

HemoCue Hb 201 DM Analyzer & HemoCue DM Docking Station



Reference Manual



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PART I

Introduction



PART I

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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, the HemoCue Hb 201 Microcuvettes.

This Reference Manual contains instructions for settings, quality assessment, patient testing, and troubleshooting of the HemoCue Hb 201 DM Analyzer, as well as installation of the HemoCue DM Docking Station. For information on the HemoCue 201 DM - DMS Software, see the separate User's Guide on the DMS Software CD.

This chapter gives a brief overview of the functions and features of the Analyzer and the Docking Station.

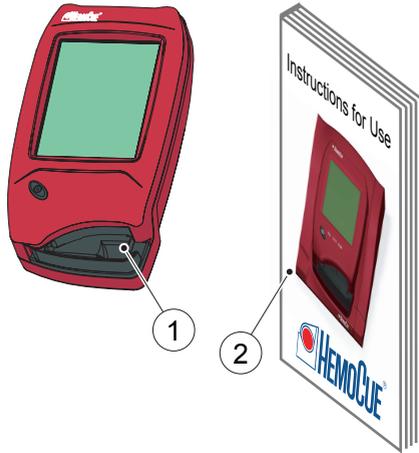
Note! Prior to starting the HemoCue Hb 201 DM Analyzer, read section 2 *Safety*, followed by section 3 *Installation/General operations*.

1.1 The HemoCue Hb 201 DM System

1.1.1 Unpacking

FIGURE 1-1

a) The Analyzer and the Docking Station are supplied in two different packages, as described below. Open up the package and unpack the contents on a dry and stable surface.



Analyzer:

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

Docking Station:

- 3 HemoCue DM Docking Station



1.1.2 Inspection

- a) Check all System Components for damage.



Electrical shock! Use of damaged electrical equipment poses a risk of electrical shock or further damage to the equipment.

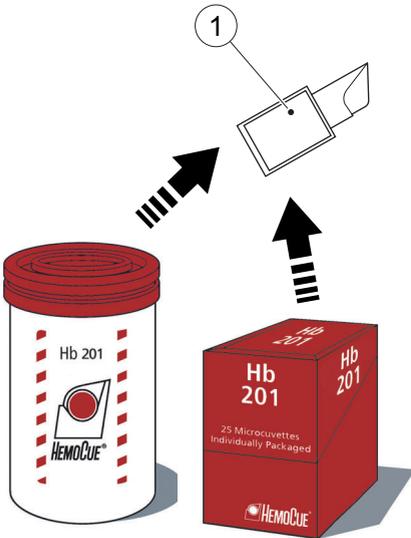
- b) If any visible or suspected damage is discovered, contact the local distributor.

1.1.3 Materials required but not provided

FIGURE 1-2
HemoCue Hb 201 Microcuvettes (1), packaged individually or in vials

System Components:

- 1 HemoCue Hb 201 Microcuvette



1.2 Abbreviations/ glossary

AC	Alternating Current
IrD	Compact Disc
CIC	Connectivity Industry Consortium The CIC was an open, non-profit, industry-driven consortium comprised of device manufacturers, information system vendors and health care providers. It was chartered to address impediments to POC device connectivity with the objective of enabling seamless information exchange between POC devices and electronic medical records and laboratory information systems.
DM	Data Management
DMS	Data Management Server
HC	HemoCue
Hub	A physical connecting device A hub is a place of convergence where data arrives from one or more directions and is forwarded in one or more other directions.
IP	Internet Protocol
IP-address	A number that identifies each sender or receiver of information that is sent in packets across the Internet
IR	Infra Red (light) Electromagnetic radiation with wavelengths longer than those of visible light but shorter than those of radio waves
IrDA	Infrared Data Association

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LAN	Local Area Network A group of computers and associated devices that share a common communications line and typically share the resources of a server within a small geographic area (e.g. an office building). The server usually has applications and data storage that are shared in common by multiple computer users.
LED	Light Emitting Diode A semiconductor device that emits visible light when an electric current passes through it. In most LEDs the light is monochromatic, i.e. occurring at a single wavelength.
LID	Lab Identification (ID) or lab number ID of a test, unique within a user site
NCCLS	A globally recognized, voluntary consensus organization developing standards, guidelines and best practices for healthcare medical testing
OR	Observation Reviewer The primary role of an OR is to host one or more services to which point-of-care diagnostic devices connect. These services facilitate the collection of test results and quality data from, as well as the management of, these devices. In addition, services hosted by an OR may exchange data with already existing information systems in the hospital or laboratory, e.g. Laboratory Information Systems (LIS).
PAT	Patient Test
PC	Personal Computer
PID	Patient Identification (ID)

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POC	Point-of-care (The immediate surroundings of a patient)
POCT	Point-of-care Testing (Testing procedures performed in the immediate surroundings of the patient)
POCT1-A	Standard for communication and messages between diagnostic instruments, specified by NCCLS, based on specifications from the Connectivity Industry Consortium (CIC)
QC	Quality Control
QC Test	A measurement of control material, providing evidence of the stability of the system
STAT	Short Turn Around Time
STAT Test	A test mode that allows a patient test to be performed without entering information required in the routine patient test mode. Testing is also possible in this mode if the routine patient testing mode of the Analyzer is locked out.
USB	Universal Serial Bus A "plug and play" interface between a computer and peripheral devices (e.g. keyboards, scanners, printers) With USB, a new device can be added to the computer without having to add an adapter card or turning the computer off.

1.3 Designated Terminology

The designations in the table below are used throughout the rest of this document.

Item	Referred to as the...
General	
HemoCue Hb 201 DM system	System
Components of the HemoCue Hb 201 DM system	System Components
System Components	
HemoCue Hb 201 DM Analyzer	Analyzer
HemoCue DM Docking Station primary	Primary (Docking Station)
HemoCue DM Docking Station secondary	Secondary (Docking Station)
HemoCue DM Docking Station (irrespective of primary or secondary)	Docking Station
HemoCue 201DM - DMS Software	DMS Software
HemoCue Hb 201 Microcuvette	Cuvette
Documentation	
HemoCue Hb 201 DM Analyzer & HemoCue DM Docking Station Reference Manual	Reference Manual
HemoCue 201 DM - DMS Software User's Guide (on CD)	DMS Software Manual

Item	Referred to as the...
Accessories	
6 V 2.5 A AC Adapter	AC Adapter
HemoCue 201 DM Battery	Battery

1.4 Functional description

1.4.1 System Components

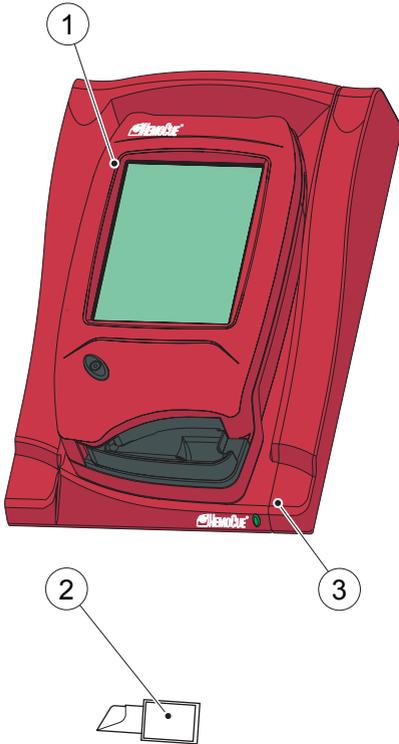
FIGURE 1-3

The System consists of a specially designed Analyzer (1), the HemoCue Hb 201 DM Analyzer, specially designed microcuvettes (2), 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

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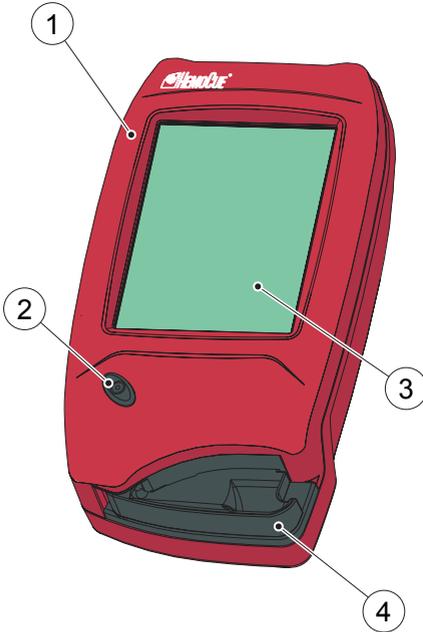
Docking Station

Full data management is possible when the Analyzer is placed in the Docking Station (3) which is connected via USB or LAN to a PC hosting the DMS Software. The Analyzer Battery is recharged while in the Docking Station.

1.4.2 Analyzer overview

Front panel

FIGURE 1-4



Note! Prior to performing a measurement, read section 2 *Safety*, and section 3 *Installation/General operations* and perform the settings and configuration according to section 4 *Settings*.

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

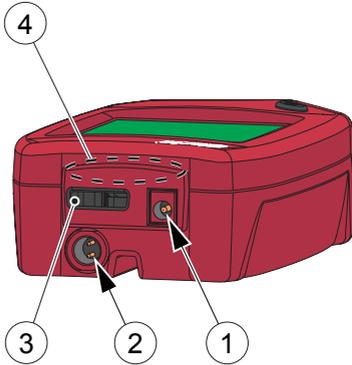
The Analyzer (1) is started when the On/Off button (2) is pressed. The screen images will be visible on the Display (3).

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 (see section 3.1.5 *Loading the Analyzer with a Cuvette*).

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 1-5

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

Data can be transmitted between the Analyzer and the Docking Station in two different ways:

- Via USB using the Power + USB signal inlet (2), if the Docking Station communicates with the DMS Software via USB
- By means of IR-light using the IR Transmitter/Receiver (4), if the Docking Station communicates with the DMS Software via LAN

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

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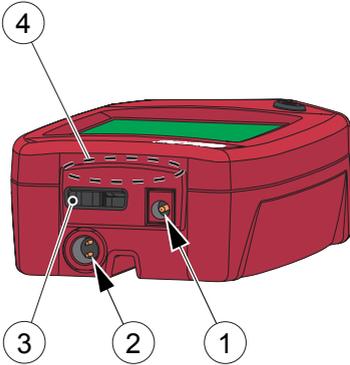


FIGURE 1-6

Settings can be transmitted between two Analyzers via the IR Transmitter/Receiver (see section 4.6 *Infra Red*). The Analyzers have to be out of the Docking Stations and positioned with the IR Transmitter/Receivers (4) facing each other.

The Power inlet (1) for the AC Adapter can only be used when the Analyzer is separated from 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).

Note! The combined Power + USB signal inlet (2) is not a standard USB port, but a special connector which fits the corresponding connector on the Docking Station.

Note! The IR Transmitter/Receiver (4) is located inside the casing of the Analyzer.

Note! Do not cover or block the items on the back panel; doing so may result in malfunction.

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

1.4.3 Docking station – General

Single Docking Station

FIGURE 1-7

A Docking Station not connected to other Docking Stations, is referred to as a *Single* Docking Station.

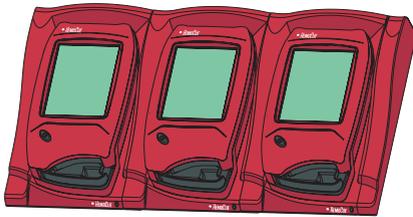


Multiple Docking Stations

FIGURE 1-8

Up to five Docking Stations can be connected to each other. These are referred to as *Multiple* Docking Stations.

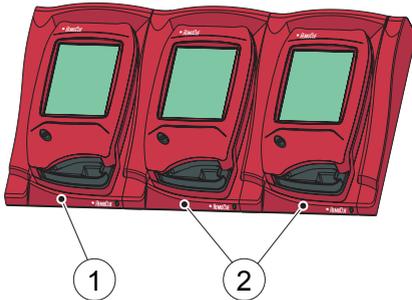
Only the Analyzer positioned furthest to the left can be connected to an AC Adapter. Power is supplied to the other Analyzers through this connection.



Primary and Secondary Docking Stations

FIGURE 1-9

Note! Primary and Secondary Docking Stations are two physically different products.



- 1 Primary or Secondary Docking Station
- 2 Secondary Docking Station

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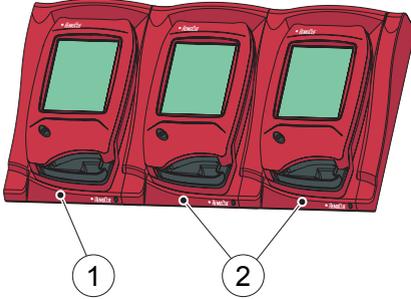


FIGURE 1-10

A Primary Docking Station can be connected to a LAN and both receive/send data itself and pass data from/to a Secondary Docking Station that is connected to the Primary.

Note! When a Primary Docking Station is connected via a USB connection, only the IP address can be changed. No other information can be sent to/from the Analyzer.

A Secondary Docking Station cannot be connected to a LAN. In order to communicate via a LAN it must be connected to a Primary Docking Station. A Secondary Docking Station can communicate directly to a PC via a USB connection.

Both Primary and Secondary Docking Stations can be used singularly.

A set of Multiple Docking Stations, (maximum five), consists of either one Primary and a number of Secondary Docking Stations or of only Secondary Docking Stations. If a Primary is included, it must be positioned furthest to the left (1) (when facing the front of the Docking Station).

Note! Two Primary Docking Stations must not be connected together.

-
- 1 Primary or Secondary Docking Station
 - 2 Secondary Docking Station

1.4.4 Docking Station overview

Front

FIGURE 1-11

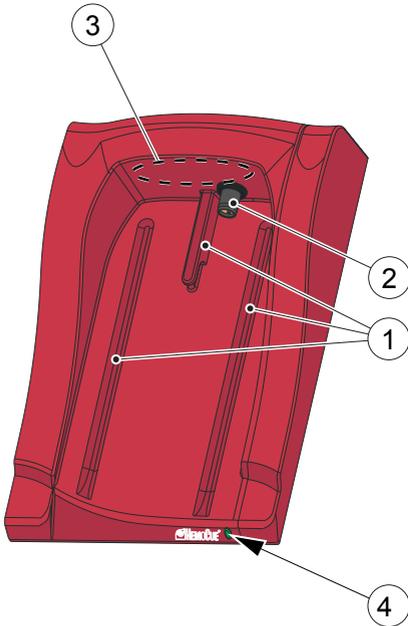
The Docking Station consists of the following items:

- Tracks (1) for the Analyzer
- Power + USB signal outlet (2) for the Analyzer
- IR Transmitter/Receiver (3) for data transmission to/from the Analyzer
- LED (4)

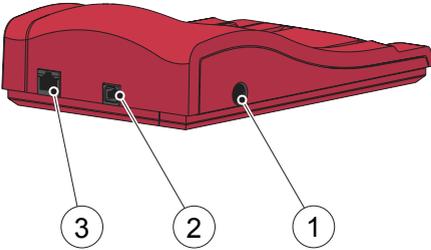
Note! The combined Power + USB signal outlet (2) is not a standard USB port, but a special connector which fits the corresponding connector on the Analyzer.

Note! The IR Transmitter/Receiver (3) is located inside the casing.

Note! Do not cover or block the items on the back panel; doing so may result in malfunction.



-
- 1 Tracks
 - 2 Power outlet
 - 3 IR Transmitter/Receiver
 - 4 LED



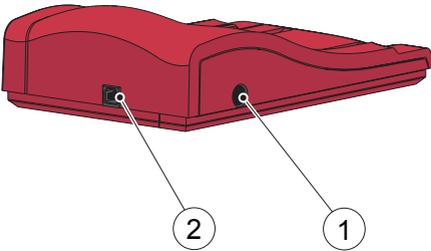
Back panel – Primary Docking Station

FIGURE 1-12

The following items are located on the back panel:

- Power inlet (1) for the AC Adapter
- USB port (2) for setting up the Primary Docking Station
- Note!** Different from the USB port in the Secondary Docking Station
- Network port (3) for data communication via a LAN

-
- 1 Power inlet for the AC Adapter
 - 2 USB port
 - 3 Network port



Back panel – Secondary Docking Station

FIGURE 1-13

The following items are located on the back panel:

- Power inlet (1) for the AC Adapter
- USB port (2) for data communication directly with the PC
- Note!** Different from the USB port in the Primary Docking Station

-
- 1 Power inlet for the AC Adapter
 - 2 USB port

Data Communication Connectors

FIGURE 1-14

The male connector (1) for data communication between Multiple Docking Stations is positioned under the Side Trim (2).

Important! The Side Trim (2) on the Docking Station should always be used to protect the Connector (1).

-
- 1 Male Connector
 - 2 Side Trim

(Continues)



(Continues)Single

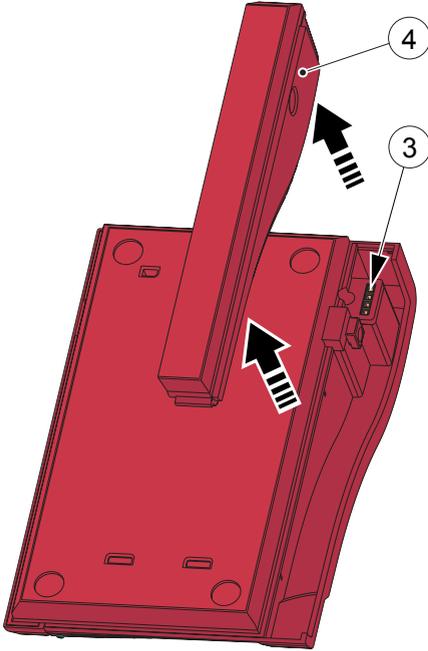


FIGURE 1-15

The female connector (3) is positioned under the Bottom Trim (4).

Note! There is no female connector (3) on a Primary Docking Station .

Important! The Bottom Trim (4) on the Docking Station should always be used to protect the Connector (3).

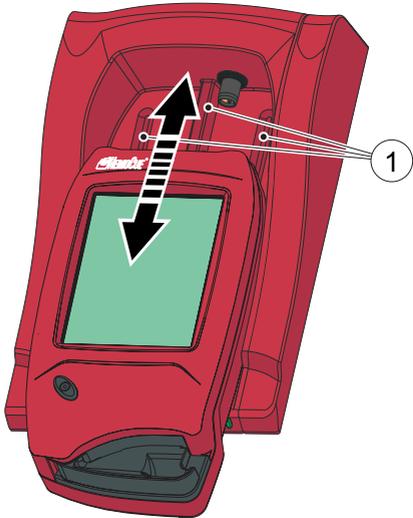
3 Female Connector

4 Bottom Trim

Placing the Analyzer in the Docking Station

FIGURE 1-16

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



1 Tracks

FIGURE 1-17

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.



1.4.5 Functions and features

The HemoCue Hb 201 DM system is a powerful data management system for decentralized testing. It can be customized by the user allowing the activation or deactivation of the following functions:

- Operator ID input, with lockout function if the Operator ID is not recognized
- Patient ID input
- Cuvette batch data input
- Lab number input
- Quality Control with input of lot numbers, range and lockout functions
- Linearity and proficiency testing
- STAT tests

The Analyzer stores:

- Approximately 4000 Patient/STAT test results (including Patient ID, Operator ID, date, time, comments, etc.)
- Approximately 500 QC test results (including QC level, Operator ID, date, time, comments, etc.)
- Approximately 500 Analyzer log entries (Error messages, maintenance etc.)

(Continues)

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The Analyzer also has the following features:

- Easy-to-use Display
- Built-in Barcode Scanner
- Powered either by a rechargeable lithium-ion Battery, AC Adapter or via the Docking Station. The Battery is recharged when connected to the Docking Station.
- Communication with DMS Software or OR via Docking Station, according to POCT1-A standard (also known as the CIC standard).

2 Safety

To ensure maximum safety, read this chapter carefully before using the Analyzer or any of the System Components in the HemoCue Hb 201 DM System.

2.1 HemoCue Hb 201 DM System

2.1.1 Usage of the System

FIGURE 2-1

All System Components are designed and manufactured to provide maximum safety. There are three procedures related to the System that may cause personal injury or damage to equipment. These procedures are found outside the core functions of the System:

- Handling of electrical components – Always handle electrical components with care, otherwise electrical shocks may occur to the user.
- Handling of blood specimens – Always handle blood specimens with care, as they might be infectious.
- Handling of the Barcode Scanner – Laser radiation. Do not stare into the beam or view directly with an optical instrument.



2.2 General

2.2.1 Hazard information

The following hazard information describes the level of risk of injury or damage to the user or equipment respectively:

Hazard information	Significance
 Warning!	Risk of serious personal injury! Failure to observe this information can result in personal injury and/or serious damage to or destruction of equipment!
 Electrical shock!	Risk of electrical shock! Failure to observe this information can result in personal injury and/or serious damage to or destruction of equipment!
Caution!	Risk of minor personal injury! Failure to observe this information can result in minor personal injury!
Important! Important!	Risk of damage to equipment! Failure to observe this information can result in damage to equipment!
Note!	Is used to emphasize important information. The Note! is not to be regarded as hazard information.

2.3 Handling of the System

2.3.1 System Components

Carefully follow the instructions in this document and pay special attention to the Hazard information in section 2.2.1 *Hazard information*.

Battery



Warning! Lithium-ion battery - Danger of explosion - Replace the Battery with the same type recommended by HemoCue.

Consult local environmental authorities for proper disposal.

Cuvette

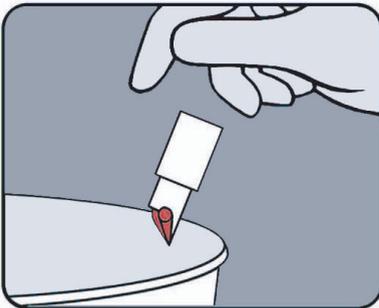
FIGURE 2-2



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

Always use protective gloves when handling Cuvettes that are filled with blood.

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



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3 Installation/General operations

This chapter describes the general operations necessary for Analyzer use.

3.1 Getting started – Analyzer

3.1.1 Power source

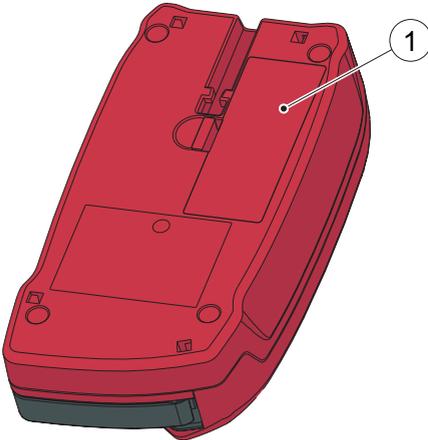
The Analyzer can be powered either by the rechargeable Battery or by a standard electrical outlet via the AC Adapter.

Recharging the Battery

FIGURE 3-1

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. A brand new Battery will take longer to charge the first 2 to 3 times.



1 Battery

(Continues)

(Continues)

A fully charged Battery will power the Analyzer for 100 hours when in the stand-by mode or for two days of normal use. Normal use is defined as 60 samples/day using the Barcode Scanner.

The Battery recharges to 70% of its capacity in less than 2 hours and to nearly 100% in less than 10 hours.

Replacing the Battery

FIGURE 3-2



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

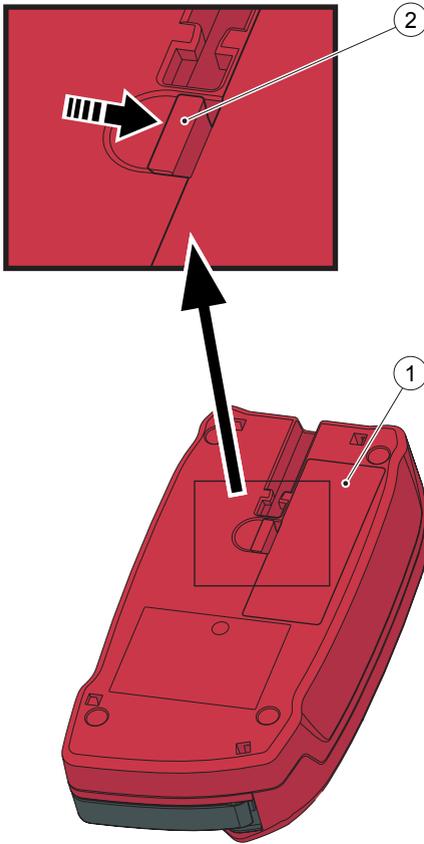
The Battery lasts for several years. It should be replaced when it fails to retain its charge for an acceptable period.

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

a) To remove the Battery (1), press the Flap (2).

-
- 1 Battery
 - 2 Flap

(Continues)



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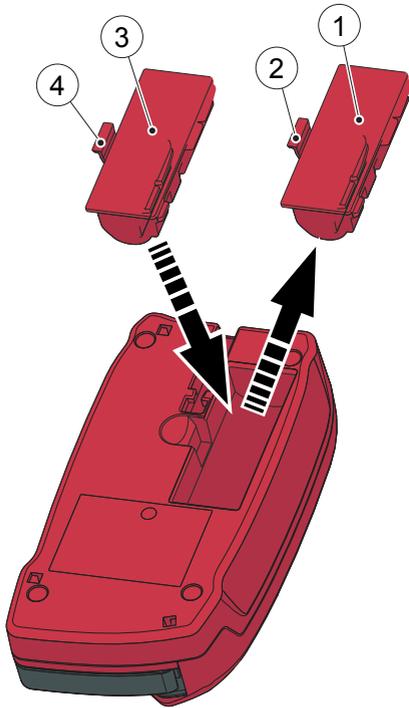


FIGURE 3-3



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

Consult local environmental authorities for proper disposal.

- 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.

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

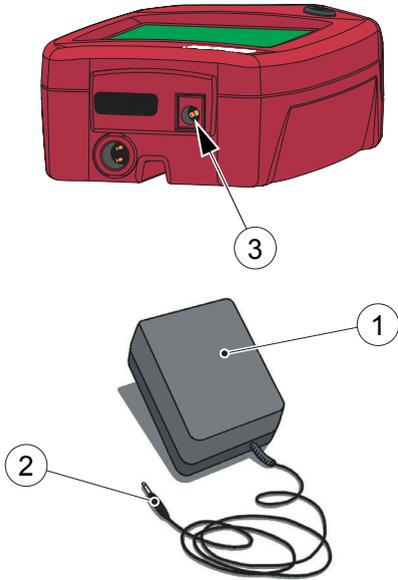
Connecting the AC Adapter

FIGURE 3-4



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.

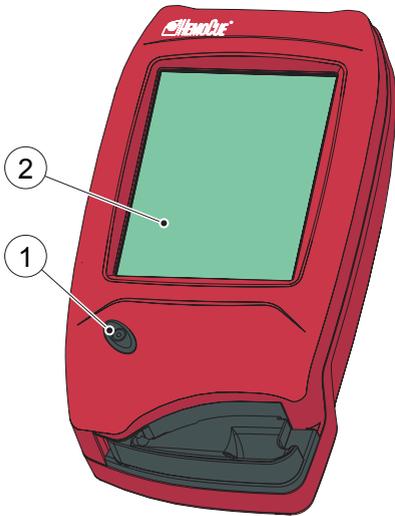
- a) Insert the AC Adapter's DC plug (2) into the Power inlet (3) on the back panel of the Analyzer.
- b) Plug the AC Adapter (1) into an electrical outlet.



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

3.1.2 Turning on the Analyzer

FIGURE 3-5



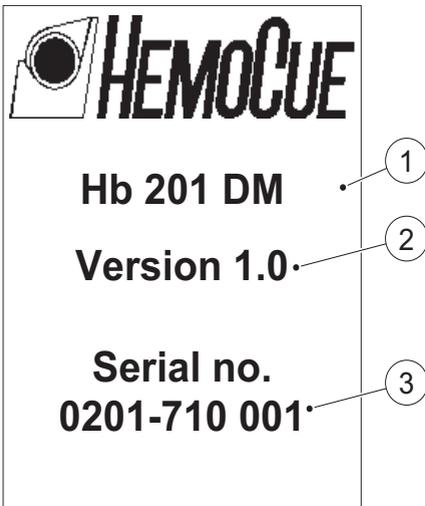
- a) Turn on the Analyzer by pressing the On/Off button (1).
- b) The Start Image, beginning with the HemoCue logo, will be displayed, as seen in FIGURE 3-6.

-
- 1 On/Off button
 - 2 Display

Start Image

FIGURE 3-6

The Start Image includes the following information: Analyzer type (1), Software version (2) and the unique Serial number (3) of the Analyzer.



- If the Cuvette holder is in the *Measuring position* (see section 3.1.5 *Loading the Analyzer with a Cuvette*), the following text will be displayed:
Please Pull Out the Cuvette Holder

-
- 1 Analyzer type
 - 2 Software version
 - 3 Serial number

(Continues)

(Continues)

- If the Cuvette holder is in the *Loading position* (see section 3.1.5 *Loading the Analyzer with a Cuvette*), the following text will be displayed:
Please Wait Selftesting ...
No inputs can be made for approximately 20 seconds during the selftest.

For information on how to operate the Display, see section 3.5 *How to operate the Display*.

For instructions on how to perform tests, see section 6 *Patient Test procedure*, section 7 *STAT Test procedure* and section 8 *QC Test procedure*.

For safety information, see section 2 *Safety*.

3.1.3 Power saver mode

When no procedures have been performed within the time predefined in the Analyzer settings (see section 4.3.2 *Power Saver*), 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.

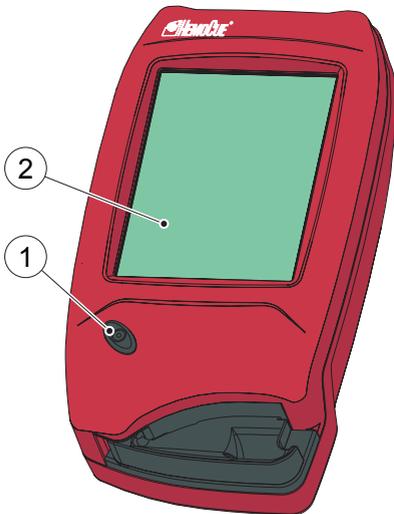
If the Analyzer is powered via the Battery, the user will be logged off and the Analyzer will be switched off. Press the On/Off button to reactivate it.

3.1.4 Turning the Analyzer off

FIGURE 3-7

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.



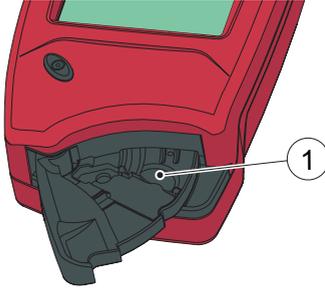
-
- 1 On/Off button
 - 2 Display

3.1.5 Loading the Analyzer with a Cuvette

The Loading position

FIGURE 3-8

FIGURE 3-8 shows the Analyzer with the Cuvette holder (1) open, referred to as the *Loading position*.

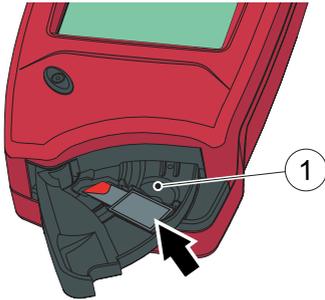


1 Cuvette holder

Inserting a Cuvette

Obtain a blood sample according to the procedure described in section 5 *Blood specimen collection*.

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



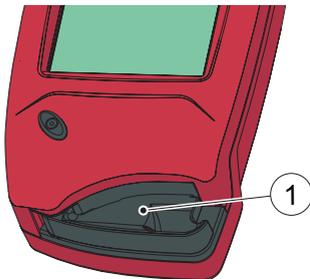
When closed, the Analyzer will automatically start the measuring procedure and the result will appear on the Display.

1 Cuvette holder

The Measuring position

FIGURE 3-9

FIGURE 3-9 shows the Analyzer with the Cuvette holder (1) in the closed position, referred to as the *Measuring position*.



1 Cuvette holder

3.2 Getting started – Single Docking Station

3.2.1 Connect to a PC or a LAN

Note! This procedure should be performed by a network administrator.

Important! Always keep electrical equipment turned off during connection procedures.

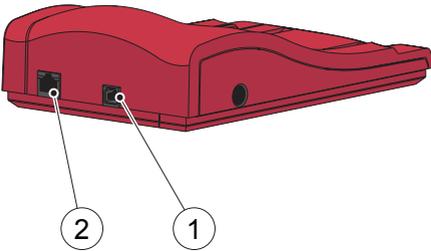
- A Single Primary Docking Station can be connected to a LAN or to a PC via the USB.

Note! When a Primary Docking Station is connected via a USB connection, only the IP address can be changed. No other information can be sent to/from the Analyzer.

- A Single Secondary Docking Station can be connected directly to a PC via the USB, **but not** to a LAN.

(Continues)

(Continues)



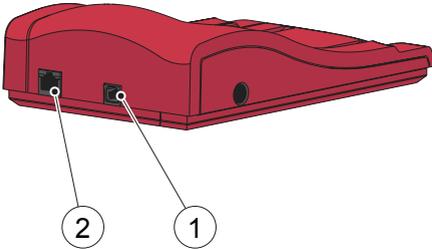
Connect Primary Docking Station to PC

FIGURE 3-10

To change settings on a Primary Docking Station, see section 4.7 *Docking Station Settings*. The Primary Docking Station must be connected to a PC directly via the USB port.

- a) Insert the USB cable into the USB port (1).
- b) Insert the USB cable into the PC's USB port.

-
- 1 USB port
 - 2 Network port



Connect a Primary Docking Station to a LAN

FIGURE 3-11

A Primary Docking Station must be connected to a LAN for data communication. The PC hosting the DMS Software, or an OR must also be connected.

The speed of the network port is 10 Mb/s.

- a) Insert one end of the Network cable into the Network port on the Docking Station (2).
- b) Insert the other end of the Network cable into a Network port on the LAN (not directly into the PC).

-
- 1 USB port
 - 2 Network port

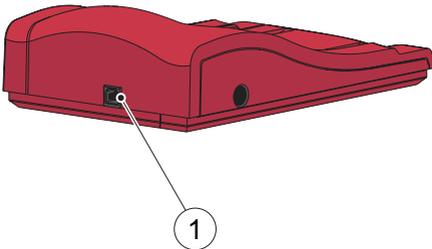
Connect a Secondary Docking Station to a PC

FIGURE 3-12

A Single Secondary Docking Station must be connected via the USB to the PC hosting the DMS Software for data communication. No settings can be changed in the Secondary Docking Station.

