HemoCue® Hb 801

Operating Manual

HemoCue®

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Contents

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 America.

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 section 18 or Hb 801 Microcuvettes package insert regarding system limitations, including interfering substances.

Intended Use

The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K_2EDTA 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.

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.

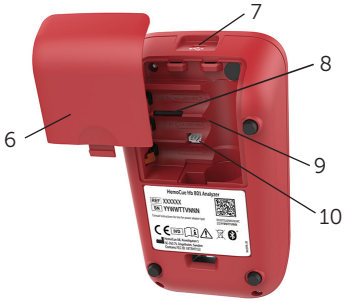
Service and Disposal

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

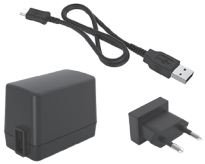
2 Components/Analyzer Overview

HemoCue Hb 801 Analyzer

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, 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

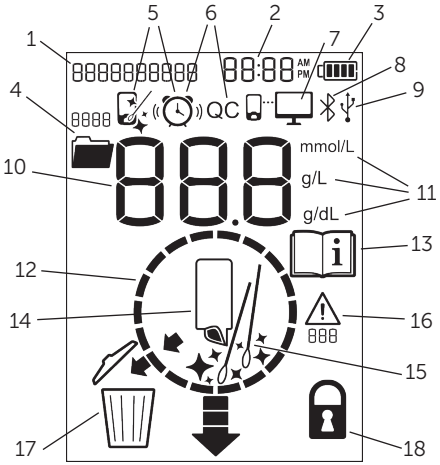
LED Indicator and Audio Signal

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.*

3 Display Overview

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



1. date
2. time
3. battery status
4. previous results, sequence
5. cleaning reminder*
6. QC reminder*
7. connectivity*
8. Bluetooth setting; on
9. USB cable connected
10. measurement result
11. unit
12. analyzer busy
13. consult instructions for use
14. ready for measurement
15. cleaning needed
16. error code
17. discard microcuvette
18. analyzer lockout*

** See section 14.*

Display Animations

Animations appearing in normal conditions:

Ready State

Starting position for most actions.

Busy State

The analyzer has work in progress. If continuously busy, see section 15.

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.

4 Power Options

The analyzer can receive power from different sources:

- USB cable and power adapter; connected to an electrical outlet
- USB cable; connected directly to a computer
- disposable or rechargeable AA batteries*
- a HemoCue Rechargeable Battery**

** For some rechargeable AA batteries, the analyzer may indicate low battery only for a short period of time before shutting down. Change or charge batteries.*
*** This option is set when ordering the analyzer. For more information, contact the local distributor or HemoCue America.*

Precaution:

- Only use USB cable, power adapter, and batteries recommended by HemoCue.
- Do not expose the HemoCue Rechargeable Battery to temperatures above 60 °C (140 °F).

When using HemoCue Rechargeable Battery, no other batteries shall be installed.

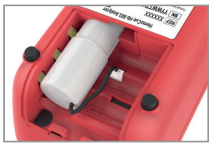
Before storing the analyzer, make sure to remove batteries.

Electrical Outlet

1. Mount the plug onto the power adapter, and connect the USB cable to the power adapter.
2. Connect the USB cable to the analyzer USB port, and then connect the power adapter to the electrical outlet.

Batteries

1. Press and remove the battery cover.



2. Insert 3 disposable or rechargeable AA batteries,
   or
   connect the HemoCue Rechargeable Battery.

   If the analyzer is delivered with a HemoCue Rechargeable Battery, the battery is already placed in the battery compartment, but not yet connected.

   If removing the HemoCue Rechargeable Battery, first disconnect, then remove the battery.

   For battery types, see section 22.

3. Push the battery cover back in place.

Charging

- Rechargeable AA batteries: Charge separately according to instructions for batteries used.
- HemoCue Rechargeable Battery: Charge in the analyzer (connected to an electrical outlet or a computer).

5 Start-up

1. Place the analyzer on a horizontal and stable surface.

2. Press and hold on/off button until all display segments show. Release, and wait a few seconds until the analyzer is in Ready State.

   For display animations, see section 3.

