cobas b 221 system

Instructions for Use Version 18.0
Software Version 8.04

Roche

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Life needs answers

Publication information

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Table 1 Revision history

Edition notice

This publication is intended for operators of the **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 publication is correct at the time of publishing. However, Roche may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the system in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Training Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Screenshots The screenshots in this publication have been added exclusively for illustration purposes. Configurable and variable data, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance.

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This open source and commercial software and the **cobas b** 221 system as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the Instructions for Use and labeling.

Please note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to the **cobas b** 221 system.

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Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals The **cobas b** 221 system meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This system complies with the emission and immunity requirements described in this part of the IEC 61326 series.

Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

IVD	For *in vitro* diagnostic use.
CE	Complies with the provisions of the applicable EU directives.
TÜV SÜD NRTL C US	Issued by TÜV SÜD for Canada and the US.
Equipment de Laboratoire / Laboratory Equipment	Laboratory Equipment is the product identifier as shown on the name plate.

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Preface

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

This manual has detailed descriptions of **cobas b** 221 system features and general operational concepts, specifications and use of controls, operating techniques, emergency procedures, product labeling, and maintenance procedures.

Intended use

The **cobas b** 221 system is a fully automated analyzer intended for In Vitro testing of samples of whole blood, serum, plasma, acetate and bicarbonate containing dialysis solutions and pleural fluid for the quantitative measurement of:

- pH
- Blood Gas (BG): PO_2, PCO_2
- Electrolyte (ISE): Na^+, K^+, Cl^-, iCa^{2+}
- Hematocrit (Hct)
- Metabolites (MSS): Glucose, Lactate, Urea/BUN (only on version <6>)
- Total Hemoglobin (tHb)
- Oxygen saturation (SO_2)
- Hemoglobin derivative COOX (O_2Hb, HHb, COHb, MetHb)
- Bilirubin (neonatal)

In addition, the **cobas b** 221 system calculates derived parameters.

The following parameters can be measured in whole blood, serum or plasma:

- pH
- Blood Gas (BG): PO_2, PCO_2
- Electrolyte (ISE): Na^+, K^+, Cl^-, iCa^{2+}
- Hematocrit (Hct)
- Metabolites (MSS): Glu, Lac, Urea/BUN
- Total hemoglobin (tHb)
- Oxygen saturation (SO_2)
- Hemoglobin derivative COOX (O_2Hb, HHb, COHb, MetHb)
- Bilirubin (neonatal)

The following parameter can be measured in pleural fluid:

- pH

Intended user

For medical purposes, the user is a trained staff member in critical care units, emergency departments, intensive care units (ICUs) or laboratories.

Use environment

The **cobas b** 221 system is intended to be operated in laboratories of hospitals as well as in the point of care setting, such as intensive care areas (ICU, NICU, PICU), emergency departments (A&E, ER) and operating rooms (OR).

Symbols and abbreviations

Symbols used in the publication

Symbol	Explanation
•	List item
▶	Start of a task
■	End of a task
	Related topics containing further information
	Tip. Extra information on correct use or useful hints.

Table 2 Symbols used in the publication

Symbols used on the instrument and consumables

Symbol	Explanation
	Catalog number
	Serial number
	Global Trade Item Number
	Manufacturer
	Date of manufacture
	Alternating current
	Caution
	Batch code
	Use by date
	Temperature limitation
	Do not use if package is damaged
	Consumable contents
	Control material
	Fragile handle with care

Table 3 Symbols used on the instrument and consumables

Symbol	Explanation
	Store upright
	Do not reuse
	Sterilized using irradiation
	Sterilized using ethylene oxide
	Sufficient for <n> tests
	Operator's manual/operating instructions
	For *in vitro* diagnostic use.
	Biological risk (according to the standard IEC/EN 61010-2-101)[1] (Instrument)
	Biological risk (according to the standard DIN EN ISO 15223-1)[2] (Consumables)
	Keep dry
	Do not stack more than 6 units
	Electrostatic-sensitive device (ESD)

Table 3 Symbols used on the instrument and consumables

(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 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (Part 1: General requirements).

Safety labels on the system and consumables (p. 28)

Abbreviations

Abbreviation	Definition
ANSI	American National Standards Institute
AQC, AutoQC	Automatic Quality Control
A_{rate}	Assisted breathing rate
ASTM	American Society for Testing and Material
BG	Blood gas
Bili	Bilirubin
BUN	Blood urea nitrogen
Cal	Calibration
CE	Conformité Européenne
CLSI	Clinical and Laboratory Standards Institute
COHb	Carboxyhemoglobin
cond	Conductivity
COOX	Co-oximetry
e.g.	for example
EC	European Community
EN	European standard
EU	European Union
FMS	Fluid mixing system
FTP	File transfer protocol
GB	Gigabyte
Glu	Glucose
Hct	Hematocrit
HHb	Deoxyhemoglobin
HIS	Health Information System
HW	Hardware
Hz	Hertz
i.e.	that is to say
IEC	International Electrotechnical Commission
ISE	Ion-selective electrode
ISO	International Organization of Standardization
IT	Information technology
IVD	*In vitro* diagnostic
kg	kilogram
Lac	Lactate
LCD	Liquid crystal display
LED	Light-emitting diode
LIS	Laboratory Information System
LoQ	Limit of Quantitation
MAP	Mean arterial pressure
MB	Megabyte
MC	Measuring chamber
MetHb	Methemoglobin
MHz	Megahertz

Table 4 Abbreviations

Abbreviation	Definition
MSS	Metabolite-sensitive sensor
MV	Minute volume
NIST	National Institute of Standards and Technology
O_2Hb	Oxyhemoglobin
PCO_2	Partial pressure of carbon dioxide
PEEP	Positive end-expiratory pressure
PIP	Peak inspiratory pressure
PO_2	Partial pressure of oxygen
POC	Point-of-care
QC	Quality control
RAM	Random access memory
RCon	Reference contact
S1	S1 Rinse Solution
S2	S2 Fluid Pack
S3	S3 Fluid Pack A
SCon	Sensor contact
SD	Standard deviation
SIP	Sample inlet path
SO_2	Oxygen saturation
S_{rate}	Spontaneous breathing rate
SSD	Solid-state drive
T&D	Turn & dock
Te	Expiratory time
tHb	Total hemoglobin
Ti	Inspiratory time
USB	Universal Serial Bus
VT	Tidal volume
W	Watt

Table 4 Abbreviations

What is new in publication version 18.0

Updated safety information

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- *Operating conditions* (p. 22)
- *Biohazardous materials* (p. 23)
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Safety information

The chapter provides information about the safe operation of the **cobas b** 221 system.

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Safety classifications

This section explains how precautionary information is presented in this manual.

The safety precautions and important user notes are classified according to the ANSI Z535.6 Standard. Familiarize yourself with the following meanings and icons:

Safety alert

The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

WARNING

- ... indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION

- ... indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

NOTICE

- ... indicates a hazardous situation that, if not avoided, may result in damage to the system.

Protective gloves and goggles, suitable protective clothing, and if necessary, mouth protection has to be worn.

Important information that is not safety relevant is indicated with the following symbol:

Tip

... indicates additional information on correct use or useful tips.

Safety precautions

To avoid serious or fatal injury, read and comply with the following safety precautions.

Operator qualification

WARNING

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow standard laboratory practices, especially when you work with biohazardous material.

Safe and proper use of the system

WARNING

Personal injury and infection due to sharps, rough edges, and/or moving parts

- Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use. Some areas of the instrument may have sharps, rough edges, and/or moving parts. Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument. Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g. suitable lab gloves, eye protection, lab coat, and footwear.

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items: eye protection with side shields, fluid-resistant laboratory coat, approved lab gloves, and face shield if there is a chance of splashing or splattering.

System not used for an extended period

- If the system will not be used for more than 24 hours, put the system out of operation.
- Remove and refrigerate any remaining reagents.
- For further information, call your Roche Service representative.

Non-approved parts

Use of non-approved parts or devices may result in malfunction of the system and may render the warranty null and void.

- Use only parts and devices approved by Roche Diagnostics.

Installation and deinstallation

Transport Risk of personal injury when lifting. The **cobas b** 221 system, without consumables in the bottle compartment and AutoQC materials in the AutoQC module, weighs approximately 45 kg.

- Perform the put out of operation procedure before moving the system.
  Shutdown (p. 69)
- Do not attempt to relocate or transport the system without the assistance of another individual.
- Do not attempt to lift the system with consumables in the bottle compartment and AutoQC materials in the AutoQC module. In addition, make sure that before lifting, there are no other objects attached to the system, and the system is not performing a measurement or a calibration.
- Lift the system only from its designated holding points.
  Designated holding points for lifting the system (p. 46)

Errors in installation Only trained Roche Service representatives may install the system.

- Leave installation that is not described to trained Roche Service representatives.

Disposal A biohazardous system may lead to infection.

- Treat the system as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the system according to the local regulations. For more information, contact your Roche service representative.

Operating conditions

WARNING

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the system.

- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the system's ventilation openings remain unobstructed always.
- Keep the analyzer away from all sources of liquids, such as sinks and wash basins.
- To maintain the operating conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

WARNING

Electromagnetic interference

Strong electromagnetic fields (originating from unshielded radio-frequency sources) can interfere with proper operation and may lead to malfunction of the system and incorrect results.

- Do not use this system near sources of strong electromagnetic fields because these fields can interfere with the proper operation.
- Evaluate the electromagnetic environment before you operate the system.
- Take measures to mitigate the interference.

Electrical safety

Electrical shock

Removing the covers of electronic equipment can cause electric shock because there are high-voltage parts inside.

- Do not remove any cover of the system except those covers specified in the instructions.
- Only Roche Service representatives may install, service, and repair the system.

Biohazardous materials

Infectious samples

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples containing material of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the system is operating.
- Follow the instructions in this manual when performing procedures with the top cover of the system removed.
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Sharp objects Contact with probes or needles may result in infection.

- When you wipe probes or needles, use several layers of gauze and wipe from the top down.
- Take care not to puncture yourself.
- Wear appropriate personal protective equipment. Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection.

Infectious waste Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Wear appropriate personal protective equipment. Take extra care when working with lab gloves. They can be easily pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Environmental harm The system generates liquid and/or solid waste. This waste contains concentrated reaction solutions and is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat this waste as infectious waste.
- Liquid and/or solid waste, unused working solutions and reagents should not be allowed to enter drains, water courses or the soil.
- Dispose liquid and solid waste, unused working solutions and reagents and empty containers as chemical and biohazardous waste.

This product includes an internal constituent containing a Substance of Very High Concern (SVHC), Lead (CAS 7439-92-1), in a concentration above 0.1% weight by weight, as identified under REACH and added to the Candidate List.

There is no direct exposure to the substance when the instrument is operated according to the instructions for use.

Mechanical safety

CAUTION

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers closed and in place while the system is operating.
- Follow the instructions in this manual when performing procedures with the top cover of the system removed.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- During operation and maintenance, carefully follow the instructions.

Reagents and working solutions

WARNING

Skin inflammation or injury

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use.
- Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

CAUTION

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance or checks that involve alcohol.
- When you use alcohol on or around the system, use no more than 20 mL at a time.

Incorrect results

WARNING

Poor accuracy and precision

Incorrect results may lead to errors in diagnosis, posing danger to the patient.

- For the proper use of the system, run QC tests and monitor the system during operation.
- Do not use reagents or consumables that have exceeded their expiry date, otherwise you may obtain inaccurate data. Do not use damaged S2 and S3 Fluid Packs. Do not mix the individual components in the fluid packs.
- For diagnostic purposes, always assess the results with the patient's medical history, clinical examination, and results from other consultations.

Incorrect reagent volume

Incorrect reagent handling may cause an undetectable loss of reagent.

- Always store reagents according to the specified storage conditions as stated in the Instructions for Use for the test.
- Do not reuse a reagent cassette whose reagent has spilled.
- Do not use a reagent cassette for different systems.

Foam, clots, films, or bubbles

Incorrect results may occur due to foam, fibrin clots, films, or bubbles in reagents or samples.

- Avoid the formation of foam, clots, and bubbles in all reagents, samples, calibrators, and controls.

Evaporation of samples or reagents

Evaporation of samples or reagents may lead to incorrect or invalid results.

- Sample material may evaporate if left open. Do not leave samples open for any length of time.
- Do not use improperly stored reagents. Ensure that reagents are stored according to the Instructions for Use.

Software and data security

WARNING

Unauthorized system access and data loss

Malicious software or unauthorized system access can result in data loss or system unavailability. External storage devices can transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The operators are responsible for the IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks.

Users of the system should be regularly trained on appropriate handling, including data privacy and cybersecurity, of the system.

To avoid infection by malicious software or the unauthorized access and misuse of the system, Roche recommends the following precautions:

- Connect the system to safe, closed networks only.
- Make sure other computer and services on the network (e.g., the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Ensure that attached networks are secure. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).
- Allow connection only to authorized external devices.
- To protect all external devices, make sure that you use appropriate security software.
- To protect access to all external devices, make sure that you use appropriate security equipment. Your Roche Service representative can recommend a suitable firewall.
- Do not copy or install any software on the system unless it is part of the system or your Roche Service representative tells you to do so.
- If extra software is required, contact your Roche Service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless your Roche Service representative or an operating instruction tells you to do so.
- Exercise care when you use external storage devices such as USB drives. Do not connect to the system any external storage device that you use on public or home computers.
- Back up your data regularly. Make sure that system backup and archive files are physically secured and are protected from any unauthorized access and disaster. This includes remote storage location, disaster recovery sites and secure transfer of backup files. Ensure data security when disposing of storage devices.
- Update to latest software versions for the specified system configuration provided by Roche as soon as possible.
- Only data required for its purpose shall be entered on a Roche device. Avoid use of direct identifiers with sensitive data or free-text fields.
- Request from Roche service the deletion of data on a regular basis, if direct identifiers are to be processed by the system.

WARNING

Corrupt data due to a disclosed password

The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security.

- Create a separate user account for each operator with appropriate operator level.
  Assign operator levels on a need-to-know basis.
- Use strong passwords.
- Always enter your password unobserved.
- Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone. Roche never asks you for your password.
- If you ever disclose your password to anyone, change it immediately afterwards.
- Do not share user accounts.
- Contact your local Roche affiliate if you think your account has been compromised.
- Remove the credentials of employees who have left the company.

Non-approved third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system.

- Install only Roche approved third-party software.

Unreliable validation due to unauthorized changes to the validation settings

Roche shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation settings included in the system at the customer's request.

- Ensure that only authorized personnel can change, if necessary, the validation settings.

Unreliable validation due to unauthorized changes to the validation and calculation rules

Roche shall not be held liable for any consequences resulting from subsequent, unauthorized modifications to the accepted validation and calculation rules included in the system at the customer's request, as well as test results.

- Ensure that only authorized personnel can change, if necessary, the validation and calculation rules, and test results.

System damage

Circuit breakers and fuses

Improper use may result in damage to the system.

- If one of the circuit breakers or fuses blows, do not attempt to operate the system before contacting your Roche Service representative.

Spilled liquid

Any liquid spilled on the system may result in malfunction or damage.

- Place samples, reagents, or any other liquid only at the intended positions. Do not place samples, reagents, or any other liquid on the covers or other surfaces of the system.
- When you remove or replace consumables, do not spill any liquid on the system.
- If liquid does spill on the system, wipe it up immediately and apply a disinfectant. Wear appropriate personal protective equipment. Dispose waste as chemical and biohazardous waste.

Safety labels on the system and consumables

The system and its consumables have warning labels to draw your attention to areas of potential hazard.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.

Only Roche Service representatives may replace damaged labels. For replacement labels, contact your Roche Service representative.

Safety labels on the system

	General warning Potential hazards located near this label may lead to death or serious injury. Refer to the manual for instructions on safe operation.
	Biohazard Potentially biohazardous materials are used near this label. Observe relevant laboratory procedures on safe usage.

Safety labels on consumables

	Direct exposure of deproteinizer or the contents inside the S2 Fluid Pack, such as inhalation, swallowing or skin contact, may lead to serious skin burns, eye damage, and other serious health risks. While handling deproteinizer or the S2 Fluid Pack, wear appropriate personal protective equipment, such as eye protection with side shields, fluid-resistant laboratory coat, approved lab gloves and face shield. Read the Material Safety Data Sheet for deproteinizer and the S2 Fluid Pack before handling.
	Swallowing the contents of the PCO_2, PO_2 and pH electrodes may cause serious health risks. While handling these electrodes, follow standard laboratory practices. Wear appropriate personal protective equipment, such as eye protection with side shields, fluid-resistant laboratory coat, approved lab gloves and face shield. Read the Material Safety Data Sheet for the PCO_2, PO_2, and pH electrodes before handling.

General descriptions

This chapter contains a general description of the system, 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 an integrated AutoQC drawer option.

Configurations

• **cobas b** 221<2> system	BG, pH, COOX, Bili
• **cobas b** 221<4> system	BG, pH, ISE, Hct, COOX, Bili
• **cobas b** 221<6> system	BG, pH, ISE, Hct, MSS, COOX, Bili

Software modes

• Analyzer	Measuring, QC measurement, system, calibration, commonly used functions (quick access)
• Setup	System settings
• Database	Data about patients, measurements, calibrations, QC, and the system
• Info	On board status of consumables, QC materials, electrodes, and system components System and about information Online help information and videos

General notes

Application area

The system has been tested for measuring parameters in whole blood, serum, plasma, pleural fluid, aqueous solutions, and acetate, bicarbonate, 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.

Roche recommends that you perform proficiency testing to verify the accuracy of measurement values. Perform QC tests on 3 levels after performing proficiency testing.

WARNING

Interfering components, missing or insufficient buffer systems, and differences in ionic strength and diffusion potential compared to biological samples can affect the accuracy of measurement values.

Operating instructions

The **cobas b** 221 system should always be switched on.

If the system is switched off for more than 24 hours, put it out of operation.

Installation and shutdown (p. 43)
Installation (p. 45)
Shutdown (p. 69)

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

WARNING

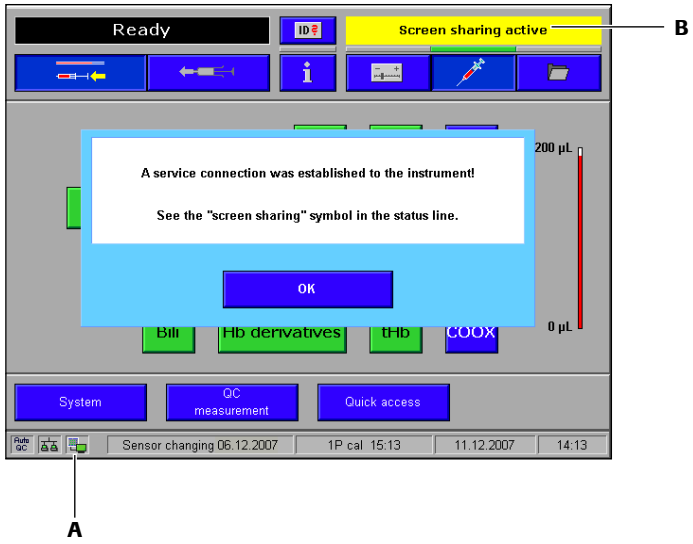
In order to ensure the quality of measurement results, perform QC tests on 3 levels after each of these actions: MSS cassette, electrode, fluid pack, proficiency test, or rinse solution replacement and start-up of the system.

Additionally, perform QC tests on a single level between 2 automatic 2P calibrations. Alternate QC tests between the 3 levels.

Quality control (p. 183).

cobas bge link software is the remote software solution for Roche blood gas analyzers. You can monitor device and consumable status, manage results and operator profile, and troubleshoot analyzers over LIS and HIS interfaces. In addition, you can perform screen sharing to connect with the blood gas analyzers in your healthcare network.

Figure 2-2 (p. 33)



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

Figure 2-2

When a **cobas bge link** user wants to use this feature on your system, a message appears on your system. Press **OK** to confirm the message on the system. The "screen sharing" symbol is added in the status line.

To avoid multiple operations of the system, the "Screen sharing active" message is displayed with a yellow background in the message window of the system.

When the "Screen sharing" symbol is displayed on the lower left-hand corner of the screen, the service connection is active. To avoid multiple operations of the system, do not press any buttons on the screen.

Important buttons on the screen

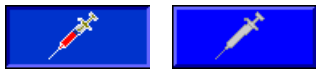
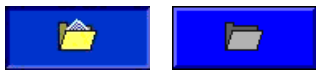
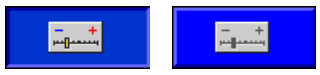
Buttons	Description
	Analyzer mode active/inactive
	Database mode active/inactive
	Setup mode active/inactive
	Info mode active/inactive

Table 2-1

Software icons (p. 239).

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 (LOD) 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.

COOX: Hemoglobin derivatives and 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

Oxygen (O_2): Calibration is performed with ambient air and a zero point solution.

PCO_2, pH, ISE: Calibration is performed by carrying out a measurement of these parameters with solutions found in the S2 Fluid Pack.

MSS: Calibration is performed by carrying out a measurement of these parameters with solutions found in the S3 Fluid Pack A.

COOX: Calibration is performed by carrying out a measurement with a tHb calibrator.

General notes on the use of the MSS cassette

WARNING

Do not remove the MSS cassette from the system after its initial contact with liquids. Removing the MSS cassette from the instrument may lead to the destruction of the sensor enzymes.

- The MSS cassette must be changed after a maximum of 28 days, or earlier in case of a failed calibration or QC.
  - *Troubleshooting – Group B (QC result exceeds the target value range)* (p. 223)
  - *Troubleshooting* (p. 317)
- Storage:
  - Storage in original packaging
  - Relative humidity: 20-85%
  - Storage life: 15 weeks at 2–8°C or 2 weeks at max. operating temperature (31°C).

Incompatible substances

To avoid destroying the MSS cassette, do not use the following substances in or around the MSS measuring chamber:

- Deproteinizer (NaOCl)
- O_2 zero point solution
- Cleaning solutions
- Sodium electrode conditioning solution
- Rinse additive
- Solutions containing heavy metals (Ag, Hg, Au, etc., e.g. Thiomersal)
- Cleaning solutions containing detergents, such as laundry detergent and dish soap
- Disinfectants and sanitizers, such as glutaric dialdehyde
- Solutions with pH values less than 6 and greater than 9

WARNING

Do not use any other anticoagulants other than heparin salts. Other anticoagulants, such as EDTA, citrate, NH4 heparin, and glycolysis inhibitors, such as NaF and oxalate compromise the integrity of the blood sample. This may lead to inaccurate patient results.

Inserting the MSS cassette

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

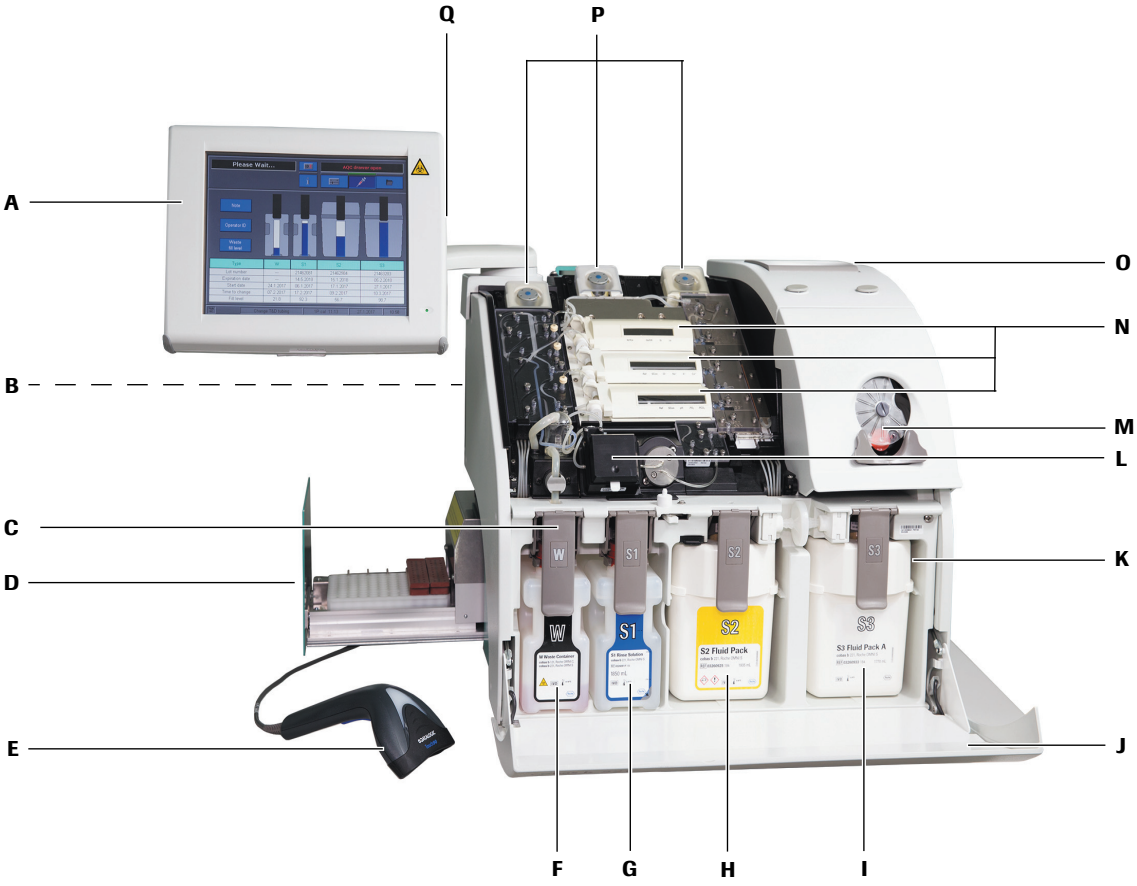
To achieve the best start-up time, store the MSS cassette at 2–8 °C.

Changing the MSS cassette (cobas b 221<6> system only) (p. 306)

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 A	**O**	Printer
D	AutoQC drawer	**J**	Bottle compartment cover	**P**	Pumps
E	Barcode scanner	**K**	Bottle compartment	**Q**	USB 3.0 (SN > 21000)
F	W Waste Container	**L**	COOX 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.

The screen/PC unit also contains a diskette drive (SN < 21000) or a USB interface (SN > 21000).

Printer

Low-noise thermoprinter with integrated paper cutter (manually activated using the “Cut” key).

The “Feed” key feeds in the paper.

Measuring chambers

The BG, ISE, and MSS measuring chambers are found underneath the top cover of the system. You can find electrodes inside the BG and ISE measuring chambers, and the MSS cassette inside the MSS measuring chamber.

COOX module

The COOX module is found underneath the top cover of the system. It is made up of the hemolyzer and the COOX measuring chamber.

Pumps

Depending on the configuration, up to 3 peristaltic pumps transport the sample and the operating fluids inside the system.

Input unit

The input unit is responsible for collection samples for analysis into the system. It is made up of the following parts:

- T&D module:
  - T&D disk
  - T&D tubing set
  - Plug control
  - Fill port
  - Sample needle
  - Sample inlet port
- Sample drip tray

Bottle compartment

The S1 Rinse Solution bottle, S2 Fluid Pack, W Waste Container, and S3 Fluid Pack A (**cobas b** 221<6> system only) are found inside the bottle compartment.

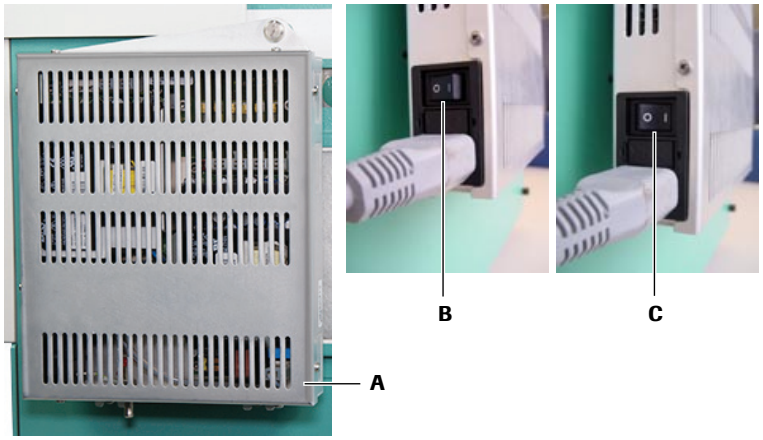
Reverse side

A Power supply
B Main power switch and connector
C Air filter
D Interfaces

Figure 2-4 Reverse side

Power supply

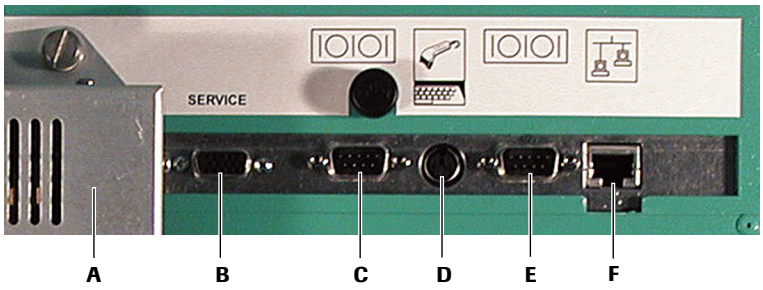
This unit also contains the main power switch and the connector.



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

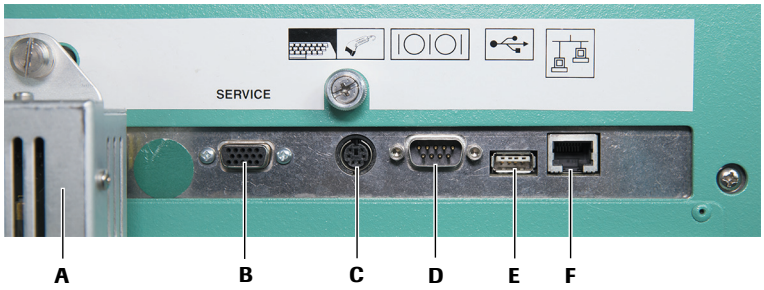
Figure 2-5 Power supply

Interfaces



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

Figure 2-6 Interfaces (without USB)



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

Figure 2-7 Interfaces (with USB)

- Variant 2:

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

Figure 2-6 *Interfaces (without USB)* (p. 39)

- Variant 1:

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

Figure 2-7 *Interfaces (with USB)* (p. 39)

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

RS 232 interface assignments

RS 232 interface connections may be used to establish connections with other devices, such as external ticket printers. 9-pin SUBMIN D ports are available for these interface connections.

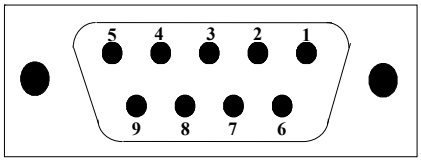


Figure 2-8 RS 232 interface assignments

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

Barcode scanner

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

If you have not disabled the trigger tone on your barcode scanner, you hear it and see a brief illumination of the LED light on the top of the barcode scanner when you have successfully scanned in a barcode.

For further information, see the manufacturer's Reference Guide. The Reference Guide is available from your Roche representative.

Barcode printing quality To assure optimal barcode scanning performance, it is required that sample barcodes have a print quality of ISO/IEC 15416 grade 2.5 to 4.0 (corresponds to ANSI X3, 182-1990, Grade A or B (A=3.5 to 4.0 / B=2.5 to <3.5)).

To further assure barcode scanning performance, follow these recommendations:

- The label or piece of paper with the printed barcode should be smooth and unfolded.
- The printed barcode must not be distorted in the printing process. Make sure that quality printing ink, ribbon and/or toner is used.
- Use special color ink and non-white paper or labels with caution, as they can impact the scanner function. For example, avoid the use of red ink or red paper because the light source of the barcode scanner is red.
- Do not use printing materials with shiny or reflective surfaces.

Name plate

Refer to *Symbols used on the instrument and consumables* (p. 11) to find the meaning of the symbols used on the name plate.

Installation and shutdown

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

In this chapter

Chapter **3**

Installation....45
Location....45
Accessories....46
Installation procedure....48
Installing and using ticket printers....67
Shutdown....69
Less than 24 hours....69
Longer than 24 hours....69

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Installation

Location

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

For best results, a suitable, level location that is not subject to direct sunlight is required for the system.

When installing an system that was stored in a cool room or was transported at low temperatures, be aware that condensation may have formed and could have caused disturbances to the system. The system has to be acclimatized at room temperature for at least one hour before beginning operation.

The following conditions have to be fulfilled:

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

WARNING

PO_2 specifications are no longer valid at 3000 m above sea level, or air pressures lower than 526 mmHg (70.13 kPa). Under these conditions, PO_2 results can no longer be used for clinical decisions.

▶ After you finish the installation, permanently deactivate the parameter.

27. Checking the barometer value (p. 66)

- 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: 100–240 VAC (±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 system for operation:

- First, check the system 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 your 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.

NOTICE

Inserting damaged consumables may damage the system

If damaged consumables are inserted into the **cobas b** 221 system, locations where consumables come into contact with the system, such as the docking mechanism in the bottle compartment, may become damaged.

- Before inserting consumables into the system for the first time, check for possible damage during transportation. If a consumable shows evidence of damage, do not insert it into the system.

WARNING

Personal injury due to heavy loads

The **cobas b** 221 system, without consumables in the bottle compartment and AutoQC materials in the AutoQC module, weighs approximately 45 kg. Take care not to hurt your hands and fingers, or injure your back while putting the system in place.

- Perform the put out of operation procedure before moving the system.

  Shutdown (p. 69)

- Do not attempt to relocate or transport the system without the assistance of another individual.
- Do not attempt to lift the system with consumables in the bottle compartment and AutoQC materials in the AutoQC module. In addition, make sure that before lifting, there are no other objects attached to the system, and the system is not performing a measurement or a calibration.
- Lift the system only from its designated holding points.

  Designated holding points for lifting the system (p. 46)

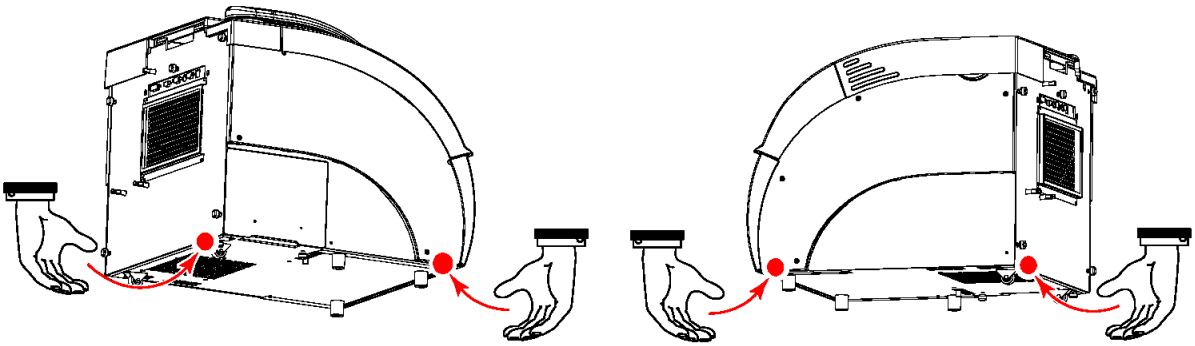


Figure 3-1 Designated holding points for lifting the system

Accessories

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

- 1 barcode scanner
- 1 roll printer paper
- 1 fill port
- 1 shutdown kit

Not shown in Figure 3-2 *Accessories* (p. 47):

- 1 screen/PC unit
- 1 power supply
- 1 fill port
- 3 pump tubes
- 1 sample inlet path (glass tube)

Figure 3-2 Accessories

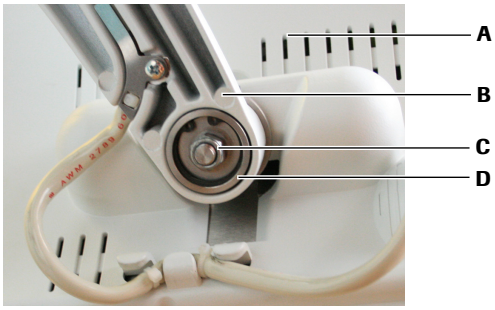
Installation procedure

1. Screen/PC unit

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 an appropriate wrench.



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

Figure 3-3 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 2 adapter connectors, on the holder and position them.

A Screw
B Holder

Figure 3-4 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 system on and wait until the program has finished loading. Set the operating language, the date, and the time.

■

5. Installation

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

Installation has to be carried out completely and cannot be interrupted.

Observe the listed sequence while performing the actions.

If the automatic first installation is unsuccessful, 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 has to 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 **Setup > Instrument > Language**

If the current language is English: **Instrument > Language**

2 Select the language.

■

7. Change the keyboard layout language (optional)

1 **Setup > Instrument > Select keyboard layout**

2 Choose the desired keyboard layout language.

3 Choose the **Yes** button.

4 Wait for the software restart to finish.

■

8. Change the sound settings (optional)

1 **Setup > Instrument > Sound**

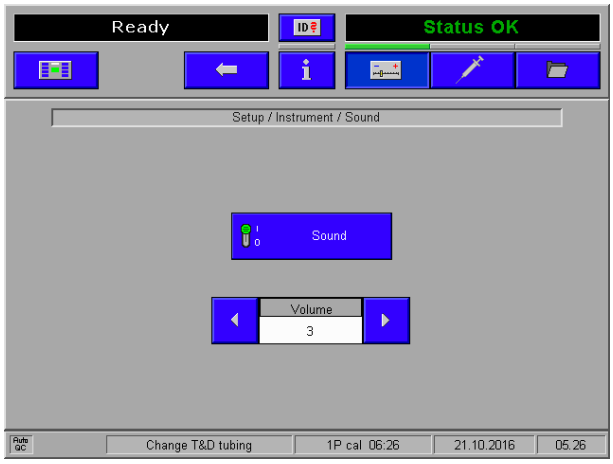


Figure 3-5 Sound settings screen

2 To mute the sound, turn off the **Sound** switch. To turn on the sound, turn on the **Sound** switch.

3 To change the volume level, press the ◄ and ► buttons.

Assigning higher volume levels generates louder sounds.

4 To save your sound settings, press the ← button.

■

9. Change the instrument ID and hospital information (optional)

1 **Setup > Instrument > Instrument ID**

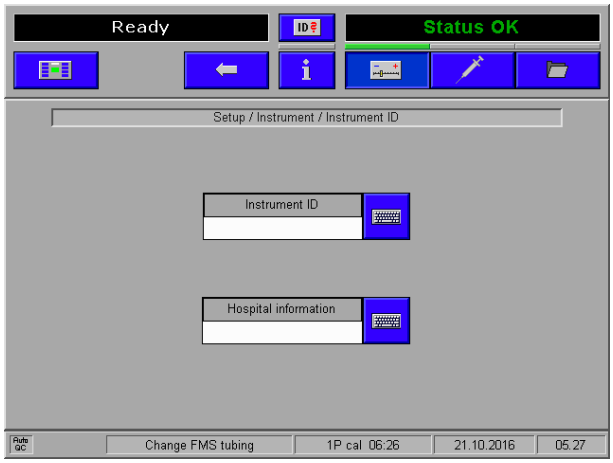


Figure 3-6 Instrument ID setup screen

2 To change the **Instrument ID**, press the ⌨ button.

3 Enter your instrument ID using the keyboard box that appears on the screen. To apply it, press the ↵ button.

4 To change the **Hospital information**, press the button.

5 Enter your hospital information using the keyboard box that appears on the screen. To apply it, press the button.

6 To save your instrument ID and/or hospital information, press the button.

■

10. Set the date and time

1 **Setup > Times & intervals > Current date & time**

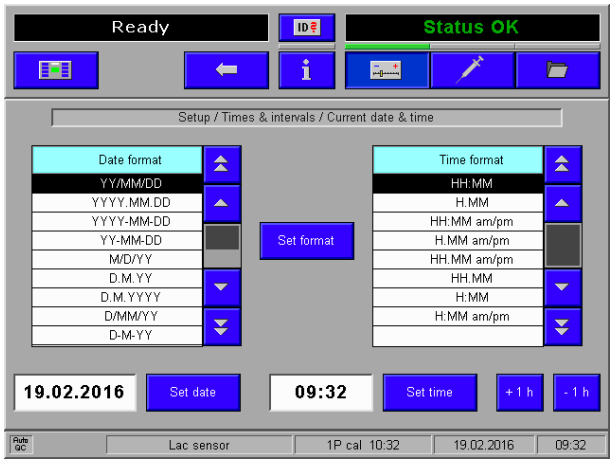


Figure 3-7 Current date & time

The analyzer must be manually adjusted for daylight saving time.

■

11. Cal. intervals & timing

1 **Setup > Times & intervals > Cal. intervals & timing**

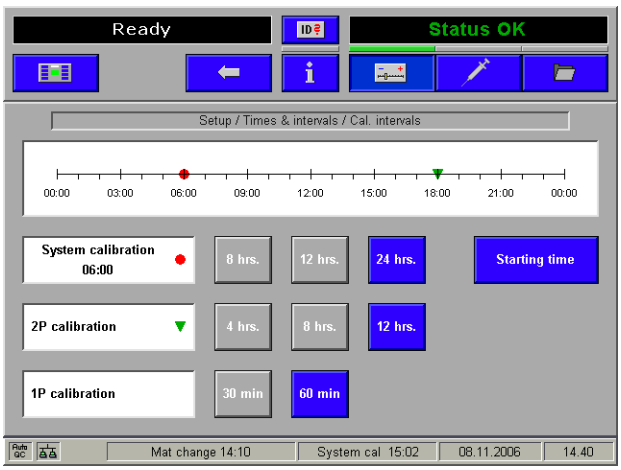


Figure 3-8 Cal. intervals

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 **Starting time** of a system calibration to which all calibrations are oriented.
2P calibration	Every 4, 8 or 12 hours.
1P calibration	Every 30 or 60 minutes.

■

12. 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.

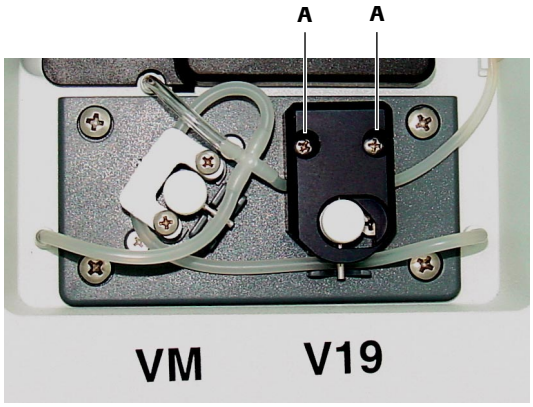
■

13. Fix screws at V19 (bottle compartment)

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

2 Tighten the screws on valve V19 (approximately 2–3 rotations).

Figure 3-9 *Valve V19 and VM* (p. 52)



A Screws on valve V19

Figure 3-9 Valve V19 and VM

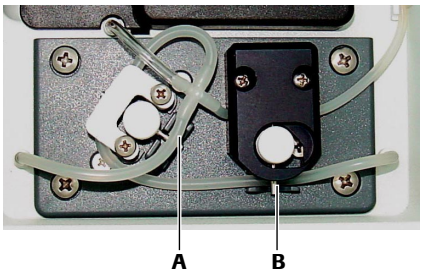
3 To return to the installation window, close the docking mechanism and the bottle compartment cover.

■

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

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

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



A VM **B** V19

Figure 3-10 Valve VM

Figure 3-11 Valve VM

3 Close docking mechanism and bottle compartment cover.

■

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

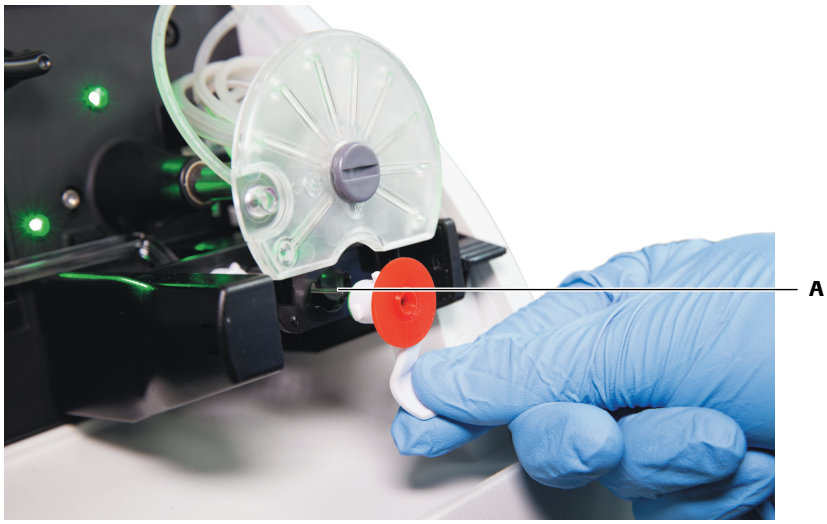
1 Pull out the sample drip tray.

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

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

4 Push the fill port straight onto the insert needle.

Do not bend the insert needle during this process.



A Needle

Figure 3-12 Insert needle

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

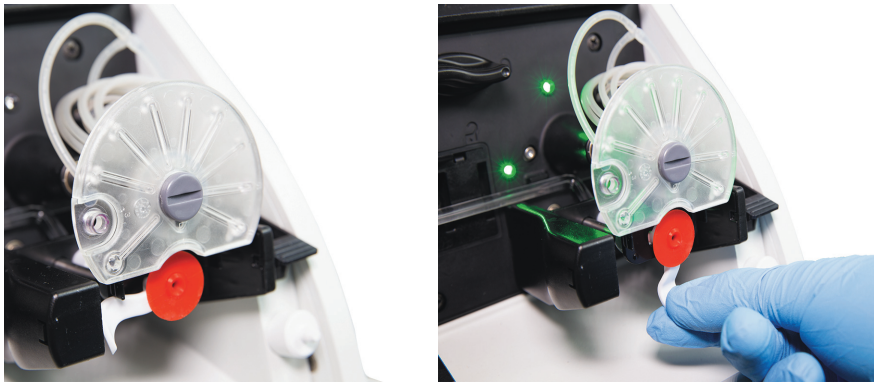


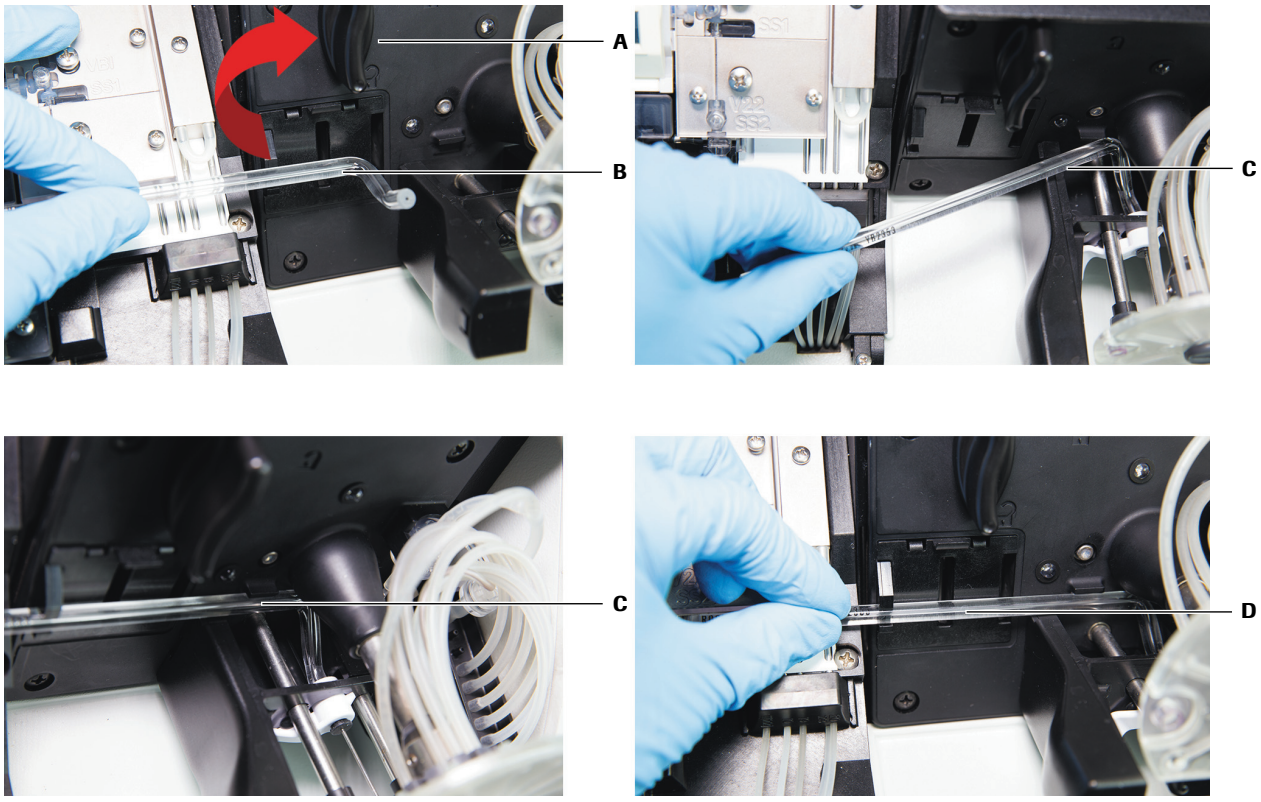
Figure 3-13

6 Open the T&D lock.

Figure 3-14 *Glass tube* (p. 55), A

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

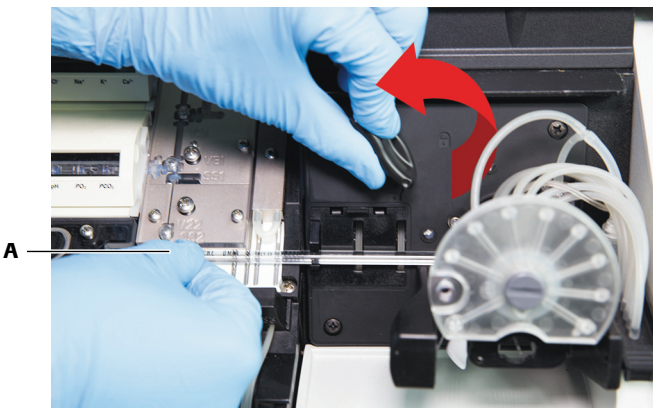
Figure 3-14 *Glass tube* (p. 55), C
Figure 3-14 *Glass tube* (p. 55), D



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

Figure 3-14 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 3-15 T&D lock

9 Install the T&D cover.

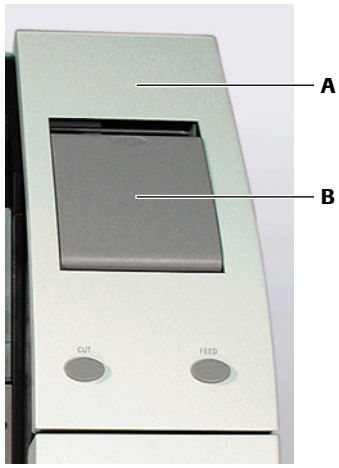
10 Insert the sample drip tray.