- a) Insert one end of the USB cable into the USB port of the Docking Station (1).
- b) Insert the other end of the USB cable into the PC's USB port.

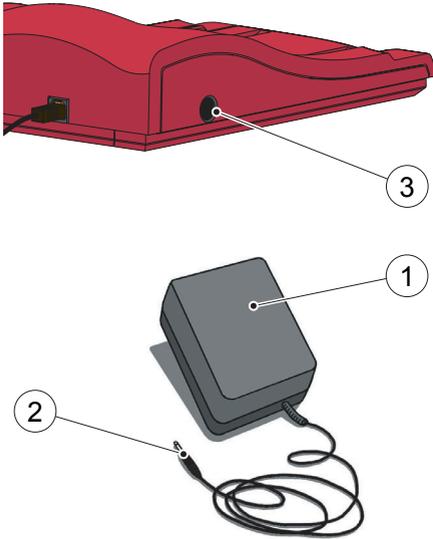
-
- 1 USB port



3.2.2 Power source

Connecting the AC Adapter

FIGURE 3-13



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).
- b) Plug the AC Adapter (1) into an electrical outlet.

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

3.3 Getting started – Multiple Docking Stations

3.3.1 Connecting Docking Stations

FIGURE 3-14

Important! Docking Stations should be connected to each other before connecting to the Power source, the PC or the LAN.

A set of Multiple Docking Stations, (maximum five), consists of either one Primary and a number of Secondary Docking Stations or a number of Secondary Docking Stations only. If a Primary is included, it must be positioned furthest to the left (when facing the Docking Station fronts).

Note! Two Primary Docking Stations must not be connected together.

Note! Maximum four Secondary Docking Stations should be connected to a Primary Docking Station.

- a) Remove the Side Trim (2) from the Primary Docking Station by first removing the screw from the bottom side (if present), and then gently pressing the Side Trim inwards, while lifting it upwards. The male connector (1) is uncovered.



-
- 1 Male Connector
 - 2 Side Trim

(Continues)

(Continues)

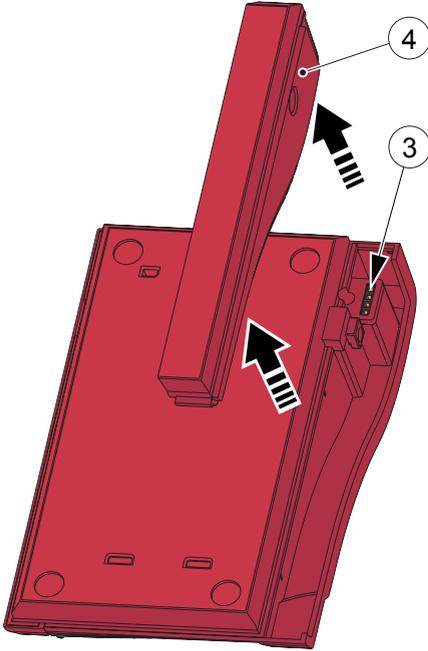


FIGURE 3-15

b) Remove the Bottom Trim (4) from the Secondary Docking Station to uncover the female connector (3). This is done by gently inserting a small screwdriver into the small openings and gently lifting the trim upwards.

- 3 Female Connector
- 4 Bottom Trim

(Continues)

(Continues)

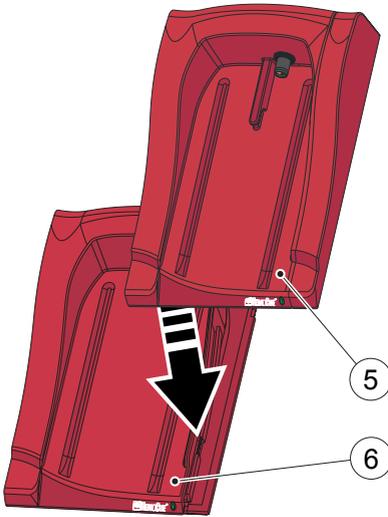


FIGURE 3-16

c) Gently press the Secondary Docking Station (5) downwards onto the Primary Docking Station (6), fitting the Female Connector and the Male connector together.

Note! The Docking Stations must be securely connected to each other in order to ensure good electrical contact.

-
- 5 Secondary Docking Station
 - 6 Primary Docking Station

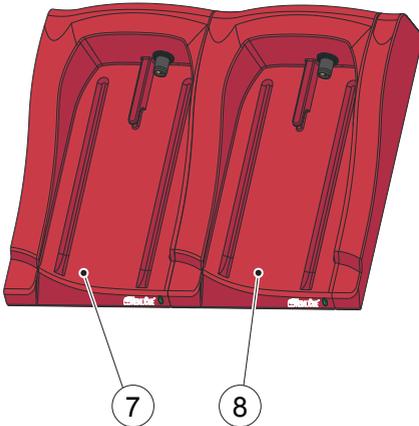


FIGURE 3-17

d) If more Secondary Docking Stations are to be added, remove the Side Trim from the previously added Docking Station and the bottom trim of the new Secondary Docking Station, as shown in *FIGURE 3-14* and *FIGURE 3-15* . Repeat the procedure in *FIGURE 3-16* with the new Secondary Docking Station.

-
- 7 Previous Secondary Docking Station
 - 8 New Secondary Docking Station

3.3.2 Connect to a PC or a LAN

Note! This procedure should be performed by a Network administrator.

Important! Always keep electrical equipment turned off during connection procedures.

- A Primary Docking Station in a multiple set can be connected to a PC via the LAN. It can also be connected via the USB, in this case only the IP address of the Primary Docking Station can be changed.
- A Secondary Docking Station in a multiple set containing a Primary can communicate with a LAN via the Primary. It can also be connected directly to a PC, via the USB, in which case, the USB connection takes preference.
- A Secondary Docking Station in a multiple set consisting solely of Secondary Docking Stations, can only be connected to a PC directly via the USB. Only electrical power will be transferred between these Docking Stations.
- A Secondary Docking Station cannot be directly connected to a LAN.

Connect the Primary Docking Station in a multiple set to a PC

See section *FIGURE 3-10*.

Connect the Primary Docking Station in a multiple set to a LAN

See *FIGURE 3-11*.

Connect the Secondary Docking Station in a multiple set to a PC

If the set consists solely of Secondary Docking Stations, each Docking Station must be connected via the USB to the PC hosting the DMS Software for data communication, see *FIGURE 3-12*.

If the set contains a Primary which is connected to a LAN, the USB connection is not necessary.

3.3.3 Power source

The Docking Station (Primary or Secondary) furthest to the left is connected to the Power source as described in section 3.2.2 *Power source*.

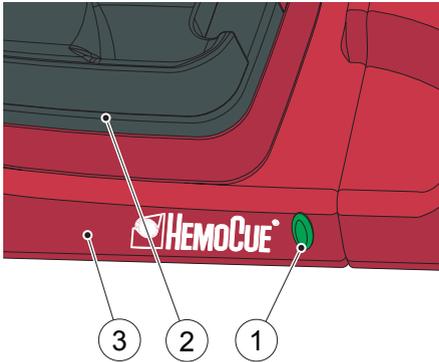
The rest of the Docking Stations in a multiple set are connected to the Power source via this Docking Station and can not be connected separately.

3.4 Docking Station LED

Steady green light

FIGURE 3-18

A steady green light from the LED (1) indicates that the Docking Station (3) is receiving power and that the Battery is fully charged.

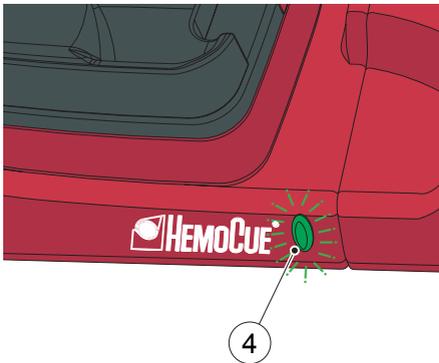


- 1 LED
- 2 Docked Analyzer
- 3 Docking Station

Flashing green light

FIGURE 3-19

A flashing green light from the LED (4) indicates that the Battery in the docked Analyzer is charging.



- 4 LED

Steady red light

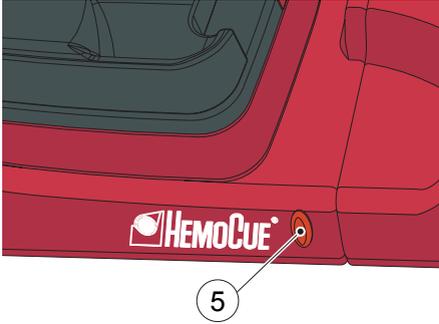
FIGURE 3-20

Note! Can only occur on a Primary Docking Station

A steady red light from the LED (5) indicates an internal communication error within the Docking Station.

See section *12 Troubleshooting*.

5 LED



Flashing red light

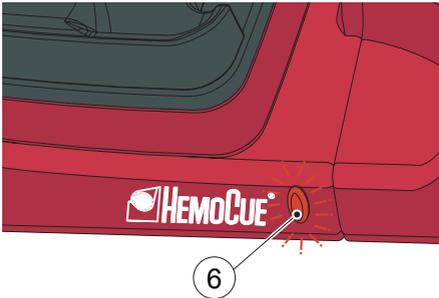
FIGURE 3-21

Note! Can only occur on a Primary Docking Station

A flashing red light from the LED (6) indicates an external communication error. The connection with the LAN is faulty.

See section *12 Troubleshooting*.

6 LED



3.5 How to operate the Display

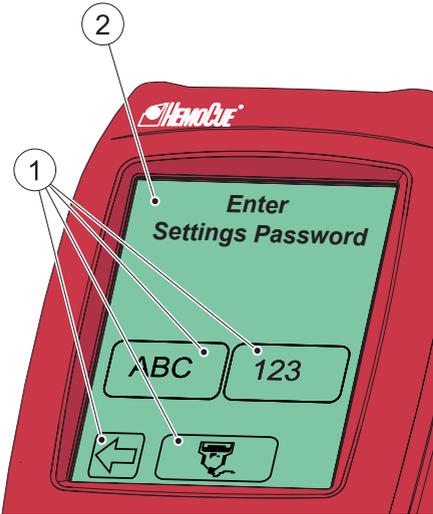
3.5.1 Display buttons

FIGURE 3-22

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.



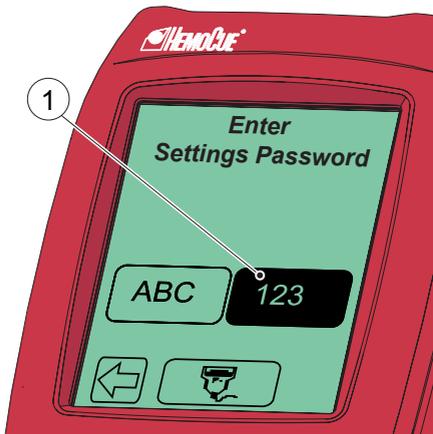
- 1 Buttons
- 2 Display

Activating a function

FIGURE 3-23

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, see section 4.3.3 Audible Signals.



- 1 Button, highlighted

Changing a function

FIGURE 3-24

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



FIGURE 3-25

- 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 3-26

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

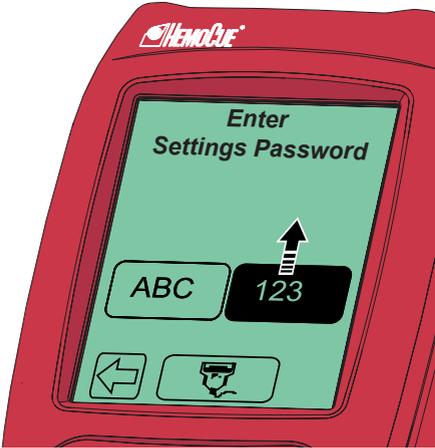


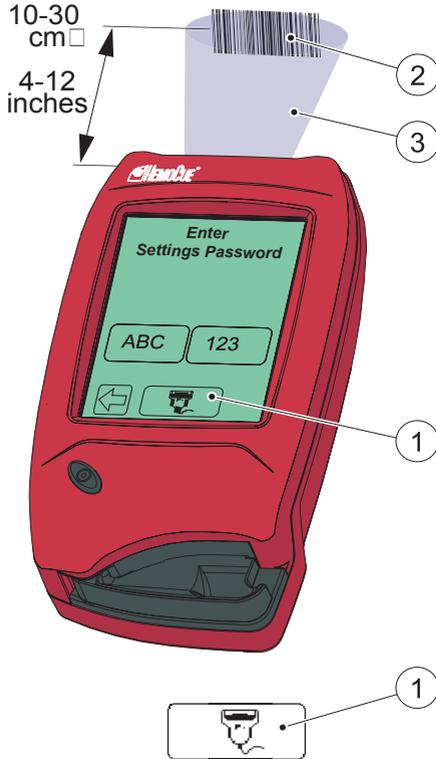
FIGURE 3-27

- 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.



3.5.2 Using the Barcode Scanner button

FIGURE 3-28



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

See also section 3.7.6 *Entering information from barcodes.*

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

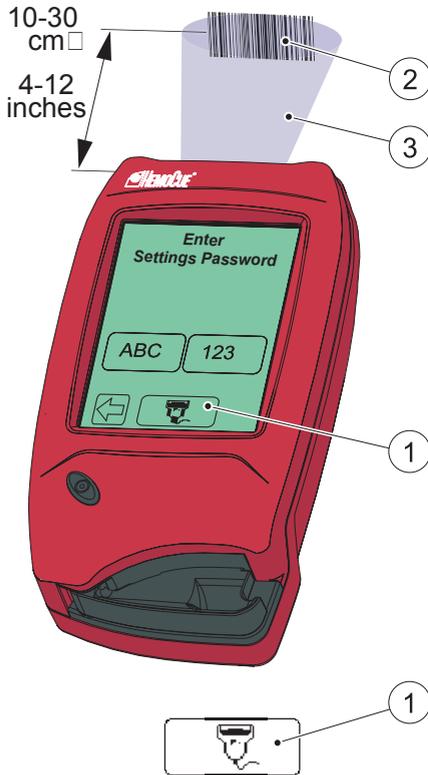


FIGURE 3-29

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

3.6 Operating the Analyzer

3.6.1 Start up

- a) Turn the Analyzer on (see 3.1 *Getting started – Analyzer*). The Start Image, beginning with the HemoCue logo, will be displayed.
- b) If the Cuvette holder is in the measuring position, the following text will be displayed:
Please Pull Out the Cuvette Holder.
Pull the Cuvette holder out to the loading position.

Note! When the Cuvette holder is in the loading position the following text:

Please Wait Selftesting ...

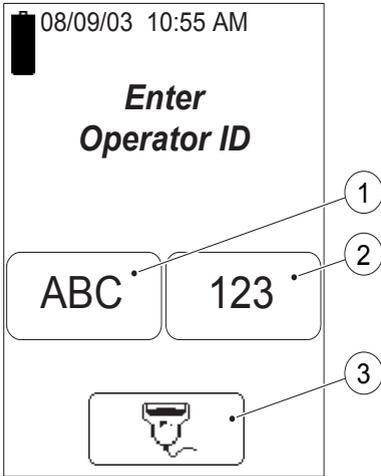
is displayed for approximately 20 seconds while the Analyzer is selftesting. No functions can be activated during the selftest.

- c) If the requirement for Operator ID is set to “Not Used” (see section 4 *Settings*), the Main Menu will be displayed, *FIGURE 3-31*, without the Operator Name.
If Operator ID is required, the Login Image will be displayed, *FIGURE 3-30*.

3.6.2 Login Image

FIGURE 3-30

Note! Not displayed if the requirement for Operator ID is set to “Not Used” (see section 4 *Settings*).



- a) Enter Operator ID either directly on the Display via the Text mode (1) and Numeric mode (2) buttons or by the Barcode Scanner, via the Barcode Scanner button (3) see section 3.7.5 *Entering information with letters and digits* or 3.7.6 *Entering information from barcodes*.

Note! Use of the Barcode Scanner eliminates manual input errors.

- b) When a valid Operator ID is entered, the Main Menu will be displayed, see *FIGURE 3-31*.

-
- 1 Text mode button
 - 2 Numeric mode button
 - 3 Barcode Scanner button

3.6.3 Main Menu and On-line Help

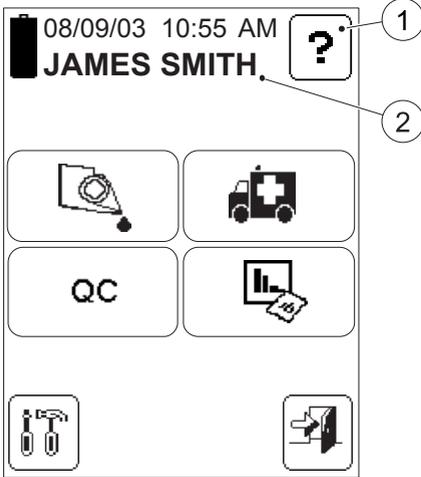


FIGURE 3-31

FIGURE 3-31 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.

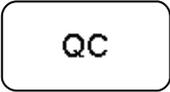
-
- 1 Help button
 - 2 Operator name, Operator ID or blank, depending on the settings

3.7 Display buttons and symbols

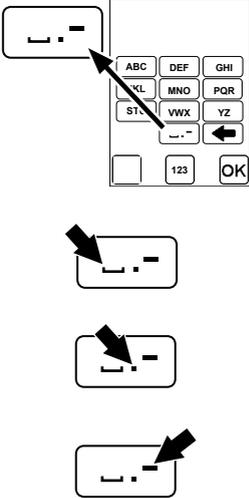
3.7.1 Navigation buttons

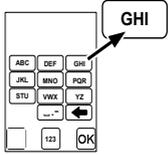
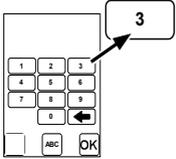
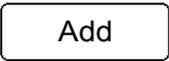
Button	Designation	Function
	Erase button	Erases the last input
	Previous image button	Returns to the previous image NOTE: Inputs/changes made in the current image will not be saved
	Text mode button	Switches to text input mode
	Numeric mode button	Switches to the numeric input mode
	Barcode Scanner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

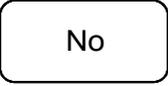
3.7.2 Procedure buttons

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 Comment input button (dotted)	Allows a comment to be added to the current result Button appearance confirms that comments have been added to the result

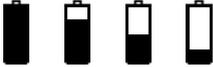
3.7.3 Other display buttons

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.
	Special Character button	Enters a special character (see explanations below) NOTE: Other special characters can only be loaded into the Analyzer by means of the Barcode Scanner.
	View button	Provides a more detailed description of the highlighted item

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>

Button	Designation	Function
	Save button	Stores the entered information
	No button	The entered information will not be stored.
	Continue button	Continues the current operation
	Statistics button	Displays statistics on the chosen subject
	Date format button	Switches between the following date formats: <ul style="list-style-type: none"> • YYYYMMDD • DD.MM.YY • MM/DD/YY
	Time format button	Switches between the following time formats: <ul style="list-style-type: none"> • 12 hours • 24 hours
	AM/PM button	Enables adding "AM/PM" (only 12-hour format)

3.7.4 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.

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.

3.7.5 Entering information with letters and digits

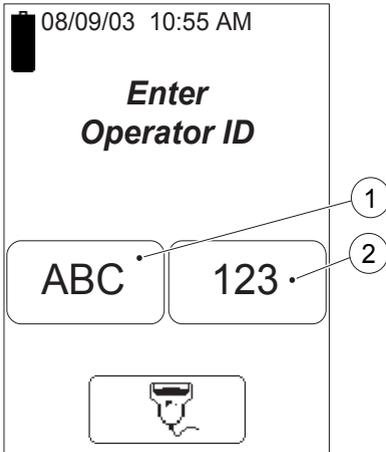


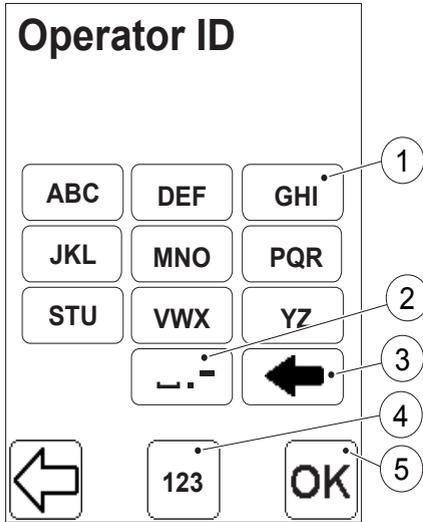
FIGURE 3-32

Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the Display or via the Barcode Scanner (see section 3.7.6 *Entering information from barcodes*)

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 3-33* or *FIGURE 3-34*.

-
- 1 Text mode button
 - 2 Numeric mode button



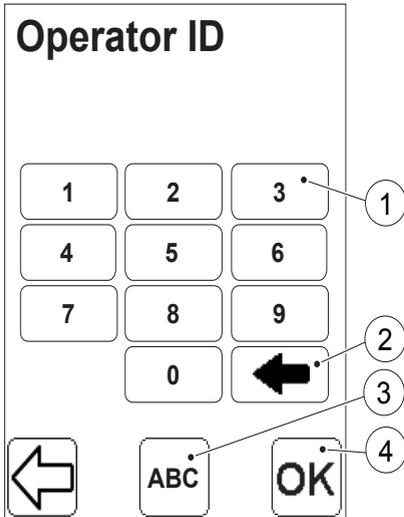
Text mode

FIGURE 3-33

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 3-34* 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 3-34

- 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 3-33* 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

3.7.6 Entering information from barcodes

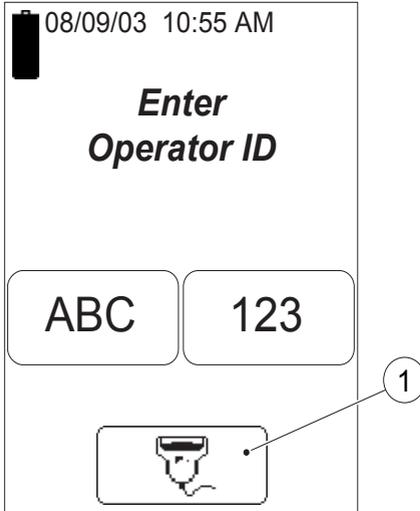


FIGURE 3-35

Also see 3.5.2 *Using the Barcode Scanner button.*

Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the Barcode Scanner or via the Display (see 3.7.5 *Entering information with letters and digits*). Use of the Barcode Scanner eliminates manual input errors.

Note! Special characters can be entered into the Analyzer by means of the Barcode Scanner.

- a) Press and hold the Barcode Scanner button (1). The Barcode Scanner lights up and scanning can be performed.
- b) When the barcode has been read, the information will appear on the Display.
- c) The Barcode Scanner will be switched off.
- d) As long as the Barcode Scanner button (1) is kept pressed, the scanned information will be displayed.
- e) Release the button. The scanned information is stored and the next image will be displayed.

1 Barcode Scanner button

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PART II

Settings



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4 Settings

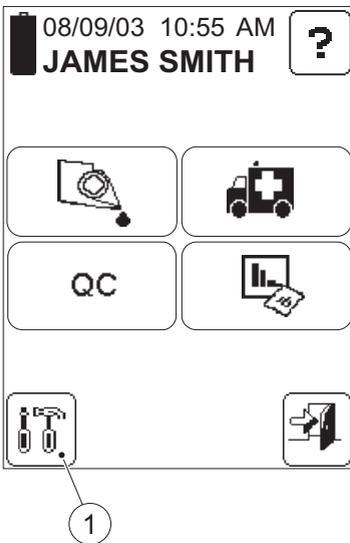
This chapter guides you through the process of setting and configuring the Analyzer and the Docking Station.

4.1 Activating the Settings procedure

FIGURE 4-1

Note! Access to the Settings function is dependent on the setting for Operator ID entry and on the operator's user level. The Analyzer is delivered with the Operator ID set to "Not Used".

- a) In the Main Menu, press the Settings button (1).
- b) If the requirement for Operator ID entry is set to "Not Used" (see 4.4.1 *General Settings*) FIGURE 4-2 will be displayed, as this is a password protected function.
Two other screens may be displayed, dependent on the setting for entry of the Operator ID:
If the operator's user level does not permit access to Settings, FIGURE 4-3 will be displayed.
If the operator's user level permits access to Settings, FIGURE 4-4 will be displayed.



-
- 1 Settings button

(Continues)

(Continues)

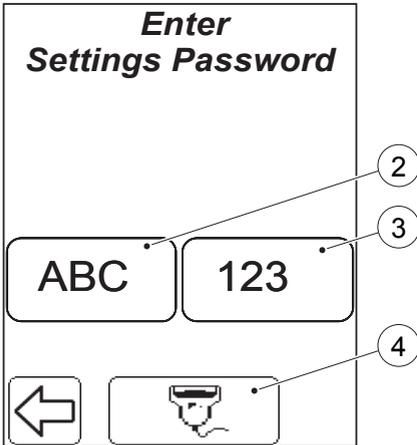


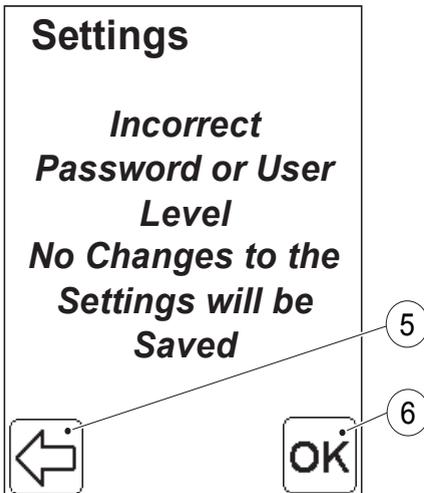
FIGURE 4-2

Note! Only displayed if the Operator ID requirement at startup is set to “Not used” (see 4.4.1 *General Settings*)

- c) Enter the Settings Password (default value is “0000”), either directly on the Display via the Text mode (2) and Numeric mode (3) buttons, or with the Barcode Scanner via the Barcode Scanner button (4).
- d) If the wrong password is entered, *FIGURE 4-3* will be displayed. If the correct password is entered *FIGURE 4-4* will be displayed.

- 2 Text mode button
- 3 Numeric mode button
- 4 Barcode Scanner button

FIGURE 4-3



- e) Pressing the Previous image button (5) will result in a return to, either the Main Menu (if the operator’s user level does not permit access to the Settings), or *FIGURE 4-2* (if the Operator ID is set to “Not Used”). Pressing the Confirm button (6) allows the Settings to be viewed only. *FIGURE 4-4* will be displayed.

Note! In this “view only” mode, the pressing of any button will highlight the option but no change will be effected.

- 5 Previous image button
- 6 Confirm button

(Continues)

(Continues)

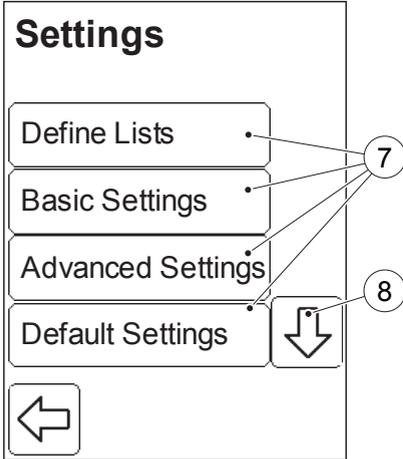


FIGURE 4-4

The Settings menu with the following Setting categories (7) is displayed:

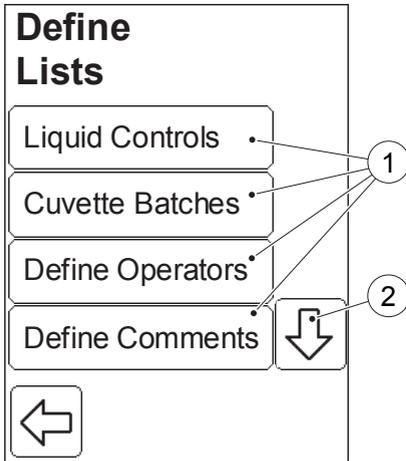
- Define Lists (see 4.2 *Define Lists*)
- Basic Settings (see 4.3 *Basic Settings*)
- Advanced Settings (see 4.4 *Advanced Settings*)
- Default Settings (see 4.5 *Default Settings*)
- Infra Red (see 4.6 *Infra Red*)

f) Press the Scroll bar arrow (8) to view categories (7) not initially visible on the Display .

g) Select a Settings category (7) by pressing it.

7 Settings categories

8 Scroll bar arrow



4.2 Define Lists

FIGURE 4-5

When the Define Lists button is pressed in the Settings menu (see *FIGURE 4-4*), the following Define Lists categories (1) are displayed:

- Liquid Controls (see 4.2.1 *Liquid Controls*)
- Cuvette Batches (see 4.2.2 *Cuvette Batches*)
- Define Operators (see 4.2.3 *Define Operators*)
- Define Comments (see 4.2.4 *Define Comments*)
- Define Log (see 4.2.5 *Define Log Notes*)

Note! *Define Operators* may only be activated if the operator is designated as Supervisor, or if the correct password has been entered.

- a) View Define Lists categories (1) not initially visible by pressing the Scroll bar arrow (2).
- b) Select a Define Lists function (1) by pressing it.

-
- 1 Define Lists categories
 - 2 Scroll bar arrow

4.2.1 Liquid Controls

A Liquid Control is a liquid with a known concentration, intended for checking the accuracy of the system.

Results from Liquid Controls can only be stored as QC measurements if the Liquid Control specifications have been entered.

FIGURE 4-6

When the Liquid Controls button is pressed in the Define Lists menu (see FIGURE 4-5), the Liquid Controls list (1) is displayed (see FIGURE 4-6). The Liquid Controls list can hold up to twelve different Liquid Control specifications.

When pressing the Add button (2) to add a new Liquid Control specification, the following Liquid Controls options (1) are displayed:

- Low
- Normal
- High
- Other level

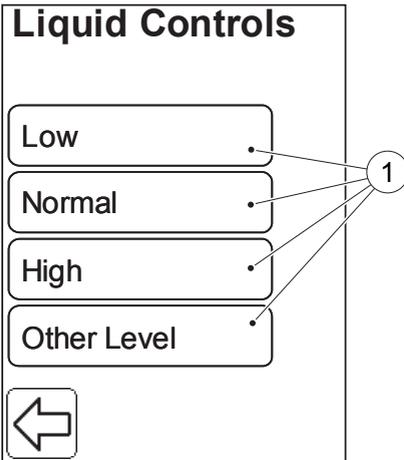
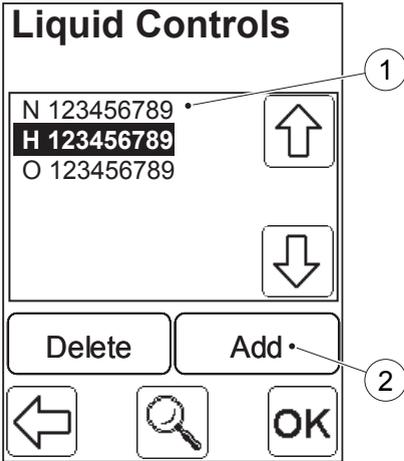
FIGURE 4-7

Note! Low, Normal, High and Other Level refer to the different concentration levels of Liquid Controls. The settings procedure is the same for all concentration levels. For this reason, only the Low level is described.

c) Select a Liquid Control option (1) by pressing it, in this example *Low*.

1 Liquid Controls option

(Continues)



(Continues)

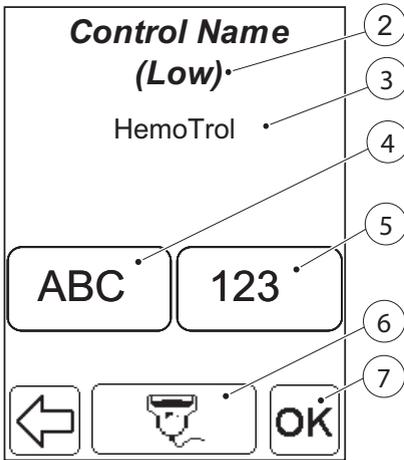


FIGURE 4-8

The control level (2) is displayed and a name (3) can be entered.

d) Enter Liquid Control name (3) either directly on the Display via the Text mode (4) and Numeric mode (5) buttons, or with the Barcode Scanner via the Barcode Scanner button (6).

e) Press the Confirm button (7).

-
- 2 Liquid Control concentration level
 - 3 Liquid Control name
 - 4 Text mode button
 - 5 Numeric mode button
 - 6 Barcode Scanner button
 - 7 Confirm button

(Continues)

(Continues)

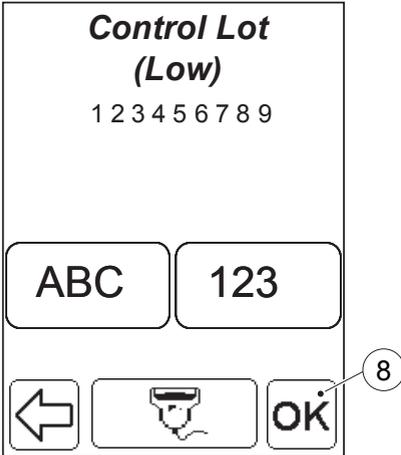


FIGURE 4-9

- f) Enter the Lot No. for the Liquid Control either directly on the Display via the Text mode and Numeric mode buttons, or by the Barcode Scanner via the Barcode Scanner button.
- g) Press the Confirm button (8).

8 Confirm button

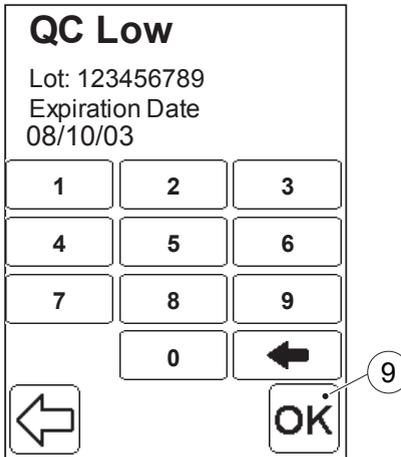


FIGURE 4-10

- h) The Expiration Date of the specific control Lot can be entered or changed using the numeric buttons, if desired.
- i) Press the Confirm button (9).

