HemoCue® Plasma/Low Hb

Operating manual

HEMOCUE®

EN/US

Table of Contents

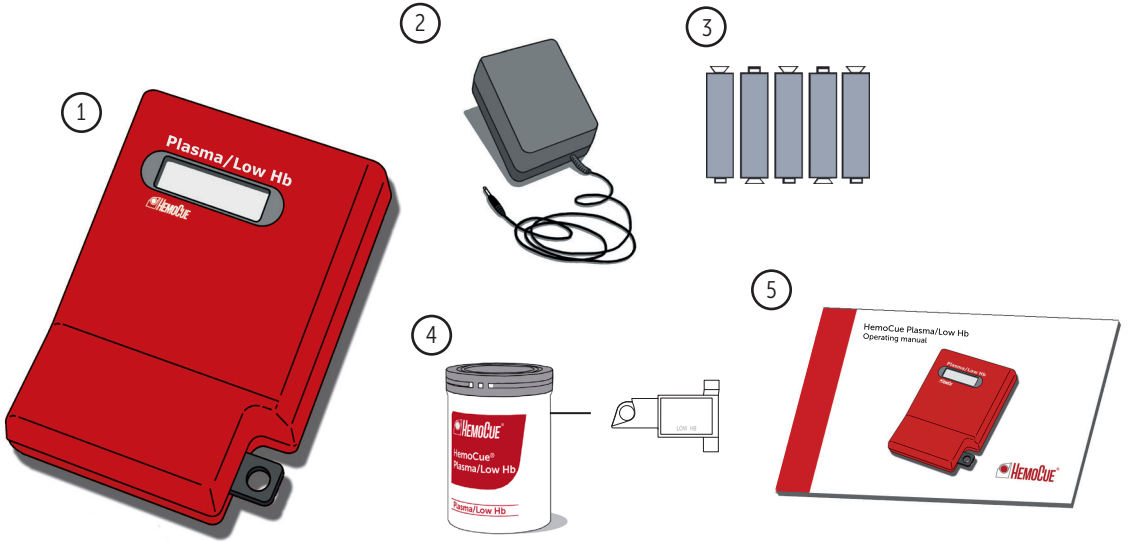
HemoCue® Plasma/Low Hb System

EN/US

Thank you for choosing the HemoCue® Plasma/Low Hb System. The 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.

⚠ *Read and follow this operating manual and the HemoCue Plasma/Low Hb Microcuvettes package insert to attain optimum performance and safety. Any other use of the system than recommended by the manufacturer may impair the safety.*

Components


1
Plasma/Low Hb
2
3
4
HemoCue®
Plasma/Low Hb
5
HemoCue Plasma/Low Hb
Operating manual

1. HemoCue Plasma/Low Hb Photometer*
2. Power adapter**
3. 5 alkaline type AA batteries***
4. A vial of HemoCue Plasma/Low Hb Microcuvettes***
5. HemoCue Plasma/Low Hb Operating Manual

Open the carton and lift out the photometer and accessories.
If no AC power is available, use 5 alkaline type AA batteries. On the bottom of the photometer there is a lid covering the battery compartment. Press the flap to remove the lid. Place the batteries in the battery compartment and replace the lid.
Consult local environmental authorities for proper disposal of batteries.

