

HemoCue® Hb 201 DM Analyzer

Instructions for Use



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1 Introduction

Thank you for choosing the HemoCue Hb 201 DM system.

The HemoCue Hb 201 DM system is a compact, portable, yet versatile, hemoglobin measuring system. It is ideally suited for health care facilities that require central lab quality values within a few minutes, at the point of care location.

The System consists of the HemoCue Hb 201 DM Analyzer, the HemoCue 201 DM Docking Station and the HemoCue Hb 201 Microcuvettes.

This Manual contains step-by-step instructions for the routine use of the HemoCue Hb 201 DM Analyzer. For configuration of the Analyzer and set-up of the System, consult the HemoCue 201 DM Reference Manual. Installation of HemoCue DM Docking Station has been described in HemoCue 201 DM Docking Station Manual.

The HemoCue Hb 201 DM system complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.



Read and follow this operating manual and the HemoCue Hb 201 Microcuvettes package insert to attain optimum performance and safety. Any other use of the system than recommended by the manufacturer may impair the safety.

Usage Disclaimer

The HemoCue Hb 201 DM system has flexible settings to meet different user needs. The setting options are configured in the settings menu, requiring a pin code. The selected settings are the responsibility of the local administrator. HemoCue AB does not take responsibility for user configurations that may cause system conflicts, loss of data or prevent the end-user to perform tests.

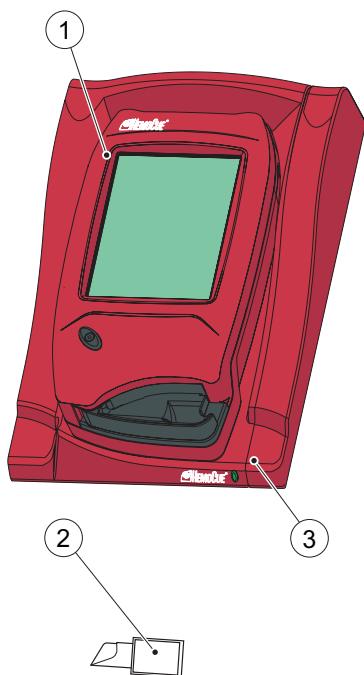
1.1 Unpacking



FIGURE 1-1

- a) Open up the package and unpack the contents on a dry and stable surface.
- b) Check all Components for damage. If any visible or suspected damage is discovered, contact HemoCue AB or the local distributor.

-
- 1 HemoCue Hb 201 DM Analyzer
 - 2 HemoCue Hb 201 DM Analyzer Instructions for Use



1.2 Functional description

1.2.1 System Components

FIGURE 1-2

The System consists of a specially designed Analyzer (1), the HemoCue Hb 201 DM Analyzer, specially designed Cuvettes (2), the HemoCue Hb 201 Microcuvettes and a specially designed Docking Station (3), the HemoCue 201 DM Docking Station.

Analyzer

The HemoCue Hb 201 DM Analyzer (1) is only to be used together with the HemoCue Hb 201 Microcuvettes (2).

The System is intended for *In Vitro* diagnostic use only.

-
- 1 Analyzer
 - 2 Cuvette
 - 3 Docking Station

1.2.2 Analyzer overview

Front panel

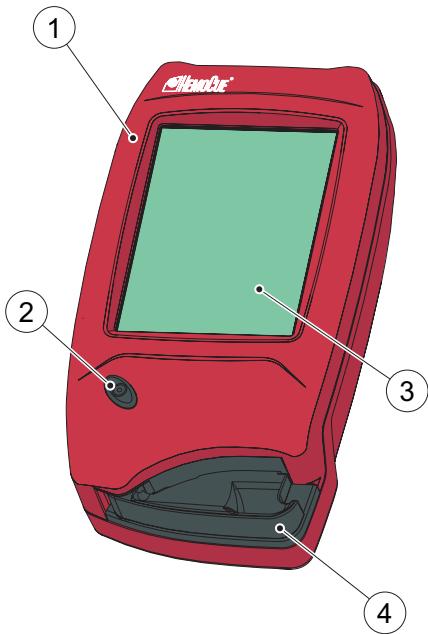


FIGURE 1-3

The Analyzer (1) is started when the On/Off button (2) is pressed. The screen images will be visible on the Display (3).

All navigation and information handling is performed by pressing the appropriate touch buttons directly on the Display (3).

To perform a measurement, the Cuvette is filled with sample material and placed in the Cuvette holder (4). The Cuvette holder is inserted into the Analyzer.

To turn off the Analyzer (1), press the On/Off button (2).

-
- 1 Analyzer
 - 2 On/Off button
 - 3 Display
 - 4 Cuvette holder

Back panel

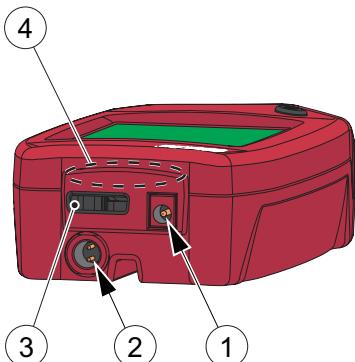


FIGURE 1-4

The following items are found on the back panel of the Analyzer.

- Power inlet (1) for the Power Adapter
- Power + USB signal inlet (2) for connection to the Docking Station
- Built-in Barcode Scanner (3)
- IR Transmitter/Receiver (4) for data transfer to/from the Docking Station

The Power inlet (1) for the Power Adapter can only be used when the Analyzer is out of the Docking Station. When the Analyzer is placed in a Docking Station, this inlet will be blocked and the Analyzer receives power via the Power + USB signal inlet (2).

-
- 1 Power inlet (for Power Adapter)
 - 2 Power + USB signal inlet (for Docking Station)
 - 3 Barcode Scanner
 - 4 IR Transmitter/Receiver

Placing the Analyzer in the Docking Station

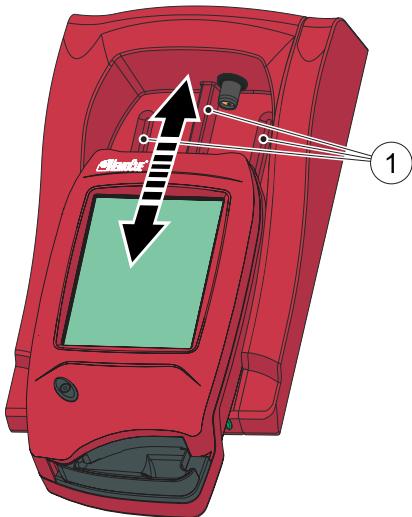


FIGURE 1-5

Always slide the Analyzer into and out of the Docking Station by means of the Tracks (1). Make sure the Analyzer is fully inserted.

Never try to lift the Analyzer out of the Docking Station or press the Analyzer downwards into the Docking Station. This may damage the casing and power outlets of the Analyzer and/or the Docking Station.

Remove the Analyzer if there is no communication between the Analyzer and the Docking Station and then re-dock the Analyzer in the Docking Station.

1 Tracks

2 General operations

This chapter describes the general operations necessary for Analyzer use.

2.1 Getting started – Analyzer

Always follow the operating and storage conditions listed under section *Technical Specifications*. Allow the Analyzer to reach operating temperature before use.

2.1.1 Power source

The Analyzer can be powered either by the rechargeable Battery or by a standard electrical outlet via the Power Adapter.

Recharging the Battery

FIGURE 2-1

The rechargeable Battery (1) is located in a battery compartment on the bottom of the Analyzer.