9 Confirm button

(Continues)

(Continues)

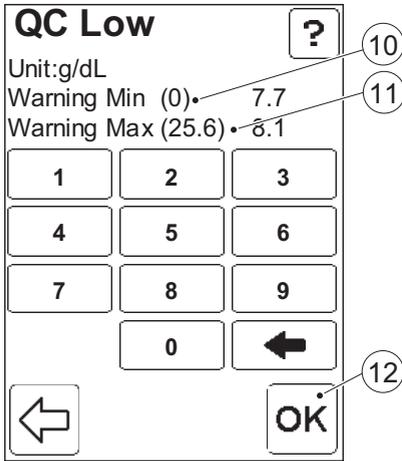


FIGURE 4-11

The warning limits define the range of results for QC testing that must be obtained to prevent a warning from being displayed.

j) Enter min. value (10) and max. value (11) for the warning interval.

k) Press the Confirm button (12).

A similar image for the lockout limits will be displayed. The lockout limits define the range for QC testing that must be obtained to prevent the Analyzer from performing a lockout.

l) In the image for the lockout limits, enter min. value (10) and max. value (11) for the lockout interval.

m) Press the Confirm button (12).

-
- 10 Min. value
 - 11 Max. value
 - 12 Confirm button

(Continues)

(Continues)

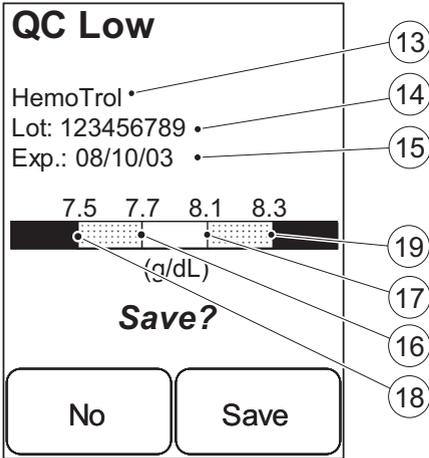


FIGURE 4-12

All settings for the Control are shown in a summary display.

n) Press Save to store the setting information or press No to cancel.

- 13 Control Liquid name
- 14 Control Liquid Lot No.
- 15 Control Liquid expiration date
- 16 Warning interval min. value
- 17 Warning interval max. value
- 18 Lockout interval min. value
- 19 Lockout interval max. value

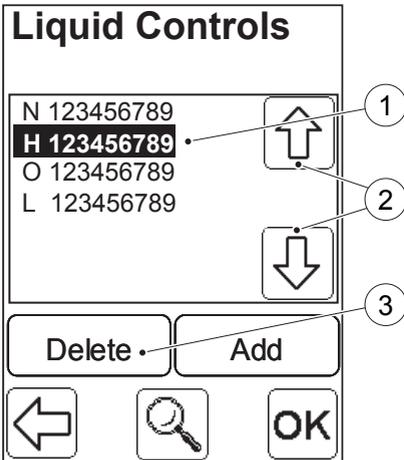


FIGURE 4-13

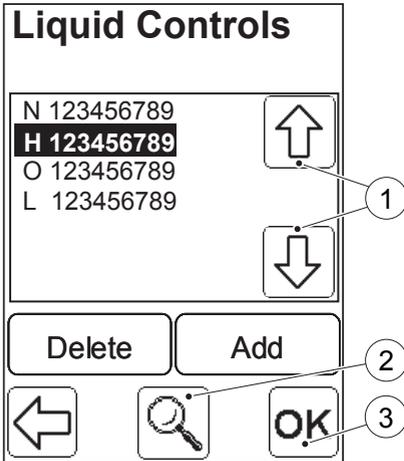
Delete a Liquid Control specification

a) To choose the Liquid Control specification that is to be deleted, highlight the Liquid Control specification (1) by pressing the Scroll Bar Arrows (2). Press the Delete button (3).

b) A confirm dialogue is displayed. Press Delete to delete the Liquid Control or press No to cancel.

c) The updated Liquid Control list will be displayed. Press the Confirm button in this display to return to the Define List menu (see FIGURE 4-5).

- 1 Liquid Control specification (to be deleted)
- 2 Scroll bar arrows
- 3 Delete button



View/Change Liquid Control specification

FIGURE 4-14

- a) To choose the Liquid Control specification that is to be viewed/changed, highlight the Liquid Control specification by pressing the Scroll bar arrows (1). Press the View button (2). By pressing repeatedly on the confirm button *FIGURE 4-8* to *FIGURE 4-12* will be displayed. Press the Save button to store any changes made and return to the Liquid Controls List.
- b) Press the Confirm button (3) to return to the Define Lists menu (see *FIGURE 4-5*).

-
- 1 Scroll bar arrows
 - 2 View button
 - 3 Confirm button

4.2.2 Cuvette Batches

Note! A Cuvette Batch is a set of cuvettes manufactured in one series under the same conditions. Information entered for a specific batch will apply to all cuvettes within that batch. Five distinct Cuvette Batches with corresponding information can be stored in the Analyzer.

Add Cuvette Batch Information

FIGURE 4-15

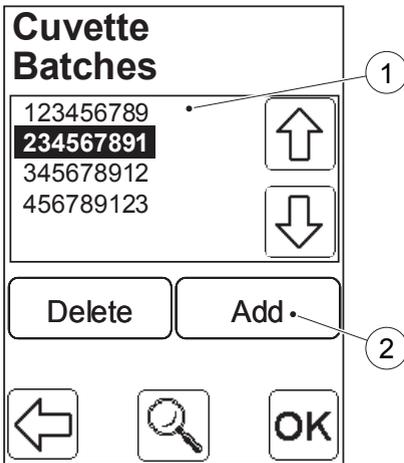
When the Cuvette Batches button is pressed in the Define Lists menu (see FIGURE 4-5), the Cuvette Batch list (1) will be displayed.

Note! In the initial settings, the Cuvette Batch list (1) will be empty.

Note! When trying to enter more than five Batches, the following text will be displayed:

Maximum Five Batches are Allowed.

a) To add a Cuvette Batch to the list, press the Add button (2).



- 1 Cuvette Batches list
- 2 Add button

(Continues)

(Continues)

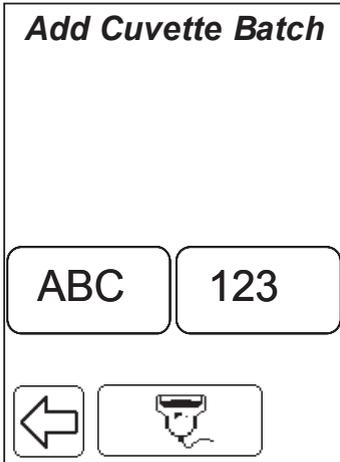


FIGURE 4-16

- b) Enter the Cuvette Batch No., either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.
- c) If the Batch No. was entered via the Barcode Scanner from the barcode on the Cuvette vial, FIGURE 4-18 will be displayed, otherwise FIGURE 4-17 will be displayed.

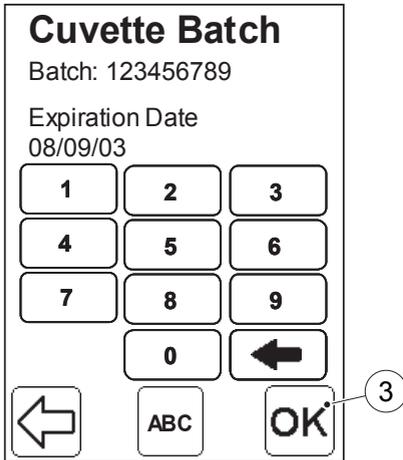


FIGURE 4-17

- Note!** This screen will not be displayed if the Cuvette Batch No. was entered via the Barcode Scanner from the barcode on the Cuvette vial.
- d) Enter the Expiration Date for the Cuvette Batch.
 - e) Press the Confirm button (3).
 - f) A summary is displayed, (see FIGURE 4-18).

3 Confirm button

(Continues)

(Continues)

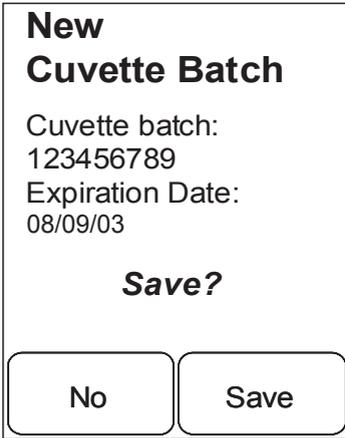
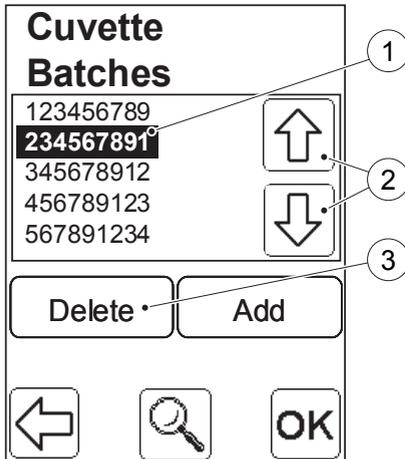


FIGURE 4-18

- g) Press Save to store the information or press No to cancel.
- h) The updated Cuvette Batch list will be displayed. Press the Confirm button in this display to return to the Define List menu (see FIGURE 4-5).

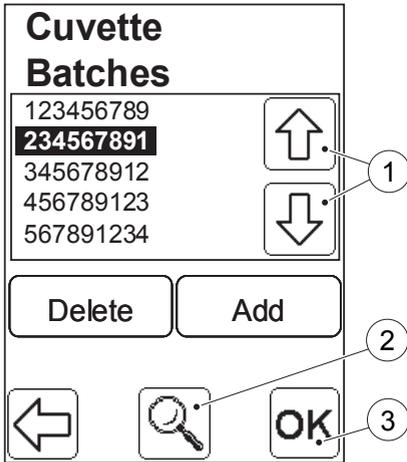


Delete Cuvette Batch Information

FIGURE 4-19

- a) To choose the Cuvette Batch information that is to be deleted, highlight the Cuvette Batch No. (1) by pressing the Scroll Bar Arrows (2). Press the Delete button (3).
- b) A confirm dialogue is displayed. Press Delete to delete the Cuvette Batch or press No to cancel.
- c) The updated Cuvette Batch list will be displayed. Press the Confirm button in this display to return to the Define List menu (see FIGURE 4-5).

- 1 Cuvette Batch (to be deleted)
- 2 Scroll bar arrows
- 3 Delete button

View Cuvette Batch InformationFIGURE 4-20

- a) To choose the Cuvette Batch information that is to be viewed, highlight the Cuvette Batch No. by pressing the Scroll bar arrows (1). Press the View button (2). A summary of the stored information will be displayed. Press the Confirm button (3). The Cuvette Batch List will be displayed.
- b) Press the Confirm button (3) in the new display to return to the Define Lists menu (see *FIGURE 4-5*).

-
- 1 Scroll bar arrows
 - 2 View button
 - 3 Confirm button

4.2.3 Define Operators

A list of Operators that can log in and use the System can be stored in the Analyzer.

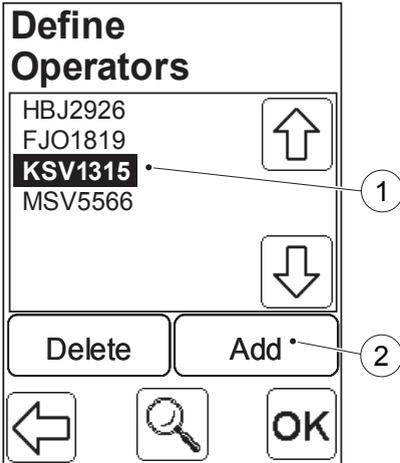
Add Operator

FIGURE 4-21

When the Define Operators button is pressed in the Define Lists menu (see FIGURE 4-5), the Define Operators list (1) will be displayed.

Note! In the initial settings, the Define Operators list (1) will only contain the default name "SUPERVISOR".

a) To add an Operator to the list, press the Add button (2).

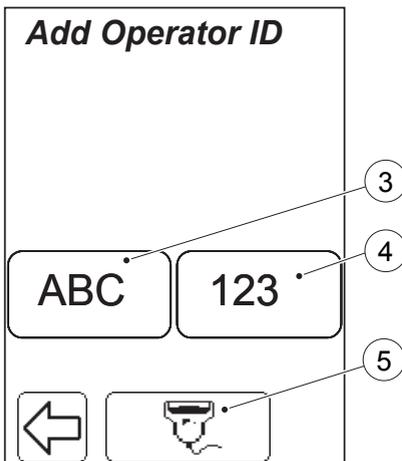


- 1 Define Operators list
- 2 Add button

FIGURE 4-22

b) Enter the Operator ID either directly on the Display via the Text mode (3) and Numeric mode (4) buttons, or with the Barcode Scanner via the Barcode Scanner button (5).

c) A similar image for Operator name will be displayed. Enter the Operator name according to instructions b) above.



- 3 Text mode button
- 4 Numeric mode button
- 5 Barcode Scanner button

(Continues)

(Continues)

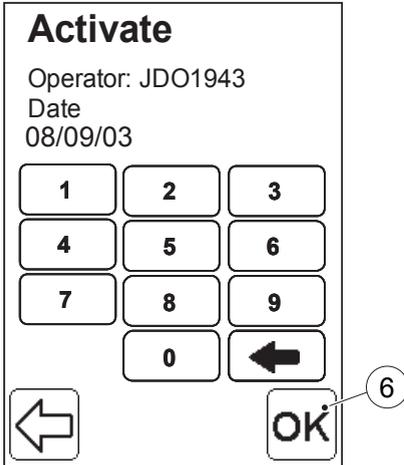


FIGURE 4-23

- d) Enter the date from which the Operator will have access to the Analyzer.
- e) Press the Confirm button (6). *FIGURE 4-24* will be displayed.

6 Confirm button

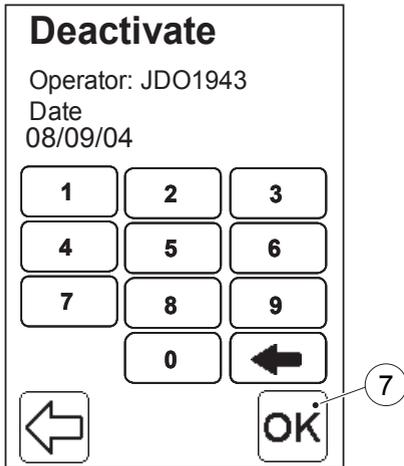


FIGURE 4-24

- f) Enter the date after which the Operator will be denied access to the Analyzer.
- g) Press the Confirm button (7). *FIGURE 4-26* will be displayed.

7 Confirm button

(Continues)

(Continues)

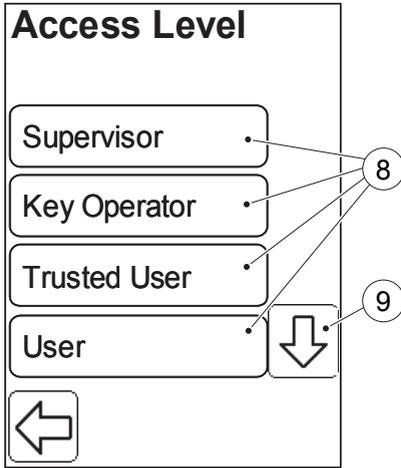


FIGURE 4-25

h) The following Access Level options (8) are available:

- Supervisor
- Key Operator
- Trusted User
- User
- Training

i) Press the Scroll bar arrow (9) to view options not initially visible on the screen.

Each operator belongs to only one Access Level.

The different Access Levels give the Operator the following authority:

-
- 8 Access Level options
 - 9 Scroll bar arrow

Operator category	Authority description
Supervisor	Full Access to system
Key Operator	Same as Supervisor
Trusted User	Patient and QC function access only
User	Same as Trusted User
Training	Patient and QC function access only. No results are stored.

(Continues)

(Continues)

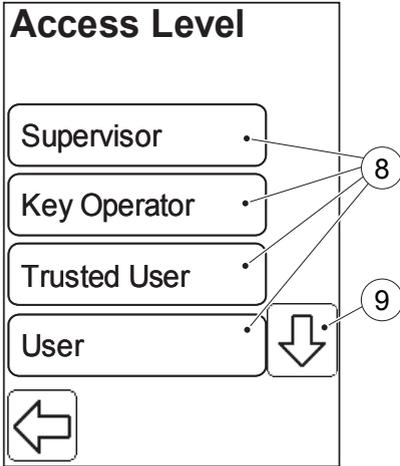


FIGURE 4-26

- j) Select an Access Level option (8) by pressing it.
- k) A summary of the entered information is displayed. Press Save to store the information or press No to cancel.
- l) The updated Define Operators list will be displayed. Press the Confirm button in this display to return to the Define List menu (see FIGURE 4-5).

-
- 8 Access Level options
 - 9 Scroll bar arrow

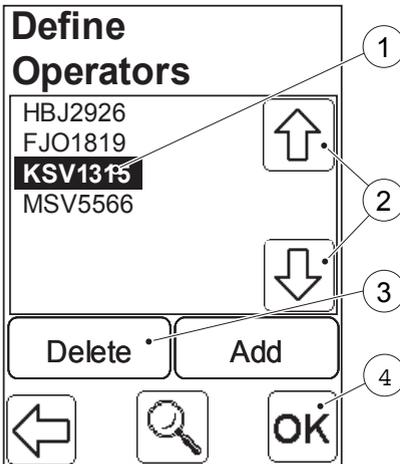


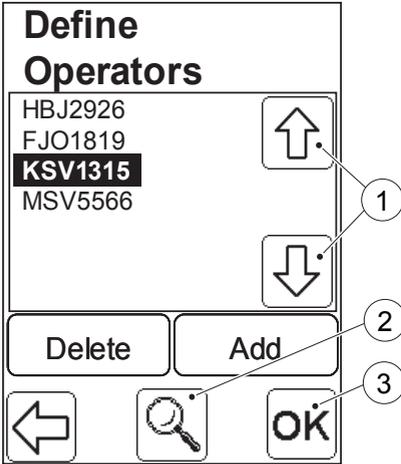
FIGURE 4-27

- a) To choose the Operator information that is to be deleted, highlight the Operator ID (1) by pressing the Scroll bar arrows (2). Press the delete button (3).
- b) A confirm dialogue is displayed. Press Delete to delete the Operator information or press No to cancel.
- c) The updated Define Operators list will be displayed. Press the Confirm button (4) to return to the Define List menu (see FIGURE 4-5).

-
- 1 Operator (to be deleted)
 - 2 Scroll bar arrows
 - 3 Delete button
 - 4 Confirm button

View Operator

FIGURE 4-28



a) To choose the Operator information that is to be viewed, highlight the Operator ID by pressing the Scroll bar arrows (1). Press the View button (2). A summary of the stored information will be displayed. Press the Confirm button (3). The Define Operator List will be displayed.

b) Press the Confirm button in the new display to return to the Define Lists menu (see *FIGURE 4-5*).

-
- 1 Scroll bar arrows
 - 2 View button
 - 3 Confirm button

4.2.4 Define Comments

A comment is a short piece of text that can be added to a result.

Add Comment

FIGURE 4-29

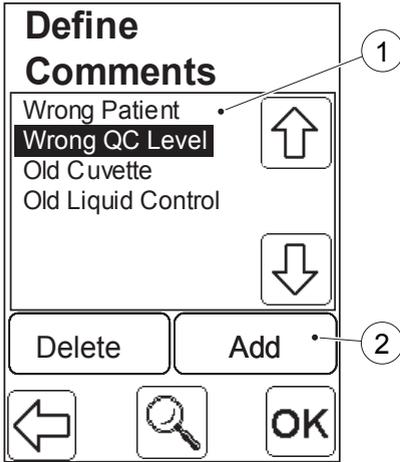
When the Define Comments button is pressed in the Define Lists menu (see FIGURE 4-5), the Define Comments list (1) will be displayed.

Note! In the initial settings, the Define Comments list (1) will be empty.

Note! When trying to enter more than 30 Comments, the following text will be displayed:

Maximum 30 Comments are Allowed in the List.

a) To add a Comment to the list, press the Add button (2).



- 1 Define Comments list
- 2 Add button

(Continues)

(Continues)

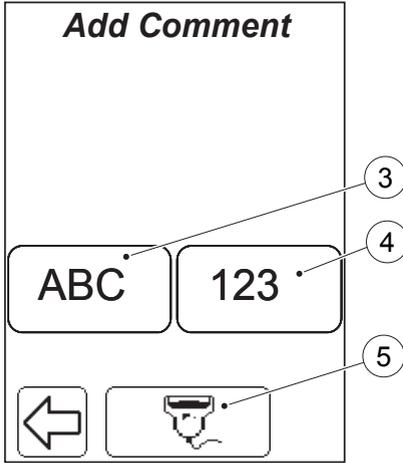


FIGURE 4-30

- b) Enter the Comment either directly on the Display via the Text mode (3) and Numeric mode (4) buttons, or with the Barcode Scanner via the Barcode Scanner button (5).
- c) The updated Define Comments list will be displayed. Press the Confirm button in that display to return to the Define List menu, (see FIGURE 4-5).

- 3 Text mode button
- 4 Numeric mode button
- 5 Barcode Scanner button

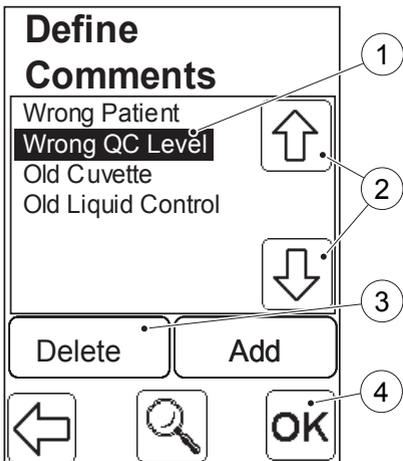
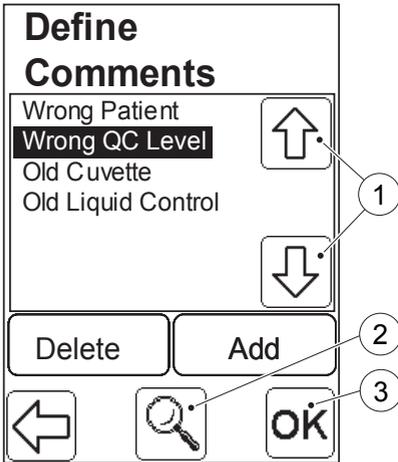


FIGURE 4-31

- a) To choose the Comment that is to be deleted, highlight the Comment (1) by pressing the Scroll Bar Arrows (2). Press the Delete button(3).
- b) A confirm dialogue is displayed. Press Delete to delete the Comment or press No to cancel.
- c) The updated Define Comments list will be displayed. Press the Confirm button (4) to return to the Define List menu, (see FIGURE 4-5).

- 1 Comment (to be deleted)
- 2 Scroll bar arrows
- 3 Delete button
- 4 Confirm button



View Comment

FIGURE 4-32

A Comment that requires more space than is available in the current display can be viewed by pressing the View button.

- a) To choose the comment that is to be viewed, highlight the Comment by pressing the Scroll bar arrows (1). Press the View button (2). The complete comment will be displayed. Press the Confirm button (3). The Define Comment List will be displayed.
- b) Press the Confirm button in the new display to return to the Define Lists menu (see *FIGURE 4-5*).

-
- 1 Scroll bar arrows
 - 2 View button
 - 3 Confirm button

4.2.5 Define Log Notes

A log note is a short text, used to define specific actions performed on the Analyzer.

Add Log

FIGURE 4-33

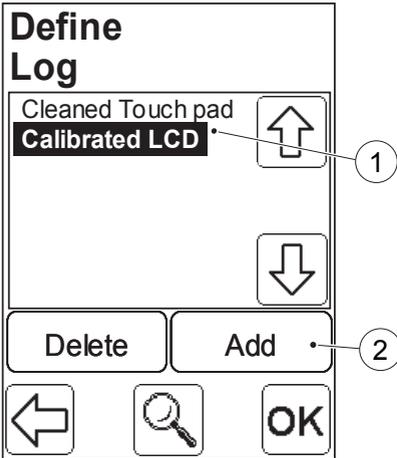
When the Define Log button is pressed in the Define Lists menu (see FIGURE 4-5), the Define Log list (1) will be displayed.

Note! In the initial settings, the Define Log list (1) will be empty.

Note! When trying to enter more than 30 Log notes, the following text will be displayed:

Maximum 30 Log Notes are Allowed in the List.

a) To add a Log note to the list, press the Add button (2).



- 1 Define Log list
- 2 Add button

(Continues)

(Continues)

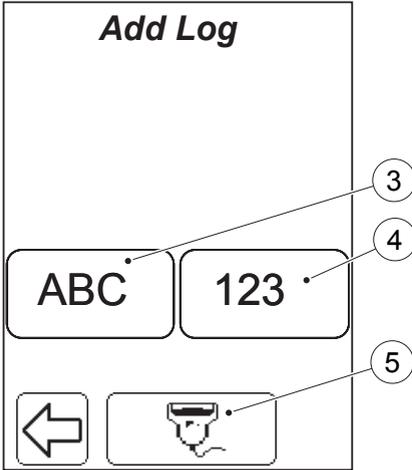


FIGURE 4-34

- b) Enter the Log note either directly on the Display via the Text mode (3) and Numeric mode (4) buttons, or with the Barcode Scanner via the Barcode Scanner button (5).
- c) The updated Define Log list will be displayed. Press the Confirm button in the new display to return to the Define List menu, (see FIGURE 4-5).

-
- 3 Text mode button
 - 4 Numeric mode button
 - 5 Barcode Scanner button

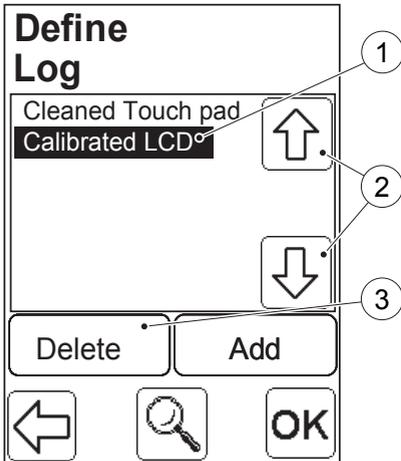
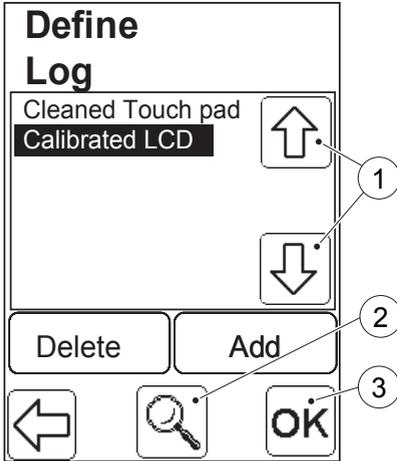


FIGURE 4-35

- a) To choose the Log note that is to be deleted, highlight the Log note (1) by pressing the Scroll bar arrows (2). Press the delete button (3).
- b) A confirm dialogue is displayed. Press Delete to delete the Log or press No to cancel.
- c) The updated Define Log list will be displayed. Press the Confirm button in the new display to return to the Define List menu, (see FIGURE 4-5).

-
- 1 Log (to be deleted)
 - 2 Scroll bar arrows
 - 3 Delete button



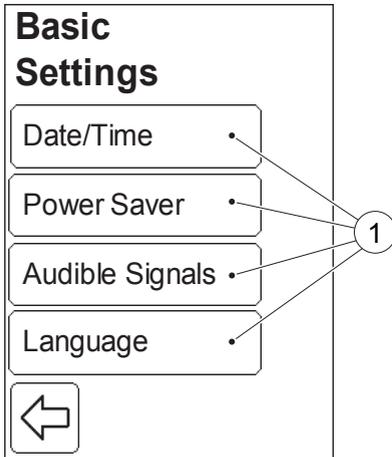
View Log

FIGURE 4-36

A Log note that requires more space than is available in the current display can be viewed by pressing the View button.

- a) To choose the Log note that is to be viewed, highlight the Log note by pressing the Scroll bar arrows (1). Press the view button (2). The complete Log note will be displayed. Press the Confirm button (3). The Define Log List will be displayed.
- b) Press the Confirm button in the new display to return to the Define Lists menu (see *FIGURE 4-5*).

-
- 1 Scroll bar arrows
 - 2 View button
 - 3 Confirm button



4.3 Basic Settings

FIGURE 4-37

When the Basic Settings button is pressed in the Settings menu (see *FIGURE 4-4*), the following Basic Settings categories (1) are displayed:

- Date/Time (see *4.3.1 Date/Time*)
- Power Saver (see *4.3.2 Power Saver*)
- Audible Signals (see *4.3.3 Audible Signals*)
- Language (see *4.3.4 Language*)

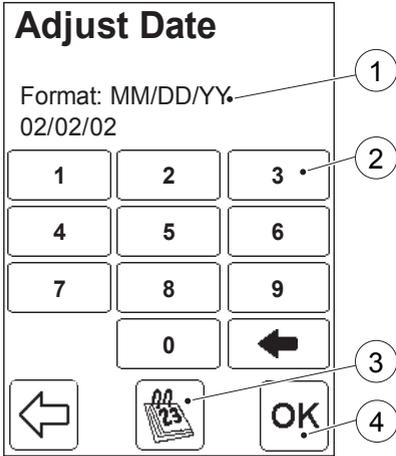
a) Select a Basic Settings category (1) by pressing it.

1 Basic Settings categories

4.3.1 Date/Time

FIGURE 4-38

When the Date/Time button is pressed in the Basic Settings menu (see *FIGURE 4-37*), the date setting function is displayed first.



a) Select the Date format (1) with the Date format button (3). The formats available are:

- MM/DD/YY (default format)
- DD.MM.YY (press once)
- YY-MM-DD (press twice)

MM symbolizes the month as two digits. DD symbolizes the day of the month as two digits.

YY symbolizes the year as two digits.

b) Enter the current date with the Digit buttons (2)

c) Press the Confirm button (4). *FIGURE 4-39* will be displayed

-
- 1 Date format
 - 2 Digit button
 - 3 Date format button
 - 4 Confirm button

(Continues)

(Continues)

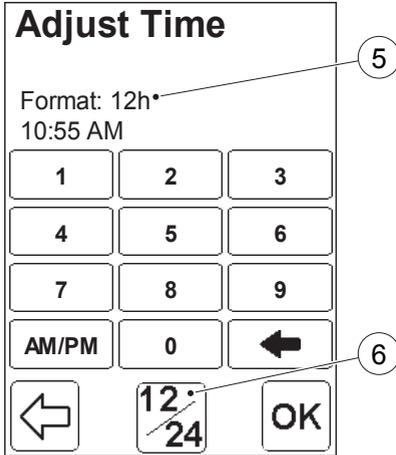


FIGURE 4-39

The time setting function is now displayed.

a) Select the Time format (5) with the Time format button (6). The following formats are available:

- 24hours
- 12hours

-
- 5 Time format
 - 6 Time format button

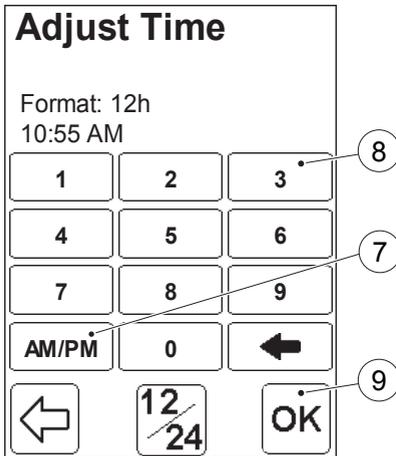


FIGURE 4-40

b) If the 12h-format is selected, select AM or PM by means of the AM/PM button (7).

Note! The AM/PM button (7) will only be displayed if the 12h-format is selected.

- c) Enter the current time with the Digit buttons (8).
- d) Press the Confirm button (9). The Basic Settings menu will be displayed (see FIGURE 4-37).

-
- 7 AM/PM button
 - 8 Digit button
 - 9 Confirm button

4.3.2 Power Saver

A detailed description of the Power Saver mode is described in 3.1.3 *Power saver mode*

FIGURE 4-41

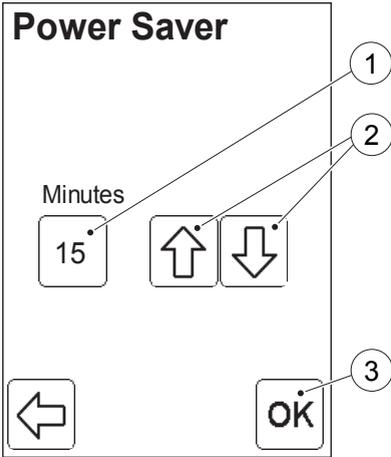
When the Power Saver button is pressed in the Basic Settings menu (see *FIGURE 4-37*), the Power Saver settings function is displayed.

a) To change the Power Saver time (1) press the Scroll bar arrows (2).

Note! The Power Saver time is set in five minute intervals from 5 - 30 minutes.

b) Press the Confirm button (3).

c) The Basic Settings menu will be displayed (see *FIGURE 4-37*).



-
- 1 Power Saver time
 - 2 Scroll bar arrows
 - 3 Confirm button

4.3.3 Audible Signals

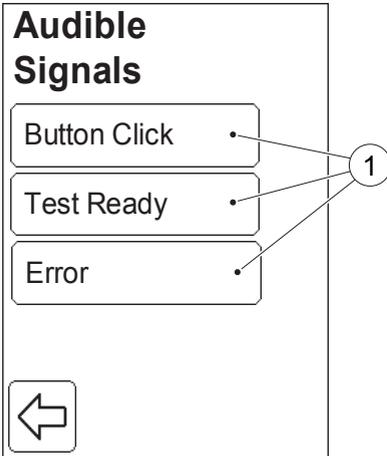
FIGURE 4-42

When the Audible Signals button is pressed in the Basic Settings menu (see FIGURE 4-37), the following Audible Signal setting choices are displayed:

- Button Click
- Test Ready
- Error

a) To adjust the volume of an audible signal, press one of the Audible Signal buttons (1).

