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Life needs answers

cobas b 221 system

Instructions for Use

Roche

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Revision History

Manual Version	Software Version	Revision date	Changes
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Edition notice

cobas b 221 system

In the course of 2006 the Roche OMNI S system was relaunched under the Roche Diagnostics professional IVD user brand **cobas®**.

Systems with a serial number of 5001 or above are **cobas b** 221 systems.

Systems with a serial number up to 5000 are Roche OMNI S systems.

Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics GmbH 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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Appendix Part E

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Preface

The **cobas b** 221 system is an analyzer with integrated AutoQC drawer option.

This manual has detailed descriptions of **cobas b** 221 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 manual 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.

Where to find information

In addition to the Instructions for Use, the following documents are also provided to assist in finding desired information quickly:

- **cobas b** 221 system Reference Manual
- **cobas b** 221 system Short Instruction

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 Helping to locate and interpret information in this manual the following symbols are used:

Symbol	Used for
►	Procedural step
•	List item
👁	Cross-reference
☞	Call up of screen
	Note

Symbol	Used for
	**Caution** 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** 221 system, and which therefore should never be attempted and 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
	Conformité Européenne: This product complies with the requirements in the guideline for In Vitro Diagnostic 98/79/EC.
	Lot designation
	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.
	Temperature limitation The conditions necessary to preserve the product's shelf life before opening.
	In Vitro Diagnostic Medical Device
	Manufacturer (according to In Vitro Diagnostic guidelines 98/79/EG)
	Catalogue number
	Serial number (model plate)
	Caution, consult accompanying documents
	Please consult instructions for use

(a) DIN EN 980: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (Part 1: General requirements)

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

Symbol	Description
	Biological risk! (according to the standard IEC/EN 61010-2-101)[a] (Instrument)
	Biological risk! (according to the standard DIN EN ISO 980)[b] (Consumables)
	Do not use if package damaged
	Do not reuse
	Fragile. Handle with care
	Handle with care
	**Valid only for Roche MICROSAMPLER:** Method of sterilization using ethylene oxide
	**Valid only for BS2 Blood Sampler:** Method of sterilization using irradiation

(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 ISO 980: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (Part 1: General requirements).

Other symbols

The following symbols are listed as additional information:

Symbol	Description
	Electrodes: This date indicates the limit of the maximum storage time of an electrode. The electrode must be installed in the instrument no later than the imprinted date. If the installation takes place on the imprinted date, it still falls within the specifications. The calculation of the “Install before” date is based on the production date of the elctrode.
	Danger symbol: "Irritant" (on the label and the packaging of S2 Fluid Pack) Rating: Although not corrosive, momentary, longer-lasting, or repeated contact with skin or mucous membrane may result in inflammation. Danger of sensitization during contact with skin (when classified with R 43). Caution: Avoid contact with eyes and skin, do not inhale vapors.

Symbol	Description
	Invisible Laser Radiation Avoid direct radiation to eyes! Laser Class 3R according to EN 60825-1 P0 ≤ 5 mW λ = 635 - 850 nm
	Store upright
	"Grüner Punkt" (in Germany)
	Protective gloves, protective goggles and suitable protective clothing must be worn.

Abbreviations

The following abbreviations are used:

Abbreviation	Definition
A	
ANSI	American National Standards Institute
AQC	Automatic Quality Control
B	
BG	Blood gas
BUN	Abbr. for blood urea nitrogen
C	
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
cond	Conductivity
CSA	Canadian Standards Association
D	
dBA	Decibel weighted against the A-frequency response curve. This curve approximates the audible range of the human ear.
DIL	Diluent
DNS	Domain Name Server
E	
EC	European community
e.g.	*exempli gratia* – for example
EN	European standard
F	
FMS	Fluid mixing system
H	
Hct	Hematrocrit
HIV	Human immunodeficiency virus
HW	Hardware

Abbreviation	Definition
I	
i.e.	*id est* – that is to say
ISE	Ion selective electrode
IVD	In vitro Diagnostic Directive
L	
LCD	Liquid cristal display
LIS	Laboratory Information System
LJ	Levey Jennings
M	
MAC	Media Access Control
MC	Measuring chamber
MSDS	Material safety data sheet
MSS	Metabolite sensitive sensor
MV	Mean value
P	
PP	Peristaltic pump
Q	
QC	Quality control
R	
RCon	Reference contact
REF	Reference solution
S	
SIP	Sample inlet path
SDC	Sample distributor cartridge
S1	S1 Rinse Solution
S2	S2 Fluid Pack
S3	S3 Fluid Pack
SCon	Sensor contact
SD	Standard deviation
SO_2	Oxygen saturation
T	
T&D	Turn & dock
tHb	Total hemoglobin
U	
UL	Underwriters Laboratories Inc.
V	
VDE	Association of German Electrical Engineers (Verband Deutscher Elektrotechniker)

For writing the measuring, calculated and input values see Chapter 9 *Softwaremodi* > *Parameter* on page B-75!

Introduction and specifications

A

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 **1**

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 electrodes.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument.

Additionally complete a quality control test on one level between two automatic 2P calibrations. The level have to be alternated (low, normal, high).

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 (refer to accompanying documents)!

Please refer to safety-related notes in the manual accompanying this instrument.

Operating safety information

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

- IEC/EN 61010-1
- IEC/EN 61010-2-101
- IEC/EN 61010-2-081 + A1

It was delivered from the factory in flawless condition with regards to safety features. In order to preserve this condition and ensure safe operation, the user must respect the notices and warnings that are contained in these Instructions for Use.

- This equipment is a Class I laser product, and it complies with FDA Radiation Performance Standards, 21 CFR Subchapter J (only valid for **cobas b** 221<1> system, **cobas b** 221<3> system and **cobas b** 221<5> system with tHb/SO_2 module).
- This instrument is classified under the protection class I according to IEC /EN 61010-1.
- The instrument meets the conditions for overvoltage category II.
- The instrument meets the conditions for contamination level 2.
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- 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.

- *The power cord must be plugged into a grounded power receptacle. When using an extension cord, make sure it is properly grounded.*
- *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 only the original power plug delivered with the **cobas b** 221 system.*
- *The use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*

General descriptions

This chapter contains a general description of the instrument, as well as precautionary measures against special dangers and the proper handling of sensors, solutions and the MSS cassette.

In this chapter *Chapter* 2

Introduction

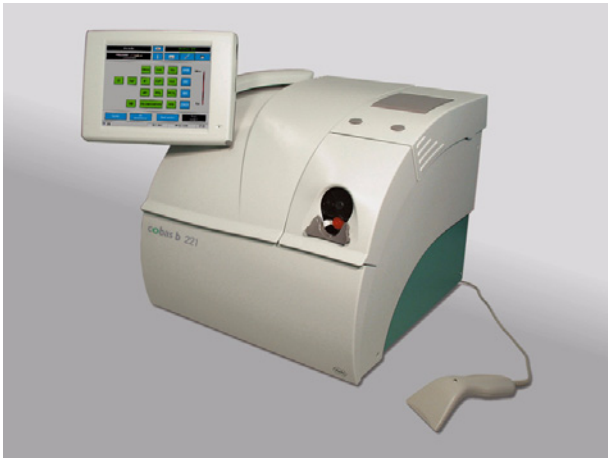


Figure A-1 **cobas b** 221 system

The **cobas b** 221 system is an analyzer with integrated AutoQC drawer option. Depending on combination and configuration, the following parameters can be measured in whole blood, serum, plasma, acetate and bicarbonate containing dialysis solutions and QC materials:

- pH
- Blood gas BG (PO_2, PCO_2)
- Electrolyte ISE (Na^+, K^+, Cl^-, Ca^{2+})
- Hematocrit (Hct)
- Metabolite MSS

*Urea/BUN - only **cobas b** 221<6> system*

- Total hemoglobin (tHb)
- Oxygen saturation (SO_2)
- Hemoglobin derivative COOX (O_2Hb, HHb, COHb, MetHb)
- Bilirubin (neonatal)

The following configurations are available:

• **cobas b** 221<1> system[(a)]	BG, pH, tHb/SO_2
• **cobas b** 221<2> system	BG, pH, COOX, Bili
• **cobas b** 221<3> system [(a)]	BG, pH, ISE, Hct, tHb/SO_2
• **cobas b** 221<4> system	BG, pH, ISE, Hct, COOX, Bili
• **cobas b** 221<5> system[(a)]	BG, pH, ISE, Hct, MSS, tHb/SO_2
• **cobas b** 221<6> system	BG, pH, ISE, Hct, MSS, COOX, Bili

(a) are no longer manufactured or offered.

During the measurement or calibration or other processes, it is possible to conduct database operations, perform certain settings or call up general information at the same time.

For details see Chapter 9 *Software modes*

The individual, mutually independent software modes are defined as follows:

- Analyzer — Measuring, QC measurement, system, calibration, commonly used functions (quick access)
- Setup — Instrument settings
- Database — Data about patients, measurements, calibrations, QC, and the instrument
- Info

General notes

Application area

The instrument has been tested for measuring parameters in whole blood, serum, plasma and dialysis solutions (electrolytes only) and the validity of measurements was tested accordingly.

In order to achieve accurate measurements of recommended aqueous control solutions (with regards to deviations from biological samples), choose the proper components and make the corresponding corrections in the QC measurement mode.

The accuracy of measurement values of undefined aqueous solutions cannot be guaranteed (e.g. due to the possibility of interfering components and/or missing or insufficient buffer systems, and/or differences in ionic strength and diffusion potential when compared to biological samples).

Operating instructions

The **cobas b** 221 system should be switched on at all times!

If the instrument is switched off for an extended period of time (more than 24 hours), a shutdown must be performed.

👁 For additional information, see Chapter 3 *Installation and shutdown*, section *Installation* on page A-27 and *Shutdown* on page A-48.

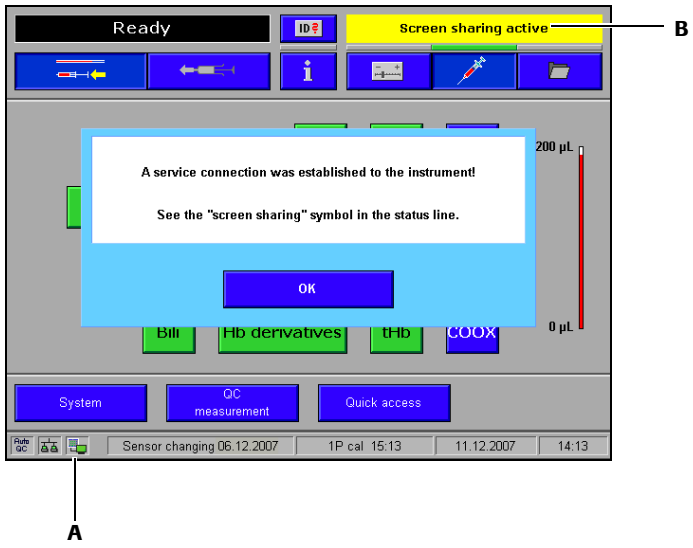
Prevent any other liquids from entering the instrument except samples and QC material at the fill port.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument.
Additionally complete a quality control test on one level between two automatic 2P calibrations. The level have to be alternated (low, normal, high).

👁 For additional information, see Chapter 7 *Quality control*.

With Software V 6.0 onwards, using **cobas** bge link, the instrument can be monitored from one location, any disturbances can be remedied and the analytical quality monitored.
cobas bge link is a remote monitoring and remote maintenance software for Roche Point-of-Care analyzers.

👁 see Figure A-2 on page A-12!



A "Screen sharing" Symbol **B** "Screen sharing" active

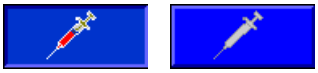
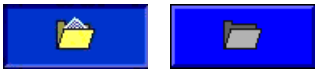
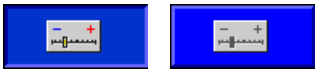
Figure A-2

Confirm the message with [OK] either on the instrument or on the PC. The "screen sharing" symbol is added in the status line.

To avoid multiple operation of the instrument, the message "Screen sharing active" is displayed with a yellow background in the error and message window of the instrument.

As long as the "screen sharing" symbol is displayed in the status line, the service connection is active. In order to prevent multiple operation of the instrument, no buttons on the screen should be pressed!

Important buttons on the screen

Buttons	Description
	"Analyzer" active / inactive
	"Database" active / inactive
	"Setup" active / inactive
	"Info" active / inactive

For additional information, see Chapter 9 *Software modes*, section *Buttons* on page B-76.

Measurement and calibration procedure

Measurement procedure

PO_2: Use of the Clark measurement principle: measurement of current generated by the reduction of oxygen.

PCO_2: Use of the Severinghouse principle: potentiometric measurement of the pH change in the electrode caused by CO_2.

pH- , Na^+-,K^+-, Ca^{2+}- und Cl^- electrodes are potentiometric electrodes. Special glasses are used as the sensitive element for pH and Na^+. The potassium and calcium membranes contain special neutral carriers. A special ion exchanger is used for chloride membranes. Calculation of these variables also requires the use of a reference electrode—a permanently contacted chloride electrode in the **cobas b** 221 system.

Glucose, lactate: Glucose oxidizes to form gluconolacton using atmospheric oxygen and the glucose-oxidase (GOD) enzyme, lactate oxidizes to form pyruvate using the lactate oxidase enzyme.
The generated H_2O_2 is determined amperometrically by using manganese dioxide/ carbon electrode at 350 mV.

Urea: Urea is broken into ammonia and carbon dioxide through urease. Ammonia and carbon dioxide react through hydrolysis with physiological pH to form ammonia or bicarbonate ions. The ammonia ions can be determined using a potentiometrical ammonia ion-selective electrode. This measurement requires a reference electrode such as those used in ion-selective electrodes.

tHb/SO_2: Light absorption in whole blood is measured at four different wavelengths, the sample is subjected to light radiation and the dispersed light is also evaluated.

COOX: The hemoglobin derivatives and the total bilirubin (= neonatal) are determined spectrophotometrically based on the Lambert-Beer law.

Hematocrit: Measurement of the sample's conductivity in the ISE measuring chamber.

Calibration procedure

tHb and SO_2 was calibrated when the instrument was manufactured.

Oxygen (O_2): Ambient air and a zero point solution are used to calibrate oxygen.

PCO_2, pH, ISE: are calibrated using two solutions mixed under different conditions, thereby avoiding the gas supply which is required by other instruments.

MSS: The calibration is carried out with four (Glu, Lac) or five solutions (Urea/BUN) whose weighing concentrations form the basis for measured value determination.

COOX: Determining the hemoglobin derivatives and the total bilirubin (= neonatal) are carried out spectral-photometrically using a cuvette.

Measurement evaluation

The validity of the test results from the **cobas b** 221 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 test results.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument.

Additionally complete a quality control test on one level between two automatic 2P calibrations. The level have to be alternated (low, normal, high).

For detailed information, see Chapter 7 *Quality control*.

Safety instructions for specific dangers

Handling samples

While handling samples, all necessary regulations concerning hygiene must be observed. Dangerous pathogenic agents could be present.

For more detailed information, see Chapter 6 *Measurement*

Disposal of waste water, bottles, packs, electrodes and the instrument

Dispose of waste water, bottles, packs, electrodes and the instrument according to local and/or labor regulations (biologically contaminated—hazardous waste!).

Decontamination

The purpose of this decontamination is to minimize risk when handling items that were in contact with biological samples.

Roche recommends following a decontamination procedure in addition to regulations specific to the laboratory.

These decontamination procedures should be performed periodically to minimize the risk of infections.

Always wear gloves!

For more detailed information about decontamination, see Chapter 10 *Maintenance*

Handling solutions

Store the **cobas b** 221 system wash/calibrating solutions according to the specified packaging requirements. The temperature of the solutions should be adapted to the ambient temperature before use.

The shelf life of the solutions is limited.

Please read the bottle label and the packaging for the correct storage temperature and the maximum shelf life.

DO NOT FREEZE!

If frozen, the solution's concentration may change and cause calibration errors!

Do not use damaged fluid packs (S2 and S3)! Do not mix the individual components!

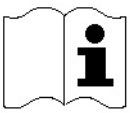
For "Storage specifications", see Chapter 4 *Specifications*.

Handling electrodes

Store the electrodes according to the packaging specifications.

The shelf life of the electrodes is limited.

Please read the label and the packaging for the correct storage temperature and the maximum shelf life.



CAUTION! Installation note for the *P*CO_2 electrode

Insert the electrode into the measuring chamber within 5 minutes of opening the ALU-PE packaging.

A special protective gas atmosphere designed to condition the PCO_2 electrode during storage is found inside the ALU-PE packaging.

This gas atmosphere ensures immediate potential stability during insertion of the electrode into the measuring chamber and immediate readiness for measuring the first 2 point calibration.

If more than 5 minutes elapse after opening the ALU-PE packaging, the level of gas conditioning could be lost and the time required for the first-time calibration could be increased.

For "Storage specifications", see Chapter 4 *Specifications*.

General notes on the use of the MSS cassette

For instrument versions with MSS module only!

Attention:

MSS cassette may only be brought into contact with liquids in the ***cobas b*** *221 system while electrodes are changed!*

Replace the MSS cassette within 28 days of installation!

After initial contact with liquids, the MSS cassette may no longer be removed from the instrument. It may lead to the destruction of the enzyme sensors.

Storage:

At 2 – 8 °C, maximum of 2 weeks at room temperature.

MSS cassette removed from the measuring chamber

Once an MSS cassette is exposed to liquid, it must not be allowed to dry out under any circumstances since this would destroy the enzymes. The enzymes are equipped with a special protectant prior to shipping for transportation purposes. This protectant is washed out inside the instrument during the warm-up phase and MSS polarization.

Incompatible substances

The following substances may not be introduced into the MSS measuring chamber under any circumstances since they would immediately destroy the MSS sensors or severely impact their functionality.

- Deproteinizer (NaOCl)
- O_2 zero point solution
- Cleaning solution
- Na electrode conditioning solution
- Rinse additive
- Solutions containing heavy metals (Ag, Hg, Au, etc., e.g. Thiomersal)
- Cleaning solutions containing detergent (e.g. washing material or liquid detergents)
- All solutions for disinfections (e.g. high-percentage alcohol, glutaric dialdehyde, cresol, etc.)
- Solutions with pH values that deviate greatly from neutral (e.g. pH value of < 6.0 and > 9.0)

The use of anticoagulants other than those approved by Roche Diagnostics (approved: heparin salts), such as EDTA, citrate, NH4 heparin and glycolysis inhibitor such as NaF and oxalate can lead to erroneous results.

Inserting the MSS cassette

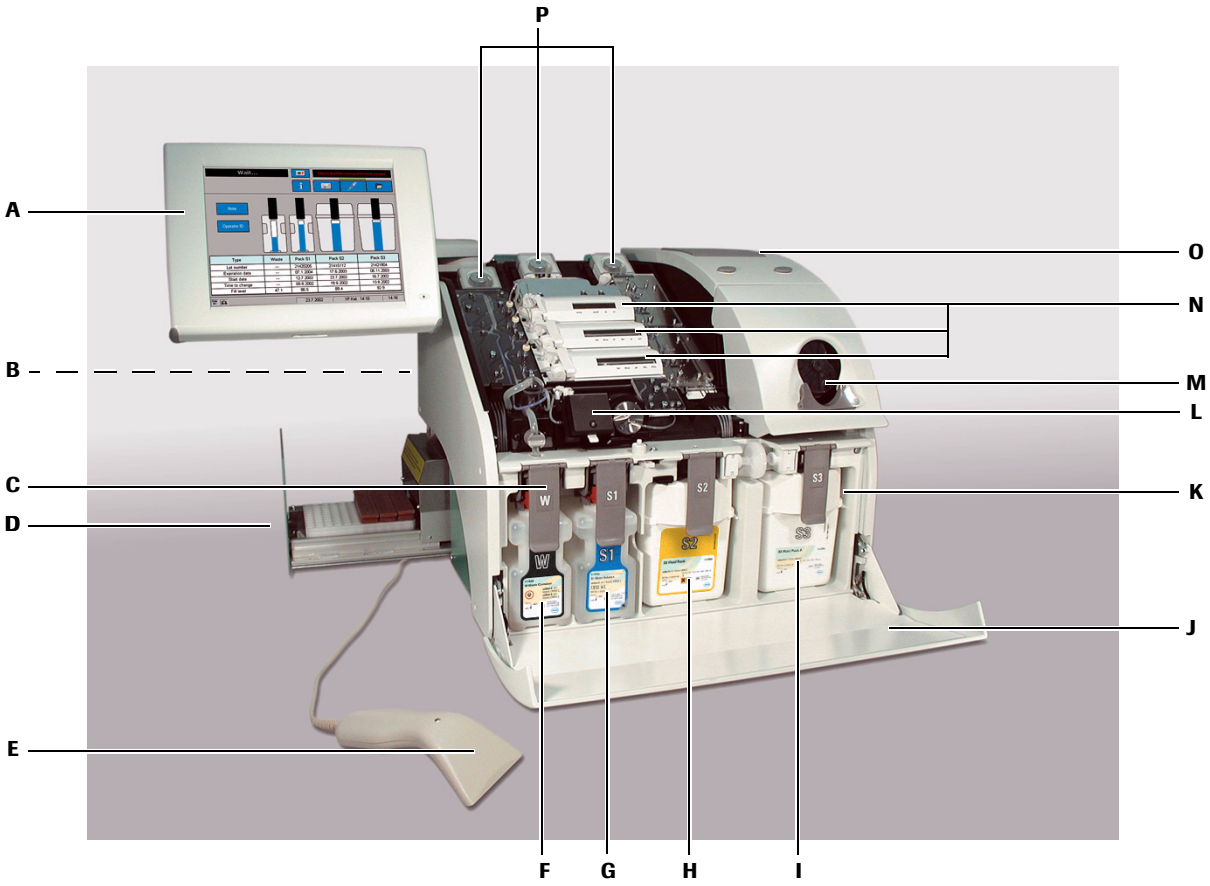
Hold the MSS cassette only at the designated handle and avoid touching the contacts.

For a detailed description see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32.

System description

Visual identification

For example: **cobas b** 221<6> system



A	Screen/PC unit	**G**	S1 Rinse Solution	**M**	Input unit
B	Reverse side	**H**	S2 Fluid Pack	**N**	Measuring chambers
C	Docking mechanism	**I**	S3 Fluid Pack	**O**	Printer
D	AutoQC drawer	**J**	Bottle compartement cover	**P**	Pumps
E	Barcode scanner	**K**	Bottle compartement		
F	W Waste container	**L**	COOX module (tHb/SO_2 module)		

Figure A-3 **cobas b** 221<6> system

Screen/PC unit

The screen/PC unit serves as the graphical user interface.

All information (results, error messages, alarms, warnings, etc.) is displayed on the screen. The screen consists of a color LCD that is covered with a touch-sensitive film ("touch screen").

As sharp objects can damage the touch-sensitive film, only touch the film using suitable pins and/or with your fingers.

The screen/PC unit also contains a diskette drive.

Printer

Low-noise thermoprinter with integrated paper cutter (manually activated using the "Cut" key) and optional winder.

The "Feed" key feeds in the paper.

With an installed winder, the "Automatic Cut" function is deactivated.

Measuring chamber

Underneath the top cover are the BG and, depending on the configuration, ISE measuring chamber with the electrodes, the MSS measuring chamber with the MSS cassette and the tHb/SO_2 or COOX module.

The electrodes are flow-through electrodes with a visible sample channel.

tHb/SO_2 module

Figure A-4 tHb/SO_2 module

The tHb/SO_2 module is an optical sensor module for determining the level of total hemoglobin (tHb) and oxygen saturation (SO_2) in whole blood.

COOX module

The COOX module consists of the hemolyzer and the COOX measuring chamber. The measurement is based on the principle of spectral photometry.

Pumps

Depending on the configuration, up to three peristaltic pumps transport the sample and the operating fluids inside the instrument.

Input unit

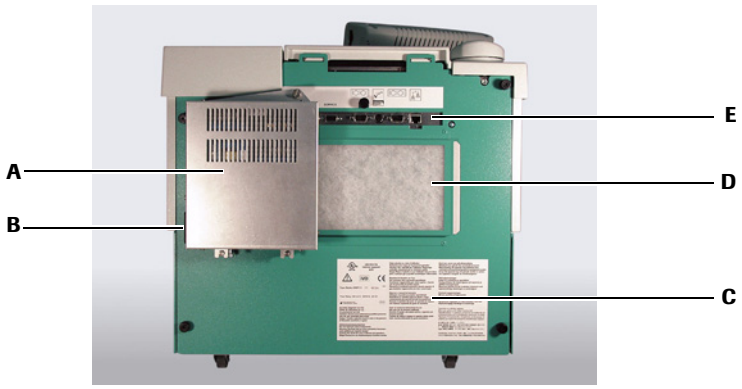
The sample insertion as well as the aspiration of solutions is carried out via input unit which consists of the following:

- T&D module:
  - T&D disk
  - T&D tubing set with wash-water jet
  - Plug control
  - Fill port
- Sample drip tray

Bottle compartment

Behind the bottle compartment cover are the S1 Rinse Solution bottle, the S2 Fluid Pack, the W Waste Container and, depending on the configuration, S3 Fluid Pack (**cobas b** 221<5> system and **cobas b** 221<6> system only).

Reverse side

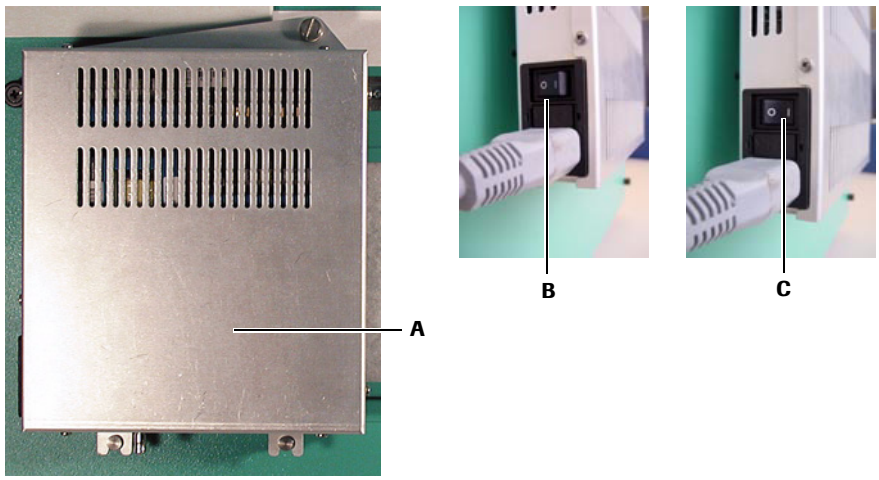


A Power supply
B Main power switch and connector
C Warning and identification labels
D Air filter
E Interfaces

Figure A-5 Reverse side

Power supply

This unit also contains the main power switch and the connector.

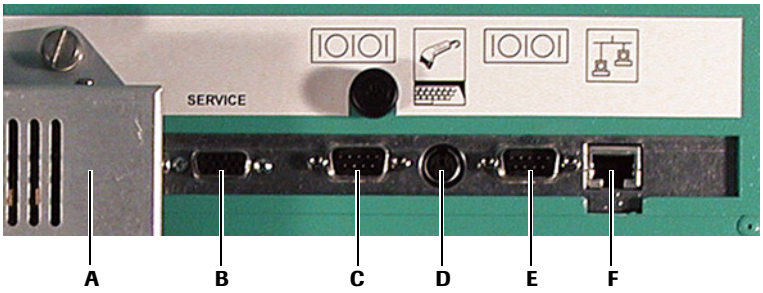


A Power supply
B Main power switch OFF
C Main power switch ON

Figure A-6 Power supply

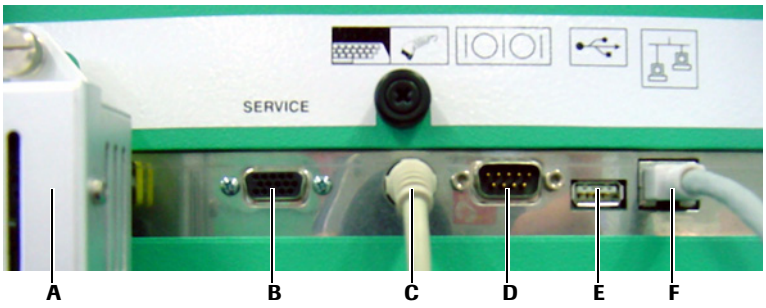
Interfaces

Only data processing units manufactured according to the standards IEC 950 (UL1950) may be attached to the interface connections!



A	Power supply	**D**	Ext. keyboard/barcode scanner
B	Service connector	**E**	RS 232
C	RS 232	**F**	10BaseT

Figure A-7 Interfaces (without USB)



A	Power supply	**D**	RS 232
B	Service connector	**E**	USB
C	Ext. keyboard/barcode scanner	**F**	10BaseT

Figure A-8 Interfaces (with USB)

- Variant 2:

  2x RS 232 interfaces (COM 1 and COM 2) (SN < 1500)

  see Figure A-7 on page A-22
- Variant 1:

  1x RS 232 interface (COM 1) and 1x USB (SN > 1500)

  see Figure A-8 on page A-22
- 1x 10BaseT Ethernet (RJ45)
- Ext. keyboard / barcode scanner: PS/2 DIN - 6 pin female connector
- 1 service connector
- Power (power supply is connected)

No reverse compatibility from Variant 2 to Variant 1 possible.

Barcode scanner

Figure A-9 Barcode scanner

- Scanning of electrode data (type, lot, expiration date)
- Scanning of patient or user identity
- Scanning of QC data (QC material, lot, basis, expiration date, target values, etc.)
- Scanning of desired alphanumeric code

Press the button on the underside to activate the scanner! A beeping sound and a brief illumination of the LED on the upper side indicate the successful scanning of the barcode.

For more detailed information, please see enclosed manual of the PS2 hand-held scanner (included in scope of delivery).

Warning and identification labels (incl. nameplate)

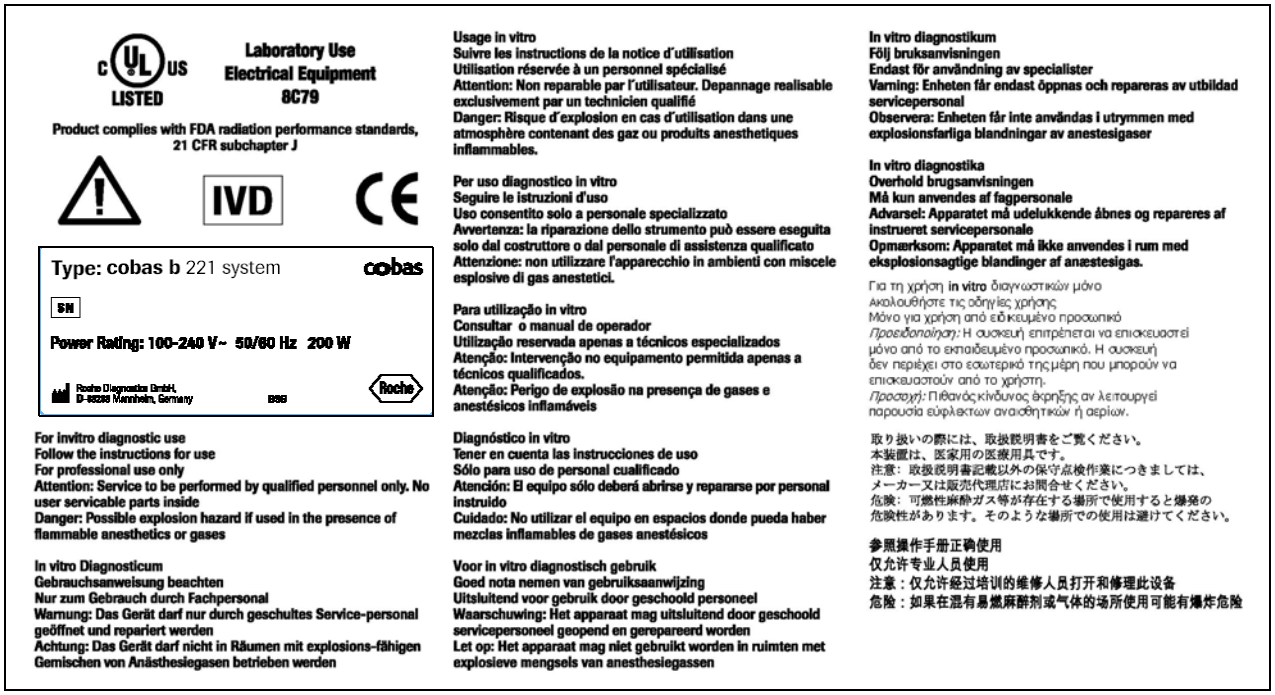


Figure A-10 **cobas b** 221<1> system, **cobas b** 221<3> system and **cobas b** 221<5> system (with tHb/SO_2 module)

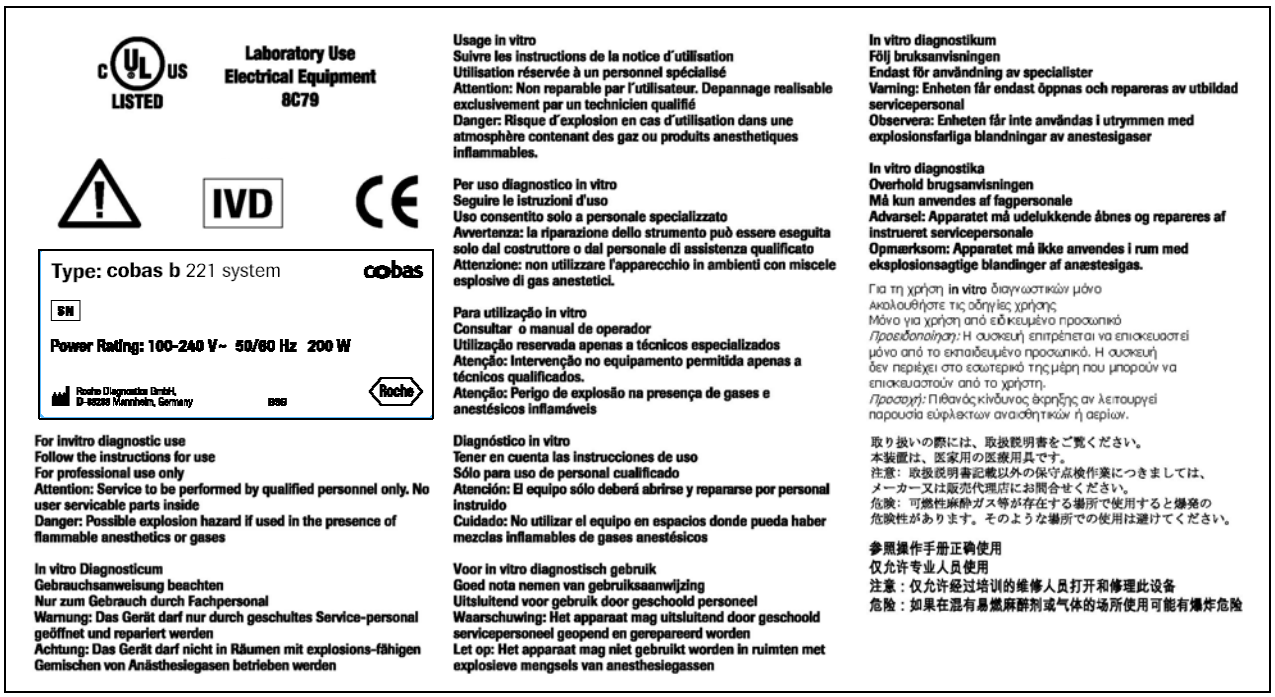


Figure A-11 **cobas b** 221<2> system, **cobas b** 221<4> system and **cobas b** 221<6> system

Installation and shutdown

In this chapter, the software-guided installation and shutdown of the instrument are described step by step. The sequence of the steps described must be strictly followed.

In this chapter *Chapter* 3

Installation

Location

For best results, a suitable, level location that is not subject to direct sunlight is required for the instrument.
When installing an instrument that was stored in a cool room or was transported at low temperatures, be aware that condensation may have formed and could cause disturbances to the instrument. The instrument must be climatized at room temperature for at least one hour before beginning operation.

The following conditions must be fulfilled:

- Ambient temperature: 15 °C to 31 °C
- Ambient air pressure: 797 - 526 mmHg (106.225 - 70.13 kPa)

From approx. 3000 m above sea level or air pressure < 526 mmHg (70.13 kPa), the specifications for parameter PO_2 are no longer fulfilled and the parameter must no longer be used for evaluation of the clinical decisions.

After successful installation, the parameter must be permanently deactivated.

See section *23. Checking the barometer value* on page A-47

- Avoid direct sunlight, vibration and strong electromagnetic fields (electric motors, transformers, X-ray equipment, cellular phones...).
- A stable and level work surface (max. 1° incline with bottles installed)
- Relative humidity: 20 to 85%
- At least 10 cm free space around the instrument for air circulation and electrical connections
- Correct voltage: 100 to 240 VAC (±10%)

After setting up the **cobas b** 221 system at a location that meets the necessary conditions, the following steps must be performed to ensure the instrument is ready for operation:

- First check the instrument and the accessories for completeness and damage. The completeness of the delivery can be checked through comparison with the delivery packing slip.

If anything is missing, inform the Roche representative immediately.

If the delivery has suffered damage despite careful packing, inform the transportation company immediately. Retain the packing material and products as evidence for the damage claim.

Handle the instrument only at the specified holding points — risk of injury!

Take care when lifting - weight of the instrument without wash/calibrating solutions and AutoQC is approx. 45 kg!

See illustration on the outer packaging and in Chapter 4 *Specifications*, section *Holding points* on page A-92!

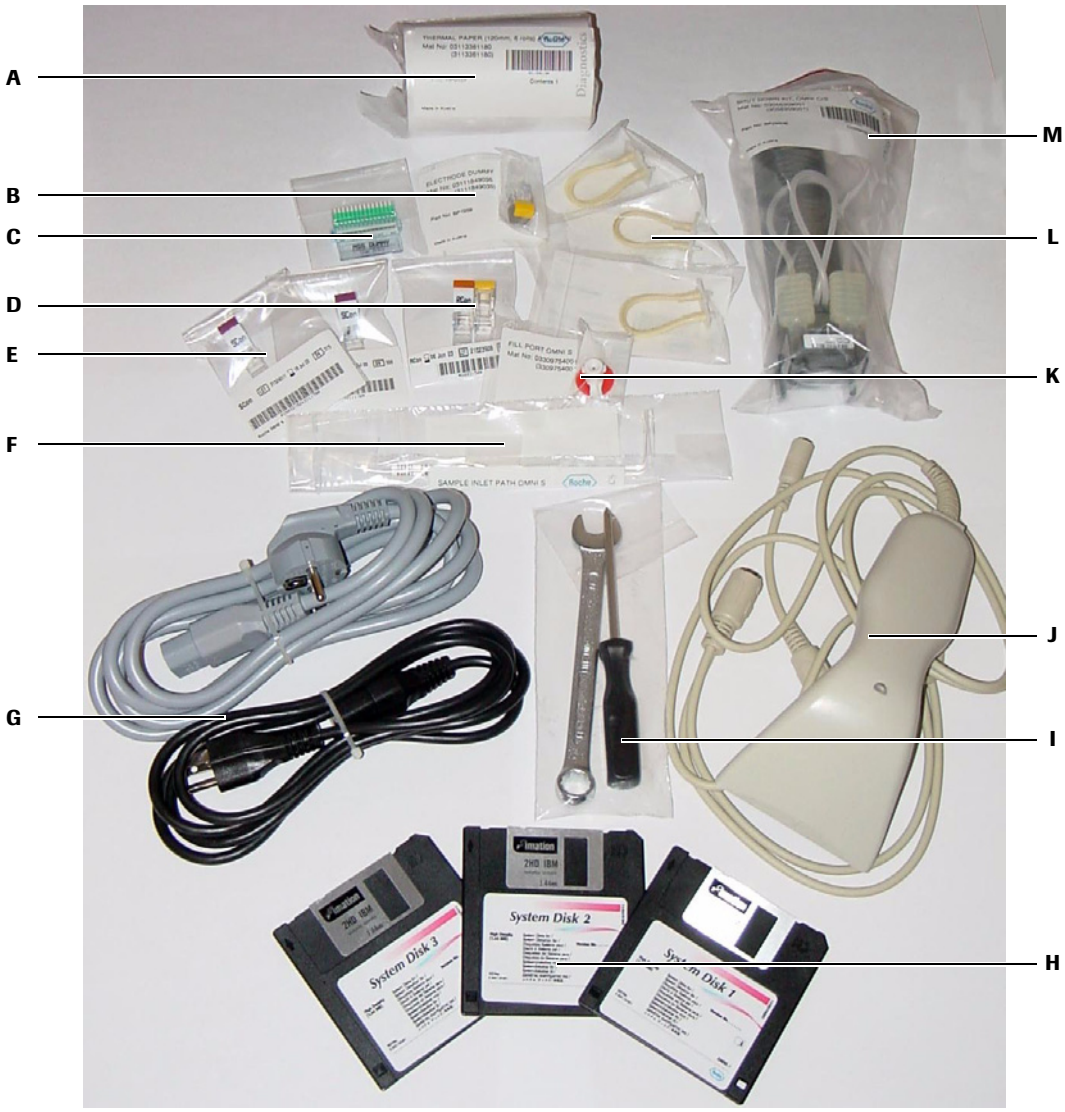
Accessories

The following parts are delivered as standard equipment with the **cobas b** 221 system:

- 1 barcode scanner
- 2 Power cords (US and European version)
- 1 roll printer paper
- 2 pcs fill port
- 1 sample inlet path (glass tube)
- 5 system disks
- 1 RCon (reference contact)
- 1 shutdown kit
- 1 dummy electrode
- 1 dummy MSS cassette
- 2 SCon (sensor contact)
- 1 13 mm wrench (for screen/PC unit)
  1 Phillips screwdriver
- 3 pump tubes

Not shown in Figure A-12 on page A-29:

- *1 screen/PC unit*
- *1 power supply*
- *1 fill port*
- *2 system disks*



A 1 Roll printer paper
B 1 Dummy electrode
C 1 Dummy MSS cassette
D RCon (reference contact)
E SCon (sensor contact)
F 1 Sample inlet path (glass tube)
G 2 Power cords (US and European version)
H System disks (total of 5 pcs.)
I 1 13 mm wrench (for screen/PC unit); 1 Phillips screwdriver
J 1 Barcode scanner
K 1 Fill port
L 3 Pump tubes
M 1 Shutdown kit

Figure A-12 Accessories

Installation

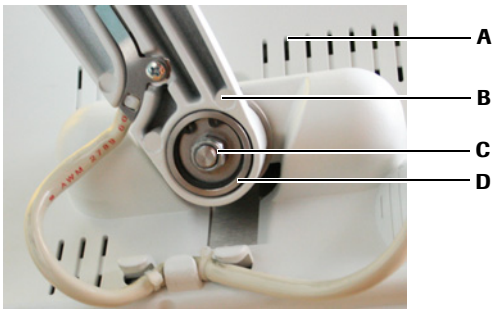
1. Screen/PC unit

Ensure that the printed serial number on the rear of the screen/PC unit is the same as the unit serial number on the nameplate!

1 Unscrew the fixing nut from the screen.

2 Place the screen/PC unit on the swivel arm.

3 At the base of the swivel arm, place the brake packet and lock nut on the shaft and tighten using the 13 mm wrench provided in the accessories.



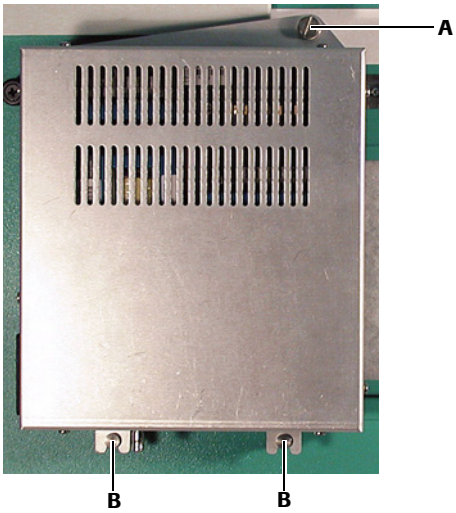
A Screen/PC unit
B Swivel arm
C Fixing nut
D Brake packet

Figure A-13 Swivel arm of the Screen/PC unit

4 Connect the cable to the screen and push it into the cable routing bar.

2. Power supply

1 Place the power supply, including the two adapter connectors, on the holder and position them.



A Screw **B** Holder

Figure A-14 Power supply

2 Tighten the screw.

3. Attach power cord and barcode scanner

1 Connect the power cord.

2 Connect the barcode scanner, and, if necessary, the network connection to the appropriate port on the rear side of the **cobas b** 221 system.

4. Switch on

- Switch the instrument on and wait until the program has completely loaded and started. Before starting the installation, you must set the language, in which the unit is to be operated, the date and the time.

5. Installation

When carrying out the installation, follow the on-screen instructions.

Installation must be carried out completely and may not be interrupted.

Observe the listed sequence while performing the actions.

If the automatic first installation is unsuccessful, you must carry out the installation process manually. To do this, press the following buttons:
[System] > [Utilities] > [Installation]

Processing the actions

Manual The corresponding line of the list box contains an instruction which must be performed manually. Then press [Confirm action].

Automatic If there is an automatic sequence for any action, you can start this by clicking [Start process].

If an action has been completed successfully (manually or automatically), this symbol is displayed.

6. Select language

1 Press the following buttons:

☞ Setup > Instrument > Language

If the current language is "English": [Instrument] > [Language]

2 Select the language.

7. Set the date and time

- Press the following buttons:

☞ Setup > Times & Intervals > Act. time / date

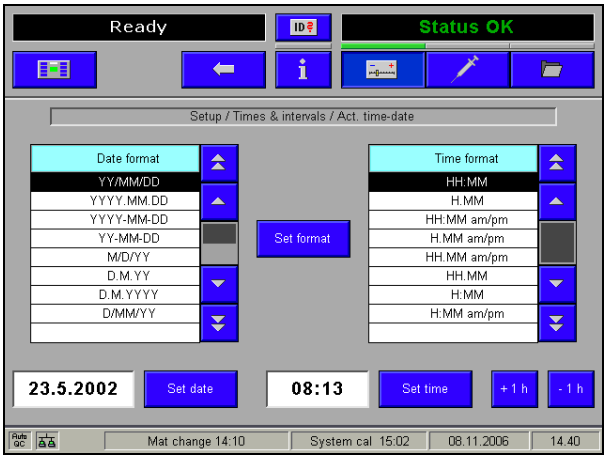


Figure A-15 Act. time / date

8. Cal. intervals & timing

- Press the following button:

☞ Setup > Times & intervals > Cal. intervals & timing

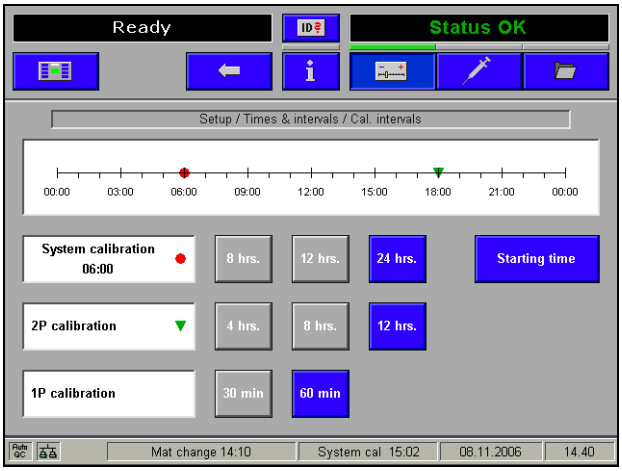


Figure A-16 Cal. intervals

Use this function to enter the automatic calibration times and intervals for system, 1 point and 2 point calibrations.

The time scale uses markers to show the selected interval for the 2P calibration and the start time for the system calibration.

Intervals:

System calibration Every 8, 12 or 24 hours.

Enter the [Start time] of a system calibration to which all calibrations are oriented.

2P calibration Every 4, 8 or 12 hours.

1P calibration All 30 or 60 minutes (USA: only every 30 minutes).

9. Set valves for FMS[(a)] tubing exchange

- Press [Start process]. This action is performed automatically.

Valve V19 is pushed in to prevent the tube from being pinched while the aluminum part is tightened! Valve VM is pushed out.

(a) "Fluid Mixing System" - Mixing of calibration solution A and B in a certain ratio

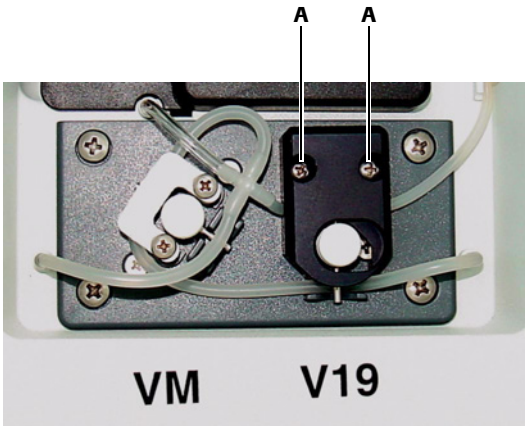
10. Fix screws at V19 (bottle compartment)

1 Open the bottle compartment cover and the docking mechanism "S3".

2 Tighten the screws on valve V19 (approx. 2-3 rotations).

see Figure A-17!

Use the delivered screwdriver!



A Screws on valve V19

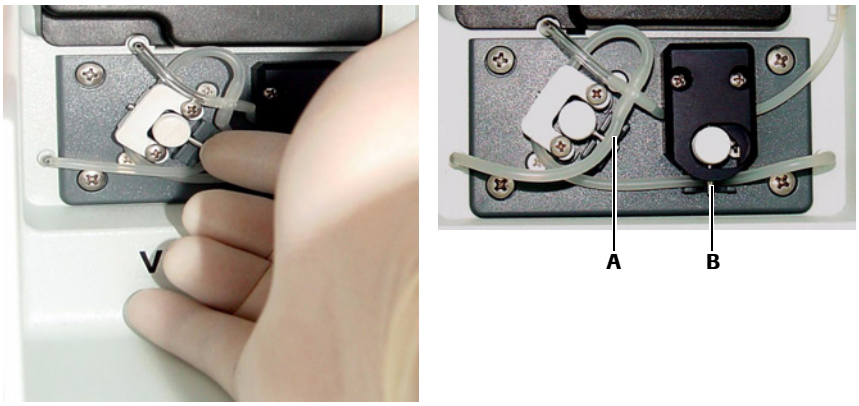
Figure A-17 Valve V19 and VM

3 To return to the installation window, close the docking mechanism and the bottle compartment cover.

11. Insert right FMS tube at VM (bottle compartment)

1 Open the bottle compartment cover and the docking mechanism "S3".

2 Slide the tube under the tube clip of valve VM.



A VM **B** V19

Figure A-18 Valve VM

3 Close docking mechanism and bottle compartment cover.

12. Insert fill port and sample inlet path (glass tube)

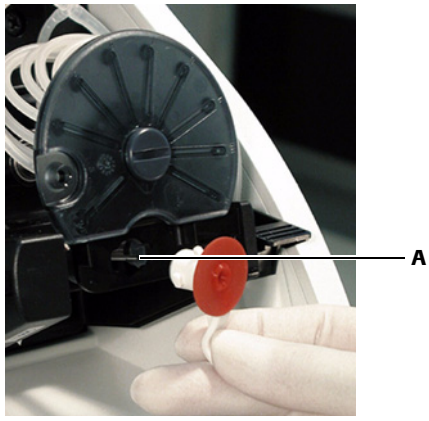
1 Pull out the sample drip tray.

2 Remove the T&D cover and the unit cover.

3 Insert the fill port started from the 6 o'clock position as shown below.

4 Push the fill port straight onto the insert needle.

Do not bend the insert needle during this process!