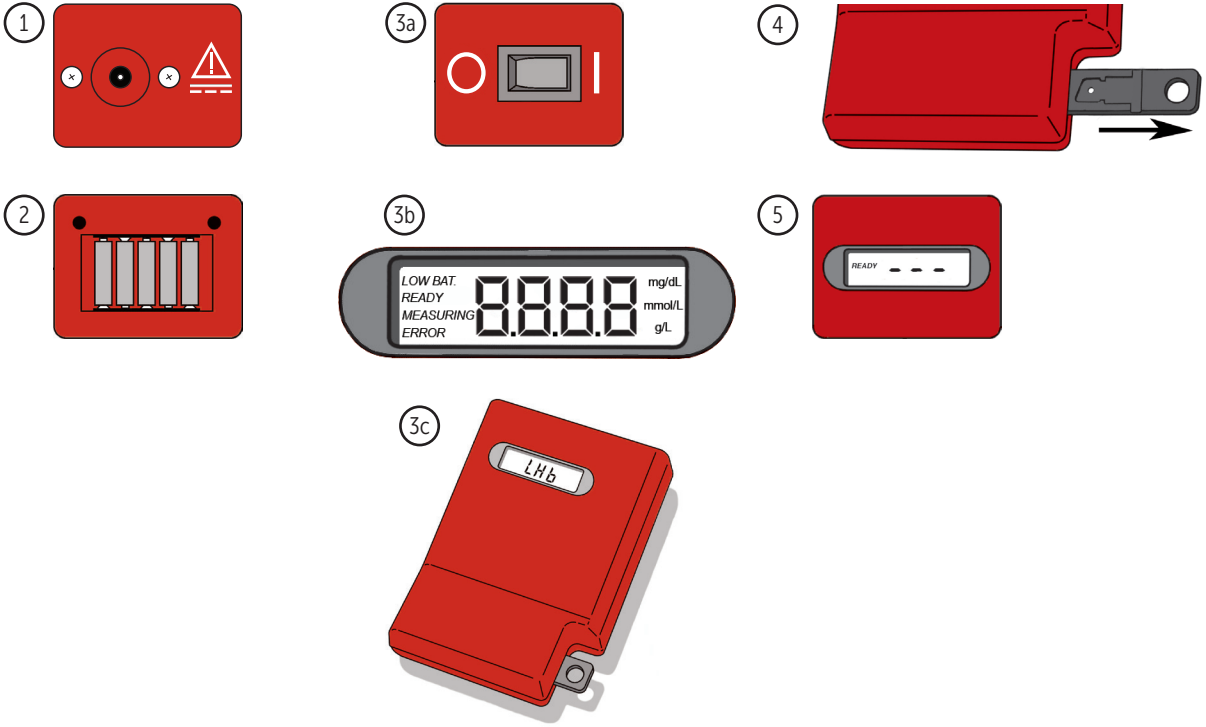
* Do not open the cover of the photometer.
Note: The warranty is void if the cover of the photometer has been opened.

** ⚠ Only use power adapters listed under *Specifications*.

*** Not included.

For infomation about HemoCue Plasma/Low Hb Microcuvettes please contact the HemoCue distributor.

Start-up


1
3a
4
2
3b
LOW BAT.
READY
MEASURING
ERROR
mg/dL
mmol/L
g/L
5
READY
3c

Make sure the photometer is placed horizontally and on a stable surface.

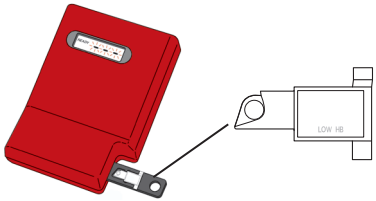
⚠ Only use power adapters approved by HemoCue, as listed under T*echnical Specifications*.

1. If AC power is available, use the power adapter.
2. If no power is available, insert 5 alkaline type AA batteries.
3. Turn the switch to the 'ON' position (3a). All symbols appear on the display (3b), and after approximately 10 seconds the letter 'LHb' will be displayed (3c).
4. Pull out the cuvette holder to its loading position. This point, which should not be exceeded, is easily established by paying attention to a distinct stop.
5. After approximately 15 seconds the indication 'READY' appears on the display together with three flashing dashes. The photometer is ready for measurement.

Turn the photometer off by switching power switch to the 'OFF' position.

Measuring Sample material

1



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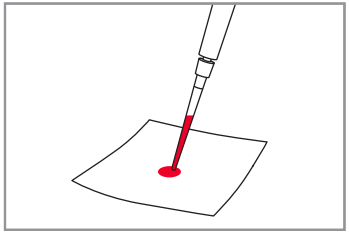

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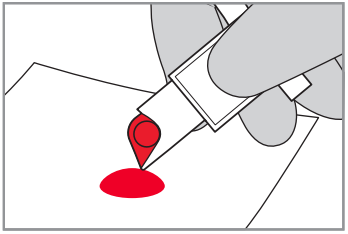

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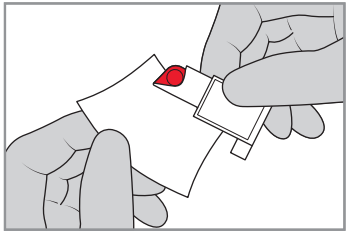

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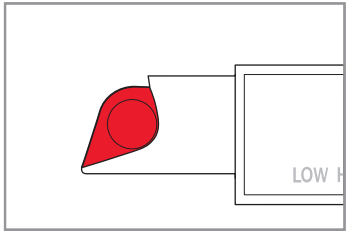
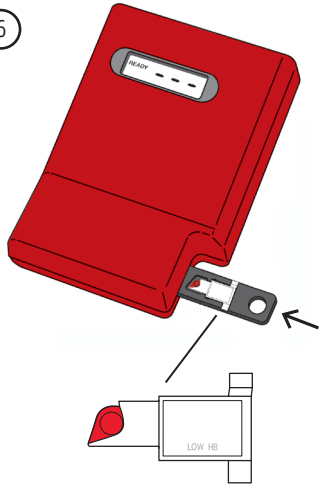


⚠ Always wear protective gloves. Handle blood with care, as it may be infectious. Follow local safety procedures for disposal of used microcuvettes.

