



Plasma/Low Hb Photometer Operating Manual



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General



The HemoCue® Plasma/Low Hb system consists of disposable Plasma/Low Hb-microcuvettes containing reagents in dry form and a single purpose designed photometer. The microcuvette is used for measuring the sample, as reaction vessel and as measuring cuvette. No dilution is required. Reading of low hemoglobin concentration takes place in the photometer, which follows the reaction and presents the result only when the reaction has stopped. The photometer is calibrated at the factory against the hemiglobincyanide-(HiCN) method, which is the international reference method for the determination of the total hemoglobin concentration.

The photometer and a transformer (battery eliminator) are delivered in a carton. Open the carton on a stable surface and lift out the photometer and the accessories. The photometer may be powered by batteries. As with all electronic instrumentation, allow the photometer to reach ambient temperature.

Intended Purpose/Intended Use

HemoCue Plasma/Low Hb system is used for quantitative determination of low levels of hemoglobin in plasma and serum specimens, aqueous solutions, or stored or banked erythrocytes using a specially designed photometer, the HemoCue Plasma/Low Hb photometer and specially designed microcuvettes, the HemoCue Plasma/Low Hb microcuvettes. The HemoCue Plasma/Low Hb photometer is only to be used with HemoCue Plasma/Low Hb microcuvettes.

The HemoCue Plasma/Low Hb microcuvettes are for in vitro diagnostic use only.

Installation of the Photometer



At the back of the photometer is a power switch and a connector. Connect the transformer to the "POWER INLET" and to the main power supply. Turn the switch to the "ON" position.



The letters "LHb" should now be seen on the display. If not, check the connections to the photometer and to the main power supply. If the photometer is still not functioning after these checks, turn to "Troubleshooting Guide," page 16.



The cuvette holder, which is used to move the cuvette in and out of the photometer, has three positions: Completely pushed in – measuring position.



Pulled out – loading position.



Completely withdrawn – for cleaning.
(See maintenance section, page 14).

Battery Power

Underneath the photometer there is a lid covering the battery compartment which holds five batteries type R6 or AA.



Place five batteries, type R6 or AA, in the battery compartment observing the indication of polarity in the battery holder. Replace the lid. New batteries can operate continuously for approximately 100—150 hours. If battery powered, batteries can be readily conserved by switching off the photometer between measurements.

NOTE: When going from battery power to main power supply, turn off the photometer, “OFF”, before connecting.

Consult local environmental authorities for proper disposal of batteries.



Checking the Photometer

Pull out the cuvette holder to the loading position. This point, which should not be exceeded, is easily established by paying attention to a distinct stop. The display shows the letters “LHb”.



After approximately 15 seconds the indication “READY” appears on the display together with three flashing dashes. The photometer is ready for measurement.



Use a Plasma/Low Hb Control Solution for checking the photometer.
Fill the cuvette with the Plasma/Low Hb Control Solution (See page 10).
Place the filled cuvette into the cuvette holder and carefully push it into the measuring position.
Slamming the cuvette holder into place with undue force will cause splashing of the sample material onto the optical surfaces.



The display now shows “MEASURING” and three fixed dashes. The photometer is measuring.



In less than one minute the photometer displays the result. Compare this value to the assigned value on the Plasma/Low Hb Control solution vial. If the result is out of range refer to “Troubleshooting Guide”, page 16.



How to Perform a Plasma/Low Hb Determination

Sample material: See page 12.

Turn the switch at the back of the photometer to the position “ON”.

Pull out the holder to the loading position. This is noted by a distinct stop which should not be exceeded. The display shows “LHb” and after 15 seconds “READY” with three flashing dashes.

Take the cuvette out of the container. Hold the cuvette by the rear winged end. Reseal the container immediately.