A Needle

Figure A-19 Insert needle

5 Rotate the fill port 90° clockwise and upwards until it snaps into place.

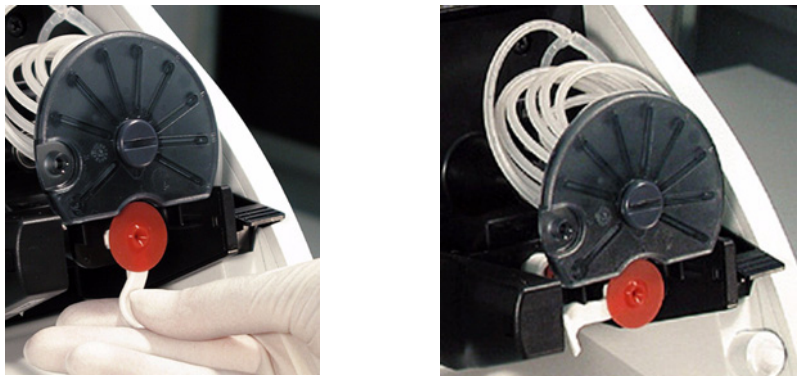


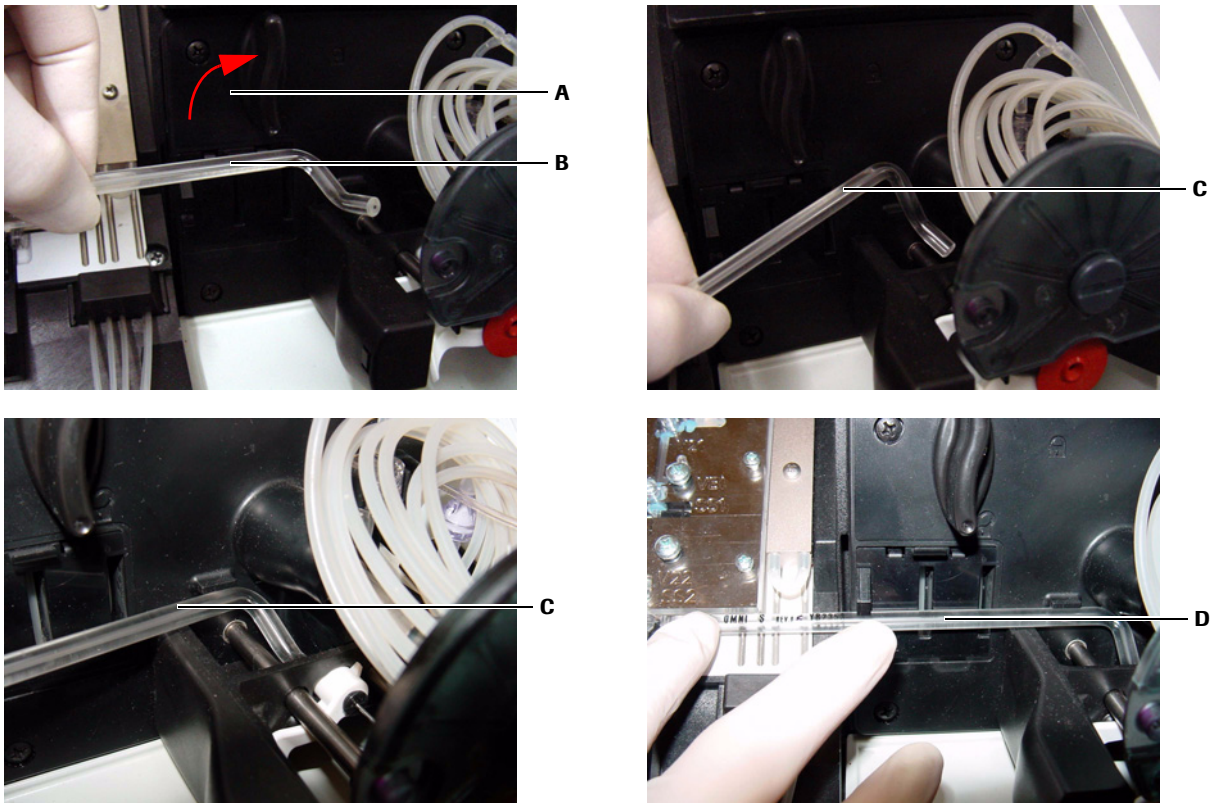
Figure A-20

6 Open the T&D lock.

see Figure A-21 on page A-36, A

7 Insert the glass tube into the guides, fasten it and check it for a correct position.

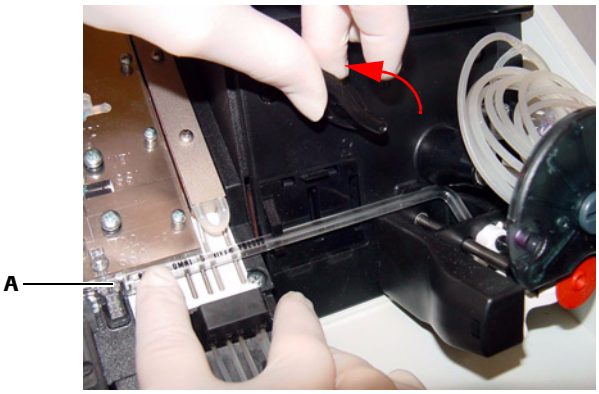
see Figure A-21 on page A-36, C
see Figure A-21 on page A-36, D



A T&D lock
B Glass tube
C Insert the glass tube into the guides
D Fasten and check for correct position

Figure A-21 Glass tube

8 Close the T&D lock again. Check the correct positioning of the sample inlet path to the bypass nipple (see below)!



A Bypass nipple

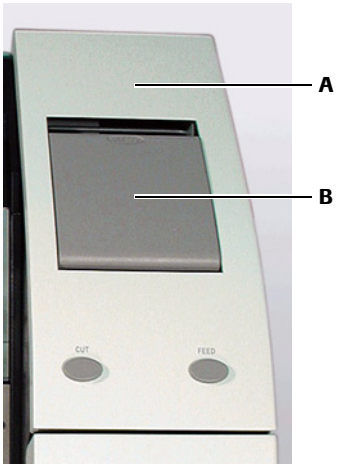
Figure A-22 T&D lock

9 Close the T&D cover.

10 Insert the sample drip tray.

13. Insert printer paper

The printer paper is heat sensitive on one side only. Observe the correct insertion of the thermal paper roll.



A Printer cover **B** Paper lid

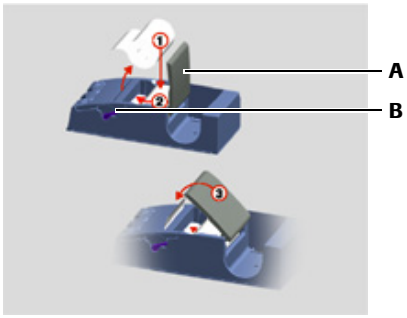
Figure A-23 Printer

1. Open the printer cover and the paper lid.
2. Cut the start of the paper so that it is straight.
3. Place the paper roll into the holder.
4. Make sure that the printer lever is in the "down" position (see below).

A Printer lever "down" position

Figure A-24 Printer lever

5 Insert the beginning of the paper according to the instructions on the inside of the paper lid (see below).



A Paper lid **B** Printer lever

Figure A-25 Insert printer paper - without take-up unit

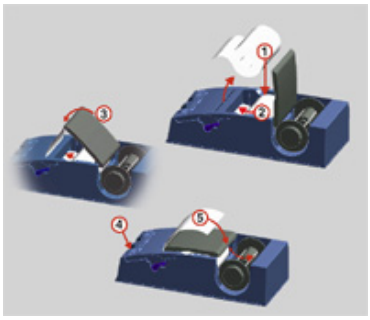


Figure A-26 Insert printer paper - with take-up unit (optional)

6 The paper is automatically pulled into the printer.

7 Close paper lid.

With take-up unit (optional)

1 Press the paper feed button until the paper is long enough.

2 Insert the beginning of the paper in the take-up unit according to the instructions on the inside of the paper lid.

see Figure A-26 on page A-38

Press the take-up unit (rods) fully onto the holder and rotate until the paper is taut on the rods and paper lid, so that the entire roll of paper can be taken up. During operation, the paper should be tautened now and then by turning the take-up roller.

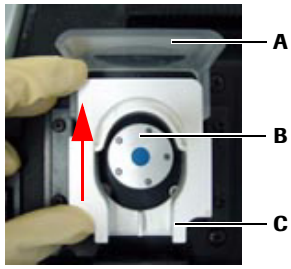
3 Close printer cover.

With an installed take-up unit, the "Automatic Cut" function is deactivated.

14. Insert peristaltic pump tubes

1 Open the peristaltic pump's clear plastic cover (tension lever).

2 Push the linear bracket (white plastic part) upwards (see below).

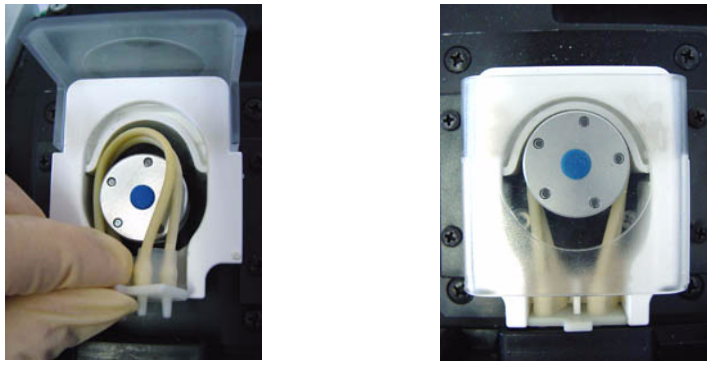


A Tension lever
B Pump head
C Linear bracket

Figure A-27 Peristaltic pump

3 Place the tubing set around the corresponding rolling wheel (see below/A). Check that the tubing set is correctly orientated (the grip end must be pointing upwards, see below/B).

4 Close the clear plastic cover (tension lever). The tubing holder is then pressed into the sealer (see below/B).



A Place the tubing set **B** Close the tension lever

Figure A-28 Peristaltic pump

AutoQC module (option)

The installation with an AutoQC module (optional) must be performed by a Roche Diagnostics Service Representative!

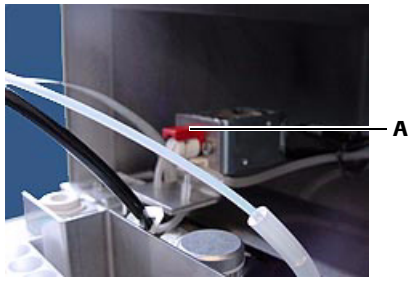
15. Go to AutoQC service position

- Press [Start process]. This action is performed automatically.

16. Open the AutoQC drawer and remove the AutoQC valve clamp

1 Pull out the AutoQC drawer.

2 Pull the key of the AutoQC valve up and out (see below).



A AutoQC valve clamp

Figure A-29 AutoQC valve clamp

3 Close the AutoQC drawer.

17. Go to AutoQC home position

- Press [Start process]. This action is performed automatically.

18. Open AutoQC drawer and insert ampoule holder

1 Pull the AutoQC drawer out again.

A without ampoule holder **B** with ampoule holder

Figure A-30 AutoQC drawer

2 Insert the AutoQC ampoule holder.

3 Close the AutoQC drawer.

19. Open the measuring chamber cover and insert the sensors

► BG / ISE measuring chamber

1 Open the measuring chamber cover (push the right edge of the MC cover to the left with a finger and open up the MC cover).

In each case, open only the relevant measuring chamber.
Keep the bottle compartment cover closed.

The following screen appears:

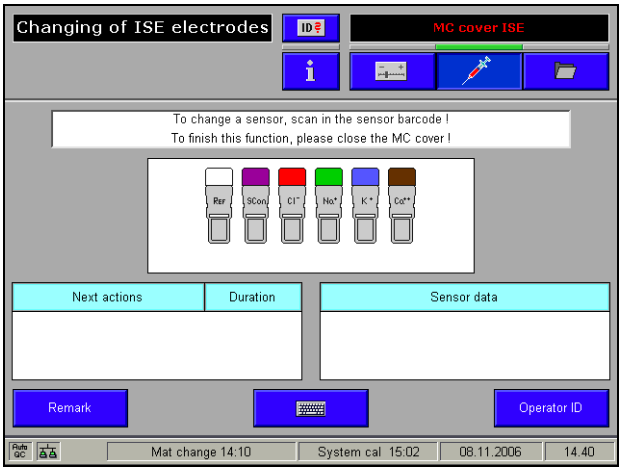


Figure A-31 Changing of electrodes

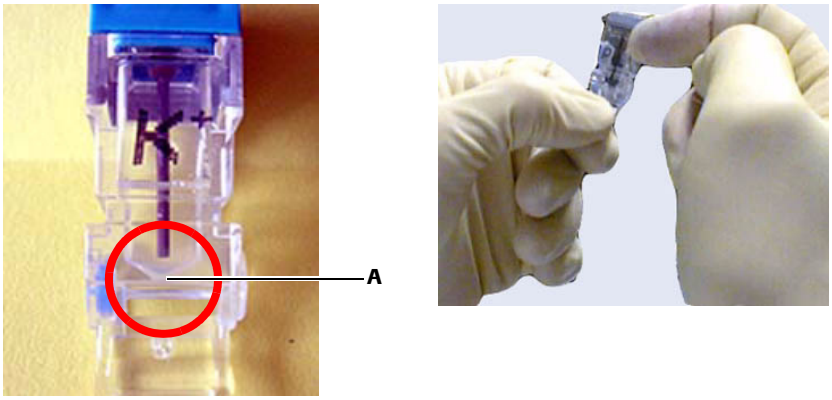
2 Open the locking lever.

see Figure A-34 on page A-42

3 Follow the instructions on the screen.

Check the internal electrolyte of the electrodes for possible air bubbles (see below).
If there are air bubbles between the contact pin and the membrane, there will not be effective electrical conduction. Result: calibration and measurement errors!

4 Remove any air bubbles.
Remove air bubbles by holding the electrode vertically and by tapping lightly with a fingernail against the electrode body (see below).



A Free of air bubbles!

Figure A-32 Electrode

5 Insert the electrodes, beginning at the right and proceeding left according to the color code.

6 Push all electrodes slightly to the right so that they are lined up together without gaps.

► Insertion of the reference electrode

1 Insert the reference electrode.

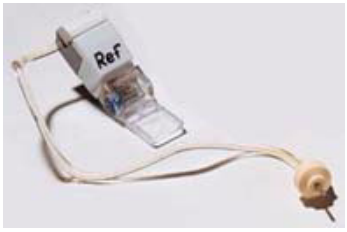
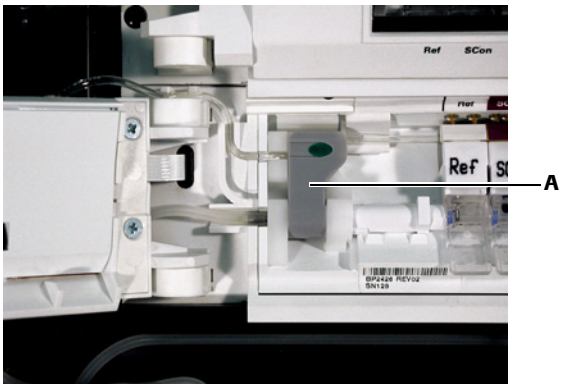


Figure A-33 Reference electrode

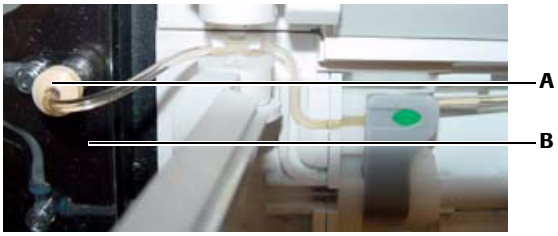
2 Insert the reference tube into the upper tube guide channel of the left locking lever and into the tube holder of the cover hinge. Close the locking lever (see below).



A Locking lever

Figure A-34 Insertion of the reference electrode

3 Connect the white connector on the end of the tube to the measuring chamber cassette (see below).



A Connector **B** Measuring chamber cassette

Figure A-35 Insertion of the reference electrode 2

4 Scan the barcodes located on the inner packaging of each electrode or enter the barcodes manually with the help of the keyboard.

5 Close the measuring chamber cover.

► MSS measuring chamber (for instrument versions with MSS module only)

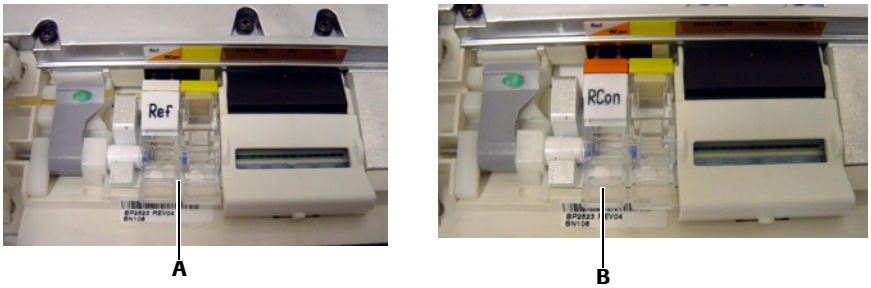
Hold the MSS cassette only at the designated handle and avoid touching the contacts.

1 Open the cover of the MSS measuring chamber (apply force to the right edge of the MC cover with a finger to push it to the left and open up the MC cover).

Keep the bottle compartment cover closed!

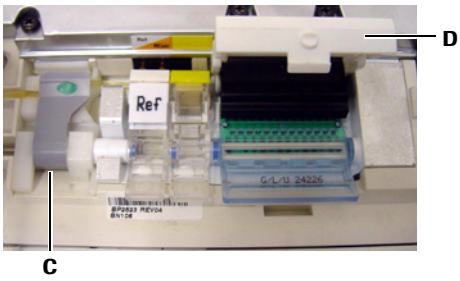
2 Open the contact clip and the locking lever.

3 Depending on the MSS parameter configuration, insert the MSS reference electrode (Ref + dummy) (see Figure A-36/A) or the reference contact (RCon) (see Figure A-36/B) and the MSS cassette, close the contact clip and the locking lever.



A Ref + dummy (for Glu/Lac/Urea)

B RCon (Glu or Glu/Lac)



C Locking lever

D Contact clip

Figure A-36 MSS measuring chamber

4 Read in the barcode of the packaging.

5 Close the measuring chamber cover.

6 Close the top cover.

7 Prepare a syringe or capillary with whole blood for polarization. Having completed the installation process, the unit requests a blood sample.

The blood should have a volume of at least 150 µL, contain heparin as an anticoagulant, and be stored for less than 24 hours.

20. Open bottle compartment cover and insert Waste container & packs

A Ruber sealings

B **cobas b** 221<5> system and **cobas b** 221<6> system only

Figure A-37 Waste container & packs

1 Open the bottle compartment cover.

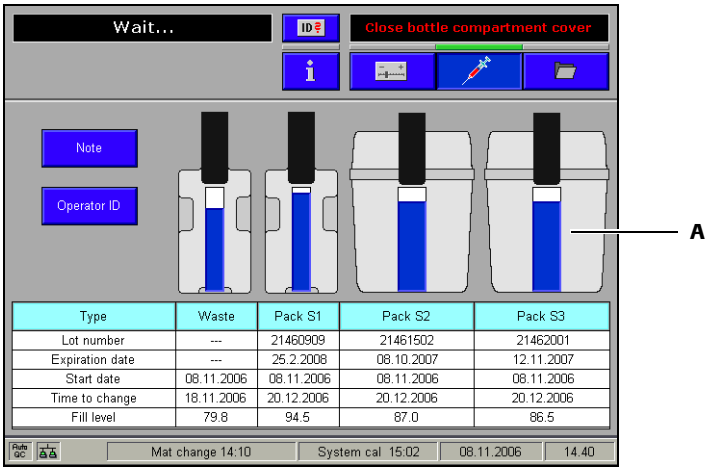
2 Open the corresponding docking mechanism.

3 Insert an empty waste water bottle and a S1 Rinse Solution bottle.

Remove packs' rubber sealings.

4 Push the two packs into the appropriate location in accordance with the labeling on the docking mechanisms until the packs lock.

Using the transponder attached to the bottle/packs, the instrument automatically recognizes the corresponding bottle or packs.



A **cobas b** 221<5> system and **cobas b** 221<6> system only

Figure A-38 Changing of bottles and packs

A **cobas b** 221<5> system and **cobas b** 221<6> system only

Figure A-39 Bottle compartment

5 Close the docking mechanism and the bottle compartment cover.

To avoid splashing the S1 Rinse Solution, deaerate the bottle at about 3000 m above sea level or higher before inserting it.

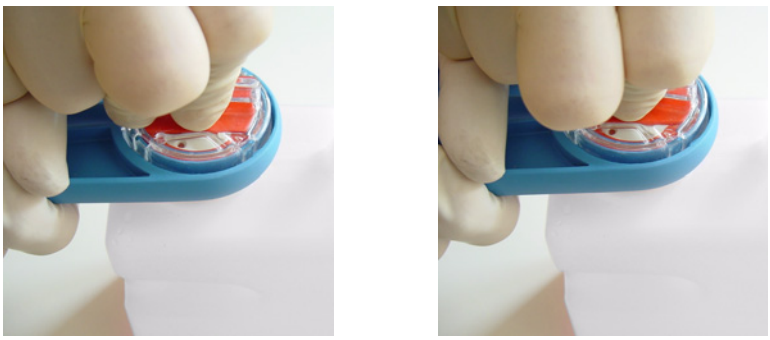
6 Place the bottle tool on the screw cap of the S1 Rinse Solution (see below).

A Bottle tool **B** Screw cap with placed bottle tool

Figure A-40 Screw cap

7 Press the grips together and press the transparent disk downward (see below/A).

8 Rotate the transparent disk clockwise and stop when you notice a resistance after a short distance (see below/B).



A **B**

Figure A-41 Open bottle

21. Complete installation

1 Press the [Complete installation] button.
Automatic sequences take place and the unit warms up.

2 Installation is complete.

If a power failure occurs during installation, the installation starts anew with the next restart. Actions which were performed successfully are discarded.

22. Perform MSS polarization (cobas b 221<5> system and cobas b 221<6> system only)

1 Prepare a syringe or capillary with whole blood for polarization.

The blood should have a volume of at least 150 µL, contain heparin as an anticoagulant, and be stored for less than 24 hours.

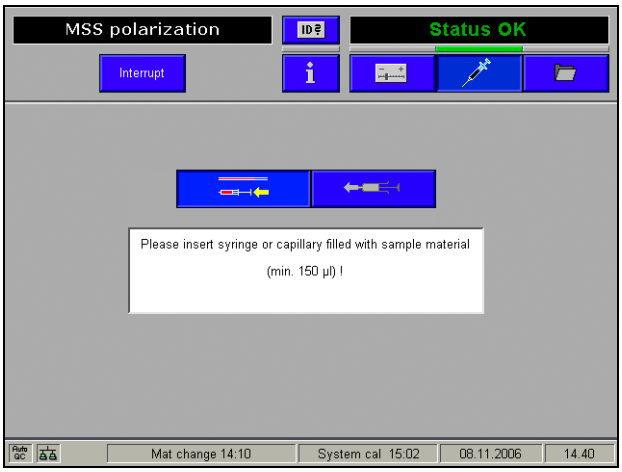


Figure A-42 MSS polarization

2 The blood sample is inserted via fill port similar to a measurement.

see Chapter 6 *Measurement*

3 The MSS cassette is subsequently exposed to liquid, polarized and heated.

4 A system calibration is carried out.

5 If, after inserting the cassette, the automatic polarization was not successful and the MSS sensors are not calibrated, you must manually polarize the MSS cassette. To do this, press the following buttons:

System > Utilities > MSS polarization

6 Follow the instructions on the screen!

23. Checking the barometer value

☞ System > Component test > Control sensors > Baro sensor

1 If the barometer value deviates by more than ± 4 mbar from the value indicated by a precision barometer, it will be necessary for Technical support to calibrate the barometer!

A wrong barometer value leads to wrong PO_2 measurement results.

Important:

From approx. 3000 m above sea level or air pressure < 526 mmHg (70.13 kPa), the specifications for parameter PO_2 are no longer fulfilled and the parameter must no longer be used for evaluation of the clinical decisions. The parameter PO_2 must be permanentely deactivated.

2 To deactivate the parameter PO_2 press the following buttons:

☞ Setup > Parameter > Miscellaneous settings > Activated / deactivated for calibrations

24. Quality control

1 Define the material and if an AutoQC drawer (option) is available insert the mats before performing a quality control measurement.

👁 For details, see Chapter 7 *Quality control*

2 Perform quality control tests for all 3 levels (low, normal, high). Make sure that the results agree with the target values.

👁 See Chapter 7 *Quality control*

Shutdown

Less than 24 hours

If the **cobas b** 221 system is not used for a short period of time only (< 24 hours), then activate the following function, starting with the top level of the analyzer mode:

☞ System > Utilities > Shutdown PC

This function allows for switching off the touch screen/PC unit and is completed with manually switching off the instrument.

Follow the instructions on the screen!

MSS sensors (Glu / Lac / Urea/BUN) are destroyed during this operation.
If the instrument is turned on again, a new MSS cassette must be inserted.

👁 See section *19. Open the measuring chamber cover and insert the sensors* on page A-40.

Longer than 24 hours

If the **cobas b** 221 system will be shut down for longer than 24 hours, perform the following procedure.

Before performing a shutdown, Roche Diagnostics recommends decontaminating all surfaces and tube paths.

👁 see Chapter 10 *Maintenance*, Abschnitt *Decontamination* on page C-5!

Activate the following function, starting with the top level of the analyzer mode:

☞ System > Utilities > Put out of operation

All solutions and electrodes have to be removed during the shutdown procedure.
The procedure ends in switching off the instrument.
Follow the instructions on the screen.

Observe the listed sequence while performing the actions.

Processing the actions:

Manual: The corresponding line of the list box contains an instruction which must be performed manually. Then press [Confirm action].

Automatic: If there is an automatic sequence for any action, you can start this by clicking [Start process].

Upon successful completion, this symbol is displayed.

1. Open bottle compartment cover and only remove bottle S1 and packs (depending on the configuration S2 and S3).

1 Open bottle compartment cover and docking mechanism and remove bottle S1 and the packs (S2 and S3).

Do not remove the waste container!

2 Close docking mechanism and bottle compartment cover.

2. Fill the shutdown kit with distilled water

- Fill the shutdown kit about halfway with distilled water.

Figure A-43 Shutdown kit

3. Insert shutdown kit into space S2

1 Open bottle compartment cover and docking mechanism S2 and insert the shutdown kit into space S2.

2 Close docking mechanism and bottle compartment cover.

3 Perform "Washing of the tubes".

4. Remove shutdown kit from space S2

1 Open bottle compartment cover and docking mechanism S2 and remove the shutdown kit.

2 Close docking mechanism and bottle compartment cover.

3 Perform "Emptying of the tubes".

5. Insert shutdown kit into space S3 (cobas b 221<5> system and cobas b 221<6> system only)

1 Open bottle compartment cover and docking mechanism S3 and insert the shutdown kit into space S3.

2 Close docking mechanism and bottle compartment cover.

3 Perform "Washing of the tubes".

6. Remove shutdown kit from space S3 (cobas b 221<5> system and cobas b 221<6> system only)

1 Open bottle compartment cover and docking mechanism S3 and remove the shutdown kit.

2 Close docking mechanism and bottle compartment cover.

3 Perform "Emptying of the tubes".

7. Remove Waste container

1 Open bottle compartment cover and docking mechanism W.

2 Remove the waste water container (W Waste Container).

3 Close docking mechanism and bottle compartment cover.

8. Open the measuring chamber cover and remove the sensors

1 Remove the top cover and open all measuring chamber covers.

2 Open the measuring chamber cover (push the right edge of the MC cover to the left with a finger and open up the MC cover).

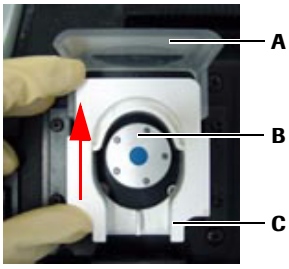
3 Open the locking levers and the contact clip (MSS measuring chamber).

4 Sequentially remove the electrodes and the MSS cassette from the measuring chambers.

5 Close the locking lever, the contact clip and all the measuring chamber covers.

9. Remove the peristaltic pump tubes

1 Open the peristaltic pump's clear plastic cover (tension lever) (see below).

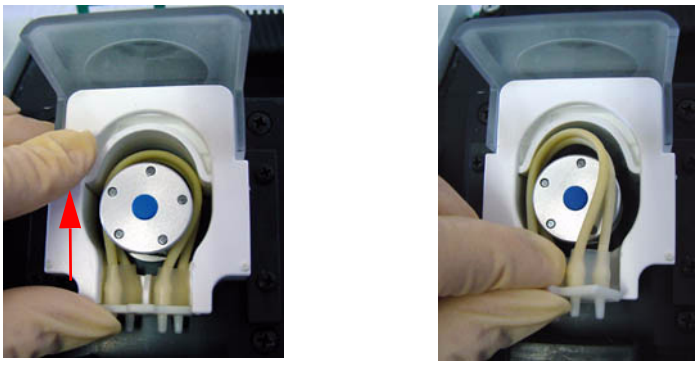


A Tension lever
B Pump head
C Linear bracket

Figure A-44 Peristaltic pump

2 Push the linear bracket (white plastic part) upwards (see below/A).

3 Remove the complete tubing set (tubing holder and tubing) of the corresponding pump (see below/B)



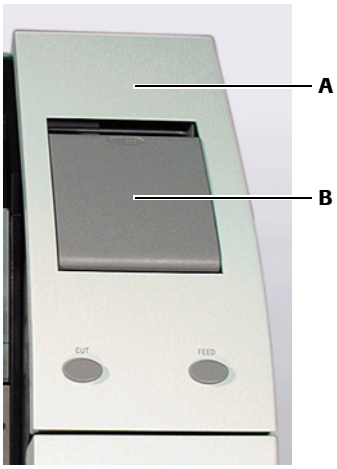
A Push the linear bracket upwards **B** Remove the tubing set

Figure A-45 Peristaltic pump

4 Close the tension lever.

10. Remove the printer paper

1 Open the printer cover and the paper lid.



A Printer cover **B** Paper lid

Figure A-46 Printer cover / paper lid

2 Move the printer lever upwards (see below/A).

A Printer lever "upwards" **B** Printer lever "down"

Figure A-47 Printer lever

3 Remove the printer paper.

4 Move the printer lever down again (see above/B).

5 Close the paper lid and the printer cover.

11. Open T&D

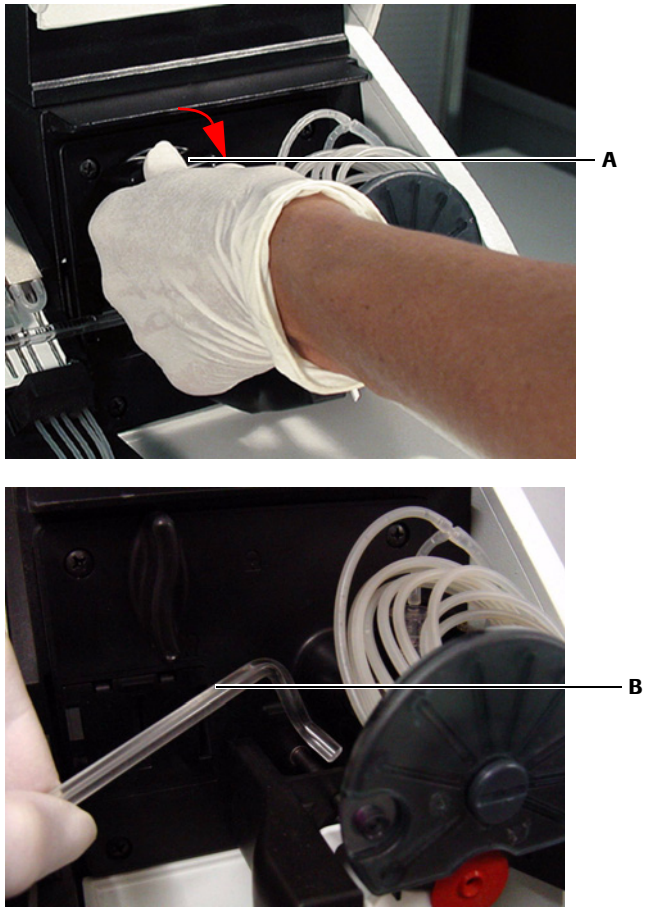
- Press [Start process]. This action is performed automatically.
  The T&D disk turns to position 1.

12. Remove fill port and sample inlet path (glass tube)

1 Remove the sample drip tray.

2 Remove the T&D cover.

3 Open the T&D lock and remove the sample inlet path (glass tube).

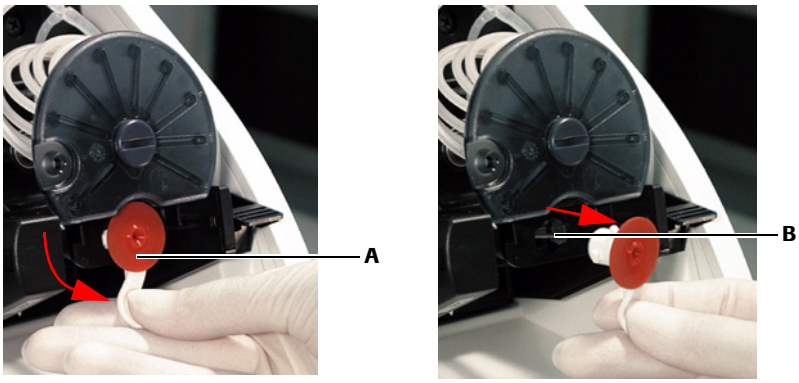


A T&D lock **B** Sample inlet path (glass tube)

Figure A-48 T&D lock & sample inlet path

4 Turn the fill port downward by 90° and pull it straight off of the needle.

Do not bend the needle!



A Fill port **B** Needle

Figure A-49 Fill port

5 Close the T&D lock again.

6 Close the T&D cover.

13. Set valves for FMS tubing exchange

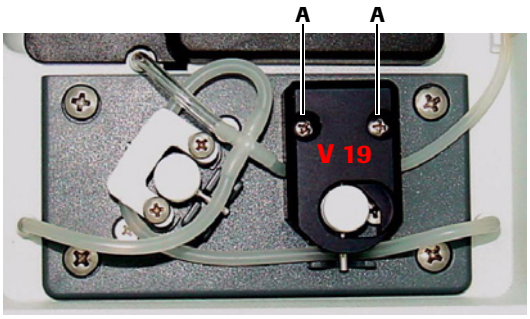
- Press [Start process]. This action is performed automatically.

Both valves are pushed out.

14. Release screws at V19 (bottle compartment)

1 Open the bottle compartment cover and the docking mechanism S3.

2 Loosen the screws (A) of the aluminum part of valve V19 (approx. 2-3 turns).



A Screws

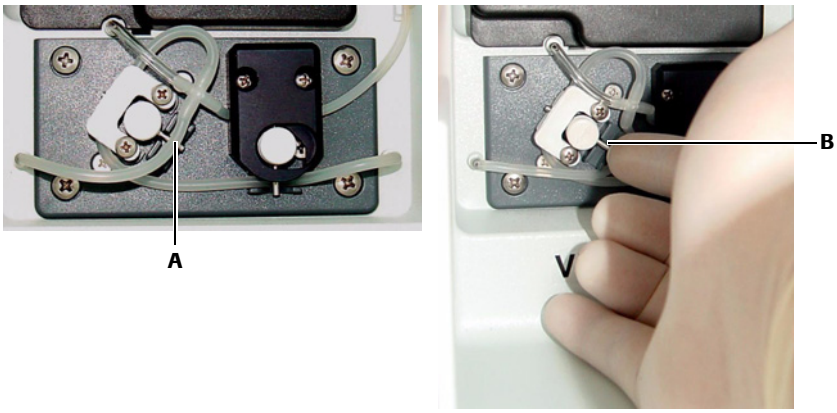
Figure A-50 Valve V19

3 Close the docking mechanism S3 and the bottle compartment cover.

15. Remove right FMS tube at VM (bottle compartment)

1 Open the bottle compartment cover and the docking mechanism S3.

2 Slide the tube out under the tube clip of valve VM.



A VM **B** Tube clip

Figure A-51 Valve VM

3 Pressure is removed from the tubes.

4 Close the docking mechanism and the bottle compartment cover.

If available (option):

16. Go to AutoQC home position

- Press [Start process]. This action is performed automatically.

17. Open the AutoQC drawer and remove the ampoule holder

1 Pull out the AutoQC drawer.

2 Remove the AutoQC ampoule holder.

3 Remove the already opened ampoules from the mats and dispose of them according to the local guidelines.

If individual ampoules remain in the white ampoule holder after removing the mats, note that these open ampoules may break on removal with the attendant risk of injury.

Before inserting a new mat remove them all carefully!

Always wear gloves! CAUTION: Danger of spilling!

4 Leave the full ampoules in the mats and store them in a refrigerator in accordance with their storage temperature (see packaging insert).

5 Close the AutoQC drawer.

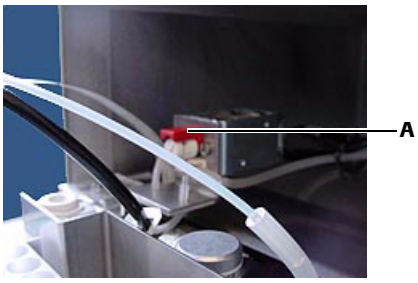
18. Go to AutoQC service position

- Press [Start process]. This action is performed automatically.

19. Open AutoQC drawer and insert the AutoQC valve clamp

1 Pull out the AutoQC drawer.

2 Insert the clamp of the AutoQC valve (see below).



A AutoQC valve clamp

Figure A-52 AutoQC valve clamp

3 Close the AutoQC drawer.

20. Go to AutoQC home position

- Press [Start process]. This action is performed automatically.

21. Complete shutdown

1 Press the [Complete shutdown] button.

Shut down is complete. The following screen appears:

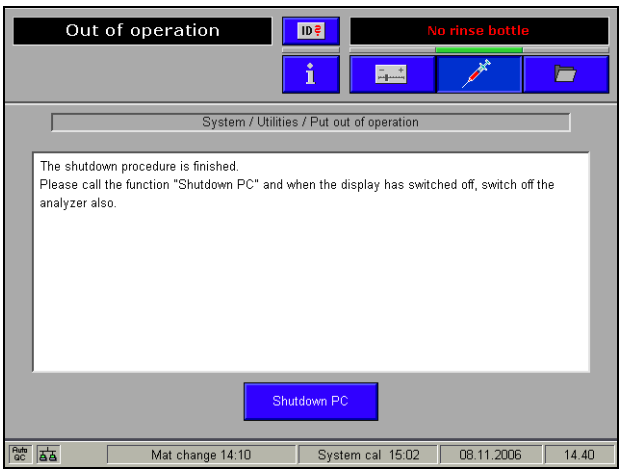


Figure A-53 Shutdown

2 Press the [Shutdown PC] button. Follow the instructions on the screen.
The PC is booted down.

3 Turn off the device.

4 Close top cover.

Remove the transport, power cable, scanner and, if available, network connectors.

Specifications

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

In this chapter *Chapter* 4

Contents

Performance data

Measurement parameters

Parameter	specified for	specified range	
PO_2	B/Q	0 - 800 mmHg	
PCO_2	B/Q	4 – 200 mmHg	
pH	B/Q/S/PF	6.0 - 8.0	
Sodium	B/Q/S/A/D	20 - 250 mmol/L	
Potassium	B/Q/S/A/D	0.2 - 20 mmol/L	
Chloride	B/Q/S	20 - 250 mmol/L	
ionized Calcium	B/Q/S/A/D	0.1 - 4.0 mmol/L	0.4008 - 16.032 mg/dL
Hct	B/Q	10 – 80 %	
Glucose[(a)] (**cobas b** 221<5> system, **cobas b** 221<6> system only)	B/Q/S	0.5 – 40 mmol/L	9.01 - 720.8 mg/dL
Lactate (**cobas b** 221<5> system, **cobas b** 221<6> system only)	B/Q/S	0.2 – 20 mmol/L	1.8016 - 180.16 mg/dL
Urea (**cobas b** 221<6> system only)	B/Q/S	0.5 – 30 mmol/L	3.0028 - 180.168 mg/dL
tHb module	B/Q	3 – 25 g/dL	1.8606 - 15.505 mmol/L
SO_2 module	B/Q	50 – 100 %	
tHb (COOX)	B/Q	3 – 25 g/dL	
SO_2 (COOX)	B/Q	0 – 100 %	
HHb (COOX)	B/Q	0 – 100 %	
COHb (COOX)	B/Q	0 – 100 %	
O_2Hb (COOX)	B/Q	0 – 100 %	
MetHb (COOX)	B/Q	0 – 100 %	
Bilirubin (neonatal) (COOX)	B/Q	3 - 50 mg/dL	51.3 - 855 µmol/L
Baro		450 - 800 mmHg	

Table A-1 Measurement parameters

(a) Due to the current specifications, clinically significant deviations in the range < 3mmol/L can occur compared to other glucose measuring systems. Especially in the neonatal field, we therefore recommend carrying out a comparative blood measurement relative to a known reference system or to adapt the correlation table (refer to the Reference Manual, chapter "Setup" section "Correlation"). For any questions concerning this matter, contact the local Roche organization.

B	Whole blood
Q	Aqueous QC material[(a)]
A	Dialysis solutions containing acetate
D	Dialysis solutions containing bicarbonate
S	Serum or plasma
PF	Pleural fluid (can be measured in serum/plasma mode)

(a) with approximate physiological ion matrix and buffer capacity

Reproducibility

"Within-Run (Swr)" and "Total Precision (ST)" was determined from 2 runs per day with 2 replicates per run for 20 days on four **cobas b** 221 systems.

The mean value is the measured value of the corresponding parameter for which S_{wr} and S_T are representative resp. have been determined.

Parameter	Unit
pH	pH units
PCO_2	mmHg
PO_2	mmHg
Sodium	mmol/L
Potassium	mmol/L
Chloride	mmol/L
ionized Calcium	mmol/L
Hct	%
Lactate (**cobas b** 221<5> system, **cobas b** 221<6> system only)	mmol/L
Glucose (**cobas b** 221<5> system, **cobas b** 221<6> system only)	mmol/L
Urea (**cobas b** 221<6> system only)	mmol/L
tHb (tHb module)	g/dL
SO_2 (tHb module)	%
tHb (COOX)	g/dL
SO_2 (COOX)	%
O_2Hb	%
COHb	%
MetHb	%
HHb	%
Bilirubin (neonatal)	mg/dL

Table A-2 Units of the parameters

Material: acetat - standard solution (Level 1), NIST Traceable, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Sodium	140.0	0.5600	0.40	0.7405	0.53
Potassium	2.02	0.0165	0.82	0.0290	1.44
Chloride	-	-	-	-	-
ionized Calcium	1.622	0.0155	0.96	0.0205	1.26

Table A-3 Acetat - standard solution (Level 1), NIST Traceable, n=80

Material: acetat – standard solution (Level 2), NIST Traceable, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Sodium	140.1	0.5107	0.36	0.7747	0.55
Potassium	4.00	0.0171	0.43	0.0273	0.68
Chloride	-	-	-	-	-
ionized Calcium	1.166	0.0077	0.66	0.0141	1.21

Table A-4 Acetat - standard solution (Level 2), NIST Traceable, n=80

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

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.441	0.0042	0.06	-	-
PCO_2	18.3	0.3331	1.82	0.6262	3.42
PO_2	137.9	0.9371	0.68	2.3258	1.69
Sodium	139.5	0.4878	0.35	-	-
Potassium	4.58	0.0260	0.57	-	-
Chloride	108.4	0.4310	0.40	-	-
ionized Calcium	1.181	0.0079	0.67	-	-
Hct	43.3	0.3203	0.74	-	-
Lactate	11.5	0.1769	1.54	-	-
Glucose	1.8	0.0648	3.51	-	-
Urea	4.8	0.0529	1.11	-	-
tHb (tHb module)	15.4	0.1461	0.95	-	-
SO_2 (tHb module)	96.6	0.3744	0.39	-	-
tHb (COOX)	14.1	0.0773	0.55	-	-
SO_2 (COOX)	99.9	0.0613	0.06	-	-
O_2Hb	97.9	0.0684	0.07	-	-
COHb	1.4	0.0377	2.79	-	-
MetHb	0.7	0.0287	4.10	-	-
HHb	0.1	0.0601	-	-	-

Table A-5 Tonometered human whole blood, 20 different probands, n=80

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

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.129	0.0049	0.07	-	-
PCO_2	79.5	1.2629	1.59	1.9644	2.47
PO_2	40.1	0.3297	0.82	0.5976	1.49
Sodium	142.3	0.7126	0.50	-	-
Potassium	4.32	0.0392	0.91	-	-
Chloride	105.2	0.5184	0.49	-	-
ionized Calcium	1.301	0.0136	1.05	-	-
Hct	40.4	0.2795	0.69	-	-
Lactate	8.7	0.2021	2.33	-	-
Glucose	2.3	0.0977	4.31	-	-
Urea	4.9	0.0583	1.18	-	-
tHb (tHb module)	15.9	0.1315	0.83	-	-
SO_2 (tHb module)	55.0	0.8839	1.61	-	-
tHb (COOX)	14.1	0.1691	1.20	-	-
SO_2 (COOX)	67.8	0.2479	0.37	-	-
O_2Hb	66.9	0.3437	0.51	-	-
COHb	1.6	0.0549	3.53	-	-
MetHb	0.4	0.0504	12.14	-	-
HHb	31.5	0.3121	0.99	-	-

Table A-6 Tonometered human whole blood, 20 different probands, n=80

Material: human plasma, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.670	0.0097	0.13	0.0549	0.72
PCO_2	-	-	-	-	-
PO_2	-	-	-	-	-
Sodium	140.9	0.7783	0.55	0.9920	0.70
Potassium	3.99	0.0514	1.29	0.0603	1.51
Chloride	106.0	0.4967	0.47	0.7877	0.74
ionized Calcium	1.155	0.0174	1.51	0.0339	2.94
Hct	-	-	-	-	-
Lactate	2.3	0.0349	1.52	0.1150	5.00
Glucose	5.7	0.0818	1.44	0.1695	2.97
Urea	4.8	0.0873	1.81	0.1005	2.08

Table A-7 Human plasma, n=80

Material: serum, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.731	0.0120	0.15	0.0334	0.43
PCO_2	-	-	-	-	-
PO_2	-	-	-	-	-
Sodium	140.2	0.3226	0.23	0.6567	0.47
Potassium	4.18	0.0149	0.36	0.0330	0.79
Chloride	105.2	0.4310	0.41	0.6871	0.65
ionized Calcium	1.098	0.0092	0.84	0.0323	2.94
Hct	-	-	-	-	-
Lactate	2.3	0.0353	1.53	0.0989	4.30
Glucose	5.1	0.0737	1.45	0.1834	3.62
Urea	5.2	0.0451	0.86	0.1197	2.29

Table A-8 Serum, n=80

Material: bicarbonate, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Sodium	137.9	0.7201	0.52	1.0185	0.74
Potassium	2.00	0.0224	1.12	0.0301	1.51
Chloride	-	-	-	-	-
ionized Calcium	1.605	0.0091	0.57	0.0167	1.04

Table A-9 Bicarbonate, n=80

Material: AUTOTROL PLUS B Level 1, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.182	0.0039	0.05	0.0060	0.08
PCO_2	65.8	0.8109	1.23	1.7861	2.72
PO_2	55.4	3.6232	6.53	4.5447	8.20
Sodium	121.2	0.6188	0.51	1.1226	0.93
Potassium	2.97	0.0161	0.54	0.0283	0.95
Chloride	84.2	0.4971	0.59	1.6465	1.96
ionized Calcium	1.557	0.0089	0.57	0.0153	0.98
Hct	51.8	0.9534	1.84	1.1250	2.17
Lactate	9.2	0.0821	0.89	0.4539	4.92
Glucose	5.4	0.0612	1.12	0.1299	2.38
Urea	23.5	0.3307	1.41	0.6664	2.84
tHb (tHb module)	-	-	-	-	-
SO_2 (tHb module)	-	-	-	-	-
tHb (COOX)	7.8	0.0317	0.41	0.0599	0.77
SO_2 (COOX)	72.1	0.0690	0.10	0.1941	0.27
O_2Hb	46.8	0.0844	0.18	0.2383	0.51
COHb	23.0	0.0371	0.16	0.1043	0.45
MetHb	12.0	0.0180	0.15	0.0513	0.43
HHb	18.1	0.0294	0.16	0.0830	0.46
Bili	6.1	0.0287	0.47	0.0477	0.78

Table A-10 AUTOTROL PLUS B Level 1, n=40

Material: AUTOTROL PLUS B Level 2, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.411	0.0031	0.04	0.0047	0.06
PCO_2	41.0	0.4626	1.13	0.7116	1.74
PO_2	93.2	2.9752	3.19	5.0160	5.38
Sodium	139.6	0.3827	0.27	0.7718	0.55
Potassium	4.76	0.0131	0.27	0.0250	0.53
Chloride	101.0	0.3290	0.33	0.9795	0.97
ionized Calcium	1.154	0.0064	0.55	0.0138	1.20
Hct	38.6	0.2840	0.74	0.6195	1.60
Lactate	1.9	0.0135	0.70	0.0798	4.12
Glucose	2.4	0.0197	0.81	0.1172	4.83
Urea	7.3	0.0538	0.74	0.1939	2.67
tHb (tHb module)	-	-	-	-	-
SO_2 (tHb module)	-	-	-	-	-
tHb (COOX)	12.1	0.0715	0.59	0.1182	0.98
SO_2 (COOX)	89.6	0.1442	0.16	0.1507	0.17
O_2Hb	74.3	0.2843	0.38	0.3011	0.41

Table A-11 AUTOTROL PLUS B Level 2, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
COHb	11.1	0.1265	1.14	0.1306	1.18
MetHb	6.0	0.0577	0.96	0.0671	1.12
HHb	8.6	0.1001	1.17	0.1041	1.21
Bili	12.4	0.0857	0.69	0.1188	0.96

Table A-11 AUTOTROL PLUS B Level 2, n=40

Material: AUTOTROL PLUS B Level 3, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.571	0.0027	0.04	0.0050	0.07
PCO_2	20.3	0.3114	1.53	0.5568	2.74
PO_2	144.2	5.3745	3.73	6.5040	4.51
Sodium	158.9	0.5680	0.36	0.8495	0.53
Potassium	6.97	0.0343	0.49	0.0514	0.74
Chloride	119.0	0.4810	0.40	1.0305	0.87
ionized Calcium	0.546	0.0041	0.76	0.0078	1.43
Hct	26.9	0.4193	1.56	0.4298	1.60
Lactate	0.8	0.0103	1.29	0.0562	7.02
Glucose	21.0	0.1298	0.62	0.4006	1.91
Urea	2.1	0.0202	0.94	0.0757	3.53
tHb (tHb module)	-	-	-	-	-
SO_2 (tHb module)	-	-	-	-	-
tHb (COOX)	20.4	0.1940	0.95	0.2357	1.15
SO_2 (COOX)	97.5	0.1396	0.14	0.1400	0.14
O_2Hb	92.5	0.3581	0.39	0.3617	0.39
COHb	3.3	0.1564	4.75	0.1565	4.75
MetHb	1.9	0.0773	4.13	0.0809	4.32
HHb	2.4	0.1244	5.23	0.1249	5.25
Bili	21.6	0.1621	0.75	0.1690	0.78

Table A-12 AUTOTROL PLUS B Level 3, n=40

Material: AUTOTROL PLUS B Level 4B, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.418	0.0014	0.02	0.0050	0.07
PCO_2	41.3	0.2720	0.66	0.6088	1.48
PO_2	96.4	5.0118	5.20	8.9120	9.24
Sodium	140.6	0.3242	0.23	0.5710	0.41
Potassium	4.77	0.0135	0.28	0.0220	0.46
Chloride	101.6	0.3679	0.36	0.9279	0.91
ionized Calcium	1.104	0.0048	0.43	0.0092	0.83
Hct	36.7	0.3883	1.06	0.5049	1.38
Lactate	5.6	0.0304	0.54	0.1607	2.85

Table A-13 AUTOTROL PLUS B Level 4B, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Glucose	1.4	0.0204	1.45	0.1026	7.26
Urea	13.1	0.2512	1.91	0.7169	5.46
tHb (tHb module)	-	-	-	-	-
SO_2 (tHb module)	-	-	-	-	-
tHb (COOX)	6.4	0.0265	0.41	0.1241	1.93
SO_2 (COOX)	62.7	0.2002	0.32	0.2514	0.40
O_2Hb	36.5	0.1973	0.54	0.2474	0.68
COHb	27.6	0.0869	0.32	0.1091	0.40
MetHb	14.2	0.0414	0.29	0.0518	0.36
HHb	21.7	0.0690	0.32	0.0866	0.40
Bili	4.2	0.0146	0.34	0.0707	1.67

Table A-13 AUTOTROL PLUS B Level 4B, n=40

Material: AUTOTROL PLUS B Level 5B, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.412	0.0033	0.04	0.0061	0.08
PCO_2	41.4	0.3787	0.91	0.7924	1.91
PO_2	94.7	3.1077	3.28	3.2578	3.44
Sodium	139.4	0.7465	0.54	0.8404	0.60
Potassium	4.76	0.0365	0.77	0.0339	0.71
Chloride	102.1	0.7601	0.74	1.3617	1.33
ionized Calcium	1.119	0.0062	0.56	0.0103	0.92
Hct	38.0	1.4404	3.79	1.4027	3.69
Lactate	12.9	0.1628	1.26	0.5348	4.14
Glucose	25.4	0.1913	0.75	0.5098	2.00
Urea	26.4	0.4122	1.56	2.5774	9.75
tHb (tHb module)	-	-	-	-	-
SO_2 (tHb module)	-	-	-	-	-
tHb (COOX)	23.0	0.2175	0.94	0.3139	1.36
SO_2 (COOX)	98.1	0.1568	0.16	0.1744	0.18
O_2Hb	94.2	0.4087	0.43	0.4554	0.48
COHb	2.5	0.0852	3.37	0.1053	4.16
MetHb	1.4	0.0397	2.77	0.0519	3.62
HHb	1.8	0.0675	3.83	0.0837	4.75
Bili	24.1	0.2629	1.09	0.2728	1.13

Table A-14 AUTOTROL PLUS B Level 5B, n=40

Material: AUTOTROL TS+ Level 1, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.172	0.0037	0.05	0.0054	0.08
PCO_2	62.3	0.8276	1.33	1.5073	2.42
PO_2	50.6	4.2084	8.32	5.4278	10.74
Sodium	121.9	0.8432	0.69	1.0952	0.90
Potassium	2.98	0.0333	1.12	0.0352	1.18
Chloride	84.8	0.5243	0.62	0.9029	1.06
ionized Calcium	1.591	0.0170	1.07	0.0217	1.36
Hct	56.8	1.5547	2.74	1.5912	2.80
Lactate	9.3	0.0710	0.76	0.4680	5.01
Glucose	5.5	0.0564	1.02	0.1729	3.13
tHb (tHb module)	18.7	0.0256	0.14	0.0440	0.24
SO_2 (tHb module)	100.0	0.0112	0.01	0.0112	0.01

Table A-15 AUTOTROL TS+ Level 1, n=40

Material: AUTOTROL TS+ Level 2, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.406	0.0022	0.03	0.0043	0.06
PCO_2	43.1	0.3800	0.88	0.5716	1.33
PO_2	92.5	2.8967	3.13	3.5631	3.85
Sodium	136.9	0.5024	0.37	0.7705	0.56
Potassium	4.70	0.0303	0.64	0.0414	0.88
Chloride	99.4	0.3950	0.40	0.5617	0.56
ionized Calcium	1.146	0.0141	1.23	0.0178	1.56
Hct	41.6	0.3827	0.92	0.7501	1.80
Lactate	1.9	0.0163	0.86	0.0672	3.53
Glucose	2.5	0.0204	0.83	0.1044	4.23
tHb (tHb module)	14.3	0.0773	0.54	0.0794	0.56
SO_2 (tHb module)	93.3	0.1776	0.19	0.1855	0.20

Table A-16 AUTOTROL TS+ Level 2, n=40

Material: AUTOTROL TS+ Level 3, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.567	0.0023	0.03	0.0047	0.06
PCO_2	22.9	0.2652	1.16	0.4763	2.08
PO_2	141.8	3.4549	2.44	4.0597	2.86
Sodium	156.3	0.8170	0.52	1.0626	0.68
Potassium	7.03	0.0510	0.72	0.0628	0.89
Chloride	120.3	0.4829	0.40	0.6012	0.50
ionized Calcium	0.599	0.0100	1.67	0.0128	2.13

Table A-17 AUTOTROL TS+ Level 3, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Hct	22.9	0.5431	2.37	0.5799	2.53
Lactate	0.8	0.0316	4.02	0.0446	5.68
Glucose	21.3	0.6006	2.82	0.7883	3.70
tHb (tHb module)	8.3	0.0122	0.15	0.0319	0.39
SO_2 (tHb module)	93.3	0.0355	0.04	0.0450	0.05

Table A-17 AUTOTROL TS+ Level 3, n=40

Material: AUTOTROL TS+ Level 4A, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	6.880	0.0054	0.08	0.0076	0.11
PCO_2	87.5	1.3229	1.51	2.4825	2.84
PO_2	22.7	3.6828	16.23	5.1660	22.77
Sodium	88.0	0.5162	0.59	0.8391	0.95
Potassium	8.94	0.0584	0.65	0.1029	1.15
Chloride	67.8	0.5941	0.88	1.3054	1.93
ionized Calcium	2.543	0.0272	1.07	0.0452	1.78
Hct	75.8	0.8202	1.08	1.0158	1.34
Lactate	-	-	-	-	-
Glucose	-	-	-	-	-
Urea	-	-	-	-	-
tHb (tHb module)	11.0	0.0206	0.19	0.0281	0.26
SO_2 (tHb module)	88.2	0.0303	0.03	0.0450	0.05

Table A-18 AUTOTROL TS+ Level 4A, n=40

Material: AUTOTROL TS+ Level 5A, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.730	0.0042	0.05	0.0061	0.08
PCO_2	9.2	1.3769	15.03	1.4213	15.51
PO_2	253.6	6.0686	2.39	8.7795	3.46
Sodium	174.5	0.8890	0.51	1.2891	0.74
Potassium	2.00	0.0250	1.25	0.0346	1.73
Chloride	130.3	0.7821	0.60	1.1922	0.91
ionized Calcium	0.403	0.0065	1.61	0.0109	2.70
Hct	22.0	0.6997	3.18	0.7713	3.50
Lactate	-	-	-	-	-
Glucose	-	-	-	-	-
Urea	-	-	-	-	-
tHb (tHb module)	15.8	0.0196	0.12	0.0316	0.20
SO_2 (tHb module)	95.8	0.0469	0.05	0.0596	0.06

Table A-19 AUTOTROL TS+ Level 5A, n=40

Material: MSS Level 1, NIST Traceable, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Lactate	9.4	0.0670	0.71	0.2626	2.78
Glucose	5.7	0.0337	0.60	0.1231	2.18
Urea	4.9	0.0391	0.80	0.1837	3.74

Table A-20 MSS Level 1, NIST Traceable, n=80

Material: MSS Level 2, NIST Traceable, n=80

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Lactate	1.9	0.0188	0.96	0.0497	2.55
Glucose	2.6	0.0267	1.05	0.0972	3.81
Urea	14.5	0.2263	1.56	0.4100	2.83

Table A-21 MSS Level 2, NIST Traceable, n=80

Material: human whole blood incl. bilirubin Level 1, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Bili	8.2	0.1202	1.47	0.6198	7.56

Table A-22 Human whole blood incl. bilirubin Level 1, n=40

Material: human whole blood incl. bilirubin Level 2, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Bili	24.1	0.1171	0.49	0.9663	4.01

Table A-23 Human whole blood incl. bilirubin Level 2, n=40

Material: human whole blood incl. bilirubin Level 3, n=40

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Bili	44.0	0.1623	0.37	2.1509	4.89

Table A-24 Human whole blood incl. bilirubin Level 3, n=40

Linearity

Tonometered whole blood Whole blood was tonometered at 37 °C to various level of gravimetrically prepared gases with CO_2 and O_2 concentrations certified to ± 0.03% absolute by the manufacturer. Expected and observed values for PCO_2 and PO_2 were corrected to 760 mmHg.

