

HemoCue® Hb 801 System



Innovation at its best from the pioneers in Hb testing

With the introduction of HemoCue® Hb 801 System we are taking the Hb point-of-care testing to a new level. The system is designed with your needs in mind, maintaining the robustness and quality you expect from HemoCue products. It provides ease of use and enables work flow efficiency with connectivity options delivering fast result at the time of care.

HemoCue® Hb 801 System is optimized for hemoglobin testing in hospital, primary care, public health and road ambulance settings.* The system provides quick, easy access to lab-quality results without compromising accuracy, even in demanding climates with high temperatures and humidity.

S1

Maximize Time with Your Patients

- ▶ Immediate result in less than 1 second
- ▶ Work everywhere with flexible power supply options
- ▶ Easy to clean - less down time

Experience Daily Operational Efficiency

- ▶ Large display and symbols allow you to quickly monitor workflow and result
- ▶ "Let-go-grip" - no need to keep holding the microcuvette down during measurement
- ▶ Vendor-neutral connectivity offers flexibility for e.g. data transfer

Trust Your Results at the Point of Care

- ▶ Factory calibrated against the ICSH recommended reference method. No further calibration needed
- ▶ Robust design and accurate testing within a wide range of temperatures and humidity
- ▶ Built in self-test

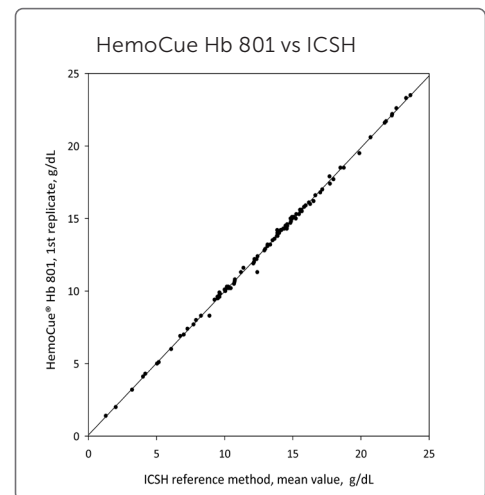
To learn more about the HemoCue® Hb 801 System, visit hemocue.com

* Hospital and road ambulance settings only for markets where EU IVDD CE mark is applicable

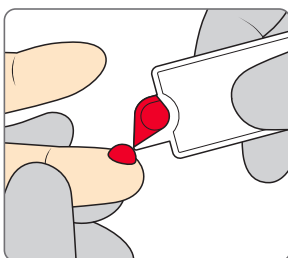


HemoCue® Hb 801 System

<p>Principle</p> <p>S2</p> <p>S9 Calibration</p> <p>S6 Sample Material</p> <p>S5 Measurement Range</p> <p>S8 Measuring Time</p> <p>S7 Sample Volume</p> <p>Dimensions</p> <p>Weight</p> <p>Storage Temp.</p> <p>Operating Temp.</p> <p>S14 Power</p> <p>S13 Interface</p> <p>S10 Quality Control</p>	<p>The HemoCue® Hb 801 System consists of an analyzer together with microcuvettes. Blood is drawn into the microcuvette cavity by capillary action. The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/HbO₂ isosbestic point.</p> <p>The HemoCue® Hb 801 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method recommended by ICSH, for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration.</p> <p>Capillary or venous whole blood</p> <p>1.0-25.6 g/dL (10-256 g/L, 0.62-15.9 mmol/L)</p> <p>< 1 sec</p> <p>10 µL</p> <p>143x87x45 mm (5.6x3.4x1.8 in)</p> <p>< 250 g (0.55 lbs), batteries excluded</p> <p>Analyzer: 0-50 °C (32-122 °F) Microcuvettes: 10-40 °C (50-104 °F). Opened or unopened vials of microcuvettes can be stored for a shorter period of time (6 weeks) between -18-50 °C (0-122 °F).</p> <p>10-40 °C (50-104 °F)</p> <p>USB adapter or 3 AA batteries (1.5 V Alkaline or 1.2 V NiMH). Optional: HemoCue Rechargeable battery</p> <p>USB and Bluetooth Low Energy Vendor-neutral connectivity</p> <p>Built-in self-test, optional liquid controls</p>
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Three Simple Steps



1 Fill microcuvette.



2 Place microcuvette into analyzer.



3 View results.

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HemoCue has been a leader in point-of-care medical diagnostics for over 35 years. We specialize in giving healthcare providers lab-quality results comparable to that of a clinical lab.