■

16. Insert printer paper

The printer paper is heat-sensitive on one side only. Ensure that you insert the paper roll correctly, with the heat-sensitive side up.

1 Remove the printer cover.



A Printer cover **B** Paper lid

Figure 3-16 Printer

2 Open the paper lid.

3 To help guide the new paper roll through the rollers, make sure that it has clean leading edge. To create a clean leading edge, cut the end of the paper roll in a straight line.

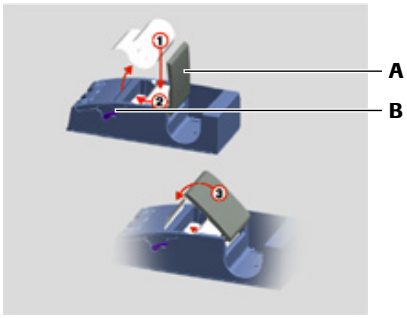
4 Place the new paper roll into the holder. The roll has to feed from the bottom.

5 Make sure that the printer lever is in the down position (see below). You can only see the printer lever when the paper cover is open.

A Printer lever “down” position

Figure 3-17 Printer lever

6 Feed in the beginning of the paper roll, as shown in the diagram found on the inside of the paper lid.



A Paper lid **B** Printer lever

Figure 3-18 Insert printer paper

7 The paper is automatically pulled into the printer.

8 Install the paper lid.

If you feed in the paper roll incorrectly, open the paper cover and printer lever, and realign the paper roll. Then, close the printer level and install the paper lid.

■

17. Change the printer settings (optional)

1 **Setup > Instrument > Printer settings**

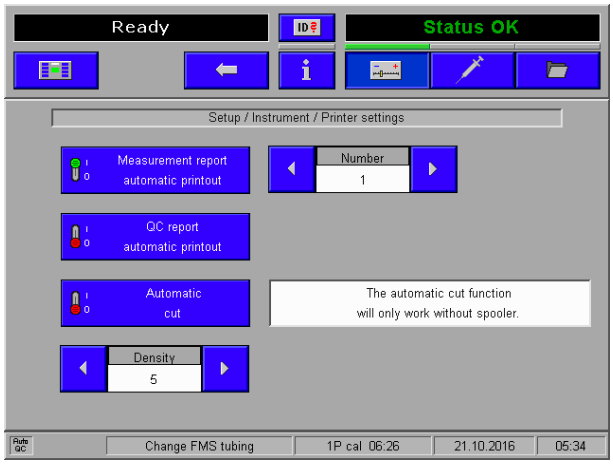


Figure 3-19 Printer settings screen

2 To activate the automatic printout of measurement reports after each measurement, make sure that the **Measurement report automatic printout** switch is turned on.

To deactivate it, turn off the **Measurement report automatic printout** switch.

3 To change the number of measurement reports that are automatically printed, press the ◀ and ▶ buttons beside the **Measurement report automatic printout** switch button.

4 To activate the automatic printout of QC reports after each QC measurement, make sure that the **QC report automatic printout** switch is turned on.

To deactivate it, turn off the **QC report automatic printout** switch.

5 To activate the automatic cutting of printouts, make sure that the **Automatic cut** switch is turned on.

To deactivate it, turn off the **Automatic cut** switch.

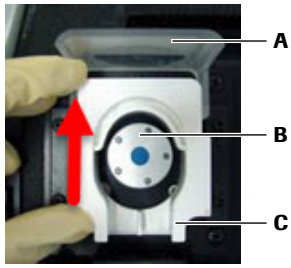
6 To change the print density level, press the ◀ and ▶ buttons.

Assigning higher print density levels generates printouts with more ink coverage.

■

18. Insert peristaltic pump tubes

1 Open the tension lever (see below/A).



A Tension lever
B Pump head
C Linear bracket

Figure 3-20 Peristaltic pump

2 Push the linear bracket upwards.

3 Place the tube around the corresponding rolling wheel. Check that the tubing set is lined up correctly. The grip end has to point upwards (see below/B).

4 Close the tension lever. The tubing holder is moved into the sealer.

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

Figure 3-21 Peristaltic pump

AutoQC module (option)

A Roche Service representative has to install the AutoQC module.

■

19. Go to AutoQC service position

1 Press **Start process**. This action is performed automatically.

■

20. Remove the transport lock

1 Open the AutoQC drawer.

2 To remove the AutoQC valve clamp, pull up and remove it (see below).

A AutoQC valve clamp

Figure 3-22 AutoQC valve clamp

3 Close the AutoQC drawer.

■

21. Go to AutoQC home position

1 Press **Start process**. This action is performed automatically.

■

22. Insert ampoule holder

1 Open the AutoQC drawer.

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

Figure 3-23 AutoQC drawer

2 Insert the AutoQC ampoule holder.

3 Close the AutoQC drawer.

■

23. Install containers and fluid packs

1 Open the bottle compartment cover.

A Rubber seals **B** **cobas b** 221<6> system only

Figure 3-24 W Waste Container & packs

2 Open the corresponding docking mechanisms.

A Docking mechanism **B** **cobas b** 221<6> system only

Figure 3-25 Bottle compartment

3 Insert the containers and fluid packs into the bottle compartment.

Remove fluid packs' rubber seals.

4 Close the corresponding docking mechanisms and the bottle compartment.

If your facility is 3000 m above sea level or higher, deaerate the S1 Rinse Solution bottle before inserting it inside the system to avoid splashing its contents.

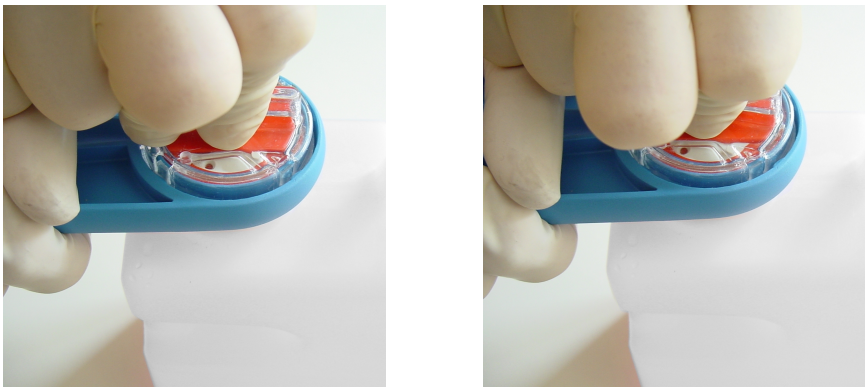
5 Place the bottle tool on the screw cap of the S1 Rinse Solution (see below/B).

A Bottle tool **B** Bottle tool on the screw cap

Figure 3-26 Bottle tool

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

7 Rotate the transparent disk clockwise and stop when there is resistance after a short distance (see below/B).



A **B**

Figure 3-27 Deaerate the S1 Rinse Solution

■

24. Open the measuring chamber cover and insert the sensors

1 BG/ISE measuring chamber

Open the measuring chamber cover. Apply force to the right edge of the MC cover with one finger, and at the same time, push it to the left and lift.

Open only the measuring chamber of the module, whose electrodes you want to insert.

The following screen appears:

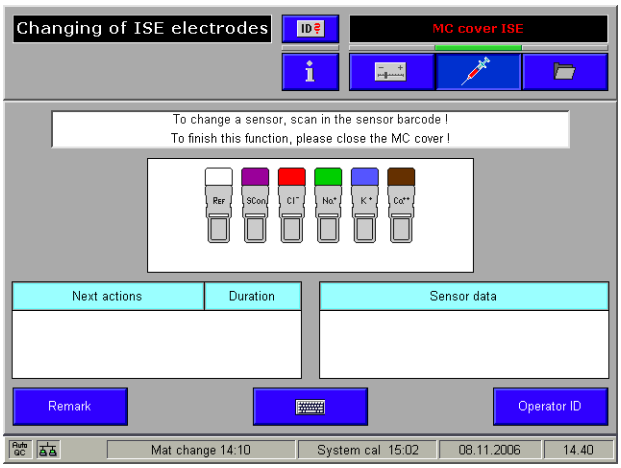


Figure 3-28 Changing of electrodes

2 Open the locking lever.

Figure 3-31 *Inserting the reference electrode* (p. 64)

3 Follow the instructions on the screen.

4 Make sure that the internal electrolyte of the electrodes does not contain any air bubbles.

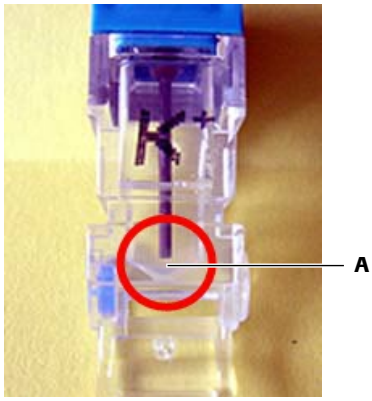
WARNING

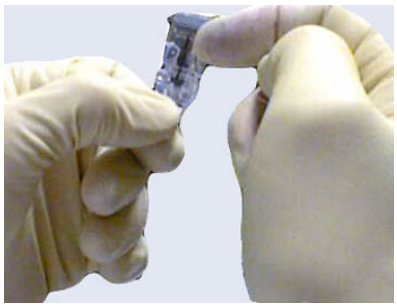
Air bubbles may lead to incorrect results

Air bubbles in the electrolyte solution inside of the electrodes prevents proper electrical conduction with samples. This may lead to incorrect patient results and/or loss of samples.

- Before installing each electrode for the first time, check for air bubbles inside the electrode. If there are any air bubbles, hold the electrode upright and lightly tap the side of the electrode body with your fingernail.

Figure 3-29 *Electrode* (p. 62)





A Free of air bubbles

Figure 3-29 Electrode

5 Insert the electrodes using the color code on the inside of the system.

Caution: Installation note for the PCO_2 electrode

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

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

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

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

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

7 Close the locking lever.

8 Close the measuring chamber cover.

■

Insert the reference electrode

WARNING

Using expired reference electrodes and/or reference electrodes that have exceeded their maximum in-use time may lead to incorrect results

The reference electrode produces a stable electrode potential that other electrodes reference to compute their respective voltages. Using expired reference electrodes and/or reference electrodes that have exceeded their maximum in-use time may lead to incorrect results, which may endanger patient lives.

- Do not install reference electrodes after the “Install before” date.
- Do not use reference electrodes after their maximum in-use time. Reference electrodes have to be replaced after 52 weeks of in-use time.

1 Open the measuring chamber cover.

2 Insert the reference electrode.

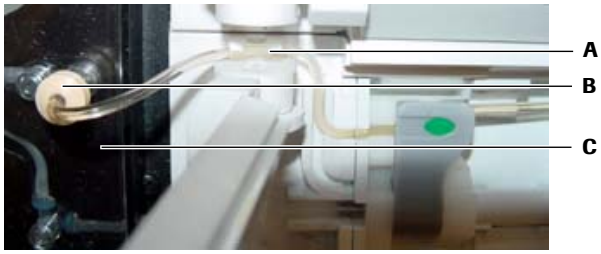
Figure 3-30 Reference electrode

3 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 level **B** Upper tube guide channel

Figure 3-31 Inserting the reference electrode

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



A Upper tube guide channel
B Connector
C Measuring chamber cartridge

Figure 3-32 Inserting the reference electrode

5 Scan the barcodes on the inner packaging of each electrode. If you cannot scan the barcode, enter the barcode manually using the keyboard.

6 Close the measuring chamber cover.

■

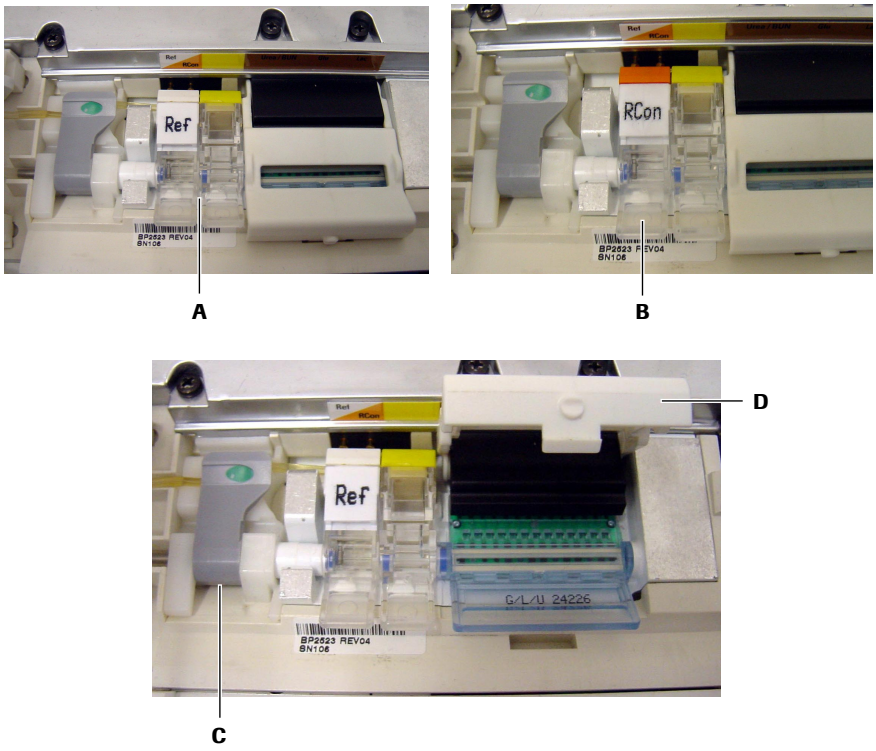
MSS measuring chamber (cobas b 221<6> system only)

1 Open the MSS module cover. Apply force to the right edge of the MC cover with one finger, and at the same time, push it to the left and lift.

2 Open the contact clip and the locking lever.

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

3 Insert the MSS reference electrode (Ref + dummy) (see below/A) or the reference contact (RCon) (see below/B), and the MSS cassette. This depends on your MSS parameter configuration.



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

Figure 3-33 MSS measuring chamber

4 Close the locking lever and the contact clip.

5 Read in the barcode from the packaging of the MSS cassette.

6 Close the measuring chamber cover.

7 Close the top cover.

■

25. Complete installation

1 Press **Complete installation**.

Automatic sequences take place and the unit warms up.

2 Installation is complete.

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

■

26. Perform MSS polarization (cobas b 221<6> system only)

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

Use whole blood for polarization. The blood should have a volume of at least 150 µL and contain heparin as an anticoagulant.

Measurement (p. 143)

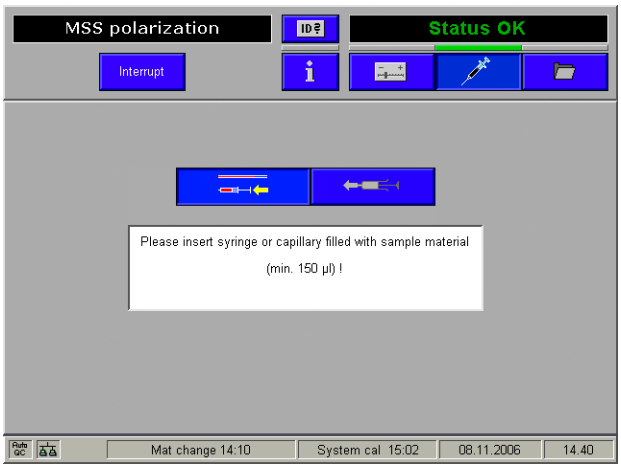


Figure 3-34 MSS polarization

2 Insert the prepared blood sample through the fill port.

The MSS cassette is polarized and calibrated.

3 If you cannot calibrate the MSS parameters after performing the automatic MSS polarization, perform a manual MSS polarization.

4 **System > Utilities > MSS polarization**

5 Follow the instructions on the screen.

■

27. Checking the barometer value

1 **System > Component test > Control sensors > Baro sensor**

If the barometer value deviates by more than ± 4 mbar from the measured value of a precision barometer, contact your Roche Service representative to calibrate it.

WARNING

Incorrect barometer values may lead to incorrect PO_2 measurement results.

- PO_2 specifications are no longer valid at 3000 m above sea level, or air pressures lower than 526 mmHg (70.13 kPa). Under these conditions, PO_2 results can no longer be used for clinical decisions, and the parameter should be permanently deactivated.

Specifications (p. 79)

2 To deactivate the parameter PO_2, press the following buttons: **Setup > Parameter > Miscellaneous settings > Activated/deactivated for calibrations**

■

28. Quality control

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

Quality control (p. 183)

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

When you install your QC materials, their target values are saved in the system. If QC measurements for a parameter fall outside its target value range, a QC warning or QC lock is applied to this parameter.

Quality control (p. 183)

■

Installing and using ticket printers

Ticket printers can also be used to print measurement reports.

To install a ticket printer

1 Connect the ticket printer to the **cobas b** 221 system at the COM 1 serial interface with an appropriate serial cable.

2 To assign the COM 1 serial interface to the ticket printer, press the following buttons: **Setup > Interfaces > COM 1**

Modify the COM 1 serial interface settings according to the specifications of the ticket printer manufacturer.

■

To activate a ticket printer

1 **Setup > Instrument > Ticket printer**

2 Turn on the **Measurement report printout** switch.

To deactivate it, turn off the switch.

■

To print imported files using a ticket printer

1 To import files, such as measurement reports, for printing from a ticket printer, press the **Import file** button.

2 Using a USB storage device or a floppy disk, load your file onto the system

If you have a system with an SN > 3000, use a USB storage device to import and export files. You can also use a floppy disk if you have issues using your USB storage device, and your system has a floppy disk drive (SN < 21000).

You can find your imported files on the system's database. You can print your imported files directly from the Data Manager.

Data Manager (p. 248)

If you have defined correlation factors for measurement parameters on your imported files, the “(c)... User correlation activated” status message does not appear on the printed measurement report.

■

Shutdown

Less than 24 hours

If the **cobas b** 221 system remains inactive for less than 24 hours, you have 2 options. You can shut down your system, or activate economy mode.

When you shut down your system, the touch screen/PC unit is switched off. All MSS cassettes are destroyed during a shutdown. When you restart your system, you have to insert a new MSS cassette. To shut down your system, press **System > Utilities > Shutdown PC**

Alternatively, you can manually activate economy mode. Activating economy mode reduced the solution consumption of your system while it is inactive, and preserves its electrodes' conditions. To manually activate economy mode, press **System > Utilities > Manual economy mode**

Longer than 24 hours

If the **cobas b** 221 system will be shut down for longer than 24 hours, press the following buttons: **System > Utilities > Put out of operation**

Roche recommends decontaminating all surfaces before shutting down the system. All steps in the routine have to be performed in the correct order.

Decontamination (p. 271).

To complete some steps, you have to manually perform an action on the system. When this action is complete, press the **Confirm action** button. The system automatically performs all other steps. To start an automatic action, press the **Start process** button.

Successfully completed actions are displayed with the icon.

1. Remove S1 Rinse Solution and fluid packs

1 Open the bottle compartment cover and the docking mechanism, and then remove the S1 Rinse Solution and the packs.

WARNING

Removing the W Waste Container during the shutdown procedure may result in infection

The W Waste Container collects waste during the shutdown procedure. This may include trace amounts of biohazardous materials found in the system. Direct contact with these materials may lead to biohazardous contamination, resulting in infection.

- Do not remove the W Waste Container from the bottle compartment until you are instructed to do so.

2 Close the docking mechanism and the bottle compartment cover.

■

2. Fill the shutdown kit with distilled water

1 Fill the shutdown kit about halfway with distilled water.

Figure 3-35 Shutdown kit

■

3. Insert shutdown kit into the S2 docking mechanism

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

2 Close the docking mechanism and the bottle compartment cover.

3 Perform “Washing of the tubes”.

■

4. Remove shutdown kit from the S2 docking mechanism

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

2 Close the docking mechanism and the bottle compartment cover.

3 Perform “Emptying of the tubes”.

■

5. Insert shutdown kit into the S3 docking mechanism (cobas b 221<6> system only)

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

2 Close the docking mechanism and the bottle compartment cover.

3 Perform “Washing of the tubes”.

■

6. Remove shutdown kit from the S3 docking mechanism (cobas b 221<6> system only)

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

2 Close the docking mechanism and the bottle compartment cover.

3 Perform “Emptying of the tubes”.

■

7. Remove W Waste Container

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

2 Remove the W Waste Container.

3 Close the docking mechanism and the bottle compartment cover.

■

8. Open the measuring chamber cover and remove the sensors

1 Remove the top cover.

2 Open all of the measuring chamber covers. To open the measuring chamber cover, apply force to the right edge of the MC cover with one finger, and at the same time, push it to the left and lift.

3 Open the locking levers and the contact clip (**cobas b** 221<6> system only).

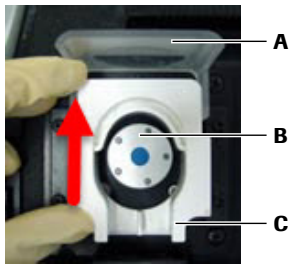
4 Remove the electrodes and the MSS cassette from the measuring chambers (**cobas b** 221<6> system only).

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

■

9. Remove the peristaltic pump tubes

1 Open the tension lever (see below).

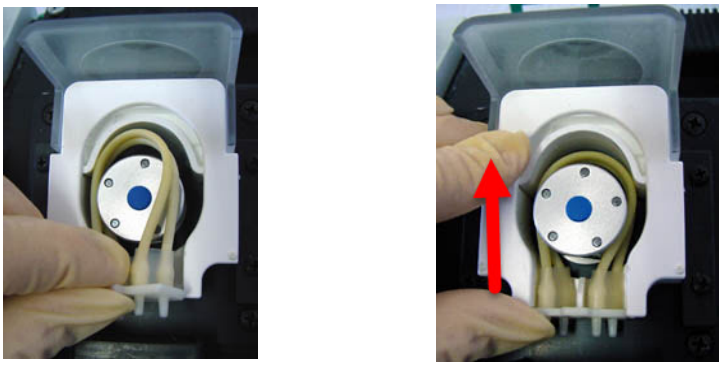


A Tension lever
B Pump head
C Linear bracket

Figure 3-36 Peristaltic pump

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

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



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

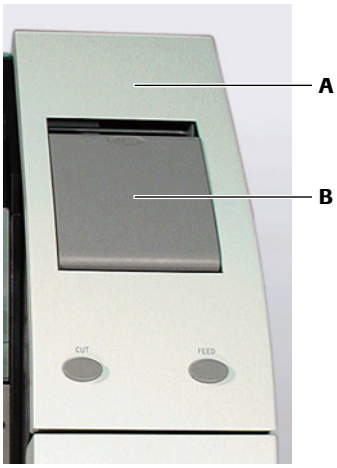
Figure 3-37 Peristaltic pump

4 Close the tension lever.

■

10. Remove the printer paper

1 Remove the printer cover.



A Printer cover **B** Paper lid

Figure 3-38 Printer cover/paper lid

2 Open the paper lid.

3 Move up the printer lever. (see below/A).

A Printer lever “up” **B** Printer lever “down”

Figure 3-39 Printer lever

4 Remove the paper roll.

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

6 Install the paper lid and the printer cover.

■

11. Open the T&D disk

1 Press **Start process**.

This action is performed automatically. The T&D disk turns to position 1.

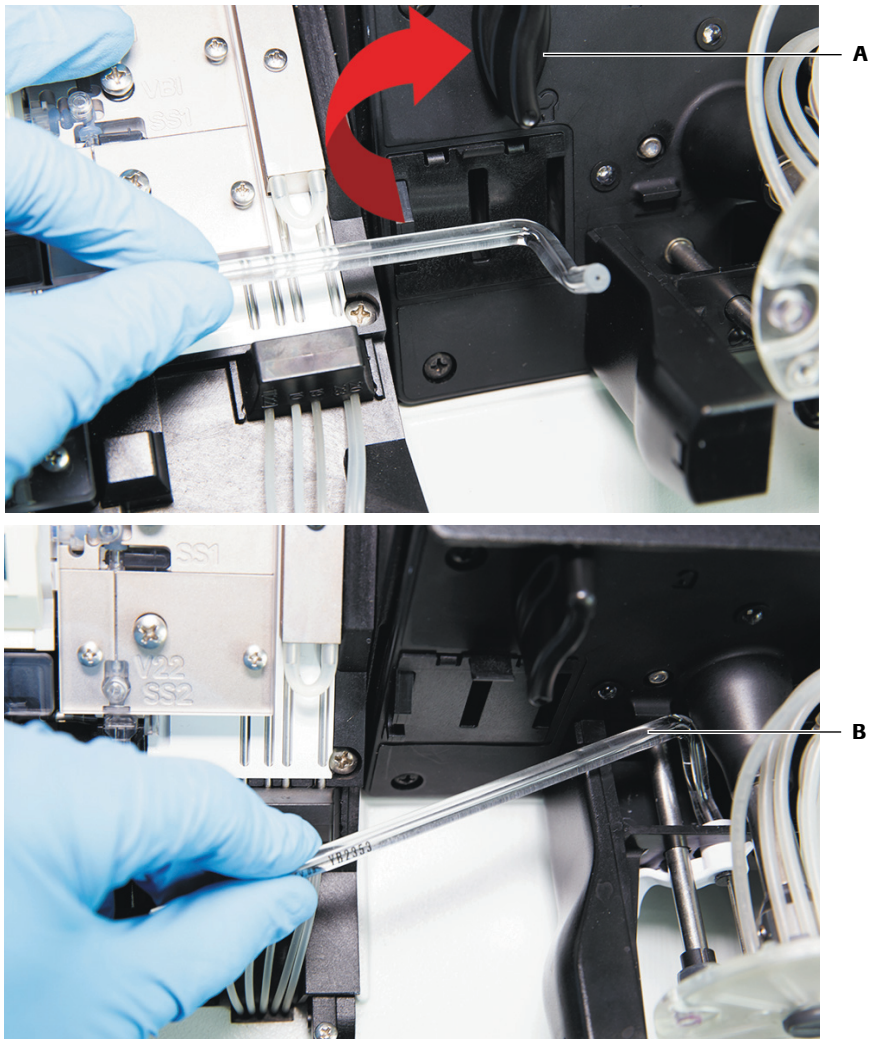
■

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

1 Remove the sample drip tray.

2 Remove the T&D cover.

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

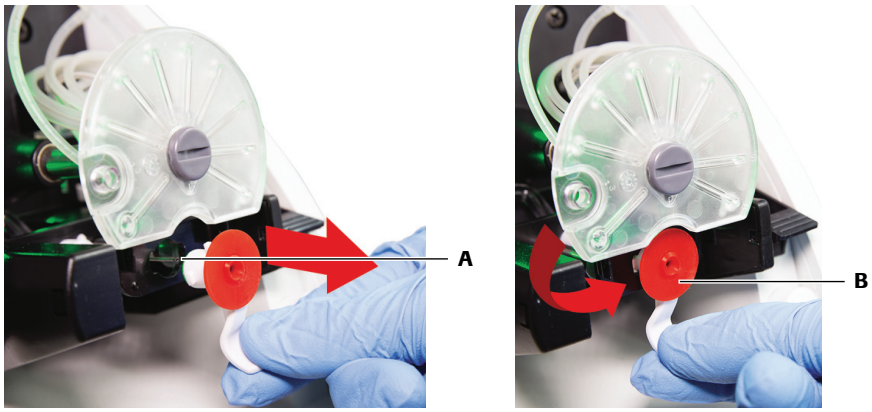


A T&D lock **B** Sample inlet path (glass tube)

Figure 3-40 T&D lock & sample inlet path

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

Do not bend the needle.



A Needle **B** Fill port

Figure 3-41 Fill port

5 Close the T&D lock again.

6 Install the T&D cover.

■

13. Set valves for FMS tubing exchange

1 Press **Start process**. This action is performed automatically.

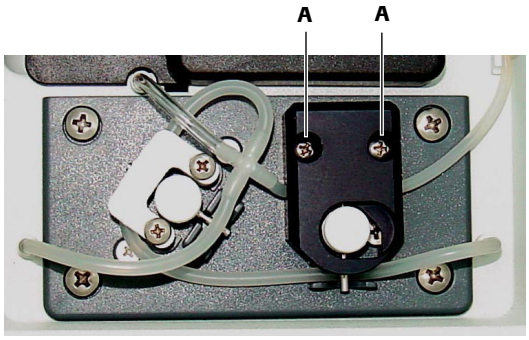
Both valves are pushed out.

■

14. Release screws at V19 (bottle compartment)

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

2 Loosen the screws (A) of the aluminum part of valve V19 (approximately 2–3 turns).



A Screws

Figure 3-42 Valve V19

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

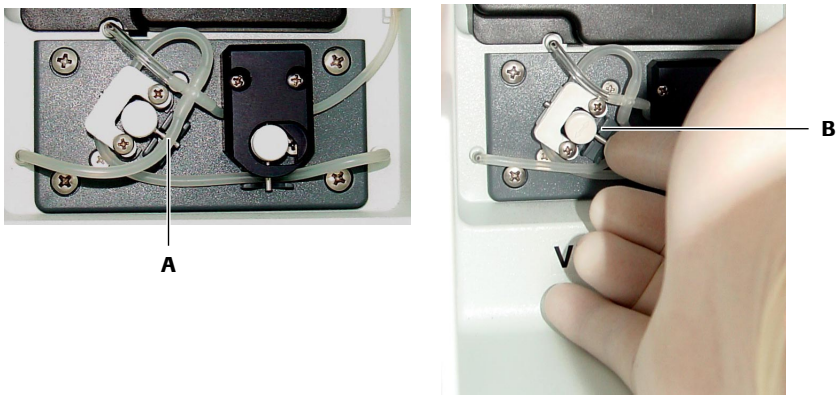
■

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

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

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

Pressure is released from the tubes.



A VM **B** Tube clip

Figure 3-43 Valve VM

3 Close the docking mechanism and the bottle compartment cover.

AutoQC module (option):

■

16. Go to AutoQC home position

1 Press **Start process**. This action is performed automatically.

■

17. Remove the ampoule holder

1 Open 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.

Removing ampoules from the ampoule holder may result in injury

Ampoules are made of fragile glass that splinters easily. They may break when you remove them from the ampoule holder, and result in personal injury.

- Wear appropriate personal protective equipment, such as protective gloves and safety glasses. Take extra care when working with protective gloves, which can easily be pierced or cut, leading to personal injury.

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

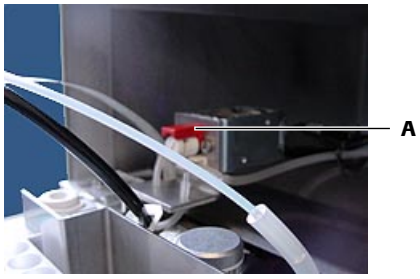
1 Press **Start process**. This action is performed automatically.

■

19. Insert the transport lock

1 Open the AutoQC drawer.

2 To insert the AutoQC valve clamp, place it in the location shown in the figure below.



A AutoQC valve clamp

Figure 3-44 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 **Complete shutdown**.

Shutdown is complete. The following screen appears:

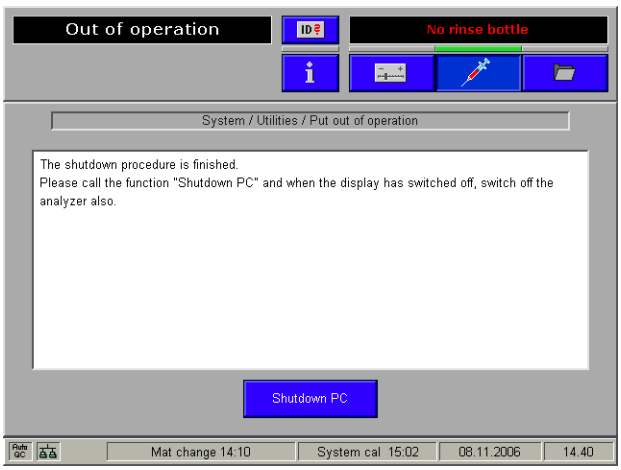


Figure 3-45 Shutdown

2 Press **Shutdown PC**. Follow the instructions on the screen.

The PC is shut down.

3 Turn off the device.

4 Install the top cover.

5 Disconnect all cables that are attached to your system.

■

Specifications

In this chapter, performance data for BG, ISE, COOX, and the MSS Cassette are provided. In addition, product and environmental data are described.

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Performance data

Measurement parameters

This section describes measurement parameters for BG, ISE, COOX, and the MSS Cassette (material 0326xxxx184).

Parameter	specified for	specified range	
PO_2 (1)(2)	B/Q	0–800 mmHg	
PCO_2	B/Q	4–200 mmHg	
pH	B/Q/S/PF	6.0–8.0	
Sodium	B/Q/S/A/D	20–250 mmol/L	
Potassium(1)	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(3) (**cobas b** 221<6> system only)	B/Q/S	0.5–40 mmol/L	9.01–720.8 mg/dL
Lactate (**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)(2)	B/Q/S	0.5–30 mmol/L	3.0028–180.168 mg/dL
tHb (COOX)	B/Q	3–25 g/dL	
SO_2 (COOX)	B/Q	0–100%	
HHb (COOX)(1)(2)	B/Q	0–100%	
COHb (COOX)(1)(2)	B/Q	0–100%	
O_2Hb (COOX)(1)(2)	B/Q	0–100%	
MetHb (COOX)(1)(2)	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: PO_2: 1.15 mmHg, Urea: 0.537 mmol/L, K: 0.516 mmol/L, HHb: 1.26%, COHb: 1.37%, O_2Hb: 4.504% and MetHb: 0.691%. If the measured value is lower than the LoQ value, the parameter is flagged with a # on the measurement report.

(2) The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with the respective specified total error for the analyte. It is determined using low concentration whole blood samples of each analyte. Specified total error: PO_2: 3mmHg, Urea: 0.5 mmol/L, MetHb: 3%, COHb: 3%, HHb: 2%, O_2Hb: 3%, K: 0.2 mmol/L.

(3) Due to current specifications, clinically significant deviations in the range of < 3 mmol/L can occur compared to other glucose measuring systems. This can have a greater effect on neonatal glucose measurements. Therefore, we recommend carrying out a comparative blood measurement relative to a known reference system or to adapt the correlation table (*To assign a correlation factor to a parameter* (p. 140)). Contact your local Roche organization for more information.

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_r)"and "Intermediate precision (S_i)" were determined from 2 runs per day with 2 replicates per run for 20 days on 4 **cobas b** 221 systems.

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

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

Table 4-2

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

Parameter	Mean	S_r	(CV%)	S_i	(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 Acetate - standard solution (Level 1), NIST Traceable, n=80

Material: acetate - standard solution (Level 2), NIST Traceable, n=80

Parameter	Mean	S_r	(CV%)	S_i	(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 Acetate - standard solution (Level 2), NIST Traceable, n=80

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

Parameter	Mean	S_r	(CV%)	S_i	(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 (COOX)	14.1	0.0773	0.55	-	-
SO_2 (COOX)	99.9	0.0613	0.06	-	-
O_2Hb	97.9	0.0684	0.07	-	-
COHb	1.4	0.0377	2.79	-	-
MetHb	0.7	0.0287	4.10	-	-
HHb	0.1	0.0601	-	-	-

Table 4-5 Tonometered human whole blood, 20 different probands, n=80

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
pH	7.129	0.0049	0.07	-	-
PCO_2	79.5	1.2629	1.59	1.9644	2.47
PO_2	40.1	0.3297	0.82	0.5976	1.49
Sodium	142.3	0.7126	0.50	-	-
Potassium	4.32	0.0392	0.91	-	-
Chloride	105.2	0.5184	0.49	-	-
Ionized Calcium	1.301	0.0136	1.05	-	-
Hct	40.4	0.2795	0.69	-	-
Lactate	8.7	0.2021	2.33	-	-
Glucose	2.3	0.0977	4.31	-	-
Urea	4.9	0.0583	1.18	-	-
tHb (COOX)	14.1	0.1691	1.20	-	-

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

Performance data

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
SO_2 (COOX)	67.8	0.2479	0.37	-	-
O_2Hb	66.9	0.3437	0.51	-	-
COHb	1.6	0.0549	3.53	-	-
MetHb	0.4	0.0504	12.14	-	-
HHb	31.5	0.3121	0.99	-	-

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

Material: human plasma, n=80

Parameter	Mean	S_r	(CV%)	S_i	(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_r	(CV%)	S_i	(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_r	(CV%)	S_i	(CV%)
Sodium	137.9	0.7201	0.52	1.0185	0.74

Table 4-9 Bicarbonate, n=80

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
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_r	(CV%)	S_i	(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 (COOX)	7.8	0.0317	0.41	0.0599	0.77
SO_2 (COOX)	72.1	0.0690	0.10	0.1941	0.27
O_2Hb	46.8	0.0844	0.18	0.2383	0.51
COHb	23.0	0.0371	0.16	0.1043	0.45
MetHb	12.0	0.0180	0.15	0.0513	0.43
HHb	18.1	0.0294	0.16	0.0830	0.46
Bili	6.1	0.0287	0.47	0.0477	0.78

Table 4-10 AUTOTROL PLUS B Level 1, n=40

Material: AUTOTROL PLUS B Level 2, n=40

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

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
O_2Hb	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_r	(CV%)	S_i	(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 (COOX)	20.4	0.1940	0.95	0.2357	1.15
SO_2 (COOX)	97.5	0.1396	0.14	0.1400	0.14
O_2Hb	92.5	0.3581	0.39	0.3617	0.39
COHb	3.3	0.1564	4.75	0.1565	4.75
MetHb	1.9	0.0773	4.13	0.0809	4.32
HHb	2.4	0.1244	5.23	0.1249	5.25
Bili	21.6	0.1621	0.75	0.1690	0.78

Table 4-12 AUTOTROL PLUS B Level 3, n=40

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

Parameter	Mean	S_r	(CV%)	S_i	(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

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
tHb (COOX)	6.4	0.0265	0.41	0.1241	1.93
SO_2 (COOX)	62.7	0.2002	0.32	0.2514	0.40
O_2Hb	36.5	0.1973	0.54	0.2474	0.68
COHb	27.6	0.0869	0.32	0.1091	0.40
MetHb	14.2	0.0414	0.29	0.0518	0.36
HHb	21.7	0.0690	0.32	0.0866	0.40
Bili	4.2	0.0146	0.34	0.0707	1.67

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

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

Parameter	Mean	S_r	(CV%)	S_i	(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 (COOX)	23.0	0.2175	0.94	0.3139	1.36
SO_2 (COOX)	98.1	0.1568	0.16	0.1744	0.18
O_2Hb	94.2	0.4087	0.43	0.4554	0.48
COHb	2.5	0.0852	3.37	0.1053	4.16
MetHb	1.4	0.0397	2.77	0.0519	3.62
HHb	1.8	0.0675	3.83	0.0837	4.75
Bili	24.1	0.2629	1.09	0.2728	1.13

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

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

Parameter	Mean	S_r	(CV%)	S_i	(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 4-15 MSS Level 1, NIST Traceable, n=80

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

Parameter	Mean	S_r	(CV%)	S_i	(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 4-16 MSS Level 2, NIST Traceable, n=80

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
Bili	8.2	0.1202	1.47	0.6198	7.56

Table 4-17 Human whole blood including bilirubin Level 1, n=40

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
Bili	24.1	0.1171	0.49	0.9663	4.01

Table 4-18 Human whole blood including bilirubin Level 2, n=40

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

Parameter	Mean	S_r	(CV%)	S_i	(CV%)
Bili	44.0	0.1623	0.37	2.1509	4.89

Table 4-19 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 CO_2 and O_2 concentrations certified to ± 0.03% absolute by the manufacturer. Expected and observed values for PCO_2 and PO_2 were corrected to 760 mmHg.

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

NIST standards Standard Reference Materials were used to determine performance characteristics.

Hematocrit Measurement results for the hemofuge, which represents the gold standard for hematocrit measurements, were 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: PO_2 (mmHg)

Material: tonometered whole blood

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

Measurements per measuring point and instrument: 5

Expected value	Mean	S_r	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 4-20 Parameter PO_2 (mmHg)

Correlation	
Slope	0.9904–1.0097
Intercept	± 0.857
Correlation coefficient	0.9998

Table 4-21

Parameter: PCO_2 (mmHg)

Material: Tonometered whole blood

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

Measurements per measuring point and instrument: 5

Expected value	Mean	S_r	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 4-22 Parameter PCO_2 (mmHg)

Correlation	
Slope	0.9898–1.0103
Intercept	± 1.225
Correlation coefficient	0.9999

Table 4-23

Parameter: pH

Material: Tonometered whole blood

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

Measurements per level and instrument: 5

Expected value	Mean	S_r	Recovery
7.52	7.52	0.0050	100
7.32	7.32	0.0042	100
6.98	6.99	0.0066	100.1

Table 4-24 Parameter pH

Correlation	
Slope	0.9825–1.0178
Intercept	± 0.133
Correlation coefficient	0.9998

Table 4-25

Parameter: Hct (%)

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

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

Measurements per level and instrument: 5

Expected value	Mean	S_r	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 4-26 Parameter Hct (%)

Correlation	
Slope	0.997–1.003
Intercept	± 0.620
Correlation coefficient	0.999

Table 4-27

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_r	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 4-28 Parameter Sodium (mmol/L)

Correlation	
Slope	0.988–1.012
Intercept	± 0.365
Correlation coefficient	0.9999

Table 4-29

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_r	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 4-30 Parameter Potassium (mmol/L)

Correlation	
Slope	0.960–1.042
Intercept	± 0.109
Correlation coefficient	0.9999

Table 4-31

Parameter: Ionized Calcium (mmol/L)

Material: aqueous solution, NIST traceable

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

Measurements per level and instrument: 15

Expected value	Mean	S_r	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 4-32 Parameter ionized Calcium (mmol/L)

Correlation	
Slope	0.975–1.026
Intercept	± 0.024
Correlation coefficient	0.9999

Table 4-33

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_r	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 4-34 Parameter Chloride (mmol/L)

Correlation	
Slope	0.959–1.043
Intercept	± 2.908
Correlation coefficient	0.9999

Table 4-35

Parameter: pH

Material: aqueous solution, NIST traceable

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

Measurements per level and instrument: 15

Expected value	Mean	S_r	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 4-36 Parameter pH

Correlation	
Slope	0.960–1.042
Intercept	± 0.293
Correlation coefficient	1.0000

Table 4-37

Parameter: CO_2 (mmHg)

Material: tonometered aqueous solution

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

Measurements per level and instrument: 15

Expected value	Mean	S_r	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 4-38 Parameter: CO_2 (mmHg)

Correlation	
Slope	0.961–1.041
Intercept	± 0.865
Correlation coefficient	0.9994

Table 4-39

Parameter: O_2 (mmHg)

Material: tonometered aqueous solution

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

Measurements per level and instrument: 15

Expected value	Mean	S_r	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 4-40 Parameter O_2 (mmHg)

Correlation	
Slope	0.908–1.101
Intercept	± 6.609
Correlation coefficient	0.9995

Table 4-41

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_r	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 4-42 Parameter Glucose (mmol/L)

Correlation	
Slope	0.919–1.088
Intercept	± 1.773
Correlation coefficient	0.998

Table 4-43

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_r	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 4-44 Parameter Lactate (mmol/L)

Correlation	
Slope	0.961–1.041
Intercept	± 0.191
Correlation coefficient	0.9989

Table 4-45

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_r	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 4-46 Parameter Urea (mmol/L)

Correlation	
Slope	0.979–1.021
Intercept	± 0.198
Correlation coefficient	0.9991

Table 4-47

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_r	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 4-48 Parameter Glucose (mmol/L)

Correlation	
Slope	0.9591–1.0426
Intercept	± 0.4273
Correlation coefficient	0.9991

Table 4-49

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_r	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 4-50 Parameter Sodium (mmol/L)

Correlation	
Slope	0.9719–1.0289
Intercept	± 4.0475
Correlation coefficient	0.9999

Table 4-51

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_r	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 4-52 Parameter Potassium (mmol/L)

Correlation	
Slope	0.9629–1.0385
Intercept	± 0.1788
Correlation coefficient	0.9999

Table 4-53

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_r	Recovery
120.76	119.96	0.3662	99.3
141.00	144.31	0.4298	102.3

Table 4-54 Parameter Sodium (mmol/L)

Correlation	
Slope	0.8311–1.2032
Intercept	± 25.3383
Correlation coefficient	0.9997

Table 4-55

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_r	Recovery
3.42	3.29	0.0162	96.1
6.28	6.56	0.0273	104.4

Table 4-56 Parameter Potassium (mmol/L)

Correlation	
Slope	0.8738–1.1444
Intercept	± 0.6284
Correlation coefficient	1.0000

Table 4-57

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_r	Recovery
89.11	88.59	0.6674	99.4
119.43	115.96	0.9763	97.1

Table 4-58 Parameter Chloride (mmol/L)

Correlation	
Slope	0.9032–1.1072
Intercept	± 8.1053
Correlation coefficient	0.9990

Table 4-59

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_r	Recovery
5.40	5.06	0.0294	93.7
15.00	12.17	0.1239	81.1

Table 4-60 Parameter Glucose (mmol/L)

Correlation	
Slope	0.7429–1.3461
Intercept	± 1.0482
Correlation coefficient	0.9997

Table 4-61

Parameter: Urea (mmol/L)

Material: NIST 909b

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

Measurements per level and instrument: 15

Expected value	Mean	S_r	Recovery
5.51	5.40	0.0248	98.0

Table 4-62 Parameter Urea (mmol/L)

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_r	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 4-63 Parameter Bilirubin (mg/dL)

Correlation	
Slope	0.9038–1.1064
Intercept	± 1.514
Correlation coefficient	0.9996

Table 4-64

Parameter correlation to other methods

The method comparison study determines the relative bias between 2 analytic methods. A single sample is measured with each method and the results are compared. Over the measurement range, slope, intercept, bias, and correlation coefficient are calculated.

