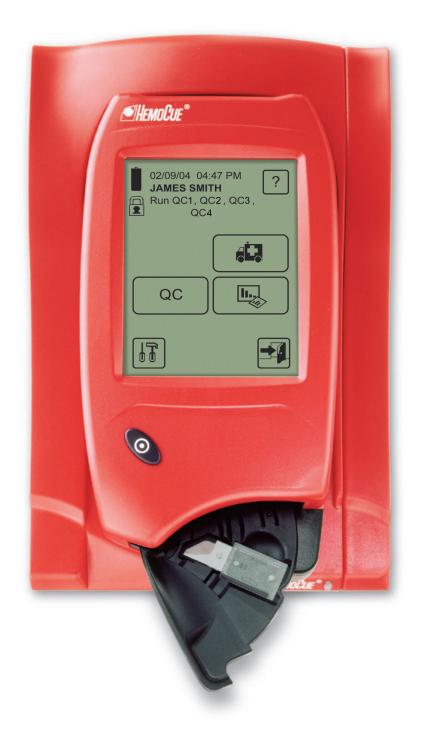
Total Assurance

HemoCue[®] 201 DM Systems for glucose and hemoglobin



Data management systems with lab-quality test results





The HemoCue[®] 201 DM Systems consist of a portable analyzer together with docking station, and microcuvettes.

Introducing HemoCue 201 DM

With the HemoCue data management systems for glucose and hemoglobin, lab-quality results are not only easy to achieve, they are also easy to manage.

These POCT (point-of-care testing) devices are based on the same HemoCue testing methodology that has proven to be accurate and effective for over 40 years, while also taking full advantage of today's computer technology.

A wide range of settings and definable options allows you to customize the analyzer operations. This means it can be adjusted to reflect, or even influence, the way quality care is given.

More importantly, test results and related information are stored in the memory, eliminating transcription error. When placed in a docking station, the analyzer sends the stored data to a network PC, where it can be viewed by a POCT coordinator or sent to other hospital information systems.

The entire process is quick, secure, and automatic. Best of all, it follows the globally approved standard for POCT device communication called CLSI POCT1-A, also known as the CIC standard.

In other words, HemoCue[®] 201 DM Systems let you meet the needs of today, while staying prepared for the needs of tomorrow.

Three simple steps...

If you are a current user of HemoCue glucose and hemoglobin analyzers, you will notice many similarities in our 201 DM systems. Above all, you can be assured of the same reliable, lab-quality results you have come to expect from our three-step testing procedure.

> 1. Apply the microcuvette to a drop of venous, arterial, or capillary blood.



2. Insert the filled microcuvette into the cuvette holder.



3. The lab-quality result is displayed when all required information has been entered and the measurement is complete.



...with added assurance

In addition, HemoCue[®] 201 DM Systems have features that improve your point-of-care routines. Setting options let you determine which actions and information are necessary in providing optimal care.

The analyzer provides prompts in a clear and simple manner, and required information may be selected from pre-defined lists. Other information can be entered as free text, or scanned using the analyzer built-in barcode scanner.

All information, including each test result, is stored in the memory. From there, it may easily be reviewed on the analyzer display or automatically transferred into a computerized information system.

Assured security



Ensuring the authorized and appropriate use of equipment is important for all healthcare providers. By improving POCT procedures, it is possible to improve patient care. HemoCue[®] 201 DM systems can help eliminate errors through a number of features, all of which ensure that incorporated POCT devices are operated with optimal security.



User verification

The analyzer can be set to require an Operator ID, which is compared with a list of authorized operators determined by the POCT coordinator or supervisor. If no match is found, operator access may be limited or even denied. Operators can be assigned specific levels of access, and a deactivation date can be set for added security.



Password protection

If your healthcare facility finds the use of Operator ID unnecessary, password protection can be activated instead. This provides a simple and effective form of security, protecting vital functions such as the ability to change settings.

Assured information



Just as quality care is easier to provide with the correct information at your fingertips, lab-quality results become even more valuable when specific patient information is known. HemoCue[®] 201 DM Systems have options for storing a wide range of information, making them valuable aids in tracking, reviewing, and billing for tests.



Patient identity

Storing test results with the Patient ID (PID) is an important requirement for many healthcare providers. The analyzer can therefore be set to require the Patient ID before a test is performed. The Patient ID can be entered manually, or be scanned quickly with the built-in barcode scanner – a useful feature when barcoded patient wristbands are in use.