Aqueous Solutions Expected values for the aqueous solutions are based on weighted samples.

NIST standards NIST standards are precise serums with accredited target values.

Hematocrit Measurement results of the hemofuge, which is representing the Golden Standard for hematocrit measurements, are used as expected values for hematocrit results.

Human whole blood incl. bilirubin Expected bilirubin values for human whole blood incl. bilirubin are based on weighted samples.

Parameter: PO_2 (mmHg)

Material: tonometered whole blood

Number of instruments: 4 **cobas b** 221 systems

Measurements per measuring point and instrument: 5

Expected value	Mean	S_{wr}	Recovery
55.39	55.66	0.4860	100.5
83.83	83.45	0.4982	99.5
103.55	103.16	0.9034	99.6
216.97	218.54	1.9437	100.7

Table A-25 Parameter PO_2 (mmHg)

Correlation

Slope	0.9904 - 1.0097
Intercept	± 0.857
Correlation coefficient	0.9998

Parameter: PCO_2 (mmHg)

Material: Tonometered whole blood

Number of instruments: 4 **cobas b** 221 systems

Measurements per measuring point and instrument: 5

Expected value	Mean	S_{wr}	Recovery
14.90	13.78	0.1141	92.5
39.74	37.78	0.3911	95.1
119.43	117.09	1.3505	98.0

Table A-26 Parameter PCO_2 (mmHg)

Correlation

Slope	0.9898 - 1.0103
Intercept	± 1.225
Correlation coefficient	0.9999

Parameter: pH (pH units)

Material: Tonometered whole blood

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 5

Expected value	Mean	S_{wr}	Recovery
7.52	7.52	0.0050	100
7.32	7.32	0.0042	100
6.98	6.99	0.0066	100.1

Table A-27 Parameter pH (pH units)

Correlation

Slope	0.9825 - 1.0178
Intercept	± 0.133
Correlation coefficient	0.9998

Parameter: Hct (%)

Material: human whole blood, traceable to golden standard (micro centrifuge)

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 5

Expected value	Mean	S_{wr}	Recovery
11.00	11.72	0.4146	106.5
24.00	23.60	0.1804	98.3
36.00	36.51	1.0171	101.4
48.00	49.73	1.0046	103.6
68.00	68.16	0.2210	100.2
78.00	77.80	0.3925	99.7

Table A-28 Parameter Hct (%)

Correlation

Slope	0.997 - 1.003
Intercept	± 0.620
Correlation coefficient	0.999

Parameter: sodium (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
19.85	21.25	0.4979	107.1
91.52	92.44	0.3018	101.0
153.49	154.83	0.3808	100.9
205.66	208.30	0.5619	101.3
258.42	262.68	1.6465	101.6

Table A-29 Parameter Sodium (mmol/L)

Correlation

Slope	0.988 - 1.012
Intercept	± 0.365
Correlation coefficient	0.9999

Parameter: potassium (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
0.23	0.26	0.0159	115.0
3.12	3.12	0.0114	100.0
5.11	5.13	0.0144	100.4
9.96	10.16	0.0378	102.0
14.71	15.19	0.0624	103.3
19.36	20.15	0.0757	104.1

Table A-30 Parameter Potassium (mmol/L)

Correlation

Slope	0.960 - 1.042
Intercept	± 0.109
Correlation coefficient	0.9999

Parameter: ionized Calcium (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
0.10	0.09	0.0042	92.0
0.80	0.76	0.0067	94.7
1.25	1.19	0.0055	95.2
2.50	2.39	0.0122	95.7
4.00	3.86	0.0225	96.5
6.00	5.84	0.0347	97.4

Table A-31 Parameter ionized Calcium (mmol/L)

Correlation

Slope	0.975 - 1.026
Intercept	± 0.024
Correlation coefficient	0.9999

Parameter: chloride (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
24.86	25.84	0.5081	103.9
93.20	93.08	0.2241	99.9
149.34	146.85	0.3541	98.3
194.98	190.16	0.6110	97.5
239.86	232.04	1.0721	96.7

Table A-32 Parameter Chloride (mmol/L)

Correlation

Slope	0.959 - 1.043
Intercept	± 2.908
Correlation coefficient	0.9999

Parameter: pH (pH units)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
6.20	6.24	0.0022	100.7
6.87	6.89	0.0024	100.2
7.38	7.38	0.0023	100.1
7.70	7.67	0.0023	99.7
8.00	7.97	0.0035	99.7

Table A-33 Parameter pH (pH units)

Correlation

Slope	0.960 - 1.042
Intercept	± 0.293
Correlation coefficient	1.0000

Parameter: CO_2 (mmHg)

Material: tonometered aqueous solution

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
10.00	11.36	0.1389	113.6
20.00	20.59	0.1962	103.0
60.00	57.57	0.6557	95.9
120.00	114.24	1.5521	95.2
180.00	175.37	2.4358	97.4

Table A-34 Parameter: CO_2 (mmHg)

Correlation

Slope	0.961 - 1.041
Intercept	± 0.865
Correlation coefficient	0.9994

Parameter: O_2 (mmHg)

Material: tonometerd aqueous solution

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
600.00	550.24	8.2594	91.7
300.00	278.07	3.7131	92.7
140.00	140.25	0.5353	100.2
60.00	60.29	0.2923	100.5
10.00	11.71	0.4329	117.1

Table A-35 Parameter O_2 (mmHg)

Correlation

Slope	0.908 - 1.101
Intercept	± 6.609
Correlation coefficient	0.9995

Parameter: glucose (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
0.80	0.80	0.0309	100.5
10.00	10.91	0.1274	109.1
20.00	20.21	0.3101	101.0
30.00	29.97	0.4377	99.9
40.00	38.12	0.8833	95.3

Table A-36 Parameter Glucose (mmol/L)

Correlation

Slope	0.919 - 1.088
Intercept	± 1.773
Correlation coefficient	0.998

Parameter: lactate (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
0.50	0.45	0.0064	89.8
5.00	5.00	0.0420	99.9
10.00	10.11	0.0873	101.1
15.00	14.84	0.0920	98.9
20.00	19.07	0.2818	95.3

Table A-37 Parameter Lactate (mmol/L)

Correlation

Slope	0.961 - 1.041
Intercept	± 0.191
Correlation coefficient	0.9989

Parameter: urea (mmol/L)

Material: aqueous solution, NIST traceable

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
0.6	0.83	0.0145	138.8
7.50	7.58	0.0921	101.0
15.00	14.84	0.2328	98.9
22.50	22.13	0.3211	98.4
30.00	29.62	0.5094	98.7

Table A-38 Parameter Urea (mmol/L)

Correlation

Slope	0.979 - 1.021
Intercept	± 0.198
Correlation coefficient	0.9991

Parameter: glucose (mmol/L)

Material: NIST 965

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
5.68	5.56	0.1221	97.9
11.10	11.01	0.2250	99.2
16.36	16.69	0.3826	102.1

Table A-39 Parameter Glucose (mmol/L)

Correlation

Slope	0.9591 - 1.0426
Intercept	± 0.4273
Correlation coefficient	0.9991

Parameter: sodium (mmol/L)

Material: NIST 956a

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
121.40	122.04	0.4136	100.5
141.00	141.37	0.2483	100.3
160.90	160.29	0.3127	99.6

Table A-40 Parameter Sodium (mmol/L)

Correlation

Slope	0.9719 - 1.0289
Intercept	± 4.0475
Correlation coefficient	0.9999

Parameter: potassium (mmol/L)

Material: NIST 956a

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
6.01	6.04	0.0202	100.6
3.99	4.00	0.0103	100.3
2.03	1.91	0.0209	94.1

Table A-41 Parameter Potassium (mmol/L)

Correlation

Slope	0.9629 - 1.0385
Intercept	± 0.1788
Correlation coefficient	0.9999

Parameter: sodium (mmol/L)

Material: NIST 909b

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
120.76	119.96	0.3662	99.3
141.00	144.31	0.4298	102.3

Table A-42 Parameter Sodium (mmol/L)

Correlation

Slope	0.8311 - 1.2032
Intercept	± 25.3383
Correlation coefficient	0.9997

Parameter: potassium (mmol/L)

Material: NIST 909b

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
3.42	3.29	0.0162	96.1
6.28	6.56	0.0273	104.4

Table A-43 Parameter Potassium (mmol/L)

Correlation

Slope	0.8738 - 1.1444
Intercept	± 0.6284
Correlation coefficient	1.0000

Parameter: chloride (mmol/L)

Material: NIST 909b

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
89.11	88.59	0.6674	99.4
119.43	115.96	0.9763	97.1

Table A-44 Parameter Chloride (mmol/L)

Correlation

Slope	0.9032 - 1.1072
Intercept	± 8.1053
Correlation coefficient	0.9990

Parameter: glucose (mmol/L)

Material: NIST 909b

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
5.40	5.06	0.0294	93.7
15.00	12.17	0.1239	81.1

Table A-45 Parameter Glucose (mmol/L)

Correlation

Slope	0.7429 - 1.3461
Intercept	± 1.0482
Correlation coefficient	0.9997

Parameter: urea (mmol/L)

Material: NIST 909b

Number of instruments: 4 **cobas b** 221 systems

Measurements per level and instrument: 15

Expected value	Mean	S_{wr}	Recovery
5.51	5.40	0.0248	98.0

Table A-46 Parameter Urea (mmol/L)

Parameter: tHb (g/dL), SO_2 (%)

Material: Tonometered whole blood

Number of instruments: 4 **cobas b** 221<5> systems

Parameter	Slope	intercept	Coefficient	Range	n
tHb	0.9892 - 1.0109	± 0.0833	0.9904	6-18 [g/dl]	250
SO_2	0.99999 - 1.00001	± 0.856	0.9874	51.7-100 [%]	382

Table A-47 Parameter tHb (g/dL), SO_2 (%)

Parameter: bilirubin (mg/dL)

Material: human whole blood incl. bilirubin

Number of instruments: 2 **cobas b** 221 systems

Measurements per level and instrument: 3

Expected value	Mean	S_{wr}	Recovery
6.00	6.86	0.0928	114.33
14.00	14.55	0.1417	103.93
28.00	26.28	0.1901	93.86
44.00	41.52	0.0920	94.36

Table A-48 Parameter Bilirubin (mg/dL)

Correlation

Slope	0.9038 - 1.1064
Intercept	± 1.514
Correlation coefficient	0.9996

Correlation to other methods

pH

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = -0.063 + 1.009*X	+0.007	0.990	134
Radiometer 725	Y = 0.496 + 0.933*X	+0.003	0.990	99
pH meter[(a)]	Y = 0.9963*X	0	0.999	20

Table A-49 pH

(a) pleural fluid - pH measuring instrument, temperature-corrected

PO_2

Unit: [mmHg]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = -0.643 + 1.031*X	+1.6 %	0.987	136
Radiometer 725	Y = 4.433 + 1.013*X	+6.6 %	0.996	137

Table A-50 PO_2

PCO_2

Unit: [mmHg]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
cobas b 121 System	Y = -1.452 + 1.038*X	+0.4 %	0.988	129
Radiometer 55	Y = -0.301 + 1.000*X	-1.2 %	0.992	144

Table A-51 PCO_2

tHb (cobas b 221 system with tHb/SO_2 module)

Unit: [g/dL]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
Radiometer 725	Y = -0.581 + 1.083*X	+2.0 %	0.814	96

Table A-52 tHb

SO_2 (cobas b 221 system with tHb/SO_2 module)

Unit: [%]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
cobas b 121 System	Y = 10.066+ 0.903*X	+1.1 % abs.	0.991	130
Radiometer 715	Y = -3.969 + 1.037*X	- 0.4 %	0.904	102

Table A-53 SO_2

tHb (cobas b 221 system with COOX module)

Unit: [g/dL]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -0.100+ 1.000*X	-1.0 %	0.980	135
Radiometer 700	Y = 0.200 + 1.000*X	+1.1 %	0.977	125

Table A-54 tHb

O_2Hb (cobas b 221 system with COOX module)

Unit: [%]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = 2.394+ 0.971*X	-0.3 % abs.	0.986	132
Radiometer 725	Y = 14.492 + 0.846*X	+0.1 % abs.	0.986	132

Table A-55 O_2Hb

HHb (cobas b 221 system with COOX module)

Unit: [%]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = -0.069+ 0.987*X	-0.1 % abs.	0.986	132
Radiometer 725	Y = 0.316 + 0.816*X	-0.5 % abs.	0.980	132

Table A-56 HHb

MetHb (cobas b 221 system with COOX module)

Unit: [%]

For values less than 1.3%:

Comparison instrument	Deviation of mean values	No. of samples
OMNI 9	-0.3 % abs.	129
Radiometer 725	+0.2 % abs.	131

Table A-57 MetHb

COHb (cobas b 221 system with COOX module)

Unit: [%]

For values less than 3.5%:

Comparison instrument	Deviation of mean values	No. of samples
OMNI 9	+0.7 % abs.	130
Radiometer 725	+0.1 % abs.	132

Table A-58 COHb

SO_2 (cobas b 221 system with COOX module)

Unit: [%]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = 0.100+ 1.000*X	+0.1 % abs.	0.967	132
Radiometer 725	Y = 17.341 + 0.824*X	+0.5 % abs.	0.988	132

Table A-59 SO_2

Bilirubin (cobas b 221 system with COOX module)

Unit: [mg/dL]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
Hitachi TBil	Y = -0.127+ 0.968*X	+3.7 % abs.	0.986	85
Beckman LX 20 tBil	Y = -0.537 + 1.060*X	+1.4 % abs.	0.980	76
Kodak Vitros tBil	Y = -0.119 + 0.988*X	-2.4 % abs.	0.984	73
Radiometer	Y = -0.327 + 1.044 *X	+10.5 % abs.	0.974	82

Table A-60 Bilirubin

Hct

Unit: [%]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -0.182+ 1.003*X	-0.4 % abs.	0.918	137
cobas b 121 System	Y = -0.689+ 1.040*X	+0.6 % abs.	0.946	141

Table A-61 Hct

Sodium

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -13.193+ 1.106*X	+0.9 %	0.948	108
Radiometer 715	Y = -2.143 + 1.028*X	+1.4 %	0.972	107

Table A-62 Sodium

Potassium

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 6	Y = -0.126+ 1.020*X	-1.4 %	0.986	131
Radiometer 725	Y = -0.323 + 1.083*X	+0.6 %	0.989	98

Table A-63 Potassium

Calcium

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -0.039+ 1.024*X	-0.8 %	0.941	108
cobas b 121 System	Y = -0.036+ 1.042*X	+1.3 %	0.962	140
Radiometer 725	Y = -0.096 + 1.073*X	-1.1 %	0.981	98

Table A-64 Calcium

Chloride

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
cobas b 121 System	Y = -12.459+ 1.118*X	-0.7 %	0.960	139
Radiometer 725	Y = 17.100 + 0.800*X	-4.0 %	0.965	98

Table A-65 Chloride

Glucose

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -0.461+ 1.034*X	-3.9 %	0.938	134
Radiometer 715	Y = -0.867 + 1.201*X	+5.2 %	0.986	107
Hitachi (Plasma)	Y = -1.207+ 1.127*X	-4.9 %	0.990	60
Cobas Mira (Plasma)	Y = -0.807 + 1.121*X	+0.4 %	0.946	135

Table A-66 Glucose

Urea

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = 0.343 + 0.850*X	-10.8 %	0.957	122
Hitachi (Plasma)	Y = 0.053 + 0.882*X	-11.1 %	0.990	53
Cobas Mira (Plasma)	Y = -0.001 + 0.887*X	-11.1 %	0.981	129

Table A-67 Urea

Lactate

Unit: [mmol/L]

Comparison instrument	Slope and intercept	Bias	Corr. coeff. [r]	No. of samples
OMNI 9	Y = -0.200+ 1.000*X	-9.5 %	0.936	136
Hitachi (Plasma)	Y = -0.286+ 1.149*X	+0.7 %	0.993	60
Cobas Mira (Plasma)	Y = -0.297 + 1.074*X	-3.0 %	0.968	137

Table A-68 Lactate

Sample throughput

Activated / installed modules	Sample throughput [samples/hours]	
	Syringe	Capillary
BG - tHb/SO_2	31	29
BG - COOX	31	29
BG - ISE - tHb/SO_2	31	28
BG - ISE - COOX	31	29
BG - ISE - MSS - tHb/SO_2	31	28
BG - ISE - MSS (Glu/Lac) - COOX	30	27
BG - ISE - MSS (Glu/Lac/Urea) - COOX	30	27

Table A-69 Sample throughput

Measurement times of the samples

Activated / installed modules	Measurement times [seconds]	
	Total time	Until display
BG - tHb/SO_2	110	66
BG - COOX	110	76
BG - ISE - tHb/SO_2	115	66
BG - ISE - COOX	110	76
BG - ISE - MSS (Glu, Lac) - tHb/SO_2	115	88
BG - ISE - MSS (Glu, Lac) - COOX	120	88
BG - ISE - MSS (Glu, Lac, Urea) - COOX	120	120

Table A-70 Measurement times of the samples

Sample volumes

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

Activated / installed modules	Typical sample volume [µL][(a)]	Typical sample volume [µL][(b)]	Max. sample volume (volume limitation by the sample sensor) [µL][(c)]
BG - tHb/SO_2 or COOX	88	102	111
BG - ISE - tHb/SO_2 or COOX	112	128	148
BG - ISE - MSS - tHb/SO_2 or COOX	172	186	210

Table A-71 Sample volumes

(a) typical sample volume for Hct ≤ 45%

(b) typical sample volume for 45% < Hct ≤ 75%: if a sample with high Hct is expected, the sample volume for high Hct is recommended.

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

The volume limitation by the sample sensor depends on INSTALLED modules, regardless whether they are activated or deactivated!

The actual required sample volume depends on the used sample container.

Activated / installed modules	Sample container	Minimum level
BG - ISE - MSS - tHb/SO_2 or COOX	1 mL syringe	300 µL
	3 mL syringe	700 µL
	5 mL syringe	1 mL
	200 µL capillary	186 µL

Table A-72 Sample container

Sample types

- Whole blood
- Serum
- Plasma[(a)]
- Dialysis solutions containing acetate and bicarbonate[(b)]
- Recommended QC material[(c)]

(a) also used for pH measurements in the pleural fluid

(b) only for electrolytes

(c) with approximate physiological ion matrix and buffer capacity

Calibrations

Calibrations	Time intervals	Duration without MSS [min]	Duration with MSS [min]
System calibration	every 24 hours (alternatively 8, 12 or 24 hours)	11	Glu/Lac: 15.5 Glu/Lac/Urea: 17
1P calibrations	every 30 minutes (alternatively 1 hour)	1.6	3.3
2P calibrations	every 12 hours (alternatively 4, 8 or 12 hours)	6.2	11.4
Warm-up phase	when turning ON[(a)]	32	43
Warm-up phase	power failure < 1 minute	2.5	2.5
Electrode exchange	as needed	25	50

Table A-73 Calibrations

(a) incl. calibration

Environmental parameters

Temperature / humidity / stability

Instrument

Operating conditions

• Ambient temperature	15 to 31 °C
• Ambient air pressure	526 - 797 mmHg (70.13 - 106.225 kPa)
• Relative humidity	20 - 85%
• Measuring chamber temperature	
BG & ISE	37 ± 0.2 °C
MSS	30 ± 0.2 °C
COOX	37 ± 0.5 °C
tHb/SO_2	37 °C (35 to 37.5 °C)

Storage and transportation conditions

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

Electrodes

Operating conditions

• Temperature	
BG, ISE	37 ± 0.2 °C
MSS (Glu, Lac, Urea/BUN)	30 ± 0.2 °C
• Relative humidity	20 to 85%

Storage conditions in original packaging

• Temperature	
BG, ISE	15 to 30 °C
MSS (Glu, Lac, Urea/BUN)	2 to 8 °C
• Relative humidity	20 to 85% (not condensed)

Transportation conditions in original packaging

• Temperature	
BG, ISE	-5 to 40 °C over a period of 3 days
MSS (Glu, Lac, Urea/BUN)	-5 to 35 °C over a period of 5days
• Humidity	20 to 85 % (not condensed) over a period of 3 days
• Shock resistance	< 30 g

Solutions

Operating conditions

- Ambient temperature 15 to 35 °C
- Relative humidity 20 to 85%

Storage conditions in original packaging

- Temperature

  S1 rinse Solution 2 to 30 °C (24 months[(a)])
  S2 fluid Pack 2 to 30 °C (18 months[(a)])
  S3 fluid Pack 2 to 25 °C (18 months[(a)])
- Relative humidity 20 to 85%

(a) storage time contains also transportation time and the storage time in Mannheim!

Transportation conditions in original packaging

- Temperature 2 to 35 °C over a period of 7 days
- Relative humidity 20 - 85%
- Shock resistance < 30 g

Stability during operation

Solutions	Description	with 15 - 31 °C ambient temperature [weeks]
• S1 Rinse Solution	Wash solution	6
• S2 Fluid Pack	Calibration solution BG, ISE	6
• S3 Fluid Pack	Calibration solution Glu, Lac, Urea/BUN	6

QC material

Storage conditions in original packaging

cobas b 221<1>/<3>/<5> system

- COMBITROL TS+ up to 24 months at 2 to 8 °C
- AUTO-TROL TS+ up to 24 months at 2 to 8 °C

cobas b 221<2>/<4>/<6> system

- COMBITROL PLUS B up to 24 months at 2 to 8 °C
- AUTO-TROL PLUS B up to 24 months at 2 to 8 °C

Stability during operation

cobas b 221<1>/<3>/<5> system

- COMBITROL TS+ Up to 3 months at room temperature up to 28 °C
- AUTO-TROL TS+ Up to 3 months at room temperature up to 28 °C (incl. max. 1 month in the AutoQC module)

cobas b 221<2>/<4>/<6> system

- COMBITROL PLUS B Up to 3 months at room temperature up to 28 °C
- AUTO-TROL PLUS B Up to 3 months at room temperature up to 28 °C (incl. up to 60 days in the AutoQC module)

Product data

Electrical data

Mains voltage range:	100 to 240 VAC ±10% permissible tolerance
Frequency:	50/60 Hz
Required power:	200 W

Classification

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

Dimensions

Width:	51 cm
Height:	59 cm
Depth:	60 cm

Weight

cobas b 221 system (instrument):	approx. 45 kg (without wash/calibrating solutions and AutoQC!)

Acoustic noise level

In all operating conditions:	min. 37.0 dB
	max. 51.8 dB

Holding points

Take care when lifting - weight of the instrument without wash/calibrating solutions and AutoQC is approx. 45 kg!

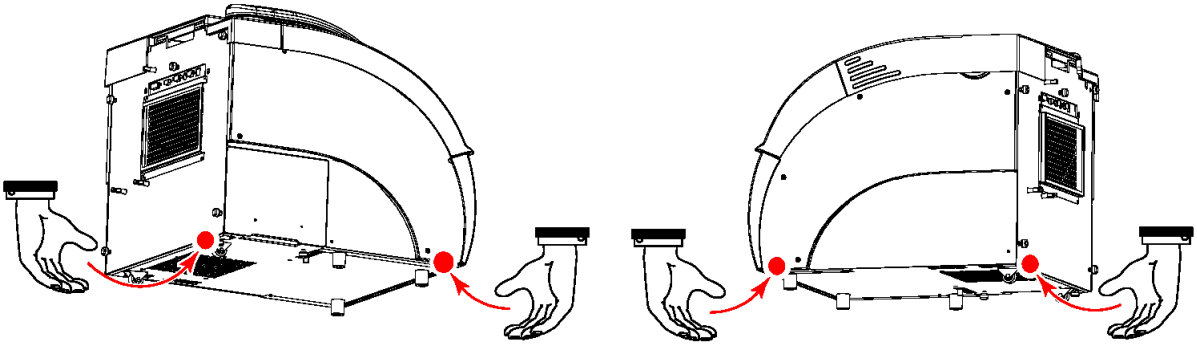


Figure A-54 Holding points

AutoQC

Number of ampoules:	6 mats each with 20 ampoules

Printer

Type:	Thermal printer with integrated paper cutter and optional take-up unit
Resolution:	8 dots / mm
Full graphics:	864 dots / line
Printing speed:	max. 20 mm / sec
Paper width:	111 mm
Paper length:	about 50 m

Touch screen-PC unit

SN < 1500

PC:	AMD 5x86 Single Board PC, 133 MHz
Memory:	32 MB RAM
Hard disk:	2 GB Harddisk
Floppy disk drive:	1.44 MB; integrated at the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inch
Resolution:	640 x 480 pixel

SN > 1500

PC:	GEODE GXII, 200 MHz
Memory:	128 MB RAM
Hard disk:	20 GB Harddisk
Floppy disk drive:	1.44 MB; integrated at the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inch
Resolution:	640 x 480 pixel

SN > 5000

PC:	GEODE GXII, 200 MHz
Memory:	128 MB RAM
Hard disk:	40 GB Harddisk
Floppy disk drive:	1.44 MB; integrated at the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inch
Resolution:	640 x 480 pixel

Barcode scanner

Type:	MT 9060/4 Wedge PS2 hand scanner with integrated decoder
Reading speed:	up to 45 scans/s
Resolution:	0.1 mm
Reading distance:	up to 5 cm
Reading width:	up to 8 cm
Preprogrammed code types[(a)]:	• China Postal Code • Codabar • Code 39 • Code 128 • EAN-8 • EAN-13 • EAN-128 • Interleaved 2 of 5 • UPC-A • UPC-E

(a) Further available barcode types can be programmed in accordance with the enclosed manual of the PS2 hand-held 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** 221 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 otherwise noted, all measured values used in the equations are no longer valid 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	
BUN	1 mmol/L	= 1.4007 mg/dL	
Urea	1 mmol/L	= 6.0056 mg/dL	
Urea/BUN	1 mmol/L Urea	= 2 mmol/L BUN	= 2.8014 mg/dL BUN
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 A-74 Conversion table for units

Temperature

Equation A-1 $$T\,[^\circ F] = \frac{9}{5} \times T\,[^\circ C] + 32$$

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

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 A-75 Standard values and ranges

Equations[a]

All literature data stated in this section (e.g. [1]) are stated afterwards in the section "Bibliography".

The validity of calculated results from the **cobas b** 221 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.

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

$cHCO_3^-$

Bicarbonate concentration in plasma.[1]

Unit: [mmol/L]

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

$ctCO_2(P)$

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

Unit: [mmol/L]

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

FO_2Hb

Fractional oxygen saturation[1]

Unit: [-]

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

(a) all not listed equations are not realized!

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]

Unit: [mmol/L]

Equation A-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 A-40 on page A-107 !

BE_{ecf}

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

Unit: [mmol/L]

Equation A-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]

Unit: [mmol/L]

Equation A-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: [%]

COOX module: **Equation A-10**

$$sO_2 = \frac{O_2Hb}{O_2Hb + HHb} \cdot 100$$

tHb/SO_2 module sO_2 is measured

$SO_2(c)$

No SO_2 data available:

Measured SO_2 has a higher priority than the calculated $SO_2(c)$.
No calculation without pH, PO_2 or BE.

Unit: [%]

Equation A-11

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

At which:

Equation A-12

$$\lg Q = 2.9 \cdot \lg P{O_2}^k + F1 \cdot 10^{-F2 \cdot P{O_2}^k} - F3$$

$$\lg P{O_2}^k = \lg P{O_2} + 0.48 \cdot (pH - 7.4) - \lg\left(\frac{P50}{26.7}\right) + 0.0013 \cdot BE$$

Adult $P_{50} = 26.7$

F1 = 1.661
F2 = 0.074
F3 = 4.172

Fetal $P_{50} = 21.5$

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).[3]

The **cobas b** 221 system enables the derivation of the P_{50} from SO_2%, PO_2 and pH.

Unit: [mmHg]

Measured SO_2 values available:

Equation A-13

$$P50 = 26.7 \cdot 10^{\left(\lg P{O_2} - \lg P{O_2}^k\right)}$$

At which:

Equation A-14

$$\lg P{O_2}^k = \frac{(\lg Q + F3)}{2.9}$$

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

Adult F3 = 4.172

Fetal F3 = 4.113

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 A-15

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

At which:

cobas b 221 system with COOX module: X = O_2Hb

cobas b 221 system with tHb/SO_2 Module: X = SO_2

Only BG values available: X = SO_2(c)

see equation SO_2 on page A-99 !

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).

Unit: [mmol/L]

Equation A-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 A-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, SO_2(c) Equation A-11 on page A-99.

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.

Unit: [pH unit]

Equation A-18

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

$cHCO_3^-{}_{st}$

Standard bicarbonate of the blood, 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.

Unit: [mmol/L]

Equation A-19 $$c\mathrm{HCO_3^-}_{st} = 10^{(\mathrm{pH_{st}} - 6.022)}$$

PAO_2

The alveolar oxygen partial pressure is used to calculate several parameters used for oxidation and breathing.[1]

Unit: [mmHg]

Equation A-20 $$P\mathrm{AO_2} = (P_{\mathrm{total}} - 47)\cdot F\mathrm{IO_2} - P\mathrm{ACO_2}\cdot\left[F\mathrm{IO_2} + \frac{1 - F\mathrm{IO_2}}{\mathrm{R}}\right]$$

$P\mathrm{ACO_2} = P\mathrm{aCO_2}$ (alveolar PCO_2)

for $P\mathrm{AO_2} \geq P\mathrm{O_2}$; otherwise $P\mathrm{AO_2} = P\mathrm{O_2}$

For t unequal 37°C see Equation PAO_2^t on page A-105 !

$AaDO_2$

The alveolar arterial oxygen partial pressure gradient ($P\mathrm{AO_2}$ - $P\mathrm{aO_2}$) is the difference between the alveolar oxygen partial pressure, as calculated above, and the measured oxygen partial pressure of arterial blood. [1]

Unit: [mmHg]

Equation A-21 $$\mathrm{AaDO_2} = P\mathrm{AO_2} - P\mathrm{aO_2}$$

For t unequal 37°C see equation $AaDO_2^t$ on page A-105 !

a/AO_2

Arterial alveolar oxygen partial pressure ratio.[1]

Unit: [%]

Equation A-22 $$\mathrm{a/AO_2} = \frac{P\mathrm{aO_2}}{P\mathrm{AO_2}} \cdot 100$$

For t unequal 37°C see equation a/AO_2^t on page A-106 !

$avDO_2$

The arterial venous oxygen tension ratio.[4]

Unit: [vol%]

Formula - data from venous blood available:

Equation A-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 A-14 on page A-101 !

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.[1]

Unit: [%]

Equation A-24

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

For t unequal 37°C see Equation A-34 on page A-106 !

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).[1]

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

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"

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

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

With a combination of arterial and venous blood, the Qs/Qt value cannot be determined.

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 not limited by the instrument.

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.

☞ Setup > Display & Reports> Measurement > Input value

Unit: [%]

Equation A-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

ctO_2(a) and ctO_2(v) are calculated according to Equation A-14 for arterial and mixed venous blood:

👁 for ctO_2 see Equation A-14 on page A-101 !

If no measurement data is available for mixed venous blood, then the following is valid:

Equation A-26 $ctO_2(a)\text{-}ctO_2(v) = 5.15$ vol%

nCa^{2+}

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

Unit: [mmol/L]

Equation A-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]

Unit: [mmol/L]

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

pH^t

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

Unit: [pH-Unit]

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

PCO_2^t

PCO_2 value at a patient temperature which is not 37 °C.[3]

Unit: [mmHg]

Equation A-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.[3]

Unit: [mmHg]

Equation A-32 $$PO_2{}^t = PO_2 \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_2{}^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_2{}^{3.88} + 2.30}\right] \cdot (t-37)}$$

PAO_2^t

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[1]

Unit: [mmHg]

Equation A-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: $$PH_2O^t = 47 \cdot 10^{[0.0237 - 0.0001 \cdot (t-37)] \cdot (t-37)}$$

$AaDO_2^t$

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[1]

Unit: [mmHg]

Equation A-34 $$AaDO_2{}^t = PAO_2{}^t - PaO_2{}^t$$

a/AO_2^t

Arterial alveolar oxygen partial pressure ratio at the patient's temperature.[1]

Unit: [%]

Equation A-35 $$a/AO_2^t = \frac{PaO_2^t}{PAO_2^t} \cdot 100$$

RI^t

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

Unit: [%]

Equation A-36 $$RI^t = \frac{(PAO_2^t - PaO_2^t)}{PaO_2^t} \cdot 100$$

Hct(c)

Hct as a function of tHb.[4]

Equation A-37 $$Hct(c) = tHb \cdot \frac{F}{100}$$

Default value of F = 3.00 (input range: 2.70 to 3.30).

Only measured tHb is permitted!

MCHC

Mean corpuscular hemoglobin concentration.[4]

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

Equation A-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 A-39 $$BO_2 = tHb \cdot \left[1 - \frac{(COHb - MetHb - SulfHb)}{100}\right] \cdot 1.39$$

SulfHb = 0, if SulfHb is not measured!

BE_{act}

Base deviation at actual oxygen saturation.[2]

Unit: [mmol/L]

Equation A-40

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

Osmolality

Unit: [mOsm/kg][3]

Equation for blood, plasma, serum:

Equation A-41

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

Equation for aqueous solution, acetate, bicarbonate:

Equation A-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:	if no measurement value is available, the default value is used for the calculation
Glu:	if no measurement value is available, the default value is used for the calculation

OER

Oxygen extraction ratio.

Unit: [%]

Equation A-43

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

👁 for ctO_2 see Equation A-14 on page A-101 !

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

Heart minute volume (Q_t)

Unit: [vol%][1]

Equation A-44

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

SaO_2: arterial oxygen saturation fraction

P/F Index

Ration PaO_2/FIO_2 [1]

Unit: [mm/Hg]

Equation A-45

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

Bibliography

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Clinical significance

pH

The pH value of blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

pH < 7.35
- primary bicarbonate deficit – metabolic acidosis
- primary hypoventilation – respiratory acidosis

pH > 7.45
- primary bicarbonate excess – metabolic alkalosis
- primary hyperventilation – respiratory alkalosis

An increase in blood, serum or plasma pH (alkalosis) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis because of an increased elimination of CO_2 due to hyperventilation.

A decrease of the pH value (acidosis) in blood, serum or plasma may occur due to an increased formation of organic acids, a decreased excretion of H^+ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

Standard values:

- Arterial blood: 7.35 - 7.45
- Venous blood: 7.31 - 7.41

Critical values[(a)]:

- pH < 7.2
- pH > 7.6

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

Critical values:

- pH > 7.3 — uncomplicated parapneumonic effusions
- pH < 7.6 — complicated parapneumonic effusions, exudative in nature. These exudates are caused by pleural empyemas, malignant tumors, collagenoses, tuberculosis, esophageal rupture, or hemothorax.

PCO_2

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO_2 production. An arterial PCO_2 below the normal range is termed respiratory alkalosis and indicates hypocapnia, a condition caused by increased alveolar ventilation such as hyperventilation.

An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates hypercapnia, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Standard values:

- Arterial blood: 35 - 45 mmHg
- Venous blood: 41 - 51 mmHg

Critical values[a]:

- $PCO_2 < 20$ mmHg or 2.7 kPa
- $PCO_2 > 70$ mmHg or 9.3 kPa

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

PO_2

The PO_2 value in arterial blood is one of the main factors in calculating arterial oxygenation. Values below the normal range (arterial hypoxia) are normally caused by blockages in the lung and respiratory tract as well as in the blood circulatory system (for example: bronchial obstruction, vascular disturbances, lessened cardiac function, increased need for oxygen, anatomical cardiac defect, lower level of inspired O_2). In general, PO_2 values over 100 mmHg do not contribute significantly to the oxygen level because with a normal hemoglobin concentration of 80-100 mmHg PO_2, a saturation level of 97% has already been achieved.

Standard values:

- Arterial blood: > 80 mmHg
- Venous blood: 30 - 40 mmHg

Critical values[a]:

- $PO_2 < 40$ mmHg or 5.3 kPa

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Sodium

The fast majority of sodium in organisms is located in the extracellular area (about 97 %).

Even with greatly varying supply with nourishment, the sodium concentration in serum is subject to strong regulation. In the kidneys, sodium is glomerularly filtered and most of this (about 60 - 70 %) is reabsorbed in the proximal tubule.

The most important function of the sodium is to maintain constant osmolarity in the extracellular fluid. For that reason, the level of sodium and water are always closely interrelated. However, in pathological operations, there may be marked tissue hypo or hyperhydration with values in the standard range. Conversely, an increased, respectively a decreased sodium concentration is found in serum due to a loss or gain of water when there is a normal level of sodium.

An increased sodium level in serum occurs when there is:

- a decreased supply of liquid
- increased loss of water
- through the kidneys
  - central diabetes insipidus
  - renal diabetes insipidus
  - osmotic diuresis (e.g. mannitin fusions)
- through the intestine
  - infection deseases (especially dysentery and cholera)
- excessive supply of hypertonic saline solution(infusion therapy dosed too high)
- increase of aldosterone-induced sodium reabsorption
  - primary hyperaldosteronism (CONN syndrome)
  - secondary hyperaldosteronism

Reduced sodium level in serum occurs following:

- excessive supply of liquid without sufficient absorption of sodium
- excessive water supply with normal level of sodium in the organism (for example: congestive heart failure)
- disturbance of sodium reabsorption caused by aldosterone deficiency
  - suprarenal gland insufficiency (M. ADDISON)
  - adrenogenital syndrome with saline loss (aldosterone insufficiency with high grade enzyme defect)

Standard values:

- Adult: 135 - 148 mmol/L
- Newborn: 134 - 144 mmol/L
- Child: 138 - 144 mmol/L

Critical values[(a)]:

- $Na^+ < 120$ mmol/L
- $Na^+ > 160$ mmol/L

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Potassium

About 97% of potassium within the organism is intracellular. Transport into the cells is regulated by the Na/K ATPase localized in the cell membrane. Only about 3% of the potassium is contained in the extracellular fluid. Potassium is glomerularly filtered and most of it (about 90%) is reabsorbed in the proximal tubule and in Henle's loop. Reabsorption or excretion in the distal tubulus is influenced especially by aldosterone and the blood pH value.

Due to the high intracellular concentration of potassium, the serum potassium values do not always reflect the potassium level of the organism. Therefore, the data obtained from the serum may be interpreted only with careful consideration of the patient's clinical situation and acid-base status. Consider the following examples: diabetic coma, during which the flow of potassium into the cell is reduced due to the lack of insulin, and acute intoxication with heart glycosides with accompanying inhibition of the Na/K ATPase membrane. In both cases exists, despite a more or less greatly increased serum potassium level, intracellular potassium deficiency.

Increased potassium concentration in serum occurs during:

- decreased excretion through the kidneys
  - acute and chronic kidney insufficiency (especially pronounced with oliguria and anuria)
  - Aldosterone deficiency with suprarenal gland insufficiency (M. ADDISON)
  - dosage of potassium-saving diuretic
  - oral potassium substitution with (possibly unknown) mild limitation of kidney functions
- displacement between intracellular and extracellular potassium
  - severe insulin deficiency
  - intoxication with heart glycosides
  - severe acidosis
  - (each 0.1 reduction of the blood pH results in a rise in potassium of 0.4 to 1.2 mmol/L serum)
  - malignant hyperthermia
- Reales of potassium on massive cell destruction
  - hemolytic crisis
  - transfusions with cold or very cold blood
  - cytostatic therapy for leukemia and others
  - burns
  - severe soft tissue injuries

Hypokalemia is observed during:

- gastrointestinal potassium losses
  - laxative abuse
  - massive diarrhea
  - fistulas in the area of the gastrointestinal tract
  - villous papillary adenoma
  - VERNER-MORRISON syndrome (pancreatic cholera)
- increased renal excretion

  - primary hyperaldosteronism (CONN syndrome)
  - secondary hyperaldosteronism
  - cirrhosis of the liver (caused by decreased aldosterone breakdown)
  - therapy with loop diuretics and thiazides
  - CUSHING syndrome
  - Aldosterone producing suprarenal gland carcinoma
  - overdose of mineral corticoids
  - renal tubular acidosis
- displacement between intracellular and extracellular potassium
  - severe alkalosis
  - insulin therapy for diabetic coma (potassium substitution required!)

Normal values:

- Adult: 3.5 – 4.5 mmol/L
- Newborn: 3.7 – 5.9 mmol/L
- Child: 3.4 – 4.7 mmol/L

Critical values[(a)]:

- $K^+ < 2.8$ mmol/L
- $K^+ > 6.2$ mmol/L

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Chloride

Chloride is the most important anion in bodily fluids. Chloride is located – like sodium – mostly in the extracellular area. Erythrocytes represent the highest intracellular content. The concentration of chloride in serum, like the level of sodium, is held constant within tight limits in healthy people. Chloride is glomerulary filtered in the kidneys and is tubularly reabsorbed by passively following the sodium.

Chloride may be exchanged for bicarbonates during disturbances to the acid/base status, causing chloride to adopt the additional task (in addition to maintaining the isotones in the extracellular area) of working with sodium to regulate the acid/base status.

Changes to the chloride and sodium concentrations in serum usually occur in parallel.

Exceptions to this occur during disturbances to the acid/base status caused by the previously mentioned exchange of chloride for bicarbonates as well as during massive chloride loss with gastric juices during extended periods of vomiting (hypochloremic alkalosis).

Normal values[(a)]:

- Adult: 98 - 107 mmol/L
- Newborn: 98 - 113 mmol/L

(a) Tietz Textbook of Clinical Chemistry, 3rd Edition 1999

Critical values[(a)]:

- Cl^- < 75 mmol/L
- Cl^- > 126 mmol/L

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Ionized calcium

Approximately 99% of calcium in the human body is localized in bone substance – mostly in the form of hydroxylapatite.

About 1% of the cations are located in the extracellular area. Only very small amounts exist intracellularly; the calcium ions here act especially as activators for numerous enzymes and play a role in the effect mechanism of hormones.

It is possible to exchange calcium in the extracellular fluid for that in bones.

In addition, hydroxylapatite serves as a reserve holder from which calcium can be rapidly mobilized when needed.

Calcium is present in plasma in 3 forms:

- About 50% are ionized and biologically active,
- about 40% are bound to proteins (especially albumin) and
- about 10% are present in complex bonds with citrate, phosphate, bicarbonate, lactate, and others.

Protein bonding is dependent on the concentration of albumen in plasma and on the pH level of the blood:

With lower total albumen and an acidic pH level, fewer calcium ions are bound, causing the ionized proportion to increase. This also explains why, despite a low level of calcium in serum during severe acidosis (due to chronic kidney insufficiency), tetanic reactions do not occur.

The portion of calcium suitable for ultrafiltration (ionized and complex bound) is glomerularly filtered in the kidneys and up to 95 - 99% reabsorbed in the proximal and distal tubule.

A small portion of the calcium can also be excreted via the intestine.

The regulation of calcium exchange is closely related to the regulation of the phosphate level. Therefore, the concentrations of both substances in serum and the excretion with urine should always be seen and judged in relationship to each other.

The level of calcium in plasma is decisive for calcium-phosphate exchange. Three hormones play roles in the regulation. They affect the maintenance of the extracellular calcium concentration via the reabsorption of calcium ions from the intestine, the release or storage processes in bones and the extent of the renal excretion.

Parathormone and 1.25-dihydroxycholecalciferol:

- lead to an increase of the calcium concentration in plasma

Calcitonin:

- reduces the level of calcium

Increased concentrations of calcium in serum occur during:

- disturbances to the hormonal regulation of primary and tertiary hyperparathyreoidism
- increased release from the bones
  - osteolysis through bone metastasis
  - plasmocytome
  - paraneoplastic symptom (through ectopic production of parathormone or similar substances or prostaglandin E2)

  - long-lasting immobilization
- vitamin D intoxication within the scope of therapeutic measures
- sarcoidosis

Reduced calcium level in serum will be noticed as a result of:

- insufficient calcium reabsorption
  - undernourishment
  - mal-absorption syndrome
  - vitamin D3 deficiency
  - deficiency of 1.25-dihydroxycholecalciferol
  - chronic kidney insufficiency
  - hypoparathyreoidism
  - hypomagnesium
- greatly decreased concentration of albumen in the serum (Note: ionized calcium is in the normal range!)
  - nephrotic syndrome
  - cirrhosis of the liver
- acute pancreatitis

Normal values:

- Adult: 1.12 – 1.32 mmol/L
- Child: 1.10 – 1.50 mmol/L

Critical values[(a)]:

- $Ca^{2+} < 0.82$ mmol/L or 3.28 mg/dL
- $Ca^{2+} > 1.55$ mmol/L or 6.20 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Hematocrit

The Hct is the cellular volume portion of the blood, which is occupied by the red blood cells, in relation to the volume of the whole blood. The Hct can be expressed as percentage or fraction.

Reduced Hct values are an indication for anemia (together with a simultaneous reduction of ctHb and RBC) of leukemia, hypothyroidism, cirrhosis, acute massive blood loss and with hemolytic reactions due to transfusions with incompatible blood, incompatibility with certain chemicals, infectious and physical agents.

Increased Hct values can be associated with polycythemia, erythrocytosis and heavy loss of water and with shock.

The **cobas b** 221 system offers the user a direct measured hematocrit (Hct) using conductivity method and a calculated Hct(c), which is derived from the patient total hemoglobin result.

The use of Hct or Hct(c) must carefully be examined by medical professional who will evaluate the patients clinical situation before any treatment decisions are made.

