BACK TO MY LEARNING

HEMOCUE®

HEMATOLOGY PRODUCT PROFILE

BEGIN COURSE

HemoCue Hematology Product Portfolio

Providing lab-quality and ease of use, the HemoCue Hematology Systems have become a standard in point-of-care testing. Healthcare providers around the world rely on immediate results so they can make the right decisions when they need them most.

HemoCue hemoglobin systems are used in various clinical settings, including general anemia screening, assessing blood loss in acute settings, and screening blood donors prior to donation. Our hemoglobin products include the HemoCue® Hb 801 System, HemoCue® Hb 201+ System, HemoCue® Hb 201 DM System, HemoCue® Hb 301 System, and HemoCue® Plasma/Low Hb System.

The HemoCue® WBC System provides the quantitative analysis of total white blood cell counts in about three minutes. When a patient presents with suspected infection or acute nonspecific fever, every minute can make a difference. In combination with a careful clinical assessment, this simple point of care test during the patient consultation provides critical information to support clinical decision-making and more effective treatment.

The following pages detail each of our primary test systems providing information on intended use and system specifications.

CONTINUE

HemoCue® Hb 801 System

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HemoCue® Hb 801 System Intended Use

The HemoCue® Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K2EDTA and Li-Heparin) in point-of-care settings*. The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1-month-old. The HemoCue® Hb 801 System is for professional in vitro diagnostic use only.

The HemoCue® Hb 801 System consists of an analyzer together with microcuvettes. The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO2 isosbestic point.

*Primary Care

CONTINUE

HemoCue® Hb 801 System Specifications*

- Measuring range: 1.0–25.6 g/dL
- Measuring time: < 1 second
- Sample material: Capillary or venous whole blood
- Sample volume: 10 µL
- Operating temperature: 50-104 °F (10-40 °C)
- Dimensions: 3.4x5.6x1.8 in (87x143x45 mm)
- Weight (batteries excluded): 0.55 lbs
- QC: Built-in self-test, optional liquid controls**
- Power supply alternatives:
  - USB cable and power adapter, connected to an electrical outlet or direct to a computer
  - Disposable or rechargeable AA batteries
  - HemoCue rechargeable battery (sold as an accessory)

* Operating Manual: Article # 901912 190204 US
** Refer to your local or regulatory agency for any external control requirements

HemoCue® Hb 801 Microcuvettes

- The microcuvette serves as pipette, test tube and measuring vessel
- "Let-go-grip" simply insert and release directly, no need to hold during measurement
- The microvettes are large, allowing better grip and can be inserted either way in the microcuvette holder
- Packaged in vials: 4 x 50 microcuvettes

Storage
-Store the microcuvettes in 50-104 °F (10-40 °C)

Stability
-Microcuvettes in the vial (opened or unopened) are stable until the expiration date, printed on the package

Sample Material
-Capillary or venous whole blood*
-Anticoagulant e.g. K2EDTA or Li-Heparin

Running a Test
-Test must be started within 40 seconds of filling the microcuvette

* Currently no tests performed with arterial blood

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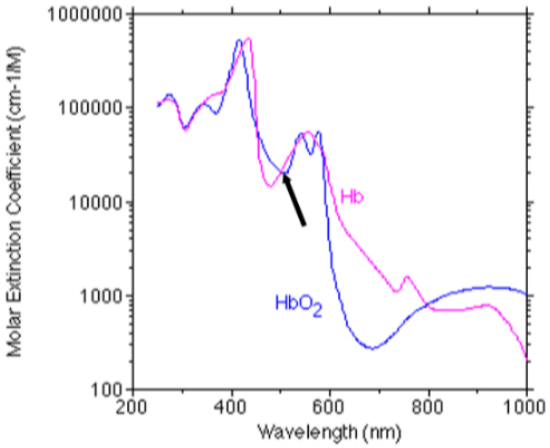
HemoCue® Hb 801 System Measuring Principle



Measurement of whole blood at a Hb/HbO2 isosbestic point. The HemoCue® Hb 801 System has an optical way to measure through the red cells (erythrocytes) and a special algorithm to calculate the hemoglobin concentration.

Traceable to the international reference method for hemoglobin determination (ICSH).

Hb/HbO2 isosbestic point
Normally, nearly all hemoglobin is present as oxyhemoglobin (HbO2) and deoxyhemoglobin (Hb).

