



cobas b 221 system

Instructions for Use



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Table 1 Revision history

Edition notice

cobas b 221 system

In the course of 2006 the Roche OMNI S system was relaunched under the Roche 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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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 Instruction 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 Instruction 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 |

Table 2 Symbols




| Symbol | Used for |
|---|--|
|  | <p>Attention</p> <p>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.</p> <p>Warning</p> <p>Sections marked with this symbol contain information that must be observed to avoid potential injuries (to patients, users and third parties).</p> |
|  | <p>Risk of infection</p> <p>All sections and parts of texts that are marked with this symbol describe procedures that may involve risk of infection.</p> |
|  | <p>ESD protective measures</p> <p>All sections/text passages that are marked with this symbol refer to components that require special care with respect to electrostatic discharges. Packaging with this label may be opened by trained personnel only.</p> |

Table 2 Symbols

IVD symbols The symbols are used in accordance with DIN EN 980⁽¹⁾ and DIN EN ISO 780⁽²⁾.




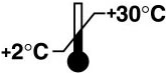






| Symbol | Description |
|---|--|
|  | <p>Conformité Européenne:</p> <p>This product complies with the requirements in the guideline for In Vitro Diagnostic 98/79/EC.</p> |
|  | Batch code |
|  | <p>Use by..</p> <p>The product should not be used after expiry of the specified date. If a day is not indicated, apply the last day of the respective month.</p> |
|  | <p>Temperature limitation</p> <p>The conditions necessary to preserve the product's shelf life before opening.</p> |
|  | In Vitro Diagnostic Medical Device |
|  | <p>Manufacturer</p> <p>(according to In Vitro Diagnostic guidelines 98/79/EG)</p> |
|  | Catalogue number |
|  | Serial number (model plate) |
|  | Caution, consult accompanying documents |
|  | Please consult instructions for use |

Table 3 IVD symbols

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

(2) 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) ⁽¹⁾ (Instrument) |
|  | Biological risk (according to the standard DIN EN ISO 980) ⁽²⁾ (Consumables) |
|  | Do not use if package is damaged |
|  | Do not reuse |
|  | Fragile. Handle with care |
|  | Handle with care |
|  | Valid only for Roche MICROSAMPLER PROTECT: Method of sterilization using ethylene oxide |
|  | Valid only for BS2 Blood Sampler: Method of sterilization using irradiation |

Table 3 IVD symbols

- (1) 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).
- (2) 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 |
|--|--|
|  | <p>Electrodes:</p> <p>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.</p> <p>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 electrode.</p> |
|  IRRITANT REIZEND IRRITANTE Bijzand REITANDE IRRITAMENT ερεθιστικό XI:R36/37/38, S26-37 | <p>Danger symbol: "Irritant" (on the label and the packaging of S2 Fluid Pack)</p> <p>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).</p> <p>Caution: Avoid contact with eyes and skin, do not inhale vapors.</p> |
|  | <p>Danger symbol: "Corrosion" (on the label and the packaging of S2 Fluid Pack)</p> <p>Hazard statement: Causes severe skin burns and eye damage.</p> <p>Prevention: Avoid contact with eyes and skin, do not swallow or inhale vapor. Wear protective, gloves, clothing, eye and face protection.</p> |
|  | <p>Warning symbol: "Exclamation mark" (on the label and the packaging of S2 Fluid Pack)</p> <p>Hazard statement: Harmful if swallowed.</p> <p>Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product..</p> |
|  Invisible Laser Radiation Avoid direct radiation to eyes. Laser Class 3R according to EN 60825-1 P0 ≤ 5 mW λ = 635 - 850 nm | <p>Invisible Laser Radiation</p> <p>Avoid direct radiation to eyes.</p> <p>Laser Class 3R according to EN 60825-1</p> <p>P0 ≤ 5 mW</p> <p>λ = 635 - 850 nm</p> |
|  | Store upright |
|  | "Grüner Punkt" (in Germany) |
|  | Protective gloves, protective goggles and suitable protective clothing must be worn. |

Table 4 Other symbols

Abbreviations The following abbreviations are used:

| Abbreviation | Definition |
|--------------|---------------------------------------|
| A | |
| ANSI | American National Standards Institute |
| AQC, AutoQC | Automatic Quality Control |

Table 5 Abbreviations

| Abbreviation | Definition |
|--------------|--|
| ASTM | American Society for Testing and Material |
| B | |
| BG | Blood gas |
| BUN | Blood urea nitrogen |
| C | |
| CE | Conformité Européenne |
| CLIA | Clinical Laboratory Improvement Amendments |
| CLSI | Clinical and Laboratory Standards Institute |
| COHb | Carboxyhemoglobin |
| cond | Conductivity |
| COOX | CO-Oximetry |
| 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 |
| DIN | German Institute for Standardization |
| DNS | Domain Name Server |
| E | |
| EC | European community |
| e.g. | for example |
| EN | European standard |
| F | |
| FMS | Fluid mixing system |
| G | |
| GB | Gigabyte |
| Glu | Glucose |
| H | |
| Hct | Hematocrit |
| HHb | Desoxyhemoglobin |
| HIV | Human immunodeficiency virus |
| HW | Hardware |
| Hz | Hertz |
| I | |
| i.e. | that is to say |
| IEC | International Electrotechnical Commission |
| ISE | Ion selective electrode |
| ISO | International Organization of Standardization |
| IVDD | In vitro Diagnostic Directive |
| K | |
| KCl | Potassium chloride |
| kg | kilogram |
| L | |


Table 5 Abbreviations

| Abbreviation | Definition |
|-------------------|--|
| Lac | Lactate |
| LCD | Liquid crystal display |
| LED | Light emitting diode |
| LIS | Laboratory Information System |
| LJ | Levey Jennings |
| LoD | Limit of Detection |
| M | |
| MAC | Media Access Control |
| MB | Megabyte |
| MC | Measuring chamber |
| MetHb | Methemoglobin |
| MHz | Megahertz |
| MSDS | Material safety data sheet |
| MSS | Metabolite sensitive sensor |
| MV | Mean value |
| N | |
| NIST | National Institute of Standards and Technology |
| NRTL | Nationally Recognized Testing Laboratory |
| O | |
| O ₂ Hb | Oxyhemoglobin |
| P | |
| PCO ₂ | Partial pressure of carbon dioxide |
| PO ₂ | Partial pressure of oxygen |
| PP | Peristaltic pump |
| Q | |
| QC | Quality control |
| R | |
| RCon | Reference contact |
| REF | Reference solution |
| S | |
| SCon | Sensor contact |
| SD | Standard deviation |
| SDC | Sample distributor cartridge |
| SIP | Sample inlet path |
| SO ₂ | Oxygen saturation |
| S1 | S1 Rinse Solution |
| S2 | S2 Fluid Pack |
| S3 | S3 Fluid Pack |
| T | |
| T&D | Turn & dock |
| tHb | Total hemoglobin |
| U | |
| USB | Universal Serial Bus |

Table 5 Abbreviations

| Abbreviation | Definition |
|--------------|--|
| V | |
| VDE | Association of German Electrical Engineers |
| W | |
| W | Watt |

Table 5 Abbreviations

 For writing the measuring, calculated and input values see *Software modes* (p. 217) > *Parameters/icons* (p. 221)

Introduction and specifications

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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

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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 (1 = low, 2 = normal, 3 = high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument (switched off more than 24 hours).

Additionally complete a quality control test on one level between two automatic 2P calibrations. The levels have to be alternated (1 = low, 2 = normal, 3 = 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⁽¹⁾
- IEC/EN 61010-2-101⁽²⁾
- IEC/EN 61010-2-081⁽³⁾

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 according to IEC /EN 61010-1, 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/SO₂ module)⁽⁴⁾.
- 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.



Warning

- ▶ 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.

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

(2) 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)

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

(4) are no longer manufactured or offered.

IT Security Advisory

Description

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

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

cobas b 221 system does not contain anti-virus protection software. Therefore, it is essential to follow the necessary precautions listed below to prevent the transmission of malware.

Security precautions



Warning

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

-
- Check all external storage devices with an anti-virus program (on another PC) to ensure that they are malware free before using them on the system.
 - Recheck the external storage device between use on different systems in order to avoid cross-interference.
 - At no time should portable storage media, particularly USB memory drives/sticks, be used at home or at public computer systems and then be used to connect to a work or customer system.
 - Do not use the USB ports to connect other external storage devices unless stated in **cobas b 221 system**-specific documentation.
 - Keep all external storage devices in a secure place so that they can be accessed only by authorized personnel.
 - Do not add, move or delete any files or software unless stated in **cobas b 221 system**-specific documentation.
 - Never copy and install any non-Roche software on the system.
 - If a system requires additional software please contact the appropriate system hot line.
 - Use any remote services capability (e.g. **cobas**[®] e-support) only to connect to the Roche Service Network.
 - Do not connect to the Internet unless stated in **cobas b 221 system**-specific documentation.
 - Make sure only validated computers are connected to the instrument system network.

- Ensure other computers on attached networks (e.g. the LIS, FTP) are properly secured and protected from malware. This is the responsibility of the customer and their IT specialists.
- The use of a **cobas** IT firewall is strongly recommended or even mandatory depending on the system installation.

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

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Introduction



Figure 2-1 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 human 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 ⁽¹⁾ | BG, pH, tHb/ SO_2 |
| • cobas b 221<2> system | BG, pH, COOX, Bili |
| • cobas b 221<3> system ⁽¹⁾ | BG, pH, ISE, Hct, tHb/ SO_2 |
| • cobas b 221<4> system | BG, pH, ISE, Hct, COOX, Bili |
| • cobas b 221<5> system ⁽¹⁾ | BG, pH, ISE, Hct, MSS, tHb/ SO_2 |
| • cobas b 221<6> system | BG, pH, ISE, Hct, MSS, COOX, Bili |

(1) 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 *Software modes* (p. 217)

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

Introduction

| | |
|------------|--|
| • 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 *Installation and shutdown* (p. 43), section *Installation* (p. 45) and *Shutdown* (p. 65).

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 (1 = low, 2 = normal, 3 = high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument (switched off more than 24 hours).

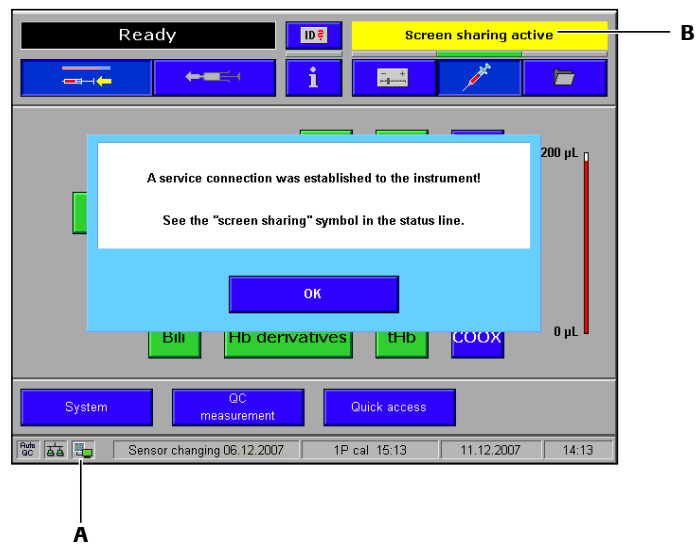
Additionally complete a quality control test on one level between two automatic 2P calibrations. The levels have to be alternated (1 = low, 2 = normal, 3 = high).

•☒ For additional information, see *Quality control* (p. 173).

With Software V 6.0 onwards, using **cobas bge link** software, the instrument can be monitored from one location, any disturbances can be remedied and the analytical quality monitored.

cobas bge link software is a remote monitoring and remote maintenance software for Roche Point-of-Care analyzers.

•☒ see Figure 2-2 (p. 28)



A "Screen sharing" Symbol

B "Screen sharing" active

Figure 2-2

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.



Caution

- ▶ 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

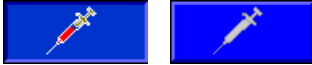




| Buttons | Description |
|---|----------------------------|
|  | "Analyzer" active/inactive |
|  | "Database" active/inactive |
|  | "Setup" active/inactive |
|  | "Info" active/inactive |

Table 2-1

 For additional information, see section *Buttons* (p. 224).

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+} - and 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



Warning

- ▶ The measurement results that are output by the **cobas b 221** system must always be checked for plausibility by medical specialists with consideration of the clinical situation of the patient before a clinical decision is made based on the results.
-

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument (switched off more than 24 hours).


Additionally complete a quality control test on one level between two automatic 2P calibrations. The levels have to be alternated (1 = low, 2 = normal, 3 = high).

ⓘ For detailed information, see *Quality control* (p. 173).


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 *Measurement* (p. 143)

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 laboratory 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 *Maintenance* (p. 245)

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.



Warning: 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 *Specifications* (p. 75).

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 PCO₂ 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 PCO₂ 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 *Specifications* (p. 75).

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)
- O₂ 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 (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.

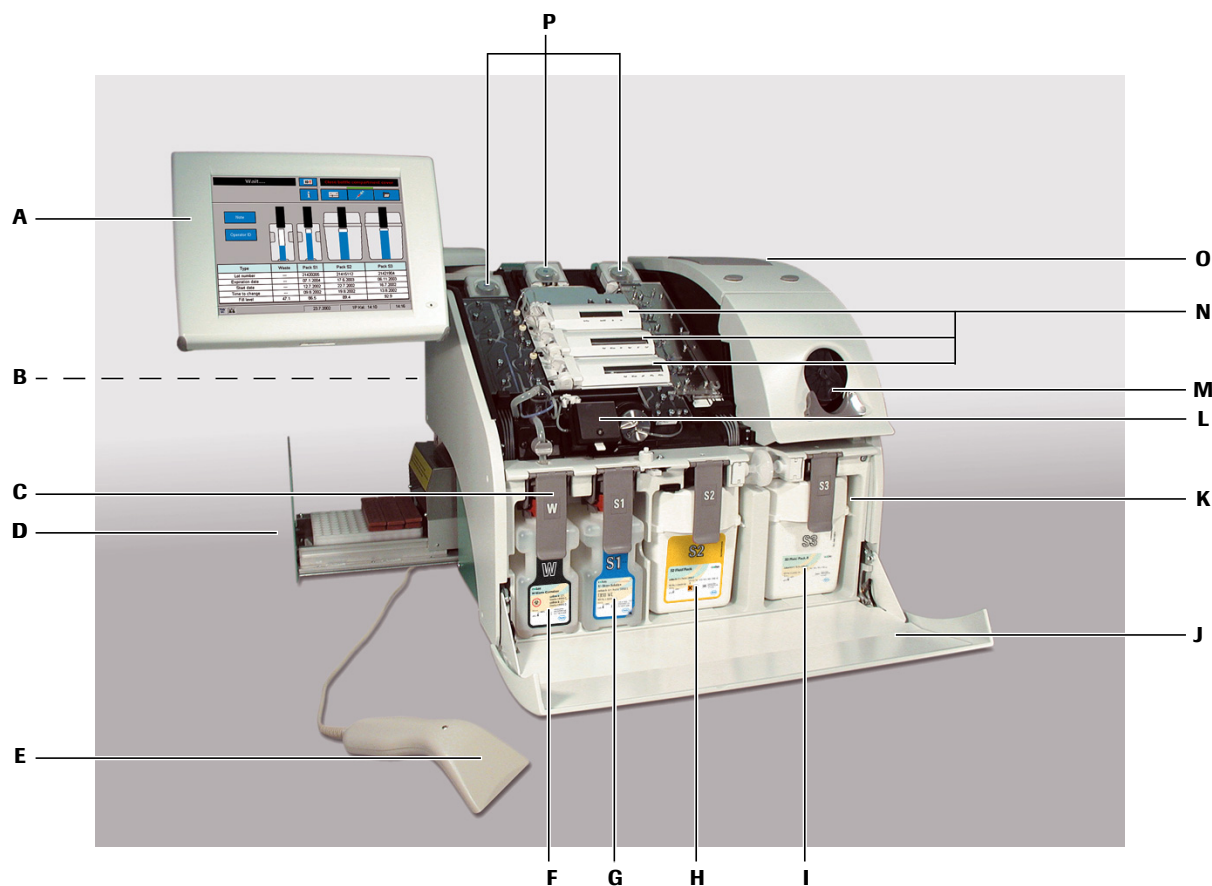


For a detailed description see section *Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)* (p. 280).

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 compartment cover | P Pumps |
| E Barcode scanner | K Bottle compartment | |
| F W Waste container | L COOX module (tHb/SO ₂ module) | |

Figure 2-3 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").

**Caution**

- ▶ 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.

**Caution**

- ▶ 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/SO₂ or COOX module.

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

tHb/SO₂ module

Figure 2-4 tHb/SO₂ module

The tHb/SO₂ module is an optical sensor module for determining the level of total hemoglobin (tHb) and oxygen saturation (SO₂) 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

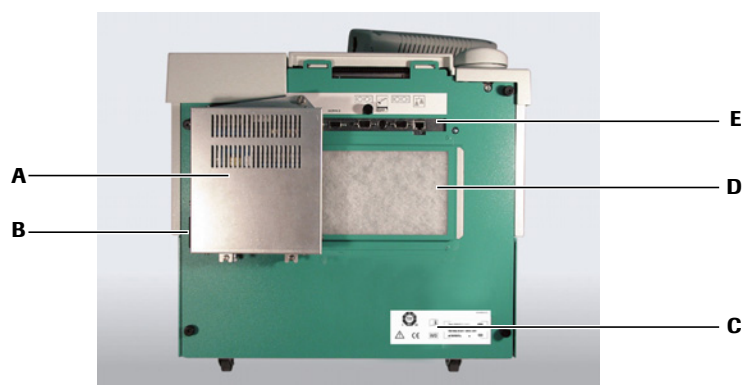
The sample insertion as well as the aspiration of solutions is carried out via input unit which consists of the following:

- 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

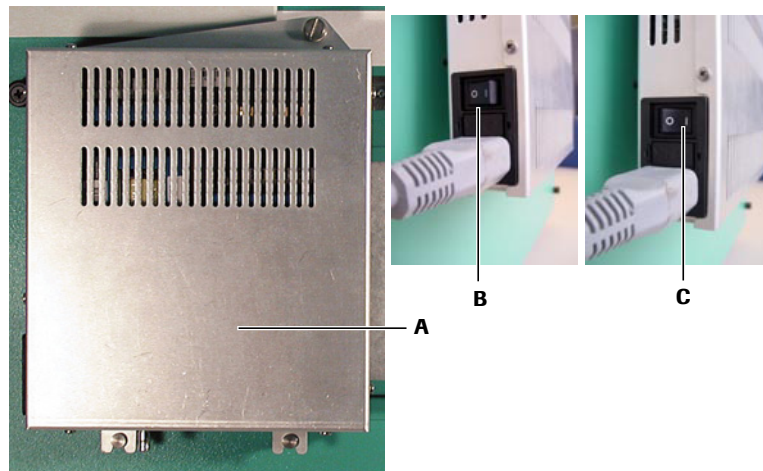


- | | |
|--|---------------------|
| A Power supply | D Air filter |
| B Main power switch and connector | E Interfaces |
| C Warning and identification labels | |

Figure 2-5 Reverse side

Power supply

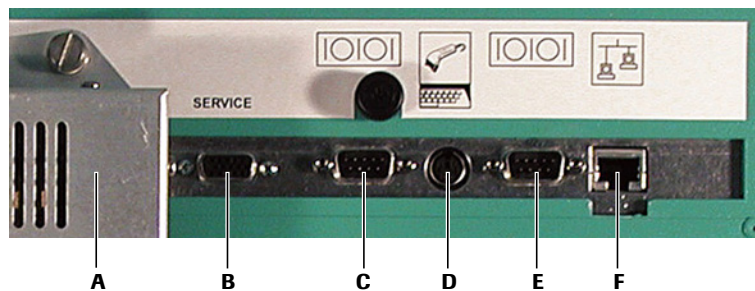
This unit also contains the main power switch and the connector.



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

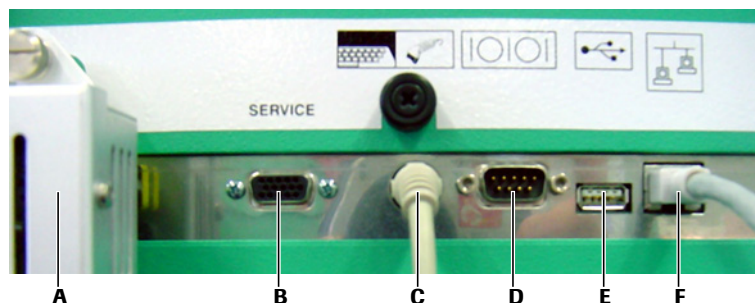
Figure 2-6 Power supply

Interfaces





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

Figure 2-7 Interfaces (without USB)



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

Figure 2-8 Interfaces (with USB)

- Variant 2:
2x RS 232 interfaces (COM 1 and COM 2) (SN < 1500)
-  see Figure 2-7 *Interfaces (without USB)* (p. 40)
- Variant 1:
1x RS 232 interface (COM 1) and 1x USB (SN > 1500)
-  see Figure 2-8 *Interfaces (with USB)* (p. 40)
- 1x 10BaseT Ethernet (RJ45)
- Ext. keyboard/barcode scanner: PS/2 DIN - 6 pin female connector
- 1 service connector
- Power (power supply is connected)




CAUTION

Caution

- ▶ No reverse compatibility from Variant 2 to Variant 1 possible.

Barcode scanner**Figure 2-9** 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).

System description

Warning and identification labels (including nameplate)

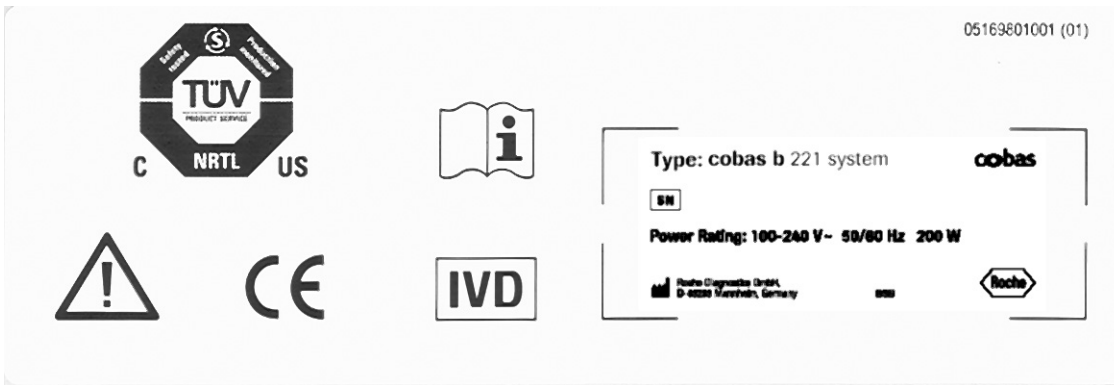


Figure 2-10

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..... | 45 |
| Location..... | 45 |
| Accessories..... | 46 |
| Procedure..... | 47 |
| Shutdown..... | 65 |
| Less than 24 hours..... | 65 |
| Longer than 24 hours..... | 65 |

Installation

Location



Note

Never set up the **cobas b** 221 system in the immediate vicinity of patients. Maintain a safety distance of 1.5 meters (5 feet).

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)



CAUTION

Caution

- ▶ From approximately 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 24. *Checking the barometer value* (p. 63)

- 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%
- For proper air circulation and the electrical connections, the following clearances should be observed around the instrument:
 - 8 cm on each side
 - 15 cm behind the instrument
 - 13 cm above the instrument
- Correct voltage: 100 to 240 VAC ($\pm 10\%$), 50 - 60 Hz

After the **cobas b** 221 system has been set up at a location that meets the necessary conditions, carry out the following steps to prepare the instrument for operation:

- First, check the instrument and accessories for completeness and potential damage. Verify that the shipment is complete by comparing components with the shipping order.

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.

**Caution**

- ▶ Do not under any circumstances insert consumables into the instrument if the packaging of these consumables suffered massive damage.
Using damaged consumables can cause malfunctions of the instrument.

**Warning**

- ▶ 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 approximately 45 kg.

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)
- 1 RCon (reference contact)
- 1 shutdown kit
- 1 dummy electrode
- 1 dummy MSS cassette
- 2 SCon (sensor contact)
- 3 pump tubes



Not shown in Figure 3-1 *Accessories* (p. 46):

- 1 screen/PC unit
- 1 power supply
- 1 fill port



Figure 3-1 Accessories

Procedure

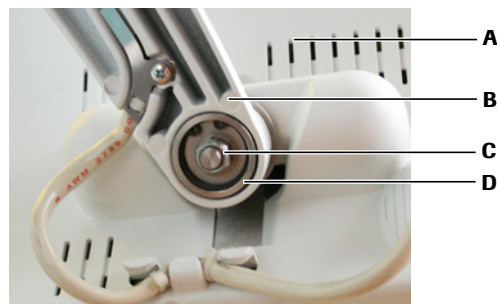


1. Screen/PC unit

Caution

- ▶ 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 | C Fixing nut |
| B Swivel arm | D Brake packet |

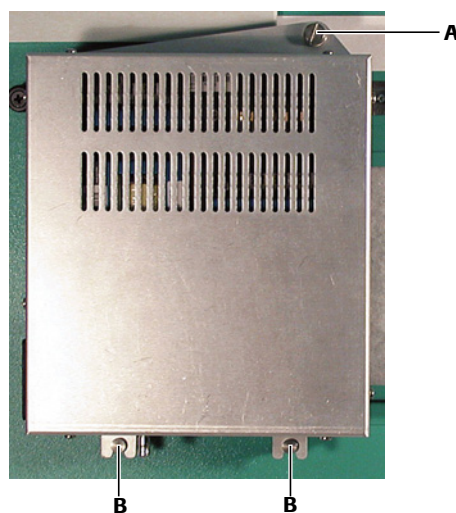
Figure 3-2 Swivel arm of the Screen/PC unit

- 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 3-3 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

- 1 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

- 1 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]

2 Processing the actions manually

Manual:

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

3 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. Change the keyboard layout language (optional)

⊙ Changing the keyboard layout language requires a software (SW) restart.

- 1 Choose the following buttons:
 ☰ Setup > Instrument > Select keyboard layout
- 2 Choose the desired keyboard layout language.
- 3 Choose the **Yes** button.
- 4 Wait for the SW restart procedure to complete.



▶ 8. Set the date and time

- 1 Press the following buttons:

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

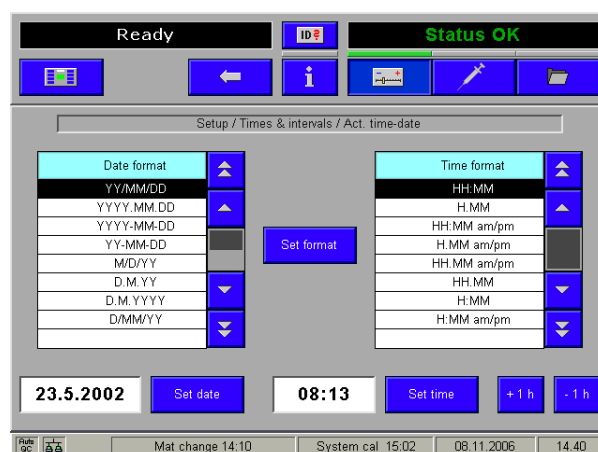


Figure 3-4 Act. time/date



▶ 9. Cal. intervals & timing

- 1 Press the following button:

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

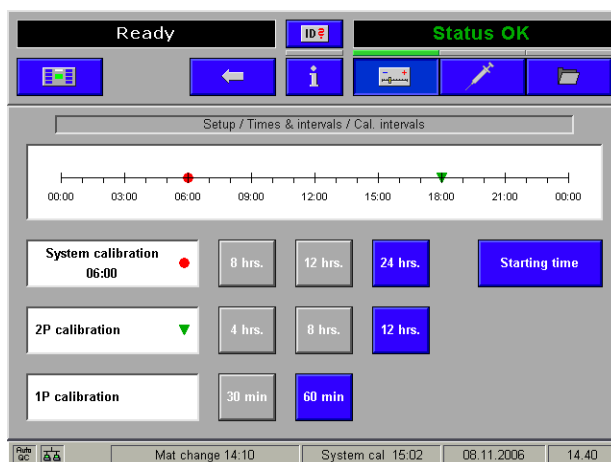


Figure 3-5 Cal. intervals

Use this function to enter the automatic calibration times and intervals for system, 1P and 2P 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). |



▶ 10. Set valves for FMS tubing exchange

- 1 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.



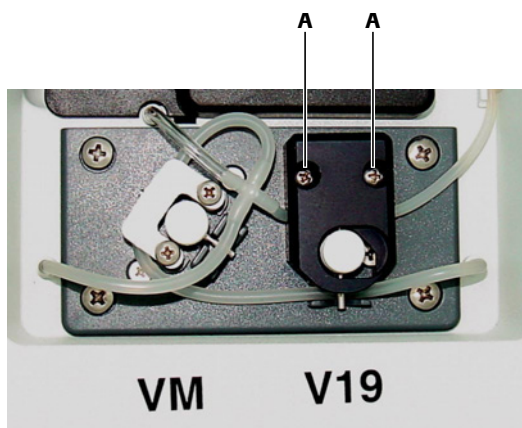
▶ 11. Fix screws at V19 (bottle compartment)

- 1 Open the bottle compartment cover and the docking mechanism "S3".
- 2 Tighten the screws on valve V19 (approximately 2-3 rotations).

📖 see Figure 3-6 *Valve V19 and VM* (p. 51)



Use the delivered screwdriver.



A Screws on valve V19 B

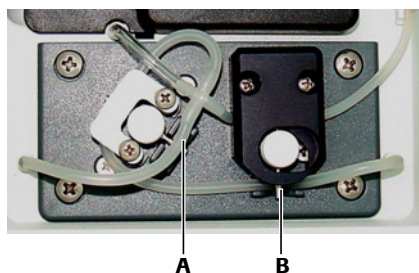
Figure 3-6 Valve V19 and VM

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



▶ **12. 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 3-7 Valve VM



Figure 3-8 Valve VM

- 3 Close docking mechanism and bottle compartment cover.



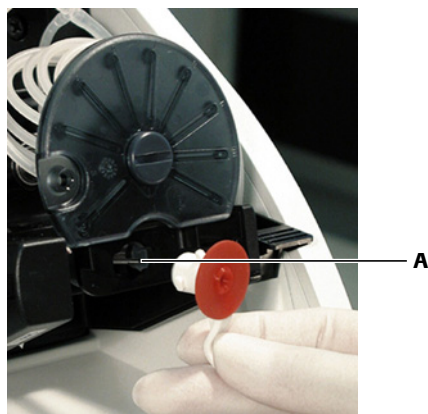
▶ **13. Insert fill port and sample inlet path (glass tube)**

- 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.



Warning

- ▶ Do not bend the insert needle during this process.



A Needle

Figure 3-9 Insert needle

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

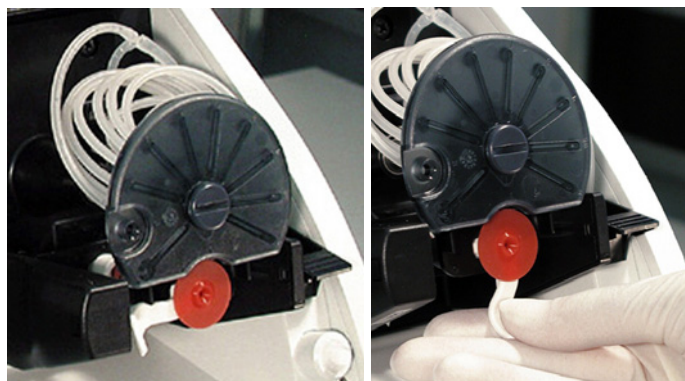
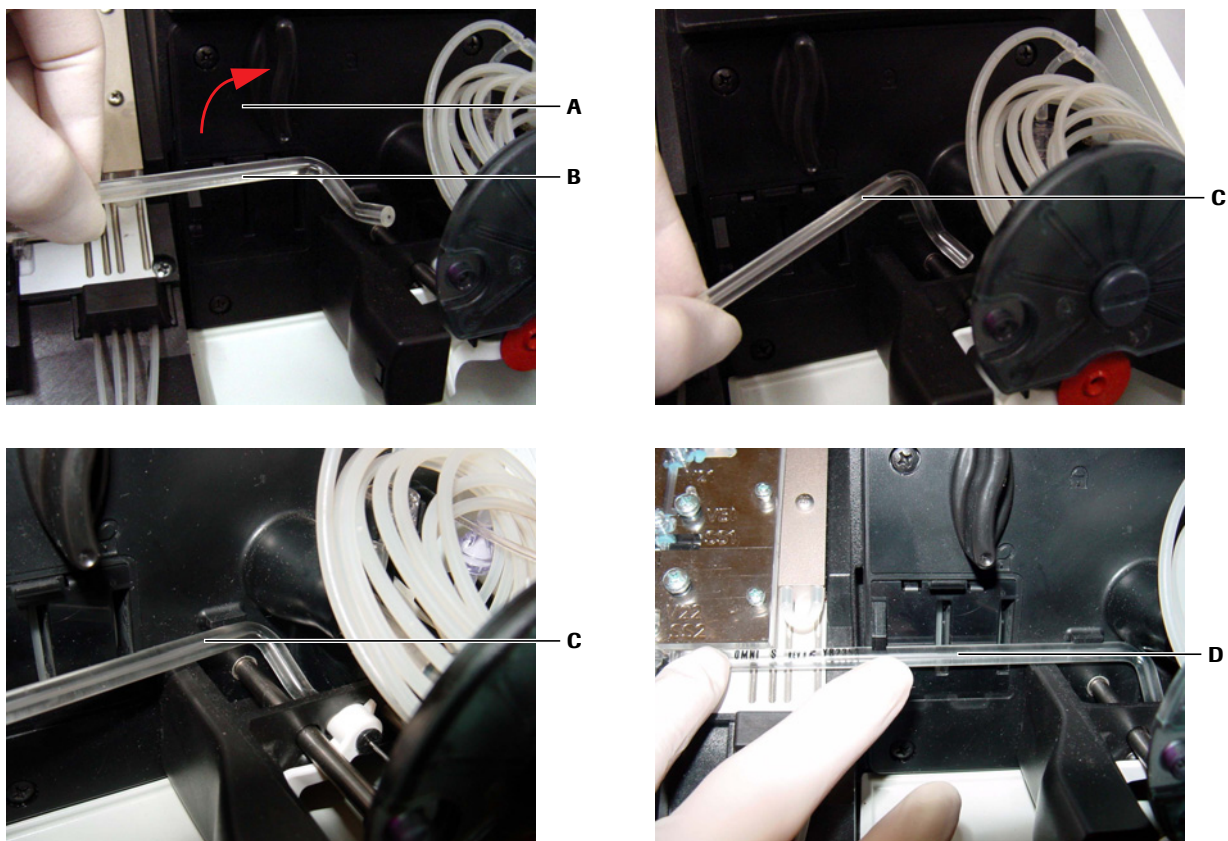


Figure 3-10

- 6 Open the T&D lock.
 - Ⓜ see Figure 3-11 *Glass tube* (p. 53), A
- 7 Insert the glass tube into the guides, fasten it and check it for a correct position.
 - Ⓜ see Figure 3-11 *Glass tube* (p. 53), C
 - Ⓜ see Figure 3-11 *Glass tube* (p. 53), D

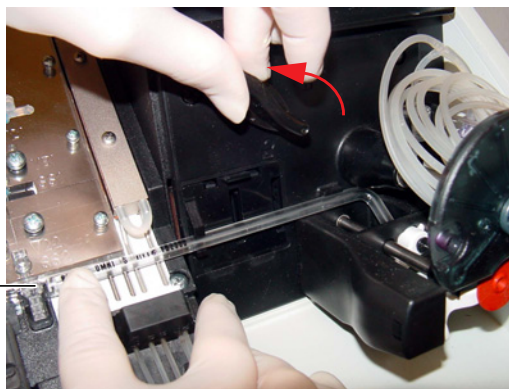


A T&D lock
B Glass tube

C Insert the glass tube into the guides
D Fasten and check for correct position

Figure 3-11 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 3-12 T&D lock

9 Close the T&D cover.

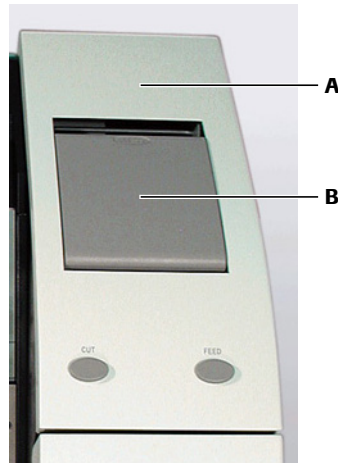
10 Insert the sample drip tray.



▶ **14. Insert 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 and the paper lid.



A Printer cover

B Paper lid

Figure 3-13 Printer

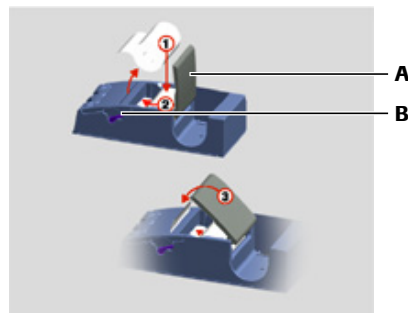
- 2 Cut the start of the paper so that it is straight.
- 3 Place the paper roll into the holder.
- 4 Make sure that the printer lever is in the "down" position (see below).



A Printer lever "down" position

Figure 3-14 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 3-15 Insert printer paper - without take-up unit

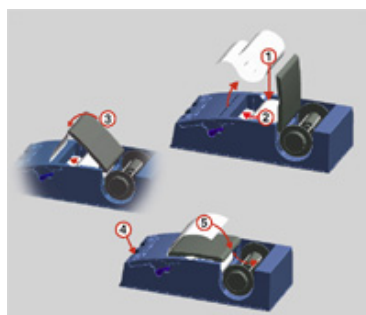


Figure 3-16 Insert printer paper - with take-up unit (optional)

- 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 3-16 *Insert printer paper - with take-up unit (optional)* (p. 55)



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.

Caution

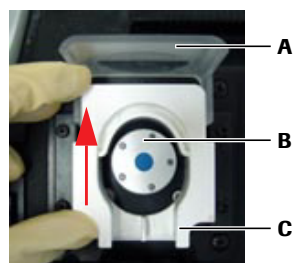
▶ With an installed take-up unit, the "Automatic Cut" function is deactivated.



CAUTION

▶ **15. 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 3-17 Peristaltic pump

Installation

- 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 3-18 Peristaltic pump**AutoQC module (option)**

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

**16. Go to AutoQC service position**

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

**17. 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

B

Figure 3-19 AutoQC valve clamp

- 3 Close the AutoQC drawer.



▶ **18. Go to AutoQC home position**

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



▶ **19. Open AutoQC drawer and insert ampoule holder**

- 1 Pull the AutoQC drawer out again.