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 4-65 pH

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

PO_2

Unit: [mmHg]

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

Table 4-66 PO_2

PCO_2

Unit: [mmHg]

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

Table 4-67 PCO_2

tHb (cobas b 221 system with COOX module)

Unit: [g/dL]

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

Table 4-68 tHb

O_2Hb (cobas b 221 system with COOX module)

Unit: [%]

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

Table 4-69 O_2Hb

HHb (cobas b 221 system with COOX module)

Unit: [%]

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

Table 4-70 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 4-71 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 4-72 COHb

SO_2 (cobas b 221 system with COOX module)

Unit: [%]

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

Table 4-73 SO_2

Bilirubin (cobas b 221 system with COOX module)

Unit: [mg/dL]

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

Table 4-74 Bilirubin

Hct

Unit: [%]

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

Table 4-75 Hct

Sodium

Unit: [mmol/L]

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

Table 4-76 Sodium

Potassium

Unit: [mmol/L]

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

Table 4-77 Potassium

Calcium

Unit: [mmol/L]

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

Table 4-78 Calcium

Chloride

Unit: [mmol/L]

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

Table 4-79 Chloride

Glucose

Unit: [mmol/L]

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

Table 4-80 Glucose

Urea

Unit: [mmol/L]

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

Table 4-81 Urea

Lactate

Unit: [mmol/L]

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

Table 4-82 Lactate

Environmental parameters

Temperature/humidity/stability

This section describes environmental parameters for BG, ISE, COOX, and MSS Cassette (material 0326xxxx184).

Instrument

Operating conditions	
• Ambient temperature	15–31 °C
• Ambient air pressure	526–797 mmHg (70.13–106.225 kPa)
• Relative humidity	20–85% (no condensation)
• Measuring chamber temperature	
BG & ISE	37 ± 0.2 °C
MSS	30 ± 0.2 °C
COOX	37 ± 0.5 °C

Table 4-83

Storage and transportation conditions	
• Temperature	-20 °C to 50 °C
• Humidity	20–85% (no condensation)

Table 4-84

Electrodes

Storage conditions in original packaging	
• Temperature	
BG, ISE	15–30 °C
MSS (Glu, Lac, Urea/BUN)	2–8 °C
• Relative humidity	20% to 85% (no condensation)

Table 4-85

Transportation conditions in original packaging	
• Temperature	0–30°C over a period of 5 days
• Humidity	20% to 85% (no condensation)

Table 4-86

Solutions

Storage conditions in original packaging	
• Temperature	
S1 Rinse Solution	2–30 °C (24 months[1])
S2 Fluid Pack	2–30 °C (18 months[1])
S3 Fluid Pack A	2–25 °C (18 months[1])
• Relative humidity	20% to 85%

Table 4-87

(1) Storage time includes transportation and storage time at Roche.

Transportation conditions in original packaging	
• Temperature	2–35 °C over a period of 7 days
• Relative humidity	20–85%

Table 4-88

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 A	Calibration solution Glu, Lac, Urea/BUN	6

Table 4-89

QC material

Storage conditions in original packaging	
• COMBITROL PLUS B	Up to 24 months at 2 °C to 8 °C
• AUTO-TROL PLUS B	Up to 24 months at 2 °C to 8 °C

Table 4-90

Stability during operation	
• COMBITROL PLUS B	Up to 3 months at 15°C to 31°C
• AUTO-TROL PLUS B	Up to 3 months at 15°C to 31°C (including up to 60 days in the AutoQC module)

Table 4-91

Sample throughput

Activated/installed modules	Sample throughput [samples/hours]	
	Syringe	Capillary
BG - COOX	31	29
BG - ISE - COOX	31	29
BG - ISE - COOX - MSS Cassette (material 0326xxxx184) (Glu/Lac/Urea)	30(1)	27(1)

Table 4-92 Sample throughput

(1) Best-case scenario in operational phase

Measurement times of the samples

Activated/installed modules	Measurement times [seconds]	
	Total time	Until display
BG - COOX	110	76
BG - ISE - COOX	110	76
BG - ISE - COOX - MSS Cassette (material 0326xxxx184) (Glu/Lac/Urea)	120(1)	120(1)

Table 4-93 Measurement times of the samples

(1) Best-case scenario in operational phase

Sample volumes

The minimum sample volume requirement depends 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 - COOX	88	102	111
BG - ISE - COOX	112	128	148
BG - ISE - MSS - COOX	172	186	210

Table 4-94 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.

Volume limitations for sample sensors depend on which modules are installed on the system, not on which modules are activated or deactivated on the system.

The amount of sample volume required depends on the type of sample container used.

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

Table 4-95 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 4-96 Calibrations

(1) Including calibration

Product data

Electrical data

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

Classification

Protection class:	I
Overvoltage category:	II
Pollution degree:	2

Dimensions

Width:	51 cm + 20 cm (extendible AutoQC module) + 45 cm (adjustable touch screen-PC unit)
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 normal operating condition:	< 60 dB(A)
Printing noise:	< 65 dB(A)
Alarm signal noise:	< 80 dB(A)

AutoQC

Number of ampoules:	6 mats each with 20 ampoules

Printer

Type:	Thermal printer with integrated paper cutter
Resolution:	8 dots/mm
Full graphics:	864 dots/line
Printing speed:	about 20 mm/sec
Paper width:	111 mm
Paper length:	about 50 m

Radio-frequency identification (RFID)

Operating frequency:	126 kHz
Maximum RF transmission power:	< 10 mW

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 on the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inches
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 on the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inches
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 on the right side of the screen
Screen - type:	TFT-LCD-screen
Format:	10.4 inches
Resolution:	640 x 480 pixel

SN > 21000

PC:	Intel Celeron Quad Core, 1.83 GHz
Memory:	4 GB RAM
Drive:	32 GB SSD
Screen - type:	TFT-LCD Screen
Format:	10.4 inches

Touch screen-PC unit

Resolution:	640 x 480 pixel
USB Interface at the Display Unit:	1x USB 3.0

Barcode scanner

Datalogic Touch 90

Type:	TD1170-90 PS2 hand-held scanner with integrated decoder
Resolution:	0.13 mm
Reading window:	90 mm
Reading distance(1):	up to 18.5 cm
Preprogrammed code types(2):	• UPC-A
	• UPC-E
	• EAN-8
	• EAN-13
	• EAN-128
	• Interleave 2 of 5
	• Code 39
	• Code 93
	• Code 128

(1) Depending on symbol length, scan angle, printing resolution, contrast and ambient light

(2) Roche default settings applied. Further available barcode types can be programmed in accordance with the manufacturer's PS2 scanner Reference Guide. The Reference Guide is available via your Roche representative on demand.

Barcode scanner

Theoretical foundations

This chapter contains theoretical information on how calculated values are derived, and reference ranges for measured parameters. Also, you can find more information about how to assign reference and critical ranges, and correlation factors.

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Parameters and calculations

Assigning unit formats to a measured parameter

The following table lists the unit formats that you can assign to measured parameters.

Parameter	Format & unit 1 (Default unit format)	Format & unit 2	Format & unit 3
pH(1)	x.xxx [-]		
H^{+}(1)	xxx.x [nmol/L]		
PO_2	xxx.x [mmHg]	xxx.xx [kPa]	
PCO_2	xxx.x [mmHg]	xxx.xx [kPa]	
Hct	xx.x [%]	[-]	
Na^{+}	xxx.x [mmol/L]		
K^{+}	xx.xx [mmol/L]		
Ca^{2+}	x.xxx [mmol/L]	xx.xx [mg/dL]	
Cl^{-}	xxx.x [mmol/L]		
tHb	xx.xx [g/dL]	xxx.x [g/L]	xx.xx [mmol/L]
SO_2	xxx.x [%]		
Hb derivates	xxx.x [%]	x.xxx [-]	
Bilirubin	xxx [µmol/L]	xx.x [mg/dL]	
Glu	xx.xx [mmol/L]	xxx.x [mg/dL]	
Lac	xx.xx [mmol/L]	xxx.x [mg/dL]	
Urea	xx.xx [mmol/L]	xxx.x [mg/dL]	
BUN (a)	xxx.x [mg/dL]		

Table 5-1 Unit formats for measured parameters

(1) You can interchange between pH and $H^{+}$with their respective unit formats.

To assign a unit format to a measured parameter

You can only assign unit formats for measured parameters that have more than one unit format. In addition, you can interchange between pH and H^+ unit formats.

Assigning unit formats to a measured parameter (p. 119)

1 **Setup > Parameter > Miscellaneous settings**

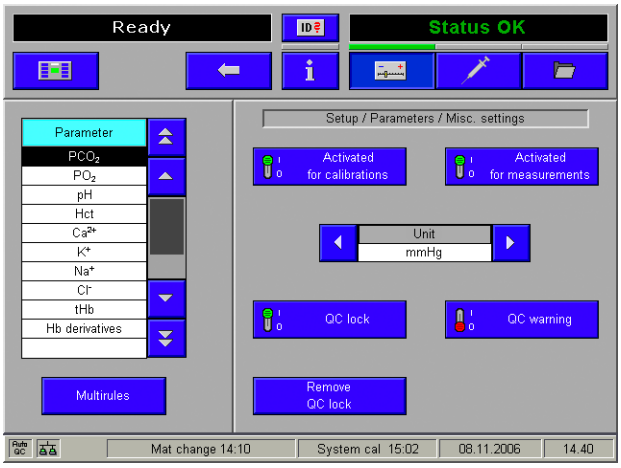

Figure 5-1 Unit formatting for measured parameters setup screen

2 Choose the parameter from the drop-down list.

3 To assign the parameter's unit format, press the ◀ and ▶ buttons on the **Unit** panel.

4 To save your new configuration, press the ⬅ button.

■

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	= 17.0911 µmol/L	
Osmolality	1 mOsm/kg	= 1 mmol/kg	

Table 5-2 Conversion table for units

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 5-2 Conversion table for units

Temperature

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

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

Standard values and ranges

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

Table 5-3 Standard values and ranges

Equations

If calculated values exceed their critical ranges, verify the validity of your results with a medical specialist before making any clinical decisions.

Default units are used for the calculation of the equations.

Calculated values that require measurement results from arterial blood are only provided for “arterial” and “capillary” blood types.

You can find all referenced publications in the bibliography at the end of this section.

H^+

Hydrogen ion concentration[1]

Unit: [nmol/L]

Equation 5-3

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

$cHCO_3^-$

Bicarbonate concentration in plasma.[1]

Unit: [mmol/L]

Equation 5-4

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

$ctCO_2(P)$

Total CO_2 concentration in plasma[1]

Unit: [mmol/L]

Equation 5-5

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

FO_2Hb

Fractional oxygen saturation[1]

Unit: [-]

Equation 5-6

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

BE

The base deviation of blood determines the titratable base of the blood. Theoretically, this is measured by titrating 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 5-8 (p. 122).

BE_{ecf}

The base deviation of extracellular fluid determines the non-respiratory components of the 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

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

SO_2

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

Unit: [%]

COOX module: **Equation 5-10**

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

SO_2(c)

No SO_2 data available:

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

Unit: [%] [7], [8]

Equation 5-11

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

At which:

Equation 5-12

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

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

Adult [7] $P_{50} = 26.7$

F1 = 1.661
F2 = 0.074
F3 = 4.172

Fetal[7] P_{50} = 21.5

F1 = 1.3632
F2 = 0.0533
F3 = 4.113

P_{50}

The PO_2 value at which 50% of the hemoglobin is saturated with oxygen. P_{50} can only be calculated if measured SO_2 is available.

Unit: [mmHg]

Equation 5-13

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

At which:

Equation 5-14

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

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

Adult[3] F3 = 4.172

Fetal[3] F3 = 4.113

ctO_2

Oxygen content is the sum of oxygen bound to hemoglobin as O_2Hb and the amount of oxygen dissolved in the plasma.[1] ctO_2 can only be calculated if measured SO_2 is available.

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 = O_2Hb

Only BG values available: X = SO_2(c)

see equation SO_2 (p. 123)

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

$ctCO_2(B)$

$ctCO_2(B)$ is the sum of the total CO_2 in plasma and red blood cells (erythrocyte fluid = ERY).[4]

Unit: [mmol/L]

Equation 5-16

$$c\mathrm{tCO_2(B)} = 0.000768 \cdot P\mathrm{CO_2} \cdot \mathrm{tHb} \cdot (1+10^{(\mathrm{pH_{ERY}}-\mathrm{pK_{ERY}})}) + c\mathrm{tCO_2(P)} \cdot (1-\frac{\mathrm{tHb}}{33.8})$$

At which:

Equation 5-17

$$\mathrm{pH_{ERY}} = 7.19 + 0.77 \cdot (\mathrm{pH}-7.4) + 0.035 \cdot (1-\frac{S\mathrm{O_2}}{100})$$

$$\mathrm{pK_{ERY}} = 6.125 - \lg(1+10^{(\mathrm{pH_{ERY}}-7.84-0.06\cdot\frac{s\mathrm{o_2}}{100})})$$

$S\mathrm{O_2}$ or if $S\mathrm{O_2}$ not available, $S\mathrm{O_2}$(c) Equation 5-10 (p. 123).

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 $P\mathrm{CO_2}$ = 40 mmHg.[3]

Unit: [pH unit]

Equation 5-18

$$\mathrm{pH_{st}} = (0.8262 - 0.01296 \cdot \mathrm{tHb} + 0.006942 \cdot \mathrm{BE}) \cdot \lg(0.025 \cdot P\mathrm{CO_2}) + \mathrm{pH}$$

$cHCO_3^-{}_{st}$

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 °C with a gas mixture having a $P\mathrm{CO_2}$ = 40 mmHg.[3]

Unit: [mmol/L]

Equation 5-19

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

PAO_2

The alveolar oxygen partial pressure is used to calculate several parameters used for oxidation and breathing.[5]

Unit: [mmHg]

Equation 5-20

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

If the result of the calculation is $PAO_2 < PO_2$, then the value PAO2 is set to the same value as PO_2. Consequently, $PACO_2$ corresponds to the measured PCO_2.

For t not equal to 37°C, PAO_2^t (p. 129)

$AaDO_2$

The alveolar arterial oxygen partial pressure gradient (PAO_2 - PaO_2) is the difference between the alveolar oxygen partial pressure, as calculated above, and the measured oxygen partial pressure of arterial blood.[5]

Unit: [mmHg]

Equation 5-21

$$AaDO_2 = PAO_2 - PaO_2$$

For t not equal to 37°C, $AaDO_2^t$ (p. 130)

a/AO_2

Arterial alveolar oxygen partial pressure ratio.[5]

Unit: [%]

Equation 5-22

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

For t not equal to 37°C, a/AO_2^t (p. 130)

$avDO_2$

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

For ctO_2, see Equation 5-17 (p. 125)

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.[5]

Unit: [%]

Equation 5-24

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

For t not equal to 37°C, RI^t (p. 130)

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).[5]

In order to determine the “shunt” (Qs/Qt), 2 independent measurements are necessary.

Both measurements have to be carried out with the same patient ID. The patient ID has to 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 has to be used as the first measurement.

You cannot calculate the shunt value with a combination of arterial and venous blood.

You can measure samples from other patients while you wait for the 2 Qs/Qt partial measurements.

Your system does not the limit the period between the 2 Qs/Qt partial measurements.

Additional information

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

- tHb, SO_2 (arterial)
- PO_2 (arterial)
- PAO_2
- ctO_2(arterial)

In order to obtain these measurement and calculation values, the blood type “arterial” has to be selected.

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

- ctO_2(mixed venous)

To compute, the blood type “mixed venous” has to be selected.

In order to be able to select the blood type, it has to 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. 124) for arterial and mixed venous blood:

For ctO_2, see Equation 5-15 (p. 124)

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.[6]

Unit: [mmol/L]

Equation 5-27

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

Blood: F5 = 0.22

Serum/plasma: F5 = 0.24

This equation is valid for pH ranges between 7.2–7.6.

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]

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

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

PCO_2^t

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

Unit: [mmHg]

Equation 5-31

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

PO_2^t

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

Unit: [mmHg]

Equation 5-32

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

PAO_2^t

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[5]

Unit: [mmHg]

Equation 5-33

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

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

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

$AaDO_2^t$

Alveolar oxygen partial pressure at a patient temperature other than 37 °C.[5]

Unit: [mmHg]

Equation 5-34

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

a/AO_2^t

Arterial alveolar oxygen partial pressure ratio at the patient's temperature.[5]

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.[5]

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.[7]

Equation 5-37

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

Default value of F = 3.00 (F = 100/MCHC [g/dL])[8]

Input range: 2.70–3.30.

This corresponds to an MCHC of 30.3 g/dL to 37 g/dL (= reference range for adults).[7]

Only measured tHb is permitted.

MCHC

Mean corpuscular hemoglobin concentration.[7]

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

Equation 5-38

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

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

BO_2

Oxygen capacity.[1]

Unit: [vol%]

Equation 5-39

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

SulfHb = 0, if SulfHb is not measured.

BE_{act}

Base deviation at actual oxygen saturation.[2]

Unit: [mmol/L]

Equation 5-40

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

Osmolality

Unit: [mOsm/kg][9]

Equation for blood, plasma, serum:

Equation 5-41

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

Equation for aqueous solution, acetate, bicarbonate:

Equation 5-42

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

Default values:

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

Explanation:

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

OER

Oxygen extraction ratio.[1]

Unit: [%]

Equation 5-43

$$\mathrm{OER} = \frac{(c\mathrm{tO}_{2(a)} - c\mathrm{tO}_{2(v)})}{c\mathrm{tO}_{2(a)}} \cdot 100$$

For ctO_2, see Equation 5-15 (p. 124)

There are different ways to calculate OER, depending on whether COOX values are available.

Heart minute volume (Q_t)

Unit: [vol%][5]

Equation 5-44

$$\mathrm{Q_t} = c\mathrm{tO}_2(\mathrm{A}) - c\mathrm{tO}_2(\mathrm{v})$$
$$= [(c\mathrm{tO}_2(\mathrm{a}) - c\mathrm{tO}_2(\mathrm{v})) + 1.39 \cdot \mathrm{tHb} \cdot (1 - \frac{S\mathrm{aO}_2}{100}) + (P\mathrm{AO}_2 - P\mathrm{aO}_2) \cdot 0.00314]$$

$S\mathrm{aO}_2$: arterial oxygen saturation fraction

P/F Index

Ratio of $\mathrm{PAO}_2/F\mathrm{IO}_2$[5]

Unit: [mmHg]

Equation 5-45

$$\mathrm{P/F\ \ Index} = \frac{P\mathrm{aO}_2}{F\mathrm{IO}_2}$$

Lactate Clearance

Lactate Clearance calculates the hourly change in percent of the measured lactate.[4], [10]

Lactate Clearance requires 2 independent measurements.

Both measurements have to be carried out with the same patient ID.

The patient ID has to be defined as an input value.

Samples from patients with other patient IDs can be measured between the 2 Qs/Qt partial measurements.

When calculating lactate clearance, either the current or the previous lactate value has to be greater than 4 mmol/L.

A minimum of 2 hours, but no more than 8 hours, has to pass between 2 lactate partial measurements.

Unit: [%]

Equation 5-46

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

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

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Reference and critical ranges

The result of laboratory tests has 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. However, reference values may need to be adapted for specific patient groups, whose physiological data are known to differ from the healthy population.

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

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

Assigning reference and critical ranges (p. 138)

(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	0.04–1.52	Whole blood heparin	% of total Hb	0.0–1.5(2)	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2160
O_2Hb	94.0–98.0	Arterial blood	%	94.0–98.0	Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 535
SO_2/O_2	94.0–98.0	Whole blood arterial	saturation %	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	11.5-16.0 (female adult) 13.5-17.8 (male adult)	Capillary blood	g/dL	11.50–17.80 unknown(3)	Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 827
Bili	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/newborn)(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	32–45 (female adult) 35–48 (male adult)	Whole blood, arterial heparin	mmHg	32.0–48.0 unknown(3)	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2137
PO_2	83–108	Whole blood arterial	mmHg	83.0–108.0	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2162
Na^+	136–145	Serum, plasma	mmol/L	136.0–145.0	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2168
K^+	3.5–5.1	Serum	mmol/L	3.50–5.10	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2164

Table 5-4 Reference/normal ranges

Parameter	Normal range	Sample matrix	Unit	Reference values (Default values, also seen on printouts)	Source
Ca^{2+}	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
Cl^-	98–107	Serum, plasma	mmol/L	98.0–107.0	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2139
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
Glu	4.1–5.6	Serum	mmol/L	4.10–5.60	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2149
Lac	< 1.8	Arterial whole blood plasma, bed rest	mmol/L	0.20–1.80	Lothar Thomas, Labor und Diagnose, 8. Auflage, p. 336
Urea/BUN	2.1–7.1	Serum	mmol/L	2.10–7.10	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th edition 2012, p. 2173

Table 5-4 Reference/normal ranges

(1) Upper limit refers to nonsmokers.

(2) Default value rounded to one tenth place value.

(3) Refers to lower limit for females to upper limit of males if the gender is unknown.

(4) For "fetal/newborn", the proposed reference range refers to the lower level of 0-1 day old full-term to the 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 adult reference ranges. You cannot edit reference ranges outside of the measuring range. However, you can set new reference values for age-specific reference ranges. (*To assign reference and critical ranges* (p. 138))

(5) Refers to the lower limit for Caucasian females to the upper limit of Caucasian males.

The availability of parameters depends on the configuration:

• **cobas b** 221<2> system	BG, pH, COOX, Bili
• **cobas b** 221<4> system	BG, pH, ISE, Hct, COOX, Bili
• **cobas b** 221<6> system	BG, pH, ISE, Hct, MSS, COOX, Bili

Critical ranges

Normal values depend, among 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 approximated and need special attention if used for therapy decision. By default, critical values are not contained in the default setting. Laboratories have to adjust the critical ranges to fulfill their own requirements.

Assigning reference and critical ranges

To assign reference and critical ranges

If you change reference and/or critical ranges for a parameter, you have to change these ranges for all patient settings.

To set all reference ranges to their default values, press the **Set default ranges** button.

New **cobas b** 221 systems do not provide default critical ranges. When you assign critical ranges for a parameter for the first time, they become the default critical ranges for this parameter. When you press the **Set default ranges** button, the critical ranges are set to the first critical ranges that you have assigned for each parameter.

1 **Setup > Parameters > Ref./crit. ranges**

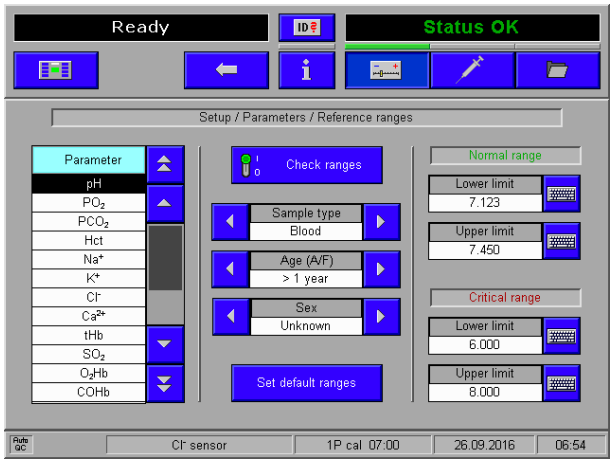

Figure 5-2 Reference/critical ranges setup screen

2 On the left panel of the screen, choose the parameter that you want to assign your reference and/or critical ranges to.

3 To choose the patient and sample settings for which your reference and critical ranges are valid, press the ◀ and ▶ buttons on the middle panel of the screen.

4 To enter your reference or critical ranges, press the ⌨ button.

5 Enter your new reference or critical ranges using the numeric keyboard box that appears on the screen. To apply them, press the ↵ button.

6 To save your new reference and/or critical ranges, press the ← button.

7 To confirm that they have been entered correctly, press the **Ref./crit. ranges** button. Search for your new reference and/or critical ranges by selecting the correct parameter and patients settings for which they are valid.

■

Monitoring reference and critical ranges on measurement reports

To activate/deactivate reference and critical ranges monitoring on measurement reports

1 **Setup > Parameters > Ref./crit. ranges**

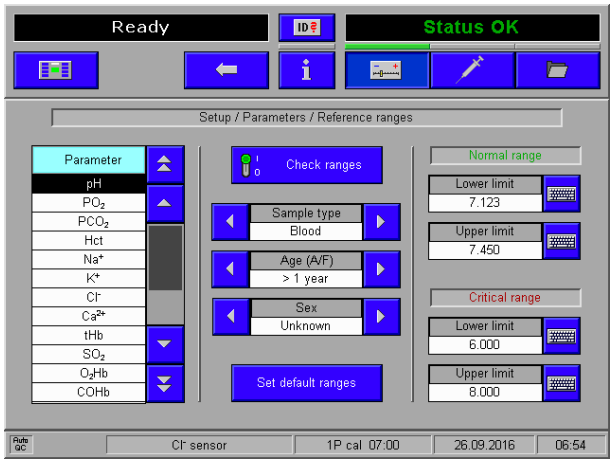

Figure 5-3 Reference/critical ranges setup screen

2 To activate this feature, make sure that the **Check ranges** switch is turned on.

Measurement reports display status messages to indicate which parameters are inside or outside of the reference and critical ranges.

(-) / (+)	Measurement value is outside (below (-)/above(+)) the normal range, within the critical range.
(--) / (++)	Measurement value is outside (below(--)/above(++)) the normal range, and outside the critical range.

3 To deactivate it, ensure that the **Check ranges** switch is turned off.

■

Assigning a correlation factor to a parameter

Correlation factors are used to align results for a parameter between different analytical systems or methods.

Changes to correlation factors have no effect on QC measurements.

To set all reference and critical ranges to their default values, press the **Set default value** button.

To assign a correlation factor to a parameter

1 **Setup > Parameters > Correlations**

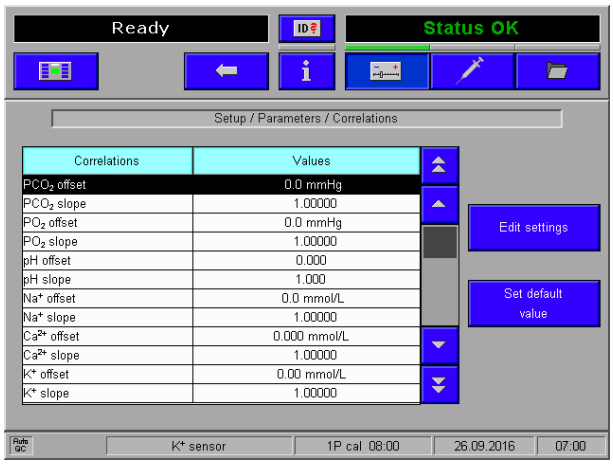

Figure 5-4 Correlations setup screen

2 To edit the offset and/or slope for a parameter, use the drop-down list to choose the parameter and the offset and/or slope setting that you want to assign to your correlation factor. Then, press **Edit settings** button.

3 Enter your correlation factor using the numeric keyboard box that appears on the screen. To apply it, press the button.

4 To save your new correlation factor, press the button.

5 To confirm that it has been entered correctly, press the **Correlations** button. Search for your new correlation factor by parameter and offset or slope setting in the drop-down list.

■

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Measurement

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

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Preanalytics

Sample collection

Inappropriate collecting and handling of samples of human origin may result in infection

Inappropriate collecting and/or handling samples of human origin may lead to the transmission of blood or urine borne pathogens.

- Follow standard laboratory practices.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, to prevent direct contact.
- If a sample of human origin is spilled, wipe it up immediately and apply a disinfectant.
- If a sample of human origin comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; CLSI document M29-A4; Approved Guidelines (2014), Vol. 34, No. 8.

Sample acquisition

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

Incorrect patient results due to inappropriate sample collection practices

Squeezing the puncture site adds tissue fluid to the blood sample and may lead to the premature onset of clotting despite sufficient heparinization of the sample collection containers. This may lead to errors and discrepancies in the measurement values.

- Do not squeeze the puncture site before collecting your blood sample.
- Use the correct sample container for your measurement. Roche recommends using the Roche MICROSAMPLER PROTECT for blood collection.

Clinical and Laboratory Standards Institute. Procedures for the collection of arterial blood specimens; CLSI document H11-A4; Approved Standard (2004), Vol. 24, No. 28.

Anticoagulants

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

Sample collection especially for tHb, SO_2 and Hct measurement

Whole blood, especially for the analysis of tHb, SO_2 and Hct, has to 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 2 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, gently rotate the syringe. The up and down motion of the disk or ball inside the syringe cylinder ensures consistent mixing.

Clinical and Laboratory Standards Institute. Blood gas and pH related measurements, CLSI document C46-A2; Approved Guideline (2009), Vol. 29 No. 8.

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

Glucose

Patient preparation: 12 hour fasting period for blood glucose. Optimal postprandial blood sampling is 1 hour 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 has to be centrifuged immediately and the excess serum or plasma has to 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 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 has to be centrifuged immediately in a cooled centrifuge and the excess serum or plasma has to 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 has to 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, specifically for bilirubin measurements

WARNING

Bilirubin sample collection

- Treat whole blood samples as light-sensitive samples:
  - Protect sample containers from light during transport.
  - Avoid leaving sample containers in direct sunlight.
- Samples should be analyzed immediately after collection.
- Switch off phototherapy light before and during sampling from neonatal patients.

Sample containers

NOTICE

We recommend using the sample containers offered by Roche.

A BS2 Blood Sampler
B Capillary tubes
C Roche MICROSAMPLER PROTECT

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 minimizes 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 high PO_2 values are expected, the sample should be analyzed as quickly as possible after the sampling.

WARNING

Using non-heparinized syringes or syringes with liquid heparin may lead to inaccurate patient results

Non-heparinized syringes and syringes filled with liquid heparin, whose volume exceeds the sample volume, does not prevent blood clotting in the syringe. Blood clots compromise the integrity of the blood sample, which may lead to inaccurate patient results.

- Use syringes containing balanced heparin salts. Roche recommends using the Roche MICROSAMPLER PROTECT for blood collection.

Accessories (p. 373)

Capillary tubes

Depending on system configuration, capillary tubes have to have a minimum volume of 115 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 system.

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 for 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.

Accessories (p. 373)

Sample collection container accessories

The Clot Catcher is not suitable for measurements in “Aspiration from syringe” mode.

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.

For additional information, refer to the accompanying package insert:

- Clot Catcher

Sample handling

If you are not able to measure the sample immediately you have the following options:

If the sampling device is glass:

- Keep the sample at room temperature, and measure it within 15 minutes.
- Cool the sample in an ice bath, and measure it within 60 minutes. Be careful not to freeze the sample.

If the sampling device is plastic:

- Keep it at room temperature and measure the sample within 30 minutes.

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.

WARNING

Air bubbles may lead to incorrect results

Air bubbles in samples deteriorate electrode performance and the integrity of patient samples, which may lead to incorrect patient results. In addition, it may lead to a loss of sample.

- ▶ Remove all air bubbles from sample collection containers immediately after collecting samples.

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 gently rotating. Properly label the samples, following the standard documentation procedure.

Whole blood samples have to be thoroughly mixed immediately before measuring in order to have an even distribution of red blood cells and plasma.

To ensure optimum mixing, roll the syringe in your hands, invert and roll it again. Repeat this for 30 seconds. If there are sedimented red blood cells in the syringe, repeat the mixing procedure for 1-2 minutes.

Glass capillary tubes

- Samples that are measured within 15 minutes may be retained at room temperature.
- If you are unable to measure samples within 15 minutes, place them temporarily in ice water. Complete the measurement within 30 minutes.
- Samples with a PO_2 level above 200 mmHg (26 kPa) should be collected in a glass container if the measurement cannot be performed within 15 minutes.

Plastic capillary tubes

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

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 has to 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 have to be recentrifuged 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

Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. Effects of concentrations exceeding these recommendations have not been characterized.

Interference study: A study was carried out to evaluate the influence of substances that could possibly interfere with the measurement of the following parameters: BG/ISE/MSS and COOX [(1)].

Find the updated list of potential interfering substances for BG/ISE/MSS and COOX parameters in the following sections:

- *Substances with effect on whole blood samples for pH, Hct, ISE* (p. 152)
- *Substances with effect on whole blood samples for MSS Cassette* (p. 154)
- *Substances with effect on whole blood samples for Hb derivatives and bilirubin* (p. 155)

Substances with effect on 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
	100 mg/dL	pH	7.87	-0.94 ± 0.02
		Ca^{2+}	1.09 mmol/L	0.31 ± 0.02
	200 mg/100mL	pH	7.65	-1.08 ± 0.03
		Ca^{2+}	1.08 mmol/L	0.20 ± 0.01
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
		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

Table 6-1 Substances with effect on pH, Hct, ISE

(1) The study was designed in accordance with the CLSI: "Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition", EP07-A2, Appendix B and was performed with whole blood.

Substance	Concentration of the substance	Parameter	Parameter concentration	Effect of the substance
	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(1)	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
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

Table 6-1 Substances with effect on pH, Hct, ISE

Substance	Concentration of the substance	Parameter	Parameter concentration	Effect of the substance
	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 6-1 Substances with effect on pH, Hct, ISE

(1) All other sample types use direct ISE measurement.

Substances with effect on whole blood samples for MSS Cassette

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
	200 mg/100 mL	Lac	2.90 mmol/L	-0.81 ± 0.13
Uric acid	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 6-2 Substances with effect on MSS Cassette

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

Substance	Concentration of the substance	Parameter	Parameter concentration	Effect of the substance
Cyanomet 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	0.00 ± 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_2Hb	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
	67.50 mg/100mL	tHb	12.93 g/dL	0.58 +0.03/-0.04
		SO_2	99.72%	-6.68 ± 0.07
		O_2Hb	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_2Hb	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_2Hb	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

Table 6-3 Substances with effect on Hb derivatives and bilirubin

Interferences

Substance	Concentration of the substance	Parameter	Parameter concentration	Effect of the substance
		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
Methylene 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_2Hb	*	*
		COHb	*	*
		MetHb	*	*
		HHb	*	*
		Bilirubin	*	*
	3.0 mg/100mL	tHb	11.40 g/dL	-0.84 ± 0.09
		SO_2	*	*
		O_2Hb	*	*
		COHb	*	*
		MetHb	*	*
		HHb	*	*
		Bilirubin	*	*
	2.0 mg/100mL	tHb	11.56 g/dL	-0.42 ± 0.07
		SO_2	*	*
		O_2Hb	*	*
		COHb	*	*
		MetHb	*	*
		HHb	*	*
		Bilirubin	*	*
	1.0 mg/100mL	SO_2	99.70%	0.00 ± 0.01
		O_2Hb	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

Table 6-3 Substances with effect on Hb derivatives and bilirubin

Substance	Concentration of the substance	Parameter	Parameter concentration	Effect of the substance
		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 6-3 Substances with effect on Hb derivatives and bilirubin

Limitations of clinical analysis

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

- *Interferences* (p. 152)
- *tHb/SO_2* (p. 159)
- *Metabolites* (p. 159)

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. Concerning the **cobas b** 221 system, an attempt was made to identify or evaluate these possible influences. Since it is not possible to check all medication or substances, you 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 more measurements in your own laboratory, if necessary.

WARNING

Incorrect patient results due to mismatch between sample type and sample type selected as an input value

If the sample type selected as an input value for a measurement does not match your measured sample type, incorrect patient results may be generated. This may lead to errors in diagnosis, posing danger to the patient.

- Define sample type as a mandatory input value.
  Mandatory input (p. 173)
- During the measurement, make sure that the sample type selected as an input value on the system matches your measured sample type.
- After each measurement, confirm that the sample type on your measurement report matches your measured sample type.

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 before taking a blood sample.

Blood gas

A whole blood sample is preferred for performing these measurements. Contaminating the blood sample with air significantly distorts the measurements. The notes and restrictions in the section **Preanalytics** should be observed in any case.(1)

Preanalytics (p. 145)

tHb/SO_2

The **cobas b** 221 system tHb measurement is sensitive to the sedimentation rate of red blood cells, particularly if the sedimentation rate is 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.

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.

Preanalytics (p. 145)

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. Glucose and lactate measurements feature an additional integrated sensor that largely eliminates any possible occurring interferences endogenously (e.g. uric acid) or exogenously (e.g. actetylsalicylic acid).

To achieve the highest possible perfection in interference compensation, the compensation sensor with the actual biosensors is adjusted daily as part of the system calibration. The influence of the most important known interferents was determined during development.

Substances with effect on whole blood samples for MSS Cassette (p. 154)

Hemoglobin derivatives and bilirubin

Contrast agents, such as indocyanine and methylene blue, and other substances, such as fat emulsions, may cause considerable light absorption and scattering during hemoglobin derivative and bilirubin measurements. If the system detects the presence of these substances above a specific concentration, the system does not display hemoglobin derivative and bilirubin results.

Substances with effect on whole blood samples for Hb derivatives and bilirubin (p. 155)

(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).

Configuring measurement input values

You can assign input values that can be edited during a measurement. This feature allows you to easily change measurement-specific information, such as patient ID.

To configure measurement input values

1 **Setup > Display & reports > Measurement > Input values**

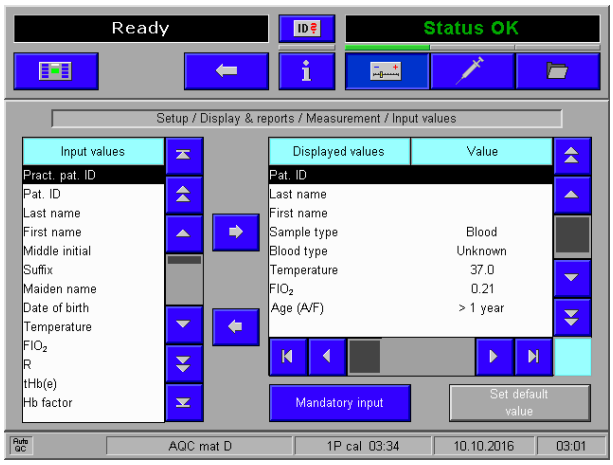


Figure 6-2 Measurement input values setup screen

2 To add an input value, choose it from the left panel of the screen and press the button.

3 To delete an input value, choose it from the list on the right panel of the screen and press the button.

4 To assign an input value as a mandatory input, choose it from the list on the right panel of the screen and press the **Mandatory input** button.

The input value is shown in red. Mandatory input values have to be entered for each measurement.

5 To set a default value for an input value, choose it from the list on the right panel of the screen and press the **Set default value** button.

This feature is not available for all input values. If it is available for your selected input value, the screen displays a numeric keyboard box or check box.

6 Enter your new default value in the numeric keyboard box or select it in the check box. To apply it, press the button.

7 To save your new configurations, press the button.

■

Configuring the measurement results screen

You can assign which parameters are displayed on the measurement results screen. This feature allows you to quickly display and record specific parameters for all measurements.

▶ To add or remove parameters on the measurement results screen

1 **Setup > Display & reports > Measurement > Measurement display**

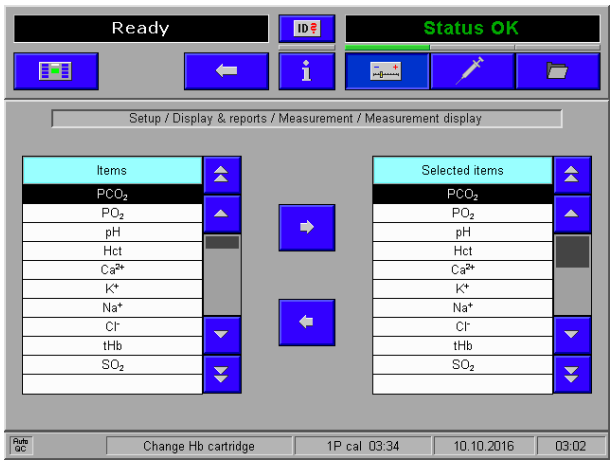


Figure 6-3 Measurement results setup screen

2 To add a parameter, choose it from the **Items** list and press the button.

3 To remove a parameter, choose it from the **Selected items** list and press the button.

4 To save your new configuration, press the button.

■

Creating and configuring measurement printout reports

You can create and configure measurement printout reports to display specific measured and calculated parameters, reference ranges, and input values.

▶ To create a measurement printout report

1 **Setup > Display & reports > Measurement > Measurement report**

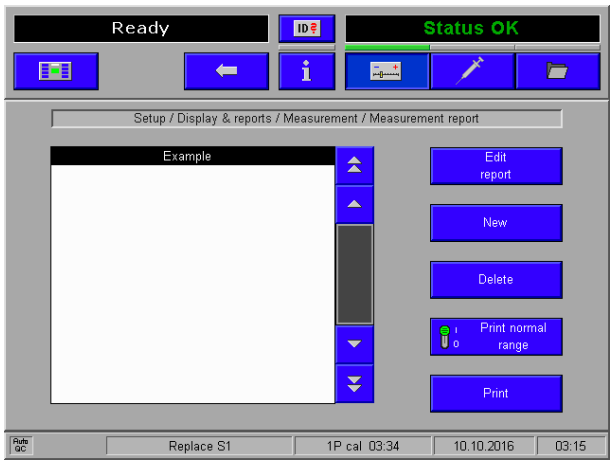


Figure 6-4 Measurement printout report setup screen

2 Press the **New** button.

The screen displays an alphanumeric keyboard box.

3 Enter the name of the new report using the alphanumeric keyboard box. To save the report name, press the button.

■

To configure a measurement printout report

1 **Setup > Display & reports > Measurement > Measurement report**

2 Choose the report from the list.

3 To add or remove an item, press the **Edit report** button.

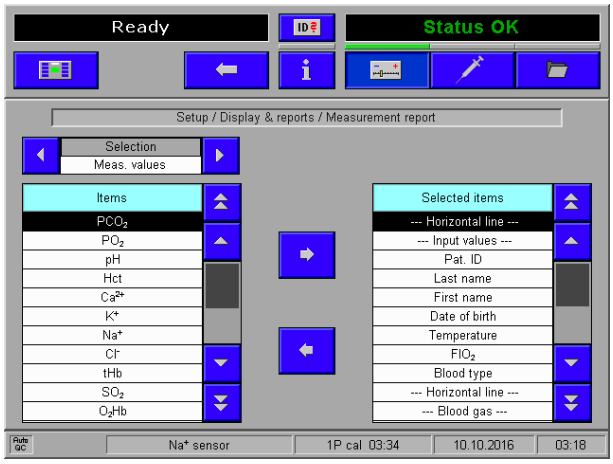


Figure 6-5 Editing measurement printout report screen

To create a more understandable report, create sections using header titles and separate sections using horizontal or blank lines. In addition, group parameters and input values based on common characteristics.

4 To choose which type of item to add, press the and buttons on the **Selection** panel.

5 To add an item, choose it in the **Items** list and press the button.

6 To remove an item, choose it in the **Selected items** list and press the button.

7 To save your new configuration, press the button.

8 To print the new report, choose the report from the list and press the **Print** button.

■

To add normal ranges to the measurement printout report

1 **Setup > Display & reports > Measurement > Measurement report**

2 Choose the report from the list.

3 Turn on the **Print normal range** switch.

To deactivate it, turn off the switch.

■

To delete a measurement printout report

1 **Setup > Display & reports > Measurement > Measurement report**

2 Press the **Delete** button.

The report is removed from the list.

■

Measuring procedure

Before starting a measurement, all parameters have to be ready for measurement.

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

Configuring measurement input values (p. 160)

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

Syringe mode

Using non-heparinized syringes or syringes with liquid heparin may lead to inaccurate patient results

WARNING

Non-heparinized syringes and syringes filled with liquid heparin, whose volume exceeds the sample volume, does not prevent blood clotting in the syringe. Blood clots compromise the integrity of the blood sample, which may lead to inaccurate patient results.

- Use syringes containing balanced heparin salts. Roche recommends using the Roche MICROSAMPLER PROTECT for blood collection.

1 Securely attach the syringe to the fill port.

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

Figure 6-6

When using syringes with an excentric tapered tip, make sure that the tapered tip is in the lower position when attaching the syringe to the fill port.

Figure 6-7 (p. 165)

Figure 6-7

2 The following screen appears:

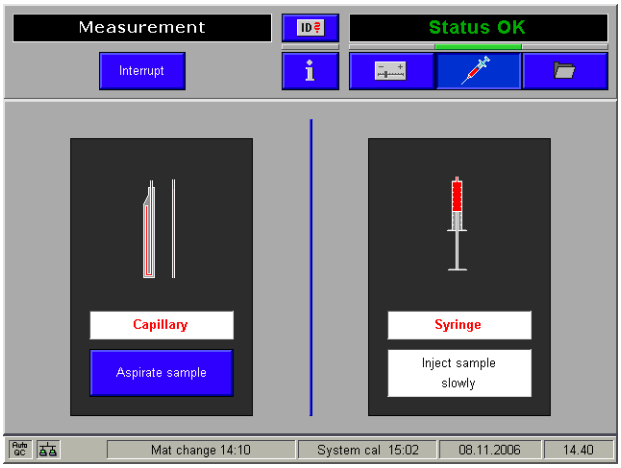


Figure 6-8

3 Inject the sample slowly until the signal sounds.

WARNING

Selecting capillary mode functions during a syringe measurement may result in infection

Pressing software buttons related to capillary mode functions while measuring in syringe mode may lead to the sample leaking from the fill port. This may result in the transmission of blood and urine borne pathogens. In addition, it may lead to a loss of sample.

- Do not press the **Aspirate sample** button while measuring in syringe mode.
- If a sample of human origin is spilled, wipe it up immediately and apply a disinfectant.
- If a sample of human origin comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

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

5 The measurement starts.

■

Capillary measurement

NOTICE

Using inappropriate capillary tubes may result in damage to the analyzer

Performing capillary measurement with inappropriate capillary tubes may damage the analyzer.

- Roche recommends using its plastic capillary tubes for blood collection. If you use glass capillary tubes from other manufacturers, ensure that they have heat-polished ends.

Available accessories and consumables (p. 367)

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 is backlit in green.

Figure 6-9

2 Press the **Aspirate sample** button.

Figure 6-8 (p. 165)

3 Detach the capillaries or the Roche MICROSAMPLER PROTECT after the message “Remove sample container” appears.

4 The measurement starts.

■

Configuring measurement settings

Various measurement settings are available to help you to quickly and effectively prepare measurements, and view and organize your results.

Activating and measuring in Aspirate from syringe mode

▶ To activate Aspirate from syringe mode

In **Aspirate from syringe** mode, 1 mL syringes cannot be used. In addition, you have to use syringes with a minimum fill height of 15 mm.

1 **Setup > Instrument > Switches**

2 Turn on the **Activate aspirate from syringe** switch button.

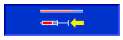
3 To save your new configuration, press the button.

in the step content and in the figure titleThe and buttons are displayed on the top right-hand corner of the Analyzer mode screen.

Figure 6-10 Analyzer mode screen when **Aspirate from syringe** mode is activated

■

To measure in Aspirate from syringe mode

1 To measure in capillary mode, press the  button.

To measure in syringe mode, press the button.

2 Attach the sample container securely to the fill port.

When the sample container position is correct, the T&D disk lights up in green.

Figure 6-11

3 Press the **Aspirate sample** button.

4 When the **Remove sample container** message appears, carefully detach the sample container from the T&D disk.

The data input screen is displayed on the screen.

