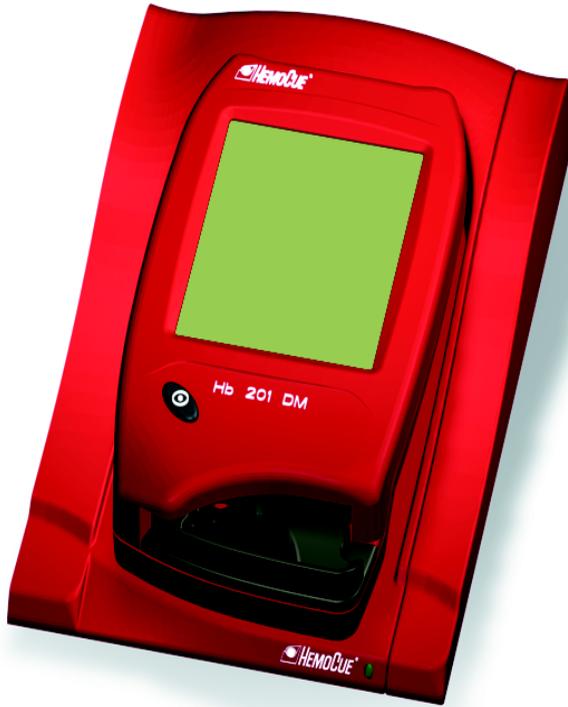


HemoCue Hb 201 DM Analyzer



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 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 installation, set-up and other vital information, consult the HemoCue Hb 201 DM Reference Manual.

1.1 Functional description

1.1.1 System Components

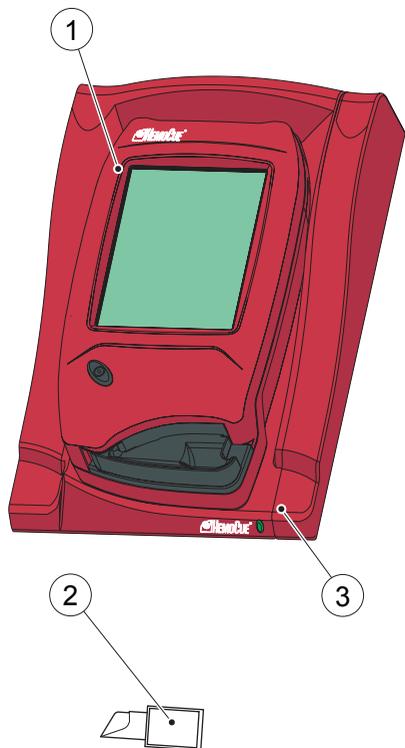
FIGURE 1-1

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

Analyzer

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

Note! The system is intended for in vitro diagnostic use only.



-
- 1 Analyzer
 - 2 Cuvette
 - 3 Docking Station

(Continues)

1.1.2 Analyzer overview

Front panel

FIGURE 1-2

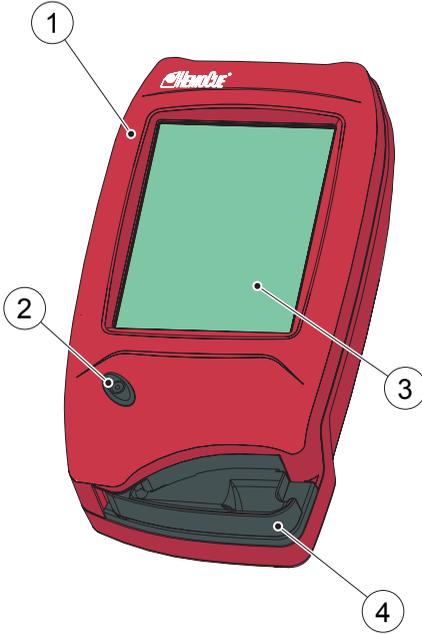
Note! Do not turn off the Analyzer in the middle of a procedure. Data may be lost.

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).

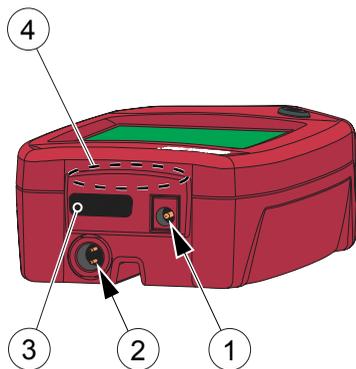
To perform a measurement, the Cuvette is filled with sample material and placed in the Cuvette holder (4). The Cuvette holder is inserted into the Analyzer.

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



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

1 Introduction



Back panel

FIGURE 1-3

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

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

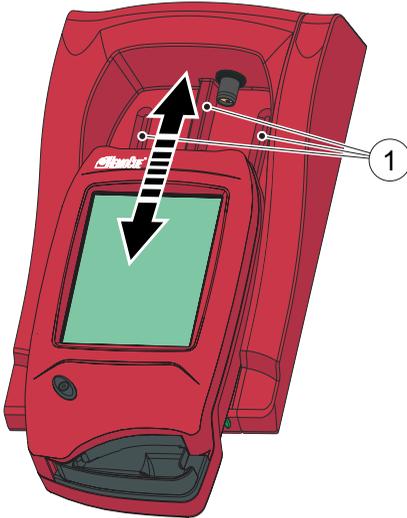
Placing the Analyzer in the Docking Station

FIGURE 1-4

Important! Always **slide** the Analyzer into and out of the Docking Station by means of the Tracks (1).

Important! 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.



1 Tracks

1 Introduction

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2 General operations

This chapter describes the general operations necessary for Analyzer use.