   To make sure all measurement result segments on the display are working properly, continue pressing the on/off button during start-up. To compare, see section 3.

6 Turn Off

1. Press and hold on/off button until the analyzer is in Busy State. Release, and wait for the analyzer to turn off.

   When changing settings (in section 7) or viewing previous results (in section 13), it is not possible to turn off the analyzer. If needed, exit the settings or previous results, and then turn off.

Power Save

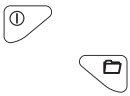
If not in use, the analyzer automatically turns off after a period of time.* Analyzers supplied by power from HemoCue Rechargeable Battery will not turn off during charging.

Power Supply	Power Save Time (default)
batteries	5 minutes
USB cable	30 minutes

** To change this setting, see section 14.*

7 Settings Date and Time, or Bluetooth®

Follow these procedures to change date and time, or *Bluetooth®* settings.
To exit settings at any time, press both buttons once.

Date and Time	Buttons	Extra Information
1. Make sure the analyzer is in Ready State.		*Display showing:* 
2. **Enter:** Press and hold both buttons until the date, time, and Bluetooth areas on the display starts to flash.		
3. To change date and time, press left button.		
4. Set the correct values. Go to next value.		*To quickly scroll between digits, press and hold the left button.*
5. **Exit:** Press both buttons once.		

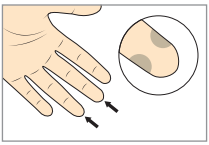
Bluetooth®	Buttons	Extra Information
1. Make sure the analyzer is in Ready State.		*Display showing:* 
2. **Enter:** Press and hold both buttons until the date, time, and Bluetooth areas on the display starts to flash.		
3. To turn Bluetooth® on/off, press right button.		
4. Choose on or off.		***On*** *- Bluetooth icon visible.* ***Off*** *- no Bluetooth icon visible.*
5. **Exit:** Press both buttons once.		

8 Measuring Capillary Blood

Follow this procedure to collect a capillary sample, and perform a measurement.

Precaution:

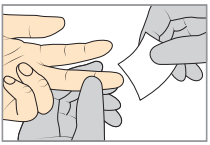
- Always wear protective gloves. Handle blood with care, as it may be infectious. Follow local safety procedures for disposal of used microcuvettes.
- HemoCue Hb 801 Microcuvettes are for single use only.
- Be aware that peripheral circulatory failure of the patient can affect the result of a capillary sample.



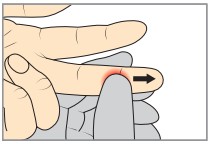
1. Make sure the patient's hand is warm and relaxed.

   Use the middle or ring finger for sampling. Avoid fingers with rings on.

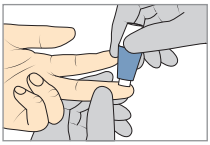
   Sample at the side of the fingertip for best blood flow and comfort.



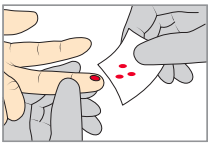
2. Clean the fingertip and allow to dry.



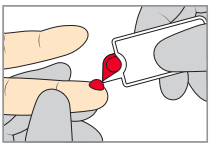
3. Using your thumb, lightly press the finger from the top of the knuckle towards the fingertip to stimulate blood flow.



4. Press lightly towards the fingertip, and puncture using a high-flow lancet.

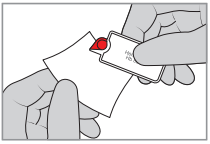


5. Wipe away the first 2 or 3 drops of blood. Press lightly towards the fingertip until another drop of blood appears.



6. Fill the microcuvette. Make sure the blood drop is large enough to fill the microcuvette completely in one single step. Do not refill.

   Do not let more than 40 seconds pass between step 6 (filling) and step 9 (inserting the microcuvette into the microcuvette holder).



7. Wipe off excess blood from the outside of the micro-cuvette. Make sure that no blood is drawn out from the microcuvette.

8. Visually inspect the microcuvette.

Precaution:
- If the microcuvette is not completely filled with blood, or if there are air bubbles, discard and fill a new microcuvette.

