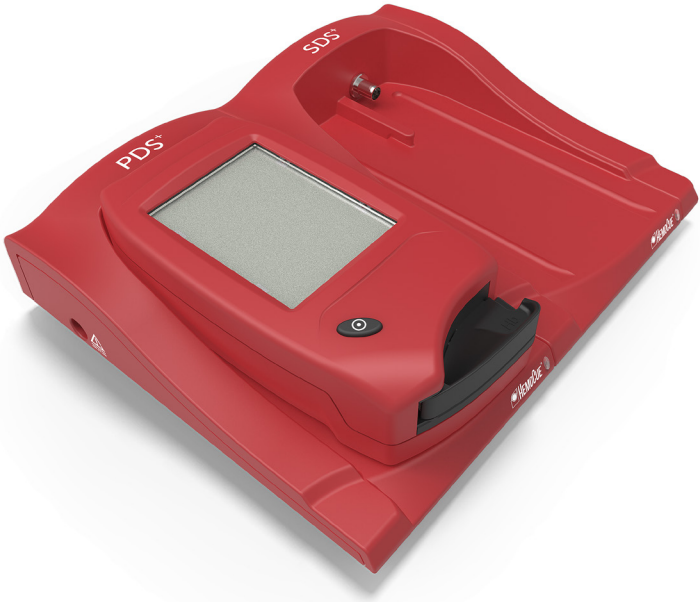
HemoCue® 201 DM Analyzer
&
HemoCue® 201 DM Docking Station



Reference Manual

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Introduction

1 Introduction

Thank you for choosing the HemoCue 201 DM system.

The HemoCue 201 DM system is a compact, portable, yet versatile, 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 201 DM Analyzer (either HemoCue Hb 201 DM Analyzer, HemoCue Glucose 201 DM Analyzer or HemoCue Glucose 201 DM RT Analyzer), the HemoCue 201 DM Docking Station and the respective HemoCue Microcuvettes.

This Reference Manual contains instructions for configuration of the Analyzer and setup of the System. For installation of the Docking Stations see Hemocue 201 DM Docking Station Manual. For information on the HemoCue 201 DM - DMS Software, see the separate User's Guide on the DMS Software CD. Instructions for everyday routine use (including sampling procedure and maintenance) have been provided in Instructions for Use for the respective Analyzer.

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

Usage Disclaimer

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

1.1 Abbreviations/glossary

AC	Alternating Current
CD	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-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
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.
CLSI	Clinical and Laboratory Standards Institute (formerly 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, normally referred to as a middleware, 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
PDS+	Primary Docking Station
PDS	Primary Docking Station (Unlabelled)
PID	Patient Identification (ID)
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 CLSI, 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
SDS+	Secondary Docking Station
SDS	Secondary Docking Station (Unlabelled)
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.
TCP/IP	Transmission Control Protocol/Internet Protocol
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.

1.2 Designated Terminology

Designations in table below are used throughout this document.

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

Item	Referred to as the...
HemoCue Hb 201 DM Instructions for Use HemoCue Glucose 201 DM Instructions for Use HemoCue Glucose 201 DM RT Instructions for Use	Instructions for Use
HemoCue 201 DM - DMS Software User's Guide (on CD)	DMS Software Manual
Spare parts	
HemoCue recommended Power Adapter	Power Adapter
HemoCue 201 DM Battery	Battery

1.3 Functional description

1.3.1 System Components

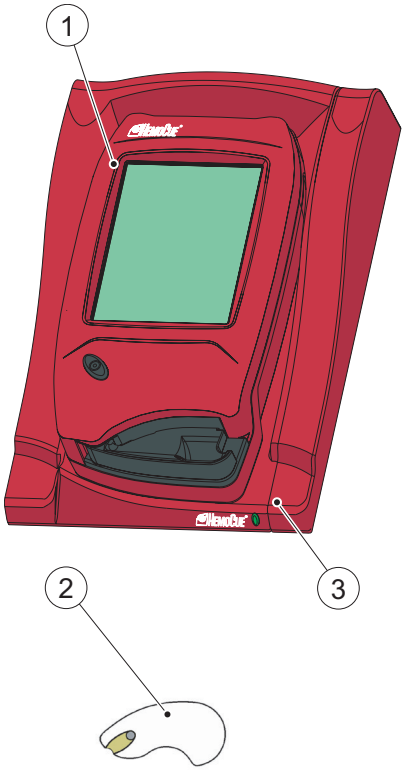


FIGURE 1-1

The System consists of a specially designed Analyzer (1), specially designed Cuvettes, and a specially designed Docking Stations (2). The System is intended for *In Vitro* diagnostic use only.

Analyzer

The Analyzer (1) is only to be used together with the respective Cuvette (see relevant Instructions for Use and Package insert).

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.

Analyzer must always be fully inserted in the Docking Station to ensure connectivity and charging of the Battery.

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

1 Analyzer
2 Cuvette*
3 Docking Station

** Not all Cuvettes shown. Note that the Cuvette is specific for a System.*

1.3.2 Analyzer overview

Front panel

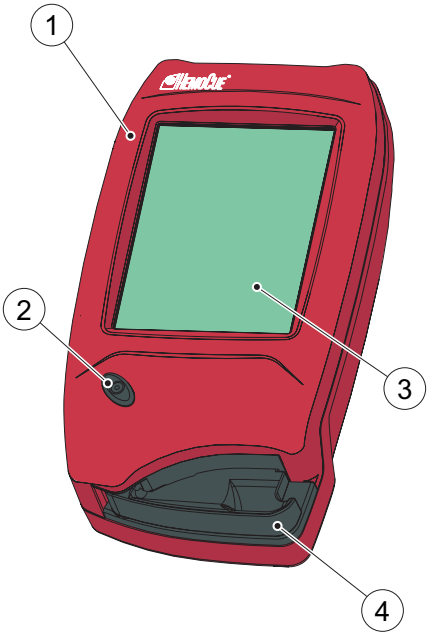


FIGURE 1-2

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

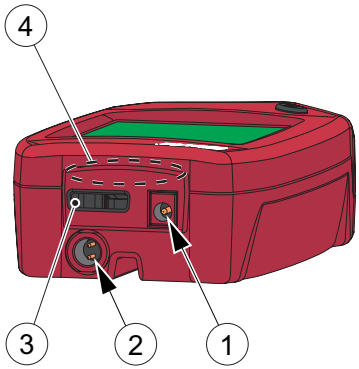
All navigation and information handling is performed by pressing the appropriate touch buttons directly on the Display (3).

For information on how to operate the Display, see section *2.1 How to operate the Display*.

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

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

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



Back panel

FIGURE 1-3

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

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

Data can be transmitted between the Analyzer and the Docking Station in different ways depending on which version of Docking Station is used and how the Docking Station is connected to Software:

- Via USB using the Power + USB signal inlet (2), if the Docking Station communicates with the DMS Software via USB or if the Docking Station is labelled "+" and communicates with the DMS Software via LAN
- By means of IR-light using the IR Transmitter/Receiver (4), if the Docking Station is NOT labelled "+" and communicates with the DMS Software via LAN

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

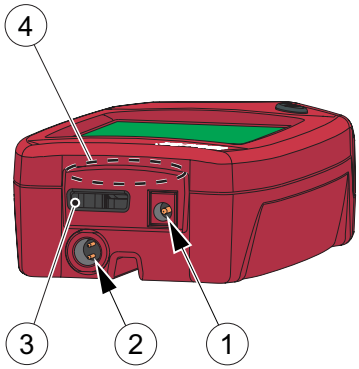


FIGURE 1-4

Settings can be transmitted between two Analyzers via the IR Transmitter/Receiver (see section *3.6 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 Power 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).

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.

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

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

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

1.3.3 Docking station – General

Single Docking Station

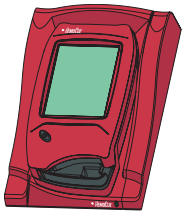


FIGURE 1-5

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

Multiple Docking Stations

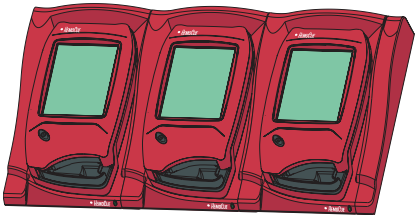


FIGURE 1-6

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

Only the Docking Station positioned furthest to the left can be connected to a Power Adapter. Power is supplied to the other Analyzers through this connection.

Primary and Secondary Docking Stations

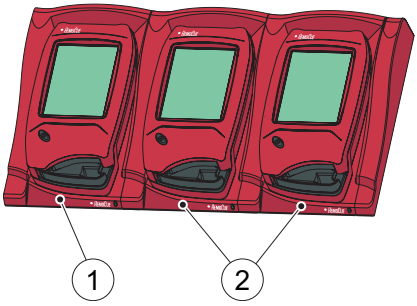


FIGURE 1-7

Primary and Secondary Docking Stations are two physically different products.

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.

When a Primary Docking Station is connected via a USB connection, only the TCP/IP settings can be changed. To change settings use PDS Configuration tool or DMS Software. No other information can be sent to/from the Analyzer.

1 Primary or Secondary Docking Station
2 Secondary Docking Station

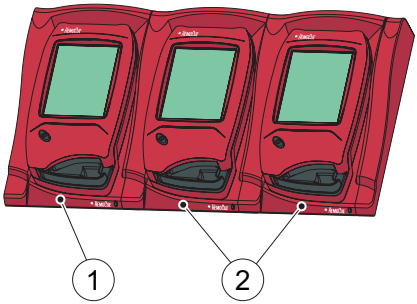


FIGURE 1-8

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).

Two Primary Docking Stations must not be connected together.

Primary Docking Stations labelled PDS+ shall only be connected to a Secondary Docking Station labelled SDS+. Secondary Docking Stations labelled SDS+ shall only be connected to Docking Stations labelled PDS+ or SDS+.
Malfunction will occur if non-labelled Docking Stations are connected to PDS+ or SDS+.

1 Primary or Secondary Docking Station
2 Secondary Docking Station

1.3.4 Docking Station overview

Front

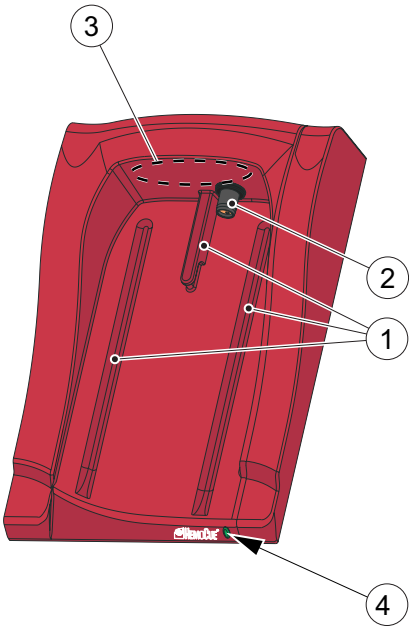


FIGURE 1-9

The Docking Station consists of the following items:

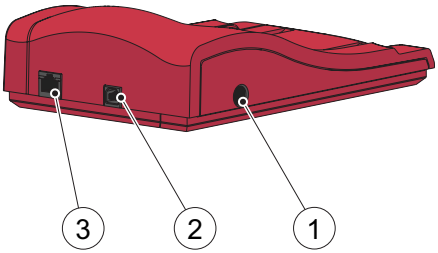
- Tracks (1) for the Analyzer
- Power + USB signal outlet (2) for the Analyzer
- IR Transmitter/Receiver (3) for data transmission to/from the Analyzer
- LED (4)

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.

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

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 (not in Docking Stations labelled PDS+ or SDS+)
4 LED



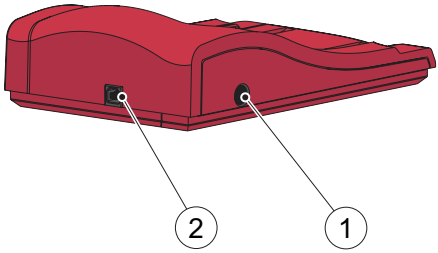
Back panel – Primary Docking Station

FIGURE 1-10

The following items are located on the back panel:

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

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



Back panel – Secondary Docking Station

FIGURE 1-11

The following items are located on the back panel:

- Power inlet (1) for the Power Adapter
- USB port (2) for data communication directly with the PC (different from the USB port in the Primary Docking Station)

1 Power inlet for the Power Adapter
2 USB port

Data Communication Connectors

FIGURE 1-12

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

A Torx screwdriver size T10 is needed to remove the Side Trim.

Note that the Side Trim (2) on the Docking Station should always be used to protect the Connector (1).

1 Male Connector
2 Side Trim

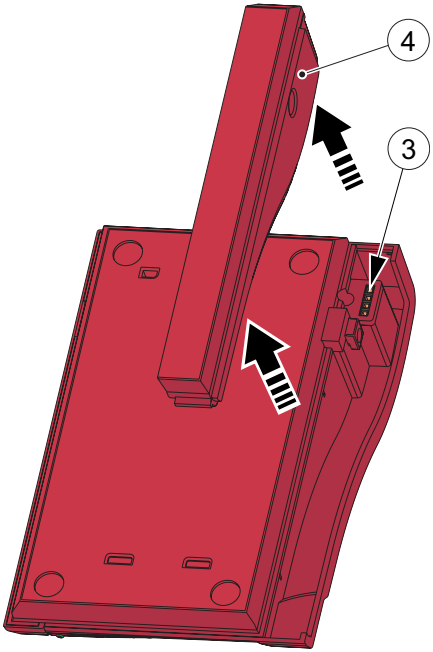


FIGURE 1-13

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

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

Note that 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

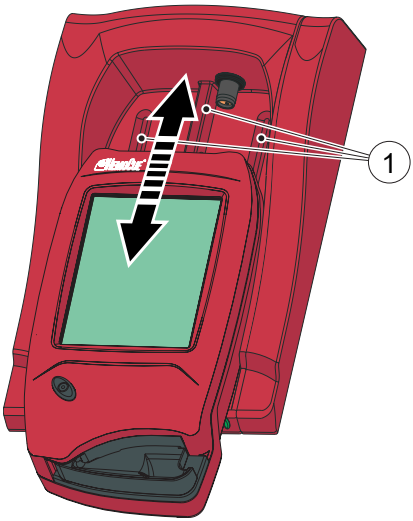


FIGURE 1-14

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

1 Tracks

FIGURE 1-15

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.

1.3.5 Functions and features

HemoCue 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 and 500 QC test results (incl. ID, date, time, comments, etc.)
- Approximately 500 Analyzer log entries (Error messages, maintenance etc.)

The Analyzer also has the following features:

- Touchscreen Display
- Built-in Barcode Scanner
- Powered either by a rechargeable lithium ion battery, Power 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 General operations

This chapter describes the general operations necessary for Analyzer use.

2.1 How to operate the Display

2.1.1 Display buttons

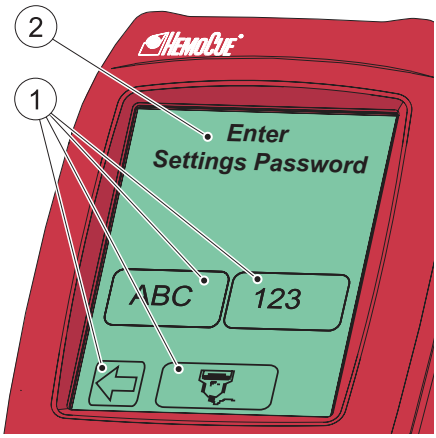
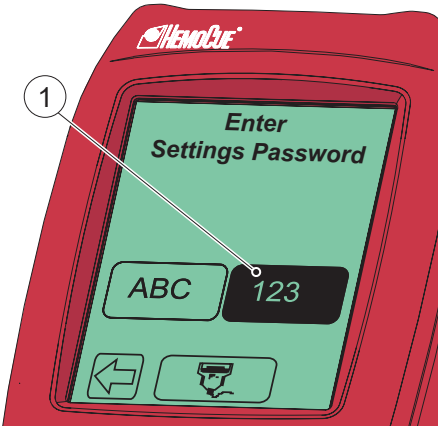


FIGURE 2-16

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

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

1 Buttons
2 Display



Activating a function

FIGURE 2-17

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 *3.3.3 Audible Signals*.

1 Button, highlighted

Changing a function

FIGURE 2-18

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

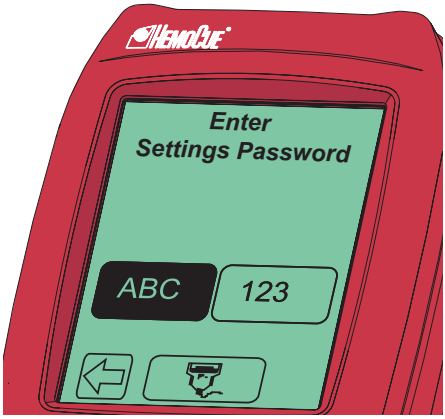


FIGURE 2-19

b) The original button will cease to appear highlighted and the new button will appear highlighted.

c) When the new Button is released, the new function will be activated.

Cancelling a function

FIGURE 2-20

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

FIGURE 2-21

b) No Button will appear highlighted.

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

2.2 Operating the Analyzer

2.2.1 Start up

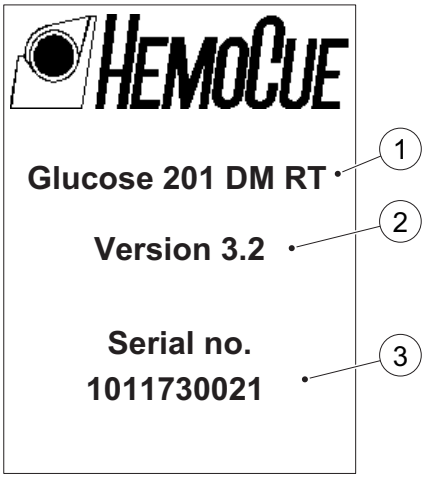


FIGURE 2-22

a) Turn the Analyzer on (see *1.3.2 Analyzer overview*). The Start Image, beginning with the HemoCue logo, will be displayed.

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

1 Analyzer type
2 Software version
3 Serial number

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.

When the Cuvette holder is in the loading position the Analyzer will perform a self-test. No function can be activated for approximately 20 seconds during the selftesting.

c) If the requirement for Operator ID is set to "Not Used" (see section *3 Settings*), the Main Menu will be displayed, *FIGURE 2-24*, without the Operator Name.
If Operator ID is required, the Login Image will be displayed, *FIGURE 2-23*.

For information on how to operate the Display, see section *2.1 How to operate the Display*.

For instructions on how to perform tests, see section *4 Patient Test procedure*, section *5 STAT Test procedure* and section *6 QC Test procedure*.

2.2.2 Login image

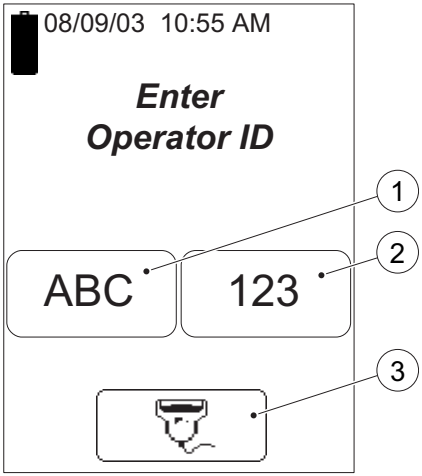


FIGURE 2-23

Not displayed if the requirement for Operator ID is set to "Not Used" (see section *3 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).

Use of the Barcode Scanner eliminates manual input errors. Refer to *Instructions for Use* for information on the Barcode Scanner.

b) When a valid Operator ID is entered, the Main Menu will be displayed, see *FIGURE 2-24*.

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

2.2.3 Main Menu and Help

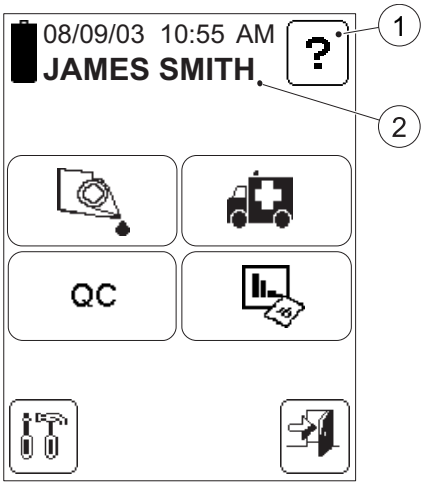


FIGURE 2-24

FIGURE 2-24 is referred to as the *Main Menu*. It is displayed as the Startup Image for all Tests, Setting procedures, etc.

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

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

2.2.4 Power saver mode

When no procedures have been performed within the time predefined in the Analyzer settings (see section *3.3.2 Power Saver*), the Analyzer will switch to power save mode.

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

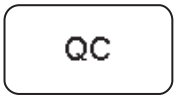
If the Analyzer is powered via the Battery, the user will be logged off and the Analyzer will be switched off. Press the On/Off button to reactivate it.

2.3 Display buttons and symbols

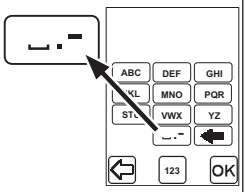
2.3.1 Navigation buttons

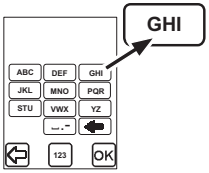
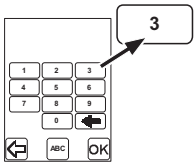
Button	Designation	Function
	Erase button	Erases the last input.
	Previous image button	Returns to the previous image Note that Inputs/changes made in the current image will not be saved.
	Text mode button	Switches to text input mode.
	Numeric mode button	Switches to the numeric input mode.
	Barcode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

2.3.2 Procedure buttons

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

2.3.3 Other display buttons

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

Button	Designation	Function
	Letter buttons	Allows input of a text Example: To enter a "G" – press once To enter an "H" – press twice To enter an "I"– press three times Only capital letters will be entered. Lower-case letters can be entered into the Analyzer by means of the Barcode Scanner.
	Digit buttons	Allows input of a digit.
	Dilution button*	Allows measurement of a diluted sample. The Dilution button is only displayed if activated in the Settings menu. **only applicable for HemoCue Glucose 201 DM Analyzer* *The Dilution function is not available in all markets.*
Add	Add button	Allows addition of a comment to a result, an item to a list, etc.
Delete	Delete button	Allows deletion of a comment from a result, an item from a list, etc.
Accept	Accept button	Accepts a result. An accepted result will be saved and flagged as accepted.

Button	Designation	Function
Reject	Reject button	Rejects a result. A rejected result will be saved and flagged as rejected.
Save	Save button	Stores the entered information.
No	No button	The entered information will not be stored.
Continue	Continue button	Continues the current operation.
	Statistics button	Displays statitics on the chosen subject.
	Date format button	Switches between the following date formats: • YYMMDD • DD.MM.YY • MM/DD/YY
	Time format button	Switches between the following time formats: • 12 hours • 24 hours
AM/PM	AM/PM button	Enables adding “AM/PM” (only 12-hour format)

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

2.3.5 Entering information with letters and digits

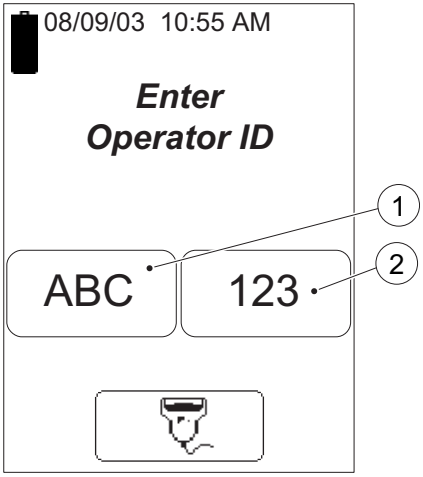


FIGURE 2-25

Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the display or via the Barcode Scanner (see section *2.3.6 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 2-26* or *FIGURE 2-27*.