A without ampoule holder

B with ampoule holder

Figure 3-20 AutoQC drawer

- 2 Insert the AutoQC ampoule holder.
- 3 Close the AutoQC drawer.



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

- 1 Open the bottle compartment cover.



A Rubber seals

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

Figure 3-21 Waste container & packs

- 2 Open the corresponding docking mechanism.
- 3 Insert an empty waste water bottle and a S1 Rinse Solution bottle.

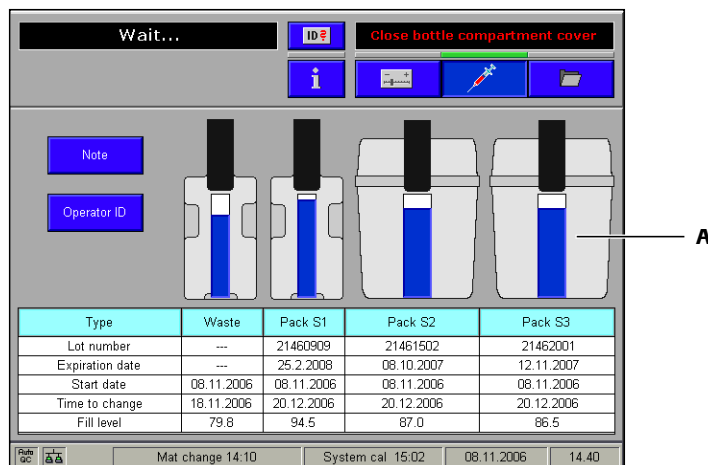
Caution

- ▶ Remove packs' rubber seals.



- 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 3-22 Changing of bottles and packs



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

Figure 3-23 Bottle compartment

- 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.

- 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 3-24 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).

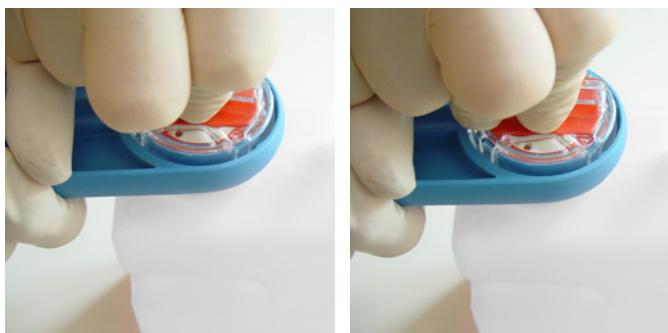


Figure 3-25 Open bottle



▶ 21. Open the measuring chamber cover and insert the sensors

1 BG/ISE measuring chamber

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:

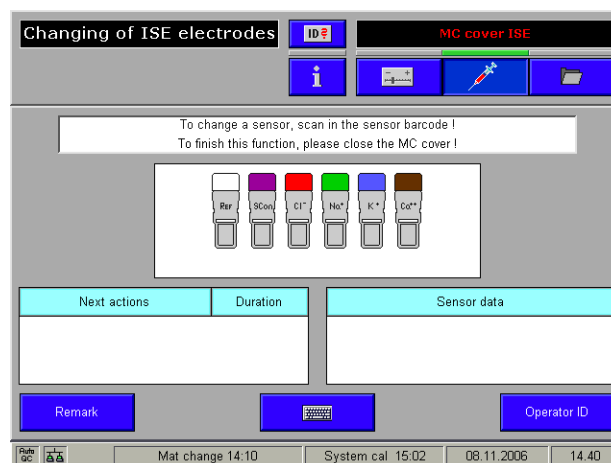


Figure 3-26 Changing of electrodes

- 2 Open the locking lever.
 - Ⓜ see Figure 3-29 *Insertion of the reference electrode* (p. 61)
- 3 Follow the instructions on the screen.

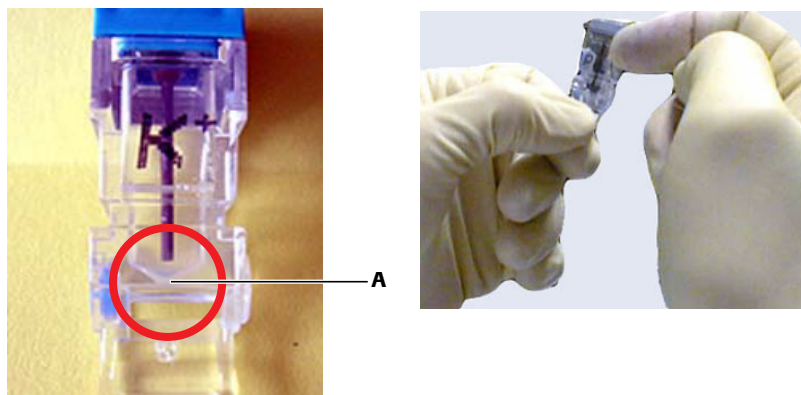


Warning

- ▶ 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 3-27 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.



▶ Insert the reference electrode

Warning

- ▶ The reference electrode must be installed in the instrument no later than the imprinted "Install before" date. The reference electrode must be replaced after 52 weeks of in-use time. Therefore, set up an alert in the Maintenance schedule:

Ⓜ see *Setting up the Maintenance schedule* (p. 272)



1 Insert the reference electrode.

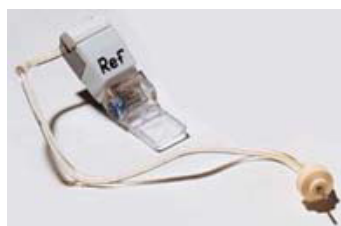


Figure 3-28 Reference electrode

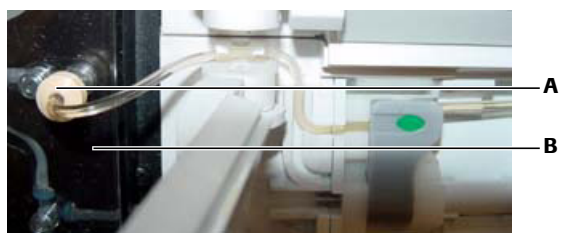
- 2 Insert the reference tube into the upper tube guide channel of the left locking lever and into the tube holder of the cover hinge. Close the locking lever (see below).



A Locking lever

Figure 3-29 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 3-30 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.

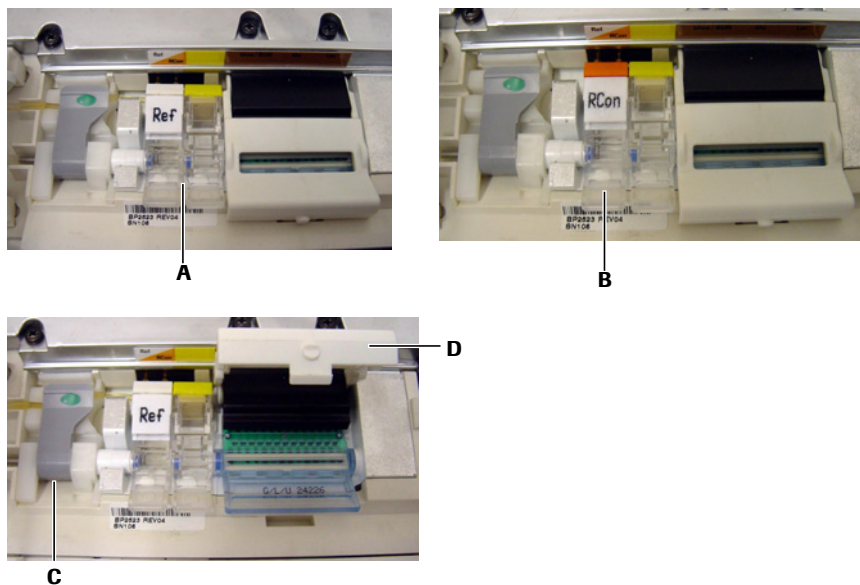
- 1 Open the cover of the MSS measuring chamber (apply force to the right edge of the MC cover with a finger to push it to the left and open up the MC cover).

⚠ Keep the bottle compartment cover closed.

- 2 Open the contact clip and the locking lever.

Installation

- 3 Depending on the MSS parameter configuration, insert the MSS reference electrode (Ref + dummy) (see Figure 3-31 *MSS measuring chamber* (p. 62)/A) or the reference contact (RCon) (see Figure 3-31 *MSS measuring chamber* (p. 62)/B) and the MSS cassette, close the contact clip and the locking lever.



A Ref + dummy (for Glu/Lac/Urea) **C** Contact clip
B Locking lever **D** RCon (Glu or Glu/Lac)

Figure 3-31 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.



22. 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.



▶ **23. 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.

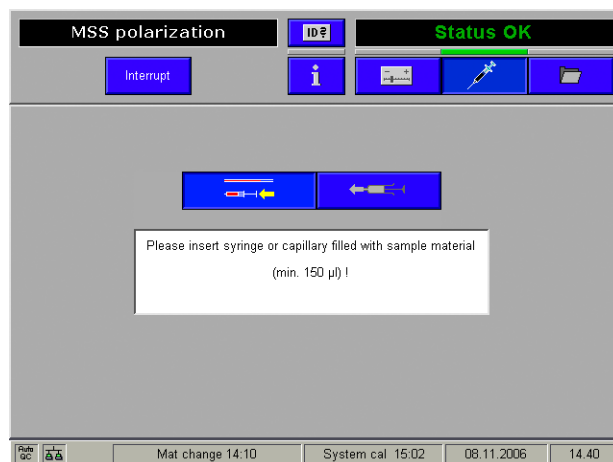


Figure 3-32 MSS polarization

- 2 The blood sample is inserted via fill port similar to a measurement.
 - Ⓜ see *Measurement* (p. 143)
- 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.



▶ **24. Checking the barometer value**

- 1 ☰ System > Component test > Control sensors > Baro sensor

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.

Caution


- ▶ A wrong barometer value leads to wrong PO_2 measurement results.

Important:

- ▶ From approximately 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 permanently deactivated.




- 2 To deactivate the parameter PO_2 press the following buttons:

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




25. 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 *Quality control* (p. 173)

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

 See *Quality control* (p. 173)



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.



CAUTION

Caution

- ▶ 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 21. *Open the measuring chamber cover and insert the sensors* (p. 59).

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 recommends decontaminating all surfaces and tube paths.

 see section *Decontamination* (p. 247).

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


 System > Utilities > Put out of operation

Warning

- ▶ 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.



WARNING

 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).



Warning

- ▶ Do not remove the waste container.

- 2 Close docking mechanism and bottle compartment cover.



▶ **2. Fill the shutdown kit with distilled water**

- 1 Fill the shutdown kit about halfway with distilled water.



Figure 3-33 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.



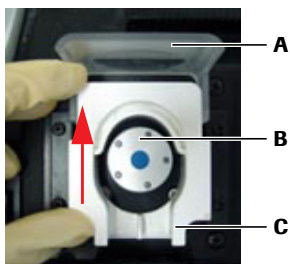
▶ **8. Open the measuring chamber cover and remove the sensors**

- 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**

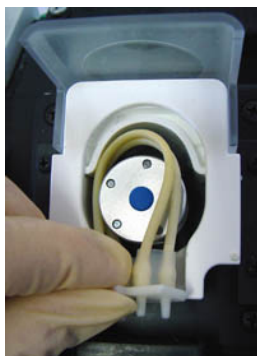
- 1 Open the peristaltic pump's clear plastic cover (tension lever) (see below).



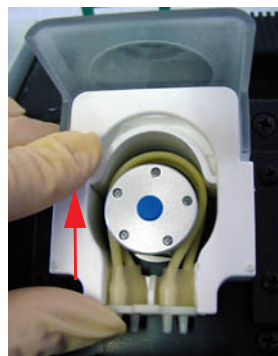
- A** Tension lever
- B** Pump head
- C** Linear bracket

Figure 3-34 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

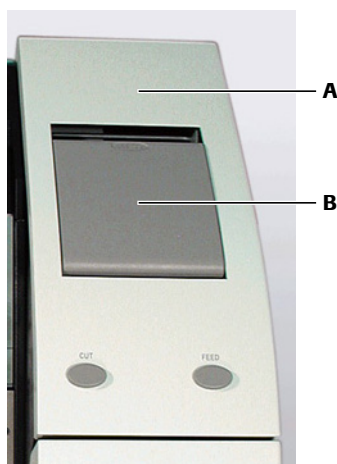
Figure 3-35 Peristaltic pump

- 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 3-36 Printer cover/paper lid

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



A Printer lever "upwards"



B Printer lever "down"

Figure 3-37 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**

- 1 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.

Shutdown

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



A T&D lock

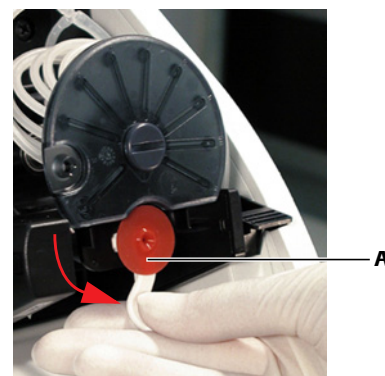
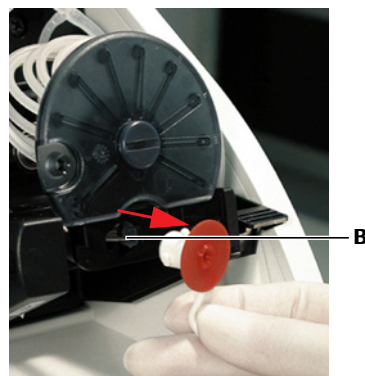
B Sample inlet path (glass tube)

Figure 3-38 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 3-39 Fill port

- 5 Close the T&D lock again.

6 Close the T&D cover.



▶ **13. Set valves for FMS tubing exchange**

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

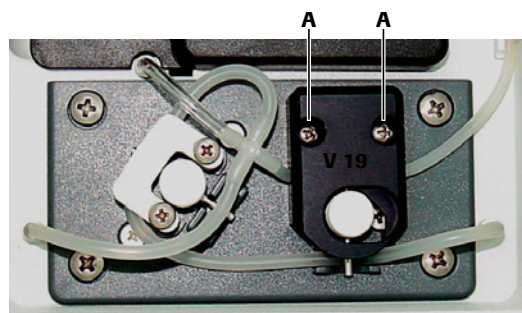


Both valves are pushed out.



▶ **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 (approximately 2-3 turns).



A Screws

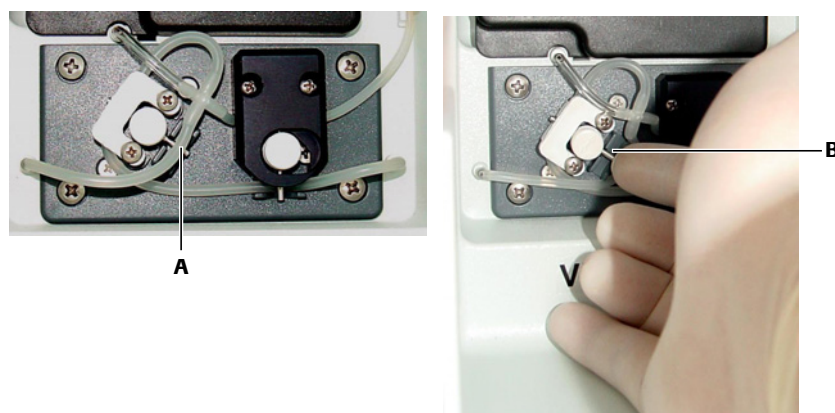
Figure 3-40 Valve V19

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 3-41 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**

- 1 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**

- 1 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 3-42 AutoQC valve clamp

- 3 Close the AutoQC drawer.



▶ **20. Go to AutoQC home position**

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



▶ **21. Complete shutdown**

- 1 Press the [Complete shutdown] button.

Shutdown is complete. The following screen appears:

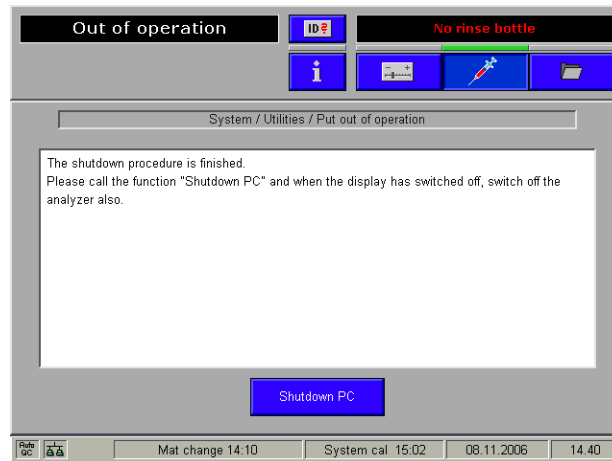


Figure 3-43 Shutdown

- 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.



Shutdown

Specifications

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

In this chapter

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| MetHb (cobas b 221 system with COOX module)..... | 100 |
| COHb (cobas b 221 system with COOX module)..... | 100 |
| SO ₂ (cobas b 221 system with COOX module)..... | 100 |
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Performance data

Measurement parameters

| Parameter | specified for | specified range | |
|--|---------------|------------------|------------------------|
| PO ₂ ⁽¹⁾ | 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 ⁽²⁾ (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) ⁽¹⁾ | 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) ⁽¹⁾ | B/Q | 0 - 100% | |
| COHb (COOX) ⁽¹⁾ | B/Q | 0 - 100% | |
| O ₂ Hb (COOX) ⁽¹⁾ | B/Q | 0 - 100% | |
| MetHb (COOX) ⁽¹⁾ | B/Q | 0 - 100% | |
| Bilirubin (neonatal) (COOX) | B/Q | 3 - 50 mg/dL | 51.3 - 855 µmol/L |
| Baro | | 450 - 800 mmHg | |

Table 4-1 Measurement parameters

- (1) Limit of Quantitation (LoQ) values: PO₂: 1.15 mmHg, Urea: 0.537 mmol/L, HHb: 1.26%, COHb: 1.37%, O₂Hb: 36.6% and MetHb: 0.691%. If the measured value is lower than the value stated here, then the parameter is flagged with a #.
- (2) 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 ⁽¹⁾ |
| A | Dialysis solutions containing acetate |
| D | Dialysis solutions containing bicarbonate |
| S | Serum or plasma |
| PF | Pleural fluid (can be measured in serum/plasma mode) |

(1) with approximate physiological ion matrix and buffer capacity

Precision

"Repeatability (S_{wr})" and "Intermediate precision (S_T)" 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 ₂ Hb | % |
| COHb | % |
| MetHb | % |
| HHb | % |
| Bilirubin (neonatal) | mg/dL |

Table 4-2

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 4-3 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 4-4 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 ₂ Hb | 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 4-5 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 | - | - |

Table 4-6 Tonometered human whole blood, 20 different probands, n=80

Performance data

| Parameter | Mean | S _{wr} | (CV%) | S _T | (CV%) |
|------------------------------|------|-----------------|-------|----------------|-------|
| 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 ₂ Hb | 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 4-6 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 4-7 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 4-8 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 4-9 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 ₂ Hb | 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 4-10 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 |

Table 4-11 AUTOTROL PLUS B Level 2, n=40

Performance data

| Parameter | Mean | S _{wr} | (CV%) | S _T | (CV%) |
|------------------------------|------|-----------------|-------|----------------|-------|
| 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 ₂ Hb | 74.3 | 0.2843 | 0.38 | 0.3011 | 0.41 |
| 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 4-11 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 ₂ Hb | 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 4-12 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 |
| 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 ₂ Hb | 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 4-13 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 ₂ Hb | 94.2 | 0.4087 | 0.43 | 0.4554 | 0.48 |

Table 4-14 AUTOTROL PLUS B Level 5B, n=40

Performance data

| Parameter | Mean | S _{wr} | (CV%) | S _T | (CV%) |
|-----------|------|-----------------|-------|----------------|-------|
| 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 4-14 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 4-15 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 4-16

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 |
| 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 4-17 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 4-18 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 |

Table 4-19 AUTOTROL TS+ Level 5A, n=40

Performance data

| Parameter | Mean | S _{wr} | (CV%) | S _T | (CV%) |
|------------------------------|------|-----------------|-------|----------------|-------|
| 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 4-19 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 4-20 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 4-21 MSS Level 2, NIST Traceable, n=80

Material: human whole blood including 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 4-22 Human whole blood including bilirubin Level 1, n=40

Material: human whole blood including 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 4-23 Human whole blood including bilirubin Level 2, n=40

Material: human whole blood including 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 4-24 Human whole blood including bilirubin Level 3, n=40

Linearity

Tonometered whole blood Whole blood was tonometered at 37 °C to various levels of gravimetrically prepared gases with CO₂ and O₂ concentrations certified to ± 0.03% absolute by the manufacturer. Expected and observed values for PCO₂ and PO₂ 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 including bilirubin Expected bilirubin values for human whole blood including bilirubin are based on weighted samples.

Parameter: PO₂ (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 4-25 Parameter PO₂ (mmHg)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9904 - 1.0097 |
| Intercept | ± 0.857 |
| Correlation coefficient | 0.9998 |

Table 4-26

Parameter: PCO₂ (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 4-27 Parameter PCO₂ (mmHg)

Performance data

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9898 - 1.0103 |
| Intercept | ± 1.225 |
| Correlation coefficient | 0.9999 |

Table 4-28

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 4-29 Parameter pH (pH units)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9825 - 1.0178 |
| Intercept | ± 0.133 |
| Correlation coefficient | 0.9998 |

Table 4-30

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 4-31 Parameter Hct (%)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.997 - 1.003 |
| Intercept | ± 0.620 |
| Correlation coefficient | 0.999 |

Table 4-32

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 4-33 Parameter Sodium (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.988 - 1.012 |
| Intercept | ± 0.365 |
| Correlation coefficient | 0.9999 |

Table 4-34

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 4-35 Parameter Potassium (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.960 - 1.042 |
| Intercept | ± 0.109 |
| Correlation coefficient | 0.9999 |

Table 4-36

Parameter: ionized Calcium (mmol/L)

Material: aqueous solution, NIST traceable

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

Measurements per level and instrument: 15

Performance data

| 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 4-37 Parameter ionized Calcium (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.975 - 1.026 |
| Intercept | ± 0.024 |
| Correlation coefficient | 0.9999 |

Table 4-38

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 4-39 Parameter Chloride (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.959 - 1.043 |
| Intercept | ± 2.908 |
| Correlation coefficient | 0.9999 |

Table 4-40

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 4-41 Parameter pH (pH units)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.960 - 1.042 |
| Intercept | ± 0.293 |
| Correlation coefficient | 1.0000 |

Table 4-42

Parameter: CO₂ (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 4-43 Parameter: CO₂ (mmHg)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.961 - 1.041 |
| Intercept | ± 0.865 |
| Correlation coefficient | 0.9994 |

Table 4-44

Parameter: O₂ (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 4-45 Parameter O₂ (mmHg)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.908 - 1.101 |
| Intercept | ± 6.609 |
| Correlation coefficient | 0.9995 |

Table 4-46

Performance data

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 4-47 Parameter Glucose (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.919 - 1.088 |
| Intercept | ± 1.773 |
| Correlation coefficient | 0.998 |

Table 4-48

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 4-49 Parameter Lactate (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.961 - 1.041 |
| Intercept | ± 0.191 |
| Correlation coefficient | 0.9989 |

Table 4-50

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 4-51 Parameter Urea (mmol/L)

| Correlation | |
|-------------------------|---------------|
| Slope | 0.979 - 1.021 |
| Intercept | ± 0.198 |
| Correlation coefficient | 0.9991 |

Table 4-52

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 4-53 Parameter Glucose (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9591 - 1.0426 |
| Intercept | ± 0.4273 |
| Correlation coefficient | 0.9991 |

Table 4-54

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 4-55 Parameter Sodium (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9719 - 1.0289 |
| Intercept | ± 4.0475 |
| Correlation coefficient | 0.9999 |

Table 4-56

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 4-57 Parameter Potassium (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9629 - 1.0385 |
| Intercept | ± 0.1788 |
| Correlation coefficient | 0.9999 |

Table 4-58

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 4-59 Parameter Sodium (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.8311 - 1.2032 |
| Intercept | ± 25.3383 |
| Correlation coefficient | 0.9997 |

Table 4-60

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 4-61 Parameter Potassium (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.8738 - 1.1444 |
| Intercept | ± 0.6284 |
| Correlation coefficient | 1.0000 |

Table 4-62

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 4-63 Parameter Chloride (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9032 - 1.1072 |
| Intercept | ± 8.1053 |
| Correlation coefficient | 0.9990 |

Table 4-64

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 4-65 Parameter Glucose (mmol/L)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.7429 - 1.3461 |
| Intercept | ± 1.0482 |
| Correlation coefficient | 0.9997 |

Table 4-66

Parameter: urea (mmol/L)

Material: NIST 909b

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

Performance data

Measurements per level and instrument: 15

| Expected value | Mean | S _{wr} | Recovery |
|----------------|------|-----------------|----------|
| 5.51 | 5.40 | 0.0248 | 98.0 |

Table 4-67 Parameter Urea (mmol/L)**Parameter: tHb (g/dL), SO₂ (%)**

Material: Tonometered whole blood

Number of instruments: 4 **cobas b 221** 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 4-68 Parameter tHb (g/dL), SO₂ (%)**Parameter: bilirubin (mg/dL)**

Material: human whole blood including 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 4-69 Parameter Bilirubin (mg/dL)

| Correlation | |
|-------------------------|-----------------|
| Slope | 0.9038 - 1.1064 |
| Intercept | ± 1.514 |
| Correlation coefficient | 0.9996 |

Table 4-70**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 ⁽¹⁾ | Y = 0.9963*X | 0 | 0.999 | 20 |

Table 4-71 pH

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

PO₂

Unit: [mmHg]

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

Table 4-72 PO₂**PCO₂**

Unit: [mmHg]

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

Table 4-73 PCO₂**tHb (cobas b 221 system with tHb/SO₂ module)**

Unit: [g/dL]

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

Table 4-74 tHb**SO₂ (cobas b 221 system with tHb/SO₂ module)**

Unit: [%]

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

Table 4-75 SO₂**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 | $Y = -0.100 + 1.000 \cdot X$ | -1.0% | 0.980 | 135 |
| Radiometer 700 | $Y = 0.200 + 1.000 \cdot X$ | +1.1% | 0.977 | 125 |

Table 4-76 tHb**O₂Hb (cobas b 221 system with COOX module)**

Unit: [%]

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

Table 4-77 O₂Hb

Performance data

HHb (cobas b 221 system with COOX module)

Unit: [%]

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

Table 4-78 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 4-79 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 4-80 COHb**SO₂ (cobas b 221 system with COOX module)**

Unit: [%]

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

Table 4-81 SO₂**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 | $Y = -0.127 + 0.968 \cdot X$ | +3.7% abs. | 0.986 | 85 |
| Beckman LX 20 tBil | $Y = -0.537 + 1.060 \cdot X$ | +1.4% abs. | 0.980 | 76 |
| Kodak Vitros tBil | $Y = -0.119 + 0.988 \cdot X$ | -2.4% abs. | 0.984 | 73 |
| Radiometer | $Y = -0.327 + 1.044 \cdot X$ | +10.5% abs. | 0.974 | 82 |

Table 4-82 Bilirubin

Hct

Unit: [%]

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

Table 4-83 Hct**Sodium**

Unit: [mmol/L]

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

Table 4-84 Sodium**Potassium**

Unit: [mmol/L]

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

Table 4-85 Potassium**Calcium**

Unit: [mmol/L]

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

Table 4-86 Calcium**Chloride**

Unit: [mmol/L]

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

Table 4-87 Chloride

Performance data

Glucose

Unit: [mmol/L]

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

Table 4-88 Glucose**Urea**

Unit: [mmol/L]

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

Table 4-89 Urea**Lactate**

Unit: [mmol/L]

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

Table 4-90 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 4-91 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 4-92 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] ⁽¹⁾ | Typical sample volume [μL] ⁽²⁾ | Max. sample volume (volume limitation by the sample sensor) [μL] ⁽³⁾ |
|--|---|---|---|
| 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 4-93 Sample volumes

(1) typical sample volume for Hct ≤ 45%

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

(3) 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 4-94 Sample container

Sample types

- Whole blood
- Serum
- Plasma⁽¹⁾
- Dialysis solutions containing acetate and bicarbonate⁽²⁾
- Recommended QC material⁽³⁾

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

(2) only for electrolytes

(3) 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 ⁽¹⁾ | 32 | 43 |
| Warm-up phase | power failure < 1 minute | 2.5 | 2.5 |
| Electrode exchange | as needed | 25 | 50 |

Table 4-95 Calibrations

(1) including 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) |

Table 4-96

Storage and transportation conditions

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

Table 4-97

Electrodes

Operating conditions

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

Table 4-98

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) |

Table 4-99

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 5 days |
| • Humidity | 20 to 85% (not condensed) over a period of 3 days |
| • Shock resistance | < 30 g |

Table 4-100**Solutions****Operating conditions**

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

Table 4-101**Storage conditions in original packaging**

| | |
|---------------------|--|
| • Temperature | |
| S1 rinse Solution | 2 to 30 °C (24 months ⁽¹⁾) |
| S2 fluid Pack | 2 to 30 °C (18 months ⁽¹⁾) |
| S3 fluid Pack | 2 to 25 °C (18 months ⁽¹⁾) |
| • Relative humidity | 20 to 85% |

Table 4-102

(1) storage time contains also transportation time and the storage time in Mannheim, Germany.

Transportation conditions in original packaging

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

Table 4-103**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 |

Table 4-104**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 |

Table 4-105

Storage conditions in original packaging**cobas b 221<1>/<3>/<5> system****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 |

Table 4-105**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 (including 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 (including up to 60 days in the AutoQC module) |

Table 4-106

Product data

Electrical data

| | |
|----------------------|--|
| Mains voltage range: | 100 to 240 VAC \pm 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): | approximately 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



Warning

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

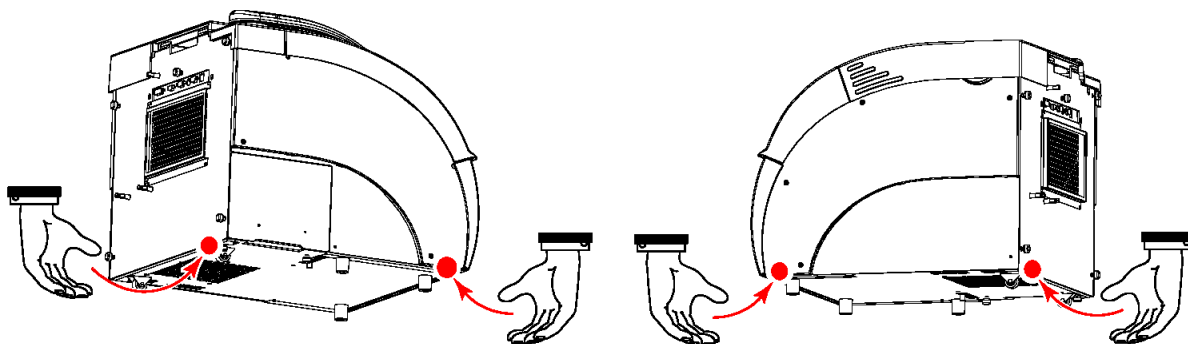


Figure 4-1 Holding points

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 Hard disk |
| 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 Hard disk |
| 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 Hard disk |
| 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: | MS180 PS2 hand scanner with integrated decoder |
| Reading speed: | up to 33 scans/s |
| Resolution: | 0.1 mm |
| Reading distance: | up to 5 cm |
| Reading width: | up to 8 cm |
| Preprogrammed code types ⁽¹⁾ : | <ul style="list-style-type: none">• UPC-A• UPC-E• EAN-8• EAN-13• EAN-128• Interleave 2 of 5• Code 39• Code 93• Code 128 |

(1) 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.

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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 stated otherwise, all measurement values that are used in the equations were measured at 37 °C.

| | | | |
|--|---------------|---------------------------------------|--------------------|
| ctO ₂ , avDO ₂ , ctCO ₂ | 1 vol% | = 1 mL/dL | = 0.4464 mmol/L |
| Ca ²⁺ | 1 mmol/L | = 4.008 mg/dL | |
| tHb | 1 g/dL | = 10 g/L | = 0.6202 mmol/L |
| Glucose | 1 mmol/L | = 18.02 mg/dL | |
| Lactate | 1 mmol/L | = 9.008 mg/dL | |
| 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 | = 39.37x10 ⁻³ Inch [in.]Hg | |

Table 5-1 Conversion table for units

Temperature

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

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

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 |


Table 5-2 Standard values and ranges

| Parameter | Standard value | Possible range |
|-----------------------|----------------|------------------|
| 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 5-2 Standard values and ranges

Equations

 All not listed equations are not realized.

 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 5-3

$$H^+ = 10^{(9-pH)}$$

cHCO₃⁻

Bicarbonate concentration in plasma.^[1]

Unit: [mmol/L]

Equation 5-4

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

ctCO₂(P)

Total concentration of CO₂ in plasma, the sum of dissolved CO₂ and bicarbonate.^[1]

Unit: [mmol/L]

Equation 5-5

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

FO₂Hb

Fractional oxygen saturation^[1]

Unit: [-]

Equation 5-6

$$FO_2Hb = \frac{O_2Hb}{100}$$


BE

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

Unit: [mmol/L]

Equation 5-7

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

 For BE_{act} see Equation 5-40 (p. 128).

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 5-8

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

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 5-9

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

SO₂

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 5-10**

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

tHb/SO₂ module SO₂ is measured

SO₂(c)

No SO₂ data available:

 Measured SO₂ has a higher priority than the calculated SO₂(c).
No calculation without pH, PO₂ or BE.

Unit: [%] ^{[7], [8]}

Equation 5-11

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

At which:

Equation 5-12

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

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

Adult [7] P₅₀ = 26.7

F1 = 1.661

F2 = 0.074

F3 = 4.172

Fetal[7] P₅₀ = 21.5

F1 = 1.3632

F2 = 0.0533

F3 = 4.113

P₅₀

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

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 5-13

$$P_{50} = 26.7 \cdot 10^{(\lg PO_2 - \lg PO_2^k)}$$

At which:

Equation 5-14

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

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

Adult [7] F3 = 4.172

Fetal [7] F3 = 4.113



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

ctO₂

Oxygen content is the sum of oxygen bound to hemoglobin as O₂Hb and the amount of oxygen dissolved in the plasma.^[1]

Unit: [vol%]

Equation 5-15

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

At which:

cobas b 221 system with COOX module: X = O₂Hb

cobas b 221 system with tHb/SO₂ Module: X = SO₂

Only BG values available: X = SO₂(c)

see equation SO₂ (p. 120)

If PO_2 is not available, ctO₂ is calculated with $PO_2 = 90$ mmHg.

ctCO₂(B)

Total concentration of CO₂ in the blood, the sum of the total CO₂ in plasma and the red blood cell (erythrocyte fluid = ERY).[10]

Unit: [mmol/L]

Equation 5-16

$$\text{ctCO}_2(\text{B}) = 0.000768 \cdot \text{PCO}_2 \cdot \text{tHb} \cdot (1 + 10^{(\text{pH}_{\text{ERY}} - \text{pK}_{\text{ERY}})}) + \text{ctCO}_2(\text{P}) \cdot \left(1 - \frac{\text{tHb}}{33.8}\right)$$

At which:

Equation 5-17

$$\text{pH}_{\text{ERY}} = 7.19 + 0.77 \cdot (\text{pH} - 7.4) + 0.035 \cdot \left(1 - \frac{\text{SO}_2}{100}\right)$$

$$\text{pK}_{\text{ERY}} = 6.125 - \lg\left(1 + 10^{(\text{pH}_{\text{ERY}} - 7.84 - 0.06 \cdot \frac{\text{SO}_2}{100})}\right)$$

SO₂ or if SO₂ not available, SO₂(c) Equation 5-8 (p. 119).



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 PCO₂ = 40 mmHg.[7]

Unit: [pH unit]

Equation 5-18

$$\text{pH}_{\text{st}} = (0.8262 - 0.01296 \cdot \text{tHb} + 0.006942 \cdot \text{BE}) \cdot \lg(0.025 \cdot \text{PCO}_2) + \text{pH}$$

cHCO₃⁻_{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 PCO₂ = 40 mmHg.[7]

Unit: [mmol/L]

Equation 5-19

$$\text{cHCO}_3^-_{\text{st}} = 10^{(\text{pH}_{\text{st}} - 6.022)}$$

PAO₂

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

Unit: [mmHg]

Equation 5-20

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

If the result of the calculation is PAO₂ < PO₂, PAO₂ = PO₂ is set. PACO₂ corresponds to the measured PCO₂.

⊕ For t unequal 37°C see equation PAO₂t (p. 127)

AaDO₂

The alveolar arterial oxygen partial pressure gradient (PAO₂ - PaO₂) is the difference between the alveolar oxygen partial pressure, as calculated above, and the measured oxygen partial pressure of arterial blood.^[6]

Unit: [mmHg]

Equation 5-21

$$AaDO_2 = PAO_2 - PaO_2$$

⊕ For t unequal 37°C see equation AaDO₂t (p. 127)

a/AO₂

Arterial alveolar oxygen partial pressure ratio.^[6]

Unit: [%]

Equation 5-22

$$a/AO_2 = \frac{PaO_2}{PAO_2} \cdot 100$$

⊕ For t unequal 37°C see equation a/AO₂t (p. 127)

avDO₂

The arterial venous oxygen tension ratio.^[1]

Unit: [vol%]

Formula - data from venous blood available:

Equation 5-23

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

Calculated ctO₂(a) and ctO₂(v) according to the calculation for ctO₂ for arterial and venous blood.

⊕ for ctO₂ see Equation 5-11 (p. 120)

Calculation only under the following conditions:

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


RI

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

Unit: [%]

Equation 5-24

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

 For t unequal 37°C see Equation 5-34 (p. 127)

Shunt

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

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

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.



WARNING

Warning

- ▶ 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, SO₂ (arterial)
- PO₂ (arterial)
- PAO₂
- ctO₂(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:

- $ctO_2(\text{mixed venous})$

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 5-25

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

| | |
|-----------|-------------------------------------|
| 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 5-15 (p. 121) for arterial and mixed venous blood:

 for ctO_2 see Equation 5-15 (p. 121)

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

Equation 5-26

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

nCa²⁺

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

Unit: [mmol/L]

Equation 5-27

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

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 5-28

$$AG = Na^+ + K^+ - Cl^- - cHCO_3^-$$

pH^t

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

Unit: [pH-Unit]

Equation 5-29

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

H^{+t}

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

Unit: [nmol/L]

Equation 5-30

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

PCO₂^t

PCO₂ value at a patient temperature which is not 37 °C.^[1]

Unit: [mmHg]

Equation 5-31

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

PO₂^t

PO₂ value at a patient temperature which is not 37 °C.^[1]

Unit: [mmHg]

Equation 5-32

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

PAO₂^t

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

Unit: [mmHg]

Equation 5-33

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

for: $PAO_2^t \leq PO_2^t$ otherwise $PAO_2^t = PO_2^t$

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

AaDO₂^t

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

Unit: [mmHg]

Equation 5-34

$$AaDO_2^t = PAO_2^t - PaO_2^t$$

a/AO₂^t

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

Unit: [%]

Equation 5-35

$$a/AO_2^t = \frac{PaO_2^t}{PAO_2^t} \cdot 100$$

RI^t

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

Unit: [%]

Equation 5-36

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

Hct(c)

Hct as a function of tHb.^[4]


Equation 5-37

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

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

Input range: 2.70 to 3.30.