1. To perform a test, the cuvette holder should be in its loading position. The display will show three flashing dashes and 'READY'. Remove a HemoCue Plasma/ Low Hb Microcuvette from the vial.
2. Place a drop of well mixed sample onto a hydrophobic surface using a suitable transfer device.
3. Fill the microcuvette in one continuous process. Do NOT refill.
4. Wipe off excess sample from the outside of the microcuvette with a clean, lint-free wipe. Do not touch the filling end of the microcuvette. If a second sample is to be taken, fill a new microcuvette from a new drop of sample. This should not be done until the measurement of the first sample is completed.
5. Visually inspect the microcuvette. If the microcuvette is not completely filled with sample or there are air bubbles, discard and fill a new microcuvette. Small bubbles around the edge can be ignored.

6



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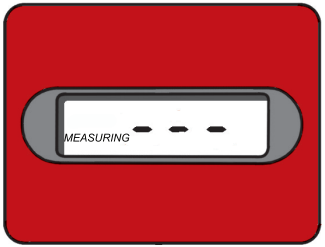

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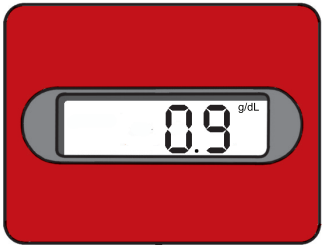

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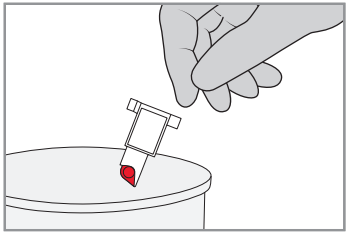
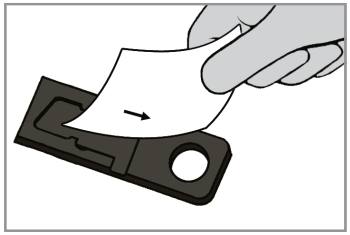


Note: Visually turbid samples should be filtered before analysis using a 0.2 µm filter.

6. Place the microcuvette into the cuvette holder and start measurement as soon as possible but no later than 60 seconds after filling the microcuvette by gently pushing the cuvette holder to its measuring position. Note: Slamming the cuvette holder into place with undue force will cause splashing of the sample material onto the optical surfaces.
7. During measurement 'MEASURING' and three fixed dashes will be shown.
8. After approximately 15–60 seconds, the hemoglobin value is displayed. The result will remain on the display as long as the cuvette holder is in its measuring position. Do not remeasure the microcuvette.
9. Discard the microcuvette after measurement. Microcuvettes are for single use only. Follow local safety procedures for disposal of used microcuvettes.

Maintenance

1



2

The cuvette holder should be cleaned after each day of use. Make sure that the photometer is turned off and that the display is blank.

1. Pull the cuvette holder completely out. Clean the cuvette holder with alcohol (20–70%) or mild detergent. The cuvette holder can also be autoclaved. The cover may be cleaned with alcohol (20–70%) or a mild detergent.
2. If the optical parts become dirty, an error code will be displayed. Before cleaning the optical parts, the cuvette holder should be completely removed as described above in step 1. To clean the optical parts inside the analyzer, push a HemoCue Cleaner swab into the opening of the optic unit. For optimal cleaning push the cleaner only as far as until the white part of the cleaner swab is inside the optic unit. Move the cleaner back and forth 5–10 times. If the cleaner swab becomes stained, repeat with a new cleaner. Wait 15 minutes before replacing the cuvette holder.

EN/US Troubleshooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please contact the local HemoCue distributor or HemoCue AB. Prior to service or disposal, the photometer should be cleaned as recommended under *Maintenance* section. Consult local environmental authorities for proper disposal. The photometer has no serviceable parts. Do not open the cover of the photometer. Note: The warranty is void if the cover of the photometer has been opened.