1 Text mode button
2 Numeric mode button

Text mode

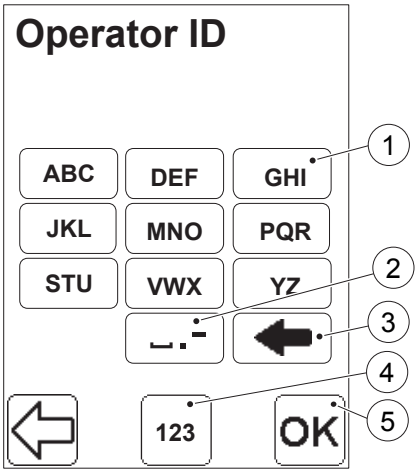


FIGURE 2-26

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

a) In the text mode, inputs are made using the Letter buttons (1) and the Special Character button (2).

b) The Erase button (3) erases the last input.

c) If a digit is to be entered, switch to the numeric input mode by pressing the Numeric mode button (4). *FIGURE 2-27* will be displayed.

d) When all information has been entered, press the Confirm button (5).

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

Numeric mode

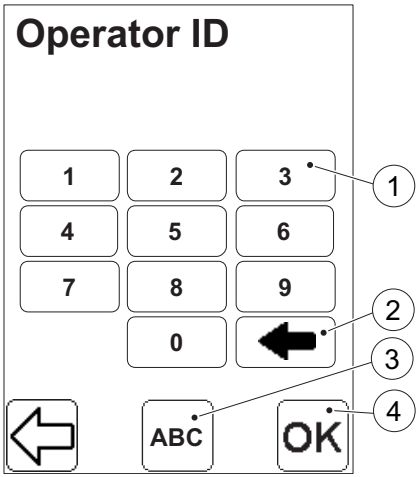


FIGURE 2-27

a) In the numeric mode, inputs are made using the Digit buttons (1).

b) The Erase button (2) erases the last input.

c) If a letter or a special character is to be entered, switch to the text input mode by pressing the Text mode button (3). *FIGURE 2-26* will be displayed.

d) When all information has been entered, press the Confirm button (4).

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

2.3.6 Entering information from barcodes

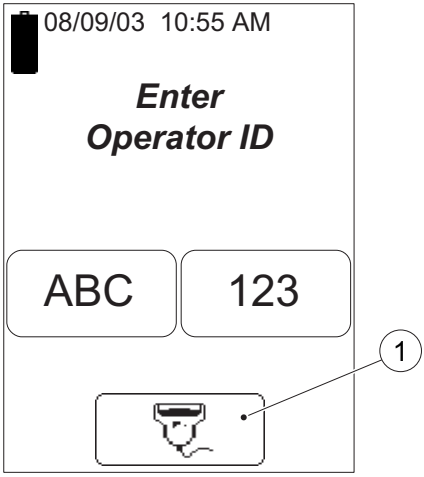


FIGURE 2-28

Inputs to the Analyzer such as Operator ID, Patient ID, etc. can be made via the built-in Barcode Scanner or via the display (see *2.3.5 Entering information with letters and digits*). Use of the Barcode Scanner eliminates manual input errors.

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

For more information on how to use the Barcode Scanner see *Instructions for Use*.

1 Barcode scanner button

PART II
Settings

3 Settings

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

3.1 Activating the Settings procedure

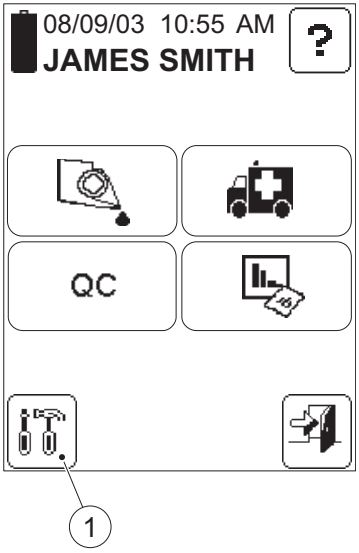


FIGURE 3-1

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 *3.4.1 General Settings*) *FIGURE 3-2* 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 3-3* will be displayed.
If the operator's user level permits access to Settings, *FIGURE 3-4* will be displayed.

1 Settings button

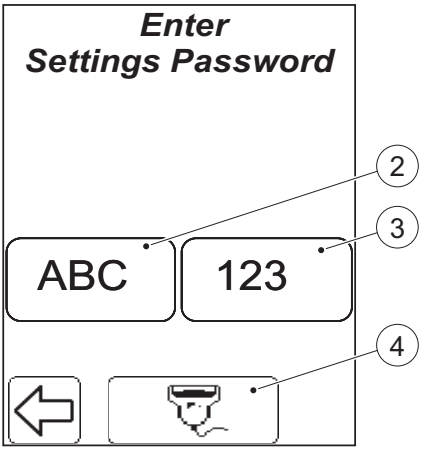


FIGURE 3-2

Only displayed if the Operator ID requirement at startup is set to "Not used" (see *3.4.1 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 3-3* will be displayed.
If the correct password is entered *FIGURE 3-4* will be displayed.

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

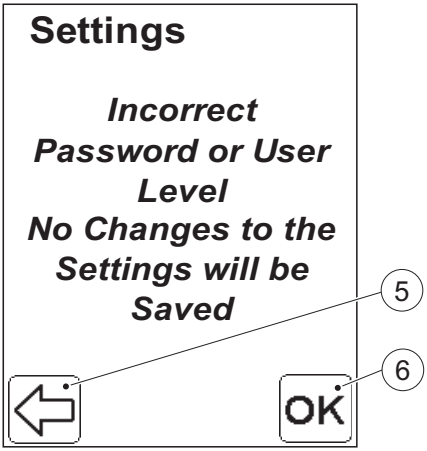


FIGURE 3-3

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 3-2* (if the Operator ID is set to "Not Used").
Pressing the Confirm button (6) allows the Settings to be viewed only. *FIGURE 3-4* will be displayed.

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

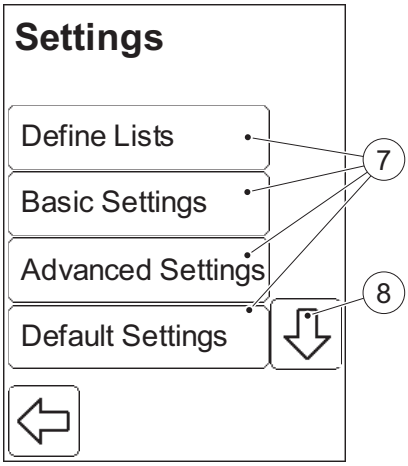


FIGURE 3-4

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

- Define Lists (see *3.2 Define Lists*)
- Basic Settings (see *3.3 Basic Settings*)
- Advanced Settings (see *3.4 Advanced Settings*)
- Default Settings (see *3.5 Default Settings*)
- Infra Red (see *3.6 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

3.2 Define Lists

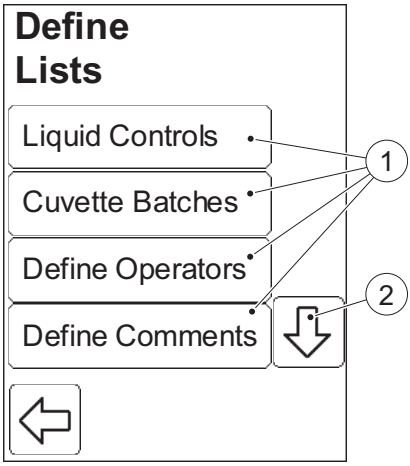


FIGURE 3-5

When the Define Lists button is pressed in the Settings menu (see *FIGURE 3-4*), the following Define Lists categories (1) are displayed:

- Liquid Controls (see *3.2.1 Liquid Controls*)
- Cuvette Batches (see *3.2.2 Cuvette Batches*)
- Define Operators (see *3.2.3 Define Operators*)
- Define Comments (see *3.2.4 Define Comments*)
- Define Log (see *3.2.5 Define Log Notes*)

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

3.2.1 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.

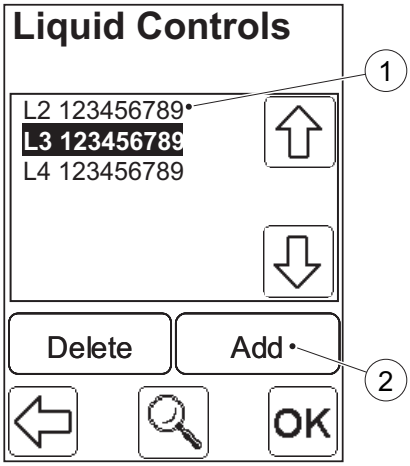


FIGURE 3-6

When the Liquid Controls button is pressed in the Define Lists menu (see *FIGURE 3-5*), the Liquid Controls list (1) is displayed (see *FIGURE 3-6*). 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:

- Level 1
- Level 2
- Level 3
- Level 4
- Level 5

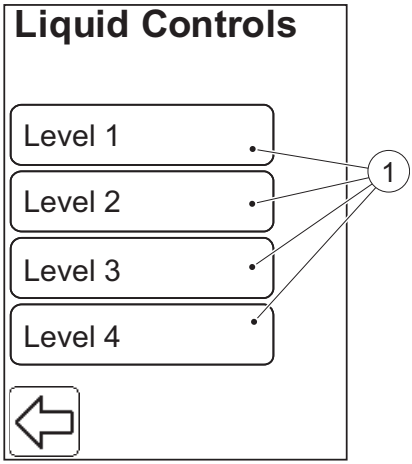


FIGURE 3-7

Level 1, Level 2, Level 3, Level 4 and Level 5 refer to the different concentration levels of Liquid Controls. The settings procedure is the same for all concentration levels. For this reason, only the Level 1 is described.

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

1 Liquid Controls option

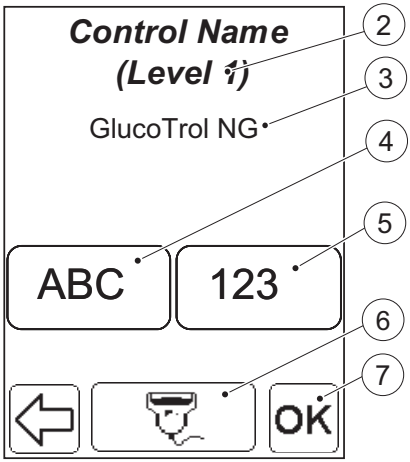


FIGURE 3-8

The control level (2) and the currently used name (3) of the Liquid Control are displayed.

If no information had been entered previously, the Liquid Control name (3) will not appear.

If the Confirm button is repeatedly pressed through *FIGURE 3-8* to *FIGURE 3-11*, no changes will be effected.

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

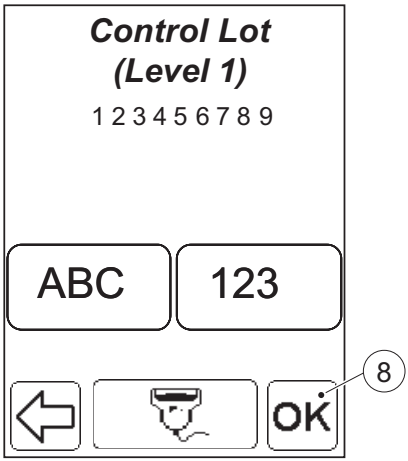


FIGURE 3-9

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

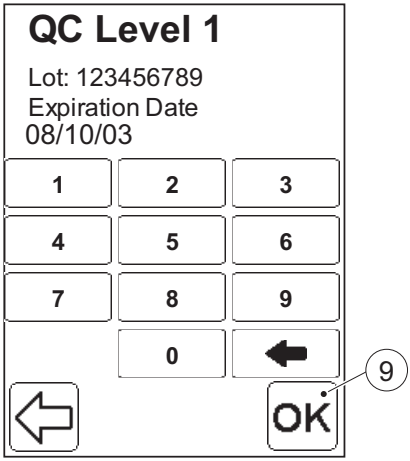


FIGURE 3-10

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

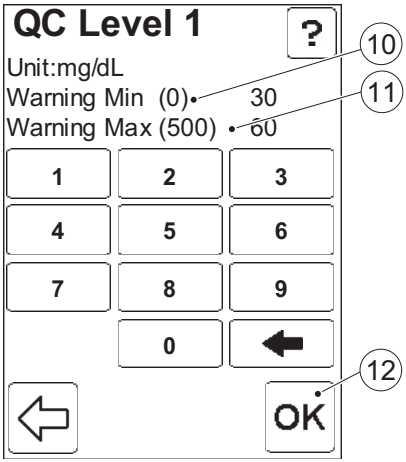


FIGURE 3-11

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

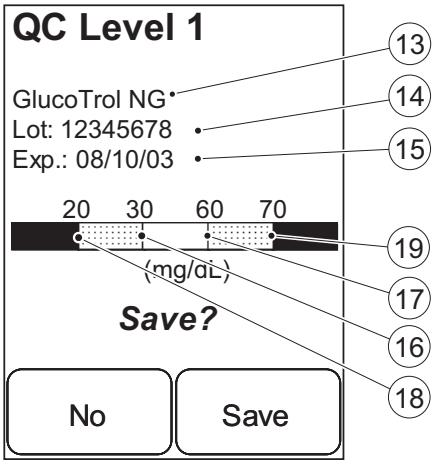
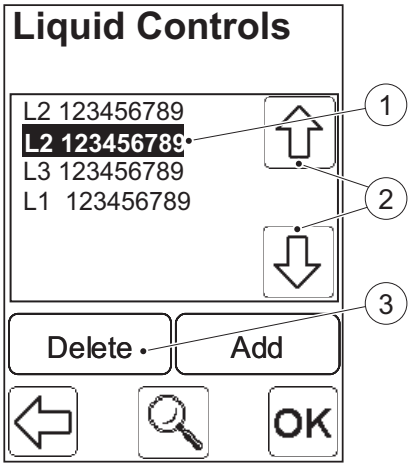


FIGURE 3-12

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



Delete a Liquid Control specification

FIGURE 3-13

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 3-5*).

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

View/Change Liquid Control specification

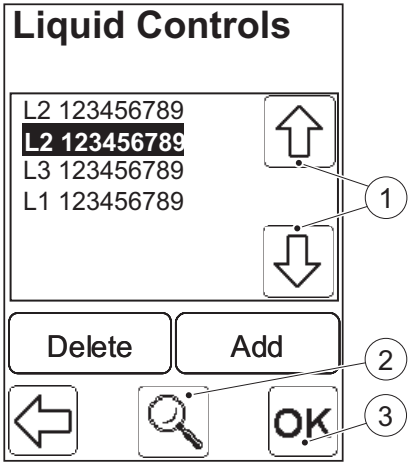


FIGURE 3-14

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 3-8* to *FIGURE 3-12* 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 3-5*).

1 Scroll bar arrows
2 View button
3 Confirm button

3.2.2 Cuvette Batches

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

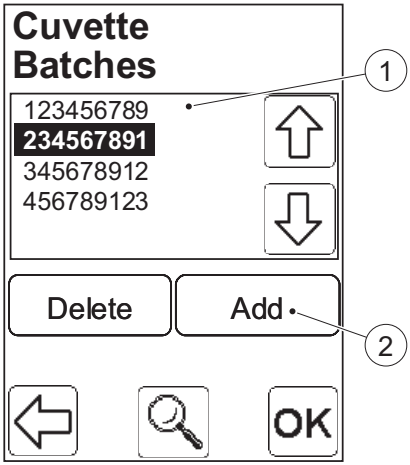


FIGURE 3-15

When the Cuvette Batches button is pressed in the Define Lists menu (see *FIGURE 3-5*), the Cuvette Batch list (1) will be displayed.

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

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

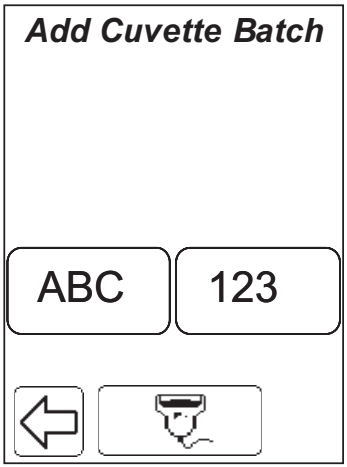


FIGURE 3-16

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 3-18* will be displayed, otherwise *FIGURE 3-17* will be displayed.

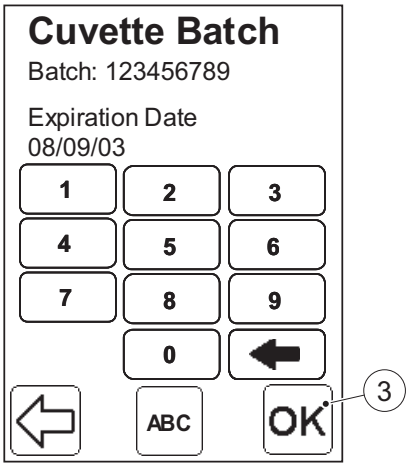


FIGURE 3-17

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 3-18*).

3 Confirm button

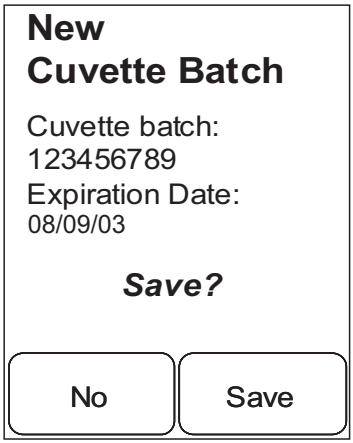
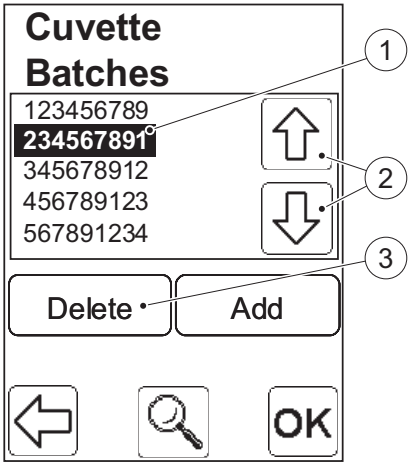


FIGURE 3-18

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 3-5*).



Delete Cuvette Batch Information

FIGURE 3-19

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 3-5*).

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

View Cuvette Batch Information

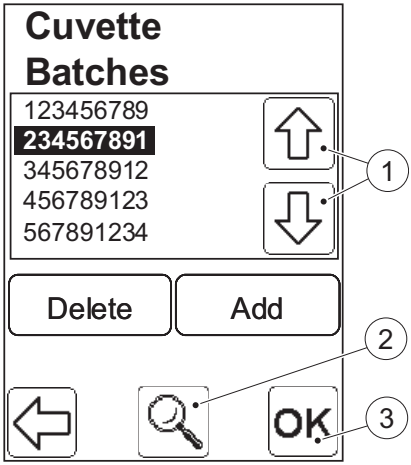


FIGURE 3-20

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 3-5*).

1 Scroll bar arrows
2 View button
3 Confirm button

3.2.3 Define Operators

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

Add Operator

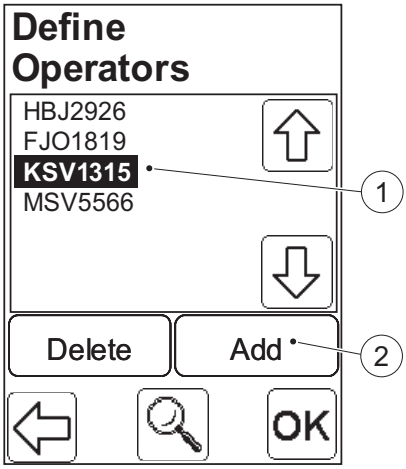


FIGURE 3-21

When the Define Operators button is pressed in the Define Lists menu (see *FIGURE 3-5*), the Define Operators list (1) will be displayed.

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

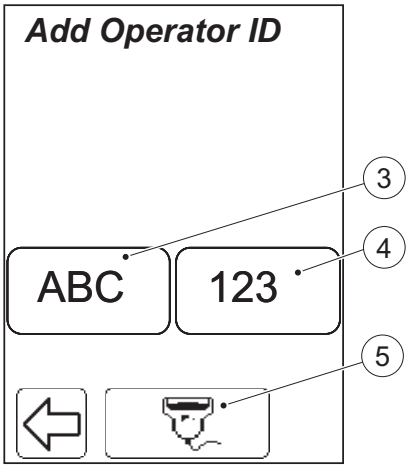


FIGURE 3-22

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

FIGURE 3-23

d) Enter the date from which the Operator will have access to the Analyzer.

e) Press the Confirm button (6). *FIGURE 3-24* will be displayed.

6 Confirm button

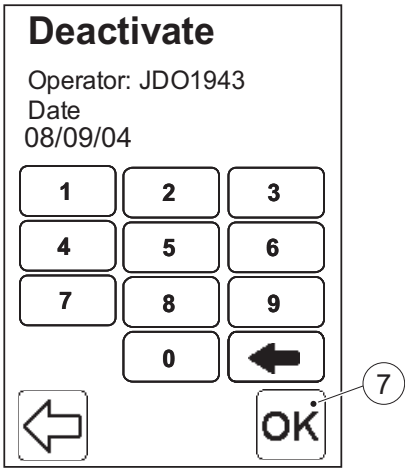


FIGURE 3-24

f) Enter the date after which the Operator will be denied access to the Analyzer.

g) Press the Confirm button (7). *FIGURE 3-26* will be displayed.

7 Confirm button

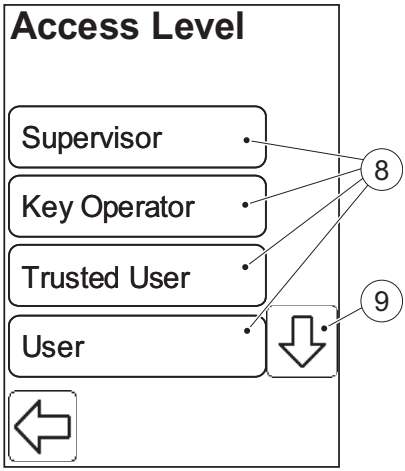


FIGURE 3-25

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.

8 Access Level options
9 Scroll bar arrow

The different Access Levels give the Operator the following authority:

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.

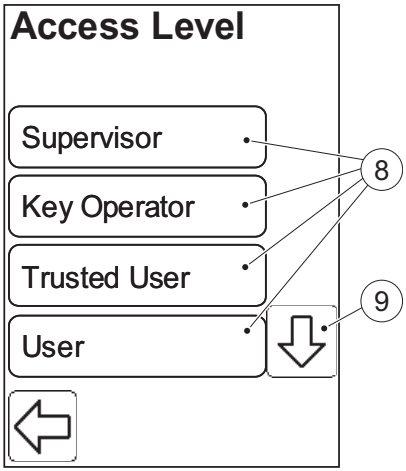
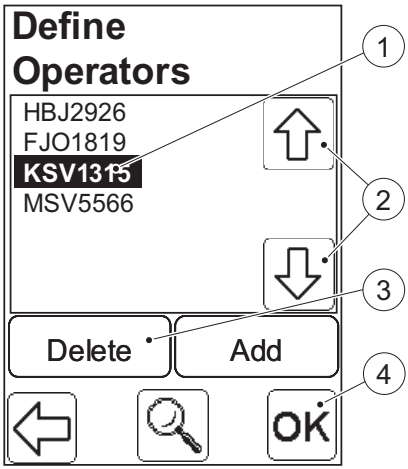


FIGURE 3-26

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 3-5*).



Delete Operator

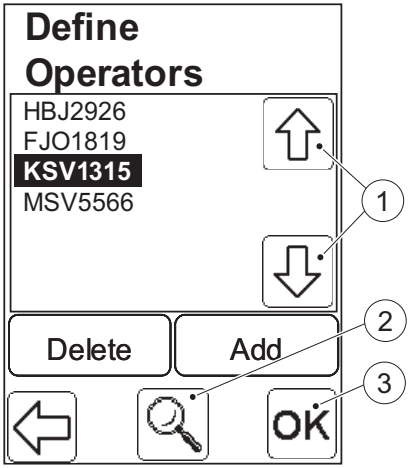
FIGURE 3-27

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 3-5*).

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



View Operator

FIGURE 3-28

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 3-5*).

1 Scroll bar arrows
2 View button
3 Confirm button

3.2.4 Define Comments

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

Add Comment

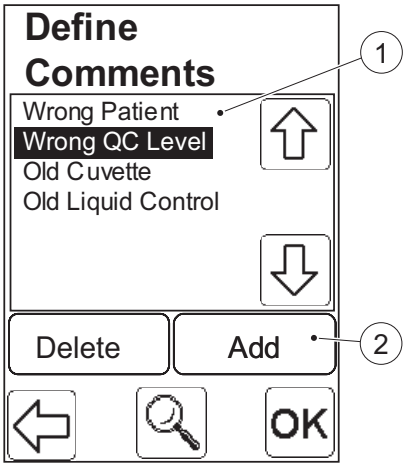


FIGURE 3-29

When the Define Comments button is pressed in the Define Lists menu (see *FIGURE 3-5*), the Define Comments list (1) will be displayed.