2.1 Getting started – Analyzer

2.1.1 Power source

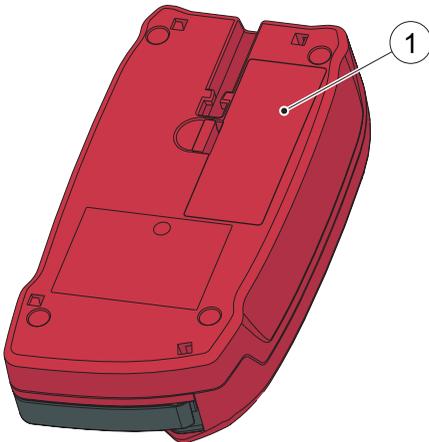
The Analyzer can be powered either by the rechargeable Battery or by a standard electrical outlet via the AC Adapter.

Recharging the Battery

FIGURE 2-1

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

- a) Recharge the Battery (1) by connecting the AC Adapter to the Analyzer or by placing the Analyzer in the Docking Station.



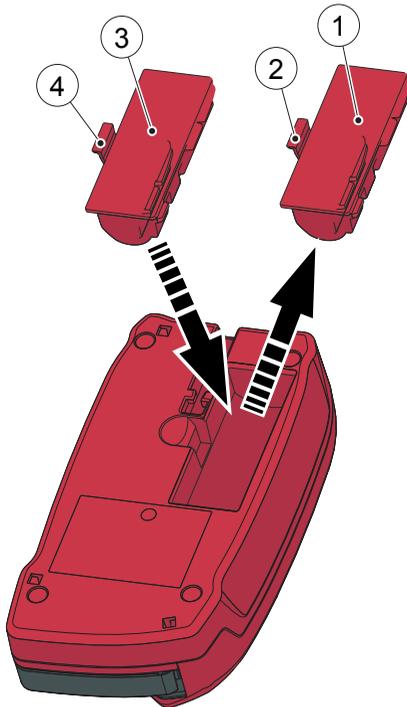
1 Battery

(Continues)

2 General operations

Replacing the Battery

FIGURE 2-2



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

Warning! 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.

The Battery is available as an accessory through HemoCue and HemoCue distributors.

- a) To remove the Battery (1), press the Flap (2).
- b) Carefully loosen the Battery (1) and lift it upwards.
- c) 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

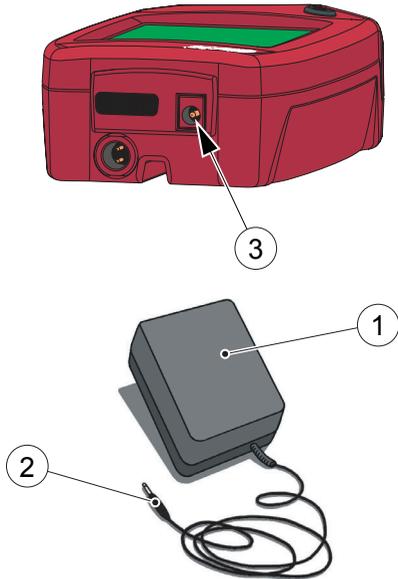
Connecting the AC Adapter

FIGURE 2-3



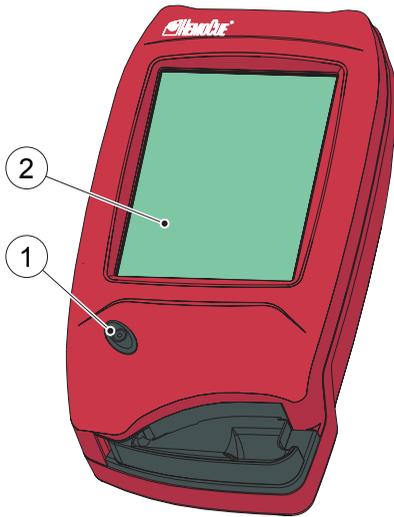
Warning! Only use the AC Adapter that is recommended by HemoCue. Other AC Adapters, although physically able to be plugged into the Analyzer, may cause serious damage or fire.

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



-
- 1 AC Adapter
 - 2 DC plug
 - 3 Power inlet

2 General operations



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, the following text will be displayed:
Please Wait Selftesting ...
No inputs can be made for approximately 20 seconds during the selftest.

-
- 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 AC 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.

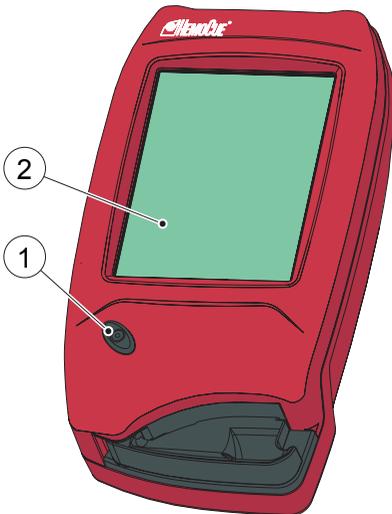
2.1.4 Turning the Analyzer off

FIGURE 2-5

Note! Do not turn off the Analyzer in the middle of a procedure. Data may be lost.

- a) Turn off the Analyzer by pressing the On/Off button (1).
- b) The image on the Display (2), disappears.

-
- 1 On/Off button
 - 2 Display



2 General operations

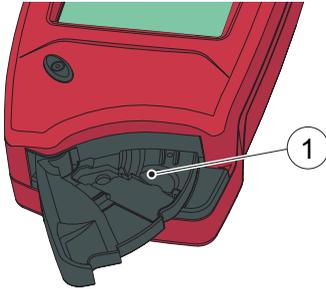
2.1.5 Loading the Analyzer with a Cuvette

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

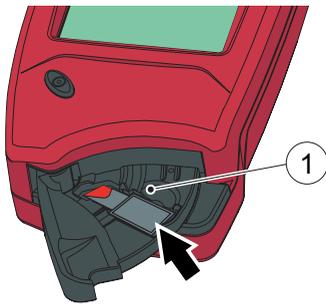
FIGURE 2-7

Obtain a blood sample according to the procedure described in section 3 *Blood specimen collection*.

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

The Analyzer will automatically start the measuring procedure.