In this example the Button Click button is pressed.



1 Audible Signal buttons

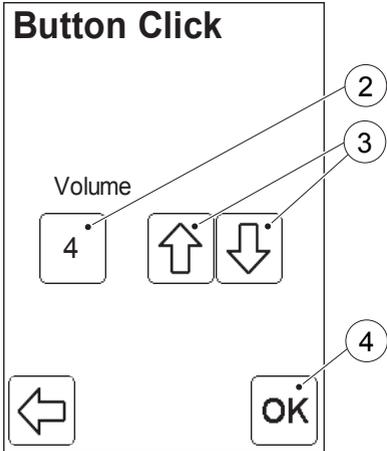
FIGURE 4-43

b) Set the Volume (2) from 0 - 4 by means of the Scroll bar arrows (3).

Note! To turn an Audible Signal off, set the Volume (2) to value 0.

c) Press the Confirm button (4).

d) The Audible Signal settings will be displayed (see FIGURE 4-42).



- 2 Volume
- 3 Scroll bar arrows
- 4 Confirm button

4.3.4 Language

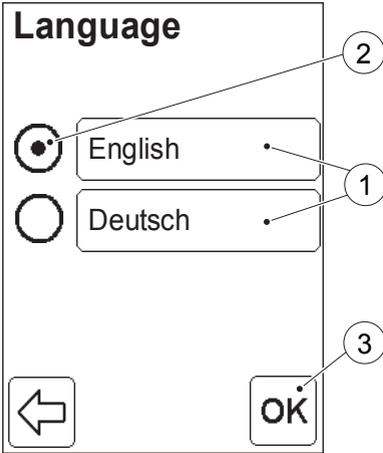
An Analyzer is delivered with two predefined language options.

FIGURE 4-44

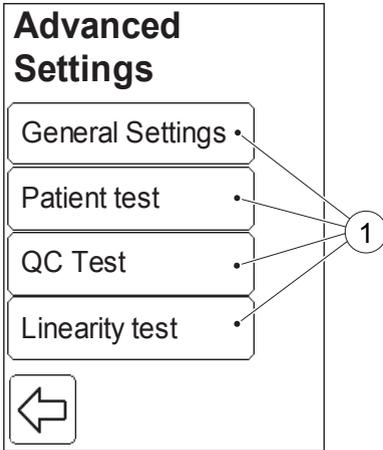
When the Language button is pressed in the Basic Settings menu (see *FIGURE 4-37*), the Language settings function is displayed.

The two language options are displayed as Language buttons (1). The language currently in use is indicated by the selected Radio button (2).

- a) To change the language, press the desired Language button (1).
- b) Press the Confirm button (3).
- c) The Basic Settings menu will be displayed (see *FIGURE 4-37*).



-
- 1 Language buttons
 - 2 Radio button
 - 3 Confirm button



4.4 Advanced Settings

FIGURE 4-45

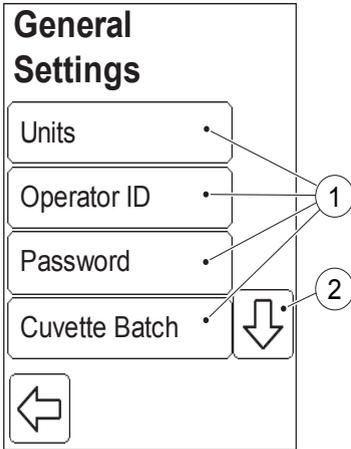
When the Advanced Settings button is pressed in the Settings categories menu (see *FIGURE 4-4*), the following Advanced Settings categories (1) are displayed:

- General Settings (see *4.4.1 General Settings*)
- Patient test (see *4.4.2 Patient Test Settings*)
- QC test (see *4.4.3 QC Test Settings*)
- Linearity test (see *4.4.4 Linearity Test Settings*)

a) Select one of the Advanced Settings categories (1) by pressing the button.

The Advanced Settings categories are explained on the following pages.

1 Advanced Settings categories



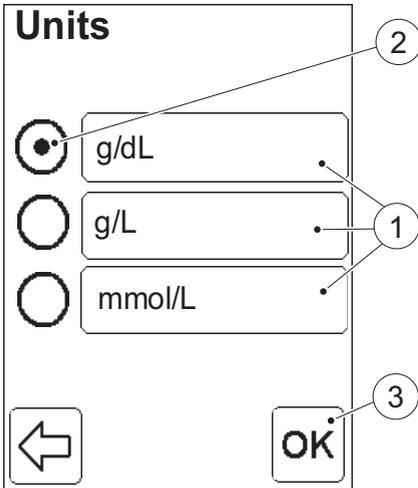
4.4.1 General Settings

FIGURE 4-46

When the General Settings button is pressed in the Advanced Settings menu (see *FIGURE 4-45*), the following General Settings categories are displayed:

- Units (See *FIGURE 4-47*)
 - Operator ID (See *FIGURE 4-48*)
 - Password (See *FIGURE 4-50*)
 - Cuvette Batch (See *FIGURE 4-52*)
 - Patient List (See *FIGURE 4-53*)
 - Memory (See *FIGURE 4-54*)
- a) Press the Scroll bar arrow (2) to view categories not initially visible on the display.
- b) Select a General Settings function (1) by pressing it.

-
- 1 General Settings categories
 - 2 Scroll bar arrow



Unit for Test Results

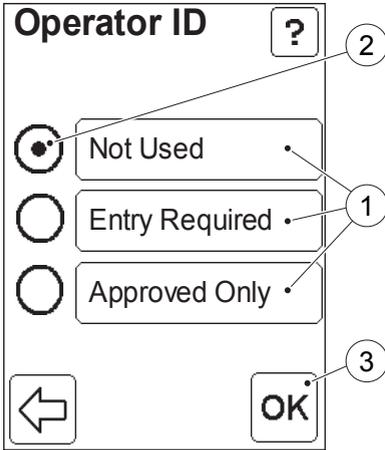
FIGURE 4-47

When the Units button is pressed in the General Settings menu (see *FIGURE 4-46*), the settings for Test Result Units are displayed.

The Units options are displayed as Units buttons (1). The option currently in use is indicated by the selected Radio button (2).

- a) To change the setting, press the button for the desired units (1).
- b) Press the Confirm button (3) to return to the General Settings menu (see *FIGURE 4-46*).

-
- 1 Units option
 - 2 Selected Unit
 - 3 Confirm button



Operator ID requirement

FIGURE 4-48

When the Operator ID button is pressed in the General Settings menu (see FIGURE 4-46), the settings for Operator ID requirement are displayed.

The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

Not Used : The Operator ID cannot be entered at startup. An Operator may perform all functions except the password protected functions (see FIGURE 4-50).

Entry required : An Operator ID must be entered at startup. Any operator not verified against the Operator List will be considered as belonging to the “user” category (see FIGURE 4-22).

Approved Only : An Operator ID must be entered at startup. Any operator not verified against the operator list will be denied access to the Analyzer.

Note! The *Approved Only* function will provide optimal operator traceability.

- a) To change the setting, press the button for the desired option (1).
- b) Press the Confirm button (3).

-
- 1 Options for Operator ID requirement
 - 2 Selected option
 - 3 Confirm button

(Continues)

(Continues)

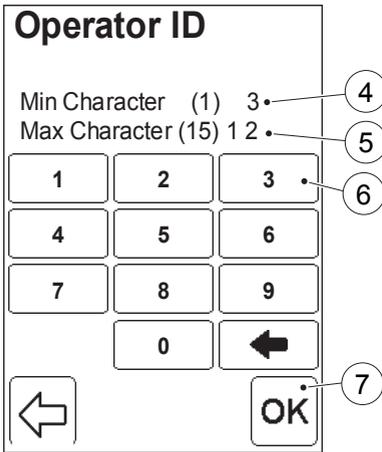
If *Entry Required* or *Approved Only* was selected, *FIGURE 4-49* will be displayed for setting the Operator ID specifications. If *Not Used* was selected, the General Settings menu, *FIGURE 4-46*, will be displayed.

FIGURE 4-49

The settings for the min. and the max. number of characters for the Operator ID are displayed.

Note! Numbers in brackets show the lowest and the highest allowable number of characters. To allow only an exact number of characters, enter the same value in the Min. and Max. settings.

- c) Enter the min. No. of characters (4) for the Operator ID via the Digit (6) buttons. Press the Confirm button (7).
- d) Enter the max. No. of characters (5) for the Operator ID via the Digit buttons (6). Press the Confirm button (7). *FIGURE 4-46* will be displayed.



-
- 4 Operator ID, min. number of characters
 - 5 Operator ID, max. number of characters
 - 6 Digit button
 - 7 Confirm button

Password for protected functions

Some Analyzer functions are password protected. The password protection function is only activated when the Operator ID requirement is set to “Not Used”.

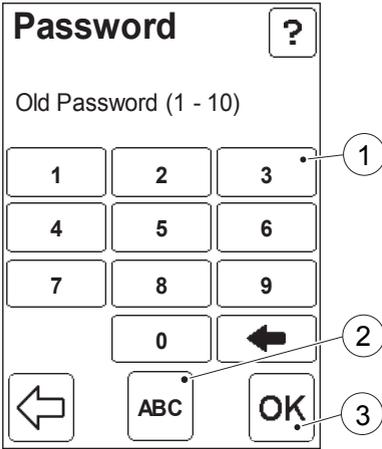


FIGURE 4-50

When the Password button is pressed in the General Settings menu (see FIGURE 4-46), the settings for Password are displayed.

Note! Numbers in brackets show the lowest and the highest allowable number of characters.

a) To change the password, enter the Old Password using the Digit buttons (1) and the Letter buttons that are displayed when the Text Mode button (2) is pressed. (The default password is 0000).

b) Press the Confirm button (3).

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

(Continues)

(Continues)

Password

New Password (1 - 10)

1	2	3
4	5	6
7	8	9
	0	←
←	ABC	OK

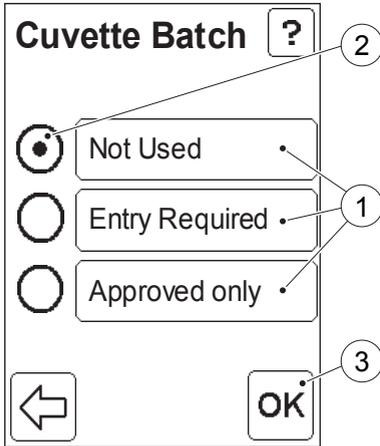
4

FIGURE 4-51

- c) Enter the New Password.
- d) Press the Confirm button (4).
- e) *FIGURE 4-51* will be displayed again. Verify the New Password by re-entering it.
- f) Press the Confirm button to return to the General Settings menu (see *FIGURE 4-46*).

Note! If the re-entered password is incorrect, a display with the text **Invalid Entry** will be displayed. Press the back arrow to return to the previous display.

4 Confirm button



Cuvette Batch requirement

FIGURE 4-52

When the Cuvette Batch button is pressed in the General Settings menu (see FIGURE 4-46), the settings for Cuvette Batch requirements are displayed.

The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

Not Used : The Cuvette Batch No. cannot be entered.

Entry required : The Cuvette Batch No. must be entered. The Cuvette Batch No. entered is not verified against the predefined list.

Approved Only : The Cuvette Batch No. must be entered and verified against the predefined Cuvette Batch list in the Analyzer for the result to be displayed.

- a) To change the setting, press the button for the desired option (1).
- b) Press the Confirm button (3) to return to the General Settings menu, FIGURE 4-46.

-
- 1 Options for Cuvette Batch No. requirement
 - 2 Selected option
 - 3 Confirm button

Patient List setting

A Patient List is a list containing Patient ID's and corresponding Patient names. If an OR supports the sending of Patient Lists to the HemoCue Hb 201 DM Analyzer, the Analyzer can display the name of a patient after the patient ID has been entered, allowing for positive patient identification.

FIGURE 4-53

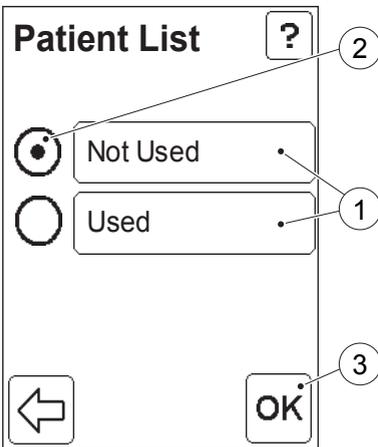
When the Patient List button is pressed in the General Settings menu (see FIGURE 4-46), the Patient List settings are displayed.

The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

Not Used : The Patient List feature is not used.

Used : The Patient List feature is used when running a Patient test. See chapter 6 *Patient Test procedure* for more information.

- a) To change the setting, press the button for the desired option (1).
- b) Press the Confirm button (3) to return to the General Settings menu, FIGURE 4-46.



-
- 1 Options for Patient List
 - 2 Selected option
 - 3 Confirm button

Full Memory Options

FIGURE 4-54

Up to 4000 Patient/STAT tests can be stored in the Analyzer. When the Memory button is pressed in the General Settings menu (see *FIGURE 4-46*), the options for when the patient memory is full are displayed.

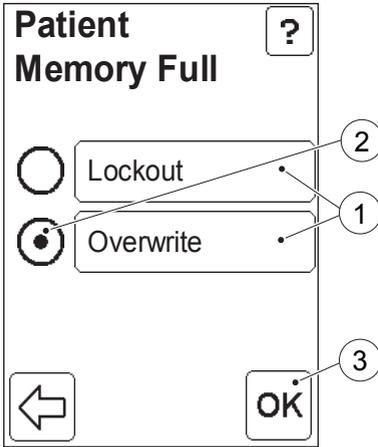
The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

Lockout : The Analyzer is locked out when the patient memory is full. No patient tests can be performed until the stored results have been deleted from the Patient Memory function.

Overwrite : When the patient memory is full, the Analyzer stores the new patient test result by overwriting the oldest result.

- a) To change the setting, press the button for the desired option (1).
- b) Press the Confirm button (3).

FIGURE 4-55 will be displayed.



-
- 1 Full Memory options
 - 2 Selected option
 - 3 Confirm button

(Continues)

(Continues)

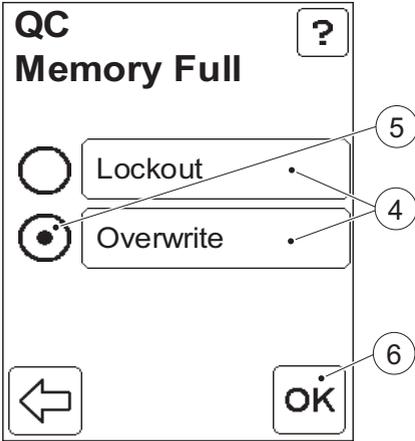


FIGURE 4-55

The options for QC Memory full will be displayed. The option currently in use is indicated by the selected Radio button (5).

c) To change the setting, press the button for the desired option (4).

d) Press the Confirm button (6) to return to the General Settings menu, *FIGURE 4-46*.

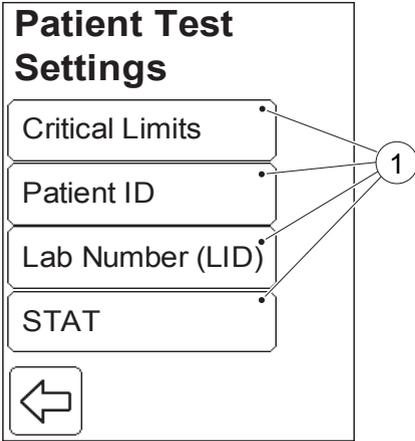
Note! The option selected for QC Memory Full will automatically be selected for Log Memory Full.

-
- 4 Memory Full option buttons
 - 5 Selected option
 - 6 Confirm button

4.4.2 Patient Test Settings

FIGURE 4-56

When the Patient test button is pressed in the Advanced Settings menu (see FIGURE 4-45), the following Patient Test Settings categories are displayed:



- Critical Limits (See FIGURE 4-57)
- Patient ID (See FIGURE 4-58)
- Lab Number (LID) (See FIGURE 4-61)
- STAT (See FIGURE 4-63)

a) Select a Patient Test Settings category (1) by pressing it.

1 Patient Test Settings categories

Critical Limits

The Critical Limits define the range of values outside of which the patient test results will be listed as critical.

FIGURE 4-57

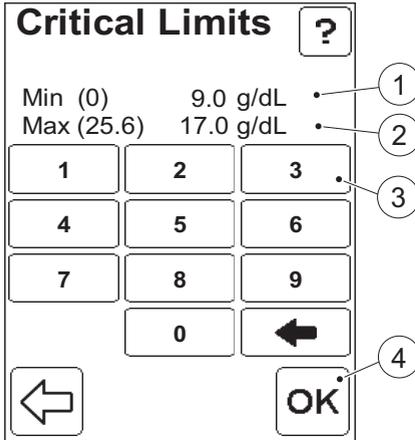
When the Critical Limits button is pressed in the Patient Test Settings menu (see *FIGURE 4-56*), the settings for Critical Limits are displayed.

Note! The numbers in brackets show the lowest and the highest values for the critical limits.

a) Enter the min. value (1) via the Digit buttons (3). Press the Confirm button (4).

b) Enter the max. value (2) via the Digit buttons (3). Press the Confirm button (4).

The Patient Test Settings menu, *FIGURE 4-56*, will be displayed.



-
- 1 Min. value
 - 2 Max. value
 - 3 Digit button
 - 4 Confirm button

Patient ID

FIGURE 4-58

When the Patient ID button is pressed in the Patient Test Settings menu (see *FIGURE 4-56*), the settings for the Patient ID requirements are displayed.

The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

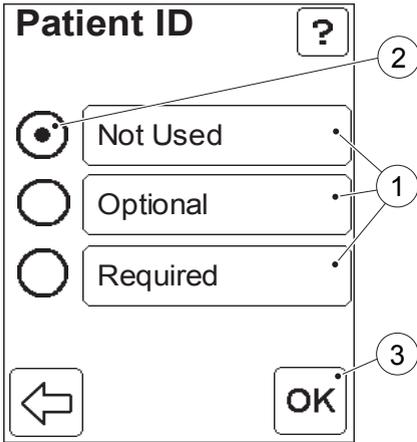
Not Used : The Patient ID cannot be entered.

Optional : The Patient ID can be entered or left blank.

Required : The Patient ID must be entered.

a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3).



- 1 Options for Patient ID requirement
- 2 Selected option
- 3 Confirm button

(Continues)

(Continues)

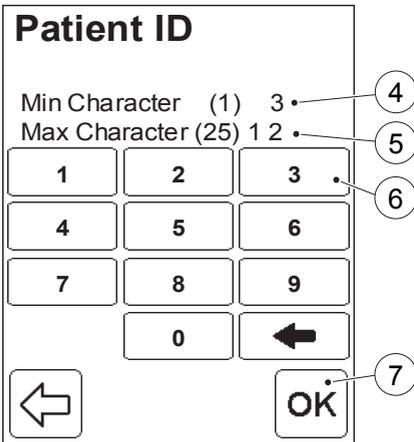
If *Optional* or *Required* was selected, *FIGURE 4-59* will be displayed for setting the Patient ID specifications. If *Not Used* was selected, the General Settings menu, *FIGURE 4-56*, will be displayed.

FIGURE 4-59

Note! Numbers in brackets show the lowest and the highest allowable number of characters. To allow only an exact number of characters, enter the same value in the Min. and Max. options.

c) Enter the min. No. of characters (4) via the Digit buttons (6). Press the Confirm button (7).

d) Enter the max. No. of characters (5) via the Digit buttons (6). Press the Confirm button (7). *FIGURE 4-60*, will be displayed.



-
- 4 Min. number of characters
 - 5 Max. number of characters
 - 6 Digit button
 - 7 Confirm button

(Continues)

(Continues)

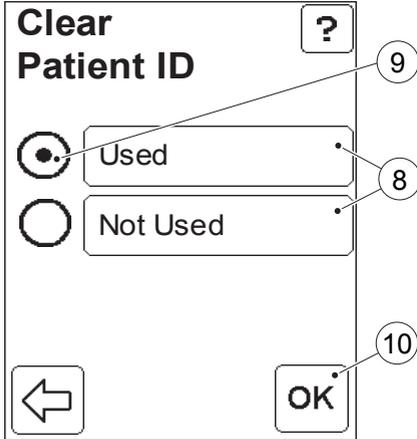


FIGURE 4-60

The setting for clearing the Patient ID is displayed.

The options available are displayed as buttons (8). The option currently in use is indicated by the selected Radio button (9).

Used : The previous Patient ID will be cleared when a new test is initiated.

Not Used : The previous Patient ID will be displayed until a new Patient ID is entered.

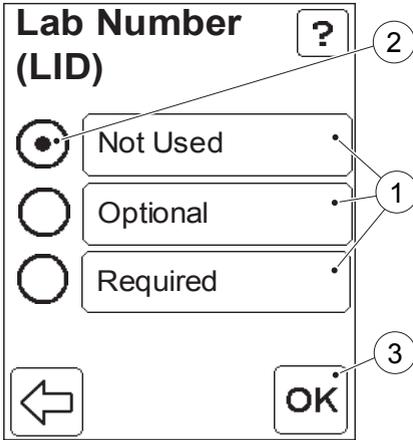
e) To change the setting, press the button for the desired option (8).

f) Press the Confirm button (10) to return to the Patient Test Settings menu (see FIGURE 4-56).

8 Clear Patient ID options

9 Selected option

10 Confirm button



Lab Number (LID) requirement

FIGURE 4-61

When the Lab Number (LID) button is pressed in the Patient Test Settings menu (see FIGURE 4-56), the settings for Lab ID requirement are displayed (1). The option currently in use is indicated by the selected Radio button (2).

Not Used : The Lab No. cannot be entered.

Optional : The Lab No. can be entered or left blank.

Required : The Lab No. must be entered.

a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3).

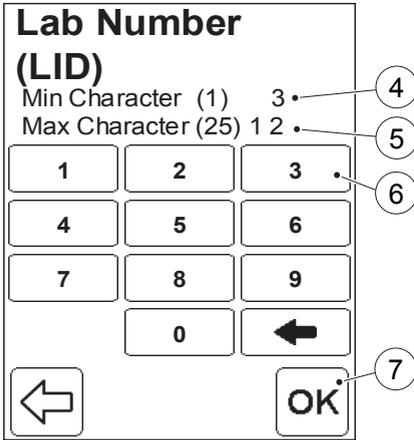
1 Options for Lab Number requirement

2 Selected option

3 Confirm button

(Continues)

(Continues)



If *Optional* was selected, *FIGURE 4-62* will be displayed for setting the Lab Number specifications.

If *Not Used* was selected, the Patient Test Settings menu, *FIGURE 4-56*, will be displayed.

The settings for the min. and the max. length of the Lab Number are displayed.

FIGURE 4-62

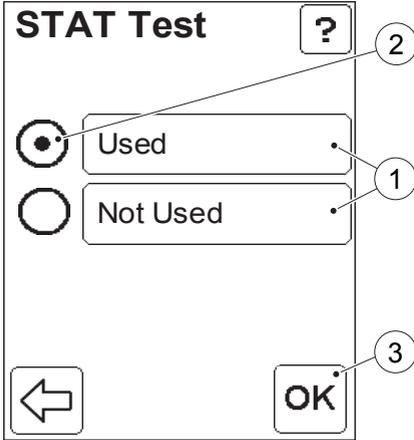
Note! Numbers in brackets show the lowest and the highest allowable number of characters.

c) Enter the min. No. of characters (4) via the Digit buttons (6). Press the Confirm button (7).

d) Enter the max. No. of characters (5) via the Digit buttons (6). Press the Confirm button (7).

The Patient Test Settings menu, *FIGURE 4-56*, will be displayed.

-
- 4 Min. number of characters
 - 5 Max. number of characters
 - 6 Digit button
 - 7 Confirm button



STAT Test usage

FIGURE 4-63

When the STAT button is pressed in the Patient Test Settings menu (see *FIGURE 4-56*), the settings for STAT Tests are displayed.

The options available are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

Used : STAT tests are permitted even when the Analyzer has performed a QC lockout.

Not Used : STAT tests are not permitted.

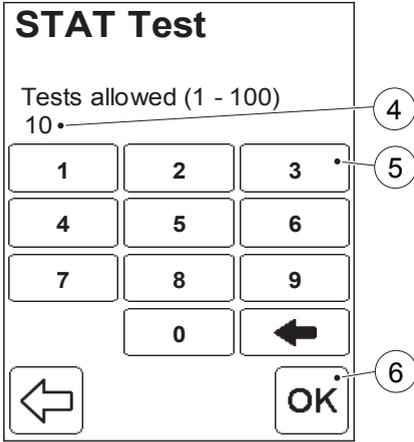
a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3).

-
- 1 Options for STAT test usage
 - 2 Selected option
 - 3 Confirm button

(Continues)

(Continues)



If *Used* was selected, *FIGURE 4-64* will be displayed for setting the STAT Test specifications.

If *Not Used* was selected, the General Settings menu, *FIGURE 4-56*, will be displayed.

FIGURE 4-64

Note! The numbers in brackets show the lowest and the highest number of tests that can be set.

c) Enter the max. No. of STAT tests that will be allowed after the Analyzer has performed a QC lockout, via the Digit buttons (5). Press the Confirm button (6).

The Patient Test Settings menu, *FIGURE 4-56*, will be displayed.

-
- 4 Max. number of STAT tests
 - 5 Digit button
 - 6 Confirm button

4.4.3 QC Test Settings

FIGURE 4-65

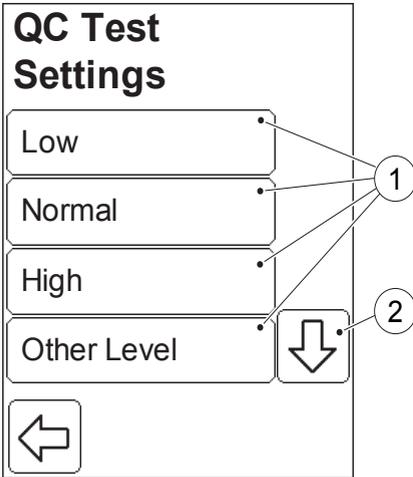
When the QC test button is pressed in the Advanced Settings menu (see FIGURE 4-45), the following QC Test Settings options are displayed:

- Low (See FIGURE 4-66)
- Normal
- High
- Other Level
- Reminder Time (See FIGURE 4-74)
- QC Result Options (See FIGURE 4-76)
- Failed QC Comment (See FIGURE 4-77)

Low, Normal, High and Other Level, refer to the different concentration levels of Liquid Controls used in QC tests. The settings procedure is the same for all concentration levels. For this reason, only one of these is described.

- a) Press the Scroll bar arrow (2) to view options (1) not initially visible on the display.
- b) Select a QC Test Settings option (1) by pressing it.

-
- 1 QC Test Settings options
 - 2 Scroll bar arrow



QC Test settings for distinct concentration levels

An Analyzer can be set to perform a lockout if the required QC test is not performed within a pre-defined time or after a pre-defined number of measurements. The Analyzer will be unlocked when an approved QC test at the required concentration level has been performed. The lockout configuration must be set for each concentration level of Liquid Control.

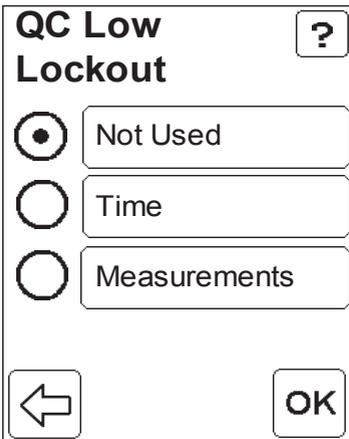


FIGURE 4-66

When the Low button is pressed in the QC Test Settings menu (see FIGURE 4-65), the settings for QC lockout at this level are displayed.

The options available are displayed as buttons. The option currently in use is indicated by the selected radio button.

Not Used : No QC lockout will be performed.

Time : The QC lockout will be activated if the required QC test has not been performed within the defined time interval.

(Continues)

(Continues)

Measurements : The QC lockout will occur if the required QC test has not been performed within the predefined number of measurements.

FIGURE 4-67

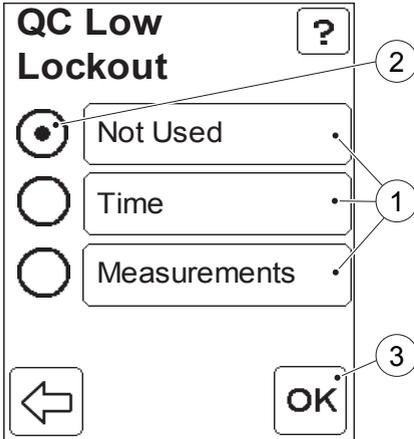
a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3).

If “Not Used” is selected, the QC Test Settings Menu, *FIGURE 4-65*, is displayed.

If “Time” is selected, *FIGURE 4-68*, is displayed.

If “Measurements” is selected, *FIGURE 4-72*, is displayed.



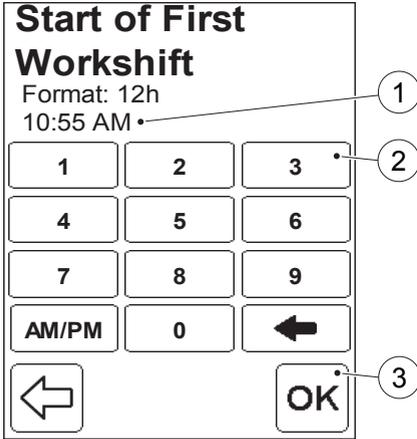
-
- 1 Options for QC lockout criteria
 - 2 Selected option
 - 3 Confirm button

QC lockout determined by time

FIGURE 4-68

If Time was selected in the QC lockout menu, the setting for the QC lockout based on time is displayed.

a) Enter the start time (1) for the beginning of the interval using the Digit button (2). Press the Confirm button (3).



- 1 Start time
- 2 Digit button
- 3 Confirm button

(Continues)

(Continues)

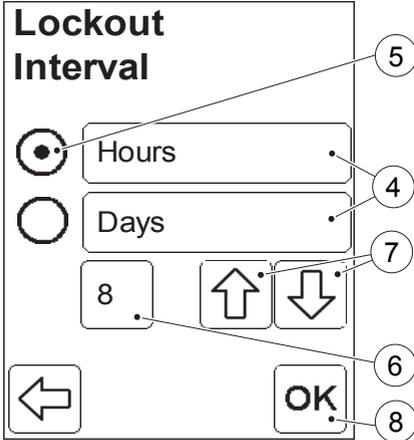


FIGURE 4-69

The QC lockout interval may be set in either Hours or Days (4).

The options are displayed as buttons. The option currently in use is indicated by the selected Radio button (5).

The number of Hours or Days is also displayed (6).

- a) To change the setting, press the button for the desired option (4).
- b) To change the length of the time interval, use the Scroll bar arrows (7).
- c) Press the Confirm button (8).

If the reminder time needs to be adjusted, *FIGURE 4-70* will be displayed. Otherwise *FIGURE 4-71* will be displayed.

-
- 4 Time interval options
 - 5 Selected option
 - 6 Selected time interval
 - 7 Scroll bar arrows
 - 8 Confirm button

(Continues)

(Continues)

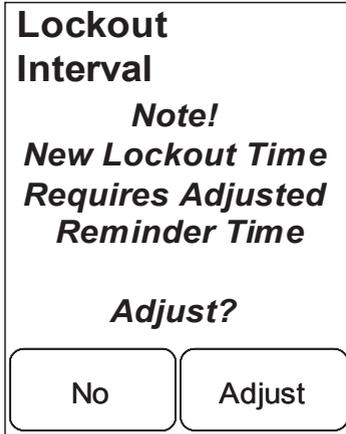


FIGURE 4-70

d) To adjust the reminder time to fit the new QC lockout time, press Adjust. After adjusting to an acceptable reminder time (See FIGURE 4-74), FIGURE 4-71 will be displayed. To return to FIGURE 4-69, press No. The selected time interval until the next QC lockout will then need to be adjusted.

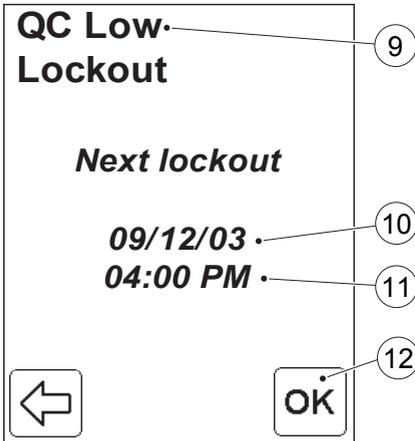


FIGURE 4-71

The date and time of the next QC lockout for the chosen QC level will be displayed.

e) Press the Confirm button (12) to return to the QC Test Settings menu, FIGURE 4-65.

-
- 9 Concentration level of QC test
 - 10 Date for next QC lockout
 - 11 Time point for next QC lockout
 - 12 Confirm button

QC lockout determined by number of measurements

FIGURE 4-72

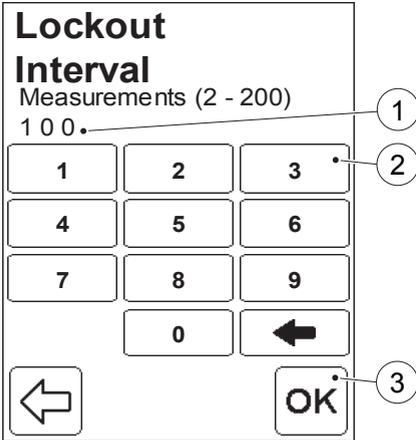
If Measurements was selected in the QC lockout menu (see *FIGURE 4-66*), the setting for the QC lockout based on the number of patient or STAT test measurements performed is displayed.

Note! The numbers in brackets show the lowest and the highest number of tests that can be set.

a) Enter the number of measurements after which QC lockout will occur (1) via the Digit buttons (2). Press the Confirm button (3).

b) If the reminder value needs to be adjusted, *FIGURE 4-73* will be displayed.

Otherwise there will be a return to *FIGURE 4-65*.



