cobas b 123 POC system

Instructions for Use

Roche

cobas®

Life needs answers

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Revision history

Manual Version	Software Version	Revision date	Changes
1.0		November 2009	not delivered
2.0	2.0	November 2010	Launch
2.1		April 2011	FDA submission draft
3.0	2.3	August 2011	
4.0	≥ 2.4	December 2011	
5.0	≥ 3.0	July 2012	
6.0	4.0	December 2012	internal released - not launched
7.0	≥ 4.0	January 2013	
8.0	≥ 4.1	July 2013	
9.0	≥ 4.5	April 2014	

Edition notice

cobas b 123 POC system

This manual is for users of the **cobas b** 123 POC system.

Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Software updates are done by Roche Service representatives.

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Brands

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Edition

Revision 9.0, April 2014

First edition: November 2009

REF/No. 05337631001

Local service contact

Table of contents

Preface

The **cobas b** 123 POC system is an analyzer with integrated AutoQC and oximeter module option.

This manual has detailed descriptions of **cobas b** 123 POC system features and general operational concepts, specification functions and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.

How to use this manual

- Keep this Instructions for Use in a safe place to ensure that it is not damaged and remains available for use.
- This Instructions for Use should be easily accessible at all times.

To help you find information quickly, there is a table of contents at the beginning of the book and each chapter. In addition, a complete index can be found at the end.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly, This section explains formatting conventions used in this manual.

Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
•	List item
👁	Cross-reference
☞	Call-up (software reference)
	Tip
	Attention All sections/passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction in the **cobas b** 123 POC system.
	Warning Sections marked with this symbol contain information that must be observed to avoid potential injuries (to patients, users and third parties).
	Risk of infection All sections and parts of texts that are marked with this symbol describe procedures that may involve risk of infection.

IVD symbols The symbols are used in accordance with DIN EN 980[(a)] and DIN EN ISO 780[(b)].

Symbol	Description
CE	Conformité Européenne: This product complies with the requirements in the guideline for In Vitro Diagnostic 98/79/EC.
LOT	Batch code
	Use by... The product should not be used after expiry of the specified date. If a day is not indicated, apply the last day of the respective month.
+2°C +30°C	Temperature limitation The conditions necessary to preserve the product's shelf life before opening.
IVD	In Vitro Diagnostic Medical Device
	Manufacturer (according to In Vitro Diagnostic guidelines 98/79/EG)
	Date of manufacture (dd-mm-yyyy)
REF	Catalogue number
	Caution, consult accompanying documents.
	Consult Instructions for Use.
SN	Serial number (model plate)
	Do not use if package damaged.
2	Do not reuse.
	Fragile. Handle with care.
	Handle with care.

(a) DIN EN 980: Symbols for use in the labelling of medical devices

(b) DIN EN ISO 780: Packaging - Pictorial marking for the handling of goods

Symbol	Description
	Contains sufficient for <x> tests (**cobas b** 123 Fluid Pack)
	Keep dry
	**Valid only for Roche MICROSAMPLER PROTECT:** Method of sterilization using ethylene oxide
	**Valid only for BS2 Blood Sampler:** Method of sterilization using irradiation
	Biological risk (according to the standard EN 61010-2-101[a]) (Instrument)
	Biological risk (according to the standard DIN EN 980[b]) (Consumables)
	Direct current[c]

(a) IEC/EN 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use - (Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment)

(b) DIN EN 980: Symbols for use in the labelling of medical devices

(c) IEC/EN 60417: Graphical symbols for use on equipment

Other symbols

The following symbols are listed as additional information:

Symbol	Description
	This way up (store upright)
	"Grüner Punkt" (in Germany)
	Protective gloves, protective goggles and suitable protective clothing must be worn.
	Software symbol for the **cobas b** 123 Fluid Pack
	Software symbol for the **cobas b** 123 AutoQC Pack
	Software symbol for the **cobas b** 123 Sensor Cartridge

Abbreviations The following abbreviations are used:

Abbreviation	Definition
1P-cal	1-point calibration
2P-cal	2-point calibration
A	
A	Ampere
$AaDO_2$	Alveolar-arterial oxygen partial pressure
$AaDO_2^t$	Alveolar arterial pressure at patient's temperature
a/AO_2	Alveolar-arterial oxygen partial pressure ratio
a/AO_2^t	Alveolar-arterial oxygen partial pressure at patient's temperature
AC	Alternating current
AMR	Analytical measurement range
ANSI	American National Standards Institute
A_{rate}	Ventilator setting: Aspiration rate
ASTM	American Society for Testing and Material
AutoQC	Automatic Quality Control
AutoQC Pack	**cobas b** 123 AutoQC Pack
AutoCVC Pack	**cobas b** 123 AutoCVC Pack (calibration verification control)
$avDO_2$	Arterial-venous oxygen level difference
B	
BE	Base excess of blood
BE_{act}	Base excess of blood at current oxygen saturation
BE_{ecf}	Base excess of the extracellular fluid
BB	Buffer bases
BG	Blood gas
Bili	Bilirubin
BO_2	Oxygen capacity
BSA	Bovine serum albumin
C	
ca.	circa
nCa^{2+}	Standardized ionized calcium (pH = 7.4)
CCD	Charge coupled device
CE	Conformité Européenne (European Conformity)
CF	CompactFlash
$cHCO_3^-$	Bicarbonate concentration in plasma
$cHCO_3^-{}_{st}$	Standard bicarbonate concentration in plasma
$ctCO_2(P)$	Total CO_2 concentration in the plasma
$ctCO_2(B)$	Total carbon dioxide concentration in the blood
ctO_2	Total oxygen concentration
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical Laboratory Standard Institute
cm	centimeter
COHb	Carboxyhemoglobin
COOX	CO-Oximetry

Abbreviation	Definition
CPAP	Ventilator setting: Continuous Positive Air Pressure
CSA	Canadian Standards Association
CSV	Comma-separated values
CVC	Calibration verification control
D	
dBA	Decibel weighted against the A-frequency response curve. This curve approximates the audible range of the human ear.
DC	Direct current
DIN	German Institute for Standardization (Deutsches Institut für Normung)
DNS	Domain Name Server
dpi	dots per inch
E	
EAN	European Article Number
EDTA	Ethylenediaminetetraacetic acid
EC	European community
e.g.	*exempli gratia* – for example
EN	European standard
F	
FCM	Fluidic control module
FIO_2	Proportion of inspiratory oxygen
Flowrate	Ventilator setting: Flowrate
Fluid Pack	**cobas b** 123 Fluid Pack
FO_2Hb	Fractional oxygen saturation
G	
GB	gigabyte
Glu	Glucose
H	
H^+	Hydrogen ion concentration
H^{+t}	Hydrogen ion concentration at patient's temperature
Hb factor	Serves to calculate Hct(c) values from tHb values
Hct	Hematocrit
Hct(c)	Hct calculated from tHb
HHb	Desoxyhemoglobin
HIV	Human immunodeficiency virus
Hz	hertz
I	
i.e.	*id est* – that is to say
IEC	International Electrotechnical Commission
ISE	Ion selective electrode
ISO	International Organization for Standardization
IVD	In vitro Device
IVDD	In vitro Diagnostic Directive
K	

Abbreviation	Definition
KCl	potassium chloride
kg	kilogram
L	
Lac	Lactate
LCD	Liquid crystal display
LED	Light emitting diode
LIS	Laboratory Information System
LJ	Levey Jennings
M	
MAC	Media Access Control
MAP	Ventilator setting: Mean Airway Pressure
MB	megabyte
MCHC	Middle corpuscular hemoglobin concentration
MCM	Measuring chamber module
MCT	Medium chain triglycerides
MetHb	Methemoglobin
MHz	megahertz
mm	millimeter
m	meter
MSDS	Material safety data sheet
MV	Mean value
MV	Ventilator setting: Minute volume
N	
NIST	National Institute of Standards and Technology
NRTL	Nationally Recognized Testing Laboratory
O	
O_2Hb	Oxyhemoglobin
OER	Oxygen extraction ratio
Osm	Osmolality
P	
*P*50	Oxygen partial pressure at 50% oxygen saturation calculated with SO_2 as measured value
PAO_2	Alveolar oxygen partial pressure
PAO_2^t	Alveolar oxygen partial pressure at patient's temperature
PCO_2	Partial pressure of carbon dioxide
PCO_2^t	PCO_2 at patient's temperature
PEEP	Ventilator setting: Positive End-Expiratory Pressure
P/F index	PaO_2/FIO_2 ratio
pH_{st}	Standard pH value
pH^t	pH at patient's temperature
PIP	Ventilator setting: Peak Inspiratory Pressure
PO_2	Partial pressure of oxygen
PO_2^t	PO_2 at patient's temperature
POC	Point of Care

Abbreviation	Definition
POCT1-A	Standard for Point-of-Care Testing Instruments (POCT)
Q	
QC	Quality Control
Qt	Difference of oxygen concentration between alveolar and mixed venous blood
Qs/Qt	Shunt - quotient between both oxygen concentration differences
R	
R	Gas exchange quotient
RAM	Random access memory
RECAL	Recalibration
REF	Reference solution
RI	Respiratory index
RI^t	Respiratory index at patient's temperature
RQ	Respiratory quotient
S	
SD	Standard deviation
Sensor Cartridge	**cobas b** 123 Sensor Cartridge
SIM	Sample input module
SO_2	Oxygen saturation
$SO_2(c)$	Functional oxygen saturation calculated with $P50$ as input value
S_{rate}	Ventilator setting: Sigh rate
STDBY	Standby solution
T	
TFT	Thin-film transistor
tHb	Total hemoglobin
tHb(e)	Entered tHb value (not measured)
Te	Ventilator setting: Expiration time
Ti	Ventilator setting: Inspiration time
U	
UIM	User interface module
UPC	Universal Product Code
UPS	Un-interruptible Power Supply
USB	Universal Serial Bus
V	
V AC	volt - alternating current voltage
V DC	volt - direct current voltage
VDE	Association of German Electrical Engineers (Verband Deutscher Elektrotechniker)
VT	Ventilator setting: Tidal volume
W	
W	watt
WET	wetting solution

For writing the measuring, calculated and input values see chapter 8 *Measurement*, section *Notation of the measured, input, and calculated values* on page D-65.

Short Instruction A

Short Instruction

This chapter describes in a short way how to start up and shut down the instrument, how to carry out a measurement and a QC measurement and the process of changing the consumables.

In this chapter *Chapter* 1

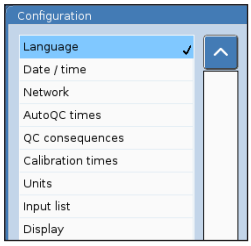
Table of contents

Installation

1 Connect the barcode scanner and, if necessary, the network connection to the corresponding interface on the rear side of the **cobas b** 123 POC system.

2 First connect the external power supply to the instrument and then to the power supply network.

3 Switch on the instrument. The installation routine starts automatically.



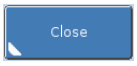
Configuration wizard

4 A list of the most important settings that must be checked and modified in the first step of the installation routine. Start the configuration wizard by pressing the [Configure] button.

For data input or to modify existing data, select the desired data from the list or press the [Pencil] button.

By pressing the [Close] button, all changes are saved automatically.


Pencil




Fluid Pack

5 The installation is prepared (automatic step).

6 Open the front door.

7 Insert the Fluid Pack.

8 Insert the Sensor Cartridge.


Sensor Cartridge

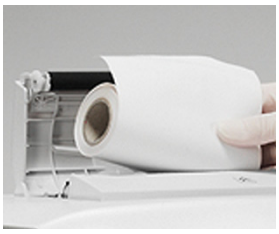

AutoQC Pack

9 Insert the AutoQC Pack (optional).

10 Close the front door.

11 Insert the printer paper (optional).

12 Finish the installation routine by pressing the [Complete] button.


Printer paper

13 Follow-up actions are started.

For detailed information refer chapter 7 *Installation and put out of operation*, section *Installation* on page D-5.

WARNING

Warning

To ensure the quality of measurement results, each time a Fluid Pack and/or Sensor Cartridge is changed, you must run a quality control in 3 levels. (1 = low, 2 = normal, 3 = high).

Put out of operation

For less than 24 hours

Go to the "Utilities" menu and press the following button:

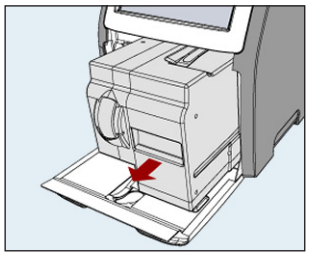
☞ [Switch off]

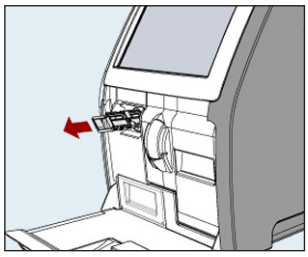
For more than 24 hours

Go to the "Utilities" menu and press the following button:

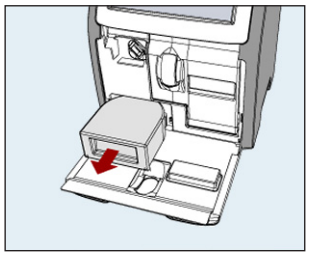
☞ [Put out of operation]

1 To start the put out of operation procedure. acknowledge the warning with [OK].
2 Preparing for removal (automatic step).
3 Open the front door.
4 Remove the Fluid Pack.





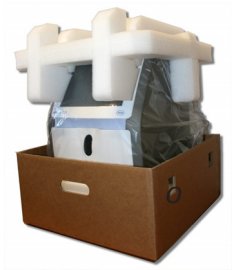
5 Remove the Sensor Cartridge.
6 Remove the AutoQC Pack (optional).
7 Press the [Switch off] button to conclude the put out of operation routine.



Note

To lock the front door, close the front door before pressing the [Switch off] button.

For detailed information refer chapter 7 *Installation and put out of operation*, section *Put out of operation* on page D-14.



Disconnect the power supply first from the power supply network and then from the instrument. If present,

- disconnect the barcode scanner and the network connection on the rear panel.
- remove the USB storage device.
- remove the printer paper.

Measurement

Always wear protective clothing, protective gloves and protective goggles when handling blood or parts potentially contaminated with blood.

A measurement can be started from the "Overview" menu only.

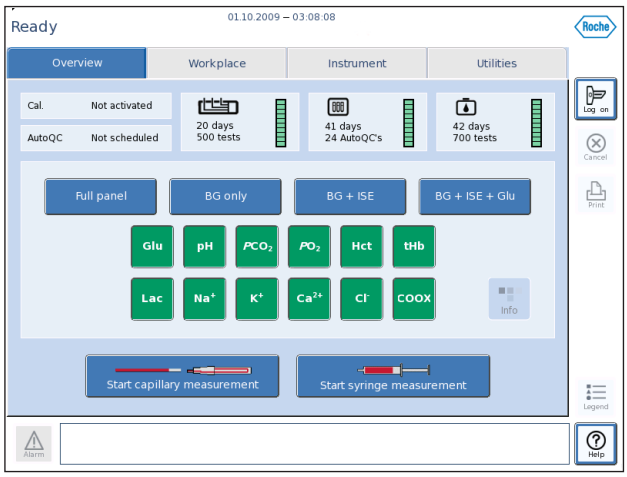
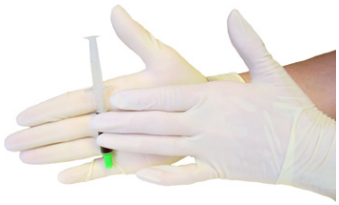
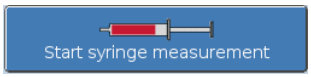


Figure A-1 Overview screen

Syringe sample



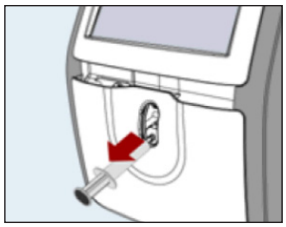


1. Gently roll syringe for proper sample mixing.
2. Select/deselect the desired parameters or parameter panels at the "Overview" screen.

Activated for next measurement & calibration

Deactivated for next measurement

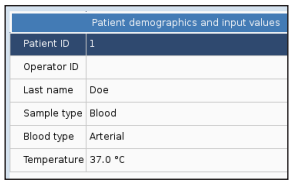
3. Press the [Start syringe measurement] button.
4. Securely attach the syringe at the fill port and press [Yes].
5. The sample is aspirated.



6 After the prompt "Remove the syringe", remove the syringe and press [Yes].

7 The measurement is started.

8 Enter all input values. The correct sample type must be entered in order to avoid false values.



For detailed information refer chapter 8 *Measurement*, section *Syringe measurement* on page D-40 and *Data input* on page D-47.

Capillary & Roche MICROSAMPLER PROTECT sample

Always wear protective clothing, protective gloves and protective goggles when handling blood or parts potentially contaminated with blood.

Activated for next measurement & calibration

Deactivated for next measurement

1 Make sure the sample is analyzed within 15 minutes.

2 A measurement can be started from the "Overview" menu only.

see *Overview screen* on page A-7.

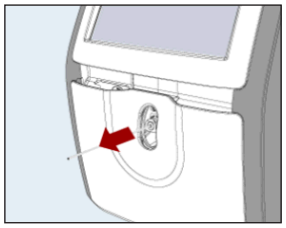
3 Select/deselect the desired parameters or parameter panels at the "Overview" screen.

4 Press the [Start capillary measurement] button.

5 Securely attach the capillary or Roche MICROSAMPLER PROTECT to the fill port and press [Yes].

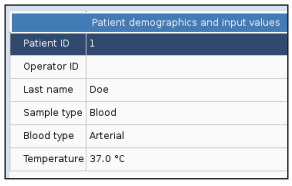
6 The sample is aspirated.

7 After the prompt "Remove the capillary", remove the capillary or Roche MICROSAMPLER PROTECT and press [Yes].



8 The measurement is started.

9 Enter all input values. The correct sample type must be entered in order to avoid false values.



For detailed information refer chapter 8 *Measurement*, section *Capillary measurement* on page D-42 and *Data input* on page D-47.

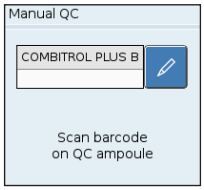
Quality control

Manual QC measurement

Go to the "Workplace" menu and press the following button:

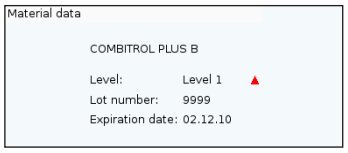
☞ [QC measurement]

1 Remove the corresponding level ampoule of the desired QC material from the packaging.



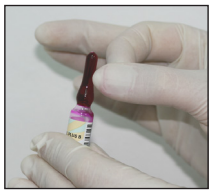
2 Using the barcode scanner, scan the barcode from the label of the ampoule. Once the material has been detected, the user interface switches automatically to the next step (refer to point 4).

3 If no barcode scanner is available for the input, read off the lot number of the ampoule and enter it manually using the [Pencil] button.



4 Check the data on the screen against the data of the QC material.

5 Press the following buttons to start a QC measurement: [Start capillary measurement]



6 Tap your fingernail against the ampoule to remove the liquid from the ampoule neck.

7 Break open the ampoule.

8 Carry out the measurement using an ampoule adapter directly from the ampoule. Securely attach the adapter to the fill port.

9 To start the aspiration process, press the [Yes] button. The control material is aspirated.

10 After the prompt "Remove the capillary", pull out the adapter and press [Yes].

11 The QC measurement is started.

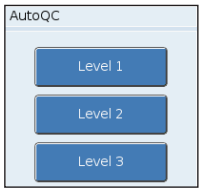
12 Enter the input values completely.

13 Press the [Accept] or [Reject] button to conclude the QC measurement routine.

Manual AutoQC measurement

Warning

To prevent injuries, protect your hands with gloves and cellulose when breaking open the ampoule.



For a manually activated AutoQC measurement starting from the "Workplace" menu, press the following button: [QC measurement]

The AutoQC measurement is started by pressing the desired level.

Proficiency test

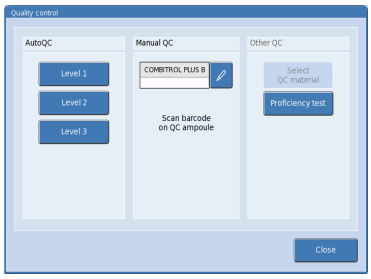
Note

In case security level 3 or 4 is activated, the Proficiency test function will be available only for the following operator profiles: trusted operator, service operator, key operator and supervisor.

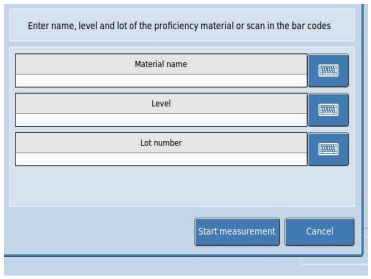
For detailed information refer to Software functions, Chapter 12 *Operators* on page D-148

From the "Workplace" menu, press the following button:

☞ [QC measurement]



1 Press the [Proficiency test] button

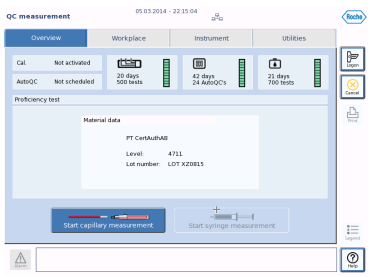


2 Enter the material name, level and/or lot number of the proficiency test material. Details can be entered manually using the [Pencil] button, or by using the barcode scanner when barcodes are available.

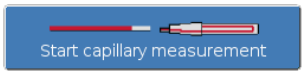
3 Press the [Start measurement] button

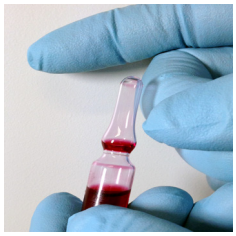
Note

Strictly follow the instructions that are usually provided together with the proficiency test material regarding storage conditions, temperature equilibrium and mixing prior to use. If the conditions above were not satisfied, press [Cancel]



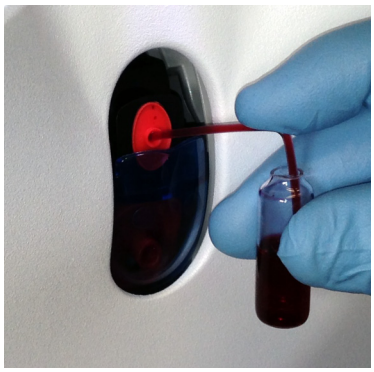
4 Press the [Start capillary measurement] button



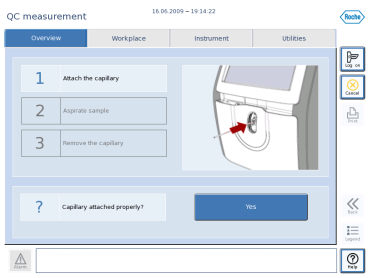


5 Tap your fingernail against the ampoule to remove the liquid from the ampoule neck.

6 Break open the ampoule.



7 Carry out the measurement using an ampoule adapter directly from the ampoule. Securely attach the adapter to the fill port.



8 To start the aspiration process, press the [Yes] button. The proficiency test material is aspirated

9 After the prompt "Remove the capillary", pull out the adapter and press [Yes].

10 The Proficiency test is started

11 Press the [Accept] or [Reject] button to conclude the Proficiency test routine.

Note

No target ranges apply for proficiency test. The Levey-Jennings graph is not available for proficiency test.

Warning

To prevent injuries, protect your hands with gloves and cellulose when breaking open the ampoule.

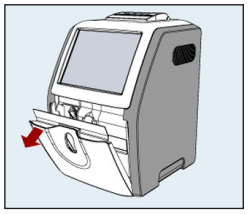
For detailed information refer to Quality Control, Chapter 9 *Proficiency test* on page D-82

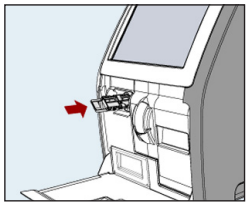
Consumable change

Sensor Cartridge change

Go to the "Workplace" menu and press the following button:

☞ [Change Sensor Cartridge]

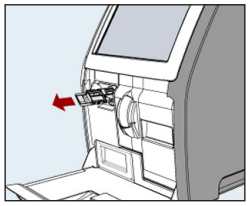




1 The instrument automatically prepares for the Sensor Cartridge change.
Wait until the preparation time is finished.

2 Open the front door.

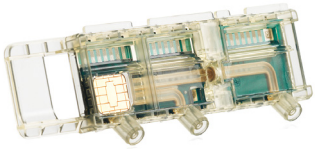
3 Remove the Sensor Cartridge.



4 Insert the new Sensor Cartridge.

5 Close the front door.

6 Follow-up actions are started.



WARNING

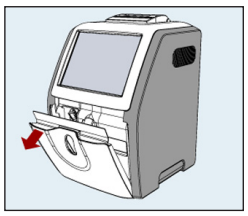
Warning

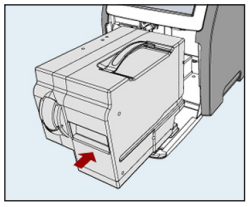
To ensure the quality of measurement results, each time the Sensor Cartridge is changed, you must run a quality control in 3 levels (1 = low, 2 = normal, 3 = high).

Fluid Pack change

Go to the "Workplace" menu and press the following button:

☞ [Change Fluid Pack]

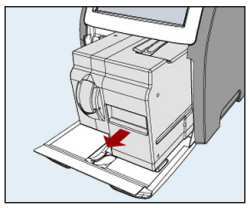




1 The instrument automatically prepares for the Fluid Pack change.
Wait until the preparation time is finished.

2 Open the front door.

3 Remove the Fluid Pack.



4 Insert the new Fluid Pack.

5 Close the front door.

6 Follow-up actions are started.

WARNING

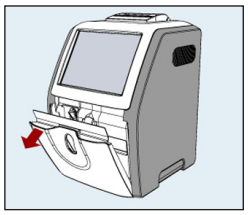
Warning

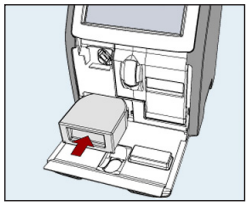
To ensure the quality of measurement results, each time the Fluid Pack is changed, you must run a quality control in 3 levels (1 = low, 2 = normal, 3 = high).

AutoQC Pack change (optional)

Go to the "Workplace" menu and press the following button:

☞ [Change AutoQC Pack]





1 A new AutoQC Pack must be adjusted to room temperature at least 24 hours prior to use.

2 The instrument automatically prepares for the AutoQC Pack change.
Wait until the preparation time is finished.

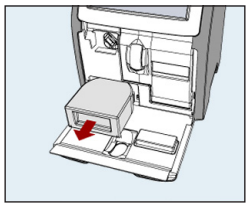
3 Open the front door.

4 Remove the AutoQC Pack.

5 Insert the new AutoQC Pack.

6 Close the front door.

7 Follow-up actions are started.



Introduction and specifications

B

Safety Information

The information provided in this chapter is essential for the safe, trouble-free operation of the instrument and must be read and understood by the user.

In this chapter

Chapter **2**

Table of contents

Important information

These Instructions for Use contain vital warnings and safety information.

This instrument is intended to be used only for the specialized purpose described in the instructions. The most important prerequisites for use, operation, and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the machine is used in ways other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.

Suitable protective equipment, like laboratory clothing, protective gloves, protective goggles and if necessary mouth protectors, must be worn to prevent direct contact with biological working materials. In addition, a face mask is required if there is a risk.

Adjustments and maintenance performed with covers removed and power connected may be attempted only by a qualified technician who is aware of the associated dangers.

Instrument repairs are to be performed only by the manufacturer or qualified service personnel.

Only accessories and supplies either delivered by or approved by Roche are to be used with the instrument. These items are manufactured especially for use with this instrument and meet the highest quality requirements.

Operation of the instrument with solutions whose composition is not consistent with that of the original solutions can negatively affect the long-term measurement accuracy. Deviations in the composition of the solutions can also decrease the service life of the Sensor Cartridge.

For safety reasons, quality control measurements must be performed daily. Since the measurements of the instrument depend not only on the correct characteristic function, but also on a series of marginal conditions (e.g. pre-analysis), results obtained from the instrument should be submitted for an expert opinion before taking additional measures based on the supplied measurements.

CAUTION

Caution: Observe the documentation

If the instrument is not used according to the Instructions for Use, existing safety mechanisms may be impaired.

Operating safety information

The instrument has been constructed and tested according to the following European Standards:

- IEC/EN 61010-1[(a)]
- IEC/EN 61010-2-101[(b)]
- IEC/EN 61010-2-081[(c)]
- IEC/EN 61326-1[(d)]
- IEC/EN 61326-2-6[(e)]

The instrument was manufactured to meet all relevant safety standards. To maintain this condition and ensure safe operation, follow all instructions and warnings contained in this manual.

- This instrument is classified under the protection class I according to IEC/EN 61010-1.
- The instrument meets the conditions for overvoltage category I.
- The instrument meets the conditions for contamination level 2.
- The instrument is classified according to EN ISO 9614-1[(f)] and has a noise level lower than 55 dB.
- Do not operate the instrument in an explosive environment or in the vicinity of explosive or combustible mixtures of anesthetics with air, oxygen or nitrous oxide.
- Service must be carried out by authorized personnel only. The instrument does not contain any user-serviceable parts.
- The instrument is maintenance-free, as all wear parts are replaced by changing the consumables.
  Recurring inspections are to be carried out based on local regulations.
  According to IEC/EN 62353[(g)] recurring inspections are to be carried out every 24 months.
- If objects or liquids enter the internal areas of the instrument, remove the instrument from its power supply and allow an expert to check it thoroughly before using it again.
- The instrument is suitable for long-term operation indoors.

(a) IEC/EN 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use (Part 1: General requirements)

(b) IEC/EN 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use (Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment)

(c) IEC/EN 61010-2-081: Safety requirements for electrical equipment for measurement, control and laboratory use (Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes)

(d) IEC/EN 61326-1: Electrical equipment for measurement, control and laboratory use - EMC requirements (Part 1: General requirements)

(e) IEC/EN 61326-2-6: Electrical equipment for measurement, control and laboratory use - EMC requirements (Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment)

(f) EN ISO 9614-1: Acoustics - Determination of sound power levels of noise sources using sound intensity (Part 1: Measurement at discrete points)

(g) IEC/EN 62353: Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

Warning

When the front door is open and consumables are removed at the same time, there is a risk of injury. Observe the regulations and safety instructions in the respective chapters of the Instructions for Use.

- The power cord must be plugged into a grounded power receptacle. When using an extension cord, make sure it is properly grounded.
- The power cable must conform to country-specific requirements.
  Orders can be placed via the local Roche organization only.
- Any rupture of the ground lead inside or outside the instrument or a loose ground connection may result in hazardous operating conditions for the operating personnel. Intentional disconnection of the grounding is not permitted.
- The instrument is not suitable for operation with a direct current power supply.
- Use the original power supply for the **cobas b** 123 POC system only. The power supply must not be repaired or opened.

IT Security Advisory

Description

All devices based on common off-the-shelf operating systems (Microsoft Windows, Linux, etc.) with the capability to connect external storage devices (USB memory drives/sticks, hard disks, floppy disks, CD-ROM, DVS, cameras, PDA, wireless communication devices, etc.) are concerned. This usually applies but is not limited to all products which come with a PC or Notebook.

External storage media can be infected with and transmit computer malware (e.g. Virus, Trojan Horse, Spyware, etc.)

cobas b 123 POC system does not contain anti-virus protection software. Therefore, it is essential to follow the necessary precautions listed below to prevent the transmission of malware.

Security precautions

Caution

Failure to observe the following recommendations may result in data loss, loss of integrity of patient results or unavailability of the system, which may put patients at risk.

- Check all external storage devices with an anti-virus program (on another PC) to ensure that they are malware free before using them on the system.
- Recheck the external storage device between use on different systems in order to avoid cross-interference.
- At no time should portable storage media, particularly USB memory drives/sticks, be used at home or at public computer systems and then be used to connect to a work- or customer-system.
- Do not use the USB ports to connect other external storage devices unless stated in **cobas b** 123 POC system-specific documentation.
- Keep all external storage devices in a secure place so that they can be accessed only by authorized personnel.

- Do not add, move or delete any files or software unless stated in **cobas b** 123 POC system-specific documentation.
- Never copy and install any non-Roche software on the system.
- If a system requires additional software please contact the appropriate system hotline.
- Use any remote services capability only to connect to the Roche Service Network.
- Do not connect to the Internet unless stated in **cobas b** 123 POC system-specific documentation.
- Make sure only validated computers are connected to the instrument system network.
- Ensure other computers on attached networks (e.g. the LIS, FTP) are properly secured and protected from malware. This is the responsibility of the customer and their IT specialists.

General description

This chapter contains a general description of the instrument, the safety precautions against specific dangers and the correct handling of the Sensor Cartridge, Fluid Pack and AutoQC Pack.

In this chapter *Chapter* 3

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Introduction

Figure B-1 **cobas b** 123 POC system

The **cobas b** 123 POC system is a fully automated POC system for in vitro measurement of pH, blood gases (BG), electrolytes (ISE), hematocrit (Hct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O_2Hb, HHb, COHb, MetHb), oxygen saturation (SO_2) and neonatal bilirubin (Bili).(a)

In addition the **cobas b** 123 POC system calculates derived parameters.

It is dedicated for use in a Point-of-Care environment and laboratory.
The integrated AutoQC module and the oximeter module are available as an option.

Depending on the equipment configuration of the instrument, the Sensor Cartridge used and the Fluid Pack used, the following parameters are measured in human whole blood, dialysis solution and QC materials:

Instrument version	Measured parameters	Optional modules
cobas b 123<1> system	pH, BG (PO_2, PCO_2), ISE (Na^+, K^+, Cl^-, Ca^{2+}), Hct, Glu, Lac	
cobas b 123<2> system	pH, BG (PO_2, PCO_2), ISE (Na^+, K^+, Cl^-, Ca^{2+}), Hct, Glu, Lac	AutoQC module
cobas b 123<3> system	pH, BG (PO_2, PCO_2), ISE (Na^+, K^+, Cl^-, Ca^{2+}), Hct, Glu, Lac tHb, O_2Hb, HHb, COHb, MetHb, SO_2, Bili	Oximeter module
cobas b 123<4> system	pH, BG (PO_2, PCO_2), ISE (Na^+, K^+, Cl^-, Ca^{2+}), Hct, Glu, Lac tHb, O_2Hb, HHb, COHb, MetHb, SO_2, Bili	AutoQC & Oximeter module

Table B-1 **cobas b** 123 POC system - versions

Sample type	Measured parameters
Whole blood. QC material	pH, BG (PO_2, PCO_2), ISE (Na^+, K^+, Cl^-, Ca^{2+}), Hct, Glu, Lac, tHb, O_2Hb, HHb, COHb, MetHb, SO_2, Bili
Dialysis solution	Na^+, K^+, Ca^{2+}

For a list of Sensor Cartridge versions, refer to chapter 6 *System components*, section *cobas b 123 Sensor Cartridge* on page C-17.

For a list of all consumables, refer to chapter 15 *List of consumables*.

(a) total bilirubin

General instructions

Application area

The instrument is designed for measuring parameters in human whole blood and the specifications or performance characteristics of measurement values have been tested for this application area.

The specifications or performance characteristics of measurement values for recommended aqueous control solutions are ensured by choosing suitable ingredients and by making the corresponding corrections in QC measuring mode.

The accuracy of measurement values for undefined aqueous solutions cannot be guaranteed (for example, due to potentially interfering components and/or missing or insufficient buffer systems and/or differences in ion concentration and diffusion potential as compared to biological sample materials).

General instructions for operation

The instrument should be switched on at all times.

If the instrument is to be deactivated for a longer period (> 24 h) of time, it is necessary to carry out put out of operation procedures.

For additional information, refer to chapter 7 *Installation and put out of operation*.

Any fluids other than samples and QC material must be prevented from entering into the interior of the instrument through the fill port.

To ensure the quality of measurement results, you must run quality control on three levels (1 = low, 2 = normal, 3 = high) after each Sensor Cartridge replacement, Fluid Pack replacement and after installing the instrument.

In addition, at least one QC measurement at alternating levels (1 = low, 2 = normal, 3 = high) is required in between two automatic 2-point calibrations (2P cal.).

For additional information, refer to chapter 9 *Quality control*.

Calibration principle

The parameters of the **cobas b** 123 POC system are calibrated using three stable aqueous solutions, which are in airtight bags inside the Fluid Pack. Additional calibration media are not required. This makes a supply with precision gas unnecessary.

ISE, pH, CO_2 sensors

The Na^+, K^+, Ca^{2+}, Cl^-, pH and CO_2 parameters are calibrated using standby and CAL 2 solutions, which contain a defined quantity of electrolytes and acidic or alkaline components of a pH buffer system. By ensuring airtight access to the calibration solutions, the CO_2 content can be kept steady and then used as a basis for calibration.

O_2 sensor

The CAL 2 solution contains a very low concentration of oxygen and thus is used to calibrate the low calibration point. Once an hour, the high calibration point is calibrated using the standby solution. The oxygen concentration of the standby solution corresponds to that of the ambient air. This calibration point is verified once daily by calibration using ambient air.

Hct

Hct is calibrated by means of conductivity measurements using an electronic reference point and the standby solution, which has a high conductivity.

Glu/Lac sensors

Due to the nature of the calibration curve, three calibration points must be determined for calibrating the Glu and Lac measurement parameters. The standby, CAL 1 and CAL 2 solutions are used for this purpose.

Oximeter module (tHb, *SO*$_2$, Hb derivates and bilirubin)

Calibrating the oximeter module requires wavelength calibration of the polychromator and layer thickness calibration of the cuvette.

Polychromator calibration Through known intensity maxima of the spectral light source, an exact assignment between the measurement signal and wavelength is possible using the polychromator calibration.

Layer thickness of the cuvette The layer thickness of the cuvette must be calibrated because it is directly associated with the measured absorption. Use the CAL 2 solution which contains a dye for this purpose.

Measurement evaluation

Warning

The measurement results that are output by the **cobas b** 123 POC system must always be checked for plausibility by medical specialists with consideration of the clinical situation of the patient before a clinical decision is made based on the results.

To ensure the quality of measurement results, you must run quality control on three levels (1 = low, 2 = normal, 3 = high) after each Sensor Cartridge replacement, Fluid Pack replacement and after installing the instrument.

In addition, at least one QC measurement at alternating levels (1 = low, 2 = normal, 3 = high) is required in between two automatic 2-point calibrations (2P cal.).

For detailed information, refer to chapter 9 *Quality control*.

Safety precautions against specific dangers

Safety Instructions

Observe the necessary sanitary regulations when handling sample materials. They can contain dangerous pathogens.

For detailed information, refer to chapter 8 *Measurement*.

Disposal of consumables and instrument

Safety Instructions

The Fluid Pack, Sensor Cartridge, used sampling materials and the instrument must be disposed according to the applicable local laws and laboratory regulations (biologically contaminated – hazardous waste.).

Disinfection

The purpose of the disinfection is to minimize the risk that exists when handling parts which have been in contact with biological sample materials.

Roche recommends carrying out a disinfection procedure. Furthermore, general laboratory regulations must be observed.

This disinfection must be performed regularly according to typical laboratory regulations to minimize the risk of infection.

For more detailed information on disinfection, refer to chapter 13 *Consumable change*, section *Disinfection* on page E-5.

Safety Instructions

After use, the Fluid Pack and Sensor Cartridge contain biological fluids or fluid residue that pose a risk for infection.

Handle these components with care observing the regulations for handling potentially infectious material. Avoid skin contact.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Handling of the cobas b 123 Fluid Pack

Safety Instructions

In case of fluid leakage from the Fluid Pack (e.g. during operation or after replacement) observe the regulations for handling potentially infectious material.

The Fluid Pack must be stored according to the specifications provided on the packaging. The temperature of the solutions should be adjusted to the ambient temperature prior to use.

The Fluid Pack has a limited shelf life.

The storage temperature and maximum shelf life are specified on the Fluid Pack label and the packaging.

Caution: Do not freeze

Freezing the Fluid Pack can result in changing the concentration of the solution and thus calibration errors.

Do not use damaged Fluid Packs.

For "Storage and transport conditions", refer to chapter 4 *Specifications*.

Handling of the cobas b 123 Sensor Cartridge

The Sensor Cartridge must be stored according to the specifications on the packaging. The Sensor Cartridge has a limited shelf life.

The storage temperature and maximum shelf life are specified on the Sensor Cartridge packaging.

For "Storage and transport conditions", refer to chapter 4 *Specifications*.

Sensor phases

Phase	Instrument performance
START-UP phase	No measuring operation
RUN-IN phase	Measuring operation with longer time-to-display or time-to-ready
Stable phase	Regular operation
IN-USE time	Service life of the Sensor Cartridge

Table B-2

After inserting a new Sensor Cartridge allow a START-UP phase of 60 minutes. During this time, the Sensor Cartridge is moistened and a system calibration is carried out. Then, the instrument must be calibrated frequently (RUN-IN phase).

START-UP phase

The START-UP phase describes the time from inserting a new, dry Sensor Cartridge until the sensors are ready for the first measurement. This phase consists of the following parts:

- WET-UP procedure
- Couple check
- First system calibration

The START-UP phase is typically completed in 60 minutes.

Note

The START-UP phase is initiated when a new Sensor Cartridge is inserted.

WET-UP procedure During the WET-UP procedure, a standby solution is aspirated. This moistens the Sensor Cartridge and activates it at an increased temperature.

Couple check The thermocouple check ensures that the different temperature zones for BG (37° C) and ISE/Glu/Lac (30° C) can be correctly maintained.

Note

If the instrument stops during the couple check, the Sensor Cartridge must be removed and checked for foreign objects and damage.

Swelling time Describes the time between the end of the couple check and the first system calibration. This depends on the sensor and is already saved to the smart memory chip of the Sensor Cartridge when delivered.

First system calibration The first system calibration ends the START-UP phase. All calibration data are newly determined during this calibration; therefore, it takes longer than a normal system calibration. The start time for the calibration depends on the sensor and is already saved to the smart memory chip of the Sensor Cartridge when delivered.

RUN-IN phase

The RUN-IN phase begins with the end of the START-UP phase and continues for a RUN-IN time stored on the Sensor Cartridge.

In the RUN-IN phase, due to stability, the Sensor Cartridge does not yet achieve the full performance with respect to sampling rate, measurement speed, utilization time, etc. However, there are no limitations on the measuring accuracy and precision.

Stable phase

The "Stable phase" begins after the RUN-IN phases have ended, until the end of the service life of the Sensor Cartridge.

IN-USE time

The IN-USE time is the time from the beginning of the RUN-IN phase until the end of the "Stable phase" (end of the service life of the Sensor Cartridge).

For "Stability during operation", refer to chapter 4 *Specifications*, section *cobas b 123 Sensor Cartridge* on page B-51.

Handling of the cobas b 123 AutoQC Pack

The AutoQC Pack must be stored according to the specifications provided on the packaging. The temperature of the AutoQC Pack should be adjusted to the ambient temperature prior to use.

The AutoQC Pack has a limited shelf life.

The storage temperature and maximum shelf life are specified on the AutoQC Pack label and the packaging.

Caution: Do not freeze

Freezing the AutoQC Pack can result in changing the concentration of the solution and thus QC errors.

Do not use damaged AutoQC Packs.

For "Storage and transport conditions", refer to chapter 4 *Specifications*.

Specifications

In this chapter, the performance data, as well as product and environmental data are described.

In this chapter

Chapter **4**

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Performance data

Measurement parameters

Parameter	specified for	specified range	
PO_2	B/Q/C	10 - 700 mmHg	
PCO_2	B/Q/C	10 - 150 mmHg	
pH	B/Q/C	6.5 - 8.0	
Sodium	B/Q/C	100 - 200 mmol/L	
	DS	120 - 155 mmol/L	
Potassium	B/Q/C	1.0 - 15 mmol/L	
	DS	1.0 - 6.0 mmol/L	
Chloride	B/Q/C	70 - 150 mmol/L	
ionized Calcium	B/Q/C	0.1 - 2.5 mmol/L	0.4008 - 10.02 mg/dL
	DS	0.9 - 1.85 mmol/L	3.6072 - 7.42 mg/dL
Hct	B/Q	10 - 75%	
Glucose	B/Q/C	1.0 - 30 mmol/L	18.016 - 540.48 mg/dL
Lactate	B/Q/C	1.0 - 20 mmol/L	9.0080 - 180.16 mg/dL
tHb (COOX)	B/Q	4 - 25 g/dL	
SO_2 (COOX)	B/Q	30 - 100%	
HHb (COOX)	B/Q	0 - 70%	
COHb (COOX)	B/Q	0 - 70%	
O_2Hb (COOX)	B/Q	30 - 100%	
MetHb (COOX)	B/Q	0 - 70%	
Bilirubin (neonatal) (COOX)	B/Q	3 - 50 mg/dL	51.3 - 855 µmol/L
Baro		530 - 800 mmHg	

Table B-3 Measurement parameters

B	Whole blood
DS	Dialysis solution
Q	Aqueous QC material[(a)]
C	Aqueous solution

(a) with approximate physiological ion matrix and buffer capacity.

Precision (sample mode: normal)

"Repeatability (S_R)" - and "Intermediate precision (S_I)" data were determined using the **cobas b** 123 POC systems over a 20-day period with two daily runs and two measurements per run.

The mean value is the measured value of the corresponding parameter for which S_R and S_I are representative or have been determined.

Tonometered whole blood Whole blood was tonometered at 37°C with high-precision gas mixtures.

Prepared whole blood Expected values for prepared whole blood are based on reference methods.

pH

Unit: [pH units]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	7.237	0.0029	0.04	0.0033	0.04
Sample 2	7.441	0.0029	0.03	0.0032	0.04
Sample 3	7.568	0.0054	0.07	0.0050	0.06

Table B-4

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	7.149	0.0026	0.04	0.0059	0.08
Level 2	7.393	0.0016	0.02	0.0043	0.06
Level 3	7.543	0.0016	0.02	0.0044	0.06

Table B-5

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	6.883	0.0017	0.02	0.0083	0.12
Level 5	7.731	0.0015	0.02	0.0061	0.08

Table B-6

PO_2

Unit: [mmHg]

Material: tonometered human whole blood, 20 different probands, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	145.4	0.7404	0.51	3.2402	2.23
Sample 2	40.5	0.6888	1.70	2.4680	6.09
Sample 3	352.2	2.0866	0.59	8.7645	2.49

Table B-7

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	58.5	1.0476	1.79	1.7558	3.00
Level 2	98.7	1.6680	1.69	3.5239	3.57
Level 3	147.6	1.1515	0.78	4.6708	3.17

Table B-8

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	28.9	1.8232	6.32	2.3972	8.31
Level 5	448.5	5.6049	1.25	16.8744	3.76

Table B-9

PCO_2

Unit: [mmHg]

Material: tonometered human whole blood, 20 different probands, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	23.5	0.1174	0.50	0.5186	2.21
Sample 2	72.7	0.3728	0.51	2.3130	3.18
Sample 3	128.6	1.7942	1.39	3.3567	2.61

Table B-10

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	64.2	0.4441	0.69	1.0526	1.64
Level 2	41.9	0.2699	0.64	0.6055	1.44
Level 3	25.7	0.0935	0.36	0.4348	1.69

Table B-11

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	123.5	0.7458	0.60	3.3313	2.70
Level 5	19.2	0.1436	0.75	0.4081	2.12

Table B-12

Sodium

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	117.7	0.2845	0.24	0.5352	0.45
Sample 2	138.6	0.2709	0.19	0.4388	0.31
Sample 3	156.2	0.5890	0.37	0.5361	0.34

Table B-13

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	117.4	0.3946	0.34	0.5152	0.44
Level 2	141.0	0.1519	0.11	0.4866	0.35
Level 3	153.7	0.4462	0.29	0.8063	0.52

Table B-14

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	113.2	0.1765	0.16	0.7363	0.65
Level 5	177.5	0.2032	0.11	1.2176	0.69

Table B-15

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	140.7	0.6789	0.48	1.8788	1.34
High level	160.9	0.2104	0.13	0.9028	0.56

Table B-16

Material: prepared dialysis solution, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	122.5	0.3801	0.31	0.5162	0.42
Level 2	139.1	0.3207	0.23	0.4397	0.32
Level 3	150.5	0.2882	0.19	0.4577	0.30

Potassium

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	3.05	0.0221	0.72	0.0228	0.74
Sample 2	5.00	0.0148	0.29	0.0198	0.39
Sample 3	6.10	0.0198	0.32	0.0238	0.39

Table B–17

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	2.98	0.0110	0.37	0.0170	0.57
Level 2	4.72	0.0070	0.15	0.0174	0.37
Level 3	7.01	0.0225	0.32	0.0515	0.74

Table B-18

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	9.25	0.0152	0.16	0.1166	1.26
Level 5	2.02	0.0060	0.30	0.0292	1.44

Table B-19

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	3.67	0.0161	0.44	0.0476	1.30
High level	6.45	0.0104	0.16	0.1259	1.95

Table B-20

Material: prepared dialysis solution, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	1.28	0.0086	0.67	0.0239	1.87
Level 2	3.97	0.0061	0.15	0.0131	0.33
Level 3	5.76	0.0053	0.09	0.0157	0.27

Chloride

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	78.2	0.3529	0.45	0.6415	0.82
Sample 2	101.4	0.3478	0.34	0.4932	0.48
Sample 3	126.6	0.7057	0.55	0.7989	0.63

Table B-21

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	81.5	0.5086	0.62	1.3698	1.68
Level 2	99.5	0.2633	0.26	1.0743	1.08
Level 3	115.6	0.3831	0.33	1.0635	0.92

Table B-22

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	89.4	0.0815	0.09	0.4791	0.54
Level 5	133.5	0.3652	0.27	1.9308	1.45

Table B-23

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	105.0	0.3959	0.38	1.5632	1.49
High level	125.6	0.2029	0.16	1.1795	0.94

Table B-24

Ionized calcium

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.72	0.01	1.07	0.01	1.85
Sample 2	1.18	0.01	0.79	0.02	1.79
Sample 3	1.40	0.02	1.25	0.02	1.25

Table B-25

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	1.709	0.0105	0.61	0.0132	0.77
Level 2	1.219	0.0029	0.24	0.0045	0.37
Level 3	0.661	0.0049	0.74	0.0061	0.92

Table B-26

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 4	2.157	0.0053	0.25	0.0168	0.78
Level 5	0.400	0.0025	0.63	0.0076	1.89

Table B-27

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	1.079	0.0129	1.20	0.0389	3.61
High level	1.026	0.0066	0.64	0.0088	0.86

Table B-28

Material: prepared dialysis solution, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	1.831	0.0126	0.69	0.0189	1.03
Level 2	1.338	0.0066	0.49	0.0100	0.75
Level 3	0.953	0.0036	0.38	0.0062	0.65

Hct

Unit: [%]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	22.1	0.2461	1.11	0.3649	1.65
Sample 2	38.5	0.1597	0.41	0.4427	1.14
Sample 3	62.3	0.2370	0.38	0.5559	0.89

Table B-29

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	58.9	0.1416	0.24	0.4716	0.80
Level 2	40.9	0.0874	0.21	0.4306	1.05
Level 3	32.5	0.0732	0.22	0.3460	1.06

Table B-30

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	19.0	0.0731	0.38	0.2233	1.18
Level 6	63.6	0.0573	0.09	0.4745	0.75

Table B-31

Lactate

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.90	0.01	1.18	0.07	8.11
Sample 2	1.40	0.01	0.69	0.10	7.10
Sample 3	3.60	0.06	1.56	0.20	5.55

Table B-32

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	10.7	0.0399	0.37	0.2491	2.34
Level 2	3.2	0.0076	0.24	0.0647	2.03
Level 3	1.7	0.0056	0.32	0.0464	2.65

Table B-33

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	6.3	0.0653	1.04	0.1489	2.37
Level 6	14.2	0.1022	0.72	0.4257	3.00

Table B-34

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	5.6	0.0894	1.61	0.1525	2.75
High level	5.3	0.0462	0.87	0.2002	3.75

Table B-35

Glucose

Unit: [mmol/L]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	2.60	0.06	2.28	0.16	6.11
Sample 2	5.00	0.06	1.27	0.25	4.91
Sample 3	27.10	0.15	0.56	1.42	5.24

Table B-36

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	6.1	0.0361	0.59	0.1015	1.67
Level 2	2.6	0.0221	0.85	0.0584	2.23
Level 3	25.0	0.0930	0.37	0.5734	2.29

Table B-37

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	2.5	0.0229	0.91	0.0886	3.55
Level 6	25.5	0.1963	0.77	0.7065	2.77

Table B-38

Material: aqueous solution with increased glucose value, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	28.1	0.3642	1.30	0.8414	3.00

Table B-39

Material: plasma, n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Normal level	4.1	0.0623	1.52	0.1431	3.48
High level	28.6	0.1678	0.59	0.8775	3.07

Table B-40

tHb

Unit: [g/dL]

Material: prepared human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	6.5	0.1058	1.62	0.0938	1.44
Sample 2	12.9	0.0874	0.67	0.1298	1.00
Sample 3	20.7	0.0703	0.33	0.1402	0.67

Table B-41

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	7.1	0.0469	0.66	0.1624	2.29
Level 2	11.5	0.0830	0.72	0.1281	1.12
Level 3	19.6	0.1613	0.82	0.2362	1.21

Table B-42

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	6.1	0.0368	0.60	0.1303	2.12
Level 6	21.7	0.1368	0.63	0.2309	1.06

Table B-43

SO_2

Unit: [%]

Material: tonometered human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	82.6	1.2561	1.52	1.1740	1.42
Sample 2	96.8	0.4976	0.51	0.6130	0.63
Sample 3	99.7	0.1190	0.11	0.1639	0.16

Table B-44

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	73.4	0.0937	0.13	0.2069	0.28
Level 2	90.3	0.2058	0.23	0.2343	0.26
Level 3	97.1	0.1434	0.15	0.1490	0.15

Table B-45

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	68.2	0.1057	0.16	0.1868	0.27
Level 6	98.0	0.1434	0.15	0.1370	0.14

Table B-46

O_2Hb

Unit: [%]

Material: tonometered human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	80.6	1.2296	1.52	1.1741	1.45
Sample 2	94.5	0.5108	0.54	0.6363	0.67
Sample 3	97.4	0.1342	0.13	0.2651	0.27

Table B-47

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	48.3	0.1188	0.25	0.2616	0.54
Level 2	75.8	0.4170	0.55	0.4746	0.63
Level 3	92.0	0.3703	0.40	0.3849	0.42

Table B-48

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	42.1	0.1177	0.28	0.2080	0.49
Level 6	94.3	0.3817	0.40	0.3647	0.39

Table B-49

COHb

Unit: [%]

Material: tonometered human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	2.0	0.0946	4.73	0.2316	11.58
Sample 2	5.4	0.0688	1.27	0.2238	4.14
Sample 3	13.4	0.0894	0.66	0.1997	1.49

Table B-50

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	22.4	0.0530	0.24	0.1164	0.52
Level 2	10.4	0.1860	1.78	0.2115	2.03
Level 3	3.5	0.1633	4.63	0.1699	4.82

Table B-51

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	25.1	0.0525	0.21	0.0926	0.37
Level 6	2.5	0.1685	6.65	0.1611	6.36

Table B-52

MetHb

Unit: [%]

Material: tonometered human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	1.3	0.0672	5.16	0.0975	7.50
Sample 2	5.8	0.1125	1.93	0.1106	1.90
Sample 3	30.7	0.3221	1.04	0.3181	1.03

Table B-53

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	11.7	0.0242	0.21	0.0537	0.46
Level 2	5.7	0.0849	1.49	0.0968	1.70
Level 3	2.0	0.0783	3.98	0.0812	4.13

Table B-54

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	13.1	0.0240	0.18	0.0426	0.33
Level 6	1.4	0.0804	5.67	0.0768	5.41

Table B-55

HHb

Unit: [%]

Material: tonometered human whole blood, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	5.2	0.1828	3.51	0.3268	6.28
Sample 2	9.5	0.2190	2.31	0.3718	3.91
Sample 3	17.0	1.2248	7.20	1.1417	6.71

Table B-56

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	17.6	0.0414	0.24	0.0909	0.52
Level 2	8.2	0.1451	1.78	0.1651	2.02
Level 3	2.7	0.1279	4.73	0.1329	4.92

Table B-57

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	19.7	0.0410	0.21	0.0723	0.37
Level 6	1.9	0.1319	6.88	0.1260	6.58

Table B-58

Bilirubin

Unit: [mg/dL]

Material: **cobas b** 123 AutoQC Pack TRI-LEVEL**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 1	5.8	0.0247	0.43	0.1176	2.03
Level 2	11.7	0.0988	0.84	0.1532	1.31
Level 3	20.2	0.2123	1.05	0.2663	1.32

Table B-59

Material: **cobas b** 123 AutoCVC Pack**,** n=80

	Mean	S_R	(CV%)	S_I	(CV%)
Level 5	4.7	0.0183	0.39	0.0915	1.96
Level 6	22.2	0.1650	0.74	0.2292	1.03

Table B-60

Material: prepared whole blood including bilirubin, n=40

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	5.3	0.113	2.12	0.245	4.60
Sample 2	14.74	0.132	0.90	0.255	1.73
Sample 3	23.20	0.111	0.48	0.389	1.68

Table B-61

Precision (sample mode: micro sample)

"Repeatability (S_R)" - and "Intermediate precision (S_I)" data were determined with **cobas b** 123 POC systems in a 10-day precision.

The mean value is the measured value of the corresponding parameter for which S_R and S_I are representative or have been determined.

Tonometered whole blood Whole blood was tonometered at 37°C with high-precision gas mixtures.

Prepared whole blood Expected values for prepared whole blood are based on reference methods.

Prepared whole blood including bilirubin Expected bilirubin values for human whole blood including bilirubin are NIST traceable, based on weighted samples or based on reference methods.

pH

Unit: [pH units]

Parameter group: BG only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	7.143	0.0049	0.07	0.0087	0.12
Sample 2	7.433	0.0031	0.04	0.0061	0.08
Sample 3	7.702	0.0077	0.10	0.0085	0.11

Table B-62

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	7.146	0.0060	0.08	0.0079	0.11
Sample 2	7.426	0.0044	0.06	0.0066	0.09
Sample 3	7.694	0.0051	0.07	0.0060	0.08

Table B-63

PO_2

Unit: [mmHg]

Parameter group: BG only

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	140.5	0.7496	0.53	2.9134	2.10
Sample 2	45.7	0.5529	1.21	3.0277	6.62
Sample 3	327.8	2.2800	0.70	8.8025	2.69

Table B-64

Parameter group: BG and COOX

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	140.8	1.0871	0.77	3.4533	2.45
Sample 2	45.8	0.6555	1.43	3.4589	7.54
Sample 3	332.5	3.7003	1.11	10.0589	3.03

Table B-65

PCO_2

Unit: [mmHg]

Parameter group: BG only

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	68.4	0.4721	0.69	1.0934	1.60
Sample 2	122.7	1.4066	1.15	2.4542	2.00
Sample 3	24.3	0.1840	0.76	0.5821	2.40

Table B-66

Parameter group: BG and COOX

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	69.3	0.7461	1.08	1.0505	1.52
Sample 2	126.3	1.8925	1.50	2.7580	2.18
Sample 3	24.3	0.2841	1.17	0.6432	2.65

Table B-67

Hct

Unit: [%]

Parameter group: BG only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	22.9	1.3787	6.01	1.5121	6.59
Sample 2	47.9	0.5614	1.17	0.6163	1.29
Sample 3	66.3	0.8662	1.31	1.1438	1.73

Table B-68

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	22.7	0.5613	2.48	0.6156	2.72
Sample 2	48.3	1.5060	3.12	1.5797	3.27
Sample 3	67.1	1.1035	1.64	1.6227	2.42

Table B-69

tHb

Unit: [g/dL]

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	7.1	0.0639	0.90	0.1016	1.43
Sample 2	16.2	0.1978	1.22	0.3517	2.17
Sample 3	19.9	0.3303	1.66	0.2962	1.49

Table B-70

Parameter group: COOX only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	7.0	0.1643	2.36	0.1584	2.27
Sample 2	16.4	0.1985	1.21	0.3125	1.91
Sample 3	20.3	0.1113	0.55	0.2787	1.37

Table B-71

SO_2

Unit: [%]

Parameter group: BG and COOX

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	81.5	0.9869	1.21	1.1530	1.42
Sample 2	96.3	0.6119	0.64	0.6813	0.71
Sample 3	99.8	0.0725	0.07	0.1437	0.14

Table B-72

Parameter group: COOX only

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	82.5	0.7237	0.88	0.9243	1.12
Sample 2	96.7	0.3895	0.40	0.5919	0.61
Sample 3	99.7	0.1283	0.13	0.1902	0.19

Table B-73

O_2Hb

Unit: [%]

Parameter group: BG and COOX

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	79.8	0.9521	1.19	1.1771	1.48
Sample 2	94.3	0.5132	0.54	0.6293	0.67
Sample 3	97.8	0.0734	0.08	0.2777	0.28

Table B-74

Parameter group: COOX only

Material: tonometered human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	80.8	0.7441	0.92	0.9247	1.15
Sample 2	94.7	0.3349	0.35	0.6138	0.65
Sample 3	97.8	0.1145	0.12	0.2440	0.25

Table B-75

COHb

Unit: [%]

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	1.4	0.0676	4.78	0.1780	12.58
Sample 2	4.0	0.1092	2.70	0.1915	4.73
Sample 3	13.9	0.0823	0.59	0.1766	1.27

Table B-76

Parameter group: COOX only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	1.4	0.0613	4.34	0.1824	12.91
Sample 2	4.0	0.0677	1.67	0.1893	4.67
Sample 3	13.9	0.0655	0.47	0.1577	1.14

Table B-77

MetHb

Unit: [%]

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.9	0.1104	12.94	0.1329	15.59
Sample 2	5.3	0.0851	1.61	0.1105	2.09
Sample 3	36.4	0.9648	2.65	0.7701	2.12

Table B-78

Parameter group: COOX only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.9	0.1470	17.10	0.1653	19.22
Sample 2	4.4	0.1368	3.12	0.1554	3.54
Sample 3	38.5	0.7735	2.01	0.5996	1.56

Table B-79

HHb

Unit: [%]

Parameter group: BG and COOX

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.2	0.0712	34.88	0.1407	68.96
Sample 2	3.6	0.6032	16.55	0.6698	18.38
Sample 3	18.2	0.9752	5.37	1.1243	6.19

Table B-80

Parameter group: COOX only

Material: prepared human whole blood, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	0.3	0.1258	48.71	0.1866	72.29
Sample 2	3.2	0.4958	12.03	0.5058	18.17
Sample 3	17.1	0.7014	4.11	0.9031	5.29

Table B-81

Bilirubin

Unit: [mg/dL]

Parameter group: BG and COOX

Material: prepared whole blood including bilirubin, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	5.2	0.3588	6.93	0.6710	12.95
Sample 2	9.8	0.6240	6.38	0.8738	8.93
Sample 3	14.7	0.4676	3.18	0.8140	5.53

Table B-82

Parameter group: COOX only

Material: prepared whole blood including bilirubin, n=20

	Mean	S_R	(CV%)	S_I	(CV%)
Sample 1	5.2	0.1721	3.31	0.6081	11.71
Sample 2	9.7	0.2864	2.94	0.6832	7.03
Sample 3	13.7	0.3169	2.31	0.4290	3.12

Table B-83

Linearity (normal sample)

Tonometered whole blood Whole blood was tonometered at 37°C with high-precision gas mixtures.

Prepared whole blood Expected values for prepared whole blood are based on reference methods.

Prepared whole blood including bilirubin Expected bilirubin values for human whole blood including bilirubin are NIST traceable, based on weighted samples or based on reference methods.

Prepared dialysis solution Expected values for prepared dialysis solution are based on reference methods.