A cross-over point in the absorption spectra of two substances is called an isosbestic point and Hb 801 measures Hb/HbO2 at the isosbestic point at 506 nm.

References:

Hoxter, G. "Suggested Isosbestic Wavelength Calibration in Clinical Analyses." *Clinical Chemistry*, vol. 25, no. 1, 1979, pp. 143–146.

Sanjeev, R., Jagannadham, V., and Veda Vrath, R. "Implications of a novel interpretation of the isosbestic point." *Chemistry in New Zealand,* 2012, pp. 133-135.

HemoCue® Hb 801 System Measuring Principle

The HemoCue® Hb 801 Analyzer has an internal quality control, the "self-test".

The self-test automatically verifies the performance of the analyzer every time the analyzer is turned on when the cuvette holder is put back into place after removal, and every hour when in use.

If an external quality control is required by local or other regulations, only use controls recommended by HemoCue.

HemoTrol Duo Control (manufactured by Eurotrol B.V.)*

Formulated from purified bovine hemolysate and is an assayed hemoglobin control intended for use in the verification of the precision and accuracy of the HemoCue® Hb 801 System.

Features a **9-month-**closed-vial stability (from date of manufacturer, refrigerated; 35.6-46.4 °F (2-8 °C)) and a 31-day-open-vial stability (refrigerated/room temperature; 35.6-86 °F (2-30 °C)).

Available in three ranges: low, normal and high:

- Low ~ 6.7 – 7.3 g/dL
- Normal ~ 12.7 – 13.3 g/dL
- High ~ 16.7 – 17.3 g/dL

Packed in 2 x 1.0 mL plastic vials

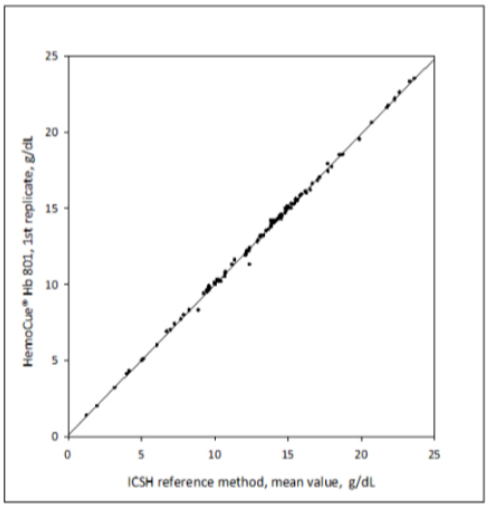
*Eurotrol IFU #s: ANO1624A01, ANO1624A02, ANO1624A03

HemoCue® Hb 801 System Measuring Principle

The HemoCue® Hb 801 System is calibrated against the international reference method for hemoglobin determination (HiCN by ICSH).

This assures that the system will give a lab-quality result when used correctly.

The system is factory calibrated and needs no further calibration.



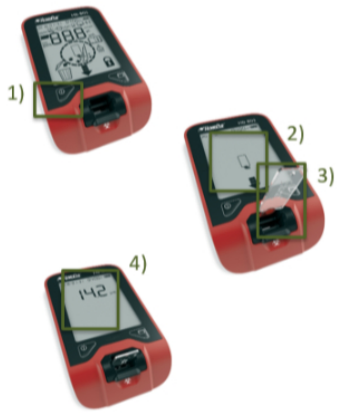
*Graph: Each point on the diagram represents an actual hemoglobin test result. The closer to the line, the more closely related the result is to the "gold standard" reference method.**

** HemoCue® Hb 801 System V&V Graphs, Figure 2. HemoCue® Hb 801 System vs ICSH, venous blood samples; HCAB:000020941[2]*

HemoCue® Hb 801 System How to Use

Performing a Patient Test

1. Press and hold on/off button until all display segments are displayed.
2. Release, and wait a few seconds until the analyzer is in Ready State (display of a microcuvette and an arrow towards the cuvette holder).
3. Fill a microcuvette with sample and insert into the microcuvette holder (within 40 s) and press down. The result will be displayed within a second.
4. When a result is displayed, remove and discard the microcuvette.



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HemoCue® Hb 801 Analyzer Cleaning and Disinfection Materials

Cleaning is an important step to prepare for an efficient disinfection. The analyzer should be cleaned and disinfected on a regular basis.