Normal values (arterial blood at 37°C)[(a)]:

- Women: 0.34 - 0.45 or 34 - 45 %
- Men: 0.34 - 0.48 or 34 - 48 %
- Newborn (3 - 7 weeks): 0.36 - 0.46 or 36 - 46 %

(a) Clinical Laboratory Diagnostics: use and assessment of clinical laboratory results, edited by Lothar Thomas, M.D, Edition 1998

Critical values[(a)]:

- Hct < 0.20 or 20 %
- Hct > 0.60 or 60 %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

*In patients suffering an extensive blood loss, during massive infusion therapy and during complicated surgery, especially open-heart surgery, determination of the hematocrit value with the conductivity method used in the **cobas b** 221 system can lead to incorrect results. Especially with infusions with protein-free electrolyte solutions or when hyperosmolar solutions are used, the measured hematocrit value can be significantly reduced. This artificially reduced hematocrit value may lead to an unnecessary premature decision regarding transfusion.*

If this is the case, we recommend either direct measurement of the hematocrit (micro centrifugation or PCV) or indirect determination via the measurement of the total hemoglobin using the calculated value Hct(c).

*To take into account possible influences due to infusion solutions, the **cobas b** 221 system has special correction algorithms for the calculation of patient results. These algorithms are particularly optimized with Ringers solution. However for those patients receiving infusions other than Ringers or whose hematocrit is pathologically low, false hematocrit measurement values cannot be excluded. In these instances, the aforementioned limitations and evaluation of patient results must be considered.*

tHb (total hemoglobin concentration)

Hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram/dL of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than the others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid.

Decreased hemoglobin values appear in connection with hemolytical reactions caused by transfusions of untolerated blood, but can also be caused by a loss of blood or a number of other factors.

Increased hemoglobin values found in the blood hemoconcentrations with chronically obstructive pulmonary illnesses.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

tHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Normal values (arterial blood at 37°C)[a]:

- Women: 11.7 - 16.1 g/dL
- Men: 12.6-17.4 g/dL
- Newborn: 4 - 20 g/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[a]:

- tHb < 70 g/L or 7 g/dL
- tHb > 200 g/L or 20 g/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Oxygen saturation

Oxygen saturation is the measured portion of the oxyhemoglobin in total hemoglobin.

Reference values[a]:

- Adult: in arterial blood 95 – 98 %
  in venous blood approx. 73 %
- Newborn: in arterial blood 40 - 90 %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[a]:

- SO_2 < 80 %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

The measurement of SO_2 is used to judge oxygenation, usually in connection with other parameters, for example PO_2, PCO_2 and hemoglobin.

For monitoring of patients with possible hypoxia[a] SO_2-Werte > 90 % are acceptable.

In principle, SO_2 measurements are better than estimated values (O_{2sat}); however, when using SO_2 measurements during the presence of abnormal hemoglobins (for example carboxyhemoglobin[b]) incorrect results may arise [for example, assuming a comatose patient with 15 % COHb, an SO_2 value of 95 % may be shown, although in reality the level of oxyhemoglobin (FO_2Hb) is only 80 % (100 % is the summation of all hemoglobins)].

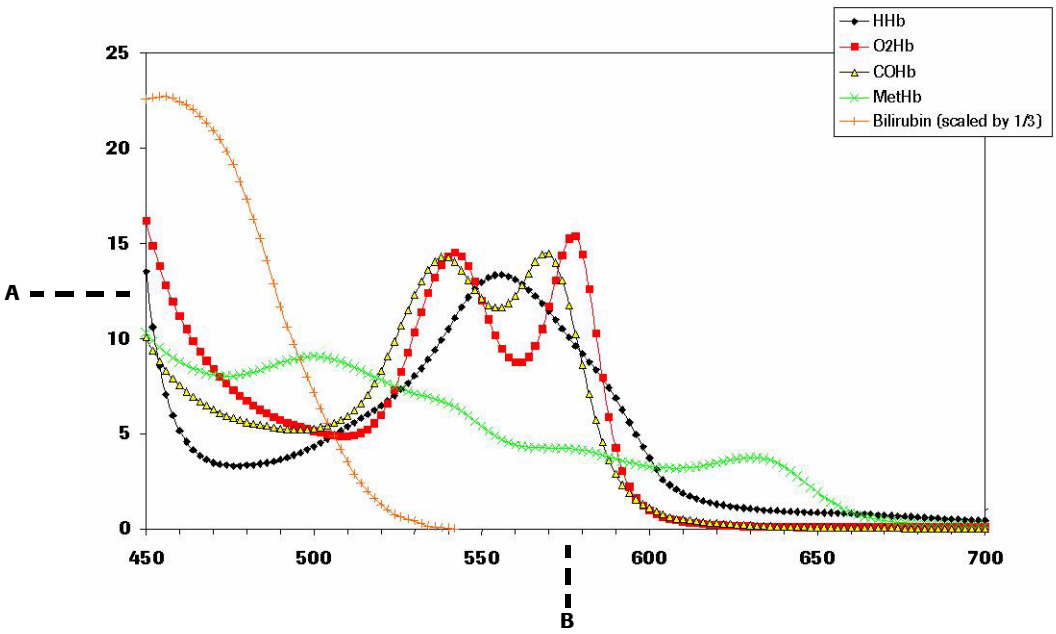
For this reason, the CLSI suggests evaluation of the dyshemoglobins[c] instead of a clinical evaluation of a single SO_2 value.

(a) Indicative for a decreased level of oxygen in blood

(b) COHb

(c) COHb, MetHB, SulfHb

Hemoglobin derivatives and bilirubin



A ε [L mmol^{-1} cm^{-1}] **B** Wavelength [nm]

Figure A-55 Absorption spectrum of the Hb derivatives and Bilirubin

Each hemoglobin molecule consists of four hemo groups each containing an iron atom. This iron atom can either exist as two value (reduced) or three value (oxidized) iron. In the two value state, each iron atom of the deoxygenized hemoglobin (HHb) can be in the reversible molecular oxygen (O_2Hb) or carbon monoxide (COHb). With methemoglobin (MetHb), three value iron can be in the hydroxyl ions, cyanide and sulfur components.

On account of their capability to transport oxygen, HHb and O_2Hb is termed functional hemoglobin. Carboxyhemoglobin, methemoglobin or sulfhemoglobin are nonfunctional hemoglobin types.

The amount of hemoglobin loaded with oxygen in the total hemoglobin is termed the oxyhemoglobin fraction (FO_2Hb) and is used to estimate the amount of oxygen in the tissue with tHb and PO_2 to calculate the oxygen content.

The amount of hemoglobin loaded with oxygen in the functional hemoglobin is determined by the PO_2 and is defined as oxygen saturation (SO_2).

The oxygen affinity of hemoglobin is primarily dependent on five factors: temperature, pH, PCO_2, concentration of 2.3 DPG and the hemoglobin type.

A limitation of the oxygen transport from the lung to hemoglobin, inadequate circulation or shunt can cause a reduction of PO_2 and oxygen saturation and finally a decrease in oxygen transport to tissue.

Clinically, it is important to make a distinction between hypoxia (lack of oxygen in tissue) and cyanosis (reduced oxygen content in blood through an abnormally high concentration of deoxyhemoglobin or the formation of nonfunction hemoglobin derivatives). Cyanosis occurs when the capillary content of deoxyhemoglobin exceeds 5 g/100 mL.

This situation can occur when the arterial hemoglobin is not saturated or the oxygen acceptance of tissue is too high. Comparable degrees of cyanosis occur at concentrations of 1.5 MetHb/dL blood. Abnormally high MetHb concentrations generally result from drug and chemical reactions. Methemoglobin anaemia rarely occurs at birth.

Oxyhemoglobin (O_2Hb)

When each hemogroup of hemo-molecule is bound to an oxygen molecule, the hemoglobin is termed oxyhemoglobin (O_2Hb). The percentage of oxyhemoglobin (in comparison to total hemoglobin) is termed the oxyhemoglobin fraction (FO_2Hb) of the total hemoglobin. The oxygen bound in this way forms the largest component in the total blood oxygen content (approx. 98%).

Standard values (arterial blood at 37°C)[(a)]:

- Adult: 90 - 95 % or 0.90 - 0.95
- Newborn: 40 - 90 % or 0.40 - 0.90

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[(a)]:

- $O_2Hb < 80$ %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Desoxyhemoglobin (HHb)

Deoxyhemoglobin is hemoglobin whose two value iron molecule in the hemogroup is capable of binding an oxygen molecule. The sum of deoxyhemoglobin and oxyhemoglobin (those derivatives capable of transporting oxygen in the blood) are termed function hemoglobin.

Standard values (arterial blood at 37°C)[(a)]:

- Adult: 1.4 - 4.9 % or 0.014 - 0.049

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Carboxyhemoglobin (COHb)

Hemoglobin is capable of binding carbon monoxide to the same ratio as oxygen. This means that a hemogroup can bind a carbon monoxide molecule. However, the hemoglobin molecule has an affinity to carbon monoxide 200 - 300 times greater than to oxygen. This is also the reason why very small quantities of carbon monoxide can cause a fatal concentration of COHb in the blood. A concentration of approximately 6% COHb has already be found in the blood of moderate smokers.

Concentrations of 10 - 20% in the blood cause headaches and a slight shortage of breath.

A concentration of 30 - 40% causes weakness and visual faults. A concentration of 40 - 50% causes tachypnoea, tachycardia, ataxia and fainting. A concentration of 50 - 70% leads to seizures, coma and restricted heart and lung functions. Higher concentrations are usually fatal.

Clinical diagnoses require CO oxymetry as the calculated oxygen saturation of blood gas and acid-alkali measurements is confusingly high.

Small quantities of carbon monoxide are generated in the body by the conversion of haem into biliverdin. This production of small quantities of endogenous carbon monoxide is increased by hemolytic anaemia.

Standard values (arterial blood at 37°C)[(a)]:

- Nonsmoker: 0.5 - 1.5 % or 0.005 - 0.015
- Smoker: 8.0 - 9.0 % or 0.080 - 0.090

(a) Labor und Diagnose; Lothar Thomas, 5th expanded edition 2000; Page 490

Critical values[(a)]:

- COHb > 15 %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Methemoglobin (MetHb)

Methemoglobin is created through oxidation of two to three value hemoglobin iron. This reduces the oxygen binding capacity, as Fe^{3+} cannot bind oxygen reversibly. This hemoglobin occurs increasingly in large amounts in chronic hypoxaemia and in residential areas. Methemoglobin is also formed by a number of organic and anorganic oxidation agents and pharmaceuticals.

MetHb also occurs in patients with inherited structural abnormalities of hemoglobin. Concentrations of up to 20% are usually tolerable, concentrations of 30 - 40% cause headaches, nausea and cyanosis. Concentrations above 40% require therapy; normally intravenous treatment with methylene blue, which occurs as the activator of NADPH dehydrogenase. In patients with known enzyme deficiencies, concentrations of MetHb of up to 70% can occur.

Standard values (arterial blood at 37°C)[(a)]:

- Adult: < 0.8 % or < 0.008

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[(a)]:

- MetHb > 30 %

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Total bilirubin (= neonatal)[a]

Neonatal bilirubin occurs in newborns. By increasing this primarily unconjugated bilirubin, the so-called jaundice in newborns (Icterus neonatorum) occurs, which is created due to transitional immaturity of the transport (e.g. ligandin) and coupling systems (UDP glucuronic transferase) in the liver. In newborns, it leads to a significant enteral backresorption of unconjugated bilirubin; the serum bilirubin concentration increases post natum, reaches approx. 100 µmol/L (6 mg/dL) as maximum for full-term newborns on the 3rd to 5th day, and then drops down to the standard level in the 2nd to 3rd week. Higher bilirubin concentrations occur particularly in premature newborns, and the icterus remains for a longer time (hyperbilirubin anemia in newborns). Higher bilirubin concentrations are very important in newborns since the "blood-brain-barrier" is not completely developed yet and bilirubin may enter the brain. Bilirubin acts toxic on nerve cells so that high bilirubin values in the first ten days after birth can lead to brain damage or death.

Depending upon the bilirubin concentration or whether the newborn is a healthy full-term one or a premature one, icterus neonatorum is treated with photo therapy or with exchange transfusions or with both options.

Normal values - Premature birth[a]:

- Umbilical cord: < 2.0 mg/dL or < 34.2 µmol/L
- 0 - 1 day: < 8.0 mg/dL or < 137.0 µmol/L
- 1 - 2 days: < 12.0 mg/dL or < 205.0 µmol/L
- 3 - 5 days: < 16.0 mg/dL or < 274.0 µmol/L

(a) Tietz Textbook of Clinical Chemistry, 3rd Edition 1999; page 1803

Normal values - normal birth[a]:

- Umbilical cord: < 2.0 mg/dL or < 34.2 µmol/L
- 0 - 1 day: 1.4 - 8.7 mg/dL or 24.0 - 149.0 µmol/L
- 1 - 2 days: 3.4 - 11.5 mg/dL or 58.0 - 197.0 µmol/L
- 3 - 5 days: 1.5 - 12.0 mg/dL or 26.0 - 205.0 µmol/L

(a) Tietz Textbook of Clinical Chemistry, 3rd Edition 1999; page 1803

Critical values[a]:

- Bilirubin > 15.0 mg/dL or > 256.5 µmol/L

(a) Tietz Textbook of Clinical Chemistry, 3rd Edition 1999; page 1846

(a) Total bilirubin = unconjugated (free) and conjugated form

Glucose

Glucose detection is an important test to monitor hyperglycemia or hypoglycemia.

Hyperglycaemia is an increased blood sugar concentration
(blood sugar level > 130 mg/dL or 7.2 mmol/L).

The most common forms of diabetes mellitus are:

- Type II diabetes

  Insulin independent diabetes (=NIDDM, adult diabetes)

  Frequency: 80%

- Type I diabetes

  Insulin dependent diabetes (=IDDM, juvenile diabetes)

  Frequency: 20%

During operative intervention, hyperglycaemia, caused by hypoxia, can cause serious acidosis.

If the blood sugar level drops below 40 mg/dL, this state is termed hypoglycaemia.

This can be caused by one of the following circumstances:

Reduced glucose supply:

- Reduction in hepatic gluconeogenesis:
  - Congenital metabolism defect
  - Terminal cirrhosis of the liver
  - Alcohol toxication
  - Poisoning
- Malabsorption
- Dumping syndrome (gastrectomy)
- Fasting
- Increased peripheral use of glucose:
- Physical activity
- Endogenous hyperinsulinism:
  - Islet cell tumours in pancreas
  - Lack of insulin antagonists
  - M. Addison
  - Hypopituitarism
  - Sulfon urea therapy
- Insulin overdose
- Renal glucosuria (very rare)

Normal values[a]:

- Adult (after fasting): 4.1 - 5.9 mmol/L or 74 - 106 mg/dL
- Adult (1 hour after consumption of 75 g glucose): < 10.0 mmol/L or < 180 mg/dL
- Newborns (after fasting): 2.0 - 5.5 mmol/L or 36 - 100 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[a]:

- Glu < 2.2 mmol/L or 40 mg/dL
- Glu > 25.0 mmol/L or 450 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Lactate

Lactate acts as an early warning signal for hypoxic states in human tissues, for recognition and estimation of the severity and progress of a shock (also of septic shock) and particularly as a measure for limiting hyperlactataemia.

The physiological lactate value of blood is 1 +/- 0.5 mmol/L.

A lactate rise to up to 5 mmol/L in blood, with accompanying metabolic acidosis is termed hyperlactataemia. A lactate level of over 5 mmol/L with causally linked metabolic acidosis is termed lactate acidosis.

Normal values[a]:

- Adult: 0.9 - 1.7 mmol/L or 8.1 - 15.3 mg/dL
- Newborns: 0.5 - 2.0 mmol/L or 4.5 - 18.0 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Critical values[a]:

- Lac > 3.4 mmol/L or 31.0 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Urea/BUN

Urea is the most important catabolic product of the protein metabolism. It indicates a limited or insufficient kidney function (reduced or nonexistant filtration in cases of shock, heart failure, hypertonia, dehydration, tumours, etc.). The urea value is also an important parameter for monitoring the protein supply in patients with malfunctioning kidneys and for monitoring the therapy of dialysis patients with kidney failures.

Normal values[(a)]:

- Adult: Urea 2.1 - 7.1 mmol/L or 13.0 - 43.0 mg/dL
  BUN 6.0 - 20.0 mg/dL
- Newborns: Urea 1.0 - 5.0 mmol/L or 6.0 - 30.0 mg/dL
  BUN 2.9 - 14.0 mg/dL

(a) Labor und Diagnose; Lothar Thomas, 5th expanded edition 2000; Page 385

Critical values[(a)]:

- Urea > 16.7 mmol/L or 100.0 mg/dL

(a) Critical Care Testing: A Quick Reference Guide by Andrew St John, First Edition 2001

Operation B

Measurement

In this chapter, all information necessary for carrying out measurements is described.

In this chapter *Chapter* 6

Preanalytics

Sample collection

Follow the usual applicable safety precautions when drawing blood samples. When handling blood samples, there always exists the danger of transmission of HIV, hepatitis B and C viruses or other pathogens transmissible by blood. Employ suitable blood sampling techniques in order to reduce risk to personnel.

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.

Gudelines 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..

Sample acquisition

Only qualified personnel may perform the collection of blood needed for analytical purposes.

The puncture site may never be squeezed! Mixing the blood sample with tissue fluid may lead to the premature onset of clotting despite sufficient heparinization of the sample collection containers! Incorrect sample collection or the use of an unsuitable sample collection container may lead to errors and discrepancies in the measurement values.

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

The only clot inhibitors that may be used for analyses in the **cobas b** 221 system are heparin salts. Other clot inhibitors, such as EDTA, citrate, oxalate, fluoride, and ammonium-based materials have significant influence on the blood's pH and other parameters and may not be used for this reason.

Sample collection especially for tHb, SO_2 and Hct measurement

Whole blood, especially for the analysis of tHb, SO_2 and Hct, must be thoroughly mixed immediately before analysis in order to achieve consistent distribution of red blood cells and plasma before insertion of the sample.

Carefully rotate the sample about two axis using your hand or a mechanical device or insert a metal disk or ball in the syringe before collecting the sample. Shortly before using the sample, carefully shake the syringe. The up and down motion of the disk or ball inside the syringe cylinder ensures consistent mixing.

Refer to CLSI document C46-A, "Blood gas and pH analysis related measurements; Approved Guideline 2001".

Sample collection especially for glucose / lactate measurement (cobas b 221<5> system, cobas b 221<6> system only)

Glucose

Patient preparation: 12 hr. fasting period for blood glucose. Optimal postprandial blood sampling is 1 hr. after ingestion of food.

Samples should be analyzed immediately after collection, since the sample metabolism causes a decrease in the glucose concentration within a few minutes of sample collection. If immediate analysis is not possible, the blood sample must be centrifuged immediately and the excess serum or plasma must be separated by pipette.

Plasma and serum samples collected in this manner and stored under refrigeration are suitable for glucose analysis for up to 24 hours.

Lactate

Patient preparation: Collection after physical rest (at least 2 hours). Even minor physical activities will lead to an increase in lactate concentration.

Samples should be analyzed immediately after collection, since the sample metabolism causes an increase in the lactate concentration within a few minutes of sample collection. If immediate analysis is not possible, the blood sample must be centrifuged immediately in a cooled centrifuge and the excess serum or plasma must be separated by pipette.

Plasma and serum samples collected in this manner and stored under refrigeration are suitable for lactate analysis for up to 24 hours.

There are significant arteriovenous differences depending on forearm activity and oxygenation of the forearm muscle. Immediately following the collection of the sample, the protein in the sample must be removed using ice-cold perchloric acid. If glycolysis inhibitors are used, heparin blood can be processed without removing the protein. Such a sample is stable up to 2 hours after collection. Otherwise, the supernatant lactate concentration after centrifugation remains constant for 24 hours if stored under refrigeration.

Sample collection especially for bilirubin measurement (cobas b 221<2> system, cobas b 221<4> system, cobas b 221<6> system only)

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 containers

We recommend using the sample containers offered by Roche Diagnostics.

Syringes

If using another manufacturer's product with liquid heparin as a clot inhibitor, the collection container should not be larger than required for the blood volume. This will minimize the effects of the clot inhibitor on the thinning of the blood. Plastic syringes are normally used, but there are cases when the use of plastic syringes is not appropriate, for example, when PO_2 values are expected to be outside the normal range. If very high PO_2 values are expected, the sample should be analyzed as quickly as possible after the sampling.

Use only heparinized syringes. Improper use of syringes with liquid heparin will affect the parameters, especially the ISE parameters!

Capillary tubes

Depending on instrument configuration, capillary tubes must have a minimum volume of 115 µL, 140 µL or 200 µL.

Capillary tubes with ceramic sealing caps should not be used because the fracture that forms when opening the capillary can damage the fill port of the **cobas b** 221 system.

Only glass capillary tubes with heat-polished ends or the plastic capillary tubes offered by Roche Diagnostics may be used in order to prevent damage to the instrument.

When using stirring rods like those offered by a few manufacturers, remove these rods before inserting the sample in order to avoid clogging the sample path of the **cobas b** 221 system .

Roche MICROSAMPLER [(a)]

The Roche MICROSAMPLER was developed for the technical facilitation of taking samples of arterial blood.

The Roche MICROSAMPLER, which consists of two capillary tubes (220 µL) in a plastic container, is ideally suited to a traumatic arterial blood collection.

Each laboratory should document the permissibility of sample containers that are used. These products vary from manufacturer to manufacturer and sometimes from lot to lot.

The use of sample containers or clot inhibitors other than those manufactured by Roche Diagnostics 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.

(a) is a trademark of Roche

Clot catcher

To prevent a blockage of the sample path, the use of a clot catcher is recommended for measuring critical blood, e.g. blood from newborns taken from earlobes and heels.

The clot catcher (coagulate trap), which is placed on the top of the syringe or capillary, prevents blood clots and tissue particles from entering the **cobas b** 221 system.

Clot catchers are not suitable for measurements in "Aspiration from syringe" mode!

Sample handling

Whole blood

Withdraw whole blood samples using heparinized syringes, capillaries, or the Roche MICROSAMPLER and analyze the samples as soon as possible after sampling. 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. This can be done by rolling the sample between both hands or shaking. Properly label the samples, following the standard documentation procedure.

Glass capillary tubes

- Samples that are measured within 15 minutes may be retained 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 can not be performed within 15 minutes.

Plastic capillary tubes

If unable to measure samples immediately store the sample at room temperature for no longer than 30 minutes.

When using capillaries analyze samples for tHb, SO_2, Hct, glucose and lactate measurements immediately after sampling to ensure correct and accurate measurement results.

Despite proper sampling procedures, errors can arise in the blood gas analysis:

- due to insufficient mixing of the sample after sampling and before the measurement
- due to ambient air contamination caused by air bubbles that are not removed after sampling
- due to changes in metabolism in the sample

Serum

After the appearance of spontaneous clotting, process the sample in a centrifuge to separate the cellular, solid components and the fibrin from the watery serum. Transfer the serum to a suitable sample container and seal.

If it is necessary to store the sample, close the sample container tightly and cool it to +4 - +8 °C. If a sample has been cooled, warm it to room temperature (+15 - +33 °C) before analysis.

Plasma

Plasma samples are obtained by centrifuging heparinized whole blood, during which the cellular components of the blood are removed from plasma.

Complete the analysis as quickly as possible.

If immediate lactate analysis is not possible, the blood sample must be centrifuged immediately in a cooled centrifuge.

If it is necessary to store the sample, close the sample container tightly and cool it to +4 - +8 °C. If a sample has been cooled, warm it to room temperature (+15 - +33 °C) before analysis.

Plasma samples older than 1 hour must be re-centrifuged in order to remove fibrin clumps that may have formed.

Pleural fluid

The procedure for handling pleural fluids is the same as for plasma samples.

Interferences

The measuring module and measuring sensors were tested with respect to their interference stability with the given chemical substances and pharmaceuticals. Respective concentrations of the interference substances were added to the whole blood samples, as suggested by the CLSI, and then measured again.

(I)	Control serum + interference substance
(K)	Control serum
MV	Mean value
SD	Standard deviation

tHb/SO_2

Substance	tHb	SO_2
Indocyanin green 5 mg/L		
MV (I)-(K) ± SD (n=4)	3.83 ± 0.15	----------
MV (I)	19.40	----------
MV (K)	15.60	----------
Intralipid 10 g/L		
MV (I)-(K) ± SD (n=4)	2.23 ± 0.17	----------
MV (I)	17.23	----------
MV (K)	15.00	----------
Methylene blue 30 mg/L		
MV (I)-(K) ± SD (n=4)	----------	-25.20 ± 1.47
MV (I)	----------	75.73
MV (K)	----------	99.90
Lipofundin 10 g/L		
MV (I)-(K) ± SD (n=4)	1.33 ± 0.25	----------
MV (I)	16.30	----------
MV (K)	14.98	----------

Table B-1 Interferences tHb/SO_2 module

pH, ISE

Substance	pH	Ca	K
Aspirin (Acetylsalicylic acid) (100 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	0.16 ± 0.01	----------
MW (I)	----------	1.22	----------
MW (K)	----------	1.06	----------
Bovine albumin (6 g/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	0.30 ± 0.02	----------
MW (I)	----------	1.34	----------
MW (K)	----------	1.03	----------
Dobesilate (20 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	----------	1.06 ± 0.02
MW (I)	----------	----------	6.16
MW (K)	----------	----------	5.09
Glycolic acid (50 mg/dL)			
MW (I)-(K) ± SD (n=16)	----------	0.15 ± 0.00	----------
MW (I)	----------	1.24	----------
MW (K)	----------	1.09	----------
Glycolic acid (100 mg/dL)			
MW (I)-(K) ± SD (n=16)	-0.94 ± 0.02	0.31 ± 0.02	----------
MW (I)	6.93	1.39	----------
MW (K)	7.87	1.09	----------
Glycolic acid (200 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	-1.08 ± 0.03	0.20 ± 0.01	----------
MW (I)	6.56	1.29	----------
MW (K)	7.65	1.08	----------
Potassium thiocyanate (23.2 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	----------	2.25 ± 0.02
MW (I)	----------	----------	6.17
MW (K)	----------	----------	3.91
Potassium thiocyanate (232 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	----------	----------
MW (I)	----------	----------	----------
MW (K)	----------	----------	----------
Magnesium nitrate (128.2 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	0.26 ± 0.01	----------	----------
MW (I)	1.24	----------	----------
MW (K)	0.98	----------	----------

Table B-2 Interferences pH, ISE

Substance	Ca	Na	K	Cl
Sodium bromide (102.9 mg/dL)				
MW (I)-(K) ± SD (n=16)	----------	----------	----------	14.81 ± 3.87
MW (I)	----------	----------	----------	118.38
MW (K)	----------	----------	----------	103.58
Sodium citrate. diluted (1000 mg/100 mL)				
MW (I)-(K) ± SD (n=16)	-1.05 ± 0.02	60.79 ± 1.36	-0.58 ± 0.04	----------
MW (I)	-0.01	204.59	3.36	----------
MW (K)	1.04	143.80	3.95	----------
Sodium chloride (140 mmol/L)				
MW (I)-(K) ± SD (n=16)	0.19 ± 0.01	37.23 ± 0.45	----------	28.46 ± 4.20
MW (I)	1.28	179.63	----------	132.59
MW (K)	1.08	142.40	----------	104.13
Sodium chloride, diluted (120 mmol/L)				
MW (I)-(K) ± SD (n=16)	----------	16.29 ± 0.43	----------	13.72 ± 2.04
MW (I)	----------	158.43	----------	119.86
MW (K)	----------	142.14	----------	106.14
Sodium chloride, diluted (130 mmol/L)				
MW (I)-(K) ± SD (n=16)	0.12 ± 0.01	25.73 ± 0.44	----------	20.90 ± 2.75
MW (I)	1.24	167.99	----------	124.35
MW (K)	1.12	142.26	----------	103.45
Sodium hydrogen carbonate (336 mg/100 mL)				
MW (I)-(K) ± SD (n=16)	-0.14 ± 0.01	32.45 ± 0.61	----------	----------
MW (I)	1.00	175.98	----------	----------
MW (K)	1.14	143.53	----------	----------

Table B-3 Interferences pH, ISE

MSS

Substance	Glu	Lac
Ascorbic acid (30 mg/100 mL)		
MW (I)-(K) ± SD (n=16)	-0.64 ± 0.41	-0.19 ± 0.24
MW (I)	3.56	2.64
MW (K)	4.23	2.86
Dopamine (13 mg/100 mL)		
MW (I)-(K) ± SD (n=16)	-2.14 ± 0.26	-1.34 ± 0.39
MW (I)	2.06	1.47
MW (K)	4.21	2.81
Dopamine, diluted (5 mg/dL)		
MW (I)-(K) ± SD (n=16)	-1.68 ± 0.23	-0.88 ± 0.12
MW (I)	2.41	2.10
MW (K)	4.09	2.98
Dopamine, diluted (2 mg/dL)		
MW (I)-(K) ± SD (n=16)	-0.72 ± 0.32	-0.48 ± 0.39
MW (I)	4.53	3.40
MW (K)	5.25	3.88
Gentisic acid (50 mg/100 mL)		
MW (I)-(K) ± SD (n=16)	-0.87 ± 0.61	-0.52 ± 0.24
MW (I)	3.46	3.25
MW (K)	4.33	3.77
Glycolic acid (10 mg/dL)		
MW (I)-(K) ± SD (n=16)	----------	0.83 ± 0.26
MW (I)	----------	4.62
MW (K)	----------	3.79
Glycolic acid (50 mg/dL)		
MW (I)-(K) ± SD (n=16)	----------	1.92 ± 1.05
MW (I)	----------	5.67
MW (K)	----------	3.75
Glycolic acid (100 mg/dL)		
MW (I)-(K) ± SD (n=16)	-0.42 ± 0.16	0.99 ± 1.00
MW (I)	3.69	3.13
MW (K)	4.11	2.14
Glycolic acid (200 mg/100 mL)		
MW (I)-(K) ± SD (n=16)	----------	-0.81 ± 0.13
MW (I)	----------	2.09
MW (K)	----------	2.90

Table B-4 Interferences MSS

Substance	Glu	Lac	Urea
Uric acid (20 mg /100 mL)			
MW (I)-(K) ± SD (n=16)	-0.46 ± 0.32	----------	----------
MW (I)	4.71	----------	----------
(MW K)	5.17	----------	----------
Uric acid, diluted (7 mg /100 mL)			
MW (I)-(K) ± SD (n=16)	-0.40 ± 0.16	----------	----------
MW (I)	3.70	----------	----------
MW (K)	4.10	----------	----------
Hydroxyurea (0.76 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	-0.65 ± 0.31	-0.35 ± 0.15	----------
MW (I)	4.21	2.57	----------
MW (K)	4.86	2.92	----------
Hydroxyurea, diluted (0.4 mg/dL)			
MW (I)-(K) ± SD (n=16)	-0.36 ± 0.10	----------	----------
MW (I)	3.74	----------	----------
MW (K)	4.10	----------	----------
Potassium oxalate (800 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	-0.44 ± 0.24	----------	-1.24 ± 1.39
MW (I)	3.64	----------	3.92
MW (K)	4.08	----------	5.16
Sodium bromide (10 mg/dL)			
MW (I)-(K) ± SD (n=16)	-0.33 ± 0.45	----------	----------
MW (I)	4.74	----------	----------
MW (K)	5.07	----------	----------
Sodium bromide (20 mg/dL)			
MW (I)-(K) ± SD (n=16)	-0.96 ± 0.35	-0.41 ± 0.23	----------
MW (I)	3.08	1.69	----------
MW (K)	4.04	2.09	----------
Sodium bromide (102.9 mg/dL)			
MW (I)-(K) ± SD (n=16)	-0.59 ± 0.33	-0.23 ± 0.13	----------
MW (I)	3.58	2.63	----------
MW (K)	4.17	2.86	----------

Table B-5 Interferences MSS

Substance	Glu	Lac	Urea
Sodium citrate (1000 mg/100 mL)			
MW (I)-(K) ± SD (n=16)	----------	----------	-0.61 ± 0.07
MW (I)	----------	----------	4.29
MW (K)	----------	----------	4.91
Sodium chloride (140 mmol/L)			
MW (I)-(K) ± SD (n=16)	-0.49 ± 0.17	----------	----------
MW (I)	4.84	----------	----------
MW (K)	5.33	----------	----------
Sodium fluoride (1000 mg /100 mL)			
MW (I)-(K) ± SD (n=16)	-0.20 ± 0.39	0.27 ± 0.17	-1.37 ± 0.23
MW (I)	3.45	3.38	2.80
MW (K)	3.65	3.11	4.17
Paracetamol (150 mg/100mL)			
MW (I)-(K) ± SD (n=16)	-2.99 ± 0.59	-1.61 ± 0.36	----------
MW (I)	4.79	1.73	----------
MW (K)	7.79	3.33	----------

Table B-5 Interferences MSS

Hb derivatives and bilirubin

Substance	HHb	MetHb	Bilirubin
Evans blue (5 mg/L)			
MW (I)-(K) ± SD (n=8)	0.00 ± 0.02	0.68 ± 0.05	----------
MW (I)	0.03	1.34	----------
MW (K)	0.02	0.65	----------
Indocyanine (5 mg/L)			
MW (I)-(K) ± SD (n=8)	0.01 ± 0.02	-0.06 ± 0.06	----------
MW (I)	0.03	0.56	----------
MW (K)	0.02	0.63	----------
Intralipid (10mg/L)			
MW (I)-(K) ± SD (n=8)	0.00 ± 0.02	----------	----------
MW (I)	0.03	----------	----------
MW (K)	0.03	----------	----------
Lipofundin (10mg/L)			
MW (I)-(K) ± SD (n=8)	-0.01 ± 0.02	----------	----------
MW (I)	0.02	----------	----------
MW (K)	0.03	----------	----------
Methylene blue (7.5 mg/L)			
MW (I)-(K) ± SD (n=8)	0.00 ± 0.02	-1.09 ± 0.05	----------
MW (I)	0.02	-0.44	----------
MW (K)	0.02	0.65	----------
Methylene blue (30 mg/L)			
MW (I)-(K) ± SD (n=8)	0.01 ± 0.02	-4.61 ± 0.20	-3.02 ± 0.14
MW (I)	0.03	-3.83	17.63
MW (K)	0.02	0.77	20.65
Propofol (2µL/mL)			
MW (I)-(K) ± SD (n=8)	0.00 ± 0.03	----------	----------
MW (I)	0.03	----------	----------
MW (K)	0.03	----------	----------

Table B-6 Interferences Hb derivates and Bilirubin

Limitations of clinical analysis

The determined performance data can be influenced by known and unknown factors as described below.

For details, see section *Interferences*, *tHb/SO_2* on page B-18 and *Metabolites* on page B-18.

General

The literature lists various substances which may negatively impact upon the measurement result of the blood and plasma/serum sample material. A detailed discussion of these phenomena can be found at different places in the technical literature. With respect to the **cobas b** 221 system, an attempt was made to identify or evaluate these possible influences. But since it is not possible to check all medication or substances, the user should be immediately informed with abnormal deviations of the measurement results—as with every clinical analysis—and evaluate the complete picture of the patient or perform expanded measurements in his own laboratory, if necessary.

Ensure that the selected sample type matches the sample to be measured. If the sample and sample type do not match, incorrect measurements will result.

Electrolytes

It is well-known, for example, that the potassium value of a patient can vary by up to 20% from the normal state, simply because of the presence of a pressure bandage. Hence, taking a blood sample while a pressure bandage is present should be avoided. In general, a local hemolysis caused by pressure should be avoided prior to taking a blood sample.

Blood gas

A whole blood sample is prefered for performing these measurements. Contaminating the blood sample with air will significantly distort the measurements. The notes and restrictions in the section *Preanalytics* should be observed in any case.[(a)]

see section *Preanalytics* on page B-5

(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).

tHb/SO_2

The **cobas b** 221 system tHb measurement is sensitive to the sedimentation rate of red blood cells, particularly if the sedimentation rate is very high, as it may be the case, e.g. with special pathological samples. The measurement procedure of the **cobas b** 221 system is designed so that this effect does not occur during the measurement. However, this assumes an extensive and proper rolling of the sample container to avoid this type of sedimentation in the sample.

see section *Preanalytics* on page B-5

Metabolites

The most important influence in glucose/lactate determination is the treatment of the sample until the measurement due to the glycolysis in the erythrocytes of the blood sample.

Detailed information about the correct treatment of samples are listed in the section *Preanalytics* on page B-5.

The following principle holds: Perform metabolite measurements from heparinized whole blood as quickly as possible or centrifuge the sample as quickly as possible for plasma extraction and immediately pipette off the supernatant of the sample.

The **cobas b** 221 system metabolite measurement is performed with an active interference correction. As such, the glucose or lactate measurement features an additional integrated sensor that largely eliminates any possible occurring interferences endogenously (e.g. uric acid) or exogenously (e.g. actetylsalicylic acid). To achieve the highest possible perfection in interference compensation, the compensation sensor with the actual biosensors is adjusted daily as part of the system calibration. The influence of the most important known interferents was determined during development.

summarized in section *MSS* on page B-13.

In spite of these interference compensation sensors, a metabolite determination is only possible with samples with an approximate physiological ion background and pH value as well as a mean physiological buffer capacity of the sample.

Hemoglobin derivatives and bilirubin

As well as the restrictions applicable to determining the blood gases, measurement of the Hb derivatives and bilirubin by light-absorbing substances in the blood sample (e.g. contrast agent) can be disrupted. The influence of the most important known interferents was determined during development

summarized in section *Hb derivatives and bilirubin* on page B-16.

pH measurements in pleural fluid

Only pH measurement results are specified in pleural fluids. Any other measurement results that are output do not conform to specifications.

Measuring procedure

QC measurements must be performed in their entirety (i.e., all three QC levels must be measured). Omitting QC measurements or ignoring QC measurement results may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

Before starting a measurement, all parameters must be ready for measurement.

Depending on the setting, the operator ID and a password may be required.

see Reference Manual chapter *Software modes*, section *Setup*

You have the option of measuring samples from syringes (without needles), ampoules and capillaries.

Syringe mode

Improper heparinization of syringes with liquid heparin may cause erroneous results. ISE parameters are particularly susceptible.

1 Securely attach the syringe to the fill port.

If the position of the syringe is correct, the T&D disk will be backlit in green.

Figure B-1

Using syringe with an excentric tapered tip make sure that the tapered tip is in lower position while attaching the syringe to the fill port!

For details, see Figure B-2 on page B-20!

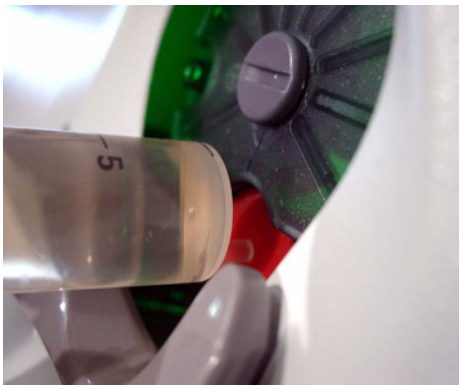


Figure B-2

2 The following screen appears:

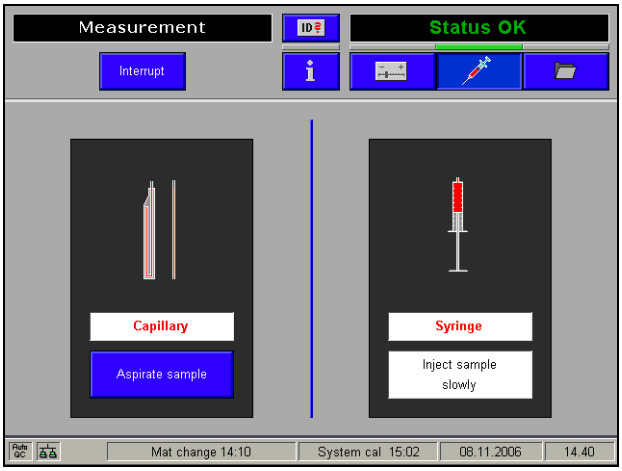


Figure B-3

3 Inject the sample slowly until the signal sounds.

Do not press the [Aspirate sample] button, or the sample will spill out — danger of infection!

4 Detach the syringe after the message "Remove sample container" appears.

5 The measurement starts.

Capillary measurement

Only glass capillary tubes with heat-polished ends or the plastic capillary tubes offered by Roche Diagnostics may be used in order to prevent damage to the instrument.

see *Capillary tubes* on page B-7 in the section *Sample containers*

1 Insert the capillaries or the Roche MICROSAMPLER into the fill port.

If the position of the capillary is correct, the T&D disk will be backlit in green.

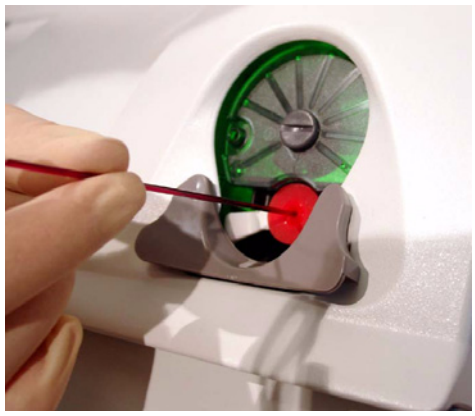


Figure B-4

2 Press the [Aspirate sample] button.

see Figure B-3 on page B-20

3 Detach the capillaries or the Roche MICROSAMPLER after the message "Remove sample container" appears.

4 The measurement starts.

Aspirate from syringe

This option is activated in the [Setup] mode.

1mL syringes cannot be used for the software mode "Aspirate from syringe"!

A minimum fill height of 15 mm is required!

see Chapter 4 *Specifications*, section *Sample volumes*, Table A-72 page A-87!

Press the following buttons:

Setup > Instrument > Switch > Aspirate from syringe

This option is now also displayed at the top level of the analyzer mode.

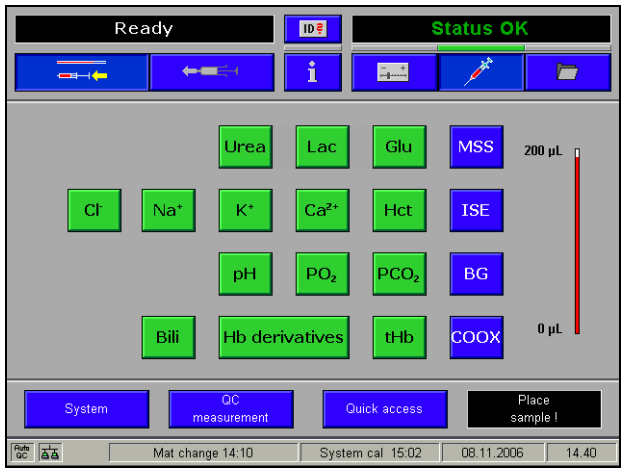
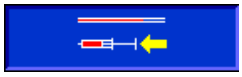
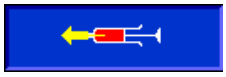


Figure B-5

1 Pressing  or  turns the T&D disk to the corresponding position.

2 Securely attach the syringe to the fill port.

If the position of the syringe is correct, the T&D disk will be backlit in green.

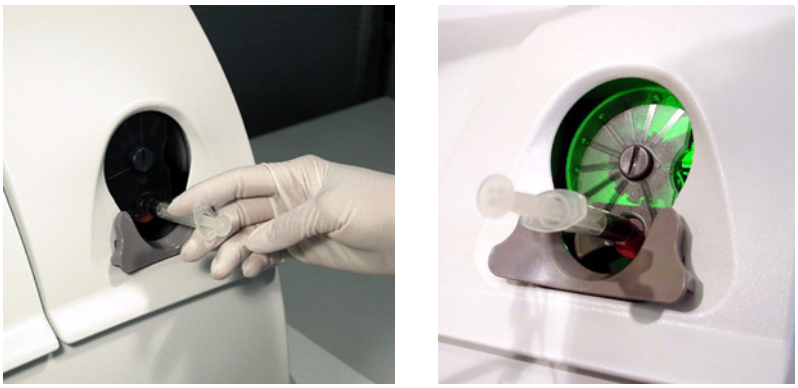


Figure B-6

3 Press the [Aspirate sample] button.

4 The sample is aspirated from the syringe.

5 Detach the syringe after the message "Remove sample container" appears.

6 The measurement starts.

Use as default setup

It is possible to set either the "Capillary mode" or "Aspirate from syringe" as standard measurement method.

Press the following buttons.

☞ Setup > Instrument > Switches

1 Press [Activate aspirate from syringe].

2 Activate [Use as default setup].

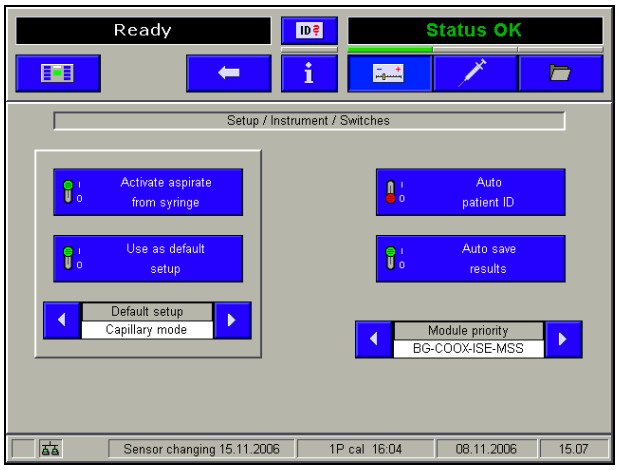


Figure B-7

3 Activate "Capillary mode" (= aspirate with capillary or inject sample) or "Activate aspirate from syringe" as the standard setting.
Depending on which mode has been selected as the standard setting, the T&D disk turns to the position intended for it at the end of a measurement.

The following setting combinations are possible:

- Capillary mode
- Switch between "Activate aspirate from syringe" and "Capillary mode"
- Standard setting "Activate aspirate from syringe":
  For the next measurement "Capillary mode" can be switched to.
- Standard setting "Capillary mode":
  For the next measurement, "Activate aspirate from syringe" can be switched to.

Data input

During measurement, various patient, operator, and sample-specific data may be entered.

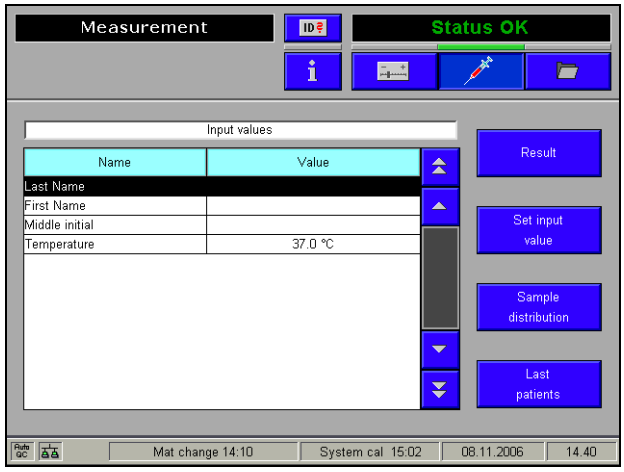


Figure B-8

Use the buttons / to select an entry.

Press [Edit input value] to enter data or change existing data.

A keyboard appears on the screen — enter the "Patient ID".

*If the patient already exists in the **cobas b** 221 system database, patient-specific data appears in the respective lines.*

Scanning in patient and user data is possible by means of a barcode scanner!

The user must carry out a plausibility check for all barcode data read in and displayed by the instrument!

If the patient is not yet registered, press [New patient] and the patient related data will be stored.

The "Remark" input field is limited to 25 characters.

Mandatory input

If mandatory input fields are defined ([Setup] > [Display & reports] > [Measurement] > [Input values]), they are displayed in a red font.

An entry must be made in these fields; otherwise, the measurement values are discarded.

If a standard value is defined as mandatory input, it must be confirmed or edited, if necessary.

Sample distribution

This function can be used to monitor the sample distribution during measurement (see below).

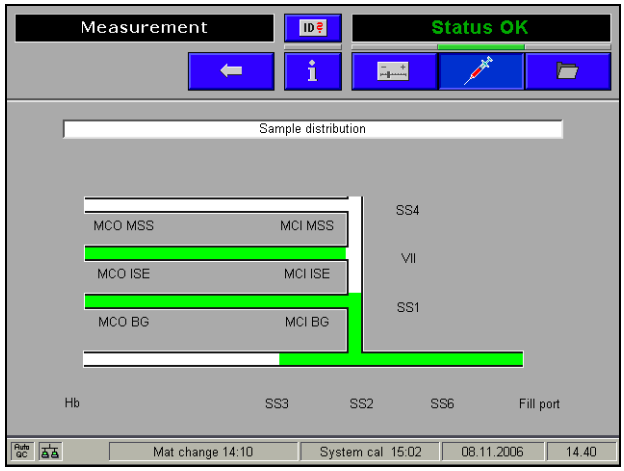


Figure B-9

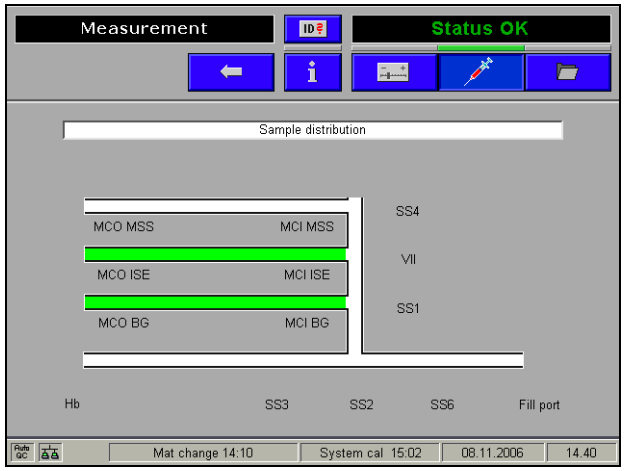


Figure B-10

Result

After the measurement is completed and all data is entered, the results are displayed on the screen and printed out.

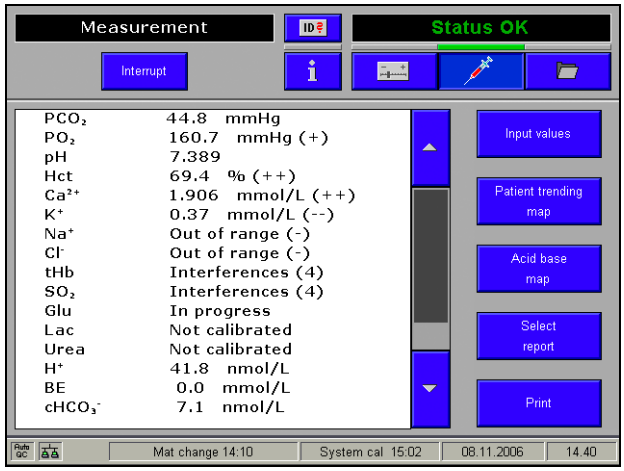


Figure B-11

[Input values] A subsequent correction of the input values is still possible after the conclusion of the measurement by pressing the [Input values] button.

If a connection to an ASTM host and the function "Send immediately" (Setup > Interfaces > ASTM) is activated, the input values cannot be corrected after the measurement is finished!

see *Reference Manual* chapter 2 *Description of system components*, section *ASTM*.

[Select report] Select one of the predefined forms ([Setup] > [Display & reports] > [Measurement] > [Measurement report])

[Print] Starts the printout of the measurement report.

[Patient trending map] By means of this map, the course of individual parameters (measurement and calculation values) of a patient over any required period (standard setting = one day) can be shown and printed out.

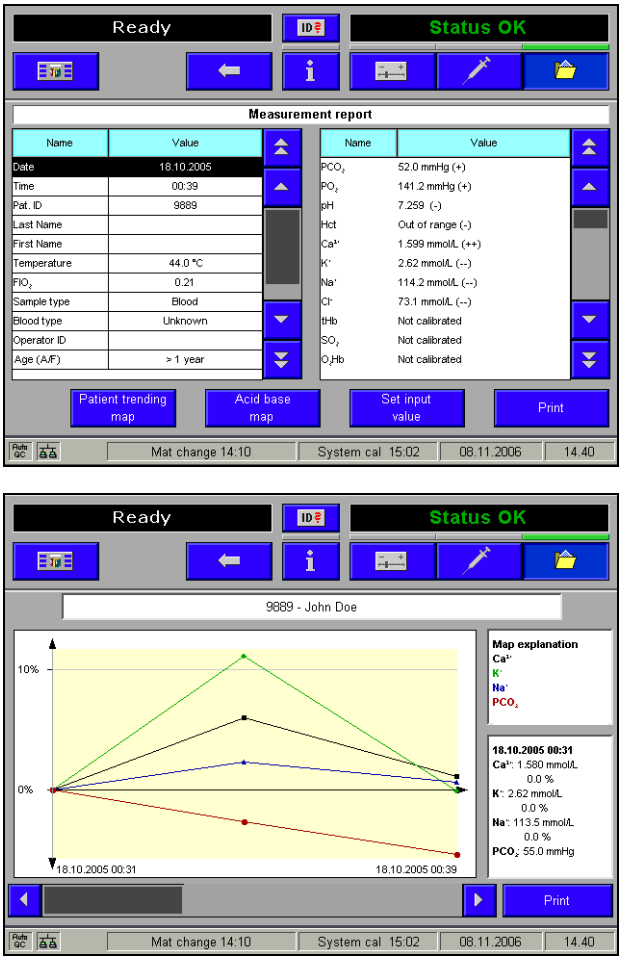


Figure B-12

Should another start/end date and/or another start/end time be required, it can be entered manually (see above).