Symptom	Explanation	Action
The photometer shows an error code	May be a temporary fault.	Turn off the photometer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below.
ERROR 900	No stable endpoint of the measurement is found within the time range. 1. The microcuvette is faulty. 2. The circuit board is out of order.	1a. Check the expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The photometer needs service. Contact the 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. Contact the distributor.
ERROR 901–905	1. Dirty optical parts or faulty electronics or optronic unit.	1a. Turn off the photometer and clean the optical parts as described in the *Maintenance* section. 1b. The photometer needs service. Contact the distributor.
ERROR 906	1. Unstable blank value. The photometer might be cold.	1. Turn off the photometer and allow it to reach operating temperature. If the problem continues, the photometer needs service. Contact the 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, 5 alkaline type AA. 1b. Use the power adapter.
ERROR 908	The absorbance is too high. 1. Light blocking item in the cuvette holder.	1a. Check that the photometer and microcuvettes are used according to the HemoCue Plasma/Low Hb operating manual and package insert. 1b. The photometer needs service. Contact the distributor.
ERROR 916	High turbidity sample.	Filter visually turbid sample before analysis.
ERROR 918	Hardware or internal error.	The photometer needs service. Contact the distributor.

Symptom	Explanation	Action
HHH	1. Measured value exceeds 30.0 g/L (3.00 g/dL, 3,000 mg/dL, 1.86 mmol/L).	1a. Check expiry dates of the microcuvettes. 1b. For sample above 30.0 g/L (3.00 g/dL, 3,000 mg/dL, 1.86 mmol/L) use the HemoCue 201[+] system.
No characters on the display	1. The photometer is not receiving power. 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 photometer and the AC power supply. 1b. Check that the cable is not damaged. 2. Turn off the photometer and replace the batteries, 5 alkaline type AA. 3. The photometer needs service. Contact the distributor.
The display contains erroneous characters	1. The display is out of order. 2. The microprocessor is out of order.	1. The photometer needs service. Contact the distributor. 2. The photometer needs service. Contact the distributor.
The display shows 'LOWBAT'	1. The batteries need to be replaced. 2. If on AC power, the power adapter or the circuit board is out of order.	1. Turn off the photometer and replace the batteries, 5 alkaline type AA. 2a. Check that the power adapter is properly connected and working. 2b. The photometer needs service. Contact the distributor.
The display does not switch from 'LHb' to 'READY' or from 'READY' to 'MEASURING'	1. The cuvette holder sensor is out of order.	1. The photometer needs service. Contact the distributor.

Symptom	Explanation	Action
Measurement on control materials is out of range – either too high or too low	1. The microcuvettes are beyond their expiry date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. The controls are beyond their expiry dates or have been improperly stored. 4. The control has not been mixed properly and/or is not at room temperature. 5. The microcuvette has not been placed in the photometer within 60 seconds of filling. 6. Air bubbles in the microcuvette. 7. The optical parts are dirty. 8. The control is not suitable for use with the HemoCue Plasma/Low Hb system. 9. The calibration of the photometer has been changed.	1. Check the expiry date and the storage conditions of the microcuvettes. 2. Remeasure the control with a new microcuvette. 3. Check the expiry date and the storage conditions of the control. Remeasure the control with a new microcuvette. If the problem continues, contact the manufacturer of the control. 4. Make sure that the control is mixed properly and at room temperature. If the problem continues, contact the manufacturer of the control. 5. Remeasure the control with a new microcuvette. 6. Check the microcuvette for air bubbles. Remeasure the control with a new microcuvette. 7. Clean the optical parts as described in the *Maintenance* section. 8. Contact the distributor for control information. 9. The photometer needs service. Contact the distributor.
Measurement on samples are higher or lower than antipicipated	1. Improper sampling technique. 2. The microcuvettes are beyond their expiry date, damaged or have been improperly stored. 3. The optical eye of the microcuvette is contaminated. 4. The sample has not been mixed properly. 5. Air bubbles in the microcuvette. 6. The optical parts are dirty. 7. The calibration of the photometer has been changed.	1. See the *Measuring* section in this manual. 2. Check the expiry date and the storage conditions of the microcuvettes. 3. Remeasure the sample with a new microcuvette. 4. Make sure the sample is properly mixed. 5. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 6. Clean the optical parts as described in the *Maintenance* section. 7. The photometer needs service. Contact the distributor.

EN/US Specifications

Intended Purpose/Intended Use

The 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 Microcuvettes are for *In Vitro* Diagnostic use only. The HemoCue Plasma/Low Hb Photometer is only to be used with HemoCue Plasma/Low Hb Microcuvettes.