- Cleaning agents: water, alcohol (20-70%), mild detergent, or recommended disinfectant
- Disinfectants: only use disinfectants recommended by HemoCue -Refer to Operating Manual; Super-Sani-Cloth Germicidal Disposable Wipes

HemoCue® Hb 801 Analyzer Cleaning

Follow this procedure to first clean and then disinfect the analyzer. Cleaning is an important step to prepare for an efficient disinfection.

Cleaning agents: water, alcohol (20–70 %), mild detergent, or recommended disinfectant.

Disinfectant: Super Sani-Cloth Germicidal Disposable Wipe, EPA Reg. No. 9480-4.

Only use disinfectant recommended by HemoCue. Read and follow instructions for the disinfectant used.

⚠ Precaution:

- Make sure to clean and disinfect the analyzer on a regular basis.

Cleaning

1. Turn off the analyzer, and remove the microcuvette holder.

2. Lightly dampen a cotton swab with cleaning agent. Clean all surfaces in the cavity; make sure to clean all the way down.

3. Clean the microcuvette holder with cleaning agent.

   Let the microcuvette holder dry outside of the analyzer, while moving on to step 4.

4. Lightly dampen a wipe with cleaning agent, and clean all outer surfaces.
   Now the analyzer is ready for disinfection. Follow steps 5-8 to disinfect.

   If no disinfection is needed, make sure all parts are completely dry before reattaching the microcuvette holder.

HemoCue® Hb 801 Analyzer Disinfection

Before disinfection, the analyzer must be cleaned.

1. Wipe the microcuvette holder repeatedly with a new Super Sani-Cloth Germicidal Disposable Wipe. Make sure that all surfaces stay wet for 2 minutes.
2. Wipe all outer surfaces repeatedly with a Super Sani-Cloth Germicidal Disposable Wipe. Make sure that all surfaces stay wet for 2 minutes.
3. Make sure that the surfaces in steps 1 and 2 have been wiped repeatedly in order to stay wet for the whole 2 minutes (wet-time/contact time).
4. Remove any excess disinfectant, or allow to air dry. Make sure all parts are completely dry before reattaching the microcuvette holder and turning on the analyzer.

1) 

2) 

3) 

4) 

HemoCue® Hb 201+ System

The HemoCue® Hb 201+ System is a widely used point-of-care test for detecting anemia.

The HemoCue® Hb 201+ System is a widely used hemoglobin point of care test system in the world. The system consists of two primary components, the HemoCue® Hb 201+ Analyzer, which is a dual-wavelength spectrophotometer, and the HemoCue® Hb 201 Microcuvettes. The microcuvette automatically collects a precise amount of blood, which is placed into the analyzer for measurement.

CONTINUE

HemoCue® Hb 201+ System

Intended Use: Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

The "Intended Use" of any medical device may be found in the system's package insert. The package insert for the HemoCue® Hb 201+ System is included with each new box of microcuvettes.

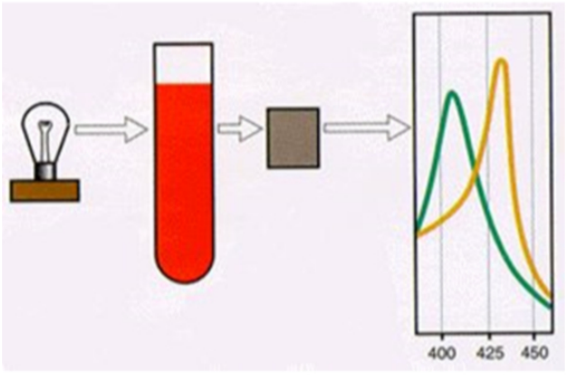
The purpose of the package insert is to detail the specific approved uses of the product based on its FDA submission and clearance. It is important to note that no claims about product use can be made that are not indicated in the product's package insert. Be sure to read and understand the information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

Hemoglobin concentration is commonly used to detect anemia, identify bleeding, and manage red blood cell transfusions. Anemia can be developed as a result of acute or chronic blood loss, due to nutritional deficiencies or infections, or due to inherited disorders (e.g. thalassemia and sickle cell disease). Anemia can also be a result of an increased demand for red cells (e.g. during pregnancy).*

**WHO 2001, the clinical use of blood in Medicine, Obstetrics, Paediatrics, Surgery & Anaesthesia, Trauma & Burns*

CONTINUE

HemoCue® Hb 201+ System Specifications



The HemoCue® Hb 201+ System includes the following primary specifications:

Spectrophotometry: The system measures through the use of Spectrophotometry which is a method to measure how much a chemical substance absorbs light by measuring the intensity of light as a beam of light passes through sample solution. The basic principle is that each compound absorbs or transmits light over a certain range of wavelength. So, if the wavelength(s) of a specific substance are known, specific wavelengths of light can be used to measure that substance. The HemoCue® Hb 201+ System measures hemoglobin at two wavelengths, 570 and 880 nm (nanometers).