For reasons of clarity, only four parameters can be selected from the selection list (see above), from which the map is then made.

In order to obtain a clear representation, the result of the first measurement in the observation period of the respective parameter is standardized to 100%, and is thus the basis for the trend curve.

If only one parameter was selected the representation takes place in absolute values and in the adjusted unit. As soon as a further parameter is selected changes the representation on the 100% standardization of the respective parameter.

Furthermore, when only one parameter is selected, the display is in absolute values and in the configured unit. As soon as another parameter is selected, the display switches to 100% scaling of the relevant parameter.

The "Patient trending map" can be called up either immediately after measurement or later in the data manager.

[Acid base map] If PCO_2 and pH-measurements are available, the diagram can be displayed and printed.

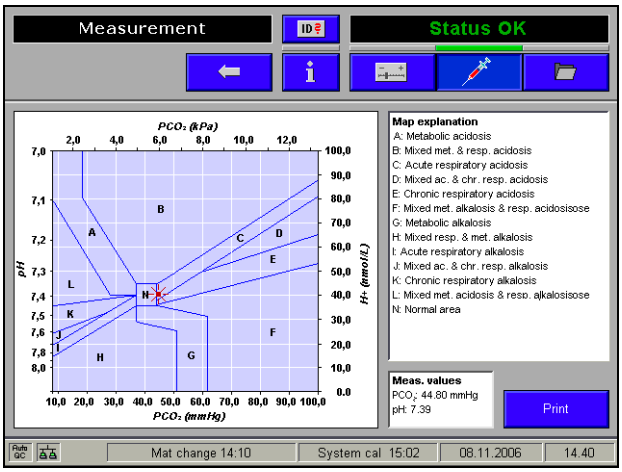


Figure B-13

There is also the possibility of displaying and printing out an acid base trend diagram in the data manager.

For a detailed description refer to the *Reference Manual* chapter 4 *Data manager*, section *Measurement*.

Last patients

The last patients whose samples have been measured are listed here.

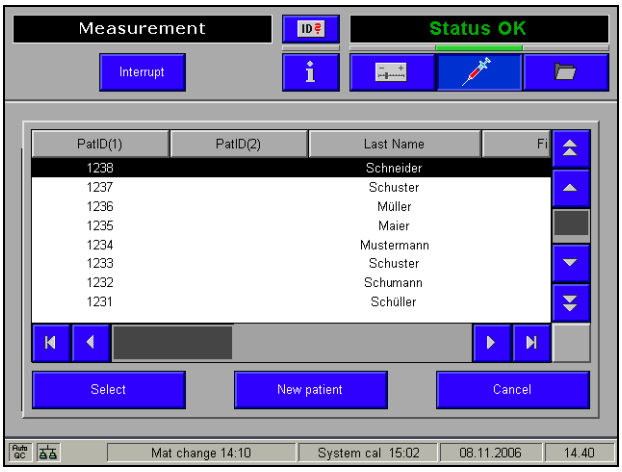


Figure B-14

POC mode (Point-of-care mode)

The POC mode is a user interface simplified to suit the needs of POC users, with very restricted user rights.

Before the POC mode is activated, the newly created POC profile in the profile management must be assigned to a "POC user" user profile.

see *Reference manual* chapter 3 *Setup*, section *Security*.

Setup > Security > Instrument functions

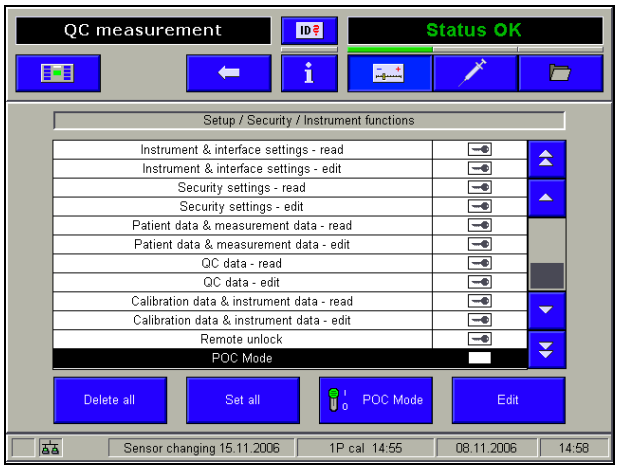


Figure B-15 POC mode

In the POC mode there is no possibility for interrupting any actions started. Persons registered as POC users are able to call up the functions offered on the "Ready" screen, all the functions under "Info" and if available, also the video sequences.

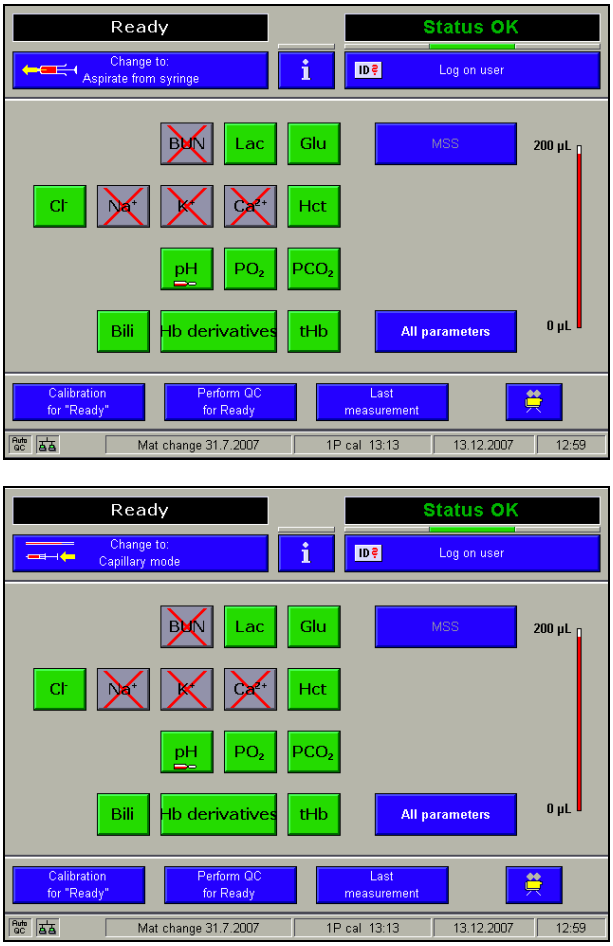


Figure B-16 Ready screen at POC mode

Quality control

For safety reasons, quality control measurements must be carried out on a daily basis. In this chapter, all steps are described that are necessary for a successful QC measurement.

In this chapter

Chapter **7**

Quality control – general

QC measurements must be performed in their entirety (i.e., all three QC levels must be measured). Omitting QC measurements or ignoring QC measurement results may lead to incorrect patient measurements, which may result in incorrect clinical decisions, possibly endangering the patient's health.

General QC concept

Roche Diagnostics 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 blood gas/ electrolyte QC materials, such as COMBITROL TS+, AUTO-TROL TS+, etc., are offered to ensure that the **cobas b** 221 system provides measurements of high quality to protect customers or its patients.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument.

Additionally complete a quality control test on one level between two automatic 2P calibrations. The level have to be alternated (low, normal, high).

For example (2P calibration interval: 12 hours):

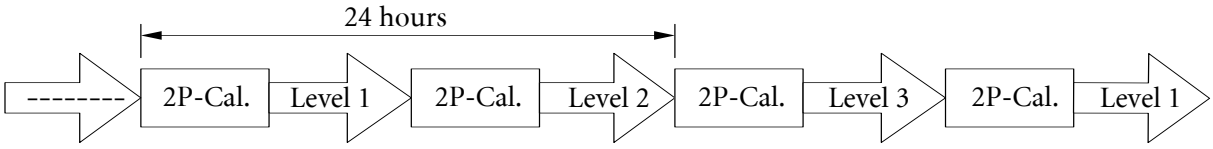


Figure B-17

The automatic system calibration includes a complete 2P calibration.

Complete at least two quality control tests on different level once daily or more often in accordance with local regulations.

Run quality control tests ideally prior to sample measurements.

A quality control program includes the analysis of sample materials with known ranges of expected values and the comparison of these values with analyzer results.

The following control material is recommended:

For BG, ISE, Glu, Lac, Hct, tHb/SO_2 (**cobas b** 221<1> system, **cobas b** 221<3> system, **cobas b** 221<5> system):

- COMBITROL TS+
- AUTO-TROL TS+ (AutoQC material)

For BG, ISE, Glu, Lac, Urea/BUN, COOX/bilirubin (**cobas b** 221<2> system, **cobas b** 221<4> system, **cobas b** 221<6> system):

- COMBITROL PLUS B
- AUTO-TROL PLUS B (AutoQC material)

Colour code of the ampoules

- Level 1 - red marking line
- Level 2 - yellow marking line
- Level 3 - blue marking line

The target areas listed in the package text should be taken as 2 SD areas (SD = standard deviation) (e.g. for PO_2, 2SD = 12 mmHg, 1SD = 6 mmHg).

The QC measurement results within the target value range ± 2SD are acceptable.

If QC measurement results fall outside the target value range ± 3SD, the parameter must be locked

see section *Important information concerning the analysis of QC measurement results* on page B-35!

QC measurement results that are greater than the target value ± 2SD, but less than the target value ± 3SD , cause QC warning and must be treated accordingly.

see section*Important information concerning the analysis of QC measurement results* on page B-35!

Important information concerning the analysis of QC measurement results

Ensure, that "Multirules" rule 1 and 2 are activated and the QC consequence "QC lock" was assigned to the parameters!

see section *Multirules* on page B-53
see section *QC consequences* on page B-55

The evaluation depends upon which SD areas are featured in the QC measurement results:

- **Measured value is within the target value range ± 2SD**

  The parameter is acceptable.

  The QC measurement results are within ± 2SD from the target value and the parameter is/remains activated for measurements.

- **Measured value is outside the target value range ± 3 SD**

  Consequence: A "QC lock" is assigned to the parameter.

  The QC measurement result is not acceptable. The parameter is locked for additional measurements and may only be released for further patient measurements, after the cause of the lockout has been determined and the error has been corrected.

  see section *Remove the QC lock* on page B-56

- **Measured value is larger than target value ± 2SD, but smaller than target value ± 3 SD**

  Consequence: A "QC warning" is assigned to the parameter.

  The user must now analyze the QC measurement results in accordance with applicable regulations or repeat the measurement.
  Call up the QC statistics in the QC database to aid in the analysis.

  see Chapter 9 *Software modes*, section *QC measurements* on page B-84

  The analysis can be automated by activating additional multirules.

  see section *Multirules* on page B-53

  If the result of the repeated measurement is greater than target value ± 2SD, but less than target value ± 3SD, the parameter is not locked, but must not be used for further patient measurements.

To eliminate the error, replace the electrode and/or contact customer support.

Material setup

Take the lot, expiration date, sample type and target values (ranges) as well as the corresponding barcodes from the text included in the recommended QC material.

The QC material must be defined prior to the QC measurement.

Select the QC material according to the instrument version!

The barcode scanner facilitates easy entry of the required information.

Press the following buttons:

☞ Setup > QC materials > QC materials

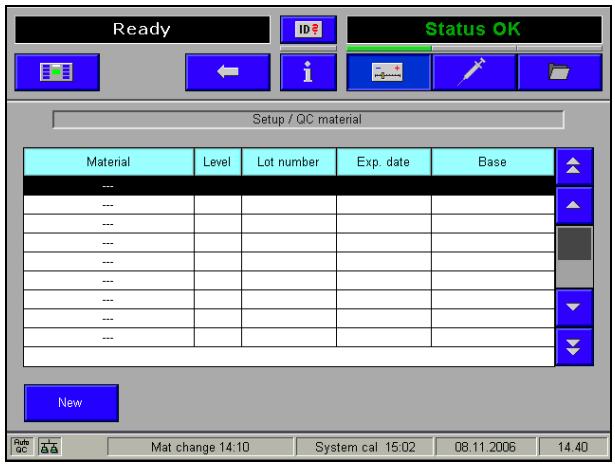


Figure B-18

To define a new QC material, read in the material code with the barcode scanner from the packing insert **or** press the [New] button and enter the information manually.

The material code contains the information for the material, the proper level, lot number, expiration date, and sample type.

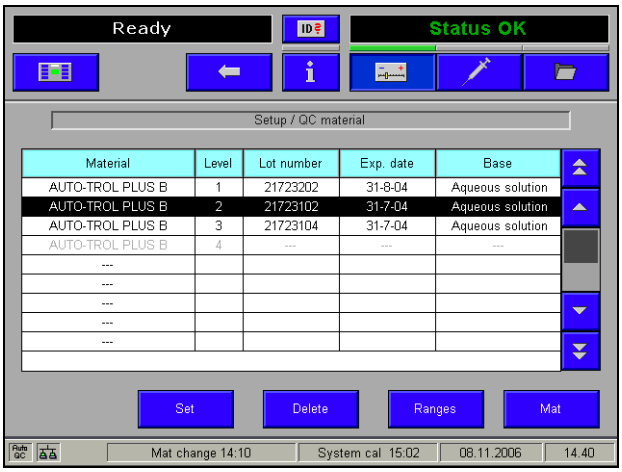


Figure B-19

Press [Ranges] and read in the additional barcodes for the target values.

The **cobas b** 221 system automatically assigns these.

If no barcode scanner is available, the target values can also be entered manually.

Press [Set] to edit a previously defined material/level combination.

Material assignment – AutoQC materials

The selected AutoQC material must be assigned prior to the AutoQC measurement.

Select the material and level to be assigned and select [Mat].

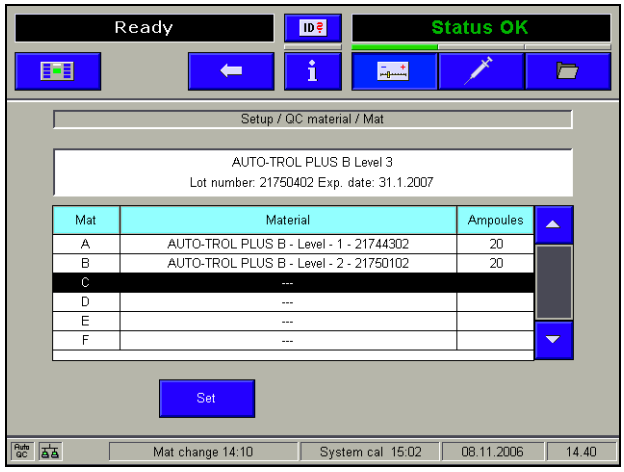


Figure B-20

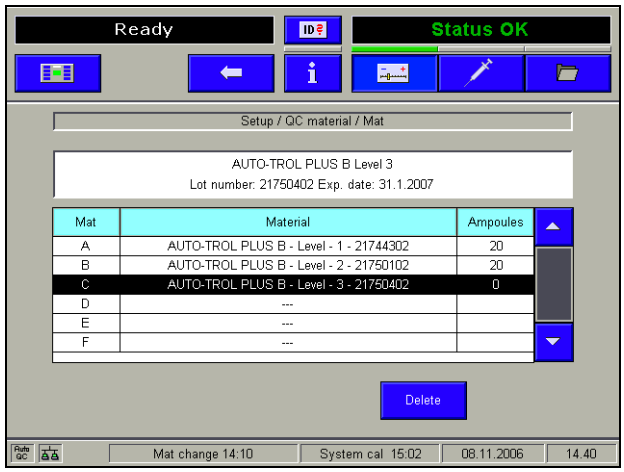


Figure B-21

The selected material/level combination is assigned to a mat (A-F) by pressing [Set].

Press the "Back" button to save the material assignment.

Inserting the AutoQC mats

Starting with the top level of the **Analyzer mode**, insert the ampoule mats in the ampoule holder as follows:

1 Pull out the AutoQC drawer.

The following screen appears:

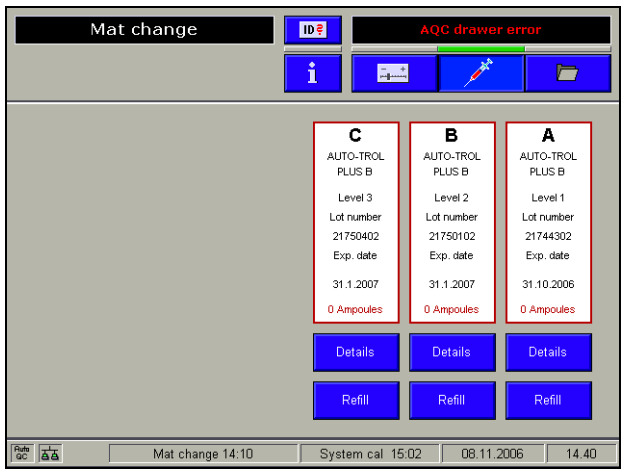


Figure B-22

2 Take a full mat (20 ampoules) from the package.

3 Turn the mat so that the necks of the ampoules face down. Gently wave but do not shake the mat and ensure that the necks of the ampoules are free of air bubbles.

Figure B-23 AutoQC-Mat

4 Place the mat in the defined position of the ampoule block so that the ampoules are no longer visible.

5 Press [Refill].

The following question appears:

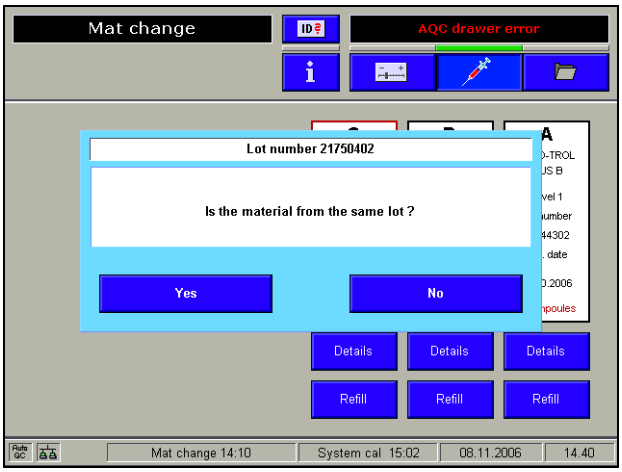


Figure B-24

6 Press [Yes] – if the mat is replaced with a new one of the same lot. The number of the ampoules is set to 20.

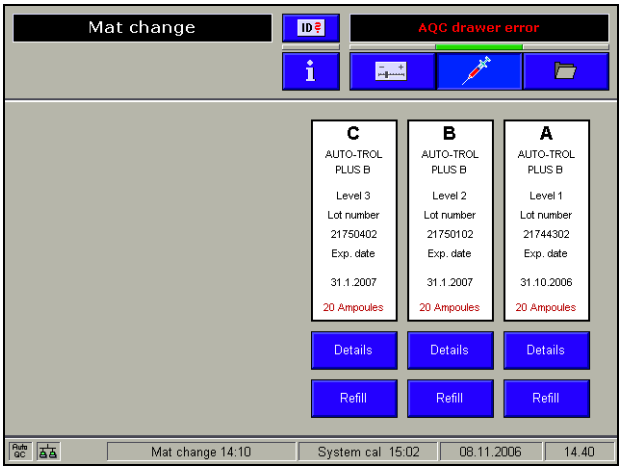


Figure B-25

7 In case the mats that are not completely filled press [Details]. By pressing the corresponding key the status of the selected ampoule can be changed and/or the ampoules to be measured can be selected (blue - full, gray - empty).

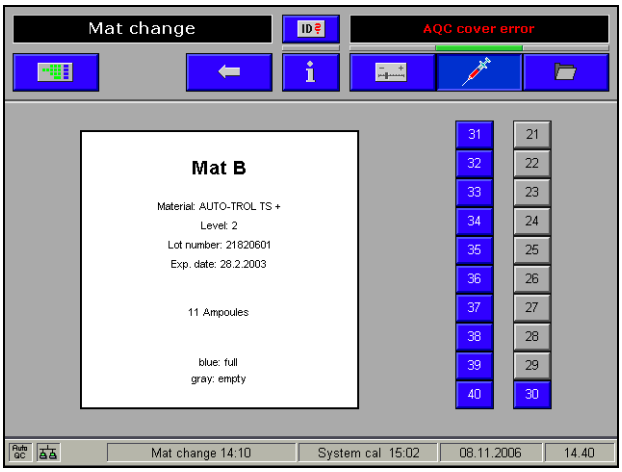


Figure B-26

This function can also be used when full ampoules are removed from the mat for manual measurement

8 Repeat the procedure for all mats.

9 Close the AutoQC-drawer.

QC timing

Depending on the selected material/level, this function is used to select the start time(s) for the AutoQC measurement(s) and/or the time for performing a manual QC measurement. After reaching the set time, a note appears in the instruction window.

Press the following buttons:

☞ Setup > Times & intervals > QC timing

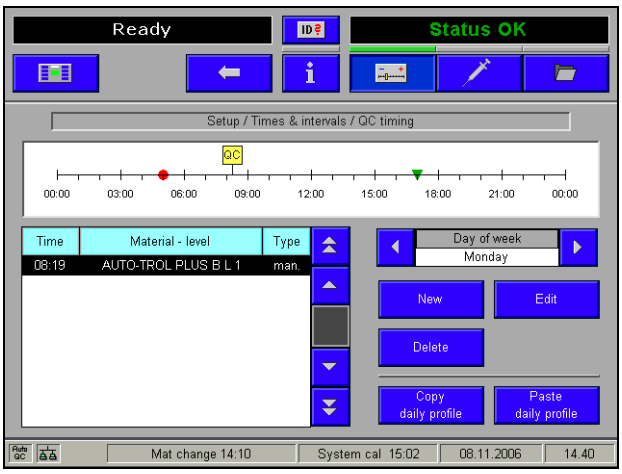


Figure B-27

A little marker ("QC") on the time scale indicates the defined start time(s) and for a better coordination with the QC timing a little marker on the time scale also indicates

the defined calibration intervals. Small red-colored point - System calibration, small green-colored triangle - 2P calibration.

Setting start time(s)

Select the day from the "Day of Week" list on which the QC measurement should be performed.

"New" Enter start time, material and measurement repeats.
Press [Use another material] to define the material used for a possible measurement repeat.
Press [Repeats] to define the number (0-3) of QC measurements to be repeated.

"Edit" Change or modify start time, material and measurement repeats. Press [Use another material] to define the material used for a possible measurement repeat.

"Delete" Delete the marked entry from the list.

"Copy daily profile" The start time(s) will be copied to a cache (see "Paste daily profile").

"Paste daily profile" Select another day of the week and press [Paste daily profile] - the cached entry will be entered for the new day of the week.

Change lot (applies only to AutoQC measurements)

By means of this function, a follow-up material of a new lot can be assigned to a current Material/Level Combination (= main material). The defined starting times for the AutoQC measurement(s) are thus taken over immediately after the current material has been used up for the follow-up material of a new lot. This means there is no interruption of the AutoQC measurements.

First define the new material (follow-up material), assign the material and insert the mats.

Material setting / Material assignment – Follow-up material

The follow-up material has the same material name and QC level, but a different batch number.

Press the following buttons:

☞ Setup > QC Material > QC Material

1. Read in the material code from the package insert using the barcode scanner or press the [New] button and manually enter the information.
2. Press the [Ranges] button.
3. Read in the other barcodes for the target values.
4. Select the material/level combination and press [Mat].
5. If no mat position is available, a mat position of the main material that does no longer contain an ampoule must be deleted (to find out which mat position can be deleted, press [Info] > [AQC status]).

6 Press [Set] and the selected material/level combination will be assigned to a mat (A-F).

Press this button to store the assignment.

7 Press the "Analyzer" button to change to the analyzer mode.

8 Pull out the AutoQC drawer.

9 Take a full mat of the follow-up material from the package.

10 Turn the mat so that the necks of the ampoules face down. Gently wave the mat twice, but do not shake it. Ensure that the necks of the ampoules are free of air bubbles!

Make sure there are no air bubbles in the ampoule necks!

11 Place the mat in the previously defined position (A-F) of the ampoule block.

12 Press [Refill].

13 Close the AutoQC drawer.

At least one mat of the replacement material must be present in the AutoQC module.

No QC times should be assigned to the follow-up material. The defined starting times for the AutoQC measurement(s) are taken over immediately after the current material has been used up for the follow-up material of a new lot.

14 Next, press the following button:

☞ Setup > QC material > Change lot

15 Select the material/level combination to which a replacement material of a new lot must be assigned.

For this material/level combination (= main material), at least one QC measuring time must be defined so that a follow-up material can be assigned.

16 In the "New lot number" window, select the lot of the replacement material.

17 Press [Select new lot number] – the new lot becomes the follow-up material of the current material.

Press this button to store the assignment.

QC setup wizard

This chapter describes the software supported setup of QC material step by step.

To start the QC setup wizard, the user must have the right to change QC materials. Otherwise the start is refused with the message "Insufficient user privileges!"

see *Reference Manual* chapter 3 *Setup*, section *Security*!

Starting with the top level of the analyzer mode:

1 Open the AQC drawer.

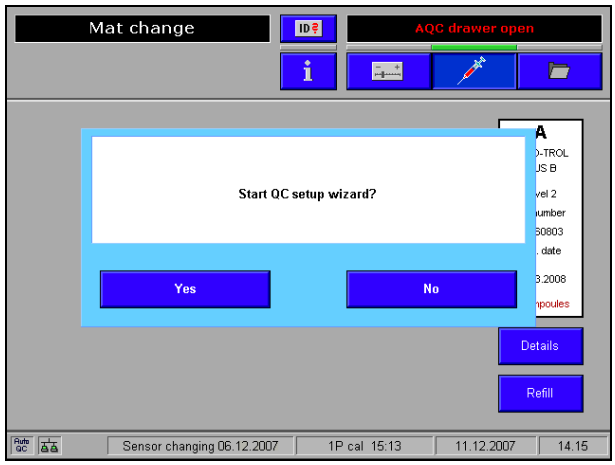


Figure B-28

2 Press [Yes]. Following screen appears:

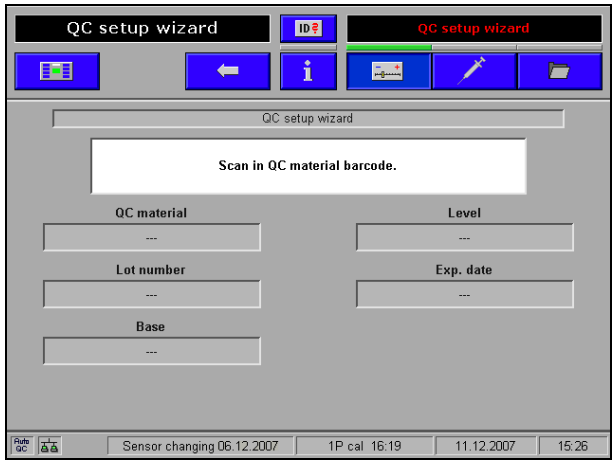


Figure B-29

To execute, follow the additional instructions on screen for completing the other fields!

Scanning the material code

The system determines whether a new QC material or a previously installed one with the same lot number is being scanned.

New QC material

There is the ability to scan in up to 4 different materials. If this number is reached, you first have to delete an existing AQC material ([Setup] > [QC material] > [Delete]). A corresponding prompt appears on the screen.

Already installed AQC material

AQC material with the same lot number

If the barcode of a previously installed QC material with the same lot number is scanned, the procedure is continued and a corresponding information message is displayed.

AQC material with different lot number

If the barcode for a previously installed AQC material with a different lot number is scanned in, after you press the [Continue] button, you can choose between two options:

- Carry out lot change automatically
  see *Change lot (applies only to AutoQC measurements)* on page B-42
- Do not carry out lot change

Allows you to review or discard your entries.

Exits the QC setup wizard.

Scanning ranges

New QC material

The following screen appears:

Figure B-30

As soon as a valid range is scanned, the corresponding module is marked and the [Continue] button appears. This allows continuation of the process without having entered all ranges.

Previously installed QC material

In this case, the system checks whether the ranges have already been assigned. If this information is missing, the range is scanned, the corresponding module is marked and the [Continue] button appears.

Changes to existing ranges cannot be made using the QC setup wizard!

Checking for AutoQC compatibility

After all ranges are set, the QC material is checked for AutoQC compatibility.

AutoQC compatible materials:

- AUTO-TROL TS+
- AUTO-TROL PLUS B

The following QC materials do not meet these requirements:

- COMBITROL TS
- COMBITROL TS+
- COMBITROL PLUS
- COMBITROL PLUS B

Figure B-31

If the QC material is not AutoQC-compatible, it will still be installed successfully. In this case, press the [Exit QC wizard] button to exit the setup wizard.

Read in additional material	You can scan more QC materials. See Figure B-30 on page B-46!

For AutoQC-compatible materials, the process continues and checks whether an AutoQC module is installed.

Assigning the mats

The scanned QC material now has to be assigned a position in the AutoQC module.

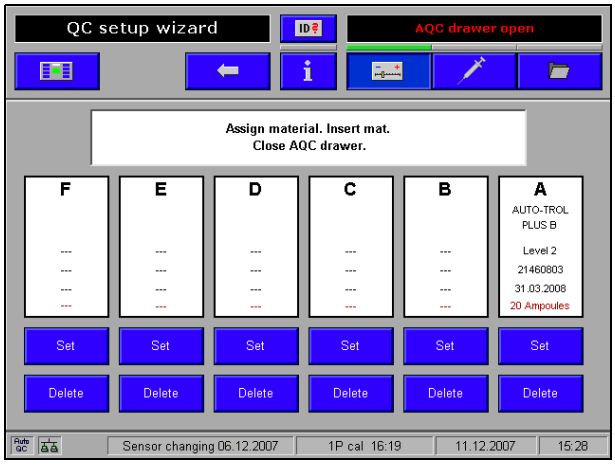


Figure B-32

All previously assigned mats are displayed. If no position is available, you first have to delete a position using [Delete].

1. Press [Set]; a material/level combination is assigned to a mat (A-F).
2. Take a full mat out of the package.
3. Tun the mat so that the ampoule necks point down. Turn the mat twice (do not shake it!).

Ensure that the ampoule necks are free of air bubbles.

Figure B-33

4 Insert the mat into the previously defined position (A-F) of the ampoule block.

5 Close the AQC drawer. The ampoule status is automatically set to 20.

You cannot change the number of ampoules in the QC setup wizard!

AQC timing

If a lot change has been carried out, the AQC times are already defined and are accepted automatically.

Using this function, depending on the newly installed material/level combination, the start time(s) for the AutoQC measurement(s) are defined and/or the time is determined. After the set time is reached, a note appears in the message window.

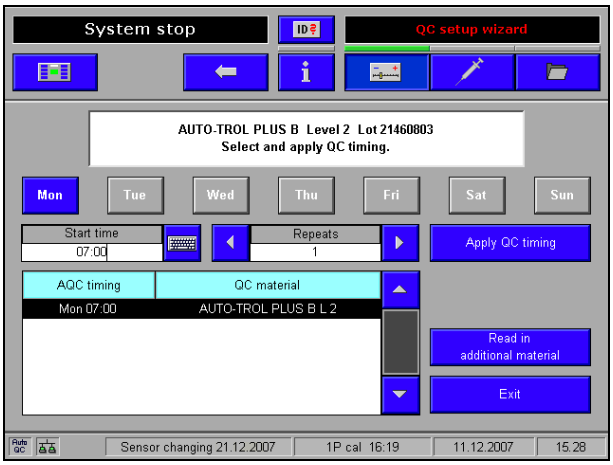


Figure B-34

All previously defined AQC times are shown in the list.

1 Using the [Mon] - [Sun] buttons, select the day of the week on which the AQC measurement is to be carried out.

2 Enter starting time and change the number of "Repeats".

3 Press the [Apply QC timing] button. The entries are saved.

If, when entering the start time, there is an overlap with another QC measurement, a corresponding message is displayed.

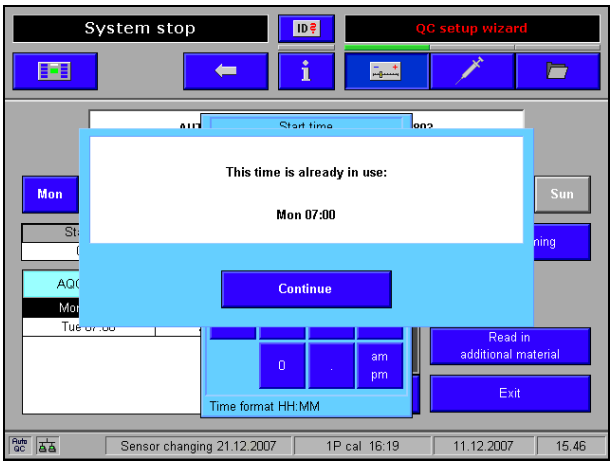


Figure B-35

If no day of the week was selected, the QC times cannot be accepted and a corresponding message is displayed.

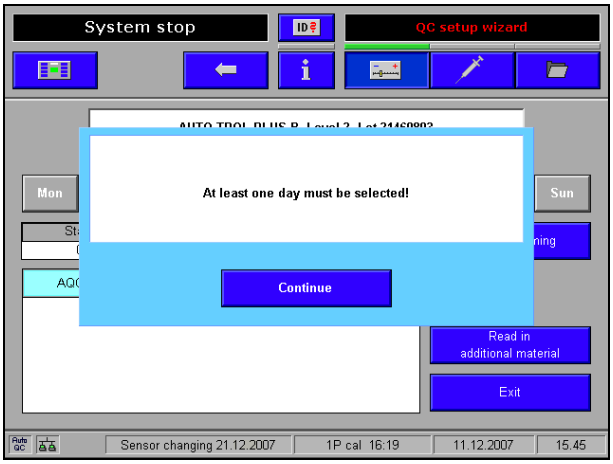


Figure B-36

Press this button to exit the QC setup wizard and save the input.

Press this button to save the input and restart the QC setup wizard.

Press this button to save the input and switch the display to the section for assigning mats.

see the section on *Assigning the mats* on page B-47

Other options for starting the QC setup wizard are:

- *Pressing the buttons [Setup] > [QC material] > [QC setup wizard].*

Follow the additional instructions on the screen.

QC measurement

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (low, normal, high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument.

Additionally complete a quality control test on one level between two automatic 2P calibrations. The level have to be alternated (low, normal, high).

see *General QC concept* on page B-33

Manual QC measurement

1 Press the following buttons, starting with the top level of the analyzer mode:

☞ QC measurement

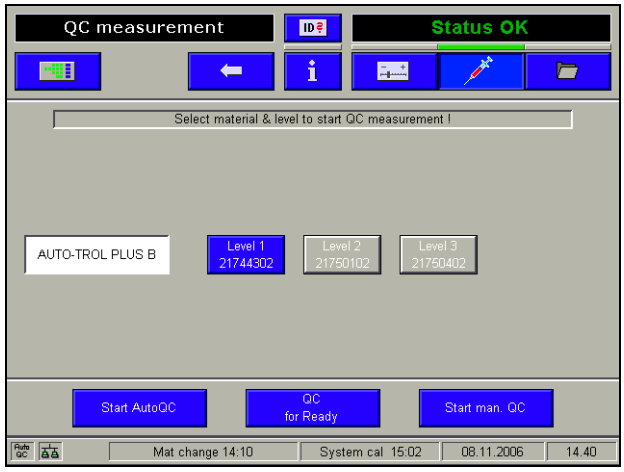


Figure B-37

2 Activate the corresponding QC material and the selected level (for example, level 1).

3 Remove the ampoule of the corresponding level of the desired QC material from the packaging or of the AutoQC material from the mat.

4 Gently tap the head of the ampoule with your fingernail to remove any liquid from the top.

5 Break open the ampoule.

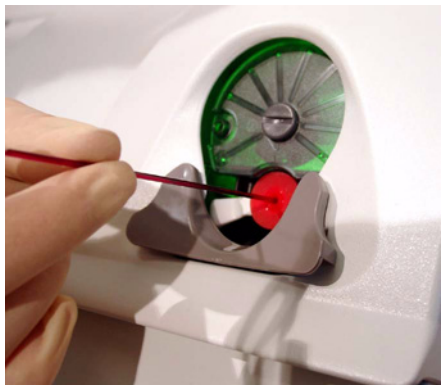
To avoid injury, protect your hands with gloves and tissues when breaking open the ampoule.

Use the control material within 30 seconds of opening.

Never reuse the ampoule.

It is recommended to use an ampoule adapter!

6 Insert the adapter (see below/A) or the filled capillary (see below/B) into the fill port.



A Ampoule with adapter **B** Capillary

Figure B-38 Manual QC measurement

7 Press the [Aspirate sample] button.

8 Detach the ampoule adapter or the capillaries after the message "Remove sample container" appears.

9 The measurement starts.

10 If the user does not reject the results, they are printed and automatically saved in the QC database.

For details about the "Database" see Chapter 9 *Software modes*, section *Data manager* on page B-81 and/or Reference manual, chapter *Softwaremodi*.

AutoQC measurement

The AutoQC measurement can be performed in programmed or manual mode ([Setup] > [Times & intervals] > [QC timing]).

For this purpose, press [QC measurement] in the analyzer mode, and activate the corresponding AutoQC material (e.g. AUTO-TROL TS+) and the selected level (e.g. Level 1).

Start the AutoQC measurement by pressing [Start AutoQC].

Multirules

The evaluation of QC results is based on the Westgard rules[(a)] and their interpretation for blood gas analysis[(b)]. The Multirule process was derived from these rules. It permits early detection of random and systematic errors associated with the measuring device and its operation.

The Multirules procedure can only be applied in connection with a suitable control material (e.g. COMBITROL TS+, AUTO-TROL TS+).

The Multirule procedures produce the best results when 3 QC measurements with randomly selected level are completed per series (time between two 2-point calibrations). A minimum of 2 QC measurements / series or 6 QC measurements / 3 series is required.

The QC concept expects Multirules rule 1 and 2 to be activated.
Press the following buttons to check the settings:

☞ Setup > Parameters > Miscellaneous settings > Multirules

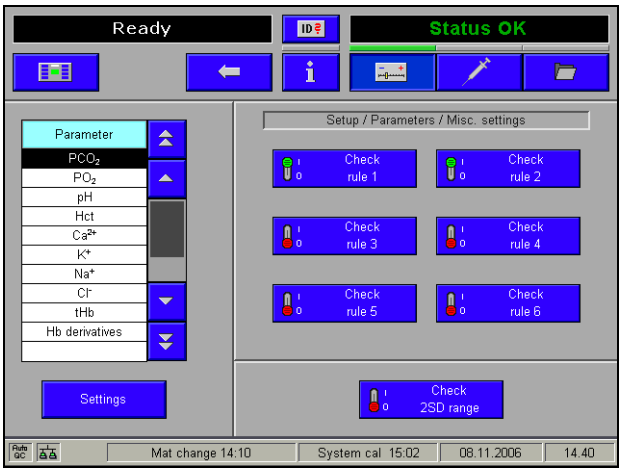


Figure B-39

Select additional desired rules in the right part of the window and assign it to the corresponding parameter which is listed in the left part of the window under "Parameter".

The activation of range 2SD automatically deactivates all other rules (rules 1-6).

(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

Overview of the Multirules

Serie	time between two 2-point calibrations
N_T	number of individual measurements of all level (T=total)
N_L	number of individual measurements per level (L=Level)
m	QC measurement value of one level and one parameter
$\bar{x}$	mean value, taken from the insert sheet or calculated based on at least 20 and no more than 100 individual measurements
σ	standard deviation

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. $(2 \text{ von } 3)_{2\sigma}$	Two of three QC measurement values are outside $\bar{x} \pm 2\sigma$ Observation time period: 1 series (within run) $N_T = 3$
4. $2_{2\sigma}$	2 QC measurement values (m) are outside $\bar{x} \pm 2\sigma$ Observation time period: 2 series $N_L \geq 2$
5. $6_{1\sigma}$	6 QC measurement values (m) are outside $\bar{x} \pm 1\sigma$ Observation time period: 3 series $N_T \geq 6$
6. 9_m	9 QC measurement values (m) are on the same side as the mean value Observation time period: 5 series $N_T \geq 9$
2SD range	Defined target values (ranges)

Table B-7 Multirules

The Multirule process is applied after each individual measurement.
Multirules are only applied to the corresponding control material (e.g. COMBITROL TS+).

QC consequences

By default, the QC consequence "QC lock" should be assigned to all parameters.

Press the following buttons to set or check the assigned QC consequences:

☞ Setup > Parameter > Miscellaneous settings > QC lock

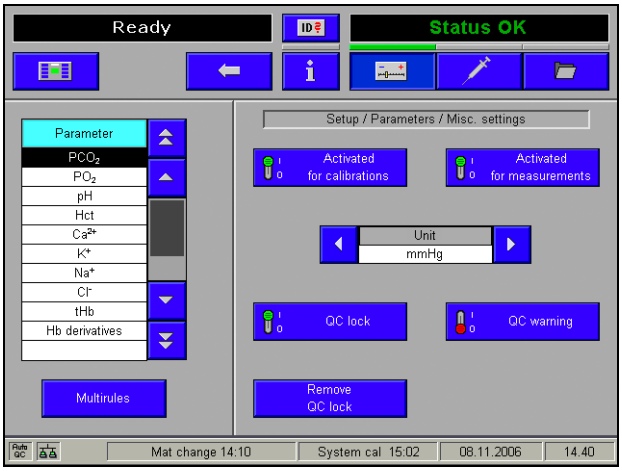
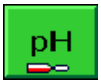


Figure B-40

Description of the QC consequences:



QC-Warning: through a warning, the respective parameter will be marked in the "Ready" screen, but remains ready for measurement

The measurement protocol now displays "(q)" and "(q) .. QC warning" if the "QC warning" is activated and the paramter is in the "QC Warning" status.

QC lock: the parameter will be blocked if one of the adjusted rules is broken. The parameter will be identified accordingly in the Ready screen.

A status report appears after pressing the parameter button.

Remove the QC lock

QC warning

Proper execution of a QC measurement using the same material/level combination removes the warning.

QC lock

Automatic correction

Using the "QC for ready" function, the required AutoQC measurements are carried out with the corresponding material/level combination, which can remove this lock.

Proper execution of a QC measurement using the same material/level combination removes the block.

Manual correction

A manual correction is only allowed if the same material/level combination is no longer available.

In this case, repeat the QC measurement with a new material/level combination of a different lot and analyze it as described under "Important information concerning the analysis of QC measurement results".

see section *Important information concerning the analysis of QC measurement results* on page B-35!

To ignore the result violates the accepted QC rules!

Press the following buttons to unlock the QC lock:

Setup > Parameter > Miscellaneous settings > Remove QC lock

To remove a QC lock, the correct parameter must be selected.

A calibration, changing electrodes and/or changing an MSS cassette do not remove a QC lock!

Exchange the electrode

see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27

QC for Ready (with AutoQC module)

Parameters will be blocked if one of the adjusted rules is broken and identified accordingly in the Ready screen.

The function "QC for Ready" generates a list of the required manual QC measurements (material/level combination) that can remove this lock again.

Proceeding from the uppermost level of the analyzer mode, press the following buttons:

☞ QC measurement

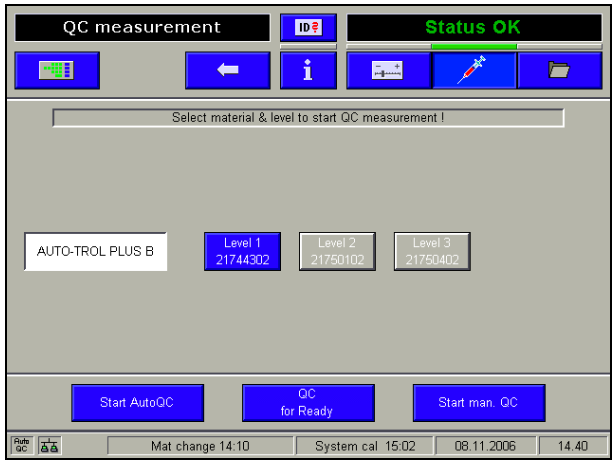


Figure B-41

1 Press [QC for Ready]. When all parameters are ready for measurement, the AutoQC measurement is started automatically.

2 If the parameters are not all ready for measuring, the following screen appears:

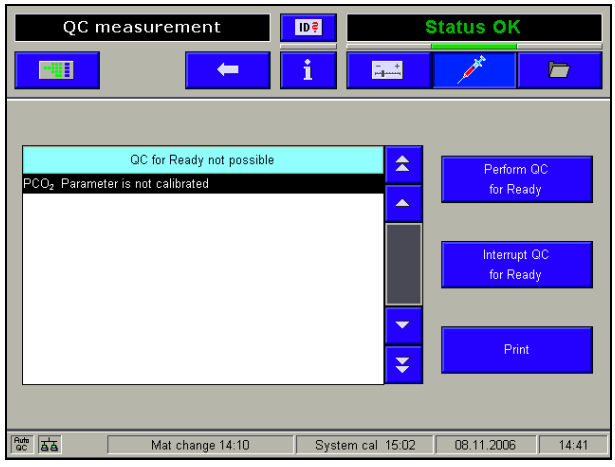


Figure B-42

3 Here, a list is given of all the parameters for which a measurement "QC for Ready" is not possible, and the reason why. If required, print the list [Print], remedy the cause and repeat the procedure.

4 Press [Perform QC for Ready]. The AutoQC measurement is started for all parameters ready for measurement.

5 With the [Interrupt QC for Ready] key, the procedure can be interrupted.

6 The measurement results are printed out and stored automatically in the QC database.

QC for Ready (without AutoQC module)

Parameters will be blocked if one of the adjusted rules is broken and identified accordingly in the Ready screen.

The function "QC for Ready" generates a list of the required manual QC measurements (material/level combination) that can remove this lock again.

Proceeding from the uppermost level of the analyzer mode, press the following buttons:

☞ QC measurement

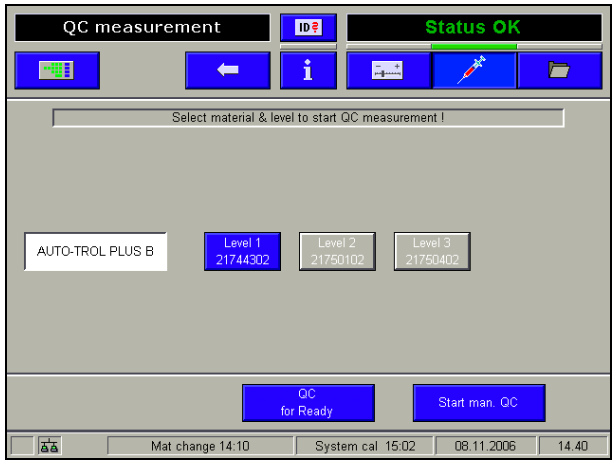


Figure B-43

1 Press [QC measurement for Ready].

2 If the parameters are not all ready for measurement, the following screen appears:

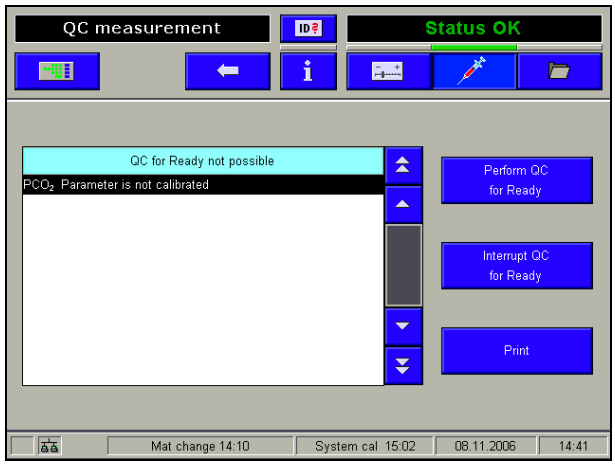


Figure B-44

3 Here, all the parameters are listed for which a measurement "QC measurement for Ready" is not possible, and the reason why. If required, print the list [Print], remedy the cause and repeat the procedure.

4 Press the button [Perform QC for Ready].
The following screen appears:

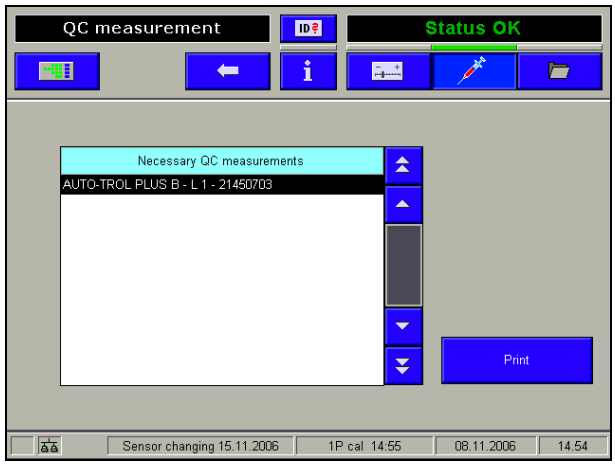


Figure B-45

5 Here, the respective material/level combinations are listed that can remove this lock again.

6 Print the list [Print] and perform a manual QC measurement with the listed QC materials.

see section *Manual QC measurement* on page B-51!

QC troubleshooting

Description of the current problem

After a QC measurement, one or more parameters are assessed as "not OK" (QC warning or QC block).

The affected parameters and the QC material (material type, level) causing the error are listed under [Info] > [QC status]. The QC problem can only be solved by a correct QC measurement within the range if the same material / level combination is measured.

Classification of QC problems

Group A

The cause is an aspirating or positioning problem with the QC sample. In this case, usually more than one parameter is affected. A cause in Group A can be recognized in the data manager under [QC measurements] > [Details], where instead of a result an error message appears for the respective parameter.

Group B

The cause is a QC result that exceeds the target value range.

A cause in Group B can be recognized in the data manager under [QC measurements] > [Details], where a result is available but exceeds the target value range.

Troubleshooting – Group A (aspirating or positioning problem)

1. Check whether all parameters are calibrated.
2. Repeat the QC measurement (with same material / level combination).
3. In event of repeat error:
   - If an AutoQC module is in use, a manual QC measurement with the same material / level combination must be carried out.
   - If the manual QC measurement shows the same problem, continue with Point 4.
   - If the manual QC measurement is "OK", the fill port and T&D disk must be cleaned and the ampoule status under [Info] > [AQC status] must be compared with the actual availability of the ampoules in the AutoQC module.
   - Repeat the QC measurement (with same material / level combination).
   - If the error persists, contact customer service.

4 For the affected measurement chamber, an internal cleaning must be called up (exception: MSS measurement chamber). Measurement of a blood sample must then be carried out in order to wet the fluid channels.

5 Repeat the QC measurement (with same material / level combination)

If the error persists, contact customer service.

Troubleshooting – Group B (QC result exceeds the target value range)

1 A system calibration must be carried out for the affected parameters.

- Should parameters of the COOX module be affected, a COOX calibration must also be carried out.

2 The following points must be checked:

- It must be checked whether the target value ranges under [Setup] > [QC material] > [QC material] > [select appropriate material] > [Ranges] correspond to the target value ranges stated in the package insert.
- If an AutoQC module is in use, it must be checked whether the batch number printed on the AutoQC mat corresponds to that under [Setup] > [QC material] > [QC material].
- It must be checked whether before use the QC ampoules have been stored for at least 24 hours at room temperature or in the AutoQC module.
- In event of manual QC measurement, it must be ensured that the time between opening the ampoules and the QC measurement is kept as short as possible. Furthermore, it must be ensured that the ampoule adapter is used.
- If an AutoQC module is in use, it must be ensured that the AutoQC temperature deviates by less than 5 °C from the ambient temperature. Check under [System] > [Component test] > [Control sensors] > [Temperature control] > [AutoQC temperature].

3 Repeat the QC measurement (with same material / level combination)

- If the error persists, internal cleaning of the affected measurement chamber must be carried out (exception: MSS measurement chamber). For this measurement chamber, a wetting routing must then be called up.