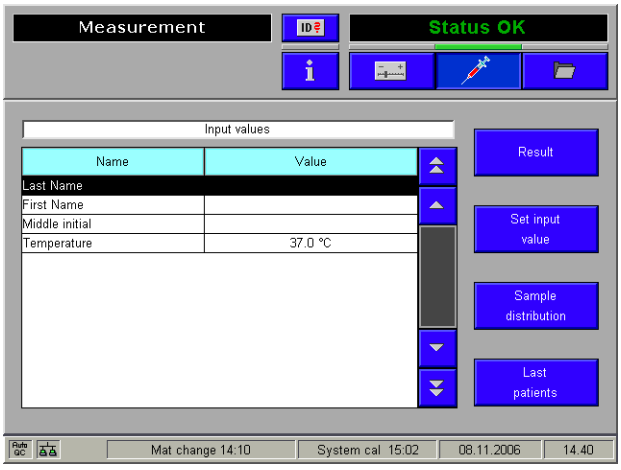


Figure 6-12 Data input screen

■

Defining the default measurement mode

To define the default measurement mode

1 **Setup > Instrument > Switches**

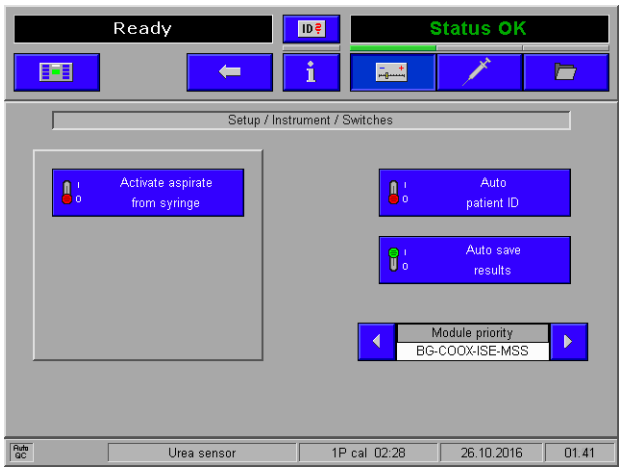


Figure 6-13 Instrument switches setup screen

2 Turn on the **Activate aspirate from syringe** switch button.

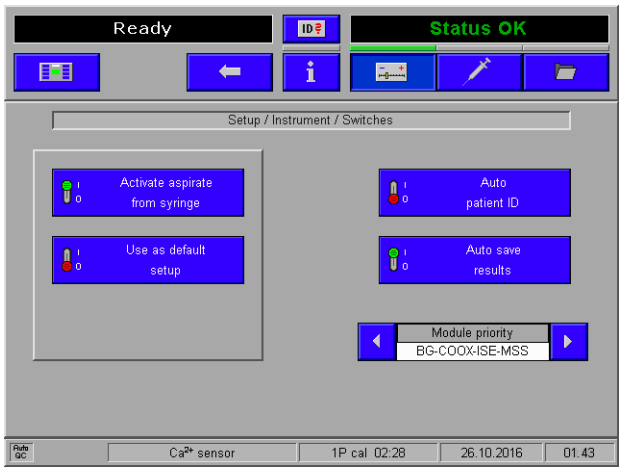


Figure 6-14 Instrument switches setup screen

3 Turn on the **Use as default setup** switch button

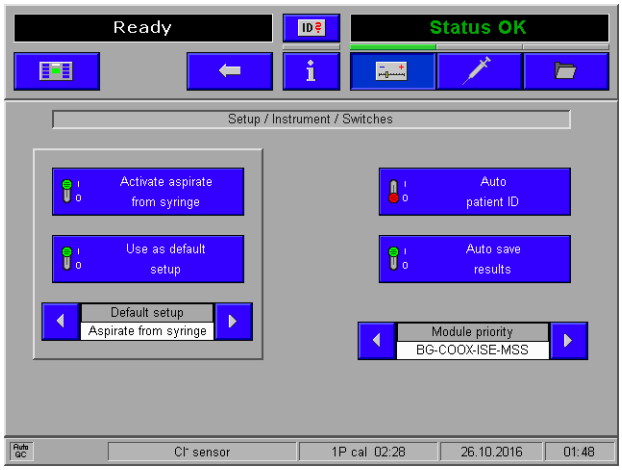


Figure 6-15 Instrument switches setup screen

4 To change the default measurement mode, press the ◀ and ▶ buttons on the **Default setup** panel.

5 To save your new configuration, press the ⬅ button.

■

Automatically assigning patient IDs

▶ To automatically assign patient IDs to measurements

1 **Setup** > **Instrument** > **Switches**

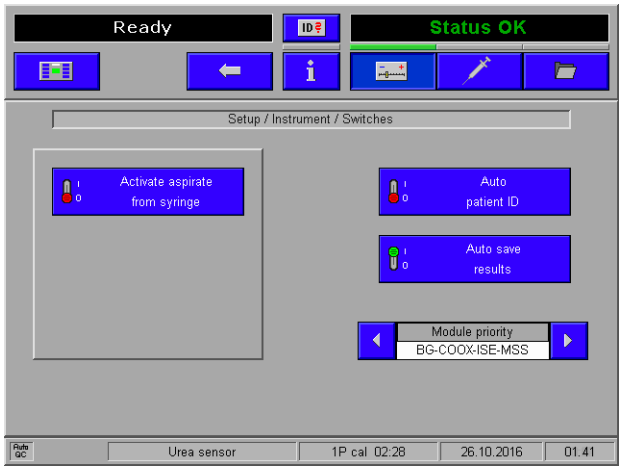


Figure 6-16 Instrument switches setup screen

2 Turn on the **Auto patient ID** switch button.

3 To save your new configuration, press the ⬅ button.

■

Automatically saving measurement results to the Data Manager

▶ To automatically save measurement results to the Data Manager

1 **Setup > Instrument > Switches**

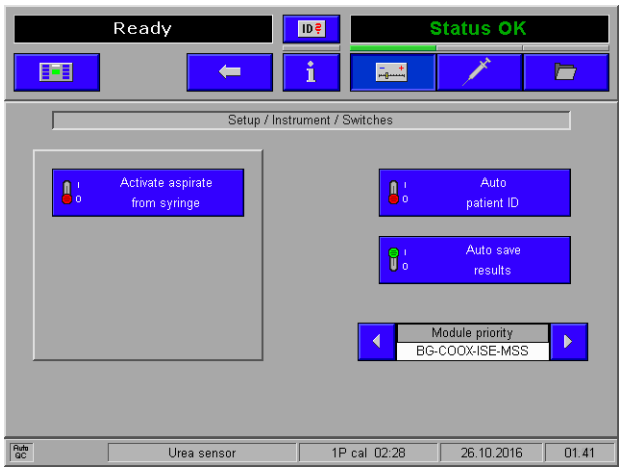


Figure 6-17 Instrument switches setup screen

2 Turn on the **Auto save results** switch button.

3 To save your new configuration, press the button.

■

Defining sample distribution priority during a measurement

You can change the sample distribution so that the COOX or the ISE module receives the sample before the other module. The sample distribution order of the BG and MSS modules cannot be changed.

This feature is useful when you have a small sample quantity and would prefer parameter results from the COOX or the ISE module.

To prioritize the COOX module, set the module priority to BG-COOX-ISE-MSS.

To prioritize the ISE module, set the module priority to BG-ISE-COOX-MSS.

To define sample measurement priority during a measurement

1 **Setup > Instrument > Switches**

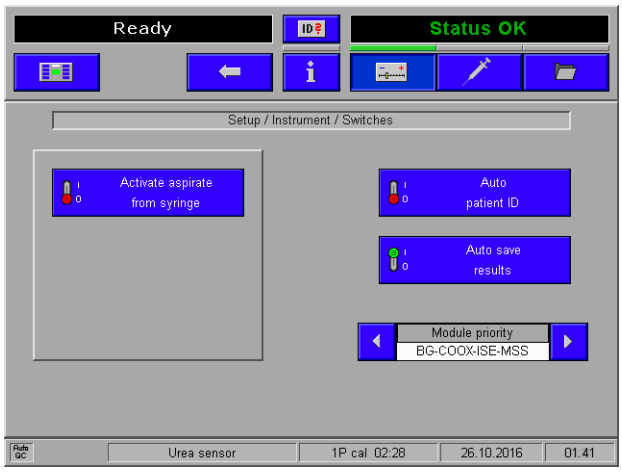


Figure 6-18 Instrument switches setup screen

2 To change the module priority, press the ◀ and ▶ buttons on the **Module priority** panel.

3 To save your new configuration, press the ← button.

■

Data input

During measurement, various patient, operator, and sample-specific data may be entered.

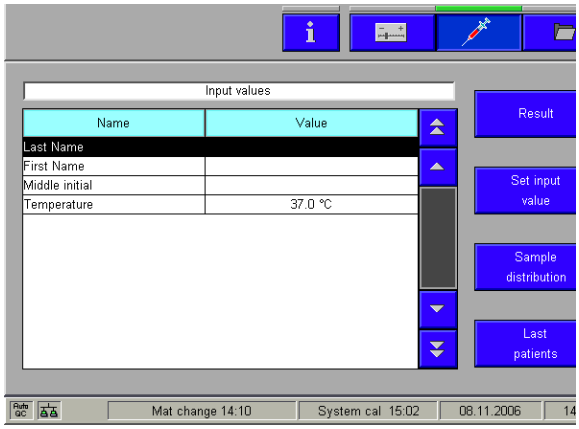


Figure 6-19

Use the buttons ▲/▼ to select an entry.

Press **Set input value** to enter data or change existing data.

A keyboard appears on the screen — enter the “Patient ID”.

If the patient is in the **cobas b** 221 system database, patient-specific data appears in the respective lines.

Scanning in patient and user data is possible with a barcode scanner.

WARNING

Incorrect results due to errors in scanning barcodes

Errors in scanning barcodes may lead to patient-specific information being incorrectly entered into the system. This leads to incorrect results, which may lead to incorrect patient diagnoses and endanger patient lives.

- Immediately after scanning a barcode, check that the displayed patient information on the system matches the registered patient information.

If the patient is not yet registered, press **New patient** and patient related data are 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 has to be made in these fields; otherwise, the measurement values are discarded.

If the **Pat ID** field is defined as an input field, a value must be provided. By entering a value in the **Pat ID** field all patient-related fields are considered to be confirmed, even if these fields are defined as mandatory.

If other mandatory fields are defined these must be confirmed, otherwise the measurement values are discarded.

If a standard value is defined as a mandatory input, it has to be confirmed or edited, if necessary.

Sample distribution

This function can be used to monitor the sample distribution during measurement (see below).

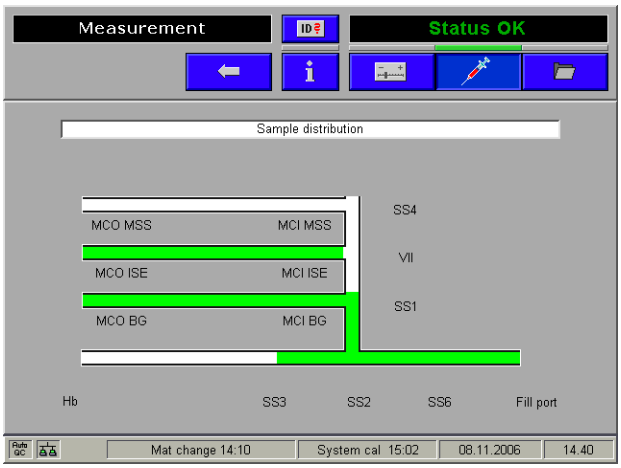


Figure 6-20

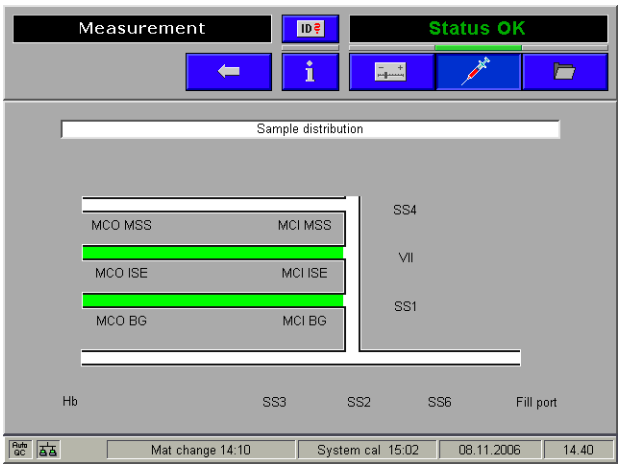


Figure 6-21

Result

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

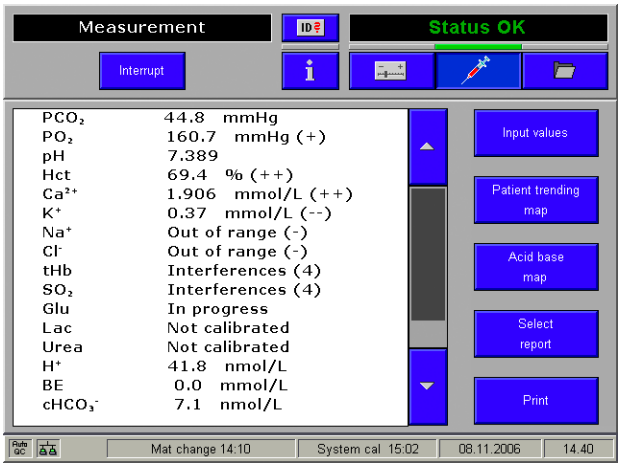


Figure 6-22

[Input values] A subsequent correction of the input values is still possible after the measurement by pressing **Input values**.

[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] You can use patient trending maps to follow the results of individual parameters (measurement and calculation values) of a patient over a specific period. You can create and print trending maps after a measurement, or at any time in the Data Manager.

Patient trending requires measurements from at least 2 days.

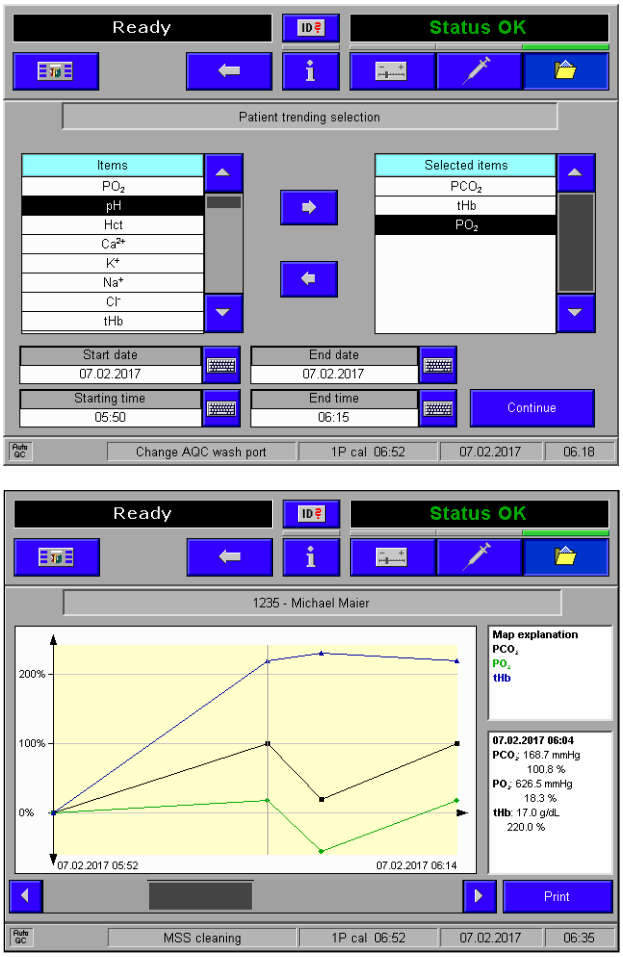


Figure 6-23 Creating and viewing patient trending maps

You can define your start and end dates and times. You can view patient trending maps for a maximum of 4 parameters at once.

The first measurement in the defined time range is set as the reference data point for the trending map. If you choose to create trending maps for only one parameter, the trending map displays the data in absolute and adjusted units. When you choose to create trending maps for 2 or more parameters, the trending map displays the data as a percentage of the first measurement in the defined time range.

[Acid base map] If PCO_2 and pH-measurements are available, the diagram can be displayed and printed.

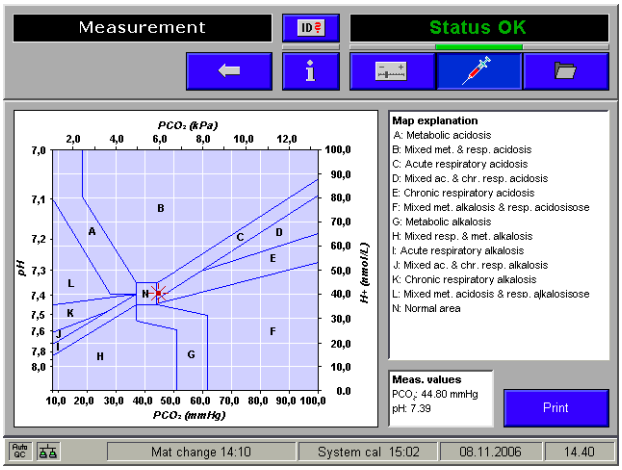


Figure 6-24

There is also the possibility of displaying and printing an acid base trend diagram in the Data Manager.

Last patients

The last patients whose samples have been measured are listed here.

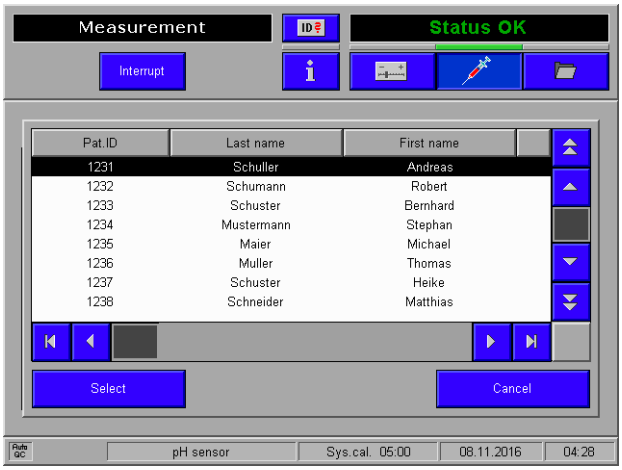


Figure 6-25

Defining parameter units

You can define selected parameters to display their values in their available units.

To define a parameter's units

1 **Setup > Instrument > Other units**

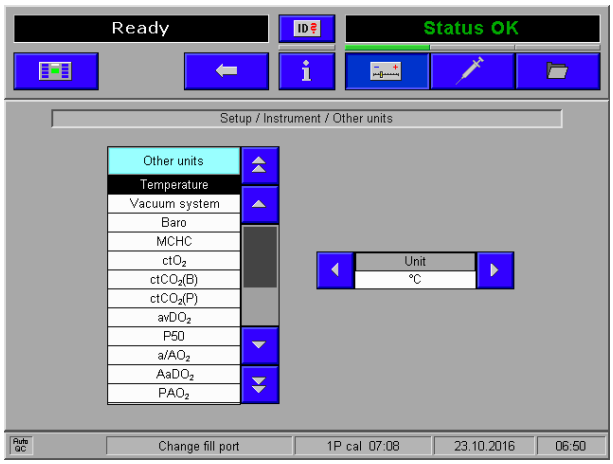


Figure 6-26 Parameter units setup screen

2 Choose the parameter from the drop-down list.

3 To define the parameter's units, press the ◀ and ▶ buttons on the **Unit** panel.

4 To save your new configuration, press the ← button.

■

Importing and exporting system configurations

You can import and export your system configurations, such as measurement printout reports, and security settings, onto a storage device. This feature can be useful to share configurations between **cobas b** 221 systems, or to backup system configurations, in case they have to be later loaded onto a system.

If you have a system with an SN > 3000, use a USB storage device to export and import your system configurations.

If the USB storage medium or the floppy disk drive is full, write-protected, or is disconnected, an “Error exporting data” message is displayed.

You can also use a floppy disk if you have issues using your USB storage device, and your system has a floppy disk drive (SN < 21000).

To export system configurations

1 **Setup > Load & save > Export**

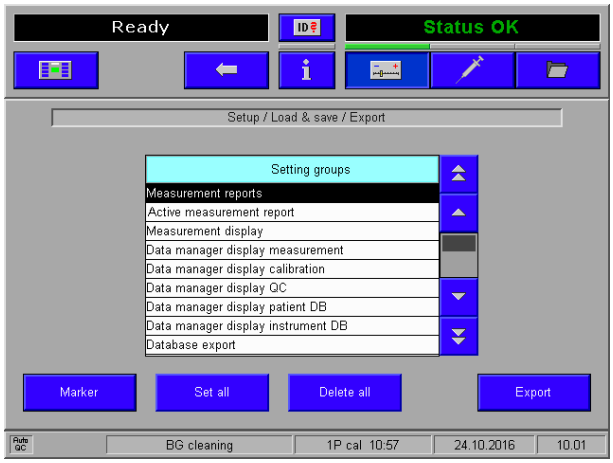


Figure 6-27 Setup screen for exporting system configurations

2 To add a system configuration for export, use the drop-down list to choose it. Then, press the **Marker** button.

System configurations for export are highlighted in yellow.

3 To select all system configurations for export, press the **Set all** button.

4 To remove all system configurations for export, press the **Delete all** button.

5 To export your system configurations, connect your storage device onto the system and press the **Export** button.

■

To import system configurations

1 **Setup > Load & save > Import**

2 Connect your storage device onto the system.

3 To add a system configuration for import, use the drop-down list to choose it. Then, press the **Marker** button.

System configurations for import are highlighted in yellow.

4 To select all system configurations for import, press the **Set all** button.

5 To remove all system configurations for import, press the **Delete all** button.

6 To import your system configurations, press the **Import** button.

■

System modes

Economy mode

When the system remains inactive for an extended time, activating the economy mode reduces solution consumption and preserves the electrodes' condition.

You can automatically activate economy mode for regular daily and weekly intervals. In addition, you can manually activate economy mode as needed.

To manually activate economy mode

1 **System > Utilities > Manual economy mode**

To deactivate manual economy mode, press the **Exit** button.

■

To automatically activate daily economy mode

1 **Setup > Times & intervals > Economy mode timing**

2 Turn on the switch button on the **Daily** panel.

3 To change the start and stop times, press the button.

4 Enter your new start and stop times using the numeric keyboard box that appears on the screen. To apply your new start and stop times, press the button.

5 To save your daily economy mode settings, press the button.

■

To automatically activate weekly economy mode

1 **Setup > Times & intervals > Economy mode timing**

2 Turn on the switch button on the Weekly panel.

3 To change the start and stop days, press the and buttons.

4 To change the start and stop times, press the button.

5 Enter your new start and stop times using the numeric keyboard box that appears on the screen. To apply your new start and stop times, press the button.

6 To save your weekly economy mode settings, press the button.

■

POC mode

The POC mode is a user interface simplified to suit the needs of POC users, with restricted user rights.

Before the POC mode is activated, the newly created POC user profile in profile management has to be assigned to a “POC user” user profile.

Managing security settings (p. 261)

To change the POC mode settings, press **Setup > Security > Instrument functions**.

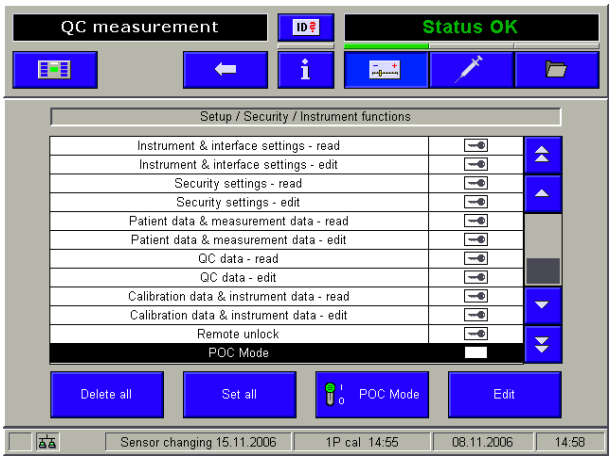


Figure 6-28 POC mode

In the POC mode, there is no possibility for interrupting any actions started. Operators registered as POC users are able to call up the functions offered on the “Ready” screen, all the functions in Info mode and if available, the video sequences.

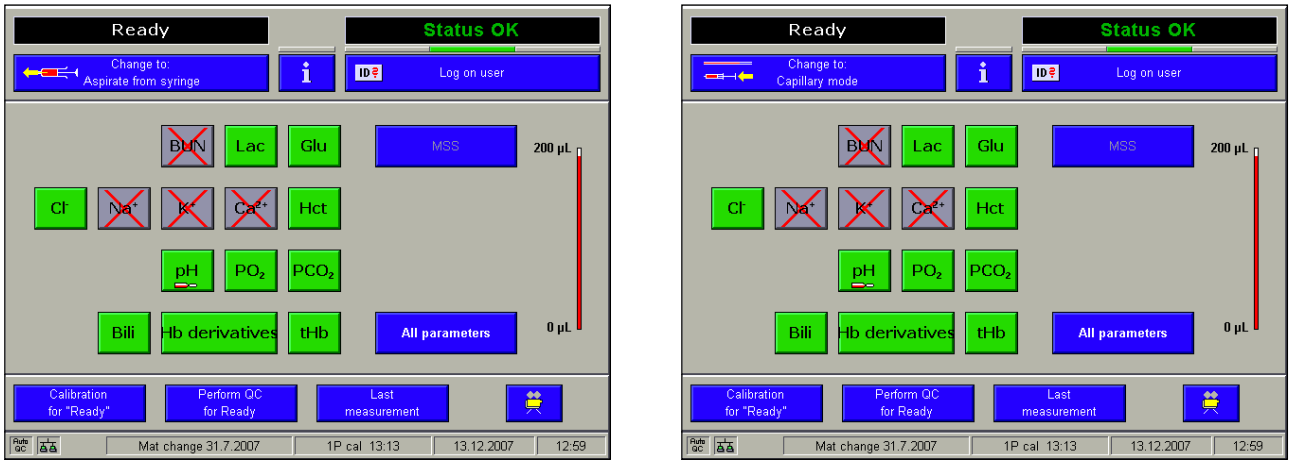


Figure 6-29 Ready screen in POC mode

Quality control

For safety reasons, quality control measurements have to be carried out daily. In this chapter, all steps are described that are necessary for a successful QC measurement.

In this chapter *Chapter* 7

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Quality control – general

WARNING

Failure to follow QC protocols or ignoring QC results may lead to incorrect patient results

Failure to follow QC protocols or ignoring QC results may lead to incorrect patient results, which may endanger patient lives.

- Follow quality control practices according to local regulations.
- Perform a minimum of one QC measurement each day. In addition, alternate through the 3 levels of available QC materials over the course of 3 days. For example, perform a QC measurement on day 1 with a level 1 QC material, on day 2 with a level 2 QC material and on day 3 with a level 3 QC material.
- Perform QC tests on 3 levels after each of these actions:
  - Replacement of MSS cassette, electrode, fluid pack, or rinse solution
  - Start-up of the system
  - After performing proficiency testing
- If QC results do not match their expected results, perform the QC measurements again. If QC results still do not to match their expected results, refer to the QC troubleshooting section (*QC troubleshooting* (p. 222)). If the error persists, contact your Roche Service representative.
- Do not use the system for diagnostic purposes until QC results match their expected results.

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

- For longer than 25 minutes during the first 24 hours of the sensor's lifetime
- For longer than 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. 330)

If the MSS sensor wetting is not performed within the above mentioned times, glucose and lactate parameters may become sensitive to the wrong enzymes. If this occurs, perform QC measurements at each of the 3 levels to maintain sensor accuracy.

The system automatically locks AUTO-TROL materials. If no AUTO-TROL materials are installed, the system locks COMBITROL materials.

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.

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 system (switched off more than 24 hours).

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

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

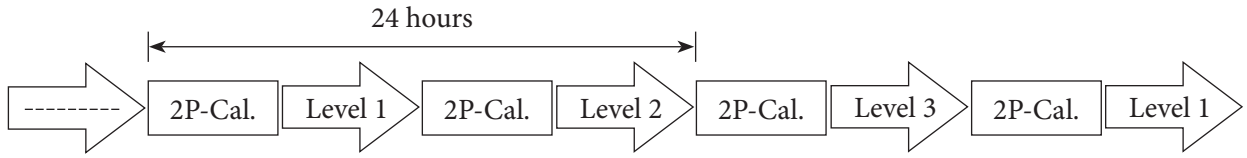


Figure 7-1

The automatic system calibration includes a complete 2P calibration.

Complete at least 2 quality control tests on different levels once daily or more often in accordance with local regulations.

Run quality control tests before you measure.

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 materials are recommended:

- 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 PO_2, 2SD = 12 mmHg, 1SD = 6).

The QC measurement results within the target value range ± 2SD are acceptable.

If QC measurement results fall outside the target value range ± 3SD, the parameter has to be locked

Important information concerning the analysis of QC measurement results (p. 187).

QC measurement results that are greater than the target value ± 2SD, but less than the target value ± 3SD, cause a QC warning and have to be treated accordingly.

Important information concerning the analysis of QC measurement results (p. 187).

Important information concerning the analysis of QC measurement results

Make sure that Multirules rules 1 and 2 are activated and a QC lock was assigned to the parameters.

Multirules (p. 212)
QC consequences (p. 216)

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

- **Measured value is within the target value range ± 2SD**

  The parameter is acceptable.

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

- **Measured value is outside the target value range ± 3SD**

  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.

Remove the QC lock (p. 217)

- **Measured value is larger than target value ± 2SD, but smaller than target value ± 3SD**

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

  Quality control - general (p. 185)

  You have to 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.

QC measurements (p. 251)

The analysis can be automated by activating additional multirules.

Multirules (p. 212)

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

To remove the QC lock, replace the electrode or contact your Roche Service representative.

Material setup

Take the lot, expiration date, sample type, and target values (ranges) as well as the corresponding barcodes from the package insert included in the recommended QC material.

The QC material must be defined before the QC measurement.

Your barcode scanner helps you enter the required information.

Setup > QC material > QC material

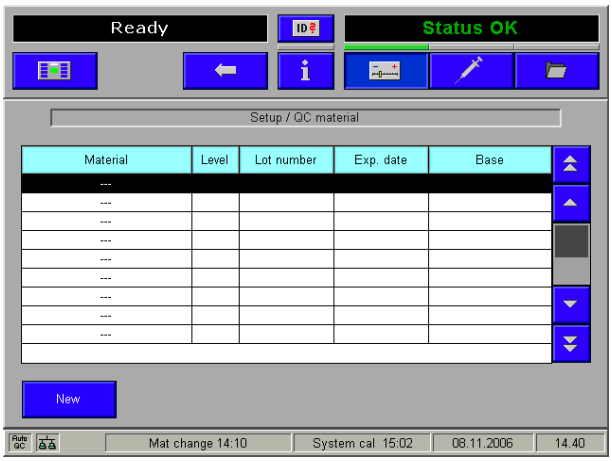


Figure 7-2

To define a new QC material, read in the material code with the barcode scanner from the packing insert **or** press **New** and enter the information manually.

The material code contains the information for the material, the proper level, lot number, expiration date, and sample type.

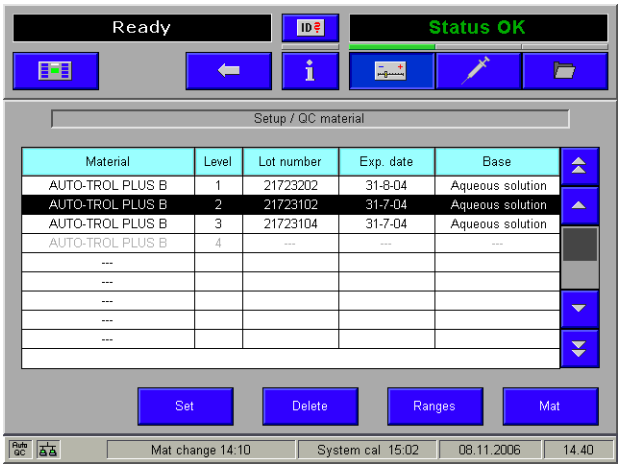


Figure 7-3

Press **Ranges** and read in the additional barcodes for the target values.

The **cobas b** 221 system automatically assigns the target values.

If no barcode scanner is available, the target values can also be entered manually.

Press **Set** to edit a previously defined material/level combination.

Unused materials can be deleted by selecting the material and pressing the **Delete** button at the bottom of the panel.

You can delete a specific material by selecting the material, choosing the **Mat** button, selecting the material and then choosing the **Delete** button.

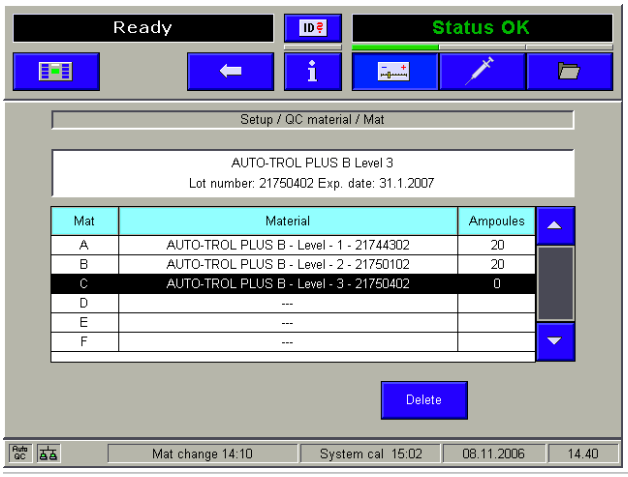


Figure 7-4

Material assignment – AutoQC materials

The selected AutoQC material must be assigned before the AutoQC measurement.

Select the material and level to be assigned and select **Mat**.

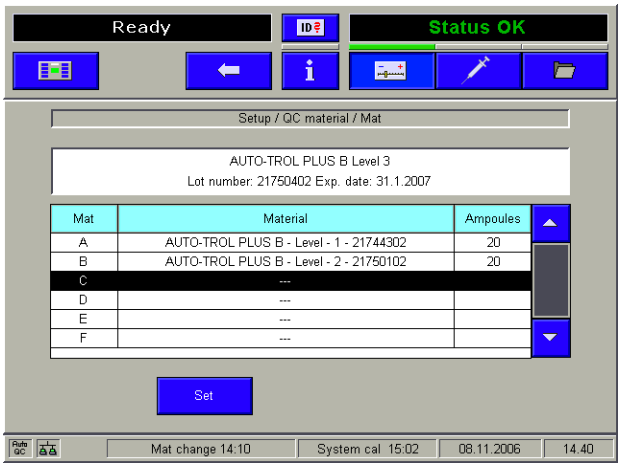


Figure 7-5

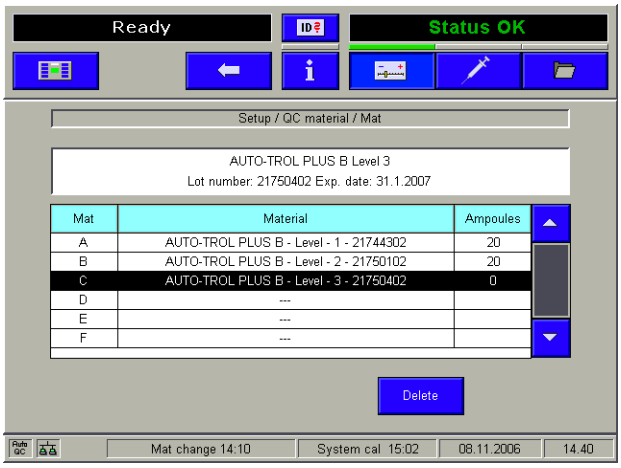


Figure 7-6

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

1 Starting with the top level of the Analyzer mode, insert the ampoule mats in the ampoule holder as follows:

Open the AutoQC drawer.

The following screen appears:

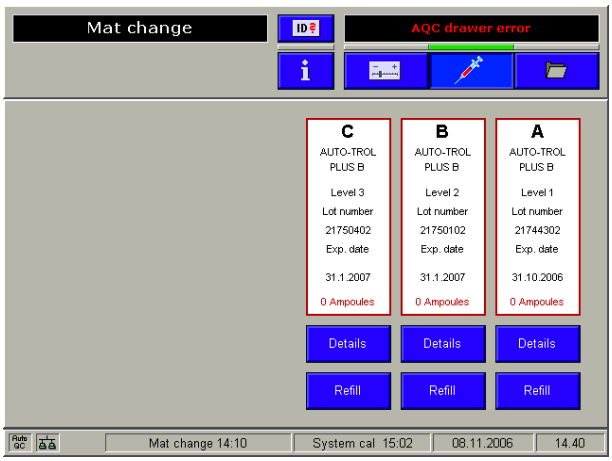


Figure 7-7

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 7-8 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:

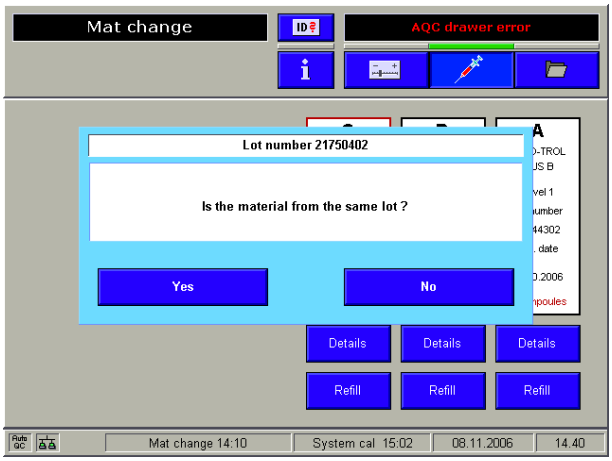


Figure 7-9

6 Press **Yes** – if the mat is replaced with a new mat of the same lot. The number of the ampoules is set to 20.

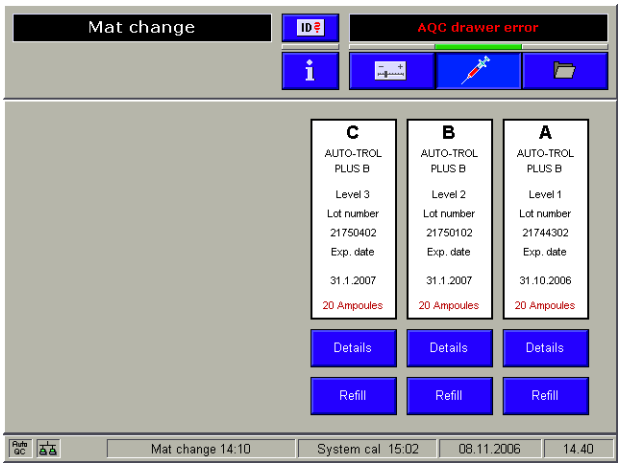


Figure 7-10

7 In case the mats are not 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).

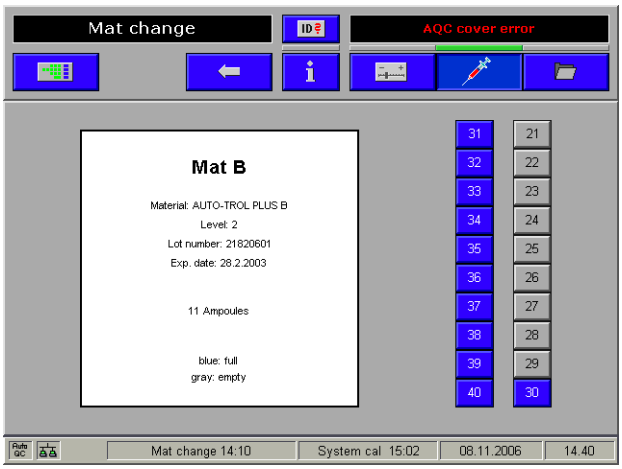


Figure 7-11

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 message window.

Setup > Times & intervals > QC timing

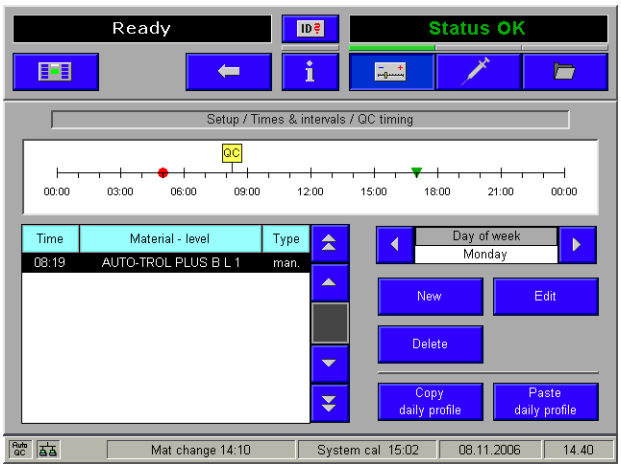


Figure 7-12

A small marker (“QC”) on the time scale indicates the defined start time(s), and for better coordination with the QC timing, another small 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) are 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 is entered for the new day of the week.

Change lot (applies only to AutoQC measurements)

You can use the change lot feature to replace an existing AutoQC material with a new AutoQC material without changing your QC timing settings.

First, define the new material. Then, 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. **Setup > QC material > QC material**
2. Read in the material code from the package insert using the barcode scanner or press **New** and manually enter the information.
3. Press **Ranges**.
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 no longer contains 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 is assigned to a mat (A-F).

Press this button to store the assignment.

8. Press the button to change to the Analyzer mode.
9. Open 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. Make sure that 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.

15. Next, press the following buttons: **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.

You may have to scroll up or down to select additional lot numbers from the list of QC materials.

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

To monitor the on board time of new QC materials or QC materials already in use, press **Setup > QC material > Control - on board time**.

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

QC material (p. 105)

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

To install a new QC material using the QC setup wizard

1 Place the system in the top level of the Analyzer mode.

You have to have sufficient user privileges to use the QC setup wizard.

Managing security settings (p. 261)

2 Open the AQC drawer.

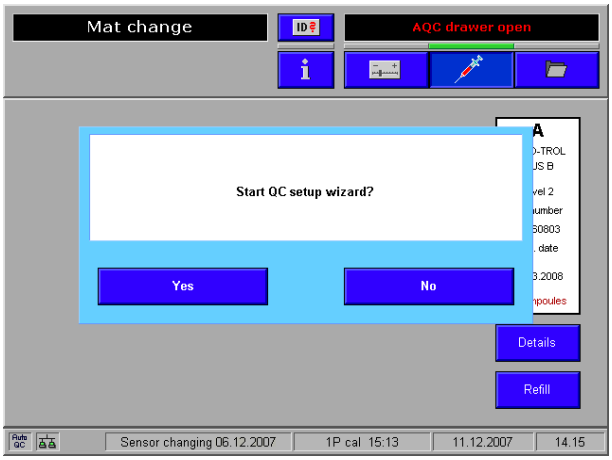


Figure 7-13

3 Press **Yes**.

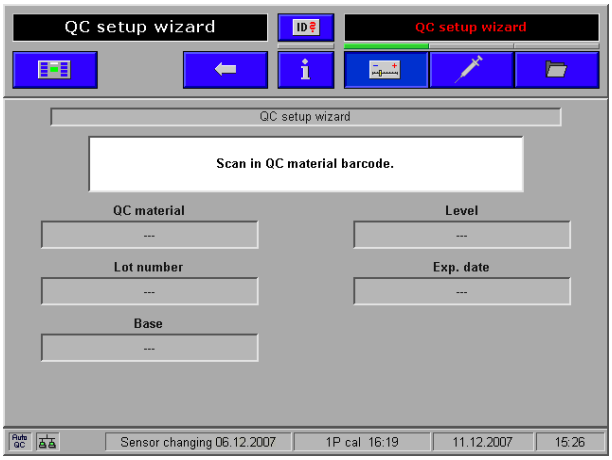


Figure 7-14

To complete the empty fields, follow the instructions on the screen.

■

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 **Continue**, you can choose between 2 options:

- Carry out lot change automatically

Change lot (applies only to AutoQC measurements) (p. 195)

- Do not carry out lot change

	Saves changes made in the dialog.
	Exits the QC setup wizard.

Scanning ranges

New QC material

The following screen appears:

Figure 7-15

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 PLUS B

The following QC materials do not meet these requirements:

- COMBITROL PLUS
- COMBITROL PLUS B

Figure 7-16

If the QC material is not AutoQC-compatible, it will still be installed successfully. In this case, press **Exit** to exit the setup wizard.

Read in additional material	You can scan more QC materials. Figure 7-15 (p. 200)

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.

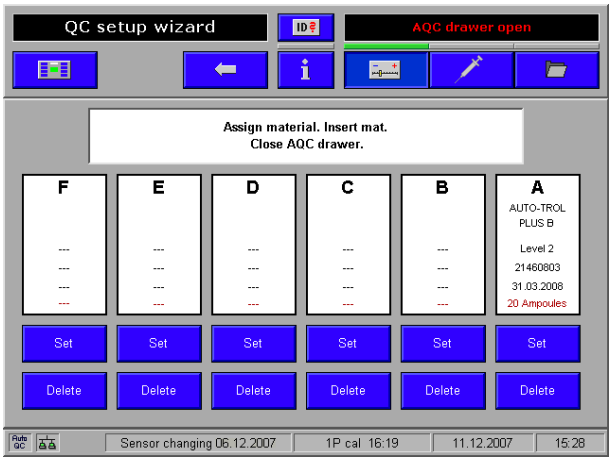


Figure 7-17

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 7-18

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

1 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.

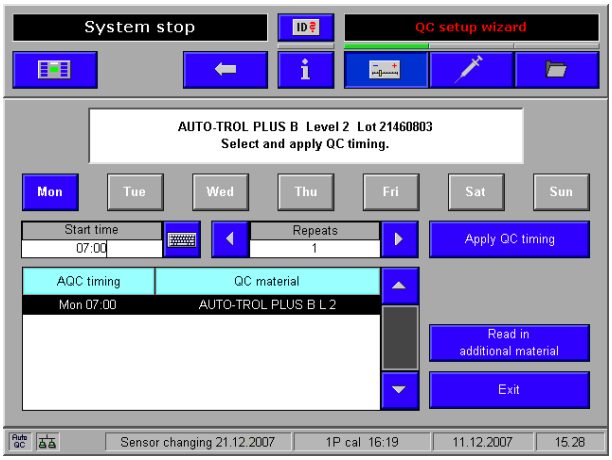


Figure 7-19

All previously defined AQC times are shown in the list.

2 Using the **Mon** - **Sun** buttons, select the day of the week when the AQC measurement is to be performed.

3 Enter starting time and change the number of "Repeats".

4 Press **Apply QC timing**. The entries are saved.

If, when entering the start time, there is an overlap with another QC measurement, a corresponding message is displayed.

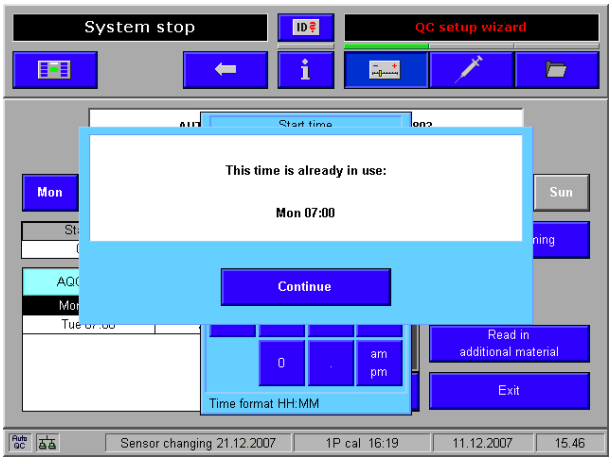


Figure 7-20

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

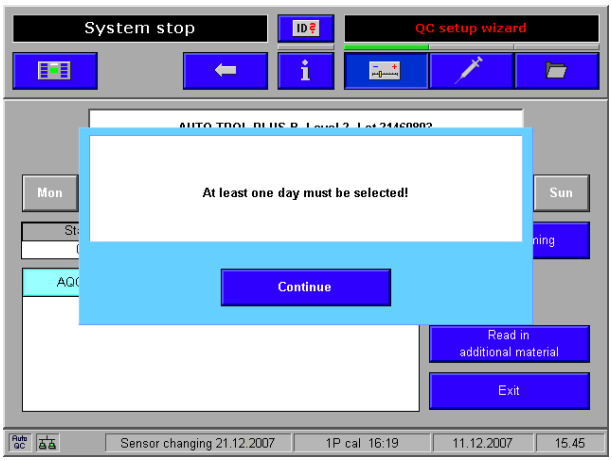


Figure 7-21

Press one of these buttons to exit the QC setup wizard and save the input.

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

Press this button to save the input and switch the display to the section for assigning mats.

Checking for AutoQC compatibility (p. 201)

Other options for starting the QC setup wizard:

Follow the instructions on the screen.

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 system (switched off more than 24 hours).