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

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

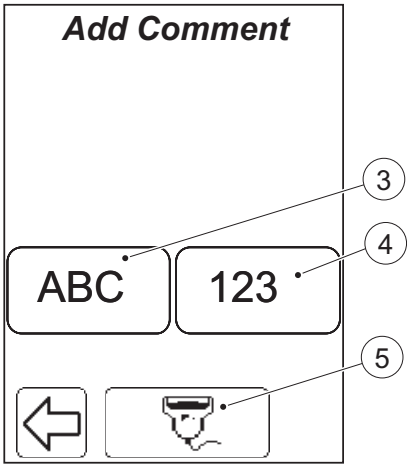
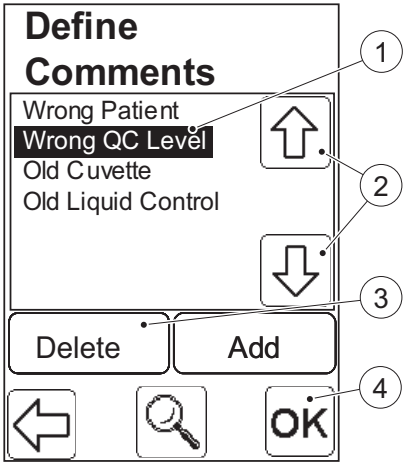


FIGURE 3-30

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 3-5*).

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



Delete Comment

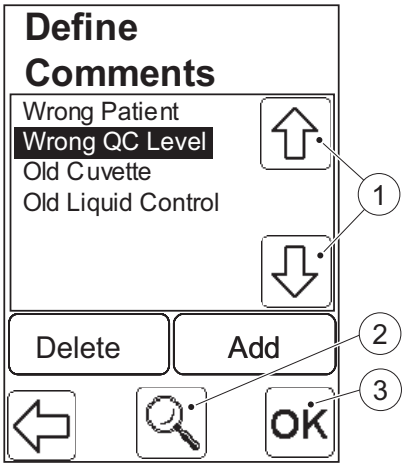
FIGURE 3-31

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 3-5*).

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



View Comment

FIGURE 3-32

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 3-5*).

1 Scroll bar arrows
2 View button
3 Confirm button

3.2.5 Define Log Notes

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

Add Log

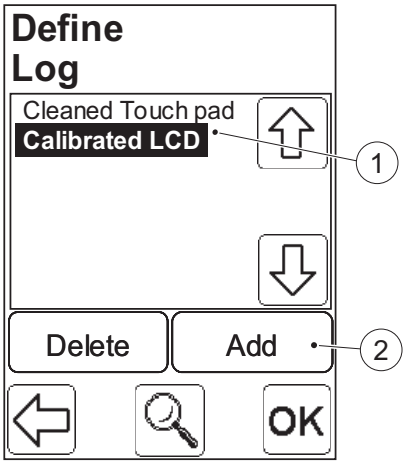


FIGURE 3-33

When the Define Log button is pressed in the Define Lists menu (see *FIGURE 3-5*), the Define Log list (1) will be displayed.

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

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

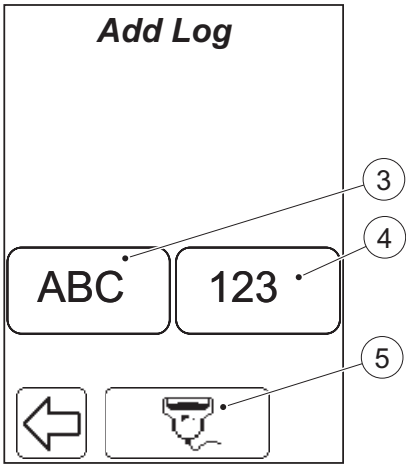
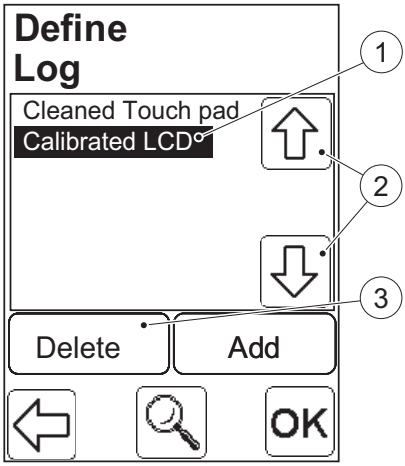


FIGURE 3-34

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 3-5*).

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



Delete Log Notes

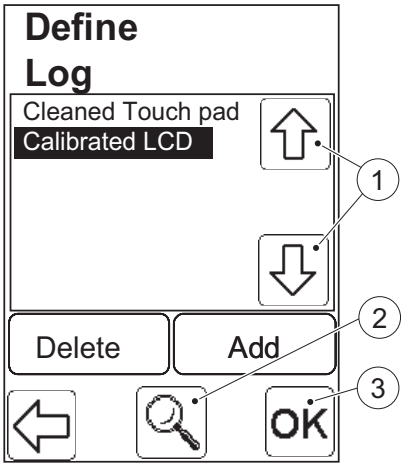
FIGURE 3-35

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 3-5*).

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



View Log

FIGURE 3-36

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 3-5*).

1 Scroll bar arrows
2 View button
3 Confirm button

3.3 Basic Settings

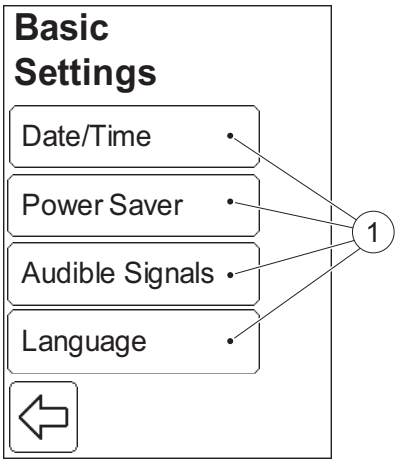


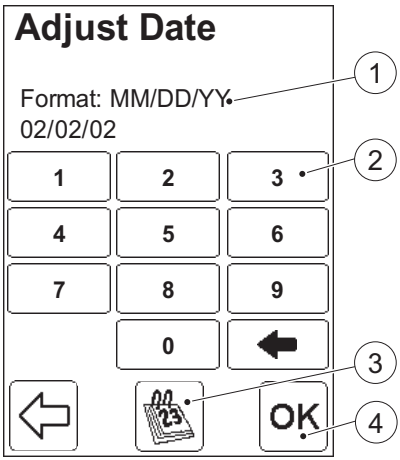
FIGURE 3-37

When the Basic Settings button is pressed in the Settings menu (see *FIGURE 3-4*), the following Basic Settings categories (1) are displayed:

- Date/Time (see *3.3.1 Date/Time*)
- Power Saver (see *3.3.2 Power Saver*)
- Audible Signals (see *3.3.3 Audible Signals*)
- Language (see *3.3.4 Language*)

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

1 Basic Settings categories



3.3.1 Date/Time

FIGURE 3-38

When the Date/Time button is pressed in the Basic Settings menu (see *FIGURE 3-37*), 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 3-39* will be displayed.

---

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

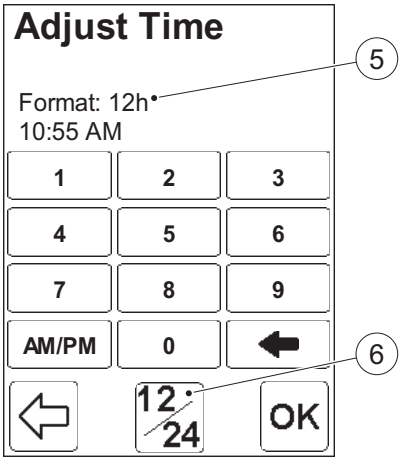


FIGURE 3-39

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

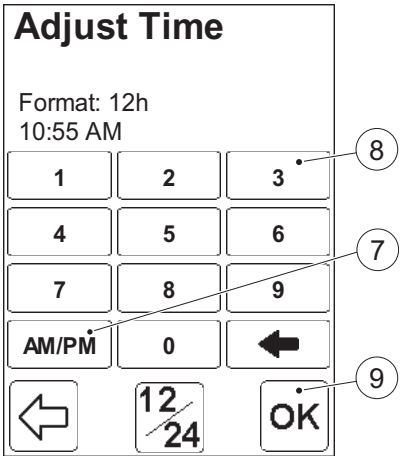


FIGURE 3-40

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

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 3-37*).

7 AM/PM button
8 Digit button
9 Confirm button

3.3.2 Power Saver

A detailed description of the Power Saver mode can bew found in *2.2.4 Power saver mode*.

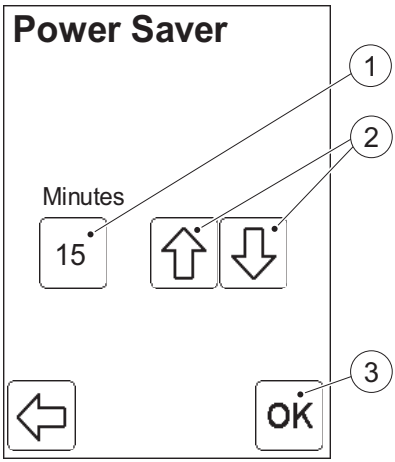


FIGURE 3-41

When the Power Saver button is pressed in the Basic Settings menu (see *FIGURE 3-37*), the Power Saver settings function is displayed.

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

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 3-37*).

1 Power Saver time
2 Scroll bar arrows
3 Confirm button

3.3.3 Audible Signals

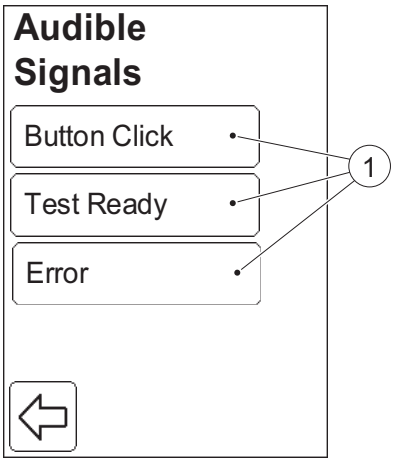


FIGURE 3-42

When the Audible Signals button is pressed in the Basic Settings menu (see *FIGURE 3-37*), 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

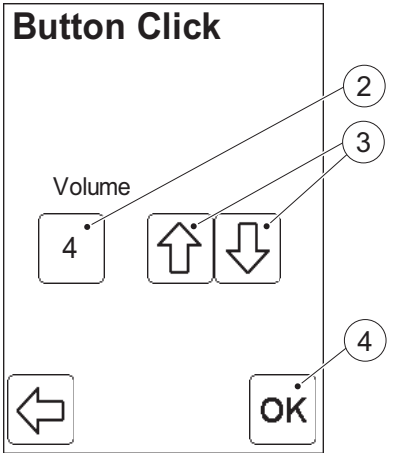


FIGURE 3-43

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

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 3-42*).

2 Volume
3 Scroll bar arrows
4 Confirm button

3.3.4 Language

An Analyzer is delivered with two predefined language options.

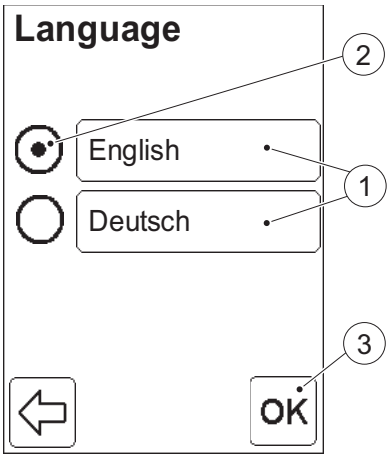


FIGURE 3-44

When the Language button is pressed in the Basic Settings menu (see *FIGURE 3-37*), 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 3-37*).

1 Language buttons
2 Radio button
3 Confirm button

3.4 Advanced Settings

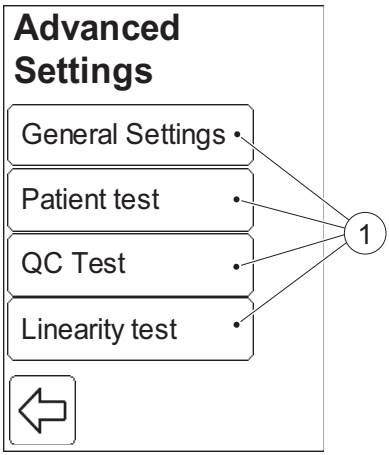


FIGURE 3-45

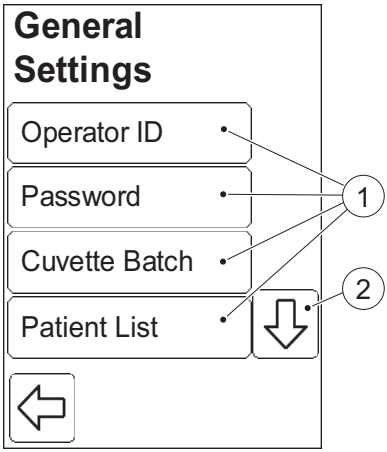
When the Advanced Settings button is pressed in the Settings categories menu (see *FIGURE 3-4*), the following Advanced Settings categories (1) are displayed:

- General Settings (see *3.4.1 General Settings*)
- Patient test (see *3.4.2 Patient Test Settings*)
- QC test (see *3.4.3 QC Test Settings*)
- Linearity test (see *3.4.4 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



3.4.1 General Settings

FIGURE 3-46

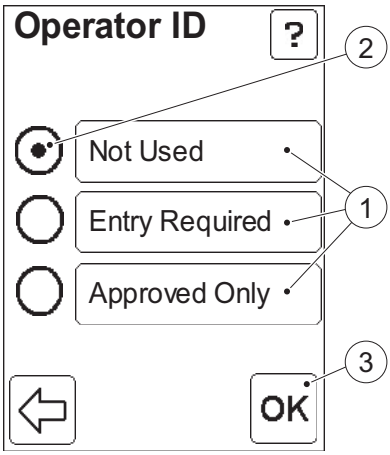
When the General Settings button is pressed in the Advanced Settings menu (see *FIGURE 3-45*), the following General Settings categories are displayed:

- Operator ID (See *FIGURE 3-47*)
- Password (See *FIGURE 3-49*)
- Cuvette Batch (See *FIGURE 3-51*)
- Patient List (See *FIGURE 3-52*)
- Memory (See *FIGURE 3-53*)

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



Operator ID requirement

FIGURE 3-47

When the Operator ID button is pressed in the General Settings menu (see *FIGURE 3-46*), 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 4-49*).

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 3-22*).

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.

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

If *Entry Required* or *Approved Only* was selected, *FIGURE 3-48* will be displayed for setting the Operator ID specifications.
If *Not Used* was selected, the General Settings menu, *FIGURE 3-46*, will be displayed.

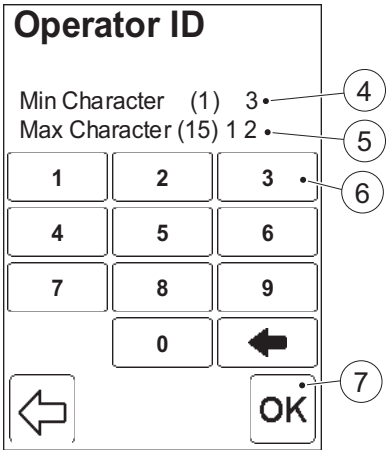


FIGURE 3-48

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

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 3-46* 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".

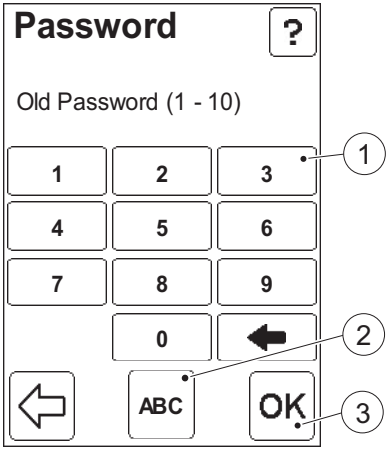


FIGURE 3-49

When the Password button is pressed in the General Settings menu (see *FIGURE 3-46*), the settings for Password are displayed.

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

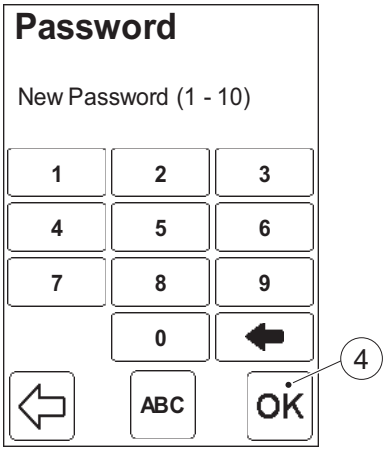


FIGURE 3-50

c) Enter the New Password.

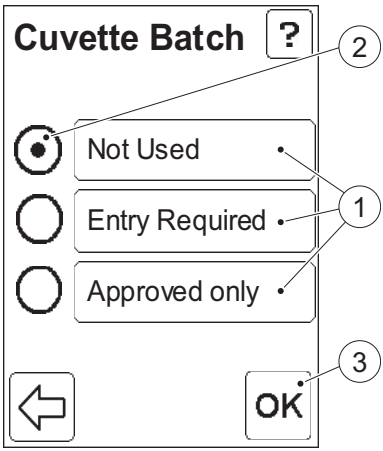
d) Press the Confirm button (4).

e) *FIGURE 3-50* 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 3-46*).

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 3-51

When the Cuvette Batch button is pressed in the General Settings menu (see *FIGURE 3-46*), 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 3-46*.

---

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 Analyzer, the Analyzer can display the name of a patient after the patient ID has been entered, allowing for positive patient identification.

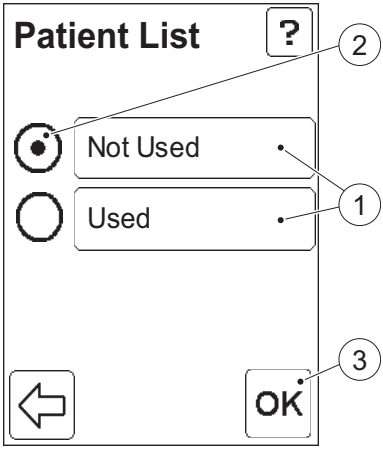


FIGURE 3-52

When the Patient List button is pressed in the General Settings menu (see *FIGURE 3-46*), 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).

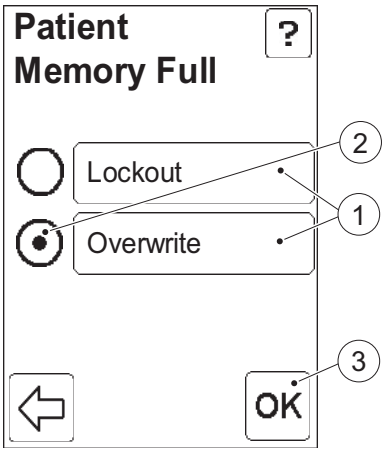
Not Used: The Patient List feature is not used.

Used: The Patient List feature is used when running a Patient test. See chapter *4 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 3-46*.

1 Options for Patient List
2 Selected option
3 Confirm button



Full Memory Options

FIGURE 3-53

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 3-46*), 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 3-54* will be displayed.

1 Full Memory options
2 Selected option
3 Confirm button

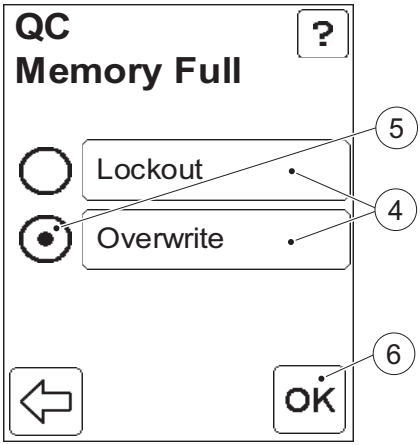


FIGURE 3-54

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 3-46*.

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

3.4.2 Patient Test Settings

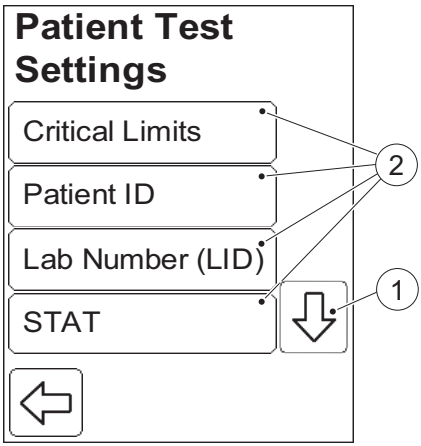


FIGURE 3-55

When the Patient test button is pressed in the Advanced Settings menu (see *FIGURE 3-45*), the following Patient Test Settings categories are displayed:

- Critical Limits (see *FIGURE 3-56*)
- Patient ID (see *FIGURE 3-57*)
- Lab Number (LID) (see *FIGURE 3-60*)
- STAT (see *FIGURE 3-62*)
- Duplicate Sampling (see *FIGURE 3-64*)
- Dilution (see *FIGURE 3-66)**

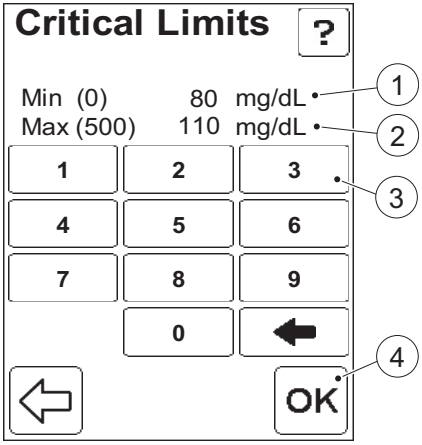
a) Press the Scroll bar arrow (1) to view categories not initially visible on the display.

b) Select a Patient Test Settings category (2) by pressing it.

---

1 Scroll bar arrow
2 Patient Test Settings categories

** Only available for HemoCue Glucose 201 DM Analyzer. The Dilution function is not available in all markets.*



Critical Limits

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

FIGURE 3-56

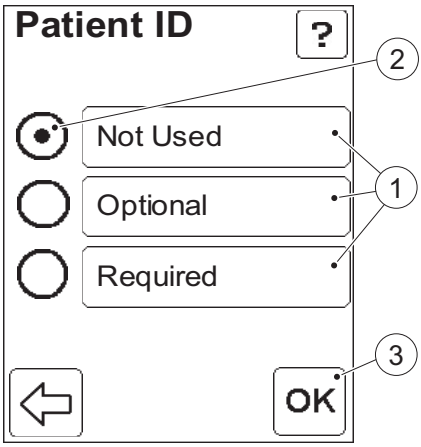
When the Critical Limits button is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), the settings for Critical Limits are displayed.

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 3-55*, will be displayed.

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



Patient ID

FIGURE 3-57

When the Patient ID button is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), 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

If *Optional* or *Required* was selected, *FIGURE 3-58* will be displayed for setting the Patient ID specifications.

If *Not Used* was selected, the General Settings menu, *FIGURE 3-55*, will be displayed.

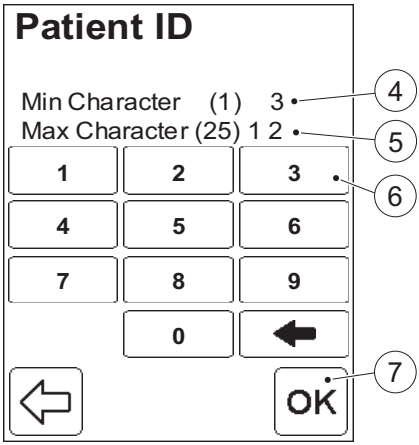


FIGURE 3-58

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 3-59, will be displayed.

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

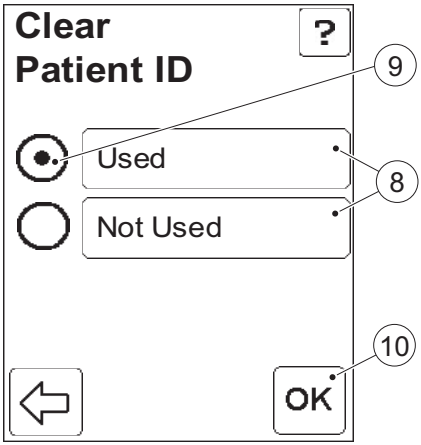


FIGURE 3-59

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).