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

 Only measured tHb is permitted.

MCHC

Mean corpuscular hemoglobin concentration.^[4]

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

Equation 5-38

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

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

BO₂

Oxygen capacity.^[1]

Unit: [vol%]

Equation 5-39

$$\text{BO}_2 = \text{tHb} \cdot \left[1 - \frac{(\text{COHb} - \text{MetHb} - \text{SulfHb})}{100} \right] \cdot 1.39$$

SulfHb = 0, if SulfHb is not measured.

BE_{act}

Base deviation at actual oxygen saturation.^[2]

Unit: [mmol/L]

Equation 5-40

$$\text{BE}_{\text{act}} = (1 - 0.0143 \cdot \text{tHb}) \cdot [(1.63 \cdot \text{tHb} + 9.5) \cdot (\text{pH} - 7.4) - 24.26 + \text{cHCO}_3^-] - 0.2 \cdot \text{tHb} \cdot \left(1 - \frac{\text{SO}_2}{100} \right)$$

OsmolalityUnit: [mOsm/kg]^[3]

Equation for blood, plasma, serum:

Equation 5-41

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

Equation for aqueous solution, acetate, bicarbonate:

Equation 5-42

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

Default values:

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

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

Ca²⁺: if no measurement value is available, the default value is used for the calculation

Mg²⁺: 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


OEROxygen extraction ratio.^[1]

Unit: [%]

Equation 5-43

$$\text{OER} = \frac{(\text{ctO}_{2(a)} - \text{ctO}_{2(v)})}{\text{ctO}_{2(a)}} \cdot 100$$

 for ctO₂ see Equation 5-15 (p. 121)

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

Heart minute volume (Q_t)Unit: [vol%]^[6]**Equation 5-44**

$$Q_t = ctO_2(A) - ctO_2(v)$$

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

SaO₂: arterial oxygen saturation fraction**P/F Index**Ration PaO₂/FIO₂^[6]

Unit: [mm/Hg]

Equation 5-45

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

Lactate Clearance

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

The determination of the Lactate Clearance requires two independent measurements.

**Note:**

Both measurements must be carried out with the same patient ID.

The patient ID must therefore be defined as an input value.

**Warning**

- ▶ Samples from patients with other patient IDs can be measured between the two lactate partial measurements.
- ▶ For calculating Lactate Clearance, either the current or the historic lactate value must be greater than 4 mmol/L.
- ▶ At least 2 hours must pass between the two lactate partial measurements, but no more than 8 hours.

Unit: [%]

Equation 5-46

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

Lac is the latest measured lactate value

Lachist is the historical lactate value

h h = 1

Δ is the time interval between the both lactate measurements

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Reference and critical values

The result of laboratory tests have little practical utility until clinical studies have ascribed various states of health and disease to intervals of values.⁽¹⁾

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

Reference intervals, although useful as guideline for clinicians, should not be used as absolute indicators of health and disease.⁽²⁾



Warning

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

pH

| Reference values: | | | |
|---|-----------------|-----------------------|-------------|
| • Whole blood, arterial: ⁽¹⁾ | Cord blood | | 7.18 - 7.38 |
| • Whole blood, venous: ⁽¹⁾ | Cord blood | | 7.25 - 7.45 |
| • Whole blood, arterial: ⁽¹⁾ | Newborn | Premature, 48 h | 7.35 - 7.50 |
| | Newborn | Fullterm, birth | 7.11 - 7.36 |
| | Newborn | Fullterm, 5 - 10 min. | 7.09 - 7.30 |
| | Newborn | Fullterm, 30 min. | 7.21 - 7.38 |
| | Newborn | Fullterm, 1 h | 7.26 - 7.49 |
| | Newborn | Fullterm, 1 day | 7.29 - 7.45 |
| • Whole blood, arterial: ⁽¹⁾ | Adult, children | | 7.35 - 7.45 |
| • Whole blood, venous: ⁽¹⁾ | Adult, children | | 7.32 - 7.43 |
| • Whole blood, arterial: ⁽¹⁾ | Adult | 60 - 90 years | 7.31 - 7.42 |
| | Adult | > 90 years | 7.26 - 7.43 |
| • Whole blood, mixed-venous: ⁽²⁾ | | | 7.35 - 7.43 |

Table 5-3

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

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

| Critical values: | Lower Limit | Upper Limit |
|---|-------------|-------------|
| • Whole blood, arterial or whole blood capillary ⁽¹⁾ | < 7.2 | > 7.6 |

Table 5-4

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

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

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

PO₂

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

Table 5-5

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

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

| Critical values: | | Lower Limit | Upper Limit |
|---|----------|--------------------|----------------------|
| • Whole blood, arterial: ⁽¹⁾ | Adult | 40 mmHg or 5.3 kPa | --- |
| • Whole blood, arterial: ⁽¹⁾ | Children | 45 mmHg or 6 kPa | 125 mmHg or 16.7 kPa |
| • Whole blood, arterial: ⁽¹⁾ | Newborn | 35 mmHg or 4.7 kPa | 90 mmHg or 12 kPa |

Table 5-6

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

PCO₂

| Reference values: | | [mmHg] | [kPa] | |
|---|---------|---------|-------------|-------------|
| • Whole blood, arterial (heparin): ⁽¹⁾ | Newborn | 27 - 40 | 3.59 - 5.32 | |
| • Whole blood, arterial (heparin): ⁽¹⁾ | Infant | 27 - 41 | 3.59 - 5.45 | |
| • Whole blood, arterial (heparin): ⁽¹⁾ | Adult | male | 35 - 48 | 4.66 - 6.38 |
| | Adult | female | 32 - 45 | 4.26 - 5.99 |
| • Whole blood, mixed-venous: ⁽²⁾ | | 37 - 50 | 4.9 - 6.7 | |

Table 5-7

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

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

| Critical values: | | Lower Limit | Upper Limit |
|--|-------|--------------------|--------------------|
| • Whole blood, arterial or whole blood capillary: ⁽¹⁾ | Adult | 20 mmHg or 2.7 kPa | 70 mmHg or 9.3 kPa |

Table 5-8

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

Sodium

| Reference values: ⁽¹⁾ | [mmol/L] | [mEq/L] |
|----------------------------------|-----------|-----------|
| Premature, cord | 116 - 140 | 116 - 140 |
| Premature, 48 h. | 128 - 148 | 128 - 148 |
| Newborn, cord | 126 - 166 | 126 - 166 |
| Newborn | 133 - 146 | 133 - 146 |
| Infant | 139 - 146 | 139 - 146 |
| Child | 138 - 145 | 138 - 145 |
| Adult | 136 - 145 | 136 - 145 |
| Adult > 90 years | 132 - 146 | 132 - 146 |

Table 5-9

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

| Critical values: | Lower Limit | Upper Limit |
|-----------------------------------|-------------|-------------|
| • Serum or plasma: ⁽¹⁾ | 120 mmol/L | 160 mmol/L |

Table 5-10

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

Potassium

| Reference values: | | [mmol/L] | [mEq/L] |
|-----------------------------------|------------------|------------|------------|
| • Serum ⁽¹⁾ | Premature, cord | 5.0 - 10.2 | 5.0 - 10.2 |
| | Premature, 48 h. | 3.0 - 6.0 | 3.0 - 6.0 |
| | Newborn, cord | 5.6 - 12.0 | 5.6 - 12.0 |
| | Newborn | 3.7 - 5.9 | 3.7 - 5.9 |
| | Infant | 4.1 - 5.3 | 4.1 - 5.3 |
| | Child | 3.4 - 4.7 | 3.4 - 4.7 |
| | Adult | 3.5 - 5.1 | 3.5 - 5.1 |
| • Plasma (heparin) ⁽¹⁾ | Adult, male | 3.5 - 4.5 | 3.5 - 4.5 |
| | Adult, female | 3.4 - 4.4 | 3.4 - 4.4 |

Table 5-11

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

| Critical values: | | Lower Limit | Upper Limit |
|-----------------------------------|---------|-------------|-------------|
| • Serum or plasma: ⁽¹⁾ | Adult | 2.8 mmol/L | 6.2 mmol/L |
| | Newborn | 2.8 mmol/L | 7.8 mmol/L |

Table 5-12

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

Chloride

| Reference values: | | [mmol/L] | [mEq/L] |
|---------------------------------|--------------------|----------|----------|
| • Serum, plasma: ⁽¹⁾ | Cord | 96 - 104 | 96 - 104 |
| | Premature | 95 - 110 | 95 - 110 |
| | 0 - 30 days | 98 - 113 | 98 - 113 |
| | Adults | 98 - 107 | 98 - 107 |
| | Adults, > 90 years | 98 - 111 | 98 - 111 |

Table 5-13

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

| Critical values: | Lower Limit | Upper Limit |
|-----------------------------------|-------------|-------------|
| • Serum or plasma: ⁽¹⁾ | 80 mmol/L | 120 mmol/L |

Table 5-14

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

Ionized calcium

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

Table 5-15

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

| Critical values: | Lower Limit | Upper Limit |
|--------------------------|---------------------------|--------------------------|
| • Plasma: ⁽¹⁾ | 0.75 mmol/L or 3.01 mg/dL | 1.6 mmol/L or 6.41 mg/dL |

Table 5-16

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

Hematocrit

| Reference values: | | | % Packed Red Cell Volume: | Volume fraction: |
|-------------------------------|-------|-------------------|---------------------------|------------------|
| • Whole blood: ⁽¹⁾ | Adult | Caucasian, female | 36 - 48 | 0.36 - 0.48 |
| | Adult | Caucasian, male | 40 - 53 | 0.40 - 0.53 |
| | Adult | Afro, female | 34 - 43 | 0.34 - 0.43 |
| | Adult | Afro, male | 34 - 48 | 0.34 - 0.48 |
| | Adult | Athlete, female | 37 - 45 | 0.37 - 0.45 |
| | Adult | Athlete, male | 40 - 50 | 0.40 - 0.50 |

Table 5-17

Reference and critical values

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

Table 5-17

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

| Critical values: | Lower Limit | Upper Limit |
|------------------------|-------------|-------------|
| Adult ⁽¹⁾ | 20% | 60% |
| Newborn ^(a) | 33% | 71% |

Table 5-18

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

tHb (total hemoglobin concentration)

| Reference values: | | | [g/dL] | [g/L] |
|---|-------|----------------------------|-------------|-----------|
| • Whole blood, arterial (heparin): ⁽¹⁾ | Adult | female | 12.0 - 16.0 | 120 - 160 |
| | Adult | male | 13.5 - 17.5 | 135 - 175 |
| | Fetus | Week of gestation: 15 | 10.9 ± 0.7 | 109 ± 7 |
| | Fetus | Week of gestation: 16 | 12.5 ± 0.8 | 125 ± 8 |
| | Fetus | Week of gestation: 17 | 12.4 ± 0.9 | 124 ± 9 |
| | Fetus | Week of gestation: 18 - 21 | 11.7 ± 1.3 | 117 ± 13 |
| | Fetus | Week of gestation: 22 - 25 | 12.2 ± 1.6 | 122 ± 16 |
| | Fetus | Week of gestation: 26 - 29 | 12.9 ± 1.4 | 129 ± 14 |

Table 5-19

| Reference values: | | [g/dL] | [g/L] |
|-------------------|-------------------------|-------------|-----------|
| Fetus | Week of gestation: > 30 | 13.6 ± 2.2 | 136 ± 22 |
| Cord blood | | 13.5 - 20.7 | 135 - 207 |
| Newborn | 1 day | 15.2 - 23.5 | 152 - 235 |
| Newborn | 2 - 6 days | 15.0 - 24.0 | 150 - 240 |
| Infant | 14 - 23 days | 12.7 - 18.7 | 127 - 187 |
| Infant | 24 - 37 days | 10.3 - 17.9 | 103 - 179 |
| Infant | 40 - 50 days | 9.0 - 16.6 | 90 - 166 |
| Infant | 2.0 - 2.5 months | 9.2 - 15.0 | 92 - 150 |
| Infant | 3.0 - 3.5 months | 9.6 - 12.8 | 96 - 128 |
| Infant | 5 - 7 months | 10.1 - 12.9 | 101 - 129 |
| Infant | 8 - 10 months | 10.5 - 12.9 | 105 - 129 |
| Children | 11.0 - 13.5 months | 10.7 - 13.1 | 107 - 131 |
| Children | 1.5 - 3 years | 10.8 - 12.8 | 108 - 128 |
| Children | 5 years | 11.1 - 14.3 | 111 - 143 |
| Children | 10 years | 11.9 - 14.7 | 119 - 147 |
| Children | 12 years | 11.8 - 15.0 | 118 - 150 |
| Children | 15 years | 12.8 - 16.8 | 128 - 168 |

Table 5-19

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

| Critical values: | Lower Limit | Upper Limit |
|------------------------|-------------|-------------|
| Adult ⁽¹⁾ | 7 g/dL | 20 g/dL |
| Newborn ^(a) | 10 g/dL | 22 g/dL |

Table 5-20

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

Oxygen saturation (SO₂)

| Reference values: | | % Saturation | Fraction Saturation |
|---|------------|--------------|---------------------|
| • Whole blood, arterial: ⁽¹⁾ | Newborn | 40 - 90 | 0.40 - 0.90 |
| | Thereafter | 94 - 98 | 0.94 - 0.98 |
| • mixed-venous: ⁽¹⁾ | | 70 - 80 | 0.70 - 0.80 |

Table 5-21

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

Oxyhemoglobin (O₂Hb)

| Reference values: | | % O ₂ Hb | Fraction O ₂ Hb |
|-------------------------------|-----------|---------------------|----------------------------|
| • Whole blood: ⁽¹⁾ | Nonsmoker | 94 - 98 | 0.94 - 0.98 |

Table 5-22

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

Desoxyhemoglobin (HHb)

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

Table 5-23

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

Carboxyhemoglobin (COHb)

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

Table 5-24

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

Methemoglobin (MetHb)

| Reference values: | | | |
|-------------------------------|-----------------------|--------------------------|---|
| • Whole blood: ⁽¹⁾ | | 0.06 - 0.24 g/dL | 9.3 - 37.2 µmol/L |
| | | 0.04 - 1.52% of total Hb | 0.0004 - 0.0152 mass fraction of total Hb |
| | Toxic ⁽²⁾ | > 15% | |
| | Lethal ⁽²⁾ | > 70% | |

Table 5-25

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

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

Total bilirubin (=neonatal)

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

Table 5-26

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

| Critical values: ⁽¹⁾ | | Lower Limit | Upper Limit |
|---------------------------------|---------|-------------|-------------|
| • Serum or plasma | Newborn | --- | 15 mg/dL |

Table 5-27

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

Glucose

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

Table 5-28

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

| Critical values: ⁽¹⁾ | | Lower Limit | Upper Limit |
|---------------------------------|---------|-------------|-------------|
| • Serum or plasma | Adult | 40 mg/dL | 450 mg/dL |
| | Child | 46 mg/dL | 445 mg/dL |
| | Newborn | 30 mg/dL | 325 mg/dL |

Table 5-29

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

Lactate

| Reference values: | | [mg/dL] | [mmol/L] |
|-------------------------------|------------------------|---------|-------------|
| • Whole blood: ⁽¹⁾ | venous (at bed rest) | 5 - 15 | 0.56 - 1.39 |
| | arterial (at bed rest) | 3 - 7 | 0.36 - 0.75 |

Table 5-30

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

| Critical values: ⁽¹⁾ | | Lower Limit | Upper Limit |
|---------------------------------|-------|-------------|-------------|
| | Adult | --- | 3.4 |
| | Child | --- | 4.1 |

Table 5-31

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

Urea/BUN

| Reference values (BUN): | | [mg/dL] | [mmol/L] |
|-------------------------|--------------------|---------|------------|
| • Serum ⁽¹⁾ | Cord blood | 21 -40 | 7.5 - 14.3 |
| | Premature (1 week) | 3 - 25 | 1.1 - 8.9 |
| | Newborn, 1 day | 4- 12 | 1.4 - 4.3 |
| | Infant/child | 5 - 18 | 1.8 - 6.4 |
| | Adult | 6 - 20 | 2.1 - 7.1 |
| | Adult > 60 years | 8 - 23 | 2.9 - 8.2 |

Table 5-32

(1) Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: 4th Edition 2006, p. 2301.

| Critical values (BUN): ⁽¹⁾ | | Lower Limit | Upper Limit |
|---------------------------------------|----------|-------------|-------------|
| Serum oder Plasma | Adult | --- | 80 mg/dL |
| | Children | --- | 55 mg/dL |

Table 5-33

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

Conversion BUN > Urea Indication of BUN in mg/dL (mmol/L):

$$\text{Urea} = \text{BUN} \times 2.14$$

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Measurement

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

In this chapter

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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.

- ⓘ Guidelines and additional information about handling blood samples are provided in CLSI document M29-A3, "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guidelines - 3rd edition 2005" and other documents.

Sample acquisition



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

Warning

- ▶ 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, SO₂ and Hct measurement

Whole blood, especially for the analysis of tHb, SO₂ 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<6> system, cobas b 221<5> 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.

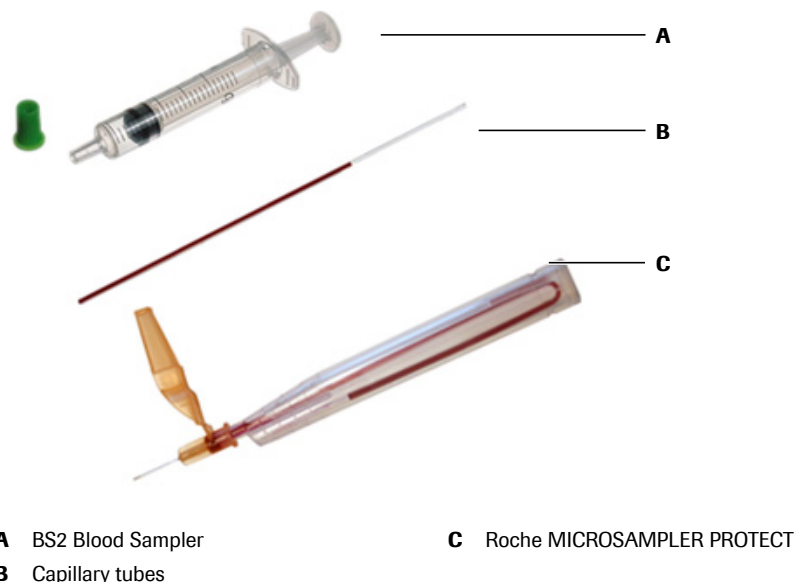


Figure 6-1

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.



Warning

- ▶ 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 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 PROTECT

To make arterial sample collection technically easier, the Roche MICROSAMPLER PROTECT was developed.

The Roche MICROSAMPLER PROTECT consists of one curved plastic capillary tube (~220 µL) in a plastic container and is ideally suited to atraumatic arterial blood collection.

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



Warning

- ▶ The use of sample containers or clot inhibitors other than those manufactured by Roche may lead to adulteration of the samples and errors and differences in the measurement values.
- ▶ Roche developed a specialized sample collection container for this purpose and recommends its use for this reason.

Sample collection container accessories

The use of the Clot Catcher is recommended to prevent clogging of the sample path during measurement of critical blood, for example, when sampling blood of newborns from earlobes or heels.

Clot catcher The Clot Catcher, which is placed on top of the capillary, **syringe** or **Roche MICROSAMPLER PROTECT**, prevents blood clots and tissue particles from entering the **cobas b 221** system.

Using the Clot Catcher is suitable for the **capillary mode** of the **cobas b 221** system only.



Warning

- ▶ The Clot catcher is not suitable for measurements in "Aspiration from syringe" mode.

Option

Clot Catcher PRO The Clot Catcher PRO, which is placed on top of a syringe, prevents blood clots and tissue particles from entering the **cobas b 221** system.

Using the Clot Catcher PRO is suitable for the **capillary mode** of the **cobas b 221** system only.



Warning

- ▶ The Clot Catcher PRO is not suitable for measurements in syringe mode and in "Aspiration from syringe" mode.



For additional information, refer to the accompanying package insert:

- Clot Catcher
- Clot Catcher PRO.

Sample handling

Whole blood

Withdraw whole blood samples using heparinized syringes, capillaries, or the Roche MICROSAMPLER PROTECT and analyze 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.



WARNING

Warning

- ▶ 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

Interference study: ⁽¹⁾A study was carried out to evaluate the influence of substances that could possibly interfere on the measurement of the following parameters:

BG/ISE/MSS and tHb/SO₂ and COOX on the **cobas b 221** system.

Find the updated list of potential interfering substances for the parameters BG/ISE/MSS and tHb/SO₂ and COOX, measured on the **cobas b 221** system, in the following sections:

- Ⓢ Substances with effect in whole blood samples for tHb/SO₂ (p. 151)
- Ⓢ Substances with effect in whole blood samples for pH, Hct, ISE (p. 151)
- Ⓢ Substances with effect in whole blood samples for MSS (p. 153)
- Ⓢ Substances with effect in whole blood samples for Hb derivatives and bilirubin (p. 154)

Substances with effect in whole blood samples for tHb/SO₂

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|------------------|--------------------------------|-----------------|-------------------------|-------------------------|
| Indocyanin green | 5 mg/L | tHb | 15.60 g/dL | 3.83 ± 0.15 |
| Intralipid | 10 g/L | tHb | 15.00 g/dL | 2.23 ± 0.17 |
| Methylen blue | 30 mg/L | SO ₂ | 99.90% | -25.20 ± 1.47 |
| Lipofundin | 10 g/L | tHb | 14.98 g/dL | 1.33 ± 0.25 |

Table 6-1 Interferences tHb/SO₂ module

Substances with effect in whole blood samples for pH, Hct, ISE

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|--------------------------------|--------------------------------|------------------|-------------------------|-------------------------|
| Acetylsalicylic acid (Aspirin) | 100 mg/100mL | Ca ²⁺ | 1.06 mmol/L | 0.16 ± 0.01 |
| Bovine Albumin | 6% | Hct | 47.75% | 5.36 ± 0.42 |
| | 4.5% | Hct | 44.86% | 2.16 ± 0.86 |
| Dobesilate | 20 mg/100mL | K ⁺ | 5.09 mmol/L | 1.06 ± 0.02 |
| Glycolic acid | 50 mg/dL | Ca ²⁺ | 1.09 mmol/L | 0.15 ± 0.00 |
| | | pH | 7.87 | -0.94 ± 0.02 |
| | 200 mg/100mL | Ca ²⁺ | 1.09 mmol/L | 0.31 ± 0.02 |
| | | pH | 7.65 | -1.08 ± 0.03 |
| Potassium chloride | 75 mg/100mL | K ⁺ | 3.90 mmol/L | 9.76 ± 0.07 |
| Potassium thiocyanate | 23.2 mg/100mL | K ⁺ | 3.91 mmol/L | 2.25 ± 0.02 |
| | 6.8800 mmol/L | Na ⁺ | 135.5 mmol/L | -4.95 ± 0.33 |

Table 6-2 Interferences pH, ISE

(1) The study was designed in accordance with the CLSI: "Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition", EP7-A2, Appendix B and was performed with whole blood.

Interferences

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|--------------------------------|--------------------------------|------------------|-------------------------|-------------------------|
| | | Cl ⁻ | 100.2 mmol/L | 5.81 ± 0.54 |
| | 5.1600 mmol/L | Na ⁺ | 135.5 mmol/L | -3.46 ± 0.29 |
| | | Cl ⁻ | 99.3 mmol/L | 6.11 ± 0.33 |
| | 3.4400 mmol/L | Na ⁺ | 136.3 mmol/L | -2.20 ± 0.35 |
| | | Cl ⁻ | 99.4 mmol/L | 3.98 -0.22/-0.23 |
| Magnesium acetate | 15.000 mmol/L | Na ⁺ | 132.8 mmol/L | -3.12 ± 0.51 |
| | | K ⁺ | 4.50 mmol/L | -0.27 ± 0.02 |
| | | Ca ²⁺ | 1.18 mmol/L | 0.20 ± 0.01 |
| | 11.250 mmol/L | Na ⁺ | 134.5 mmol/L | -1.5 +0.66/-0.62 |
| | | K ⁺ | 4.56 mmol/L | -0.33 ± 0.03 |
| | | Ca ²⁺ | 1.15 mmol/L | 0.20 ± 0.02 |
| | 7.500 mmol/L | K ⁺ | 4.46 mmol/L | -0.11 ± 0.03 |
| | | Ca ²⁺ | 1.17 mmol/L | 0.16 ± 0.02 |
| | 3.750 mmol/L | Ca ²⁺ | 1.15 mmol/L | 0.11 ± 0.02 |
| Magnesium nitrate | 128.2 mg/100mL | Ca ²⁺ | 0.98 mmol/L | 0.26 ± 0.01 |
| | | Cl ⁻ | 101.76 mmol/L | 15.58 ± 1.95 |
| Sodium bromide | 37.5 mmol/L | Cl ⁻ | 99.6 mmol/L | 73.09 ± 9.21 |
| | | pH | 7.405 | -0.034 +0.008/-0.007 |
| | 28.1 mmol/L | Cl ⁻ | 98.3 mmol/L | 59.82 ± 15.2 |
| | | pH | 7.410 | +0.040/-0.013 |
| | 18.8 mmol/L | Cl ⁻ | 100.2 mmol/L | 32.45 ± +7.19/-7.2 |
| | | pH | 7.415 | -0.03 ± 0.012 |
| | 9.4 mmol/L | Cl ⁻ | 101.0 mmol/L | 14.94 ± 2.24 |
| | 7.0 mmol/L | Cl ⁻ | 100.8 mmol/L | 3.90 +0.34/-0.35 |
| Sodium citrate, diluted | 1000 mg/100mL | Ca ²⁺ | 1.04 mmol/L | -1.05 ± 0.02 |
| | | Na ⁺ | 143.80 mmol/L | 60.79 ± 1.36 |
| | | K ⁺ | 3.95 mmol/L | -0.58 ± 0.04 |
| Sodium chloride | 140 mmol/L | Na ⁺ | 142.40 mmol/L | 37.23 ± 0.45 |
| | | Cl ⁻ | 104.13 mmol/L | 28.46 ± 4.20 |
| | 130 mmol/L | Na ⁺ | 142.26 | 25.73 ± 0.44 |
| | | Cl ⁻ | 103.45 mmol/L | 20.90 ± 2.75 |
| | 120 mmol/L | Na ⁺ | 142.14 | 16.29 ± 0.43 |
| | | Cl ⁻ | 106.14 mmol/L | 13.72 ± 2.04 |

Table 6-2 Interferences pH, ISE

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|---------------------------|--------------------------------|------------------|-------------------------|-------------------------|
| Sodium hydrogen carbonate | 336 mg/100mL | Ca ²⁺ | 1.14 mmol/L | -0.14 ± 0.01 |
| | | Na ⁺ | 143.53 mmol/L | 32.45 ± 0.61 |
| | 35.000 mmol/L | K ⁺ | 6.93 mmol/L | -0.53 +0.06/-0.05 |
| | 26.250 mmol/L | K ⁺ | 6.81 mmol/L | -0.45 +0.05/-0.06 |
| | 17.500 mmol/L | K ⁺ | 7.12 mmol/L | -0.69 +0.10/-0.09 |
| | 8.750 mmol/L | K ⁺ | 6.80 mmol/L | -0.30 ± 0.03 |
| Thiopental | 0.248 mmol/L | Na ⁺ | 134.28 mmol/L | 3.31 +0.26/-0.25 |
| | 0.186 mmol/L | Na ⁺ | 139.78 mmol/L | 1.26 ± 1.22 |

Table 6-2 Interferences pH, ISE

Substances with effect in whole blood samples for MSS



Note:

With its interference detection and correction algorithm **cobas b 221** systems provide stable and reliable results for MSS parameters. **cobas b 221** system version > 7.06 informs with an interference flag (I...) on the measurement report as soon as 30% of the detected signal of the Glu or Lac sensor is caused by an interfering substance. This warning message does not mean that the flagged results are not within specifications but in case the interference signal climbs to very high levels there is a certain risk that the results are compromised. Therefore, if this warning message appears, it is absolutely necessary that a clinical-medical specialist, who takes the patient's clinical condition into consideration, proves the validity of the test results before any clinical decisions are reached based on these test results.

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|---------------|--------------------------------|-----------|-------------------------|-------------------------|
| Ascorbic acid | 30 mg/100mL | Glu | 4.23 mmol/L | -0.64 ± 0.41 |
| | | Lac | 2.86 mmol/L | -0.19 ± 0.24 |
| Dopamine | 13 mg/100mL | Glu | 4.21 mmol/L | -2.14 ± 0.26 |
| | | Lac | 2.81 mmol/L | -1.34 ± 0.39 |
| | 5 mg/dL | Glu | 4.09 mmol/L | -1.68 ± 0.23 |
| | | Lac | 2.98 mmol/L | -0.88 ± 0.12 |
| | 2 mg/dL | Glu | 5.25 mmol/L | -0.72 ± 0.32 |
| | | Lac | 2.88 mmol/L | -0.48 ± 0.39 |
| Gentisic acid | 50 mg/100mL | Glu | 4.33 mmol/L | -0.87 ± 0.61 |
| | | Lac | 3.77 mmol/L | -0.52 ± 0.24 |
| Glycolic acid | 10 mg/dL | Lac | 3.79 mmol/L | 0.83 ± 0.26 |
| | 50 mg/dL | Lac | 3.75 mmol/L | 1.92 ± 1.05 |
| | 100 mg/dL | Glu | 4.11 mmol/L | -0.42 ± 0.16 |
| | | Lac | 2.14 mmol/L | 0.99 ± 1.00 |

Table 6-3 Interferences MSS

Interferences

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|-------------------|--------------------------------|-------------|-------------------------|-------------------------|
| Uric acid | 200 mg/100 mL | Lac | 2.90 mmol/L | -0.81 ± 0.13 |
| | 20 mg/100 mL | Glu | 5.17 mmol/L | -0.46 ± 0.32 |
| | 7 mg/100 mL | Glu | 4.10 mmol/L | -0.40 ± 0.16 |
| Hydroxy urea | 0.76 mg/100mL | Glu | 4.86 mmol/L | -0.65 ± 0.31 |
| | | Lac | 2.92 mmol/L | -0.35 ± 0.15 |
| | 0.4 mg/dL | Glu | 4.10 mmol/L | -0.36 ± 0.10 |
| Potassium oxalate | 800 mg/100mL | Glu | 4.08 mmol/L | -0.44 ± 0.24 |
| | | Urea | 5.16 mmol/L | -1.24 ± 1.39 |
| Sodium bromide | 10 mg/dL | Glu | 5.07 mmol/L | -0.33 ± 0.45 |
| | 20 mg/dL | Glu | 4.04 mmol/L | -0.96 ± 0.35 |
| | | Lac | 2.09 mmol/L | -0.41 ± 0.23 |
| | 102.9 mg/dL | Glu | 4.17 mmol/L | -0.59 ± 0.33 |
| Lac | | 2.86 mmol/L | -0.23 ± 0.13 | |
| Sodium citrate | 1000 mg/100mL | Urea | 4.91 mmol/L | -0.61 ± 0.07 |
| Sodium chloride | 140 mmol/L | Glu | 5.33 mmol/L | -0.49 ± 0.17 |

Table 6-3 Interferences MSS

Substances with effect in whole blood samples for Hb derivatives and bilirubin

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|-----------------------|--------------------------------|-------------------|-------------------------|-------------------------|
| Cyanometh hemoglobine | > 4.0% | tHb | 15.11 g/dL | -0.86 ± 0.07 |
| | | SO ₂ | 99.73% | -2.54 |
| | | | | +0.05/-0.06 |
| | | HHb | 0.27% | 2.51 |
| | | | | +0.05/-0.06 |
| | 3.0% | tHb | 15.03 g/dL | -0.53 ± 0.11 |
| SO ₂ | | 99.74% | -1.23 | |
| | | | +0.28/-0.29 | |
| | | HHb | 0.26% | 1.22 |
| | | | | +0.28/-0.29 |
| Evans blue | | 5 mg/L | HHb | 0.02 |
| | MetHb | | 0.65 | 0.68 ± 0.05 |
| Hydroxocobalamine | 90.0 mg/100mL | tHb | 12.81 g/dL | 0.79 |
| | | | | +0.04/-0.03 |
| | | SO ₂ | 99.74% | -8.16 |
| | | | | +0.05/-0.06 |
| | | O ₂ Hb | 95.25% | -7.58 |
| | | | | +0.07/-0.06 |
| | HHb | 0.25% | 7.82 | |
| | | | +0.05/-0.06 | |
| | | Bilirubin | 7.67 mg/dL | -3.03 ± 0.07 |

Table 6-4 Interferences Hb derivatives and bilirubin

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|----------------------|--------------------------------|-------------------|-------------------------|-------------------------|
| | 67.50 mg/100mL | tHb | 12.93 g/dL | 0.58 +0.03/-0.04 |
| | | SO ₂ | 99.72% | -6.68 ± 0.07 |
| | | O ₂ Hb | 95.23% | -6.21 +0.08/-0.07 |
| | | HHb | 0.27% | 6.39 ± -0.07 |
| | | Bilirubin | 7.57 mg/dL | -2.34 +0.11/-0.10 |
| | 45.00 mg/100mL | tHb | 13.16 g/dL | 0.37 ± 0.03 |
| | | SO ₂ | 99.74% | -4.87 ± 0.04 |
| | | O ₂ Hb | 95.29% | -4.53 ± 0.07 |
| | | HHb | 0.25% | 4.66 ± -0.04 |
| | | Bilirubin | 7.90 mg/dL | -1.51 ± 0.08 |
| 22.50 mg/100mL | SO ₂ | 99.73% | -2.72 ± 0.05 | |
| | O ₂ Hb | 95.24% | -2.49 ± 0.09 | |
| | HHb | 0.26% | 2.60 +0.04/-0.05 | |
| | Bilirubin | 7.89 mg/dL | -0.89 +0.09/-0.08 | |
| | 11.25 mg/100mL | SO ₂ | 99.75% | -0.11 ± 0.06 |
| HHb | | 0.25% | 0.10 +0.06/-0.05 | |
| Indocyanine | 5 mg/L | HHb | 0.02% | 0.01 ± 0.02 |
| | | MetHb | 0.63% | -0.06 ± 0.06 |
| Intralipid | 10 mg/L | HHb | 0.03% | 0.00 ± 0.02 |
| Lipofundin | 10 mg/L | HHb | 0.03% | -0.01 ± 0.02 |
| Methylen blue | 7.5 mg/L | HHb | 0.02% | 0.00 ± 0.02 |
| | | MetHb | 0.65% | -1.09 ± 0.05 |
| | 30 mg/L | HHb | 0.02% | 0.01 ± 0.02 |
| | | MetHb | 0.77% | -4.61 ± 0.20 |
| | | Bilirubin | 20.65 mg/dL | -3.02 ± 0.14 |
| | 4.0 mg/100mL | tHb | 11.46 g/dL | -1.08 +0.07/-0.06 |
| | | SO ₂ | * | * |
| | | O ₂ Hb | * | * |
| | | COHb | * | * |
| | | MetHb | * | * |
| HHb | | * | * | |
| Bilirubin | | * | * | |
| 3.0 mg/100mL | | tHb | 11.40 g/dL | -0.84 ± 0.09 |
| | SO ₂ | * | * | |
| | O ₂ Hb | * | * | |

Table 6-4 Interferences Hb derivatives and bilirubin

Interferences

| Substance | Concentration of the substance | Parameter | Parameter concentration | Effect of the substance |
|--------------------|--------------------------------|-------------------|-------------------------|-------------------------|
| | | COHb | * | * |
| | | MetHb | * | * |
| | | HHb | * | * |
| | | Bilirubin | * | * |
| | 2.0 mg/100mL | tHb | 11.56 g/dL | -0.42 ± 0.07 |
| | | SO ₂ | * | * |
| | | O ₂ Hb | * | * |
| | | COHb | * | * |
| | | MetHb | * | * |
| | | HHb | * | * |
| | | Bilirubin | * | * |
| | 1.0 mg/100mL | SO ₂ | 99.70% | 0.00 ± 0.01 |
| | | O ₂ Hb | 96.69% | 0.37 ± 0.06 |
| | | COHb | 2.57% | -0.02 +0.06/-0.05 |
| | | MetHb | 0.45% | -0.35 +0.03/-0.04 |
| | | HHb | 0.29% | 0.00 ± 0.01 |
| | | Bilirubin | * | * |
| Patent blue | 1.0 mg/100mL | MetHb | 0.58% | 2.65 ± 0.03 |
| | | Bilirubin | 15.98 mg/dL | 3.81 ± 0.11 |
| | 0.75 mg/100mL | MetHb | 0.57% | 1.95 ± 0.03 |
| | | Bilirubin | 16.23 mg/dL | 2.66 +0.13/-0.14 |
| | 0.50 mg/100mL | MetHb | 0.47% | 1.21 +0.04/-0.03 |
| | | Bilirubin | 15.95 mg/dL | 1.89 +0.06/-0.07 |
| | 0.25 mg/100mL | MetHb | 0.47% | 0.61 +0.07/-0.06 |
| | | Bilirubin | 16.24 mg/dL | 0.93 +0.10/-0.09 |
| Propofol | 2 µl/mL | HHb | 0.03% | 0.00 ± 0.03 |

Table 6-4 Interferences Hb derivatives 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* (p. 151), *tHb/SO2* (p. 158) and *Metabolites* (p. 158).

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.



Warning

- ▶ 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 preferred 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.⁽¹⁾

ⓘ see section *Preanalytics* (p. 145)

(1) 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/SO₂

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* (p. 145)

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* (p. 145).

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. acetylsalicylic 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 *Substances with effect in whole blood samples for MSS* (p. 153).

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 *Substances with effect in whole blood samples for Hb derivatives and bilirubin* (p. 154).

pH measurements in pleural fluid



Warning

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

Measuring procedure



Warning

- ▶ 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**

It is possible to measure samples from syringes (without needles), ampoules and capillaries.

▶ Syringe mode



Warning

- ▶ 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 6-2



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 6-3 (p. 161)

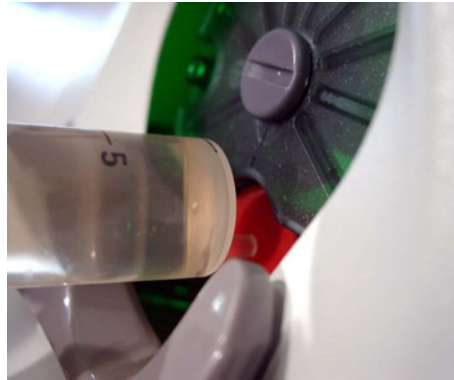


Figure 6-3

- The following screen appears:

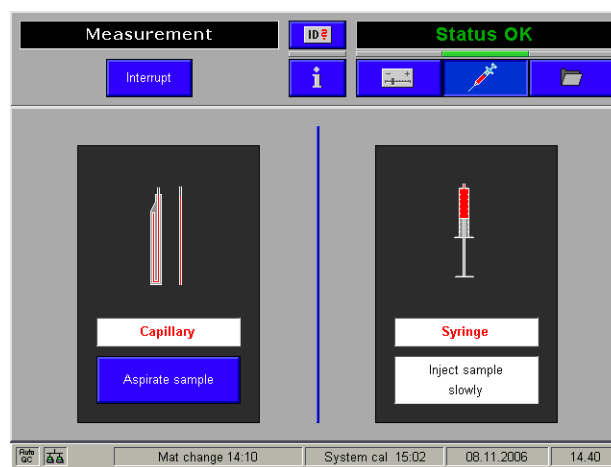


Figure 6-4

- Inject the sample slowly until the signal sounds.