9. Make sure the analyzer is in Ready State. Insert the filled microcuvette into the microcuvette holder and press down. The result will be displayed within a second.

10. When a result is displayed, remove and discard the micro-cuvette.

The result is displayed for 10 seconds after measurement. To change this setting, see section 14.

To see the result again, see section 13.

Repeat Testing

Pre-analytical factors can influence hemoglobin values obtained from capillary blood. These factors can include, but are not limited to:

- Lancet size and type
- Capillary circulation status
- Extracellular fluid in sample due to poor sampling technique
- Selection of puncture site
- Improper filling of microcuvette

Confirmation of an unacceptable or unexpected laboratory result is common. The individual performing the test may not always be aware of potential factors influencing results; therefore, a second finger stick should be performed when wanting to rule out pre-analytical factors as a cause of unacceptable or unexpected results. Performance of a second finger stick by a different, experienced individual can aid in minimizing the effect of the factors that may have been technique related.

9 Measuring Venous Blood and Control Material

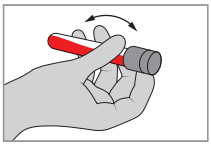
Follow this procedure to perform a measurement on a venous sample or control material.

For venous samples, use anticoagulant (K_2-EDTA or Li-Heparin). Venous samples can be stored and transported for up to 24 hours, at room temperature or in refrigerator, before measuring.

If an external quality control is required by local or other regulations, follow this procedure together with guidelines or instructions for the quality control material used.
For information regarding quality control material, see the package insert. Only use controls recommended by HemoCue.
For more information regarding internal quality control, see section 11.

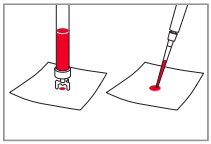
⚠ Precaution:

- 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.
- Make sure venous blood samples are properly mixed before use.

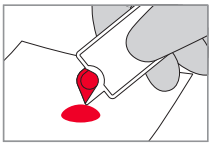


1. If refrigerated, allow the sample to reach operating conditions. Mix thoroughly on mixer for at least 2 minutes, or invert manually 8–10 times.

   When mixing controls, follow instructions for the control material used.

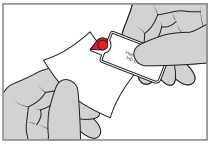


2. Place a drop of blood or control material onto a hydrophobic surface, using a suitable transfer device.

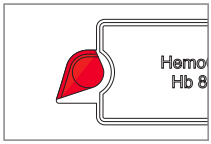


3. Fill the microcuvette completely—in one single step. Do not refill.

   Do not let more than 40 seconds pass between step 3 (filling) and step 6 (inserting the microcuvette into the microcuvette holder).



4. Wipe off excess blood from the outside of the microcuvette. Make sure that no blood is drawn out from the microcuvette.



5. Make a visual inspection.

   ⚠ Precaution:

   - If the microcuvette is not completely filled with blood, or if there are air bubbles, discard and fill a new microcuvette.

6. Make sure the analyzer is in Ready State. Insert the filled microcuvette into the microcuvette holder and press down. The result will be displayed within a second.

7. When a result is displayed, remove and discard the micro-cuvette.

   The result is displayed for 10 seconds after measurement. To change this setting, see section 14.

   To see the result again, see section 13.

10 Cleaning and Disinfection

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

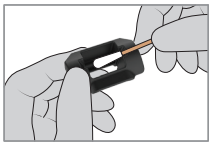
- **Cleaning agents**: water, alcohol (20–70 %), mild detergent, or recommended disinfectant.
- **Disinfectant**: Super Sani-Cloth Germicidal Disposable Wipe, EPA Reg. No. 9480-4. Only use disinfectant recommended by HemoCue. Read and follow instructions for the disinfectant used.

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.



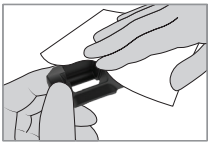
3. Clean the microcuvette holder with cleaning agent.

   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.

Disinfection



Before disinfection, the analyzer must be cleaned (steps 1-4 above).

5. Wipe the microcuvette holder repeatedly with a new Super Sani-Cloth Germicidal Disposable Wipe. Make sure that all surfaces stay wet for 2 minutes.