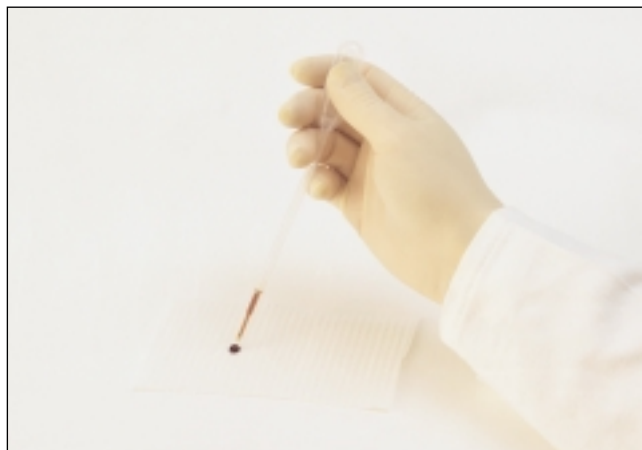
The microcuvettes are to be stored dry at room temperature (15-30 °C, 59-86 °F). Once opened, the microcuvettes are stable for three months, see page 12.



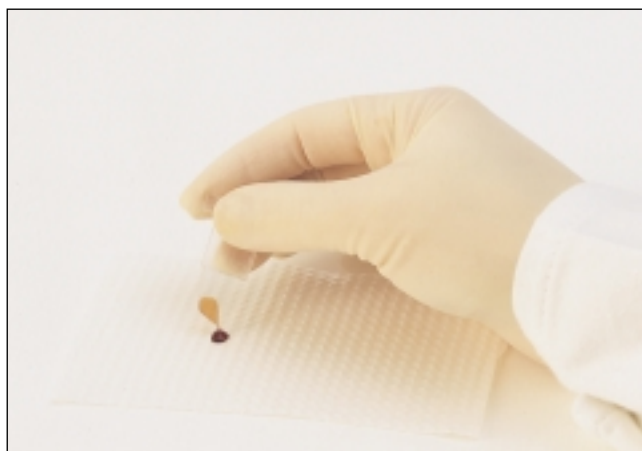
Filling of Cuvettes

Use a pipette to place a large drop of well-mixed sample on a hydrophobic surface, for example a piece of plastic film. The cuvette can be filled directly from a tube if the tube is not to be used for further analyses.

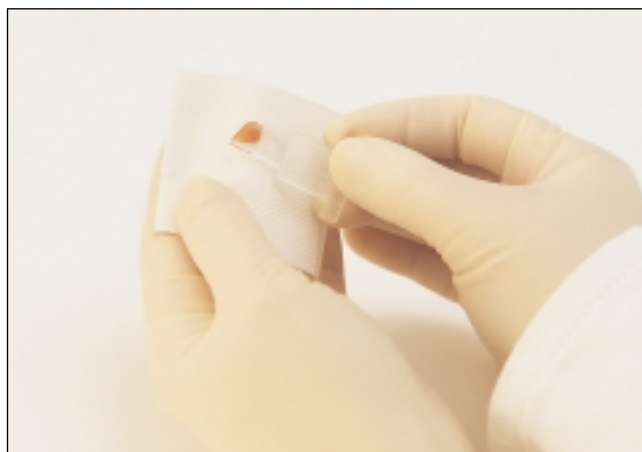
Visually turbid samples should be filtered before analysis using a 0.2 μm filter.



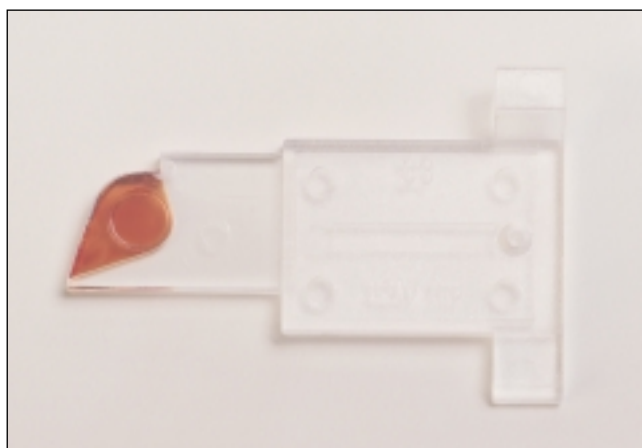
Introduce the cuvette into the middle of the drop in such a way that the cuvette is filled in one step. It should never be topped up.