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

- Detach the syringe after the message "Remove sample container" appears.
- The measurement starts.





▶ Capillary measurement

Caution

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

ⓘ see *Capillary tubes* (p. 147) in the section *Sample containers* (p. 147)

- 1 Insert the capillaries or the Roche MICROSAMPLER PROTECT into the fill port. If the position of the capillary is correct, the T&D disk will be backlit in green.



Figure 6-5

- 2 Press the [Aspirate sample] button.
ⓘ see Figure 6-4 (p. 161)
- 3 Detach the capillaries or the Roche MICROSAMPLER PROTECT after the message "Remove sample container" appears.
- 4 The measurement starts.
■

Aspirate from syringe

This option is activated in the [Setup] mode.



Caution

- ▶ 1mL syringes cannot be used for the software mode "Aspirate from syringe".

 A minimum fill height of 15 mm is required.

Press the following buttons:

 Setup > Instrument > Switch > Aspirate from syringe

This option is now also displayed at the top level of the analyzer mode.

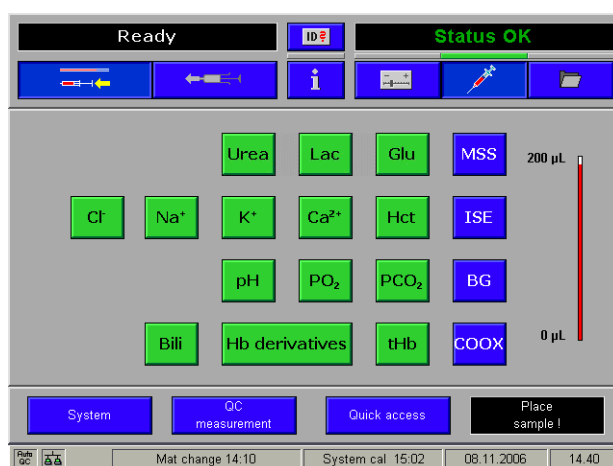
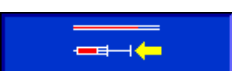



Figure 6-6



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.

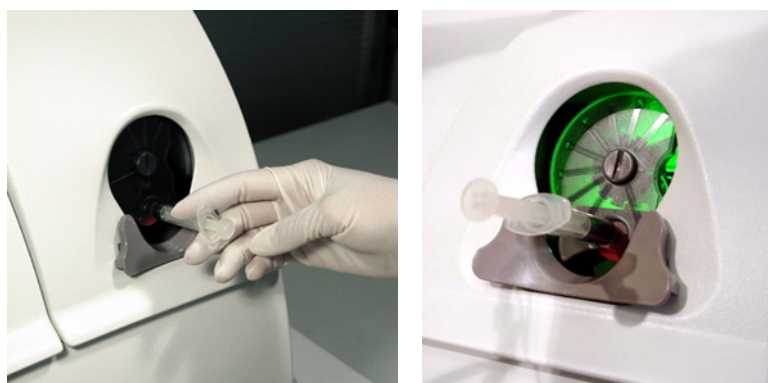


Figure 6-7

3 Press the [Aspirate sample] button.

Aspirate from syringe

- 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 6-8

- 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.

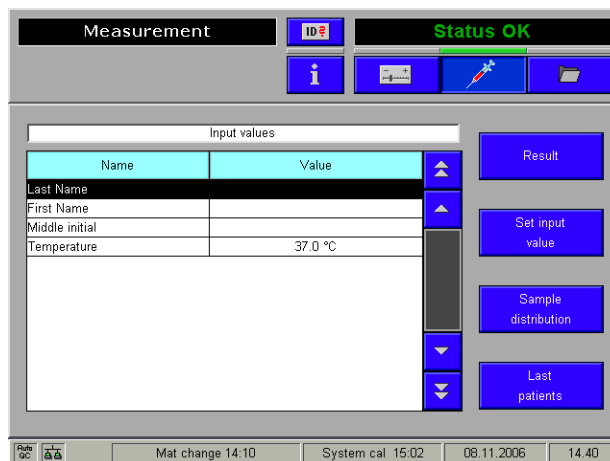





Figure 6-9

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.



WARNING

Warning

- ▶ 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).

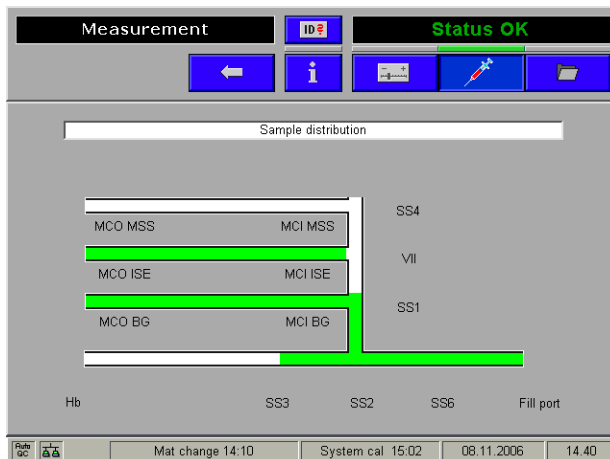


Figure 6-10

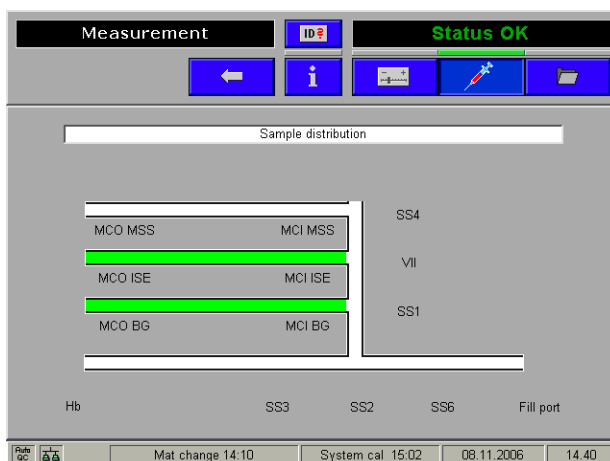


Figure 6-11

Result

After the measurement is completed and all data is entered, the results are displayed on the screen and printed out.

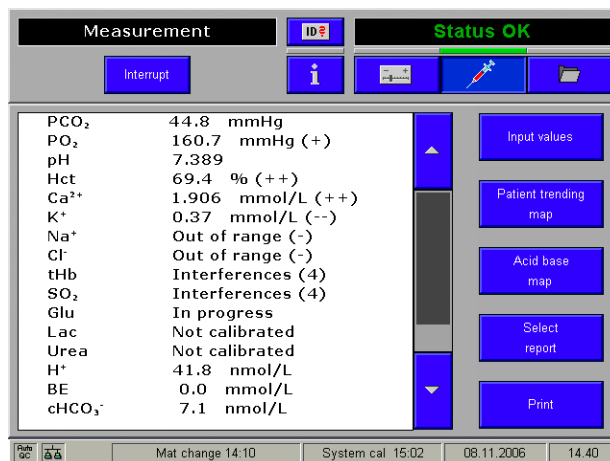


Figure 6-12

[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 must not be changed anymore after the measurement is finished. If changed after sent to the LIS system an inconsistency (worst case data - patient mismatch) between measurement database and LIS database will occur.

Ⓜ 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.

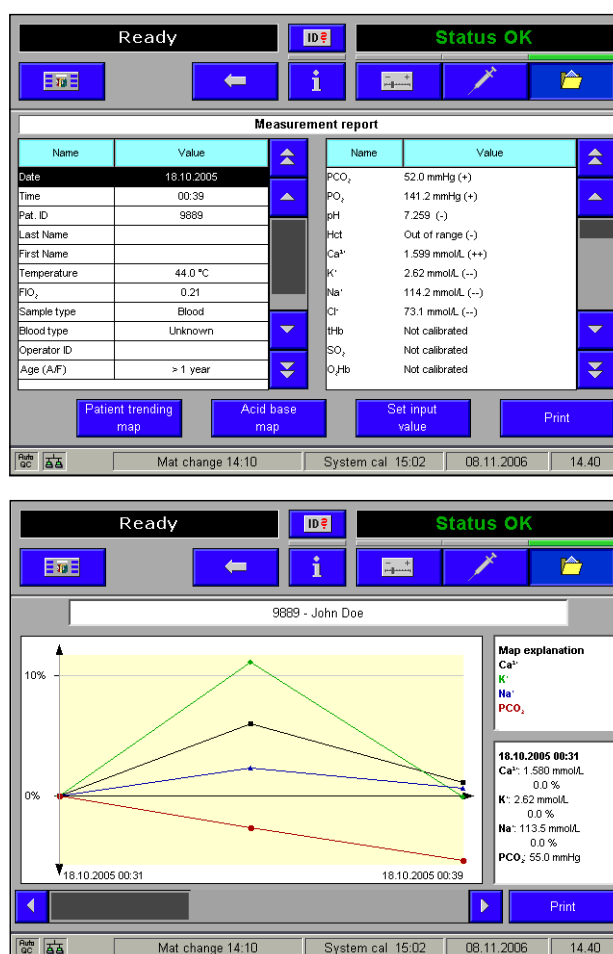


Figure 6-13

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 PCO₂ and pH-measurements are available, the diagram can be displayed and printed.

Data input

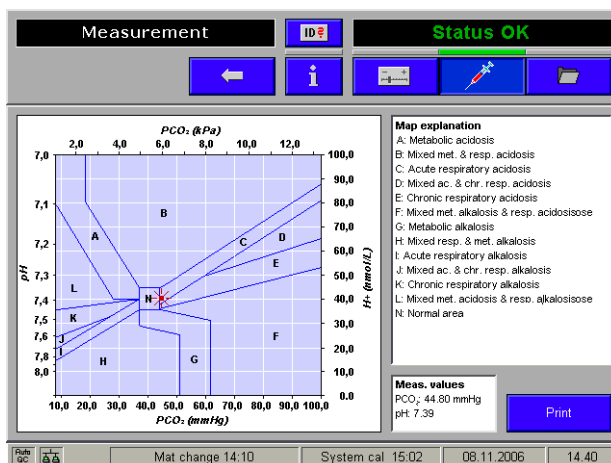


Figure 6-14

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.

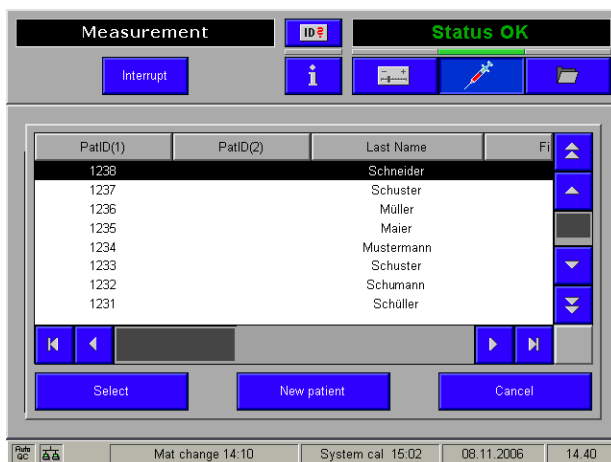


Figure 6-15

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.



Warning

- ▶ 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

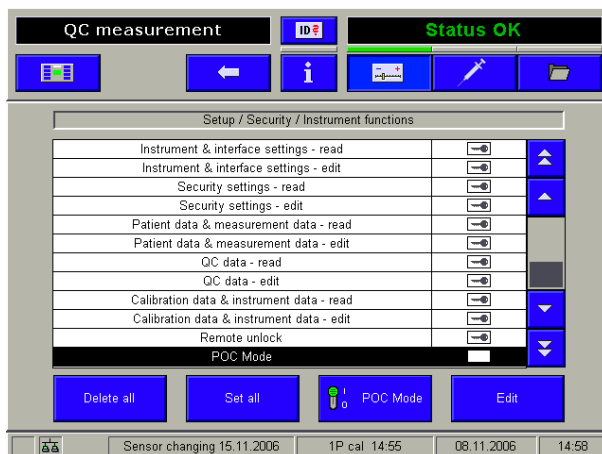


Figure 6-16 POC mode

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.

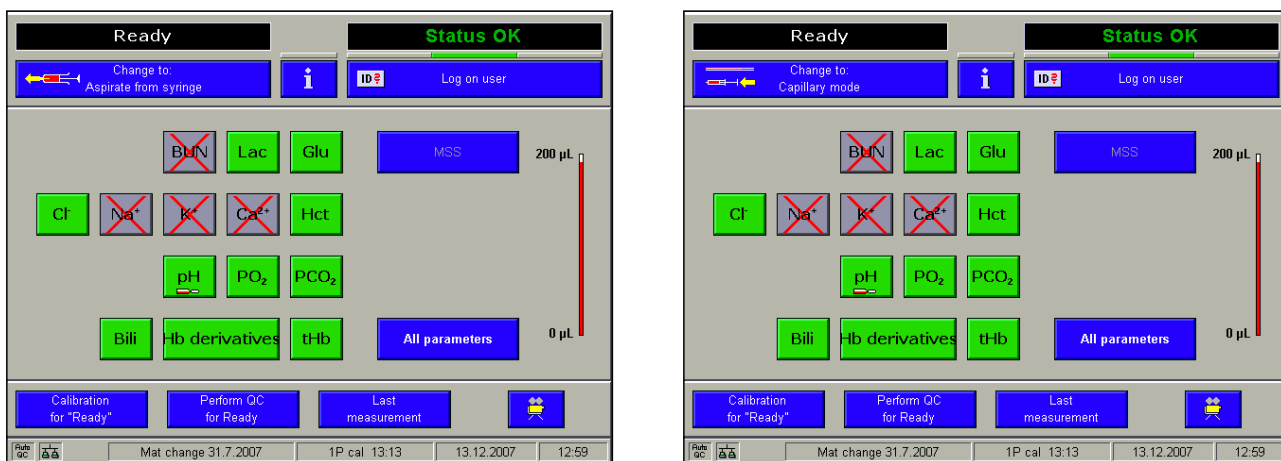


Figure 6-17 Ready screen at POC mode

POC mode (Point-of-care 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.

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Quality control - general




Warning

- ▶ 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.

Automatic application of configured user defined QC consequences (QC lock or QC warning) if MSS sensor cannot be wetted (using standby solution):

- For over 25 minutes during the first 24 hours of the sensor's lifetime
- For over 80 minutes during the remaining sensor lifetime

This is necessary due to uncertain drift of the sensor signal in such cases.

 see No. 30006, Undefined sensor status, *System warnings* (p. 304) ,



Caution

- ▶ If the MSS sensor wetting is not applied for the above defined period of time, the parameters Glu and Lac might be sensitive to the other enzyme. Therefore, a full QC measurement (level 1, level 2, level 3) will become necessary to ensure sensor accuracy.

The system will automatically lock AUTO-TROL materials, if no AUTO-TROL materials are installed, the system will lock COMBITROL.

General QC concept

Roche always strives to ensure the highest quality standards for its products. This quality awareness is the result of a sense of responsibility toward the customer and the well-being of the patient.

The quality control is an important element of this claim. Aqueous 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 (1 = low, 2 = normal, 3 = high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument (switched off more than 24 hours).

Additionally complete a quality control test on one level between two automatic 2P calibrations. The levels have to be alternated (1 = low, 2 = normal, 3 = high).

For example (2P calibration interval: 12 hours):

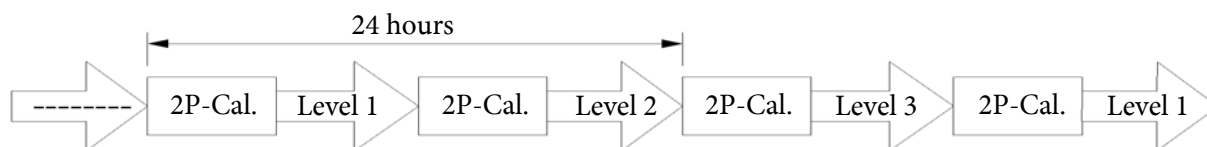


Figure 7-1

- ⊕ The automatic system calibration includes a complete 2P calibration.

Complete at least two quality control tests on different levels once daily or more often in accordance with local regulations.

- ⊕ 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/SO₂ (**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)

- Color 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 PO₂, 2SD = 12 mmHg, 1SD = 6 mmHg).

The QC measurement results within the target value range $\pm 2SD$ are acceptable.

If QC measurement results fall outside the target value range $\pm 3SD$, the parameter must be locked

ⓘ see section *Important information concerning the analysis of QC measurement results* (p. 178).

QC measurement results that are greater than the target value $\pm 2SD$, but less than the target value $\pm 3SD$, cause QC warning and must be treated accordingly.

ⓘ see section *Important information concerning the analysis of QC measurement results* (p. 178).


Important information concerning the analysis of QC measurement results



Warning

- ▶ Ensure, that "Multirules" rule 1 and 2 are activated and the QC consequence "QC lock" was assigned to the parameters.

 see section *Multirules* (p. 199)

 see section *QC consequences* (p. 201)

The evaluation depends upon which SD areas are featured in the QC measurement results:

- **Measured value is within the target value range $\pm 2SD$**


The parameter is acceptable.

The QC measurement results are within $\pm 2SD$ from the target value and the parameter is/remains activated for measurements.

- **Measured value is outside the target value range $\pm 3 SD$**

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* (p. 202)

- **Measured value is larger than target value $\pm 2SD$, but smaller than target value $\pm 3 SD$**

Consequence: The parameter is flagged with the information "warning" on the printout. However, the parameter will not be marked as QC warned in the "Ready" screen.

 see *Quality control - general* (p. 175)

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 section *QC measurements* (p. 232)

The analysis can be automated by activating additional multirules.

 see section *Multirules* (p. 199)

If the result of the repeated measurement is greater than target value $\pm 2SD$, but less than target value $\pm 3SD$, the parameter is not locked, but must not be used for further patient measurements.



Caution

- ▶ 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

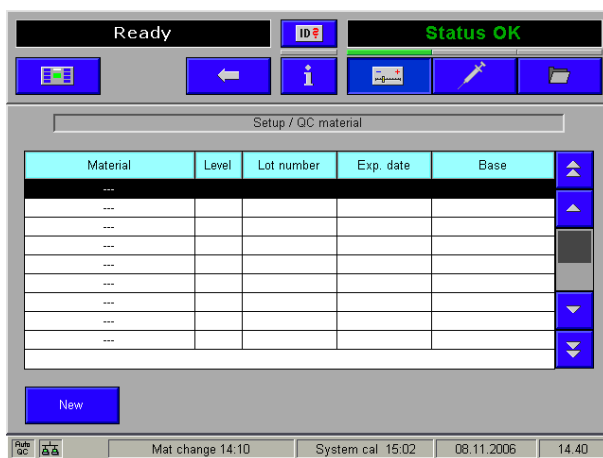


Figure 7-2

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.

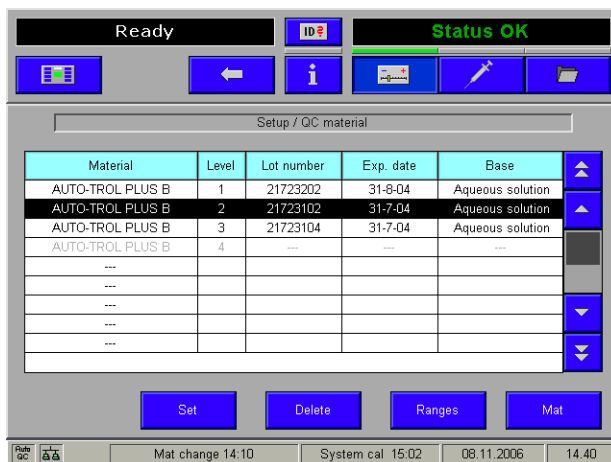


Figure 7-3

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].

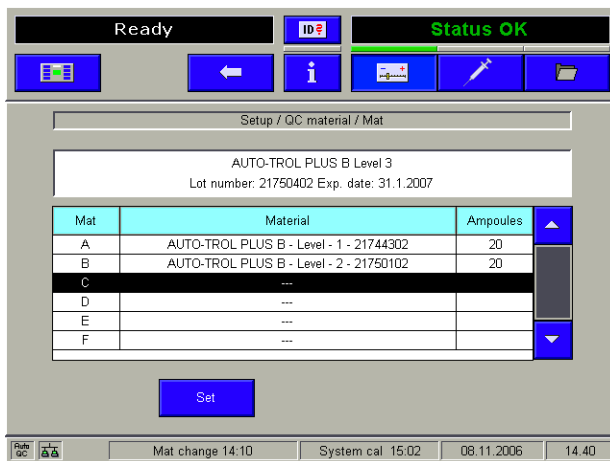


Figure 7-4



Figure 7-5

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:

Pull out the AutoQC drawer.

The following screen appears:

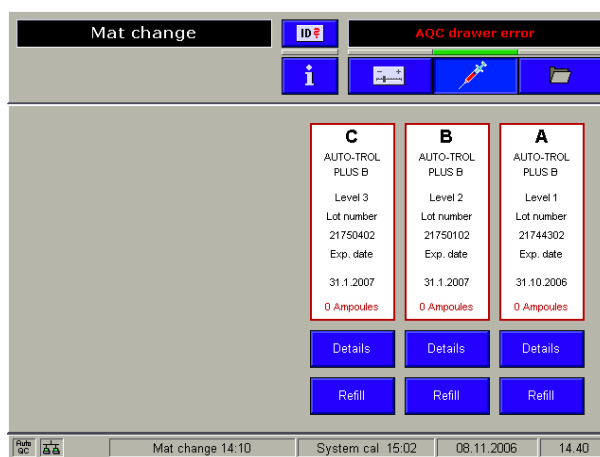


Figure 7-6

- 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 7-7 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:

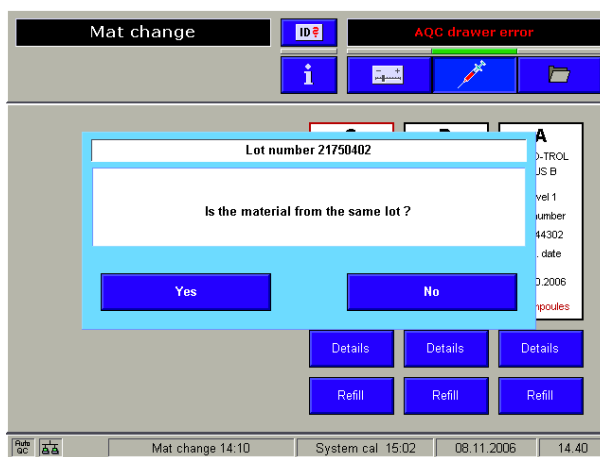


Figure 7-8

- 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.

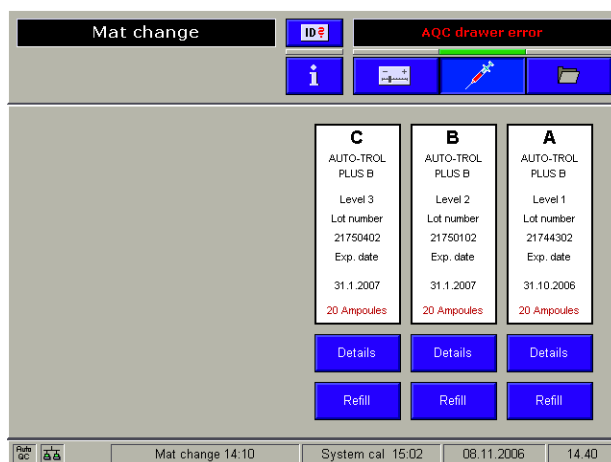


Figure 7-9

- 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).

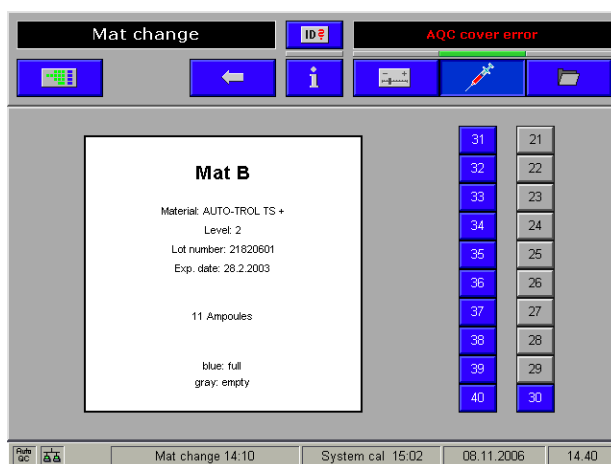


Figure 7-10

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

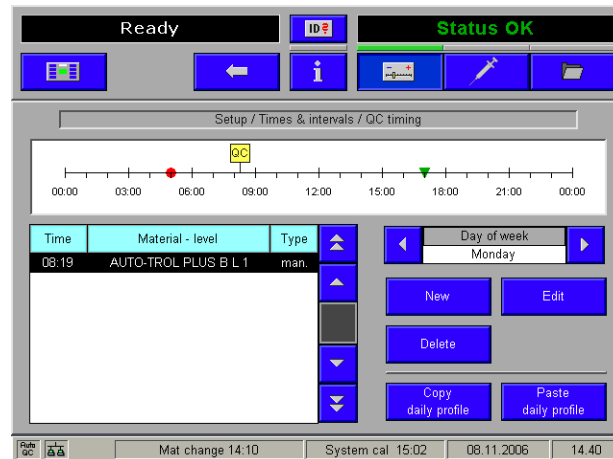


Figure 7-11

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)

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.

1 Press the following buttons:

 Setup > QC Material > QC Material

2 Read in the material code from the package insert using the barcode scanner or press the [New] button and manually enter the information.

3 Press the [Ranges] button.

4 Read in the other barcodes for the target values.

5 Select the material/level combination and press [Mat].

6 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]).

7 Press [Set] and the selected material/level combination will be assigned to a mat (A-F).



Press this button to store the assignment.

8 Press the "Analyzer" button to change to the analyzer mode.

9 Pull out the AutoQC drawer.

10 Take a full mat of the follow-up material from the package.


11 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.

12 Place the mat in the previously defined position (A-F) of the ampoule block.


13 Press [Refill].

14 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.

Change lot (applies only to AutoQC measurements)

15 Next, press the following button:

 Setup > QC material > Change lot

16 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.

17 In the "New lot number" window, select the lot of the replacement material.

18 Press [Select new lot number] – the new lot becomes the follow-up material of the current material.



Press this button to store the assignment.



Control - on board time

☰ Setup > QC material > Control - on board time

Activating this function allows you to monitor the on board time of new QC material or QC material already in use.

When installing expired QC material, a warning is output during the installation process. With each QC measurement a message is displayed on the QC report and in the QC database.

Depending on the material status, the following notes are displayed on the QC report and in the QC database:

| Material status | Displayed message |
|------------------------|--------------------------|
| QC material expired | "Material expired" |
| On board time exceeded | "On board time exceeded" |

Table 7-1

⚠ Expired QC material is not locked. QC measurements continue to be possible.

▶ QC setup wizard

1 Starting with the top level of the analyzer mode:

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*.

2 Open the AQC drawer.

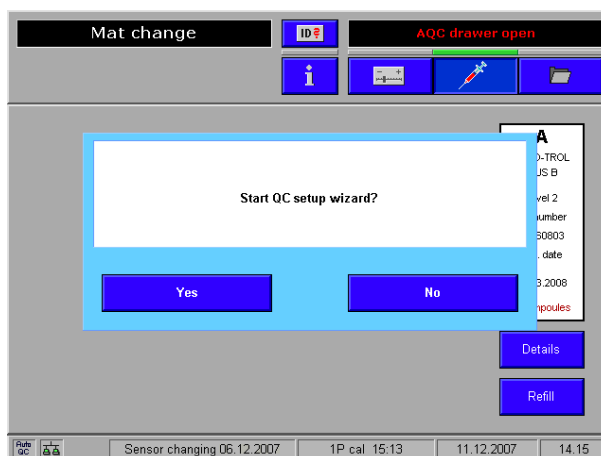


Figure 7-12

3 Press [Yes]. Following screen appears:



Figure 7-13

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)* (p. 186)
- 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 7-14

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+ (only for system 1,3 and 5)
- AUTO-TROL PLUS B

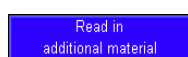
The following QC materials do not meet these requirements:

- COMBITROL TS
- COMBITROL TS+ (only for system 1,3 and 5)
- COMBITROL PLUS
- COMBITROL PLUS B



Figure 7-15

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.



You can scan more QC materials.



See Figure 7-14 (p. 191)

Table 7-2

For AutoQC-compatible materials, the process continues and checks whether an AutoQC module is installed.

▶ Assigning the mats

- 1 The scanned QC material now has to be assigned a position in the AutoQC module.



Figure 7-16

- 2 All previously assigned mats are displayed. If no position is available, you first have to delete a position using [Delete].
- 3 Press [Set]; a material/level combination is assigned to a mat (A-F).
- 4 Take a full mat out of the package.
- 5 Turn 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 7-17

- 6 Insert the mat into the previously defined position (A-F) of the ampoule block.
- 7 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

- 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.



If a lot change has been carried out, the AQC times are already defined and are accepted automatically.

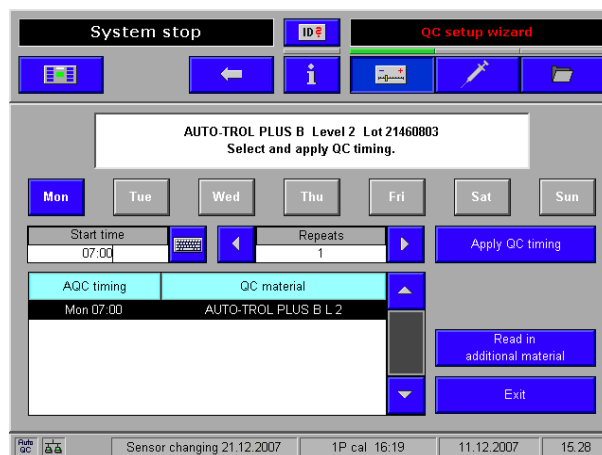


Figure 7-18

All previously defined AQC times are shown in the list.

- Using the [Mon] - [Sun] buttons, select the day of the week on which the AQC measurement is to be carried out.
- Enter starting time and change the number of "Repeats".
- 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.

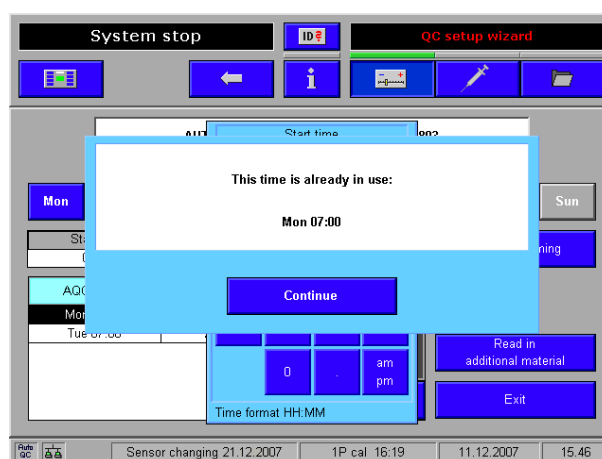


Figure 7-19

If no day of the week was selected, the QC times cannot be accepted and a corresponding message is displayed.

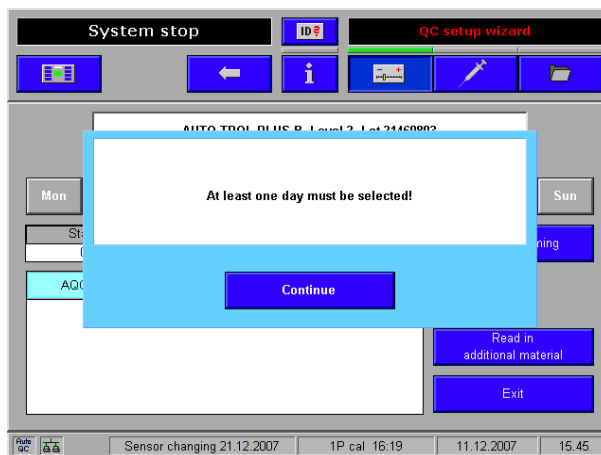
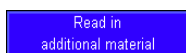


Figure 7-20



Press this button to exit the QC setup wizard and save the input.
DRAFT



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 section *Checking for AutoQC compatibility* (p. 192)



Other options for starting the QC setup wizard are:

Follow the additional instructions on the screen.


- Pressing the buttons [Setup] > [QC material] > [QC setup wizard].



QC measurement


In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = high) after each electrode exchange, after each exchange of solutions and packs and after startup of the instrument (switched off more than 24 hours).

Additionally complete a quality control test on one level between two automatic 2P calibrations. The levels have to be alternated (1 = low, 2 = normal, 3 = high).

 see *General QC concept* (p. 176)

Manual QC measurement

- 1 Press the following buttons, starting with the top level of the analyzer mode:

 QC measurement

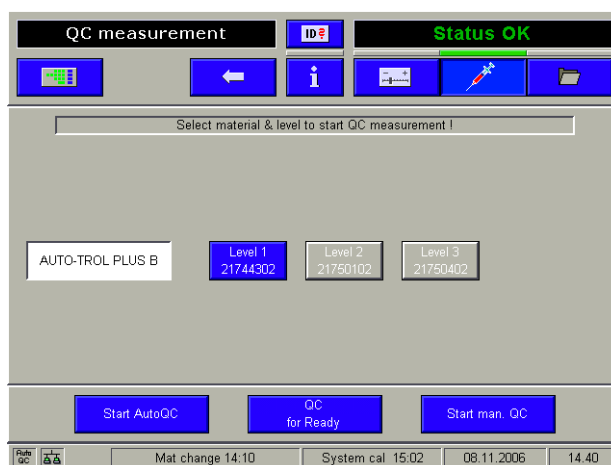


Figure 7-21

- 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 7-22 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 section *Data manager* (p. 229) 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⁽¹⁾ and their interpretation for blood gas analysis⁽²⁾. 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

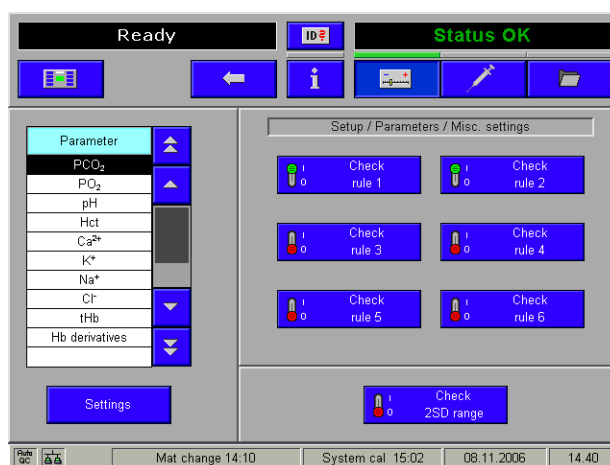



Figure 7-23

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).

If only Rule 1 is activated, in case of violation, this results in a warning only; the parameter is not locked in the rest of the sequence.

(1) James O. Westgard, et al: A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry. Clinical Chemistry, Vol. 27, No.3, 1981

(2) 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 levels (T=total) |
| N_L | number of individual measurements per level (L=Level) |
| m | QC measurement value of one level and one parameter |
| 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 $x \pm 2\sigma$ |
| 2. 1_{3s} | QC measurement value (m) is outside $x \pm 3\sigma$ |
| 3. $(2 \text{ von } 3)_{2s}$ | Two of three QC measurement values are outside $x \pm 2\sigma$ Observation time period: 1 series (repeatability) $N_T = 3$ |
| 4. 2_{2s} | 2 QC measurement values (m) are outside $x \pm 2\sigma$ Observation time period: 2 series $N_L \geq 2$ |
| 5. 6_{1s} | 6 QC measurement values (m) are outside $x \pm 1\sigma$ 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 7-3 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

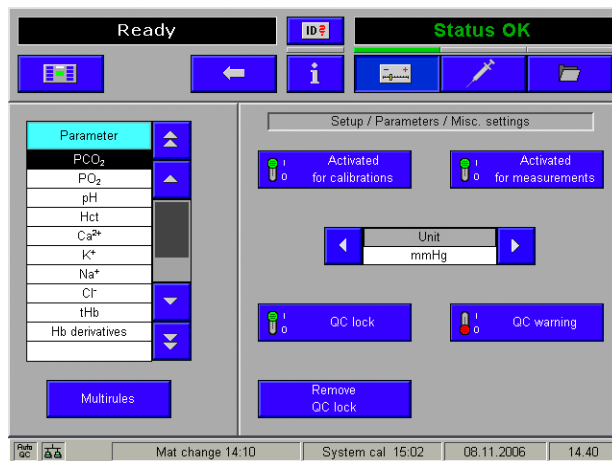


Figure 7-24

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 parameter 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



Warning

- ▶ 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".
-

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 section *Replacement of the electrodes* (p. 270)

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

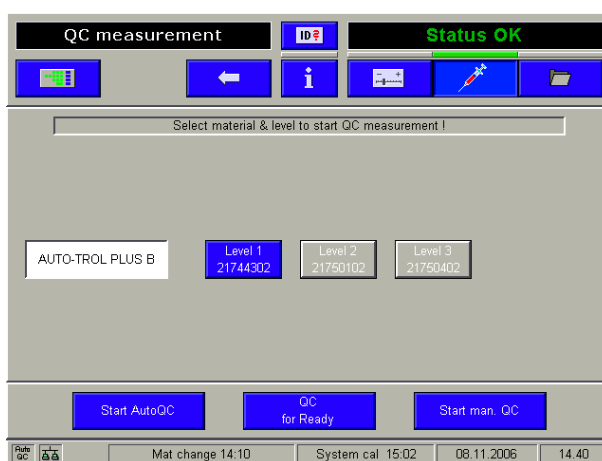


Figure 7-25



- 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:

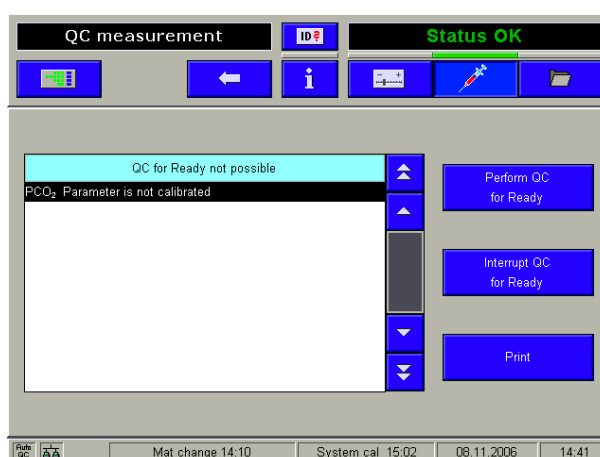


Figure 7-26

- 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.