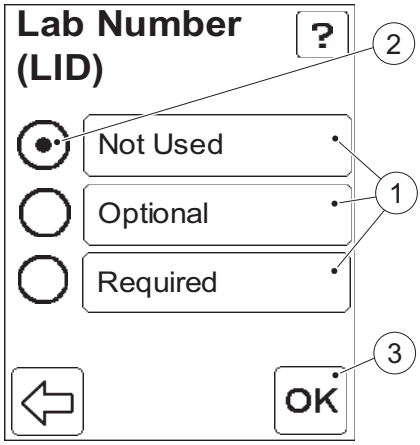
Used: The previous Patient ID will be cleared when a new test is initiated.

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 3-55*).

8 Clear Patient ID options
9 Selected option
10 Confirm button



Lab Number (LID) requirement

FIGURE 3-60

When the Lab Number (LID) button is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), 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

If *Optional* was selected, *FIGURE 3-61* will be displayed for setting the Lab Number specifications.
If *Not Used* was selected, the Patient Test Settings menu, *FIGURE 3-55*, will be displayed.

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

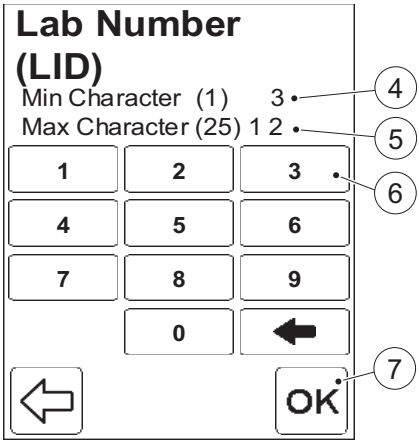


FIGURE 3-61

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 3-55*, will be displayed.

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

STAT Test usage

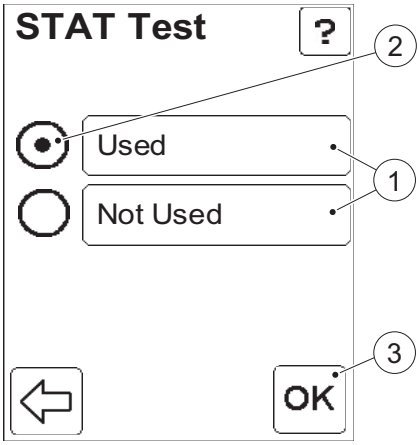


FIGURE 3-62

When the STAT button is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), 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

If *Used* was selected, *FIGURE 3-63* will be displayed for setting the STAT Test specifications.
If *Not Used* was selected, the General Settings menu, *FIGURE 3-55*, will be displayed.

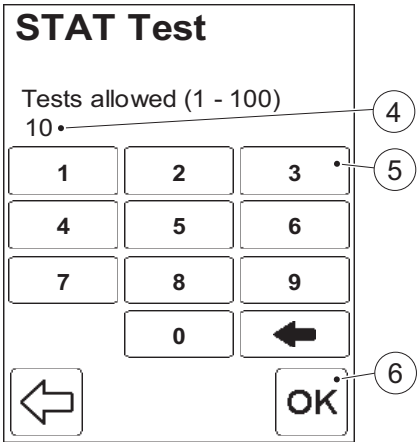


FIGURE 3-63

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 3-55*, will be displayed.

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

Duplicate sampling

In order to minimize errors due to preanalytical factors, local recommendations might involve measurements in duplicates when capillary blood is used. The Duplicate sampling function is used to facilitate these recommendations.

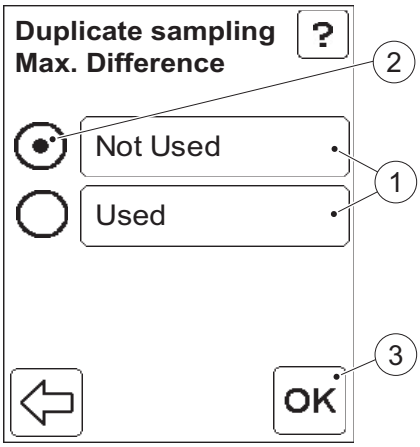


FIGURE 3-64

When Duplicate sampling is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), the setting to enable the use of the duplicate sampling function is 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 duplicate sampling function is not activated on the Analyzer.

Used: The duplicate sampling function is activated on the Analyzer.

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

b) Press the Confirm button (3).

1 Options for duplicate sampling function
2 Selected option
3 Confirm button

If *Used* was selected, *FIGURE 3-65* will be displayed for setting the Duplicate Sampling specifications.
If *Not Used* was selected, the General Settings menu, *FIGURE 3-55*, will be displayed.

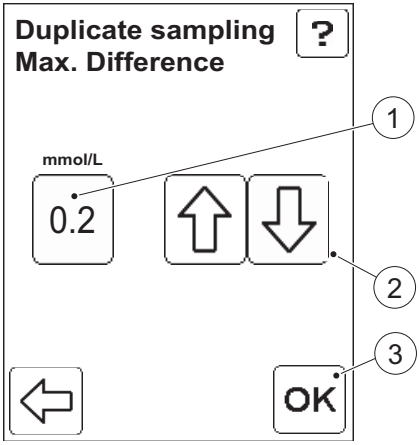


FIGURE 3-65

c) To change the maximum difference allowed between two samples (1), press the arrows (2) for the desired value.

d) Press the Confirm button (3) to return to the Patient Test Settings menu, *FIGURE 3-55*.

1 Max. allowed difference between samples
2 Arrows for increasing/decreasing the Difference
3 Confirm button

Dilution possibilities

Dilution function is only applicable for HemoCue Glucose 201 DM Analyzer. The function is not available in all markets.

Whole Blood: Results above 400 mg/dL (22.2 mmol/L) will be displayed as overrange. The measuring range may be extended to 800 mg/dL (44.4 mmol/L) by dilution with saline, 1+1.

Plasma equivalent: Results above 444 mg/dL (24.6 mmol/L) will be displayed as overrange. The measuring range may be extended to 888 mg/dL (49.2 mmol/L) by dilution with saline, 1+1.

Samples must be mixed thoroughly before dilution and measurement.

By using the dilution function in the Analyzer, the stored and displayed result will automatically be multiplied by a factor of 2.

Dilution of the sample may reduce the accuracy of the result.

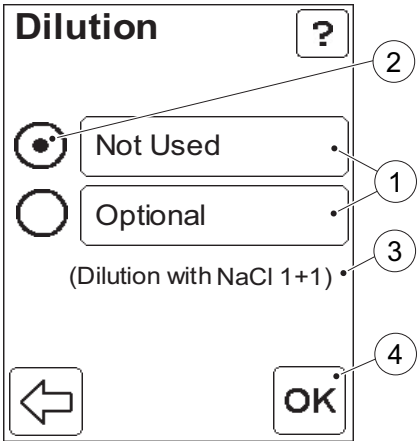


FIGURE 3-66

When the Dilution button is pressed in the Patient Test Settings menu (see *FIGURE 3-55*), the setting to enable the use of diluted samples is displayed.

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

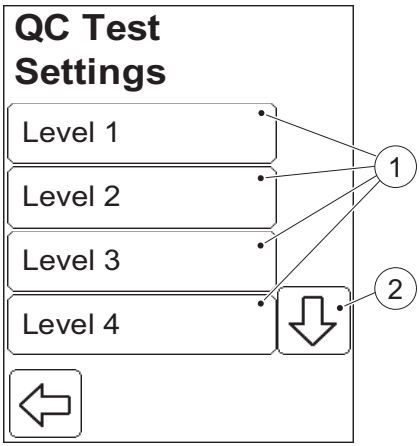
Not Used : The dilution function cannot be activated on the Analyzer.

Optional : The dilution function can be activated on the Analyzer.

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

b) Press the Confirm button (4) to return to the Patient Test Settings menu, *FIGURE 3-55*.

1 Options for dilution function
2 Selected option
3 Explanation of the type of dilution possible
4 Confirm button



3.4.3 QC Test Settings

FIGURE 3-67

When the QC test button is pressed in the Advanced Settings menu (see *FIGURE 3-45*), the following QC Test Settings options are displayed:

- Level 1 (see *FIGURE 3-68*)
- Level 2
- Level 3
- Level 4
- Level 5
- Reminder Time (see *FIGURE 3-76*)
- QC Result Options (see *FIGURE 3-78*)
- Failed QC Comment (see *FIGURE 3-79*)

Level 1, Level 2, Level 3, Level 4 and Level 5, 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.

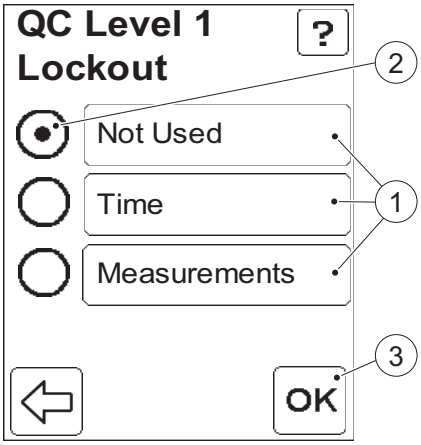


FIGURE 3-68

When the Level 1 button is pressed in the QC Test Settings menu (see *FIGURE 3-67*), 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.

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

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

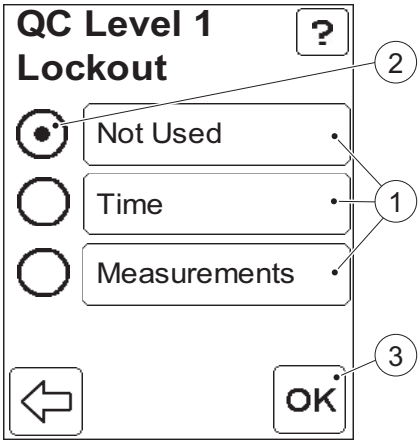


FIGURE 3-69

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 3-67*, is displayed.

If "Time" is selected, *FIGURE 3-70*, is displayed.

If "Measurements" is selected, *FIGURE 3-74*, is displayed.

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

QC lockout determined by time

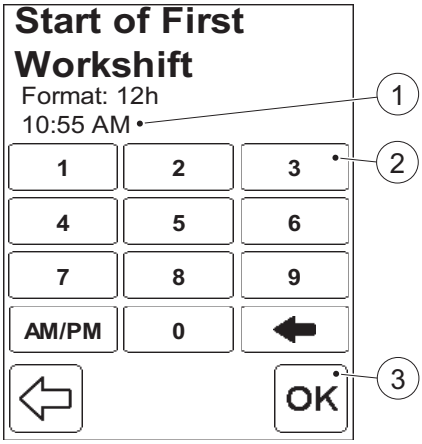


FIGURE 3-70

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

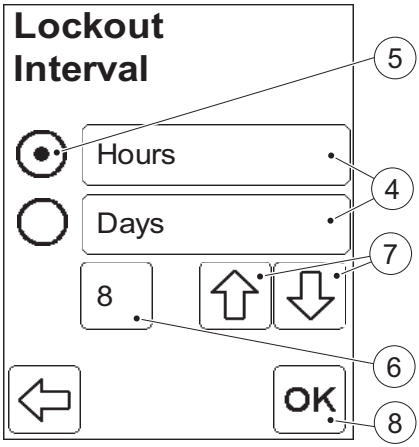


FIGURE 3-71

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 3-72* will be displayed.
Otherwise *FIGURE 3-73* will be displayed.

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

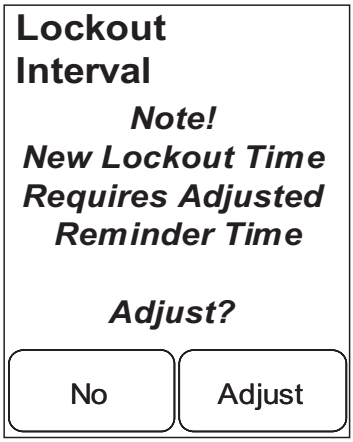


FIGURE 3-72

d) To adjust the reminder time to fit the new QC lockout time, press Adjust. After adjusting to an acceptable reminder time (see *FIGURE 3-76*), *FIGURE 3-73* will be displayed.
To return to *FIGURE 3-71*, press No. The selected time interval until the next QC lockout will then need to be adjusted.

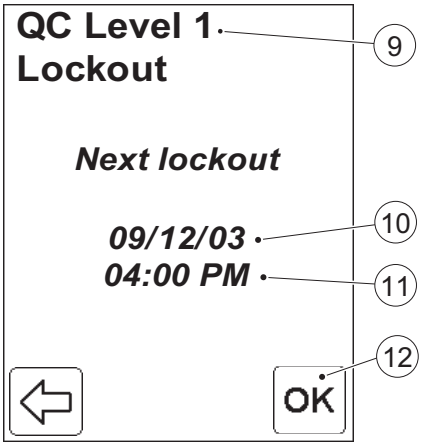
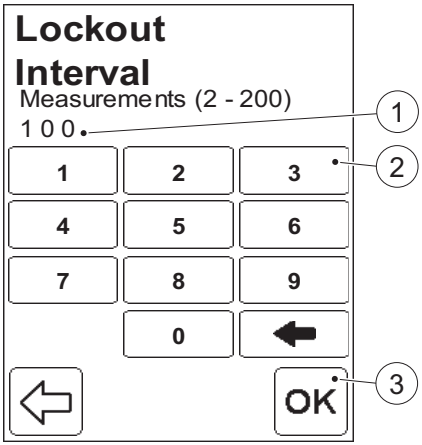


FIGURE 3-73

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 3-67*.

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 3-74

If Measurements was selected in the QC lockout menu (see *FIGURE 3-68*), the setting for the QC lockout based on the number of patient or STAT test measurements performed is displayed.

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 3-75* will be displayed. Otherwise there will be a return to *FIGURE 3-67*.

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

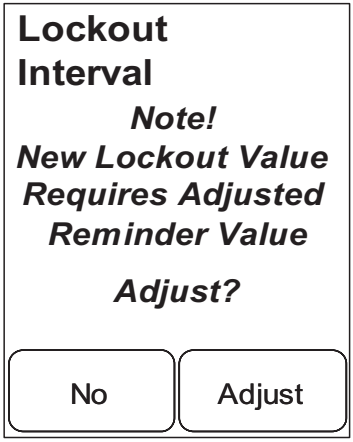
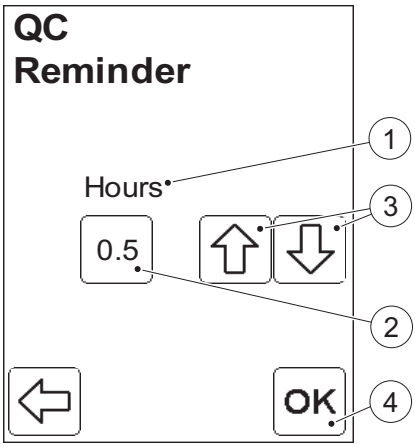


FIGURE 3-75

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 3-77*), there will be a return to the QC Test Settings menu, *FIGURE 3-67*.

Otherwise, to return to *FIGURE 3-74*, 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 3-76

When the Reminder Time button is pressed in the QC Test menu (see *FIGURE 3-67*), 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).

To turn the Reminder Time function off, set the value (2) to "0".

b) Press the Confirm button (4). *FIGURE 3-78* will be displayed.

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

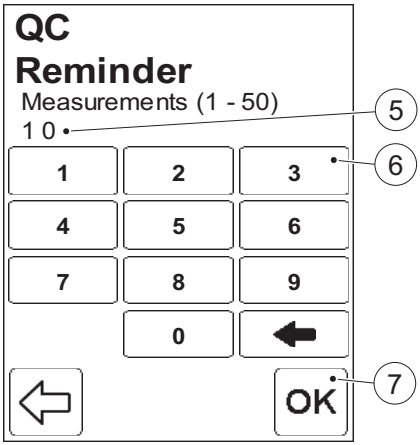


FIGURE 3-77

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.

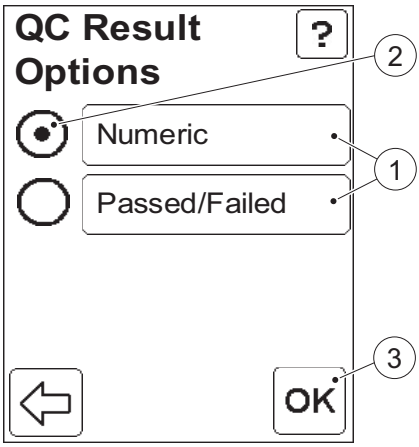
The number of measurements for this reminder can be set to no more than half the lowest number of measurements, irrespective as to which level this refers.

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 3-67* will be displayed.

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



QC Result Presentation Options

FIGURE 3-78

When the QC Result Option button is pressed in the QC Test menu (see *FIGURE 3-67*), 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 3-67*.

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

Failed QC Comment

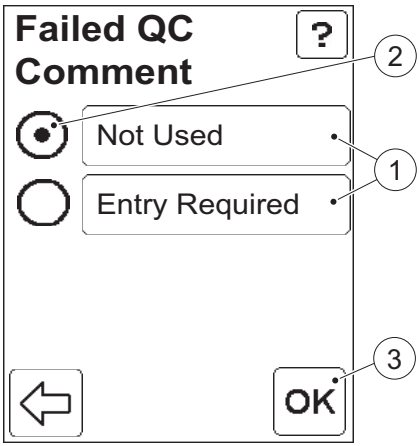


FIGURE 3-79

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 3-67*.

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

3.4.4 Linearity Test Settings

For a description of linearity tests, see *6.2.2 Linearity Test*.

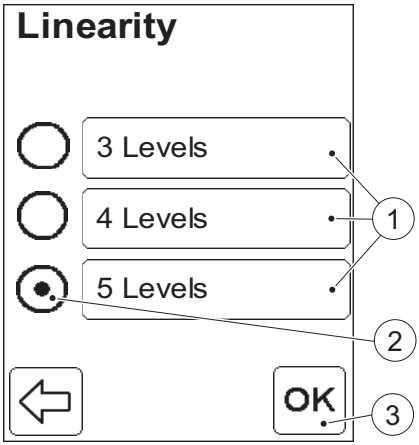


FIGURE 3-80

When the Linearity test button is pressed in the Advanced Settings menu (see *FIGURE 3-45*), 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 3-81* will be displayed.

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

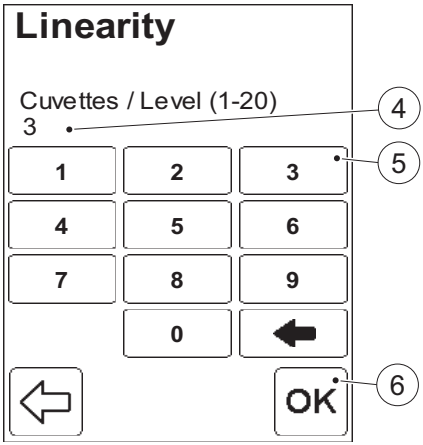


FIGURE 3-81

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 3-45* will be displayed.

4 Number of Cuvettes per level
5 Digit button
6 Confirm button

3.5 Default Settings

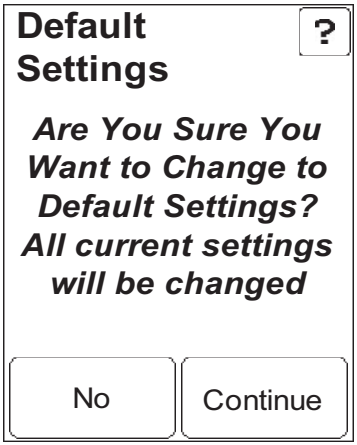


FIGURE 3-82

When the Default Settings button is pressed in the Settings menu (see *FIGURE 3-4*), confirmation or cancellation of the requested change to the Analyzer default setting is required. A question will be displayed.

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 3-4* will be displayed.

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 3-4*, will be displayed again.

3.6 Infra Red

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

3.6.1 The transmitting Analyzer

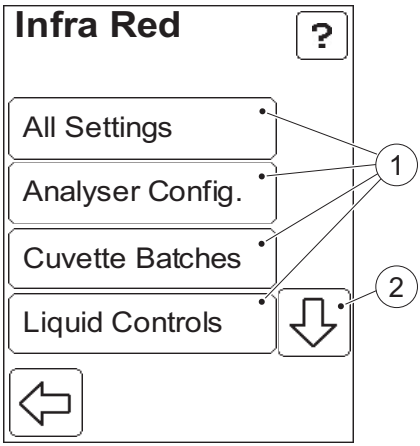


FIGURE 3-83

When the Infra Red button is pressed in the Settings menu (see *FIGURE 3-4*), the categories (1) that can be transferred are displayed

- All Settings (include all the categories in the rest of the options)
- Analyzer Configuration (see *3.3 Basic Settings* and *3.4 Advanced Settings*)
- Cuvette Batches (see *3.2.2 Cuvette Batches*)
- Liquid Controls (see *3.2.1 Liquid Controls*)
- Operator List (see *3.2.3 Define Operators*)
- Comment List (see *3.2.4 Define Comments*)
- Log List (see *3.2.5 Define Log Notes*)

1 Settings options
2 Scroll bar arrow

All options are transfered 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 transfered by pressing the corresponding button.

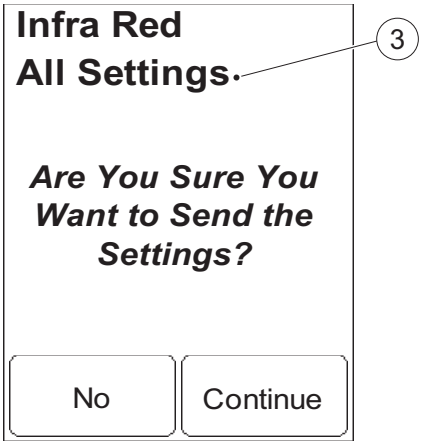


FIGURE 3-84

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

e) If a connection was established successfully and the transfer was accepted by the receiving Analyzer (see *FIGURE 3-85*), 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 3-83 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 section *Troubleshooting*.
Press the Confirm button.
FIGURE 3-83 will be displayed.

3.6.2 The Receiving Analyzer

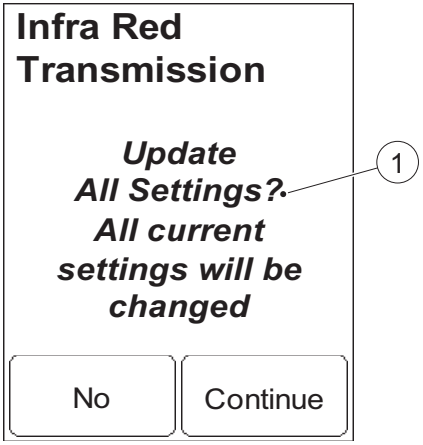


FIGURE 3-85

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

3.7 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 a software application. In order to perform the settings, the Docking Station must be connected to the PC hosting the DMS Software or the PDS Configuration Tool, see section *8.2 Docking station setup*.

PART III
Routine use

4 Patient Test procedure

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

4.1 Patient Test

The Patient Test procedure may vary, depending on which information requirements have been activated in the Settings, see section *3.4.2 Patient Test Settings*. The following information may be required:

- Cuvette Batch No.
- Patient ID
- Lab ID

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

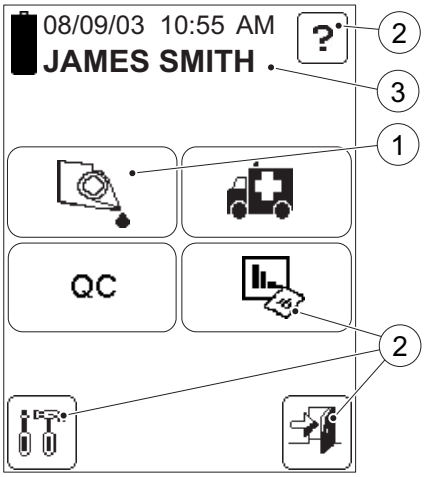


FIGURE 4-1

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

b) *FIGURE 4-2* will be displayed.