1 Cuvette holder

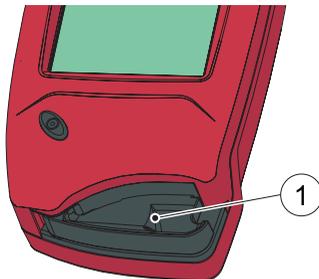


The Measuring position

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

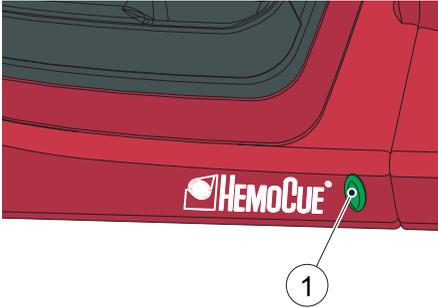


FIGURE 2-9

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

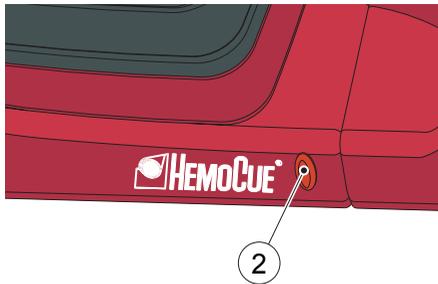


FIGURE 2-10

Note! Can only occur on a Primary Docking Station

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

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

Refer to the Reference Manual.

2 LED

2.3 How to operate the Display

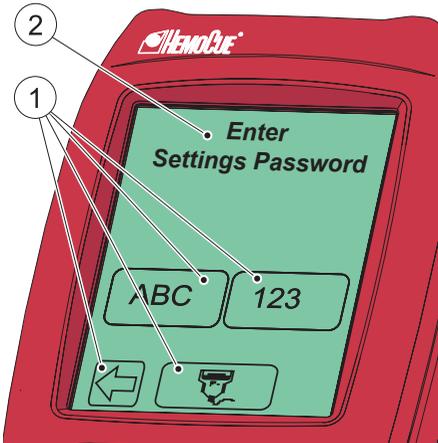
2.3.1 Display buttons

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.

Important! Sharp-edged objects can damage the Display.



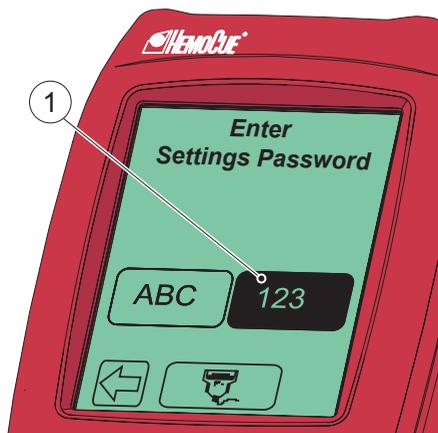
-
- 1 Buttons
 - 2 Display

Activating a function

FIGURE 2-12

a) When a Button (1) is pressed, it will appear highlighted as long as it is kept pressed.

b) 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.



2 General operations

Cancelling a function

FIGURE 2-15



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

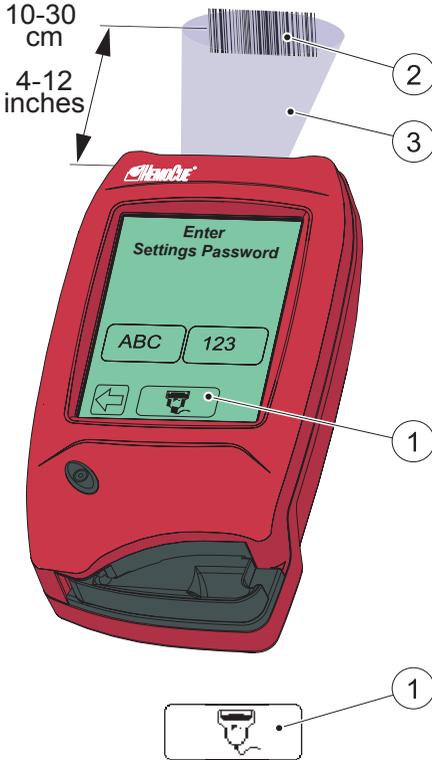
FIGURE 2-16



- 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



Warning! Laser radiation – Do not stare into the beam or view directly with an optical instrument.

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

Note! 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 lights up 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.

-
- 1 Barcode Scanner button
 - 2 Barcode
 - 3 Scanning area

2 General operations



FIGURE 2-18

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 On-line Help

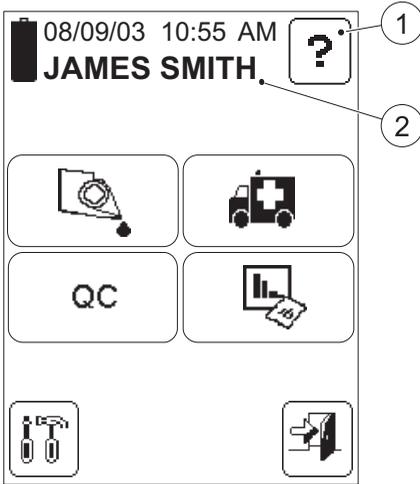


FIGURE 2-19

FIGURE 2-19 is referred to as the *Main Menu*. It is displayed as the Startup Image for all Tests, Setting procedures, etc.

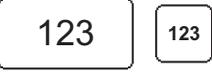
The Help button (1) may be used to display information about other buttons, procedures, etc.