4 Repeat the QC measurement (with same material / level combination)

- If the error persists, the affected electrode / sensor must be replaced. If all ISE parameters are affected simultaneously, the reference electrode must be replaced.

If the problem cannot be solved successfully, the Customer Service must be notified.

Calibration

In this chapter, all automatic and user-activated calibrations are described.

In this chapter

Chapter **8**

Contents

Calibration – general

The **cobas b** 221 system uses a technology for simultaneous calibration of PCO_2, pH, Na^+, K^+, Ca^{2+} and Cl^-, which requires only two aqueous solutions (contained in S2 Fluid Pack).

Oxygen (O_2) is calibrated with ambient air and a zero point solution.

The MSS calibration is carried out with the solutions contained in S3 Fluid Pack (for instrument versions with MSS module only, **cobas b** 221<5> system und **cobas b** 221<6> system).

The COOX calibration is carried out by entering a tHb calibrator whose exact values are known (for instrument versions with COOX module only).

Automatic calibrations

The following calibrations are automatically initiated and performed by the analyzer.

System calibration

Every **8, 12** or **24 hours** (**default**) which includes the following:

- Wavelength calibration of polychromator (for instruments with COOX module only)
- Cleaning with internal cleaning solution
- Automatic conditioning of the Na^+ electrode (every 24 hours)
- Calibration of the mixing system
- 2 point calibration of all parameters

*The user can set a permanent start time for the system calibration. This enables completion of calibration tasks while the **cobas b** 221 system is not in use or when the workload in the laboratory or station is smaller.*

see Reference manual, chapter *Software modes*, section *Setup*.

2P calibration (2P cal)

Adjustable: **4, 8**, and **12 hours** (**standard**).

1P calibration (1P cal) incl. O_2

Adjustable: **every 30 minutes (standard), 1 hour.**

USA: 30 min only!
(adjustable: [Setup] > [Protected setup] - this area is password protected and is accessible only to authorized personnel or customer service representative!).

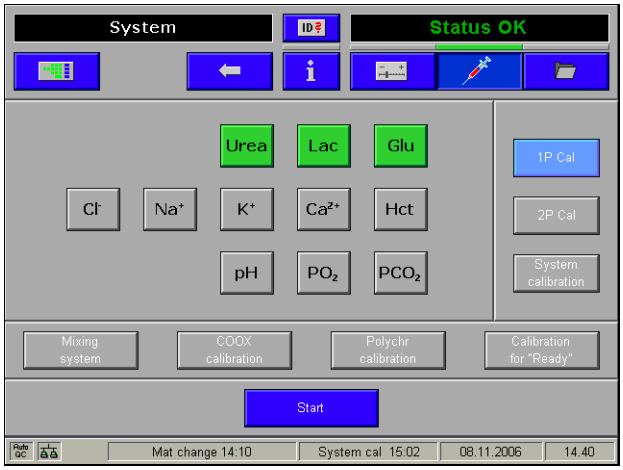
Recalibration - without O_2

After every measurement.

User-activated calibrations

Activation in analyzer mode:

☞ System > Calibration



A Example: Instrument with COOX and MSS module

Figure B-46 User-activated calibrations

Performing a "user-activated calibration" does not influence the time lapse of "automatic calibrations".

Select the parameters to be calibrated. It is not possible to select individual parameters, instead only functionally coherent groups of parameters can be selected.

The following groups can be selected:

- all MSS parameters (for instrument versions with MSS module only (**cobas b** 221<5> system and **cobas b** 221<6> system))
- all ISE parameters, except for Hct
- Hct
- pH and PCO_2
- PO_2

The following calibrations can be performed:

- Calibration for "Ready":
  The system automatically selects a calibration which will transfer all selected parameters to the state "Ready".
- System calibration
- 1P calibration
- 2P calibration
- Mixing system:
  Calibration of the conductivity system
- COOX calibration (for instruments with COOX module only)

  For a detailed description of how to do this, see Chapter 10 *Maintenance*, *COOX calibration (for instrument versions with COOX module only)* on page C-10!
- Polychromator calibration (for instruments with COOX module only):
  Wavelength calibration of polychromator

To execute the desired calibration, first press the corresponding selection button. Activate the calibration by pressing the [Start] button.

Display of parameters during calibration

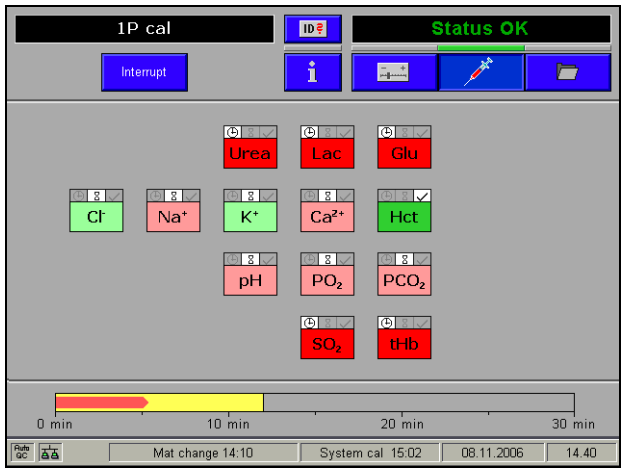
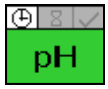
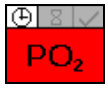


Figure B-47 System calibration

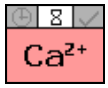


The already calibrated parameter is also intended for the current calibration.

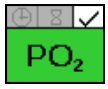


The parameter which was not calibrated previously is also intended for the current calibration.

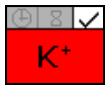
The parameter is currently being calibrated – chances for a successful calibration are very high.



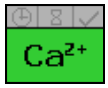
The parameter is currently being calibrated – chances for a successful calibration are very low.



The parameter was successfully calibrated during the current calibration.



The parameter was not successfully calibrated during the current calibration.



The parameter was calibrated and is not influenced by the current calibration.

The parameter was not calibrated and is not intended for the current calibration.

Software modes

In this chapter, all the individual, independent software modes (analyzer, settings, data manager and info) are described.

In this chapter *Chapter* 9

Software modes – general

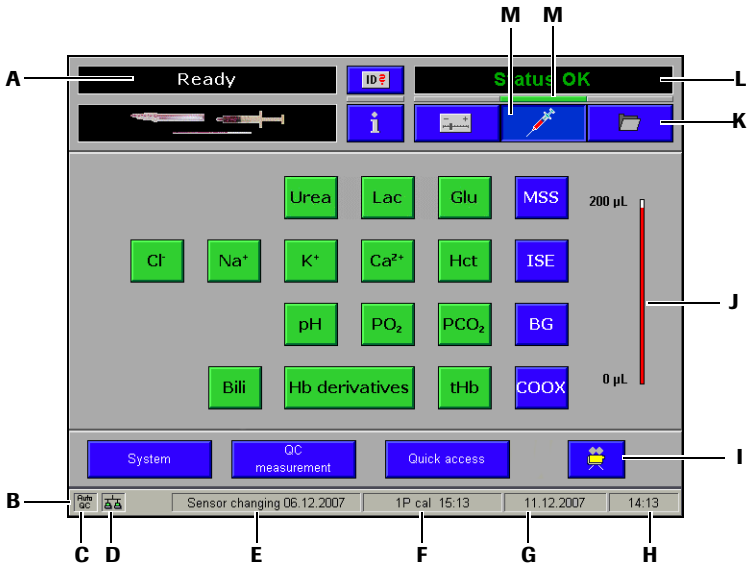
During measurement, calibration or other processes, it is possible to conduct database operations, perform certain settings or call up general information.

The software modes, which may be run independently are defined as follows:

- **Analyzer** Place sample (measurement), system, QC measurement, calibration, quick access (which contains commonly used functions)
- **Setup** Instrument settings
- **Database** Data about patients, measurements, calibrations, QC, and the instrument
- **Info**

User interface

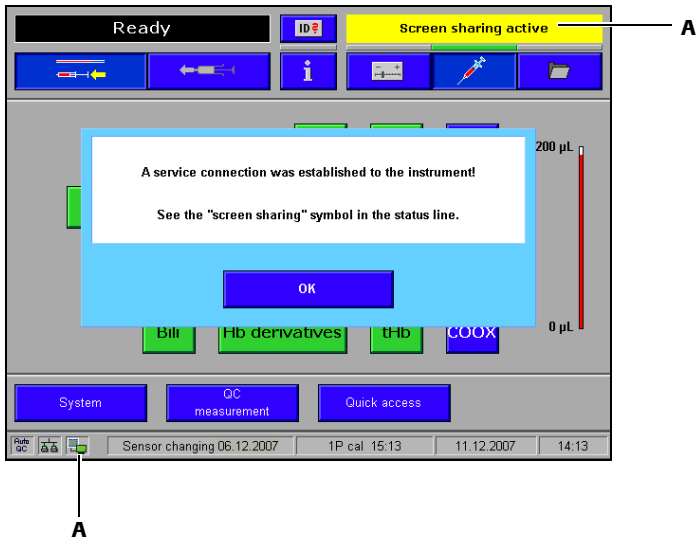
For example: Top level of the analyzer mode - "Ready"



A Current status of the analyzer mode
B Status line
C AutoQC act. / deact.
D Network connection act. / deact.
E Pending maintenance
F Type and time of next calibration
G Current date
H Current time
I Direct call-up of the video sequences offered
J Required sample volume (display varies according to activated/deactivated modules)
K Software modes (Info, setup, analyzer, database)
L Error / instruction window
M "active"

Figure B-48 "Ready" screen

For example: "Screen sharing" (a remote monitoring and remote maintenance software is active)



A "Screen sharing" (a remote monitoring and remote maintenance software is active)

Figure B-49

For example: User-defined parameter groups

☞ Setup > Parameter > User-defined parameter groups

This function helps to define three parameter groups.

👁 For a detailed description, see the Reference Manual, chapter 3 *Setup*, section *User defined parameter groups*!

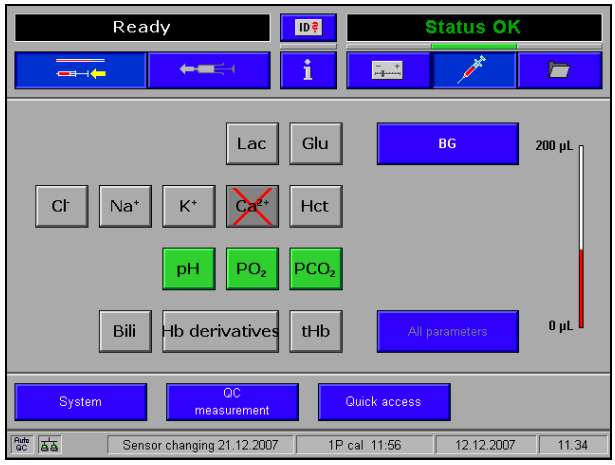


Figure B-50

Parameters / icons

Display on the Ready screen (analyzer mode)

Depending on the settings and the status of the instrument, the parameter buttons may have the following appearance:

Parameter activated and ready

Parameter temporarily deactivated (but calibrated)

Parameter activated with QC warning

Parameter temporarily deactivated with QC warning

Parameter not ready (not calibrated)[a]

Parameter not ready (due to QC lock)[b]

Parameter not ready due to remote lock

Parameter permanently deactivated (under "Setup")

(a) A status report appears after pressing the parameter button.
(b) A status report appears after pressing the parameter button.

Notation of the measurement, input, and calculation values[a]

Measurements (depending on configuration):

PO_2	Oxygen partial pressure
PCO_2	Carbon dioxide partial pressure
pH	Negative decadic 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

(a) Details and calculation, see Chapter 5 *Theoretical foundations*

HHb	Desoxyhemoglobin
COHb	Carboxyhemoglobin
MetHb	Methemoglobin
Bili	Bilirubin (neonatal)
SO_2	Functional oxygen saturation
Glu	Glucose
Lac	Lactate
Urea/BUN	Urea
Baro	Air pressure

Calculation values:

H^+	Hydrogen ion concentration
$cHCO_3^-$	Bicarbonate concentration in plasma
$ctCO_2(P)$	Total CO2 concentration in plasma
$ctCO_2(B)$	Total carbon dioxide concentration in 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 measurement 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	Ratio PaO_2/FIO_2
BO_2	Oxygen capacity
BUN	Urea calculated using Urea

Calculation values 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 oxygen partial pressure at patient's temperature
a/AO_2^t	Alveolar-arterial oxygen partial pressure ratio 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 concentration at patient's temperature

Input parameters:

R	Gas exchange quotient
FIO_2	Proportion of inspiratory oxygen
tHb(e)	Entered tHb value (not measured)
Hb factor	to calculate Hct(c) from tHb values

Additional items:

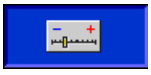
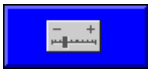
- Pract. Pat. ID
- Pat. ID
- Last name
- First name
- Middle initial
- Suffix
- Maiden name
- Date of birth
- Temperature
- Sample type
- Blood type
- Puncture site
- Operator ID
- Order ID
- Date drawn
- Admission time
- Discharge date
- Discharge time
- Date changed
- Time changed
- Specimen ID
- Sample container
- Address
- Billing code
- Danger code
- Diagnostic code type
- Isolation status
- Marital status
- Age (A/F)
- Diagnosis
- Religion
- Sex
- Title
- Phone no.
- Doctor
- Accepted by:
- Clinic info
- Vent. mode
- VT
- S_{rate}
- PEEP
- PIP
- MAP
- Ti
- Te

- Time drawn
- Hospital service
- Ward
- Department
- Location
- Admission status
- Admission date
- Diet
- Size
- Weight
- Insurance code
- Patient language
- Medication
- Ethnic origin
- MV
- A_{rate}
- Flowrate
- 24h Urine
- ALLEN test
- Remark
- Samples

Buttons

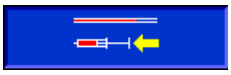
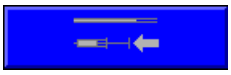

"Analyzer" active / inactive


"Database" active / inactive

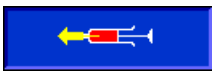
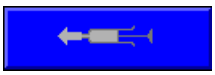



"Setup" active / inactive


"Info" active / inactive

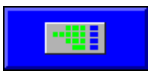



"Aspirate from capillary" resp. "Injection" active

"Aspirate from syringe" active


User logged on / no user logged on



Return to the highest level of the Analyzer mode

Return to the highest level of the Setup mode

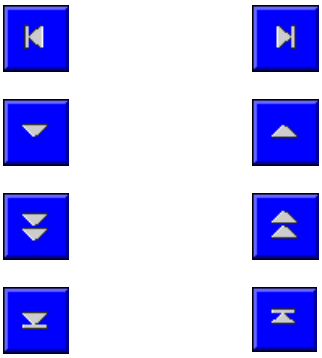
Return to the highest level of the Database mode

Return to the highest level of the Info mode

Back one level (used as an enter key to store information or to return to previous screen)

User stop


Move one entry to the left / right



Move left to start / right to end

Move one entry up / down

Move one page down / up

Move to bottom / top

Example for switch button - ON

Example for switch button - OFF

Analyzer mode

The Analyzer mode contains parameter information (e.g. Ready), system settings, quick access and the QC measurement. The "Ready" screen is the highest level of the menu tree available.

"Ready" screen

Figure B-51

On this screen, buttons must be pressed to:

- activate / deactivate all available parameters individually
- activate / deactivate a complete module
- start a measurement
- start a QC measurement by pressing the [QC measurement] button
- call up additional menus

The capillary tube shown indicates required sample size depending on parameters selected.

System

The following main menus are available:

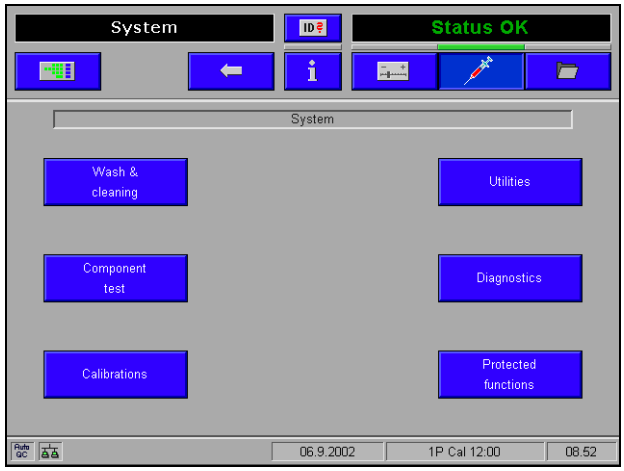


Figure B-52

For a detailed description, see the Reference Manual, Chapter *Software modes*, section *Analyzer* > *System*!

Quick access

Use these functions to start the following actions:

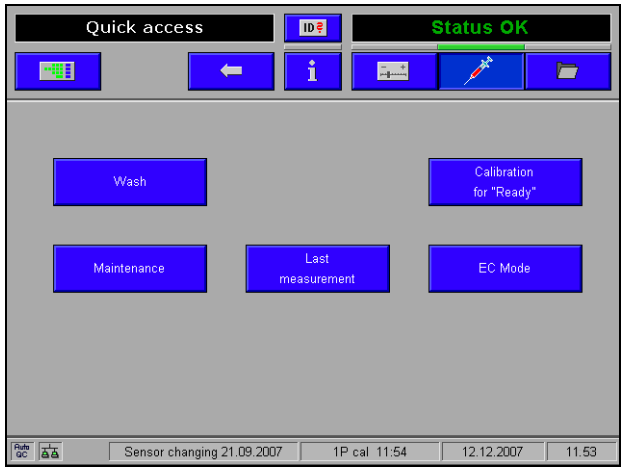


Figure B-53

For a detailed description, see the Reference Manual, Chapter *Software modes*, section *Analyzer* > *Quick access*!

QC measurement

This function helps start a quality control measurement.

For more detailed information, see Chapter 7 *Quality control*.

Setup

Use this function to make the following settings:

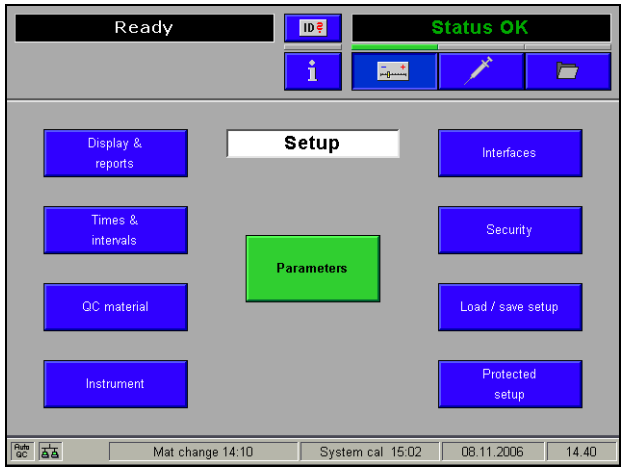


Figure B-54

For a detailed description, see the Reference Manual, chapter *Software modes*, section *Analyzer* > *Setup*!

Data manager

Use this function to retrieve the following data:

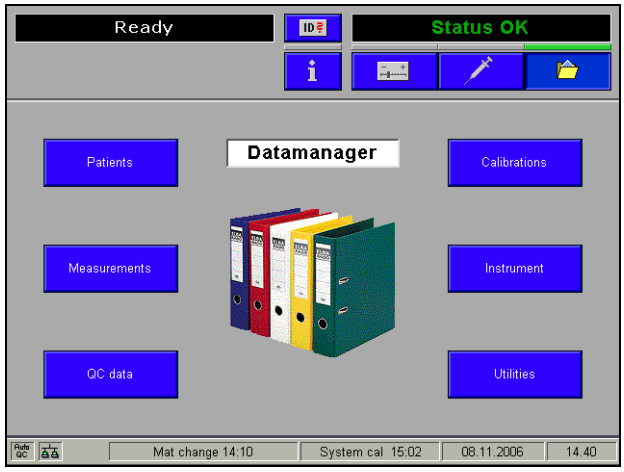
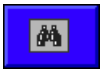


Figure B-55

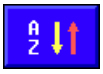
For a detailed description, see the Reference Manual, chapter *Softwaremodi*, section *Data manager*!

General data manager functions

Details - all the available detailed information for the selected dataset is displayed and can be edited.



Find - the function allows to search for datarecords using defined search criteria.



Sort - this function allows to sort the recordings.

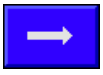
Marker - the current datarecord is permanently marked and now has a yellow background to make it more easily visible.

Mark range - use this function to mark a range.

Tip: The marking criterion corresponds to the current sort criterion of the datarecords.

Print - the datasets of a marked range or of a marked line are printed out.

Delete - the datasets of the marked range or the marked line are deleted.



"More" - additional available functions are displayed.

Data export to diskette or USB

With this function, the marked data records are exported to a diskette or an USB storage medium.

If it is a device with an SN > 3000, the marked data records are exported to a connected USB storage medium. If no USB storage medium is available, the marked data records are automatically exported to a diskette.

If the USB storage medium is full or write-protected, or if during the read or write process it is disconnected, the error message "Error exporting data" appears.

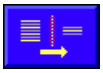
Repeated transmission of measuring data

Using this function, marked data records of the measurement database are exported again via ASTM to a connected LIS/HIS system.

Requirement:

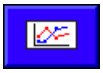
The format must be changed to ASTM!

For calibrations and QC measurements only:



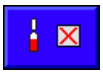
Filter - to set the required filter.

For QC measurements only:



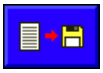
L.-J. graph - use this function to create a Levey-Jennings graph of the selected datasets from the QC database

QC measurement (Accepted) - using this function the display switches over to the list of the accepted QC measurements.

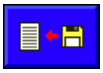


QC measurement (Rejected) - using this function, the display switches over to the list of rejected QC measurements.

For Backup / Restore only:



Copy to disk - the marked archive(s) are copied to a disk.



Copy from disk - the archive(s) saved on disk are copied directly back to the archive overview.

Restore archive - the marked dataset(s) are reinserted into the current database.

Backup now - a full databank backup is started.

Patients

Patient data that were entered are listed depending on the definition of the display ([Setup] > [Display & reports] > [Patient database] > [Patient database overview]).

Use the buttons "Page up / down" or "Up / down" to select an entry and press the [Details] button. All available information about the selected entry are displayed.

For a detailed description, see the Reference Manual, chapter *Software modes*, section *Data manager*!

Measurements

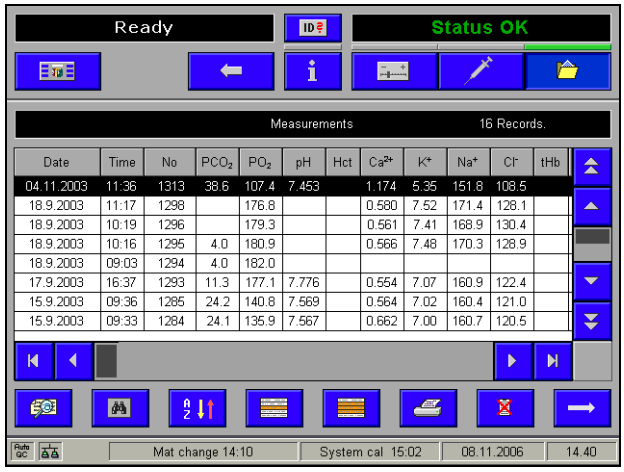


Figure B-56

Measurements that were carried out are listed depending on the definition of the display ([Setup] > [Display & reports] > [Measurement] > [Sample database overview]).

Use the buttons "Page up / down" or "Up / down" to select an entry and press the [Details] button. All available information about the selected entry are displayed.

For a detailed description, see the Reference Manual, chapter *Software modes*, section *Data manager*!

Calibrations

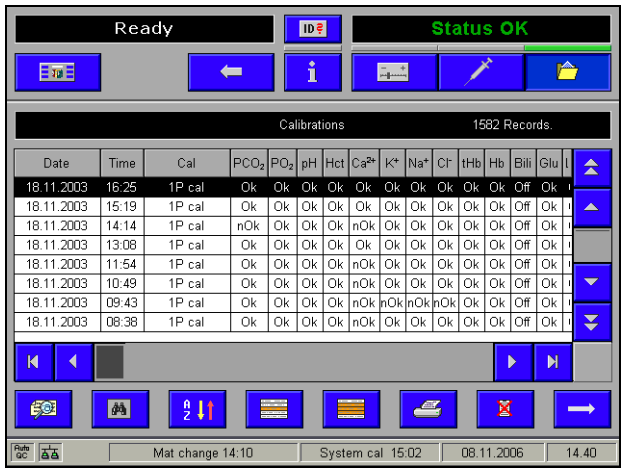


Figure B-57

Calibrations that were carried out are listed depending on the definition of the display ([Setup] > [Display & reports] > [Calibration] > [Calibration database overview]).

Use the buttons "Page up / down" or "Up / down" to select an entry and press the [Details] button. All available information about the selected entries are displayed.

QC measurements

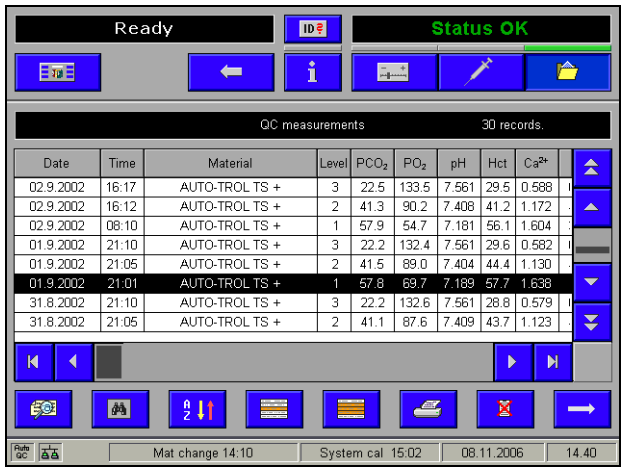


Figure B-58

QC measurements that were carried out are listed depending on the definition of the display ([Setup] > [Display & reports] > [QC measurement] > [QC database overview]).

Use the buttons "Page up / down" or "Up / down" to select an entry and press the [Details] button. All available information about the selected entry are displayed.

Instrument

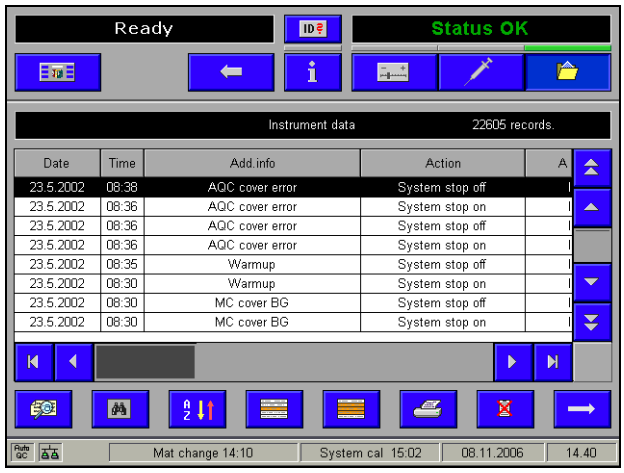


Figure B-59

Stored instrument data are listed depending on the definition of the display ([Setup] > [Display & reports] > [Instrument database] > [Instrument database overview]).

Use the buttons "Page up / down" or "Up / down" to select an entry and press the [Details] button. All information about the selected entry are displayed.

Utilities

Backup / Restore

Use this function to perform a data backup.

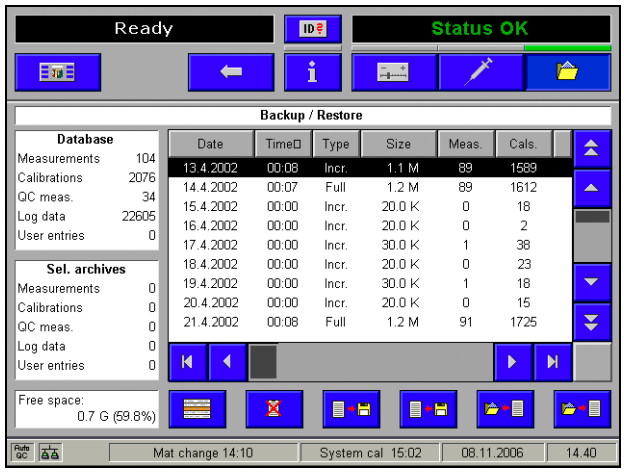


Figure B-60

For a detailed description, see the Reference Manual, chapter *Software modes*, section *Data manager*!

Protected DB functions

This area is password-protected and only accessible to authorized personnel or customer service!

Info

The following information can be displayed:

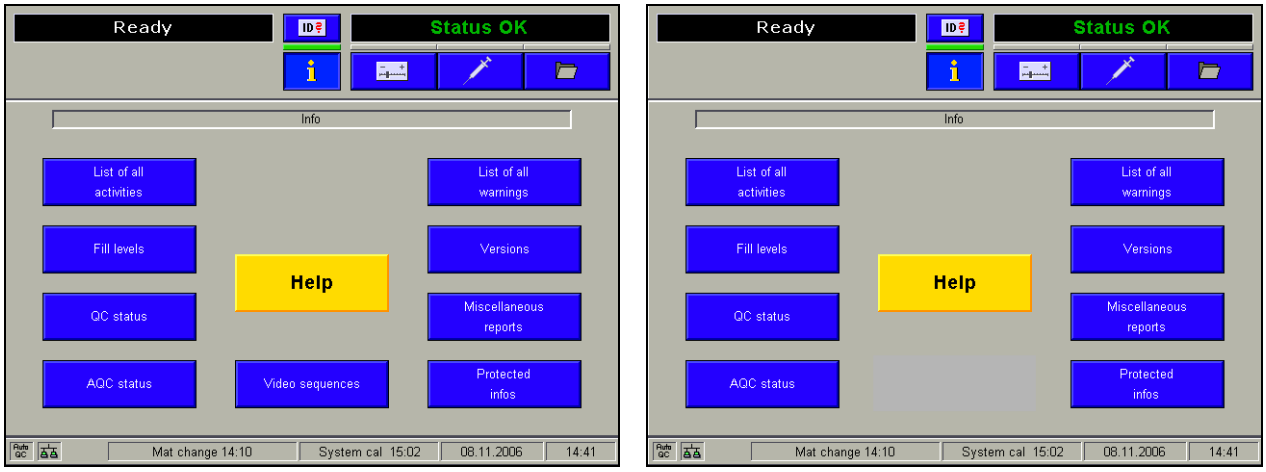


Figure B-61

Help

Use this function to retrieve online help information.

Fill level

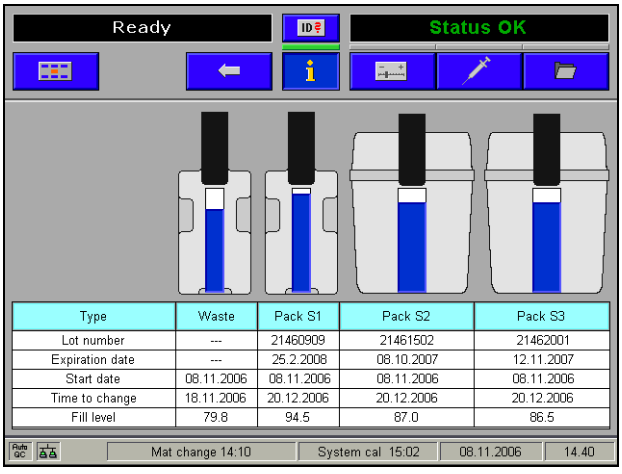


Figure B-62

This view lists all the data of the solutions, such as lot number, expiration date, expiration date, start date, the remaining "Time to change" and fill level.

QC status

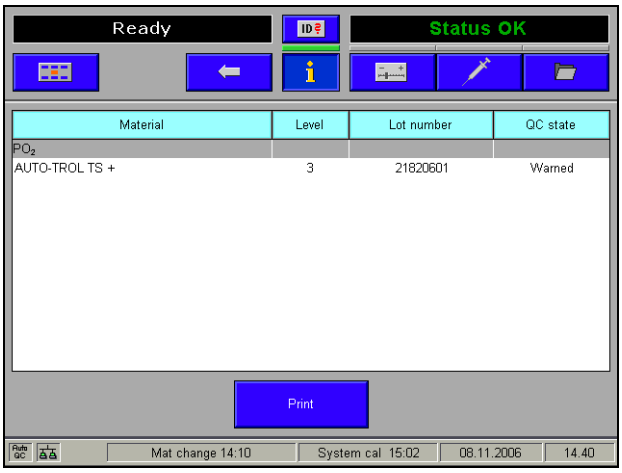


Figure B-63

Use this function to determine which material/level combination is blocking a parameter.

Press the [Print] button to print out the QC Lock Status report.

Video sequences

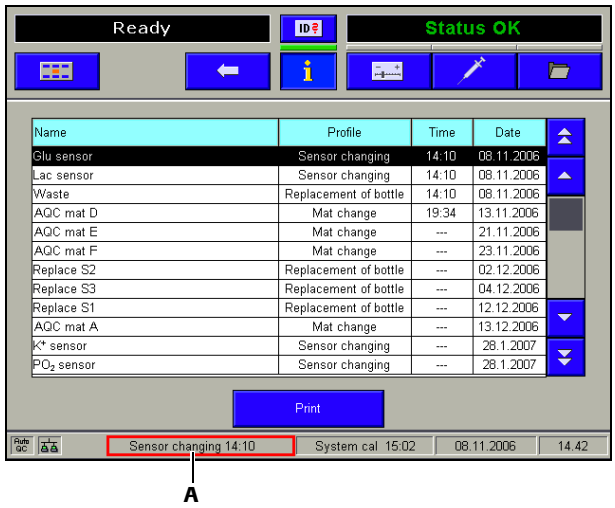
If this function is not available, contact customer service!

see Figure B-61 on page B-87!

List of all activities

Here, all the activities are listed that have to be carried out (including all the maintenance added under Setup > Times & intervals > Maintenance schedule).

Press the button [Print] to print out the list.



A Warning window for pending maintenance

Figure B-64

The warning window will always display the oldest message.

see Figure B-64!

Make sure that the tasks displayed on the screen are executed properly and immediately, as any additional pending warnings or information can otherwise not be visualized accordingly.

Sensor changing:

The sensors must be replaced without delay as soon as the specified time for sensor replacement has been reached. MSS sensors must be replaced no later than after 28 days.

Sensors that remain in the instrument after an alarm will suffer decreased performance, which can result in longer calibration times and deviating measurement values.

The time stated for changing a sensor is a standard value as from the time of insertion of a new sensor or a new electrode. During operation this value is adjusted to the respective state of the sensor/electrode and thus becomes more and more exact.

MSS cassette:

The sensors for the parameters glucose, lactate and urea are listed separately in the "List of all activities", but refer to one sensor; these sensors, however, are not changed separately, but together with an MSS cassette.

Info

List of all warnings

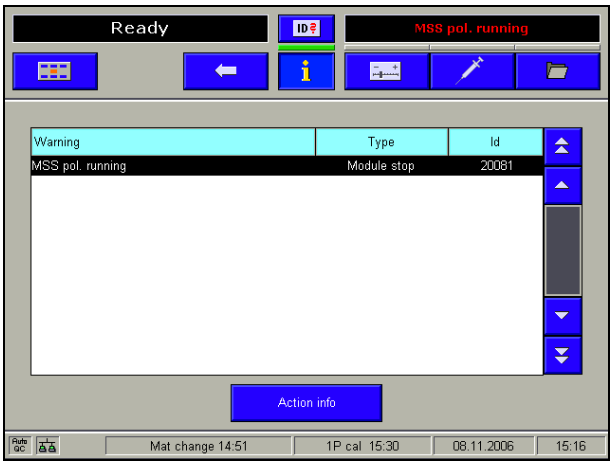


Figure B-65

Here, all the module stops and warnings are listed with their code, or it can be found in Chapter 11 *Troubleshooting*, using the respective error code (ID)

[Action info] Further information is displayed on the errors indicated.

AQC status

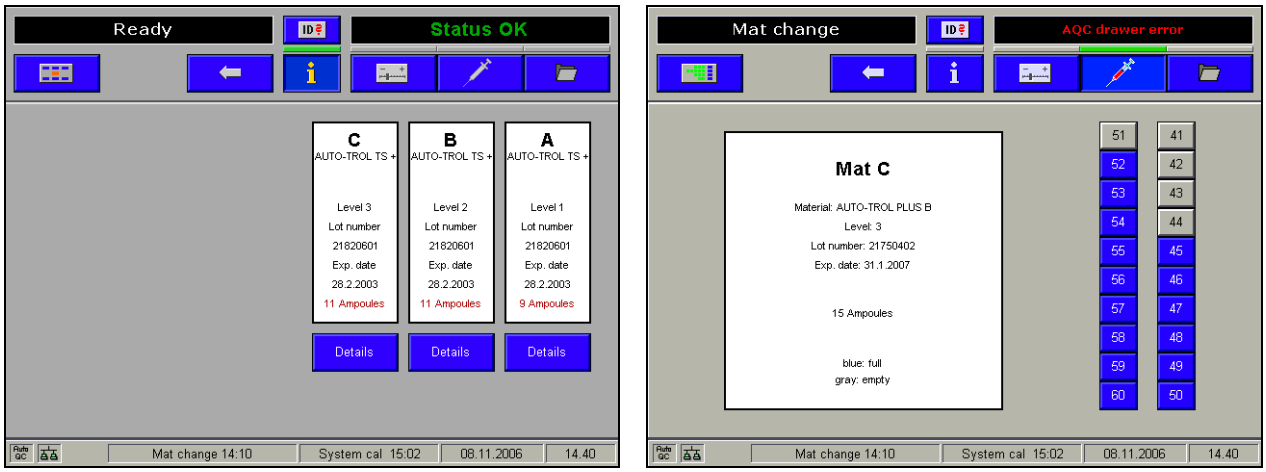


Figure B-66

It shows an overview of the mats and the AutoQC material being used.

Press the [Details] button to display the ampoule status of the selected mat (blue - full, gray - empty).

Versions

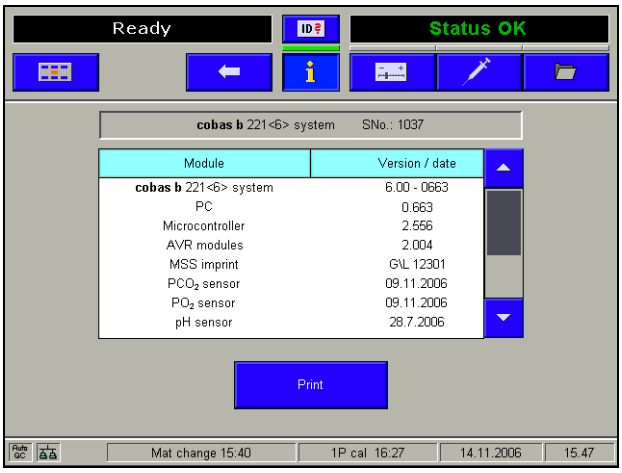


Figure B-67

Here, the software versions, the instrument serial number, the MSS cassette label and the date of insertion of the sensors are listed.

Press the button [Print] to print out the list.

Miscellaneous reports

Parameter report

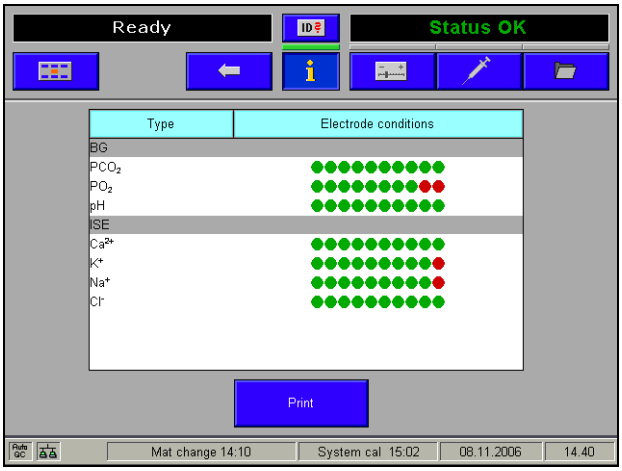


Figure B-68

Displays the status of the electrodes.

Sensor report

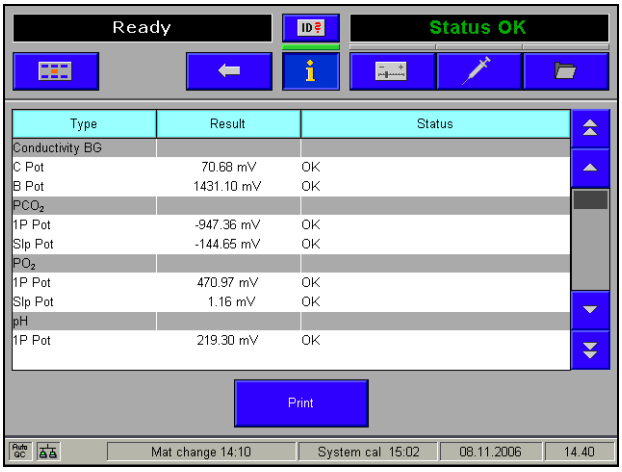


Figure B-69

Displays the current status of the electrodes / sensors.
Press the [Print] button to print out the sensor report.

Status report

Pressing [Print status report] information about the instrument and a multitude of settings will be printed.

Protected information

This area is password-protected and only accessible to authorized personnel or customer service!

Maintenance C

Maintenance

In this chapter, all maintenance work is described that is necessary for trouble-free operation of the instrument.

In this chapter *Chapter* 10

Maintenance – general

*After use, components of the **cobas b** 221 system, including tubing, waste container, fill port, etc., contain biological fluids and therefore represents a possible infectious risk.*

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. Suitable disinfection and sterilization procedures must be applied.

Decontamination

The purpose of this procedure is to minimize the risk of infections when replacing items that were in contact with blood.
Perform these decontamination procedures regularly.

Roche recommends following a decontamination procedure in addition to regulations specific to the laboratory.

Use only liquid disinfectant such as protein remover (Roche deproteinizer) or an alcohol-based (about 70%) surface disinfectant.

Do not spray disinfectant directly onto the instrument because this could cause malfunctions in the electronics.

Do not use any type of bleaching agent. Exception: Roche Deproteinizer

Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.

Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate—Danger of fire and explosion!

For safety reasons, only authorized technical service personnel may decontaminate the power pack!

Regularly decontaminate the following parts of the instrument:

- Input unit consisting of T&D module (incl. fill port) and the sample drip tray
- Touch screen
- Surfaces of the instrument
- Tubing paths

Input unit

see *Cleaning fill port and sample drip tray* on page C-8!
see *Quarterly* on page C-9!
see *Exchanging the fill port* on page C-22!

Touch Screen

see *Cleaning the touch screen* on page C-8!

Surfaces of the instrument

see *Surfaces* on page C-35!

Tubing paths

see *Cleaning the modules and tubing paths* on page C-19!

Recommended disinfectants

Do not use any type of bleaching agent. Exception: Roche Deproteinizer

Surfaces 70% alcohol surface decontaminant

Tubing paths Protein remover (Roche deproteinizer)

- **Potential dangers**

  Due to the alkaline and oxidizing character of this preparation, we cannot rule out local irritation to the skin, eyes, and mucous membranes.

- **First Aid measures**
  - After inhalation: breath fresh air, drink large amounts of water
  - After skin contact: wash with generous amounts of water, remove contaminated clothing
  - After eye contact: rinse eyes with generous amounts of water, contact an eye doctor
  - After drinking: drink large amounts of water, avoid vomiting, contact a doctor

Daily

Checking fill level

Press

☞ Info > Fill level

to check the fill level of the solutions (S1 rinse solution, S2 Fluid Pack, S3 Fluid Pack) and the waste container (W Waste Container) on a daily basis.

Exchange empty bottles, bottles whose usage date has expired, and full waste water bottle.

👁 see section *Exchange of solutions and packs* on page C-13 or section *Waste water* on page C-16.

Checking printer paper

Check daily to be sure that sufficient paper is available and exchange it, if necessary.

The printer paper is heat sensitive on one side only. Please make sure that you insert the paper roll correctly!

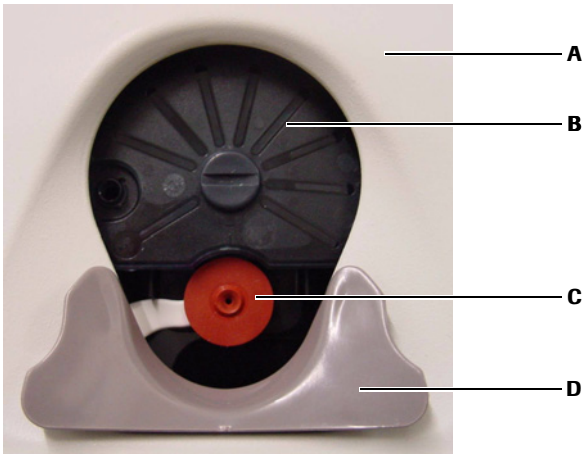
Weekly

Cleaning fill port and sample drip tray

Handle these parts with care — danger of injury!
Always wear gloves! Danger of infection!

Activate the following function, starting with the top level of the analyzer mode:

☞ System > Wash & cleaning > Clean input unit



A T&D cover
B T&D disk
C Fill port
D Sample drip tray

Figure C-1 Input unit

1 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.

2 Reinsert the sample drip tray.

3 Clean the fill port with a soft cotton swab moistened with disinfectant.

Cleaning the touch screen

Activate the following function, starting with the top level of the analyzer mode:

☞ System > Wash & cleaning > Clean screen

The keys on the screen are deactivated for 30 seconds.

Clean only with a moist cloth (for example, one that is soaked with disinfectant).
Do not use water and sprays!

Quarterly

Cleaning the T&D disk

Activate the following function, starting with the top level of the analyzer mode:

☞ System > Wash & cleaning > Clean input unit

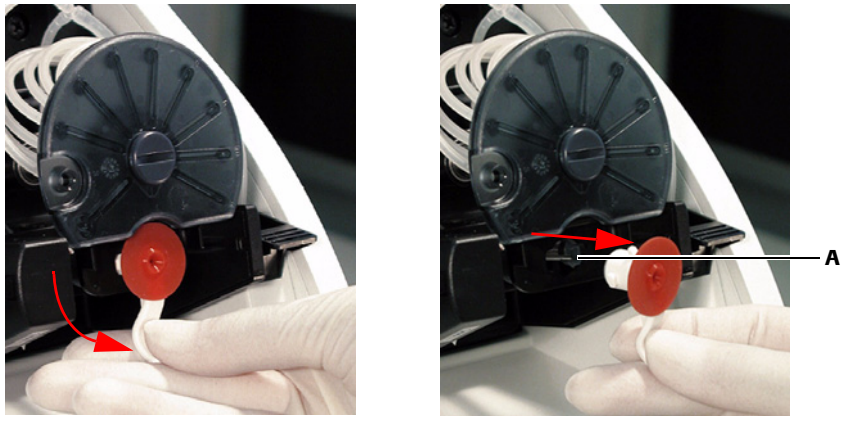
1 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.

👁 see Figure C-1 on page C-8

2 Remove the T&D cover.

3 Clean the fill port with a soft cotton swab moistened with disinfectant.

4 Rotate the fill port 90° downward and remove it.



A Needle

Figure C-2 T&D disk

5 Insert the fill port with the flat side into the slot in the T&D disk and turn it 90 degrees to the right or left. Hold the T&D disk in place during this process.

6 Remove the T&D disk.

7 Clean and decontaminate the front and back of the T&D disk.

Do not use alcohol for cleaning the T&D disk.

8 Re-install the disk in reverse order.

9 Re-insert the fill port.

10 Close the T&D cover.

11 Insert the sample drip tray.

Changing the air filter

1 Pull out the air filter using the box tongue (see below)!

Figure C-3 Air filter

2 Dispose of the air filter according to local regulations (hazardous waste!)

3 Push in the new air filter according to the figure.

see Figure C-3 on page C-10

The exchange may be performed less frequently in clean lab operations and at room temperature (significantly below the maximum permissible operating temperature).

COOX calibration (for instrument versions with COOX module only)

This calibration must always be performed following a manipulation of the cuvette, but not later than every 3 months.

To calibrate the COOX module, enter the tHb calibrator or a blood sample whose tHb values are exactly known.

To avoid injury, protect your hands with gloves and tissues when breaking open the ampoule.

Never reuse the ampoule and the capillary!

1 Take the ampoule out of the package.

2 Carefully shake the ampoule.

3 Gently tap the head of the ampoule with your fingernail to remove any liquid from the top.

4 Break open the ampoule. Completely insert the ampoule adapter into the ampoule or fill the sample into a capillary.

5 Activate the following function, starting with the top level of the analyzer mode:

☞ System > Calibration > COOX calibration

6 To start the calibration, press [Start].

The following screen appears:

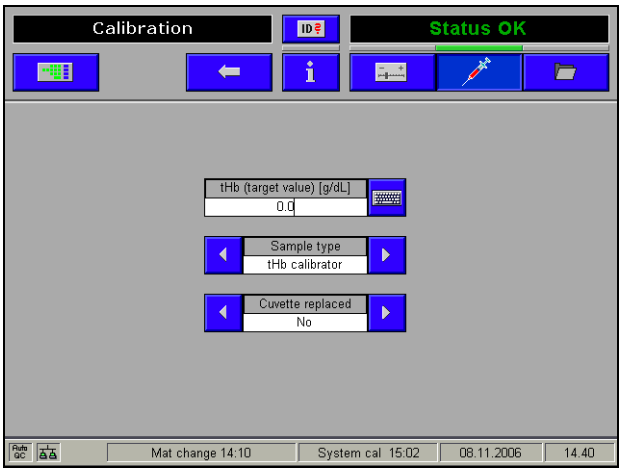


Figure C-4

7 "tHb (target value) [g/dL]": enter the desired target value using the keyboard.

Take the target value for the tHb calibrator from the label of the tHb calibrator recommended by Roche Diagnostics.

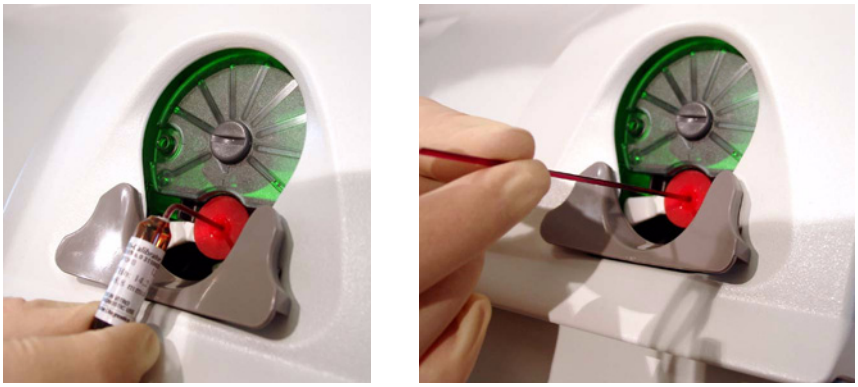
8 The unit is standard [g/dL] and can be changed, if necessary.

9 "Cuvette replaced" - Press [Yes] after a cuvette was replaced, otherwise press [No].

10 "Sample type". It is possible to select between "tHb calibrator" and "Blood" as calibration solution.

11 The target value for blood must be a known setpoint.

12 Attach the ampoule adapter (see below/A) or the capillary (see below/B) filled with tHb calibrator to the fill port (follow the instructions on the screen!).



A Ampoule adapter **B** Capillary

Figure C-5 Ampoule adapter / Capillary

The COOX calibration is carried out.

After the measurement, the result is displayed. In ideal circumstances, the tHb(i) value should be identical with the tHb(m) measurement.

If the cuvette has been replaced, no calibration value appears, just the comment "COOX calibration performed".
In event of error, repeat the COOX calibration!

This function allows for the introduction of tightened "limits" in your own estimation. In general, values in the range of +/- 20% of the setpoint can be accepted in accordance with the adjustability of the module.

If the calibration values are not acceptable, press [Reject]. The module is not calibrated and transferred to an alarm state.

A recalibration should be performed.

By pressing [Accept], the calibration values are accepted and used for calculating the layer thickness of the cuvette.

If the calculated thickness layer and the corresponding reference value do not fall within the specified internal limits, the COOX module is failed and the calibration needs to be repeated.

Sample-dependent maintenance procedures

Exchange of solutions and packs

In order to ensure the quality of the measurement results, complete a quality control test on 3 level (low, normal, high) after each exchange of solutions.

These solutions should be exchanged depending on the rate of measurement and/or the onboard stability. The screen displays the appropriate information.

A Rubber sealings

B **cobas b** 221<5> system and **cobas b** 221<6> system only

Figure C-6 Solutions and packs

S1 Rinse Solution / S2 Fluid Pack / S3 Fluid Pack

Depending on the rate of measurement and/or the onboard stability, this fluid packs should be exchanged every 6 weeks. The screen displays the appropriate information.