6. Wipe all outer surfaces repeatedly with a Super Sani-Cloth Germicidal Disposable Wipe. Make sure that all surfaces stay wet for 2 minutes.

7. Make sure that the surfaces in step 5 and 6 have been wiped repeatedly in order to stay wet for the whole 2 minutes (wet-time/contact time).

8. 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.

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 microcuvette 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, see section 9 for procedure instructions.
For information regarding quality control material, see the package insert. Only use controls recommended by HemoCue.

12 Principle of Method

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 (506 nm), and at a wavelength (880 nm) to compensate for possible interfering background (e.g. turbidity).

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

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 America.*

Security Guidelines

- Turn off the Bluetooth® function when there is no need for a wireless connection (see section 7).
- Only connect the analyzer to known and trusted devices.
- Do not leave the analyzer exposed or unattended.

HemoCue AB is not responsible for any threats related to cybersecurity originating from the user's IT infrastructure or logistics.
The user of the HemoCue Hb 801 System is responsible for the physical protection of the analyzer.

15 Troubleshooting

Do not open the cover of the analyzer. Warranty is void if the analyzer has been opened.
If analyzer parts are lost or damaged, contact the local distributor or HemoCue America.

Main Actions

Actions to solve most problems (if needed, perform all):

1. Remove the microcuvette from the microcuvette holder.
2. Turn off the analyzer, and then turn it on again.
3. Clean the analyzer according to steps 1-2 in section 10. Let the analyzer dry.
4. Make sure the analyzer has reached operating and ambient conditions before start-up. Avoid direct sunlight.
5. Always follow information and procedures as described in this operating manual.

If the problem remains, see Further Actions below.

If the problem still remains after Further Actions, contact the local distributor or HemoCue America.

Symptom	Further Actions
 E00-E30	Perform Main Actions above.
analyzer not measuring	Perform Main Actions above. Make sure to press down the microcuvette during measurement.
	If the display shows --- instead of a result, fill a new microcuvette and perform a measurement, see section 8 or 9. If needed, perform Main Actions above.
unexpected result*	Possible causes are e.g. incorrect sampling technique or incorrect mixing of sample. Fill a new microcuvette and perform a measurement, see section 8 or 9. Check expiration date for the materials used. Make sure all result segments on the display are working properly, see section 5.
	The result is below (LLL) or above (HHH) measuring range.
	Clean the analyzer according to steps 1-2 in section 10. Let the analyzer dry.
	The microcuvette holder is either not in position, missing, or broken.
	The microcuvette is either empty or incorrectly inserted. Fill a new microcuvette and perform a measurement, see section 8 or 9.

	If the analyzer is continuously busy, turn the analyzer off and then on again.
sudden analyzer shut down, or battery indicator flashing	Change or charge the battery/batteries, or make sure the adapter is properly connected and that the USB cable is not damaged.
analyzer not responding or starting	Change or charge the battery/batteries, or make sure the adapter is properly connected and that the USB cable is not damaged. Force a restart: Press and hold both buttons for 15 seconds.
date and time area flashing in Ready State	Set date and time. If the problem occurs again: Set date and time, and keep the analyzer powered for at least 24 hours (either by batteries, or USB cable).
bad wireless or USB connection	Follow instructions for software application used.

** If the result is still deviating from expected value after performing all actions in the list, it is recommended to confirm the result with a suitable laboratory method. Follow local recommendations regarding obtaining and shipping blood samples for confirmation testing.*

16 Expected Values

Due to a wide range of conditions (dietary, geographical, etc.), which affect normal values, it is recommended that each laboratory establishes its own normal range. For general guidance to normal reference values applicable to most healthy adults and children, see reference ranges below.

Subject Group	Age	Hb, g/dL
Infant*	>1 month–2 years	9.4–14.1
Child*	>2–12 years	11.0–15.5
Adolescent**	>12–21 years	10.9–15.1
Adult male*	>21 years	13.0–17.0
Adult female*	>21 years	12.0–15.0

* According to Dacie and Lewis, Practical Haematology
** According to Soldin, Pediatric Reference Intervals

17 Specific Performance Characteristics

Precision

Results summarized below were determined according to CLSI EP05-A3.