HemoCue® Hb 801 Microcuvettes, 4x50 Microcuvettes

HemoCue Hb 801 System consists of HemoCue Hb 801 Analyzer and HemoCue Hb 801 Microcuvettes.

Read and follow this package insert together with the operating manual (provided with the analyzer), for optimum performance and safety. For more information, contact the local distributor or HemoCue America.

Only use HemoCue Hb 801 Analyzer together with HemoCue Hb 801 Microcuvettes.

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.

IVD Medical Device Directive

The HemoCue Hb 801 Microcuvettes comply with the IVD Medical Device Directive 98/79/EC and carry the CE mark.

Composition

The microcuvettes are made of polystyrene plastic, and contain no active ingredients.

Precautions

Always wear protective gloves. Handle blood with care, as it may be infectious. Follow local safety procedures for disposal of used microcuvettes.

HemoCue Hb 801 Microcuvettes are for single use only.

For system information regarding precautions, read the operating manual.

Storage and Handling

Store the microcuvettes in 10–40 °C (50–104 °F). Microcuvettes in the vial (opened or unopened) are stable until expiration date, printed on the package. Use the microcuvettes prior to expiration date.

Microcuvettes in the vial (opened or unopened) can be stored for a shorter period of time (6 weeks) between -18–50 °C (0–122 °F).

Keep all unused microcuvettes in the original package.

Measuring

Operating temperature for HemoCue Hb 801 System is 10–40 °C (50–104 °F).

For proper use of the system, read the operating manual regarding measuring capillary and venous samples, measuring control material, cleaning and disinfection, principle of method, and technical specifications.

Make sure the microcuvette is completely filled before measuring.

Immediately after filling, insert the microcuvette into the analyzer to perform a measurement. Do not let more than 40 seconds pass.

Quality Control

The HemoCue Hb 801 Analyzer has an internal quality control, a self-test. For more information, read the operating manual. If an external quality control is required by local or other regulations, use quality control material: Eurotrol HemoTrol® Duo or Eurotrol HemoTrol® WB. Only use controls recommended by HemoCue.

Declaration of Conformity

Manufacturer Eurotrol B.V.
Keplerlaan 20
6716BS Ede
The Netherlands
(+31)0318695777

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product(s)	REF Number	Name	Intended Use
S10	AN01637A01	HemoTrol® Duo Low	HemoTrol® Duo is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue® Hb 301 and <u>HemoCue® Hb 801 System</u> . HemoTrol® Duo is intended for the quantitative determination of hemoglobin.
	AN01637A02	HemoTrol® Duo Normal	
	AN01637A03	HemoTrol® Duo High	

Means of conformity The product(s) of the declaration described above is/are in conformity with the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and the transitional provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as amended by Regulation (EU) 2022/112.

Classification Other in-vitro medical devices (Article 9(1) of Directive 98/79/EC), handled as Class C device with regards to the transitional provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as amended by Regulation (EU) 2022/112.

Method of Assessment Conformity assessment according to Annex III of Directive 98/79/EC.

References The product(s) of the declaration described above is/are manufactured according to procedures which meet EN-ISO 13485:2016.