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 optics system is functioning properly. The self-test is performed each time the analyzer is turned on and every two hours that the analyzer is in use.

Audio Signal: A "beep" sounds for various functions in the analyzer such as when a test result is complete or when an error occurs. This audio signal can be turned on or off by the end-user as desired.

Measuring Range: The measuring range is the range in which the system will provide a result. Anything greater than the measuring range will display HHH. The measuring range for the HemoCue® Hb 201+ Analyzer is 0-25.6 g/dL (grams per deciliter).

Measuring Time: The time to result for the HemoCue® Hb 201+ Analyzer is within 60 seconds.

HemoCue® Hb 201 Microcuvettes

The HemoCue® Hb 201 Microcuvette is the primary device used to collect the sample and transform the sample into something that can be measured by the HemoCue® Hb 201+ Analyzer. The microcuvette holds a sample size of 10 microliters (ul) and must be measured within 10 minutes of filling.

Microcuvettes are available in vials or individual packages. Customers can purchase microcuvettes in two formats: a box of 4 vials of 50 microcuvettes each (200 total tests), or a package of 4 boxes of 25 individually wrapped microcuvettes each (100 total tests).

Microcuvettes are to be stored at room temperature and always used prior to their expiration date which is printed on the vial along with a lot number or on the individually wrapped microcuvette. Once the seal on the vial is broken, the cuvettes are stable for 3 months. Always keep the vial properly closed. It is also recommended that the date of opening and expiration be written on the vial. Individually wrapped cuvettes have an expiry date imprinted on each cuvette.

Be sure to only use HemoCue® Hb 201 Microcuvettes with the HemoCue® Hb 201+ Analyzer.

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HemoCue® Hb 201 Microcuvettes

Ready to use: HemoCue's unique microcuvette technology ensures that hemoglobin tests are ready to use when needed. Each microcuvette contains customized reagents with no additional components needed.

Convenient packaging: Microcuvettes are available in individually wrapped and multipack vial formats, offering flexibility to optimize shelf life.

Simple microcuvette packaging: The design of the microcuvette means that it is 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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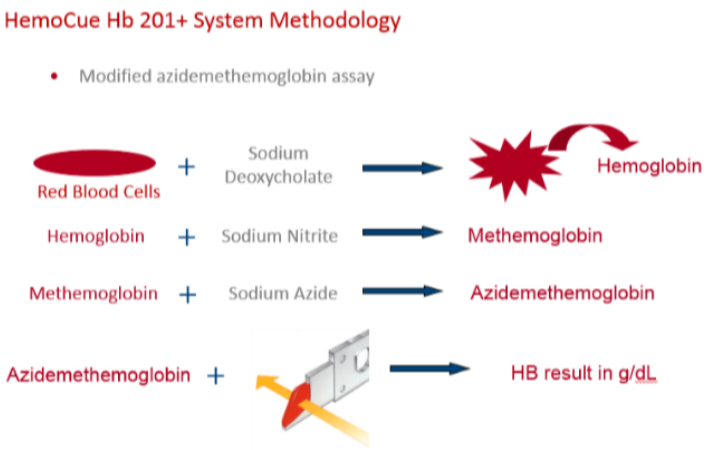
HemoCue® Hb 201+ System Methodology



The methodology performed in each HemoCue® Hb 201 Microcuvette is called a Modified Azidemethemoglobin Assay. This simply means that the chemical reagents already in the microcuvette react with the blood sample to transform it into something that can be measured spectrophotometrically.