-
- 1 No. of measurements after which QC lockout occurs
 - 2 Digit button
 - 3 Confirm button

(Continues)

(Continues)

Lockout Interval

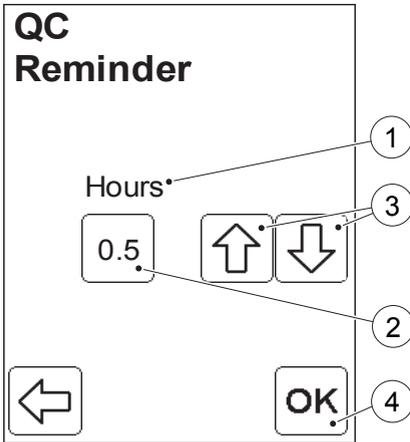
Note!
New Lockout Value Requires Adjusted Reminder Value

Adjust?

No Adjust

FIGURE 4-73

c) To adjust the number of measurements for the reminder so that it corresponds with the new value for the number of measurements before QC lockout, press Adjust. After adjusting to an acceptable value (See *FIGURE 4-75*), there will be a return to the QC Test Settings menu, *FIGURE 4-65*. Otherwise, to return to *FIGURE 4-72*, press No. The selected time/Number of measurements until the next QC lockout will then need to be adjusted, in order to correspond with the defined reminder.



QC Test Reminder settings

FIGURE 4-74

When the Reminder Time button is pressed in the QC Test menu (see FIGURE 4-65), the settings for the QC reminder based on time is displayed. A reminder message will be shown at this set time, prior to QC lockout.

The Reminder time can be set to no more than half the shortest of the QC lockout times, irrespective as to which level this refers.

The current value of the reminder time (2) expressed in the given unit (1) is displayed.

a) Set the reminder time using the Scroll bar arrows (3).

Note! To turn the Reminder Time function off, set the value (2) to “0”.

b) Press the Confirm button (4). FIGURE 4-76 will be displayed.

-
- 1 Unit for reminder time
 - 2 Reminder time value
 - 3 Scroll bar arrows
 - 4 Confirm button

(Continues)

(Continues)

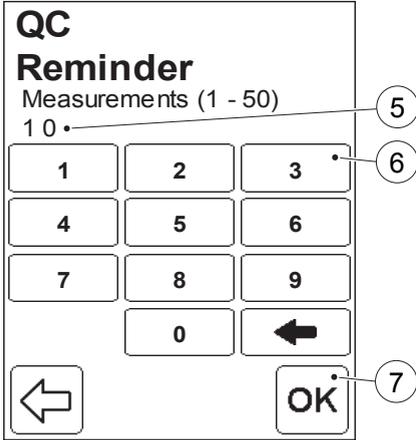


FIGURE 4-75

The settings for the QC reminder based on the number of Patient or Stat tests performed is displayed. A reminder message will be shown when this number of tests are remaining, prior to QC lockout.

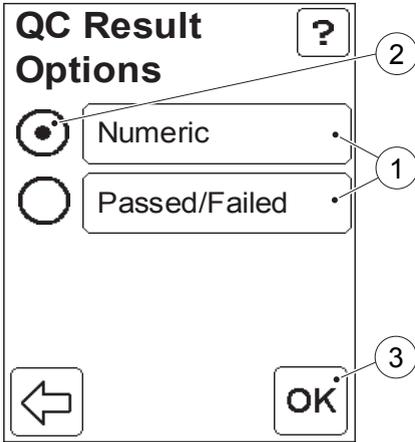
The number of measurements for this reminder can be set to no more than half the lowest number of measurements, irrespective as to which level this refers.

Note! The numbers in brackets show the lowest and the highest number of tests that can be set.

- a) Enter the number of measurements for the reminder (5) via the Digit buttons (6).
- b) Press the Confirm button (7).

FIGURE 4-65 will be displayed.

-
- 5 No. of measurements for reminder
 - 6 Digit button
 - 7 Confirm button



QC Result Presentation Options

FIGURE 4-76

When the QC Result Option button is pressed in the QC Test menu (see *FIGURE 4-65*), two options are displayed.

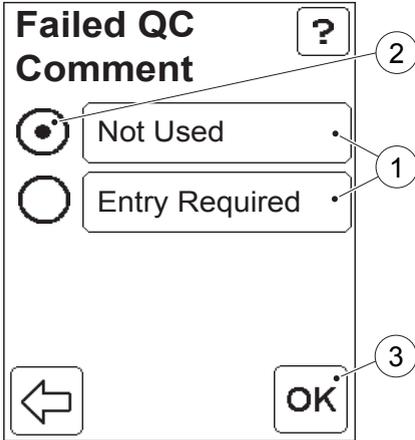
QC Test results can be presented either as quantitative (numerical) or qualitative (“Passed”/“Failed”) values.

The options are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3) to return to the QC Test Settings menu, *FIGURE 4-65*.

-
- 1 Options for presentation of test results
 - 2 Selected option
 - 3 Confirm button



Failed QC Comment

FIGURE 4-77

When the Failed QC Comment button is pressed in the QC Test menu, two options are displayed.

When Failed QC Comment is set to *Entry Required* it forces the operator to enter at least one comment to a QC Test that has failed.

The options are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3) to return to the QC Test Settings menu, *FIGURE 4-65*.

-
- 1 Options for Failed QC Comment
 - 2 Selected option
 - 3 Confirm button

4.4.4 Linearity Test Settings

For a description of linearity tests, see *8.2.2 Linearity Test*.

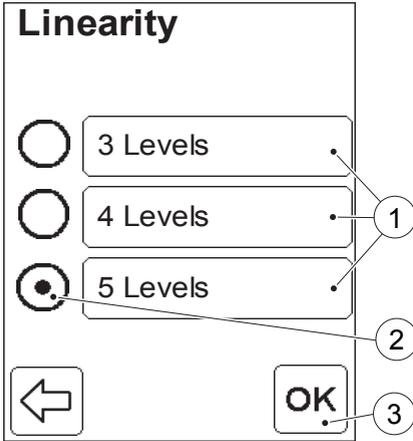


FIGURE 4-78

When the Linearity test button is pressed in the Advanced Settings menu (see *FIGURE 4-45*), options for the number of concentration levels for the linearity test are displayed.

The options are displayed as buttons (1). The option currently in use is indicated by the selected Radio button (2).

a) To change the setting, press the button for the desired option (1).

b) Press the Confirm button (3).

FIGURE 4-79 will be displayed.

-
- 1 Options for number of levels
 - 2 Selected option
 - 3 Confirm button

(Continues)

(Continues)

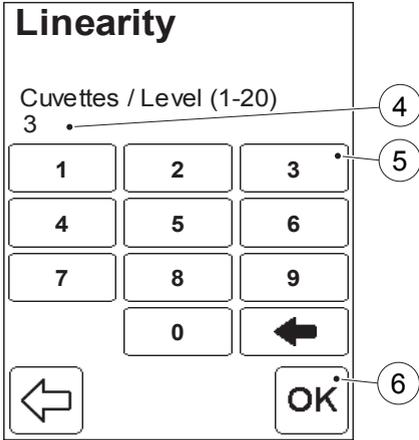


FIGURE 4-79

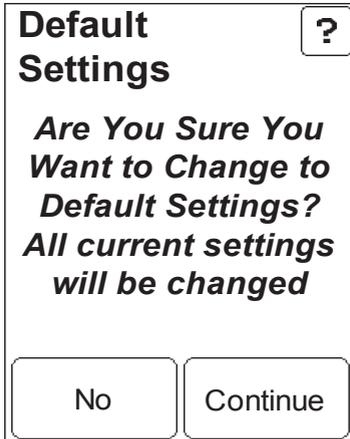
Note! The numbers in brackets show the lowest and the highest number of tests that can be set.

c) Enter the number of cuvettes (4) for each level, via the Digit buttons (5)

d) Press the Confirm button (6).

FIGURE 4-45 will be displayed.

-
- 4 Number of cuvettes per level
 - 5 Digit button
 - 6 Confirm button



4.5 Default Settings

FIGURE 4-80

When the Default Settings button is pressed in the Settings menu (see *FIGURE 4-4*), confirmation or cancellation of the requested change to the Analyzer default setting is required. A question will be displayed.

Note! Default settings affect only the Analyzer configuration (including password). Measurement results or lists (Liquid Controls, Cuvette Batches, Operators, Comments or Logs) will not be affected. For a list of default values see *Appendix A – Default Settings*.

- a) If all the settings in the Analyzer are to be changed to Default settings, press Continue. Otherwise, press No. *FIGURE 4-4* will be displayed.

Note! If the choice was to change all settings to default, the following text will be displayed for a few seconds:
Settings have Now Changed to Default Settings.

- b) The Settings menu, *FIGURE 4-4*, will be displayed again.

4.6 Infra Red

Settings (but not measurements) can be transmitted between two Analyzers when the IR-ports are facing each other.

4.6.1 The transmitting Analyzer

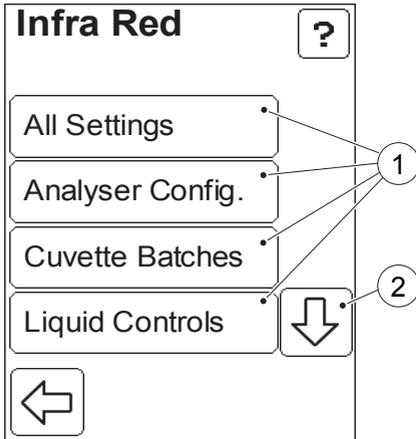
FIGURE 4-81

When the Infra Red button is pressed in the Settings menu (see *FIGURE 4-4*), the categories (1) that can be transferred are displayed

- All Settings (include all the categories in the rest of the options)
- Analyser Configuration (see *4.3 Basic Settings* and *4.4 Advanced Settings*)
- Cuvette Batches (see *4.2.2 Cuvette Batches*)
- Liquid Controls (see *4.2.1 Liquid Controls*)
- Operator List (see *4.2.3 Define Operators*)
- Comment List (see *4.2.4 Define Comments*)
- Log List (see *4.2.5 Define Log Notes*)

-
- 1 Settings options
2 Scroll bar arrow

(Continues)



(Continues)

All options are transferred by the Analyzer in the same manner, therefore, only one of these, "All Settings" is described.

- a) Press the Scroll bar arrow (2) to view options not visible on the display.
- b) Select the settings category (1) to be transferred by pressing the corresponding button.

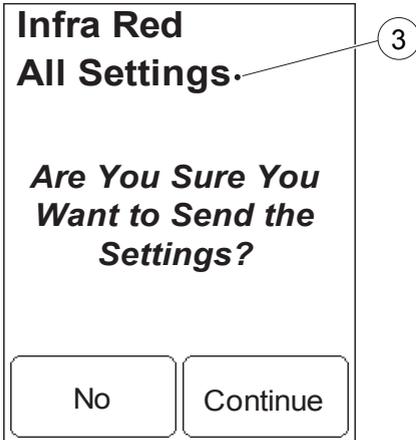


FIGURE 4-82

Confirmation or cancellation of the transfer of the desired setting (3) is required.

- c) To initiate data transfer of the category indicated (3) to the receiving Analyzer, press Continue. To cancel, press No.
- d) If the process was initiated, the connection will be established and the following text will be displayed:
Transmitting via IR port ...

3 Settings to transfer

(Continues)

(Continues)

- e) If a connection was established successfully and the transfer was accepted by the receiving Analyzer (see *FIGURE 4-83*), the same text will continue to be displayed during data transfer. When the transfer is completed, the following text will be displayed for a few seconds:

Transmission OK

and a beep will be heard if the audible signal is enabled.

FIGURE 4-81 will be displayed.

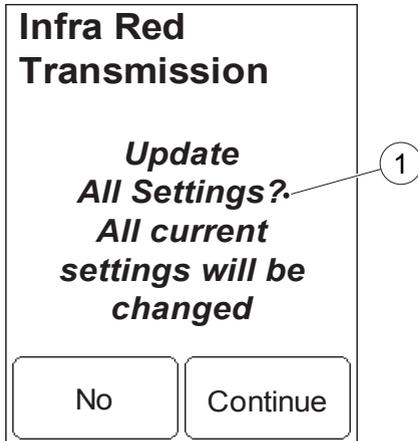
- f) If no connection was established or transfer was rejected by the receiving Analyzer, the following text will be displayed:

No Connection With Compatible IR Device

An error beep will be heard if the audible signal is enabled. See *Troubleshooting* on page 245.

Press the Confirm button.

FIGURE 4-81 will be displayed.



4.6.2 The Receiving Analyzer

FIGURE 4-83

Confirmation or cancellation of the transmitted setting information (1) is required on the receiving Analyzer.

- a) To accept data transfer of the category indicated (1) from the sending Analyzer, press Continue. To cancel, press No.
- b) If the transfer is accepted, while data is being received, the following text will be displayed:

Receiving via IR port ...

with slight variations depending on the category of settings information.

- c) When the transfer is completed, the following text will be displayed for a few seconds:

Transmission OK

1 Settings to receive

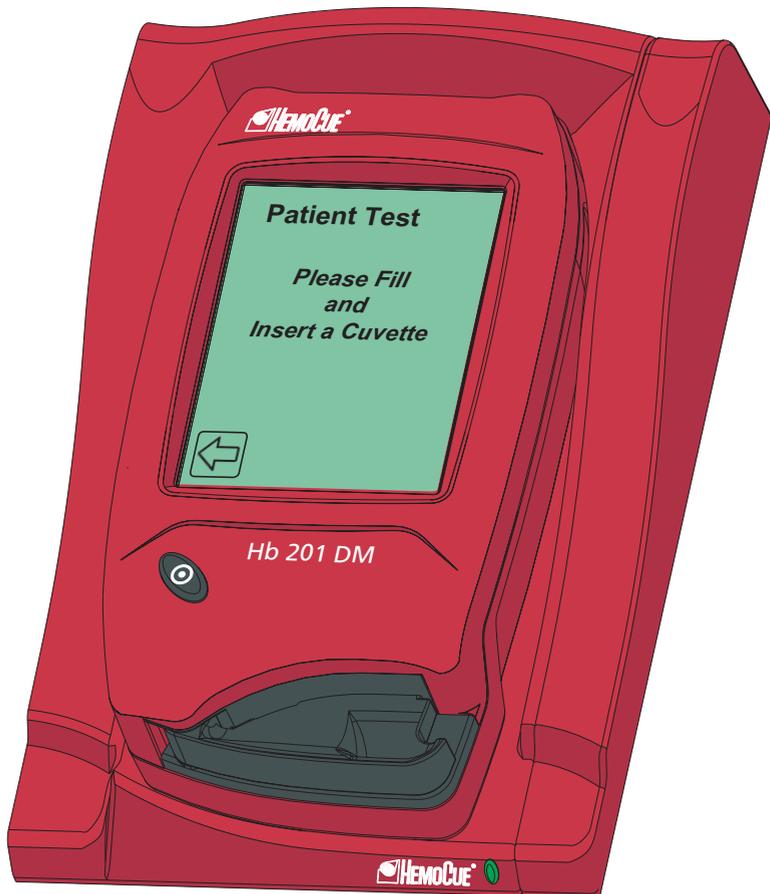
4.7 Docking Station Settings

The settings of a Docking Station consist of network parameters necessary to enable communication with a LAN, such as the IP address of the Docking Station. Settings can only be made on Primary Docking Stations, not on Secondary, see *Primary and Secondary Docking Stations*.

The setting of a Docking Station is made from the DMS Software application. In order to perform the settings, the Docking Station must be connected to the PC hosting the DMS Software, see section *10.2 Docking station setup*.

PART III

Routine use



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5 Blood specimen collection

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

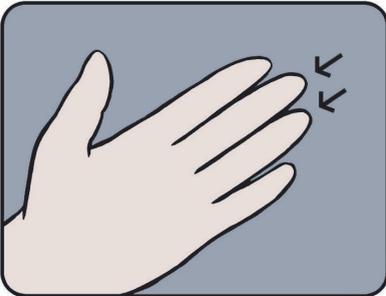
5.1 Capillary blood

Before obtaining a blood sample, the Analyzer should be in the “Ready” mode. To perform a Patient test, see section 6 *Patient Test procedure*. To perform a STAT test, see section 7 *STAT Test procedure*.

FIGURE 5-1

- 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)



(Continues)

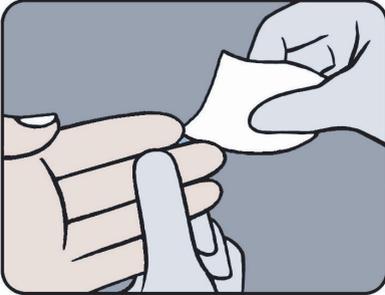


FIGURE 5-2

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



FIGURE 5-3

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.

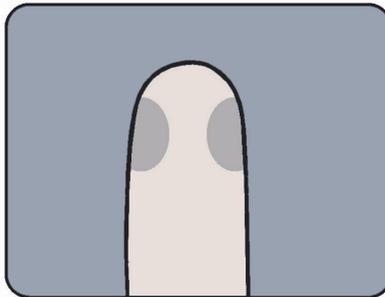


FIGURE 5-4

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

(Continues)

(Continues)



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

FIGURE 5-5

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

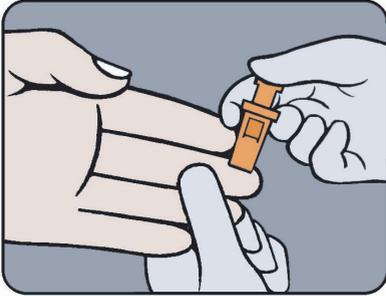
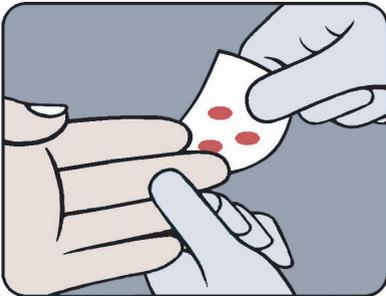


FIGURE 5-6

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

Note! Do not use cotton balls.

(Continues)



(Continues)

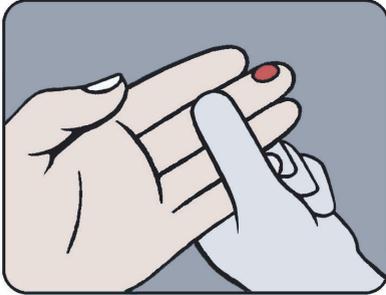


FIGURE 5-7

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

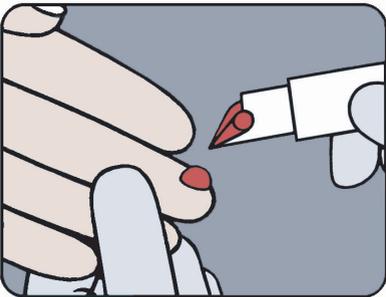


FIGURE 5-8

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

Note! Do not refill!

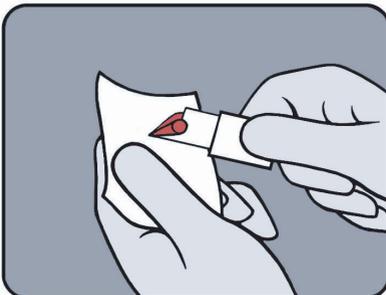


FIGURE 5-9

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.

(Continues)

(Continues)

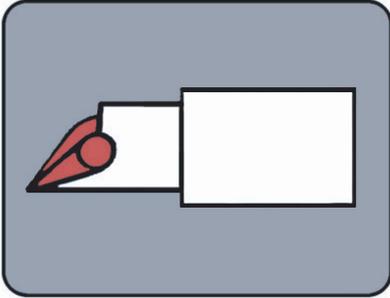


FIGURE 5-10

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.

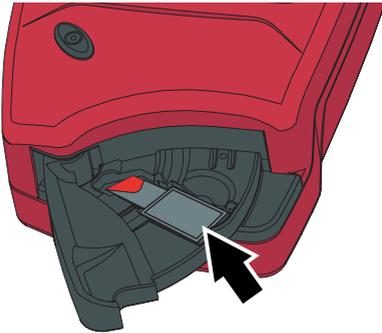


FIGURE 5-11

k) Place the filled Cuvette in the Cuvette holder, see *FIGURE 5-11*.

(Continues)

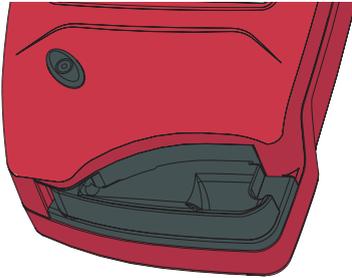


FIGURE 5-12

To perform a Patient test, see in section 6 *Patient Test procedure*. To perform a STAT test, see section 7 *STAT Test procedure*.

- 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 to 45 seconds, the result will be displayed. See an example of the display appearance in 6.1.1 *Patient Test Result*.

The result will remain on the display until the Confirm button has been pressed, see *FIGURE 6-9* in 6.1.1 *Patient Test Result*.

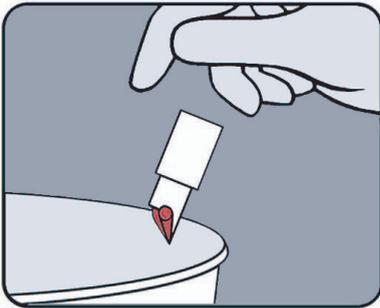


FIGURE 5-13

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

5.2 Venous and Arterial Blood

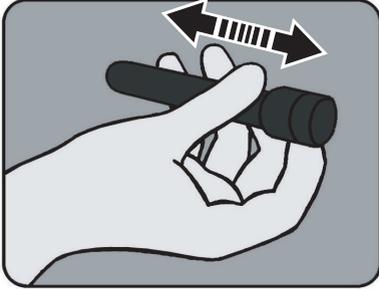


FIGURE 5-14

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

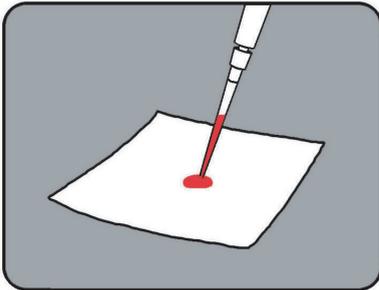


FIGURE 5-15

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

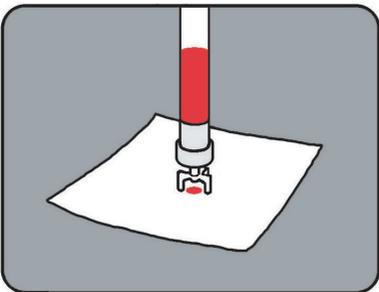


FIGURE 5-16

A suitable blood transfer device can also be used.

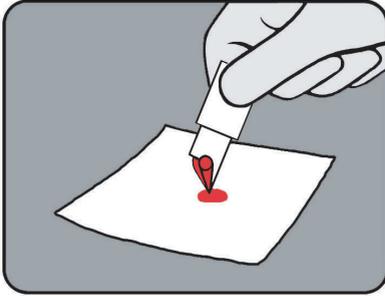


FIGURE 5-17

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.

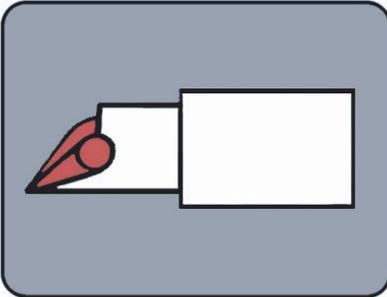


FIGURE 5-18

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 5-11*, *FIGURE 5-12* and *FIGURE 5-13* in section 5.1 *Capillary blood*.

6 Patient Test procedure

This chapter guides you through the process of performing a Patient Test.

6.1 Patient Test

The Patient Test procedure may vary, depending on which information requirements have been activated in the Settings, see section 4.4.2 *Patient Test Settings*. The following information may be required:

- Cuvette Batch No.
- Patient ID
- Lab ID

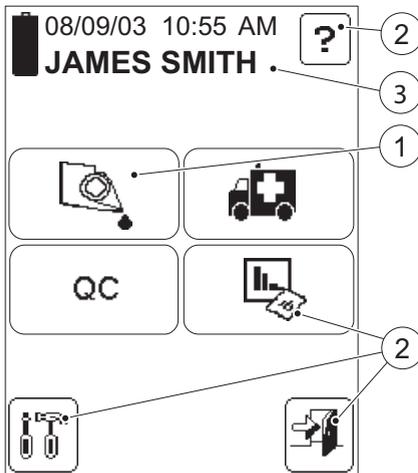


FIGURE 6-1

Note! If a Cuvette is inserted without any button being pressed, the Analyzer will enter the Patient Test procedure, and FIGURE 6-3 will be displayed.

a) In the Main Menu, press the Patient Test button (1).

Note! If the small hourglass is displayed only the buttons (2) can be used.

b) FIGURE 6-2 will be displayed.

- 1 Patient Test button
- 2 See Note! above.
- 3 Operator name, Operator ID or blank, depending on the settings

(Continues)

(Continues)



FIGURE 6-2

- c) Obtain a blood sample according to the procedure described in section 5 *Blood specimen collection*.
- d) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
FIGURE 6-3 will be displayed.

(Continues)

(Continues)

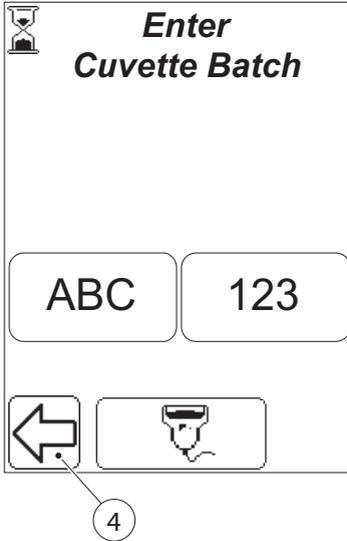


FIGURE 6-3

Note! FIGURE 6-3 will not be displayed if the Cuvette Batch No. requirement is set to “Not Used” in the Settings (see 4.4.1 *General Settings*).

- e) Enter Cuvette Batch No. either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

Note! If Cuvette Batch No. requirement is set to *Entry required* (see 4.4.1 *General Settings*), and a Cuvette Batch No. that has not previously been stored in the Analyzer (see 4.2.2 *Cuvette Batches*) is entered, **or** the Cuvette Batch is expired, the following text will be displayed:

Invalid Cuvette Batch.

If the Previous image button (4) is pressed, the Main Menu will be displayed (see 3.6.3 *Main Menu and On-line Help*).

- f) If Cuvette Batch No. requirement is set to *Entry required* (see 4.4.1 *General Settings*), and the Cuvette Batch No. is entered via the Barcode Scanner using the barcode from the Cuvette vial, the expiration date is automatically entered, and FIGURE 6-5 will be displayed. Otherwise FIGURE 6-4 will be displayed.

4 Previous image button

(Continues)

(Continues)

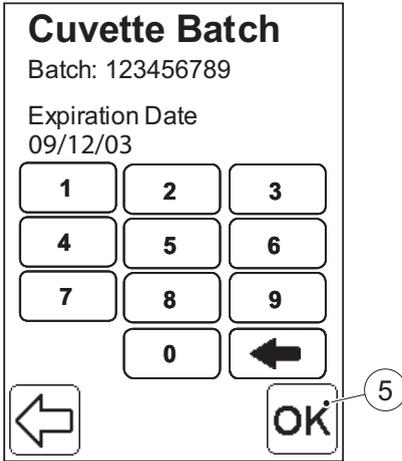


FIGURE 6-4

Note! Will only be displayed if the Cuvette Batch No. requirement when inserting a cuvette is set to “Entry required” (see 4.4.1 *General Settings*), and Cuvette Batch No. was not entered via the Barcode Scanner using the barcode from Cuvette vial

- g) Enter the Expiration Date for the Cuvette Batch via the Numeric mode buttons.
- h) Press the Confirm button (5).

5 Confirm button

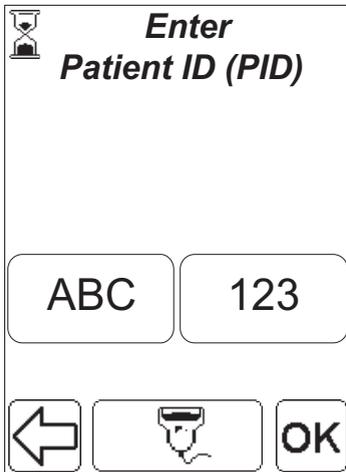


FIGURE 6-5

Note! Will not be displayed if the Patient ID requirement is set to “Not Used” (see 4.4.2 *Patient Test Settings*).

- i) Enter the Patient ID (PID) via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

(Continues)

(Continues)

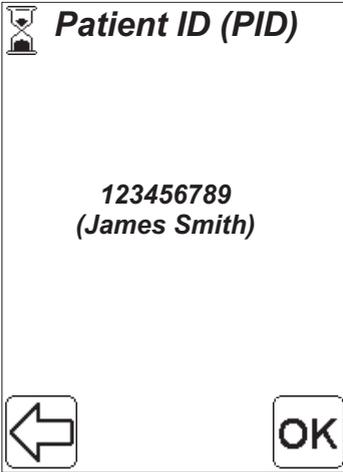


FIGURE 6-6

Note! Will not be displayed if the Patient List setting is set to “Not Used” (see 4.4.1 *General Settings*), or the Patient ID requirement is set to “Not Used”.

If the Patient List setting is set to “Used” and there is a Patient List on the Analyzer that contains the Patient ID and corresponding Patient Name, this display will show the Patient ID and corresponding Patient Name as a means of positive patient identification. If the Patient List doesn’t contain a Patient Name corresponding to the entered Patient ID, then the text (**Unknown Patient Name**) will be displayed.

- j) Press OK to continue or the back arrow to go back and re-enter the Patient ID.

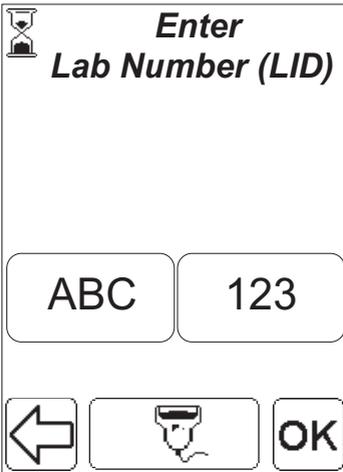


FIGURE 6-7

Note! Will not be displayed if the Lab ID requirement is set to “Not Used” (see 4.4.2 *Patient Test Settings*).

- k) Enter the Lab Number (LID) either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

(Continues)

(Continues)

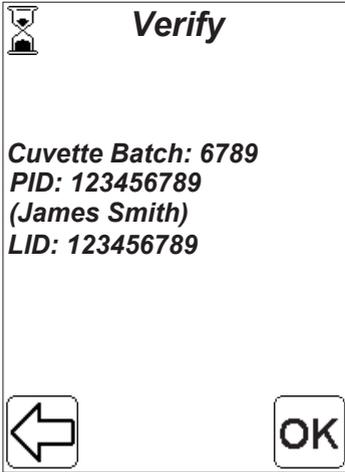


FIGURE 6-8

- l) A display will be shown where it is possible to verify all entered information. If some of the entered information is wrong, press the back arrow to go back and re-enter the information, otherwise press OK to continue.
- m) The following text will be displayed:
Please Wait Measuring ...
if the measurement has not been completed.
- n) The result is presented. For an example of the display appearance, see *FIGURE 6-9*.

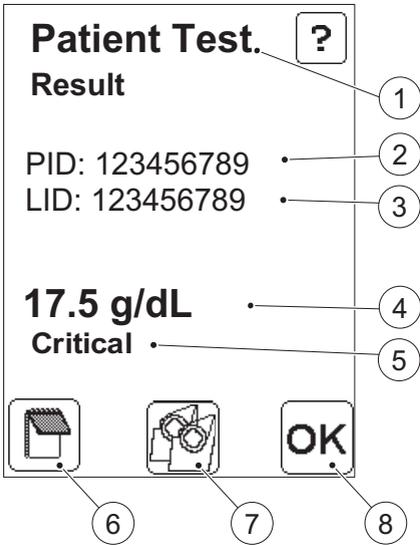
6.1.1 Patient Test Result

FIGURE 6-9

Position numbers (1) to (3) are explained in the position list below.

The Result (4) is presented in **bold** print.

The Note (5) *Critical* will be displayed if the result is outside the critical limits that are defined in the Settings (see 4.4.2 *Patient Test Settings*).



-
- 1 Type of test
 - 2 Patient ID
 - 3 Lab Number ID
 - 4 Result
 - 5 Critical Note
 - 6 Comment input button
 - 7 Verify button
 - 8 Confirm button

(Continues)

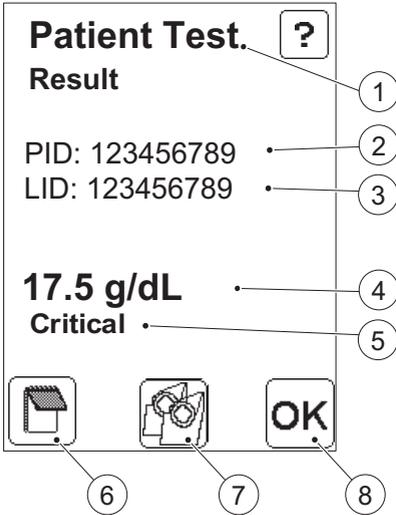
(Continues)

FIGURE 6-10

To add comments to the result press, the Comment input button (6). See 6.1.3 *Entering Comments*.

The Verify button (7) allows the verification of the result by measuring a new sample from the patient (see 6.1.2 *Verify*).

Note! Do not press the Confirm button (8) in this screen if the result is to be verified.

a) Press the Confirm button (8) to store the information.

The Main Menu, *FIGURE 6-1* will be displayed.

Note! 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.

-
- 1 Type of test
 - 2 Patient ID
 - 3 Lab Number ID
 - 4 Result
 - 5 Critical Note
 - 6 Comment input button
 - 7 Verify button
 - 8 Confirm button

6.1.2 Verify

FIGURE 6-11

Results may be verified by obtaining a second sample from the same patient and performing a new measurement.

- a) When the first result is displayed, press the Verify button (1). *FIGURE 6-12* will be displayed.