			Repeatability		Within-laboratory Precision		Reproducibility	
Control Level	N	$\bar{x}$ g/dL	SD g/dL	CV %	SD g/dL	CV %	SD g/dL	CV %
1	240	6.34	0.05	0.7	0.04	0.7	0.06	0.9
2	240	11.50	0.05	0.4	0.05	0.5	0.06	0.5
3	240	15.36	0.15	1.0	0.16	1.0	0.17	1.1

Results summarized from capillary precision study (repeatability):

Hb Level g/dL	N	Min g/dL	Max g/dL	SD g/dL	CV %
≤7.0	2	1.4	5.0	0.11	--
>7.0	40	7.1	23.3	--	2.3

Accuracy

Results summarized below were determined according to CLSI EP09-A3.

Study	N	Min g/dL	Max g/dL	Regression Line	Correlation Coefficient (r)
1	102	1.3	23.6	Y = 0.99X + 0.09	1.00
2	100	11.8	18.4	Y = 0.96X + 0.92	0.92

1 = venous blood, compared to the HiCN reference method according to the International Council for Standardization in Haematology (ICSH)
2 = capillary blood, compared to the HiCN reference method according to the International Council for Standardization in Haematology (ICSH)

Method Comparison

Results summarized below were determined according to CLSI EP09-A3.

Study	N	Min g/dL	Max g/dL	Regression Line	Correlation Coefficient (r)
1	264	1.5	25.4	Y = 1.00X - 0.14	1.00
2	233	4.7	23.2	Y = 1.07X - 0.91	0.96

1 = multicenter study, venous blood, compared to HemoCue Hb 301
2 = multicenter study, capillary blood, compared to HemoCue Hb 301

Non-interfering Substances

The following substances have been tested according to CLSI EP07 at hemoglobin concentrations 10±0.5 and 20±1.0 g/dL. No interference was found at following concentrations of the substances tested.

Substance	Test Concentration	Unit
Acetaminophen	1324	µmol/L
Ascorbic acid	342	µmol/L
Creatinine	442	µmol/L
HbCO	10	%
HbO_2	≤ 50	%
Hemolysis	10	g/L
Ibuprofen	2425	µmol/L
MetHb*	25	%
Platelets	2000	x 10^9/L

Substance	Test Concentration	Unit
Total protein	15	g/dL
Salicylic acid	4.34	mmol/L
Simvastatin	49	µmol/L
Tetracycline	34	µmol/L
Triglyceride	1500	mg/dL
Urea	42.9	mmol/L
Uric acid	1.4	mmol/L
Warfarin	32.5	µmol/L

* Multiple concentrations of MetHb up to 25% were tested and do not interfere with hemoglobin measurement at Hb-level 10±0.5 or 20±1.0 g/dL.

Normal blood pH and above, up to 8, at Hb level 10±0.5 or 20±1.0 g/dL do not interfere with the system. The test has been performed according to CLSI EP07.

18 Limitations

a) Start the measurement immediately after filling the microcuvette. Do not let more than 40 seconds pass.
b) Venous samples (K_2EDTA or Li-Heparin) can be stored and transported for up to 24 hours in room temperature or refrigerator, before measuring.
c) The following substances have been tested according to CLSI EP07 to determine the interfering concentration.

Substance	Concentration (unit)	Hb Concentration (g/dL)	Result
Conjugated bilirubin	>23 (mg/dL)	10	Interfering*
	Up to 40 (mg/dL)	20	Non-interfering
Unconjugated bilirubin	>12 (mg/dL)	10	Interfering*
	>23 (mg/dL)	20	Interfering*
Intralipid®	>214 (mg/dL)	10	Interfering*
	>483 (mg/dL)	20	Interfering*
Leucocytes	>260 x 10^9/L	6.8–14.7	Interfering*

* May give elevated results in higher substance concentrations.

19 Safety and Compliance

The HemoCue Hb 801 System complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

HemoCue AB hereby declares that this product is compliant with the essential requirements and provisions of the Radio Equipment Directive (RED) 2014/53/EU and ROHS directive 2011/65/EU.