- 1 Proceeding from the uppermost level of the analyzer mode, press the following buttons:

QC measurement

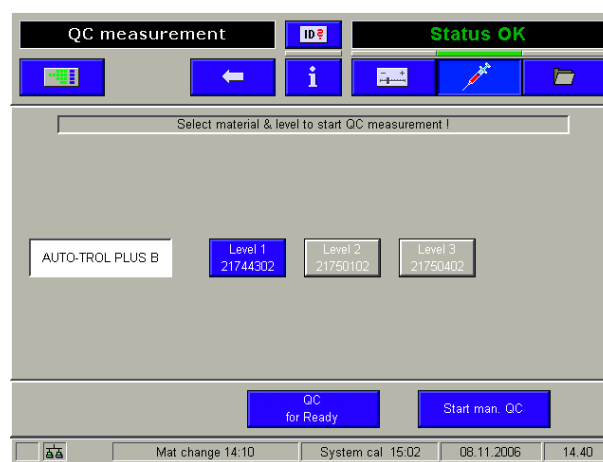


Figure 7-27

- 2 Press [QC measurement for Ready].
- 3 If the parameters are not all ready for measurement, the following screen appears:

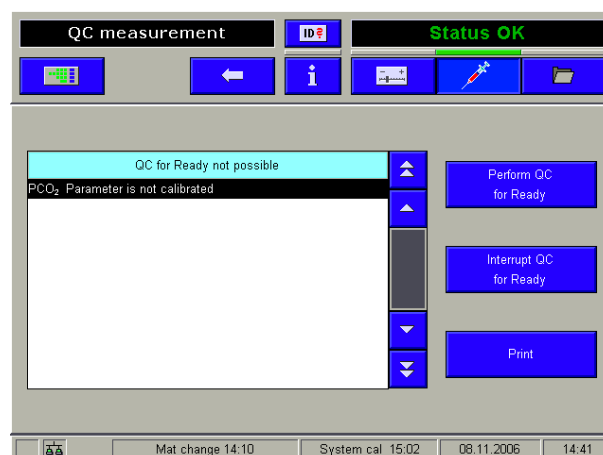


Figure 7-28

- 4 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.

- 5 Press the button [Perform QC for Ready]. The following screen appears:

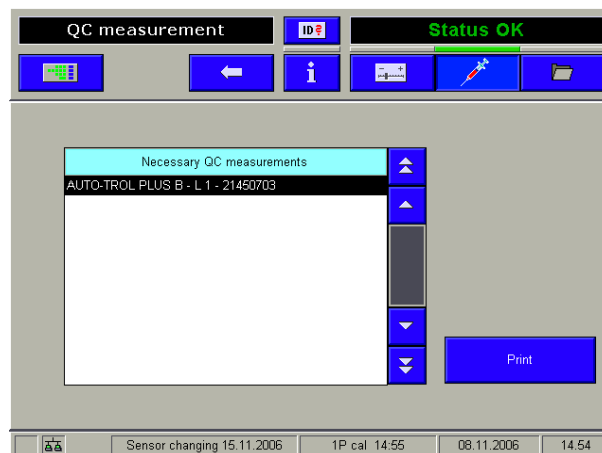


Figure 7-29

- 6 Here, the respective material/level combinations are listed that can remove this lock again.
- 7 Print the list [Print] and perform a manual QC measurement with the listed QC materials.

④ see section *QC measurement* (p. 196)



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.
- 5 If the problem cannot be solved successfully, the Customer Service must be notified.



Note:

For optimal display of the QC results on the screen and the printout, the QC values are rounded. However, unrounded values are used for evaluating the individual QC results. This can cause a "nOK" evaluation of a QC result, even if the QC result shown lies within the target range.

This procedure is necessitated by the software and does not result in an increased patient risk.



Calibration

In this chapter, all automatic and user-activated calibrations are described.

In this chapter

Chapter **8**

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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 and **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) including O_2

Adjustable: **every 30 minutes (standard), 1 hour**.



Warning

- ▶ USA: 30 min only
(adjustable: [Setup] > [Protected setup] - this area is password protected and is accessible only to authorized personnel or customer service representative).

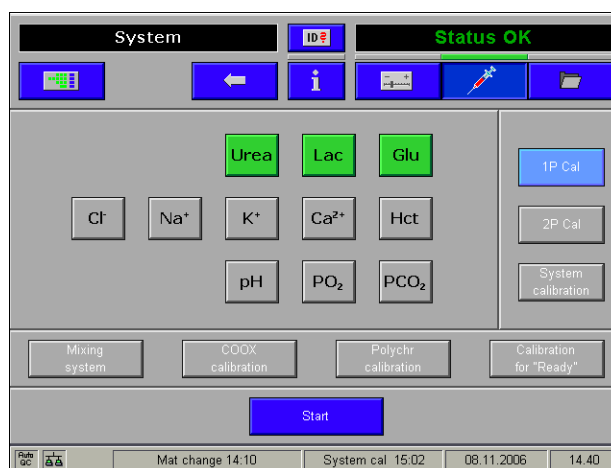
Recalibration - without O₂

After every measurement.

User-activated calibrations

Activation in analyzer mode:

System > Calibration



A Example: Instrument with COOX and MSS module

Figure 8-1 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 PCO₂
- PO₂

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 *COOX calibration (for instrument versions with COOX module only)* (p. 253).
- 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

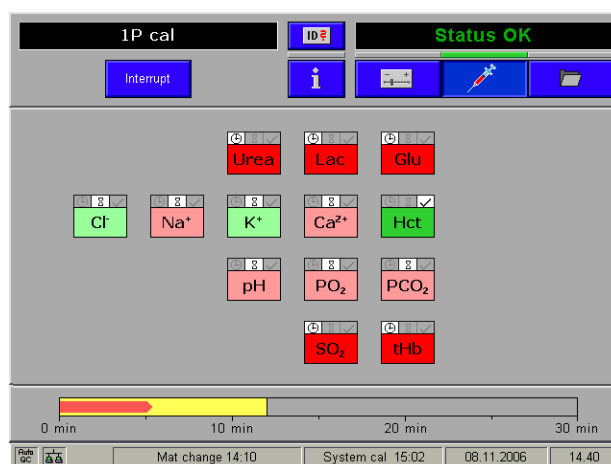


Figure 8-2 System calibration

| | |
|--|---|
| | 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**

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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"

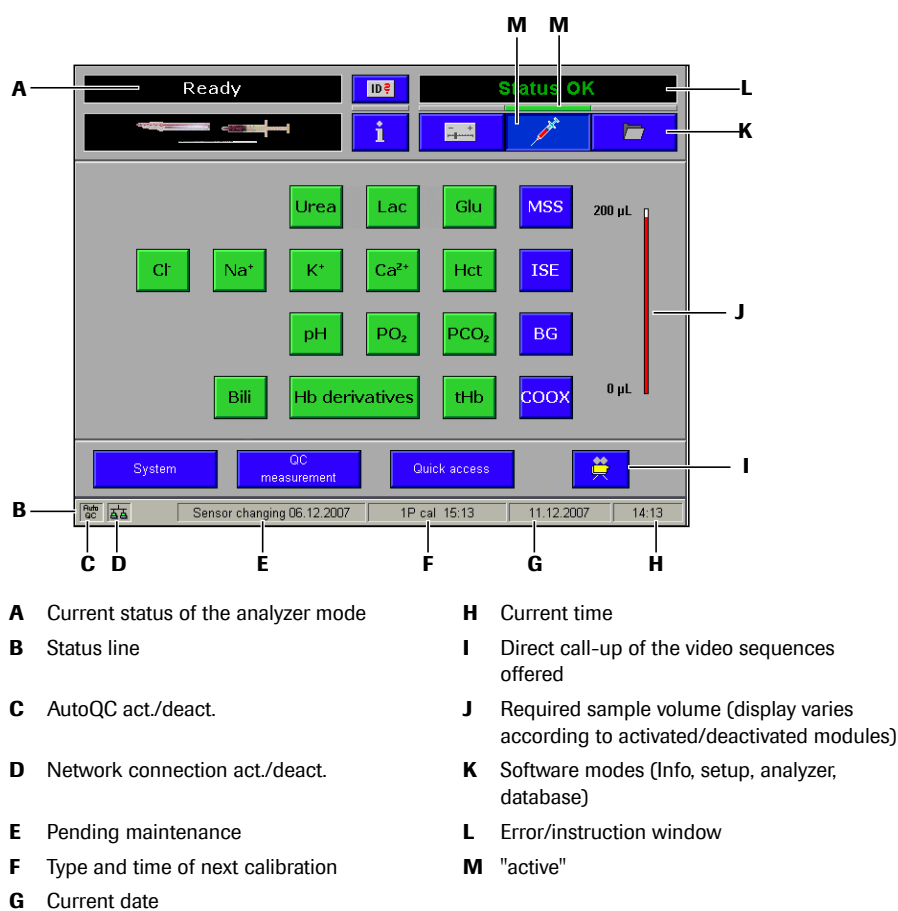
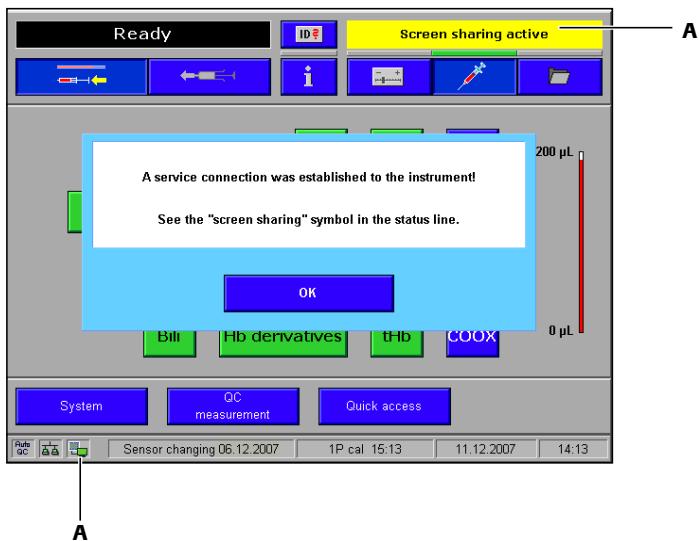


Figure 9-1 "Ready" screen

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 9-2

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 9-3

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) ⁽¹⁾ |
|  | Parameter not ready (due to QC lock) ⁽¹⁾ |
|  | Parameter not ready due to remote lock |
|  | Parameter permanently deactivated (under "Setup") |

(1) A status report appears after pressing the parameter button.

Notation of the measurement, input, and calculation values

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 |

Parameters/icons

| | |
|-------------------|--------------------------------|
| tHb | Total hemoglobin concentration |
| O ₂ Hb | Oxyhemoglobin |
| 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 CO ₂ 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 |
| P50 | Oxygen partial pressure at 50% oxygen saturation calculated with SO ₂ as measurement value |
| FO ₂ Hb | Fractional oxygen saturation |
| SO ₂ | Oxygen saturation |
| SO ₂ (c) | Functional oxygen saturation calculated with P50 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 | • Admission time | • Religion |
| • Pat. ID | • Discharge date | • Sex |
| • Last name | • Discharge time | • Title |
| • First name | • Date changed | • Phone no. |
| • Middle initial | • Time changed | • Doctor |
| • Suffix | • Specimen ID | • Accepted by: |
| • Maiden name | • Sample container | • Clinic info |
| • Date of birth | • Address | • Vent. mode |
| • Temperature | • Billing code | • VT |
| • Sample type | • Danger code | • S _{rate} |
| • Blood type | • Diagnostic code type | • PEEP |
| • Puncture site | • Isolation status | • PIP |
| • Operator ID | • Marital status | • MAP |
| • Order ID | • Age (A/F) | • Ti |
| • Date drawn | • Diagnosis | • Te |
| • Time drawn | • Diet | • MV |
| • Hospital service | • Size | • A _{rate} |
| • Ward | • Weight | • Flowrate |
| • Department | • Insurance code | • 24h Urine |
| • Location | • Patient language | • ALLEN test |
| • Admission status | • Medication | • Remark |
| • Admission date | • Ethnic origin | • 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/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 9-4

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 9-5

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 9-6

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 *Quality control* (p. 173).

Setup

Use this function to make the following settings:

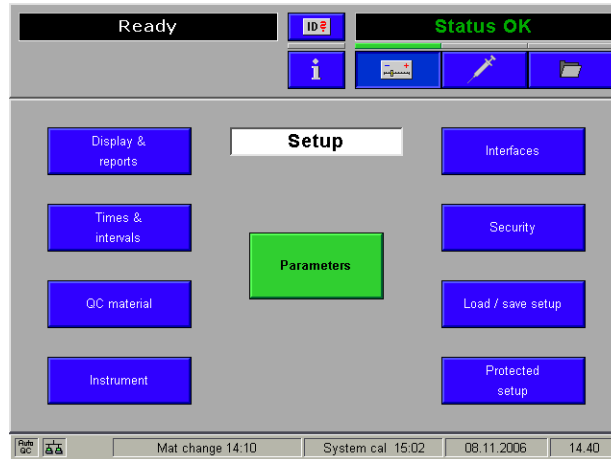


Figure 9-7

For a detailed description, see the *Reference Manual*, chapter *Software modes*, section *Analyzer > Setup*

Data manager

Use this function to retrieve the following data:

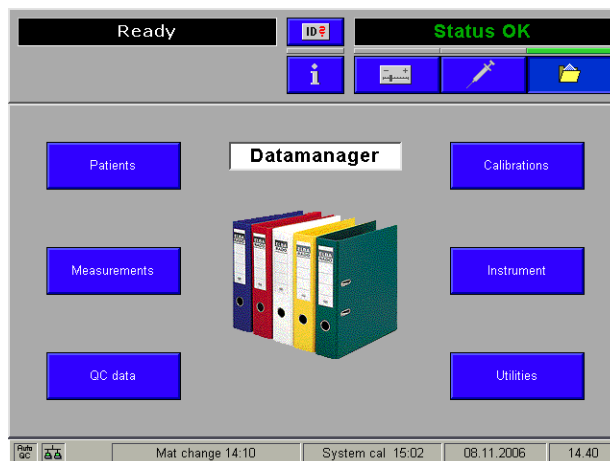



Figure 9-8

 For a detailed description, see the *Reference Manual*, chapter *Software mode*, section *Data manager*

General data manager functions



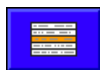
Details - all the available detailed information for the selected dataset is displayed and can be edited.



Find - the function allows to search for data records using defined search criteria.



Sort - this function allows to sort the recordings.



Marker - the current data record is permanently marked and now has a yellow background to make it more easily visible.



Mark range - use this function to mark a range.

The marking criterion corresponds to the current sort criterion of the data records.

All data sets are marked only if the "From" input field is empty and "zz" is specified in the "To" field.



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

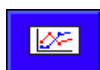
Using this function, marked data records of the measurement database are exported again via ASTM to a connected LIS/HIS system.

**Requirement:**

The format must be changed to ASTM.

For calibrations and QC measurements only:

Filter - to set the required filter.

For QC measurements only:

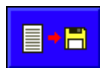
L.-J. graph - use this function to create a Levey-Jennings graph of the selected datasets from the QC database



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:

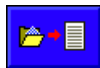
Copy to disk - the marked archive(s) are copied to a disk.



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.

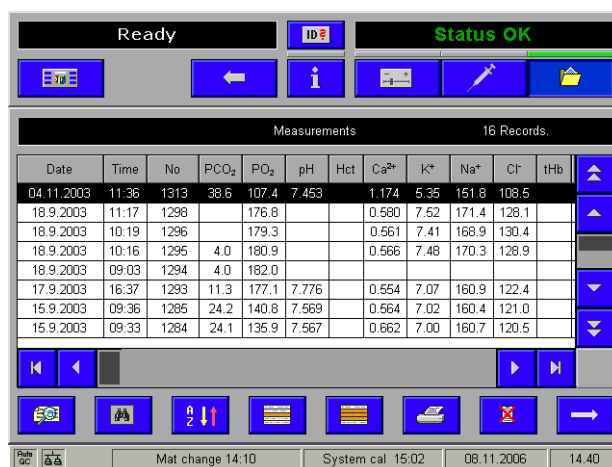
Patients

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




| Date | Time | No | PCO ₂ | PO ₂ | pH | Hct | Ca ²⁺ | K ⁺ | Na ⁺ | Cl ⁻ | tHb |
|------------|-------|------|------------------|-----------------|-------|-----|------------------|----------------|-----------------|-----------------|-----|
| 04.11.2003 | 11:36 | 1313 | 38.6 | 107.4 | 7.453 | | 1.174 | 5.35 | 151.8 | 108.5 | |
| 18.9.2003 | 11:17 | 1298 | | 176.8 | | | 0.580 | 7.52 | 171.4 | 128.1 | |
| 18.9.2003 | 10:19 | 1296 | | 179.3 | | | 0.561 | 7.41 | 168.9 | 130.4 | |
| 18.9.2003 | 10:16 | 1295 | 4.0 | 180.9 | | | 0.566 | 7.48 | 170.3 | 128.9 | |
| 18.9.2003 | 09:03 | 1294 | 4.0 | 182.0 | | | | | | | |
| 17.9.2003 | 16:37 | 1293 | 11.3 | 177.1 | 7.776 | | 0.554 | 7.07 | 160.9 | 122.4 | |
| 15.9.2003 | 09:36 | 1285 | 24.2 | 140.8 | 7.569 | | 0.564 | 7.02 | 160.4 | 121.0 | |
| 15.9.2003 | 09:33 | 1284 | 24.1 | 135.9 | 7.567 | | 0.662 | 7.00 | 160.7 | 120.5 | |

Figure 9-9

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.

 An edit of the specimen ID in the measurement database causes to an automatic delete of all patient relevant information. There is no specimen query started in case of a change of the specimen ID in the database.


In case the patient relevant data is known and needed for patient trending, it is necessary to enter additionally the corresponding patient ID. After the entry of the patient ID the patient demographic query is started automatically.

Because of editing the specimen ID or patient ID, the changed dataset have to be resent to the LIS/HIS manually.

Important:

If the specimen ID is not unique in the LIS, a mismatch of patient related data in the LIS is very likely and it could happen that a measurement is assigned to the wrong patient in the LIS.

Ensure a unique ID in the hospital environment.

 For a detailed description, see the *Reference Manual*, chapter *Software modes*, section *Data manager*.

Calibrations

| Date | Time | Cal | PCO ₂ | PO ₂ | pH | Hct | Ca ²⁺ | K ⁺ | Na ⁺ | Cl ⁻ | tHb | Hb | Bili | Glu |
|------------|-------|--------|------------------|-----------------|----|-----|------------------|----------------|-----------------|-----------------|-----|----|------|-----|
| 18.11.2003 | 16:25 | 1P cal | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 15:19 | 1P cal | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 14:14 | 1P cal | nOk | Ok | Ok | Ok | nOk | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 13:08 | 1P cal | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 11:54 | 1P cal | Ok | Ok | Ok | Ok | nOk | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 10:49 | 1P cal | Ok | Ok | Ok | Ok | nOk | Ok | Ok | Ok | Ok | Ok | Off | Ok |
| 18.11.2003 | 09:43 | 1P cal | Ok | Ok | Ok | Ok | nOk | nOk | nOk | nOk | Ok | Ok | Off | Ok |
| 18.11.2003 | 08:38 | 1P cal | Ok | Ok | Ok | Ok | nOk | Ok | Ok | Ok | Ok | Ok | Off | Ok |

Figure 9-10

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

| Date | Time | Material | Level | PCO ₂ | PO ₂ | pH | Hct | Ca ²⁺ |
|-----------|-------|----------------|-------|------------------|-----------------|-------|------|------------------|
| 02.9.2002 | 16:17 | AUTO-TROL TS + | 3 | 22.5 | 133.5 | 7.561 | 29.5 | 0.588 |
| 02.9.2002 | 16:12 | AUTO-TROL TS + | 2 | 41.3 | 90.2 | 7.408 | 41.2 | 1.172 |
| 02.9.2002 | 08:10 | AUTO-TROL TS + | 1 | 57.9 | 54.7 | 7.181 | 56.1 | 1.604 |
| 01.9.2002 | 21:10 | AUTO-TROL TS + | 3 | 22.2 | 132.4 | 7.561 | 29.6 | 0.582 |
| 01.9.2002 | 21:05 | AUTO-TROL TS + | 2 | 41.5 | 89.0 | 7.404 | 44.4 | 1.130 |
| 01.9.2002 | 21:01 | AUTO-TROL TS + | 1 | 57.8 | 89.7 | 7.189 | 57.7 | 1.638 |
| 31.8.2002 | 21:10 | AUTO-TROL TS + | 3 | 22.2 | 132.6 | 7.561 | 28.8 | 0.579 |
| 31.8.2002 | 21:05 | AUTO-TROL TS + | 2 | 41.1 | 87.6 | 7.409 | 43.7 | 1.123 |

Figure 9-11

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 9-12

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.

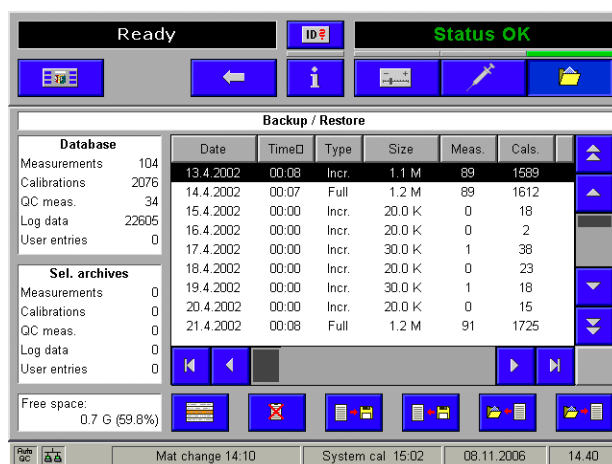


Figure 9-13

For a detailed description, see the *Reference Manual*, chapter *Software modes*, section *Data manager*.

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:

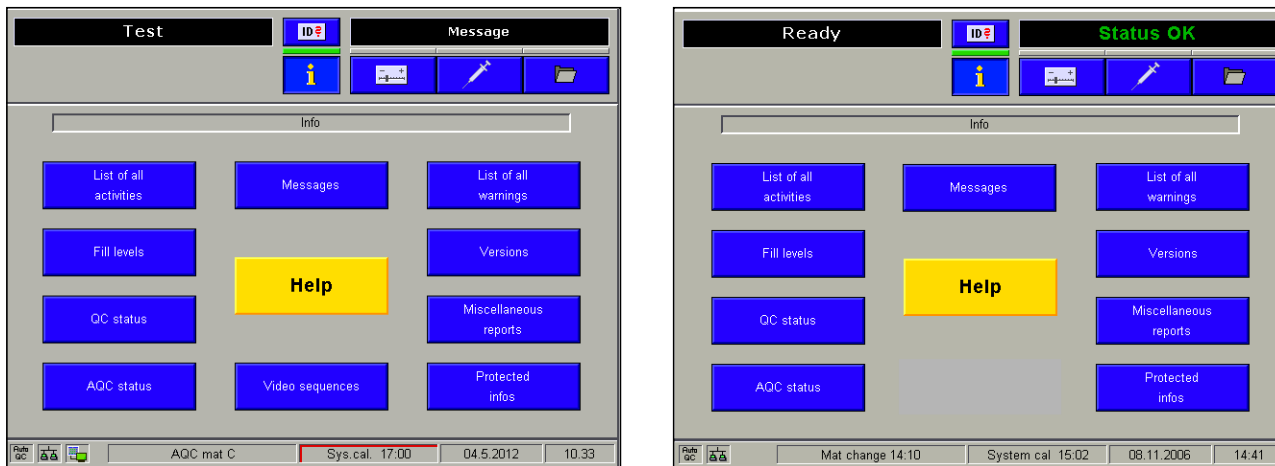


Figure 9-14

Help

Use this function to retrieve online help information.

Fill level

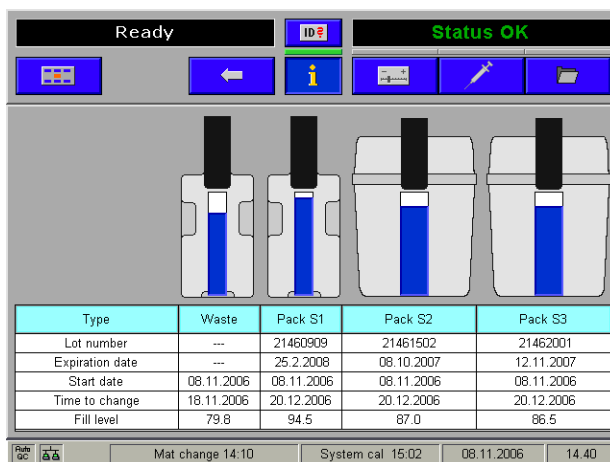


Figure 9-15

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.

Info

QC status

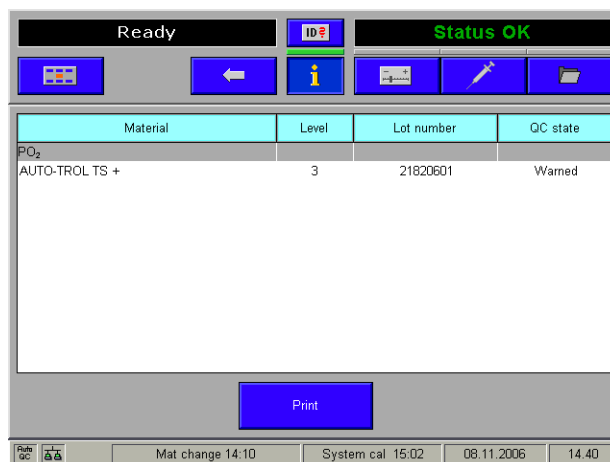




Figure 9-16

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

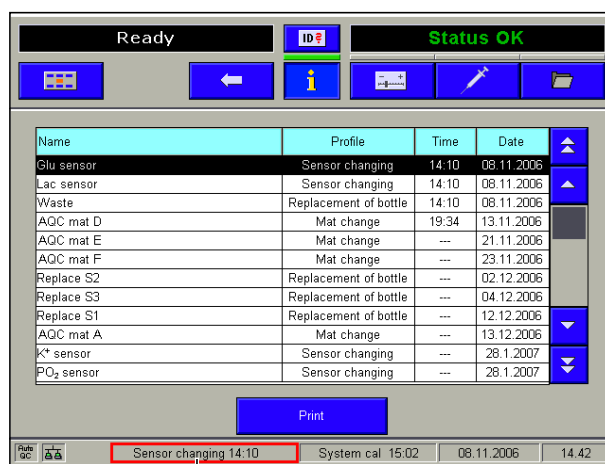
 If this function is not available, contact customer service.

 see Figure 9-14 (p. 235)

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

A Warning window for pending maintenance, rotating display

Figure 9-17

- ⓘ All pending maintenance tasks are shown in a rotating display.

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.

- ⓘ See Figure 9-17 (p. 237).

- ⓘ **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

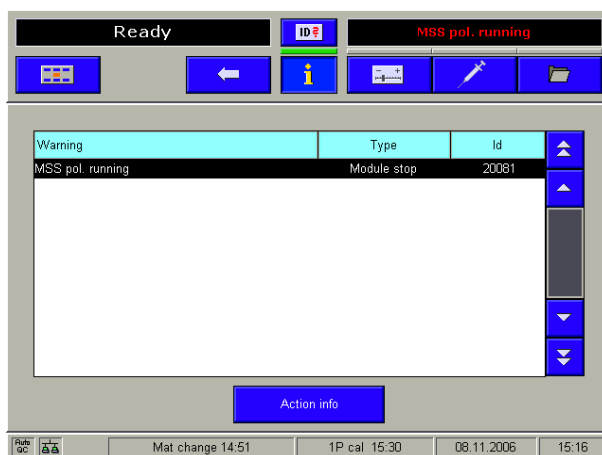


Figure 9-18

Here, all the module stops and warnings are listed with their code, or it can be found in *Troubleshooting* (p. 291), using the respective error code (ID)

[Action info] Further information is displayed on the errors indicated.

AQC status

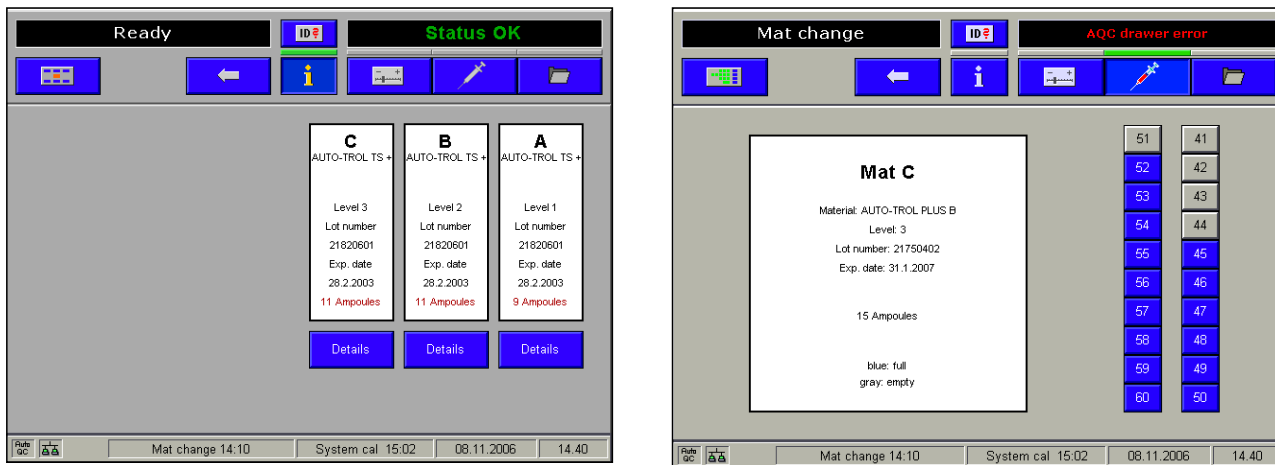


Figure 9-19

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 9-20

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 9-21

Displays the status of the electrodes.

Info

Sensor report

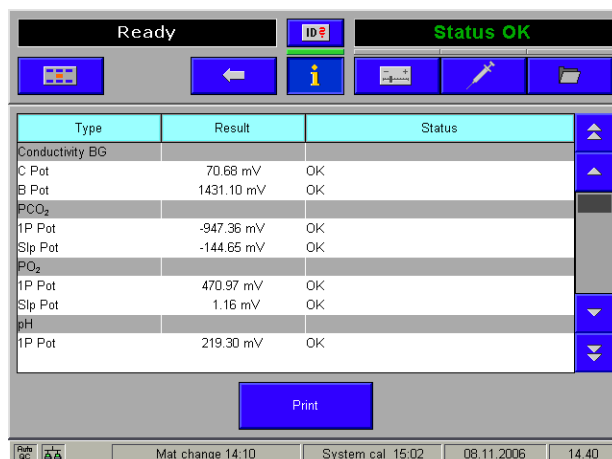


Figure 9-22

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.

Messages

All messages sent by **cobas bge link** software are displayed here.

The "Message" note is displayed in the error/instruction window of the screen (upper right). This message continues to be displayed as long as there are messages in the message buffer.

Press the [Show message] button to view the entire message.

Press the [Delete message] button to delete the selected message.

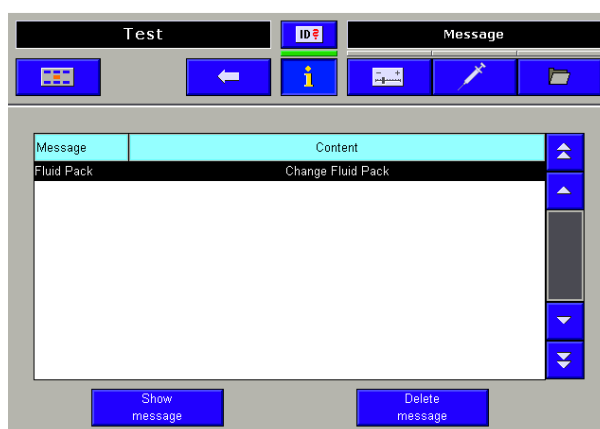


Figure 9-23

Protected information

This area is password-protected and only accessible to authorized personnel or customer service.

Info

Maintenance

10 Maintenance..... 245

Maintenance

In this chapter, all maintenance work is described that is necessary for trouble-free operation of the instrument.

In this chapter

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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.



Caution

- ▶ 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



Warning

- ▶ 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 (including fill port) and the sample drip tray
- Touch screen
- Surfaces of the instrument
- Tubing paths


Input unit

- ④ see *Cleaning fill port and sample drip tray* (p. 250)
- ④ see *Quarterly* (p. 252)
- ④ see *Exchanging the fill port* (p. 265)


Touch Screen

 see *Cleaning the touch screen* (p. 250)

Surfaces of the instrument

 see *Surfaces* (p. 283)

Tubing paths

 see *Cleaning the modules and tubing paths* (p. 262)

Recommended disinfectants



Caution

▶ 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* (p. 256) or section *Waste water* (p. 259).

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

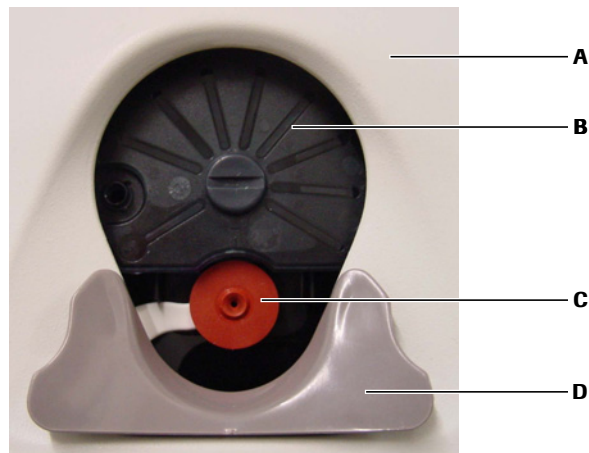


Handle these parts with care — danger of injury. Always wear gloves.
Danger of infection.

▶ Cleaning fill port and sample drip tray

1 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 10-1 Input unit

2 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.

3 Reinsert the sample drip tray.

4 Clean the fill port with a soft cotton swab moistened with disinfectant.



Cleaning the touch screen

▶ Cleaning the touch screen

1 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.



Caution

- ▶ Clean only with a moist cloth (for example, one that is soaked with disinfectant). Do not use water and sprays.
-

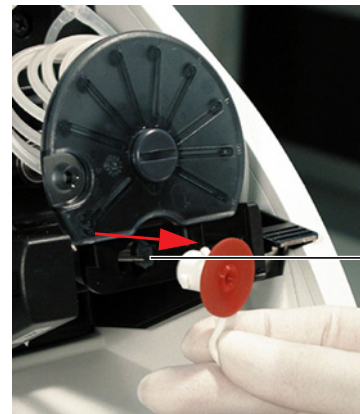
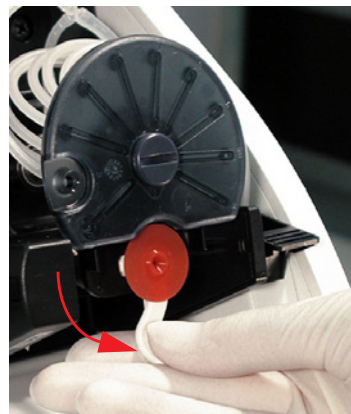


Quarterly

Cleaning the T&D disk

▶ Cleaning the T&D disk

- 1 Activate the following function, starting with the top level of the analyzer mode:
☰ System > Wash & cleaning > Clean input unit
- 2 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.
📖 see Figure 10-1 *Input unit* (p. 250)
- 3 Remove the T&D cover.
- 4 Clean the fill port with a soft cotton swab moistened with disinfectant.
- 5 Rotate the fill port 90° downward and remove it.



A Needle

Figure 10-2 T&D disk

- 6 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.
- 7 Remove the T&D disk.
- 8 Clean and decontaminate the front and back of the T&D disk.

Caution

- ▶ Do not use alcohol for cleaning the T&D disk.



- 9 Re-install the disk in reverse order.
- 10 Re-insert the fill port.
- 11 Close the T&D cover.
- 12 Insert the sample drip tray.



Changing the air filter

▶ Changing the air filter

- 1 Pull out the air filter using the box tongue (see below).



Figure 10-3 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 10-3 *Air filter* (p. 253)

⚠ 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.

▶ Performing a COOX calibration

- 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

- To start the calibration, press [Start].

The following screen appears:

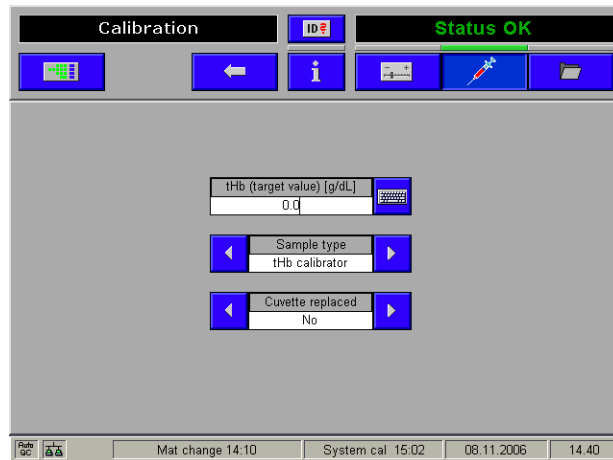


Figure 10-4

- "tHb (target value) [g/dL]": enter the desired target value using the keyboard.

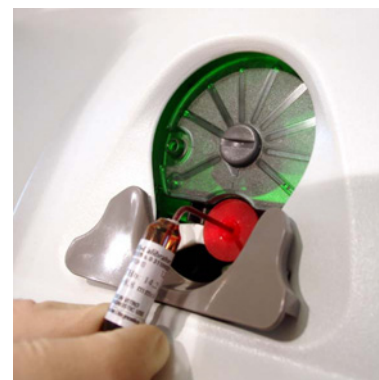


Take the target value for the tHb calibrator from the label of the tHb calibrator recommended by Roche.

- The unit is standard [g/dL] and can be changed, if necessary.
- "Cuvette replaced" - Press [Yes] after a cuvette was replaced, otherwise press [No].
- "Sample type". It is possible to select between "tHb calibrator" and "Blood" as calibration solution.
- The target value for blood must be a known set point.
- 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 10-5 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.



Warning

- ▶ 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 set point 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



Warning

- ▶ In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = 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 10-6 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.