The steps listed in the slide above are as follows:

1. The blood enters the microcuvette and mixes with sodium deoxycholate, which is a detergent. When the detergent mixes with the red blood cells, the red blood cells are hemolized (broken apart) releasing all of the hemoglobin into the cuvette chamber.
2. Next, a chemical called sodium nitrite reacts with each hemoglobin molecule forming Methemoglobin.
3. Next, the methemoglobin reacts with Sodium Azide forming Azidemethemoglobin which can be measured at known wavelengths of light – 560 and 880 nm.
4. Finally, the azidemethemoglobin is measure in the HemoCue® Hb 201+ Analyzer at these two wavelengths and a result is provided in g/dL.

HemoCue® Hb 201 DM System

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

The HemoCue® Hb 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® Hb 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

HemoCue® Hb 201 DM System

The HemoCue® Hb 201 DM Analyzer 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® Hb 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 and 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® Hb 201 DM Analyzer can be used for approximately 100 hours.

HemoCue® Hb 201 DM System

The basic functionality of the HemoCue® Hb 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.

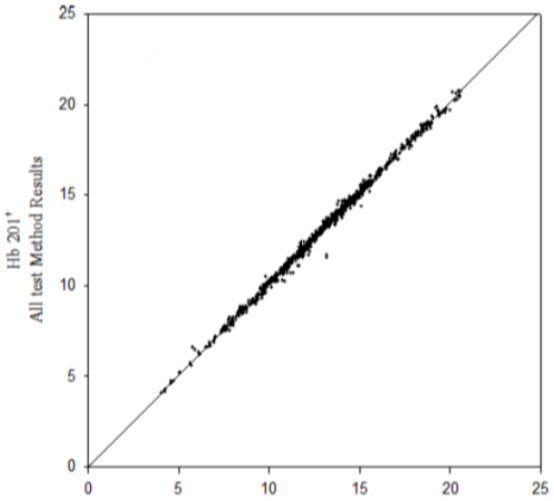
Patient ID: Captures the specific patient ID in order to tie the test result to the specific patient record.

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® Hb 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® Hb 201 DM System has numerous software options for the management of the system. These include The HemoCue® Hb DM 201 Software and various 3rd Party connectivity solutions. The standard HemoCue® Hb 201+ System also has a connectivity software solution 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.

HemoCue® Hb 201+ System Calibration



Method comparison according to CLSI EP9-A. HemoCue® Hb 201+ System vs ICSH, venous blood samples, g/dL.*

**Method Comparison and Bias Estimation using patient samples acording to NCCLS EP-9 for Hb 201+ versus ICSH (A^{540}-A^{700}), Site A-D, Multicenter Study (FRE0807/1).*

Both the HemoCue® Hb 201+ System and the HemoCue® Hb 201 DM System are factory calibrated and require no additional calibration by the customer. All HemoCue products are calibrated to the international reference method called the ICSH or Isotope Dilution Mass Chromatography Gas Spectrometry method. Since all Hb systems worldwide are calibrated to this same standard, it is simple to demonstrate the accuracy and precision of the HemoCue Hb systems when performing side by side correlation studies.

The chart above is a simple graph demonstrated the correlation between the HemoCue® Hb 201+ System and the ICSH Methods.

CONTINUE

HemoCue Hb 201+ System Quality Control

As discussed earlier, the HemoCue® Hb 201+ System and HemoCue® Hb 201 DM System both have the internal self-test feature built-in to the system. No tests can be run unless the system passes this self-test. This feature is a unique differentiator from some of our competitors.

Some customers will require additional liquid control to meet local, state or other regulatory guidelines. Although HemoCue only requires the self-test functionality 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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HemoCue® Hb 301 System

Intended Use: Quantitative whole blood hemoglobin determination in primary care or blood donation settings.

The HemoCue® Hb 301 System is a separate product for the Blood Donor and Public Health market. It may only be sold to these customers. Currently, the HemoCue® Hb 301 is only sold by the KAR organization (Key Account Representative) and therefore is not detailed in this pre-read document. Should a customer request information on this product, please consult with your National Sales Manager.

CONTINUE

HemoCue® Hb 301 Analyzer Maintenance

- No preventative maintenance, other than cleaning, is needed for the electronic components of the photometer
- Clean the microcuvette holder each day of use, or more frequently if needed, using alcohol or mild detergent. Dry the holder completely before re-inserting into the photometer
- Dirty optronic unit (displayed error code) should be cleaned with the HemoCue® Cleaner

CONTINUE

HemoCue® Plasma/Low Hb System

Intended Use: For the quantitative determination of low levels of hemoglobin in plasma and serum specimens, aqueous solutions, or stored or banked erythrocytes.