Using laboratory tissue, carefully wipe off the excess sample on the outside of the cuvette. Make sure that no sample is drawn out of the cuvette during this procedure.



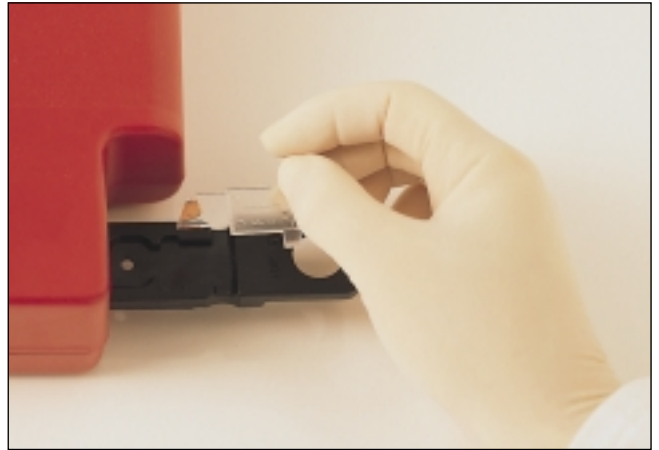
The filled cuvette should be visually inspected to check that the cuvette is properly filled i.e. completely filled up to the edge and without air bubbles in the optical eye.



Place the filled cuvette into the cuvette holder and carefully push it into the measuring position. The filled cuvette should be analyzed immediately and at the latest within 1 minute after filling. Filled cuvettes are to be kept lying down.

NOTE: **Slamming the cuvette holder into place with undue force will cause splashing of the sample material onto the optical surfaces.**

It is important that the cuvette holder is completely dry since fluid between the holder and cuvette can withdraw sample from the cuvette by capillary action.



In less than 1 minute the result is displayed. The result will remain on the display as long as the cuvette holder is in its measuring position. The cuvette should be disposed of after the measurement.

Although the reagents are present in the micro-cuvette in extremely low quantities, consult local environmental authorities for proper disposal. Always handle blood specimens with care as they may be infectious.

The cuvette cannot be remeasured. If "ERROR" code appears, turn to "Troubleshooting Guide," page 16. When the measurement procedure has been completed, turn the photometer's power switch to the "OFF" position.



Method

Vanzetti, G., Am. J. Lab & Clin Med 67, 116 (1966).

Principle

Sodium deoxycholate hemolyses the erythrocytes and hemoglobin is released. Sodium nitrite converts hemoglobin to methemoglobin which, together with sodium azide, gives azidemetemoglobin. The absorbance is measured at two wavelengths, 570 and 880 nm. The absorbance at 570 nm is used for the determination of hemoglobin concentration and the absorbance at 880 nm is used to compensate for a certain degree of turbidity.

Storage and environmental requirements

The microcuvette

The microcuvettes are to be stored dry at room temperature (15-30 °C, 59-86 °F). The expiration date is printed on each container. Once opened the microcuvettes are stable for three months. Always keep the containers closed.

The photometer

The photometer can be stored at 0-50 °C (32-122 °F). The operating temperature is 15-40 °C (59-104 °F). Allow the photometer to reach ambient temperature before use. The photometer should not be operated at high (>90 % noncondensing) humidity.

Calibration

The photometer is delivered factory calibrated against the hemiglobincyanide (HiCN) method recommended by the International Committee for the Standardization of Hemoglobin (ICSH) for determination of the total Hemoglobin concentration.

Sample Material

Acceptable sample material includes plasma and serum specimens, aqueous solutions, or stored or banked erythrocytes which contains low concentrations of hemoglobin, such as irrigating fluid used during surgery or erythrocyte suspension media. All specimens must be allowed to reach room temperature before use. Visually turbid samples should be filtered before analysis with a 0.2 µm filter.