Material: tonometered whole blood

Number of instruments: 4 **cobas b** 123<4> systems

Parameter	Unit	Coefficient (Pearson)	Range	n
PCO_2	[mmHg]	0.9990	10.27 - 172.81	197
PO_2	[mmHg]	0.9966	8.90 - 604.68	200

Table B-84 Material: tonometered whole blood

Material: prepared whole blood

Number of instruments: 4 **cobas b** 123<4> systems

Parameter	Unit	Coefficient (Pearson)	Range	n
pH	[---]	0.9996	6.499 - 8.319	40
Sodium	[mmol/L]	0.9993	88.16 - 212.3	36
Potassium	[mmol/L]	0.9989	0.752 - 16.61	34
Chloride	[mmol/L]	0.9990	58.5-167.4	36
ionized Calcium	[mmol/L]	0.985	0.756 - 12.84	36
Lactate	[mmol/L]	0.9969	4.1 - 214.3	36
Glucose	[mmol/L]	0.9942	11.1 - 543.4	36
Hct	[%]	0.9934	8.3 - 81.0	66
tHb	[g/dL]	0.9972	3.132 - 27.01	194
SO_2	[%]	0.9990	31.8 - 99.6	80
O_2Hb	[%]	0.9991	3.2 - 98.1	615
COHb	[%]	0.9999	1.0 - 78.9	167
MetHb	[%]	1.0000	0.6 - 79.2	295
HHb	[%]	0.9989	0.0 - 95.0	615

Table B-85 Material: prepared whole blood

Material: prepared whole blood including bilirubin

Number of instruments: 4 **cobas b** 123<4> systems

Parameter	Unit	Coefficient (Pearson)	Range	n
Bilirubin	[mg/dL]	0.995	2.847 - 46.6215	646

Table B-86 Material: prepared whole blood including bilirubin

Material: prepared aqueous solution

Number of instruments: 4 **cobas b** 123<4> systems

Parameter	Unit	Coefficient (Pearson)	Range	n
pH	[--]	0.9997	6.30 - 8.00	198

Table B-87 Material: prepared aqueous solution

Material: prepared dialysis solution

Number of instruments: 3 **cobas b** 123<4> systems

Parameter	Unit	Coefficient (Pearson)	Range	n
Sodium	[mmol/L]	0.9998	108.3 - 169.1	42
Potassium	[mmol/L]	0.9996	0.62 - 7.01	42
ionized Calcium	[mmol/L]	0.9998	0.764 - 1.971	42

Table B-88 Material: prepared dialysis solution

Linearity (micro sample)

Tonometered whole blood Whole blood was tonometered at 37°C with high-precision gas mixtures.

Prepared whole blood Expected values for prepared whole blood are based on reference methods.

Prepared whole blood including bilirubin Expected bilirubin values for human whole blood including bilirubin are NIST traceable, based on weighted samples or based on reference methods.

Material: tonometered whole blood

Number of instruments: 8 **cobas b** 123 POC systems

Parameter	Unit	Coefficient (Pearson)	Range	n
PCO_2	[mmHg]	1.000	3.6 - 183.3	127
PO_2	[mmHg]	1.000	0 - 659.5	144

Table B-89 Material: tonometered whole blood

Material: prepared whole blood

Number of instruments: 8 **cobas b** 123 POC systems

Parameter	Unit	Coefficient (Pearson)	Range	n
pH	[---]	1.000	6.34 - 8.12	70
Hct	[%]	1.000	11.7 - 81.7	198
tHb	[g/dL]	1.000	3 - 29	580
SO_2	[%]	1.000	29 - 100	404
O_2Hb	[%]	1.000	28.4 - 98.0	403
COHb	[%]	1.000	5.7 - 79.7	438
MetHb	[%]	1.000	4.3 - 80.9	449
HHb	[%]	1.000	0 - 69.57	403

Table B-90 Material: prepared whole blood

Material: prepared whole blood including bilirubin

Number of instruments: 8 **cobas b** 123 POC systems

Parameter	Unit	Coefficient (Pearson)	Range	n
Bilirubin	[mg/dL]	1.000	3.4 - 47.9	566

Table B-91 Material: prepared whole blood including bilirubin

Correlation to other methods

pH

Unit: [pH units]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	691	0.009	0.99	0.08	0.99

Table B-92 pH

(a) Median absolute bias

PO_2

Unit: [mmHg]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	677	---	0.97	-0.76	1.00

Table B-93 PO_2

(a) Median absolute bias

PCO_2

Unit: [mmHg]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	687	-0.2	0.95	1.85	0.99

Table B-94 PCO_2

(a) Median absolute bias

tHb (cobas b 123 POC system with COOX module)

Unit: [g/dL]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	682	-0.3	0.95	0.25	0.98

Table B-95 tHb

(a) Median absolute bias

O_2Hb (cobas b 123 POC system with COOX module)

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	666	0.5	1.01	-0.17	1.00

Table B-96 O_2Hb

(a) Median absolute bias

HHb (cobas b 123 POC system with COOX module)

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	668	-0.6	1.01	-0.72	1.00

Table B-97 HHb

(a) Median absolute bias

MetHb (cobas b 123 POC system with COOX module)

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	682	0.1	1.00	0.10	0.67

Table B-98 MetHb

(a) Median absolute bias

COHb (cobas b 123 POC system with COOX module)

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	682	0.0	1.00	0.00	0.97

Table B-99 COHb

(a) Median absolute bias

Bilirubin comparison

Unit: [mg/dL]

Material: whole blood (neonatal)

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	162	0.02	1.0	-0.15	0.994

Table B-100 Bilirubin

(a) Median absolute bias

SO_2 (cobas b 123 POC system with COOX module)

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	484	0.431	0.9861	1.5720	0.9992

Table B-101 SO_2

(a) Median absolute bias

Hct

Unit: [%]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	691	-0.1	0.95	1.62	0.99

Table B-102 Hct

(a) Median absolute bias

Sodium

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	691	0.02	1.03	-4.57	0.94

Table B-103 Sodium

(a) Median relative bias

Material: prepared dialysis solution

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	229	1.43	0.97	6.65	0.98

Table B-104 Sodium

(a) Median absolute bias

Potassium

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	682	-0.03	0.96	0.15	0.99

Table B-105 Potassium

(a) Median absolute bias

Material: prepared dialysis solution

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	230	0.00	1.00	0.01	1.00

Table B-106 Potassium

(a) Median absolute bias

Ionized calcium

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	689	-0.010	0.95	0.05	0.94

Table B-107 Calcium

(a) Median absolute bias

Material: prepared dialysis solution

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	227	2.93	1.03	-0.01	0.99

Table B-108 Calcium

(a) Median absolute bias

Chloride

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas b 221 system	657	1.2	1.15	-14.91	0.98

Table B-109 Chloride

(a) Median relative bias

Glucose

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas® 6000	686	-2.4	0.98	-0.04	0.98

Table B-110 Glucose

(a) Median relative bias

Lactate

Unit: [mmol/L]

Material: whole blood

Comparison instrument	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
cobas® 6000	590	---	1.00	0.06	0.99

Table B-111 Lactate

(a) Median absolute bias

Comparison of micro samples to normal samples

The trueness of measurement values of the sample mode "micro sample BG-only (40 µL)" and "micro sample BG with COOX (55 µL)" have been proven by comparison to measurement values in the normal sample mode (150 µL).

Number of instruments: 8 **cobas b** 123 POC systems

Material: whole blood

Parameter	Unit	No. of samples [n]	Bias[(a)]	Slope [b]	Intercept [a]	Pearson's Corr. coeff. [r]
pH	[pH units]	149	0.00	0.9932	0.0506	0.9996
PO_2	[mmHg]	205	0.564	0.994	1.0251	0.9995
PCO_2	[mmHg]	133	0.09	0.9646	1.4684	0.9989
Hct	[%]	370	-0.026	1.0034	-0.1195	0.9988
tHb	[g/dL]	244	-0.044	1.033	-0.4168	0.9998
O_2Hb	[%]	403	0.571	0.9806	2.1444	0.9993
HHb	[%]	403	-0.558	0.9799	-0.2087	0.9993
MetHb	[%]	176	-0.332	0.9948	-0.0827	0.9999
COHb	[%]	278	-0.034	1.0001	-0.038	1.0000
SO_2	[%]	484	0.431	0.9861	1.572	0.9992
Bilirubin	[mg/dL]	232	-0.506	0.9975	-0.4805	0.9982

Table B-112

(a) Median absolute bias

Sample throughput

Activated/installed modules	Sample throughput [samples/hours]
	Syringe/Capillary
BG - ISE - Hct - Glu - Lac	30
BG - ISE - Hct - Glu - Lac - AutoQC	30
BG - ISE - Hct - Glu - Lac - COOX	30
BG - ISE - Hct - Glu - Lac - COOX - AutoQC	30

Table B-113 Sample throughput

Sample volumes

Note

The minimum sample volume requirement is dependent on Hct concentration in the sample.

Activated/installed modules	Typical sample volume [µL][(a)]	Max. sample volume (volume limitation by the sample sensor) [µL][(b)]
BG - ISE - Hct - Glu - Lac	102	188
BG - ISE - Hct - Glu - Lac - COOX	123	211
COOX only	25	87
BG[(c)] (micro sample)	37	--
BG[(c)] - COOX (micro sample)	55	--

Table B-114 Sample volumes

(a) Typical sample volume for 10% < Hct ≤ 75%.

(b) The sample volume limitation is the maximum volume of sample which is aspirated from the container.

(c) The parameter Hct is listed in the BG area of the sensor and thus is also measured during micro sample BG or BG - COOX.

Note

The volume limitation depends on INSTALLED modules, regardless whether they are activated or deactivated.

Sample types

- Whole blood
- Dialysis solution
- Aqueous solutions
- Recommended QC material[(a)]

(a) with approximate physiological ion matrix and buffer capacity

Measurement times of the samples

Activated/installed modules	Measurement times [seconds]	
	Total time	Until display
BG - ISE - Hct - Glu - Lac	120	120
BG - ISE - Hct - Glu - Lac - COOX	120	120

Table B-115 Measurement times of the samples

Note

In the RUN-IN phase, due to stability, the Sensor Cartridge does not yet achieve the full performance with respect to sampling rate, measurement speed, utilization time, etc. However, there are no limitations on the measuring accuracy and precision.

For additional information, refer to chapter 3 *General description*, section *Sensor phases* on page B-16.

Calibrations

Calibrations	Time intervals	Duration [min]
System calibration	every 24 hours	16
1P calibrations	every 60 minutes	3
2P calibrations	every 12 hours (alternatively 4, 8 or 12 hours)	12
STDBY calibration	every 30 minutes(b)	1

(b) Corresponds to 1P BG calibration for USA.

Table B-116 Calibrations

Environmental parameters

Temperature/humidity/stability

Instrument

Operating conditions

• Ambient temperature	15 to 32 °C
• Ambient air pressure	530 to 800 mmHg (-100 to 2500 m)
• Relative humidity	15 to 90% (not condensed)

Storage and transportation conditions

• Temperature	-20 to +50 °C
• Humidity	15 to 85% (not condensed)
• Shock resistance	< 30 g

cobas b 123 Sensor Cartridge

Operating conditions

• Temperature: BG, Hct	up to 28 days at 37°C
• Temperature: ISE, Glu	up to 28 days at 30°C
• Temperature: Lac	up to 21 days at 30°C
• Relative humidity	15 to 90% (not condensed)

Storage conditions in original packaging

• Temperature	up to 5 months at 2 to 8°C
• Humidity	20 to 85% (not condensed)

Stability during operation

• BG - Hct	up to 28 days or up to 700 tests
• BG - ISE - Hct	up to 28 days or up to 700 tests
• BG - ISE - Hct - Glu	up to 28 days or up to 700 tests
• BG - ISE - Hct - Glu - Lac	up to 21 days or up to 500 tests

cobas b 123 Fluid Pack

Operating conditions

• Ambient temperature	up to 42 days at 15 to 32 °C
• Relative humidity	15 - 90% (not condensed)

Storage conditions in original packaging

• Temperature	up to 9 months at 15 to 25 °C
• Relative humidity	15 to 85% (not condensed)

Stability during operation

• **cobas b** 123 Fluid Pack COOX 200	up to 200 tests or up to 42 days[(a)]
• **cobas b** 123 Fluid Pack COOX 400	up to 400 tests or up to 42 days[(a)]
• **cobas b** 123 Fluid Pack COOX 700	up to 700 tests or up to 42 days[(a)]
• **cobas b** 123 Fluid Pack 200	up to 200 tests or up to 42 days[(a)]
• **cobas b** 123 Fluid Pack 400	up to 400 tests or up to 42 days[(a)]
• **cobas b** 123 Fluid Pack 700	up to 700 tests or up to 42 days[(a)]

(a) All Fluid Packs can be used for up to 42 days. The indicated number of tests will be achieved when minimum number of measurements are performed per day.

For more information, see chapter 6 *System components*, Table C-4 on page C-22.

QC material

Storage conditions in original packaging

• COMBITROL PLUS B (Level 1 to 3)	up to 24 months at 2 to 8 °C
• **cobas b** 123 AutoQC Pack	up to 24 months at 2 to 8 °C
• **cobas b** 123 AutoCVC Pack	up to 24 months at 2 to 8 °C
• Relative humidity	15 to 85% (not condensed)

Stability during operation

• COMBITROL PLUS B (Level 1 to 3)	up to 3 months at room temperature up to 28 °C
• **cobas b** 123 AutoQC Pack	up to 3 months in the instrument
• **cobas b** 123 AutoCVC Pack	up to 3 months in the instrument

Note

For more information, read the package inserts included in the QC materials mentioned above.

Product data

Electrical data

Mains voltage range:	100 to 240 V AC (+/- 10%)
Frequency:	50 to 60 Hz (+/- 5%)
Required power:	max. 120 W

Note

The power supply supplies the instrument with 12 V DC (10 A).

Classification (according IEC/ISO)

Protection class:	I
Overvoltage category:	I
Contamination level:	2

Dimensions

Width:	32 cm
Height:	47 cm
Depth:	33 cm

Weight

cobas b 123 POC system (instrument):	ca. 18 kg (without Fluid Pack and AutoQC Pack)
cobas b 123 POC system (instrument):	ca. 24.5 kg (with Fluid Pack and AutoQC Pack)

Acoustic noise level

In all operating conditions:	< 55 dB

Holding points

Two slots on each side facilitate lifting and carrying of the instrument.

The equipment always with both hands lift and carry.

A Holding points

Figure B-2 Holding points

Printer

Type:	Thermal printer
Resolution:	203 dpi (8 dots/mm)
Full graphics:	832 dots/line
Printing speed:	Standard measurement report < 10 seconds
Paper width:	113.5 +/- 0.5 mm
Paper length:	about 45 m

User interface module

PC:	Intel Celeron M 800 MHz
Memory:	256 MB RAM
Hard disk:	40 GB storage capacity
CompactFlash card:	2 GB
USB storage device:	2 GB
Screen - type:	TFT-LCD-screen
Format:	10.4 inch
Resolution:	800 x 600 pixel

Barcode scanner (standard)

Type:	MS 180 PS2 hand scanner with integrated decoder
Reading speed:	up to 33 scans/s
Resolution:	0.1 mm
Reading distance:	up to 5 cm
Reading width:	up to 8 cm
Pre-programmed code types[(a)]:	• UPC-A • UPC-E • EAN-8 • EAN-13 • EAN-128 • Interleave 2 of 5 • Code 39 • Code 93 • Code 128

(a) Further available barcode types can be programmed in accordance with the enclosed manual of the PS2 barcode scanner (included in scope of delivery).

Imaging scanner (optional)

Type:	Magellan® 1100i Imaging Scanner with optional holder
Reading speed:	1100 digital scan/s.
Resolution:	0.13 mm
Reading width:	0 - 17.15 cm[(a)]
Pre-programmed code types[(b)]:	• UPC-A • UPC-E • EAN-8 • EAN-13 • Standard 2 of 5 • Interleave 2 of 5 • Code 39 • Code 128 • Codabar • MSI Plessey

(a) Depending on the length of the barcode and the scanning angle.

(b) Further available barcode types can be programmed in accordance with the enclosed manual of the barcode scanner (included in scope of delivery).

Theoretical foundations

This chapter contains the formulae for calculation values, factors and unit conversion, as well as the clinical significance of measurement parameters.

In this chapter *Chapter* 5

Parameters and calculations

Conversion table for units

The **cobas b** 123 POC system provides an array of useful parameters, which are calculated from the measurement values of each sample. Refer to the following table for an explanation of the symbols used in the equations. Unless stated otherwise, all measurement values that are used in the equations were measured at 37 °C.

ctO_2, $avDO_2$, $ctCO_2$	1 vol%	= 1 mL/dL	= 0.4464 mmol/L
Ca^{2+}	1 mmol/L	= 4.008 mg/dL	
tHb	1 g/dL	= 10 g/L	= 0.6202 mmol/L
Glucose	1 mmol/L	= 18.02 mg/dL	
Lactate	1 mmol/L	= 9.008 mg/dL	
Bilirubin	1 mg/dL	= 17.1 µmol/L	
Osmolality	1 mOsm/kg	= 1 mmol/kg	
MCHC	1 g Hb/dL Ery	= 0.155 mmol Hb/L Ery	
Air pressure. PCO_2. PO_2	1 mmHg	= 1.3333 mbar	= 0.1333 kPa
	1 mmHg	= 39.37×10^{-3} Inch [in.]Hg	

Table B-117 Conversion table for units

Temperature

Equation B-1
$$T\,[°F] = \frac{9}{5} \cdot T\,[°C] + 32$$

Equation B-2
$$T\,[°C] = \frac{5}{9} \times (T\,[°F] - 32)$$

Standard values and ranges

Parameter	Standard value	Possible range
tHb	15.0 g/dL	1.0 - 26.0 g/dL
	150 g/L	1 - 260 g/L
	9.0 mmol/L	1.0 - 16.0 mmol/L
FIO_2	0.21	0.10 - 1.00
R (Respiratory quotient)	0.84	0.70 - 2.00
Patient's temperature	37.0 °C	2.0 - 44.0 °C
	98.6 F	35.6 - 111.0 F
Hb factor	3.0	2.7 - 3.3

Table B-118 Standard values and ranges

Equations

Note

All references listed in the "Equations" section (e.g. [1]) are subsequently listed in the "Bibliography" section.

See *Bibliography* on page B-75.

The validity of calculated results from the **cobas b** 123 POC system must be carefully examined by a clinical-medical specialist who will take the patient's clinical condition into consideration before any clinical decisions are reached based on the calculated results especially if one of the according measurement results exceeds its critical range.

Note

Calculated values that require measurement results from arterial blood are issued only for the set blood types "arterial" and "capillary".

H^+

Hydrogen ion concentration[1]

Unit: [nmol/L]

Equation B-3 $H^+ = 10^{(9\text{-}pH)}$

$cHCO_3^-$

The bicarbonate concentration in the plasma of the blood sample results from the calculation of the pH and PCO_2 measured values.[1]

Unit: [mmol/L]

Equation B-4 $cHCO_3^- = 0.0307 * PCO_2 * 10^{(pH\text{-}6.105)}$

$ctCO_2(P)$

Total concentration of CO_2 in plasma. the sum of dissolved CO_2 and bicarbonate.[1]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-5 $ctCO_2(P) = cHCO_3^- + (0.0307 * PCO_2)$

FO_2Hb

Fractional oxygen saturation[1]

Unit: [-]

Equation B-6 $$FO_2Hb = \frac{O_2Hb}{100}$$

BE

The base deviation of the blood results from a calculation to determine the titratable base of the blood. which in principle is measured by titration of the blood with a strong acid or base to a pH of 7.4 with PCO_2 = 40 mmHg at 37 °C.[1]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-7

$$BE = (1 - 0.014 \cdot tHb) \cdot [(1.43 \cdot tHb + 7.7) \cdot (pH - 7.4) - 24.8 + cHCO_3^-]$$

For BE_{act} see Equation B-40 on page B-71.

BE_{ecf}

The base deviation of extracellular fluid is a quantity that reflects only the non-respiratory components of acid-base balance.[1]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-8

$$BE_{ecf} = 16.2 \cdot (pH - 7.4) - 24.8 + cHCO_3^-$$

BB

The buffer base is the concentration of buffering anions which is available in whole blood to buffer strong acids and consists mainly of protein anions and bicarbonate. Of the protein anions, hemoglobin is the most significant.[2]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-9

$$BB = BE + 41.7 + 0.42 \cdot tHb$$

SO_2

The quantity of oxyhemoglobin in the blood related to the quantity of hemoglobin in the blood which can bind oxygen.[1]

Unit: [%]

Equation B-10

$$SO_2 = \frac{O_2Hb}{O_2Hb + HHb} \cdot 100$$

$SO_2(c)$

Note

Measured SO_2 has a higher priority than the calculated $SO_2(c)$.
No calculation without pH. PCO_2. PO_2 and define input value Age (a/f).

Unit: [%][7]. [8]

Equation B-11

$$SO_2(c) = SO_2(PO_2, pH, P50, a/f, BE) = \frac{Q}{Q+1} \cdot 100$$

At which:

Equation B-12

$$\lg Q = 2.9 \cdot \lg PO_2^{\,k} + F1 \cdot 10^{-F2 \cdot PO_2^{\,k}} - F3$$

$$\lg PO_2^{k} = \lg PO_2 + 0.48 \cdot (pH - 7.4) - \lg\left(\frac{P50}{26.7}\right) + 0.0013 \cdot BE$$

Adult [7]

$P_{50} = 26.7$

F1 = 1.661
F2 = 0.074
F3 = 4.172

Fetal [7]

$P_{50} = 21.5$

F1 = 1.3632
F2 = 0.0533
F3 = 4.113

P_{50}

The oxygen partial pressure at half saturation. P_{50}. is defined as the PO_2 value at which 50% of the hemoglobin is saturated with oxygen. The actual P_{50} value can be calculated from interpolation after measurement of the actual oxygen saturation if a blood sample is tonometered with oxygen so that an oxyhemoglobin of 50% is achieved (pH value = 7.4 and PCO_2 = 40 mmHg).[7]. [8]

Note

No calculation without measured PO_2 and defined input value Age (a/f).

The **cobas b** 123 POC system enables the derivation of the P_{50} from SO_2%. PO_2 and pH.

Unit: [mmHg]

Measured SO_2 values available:

Equation B-13

$$P50 = 26.7 \cdot 10^{\left(\lg PO_2 - \lg PO_2^{\,k}\right)}$$

At which:

Equation B-14

$$\lg PO_2^{\,k} = \frac{(\lg Q + F3)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

Adult [7] F3 = 4.172

Fetal [7] F3 = 4.113

Note

If no measured SO_2 values are available. no calculation is possible.

ctO_2

Oxygen content is the sum of oxygen bound to hemoglobin as O_2Hb and the amount of oxygen dissolved in the plasma.[1]

Unit: [vol%]

Equation B-15

$$ctO_2(PO_2, SO_2, tHb) = 1.39 \cdot \frac{X}{100} \cdot tHb + 0.00314 \cdot PO_2$$

At which:

O_2Hb present: X = O_2Hb

O_2Hb not present: X = SO_2(c)

See section *SO2(c)* on page B-62.

If PO_2 is not available. ctO_2 is calculated with PO_2 = 90 mmHg.

$ctCO_2$(B)

Total concentration of CO_2 in the blood, the sum of the total CO_2 in plasma and the red blood cell (erythrocyte fluid = ERY).[12]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-16

$$ctCO_2(B) = 0.000768 \cdot PCO_2 \cdot tHb \cdot (1 + 10^{(pH_{ERY} - pK_{ERY})}) + ctCO_2(P) \cdot (1 - \frac{tHb}{33.8})$$

At which:

Equation B-17

$$pH_{ERY} = 7.19 + 0.77 \cdot (pH - 7.4) + 0.035 \cdot (1 - \frac{SO_2}{100})$$

$$pK_{ERY} = 6.125 - \lg(1 + 10^{(pH_{ERY} - 7.84 - 0.06 \cdot \frac{SO_2}{100})})$$

SO_2 or if SO_2 not available, see *SO2(c)* on page B-62.

Note

A correct calculation of the calculated value is possible only after measurement of a whole blood sample in the sample type setting "blood".

pH_{st}

Standard pH value of the blood is defined as the pH value of a blood sample which has been equilibrated at 37 °C with a gas mixture having a PCO_2 = 40 mmHg.[7]

Note

No calculation without pH and PCO_2.

Unit: [pH unit]

Equation B-18

$$pH_{st} = (0.8262 - 0.01296 \cdot tHb + 0.006942 \cdot BE) \cdot \log(0.025 \cdot PCO_2) + pH$$

$cHCO_3^-{}_{st}$

Standard bicarbonate of the blood is defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 °C with a gas mixture having a PCO_2 = 40 mmHg.[7]

Note

No calculation without pH and PCO_2.

Unit: [mmol/L]

Equation B-19

$$cHCO_3^-{}_{st} = 10^{(pH_{st} - 6.022)}$$

PAO_2

The alveolar oxygen partial pressure is used to calculate several parameters used for oxidation and breathing.[6]

Unit: [mmHg]

Equation B-20

$$PAO_2 = (P_{total} - 47) \cdot FIO_2 - PACO_2 \cdot \left[FIO_2 + \frac{1 - FIO_2}{R} \right]$$

If the result of the calculation is $PAO_2 < PO_2$, $PAO_2 = PO_2$ is set, $PACO_2$ corresponds to the measured PCO_2.

Note

The **cobas b** 123 POC system does not carry out the calculation unless either "Arterial" or "Capillary blood" was selected as the blood type.

No calculation without PO_2 and input values FIO_2 and RQ.

P_{total} = Baro

R = RQ

For patient temperature (t) other than 37°C see equation $PAO_2{}^t$ on page B-69.

$AaDO_2$

The alveolar arterial oxygen partial pressure gradient (PAO_2 - PaO_2) is the difference between the alveolar oxygen partial pressure, as calculated above, and the measured oxygen partial pressure of arterial blood.[6]

Unit: [mmHg]

Equation B-21 $AaDO_2 = PAO_2 - PaO_2$

$PaO_2 = PO_2$

For patient temperature (t) other than 37°C see equation $AaDO_2^t$ on page B-69.

Note

The **cobas b** 123 POC system does not carry out the calculation unless either "Arterial" or "Capillary blood" was selected as the blood type.

No calculation without PO_2, PCO_2 and input values FIO_2 and RQ.

a/AO_2

Arterial alveolar oxygen partial pressure ratio.[6]

Note

No calculation without PO_2, PCO_2 and input values FIO_2 and RQ.

Unit: [%]

Equation B-22 $$a/AO_2 = \frac{PaO_2}{PAO_2} \cdot 100$$

$PaO_2 = PO_2$

For patient temperature (t) other than 37°C see Equation a/AO_2^t on page B-69.

$avDO_2$

The arterial venous oxygen tension ratio.[1]

Unit: [vol%]

Equation B-23 $avDO_2 = ctO_2(a) - ctO_2(v)$

Calculated ctO_2(a) and ctO_2(v) according to the calculation for ctO_2 for arterial and venous blood.

For ctO_2 see equation ctO_2 on page B-63.

Calculation only under the following conditions:

- same patient numbers for both measurements
- two consecutive measurements
- sample type is arterial and mixed venous blood

RI

The respiratory index is calculated as the ratio of the alveolar-arterial oxygen tension gradient to the arterial oxygen tension.[6]

Note

The **cobas b** 123 POC system does not carry out the calculation unless either "Arterial" or "Capillary blood" was selected as the blood type.

No calculation without PO_2 and input values FIO_2 and RQ.

Unit: [%]

Equation B-24

$$RI = \frac{(PAO_2 - PaO_2)}{PaO_2} \cdot 100$$

$PaO_2 = PO_2$

For patient temperature (t) other than 37°C see Equation RI^t on page B-70.

Shunt

The shunt parameter is a measure of the direct mixing of venous blood into the oxygenated blood circulation. The Shunt parameter gives the short circuit volume relating to the total volume (% - value).[6]

In order to determine the "shunt" (Qs/Qt), two independent measurements are necessary.

Note

Both measurements must be carried out with the same patient ID.
The patient ID must therefore be defined as an input value.

1. Measurement with blood type "mixed venous":
   Select blood type "mixed venous".
2. Measurement with blood type "arterial":
   Select blood type "arterial". The desired value for Qs/Qt is determined.

Note

The same patient ID must be used as for the first measurement.

WARNING

Warning

With a combination of arterial and venous blood, the Qs/Qt value cannot be determined. Subsequent modification of input values that are relevant for shunt measurement is not possible.

Samples from patients with other patient ID can be measured between the two Qs/Qt partial measurements.

The period between the two Qs/Qt partial measurements is limited to 30 minutes.

Additional information

The internal calculation procedure requires the following measurement and calculation values:

- tHb. SO_2 (arterial)
- PO_2 (arterial)
- PAO_2

- ctO$_2$ (arterial)

In order to obtain these measurement and calculation values. the blood type "arterial" must be selected.

Furthermore, the internal calculation procedure requires the following calculation value:

- ctO$_2$ (mixed venous)

To produce this computing value, the blood type "mixed venous" must be selected.

In order to be able to select the blood type, it must be defined as an input value.

☞ [Utilities] > [Configuration] > [Measurement] > [Data input] > [Input values]

Unit: [%]

Equation B-25

$$\frac{Q_s}{Q_t} = \frac{100 \cdot [1.39 \cdot tHb \cdot (1 - \frac{SaO_2}{100}) + (PAO_2 - PaO_2) \cdot 0.00314]}{[(ctO_2(a) - ctO_2(v)) + 1.39 \cdot tHb \cdot (1 - \frac{SaO_2}{100}) + (PAO_2 - PaO_2) \cdot 0.00314]}$$

Q_s	shunt flow
Q_t	heart minute volume
Q_s/Q_t	fraction of cardiac output shunted
SaO_2	arterial oxygen saturation fraction

avDO$_2$ is used for the calculation instead of ctO$_2$(a) and ctO$_2$(v).

👁 For avDO$_2$, refer to section *avDO$_2$* on page B-65.

Shunt estimated

For calculation of shunt (estimated) a fixed value of 5.15 vol% (=2.3 mmol/L) is used for arteriovenous oxygen difference avDO$_2$.[12]

In order to determine the "shunt$_{est}$" (Qs/Qt$_{est}$), one independent measurement of arterial blood is necessary.

- Select blood type "arterial". The desired value for Qs/Qt$_{est}$ is determined.

Additional information

The internal calculation procedure requires the following measurement and calculation values:

- tHb, SO_2 (arterial)
- PO_2 (arterial)
- PAO_2 (arterial)

Unit: [%]

Equation B-26

$$\frac{Q_s}{Q_t}(est) = \frac{100 \cdot [1.39 \cdot tHb(a) \cdot (1 - \frac{SO_2(a)}{100}) + (PAO_2(a) - PO_2(a)) \cdot 0.00314]}{[5.15 + 1.39 \cdot tHb(a) \cdot (1 - \frac{SO_2(a)}{100}) + (PAO_2(a) - PO_2(a)) \cdot 0.00314]}$$

Q_s	shunt flow
Q_t	heart minute volume

$Q_s/Q_{t\ (est)}$	fraction of cardiac output shunted (estimated)
SaO_2	arterial oxygen saturation fraction
(a)	arterial measurement value

nCa^{2+}

The ionized calcium value standardized to pH = 7.40.[5]

Note

No calculation without pH and Ca^{2+}.

Unit: [mmol/L]

Equation B-27 $$nCa^{2+}(pH = 7.4) = Ca^{2+} \cdot 10^{F5 \cdot (pH - 7.4)}$$

Blood: F5 = 0.22

Serum/plasma: F5 = 0.24

This equation is released for pH 7.2 to 7.6.

AG

The anion gap is a calculated parameter used to express the difference in concentrations of major cations and anions in the blood sample.[2]

Note

No calculation without PCO_2, Na^+, K^+ and Cl^-.

Unit: [mmol/L]

Equation B-28 $$AG = Na^+ + K^+ - Cl^- - cHCO_3^-$$

pH^t

pH corrected to patient temperature other than 37 °C.[1]

Unit: [pH-Unit]

Equation B-29 $$pH^t = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37)$$

H^{+t}

Hydrogen ion concentration at a patient temperature other than 37 °C.[1]

Unit: [nmol/L]

Equation B-30 $$H^{+t} = 10^{(9 - pH^t)}$$

PCO_2^t

PCO_2 value at a patient temperature which is not 37 °C.[1]

Unit: [mmHg]

Equation B-31 $$PCO_2^t = PCO_2 \cdot 10^{0.019 \cdot (t - 37)}$$

PO_2^t

PO_2 value at a patient temperature which is not 37 °C.[1]

Unit: [mmHg]

Equation B-32

$$PO_2^{\,t} = PO_2 \cdot 10^{\left[\frac{5.49\cdot10^{-11}\cdot PO_2^{\,3.88}+0.071}{9.72\cdot10^{-9}\cdot PO_2^{\,3.88}+2.30}\right]\cdot(t-37)}$$

PAO_2^t

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[6]

Note

No calculation without input values FIO_2 and RQ.

Unit: [mmHg]

Equation B-33

$$PAO_2^{\,t} = \left(P_{total} - PH_2O^t\right)\cdot FIO_2 - PACO_2^{\,t}\cdot\left[FIO_2 + \left(\frac{1-FIO_2}{R}\right)\right]$$

for: $PAO_2^{\,t} \le PO_2^{\,t}$ otherwise $PAO_2^{\,t} = PO_2^{\,t}$

with: $PH_2O^t = 47\cdot10^{[0.0237-0.0001\cdot(t-37)]\cdot(t-37)}$

P_{total} = Baro

R = RQ

$AaDO_2^t$

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[6]

Unit: [mmHg]

Equation B-34

$$AaDO_2^{\,t} = PAO_2^{\,t} - PaO_2^{\,t}$$

$PaO_2^t = PO_2^t$

Note

The **cobas b** 123 POC system does not carry out the calculation unless either "Arterial" or "Capillary blood" was selected as the blood type.

No calculation without PCO_2 and input values FIO_2 and RQ.

a/AO_2^t

Arterial alveolar oxygen partial pressure ratio at the patient's temperature.[6]

Note

No calculation without PCO_2 and input values FIO_2 and RQ.

Unit: [%]

Equation B-35

$$a/AO_2^{\,t} = \frac{PaO_2^{\,t}}{PAO_2^{\,t}}\cdot100$$

RI ^{t}

Respiratory index corrected to patient temperature other than 37 °C.[6]

Note

The **cobas b** 123 POC system does not carry out the calculation unless either "Arterial" or "Capillary blood" was selected as the blood type.

No calculation without PO_2 and input values FIO_2 and RQ.

Unit: [%]

Equation B-36

$$RI^{t} = \frac{(PAO_2{}^{t} - PaO_2{}^{t})}{PaO_2{}^{t}} \cdot 100$$

$PaO_2{}^{t} = PO_2{}^{t}$

Hct(c)

Hct as a function of tHb.[4]

Unit: [-]

Equation B-37

$$Hct(c) = tHb \cdot \frac{F}{100}$$

Default value of F = 3.00 (F = 100/MCHC [g/dL])[9]

Input range: 2.70 to 3.30.
This corresponds to an MCHC of 30.3 to 37 g/dL (= reference range for adults).[4]

Note

Only measured tHb is permitted.

MCHC

Mean corpuscular hemoglobin concentration.[4]

Units: [g (Hb)/dL (Ery)]

Equation B-38

$$MCHC = \frac{tHb}{Hct} \cdot 100$$

Only displayed as a calculated value if both values are measured.

BO_2

Oxygen capacity.[1]

Unit: [vol%]

Equation B-39

$$BO_2 = tHb \cdot \left[1 - \frac{(COHb - MetHb - SulfHb)}{100}\right] \cdot 1.39$$

SulfHb = 0

BE_{act}

Base deviation at actual oxygen saturation.[2]

Note

No calculation without pH, PCO_2, PO_2 and define input value Age(a/f).

Unit: [mmol/L]

Equation B-40

$$BE_{act} = (1 - 0.0143 \cdot tHb) \cdot [(1.63 \cdot tHb + 9.5) \cdot (pH - 7.4) - 24.26 + cHCO_3^-] - 0.2 \cdot tHb \cdot \left(1 - \frac{SO_2}{100}\right)$$

The calculation takes place with SO_2 or, if not available with $SO_2(c)$.

Osmolality

Unit: [mOsm/kg][3]

Equation for blood, plasma, serum:

Equation B-41

$$Osm = 1.86 \cdot Na^+ + Glu + Urea + 9$$

Equation for aqueous solution, acetate, bicarbonate:

Equation B-42

$$Osm = 2 \cdot (Na^+ + K^+) + 3 \cdot (Ca^{2+} + Mg^{2+}) + Glu + Urea$$

Default values:

- K^+ = 4.3 mmol/L
- Ca^{2+} = 1.25 mmol/L
- Mg^{2+} = 0.6 mmol/L
- Glu = 4.5 mmol/L
- Urea = 5 mmol/L

Explanation:

Na^+:	if no measurement value is available, no osmolality is calculated
K^+:	if no measurement value is available, the default value is used for the calculation
Ca^{2+}:	if no measurement value is available, the default value is used for the calculation
Mg^{2+}:	the default value is used for the calculation
Urea:	the default value is used for the calculation
Glu:	if no measurement value is available, the default value is used for the calculation

Osmolality (optimized)

Unit: [mOsm/kg][13]

Equation for blood, plasma, serum:

Equation B-43 $Osm_{opt} = (Na^+ + K^+ + Cl^- + Lac + Glu + HCO3^- + Urea + 6.5) * 0{,}985$

Note

Osm_{opt} is calculated only if all measured, calculated and input values are available.

Osm_{opt} Gap

Difference (gap) between the measured and the calculated osmolality.[13]

Unit: [mOsm/kg]

Equation B-44 Osm_{opt} Gap = measured Osmolality(a) - calculated Osmolality

(a) with the help of the freezing point depression

Note

Osm_{opt} Gap is calculated only if the input value Osm(e) (measured osmolality) and the calculated value Osm_{opt} (optimized osmolality) are available.

OER

Oxygen extraction ratio.[1]

Unit: [%]

Equation B-45
$$OER = \frac{(ctO_{2(a)} - ctO_{2(v)})}{ctO_{2(a)}} \cdot 100$$

For ctO_2 see equation *ctO_2* on page B-63.

Calculation only under the following conditions:

- same patient numbers for both measurements
- two consecutive measurements
- sample type is arterial and mixed venous blood

Note

Different calculation, depending on whether COOX values are available or not.

Heart minute volume (Q_t)

Unit: [vol%][6]

Equation B-46

$$Q_t = ctO_2(A) - ctO_2(v)$$
$$= [(ctO_2(a) - ctO_2(v)) + 1.39 \cdot tHb \cdot (1 - \frac{SaO_2}{100}) + (PAO_2 - PaO_2) \cdot 0.00314]$$

SaO_2: arterial oxygen saturation fraction

$ctO_2(a)$ - $ctO_2(V)$ = $avDO_2$

Calculation only under the following conditions:

- same patient numbers for both measurements
- two consecutive measurements
- sample type is arterial and mixed venous blood

P/F Index

Ratio PaO_2/FIO_2[6]

Note

No calculation without PO_2 and input value FIO_2.

Unit: [mm/Hg]

Equation B-47

$$\text{P/F Index} = \frac{PaO_2}{FIO_2}$$

$PaO_2 = PO_2$

Lactate Clearance

The Lactate Clearance (LacClear) calculates the hourly change in percent of the measured lactate.[10], [11]

The determination of the Lactate Clearance requires two independent measurements.

Note

Both measurements must be carried out with the same patient ID.
The patient ID must therefore be defined as an input value.

WARNING

Warning

Samples from patients with other patient IDs can be measured between the two lactate partial measurements.

For calculating Lactate Clearance, either the current or the historic lactate value must be greater than 4 mmol/L.

At least 2 hours must pass between the two lactate partial measurements, but no more than 8 hours.

Unit: [%]

Equation B-48

$$LacClear = \frac{Lac_{hist} - Lac}{Lac_{hist}} \cdot 100 \cdot \frac{h}{\Delta}$$

Lac	is the latest measured lactate value
Lac_{hist}	is the historical lactate value
h	h = 1
Δ	is the time interval between the both lactate measurements

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Reference and critical values

The result of laboratory tests have little practical utility until clinical studies have ascribed various states of health and disease to intervals of values.(a)

Reference intervals are useful because they attempt to describe the typical results found in a defined population of apparently healthy people. Different methods may yield different values. depending on calibration and other technical considerations. Hence. different reference intervals and results may be obtained in different laboratories.

Reference intervals, although useful as guideline for clinicians. should not be used as absolute indicators of health and disease.(b)

Warning

The reference intervals presented in this chapter are for general information purposes only. Individual laboratories should generate their own set of reference intervals.

pH

Reference values:

• Whole blood. arterial:(a)	Cord blood		7.18 - 7.38
• Whole blood. venous:(a)	Cord blood		7.25 - 7.45
• Whole blood. arterial:(a)	Newborn	Premature. 48 h	7.35 - 7.50
	Newborn	Fullterm. birth	7.11 - 7.36
	Newborn	Fullterm. 5 - 10 min.	7.09 - 7.30
	Newborn	Fullterm. 30 min.	7.21 - 7.38
	Newborn	Fullterm. 1 h	7.26 - 7.49
	Newborn	Fullterm. 1 day	7.29 - 7.45
• Whole blood. arterial:(a)	Adult. children		7.35 - 7.45
• Whole blood. venous:(a)	Adult. children		7.32 - 7.43
• Whole blood. arterial:(a)	Adult	60 - 90 years	7.31 - 7.42
	Adult	> 90 years	7.26 - 7.43
• Whole blood. mixed-venous:(b)			7.35 - 7.43

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2289

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 470

Critical values:	**Lower Limit**	**Upper Limit**
• Whole blood. arterial or whole blood capillary(a)	< 7.2	> 7.6

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th Edition 2006, p. 2252

(b) see Chapter 16 of "Tietz' Textbook of Clinical Chemistry and Molecular Diagnostics". 4th Edition 2006

pO_2

Reference values:

• Whole blood. arterial:[(a)]	Cord blood		5.7 - 30.5 mmHg	0.8 - 4.0 kPa
• Whole blood. venous:[(a)]	Cord blood		17.4 - 41.0 mmHg	2.3 - 5.5 kPa
• Whole blood. arterial:[(a)]	Newborn	Birth	8 - 24 mmHg	1.06 - 3.19 kPa
	Newborn	5 - 10 min.	33 - 75 mmHg	4.39 - 9.96 kPa
	Newborn	30 min.	31 - 85 mmHg	4.12 - 11.31 kPa
	Newborn	1 h	55 - 80 mmHg	7.32 - 10.64 kPa
	Newborn	1 day	54 - 95 mmHg	7.18 - 12.64 kPa
• Whole blood. arterial:[(a)]	Adult. children	2 days - 60 years	83 - 108 mmHg	11.04 - 14.36 kPa
• Whole blood. arterial:[(a)]	Adult	> 60 years	> 80 mmHg	> 10.64 kPa
	Adult	> 70 years	> 70 mmHg	> 9.31 kPa
	Adult	> 80 years	> 60 mmHg	> 7.98 kPa
	Adult	> 90 years	> 50 mmHg	> 6.65 kPa
• Whole blood. mixed-venous:[(b)]			36 - 44 mmHg	4.8 - 5.9 kPa

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2289
(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 470

Critical values:		**Lower Limit**	**Upper Limit**
• Whole blood. arterial:[(a)]	Adult	40 mmHg or 5.3 kPa	---
• Whole blood. arterial:[(a)]	Children	45 mmHg or 6 kPa	125 mmHg or 16.7 kPa
• Whole blood. arterial:[(a)]	Newborn	35 mmHg or 4.7 kPa	90 mmHg or 12 kPa

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

pCO_2

Reference values:

• Whole blood. arterial (heparin):[(a)]	Newborn		27 - 40 mmHg	3.59 - 5.32 kPa
• Whole blood. arterial (heparin):[(a)]	Infant		27 - 41 mmHg	3.59 - 5.45 kPa
• Whole blood. arterial (heparin):[(a)]	Adult	male	35 - 48 mmHg	4.66 - 6.38 kPa
	Adult	female	32 - 45 mmHg	4.26 - 5.99 kPa
• Whole blood. mixed-venous:[(b)]			37 - 50 mmHg	4.9 - 6.7 kPa

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2259
(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 470

Critical values:		**Lower Limit**	**Upper Limit**
• Whole blood. arterial or whole blood. capillary:[(a)]	Adult	20 mmHg or 2.7 kPa	70 mmHg or 9.3 kPa

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Sodium

Reference values:[(a)]

Premature. cord	116 - 140 mmol/L	116 - 140 mEq/L
Premature. 48 h.	128 - 148 mmol/L	128 - 148 mEq/L
Newborn. cord	126 - 166 mmol/L	126 - 166 mEq/L
Newborn	133 - 146 mmol/L	133 - 146 mEq/L
Infant	139 - 146 mmol/L	139 - 146 mEq/L
Child	138 - 145 mmol/L	138 - 145 mEq/L
Adult	136 - 145 mmol/L	136 - 145 mEq/L
Adult > 90 years	132 - 146 mmol/L	132 - 146 mEq/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2294 f.

Critical values:	**Lower Limit**	**Upper Limit**
• Serum or plasma:[(a)]	120 mmol/L	160 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Potassium

Reference values:

• Serum[(a)]	Premature. cord	5.0 - 10.2 mmol/L	5.0 - 10.2 mEq/L
	Premature. 48 h.	3.0 - 6.0 mmol/L	3.0 - 6.0 mEq/L
	Newborn. cord	5.6 - 12.0 mmol/L	5.6 - 12.0 mEq/L
	Newborn	3.7 - 5.9 mmol/L	3.7 - 5.9 mEq/L
	Infant	4.1 - 5.3 mmol/L	4.1 - 5.3 mEq/L
	Child	3.4 - 4.7 mmol/L	3.4 - 4.7 mEq/L
	Adult	3.5 - 5.1 mmol/L	3.5 - 5.1 mEq/L
• Plasma (heparin)[(a)]	Adult. male	3.5 - 4.5 mmol/L	3.5 - 4.5 mEq/L
	Adult. female	3.4 - 4.4 mmol/L	3.4 - 4.4 mEq/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2291

Critical values:		**Lower Limit**	**Upper Limit**
• Serum or plasma:[(a)]	Adult	2.8 mmol/L	6.2 mmol/L
	Newborn	2.8 mmol/L	7.8 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Chloride

Reference values:

• Serum. plasma:[(a)]	Cord	96 - 104 mmol/L	96 - 104 mEq/L
	Premature	95 - 110 mmol/L	95 - 110 mEq/L
	0 - 30 days	98 - 113 mmol/L	98 - 113 mEq/L
	Adults	98 - 107 mmol/L	98 - 107 mEq/L
	Adults. > 90 years	98 - 111 mmol/L	98 - 111 mEq/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2260

Critical values:	**Lower Limit**	**Upper Limit**
• Serum or plasma:[(a)]	80 mmol/L	120 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Ionized calcium

Reference values:

• Whole blood. serum. plasma:[(b)]	Adult	female & male	1.15 - 1.35 mmol/L	4.6 - 5.4 mg/dL
	Cord blood		1.30 +/- 0.061 mmol/L	5.20 +/- 0.24 mg/dL
	Newborn	1 day	1.10 +/- 0.059 mmol/L	4.40 +/- 0.24 mg/dL
	Newborn	3 days	1.13 +/- 0.051 mmol/L	4.52 +/- 0.20 mg/dL
	Newborn	5 days	1.22 +/- 0.053 mmol/L	4.86 +/- 0.21 mg/dL
	Children	1 - 20 years	1.18 +/- 0.069 mmol/L	4.70 +/- 0.28 mg/dL

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 332

Critical values:		**Lower Limit**	**Upper Limit**
• Plasma:[(a)]	Adult	0.75 mmol/L or 3.01 mg/dL	1.6 mmol/L or 6.41 mg/dL

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Hematocrit

Reference values:			% Packed Red Cell Volume:	Volume fraction:
• Whole blood:[(b)]	Adult	Caucasian. female	36 - 48	0.36 - 0.48
	Adult	Caucasian. male	40 - 53	0.40 - 0.53
	Adult	Afro. female	34 - 43	0.34 - 0.43
	Adult	Afro. male	34 - 48	0.34 - 0.48
	Adult	Athlete. female	37 - 45	0.37 - 0.45
	Adult	Athlete. male	40 - 50	0.40 - 0.50
	Fetus	Week of gestation: 15	28 - 42	0.28 - 0.42
	Fetus	Week of gestation: 16	34 - 42	0.34 - 0.42
	Fetus	Week of gestation: 17	31 - 43	0.31 - 0.43
	Fetus	Week of gestation: 18 - 21	31 - 45	0.31 - 0.45
	Fetus	Week of gestation: 22 - 25	31 - 47	0.31 - 0.47
	Fetus	Week of gestation: 26 - 29	32 - 50	0.32 - 0.50
	Fetus	Week of gestation: > 30	30 - 58	0.30 - 0.58
	Newborn	Cord blood	48 - 56	0.48 - 0.56
	Infant	2 - 6 days	40 - 70	0.40 - 0.70
	Infant	1 - 2 weeks	38 - 70	0.38 - 0.70
	Infant	2 - 3 weeks	38 - 60	0.38 - 0.60
	Infant	3 - 7 weeks	36 - 46	0.36 - 0.46
	Infant	7 - 12 weeks	30 - 38	0.30 - 0.38
	Infant	10 - 12 months	35 - 43	0.35 - 0.43
	Children	4 - 5 years	32 - 40	0.32 - 0.40
	Children	6 - 8 years	32 - 41	0.32 - 0.41
	Children	10 - 13 years	34 - 44	0.34 - 0.44
	Children. female	14 - 16 years	35 - 43	0.35 - 0.43
	Children. male	14 - 16 years	38 - 49	0.38 - 0.49
• Whole blood. venous	Newborn	2 hours after birth	49 - 71	0.49 - 0.71
	Newborn	6 hours after birth	44 - 68	0.44 - 0.68

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 693

Critical values:		Lower Limit	Upper Limit
	Adult[(a)]	20%	60%
	Newborn[(a)]	33%	71%

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

tHb (total hemoglobin concentration)

Reference values:

• Whole blood. arterial (heparin):[(b)]	Adult	female	12.0 - 16.0 g/dL	120 - 160 g/L
	Adult	male	13.5 - 17.5 g/dL	135 - 175 g/L
	Fetus	Week of gestation: 15	10.9 +/- 0.7 g/dL	109 +/- 7 g/L
	Fetus	Week of gestation: 16	12.5 +/- 0.8 g/dL	125 +/- 8 g/L
	Fetus	Week of gestation: 17	12.4 +/- 0.9 g/dL	124 +/- 9 g/L
	Fetus	Week of gestation: 18 - 21	11.7 +/- 1.3 g/dL	117 +/- 13 g/L
	Fetus	Week of gestation: 22 - 25	12.2 +/- 1.6 g/dL	122 +/- 16 g/L
	Fetus	Week of gestation: 26 - 29	12.9 +/- 1.4 g/dL	129 +/- 14 g/L
	Fetus	Week of gestation: > 30	13.6 +/- 2.2 g/dL	136 +/- 22 g/L
	Cord blood		13.5 - 20.7 g/dL	135 - 207 g/L
	Newborn	1 day	15.2 - 23.5 g/dL	152 - 235 g/L
	Newborn	2 - 6 days	15.0 - 24.0 g/dL	150 - 240 g/L
	Infant	14 - 23 days	12.7 - 18.7 g/dL	127 - 187 g/L
	Infant	24 - 37 days	10.3 - 17.9 g/dL	103 - 179 g/L
	Infant	40 - 50 days	9.0 - 16.6 g/dL	90 - 166 g/L
	Infant	2.0 - 2.5 months	9.2 - 15.0 g/dL	92 - 150 g/L
	Infant	3.0 - 3.5 months	9.6 - 12.8 g/dL	96 - 128 g/L
	Infant	5 - 7 months	10.1 - 12.9 g/dL	101 - 129 g/L
	Infant	8 - 10 months	10.5 - 12.9 g/dL	105 - 129 g/L
	Children	11.0 - 13.5 months	10.7 - 13.1 g/dL	107 - 131 g/L
	Children	1.5 - 3 years	10.8 - 12.8 g/dL	108 - 128 g/L
	Children	5 years	11.1 - 14.3 g/dL	111 - 143 g/L
	Children	10 years	11.9 - 14.7 g/dL	119 - 147 g/L
	Children	12 years	11.8 - 15.0 g/dL	118 - 150 g/L
	Children	15 years	12.8 - 16.8 g/dL	128 - 168 g/L

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 682

Critical values:	**Lower Limit**	**Upper Limit**
Adult[(a)]	7 g/dL	20 g/dL
Newborn[(a)]	10 g/dL	22 g/dL

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Oxygen saturation (sO_2)

Reference values:		**% Saturation**	**Fraction Saturation**
• Whole blood. arterial:(b)	Newborn	40 - 90	0.40 - 0.90
	Thereafter	94 - 98	0.94 - 0.98
• mixed-venous:(b)		70 - 80	0.70 - 0.80

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 470

Oxyhemoglobin (O_2Hb)

Reference values:		**% O_2Hb**	**Fraction O_2Hb**
• Whole blood:(c)	Nonsmoker	94 - 98	0.94 - 0.98

(c) American environmental laboratory: The laboratory assessment of oxygenation: Robert F. Morgan: 1993. 5 (4), p. 147 - 153

Desoxyhemoglobin (HHb)

Reference values:	**% HHb**	**Fraction HHb**
• Whole blood:(c)	1 - 5	0.01 - 0.05

(c) American environmental laboratory: The laboratory assessment of oxygenation: Robert F. Morgan: 1993. 5 (4), p. 147 - 153

Carboxyhemoglobin (COHb)

Reference values:		**% COHb**	**Fraction COHb**
• Whole blood:(a)	Nonsmoker	0.5 - 1.5	0.005 - 0.015
	Smoker. 1 - 2 packs/day	4 - 5	0.04 - 0.05
	Smoker. > 2 packs/day	8 - 9	0.08 - 0.09
	Toxic	> 20	> 0.20
	Lethal	> 50	> 0.50

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2259

Methemoglobin (MetHb)

Reference values:

• Whole blood:[a]		0.06 - 0.24 g/dL	9.3 - 37.2 µmol/L
		0.04 - 1.52% of total Hb	0.0004 - 0.0152 mass fraction of total Hb
	Toxic[b]	> 15%	
	Lethal[b]	> 70%	

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2286

(b) Labor und Diagnose: Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik. Thomas Lothar, 7. Auflage, S. 698

Total bilirubin (=neonatal)

Reference values:

• Serum:[a]	Cord. premature	< 2.0 mg/dL	< 34.2 µmol/L
	Cord. full term	< 2.0 mg/dL	< 34.2 µmol/L
	0 - 1. day (premature)	1.0 - 8.0 mg/dL	17 - 187 µmol/L
	0 - 1. day (full term)	2.0 - 6.0 mg/dL	34 - 103 µmol/L
	1. - 2. day (premature)	6.0 - 12.0 mg/dL	103 - 205 µmol/L
	1. - 2. day (full term)	6.0 - 10.0 mg/dL	103 - 171 µmol/L
	3. - 5. day (premature)	10.0 - 14.0 mg/dL	171 - 240 µmol/L
	3. - 5. day (full term)	4.0 - 8.0 mg/dL	68 - 137 µmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2258

Critical values:[a]		**Lower Limit**	**Upper Limit**
• Serum or plasma	Newborn	---	15 mg/dL

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Glucose

Reference values:

• Serum. fasting:[(a)]	Cord blood	45 - 96 mg/dL	2.5 - 5.3 mmol/L
	Premature	20 - 60 mg/dL	1.1 - 3.3 mmol/L
	Neonate	30 - 60 mg/dL	1.7 - 3.3 mmol/L
	Newborn. 1 day	40 - 60 mg/dL	2.2 - 3.3 mmol/L
	Newborn. > 1 day	50 - 80 mg/dL	2.8 - 4.5 mmol/L
	Child	60 - 100 mg/dL	3.3 - 5.6 mmol/L
	Adult	74 - 100 mg/dL	4.1 - 5.6 mmol/L
	Adult. > 60 years	82 - 115 mg/dL	4.6 - 6.4 mmol/L
	Adult. > 90 years	75 - 121 mg/dL	4.2 - 6.7 mmol/L
• Whole blood (heparin):[(a)]	Adult	65 - 95 mg/dL	3.5 - 5.3 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2270 f.

Critical values:[(a)]		**Lower Limit**	**Upper Limit**
• Serum or plasma	Adult	40 mg/dL	450 mg/dL
	Child	46 mg/dL	445 mg/dL
	Newborn	30 mg/dL	325 mg/dL

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

Lactate

Reference values:

• Whole blood:[(a)]	venous (at bed rest)	5 - 15 mg/dL	0.56 - 1.39 mmol/L
	arterial (at bed rest)	3 - 7 mg/dL	0.36 - 0.75 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2282

Critical values:[(a)]		**Lower Limit**	**Upper Limit**
	Adult	---	3.4 mmol/L
	Child	---	4.1 mmol/L

(a) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2317

System components C

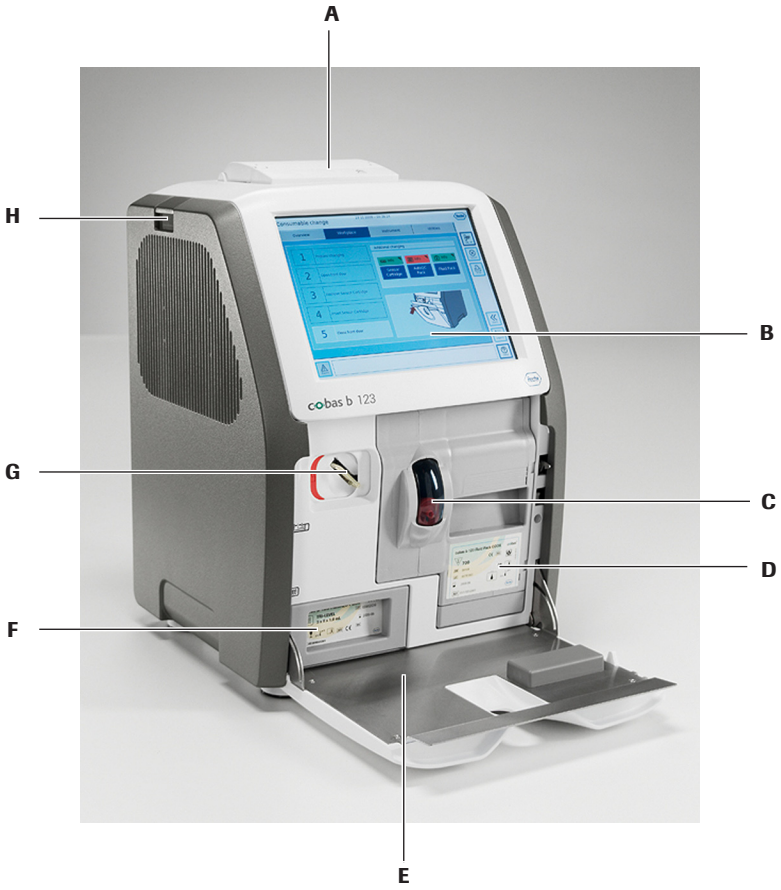
System components

This chapter contains the descriptions of the individual modules and consumables of the **cobas b** 123 POC system.

In this chapter *Chapter* 6

Visual identification

cobas b 123 POC system

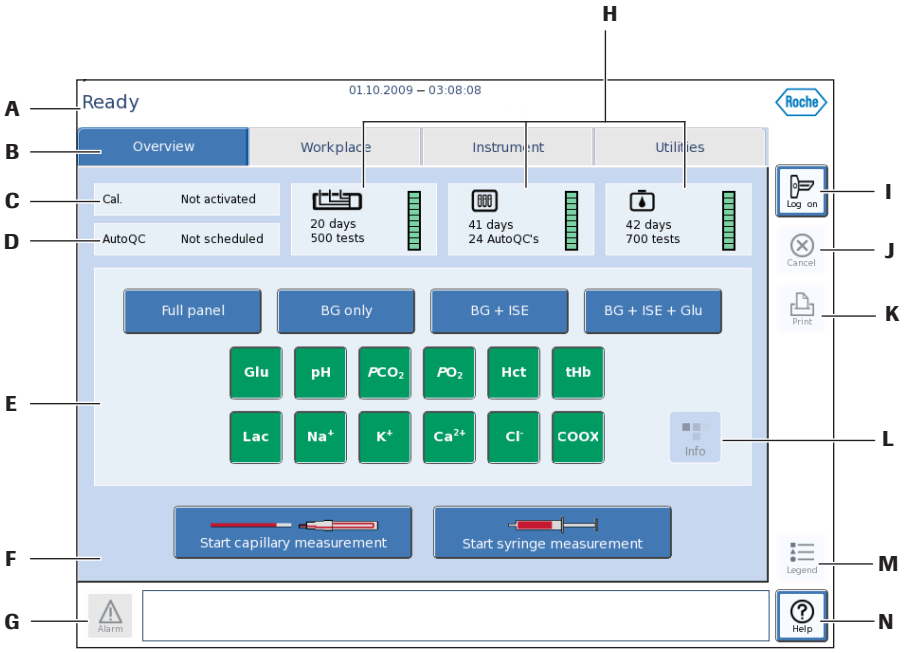


A Printer (part of the user interface module)
B Screen (part of the user interface module)
C Sample input module (part of the Fluid Pack)
D Fluid Pack
E Front door
F AutoQC module with AutoQC Pack
G Measuring chamber module with Sensor Cartridge
H USB interface

Figure C-1 **cobas b** 123 POC system

User interface module

Screen



A	Status area	**H**	Status display for consumables
B	Menu	**I**	Log on
C	Next calibration	**J**	Cancel
D	Next AutoQC measurement	**K**	Print
E	Parameter selection field	**L**	Info
F	Start measurement	**M**	Legend
G	Alarm area	**N**	Online help

All of the data (results, operating instructions, alarms, warnings, etc.) are displayed on this screen.

It is possible to start measurements in this mode.

The screen is an LCD color screen that has a touch-sensitive film (touch screen).

Note

As the touch-sensitive film can be destroyed by sharp objects, only touch it with your finger or with a suitable pen.

Description of the screen areas

Status area

The current status of the instrument and the date and time are displayed in this area. If a user is logged into the instrument, his or her user name is displayed.

Figure C-2 Status area including date and time

Additional information that may appear in this area:

[User name]	Logged in user (first and last name in the second line)
	Network connection is active
	Network connection not active
	Service connection is active (additionally, the status area is highlighted in yellow).
	ASTM/POCT1-A connection active
	ASTM/POCT1-A connection not active

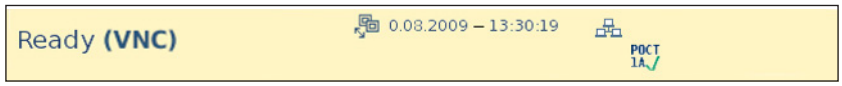


Figure C-3 Status area highlighted in yellow = active service connection

Menu selection

It is possible to configure certain settings or call up general information while measurements or calibrations are performed or other procedures execute database actions at the same time.

Figure C-4

The following menu items are available:

Overview	All of the data (results, operating instructions, alarms, warnings, etc.) are displayed on this screen. Measurements are started in this menu as well.
Workplace	In this menu, you can call up individual replacement routines, manual QC measurements and individual databases.
Instrument	All data relating to the instrument (e.g. status display) are displayed here. It is also possible to manually start calibrations and call up various maintenance tasks in this menu.
Utilities	Apart from utilities (troubleshooting routine, software update, etc.), you will also find the installation and put out of operation functions in this menu. Moreover, you can configure various settings in this menu.

Next calibration

The time for the next calibration is displayed.

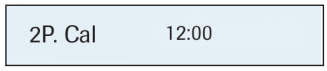


Figure C-5 Next calibration

For additional information, refer to chapter 10 *Calibration*, section *Settings for calibration* on page D-110.

Next AutoQC measurement

The time for the next AutoQC measurement is displayed.

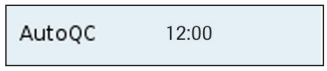
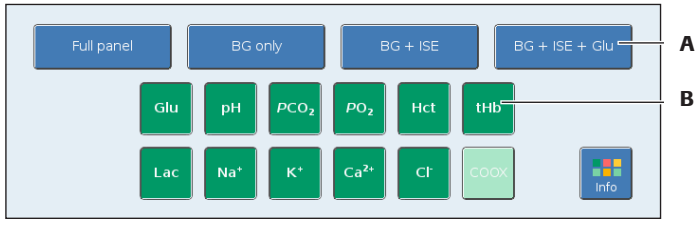


Figure C-6 Next AutoQC measurement

For additional information, refer to chapter 9 *Quality control*, section *Settings for quality control* on page D-86.

Parameter selection field

The parameter selection field allows you to select the measurement parameters or a parameter group and indicates the status of the individual parameters.



A Parameter group **B** Parameter buttons

If a parameter is not ready, a status report is displayed when the corresponding parameter button is pressed.