The HemoCue® Plasma/Low Hb System is also a unique product sold only by the KAR organization. This test system measures low levels of hemoglobin in plasma, serum, aqueous solutions or measurement of stored blood. Be aware of this product but if you have any customer inquiries, please consult your National Sales Manager.

CONTINUE

HemoCue's Hb Portfolio

	HemoCue® Hb 801 Analyzer	HemoCue® Hb 201+ Analyzer	HemoCue® Hb 201 DM Analyzer	HemoCue® Hb 301 Analyzer	HemoCue® Plasma/Low Hb Analyzer
					
Methodology	Isosbestic Point	Azide methemoglobin	Azide methemoglobin	Isosbestic Point	Azide methemoglobin
Positioning	Physician Office	Physician Office	Hospital Select Physician	Blood Center	Blood Center Hospital
Range	1.0-25.6 g/dL	0-25.6 g/dL	0-25.6 g/dL	0-25.6 g/dL	0-3000 mg/dL
Sample volume	10 µL	10 µL	10 µL	10 µL	20 µL
Measurement within	40 seconds	10 minutes	10 minutes	40 seconds	5 minutes
Measuring time	<1 second	<60 seconds	<60 seconds	~3 seconds	<60 seconds
Temperature/humidity	Wider temperature and humidity range	No	No	Wider temperature and humidity range	No
Interferences	Extremely high levels of conjugated bilirubin (> 350 µmol/L)	No*	No*	Extremely high levels of conjugated bilirubin (> 350 µmol/L)	High turbidity

*No interference found at concentrations of the substances tested.

The above chart details the specific methodology, positioning and other specifications for each of the five primary hemoglobin systems.

References:

HemoCue® Hb 801 Operating Manual 901912 190204 US
HemoCue® Hb 201+ Operating Manual 901702 180926
HemoCue® Hb 201 DM Operating Manual 901114 180411
HemoCue® Hb 301 Operating Manual901801 181205 EN/US
HemoCue® Plasma/Low Hb Operating Manual 900326 181122

HemoCue® WBC System

Intended Use: Designed for the quantitative determination of white blood cell count in venous or capillary blood. The system is indicated for use in clinical laboratories and for point-of-care settings.

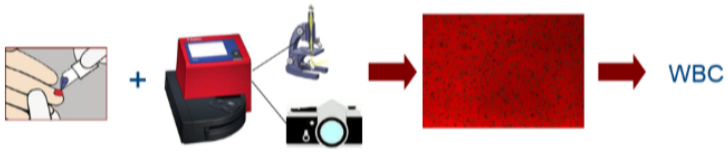
The HemoCue® WBC System has been found to be a niche product for certain physician offices and hospitals. The HemoCue® WBC System provides a lab-quality, total white blood cell count in under three minutes. A low or normal white blood cell (WBC) count is usually associated with viral illnesses*, and results can quickly aid in deciding on further tests and evaluation.

The system is based on a single-use microcuvette and an analyzer. Unlike our other test systems that utilize spectrophotometry, the HemoCue® WBC Analyzer contains a camera, microscope and image analysis software which work together to photograph and then count the total number of white cells in the blood sample.

The biggest challenge to date with the success of the product has been the inability of HemoCue to get CLIA-waived certification for the product. A CLIA-waiver is required for a large majority of the physician office labs (POLs) to be able to use the system for testing. Only a small percentage of POLs have the proper licensing to do testing that is not CLIA-waived thus limiting our potential market for this product.

**Casey JR, Pichichero ME. A comparison of 2 white blood cell count devices to aid judicious antibiotic prescribing. Clin Pediatr. 2009; 48:291-294.*

HemoCue® WBC System Methodology



The HemoCue® WBC System methodology is based on a microcuvette and the analyzer.

1. When the microcuvette is filled with blood, a hemolysing agent will lyse (break apart the red cells) and a staining agent (methylene blue) will then stain the white cells.
2. Once the microcuvette is placed in the analyzer, an image is taken by the microscope and camera of the sample with the stained white cells clearly visible. The image is then analyzed by software in the analyzer which counts and analyzes the stained cells. When done, a result is displayed on the screen.