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

General QC concept (p. 186)

Manual QC measurement

1 Press the **QC measurement** button from the top level of the Analyzer mode:

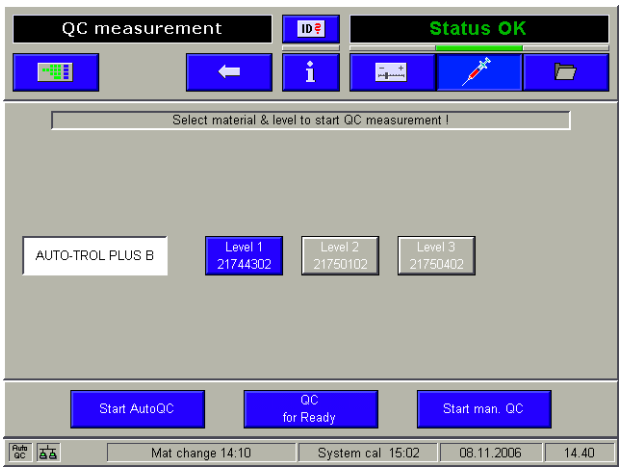


Figure 7-22

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.

Personal injury due to contact with glass splinters from broken QC ampoules

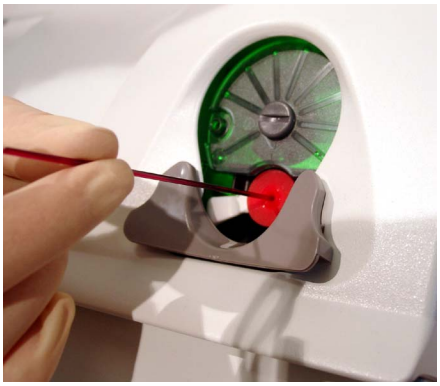
Glass splinters created when breaking QC ampoules may result in personal injury

- When you break QC ampoules, wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, and safety glasses, and use several layers of gauze.

- Aspirate manual QC materials within 1 minute after opening the ampoule. Roche recommends using an ampoule adapter to measure.

Available accessories and consumables (p. 367)

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 7-23 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 you do not reject the results, they are printed and automatically saved in the QC database.

Data Manager (p. 248)

■

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 PLUS B) and the selected level (e.g. Level 1).

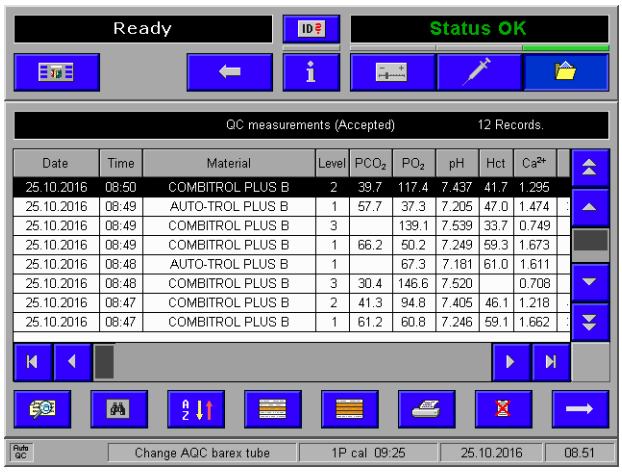
Start the AutoQC measurement by pressing **Start AutoQC**.

Creating a Levey-Jennings graph

Levey-Jennings graphs show the progress QC measurement results, in order to help you find errors in how the system measures.

To create a Levey-Jennings graph

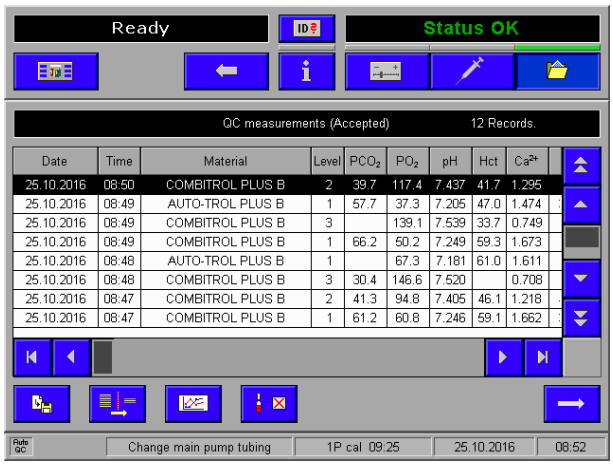
1 Data manager > QC data



Date	Time	Material	Level	PCO_2	PO_2	pH	Hct	Ca^{2+}
25.10.2016	08:50	COMBITROL PLUS B	2	39.7	117.4	7.437	41.7	1.295
25.10.2016	08:49	AUTO-TROL PLUS B	1	57.7	37.3	7.205	47.0	1.474
25.10.2016	08:49	COMBITROL PLUS B	3		139.1	7.539	33.7	0.749
25.10.2016	08:49	COMBITROL PLUS B	1	66.2	50.2	7.249	59.3	1.673
25.10.2016	08:48	AUTO-TROL PLUS B	1		67.3	7.181	61.0	1.611
25.10.2016	08:48	COMBITROL PLUS B	3	30.4	146.6	7.520		0.708
25.10.2016	08:47	COMBITROL PLUS B	2	41.3	94.8	7.405	46.1	1.218
25.10.2016	08:47	COMBITROL PLUS B	1	61.2	60.8	7.246	59.1	1.662

Figure 7-24 QC measurements database in Data Manager

2 To view more options, press the → button.



Date	Time	Material	Level	PCO_2	PO_2	pH	Hct	Ca^{2+}
25.10.2016	08:50	COMBITROL PLUS B	2	39.7	117.4	7.437	41.7	1.295
25.10.2016	08:49	AUTO-TROL PLUS B	1	57.7	37.3	7.205	47.0	1.474
25.10.2016	08:49	COMBITROL PLUS B	3		139.1	7.539	33.7	0.749
25.10.2016	08:49	COMBITROL PLUS B	1	66.2	50.2	7.249	59.3	1.673
25.10.2016	08:48	AUTO-TROL PLUS B	1		67.3	7.181	61.0	1.611
25.10.2016	08:48	COMBITROL PLUS B	3	30.4	146.6	7.520		0.708
25.10.2016	08:47	COMBITROL PLUS B	2	41.3	94.8	7.405	46.1	1.218
25.10.2016	08:47	COMBITROL PLUS B	1	61.2	60.8	7.246	59.1	1.662

Figure 7-25 More options screen in the QC measurements database

3 To filter for QC measurements, press the button.

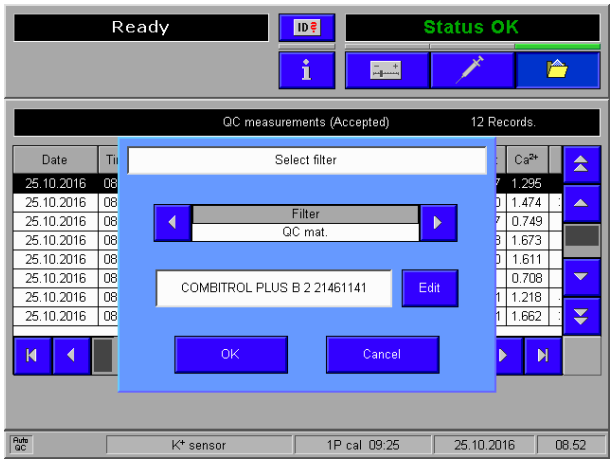


Figure 7-26 Filter the QC measurements database for results from specific QC materials

A dialog box is displayed on the screen.

4 Press the and buttons on the Filter panel in the dialog box until **QC mat.** is displayed.

5 To filter for QC measurements from a specific QC material, press the **Edit** button.

Figure 7-27 List of available QC materials to create Levey-Jennings graph

A drop-down list with all of the QC materials used for the QC measurements in the database is displayed.

6 Choose the QC material that you want to create a Levey-Jennings graph for from the drop-down list. Press the **OK** button.

7 To add QC measurements to the Levey-Jennings graph, choose it from the drop-down list and press the button. To undo the selection, press the button again.

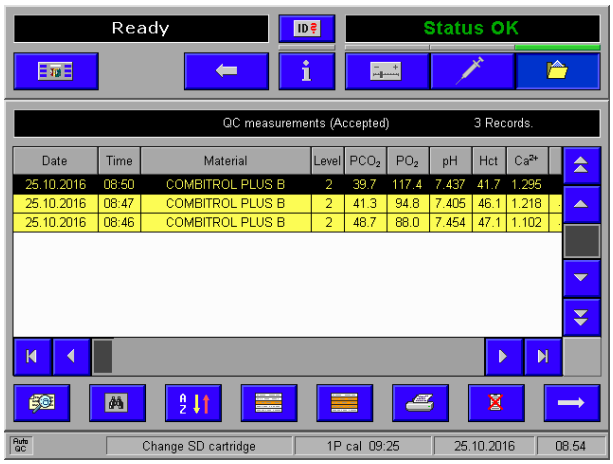


Figure 7-28 List of available QC measurements to create a Levey-Jennings graph

Added QC measurements are highlighted in yellow.

8 To create a Levey-Jennings graph, press the button.

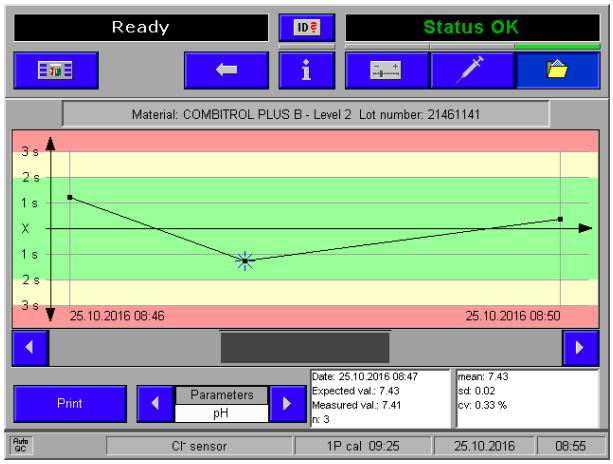
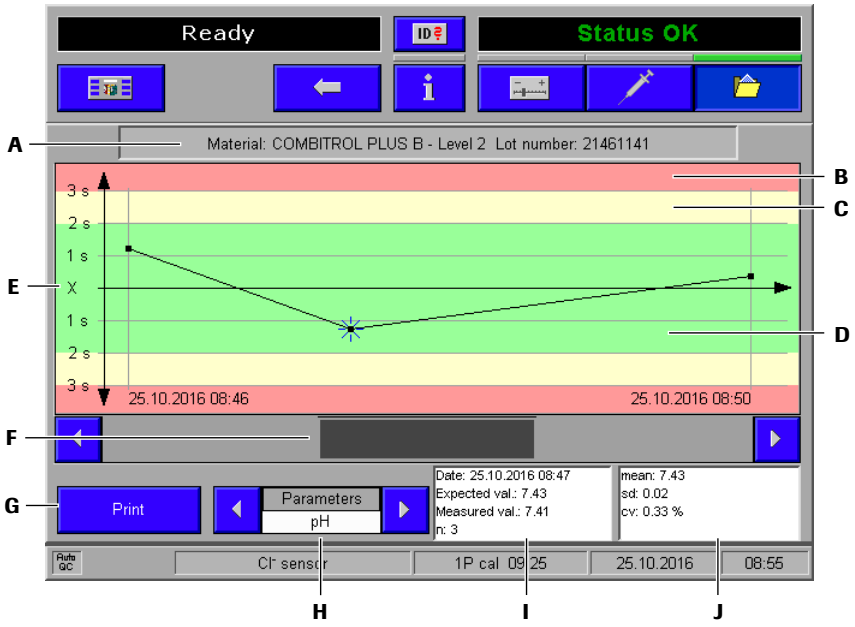


Figure 7-29 Levey-Jennings graph

■

Interpreting a Levey-Jennings graph



A QC material information
B Red range
C Yellow range
D Green range
E Mean value
F Scroll bar
G Print button
H Parameter panel
I QC measurement information
J QC measurement statistics

Figure 7-30 Levey-Jennings graph

Figure caption	Caption description	Levey-Jennings graph information
A	QC material information	Provides the name, level, and lot number of the QC material
B	Green range	Range between -2 SD and +2 SD
C	Yellow range	Range between -2 and -3 SD and +2 and +3 SD
D	Red range	Range below -3 SD and above +3 SD
E	Mean value	Mean value defined by the QC material
F	Scroll bar	Selects data points on the graph
G	Print button	Prints the graph
H	Parameter panel	Selects which parameter to graph
I	QC measurement information	Provides the time, and measured and expected values of the QC measurement
J	QC measurement statistics	Provides the mean value for all QC measurements shown on the graph, and the standard deviation and coefficient of variation of the QC measurement

Table 7-3 Levey-Jennings graph information

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 with a suitable control material (e.g. COMBITROL PLUS B, AUTO-TROL PLUS B).

The Multirule procedures produce the best results when 3 QC measurements with randomly selected level are completed per series (time between 2 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. To check the settings, **Setup > Parameters > Miscellaneous settings > Multirules**.

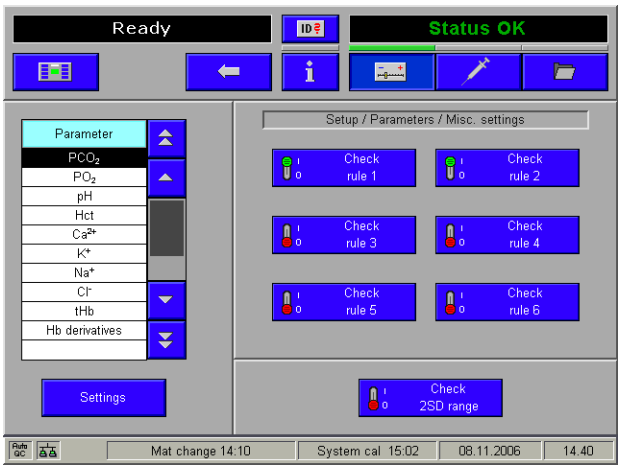


Figure 7-31

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”.

If you activate the **Check 2SD range** switch, all multirules are automatically deactivated.

If Rule 1 is violated for a parameter, this results in a QC warning. The parameter is not QC locked.

(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

Series	time between 2 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.	$(2 \text{ of } 3)_{2s}$	2 of 3 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 7-4 Multirules

The Multirule process is applied after each individual measurement. Multirules are only applied to the corresponding control material (e.g. COMBITROL PLUS B).

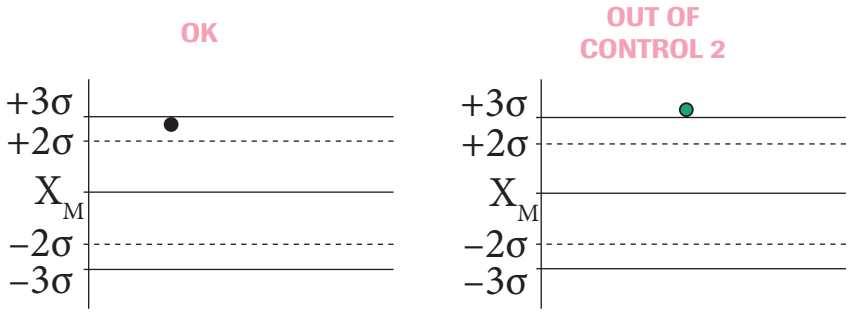
Possible Multirule combinations

NOTE

The activation of range 2SD automatically deactivates all other rules (rules 1–6).

The following Multirules rule combinations are possible on the **cobas b** 221 system:

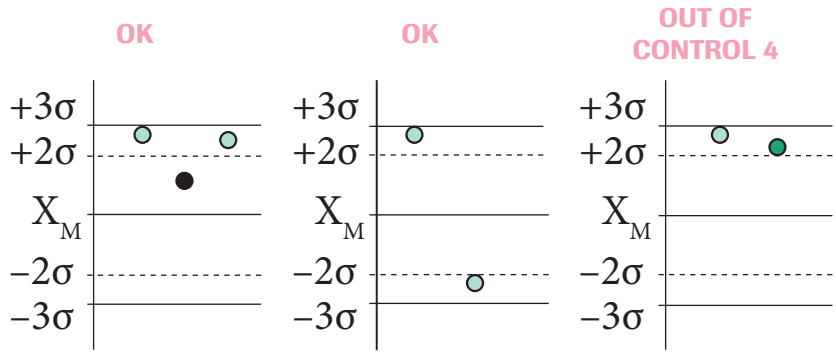
Example 1 Rule 1 and Rule 2.



A (Rule 1 = NOK) AND (Rule 2 = OK) = OK **B** (Rule 1 = NOK) AND (Rule 2 = NOK) = NOK

Figure 7-32 Multirules example 1

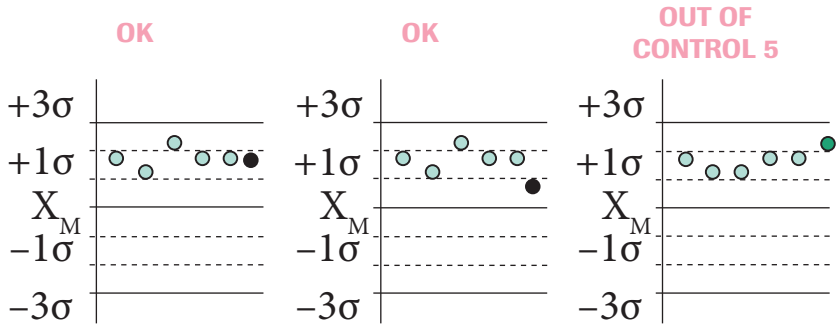
Example 2 Rule 1, Rule 2, and Rule 4.



A (Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK)) = OK **B** (Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK)) = OK **C** (Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = NOK)) = NOK

Figure 7-33 Multirules example 2

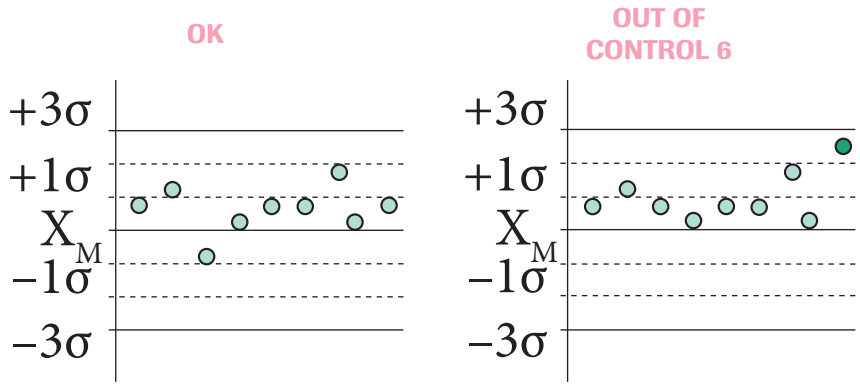
Example 3 Rule 1, Rule 2, Rule 4, and Rule 5.



A (Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK)) = OK **B** (Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = NOK)) = OK **C** (Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = NOK)) = NOK

Figure 7-34 Multirules example 3

Example 4 Rule 1, Rule 2, Rule 4, Rule 5, and Rule 6.



A (Rule 1 = OK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK) OR (Rule 6 = OK)) = OK

B (Rule 1 = NOK) AND ((Rule 2 = OK) OR (Rule 4 = OK) OR (Rule 5 = OK) OR (Rule 6 = NOK)) = NOK

Figure 7-35 Multirules example 4

QC consequences

By default, the QC consequence “QC lock” should be assigned to all parameters.

To set or check the assigned QC consequences, press **Setup > Parameter > Miscellaneous settings > QC lock**.

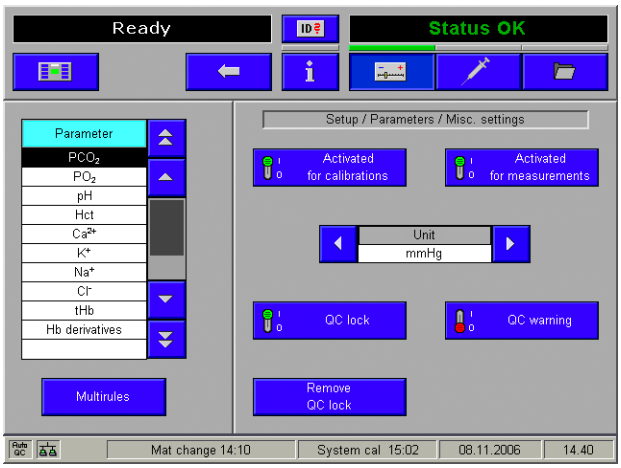


Figure 7-36

Description of the QC consequences:

	QC warning: through a warning, the respective parameter is 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 is blocked if one of the adjusted rules is broken. The parameter is 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 lock.

Manual correction

A manual correction is only allowed if the same QC material and level combination is no longer available.

If you have to perform a manual correction, repeat the QC measurement with a new QC material and level combination of a different lot and analyze the QC result as described in this manual.

Important information concerning the analysis of QC measurement results (p. 187)

To unlock the QC lock, press **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.

QC for Ready (with AutoQC module)

Parameters are 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.

Press the **QC measurement** button from the top level of the Analyzer mode:

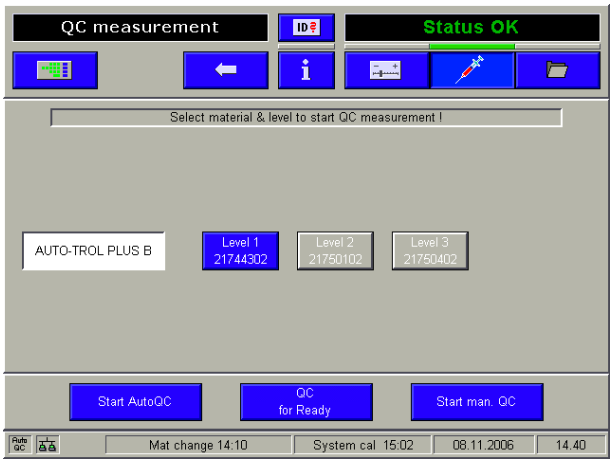


Figure 7-37

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:

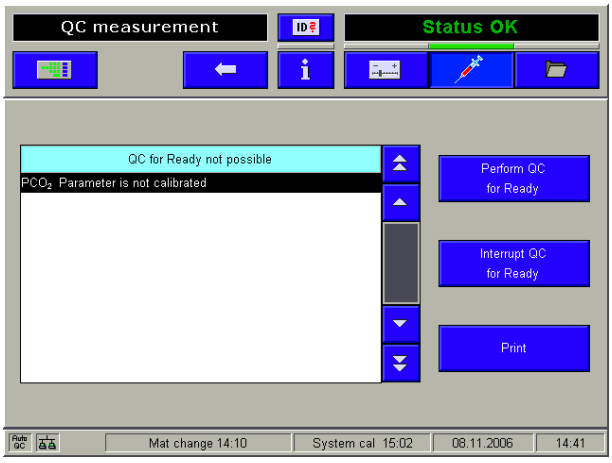


Figure 7-38

3 Here, a list of all parameters is given for which a “QC for Ready” measurement is not possible, and the reason why. If necessary, print the list, 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 and stored automatically in the QC database.

■

QC for Ready (without AutoQC module)

Parameters are 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 Press the **QC measurement** button from the top level of the Analyzer mode:

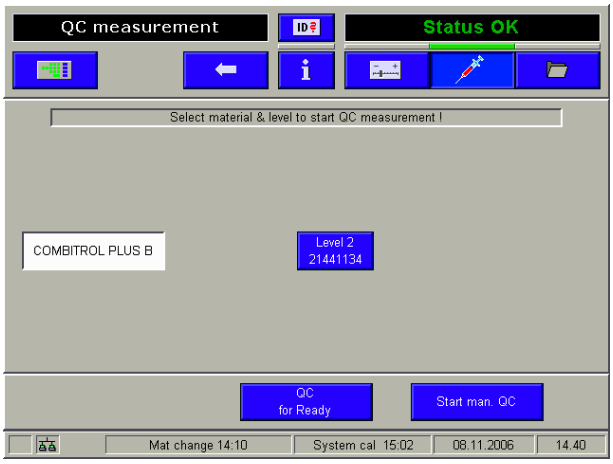


Figure 7-39

2 Press **QC for Ready**.

3 If the parameters are not all ready for measurement, the following screen appears:

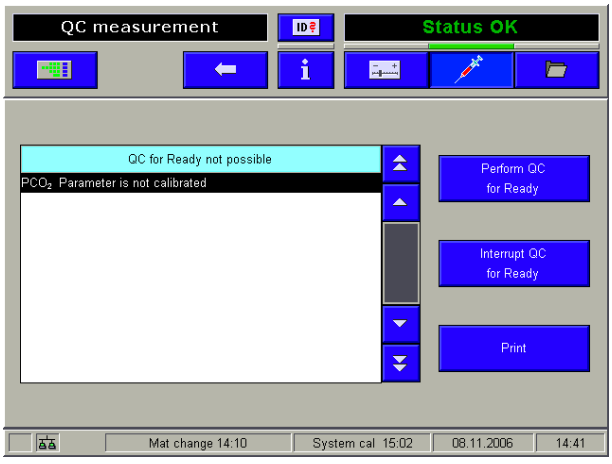


Figure 7-40

4 Here, a list of all parameters is given for which a “QC for Ready” measurement is not possible, and the reason why. If necessary, print the list, remedy the cause, and repeat the procedure.

5 Press **Perform QC for Ready**. The following screen appears:

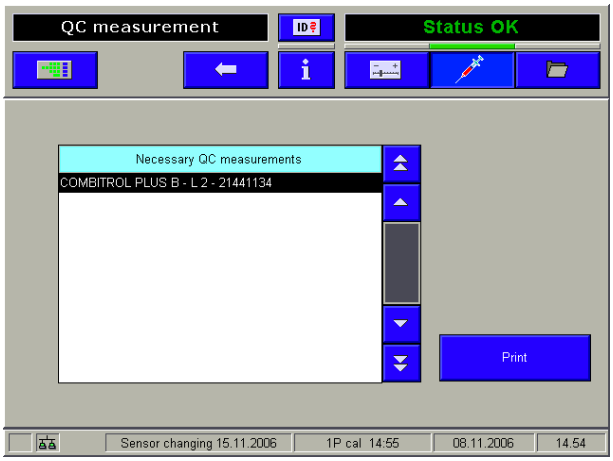


Figure 7-41

6 Here, the respective material/level combinations are listed that can remove this lock again.

7 To print the list, press the **Print** button. Perform a manual QC measurement with the listed QC materials.

QC measurement (p. 205)

■

QC troubleshooting

Description of the current problem

After a QC measurement, one or more parameters are assessed as “not OK” (QC warning or QC lock).

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, more than one parameter is usually 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 (maximum 1 minute). 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 routine 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, contact your Roche Service representative.

Note:

For optimal display of the QC results on the screen and the printout, the QC values are rounded. However, values that are not rounded 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 has to be performed 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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Automatic calibrations 227
System calibration 227
2P calibration (2P cal) 227
1P calibration (1P cal) including O_2 227
Recalibration - without O_2 228
User-activated calibrations 228
Display of parameters during calibration 230

Calibration – general

The **cobas b** 221 system performs simultaneous calibration of PCO_2, pH, Na^+, K^+, Ca^{2+} and Cl^-parameters using solutions in the S2 Fluid Pack.

Oxygen (O_2) is calibrated with ambient air and a zero point solution.

The MSS calibration is carried out using solutions in the S3 Fluid Pack A (for **cobas b** 221<6> system only).

The COOX calibration is carried out using a tHb calibrator.

Automatic calibrations

After a general fluidic test an automatic calibration is performed.

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

You can set a permanent start time for the system calibration, so it can occur when the system is not in use, or the system's workload is lower.

11. Cal. intervals & timing (p. 51)

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**.

Recalibration - without O_2

After every measurement.

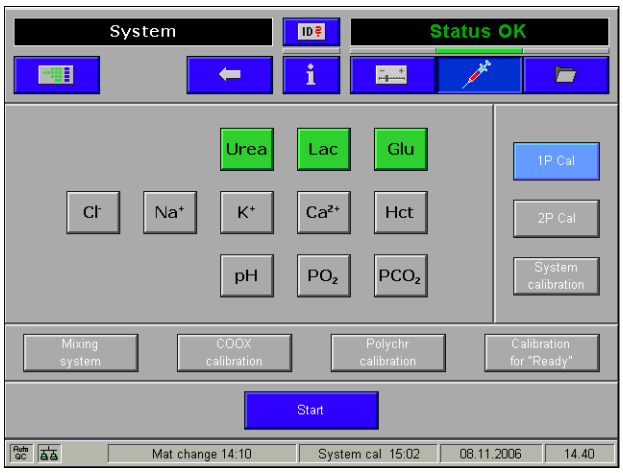
A recalibration is automatically performed after the following actions:

- General fluidic test
- Wetting routines
- Fill routines
- Maintenance routines (except cleaning routines)
- MSS polarization
- MSS contamination test
- Wash & cleaning / Clean input unit
- Wash & cleaning / Start external cleaning

User-activated calibrations

Activation in Analyzer mode:

System > Calibration



A Example: Instrument with COOX and MSS module

Figure 8-1 User-activated calibrations

User-activated calibrations do not affect the scheduling of automatic calibrations.

Select the parameters you want to calibrate. However, you cannot select individual parameters for user-activated calibrations. Instead, you can only select specific parameter groups for calibration.

The following groups can be selected:

- all MSS parameters (**cobas b** 221<6> system only)
- all ISE parameters, except for Hct
- Hct
- pH and PCO_2
- PO_2

The following types of calibrations can be performed:

- Calibration for “Ready”:
  The system automatically selects a calibration which transfers all selected parameters to the state “Ready”.

Calibration for “Ready” does not calibrate parameters measured by the COOX module. To calibrate COOX parameters, perform a COOX calibration.

COOX calibration (p. 277).

- System calibration
- 1P calibration
- 2P calibration
- Mixing system: Calibration of the conductivity system
- COOX calibration

  COOX calibration (p. 277).
- Polychromator calibration: Wavelength calibration of polychromator

To perform the desired calibration, press the corresponding calibration type button. Then, press **Start**.

Display of parameters during calibration

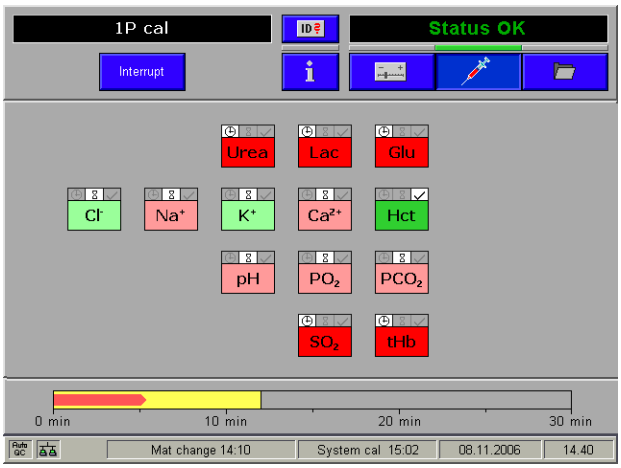
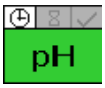
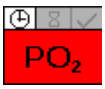
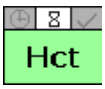
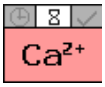
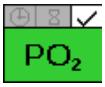
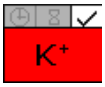
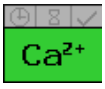


Figure 8-2 System calibration

	An already calibrated parameter will be calibrated.
	A parameter that was previously not calibrated will be calibrated.
	The parameter is being calibrated, and will likely be calibrated.
	The parameter is being calibrated, and will likely not be calibrated.
	The parameter is successfully calibrated.
	The parameter is not successfully calibrated.
	The parameter is calibrated and is not be affected by the current calibration.
	The parameter is not calibrated and is not be affected by the current calibration.

Software modes

In this chapter, all the individual, independent software modes (Analyzer, Setup, Data Manager, and Info) are described.

In this chapter *Chapter* 9

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Software modes – general

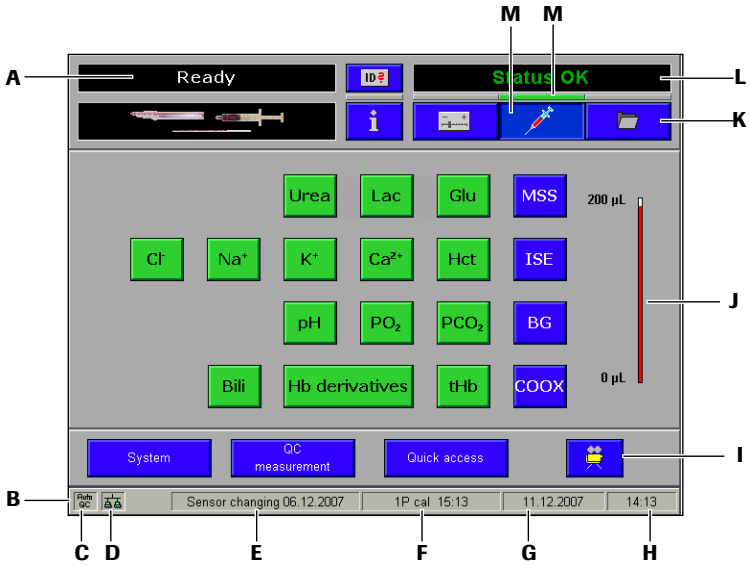
During measurement, calibration or other processes, it is possible to conduct database operations, perform certain settings or call up general information.

The software modes, which may be run independently are defined as follows:

• **Analyzer mode**	Place sample (measurement), system, QC measurement, calibration, quick access (which contains frequently used functions)
• **Setup mode**	Instrument settings
• **Database mode**	Data about patients, measurements, calibrations, QC, and the system
• **Info mode**	On board status of consumables, QC materials, electrodes, and system components System and about information Online help information and videos

User interface

For example: Top level of the Analyzer mode - "Ready"



A Current status of the Analyzer mode

B Status line

C AutoQC activated/deactivated

D Network connection activated/deactivated

E Pending maintenance

F Type and time of next calibration

G Current date

H Current time

I Direct call-up of the video sequences offered

J Required sample volume (display varies according to activated/deactivated modules)

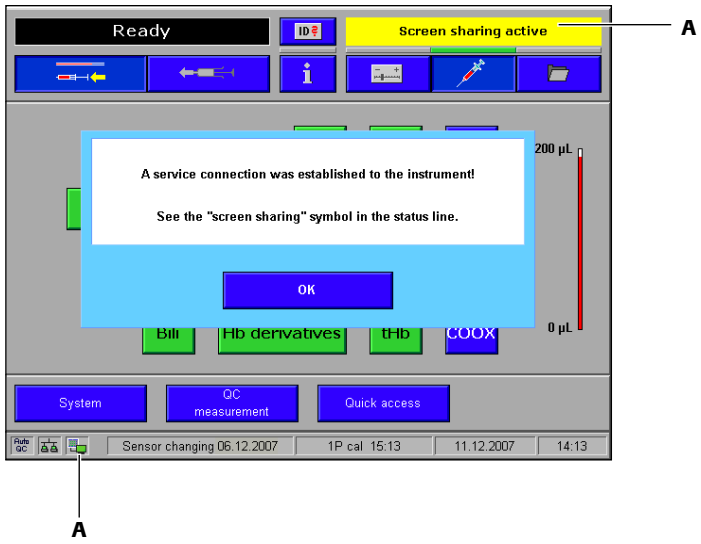
K Software modes (Info, Setup, Analyzer, Database)

L Message window

M “active”

Figure 9-1 “Ready” screen

For example: “Screen sharing” (remote monitoring and remote maintenance software is active)



A “Screen sharing” (a remote monitoring and remote maintenance software is active)

Figure 9-2

Creating user-defined parameter groups

Creating user-defined parameter groups makes it easier for you to activate the measurement parameters you use most on the main screen of the system. You can create up to 3 user-defined parameter groups with this feature.

To activate this feature, you have to select the user-defined parameter group before measuring. The feature is deactivated after each measurement.

To create a user-defined parameter group

1 Setup > Parameter > User-defined parameter groups

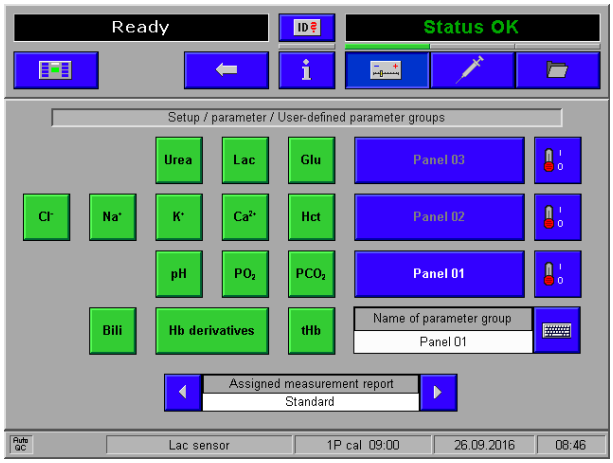


Figure 9-3 User-defined parameter group setup screen

2 To select a panel for the user-defined parameter group, choose one of the 3 panel buttons, labeled Panel01, Panel02, and Panel03.

To change the name of the group, press the button. Enter your new name using the keyboard box that appears on the screen. To apply your name change, press the button.

3 To add parameters to the user-defined group, first, press the group panel button. Next, select the parameters you want to assign to or remove from the group.

Parameters, which are shown in green, are added to the group.

Parameters, which are shown in gray, are not added to the group.

4 To assign a measurement report to the group, press the and buttons on the side of the **Assigned measurement report** panel until you find the correct measurement report.

If no measurement report is assigned to a group, the default measurement report is applied.

5 To display the group on the main screen of the system, make sure that the switch beside the group panel button is turned on. To hide the group from the main screen of the system, turn the switch off.

6 To save your new group, press the button.

7 To confirm that your new group has been created correctly, first, press the button. Next, press the panel button of your new group. Make sure that your added parameters are shown in green.

■

Parameters/icons

Display on the Ready screen (Analyzer mode)

Depending on the settings and the status of the system, 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

tHb	Total hemoglobin concentration
O_2Hb	Oxyhemoglobin
HHb	Deoxyhemoglobin
COHb	Carboxyhemoglobin
MetHb	Methemoglobin
Bili(1)	Bilirubin (neonatal)
Glu	Glucose
Lac	Lactate
Urea/BUN	Urea
Baro	Air pressure

(1) Total Bili = Direct + Indirect bilirubin = Conjugated + Unconjugated

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 CO_2 concentration in blood
BE	Base excess of blood
BE_{act}	Base excess of blood at current oxygen saturation
BE_{ecf}	Base excess of the extracellular fluid
BB	Buffer bases
ctO_2	Total oxygen concentration
pH_{st}	Standard pH value
$cHCO_3^-{}_{st}$	Standard bicarbonate concentration in plasma
PAO_2	Alveolar oxygen partial pressure
RI	Respiratory index
nCa^{2+}	Standardized ionized calcium (pH = 7.4)
Qs/Qt	Shunt—quotient between both oxygen concentration differences
Qt	Difference of oxygen concentration between alveolar and mixed venous blood
P_{50}	Oxygen partial pressure at 50% oxygen saturation calculated with SO_2 as measurement value
FO_2Hb	Fractional oxygen saturation
$SO_2(c)$	Calculated oxygen saturation
$AaDO_2$	Alveolar-arterial oxygen partial pressure
a/AO_2	Alveolar-arterial oxygen partial pressure ratio
$avDO_2$	Alveolar-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	Blood urea nitrogen
LacClear	Lactate clearance

Calculated 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

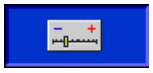
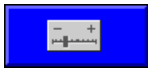
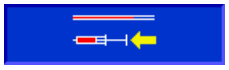
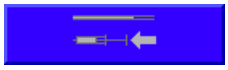
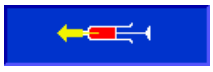
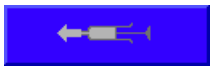
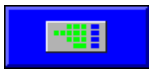
Input parameters:

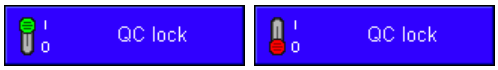
R	Gas exchange quotient
FIO_2	Proportion of inspiratory oxygen
tHb(e)	Entered tHb value (not measured)
Hb factor	To calculate Hct(c) from tHb values

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 (Adult/Fetal)	• 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

Software icons

	Analyzer mode active/inactive
	Database mode active/inactive
 	Setup mode active/inactive
	Info mode active/inactive
 	“Aspirate from capillary” or “Injection” active/inactive
 	“Aspirate from syringe” active/inactive
	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

Data Manager icons (p. 248)

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 **QC measurement**
- Call up additional menus

The capillary tube shown indicates required sample size depending on parameters selected.

System

The following main menus are available:

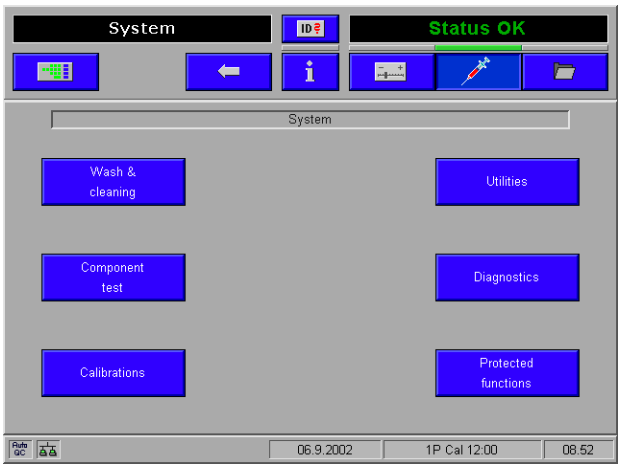


Figure 9-5

Quick access

This menu contains the most frequently used actions, in order to make opening important functions easier.

Figure 9-6

QC measurement

This function helps start a quality control measurement.

Quality control (p. 183).

Setup

Use this function to make the following settings:

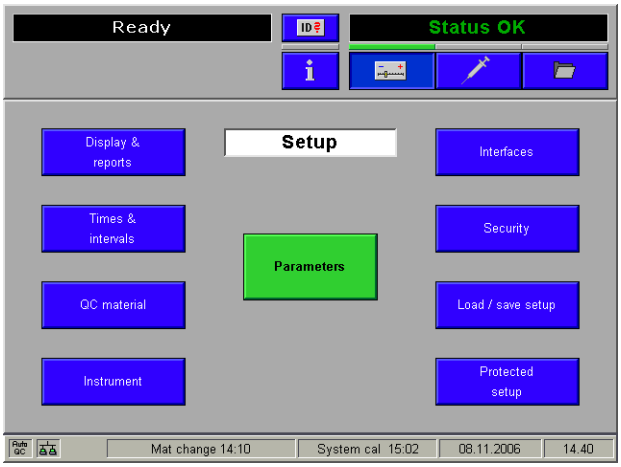


Figure 9-7

Some settings are not permanently stored after leaving the **Setup** screen, but are only saved following a reboot. These include the following settings:

- ASTM settings (**Setup > Interfaces > ASTM**)
- Parameter changes regarding the units (**Setup > Parameters > Miscellaneous settings**)
- Default values such as **Mandatory Input** or **Sample Type** (**Setup > Display & reports > Measurement > Input values**)

To prevent losing these settings, reboot the analyzer after changing them.

Configuring the Data Manager

You can configure which data is shown in the Overview and Details screens of the Data Manager. This feature allows you to quickly find specific data in the Data Manager.

Configuring data in the Overview screen

▶ To configure how measurement data is displayed in the Overview screen

Patient, calibration, QC, and system data can also be configured using this procedure.

To start configuring patient data, go to **Setup > Display & reports > Patient database > Patient database overview**.

To start configuring calibration data, go to **Setup > Display & reports > Calibration > Cal. database overview**.

To start configuring QC data, go to **Setup > Display & reports > QC measurement > QC database overview**.

To start configuring system data, go to **Setup > Display & reports > Instrument database > Instrument database overview**.

1 **Setup > Display & reports > Measurement > Measuring database overview**

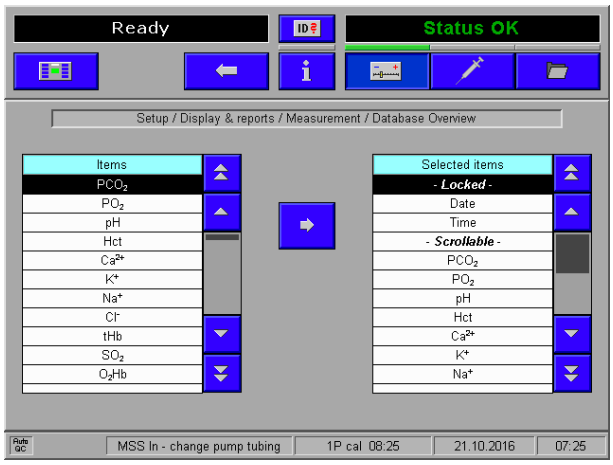


Figure 9-8 Setup screen for configuring the measurement database overview screen

Items in the **Locked** group from the **Selected items** list remain on the Overview screen when you use the scroll bar to search for more data from a specific measurement.

Items in the **Scrollable** group do not remain on the Overview screen when you use the scroll bar.

Items cannot be added to both the **Locked** and the **Scrollable** group.

2 To add an item to the **Locked** group, first choose it from the **Items** list. Then, choose one of the items in the **Locked** group and press the button.

3 To add an item to the **Scrollable** group, first choose it from the **Items** list. Then, choose one of the items in the **Scrollable** group and press the button.

4 To remove an item, choose it from the **Selected items** list and press the button.

5 To save your new configuration, press the button.

■

Configuring data in the Details screen

▶ To configure how measurement data is displayed in the Details screen

1 **Setup > Display & reports > Measurement > Measurement database zoom**

Figure 9-9 Setup screen for configuring the measurement database details screen

- To edit input values, press the **Edit list** button below the **Input values** drop-down list,
  or,
- To edit parameters, press the **Edit list** button below the **Results** drop-down list.

2 To add an input value or parameter, choose it from the **Items** list and press the button.

3 To remove an input value or parameter, choose it from the **Selected items** list and press the button.

4 To save your new configuration, press the button.

■

To configure how patient data is displayed in the Details screen

Calibration data can also be configured using the same procedure.

To start configuring calibration data, go to **Setup > Display & reports > Calibration > Cal. database zoom**.

1 **Setup > Display & reports > Patient database > Patient database zoom**

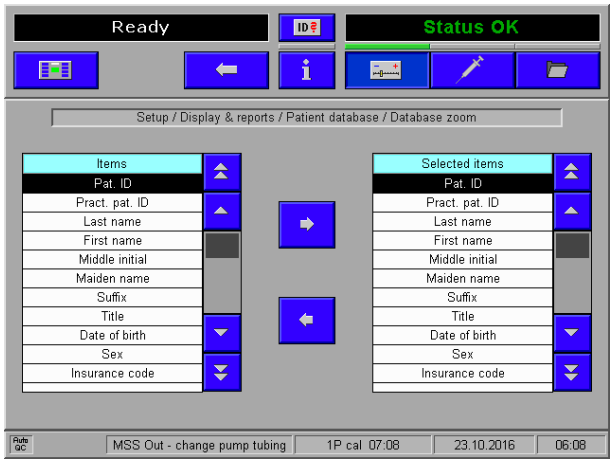


Figure 9-10 Setup screen for configuring the patient database details screen

2 To add an item, choose it from the **Items** list and press the button.

3 To remove an item, choose it from the **Selected items** list and press the button.

4 To save your new configuration, press the button.

■

Configuring data exports from Data Manager

You can configure which data is exported from Data Manager. This feature allows you to efficiently export data from the **cobas b** 221 system.

▶ To configure which measurement data is exported from Data Manager

Patient, calibration, QC and system data can also be configured using this procedure.

To start configuring patient data exports, go to **Setup > Display & reports > Patient database > Patient data export**.

To start configuring calibration data exports, go to **Setup > Display & reports > Calibration > Cal. data export**.

To start configuring QC data exports, go to **Setup > Display & reports > QC measurement > QC data export**.

To start configuring system data exports, go to **Setup > Display & reports > Instrument database > Instrument data export**.