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

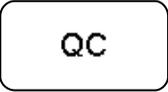
2 General operations

2.4 Display buttons and symbols

2.4.1 Navigation buttons

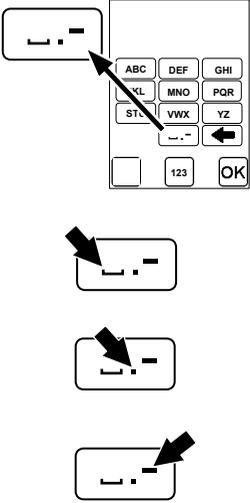
Button	Designation	Function
	Erase button	Erases the last input
	Previous image button	Returns to the previous image NOTE: Inputs/changes made in the current image will not be saved
	Text mode button	Switches to text input mode
	Numeric mode button	Switches to the numeric input mode
	Barcode Scanner button	Switches to the Barcode Scanner mode
	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

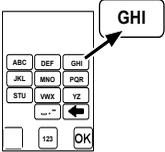
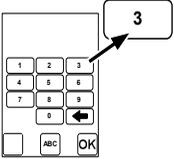
Button	Designation	Function
	Patient test button	Activates the Patient Test procedure
	STAT test button	Activates the STAT (Short Turn Around Time) Test procedure
	QC test button	Activates the QC (Quality Control) Test procedure
	Stored data button	Activates the Stored Data function
	Settings button	Activates the Settings menu
	Verify 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 General operations

2.4.3 Other display buttons

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

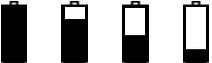
2 General operations

Button	Designation	Function
	Letter buttons	<p>Allows input of a text</p> <p>Example: To enter a “G” – press once To enter an “H” – press twice To enter an “I” – press three times</p> <p>NOTE: 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 measurement
	Reject button	<p>Rejects a result</p> <p>A rejected result will be saved and flagged as rejected.</p>

2 General operations

Button	Designation	Function
 A rounded rectangular button with the word "Continue" centered inside.	Continue button	Continues the current operation
 A square button containing a grid with a line graph showing an upward trend.	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 selftesting state. NOTE: The big hourglass is rotating when displayed.
	Small hourglass	When the small hourglass is displayed, the instrument is in a measuring or blanking state. NOTE: 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.

2 General operations

Symbol	Designation	Function
	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. A text that indicates this will be displayed.

2.4.5 Entering information with letters and digits

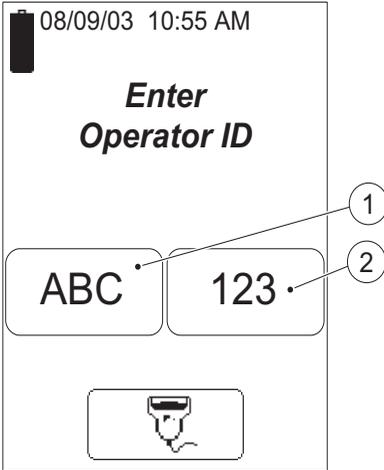


FIGURE 2-20

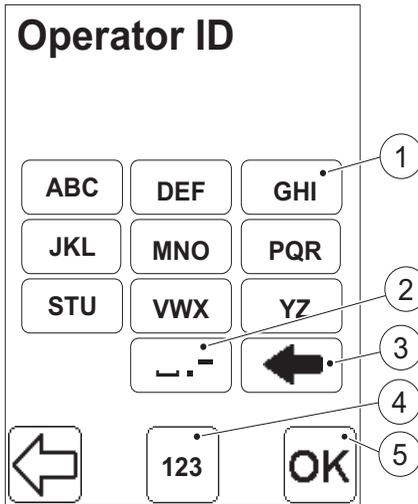
Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the display or via the Barcode scanner.

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 2-21* or *FIGURE 2-22*.

-
- 1 Text mode button
 - 2 Numeric mode button

2 General operations



Text mode

FIGURE 2-21

Note! 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.

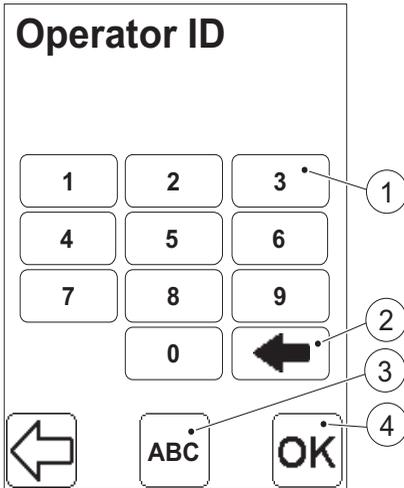
- a) In the text mode, inputs are made using the Letter buttons (1) and the Special Character button (2).
- b) The Erase button (3) erases the last input.
- c) If a digit is to be entered, switch to the numeric input mode by pressing the Numeric mode button (4). FIGURE 2-22 will be displayed.
- d) When 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 2-22

- a) In the numeric mode, inputs are made using the Digit buttons (1).
- b) The Erase button (2) erases the last input.
- c) 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 2-21* will be displayed.
- d) When all information has been entered, press the Confirm button (4).



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

2 General operations

This page intentionally left blank

3 Blood specimen collection

This chapter describes the procedure for obtaining a blood sample to be used for hemoglobin analysis.

3.1 Capillary blood

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

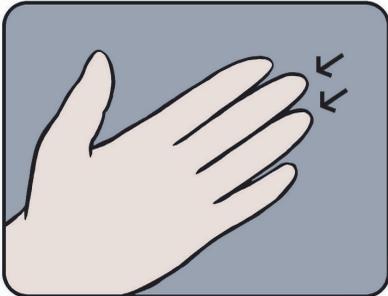


FIGURE 3-1

a) Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.

(Continues)

3 Blood specimen collection

(Continues)

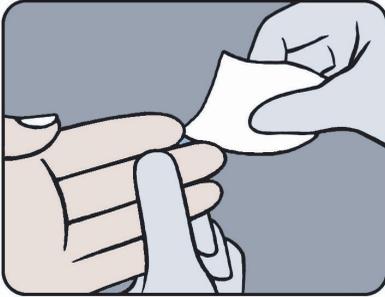


FIGURE 3-2

b) Clean with disinfectant and allow to dry or wipe off with a dry, lint-free tissue.



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.