1 Patient Test button
2 If the small hourglass is displayed only these buttons can be used.
3 Operator name, Operator ID or blank, depending on the settings

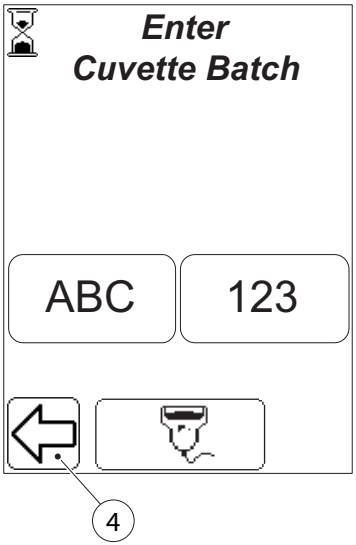


FIGURE 4-2

Note that *FIGURE 4-2* will not be displayed if the Cuvette Batch No. requirement is set to "Not Used" in the Settings (see *3.4.1 General Settings*).

c) 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.

If Cuvette Batch No. requirement is set to *Entry required* (see *3.4.1 General Settings*), and a Cuvette Batch No. that has not previously been stored in the Analyzer (see *3.2.2 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 *2.2.3 Main Menu and Help*).

d) If Cuvette Batch No. requirement is set to *Entry required* (see *3.4.1 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 4-4* will be displayed. Otherwise *FIGURE 4-3* will be displayed.

---

4 Previous image button

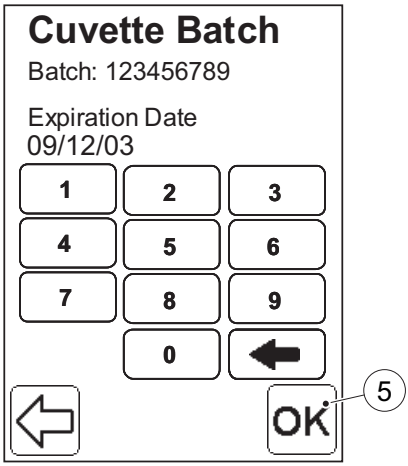


FIGURE 4-3

This will only be displayed if the Cuvette Batch No. requirement when inserting a Cuvette is set to "Entry required" (see *3.4.1 General Settings*), and Cuvette Batch No. was not entered via the Barcode Scanner using the barcode from Cuvette vial.

e) Enter the Expiration Date for the Cuvette Batch via the Numeric mode buttons.

f) Press the Confirm button (5).

5 Confirm button

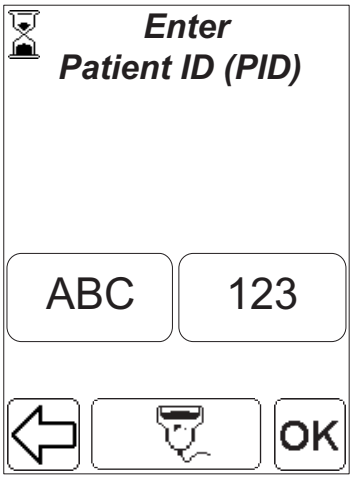


FIGURE 4-4

This will not be displayed if the Patient ID requirement is set to "Not Used" (see *3.4.2 Patient Test Settings*).

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

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

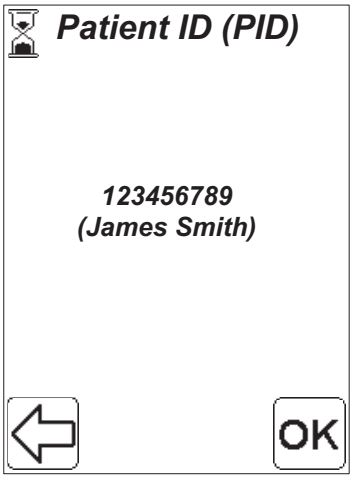


FIGURE 4-5

This will not be displayed if the Patient List setting is set to "Not Used" (see *3.4.1 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.

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

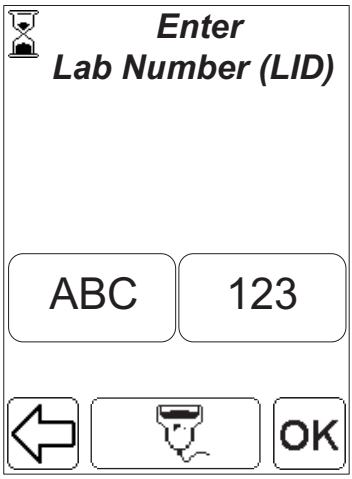


FIGURE 4-6

This will not be displayed if the Lab ID requirement is set to "Not Used" (see *3.4.2 Patient Test Settings*).

i) 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.

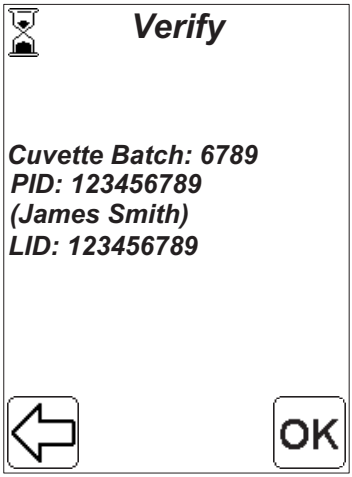


FIGURE 4-7

j) 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.

For a diluted sample follow *FIGURE 4-9* , otherwise continue with step k).

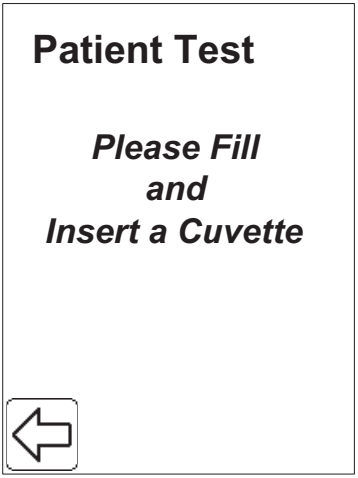


FIGURE 4-8

k) Obtain a blood sample according to the procedure described in relevant *Instructions for Use*.

l) Place the filled Cuvette in the Cuvette holder and gently insert it into the measuring position.

m) When the measurement is ready, *FIGURE 4-11* will be displayed.

Diluted sample

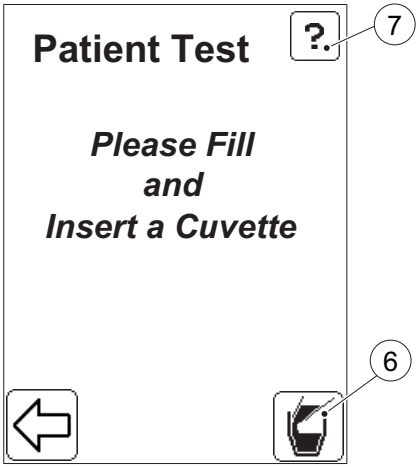


FIGURE 4-9

Dilution function is only applicable for HemoCue Glucose 201 DM Analyzer.

The function is not available in all markets.

Note that the Dilution button (6) and the Help button (7) will only be displayed if the dilution option has been chosen (see section *3 Settings*).

For the Dilution function the sample must be diluted with NaCl (Saline), one part blood and one part NaCl.

n) If the sample is diluted, press the Dilution button (6). *FIGURE 4-10* will be displayed.

6 Dilution button
7 Help button

FIGURE 4-10

o) Confirm with Yes or No. *FIGURE 4-9* will then be displayed again.

p) Obtain a blood sample according to the procedure described in relevant *Instructions for Use*.

q) Place the filled Cuvette in the Cuvette holder and gently insert it into the measuring position.

r) When the measurement is ready, *FIGURE 4-11* will be displayed.

4.1.1 Patient Test Result

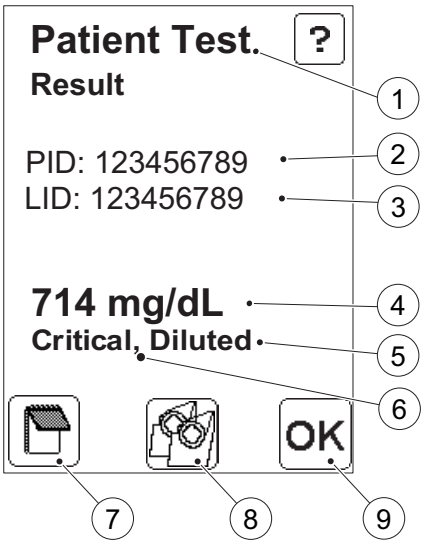


FIGURE 4-11

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

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

The Note (6) **Critical** will be displayed if the result is outside the critical limits that are defined in the Settings (see *3.4.2 Patient Test Settings*).

The Comment **Diluted** (5) will automatically be displayed and added to the results Comment list (see *4.1.3 Entering Comments*) if the sample was diluted and the result was calculated.

1 Type of test
2 Patient ID
3 Lab Number ID
4 Result
5 Comment to mark diluted sample
6 Critical Note
7 Comment input button
8 Verify/Duplicate sampling button
9 Confirm button

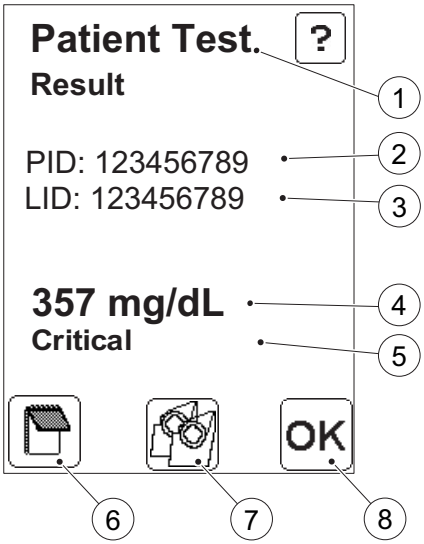


FIGURE 4-12

To add comments to the result, press the Comment input button (6). See *4.1.3 Entering Comments*.

The Verify/Duplicate sampling button (7) allows the verification of the result by measuring a new sample from the patient (see *4.1.2 Verify/Duplicate sampling*).

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

Never re-measure a Cuvette!

a) Press the Confirm button (8) to store the information.
   The Main Menu, *FIGURE 4-1* will be displayed.

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/Duplicate sampling button
8 Confirm button

4.1.2 Verify/Duplicate sampling

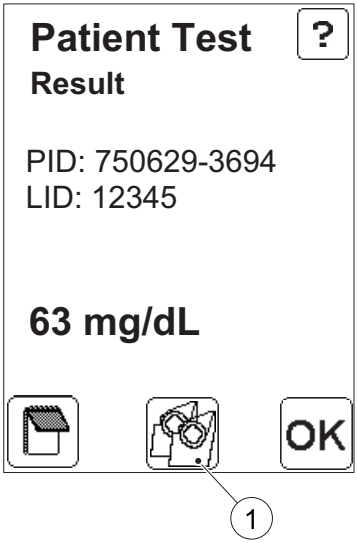


FIGURE 4-13

Results may be verified by obtaining a second sample from the same patient and performing a new measurement. Depending on whether the Duplicate sampling function (see *Duplicate sampling*) has been activated or not the outcome of this procedure may vary.

Never re-measure a Cuvette!

a) When the first result is displayed, press the Verify/Duplicate Sampling button (1). *FIGURE 4-14* will be displayed.

1 Verify/Duplicate sampling button

FIGURE 4-14

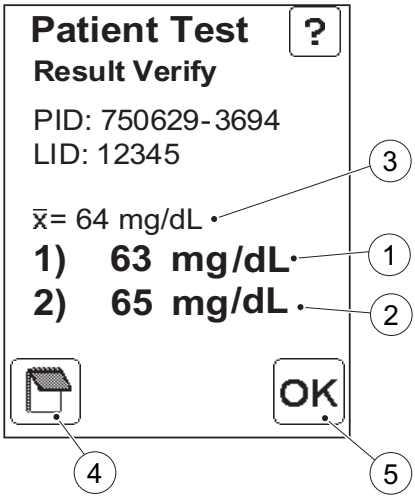
b) Accept the information for the new measurement by pressing the Confirm button (2).

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 4-15*.

2 Confirm button



Result Verification

FIGURE 4-15

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

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

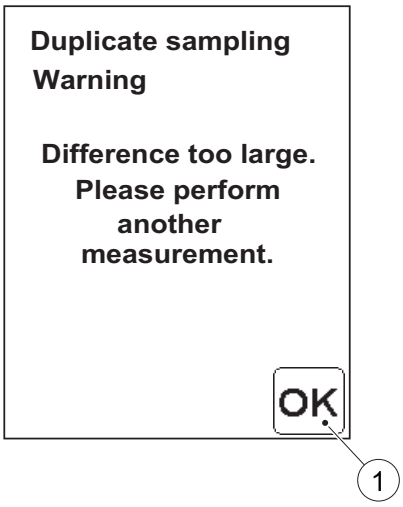
$\bar{x}$ indicates the Mean value (3) for these two measurements.

If the Duplicate sampling function is used and the two results differ more than the maximum difference set in the settings (see *FIGURE 3-65*), the results will automatically be rejected and instead of the mean value the following text will be displayed *Difference too large*.

When the confirm button is pressed *FIGURE 4-16* is displayed. When pressing the confirm button (1) in *FIGURE 4-16* the Main Menu will be displayed.

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

FIGURE 4-16



When the Duplicate sampling function is used, predefined comments will automatically be added to the two results, pairing them together. This will enable OR's to see that the two results belong together and make it possible to calculate a mean value.

To add comments, press the Comment input button (4), see *4.1.4 Entering Comments – Verified sample*.

a) Press the Confirm button (5) to store the information.
   The Main Menu, *FIGURE 4-1* will be displayed.

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.

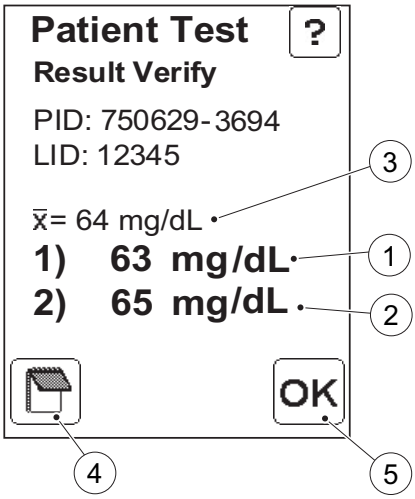


FIGURE 4-17

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 *4.1.4 Entering Comments – Verified sample*.

b) Press the Confirm button (5) to store the information.
   The Main Menu, *FIGURE 4-1* will be displayed.

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

4.1.3 Entering Comments

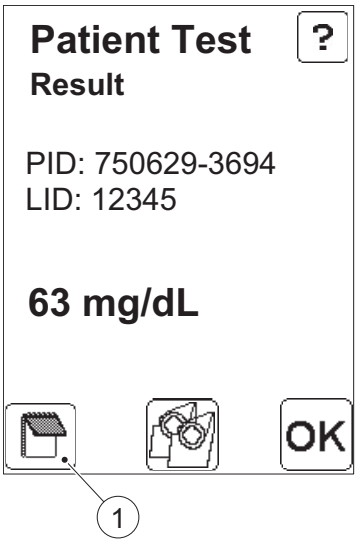


FIGURE 4-18

Comments may be entered prior to saving the result.

a) When the result is displayed, press the Comment input button (1).
FIGURE 4-19 will be displayed.

1 Comment input button

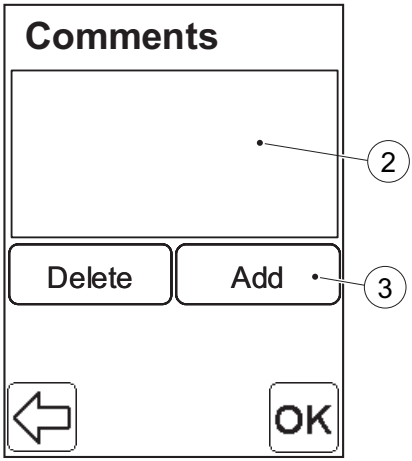


FIGURE 4-19

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

Note that the only exception is the auto generated comment ***Diluted***, displayed in the results Comment list (2) if the Dilution button has been pressed earlier (see *FIGURE 4-9*).

b) To add a comment, press the Add button (3).
FIGURE 4-20 will be displayed.

2 Result Comment list
3 Add button

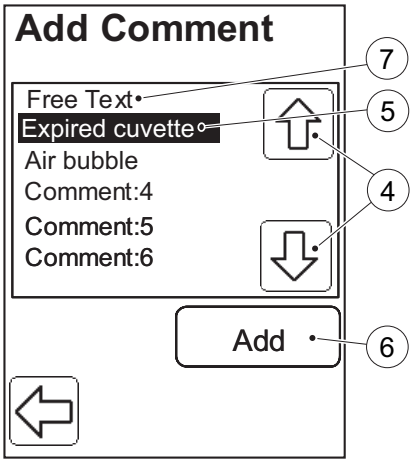


FIGURE 4-20

This list will be empty if no comments have been pre-defined in the Settings menu, see *3.2.4 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 4-21* will be displayed.

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

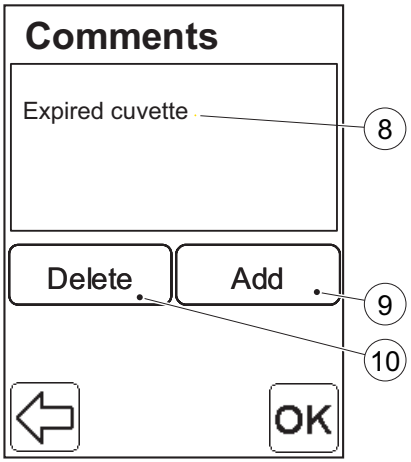


FIGURE 4-21

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 4-20*.

f) If comments are to be deleted, press the Delete button (10).
FIGURE 4-22 will be displayed.

8 Result Comment list
9 Add button
10 Delete button

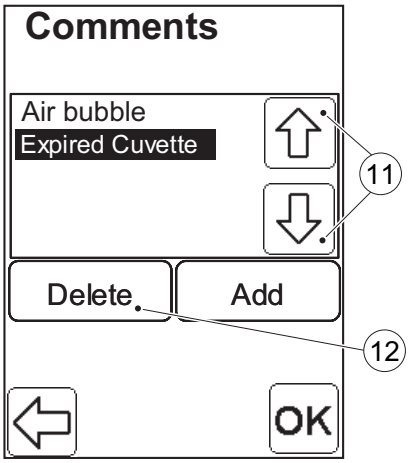


FIGURE 4-22

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

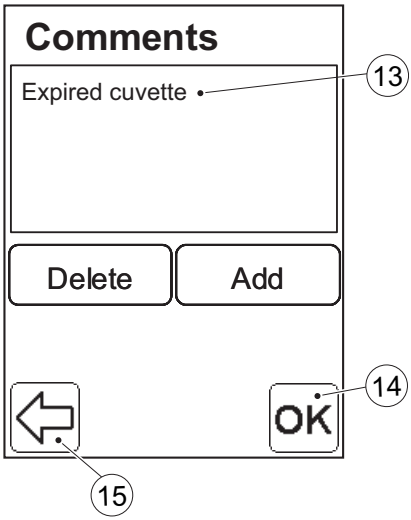


FIGURE 4-23

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

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.

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 4-24* will be displayed.

13 Result Comment list
14 Confirm button
15 Previous image button

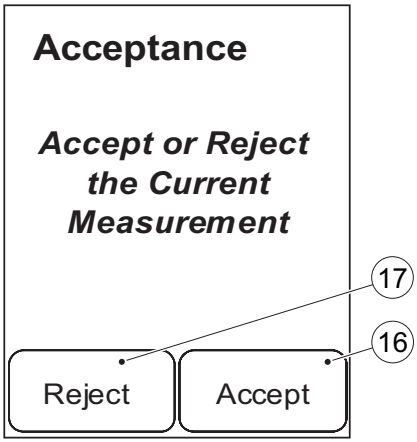


FIGURE 4-24

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

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

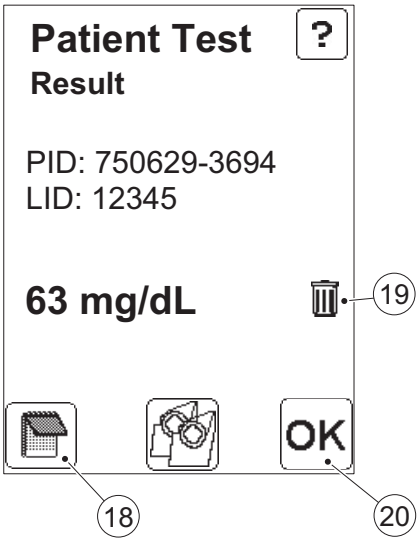


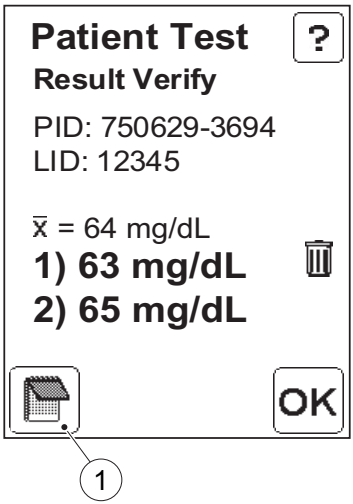
FIGURE 4-25

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 4-24*).

m) Press the Confirm button (20).
The Main menu, *FIGURE 4-1* will be displayed.

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



4.1.4 Entering Comments – Verified sample

FIGURE 4-26

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 *4.1.3 Entering Comments*, *FIGURE 4-19* to *FIGURE 4-23*.

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 *4.1.3 Entering Comments*, *FIGURE 4-19* to *FIGURE 4-23*.

f) *FIGURE 4-27* will be displayed.

1 Comment input button

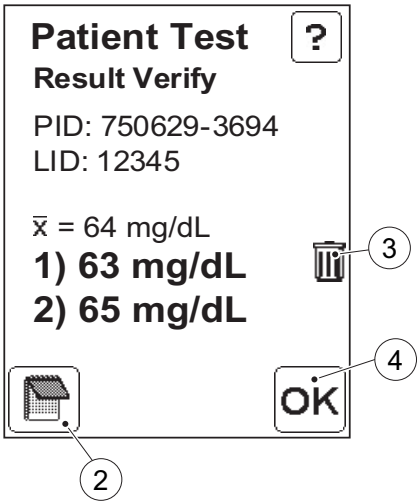


FIGURE 4-27

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 4-1*, will be displayed.

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

5 STAT Test procedure

This chapter guides you through the process of performing a STAT Test. The STAT Test fulfills 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.

5.1 STAT Test

STAT tests are only available if enabled during the configuration of the Analyzer settings (see *3.4.2 Patient Test Settings*).

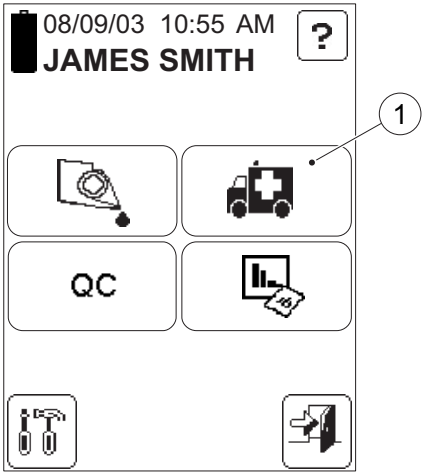


FIGURE 5-1

a) In the Main Menu, press the STAT Test button (1) to enter the STAT Test procedure.

1 STAT Test button

b) Enter the information for the 3 following images:
Enter Cuvette Batch
Enter Patient ID (PID)
Enter Lab Number (LID)
(see section *4 Patient Test procedure*) or just press the Confirm button if no data is to be added. *FIGURE 5-2* will be displayed.

The three images above will not be displayed if the Cuvette Batch No. requirement (see *3.4.1 General Settings*), the Patient ID requirement (see *3.4.2 Patient Test Settings*) and the Lab ID requirement (see *3.4.2 Patient Test Settings*) are set to "Not Used".

For a diluted sample follow *FIGURE 5-3 ,* otherwise continue with step c).

FIGURE 5-2

c) Obtain a blood sample according to the procedure described in the respective *Instructions for Use*.

d) Place the filled Cuvette in the Cuvette holder and gently insert it into the measuring position.

e) When the measurement is ready, *FIGURE 5-5* will be displayed.