Comments and acceptance

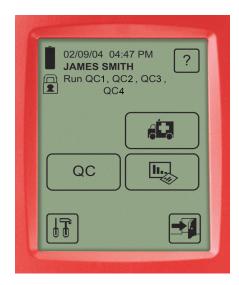
In certain circumstances, details about the test or testing conditions should be known in conjunction with a test result. Therefore, the analyzer makes it possible to attach comments to a result. For convenience, a list of user-defined comments can be stored in the analyzer.

The ability of the operator to accept or reject results is a valuable feature. A rejected result can only be saved if an explanation has been added to it, making it easier to evaluate at a later date.

Assured quality



No healthcare facility can afford to cut corners on Quality Control (QC), even when things are busy at the point of care. Without accurate POCT devices and valid control material and cuvettes, quality results may be compromised, putting patients and healthcare providers at risk. HemoCue[®] 201 DM Systems make QC easy to perform – and difficult to ignore.



True QC lockout and QC reminder The analyzer can be set to perform a QC lockout if scheduled QC testing has not been completed. When a lockout occurs, the analyzer can only be unlocked by performing the appropriate QC test. This minimizes the risk of reporting incorrect results, as well as the risk of bypassing established procedures. Lockouts can be set to occur after a certain period of time, or after a specific number of patient tests have been performed. However, lockouts should never come as a surprise when the analyzer is needed the most. A reminder always appears when the time for a lockout is approaching, so that QC testing can be performed in time.

STAT testing

There may be situations in which immediate testing is necessary, despite a QC lockout or prompts for information. Thus the analyzer can be set to allow STAT (Short-Turn-Around-Time) tests even after a QC lockout has occurred, or without entering patient data or cuvette batch. The number of STAT tests allowed after a QC lockout can be specified in the analyzer setup by the POCT coordinator or supervisor.



Approved supplies

To help manage QC procedures, a POCT coordinator or supervisor can create a list of approved cuvette batches and control material, complete with lot numbers and expiration dates. This information can be entered manually or scanned from the packaging using the analyzer built-in barcode scanner. If cuvettes and control material are not compatible with the pre-defined list, testing is not allowed.

The same process can be used to verify cuvette batch numbers during patient testing. Operators can be required to enter or scan the batch number to ensure that the cuvettes are approved for use. This information is then stored in the analyzer, to be accessed later along with test results.



Assured connectivity

The features of HemoCue[®] 201 DM Systems provide the means for standardizing and improving patient care. But there is much more to data management than passwords and prompts. Many benefits begin when the analyzer leaves the operator's hands.

Automatic transfer

The wide range of information stored in the analyzer is useful not only for immediate patient care, but also for future statistics, analysis and billing. Fortunately, thanks to the ability to transfer data, manual archiving is not necessary. Whenever the analyzer is placed in a 201 DM docking station, all information is sent electronically to a specified PC.

Result processing

The PC receiving the data may be a single computer running the HemoCue® 201 DM -DMS Software or a third party observation reviewer managing many different POCT devices. Both cases provide for administrators and other appropriate users to review, approve, and report recorded data. In larger facilities, this data may in turn be connected to other information systems throughout the healthcare facility, such as LIS or HIS.

Two-way communication

Information can also be sent in the opposite direction – from a PC to one or more analyzers. Thus, a POCT coordinator or supervisor can update settings for a single analyzer, or simultaneously update a group of analyzers spread across a hospital. In this way, the change or entering of data, e.g. new cuvette batches or quality control specifications, can be done without leaving the office.

Total savings

Such connectivity saves more than transcription time. The time spent investigating transcription errors, undocumented results, unauthorized users and non-compliance is also costly for healthcare facilities, as is the time spent on retraining to correct these problems.

By facilitating effective data collection and accounting, and by decreasing the labor costs involved, HemoCue 201 DM is a key step toward better and more cost-efficient healthcare.



Multiple docking stations can be linked to a single network connection.

The whole picture

As the name suggests, data management is more than just transferring results. It involves the whole flow of information in healthcare facilities. HemoCue 201 DM is the first link in a chain that will increase efficiency and help improve healthcare.

Room to grow

Thanks to their many advantages over stationary laboratory systems, the use of POCT devices is on the rise. Increasingly healthcare facilities will rely on many different POCT devices, both from HemoCue and from other manufacturers.

Data management capabilities, like those of HemoCue[®] 201 DM Systems, make such a network of devices far easier to manage. With built-in connectivity, information gathered at the point of care is automatically transferred to a central Data Management Server (DMS), also known as an Observation Reviewer.

Accessible benefits

In a full data management system, the DMS does more than simply store results. With the help of third-party software, e.g. AQURE[™] or POCcelerator[™] or AegisPOC[™], it can be seamlessly linked with Laboratory Information Systems (LIS) and Hospital Information Systems (HIS).