Quality Control

Two levels of liquid control is recommended to be run on the day of use, or as required by accrediting agencies or local policy.

NOTE: A control cuvette is not included in the HemoCue Plasma/Low Hb system.

Plasma/Low Hb control analysis

Allow the control to reach room temperature and mix it well before use.

Assay this control sample by filling and reading the cuvette as previously described.

If the result is not within the range, repeat the analysis using the same control solution. If the result is still out of range, perform the assay with a new control. If this result is out of range refer to “Troubleshooting Guide”, page 16.

Specifications

For performance characteristics, see HemoCue Plasma/Low Hb microcuvette instructions for use.

Measuring Range

The system is linear between 0.3-30.0g/L (0.03-3.00 g/dL, 30-3000 mg/dL, 0.02-1.90 mmol/L). Caution should be taken when evaluating instrument readings below 0.3 g/L (0.03 g/dL, 30 mg/dL, 0.02 mmol/L). Results above 30.0 g/L (3.00 g/dL, 3000 mg/dL, 1.90 mmol/L) will display an error code “HHH”.

Limitation

The HemoCue Plasma/Low Hb photometer is only to be used with HemoCue Plasma/Low Hb microcuvettes.

The HemoCue Plasma/Low Hb microcuvettes are for in vitro diagnostic use only.

For further limitations of the procedure, see HemoCue Plasma Low/Hb microcuvette instructions for use.

Warranty

The photometer carries a 24 month warranty from the day of receipt.

Maintenance

The photometer is designed to work for a long period of time without any direct service. No preventative maintenance is needed for the electronic components of the photometer.

At the end of each days use, remove the cuvette holder and clean with alcohol or a mild soap solution. The cuvette holder can also be autoclaved. It is important that the holder is completely dry before being replaced in the photometer.

To clean the optronic unit, use the HemoCue Cleaner. Follow the instructions in the package.

The cover may be cleaned with alcohol or mild soap solution.

No instrument modifications (i.e. recalibration) should be performed.

Technical Service

After the warranty period service/repair is made at fixed prices.

Spare Parts List

The HemoCue Plasma/Low Hb Photometer is Constructed with few parts. The following spare parts are available:

Cover – Transformer – Cuvette holder

Technical data

Voltage: 6-9 VDC

Current input: 100 mA

Pollution degree: II

Over voltage category: 2

The instrument is tested according to EN 61010-1/IEC 61010-1 and amendments 1 and 2, and EN 60601-1-2 and complies with IVD Medical Device Directive 98/79/EC. The instruments is marked with CE.

Dimensions: 16.0 cm x 21.0 cm x 9.0 cm

Weight: 1 Kg.

Transformer: CE-marked, 230 V AC, 50 Hz,

Output 6 V DC, 350 mA.

For the USA market please use transformer:


Input 120 V AC (105-135) 60 Hz,

Output 6 V DC 500 mA. (UL file number E199967(N),

Volume 1.)

Symbols used

 CE mark

 Only valid within the European Community.
Indicates separate collection for waste of electrical and electronic equipment.

Manufactured by
HemoCue AB, Ängelholm, Sweden

Trouble Shooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please call your distributor.