1 **Setup > Display & reports > Measurement > Measuring data export**

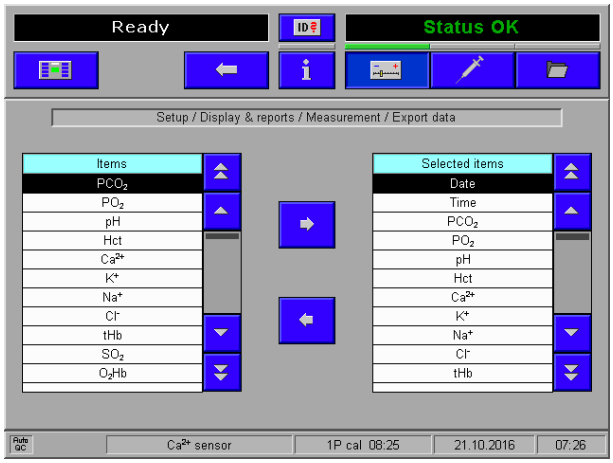


Figure 9-11 Setup screen for configuring measurement data exports

2 To add an item, choose it from the **Items** list and press the button.

3 To remove an item, choose it from the **Selected items** list and press the button.

4 To save your new configuration, press the button.

■

Data Manager

Use this function to retrieve the following data:

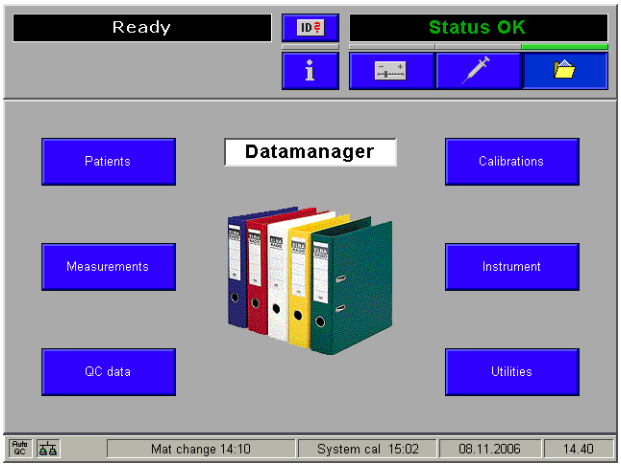
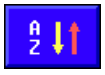
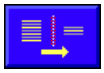
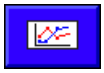
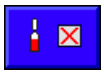
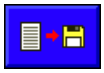
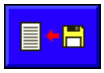


Figure 9-12

Data Manager icons

	Details - all the available detailed information for the selected dataset is displayed and can be edited.
	Find - Searches for data records using defined search criteria.
	Sort - Sorts information.
	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.
	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 a 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 (SN < 21000) or USB storage device (SN > 21000). 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. The format has to 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 - one or more marked archives are copied to a diskette (SN < 21000) or USB storage device (SN > 21000).
	Copy from disk - one or more archives saved on diskette (SN < 21000) or USB storage device (SN > 21000), are copied directly back to the archive overview.
	Restore archive - one or more marked datasets are reinserted into the current database.
	Backup now - a full database backup is started.

Software icons (p. 239)

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 button. All available information about the selected entry is displayed.

Configuring measurement input values (p. 160)
Configuring the Data Manager (p. 244)

Measurements

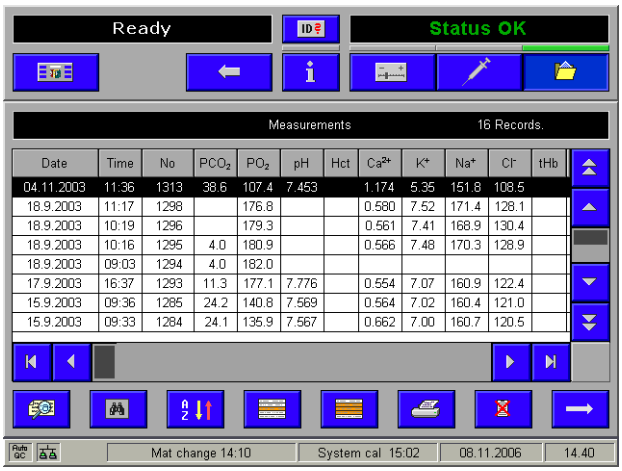


Figure 9-13

Measurements that were carried out are listed depending on the definition of the display (**Setup > Display & reports > Measurement > Measuring database overview**).

Use the buttons “Page up/down” or “Up/down” to select an entry and press the button. All available information about the selected entry is displayed.

If you edit the patient ID in the measurement database, all patient-relevant information is automatically deleted.

If patient-relevant data is known and needed for patient trending, you also have to enter the corresponding patient ID. After you enter the patient ID, the patient query is automatically started.

If you edit the patient ID, you have to manually resend the changed dataset to the LIS/HIS.

Important:

If the patient ID is already found in the LIS, there may be a mismatch of patient data in the LIS, which may assign measurements to the wrong patient in the LIS.

Make sure unique IDs are used in the hospital environment.

Configuring the Data Manager (p. 244)

Calibrations

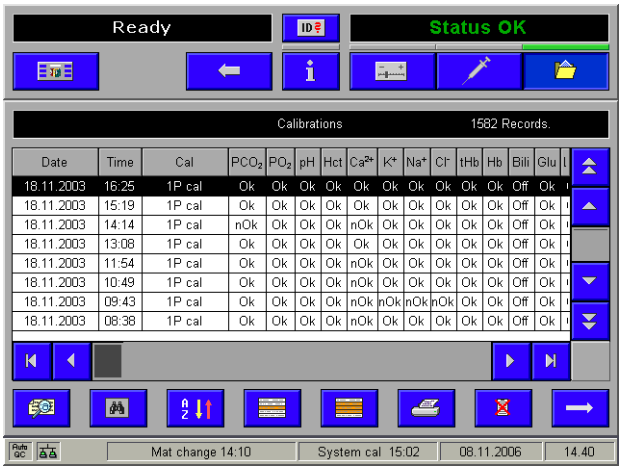


Figure 9-14

Calibrations that were carried out are listed depending on the definition of the display (**Setup > Display & reports > Calibration > Cal. database overview**).

Use the buttons “Page up/down” or “Up/down” to select an entry and press the button. All available information about the selected entries is displayed.

QC measurements

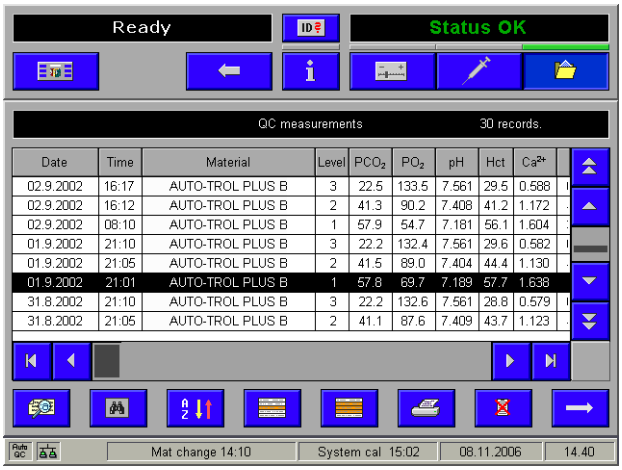


Figure 9-15

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 button. All available information about the selected entry is displayed.

Instrument

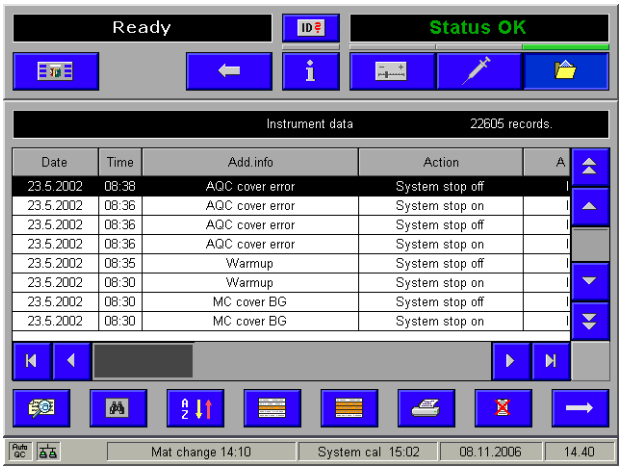


Figure 9-16

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 button. All information about the selected entry is displayed.

Utilities

Backup/Restore

Use this function to perform a data backup.

Managing data (p. 253)

Protected DB functions

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

Managing data

You can back up and restore datasets, and import and export data to and from storage devices in the Data Manager.

Backing up and restoring data

To back up datasets to a storage device

1 Data Manager > Utilities > Backup/Restore

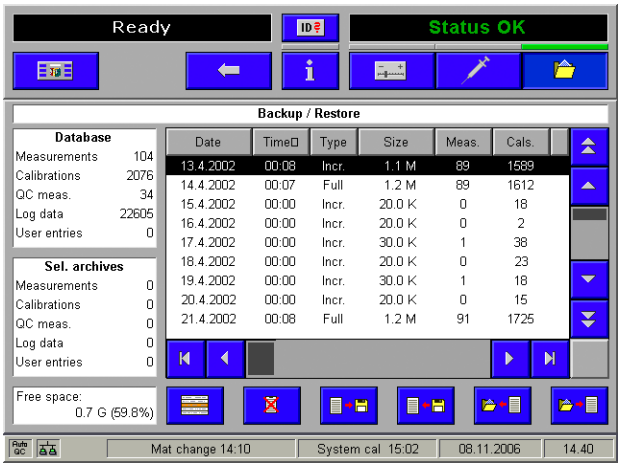


Figure 9-17 Backup/restore screen

2 To add a dataset for backup, use the drop-down list to choose it. Then, press the button. To undo your selection, press the button again.

Added datasets for backup are highlighted in yellow.

3 To back up your added datasets, connect your storage device onto the system and press the button.

■

To restore datasets from a storage device

1 Data Manager > Utilities > Backup/Restore

2 Connect your storage device onto the system.

3 To add a dataset to restore, use the drop-down list to choose it. Then, press the button. To undo your selection, press the button again.

Added datasets for backup are highlighted in yellow.

4 To restore your added datasets, press the button.

■

Importing and exporting data

To export data to a storage device

1 Data Manager > Utilities > Backup/Restore

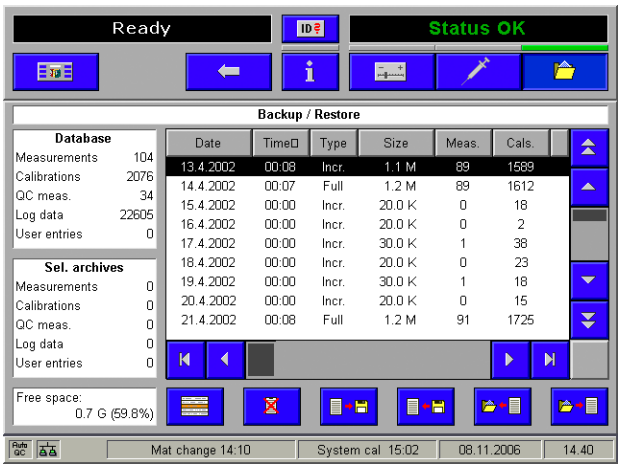


Figure 9-18 Backup/restore screen

2 To add a dataset for export, use the drop-down list to choose it. Then, press the button. To undo your selection, press the button again.

Added data for export are highlighted in yellow.

3 To export your added data, connect your storage device onto the system and press the button.

■

To import data from a storage device

1 Data Manager > Utilities > Backup/Restore

2 Connect your storage device onto the system.

3 To add data for import, use the drop-down list to choose it. Then, press the button. To undo your selection, press the button again.

Added data for import are highlighted in yellow.

4 To import your added data, press the button.

■

Info

The following information can be displayed:

Figure 9-19

Help

Use this function to retrieve online help and about information.

Fill level

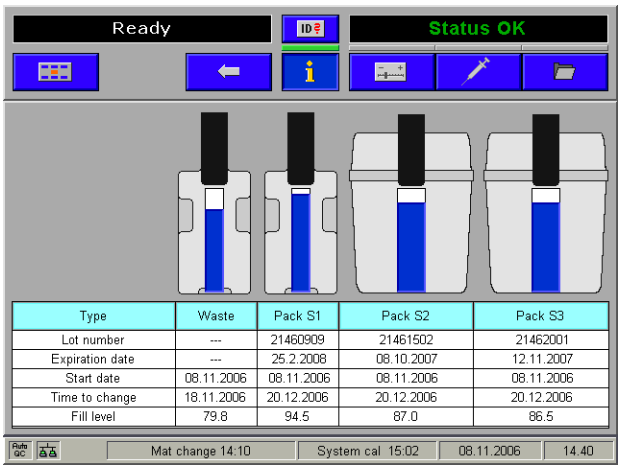


Figure 9-20

This view lists all the data of the solutions, such as lot number, expiration date, start date, the remaining “Time to change” and fill level.

For S2 and S3 fluid packs, the fill level displayed by the system is normally that of the leading solution pouch. This solution typically has the highest rate of consumption and the largest volume within the fluid pack. If the fill level of another solution pouch drops below a specific warning level, the system displays the fill level of this solution pouch instead.

QC status

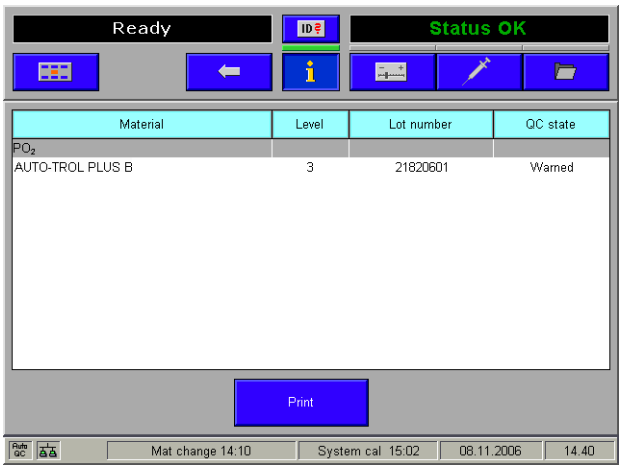


Figure 9-21

Use this function to determine which material/level combination is blocking a parameter.

Press **Print** to print the QC Lock Status report.

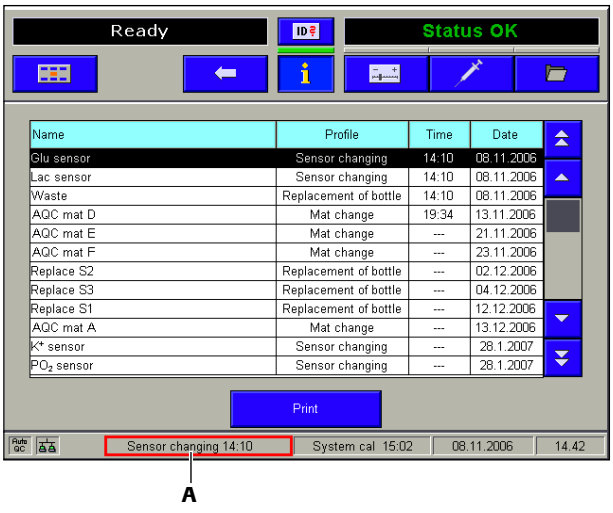
Video sequences

Use this function to play videos of the listed topics.

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 **Print** to print the list.



A Warning window for pending maintenance, rotating display

Figure 9-22

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 otherwise cannot be visualized.

Figure 9-22 (p. 256).

MSS cassette:

Parameter information for glucose, lactate, and urea is listed separately in the **List of all activities** feature in **Info** mode, but refer to the same sensor.

List of all warnings

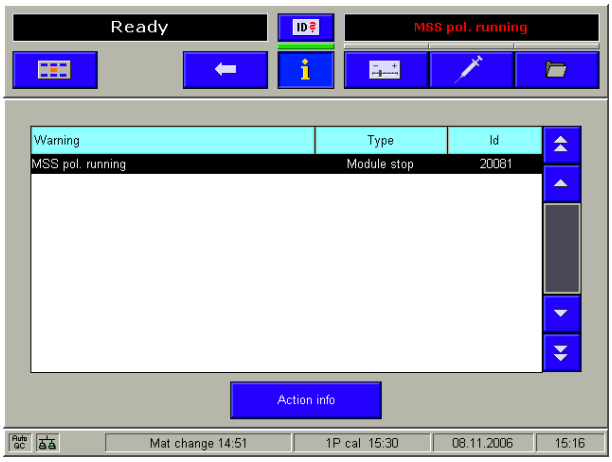


Figure 9-23

Here, all the module stops and warnings are listed with their code, or it can be found in *Troubleshooting* (p. 317), using the respective error code (ID).

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

AQC status

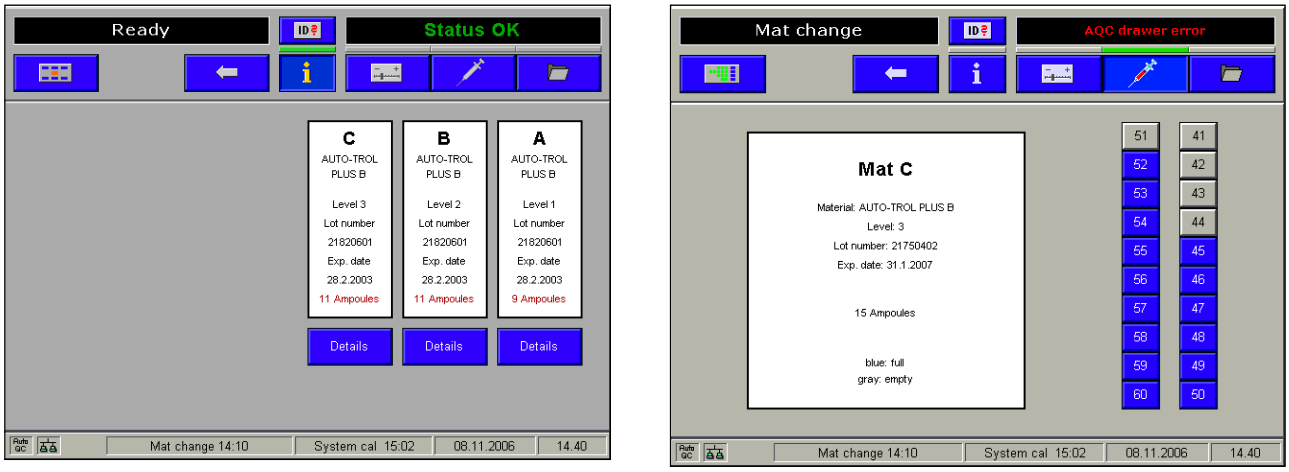


Figure 9-24

It shows an overview of the mats and the AutoQC material being used.

Press **Details** to display the ampoule status of the selected mat (blue - full, gray - empty).

Versions

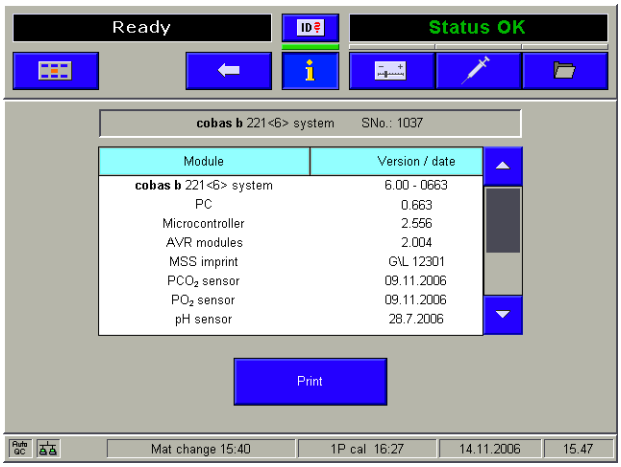


Figure 9-25

Here, the software versions, the instrument serial number, the MSS cassette label, and the date of insertion of the sensors are listed.

Press **Print** to print the list.

Miscellaneous reports

Parameter report

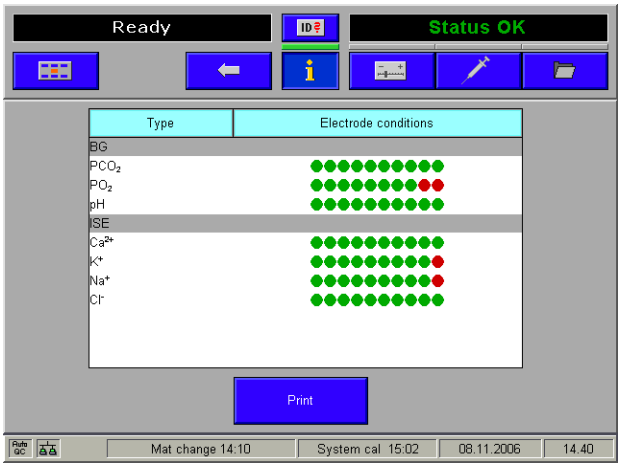


Figure 9-26

The parameter report displays the status of the electrodes. Green and red dots represent the electrode's condition. More green dots represent that the electrode is in better condition. If the electrode's condition only shows red dots, exchange the electrode.

Replacing electrodes (p. 297)

Sensor report

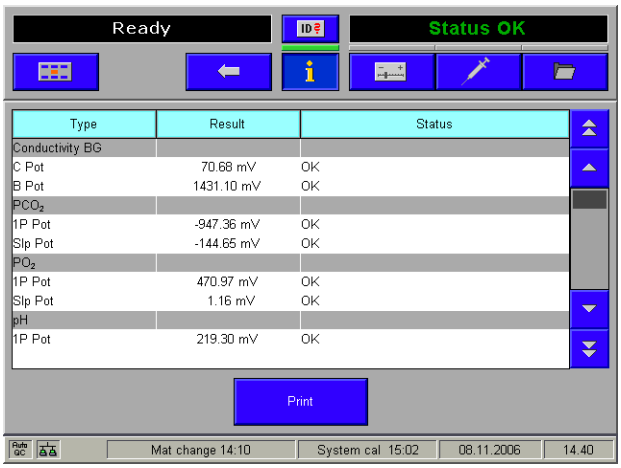


Figure 9-27

Displays the status of the electrodes/sensors.

Press **Print** to print the sensor report.

Status report

To find information about the system and instrument settings, press the **Status report** button.

Messages

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

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

Press **Show message** to view the entire message.

Press **Delete message** to delete the selected message.

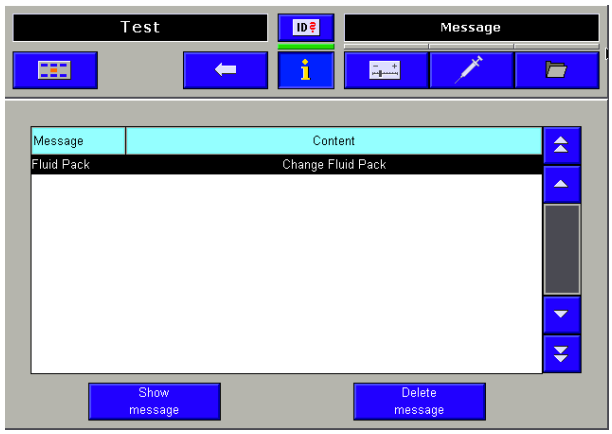


Figure 9-28

Protected information

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

Managing security settings

WARNING

Data loss or unauthorized access to system data

Unsecured databases and access to mass storage devices can result in data loss or unauthorized access to system data.

- Ensure restricted access to the system database and mass storage devices.

To manage user access on the system, you can create and assign profiles for specific users, and/or restrict selected functions from non-administrative users.

Create an administrative profile that allows access to all system functions. In addition, create an administrative user and assign this user to the administrative profile.

If there is no administrative user and system functions are restricted, system functions are no longer available.

Managing user profiles

To create a user profile

1 **Setup > Security > Profile management > New**

Figure 9-29 Setup screen for creating user profiles

2 To enter the name of the user profile, press the button. Enter your new name using the keyboard box that appears on the screen. To apply your name change, press the button.

3 To save your new user profile, press the button.

■

To edit a user profile

1 **Setup > Security > Profile management**

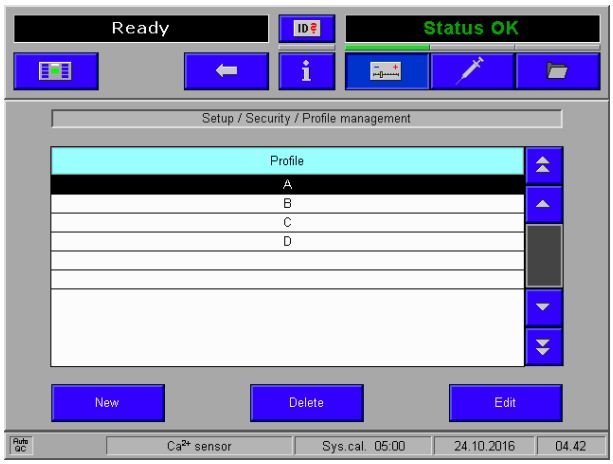


Figure 9-30 Setup screen for creating user profiles

2 Choose the profile from the drop-down list and press the **Edit** button.

3 To edit the name of the user profile, press the button. Enter your new name using the keyboard box that appears on the screen. To apply your name change, press the button.

4 To grant or remove user access to an instrument function, use the drop-down list to choose the instrument function that you want to change. Then, press the **Edit** button.

Users are granted access to instrument functions displaying the icon.

Users are denied access to instrument functions displaying the icon.

5 To grant user access to all of the instrument functions, press the **Set all** button.

6 To remove user access to all of the instrument functions, press the **Delete all** button.

7 To restrict user access to the POC profile instrument functions, press the **Set POC profile** button.

In POC mode, users are granted access only to those instrument functions available on the “Ready” screen, and in the “Info” software mode.

POC mode (p. 182)

8 To save your changes, press the button.

■

To delete a user profile

1 **Setup > Security > Profile management > Delete**

A dialog box is displayed on the screen.

2 Press the **Yes** button.

■

Managing users

To create a user

1 **Setup > Security > User management > New**

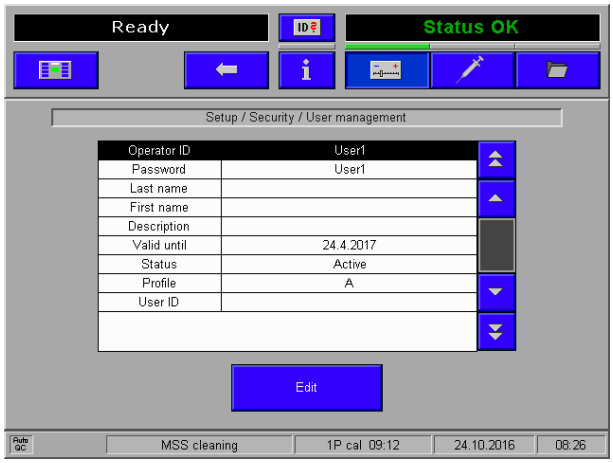


Figure 9-31 Setup screen for creating user profiles

2 To save your new user, press the button

■

To edit user settings

1 **Setup > Security > User management**

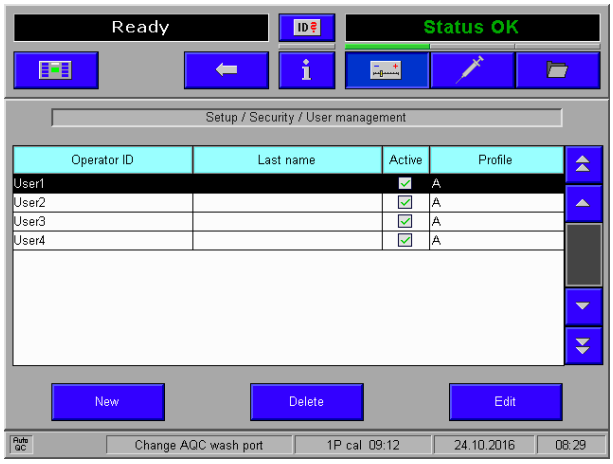


Figure 9-32 Setup screen for editing user profiles

2 Choose the user from the drop-down list and press the **Edit** button.

3 Choose the setting that you want to edit from the drop-down list and press the **Edit** button.

4 Enter your new settings using the numeric or alphanumeric keyboard box that appears on the screen. To apply them, press the button.

To change the Status setting, press the **Edit** button.

When creating an administrative user, create also a password.

Passwords have to meet the following criteria:

- At least 8 characters in length
- Cannot contain the user's account name
- Cannot contain more than 2 consecutive characters from the user's full name
- Contain characters from at least 3 of these 4 categories: 1 English alphabetic uppercase letter (A-Z), 1 English alphabetic lowercase letter (a-z), 1 numeric character (0-9), 1 non-alphabetic character (e.g. !, $, #)

Warning (p. 27)

5 To save your changes, press the button.

■

To delete a user

1 **Setup > Security > User management > Delete**

A dialog box is displayed on the screen.

2 Press the **Yes** button.

■

Assigning user profiles

To assign a profile to a user

1 **Setup > Security > User management**

2 Choose the user from the drop-down list and press the **Edit** button.

3 Choose the Profile entry from the drop-down list and press the **Edit** button.

Figure 9-33 Setup screen for assigning user profiles

4 Choose the profile that you want to assign to the user from the drop-down list. Press the button.

5 To save your changes, press the button.

■

Managing user access to instrument functions

Restricting user access to an instrument function affects all non-administrative users. If no administrative user has been assigned, this instrument function is no longer available.

To manage user access to instrument functions

1 **Setup > Security > Instrument functions**

Figure 9-34 Setup screen for managing user access to instrument functions

2 To grant or remove user access to an instrument function, use the drop-down list to choose the instrument function that you want to change. Then, press the **Edit** button.

All users are granted access to instrument functions displaying the icon.

All users are denied access to instrument functions displaying the icon.

3 To grant all users access to all instrument functions, press the **Set all** button

4 To deny all users access to all instrument functions, press the **Delete all** button

5 To restrict user access to the POC profile instrument functions, turn on the **POC mode** switch button.

In POC mode, users are granted access only to those instrument functions available on the “Ready” screen, and in the “Info” software mode.

POC mode (p. 182)

6 To save your changes, press the button

■

Maintenance

10 Maintenance..... 269

Maintenance

All maintenance work that is required for trouble-free operation is described.

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Maintenance – general

Infection and injury due to contact with used components

Contact with some used components, such as the fill port, pump tubing, and the W Waste Container, may lead to biohazardous contamination, resulting in personal injury and/or infection.

- Treat these components as infectious waste. Dispose of the system and consumables as chemical and biohazardous waste. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- Take extra care when working with protective gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Decontamination

Decontamination minimizes the risk of infections when replacing items that were in contact with blood. Perform these decontamination procedures regularly.

Roche recommends adding a decontamination procedure to your standard laboratory practices.

Use only liquid disinfectant, such as Roche deproteinizer, or a 70% alcohol-based surface disinfectant. Do not spray disinfectant directly onto the instrument.

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

Cleaning fill port and sample drip tray (p. 274)
Quarterly maintenance (p. 276)
Exchanging the fill port (p. 293)

Touch screen

Cleaning the touch screen (p. 275)

Surfaces of the instrument

Decontaminating instrument surfaces (p. 311)

Tubing paths

Cleaning the modules and tubing paths (p. 287)

Recommended disinfectants

Surfaces 70% alcohol surface decontaminant

Do not use alcohol-based solvents to clean the waste separator. Cleaning the waste separator with Roche deproteinizer preserves the plastic surface of the waste separator.

Tubing paths Protein remover (Roche deproteinizer)

Daily maintenance

Checking fill level

Press **Info > Fill level** to check the fill level of the solutions and packs (S1 Rinse Solution, S2 Fluid Pack, S3 Fluid Pack A) and the W Waste Container daily.

Exchange empty and expired solutions and packs, and full W Waste Containers.

Exchanging solutions and packs (p. 280)
W Waste Container (p. 282)

Checking printer paper

Check daily that there is sufficient printer paper available in the system and exchange it, if necessary.

The printer paper is heat-sensitive on one side only. Ensure that you insert the paper roll correctly, with the heat-sensitive side up.

Weekly maintenance

Cleaning fill port and sample drip tray

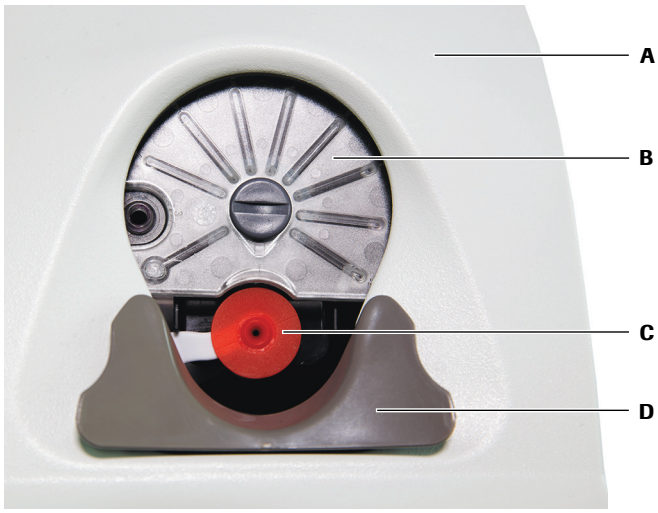
Infection and injury due to contact with the fill port and sample drip tray

Contact with the fill port and sample drip tray may lead to biohazardous contamination, resulting in personal injury and/or infection.

- Treat these components as infectious waste. Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- Take extra care when working with protective gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If any biohazardous material comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Cleaning fill port and sample drip tray

1 **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 System > Wash & cleaning > Clean screen

The keys on the screen are deactivated for 30 seconds.

Clean with a moist cloth only, such as a cloth soaked with disinfectant. Do not use water to clean the screen.

■

Quarterly maintenance

Cleaning the T&D disk

Cleaning the T&D disk

1 **System > Wash & cleaning > Clean input unit**

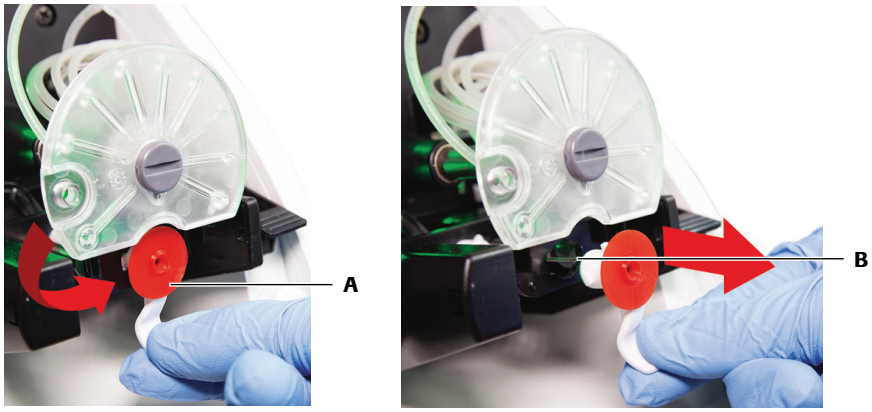
2 Pull out the sample drip tray and clean it with a cloth moistened with disinfectant.

Figure 10-1 *Input unit* (p. 274)

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 Fill port **B** 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 with Roche deproteinizer.

9 Reinstall the disk in the reverse order.

10 Reinsert 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.

Figure 10-3 Air filter

2 Dispose the air filter according to local regulations. The air filter is classified as hazardous waste.

3 Insert the new air filter.

Figure 10-3 *Air filter* (p. 277)

■

COOX calibration

Perform a COOX calibration each time you adjust the cuvette. Calibrate the COOX module at least once every 3 months.

To calibrate the COOX module, enter the tHb calibrator or a blood sample with known tHb values.

To perform a COOX calibration

1 Remove the ampoule from the package.

2 Gently rotate the ampoule.

3 To remove liquid from the top of the ampoule, gently tap the top of the ampoule with your fingernail.

4 Break open the ampoule. Insert the contents of the ampoule using an ampoule adapter or a capillary.

Personal injury due to contact with glass splinters from broken QC ampoules

Glass splinters created when breaking QC ampoules may result in personal injury

- When you break QC ampoules, wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, and safety glasses, and use several layers of gauze.

Do not reuse ampoules, ampoule adapters, or capillaries.

5 **System > Calibration > COOX calibration**

Figure 10-4

6 Press **Start**.

The following screen appears:

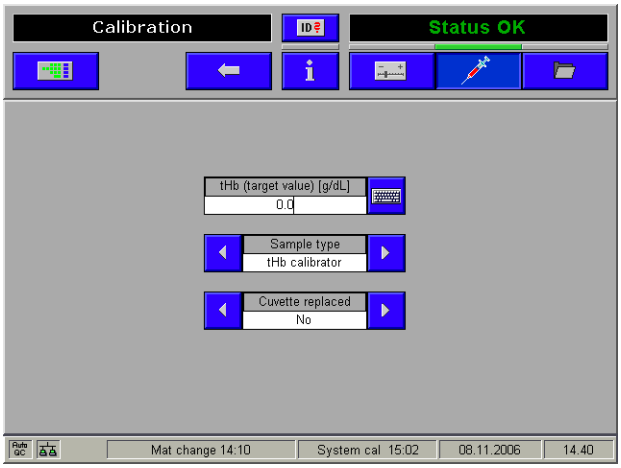


Figure 10-5

7 Enter your target value in the **tHb (target value)** panel using the keyboard. You can find the target value on the label of your tHb calibrator.

You can change the tHb standard unit to g/L or mmol/L.

Assigning unit formats to a measured parameter (p. 119)

8 To select tHb calibrator or blood as the sample type for your calibration, press the ◀ and ▶ buttons in the **Sample type** panel.

If you perform your calibration with blood, enter its target value.

9 Attach the capillary (see below/A) or the ampoule adapter (see below/B) filled with tHb calibrator to the fill port. Follow the instructions on the screen.

A Capillary **B** Ampoule adapter

Figure 10-6 Ampoule adapter/Capillary

Repeat the COOX calibration.

Your results appear on the screen.

Measured tHb values that are within 20% of the known tHb value can be accepted.

If your measured values fall outside of this range, press **Reject**. Repeat the COOX calibration.

If your measured values are acceptable, press **Accept**.

Your results are used to calculate the layer thickness of the cuvette. If the calculated layer thickness and the corresponding reference value do not fall within specific internal limits, you have to repeat the COOX calibration.

■

Sample-dependent maintenance procedures

Exchanging solutions and packs

WARNING

Perform QC measurements on 3 levels after each solution and fluid pack exchange.

Quality control (p. 183)

Press **Info > Fill level** to check the fill level of the solutions and packs (S1 Rinse Solution, S2 Fluid Pack, S3 Fluid Pack A) and the W Waste Container.

A Rubber sealings **B** **cobas b** 221<6> system only

Figure 10-7 Solutions and packs

S1 Rinse Solution/S2 Fluid Pack/S3 Fluid Pack A

Your rate of exchanging fluid packs depends on how often you measure, and on the onboard stability of your fluid packs. Typically, fluid packs are exchanged every 6 weeks.

Fill level determination

Time to change	Time to change is based on the installation date (start date) of solutions and packs, and the sample and calibration throughput of the last 14 days. With low sample throughput, onboard time can limit the time to change.
Onboard time	The onboard time for solutions and packs is 42 days.

Inappropriate handling and disposal of used S1 Rinse Solution, S2 Fluid Pack, and S3 Fluid Pack A containers may cause injury and environmental harm

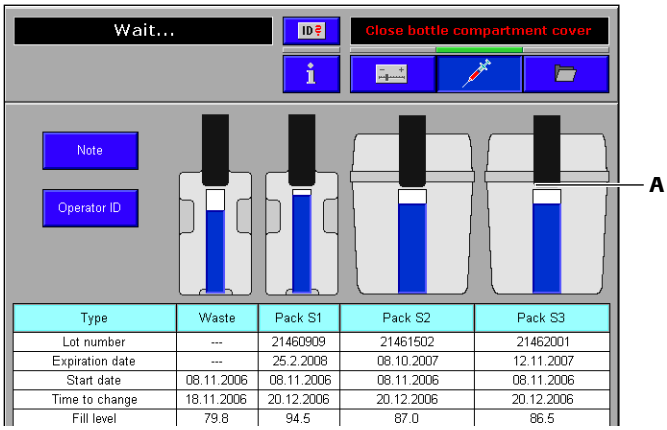
Used S1 Rinse Solution, S2 Fluid Pack, and S3 Fluid Pack A containers may contain trace amounts of hazardous liquids. Inappropriate handling of these used consumables may lead to direct exposure of these liquids, which may lead to serious skin burns, eye damage and other serious health risks. In addition, inappropriate disposal may contaminate the environment.

- Treat used consumables as hazardous waste and dispose them as chemical and biohazardous waste. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- When handling used consumables, keep them upright to avoid spillage.
- If you spill contents from used consumables, wipe it up immediately.
- If contents from used consumables come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

To exchange a solution or fluid pack

1 Open the bottle compartment cover.

The following screen appears:



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

Figure 10-8

2 Open the docking mechanism and pull out the bottles/packs to be exchanged.

Before installing a new fluid pack, remove the rubber sealings from the fluid pack.

Figure 3-24 *W Waste Container & packs* (p. 60)

3 Insert the new solution or fluid pack in the corresponding position.

4 Close the docking mechanism and the bottle compartment cover.

5 Perform QC measurements on 3 different levels.

If your facility is 3000 m above sea level or higher, deaerate the S1 Rinse Solution bottle before inserting it inside the system to avoid splashing its contents.

■

To deaerate the S1 Rinse Solution bottle

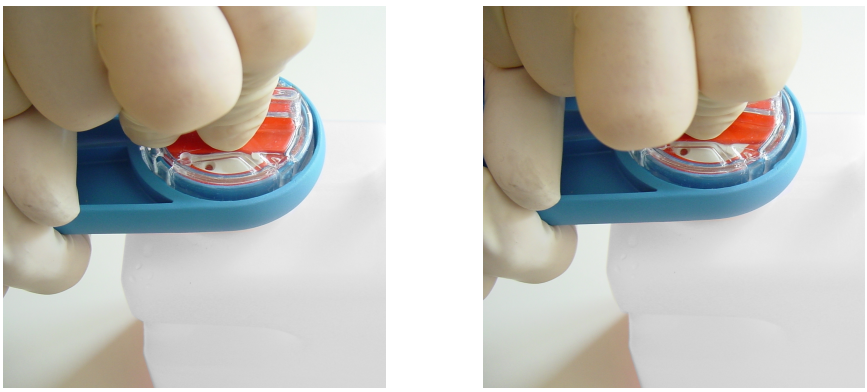
1 Place the bottle tool on the screw cap of the S1 Rinse Solution (see below/B).

A Bottle tool **B** Bottle tool on the screw cap

Figure 10-9 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 there is resistance after a short distance (see below/B).



A **B**

Figure 10-10 Deaerate the S1 Rinse Solution

■

W Waste Container

WARNING

Inappropriate handling and disposal of the W Waste Container may cause infection and environmental harm

The W Waste Container contains liquid and/or solid waste. Inappropriate handling of this waste may lead to the transmission of blood or urine borne pathogens. In addition, inappropriate disposal may contaminate the environment.

- Treat the contents inside the W Waste Container as chemical and biohazardous waste and dispose it accordingly. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- If you spill contents from the W Waste Container, wipe it up immediately and apply a disinfectant.
- If contents from the W Waste Container come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

To replace the W Waste Container

1 Open the bottle compartment cover.

The following screen appears:

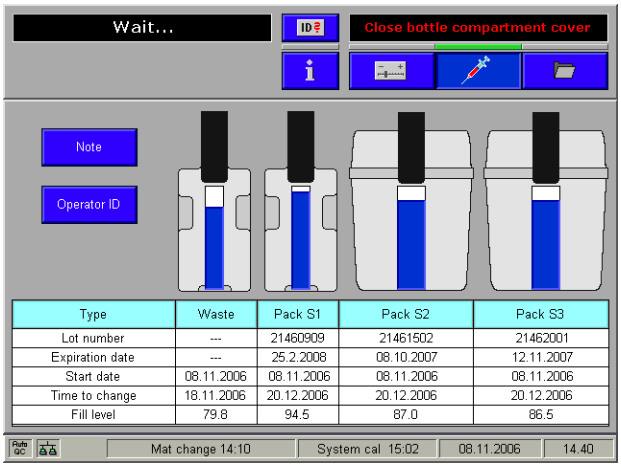


Figure 10-11

2 Open the docking mechanism, hold the W Waste Container by its grip recesses, and remove it carefully.

■

1. Empty the W Waste Container

WARNING

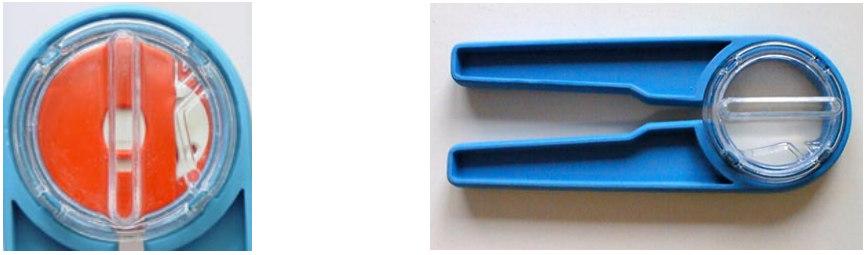
Inappropriate handling and disposal of the contents inside the W Waste Container may cause infection and environmental harm

The W Waste Container contains liquid and/or solid waste. Inappropriate handling of this waste may lead to the transmission of blood or urine borne pathogens. In addition, inappropriate disposal may contaminate the environment.

- Treat the contents inside the W Waste Container as biohazardous waste and dispose it according to the local regulations. In addition, decontaminate the W Waste Container after disposing its contents according to the local regulations. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- If you spill contents from the W Waste Container, wipe it up immediately and apply a disinfectant.
- If contents from the W Waste Container come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
- Regularly replace the W Waste Container and its screw cap. Roche recommends replacing the W Waste Container and its screw cap after emptying it 5 times.

To empty the W Waste Container

1 Place the bottle tool on the screw cap.



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

Figure 10-12 Bottle tool

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

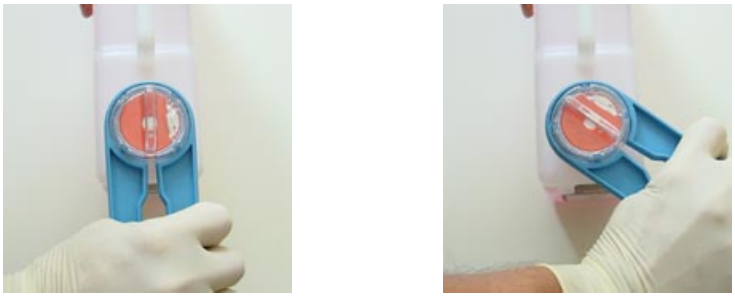


Figure 10-13 Open the screw cap

3 When removing the screw cap, make sure that the green element inside the container is not moved or removed. Next, flush the W Waste Container screw cap with plenty of water.

Figure 10-14 Screw cap

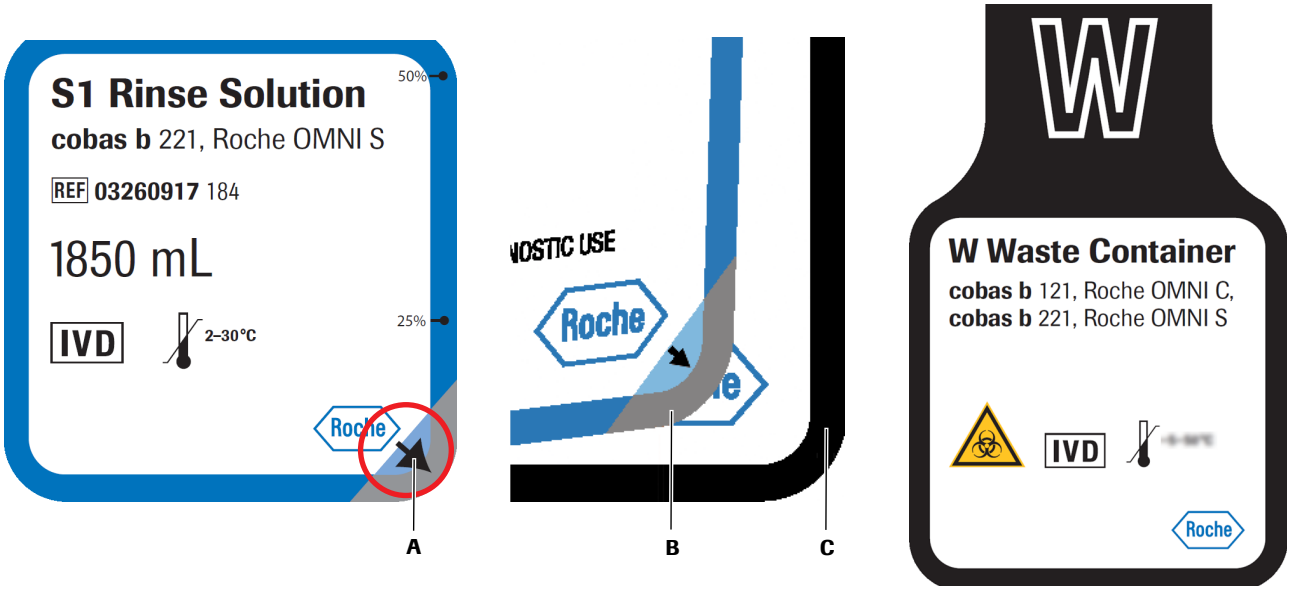
4 Dispose the contents inside the W Waste Container as chemical and biohazardous waste. Then, decontaminate the W Waste Container. Apply a small amount of Roche deproteinizer onto a moist cloth and wipe the exterior of the W Waste Container.

