Quality Control



Self-test: HemoCue's built-in self-test performs an electronic test of the electronics and optics of the system to ensure that the analyzer is functioning properly. This self-test ensures that no tests are run and no results are provided unless the system is functioning properly. The self-test is performed each time the analyzer is turned on and every 2 hours that the analyzer is in use.

Some customers will require additional liquid control to meet local, state or other regulatory guidelines. Although HemoCue only requires the one level per day per our manufacturer's instructions, we do have two approved suppliers for liquid control requirements, EuroTrol and R&D Systems. Consult your HemoCue price list for price and ordering information. Controls are available at various levels and volumes.

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Maintenance



No preventative maintenance is required for the HemoCue® Glucose 201 System, simply regular cleaning.

It is recommended that the microcuvette holder be cleaned each day of use or more frequently if needed. Alcohol or a mild detergent is recommended. Once cleaned, the microcuvette holder should be dried before being re-inserted into the analyzer.

If the analyzer displays an error code requiring cleaning, a HemoCue® Cleaner should be used.

The cover may be cleaned with alcohol (20–70%) or mild detergent.

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HemoCue® Glucose 201 DM System



The second HemoCue® Glucose System is the HemoCue® Glucose 201 DM (Data Management) System. It is based on the same platform as HemoCue® Glucose 201 and utilizes the same microcuvettes and methodology.

The HemoCue® Glucose 201 DM System is a higher-end system with full data capabilities to capture results, operator info, QC data and other information needed by certain types of customers including hospitals and large IDN networks that want full control over their point of care testing systems.

Hospitals generally require this type of data management functionality in order to connect to their Laboratory or Hospital Information Systems (LIS/HIS).

The HemoCue® Glucose 201 DM System can connect to the LIS or HIS using the hospital's computer network and can meet most needs for data capture and reporting*:

- **Data Entry** — Touch-screen display and built-in barcode scanner
- **Interface Capabilities** — Interface with existing network using POCT1-A (CIC standard) with our DMS software. Docking solution enables connection of up to 5 analyzers.
- **Configurable Functions** — Operator ID, Patient ID, Lot ID, Site ID; Patient comments; Critical value alerts; STAT Testing
- **Results Storage** — 4,000 patient/STAT tests, 500 QC tests, 500 analyzer logs, 200 patient IDs
- **DMS Software** — Patient and QC reports
- **Quality Control Data Management** — QC lock-out; QC scheduling; Linearity Reports

*HemoCue® 201 DM Reference Manual; 901041 180503

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HemoCue® Glucose 201 DM System



The HemoCue® Glucose 201 DM Analyzer has four main features:

Touchscreen Display: Similar to early versions of phone touchscreens, the analyzer utilizes a user-friendly display that walks the user through each test or other function.

Bar Code Reader: Many hospital customers utilize barcoding for operator and patient information. The HemoCue® Glucose 201 DM Analyzer has an integrated bar code reader that allows the user to scan in barcoded information as that information is required. For example, the user will scan their barcoded badge to identify them to the system. Once the bar code reader matches a User ID to an approved user in the system, that user will be logged on and can continue to use the analyzer to perform a test.

Rechargeable Batteries: The analyzer contains a lithium-ion rechargeable battery that recharges each time the analyzer is plugged into an A/C adapter or placed into a docking station that is powered. The analyzer can also be used without the battery by plugging directly into an A/C adapter or powered docking station. A fully charged HemoCue® Glucose 201 DM Analyzer can be used for approximately 100 hours.

Docking Station: The docking station has two primary purposes.

- As a bridge between the HemoCue® Glucose 201 DM Analyzer and any software connectivity solution
- A recharging station for the analyzer

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HemoCue® Glucose 201 DM System



The basic functionality of the HemoCue® Glucose 201 DM Analyzer includes the following features:

Operator ID: The ability to create specific users in the system with a login ID, password and user level. This ensures that only approved users gain access to the system for testing and only approved users with appropriate access levels are able to make changes to the analyzer or system.

Patient ID: Captures the specific patient ID in order to tie the test result to the specific patient record.

Microcuvette Batch: The system has the ability to confirm that only approved batches of microcuvettes are able to be used in the system. The batch number is a specific number assigned by the manufacturer during manufacturing and is printed on the microcuvette packaging.

QC Control: One of the most important functions of the HemoCue® Glucose 201 DM Analyzer is the QC function. Most hospitals require specific QC to be run on point-of-care systems daily or even more frequently. The QC control function allows the customer to set up a specific QC routine which details the frequency, level and acceptable range for all QC testing.

Connectivity: The HemoCue® Glucose 201 DM System has numerous software options for the management of the system. These include The HemoCue® DM 201 Software and various 3rd Party connectivity solutions. The standard HemoCue® Glucose 201 System also has a connectivity software solutions called Basic Connect which may meet the need of certain customers. Each customer's needs are different but can be met with various configurations of software and networking. HemoCue America has internal resources that can help you determine the best solution and work with you and your customers to meet their needs.