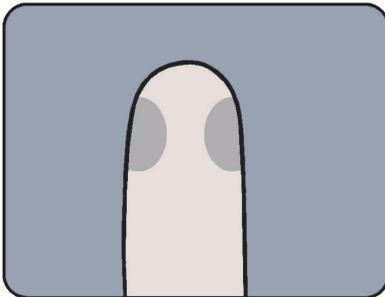


FIGURE 3-4

d) For best blood flow and least pain, sample at the side of the fingertip, not the center.



Warning! Always handle blood specimens with care, as they might be infectious.

(Continues)

3 Blood specimen collection

(Continues)

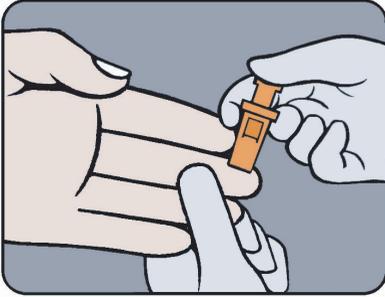


FIGURE 3-5

- e) While applying light pressure toward the fingertip, puncture the finger using the lancet.

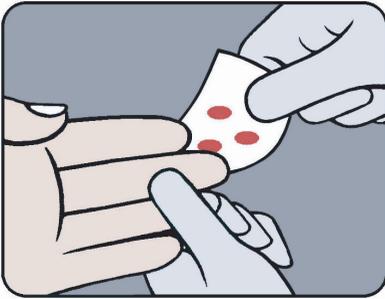


FIGURE 3-6

- f) Wipe away the first 2 or 3 drops of blood with a lint free wipe.

Note! Do not use cotton balls.

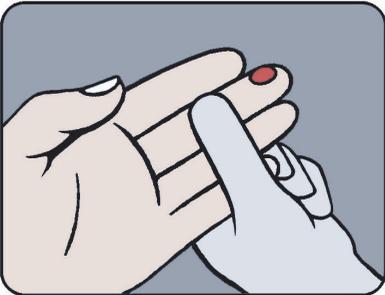


FIGURE 3-7

- g) Re-apply light pressure towards the fingertip until another drop of blood appears.

(Continues)

3 Blood specimen collection

(Continues)

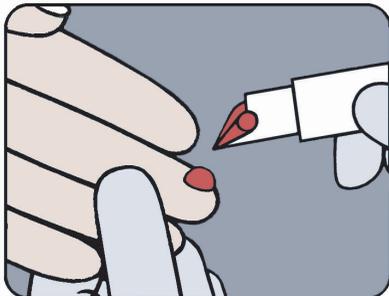


FIGURE 3-8

h) When the blood drop is large enough, fill the Cuvette in one continuous process.

Note! Do not refill!

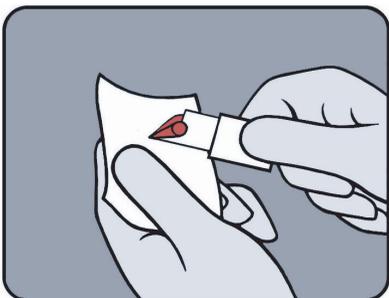


FIGURE 3-9

i) Wipe off excess blood from the outer surface of the Cuvette with lint-free tissue, being careful not to touch the open end of the Cuvette.

Note! Make sure that no blood is drawn out of the Cuvette during this procedure.

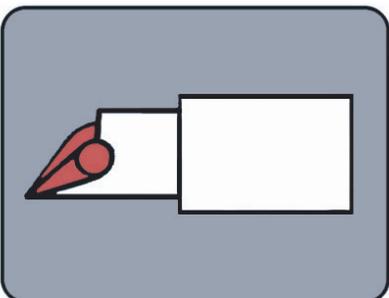


FIGURE 3-10

j) Look for air bubbles in the filled Cuvette. If any air bubbles are present, fill a new Cuvette. Small bubbles around the edge can be ignored.

Note! If a second sample is to be taken from the same finger stick, wipe away the remains of the initial sample and fill a second Cuvette from a new drop of blood.

(Continues)

3 Blood specimen collection

(Continues)

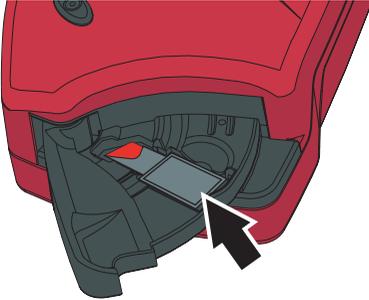


FIGURE 3-11

k) Place the filled Cuvette in the Cuvette holder, see *FIGURE 3-11*.

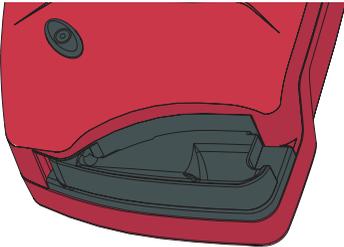


FIGURE 3-12

l) Push the Cuvette holder to the Measuring position.

Note! This should be performed within 10 minutes after filling the Cuvette!

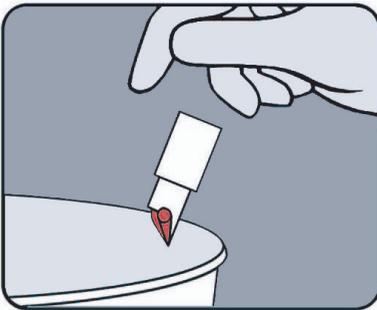
m) Enter the required information.

After 15 seconds to 60 seconds, the result will be displayed.

The result will remain on the display until the Confirm button has been pressed.

FIGURE 3-13

Note! Although the reagents are present in the Cuvette in extremely low quantities, consult local environmental authorities for proper disposal.



3 Blood specimen collection

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3.2 Venous and Arterial Blood

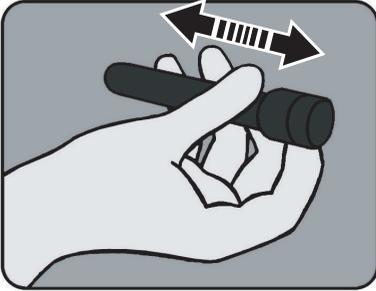


FIGURE 3-14

a) The blood should be well mixed prior to performing the measurement.