Principle of the method/procedure

Principle of the method

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocytes are hemolyzed to release the hemoglobin. The hemoglobin is converted to methemoglobin and then combined with azide to form azidemethemoglobin. The measurement takes place in the photometer in which the transmittance is measured and the absorbance and hemoglobin level is calculated. The absorbance is directly proportional to the hemoglobin concentration.

Principle of the procedure

The system consists of a photometer together with the microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A sample of approximately 20 µL is drawn into the cavity by capillary action. The photometer measures at two wavelengths in order to compensate for a certain degree of turbidity, and the hemoglobin level is calculated and presented (limitations apply as described in the paragraph *Limitations of the procedure*). The HemoCue Plasma/Low Hb system is calibrated against the international reference method for hemoglobin determination, ICSH and needs no further calibration.

Warning and precautions

The microcuvettes are for *In Vitro* Diagnostic use only. Non-laboratory personnel should receive adequate training before using this system for the first time. Always handle blood specimens with care as they may be infectious. Consult local environmental authorities for proper disposal.

Storage and handling

Operating temperature for the system is 15–30 °C (59–86 °F). The system should not be operated at < 5% or > 90% non-condensing humidity.

HemoCue® Plasma/Low Hb Microcuvettes

The microcuvettes are to be stored at 15–30 °C (59–86 °F). Do not refrigerate. Use the microcuvettes prior to the expiration date that is printed on the package. Once the seal of the vial is broken, the microcuvettes are stable for three months. Keep the vial properly closed. All unused microcuvettes should remain in the original package.

HemoCue® Plasma/Low Hb Photometer

The photometer can be stored and transported in temperatures between 0–50 °C (32–122 °F). Allow the photometer to reach operating temperature before use. The photometer should not be stored at < 5% or > 90% non-condensing humidity.

Specimen collection and preparation

Plasma/serum specimens and aqueous solutions containing hemoglobin, such as irrigating fluid from surgical procedures, may be used. Mix the specimen thoroughly before use. Supernatant from erythrocyte suspensions may be used. Carefully separate the supernatant from the erythrocytes using accepted laboratory procedure.

Materials required

- HemoCue Plasma/Low Hb Photometer
- HemoCue Plasma/Low Hb Microcuvettes
- Pipette or other transfer device
- Disposable pipette tips
- Lint-free wipe (non-fraying)
- Hydrophobic surface

Quality Control

Two levels of liquid control is recommended to be run on the day of use, or follow local guidelines regarding quality control procedures. Only use controls recommended by HemoCue, see relevant package insert for more information.

Measuring range

The system is linear between 0.3–30.0 g/L (0.03–3.00 g/dL, 30–3,000 mg/dL, 0.02–1.86 mmol/L). Caution should be taken when evaluating instrument readings between 0 and 0.3 g/L (0–0.03 g/dL, 0–30 mg/dL, 0–0.02 mmol/L).

Results

The measured hemoglobin value is read directly from the HemoCue Plasma/Low Hb Photometer. No calculations are necessary. Applications sheets for use in determining blood loss and for calculating the amount of free hemoglobin in salvaged or stored blood are available from HemoCue AB.

Limitations of the procedure

a) If 'HHH' is displayed, the result exceeds the measuring range of the system.
b) For values above 30.0 g/L (3.00 g/dL, 3,000 mg/dL, 1.86 mmol/L) use a suitable laboratory method or the HemoCue Hb 201[+] system.
c) Sulfhemoglobin is not measured with this method.
d) Levels of bilirubin up to 340 µmol/L (20 mg/dL) do not influence the assay.
e) The presence of lipids may interfere with the hemoglobin determination. Therefore, samples which are visibly turbid should be filtered (pore size 0.2 µm). If the user feels uncertain about the degree of turbidity, we recommend filtering the sample.
f) The performance characteristics of this system have not been determined using samples obtained from uremic patients.

Specific performance characteristics

The results given below are from a HemoCue Plasma/Low Hb Photometer standardized against the HiCN-(ICSH)[2] method.

Within-run precision

Within-run precision was determined on 5 photometers and by using within house prepared aqueous and plasma solutions.

	Solution	Mean (g/L)	SD (g/L)	CV %	Number
Hemoglobin in 0.9% NaCl	Low	1.59	0.06	3.6	20
	Mean	16.30	0.14	0.8	20
	High	25.30	0.16	0.6	20
Hemoglobin in heparinized plasma.	Low	1.95	0.08	4.2	20
	Mean	15.30	0.11	0.7	20
	High	25.50	0.22	0.9	20

Between-run precision

Between-run precision was determined by using within house prepared solutions. The samples were analyzed on 20 consecutive working days, twice a day, in duplicate.