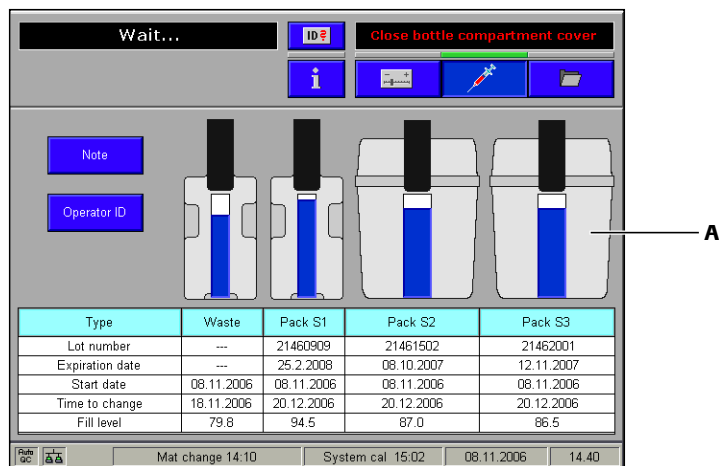
Warning

- ▶ 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 10-7

- 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).



Warning

- ▶ 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 (1 = low, 2 = normal, 3 = high) must be performed after every exchange of solutions and packs.
- 8 Make sure that the results are in line with the target values.

Ⓜ see *Quality control* (p. 173)



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.



▶ Procedure

- 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 10-8 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 10-9 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.

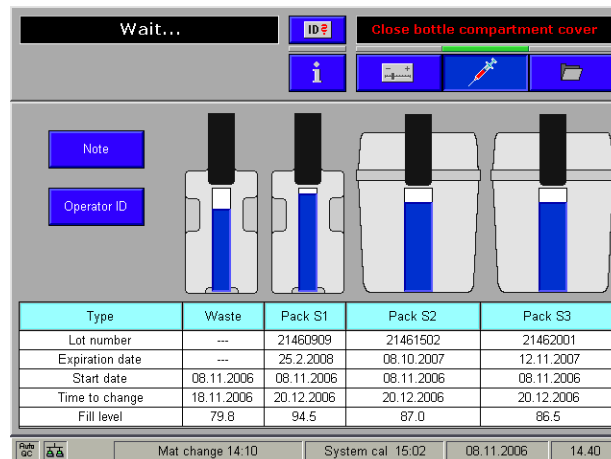


Figure 10-10



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.

▶ **Emptying the W Waste Container**

- 1 Place the bottle tool on the screw cap.



A Bottle tool



B Screw cap with placed bottle tool

Figure 10-11 Bottle tool

- 2 Open the screw cap by pressing the two grips together and rotate them counter-clockwise.



Figure 10-12 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 10-13 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 approximately 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.

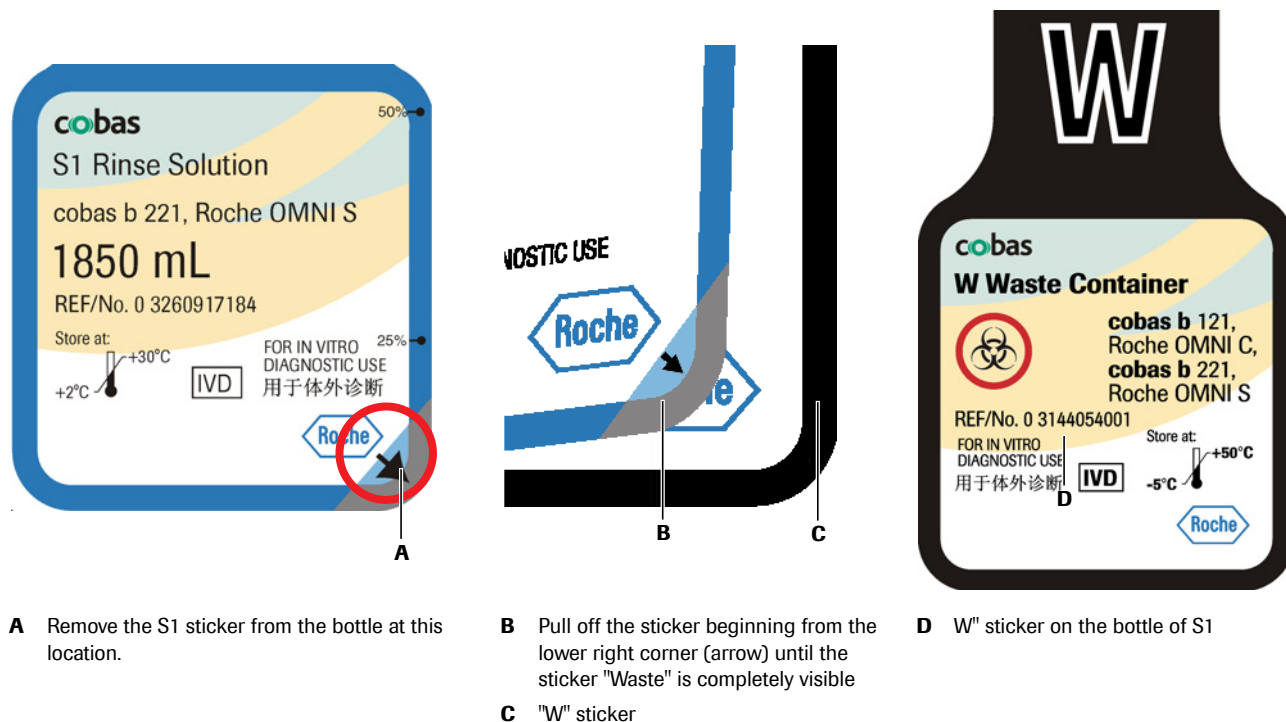


Figure 10-14 Sticker

Installing the waste water container

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 10-1

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 10-15

▶ **BG-/ISE-/ COOX- or tHb/SO₂ 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 PO₂ QC recoveries due to microscopic bacterial contamination of the PO₂ 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):**

- 1 This cleaning should be performed with every exchange of the cassette, but not more than once per month (e.g. obstruction).
- 2 Activate the MSS module and press [Start external cleaning].
- 3 The external cleaning agent is inserted like a sample (syringe or capillary) via the fill port.
- 4 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)* (p. 280)

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.

Warning

- ▶ In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = 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.

Sample-dependent maintenance procedures

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

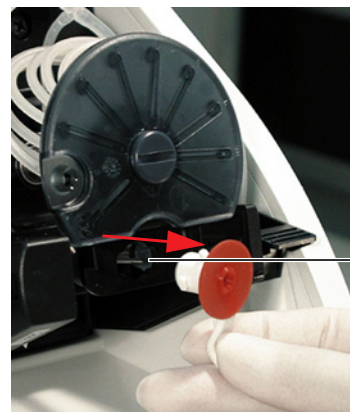
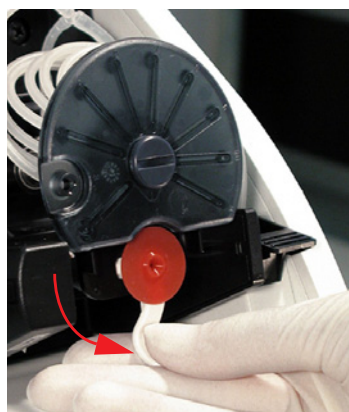
Exchanging the fill port



Dispose of the used fill port in accordance with local regulations (hazardous waste).

▶ Exchanging the fill port

- 1 Activate the following function, starting with the top level of the analyzer mode:
☰ System > Wash & cleaning > Clean input unit
- 2 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.
- 3 Open the T&D cover.
- 4 Rotate fill port 90° downward and carefully remove it from the needle.



A Needle

Figure 10-16

- 5 Insert new fill port.

Caution

- ▶ Do not bend the needle.

- 6 Close the T&D cover.
- 7 Reinsert the sample drip tray.
- 8 Close the bottle compartment cover.



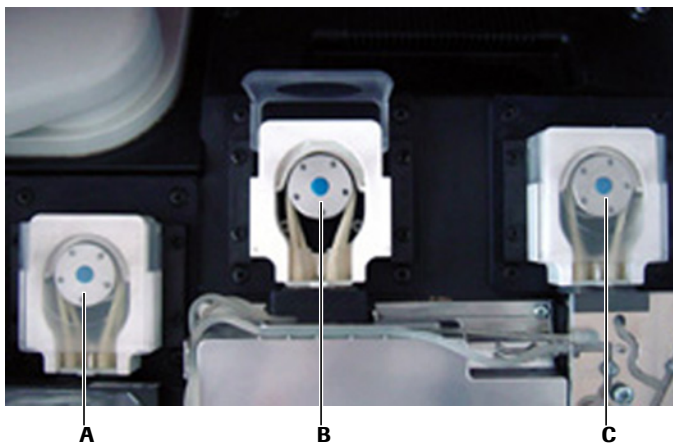
Exchanging the peristaltic pump tubes

▶ Exchanging the peristaltic pump tubes

- 1 When changing the peristaltic pump tubes, proceed as follows:

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

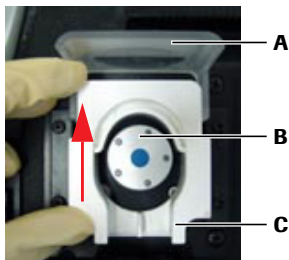
☰ Quick access > Maintenance



A Main pump
B MSS output pump
C MSS input pump

Figure 10-17 Peristaltic pump

- 2 Select the appropriate pump tube to be changed from the list and press [Perform].
- 3 Remove the top cover.
- 4 Open the peristaltic pump's clear plastic cover (tension lever) (see below/A).

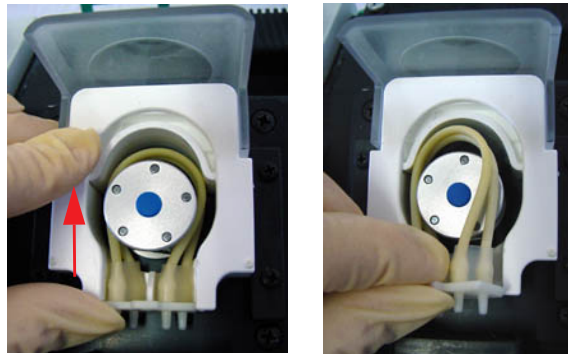


A Tension lever
B Pump head
C Linear bracket

Figure 10-18 Peristaltic pump

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

- 6** 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 10-19 Peristaltic pump

- 7** Check if the five rollers are easily moveable.

In case of malfunction contact customer service.

- 8** 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).
- 9** Close the clear plastic cover (tension lever). The tubing holder is then pressed into the sealer.
- 10** 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* (p. 286)



Cleaning the bottle compartment

▶ Cleaning the bottle compartment

- 1 Open the bottle compartment cover.

The bottle exchange image appears on the display.

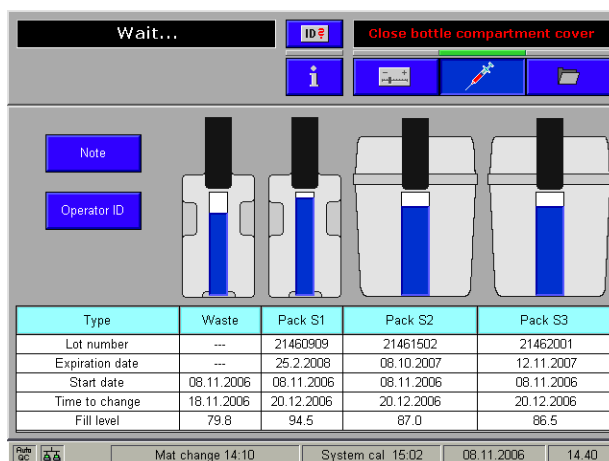


Figure 10-20

- 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* (p. 256)
- 5 Close the docking mechanism and the bottle compartment cover.



Replacing printer paper

▶ Replacing the printer paper

- 1 Open the printer cover.



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

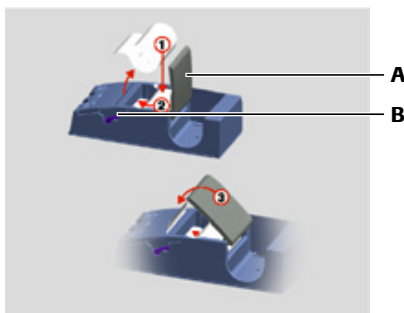
- 2 Open the paper lid.
- 3 Remove the empty paper roll.
- 4 Ensure the paper has a clean leading edge to help start the paper through the rollers. If necessary cut the paper at a right angle.
- 5 Place the new paper roll into the holder, so that the roll feeds from the bottom.

- 6 Ensure that the printer lever is in the "down" position (see below) (only visible with opened paper cover).



Figure 10-21 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 10-22 Place printer paper- without take-up unit

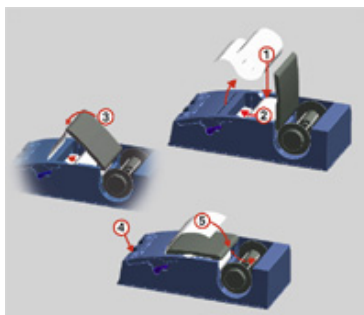


Figure 10-23 Place printer paper - with take-up unit (optional)

- 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 10-23 *Place printer paper - with take-up unit (optional)* (p. 269)



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.



Caution

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



Replacement of the electrodes



Replacing of the electrodes

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).



Warning

▶ The electrode must be installed in the instrument no later than the imprinted "Install before" date.

ⓘ see *Conventions used in this manual* (p. 7) > *Other symbols* (p. 10)

▶ In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = high) after each electrode exchange.



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

The following screen appears:

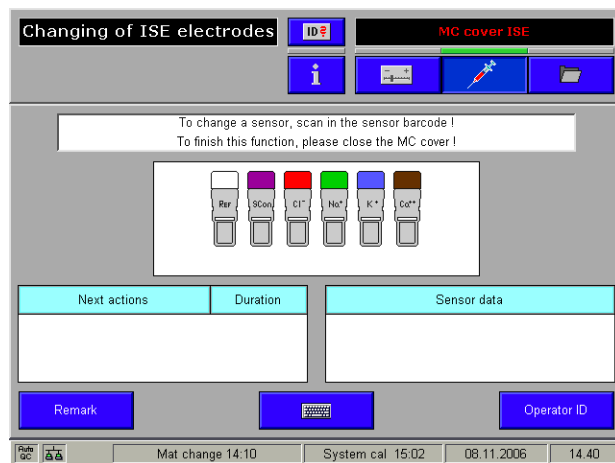


Figure 10-24

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).



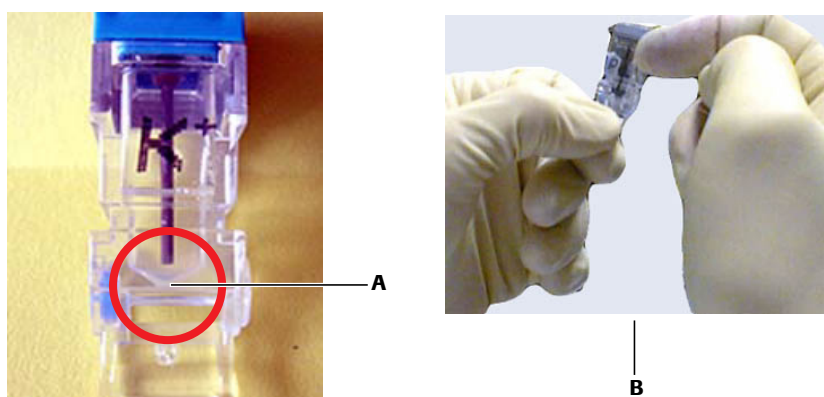
If a new electrode is not available, insert a dummy electrode instead.
SCon and the reference electrode may not be replaced with a dummy electrode.



Caution

- ▶ 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 10-25 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.

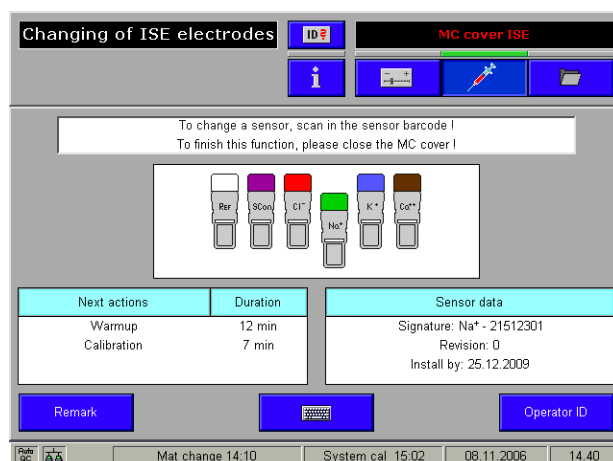



Figure 10-26

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 (1 = low, 2 = normal, 3 = high).

16 Make sure that the results are in line with the target values.

 see *Quality control* (p. 173)



Setting up the Maintenance schedule

The Maintenance schedule is used to alert users when the reference electrode or other electrodes, e.g. ISE, and MSS (Urea) must be replaced.



WARNING

Warning

- ▶ The reference electrode must be replaced after 52 weeks of in-use time.

▶ **Set up a new Maintenance schedule**

1 Press the following buttons:

☰ Setup > Times & interval > Maintenance schedule



Figure 10-27 Maintenance schedule

2 Choose the New button.

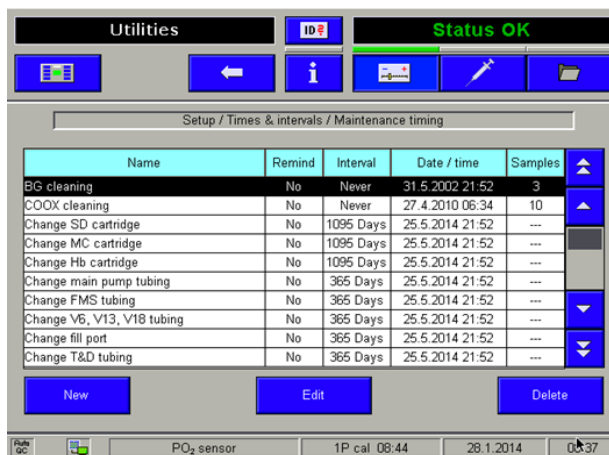


Figure 10-28 New schedule

Unscheduled

- Fill out the schedule fields using the  button. The reference electrode has an in-use time of 52 weeks. For the Interval field, select one year.

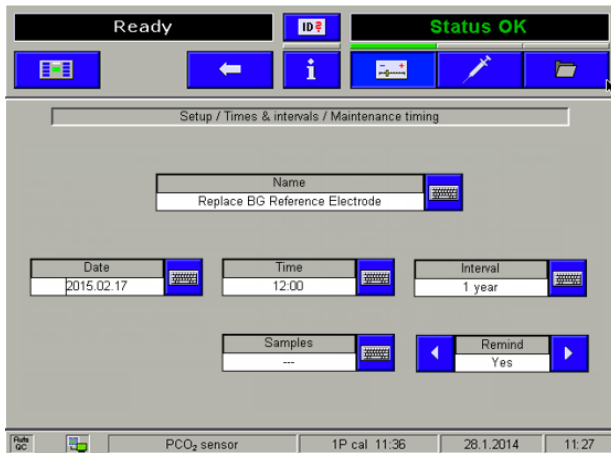


Figure 10-29 Fill out the schedule fields

- Choose the  button to save the setup.
- Confirm schedule setup.



Figure 10-30 Confirm schedule setup



Note

Use the Maintenance schedule to set up an alert for the ISE and MSS (Urea) reference electrodes.



▶ **Edit an existing Maintenance schedule**

- 1 Press the following buttons:

☰ Setup > Times & interval > Maintenance schedule



Figure 10-31 Maintenance schedule

- 2 Select the schedule for editing and choose the **Edit** button.

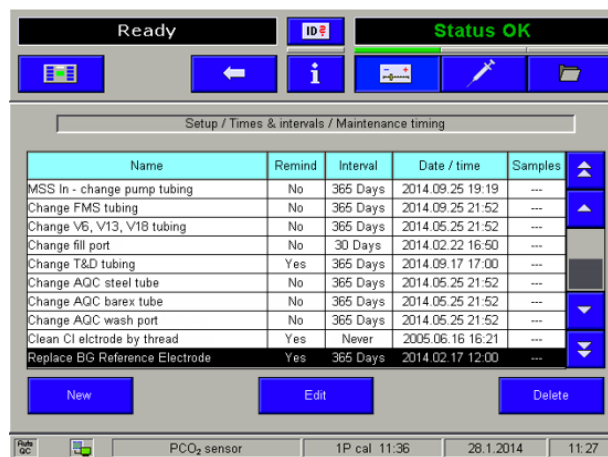


Figure 10-32 Select schedule

Unscheduled

- 3 Edit the schedule fields using the  button. The reference electrode has an in-use time of 52 weeks. For the Interval field, select one year.

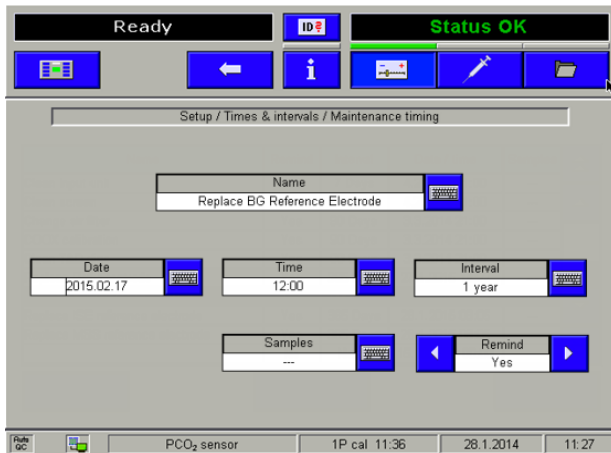


Figure 10-33 Edit schedule fields

- 4 Choose the  button to save the setup.
- 5 Confirm the schedule setup.



Figure 10-34 Confirm schedule setup



▶ **Delete a Maintenance schedule**

1 Press the following buttons:

☰ Setup > Times & interval > Maintenance schedule



Figure 10-35 Maintenance schedule

2 Select the schedule for deletion and choose the **Delete** button.

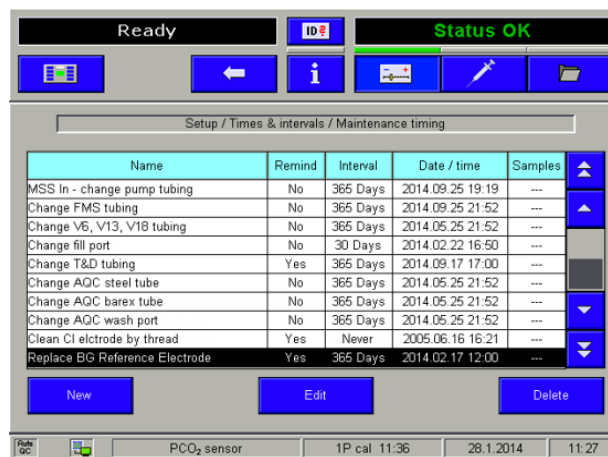


Figure 10-36 Select schedule

3 Confirm the schedule has been deleted.

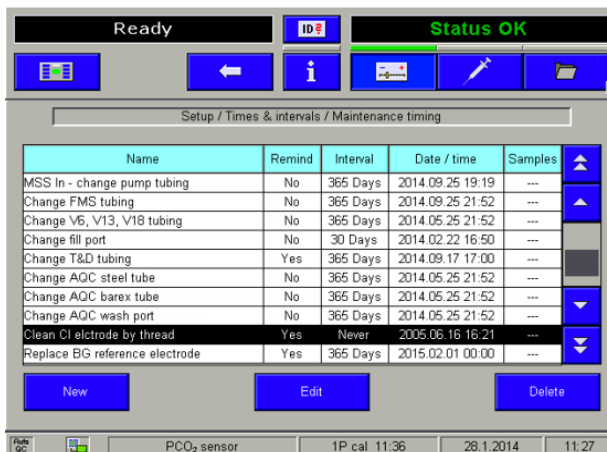


Figure 10-37 Confirm schedule deletion



Changing the reference electrode

▶ Changing the reference electrode

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



WARNING

Warning

- ▶ The reference electrode must be installed in the instrument no later than the imprinted "Install before" date. The reference electrode must be replaced after 52 weeks of in-use time. Therefore, set up an alert in the Maintenance schedule.
 - ⓘ see *Setting up the Maintenance schedule* (p. 272)
 - ⓘ see *Conventions used in this manual* (p. 7) > *Other symbols* (p. 10)
- ▶ In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1 = low, 2 = normal, 3 = high) after each electrode exchange.

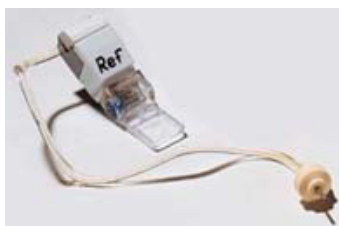


Figure 10-38 Reference electrode



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

The following screen appears:

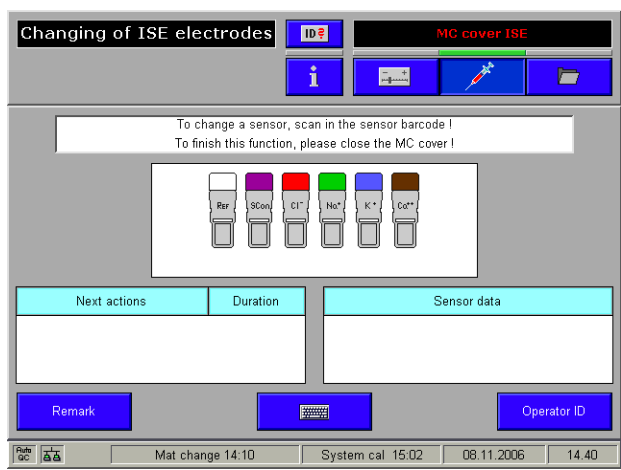
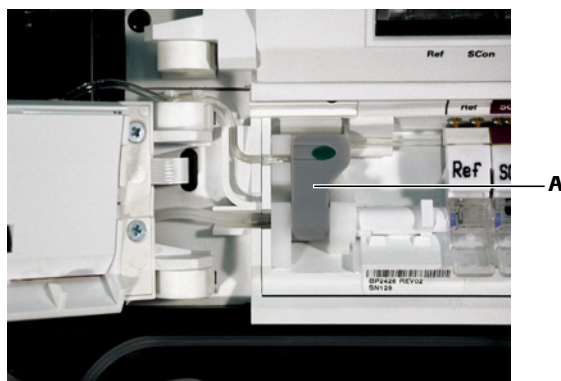


Figure 10-39

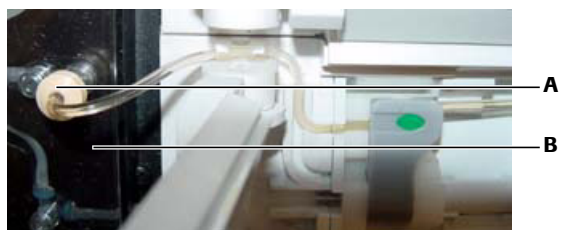
- 2 Open the locking lever.
- 3 Remove the reference electrode.
- 4 Remove the white connector from the measuring chamber cartridge.
- 5 Insert the new reference electrode.
- 6 Attach the white connector at the end of the tube to the measuring chamber cartridge.
- 7 Insert the reference tube into the 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 10-40 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 10-41 Insert the reference electrode 2

Unscheduled

- 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 levels (1 = low, 2 = normal, 3 = high) must be performed after every exchange of a reference electrode.

Make sure that the results are in line with the target values.

 see *Quality control* (p. 173)




Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)

Changing the MSS cassette

- 1 Remove the top cover.



Warning

- ▶ The MSS cassette must be installed in the instrument no later than the imprinted "Install before" date.
 -  see *Conventions used in this manual* (p. 7) > *Other symbols* (p. 10)
- ▶ 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 levels (1 = low, 2 = normal, 3 = 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.

- 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:

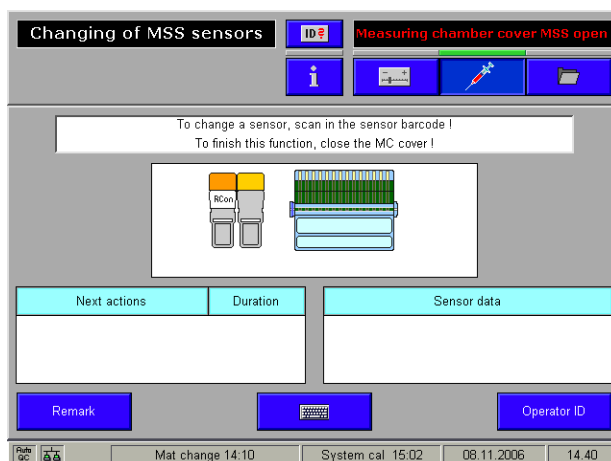
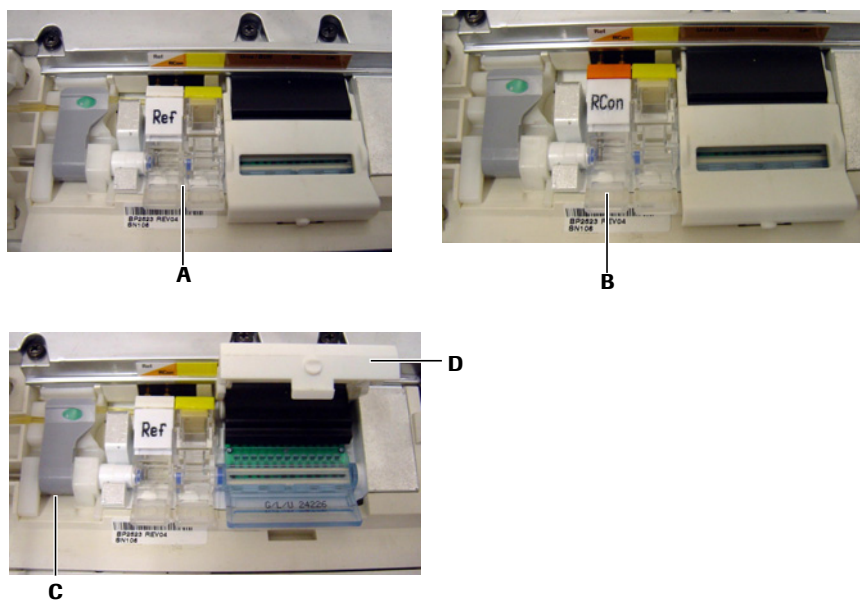


Figure 10-42

- 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 | C | Locking lever |
| B | Glu or Glu/Lac | D | Contact clip |

Figure 10-43 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 *Measurement* (p. 143)

- 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

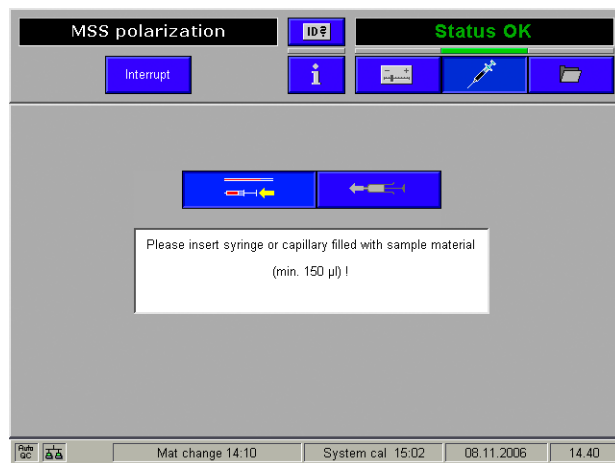


Figure 10-44

- 12 Follow the instructions on the screen.
- 13 A new QC measurement must be performed with all three level (1 = low, 2 = normal, 3 = high) after every exchange of the MSS cassette.

Make sure that the results are in line with the target values.

☰ see *Quality control* (p. 173)



Cleaning the measuring chambers

▶ Cleaning the measuring chambers

- 1 Remove the top cover and open the measuring chamber cover.
- 2 Remove all electrodes.
☰ see *Replacement of the electrodes* (p. 270)
- 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 section *User-activated calibrations* (p. 214)



Surfaces



Warning

- ▶ 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.



Warning

- ▶ Never spray parts that cannot be removed or that are inside the instrument.

 see section *Decontamination* (p. 247)

Changing of AutoQC mats

▶ Changing of AutoQC mats

- 1 Starting with the top level of the analyzer mode.
- 2 Pull out the AutoQC drawer.

The following screen appears:

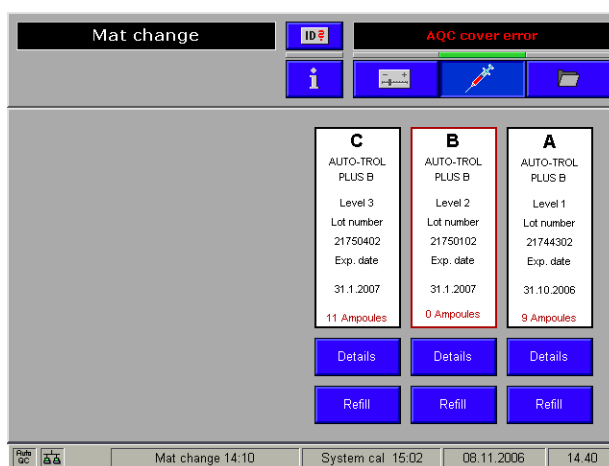


Figure 10-45

3 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.

4 Take a full mat (20 ampoules) from the package.

5 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.

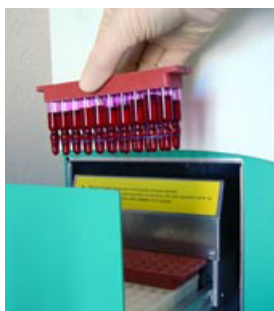


Figure 10-46 AutoQC mat

6 Place the mat in the defined position (A-F) of the ampoule block so that the ampoules are no longer visible.

7 Press [Refill].

The following question appears:

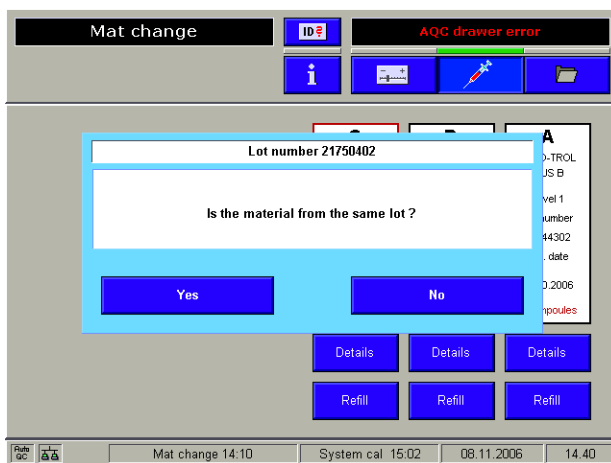


Figure 10-47

8 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 section *Material setup* (p. 179)

- 9 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.

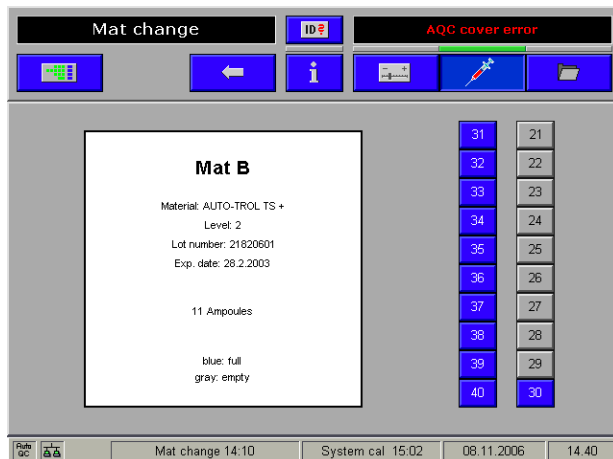


Figure 10-48

- 10 Close the AutoQC drawer.



Additional maintenance procedures



Caution

- ▶ 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 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

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

- Cuvette
- Cuvette seals
- Hemolyzer tube



Warning

- ▶ 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



Warning

- ▶ The tubing paths must also be disinfected annually and the baro value must be checked.
-

Troubleshooting

11 *Troubleshooting*..... 291

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**

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| Emergency routine..... | 294 |
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| Barcode..... | 325 |

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 sterilization 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.

Follow the instructions on the screen.

Emergency routine

In case of a system stop, the emergency routine will initially be started after 50 minutes and then every 4 hours to prevent crystallizations in tubings, pipes and electrodes. This routine cannot be interrupted. In the process Mix1 is positioned into the BG and the ISE measuring chamber and MSS standby solution is positioned into the MSS measuring chamber.