1 Verify button

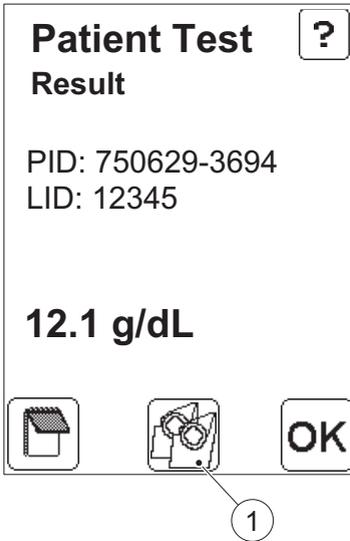
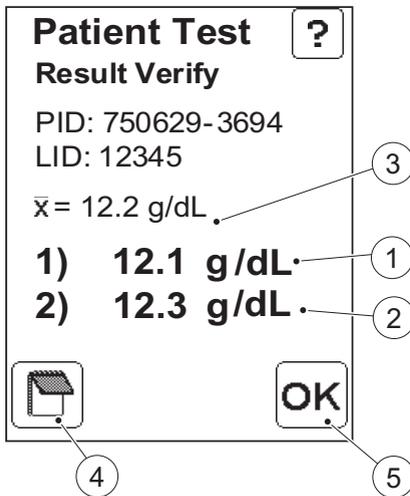


FIGURE 6-12

- b) Accept the information for the new measurement by pressing the Confirm button (2).
- c) The following text will be displayed: **Please Fill and Insert a Cuvette.**
- d) When the new Cuvette is inserted and the measurement is in progress, the following text will be displayed: **Please Wait Measuring ...**
- e) Upon completion of the measurement, the result is displayed, see *FIGURE 6-13*.

2 Confirm button





Result Verification

FIGURE 6-13

1) indicates the result from the first measurement (1).

2) indicates the result from the second measurement (2).

\bar{x} indicates the Mean value (3) for these two measurements.

The Comment input button (4) indicates that there are no comments added to the result.

To add comments, press the Comment input button (4), see *6.1.4 Entering Comments – Verified sample*.

a) Press the Confirm button (5) to store the information.

The Main Menu, *FIGURE 6-1* will be displayed.

Note! 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.

-
- 1 Result from first measurement
 - 2 Result from second measurement
 - 3 Mean value
 - 4 Comment input button
 - 5 Confirm button

6.1.3 Entering Comments

FIGURE 6-14

Comments may be entered prior to saving the result.

- a) When the result is displayed, press the Comment input button (1).
FIGURE 6-15 will be displayed.

1 Comment input button

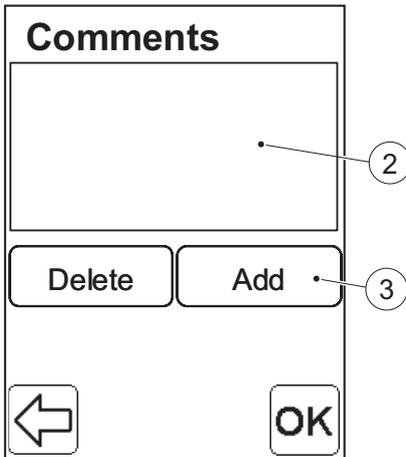


FIGURE 6-15

The Comment list (2) is empty prior to the addition of any comments.

- b) To add a comment, press the Add button (3).
FIGURE 6-16 will be displayed.

2 Result Comment list
3 Add button



(Continues)

(Continues)

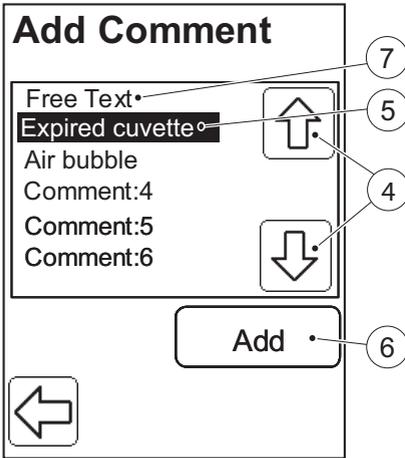


FIGURE 6-16

Note! This list will be empty if no comments have been pre-defined in the Settings menu, see 4.2.4 *Define Comments*.

- c) Press the Scroll bar arrows (4) to select a Comment (5). In this example: *EXPIRED CUVETTE*.
- d) Press the Add button (6). *FIGURE 6-17* will be displayed.

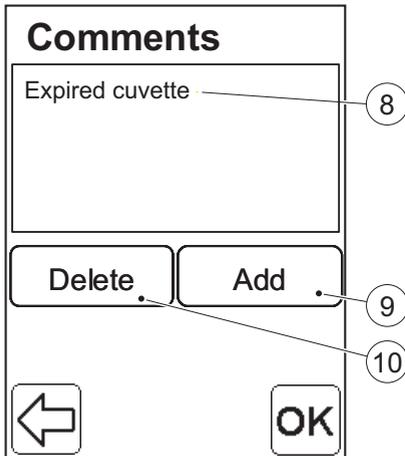
Note! If information is to be added as text and numbers or via the Barcode Scanner, press the Free text button (7).

- 4 Scroll bar arrows
- 5 Selected comment
- 6 Add button
- 7 Free text button

FIGURE 6-17

The added comment is displayed in the Comment list (8).

- e) If more comments are to be added, press the Add button (9) again and repeat the procedure according to *FIGURE 6-16*.
- f) If comments are to be deleted, press the Delete button (10). *FIGURE 6-18* will be displayed.



- 8 Result Comment list
- 9 Add button
- 10 Delete button

(Continues)

(Continues)

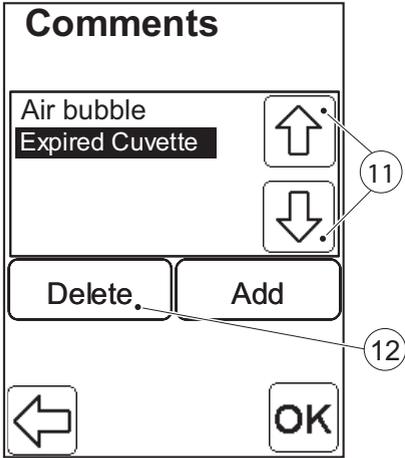


FIGURE 6-18

All added comments are displayed. In this example, *Air bubble* and *Expired Cuvette* are displayed.

g) Press the Scroll bar arrows (11) to select a Comment, in this example *Expired Cuvette*.

h) Press the Delete button (12)

11 Scroll bar arrows

12 Delete button

(Continues)

(Continues)

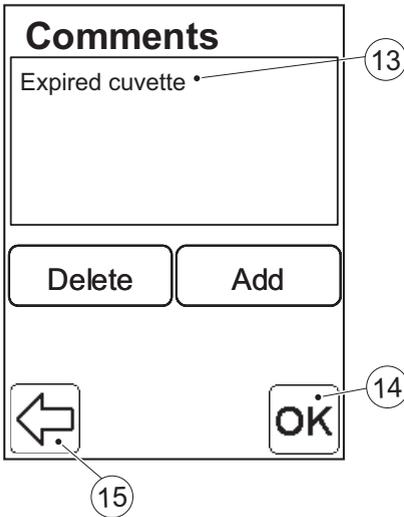


FIGURE 6-19

i) When all comments that are to be added are displayed in the Comment list (13), press the Confirm button (14).

Note! If the Previous image button (15) is pressed, this text will be displayed:

If you continue no comment changes will be saved. Continue?

If *Continue* is pressed again all changes entered in the Comment list (13) will be lost.

Note! If an attempt is made to add more than four comments to the result, the following text will be displayed:

Maximum four Comments are allowed.

j) FIGURE 6-20 will be displayed.

13 Result Comment list

14 Confirm button

15 Previous image button

(Continues)

(Continues)

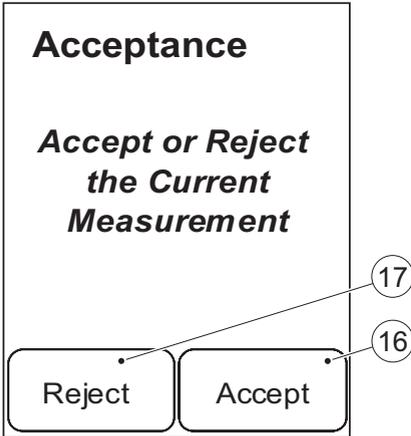


FIGURE 6-20

k) The result may now be accepted or rejected, by means of the Accept button (16) or Reject button (17) respectively.

Note! Both accepted and rejected results will be stored.

l) If the Reject button (17) is pressed without any comments being added, this text will be displayed:

To Reject a Sample, Enter at least one Comment.

-
- 16 Accept button
 - 17 Reject button

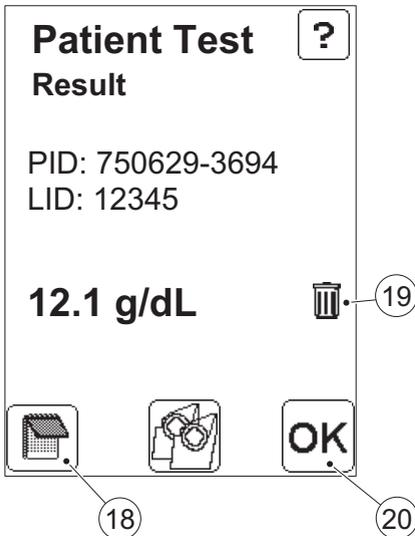


FIGURE 6-21

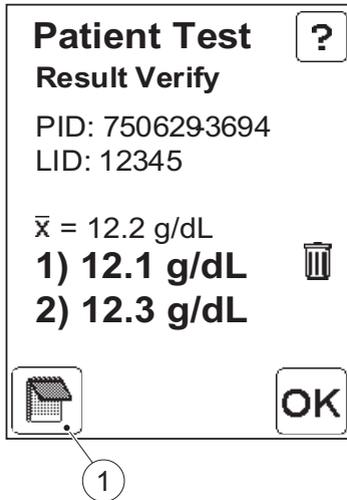
The dotted Comment input button (18) indicates that there are comments added to the result.

The Waste bin (19) indicates that the result has been rejected (see FIGURE 6-20).

m) Press the Confirm button (20).

The Main menu, FIGURE 6-1 will be displayed.

-
- 18 Comment input button
 - 19 Indicator for rejected test result
 - 20 Confirm button



6.1.4 Entering Comments – Verified sample

FIGURE 6-22

Comments may be added to the results of verified samples before saving.

- a) When the results are presented, press the Comment input button (1).
- b) This text will be displayed:
Comment Cuvette Number 1.
- c) To add comments to the result from the first cuvette, follow the same procedure as in 6.1.3 *Entering Comments*, FIGURE 6-15 to FIGURE 6-19.
- d) When the comments for the first Cuvette are made, this text will be displayed:
Comment Cuvette Number 2.
- e) To add comments to the result from the second cuvette, follow the same procedure as in 6.1.3 *Entering Comments*, FIGURE 6-15 to FIGURE 6-19.
- f) FIGURE 6-23 will be displayed.

1 Comment input button

(Continues)

(Continues)

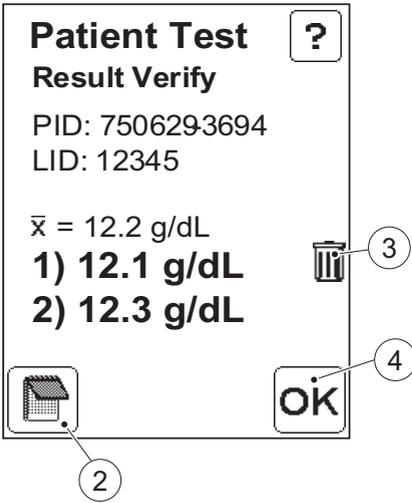


FIGURE 6-23

The dotted Comment input button (2) indicates that comments have been added.

In this example the Waste bin (3) indicates that the result for the first Cuvette has been rejected.

g) Press the Confirm button (4).
The Main menu, *FIGURE 6-1*, will be displayed.

-
- 2 Comment input button
 - 3 Indicator for rejected test result
 - 4 Confirm button

7 STAT Test procedure

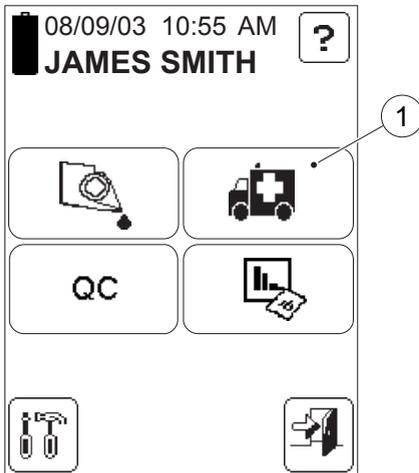
This chapter guides you through the process of performing a STAT Test. The STAT Test fulfils the same function as a Patient Test but a predefined number of STAT tests can be performed by overriding the requirement of performing any type of QC Test. When performing a STAT Test, it is optional whether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

7.1 STAT Test

Note! STAT tests are only available if enabled during the configuration of the Analyzer settings (see 4.4.2 Patient Test Settings).

FIGURE 7-1

- a) In the Main Menu, press the STAT Test button (1) to enter the STAT Test procedure. *FIGURE 7-2* will be displayed.



- 1 STAT Test button

(Continues)

(Continues)

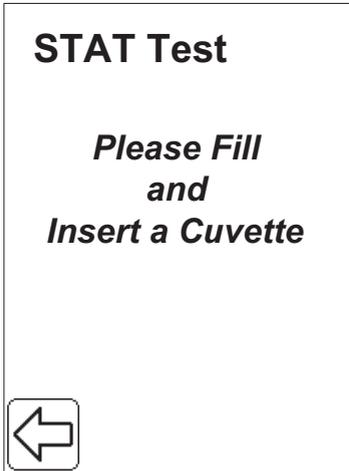


FIGURE 7-2

- b) Obtain a blood sample according to the procedure described in section 5 *Blood specimen collection*.
- c) Fill a Cuvette and place it in the Cuvette holder and gently insert it into the measuring position.
- d) Enter the information for the 3 following images:
 - Enter Cuvette Batch**
 - Enter Patient ID (PID)**
 - Enter Lab Number (LID)**(see section 6 Patient Test procedure) or just press the Confirm button if no data is to be added.

Note! The three images above will not be displayed if the Cuvette Batch No. requirement (see 4.4.1 *General Settings*), the Patient ID requirement (see 4.4.2 *Patient Test Settings*) and the Lab ID requirement (see 4.4.2 *Patient Test Settings*) are set to “Not Used”.

7.1.1 STAT Test Result

FIGURE 7-3

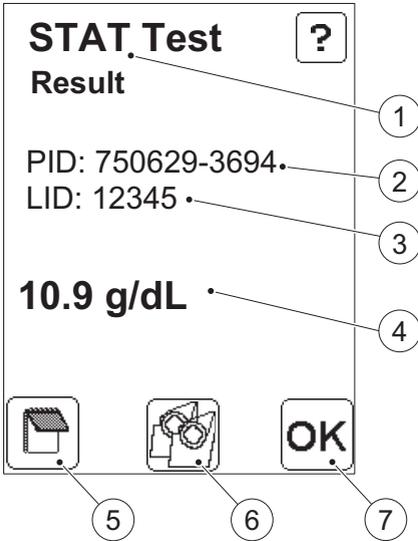
The result (4) is presented in **bold** print.

To add a comment to the result, press the Comment input button (5). The procedure is the same as for a Patient Test, see 6.1.3 *Entering Comments*.

The Verify button (6) allows the verification of the result by measuring a new sample from the same patient. The procedure is the same as for a Patient Test, see 6.1.2 *Verify*.

a) Press the Confirm button (7) to store the information.

Note! The result will remain on the display even if the Cuvette holder is pulled out, allowing for the examination of the Cuvette before comments are made.



-
- 1 Type of test
 - 2 Patient ID
 - 3 Lab Number ID
 - 4 Result
 - 5 Comment input button
 - 6 Verify button
 - 7 Confirm button

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8 QC Test procedure

This chapter describes the process of performing QC Tests, Linearity Tests and Proficiency Tests

8.1 Events necessitating QC Tests

8.1.1 QC Reminder

Based on the settings made for the QC Test Reminder, the Reminder icon (1) will be displayed to warn of an impending QC lockout.

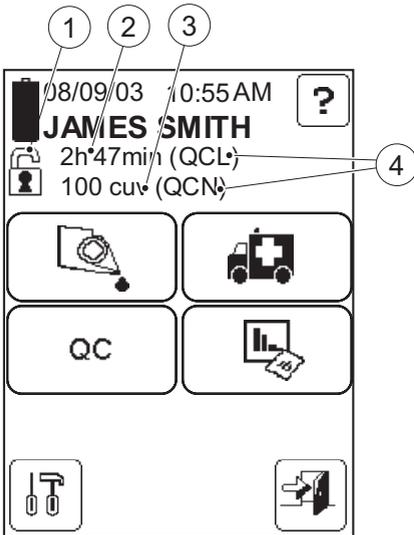
FIGURE 8-1

The QC Reminder (1) indicates Time (2) or Number of measurements (3) remaining before the QC Lockout.

Note! The number of measurements remaining refer only to Patient Tests and STAT tests.

The text inside the brackets indicates the types of QC Tests (4) that must be performed in order to avoid a QC lockout.

- QCL = QC Test Low
- QCN = QC Test Normal
- QCH = QC Test High
- QCO = QC Test Other Level



- 1 QC Reminder
- 2 Time remaining before QC Lockout
- 3 Number of measurements remaining before QC Lockout
- 4 Type of QC Test required

(Continues)

(Continues)

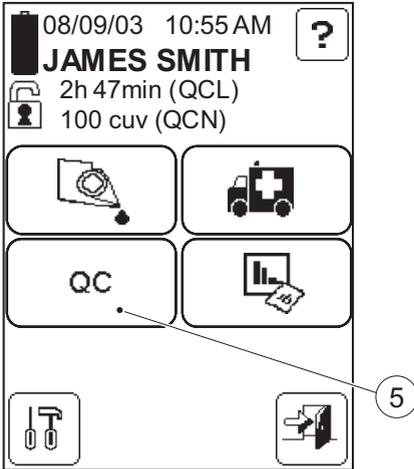


FIGURE 8-2

If the required QC Test is performed after the reminder is displayed, but before the QC lockout, the time/measurement counter is reset to the max. time/number of measurements until the next QC lockout.

a) To enter the QC Test procedure, press the QC Test button (5).

FIGURE 8-6 will be displayed.

5 QC Test button

8.1.2 QC Lockout

If the required QC Test is not performed within the time or number of measurements indicated by the QC Reminder, *FIGURE 8-1*, the Analyzer will perform a QC lockout. *FIGURE 8-3* will be displayed.

FIGURE 8-3

The QC Lockout (1) indicates that the Analyzer has performed a QC lockout.

Note! Patient Tests are not allowed when the Analyzer has performed a QC lockout.

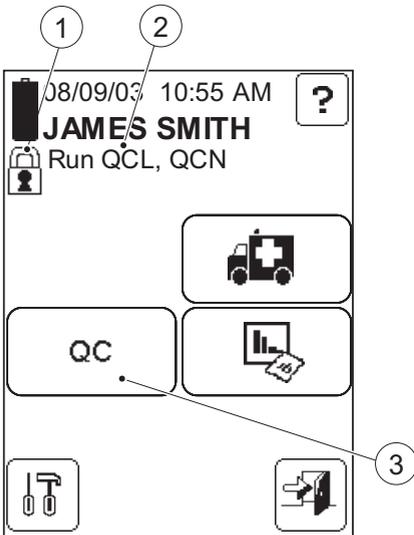
Note! Linearity and Proficiency Tests are not allowed when the Analyzer has performed a QC lockout.

Note! STAT Tests are not allowed when the Analyzer has performed a QC lockout if usage of STAT Tests is set to “Not Used” (see 4.4.2 *Patient Test Settings*) or if the number of STAT Tests performed has reached the max. limit allowed.

The Information text (2) indicates the types of QC Tests required to unlock the QC Lockout.

a) To enter the QC Test procedure, press the QC Test button (3).

FIGURE 8-6 will be displayed.

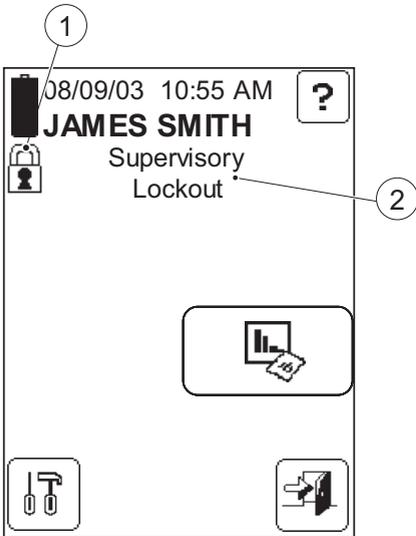


-
- 1 QC Lockout
 - 2 Information text
 - 3 QC Test button

8.1.3 Supervisory Lockout

FIGURE 8-4

The Analyzer has been locked out by the Supervisor. This can only be performed via the DMS Software or an Observation Reviewer (OR). The Analyzer can only be unlocked by the Supervisor via the DMS Software or an OR.



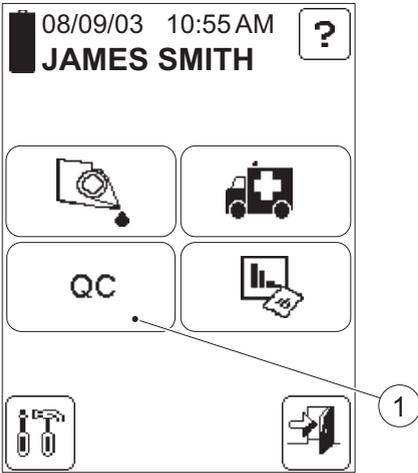
- 1 QC Lockout
- 2 Supervisory Lockout Text

8.2 Performing a QC Test

FIGURE 8-5

a) In the Main Menu, press the QC Test button (1).

FIGURE 8-6 will be displayed.



-
- 1 QC Test button

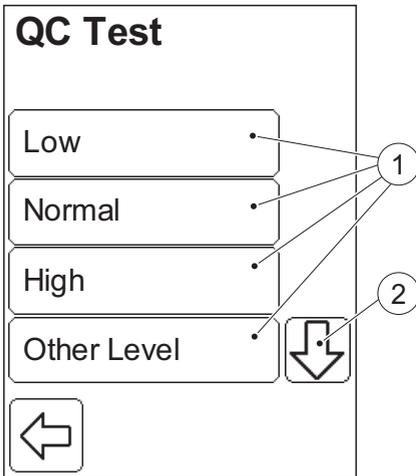


FIGURE 8-6

There are 6 QC Test options (1):

- Low (See 8.2.1 *QC Tests at a specific concentration level*)
- Normal
- High
- Other Level
- Linearity (See 8.2.2 *Linearity Test*)
- Proficiency (See 8.2.3 *Proficiency Test*)

a) View options (1) not initially visible by pressing the Scroll bar arrow (2).

b) Select a QC Test option by pressing it.

Note! Low, Normal, High and Other Level, refer to the different concentration levels of Liquid Controls used in QC tests. The procedure for performing a QC test is the same for all the concentration levels. Therefore only one, Low, is described.

1 QC Test options

2 Scroll bar arrow

8.2.1 QC Tests at a specific concentration level

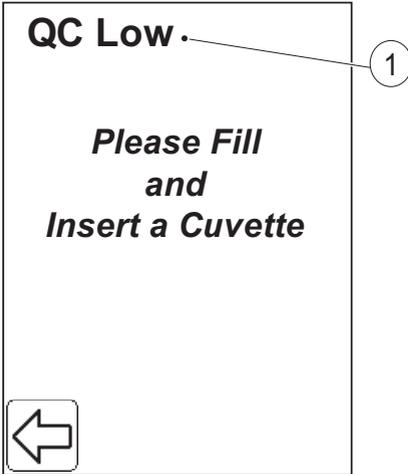
FIGURE 8-7

Note! The QC Tests procedure for Low, Normal, High and Other Level are identical, and therefore only one, Low, is described.

The concentration level of the QC Test (1) is displayed.

- a) Fill a Cuvette with the appropriate level of Liquid Control (1).
- b) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.

FIGURE 8-8 will be displayed.



1 Concentration level of QC Test

(Continues)

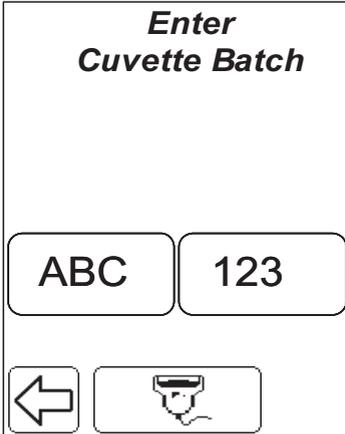
(Continues)

FIGURE 8-8

- c) Enter the Cuvette Batch No. either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

FIGURE 8-9 will be displayed.

Note! If the Cuvette Batch No. requirement is set to *Approved only* (see 4.4.1 *General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see 4.2.2 *Cuvette Batches*) is entered, **or** the Cuvette Batch has expired, the following text will be displayed:

Invalid Cuvette Batch.

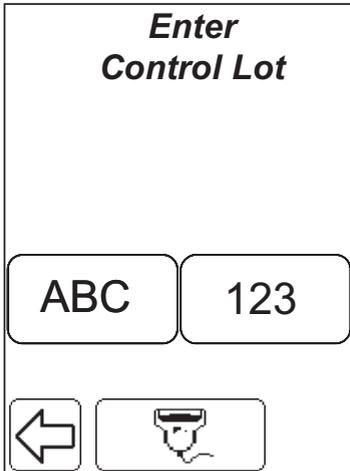
FIGURE 8-9

- d) Enter the Lot No. for the Liquid Control used, either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

FIGURE 8-10 will be displayed.

Note! If a Liquid Control Lot has not previously been stored in the Analyzer (see 4.2.1 *Liquid Controls*) and/or has expired, the following text will be displayed:

Invalid Control Lot.

*(Continues)*

(Continues)

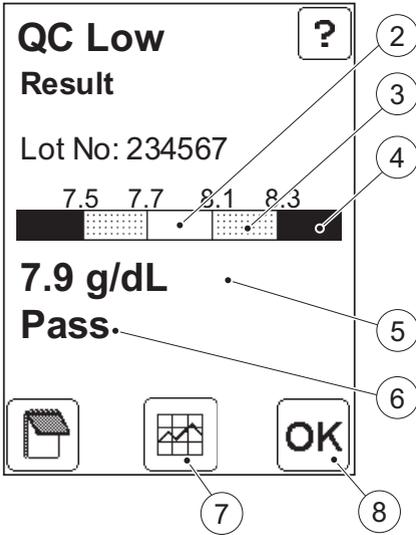


FIGURE 8-10

The Numeric Test Result (5) and the Qualitative Test Result (6) are displayed in bold text.

For a result within the Approved area (2) (the blank area), the Qualitative Test Result (6) will indicate “Pass”.

For a result within the Warning area (3) (the dotted area), the Qualitative Test Result (6) will indicate “Pass, Warning”.

For a result within the Fail area (4) (the solid area), or for two consecutive results within the Warning area (3), the Qualitative Test Result will (6) indicate “Fail”.

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

e) To view a graphic presentation of the most recent QC Tests, press the Statistics button (7).

FIGURE 8-12 will be displayed.

f) Press the Confirm button (8). FIGURE 8-6 or FIGURE 8-11 will be displayed.

-
- 2 Approved area
 - 3 Warning area
 - 4 Fail area
 - 5 Numeric Test Result
 - 6 Qualitative Test Result
 - 7 Statistics button
 - 8 Confirm button

(Continues)

(Continues)



FIGURE 8-11

g) If the Failed QC Comment setting is set to “Entry Required” (see 4.4.3 *QC Test Settings*) and the QC Test has failed, then *FIGURE 8-11* will be displayed when the Confirm button shown in *FIGURE 8-10* is pressed. Use the Previous Image button (1) to go back and add at least one comment.

9 Previous Image button

(Continues)

(Continues)

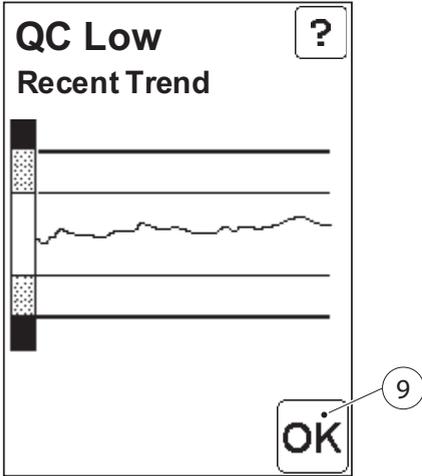


FIGURE 8-12

The diagram shows the trend for the most recent QC measurements performed on the control lot.

h) To continue to the statistics image, *FIGURE 8-13*, press the Confirm button (9).

10 Confirm button

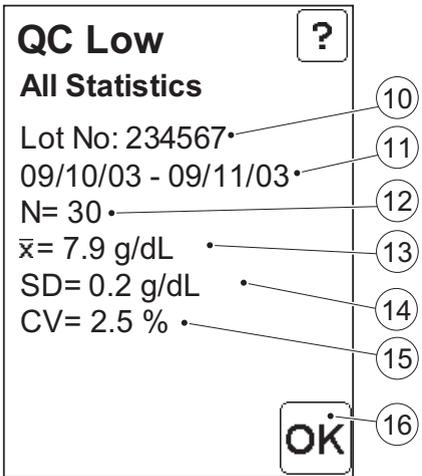


FIGURE 8-13

The All Statistics report shows statistical data for all QC Tests for the level of control and Lot No. displayed.

i) Press the Confirm button (16). *FIGURE 8-10* will be displayed.

-
- 11 Lot No. of Liquid Control used in QC tests
 - 12 Date interval of test results
 - 13 No. of test results on which statistics are based
 - 14 Mean value
 - 15 Standard Deviation
 - 16 Coefficient of Variation
 - 17 Confirm button

8.2.2 Linearity Test

A linearity test consists of replicate testing of different concentrations of the desired analyte within the measuring range of the Analyzer. The purpose of the test is to make sure that the relationship between the analyte concentration and the system output is linear.

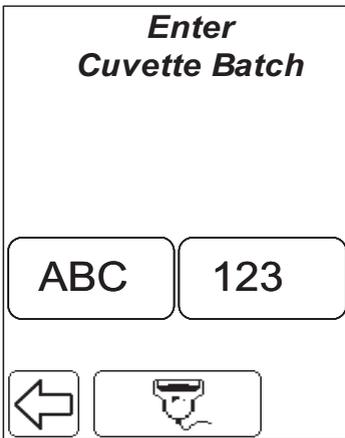


FIGURE 8-14

- a) To perform a Linearity Test, press the linearity button in the QC test options display, see FIGURE 8-6 .
- b) Enter the Cuvette Batch No. of the cuvettes to be used, either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

Note! If the Cuvette Batch No. requirement is set to *Approved only* (see 4.4.1 *General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see 4.2.2 *Cuvette Batches*) is entered, **or** the Cuvette Batch has expired, the following text will be displayed:

Invalid Cuvette Batch.

- c) If the linearity test is interrupted and then resumed within 10 hours by the same operator, using the same Cuvette Batch No. FIGURE 8-15 will be displayed. Otherwise FIGURE 8-16 will be displayed.

(Continues)

(Continues)

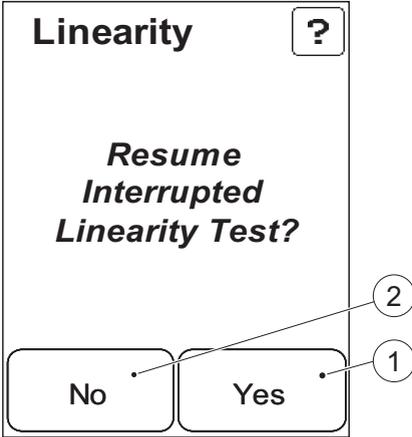


FIGURE 8-15

d) To resume a previously interrupted linearity test, press Yes.

FIGURE 8-17 will be displayed
Otherwise press No.

FIGURE 8-14 will be displayed.

-
- 1 Yes button
 - 2 No button

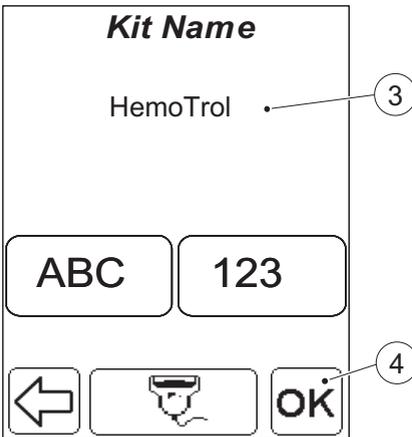


FIGURE 8-16

If a kit name was entered previously, it will be displayed (3).

e) If desired, change the kit name (3) either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

f) Press the Confirm button (4).
FIGURE 8-17 will be displayed.

-
- 3 Kit name
 - 4 Confirm button

(Continues)

(Continues)

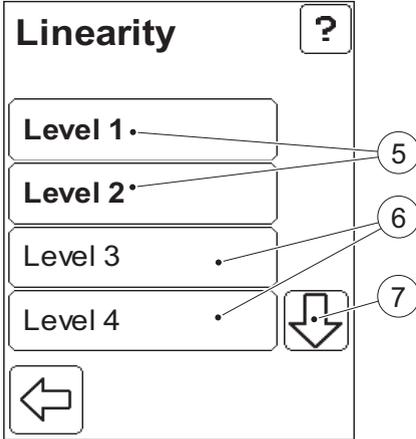


FIGURE 8-17

If there are any already completed levels within the linearity test, the buttons for these will have bold text (5).

Continue testing until all levels have been completed.

g) The levels not visible initially are available by pressing the Scroll bar arrow (7).

h) Select a level by pressing the button for it (6).

i) If testing for the selected level has been completed (5) the following will be displayed:

Chosen Level has been completed. Do You Wish to Retest this Level?

Press No to return to the current image or press Yes to continue to image *FIGURE 8-18*.

If testing for the selected level (6) is not complete, *FIGURE 8-18* is displayed.