5 Screw the cap back onto the container until it is closed.

■

2. Using the empty S1 Rinse Solution bottle as W Waste Container

- Remove the sticker from the empty S1 Rinse Solution bottle, and immediately discard it.



A Remove the S1 Rinse Solution sticker from the bottle here.

B Pull off the sticker, beginning from the lower right corner, where the arrow is shown, until the W sticker is fully visible.

C "W" sticker on the S1 Rinse Solution bottle

Figure 10-15 Removing the S1 Rinse Solution sticker

Installing the W Waste Container

To install the W Waste Container

1 Open the bottle compartment cover.

2 Insert the W Waste Container in the W position.

3 Close the docking mechanism.

4 The fill level monitoring feature detects an empty W Waste Container.

If your W Waste Container is not empty, press **Waste fill level**. Enter the fill level using the keyboard. You can estimate the fill level by using the scaling on the container label.

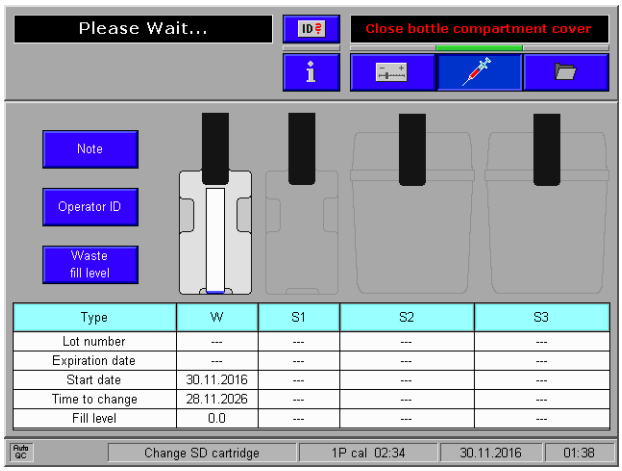


Figure 10-16 Inserting an empty W Waste Container

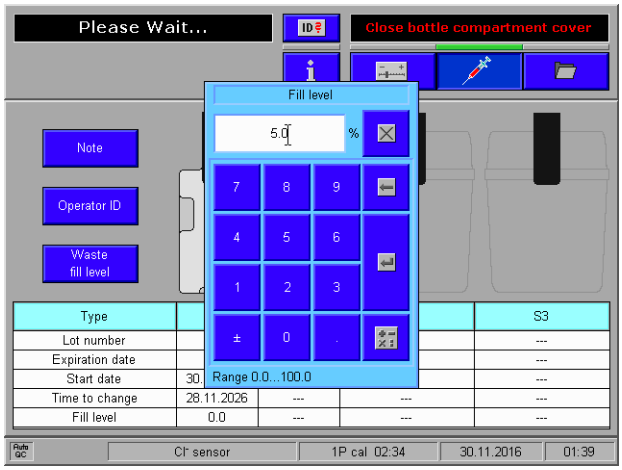


Figure 10-17 Entering the W Waste Container's fill level

5 Close the bottle compartment cover.

■

Cleaning the modules and tubing paths

Module cleaning

An internal cleaning procedure is automatically carried out during 2P and system calibrations.

The default settings for automatic internal cleaning are:

Measuring module	Samples	Cycle
BG	500	never
ISE	200	never
COOX	20	never
MSS	---	never

Table 10-1

Automatic BG cleaning When you activate automatic BG cleaning, system data, such as how often you measure and sensor drift behavior, is used to automatically select the best cleaning interval for your system.

Setting up the maintenance scheduler (p. 300)

External cleaning When the measuring chamber is contaminated (protein deposits) or sample path components have to be exchanged, perform an additional external cleaning with Roche deproteinizer.

System > Wash & cleaning > Cleaning modules

Figure 10-18

BG/ISE/COOX modules:

Clean the ISE module as often as required. Your cleaning frequency depends on how often you measure with specific blood types that leave blood particles in the module.

Only clean the BG module if there are visible blood clots in the module, or you are having issues passing QC measurements for PO_2.

1 Turn on the switch button of the corresponding module and press the **Start external cleaning** button.

2 Insert the external cleaning agent via the fill port.

3 After each external cleaning, perform a wetting routine with whole blood or serum. Press **System > Utilities > Fluid actions > Wetting routines**.

4 To perform a cleaning with an internal cleaning solution, press **Start internal cleaning**.

■

MSS module (cobas b 221<6> system only):

1 Turn on the MSS module switch button and press the **Start external cleaning** button.

Clean the MSS module each time you insert a new MSS cassette. However, do not clean the module more than once per month.

2 Insert the external cleaning agent via the fill port.

3 Insert a new MSS cassette.

Changing the MSS cassette (cobas b 221<6> system only) (p. 306)

Lastly, perform a manual polarization of the new MSS cassette.

■

Tubing paths

You need the shutdown kit to decontaminate the tubing paths.

Perform QC measurements on 3 levels after each decontamination routine.

Quality control (p. 183)

To decontaminate the tubing paths

1 **System > Wash & cleaning > Decontamination**

2 Remove all of the solutions and electrodes from the system. Then, press **Continue.**

Perform all steps in the routine in the correct order, and without interruption.

3 Follow the instructions on the screen.

To complete some steps, you may have to manually perform an action on the system. When this action is complete, press the **Confirm action** button. The system automatically performs all other steps. To start an automatic action, press the **Start process** button.

Successfully completed actions are displayed with the icon.

■

Monitoring MSS contamination

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

You have to 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 your Roche Service representative has performed the MSS maintenance procedure on the system.

WARNING

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**

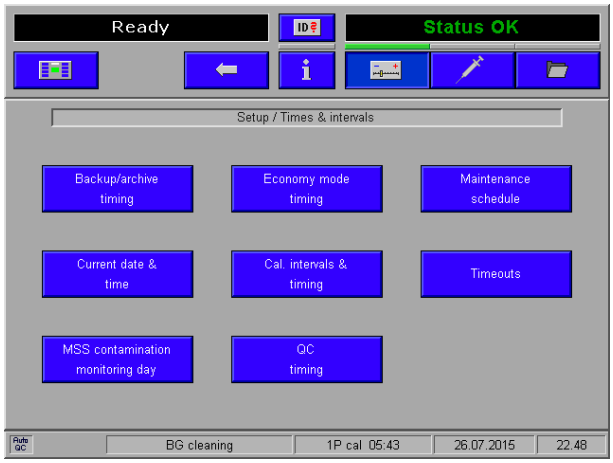


Figure 10-19 Times & intervals screen in Setup mode

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

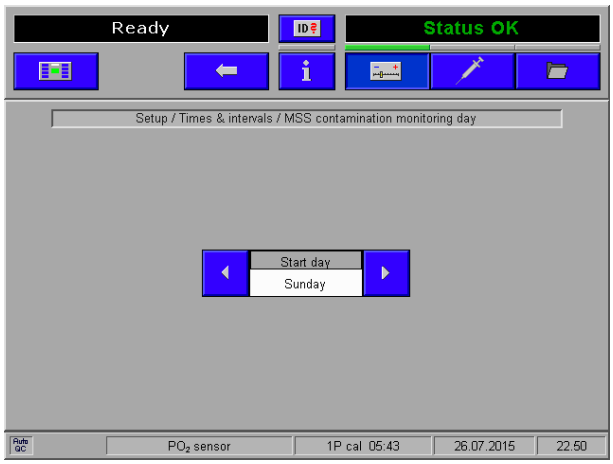


Figure 10-20 MSS contamination monitoring setup screen

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 your Roche Service representative will need to visit your system to perform service actions.

■

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
- PO_2 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, see *Calibrations* (p. 251).

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

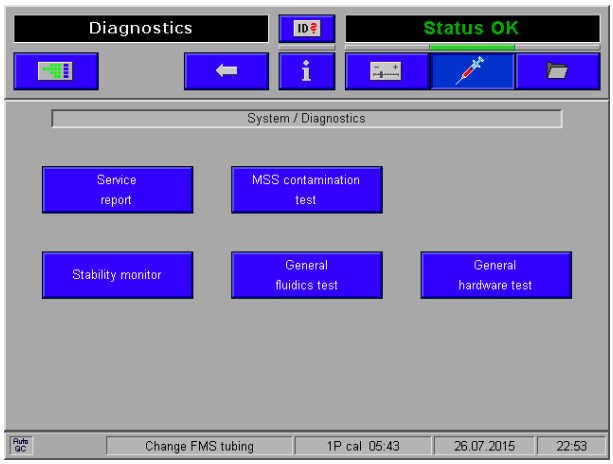


Figure 10-21 Diagnostics screen in System mode

■

Unscheduled maintenance

Exchanging the fill port

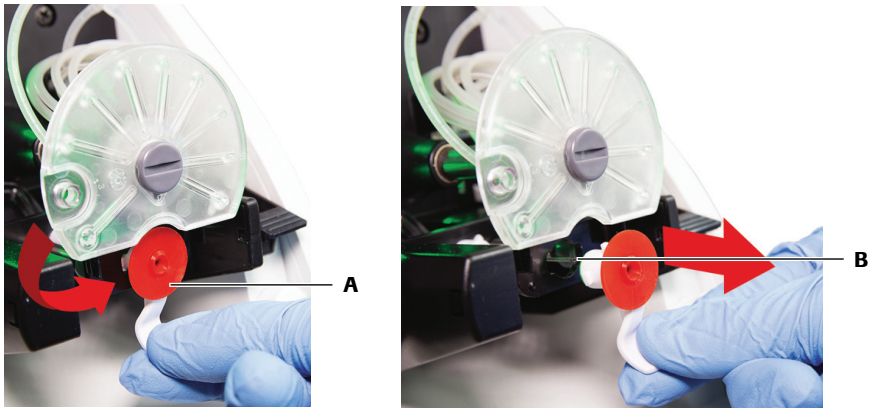
Inappropriate handling and disposal of the fill port may cause infection and environmental harm

The fill port may contain liquid and/or solid waste. Inappropriate handling of this waste during disposal may lead to the transmission of blood or urine borne pathogens. In addition, inappropriate disposal may contaminate the environment.

- Treat the fill port as biohazardous waste and dispose it accordingly. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- Take extra care when working with protective gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

To exchange the fill port

1. **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 Fill port **B** Needle

Figure 10-22 T&D disk

5. Insert new fill port, while making sure that you do not bend the needle.

6 Install the T&D cover.

7 Reinsert the sample drip tray.

8 Close the bottle compartment cover.

■

Exchanging the peristaltic pump tubes

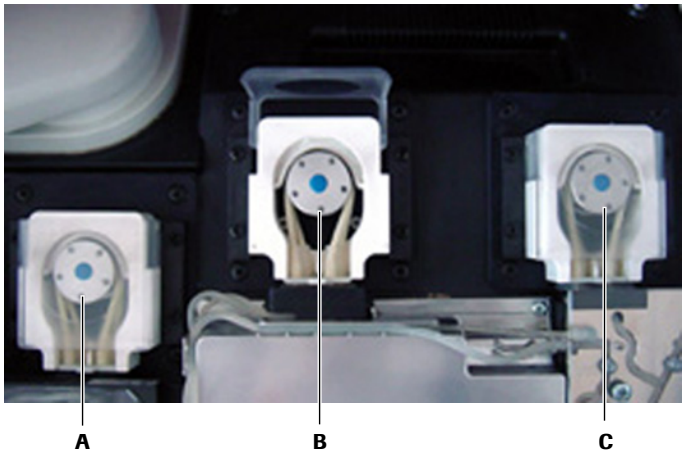
Inappropriate handling and disposal of the peristaltic pump tubes may cause infection and environmental harm

The peristaltic pump tubes may contain liquid and/or solid waste. Inappropriate handling of this waste during disposal may lead to the transmission of blood or urine borne pathogens. In addition, inappropriate disposal may contaminate the environment.

- Treat the fill port as biohazardous waste and dispose it accordingly. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- Take extra care when working with protective gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

▶ To exchange the peristaltic pump tubes

1 **Quick access > Maintenance**



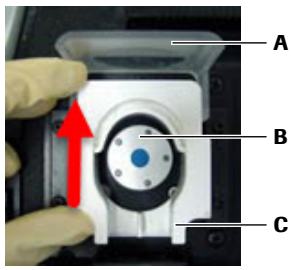
A Main pump
B MSS output pump
C MSS input pump

Figure 10-23 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 tension lever (see below/A).

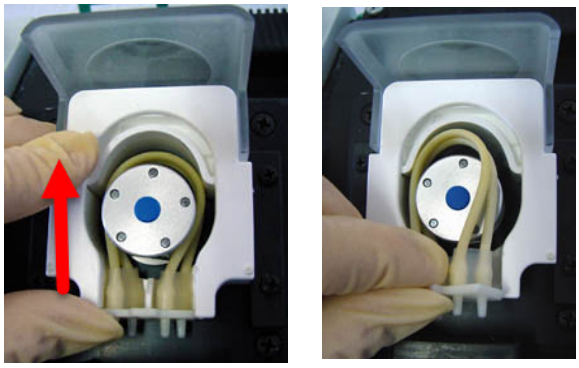


A Tension lever
B Pump head
C Linear bracket

Figure 10-24 Peristaltic pump

5 Push the linear bracket 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 10-25 Peristaltic pump

7 Check that you can freely move the 5 rollers.

If you cannot freely move the rollers, contact your Roche Service representative.

8 Place the tube around the corresponding rolling wheel. Check that the tubing set is lined up correctly. The grip end has to point upwards. (see above/B)

9 Close the tension lever. The tubing holder is moved into the sealer.

10 Close the top cover.

■

Cleaning the bottle compartment

To clean the bottle compartment

1 Open the bottle compartment cover.

The following screen appears:

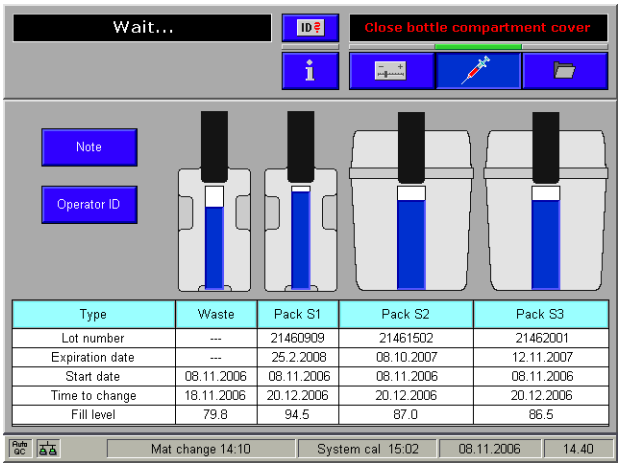


Figure 10-26

2 Open the docking mechanism and remove all bottles and packs.

3 Clean the bottle compartment with a cloth moistened with disinfectant (e.g. disinfectant containing 70% alcohol).

4 Allow the disinfectant to evaporate from the bottle compartment for 15 minutes.

5 Install the bottles and packs.

Exchanging solutions and packs (p. 280)

6 Close the docking mechanism and the bottle compartment cover.

■

Replacing printer paper

The printer paper is heat-sensitive on one side only. Ensure that you insert the paper roll correctly, with the heat-sensitive side up.

To replace the printer paper

1 Remove the printer cover.

2 Open the paper lid.

3 Remove the empty paper roll.

4 To help guide the new paper roll through the rollers, make sure that it has clean leading edge. To create a clean leading edge, cut the end of the paper roll in a straight line.

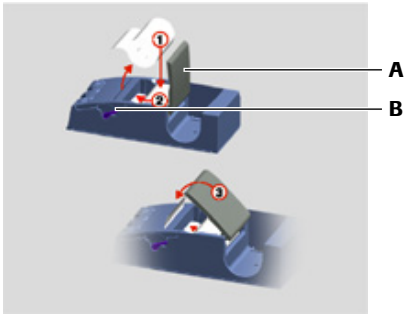
5 Place the new paper roll into the holder. The roll has to feed from the bottom.

6 Make sure that the printer lever is in the down position (see below). You can only see the printer lever when the paper cover is open.

A Printer lever “down” position

Figure 10-27 Printer lever

7 Feed in the beginning of the paper roll, as shown in the diagram found on the inside of the paper lid.



A Paper lid **B** Printer lever

Figure 10-28 Place printer paper

8 The paper is automatically pulled into the printer.

If you feed in the paper roll incorrectly, open the paper cover and printer lever, and realign the paper roll. Then, close the printer lever and install the paper lid.

■

Replacing electrodes

WARNING

Installing or using expired electrodes may lead to incorrect results

Data obtained using expired electrodes are not reliable. This may lead to incorrect results, which may endanger patient lives.

- Do not install electrodes after the “Install before” date. Do not use electrodes that have exceeded their expiry dates.
- Immediately after installing a new electrode, set up an alert in the maintenance scheduler to replace it after it has expired.

Setting up the maintenance scheduler (p. 300)

To replace an electrode

1 Remove the top cover and open the measuring chamber cover of the corresponding module. Apply force to the right edge of the MC cover with one finger, and at the same time, push it to the left and lift.

Open only the measuring chamber of the module, whose electrode you have to change.

The following screen appears:

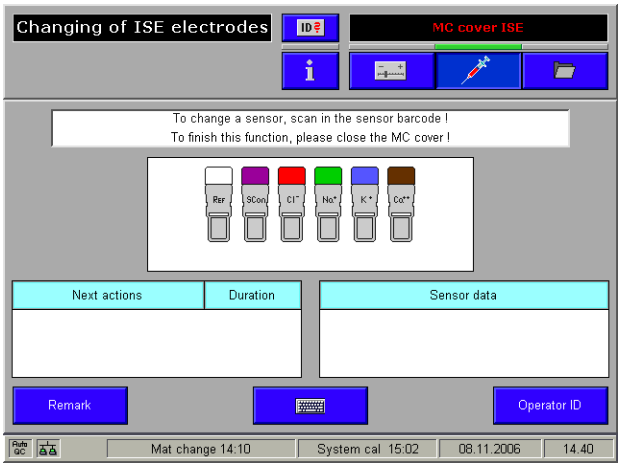


Figure 10-29

2 Open the locking lever.

3 Take the appropriate electrode, move it to the left and remove it.

Inappropriate handling and disposal of used electrodes may cause injury and environmental harm

Used electrodes may contain trace amounts of hazardous liquids. Inappropriate handling of used electrodes may lead to direct exposure of these liquids, which may lead to serious skin burns, eye damage and other serious health risks. In addition, inappropriate disposal may contaminate the environment.

- Treat used electrodes as chemical and biohazardous waste and dispose them accordingly. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- If you spill contents from used electrodes, wipe it up immediately.
- If contents from used electrodes come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

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.

Do not replace an SCon or reference electrode with a dummy electrode.

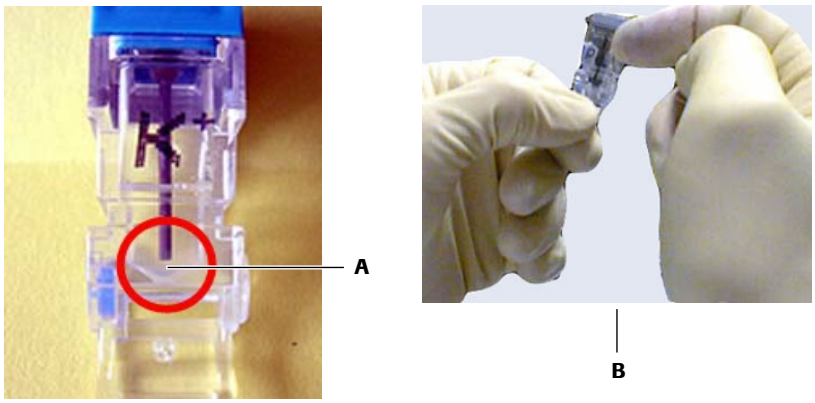
If you replace an electrode with a dummy electrode, immediately deactivate these parameters permanently for measurements and calibrations.

To deactivate a parameter for calibrations, press the following buttons: **Setup > Parameter > Miscellaneous settings**. Then, turn off the **Activated for calibrations** switch.

To deactivate a parameter for measurements, turn off the **Activated for measurements** switch.

5 Make sure that the internal electrolyte of the electrodes does not contain any air bubbles.

If there are air bubbles, hold the electrode vertically and lightly tap your fingernail on the side of the electrode body (see below/B).



A Free of air bubbles **B** Removing air bubbles

Figure 10-30 Electrode

6 Insert the new electrode using the color code on the inside of the system.

Caution: Installation note for the PCO_2 electrode

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

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

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

If more than 5 minutes has elapsed after opening the ALU-PE packaging, the level of gas conditioning may be lost and the time needed for the first calibration may increase.

7 Push all electrodes slightly to the right so that they are lined up next to each other without gaps.

8 Close the locking lever.

9 Scan the barcode of the installed electrode. If you cannot scan the barcode, enter the barcode manually using the keyboard.

10 The replaced electrode is shown lower than the other electrodes displayed on the screen.

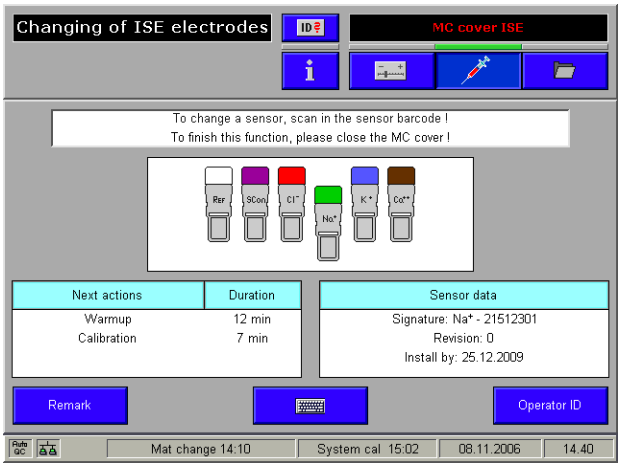


Figure 10-31

11 Close the measuring chamber cover first. Then, close the top cover.

The electrode goes first through a warm-up phase, and is then calibrated.

12 Perform QC measurements on 3 different levels.

Quality control (p. 183)

■

Setting up the maintenance scheduler

The maintenance scheduler is used to alert users when electrodes or other components have to be replaced, or other actions have to be done. Some actions are already found in the system, while you have to perform other actions.

▶ To set up a new alert in the maintenance scheduler

1 **Setup > Times & intervals > Maintenance schedule**

2 Choose the **New** button.

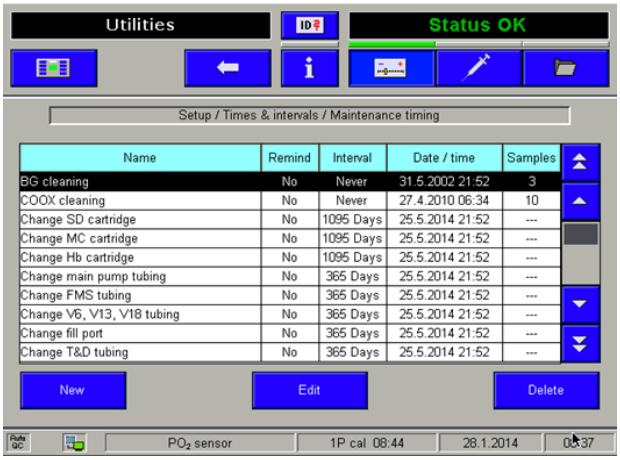


Figure 10-32

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

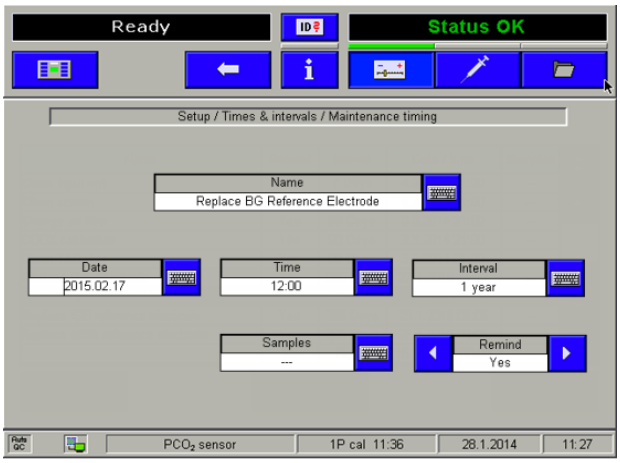


Figure 10-33

4 Choose the button to save your setup.

5 To confirm that you have set up your alert correctly, select it from the maintenance scheduler.

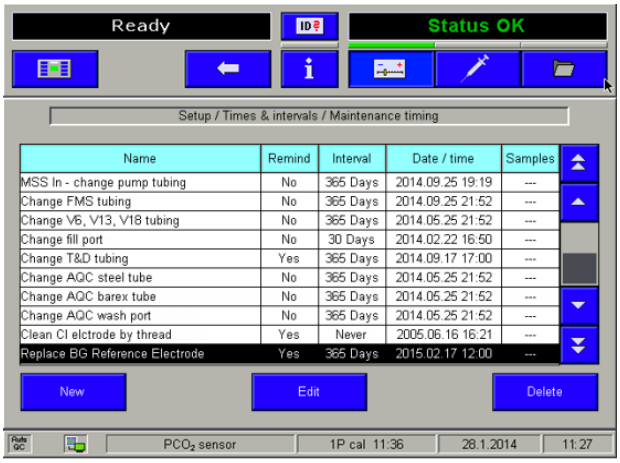


Figure 10-34

■

To edit an alert in the maintenance scheduler

1 **Setup > Times & intervals > Maintenance schedule**

2 Select the alert you want to edit and choose the **Edit** button.

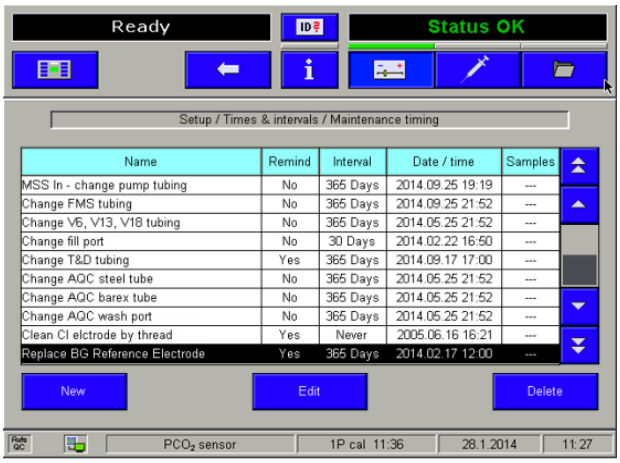


Figure 10-35

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

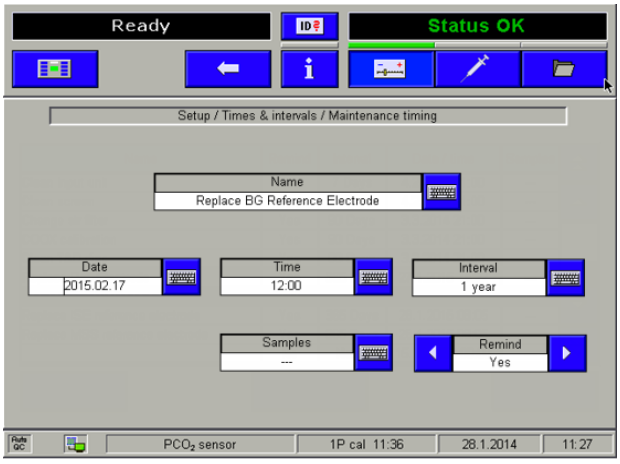


Figure 10-36

4 Choose the button to save your setup.

5 To confirm that you have edited your alert correctly, select it from the maintenance scheduler.

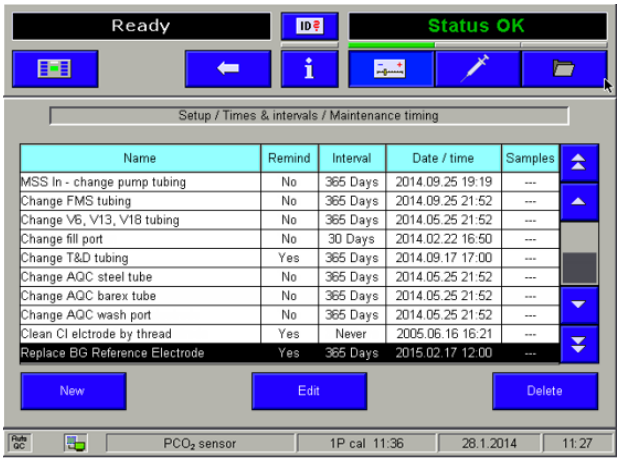


Figure 10-37

■

To delete an alert in the maintenance scheduler

1 **Setup > Times & intervals > Maintenance schedule**

2 Select the alert you want to delete and choose the **Delete** button.

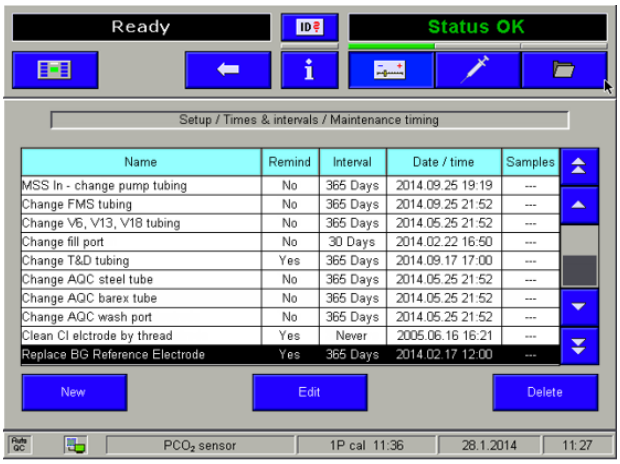


Figure 10-38

3 To confirm that you have deleted your alert, make sure that you do not see it in the maintenance scheduler.

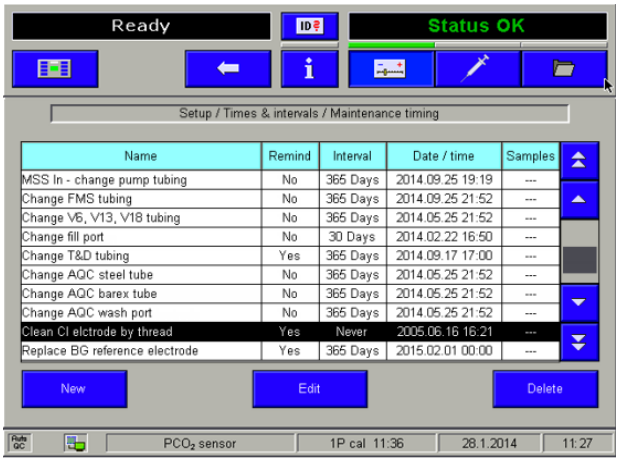


Figure 10-39

■

Changing the reference electrode

WARNING

Using expired reference electrodes and/or reference electrodes that have exceeded their maximum in-use time may lead to incorrect results

The reference electrode produces a stable electrode potential that other electrodes reference to compute their respective voltages. Using expired reference electrodes and/or reference electrodes that have exceeded their maximum in-use time may lead to incorrect results, which may endanger patient lives.

- Do not install reference electrodes after the “Install before” date.
- Do not use reference electrodes after their maximum in-use time. Reference electrodes have to be replaced after 52 weeks of in-use time.

To change the reference electrode

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

Figure 10-40 Reference electrode

Open only the measuring chamber of the module, whose reference electrode you have to change.

The following screen appears:

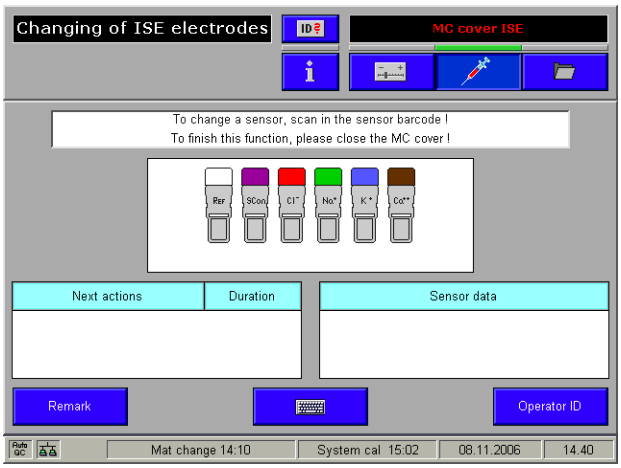


Figure 10-41

2 Open the locking lever.

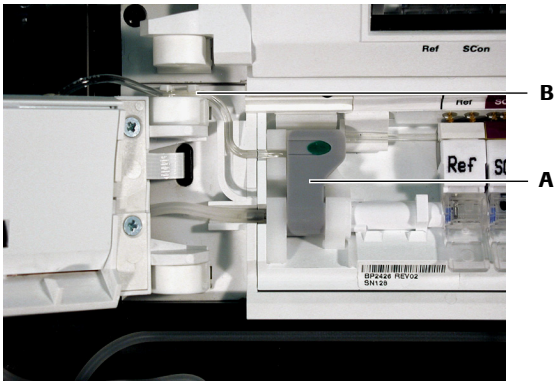
3 Remove the reference electrode.

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.

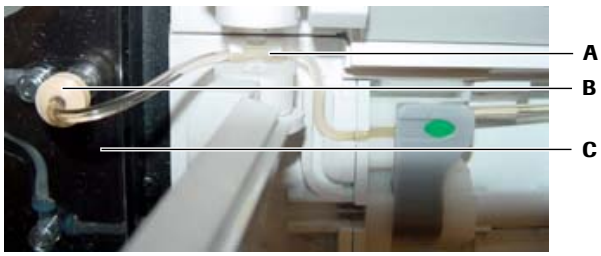
7 Insert the reference tube into the upper tube guide channel of the left locking lever and into the tube holder of the cover hinge. Close the locking lever.



A Locking lever **B** Upper tube guide channel

Figure 10-42 Inserting the reference electrode

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



A Upper tube guide channel
B Connector
C Measuring chamber cartridge

Figure 10-43 Inserting the reference electrode

9 Scan the barcode of the installed reference electrode. If you cannot scan the barcode, enter the barcode manually using the keyboard.

10 Close the measuring chamber and top cover.

11 Perform QC measurements on 3 different levels.

Quality control (p. 183)

■

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

A new QC measurement must be performed with all 3 levels (1 = low, 2 = normal, 3 = high) after each exchange of the MSS cassette.

WARNING

Using expired MSS cassettes and/or MSS cassettes that have exceeded their maximum in-use time may lead to incorrect results

Data obtained using expired MSS cassettes and/or MSS cassettes that have exceeded their maximum in-use time are not reliable. This may lead to incorrect results, which may endanger patient lives.

- Do not install MSS cassettes after the “Install before” date. Do not use MSS cassettes after their maximum in-use time.
- Immediately after installing a new MSS cassette, set up an alert in the maintenance scheduler. The MSS cassette must be changed after a maximum of 28 days, or earlier in case of a failed calibration or QC.

Troubleshooting – Group B (QC result exceeds the target value range) (p. 223)
Troubleshooting (p. 317)
Setting up the maintenance scheduler (p. 300)

To change the MSS cassette

1 Remove the top cover and open the MSS module cover. Apply force to the right edge of the MC cover with one finger, and at the same time, push it to the left and lift.

The following screen appears:

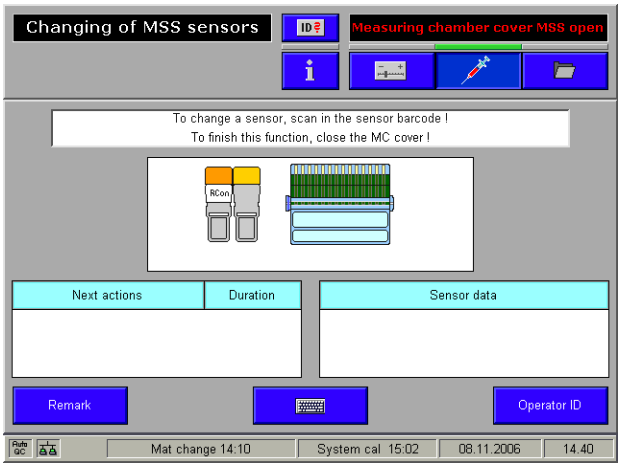


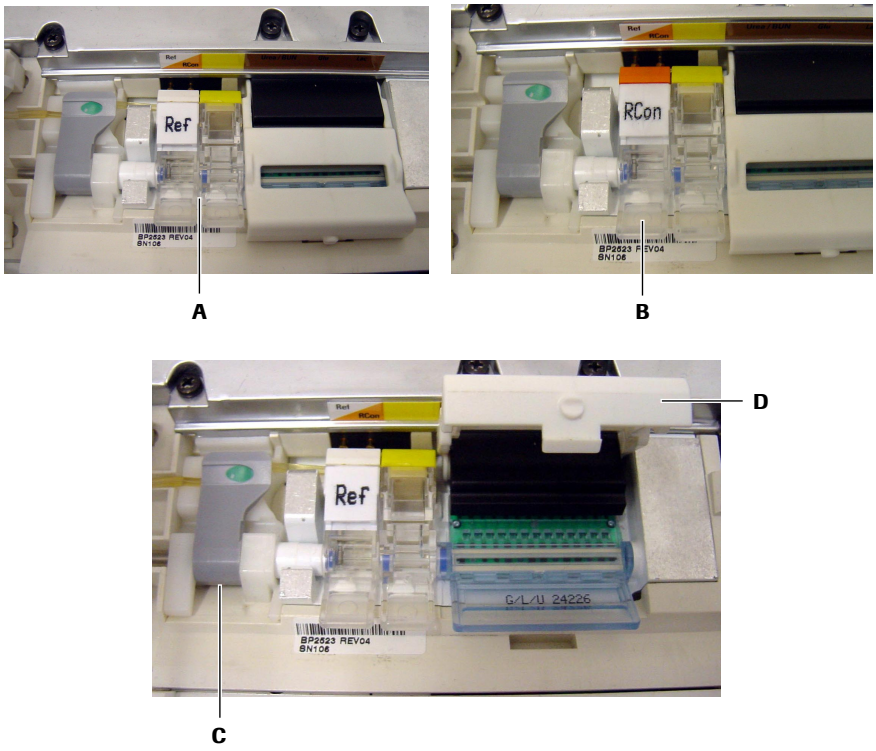
Figure 10-44

Before changing the MSS cassette, prepare a syringe or capillary with whole blood for polarization. The blood should have a volume of at least 150 µL and contain heparin as an anticoagulant.

To avoid touching the sensor contacts, hold the MSS cassette at its handle.

2 Open the contact clip and the locking lever.

3 Push the reference contact (RCon) (see below/B) or the MSS reference electrode (Ref+ Dummy) (see below/A) and the MSS cassette slightly to the left in the direction of the arrow and remove the MSS cassette.



A Glu/Lac/Urea
B Glu or Glu/Lac
C Locking lever
D Contact clip

Figure 10-45 MSS measuring chamber

4 Insert the new MSS cassette, and close the locking lever and the contact clip.

5 Read in the barcode from the packaging of the MSS cassette.

6 Close the measuring chamber and top cover.

7 Follow the instructions on the screen. Insert the prepared blood sample into the fill port.

The MSS cassette is polarized and calibrated.

8 If you cannot calibrate the MSS parameters after performing the automatic MSS polarization, perform a manual MSS polarization.

9 **System > Utilities > MSS polarization**

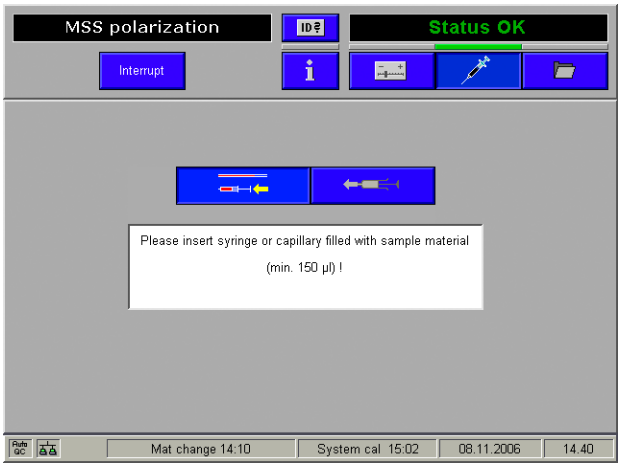


Figure 10-46

10 Follow the instructions on the screen.

11 Perform QC measurements on 3 different levels.

Quality control (p. 183)

■

Cleaning the measuring chambers

To clean the measuring chambers

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

2 Remove all electrodes.

Replacing electrodes (p. 297)

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

User-activated calibrations (p. 228)

■

Cleaning the Cl^- electrode

Proteins and other organic substances can collect on the membrane surface of the Cl^- electrode. Often, internal cleaning routines remove these substances from the Cl^- electrode. However, you have to use the Cleaning Kit for Cl^- electrode to remove remaining substances that prevent the electrode from measuring the Cl^-parameter correctly.

To clean the Cl^- electrode

Infection due to contact with the Cl^- electrode

WARNING

The Cl- electrode may contain materials of human origin. Contact with materials of human origin is potentially biohazardous and may result in infection.

- Follow standard laboratory practices.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, to prevent direct contact.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If contents from the Cl^- electrode come into contact with your skin, wash the affected area immediately with soap and water an apply a disinfectant. Consult a physician.

Using unapproved materials to clean the Cl^- electrode may damage the electrode and lead to incorrect Cl^- results

WARNING

If an unapproved material is pulled through the sample channel of the Cl^- electrode, the membrane surface of the electrode may be damaged. If the damaged electrode is not removed, this may lead to incorrect Cl^- results, which may endanger patient lives.

- Use only the threads provided in the Cleaning Kit for Cl^- electrode to perform this procedure.

Accessories (p. 373)

1. Remove the Cl^- electrode from the measuring chamber.

Replacing electrodes (p. 297)

2. Take a thread out of the Cleaning Kit for Cl^- electrode.
3. Slowly pull the entire thread once through the blue hole on the left side of the sample channel and out the other side of the sample channel.

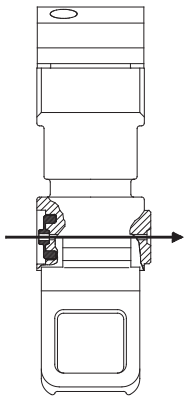


Figure 10-47 Pulling the thread through the sample channel of the Cl^- electrode

4. Reinsert the electrode into the measuring chamber.

5 Perform a system calibration for the ISE module.

■

Decontaminating instrument surfaces

Regularly decontaminate all outer surfaces of the instrument, including covers (e.g. printer cover, bottle compartment cover, top cover, T&D cover), with the correct disinfectant according to regulations specific to your use environment.

Clean dirty surfaces with a swab or paper towel that has been soaked in distilled water first. Remove and spray all removable covers, such as the instrument cover, with surface disinfectant. Then, disinfect using swabs or cellulose.

You may need extended soaking to clean some surfaces.

Do not spray parts that cannot be removed or that are inside the instrument.

Decontamination (p. 271)

Changing AutoQC mats

To change an AutoQC mat

1 Place the system in the top level of the Analyzer mode.

2 Open the AutoQC drawer.

The following screen appears:

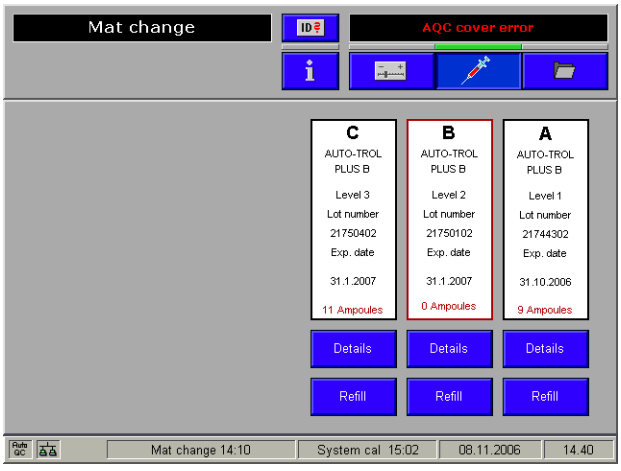


Figure 10-48

3 Remove the empty mat from the ampoule holder.

Removing ampoules from the ampoule holder may result in injury

Ampoules are made of fragile glass that splinters easily. They may break when you remove them from the ampoule holder, and result in personal injury.

- Wear appropriate personal protective equipment, such as protective gloves and safety glasses. Take extra care when working with protective gloves, which can easily be pierced or cut, leading to personal injury.

Before inserting a new mat, carefully remove all ampoules from the ampoule holder. If you have expired ampoules in the ampoule holder, dispose them as chemical hazardous waste. For more information, contact your Roche Service representative.

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

5 Turn the mat so that the necks of the ampoules face down. To remove air bubbles from the necks of the ampoules, gently wave the mat from side to side. Do not shake the mats.

Figure 10-49 AutoQC mat

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

When you have correctly installed the mat, you do not see its ampoules.

7 Press **Refill**.

The following screen appears:

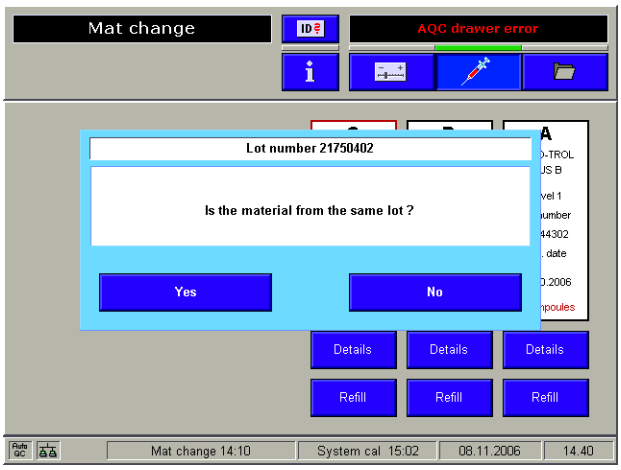


Figure 10-50

8 If you replace the mat with another mat from the same lot, press **Yes**. If you replace the mat with a mat from a different lot, you have to define the new QC material.

Material setup (p. 188)

9 If your mat does not contain 20 ampoules, press **Details**.

The following screen appears, showing which ampoules are available for an AutoQC measurement:

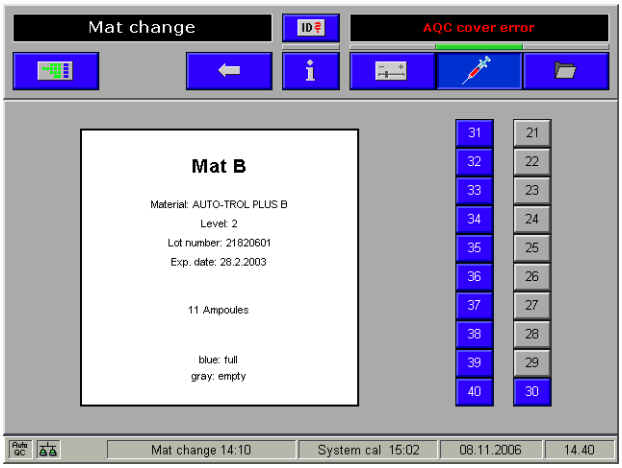


Figure 10-51

10 To assign an ampoule as being available or not available, select the ampoule number.

Blue ampoule numbers are ampoules that are available.

Gray ampoule numbers are ampoules that are not available.

11 Close the AutoQC drawer.

■

Additional maintenance procedures

Roche offers one- and three-year maintenance visits performed by authorized Roche Service representatives.

Troubleshooting

11 Troubleshooting 317

Troubleshooting

In this chapter, all error messages that appear in the software, their causes and troubleshooting actions are described.