	Solution	Mean (g/L)	SD (g/L)	CV %	Number
Hemoglobin in 0.9% NaCl	Low	1.43	0.06	4.3	20
	Mean	14.80	0.17	1.2	20
	High	24.80	0.25	1.0	20
Hemoglobin in heparinized plasma.	Low	1.78	0.09	5.0	20
	Mean	14.80	0.21	1.4	20
	High	24.50	0.25	1.0	20

Correlation study

1) Aqueous samples from surgical procedures, analyzed on the HemoCue Plasma/ Low Hb system with the HiCN-(ICSH) method as reference.
2) Erythrocyte suspensions, analyzed on the HemoCue Plasma/Low Hb system with the HiCN-(ICSH) method as reference.
3) Erythrocyte suspensions, analyzed on the HemoCue Plasma/Low Hb system with the HiCN-(ICSH) method as reference.

		Reference				HemoCue			
Group	N	Mean (g/L)	Min (g/L)	Max (g/L)	SD (g/L)	Mean (g/L)	Min (g/L)	Max (g/L)	SD (g/L)
1	42	4.04	0.94	15.18	0.047	4.05	0.84	15.64	0.059
2	20	1.47	0.65	2.49	0.066	1.66	0.70	2.75	0.130
3	64	2.54	0.40	6.45	0.122	2.65	0.40	6.70	0.084

The regression line and the coefficient of correlation

Group	N	Regression line	The coefficient of correlation	Range	Photometers
1	42	1.039 x ICSH–0.150	0.9997	0.94–15.18	5
2	20	1.149 x ICSH–0.024	0.9913	0.65–2.49	1
3	64	1.015 x ICSH–0.078	0.9981	0.40–6.45	1

Technical Specifications

Dimensions: 160 x 210 x 90 mm (6.29 x 8.26 x 3.54 inches)
Weight: 1,000 g (2.20 pounds)
Battery: 5 batteries type AA, 1.5V Alkaline
Power adapter: CE marked
Only use power adapters listed below:

Type	Input	Output
FW7333SM/12	100 V~-240 V~/50–60 Hz/200–80 mA	12 V ⎓ /700 mA
FW7660M/12	100 V~-240 V~/50–60 Hz/205–110 mA	12 V ⎓ /800 mA
FW8002.1/12	100 V~-240 V~/50–60 Hz/160–80 mA	12 V ⎓ /600 mA

Analyzer electrical rating: 12 V ⎓, 0.5 W
Pollution degree: 2
Overvoltage category: II
Altitude: up to 2000 m above sea level
The instrument is made for continuous mode

IVD Medical Device Directive

The HemoCue Plasma/Low Hb system complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

EMC and Electrical Safety

The analyzer has been tested and complies with following standards:
• IEC 61010-1
• IEC/EN 61010-2-101
• IEC/EN 61326-2-6 (including applicable parts of IEC/EN 61326-1)

The analyzer has been tested for indoor use.

It is recommended to evaluate the electromagnetic environment prior to use of the device.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g unshielded intentional RF sources), as these can interfere with the proper operation.

Note: It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

Note: It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

Warranty

The photometer carries a 24-month warranty from the day of receipt. After the expiration date of the warranty, maintenance and repairs are offered at a fixed price. Any other use of the system than recommended by the manufacturer will void the warranty.

Service and disposal

Prior to service or disposal, the photometer should be cleaned as recommended under *Maintenance* section. Consult local environmental authorities for proper disposal.

Spare parts

Power adapter*
Battery lid
Cuvette holder

Optional items

HemoCue Cleaners

** Not available in all countries*

Symbols used

 Caution

 Consult instructions for use

 CE mark

 *In Vitro* Diagnostic medical device

 Biological risk

 Manufacturer

 Serial number

 Catalogue number

 Temperature limitation

 Humidity limitation

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

 DC inlet

 'OFF' (power)

 'ON' (power)

 Efficiency Level
on power adapter

 Class II equipment
on power adapter

 For indoor use only
on power adapter

References

1. HemoCue Plasma/Low Hb package insert.
2. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard NCCLS Document H15-A.
3. ICSH Standard EP6/4: 1995, J Clin. Pathol. 1996; 49:271–274.

Manufacturer

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