Resolve all system stops:

 Info > List of all warnings





| No. | Message | Cause | Action |
|-------|-------------------------------|--|---|
| 10001 | Flap W | Docking mechanism for waste is open. | <ul style="list-style-type: none"> Close mechanism. If the error persists, contact Technical Support. |
| 10002 | Out of operation | The instrument has been taken out of operation. | <ul style="list-style-type: none"> Perform installation procedure.  see section <i>Installation</i> (p. 45) |
| 10003 | Warm up | The instrument warms up after power-on or power fail. | <ul style="list-style-type: none"> Wait until the warm up is finished and perform installation procedures if necessary.  see section <i>Installation</i> (p. 45) |
| 10004 | Economy mode | The instrument is in automatic or manual economy mode. | <ul style="list-style-type: none"> To return to the "ready" mode press Exit. |
| 10005 | Comm. error PC-μC | Communications between PC and micro controller is interrupted. | <ul style="list-style-type: none"> Turn the instrument off and on again. If the error persists, contact Technical Support. |
| 10006 | Download error | The download process to the micro controller failed. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> Insert container. If the error persists, contact Technical Support. |
| 10009 | Actuator bus current overload | An error was recognized in a hardware component. | <ul style="list-style-type: none"> Perform General hardware test to correct the error:  System > Diagnostics > General hardware test 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. | <ul style="list-style-type: none"> Perform General hardware test to correct the error:  System > Diagnostics > General hardware test If the error persists, turn the instrument off and contact Technical Support. |
| 10011 | Database not ready | The database is not ready. | <ul style="list-style-type: none"> Wait some minutes if the error occurs during warm up. Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support. |

Table 11-1 System stops







| No. | Message | Cause | Action |
|-------|---------------------------------------|---|--|
| 10012 | µC memory overrun | A micro controller memory overflow was detected | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 10016 | Bottle compartment cover open | | <ul style="list-style-type: none"> Close the bottle compartment cover. <p>If the error persists, contact Technical Support.</p> |
| 10017 | Bypass wash error 1 | Sample sensor SS2 detects not enough air during wash process. | <ul style="list-style-type: none"> Perform Wash again:  System > Wash & Cleaning > Wash if necessary replace the T&D tubing set <p>If the error persists, contact Technical Support (wash-water jet is plugged).</p> |
| 10018 | SD wash error 1 | Sample sensor SS2 detects not enough air during wash process. | <ul style="list-style-type: none"> Perform Wash again:  System > Wash & Cleaning > Wash if necessary replace the T&D tubing set <p>If the error persists, contact Technical Support (wash-water jet is plugged).</p> |
| 10019 | Waste container full | | <ul style="list-style-type: none"> Insert an empty waste water bottle or enter the correct fill info for the waste water bottle currently in use. To do so, open the docking mechanism for W briefly, then close it again. The "Enter fill info" button appears on the screen. |
| 10020 | Rinse bottle empty | The transponder on the S1 Rinse Solution bottle indicates an empty bottle | <ul style="list-style-type: none"> Insert new S1 Rinse Solution. <p> see section <i>Exchange of solutions and packs</i> (p. 256).</p> |
| 10021 | Flap S1 | Docking mechanism for S1 Rinse Solution is open. | <ul style="list-style-type: none"> Close mechanism |
| 10022 | µC Reset | | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 10023 | Power fail | A power fail occurred. | <ul style="list-style-type: none"> The instrument will be ready for operation after warm up. |
| 10024 | No wash-water container | | <ul style="list-style-type: none"> Insert S1 Rinse Solution |
| 10025 | Check date and time | | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> Perform Wash again:  System > Wash & Cleaning > Wash if necessary check the fill port area for any dirt or clogging. <p>If the error persists, contact Technical Support.</p> |
| 10027 | SD wash error 2 | Sample sensor SS2 detects not enough water during wash process. | <ul style="list-style-type: none"> Perform Wash again:  System > Wash & Cleaning > Wash if necessary check the fill port area for any dirt or clogging. <p>If the error persists, contact Technical Support.</p> |
| 10028 | S1 on board time expired | On-board time of S1 Rinse Solution expired. | <ul style="list-style-type: none"> Insert new S1 Rinse Solution |
| 10029 | S1 expired | S1 Rinse Solution expired. | <ul style="list-style-type: none"> Insert new S1 Rinse Solution |
| 10032 | Micro controller communications error | A communications problem occurred at the micro controller. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |

Table 11-1 System stops

System stops

| No. | Message | Cause | Action |
|-------|---------------------------|--|---|
| 10033 | COOX communications error | A communications problem occurred at the micro controller. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 10034 | AQC communications error | A communications problem occurred at the micro controller. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 10039 | Vacuum reduction not ok | Low pressure reduced insufficient. V13 does not open. | <ul style="list-style-type: none"> Press [Continue] to correct the error. <p>If the error persists, contact Technical Support.</p> |
| 10040 | Vacuum error | Vacuum buildup is insufficient. | <ul style="list-style-type: none"> To localize the error, perform General fluidics test: ☞ System > Diagnostics > General fluidics test Depending on the result, check the device at the displayed position for leaks or contact Technical Support. Start Vacuum pump test: ☞ System > Component test > Aggregate > Vacuum pump <p>If the pump output is more than 20% over or under the reference value, contact Technical Support.</p> |
| 10041 | Waste error 1 | The waste system is leaking | <ul style="list-style-type: none"> Insert new waste container. |
| 10042 | Waste error 2 | The waste ventilation path is blocked | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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 necessary replace Waste separator. <p>If the error persists, contact Technical Support.</p> |
| 10045 | Check Waste fill level | Measured waste fill level differs too much from calculated value | <ul style="list-style-type: none"> Insert an empty waste water bottle or enter the correct fill info for the waste water bottle currently in use. To do so, open the docking mechanism for W briefly, then close it again. The "Enter fill info" button appears on the screen. |
| 10046 | Waste line blocked | The connection from separator into the waste container is not continuous. | <ul style="list-style-type: none"> Insert new waste container. <p>If the error persists, contact Technical Support.</p> |
| 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. | <ul style="list-style-type: none"> Perform Wash again: ☞ System > Wash & Cleaning > Wash <p>If the error persists, contact Technical Support.</p> |
| 10049 | Error SS2 | The optical sample sensor at the end of the sample inlet path could not be calibrated. | <ul style="list-style-type: none"> Perform Wash again: ☞ System > Wash & Cleaning > Wash <p>If the error persists, contact Technical Support.</p> |
| 10050 | Error SS3 | The optical sample sensor in the Hb cartridge could not be calibrated. | <ul style="list-style-type: none"> Perform Wash again: ☞ System > Wash & Cleaning > Wash <p>If the error persists, contact Technical Support.</p> |

Table 11-1 System stops

| No. | Message | Cause | Action |
|------------------|---|---|---|
| 10051 | Error SS4 | The optical sample sensor at the input of the MSS module could not be calibrated. | <ul style="list-style-type: none"> Perform Wash again: ☞ System > Wash & Cleaning > Wash 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. | <ul style="list-style-type: none"> Perform Wash again: ☞ System > Wash & Cleaning > Wash 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. | <ul style="list-style-type: none"> 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 | | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. |
| 10098 | Timing error COOX measurement | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Print Measurement reports ☞ Quick access > Last measurement Print Sensor report ☞ Info > Miscellaneous reports > Sensor report and contact Technical Support. |
| 10099 - 10112 | Timing error | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Print Measurement reports ☞ Quick access > Last measurement and contact Technical Support. |
| 10113 - 10117 | Comm. error + additional information | A subprogram did not report back. | <ul style="list-style-type: none"> 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 11-1 System stops

System stops





| No. | Message | Cause | Action |
|------------------|--------------------|--|---|
| 10118 - 10119 | Timing error MSS | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected, contact Technical Support.</p> |
| 10120 - 10121 | Timing error | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected, contact Technical Support.</p> |
| 10123 - 10126 | Comm. error D cal. | A subprogram did not report back. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected, contact Technical Support.</p> |
| 10127 | Timing error MSS | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected, contact Technical Support.</p> |
| 10128 | Timing error | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected:</p> <ul style="list-style-type: none"> Print Measurement reports  Quick access > Last measurement and contact Technical Support. |
| 10130 | Timing error COOX | An asynchrony occurred between processes and measuring. | <ul style="list-style-type: none"> Press [Continue] to correct the error. If the error persists, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If this error cannot be corrected:</p> <ul style="list-style-type: none"> Print Measurement reports  Quick access > Last measurement Print Sensor report  Info > Miscellaneous reports and contact Technical Support. |
| 10155 | AQC drawer open | The AutoQC drawer is open. | <ul style="list-style-type: none"> Close the AQC drawer. <p>If the error persists (in case of closed AutoQC drawer cover with displayed "Mat change" screen) contact Technical Support.</p> |
| 10160 - 10261 | File error | A file check resulted in an error. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 10416 - 10419 | Hardware conflict | A defective module was detected within the scope of the module communications. | <ul style="list-style-type: none"> To correct the error, turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support and supply the error number. Turn the instrument off.</p> |

Table 11-1 System stops






| No. | Message | Cause | Action |
|------------------|------------------------|--|---|
| 10424 - 10452 | Hardware error | A defective module was detected within the scope of the module communications. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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 occurred at the vacuum board. | <ul style="list-style-type: none"> 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. |
| 10471 | T&D error | An error occurred at the T&D module. | <ul style="list-style-type: none"> To correct the error clean the T&D disk, the fill port and the plug control.  see <i>Maintenance</i> (p. 245) <ul style="list-style-type: none"> Press Initialization:  System > Component test > Aggregates > T&D module and press Initialization If the error persists, contact Technical Support. |
| 10472 | Transponder error S1 | The transponder data of the rinse bottle could not be read. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> Perform General hardware test:  System > Diagnostics > General hardware test If the error persists, turn the instrument off and contact Technical Support. |
| 10489 | Remote lock | Instrument locked by cobas bge link software. | <ul style="list-style-type: none"> To remove lock press [Continue]. Log on as a user with the privilege Remote unlock.  For more information on user management, see <i>Reference Manual</i> , chapter <i>Software modes</i> , section <i>Security</i> |
| 10491 | QC setup wizard active | The instrument was locked by starting the QC setup wizard. | <ul style="list-style-type: none"> The message is removed after finishing the QC setup wizard.  see <i>Quality control</i> (p. 173) |
| 10492 | Data transfer active | The device was locked by starting the data transfer. | <ul style="list-style-type: none"> The message is removed after finishing the data transfer. |

Table 11-1 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. | <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Perform Aspirate CAL B:  System > Utilities > Fluid actions > Fill routines > Aspirate CAL B Perform General fluidics test:  System > Diagnostics > General fluidics test After removing possible faults, perform the calibration Mixing system:  System > Calibration > Mixing system Install a new S2 Fluid Pack.  see <i>Exchange of solutions and packs</i> (p. 256) Replace pump tube of main pump.  see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) If the error persists, contact Technical Support. |
| 20017 | FMS error | The mixture ratio falls outside the specified range. | To localize the error: <ul style="list-style-type: none"> Perform Aspirate CAL B/CAL A:  System > Utilities > Fluid actions > Fill routines > Aspirate CAL B/Aspirate CAL A Perform General fluidics test:  System > Diagnostics > General fluidics test After removing possible faults, insert a new S2 Fluid Pack.  see <i>Exchange of solutions and packs</i> (p. 256) If the error persists, contact Technical Support. |
| 20018 | Pack S2 empty | | <ul style="list-style-type: none"> Insert a new S2 Fluid Pack.  see <i>Exchange of solutions and packs</i> (p. 256) |
| 20019 | Flap S2 | Docking mechanism for S2 Fluid Pack is open. | <ul style="list-style-type: none"> Close the docking mechanism. |
| 20020 | No pack S2 | | <ul style="list-style-type: none"> Insert the S2 Fluid Pack.  see <i>Exchange of solutions and packs</i> (p. 256) |
| 20021 | ADC error cond BG/ISE" | A hardware error occurred during mixture calibration. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> To correct the error, remove and reinsert S2 Fluid Pack. If the error persists, replace S2 Fluid Pack  see <i>Exchange of solutions and packs</i> (p. 256) |
| 20023 | S2 on board time expired | | <ul style="list-style-type: none"> Insert the S2 Fluid Pack.  see <i>Exchange of solutions and packs</i> (p. 256) |

Table 11-2 Module stops







| No. | Message | Cause | Action |
|------------------|-------------------------|--|--|
| 20032 - 20035 | BG temperature nOk | The temperature of the BG measuring chamber falls outside the specified range. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> Perform Polychromator calibration:  System > Calibration > Polychromator 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. | <ul style="list-style-type: none"> Perform Polychromator calibration:  System > Calibration > Polychromator 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. | <ul style="list-style-type: none"> Perform Polychromator calibration:  System > Calibration > Polychromator calibration If the error persists, contact Technical Support. |
| 20068 | COOX HW error | The signal acquisition could not be performed due to a hardware error. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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 micro controller of the COOX module. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support. |
| 20072 | COOX temperature nOk | The temperature of the cuvette holder falls outside the specified range. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> To correct the error, perform General hardware test:  System > Diagnostics > General hardware test 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. | <ul style="list-style-type: none"> To correct the error check PP tube (MSS output) and if necessary replace.  see section <i>Exchange of solutions and packs</i> (p. 256) Perform MSS system calibration:  System > Calibration > MSS 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. |

Table 11-2 Module stops

Module stops

| No. | Message | Cause | Action |
|------------------|--------------------------------------|--|--|
| 20082 | MSS pol. not ok | The blood sample required for MSS polarization could not be positioned. | <ul style="list-style-type: none"> Check the correct fit of the individual components in the measuring chamber (sensor, counter bearing, RCon). To correct the error, repeat the MSS polarization - follow the instructions on the screen ☞ System > Utilities > MSS polarization |
| 20083 | MSS pol not ok | The MSS polarization was canceled | <ul style="list-style-type: none"> To correct the error, repeat the MSS polarization - follow the instructions on the screen ☞ System > Utilities > MSS polarization |
| 20084 | HW test error MSS | An error was recognized in a hardware component of the MSS measuring chamber. | <ul style="list-style-type: none"> To correct the error, perform General hardware test: ☞ System > Diagnostics > General hardware test <p>If the error persists, turn the instrument off and contact Technical Support.</p> |
| 20085 | Pack S3 empty | | <ul style="list-style-type: none"> Insert a new S3 Fluid Pack. ☞ see section <i>Exchange of solutions and packs</i> (p. 256) |
| 20086 | Flap S3 | Docking mechanism for S3 Fluid Pack is open. | <ul style="list-style-type: none"> Close docking mechanism. |
| 20087 - 20089 | MSS temperature nOk | The temperature of the MSS measuring chamber falls outside the specified range. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 20091 | No pack S3 | | <ul style="list-style-type: none"> Insert new S3 Fluid Pack. ☞ see section <i>Exchange of solutions and packs</i> (p. 256) |
| 20092 | ADC error cond. MSS | A hardware error occurred during initialization. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 20093 | ADC error MSS | Signal acquisition could not be performed due to a hardware error. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 20094 | Transponder error S3 | The transponder data of the S3 Fluid Pack could not be read. | <ul style="list-style-type: none"> To correct the error, remove and reinsert S3 Fluid Pack. <p>If the error persists, replace S3 Fluid Pack.</p> |
| 20095 | S3 on board time expired | | <ul style="list-style-type: none"> Insert new S3 Fluid Pack. |
| 20096 | tHb/SO ₂ temp. error | The temperature of the tHb/SO ₂ module falls outside the specified range. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 20097 | ADC error tHb | Signal acquisition could not be performed due to a hardware error. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support.</p> |
| 20098 | tHb/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. | <ul style="list-style-type: none"> To correct the error, perform Wash AQC: ☞ System > Wash & Cleaning > Wash AQC <p>If the error persists, contact Technical Support.</p> |
| 20113 | Module error AQC | The required XY position was not reached. | <ul style="list-style-type: none"> Perform Wash AQC: ☞ System > Wash & Cleaning > Wash AQC Repeat the AutoQC measurement. <p>If the error persists, contact Technical Support.</p> |

Table 11-2 Module stops

| No. | Message | Cause | Action |
|-------------------------|---------------------|---|--|
| 20114 | Module error AQC | The required Z position was not reached. | <ul style="list-style-type: none"> Perform Wash AQC: ☰ System > Wash & Cleaning > Wash AQC Repeat the AutoQC measurement. If the error persists, contact Technical Support. |
| 20115 20116 20118 | Module error AQC | The required position was not reached. | <ul style="list-style-type: none"> Perform Wash AQC: ☰ System > Wash & Cleaning > Wash AQC 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. | <ul style="list-style-type: none"> Perform Wash AQC: ☰ System > Wash & Cleaning > Wash AQC Repeat the AutoQC measurement. If the error persists, contact Technical Support. |
| 20122 - 20141 | AQC pos. error | The required position was not reached. | <ul style="list-style-type: none"> Perform AQC positioning test: ☰ System > Component test > Aggregates > AutoQC motors > AQC-positions Open AutoQC drawer and remove the ampoule holder, move to service position and go back to home position again. Reinsert ampoule holder and close AutoQC drawer. Perform Wash AQC: ☰ System > Wash & Cleaning > Wash AQC If the error persists, contact Technical Support. |
| 20142 | AQC temperature nOk | The temperature of the AQC module is outside the specified range. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. If the error persists, contact Technical Support. |

Table 11-2 Module stops

System warnings










| No. | Message | Cause | Action |
|-------|---|---|---|
| 30005 | Cl ⁻ electrode is contaminated (defective) | | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Wash & Cleaning > Wash > Cleaning modules > select ISE module and press Start internal cleaning. 2. Press:  System > Wash & Cleaning > Wash > Cleaning modules > select ISE module and press Start internal cleaning. 3. Remove Cl⁻ electrode and clean the electrode using the "Cleaning Kit for Cl⁻ Electrode" according package insert.  For instructions, refer to the "Cleaning Kit for Cl⁻ Electrode" package insert. 4. Perform Calibration for Ready:  Quick access > Calibration for Ready 5. Replace Cl⁻ electrode.  see section <i>Replacement of the electrodes</i> (p. 270) |
| 30006 | Undefined sensor status | No standby solution aspirated for a defined time frame. | <p>Fluidic time-out for standby solution exceeded. QC measurement required to ensure sensor accuracy.</p> <ul style="list-style-type: none"> • Press QC measurement. Select the corresponding level and if available press the button AQC measurement. |
| 30008 | Pack S2 level is low | S2 Fluid Pack will be empty in the next 12 to 24 hours. | <ul style="list-style-type: none"> • If necessary, insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) |
| 30009 | Pack S3 level is low | S3 Fluid Pack will be empty in the next 12 to 24 hours. | <ul style="list-style-type: none"> • If necessary, insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) |
| 30010 | Rinse level is low | S1 Rinse Solution will be empty in the next 12 to 24 hours. | <ul style="list-style-type: none"> • If necessary, insert a new S1 Rinse Solution.  see section <i>Exchange of solutions and packs</i> (p. 256) |
| 30011 | Waste is nearly full | The waste bottle will be full in the next 12 to 24 hours | <ul style="list-style-type: none"> • If necessary, replace and/or empty the bottle.  see section <i>Waste water</i> (p. 259) |

Table 11-3 System warnings














| No. | Message | Action |
|-------|-----------------------------|---|
| 30012 | Prep. of rinse not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Press:  System > Component test > Aggregates > Vacuum pump. If a defect is detected, contact Technical Support. Press:  System > Utilities > Fluid actions > Fill routines and start Aspirate rinse . Insert a new S1 Rinse Solution. <p>If this does not remove the warning, contact Technical Support.</p> |
| 30013 | Prep. of CAL B not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Press:  System > Utilities > Fluid actions > Fill routines and start Aspirate CAL B. Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30014 | Prep. of CAL A not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate CAL A. Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30017 | Prep. of O2 zero not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Clean T&D disk:  System > Wash & cleaning > Clean input unit Perform fill routine Aspirate O2 zero point solution:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate O2 zero point solution. Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30018 | Prep. of Na cond. not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate Na conditioning solution. Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30019 | Prep. of clean. sol. not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate cleaning solution. Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |

Table 11-4 System warnings

System warnings













| No. | Message | Action |
|-------|---|--|
| 30020 | Prep. of standby not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate standby solution. 2. Check MSS sensor for correct fit. 3. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30021 | Prep. of Ref. MSS not ok (only if Urea is installed) | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Fill ref. electrode MSS. 2. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30022 | Prep. of CAL 1 not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate CAL 1. 2. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30023 | Prep. of CAL 2 not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate CAL 2. 2. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) <p>If this does not remove the warning, contact Technical Support.</p> |
| 30024 | Prep. of CAL 3 not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate CAL 3. 2. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256). <p>If this does not remove the warning, contact Technical Support.</p> |
| 30025 | Prep. of CAL 4 not ok | <p>Perform the following troubleshooting options step by step until the warning disappears:</p> <ol style="list-style-type: none"> 1. Press:  System > Utilities > Fluid actions > Fill routines and start the fill routine Aspirate CAL 4. 2. Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256). <p>If this does not remove the warning, contact Technical Support.</p> |

Table 11-4 System warnings











| No. | Message | Cause | Action |
|-------|--------------------------------|--|--|
| 30028 | Check AQC material | At least 1 mat in the AutoQC module contains only two more full ampoules. | <ul style="list-style-type: none"> If necessary, insert a new mat.  see section <i>Changing of AutoQC mats</i> (p. 283) |
| 30029 | Check parameter states | One or more parameters are not calibrated | <ul style="list-style-type: none"> To eliminate this error, perform "Calibration for Ready":  Quick access > Calibration for Ready |
| 30030 | Perform manual QC measurement | Manual QC measurement is pending | <ul style="list-style-type: none"> Press QC measurement. Select the corresponding level and if available press the button AQC measurement. |
| 30031 | Perform maintenance | One or more maintenance processes must be carried out. | <ul style="list-style-type: none"> Perform maintenance.  see <i>Maintenance</i> (p. 245)  Quick access > Maintenance Select and run the corresponding maintenance. If maintenance tasks are pending that require a service call, contact Technical Support. |
| 30032 | Printer - printer lever opened | Printer lever is open | <ul style="list-style-type: none"> Close printer lever.  see section <i>Replacing printer paper</i> (p. 268) |
| 30033 | Printer - No paper | No paper available | <ul style="list-style-type: none"> Insert printer paper.  see section <i>Replacing printer paper</i> (p. 268) |
| 30034 | Messages | cobas bge link software has sent a message. | <ul style="list-style-type: none"> Delete the message in the message buffer.  Info > Message > Delete message |
| 30035 | Automatic software update | Change to another MSS sensor generation detected. This requires an automatic software update. | Follow the informations given on the screen. No user interaction necessary. |
| 30036 | HW test error fan | Result of the general hardware test. | <ul style="list-style-type: none"> Turn the instrument off, wait at least 3 minutes, and turn it back on. <p>If the error persists, contact Technical Support and supply the error number.</p> |
| 30037 | Screen sharing active | A service connection was established to the instrument. The "Screen sharing" indicator will be displayed in the status line. | <ul style="list-style-type: none"> This message will be removed after screen sharing was finished. |
| 30040 | S1 expires | On board time for S1 Rinse Solution in progress. | <ul style="list-style-type: none"> Insert new S1 Rinse Solution.  see section <i>Exchange of solutions and packs</i> (p. 256). |
| 30041 | S2 expires | On board time for S2 Fluid Pack in progress. | <ul style="list-style-type: none"> Insert a new S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256). |
| 30042 | S3 expires | On board time for S3 Fluid Pack in progress. | <ul style="list-style-type: none"> Insert a new S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256). |

Table 11-5 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: <ul style="list-style-type: none"> Blockage or leak Separation of electrode membrane Leaking electrodes | <ul style="list-style-type: none"> If discoloration can be detected by sample material in the internal electrolyte of the electrode, it must be replaced.  see section <i>Replacement of the electrodes</i> (p. 270) If the error persists perform General fluidics test to isolate the error:  System > Diagnostics > General fluidics test and afterwards contact Technical Support |
| 1001 | Sample pos. error (2) | The conductivity is too low. Possible causes: <ul style="list-style-type: none"> Blockage No fluid in measuring chamber | <ul style="list-style-type: none"> If the error persists replace S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) Perform General fluidics test to isolate the error:  System > Diagnostics > General fluidics test Depending on the result, check the device for leaks or clogs or 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: <ul style="list-style-type: none"> Deposits or blockage in measuring chamber. | Contact Technical Support. |
| 1003 | Ref. sol. asp. error | No reference solution was detected. Possible causes: <ul style="list-style-type: none"> Blockage or leaks in reference system | <ul style="list-style-type: none"> Perform Fill Reference Electrode:  System > Utilities > Fluid actions > Fill routines If the error persists replace S2 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256) If this error cannot be corrected, contact Technical Support. |
| 1004 | Ref. sol. pos. error | Conductivity level could not be maintained. Possible causes: <ul style="list-style-type: none"> Detachment of electrode membrane Leaking electrodes | <ul style="list-style-type: none"> Check the electrode seating. Perform Calibration for Ready:  Quick access > Calibration for Ready If this error cannot be corrected, contact Technical Support. |
| 1005 | End of sample detected | SS1 detects the end of the sample, but the measuring chamber is not yet filled. Possible causes: <ul style="list-style-type: none"> Irregular sample Insufficient sample Improper sample | <ul style="list-style-type: none"> Repeat the measurement/calibration, check for sufficient and homogeneous sample input. If the error persists, contact Technical Support. |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|-----------------------|--|---|
| 1006 | Irregular sample (1) | The measuring chamber is not filled homogeneously. Possible causes: <ul style="list-style-type: none"> • The sample was irregular • Leak in measuring channel • Air bubbles were detected in the measuring channel | <ul style="list-style-type: none"> • Repeat measurement/calibration. <p>If the error persists, contact Technical Support.</p> |
| 1007 | Cuvette not empty | A sample detection was not possible. Possible causes: <ul style="list-style-type: none"> • Deposits in the cuvette • Light level too low | <ul style="list-style-type: none"> • Perform Internal cleaning: ☰ System > Wash & Cleaning > Clean module > select appropriate module and press Start internal cleaning. • If the error persists replace PP tube (main pump). Ⓜ see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) <p>If error cannot be corrected, contact Technical Support.</p> |
| 1008 | Irregular sample (2) | The conductivity changed after closing the valve at the measuring chamber input. Possible causes: <ul style="list-style-type: none"> • Insufficient wetting in the measuring channel • Separation of the electrode diaphragm • Leaky electrode | <ul style="list-style-type: none"> • Perform Wetting routine: ☰ System > Utilities > Fluid actions <p>If error cannot be corrected, contact Technical Support.</p> |
| 1009 | Sample pos. error (3) | The measuring signal was not constant or the measuring channel was not uniformly filled. Possible cause: <ul style="list-style-type: none"> • Sample was fragmented. | <ul style="list-style-type: none"> • Ensure sufficient, uniform sample input. <p>If the error persists, contact Technical Support.</p> |
| 1010 | Sample pos. error (4) | The conductivity was too high: Possible causes: <ul style="list-style-type: none"> • Aspiration problems with standby solution • PP tube defective | <ul style="list-style-type: none"> • Check PP tube (MSS outlet) and if necessary replace. Ⓜ see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) • Perform Aspirate standby solution: ☰ System > Utilities > Fluid actions > Fill routines <p>If error cannot be corrected, contact Technical Support.</p> |
| 1011 | Sample pos. error (5) | No constant conductivity at sensor input was detected. Possible causes: <ul style="list-style-type: none"> • Blockage or leak • PP tube (MSS outlet) defective | <ul style="list-style-type: none"> • Check PP tube (MSS outlet) and if necessary replace. Ⓜ see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) • Perform Aspirate standby solution: ☰ System > Utilities > Fluid actions > Fill routines • Perform Calibration for Ready: ☰ Quick access > Calibration for Ready • 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 11-6 Status messages of measuring and calibration values
















| No. | Message | Cause | Action |
|------|------------------------|--|---|
| 1012 | Sample pos. error (6) | <p>Conductivity at sensor input was too low.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Blockage • No fluid in measuring chamber • PP tube (MSS outlet) defective | <ul style="list-style-type: none"> • Check PP tube (MSS outlet) and if necessary replace  see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) • Perform the fill routine Aspirate standby solution:  System > Utilities > Fluid actions > Fill routines • Perform Calibration for Ready:  Quick access > Calibration for Ready • 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. |
| 1013 | Sample sep. error (2) | <p>MSS: No air packet was detected between calibration solution and sample. The sample was not aspirated or aspirated too late.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Deposits or blockage in measuring channel. • PP tube (MSS outlet) defective | <ul style="list-style-type: none"> • Check PP tube (MSS outlet) and if necessary replace  see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) • Perform Aspirate standby solution:  System > Utilities > Fluid actions > Fill routines • Perform Calibration for Ready:  Quick access > Calibration for Ready • 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) | <p>Conductivity at BSA sensor is too low.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Air bubbles • Poor wetting | <ul style="list-style-type: none"> • Perform MSS polarization:  System > Utilities (follow the instructions on the screen) • Insert sufficiently large samples <p>If error cannot be corrected, contact Technical Support.</p> |
| 1015 | Sample pos. error (8) | <p>Conductivity at lactate sensor is too low.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Air bubbles • Poor wetting | <ul style="list-style-type: none"> • Perform MSS polarization:  System > Utilities (follow the instructions on the screen) • Insert sufficiently large samples <p>If error cannot be corrected, contact Technical Support.</p> |
| 1016 | Sample pos. error (9) | <p>Conductivity at glucose sensor is too low.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Air bubbles • Poor wetting • | <ul style="list-style-type: none"> • Perform MSS polarization:  System > Utilities (follow the instructions on the screen) • Insert sufficiently large samples <p>If error cannot be corrected, contact Technical Support.</p> |
| 1017 | Sample pos. error (10) | <p>MSS: Conductivity was too low at the sensor input after positioning the sample/calibration solution in the measuring chamber.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • The sample/calibration solution was non-uniform • Insufficient sample/calibration solution detected • Insufficient wetting of the measuring channel | <p>Ensure sufficient, uniform sample input.</p> <ul style="list-style-type: none"> • Perform Wetting routine MSS:  System > Utilities > Fluid actions • If the error cannot be corrected, replace MSS cassette. <p> see section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280)</p> |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|-------------------------|---|---|
| 1020 | Sample distr. error (1) | Unable to remove excess sample. Possible causes: <ul style="list-style-type: none"> Clogging or leaky points during positioning | <ul style="list-style-type: none"> Perform General fluidics test to isolate the error. ☞ System > Diagnostics Depending on the result, check the device for leaks or clogs or contact Technical Support. |
| 1021 | Sample distr. error (2) | No solution detected at SS3 although SS2 detected a solution. Possible causes: <ul style="list-style-type: none"> Clogging Sample inlet path leaky | <ul style="list-style-type: none"> Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists, perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test Depending on the result, check the device for leaks or clogs or contact Technical Support. |
| 1022 | Sample distr. error (3) | Sample excess could not be extracted via transverse channel. Possible causes: <ul style="list-style-type: none"> Blockage | <ul style="list-style-type: none"> Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists, perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test Depending on the result, check the device for leaks or clogs or contact Technical Support. |
| 1023 | Sample distr. error (4) | SS4 did not detect solution Possible causes: <ul style="list-style-type: none"> Blockage | <ul style="list-style-type: none"> Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists, perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test Depending on the result, check the device for leaks or clogs or contact Technical Support. |
| 1024 | No sample detected (1) | SS3 and SS2 did not detect a sample. Possible causes: <ul style="list-style-type: none"> No more sample available for the Hb module | <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Fragmented sample in sample distributor | <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Fragmented sample in sample distributor | <ul style="list-style-type: none"> Ensure sample entry is free of air bubbles. Repeat measurement. If the error persists, contact Technical Support. |
| 1027 | No sample detected (4) | No sample detected in Hb module (tHb/SO ₂ or COOX module, depending on the configuration). Possible causes: <ul style="list-style-type: none"> Sample path leaky or clogged Cuvette holder is leaky Tubing of main pump is defective | <ul style="list-style-type: none"> Check PP tube (main pump) and if necessary replace ☞ see section <i>Exchanging the peristaltic pump tubes</i> (p. 266) Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists perform General fluidics test to isolate the error ☞ System > Diagnostics and afterwards contact Technical Support. |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|-------------------------|---|---|
| 1028 | Insufficient sample(1) | No sample detected in Hb module (tHb/SO ₂ or COOX module, depending on the configuration). Possible causes: <ul style="list-style-type: none"> The sample was irregular Sample was insufficient | <ul style="list-style-type: none"> Repeat measurement/calibration, check for sufficient and homogeneous sample input. <p>If the error persists, contact Technical Support.</p> |
| 1029 | Insufficient sample(2) | Insufficient sample for BG module was detected. Possible causes: <ul style="list-style-type: none"> The sample was irregular Sample was insufficient | <ul style="list-style-type: none"> Repeat measurement/calibration, check for sufficient and homogeneous sample input. <p>If the error persists, contact Technical Support.</p> |
| 1030 | Insufficient sample(3) | Insufficient sample for ISE module was detected. Possible causes: <ul style="list-style-type: none"> The sample was irregular Sample was insufficient | <ul style="list-style-type: none"> Repeat measurement/calibration, check for sufficient and homogeneous sample input. <p>If the error persists, contact Technical Support</p> |
| 1031 | Insufficient sample(4) | insufficient sample for MSS module was detected. Possible causes: <ul style="list-style-type: none"> The sample was irregular Sample was insufficient | <ul style="list-style-type: none"> Repeat measurement/calibration, check for sufficient and homogeneous sample input. With non calibrated sensors perform fill routine Aspirate CAL 2/3/4: ☞ System > Utilities > Fluid actions > Fill routines Perform Calibration for Ready: ☞ Quick access > Calibration for Ready <p>If the error persists, contact Technical Support.</p> |
| 1032 | Sample distr. error (5) | No calibration solution 1 (CAL 1) detected. Possible causes: <ul style="list-style-type: none"> Blockage or leak Tubing of main pump is defective | <ul style="list-style-type: none"> 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 <p> see section <i>Exchanging the peristaltic pump tubes</i> (p. 266)</p> <p>If the error persists, contact Technical Support.</p> |
| 1036 | Insufficient sample (5) | Insufficient sample for MSS module was detected Possible causes: <ul style="list-style-type: none"> The sample was irregular Sample was insufficient | <ul style="list-style-type: none"> Repeat the measurement/calibration, check for sufficient and homogeneous sample input. With non calibrated sensors perform fill routine Aspirate CAL 2/3/4: ☞ System > Utilities > Fluid actions > Fill routines Perform Calibration for Ready: ☞ Quick access > Calibration for Ready <p>If the error persists, contact Technical Support.</p> |
| 1037 | No sample detected (8) | No sample detected in hemolyzer: Possible causes: <ul style="list-style-type: none"> Sample path leaky or blocked | <ul style="list-style-type: none"> Perform Hemolyzer test: ☞ System > Component test > Aggregates > Hemolyzer If the error persists perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test and afterwards contact Technical Support. |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|------------------------|--|---|
| 1038 | No sample detected (9) | No rinse solution from the Hb module detected (tHb/SO2 or COOX module, depending on the configuration) (Calibration). Possible causes: <ul style="list-style-type: none"> Sample path leaky or blocked | <ul style="list-style-type: none"> Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test and afterwards contact Technical Support. |
| 1050 | No sample in SIP | No sample detected in the sample inlet path at SS2 or SS6. Possible causes: <ul style="list-style-type: none"> No sample was inserted | <ul style="list-style-type: none"> If this error occurs as part of a calibration, clean the T&D disk. ☞ System > Wash & cleaning > Clean input unit Perform Wash: ☞ System > Wash & Cleaning > Wash If the error persists perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test <p>Depending on the result, check the device for leaks or clogs or contact Technical Support.</p> |
| 1051 | No AQC sample detected | No sample was detected at SS5. Possible causes: <ul style="list-style-type: none"> Sample path leaky or blocked | <ul style="list-style-type: none"> Perform Wash AQC: ☞ System > Wash & Cleaning > Wash AQC If the error persists perform General fluidics test to isolate the error ☞ System > Diagnostics > General fluidics test and afterwards contact Technical Support. |
| 1052 | No vacuum | No regulated vacuum could be build up during aspiration process. Possible causes: <ul style="list-style-type: none"> Vacuum system defective | <ul style="list-style-type: none"> Perform test function Vacuum system: ☞ System > Component test > Control sensors <p>If the error persists, contact Technical Support.</p> |
| 2004 | Repro. not OK | Sensor signal cannot be reproduced Possible causes: <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Perform Calibration for Ready: ☞ Quick access > Calibration for Ready 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 section <i>Replacement of the electrodes</i> (p. 270) If the sample channel is visibly soiled, perform Internal cleaning: ☞ System > Wash & Cleaning > Clean module > select appropriate module and press 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 section <i>Changing the reference electrode</i> (p. 278) |
| 2009 | Recal. not OK | Signal difference occurring during recalibration of PCO2 was too large. Possible causes: <ul style="list-style-type: none"> Invalid sample type used | <ul style="list-style-type: none"> Perform Calibration for Ready: ☞ Quick access > Calibration for Ready If the error persists, replace electrode Ⓢ see section <i>Replacement of the electrodes</i> (p. 270) |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|---------------------------|---|--|
| 2011 | Sensor signal instability | <p>Sensor signal cannot be reproduced.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> If this interference applies to the complete module, the reference electrode must be replaced ☞ see section <i>Changing the reference electrode</i> (p. 278) 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 section <i>Replacement of the electrodes</i> (p. 270) Perform Calibration for Ready: ☞ Quick access > Calibration for Ready 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 section <i>Replacement of the electrodes</i> (p. 270) or <i>Changing the MSS cassette</i> (cobas b 221<5> system and cobas b 221<6> system only) (p. 280) |
| 2012 | Sensor signal drifting | <p>Sensor signal is too high.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Perform Calibration for Ready: ☞ Quick access > Calibration for Ready 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 section <i>Replacement of the electrodes</i> (p. 270) or <i>Changing the MSS cassette</i> (cobas b 221<5> system and cobas b 221<6> system only) (p. 280) 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 section <i>Replacement of the electrodes</i> (p. 270) If the error persists, perform Aspirate Rinse: ☞ System > Utilities > Fluid actions > Fill routines If necessary, replace S1 Rinse Solution ☞ see section <i>Exchange of solutions and packs</i> (p. 256) |
| 2016 | Signal too high | <p>The first sampling value of the O2 zero point calibration is > 60 mV</p> <p>Possible causes:</p> <ul style="list-style-type: none"> An air bubble falsifies the calibration Non-uniform O2 zero point solution PO2 electrode defective | <ul style="list-style-type: none"> 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, section <i>Exchange of solutions and packs</i> (p. 256) If the error persists, replace PO₂ electrode. ☞ see, section <i>Replacement of the electrodes</i> (p. 270) |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|---------------------|---|--|
| 2021 | Drift alarm | <p>A drifting of the sensor signal was detected in the "Ready" state.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Electrode drifts are exceeding the specified limit values • Invalid sample type is being used • Wetting problems <p>In case of PO₂:</p> <ul style="list-style-type: none"> • contamination possible | <ul style="list-style-type: none"> • Perform Calibration for Ready: ☰ Quick access > Calibration for Ready • 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 <p>📖 see section <i>Replacement of the electrodes</i> (p. 270) or <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280)</p> <p>In case of PO₂ drift:</p> <ul style="list-style-type: none"> • Perform Internal cleaning: ☰ System > Wash & Cleaning > Cleaning module > select appropriate module and press 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 | <p>In the "Ready" state drifting of the sensor signal was detected at the reference electrode.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • Reference system fault due to bubbles • Docking mechanism for S2 Fluid Pack soiled | <ul style="list-style-type: none"> • Perform Fill reference electrode: ☰ System > Utilities > Fluid actions > Fill routines • Perform Calibration for Ready: ☰ Quick access > Calibration for Ready > Calibration for Ready • Check S2 docking mechanism for contamination and if necessary clean it. • If the error persists replace reference electrode <p>📖 see section <i>Changing the reference electrode</i> (p. 278)</p> |
| 2023 | Sensitivity drift | <p>1 point sensitivity drifts.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • The sensor did not finished the start-up period and the 1 point sensitivity highly increases. | <ul style="list-style-type: none"> • Perform Calibration for Ready: ☰ Quick access > Calibration for Ready |
| 2024 | Air bubble detected | <p>Before washing out the sample the conductivity value was not detected as pressure-stable.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> • PO₂ electrode has not filled bubble-free • Leaky sample path in BG | <ul style="list-style-type: none"> • Perform General fluidics test: ☰ System > Diagnostics > General fluidics test if error occurs, contact Technical Support. • Replace PO₂ electrode. • Replace PCO₂ electrode |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|--------------------------|--|--|
| 2028 | Mean not OK | Measurement value of calibration is outside the expected range. Possible causes: <ul style="list-style-type: none"> Electrode limit exceeded | <ul style="list-style-type: none"> Perform module-related system calibration: ☰ System > Calibration > System calibration If several electrodes are affected, replace S2 Fluid Pack or S3 Fluid Pack (cobas b 221<5> system, cobas b 221<6> system only) ☰ see section <i>Exchange of solutions and packs</i> (p. 256) With PO2 electrode, check barometer: ☰ System > Component test > Control sensors > Barometer If the error persists, replace electrode/MSS cassette ☰ see section <i>Replacement of the electrodes</i> (p. 270) |
| 2029 | ADC >>>>> | Sensor signal is above the measuring range. Possible causes: <ul style="list-style-type: none"> Reference system not filled Leaky, empty electrode | <ul style="list-style-type: none"> Perform Fill reference electrode: ☰ System > Utilities > Fluid actions > Fill routines > Fill reference electrode Check seat of the electrode. Perform General fluidics test: ☰ System > Diagnostics > General fluidics test If the error persists, replace electrode/MSS cassette ☰ see section <i>Replacement of the electrodes</i> (p. 270) |
| 2030 | ADC <<<<< | Sensor signal is below the measuring range. Possible causes: <ul style="list-style-type: none"> Reference system not filled Leaky, empty electrode | <ul style="list-style-type: none"> Perform Fill reference electrode: ☰ System > Utilities > Fluid actions > Fill routines > Fill reference electrode Check seat of the electrode. Perform General fluidics test: ☰ System > Diagnostics > General fluidics test If the error persists, replace electrode/MSS cassette ☰ see section <i>Replacement of the electrodes</i> (p. 270) |
| 2031 | Conditioning not OK | Na electrode was not conditioned. Possible causes: <ul style="list-style-type: none"> S2 Fluid Pack docking mechanism is leaking T&D leaking during aspiration of conditioning solution | <ul style="list-style-type: none"> 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 > General fluidics test and correct the leak. |
| 2035 | Linearity not OK | The sensitivity of the sensor is too low. Possible causes: <ul style="list-style-type: none"> Sensor worn out | <ul style="list-style-type: none"> Replace the MSS cassette. ☰ see section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) If the error cannot be corrected, replace S3 Fluid Pack. ☰ see section <i>Exchange of solutions and packs</i> (p. 256) |
| 2036 | Interference sensitivity | The sensitivity of the sensor is too low. Possible causes: <ul style="list-style-type: none"> Sensor worn out | <ul style="list-style-type: none"> Replace MSS cassette. ☰ see section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) If the error cannot be corrected, replace S3 Fluid Pack. ☰ see section <i>Exchange of solutions and packs</i> (p. 256) |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|------------------------|--|--|
| 2040 | Cuvette not OK | Check of layer thickness outside the expected range. Possible causes: <ul style="list-style-type: none"> • Cuvette is contaminated • Incorrect target value | <ul style="list-style-type: none"> • Perform Polychromator calibration: ☰ System > Calibration > Polychromator calibration • Perform COOX calibration: ☰ System > Calibration > COOX calibration |
| 2041 | Ref. point not OK | Reference point is outside the expected range Possible causes: <ul style="list-style-type: none"> • Sample feeding clogged | <ul style="list-style-type: none"> • Perform Wash: ☰ System > Wash & Cleaning > Wash • If the error persists, perform General fluidics test to isolate the error: ☰ System > Diagnostics > General fluidics test and afterwards contact Technical Support. |
| 2042 | Wavelength not OK (1) | One specific wavelength is outside the expected range. | <ul style="list-style-type: none"> • Perform Polychromator calibration: ☰ System > Calibration > Polychromator calibration <p>If the error persists, contact Technical Support.</p> |
| 2043 | Hemolysis not OK (1) | Hemolyzer is not ready | <ul style="list-style-type: none"> • Perform Hemolyzer test: ☰ System > Component test > Aggregates > Hemolyzer |
| 2044 | Hemolysis not OK (2) | Hemolyzer power is outside the expected range. | <ul style="list-style-type: none"> • Visually check the drying operation. |
| 2070 | Sensor signal unstable | tHb sensor signal is disturbed Possible causes: <ul style="list-style-type: none"> • Irregular sample • Sample feeding is leaking or clogged | <ul style="list-style-type: none"> • Perform Internal cleaning: ☰ System > Wash & Cleaning > Cleaning module > tHb/SO2 module > Start internal cleaning • If the error persists, perform General fluidics test to isolate the error: ☰ System > Diagnostics > General fluidics test • Replace S1 Rinse Solution. <p>ⓘ see section <i>Exchange of solutions and packs</i> (p. 256)</p> <p>If the error persists, contact Technical Support</p> |
| 2071 | Measuring path dirty | The absolute limits of water calibration are outside the specified range. Possible causes: <ul style="list-style-type: none"> • Contaminated or defective sensor | <ul style="list-style-type: none"> • Perform Internal cleaning: ☰ System > Wash & Cleaning > Cleaning module > select appropriate module and press Start internal cleaning, repeat as necessary. • Replace S1 Rinse Solution. <p>ⓘ see section <i>Exchange of solutions and packs</i> (p. 256)</p> <p>If the error persists, contact Technical Support.</p> |
| 3000 | D2/D3 not performed | MSS standby solution was not aspirated. Possible causes: <ul style="list-style-type: none"> • Faulty aspiration of standby solution • Faulty aspiration of reference solution | <ul style="list-style-type: none"> • 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: ☰ Quick access > Calibration for Ready |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|-------------------|--|--|
| 3001 | FMS volume error | Time-out error during aspiration of calibration solution. Possible causes: <ul style="list-style-type: none"> Blockage or leak | <ul style="list-style-type: none"> Check Aspirate CAL B: ☰ System > Utilities > Fluid actions > Fill routines Perform General fluidics test: ☰ System > Diagnostics > General fluidics test <p>Depending on the result, check the device at the displayed position for leaks or clogs or contact Technical Support.</p> <ul style="list-style-type: none"> Call up Calibration for Ready: ☰ Quick access > Calibration for Ready Replace S2 Fluid Pack <p>📖 see section <i>Exchange of solutions and packs</i> (p. 256)</p> <p>If the error persists, contact Technical Support.</p> |
| 3002 | Temperature error | The module temperature is outside the permitted range. Possible causes: <ul style="list-style-type: none"> Poor heating contact Fan failure Heating failure Air filter heavily soiled or covered | <ul style="list-style-type: none"> Check the temperature signals. <p>If the temperature is outside the specified range for a long period of time, inform Technical Support.</p> |
| 3003 | FMS error | Incorrect deviation from specified value and measurement value of FMS. Possible causes: <ul style="list-style-type: none"> Blockage or leak Defective mixer valve Defective air valve Blockage or leak | <ul style="list-style-type: none"> To isolate error, check Aspirate CAL B: ☰ System > Utilities > Fluid actions > Fill routines > Aspirate CAL B Check Aspirate CAL A: ☰ System > Utilities > Fluid actions > Fill routines > Aspirate CAL A Perform General fluidics test: ☰ System > Diagnostics > General fluidics test <p>Depending on the result, check the device at the displayed position for leaks or clogs or contact Technical Support.</p> <ul style="list-style-type: none"> Call up Calibration for Ready: ☰ Quick access > Calibration for Ready Replace S2 Fluid Pack <p>📖 see section <i>Exchange of solutions and packs</i> (p. 256)</p> |
| 3004 | AQC module error" | The required position was not reached. | <ul style="list-style-type: none"> Perform AQC positioning test: ☰ System > Component test > Aggregates > AutoQC motors > AQC-positions Open AutoQC drawer and remove the ampoule holder, move to service position and go back to home position again. Reinsert ampoule holder and close AutoQC drawer. Perform Wash AQC: ☰ System > Wash & Cleaning > Wash AQC <p>If the error persists, contact Technical Support.</p> |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|------|-------------------------|--|--|
| 3013 | Ref. point D1 not OK | <p>Problem during precalibration.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> Faulty aspiration of standby solution Faulty aspiration of MSS reference solution | <ul style="list-style-type: none"> 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 | <p>Problem during precalibration.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> Faulty aspiration of standby solution Faulty aspiration of MSS reference solution | <ul style="list-style-type: none"> 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 |
| 3022 | Conductivity not OK | Conductivity calibration was not exited correctly. | <ul style="list-style-type: none"> Print out Sensor report and check the error messages for conductivity with calibration solution CAL B or CAL A: ☰ Info > Miscellaneous reports |
| 3033 | 0P not OK | <p>O₂ zero calibration was not exited correctly.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> Aspireate O₂ zero not ok Soiling or leak | <ul style="list-style-type: none"> Perform Aspirate O2 zero point solution: ☰ System > Utilities > Fluid actions > Fill routines Check fill port and the T&D disc for soiling ⊗ see <i>Maintenance</i> (p. 245) Replace S2 Fluid Pack. ⊗ see section <i>Exchange of solutions and packs</i> (p. 256) |
| 3034 | Invalid measured value | Elapsed time between sample and Cal 1 too high. The measurement value is blocked because of unclear sensor signal drift. | <ul style="list-style-type: none"> Perform Calibration for Ready: ☰ Quick access > Calibration for Ready |
| 4003 | Calibration pending (1) | Sensor reinserted, no calibration values available. | <ul style="list-style-type: none"> Perform Calibration for Ready: ☰ Quick access > Calibration for Ready |
| 4008 | Calibration pending (2) | Calibration is pending or was canceled. | <ul style="list-style-type: none"> Perform Calibration for Ready: ☰ Quick access > Calibration for Ready |
| 4024 | Calibration pending (3) | Sensor is or was deactivated. | <ul style="list-style-type: none"> Perform Calibration for Ready: ☰ Quick access > Calibration for Ready |
| 5006 | Calculation error (1) | <p>UC calculation error.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> An unapproved calculation operation occurred. | <ul style="list-style-type: none"> Remove bottles/packs and reinsert them. <p>If the error persists, contact Technical Support.</p> |
| 5007 | Calculation error (2) | <p>UC calculation error.</p> <p>Possible causes:</p> <ul style="list-style-type: none"> An unapproved calculation operation occurred. | <ul style="list-style-type: none"> Remove the affected electrode and reinsert it. <p>If the error persists, contact Technical Support.</p> |