5 Buttons for already completed levels

6 Buttons for non-completed levels

7 Scroll bar arrow

(Continues)

(Continues)

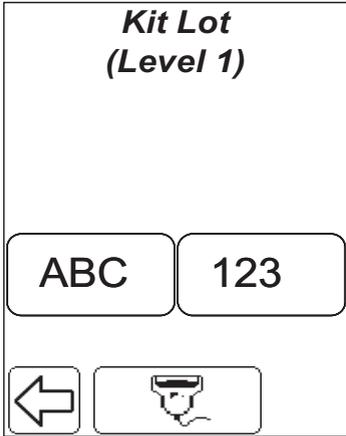


FIGURE 8-18

The Kit Lot is the Lot No. of the material used at the designated concentration level.

- j) Enter the Lot No. either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button. When finished, *FIGURE 8-19* will be displayed.

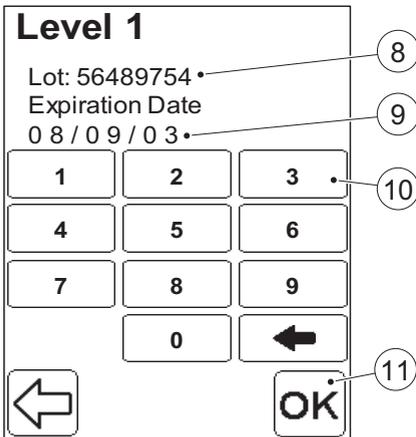


FIGURE 8-19

The Lot No. (8) is displayed.

- k) Enter the Expiration Date (9) for the current Lot via the Digit buttons (10).
- l) Press the Confirm button. *FIGURE 8-20* will be displayed.

- 8 Lot No.
- 9 Expiration Date
- 10 Digit button
- 11 Confirm button

(Continues)

(Continues)

Level 1

Unit:g/dL

Range Min (0 - 25.6) 5.0

Range Max (0 - 25.6) 6.0

1	2	3
4	5	6
7	8	9
.	0	←
←		OK

FIGURE 8-20

The level of the linearity material and its concentration unit are displayed.

If levels with known concentration ranges are used, the ranges should be entered.

Note! Numbers in brackets show the lowest and the highest allowable value.

If a range is not entered for the first level, only numerical values for each level tested will be displayed and no range can be entered for the remaining levels. If a range is entered for the first level, ranges must be entered for the remaining levels.

m) Enter the min. value for the concentration range (13) via the Digit buttons. Press the Confirm button (15).

n) Enter the max. value for the concentration range (14) via the Digit buttons. Press the Confirm button (15).

FIGURE 8-21 will be displayed.

-
- 12 Unit for concentration
 - 13 Concentration range, min. value
 - 14 Concentration range, max. value
 - 15 Confirm button

(Continues)

(Continues)

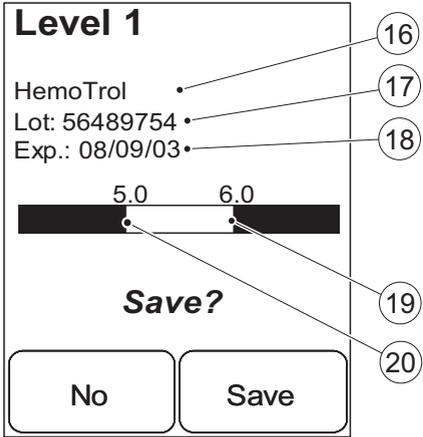


FIGURE 8-21

The previously entered values for the linearity material at the designated level are displayed for confirmation.

- o) To confirm the displayed values and to save them for future comparisons to the measured value, press Save. *FIGURE 8-22* will be displayed. Otherwise press No. *FIGURE 8-17* will be displayed.

-
- 16 Kit name
 - 17 Lot No.
 - 18 Expiration Date
 - 19 Concentration range, max. value
 - 20 Concentration range, min. value

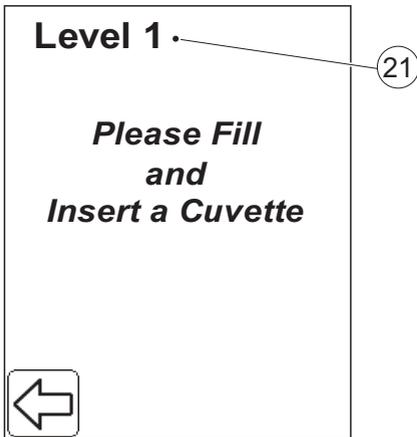


FIGURE 8-22

The level of linearity material to be tested (21) is shown on the display.

- p) Fill a Cuvette from the previously designated batch with the appropriate level of linearity material.
- q) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position. *FIGURE 8-23* will be displayed.

-
- 21 Concentration level of Linearity material
(Continues)

(Continues)

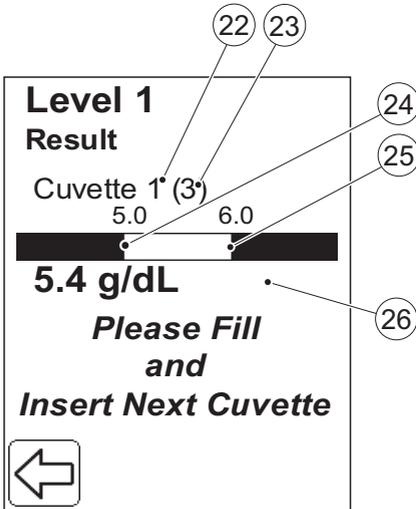


FIGURE 8-23

The result will be displayed.

Continue testing the designated level until the number of required measurements have been completed.

Note! If the result is beyond the upper measuring range of the Analyzer, the display will read:

Overrange

and a Confirm button will be shown.

If other errors occur, an error message and a Confirm button will be displayed.

When Confirm is pressed the following message will be displayed:

Error.

All Cuvettes for this Level will be Rejected.

When Confirm is pressed all measurements for the designated level are rejected but still kept in memory, and FIGURE 8-17 is displayed.

22 Measurement No.

23 Total No. of measurements required

24 Concentration range, min. value

25 Concentration range, max. value

26 Numeric test result

(Continues)

(Continues)

- r) If the result is within range and the Previous image button is pressed, the following message will be displayed:
Do You wish to Reject all Cuvettes Measured for this Level?
To reject all measurements at the current level press Yes. *FIGURE 8-17* will be displayed.
Press No to continue the Linearity test.

If *FIGURE 8-23* is displayed and the test is to be continued:

- s) Fill a Cuvette from the previously designated batch with the appropriate level of linearity material.
- t) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
If additional tests are required *FIGURE 8-23* will be displayed again.
If no additional tests are required, *FIGURE 8-24* will be displayed.

(Continues)

(Continues)

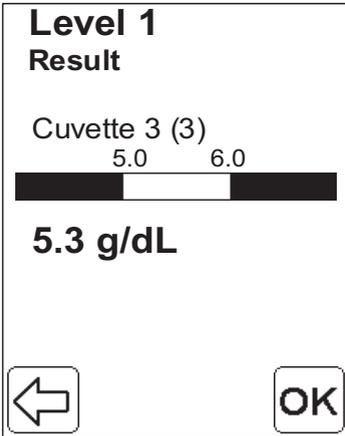


FIGURE 8-24

u) Press the Confirm button.

If other levels of the linearity material need to be measured *FIGURE 8-17* will be displayed.

If testing for all levels is completed, *FIGURE 8-25* will be displayed.

(Continues)

(Continues)

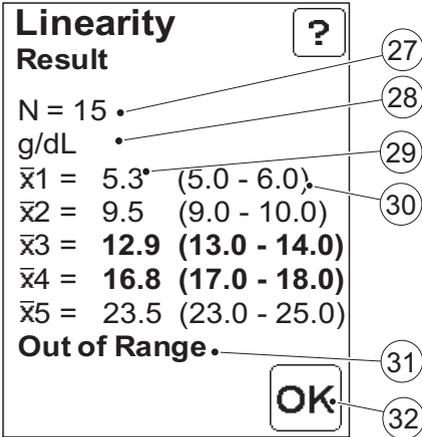


FIGURE 8-25

When all levels have been completed, an image containing all results is displayed.

If the mean result (29) for each level is within the concentration range (30) for the level, the Qualitative test result (31) will indicate “Within range”.

If the mean result (29) for any level is beyond the concentration range for the level (30), the result and the range limits will appear in bold, and the Qualitative test result (31) will indicate “Out of range”.

v) Press the Confirm button (32).

FIGURE 8-26 will be displayed.

-
- 27 Total No. of cuvettes used in the linearity test
 - 28 Unit for analyte concentration
 - 29 Mean result at the level
 - 30 Concentration min. and max. value at the level
 - 31 Qualitative Test Result
 - 32 Confirm button

(Continues)

(Continues)

Linearity [?]

Result

N = 15

Unit: g/dL

$\bar{x}_1 = 5.3$

$\bar{x}_2 = 9.5$

$\bar{x}_3 = 12.9$

$\bar{x}_4 = 15.8$

$\bar{x}_5 = 23.5$

[OK]

Callouts: (31) points to the question mark icon; (32) points to the unit 'g/dL'; (33) points to the mean values.

FIGURE 8-26

If no ranges are specified for the concentration levels (see *FIGURE 8-20*), only the mean results at each level (34) are listed and no range limits will be displayed. No Qualitative test result is given.

a) Press the Confirm button (35).

FIGURE 8-17 will be displayed.

33 Total No. of cuvettes used in the linearity test

34 Unit for analyte concentration

35 Mean result at the level

36 Confirm button

8.2.3 Proficiency Test

Proficiency testing is performed on samples from external sources. The expected value is unknown to the site performing the test. The purpose of the test is to ensure that the systems enrolled in the proficiency testing all have the same level of calibration.

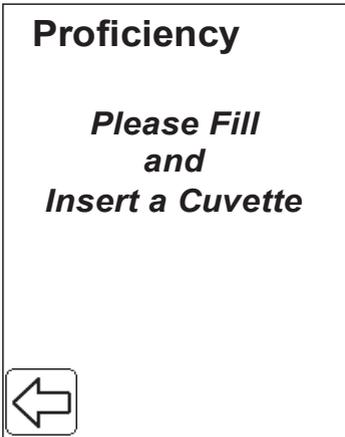


FIGURE 8-27

- a) To perform a Proficiency Test, press the Proficiency button in the QC test options display, see *FIGURE 8-6* .
- b) Fill a Cuvette with the proficiency sample.
- c) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.

FIGURE 8-28 will be displayed.

(Continues)

(Continues)

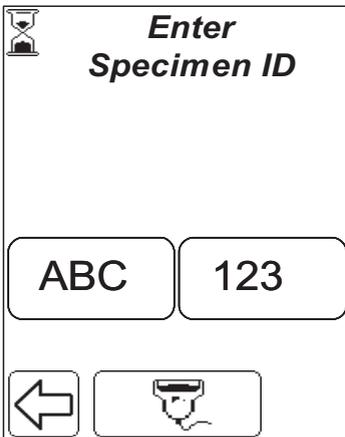
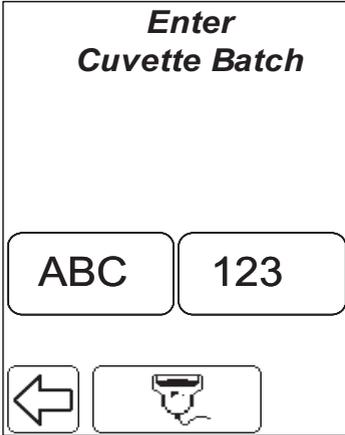


FIGURE 8-28

d) Enter the Cuvette Batch No. of the cuvette used, either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

FIGURE 8-29 will be displayed.

Note! If the Cuvette Batch No. requirement is set to *Approved only* (see 4.4.1 *General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see 4.2.2 *Cuvette Batches*) is entered, **or** the Cuvette Batch has expired, the following text will be displayed:

Invalid Cuvette Batch.

FIGURE 8-29

The Specimen ID is the ID of the proficiency sample.

e) Enter the Specimen ID either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.

When finished, *FIGURE 8-30* will be displayed.

(Continues)

(Continues)

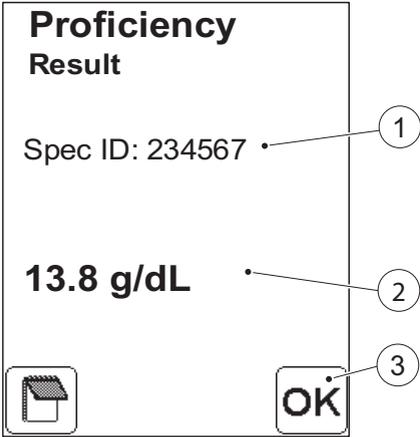


FIGURE 8-30

f) Press the Confirm button (4) to return to *FIGURE 8-27*.

-
- 1 Specimen ID
 - 2 Test Result
 - 3 Confirm button

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9 Reviewing stored data

This chapter describes the process of reviewing stored data.

9.1 Activating the Stored Data procedure

FIGURE 9-1

Note! Access to the Stored Data functions is dependent on the operator's user level and on the existing requirement for an Operator ID. Only a Supervisor can delete data, change an accepted or rejected result or add comments.

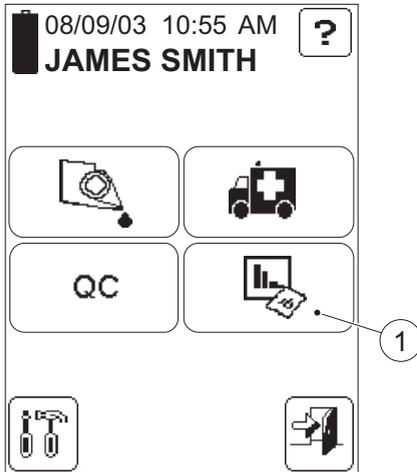
a) In the Main Menu, press the Stored Data button (1).

b) If the entry requirement for an Operator ID is set to "Not Used" (see *4 Settings*) FIGURE 9-2 will be displayed, as this is a password protected function.

Otherwise the Analyzer can respond in two different ways:

If the operator's user level does not permit access to the Stored Data (see *Figure 4-22*), FIGURE 9-3 will be displayed.

If the operator's user level permits access to the Stored Data, FIGURE 9-4 will be displayed.



1 Stored Data button

(Continues)

(Continues)

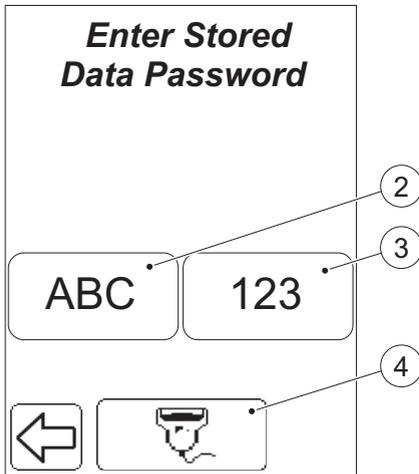


FIGURE 9-2

Note! Only displayed if the Operator ID requirement is set to “Not used” (see 4.4.1 *General Settings*).

- c) Enter the Password (default value is “0000”) for protected functions, either directly on the Display via the Text mode (2) and Numeric mode (3) buttons, or with the Barcode Scanner via the Barcode Scanner button (4).
- d) If the incorrect password is entered, *FIGURE 9-3* will be displayed. If the correct password is entered *FIGURE 9-4* will be displayed.

-
- 2 Text mode button
 - 3 Numeric mode button
 - 4 Barcode Scanner button

(Continues)

(Continues)

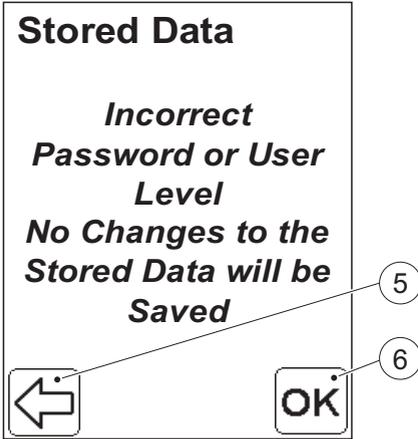


FIGURE 9-3

e) Pressing the Previous image button returns the user to *FIGURE 9-2* and allows entry of the correct password. By pressing the Confirm button Stored Data can be viewed, but not changed. *FIGURE 9-4* will be displayed.

Note! If the password is not correct, and the Confirm button is pressed, the user can make changes, but the changes will not be saved in the Analyzer.

-
- 5 Previous image button
 - 6 Confirm button

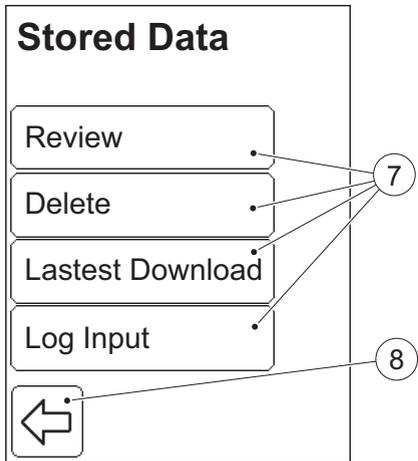


FIGURE 9-4

The following options are displayed:

- Review (see 9.2 *Review Stored Data*)
- Delete (see 9.3 *Delete Stored Data*)
- Latest Download (see 9.4 *Review Latest Download*)
- Log Input (see 9.5 *Log Input*)

The Stored Data options (7) are explained in the pages that follow.

f) Select an option by pressing it.
g) To return to the previous image, press the Previous image button (8).

-
- 7 Stored Data options
 - 8 Previous image button

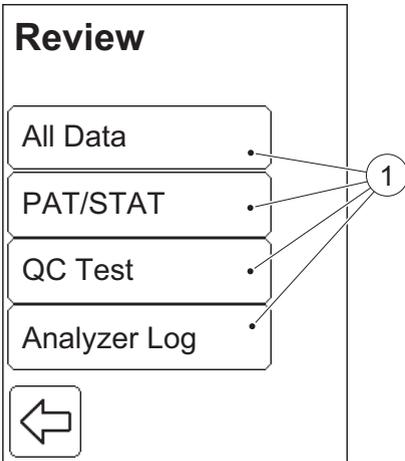
9.2 Review Stored Data

FIGURE 9-5

When the Review button is pressed in the Stored Data menu (see *FIGURE 9-4*), the following options are displayed:

- All Data (see 9.2.1 *Review All Data*)
- PAT/STAT (see 9.2.2 *Review PAT/STAT*)
- QC Test (see 9.2.3 *Review QC Tests*)
- Analyzer Log (see 9.2.4 *Review Analyzer Log*)

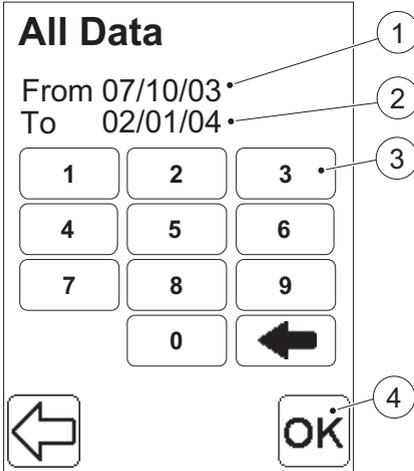
a) Select an option by pressing it.



1 Review option buttons

9.2.1 Review All Data

FIGURE 9-6



Press the All Data button in the Review menu, *FIGURE 9-5*.

The From date (1) and To date (2) displayed represent the earliest and latest stored records. It is possible to change the date interval. If no change is required, press the Confirm button (4). All stored data (Patient tests, STAT tests, QC tests and Analyzer Logs) will be available for review.

- a) If required, change the From date (1) via the Digit buttons (3). Press Confirm (4).
- b) Repeat the instruction "a)" to change the To date (2).

-
- 1 From date
 - 2 To date
 - 3 Digit button
 - 4 Confirm button

(Continues)

(Continues)

c) All stored data (Patient tests, STAT tests, QC tests and Analyzer Logs) within the date interval will be available for review. The latest record is displayed first. The different images possible are described in *FIGURE 9-8*, *FIGURE 9-12*, *FIGURE 9-15*, *FIGURE 9-17*, *FIGURE 9-19*.

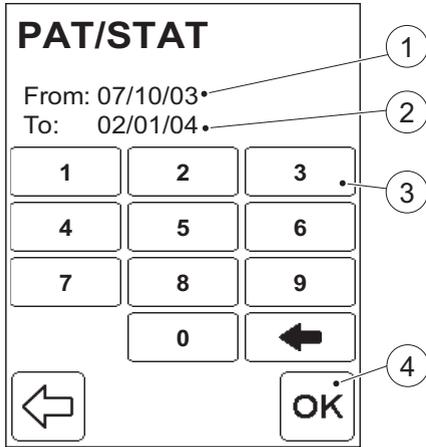
If no data within the date interval is found, the following message will be displayed:

No Records Found

Press the Previous image button to return to the All Data image, *FIGURE 9-6*.

9.2.2 Review PAT/STAT

FIGURE 9-7



Press the PAT/STAT button in the Review menu, *FIGURE 9-5*.

The From date (1) and To date (2) displayed represent the earliest and latest stored Patient Tests and STAT tests. It is possible to change the date interval. If no change is required, press the Confirm button (4). *FIGURE 9-8* will then be displayed.

- a) If required, change the From date (1) via the Digit buttons (3). Press the Confirm button (4).
- b) Repeat instruction "a)" to change the To date (2).
- c) In the next display a Patient ID No. can be entered to view specific patient data. Otherwise press the Confirm button (4) to view all Patient and STAT data.

-
- 1 From date
 - 2 To date
 - 3 Digit button
 - 4 Confirm button

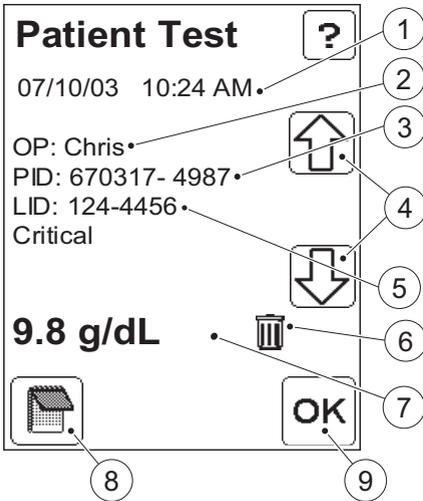
(Continues)

(Continues)

- d) All Patient Tests and STAT tests within the defined date interval will be available for review. Initially, the latest record is displayed. For Patient tests and STAT tests see *FIGURE 9-8*.
- e) If no data within the date interval is found, the following message will be displayed:
No Records Found
The Previous image button must be pressed to return to the PAT/STAT image, *FIGURE 9-7*.

Patient/STAT test

FIGURE 9-8

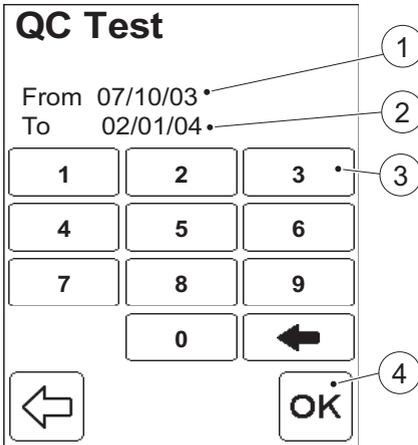


- a) To browse through the available records, use the scroll bar arrows (4).
- b) Depending on the operator's user level, comments can either be added, deleted or changed or just viewed, by pressing the Comment input button (8). See 6.1.3 *Entering Comments*.
- c) Press the Confirm button (9). *FIGURE 9-5* will be displayed.

-
- 1 Date and time of test
 - 2 Operator ID
 - 3 Patient ID
 - 4 Scroll bar arrows
 - 5 Lab Number
 - 6 Indicator for rejected test result
 - 7 Result
 - 8 Comment input button
 - 9 Confirm button

9.2.3 Review QC Tests

FIGURE 9-9



Press the QC Test button in the Review menu, *FIGURE 9-5*.

The From date (1) and To date (2) displayed represent the earliest and latest stored QC tests. It is possible to change the date interval. If no change is required, press the Confirm button (4). *FIGURE 9-10* will then be displayed.

- a) If required, change the From date (1) via the Digit buttons (3). When finished, press the Confirm button (4).
- b) Repeat instruction “a)” to change the To date (2).
- c) *FIGURE 9-10* will be displayed.

-
- 1 From date
 - 2 To date
 - 3 Digit button
 - 4 Confirm button

(Continues)

(Continues)

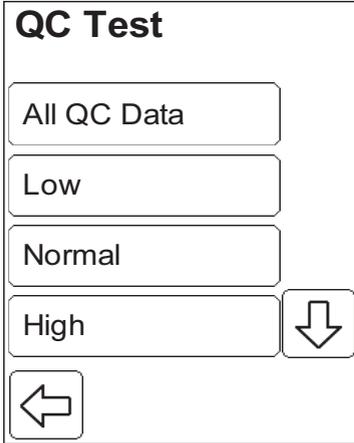


FIGURE 9-10

There are different categories of QC Test data. The following options are available:

- All QC Data
- Low
- Normal
- High
- Other Level
- Linearity
- Proficiency

(Continues)

(Continues)

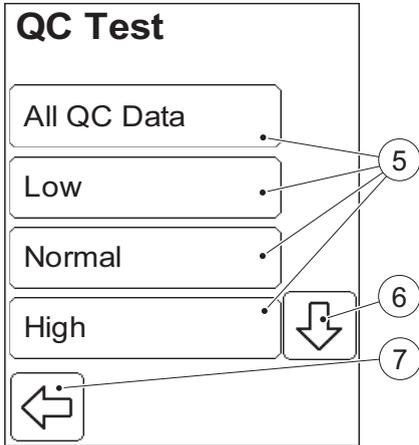


FIGURE 9-11

The categories Low, Normal, High and Other Level, refer to the different concentration levels of Liquid Controls used in a QC test. Linearity and Proficiency define other types of tests.

The procedure for reviewing QC Tests is the same for all the concentration levels. Therefore only one, Low, is described.

d) To view categories not initially visible, press the Scroll bar arrow (6).

e) Select a category by pressing it.

f) All QC tests within the selected category and the defined date interval will be available for review. The latest test is displayed first. For Low, Normal, High and Other Level see *FIGURE 9-12*. For Linearity see *FIGURE 9-15*. For Proficiency see *FIGURE 9-17*.

If no data within the date interval is found, the following message will be displayed:

No Records Found

The Previous image button (7) must be pressed to return to the QC Test categories image, *FIGURE 9-10*.

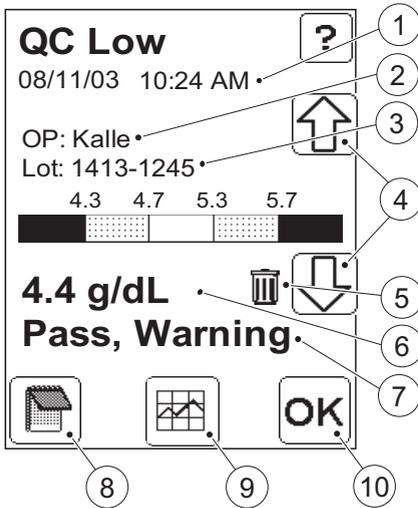
-
- 5 QC categories
 - 6 Scroll bar arrow

All QC Data

All categories of QC data within the defined date interval will be available. The different images possible are described in *FIGURE 9-12*, *FIGURE 9-15* and *FIGURE 9-17*.

QC tests at a specific concentration level

FIGURE 9-12



- a) To browse through the available records, use the scroll bar arrows (4).
- b) Depending on the operator’s user level, comments can either be added, deleted or changed or just viewed, by pressing the Comment input button (8). See *6.1.3 Entering Comments*.
- c) To view a graphic presentation of the the most recent QC tests at the defined concentration level, press the Statistics button (9). *FIGURE 9-13* will be displayed.
- d) To return to the QC Test categories image, *FIGURE 9-10*, press the Confirm button (10).

-
- 1 Date and time of test
 - 2 Operator ID
 - 3 Lot No. of Liquid Control
 - 4 Scroll bar arrows
 - 5 Indicator for rejected test result
 - 6 Result
 - 7 Qualitative test result
 - 8 Comment input button
 - 9 Statistics button
 - 10 Confirm button

(Continues)

(Continues)

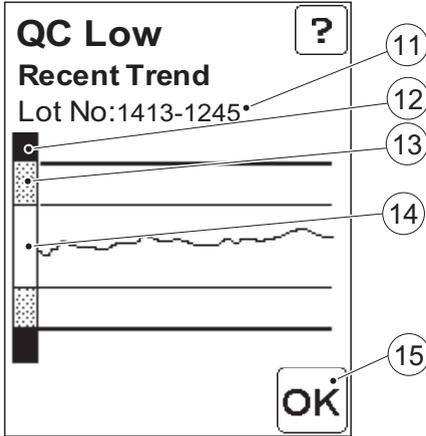


FIGURE 9-13

The diagram shows the trend for the most recent QC measurements at the defined concentration level. No consideration is given to the defined date interval.

e) Press the Confirm button (15).
 FIGURE 9-14 will be displayed.

-
- 11 Lot No. of Liquid Control
 - 12 Fail area
 - 13 Warning area
 - 14 Pass area
 - 15 Confirm button

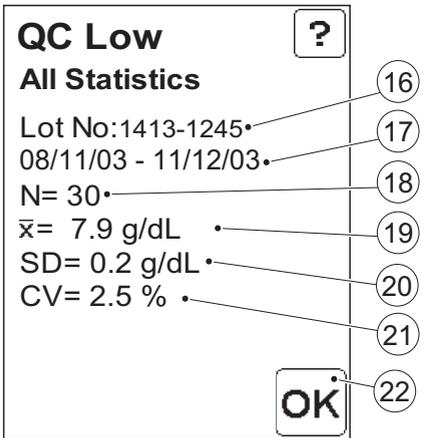
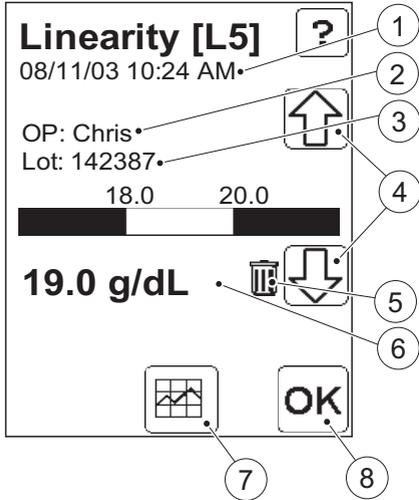


FIGURE 9-14

The image shows statistical data for all stored QC tests with the current Lot No.

f) Press the Confirm button (22).
 FIGURE 9-12 will be displayed.

-
- 16 Lot No. of Liquid Control
 - 17 Date interval of test results
 - 18 Number of test results on which statistics are based
 - 19 Mean value
 - 20 Standard Deviation
 - 21 Coefficient of Variation
 - 22 Confirm button



Linearity tests

For a description, see 8.2.2 *Linearity Test*

FIGURE 9-15

- a) To browse through the available records, use the scroll bar arrows (4).
- b) To view statistics for the linearity test, press the Statistics button (7). *FIGURE 9-16* will be displayed.
- c) Press the Confirm button (8). *FIGURE 9-10* will be displayed.

-
- 1 Date and time of test
 - 2 Operator ID
 - 3 Lot No. of Linearity material
 - 4 Scroll bar arrows
 - 5 Indicator for rejected test result
 - 6 Result
 - 7 Statistics button
 - 8 Confirm button

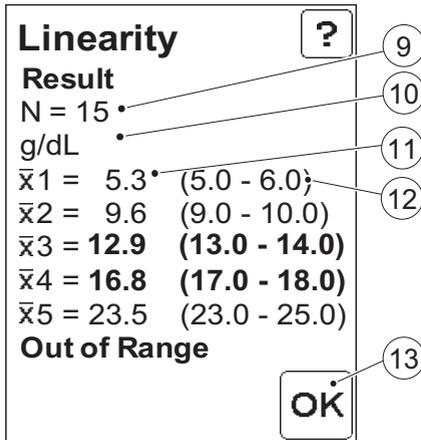


FIGURE 9-16

The image shows statistical data. For more information on the image, see *FIGURE 8-25*.

- d) Press the Confirm button. *FIGURE 9-10* will be displayed.

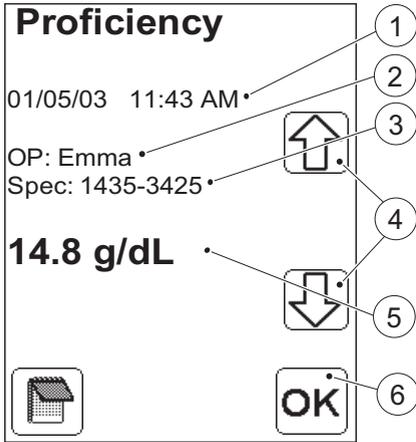
-
- 9 Total No. of cuvettes used in the linearity test
 - 10 Unit for analyte concentration
 - 11 Mean result for the level
 - 12 Concentration min. and max. value for the level
 - 13 Confirm button

Proficiency tests

For a description, see 8.2.3 *Proficiency Test*

FIGURE 9-17

- a) To browse through the available records, use the scroll bar arrows (4).
- b) Press the Confirm button (6). *FIGURE 9-10* will be displayed.



-
- 1 Date and time of test
 - 2 Operator performing the test
 - 3 Specimen ID
 - 4 Scroll bar arrows
 - 5 Result
 - 6 Confirm button

9.2.4 Review Analyzer Log

Press the Analyzer Log button in the Review menu, *FIGURE 9-5*.

An individual Analyzer Log can be either an error message or a log note.

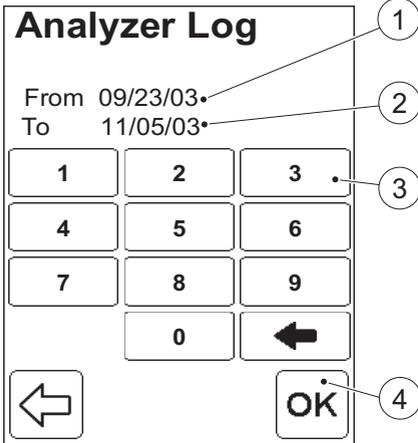


FIGURE 9-18

The From date (1) and To date (2) displayed represent the earliest and latest stored Logs. It is possible to change the date interval. If no change is required press Confirm (4). *FIGURE 9-19* will then be displayed.

a) If required, change the From date (1) via the Digit buttons (3). Press Confirm (4).

b) Repeat the instruction “a)” for the To date (2).

c) *FIGURE 9-19* will be displayed.