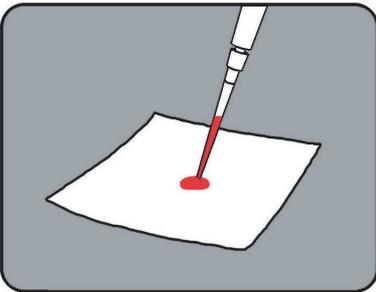


FIGURE 3-15

b) Place a drop of blood onto a hydrophobic surface, e.g. a plastic film, using a pipette.

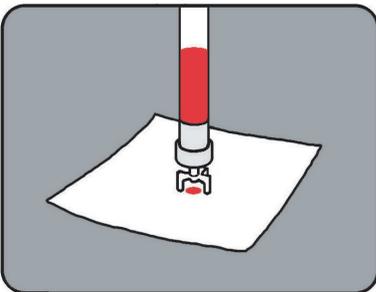


FIGURE 3-16

It is also possible to use a suitable blood transfer device.

(Continues)

3 Blood specimen collection

(Continues)

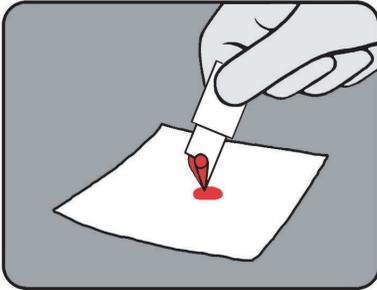


FIGURE 3-17

c) Fill the Cuvette in one continuous process.

Note! Do not refill!

Note! Wipe off excess blood from the outer surface of the Cuvette with lint-free tissue, being careful not to touch the open end of the Cuvette.

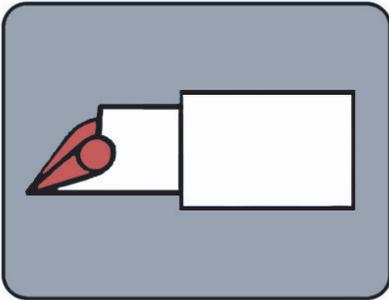


FIGURE 3-18

d) Look for air bubbles in the filled Cuvette. If any air bubbles are present, fill a new Cuvette. Small bubbles around the edge can be ignored.

e) Perform the measurement as described in *FIGURE 3-11*, and *FIGURE 3-13* in section 3.1 *Capillary blood*.

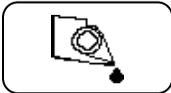
4 Routine Use

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



1. In the Main Menu, press the Patient Test button.
2. Fill and insert a Microcuvette.



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



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

(Continues)

4 Routine Use

(Continues)



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.

Note! 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. Fill and insert a microcuvette.



3. 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.



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.

Note! 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.

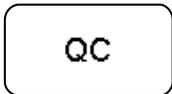
4.3 QC Test Procedure



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.



1. In the Main Menu, press the QC Test button. In the next display, choose the required QC level.

2. Fill a Cuvette with the appropriate level of Liquid Control. 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.



Note! 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.**



(Continues)

(Continues)

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.

Note! 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 Routine Use

4.4 Stored data

4.4.1 Reviewing Stored Data

Note! 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 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 text: ***Incorrect Password or User Level, No changes to the Stored Data will be Saved*** will be displayed.

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

(Continues)

(Continues)

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 PC 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.

4 Routine Use

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5 Maintenance

This chapter describes the maintenance procedure for the Analyzer.

5.1 Cleaning the Cuvette holder and the optronic unit

The Cuvette holder should be cleaned after each day of use. A dirty optronic unit may cause the Analyzer to display an error code. To clean the Cuvette holder and the optronic unit, proceed as follows:

- a) Check that the Analyzer is turned off. The display should be blank.

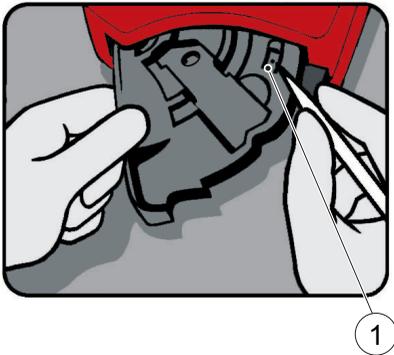
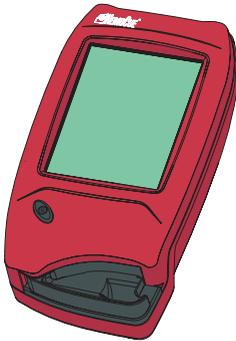


FIGURE 5-1

- 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

5 Maintenance

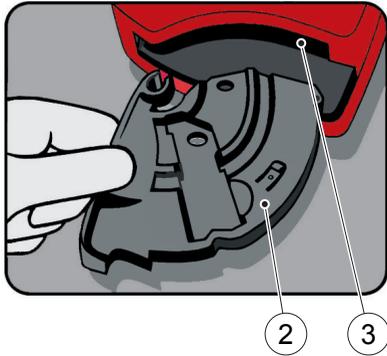


FIGURE 5-2

- 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.