	Parameter is activated and ready.
	Parameter is temporarily deactivated (but ready).
	Parameter is activated and ready (but a QC warning is assigned).
	Parameter is temporarily deactivated (but ready, however, a QC warning is assigned).
	Parameter not ready (not calibrated) or locked via remote lock. For additional details, refer to the [Info] button.
	Parameter is not ready (due to QC lock).
	Parameter is permanently deactivated

Table C-1 List of the various parameter states

To the right of the parameter selection field is the [Info] button. When the [Info] button is pressed, the status report is displayed.

	The status report contains information about the parameters that are not ready.

You can select a parameter group via the respective button. A parameter group enables or disables parameters for the measurement and the respective measurement report. Up to three user-defined parameter groups are possible.

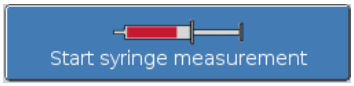
	Selection button for a parameter group.

For additional information, refer to chapter 8 *Measurement*, section *Edit panels* on page D-53.

Starting a measurement

It is possible to measure samples from syringes, without a needle or cannulae, capillaries and the Roche MICROSAMPLER PROTECT.

Press the following buttons to start a measurement:

	Start Roche MICROSAMPLER PROTECT or capillary measurement
	Start syringe measurement

For specific details, refer to chapter 8 *Measurement*, section *Measurement procedure* on page D-38.

Alarm area

In normal operation. the [Alarm] button is locked and the display field of the alarm area on the bottom of the screen is empty.

If an error occurs. the [Alarm] button is enabled and the alarm name (including date and time) is displayed in the alarm area.
The [Alarm] button changes color depending on the severity of the error.

	No warnings or errors are present. The alarm screen cannot be opened.
	Information is present. The instrument can be used normally, but there are pending actions to be completed.
	Warnings are present. The instrument can be used with potential limitations.
	Errors are present. The instrument cannot be used, or can only be used with limitations.

Table C-2 Alarm button color coding

When the [Alarm] button is pressed. a message window opens displaying details about the warnings or errors and suggesting remedies.

Please refer to chapter 14 *Troubleshooting* for more information on troubleshooting.

Status display for consumables

The status of the consumables is indicated in this area. The following symbols are used:

Sensor Cartridge

AutoQC Pack

Fluid Pack

The remaining period of use or the remaining number of measurements are displayed. In addition. a color bar symbolically indicates the fill level:

Consumable is OK. Neither the warning level nor the alarm level have been reached. The bar indicates. in 10% increments. the percentage of the remaining period of use or the remaining tests.

Warning level reached:

Consumable is OK. but must be changed within 2 days. as the maximum period of use or the maximum number of tests will be reached soon. The bar indicates. in 10% increments. the percentage of the remaining period of use or the remaining tests.

Alarm level reached:

Consumable is no longer OK. An immediate change is required. as the maximum period of use or the maximum number of tests has been reached.

Caution

Depending on the respective consumable. a red fill level indicator status can result in a system stop (Fluid Pack) or just a warning (Sensor Cartridge and AutoQC Pack).

For additional information, refer to chapter 13 *Consumable change*.

Action buttons

The following buttons are available on the right edge of the screen.
Depending on the operating status or software function. the buttons can be enabled or disabled.

Log on/Log off

This button is used to login or logout a user to or from the instrument.

Cancel

This button is used to interrupt an operation that is currently in progress, e.g. calibration.
If no operation is in progress, the [Cancel] button is disabled.

	**Print** This button is used to print results and other data that can be output via the databases.
	**Legend** This button describes the symbols on the buttons of detail views.
	**Online help** For each screen on the instrument, this button opens the corresponding page of the online help.

Log on

Using this function allows a user to log on to the instrument. Depending on the security settings of the instrument, this can be necessary in order to access certain functions.

► Logging on as a user

Call up the [Log on] function on the right edge of the screen.

The following screen appears:

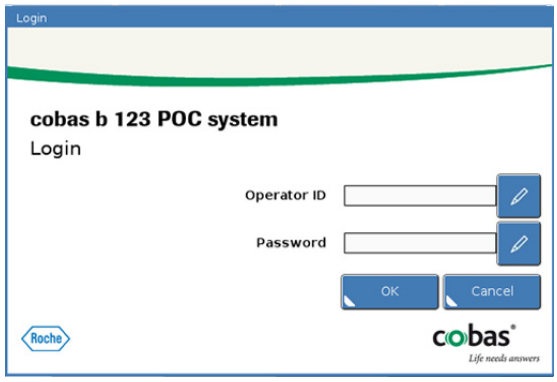


Figure C-7 Screen for log on

Enter a valid user name and the corresponding password and press the [OK] button.

If the login was successful, the user name is displayed in the status area.

► Logging out as a user

Call up the [Log off] function.

The user is logged out of the instrument.

Legend

This button describes the symbols on the buttons of detail views, for example in the database.

Refer chapter 12 *Software functions*, section *Database* on page D-129 for more details.

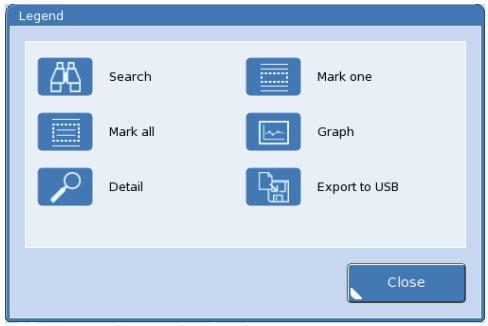


Figure C-8 Legend

Online help

Pressing the [Help] button displays the corresponding page of the online help for each screen on the instrument.

The online help contains cross-references to other relevant topics. Using the table of contents or index, topics from the online help can be found more easily. The online help also has a glossary.

	Using the [Home] button, switch to the table of contents
	Using the [Back] button, return to the last page displayed

Other buttons on the screen

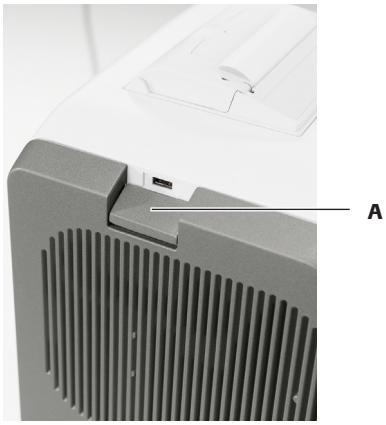
The following buttons are used in the software:

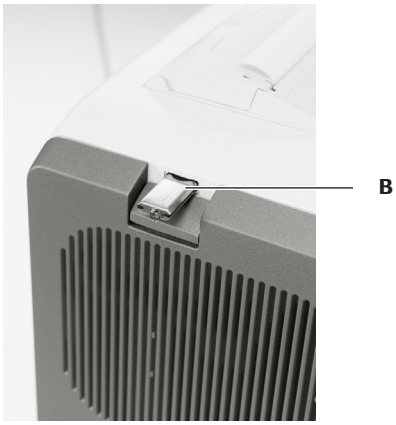
	First entry
	Move up
	Move down
	Last entry
	To the left
	To the right
	Edit sort
	Menu closed – Menu open – Menu entry
	Selection disabled – Selection enabled
	Start a procedure (without input values)
	Start a function (with input values)
	Exit a function
	active function

	temporarily inactive function
 Pencil	Edit
	Detail

USB interface

To plug in a USB storage device, push down the gray cover.





A gray cover

B USB storage device

Figure C-9 USB interfaces

Printer

Figure C-10 Thermal printer

The quiet thermal printer is a part of the user interface module.

	Paper feed button on the printer

Front door

The measuring chamber module with the Sensor Cartridge, the Fluid Pack with the sample input module and the AutoQC module with the AutoQC Pack (optional) are located behind the front door.

See Figure C-1 on page C-5.

Measuring chamber module

The measuring chamber module with the Sensor Cartridge is located behind the front door.

CAUTION

Caution

A Sensor Cartridge cannot be removed from the measuring chamber module unless the Sensor Cartridge is completely disconnected from the Fluid Pack.

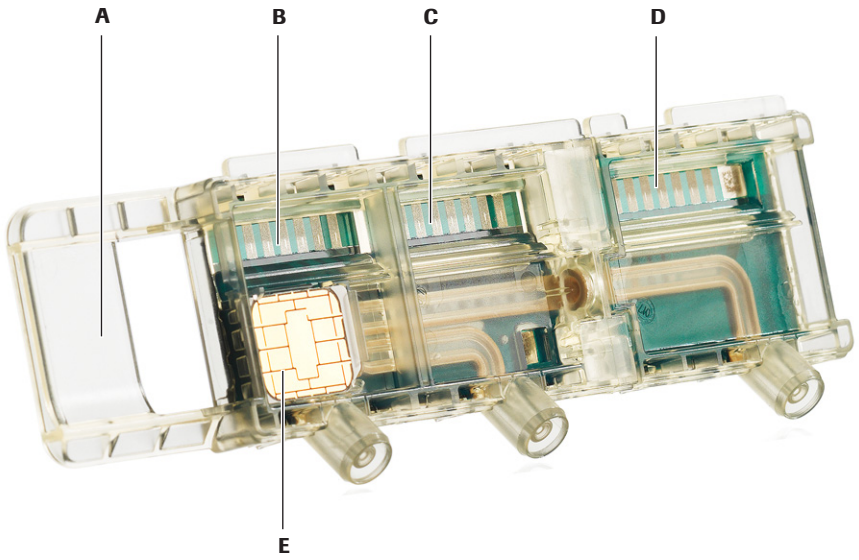
In normal operation, the Sensor Cartridge is connected to the Fluid Pack. The red area of the measuring chamber is visible (ready position).
The Sensor Cartridge is disconnected from the Fluid Pack to prepare the measuring chamber module for a Sensor Cartridge replacement. The green area of the measuring chamber becomes visible (replacement position).

A Position for replacement (green) **B** Position in normal operation (red)

Figure C-11 Measuring chamber module with Sensor Cartridge

Handle the Sensor Cartridge carefully to prevent the possibility of fluid escaping from the Sensor Cartridge.

cobas b 123 Sensor Cartridge



A Handle for touching the Sensor Cartridge
B ISE sensor part
C Glu/Lac sensor part
D BG sensor part
E Smart Memory Chip

Figure C-12 **cobas b** 123 Sensor Cartridge

The following versions are available:

cobas b 123 Sensor Cartridge	BG, Hct[(a)]
cobas b 123 Sensor Cartridge	BG, ISE, Hct[(a)]
cobas b 123 Sensor Cartridge	BG, ISE, Hct, Glu[(a)]
cobas b 123 Sensor Cartridge	BG, ISE, Hct, Glu, Lac[(b)]

Table C-3 **cobas b** 123 Sensor Cartridge - versions

(a) up to 700 tests or up to 28 days
(b) up to 500 tests or up to 21 days

A memory chip is attached on the Sensor Cartridge to save various data relating to the Sensor Cartridge that must be transmitted to the instrument. The chip is also used to transmit data from the instrument to the Sensor Cartridge.

Among others, this involves the following data:

- Lot number
- Expiration date
- Installation date
- Sensor variant
- Number of samples
- Storage period outside of the instrument

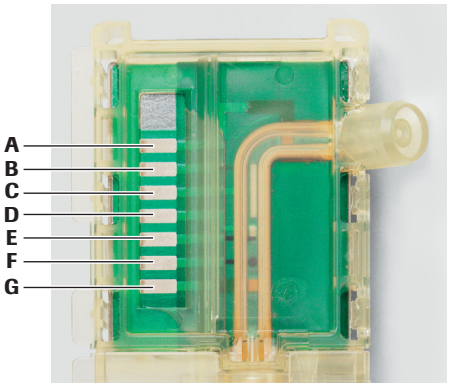
CAUTION

Caution

Do not touch the contact surface of the smart memory chip.
Do not touch the sensor parts of the Sensor Cartridge.

BG sensors

The sensors are used to measure the pH value and PO_2 and PCO_2 blood gas values.



A Conductivity contact (BG-IN)
B O_2 measuring contact
C O_2 reference contact
D CO_2 reference contact
E CO_2 measuring contact
F pH sensor (BG)
G Conductivity contact (BG-OUT)

Figure C-13 BG sensor

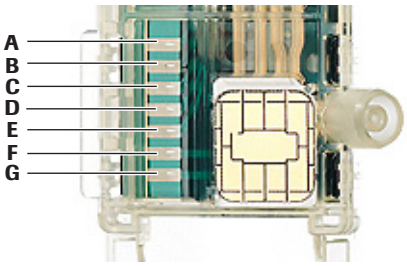
PO_2 sensor The PO_2 sensor functions according to the Clark measurement principle. This means that oxygen diffuses through a membrane to a gold multi-wire system with negative electric potential inside of the sensor. The oxygen is reduced here, which generates an electric current that is proportional to the oxygen contained in the sample. This current is measured (amperometric measurement).

PCO_2 sensor The PCO_2 sensor is a Severinghouse-type sensor. This means that CO_2 diffuses through a membrane similar to the oxygen sensor. In the sensor, the CO_2 concentration changes and causes a change of the pH value, which is measured potentiometrically.

pH sensor (BG) The pH sensor consists of a pH-sensitive membrane. Depending on the pH value of the sample, electric potential is generated at the boundary layer between the membrane and the sample. This potential can be measured potentiometrically by means of a second sensor, the reference sensor (in the ISE sensor part).

ISE sensors

The ISE sensors are used to measure the electrolyte values Na^+, K^+, Ca^{2+} and Cl^-.



A Cl^- sensor
B not used
C Ca^{2+} sensor
D K^+ sensor
E Na^+ sensor
F Conductivity contact (ISE)
G ISE reference sensor

Figure C-14 ISE sensors

The individual measurement results for the electrolytes are determined by the sensors in different ways:

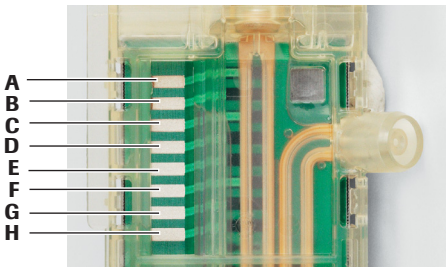
Na^+ sensor This sensor consists of a sodium sensitive membrane.

K^+, Ca^{2+}, Cl^- sensor Like the Na+- sensor, these sensors work according to the potentiometric measuring principle. They differ only by different membrane materials that enable sensitivity for the respective electrolytes.

Reference sensor All potentiometric sensors (except for the CO_2 sensor) transmit direct signals that relate to the content of the sample to be measured. The reference sensor must return a constant signal regardless of the composition of the sample. This is achieved by bringing the sample in contact with a liquid with a high KCl concentration (reference solution). The sensor consists of a chloride-sensitive membrane that is in contact with the reference solution. Since the concentration of the reference solution does not change, the signal of the reference sensor does not change either. This way the reference sensor returns a constant signal independent of the concentration.

Glu/Lac sensors

The Glu/Lac sensors are used to measure glucose and lactate.



A	BSA sensor	**E**	Glucose reference sensor
B	Lactate counter electrode	**F**	Glucose sensor
C	Lactate sensor	**G**	Glucose counter electrode
D	Lactate reference sensor	**H**	Conductivity contact (Glu/Lac)

Figure C-15 Glu/Lac sensors

Glucose sensor

Glucose is oxidized into gluconolactone with oxygen from the air and the glucose oxidase enzyme. The H_2O_2 that is formed in this process is determined amperometrically at 350 mV by means of a manganese dioxide/carbon electrode.

Since the sensor restores the oxygen that is needed for oxidation of glucose in the enzymatic reaction, the glucose value is measured independently of the oxygen concentration in the blood.

To avoid interference by electroactive substances, an interference sensor (BSA sensor) is used.

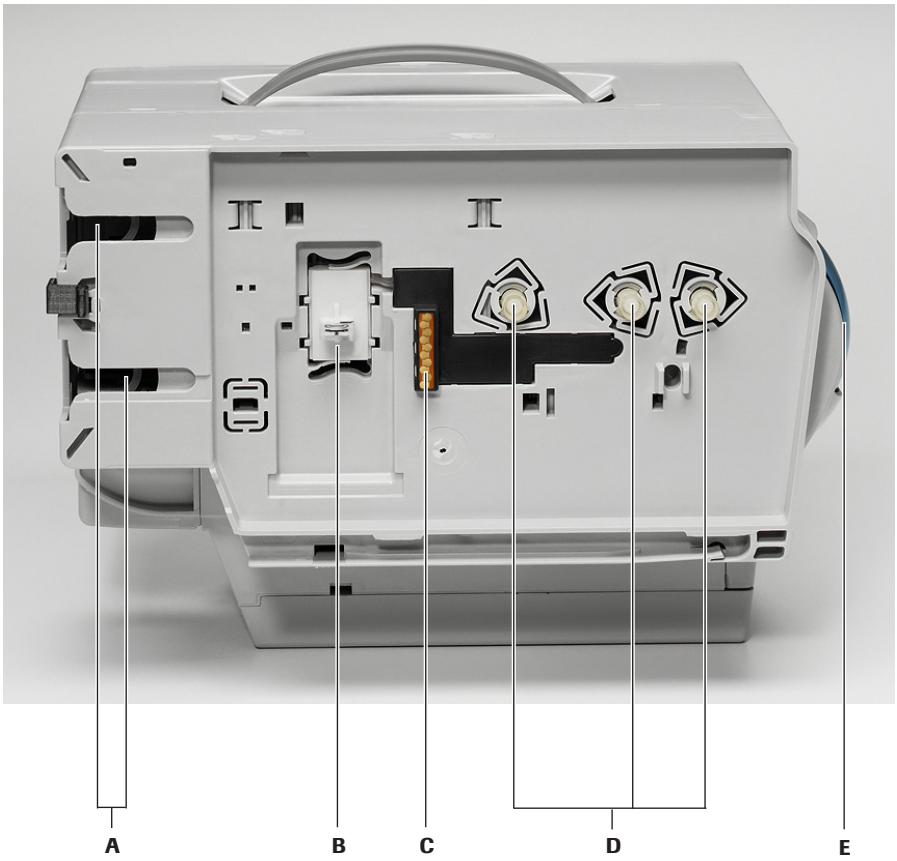
Lactate sensor

Lactate is oxidized into pyruvate with oxygen from the air and the lactate oxidase enzyme. The H_2O_2 that is formed in this process is determined amperometrically at 350 mV by means of a manganese dioxide/carbon electrode.

Since the sensor restores the oxygen that is needed for oxidation of lactate in the enzymatic reaction, the lactate value is measured independently of the oxygen concentration in the blood.

To avoid interference by electroactive substances, an interference sensor (BSA sensor) is used. The interference compensation electrode is a part of the lactate sensor system with an inactive protein instead of an enzyme.

cobas b 123 Fluid Pack



A Tubing (peristaltic pump)
B Cuvette (oximeter module)
C Sample sensor contacts
D Docking parts (measuring chamber module)
E Sample input module

Figure C-16 **cobas b** 123 Fluid Pack

The Fluid Pack includes the following components:

- 7 bags
  - 2 waste water containers
  - 1 reference solution (REF)
  - 1 wetting solution (WET) (for wetting the Sensor Cartridge)
  - 1 standby solution (STDBY) (simultaneously calibration solution)
  - Calibration solution CAL 1
  - Calibration solution CAL 2
- Sample input module (fill port, needle)
- Complete tubing (including peristaltic pump)
- Cuvette for oximeter module

The advantage of this system is that all essential fluid lines which can get dirty are combined into the Fluid Pack. Replacement by the user requires just a few simple steps and thus makes any recurring service unnecessary.

An air filter is integrated into the base of the Fluid Pack, which aspirates fresh air that is used to control the temperature of the **cobas b** 123 POC system modules.

Different Fluid Packs are optimized to support different testing frequency:

cobas b 123 Fluid Pack COOX 200[(a)]	5 or more measurements per day
cobas b 123 Fluid Pack COOX 400[(a)]	13 or more measurements per day
cobas b 123 Fluid Pack COOX 700[(a)]	33 or more measurements per day
cobas b 123 Fluid Pack 200[(b)]	5 or more measurements per day
cobas b 123 Fluid Pack 400[(b)]	13 or more measurements per day
cobas b 123 Fluid Pack 700[(b)]	33 or more measurements per day

Table C-4

(a) For all **cobas b** 123 POC systems.

(b) For **cobas b** 123<1> system + **cobas b** 123<2> system only.

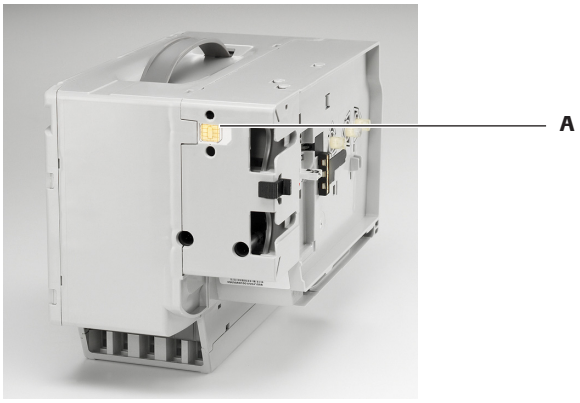
Independent of the type of the Fluid Pack or remaining solutions, the Fluid Pack will have to be changed at latest after 42 days.

For more information, refer chapter 4 *Specifications*, section *cobas b 123 Fluid Pack* on page B-52.

Note

Less frequent testing than indicated for the Fluid Pack sizes will lead to a reduced number of tests due to solutions needed for calibration.

A memory chip is attached on the rear side of the Fluid Pack to save various data relating to the Fluid Pack that must be transmitted to the instrument. The chip is also used to transmit data from the instrument to the Fluid Pack.



A Smart Memory Chip

Figure C-17

Among others, this involves the following data:

- Lot number
- Expiration date
- Installation date
- Number of samples
- Fill levels
- Concentration of calibration solutions
- Frequency of use or number of possible installations

Caution

Do not touch the contact surface of the smart memory chip.

Operating fluids

All calibration and wash solutions that are required for operating the instrument and two waste water containers are located in the Fluid Pack. The operating fluids are filled into heat-sealed bags.

The bag valves are controlled by the instrument and release the fluid from the bags, but can also be set to the shutoff or air position.

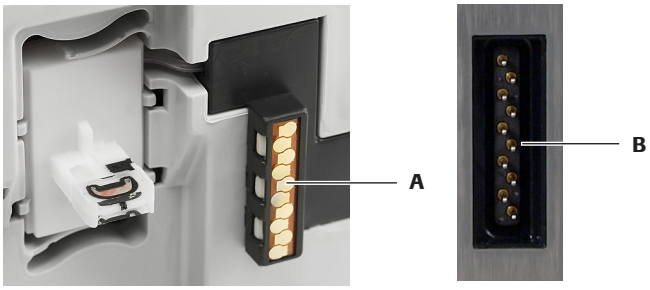
Tubing

All the tubes that are required for operation, including the pump tubes for both peristaltic pumps and the valve tubing, are integrated into the Fluid Pack.

The valves and peristaltic pumps are part of the instrument.

Sample sensor contacts

The sample sensor contacts form the electrical interface between the Fluid Pack and the measuring chamber module.



A Sample sensor contacts on the Fluid Pack

B Sample sensor contacts inside the measuring chamber module

Figure C-18 Sample sensor contacts

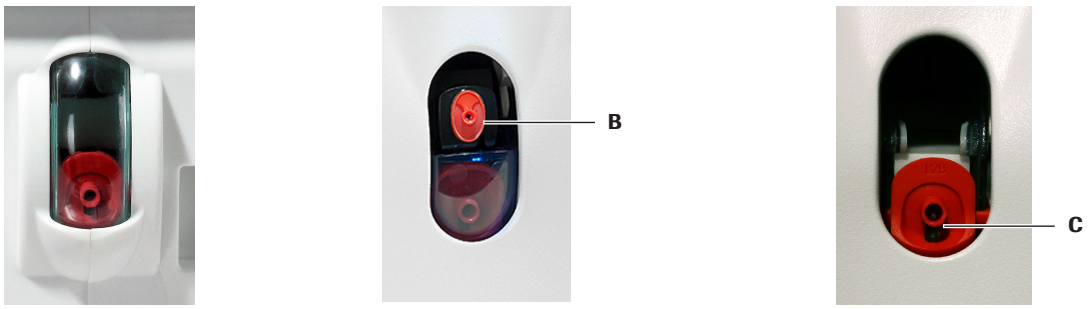
CAUTION

Caution

Do not touch the cuvette and sample sensor contacts on the side panel of the Fluid Pack.

Sample input module

The fill port enables aspiration of samples from syringes, the Roche MICROSAMPLER PROTECT, capillaries and ampoule adapters.



A Sample input module **B** Fill port (capillary position) **C** Fill port (syringe position)

Figure C-19 Sample input module

Cuvette

A Sample sensor contacts **B** Cuvette

Figure C-20 Cuvette

The cuvette, which is a part of the Fluid Pack, is mechanically connected to the oximeter module, an optional component of the instrument.

CAUTION

Caution

Do not touch the cuvette and sample sensor contacts on the side panel of the Fluid Pack.

cobas b 123 AutoQC Pack (optional)

An optional AutoQC module is provided in the **cobas b** 123 POC system for regular, automated quality control.

This module is included in the **cobas b** 123<2> system and **cobas b** 123<4> system versions.

The consumable that is inserted into the AutoQC module is the AutoQC Pack, which contains 24 glass ampoules in a revolving carousel. The 24 glass ampoules can be filled with up to three different levels.

The following version of the **cobas b** 123 AutoQC Pack is currently available:

cobas b 123 AutoQC Pack TRI-LEVEL	Level 1 – 3 for high, normal and low values

Table C-5 **cobas b** 123 AutoQC Pack version

Figure C-21 **cobas b** 123 AutoQC Pack TRI-LEVEL

The advantage of this system is that the QC fluid is withdrawn directly from the ampoule using the sample needle. The QC measurement procedure relative to transporting and handling samples corresponds exactly to the procedure for sample measurements. Special sample handling for QC materials is thus completely unnecessary.

CAUTION

Caution

Do not turn a partially used AutoQC Pack upside down if the AutoQC Pack is being installed again. Installing an AutoQC Pack that was turned upside down can destroy the AutoQC module.

A Smart memory chip of the **cobas b** 123 AutoQC Pack

Figure C-22 **cobas b** 123 AutoQC Pack

A memory chip is attached on the rear side of the AutoQC Pack to save various data relating to the AutoQC Pack that must be transmitted to the instrument. The chip is also used to transmit data from the instrument to the AutoQC Pack.

Among others, this involves the following data:

- Expiration date
- Installation date
- Level
- Product-specific lot number
- Level-specific lot numbers

CAUTION

Caution

Do not touch the contact surface of the smart memory chip.

Oximeter module (optional)

This module is included in the **cobas b** 123<3> system and **cobas b** 123<4> system versions.

The oximeter module is an optical sensor module for determining total hemoglobin (tHb), the hemoglobin derivatives oxyhemoglobin (O_2Hb), desoxyhemoglobin (HHb), carboxyhemoglobin (COHb), methemoglobin (MetHb) and bilirubin (Bili).

Functional principle

The hemoglobin derivatives are determined spectrophotometrically based on the Lambert-Beer law.

$A(\lambda) = \varepsilon(\lambda) * C * d$

where:

$A(\lambda)$	is the vector of the absorption value for each wavelength λ
$\varepsilon(\lambda)$	is the matrix of the absorption coefficient of individual components for each wavelength λ
C	is the vector of the concentration value of the components
d	is the layer thickness of the cuvette

Extinction is measured at different wavelengths and the resulting, overdetermined system of equations is solved for the hemoglobin derivative concentrations.

The basic components of the optical system are:

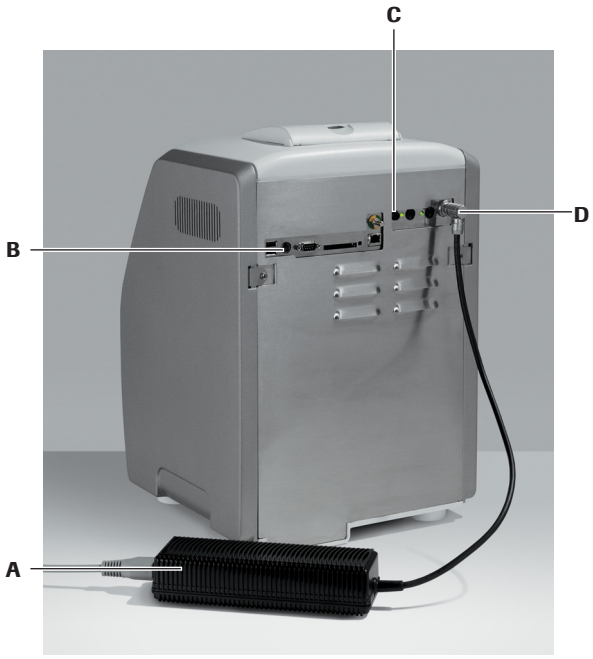
- Light source (LED)
- Hemolyzer
- Cuvette
- Polychromator

The light from a white light LED is guided to the cuvette. In the cuvette, the light is partially absorbed by the sample and partially allowed to pass through. The absorption is typical for the composition of the sample. The light that has passed through the cuvette is guided through a light guide to the polychromator, where it is fractured and mapped on the surface of a photosensitive receiver (CCD). The resulting electric signal is used to calculate the absorption and ultimately the hemoglobin derivative concentrations.

The sample in the cuvette is hemolyzed in order to reduce light scattering by the red blood cells to a minimum. During the hemolysis, the sample is subjected to a strong ultrasonic field, which causes the erythrocytes to rupture and release the hemoglobin.

As for all spectrophotometric methods, some limitations also apply for the optical determination of hemoglobin derivatives. In general, all substances that cause significant absorption or stray light besides the hemoglobin derivatives that are to be determined have a negative effect on the results. The substances that could interfere with the measurements are: diagnostic or therapeutic dyes such as cardio green and methylene blue, high concentrations or fatty emulsions such as LIPOSYN. The instrument detects the presence of such substances from a certain level and prevents that incorrect results are displayed.

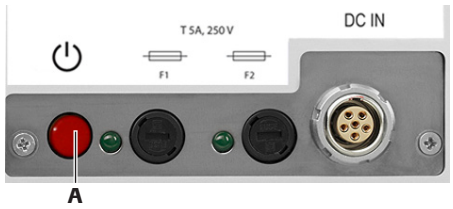
Rear panel



A Power supply
B Interfaces
C Power switch
D Connection socket for power supply

Figure C-23 Rear panel

Button (on/off)



A Button (on/off)

Figure C-24

Note

Pressing the (On/Off) button does not disconnect the instrument from the power supply. To disconnect the instrument from the power supply completely, the power supply must be disconnected from the power supply network.

POWER SUPPLY cobas b 123 POC system

CAUTION

Caution

Use the original power supply for the **cobas b** 123 POC system only.
The power supply must not be repaired or opened.

Figure C-25 POWER SUPPLY **cobas b** 123 POC system

Supply voltage range:	100 - 240 V AC (+/- 10%)
Frequency:	50 - 60 Hz (+/- 5%)
Required power:	max. 120 W

The power supply supplies the instrument with 12V DC (10 A).

CAUTION

Caution

Use the power supply in horizontal position only.

Power cable

The power cable must conform to country-specific requirements.
Orders can be placed via the local Roche organization only.

The selected power cable must fulfill the following minimum specifications:

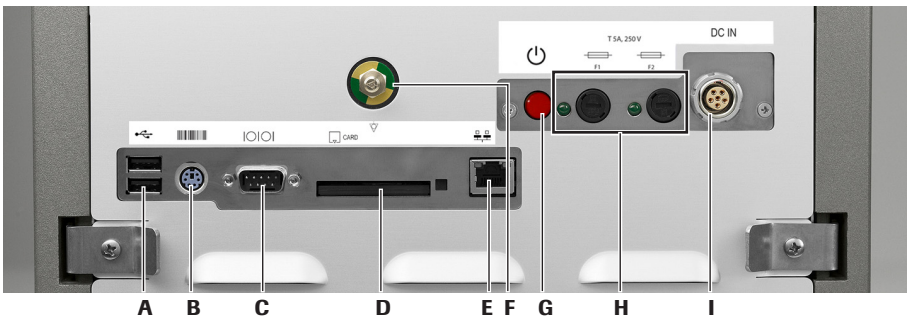
Supply voltage	Cable type	Cable cross-section	Rated current	Rated voltage	Min. length	Connector	Connection[(a)] Power supply	Additional requirements
100 - 125 V[(b)]	SVT. SJT. 3-core	18 AWG	15 A	125 V	6 feet	Molded. locally permitted. hospital grade	IEC320-EN60320/C13	Locally permitted (e.g. UL. CSA. JET. CCC. etc.). suitable for medical use
230 - 240 V	3-core. PVC insulated	Min. 0.75 mm^2 (18 AWG)	10 A	300 V	2 meters	Molded. locally permitted	IEC320-EN60320/C13	Locally permitted. HAR mark on plug or socket. suitable for medical use

Table C-6

(a) IEC320-EN60320/C13: Plugs and Socket-Outlets for Household and Similar Purposes

(b) Standard for USA, Canada, Japan.

Interfaces

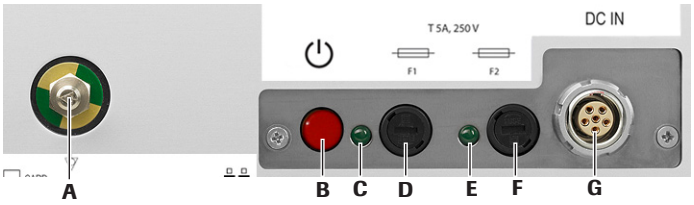


A USB (2x)
B Barcode scanner
C External ticket printer (RS 232)
D CompactFlash card
E Network: 10BaseT Ethernet (RJ45)
F Equipotential bonding plug
G Button (on/off)
H Status LEDs (2x) and fuses (2x) (Fuse 5A slow 250V)
I Power supply

Figure C-26 Interfaces

- 2x USB
- Barcode scanner: PS/2 DIN - 6p female socket
- 1x RS 232 interface (e.g. external ticket printer)
- 1x CompactFlash card slot
- 1x 10BaseT Ethernet (RJ45)
- 2x LED: control lamps for supply voltage
- 2x fuses: 5A slow blow 250V
- Power supply: connection socket for external power supply

Each voltage supply circuit has a "Power ON" display (green LEDs next to the fuses). The LEDs are wired into the circuit downstream of the fuses.



A Equipotential bonding plug
B Button (On/Off)
C Status LED (Voltage supply circuit 2)
D Fuse (Voltage supply circuit 2)
E Status LED (Voltage supply circuit 1)
F Fuse (Voltage supply circuit 1)
G Power supply

Figure C-27 Interfaces in detail

Socket assignment

CAUTION

Caution

To prevent damage of the **cobas b** 123 POC system, it is absolutely mandatory to compare the socket assignment of the **cobas b** 123 POC system with that of the customer end device before it is connected to the **cobas b** 123 POC system.

Roche assumes no liability for damage due to failure to observe these instructions.

RS 232 For the RS-232 interface (e.g. external ticket printer). a 9-pin SUBMIN D interface is available as the connection.

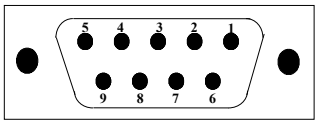


Figure C-28

Pin 1	DCD	Data carrier detected
Pin 2	RxD	Receive data
Pin 3	TxD	Transmit data
Pin 4	DTR	Data terminal ready
Pin 5	GND	Signal ground
Pin 6	DSR	Data set ready
Pin 7	RTS	Request to send
Pin 8	CTS	Clear to send
Pin 9	RI	Ring Indicator

Barcode scanner A PS/2 DIN-6p socket is provided for connecting the barcode scanner.

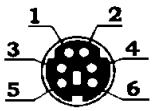


Figure C-29

Pin 1	PC data	
Pin 2	NC	
Pin 3	GND	Signal ground
Pin 4	Vcc	+ 5V power supply
Pin 5	PC-CLK	Clock
Pin 6	NC	

Network 10BaseT-Ethernet plug standard (RJ-45), to establish four-core unshielded twisted pair (UTP) Ethernet connections.

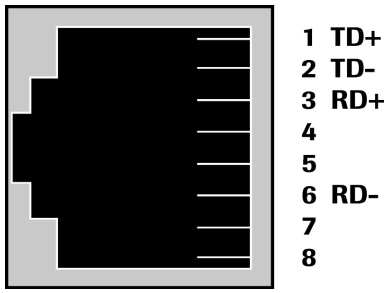


Figure C-30

USB USB stands for universal serial bus and is an industry standard used for connecting various peripheral devices.

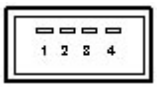


Figure C-31

Pin 1	VCC5
Pin 2	D-
Pin 3	D+
Pin 4	GND

Warning and identification signs (including nameplate)

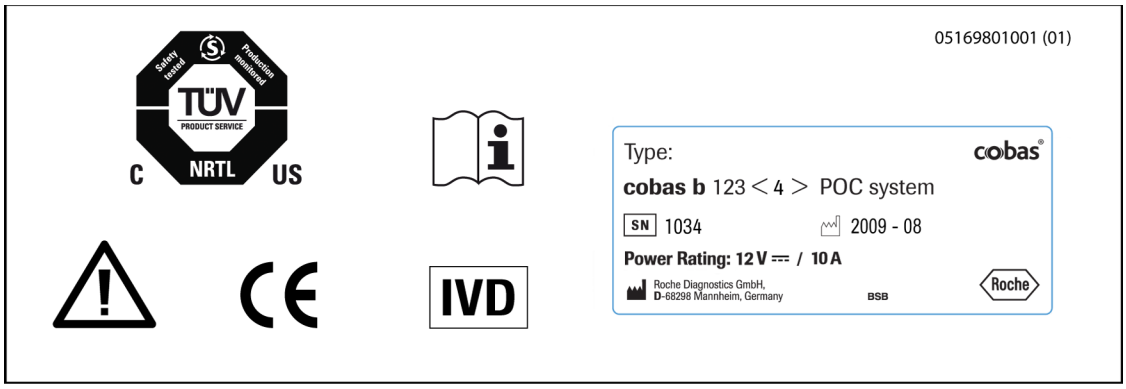


Figure C-32 Warning & identification sign and nameplate of the **cobas b** 123 POC system

Barcode scanner (standard)

Figure C-33 Barcode scanner

The barcode scanner is used for easily scanning manual QC materials (lot number, target values, etc.) and patient or user IDs.

For additional information about the barcode scanner specifications, refer chapter 4 *Specifications*, section *Barcode scanner (standard)* on page B-55.

Note

Press the button on the bottom to enable the scanner. The scanner beeps and the LED on the top flashes once to indicate a successful scan of the barcode.

Caution

If manual QC material is used, reprogramming of the barcode types "Code 39" and "Interleaved 2 of 5" (without check digits) is not permitted. The corresponding data can no longer be scanned. If it is necessary to use one of the two barcodes with check digits, notify Roche Service. For additional information, refer to the enclosed manual for the MS 180 handheld scanner (included in scope of delivery).

Recommendations for ensuring good barcode scanning quality:

- The label or piece of paper with the printed barcode should be smooth and have no folds.
- The printed barcode must not be distorted in the printing process (ensure good quality ink, printer ribbon or toner).
- Use special color ink and non-white paper or labels with caution as they can impact the scanner function (the light source of the barcode scanner is red).
- Do not use printing materials with shiny or reflective surfaces.

Note

For additional information, refer to the enclosed manual for the barcode scanner (included in the scope of delivery).

Imaging scanner (optional)

In addition to the barcode scanner (default). an imaging scanner is defined as a spare part.

Figure C-34 Imaging scanner **cobas b** 123 POC system

Using the non-directional imaging scanner. freehand scanning of small and easy-to-hold articles and handheld scanning of bulky articles is possible.

For additional information about the imaging scanner specifications, refer chapter 4 *Specifications*, section *Imaging scanner (optional)* on page B-56.

Note

For additional information, refer to the enclosed manual for the imaging scanner (included in the scope of delivery).

Operation D

Installation and put out of operation

This chapter describes point by point how to start up and shut down the instrument using the software.

In this chapter

Chapter **7**

Table of contents

Installation

Location

Note

Never set up the **cobas b** 123 POC system in the immediate vicinity of patients. Maintain a safety distance of 1.5 meters (5 feet).

A suitable, level location which must not be exposed to direct sunlight is required for proper and trouble-free operation.
When installing an instrument that was stored in a cold room or transported at low temperatures, condensation may occur, which can cause the instrument to malfunction. The instrument must be acclimated to room temperature for at least one hour prior to installation.

The following requirements must be met:

- The instrument can be operated at an elevation of -100 to +2500 meters (-328 to + 8202 feet). This corresponds to an ambient air pressure (including weather-related pressure fluctuations) of 530 to 800 mmHg or 706 to 1066 mbar.
- Ambient temperature: 15 to 32 °C
- Prevention of direct sunlight, vibrations and strong electromagnetic fields (electric motors, transformers, X-ray equipment, cellular phones, etc.)
- A stable, horizontal working surface (max. = 1° angle with consumables used)
- Relative humidity: 15 to 90% (non-condensing)
- For proper air circulation and the electrical connections, the following clearances should be observed around the instrument:
  - 8 cm on each side
  - 15 cm behind the instrument
  - 13 cm above the instrument
- Correct voltage: 100 to 240 VAC (+/- 10%), 50 - 60 Hz (+/- 5%)

After the **cobas b** 123 POC system has been set up at a location that meets the mandatory requirements, carry out the following steps to prepare the instrument for operation:

- First, check the instrument and accessories for completeness and potential damage. Verify that the shipment is complete by comparing components with the shipping order.

Should anything be missing, please notify a Roche representative immediately.

If the shipment has been damaged despite careful packaging, notify the forwarder immediately. Keep the delivered goods and packaging material until your damage claim is resolved.

CAUTION

Caution

Do not under any circumstances insert consumables into the instrument if the packaging of these consumables suffered massive damage.
Using damaged consumables can cause malfunctions of the instrument.

Accessories

The following items are included in the standard delivery of the **cobas b** 123 POC system:

- 1 barcode scanner
- 1 POWER SUPPLY **cobas b** 123 POC system
- 1 USB storage device
- 1 printer paper roll

CAUTION

Caution

Use the original power supply for the **cobas b** 123 POC system only.
The power supply must not be repaired or opened.

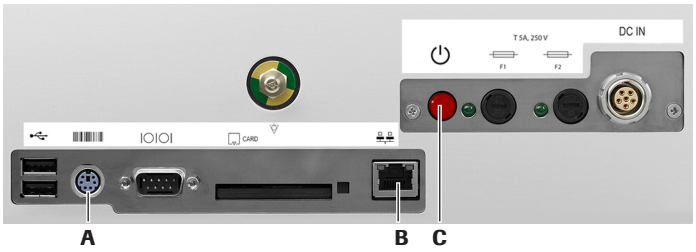
Installation

The following preparations are required to start the automated installation routine:

Preparations

Barcode scanner

Connect the barcode scanner to the corresponding interface on the rear side of the **cobas b** 123 POC system.



A Barcode scanner (PS/2 DIN - 6p Female socket)
B Network connection [10BaseT Ethernet (RJ45)]
C Button (On/Off)

Figure D-1 Rear panel of the instrument with interfaces and button (on/off)

Network connection

Connect the network jack to the corresponding interface on the rear side of the **cobas b** 123 POC system.

See Figure D-1.

*POWER SUPPLY **cobas b** 123 POC system*

First connect the external power supply to the instrument and then to the power supply network.

For more information about the power cable, refer chapter 6 *System components*, section *Power cable* on page C-29.

A Connection socket for external power supply

Figure D-2 POWER SUPPLY **cobas b** 123 POC system

Switching on the instrument

Switch on the instrument and wait until the program has finished loading and started up.

See Figure D-1 on page D-6.

Initiating installation

Note

All installation steps must be completed.

When carrying out installation actions, follow the order in which they are listed here.

If the automatically initialized installation has failed, the installation routine must be called up manually. To do so, press the following buttons: [Utilities] > [Installation].

The installation routine starts automatically.

Note

In the event of a power failure during installation, the installation routine restarts from the beginning after the instrument is restarted. Installation routine actions that have already been completed successfully are skipped automatically.

A list of actions for installation are displayed on the screen.

To execute the installation, follow the instructions on the screen.

► **Processing actions**

In the corresponding line for the installation routine are instructions that must be performed manually.

If an action has been completed successfully, the installation process automatically moves on to the next step.

If consumables are not detected by the instrument or an invalid consumable has been inserted, an error message appears on the screen.

It is possible to end the installation prematurely at any point during the installation routine using the [Cancel] button.
Depending on how far the installation process has advanced, interrupting the installation prematurely can result in a system stop.

1. Checking & modifying configuration

The most important settings that must be checked and modified if necessary are configured in the first step of the installation routine.

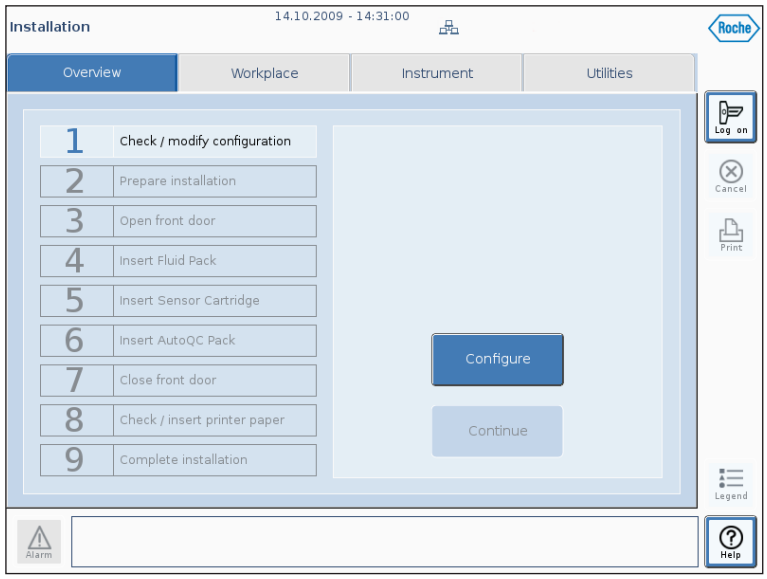


Figure D-3

To change the settings, press the [Configure] button.

An additional window opens:

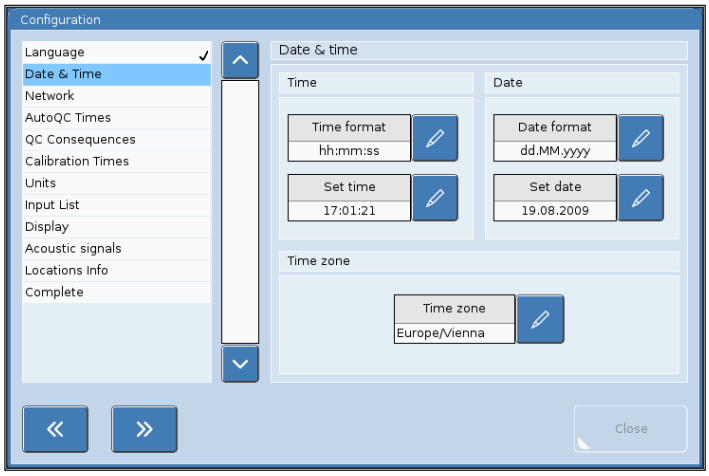


Figure D-4 Configuration wizard

Note

If the current language of the instrument is "German", select [Sprache] > [English].

The following options for handling the configuration wizard are available:

1. Select the line for the desired setting directly from the list.
2. Use the cursor keys (up/down) to move from one setting in the list to another.
3. Use the forward and back keys to move from one setting in the list to another.


Cursor key (up)


Cursor key (down)


Forward key


Back key


Pencil

For data input or to modify existing data, press the [Pencil] button.

For specific details about the individual settings, refer to chapter 12 *Software functions*, section *Configuration* on page D-134.

If a setting has been checked or successfully modified, a check mark is displayed in the list.

By pressing the [Close] button, all changes are saved automatically.

When the [Continue] button is pressed, the user interface automatically moves on to the next step of the installation routine.

2. Preparing installation

The instrument automatically prepares for the procedure of inserting all consumables. All valves and the measuring chamber module are set into the correct position for inserting consumables.

Note

The instrument checks automatically whether the consumables in the instrument are still valid. If the consumables in the instrument are valid, the instrument automatically skips the corresponding step of the installation routine.

After a short preparation time, the front door is unlocked and must be opened within 30 seconds.

3. Opening the front door

Open the front door.

4. Inserting the Fluid Pack

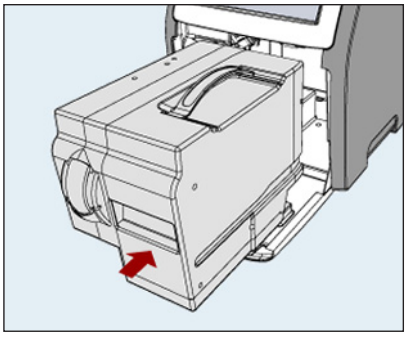


Figure D-5

CAUTION

Caution

Do not touch the cuvette and the sample sensor contacts on the side wall of the Fluid Pack.

1 Insert the Fluid Pack.

2 The data of the consumables are scanned automatically.
After the Fluid Pack chip is detected, the installation routine automatically moves on to the next step.

If an invalid consumable has been inserted, the corresponding error message appears on the screen.

5. Inserting the Sensor Cartridge

CAUTION

Caution

Touch the Sensor Cartridge only at the handle provided for this purpose.

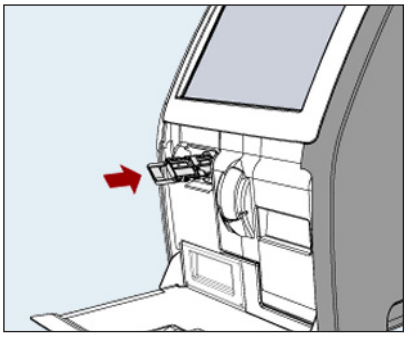


Figure D-6

1 Insert the Sensor Cartridge.

2 The data of the consumables are scanned automatically.
After the Sensor Cartridge chip is detected, the installation routine automatically moves on to the next step.

If an invalid Sensor Cartridge has been inserted, the corresponding error message appears on the screen.

6. Inserting the AutoQC Pack (optional)

For instruments without AutoQC module, the corresponding step on the screen is skipped automatically.

Note

A new AutoQC Pack must be adjusted to room temperature at least 24 hours prior to use.

Caution

Do not turn a partially used AutoQC Pack upside down if the AutoQC Pack is being installed again. Installing an AutoQC Pack that was turned upside down can destroy the AutoQC module.

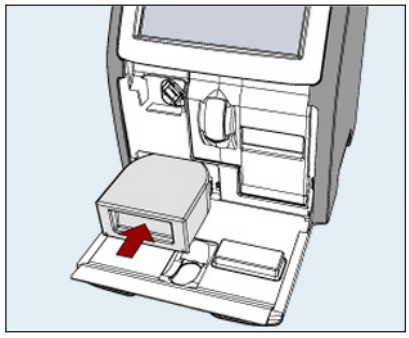


Figure D-7

1. Insert the AutoQC Pack.
2. The data of the consumables are scanned automatically.
   After the AutoQC Pack chip is detected, the installation routine automatically moves on to the next step.

If an invalid AutoQC Pack has been inserted, the corresponding error message appears on the screen.

7. Closing the front door

Close the front door after all consumables are inserted.

8. Checking and inserting printer paper

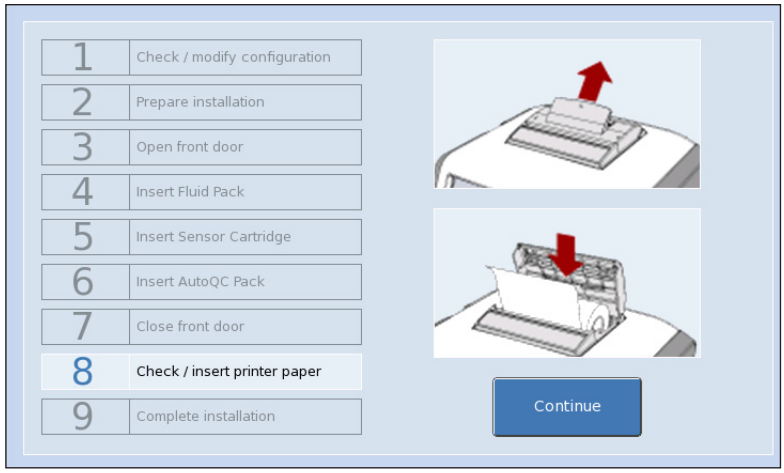


Figure D-8

If a roll of printer paper has already been inserted into the printer. move to the next step of the installation routine by pressing the [Continue] button.

Note

The printer paper is only heat-sensitive on one side. Make sure the paper roll is inserted correctly.

If there is no printer paper in the printer, install the printer paper as follows:

1 Open the printer cover.

Figure D-9

2 Insert a roll of printer paper.

Figure D-10

3 Close the printer cover securely.

4 When the [Continue] button is pressed, the user interface automatically moves on to the next step of the installation routine.

9. Finishing installation

Press the [Complete] button to conclude the installation routine.

Next, the automated follow-up actions (for example, system calibration) are started.

Quality control

Run quality control on all 3 levels (1 = low, 2 = normal, 3 = high).
Make sure that the results match the target values.

For additional information, refer to chapter 9 *Quality control*.

Put out of operation

For less than 24 hours

If the instrument is not needed for less than 24 hours (for example, transport), go to the "Utilities" menu and press the following button:

☞ [Switch off]

The instrument can be shut down using this function.

Note

To disconnect the instrument from the power supply completely. the power supply must be disconnected from the power supply network.

CAUTION

Caution

If the instrument is deactivated for longer than 24 hours. the Fluid Pack and Sensor Cartridge are destroyed in this process.
New consumables must be used.

For additional information, refer to chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.

WARNING

Warning

Each time the instrument is deactivated, the next time it is switched on, you must run a system calibration, then quality control in 3 levels (1 = low, 2 = normal, 3 = high).
If switched off for less than 60 minutes (e.g. power failure), only a 1-point calibration is required after the next time it is switched on.

For more than 24 hours

If the instrument will be put out of operation for longer than 24 hours, the following steps must be carried out.

Safety Instructions

After use, the Fluid Pack and Sensor Cartridge contain biological fluids or fluid residue that pose a risk for infection.

Handle these components with care observing the regulations for handling potentially infectious material. Avoid skin contact.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Roche recommends that all surfaces should be disinfected before the instrument is put out of operation.

For specific details, refer to chapter 13 *Consumable change*, section *Disinfection* on page E-5.

Go to the "Utilities" menu and press the following button:

☞ [Put out of operation]

Note

All consumables must be removed during the put out of operation procedure.

The procedure concludes by switching off the instrument.

Follow the instructions on the screen.

An additional warning is displayed on the screen:

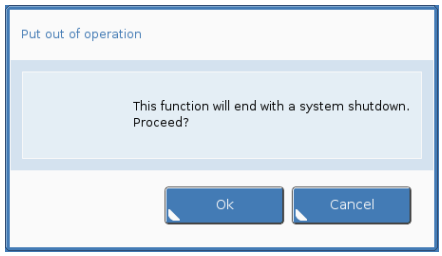


Figure D-11

Press the [OK] button to start the put out of operation routine.

To return to the "Utilities" menu, press the [Cancel] button.

► **Processing actions**

In the corresponding line for the put out of operation routine are instructions that must be performed manually.

If an action has been completed successfully, the put out of operation process automatically moves on to the next step.

It is possible to interrupt the put out of operation at any point during the put out of operation routine using the [Cancel] button.
Depending on how far the put out of operation process has advanced, interrupting the put out of operation prematurely can result in a system stop.

Note

When carrying out put out of operation actions, strictly follow the step-by-step procedures displayed in the instrument screen and described here.

1. Preparing removal of consumables

The instrument automatically prepares for the consumables removal procedure.

2. Opening the front door

Open the front door.

3. Removing the Fluid Pack

CAUTION

Caution

If a previously used Fluid Pack is not inserted into another instrument within **24 hours** after put out of operation, it can no longer be reused and a new Fluid Pack must be inserted.

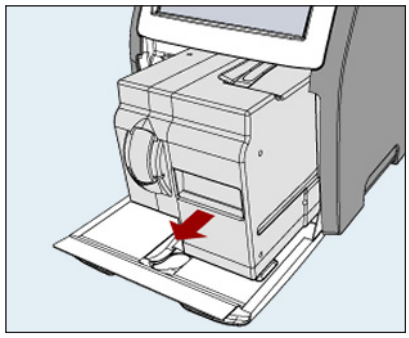


Figure D-12

CAUTION

Caution

Do not touch the cuvette and the sample sensor contacts on the side wall of the Fluid Pack if the Fluid Pack will be inserted again.

1 Remove the Fluid Pack.

2 As soon as the Fluid Pack chip is no longer detected, the put out of operation routine automatically moves on to the next step.

Disinfection of the consumable area (optional)

The consumables area can be disinfected only as part of a consumable change or during the put out of operation routine.

If the area for consumables is visibly dirty, carefully disinfect the affected surfaces using a damp cloth.

Disinfection of the left side wall (partition between the measuring chamber module and oximeter module with cuvette) should be avoided in order to protect the Sensor Cartridge and the hemolyzer.

For disinfection allow an application time of approximately 15 minutes.

Regularly disinfect the consumables area with disinfectants according to general laboratory regulations.

CAUTION

Caution

Only disinfect with a damp cloth (e.g. soaked in disinfectant).
Do not use water or sprays.

Note

During disinfection, be absolutely certain not to displace the valves.
Displaced valves cause problems inserting the Fluid Pack.

4. Removing the Sensor Cartridge

CAUTION

Caution

If a previously used Sensor Cartridge is not inserted into another instrument within **24 hours** after installation, it can no longer be reused and a new Sensor Cartridge must be inserted.

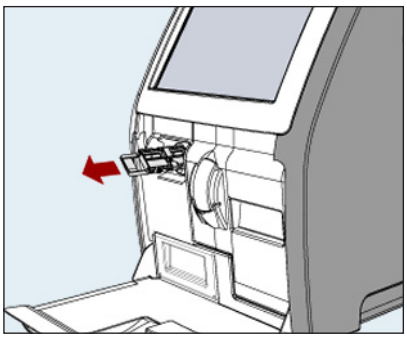


Figure D-13

1 Remove the Sensor Cartridge.

2 As soon as the Sensor Cartridge chip is no longer detected, the put out of operation routine automatically moves on to the next step.

Disinfection of the Sensor Cartridge (optional)

If there is visible dirt on the Sensor Cartridge, only the handle of the Sensor Cartridge may be disinfected, by carefully using a damp cloth.

For disinfection allow an application time of approximately 15 minutes.

CAUTION

The measuring chamber module and the Sensor Cartridge must not be cleaned.

To protect the instrument, do not spray anything on any non-removable or interior parts.

Do not use water or sprays.

5. Removing the AutoQC Pack (optional)

For instruments without AutoQC module, the corresponding step on the screen is skipped automatically.

CAUTION

Caution

If a previously used AutoQC Pack is not inserted into another instrument within **7 days** after put out of operation, it can no longer be reused and a new AutoQC Pack must be inserted.

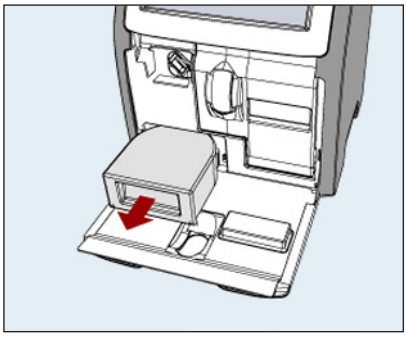


Figure D-14

1 Remove the AutoQC Pack.

2 As soon as the AutoQC Pack chip is no longer detected, the put out of operation routine automatically moves on to the next step.

Disinfection of the consumable area (optional)

The consumables area can be disinfected only as part of a consumable change or during the put out of operation routine.

If the area for consumables is visibly dirty, carefully disinfect the affected surfaces using a damp cloth.

For disinfection allow an application time of approximately 15 minutes.

WARNING

Warning

When disinfecting the AutoQC module, carefully clean the top of the interior. Because of the ampoule opener there is a risk of injury.

CAUTION

Caution

Only disinfect with a damp cloth (e.g. soaked in disinfectant).
Do not use water or sprays.

6. Closing the front door

1 Close the front door after all consumables have been removed.

7. Switching off the instrument

1 Press the [Switch off] button to conclude putting out of operation.

2 To disconnect the instrument from the power supply completely, the power supply must be disconnected from the power supply network.

Transport requirements

If the instrument will be transported, perform the following final tasks:

1 Remove the printer paper from the printer.

2 Remove the USB storage device.

3 Disconnect the barcode scanner and the network connection on the rear panel of the instrument.

4 Disconnect the power supply from the instrument.

For information about Depot-Repair, refer to chapter 14 *Troubleshooting*, section *Depot-Repair* on page F-43.

Measurement

This chapter describes all of the steps necessary to carry out a measurement.

In this chapter *Chapter* 8

Pre-analytics

Sample collection

When drawing blood samples, the generally valid safety precautions must be followed. When handing blood samples, a danger of transmission of HIV, Hepatitis B and C viruses or other blood borne pathogens exists. Suitable blood drawing techniques must be used to minimize risk for operating personnel.

Samples for analysis must be drawn by qualified personnel.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Guidelines and additional information about handling blood samples are provided in CLSI document M29-A3, "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guidelines - 3rd edition 2005" and other documents.

Whole blood

WARNING

Warning

Under no circumstances may pressure be applied to the puncture site. If the blood sample is mixed with tissue fluid, coagulation may begin prematurely despite sufficient heparinization of the sample collection containers. Incorrect sample collection or the use of unsuitable sample collection containers can cause errors and differences in the measured values. The measuring of hemolyzed blood samples may lead to sustained deviations particularly of sodium, potassium and PO_2. After measuring of a hemolyzed blood sample a 2 point calibration is recommended.

For detailed information about drawing blood and storing and handling blood samples, refer to CLSI Document H11-A4, "Procedures for the collection of arterial blood specimens; Approved Standard (Fourth Edition 2004)" and other documents.

Anticoagulants

Heparin salts are the only permitted anticoagulants for analyses in the **cobas b** 123 POC system. Other anticoagulants, such as EDTA, citrate, oxalates, fluorides and ammonia-containing anticoagulants have a significant effect on the blood pH value and other parameters and thus must not be used.

Sample collection, specifically for tHb, SO_2 and Hct measurement (only for cobas b 123<3> system and cobas b 123<4> system)

Whole blood, specifically for the analysis of tHb, SO_2 and Hct, must be mixed thoroughly immediately before the analysis in order to attain even distribution of red blood cells and plasma before sample input.

Carefully turn the sample manually or using a mechanical instrument that rotates the sample on two axes or place a metal disk or ball into the syringe before sample collection. Shortly before using the sample, swivel the syringe so that uniform mixture is ensured by the up and down movement of the disk/ball in the syringe cylinder.

Refer to CLSI document C46-A, "Blood gas and pH analysis related measurements; Approved Guideline 2001".

Sample collection, specifically for glucose/lactate measurement

Glucose

Patient preparation: 12-hour abstinence from food for fasting blood glucose. Optimum postprandial blood draw 1 hour after eating.

The blood samples should be analyzed immediately after they are drawn, as the self-metabolism of the blood samples causes a decrease of the glucose concentration within just a few minutes.

Lactate

Patient preparation: Drawn after physical rest (at least 2 hours). Even small amounts of physical exertion cause the lactate concentration to rise.

The blood samples should be analyzed immediately after they are drawn, as the self-metabolism of the blood samples causes an increase of the lactate concentration within just a few minutes.

Significant arteriovenous differences exist depending on the forearm activity and the oxygenation of the forearm musculature. Immediately after the blood is drawn, the sample must be deproteinized using ice-cold perchloric acid. When using glycolytic inhibitors, it is possible to work with heparin blood without deproteinization. Such a sample is stable up to 2 hours after being drawn.

Sample collection, specially for bilirubin measurement (only for cobas b 123<3> system and cobas b 123<4> system)

Whole blood, especially for the analysis of bilirubin, must be treated as a light sensitive sample:

- Transport of the sample container protected from light
- Avoid direct sunlight

Samples should be analyzed immediately after collection.

Sample collection, specifically for dialysis solution measurement

Samples from the fresh dialysis solution may only be taken with an untreated (free of coagulant inhibitors) syringe.

Sample collection container

Note

We suggest using the sample collection containers offered by Roche.