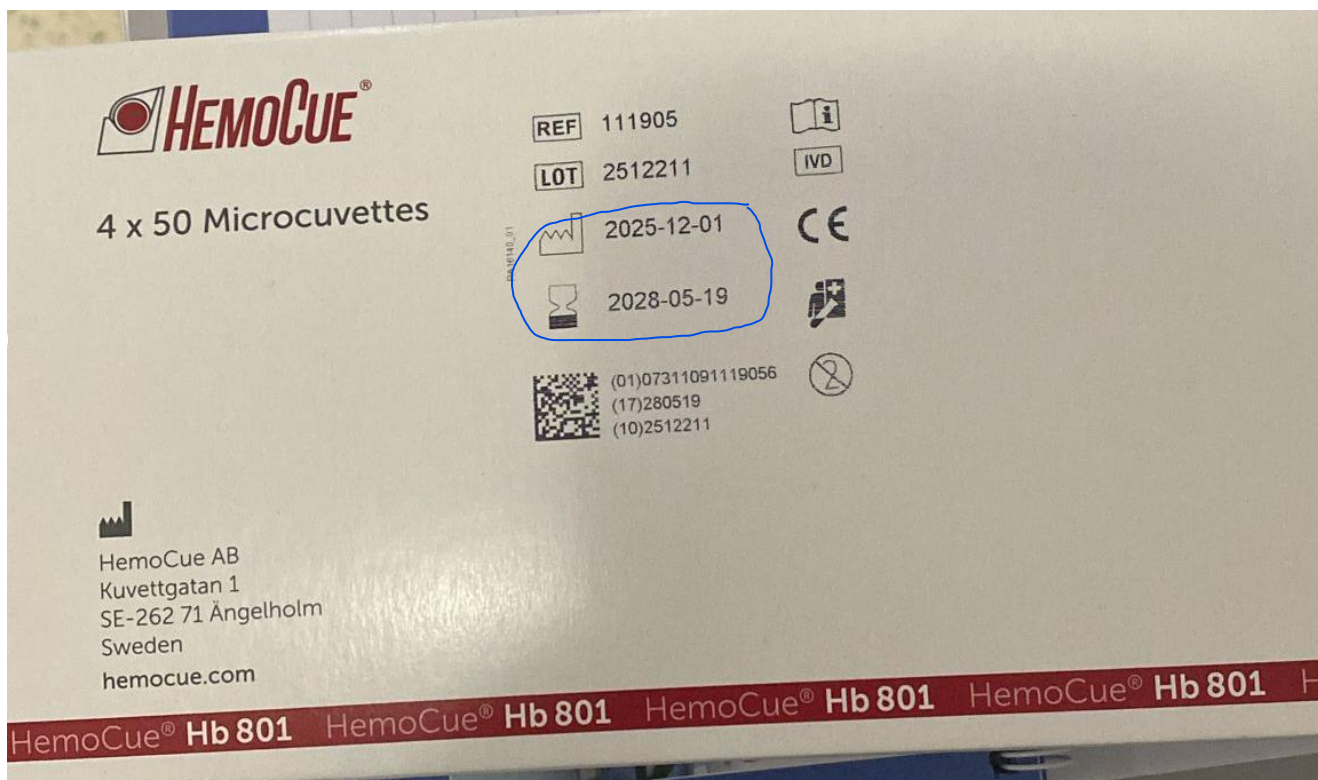
Valid until 2027-05-26

Declared by Place and date: Ede,
Name and function: D. Philippens, QA/RA Director
Signature:





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Poze produs pag. 1

S1.1 1 HemoCue® Hb 801 System

The HemoCue Hb 801 System consists of a HemoCue Hb 801 Analyzer and HemoCue Hb 801 Microcuvettes. Read and follow this operating manual together with the package insert (provided with the microcuvettes), for optimum performance and safety. For more information, contact the local distributor or HemoCue AB.

Only use the HemoCue Hb 801 Analyzer together with HemoCue Hb 801 Microcuvettes. Use the microcuvettes prior to expiration date.



Precaution:

- To achieve accurate capillary sampling results, always follow the procedure in this operating manual.
- Make sure to read and follow Hb 801 Microcuvettes package insert regarding system limitations, including interfering substances.

Intended Use

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The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood in point-of-care and blood donation settings. The HemoCue Hb 801 System is for professional *in vitro* diagnostic use only.

Warranty

The analyzer carries a 24-month warranty from the day of receipt. Any other use of the system than recommended by the manufacturer, including opening the cover of the analyzer, will void the warranty.

Service and Disposal

Consult local environmental authorities for proper disposal. Clean and disinfect the analyzer prior to service and disposal.

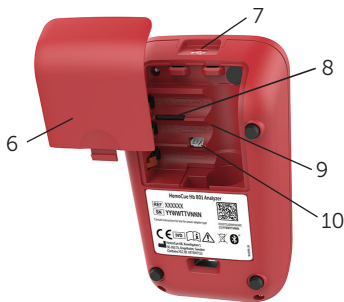
2 Components/Analyzer Overview

HemoCue Hb 801 Analyzer

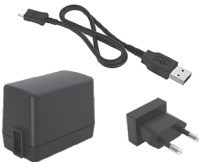


S11

1. display
2. on/off button (left button)
3. previous results button (right button)
4. microcuvette holder
5. LED indicator