Diluted sample

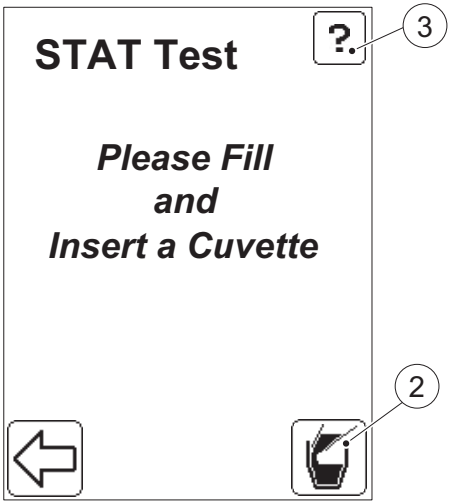


FIGURE 5-3

The Dilution function is only applicable for HemoCue Glucose 201 DM Analyzer.

The function is not available in all markets.

Note that the Dilution button (2) and Help button (3) will only be displayed if the dilution option was chosen during the configuration of the Analyzer settings (see section *3 Settings*).

For the Dilution function the sample must be diluted with NaCl (Saline), one part blood and one part NaCl.

f) If the sample is diluted, press the Dilution button (2). *FIGURE 5-4* will be displayed.

2 Dilution button
3 Help button

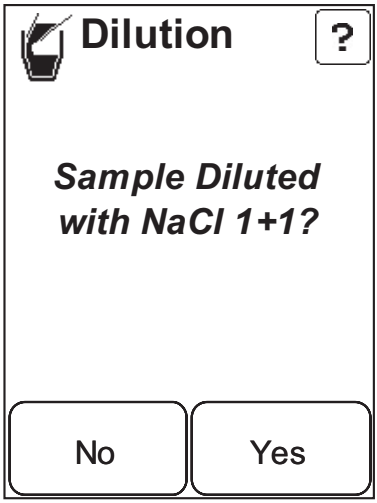


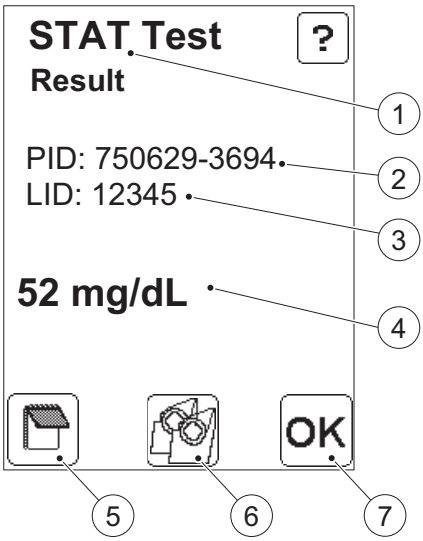
FIGURE 5-4

g) Confirm with Yes or No. *FIGURE 5-3* will then be displayed again.

h) Obtain a blood sample according to the procedure described in relevant *Instructions for Use*.

i) Place the filled Cuvette in the Cuvette holder and gently insert it into the measuring position.

j) When the measurement is ready, *FIGURE 5-5* will be displayed.



5.1.1 STAT Test Result

FIGURE 5-5

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 *4.1.3 Entering Comments*.

The Verify/Duplicate sampling 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 *4.1.2 Verify/Duplicate sampling*.

Never re-measure a Cuvette!

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

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/Duplicate Sampling button
7 Confirm button

6 QC Test procedure

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

6.1 Events necessitating QC Tests

6.1.1 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.

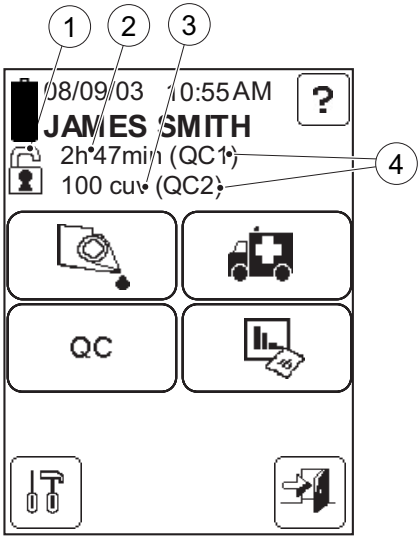


FIGURE 6-1

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

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.
QC1 = QC Test Level 1
QC2 = QC Test Level 2
QC3 = QC Test Level 3
QC4 = QC Test Level 4
QC5 = QC Test Level 5

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

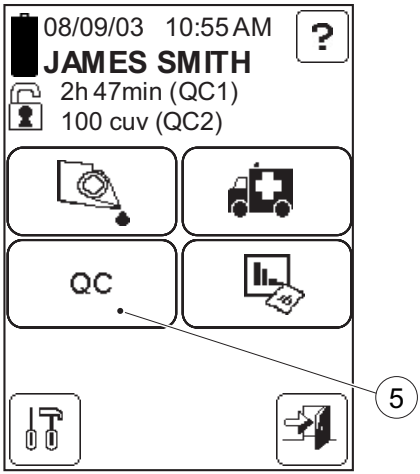


FIGURE 6-2

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 6-6 will be displayed.

5 QC Test button

6.1.2 QC Lockout

If the required QC Test is not performed within the time or number of measurements indicated by the QC Reminder, *FIGURE 6-1*, the Analyzer will perform a QC lockout. *FIGURE 6-3* will be displayed.

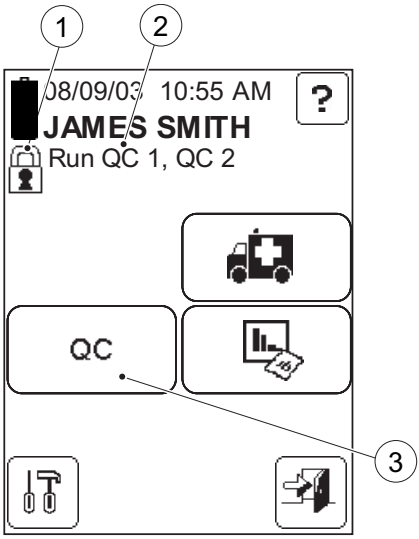


FIGURE 6-3

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

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

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

STAT Tests are not allowed when the Analyzer has performed a QC lockout if usage of STAT Tests is set to "Not Used" (see *3.4.2 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 6-6 will be displayed.

1 QC Lockout
2 Information text
3 QC Test button

6.1.3 Supervisory Lockout

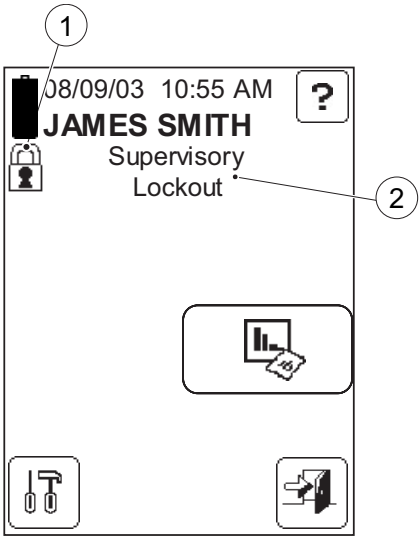


FIGURE 6-4

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

6.2 Performing a QC Test

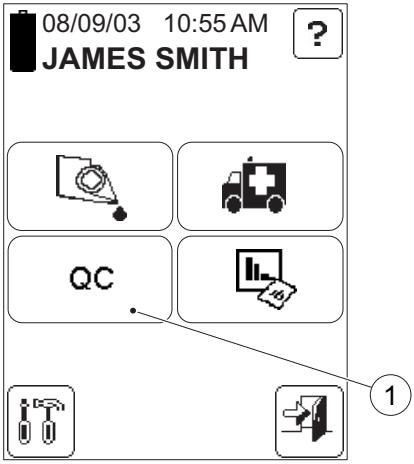


FIGURE 6-5

a) In the Main Menu, press the QC Test button (1).
FIGURE 6-6 will be displayed.

1 QC Test button

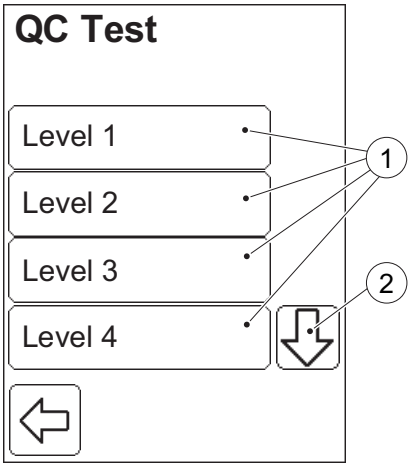


FIGURE 6-6

There are 7 QC Test options (1):

- Level 1 (See *6.2.1 QC Tests at a specific concentration level*)
- Level 2
- Level 3
- Level 4
- Level 5
- Linearity (see *6.2.2 Linearity Test*)
- Proficiency (see *6.2.3 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.

Level 1, Level 2, Level 3, Level 4 and Level 5, 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, Level 1, is described.

1 QC Test options
2 Scroll bar arrow

6.2.1 QC Tests at a specific concentration level

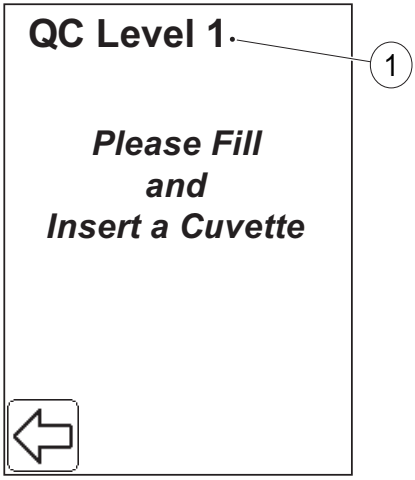


FIGURE 6-7

The QC Tests procedure for Level 1, Level 2, Level 3, Level 4 and Level 5 are identical, and therefore only one, Level 1, 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 6-8 will be displayed.

1 Concentration level of QC Test

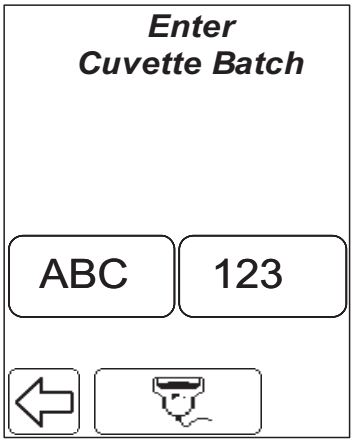


FIGURE 6-8

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 6-9 will be displayed.

If the Cuvette Batch No. requirement is set to *Approved only* (see *3.4.1 General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see *3.2.2 Cuvette Batches*) is entered, or the Cuvette Batch has expired, the following text will be displayed:

Invalid Cuvette Batch.

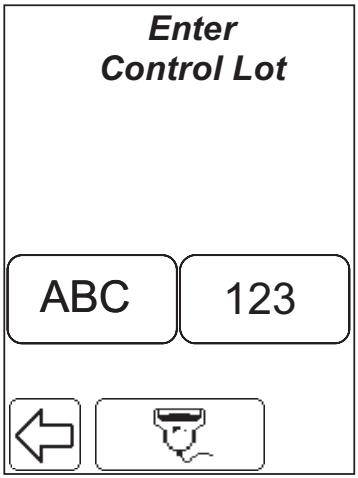


FIGURE 6-9

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 6-10 will be displayed.

If a Liquid Control Lot has not previously been stored in the Analyzer (see *3.2.1 Liquid Controls*) and/or has expired, the following text will be displayed:

Invalid Control Lot.

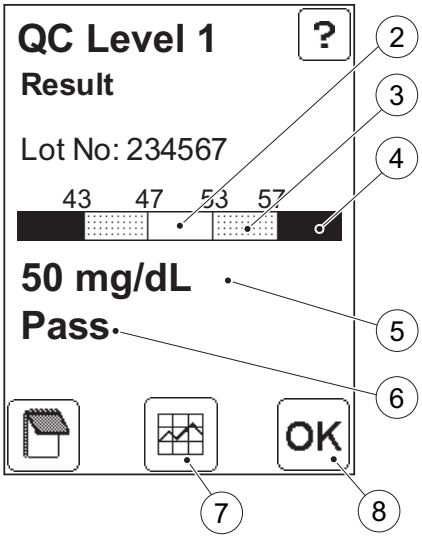


FIGURE 6-10

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 6-12 will be displayed.

f) Press the Confirm button (8). *FIGURE 6-6* or *FIGURE 6-11* 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

FIGURE 6-11

g) If the Failed QC Comment setting is set to "Entry Required" (see *3.4.3 QC Test Settings*) and the QC Test has failed, then *FIGURE 6-11* will be displayed when the Confirm button shown in *FIGURE 6-10* is pressed. Use the Previous Image button (9) to go back and add at least one comment.

9 Previous Image button

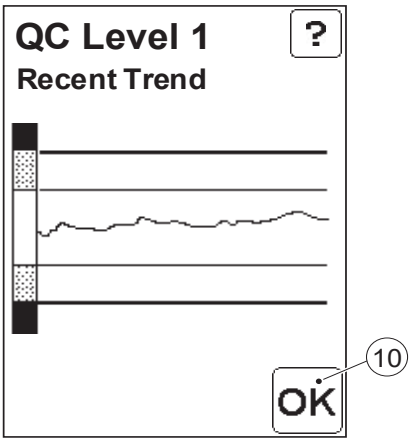


FIGURE 6-12

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

h) To continue to the statistics image, *FIGURE 6-13*, press the Confirm button (9).

10 Confirm button

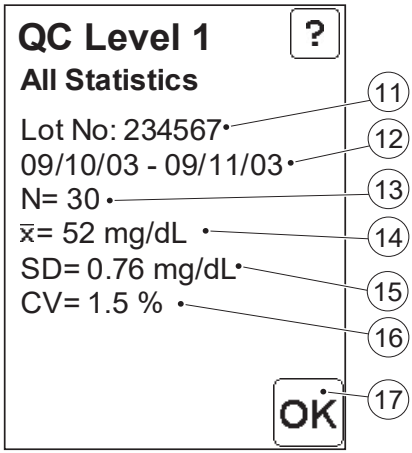


FIGURE 6-13

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 6-10* 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

6.2.2 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.

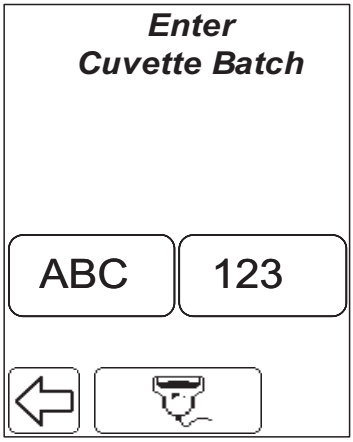


FIGURE 6-14

a) To perform a Linearity Test, press the linearity button in the QC test options display, see *FIGURE 6-6*.

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.

If the Cuvette Batch No. requirement is set to *Approved only* (see *3.4.1 General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see *3.2.2 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 6-15* will be displayed. Otherwise *FIGURE 6-16* will be displayed.

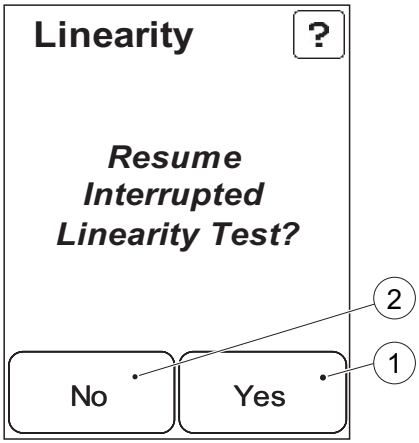


FIGURE 6-15

d) To resume a previously interrupted linearity test, press Yes.
FIGURE 6-17 will be displayed.
Otherwise press No.
FIGURE 6-14 will be displayed.

1 Yes button
2 No button

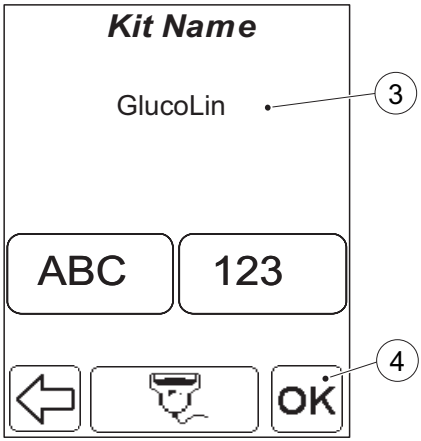


FIGURE 6-16

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 6-17 will be displayed.

3 Kit name
4 Confirm button

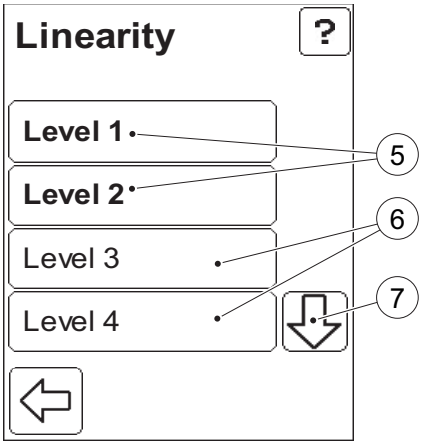


FIGURE 6-17

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?

j) Press No to return to the current image or press Yes to continue to image *FIGURE 6-18*.

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

5 Buttons for already completed levels
6 Buttons for non-completed levels
7 Scroll bar arrow

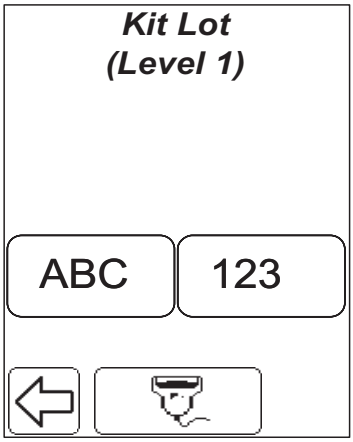


FIGURE 6-18

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

k) 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 6-19* will be displayed.

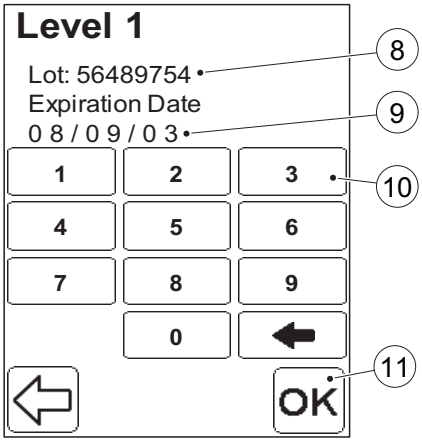


FIGURE 6-19

The Lot No. (8) is displayed.

l) Enter the Expiration Date (9) for the current Lot via the Digit buttons (10).

m) Press the Confirm button.
   FIGURE 6-20 will be displayed.

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

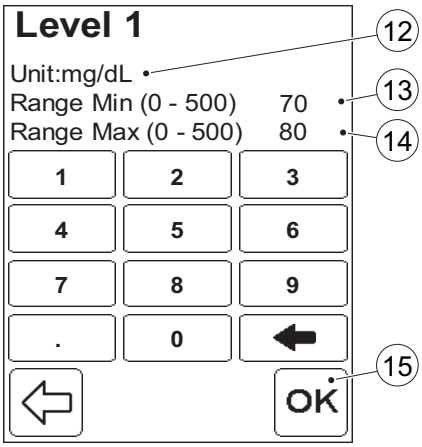


FIGURE 6-20

The level of the linearity material and it's concentration unit are displayed.

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

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.

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

o) Enter the max. value for the concentration range (14) via the Digit buttons. Press the Confirm button (15). *FIGURE 6-21* will be displayed.

---

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

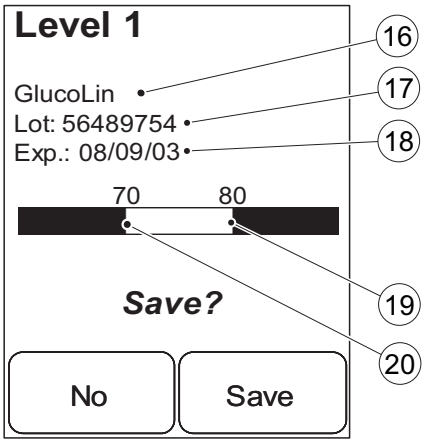


FIGURE 6-21

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

p) To confirm the displayed values and to save them for future comparisons to the measured value, press Save.
FIGURE 6-22 will be displayed.
Otherwise press No. *FIGURE 6-17* will be displayed.

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

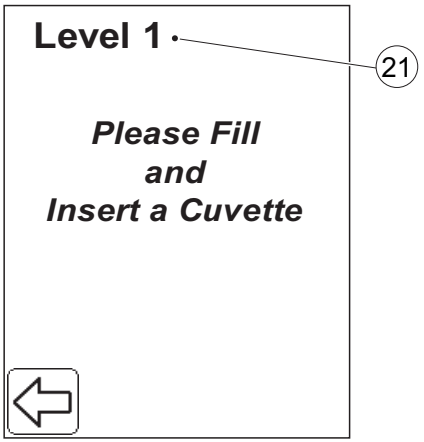


FIGURE 6-22

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

q) Fill a Cuvette from the previously designated batch with the appropriate level of linearity material.

r) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
FIGURE 6-23 will be displayed.

21 Concentration level of Linearity material

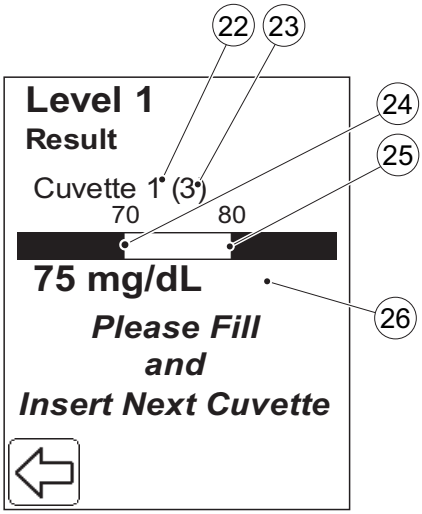


FIGURE 6-23

The result will be displayed.

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

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 6-17* 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

s) 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 6-17* will be displayed.
Press No to continue the Linearity test.

If *FIGURE 6-23* is displayed and the test is to be continued:

t) Fill a Cuvette from the previously designated batch with the appropriate level of linearity material.

u) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
If additional tests are required *FIGURE 6-23* will be displayed again.
If no additional tests are required, *FIGURE 6-24* will be displayed.

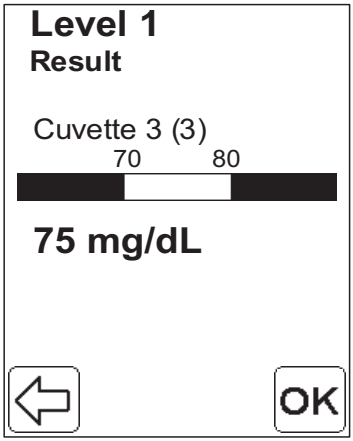


FIGURE 6-24

v) Press the Confirm button.
If other levels of the linearity material need to be measured *FIGURE 6-17* will be displayed.
If testing for all levels is completed, *FIGURE 6-25* will be displayed.

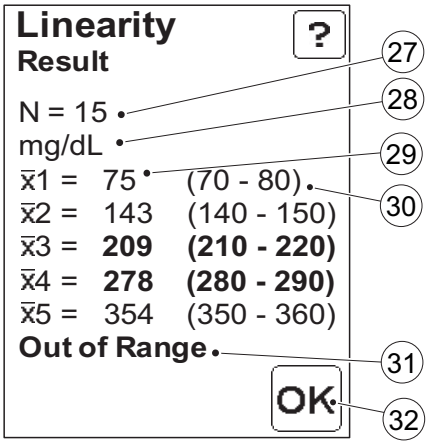


FIGURE 6-25

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".

w) Press the Confirm button (32). *FIGURE 6-26* 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

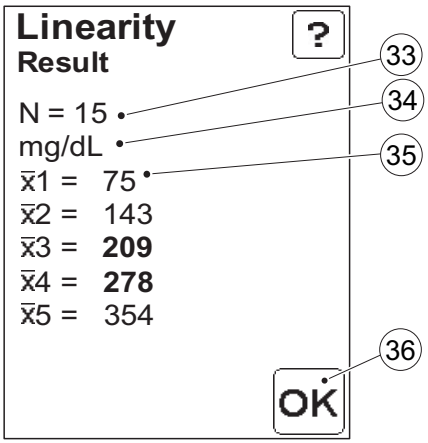


FIGURE 6-26

If no ranges are specified for the concentration levels (see *FIGURE 6-20*), 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 6-17* 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

6.2.3 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.