Syringes

If a third-party product with liquid heparin is used as an anticoagulant. the collection vials should be no larger than necessary for the required blood volume in order to minimize the effects of blood thinning by the anticoagulant. Normally, plastic syringes are used. There are also cases in which the use of plastic syringes is not suitable, such as when the PO_2 values above the normal range are expected. In this case, the sample should be analyzed as soon as possible after collection.

WARNING

Warning

Use heparinized syringes only, as the improper use of syringes with liquid heparin can falsify parameters, particularly ISE parameters.

Capillary tubes

The capillary tubes must have a minimum volume of 115 µL, 140 µL or 200 µL.

Capillary tubes with ceramic caps should not be used, as the fracture point that results when the tubes were opened can damage the fill port of the **cobas b** 123 POC system.

Only glass capillary tubes with heat-polished ends or the plastic capillary tubes offered by Roche may be used in order to prevent damage to the instrument.

When using stirring bars like those offered by some manufacturers, these must be removed before sample input to prevent clogging the sample path of the **cobas b** 123 POC system.

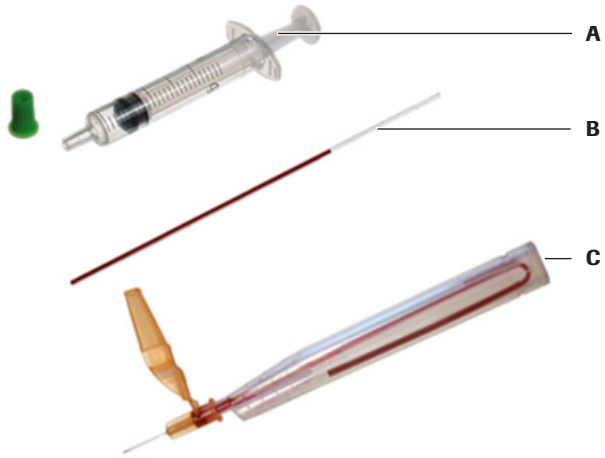
Roche MICROSAMPLER PROTECT[(a)]

To make arterial sample collection technically easier, the Roche MICROSAMPLER PROTECT was developed.

The Roche MICROSAMPLER PROTECT consists of one curved plastic capillary tube (~220 µL) in a plastic container and is ideally suited to atraumatic arterial blood collection.

Each laboratory should determine the permissibility of sample containers that are used. These products vary from manufacturer to manufacturer and sometimes from lot to lot.

(a) is a trademark of Roche



A BS2 Blood Sampler
B Capillary tubes
C Roche MICROSAMPLER PROTECT

WARNING

Warning

The use of sample containers or clot inhibitors other than those manufactured by Roche may lead to adulteration of the samples and errors and differences in the measurement values. Roche developed a specialized sample collection container for this purpose and recommends its use for this reason.

Sample collection container accessories

The use of a clot catcher is recommended to prevent clogging of the sample path during measurement of critical blood, for example, when sampling blood of newborns from earlobes or heels.

Clot Catcher

The Clot Catcher, which is placed on top of the **capillary** or **Roche MICROSAMPLER PROTECT**, prevents blood clots and tissue particles from entering the **cobas b** 123 POC system.

Using the Clot Catcher is suitable for the **capillary mode** of the **cobas b** 123 POC system only.

WARNING

Warning

The Clot Catcher is not suitable for the **cobas b** 123 POC system syringe mode.

Clot Catcher PRO

The Clot Catcher PRO, which is placed on top of a **syringe,** prevents blood clots and tissue particles from entering the **cobas b** 123 POC system.

Using the Clot Catcher PRO is suitable for the **capillary mode** of the **cobas b** 123 POC system only.

WARNING

Warning

The Clot Catcher PRO is not suitable for syringe mode of the **cobas b** 123 POC system.

For additional information, refer to the accompanying package insert:

- Clot Catcher
- Clot Catcher PRO.

Sample handling

Whole blood

Withdraw whole blood samples using heparinized syringes, capillaries, or the Roche MICROSAMPLER PROTECT and analyze them as soon as possible after collection. Remove air bubbles from the sample collection container immediately after the sampling procedure.

Immediately after withdrawing the sample with syringes, thoroughly mix the sample with anticoagulant by rolling the sample between both hands or shaking. Properly label the samples, following the standard documentation procedures.

Glass sample container

- Samples that are measured within 15 minutes may be stored at room temperature.
- If unable to measure samples within 15 minutes, place them temporarily in ice water. Complete the measurement within 30 minutes (but not after more than 60 minutes).
- Samples with a PO_2 level above 200 mmHg (26 kPa) should be collected in a glass container if the measurement cannot be performed within 15 minutes.

Plastic sample container

If unable to measure samples immediately store the sample at room temperature for no longer than 30 minutes.

Warning

When using capillaries analyze samples for tHb, SO_2, Hct, glucose and lactate measurements immediately to ensure correct and accurate measurement results.

Even if samples are removed correctly, errors may still occur in the blood gas analysis due to the following:

- Insufficient mixing of the sample following removal and before the measurement.
- Ambient air contamination caused by air bubbles that are not removed following removal of the sample.
- Changes in metabolism in the sample.

Dialysis solution

Warning

Only take samples from the fresh dialysis solution using an untreated syringe
Samples from the dialysate (the used dialysis solution) must not be used.

Interference

The measuring module and measuring sensors were tested with respect to their interference stability with the given chemical substances and pharmaceuticals.

Interferents can be a significant source of error in clinical analyses. While the precision can be determined by internal QC and the correctness can be determined by verifying reference samples, possible sources of interference cannot be identified during ongoing operation. For this reason, the effect of potentially interfering substances was determined.

For additional information, refer to Interference Testing in Clinical Chemistry; Approved Guideline EP-7 Vol, 25; No. 27 of the Clinical and Laboratory Standard Institutes (CLSI).

The results of the interference measurements have been divided into 3 categories:

1. Substances that do not impair precision and thus show no effect of interference (refer to Table D-1 and Table D-2).
2. Substances that impair precision, but for which the deviation is within the limits of correctness (see Table D-3 and Table D-4) and
3. Substances that violate the specified limits of correctness and cause a significant deviation of the measured value. The deviations as a function of the concentrations are specified in Table D-3 and Table D-4.

Substances without effect

The following substances were tested, but show no effect on the measurement parameters and thus do not violate the specifications.

BG, pH, ISE, Glu, Lac, Hct

Substance	Concentration	Tested analyte
3-beta-Hydroxybutyric acid	20.0 mmol/L	pH. ISE. Glu. Lac
Acetoacetic acid[(a)]	2.0 mmol/L	pH. ISE. Glu. Lac
Acetone[(a)]	12.0 mmol/L	BG. pH. ISE. Glu. Lac
Acetylcysteine	10.2 mmol/L	Na. K. Cl. Hct
Albumin	> 9%	BG. Na. K. Cl. Glu. Lac. Hct
Ammonium chloride[(a)]	0.107 mmol/L	BG. pH. ISE. Glu. Lac
Ampicillin[(a)]	0.15 mmol/L	BG. pH. ISE. Glu. Lac
Ascorbic acid[(a)]	0.34 mmol/L	ISE. Glu. Lac
Aspirin (Acetylsalicylic acid)[(a)]	3.62 mmol/L	Na. K. Cl. Glu. Lac
Benzalkonium chloride	0.028 mmol/L	pH. K. Ca. Cl. Glu. Lac
Bilirubin[(a)]	0.342 mmol/L	BG. pH. ISE. Glu. Lac
Calcium chloride[(a)]	5.0 mmol/L	ISE. Glu. Lac
Cefoxitin[(a)]	1.546 mmol/L	ISE. Glu. Lac
Chlorpromazine[(a)]	0.0063 mmol/L	BG. pH. ISE. Glu. Lac
Cyclosporine	0.0043 mmol/L	BG. pH. ISE. Glu. Lac
Creatinine[(a)]	0.442 mmol/L	BG. pH. ISE. Glu. Lac
Cyanide	0.1 mmol/L	BG. pH. ISE. Glu. Lac

Table D-1 Substances without effect on BG, pH, ISE, Glu, Lac, Hct

Substance	Concentration	Tested analyte
Dobesilate	0.88 mmol/L	BG. ISE. Glu. Lac
Dopamine[(a)]	0.00587 mmol/L	BG. pH. ISE. Glu. Lac
Dobutamine	0.66 mmol/L	pH. K. Ca. Cl. Glu. Lac
Doxycycline[(a)]	0.068 mmol/L	BG. pH. ISE. Glu. Lac
EDTA[(a)]	0.003 mmol/L	ISE. Glu. Lac
Ethanol[(a)]	86.8 mmol/L	BG. pH
Ethylen Glycol[(a)]	4.83 mmol/L	BG. pH. ISE. Glu. Lac
Gallamine Triethiodide	0.056 mmol/L	pH. ISE. Glu. Lac
Gentamicin[(a)]	0.021 mmol/L	BG. ISE. Glu. Lac
Gentisic acid[(a)]	0.117 mmol/L	BG. pH. ISE. Glu. Lac
Glutathione. reduced[(a)]	3.0 mmol/L	ISE. Glu. Lac
Glycolic acid	13.05 mmol/L	PO_2. Na. K. Cl. Glu
Guaiacol	0.4 mmol/L	BG. pH. ISE. Glu. Lac
HAES (Hydroxyethylstarch)	50.0%	BG. ISE. Glu. Lac. Hct
Halothane[(a)]	0.759 mmol/L	PO_2
Hemoglobin[(a)]	2.0 g/L	BG. pH. ISE. Glu. Lac
Hydroxycarbamide (Hydroxyurea)	2.50 mmol/L	BG. pH. ISE
Ibuprofen[(a)]	2.425 mmol/L	ISE. Glu. Lac
Isoflurane	3.0%	BG. pH. ISE. Glu. Lac
Isoniazid[(a)]	0.292 mmol/L	BG. pH. ISE. Glu. Lac
Potassium chloride[(a)]	7.0 mmol/L	BG. pH. ISE. Glu. Lac
Potassium oxalate[(a)]	0.081 mmol/L	ISE. Glu. Lac
Lactate[(a)]	6.6 mmol/L	ISE. Glu
L-DOPA. Levodopa	0.12 mmol/L	BG. pH. ISE. Glu. Lac
Lithium acetate[(a)]	3.20 mmol/L	BG. pH. ISE. Glu. Lac
Magnesium acetate	15.0 mmol/L	pH. ISE. Lac
Maltose	14.62 mmol/L	BG. pH. ISE. Glu. Lac
Methyldopa[(a)]	0.071 mmol/L	BG. pH. ISE. Glu. Lac
Metronidazole[(a)]	0.701 mmol/L	pH. ISE. Glu. Lac
Nitrous oxide	85%	PO_2
Norepinephrine	0.12 mmol/L	BG. pH. ISE. Lac
Sodium chloride[(a)]	45 mmol/L	BG. pH. ISE. Glu. Lac
Monosodium phosphate[(a)]	9.0 mmol/L	ISE. Glu. Lac
Sodium fluoride[(a)]	0.105 mmol/L	BG. pH. ISE. Glu. Lac
Sodium glutamate	0.86 mmol/L	ISE. Glu. Lac
Sodium heparin[(a)]	3000 IU/L	BG. ISE. Glu. Lac
Sodium Hydrogen Carbonate (Sodium Bicarbonate)[(a)]	35 mmol/L	ISE. Glu. Lac
Sodium Pyruvate[(a)]	0.309 mmol/L	BG. pH. ISE. Glu. Lac
PCO_2	85.0 mmHg	ISE. Glu. Lac
PCO_2	0.0 mmHg	PO_2. ISE. Glu. Lac

Table D-1 Substances without effect on BG, pH, ISE, Glu, Lac, Hct

Substance	Concentration	Tested analyte
PO_2	600.0 mmHg	BG. pH. ISE. Glu. Lac
PO_2	< 25 mmHg	BG. pH. ISE. Glu. Lac
Paracetamol[(a)]	1.32 mmol/L	BG. pH. ISE. Glu. Lac
Perphenazine[(a)]	0.223 µmol/L	BG. pH. ISE. Glu. Lac
Phenobarbital[(a)]	0.431 mmol/L	BG. pH. ISE. Glu. Lac
Phenylbutazone	1.3 mmol/L	ISE. Glu. Lac
Phenytoin[(a)]	0.198 mmol/L	BG. pH. ISE. Glu. Lac
Potassium thiocyanate	6.88 mol/L	BG. pH. Na. Ca. Lac
Propofol	1.0%	BG
Rifampicin[(a)]	0.078 mmol/L	BG. pH. ISE. Glu. Lac
Salicylic acid	4.34 mmol/L	K. Ca. Glu. Lac
Sodium bromide	37.5 mmol/L	pH. K. Ca. Lac
Sodium iodide	2.99 mmol/L	BG. pH. K. Ca. Glu. Lac
Sodium Nitroprusside	4.00 mmol/L	pH. K. Ca. Glu. Lac
Sodium perchlorate	1.50 mmol/L	K. Glu. Lac
Theophylline[(a)]	0.222 mmol/L	ISE. Glu. Lac
Thiopental (Trapanal)[(a)]	0.248 mmol/L	pH. ISE. Glu. Lac
Triglyceride	37.0 mmol/L	BG. pH. K. Ca. Glu. Lac
Urea[(a)]	49.2 mmol/L	BG. pH. ISE. Glu. Lac
Uric acid	1.40 mmol/L	ISE. Glu. Lac
Vancomycin[(a)]	0.069 mmol/L	BG. pH. ISE. Glu. Lac
Xylose	4.0 mmol/L	BG. pH. ISE. Glu. Lac

Table D-1 Substances without effect on BG, pH, ISE, Glu, Lac, Hct

(a) The substance and concentration are listed in the recommendation for Interference Testing in Clinical Chemistry; Approved Guideline EP-7 Vol. 25; No. 27 of the Clinical and Laboratory Standard Institute.

tHb, SO_2, Bilirubin, Hb derivatives

Substance	Concentration	Tested analyte
Beta-Carotin[(a)]	2.0 mg/L	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Evans blue	5 mg/L	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Gelofusine	Dilution 1:1	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
HAES-sterile 10%	Dilution 1:1	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Hydroxocobalamin	0.25 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Indocyanine green	5 mg/L	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Intralipid 20%	10 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Methylene blue	2.5 mg/L	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Lipofundin 20% with MCT[(a)]	10 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Lipidem	10 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Omegaven[(a)]	5 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Patent blue	2.5 mg/L	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Propofol 2%	0.11 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
SMOF Lipid 20%[(a)]	10 mg/mL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Voluven 6%[(a)]	Dilution 1:1	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
Total protein (Albumin)[(a)]	12 g/dL	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
pH low	7.1	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili
pH high	7.9	tHb. HHb. O_2Hb. COHb. MetHb. SO_2. Bili

Table D-2 Substances without effect on tHb, SO_2, Bilirubin, Hb derivatives

(a) The substance and concentration are listed in the recommendation for Interference Testing in Clinical Chemistry; Approved Guideline EP-7 Vol. 25; No. 27 of the Clinical and Laboratory Standard Institute.

Substances with effect

Effect of the substances on BG, pH, ISE, Glu, Lac, Hct

Substance	Concentration of the substance	Parameter	Parameter concentration (MV) [mmol/L]	Effect of the substance [mmol/L]	± Trueness [mmol/L]
Acetylcysteine	10.2 mmol/L[(a)]	Glu	4.1	-1.4 ± 0.5	0.5
		Lac	5.5	-1.4 ± 0.3	0.7
	2.55 mmol/L	Lac[(b)]	5.2	-0.6 ± 0.1	0.7
	1.75 mmol/L	Glu[(b)]	4.0	-0.1 ± 0.1	0.5
Benzalkonium chloride	0.0285 mmol/L	Na^+	132.2	5.3 ± 0.9	2.9
	0.0280 mmol/L	Na^+	116.47	2.81 ± 0.42	2.940
		Na^+	152.20	4.07 ± 0.83	3.630
	0.0143 mmol/L	$Na^{+(b)}$	138.4	2.1 ± 0.3	3.1
Dobutamine	0.066 mmol/L	Na^+	137.4	21.2 ± 2.3	3.1
	0.05 mmol/L	$Na^{+(b)}$	138.0	1.6 ± 0.2	3.1
Glycolic acid (Hydroxyacetic acid)	13.05 mmol/L	Lac	5.2	0.7 ± 0.5	0.7
	2.5 mmol/L	Lac[(b)]	5.4	0.4 ± 0.2	0.7
Uric acid	1.4 mmol/L[(a)]	Lac	6.0	-0.9 ± 0.1	0.7
	0.35 mmol/L	Lac[(b)]	5.4	-0.3 ± 0.1	0.7
Hydroxycarbamide (Hydroxyurea)	2.5 mmol/L	Glu	4.0	1.2 ± 0.7	0.5
		Lac	4.8	-1.2 ± 0.6	0.7
	0.63 mmol/L	Glu[(b)]	3.8	0.1 ± 0.2	0.5
		Lac[(b)]	4.5	-0.4 ± 0.2	0.7
Potassium thiocyanate	6.88 mmol/L[(a)]	Cl^-	107.7	176.5 ± 56.5	4.4
		Cl^-	79.42	130.39 ± 43.09	4.0
		Cl^-	119.93	356.92 ± 120.59	4.8
		Glu	4.0	1.2 ± 0.4	0.5
	3.44 mmol/L	Glu[(b)]	3.9	0.4 ± 0.2	0.5
	0.5 mmol/L	$Cl^{-(b)}$	104.8	3.5 ± 0.9	4.3
Sodium chloride	45 mmol/L[(a)]	Hct [(c)]	43.3%	-9.4± 0.2%	3%
	20 mmol/L	Hct [(c)]	45.6%	-3.8 ± 0.3%	3%
	10 mmol/L	Hct[(b)(c)]	45.6%	-0.9 ± 0.2%	3%
Sodium bromide	37.5 mmol/L[(a)]	Cl^-	80.09	147.99 ± 24.5	4.0
		Cl^-	103.7	111.1 ± 12.0	4.2
		Cl^-	119.01	147.04 ± 17.87	4.77
		Glu	4.0	0.5 ± 0.3	0.5
	18.75 mmol/L	Glu[(b)]	4.0	0.2 ± 0.1	0.5
	1.0 mmol/L[(a)]	$Cl^{-(b)}$	105.5	4.0 ± 0.4	4.3
Sodium iodide	2.99 mmol/L[(a)]	Cl^-	80.63	26.74 ± 7.25	4.0
		Cl^-	102.3	35.8 ± 13.8	4.2
		Cl^-	122.55	55.71 ± 19.11	4.9
	0.45 mmol/L	$Cl^{-(b)}$	105.3	1.3 ± 0.7	4.3

Table D-3 Effect of the substances on BG, pH, ISE, Glu, Lac, Hct

Substance	Concentration of the substance	Parameter	Parameter concentration (MV) [mmol/L]	Effect of the substance [mmol/L]	± Trueness [mmol/L]
Sodium nitroprusside	4 mmol/L	Cl^-	102.5	10.4 ± 6.7	4.2
	1 mmol/L	$Cl^{-(b)}$	104.4	3.3 ± 1.6	4.3
Sodium perchlorate	1.5 mmol/L	Cl^-	104.9	11.4 ± 3.8	4.3
	0.375 mmol/L	$Cl^{-(b)}$	103.5	2.3 ± 0.8	4.3
Norepinephrine	0.118 mol/L	Glu	4.1	-0.5 ± 0.2	0.5
	0.06 mmol/L	Glu(b)	4.5	-0.3 ± 0.1	0.5
Salicylic acid	4.34 mmol/L(a)	Cl^-	79.02	15.55 ± 2.84	4.0
		Cl^-	117.3	20.48 ± 4.77	4.71
		Lac	104.0	20.3 ± 6.0	4.3
	1.09 mmol/L	$Cl^{-(b)}$	103.6	1.8 ± 0.5	4.3

Table D-3 Effect of the substances on BG, pH, ISE, Glu, Lac, Hct

(a) The substance and concentration are listed in the recommendation for Interference Testing in Clinical Chemistry; Approved Guideline EP-7 Vol. 25; No. 27 of the Clinical and Laboratory Standard Institute.

(b) within the trueness specifications

(c) In the case of determining interference for hematocrit. the modification of the sample matrix (morphology of the erythrocytes. hemolysis. and osmosis effect) must be considered when adding substances. For that reason. the sample modification was determined by an absolute reference measurement using centrifugation (Hemofuge) and the values determined with the **cobas b** 123 POC system were corrected.

Effect of the substances on tHb, SO_2, Bilirubin, Hb derivatives

Substance	Concentration of the substance	Parameter	Parameter concentration (MV)	Effect of the substance	± Trueness
Methylen blue	40.00 mg/L	tHb	13.7 g/dL	-1.1 g/dL	0.5 g/dL
		O_2Hb	97%	-3.3%	3%
		MetHb	0.5%	4.50%	1%
		Bili	4.1 mg/dL	-2,94 mg/dL	1.2 mg/dL
			13.4 mg/dL	-3,80 mg/dL	1.2 mg/dL
	20.00 mg/L	tHb (a)	13.7 g/dL	-0.5 g/dL	0.5 g/dL
		O_2Hb(a)	97%	-3%	3%
		MetHb	0.5%	3.6%	1%
		Bili	4.1 mg/dL	-1.10 (a) mg/dL	1.2 mg/dL
			13.4 mg/dL	-1.43 mg/dL	1.2 mg/dL
	10.00 mg/L	MetHb	0.5%	2.3%	1%
		Bili(a)	0 mg/dL	-0.8 mg/dL	1.2 mg/dL
	5 mg/L	MetHb	0.5%	1.5%	1%
	2.5 mg/L	MetHb(a)	0.5	1.0%	1%
Evans blue	10 mg/L	MetHb	0.5%	1.3%	1%
	5 mg/L	MetHb(a)	0.5%	0.6%	1%
Patent blue	10 mg/L	MetHb	0.5%	3.2%	1%
		Bili	4.9 mg/dL	5.1 mg/dL	1.2 mg/dL
			13.7 mg/dL	5.6 mg/dL	1.2 mg/dL

Table D-4 Effect of the substances on tHb, SO_2, bilirubin, Hb derivates

Interference

Substance	Concentration of the substance	Parameter	Parameter concentration (MV)	Effect of the substance	± Trueness
	5 mg/L	MetHb	0.5%	1.6%	1%
		Bili	4.9 mg/dL	2.52 mg/dL	1.2 mg/dL
			13.7 mg/dL	2.94 mg/dL	1.2 mg/dL
	2.5 mg/L	MetHb[(a)]	0.5%	0.8%	1%
		Bili[(a)]	4.9 mg/dL	1.25 mg/dL	1.2 mg/dL
			13.7 mg/dL	1.40 mg/dL	1.2 mg/dL
Hydroxocobalamin	0.9 mg/mL	tHb	13.6 g/dL	0.6 g/dL	0.5 g/dL
		HHb	0.5%	4.2%	1.5%
		O_2Hb	97.7%	-4.1%	3.0%
		SO_2	99.5%	-4.3%	2%
		Bili	4.8 mg/dL	-1.65 mg/dL	1.2 mg/dL
			14.2 mg/dL	-1.39 mg/dL	1.2 mg/dL
	0.5 mg/mL	tHb[(a)]	13.6 g/dL	0.4 g/dL	0.5 g/dL
		HHb	0.5%	2.5%	1.5%
		O_2Hb[(a)]	97.7%	-2.4%	3.0%
		SO_2	99.5%	-2.5%	2%
	0.25 mg/mL	HHb[(a)]	0.5%	1.3%	1.5%
		SO_2[(a)]	99.5%	-4.3%	2.0%
Cyanomethemoglobin	10%	HHb	2.1%	3.8%	1.5%
		O_2Hb	95.8%	-3.4%	3.0%
		SO_2	97.9%	-3.8%	2%
Sulfhemoglobin	10%	tHb[(b)]	---[(b)]	---	---
		COHb[(b)]	---[(b)]	---	---
		HHb[(b)]	---[(b)]	---	---
		MetHb[(b)]	---[(b)]	---	---
		O_2Hb[(b)]	---[(b)]	---	---
		SO_2[(b)]	---[(b)]	---	---
		Bili[(b)]	---[(b)]	---	---
Fluorescein	0.4 mg/mL	tHb[(b)]	---[(b)]	---	---
		COHb[(b)]	---[(b)]	---	---
		HHb[(b)]	---[(b)]	---	---
		MetHb[(b)]	---[(b)]	---	---
		O_2Hb[(b)]	---[(b)]	---	---
		SO_2[(b)]	---[(b)]	---	---
		Bili[(b)]	---[(b)]	---	---
	0.25 mg/mL	tHb[(b)]	---[(b)]	---	---
		COHb[(b)]	---[(b)]	---	---
		HHb[(b)]	---[(b)]	---	---
		MetHb[(b)]	---[(b)]	---	---
		O_2Hb[(b)]	---[(b)]	---	---
		SO_2[(b)]	---[(b)]	---	---
		Bili[(b)]	---[(b)]	---	---

Table D-4 Effect of the substances on tHb, SO_2, bilirubin, Hb derivates

(a) within the trueness specifications.
(b) no results - error message "Spectral interference detected" will be displayed.

Limitations of clinical analysis

The performance data measured can be influenced by known and unknown factors, which are described below.

See section *Interference* on page D-28 for more details.

General

The relevant literature lists various substances that can impair the measurement results of blood sample material. For a detailed discussion of this phenomenon, refer to the various locations in the scientific literature. For the **cobas b** 123 POC system, an attempt has been made to detect and evaluate these possible influences. However, as it is not possible to review all medications or substances, the user—as with any clinical analysis—must be alarmed immediately in case of abnormal deviations of the measurement results and evaluate the patient's overall status and/or carry out expanded measurements in his or her own laboratory area.

Electrolyte

The patient's potassium value can vary by up to 20% from the normal status due solely to the presence of a compression bandage. Therefore, drawing blood when a compression bandage is present should be avoided. Generally, local hemolysis caused by pressure must be avoided before drawing blood.

Blood gases

A whole blood sample is optimum for carrying out these measurements. Contamination of the blood sample with air falsifies the measured values significantly. Always observe the instructions and limitations in the *Pre-analytics* section[(a)].

See the section on *Pre-analytics* on page D-23.

(a) Mahoney JJ, Wong RJ, Van Kessel AL: Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality-Control Material, Clin.Chem.39/5, 874-879 (1993).

Metabolites

The most important influencing factor for glucose/lactate measurement is the effect of sample handling before measurement due to the glycolysis in the erythrocytes of the blood sample.

For detailed instructions for correct sample handling, refer to the section *Pre-analytics* on page D-23.

The following principle applies: Metabolite measurements should be carried out from heparinized whole blood as quickly as possible.

The **cobas b** 123 POC system metabolite measurement is carried out with active interference correction. Thus an additional integrated sensor exists for glucose or lactate measurement that largely eliminates any interference from endogenous (e.g. uric acid) or exogenous (e.g. acetylsalicylic acid) reactions.
To attain the highest possible degree of perfection of the interference compensation, the compensation sensor is calibrated to the actual biosensors as part of daily system calibration. The effect of the most important known interferents was determined during development.

These are summarized in the section *Effect of the substances on BG, pH, ISE, Glu, Lac, Hct* on page D-32.

Despite this interference compensation sensor, for electrochemical reasons, metabolite measurement in samples is possible only in samples with an approximately physiological ion background and pH value as well as an average physiological buffer capacity of the sample.

Hemoglobin derivatives and bilirubin

In addition to the limitations that apply to the measurement of blood gases, the measurement of Hb derivatives and bilirubin can be impaired by light-absorbing substances in the blood sample (e.g. contrast agents). The effect of the most important known interferents was determined during development.

These are summarized in the section *Effect of the substances on tHb, SO2, Bilirubin, Hb derivatives* on page D-33.

Measurement procedure

Safety Instructions

When drawing blood samples, the generally valid safety precautions must be followed. When handing blood samples, a danger of transmission of HIV, Hepatitis B and C viruses or other blood borne pathogens exists. Suitable blood drawing techniques must be used to minimize risk for operating personnel.

Suitable safety equipment such as laboratory clothing, protective gloves, safety glasses and, if necessary, masks must be worn in order to prevent direct contact with biological substances. If there is a danger of splashes, a safety visor is also required. Suitable disinfection and sterilization procedures must be used.

CAUTION

Caution

Omitting QC measurements or ignoring QC measurement results may lead to incorrect patient measurements, which may result in incorrect clinical decisions.
Danger of injury.

It is possible to measure samples from syringes, without a needle or cannulae, capillaries and the Roche MICROSAMPLER PROTECT.

CAUTION

Caution

Never inject a sample via the fill port.

WARNING

Warning

Proficiency test materials, also known as External Quality Assurance (EQA) materials, must be measured only within the "Proficiency test" menu.

For detailed information refer to Quality Control, Chapter 9 *Proficiency test* on page D-82

A measurement can be started from the "Overview" menu only.

Figure D-15 Overview screen

Syringe measurement

Warning

Improper heparinization of syringes with liquid heparin can falsify parameters, particularly ISE parameters.

Caution

Using syringes with insufficient heparinization can cause clogs in the instrument.

Press the following button to start a syringe measurement:

☞ [Start syringe measurement]

The sample input module is prepared accordingly.

Note

If an incorrect sample container is selected, you can return to the "Overview" menu using the [Cancel] button.

Because, in this case, the sample input module is returned to the starting position, there are delays until new selection of the desired sample container is possible.

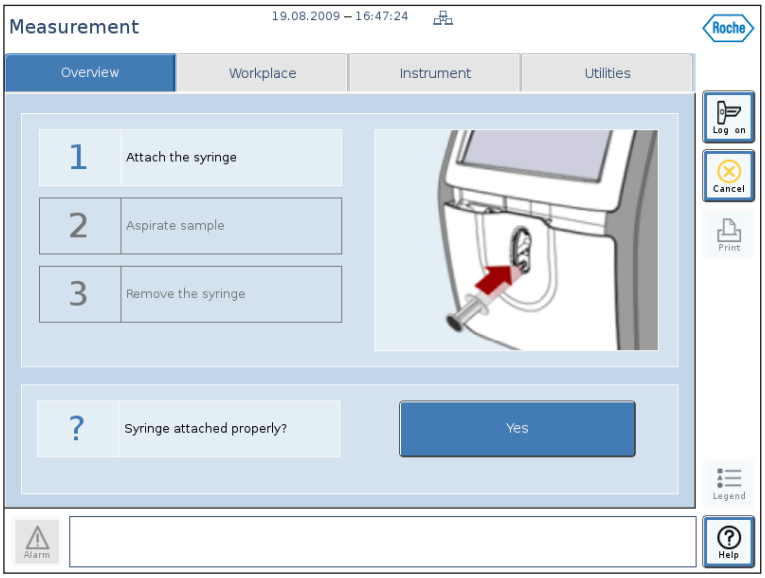


Figure D-16

1 Securely attach the syringe at the fill port and press [Yes].

Caution

Do not attach a syringe with needle at the fill port.

Figure D-17 The syringe is plugged in at the fill port.

CAUTION

Caution

Do not inject sample.
Do not hold on to the syringe during the measurement.

2 The sample is aspirated.

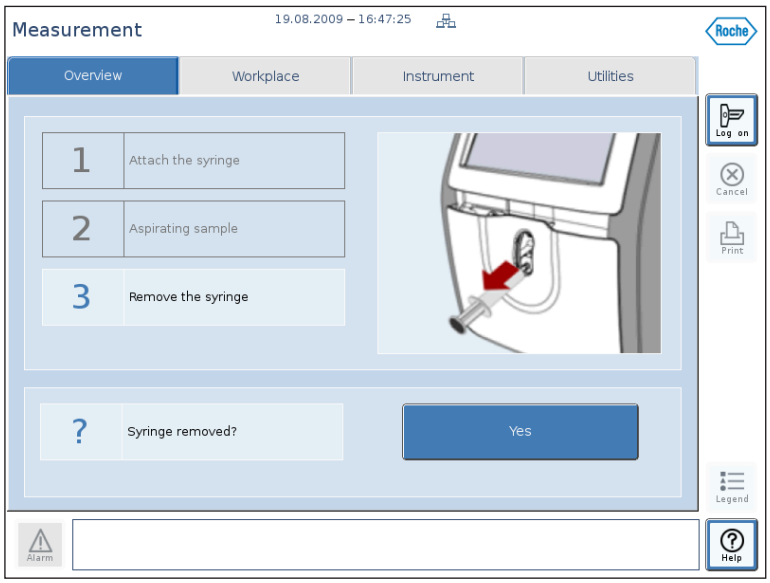


Figure D-18

3 After the prompt "Remove the syringe", pull out the syringe and press [Yes].

Note

The sample container must be removed at this time.

4 The measurement is started.

Capillary measurement

CAUTION

Caution

Only glass capillary tubes with heat-polished ends or the plastic capillary tubes offered by Roche may be used in order to prevent damage to the instrument.

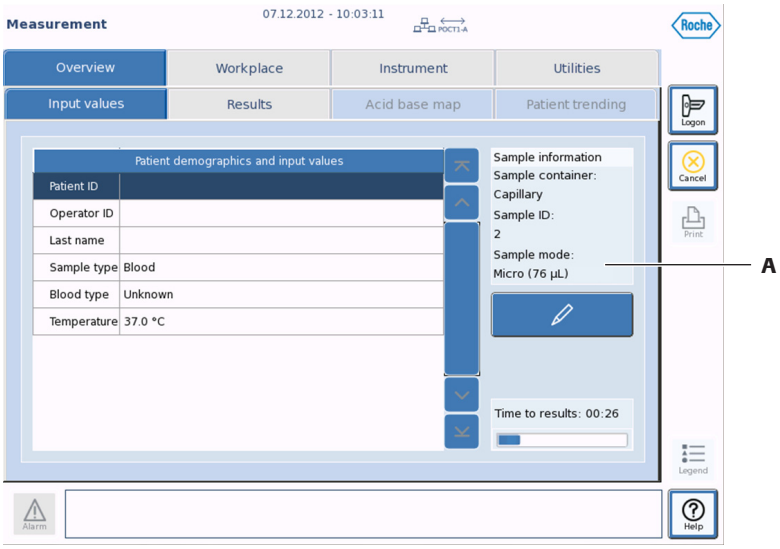
See *Capillary tubes* on page D-25 in section *Sample collection container*.

Micro sample

The micro sample is detected automatically when aspirating blood samples (< 123 µL) from the capillary.

The input value screen shows a message indicating the sample mode in which the sample was measured.

see Figure D-19.



A Sample mode: Normal/Micro

Figure D-19 Input value screen

Depending on the activated parameters and the sample volume present, measured values can be determined for the following panels:

Sample volume	BG	ISE	Glu/Lac	COOX
≥ 37 µL	☑	Insufficient volume(a)	Insufficient volume(a)	Insufficient volume(a)
≥ 55 µL	☑	Insufficient volume(a)	Insufficient volume(a)	☑

(a) Note on the result screen and on the printout.

To start a capillary measurement or a measurement with the Roche MICROSAMPLER PROTECT, press the following button:

☞ [Start capillary measurement]

The sample input module is prepared accordingly.

Note

If an incorrect sample container is selected, you can return to the "Overview" menu using the [Cancel] button.

Because, in this case, the sample input module is returned to the starting position, there are delays until new selection of the desired sample container is possible.

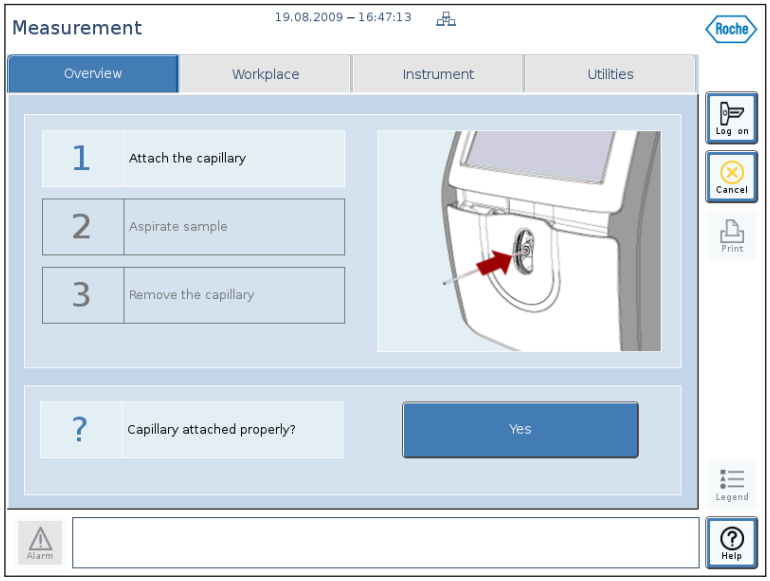


Figure D-20

1 Securely attach the capillary or Roche MICROSAMPLER PROTECT to the fill port and press [Yes].

Caution

Do not hold on to the capillary during the measurement.

Figure D-21 The Roche MICROSAMPLER PROTECT and capillaries are plugged in at the fill port.

2 The sample is aspirated.

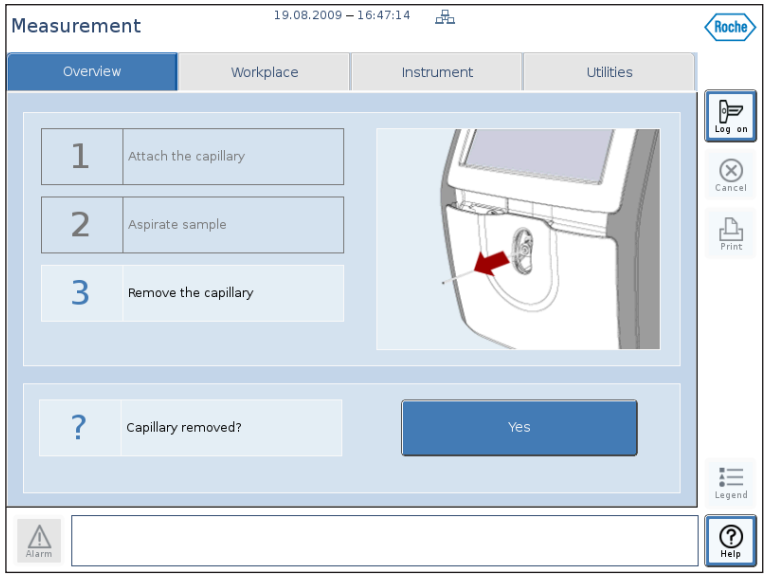


Figure D-22

3 After the prompt "Remove the capillary", pull out the capillary or Roche MICROSAMPLER PROTECT and press [Yes].
During this workflow the sample input module (SIM) will be closed immediately after confirming the removal of the capillary.

Note

During the micro sample measurement workflow the sample input module (SIM) will be closed app. 30 seconds after confirming the removal of the capillary.

Note

The sample container must be removed at this time.

If the sample container is not removed properly within the specified time and this is not confirmed with the [Yes] button, the sample cannot be used for measurement.

Then, the sample is washed out after the [Yes] button is pressed.

4 The measurement is started.

COOX measurement

Permanent disabling

To measure oximeter parameters (tHb, SO_2, Hb derivatives and bilirubin) exclusively, the sensor parameters can be disabled permanently in the settings.

Sensor parameters (BG - ISE - Glu - Lac)

The sensor parameters include the following parameters:

- pH
- PCO_2
- PO_2
- Hct
- Na^+
- K^+
- Ca^{2+}
- Cl^-
- Glu
- Lac

Oximeter parameters (tHb - COOX)

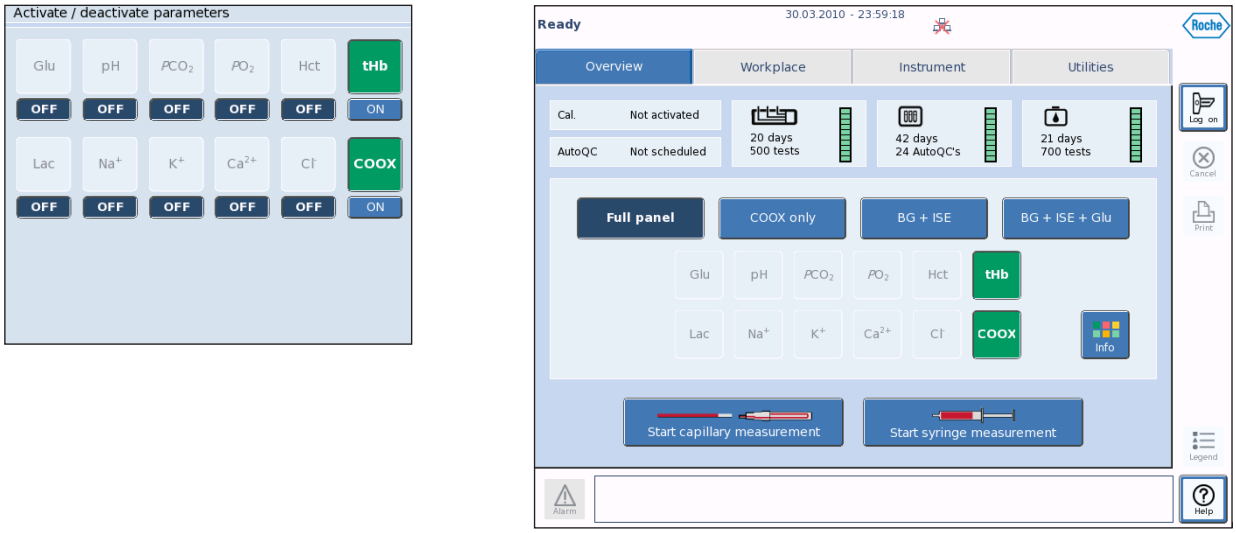
The oximeter parameters include the following parameters:

- tHb
- COOX (including COHb, MetHb, O_2Hb, HHb, SO_2 and bilirubin)

To disable the individual sensor parameters, press the following buttons:

☞ [Utilities] > [Configuration] > [Measurement] > [Parameter] > [Activ./Deactiv.] > [ON]

👁 For additional information about enabling/disabling parameters, refer to the section on *Activating/deactivating parameters* on page D-57.



A Enabling/disabling parameters in the settings

B Overview screen with disabled sensor parameters

Figure D-23

To start the measurement, return to the overview screen and select the corresponding sample container.

👁 For additional information about the measurement procedure, refer to the section on *Syringe measurement* on page D-40 or *Capillary measurement* on page D-42.

Temporary disabling

To temporarily disable the corresponding sensor parameters on the overview screen, disable them by pressing the button. The respective parameters are displayed in light green.

The parameter is disabled for the next measurement (but ready for measurement).

After the measurement, the **cobas b** 123 POC system re-enables the individual parameters and returns automatically to the overview screen.

Creating a COOX parameter group

Using the "Edit panels" function, you can create your own COOX parameter group. This parameter group can be selected before each measurement on the overview screen.

To create the COOX parameter group, press the following buttons:

☞ [Utilities] > [Configuration] > [Measurement] > [Parameter] > [Edit]

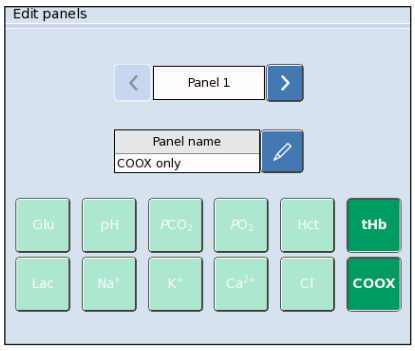
1 Disable the corresponding sensor parameters on the overview screen.

Pencil

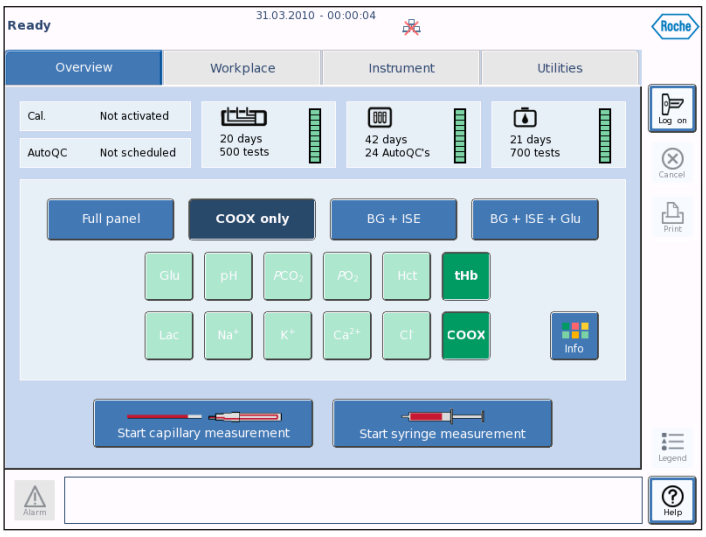
2 Enter a name for the parameter group using the [Pencil] key.

3 Select any desired parameter group using the two arrow keys.
Numbers 1 to 4 specify the position of the parameter group on the overview screen.

👁 For additional information, refer to section *Edit panels* on page D-53.



A Editing parameters in the settings



B Overview screen with COOX parameter group

Figure D-24

To start the measurement, return to the overview screen, select the "COOX only" parameter group and select the corresponding sample container.

👁 For additional information about the measurement procedure, refer to the section on *Syringe measurement* on page D-40 or *Capillary measurement* on page D-42.

Data input

After the sample container is removed, the screen switches to the input values. During the measurement, various patient, user and sample-specific data can be entered.

For setting the desired input values, refer to *Input values* on page D-58.

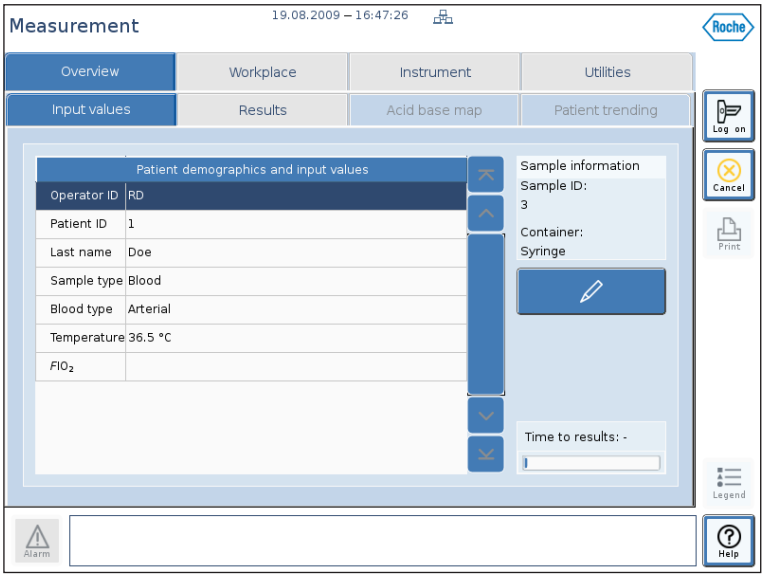


Figure D-25 Input value screen

Note

If the patient is already in the **cobas b** 123 POC system, the patient-specific data are entered automatically into the lines provided for this purpose.

If an external query to the LIS is activated, the relevant patient data are transmitted from the LIS to the **cobas b** 123 POC system. In case of an interrupted network connection, already known data from the database are used for a measurement.

Patient and user data can be scanned in using a barcode scanner.

For setting the LIS query, refer to chapter 12 *Software functions*, section *Queries* on page D-141.

Manual data input

1 Select the desired input value from the list.

Pencil

2 For data input or to modify existing data, press the [Pencil] button.
A keyboard appears on the screen.

- To enter patient data using the keyboard, press the corresponding letters or numbers on the keyboard and confirm with the [OK] button.
- Selection options are provided for some input values (e.g. blood type, sample container, puncture site and sample type).
  Selecting one of the default selection options directly applies this change in the input value list automatically.

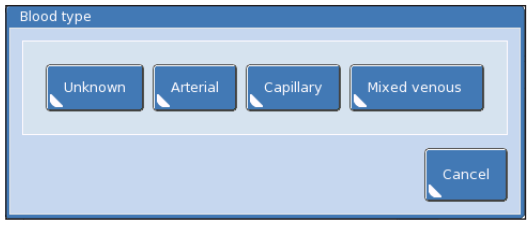


Figure D-26 Selection option for the blood type input

Scanning in data using a barcode scanner

1 Select the input value to be scanned using the barcode scanner on the screen.

2 Scan in the barcode.

3 The scanned barcode data are taken over automatically.

WARNING

Warning

The user must carry out a plausibility check for all barcode data scanned in and displayed by the instrument.

Mandatory input

If an input value is defined as a "Mandatory input", this input value is indicated by a "*".

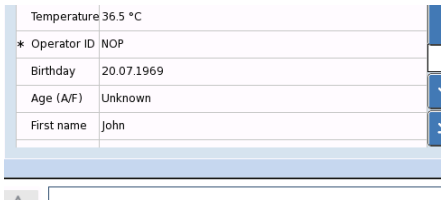


Figure D-27 Mandatory input

CAUTION

Caution

If a mandatory input is not made, the measurement is rejected automatically.
If standard values are also defined for the input values, they are applied for the mandatory input.
If, however, the sample type is defined as a mandatory input, this has to be entered during the measurement regardless or the standard value has to be confirmed.

Result

As soon as a measured value is available, the Result screen appears automatically. The entry of input values is not interrupted if measured values are available.

Depending on how the display has been defined, the results are listed on the screen.

The sort feature allows, for example, those measured values that lie outside the specified range to be shown at the beginning of the list for quick and easy reading.

For additional information, refer to *Display of results* on page D-62.

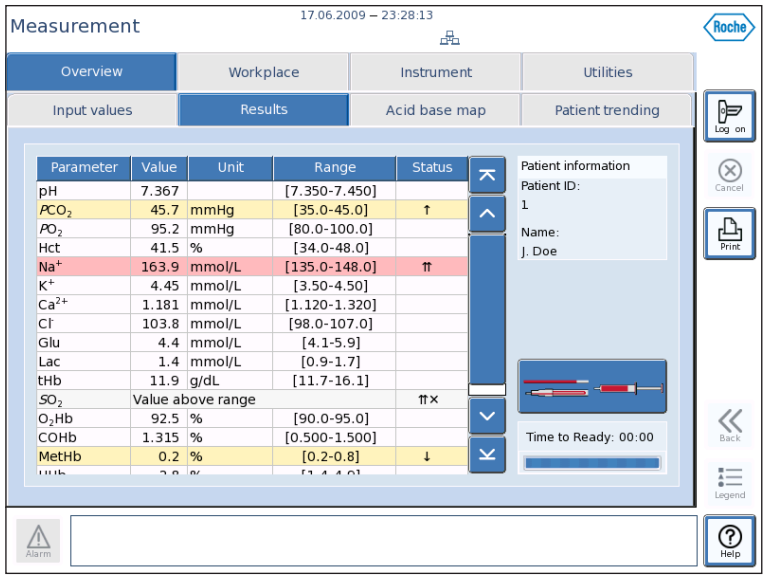


Figure D-28 Result screen

Depending on the status, the results are indicated by color-coding and icons:

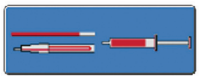
↓	The value is below the physiological range.
↑	The value is above the physiological range.
↓↓	The value is below the critical range.
↑↑	The value is above the critical range.
↑↑×	The value exceeds the upper limit of the measuring range.
↓↓×	The value is below the lower limit of the measuring range.
×	No measured value is available.

Figure D-29

The lower right area of the result screen shows the duration of the time-to-ready remaining until the instrument will again be ready.

Depending on the setting. a longer time-to-display can be defined for a more accurate control of the measured values.

For more information refer chapter 12 *Software functions*, section *Timeouts* on page D-145.



This button allows you to return to the overview screen early, before the end of the defined time-to-display. You can start a new measurement.

Printout

Printouts on the internal printer are possible as soon as all mandatory entries have been made and the first measured value appears on the result screen.

If the [Print] button is pressed before all measured values are available, these are identified on the printout with the message "Measurement in progress" instead of the measured value and the measurement that is in progress is not ended or stored. The input values can continue to be edited after the first printout. Only after all measured values are present is the workflow ended after printing, the measurement results stored in the database and the ASTM and POCT1-A report sent.

For more information refer to section *Automatic report* on page D-64.

Measuring database

Press the following buttons to call up the database:

☞ [Workplace] > [Measuring database]

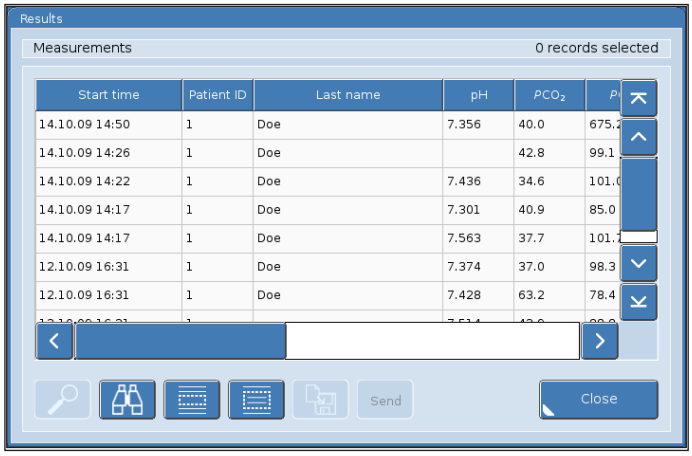


Figure D-30 Database with measurement results

Depending on how the display has been defined, the measurement results are listed on the screen.

See section *Display of results* on page D-62 for more details.

For some data (e.g. Date/time), a sorting option is provided in the corresponding column.

Select the entry using the arrow keys or by selecting the desired data directly from the list. The selected data are highlighted in dark blue.

The database has different functions such as "Search" or "Detail" to better display the results. The corresponding function keys are not activated until you mark multiple records.

Press the [Legend] button for a detailed description of the individual functions.

► Exporting the data to USB

1 Select the data for the export in the database.
2 Press this key to export the data to a USB storage device.
3 Follow the instructions on the screen.

For additional information, refer to chapter 12 *Software functions*, section *USB data export* on page D-152.

► Printout from the database

1 Select the desired data from the list.
2 Press the [Print] button on the right edge of the screen to start the print process.

Note

The print function in the database is not activated until at least one data entry in the list is marked.

Acid base map

Using this diagram, the acid-base status of a measurement can be illustrated if the measured values for PCO_2 and pH are available.

Note

Additional explanations of the legend information of the acid base map can be called up using the [Legend] button.

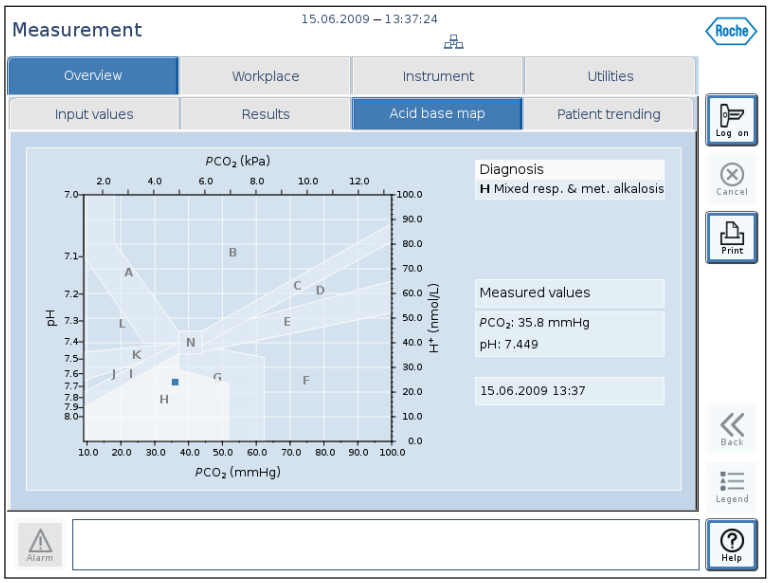


Figure D-31 Acid base map

► **Acid base map in the database**

To call up the acid base map in the database press the following buttons:

☞ [Workplace] > [Measuring database] > (select corresponding measurement) >  > [Acid base]

Patient trend diagram

Using this diagram, the course of individual parameters (measurement and calculated values) of a patient over a 10-day period can be displayed on a time scale.

Note

Only 2 parameters can be displayed at the same time.
The sequence of the parameters in the patient trending map can be defined.

► **Viewing a patient trending diagram**

1 To display the individual parameters in the patient trending map, press the two arrow keys.

2 The most recent measured values are displayed at the far right of the diagram.
The selected measured values are marked with a blue line.
The corresponding measured values are displayed at the right in the display field.

Note

The normal range of a parameter and the range outside the normal range are indicated by different colors.

3 Using these two arrow keys, you can select the previous measured values.

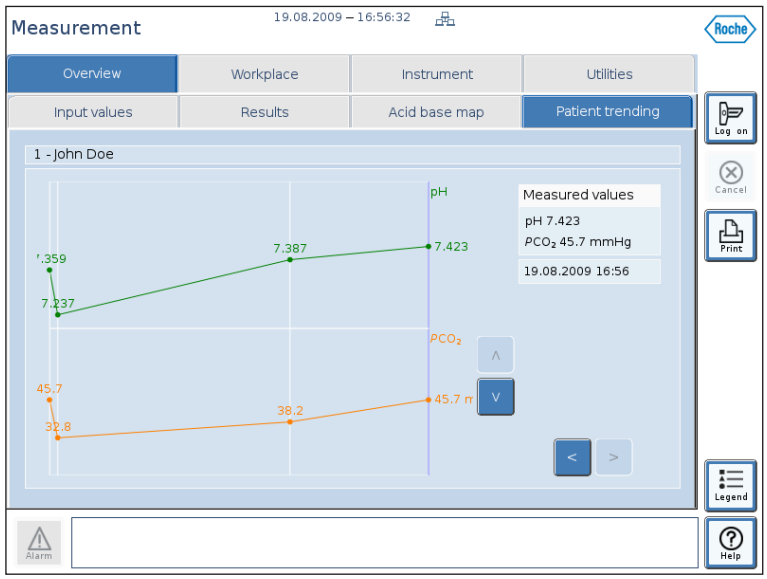


Figure D-32 Patient trend diagram

Note

Additional explanations of the patient trend diagram can be called up using the [Legend] button.

► **Patient trend diagram in the database**

To call up the patient trend diagram in the database press the following buttons:

☞ [Workplace] > [Measuring database] > (select corresponding measurement) >  > [Trending]

Settings for measurement

Go to the "Utilities" menu and press the following button:

☞ [Configuration] > [Measurement]

You can configure the following settings in this menu:

- Parameters
- Data input
- Correlations
- Display of results

Parameters

You can configure the following settings in this area:

- Edit panels
- Units
- Ranges
- Activate/Deactivate
- pH/H^+

Edit panels

By selecting parameter groups, various parameters can be enabled or disabled for measurement as long as they are ready for measurement.

Note

The selection of possible parameter groups depends on the equipment configuration of the instrument.

The parameter groups are displayed on the overview screen according to the user definition. Up to three user-defined parameter groups are possible.

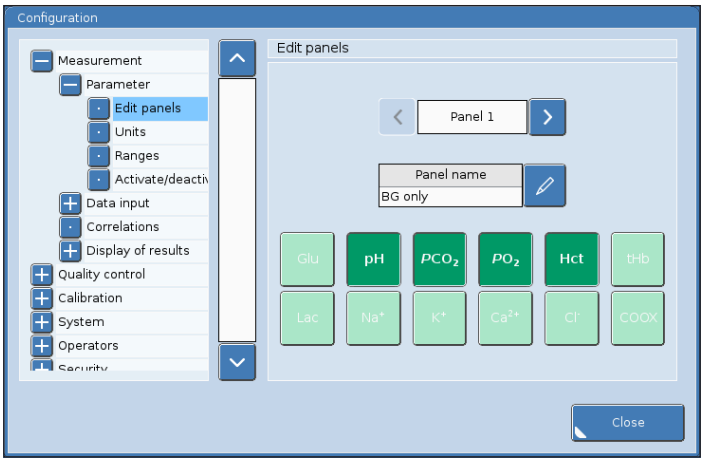


Figure D-33

Units

Using this function, you can adapt the format and unit of the parameters and measurement and calculated values as needed.

Depending on the equipment configuration of the instrument, each parameter can be assigned one of the following units:

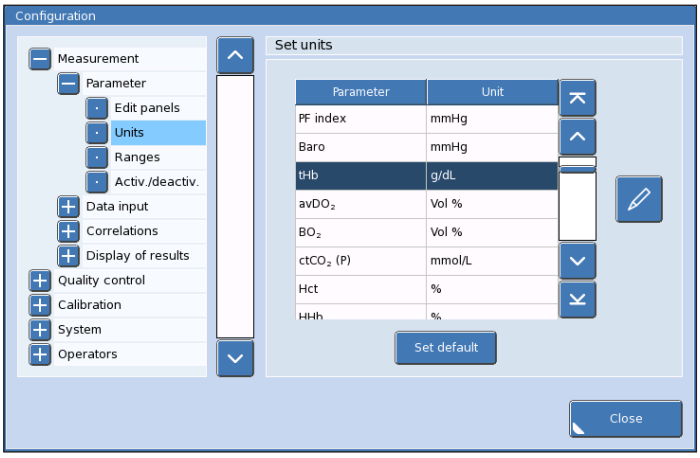


Figure D-34

► Changing the units

1 Select a parameter from the list.

2 When the [Pencil] button is pressed, an input window appears.


Pencil

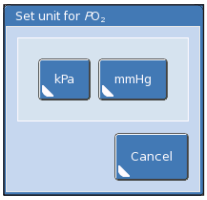


Figure D-35 Input window

3 Select the desired unit by pressing the button.

► **Reset changed units**

1 Press the [Set default] button.

The unit of the selected parameter is reset to the basic settings of the instrument.

Ranges

Using this function, you can enter the upper and lower limits of the normal and the critical range of each measurement parameter.

Note

During installation, default ranges are defined. The pre-configured default values are reference values only and must always be adapted by the customer to the specific application area.

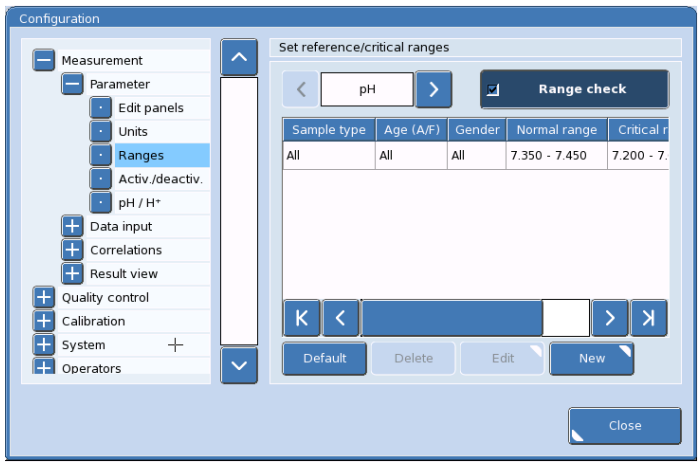
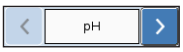


Figure D-36

► **Changing the ranges**



1 Select a parameter in the list.

2 When the [New] button is pressed, an input window is displayed.

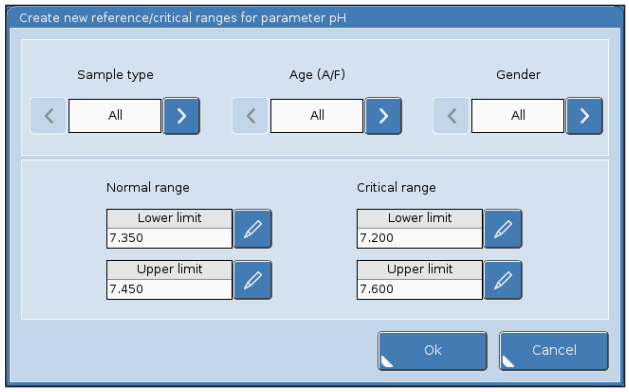


Figure D-37 Input window

For the defined ranges of a selected parameter, the following additional settings are possible:

Gender	• **Male** • **Female** • **All**
Age (A/F)	• **Fetal** • **Newborn** • **2nd day** • **< 1 year** • **> 1 year** • **All**
Sample type	• **Blood** • Dialysis solution • **Aqueous** • **All**

3 Select the desired settings by pressing the buttons.

4 Enter the upper and lower limit of the normal range.

5 Enter the upper and lower limit of the critical range.

6 When you press the [OK] button, the modified parameter ranges are available.

Note

You can edit the previously defined range settings at any time by pressing the [Edit] button.

► Checking the ranges

If the [Range check] button is enabled, a range check is carried out during the measurement. If one of the defined limits is undershot or exceeded, a corresponding message is output on the measurement report.

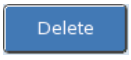
Remove the check mark to disable the range check.