- Recharge the Battery (1) by connecting the Power Adapter to the Analyzer or by placing the Analyzer in the Docking Station that is connected to the Power Adapter. New Battery will take longer to charge the first 2 to 3 times.

1 Battery



Replacing the Battery

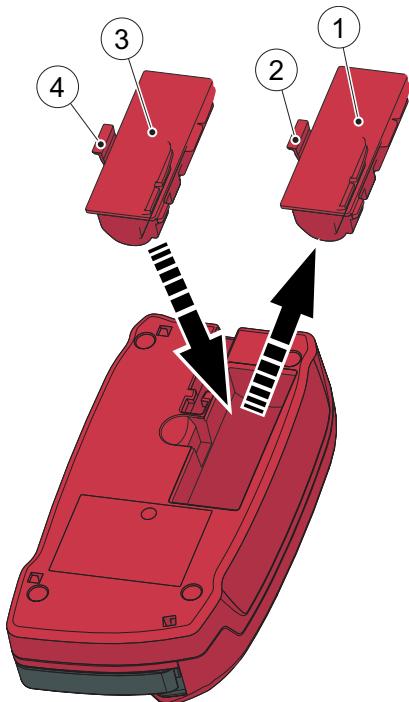


FIGURE 2-2

! Only the HemoCue 201 DM Battery can be used in the Analyzer.

! Lithium-ion battery. Never try to open the battery casing. Risk of explosion.

The Battery lasts for several years. It should be replaced when it fails to retain its charge for an acceptable period. Replace it when the capacity to hold a charge starts to deteriorate quickly.

- a) To remove the Battery (1), press the Flap (2). Carefully loosen the Battery (1) and lift it upwards.
- b) To install the new Battery (3), place it in the Analyzer and gently press downwards until the Flap (4) snaps into the locked position.

Consult local environmental authorities for proper disposal.

-
- 1 Old Battery
 - 2 Flap
 - 3 New Battery
 - 4 Flap
-

Connecting the Power Adapter

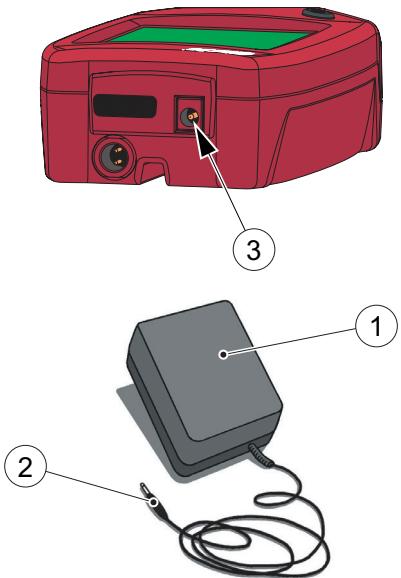


FIGURE 2-3



Only use the Power Adapter listed in section *Technical Specifications*. Other Power Adapters, although physically able to be plugged into the Analyzer, may cause serious damage or fire.

- a) Insert the Power Adapter's DC plug (2) into the Power inlet (3) on the back panel of the Analyzer.
- b) Plug the Power Adapter (1) into an electrical outlet.

1 Power Adapter

2 DC plug

3 Power inlet

2.1.2 Turning on the Analyzer

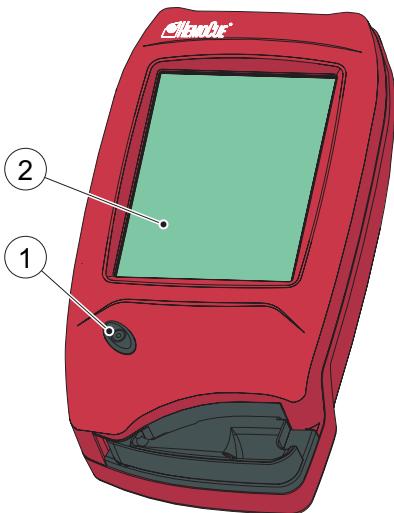


FIGURE 2-4

- a) Turn on the Analyzer by pressing the On/Off button (1).
- b) The Start Image, beginning with the HemoCue logo, will be displayed.
- If the Cuvette holder is in the *measuring position* (see FIGURE 2-8), the following text will be displayed:

Please Pull out The Cuvette Holder
- When the Cuvette holder is in the *Loading position* (see FIGURE 2-6), self-test will be performed. No inputs can be made for approximately 20 seconds during the self-test.

1 On/Off button

2 Display

2.1.3 Power saver mode

When no procedures have been performed within the time predefined in the Analyzer settings, the Analyzer will switch to power save mode.

If the Analyzer is powered via the Power Adapter, the user will be logged off, the image on the display will disappear, but the power will remain on. Touch the Display to reactivate it.

If the Analyzer is powered via the Battery, the user will be logged off and the Analyzer will be switched off. Press the On/Off button to reactivate it.

2.1.4 Turning the Analyzer off

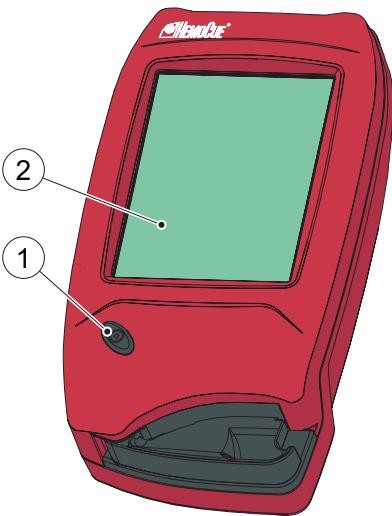
FIGURE 2-5

Make sure not to turn off the Analyzer in the middle of a procedure as data may be lost.

- a) Turn off the Analyzer by pressing the On/Off button (1). The Display (2) goes blank.

1 On/Off button

2 Display



2.1.5 Loading the Analyzer with a Cuvette

The Loading position

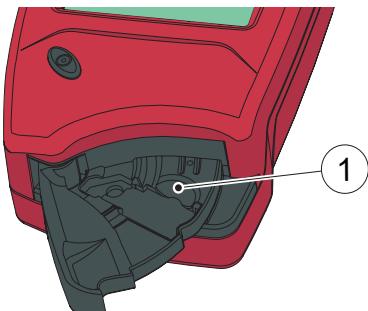
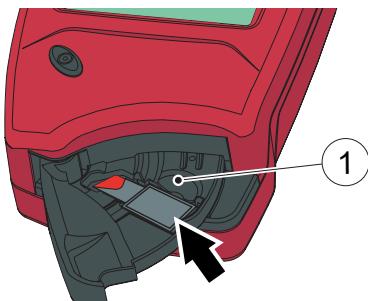


FIGURE 2-6

FIGURE 2-6 shows the Analyzer with the Cuvette holder (1) open, referred to as the *Loading position*.

1 Cuvette holder



Inserting a Cuvette

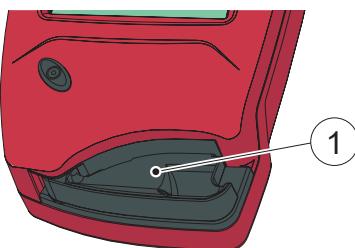
FIGURE 2-7

Obtain a blood sample according to the procedure described in section 3 *Sampling and Measuring*.

- Place the Cuvette in the Cuvette holder (1) and gently close the Cuvette holder.

The Analyzer will automatically start the measuring procedure.