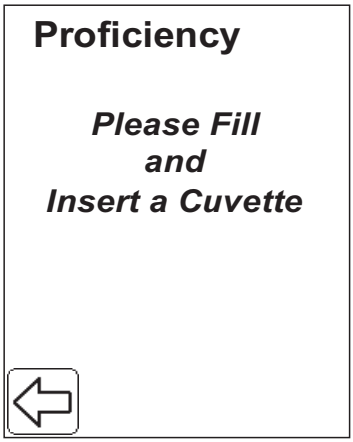


FIGURE 6-27

a) To perform a Proficiency Test, press the Proficiency button in the QC test options display, see *FIGURE 6-6*.

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 6-28 will be displayed.

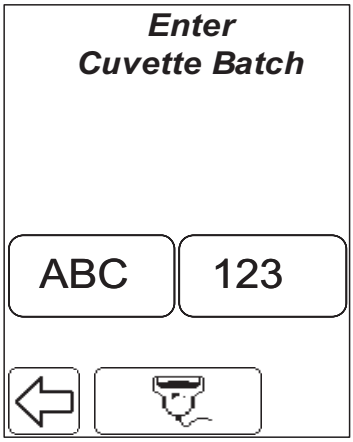


FIGURE 6-28

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 6-29 will be displayed.

If the Cuvette Batch No. requirement is set to *Approved only* (see *3.4.1 General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see *3.2.2 Cuvette Batches*) is entered, **or** the Cuvette Batch has expired, the following text will be displayed:
Invalid Cuvette Batch.

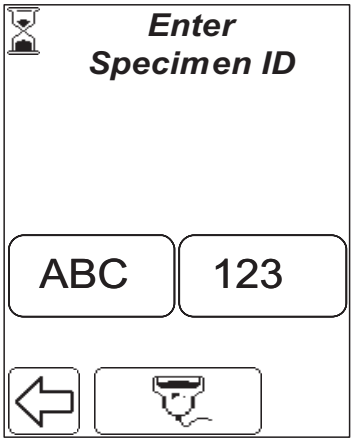


FIGURE 6-29

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 6-30* will be displayed.

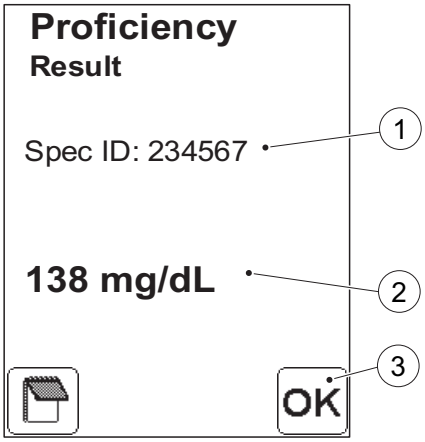


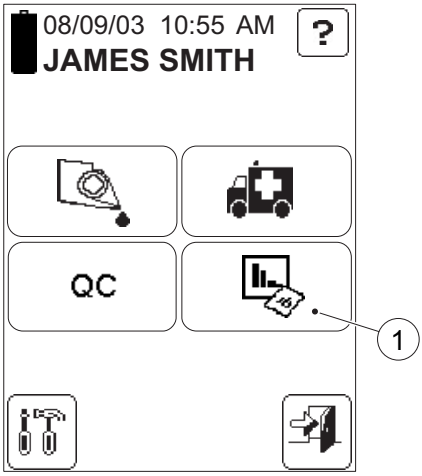
FIGURE 6-30

f) Press the Confirm button (3) to return to *FIGURE 6-27*.

1 Specimen ID
2 Test Result
3 Confirm button

7 Reviewing stored data

This chapter describes the process of reviewing stored data.



7.1 Activating the Stored Data procedure

FIGURE 7-1

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 *3 Settings*), *FIGURE 7-2* 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 3-22*), *FIGURE 7-3* will be displayed.
   If the operator's user level permits access to the Stored Data, *FIGURE 7-4* will be displayed.

1 Stored Data button

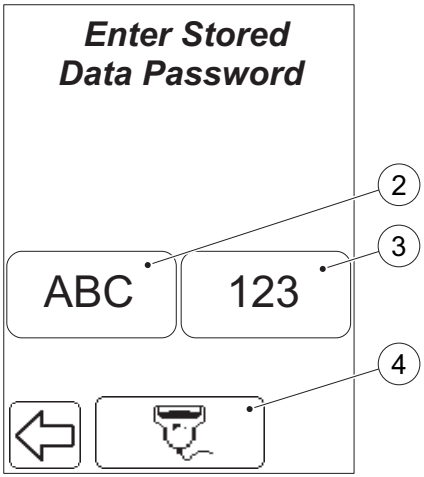


FIGURE 7-2

Only displayed if the Operator ID requirement is set to "Not used" (see *3.4.1 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 7-3* will be displayed.
If the correct password is entered *FIGURE 7-4* will be displayed.

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

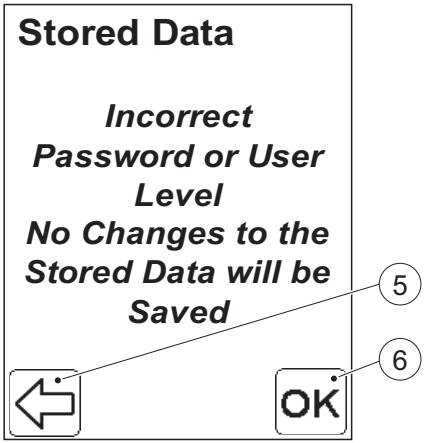


FIGURE 7-3

e) Pressing the Previous image button returns the user to *FIGURE 7-2* and allows entry of the correct password. By pressing the Confirm button Stored Data can be viewed, but not changed. *FIGURE 7-4* will be displayed.

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

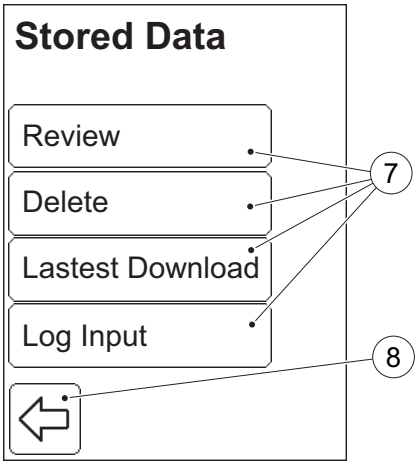


FIGURE 7-4

The following options are displayed:

- Review (see *7.2 Review Stored Data*)
- Delete (see *7.3 Delete Stored Data*)
- Latest Download (see *7.4 Review Latest Download*)
- Log Input (see *7.5 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

7.2 Review Stored Data

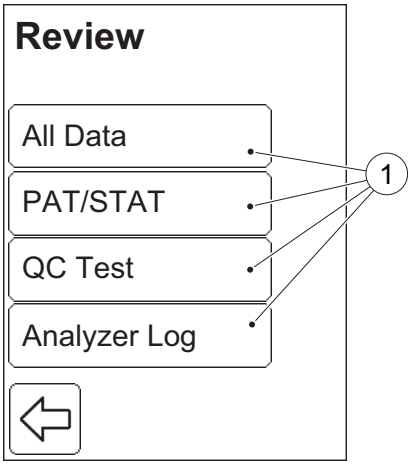


FIGURE 7-5

When the Review button is pressed in the Stored Data menu (see *FIGURE 7-4*), the following options are displayed:

- All Data (see *7.2.1 Review All Data*)
- PAT/STAT (see *7.2.2 Review PAT/STAT*)
- QC Test (see *7.2.3 Review QC Tests*)
- Analyzer Log (see *7.2.4 Review Analyzer Log*)

a) Select an option by pressing it.

1 Review option buttons

7.2.1 Review All Data

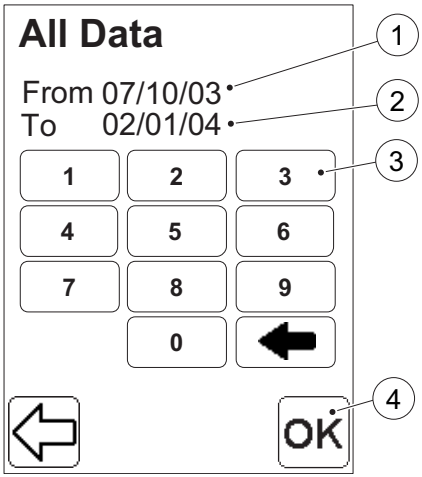


FIGURE 7-6

Press the All Data button in the Review menu, *FIGURE 7-5*.

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

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 7-8*, *FIGURE 7-12*, *FIGURE 7-15*, *FIGURE 7-17*, *FIGURE 7-19*.
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 7-6*.

7.2.2 Review PAT/STAT

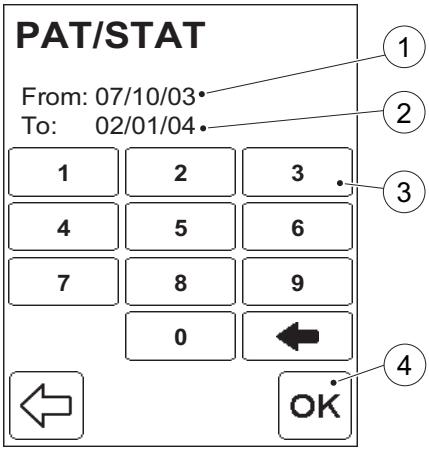


FIGURE 7-7

Press the PAT/STAT button in the Review menu, *FIGURE 7-5*.

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 7-8* 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

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 7-8*.

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 7-7*.

Patient/STAT test

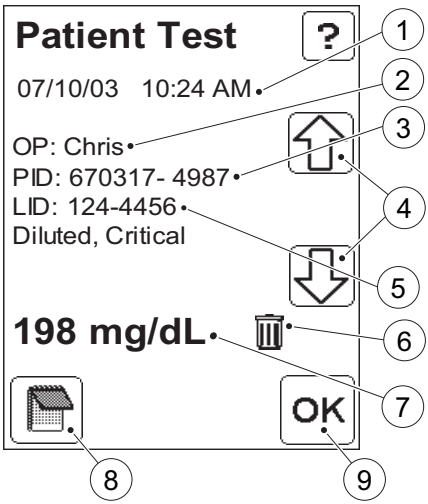


FIGURE 7-8

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 *4.1.3 Entering Comments*.

c) Press the Confirm button (9). *FIGURE 7-5* 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

7.2.3 Review QC Tests

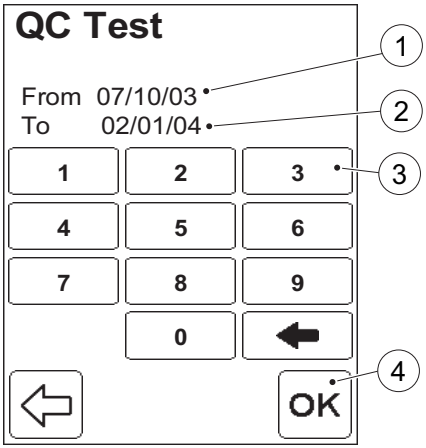


FIGURE 7-9

Press the QC Test button in the Review menu, *FIGURE 7-5*.

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 7-10* 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 7-10* will be displayed.

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

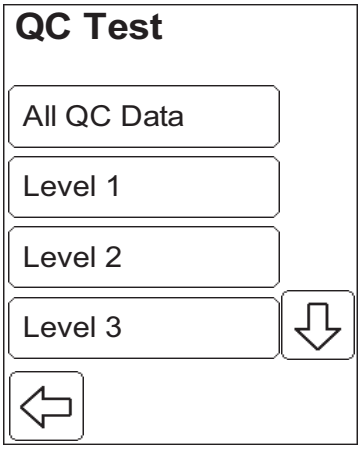


FIGURE 7-10

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

- All QC Data
- Level 1
- Level 2
- Level 3
- Level 4
- Level 5
- Linearity
- Proficiency

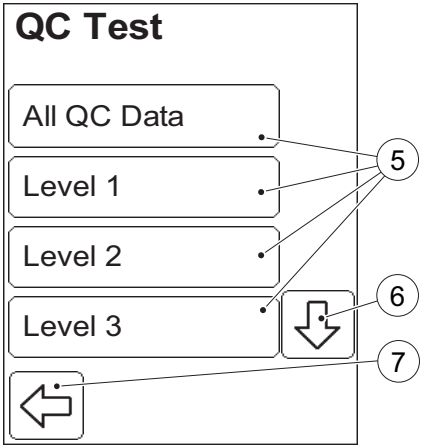


FIGURE 7-11

The categories Level 1, Level 2, Level 3, Level 4 and Level 5, 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, Level 1, is described.

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

b) Select a category by pressing it.

c) All QC tests within the selected category and the defined date interval will be available for review. The latest test is displayed first. For Level 1, Level 2, Level 3, Level 4 and Level 5 see *FIGURE 7-12*. For Linearity see *FIGURE 7-15*. For Proficiency see *FIGURE 7-17*.
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 7-10*.

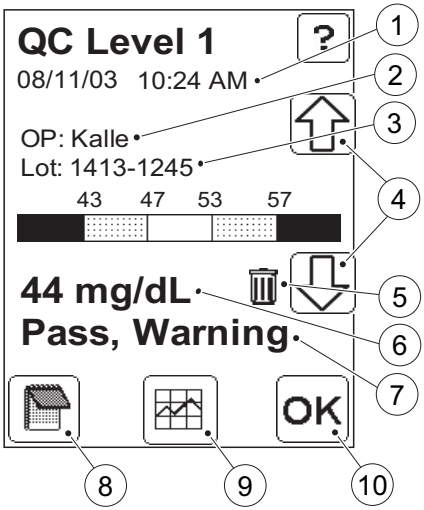
5 QC categories
6 Scroll bar arrow
7 Previous image button

All QC Data

All categories of QC data within the defined date interval will be available. The different images possible are described in *FIGURE 7-12*, *FIGURE 7-15* and *FIGURE 7-17*.

QC tests at a specific concentration level

FIGURE 7-12



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 *4.1.3 Entering Comments*.

c) To view a graphic presentation of the most recent QC tests at the defined concentration level, press the Statistics button (9).
FIGURE 7-13 will be displayed.

d) To return to the QC Test categories image, *FIGURE 7-10*, 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

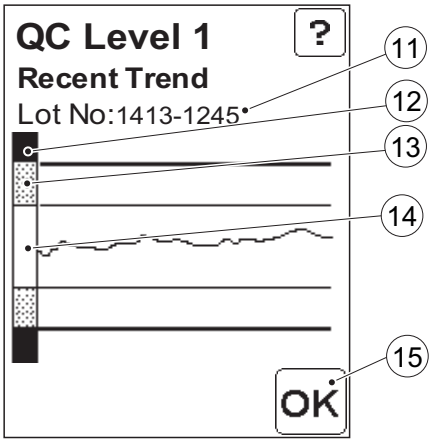


FIGURE 7-13

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 7-14* will be displayed.

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

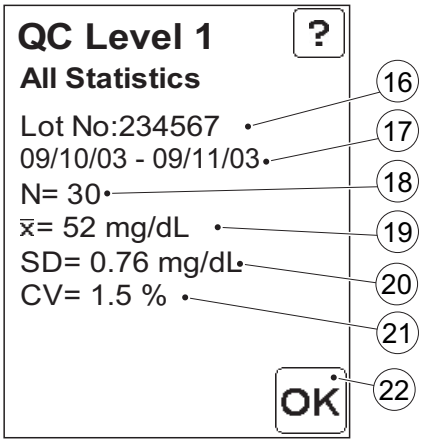


FIGURE 7-14

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

f) Press the Confirm button (22). *FIGURE 7-12* 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 *6.2.2 Linearity Test*.

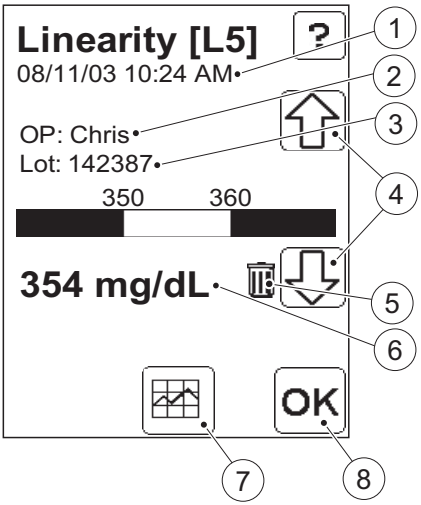


FIGURE 7-15

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 7-16* will be displayed.

c) Press the Confirm button (8). *FIGURE 7-10* 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

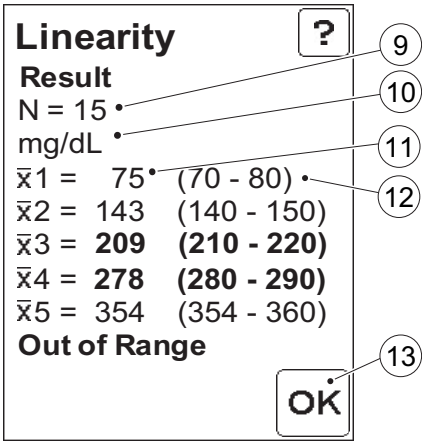
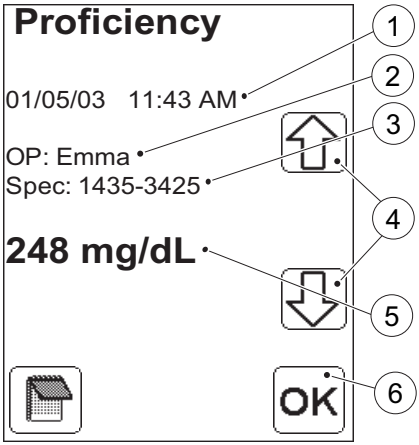


FIGURE 7-16

The image shows statistical data. For more information on the image, see *FIGURE 6-25*.

d) Press the Confirm button. *FIGURE 7-10* 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 *6.2.3 Proficiency Test*.

FIGURE 7-17

a) To browse through the available records, use the scroll bar arrows (4).

b) Press the Confirm button (6). *FIGURE 7-10* 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

7.2.4 Review Analyzer Log

Press the Analyzer Log button in the Review menu, *FIGURE 7-5*.

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

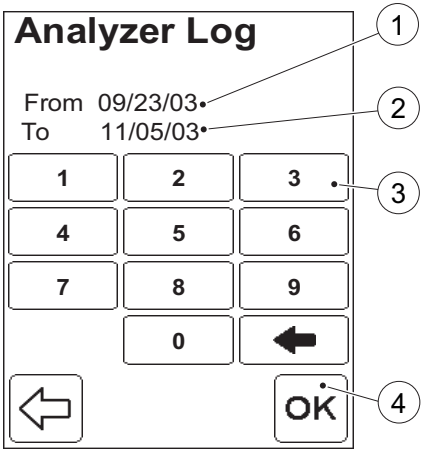


FIGURE 7-18

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 7-19* will then be displayed.

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

b) Repeat the step a) for the To date (2).

c) *FIGURE 7-19* will be displayed.

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

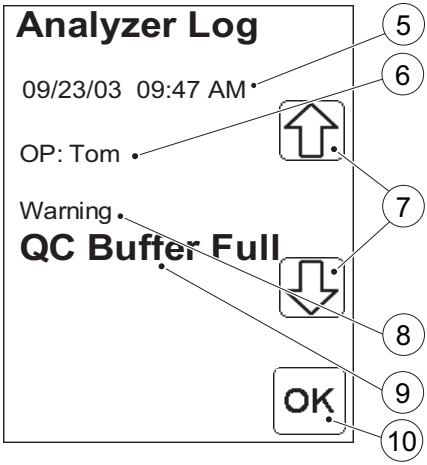


FIGURE 7-19

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 7-5* 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

7.3 Delete Stored Data

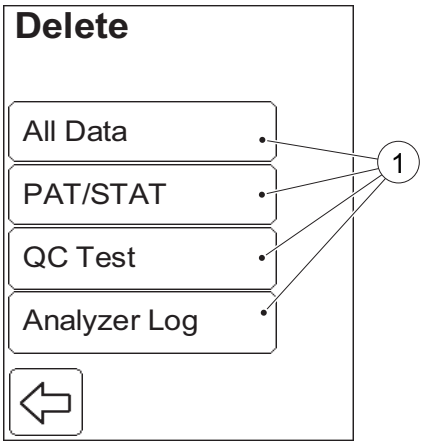


FIGURE 7-20

When the Delete button is pressed in the Stored Data menu (see *FIGURE 7-4*), the following options for deleting data are displayed:

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

a) Select an option by pressing it. *FIGURE 7-21* will be displayed.

1 Delete options

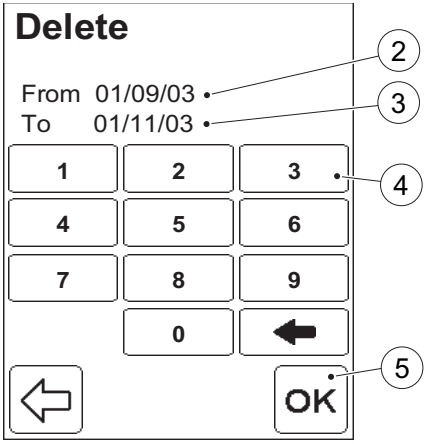


FIGURE 7-21

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 7-22* will be displayed.

b) If required, enter a new To date (3) via the Digit buttons (4). When finished press Confirm (5). *FIGURE 7-22* will be displayed.

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

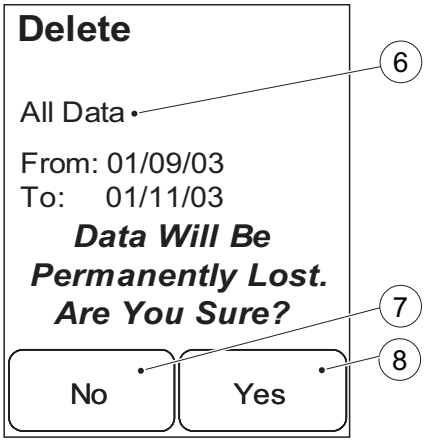


FIGURE 7-22

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 7-20*, will be displayed.

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

7.4 Review Latest Download

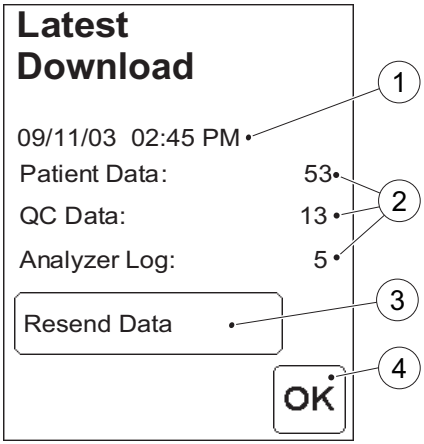


FIGURE 7-23

When the Latest Download button is pressed in the Stored Data menu, *FIGURE 7-4*, 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 7-4* will be displayed.

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

7.5 Log Input

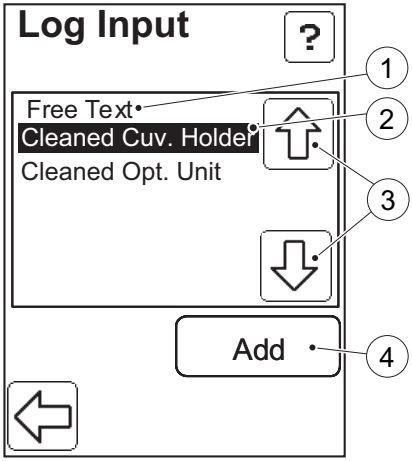


FIGURE 7-24

When the Log Input button is pressed in the Stored Data Menu, *FIGURE 7-4*, 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 7-4* will be displayed.
If the Free Text option (1) was selected *FIGURE 7-25* will be displayed.

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

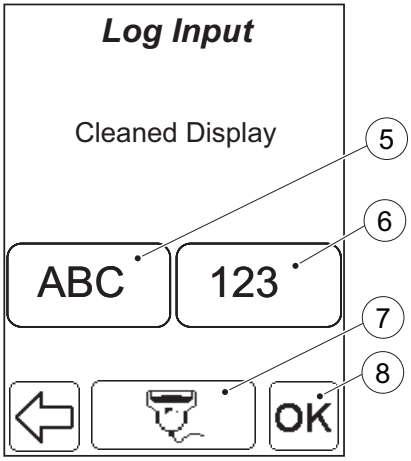


FIGURE 7-25

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 7-4* will be displayed.