► Resetting changed ranges

1 Select the corresponding parameter.

2 Press the [Default] button.

The normal range and the critical range of the selected parameter are reset to the instrument's basic settings.



Note

You can delete the specific range settings at any time by pressing the [Delete] button. Default values cannot be deleted.

Activating/deactivating parameters

In this area, you can deactivate individual parameters for both measurement and for calibration.

Parameter is activated both for measurements and for calibrations

Parameter is deactivated for measurements, but activated for calibrations

Parameter is deactivated both for measurements and for calibrations

► Deactivating a parameter for the measurement

1 Deactivate the desired parameter by pressing the button.

The color of deactivated parameter changes to light green, and the parameter is not included in the measurement until it is re-activated.

► Deactivating a parameter for calibration

1 Deactivate the desired parameter by pressing the [ON] button.

The deactivated parameter is grayed out and indicated with an "OFF". The parameter is not calibrated until it is re-activated.

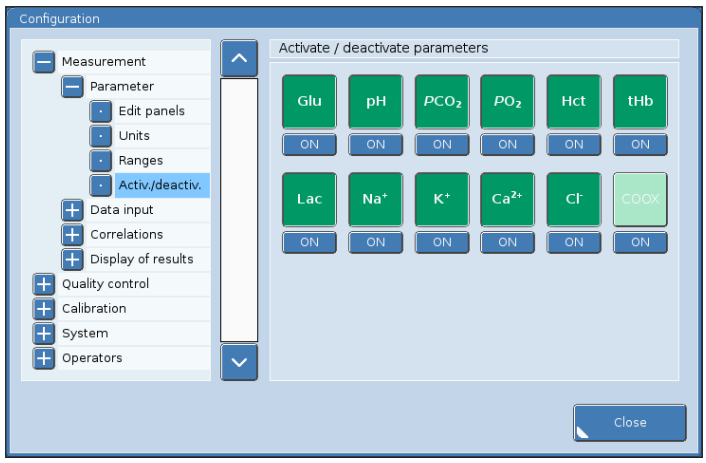


Figure D-38

CAUTION

Caution

To activate a parameter for the measurement, the same parameter must be activated for calibration.

► **Activating a parameter for calibration**

1 Activate the desired parameter by pressing the [OFF] button.

The color of the activated parameter changes to dark green and it is indicated with an "ON".

► **Activating a parameter for measurement**

1 Activate the desired parameter by pressing the button.

The color of the activated parameter changes to dark green.

pH/H^+

Using this function, you can toggle between pH and H^+.

Select the desired display by pressing the buttons.

Note

If you switch from pH to H^+ or from H^+ to pH, you may have to remeasure and configure any correction factors for pH or H^+, as direct conversion is not possible.

Data input

You can configure the following settings in this area:

- Input values
- Mandatory input
- Default values
- Patient ID

Input values

Using this function, you can define the input values to be shown on the input value screen.

See *Input value screen* on page D-47.

► Defining an input value

1 Select the corresponding input value from the list.

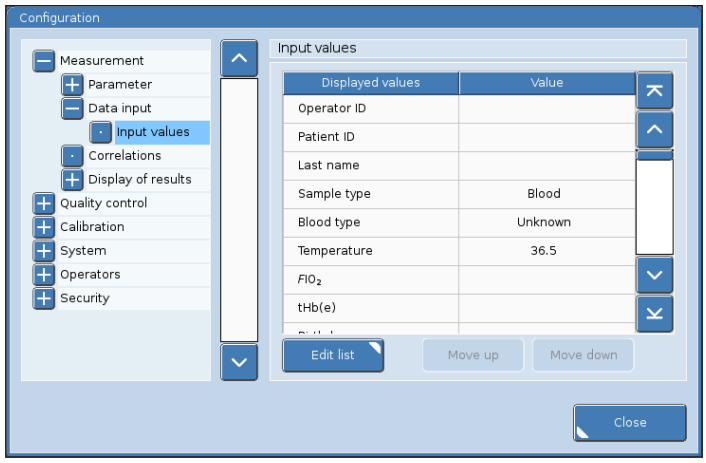


Figure D-39

2 You can change the position of the input values in the list using the [Move up] and [Move down] buttons.

3 To edit an input value, press the [Edit list] button.

The following screen appears:

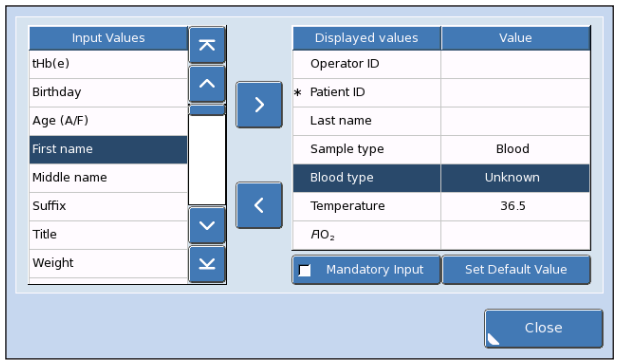


Figure D-40

The left edge of the screen shows a list of all possible input values.

So that an input value is displayed on the input value screen after the measurement, it must first be selected from the list at the left.

Using the two arrow keys in the middle, move the desired input value to the "displayed values" area.

The input value is now available on the input value screen.

Mandatory input

Each input value can also be defined as a mandatory input. If an input is defined as a mandatory input, after the measurement, the input value screen is displayed until all mandatory inputs have been made in their entirety.

For additional information, refer to section *Mandatory input* on page D-48.

Caution

If a mandatory input is not made, the measurement is rejected automatically.

An input value can be defined as a mandatory input in the "Input values" list.

► **Defining a value as a mandatory input**

1 Select the desired input value from the list.

2 Press the [Mandatory input] button.

Note

A mandatory input is identified with a star [*] and a colored background.

3 The selected mandatory input value is now available on the input value screen.

Default values

Certain input values (e.g. patient temperature) can be assigned default values (e.g. 37°C). If a measurement is carried out, these default values are displayed on the input value screen automatically.

Note

If the sample type is defined as default value, this entry has to be entered manually after the measurement.

► **Entering default values**

1 Select the desired input value from the list.

2 Press the [Set default value] button.

3 Change the input value by doing either of the following:

- Selecting one of the default selection options.
- Making a manual input. Confirm the change using the [OK] button.

4 When the [Close] button is pressed, the default values are available again.

Patient ID

Using this function, you can define an input mask for entering the Patient ID.

To configure the input mask, press the [Pencil] key.

You can use the following characters for defining the input mask:

$	Number
#	Letter
*	Any character
Other characters	These characters must be entered exactly as they have been defined.

Correlations

WARNING

Warning

The configuration of correlation factors has a direct effect on the accuracy of measured values. Correlation settings must always be verified using comparative measurements.

This function is used to define correlation factors for individual measurement parameters. Correlation factors are defined in order to adapt the results of the instrument to other existing analytical systems accurately.

For each measurement parameter, a slope value and an offset value can be entered.

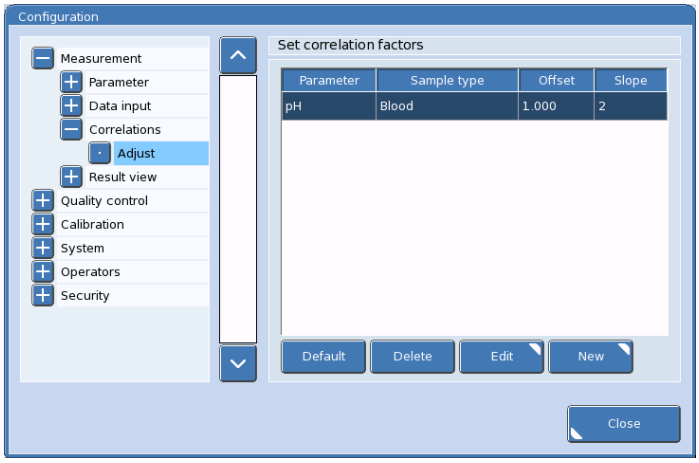


Figure D-41

Note

The default settings for the offset and slope value are always 0.0 and 1.0.

► Changing the correlations

1 To change the default settings, press the [New] button.
An additional window opens:

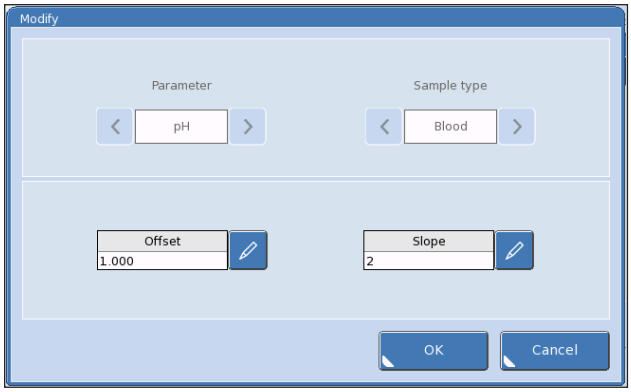


Figure D-42

2 Using the two arrow keys, the desired parameter and sample type can be selected.

3 To enter the new values, press the [Pencil] button.

4 When you press the [OK] button, the new values are available.

The modified values are marked correspondingly with a (c) during the measurement and on the measurement report.

Note

The configured correction values have no effect on QC measurements.

Note

You can edit the previously defined correlation settings at any time by pressing the [Edit] button.

Note

If, under [Utilities] > [Configuration] > [Measurement] > [Parameter] > [pH/H^+], you switch from pH to H^+ or from H^+ to pH, you may have to remeasure and configure any correction factors for pH or H^+, as direct conversion is not possible.

► Remove all correlations

1 Press the [Default] button.

The parameters are reset to the basic settings of the instrument.

Display of results

Display

In this area, you can configure settings for the display of the measurement and calculated values on the Result screen.

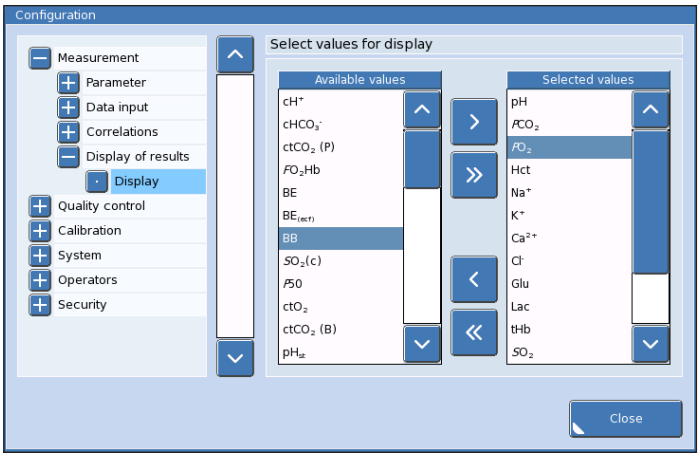


Figure D-43

The "Available values" column lists all defined measurement and calculated values.

1 Select the desired measurement or calculated value from the list.

2 Using the two arrow keys in the middle. move the marked value to the "Selected values" area.

3 To select all measurement and calculated values in the list, press the two double arrow keys in the middle.

When you press the [Close] button, the selected values are available.

Automatic report

Using this function, you can define various printer settings for the measurement. The following options are available:

Print automatically	When this function is enabled, the measurement results are printed out automatically at the printer.
Number of printouts	Defines the number of printouts (max. 3) for automatic printouts.

Ticket printer

Using this function, an external ticket printer can be used to print out a measurement report.

► **Enable ticket printer**

To activate the ticket printer, select the option [On] in the "Enable ticket printer" area.

► **Activate automatic printing**

For automatic printing of the measurement results, select [On] in the "Activate automatic report" area.

► **Configure ticket printer**

To import the configuration file (XML), press the [Import file] button in the "Load configuration file" area.

Notation of the measured, input, and calculated values

Measured values (depending on the version):

PO_2	Oxygen partial pressure
PCO_2	Carbon dioxide partial pressure
pH	Negative common logarithm of the hydrogen ion activity
Na^+	Sodium ion concentration
K^+	Potassium ion concentration
Cl^-	Chloride ion concentration
Ca^{2+}	Calcium ion concentration
Hct	Hematocrit
tHb	Total hemoglobin concentration
O_2Hb	Oxyhemoglobin
HHb	Deoxyhemoglobin
COHb	Carboxyhemoglobin
MetHb	Methemoglobin
SO_2	Functional oxygen saturation
Bili	Bilirubin (neonatal)
Glu	Glucose
Lac	Lactate

Calculated values:

H^+	Hydrogen ion concentration
$cHCO_3^-$	Bicarbonate concentration in plasma
$ctCO_2(P)$	Total CO_2 concentration in the plasma
$ctCO_2(B)$	Total carbon dioxide concentration in the blood
BE	Base excess of blood
BE_{act}	Base excess of blood at current oxygen saturation
BE_{ecf}	Base excess of the extracellular fluid
BB	Buffer bases
ctO_2	Total oxygen concentration
pH_{st}	Standard pH value
$cHCO_3^-{}_{st}$	Standard bicarbonate concentration in plasma
PAO_2	Alveolar oxygen partial pressure
RI	Respiratory index
nCa^{2+}	Standardized ionized calcium (pH = 7.4)
Qs/Qt	Shunt - quotient between both oxygen concentration differences
Qt	Difference of oxygen concentration between alveolar and mixed venous blood
*P*50	Oxygen partial pressure at 50% oxygen saturation calculated with SO_2 as measured value

FO_2Hb	Fractional oxygen saturation
SO_2	Oxygen saturation
$SO_2(c)$	Functional oxygen saturation calculated with *P*50 as input value
$AaDO_2$	Alveolar-arterial oxygen partial pressure
a/AO_2	Alveolar-arterial oxygen partial pressure ratio
$avDO_2$	Arterial-venous oxygen level difference
AG	Anion gap
MCHC	Middle corpuscular hemoglobin concentration
Osm	Osmolality
OER	Oxygen extraction ratio
Hct(c)	Hct calculated from tHb
P/F index	PaO_2/FIO_2 ratio
BO_2	Oxygen capacity

Calculated parameters at the patient's temperature:

PAO_2^t	Alveolar oxygen partial pressure at patient's temperature
RI^t	Respiratory index at patient's temperature
$AaDO_2^t$	Alveolar arterial pressure at patient's temperature
a/AO_2^t	Alveolar-arterial oxygen partial pressure at patient's temperature
pH^t	pH at patient's temperature
PCO_2^t	PCO_2 at patient's temperature
PO_2^t	PO_2 at patient's temperature
H^{+t}	Hydrogen ion concentration at patient's temperature

Input values:

R	Gas exchange quotient
FIO_2	Proportion of inspiratory oxygen
tHb(e)	Entered tHb value (not measured)
Hb factor	Serves to calculate Hct(c) values from tHb values

Additionally:

- Patient ID
- Insurance code
- First name
- Last name
- Middle name
- Suffix
- Maiden name
- Title
- Gender
- Birthday
- Age (A/F)
- Marital status
- Religion
- Ethnic origin
- Patient language
- Address
- Phone number
- Size
- Weight
- Temperature
- Diet
- Temporary Pat ID
- Operator ID
- Admission date/time
- Admission status
- Date/time drawn
- Sample type
- Blood type
- Puncture site
- Specimen ID
- Sample container
- Clinic
- Hospital Service
- Ward
- Department
- Location
- Doctor
- Accepted by
- Billing code
- Order ID
- Accession number
- Discharge date/time
- Changed date/time
- Comment
- Diagnosis
- Medication
- Diagnostic code type
- Danger code
- Isolation status
- Vent. mode
- Oxygenation device
- VT
- S_{rate}
- PEEP
- CPAP
- PIP
- MAP
- Ti
- Te
- MV
- A_{rate}
- Flowrate
- 24h urine
- ALLEN Test
- Remark 1 - 5

Quality control

For safety reasons, quality control measurements must be carried out daily. This chapter describes all of the steps required to attain a successful QC measurement.

In this chapter

Chapter **9**

General quality control concept

WARNING

Warning

Omitting QC measurements or ignoring QC results may lead to incorrect patient measurements, which may result in incorrect clinical decisions.
Danger of injury.

General QC concept

Roche always strives to ensure the highest quality standards for its products. This quality awareness is the result of a sense of responsibility toward the customer and the well-being of the patient.

The quality control is an important element of this claim.
Aqueous QC materials such as the **cobas b** 123 AutoQC Pack etc. are offered to ensure that the **cobas b** 123 POC system provides measurements of high quality to protect customers or their patients.

To ensure the quality of measurement results, you must run quality control on three levels (1 = low, 2 = normal, 3 = high) after each Sensor Cartridge replacement, Fluid Pack replacement and after installation of the instrument.

In addition, at least one QC measurement on alternating levels (1 = low, 2 = normal, 3 = high) is required in between two automatic 2-point calibrations.

For example:

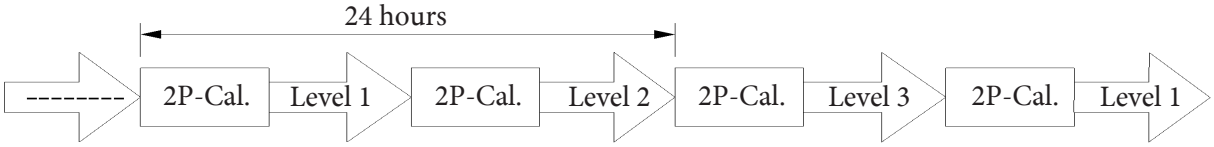


Figure D-44 Graphic illustration of the general QC concept

Note

A system calibration can take place instead of a 2P calibration.

The automatic system calibration always includes a complete 2P calibration.

Complete at least two quality control tests on different levels once daily or more often in accordance with local regulations.

Note

QC measurements should not be run immediately before a 2P calibration.

The quality control takes place by comparing the known target ranges of QC materials with the results of the device.

The following control materials:

- **cobas b** 123 AutoQC Pack:
  - TRI-LEVEL: Level 1 - 3
  - BI-LEVEL: Level 1 & 3[(a)]
  - LEVEL 2[(a)]

  Only for **cobas b** 123 POC systems with AutoQC module
- COMBITROL PLUS B (control materials for manual QC measurement)
  - Available in 3 different levels

The following applies for the COMBITROL PLUS B:

Color-coding of the COMBITROL PLUS B ampoules

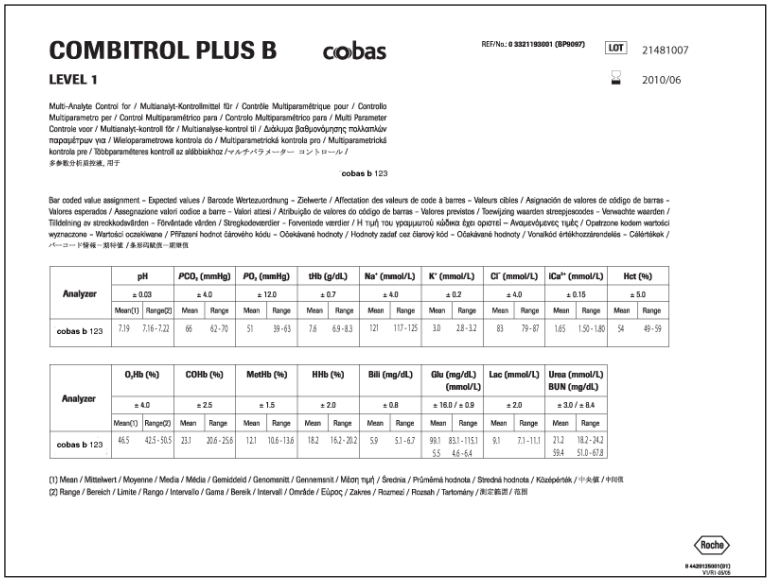
The QC ampoules are color coded for ease of identification:

▲	Red	Level 1
▲	Yellow	Level 2
▲	Blue	Level 3

The ampoule labels have a barcode that contains the lot number.

The target ranges specified in the package text should be taken as 2σ ranges (σ = standard deviation; e.g. for PO_2, 2σ = 12 mmHg, 1σ = 6 mmHg).

See section *Important information for evaluating QC results* on page D-73 for more details.



COMBITROL PLUS B cobas

REF/No.: 0 3321193001 (BP0097) LOT 21481007

LEVEL 1 2010/06

Multi-Analyte Control for / Multianalyt-Kontrollmittel für / Contrôle Multiparamétrique pour / Controllo Multiparametro per / Control Multiparamétrico para / Controlo Multiparamétrico para / Multi Parameter Controle voor / Multianalyt-kontroll för / Multianalyse-kontrol til / Διάλυμα βαθμονόμησης πολλαπλών παραμέτρων για / Wieloparametrowa kontrola do / Multiparametrická kontrola pro / Multiparametrická kontrola pre / Többparaméteres kontroll az alábbiakhoz / マルチパラメーター コントロール / 多参数分析质控液，用于

cobas b 123

Bar coded value assignment – Expected values / Barcode Wertezuordnung – Zielwerte / Affectation des valeurs de code à barres – Valeurs cibles / Asignación de valores de código de barras – Valores esperados / Assegnazione valori codice a barre – Valori attesi / Atribuição de valores do código de barras – Valores previstos / Toewijzing waarden streepjescodes – Verwachte waarden / Tildelning av streckkodsvärden – Förväntade värden / Strekgkodeverdier – Forventede verdier / Η τιμή του γραμμωτού κώδικα έχει οριστεί – Αναμενόμενες τιμές / Opatrzone kodem wartości wyznaczone – Wartości oczekiwane / Přiřazení hodnot čárového kódu – Očekávané hodnoty / Hodnoty zadať cez čiarový kód – Očakávané hodnoty / Vonalkód értékhozzárendelés – Célértékek / バーコード値検 – 期待値 / 条形码赋值 – 期望值

Analyzer	pH		PCO_2 (mmHg)		PO_2 (mmHg)		tHb (g/dL)		Na^+ (mmol/L)		K^+ (mmol/L)		Cl^- (mmol/L)		iCa^{++} (mmol/L)		Hct (%)	
	± 0.03		± 4.0		± 12.0		± 0.7		± 4.0		± 0.2		± 4.0		± 0.15		± 5.0	
	Mean(1)	Range(2)	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
cobas b 123	7.19	7.16 - 7.22	66	62 - 70	51	39 - 63	7.6	6.9 - 8.3	121	117 - 125	3.0	2.8 - 3.2	83	79 - 87	1.65	1.50 - 1.80	54	49 - 59

Analyzer	O_2Hb (%)		COHb (%)		MetHb (%)		HHb (%)		Bili (mg/dL)		Glu (mg/dL) (mmol/L)		Lac (mmol/L)		Urea (mmol/L) BUN (mg/dL)	
	± 4.0		± 2.5		± 1.5		± 2.0		± 0.8		± 16.0 / ± 0.9		± 2.0		± 3.0 / ± 8.4	
	Mean(1)	Range(2)	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
cobas b 123	46.5	42.5 - 50.5	23.1	20.6 - 25.6	12.1	10.6 - 13.6	18.2	16.2 - 20.2	5.9	5.1 - 6.7	99.1 5.5	83.1 - 115.1 4.6 - 6.4	9.1	7.1 - 11.1	21.2 59.4	18.2 - 24.2 51.0 - 67.8

(1) Mean / Mittelwert / Moyenne / Media / Média / Gemiddeld / Genomsnitt / Μέση τιμή / Średnia / Průměrná hodnota / Stredná hodnota / Középérték / 中央值 / 中间值
(2) Range / Bereich / Limite / Rango / Intervallo / Gama / Bereik / Intervall / Område / Εύρος / Zakres / Rozmezí / Rozsah / Tartomány / 测定範囲 / 范围

Roche

Figure D-45 COMBITROL PLUS B package text

(a) Available at a later point after **cobas b** 123 POC system launch.

Important information for evaluating QC results

The evaluation depends on which σ ranges the QC results have:

- **Measured value is within the range "target value ± 2σ"**

  No subsequent action. The parameter is OK.

  The QC result is acceptable and the parameter is/remains enabled for measurements.

- **Measured value is outside the range "target value ± 2σ"**

  Consequence: A QC consequence is assigned to the parameter.

  The QC measurement result is not acceptable. The parameter may be released for further patient measurements only after the cause of the lockout has been determined and the error has been corrected.

  See the section on *Removing the QC consequences* on page D-99.

Caution

If the error persists, replace the Sensor Cartridge and/or notify Roche Service Hotline.

QC measurement

To ensure the quality of measurement results, you must run quality control on three levels (1 = low, 2 = normal, 3 = high) after each Sensor Cartridge replacement, Fluid Pack replacement and after installation of the instrument.

In addition, at least one QC measurement on alternating levels (1 = low, 2 = normal, 3 = high) is required in between two automatic 2-points calibrations.

See *General QC concept* on page D-71.

The following QC measurements are available:

- AutoQC measurement (optional)
- Manual AutoQC measurement (optional)
- Manual QC measurement
  - With Roche control materials, e.g. with COMBITROL PLUS B

AutoQC measurement

An AutoQC starts automatically at the predefined times according to the settings in the QC planner.

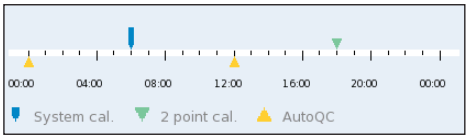


Figure D-46 View of the QC planner

See section *Settings for quality control* on page D-86 for more details.

Note

For any scheduled AutoQC measurement, no QC values are displayed at the end of the AutoQC measurement, as well as no QC report is printed out.
You can view and print the QC results at any time in the database under [Workplace] > [QC database].

Manual AutoQC measurement

Note

A manual QC measurement is possible in "Ready" status only.
If the instrument is not ready for measurement, the [QC measurement] button is disabled.

For a manually activated AutoQC measurement starting from the "Workplace" menu, press the following button:

☞ [QC measurement]

The following screen appears:

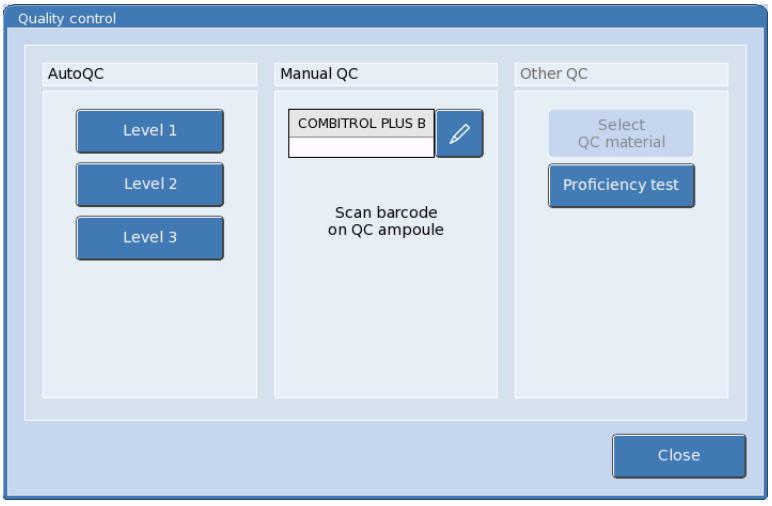


Figure D-47 Material selection screen

The AutoQC measurement is started by pressing the desired level, e.g. [Level 1], [Level 2] or [Level 3] button.

Note

If all ampoules of a certain level are used up in the AutoQC Pack, the corresponding [Level] button is blocked for selection.

Manual QC measurement with COMBITROL PLUS B

Note

Before a manual QC measurement, the corresponding QC material must be defined.

For additional information, refer to section *Material definition* on page D-90.

Note

The COMBITROL PLUS B quality control material must be stored to room temperature at least 24 hours prior to use.

Go to the "Workplace" menu and press the following button:

☞ [QC measurement]

1 Remove the corresponding level ampoule of the desired QC material from the packaging.

2 Using the barcode scanner, scan the barcode from the label of the ampoule. Once the material has been detected, the user interface switches automatically to the next step (refer to point 3).

If no barcode scanner is available for the input, read off the lot number of the ampoule and enter it manually using the [Pencil] button.

3 Check the data on the screen against the data of the QC material.

Note

If an incorrect quality control material is selected, return to the "Overview" menu using the [Cancel] button.

4 Press the following buttons to start a QC measurement:

☞ [Start capillary measurement]

5 The QC sample input is prepared, the sample input unit moves into position. Wait until the preparation time is finished.
While doing so, tap your fingernail against the ampoule to remove the liquid from the ampoule neck.

6 Break open the ampoule.

To prevent injuries, protect your hands with gloves and cellulose when breaking open the ampoule. Use the control material within half a minute after opening. Never use an ampoule twice. We recommend using an ampoule adapter.

After the preparation time, the following screen appears:

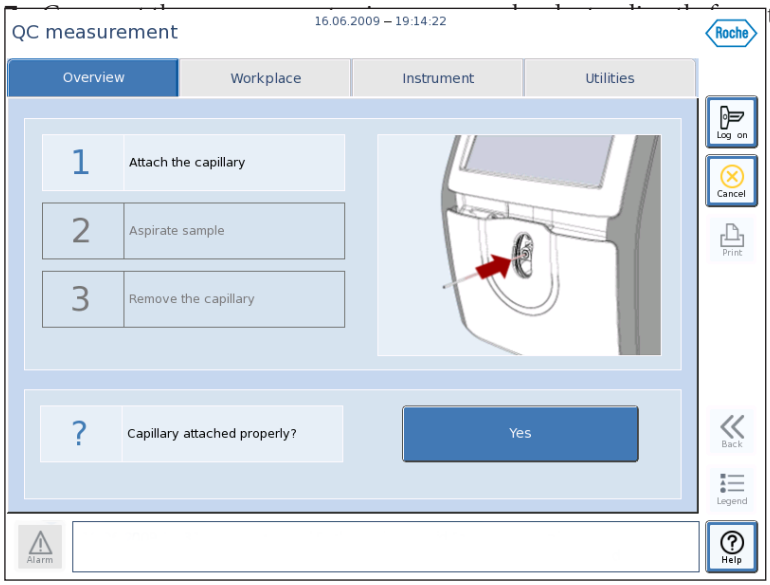


Figure D-48

Securely attach the adapter (see below) to the fill port.

A Ampoule with adapter

Figure D-49

8 To start the aspiration process, press the [Yes] button.
The control material is aspirated.

9 After the prompt "Remove the capillary", pull out the adapter and press [Yes].

10 The QC measurement is started.

For QC results, see section *QC results display* on page D-78.

QC results display

Note

After the QC sample input, an automatic changeover to the QC values takes place only if the ampoule adapter has been removed properly and the removal of the ampoule adapter has been confirmed on the instrument by pressing the [Yes] button.

Note

For an automatic AutoQC measurement, no QC values appear at the end of a QC measurement. You can view the QC results at any time in the database under [Workplace] > [QC database].

While a QC measurement is in progress, the operator ID can be entered.

QC results are automatically displayed on the Results screen when available. How the results are displayed, depends on how the display is configured.

The sort by "Status" feature, allows specific QC measured values to be found quickly. i.e. NOK values, as shown below.

See section *Settings for quality control* on page D-86.

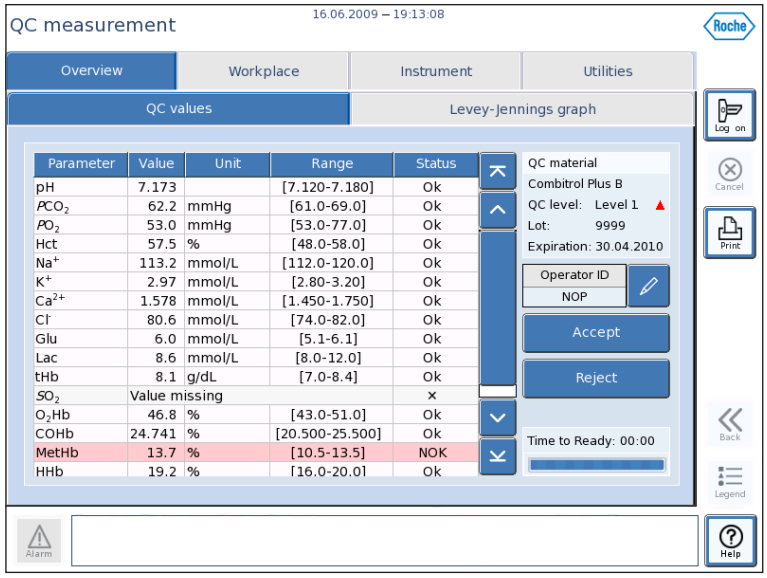


Figure D-50 Result screen

Depending on the status, the QC results are indicated by an additional text:

For additional information, refer to section *QC troubleshooting* on page D-100.

OK	QC results are inside the target range
nOK	QC results are outside the target range (the corresponding lines have a red background)

Table D-5 QC status display

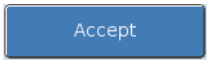
Note

For optimal display of the QC results on the screen and the printout, the QC values are rounded. However, exact values are used for evaluating the individual QC results.

This can cause a "nOK" evaluation of a QC result, even if the QC result shown lies within the target range. This procedure is needed by the software and does not cause any patient risk.

Confirming QC results manually

Press the [Accept] button for a manual confirmation of the QC results.



QC results are confirmed manually and saved.

Rejecting QC results manually

To not confirm the QC results, press the [Reject] button.

QC results are not confirmed and not stored in the database.

QC report

As soon as all QC results are available, the QC report is printed out automatically if this has been defined in the "Configuration" menu.

If not, press the [Print] button on the right edge of the screen to obtain a printout.

See section *Automatic report* on page D-93 for more details.

Note

For any scheduled AutoQC measurement, no QC values are displayed at the end of the AutoQC measurement, as well as no QC report is printed out.
You can view and print the QC results at any time in the database under [Workplace] > [QC database].

Levey-Jennings graph

The Levey-Jennings graph shows the course of quality control for the individual levels.

Press the following buttons to call up the Levey-Jennings graph:

Note

The Levey-Jennings graph is not available for the proficiency test measurements.

☞ [Overview] > [Levey-Jennings graph]

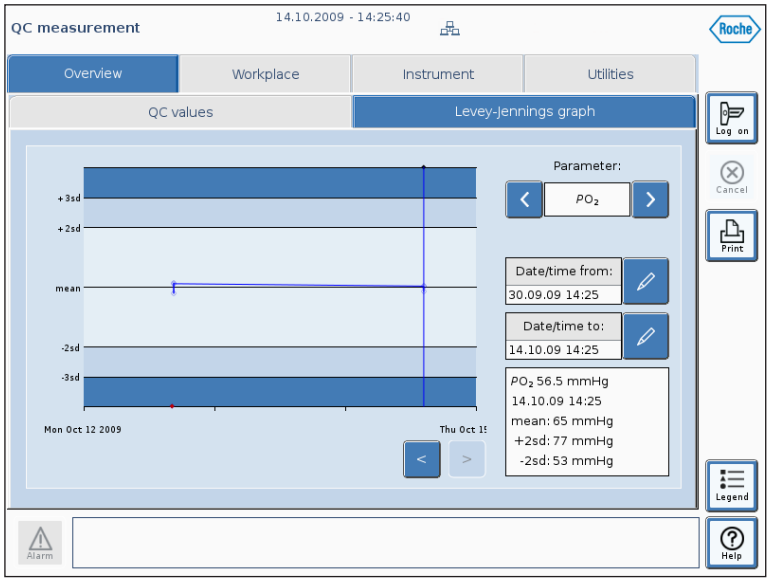
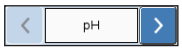


Figure D-51 Levey-Jennings graph

You can call up explanations about the Levey-Jennings graph using the [Legend] button.

► Creating a Levey-Jennings graph



1 Select the corresponding parameter using the arrow keys at the top right.

2 Use the [Pencil] button to define the desired display time frame of the QC measurements.

3 Using the lower arrow keys, you can select the previous measurements.
The displayed measurement is marked with a blue line.
The corresponding measured values are displayed at the right in the display field.

► **Levey-Jennings graph in the database**

To call up the Levey-Jennings graph in the database press the following buttons:

☞ [Workplace] > [QC database] > (select corresponding QC measurement) > 

QC database

Press the following buttons to call up the database:

☞ [Workplace] > [QC database]

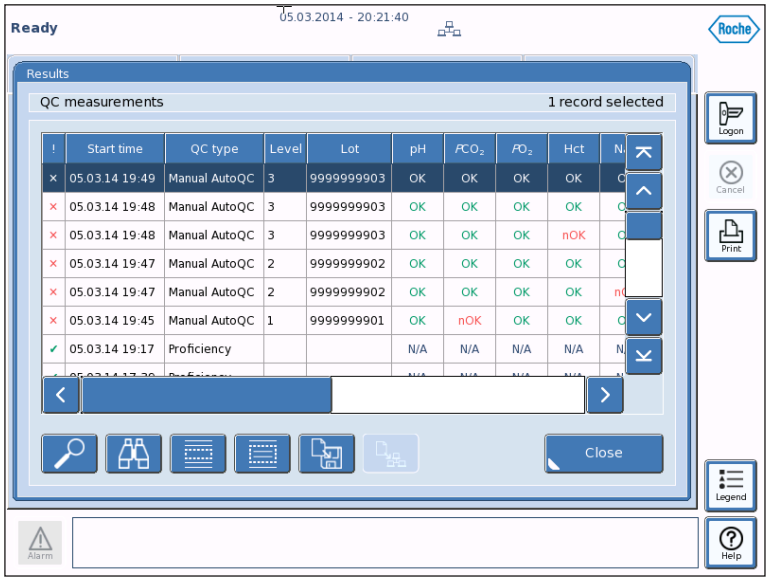


Figure D-52 Database with QC and Proficiency test results

Depending on how the display has been defined, the QC results are listed on the screen.

👁 See section *Display of results* on page D-93 for more details.

For some data (e.g. Date/Time), a sorting option is provided in the corresponding column.

The first column summarizes the overall status of all parameters of a QC measurement. The following symbols are used for this purpose:

✔	For this QC measurement, no parameters have been assigned a QC warning or QC lock.
×	For this QC measurement, one or more parameters have been assigned a QC warning or QC lock.

Select the entry using the arrow keys or by selecting the desired data directly from the list. The selected data are highlighted in dark blue.

The database has different functions such as "Search" or "Detail" to better display QC results. The corresponding function keys are not activated until you mark multiple records.

Press the [Legend] button for a detailed description of the individual functions.

► **Exporting the data to USB**

1 Select the data for the export in the database.
2 Press this key to export the data to a USB storage device.
3 Follow the instructions on the screen.

👁 For additional information, refer to chapter 12 *Software functions*, section *USB data export* on page D-152.

► **Printout from the database**

1 Select the desired data from the list.
2 Press the [Print] button on the right edge of the screen to start the print process.

Note

The print function in the database is not activated until at least one data entry in the list is marked.

Proficiency test

Warning

The cobas b 123 POC system is prepared to measure Proficiency test or External Quality Assurance (EQA) materials. However, due to their unknown concentrations, some results may not be obtained when the results are out of the measuring ranges or system specifications, as well as their formulations may be incompatible with the instrument.

Roche recommends that the participation in those external programs should be carefully established and the results should be compared within the same peer groups, i.e. cobas b 123 POC systems. Strictly follow all material instructions relating to the transportation, storage, and were the packaging and/or materials are damaged.

Note

In cases where security level 3 or 4 is activated, the proficiency test function is available only for the following operator profiles: trusted operator, service operator, key operator, and supervisor.

👁 see Software Functions, section Operators on page D-138.

Warning

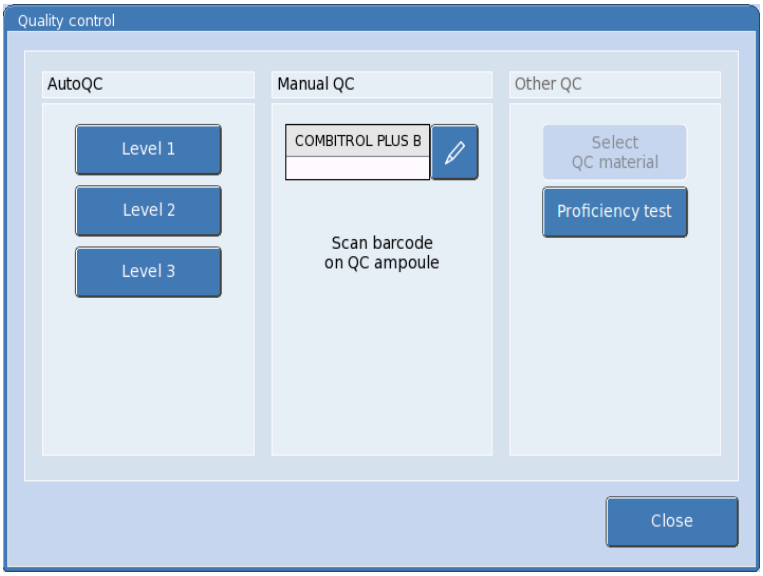
Before starting proficiency test, ensure that QC materials are being regularly measured, and their results are within expected ranges.

👁 For detailed information refer to Quality Control, *General QC concept* on page D-71

Go to the "Workplace" menu and press the following button:

☞ [QC measurement]

1 Press the [Proficiency test] button.



2 Enter the material name, level and/or lot number of the proficiency test material. Details can be entered manually using the [Pencil] button, or by using the barcode scanner when barcodes are available.

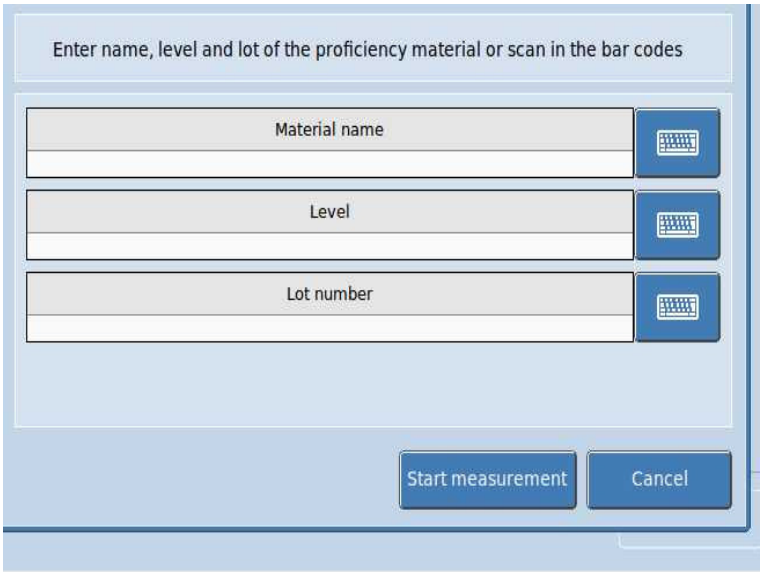


Figure D-53 Proficiency material setup

Note

Strictly follow the instructions that are usually provided together with the proficiency test material regarding storage conditions, temperature equilibrium and mixing prior to use. If the conditions above were not satisfied, press [Cancel]

3 Press the [Start measurement] button.

4 To start the proficiency test:

☞ Press the [Start capillary measurement] button.

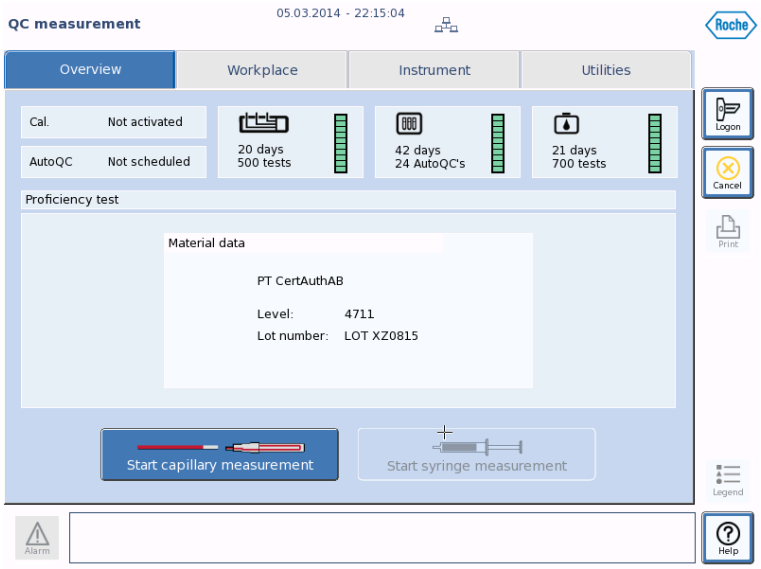


Figure D-54 Start capillary measurement

5 The sample input module is prepared. Wait until the preparation is finished.

6 Break open the ampoule.

CAUTION

Caution

To prevent injuries, protect your hands with gloves and cellulose when breaking open the ampoule. We recommend using an ampoule adapter.

After preparation is finished, the following screen is displayed:

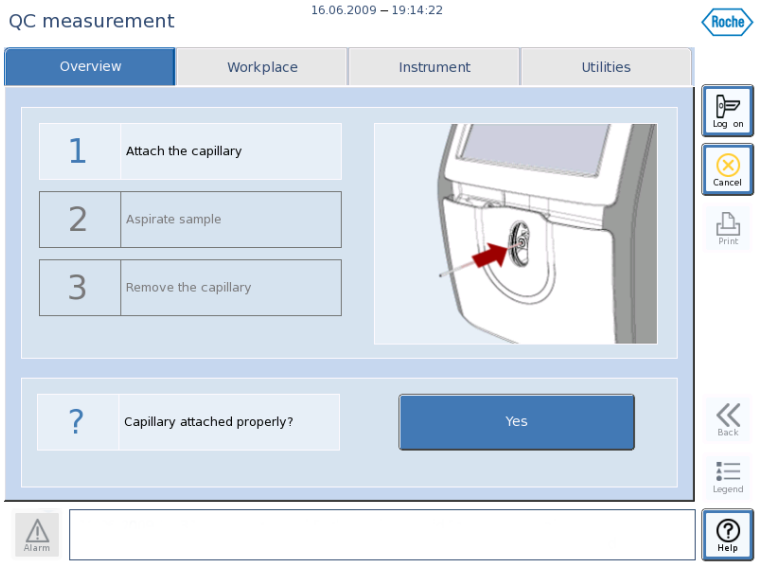


Figure D-55 Attach the capillary

7 Carry out the measurement using an ampoule adapter directly from the ampoule. Securely attach the adapter to the fill port, as shown in the figure below.

Note

The use of capillaries is not recommended because they are heparinized collecting devices and may affect results. Use only appropriate ampoule adapters.

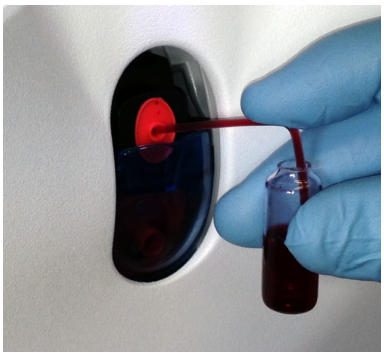


Figure D-56 Ampoule with adapter

8 To start the aspiration process, press the [Yes] button. The proficiency test material is aspirated.

9 When the Remove the capillary prompt is displayed, pull out the ampoule adapter and press the [Yes] button.

10 The proficiency test is started

For proficiency test results, see section *Proficiency test results display* on page D-85

Proficiency test results display

Note

After proficiency test material aspiration, the Result screen is displayed automatically if the ampoule adapter was removed correctly, and its removal confirmed on the instrument. Pressing the [Yes] button, confirms removal.

While a proficiency test is in progress, the operator ID can be entered.

Proficiency test results, are automatically displayed on the Results screen when available. How the results are displayed, depends on how the display is configured.

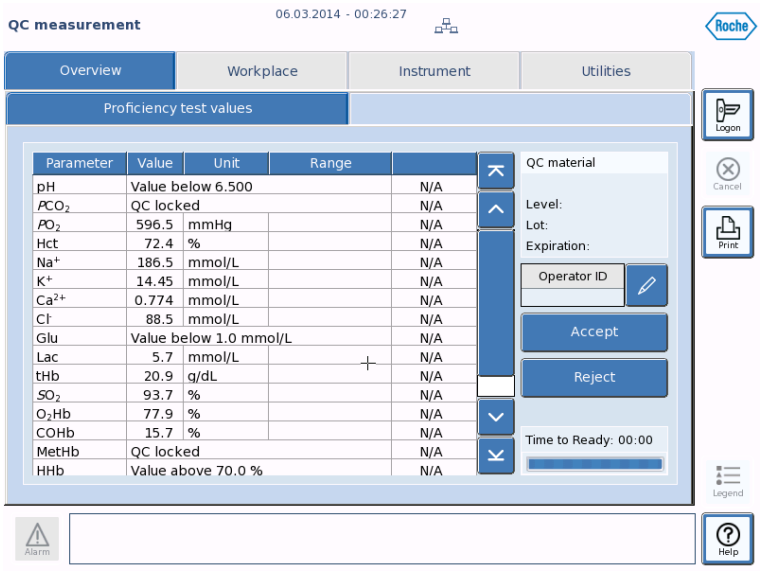
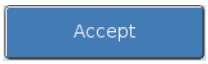


Figure D-57 Proficiency test values

Note

No target ranges apply for proficiency test. The Levey-Jennings graph is not available for proficiency test.

To confirm the proficiency test results manually:



1 Press the [Accept] button.

The proficiency test results are confirmed manually, and saved.

To reject the proficiency test results manually:

1 Press the [Reject] button.

The Proficiency test results are not confirmed and not stored in the database.

Proficiency test report

As soon as all proficiency test results are available, the proficiency test report is printed automatically if defined in the "Configuration" menu.

1 Press the [Print] button on the right edge of the screen to obtain a printout.

See section *Automatic report* on page D-93

Settings for quality control

Go to the "Utilities" menu and press the following buttons:

☞ [Configuration] > [Quality control]

A menu tree for selecting miscellaneous settings appears on the left edge of the screen.

The following quality control settings can be configured:

- Times/intervals
- AutoQC as follow-up
- Material definition
- Display of results
- Rules & consequences

Note

Using the barcode scanner makes it easier to enter QC material data, and prevents data entry errors.

Times and intervals

In the AutoQC scheduler, times for AutoQC measurements can be defined.

For accurate QC scheduling, the calibration times are displayed in addition to the times of the AutoQC measurement.

Note

For any scheduled AutoQC measurement, no QC values are displayed at the end of the AutoQC measurement, as well as no QC report is printed out.
You can view and print the QC results at any time in the database under [Workplace] > [QC database].

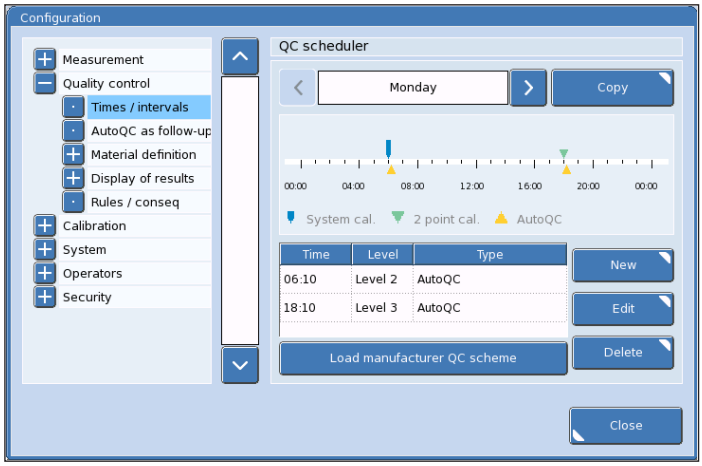


Figure D-58 AutoQC scheduler

Load manufacturer QC scheme

You can press the [Load manufacturer QC scheme] to take over a manufacturer-recommended QC scheme.

The recommended QC scheme contains the required number of daily QC measurements for an entire week. The QC scheme automatically matches the time of the QC measurements both to the start time of the system calibration and to the 2-point calibration interval.

Note

The number of daily QC measurements will not be changed by additional 2-point calibrations or system calibrations neither manually activated nor automatically activated during the RUN-IN phase or by the drift dependent adaption of the calibration scheme.

If the 2-point calibration interval is changed. an activated manufacturer QC scheme is not adjusted automatically and has to be reactivated.

see section *General QC concept* on page D-71.

Creating a new QC time

1 Using the arrow keys, select the corresponding day of the week for a new entry.

2 You can define a new QC time using the [New] button.
An additional input window opens:

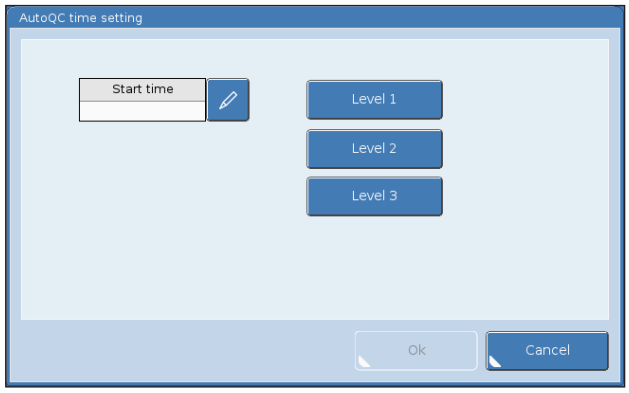


Figure D-59

3 You can set the starting time using the [Pencil] button.

4 Select the desired level by pressing the corresponding button.
The activated level has a dark blue background.

5 Press the [OK] button.
The new QC time is now available on the selected day of the week.

Copying a day profile

When all settings for a day have been carried out, these can be copied to other days of the week.

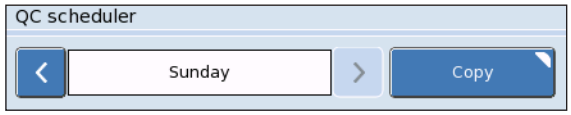


Figure D-60

1 When the [Copy] button is pressed, an additional input window appears:

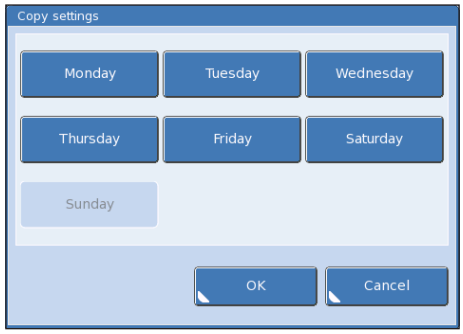


Figure D-61 Input window

2 Select one or more desired days of the week and press the [OK] button.

Note

The selected days of the week have a dark blue; a day of the week to be copied has a light blue background.

The QC times are now available on the selected days of the week.

Editing an existing QC time

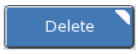
1 Using the arrow keys. select the corresponding day of the week for editing.

2 Select the existing start time in the list and press the [Edit] button.

3 Enter the new starting time or level.

4 Pressing the [OK] button saves the changes.

You can edit an entry that has already been defined.



You can delete an entry that has already been defined.

AutoQC measurements as a follow-up action

Note

To ensure the quality of measurement results, you must run quality control on all three levels (1 = low, 2 = normal, 3 = high) after each Sensor Cartridge replacement, after each Fluid Pack replacement and after each restart of the instrument.

Using this function, you can configure these AutoQC measurements in advance. The AutoQC measurements are triggered and carried out automatically if the corresponding event occurs.

To configure the individual AutoQC measurements, use the two arrow keys.

Material definition

In the [Utilities] > [Configuration] > [Quality control] > [Material definition] > [Set up] area, the settings for a QC material are configured.

Note

An AutoQC Pack is defined automatically by reading in the chip data. No additional material definition is required.

Defining a new QC material

1 Press the [New] button.

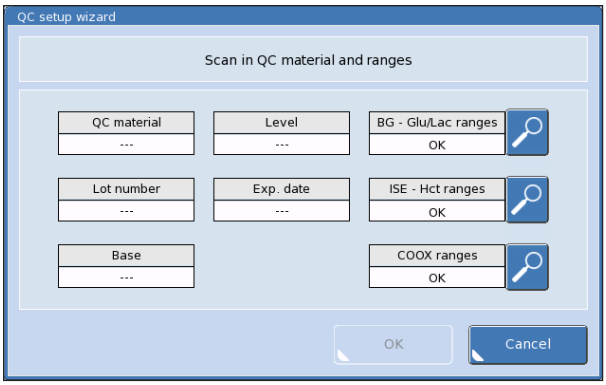


Figure D-62

2 Read in the material code and the range codes (1-3) from the package insert using a barcode scanner.

3 To view the range limits press the [Detail] button.

4 Close the view by pressing the [OK] button.

5 Pressing the [OK] button adds the newly created material.

Editing an existing QC material

Setting individual range limits

Setting the limits is subject to the following limitations and boundary conditions:

- The starting value is the currently valid value for the upper/lower limit:
  - Factory value (2SD)
  - RiliBÄK (Guidelines of the German Federal Medical Society) value (calculated from the factory value)
  - A previously configured value
- It is necessary to ensure that the value entered by the user for the upper limit is greater than the lower limit.
  Entering two equal values as the upper and lower limit is not permitted.
- The permitted range for entering the individual limits is restricted to the range of the factory limits. The limits cannot be extended. as this would not ensure the system specifications.

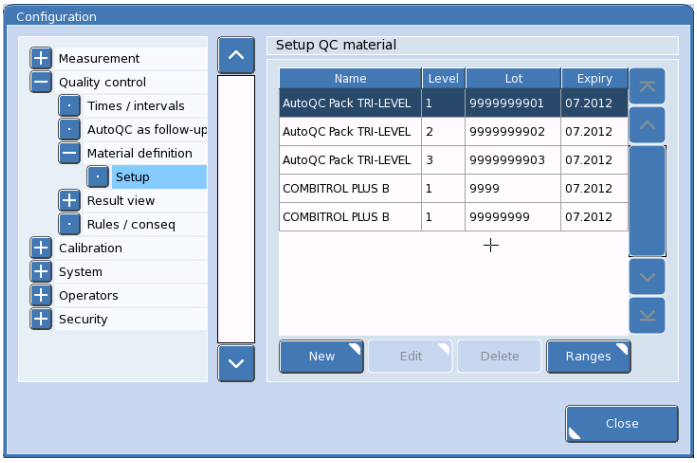


Figure D-63

1 Select the corresponding material in the list and press the [Ranges] button.

2 In the editing window for the respective limit. select the parameter to be modified in the list and enter the corresponding new target values.

In the "Type" column, an (E) is added to the configured rule.

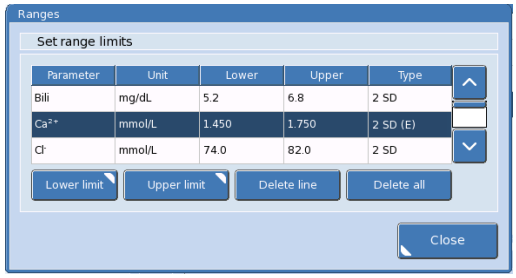


Figure D-64

Lower limit	Editing the lower limit of a target range.
Upper limit	Editing the upper limit of a target range.
Delete line	The entered values of the selected line are deleted and reset to the starting values.
Delete all	All entered values are deleted and reset to the starting values.

3 After pressing the [OK] button and confirm the prompt: [Confirm changes to QC ranges], the new range limits are taken over and activated.

Range limit correction due to new manufacturer specifications

Correction of range limits due to new manufacturer specifications from Roche for known QC materials is carried out using a modification-barcode-sheet made available by Roche Service. An accompanying letter lists the parameter(s) for which new range limits are provided.

CAUTION

Caution

If individual range limits have been configured for one of the parameters affected by the range limit correction, these are overwritten and the new factory values (2SD) and the German RiliBÄK limits derived from them are taken over.

The identifier (E) is deleted in the "Type" column.

The limits of parameters that are not affected by the range limit correction are unchanged. Any existing individual limits are maintained and identified using an (E).

Press the [New] button. All four barcodes have to be scanned using the barcode scanner.

See *Material definition* on page D-90.

The new target values of the affected parameters are entered and in the "Type" column, an (E) is added to the corresponding parameter and configured rule.

Note

If the QC material is not yet known, the adaptation barcode sheet cannot be used; instead, the modified barcode sheet must be scanned.

See *Material definition* on page D-90.

Display of results

Automatic report

Using this function, you can define various printer settings for the QC results. The following options are available:

Print automatically	When this function is enabled, manual QC and manual AutoQC results are printed out automatically. Scheduled AutoQC measurements are never printed out automatically, irrespective whether this function is enabled or not.
Number of printouts	Defines the number of printouts (max. 3) for automatic printouts.

QC evaluation

Note

If a parameter is not calibrated, no QC evaluation can take place.
To remedy this, calibrate the respective parameter and repeat the QC measurement.

The following methods are used to evaluate the QC results:

Verifying the ± 2σ range

If the current QC result is within the ± 2σ range corresponding to the specified target value range (refer to package text or stored data on the memory chip), the respective parameter is evaluated as "OK".

If the current QC result is outside the ± 2σ range, the respective parameter is evaluated as "nOK".

For additional information, refer to section *QC rules and consequences* on page D-97.

Multirules

The evaluation of QC results is based on the Westgard[(a)] rules and their interpretation for blood gas analysis[(b)]. The Multirules process was derived from these rules. It permits early detection of random and systematic errors associated with the measuring device and its operation.

The aim of using a Multirule evaluation of your QC results is to keep false rejections low while the error detection rate is kept high at the same time.

Within the Multirule evaluation Rule 1 (2 SD limits) is not the only criteria for evaluating but it is the precondition for any further evaluation by the other rules. QC results within the 2 SD limits are in any case ok but a violation of the 2 SD limit is the precondition to take the other rules into consideration. So a QC measurement always has to violate a combination of rules to be evaluated as nok.

Note

The Multirules process can be applied in conjunction with a suitable control material only.

Overview of the Multirules

$\mathbf{N_L}$	number of individual measurements per level (L=Level)
m	QC measurement value of one level and one parameter
$\bar{\mathbf{x}}$	mean value. taken from the insert sheet or calculated based on at least 20 and no more than 100 individual measurements
σ	standard deviation

(a) James O. Westgard. et al: *A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry.* Clinical Chemistry, Vol. 27, No.3, 1981

(b) Elsa F. Quam BS. Lorene K. Haessig BS. Marlene J. Koch BS: *A Comprehensive Statistical Quality Control Program for Blood Gas Analyzers.* Journal of Medical Technology 2:1 January 1985

Rule	Description
1. $1_{2\sigma}$	QC measurement value (m) is outside $\bar{x} \pm 2\sigma$
2. $1_{3\sigma}$	QC measurement value (m) is outside $\bar{x} \pm 3\sigma$
3. $(2 \text{ of } 3)_{2\sigma}$ [(a)]	Two of three QC measurement values are outside $\bar{x} \pm 2\sigma$ $N_L = 3$
4. $2_{2\sigma}$	2 QC measurement values (m) are outside $\bar{x} \pm 2\sigma$ $N_L \geq 2$
5. $6_{1\sigma}$	6 QC measurement values (m) are outside $\bar{x} \pm 1\sigma$ $N_L \geq 6$
6. 9_m	9 QC measurement values (m) are on the same side as the mean value $N_L \geq 9$
2SD range	Defined target values (ranges)

Table D-6 Multirules

(a) This rule is not used for QC evaluation on the **cobas b** 123 POC system.

Note

The Multirules process is applied after each individual QC measurement.
The Multirules are always applied only to the respective material/level combination.

The QC concept of the **cobas b** 123 POC system uses combinations of multiple Multirules rules for evaluation.

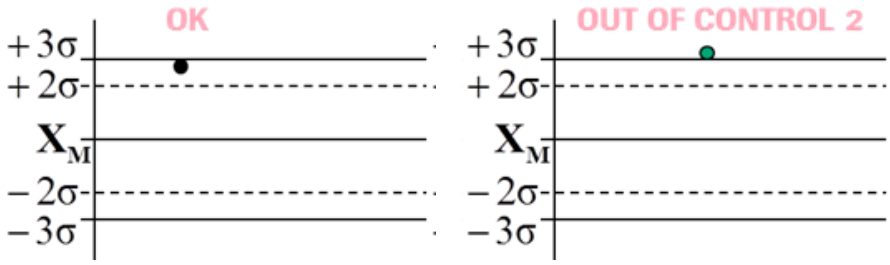
Multirules rule combinations

Note

The activation of range 2SD automatically deactivates all other rules (rules 1-6).

The following Multirules rule combinations are possible on the **cobas b** 123 POC system:

Set 1 Rule 1 and Rule 2.