Symptom	Explanation	Action
The photometer shows "ERROR" and a digit code 900-908.	May be an occasional fault.	Turn off the photometer and switch it on again after 30 seconds. Take a new cuvette and repeat the measurement. If the problem continues, see specific error code below.
"ERROR" 900	No stable endpoint within the time range. 1. The cuvette is unstable. 2. The circuit board is out of order.	1a. Check expiry date for the cuvettes. 1b. Take a new cuvette and repeat the measurement. 2. The photometer needs service. Call your distributor.
"ERROR" 901 or 902	1. Light intensity of the diodes are too low. This is often the result of dirt in the light path. 2. The optronic unit is out of order.	1. Clean the optronic unit, using the HemoCue cleaner. 2. The photometer needs service. Call your distributor.
"ERROR" 903	1. Disturbances on main power supply. 2. The optronic unit is out of order.	1. Change the wall socket or use battery power. 2. The photometer needs service. Call your distributor.
"ERROR" 905	Light intensity for one of the light diodes is too high.	The photometer needs service. Call your distributor.
"ERROR" 906	Unstable blank value. The photometer might be cold.	Turn off the photometer and allow it to reach room temperature. If the problem continues call your distributor.
"ERROR" 907	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the photometer and replace the batteries, five type AA. 1b. Use the main power supply.
"ERROR" 908	1. The absorbance is too high. Light blocking item in the cuvette holder.	1a. Check that the photometer and the cuvettes are used according to the operating manual and the instructions for use. 1b. The photometer needs service. Call your distributor.
"ERROR" 916	The signal from the compensating wavelength is too high. This may be a result of high turbidity in the sample.	Filter visually turbid samples before analysis.
"ERROR" HHH	1. Displayed value is above 30.0 g/L (3.00 g/dL, 3000 mg/dL, 1.90 mmol/L).	1a. Check expiry date for the cuvettes. 1b. For samples with values above 30.0 g/L (3.00 g/dL, 3000 mg/dL, 1.90 mmol/L,) use the HemoCue B-Hemoglobin system.
No characters on the display.	1. There is no power supply to the photometer. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adapter is connected to the main power supply. 1b. Check that the power adapter is securely connected to the photometer. 1c. Check that the cable is not damaged. 2. Turn off the photometer and replace the batteries, five type AA. 3. The photometer needs service. Call your distributor.

Symptom	Explanation	Action
The display gives erroneous characters.	<ol style="list-style-type: none"> 1. The display is out of order. 2. The microprocessor is out of order. 	<ol style="list-style-type: none"> 1. The photometer needs service. Call your distributor. 2. The photometer needs service. Call your distributor.
The display shows "LOWBAT".	<ol style="list-style-type: none"> 1. The batteries need to be replaced. 2. If on main power, the optronic unit or the circuit board is out of order. 	<ol style="list-style-type: none"> 1. Turn off the photometer and replace the batteries, five type AA. 2. The photometer needs service. Call your distributor.
The display does not switch from "LHb" to "READY" or from "READY" to "MEASURING".	<ol style="list-style-type: none"> 1. The magnet in the cuvette holder may be missing. 2. The reed switch in the optronic unit is out of order. 	<ol style="list-style-type: none"> 1. Call your distributor. 2. The photometer needs service. Call your distributor.
Too high or too low values on controls.	<ol style="list-style-type: none"> 1. The cuvettes are too old or damaged, improper storage. 2. The optical eye of the cuvette is contaminated. 3. The control is not mixed well and/or not at room temperature. 4. Air bubbles in the cuvette. 5. The optronic unit is dirty. 6. The quality control is not suitable for the HemoCue system. 7. The calibration of the photometer has been changed. 	<ol style="list-style-type: none"> 1. Check the expiry date and storage of the cuvettes. 2. Remeasure the sample with a new cuvette. 3. Make sure that the control is mixed well and at room temperature. 4. Check the cuvette for air bubbles. Remeasure the sample with a new cuvette. 5. Clean the optronic unit, using the HemoCue Cleaner. 6. See "Quality Control," page 13. See also instruction from the manufacturer of the control. 7. Call your distributor.
Too high or too low values on samples in comparison with those expected.	<ol style="list-style-type: none"> 1. The cuvettes are too old or damaged, improper storage. 2. The optical eye of the cuvette is contaminated. 3. The sample is not mixed well. 4. Air bubbles in the cuvette. 5. The optronic unit is dirty. 6. The calibration of the photometer has been changed. 	<ol style="list-style-type: none"> 1. Check the expiry date and storage of the cuvettes. 2. Remeasure the sample with a new cuvette. 3. Make sure that the sample is mixed well. 4. Check the cuvette for air bubbles. Remeasure the sample with a new cuvette. 5. Clean the optronic unit, using the HemoCue Cleaner. 6. Call your distributor.

**Manufacturer**

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