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

8 Data communications

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

8.1 Interaction Application – Analyzer

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

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

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

Depending on the settings, one or several Analyzers can be connected and administered by the same PC or OR via the Docking Stations (see *8.2 Docking station setup*).

8.2 Docking station setup

Single Primary Docking

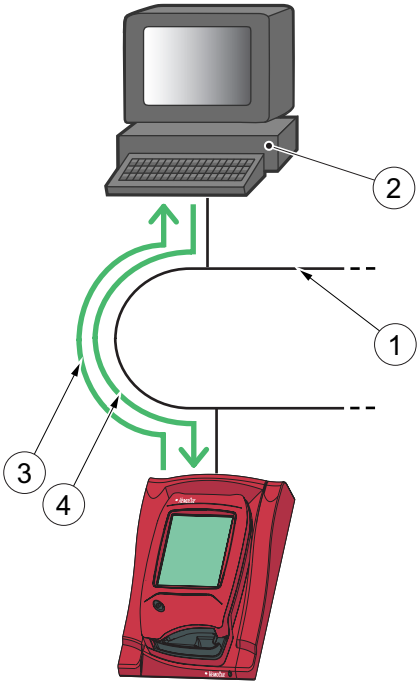


FIGURE 8-1

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.

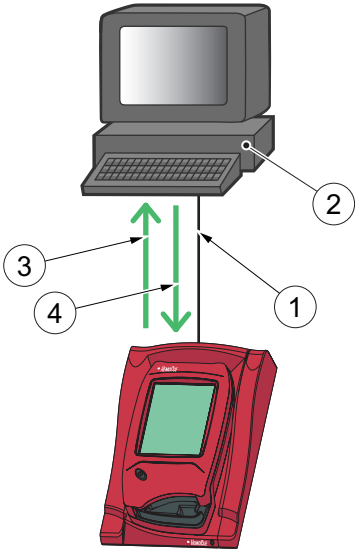
The communication Analyzer - DMS Software is two-way:

- 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 8-2*).

When a Primary Docking Station is connected via a USB connection, only the TCP/IP settings 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 8-2

A Single Secondary Docking Station must be connected via a USB (1) to the PC hosting the DMS Software (2). A Secondary Docking Station 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

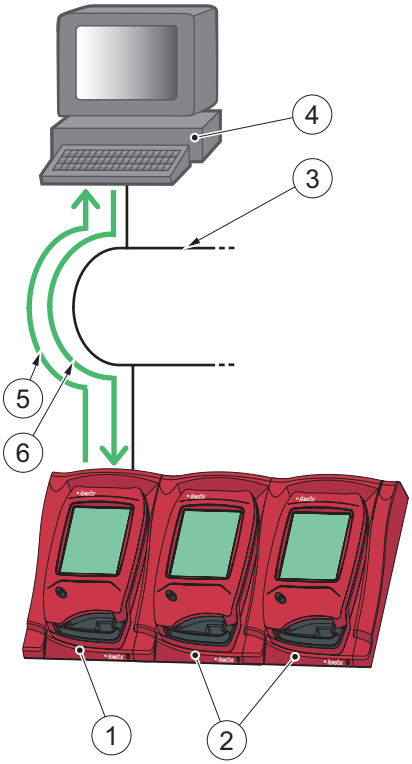


FIGURE 8-3

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

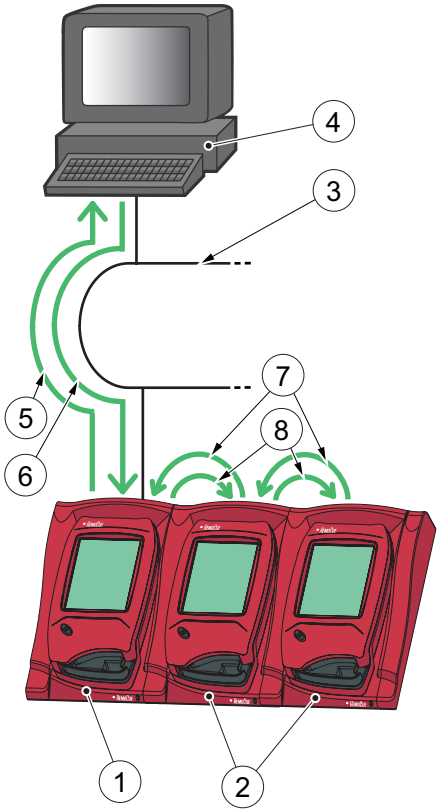


FIGURE 8-4

For Analyzer in 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).

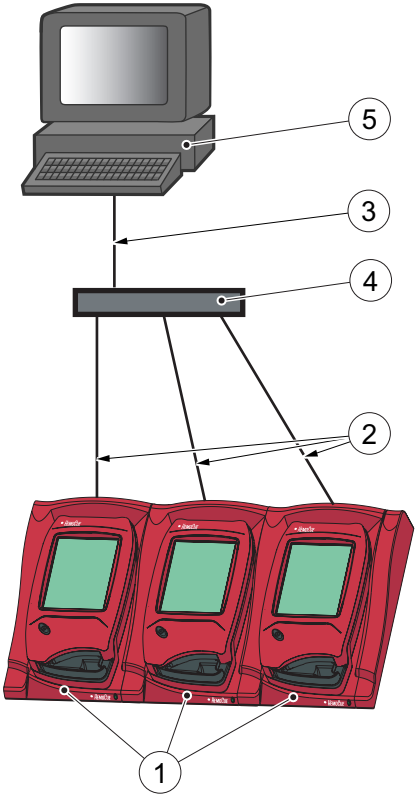
Secondary Docking Station in such a set, can at the same time be connected separately to a PC via USB and then the USB connection will override the LAN connection. Normally there is no reason for this type of configuration.

For Secondary Docking Stations labelled SDS+, in such a set, the Analyzer needs to be restarted or re-docked to establish connection to PC via USB.

To restore the LAN connection for the Secondary Docking Station labelled SDS+, remove the USB cable and restart or re-dock the Analyzer in the Docking Station.

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 8-2*).

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



Multiple set consisting solely of Secondary Docking Stations

FIGURE 8-5

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.

A secondary Docking Station cannot be directly connected to a LAN.

Analyzers in a multiple set consisting solely of Secondary Docking Stations communicate with the DMS Software according to *FIGURE 8-6*.

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

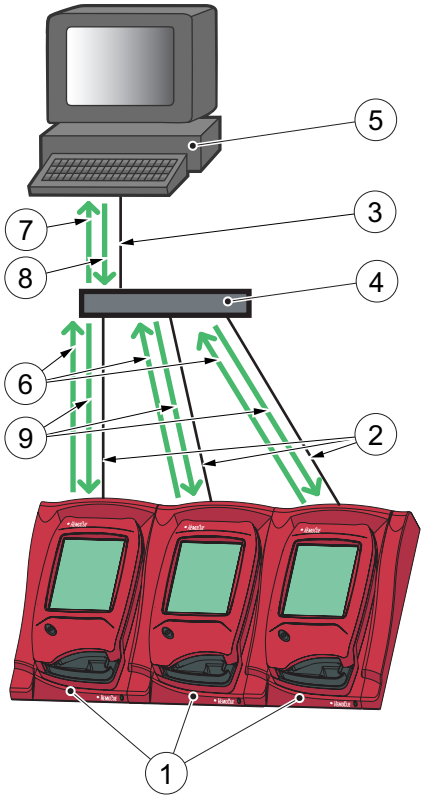


FIGURE 8-6

- 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

8.3 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, either by connecting a docking station containing an Analyzer to the PC, or by placing an Analyzer in a docking station already 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 8-7

When the data transfer process is being activated, *FIGURE 8-7* 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 8-8

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

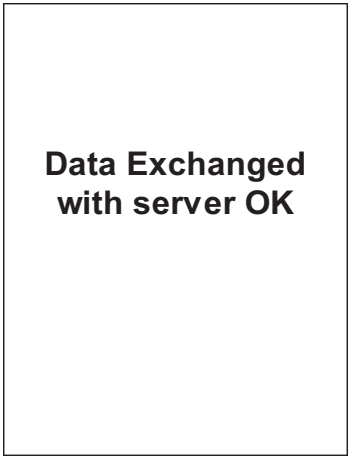


FIGURE 8-9

When an Analyzer is removed from the docking station, *FIGURE 8-9* will be displayed.

After removing the Analyzer from the docking station it can take up to 20 seconds before *FIGURE 8-9* is displayed.

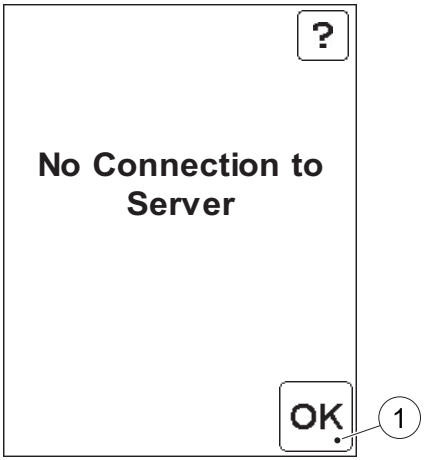


FIGURE 8-10

When the data transfer process is being activated, but the connection is not established successfully, *FIGURE 8-10* will be displayed.

One of the following errors has occured:

- 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 2-24*.

1 Confirm button

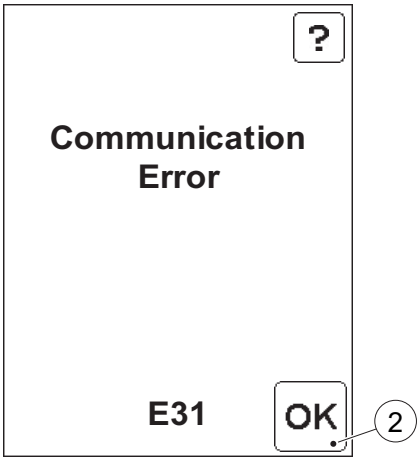


FIGURE 8-11

If, during data transfer, an error or malfunction between the Analyzer and the recieving computer is detected, *FIGURE 8-11* will be displayed. Refer to the section *8 Data communications*.

a) Press the Confirm button (2) to return to the Main Menu, *FIGURE 2-24*.

2 Confirm button

PART IV
Other actions

9 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 America, Technical Support. There are no serviceable parts inside the Analyzer.

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

Symptom	Explanation	Action
E08	The absorbance is too high. Light blocking item in the Cuvette holder.	a) Check that the Analyzer and Cuvettes are used according to the *Instructions for Use*. b) Analyzer needs service. Contact the distributor.
E11	Hardware Error	Analyzer needs service. Contact distributor.
E17	Internal Error	Analyzer needs service. Contact distributor.
E23	Data Error Real Time Clock Real Time Clock backup battery has been drained.	The backup battery needs to be replaced. Contact distributor.
E25	Analyzer not calibrated.	Analyzer needs service. Contact 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 *7.3 Delete Stored Data*) b) Change Analyzer settings regarding full internal memory for Patient tests to "Overwrite" (see *3.4.1 General Settings*).

Symptom	Explanation	Action
E27	The QC memory is full. No more QC 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 QC Tests stored in the Analyzer (see *7.3 Delete Stored Data*) b) Change Analyzer settings regarding full internal memory for QC tests to "Overwrite" (see *3.4.1 General Settings*).
E28	The Analyzer log memory is full. No more Error Codes and Log Notes can be saved.	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. a) Delete all or part of the Analyzer logs stored in the Analyzer (see *7.3 Delete Stored Data*) 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 *3.4.1 General Settings*).
E29	The electronic self-test failed. The communication self-test failed. The Analyzer may not work properly when connected to a docking station.This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	Analyzer needs service. Contact distributor.

Symptom	Explanation	Action
E30	The electronic self-test failed. The optical self-test failed. The Analyzer may not work properly when measuring.This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	a) Turn off the Analyzer and clean the optronic unit as described in the *Instructions for Use*. b) Analyzer needs service. Contact distributor.
E31	Communication Error.	a) Check that the LED on the Docking Station does not show a red light (stable or flashing). See Symptom "*Docking Station LED red*". b) See Symptom "*No transfer of data*" If problems remain contact distributor.
E70/E71*	The Cuvette is faulty or the sample might be grossly lipemic. ** this error code is only displayed in HemoCue Glucose 201 DM Anlyzer and HemoCue Glucose 201 DM RT Analyzer*	Check that the system is used according to the *Instructions for Use*. Fill a new Cuvette and perform a measurement. If the error code appears again, use a suitable laboratory reference method to analyze the specimen.

Symptom	Explanation	Action
Overrange	**HemoCue Hb 201 DM:** Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L). **HemoCue Glucose 201 DM:** *Whole blood:* The measured value exceeds 400 mg/dL (22.2 mmol/L). *Plasma Equivalent:* The measured value exceeds 444 mg/dL (24.6 mmol/L). **HemoCue Glucose 201 DM RT:** *Whole blood*: The measured value exceeds 500 mg/dL (27.8 mmol/L). *Plasma Equivalent:* The measured value exceeds 560 mg/dL (31 mmol/L).	**HemoCue Hb 201 DM and HemoCue Glucose 201 DM RT:** The result is above the measuring range. **HemoCue Glucose 201 DM:** *Whole blood*: The measuring range may be extended to 800 mg/dL (44.4 mmol/L) by using the Dilution function. *Plasma Equivalent*: The measuring range may be extended to 888 mg/dL (49.2 mmol/L) by using the Dilution function. *Note that the Dilution function is not available in all markets.*
Non-responsive display	Display needs recalibration.	Follow section *5.4 Calibrating the Display* in *Instructions for Use*. If the recalibration fails, the Analyzer needs service. Contact the distributor.

Symptom	Explanation	Action
No characters on the display	1) The Analyzer is not receiving power. 2) If on battery power, the Battery needs to be recharged. 3) The display is out of order.	1a) Check that the Power Adapter is connected to the power supply. 1b) Check that the Power Adapter is securely connected to the Analyzer or Docking Station. 1c) If the Analyzer is docked, check that the green LED on the Docking Station gives a flashing green light. 1d) Check that the adapter is not damaged. 2) Recharge the Battery via an Power Adapter or a Docking Station. 3) Analyzer needs service. Contact distributor.
The display gives erroneous characters.	1) The display is out of order. 2) The microprocessor is out of order.	1,2) Analyzer needs service. Contact distributor.
Scanner is malfunc-tioning	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 indinstinct. 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 relevant section in *Instructions for Use*. 6) The standards that can be scanned are listed in section *10.1 Technical Specifications*. 7) Analyzer needs service. Contact distributor.

Symptom	Explanation	Action
Docking Station LED red	1) Flashing red light - external communication error. 2) Steady red light - internal error in the Docking Station.	1) See Symptom *"No transfer of data"*. 2a) Disconnect and then reconnect the Power Adapter. 2b) Contact HemoCue AB or the distributor.
No transfer of data via USB	No USB-communication.	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 and that the USB driver is installed. f) Check the electrical connection. The LED on the docking station should give a stable or flashing green light.

Symptom	Explanation	Action
No transfer of data	1) No network communication with OR or PC. 2) Communication error. 3) No communication. 4) No communication between the first and second Docking Station. 5) No communication between the Secondary Docking Stations. 6) No communication with any Docking Station.	1a) Check that the LED on the Docking Station does not show a flashing red light. 1b) Check the network configuration of PDS/PDS+. 1c) If multiple Docking Stations are used, make sure not to mix Docking Stations labelled PDS+/ SDS+ with unlabelled Docking Stations. 1d) Check the external set-up and settings (OR/PC, firewall, network infrastructure). 2a) More than 5 Docking Stations are docked together. 2b) If multiple Docking Stations are used, make sure not to mix Docking Stations labelled PDS+/ SDS+ with unlabelled Docking Stations. 3a) Check that a USB connection is not used for communication in a Primary Docking Station. 3b) If multiple Docking Stations are used, make sure not to mix Docking Stations labelled PDS+/ SDS+ with unlabelled Docking Stations. 4) Check that two Primary Stations are not docked together. 5a) Check the electrical connections. The LED on the docking station should give either a stable green light or a flashing green light. 5b) If multiple Docking Stations are used, make sure not to mix Docking Stations labelled PDS+/ SDS+ with unlabelled Docking Stations. 6) Check the electrical connection. The LED on the Docking Station should give either a stable green light or a flashing green light. If problems remain contact distributor.

Symptom	Explanation	Action
Analyzer not charged	No charging of the Battery	a) Check that the Analyzer is properly docked. b) Check that the green LED on the Docking Station gives a flashing green light when docking the Analyzer. c) Replace the Battery.
Empty Cuvette*	1) The Cuvette is empty. Empty Cuvette function captures primarily empty Cuvettes, not under-filled Cuvettes. 2) No chemical reaction is identified in the blood filled Cuvette. ** this error code is only displayed in HemoCue Glucose 201 DM Analyzer and HemoCue Glucose 201 DM RT Analyzer*	1-2)Fill a new Cuvette and perform a measurement as described in relevant sections of *Instructions for Use*. If the Empty Cuvette message appears again, contact your local distributor or HemoCue AB. Use another HemoCue analyzer or a suitable laboratory reference method to analyze the specimen.

Symptom	Explanation	Action
Unexpected patient or control results	*Patient or control samples* 1) Improper sampling technique. 2)The Cuvettes have passed the expiry date, are faulty or have been improperly stored. 3) The optical eye of the Cuvette is contaminated. 4) Air bubbles in the Cuvette. 5) The optical parts are dirty. 6) Incompletely filled Cuvette. 7) The measurement needs to be started no later than 40 seconds (for Glucose 201 DM and Glucose 201 DM RT) or 10 minutes (for Hb 201 DM) after filling the Cuvette. 8) The analyzer is damaged or malfunctioning. *Control sample*s 9) The control has not been properly mixed and/or has not reached room temperature. 10a)Control solution not compatible. 10b) Control solution expired or improperly stored.	*Patient or control samples* 1) See relevant section in *Instructions for Use*. 2) Check the expiry date and the storage conditions of the Cuvettes. 3) Fill a new Cuvette and perform a new measurement. 4) Check the Cuvette for air bubbles. Remeasure the control/sample with a new Cuvette. 5) Clean the optical parts as described in relevant section of *Instructions for Use*. 6) Fill a new Cuvette and perform a new measurement. 7) Fill a new Cuvette and perform a new measurement. 8) The analyzer needs service. Contact the distibutor. *Control samples* 9) Make sure that the control is properly mixed and that it has reached room temperature. If the problem continues, contact the manufacturer of the control. 10a)If a quality control test is to be performed, only use quality controls recommended by HemoCue, see relevant package insert for more information. 10b)Check the expiry date and the storage conditions of the control. Repeat the measurement with a new control/ sample. If the problem continues, contact the manufacturer of the control.

PART V
Miscellaneous

10 Specifications

10.1 Technical Specifications

10.1.1 Analyzer

Dimensions	170 × 93 × 50 mm (6.70 × 3.66 × 1.97 inches)
Weight	350 g (0.77 pounds)
System operating temperature	*See relevant Instructions for Use*
Analyzer storage and transport temperature	0 - 50 °C (32 - 122 °F)
Analyzer operating and storage humidity	< 90% RH (non-condensing)
Barcodes that can be scanned	UPC/EAN (UPC-A; UPC/E; EAN-8; EAN-13); Code 128 (USS-128; UCC/EAN-128; ISBT 128); Code 39; Interleaved 2 of 5; Codabar
Pollution degree	2
Overvoltage category	II
Altitude	up to 2000 m above sea level
Power Adapter/Input	FW7556M/06: 100-240V~/50–60 Hz/400-200 mA FW8001/06: 100-240V~/ 50–60 Hz/400-200 mA
Power Adapter/Output	FW7556M/06: 6 V ⎓ /2500 mA FW8001/06: 5.9 V ⎓ /3000 mA
Battery	HemoCue Li-Ion rechargeable power battery 201 DM 3.6V 2.6Ah
Battery capacity	≥ 120 tests/100 hours using the Barcode Scanner and a power save setting of 5 minutes
Battery charging time	75% of its capacity < 4 hours > 95% of its capacity < 6 hours

10.1.2 Docking station

Dimensions	206 × 135 × 61 mm (8.10 × 5.30 × 2.40 inches)
Weight	566 g (1.24 pounds)
Network communication speed:	PDS+: 100Mbps PDS: 10Mbps
System operating temperature	*See relevant Instructions for Use*
Docking station storage and transport temperature	0 - 50 °C (32 - 122 °F)
Docking station operating and storage humidity	< 90% RH (non-condensing)
Pollution degree	2
Overvoltage category	II
Altitude	up to 2000 m above sea level
Power Adapter/Input	FW7556M/06: 100-240V~/50–60 Hz/400-200 mA FW8001/06: 100-240V~/ 50–60 Hz/400-200 mA
Power Adapter/Output	FW7556M/06: 6 V ⎓ /2500 mA FW8001/06: 5.9 V ⎓ /3000 mA

10.2 EMC and Electrical Safety

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

The System has been tested for indoor use.

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

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

The electromagnetic environment in which the System will be operated should be evaluated prior to operation of the device. Do not use the System in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources) as these can interfere with the proper operation.

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

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

10.3 IVD Medical Device Directive

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

10.4 Warranty

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

10.5 Service and Disposal

Prior to service and disposal the Analyzer and Docking Stations should be cleaned as recommended in Instructions for Use. Consult your local environmental authorities for proper disposal.

10.6 Spare parts

- Power Adapter
- HemoCue 201 DM Battery
- Cuvette holder

10.7 Optional items

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

10.8 Symbols used

Caution

Consult instructions for use

CE mark

Biological risk

In Vitro diagnostic medical device

Temperature limitation

Manufacturer

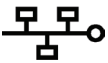
Humidity limitation

Alternating current

Catalogue number

USB

Serial number



Ethernet

DC inlet

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

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

Warning - Laser beam

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

Do not expose to fire

For indoor use only

Do not expose to any liquids

Efficiency Level

Do not expose to temperatures above 50 °C

Class II equipment

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			
Operator ID	Not Used Entry Required Approved Only	Not Used	
Min/Max characters in Operator ID	1/15	3/12	

Section Identifier	Available options	Default value	Customer Settings
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 (Whole Blood)	**Hb 201 DM:** 0.0-25.6 g/dL 0-256 g/L 0.0-15.9 mmol/L	**Hb 201 DM:** 0-25.6 g/dL	
	Glucose 201 DM: 0-400 mg/dL 0.0-22.2 mmol/L	**Glucose 201 DM:** 0-400 mg/dL	
	Glucose 201 DM RT: 0-500 mg/dL 0.0-27.8 mmol/L	**Glucose 201 DM RT:** 0-500 mg/dL	
Critical Limits (Plasma Equiv.)	**Glucose 201 DM:** 0-444 mg/dL 0.0-24.6 mmol/L	**Glucose 201 DM:** 0-444 mg/dL	
	Glucose 201 DM RT: 0-560 mg/dL 0.0-31 mmol/L	**Glucose 201 DM RT:** 0-560 mg/dL	
Patient ID	Not Used Optional Required	Not Used	

Section Identifier	Available options	Default value	Customer Settings
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	
Min/Max characters in Lab Number	1/25	3/12	
STAT Test	Used Not Used	Used	
STAT Tests Allowed	1-100	10	
Duplicate sampling	Not Used Used	Not Used	
Duplicate sampling Max. Difference	**Hb 201 DM**: 4.0 g/dL 40 g/L 2.5 mmol/L	0 mg/dL	
	Glucose 201 DM: 0-40 mg/dL 0-2.2 mmol/L	0 mg/dL	
	Glucose 201 DM RT: 0-40 mg/dL 0-2.2 mmol/L	0 mg/dL	
Dilution *function only available in Glucose 201 DM Analyzer*	Not Used Optional	Not used	
QC Test Settings			
QC Level 1 Lockout	Not Used Time Measurement	Not Used	

Section Identifier	Available options	Default value	Customer Settings
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 Level 2 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 Level 3 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 Level 4 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	

Section Identifier	Available options	Default value	Customer Settings
QC Level 5 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

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