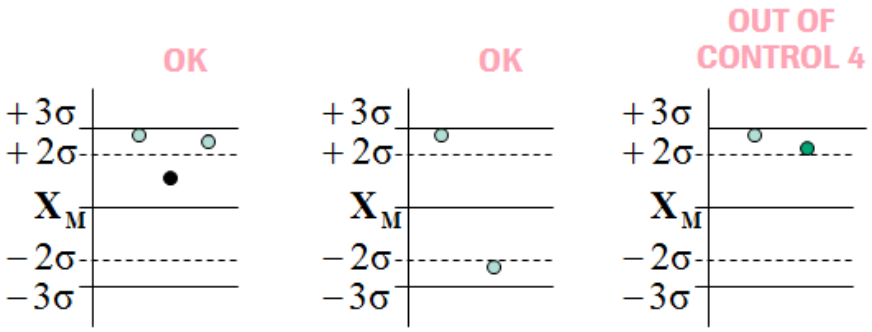


(Rule 1 = NOK) AND (Rule 2 = OK) = OK

(Rule 1 = NOK) AND (Rule 2 = NOK) = NOK

Figure D-65 Set 1

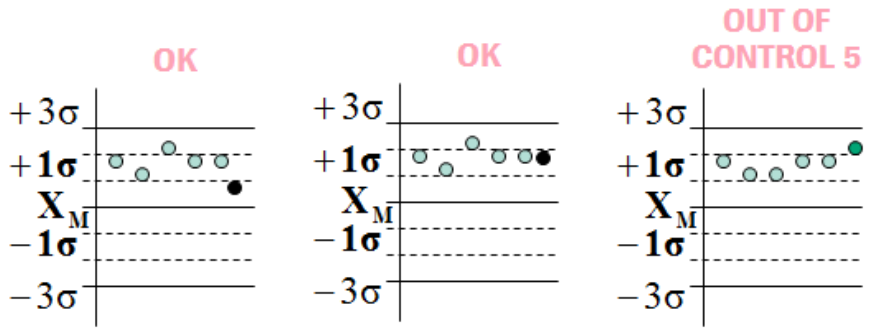
Set 2 Rule 1, Rule 2 and Rule 4.



(Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK)) = OK	(Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK)) = OK	(Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = NOK)) = NOK

Figure D-66 Set 2

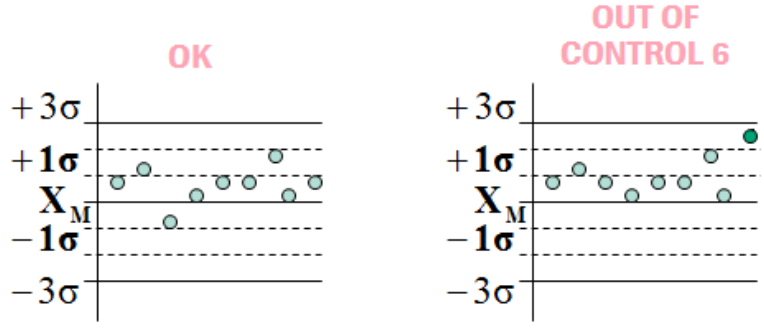
Set 3 Rule 1, Rule 2, Rule 4 and Rule 5.



(Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK)) = OK	(Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = NOK)) = OK	(Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = NOK)) = NOK

Figure D-67

Set 4 Rule 1, Rule 2, Rule 4, Rule 5 and Rule 6.



(Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK) OR (Rule 6 = OK)) = OK	(Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK) OR (Rule 6 = NOK)) = NOK

Figure D-68 Set 4

QC rules and consequences

To ensure that if the rules for QC evaluation are broken. the respective parameter cannot be used for sample measurement despite deviation from the specifications. all parameters should be assigned the QC consequence "QC lock".

To configure and review the assigned QC consequences, press the following keys:

☞ [Utilities] > [Configuration] > [Quality control] > [Rules & consequences]

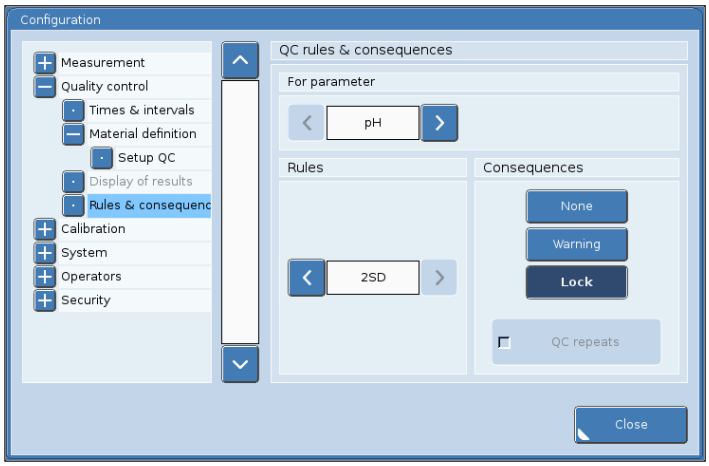
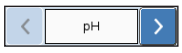


Figure D-69

► Defining QC rules & consequences



1 Select the desired parameter in the upper area of the screen using the arrow keys.

2 Select the corresponding QC rule by pressing the arrow keys.

You can select the following QC rules:

None	No rule
RiliBÄK	RiliBÄK ranges
Set 1	Rule 1 & Rule 2
Set 2	Rule 1. Rule 2 & Rule 4
Set 3	Rule 1. Rule 2. Rule 4 & Rule 5
Set 4	Rule 1. Rule 2. Rule 4. Rule 5 & Rule 6
2SD	Default

Table D-7

See section *QC rules and consequences* on page D-97.

Note

If "None - No rule" is selected as the rule, setting a consequence is disabled. It is not possible to select a consequence.

3 After selecting the desired rule, assign the corresponding consequence.

You can select the following QC consequences:

None	No consequence
Warning	QC warning
Lock	QC lock (default setting)

4 Press the [Close] button to apply the configured QC rules and consequences.

► Enabling QC repeats

If the rules for QC evaluation are broken for one or more parameters. it is possible to carry out an automatic repeat measurement of the corresponding level if the measurement is an automatically called AutoQC measurement.

If the [QC repeats] button is enabled, after the QC measurement with QC rule violation, a repeat measurement is carried out in the same level.
Remove the check mark to disable the QC repeat measurements.

Display of the QC consequences

If the configured rules for QC evaluation are broken, the following parameter symbols appear on the overview screen:

QC warning:

For a warning, the corresponding parameter has a dark yellow background in the parameter selection field, but continues to be ready for measurement.

QC lock:

For a lock, the corresponding parameter in the parameter selection field is marked in red and indicated by an ampoule icon. The parameter is not available for a measurement.

No consequence:

Although one of the configured rules for QC evaluation has been broken, the parameter is available for a measurement.

Warning

Ignoring QC measurement results may lead to incorrect patient measurements, which may result in incorrect clinical decisions. Danger of injury.

Removing the QC consequences

A QC lock or QC warning can be removed via the [Info] button in the overview screen only.

When the [Info] button is pressed, the "Parameter information" screen is displayed.

The "Parameter information" screen lists the parameters to which a QC lock or QC warning has been assigned as the QC consequence.
The affected parameters are listed with the corresponding material/level combination.

Automatic correction

To remove a QC lock or a QC warning, carry out a proper QC measurement within the range, the lock is removed when the same level is measured. This can be done by either an automatic or manual QC measurement.

Manual correction

Warning

A manual correction of a QC lock or QC warning is permitted only if no Roche QC material is available, otherwise it would violate the accepted QC rules.

► **Removing a QC consequence:**

1. Press the [Info] button.
2. Select the corresponding parameter and press [Remove parameter QC lock/QC warning].
3. Carry out a QC measurement with an available QC material.

Note

Calibration and/or replacement of a Sensor Cartridge do not result in a QC lock.

QC troubleshooting

Description of the current problem

After a QC measurement, one or more parameters receive the evaluation "nOK" (QC warning or QC lock).

The respective parameters and the QC material (material type, level) that are causing the problem in the database are listed under [Workplace] > [QC database].

The QC problem can be solved only by performing a QC measurement correctly and within range, using the same material/level combination.

Classification of QC problems

Group A

The cause is an aspiration or positioning problem of the QC sample. In this case, more than one parameter is usually affected. A cause belonging to Group A can be identified in the database under [Workplace] > [QC database] > (select corresponding QC measurement) > [Detail] when an error message appears for the corresponding parameter instead of a result.

Group B

The cause is a QC result that exceeds the target value range.
A cause belonging to Group B can be identified in the database under [Workplace] > [QC database] > (select corresponding QC measurement) > [Detail] where a QC result is present, but it exceeds the target value range or breaks the rules of evaluation and is indicated with "nOK".

Troubleshooting – Group A (aspiration or positioning problem)

1 Check that all parameters are calibrated.

2 Repeat the QC measurement (with the same level)

If the error persists, notify the Roche Service Hotline.

Troubleshooting – Group B (QC result exceeds the target value range)

1 Carry out a system calibration.

2 Check the following points:

- **QC measurement took place after a replacement of a Fluid Pack:**
  - Check whether the Fluid Pack was stored according to the specifications prior to installation.

  For specific details about the specifications, refer to chapter 4 *Specifications*, section *Temperature/humidity/stability* on page B-51.
- **Manual QC measurement**
  - Check whether the QC ampoules were stored at room temperature for at least 24 hours before use.
  - If the material is a manually defined QC material, check that the target value ranges under [Utilities] > [Configuration] > [Quality control] > [Material definition] > (select corresponding material) > [Ranges] match the target value ranges in the package insert.
  - If carrying out a manual QC measurement, make sure to keep the time between opening the ampoule and the QC measurement as short as possible. Also, make sure to use ampoule adapters.
- **AutoQC measurement**
  - If using an AutoQC module, ensure that the AutoQC Pack has been stored at least 24 hours at room temperature or in the AutoQC module before use.
  - Repeat the AutoQC measurement.
    - If the error persists, carry out a manual QC measurement with the same level to rule out contamination of the QC materials due to improper storage of the AutoQC Pack.

3 Repeat the QC measurement (with the same level)

- If the error persists, replace the Fluid Pack if parameters of the oximeter module (sO_2, tHb, Hb derivatives, bilirubin) are affected.

4 Repeat the QC measurement (with the same level)

- If the error persists, replace the Sensor Cartridge if parameters of the Sensor Cartridge are affected.

5 If the solution is unsuccessful, notify the Roche Service Hotline.

Calibration

In this chapter, all automatic and user-activated calibrations are described.

In this chapter *Chapter* 10

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General information about calibrations

Calibrations are necessary to prepare the individual measurement parameters for the measurement. The parameters of the **cobas b** 123 POC system are calibrated using three stable. aqueous solutions. which are in airtight bags inside the Fluid Pack. Apart from ambient air. no additional calibration media are required.

Calibrations are performed automatically at defined times. but they can also be called up manually at any time.

Calibration scheme

After a new Sensor Cartridge is inserted. excessive parameter drift can occur. particularly during the RUN-IN phase. The **cobas b** 123 POC system carries out monitoring measures on its own and. as a remedial action. enables a shortened interval for the 2P calibration and additional PO2 calibrations.

Calibration scheme A	Normal calibration interval according to the setting.
Calibration scheme B	The configured calibration interval is divided by two. In addition. a standby calibration is run.
Calibration scheme C	The configured calibration interval is divided by four. In addition. a standby calibration is run and post-calibration mode is enabled.
Calibration scheme D	The configured calibration interval is divided by four. In addition. a standby calibration is run. post-calibration mode is enabled and PO_2 is assigned a calibration alarm.

The current calibration scheme is visible in the instrument database and in the consumables status.

☞ [Instrument] > [Consumables status] > [Sensor Cartridge]

Automated calibrations

The following calibrations are initiated and performed automatically by the instrument and ensure that the **cobas b** 123 POC system is ready for measurements.

Caution

During various calibrations it is not possible to carry out measurements. QC measurements or replacement routines.

If one of the following calibrations are performed. the overview screen changes and now displays a progress bar on the screen.

When a 2P calibration or system calibration is running. it can be stopped at any time using the [Cancel] button.

A 1P calibration cannot be stopped prematurely using the [Cancel] button.

Expect short delays until the instrument has returned to "Ready" mode.

System calibration (Sys. cal.)

Note

The starting time for the system calibration can be permanently set by the user. In other words. the calibration can be performed at a time when the **cobas b** 123 POC system is not needed or the sample volume of the lab or hospital ward is low.

This calibration is performed every **24 hours** (fixed interval. user-defined starting time) and comprises:

- Wavelength calibration of the polychromator (optional)
- Calibration of the oximeter module lamps (optional)
- Layer thickness calibration of the cuvette (optional)
- 2-point calibration of all parameters
- O_2 air calibration
- Determining the actual O_2 value of the standby solution

For settings, refer to the section *Settings for calibration* on page D-110.

Note

After a new Sensor Cartridge is inserted. the first system calibrations in the RUN-IN phase are called "Sys. cal. RUN-IN".

2-point calibration (2P cal.)

The 2P calibration is performed automatically every **4. 8** or **12 hours (default)**. The measurement parameters are calibrated with three solutions (Cal 1. Cal 2. and standby solution) of different concentration. The 2P calibration consists of the following substeps:

- Layer thickness calibration of the cuvette (optional)
- 2-point calibration of all parameters

For settings, refer to the section *Settings for calibration* on page D-110.

1-point calibration (1P cal.)

1P calibrations are performed automatically. The time interval between the 1P calibrations is **60 minutes** (for BG in the USA. the required O_2 1P calibration interval is 30 minutes). The measurement parameters are calibrated using a solution (CAL 1 solution). The 1P calibration consists of the following substep:

- 1-point calibration of the sensor parameters

PO_2 calibration (*P*O_2 cal.)

The *P*O_2 calibration or actual value determination calibrates the *P*O_2 sensor and measures the oxygen content of the standby solution. During the RUN-IN phase. the *P*O_2 calibration appears as a standalone calibration. After the RUN-IN phase. the *P*O_2 calibration is part of the system calibration.

Recalibration (RECAL)

Recalibration is an automatic calibration carried out after each measurement. The measurement parameters are calibrated using a solution (STDBY solution).

Oximeter calibration (Oxi cal.)[(a)]

Calibrating the oximeter module requires wavelength calibration of the polychromator. calibration of the integration time and layer thickness calibration of the cuvette.

Wavelength calibration of the polychromator

This calibration is carried out in the course of the system calibration. A built-in neon lamp (spectral light source) is used together with the colorless standby solution to calibrate the polychromator.

A shortened wavelength calibration of the polychromator (1P calibration) takes place with each measurement.

Calibration of the integration time

The integration time is also calibrated in the course of the system calibration.

Layer thickness calibration of the cuvette (Oxi LT cal.)

This calibration is carried out in the course of the 2P calibration and the system calibration. The layer thickness of the cuvette must be calibrated because it is directly associated with the measured absorption. Use the CAL 2 solution which contains a dye for this purpose.

Caution

When using a new Fluid Pack. the cuvette requires a running-in time of 24 hours. During this time. a layer thickness calibration is automatically carried out at predefined time intervals.

Standby calibration (STDBY cal.)[(b)]

In case of a parameter status change. the standby calibration is carried out automatically every 30 minutes of the end of the last 1P calibration. The measurement parameters are calibrated using a solution (STDBY solution).

Monitoring

In case of a temporary status change of PO_2 between two calibrations. an entry called "Monitoring" is created in the calibration database and the parameter is set to "Not calibrated".

STDBY shifting

Every 20 minutes after the last fluidic action (e.g. measurement or calibration). the standby solution in the measuring chamber is moved automatically and an entry is made in the calibration database called "STDBY shifting".

(a) For instruments with COOX module only.

(b) Corresponds to BG 1P calibration for USA.

Wash cycle

During the RUN-IN phase. the measuring chamber is filled every hour with new standby solution and an entry in the calibration database called "Wash cycle" is made.

Calibrations activated by the user

In the "Instrument" menu, you can also call up calibrations manually.

The following calibrations can be performed manually:

- Calibration for "Ready"
- 1-point calibration (1P cal)
- 2-point calibration (2P cal)
- System calibration
- Oximeter calibration[(a)]

To execute the desired calibration, press the corresponding selection button.

See section *Automated calibrations* on page D-105 for more details.

Note

Performing a "user-activated calibration" does not affect the scheduled time for "automated calibrations".

When a 2P calibration or system calibration is running. it can be stopped at any time using the [Cancel] button.

A 1P calibration cannot be stopped prematurely using the [Cancel] button.

Expect short delays until the instrument has returned to "Ready" mode.

Calibration for "Ready"

The system automatically selects the calibration needed to bring all measurement parameters into "Ready" mode.

(a) For instruments with COOX module only.

Display of results

The calibration data is displayed in the database.
Press the following buttons to call up the database:

☞ [Workplace] > [Calibration database]

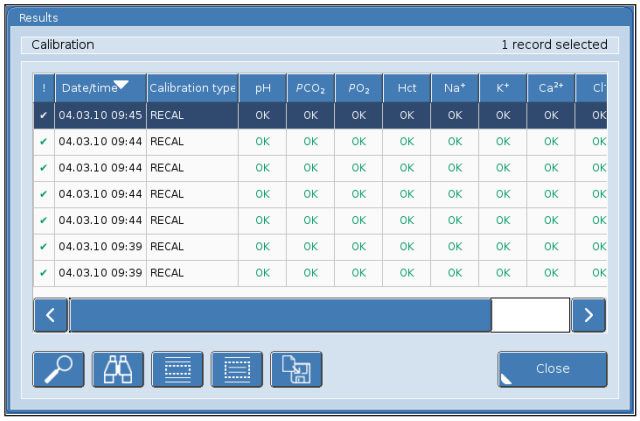

Figure D-70 Database with calibration data

The calibration data are listed on the screen based on how the display settings have been defined.

See section *Settings for calibration* on page D-110 for more details.

For some data (e.g. Date/Time). a sorting option is provided in the corresponding column.

The first column summarizes the overall status of all parameters of a calibration. The following symbols are used for this purpose:

✔	For this calibration. all parameters are calibrated.
✕	For this calibration. one or more parameters are not calibrated.

Select the entry using the arrow keys or by selecting the desired data directly from the list. The selected data are highlighted in dark blue.

The database has different functions such as "Search" or "Detail" to better display calibration data. The corresponding function keys are not activated until you mark multiple records.

Press the [Legend] button for a detailed description of the individual functions.

► **Exporting the data to USB**

1 Select the data for the export in the database.

2 Press this key to export the data to a USB storage device.

3 Follow the instructions on the screen.

👁 For additional information, refer to chapter 12 *Software functions*, section *USB data export* on page D-152.

► **Printout of the report**

As soon as all calibration data are available in the database. a report can be printed out from the database.

Press the [Print] button on the right edge of the screen for a printout.

👁 Refer to section *Report* on page D-112 for more details.

Settings for calibration

Go to the "Utilities" menu and press the following button:

☞ [Configuration] > [Calibration]

A menu tree for selecting miscellaneous settings appears on the left edge of the screen.

The following calibration settings can be configured:

- Times/intervals
- Report

Times and intervals

In the calibration scheduler, you can define the starting time for the system calibration and select the interval for the 2-point calibration.

Note

The starting time for the system calibration can be permanently set by the user. In other words. the calibration can be performed at a time when the **cobas b** 123 POC system is not needed or the sample volume of the lab or hospital ward is low.

The calibration times are displayed on a time scale.

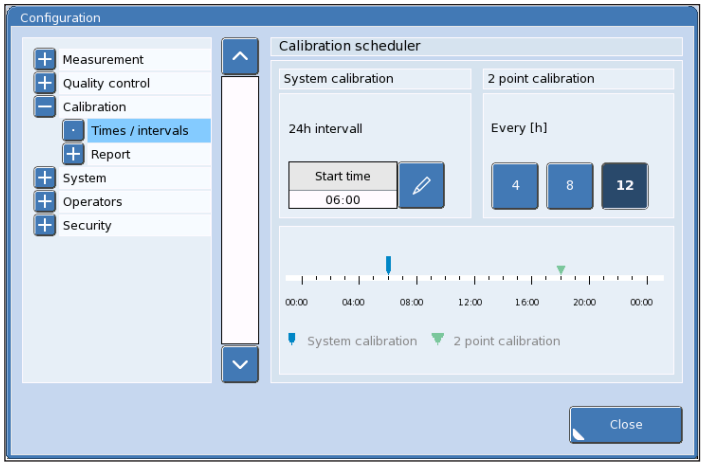

Figure D-71 Calibration scheduler including time scale

Determining the starting time of the system calibration

The system calibration is performed automatically every 24 hours.

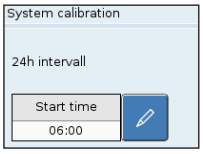

Figure D-72 Changing the starting time

1 In order to enter a new starting time or change an existing one, press the [Pencil] button.

2 An additional input field appears.
The starting time can be changed using the arrow keys.

3 The starting time input field is closed by pressing the [OK] button.

Changing the interval of the 2P calibration

The 2-point calibration is performed automatically every **4. 8** and **12 hours (default)**.

The interval between the individual 2-point calibrations can be determined by pressing one of the buttons available for selection.

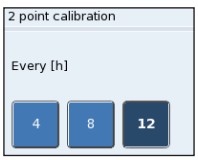

Figure D-73 Changing the 2P calibration interval

The enabled interval is highlighted in dark blue.

Beginning with the starting time for the system calibration. an automated 2-point calibration is performed in this interval.

Report

Using this function, you can define various printer settings for the calibration.
The following options are available:

Print automatically	When this function is enabled. the calibration reports are printed out automatically at the printer.

Calibration verification control

In this chapter the AutoCVC workflow is described.

In this chapter *Chapter* 11

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General information

Calibration verification is testing of materials of known concentration to assure that the instrument is accurately measuring values throughout the reportable range.

This CVC must be performed to fulfill CLIA-88 regulations at 42CFR493.1255(b)(3) at least once every 6 month or more frequently whenever the following occur:

- Fluid Pack and/or Sensor Cartridge are changed to new lot numbers, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes,
- there is a major preventive maintenance or replacement of critical parts that may influence the performance of the instrument,
- after Depot-Repair,
- control materials reflect an unusual trend or shift, or are outside of the specified ranges.

Insert AutoCVC Pack

Note

The AutoCVC Pack must be stored to room temperature at least 24 hours prior to use.

CAUTION

Caution

Always store **cobas b** 123 AutoCVC Packs upright.

Starting from the "Workplace" menu, press the following button for inserting the AutoCVC Pack:

☞ [Change AutoQC Pack]

Follow the instructions on the screen.

1 The instrument automatically prepares the procedure like the AutoQC Pack change.
Wait until the preparation time is finished.

The front door is unlocked and must be opened within 30 seconds.

👁 For details, refer to the section *Unlocking the front door* on page E-17.

2 Open the front door.

When removing the AutoQC Pack. fragments of ampoules that have been broken open could escape from the AutoQC Pack. There is a risk of injury.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Dispose of the AutoQC Pack according to applicable local codes and regulations.

Caution: Danger of spills.

3 Remove the AutoQC Pack.

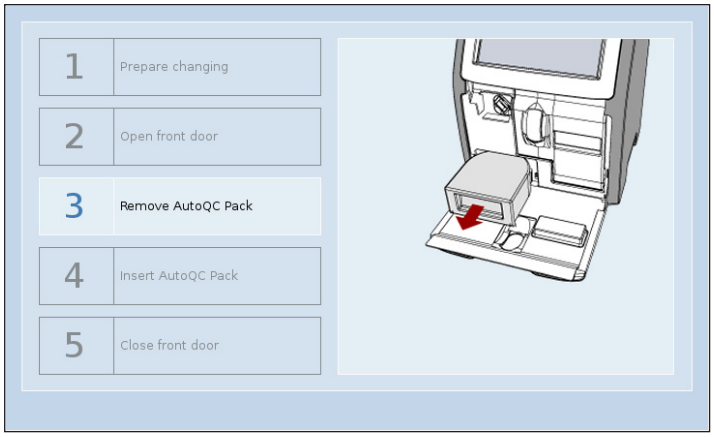


Figure D-74

Note

Dispose of the AutoQC Pack according to local regulations.

4 Insert the AutoCVC Pack.

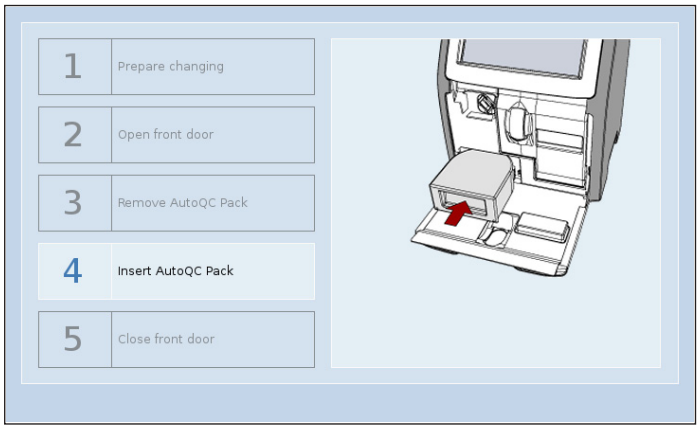


Figure D-75

CAUTION

Caution

If you suspect damage to a new AutoCVC Pack. do not under any circumstances insert the defective AutoCVC Pack into the instrument. Using a damaged AutoCVC Pack can destroy the AutoQC module.

The data of the consumables are imported automatically.

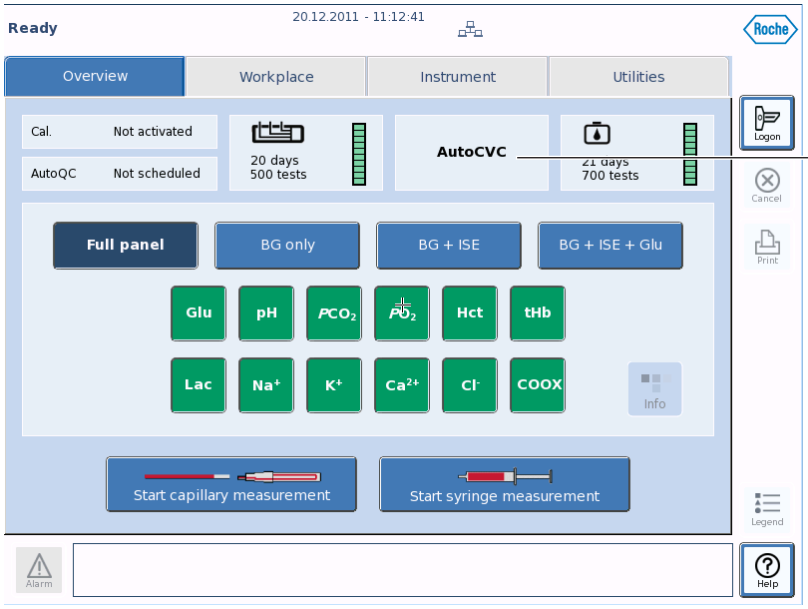
After the AutoCVC Pack chip is detected. the user interface automatically moves on to the next step.

If an invalid AutoCVC Pack has been inserted. the corresponding error message appears on the screen.

For an exact description, see chapter 14 *Troubleshooting*.

5 Close the front door. The AutoCVC material is installed and instead of the AutoQC Pack information. the text "AutoCVC" appears on the screen.

See Figure D-76.



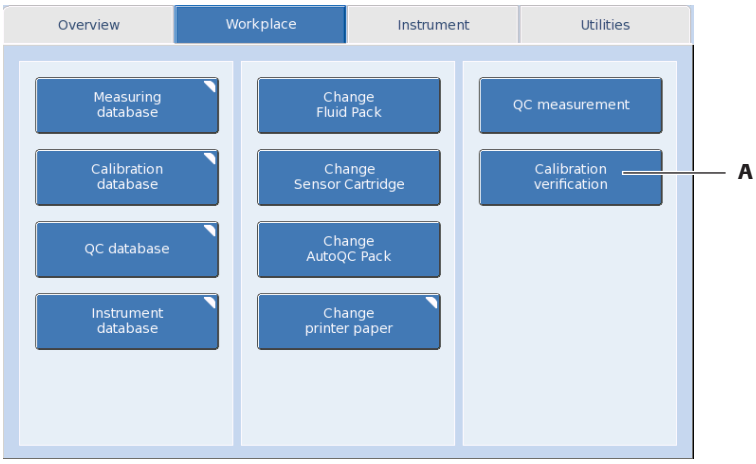
A Installed AutoCVC Pack

Figure D-76

Manual AutoCVC measurement

Go to the "Workplace" menu and press the following button:

☞ [Calibration verification]



A Button "Calibration verification"

Figure D-77

The following screen appears:

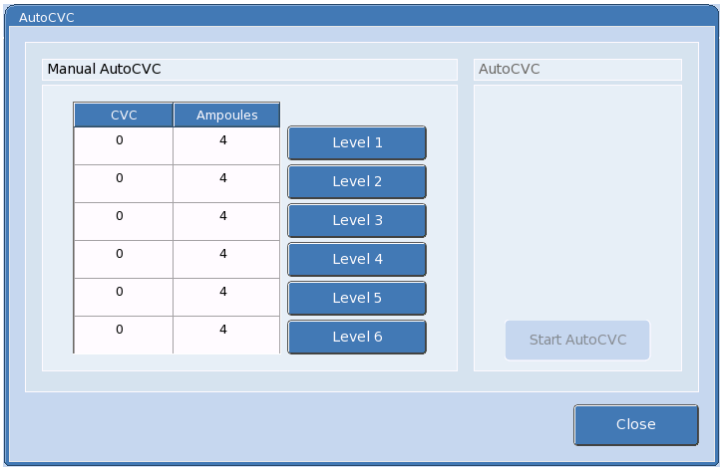


Figure D-78

The CVC measurement is started by pressing the desired level. e.g. the [Level 1]. [Level 2] and [Level 6] button.

In the table all performed CVC measurements and the remaining ampoules are listed.

Note

The feature [Start AutoCVC] will be released in an upcoming software version.

As soon as the CVC measurement process is finished the results appear on the "CVC values" screen automatically. Depending on how the display has been defined. the results are listed on the screen.

The sort feature by "Status" allows. for example. those CVC measured values that lie outside the specified range to be found quickly.

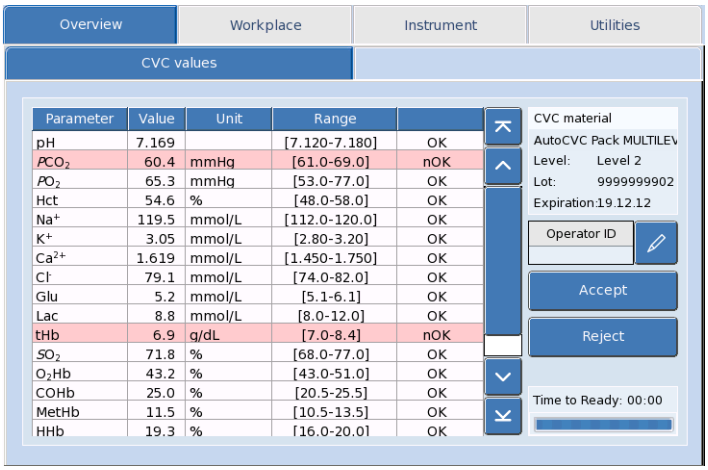


Figure D-79 Result screen

Depending on the status. the CVC results are indicated by an additional text:

OK	CVC results are inside the target range
nOK	CVC results are outside the target range (the corresponding lines have a red background)

Table D-8 CVC status display

Confirming CVC results manually

Press the [Accept] button for a manual confirmation of the CVC results.

Accept	CVC results are confirmed manually and saved.

Rejecting CVC results manually

To not confirm the CVC results, press the [Reject] button.

Reject	CVC results are not confirmed. but stored in a separate area of the database.

Note

If neither the [Accept] nor the [Reject] button is pressed, the CVC measurement will be accepted after the timeout.
If mandatory inputs are missing, the CVC measurement is rejected.

CVC database

Press the following buttons to call up the database:

☞ [Workplace] > [QC database]

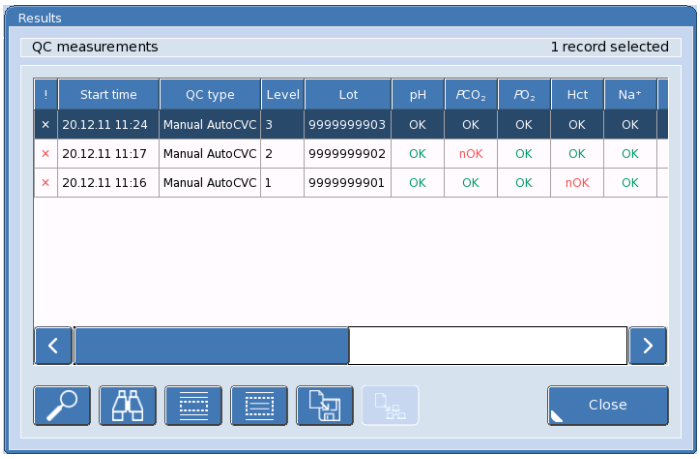


Figure D-80 Database with QC results

Depending on how the display has been defined, the CVC results are listed on the screen.

See section *Display of results* on page D-62 for more details.

For some data (e.g. Date/Time), a sorting option is provided in the corresponding column.

The first column summarizes the overall status of all parameters of a CVC measurement. The following symbols are used for this purpose:

✔	For this CVC measurement, all parameters meet the target ranges.
×	For this CVC measurement, one or more parameters did not meet the target ranges.

Select the entry using the arrow keys or by selecting the desired data directly from the list. The selected data are highlighted in dark blue.

The database has different functions such as "Search" or "Detail" to better display CVC results. The corresponding function keys are not activated until you mark multiple records.

Press the [Legend] button for a detailed description of the individual functions.

► **Exporting the data to USB**

1 Select the data for the export in the database.

2 Press this key to export the data to a USB storage device.

3 Plug in the USB storage device.

Figure D-81

4 Press the [Start] button to start the data transfer.

Note

If the USB storage device does not have sufficient storage space available, a corresponding error message appears. Data transfer is cancelled.

5 Disconnect the USB storage device after the data transfer has been completed.

For additional information, refer to chapter 12 *Software functions*, section *USB data export* on page D-152.

► Printout from the database

1 Select the desired data from the list.

2 Press the [Print] button on the right edge of the screen to start the print process.

Note

The print function in the database is not activated until at least one data entry in the list is marked.

Configuration of the analytical measurement range (AMR)

When the CVC measurement is finished and the results are evaluated. it may be necessary to adapt the analytical measuring range (AMR) according to the results of CVC measurement.

This modification can be done according to the customer's own calculation and local regulations.

Press the following buttons:

☞ [Utilities] > [Configuration] > [Measurement] > [Parameter] > [AMR]

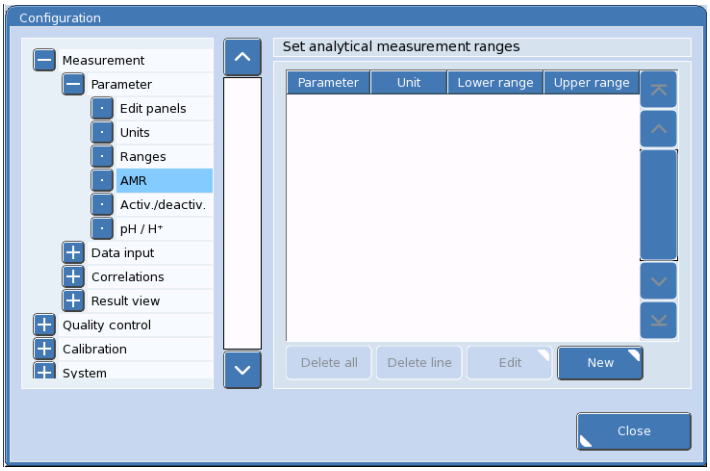


Figure D-82

► **Setting up the AMR**

1 Press the [New] button.

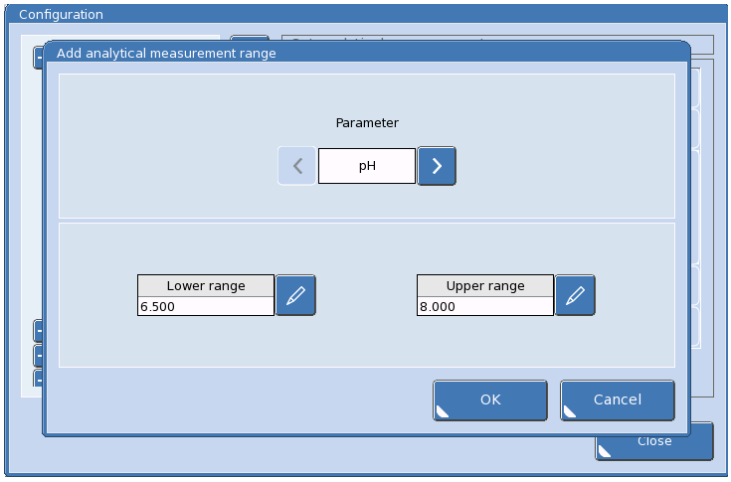
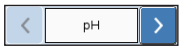


Figure D-83



2 Use the arrow keys to select the desired parameter to be modified.


Pencil

3 To edit the lower range press the [Pencil] button.

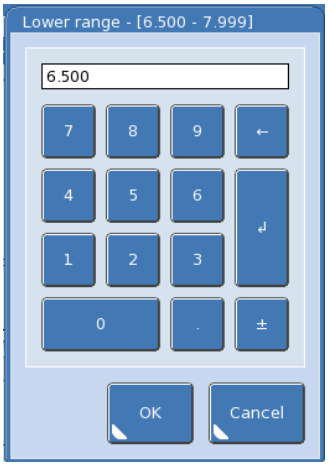


Figure D-84

4 Enter the new value.


CAUTION

Caution

The new value has to be within the measurement ranges provided by Roche.

5 Press the [OK] button to save the changes.

6 Repeat the procedure for the upper range and for additional parameters.

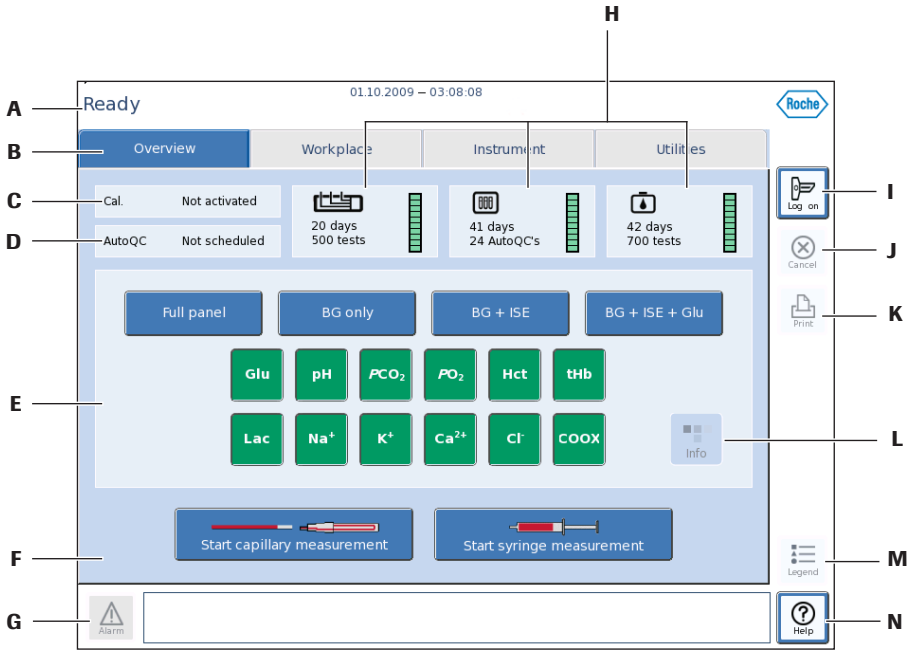
Software functions

This chapter describes the individual software functions.

In this chapter *Chapter* 12

"Overview" menu

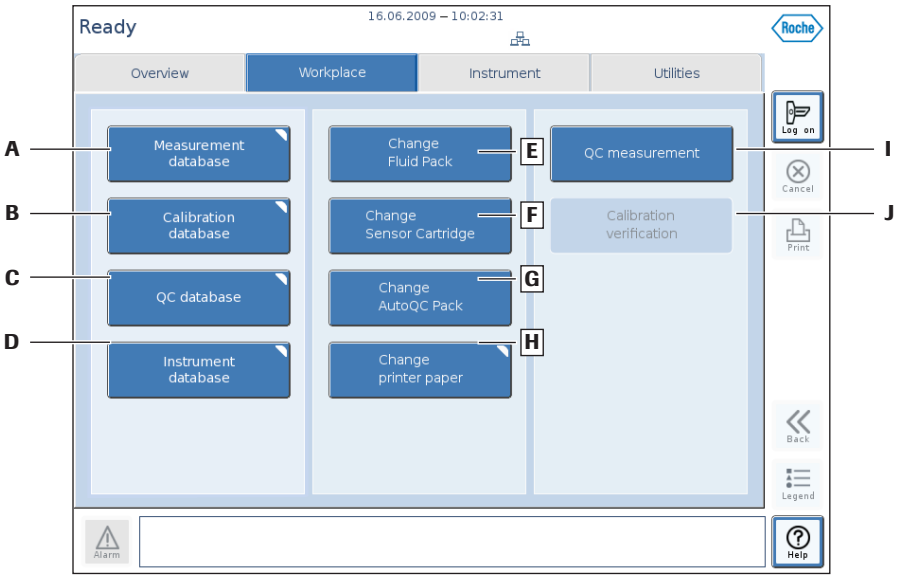
All of the data (results, operating instructions, alarms, warnings, etc.) are displayed on this screen. Measurements are started in this menu as well.



A	Status area	**H**	Status display for consumables
B	Menu	**I**	Log on
C	Next calibration	**J**	Cancel
D	Next AutoQC measurement	**K**	Print
E	Parameter selection field	**L**	Info
F	Start measurement	**M**	Legend
G	Alarm area	**N**	Online help

"Workplace" menu

In this menu, you can call up individual replacement routines, manual QC measurements and individual databases.



A Measuring database
B Calibration database
C QC database
D Instrument database
E Change Fluid Pack
F Change Sensor Cartridge
G Change AutoQC Pack
H Change printer paper
I QC measurement
J Calibration verification

Figure D-85

Database

All results of measurements, calibrations and quality control procedures and instrument data are stored in the corresponding databases, from where they can be displayed and printed at any time.

The following databases are available in the "Workplace" menu:

- Measuring database
- Calibration database
- QC database
- Instrument database

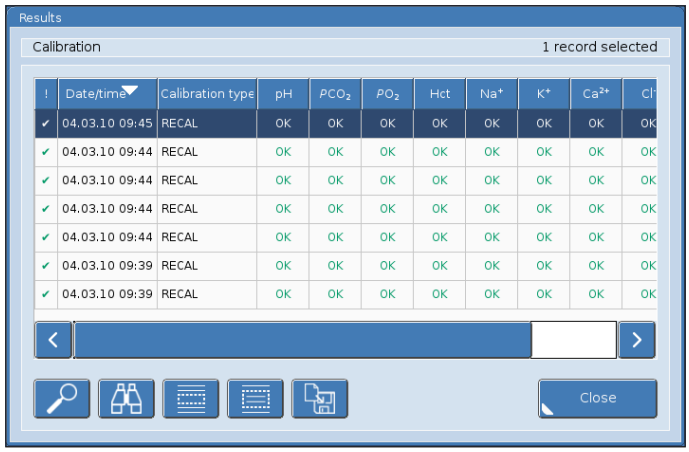


Figure D-86 Calibration database

Depending on how the display has been defined, the results are listed on the screen.

For the settings of the various databases, refer to chapter 8 *Measurement*, section *Display of results* on page D-62 and chapter 9 *Quality control*, section *Display of results* on page D-93.

For some data (e.g. Date/Time), a sorting option is provided in the corresponding column.

Select the entry using the arrow keys or by selecting the desired data directly from the list. The selected data are highlighted in dark blue.

The database has different functions such as "Search" or "Detail" to better display the results. The corresponding function keys are not activated until you mark multiple records.

Press the [Legend] button for a detailed description of the individual functions.

Functions

Search You can use the search function to search for the following data entries in the database:

• Patient ID	• Last name
• Sample ID	• First name
• Order ID	• Birthday
• Operator ID	• Start time/End time

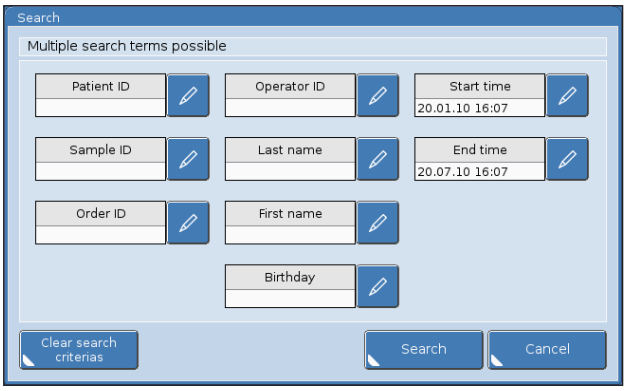


Figure D-87

► Starting the search


Pencil

1 Enter one or more search criteria using the [Pencil] button.

2 Pressing the [Search] button starts the search.

Note

Pressing the [Clear search criterias] button deletes all search criteria entered into the search screen.

3 If the search is successful, only those records that meet the search criteria appear on the screen.

Detail This function displays all measurement and calculated values of a selected data entry. Input values and patient data can be edited here.

Select additional lines After this function is activated, multiple data entries can be marked simultaneously.

Select all lines You can use this function to select and, where applicable, export all data entries. e.g. after doing a search.

Create Levey-Jennings graph This function is available in the detail view of a selected file entry only.

For additional information refer chapter 9 *Quality control*, section *Settings for quality control* on page D-86.

Send data You can use this function to resend selected data to a connected IT system.

For additional information refer to section *ASTM* on page D-139 and section *POCT1-A* on page D-140.

Export data

See section *USB data export* on page D-152 for more details.

Printout

► **Printout from the database**

1 Select the desired data from the list.

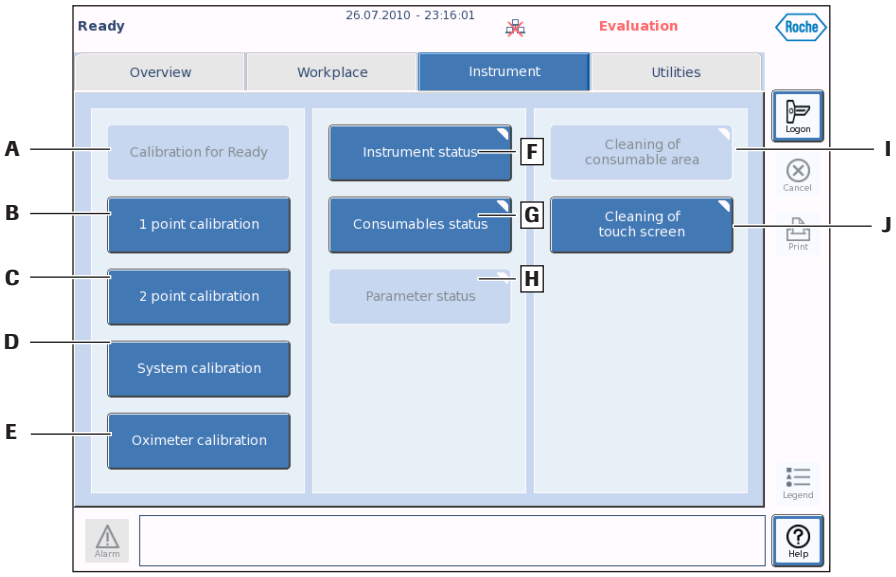
2 Press the [Print] button on the right edge of the screen to start the print process.

Note

The print function in the database is not activated until at least one data entry in the list is marked.

"Instrument" menu

All data relating to the instrument (e.g. status display) are displayed here. It is also possible to manually start calibrations and call up various maintenance tasks in this menu.



A	Calibration for "Ready"	**F**	Instrument status
B	1 point calibration	**G**	Consumables status
C	2 point calibration	**H**	Parameter status
D	System calibration	**I**	Disinfection of consumable area
E	Oximeter calibration	**J**	Disinfection of touch screen

Figure D-88

Instrument status

The instrument status shows the instrument version, serial number and the respective module status. In addition, network and software information are also shown there, and the sample counters are shown.

Consumable status

This function indicates the current status of the individual consumables.

For additional information, refer to chapter 6 *System components*, section *Status display for consumables* on page C-10.

Parameter status

This function indicates the current status of the measurement parameters.

Disinfection of consumable area[(a)]

This function allows you to disinfect the consumable area.

For details, refer to chapter 13 *Consumable change*, section *Disinfection of consumable area* on page E-6.

Disinfection of touch screen

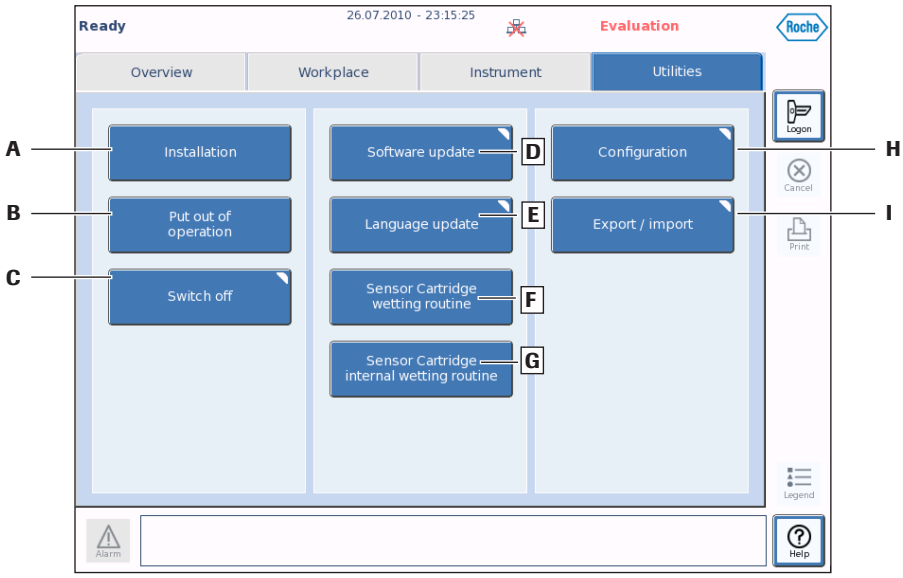
This function allows you to disinfect the touch screen by disabling the touch-sensitive layer of the screen for a short time.

For details, refer chapter 13 *Consumable change*, section *Disinfection of the instrument screen* on page E-6.

(a) Available at a later point after **cobas b** 123 POC system launch.

"Utilities" menu

Apart from utilities (troubleshooting routine, software update. etc.), you will also find the installation and put out of operation functions in this menu. Moreover, you can configure various settings in this menu.



A Installation
B Put out of operation
C Switch off
D Software update
E Language update
F Sensor Cartridge wetting routine
G Sensor Cartridge internal wetting routine
H Configuration
I Export/Import

Figure D-89

Configuration

You can configure the following settings in this menu:

- Measurement
- Quality control
- Calibration
- System
- Operators
- Security

Note

For explanations and instructions for the measurement, calibration and quality control settings, refer to the corresponding chapters of these Instructions for Use.

For additional information, refer to chapter 8 *Measurement*, section *Settings for measurement* on page D-53, chapter 9 *Quality control*, section *Settings for quality control* on page D-86 and chapter 10 *Calibration*, section *Settings for calibration* on page D-110.

A menu tree for selecting miscellaneous settings appears on the left edge of the screen.

Select the entry using the arrow keys or by selecting the desired setting function in the list.

► **Saving the settings**

When the [Close] button is pressed, an additional message box appears prompting the user to confirm the changes made to the settings.

The following options are available:

OK	The changes are saved.
Discard	The previous settings are restored.
Cancel	Return to the previous settings to make additional changes.

System

You can configure the following settings in this menu:

- Date/time
- Language
- Connectivity
- Instrument
- Export/Import

Date/time

In this area, you can define the date, time and the display format.

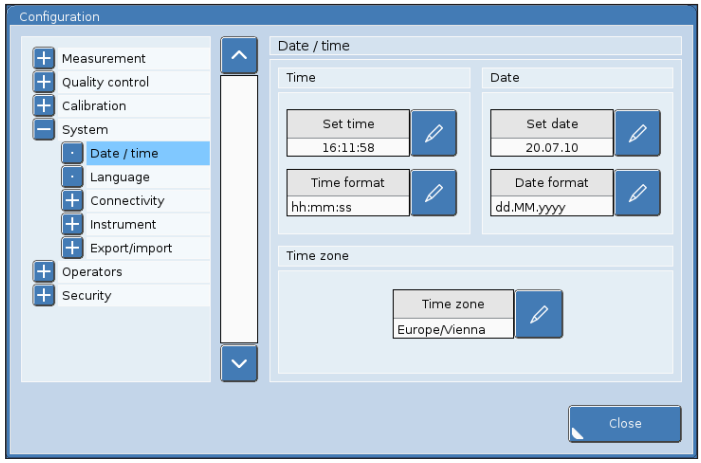


Figure D-90 Set the date/time

► Setting the time

1 To enter the time, press the [Pencil] button.
An additional input field appears.

2 The time can be changed using the arrow keys.

3 Pressing the [OK] button accepts the settings.

► Setting the time format

1 To set the time format, press the [Pencil] button.

2 A selective list appears on the screen. Select the corresponding time format.

3 Pressing the [OK] button accepts the settings.

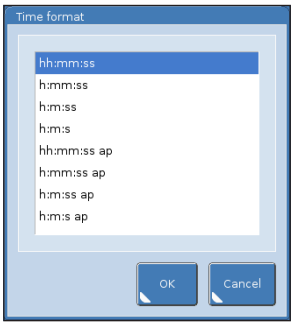


Figure D-91 Setting the time format

► Setting the date

1 To enter the date, press the [Pencil] button. An additional input field appears.

2 The month and the year can be changed using the arrow keys. Select the desired day in the calendar directly.

3 Pressing the [OK] button accepts the settings.

► Entering the date format

1 To set the date format, press the [Pencil] button.

2 A selective list appears on the screen. Select the corresponding date format.

3 Pressing the [OK] button accepts the settings.

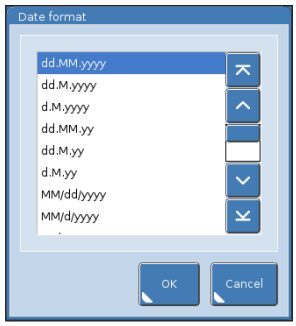


Figure D-92 Entering the date format

► Defining the region and the time zone

1 To enter the desired time zone, press the [Pencil] button.

2 A selective list appears on the screen. Select the corresponding region and time zone.

3 Pressing the [OK] button accepts the settings.

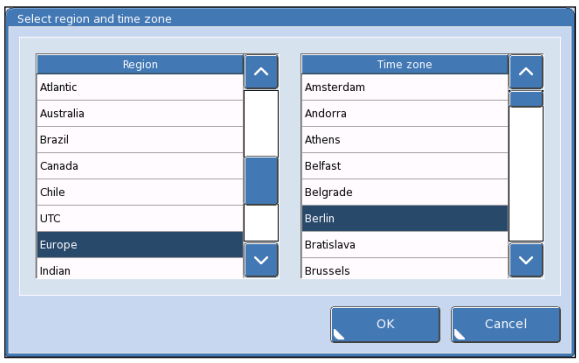


Figure D-93 Select region and time zone

Note

The instrument has to be restarted after changing the time zone. Press the [OK] button to start the procedure.

Language

In this area, you can define the language with which to operate the instrument. The screen texts, printouts and online help (where available) are displayed in this language.

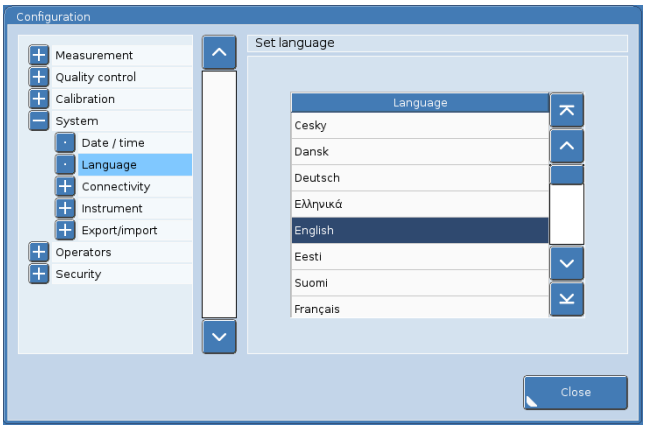


Figure D-94

► **Setting the language**

1 Select the desired language directly from the list.

2 When the [Close] button is pressed, an additional message box appears prompting the user to confirm the changes made to the settings.

Connectivity

You can configure the following settings in this area:

- Network
- ASTM
- POCT1-A
- **cobas**® e-support
- Queries
- Protocols
- Parameter

Network

Using this function, you can configure the desired network settings.

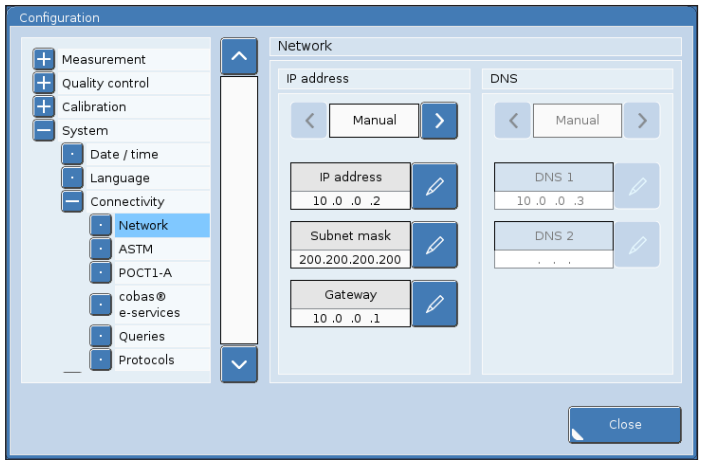


Figure D-95

► **Configuring the settings for a network connection manually**

1 In the "IP address" area, select the option [Manual].

2 Press the [Pencil] button to enter the desired IP address, subnet mask and gateway.

3 An additional input window opens for each of the entries.
Enter the required data.

4 Confirm the input using the [OK] button.

► **Obtaining the settings for a network connection automatically**

1 In the "IP address" area, select the option [DHCP].

2 The IP address, subnet mask and gateway are assigned automatically via the network.

► **Configuring the settings for DNS manually**

1 In the "DNS" area, select the option [Manual].

2 To enter the desired DNS servers 1 & 2, press the [Pencil] button.

3 An additional input window opens for each of the entries.
Enter the required data.

4 Confirm the input using the [OK] button.

► **Obtaining the settings for a DNS automatically**

1 In the "DNS" area, select the option [Automatic].

2 The data is assigned automatically via the network.

ASTM

Using this function allows the data of completed measurements to be transmitted.

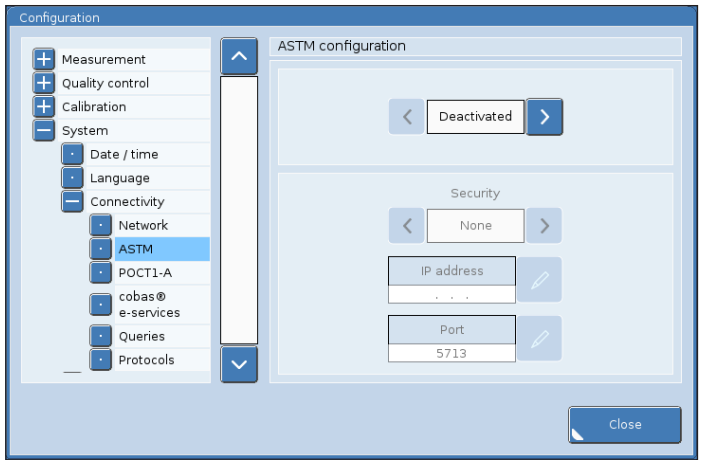


Figure D-96

► Configuring the settings for ASTM

1 For a connection to the ASTM host, select the [Activated] option.

Note

For transmitting an encrypted transmission protocol, select the option "SSLv3/TLSv1" in the "Security" area.

2 Press the [Pencil] button to enter the desired IP address and port.

3 An additional input window opens for each of the entries.
Enter the required data.

4 Confirm the input using the [OK] button.

POCT1-A

Using this function allows reports to be transmitted.

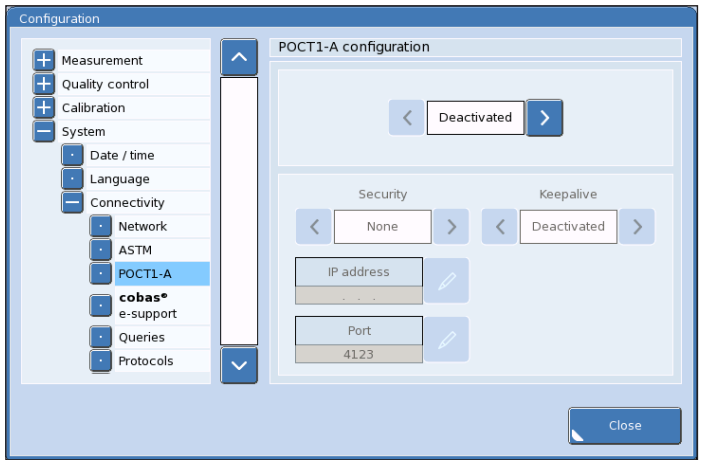


Figure D-97

► Configuring the settings for POCT1-A

1 For a connection to the POCT1-A host, select the [Activated] option.

Note

For transmitting an encrypted transmission protocol, select the option "SSLv3/TLSv1" in the "Security" area.

Activate "Keepalive" - this is a message sent by the instrument to LIS to check if the link between the two is operating or to prevent this link from being broken.

2 Press the [Pencil] button to enter the desired IP address and port.

3 An additional input window opens for each of the entries. Enter the required data.

4 Confirm the input using the [OK] button.

cobas® e-support

Using this function, you can transfer the following data between the **cobas b** 123 POC system and **cobas®** e-support:

- Log files
- Language files
- Troubleshooting-Report
- Software
- Configuration data

► Activate cobas® e-support

1 To activate a connection to **cobas®** e-support, select the [Activated] option.

Queries

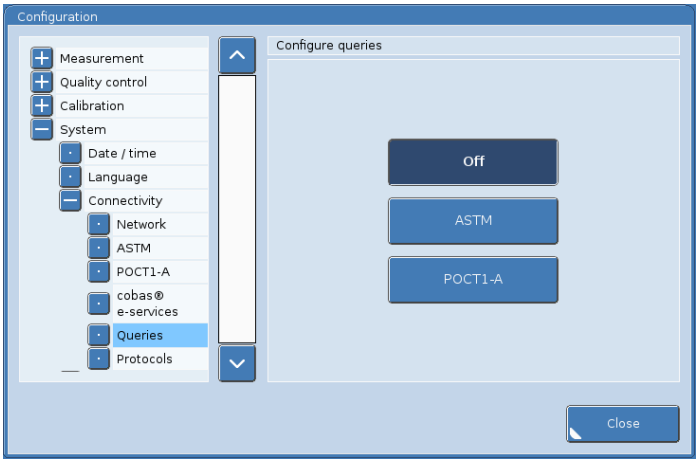


Figure D-98

Using this function, you can select the desired system that is to transfer the patient data to the **cobas b** 123 POC system in the event of a query.

For a query of the patient data, the input parameters "Patient ID" or "Specimen ID" can be transmitted by the **cobas b** 123 POC system to the laboratory information system and used by this system as a reference.

For setting the desired input values, refer to chapter 8 *Measurement*, section *Input values* on page D-58.

The laboratory information system then transmits the patient data to the **cobas b** 123 POC system.

Note

To start a query, either ASTM or POCT1-A must be enabled in the network settings.

Protocols

If the remote operator management is enabled, operator configuration on the instrument is deactivated.

Press the [Remote management] key to disable remote operator management.

Note

If the remote operator management is enabled on the **cobas b** 123 POC system, settings of the operator configuration can be changed using the Roche IT solutions (**cobas** IT 1000, **cobas bge link** software) only.

Parameter

Using this function to select measurement, calculated and input values, which are sent via ASTM-A and POCT1-A.