-
- 1 From date
 - 2 To date
 - 3 Digit button
 - 4 Confirm button

(Continues)

(Continues)

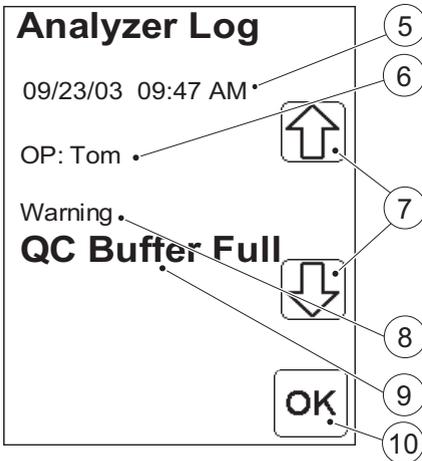


FIGURE 9-19

The individual Analyzer Logs can have different degrees of severity.

- Critical (error messages)
- Warning (error messages)
- Note (log notes)

d) To browse through the available records use the scroll bar arrows (7).

e) Press the Confirm button (10).

FIGURE 9-5 will be displayed.

-
- 5 Date and time of test
 - 6 Operator ID
 - 7 Scroll bar arrows
 - 8 Degree of severity of the Analyzer Log
 - 9 Log note
 - 10 Confirm button

9.3 Delete Stored Data

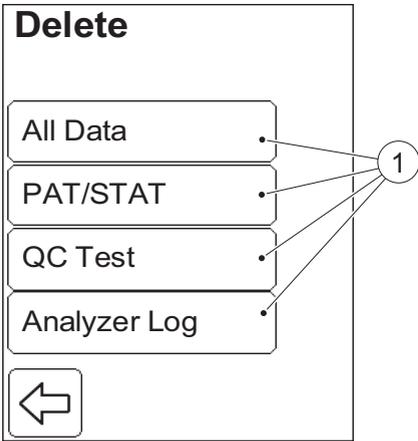
FIGURE 9-20

When the Delete button is pressed in the Stored Data menu (see FIGURE 9-4), the following options for deleting data are displayed:

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

a) Select an option by pressing it.

FIGURE 9-21 will be displayed



1 Delete options

(Continues)

(Continues)

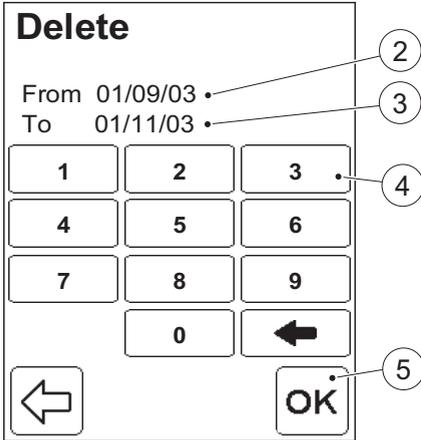


FIGURE 9-21

The From date (2) and To date (3) displayed represent the earliest and latest stored records of the selected type. It is possible to alter the To date but not the From date. If no change is required, press Confirm (5). FIGURE 9-22 will be displayed.

b) If required, enter a new To date (3) via the Digit buttons (4). When finished press Confirm (5). FIGURE 9-22 will be displayed.

-
- 2 From date
 - 3 To date
 - 4 Digit button
 - 5 Confirm button

(Continues)

(Continues)

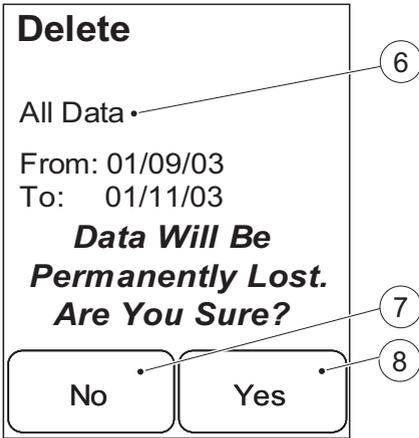


FIGURE 9-22

c) To cancel the request to delete the data, press No (7).
To confirm the request to delete the data, press Yes (8)
The Delete menu, *FIGURE 9-20*, will be displayed.

-
- 6 The type of data requested for deletion
 - 7 No button
 - 8 Yes button

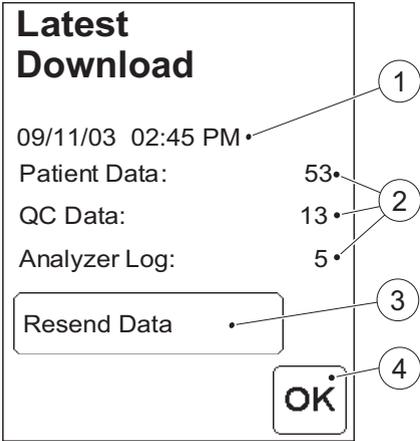
9.4 Review Latest Download

FIGURE 9-23

When the Latest Download button is pressed in the Stored Data menu, *FIGURE 9-4*, data regarding the latest information exchange with an OR is displayed.

a) To transfer the Data again, press the Resend Data button (3)

b) Press the Confirm button (4). *FIGURE 9-4* will be displayed.



- 1 Date and time of transfer
- 2 No. of transferred records
- 3 Resend Data button
- 4 Confirm button

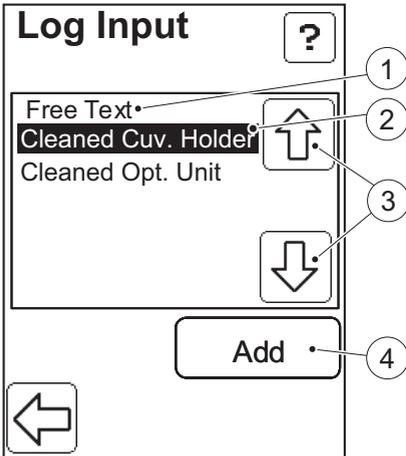
9.5 Log Input

FIGURE 9-24

When the Log Input button is pressed in the Stored Data Menu, *FIGURE 9-4*, data for reviewing or adding logs to the Analyzer log list is displayed.

It is possible to enter free text or to choose log notes from a predefined list.

- a) Press the Scroll bar arrows (3) to select either a log note (2), or the Free Text option (1).
- b) Press the Add button (4)
- c) If a log note was selected, it will be added to the Analyzer Log and *FIGURE 9-4* will be displayed. If the Free Text option (1) was selected *FIGURE 9-25* will be displayed.



-
- 1 Free text option
 - 2 Selected Log Note
 - 3 Scroll bar arrows
 - 4 Add button

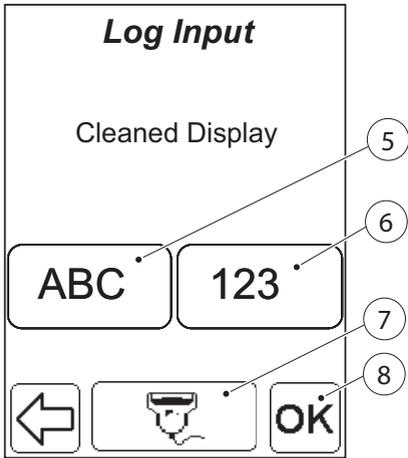


FIGURE 9-25

- d) Enter a free text notation either directly on the Display via the Text mode (5) and Numeric mode (6) buttons, or with the Barcode Scanner via the Barcode Scanner button (7).
- e) Press the Confirm button (8). *FIGURE 9-4* will be displayed.

-
- 5 Text mode button
 - 6 Numeric mode button
 - 7 Barcode Scanner button
 - 8 Confirm button

10 Data communications

This chapter briefly describes the data communication between the Analyzers and the DMS Software.

10.1 Interaction Application – Analyzer

Specially developed DMS Software is necessary to provide full data management for the Analyzers. Results of measurement are transferred to the DMS Software for storage and evaluation. Settings in an Analyzer can be updated from the DMS Software.

The Analyzer must be placed in a Docking Station that is connected to a PC or to an Observation Reviewer (OR) to facilitate communication with the DMS Software or OR.

Depending on the settings, one or several Analyzers can be connected and administered by the same PC via the Docking Stations (see *10.2 Docking station setup*).

10.2 Docking station setup

Single Primary Docking

FIGURE 10-1

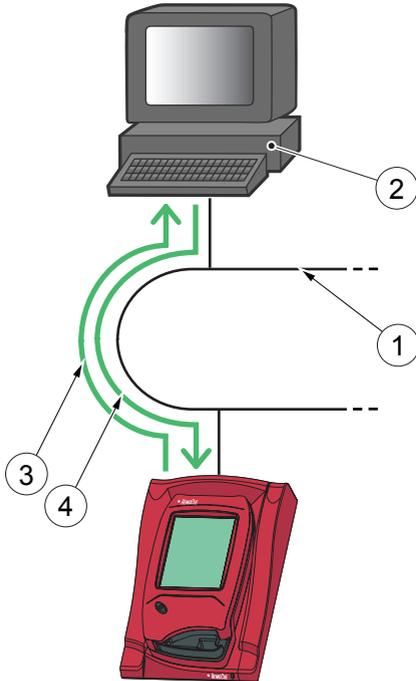
A Single Primary Docking Station must be connected to a LAN (1) to which the PC hosting the DMS Software (2), or an OR, is also connected.

The communication Analyzer - DMS Software is two-way:

- Analyzer Data is transmitted from the Analyzer to the PC (2) for Data Management, see Arrow (3).
- Analyzer Settings are transmitted from the PC (2) to the Analyzer, see Arrow (4).

To make settings on a Primary Docking Station, e.g. IP-address, it must be connected to a PC via a USB (the same type of connection a Secondary Docking Station uses for data communication, see FIGURE 10-2).

Note! When a Primary Docking Station is connected via a USB connection, only the IP address can be changed. No other information can be sent to/from the Analyzer.



- 1 LAN
- 2 PC hosting the DMS Software or OR
- 3 Analyzer Data to DMS Software or OR
- 4 Analyzer Settings from DMS Software or OR

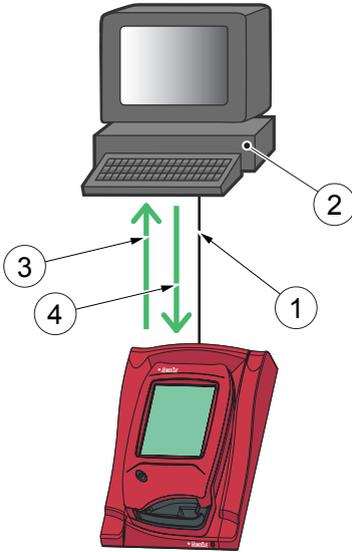
Single Secondary Docking Station

FIGURE 10-2

A Single Secondary Docking Station must be connected via a USB (1) to the PC hosting the DMS Software (2). A Secondary is only connected to a PC for data communication. No settings can be made on the Secondary Docking Station.

The communication between the Analyzer and the DMS Software is two-way:

- Analyzer Data is transmitted from the Analyzer to the PC (2) for Data Management, see Arrow (3).
- Analyzer Settings are transmitted from the PC (2) to the Analyzer, see Arrow (4).



-
- 1 USB connection
 - 2 PC hosting the DMS Software
 - 3 Analyzer Data to DMS Software
 - 4 Analyzer Settings from DMS Software

Set of Multiple Docking Stations containing a Primary

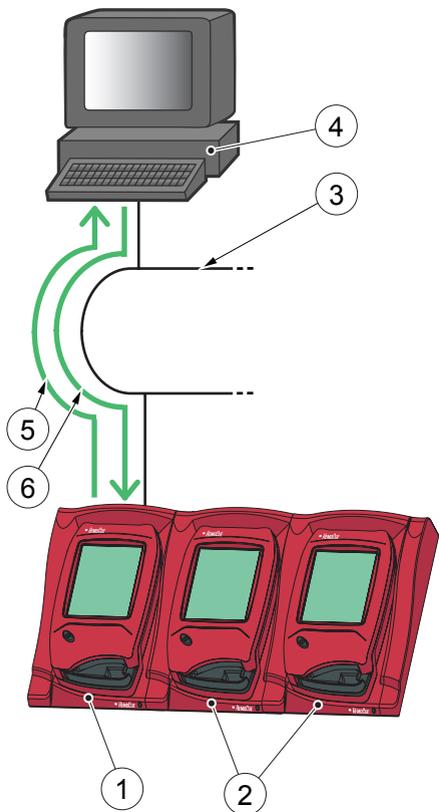
FIGURE 10-3

In a set of Multiple Docking Stations containing a Primary (1), the Primary is connected to a LAN (3) to which the PC hosting the DMS Software (4), or the OR, is also connected.

The communication between the Analyzer and the DMS Software is two-way.

For the Analyzer in the Primary Docking Station (1) the following applies:

- Analyzer Data is transmitted from the Analyzer in the Primary Docking Station (1) to the PC (4) for Data Management, see Arrow (5).
- Analyzer Settings are transmitted from the PC (4) to the Analyzer in the Primary Docking Station (1), see Arrow (6).



-
- 1 Primary Docking Station
 - 2 Secondary Docking Station
 - 3 LAN
 - 4 PC hosting the DMS Software or OR
 - 5 Analyzer Data to PC
 - 6 Analyzer Settings from PC

(Continues)

(Continues)

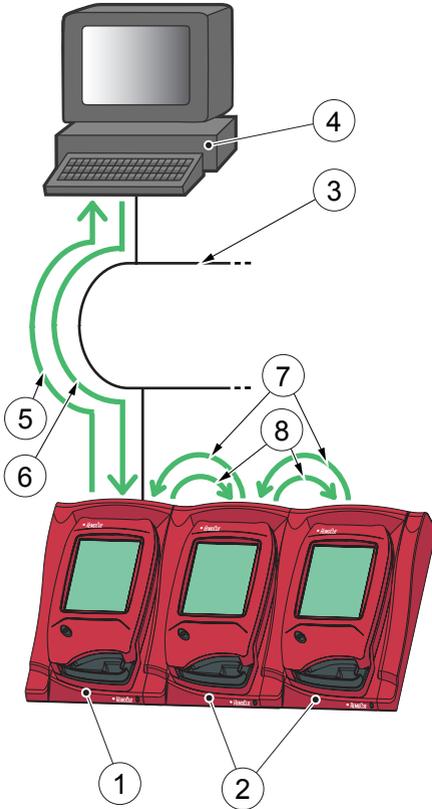


FIGURE 10-4

For an Analyzer in a Secondary Docking Station (2), the following applies:

- Analyzer Data is transmitted via the Secondary Docking Stations to the Primary Docking Station (1), see Arrow (7). The Primary Docking Station (1) transmits the Data to the PC (4), see Arrows (5).
- Analyzer Settings are transmitted from the PC (4) via the Primary (1) and Secondary Docking Stations, to the Analyzers in the Secondary Docking Station (2), see Arrow (6) and (8).

A Secondary Docking Station in such a set, can at the same time, be connected separately to a PC via a USB, in which case the USB connection overrides the LAN connection. Normally there is no reason for this type of configuration.

-
- 1 Primary Docking Station
 - 2 Secondary Docking Station
 - 3 LAN
 - 4 PC hosting the DMS Software or OR
 - 5 Analyzer Data to PC
 - 6 Analyzer Settings from PC
 - 7 Analyzer Data from Secondary via Primary
 - 8 Analyzer Settings to Secondary via Primary

(Continues)

(Continues)

To make settings on the Primary Docking Station in such a set, e.g. the IP-address, it must be directly connected to a PC via a USB (the same type of connection a Secondary Docking Station uses for data communication, see *FIGURE 10-2*).

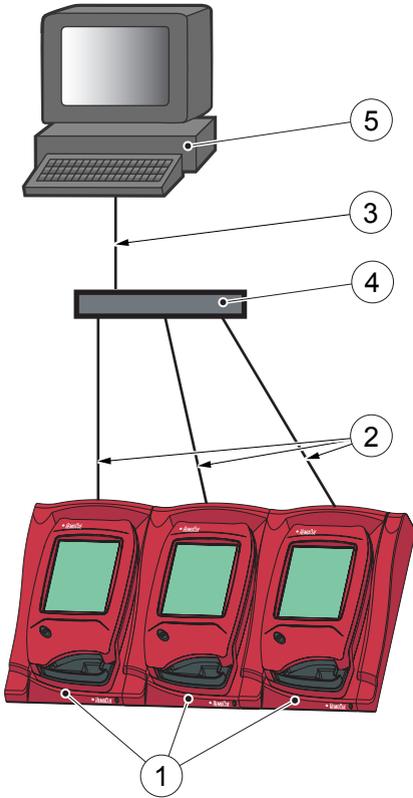
Multiple set consisting solely of Secondary Docking Stations

FIGURE 10-5

In a multiple set consisting solely of Secondary Docking Stations, each Docking Station (1) must, for data communication, be connected separately to a USB port (4) on the PC hosting the DMS Software (5). If the PC doesn't have enough USB ports, a USB hub can be used.

Only electrical power can be transferred between Docking Stations in this configuration.

Analyzers in a multiple set consisting solely of Secondary Docking Stations communicate with the DMS Software according to *FIGURE 10-6*.



- 1 Secondary Docking Station
- 2 USB connection Docking Station - hub
- 3 USB connection hub to PC
- 4 USB hub
- 5 PC hosting the DMS Software

(Continues)

(Continues)

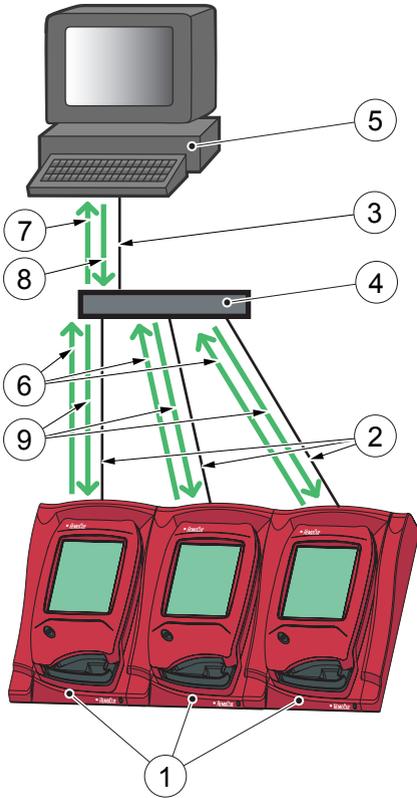


FIGURE 10-6

- Analyzer Data is transmitted directly from the Analyzers in the Secondary Docking Station (1) via a USB cable (2) and (3) through the USB hub (4) on to the PC (5) according to Arrows (6) and (7).
- Analyzer Settings are transmitted directly from the PC (5) via a USB (3) and (2) through the USB hub (4) on to the Analyzer in the Secondary Docking Station (1) according to Arrows (8) and (9).

-
- 1 Secondary Docking Stations
 - 2 USB connection Docking Station to hub
 - 3 USB connection hub to PC
 - 4 USB hub
 - 5 PC hosting the DMS Software
 - 6 Analyzer Data to PC via hub
 - 7 Analyzer Data to PC via hub
 - 8 Analyzer Settings from PC via hub
 - 9 Analyzer Settings from PC via hub

10.3 Data transfer

Analyzers can be administered by the DMS Software from a central PC. The central PC can communicate with several Analyzers at the same time. The communication between the DMS Software and the Analyzer is two-way, using the POCT1-A standard (also known as the CIC standard).

Data transfer from the PC to an Analyzer is activated manually from the DMS Software.

Data transfer from an Analyzer to the PC is activated automatically when a data communications connection is established by placing an Analyzer in a docking station connected to the PC. If the Analyzer is busy with a measurement when the connection is established, data transfer will start as soon as the measurement is completed.

Data transfer from an Analyzer to the PC will always contain measurement results not already transferred.

During the activation and data exchange process a number of images can/will appear on the Analyzer Display.



FIGURE 10-7

When the data transfer process is being activated, *FIGURE 10-7* will be displayed for as long as it takes to establish the connection. This may happen instantly, in which case this image will not appear at all.



FIGURE 10-8

During data transfer, *FIGURE 10-8* will be displayed until the process is completed or interrupted.

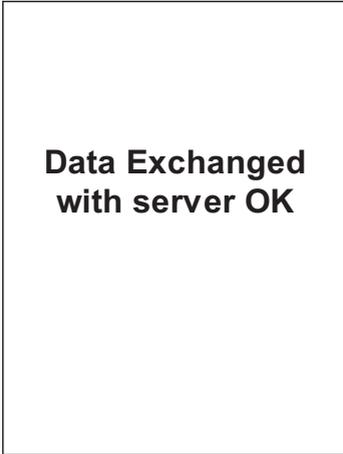


FIGURE 10-9

When the Analyzer is removed from the docking station, and the connection is taken down successfully, *FIGURE 10-9* will be displayed.

Note! It can take up to 20 seconds for the message to appear on the display, depending on which docking station is used.

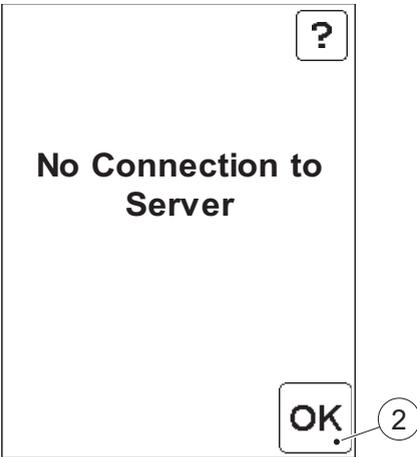


FIGURE 10-10

When the data transfer process is being activated, but the connection is not established successfully, *FIGURE 10-10* will be displayed.

One of the following errors has occurred:

- The Docking Station is not properly connected to the network.
- The network server is not available.
- There is a fault in the Docking Station.

a) Press the Confirm button (2) to return to the Main Menu, *FIGURE 3-31*

1 Confirm button

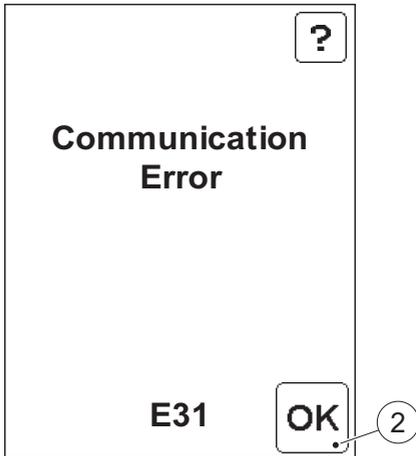


FIGURE 10-11

If, during data transfer, an error or malfunction between the Analyzer and the receiving computer is detected, *FIGURE 10-11* will be displayed. Refer to the section *10 Data communications*.

a) Press the Confirm button (2) to return to the Main Menu, *FIGURE 3-31*

1 Confirm button

PART IV

Other actions



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11 Maintenance

This chapter describes the maintenance procedure for the Analyzer.

11.1 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 optronic unit, proceed as follows:

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

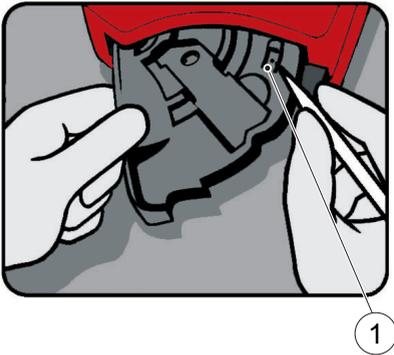


FIGURE 11-1

- 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

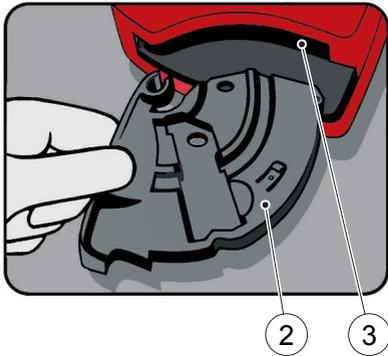


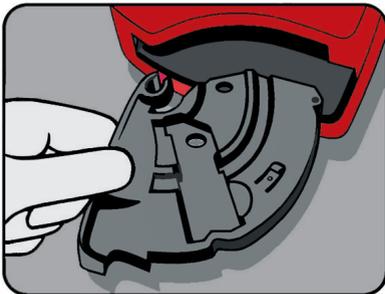
FIGURE 11-2

- 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 11-3



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

11.2 Cleaning the Display

The display can be cleaned with alcohol, without additives.

11.3 Cleaning of the Analyzer Outer case and the Docking Station

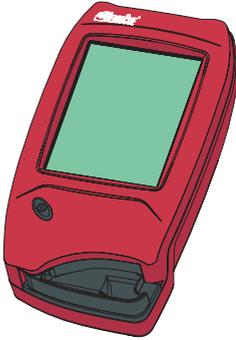


FIGURE 11-4

- 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.

11.4 Calibrating the Display

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

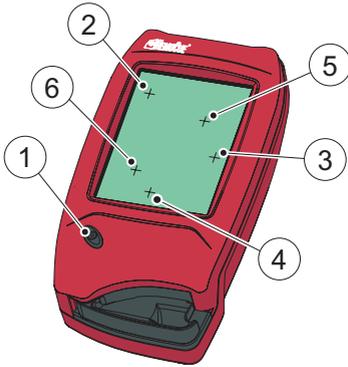


FIGURE 11-5

- 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.
- Note!** This is the only occasion when anything other than the fingertips should be used to touch the display. Sharp edged objects 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).

(Continues)

(Continues)

f) If the verification of the calibration is successful, the Analyzer will continue with the normal startup. 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

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12 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.

12.1 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

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 data can be saved.	Save test results by placing the Analyzer in a Docking Station connected to DMS Software or OR. For the following, supervisory authority is needed. a) Delete all or part of the Patient Tests stored in the Analyzer (see <i>9.3 Delete Stored Data</i>) b) Change Analyzer settings regarding full internal memory for Patient tests to "Overwrite" (see <i>4.4.1 General Settings</i>).

Symptom	Explanation	Action
E27	The QC memory is full. No more QC data can be saved.	<p>Save test results by placing the Analyzer in a Docking Station connected to DMS Software or OR. For the following, supervisory authority is needed.</p> <ul style="list-style-type: none"> a) Delete all or part of the QC Tests stored in the Analyzer (see 9.3 <i>Delete Stored Data</i>) b) Change Analyzer settings regarding full internal memory for QC tests to "Overwrite" (see 4.4.1 <i>General Settings</i>).
E28	The Analyzer log memory is full. No more Error Codes and Log Notes can be saved.	<p>Save test results by placing the Analyzer in a Docking Station connected to DMS Software or an OR. For the following, supervisory authority is needed.</p> <ul style="list-style-type: none"> a) Delete all or part of the Analyzer logs stored in the Analyzer (see 9.3 <i>Delete Stored Data</i>) b) As the Analyzer settings regarding full memory for Analyzer logs is the same as the setting for full memory of QC tests, change Analyzer behaviour for QC tests to "Overwrite" (see 4.4.1 <i>General Settings</i>).

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 maintance section. b) The Analyzer needs service. Contact your distributor

Symptom	Explanation	Action
E31	Communication Error	a) Check the network parameters. b) Check that the LED on the Primary Docking Station does not show a red light (stable or flashing). c) More than 5 Docking Stations are docked together. d) Check that a USB connection is not used for communication in a Primary Docking Station. e) Check that two Primary Stations are not docked together. f) Check the electrical connections. The LED on the docking station should give either a stable green light or a flashing green light. If problems remain contact your distributor.
Overrange	The measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L)	
No characters on the display	1) The Analyzer is not receiving power. 2) If on battery power, the Battery need to be recharged. 3) The display is out of order.	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.

Symptom	Explanation	Action
The display gives erroneous characters.	1) The display is out of order. 2) The microprocessor is out of order.	1) The Analyzer needs service. Contact your distributor. 2) The Analyzer needs service. Contact your distributor.
The Scanner is malfunctioning	1) The 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.	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>11.3 Cleaning of the Analyzer Outer case and the Docking Station</i> 6) The standards that can be scanned are listed in section <i>13.11 Technical Specifications</i> . 7) The Analyzer needs service. Contact your distributor.

Symptom	Explanation	Action
<p>No transfer of data</p>	<ol style="list-style-type: none"> 1) No network communication with OR 2) No network communication with PC 3) Communication error 4) No communication 5) No communication between the first and second Docking Station 6) No communication between the Secondary Docking Stations 7) No communication with any Docking Station 	<ol style="list-style-type: none"> 1a) Check the network parameters. 1b) Check that the LED on the Primary Docking Station does not show a red light (stable or flashing). 2a) Check the network parameters. 2b) Check that the LED on the Primary Docking Station does not show a red light (stable or flashing). 3) More than 5 Docking Stations are docked together. 4) Check that a USB connection is not used for communication in a Primary Docking Station. 5) Check that two Primary Stations are not docked together. 6) Check the electrical connections. The LED on the docking station should give either a stable green light or a flashing green light. 7) Check the electrical connection. The LED on the docking station should give either a stable green light or a flashing green light. <p>If problems remain contact your distributor.</p>

Symptom	Explanation	Action
No transfer of data via USB	No USB-communication	<ul style="list-style-type: none"> a) Check that the Analyzer is properly docked. b) Check the cable connections in both the Docking Station and the PC. c) Check that the Docking Station is not a Primary Docking station. d) Check that all Docking Stations that should communicate are connected with a USB cable to the PC. e) Check that the DMS Software is properly installed.
Analyzer not charged	No charging of the Battery	<ul style="list-style-type: none"> 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	<p>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).</p> <p>Note! To prevent data from being unintentionally transmitted, keep the Analyzer away from the Docking Station.</p>

PART V

Miscellaneous



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APPENDICES

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13 Technical specifications

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

13.1 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.

13.2 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.

13.3 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.

13.4 Reagents

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

13.5 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.

13.6 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.

13.7 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.

13.8 Measuring range

13.8.1 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.

13.9 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.

13.10 Expected values

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

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

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

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.

13.11 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.

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(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.

13.12 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.

13.13 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		

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		

13.14 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.

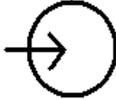
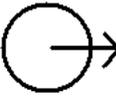
13.15 Spare parts and accessories

The following spare parts and accessories are available:

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

13.16 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.

	<p>Input</p>
	<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>

13.17 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.

Appendix A – Default Settings

Analyzer Serial Number :

Date :

Section Identifier	Available options	Default value	Customer Settings
Basic Settings			
Date format	MM/DD/YY DD.MM.YY YY-MM-DD	MM/DD/YY	
Time format	12 AM/PM 24 H	12 AM/PM	
Power saver time	5-30 min.	15 min.	
Audible signals (volume) Button Click	0-4	4	
Audible signals (volume) Test Ready	0-4	4	
Audible signals (volume) Error	0-4	4	
Language	Language 1 Language 2	Language 1	
Advanced Settings			
General Settings			
Units	g/dL g/L mmol/L	g/dL	

Section Identifier	Available options	Default value	Customer Settings
Operator ID	Not Used Entry Required Approved Only	Not Used	
Min/Max characters in Operator ID	1/15	3/12	
Password for protected functions	Free choice (1-10 characters)	0000	
Cuvette Batch	Not Used Entry Required Approved Only	Not Used	
Patient List	Not Used Used	Not Used	
Patient Memory Full	Lockout Overwrite	Overwrite	
QC Memory Full	Lockout Overwrite	Overwrite	
Patient Test settings			
Critical Limits)	0.0-25.6 g/dL 0-256 g/L 0.0-15.9 mmol/L	0-25.6 g/dL	
Patient ID	Not Used Optional Required	Not Used	
Min/Max characters in Patient ID	1/25	3/12	
Clear Patient ID	Used Not Used	Used	
Lab Number (LID)	Not Used Optional	Not Used	

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Section Identifier	Available options	Default value	Customer Settings
Min/Max characters in Lab Number	1/25	3/12	
STAT Test	Used Not Used	Used	
STAT Tests Allowed	1-100	10	
QC Test Settings			
QC Low Lockout	Not Used Time Measurement	Not Used	
Start of First Workshift	Free choice of time	12:00 AM	
Lockout Interval, time	1, 2, 3, 4, 6, 8, 12, 24 hours, 2-7 days	8 hours	
Lockout Interval, measurement	2-200	100	
QC Normal Lockout	Not Used Time Measurement	Not Used	
Start of First Workshift	Free choice of time	12:00 AM	
Lockout Interval, time	1, 2, 3, 4, 6, 8, 12, 24 hours, 2-7 days	8 hours	
Lockout Interval, measurement	2-200	100	
QC High Lockout	Not Used Time Measurement	Not Used	
Start of First Workshift	Free choice of time	12:00 AM	

Section Identifier	Available options	Default value	Customer Settings
Lockout Interval, time	1, 2, 3, 4, 6, 8, 12, 24 hours, 2-7 days	8 hours	
Lockout Interval, measurement	2-200	100	
QC Other Lockout	Not Used Time Measurement	Not Used	
Start of First Workshift	Free choice of time	12:00 AM	
Lockout Interval time	1, 2, 3, 4, 6, 8, 12, 24 hours, 2-7 days	8 hours	
Lockout Interval, measurement	2-200	100	
QC Reminder, time	0,30 min, 1, 2, 3, 4 hours	1 hour	
QC Reminder, measurements	1-50	20	
QC Result Options	Numeric Passed/Failed	Numeric	
Failed QC Comment	Not Used Entry Required	Not Used	
Linearity Settings			
Linearity	3, 4, 5 Levels	5 Levels	
Linearity, Cuvettes/ level	1-20	3	

Manufacturer

HemoCue AB

Box 1204

SE - 262 23 Ängelholm

Sweden

Phone: + 46 431 45 82 00

Fax: + 46 431 45 82 25

E-mail: info@hemocue.se

www.hemocue.com

HemoCue Distributor USA

HemoCue Inc.

40 Empire Drive

Lake Forest, CA 92630

Phone 949-859-2630

Order 800-323-1674

Technical support 800-426-7256

Fax 949-859-3066

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