1 Cuvette holder



The Measuring position

FIGURE 2-8

FIGURE 2-8 shows the Analyzer with the Cuvette holder (1) in the closed position, referred to as the *Measuring position*.

1 Cuvette holder

2.2 Docking Station LED

Green light

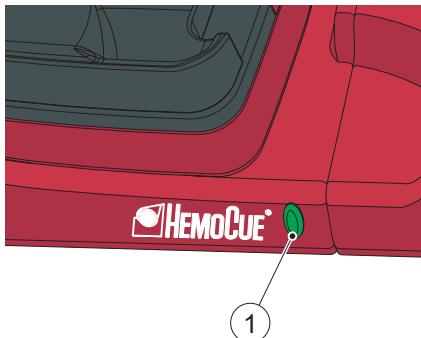


FIGURE 2-9

A steady green light from the LED indicates that the Docking Station is receiving power and that the Battery is fully charged.

A flashing green light from the LED indicates that the Battery in the docked Analyzer is charging.

1 LED

Red light



FIGURE 2-10

A steady red light from the LED indicates an internal error within the Docking Station.

A flashing red light from the LED indicates an external communication error.

The above is only valid for Primary Docking Stations and SDS+- labelled Secondary Docking Stations.

See Reference Manual for troubleshooting.

2 LED

2.3 How to operate the Display

2.3.1 Display buttons

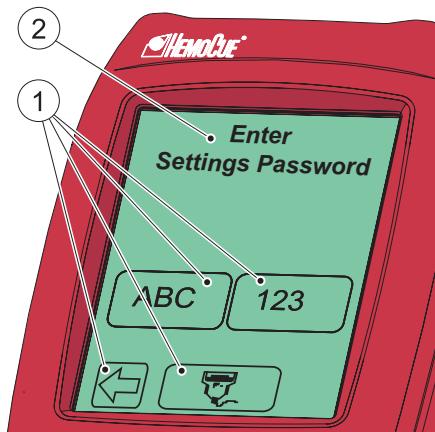


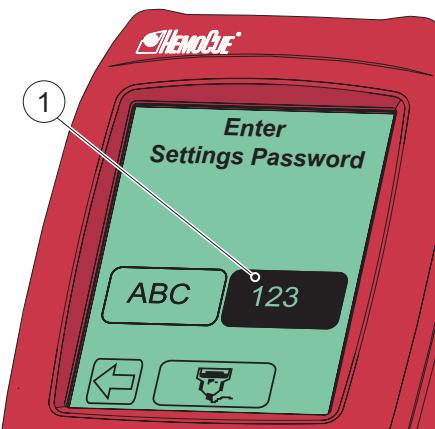
FIGURE 2-11

The Buttons (1) appearing on the Display (2) activate the specific functions symbolized by the image on the button.

The Buttons (1) should only be pressed using the fingertip. Do not use sharp-edged objects as these can damage the Display.

1 Buttons

2 Display



Activating a function

FIGURE 2-12

- When a Button (1) is pressed, it will appear highlighted as long as it is kept pressed.
- When the Button is released, the function indicated by the button is activated. An audible signal will sound if the audio function has been activated in the Settings.

1 Button, highlighted

Changing a function

FIGURE 2-13

- a) Keep pressing while moving the fingertip over to another button.



FIGURE 2-14

- b) The original button will cease to appear highlighted and the new button will appear highlighted.
- c) When the new Button is released, the new function will be activated.



Cancelling a function

FIGURE 2-15



- a) Keep pressing while moving the fingertip over to an area without Buttons.

FIGURE 2-16

- b) No Button will appear highlighted.
- c) When the finger is released from the Display, the first Button choice will be ignored and no action will be activated.



2.3.2 Using the Barcode Scanner button

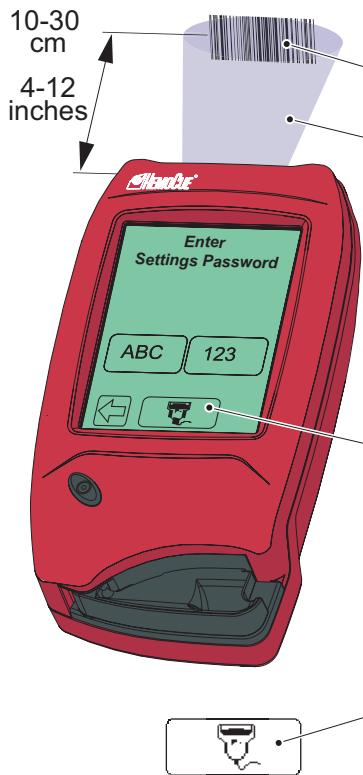


FIGURE 2-17

Important: Be aware of the laser radiation – do not stare into the beam.

To read barcodes, use the built-in Barcode Scanner in the back panel of the Analyzer.

The Scanning range (3) of the Barcode Scanner, is approximately 10–30 cm (4–12 inches) from the Scanner.

- a) Press and hold the Barcode Scanner button (1). The Barcode Scanner is activated and scanning can be performed.
- b) The decoded information from the barcode (2) appears on the Display when the Analyzer identifies the barcode. The information is displayed as long as the Barcode Scanner button (1) remains pressed. To cancel a reading, move the fingertip to an area outside the Barcode Scanner Button, before releasing.
- c) When information is displayed, remove the fingertip from the Barcode Scanner button (1). The information will be stored in the Analyzer, and is no longer displayed.

1 Barcode Scanner button

2 Barcode

3 Scanning area

2.3.3 Main Menu and Help

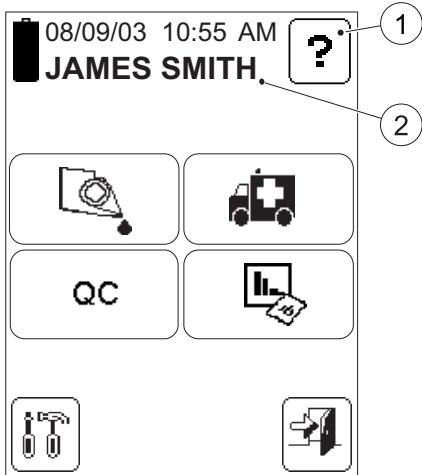


FIGURE 2-18

FIGURE 2-18 is referred to as the Main Menu. It is displayed as the Startup Image for all Tests, Setting procedures, etc.

The Help button (1) may be used to display information about other buttons, procedures, etc.

-
- 1 Help button
 - 2 Operator name, Operator ID or blank, depending on the settings*

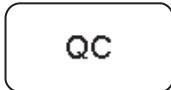
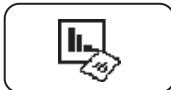
* It is recommended to use the Approved Only setting for operators to ensure optimal operator traceability.

2.4 Display buttons and symbols

2.4.1 Navigation buttons

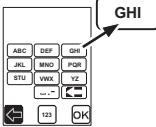
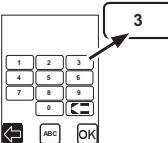
Button	Designation	Function
	Erase button	Erases the last input.
	Previous image button	Returns to the previous image. Note that inputs/changes made in the current image will not be saved.
	Text mode button	Switches to text input mode.
	Numeric mode button	Switches to the numeric input mode.
	Barcode Scanner button	Activates the Barcode Scanner.
	Scroll bar arrow (Up)	Scrolls upwards in a list of different options or in a text.
	Scroll bar arrow (Down)	Scrolls downwards in a list of different options or in a text.
	Next image button	Continues to the next image in the Help sequence.