This interaction is of no small significance. When providing care, it means quickly updated patient journals. And for administration and billing, it means clear and accurate records. Even research and evidence-based medicine benefit, since results are easily retrievable for statistics and evaluation.



A common language

For data management to provide maximum benefit, healthcare facilities must be able to integrate POCT devices of different types and from different manufacturers. HemoCue[®] 201 DM Systems comply with the international standard for POCT device communication, making them a logical choice for today and for the future.

The complicated past

Transferring POCT data electronically saves time and increases accuracy, which in turn lowers costs and improves the quality of care. Yet because manufacturers have developed separate connectivity solutions, hospitals and other facilities have often had difficulty combining POCT devices into one functioning system.

To address this problem, the Connectivity Industry Consortium (CIC) was created to standardize electronic communication, creating a single interface between POCT devices, electronic medical records, and laboratory information systems.

Adhering to standards

The work of the CIC resulted in the CLSI POCT1-A standard. This standard defines a common protocol for POCT device communication, so that even systems from different manufacturers can be utilized.

The CLSI POCT1-A standard is voluntary, but has gained more and more acceptance. Moreover, as healthcare develops and the demand for computerization increases, its importance will continue to grow. HemoCue early on recognized its benefits for you and your patients, and our 201 DM systems were among the first on the market to comply with the standard.

References

Quality in point-of-care testing. Nichols J H. Expert Rev. Mol. Diag. 2003:3(5), 563-752.

Point-of-Care Testing. Challenges of the Post Connectivity Era. Jones J. Clinical Laboratory News. June 2003.

Dubois JA, Dunka L, Allred T et al. Pointof-Care Connectivity: Approved Standard POCT1-A. Wayne, PA.: NCCLS, 2001.

Preventing medical errors in point-of-care testing: security, validation, safeguards, and connectivity. Kost GJ. Arch Pathol Lab Med. 2001;125(10):1307-15.



Technical specifications

HemoCue 201 DM

- Systems for hemoglobin and glucose
- Full connectivity possible
- Compliance with CLSI POCT1-A (CIC standard)

Hemoglobin measurement

Method: Azidemethemoglobin

Measurement range:

0.3-15.9 mmol/L (5-256 g/L, 0.5-25.6 g/dL) Measurement time: 15-60 seconds Sample volume: 10 μL

Glucose measurement

Method: Glucose dehydrogenase Reported result: Whole blood or plasma equivalent Measurement range, HemoCue 201 DM: Whole blood 0.55-22.2 mmol/L (10-400 mg/dL) plasma equivalent 0.61-24.6 mmol/L (11-444 mg/dL)

Measurement range, HemoCue 201 DM RT:

Whole blood 0.55-27.8 mmol/L (10-500 mg/dL) plasma equivalent 0.61-31 mmol/L (11-560 mg/dL) **Measurement time:** Within 1 minute for glucose levels ≤7 mmol/L (≤126 mg/dL) **Sample volume, HemoCue 201 DM:** 5 μL **Sample volume, HemoCue 201 DM RT:** 4 μL

Components

- Analyzer
- Docking station (primary, secondary)
- Microcuvettes

Connections

- Network (LAN/WAN)
- USB

Functions

Can be customized by activating or deactivating the following:

- Operator ID input
- (access denied if ID not recognized)
- Patient ID input
- · Lab number input

- Microcuvette batch data input
- · Password protection
- QC control with input of lot numbers and range (plus lockout functions and reminder time)
- Linearity and proficiency testing
- STAT tests
- · Critical value alert

Analyzer

- · Easy-to-use touch display
- Built-in barcode scanner
- Infrared transmitter (for data transfer to docking station)
- Stores 4000 Patient/STAT tests, 500 QC tests and 500 Analyzer logs
- w 93 mm/h 50 mm/d 170 mm (w 3.66 in/h 1.97 in/d 6.79 in)
- 350 g with battery (0.77 lbs)

Docking station

- Network communication with a pre-defined destination (PC or Data Management Server) via the primary docking station
- Recharges analyzer battery while analyzer is docked
- Allows measurements to be performed while docked
- Up to 4 secondary docking stations can be connected to one primary docking station

HemoCue[®] 201 DM - DMS Software

- · Generates Patient and QC reports
- Controls analyzers remotely (LAN/WAN)
- Allows downloading of patient and QC data
- Allows changing of operator lists, control batches, etc.
- Allows downloading of analyzer configurations
- Can forward measurements to host system using CLSI POCT1-A