The use of an expired fluid pack can lead to calibration errors!

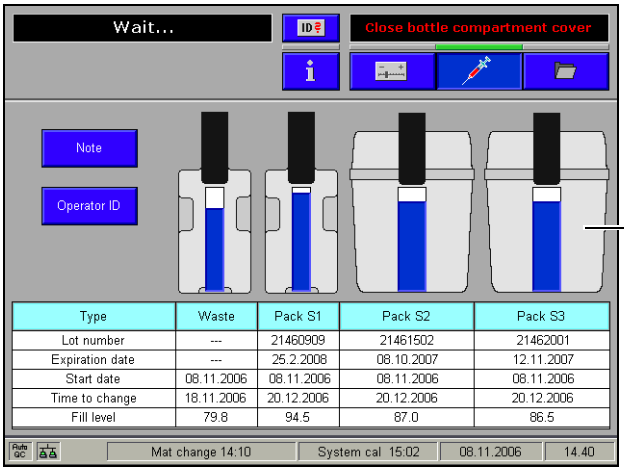
Insert a new pack which has not expired.

Never use expired bottles/packs!

Procedure starting from the analyzer mode:

1 Open the bottle compartment cover.

The following screen appears:



A **cobas b** 221<5> system and **cobas b** 221<6> system only

Figure C-7

2 Open the docking mechanism and pull out the bottles/packs to be exchanged.

Dispose of the bottles/packs according to local regulations (hazardous waste!).

Remove packs' rubber sealings.

3 Insert the new bottle or the new pack in the corresponding position until it stops.

4 The **cobas b** 221 system recognizes the correct bottle or the correct packs and verifies the expiration date.

5 If the bottle has passed the expiration date, the screen displays a warning.

6 Close the docking mechanism and the bottle compartment cover. The solutions are automatically aspirated upwards (detection in the flap).

7 A new QC measurement with all three level (low, normal, high) must be performed after every exchange of solutions and packs!

8 Make sure that the results agree with the target values.

see Chapter 7 *Quality control*!

To prevent spilling of the S1 rinse solution:

If your facility is 3000 m above sea level or higher deaerate the bottle before inserting to avoid splashing the S1 rinse solution.

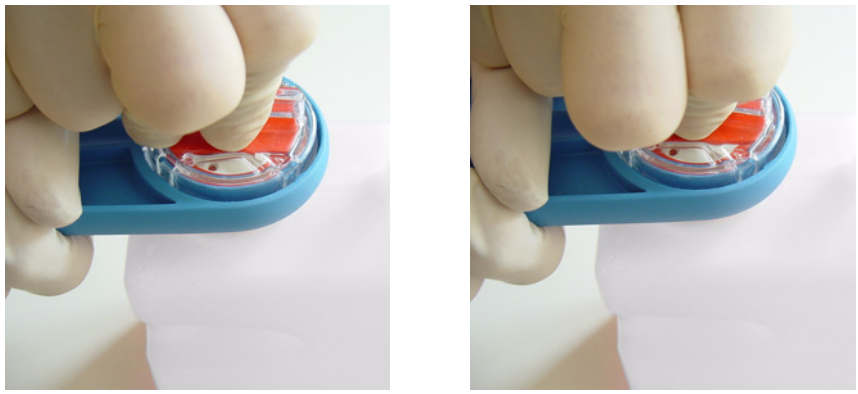
1 Place the bottle tool (see below/A) on the screw cap of the S1 rinse solution (see below/B).

A Bottle tool **B** Bottle tool on the screw cap

Figure C-8 Bottle tool

2 Press the grips together and press the transparent disk downward (see below/A).

3 Rotate the transparent disk clockwise and stop when you notice a resistance after a short distance (see below/B).



A **B**

Figure C-9 Deaerate bottle S1

Waste water

Exchange the waste water container (W Waste Container)

1 Open the bottle compartment cover.

The bottle exchange image appears on the display.

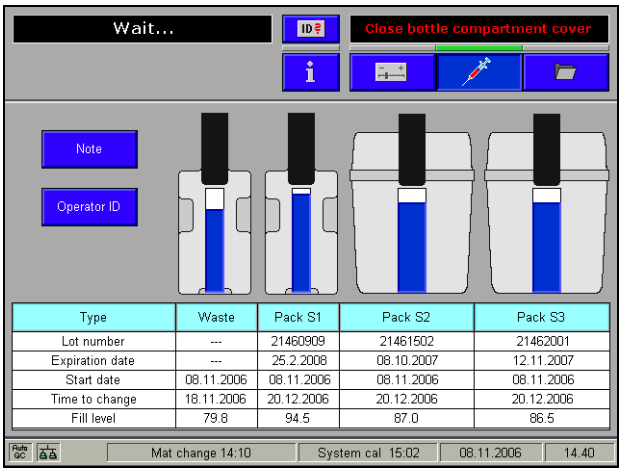


Figure C-10

Always wear gloves! Danger of infection!

2 Open the docking mechanism, hold the waste water bottle by the grip recesses and remove carefully.

Dispose of the waste water container according to local regulations (hazardous waste!).

1. Empty the W Waste Container

Always wear gloves! Danger of infection!

1 Place the bottle tool on the screw cap.

A Bottle tool **B** Screw cap with placed bottle tool

Figure C-11 Bottle tool

2 Open the screw cap by pressing the two grips together and rotate them counter-clockwise.

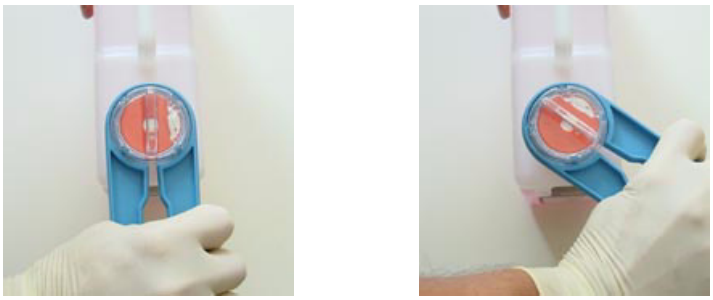


Figure C-12 Open the screw cap

3 When removing the screw cap, make sure that the green element inside the container is not moved or removed.

Figure C-13 Screw cap

Empty the waste water and decontaminate the container according to local regulations (hazardous waste!).

Flush the waste water bottle cap with plenty of water.

4 Screw the cap back onto the container.
The cap must be screwed shut until completely closed!

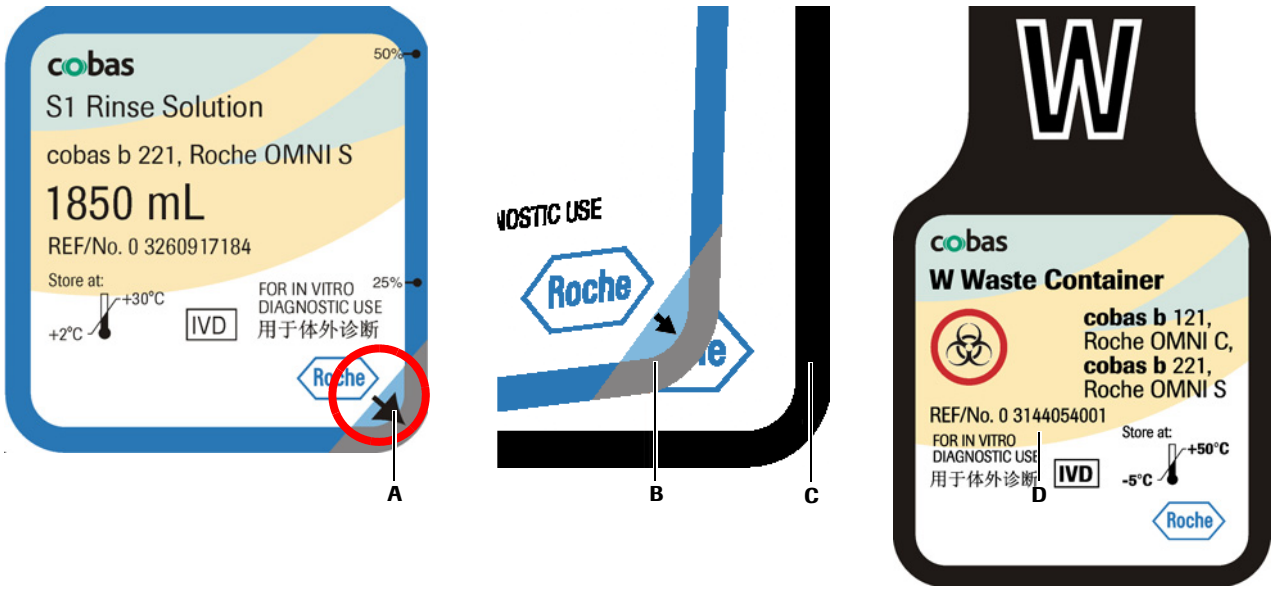
Replace waste water container and the screw cap after approx. 5 uses!

Dispose of the waste water container according to applicable local codes and regulations (hazardous waste!).

2. Using the empty S1 rinse solution bottle as W waste container

- Remove the sticker from the empty bottle of S1 rinse solution.

This sticker may not be reused – discard immediately.



A Remove the S1 sticker from the bottle at this location.

B Pull off the sticker beginning from the lower right corner (arrow) until the sticker "Waste" is completely visible

C "W" sticker

D "W" sticker on the bottle of S1

Figure C-14 Sticker

Installing the waste water container

1 Push the bottle to the position for waste water W until it engages.

2 Close the docking mechanism.

3 The fill level monitoring feature recognizes the waste container as "Empty".

If the waste water container to be used is not empty:
Press [Waste fill level] and enter the fill level (a scaling on the container label gives an approximate value).

4 Close the bottle compartment cover.

Cleaning the modules and tubing paths

Module cleaning

If required, an internal cleaning procedure is automatically carried out during the 2P calibration and a system calibration (which similarly includes a 2P calibration)!

The instrument is delivered with the following standard settings for automatic internal cleaning:

Measuring module	Samples	Cycle
BG	500	never
ISE	200	never
COOX und tHb/SO_2	20	never
MSS	---	never

Table C-1

Automatic BG cleaning

If the automatic BG cleaning is activated, internal instrument data such as the measuring frequency and drift behavior of the sensors is used to automatically select an optimum cleaning interval.

see *Reference Manual* chapter 3 *Setup*, section *Times & intervals* > *Maintenance schedule*.

External cleaning

An additional external cleaning with deproteinizer should only be carried out if the measuring chamber is contaminated (protein deposits) or if components of the sample path must be exchanged.

Activate the following function, starting with the top level of the analyzer mode:

System > Wash & cleaning > Cleaning modules

Figure C-15

BG- / ISE-/ COOX- or tHb/SO_2 module:

ISE module: the frequency of the cleaning process depends on the lab-specific type of sample (physiological, pathological, fetal blood).

BG module: should be cleaned only on demand, in the following scenario:

- *visible blood clot in the BG module*
- *low PO_2 QC recoveries due to microscopic bacterial contamination of the PO_2 electrode*

1 Activate the corresponding module and press [Start external cleaning].

2 The external cleaning agent is inserted like a sample (syringe or capillary) via the fill port.

3 Each external cleaning must be followed by a wetting using whole blood or serum, press:

☞ System > Utilities > Fluid actions > Wetting routines

4 Pressing [Start internal cleaning] to carry out a cleaning using the internal cleaning solution.

MSS module (cobas b 221<5> system **and cobas b** 221<6> system **only):**

This cleaning should be performed with every exchange of the cassette, but not more than once per month (e.g. obstruction).

1 Activate the MSS module and press [Start external cleaning].

2 The external cleaning agent is inserted like a sample (syringe or capillary) via the fill port.

3 Insert a new MSS cassette using the correct procedure.

👁 see *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32!

After the cleaning, perform a polarization of the new MSS cassette.

Tubing paths

Using the function Decontamination all the tubing paths in the instrument can be decontaminated.

In order to ensure the quality of the measurement results, complete a quality control test on 3 level (low, normal, high) after the decontamination routine.

☞ System > Wash & cleaning > Decontamination

This decontamination is carried out in a similar way to the shut down routine, except that deproteinizer is used instead of distilled water.

The shutdown kit is required for carrying out this function.

The decontamination procedure must be carried out completely and may not be interrupted.

Observe the listed sequence while performing the actions.

Processing the actions:

Manual — The corresponding line of the list box contains an instruction which must be performed manually. Then press [Confirm action].

Automatic — If there is an automatic sequence for any action, you can start this by clicking [Start process].

 If an action has been completed successfully (manually or automatically), this symbol is displayed.

Unscheduled

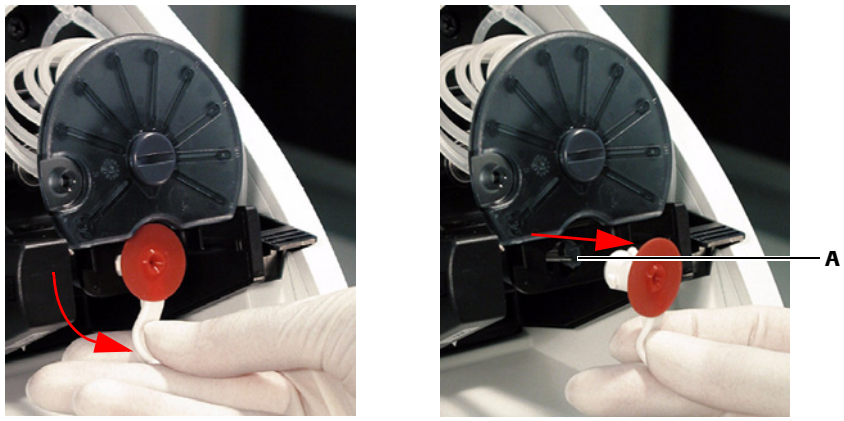
Exchanging the fill port

Dispose of the used fill port in accordance with local regulations (hazardous waste!).

Activate the following function, starting with the top level of the analyzer mode:

☞ System > Wash & cleaning > Clean input unit

1. Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.
2. Open the T&D cover.
3. Rotate fill port 90° downward and carefully remove it from the needle.



A Needle

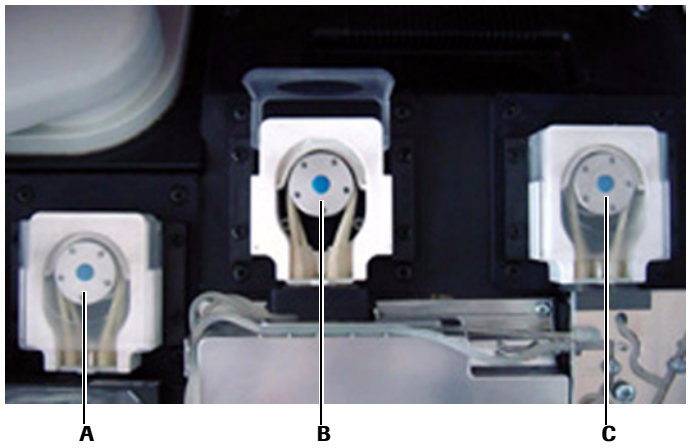
Figure C-16

4. Insert new fill port.

Do not bend the needle!

5. Close the T&D cover.
6. Reinsert the sample drip tray.
7. Close the bottle compartment cover.

Exchanging the peristaltic pump tubes



A Main pump
B MSS output pump
C MSS input pump

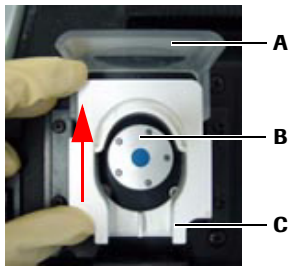
Figure C-17 Peristaltic pump

When changing the peristaltic pump tubes, proceed as follows:

Activate the following function, starting with the top level of the analyzer mode:

☞ Quick access > Maintenance

1. Select the appropriate pump tube to be changed from the list and press [Perform].
2. Remove the top cover.
3. Open the peristaltic pump's clear plastic cover (tension lever) (see below/A).

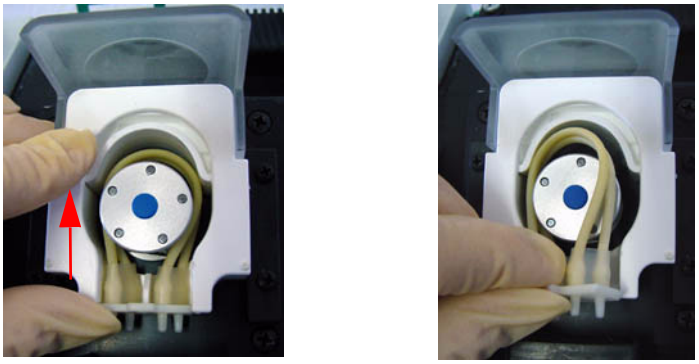


A Tension lever
B Pump head
C Linear bracket

Figure C-18 Peristaltic pump

4 Push the linear bracket (white plastic part) upwards (see below/A).

5 Remove the complete tubing set (tubing holder and tubing) of the corresponding pump (see below/B).



A Move linear bracket upwards **B** Remove tubing set

Figure C-19 Peristaltic pump

6 Check if the five rollers are easily moveable.

In case of malfunction contact customer service.

7 Place the tube around the corresponding rolling wheel. Check that the tubing set is correctly orientated (the grip end must be pointing upwards, see above/B).

8 Close the clear plastic cover (tension lever). The tubing holder is then pressed into the sealer.

9 Close the top cover.

The tubes may drip a little after being disconnected.
Remove excess fluids with a clean, absorbent cloth.

The peristaltic pump tubes are also replaced during the annual service.

see section *Additional maintenance procedures* on page C-38

Cleaning the bottle compartment

1 Open the bottle compartment cover.

The bottle exchange image appears on the display.

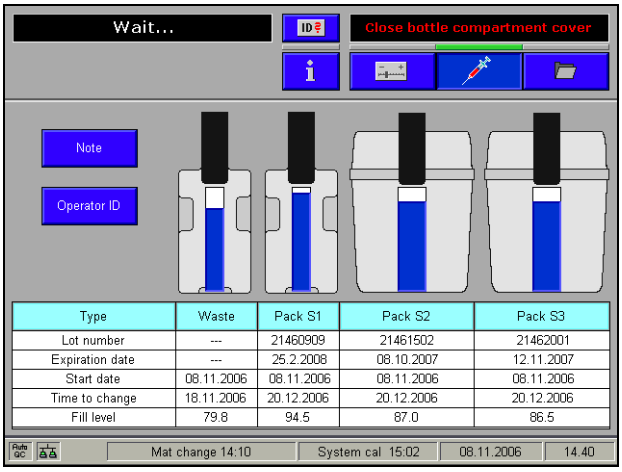


Figure C-20

2 Open the docking mechanism and pull out all the bottles or packs.

3 Clean the bottle compartment with a cloth moistened with disinfectant (e.g. disinfectant containing 70% alcohol).

4 Reinsert the bottle or packs.

see *Exchange of solutions and packs* on page C-13

5 Close the docking mechanism and the bottle compartment cover.

Replacing printer paper

The printer paper is heat sensitive on one side only. Observe the correct insertion of the thermal paper roll.

1 Open the printer cover.

2 Open the paper lid.

3 Remove the empty paper roll.

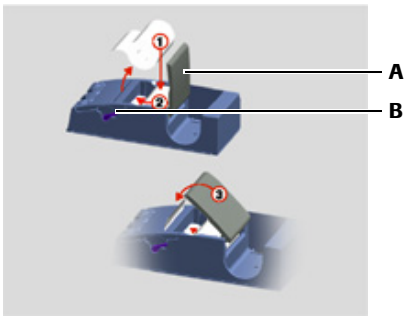
4 Ensure the paper has a clean leading edge to help start the paper through the rollers. If necessary cut the paper at a right angle.

5 Place the new paper roll into the holder, so that the roll feeds from the bottom.

6 Ensure that the printer lever is in the "down" position (see below) (only visible with opened paper cover).

Figure C-21 Printer lever

7 Feed in the beginning of the paper according to the instructions on the inside of the paper lid (see below).



A Paper lid **B** Printer lever

Figure C-22 Place printer paper- without take-up unit

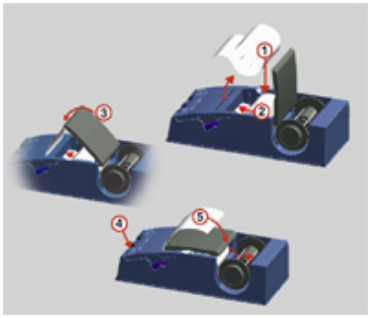


Figure C-23 Place printer paper - with take-up unit (optional)

8 The paper is automatically pulled into the printer.

If the paper is pulled in incorrectly, open the paper cover, open the printer lever and realign the paper, close the printer lever and close the paper lid again.

9 Close paper lid.

With take-up unit (optional)

1 Press the paper feed button until the paper is long enough.

2 Insert the beginning of the paper in the take-up unit according to the instructions on the inside of the paper lid.

see Figure C-23 on page C-26

Press the take-up unit (rods) fully onto the holder and rotate until the paper is taut on the rods and paper lid, so that the entire roll of paper can be taken up. During operation, the paper should be tautened now and then by turning the take-up roller.

3 Close printer cover.

With an installed take-up unit, the "Automatic Cut" function is deactivated.

Replacement of the electrodes

The electrode must be installed in the instrument no later than the imprinted "Install before" date.

see section *Conventions used in this manual* > *Other symbols* on page 7!

In order to ensure the quality of the measurement results, complete a quality control test on 3 level (low, normal, high) after each electrode exchange.

1 Remove the top cover and open the measuring chamber cover of the corresponding measurement module (apply force to push the right edge of the MC cover to the left with a finger and open up the MC cover).

In each case, open only the relevant measuring chamber.
Keep the bottle compartment cover closed.

The following screen appears:

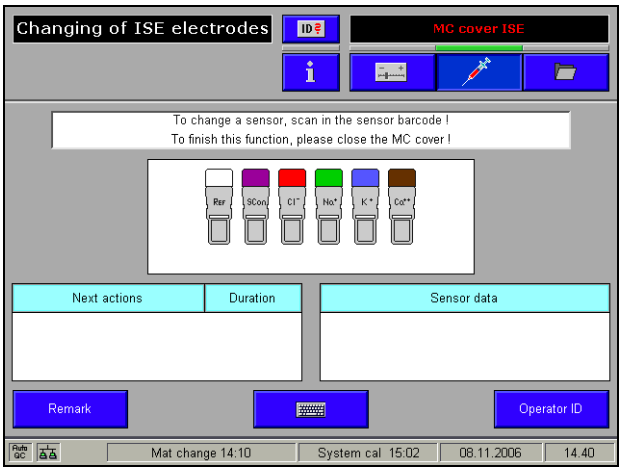


Figure C-24

2 Open the locking lever.

3 Take the appropriate electrode, move it to the left and remove it.

Dispose the electrode(s) according to local regulations (hazardous waste!).

4 If necessary, clean the measuring chamber with a cloth moistened with disinfectant (e.g. disinfectant containing 70% alcohol).

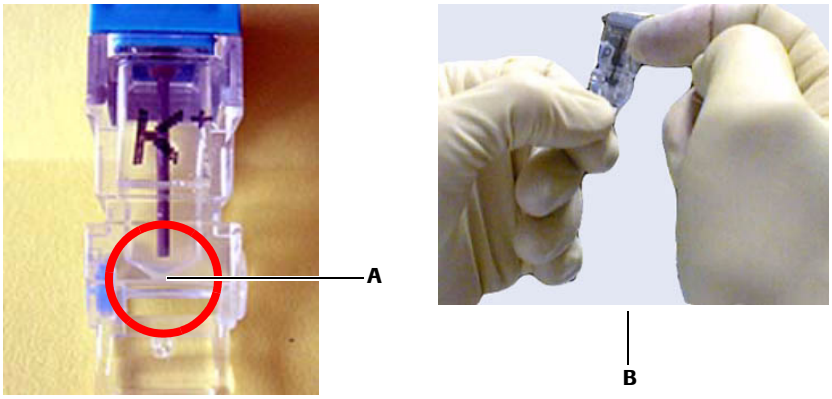
If a new electrode is not available, insert a dummy electrode instead.

SCon and the reference electrode may not be replaced with a dummy electrode.

If an electrode is replaced by a dummy electrode, it must be immediately deactivated permanently for measurements and calibrations under [Setup] > [Parameters] > [Miscellaneous settings]. To do so, deactivate the switch [Activated for calibrations].

5 Check the internal electrolyte of the electrodes for possible air bubbles (see below/A).

6 Remove any air bubbles.
Hold the electrode vertically and tap lightly with a fingernail against the electrode body (see below/B).



A Free of air bubbles! **B** Remove air bubbles

Figure C-25 Electrode

7 Insert the new electrode according to the color code.

8 Push all electrodes slightly to the right so that they are lined up together without gaps.

9 Close the locking lever.

10 Scan the barcodes located on the inner packaging of each electrode or enter the barcodes manually with the help of the keyboard.

11 The replaced electrode is shown slightly lower than the others displayed on the screen.

12 Read the next actions, their duration and the sensor data.

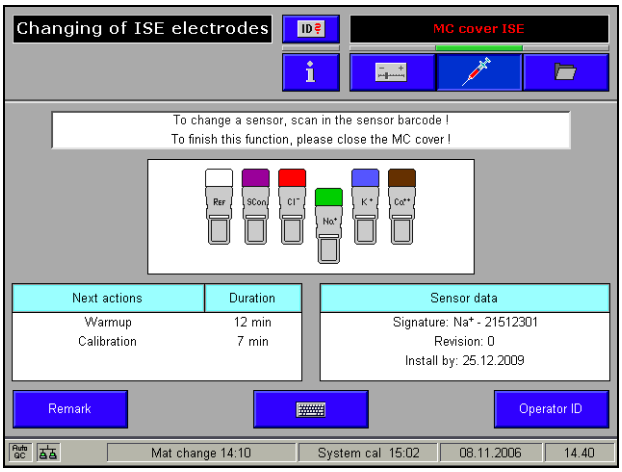


Figure C-26

13 Close the measuring chamber and then the top cover.

14 A calibration is performed following a warm-up phase.

15 After completing the calibration, perform a quality control measurement on all 3 level (low, normal, high).

16 Make sure that the results agree with the target values.

see Chapter 7 *Quality control*

Changing the reference electrode

The reference electrode must be installed in the instrument no later than the imprinted "Install before" date.

see section *Conventions used in this manual > Other symbols* on page 7!

In order to ensure the quality of the measurement results, complete a quality control test on 3 level (low, normal, high) after each electrode exchange

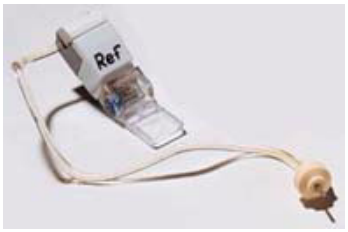


Figure C-27 Reference electrode

1 Remove the top cover and open the measuring chamber cover.

In each case, open only the relevant measuring chamber.

Keep the bottle compartment cover closed.

The following screen appears:

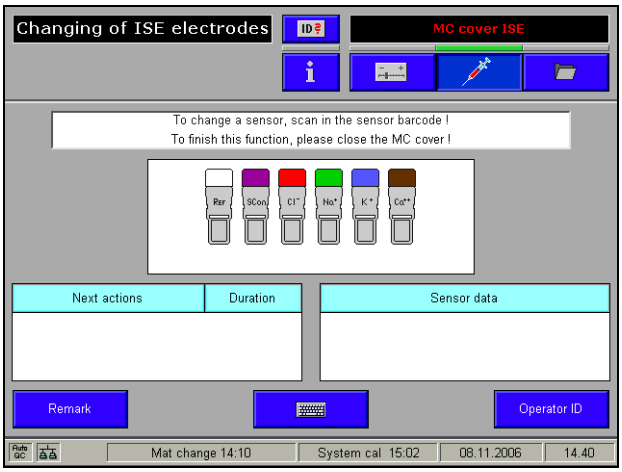


Figure C-28

2 Open the locking lever.

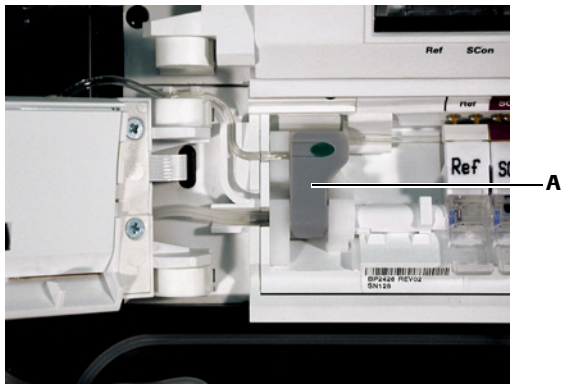
3 Remove the reference electrode.

4 Remove the white connector from the measuring chamber cartridge.

5 Insert the new reference electrode.

6 Attach the white connector at the end of the tube to the measuring chamber cartridge.

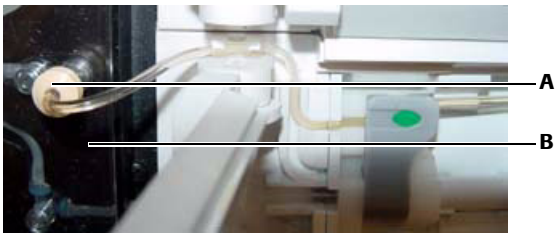
7 Insert the reference tube into the upper tube guide channel of the left locking lever and into the tube holder of the cover hinge. Close the locking lever.



A Locking lever

Figure C-29 Insert the reference electrode

8 Connect the white connector on the end of the tube to the measuring chamber cassette (see below).



A Connector **B** Measuring chamber cassette

Figure C-30 Insert the reference electrode 2

9 Scan the barcode of the exchanged reference electrode located on the inner packaging or enter the barcodes manually with the help of the keyboard.

10 Close the measuring chamber and top cover.

11 A conductivity calibration is performed following a warm-up phase.

12 A new QC measurement with all three level (low, normal, high) must be performed after every exchange of a reference electrode!

Make sure that the results agree with the target values

see Chapter 7 *Quality control*

Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)

The MSS cassette must be installed in the instrument no later than the imprinted "Install before" date.

see section *Conventions used in this manual > Other symbols* on page 7!

Attention:

Replace the MSS cassette within 28 days of installation!

In order to ensure the quality of the measurement results, complete a quality control test on 3 level (low, normal, high) after each MSS cassette exchange.

Before exchanging the MSS cassette, it is absolutely necessary to prepare a syringe or capillary with whole blood for polarization.

The blood should have a volume of at least 150 µL, contain heparin as an anticoagulant, and be stored for less than 24 hours.

Hold the MSS cassette only at the designated handle and avoid touching the contacts.

1 Remove the top cover.

2 Open the cover of the MSS module (apply force to the right edge of the MC cover with a finger to push it to the left and open up the MC cover).

Keep the bottle compartment cover closed.

The following screen appears:

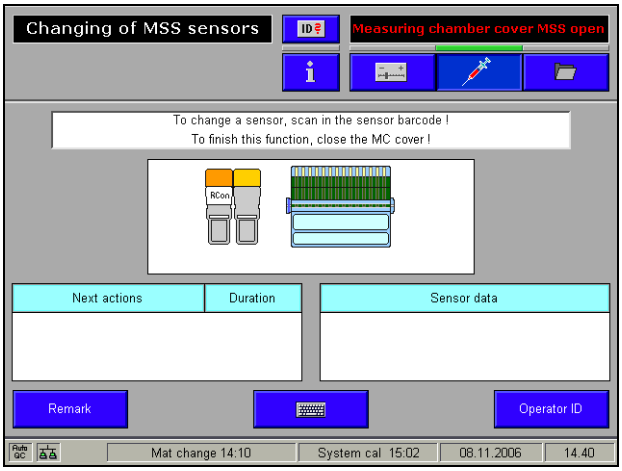
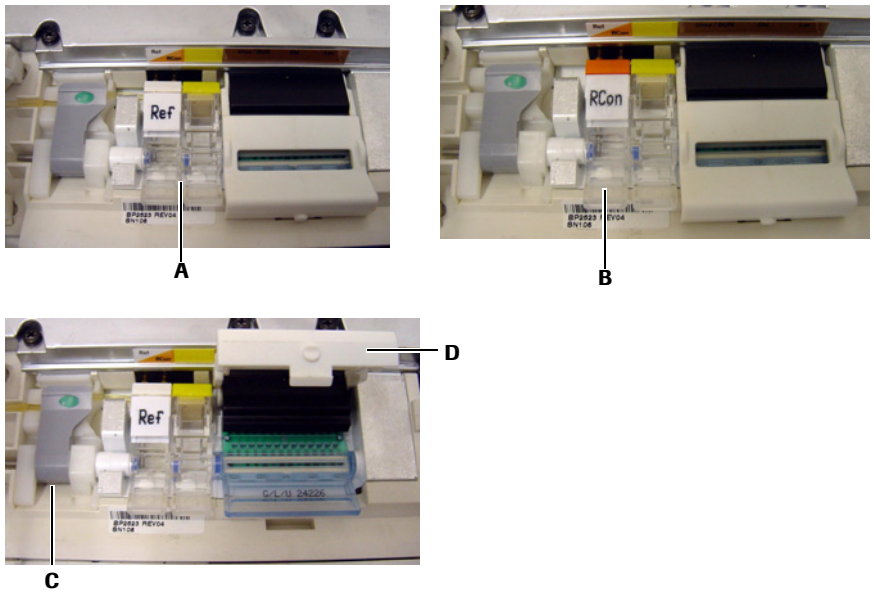


Figure C-31

3 Open the contact clip and the locking lever.

4 Push the reference contact (RCon) (see below/B) or the MSS reference electrode (Ref+ Dummy) (see below/A) and the MSS cassette slightly to the left in the direction of the arrow and remove the MSS cassette.



A Glu/Lac/Urea
B Glu or Glu/Lac
C Locking lever
D Contact clip

Figure C-32 MSS measuring chamber

5 Insert the new MSS cassette, and close the locking lever and the contact clip.

6 Read in the barcode from the packaging of the MSS cassette.

7 Close the measuring chamber and top cover.

8 Follow the instructions on the screen. The prepared blood sample is inserted into the fill port similar to a measurement

see Chapter 6 *Measurement*

9 The MSS cassette is subsequently exposed to liquid, polarized, heated and calibrated.

10 If the automatic polarization was not successful and the MSS parameters are not calibrated, a manual polarization must be performed.

11 Activate the following function, starting with the top level of the analyzer mode:

☞ System > Utilities > MSS polarization

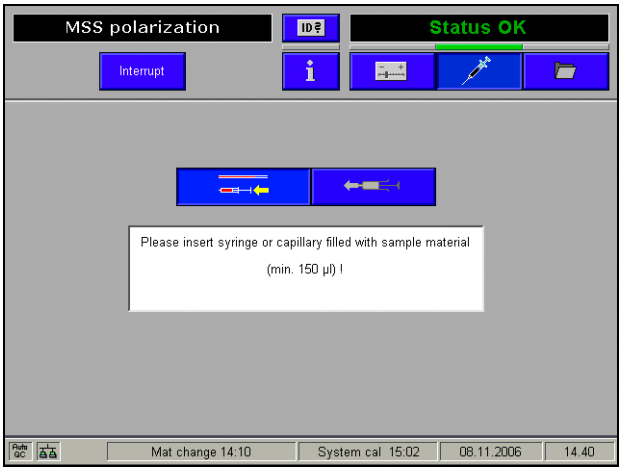


Figure C-33

12 Follow the instructions on the screen.

13 A new QC measurement must be performed with all three level (low, normal, high) after every exchange of the MSS cassette.

Make sure that the results agree with the target values.

👁 see Chapter 7 *Quality control*

Cleaning the measuring chambers

1 Remove the top cover and open the measuring chamber cover.

2 Remove all electrodes.

👁 see *Replacement of the electrodes* on page C-27

3 Clean the measuring chamber with a cloth moistened with disinfectant (e.g. disinfectant containing 70% alcohol).

4 Reinsert the electrodes.

5 Close the measuring chamber cover and top cover.

Do not scan a barcode! Instead, perform the following calibrations:

BG, ISE: calibrating the mixing system, 2P calibration

MSS: system calibration

👁 see Chapter 8 *Calibration*, section *User-activated calibrations* on page B-66

Surfaces

Do not attempt to decontaminate any part of the instrument before shutting it down and unplugging it from the power source.

Before plugging the instrument back in and turning it on, always wait 15 minutes to allow the disinfectant to evaporate — Danger of fire and explosion!

For safety reasons, only authorized customer service personnel may decontaminate the power pack!

Regularly decontaminate all outer surfaces of the instrument, including all covers (e.g. printer cover, bottle compartment cover, top cover, T&D cover), with the disinfectant according to the lab-specific regulations.

Very dirty surfaces should first be cleaned with a swab or paper towel that has been soaked in distilled water. All removable covers (e.g. instrument cover) can be removed, sprayed with surface disinfectant and subsequently disinfected using swabs or cellulose.

Some surfaces require extended soaking to achieve cleaning.

Never spray parts that cannot be removed or that are inside the instrument!

see section *Decontamination* on page C-5!

Changing of AutoQC mats

Starting with the top level of the analyzer mode.

1 Pull out the AutoQC drawer.

The following screen appears:

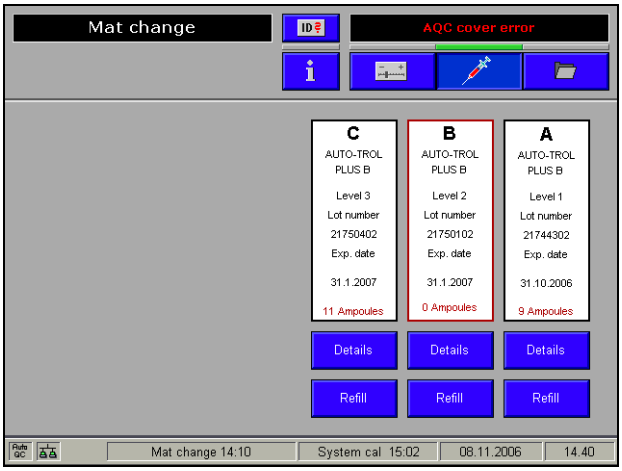


Figure C-34

2 Remove the empty mat from the ampoule holder.

If individual ampoules remain in the white ampoule holder after removing the mats, note that these open ampoules may break on removal with the attendant risk of injury.
Before inserting a new mat remove them all carefully!

Always wear gloves!

If ampoules have expired as specified in the insert sheet, dispose of mats in accordance with local regulations.

CAUTION: danger of spilling!

3 Take a full mat (20 ampoules) from the package.

4 Turn the mat so that the necks of the ampoules face down. Gently wave but do not shake the mat and ensure that the necks of the ampoules are free of air bubbles.

Figure C-35 AutoQC mat

5 Place the mat in the defined position (A-F) of the ampoule block so that the ampoules are no longer visible.

6 Press [Refill].

The following question appears:

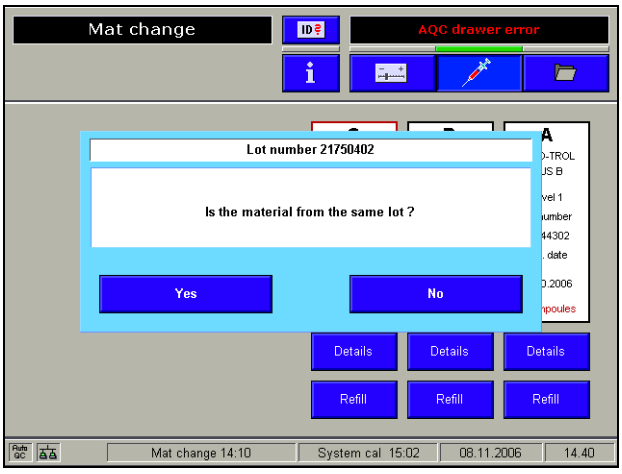


Figure C-36

7 Press [Yes] – if the mat is replaced with a new one of the same lot. The number of the ampoules is set to 20.

Press [No],], if the new mat was not inserted from the same batch.

In this case the material has to be newly defined.
See Chapter 7 Quality control, section Material setup on page B-36!

8 In case the mats are not completely filled press [Details]. By pressing the corresponding key the status of the selected ampoule can be changed (see below) and/or the ampoules to be measured can be selected.

This function can also be used when full ampoules are removed from the mat for manual measurement.

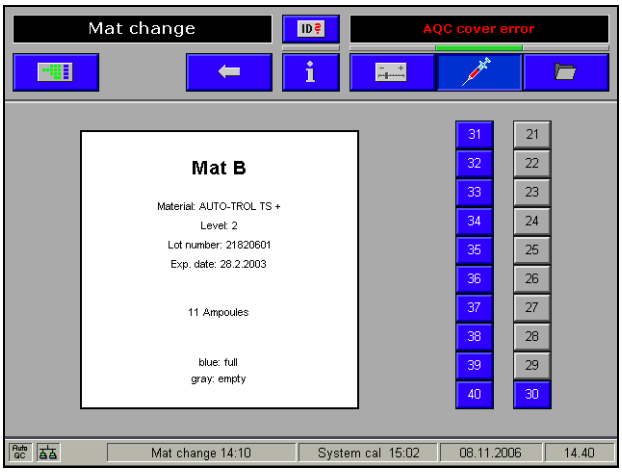


Figure C-37

9 Close the AutoQC drawer.

Additional maintenance procedures

The listed maintenance procedures may only be performed by the Technical Support or by Roche authorized personnel.

The components have been tested during development of the instrument to identify worn parts. They must be replaced at the annual service to prevent potential malfunctions.

Yearly service

In the course of the yearly service following components have to be replaced:

cobas b 221<1>-<6> system:

- Sample tube
- Fill port
- T&D tubing set
- PP pump head
- PP pump tube
- FMS tubing set
- Waste separator
- Bypass nipple
- Bacteria filter
- T&D disk
- Tubing set tHb/COOX

cobas b 221<2>/<4>/<6> system only:

- Cuvette
- Cuvette seals
- Hemolyzer tube

The tubing paths must also be disinfected annually and the baro value must be checked.

Replacement every three years

Every three years the following components have to be replaced:

cobas b 221<1>-<6> system

- Sample tube
- Fill port
- T&D tubing set
- PP pump head
- PP pump tube
- FMS tubing set
- Waste separator

- Bypass nipple
- Bacteria filter
- T&D disk
- Tubing set tHb/COOX
- Sample distributor cartridge
- Measuring chamber cartridge
- Hb cartridge
- Waste tubing
- VP tubing set

cobas b 221<2>/<4>/<6> system only:

- Cuvette
- Cuvette seals
- Hemolyzer tube

The tubing paths must also be disinfected annually and the baro value must be checked.

Troubleshooting D

Troubleshooting

In this chapter, all fault messages, their causes and remedies are described. These are also displayed directly on the instrument screen. All messages are arranged according to info number.

In this chapter *Chapter* 11

Troubleshooting – general

*After use, components of the **cobas b** 221 system, including tubing, waste container, fill port, etc., contain biological fluids and represent therefore a possible infectious risk.*

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 sterilisation procedures must be applied.

The **cobas b** 221 system can monitor for air bubbles, clots, leaks, and blockages in the system. Should the instrument detect any of these problems, an error message will occur in the form of a system stop, module stop, or status message depending on the issue.

Depending on the error, the font in the error/message window changes color:

- System stop: to red
- Module stop: to yellow
- System warnings and status messages: to white

For all system stops, module stops and status messages for measurement and calibration values, a fault analysis and removal suggestions appear directly on the screen.

System stops

This error creates a window outlined in red halting the analyzer. An error message in red is also displayed in the error window (upper right hand corner) on the display screen. The error window will remain until corrective action is taken.

No.	Message	Cause	Action
10001	Flap W	Docking mechanism for waste is open.	• Close mechnism! If the error persists, contact Technical Support!
10002	Out of operation	The instrument has been taken out of operation.	• Perform installation procedure. 👁 see Chapter 3 *Installation and shutdown*, section *Installation* on page A-27!
10003	Warmup	The instrument warms up after power-on or power fail.	• Wait until the warmup is finished and perform installation procedures if necessary. 👁 see Chapter 3 *Installation and shutdown*, section *Installation* on page A-27!
10004	Economy mode	The instrument is in automatic or manual economy mode.	• To return to the "ready" mode press [Exit].

Table D-1 System stops

No.	Message	Cause	Action
10005	Comm. error PC-µC	Communications between PC and microcontroller is interrupted.	• Turn the instrument off and on again. If the error persists, contact Technical Support.
10006	Download error	The download process to the microcontroller failed.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10008	No waste container	Waste container is missing.	• Insert container. If the error persists, contact Technical Support.
10009	Actuator bus current overload	An error was recognized in a hardware component.	• Perform **General hardware test** to correct the error: **System** > **Diagnostics** If the error persists, turn the instrument off and contact Technical Support.
10010	Valve bus current overload	An error was recognized in a hardware component.	• Perform **General hardware test** to correct the error: **System** > **Diagnostics** If the error persists, turn the instrument off and contact Technical Support.
10012	µC memory overrun	A microcontroller memory overflow was detected	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10016	Bottle compartment cover open		• Close the bottle compartment cover. If the error persists, contact Technical Support.
10017	Bypass wash error 1	Sample sensor SS2 detects not enough air during wash process.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support (wash-water jet is plugged).
10018	SD wash error 1	Sample sensor SS2 detects not enough air during wash process.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support (wash-water jet is plugged).
10019	Waste container full		• Insert empty waste container or enter correct fill level.
10020	Rinse bottle empty	The transponder on the S1 Rinse Solution bottle indicates an empty bottle	• Insert new S1 Rinse Solution. 👁 see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13.
10021	Flap S1	Docking mechanism for S1 Rinse Solution is open.	• Close mechanism!
10022	µC Reset		• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10023	Power fail	A power fail occured.	• The instrument will be ready for operation after warmup.
10024	No wash-water container		• Insert S1 Rinse Solution!

Table D-1 System stops

No.	Message	Cause	Action
10025	Check date and time		• Check date and time in the "Setup" mode and perform any necessary changes: **Setup** > **Times & intervals** > **Act. time date**
10026	Bypass wash error 2	Sample sensor SS2 detects insufficient water during wash process.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support.
10027	SD wash error 2	Sample sensor SS2 detects not enough water during wash process..	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10028	S1 on board time expired	On-board time of S1 Rinse Solution expired.	• Insert new S1 Rinse Solution
10029	S1 expired	S1 Rinse Solution expired.	• Insert new S1 Rinse Solution
10032	Microcontroller communications error	A communications problem occurred at the microcontroller.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10033	COOX communications error	A communications problem occurred at the microcontroller.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10034	AQC communications error	A communications problem occurred at the microcontroller.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10039	Vacuum reduction not ok	Low pressure reduced insufficient. V13 does not open.	• Press **Continue** to correct the error. If the error persists, contact Technical Support!
10040	Vacuum error	Vacuum buildup is insufficient.	• To localize the error, perform **General fluidics test**: **System** > **Diagnostics** • Start **Vacuum pump** test:: **System** > **Component test** > **Aggregats** If the pump output is more than 20 % over or under the reference value, contact Technical Support!
10041	Waste error 1	The waste system is leaking	• Insert new waste container.
10042	Waste error 2	The waste ventilation path is blocked	• Insert new waste container.
10043	Separator sens. error	The optical fluid sensor in the waste separator could not be calibrated.	Contact Technical Support.
10044	Separator error	The fluid in the separator could not drain.	• To correct the error, stop injection of the sample when acoustic signal or visual indication on the screen occurs. • Insert new waste container and press **Continue**. If the error persists, contact Technical Support.
10045	Check Waste fill level	Measured waste fill level differs too much from calculated value	• Check fill level and enter correctly.

Table D-1 System stops

No.	Message	Cause	Action
10046	Waste line blocked	The connection from separator into the waste container is not continuous.	• Insert new waste container. If the error persists, contact Technical Support.
10047	VPS error	The vacuum pump protection contains fluid. Vacuum buildup is not possible.	Contact Technical Support.
10048	Error SS1	The optical sample sensor at the input of the BG module could not be calibrated.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10049	Error SS2	The optical sample sensor at the end of the sample inlet path could not be calibrated.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10050	Error SS3	The optical sample sensor in the Hb cartridge could not be calibrated.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10051	Error SS4	The optical sample sensor at the input of the MSS module could not be calibrated.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10052	Error SS6	The optical sample sensor in the middle of the sample inlet path could not be calibrated.	• Perform **Wash** again: **System** > **Wash & Cleaning** If the error persists, contact Technical Support!
10054	Baro sensor error	The measured barometric pressure falls outside the specified range.	Contact Technical Support.
10056 - 10067	Process error + additional information	A subprogram did not report back.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10088	ADC error		• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10089 - 10094	Comm. error + additional information	A subprogram did not report back.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10095 - 10097	Timing error	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.

Table D-1 System stops

No.	Message	Cause	Action
10098	Timing error COOX measurement	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected: • Print **Mesurement reports** Quick access > Last measurement • Print **Sensor report** **Info > Miscellaneous reports** and contact Technical Support.
10099 - 10112	Timing error	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected: • Print **Mesurement reports** Quick access > Last measurement and contact Technical Support.
10113 - 10117	Comm. error + additional information	A subprogram did not report back.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10118 - 10119	Timing error MSS	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10120 - 10121	Timing error	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10123 - 10126	Comm. error D cal.	A subprogram did not report back.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.
10127	Timing error MSS	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.

Table D-1 System stops

No.	Message	Cause	Action
10128	Timing error	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected: • Print **Mesurement reports** Quick access > Last measurement and contact Technical Support.
10130	Timing error COOX	An asynchrony occurred between processes and measuring.	• Press **Continue** to correct the error. • If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected: • Print **Mesurement reports** Quick access > Last measurement • Print **Sensor report** **Info > Miscellaneous reports** and contact Technical Support.
10155	AQC drawer open	The AutoQC drawer is open.	• Close the AQC drawer. If the error persists (in case of closed AutoQC drawer cover with displayed "Mat change" screen) contact Technical Support.
10160 - 10261	File error	A file check resulted in an error.	• Perform a new SW update: **System > Utilities > Communication**
10288 - 10389	Program error	A communications error occurred as part of the programming of the module processors.	• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10416 - 10419	Hardware conflict	A defective module was detected within the scope of the module communications.	• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support and supply the error number. Turn the instrument off.
10424 - 10452	Hardware error	A defective module was detected within the scope of the module communications.	• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support and supply the error number. Turn the instrument off.
10456 - 10468	EEPROM error	The EEPROM data of a module processor are incorrect.	• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support and supply the error number. Turn the instrument off.
10469	Vacuum ADC error	A communications problem occured at the vacuum board.	• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
10470	Transponder error	An antenna of the transponder receiving circuit defective.	Contact Technical Support and supply the error number. Turn the instrument off.

Table D-1 System stops

No.	Message	Cause	Action
10471	T&D error	An error occured at the T&D module.	• Clean the T&D disk, the fill port and the plug control. 👁 see Chapter 10 *Maintenance* • Press **Initialization**: System > Component test > Aggregates > T&D module If the error persists, contact Technical Support.
10472	Transponder error S1	The transponder data of the rinse bottle could not be read.	• To correct the error, remove and reinsert the S1 Rinse Solution. • Insert new S1 Rinse Solution. If the error persists, contact Technical Support.
10488	HW test error	An error was recognized in a hardware component.	• Perform **General hardware test**: **System > Diagnostics** If the error persists, turn the instrument off and contact Technical Support.
10489	Remote lock	Instrument locked by **cobas** bge link.	• To remove lock press **Continue**. Log on as a user with the privileg **Remote unlock**. 👁 For more information on user management, see Reference Manual, chapter *Software modes*, section *Sicurity* !
10491	QC setup wizard active	The instrument was locked by starting the QC setup wizard.	• The message is removed after finishing the QC setup wizard. 👁 see Chapter 7 *Quality control*
10492	Data transfer active	The device was locked by starting the data transfer.	• The message is removed after finishing the data transfer.

Table D-1 System stops

Module stops

This error creates a message in yellow in the error window (upper right hand corner) on the display screen. This error is not a system stop. These errors identify individual issues affecting only a specific module of the analyzer and not the entire analyzer operation.