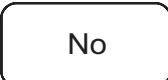
2.4.2 Procedure buttons

Button	Designation	Function
	Patient test button	Activates the Patient Test procedure.
	STAT test button	Activates the STAT (Short Turn Around Time) Test procedure.
	QC test button	Activates the QC (Quality Control) Test procedure.
	Stored data button	Activates the Stored Data function.
	Settings button	Activates the Settings menu.
	Verify/Duplicate sampling button	Allows for the performance of a second test, on the same patient, using a new Cuvette, without the need for re-entering the Patient ID and other information.
	Comment input button	Allows a comment to be added to the current result.
	Comment input button (dotted)	Button appearance confirms that comments have been added to the result.

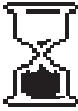
2.4.3 Other display buttons

Button	Designation	Function
	Help button	Displays help regarding other buttons, procedures, etc.
	Confirm button	Saves text or numbers and/or displays the next screen image. All inputs/changes will be saved.
	Log Out button	Logs out the operator. The Log Out button is only displayed if the Operator ID is required.
	Special Character button	Enters a special character (see explanations below). Other special characters can only be loaded into the Analyzer by means of the Barcode Scanner.
	See above	Space – press once
	See above	Period – press twice
	See above	Hyphen – press three times
	View button	Provides a more detailed description of the highlighted item.

Button	Designation	Function
	Letter buttons	<p>Allows input of a text. Example: To enter a "G" – press once To enter an "H" – press twice To enter an "I" – press three times</p> <p>Only capital letters will be entered. Lower-case letters can be entered into the Analyzer by means of the Barcode Scanner.</p>
	Digit buttons	Allows input of a digit.
	Add button	Allows addition of a comment to a result, an item to a list, etc.
	Delete button	Allows deletion of a comment from a result, an item from a list, etc.
	Accept button	Accepts a result. An accepted result will be saved and flagged as accepted.
	Reject button	Rejects a result. A rejected result will be saved and flagged as rejected.
	Save button	Stores the entered information.

Button	Designation	Function
	No button	The entered information will not be stored.
	Continue button	Continues the current operation.
	Statistics button	Displays statistics on the chosen subject.

2.4.4 Display symbols

Symbol	Designation	Function
	Battery	Indicates the voltage status of the Battery in four levels. The furthest to the left is fully charged, the one to the right is almost empty.
03/03/04	Date	Indicates the Date format chosen (from three possibilities) in the Settings Menu.
 	Big Hourglass (rotating)	The big hourglass is displayed when the Analyzer is in the measuring or self-testing state. The big hourglass is rotating when displayed.

Symbol	Designation	Function
	Small hourglass	When the small hourglass is displayed, the instrument is in a measuring or blanking state. When displayed in the Main Menu, only Settings and Stored Data functions are available. It is also possible to log out.
	Waste bin	Indicates that a result has been rejected. The result is stored in the Analyzer.
	QC Reminder	Reminder that a QC Test will be required within stated time or number of measurements.
	QC Lockout	QC Lockout, i.e. no more Patient Test measurements can be made. The required QC Test has not been performed.
	Lockout	Supervisory Lockout. The Analyzer has been locked by the Supervisor.

2.4.5 Entering information with letters and digits

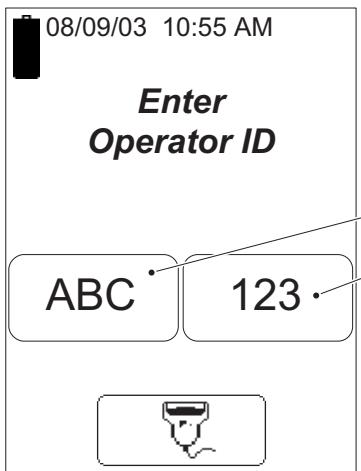


FIGURE 2-19

Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the display or via the Barcode Scanner.

The display can be set to two different modes, text mode for entering letters (including a few special characters) and numeric mode for entering digits.

- a) Press the Text mode button (1) or the Numeric mode button (2) depending on if the first character that is to be entered is a letter or a digit.
- b) Depending on the mode chosen, follow the description for FIGURE 2-20 or FIGURE 2-21.

1 Text mode button

2 Numeric mode button

Text mode

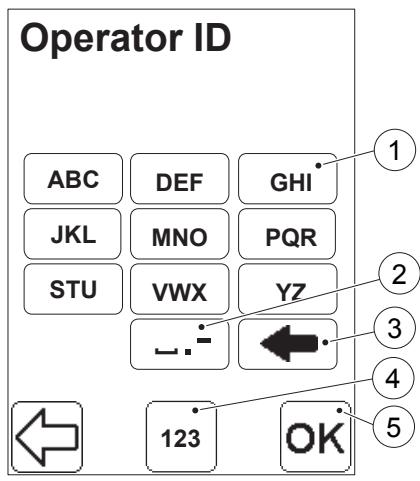


FIGURE 2-20

Only capital letters and a few special characters can be used in the text mode. Lower-case letters can only be entered into the Analyzer by means of the Barcode Scanner.

- a) In the text mode, inputs are made using the Letter buttons (1) and the Special Character button (2).
- b) The Erase button (3) erases the last input.
- c) If a digit is to be entered, switch to the numeric input mode by pressing the Numeric mode button (4). *FIGURE 2-21* will be displayed.
- d) When all information has been entered, press the Confirm button (5).

-
- 1 Letter button
 - 2 Special Character button
 - 3 Erase button
 - 4 Numeric mode button
 - 5 Confirm button

Numeric mode

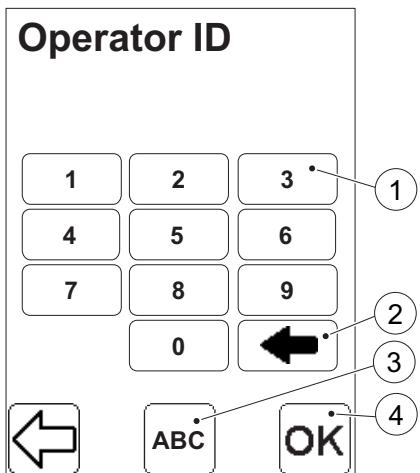


FIGURE 2-21

- In the numeric mode, inputs are made using the Digit buttons (1).
- The Erase button (2) erases the last input.
- If a letter or a special character is to be entered, switch to the text input mode by pressing the Text mode button (3). *FIGURE 2-20* will be displayed.
- When all information has been entered, press the Confirm button (4).

-
- 1 Digit button
 - 2 Erase button
 - 3 Text mode button
 - 4 Confirm button

3 Sampling and Measuring

This chapter describes how to obtain and measure a sample. Capillary, venous or arterial whole blood may be used.

3.1 Capillary blood

Be aware that peripheral circulatory failure of the patient could affect the result of a capillary sample.

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

Important: Always keep the vial properly closed. Fill the Cuvette within 3 minutes after removal from the package.

If a second sample is to be taken, wipe away the remains of the initial sample and fill a new Cuvette from a new drop of blood. This should not be done until the measurement of the first sample is completed.

Before obtaining a blood sample, the Analyzer should be in the "Ready" mode.

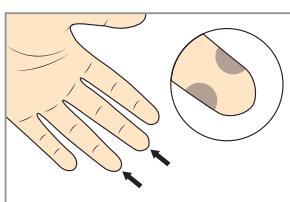


FIGURE 3-1

- Make sure the patient's hand is warm and relaxed. Use only 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.