6. battery cover
7. USB port (power supply and connectivity)
8. connector only for use by HemoCue technical personnel
9. battery compartment
10. connector for HemoCue Rechargeable Battery



USB cable

power adapter

power plug



HemoCue Hb 801
Operating Manual

HemoCue Hb 801
Quick Reference
Guide

- Materials required, but not provided: HemoCue Hb 801 Microcuvettes, protective gloves, lint-free wipe, disinfectant, high-flow lancet (for capillary samples), pipette or other transfer device (for venous samples), hydrophobic surface (for venous samples)
- Spare parts: battery cover, microcuvette holder, power adapter, USB cable, plug
- Optional items: HemoCue software applications

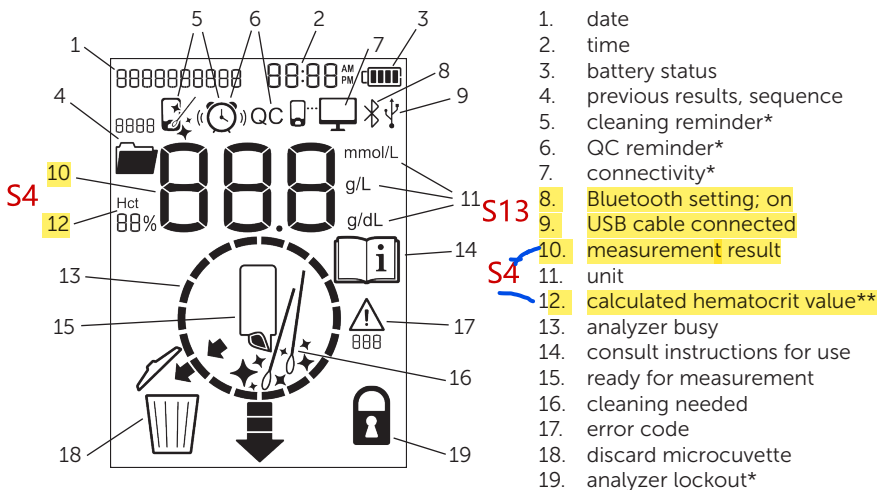
LED Indicator and Audio Signal

Scenario	Analyzer Reaction
successful measurement	green flash + audio*
self-test ongoing	green flash
error (see section 15)	red flash + audio*

* To change audio setting, see section 14.

S11 3 Display Overview

The display during start-up, when all display segments are lit:






* See section 14.

** Depending on ordered features or extra settings (see section 14), the calculated hematocrit value may be presented on the display when the result is within the range of 12.0–18.0 g/dL (120–180 g/L, 7.4–11.2 mmol/L). The calculation factor is 2.94 (g/dL). For results outside the range, the display shows --%.

Display Animations

Animations appearing in normal conditions:

 <p>Ready State Starting position for most actions.</p>	 <p>Busy State The analyzer has work in progress. If continuously busy, see section 15.</p>
 <p>Always discard the microcuvette when a result is displayed. If forgotten, this animation appears on the display. If the animation appears together with an error code or another symbol, see section 15 for actions.</p>	

S10 11 Quality Control

The HemoCue Hb 801 Analyzer has an internal quality control, a self-test. It 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. See section 9.

12 Principle of Method

S3 The HemoCue Hb 801 System consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a sample carrier. Blood is drawn into the microcuvette cavity by capillary action. The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/HbO₂ isosbestic point.

S9 The HemoCue Hb 801 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method recommended by ICSH (International Council for Standardization in Haematology), for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration.

13 Previous Results

S12

Follow this procedure to view previous results, or to view previous displays in measurement error scenarios. **The maximum number of previous results are 4000** (to change this setting, see section 14).



1. Make sure the analyzer is in Ready State. Press previous results button to see the latest result.

The most recent result is always sequence number 0001.

After 5 seconds of inactivity, the analyzer automatically exits previous results. If entered again before a new measurement is performed, the display will show the same result as it did before the exit.

2. Press left or right button to scroll between stored results.

For a quick scroll, press and hold.

3. To exit previous results, press both buttons once.

14 Connectivity and External Applications

The analyzer can be connected to external software applications, using either the USB cable, or Bluetooth Low Energy (wireless connection).* This allows for change of certain default features, or transfer of data.

** Software applications are optional items. For more information, contact the local distributor or HemoCue AB.*