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

-
- 2 Cuvette holder
 - 3 Opening of the optronic unit

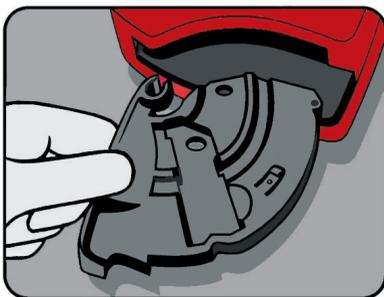


FIGURE 5-3

- 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

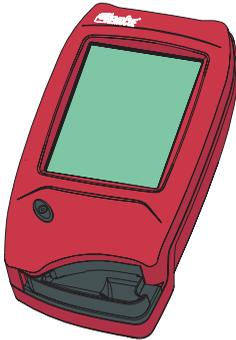


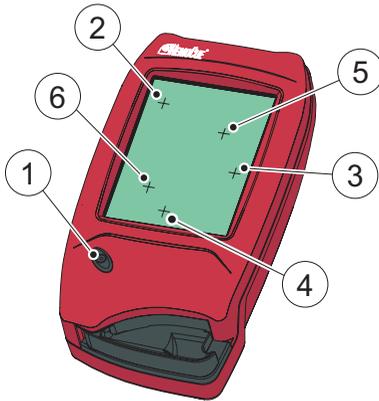
FIGURE 5-4

- a)* Make sure that the Analyzer is turned off. The display should be blank.
- b)* The outer case on 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 activated 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.
- 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).

(Continues)

(Continues)

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 Plus sign
 - 3 Plus sign
 - 4 Plus sign
 - 5 Plus sign
 - 6 Plus sign

5 Maintenance

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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 your local HemoCue distributor or HemoCue AB. Customers in the US should contact HemoCue Inc., Technical Support. There are no serviceable parts inside the Analyzer.

6.1 Error messages

Symptom	Explanation	Action
The 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) The Analyzer needs service. Contact your distributor.
E01-E05	Fault in the optics or electronics	a) Turn off the Analyzer and clean the optronic unit as described in the maintenance section. b) The Analyzer needs service. Contact your distributor

6 Troubleshooting

Symptom	Explanation	Action
E06	Unstable blank value. The Analyzer might be cold	Turn off the Analyzer and allow it to reach room temperature. If the problem continues, the Analyzer needs service. Contact your distributor
E08	The absorbance is too high. Light blocking item in the Cuvette holder	a) Check that the Analyzer and Cuvettes are used according to the Instructions for Use. b) The Analyzer needs service. Contact your distributor
E11	Hardware Error	The Analyzer needs service. Contact your distributor
E17	Internal Error	The Analyzer needs service. Contact your distributor
E23	Data Error Real Time Clock Real Time Clock backup battery has been drained	The backup battery needs to be replaced. Contact your distributor
E25	Analyzer not calibrated	The Analyzer needs service. Contact your 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 selftest failed. The communication selftest 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.	The Analyzer needs service. Contact your distributor.
E30	The electronic selftest failed. The optical selftest failed. The Analyzer may not work properly when measuring. This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	<ul style="list-style-type: none"> a) Turn off the Analyzer and clean the optronic unit as described in the maintenance section. b) The Analyzer needs service. Contact your distributor
E31	Communication Error	Refer to the troubleshooting in the Reference Manual. If problems remain contact your distributor.
Overrange	Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L)	

6 Troubleshooting

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 AC adapter is connected to the power supply. 1b) Check that the AC 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 an AC adapter or a Docking Station. 3) The Analyzer needs service. Contact your 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. 	<ol style="list-style-type: none"> 1) The Analyzer needs service. Contact your distributor. 2) The Analyzer needs service. Contact your distributor.
The 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 5.3 <i>Cleaning of the Analyzer Outer case and the Docking Station</i> 6) The standards that can be scanned are listed in section 7 <i>Technical specifications</i>. 7) The Analyzer needs service. Contact your distributor.

Symptom	Explanation	Action
No transfer of data	Refer to the troubleshooting in the Reference Manual.	Refer to the troubleshooting in the Reference Manual. If problems remain, contact your distributor.
No transfer of data via USB	No USB-communication	a) Check that the Analyzer is properly docked. Refer to the trouble shooting in the Reference Manual.
Analyzer not charged	No charging of the Battery	a) Check that the Analyzer is properly docked. b) Check that the green LED on the Docking Station gives a flashing green light when docking the Analyzer. c) Replace the Battery.
Unintentional downloading	Data is sent unintentionally	Using a Primary Docking Station (Single or within a set), the Analyzer downloads via IrDA. This means that the Analyzer will start downloading as soon as it is close enough to the Docking Station (even if not properly docked). Note! To prevent data from being unintentionally transmitted, keep the Analyzer away from the Docking Station.

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7 Technical specifications

This chapter contains the technical specifications for the System Components in the HemoCue Hb 201 DM System.

7.1 General

The HemoCue Hb 201 DM is a system used for the determination of the total amount of hemoglobin in whole blood. The system consists of a specially designed Analyzer with specially designed microcuvettes containing dry reagents. The microcuvette serves as pipette, reaction vessel and as a measuring microcuvette. No dilution is required. The hemoglobin measurements takes place in the Analyzer, which follows the progress of the reaction until the end point has been reached. The system is factory calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentrations in blood.

7.2 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.

7.3 Theory

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

7 Technical specifications

7.4 Reagents

40 % w/w Sodium Deoxycholate, 18 % w/w Sodium Azide, 20 % w/w Sodium Nitrite, 22 % w/w nonreactive substances.

7.5 Sample material

Capillary, venous or arterial blood may be used. Appropriate anticoagulants in solid form (eg EDTA, heparin or heparin/flouride) may be used. Mix all samples thoroughly on a mechanical mixer for at least 2 minutes or invert 8-10 times by hand. Alternatively, follow local recommendations. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscid and the blood should be allowed to warm up to room temperature before mixing.

7.6 Storage and environmental requirements

HemoCue Hb 201 Microcuvettes

Use the HemoCue Hb 201 Microcuvettes prior to their expiration date. The expiration date is printed on each package.

Storage of microcuvettes kept in a vial

The microcuvettes are to be stored in room temperature (15 - 30 °C, 59 - 86 °F). Do not refrigerate. The microcuvettes are stable for two years from the date of manufacture. Once the seal is broken, the microcuvettes are stable for three months. Always keep the container properly sealed.

Storage of the individually packaged microcuvettes

The microcuvettes are to be stored in room temperature (15 - 30 °C, 59 - 86 °F). Do not refrigerate. The microcuvettes are stable for fifteen months from the date of manufacture.