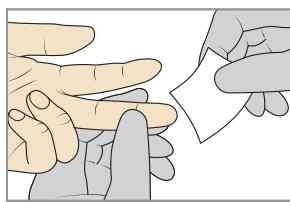


FIGURE 3-2

- Clean with disinfectant and allow to dry.

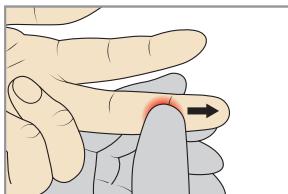


FIGURE 3-3

- c) Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates the blood flow towards the sampling point.

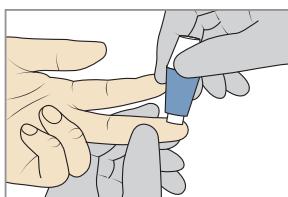


FIGURE 3-4

- d) Whilst lightly pressing towards the fingertip, puncture the finger using a lancet.

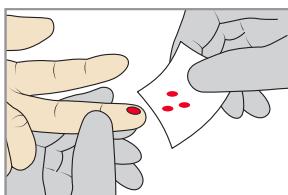


FIGURE 3-5

- e) Wipe away the first 2 or 3 drops of blood. Re-apply light pressure towards the fingertip until another drop of blood appears.

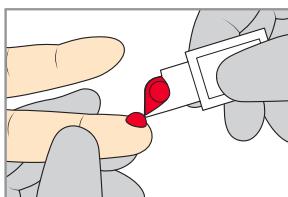


FIGURE 3-6

- f) When the blood drop is large enough, fill the Cuvette from the tip in one continuous process. The Cuvette must be completely filled.
Do not refill!

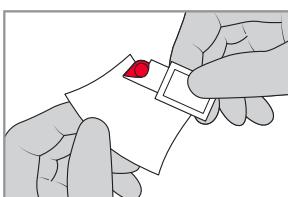


FIGURE 3-7

- g) Wipe off excess blood from the outside of the Cuvette. Make sure that no blood is drawn out of the Cuvette during this procedure.

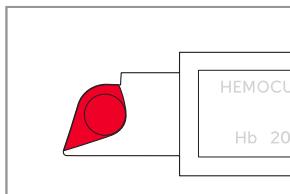


FIGURE 3-8

- h) Visually inspect the Cuvette.

Important: If the Cuvette is not completely filled with blood or if there are air bubbles, discard and fill a new Cuvette. Small bubbles around the filling end can be ignored.

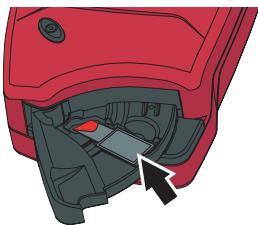


FIGURE 3-9

- i) Place the filled Cuvette into the Cuvette holder.



FIGURE 3-10

- j) Start the measurement by pushing the Cuvette holder to its measuring position.

Make sure to start the measurement as soon as possible but no later than 10 minutes after filling the Cuvette.

- k) Enter the required information. After 15 to 60 seconds (for values <20 g/dL), the result will be displayed. The result will remain on the display until the Confirm button has been pressed.

Do not re-measure the Cuvette!

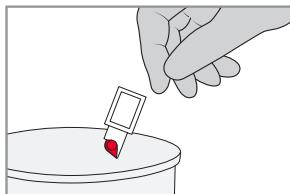


FIGURE 3-11

- l) Discard the Cuvette after measurement.
Cuvettes are for single use only. Follow local safety procedures for disposal of used Cuvettes.

3.2 Control Material, Venous or Arterial Blood



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

Appropriate anticoagulants in solid form (eg EDTA, heparin or heparin/fluoride) may be used. Hemoglobin remains stable for days, provided the blood does not become contaminated.

Important: Always keep the vial properly closed. Fill the Cuvette within 3 minutes after removal from the package.

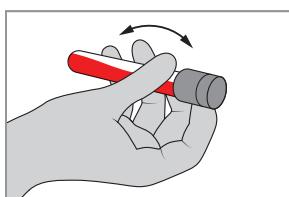


FIGURE 3-12

- a) If the specimen has been stored in a refrigerator, allow it to reach operating temperature before mixing. Mix all samples thoroughly on a mixer for at least 2 minutes or gently invert 8-10 times by hand. Alternatively, follow local recommendations.

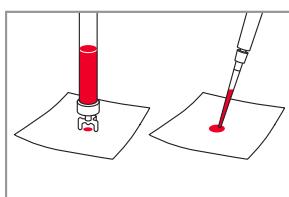


FIGURE 3-13

- b) Place a drop of specimen onto a hydrophobic surface using a suitable transfer device.

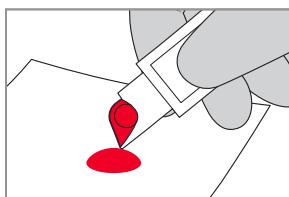


FIGURE 3-14

- c) Fill the Cuvette from the tip in one continuous process. The Cuvette must be completely filled. **Do not refill!**

- d) To complete the measurement follow steps g-l and FIGURE 3-7 to FIGURE 3-11 in section 3.1 Capillary blood. Make sure to start the measurement as soon as possible but no later than 10 minutes after filling the Cuvette.

4 Routine Use

This chapter describes the procedure for performing Patient Tests, STAT Tests and QC Tests, as well as describing the process of reviewing stored data.

4.1 Patient Test Procedure

The Patient Test procedure may vary, depending on which information requirements have been activated in the Settings. The following information may, or may not, be required:

- Cuvette Batch No.
- Patient ID
- Lab ID

It is recommended to limit the number of characters for Operator ID, Patient ID and Lab ID in order to prevent possible mix-up of identification.

A Patient Test procedure may be initiated in two different ways. The first way is described below. The other way is by filling and inserting a Cuvette, then closing the Cuvette holder, allowing required information to be entered while the sample is being analyzed.

1. In the Main Menu, press the Patient Test button.



2. Enter the required information, via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

ABC

123



To reduce the risk of errors it is recommended to use the Barcode Scanner to enter information.

3. Fill and insert a Cuvette as described in section *3 Sampling and Measuring*.

The result will be displayed when all required information has been entered and the measurement has been completed.



To add comments to the result, press the Comment input button. The result will remain on the display even if the Cuvette holder is pulled out, allowing for examination of the Cuvette before comments are made.

A dotted Comment book indicates that comments have been added to the result.



The Verify button allows the verification of the result by measuring a new sample from the patient.



Press the Confirm button to store the information. The Main Menu will be displayed.

4.2 STAT Test Procedure

The STAT Test fulfils the same function as a Patient Test but can be performed by overriding the requirement of performing any type of QC Test. When performing a STAT Test, it is optional whether or not to enter Cuvette Batch, Patient ID or Lab Number in order to make the measuring procedure quicker.

1. In the Main Menu, press the STAT Test button.



2. Enter the required information, via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button, or just press the Confirm button if no data is to be added.

ABC

123



3. Fill and insert a Cuvette as described in section 3 Sampling and Measuring.

The result will be displayed when all required information has been entered and the measurement has been completed.



To add comments to the result, press the Comment input button. The result will remain on the display even if the Cuvette holder is pulled out, allowing for examination of the Cuvette before comments are made.

A dotted Comment book indicates that comments have been added to the result.



The Verify button allows the verification of the result by measuring a new sample from the patient.



Press the Confirm button to store the information. The Main Menu will be displayed.

4.3 QC Test Procedure



Based on the settings made for the QC Test Reminder, the QC Reminder icon will be displayed in the Main menu to warn of an impending QC lockout.