The HemoCue Hb 801 System complies with following international standards:
- IEC 61010-2-101 including applicable parts of IEC 61010-1
- CSA C22.2 No. 61010-1-12 / UL 61010-1
- IEC 61326-2-6 including applicable parts of IEC 61326-1

Any external equipment has to conform to either IEC 60950, or IEC 61010-1.

The supplied adapter must not be exposed to water. The adapter is only for indoor use.

⚠ Precaution:
- Do not expose the analyzer to running water or direct sunlight.

Electromagnetic Compatibility and Immunity

This device complies with the emission and immunity requirements of IEC 61326-2-6, class B product. The device can be used in an electromagnetic environment of IVD medical equipment according to IEC 61326-2-6.

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.

It is recommended to evaluate the electromagnetic environment prior to use of the system. Do not use this system in close proximity to sources of strong electromagnetic radiation (for example unshielded intentional RF sources), as these can interfere with the proper operation. Should you suspect electromagnetic interference, make sure to:
- Place the device so that it is not adjacent to, or stacked with, other equipment.
- Place portable RF communications equipment (such as mobile phones and other wireless communication devices) no closer than 30 cm (12 inches).
- Only use cables and accessories recommended by the manufacturer.
- Move the device away from possible causes of interference.

This device contains FCC ID: A8TBM71S2.

The device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules.

Intellectual Property Rights

Patents:
- The analyzer and microcuvette are protected by patent rights. See the legal page at hemocue.com for further information.

Trademarks:

- HemoCue® name and logo
- The Bluetooth® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by HemoCue AB is under license. Other trademarks and trade names are those of their respective owners.

20 References

For information regarding storage, handling and composition for HemoCue Hb 801 Microcuvettes, see the package insert.

- CLSI EP05-A3; Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition
- CLSI EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition
- CLSI EP07-ED3; Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition
- CLSI EP09-A3; Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition
- CLSI EP37-ED1; Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition
- CLSI H15-A3 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition
- Dacie and Lewis, Practical Haematology, Elsevier Limited, 12th Edition, 2016 and references herein
- HemoCue Hb 801 Microcuvettes Package Insert
- Soldin, S. J., Pediatric Reference Intervals, AACC Press; 7th edition, 2011

21 Symbols Used

	Caution		Temperature limitation
	CE mark		Consult instructions for use
	Serial number		USB port
	Bluetooth®		Biological risk
	Humidity limitation		*In Vitro* Diagnostic medical device
	Catalog number		Manufacturer
	Only valid within the European community. Indicates separate collection for waste of electrical and electronic equipment.		This product is covered by one or more patents
	For indoor use only *adapter related symbol*		Class II equipment *adapter related symbol*
	Efficiency level *adapter related symbol*		

22 Technical Specifications

measuring range	1.0–25.6 g/dL (10–256 g/L, 0.62–15.9 mmol/L)
measuring time	< 1 s
sample volume	10 µL
operating temperature	10–40 °C (50–104 °F)
analyzer storage and transport temperature	0–50 °C (32–122 °F)
analyzer operating and storage humidity (non-condensing)	up to 90% at 25 °C (77 °F) up to 75% at 40 °C (104 °F) up to 30% at 10 °C (50 °F)
altitude	up to 3000 m above sea level
dimensions	87x143x45 mm (3.4x5.6x1.8 in)
weight (batteries excluded)	< 250 g (0.55 lbs)
power adapter alternatives (input rating)	FW8012USB/05/Y (100–240 V~/50–60 Hz/160–80 mA) PSAI05R-050QL6-R (100–240 V~/50–60 Hz/300–150 mA)
analyzer supply rating	5 V (USB) 800 mA
battery alternatives	3 type AA 1.5 V Alkaline 3 type AA 1.2 V NiMH 1 HemoCue Rechargeable Battery 131901 3.6 V 2.6 Ah
pollution degree	2
overvoltage category	II
analyzer mode	continuous

Wireless Communication

wireless communication	Bluetooth® Low Energy
frequency band	2400–2480 MHz
modulation method	GFSK
max output power	0 dBm

CE

IVD

HemoCue®

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