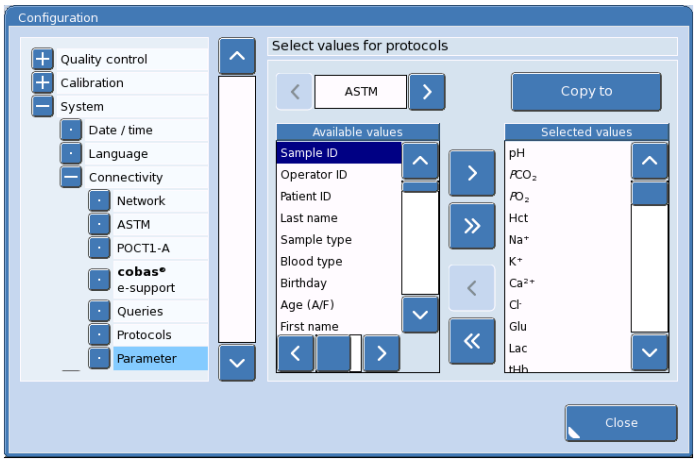


Figure D-99

The "Available values" column lists all defined values.

1 Select the desired value from the list.

2 Using the two arrow keys in the middle, move the marked value to the "Selected values" area.

3 To select all values in the list, press the two double arrow keys in the middle.

4 Pressing the [Close] button, the selected values are available.

Using this function to copy the selected values from ASTM to POCT1-A and vice versa.

Instrument

You can configure the following settings in this area:

- Volume
- Information
- Timeouts
- Printer

Volume

Using this function to enable or disable audible signals and adjust their volume.

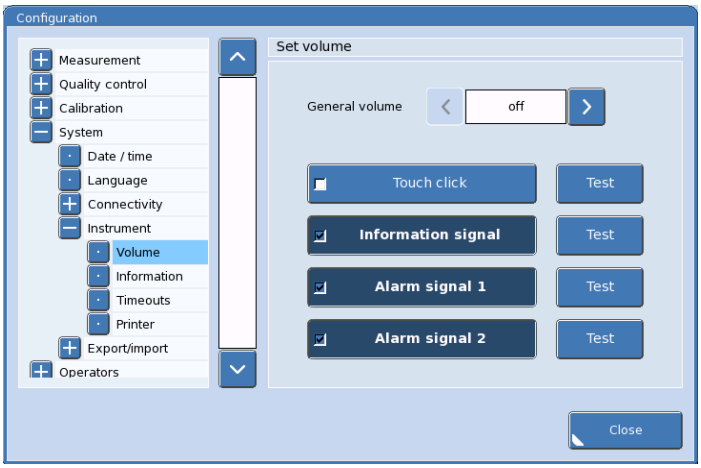


Figure D-100

► Setting the volume

1 Using the two arrow keys, set the volume for each signal type.

The following volume settings are possible:

OFF	Signal is disabled.
1, 2, 3, 4	The higher the number, the louder the signal.
max.	Max. volume

► Setting audible signals

1 Select the desired signal type by clicking.

2 The selected signal type appears with a dark blue background and is indicated by a check mark.

3 You can test the selected signal type and the volume by pressing the [Test] button.

The following signal types are possible:

- Touch click
- Information signal
- Alarm signal 1
- Alarm signal 2

► Removing audible signals

1 Remove the signal type by clicking it again.

Information

In the [Utilities] > [Configuration] > [System] > [Instrument] > [Information] area, you can assign any instrument name to the **cobas b** 123 POC system and enter the hospital information, e.g. name.


Pencil

To enter the desired data, press the [Pencil] button.

In case the instrument name and/or the hospital name are available, they will be reflected in the printed reports.

Timeouts

Using this function, you can define a delay ("timeout") for the following actions.

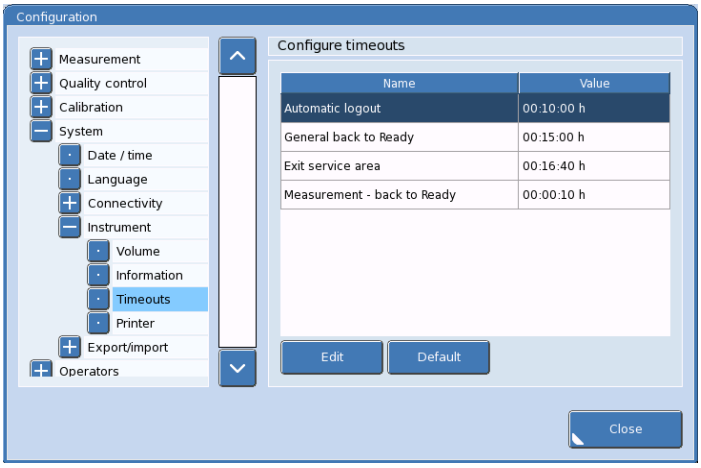


Figure D-101

Automatic logout	If the instrument is not used, the logged-in user (password) is logged out automatically after the entered time.
General back to Ready	From all menus, return to the "Ready" screen in the "Overview" menu.
Exit service area	From the protected service area, return to the "Ready" screen in the "Overview" menu. Entering the service area requires logging in with a password.
Measurement - back to Ready	Return to the "Ready" screen in the "Overview" menu.

► Editing the timeout

1 Select the desired action in the list.

2 To change the timeout, press the [Edit] button.

3 An additional input field appears. The timeout can be changed using the arrow keys.

4 Pressing the [OK] button accepts the settings.

► **Resetting changed timeouts**

1 Select the corresponding action in the list.

2 Press the [Default] button.

The timeout of the corresponding action is reset to the basic settings of the instrument.

Printer

Using this function the printout on the internal printer can be deactivated/activated.

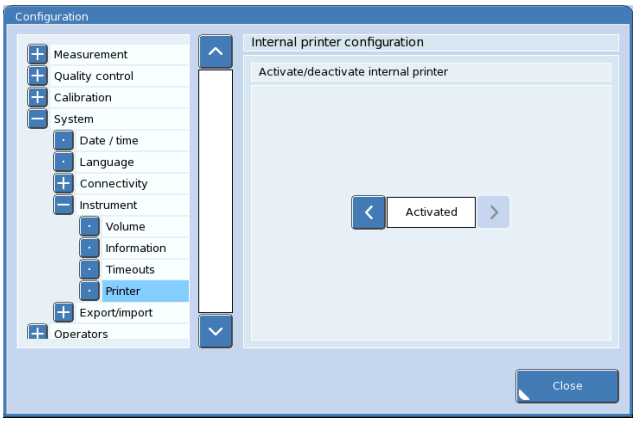


Figure D-102

Export/Import

Using this function to define the delimiter and separator to be used for exporting CSV (= comma separated values) documents. This makes it easier to import the CSV documents into a data processing program later.

Press the following buttons to configure the separator and the delimiter:

☞ [Utilities] > [Configuration] > [System] > [Export/Import] > [CSV export]

1 Using the two arrow keys, select the desired delimiter and separator.

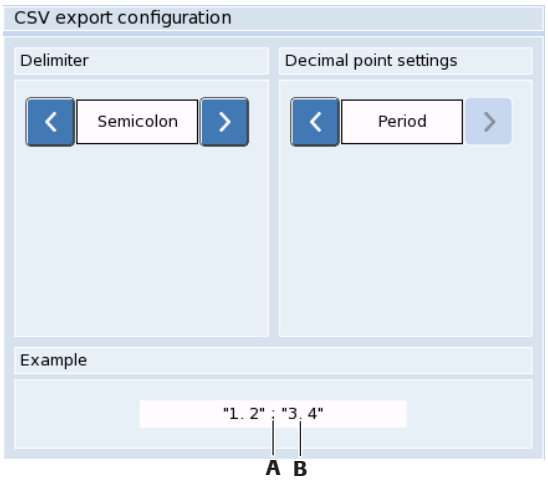
The following separators are possible:

- Comma
- Semicolon
- Space
- Tab

The following decimal points are possible:

- Comma
- Period

Example:



A Delimiter: semicolon
B Decimal point: period

Figure D-103

Operators

Creating. modifying & deleting users

Using this function, you can create various users who are allowed to operate the instrument.

Go to the "Utilities" menu and press the following buttons:

☞ [Configuration] > [Operators]

The following user profiles are possible:

- Trainee operator
- Normal operator
- Trusted operator
- Service operator
- Key operator
- Supervisor

	Supervisor	Key operator	Service operator	Trusted operator	Normal operator	Trainee operator
Measurement	+	+	+	+	+	+
QC measurement	+	+	+	+	+	+
Proficiency test	+	+	+	+	-	-
Calibration	+	+	+	-	-	-
Calibration for "Ready"	+	+	+	+	+	+
Consumable Change	+	+	+	+	+	+
Remove QC lock	+	+	+	+	-	-
View measurement results	+	+	+	+	+	+
Edit measurement results	+	+	-	-	-	-
View QC results	+	+	+	+	+	+
Edit QC results	+	+	-	-	-	-
View calibration	+	+	+	-	-	-
View instrument data	+	+	+	-	-	-
View audit trail	+	+	+	-	-	-
Disinfection of the touch screen	+	+	+	+	+	+
Installation & Put out of operation	+	+	+	-	-	-
Switch off	+	+	+	+	+	+
Software update	+	+	+	-	-	-
Configuration	+	+	+	-	-	-
Configuration of security level and operator profiles	+	-	-	-	-	-
User service area	+	+	+	-	-	-
Export/Import configurations	+	-	-	-	-	-
Export CSV	+	+	+	-	-	-
Troubleshooting	+	+	+	+	+	+
Remote lock	+	+	+	-	-	-
[Send] button	+	+	-	-	-	-
[Cancel] button	+	+	+	+	+	+
Setup QC material	+	+	+	+	-	-

Table D-9

+	This function can be exercised by the user of this profile.
-	This function is disabled for the user of this profile.

► **Creating a user**

1 When the [New] button is pressed, an additional window opens.


Pencil

2 To enter the data, press the [Pencil] button.

3 Pressing the [OK] button accepts the settings.

► **Editing a user**

1 Select the corresponding user in the list.

2 When the [Edit] button is pressed, an additional window opens.


Pencil

3 To change the settings, press the [Pencil] button.

4 Pressing the [OK] button accepts the settings.

► **Deleting a user**

1 Select the corresponding user in the list.

2 When the [Delete] button is pressed, the user is removed from the list.

► **Searching for a user**


Pencil

1 Enter one or more search criteria using the [Pencil] button.

2 Pressing the [Search] button starts the search.

3 If the search is successful, only those records that meet the search criteria appear on the screen.

Note

Pressing the [Clear search criteria] button deletes all search criteria entered into the search screen.

Security

Using this function, you can define different security levels. The individual security levels differ with regard to the freely available user functions that do not require a logged-in user.

Go to the "Utilities" menu and press the following buttons:

☞ [Configuration] > [Security]

► **Selecting a security level**

1 Select the desired security level in the list.

2 Pressing the [Close] button accepts the security level.

The following security levels are possible:

Security

	Security OFF[a]	Security level 1[b]	Security level 2[c]	Security level 3[d]	Security level 4[e]
Measurement	+	+	+	+	-
QC measurement	+	+	+	+	-
Proficiency test	+	+	+	-	-
Calibration	+	+	+	-	-
Calibration for "Ready"	+	+	+	+	-
Consumable Change	+	+	+	+	-
Remove QC lock	+	+	+	+	-
View measurement results	+	+	+	+	-
Edit measurement results	+	+	-	-	-
View QC results	+	+	+	+	-
Edit QC results	+	+	-	-	-
View calibration	+	+	+	-	-
View instrument data	+	+	+	-	-
View audit trail	+	+	+	-	-
Disinfection of the touch screen	+	+	+	+	-
Installation & Put out of operation	+	+	+	-	-
Switch off	+	+	+	+	-
Software update	+	+	+	-	-
Configuration	+	+	+	-	-
Configuration of security level and operator profiles	+	-	-	-	-
User service area	+	+	+	-	-
Export/Import configurations	+	-	-	-	-
Export CSV	+	+	+	-	-
Troubleshooting	+	+	+	+	-
Remote lock	+	-	-	-	-
[Send] button	+	+	-	-	-
[Cancel] button	+	+	+	+	-
Setup QC material	+	+	-	-	-

Table D-10

(a) No security provided
(b) Minimal security provided
(c) Data security provided
(d) Service security provided
(e) Full security provided

+	This function is freely accessible.
-	This function is not freely accessible, as it requires an authorized user to be logged in.

Note

To make all areas of the instrument freely accessible to all users, the setting [Security off] must be selected.

If the security level system is used, ensure that at least one user with the "Supervisor" profile is created.

Software update

To start a software update, press the following button:

☞ [Software update]

1 Plug in the USB storage device.

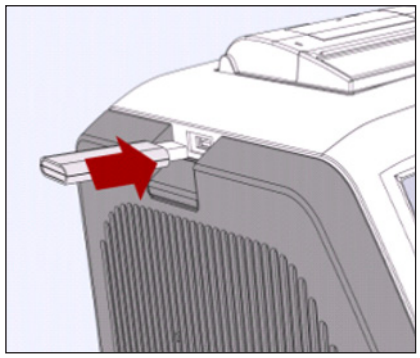


Figure D-104

After a valid USB storage device is detected, the user interface automatically moves on to the next step.

If a USB storage device with invalid or missing data has been used, a corresponding error message appears on the screen.

2 Press the [Start] button to start the data transfer.

3 After the end of the software update, pull the USB storage device back out and press the [Reboot] button.

Note

Follow the instructions on the screen.

Language update

To start a language update, press the following button:

☞ [Language update]

1 Plug in the USB storage device.

2 Press the [Start] button to start the data transfer.

3 After the language update ends, unplug the USB storage device.

Note

Follow the instructions on the screen.

USB data transfer

The functions of the **cobas b** 123 POC system provide the following options for data transfer via USB storage device:

- Data export from the database
- Data import
- Export/import configuration
  (all data that cannot be transferred via the database)
- Export instrument data

USB data export

1 Select the data for the export on the instrument, e.g. in the database.

2 Press this key to export the data to a USB storage device.

3 Plug in the USB storage device.

Figure D-105

4 Press the [Start] button to start the data transfer.

Note

If the USB storage device does not have sufficient storage space available, a corresponding error message appears. Data transfer is canceled.

5 Disconnect the USB storage device after the data transfer has been completed.

Export/import configuration

Using this function, you can import and export various settings.

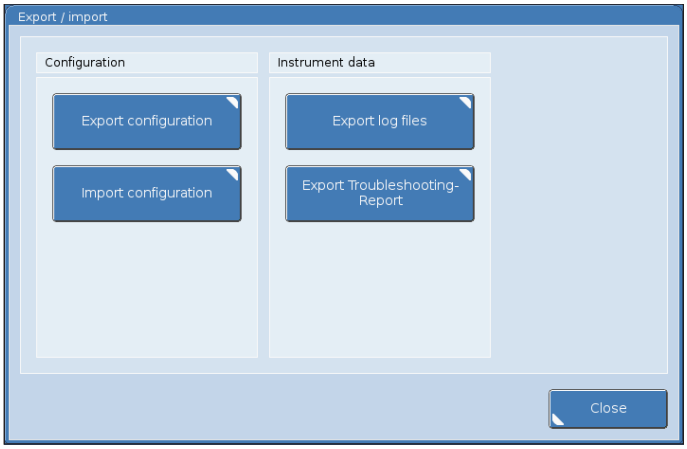


Figure D-106

► **Export configuration**

1 Plug in the USB storage device.

2 Press the [Start] button to start the data export.

Note

If the USB storage device does not have sufficient storage space available, a corresponding error message appears. Data transfer is canceled.

3 Pull out the USB storage device after the data export has been completed.

► **Import configuration**

1 Select the desired settings for the import using this key.

Note

Multiple selection is possible.

2 Then press the [Import configuration] button.

3 Plug in the USB storage device.

4 Press the [Start] button to start the data import.

5 Pull out the USB storage device after the data import has been completed.

Exporting instrument data

Using this function, you can export the following instrument data:

- Troubleshooting-Report
- Log files

Exporting the Troubleshooting-Report

For creating the Troubleshooting Report, refer to chapter 14 *Troubleshooting*, section *Creating the Troubleshooting-Report* on page F-42.

1 Select the [Export Troubleshooting-Report].

2 Plug in the USB storage device.

3 Press the [Start] button to start the data export.

Note

If the USB storage device does not have sufficient storage space available, a corresponding error message appears. Data transfer is canceled.

4 Pull out the USB storage device after the data export has been completed.

Exporting log files

1 Select the [Export log files].


Pencil

2 To export log files, a date range must be entered.
To enter the date, press the [Pencil] button.

3 Press the following button to start the data export:

☞ [Start export to USB]

4 Plug in the USB storage device.

5 Press the [Start] button to start the data export. The data are transferred.

Note

If the USB storage device does not have sufficient storage space available, a corresponding error message appears. Data transfer is canceled.

6 Pull out the USB storage device after the data export has been completed.

Service functions

Note

In the protected service function area, there are certain actions that can be carried out by a trained user with help from the hotline.

To enter the protected service function area, a user with the service operator level or higher must be logged in.

For additional information, refer to section *Operators* on page D-148.


WARNING

Warning

The following service functions should be carried out only by a specially trained user, e.g. service operator or higher level.

It is mandatory to follow the instructions of the hotline.

Instrument

- Barcode scanner test[(a)]
- Front door
- Check CF card[(a)]
- Check temperatures
- Check fans

Fluidics control module (FCM)

- Fluidic control board self check
- Valves
- Peristaltic pumps
- Sample input drive module
- Fluid Pack chip connector
- Aspiration & tightness
- Check/calibrate sample sensors[(b)]

Measuring chamber module (MCM)

- MCM self check
- Sensor simulator
- Sensor Cartridge chip connector

Oximeter module

- Oximeter module self check
- Oximeter module calibration
- Check hemolyzer

AutoQC module

- AutoQC module check
- AutoQC Pack chip connector

(a) Available at a later point after **cobas b** 123 POC system launch.
(b) Available at a later point after **cobas b** 123 POC system launch.

Utilities

- Reboot
- Delete databases[(a)]
- Remote software update[(a)]
- Stability monitor
- Prepare for Depot-Repair
- Reset printer

Audit trail

You can use this function to trace all changes in the settings and in the input values.

The following entries are displayed in the list:

- Type of the change
  - Old value
  - New value
- Time of the change
- User who carried out the change

(a) Available at a later point after **cobas b** 123 POC system launch.

Consumable change

E

Consumable change

This chapter describes the process of changing the consumables that enable proper operation of the instrument.

In this chapter

Chapter **13**

Table of contents

Disinfection

Safety Instruction

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

The purpose of this procedure is to minimize the risk of infection that exists when replacing parts that have been in contact with blood.

This disinfection should be carried out regularly.

This disinfection must be performed regularly according to typical laboratory regulations to minimize the risk of infection.

Note

Use only liquid surface disinfectants containing alcohol (approximately 70%). e.g. isopropanol 70% and/or disinfectants containing type 0.5% to max. 1.0% of the active ingredient dimethyl benzyl ammonium chloride.

Under no circumstances use bleaching agents of any kind.

Roche has tested and recommends using the following ready-to-use disinfectants:

Name	Manufacturer/sales	Active agents	Application time (min.)
Incidin liquid[(a)]	Ecolab GmbH & Co OHG	Alcohols	5
Meliseptol[(b)]	B. Braun Medical AG Sales: B. Braun Melsungen AG	Alcohol. aldehyde	5

(a) Incidin is a registered trademark of Ecolab GmbH & Co OHG.
(b) Meliseptol is a registered trademark of B. Braun Medical AG.

CAUTION

Caution

Do not aim sprays directly at the instrument, as malfunctions of the electronics may occur.
Do not spray anything on any non-removable or interior parts.

WARNING

Warning

After disinfecting the instrument. wait 15 minutes so that the disinfectant can evaporate.
Danger of fire and explosion.
For safety reasons. the power pack may be disinfected by Roche Service only.

The following parts of the instrument must be disinfected regularly:

- Touch screen
- Instrument surfaces
- Consumables area

Disinfection of the instrument screen

Go to the "Instrument" menu and press the following button:

☞ [Disinfection of touch screen]

The touch-sensitive layer of the screen is now deactivated for 30 seconds.

CAUTION

Caution

Only disinfect with a damp cloth (e.g. soaked in disinfectant).
Do not use water or sprays.

Disinfection of the instrument surfaces

Regularly disinfect all outer surfaces of the instrument. including all covers (e.g. printer cover. front door), using the disinfectant according to general laboratory guidelines.

Carry out preliminary cleaning of very dirty surfaces using a swab or cellulose sponge soaked in distilled water.

CAUTION

Caution

Do not aim sprays directly at the instrument, as malfunctions of the electronics may occur.
Do not spray anything on any non-removable or interior parts.

WARNING

Warning

After disinfecting the instrument. wait 15 minutes so that the disinfectant can evaporate.
Danger of fire and explosion.

Disinfection of consumable area

The disinfection of the consumable area must be carried out as part of a consumable change or during the put out of operation routine only.

If the area for consumables is visible dirty, carefully disinfect the affected surfaces using a damp cloth.

For disinfection allow an application time of approximately 15 minutes.

👁 For the disinfecting of the consumables area, refer to the section *Change Sensor Cartridge* on page E-8, section *Change Fluid Pack* on page E-11 and section *Change AutoQC Pack (optional)* on page E-14.

CAUTION

Caution

The measuring chamber module and the Sensor Cartridge must not be disinfected.
To protect the instrument, do not spray anything on any non-removable or interior parts.
Do not use water or sprays.

General change

Change printer paper

Note

The printer paper is only heat-sensitive on one side. Make sure the thermal paper roll is inserted correctly.

Go to the "Workplace" menu and press the following button:

☞ [Change printer paper]

The following screen appears:

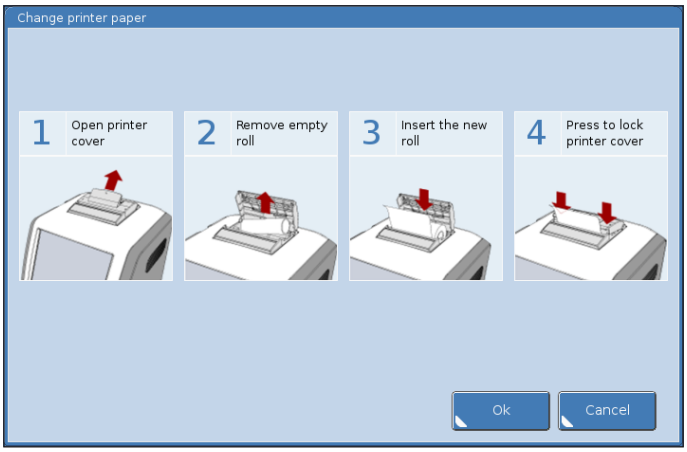


Figure E-1

Note

You can stop the change procedure at any time by pressing the [Cancel] button.

Follow the instructions on the screen:

1 Open the printer cover.

Figure E-2

2 Remove the empty paper roll.

3 Insert the new paper roll in the holder.

Figure E-3

4 Close the printer cover securely.

5 Press the [OK] button to record the change in the database under [Workplace] > [Instrument database].

Sample-dependent changing

Change Sensor Cartridge

WARNING

Warning

To ensure the quality of measurement results, each time the Sensor Cartridge is changed, you must run a quality control in 3 levels (1 = low, 2 = normal, 3 = high).

Safety Instructions

After use, the Sensor Cartridge contains biological fluid residues that pose a risk for infection.

Handle the Sensor Cartridge with care, observing the regulations for handling potentially infectious material. Avoid skin contact.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Starting from the "Workplace" menu, press the following button for the Sensor Cartridge change:

☞ [Change Sensor Cartridge]

Follow the instructions on the screen.

1 The instrument automatically prepares for the Sensor Cartridge change. Wait until the preparation time is finished.

In the preparation time, the Sensor Cartridge is disconnected from the Fluid Pack.

In normal operation, the Sensor Cartridge is connected to the Fluid Pack. The red area of the measuring chamber is visible (ready position).

The Sensor Cartridge is disconnected from the Fluid Pack to prepare the measuring chamber module for a Sensor Cartridge replacement. The green area of the measuring chamber becomes visible (replacement position).

A Position for replacement (green) **B** Position in normal operation (red)

Figure E-4 Measuring chamber module with Sensor Cartridge

The front door is unlocked and must be opened within 30 seconds.

For details, refer to the section *Unlocking the front door* on page E-17.

2 Open the front door.

3 Remove the Sensor Cartridge.

Note

Touch the Sensor Cartridge only at the handle provided for this purpose.

Handle the Sensor Cartridge carefully to prevent the possibility of fluid escaping from the Sensor Cartridge.

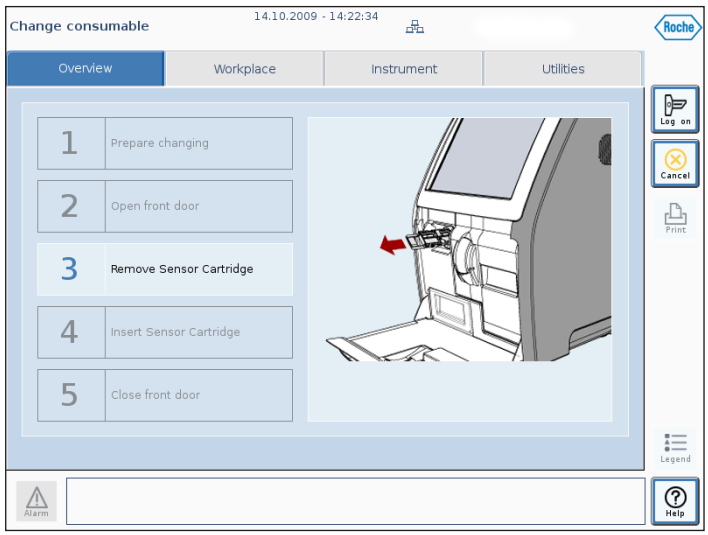


Figure E-5

If you do not want to carry out the change of the Sensor Cartridge, you can cancel the procedure using the [Cancel] button.

Dispose of the Sensor Cartridge according to local regulations (biologically contaminated - hazardous waste).

Disinfection of the Sensor Cartridge (optional)

If there is visible dirt on the Sensor Cartridge, only the handle of the Sensor Cartridge may be disinfected, by carefully using a damp cloth.

Allow an application time of approximately 15 minutes.

For additional information about disinfecting the consumables area, refer to the section *Disinfection of consumable area* on page E-6.

CAUTION

Caution

The measuring chamber module and the Sensor Cartridge must not be disinfected.
To protect the instrument, do not spray anything on any non-removable or interior parts.
Do not use water or sprays.

4 Insert the new Sensor Cartridge.

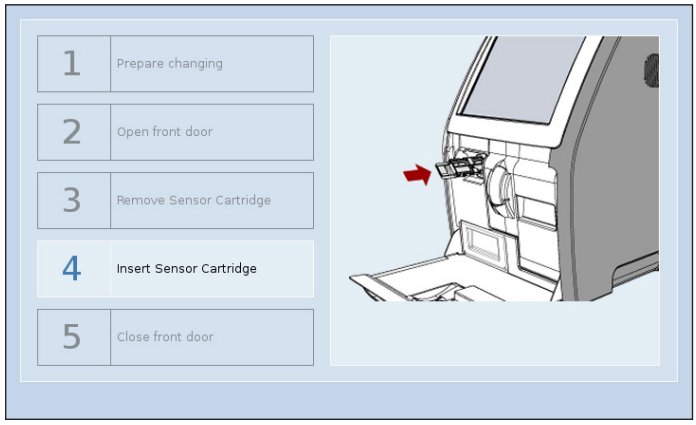


Figure E-6

The data of the consumables are scanned automatically.

After the Sensor Cartridge chip is detected, the user interface automatically moves on to the next step.

If an invalid Sensor Cartridge has been inserted, the corresponding error message appears on the screen.

For an exact description, see chapter 14 *Troubleshooting*.

5 Close the front door.
The Sensor Cartridge is reconnected to the Fluid Pack.

For the step [Close front door] you have the ability to replace additional consumables or view information about the consumables.

For details, refer to the section *Additional changing* on page E-16.

Next, the automated follow-up actions (for example, system calibration) are started.

Quality control

Each time the Sensor Cartridge is changed, you must run a QC measurement on all 3 levels (1 = low. 2 = normal. 3 = high). Make sure that the results match the target values.

For additional information, refer to chapter 9 *Quality control*.

Change Fluid Pack

Warning

To ensure the quality of measurement results. each time the Fluid Pack is changed, you must run a quality control in 3 levels (1 = low, 2 = normal, 3 = high).

Safety Instructions

After use, the Fluid Pack contains biological fluids or fluid residue that pose a risk for infection.

Handle the Fluid Pack with care, observing the regulations for handling potentially infectious material. Avoid skin contact.

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Note

Depending on the measuring rate and/or the on-board stability replace the Fluid Pack at least once every 6 weeks. A corresponding informational prompt appears on the screen.

Starting from the "Workplace" menu, press the following button for the Fluid Pack change:

☞ [Change Fluid Pack]

Follow the instructions on the screen.

1 The instrument automatically prepares for the Fluid Pack change.
Wait until the preparation time is finished.

The front door is unlocked and must be opened within 30 seconds.

👁 For details, refer to the section *Unlocking the front door* on page E-17.

2 Open the front door.

3 Remove the Fluid Pack.

Caution

By removing the Fluid Pack, be absolutely certain not to displace the valves.
Displaced valves cause problems inserting the Fluid Pack.

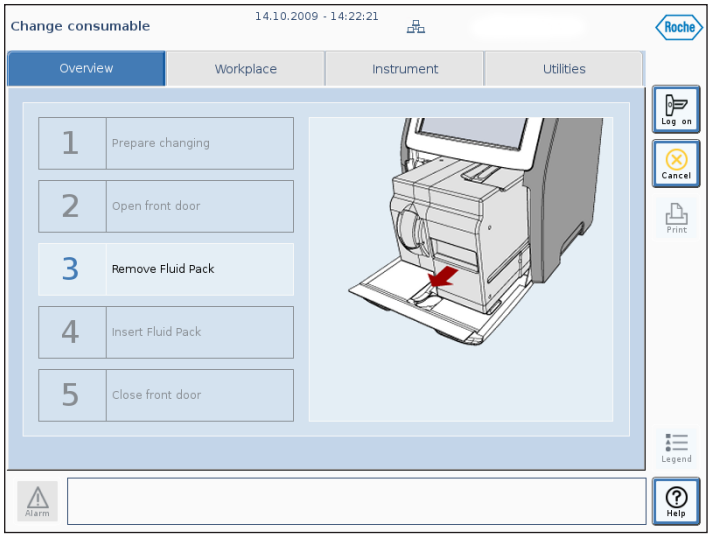


Figure E-7

If you do not want to carry out the change of the Fluid Pack, you can cancel the procedure using the [Cancel] button.

Dispose of the Fluid Pack according to local regulations (biologically contaminated - hazardous waste).

Disinfection of the consumables area (optional)

The consumables area can be disinfected only as part of a consumable change or during the put out of operation routine.

If the area for consumables is visibly dirty, carefully disinfect the affected surfaces using a damp cloth.

Disinfection of the left side wall (partition between the measuring chamber module and oximeter module with cuvette) should be avoided in order to protect the Sensor Cartridge and the hemolyzer.

For disinfection allow an application time of approximately 15 minutes.

For additional information about disinfecting the consumables area, refer to the section *Disinfection of consumable area* on page E-6.

Regularly disinfect the consumables area with disinfectants according to general laboratory regulations.

CAUTION

Caution

Only disinfect with a damp cloth (e.g. soaked in disinfectant).
Do not use water or sprays.

A Valves **B** Left side wall

Figure E-8

Note

During disinfection, be absolutely certain not to displace the valves.
Displaced valves cause problems inserting the Fluid Pack.

4 Insert the new Fluid Pack.

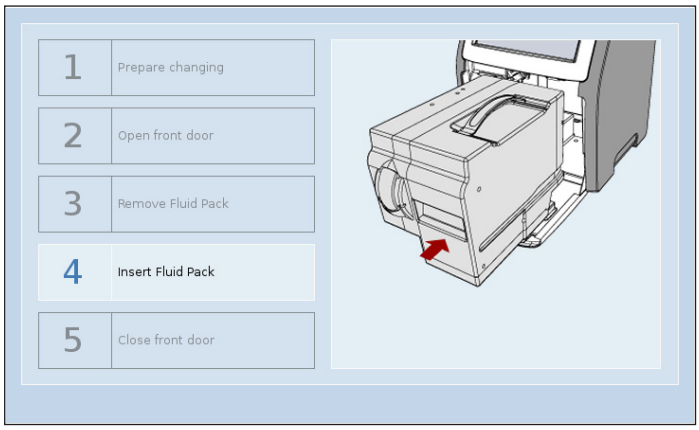


Figure E-9

Caution

Do not touch the cuvette and the sample sensor contacts on the side wall of the Fluid Pack.

The data of the consumables are scanned automatically.

After the Fluid Pack chip is detected, the user interface automatically moves on to the next step.

If an invalid Fluid Pack has been inserted, the corresponding error message appears on the screen.

For an exact description, see chapter 14 *Troubleshooting*.

Note

If the Fluid Pack is not detected, check the smart memory chip on the rear side of the Fluid Pack for visible dirt and carefully clean it dry if necessary.

5 Close the front door.

For the step [Close front door] you have the ability to replace additional consumables or view information about the consumables.

For details, refer to the section *Additional changing* on page E-16.

Next, the automated follow-up actions (for example, system calibration) are started.

Quality Control

Each time the Fluid Pack is changed, you must run a QC measurement on all 3 levels (1 = low, 2 = normal, 3 = high). Make sure that the results match the target values.

For additional information, refer to chapter 9 *Quality control*.

Change AutoQC Pack (optional)

Note

A new AutoQC Pack must be adjusted to room temperature at least 24 hours prior to use.

Caution

Always store **cobas b** 123 AutoQC Packs upright.

Starting from the "Workplace" menu, press the following button for the AutoQC Pack change:

☞ [Change AutoQC Pack]

Follow the instructions on the screen.

1 The instrument automatically prepares for the AutoQC Pack change. Wait until the preparation time is finished.

The front door is unlocked and must be opened within 30 seconds.

For details, refer to the section *Unlocking the front door* on page E-17.

2 Open the front door.

Safety Instructions

When the AutoQC Pack is removed, fragments of ampoules that have been broken open can escape from the AutoQC Pack. There is a risk of injury.
Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.
Dispose of the AutoQC Pack according to applicable local codes and regulations.
Caution: Danger of spills.

3 Remove the AutoQC Pack.

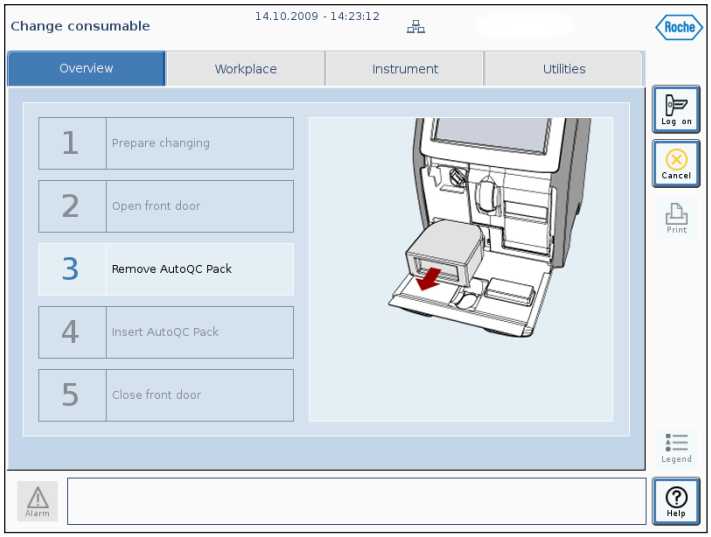


Figure E-10

Note

If you do not want to carry out the change of the AutoQC Pack, you can cancel the procedure using the [Cancel] button.

CAUTION

Caution

Do not turn a partially used AutoQC Pack upside down if the AutoQC Pack is being installed again. Installing an AutoQC Pack that was turned upside down can destroy the AutoQC module.

Note

Dispose of the AutoQC Pack according to local regulations.

Disinfection of the consumable area (optional)

The consumables area can be disinfected only as part of a consumable change or during the put out of operation routine.

If the area for consumables is visibly dirty, carefully disinfect the affected surfaces using a damp cloth.

For disinfection allow an application time of approximately 15 minutes.

For additional information about disinfection of the consumables area, refer to the section *Disinfection of consumable area* on page E-6.

WARNING

Warning

When disinfecting the AutoQC module, carefully disinfect the top of the interior. Because of the ampoule opener there is a risk of injury.

CAUTION

Caution

Only disinfect with a damp cloth (e.g. soaked in disinfectant).
Do not use water or sprays.

4 Insert the new AutoQC Pack.

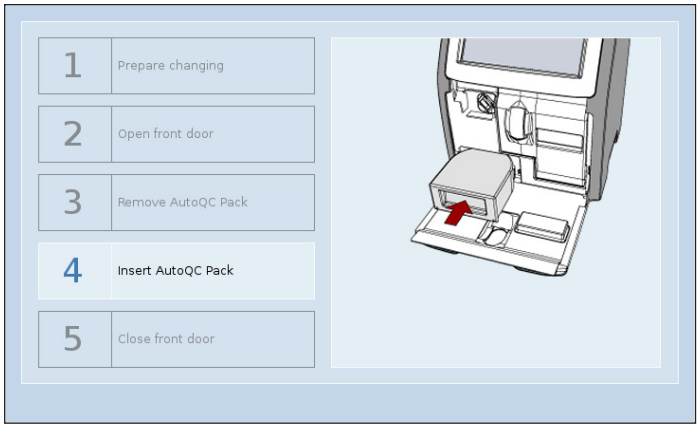


Figure E-11

CAUTION

Caution

If you suspect damage to a new AutoQC Pack, do not under any circumstances insert the defective AutoQC Pack into the instrument. Using a damaged AutoQC Pack can destroy the AutoQC module.

The data of the consumables are scanned automatically.

After the AutoQC Pack chip is detected, the user interface automatically moves on to the next step.

If an invalid AutoQC Pack has been inserted, the corresponding error message appears on the screen.

For an exact description, see chapter 14 *Troubleshooting*.

5 Close the front door.

For the step [Close front door] you have the ability to replace additional consumables or view information about the consumables.

For details, refer to the section *Additional changing* on page E-16.

Consequences are started.

Additional changing

After inserting individual consumables, you have the ability to change additional consumables.

Changing additional consumables

Press the button for the consumable to be changed:

☞ [Sensor Cartridge], [AutoQC Pack] or [Fluid Pack]

Carry out the change routine based on the instructions on the screen.

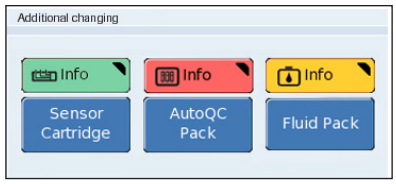


Figure E-12

Displaying the status of a consumable

The [Info] button shows the status of the respective consumable in the same color-coding as on the "Overview" screen.

For additional information about the status display of the consumables, refer to chapter 6 *System components*, section *Status display for consumables* on page C-10.

Consumable is OK.

Warning level reached:

Consumable is OK, but must be changed within 2 days, as the maximum period of use or the maximum number of tests will be reached soon.

Alarm level reached:

Consumable is no longer OK. An immediate change is required. as the maximum period of use or the maximum number of tests has been reached.

Calling up the function displays the detailed status.

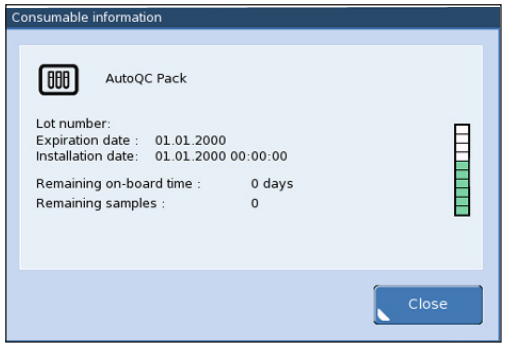


Figure E-13 Consumable information

Unlocking the front door

During the various consumable change routines, the user is prompted to open the front door.

If the front door is not opened within 30 seconds, the door locks again.

Press the [Unlock front door] button to unlock the front door.

After the front door is opened. the user interface automatically moves on to the next step of the change routine.

Troubleshooting F

Troubleshooting

This chapter describes the error messages and their causes and remedies, which are also displayed directly on the screen.

In this chapter *Chapter* 14

Troubleshooting - general

Safety Instructions

After use, the Fluid Pack and Sensor Cartridge contain biological fluids or fluid residues that pose a risk for infection.

Handle these components with care and according to regulations surrounding potentially infectious materials.

Suitable protective equipment, like laboratory clothing, protective gloves, protective goggles and if necessary mouth protectors, must be worn to prevent direct contact with biological working materials. In addition, a face mask is required if there is a risk of splashes. Suitable disinfection and sterilization procedures must be applied.

The **cobas b** 123 POC system can monitor air bubbles, blood clots, leaks and clogs that may occur in the instrument. If the instrument detects one of these problems, depending on the situation, and in case they cannot be solved automatically, a message like a system stop, an error, a warning or an information is displayed.

Alarm area

In normal operation, the [Alarm] button is disabled and the display field of the alarm area on the bottom of the screen is empty.

Figure F-1 gray [Alarm] button

If an error occurs, the [Alarm] button is enabled and the alarm name (including date, time and error designation) is displayed in the alarm area. The [Alarm] button changes color depending on the severity of the error.

	No warnings or errors are present. The alarm screen cannot be opened.
	Information is present. The instrument can be used normally, but there are pending actions to be completed.
	Warnings are present. The instrument can be used with potential limitations.
	Errors are present. The instrument cannot be used, or can only be used with limitations.

Table F-1 Alarm button color coding

Alarm screen

When the [Alarm] button is pressed, an alarm screen opens displaying details about the warnings or errors and suggesting remedies.

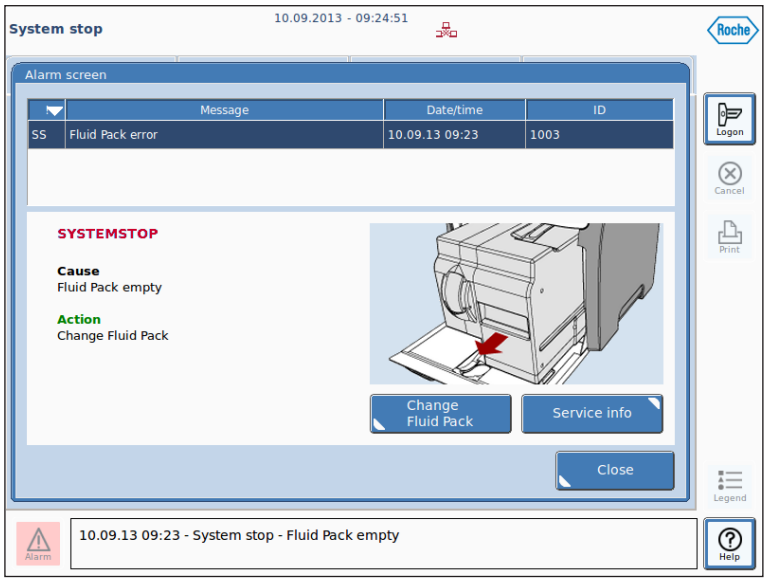


Figure F-2

Alarm list

The pending errors are listed in the upper part of the alarm screen.
The following data are displayed in the alarm list:

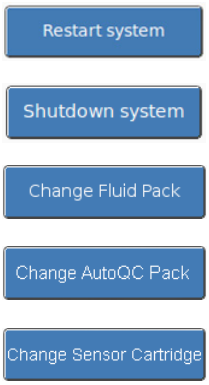
!	**Type of error:** • SS = System stop • D = Defect • W = Warning • I = Information
Date/Time	The time when this error occurred is displayed.
Message	**Error designation:** e.g. Fluid Pack error
ID	Error ID

Note

Always specify the Error ID when contacting Roche Service.

Detailed information relating to the type of error and the corresponding corrective action is displayed in the alarm screen.

► **Directly selecting a corrective action:**

	The required function for troubleshooting the error can be called up directly by pressing the corresponding button. Then follow the instructions on the screen.

Pressing the [Close] button closes the message window without calling up a corrective action.

The [Alarm] button continues to be highlighted in the corresponding color until the error has been remedied.

System stop

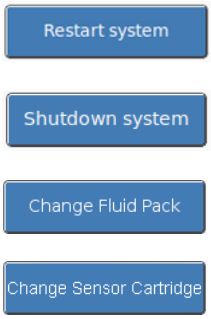
A system stop is a critical error which stops the instrument.

Caution

It is not possible to perform measurements or calibrations.

When this error occurs, a system stop window with a red border is displayed in the "Overview" menu. The respective consumable is identified by a red bar in the consumables status display, when the error is related to a specific consumable.

The system stop window contains the following data:

Category[(a)]	Type of error, if e.g. Fluid Pack Error.
Cause	Fluid Pack exhausted or expired.
Corrective Action	Change Fluid Pack.
	The required function for troubleshooting the error can be called up directly by pressing the corresponding button. Then follow the instructions on the screen.

(a) Category is not displayed for the expected systems stops due to normal operation, for example: an empty Fluid Pack, or a Sensor Cartridge with no remaining tests.

The error message is displayed until a corrective action is carried out.

► **Remedy a system stop:**

1 Call up the corresponding corrective action.

2 Follow the instructions on the screen.

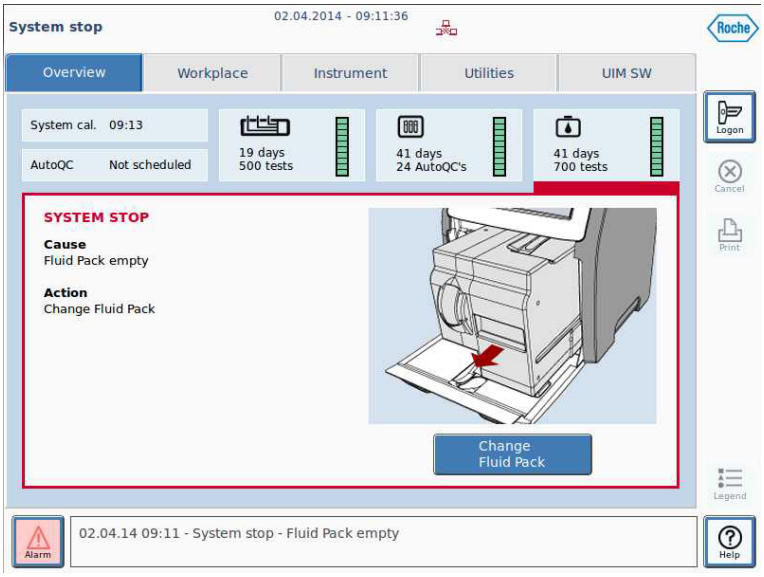


Figure F-3 Example: an empty Fluid Pack can lead to a system stop.

The following types of system stops can occur:

ID	CATEGORY	CAUSE	TYPE OF ERROR	ACTION
1	Instrument error	Analyzer defective	AutoQC system stop	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.
2	Instrument error	Internal control module not responding	Microcontroller system stop	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Restart system**] 3. Contact Roche service hotline.
3	Fluid Pack error	Fluid Pack defective	SIM system stop	To remedy the error, call up the following function: [**Change Fluid Pack**]
4	Fluid Pack error	Fluid Pack defective	Sample sensor system stop	To remedy the error, call up the following function: [**Change Fluid Pack**]
5	Fluid Pack error	Fluid Pack defective	Valve system stop	To remedy the error, call up the following function: [**Change Fluid Pack**]
6	Fluid Pack error	Fluid Pack defective	System stop triggered by washing error	To remedy the error, call up the following function: [**Change Fluid Pack**]
7	Fluid Pack error	Fluid Pack defective	System stop triggered by insufficient filling with reference solution	To remedy the error, call up the following function: [**Change Fluid Pack**]
8	Fluid Pack error	Fluid Pack defective	System stop triggered by empty system	To remedy the error, call up the following function: [**Change Fluid Pack**]
9	Fluid Pack error	Fluid Pack defective	System stop due to positioning of solution	To remedy the error, call up the following function: [**Change Fluid Pack**]
10	Fluid Pack error	Fluid Pack defective	System stop due to positioning of sample	To remedy the error, call up the following function: [**Change Fluid Pack**]
11	Operator cancel	Operator canceled action		To remedy the error, press the following button: [**Accept**]
12	Instrument error	Analyzer defective	Valves hard ware defect	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.
13	Sensor Cartridge error	Sensor Cartridge defective	Filling of Sensor Cartridge not possible	To remedy the error, call up the following function: [**Change Sensor Cartridge**]
14	Instrument error	Analyzer defective	Measuring chamber module defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.
15	Instrument error	Analyzer defective	Fluidics control board defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.
16	Instrument error	Analyzer defective	Oximeter module board defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.

ID	CATEGORY	CAUSE	TYPE OF ERROR	ACTION
17	Instrument error	Analyzer defective	UIM hardware/power supply defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
18	Sensor Cartridge error	Sensor Cartridge dirty		1. To remedy the error, call up the following function: **[Change Sensor Cartridge].** 2. Open the front door and remove Sensor Cartridge. 3. Check the rear side of the Sensor Cartridge for visible dirt and clean it carefully if necessary. 4. Reinsert the Sensor Cartridge 5. Call up the function: [Change Fluid Pack]. 6. Remove the Fluid Pack and check the docking parts of the Fluid Pack for visible dirt and clean it carefully if necessary. 7. Reinsert the Fluid Pack and close the front door. 8. If the error persists, contact Roche service hotline.
19	Fluid Pack error	Fluid Pack defective	Fluidics tightness problem	To remedy the error, call up the following function: **[Change Fluid Pack]**
20	Fluid Pack error	Fluid Pack defective	Fluidics system blocked	To remedy the error, call up the following function: **[Change Fluid Pack]**
21	Instrument error	Spare part not initialized	Unknown µC board	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
22	Instrument error	Spare part not compatible	EEPROM data conversion error	To remedy the error, call up the following function: **[Software update]**
23	Instrument error	Analyzer defective	µC power connection error	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
24	Sensor Cartridge chip communication error	Sensor Cartridge chip error	Read/write chip error	1. To remedy the error, call up the following function: **[Change Sensor Cartridge]** 2. Open the front door and remove Sensor Cartridge. 3. Check and clean (if needed) the Sensor Cartridge chip. 4. Reinsert the Sensor Cartridge and close the front door. 5. If the error persists, install a new Sensor Cartridge.
25	Fluid Pack chip communication error	Fluid Pack chip error	Read/write chip error	1. To remedy the error, call up the following function: **[Change Fluid Pack]** 2. Open the front door and remove Fluid Pack. 3. Check and clean (if needed) the Fluid Pack chip. 4. Reinsert the Fluid Pack and close the front door. 5. If the error persists, install a new Fluid Pack.
1000	Instrument error	Internal software error	Database server not started	To remedy the error, call up the following function: **[Restart system]**
1001	Sensor Cartridge error	Power fail during Sensor Cartridge change		1. To remedy the error, call up the following function: **[Change Sensor Cartridge]** 2. Open the front door and remove Sensor Cartridge. 3. Reinsert the Sensor Cartridge and close the front door. 4. If the error persists, contact Roche service hotline.

ID	CATEGORY	CAUSE	TYPE OF ERROR	ACTION
1002	Sensor Cartridge error	Exhausted or expired. 👁 See detailed information on page F-21	Sensor Cartridge invalid	To remedy the error, call up the following function: [**Change Sensor Cartridge**]
1003	Fluid Pack error	Exhausted or expired. 👁 See detailed information on page F-26	Fluid Pack invalid	To remedy the error, call up the following function: [**Change Fluid Pack**]
1004	Instrument error	Internal software error	Timeout of the scheduler	To remedy the error, call up the following function: [**Restart system**]
1005	Timeout	Sample container not removed		1. Remove the syringe. 2. To remedy the error, press the following button: [**Syringe removed**]
1006	Timeout	Sample container not removed		1. Remove the capillary. 2. To remedy the error, press the following button: [**Capillary removed**]
1007	Instrument error	CF card cannot be accessed		1. Insert a valid CF card. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. To start the **cobas b** 123 POC system, press the (On/Off) button on the rear panel of the instrument.
1008	Instrument error	Software update failed	Software version mismatch	To remedy the error, call up the following function: [**Restart system**]
1009	Instrument error	Internal software error	Data synchronization error on CF card	To remedy the error, call up the following function: [**Restart system**]
1010	Instrument error	Internal software error	Database corrupted	1. Write down the Error ID. 2. To remedy the error, call up the following function: [**Shutdown system**] 3. Contact Roche service hotline.

Caution

To remedy a system stop that is not listed here, contact the Roche service hotline.

👁 For additional information about the various corrective actions, see section *Corrective actions* on page F-16.

Defects

Note

Defects do not lead to a system stop. You can perform measurements with some limitations.

Defects refer to problems that relate only to a certain module of the instrument (e.g. AutoQC Pack empty) and not to the operation of the entire instrument.

The instrument can be used with limitations. Only those areas or parameters that are directly affected by the defect are disabled.

► **Remedy defects:**

1. Press the [Alarm] button to open the alarm screen.
2. Read the information in the alarm list.
3. Follow the instructions on the screen.
4. Call up the corresponding corrective action.

The following types of errors can occur:

ID	CATEGORY	CAUSE	ACTION
3000	AutoQC Pack error	Exhausted or expired. See detailed information on page F-30	To remedy the defect, call up the following function: **[Change AutoQC Pack]**
3001	AutoQC module error	AutoQC module defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
3002	Oximeter module error	Oximeter module defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
3003	Printer module error	Printer module defective	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Shutdown system]** 3. Contact Roche service hotline.
3004	Printer module error	No printer paper	Change paper. To change the paper, call up the following function: **[Workplace]** > **[Change printer paper]**
3005	AutoQC Pack error	AutoQC pack defective See detailed information on page F-30	To remedy the defect, call up the following function: **[Change AutoQC Pack]**
3006	AutoQC Pack chip communication error	AutoQC Pack chip error	1. To remedy the error, call up the following function: **[Change AutoQC Pack]** 2. Open the front door and remove AutoQC Pack. 3. Check and clean (if needed) the AutoQC Pack chip. 4. Reinsert the AutoQC Pack and close the front door. 5. If the error persists, install a new AutoQC Pack.

CAUTION

Caution

To remedy a defect that is not listed here, contact the Roche service hotline.

For additional information about the various corrective actions, see section *Corrective actions* on page F-16.

Warnings

If a warning is displayed in the alarm area. the instrument can be used with potential limitations.

A warning is an advance notification, e.g:

Fluid Pack warning - Critical fill level in the Fluid Pack

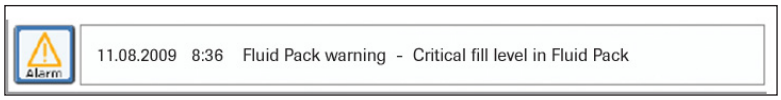


Figure F-4

► **Remedy warnings:**

1. Press the [Alarm] button to open the alarm screen.
2. Read the information in the alarm list.
3. Follow the instructions on the screen.
4. Call up the corresponding corrective action.

The following types of warnings can occur:

ID	CATEGORY	CAUSE	ACTION
5000	Fluid Pack warning	Critical fill level in Fluid Pack	To remedy the warning, call up the following function: **[Change Fluid Pack]**
5001	Fluid Pack warning	Fluid Pack nearly expired	To remedy the warning, call up the following function: **[Change Fluid Pack]**
5002	AutoQC Pack warning	Critical fill level in AutoQC Pack	To remedy the warning, call up the following function: **[Change AutoQC Pack]**
5003	AutoQC Pack warning	AutoQC Pack nearly expired	To remedy the warning, call up the following function: **[Change AutoQC Pack]**
5004	Sensor Cartridge warning	Total number of tests close to limit	To remedy the warning, call up the following function: **[Change Sensor Cartridge]**

ID	CATEGORY	CAUSE	ACTION
5005	Sensor Cartridge warning	Sensor Cartridge nearly expired	To remedy the warning, call up the following function: **[Change Sensor Cartridge]**
5006	Temperature warning	Temperature range exceeded	1. Write down the Error ID. 2. To remedy the error, call up the following function: **[Restart system]** 3. Contact Roche service hotline.
5007	Instrument warning	Magnetic switch defective	1. Write down the Error ID. 2. Contact Roche service hotline.

Caution

To remedy a warning that is not listed here, contact the Roche service hotline.

Information alarm

While an information alarm is displayed in the alarm area, the instrument can be used normally, but there are pending actions to be completed.

An information alarm, refers to a pending action initiated before, e.g:

Figure F-5

► **Remedy information alarms:**

1 Press the **[Alarm]** button to open the alarm screen.

2 Read the information in the alarm list.

3 Follow the instructions on the screen.

4 Perform the corresponding corrective action.

The following types of information alarms can occur:

ID	CATEGORY	CAUSE	ACTION
7000	Service action	Deleting of instrument database requested	To remedy the pending action, call up one of the following functions: 1. **[Restart system]** - to delete all databases and configuration. 2. **[Cancel]** - to cancel the deletion process.
7001	Service action	Software update pending	To remedy the pending action, call up one of the following functions: 1. **[Restart system]** - to complete the software update process. 2. **[Cancel]** - to cancel the software update.
7002	Service action	Configuration file pending	To remedy the pending action, call up one of the following functions: 1. **[Restart system]** - to install the imported configuration file. 2. **[Cancel]** - to cancel the installation process.

Caution

To remedy an information alarm that is not listed here, contact the Roche service hotline.

Corrective actions

Note

Before starting the corrective actions, identify the affected parameters and the number of affected parameters and follow the corresponding instructions.

Sensor parameters (BG - ISE - Glu - Lac)

The sensor parameters include the following parameters:

- pH
- PCO_2
- PO_2
- Hct
- Na^+
- K^+
- Ca^{2+}
- Cl^-
- Glu
- Lac

Oximeter parameters (tHb - COOX)

The oximeter parameters include the following parameters:

- tHb
- COOX (including COHb. MetHb. O_2Hb. HHb. SO_2 and bilirubin)

☑	The corrective action was successful. No additional corrective actions are required. Finally. carry out a quality control in 3 levels if necessary.
☒	The corrective action was not successful. To remedy the problem. continue with the next corrective action in the list.

Table F-2 Symbol explanation

Parameter not calibrated

► **One or more sensor parameter(s) is/are not calibrated**

	Corrective action	Result and follow-up action
	1. Call up a "Calibration for Ready". Press the following buttons to call up the calibration: [Instrument] > [Calibration for Ready]	☑ - ☒ Continue with next corrective action
	2. Carry out the internal wetting routine. Press the following buttons to call up the wetting routine: [Utilities] > [Sensor Cartridge internal wetting routine] Then call up another Calibration for ready.	☑ - ☒ Continue with next corrective action
	3. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	4. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, refer to chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	5. Contact the Roche service hotline for additional measures.	

► One or more oximeter parameter(s) is/are not calibrated

	Corrective action	Result and follow-up action
	1. Call up a "Calibration for Ready".	☑ -
☞	Press the following buttons to call up the calibration: [Instrument] > [Calibration for Ready]	☒ Continue with next corrective action
	2. Reinsert the already installed Fluid Pack.	☑ Carry out quality control in 3 levels.
☞	1. To remove the Fluid Pack, press the following buttons: [Workplace] > [Change Fluid Pack] 2. Open the instrument door. 3. Remove the already installed Fluid Pack. 4. Reinsert the same Fluid Pack. 5. Close the instrument door. 6. Automatic follow-up actions are started.	☒ Continue with next corrective action
📞	**3.** Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	4. Replace the Fluid Pack. Insert a new Fluid Pack. 👁 For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels ☒ Continue with next corrective action
📞	**5.** Contact the Roche service hotline for additional measures.	

Parameter with QC lock or QC warning

Note

Before starting the corrective action, identify the affected parameter and the level of the QC material that is causing the problem.

The QC problem can be solved only by performing a QC measurement correctly and within range, using the same QC level.

► One or more sensor parameter(s) is/are occupied with a QC lock or QC warning

	Corrective action	Result and follow-up action
	1. Carry out a manual QC measurement. To call up the manual QC measurement, press the following buttons: [Workplace] > [QC measurement] For additional information about the manual QC measurement, refer to chapter 9 *Quality control*, section *Manual QC measurement with COMBITROL PLUS B* on page D-76.	☑ - ☒ Continue with next corrective action
	2. Call up a system calibration. Press the following buttons to call up the calibration: [Instrument] > [System calibration] Then repeat the manual QC measurement.	☑ - ☒ Continue with next corrective action
	3. Carry out the internal wetting routine. Press the following buttons to call up the wetting routine: [Utilities] > [Sensor Cartridge internal wetting routine] Then call up another system calibration and carry out a manual QC measurement.	☑ - ☒ Continue with next corrective action
	4. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	5. Replace the Sensor Cartridge Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, refer to chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels ☒ Continue with next corrective action
	6. Contact the Roche service hotline for additional measures.	

► All sensor parameters are occupied with a QC lock or QC warning

	Corrective action	Result and follow-up action
	1. Carry out a manual QC measurement.	☑ -
☞	To call up the manual QC measurement, press the following buttons: [Workplace] > [QC measurement]	☒ Continue with next corrective action
	👁 For additional information about the manual QC measurement, refer to chapter 9 *Quality control*, section *Manual QC measurement with COMBITROL PLUS B* on page D-76.	
	2. Carry out the internal wetting routine.	☑ -
☞	Press the following buttons to call up the wetting routine: [Utilities] > [Sensor Cartridge internal wetting routine]	☒ Continue with next corrective action
	Then call up another system calibration and carry out a manual QC measurement.	
📞	**3.** Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report.
		👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.

► One or more oximeter parameter(s) is/are occupied with a QC lock or QC warning

	Corrective action	Result and follow-up action
	1. Carry out a manual QC measurement.	☑ -
☞	To call up the manual QC measurement, press the following buttons: [Workplace] > [QC measurement]	☒ Continue with next corrective action
	👁 For additional information about the manual QC measurement, refer to chapter 9 *Quality control*, section *Manual QC measurement with COMBITROL PLUS B* on page D-76.	
	2. Call up an oximeter calibration.	☑ -
☞	Press the following buttons to call up the calibration: [Instrument] > [Oximeter calibration]	☒ Continue with next corrective action
	Then repeat the manual QC measurement.	
	3. Reinsert the already installed Fluid Pack.	☑ -
☞	1. To remove the Fluid Pack, press the following buttons: [Workplace] > [Change Fluid Pack] 2. Open the instrument door. 3. Remove the already installed Fluid Pack. 4. Reinsert the same Fluid Pack. 5. Close the instrument door. 6. Automatic follow-up actions are started.	☒ Continue with next corrective action
	Then repeat the manual QC measurement.	

	Corrective action	Result and follow-up action
	4. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	5. Replace the Fluid Pack. Insert a new Fluid Pack. For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels ☒ Continue with next corrective action
	6. Contact the Roche service hotline for additional measures.	

Sensor Cartridge error

► Sensor Cartridge defective

Type of error:

ID	ERROR MESSAGE
13	Filling of Sensor Cartridge not possible

	Corrective action	Result and follow-up action
	1. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	2. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels ☒ Continue with next corrective action
	3. Contact the Roche service hotline for additional measures.	

► Sensor Cartridge dirty

Type of error:

ID	ERROR MESSAGE
18	Sensor Cartridge dirty

	Corrective action	Result and follow-up action
	1. Remove the already installed Sensor Cartridge.	☑ Carry out quality control in 3 levels ☒ Continue with next corrective action
	1. To remove the Sensor Cartridge, press the following buttons: [Workplace] > [Change Sensor Cartridge] 2. Open the front door. 3. Remove the already installed Sensor Cartridge. 4. After removing the Sensor Cartridge. inspect the rear side of the Sensor Cartridge for any dirt. Carefully clean off any dirt using a dry cloth. 5. Then reinsert the clean Sensor Cartridge. 6. Call up the function: [Change Fluid Pack]. 7. Remove the Fluid Pack and check the docking parts of the Fluid Pack for visible dirt and clean it carefully if necessary. 8. Reinsert the Fluid Pack. 9. Close the front door. 10. Automatic follow-up actions are started.	

	Corrective action	Result and follow-up action
	2. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	3. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	4. Contact the Roche service hotline for additional measures.	

► Power failure during Sensor Cartridge change

Type of error:

ID	ERROR MESSAGE
1001	Power failure during Sensor Cartridge change

	Corrective action	Result and follow-up action
	1. Remove the already installed Sensor Cartridge. 1. To remove the Sensor Cartridge, press the following buttons: [Workplace] > [Change Sensor Cartridge] 2. Open the front door. 3. Remove the already installed Sensor Cartridge. 4. Reinsert the same Sensor Cartridge. 5. Close the front door. 6. Automatic follow-up actions are started.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	2. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	3. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	4. Contact the Roche service hotline for additional measures.	

► Exhausted or expired

Note

Different reasons can lead a Sensor Cartridge to be assigned as exhausted or expired. The groups below provide the root causes for the described error messages.