If the impending QC is not performed within the pre-defined reminder time, the Analyzer will perform a lockout. To unlock the Analyzer, the required QC measurements must be performed and approved. Patient Tests cannot be performed during a lockout. STAT tests can be performed if configured.

QC

1. In the Main Menu, press the QC Test button. In the next display, choose the required QC level.
2. Fill a Cuvette with Liquid Control as described in section 3.2 *Control Material, Venous or Arterial Blood*. Make sure Liquid Control of appropriate Level is used. Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
3. Enter the required information, via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

ABC

123



If a Liquid Control Lot Number has not previously been stored in the Analyzer and/or has expired, the following text will be displayed: *Invalid Control Lot*.

The result will be displayed when all required information has been entered and the measurement has been completed.

For a result within the Approved area (the blank area), the Qualitative Test Result will indicate "Pass".

For a result within the Warning area (the dotted area), the Qualitative Test Result will indicate "Pass, Warning".

For a result within the Fail area (the solid area), or for two consecutive results within the Warning area, the Qualitative Test Result will indicate "Fail".

To avoid or unlock a QC lockout, the Qualitative Test Result must indicate "Pass".



To view a graphic presentation of the most recent QC Tests, press the Statistics button.



To add comments to the result, press the Comment input button. The result will remain on the display even if the Cuvette holder is pulled out, allowing for examination of the Cuvette before comments are made.

A dotted Comment book indicates that comments have been added to the result.



Press the Confirm button to store the information. The Main Menu will be displayed.

4.4 Stored data

4.4.1 Reviewing Stored Data

Access to the Stored Data functions is dependent on the operator's user level and on the predefined setting of Operator ID use. Only a Supervisor can delete data, change an accepted or rejected result, or add comments.



In the Main Menu, press the Stored Data button.

If the entry requirement for an Operator ID is set to "Not Used" in the Setup, a password (default password: 0000) has to be entered to be able to perform changes in the Stored Data. Otherwise the Analyzer can respond in two different ways:

If the operator's user level does not permit access to the Stored Data or the incorrect password was entered, the following text will be displayed:

Incorrect Password or User Level, No changes to the Stored Data will be Saved

Press the Confirm Button to view the Stored Data.

The following options are displayed:

- Review
- Delete
- Latest Download
- Log Input

When the Review button is pressed in the Stored Data menu, the following options are displayed:

- All Data
- PAT/STAT
- QC Test
- Analyzer Log

Select an option by pressing it.

If required, change the From date via the Digit buttons. Press Confirm. Repeat the instruction to change the To date.

The stored data within the date interval will be available for review. The latest record is displayed first. If no data within the date interval is found, the following message will be displayed: *No Records Found*

Press the Previous image button to return to the All Data image.

4.4.2 Deleting Stored Data

Only a Supervisor can delete Stored data. Refer to the Reference Manual for the procedure.

4.4.3 Review Latest Download

When the Latest Download button is pressed in the Stored Data menu, data regarding the latest information exchange with the HemoCue 201 DM - DMS Software or an Observation Reviewer is displayed.

Press the Confirm button.

4.4.4 Log Input

Only a Supervisor can review and add Log notes. Refer to the Reference Manual for the procedure.

5 Maintenance

This chapter describes the maintenance procedure for the Analyzer.

5.1 Cleaning the Cuvette holder and the optronic unit

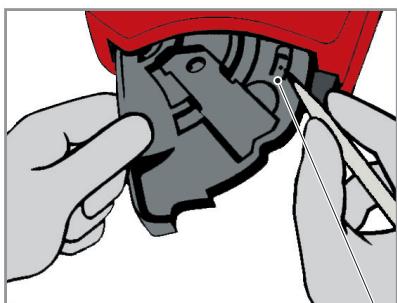
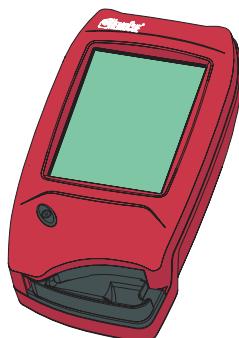


FIGURE 5-1

- b) Pull the Cuvette holder out to the Loading position.
- c) Carefully press the small catch (1) positioned in the upper right corner of the Cuvette holder.

1 Catch

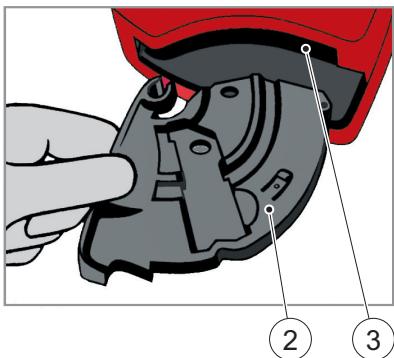


FIGURE 5-2

- d) While pressing the catch, carefully rotate the Cuvette holder sideways as far as possible to the left.
- e) Remove the Cuvette holder from the Analyzer.
- f) Clean the Cuvette holder with alcohol or mild detergent.
- g) To clean the optronic unit, push the HemoCue Cleaner into the opening of the optronic unit.
- h) Move the HemoCue Cleaner from the right to the left 5–10 times, and then pull it out.
- i) If the HemoCue Cleaner is stained, repeat with a new HemoCue Cleaner.

A cotton tip swab moistened with 70% alcohol (without additives) or water may also be used for cleaning.

2 Cuvette holder

3 Opening of the optronic unit

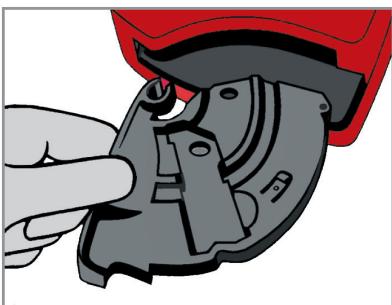


FIGURE 5-3

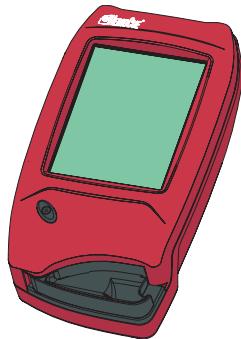
- j) Wait 15 minutes before putting the Cuvette holder back into the Analyzer. It is important that the Cuvette holder is completely dry before reinserting it into the Analyzer.

5.2 Cleaning the Display

The display can be cleaned with alcohol, without additives.

5.3 Cleaning of the Analyzer Outer case and the Docking Station

FIGURE 5-4



- a) Make sure that the Analyzer is turned off. The display should be blank.
- b) The outer case of the Analyzer and the Docking Station may be cleaned with alcohol or a mild soap solution.
- c) The Scanner glass should be cleaned gently with alcohol.

5.4 Calibrating the Display

If the function on the display is not responding when pressed, the display may need to be recalibrated.

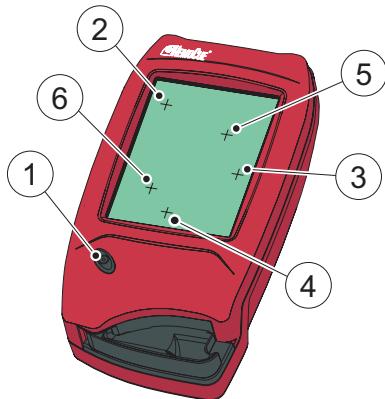


FIGURE 5-5

- a) Make sure that the Analyzer is turned off. The display should be blank.
- b) To recalibrate the display, press the On/Off button (1) for at least 10 seconds. A plus sign (2) will appear in the upper left corner of the display.
- c) Gently press the center of the plus sign (2) with a blunt object. Using the fingertip may not be precise enough.