No.	Message	Cause	Action
20000	SD temperature nOk	The temperature of the sample distributor falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20016	FMS volume error	The calibration solution is aspirated into the BG measuring chamber in the specified time.	To localize the error: • Perform **Aspirate CAL B**: **System** > **Utilities** > **Fluid actions** > **Fill routines** • Perform **General fluidics test**: **System** > **Diagnostics** • After removing possible faults, perform the calibration **Mixing system**: **System** > **Calibration** • Install a new S2 Fluid Pack. see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13 • Replace pump tube of main pump. see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 If the error persists, contact Technical Support.
20017	FMS error	The mixture ratio falls outside the specified range.	To localize the error: • Perform **Aspirate CAL B / CAL A**: **System** > **Utilities** > **Fluid actions** > **Fill routines** • Perform **General fluidics test**: **System** > **Diagnostics** • After removing possible faults, insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13 If the error persists, contact Technical Support.
20018	Pack S2 empty		• Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13
20019	Flap S2	Docking mechanism for S2 Fluid Pack is open.	• Close the docking mechanism.

Table D-2 Module stops

No.	Message	Cause	Action
20020	No pack S2		• Insert the S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13
20021	ADC error cond BG/ISE"	A hardware error occured during mixture calibration.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20022	Transponder error S2	The transponder data of the S2 Fluid Pack could not be read.	• To correct the error, remove and reinsert S2 Fluid Pack. • If the error persists, replace S2 Fluid Pack 👁 see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13
20023	S2 on board time expired		• Insert the S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, *Exchange of solutions and packs* on page C-13
20032 - 20035	BG temperature nOk	The temperature of the BG measuring chamber falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20037	ADC error BG	Signal acquisition could not be performed due to a hardware error.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20048 - 20051	ISE temperature nOk	The temperature of the ISE measuring chamber falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20053	ADC error ISE	The signal acquisition could not be performed due to a hardware error.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20065	COOX lamp error	An error occurred during control of the halogen lamp.	• Perform **Polychromator calibration**: **System** > **Calibration** If the error persists, contact Technical Support.
20066	COOX lamp error	During the measurement or polychromator calibration, an error occurred while triggering the neon lamp.	• Perform **Polychromator calibration**: **System** > **Calibration** If the error persists, contact Technical Support.
20067	COOX lamp error	During the measurement or polychromator calibration, an error occurred while triggering the neon lamp.	• Perform **Polychromator calibration**: **System** > **Calibration** If the error persists, contact Technical Support.
20068	COOX HW error	The signal acquisition could not be performed due to a hardware error.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20069	COOX HW error	The supply voltage of the COOX module falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20071	COOX HW error	A communications problem occurred at the microcontroller of the COOX module.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.

Table D-2 Module stops

No.	Message	Cause	Action
20072	COOX temperature nOk	The temperature of the cuvette holder falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20073	HW test error hemolyzer	An error was recognized in a hardware component of the hemolyzer.	• To correct the error, perform **General hardware test**: **System** > **Diagnostics** If the error persists, turn the instrument off and contact Technical Support.
20080	PP error	The pump performance of the MSS output pump falls outside the specified range.	• To correct the error check PP tube (MSS output) and if necessary replace. see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform **MSS system calibration**: **System** > **Calibration**
20081	MSS pol. running	The MSS polarization phase is not finished yet.	The sensor will be operational after the system calibration which is automatically performed.
20082	MSS pol. not ok	The blood sample required for MSS polarization could not be positioned.	• To correct the error, repeat the MSS polarization - follow the instructions on the screen! **System** > **Utilities**
20083	MSS pol not ok	The MSS polarization was canceled	• To correct the error, repeat the MSS polarization - follow the instructions on the screen! **System** > **Utilities**
20084	HW test error MSS	An error was recognized in a hardware component of the MSS measuring chamber.	• To correct the error, perform **General hardware test**: **System** > **Diagnostics** If the error persists, turn the instrument off and contact Technical Support.
20085	Pack S3 empty		• Insert a new S3 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
20086	Flap S3	Docking mechanism for S3 Fluid Pack is open.	• Close docking mechanism!
20087 - 20089	MSS temperature nOk	The temperature of the MSS measuring chamber falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20091	No pack S3		• Insert new S3 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
20092	ADC error cond. MSS	A hardware error occured during initialization.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.

Table D-2 Module stops

No.	Message	Cause	Action
20093	ADC error MSS	Signal acquisition could not be performed due to a hardware error.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20094	Transponder error S3	The transponder data of the S3 Fluid Pack could not be read.	• To correct the error, remove and reinsert S3 Fluid Pack. If the error persists, replace S3 Fluid Pack.
20095	S3 on board time expired		• Insert new S3 Fluid Pack.
20096	tHb/SO_2 temp. error	The temperature of the tHb/SO_2 module falls outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20097	ADC error tHb	Signal acquisition could not be performed due to a hardware error.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.
20098	ttHb/SO_2 module not ready	tHb/SO_2 module is not ready	Changing the tHb/SO_2 module - contact Technical Support!
20112	SS5 error	The optical sample sensor is incorrectly calibrated.	• To correct the error, perform **Wash AQC** : **System** > **Wash & Cleaning** If the error persists, contact Technical Support.
20113	Module error AQC	The required XY position was not reached.	• Perform **Wash AQC**: **System** > **Wash & Cleaning** • Repeat the AutoQC measurement. If the error persists, contact Technical Support.
20114	Module error AQC	The required Z position was not reached.	• Perform **Wash AQC**: **System** > **Wash & Cleaning** • Repeat the AutoQC measurement. If the error persists, contact Technical Support.
20115 20116 20118	Module error AQC	The required position was not reached.	• Perform **Wash AQC**: **System** > **Wash & Cleaning** • Repeat the AutoQC measurement. If the error persists, contact Technical Support.
20120	AQC wash error	The SS2 detects a bad wash profile of the AQC sample line.	• Perform **Wash AQC**: **System** > **Wash & Cleaning** • Repeat the AutoQC measurement. If the error persists, contact Technical Support.
20122 - 20141	AQC pos. error	The required position was not reached.	• Perform **Wash AQC**: **System** > **Wash & Cleaning** • Repeat the AutoQC measurement. If the error persists, contact Technical Support.
20142	AQC temperature nOk	The temperature of the AQC module is outside the specified range.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support.

Table D-2 Module stops

System warnings

No.	Message	Cause	Action
30005	Cl electrode is contaminated (defective)		Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Wash & Cleaning** > **Cleaning modules** > **Start internal cleaning**. 2. **System** > **Wash & Cleaning** > **Cleaning modules** > **Start external cleaning**. 3. Replace Cl electrode 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27
30008	Pack S2 level is low	S2 Fluid Pack will be empty in the next 12 to 24 hours.	• If necessary, insert a new S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
30009	Pack S3 level is low	S3 Fluid Pack will be empty in the next 12 to 24 hours.	• If necessary, insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
30010	Rinse level is low	S1 Rinse Solution will be empty in the next 12 to 24 hours.	• If necessary, insert a new S1 Rinse Solution. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
30011	Waste is nearly full	The waste bottle will be full in the next 12 to 24 hours	• If necessary, replace and/or empty the bottle. 👁 see Chapter 10 *Maintenance*, section *Waste water* on page C-16

Table D-3 System warnings

No.	Message	Action
30012	Prep. of rinse not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Component test > Aggregates > Vacuum pump**. If a defect is detected, contact Technical Support. 2. Press System > Utilities > Fluid actions > Fill routines and start **Aspirate rinse** . 3. Insert a new S1 Rinse Solution. If this does not remove the warning, contact Technical Support.
30013	Prep. of CAL B not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start **Aspirate CAL B**. 2. Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30014	Prep. of CAL A not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start **Aspirate CAL A**. 2. Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30017	Prep. of O2 zero not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start**Aspirate O2 zero point solution**. 2. Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30018	Prep. of Na cond. not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start **Aspirate Na conditioning solution**. 2. Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30019	Prep. of clean. sol. not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start **Aspirate cleaning solution**. 2. Insert a new S2 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30020	Prep. of standby not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System > Utilities > Fluid actions > Fill routines** and start**Aspirate standby solution**. 2. Check MSS sensor for correct fit. 3. Insert a new S3 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.

Table D-4 System warnings

No.	Message	Action
30021	Prep. of Ref. MSS not ok (only if Urea is installed)	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Utilities** > **Fluid actions** > **Fill routines** and start **Fill ref. electrode MSS**. 2. Insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30022	Prep. of CAL 1 not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Utilities** > **Fluid actions** > **Fill routines** and start **Aspirate CAL 1**. 2. Insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30023	Prep. of CAL 2 not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Utilities** > **Fluid actions** > **Fill routines** and start **Aspirate CAL 2**. 2. Insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30024	Prep. of CAL 3 not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Utilities** > **Fluid actions** > **Fill routines** and start **Aspirate CAL 3**. 2. Insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.
30025	Prep. of CAL 4 not ok	Perform the following troubleshooting options step by step until the warning disappears: 1. Press **System** > **Utilities** > **Fluid actions** > **Fill routines** and start **Aspirate CAL 4**. 2. Insert a new S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this does not remove the warning, contact Technical Support.

Table D-4 System warnings

No.	Message	Cause	Action
30028	Check AQC material	At least 1 mat in the AutoQC module contains only two more full ampoules.	• If necessary, insert a new map 👁 see Chapter 10 *Maintenance*, section *Changing of AutoQC mats* on page C-35
30029	Check parameter states	One or more parameters are not calibrated	• To eliminate this error, perform **Calibration for Ready**: **System** > **Calibration**
30030	Perform manual QC measurement	Manual QC measurement is pending	• Perform QC measurement.
30031	Perform maintenance	One or more maintenance processes must be carried out.	• Perform maintenance. 👁 see Chapter 10 *Maintenance*
30032	Printer - printer lever opened	Printer lever is open	• Close printer lever. 👁 see Chapter 10 *Maintenance*, section *Replacing printer paper* on page C-25
30033	Printer - No paper	No paper available	• Insert printer paper. 👁 see Chapter 10 *Maintenance*, section *Replacing printer paper* on page C-25
30034	HW test error fan	Result of the general hardware test.	• Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support and supply the error number.
30037	Screen sharing active	A service connection was established to the instrument. The "Screen sharing" indicator will be displayed in the status line.	• This message will be removed after screen sharing was finished.

Table D-5 System warnings

Status messages of measuring and calibration values

These messages define causes that affect the measurement values and/or calibration values of the analyzer.

No.	Message	Cause	Action
1000	Sample pos. error (1)	The conductivity is not constant. Possible causes: • Blockage or leak • Separation of electrode membrane • Leaking electrodes	• If discoloration can be detected by sample material in the internal electrolyte of the electrode, it must be replaced. 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 • If the error persists perform **General fluidics test** to isolate the error: **System > Diagnostics** and afterwards contact Technical Support.
1001	Sample pos. error (2)	The conductivity is too low. Possible causes: • Blockage • No fluid in measuring chamber	• If the error persists replace S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 • Perform General fluidics test to isolate the error: **System > Diagnostics** and afterwards contact Technical Support.
1002	Sample sep. error (1)	No air packet was detected between calibration solution and sample. The sample was not aspirated or aspirated too late. Possible causes: • Deposits or blockage in measuring chamber.	Contact Technical Support!
1003	Ref. sol. asp. error	No reference solution was detected. Possible causes: • Blockage or leaks in reference system	• Perform **Fill Reference Electrode**: **System > Utilities > Fluid actions > Fill routines** • If the error persists replace S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If this error cannot be corrected, contact Technical Support.
1004	Ref. sol. pos. error	Conductivity level could not be maintained. Possible causes: • Detachment of electrode membrane • Leaking electrodes	• Check the electrode seating. • Perform **Calibration for Ready**: **System > Calibration** If this error cannot be corrected, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1005	End of sample detected	SS1 detects the end of the sample, but the measuring chamber is not yet filled. Possible causes: • Irregular sample • Insufficient sample • Improper sample	• Repeat the measurement/calibration, check for sufficient and homogeneous sample input. If the error persists, contact Technical Support.
1006	Irregular sample (1)	The measuring chamber is not filled homogeneously. Possible causes: • The sample was irregular • Leak in measuring channel • Air bubbles were detected in the measuring channel	• Repeat measurement/calibration. If the error persists, contact Technical Support.
1007	Cuvette not empty	A sample detection was not possible. Possible causes: • Deposits in the cuvette • Light level too low	• Perform **Internal cleaning**: **System > Wash & Cleaning > Clean module** (select appropriate module) > **Start internal cleaning.** • If the error persists replace PP tube (main pump). 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 If error cannot be corrected, contact Technical Support.
1008	Irregular sample (2)	The conductivity changed after closing the valve at the measuring chamber input. Possible causes: • Insufficient wetting in the measuring channel • Separation of the electrode diaphragm • Leaky electrode	• Perform **Wetting routine**: **System > Utilities > Fluid actions** If error cannot be corrected, contact Technical Support.
1009	Sample pos. error (3)	The measuring signal was not constant or the measuring channel was not uniformly filled. Possible cause: • Sample was fragmented.	• Ensure sufficient, uniform sample input. If the error persists, contact Technical Support.
1010	Sample pos. error (4)	The conductivity was too high: Possible causes: • Aspiration problems with standby solution • PP tube defective	• Check PP tube (MSS outlet) and if necessary replace. 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** If error cannot be corrected, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1011	Sample pos. error (5)	No constant conductivity at sensor input was detected. Possible causes: • Blockage or leak • PP tube (MSS outlet) defective	• Check PP tube (MSS outlet) and if necessary replace 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration** • If error persists perform **Wetting routine**: **System > Utilities > Fluid actions** • If the error persists perform **General fluidics test**: **System > Diagnostics** and afterwards contact Technical Support.
1012	Sample pos. error (6)	Conductivity at sensor input was too low. Possible causes: • Blockage • No fluid in measuring chamber • PP tube (MSS outlet) defective	• Check PP tube (MSS outlet) and if necessary replace 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform the fill routine **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration** • If error persists perform **Wetting routine**: **System > Utilities > Fluid actions** • If the error persists perform **General fluidics test**: **System > Diagnostics** and afterwards contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1013	Sample sep. error (2)	MSS: No air packet was detected between calibration solution and sample. The sample was not aspirated or aspirated too late. Possible causes: • Deposits or blockage in measuring channel. • PP tube (MSS outlet) defective	• Check PP tube (MSS outlet) and if necessary replace 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration** • If error persists perform **Wetting routine**: **System > Utilities > Fluid actions** • If the error persists perform **General fluidics test**: **System > Diagnostics** and afterwards contact Technical Support.
1014	Sample pos. error (7)	Conductivity at BSA sensor is too low. Possible causes: • Air bubbles • Poor wetting	• Perform **MSS polarization**: **System > Utilities** (follow the instructions on the screen) • Insert sufficiently large samples If error cannot be corrected, contact Technical Support.
1015	Sample pos. error (8)	Conductivity at lactate sensor is too low. Possible causes: • Air bubbles • Poor wetting	• Perform **MSS polarization**: **System > Utilities** (follow the instructions on the screen) • Insert sufficiently large samples If error cannot be corrected, contact Technical Support.
1016	Sample pos. error (9)	Conductivity at glucose sensor is too low. Possible causes: • Air bubbles • Poor wetting •	• Perform **MSS polarization**: **System > Utilities** (follow the instructions on the screen) • Insert sufficiently large samples If error cannot be corrected, contact Technical Support.
1017	Sample pos. error (10)	MSS: Conductivity was too low at the sensor input after positioning the sample/ calibration solution in the measuring chamber. Possible causes: • The sample/calibration solution was non-uniform • Insufficient sample/calibration solution detected • Insufficient wetting of the measuring channel	Ensure sufficient, uniform sample input. • Perform **Wetting routine MSS**: **System > Utilities > Fluid actions** • If the error cannot be corrected, replace MSS cassette. 👁 see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1020	Sample distr. error (1)	Unable to remove excess sample. Possible causes: • Clogging or leaky points during positioning	• Perform **General fluidics test** to isolate the error. **System > Diagnostics** and afterwards contact Technical Support.
1021	Sample distr. error (2)	No solution detected at SS3 although SS2 detected a solution. Possible causes: • Clogging • Sample inlet path leaky	• Perform **Wash**: **System > Wash & Cleaning** • If the error persists, perform **General fluidics test** to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1022	Sample distr. error (3)	Sample excess could not be extracted via transverse channel. Possible causes: • Blockage	• Perform **Wash**: **System > Wash & Cleaning** • If the error persists, perform **General fluidics test** to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1023	Sample distr. error (4)	SS4 did not detect solution Possible causes: • Blockage	• Perform **Wash**: **System > Wash & Cleaning** • If the error persists, perform **General fluidics test** to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1024	No sample detected (1)	SS3 and SS2 did not detect a sample. Possible causes: • No more sample available for the Hb module	• Insert sufficient sample amount, repeat measurement. If the error persists, contact Technical Support.
1025	No sample detected (2)	ISE: No constant conductivity of the sample was detected. Possible causes: • Fragmented sample in sample distributor	• Ensure sample entry is free of air bubbles. Repeat measurement. If the error persists, contact Technical Support.
1026	No sample detected (3)	ISE: No constant conductivity of the sample was detected. Possible causes: • Fragmented sample in sample distributor	• Ensure sample entry is free of air bubbles. Repeat measurement. If the error persists, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1027	No sample detected (4)	No sample detected in Hb module (tHb/ SO_2 or COOX modul, depending on the configuration). Possible causes: • Sample path leaky or clogged • Cuvette holder is leaky • Tubing of main pump is defective	• Check PP tube (main pump) and if necessary replace 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 • Perform **Wash**: **System > Wash & Cleaning** • If the error persists perform **General fluidics test** to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1028	Insufficient sample(1)	No sample detected in Hb module (tHb/ SO_2 or COOX modul, depending on the configuration). Possible causes: • The sample was irregular • Sample was insufficient	• Repeat measurement/calibration, check for sufficient and homogeneous sample input. If the error persists, contact Technical Support.
1029	Insufficient sample(2)	Insufficient sample for BG module was detected. Possible causes: • The sample was irregular • Sample was insufficient	• Repeat measurement/calibration, check for sufficient and homogeneous sample input. If the error persists, contact Technical Support.
1030	Insufficient sample(3)	Insufficient sample for ISE module was detected. Possible causes: • The sample was irregular • Sample was insufficient	• Repeat measurement/calibration, check for sufficient and homogeneous sample input. If the error persists, contact Technical Support
1031	Insufficient sample(4)	nsufficient sample for MSS module was detected. Possible causes: • The sample was irregular • Sample was insufficient	• Repeat measurement/calibration, check for sufficient and homogeneous sample input. • With noncalibrated sensors perform fill routine **Aspirate CAL 2/3/4**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration** If the error persists, contact Technical Support.
1032	Sample distr. error (5)	No calibration solution 1 (CAL 1) detected. Possible causes: • Blockage or leak • Tubing of main pump is defective	• Check PP tube (main pump) • Perform **Aspirate CAL 1**: **System > Utilities > Fluid actions > Fill routines** • If this error cannot be corrected, replace main pump tube 👁 see Chapter 10 *Maintenance*, section *Exchanging the peristaltic pump tubes* on page C-23 If the error persists, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1036	Insufficient sample (5)	Insufficient sample for MSS module was detected Possible causes: • The sample was irregular • Sample was insufficient	• Repeat the measurement/calibration, check for sufficient and homogeneous sample input. • With noncalibrated sensors perform fill routine **Aspirate CAL 2/3/4**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibrationfor Ready**: **System > Calibration** • If the error persists, contact Technical Support.
1037	No sample detected (8)	No sample detected in hemolyzer: Possible causes: • Sample path leaky or blocked	• Perform **Hemolyzer test**: **System > Component test > Aggregates > Hemolyzer** • If the error persists perform General fluidics test to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1038	No sample detected (9)	No rinse solution from the Hb module detected (tHb/SO_2 or COOX module, depending on the configuration) (Calibration). Possible causes: • Sample path leaky or blocked	• Perform **Wash**: **System > Wash & Cleaning** • If the error persists perform General fluidics test to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1050	No sample in SIP	No sample detected in the sample inlet path at SS2 or SS6. Possible causes: • No sample was inserted	• Perform **Wash**: **System > Wash & Cleaning** • If the error persists perform General fluidics test to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1051	No AQC sample detected	No sample was detected at SS5. Possible causes: • Sample path leaky or blocked	• Perform **Wash AQC**: **System > Wash & Cleaning** • If the error persists perform General fluidics test to isolate the error **System > Diagnostics** and afterwards contact Technical Support.
1052	No vacuum	No regulated vacuum could be build up during aspiration process. Possible causes: • Vacuum system defective	• Perform test function **Vacuum system**: **System > Component test> Control sensors** If the error persists, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2004	Repro. not OK	Sensor signal cannot be reproduced Possible causes: • Measuring channel contaminated • Bubbles on the diaphragm in the inside electrolyte of the electrode • Interference signals in the measuring channel during measurement value acquisition • Interference signals via the reference electrode during measured value acquisition • Sensitivity loss of the electrode	• Perform **Calibration for Ready**: **System > Calibration** • If error cannot be corrected, perform **Wetting routine**: **System > Utilities > Fluid actions** • Check electrode for bubbles: carefully tap against the electrode body with a finger nail to release any air bubbles from the membrane. If error cannot be corrected, replace the electrode 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 • If the sample channel is visibly soiled, perform **Internal cleaning**: **System > Wash & Cleaning > Clean module** (select appropriate module) **> Start internal cleaning.** • If the error concerns the parameter s pH, Urea, or several ISE parameters, perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • If the error persists replace reference electrode 👁 see Chapter 10 *Maintenance*, section *Changing the reference electrode* on page C-29
2009	Recal. not OK	Signal difference occurring during recalibration of PCO_2 was too large. Possible causes: • Invalid sample type used	• **Perform Calibration for Ready**: **System > Calibration** • If the error persists, replace electrode 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2011	Sensorsignal instabil	Sensor signal cannot be reproduced. Possible causes: • Invalid sample type is being used • Measuring channel contaminated • Air bubbles at the membrane in the internal electrolyte of the electrodes • Interference signals in the measuring channel during measurement acquisition • Interference signals via reference electrodes during measurement acquisition	• If this interference applies to the complete module, the reference electrode must be replaced 👁 see Chapter 10 *Maintenance*, section *Changing the reference electrode* on page C-29 • In the case of individual electrodes, they must be checked for air bubbles. Carefully tap against the electrode body with a finger nail to release any air bubbles from the membrane 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 • Perform **Calibration for Ready**: **System** > **Calibration** • Start **Stability monitor**: **System** > **Diagnostics** > **Stability monitor** and check **Details** of the **Sensor slope**. • IIf the electrode/MSS cassette is defective, it is displayed. Replace the corresponding electrode or the MSS cassette 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 bzw. *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2012	Sensor signal drifting	Sensor signal is too high. Possible causes: • Invalid sample type is being used • Rinse contaminated • Rinse - problem during aspiration • Air bubbles at the membrane in the internal electrolyte of the electrodes • Interference signals in the measuring channel during measurement acquisition • Interference signals via reference electrodes during measurement acquisition	• Perform **Calibration for Ready**: **System > Calibration** • If error cannot be corrected, start **Stability monitor**: **System > Diagnostics > Stability monitor** and check **Details** of the **Sensor slope**. • If the electrode/MSS cassette is defective, it is displayed. Replace the corresponding electrode or MSS cassette 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 or *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32 • Check electrode for air bubbles: Carefully tap against the electrode body with a finger nail to release any air bubbles from the membrane. If error cannot be corrected, replace electrode 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 • If the error persists, perform **Aspirate Rinse**: **System > Utilities > Fluid actions > Fill routines** • If necessary, replace S1 Rinse Solution 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
2016	Signal too high	The first sampling value of the O_2 zero point calibration is > 60 mV Possible causes: • An air bubble falsifies the calibration • Non-uniform O2 zero point solution • PO_2 electrode defective	• Perform **Wetting routine** for **BG**: **System > Utilities > Fluid actions** • If the error cannot be corrected, perform **Aspirate solution O2 zero**: **System > Utilities > Fluid actions > Fill routines** • If necessary, replace S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 • If the error persists, replace PO_2 electrode. 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2021	Drift alarm	A drifting of the sensor signal was detected in the "Ready" state. Possible causes: • Electrode drifts are exceeding the specified limit values • Invalid sample type is being used • Wetting problems In case of PO_2: • contamination possible	• Perform **Calibration for Ready**: **System > Calibration** • Start **Stability monitor**: **System > Diagnostics > Stability monitor** and check **Details** of the **Sensor slope**. • If the electrode/MSS cassette is defective, it is displayed. Replace the corresponding electrode or the MSS cassette see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 bzw. *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32 In case of PO_2 drift: • Perform **Internal cleaning**: **System > Wash & Cleaning > Cleaning module** (select BG module) > **Start internal cleaning** • If the error persists, optimize the cleaning interval: **Setup > Time & Intervals > Maintenance timing> BG cleaning** (change interval and/or sample counter) or contact Technical Support.
2022	Ref. drift alarm	IIn the "Ready" state drifting of the sensor signal was detected at the reference electrode. Possible causes: • Reference system fault due to bubbles • Docking mechanism for S2 Fluid Pack soiled	• Perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration** • Check S2 docking mechanism for contamination and if necessary clean it. • If the error persists replace reference electrode see Chapter 10 *Maintenance*, section *Changing the reference electrode* on page C-29
2023	Sensitivity drift	1 point sensitivity drifts. Possible causes: • The sensor did not finished the start-up period and the 1 point sensitivity highly increases.	• Perform **Calibration for Ready**: **System > Calibration**

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2024	Air bubble detected	Before washing out the sample the conductivity value was not detected as pressure-stable. Possible causes: • PO_2 electrode has not filled bubble-free • Leaky sample path in BG	• Perform **General fluidics test**: **System > Diagnostics** if error occurs, contact Technical Support. • Replace PO_2 electrode. • Replace PCO_2 electrode
2028	Mean not OK	Measurement value of calibration is outside the expected range. Possible causes: • Electrode limit exceeded	• Perform module-related system calibration: **System > Calibration > System calibration** • If several electrodes are affected, replace S2 Fluid Pack or S3 Fluid Pack (nur **cobas b** 221<5> system, **cobas b** 221<6> system) 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 • With PO_2 electrode, check barometer: **System > Component test> Control sensors > Barometer** • If the error persists, replace electrode/MSS cassette 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27
2029	ADC >>>>>	Sensor signal is above the measuring range. Possible causes: • Reference system not filled • Leaky, empty electrode	• Perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • Check seat of the electrode. • Perform **General fluidics test**: **System > Diagnostics** • If the error persists, replace electrode/MSS cassette 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27
2030	ADC <<<<<	Sensor signal is below the measuring range. Possible causes: • Reference system not filled • Leaky, empty electrode	• Perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • Check seat of the electrode. • Perform **General fluidics test**: **System > Diagnostics** • If the error persists, replace electrode/MSS cassette 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2031	Conditioning not OK	Na electrode was not conditioned. Possible causes: • S2 Fluid Pack docking mechanism is leaking • T&D leaking during aspiration of conditioning solution	• Perform **Aspirate Na cond. solution:** **System > Utilities > Fluid actions > Fill routines** • Perform **Conditioning:** **System > Utilities > Fluid actions** • Insert a new S2 Fluid Pack. • If the error persists, perform **General fluidics test:** **System > Diagnostics** and correct the leak.
2035	Linearity not OK	The sensitivity of the sensor is too low. Possible causes: • Sensor worn out	• Replace the MSS cassette. see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32 • If the error cannot be corrected, replace S3 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
2036	Interference sensitivity	The sensitivity of the sensor is too low. Possible causes: • Sensor worn out	• Replace MSS cassette. see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32 • If the error cannot be corrected, replace S3 Fluid Pack. see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
2040	Cuvette not OK	Check of layer thickness outside the expected range. Possible causes: • Cuvette is contaminated • Incorrect target value	• Perform **Poylchromator calibration:** **System > Calibration** • Perform **COOX calibration:** **System > Calibration**
2041	Ref. point not OK	Reference point is outside the expected range Possible causes: • Sample feeding clogged	• Perform **Wash:** **System > Wash & Cleaning** • If the error persists, perform **General fluidics test** to isolate the error: **System > Diagnostics** and afterwards contact Technical Support.
2042	Wavelength not OK (1)	One specific wavelength is outside the expected range.	• Perform **Poylchromator calibration:** **System > Calibration** If the error persists, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2043	Hemolysis not OK (1)	Hemolyzer is not ready	• Perform **Hemolyzer test**: **System > Component test > Aggregates > Hemolyzer**
2044	Hemolysis not OK (2)	Hemolyzer power is outside the expected range.	• Visually check the drying operation.
2070	Sensor signal unstable	tHb sensor signal is disturbed Possible causes: • Irregular sample • Sample feeding is leaking or clogged	• Perform **Internal cleaning**: **System > Wash & Cleaning > Cleaning module > tHb/SO_2 module > Start internal cleaning** • If the error persists, perform **General fluidics test** to isolate the error: **System > Diagnostics** • Replace S1 Rinse Solution. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If the error persists, contact Technical Support
2071	Measuring path dirty	The absolute limits of water calibration are outside the specified range. Possible causes: • Contaminated or defective sensor	• Perform **Internal cleaning**: **System > Wash & Cleaning > Cleaning module** (select appropriate module) > Start internal cleaning, repeat as necessary. • Replace S1 Rinse Solution. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13 If the error persists, contact Technical Support.
3000	D2 / D3 not performed	MSS standby solution was not aspirated. Possible causes: • Faulty aspiration of standby solution • Faulty aspiration of reference solution	• Check **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Check aspiration of reference solution: **System > Utilities > Fluid actions > Fill routines** • Perform **Calibration for Ready**: **System > Calibration**
3001	FMS volume error	Time-out error during aspiration of calibration solution. Possible causes: • Blockage or leak	• Check **Aspirate CAL B**: **System > Utilities > Fluid actions > Fill routines** • Perform **General fluidics test**: **System > Diagnostics**

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
3002	Temperature error	The module temperature is outside the permitted range. Possible causes: • Poor heating contact • Fan failure • Heating failure • Air filter heavily soiled or covered	• Check the temperature signals. If the temperature is outside the specified range for a long period of time, inform Technical Support.
3003	FMS error	Incorrect deviation from specified value and measurement value of FMS. Possible causes: • Blockage or leak • Defective mixer valve • Defective air valve • Blockage or leak	• To isolate error, check **Aspirate CAL B**: **System > Utilities > Fluid actions > Fill routines** • Check **Aspirate CAL A**: **System > Utilities > Fluid actions > Fill routines** • Perform **General fluidics test**: **System > Diagnostics** • Replace S2 Fluid Pack 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
3004	AQC module error"	The required position was not reached. This flag corresponds to the AQC module stops.	👁 For instructions, see: module stop *20113* on page D-15, *20114* on page D-15 and *20115 20116 20118* on page D-15!
3013	Ref. point D1 not OK	Problem during precalibration. Possible causes: • Faulty aspiration of standby solution • Faulty aspiration of MSS reference solution	• Check **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Check **Fill ref. electrode MSS**: **System > Utilities > Fluid actions > Fill routines** • Perform MSS conductivity path test with standby solution: **System > Component test > Control sensors > Contact paths**
3014	Ref. point not OK	Problem during precalibration. Possible causes: • Faulty aspiration of standby solution • Faulty aspiration of MSS reference solution	• Check **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Check **Fill ref. electrode MSS**: **System > Utilities > Fluid actions > Fill routines** • Perform MSS conductivity path test with standby solution: **System > Component test > Control sensors > Contact paths**

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
3022	Conductivity not OK	Conductivity calibration was not exited correctly.	• Print out Sensor report and check the error messages for conductivity with calibration solution CAL B or A: **Info > Miscellaneous reports**
3033	0P not OK	O_2 zero calibration was not exited correctly. Possible causes: • Aspireate O_2 zero not ok • Soiling or leak	• Perform **Aspirate O_2 zero point solution**: **System > Utilities > Fluid actions > Fill routines** • Check fill port and the T&D disc for soiling 👁 see Chapter 10 *Maintenance* • Replace S2 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
4003	Calibration pending (1)	Sensor reinserted, no calibration values available.	• Perform **Calibration for Ready**: **System > Calibration**
4008	Calibration pending (2)	Calibration is pending or was canceled.	• Perform **Calibration for Ready**: **System > Calibration**
4024	Calibration pending (3)	Sensor is or was deactivated.	• Perform **Calibration for Ready**: **System > Calibration**
5006	Calculation error (1)	UC calculation error. Possible causes: • An unapproved calculation operation occurred.	• Remove bottles/packs and reinsert them. If the error persists, contact Technical Support.
5007	Calculation error (2)	UC calculation error. Possible causes: • An unapproved calculation operation occurred.	• Remove the affected electrode and reinsert it. If the error persists, contact Technical Support.
5010	Calculation error (3)	UC calculation error (COOX). Possible causes: • An unapproved calculation operation occurred.	• Turn the instrument off and on again. If the error persists, contact Technical Support.
5011	Calculation error (4)	UC calculation error (4) (COOX). Possible causes: • An unapproved calculation operation occurred.	• Perform **Polychromator calibration**: **System > Calibration** • Turn the instrument off and on again. If the error persists, contact Technical Support.
5012	Calculation error (5)	UC calculation error (5) (COOX). Possible causes: • An unapproved calculation operation occurred.	• Check the cuvette for soiling. • Perform **Polychromator calibration**: **System > Calibration** • Turn the instrument off and on again. If the error persists, contact Technical Support.
6026	ADC error		• To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
6030	COOX HW error	A hardware error occured at the COOX module.	👁 see Details of module stop *20068* on page D-13, *20069* on page D-13 und *20071* on page D-13
6031	Neon lamp not OK	The light value of the neon lamp is too low. Possible causes: • Cuvette soiled • Optical fiber damaged • Polychromator electronics defective	• Perform **Internal cleaning**: **System** > **Wash & Cleaning** > **Cleaning module** (select appropriate module) > Start internal cleaning • Perform **Polychromator calibration**: **System** > **Calibration** If the error persists, contact Technical Support.
6032	Halogen lamp not OK	The light value of the halogen lamp is too low. Possible causes: • Cuvette soiled • Optical fiber damaged • Polychromator electronics defective	• Perform **Internal cleaning**: **System** > **Wash & Cleaning** > **Cleaning module** (select appropriate module) > Start internal cleaning • Perform **Polychromator calibration**: **System** > **Calibration** If the error persists, contact Technical Support.
7034	Solution exhausted	The pH value of the O_2 zero point solution is < 5. Possible causes: • Solution exhausted • Impurity in pack	• To correct the error replace S2 Fluid Pack 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13
8036	Ifs not OK	The BSA/Glu or BSA/Lac ratios in CAL 3 are outside the range. Possible causes: • Interference correction not possible	• Perform **Calibration for Ready**: **System** > **Calibration** • If the error cannot be corrected, replace MSS cassette 👁 see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8061	Interferences (1)	The calculated tHb value is invalid Possible causes: • Interferences • Unsuitable sample type used	• Check sample material and, if necessary, reenter the sample. If the error persists, contact Technical Support.
8062	Interferences (2)	The calculated Hb derivatives are invalid. Possible causes: • Interferences • Unsuitable sample type used	• Check sample material and, if necessary, reenter the sample. If the error persists, contact Technical Support.
8063	Interferences (3)	The calculated value of Bilirubin is invalid. Possible causes: • Interferences • Unsuitable sample type used	• Check sample material. If the error persists, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
8070	IfS repro. not OK	Non-reproducible sensor signal at interference sensor. Possible causes: • Unsuitable sample type is being used	• Perform **Wetting routine MSS**: **System > Utilities > Fluid actions** Kann der Fehler nicht behoben werden MSS-Kassette tauschen 👁 see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8071 - 8072	IfS calculation error (1) - (2)	UC calculation error (1) on interference sensor. Possible causes: • An unapproved calculation operation occurred	• Remove and reinsert S3 Fluid Pack.
8073	IfS sensor signal unstable	Interference sensor signal cannot be reproduced. Possible causes: • Unsuitable sample type is being used • Measuring channel contaminated • Interference signals in the measuring channel during measurement acquisition • Interference signals via reference electrodes during measurement acquisition	• If this interference applies to the complete module, replace reference electrode 👁 see Chapter 10 *Maintenance*, section *Changing the reference electrode* on page C-29 • Perform **Calibration for Ready**: **System > Calibration** • If error cannot be corrected start **Stability monitor**: **System > Diagnostics > Stability monitor** and check **Details** of the **Sensor slope**. • If the cassette is defective, it is displayed and should be replaced 👁 see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8074	IfS ref. point not OK	Problem at reference point of standby solution at interference sensor. Possible causes: • Aspiration of MSS standby solution not ok • Aspiration of MSS reference solution not ok	• Check **Aspirate standby solution**: **System > Utilities > Fluid actions > Fill routines** • Check **Fill ref. electrode MSS**: **System > Utilities > Fluid actions > Fill routines** • Perform MSS conductivity path test with standby solution: **System > Component test > Control sensors > Contact paths**
8075	IfS ADC error		• To correct the error turn the instrument off, wait at least 3 minutes, and turn it back on. If this error cannot be corrected, contact Technical Support.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
8076	IfS mean not OK	Calibration end value of an IfS is outside the range. Possible causes: • Problems with transponder of S3 Fluid Pack	• Replace S3 Fluid Pack. 👁 see Chapter 10 *Maintenance*, section *Exchange of solutions and packs* on page C-13. • If the error persists replace MSS cassette. • see Chapter 10 *Maintenance*, section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8077	IfS ADC >>>>>	nterference sensor signal is above ADC range Possible causes: • Reference system not filled • Leak in the measuring channel	• Perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • Check seat of the electrode. • If the error persists, replace electrode/ MSS cassette. 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 bzw. section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8078	IfS ADC <<<<<	Interference sensor signal is below ADC range Possible causes: • Reference system not filled • Leak in the measuring channel	• Perform **Fill reference electrode**: **System > Utilities > Fluid actions > Fill routines** • Check seat of the electrode. • If the error persists, replace electrode/ MSS cassette. 👁 see Chapter 10 *Maintenance*, section *Replacement of the electrodes* on page C-27 bzw. section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* on page C-32
8080	Interferences (4)	Detected sample type is invalid. Possible causes: • Interferences • Unsuitable sample type used	• Check sample material.
8081	Interferences (5)	The calculated COHb value is outside the permitted range. Possible causes: • Interferences • Unsuitable sample type used	• Check sample material.
8082	Interferences (6)	The calculated SO_2 value is outside the permitted range. Possible causes: • Interferences • Unsuitable sample type used	• Check sample material.

Table D-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
8083	Sample type conflict	Detected sample type is invalid. Possible causes: • Unsuitable sample type used	• Check sample material.
8084	Invalid sample type	A different blood type than arterial or capillary blood was used. Possible causes: • All calculation values calculated from measurement values with arterial blood cannot be output.	• Use arterial or capillary blood as sample material and set the correct blood type.
9000	Calculation error (3)	PC calculation error. Possible causes: • An unapproved calculation operation occurred.	• Contact Technical Support.
9001	Not activated	Parameter is disabled for measurement (gray).	• Enable the parameter.
9002	Not activated	Parameter is not calibrated (red X).	• Perform **Calibration for Ready.**

Table D-6 Status messages of measuring and calibration values

Status messages on the measurement report

Messages	Causes
Out of range (-)	Measurement value is outside (below) the normal range.
Out of range (+)	Measurement value is outside (above) the normal range.
tHb not OK	Indicates at the parameter SO_2, that the tHb value is outside the normal range.
#...check Hct result	The instrument finds the Hct value to be implausible.

Barcode

If problems occur reading in with the PS2 hand-held scanner 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.

   see Reference manual chapter *Software modes*, section *Component test*
5. In case of a problem, the characters are transmitted and/or displayed incorrectly, or even not transmitted.
   So proceed with the next step:
6. Unplug the barcode cable from the instrument.
7. Re-plug the barcode cable.
8. Repeat step 4 for checking again the functionality. If still not ok proceed with the next step.
9. Set the scanner by using the barcode manual to default:
   - Take the barcode scanner programming manual, select Group 1, read the barcode labeled as "Default" (A001$).
   - Select Group 10 "Intercharacter Delay", read the barcode labeled as "500uS" (B011$).

If the error persists, contact Technical Support!

Appendix E

List of consumables

In this chapter, all nessary consumables and order numbers are listed.

In this chapter

Chapter 12

Order information

To measure the respective parameter following products are required:

Electrodes

	Parameter									
	Cl^-	**Na^+**	**K^+**	**Ca^{2+}**	***P*CO_2**	***P*O_2**	**pH**	**tHb/*S*O_2**	**COOX/Bili**	**MSS**
Chloride Electrode **03111571180 (BP1729)**	X	+	+	+	+	+	+	+	+	+
Sodium Electrode 03111598180 (BP1730)	+	X	+	+	+	+	+	+	+	+
Potassium Electrode 03111628180 (BP1731)	+	+	X	+	+	+	+	+	+	+
Calcium Electrode 03111644180 (BP1732)	+	+	+	X	+	+	+	+	+	+
PCO_2 Electrode 03111679180 (BP1733)	+	+	+	+	X	+	+	+	+	+
PO_2 Electrode 03111695180 (BP1734)	+	+	+	+	+	X	+	+	+	+
pH Electrode 03111717180 (BP1735)	+	+	+	+	+	+	X	+	+	+
Reference Electrode 03111873180 (BP2081)	X	X	X	X	X	X	X	+	+	X
Reference Contact (RCon) 03112071180 (BP2258)	X	X	X	X	X	X	X	+	+	X
Sensor Contact (SCon) 03260909184 (BP2608)	+	+	+	+	+	+	+	+	+	X
Micro Electrode Dummy 03111849035 (BP1959)	X	X	X	X	X	X	X	X	X	X
GLU/LAC/UREA Cassette 03261085184 (BP2500)	+	+	+	+	+	+	+	+	+	+
GLU/LAC Cassette 03260887184 (BP2501)	+	+	+	+	+	+	+	+	+	X
GLU Cassette 03260895184 (BP2502)	+	+	+	+	+	+	+	+	+	X
MSS Dummy Sensor 03351262001	+	+	+	+	+	+	+	+	+	+

Table E-1

X	Has to be installed
+	Dummy or electrode has to be used for proper filling of the measuring chamber

Solutions

	Paramenter									
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	tHb/SO_2	COOX/Bili	MSS
S1 Rinse Solution 03260917184	X	X	X	X	X	X	X	X	X	X
S2 Fluid Pack 03260925184	X	X	X	X	X	X	X	X	X	X
S3 Fluid Pack A 03260933184	X	X	X	X	X	X	X	X	X	X
W Waste Container 03144054001	X	X	X	X	X	X	X	X	X	X
Hb Calibrator 03110923035 (BP1360)	-	-	-	-	-	-	-	X	X	-

Table E-2

X	Has to be installed

QC material

	Parameter									
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	tHb/SO_2	COOX/Bili	MSS
AUTO-TROL PLUS B, Level 1 03321169001 (BP9094)	O	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 2 03321177001 (BP9095)	O	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 3 03321185001 (BP9096)	O	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 1 03321193001 (BP9097)	O	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 2 03321207001 (BP9098)	O	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 3 03321215001 (BP9099)	O	O	O	O	O	O	O	O	O	O
COOX/MSS Verification Material 03354628001 (BP9403)[(a)]	O	O	O	O	O	O	O	O	O	O
TS/MSS Verification Material 03354601001 (BP9407)[(a)]	O	O	O	O	O	O	O	O	O	O

Table E-3

(a) Only for USA available!

O	Can be used

Accessories

	Parameter									
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	tHb/SO_2	COOX/Bili	MSS
Deproteinizer 03110435180 (BP0521)	O	O	O	O	O	O	O	O	O	O
Adapter for Capillaries 03069931001 (BP0959)	O	O	O	O	O	O	O	O	O	O
Ampoule Adapter 03066762001 (BP1938)	O	O	O	O	O	O	O	O	O	O
Clot Catcher 03112012180 (BP2243)	O	O	O	O	O	O	O	O	O	O
Cleaning Kit for Cl- Electrode 03112098035 (BP2276)	O	-	-	-	-	-	-	-	-	-
Adapters for Sample Container 03112101180 (BP2277)	O	O	O	O	O	O	O	O	O	O
Caps for Roche MICROSAMPLER 03112152180 (BP2288)	O	O	O	O	O	O	O	O	O	O
Thermo Printer Paper 03113361180 (HP0107)	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER, non sterile 03113434035 (MC0015)	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER, sterile 03113442180 (MC0017)	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER, with accessories 03113663160 (US0600)[(a)]	O	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER, w/o. accessories 03113671160 (US0601)[(b)]	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
BS2 Blood Sampler (sterile) 03113493035 (MC0028)	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
Plastic Capillary Tubes, ~ 140 µL 05174791001	O	O	O	O	O	O	O	O	O	O
Sterile Capillary Holder 05174830001	-	-	-	-	O	O	O	-	-	-
Caps for Capillary Tubes 03113647035 (RE0410)	O	O	O	O	O	O	O	O	O	O

Table E-4

(a) Only for USA available

(b) Only for USA available

O	Can be used
-	Do not use!

	Parameter									
	Cl^-	**Na^+**	**K^+**	**Ca^{2+}**	***P*CO_2**	***P*O_2**	**pH**	**tHb/*S*O_2**	**COOX/Bili**	**MSS**
Customer Accessory Kit, for **cobas b** 221<2>/<4>/<6> system 04975626001	O	O	O	O	O	O	O	O	O	O
Customer Accessory Kit, for **cobas b** 221<1>/<3>/<5> system 04977203001	O	O	O	O	O	O	O	O	O	O

Tabelle E-5

O	Can be used

Glossary

A

Acid Base Diagram The log PCO_2/pH diagram serves as a basis for showing the rearranged Henderson-Hasselbalch equation.

Alkaline basic

Analyzer Software mode for measuring, QC measurement, system functions, calibration, quick access.

AQC Abbrev. for AutoQC

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.

AUTO-TROL PLUS B AutoQC material for controlling BG, ISE, Glu, Lac, Urea/BUN, COOX/Bilirubin

AUTO-TROL TS+ AutoQC material for controlling BG, ISE, Glu, Lac, Hct, tHb/SO_2

B

Barcode scanner PS2 hand-held scanner with integrated decoder for simple input of QC data, electrode data, patient or user identity.

BG Abbrev. for blood gas

BG measuring chamber The BG measuring chamber with its sensors serves 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 share.

Bottle compartment The bottle compartment contains the W Waste Container, the S1 Rinse Solution bottle, the S2 Fluid Pack (with the solutions for BG and ISE) and the S3 Fluid Pack (with the solutions for Glu, Lac and Urea/BUN - only **cobas b** 221<5> system and **cobas b** 221<6> system).
The bottle compartment also contains the necessary docking mechanisms for transporting the fluids into or out of the system.

Bottle tool serves for emptying the W Waste Container and for degassing the S1 Rinse Solution.

BUN Abbrev. for blood urea nitrogen

Bypass nipple Connection between the sample inlet path and the transverse channel

C

Calibration for Ready A calibration is selected to bring all the activated parameters into the "Ready" condition.

Clip Plastic fastener on S2 Fluid Pack and S3 Fluid Pack.

Clot catcher Coagulum catcher for use with syringes and capillaries

COMBITROL PLUS B QC material for controlling BG, ISE, Glu, Lac, Urea/BUN, COOX/Bilirubin

COMBITROL TS+ QC material for controlling BG, ISE, Glu, Lac, Hct, tHb/SO_2

Contact clip The MSS cassette inserted in the measuring chamber slit is pressed into position and thereby firmly positioned.

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

D

Docking mechanism Serves as an interface between the packs or bottles and the fluid channels in the system

Dummy electrode A flow-through electrode without any measuring function serving as a placeholder.

E

Electrodes are flow-through electrodes with a visible sample channel.

F

Filling port Enables a sample to be injected or aspirated from syringes, Roche MICROSAMPLER, capillaries and ampule adapters.

Fixation lever serves for fixing the sensors in the measuring chamber

FMS Fluid mixing system. In combination with the main pump this system guarantees the correct mixture of the calibration solutions CAL A and CAL B from the S2 Fluid Pack for the next calibrations, with the aid of the valves VM and V19.

G

Glass tube see *Sample inlet path (SIP)*

H

Hematocrit in short, 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

Input unit Consists of the T&D module and the sample drip tray.

ISE Abbrev. for ion-selective electrode

ISE measuring chamber The ISE measuring chamber with its sensors serves for measuring the hematocrit value and the electrolyte values Na^+, K^+, Ca^{2+} and Cl^-.

L

Levey-Jennings diagram QC statistical values chart

LF Conductivity

Linear bracket White plastic part of the peristaltic pump.

M

MC Abbrev. for "measuring chamber"

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 cassette serves for transporting the samples and calibration solutions to the waste system after a measurement and/or calibration and for adding the reference and rinse solution S1.

Module stop A certain module is not ready for use. Nevertheless, the parameters of other modules can still be measured.

MSS Abbrev. for metabolite sensitive sensors

MSS cassette is a multi-parameter sensor and contains the spots for measuring Glu, Lac, Urea/Bun

MSS measuring chamber The MSS measuring chamber with its sensors serves for measuring glucose, lactate and urea/BUN.

MSS polarization serves for wetting and preparing the MSS cassette.

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 sera with certified expected values.

P

Patient Trend Diagram 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 see *Pumps*!

Plasma Plasma samples are obtained by centrifuging heparinized whole blood, whereby cellular cell parts of the blood are separated.

Pleural fluid Pleural fluid is a serous fluid produced by the pleurae.

Pleural space The thin space between the two pleural layers is known as the pleural space.

Plug monitoring Infrared light barrier for detecting plugged or unplugged sample containers.

Polychromator Light is refracted and focused on the surface of a photosensitive receiver (CCD).

PP Abbrev. for peristaltic pump.

Printer A low-noise thermoprinter with integrated paper cutter and optional paper winder.

Pumps The transport of the sample and the operating fluids is effected by means of up to three peristaltic pumps, depending on the design (main pump, MSS output pump, MSS input pump).

Q

QC Abbrev. for quality control

QC material see *AUTO-TROL PLUS B*, *AUTO-TROL TS+*, *COMBITROL PLUS B*, *COMBITROL TS+*!

Quality control The known target areas of the QC materials are compared with the QC results of the instrument.

R

RCon Abbrev. for reference contact. This is used for the Glu/Lac or Glu instrument type and replaces the reference electrode and dummy electrode.

"Ready" screen Main window of the analyzer mode.

Reference electrode The reference electrode serves as a counter electrode of the measuring electrodes. Due to the reference solution, its signal remains constant, irrespective of the composition of the sample.

S

S1 Rinse Solution Wash solution

S2 Fluid Pack Calibration solutions BG, ISE

S3 Fluid Pack Calibration solutions Glu, Lac, Urea/ BUN

Sample drip tray Prevents dirtying the bottle compartment

Sample inlet path (SIP) Glass tube. Serves for transporting fluids from the T&D disc via the needle to the sample distribution block (transverse channel).

Sample throughput Number of samples per hour

Sample volume limit is the maximum volume aspirated from a sample container.

SCon Abbrev. for sensor contact. By means of the conductivity contact, this electrode supports the monitoring for filling the measuring chambers with fluid. In addition, it measures the temperature in the measuring chamber.

Screen/PC unit Serves as a graphic user interface. All the information (results, operating instructions, alarms, warnings, etc.) is displayed on the screen. The screen consists of a color LCD that is covered with a touch-sensitive film ("touch screen").

SO_2 Oxygen saturation

System calibration This is carried out every 8, 12 or 24 hours (standard) and consists of wave-length calibration of the polychromator, internal cleaning, automatic conditioning of the Na^+ electrode, calibration of the mixing system and the 2-point calibration of all the parameters.

System stop When this error occurs a window is displayed with a red outline; the instrument stops.

System warnings Warning or indication that does not require any direct action.

T

T&D module The T&D ("Turn and Dock") serves for sample input, for aspirating solutions from S1, S2, S3 and the QC material from the AutoQC module. This module guarantees the fastest possible distribution of the different fluids.

Tension lever Plexiglass cover on the peristaltic pump

tHb calibrator A calibration solution with known tHb value for calibrating the COOX module.

tHb/SO_2 module An optical measuring module for determining the total hemoglobin and the oxygen saturation in the whole blood.

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.

Transverse channel serves for optimum thermostatizing and distribution of samples and calibration solutions to the measuring modules

U

Urea Urea (diamide of carbonic acid, Lat. urea pura) is an organic compound and is produced as an end product of the metabolism of nitrogen compounds (e.g. amino acids) produced in the so-called urea cycle and then excreted in the urin.

V

Vacuum pump Responsible for washing and drying the tubing (with the exception of the measuring chambers).

Valve V19 Air mixing valve

Valve VM Mixing valve for calibration solutions CAL A and CAL B from S2 Fluid Pack.

W

W Waste Container Waste container

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