Type of error:

ID	ERROR MESSAGE
1002	See the groups below, followed by the short explanations.

► Sensor Cartridge errors - group 1

Note

These regular and expected error messages are found during normal operation. They do not represent any Sensor Cartridge or instrument malfunction.

ERROR MESSAGE	Sensor Cartridge missing
REASON	No Sensor Cartridge is installed.

ERROR MESSAGE	Sensor Cartridge expired
REASON	The expiry date of the installed Sensor Cartridge has been exceeded.

ERROR MESSAGE	No remaining tests for this Sensor Cartridge
REASON	The maximum number of tests allowed for the installed Sensor Cartridge has been reached.

	Corrective action	Result and follow-up action
1.	Replace the Sensor Cartridge. Insert a new Sensor Cartridge. For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels.. ☒ Continue with the next corrective action.
2.	Contact the Roche service hotline for additional measures.	

► Sensor Cartridge errors - group 2

Note

These error messages, caused by inappropriate Sensor Cartridge use can be avoided. They do not represent any Sensor Cartridge or instrument malfunction.

ERROR MESSAGE	Sensor Cartridge was not replaced correctly.
REASON	The Sensor Cartridge was replaced without following the correct replacement procedure, e.g. replaced while the instrument was switched off.

ERROR MESSAGE	Sensor Cartridge was exchanged too many times.
REASON	The same Sensor Cartridge was removed and reinserted more than 256 times.

ERROR MESSAGE	Sensor Cartridge has been off-board for too long.
REASON	The maximum continuous period (24 hours) to keep a used Sensor Cartridge uninstalled, or in a switched off instrument and allow reuse, was exceeded.

ERROR MESSAGE	Total Sensor Cartridge off-board time has exceeded the allowed limit.
REASON	The maximum total time (ten days) to keep a used Sensor Cartridge uninstalled, or in a switched off instrument and allow reuse, was exceeded. The total time is the sum of all single events, without exceeding a continuous period of 24 hours per event.

	Corrective action	Result and follow-up action
	1. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. 👁 For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels.. ☒ Continue with the next corrective action.
📞	**2.** Contact the Roche service hotline for additional measures.	

► Sensor Cartridge errors - group 3

Note

Error messages caused by unexpected Sensor Cartridge problems. Contact the Roche service hotline for support.

ERROR MESSAGE	Sensor Cartridge chip has invalid data.
REASON	The Sensor Cartridge chip does not contain the expected data.

ERROR MESSAGE	Sensor Cartridge chip version is not supported by current software.
REASON	The currently installed instrument software version, cannot accept the Sensor Cartridge chip data.

	Corrective action	Result and follow-up action
📞	**1.** Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	2. Replace the Sensor Cartridge. Insert a new Sensor Cartridge. 👁 For additional information about changing the Sensor Cartridge, see chapter 13 *Consumable change*, section *Change Sensor Cartridge* on page E-8.	☑ Carry out quality control in 3 levels. ☒ Continue with the next corrective action.
📞	**3.** Contact the Roche service hotline for additional measures.	Create and transmit a Troubleshooting-Report.

► Removal of Sensor Cartridge not possible

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
	2. Contact the Roche service hotline for support.	Create and transmit a Troubleshooting-Report.

Fluid Pack error

The Fluid Pack can be damaged in different ways.
These can be divided into five groups.

► Fluid Pack defective - group 1

Type of error:

ID	ERROR MESSAGE
3	SIM system stop
4	Sample sensor system stop
5	Valve system stop
6	System stop triggered by washing error
8	System stop triggered by empty system
19	Fluidics tightness problem
20	Fluidics system blocked

	Corrective action	Result and follow-up action
	1. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	2. Replace the Fluid Pack. Insert a new Fluid Pack. For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	3. Contact the Roche service hotline for additional measures.	

► Fluid Pack defective - group 2

Type of error:

ID	ERROR MESSAGE
7	System stop triggered by insufficient filling with reference solution
9	System stop due to positioning of solution
10	System stop due to positioning of sample

	Corrective action	Result and follow-up action
	1. Carry out the internal wetting routine.	☑ -
	Press the following buttons to call up the wetting routine: [Utilities] > [Sensor Cartridge internal wetting routine]	☒ Continue with next corrective action

	Corrective action	Result and follow-up action
	2. Remove the consumables installed earlier. 1. Press the following buttons to remove the consumables: [Workplace] > [Change Sensor Cartridge] 2. Open the front door. 3. Remove the already installed Sensor Cartridge. 4. Remove the already installed Fluid Pack. 5. Reinsert the same Sensor Cartridge. 6. Reinsert the same Fluid Pack. 7. Close the front door. 8. Automatic follow-up actions are started.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	3. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	4. Replace the Fluid Pack. Insert a new Fluid Pack. For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
	5. Contact the Roche service hotline for additional measures.	

For more information refer section *Checking the valve position* on page F-40.

Exhausted or expired

Note

Different reasons can lead a Fluid Pack to be assigned as exhausted or expired. The groups below provide the root causes for the described error messages.

Type of error:

ID	ERROR MESSAGE
1003	See the groups below, followed by the short explanations.

Fluid Pack errors - group 3

Note

These regular and expected error messages are found during normal operation. They do not represent any Fluid Pack or instrument malfunction.

ERROR MESSAGE	Fluid Pack missing
REASON	No Fluid Pack is installed.

ERROR MESSAGE	Fluid Pack expired
REASON	The expiry date of the installed Fluid Pack has been exceeded.

ERROR MESSAGE	Fluid Pack empty
REASON	The maximum number of tests allowed for the installed Fluid Pack has been reached.

	Corrective action	Result and follow-up action
1.	Replace the Fluid Pack. Insert a new Fluid Pack. For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
2.	Contact the Roche service hotline for additional measures.	

► Fluid Pack errors - group 4

Note

These error messages, caused by inappropriate Fluid Pack use can be avoided. They do not represent any Fluid Pack or instrument malfunction.

ERROR MESSAGE	Fluid Pack was not replaced correctly.
REASON	The Fluid Pack was replaced without following the correct replacement procedure, e.g. replaced while the instrument was switched off.

ERROR MESSAGE	Fluid Pack was exchanged too many times.
REASON	The same Fluid Pack was removed and reinserted more than 256 times.

ERROR MESSAGE	Fluid Pack has been off-board for too long.
REASON	The maximum continuous period (24 hours) to keep a used Fluid Pack uninstalled, or in a switched off instrument and allow reuse, was exceeded.

ERROR MESSAGE	Total Fluid Pack off-board time has exceeded the allowed limit
REASON	The maximum total time (40 days) to keep a used Fluid Pack uninstalled, or in a switched off instrument and allow reuse, was exceeded. The total time is the sum of all single events, without exceeding a continuous period of 24 hours per event.

	Corrective action	Result and follow-up action
1.	Replace the Fluid Pack. Insert a new Fluid Pack. For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
2.	Contact the Roche service hotline for additional measures.	

► Fluid Pack errors - group 5

Note

Error messages caused by unexpected Fluid Pack problems. Contact the Roche service hotline for support.

ERROR MESSAGE	Fluid Pack chip has invalid data
REASON	The Fluid Pack chip does not contain the expected data, e.g. a type of Fluid Pack without COOX is installed into an instrument with COOX.

ERROR MESSAGE	Fluid Pack chip version is not supported by current software.
REASON	The currently installed instrument software version, cannot accept the Fluid Pack chip data.

	Corrective action	Result and follow-up action
1.	Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. e For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
2.	Replace the Fluid Pack. Insert a new Fluid Pack (check for appropriated Fluid Pack type). For additional information about changing the Fluid Pack, refer to chapter 13 *Consumable change*, section *Change Fluid Pack* on page E-11.	☑ Carry out quality control in 3 levels. ☒ Continue with next corrective action
3.	Contact the Roche service hotline for additional measures.	Create and transmit a Troubleshooting-Report.

► Removal of the Fluid Pack not possible

	Corrective action	Result and follow-up action
1.	Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
2.	Contact the Roche service hotline for support.	Create and transmit a Troubleshooting-Report.

AutoQC Pack error

1 Exhausted or expired

Note

Different reasons can lead an AutoQC Pack to be assigned as exhausted or expired. The groups below provide the root causes for the described error messages.

Type of error:

ID	ERROR MESSAGE
3000	See the groups below, followed by the short explanations.

► AutoQC Pack errors - group 1

Note

These regular and expected error messages are found during normal operation. They do not represent any AutoQC Pack or instrument malfunction.

ERROR MESSAGE	AutoQC Pack expired
REASON	The expiry date of the installed AutoQC Pack has been exceeded.

ERROR MESSAGE	AutoQC Pack empty
REASON	The maximum number of ampoules for the installed AutoQC Pack has been reached.

	Corrective action	Result and follow-up action
1.	Replace the AutoQC Pack. Insert a new AutoQC Pack. For additional information about changing the AutoQC Pack, refer to chapter 13 *Consumable change*, section *Change AutoQC Pack (optional)* on page E-14.	☑ - ☒ Continue with next corrective action
2.	Contact the Roche service hotline for additional measures.	

► AutoQC Pack errors - group 2

Note

These error messages, caused by inappropriate AutoQC Pack use can be avoided. They do not represent any AutoQC Pack or instrument malfunction.

ERROR MESSAGE	AutoQC Pack was exchanged too many times
REASON	The same AutoQC Pack was removed and reinserted more than 256 times.

ERROR MESSAGE	AutoQC Pack has been off-board for too long
REASON	The maximum continuous period (seven days) to keep a used AutoQC Pack uninstalled, or in a switched off instrument and allow reuse, was exceeded.

ERROR MESSAGE	Total AutoQC Pack off-board time has exceeded the allowed limit
REASON	The maximum total time (seven days) to keep a used AutoQC Pack uninstalled, or in a switched off instrument and allow reuse, was exceeded. The total time is the sum of all single events, without exceeding a continuous period of seven days per event.

	Corrective action	Result and follow-up action
1.	Replace the AutoQC Pack. Insert a new AutoQC Pack. For additional information about changing the AutoQC Pack, refer to chapter 13 *Consumable change*, section *Change AutoQC Pack (optional)* on page E-14.	☑ - ☒ Continue with next corrective action
2.	Contact the Roche service hotline for additional measures.	

► AutoQC Pack defective

Type of error:

ID	ERROR MESSAGE
3005	See the errors below, followed by the short explanations.

ERROR MESSAGE	AutoQC Pack missing
REASON	No AutoQC Pack is installed.

ERROR MESSAGE	AutoQC Pack was not replaced correctly.
REASON	The AutoQC Pack was replaced without following the correct replacement procedure, e.g. replaced while the instrument was switched off.

	Corrective action	Result and follow-up action
1.	Removing the installed AutoQC Pack. 1. To remove the AutoQC Pack, press the following buttons: [Workplace] > [Change AutoQC Pack] 2. Open the front door. 3. Remove the installed AutoQC Pack. 4. Reinsert the same AutoQC Pack. 5. Close the front door.	☑ - ☒ Continue with next corrective action
2.	Replace the AutoQC Pack. Insert a new AutoQC Pack. For additional information about changing the AutoQC Pack, refer to chapter 13 *Consumable change*, section *Change AutoQC Pack (optional)* on page E-14.	☑ - ☒ Continue with next corrective action
4.	Contact the Roche service hotline for additional measures.	Create and transmit a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.

► Removal of the AutoQC Pack not possible

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
	2. Contact the Roche service hotline for support.	Create and transmit a Troubleshooting-Report.

AutoQC module error

► **AutoQC module defective**

Type of error:

ID	ERROR MESSAGE
3001	AutoQC module defective

	Corrective action	Result and follow-up action
	1. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.
	2. Replace the AutoQC Pack. Insert a new AutoQC Pack. For additional information about changing the AutoQC Pack, refer to chapter 13 *Consumable change*, section *Change AutoQC Pack (optional)* on page E-14.	☑ - ☒ Continue with next corrective action
	3. Contact the Roche service hotline for additional measures.	

Oximeter module error

► **Oximeter module defective**

Type of error:

ID	ERROR MESSAGE
3002	Oximeter module defective

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

Printer module error

► Printer module defective

Type of error:

ID	ERROR MESSAGE
3003	Printer module defective

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► No printer paper

Type of error:

ID	ERROR MESSAGE
3004	No printer paper

	Corrective action	Result and follow-up action
	1. Replace the printer paper. Insert a new roll of printer paper.	☑ - ☒ Continue with next corrective action
	2. Contact the Roche service hotline for support.	Create and transmit Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.

Instrument error

► Analyzer defective

Type of error:

ID	ERROR MESSAGE
1	AutoQC system stop
12	Valve hardware defective
14	Measuring chamber module defective
15	Fluidics control board defective
16	Oximeter module board defective
17	UIM hardware/power supply defective
23	µC power connection error

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	
☞	Then press the [Shutdown system] button.	
	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► Internal control module not responding

Type of error:

ID	ERROR MESSAGE
2	Microcontroller system stop

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	☑ - ☒ Continue with next corrective action
☞	Then press the [Restart system] button.	
	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► Internal software error

Type of error:

ID	ERROR MESSAGE
1000	Database server not started
1004	Timeout of the scheduler
1009	Data synchronization error on CF card

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	☑ - ☒ Continue with next corrective action
☞	Then press the [Restart system] button.	
📞	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► CF card cannot be accessed

Type of error:

ID	ERROR MESSAGE
1007	CF card cannot be accessed

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	☑ - ☒ Continue with next corrective action
☞	Then press the [Shutdown system] button. To start the **cobas b** 123 POC system, press the (On/Off) button on the rear panel of the instrument.	
📞	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► Software update failed

Type of error:

ID	ERROR MESSAGE
1008	Software version mismatch

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. 👁 For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	☑ - ☒ Continue with next corrective action
☞	Then press the [Restart system] button. To start the **cobas b** 123 POC system, press the (On/Off) button on the rear panel of the instrument.	
📞	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

► Spare part not initialized

Type of error:

ID	ERROR MESSAGE
21	Unknown µC board

	Corrective action	Result and follow-up action
	1. Create a Troubleshooting-Report. For additional information about the Troubleshooting-Report, refer to the section *Troubleshooting-Report* on page F-42.	☑ - ☒ Continue with next corrective action
	Then press the [Restart system] button. To start the **cobas b** 123 POC system, press the (On/Off) button on the rear panel of the instrument.	
	2. Contact the Roche service hotline for support.	Transmit a Troubleshooting-Report.

Sensor Cartridge wetting routine

The **cobas b** 123 POC system carries out the internal wetting automatically after you insert a new. unwetted Sensor Cartridge.

After the internal wetting is concluded. a 2P calibration is called up automatically as a follow-up action.

If you want additional wetting of the Sensor Cartridge, you can do this either using a wetting solution (internal wetting) or using a whole blood sample (external wetting).

Warning

Using wetting fluids other than those recommended by Roche can cause calibration and measurement errors.

Internal wetting

If necessary, you can also call up the internal wetting manually.

Go to the "Utilities" menu and press the following button:

☞ [Sensor Cartridge internal wetting routine]

For the internal wetting routine. a wetting solution (WET) from the Fluid Pack is used for wetting the Sensor Cartridge.

After the internal wetting is concluded. a 2P calibration is called up automatically as a follow-up action.

External wetting

Caution

Before starting external wetting. it is mandatory to prepare a sample container with human whole blood[(a)].

The whole blood should not be older than 24 hours. It should contain heparin as an anticoagulant.

For this wetting in **syringe mode**. a sample volume of at least **1 mL** in a 2 mL syringe is required.

For the wetting in **capillary mode**. a sample volume of at least **180 µL** is required.

(a) Blood samples shall only be used in accordance with applicable laws and ethical rules.

Go to the "Utilities" menu and press the following button:

☞ [Sensor Cartridge wetting routine]

Wetting the Sensor Cartridge can take place either in syringe mode or in capillary mode.

To select the desired input mode, press the corresponding button:

	Start wetting in the capillary mode
	Start wetting in the syringe mode

1. Then. the instrument automatically prepares for wetting the Sensor Cartridge. Wait until the preparation time is finished.
2. Securely attach the corresponding sample container to the fill port and press [Aspirate sample].

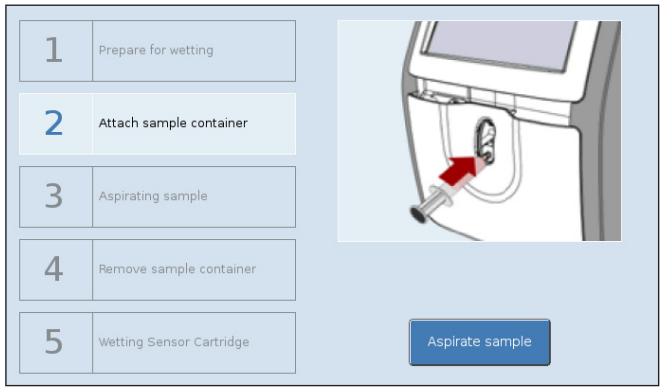


Figure F-6

3. The sample is aspirated.
4. Remove the sample container and press [Confirm removal of the sample container].

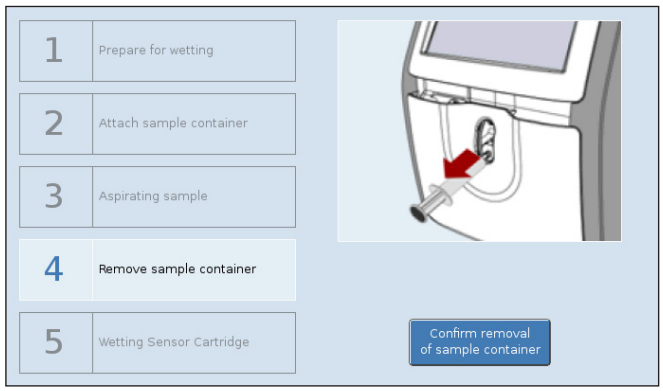


Figure F-7

5. The Sensor Cartridge is wetted automatically.

Next, the automated follow-up actions are started.

Checking the valve position

If, while remedying a Fluid Pack error, you reinsert a Fluid Pack installed earlier, be absolutely certain to check the valve position on the rear of the Fluid Pack before insertion. Also check the valve position in the instrument.

For additional information on initializing the pouch valves without Fluid Pack, refer to chapter 12 *Software functions*, section *Fluidics control module (FCM)* - Valves.

A Correct valve position **B** Incorrect valve position (3rd valve center)

Figure F-8

An incorrect valve position, as shown in the figure above, can be easily remedied, e.g. by using a pen.

In order to correct the position of any Fluid Pack valve, insert the pen tip into the valve hole, and adjust the valve position.

Safety Instructions

Suitable safety equipment must be worn in order to prevent direct contact with biological substances. Suitable safety equipment includes, laboratory clothing, protective gloves, safety glasses, and masks. If there is a danger of splashes, a safety visor is also required. In addition, suitable disinfection procedures must be used.

Barcode scanner

If problems occur reading in with the barcode scanner (MS 180 PS2 hand scanner with integrated decoder) included in the scope of delivery, carry out the following steps:

1. Make sure your scanner firmly connects with the interface connector of the instrument.
2. Inspect in detail the condition of the cable, e.g. by looking for broken areas, or loose cable parts.
3. Check the voltage supply by inspecting whether LED light is visible (continuously or flash light only). Additionally, the scanner prompts a trigger tone when reading a barcode.
4. Use the test function on the instrument to read in a barcode with known characters. In case the characters are transmitted and displayed correctly the barcode scanner will indicate this by a flash light and a trigger.
5. In case of a problem, the characters are transmitted and/or displayed incorrectly. or even not transmitted.
   Proceed with the step 6:
6. Unplug the barcode cable from the instrument.
7. Re-plug the barcode cable.
8. Repeat step 4 to check again the functionality. If the scanner is still not functional proceed with step 9.
9. Set the scanner by using the barcode manual to default:
   - In case of missing or wrong characters select Group 10 "Intercharacter Delay". read the barcode labeled as "4 mS" (B013$) or "16 mS" (B014$).
   - In case of no characters but visible LED light and the scanner prompting a trigger tone when reading a barcode select Group 1 "Computer type", read the barcode labeled as "Notebook*" (C007$).
     Be aware that this code deactivates a connected keyboard.
   - In case of a particular code type can not be read select Group 15 "Enable symbologies", read the barcode labeled as "Enable all code" (A002$).

If the error persists, contact the Roche service hotline.

Troubleshooting-Report

Creating the Troubleshooting-Report

The Troubleshooting-Report is a report generated automatically by the instrument that is used by the service hotline or Service organizations in the event of an instrument or consumable problem for comprehensive analysis.

The Troubleshooting-Report is also used to evaluate complaints.

To create the Troubleshooting-Report, press the following button:

☞ [Utilities] > [Export/import] > [Export Troubleshooting-Report]

► **Creating a Troubleshooting Report**

1 From the list. select and mark one or more problems that have occurred and press this button.

2 Continue with the [Next] button.

3 From the list. select and mark one or more corrective actions that have been taken and press this button.

4 Continue with the [Next] button.

5 To export the Troubleshooting-Report, press the following key:

☞ [Export to USB]

6 Plug in the USB storage device.

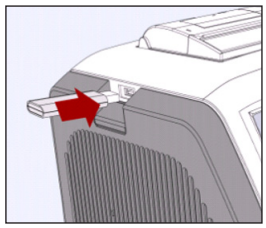


Figure F-9

7 Press the [Start] button to start the data export.

The Troubleshooting-Report is exported immediately to the previously inserted USB storage device.

Note

If the USB storage device does not have sufficient storage space available. a corresponding error message appears. Data transfer is canceled.

8 Pull out the USB storage device after the data export has been completed.

Note

Two additional USB interfaces are located on the rear side of the **cobas b** 123 POC system.

Depot-Repair

Note

The "Depot-Repair" section applies only if this service is provided by the local Roche Service. Depending on the national organization. differences or deviations may exist from the process described here.

If anything is unclear or you have any questions about the "Depot-Repair" section, contact the Roche service hotline.

General information – Instrument Swap

The Depot-Repair process is a repair process for defective customer instruments. which is not carried out onsite at the customer's location. but in a Roche internal repair center (local or global). During this time, the customer is provided with a replacement instrument, which must be set up properly to replace the customer instrument.

If a defective **cobas b** 123 POC system requires repair, a corresponding replacement instrument is provided.
The replacement instrument is shipped to the customer's address.

Instructions are included with the replacement instrument to ensure an uncomplicated instrument change.

Note

Start by carefully reading the checklist provided. Follow the instructions step by step and check off the corresponding tasks after each step.

The Depot-Repair checklist is divided into 4 areas:

1 Putting the defective instrument out of operation

2 Preparations for the replacement instrument

3 Installing the replacement instrument

4 Transport preparations for the defective instrument

The following items are included in the scope of delivery:

- Replacement instrument for the **cobas b** 123 POC system (excluding consumables, barcode scanner, CompactFlash memory card, printer paper and power supply)
- Transport packaging
- Plastic bag
- Depot-Repair user checklist
- Address label

Note

Send the completely filled-out Depot-Repair user checklist with the defective instrument to the local Roche service organization.

Putting the defective instrument out of operation

To ensure proper transport, it is mandatory that a defective instrument is properly shut down using the function provided on the instrument.

Caution

If one or more steps of the put out of operation routine cannot be carried out, contact the Roche service hotline immediately.

Roche recommends that all surfaces should be disinfected before the instrument is put out of operation.

For additional information, refer to chapter 13 *Consumable change*, section *Disinfection* on page E-5.

Note

All consumables must be removed during the put out of operation procedure.
If one or more consumables cannot be removed, contact the Roche service hotline immediately.

The procedure concludes by switching off the instrument.

Follow the instructions on the screen.

For detailed information, refer to chapter 7 *Installation and put out of operation*, section *Put out of operation* on page D-14.

Note

Before shutdown. create a Troubleshooting-Report under [Utilities] > [Export/Import] > [Export Troubleshooting-Report] and export it to a USB storage device.

For detailed information, refer to section *Troubleshooting-Report* on page F-42.

Note

If an anonymization of the patient data (patient name. etc.) is desired, run the [Prepare for Depot-Repair] service function:

☞ [Utilities] > [Service functions] > [Utilities] > [Prepare for Depot-Repair]

To enter the protected service function area, a user with the service operator level or higher must be logged in.

The function [Prepare for Depot-Repair] anonymizes the patient data (for example. patient names). When leaving the service area, the put out of operation routine starts automatically.

Go to the "Utilities" menu and press the following button:

☞ [Put out of operation]

1. Acknowledge the warning with [OK].
2. Preparing for removal (automatic step).
3. Open the front door.
4. Remove the Fluid Pack.
5. Remove the Sensor Cartridge and place it on a clean, level surface.

CAUTION

Caution

If a previously used consumable (e.g. Fluid Pack or Sensor Cartridge) is not inserted into the replacement instrument within **24 hours**, it can no longer be reused and a new consumable must be inserted.
Exception: a previously used AutoQC Pack can be reused within **7 days**.

Handle the Sensor Cartridge carefully to prevent the possibility of fluid escaping from the Sensor Cartridge.

6 Remove the AutoQC Pack (optional).

7 If the area for consumables is visibly dirty. carefully disinfect the affected surfaces using a damp cloth (optional).

8 Close the front door.

9 Press the [Switch off] button to conclude the put out of operation routine.

10 Disconnect the power supply first from the power supply network and then from the instrument.

11 Disconnect the barcode scanner and the network connection (if present) on the rear panel.

12 Remove the USB storage device (if present).

13 Remove the printer paper.

14 Remove the CompactFlash memory card from the memory card slot provided on the rear side of the defective instrument.

CAUTION

Caution

Never remove the CompactFlash memory card from the device while it is switched on.

A Press the ejecting device using a pen.

B Remove the CompactFlash memory card

Figure F-10 Removing the CompactFlash memory card

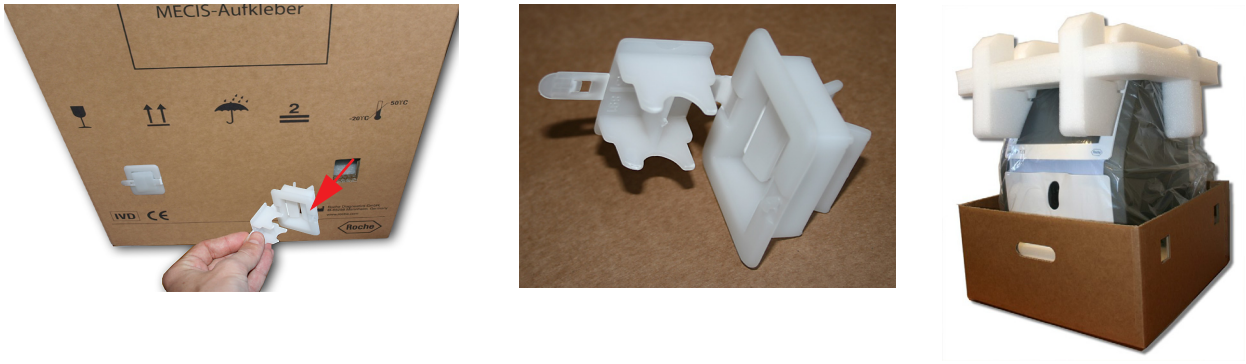
Preparations for the replacement instrument

CAUTION

Caution

Be absolutely certain to keep the transport packaging of the replacement instrument. Do not destroy the transport packaging.

1 Unpack the replacement instrument completely.



A Remove the plastic clamping pieces from the box and open the transport packaging.

B Plastic clamping piece

C Instrument in the opened transport packaging

Figure F-11

2 Set up the instrument at a suitable, level location.

For additional information, refer to chapter 7 *Installation and put out of operation*, section *Location* on page D-5.

3 Insert the CompactFlash memory card into the slot provided for this purpose on the rear side of the replacement instrument.

Figure F-12 Inserting the CompactFlash memory card

Installing the replacement instrument

For detailed information, refer to chapter 7 *Installation and put out of operation*, section *Installation* on page D-5.

1 Connect the barcode scanner and, if necessary the network connection to the corresponding interface on the rear side of the **cobas b** 123 POC system.

2 First connect the external power supply to the instrument and then to the power supply network.

3 Switch on the instrument.

4 After the software initialization is completed, a prompt is displayed asking if you want to copy the data from the compact flash memory card. To confirm this prompt, press the [Import] button.

Note

A backup copy of all settings (except the IP address) and the measurement database is loaded from the compact flash memory card to the instrument automatically.

Attention

In no case press the [Delete] button, otherwise all data from the CompactFlash memory card will be deleted.

Pressing the [Cancel button] shuts the instrument down.

5 Using the configuration wizard, check the most important settings and adjust them if necessary.

Press the [Configure] button to open the configuration wizard.

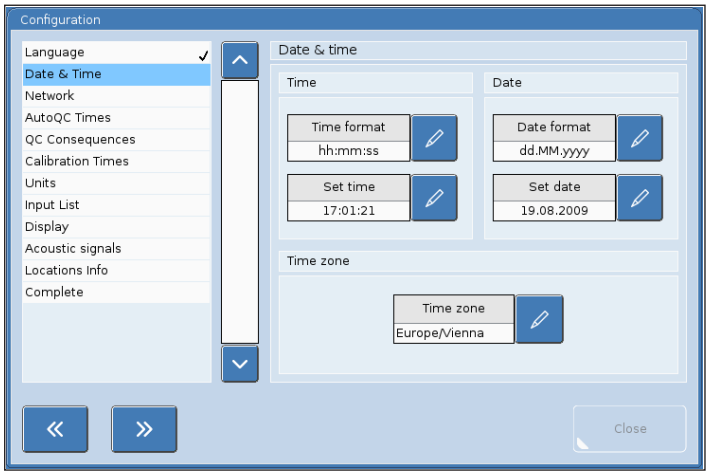


Figure F-13 Configuration wizard

By pressing the [Close] button, all changes are saved automatically.

When the [Continue] button is pressed, the user interface automatically moves on to the next step of the installation routine.

6 The installation is prepared (automatic step).

7 Open the front door.

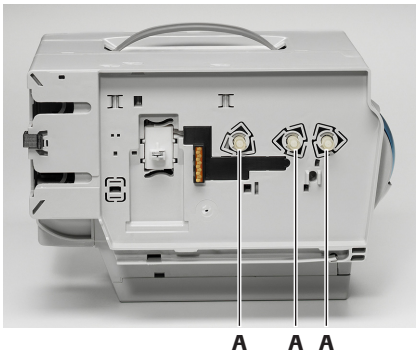
8 Insert the used Fluid Pack from the defective instrument into the replacement instrument.

If there are visible crystals on the docking parts of the Fluid Pack, carefully clean or remove these using a lightly moistened cloth (e.g. with distilled water).

Note

In case the Fluid Pack cannot be properly inserted, it is possible that Fluid Pack valves are displaced

For additional information on Fluid Pack valve positioning, see *Checking the valve position* on page F-40

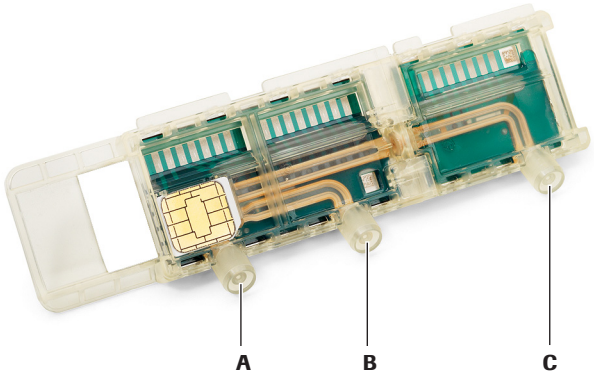


A Docking parts

Figure F-14

9 Insert the used Sensor Cartridge from the defective instrument into the replacement instrument.

If there are visible crystals on the inlets or outlet of the Sensor Cartridge, carefully clean or remove these using a lightly moistened cloth (e.g. with distilled water).



A Outlet (to peristaltic pump 1 and waste water container)

B Inlet (for reference solution)

C Inlet (for calibration solutions. standby solution and the sample)

Figure F-15

10 Insert the used AutoQC Pack from the defective instrument into the replacement instrument (optional).

11 Close the front door.

12 Insert the printer paper from the defective instrument into the replacement instrument.

13 Finish the installation routine by pressing the [Complete] button.

14 Run quality control on all 3 levels (1 = low, 2 = normal, 3 = high).
Make sure that the results agree with the target values.

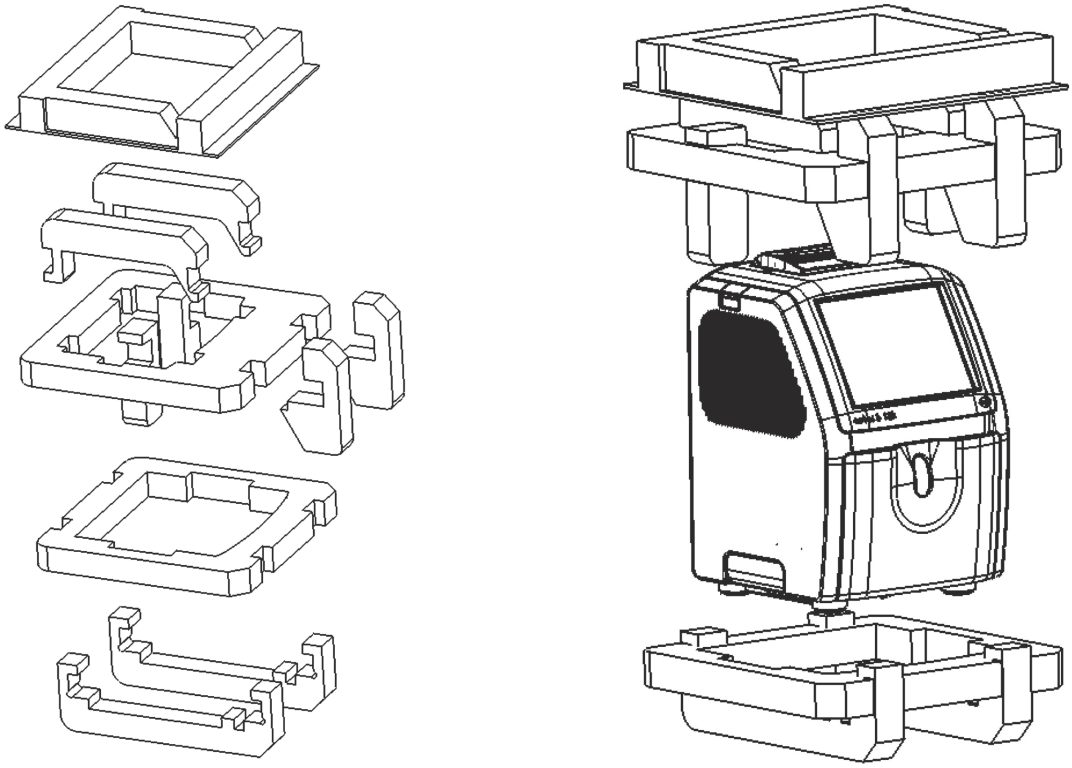
Transport preparations for the defective instrument

1 Fill in the "Client information" section on the included shipment information document (including shipment number).

Note

Fax the filled out shipment information document to the local Roche Service organization.

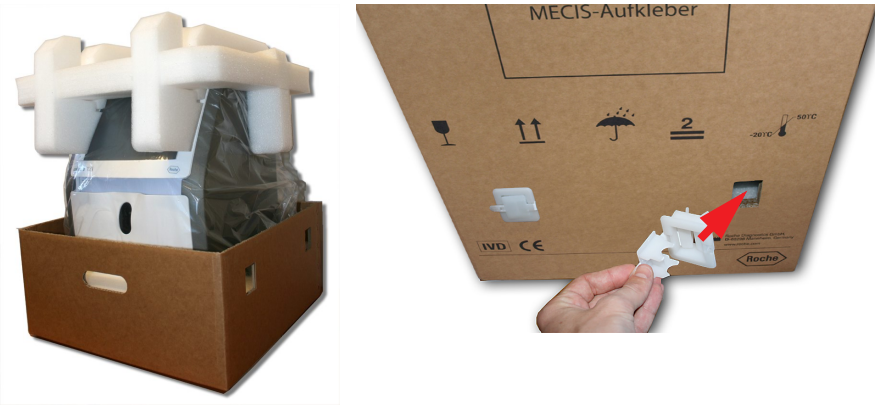
2 Assemble the transport protection and package the defective instrument (excluding consumables. CompactFlash memory card, power supply, barcode scanner and printer paper) with the packaging material received.



A Assembling the transport protection

B Placing the **cobas b** 123 POC system into packaging

Figure F-16



A Package the defective instrument according to the illustration. Close the transport packaging.

B Insert the plastic clamping pieces into the corresponding openings on the transport packaging.

Figure F-17 Transport packaging

3 Include the filled-out Depot-Repair user checklist with the defective instrument.

4 Close and seal the transport packaging.

5 Glue the address label to the transport packaging.

A Transport packaging with glued-on address label

Figure F-18

6 Send the completely packaged instrument to the corresponding Roche Service organization.

General information – Instrument Re-Swap

Once the defective **cobas b** 123 POC system has been repaired successfully in the repair center, the replacement instrument must be sent back to the repair center.

Instructions for an easy and efficient instrument replacement are provided with the repair instrument.

Note

Start by carefully reading the checklist provided. Follow the instructions step by step and check off the corresponding tasks after each step.

The Depot-Repair user checklist is divided into 4 areas:

1. Putting the loaner instrument out of operation
2. Preparations for the repaired instrument
3. Installing the repaired instrument
4. Transport preparations for the loaner instrument

The following items are included in the scope of delivery:

- Repaired instrument, (excluding consumables, barcode scanner, CompactFlash memory card, printer paper and power supply)
- Transport packaging
- Plastic bag
- Depot-Repair user checklist
- Address label

Note

Send the completely filled out Depot-Repair user checklist with the loaner instrument to the local Roche Service organization.

Putting the loaner instrument out of operation

For proper transport, it is mandatory to carry out a put out of operation of a loaner instrument.

Caution

CAUTION

If one or more steps of the put out of operation routine cannot be carried out, contact the Roche service hotline immediately.

Roche recommends that all surfaces should be disinfected before the instrument is put out of operation.

For additional information, refer to chapter 13 *Consumable change*, section *Disinfection* on page E-5.

Note

All consumables must be removed during the put out of operation procedure.
If one or more consumables cannot be removed, contact the Roche service hotline immediately.

The procedure concludes by switching off the instrument.

Follow the instructions on the screen.

For detailed information, refer to chapter 7 *Installation and put out of operation*, section *Put out of operation* on page D-14.

Note

If an anonymization of the patient data (patient name, etc is desired, run the [Prepare for Depot-Repair] service function:

☞ [Utilities] > [Service functions] > [Utilities] > [Prepare for Depot-Repair]

To enter the protected service function area, a user with the service operator level or higher must be logged in.

The function [Prepare for Depot-Repair] anonymizes the patient data (for example, patient names). When leaving the service area, the put out of operation routine starts automatically.

Go to the "Utilities" menu and press the following button:

☞ [Put out of operation]

1. Acknowledge the warning with [OK].
2. Preparing for removal (automatic step).
3. Open the front door.
4. Remove the Fluid Pack.
5. Remove the Sensor Cartridge and place it on a clean, level surface.

CAUTION

Caution

If a previously used consumable (e.g. Fluid Pack or Sensor Cartridge) is not inserted into the repair instrument within **24 hours**, it can no longer be reused and a new consumable must be inserted.
Exception: a previously used AutoQC Pack can be reused within **7 days**.

Handle the Sensor Cartridge carefully to prevent the possibility of fluid escaping from the Sensor Cartridge.

6. Remove the AutoQC Pack (optional).
7. If the area for consumables is visibly dirty, carefully clean the affected surfaces using a damp cloth (optional).
8. Close the front door.
9. Press the [Switch off] button to conclude the put out of operation routine.
10. Disconnect the power supply first from the power supply network and then from the instrument.
11. Disconnect the barcode scanner and the network connection (if present) on the rear panel.
12. Remove the USB storage device (if present).
13. Remove the printer paper.

14 Remove the CompactFlash memory card from the memory card slot provided on the rear side of the loaner instrument.

CAUTION

Caution

Never remove the CompactFlash memory card from the device while it is switched on.

A Press the ejecting device using a pen.

B Remove the CompactFlash memory card

Figure F-19 Removing the CompactFlash memory card

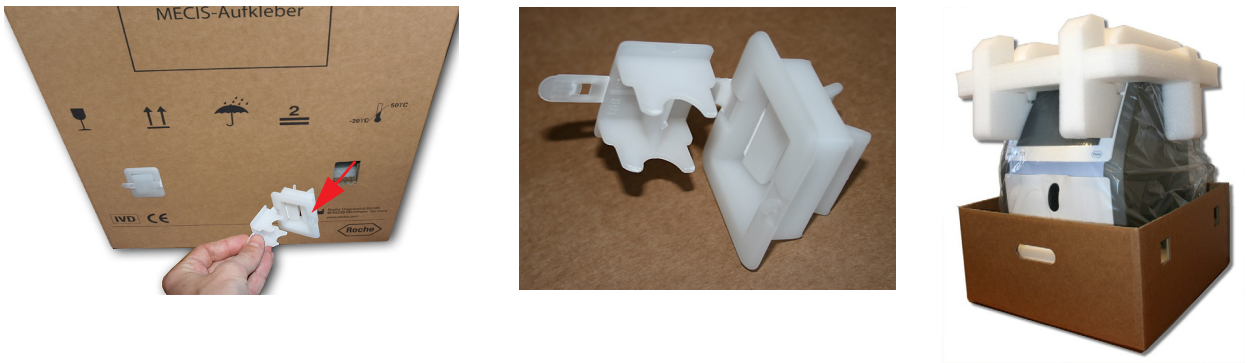
Preparations for the repaired instrument

CAUTION

Caution

Be absolutely certain to keep the transport packaging of the repaired instrument.
Do not destroy the transport packaging.

1 Unpack the repaired instrument completely.



A Remove the plastic clamping pieces from the box and open the transport packaging.

B Plastic clamping piece

C Instrument in the opened transport packaging

Figure F-20

2 Set up the instrument at a suitable, level location.

For additional information, refer to chapter 7 *Installation and put out of operation*, section *Location* on page D-5.

3 Insert the CompactFlash memory card into the slot provided for this purpose on the rear side of the repaired instrument.

Figure F-21 Inserting the CompactFlash memory card

Installing the repaired instrument

For detailed information, refer to chapter 7 *Installation and put out of operation*, section *Installation* on page D-5.

1. Connect the barcode scanner and, if necessary. the network connection to the corresponding interface on the rear side of the **cobas b** 123 POC system.
2. First connect the external power supply to the instrument and then to the power supply network.
3. Switch on the instrument.
4. After the software initialization is completed, a prompt is displayed asking if you want to copy the data from the compact flash memory card. To confirm this prompt, press the [Import] button.

Note

A backup copy of all settings (except the IP address) and the measurement database is loaded from the compact flash memory card to the instrument automatically.

Attention

In no case press the [Delete] button, otherwise all data from the CompactFlash memory card will be deleted.

Pressing the [Cancel button] shuts the instrument down.

5. Using the configuration wizard, check the most important settings and adjust them if necessary.

   Press the [Configure] button to open the configuration wizard.

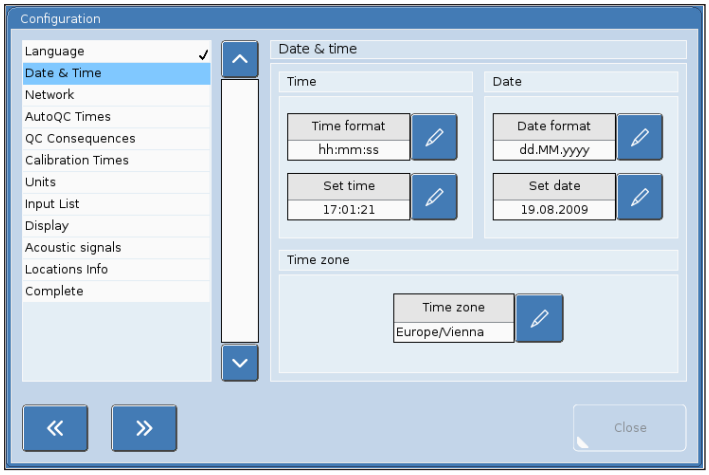


Figure F-22 Configuration wizard

By pressing the [Close] button, all changes are saved automatically.

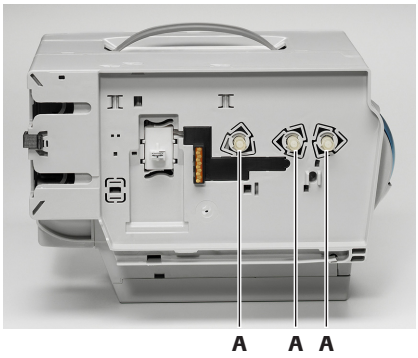
When the [Continue] button is pressed, the user interface automatically moves on to the next step of the installation routine.

6 The installation is prepared (automatic step).

7 Open the front door.

8 Insert the used Fluid Pack from the loaner instrument into the repaired instrument.

If there are visible crystals on the docking parts of the Fluid Pack. carefully clean or remove these using a lightly moistened cloth (e.g. with distilled water).

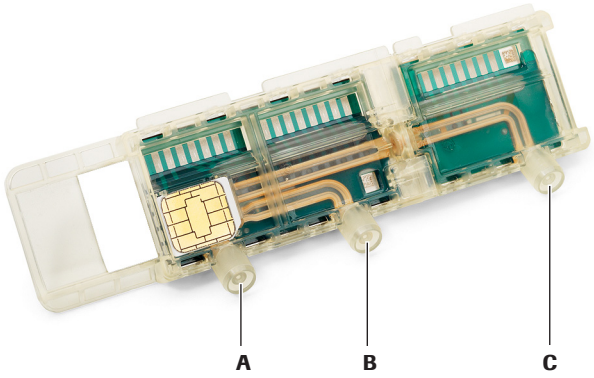


A Docking parts

Figure F-23

9 Insert the used Sensor Cartridge from the loaner instrument into the repaired instrument.

If there are visible crystals on the inlets or outlet of the Sensor Cartridge. carefully clean or remove these using a lightly moistened cloth (e.g. with distilled water).



A Outlet (to peristaltic pump 1 and waste water container)

B Inlet (for reference solution)

C Inlet (for calibration solutions. standby solution and the sample)

Figure F-24

10 Insert the used AutoQC Pack from the loaner instrument into the repaired instrument (optional).

11 Close the front door.

12 Insert the printer paper from the loaner instrument into the repaired instrument.

13 Finish the installation routine by pressing the [Complete] button.

14 Run quality control on all 3 levels (1 = low, 2 = normal, 3 = high). Make sure that the results agree with the target values.

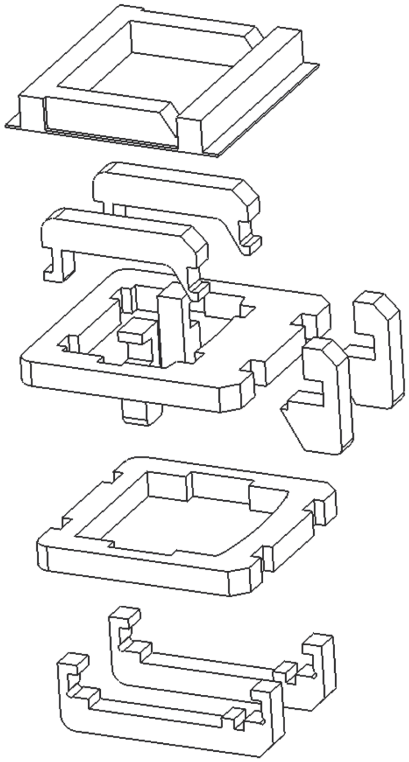
Transport preparations for the loaner instrument

1 Fill in the "Client information" section on the included shipment information document (including shipment number).

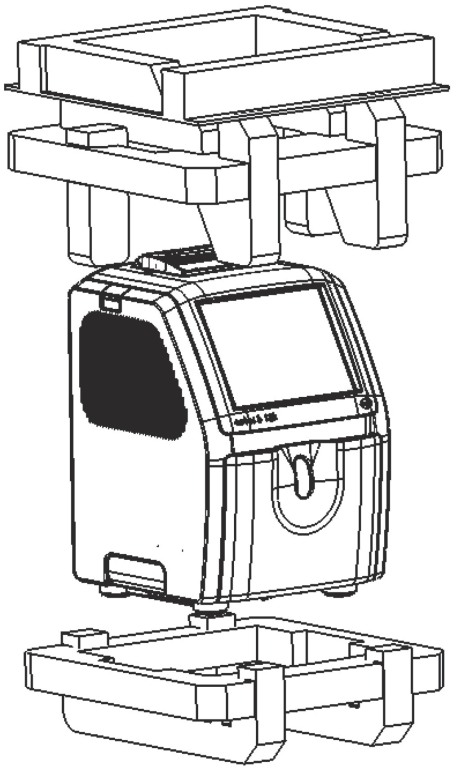
Note

Fax the filled out shipment information document to the local Roche Service organization.

2 Assemble the transport protection and package for the loaner instrument (excluding consumables, CompactFlash memory card, power supply, barcode scanner and printer paper) with the packaging material received with the repaired instrument.



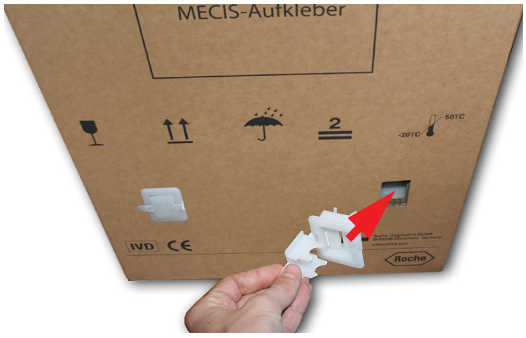
A Assembling the transport protection



B Placing the **cobas b** 123 POC system into packaging

Figure F-25

A Package the loaner instrument according to the illustration. Close the transport packaging



B Insert the plastic clamping pieces into the corresponding openings on the transport packaging.

Figure F-26 Transport packaging

3 Include the filled-out Depot-Repair checklist with the loaner instrument.

4 Close and seal the transport packaging.

5 Glue the address label to the transport packaging.

A Transport packaging with glued-on address label

Figure F-27

6 Send the completely packaged instrument to the corresponding Roche Service organization.

Appendix G

List of consumables

In this chapter, all necessary consumables and order numbers are listed.

In this chapter *Chapter* 15

Order information

To measure the respective parameter following products are required:

Sensor Cartridges types

	Parameter												
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	Hct	tHb	SO_2	COOX	Glu	Lac
cobas b 123 Sensor Cartridge BG 05170397001 (a)	-	-	-	-	X	X	X	X	+	+	+	-	-
cobas b 123 Sensor Cartridge BG/ISE 05170460001 (a)	X	X	X	X	X	X	X	X	+	+	+	-	-
cobas b 123 Sensor Cartridge BG/ISE/Glu 05331781001 (a)	X	X	X	X	X	X	X	X	+	+	+	X	-
cobas b 123 Sensor Cartridge BG/ISE/Glu/Lac 05170478001 (b)	X	X	X	X	X	X	X	X	+	+	+	X	X

Table G-1

(a) up to 28 days or up to 700 tests.
(b) up to 21 days or up to 500 tests.

-	Parameter is not measured.
X	Parameter is measured.
+	Parameter is measured via the oximeter module. Only possible for **cobas b** 123<3> system and **cobas b** 123<4> system in conjunction with one of the **cobas b** 123 Fluid Pack COOX types.

Fluid Pack types

	Parameter												
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	Hct	tHb	SO_2	COOX	Glu	Lac
cobas b 123 Fluid Pack COOX 200[a] 05169992001	X	X	X	X	X	X	X	X	X	X	X	X	X
cobas b 123 Fluid Pack COOX 400[b] 05170036001	X	X	X	X	X	X	X	X	X	X	X	X	X
cobas b 123 Fluid Pack COOX 700[c] 05170052001	X	X	X	X	X	X	X	X	X	X	X	X	X
cobas b 123 Fluid Pack 200[a] 05403308001	X	X	X	X	X	X	X	X	-	-	-	X	X
cobas b 123 Fluid Pack 400[b] 05403154001	X	X	X	X	X	X	X	X	-	-	-	X	X
cobas b 123 Fluid Pack 700[c] 05403286001	X	X	X	X	X	X	X	X	-	-	-	X	X

Table G-2

(a) This Fluid Pack can be used for up to 200 tests or up to 42 days.

(b) This Fluid Pack can be used for up to 400 tests or up to 42 days.

(c) This Fluid Pack can be used for up to 700 tests or up to 42 days.

X	Parameter is available (depending on the used Sensor Cartridge type).
-	Parameter is not available.

For more information, refer to chapter 4 *Specifications*, section *cobas b 123 Fluid Pack* on page B-52 and chapter 6 *System components*, section *cobas b 123 Fluid Pack* on page C-21.

QC material

	Parameter												
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	Hct	tHb	SO_2	COOX	Glu	Lac
cobas b 123 AutoQC Pack Tri-Level 05169933001	+	+	+	+	+	+	+	+	+	+	+	+	+
cobas b 123 AutoCVC Pack 05231183001	+	+	+	+	+	+	+	+	+	+	+	+	+
COMBITROL PLUS B Level 1 03321193001	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**
COMBITROL PLUS B Level 2 03321207001	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**
COMBITROL PLUS B Level 3 03321215001	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**	**O**

+	For **cobas b** 123<2> system and **cobas b** 123<4> system with integrated AutoQC module only.
O	For all **cobas b** 123 POC systems.

Accessories

	Parameter												
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	Hct	tHb	SO_2	COOX	Glu	Lac
cobas b 123 Printer Paper 05082595001	O	O	O	O	O	O	O	O	O	O	O	O	O
Adapter for Capillaries 03069931001	O	O	O	O	O	O	O	O	O	O	O	O	O
Ampoule Adapter 03066762001	O	O	O	O	O	O	O	O	O	O	O	O	O
Adapter for Sample Containers 03112101180	O	O	O	O	O	O	O	O	O	O	O	O	O
Clot Catcher [(a)] 03112012180	O	O	O	O	O	O	O	O	O	O	O	O	O
Clot Catcher PRO[(b)] 05689856001	O	O	O	O	O	O	O	O	O	O	O	O	O
Caps for Roche MICROSAMPLER 03112152180	O	O	O	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER PROTECT, non sterile 05772494001 (200 pcs.)	O	O	O	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER PROTECT, sterile 05772583001 (50 pcs.)	O	O	O	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER PROTECT, with accessories 05772591001[(c)]	O	O	O	O	O	O	O	O	O	O	O	O	O
BS2 Blood Sampler 03113493035 (MC0028)	O	O	O	O	O	O	O	O	O	O	O	O	O
Capillary Tubes, ~ 200 µL 03113477180 (MC0024)	O	O	O	O	O	O	O	O	O	O	O	O	O
Capillary Tubes, ~ 115 µL 03113507035 (MG0002)	O	O	O	O	O	O	O	O	O	O	O	O	O
Plastic Capillary Tubes. ~ 140 µL, 05174791001	O	O	O	O	O	O	O	O	O	O	O	O	O
Caps for Capillary Tubes 03113647035 (RE0410)	O	O	O	O	O	O	O	O	O	O	O	O	O
Sterile Capillary Holder 05174830001	O	O	O	O	O	O	O	O	O	O	O	O	O

(a) The Clot Catcher is not suitable for the **cobas b** 123 POC system syringe mode.

(b) The Clot Catcher PRO is not suitable for the **cobas b** 123 POC system syringe mode.

(c) Available in USA only.

O	Can be used.

WARNING

Warning

The Clot Catcher and Clot Catcher PRO are not suitable for the **cobas b** 123 POC system syringe mode.

Copyright information

In this chapter *Chapter* **16**

Information about software licenses

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The source code of the open source software can be requested on a standard data exchange medium from the following address:

Roche Diagnostics International Ltd
Forrenstrasse 2
6343 Rotkreuz
Switzerland

Glossary

A

Acid base map. The graphical diagram is illustrating the physiological relationship between the various acid-base variables.

Alkaline. basic

Arterial blood. Blood taken from the artery

AutoQC module. The AutoQC module is a unit that automatically takes quality control measurements programmed by the user.

B

Barcode scanner. PS2 hand-held scanner with integrated decoder for simple input of QC data, electrode data, patient or user identity.

BG. Abbreviation for blood gas

BG sensors. The BG sensors are part of the **cobas b** 123 Sensor Cartridge and they serve for measuring the pH value and blood gas values PO_2 and PCO_2.

Bilirubin. is a yellow decomposition product of the red blood pigment, hemoglobin, or more exactly, that of the hemoglobin component.

C

Calibration for Ready. A calibration is selected to bring all the activated parameters into the "Ready" condition.

Clot Catcher. Coagulum catcher for use with Roche MICROSAMPLER PROTECT and capillaries.

Clot Catcher PRO. Coagulum catcher for use with syringes.

cobas b 123 AutoQC Pack. Multi-analyte control material for controlling automatically BG, ISE, Glu, Lac, COOX/Bilirubin.

cobas b 123 Fluid Pack. Available in different types. The Fluid Pack includes all operating fluids, 2 waste bags. the sample input module, the cuvette for oximeter module (optional), the tubing for the 2 peristaltic pumps and valve tubings.

cobas b 123 Sensor Cartridge. Is a thick-film sensor and it serves for the determination of all electrochemical and electrical measuring parameters. The Sensor Cartridge is available in different types.

COMBITROL PLUS B. QC material for controlling BG, ISE, Glu, Lac, COOX/Bilirubin

COOX. see *Oximeter module*.

D

Defects. Refer to problems that relate only to a certain module of the instrument (e.g. AutoQC Pack empty) and not to the operation of the entire instrument. The instrument can be used with limitations. Only those areas or parameters that are directly affected by the malfunction are disabled.

Depot-Repair. The "Depot-Repair" process is a repair process for defective customer instruments, which is not carried out onsite at the customer's location, but in a Roche internal repair center (local or global). During this time, the customer is provided with a replacement instrument, which must be set up properly to replace the customer instrument.

F

Fill port. Is part of the **cobas b** 123 Fluid Pack. The Fill port enables a sample to be aspirated from syringes, Roche MICROSAMPLER PROTECT, capillaries and ampoule adapters.

G

Glu/Lac sensors. The Glu/Lac sensors are part of the **cobas b** 123 Sensor Cartridge and they serve for measuring the metabolite values glucose and lactate.

H

Hematocrit. in abbreviated, Hct, is the ratio of the volume of blood cells (mainly the red blood corpuscles) to the total volume of blood.

Hemoglobin. is the main component of the erythrocytes and serves for transporting oxygen.

Hemolyzer. The sample is exposed to a strong ultrasound field whereby the cell membranes of the erythrocytes are destroyed and the hemoglobin released.

Heparin salts. are the only permissible anticoagulants

I

"Instrument" menu. All data relating to the instrument (e.g. status display) are displayed here. It is also possible to manually start calibrations and call up various maintenance tasks in this menu.

IN-USE time. is the time from the beginning of the RUN-IN phase until the end of the "Stable phase" (end of the service life of the Sensor Cartridge).

ISE. Abbreviation for ion-selective electrode

ISE sensors. The ISE sensors are part of the **cobas b** 123 Sensor Cartridge and they serve for measuring the hematocrit value and the electrolyte values Na^+, K^+, Ca^{2+} and Cl^-.

L

Levey-Jennings graph. QC statistical values chart

M

Measurement evaluation. Before clinical decisions are made on the basis of the results, the plausibility of all the measuring results obtained must always be checked by medical specialists, thereby taking the clinical situation of the patient into account.

Measuring chamber module. It serves for contacting and temperature controlling of the Sensor Cartridge. The measuring chamber module is docking mechanically the Sensor Cartridge on the Fluid Pack.

Multirules . The valuation of the QC results is based on the Westgard rules and their interpretation for the blood gas analysis. The multirule procedure was derived from this. It enables malfunctions of the instrument to be detected at an early stage.

N

NIST standards. define precise serums with certified expected values.

O

"Overview" menu. All of the data (results, operating instructions, alarms, warnings, etc.) are displayed on this screen. Measurements are started in this menu as well.

Oximeter module. The oximeter module consists of the hemolyzer and the COOX measuring chamber. It is an optical sensor module for determining total hemoglobin (tHb), and the hemoglobin derivatives oxyhemoglobin (O_2Hb), desoxyhemoglobin (HHb), carboxyhemoglobin (COHb), methemoglobin (MetHb) and bilirubin (Bili).

P

Patient trend map. Using this diagram, the course of individual parameters (measuring and calculated values) of a patient over an indefinite period of time can be shown and printed out.

Peristaltic pump. The transport of the sample and the operating fluids is effected by means of up to two peristaltic pumps. The peristaltic pumps and the pump heads are part of the instrument. The tubing of the peristaltic pumps are part of the Fluid Pack.

Plasma. Plasma samples are obtained by centrifuging heparinized whole blood, whereby cellular cell parts of the blood are separated.

Polychromator. Light is refracted and focused on the surface of a photosensitive receiver (CCD).

PP. Abbreviation for peristaltic pump.

Printer. Is part of the user-interface-module. It is a low-noise thermoprinter.

Q

QC. Abbreviation for quality control

QC material. see *cobas b 123 AutoQC Pack, COMBITROL PLUS B.*

Quality control. The known target areas of the QC materials are compared with the QC results of the instrument.

R

Recalibration. Is an automatic calibration carried out after each measurement. The measurement parameters are calibrated using a solution (STDBY solution).

RiliBÄK (Guidelines of the German Federal Medical Society). The objective of the "Guidelines of the German Federal Medical Council for quality assurance of test results in medical laboratories" (RiliBÄK) is to ensure the quality of examinations and the measured parameters. It represents a minimum requirement for quality assurance with provisions directed specifically towards the measuring accuracy of quantitative analyses in medical laboratories.

RUN-IN phase. begins with the end of the START-UP phase and continues for a RUN-IN time stored on the Sensor Cartridge. During this time, the instrument must be calibrated frequently.

S

Sample port module. Contains the fill port and is part of the **cobas b** 123 Fluid Pack. You can change the sample port module only by changing the entire Fluid Pack.

Sample sensor contacts. The sample sensor contacts form the electrical interface between the Fluid Pack and the measuring chamber module.

Sample throughput. Number of samples per hour

Sensor Cartridge. see *cobas b 123 Sensor Cartridge*

SO_2. Oxygen saturation

Stable phase. The "Stable phase" begins after the RUN-IN phase has ended. From this time on, the Sensor Cartridge operates at full performance and is completely ready for use. This continues until the end of the service life of the Sensor Cartridge.

START-UP phase. After inserting a new Sensor Cartridge allow a START-UP phase. During this time, the Sensor Cartridge is moistened and a system calibration is carried out.

System calibration. This is performed every 24 hours (fixed interval, user-defined starting time) and consists of a wavelength calibration of the polychromator (optional), a calibration of the oximeter module lamps (optional), a layer thickness calibration of the cuvette (optional) 2-point calibration of all the parameters, O_2 air calibration and the determination of the actual O_2 value.

System stop. A critical error which stops the instrument. When this error occurs, a system stop window with a red border is displayed in the "Overview" menu. The respective consumable is identified by a red bar in the consumables status display. The error message is displayed until a corrective action is carried out.

T

Time-to-Display. Is the delay from the start of a measurement until the results are shown on the display.

Time-to-Ready. Is the delay from the start of a measurement until the instrument is again available for a new measurement.

Tonometered whole blood. Whole blood is set with the aid of precision gas to expectancy values to be calculated for PO_2 and PCO_2.

Tonometry. Adjusting the PO_2 and PCO_2 partial pressure of a fluid using precision gas.

Troubleshooting-Report. The Troubleshooting-Report is a report generated automatically by the instrument that is used by the service hotline or Service organizations in the event of an instrument or consumable problem for comprehensive analysis. The Troubleshooting-Report is also used to evaluate complaints.

U

User-Interface-Module. Serves as a graphic user interface. All the information (results, operating instructions, errors, warnings, etc.) is displayed on the screen. The screen consists of a color LCD that is covered with a touch-sensitive film ("touch screen").

"Utilities" menu. Apart from utilities (troubleshooting routine, software update, etc.), you will also find the installation and put out of operation functions in this menu. Moreover, you can configure various settings in this menu.

W

"Workplace" menu. In this menu, you can call up individual replacement routines, manual QC measurements and individual databases.

Warnings. Warnings are displayed in the alarm area. The instrument can be used with potential limitations. A warning is an advance notification, e.g. "Critical fill level in Fluid Pack".

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