Table 11-6 Status messages of measuring and calibration values

Status messages of measuring and calibration values




| No. | Message | Cause | Action |
|------|-----------------------|---|---|
| 5010 | Calculation error (3) | UC calculation error (COOX). Possible causes: • An unapproved calculation operation occurred. | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> Perform Polychromator calibration: ☰ System > Calibration > Polychromator 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. | <ul style="list-style-type: none"> Check the cuvette for soiling. Perform Polychromator calibration: ☰ System > Calibration > Polychromator calibration Turn the instrument off and on again. If the error persists, contact Technical Support. |
| 6026 | ADC error | | <ul style="list-style-type: none"> 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. |
| 6030 | COOX HW error | A hardware error occurred at the COOX module. |  see Details of module stop 20068 (p. 301), 20069 (p. 301) and 20071 (p. 301). |
| 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 | <ul style="list-style-type: none"> Perform Internal cleaning: ☰ System > Wash & Cleaning > Cleaning module > select appropriate module and press Start internal cleaning Perform Polychromator calibration: ☰ System > Calibration > Polychromator 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 | <ul style="list-style-type: none"> Perform Internal cleaning: ☰ System > Wash & Cleaning > Cleaning module > select appropriate module and press Start internal cleaning Perform Polychromator calibration: ☰ System > Calibration > Polychromator 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 | <ul style="list-style-type: none"> To correct the error replace S2 Fluid Pack  see section <i>Exchange of solutions and packs</i> (p. 256) |
| 8036 | IfS not OK | The BSA/Glu or BSA/Lac ratios in CAL 3 are outside the range. Possible causes: • Interference correction not possible | <ul style="list-style-type: none"> Perform Calibration for Ready: ☰ Quick access > Calibration for Ready If the error cannot be corrected, replace MSS cassette  see section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |

Table 11-6 Status messages of measuring and calibration values

| No. | Message | Cause | Action |
|-------------|---------------------------------|---|---|
| 8061 | Interferences (1) | The calculated tHb value is invalid Possible causes: <ul style="list-style-type: none"> • Interferences • Unsuitable sample type used | <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Interferences • Unsuitable sample type used | <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Interferences • Unsuitable sample type used | <ul style="list-style-type: none"> • Check sample material. If the error persists, contact Technical Support. |
| 8070 | IfS repro. not OK | Non-reproducible sensor signal at interference sensor. Possible causes: <ul style="list-style-type: none"> • Unsuitable sample type is being used | <ul style="list-style-type: none"> • Perform Wetting routine MSS: ☰ System > Utilities > Fluid actions If the error persists, change the MSS cassette.  see section, <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |
| 8071 - 8072 | IfS calculation error (1) - (2) | UC calculation error (1) on interference sensor. Possible causes: <ul style="list-style-type: none"> • An unapproved calculation operation occurred | <ul style="list-style-type: none"> • Remove and reinsert S3 Fluid Pack. |
| 8073 | IfS sensor signal unstable | Interference sensor signal cannot be reproduced. Possible causes: <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • If this interference applies to the complete module, replace reference electrode  see section <i>Changing the reference electrode</i> (p. 278) <ul style="list-style-type: none"> • Perform Calibration for Ready: ☰ Quick access > Calibration for Ready • 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 section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |
| 8074 | IfS ref. point not OK | Problem at reference point of standby solution at interference sensor. Possible causes: <ul style="list-style-type: none"> • Aspiration of MSS standby solution not ok • Aspiration of MSS reference solution not ok | <ul style="list-style-type: none"> • 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 | | <ul style="list-style-type: none"> • 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. |

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| No. | Message | Cause | Action |
|------|----------------------|---|--|
| 8076 | IfS mean not OK | Calibration end value of an IfS is outside the range. Possible causes: <ul style="list-style-type: none"> Problems with transponder of S3 Fluid Pack | <ul style="list-style-type: none"> Replace S3 Fluid Pack.  see section <i>Exchange of solutions and packs</i> (p. 256). If the error persists replace MSS cassette. see section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |
| 8077 | IfS ADC >>>>> | Interference sensor signal is above ADC range Possible causes: <ul style="list-style-type: none"> Reference system not filled Leak in the measuring channel | <ul style="list-style-type: none"> Perform Fill reference electrode:  System > Utilities > Fluid actions > Fill routines Check seat of the electrode. If the error persists, replace electrode/MSS cassette.  see section <i>Replacement of the electrodes</i> (p. 270) or section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |
| 8078 | IfS ADC <<<<< | Interference sensor signal is below ADC range Possible causes: <ul style="list-style-type: none"> Reference system not filled Leak in the measuring channel | <ul style="list-style-type: none"> Perform Fill reference electrode:  System > Utilities > Fluid actions > Fill routines Check seat of the electrode. If the error persists, replace electrode/MSS cassette.  see section <i>Replacement of the electrodes</i> (p. 270) or section <i>Changing the MSS cassette (cobas b 221<5> system and cobas b 221<6> system only)</i> (p. 280) |
| 8080 | Interferences (4) | Detected sample type is invalid. Possible causes: <ul style="list-style-type: none"> Interferences Unsuitable sample type used | <ul style="list-style-type: none"> Check sample material. |
| 8081 | Interferences (5) | The calculated COHb value is outside the permitted range. Possible causes: <ul style="list-style-type: none"> Interferences Unsuitable sample type used | <ul style="list-style-type: none"> Check sample material. |
| 8082 | Interferences (6) | The calculated SO2 value is outside the permitted range. Possible causes: <ul style="list-style-type: none"> Interferences Unsuitable sample type used | <ul style="list-style-type: none"> Check sample material. |
| 8083 | Sample type conflict | Detected sample type is invalid. Possible causes: <ul style="list-style-type: none"> Unsuitable sample type used | <ul style="list-style-type: none"> Check sample material. |
| 8084 | Invalid sample type | A different blood type than arterial or capillary blood was used. Possible causes: <ul style="list-style-type: none"> All calculation values calculated from measurement values with arterial blood cannot be output. | <ul style="list-style-type: none"> Use arterial or capillary blood as sample material and set the correct blood type. |

Table 11-6 Status messages of measuring and calibration values


| No. | Message | Cause | Action |
|------|-----------------------|--|---|
| 9000 | Calculation error (3) | PC calculation error. Possible causes: <ul style="list-style-type: none"> An unapproved calculation operation occurred. | <ul style="list-style-type: none"> Contact Technical Support. |
| 9001 | Not activated | Parameter is disabled for measurement (gray). | <ul style="list-style-type: none"> Enable the parameter. |
| 9002 | Not calibrated | Parameter is not calibrated (red X). | <ul style="list-style-type: none"> Perform Calibration for Ready:  Quick access > Calibration for Ready |
| 9011 | Interferences | The BSA/Glu or BSA/Lac ratios are outside the range. Interference correction not possible. | <ul style="list-style-type: none"> Check sample material and, if necessary, reenter the sample. <p>If the error persists, contact Technical Support.</p> |

Table 11-6 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 Hct value is implausible. |
| ? ... improper sample | The selected sample type does not match the actual concentration. |
| (c) ... User correlation activated | User defined correlation applied to the measurement value. |
| * ... demo mode | Demo Mode active. |
| (q) ... qc warning | Parameter is in QC warning state. |
| (!) ... Sensor older than 28 days | Sensor on board time exceeded. |
| # ... check plausibility | The measured value is lower than the defined Limit of Quantitation (LoQ). The BSA/Glu or BSA/Lac ratios are outside the range. Interference correction not possible. |

Table 11-7 Status messages on the measurement report

Barcode

If problems occur reading in with the PS2 hand-held scanner included in the scope of delivery, carry out the following steps:

▶ Barcode scanner troubleshooting

- 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 and read the barcode labeled as "Roche Factory Reset".

If the error persists, contact Technical Support.



Barcode

Appendix

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List of consumables

In this chapter, all necessary consumables and order numbers are listed.

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Order information

To measure the respective parameter following products are required:

Electrodes

| | Parameter | | | | | | | | | | |
|---|-----------------|-----------------|----------------|------------------|------------------|-----------------|----|---------------------|-----------|-----|--|
| | Cl ⁻ | Na ⁺ | K ⁺ | Ca ²⁺ | PCO ₂ | PO ₂ | pH | tHb/SO ₂ | COOX/Bili | MSS | |
| Chloride Electrode 03111571180 | X | + | + | + | + | + | + | + | + | + | |
| Sodium Electrode 03111598180 | + | X | + | + | + | + | + | + | + | + | |
| Potassium Electrode 03111628180 | + | + | X | + | + | + | + | + | + | + | |
| Calcium Electrode 03111644180 | + | + | + | X | + | + | + | + | + | + | |
| PCO ₂ Electrode 03111679180 | + | + | + | + | X | + | + | + | + | + | |
| PO ₂ Electrode 03111695180 | + | + | + | + | + | X | + | + | + | + | |
| pH Electrode 03111717180 | + | + | + | + | + | + | X | + | + | + | |
| Reference Electrode ⁽¹⁾ 03111873180 | X | X | X | X | X | X | X | + | + | X | |
| Reference Contact (RCon) 03112071180 | X | X | X | X | X | X | X | + | + | X | |
| Sensor Contact (SCon) 03260909184 | + | + | + | + | + | + | + | + | + | X | |
| Micro Electrode Dummy 03111849035 | X | X | X | X | X | X | X | X | X | X | |
| GLU/LAC/UREA Cassette ⁽²⁾ 03261085184 | + | + | + | + | + | + | + | + | + | + | |
| GLU/LAC Cassette 03260887184 | + | + | + | + | + | + | + | + | + | X | |
| GLU Cassette 03260895184 | + | + | + | + | + | + | + | + | + | X | |
| MSS Dummy Sensor 03351262001 | + | + | + | + | + | + | + | + | + | + | |

Table 12-1

(1) The reference electrode must be replaced after 52 weeks of in-use time.

(2) Only for cobas b 221<6> system.

| | |
|---|---|
| X | Has to be installed |
| + | Dummy or electrode has to be used for proper filling of the measuring chamber |

Table 12-2

Order information

Solutions

| | Parameter | | | | | | | | | |
|----------------------------------|-----------------|-----------------|----------------|------------------|------------------|-----------------|----|---------------------|-----------|-----|
| | 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 | - | - | - | - | - | - | - | X | X | - |

Table 12-3

X Has to be installed

Table 12-4

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 | O | O | O | O | O | O | O | O | O | O |
| AUTO-TROL PLUS B, Level 2 03321177001 | O | O | O | O | O | O | O | O | O | O |
| AUTO-TROL PLUS B, Level 3 03321185001 | O | O | O | O | O | O | O | O | O | O |
| COMBITROL PLUS B, Level 1 03321193001 | O | O | O | O | O | O | O | O | O | O |
| COMBITROL PLUS B, Level 2 03321207001 | O | O | O | O | O | O | O | O | O | O |
| COMBITROL PLUS B, Level 3 03321215001 | O | O | O | O | O | O | O | O | O | O |
| COOX/MSS Verification Material 03354628001 ⁽¹⁾ | O | O | O | O | O | O | O | O | O | O |
| TS/MSS Verification Material 03354601001 ^(a) | O | O | O | O | O | O | O | O | O | O |

Table 12-5

(1) Only for USA available.

O Can be used

Table 12-6

Accessories

| | Parameter | | | | | | | | | | |
|---|-----------------|-----------------|----------------|------------------|------------------|-----------------|----|---------------------|-----------|-----|--|
| | Cl ⁻ | Na ⁺ | K ⁺ | Ca ²⁺ | PCO ₂ | PO ₂ | pH | tHb/SO ₂ | COOX/Bili | MSS | |
| Deproteinizer 03110435180 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Adapter for Capillaries 03069931001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Ampoule Adapter 03066762001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Clot Catcher ⁽¹⁾ 03112012180 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Clot Catcher PRO ⁽²⁾ 05689856001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Cleaning Kit for Cl- Electrode 03112098035 | 0 | - | - | - | - | - | - | - | - | - | |
| Adapters for Sample Container 03112101180 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Caps for Roche MICROSAMPLER 03112152180 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Thermo Printer Paper 03113361180 (HP0107) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Roche MICROSAMPLER PROTECT, non sterile 05772494001 (200 pcs.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Roche MICROSAMPLER PROTECT, sterile 05772583001 (50 pcs.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Roche MICROSAMPLER PROTECT, with accessories 05772591001 ⁽³⁾ | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Capillary Tubes, ~ 200 µL 03113477180 (MC0024) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| BS2 Blood Sampler (sterile) 03113493035 (MC0028) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Capillary Tubes, ~ 115 µL 03113507035(MG0002) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Plastic Capillary Tubes, ~ 140 µL 05174791001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

Table 12-7

(1) The Clot catcher is not suitable for measurements in syringe mode and in "Aspiration from syringe" mode.

(2) The Clot Catcher PRO is not suitable for measurements in syringe mode and in "Aspiration from syringe" mode.

(3) Only for USA available

| | |
|---|-------------|
| 0 | Can be used |
| - | Do not use |

Table 12-8

Order information

| | Parameter | | | | | | | | | |
|---|-----------------|-----------------|----------------|------------------|------------------|-----------------|----|---------------------|-----------|-----|
| | Cl ⁻ | Na ⁺ | K ⁺ | Ca ²⁺ | PCO ₂ | PO ₂ | pH | tHb/SO ₂ | COOX/Bili | MSS |
| Sterile Capillary Holder 05174830001 | - | - | - | - | 0 | 0 | 0 | - | - | - |
| Caps for Capillary Tubes 03113647035 (RE0410) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Customer Accessory Kit, for cobas b 221<2>/<4>/<6> system 04975626001 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Table 12-9

| | |
|---|-------------|
| 0 | Can be used |
| - | Do not use |

Table 12-10

Glossary

"Ready" screen Main window of the analyzer mode.

1P 1-point calibration: an automatic calibration of sensor parameters using a CAL1 solution.

2P 2-point calibration: an automatic calibration of all parameters using CAL1, CAL2, and standby solutions of different concentrations. Optionally, cuvette layer thickness can also be calibrated.

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 abbr. for AutoQC

Arterial blood Blood taken from the artery

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/SO₂

AutoQC module The AutoQC module is a unit that automatically takes quality control measurements programmed by the user.

Barcode scanner PS2 hand-held scanner with integrated decoder for simple input of QC data, electrode data, patient or user identity.

BG abbr. 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 abbr. for blood urea nitrogen

Bypass nipple Connection between the sample inlet path and the transverse channel

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/SO₂

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 (O₂Hb), desoxyhemoglobin (HHb), carboxyhemoglobin (COHb) and methemoglobin (MetHb).

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.

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

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.

Glass tube see *Sample inlet path (SIP)* (p. 337)

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

Input unit Consists of the T&D module and the sample drip tray.

ISE abbr. 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^- .

Levey-Jennings diagram QC statistical values chart

LF Conductivity

Linear bracket White plastic part of the peristaltic pump.

MC abbr. 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 abbr. 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.

NIST standards define precise sera with certified expected values.

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* (p. 336)

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 abbr. 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).

QC abbr. for quality control

QC material see *AUTO-TROL PLUS B* (p. 335), *AUTO-TROL TS+* (p. 335), *COMBITROL PLUS B* (p. 335), *COMBITROL TS+* (p. 335)

Quality control The known target areas of the QC materials are compared with the QC results of the instrument.

RCon abbr. for reference contact. This is used for the Glu/Lac or Glu instrument type and replaces the reference electrode and dummy electrode.

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.

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 abbr. 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").

SO₂ 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&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/SO₂ 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 PO₂ and PCO₂.

Transverse channel serves for optimum thermostating and distribution of samples and calibration solutions to the measuring modules

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.

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 Waste Container Waste container

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Revisions

This chapter contains revisions to the **cobas b 221** system Instructions for Use that were necessary due to a new software update, which includes updated reference ranges and new features for monitoring bacterial contamination.

In this chapter

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Revisions to the cobas b 221 system Instructions for Use

| Manual Version | Software Version | Revision Date | Changes |
|----------------|------------------|----------------|-----------------|
| 14.1 | ≥8.01 | September 2015 | Software update |

Table 13-1 Revision History

In order to ensure that readers of the **cobas b 221 system** Instructions for Use use the most up-to-date content, Roche recommends to manually mark the affected passage(s) in the original manual.

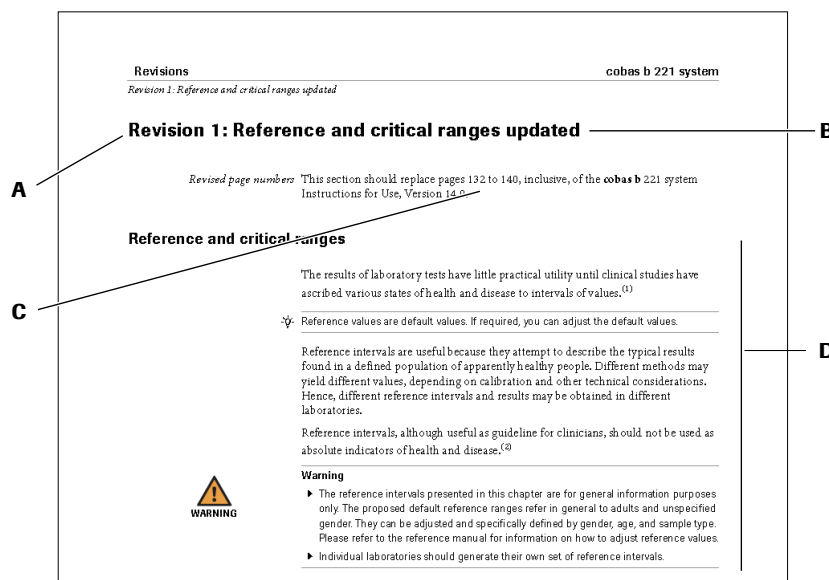
To update the **cobas b 221 system** Instructions for Use:

1. In the current chapter *Revisions*, go to the first revision.
2. Familiarize yourself with the items that have been revised.
3. Identify the page number affected in the original document.
4. Go to the appropriate page in the original document and manually mark the revisions. For example, cross out text that is no longer applicable or add a reference where to find new and revised content.

☞ If you print these pages, Roche recommends printing them single-sided. In this way, you can easily insert them in the existing document

Structure of a changed entry

The following illustration explains how revisions are presented in this document.



- A** Change ID
- B** Change summary
- C** Page(s) affected
- D** Changed element


Figure 13-1 Structure of a changed entry

Revision 1: Reference and critical ranges updated

Revised page numbers This section should replace pages 132 to 140, inclusive, of the **cobas b 221** system Instructions for Use, Version 14.0.

Reference and critical ranges

The results of laboratory tests have little practical utility until clinical studies have ascribed various states of health and disease to intervals of values.⁽¹⁾

 Reference values are default values. If required, you can adjust the default values.

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

Reference intervals, although useful as guideline for clinicians, should not be used as absolute indicators of health and disease.⁽²⁾



Warning

- ▶ The reference intervals presented in this chapter are for general information purposes only. The proposed default reference ranges refer in general to adults and unspecified gender. They can be adjusted and specifically defined by gender, age, and sample type. Please refer to the reference manual for information on how to adjust reference values.
 - ▶ Individual laboratories should generate their own set of reference intervals.
-

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

(2) see Chapter 16 of "Tietz Textbook of Clinical Chemistry and Molecular Diagnostics", 4th Edition 2006

Reference/normal ranges

| Parameter | Normal range | Sample matrix | Unit | Reference values (Default values, also seen on printouts) | Source |
|--|--|-------------------------------|--------|---|---|
| COHb (%) | ≤3 nonsmoker | Whole blood heparin | % | 0.0 - 3.0 ⁽¹⁾ | Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 848 |
| MetHb (% of total Hb) | 0.04 - 1.52 | Whole blood heparin | % | 0.0 - 1.5 ⁽²⁾ | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2160 |
| O ₂ Hb (%) | 94.0 - 98.0 | Arterial blood | % | 94.0 - 98.0 | Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 535 |
| SO ₂ /O ₂ saturation (%) | 94.0 - 98.0 | Whole blood arterial | % | 94.0 - 98.0 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2162 |
| HHb (%) | <3 | | % | 0.0 - 2.9 | Kenneth A. Wyka, Paul J. Mathews, John Rutkowski: Foundations of respiratory care, p. 153 |
| tHb (g/dL) | 11.5-16.0 (female adult), 13.5-17.8 (male adult) | Capillary blood | g/dL | 11.5 - 17.8 unknown ⁽³⁾ | Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 827 |
| Bilirubin Bili (mg/dL) | 2.0 - 6.0 (0-1 d full term) 6.0 - 10.0 (1-2 d full term) 4.0 - 8.0 (3- 5 d full term) 0.0 - 2.0 (adult) | Serum | mg/dL | 2.0 - 10.0 (fetal/new born) ⁽⁴⁾ 4.0 - 8.0 (2nd day/1 year) 0.0 - 2.0 (> 1 year) 0.0 - 2.0 (unknown) | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2136 |
| pH | 7.35 - 7.45 | Whole blood arterial | | 7.350 - 7.450 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2162 |
| pCO ₂ (mmHg) | 32 - 45 (female adult) 35 - 48 (male adult) | Whole blood, arterial heparin | mmHg | 32.0 - 48.0 unknown ^(c) | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2137 |
| pO ₂ (mmHg) | 83 - 108 | Whole blood arterial | mmHg | 83.0 - 108.0 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2162 |
| Sodium Na ⁺ (mmol/L) | 136 - 145 | Serum, plasma | mmol/L | 136.0 - 145.0 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2168 |
| Potassium K ⁺ (mmol/L) | 3.5 - 5.1 | Serum | mmol/L | 3.50 - 5.10 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2164 |
| Ionized Calcium Ca ²⁺ (mmol/L) | 1.15 - 1.33 | Serum, plasma heparin | mmol/L | 1.150 - 1.330 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2137 |

Table 5-4 Reference/normal ranges

Revision 1: Reference and critical ranges updated

| Parameter | Normal range | Sample matrix | Unit | Reference values (Default values, also seen on printouts) | Source |
|---|--|---|--------|---|---|
| Chloride Cl ⁻ (mmol/L) | 98 - 107 | Serum, plasma | mmol/L | 98.0 - 107.0 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2139 |
| Hematocrit HCT (%) | 36 - 48 (Caucasian female) 40 - 53 (Caucasian male) | Whole blood, Capillary blood | % | 36.0 - 53.0 unknown ⁽⁵⁾ | Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 840 |
| Glucose Glu (mmol/L) | 3.5 - 5.3 | Whole blood heparin | mmol/L | 3.5 - 5.3 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2149 |
| Lactate Lac (mmol/L) | 0.56 - 1.39 | Venous whole blood heparin, bed rest | mmol/L | 0.6 - 1.4 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2156 |
| Urea/BUN (mmol/L) | 2.1 - 7.1 | Serum | mmol/L | 2.1 - 7.1 | Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2173 |

Table 5-4 Reference/normal ranges

- (1) Upper limit refer to nonsmoker.
- (2) Default value rounded to one tenth place value.
- (3) Proposed reference range refers to lower limit for females to upper limit of males if the gender is unknown.
- (4) For "fetal/new born", the proposed reference range refers to lower level of 0-1 day old full-term to upper level of 1-2 days full-term. For "2nd day /1 year", the proposed reference range refers to the reference value for 3-5 days full-term. For "> 1 year" and "unknown", the proposed value refers to the one of adults. Because of the lower end of the measuring range for Bilirubin (3.0 mg/dL; 51µmol/L), it cannot be edited by the user. The user can only edit values within the measuring range. However, it is possible to set the new reference values using the button "Set default ranges" for the age specific reference range.
- (5) Proposed reference range refers to lower limit for Caucasian females to upper limit of Caucasian males.

The availability of parameters depends on the configuration:

| | |
|--|--|
| • cobas b 221<1> system ⁽¹⁾ | BG, pH, tHb/SO ₂ |
| • cobas b 221<2> system | BG, pH, COOX, Bili |
| • cobas b 221<3> system ⁽¹⁾ | BG, pH, ISE, Hct, tHb/SO ₂ |
| • cobas b 221<4> system | BG, pH, ISE, Hct, COOX, Bili |
| • cobas b 221<5> system ⁽¹⁾ | BG, pH, ISE, Hct, MSS, tHb/SO ₂ |
| • cobas b 221<6> system | BG, pH, ISE, Hct, MSS, COOX, Bili |

(1) are no longer manufactured or offered.

Critical ranges

Normal values depend, amongst other factors, on the patient, age, gender, lifestyle habits (e.g. smoking), underlying disease (e.g. asthma), and therapy (e.g. state after an infusion). This especially applies to critical ranges, as these are based on the normal values. Therefore, critical ranges can only be approximately defined and need special attention if used for therapy decision. By default, critical values are not contained in the default setting. Laboratories must adjust the critical ranges to fulfill their own requirements.

Revision 2: New maintenance procedure added

Revised page numbers This section should be placed in front of page 265 of the **cobas b 221** system Instructions for Use, Version 14.0.

Monitoring MSS contamination

Automatic and manual monitoring of MSS contamination allows you to detect bacterial contamination in the S3-fluidic pathways before it has any effect on the MSS calibration, and consequently **cobas b 221** system measurements.

You must select a day of the week when the system automatically monitors MSS contamination. In addition, you can perform a test manually if you find signs of bacterial contamination in the system.

If bacterial contamination has been detected, the system activates a warning period. This warning period can last up to 10 days. If the system reaches the end of the warning period, the MSS module stops. However, if MSS measurements no longer follow specifications, the MSS module stops immediately.

A system warning or an MSS module stop is only deactivated once Technical Support has performed the MSS maintenance procedure on the system.



Incorrect patient results due to bacterial contamination

Bacterial contamination in the S3-fluidic pathway reduces the quality and integrity of the S3 calibration solution for GLU/LAC/UREA parameters and the MSS cassette. This leads to incorrect QC measurements and/or incorrect patient results, which may endanger patient lives.

- ▶ Do not attempt to deactivate weekly MSS contamination monitoring.
- ▶ Perform the MSS contamination test immediately if you find signs of bacterial contamination in the system.



▶ To set up automatic MSS contamination monitoring

- 1 To choose an MSS contamination monitoring day, press the following buttons: **Setup > Times & intervals > MSS contamination monitoring day**



Figure 10-A Times & intervals screen in Setup mode

Revision 2: New maintenance procedure added

- 2 To scroll through the days of the week and choose an MSS contamination monitoring day, press the  and  buttons.

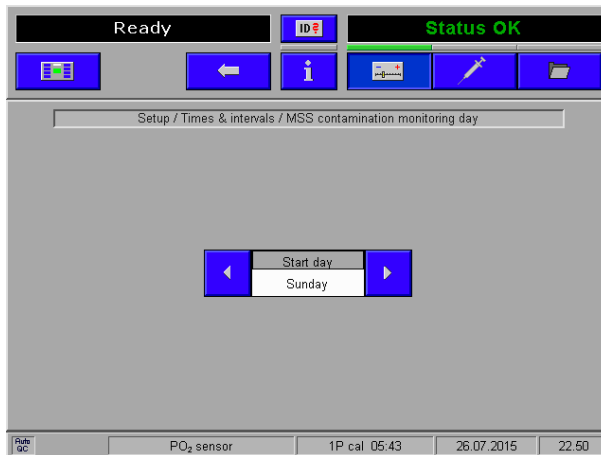



Figure 10-B MSS contamination monitoring setup screen

- 3 To save your settings, press the  button.
- 4 To confirm your schedule setup, press the **MSS contamination monitoring day** button.

⚠ Monitoring dates are automatically rescheduled to the next day if one of the following circumstances occurs to the system:

- It is not switched on
- It is on standby mode for more than 24 hours
- It cannot perform PO_2 measurements

If monitoring dates are repeatedly rescheduled, you will receive a system warning and you will require a Technical Support visit.

■

► **To test for MSS contamination manually**

⚡ MSS contamination tests can only be performed if all of these conditions are true:

- 25 minutes have elapsed since the last 1P calibration of the MSS module
- 3 hours have elapsed since the last 2P calibration of the MSS module
- PO₂ is calibrated and QC lock is not applied
- There are no active system warnings or module stops related to MSS contamination

📖 To check when previous calibrations have occurred, refer to the *Software modes* chapter in the *Instructions for Use*, under *Calibrations* in the *Data Manager* section.

1 To test for MSS contamination, press the following buttons:

System > Diagnostics > MSS contamination test

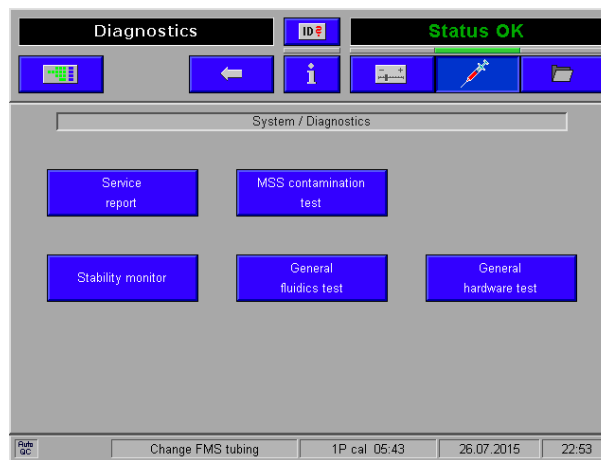


Figure 10-C Diagnostics screen in System mode

■

Revision 3: New module stop message

Revision 3: New module stop message

Revised page numbers This section should be placed in front of page 303 of the **cobas b 221** system Instructions for Use, Version 14.0.

| No. | Message | Cause | Action |
|-------|------------------|-----------------------------------|---|
| 20090 | MSS contaminated | Bacterial contamination detected. | MSS maintenance procedure is required. Contact Technical Support. |

Table 11-2 Module stops

Revision 4: New system warning message

Revised page numbers This section should be placed in front of page 305 of the **cobas b 221** system Instructions for Use, Version 14.0.

| No. | Message | Cause | Action |
|-------|------------------|-----------------------------------|---|
| 30007 | MSS contaminated | Bacterial contamination detected. | MSS maintenance procedure is required. Contact Technical Support. |

Table 11-3 System warnings

Revision 4: New system warning message