This is the only occasion when anything other than the fingertips should be used to touch the display. Do not use sharp edged objects as these can damage the Display.

- d) The first plus sign will disappear and two additional plus signs (3 and 4) will appear in sequence.
Repeat according to instruction c).
- e) Two more plus signs (5 and 6) will appear to verify the calibration of the display.
Repeat according to instruction c).
- f) If the verification of the calibration is successful, the Analyzer will continue with the normal startup (see 2.1.2 Turning on the Analyzer). If the verification of the calibration fails, then the display calibration procedure will start over again. If the procedure fails more than five times the normal startup procedure will continue, but the Analyzer probably needs service.

1 On/Off button

2-6 Plus sign

6 Troubleshooting

This chapter describes the Error Codes that may be displayed while using the Analyzer. If you are unable to resolve the problem by following this troubleshooting guide, please contact the local HemoCue distributor or HemoCue AB. Customers in the US should contact HemoCue America, Technical Support. There are no serviceable parts inside the Analyzer.

Symptom	Explanation	Action
Analyzer shows an error code	May be an occasional fault.	Turn off the Analyzer and turn it on again after 30 seconds. Take a new Cuvette and repeat the measurement. If the problem continues, see the specific error codes below.
E00	No stable endpoint found within the time range. 1) The Cuvette is faulty. 2) The circuit board is out of order.	1a) Check the expiration date for the Cuvettes. 1b) Take a new Cuvette and repeat the measurement. 2) Analyzer needs service. Contact the distributor.
E01-E02	1) Dirty optical parts. 2) Analyzer too hot/cold. 3) Magnet missing in cuvette holder.	1) Clean optical parts (see 5 Maintenance). 2) Turn analyzer off, allow to reach operating temperature before use. 3) Order new cuvette holder.
E03	Analyzer exposed to direct light.	Avoid direct light exposure.
E05-E06	Analyzer too hot/cold or exposed to direct light.	a) Turn analyzer off, allow it to reach operating temperature before use. b) Avoid direct light exposure. If the problem continues, Analyzer needs service. Contact the distributor.

Symptom	Explanation	Action
E08	The absorbance is too high. Light blocking item in the Cuvette holder.	<p>a) Check that the Analyzer and Cuvettes are used according to the Instructions for Use and relevant package insert.</p> <p>b) Analyzer needs service. Contact the distributor.</p>
E11	Hardware Error	Analyzer needs service. Contact the distributor.
E17	Internal Error	Analyzer needs service. Contact the distributor.
E23	Data Error Real Time Clock Real Time Clock backup battery has been drained.	The backup battery needs to be replaced. Contact the distributor.
E25	Analyzer not calibrated.	Analyzer needs service. Contact the distributor.
E26	The Patient test memory is full. No more patient test data can be saved.	Refer to the troubleshooting in the Reference Manual.
E27	The QC memory is full. No more QC data can be saved.	Refer to the troubleshooting in the Reference Manual.
E28	The Analyzer log memory is full. No more Error Codes and Log Notes can be saved.	Refer to the troubleshooting in the Reference Manual.

Symptom	Explanation	Action
E29	The electronic self-test failed. The communication self-test failed. The Analyzer may not work properly when connected to a docking station. This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	Analyzer needs service. Contact the distributor.
E30	The electronic self-test failed. The optical self-test failed. The Analyzer may not work properly when measuring. This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	<p>a) Turn off the Analyzer and clean the optronic unit as described in section <i>5 Maintenance</i>.</p> <p>b) Analyzer needs service. Contact the distributor.</p>
E31	Communication Error	Refer to the troubleshooting in the Reference Manual. If problems remain contact the distributor.
Overrange	Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L).	
Non-responsive display	Display needs recalibration.	Follow instructions in section <i>5.4 Calibrating the Display</i> . If the recalibration fails, the Analyzer needs service. Contact the distributor.
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. 	1,2) Analyzer needs service. Contact distributor.

Symptom	Explanation	Action
No characters on the display	<ol style="list-style-type: none"> 1) The Analyzer is not receiving power. 2) If on battery power, the Battery needs to be recharged. 3) The display is out of order. 	<ol style="list-style-type: none"> 1a) Check that the Power Adapter is connected to the power supply. 1b) Check that the Power Adapter is securely connected to the Analyzer or Docking Station. 1c) If the Analyzer is docked, check that the green LED on the Docking Station gives a flashing green light. 1d) Check that the adapter is not damaged. 2) Recharge the Battery via a Power Adapter or a Docking Station. 3) Analyzer needs service. Contact distributor.
Scanner is malfunctioning	<ol style="list-style-type: none"> 1) An incorrect barcode is being scanned. 2) The product has expired. 3) The Analyzer is too close or too far from the barcode. 4) The barcode is indistinct. 5) The Scanner glass is dirty. 6) The barcode is not compatible with the Scanner. 7) The Scanner is broken. 	<ol style="list-style-type: none"> 1) Check that you are reading the barcode from the correct product. 2) Check the expiration date of the product. 3) Hold the Analyzer within 10–30 cm (4–12 inches) from the barcode. 4) Enter the information manually. 5) Clean the Scanner glass according to section <i>5.3 Cleaning of the Analyzer Outer case and the Docking Station</i> 6) The standards that can be scanned are listed in section <i>Technical Specifications</i>. 7) Analyzer needs service. Contact distributor.
No transfer of data	Refer to the troubleshooting in the Reference Manual.	Refer to the troubleshooting in the Reference Manual. If problems remain, contact the distributor.
No transfer of data via USB	No USB-communication.	<ol style="list-style-type: none"> a) Check that the Analyzer is properly docked. <p>Refer to the troubleshooting in the Reference Manual.</p>

Symptom	Explanation	Action
Docking Station LED red	<p>1) Flashing red light - external communication error.</p> <p>2) Steady red light - internal error in the Docking Station.</p>	<p>1) Refer to the troubleshooting in the Reference Manual.</p> <p>2a) Disconnect and then reconnect the Power Adapter.</p> <p>2b) Contact HemoCue AB or the distributor.</p>
Analyzer not charged	No charging of the Battery.	<p>a) Check that the Analyzer is properly docked.</p> <p>b) Check that the green LED on the Docking Station gives a flashing green light when docking the Analyzer.</p> <p>c) Replace the Battery.</p>
Unexpected patient or control results	<p><i>Patient and control sample</i></p> <p>1) Cuvettes expired, damaged or improperly stored.</p> <p>2) Cuvette contaminated.</p> <p>3) Dirty optical parts.</p> <p>4) Air bubbles in filled Cuvette.</p> <p>5) Faulty optical parts.</p> <p>6) Incorrect sampling technique.</p> <p>7) Measurement started later than 10 minutes after filling the Cuvette.</p> <p><i>Control sample</i></p> <p>8) Control solution not compatible.</p> <p>9) Improper handling of control solution.</p> <p>10) Control solution expired or improperly stored.</p>	<p><i>Patient and control sample</i></p> <p>1) Check expiry date and storage conditions.</p> <p>2) Fill a new Cuvette and perform measurement. Follow relevant section in this operating manual.</p> <p>3) Clean optical parts. Follow relevant section in this operating manual.</p> <p>4) Fill a new Cuvette and perform measurement. Follow relevant section in this operating manual.</p> <p>5) The Analyzer needs service.</p> <p>6) Fill a new Cuvette and perform measurement. Follow relevant section in this operating manual.</p> <p>7) Start measurement no later than 10 minutes after filling the Cuvette.</p> <p><i>Control sample</i></p> <p>8) Only use controls recommended by HemoCue.</p> <p>9) Always follow instructions for use for control solution.</p> <p>10) Check expiry date and storage conditions.</p>

7 Specifications

This chapter contains technical information related to the HemoCue Hb 201 DM Analyzer.