HemoCue Hb 201 DM Analyzer and HemoCue DM Docking Station.

The Analyzer and Docking Station can be stored at 0 - 50 °C (32 - 122 °F). Operating temperature is 18 - 30 °C (64 - 86 °F). Allow the Analyzer and Docking Station to reach ambient temperature before use. The Analyzer and the Docking Station should not be operated at high (i.e. > 90 % non-condensing) humidity.

7.7 Quality Control

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

If quality control checks are required for regulatory reasons, they should be performed using Liquid Controls recommended by HemoCue.

7.8 Measuring range

7.8.1 Whole Blood

0 - 25.6 g/dL (0 - 256 g/L, 0 - 15.9 mmol/L).

Results above 25.6 g/dL (256 g/L, 15.9 mmol/L) will be displayed as overrange.

Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed using a suitable laboratory method.

7.9 Limitations

HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only. The HemoCue Hb 201 DM Analyzer is only to be used together with HemoCue Hb 201 Microcuvettes. For further limitations of the procedure, see the HemoCue Hb 201 Microcuvettes package insert.

7.10 Expected values

Adult Males 13.0 - 17.0 g/dL (130 - 170 g/L, 8.1 - 10.5 mmol/L)²

Adult Females 12.0 - 15.0 g/dL (120 - 150 g/L, 7.4 - 9.3 mmol/L)²

Infants, after neonatal period 11.0 - 14.0 g/dL (110 - 140 g/L, 6.8 - 8.7 mmol/L)²

Children, two years to teenage: gradual increase to adult normals.

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

7 Technical specifications

7.11 Technical Specifications

Analyzer

Dimensions: 170 x 93 x 50 mm (6.70 x 3.66 x 1.97 inches)

Weight: 350 g (0.77 pounds)

AC adapter: Egston

Mod. No.: N2UFMW3 (US)

Mod. No.: N2EFMW3 (EU)

Mod. No.: N2GFMW3 (GB)

Input: 100 - 240 VAC, 50 - 60 Hz

Output: 6VDC, 2.5 A

Only use adapters recommended by HemoCue.

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

Overvoltage category: II

Atmospheric pressure: 700 hPa to 1060 hPa

Equipment not suitable for use in the presence of flammable mixtures

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

This product is covered by one or more of U.S. patents, 4,758,717; 5,130,520; 5,262,628; 5,396,055; and 5,532,469.

(Continues)

(Continues)

Docking Station

Dimensions: 206x135x61 mm (8.10 x 5.30 x 2.40 inches)

Weight: 566 g (1.24 pounds)

AC adapter: Egston

Mod. No.: N2UFMW3 (US)

Mod. No.: N2EFMW3 (EU)

Mod. No.: N2GFMW3 (GB)

Input: 100 - 240 VAC, 50 - 60 Hz

Output: 6VDC, 2.5 A

Only use adapters recommended by HemoCue.

Pollution degree: 2

Over voltage category: II

Atmospheric pressure: 700 hPa to 1060 hPa

Equipment not suitable for use in the presence of flammable mixtures

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

7.12 Signal input and signal output connections

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective UL standards (i.e. UL 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations must comply with the system standard, IEC 60601-1-1. Connections of additional equipment to the signal input or signal output connections is deemed to be “configuring a medical system”, and therefore assumes responsibility for the systems compliance within the requirements of IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

7.13 Electromagnetic Compatibility

The HemoCue Hb 201 DM is intended for use in the electromagnetic environment specified below. The customer or the user of the HemoCue Hb 201 DM should assure that it is used in such an environment.

Table 1: Electromagnetic emissions

RF Emissions	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The HemoCue Hb 201 DM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The HemoCue Hb 201 DM is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Table 2: Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV ± 8 kV air		
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode		
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	Reduction: >95% for 10 ms, criteria B. Reduction: 30% for 500 ms, criteria C. Reduction: >95% for 5 s, criteria C. Reduction: 60% for 100 ms, criteria B.		Mains power quality should be that of a typical commercial or hospital environment. If the user of the HemoCue Hb 201 DM requires continued operation during power mains interruptions, it is recommended that the HemoCue Hb 201 DM be powered from an uninterruptible power supply or Battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz		

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Table 2: Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz		

7.14 Warranty

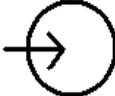
The Analyzer carries a 24-month warranty from the day of receipt. After the warranty period, service/repair is carried out at fixed prices.

7.15 Spare parts and accessories

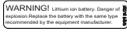
The following spare parts and accessories are available:

- AC adapter
- HemoCue 201 DM Battery
- Cuvette holder
- HemoCue 201 DM PC Software
- USB cable
- Liquid controls
- HemoCue Cleaner
- HemoCue Lancet

7.16 Symbols on System Components and Accessories

Symbol	Meaning
	Laser radiation – Do not stare into the beam or view directly with optical instruments.
	Attention! See the Instructions for Use.
	CE mark This product complies with the IVD Medical Device Directive 98/79/EC.
	Refers to Type BF Applied Part, Per EN 60601-1.
	Class II equipment, per EN 60601-1
	Direct current.
	Alternating current.
	Input

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	<p>Output</p>
	<p>Caution: Laser light. Do not stare into beam. 630nm-680nm Laser, 1.0 mW max output. Class 2 Laser Product. This product meets the requirements of IEC 60825-1:A2:2001.</p>
	<p>Only valid within the European Community. Indicates separate collection for waste of electrical and electronic equipment.</p>
	<p>WARNING! Lithium ion Battery. Danger of explosion. Replace the battery with the same type recommended by the equipment manufacturer.</p>

7.17 References

- 1 Makarem, A. In clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125 - 1147
- 2 Dacie and Lewis, Practical Haematology Ninth edition.
- 3 Jacques QWallach, M.D., Interpretation of Diagnostic Tests.

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