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HemoCue® WBC Microcuvettes

The HemoCue® WBC Microcuvette requires a blood sample of 10 microliters. Microcuvettes should be stored at room temperature and are stable for 10 months from manufacture date and 3 months once opened. When opening a vial of the microcuvettes be sure to write the opened on and expiry dates on the vial where indicated.

The microcuvettes come in vials of 40 with 4 vials contained in a box (160 tests).

CONTINUE

HemoCue® WBC System Specifications*

- Measuring range: 0.3-30.0 x 10^9/L
- Measure cuvette within 40 seconds of filling
- Measuring time: <3 minutes
- Sample material: Capillary or venous blood
- Sample volume: 10 microliters
- Quality control: Built-in self-test
- Communication: RS 232 (printer)
- Dimensions: 7.28 x 5.24 x 4.72 inches
- Weight: 1.32 pounds (including batteries)
- Power supply: 6 AA batteries or adapter

*HemoCue® WBC System Operating Manual 903007 190129

HemoCue® WBC System Maintenance

The HemoCue® WBC System requires no preventative maintenance, only 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 Plus should be used. Note that the HemoCue® Cleaner Plus is distinct from the standard HemoCue® Cleaner.

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WBC Quality Control System

The analyzer has an internal quality control, the "self-test". Every time the analyzer is turned on, it will automatically verify the measurement performance. When passing the self-test, the display will show the HemoCue symbol and three flashing dashes, indicating that the analyzer is ready to perform a measurement. In addition, during each measurement, the analyzer, the microcuvette and the sample itself are automatically checked to guarantee optimal performance. An error code will be displayed if any of the QC checks fails.

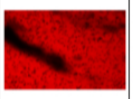
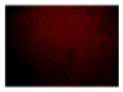
No additional quality controls are required for verification of the system functionality. Due to not having CLIA waiver, testing of 2 levels of external controls is required when testing patients.

CONTINUE

WBC Quality Control System - Internal

1. At power-up (the "self-test"):
   Test of electronics and software
   Blanking test (quality of light, check for dirt in the optics)
2. Between samples:
   Blanking test – ensures that the system does not detect any images when the analyzer is empty.

During each measurement the following checks are performed:

Detection	Image	Built-in QC System Action
Bad area - Dirt or scratches on microcuvette - Blood smear outside microcuvette - Microcuvette not filled with sample - Microcuvette not completely filled		When the background is similar to the color of stained white cells, the area is eliminated from counting. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Out of focus - Condensation on optical parts - Incorrect microcuvette position - Rough maintenance of optical parts - Abrupt movement of analyzer		If the cells are not sufficiently sharp, the area is eliminated from counting. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Air bubble - Incorrect filling of microcuvette - Microcuvette not completely filled - Incorrect storage of microcuvette		When an air bubble is detected, the bubble and the area around it are eliminated from counting because of inaccurate distribution of cells. If the eliminated area is too large, the sample is rejected and an error code is displayed.
Poor light intensity - Optical parts dirty or scratched - Poor maintenance of optical parts - Malfunctioning of LEDs		When the measuring area is so dark that the light adjustment cannot compensate to detect the cells correctly, the sample is rejected and an error code is displayed.
Bad cell distribution - Non-homogenous sample - No even cell distribution		The image is divided into sub-parts and when the counted number of cells differs significantly in any of the parts, the sample is rejected and an error code is displayed.

Technical Letter No. 24

WBC Quality Control - External

R&D Systems HC WBC Hematology Control

- 510(k) cleared
- 3 levels
  - one bottle of each level per box
  - 2 mL in each bottle
  - Level 1:~3 x 10^9/L
  - Level 2:~8 x 10^9/L
  - Level 3:~22 x 10^9/L
- Stability:
  - refrigerated, unopened 105 days
  - refrigerated, opened 30 days

CONTINUE

Summary - Why Choose HemoCue?

HemoCue's systems are being used every day by health care professionals all over the world.

Key features:

- Easy to use - can be used by non-laboratory personnel after a brief training session (except for HemoCue® WBC System and HemoCue® Plasma/Low Hb System which require laboratory personnel)
- Produce lab-quality results within moments
- The disposable microcuvette automatically draws a precise, small volume of blood
- The analyzers are factory calibrated and require a minimum of maintenance
- No calibration needed between cuvette batches
- Portable and battery operated

CONTINUE