7.1 Intended purpose/ Intended use

Quantitative determination of hemoglobin in capillary, venous or arterial blood, using a specially designed Analyzer, the HemoCue Hb 201 DM Analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes.

The HemoCue Hb 201 Microcuvettes are for *In Vitro* Diagnostic use only.

The HemoCue Hb 201 DM Analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

7.2 Principles of the method and procedure

The Cuvette serves both as a pipette and as a measuring cuvette and is for single use only. Capillary, venous or arterial whole blood may be used. No dilution is required. Blood is drawn into the Cuvette by capillary action and an azidemethemoglobin reaction occurs. Analyzer measures transmittance at two wavelengths to compensate for turbidity. The hemoglobin level is calculated and presented. The system is factory calibrated against international reference method for hemoglobin determination (hemoglobincyanide method), ICSH. No further calibration is needed.

7.3 Storage and handling

HemoCue Hb 201 Microcuvettes

Use the HemoCue Hb 201 Microcuvettes prior to their expiry date. The expiry date is printed on each package. For information regarding storage and handling, refer to HemoCue Hb 201 Microcuvettes Package Insert.

HemoCue Hb 201 DM Analyzer and HemoCue 201 DM Docking Station

See section *Technical Specifications* for storage and handling of the Analyzer. For Docking Station storage and handling see HemoCue 201 DM Docking Station Manual.

7.4 Quality Control

The HemoCue Hb 201 DM Analyzer has an internal quality control, the self-test. Every time the Analyzer is turned on, it will automatically verify the performance of the Analyzer. This test is performed every eighth hour if the Analyzer is left turned on. The result of the self-test is stored as an EQC (Electronic Quality Control).

Follow local guidelines regarding quality control procedures. If a quality control test is required by local or other regulations and therefore should be performed, only use Liquid Controls recommended by HemoCue. See relevant package insert for more information.

7.5 Limitations

For limitations, see HemoCue Hb 201 Microcuvettes package insert.

7.6 Expected values

According to Dacie and Lewis, Practical Haematology:

Children 11.0 - 14.0 g/dL (110 - 140 g/L, 6.8 - 8.7 mmol/L)

Women 12.0 - 15.0 g/dL (120 - 150 g/L, 7.4 - 9.3 mmol/L)

Men 13.0 - 17.0 g/dL (130 - 170 g/L, 8.1 - 10.5 mmol/L)

Children, 2 years to teenage, gradually increase to adult values.

Due to a wide range of conditions (dietary, geographical, etc) which affect normal values, it is recommended that each laboratory establish its own normal range.

7.7 EMC and Electrical Safety

The System is tested and complies with IEC 61010-1, IEC/EN 61010-2-101 and IEC/EN 61326-2-6 (including applicable parts of IEC/EN 61326-1).

The System has been tested for indoor use.

When using the Analyzer standalone or together with one Primary Docking Station it has been designed and tested to CISPR 11 Class B.

When using the Analyzer with a standalone Secondary Docking Station or one or several Secondary Docking Stations connected to a Primary Docking Station it has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment in which the HemoCue Hb 201 DM system will be operated should be evaluated prior to operation of the device. Do not use the HemoCue Hb 201 DM system 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.

7.8 Warranty

The Analyzer carries a 24-month warranty from the day of receipt. After the warranty period, service/repair is carried out at fixed prices. Any other use of the System than recommended by the manufacturer, including opening the cover of the Analyzer, will void the warranty.

7.9 Service and Disposal

The Analyzer should be cleaned as recommended under section 5 Maintenance prior to service or disposal. Consult your local environmental authorities for proper disposal.

7.10 Materials required but not provided

- HemoCue Hb 201 Microcuvettes
- Lancet*
- Pipette or other transfer device**
- Lint-free wipe
- Hydrophobic surface **

* For capillary samples

** For venous/arterial samples

7.11 Spare parts

- Power Adapter
- HemoCue 201 DM Battery
- Cuvette holder

7.12 Optional items

- USB cable
- LAN cable
- Software applications
- HemoCue Cleaner
- HemoCue Lancet

Manufacturer

HemoCue AB
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Phone: + 46 77 570 02 10
Fax: + 46 77 570 02 12
E-mail: info@hemocue.se
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Orders: 800.323.1674
Tech. support: 800.426.7256
Fax (Cust. service): 800.333.7043
E-mail: info@hemocue.com

7.13 Symbols used



Caution



Consult instructions for use



CE mark



Biological risk



In Vitro diagnostic medical device



Temperature limitation



Manufacturer



Humidity limitation



Alternating current



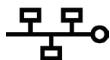
Catalogue number



USB



Serial number



Ethernet



DC inlet



Lithium-ion Battery.
Danger of explosion.
Replace the battery with
the same type
recommended by the
equipment manufacturer.



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



Warning - Laser beam



Laser radiation – Do not stare into the beam.
Class 2 Laser Product.
Maximum output: 1 mW;
Emitted Wavelength: 657 nm; This product meets
the requirements of IEC/
EN 60825-1:2014.



Do not expose to fire



For indoor use only



Do not expose to any
liquids



Efficiency Level



Do not expose to
temperatures
above 50 °C



Class II equipment

7.14 References

Dacie and Lewis, Practical Haematology, Ninth Edition, 2001

HemoCue Hb 201 Microcuvettes Package Insert

Makarem, A. In clinical Chemistry: Principles and Techniques, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125–1147

Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard; CLSI Document H15-A

Technical Specifications

Dimensions	170 x 93 x 50 mm (6.70 x 3.66 x 1.97 inches)
Weight	350 g (0.77 pounds)
Measuring range	0-25.6 g/dL (0-256 g/L, 0-15.9 mmol/L)
Measuring time	15-60 s (<20 g/dL)
Sample volume	10 µl
System operating temperature	18 - 30 °C (64 - 86 °F)
Analyzer storage and transport temperature	0 - 50 °C (32 - 122 °F)
Analyzer operating and storage humidity	< 90% RH (non-condensing)
Barcodes that can be scanned	UPC/EAN (UPC-A; UPC/E; EAN-8; EAN-13); Code 128 (USS-128; UCC/EAN-128; ISBT 128); Code 39; Interleaved 2 of 5; Codabar
Pollution degree	2
Oversupply category	II
Altitude	up to 2000 m above sea level
Power Adapter/Input	FW7556M/06: 100-240V~/50-60 Hz/400-200 mA FW8001/06: 100-240V~ / 50-60 Hz/400-200 mA
Power Adapter/Output	FW7556M/06: 6 V $\frac{---}{---}$ /2500 mA FW8001/06: 5.9 V $\frac{---}{---}$ /3000 mA
Battery	HemoCue Li-ion rechargeable power battery 201 DM 3.6V 2.6Ah
Battery capacity	\geq 120 tests/100 hours using the Barcode Scanner and a power save setting of 5 minutes
Battery charging time	75% of its capacity < 4 hours > 95% of its capacity < 6 hours



IVD

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