In this chapter

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Troubleshooting - general

WARNING

Infection and injury due to contact with used components

Contact with some used components, such as the fill port, pump tubing, and the W Waste Container, may lead to biohazardous contamination, resulting in personal injury and/or infection.

- Treat these components as infectious waste, dispose them as chemical and biohazardous waste. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- Take extra care when working with protective gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

The **cobas b** 221 system can monitor air bubbles, clots, leaks, and blockages in the system. If your system detects one of these issues, an error message appears as a system stop, module stop, or status message.

The font color in the message window depends on the type of error detected by the system:

- System stop: red
- Module stop: yellow
- System warnings and status messages: white

You are shown the cause and recommended troubleshooting actions to handle system stops and warnings, module stops, and status messages for system and calibration values that are detected by the system on the screen.

System stops

System stops are issues that affect the general operation of the system. If your system is affected by an issue that causes a system stop, a window outlined in red appears on the screen. In addition, the message window displays a message with the cause of the system stop.

Emergency routine

If your system enters a system stop, the emergency routine will be performed 50 minutes after the system has entered a system stop, and every 4 hours thereafter to prevent crystallizations in tubings, pipes and electrodes. You cannot interrupt this routine.

Press **Info > List of all warnings** to find out more information about a specific system stop.

No.	Message	Cause	Action
10001	Flap W	Docking mechanism for waste is open.	• Close the W Waste Container docking mechanism. • If this error persists, contact your Roche Service representative.
10002	Out of operation	The system has been taken out of operation.	• Perform the installation procedure. *Installation* (p. 45)
10003	Warm up	The system warms up after power-on or power fail.	• Wait for the system warm up to finish. • If necessary, perform the installation procedure. *Installation* (p. 45)
10004	Economy mode	The system is in automatic or manual economy mode.	• Press **Exit** to deactivate economy mode. *Economy mode* (p. 181)
10005	Comm. error PC-µC	Communications between PC and microcontroller are interrupted.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10006	Download error	The download process to the microcontroller failed.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10008	No waste container	W Waste Container is missing.	• Insert the W Waste Container. • If this error persists, contact your Roche Service representative.
10009	Actuator bus current overload	An error was recognized in a hardware component.	• Press **System > Diagnostics > General hardware test** • If this error persists, turn off the system and contact your Roche Service representative.
10010	Valve bus current overload	An error was recognized in a hardware component.	• Press **System > Diagnostics > General hardware test** • If this error persists, turn off the system and contact your Roche Service representative.
10011	Database not ready	The database is not ready.	• Wait for the system warm up to finish • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-1 System stops

No.	Message	Cause	Action
10012	µC memory overrun	A microcontroller memory overflow was detected.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10016	Bottle compartment cover open		• Close the bottle compartment cover. • If this error persists, contact your Roche Service representative.
10017	Bypass wash error 1	Sample sensor SS2 does not detect enough air during wash process.	• Perform another wash: **System > Wash & cleaning > Wash** • Clean and align Turn and Dock disk (T&D): **System > Component Test > Aggregates > T&D Module > P1** • Clean and consider replacement of fill port. • Check the fill level of S1 solution and replace as needed. • Replace the T&D tubing set. • If this error persists, contact your Roche Service representative.
10018	SD wash error 1	Sample sensor SS2 does not detect enough air during wash process.	• Perform another wash: **System > Wash & cleaning > Wash** • Clean and align Turn and Dock disk (T&D): **System > Component Test > Aggregates > T&D Module > P1** • Clean and consider replacement of fill port. • Replace the T&D tubing set. • If this error persists, contact your Roche Service representative.
10019	Waste container full		• Empty the W Waste Container (*To empty the W Waste Container* (p. 284)) or insert a new W Waste Container into the bottle compartment (*To install the W Waste Container* (p. 286)).
10020	Rinse bottle empty	The transponder on the S1 Rinse Solution bottle indicates an empty bottle.	• Insert a new S1 Rinse Solution. *Exchanging solutions and packs* (p. 280).
10021	Flap S1	S1 Rinse Solution docking mechanism is open.	• Close the S1 Rinse Solution docking mechanism.
10022	µC Reset		• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10023	Power fail	A power failure occurred.	• The system will be ready for operation after warm-up.
10024	No wash-water container		• Insert S1 Rinse Solution
10025	Check date and time		• Check the date and time and perform any necessary changes: **Setup > Times & intervals > Current date & time**
10026	Bypass wash error 2	Sample sensor SS2 does not detect enough water during wash process.	• Perform another wash: **System > Wash & cleaning > Wash** • If this error persists, check the fill port area for signs of dirtiness or clogging. • If this error persists, contact your Roche Service representative.

Table 11-1 System stops

No.	Message	Cause	Action
10027	SD wash error 2	Sample sensor SS2 does not detect enough water during wash process.	• Perform another wash: **System > Wash & cleaning > Wash** • If this error persists, check the fill port area for signs of dirtiness or clogging. • If this error persists, contact your Roche Service representative.
10028	S1 on board time expired	On board time of S1 Rinse Solution expired.	• Insert new S1 Rinse Solution
10029	S1 expired	S1 Rinse Solution expired.	• Insert new S1 Rinse Solution
10032	Micro controller communications error	A communications problem occurred at the microcontroller.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10033	COOX communications error	A communications problem occurred at the microcontroller.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10034	AQC communications error	A communications problem occurred at the microcontroller.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10039	Vacuum reduction not ok	Low pressure is not reduced enough. V13 does not open.	• Perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If the pump output is more than 20% over or under the reference value, contact your Roche Service representative.
10040	Vacuum error	Vacuum buildup is insufficient.	• Perform the general fluidics test: **System > Diagnostics > General fluidics test** • Check the instrument at the indicated positions for leaks. • If there are signs of leaks, contact your Roche Service representative. If there are no signs of leaks, perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If the pump output is more than 20% over or under the reference value, contact your Roche Service representative.
10041	Waste error 1	The waste system is leaking.	• Insert new W Waste Container.
10042	Waste error 2	The waste ventilation path is blocked.	• Insert new W Waste Container.
10043	Separator sens. error	The optical fluid sensor in the waste separator could not be calibrated.	Contact your Roche Service representative.
10044	Separator error	The fluid in the separator did not drain.	• Stop injecting your sample once you hear the acoustic signal from the system, or are indicated to do so on the screen. • Insert new W Waste Container. • If this error persists, contact your Roche Service representative.
10045	Check Waste fill level	Measured waste fill level differs too much from calculated value.	• Open the W Waste Container docking mechanism, and close it again. Press the **Waste fill level** button and enter the fill level. *To install the W Waste Container* (p. 286)

Table 11-1 System stops

No.	Message	Cause	Action
10046	Waste line blocked	The connection from separator into the W Waste Container is not continuous.	• Insert new W Waste Container. • If this error persists, contact your Roche Service representative.
10047	VPS error	The vacuum pump protection contains fluid. Vacuum buildup is not possible.	Contact your Roche Service representative.
10048	Error SS1	The optical sample sensor at the input of the BG module could not be calibrated.	• Perform a wash: **System > Wash & cleaning > Wash** • If this error persists, contact your Roche Service representative.
10049	Error SS2	The optical sample sensor at the end of the sample inlet path could not be calibrated.	• Perform a wash: **System > Wash & cleaning > Wash** • If this error persists, contact your Roche Service representative.
10050	Error SS3	The optical sample sensor in the Hb cartridge could not be calibrated.	• Perform a wash: **System > Wash & cleaning > Wash** • If this error persists, contact your Roche Service representative.
10051	Error SS4	The optical sample sensor at the input of the MSS module could not be calibrated.	• Perform a wash: **System > Wash & cleaning > Wash** • If this error persists, contact your Roche Service representative.
10052	Error SS6	The optical sample sensor in the middle of the sample inlet path could not be calibrated.	• Perform a wash: **System > Wash & cleaning > Wash** • If this error persists, contact your Roche Service representative.
10054	Baro sensor error	The measured barometric pressure falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10056 - 10067	Process error + additional information	A subprogram did not report back.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10088	ADC error		• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10089 - 10094	Comm. error + additional information	A subprogram did not report back.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10095 - 10097	Timing error	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10098	Timing error COOX measurement	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, print the measurement report from your last measurement (**Quick access > Last measurement**) and the sensor report (**Info > Miscellaneous reports > Sensor report**). Then, contact your Roche Service representative.
10099 - 10112	Timing error	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, print the measurement report from your last measurement (**Quick access > Last measurement**). Then, contact your Roche Service representative.

Table 11-1 System stops

No.	Message	Cause	Action
10113 - 10117	Comm. error + additional information	A subprogram did not report back.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10118 - 10119	Timing error MSS	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10120 - 10121	Timing error	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10123 - 10126	Comm. error D cal.	A subprogram did not report back.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10127	Timing error MSS	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10128	Timing error	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, print the measurement report from your last measurement (**Quick access > Last measurement**). Then, contact your Roche Service representative.
10130	Timing error COOX	An asynchrony occurred between processes and measuring.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, print the measurement report from your last measurement (**Quick access > Last measurement**) and the sensor report (**Info > Miscellaneous reports > Sensor report**). Then, contact your Roche Service representative.
10155	AQC drawer open	The AutoQC drawer is open.	• Close the AQC drawer. • If the AQC drawer is closed and the status message on the screen is **Mat change**, contact your Roche Service representative.
10160 - 10261	File error	A file check resulted in an error.	• Perform a software update: **System > Utilities > Communcation**
10288 - 10389	Program error	A communications error occurred as part of the programming of the module processors.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10416 - 10419	Hardware conflict	A defective module was detected within the scope of the module communications.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, write down the error number, turn the system off, and contact your Roche Service representative.
10424 - 10452	Hardware error	A defective module was detected within the scope of the module communications.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, write down the error number, turn the system off, and contact your Roche Service representative.

Table 11-1 System stops

No.	Message	Cause	Action
10456 - 10468	EEPROM error	The EEPROM data of a module processor are incorrect.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, write down the error number, turn the system off, and contact your Roche Service representative.
10469	Vacuum ADC error	A communications problem occurred at the vacuum board.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
10470	Transponder error	There is a transmission error between the RFID receiver board and the transponder.	• Remove the S1 Rinse Solution, S2 Fluid Pack and S3 Fluid Pack A containers, and reinsert them. • If this error persists, contact your Roche Service representative.
10471	T&D error	An error occurred at the T&D module.	• Press the following buttons: **System > Component test > Aggregates > T&D module > Initialization** • Clean the T&D disk, the fill port, and the plug control. *Maintenance* (p. 269) • If this error persists, contact your Roche Service representative.
10472	Transponder error S1	The transponder data of the S1 Rinse Solution could not be read.	• Remove the S1 Rinse Solution from the bottle compartment, and reinsert it. • Insert new S1 Rinse Solution. • If this error persists, contact your Roche Service representative.
10488	HW test error	An error was recognized in a hardware component.	• Perform the general hardware test: **System > Diagnostics > General hardware test** • Contact your Roche Service representative.
10489	Remote lock	Instrument locked by **cobas bge link**.	• Press **Continue**. Then, log on as a user with **Remote unlock** privileges.
10491	QC setup wizard active	The instrument was locked by starting the QC setup wizard.	• When the QC setup wizard is finished, the message is removed. *To install a new QC material using the QC setup wizard* (p. 197)
10492	Data transfer active	The device was locked by starting the data transfer.	• When the data transfer is finished, the message is removed.

Table 11-1 System stops

Module stops

Module stops are issues that affect specific modules of the system. If your system is affected by an issue that causes a module stop, a window outlined in yellow appears on the screen. In addition, the message window displays a message with the cause of the module stop.

No.	Message	Cause	Action
20000	SD temperature nOk	The temperature of the sample distributor falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20016	FMS volume error	The calibration solution is not aspirated into the BG measuring chamber in the specified time.	• Aspirate CAL B: **System > Utilities > Fluid actions > Fill routines > Aspirate CAL B** • Perform the general fluidics test: **System > Diagnostics > General fluidics test** • Handle the errors detected by the general fluidics test. • If this error still persists, perform the **Mixing system** calibration: **System > Calibration > Mixing system** • Install a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • Replace pump tube of main pump. *Exchanging the peristaltic pump tubes* (p. 294) • If this error still persists, contact your Roche Service representative.
20017	FMS error	The mixture ratio falls outside the specified range.	• Aspirate CAL A and CAL B: **System > Utilities > Fluid actions > Fill routines** • Perform the general fluidics test: **System > Diagnostics > General fluidics test** • Handle the errors detected by the general fluidics test. • Install a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error still persists, contact your Roche Service representative.
20018	Pack S2 empty		• Insert a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
20019	Flap S2	Docking mechanism for S2 Fluid Pack is open.	• Close the S2 Fluid Pack docking mechanism.
20020	No pack S2		• Insert the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
20021	ADC error cond BG/ISE	A hardware error occurred during mixture calibration.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20022	Transponder error S2	The transponder data of the S2 Fluid Pack could not be read.	• Remove the S2 Fluid Pack from the bottle compartment, and reinsert it. • If this error persists, replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
20023	S2 on board time expired		• Insert a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)

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.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20037	ADC error BG	Signal acquisition could not be performed due to a hardware error.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20048 - 20051	ISE temperature nOk	The temperature of the ISE measuring chamber falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20053	ADC error ISE	The signal acquisition could not be performed due to a hardware error.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20065	COOX lamp error	An error occurred during control of the halogen lamp.	• Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
20066	COOX lamp error	During the measurement or polychromator calibration, an error occurred while triggering the neon lamp.	• Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
20067	COOX lamp error	During the measurement or polychromator calibration, an error occurred while triggering the neon lamp.	• Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
20068	COOX HW error	The signal acquisition could not be performed due to a hardware error.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20069	COOX HW error	The supply voltage of the COOX module falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20071	COOX HW error	A communications problem occurred at the microcontroller of the COOX module.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20072	COOX temperature nOk	The temperature of the cuvette holder falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-2 Module stops

No.	Message	Cause	Action
20073	HW test error hemolyzer	An error was recognized in a hardware component of the hemolyzer.	• Check that there are no signs of moisture in the hemolyzer tubing. • Perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If the pump output is more than 20% over or under the reference value, contact your Roche Service representative. • If the vacuum pump test shows no issues, perform the general hardware test: **System > Diagnostics > General hardware test**. • Handle the errors detected by the general hardware test. • If this error persists, contact your Roche Service representative.
20080	PP error	The pump performance of the MSS output pump falls outside the specified range.	• Replace the MSS output PP tube. • Perform an MSS system calibration: **System > Calibration > MSS system calibration** • If this error persists, contact your Roche Service representative.
20081	MSS pol. running	The MSS polarization phase has not yet finished.	The sensor will be ready to measure after the system calibration is finished.
20082	MSS pol. not ok	The blood sample required for MSS polarization could not be positioned.	• Make sure that the MSS cassette, the counter bearing, and the RCon are correctly installed within the MSS measuring chamber. • Repeat the MSS polarization: **System > Utilities > MSS polarization**
20083	MSS pol not ok	The MSS polarization was canceled.	• Repeat the MSS polarization: **System > Utilities > MSS polarization**
20084	HW test error MSS	An error was recognized in a hardware component of the MSS measuring chamber.	• Perform the general hardware test: **System > Diagnostics > General hardware test**. • Handle the errors detected by the general hardware test. • If this error persists, contact your Roche Service representative.
20085	Pack S3 empty		• Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280)
20086	Flap S3	Docking mechanism for S3 Fluid Pack A is open.	• Close the S3 Fluid Pack A docking mechanism.
20087 - 20089	MSS temperature nOk	The temperature of the MSS measuring chamber falls outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20090	MSS contaminated	Bacterial contamination detected.	MSS maintenance procedure is required. Contact your Roche Service representative.
20091	No pack S3		• Insert new S3 Fluid Pack A *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
20092	ADC error cond. MSS	A hardware error occurred during initialization.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-2 Module stops

No.	Message	Cause	Action
20093	ADC error MSS	Signal acquisition could not be performed due to a hardware error.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
20094	Transponder error S3	The transponder data of the S3 Fluid Pack A could not be read.	• Remove the S3 Fluid Pack A from the bottle compartment, and reinsert it. • If this error persists, replace the S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280)
20095	S3 on board time expired		• Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280)
20112	SS5 error	The optical sample sensor is not correctly calibrated.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • If this error persists, contact your Roche Service representative.
20113	Module error AQC	The required XY position was not reached.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Perform an AutoQC measurement. • If this error persists, contact your Roche Service representative.
20114	Module error AQC	The required Z position was not reached.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Perform an AutoQC measurement. • If this error persists, contact your Roche Service representative.
20115 20116 20118	Module error AQC	The required position was not reached.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Perform an AutoQC measurement. • If this error persists, contact your Roche Service representative.
20120	AQC wash error	The SS2 detects a bad wash profile of the AQC sample line.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Perform an AutoQC measurement. • If this error persists, contact your Roche Service representative.
20122 - 20141	AQC pos. error	The required position was not reached.	• Perform an AQC positioning test: **System > Component test > Aggregates > AutoQC motors > AQC-positions** • Open the AutoQC drawer and remove the ampoule holder. Then, move the AutoQC motor to the service position. Lastly, return to the home position. • Reinsert the ampoule holder and close the AutoQC drawer. • Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • If this error persists, contact your Roche Service representative.
20142	AQC temperature nOk	The temperature of the AQC module is outside the specified range.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-2 Module stops

System warnings

No.	Message	Cause	Action
30005	Cl^- electrode is contaminated (defective)		• Perform an internal cleaning of the ISE measuring chamber. Press the following buttons: **System > Wash & cleaning > Cleaning modules** • Perform an external cleaning of the ISE measuring chamber. Press the following buttons: **System > Wash & cleaning > Cleaning modules** • Remove and clean the Cl^- electrode using the "Cleaning Kit for Cl^- Electrode". Follow the instructions in the "*Cleaning Kit for Cl^- Electrode*" package insert. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • If this error persists, replace the Cl^- electrode.
30006	Undefined sensor status	No standby solution aspirated for a defined time frame.	• Perform a QC measurement. *QC measurement* (p. 205)
30007	MSS contaminated	Bacterial contamination detected.	MSS maintenance procedure is required. Contact your Roche Service representative.
30008	Pack S2 level is low	S2 Fluid Pack will be empty in the next 12–24 hours.	• Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
30009	Pack S3 level is low	S3 Fluid Pack A will be empty in the next 12–24 hours.	• Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280)
30010	Rinse level is low	S1 Rinse Solution will be empty in the next 12–24 hours.	• Insert new S1 Rinse Solution. *Exchanging solutions and packs* (p. 280)
30011	Waste is nearly full	W Waste Container will be full in the next 12–24 hours.	• Empty the W Waste Container (*To empty the W Waste Container* (p. 284)) or insert a new W Waste Container into the bottle compartment (*To install the W Waste Container* (p. 286)).

Table 11-3 System warnings

No.	Message	Action
30012	Prep. of rinse not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate rinse** from the **Routines** list, and press the **Start** button. • Make sure that the AutoQC tubing, T&D tubing set, and the input unit are properly installed. • Insert new S1 Rinse Solution. *Exchanging solutions and packs* (p. 280) • Perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If this error persists, contact your Roche Service representative.
30013	Prep. of CAL B not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL B** from the **Routines** list, and press the **Start** button. • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30014	Prep. of CAL A not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL A** from the **Routines** list, and press the **Start** button. • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30015	Prep. of Ref. BG not ok	• Call up fill routine again. **System > Utilities > Fluid actions > Fill routines > Fill ref. electrode BG** • Check MC cartridge tubing. • Check S2 docking mechanism. • Insert new S2 Fluid Pack. • Perform general hardware test to test the valves. • Perform general hardware test to test the valves. **System > Diagnostics > General hardware test**.

Table 11-4 System warnings

No.	Message	Action
30016	Prep. of Ref. ISE not ok	• Call up fill routine again. **System > Utilities > Fluid actions > Fill routines > Fill ref. electrode ISE** • Check MC cartridge tubing. • Check S2 docking mechanism. • Insert new S2 Fluid Pack. • Perform general hardware test to test the valves. **System > Diagnostics > General hardware test**.

Table 11-4 System warnings

No.	Message	Action
30017	Prep. of O2 zero not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate solution O2 zero** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

Table 11-4 System warnings

No.	Message	Action
30018	Prep. of Na cond. not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate Na cond. solution** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

Table 11-4 System warnings

No.	Message	Action
30019	Prep. of clean. sol. not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate clean. sol.** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30020	Prep. of standby not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. • Make sure that the MSS cassette is properly installed in the MSS measuring chamber. • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30021	Prep. of Ref. MSS not ok (only if Urea is installed)	• Check for an obstruction in the measuring chamber. Reseat the MSS cartridge to remove block. • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30022	Prep. of CAL 1 not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 1** from the **Routines** list, and press the **Start** button. • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30023	Prep. of CAL 2 not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 2** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30024	Prep. of CAL 3 not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 3** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
30025	Prep. of CAL 4 not ok	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 4** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

Table 11-4 System warnings

No.	Message	Cause	Action
30028	Check AQC material	At least 1 mat in the AutoQC module contains only 2 more full ampoules.	• When there are no more full ampoules in a mat, install a new mat into the AutoQC module. *Changing AutoQC mats* (p. 311)
30029	Check parameter states	One or more parameters are not calibrated.	• Perform Calibration for "Ready": **Quick access > Calibration for "Ready"**
30030	Perform manual QC measurement	Manual QC measurement is pending. • Check if QC material is loaded in AQC or check results for errors.	• Perform a manual QC measurement. *Manual QC measurement* (p. 205)
30031	Perform maintenance	One or more maintenance processes have to be carried out.	• Perform maintenance: **Quick access > Maintenance** Select and run the corresponding maintenance. • If there are maintenance tasks pending that need a service call, contact your Roche Service representative
30032	Printer - printer lever opened	Printer lever is open	• Close the printer lever. *Replacing printer paper* (p. 296)
30033	Printer - No paper	No paper available	• Insert printer paper. *Replacing printer paper* (p. 296) • If this error persists, contact your Roche Service representative.
30034	Messages	**cobas bge link** has sent a message.	• Delete the message in the message buffer: **Info > Message > Delete message**
30035	Automatic software update	Change to another MSS cassette generation detected. This requires an automatic software update.	Follow the information given on the screen. No user interaction necessary.
30036	HW test error fan	Result of the general hardware test.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
30037	Screen sharing active	A service connection was established to the system. The "Screen sharing" message is displayed in the status line.	• This message is removed after screen sharing is disconnected.
30040	S1 expires	On board time for S1 Rinse Solution is about to expire.	• Insert new S1 Rinse Solution. *Exchanging solutions and packs* (p. 280)
30041	S2 expires	On board time for S2 Fluid Pack is about to expire.	• Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
30042	S3 expires	On board time for S3 Fluid Pack A is about to expire.	• Insert new S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280)
30043	Repeated MSS monitoring failure	Bacterial contamination may be present.	Contact your Roche Service representative.
30044	Replace BG Ref. electrode	On board time of the BG reference electrode has expired.	Replace the BG reference electrode. *Changing the reference electrode* (p. 304)
30045	Replace ISE Ref. electrode	On board time of the ISE reference electrode has expired.	Replace the ISE reference electrode. *Changing the reference electrode* (p. 304)
30046	Replace MSS Ref. electrode	On board time of the MSS reference electrode has expired.	Replace the MSS reference electrode. *Changing the reference electrode* (p. 304)

Table 11-5 System warnings

Status messages of measuring and calibration values

These messages define causes that affect measurement values and/or calibration values of the system.

No.	Message	Cause	Action
1000	Sample pos. error (1)	BG, ISE, or MSS conductivity is not constant. Possible causes: • Blockage or leak • Separation of electrode membrane • Leaking electrodes	• If discoloration is detected in the internal electrolyte of the electrode, replace the electrode. *Replacing electrodes* (p. 297) • To make sure that the tubing paths are open and without leaks, perform the **General fluidics test**: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1001	Sample pos. error (2)	BG, ISE, or MSS conductivity is too low. Possible causes: • Blockage • No fluid in measuring chamber	• To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If you find no leaks or clogs, replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
1002	Sample sep. error (1)	No air packet was detected between calibration solution and sample. The sample was not aspirated or aspirated too late. Possible causes: • Deposits or blockage in measuring chamber.	• To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1003	Ref. sol. asp. error	No reference solution was detected. Possible causes: • Blockage or leaks in reference system	• Perform the fill reference electrode routine: **System > Utilities > Fluid actions > Fill routines** Then, select the reference electrode filling routine for the appropriate module from the **Routines** list, and press the **Start** button. • Insert new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1004	Ref. sol. pos. error	Conductivity level could not be maintained. Possible causes: • Detachment of electrode membrane • Leaking electrodes	• To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • If this error cannot be corrected, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1005	End of sample detected	SS1 detects the end of the sample, but the measuring chamber is not yet filled. Possible causes: • Irregular sample • Insufficient sample • Improper sample	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If this error persists, contact your Roche Service representative.
1006	Irregular sample (1)	The measuring chamber is not filled with a homogeneous sample. Possible causes: • The sample was irregular • Leak in the measuring channel • Air bubbles were detected in the measuring channel	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If this error persists, contact your Roche Service representative.
1007	Cuvette not empty	Sample detection was not possible. Possible causes: • Deposits in the cuvette • Light level was too low	• Perform an internal cleaning of the COOX module: **System > Wash & cleaning > Cleaning modules** • Perform the polychromator calibration: **System > Calibrations** • Replace the main pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • If this error persists, contact your Roche Service representative.
1008	Irregular sample (2)	The conductivity changed after closing the valve at the measuring chamber input. Possible causes: • Insufficient wetting in the measuring channel • Separation of the electrode membrane • Leak in the electrode	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the wetting routine for the appropriate module: **System > Utilities > Fluid actions** • To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • If this error cannot be corrected, contact your Roche Service representative.
1009	Sample pos. error (3)	The measuring signal was not constant or the measuring channel was not uniformly filled. Possible cause: • Sample was fragmented. • Sample was not homogeneous. • Leak in the electrodes • Blockage or leakage • Separation of the electrode membrane	• Repeat your measurement, and ensure that your sample is homogeneous and sufficient for a measurement. • If discoloration is detected in the internal electrolyte of the electrode, replace the electrode. *Replacing electrodes* (p. 297) • To make sure that the tubing paths are open and without leaks, perform the **General fluidics test**: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1010	Sample pos. error (4)	The conductivity was too high. Possible causes: • Aspiration problems with standby solution • MSS output pump tube defective	• Replace the MSS output pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. If you have an installed reference electrode for measuring urea on a **cobas b** 221<6> system, select the **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1011	Sample pos. error (5)	No constant conductivity was detected at the sensor input. Possible causes: • Blockage or leak • MSS outlet pump tube defective	• Replace the MSS output pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. If you have an installed reference electrode for measuring urea on a **cobas b** 221<6> system, select the **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1012	Sample pos. error (6)	Conductivity at sensor input was too low. Possible causes: • Blockage • No fluid in measuring chamber • MSS outlet pump tube defective	• Replace the MSS output pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. If you have an installed reference electrode for measuring urea on a **cobas b** 221<6> system, select the **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1013	Sample sep. error (2)	MSS: No air packet was detected between calibration solution and sample. The sample was not aspirated or aspirated too late. Possible causes: • Deposits or blockage in measuring channel. • MSS output pump tube defective	• Replace the MSS output pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. If you have an installed reference electrode for measuring urea on a **cobas b** 221<6> system, select the **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform an MSS polarization: **System > Utilities > MSS polarization** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1014	Sample pos. error (7)	Conductivity at BSA sensor inside the MSS cassette was too low. Possible causes: • Air bubbles • Poor wetting	• Repeat your measurement, and ensure that your sample is homogeneous and sufficient for a measurement. • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • If this error persists, contact your Roche Service representative.
1015	Sample pos. error (8)	Conductivity at lactate sensor inside the MSS cassette was too low. Possible causes: • Air bubbles • Poor wetting	• Repeat your measurement, and ensure that your sample is homogeneous and sufficient for a measurement. • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • If this error persists, contact your Roche Service representative.
1016	Sample pos. error (9)	Conductivity at glucose sensor was too low. Possible causes: • Air bubbles • Poor wetting	• Repeat your measurement, and ensure that your sample is homogeneous and sufficient for a measurement. • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • If this error persists, contact your Roche Service representative.
1017	Sample pos. error (10)	MSS: Conductivity was too low at the sensor input after positioning the sample/calibration solution in the measuring chamber. Possible causes: • The sample/calibration solution was not homogeneous. • Insufficient sample/calibration solution detected • Insufficient wetting of the measuring channel	• Repeat your measurement, and ensure that your sample is homogeneous and sufficient for a measurement. • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1020	Sample distr. error (1)	No solution was detected at SS1 during positioning. Possible causes: • Blockage or leakage during positioning	• Perform **Wash**: **System > Wash & cleaning > Wash** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1021	Sample distr. error (2)	No solution was detected at SS3, despite a solution being detected at SS2. Possible causes: • Blockage or leakage	• Perform **Wash**: **System > Wash & cleaning > Wash** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1022	Sample distr. error (3)	Sample excess could not be extracted via the sample distributor. Possible causes: • Blockage	• Perform **Wash**: **System > Wash & cleaning > Wash** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1023	Sample distr. error (4)	No solution was detected at SS4. Possible causes: • Blockage	• Perform **Wash**: **System > Wash & cleaning > Wash** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1025	No sample detected (2)	ISE: No constant conductivity of the sample was detected. Possible causes: • Fragmented sample in sample distributor	• Repeat your measurement, and ensure that the sample has no air bubbles. • If this error persists, contact your Roche Service representative.
1026	No sample detected (3)	ISE: No constant conductivity of the sample was detected. Possible causes: • Fragmented sample in sample distributor	• Repeat your measurement, and ensure that the sample has no air bubbles. • If this error persists, contact your Roche Service representative.
1027	No sample detected (4)	No sample was detected in the COOX module Possible causes: • There is a blockage or leak in the sample path • There is a leak in the cuvette holder • Main pump tube defective	• Perform **Wash**: **System > Wash & cleaning > Wash** • Replace the main pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1028	Insufficient sample(1)	No sample was detected in the COOX module Possible causes: • Sample was not homogeneous • Sample volume was too low	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If this error persists, contact your Roche Service representative.
1029	Insufficient sample(2)	Insufficient sample volume was detected in the BG module Possible causes: • Sample was not homogeneous • Sample volume was too low	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1030	Insufficient sample(3)	Insufficient sample volume was detected in the ISE module Possible causes: • Sample was not homogeneous • Sample volume was too low	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If this error persists, contact your Roche Service representative.
1031	Insufficient sample(4)	Insufficient sample volume was detected in the MSS module Possible causes: • Sample was not homogeneous • Sample volume was too low	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If you have an uncalibrated MSS cassette, perform the fill routine for CAL 2, 3 and 4. Press the following buttons: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 2** from the **Routines** list, and press the **Start** button. Follow these steps to aspirate CAL 3 and CAL 4. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • If this error persists, contact your Roche Service representative.
1032	Sample distr. error (5)	No calibration solution 1 (CAL 1) detected. Possible causes: • Blockage or leak • Main pump tube defective	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 1** from the **Routines** list, and press the **Start** button. • Replace the main pump tube. *Exchanging the peristaltic pump tubes* (p. 294) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1036	Insufficient sample (5)	Insufficient sample volume was detected in the MSS module. Possible causes: • Sample was not homogeneous • Sample volume was too low	• Repeat your measurement or calibration, and ensure that your sample is homogeneous and sufficient for a measurement. • If you have an uncalibrated MSS cassette, perform the fill routine for CAL 2, 3 and 4. Press the following buttons: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate CAL 2** from the **Routines** list, and press the **Start** button. Follow these steps to aspirate CAL 3 and CAL 4. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1037	No sample detected (8)	No sample detected in hemolyzer. Possible causes: • There is a blockage or leak in the aspiration path.	• Perform the hemolyzer test: **System > Component test > Aggregates > Hemolyzer** • Replace the main pump tube. • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
1038	No sample detected (9)	No rinse solution was detected by SS3 during COOX calibration. Possible causes: • There is a blockage or leak in the aspiration path.	• Perform **Wash**: **System > Wash & cleaning > Wash** • Replace the main pump tube. • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1050	No sample in SIP	No sample detected in the sample inlet path at SS2 or SS6. Possible causes: • No sample was inserted • There is a blockage or leak in the sample path.	• Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1051	No AQC sample detected	No sample was detected at SS5. Possible causes: • There is a blockage or leak in the sample path. • Incorrect AutoQC material assignment	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Ensure that the assignment of AutoQC materials is correct. *Material assignment – AutoQC materials* (p. 190) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
1052	No vacuum	No regulated low-pressure vacuum could be built up during the aspiration process. Possible causes: • Vacuum system defective • Incorrect baro setup	• Perform the vacuum system test: **System > Component test > Control sensors > Vacuum system** Then, turn on the **Vacuum system** switch button and press the ⇐ button. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2004	Repro. not OK	Sensor signal cannot be reproduced Possible causes: • Measuring channel contaminated • Bubbles in the internal electrolyte of the electrode membrane • Interference signals in the measuring channel during measurement value acquisition • Interference signals via the reference electrode during measured value acquisition • Electrode loses sensitivity	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the wetting routine for the appropriate module: **System > Utilities > Fluid actions** • Remove the electrode and tap the electrode body with your fingernail to release any air bubbles from the electrode membrane. *Electrode* (p. 299) • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the electrode and/or the MSS cassette is defective, replace them. *Replacing electrodes* (p. 297) or *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • If the module's sample path is dirty, perform an internal cleaning of the module: **System > Wash & cleaning > Cleaning modules** If you perform the internal cleaning on the MSS module, first install a dummy electrode. • If the error affects potentiometric electrodes and sensors (pH, ISE parameters and urea), perform the fill reference electrode routine: **System > Utilities > Fluid actions > Fill routines** Then, select the reference electrode filling routine for the appropriate module from the **Routines** list, and press the **Start** button. • If this error persists, replace the reference electrode of each affected module. *Changing the reference electrode* (p. 304)
2009	Recal. not OK	Signal difference occurring during recalibration of PCO_2 was too large. Possible causes: • Invalid sample type used	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the PCO_2 electrode is defective, replace it. *Replacing electrodes* (p. 297)

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2011	Sensor signal instability	Sensor signal cannot be reproduced. Possible causes: • Invalid sample type used • Measuring channel contaminated • Bubbles in the internal electrolyte of the electrode membrane • Interference signals in the measuring channel during measurement value acquisition • Interference signals via the reference electrode during measured value acquisition	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • If the interference applies to all the parameters in a module, replace the reference electrode of the module. *Changing the reference electrode* (p. 304) • Remove the electrode and tap the electrode body with your fingernail to release any air bubbles from the electrode membrane. *Electrode* (p. 299) • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the electrode and/or the MSS cassette is defective, replace them. *Replacing electrodes* (p. 297) or *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate rinse** from the **Routines** list, and press the **Start** button. • If this error persists, contact your Roche Service representative.
2012	Sensor signal drifting	Sensor signal is drifting. Possible causes: • Invalid sample type used • S1 Rinse Solution contaminated • Aspiration issue with the S1 Rinse Solution. • Bubbles in the internal electrolyte of the electrode membrane • Interference signals in the measuring channel during measurement value acquisition	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Remove the electrode and tap the electrode body with your fingernail to release any air bubbles from the electrode membrane. *Electrode* (p. 299) • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the electrode and/or the MSS cassette is defective, replace them. *Replacing electrodes* (p. 297) or *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S1 Rinse Solution. *Exchanging solutions and packs* (p. 280). • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2016	Signal too high	The first sampling value of the O2 zero point calibration is > 60 mV Possible causes: • Air bubbles affect the result of the O2 zero point calibration • O2 zero point solution is not homogeneous • PO_2 electrode defective	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the BG wetting routine: **System > Utilities > Fluid actions** • Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate solution O2 zero** from the **Routines** list, and press the **Start** button. • Replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280). • Replace the PO_2 electrode. • If this error persists, contact your Roche Service representative.
2021	Drift alarm	Sensor signal drift was detected in the "Ready" state. Possible causes: • Electrode drifts that exceed the specified limit values • Invalid sample type is being used • Wetting problems • PO_2 contamination	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the BG wetting routine: **System > Utilities > Fluid actions** • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the electrode and/or the MSS cassette is defective, replace them. *Replacing electrodes* (p. 297) or *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • If there is drift in the PO_2 electrode, test the measuring sensors in the BG module: **System > Component test > Meas. sensors** Then, press the **Aspirate MIX 1** button. • If the standard deviation of the PO_2 sensor signal is greater than 50 mV after 2 minutes, perform an internal cleaning of the BG module: **System > Wash & cleaning > Cleaning modules** • If this error is resolved, set the BG cleaning interval to 3 days: **System > Wash & cleaning > Cleaning modules** • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2022	Ref. drift alarm	Sensor signal drift was detected at the reference electrode in the "Ready" state. Possible causes: • Bubbles interfere with the reference system • S2 Fluid Pack docking mechanism is dirty	• Perform the fill reference electrode routine: **System > Utilities > Fluid actions > Fill routines** Then, select the reference electrode filling routine for the appropriate module from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Make sure that the S2 Fluid Pack docking mechanism is clean. If the docking mechanism is dirty, clean it. *Decontamination* (p. 271) • Replace the reference electrode. *Changing the reference electrode* (p. 304) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
2023	Sensitivity drift	1 point sensitivity of the MSS sensor drifts. Possible causes: • The sensor has not completed the start-up phase, and the 1 point sensitivity is increasing considerably.	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"**
2024	Air bubble detected	Before washing out the sample, the conductivity value was not detected as pressure-stable. Possible causes: • A blood gas electrode has not been filled without bubbles. • Leak in the BG measuring chamber	• To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • Replace the PO_2 electrode. • Replace PCO_2 electrode. *Replacing electrodes* (p. 297)
2028	Mean not OK	Measurement value of calibration is outside the expected range. Possible causes: • Defective electrode • Incorrect baro value	• Perform a module-specific system calibration: **System > Calibration > System calibration** • If one electrode is affected, replace this electrode. *Replacing electrodes* (p. 297) • If more than one electrode or sensor is affected, replace the S2 Fluid Pack (BG and ISE parameters) or S3 Fluid Pack A(MSS parameters). • If this error persists, contact your Roche Service representative.
2029	ADC >>>>>	Sensor signal is above the measuring range. Possible causes: • Reference system not filled • Leak in the electrode or missing electrode	• Perform the fill reference electrode routine: **System > Utilities > Fluid actions > Fill routines** Then, select the reference electrode filling routine for the appropriate module from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • Replace the appropriate electrode or the MSS cassette.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2030	ADC <<<<<	Sensor signal is below the measuring range. Possible causes: • Reference system not filled • Leak in the electrode or missing electrode	• Perform the fill reference electrode routine: **System > Utilities > Fluid actions > Fill routines** Then, select the reference electrode filling routine for the appropriate module from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • Replace the appropriate electrode or the MSS cassette.
2031	Conditioning not OK	Na electrode was not conditioned. Possible causes: • S2 Fluid Pack docking mechanism is leaking • T&D disk is leaking when aspirating conditioning solution	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate Na cond. solution** from the **Routines** list, and press the **Start** button. • Perform Na electrode conditioning: **System > Utilities > Fluid actions > Conditioning** • Replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • Make sure that the S2 Fluid Pack docking mechanism is clean. If the docking mechanism is dirty, clean it. *Decontamination* (p. 271) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If this error persists, contact your Roche Service representative.
2035	Linearity not OK	The sensitivity of the MSS cassette is too low. Possible causes: • Sensor worn out	• If the MSS cassette is new, check the linearity of the MSS parameters (Glu, Lac, and Urea) on the sensor report: **Info > Miscellaneous reports** Then, perform a 2P calibration: **System > Calibrations** • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
2036	Interference sensitivity	The sensitivity of the MSS cassette is too low. Possible causes: • Sensor worn out	• If the MSS cassette is new, check the linearity of the MSS parameters (Glu, Lac and Urea) on the sensor report: **Info > Miscellaneous reports** Then, perform a 2P calibration: **System > Calibrations** • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S3 Fluid Pack A. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
2040	Cuvette not OK	Calibrated cuvette layer thickness is outside the expected range. Possible causes: • Cuvette is contaminated • Incorrect target value	• Contact your Roche Service representative.
2041	Ref. point not OK	Reference point is outside the expected range Possible causes: • Sample input clogged	• Perform **Wash**: **System > Wash & cleaning > Wash** • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If you find no leaks or clogs, contact your Roche Service representative.
2042	Wavelength not OK (1)	One specific wavelength is outside the expected range.	• Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
2043	Hemolysis not OK (1)	Hemolyzer is not ready for operation.	• Check that there are no signs of moisture in the hemolyzer tubing. • Perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If the pump output is more than 20% over or under the reference value, contact your Roche Service representative. • If the vacuum pump test shows no issues, perform the hemolyzer test: **System > Component test > Aggregates > Hemolyzer**. • Handle the errors detected by the hemolyzer test. • If this error persists, contact your Roche Service representative.
2044	Hemolysis not OK (2)	Hemolyzer power is outside the expected range.	• Check that there are no signs of moisture in the hemolyzer tubing. • Perform the vacuum pump test: **System > Component test > Aggregates > Vacuum pump** • If the pump output is more than 20% over or under the reference value, contact your Roche Service representative. • If the vacuum pump test shows no issues, perform the hemolyzer test: **System > Component test > Aggregates > Hemolyzer**. • Handle the errors detected by the hemolyzer test. • If this error persists, contact your Roche Service representative.
3000	D2/D3 not performed	MSS standby solution was not aspirated. Possible causes: • Faulty aspiration of MSS standby solution or reference solution	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. • Perform another fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • 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	The calibration solution is not aspirated into the BG measuring chamber in the specified time.	• Aspirate CAL B: **System > Utilities > Fluid actions > Fill routines > Aspirate CAL B** • Perform the general fluidics test: **System > Diagnostics > General fluidics test** • Handle the errors detected by the general fluidics test. • If this error still persists, perform the **Mixing system** calibration: **System > Calibration > Mixing system** • Install a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • Replace pump tube of main pump. *Exchanging the peristaltic pump tubes* (p. 294) • If this error still persists, contact your Roche Service representative.
3002	Temperature error	The module temperature is outside the permitted range. Possible causes: • Poor heating contact • Fan failure • Heating failure • Air filter is dirty or covered	• Perform the temperature control test for the affected modules: **System > Component test > Control sensors > Temperature control** • If this error persists, contact your Roche Service representative.
3003	FMS error	The mixture ratio falls outside the specified range. Possible causes: • Blockage or leak • Defective mixer valve • Defective air valve	• Aspirate CAL A and CAL B: **System > Utilities > Fluid actions > Fill routines** • Perform the general fluidics test: **System > Diagnostics > General fluidics test** • Handle the errors detected by the general fluidics test. • Install a new S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error still persists, contact your Roche Service representative.
3004	AQC module error	The required position was not reached.	• Perform an AQC wash: **System > Wash & cleaning > Wash AQC** • Perform an AutoQC measurement. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
3013	Ref. point D1 not OK	Problem during precalibration. Possible causes: • Faulty aspiration of MSS standby solution or reference solution	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. • Perform another fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • Perform the contact path test for the MSS module with standby solution: **System > Component test > Control sensors > Contact path > MSS standby solution** • If the MSS cassette is defective, replace it. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)
3014	Ref. point not OK	Problem during precalibration. Possible causes: • Faulty aspiration of MSS standby solution or reference solution	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. • Perform another fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • Perform the contact path test for the MSS module with standby solution: **System > Component test > Control sensors > Contact path > MSS standby solution** • If the MSS cassette is defective, replace it. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)
3022	Conductivity not OK	Conductivity calibration was not ended correctly.	• Print a sensor report: **Info > Miscellaneous reports** Check the error messages for conductivity with CAL A or CAL B calibration solutions. • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If you find no leaks or clogs, replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
3033	0P not OK	O_2 zero calibration was not ended correctly. Possible causes: • Error with the aspiration of the O_2 zero point solution • Dirtiness or a leak	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate solution O2 zero** from the **Routines** list, and press the **Start** button. • Clean the T&D disk: **System > Wash & cleaning > Clean input unit** *Maintenance* (p. 269) • To make sure that the tubing paths are open and without leaks, perform the general fluidics test: **System > Diagnostics > General fluidics test** • If you find no leaks or clogs, replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.
3034	Invalid measured value	Elapsed time between sample and Cal 1 too high. The measurement value is not shown because there is an unclear sensor signal drift.	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"**
4003	Calibration pending (1)	A new sensor was inserted, but there are no calibration values available.	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"**
4008	Calibration pending (2)	Calibration is missing or was canceled.	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"**
4024	Calibration pending (3)	Sensor is deactivated.	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"**
5006	Calculation error (1)	UC calculation error. Possible causes: • An incorrect calculation has occurred.	• Remove the W Waste Container, S1 Rinse Solution, S2 Fluid Pack and S3 Fluid Pack A containers, and reinsert them. • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
5007	Calculation error (2)	UC calculation error. Possible causes: • An incorrect calculation has occurred.	• Remove and reinsert the affected electrode. • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
5010	Calculation error (3)	UC calculation error (COOX). Possible causes: • An incorrect calculation has occurred.	• Check the cuvette for dirtiness. • Perform the polychromator calibration: **System > Calibrations** • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
5011	Calculation error (4)	UC calculation error (4) (COOX). Possible causes: • An incorrect calculation has occurred.	• Check the cuvette for dirtiness. • Perform the polychromator calibration: **System > Calibrations** • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
5012	Calculation error (5)	UC calculation error (5) (COOX). Possible causes: • An incorrect calculation has occurred.	• Check the cuvette for dirtiness. • Perform the polychromator calibration: **System > Calibrations** • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
6026	ADC error		• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
6030	COOX HW error	A hardware error occurred at the COOX module.	• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
6031	Neon lamp not OK	The light output of the neon lamp is too low. Possible causes: • Cuvette is dirty • Optical fiber is damaged • Polychromator electronics defective	• Perform an internal cleaning of the COOX module: **System > Wash & cleaning > Cleaning modules** • Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
6032	Halogen lamp not OK	The light output of the halogen lamp is too low. Possible causes: • Cuvette is dirty • Optical fiber is damaged • Polychromator electronics defective	• Perform an internal cleaning of the COOX module: **System > Wash & cleaning > Cleaning modules** • Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
7034	Solution exhausted	The pH value of the O_2 zero point solution is < 5. Possible causes: • There is no more $_2$ zero point solution in the S2 Fluid Pack • S2 Fluid Pack contaminated	• Replace the S2 Fluid Pack. *Exchanging solutions and packs* (p. 280)
8036	IfS not OK	The BSA/Glu or BSA/Lac ratios in CAL 3 are out of range. Possible causes: • Interference correction not possible	• Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S3 Fluid Pack A *Exchanging solutions and packs* (p. 280) • If this error persists, contact your Roche Service representative.

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: • Interferences • Unsuitable sample type used	• Check if your patient is on medication. Make sure that the medication the patient is on is not a known interfering substance for the system. *Substances with effect on whole blood samples for Hb derivatives and bilirubin* (p. 155) • If the patient is not on medication, repeat the measurement. • Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
8062	Interferences (2)	The calculated Hb derivatives are invalid. Possible causes: • Interferences • Unsuitable sample type used	• Check if your patient is on medication. Make sure that the medication the patient is on is not a known interfering substance for the system. *Substances with effect on whole blood samples for Hb derivatives and bilirubin* (p. 155) • If the patient is not on medication, repeat the measurement. • Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
8063	Interferences (3)	The calculated bilirubin value is invalid. Possible causes: • Interferences • Unsuitable sample type used	• Check if your patient is on medication. Make sure that the medication the patient is on is not a known interfering substance for the system. *Substances with effect on whole blood samples for Hb derivatives and bilirubin* (p. 155) • If the patient is not on medication, repeat the measurement. • Perform the polychromator calibration: **System > Calibrations** • If this error persists, contact your Roche Service representative.
8070	IfS repro. not OK	Non-reproducible sensor signal at interference sensor. Possible causes: • Unsuitable sample type is being used	• Perform the wetting routine for the appropriate module: **System > Utilities > Fluid actions** • Perform an MSS polarization: **System > Utilities > MSS polarization** • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • If this error persists, contact your Roche Service representative.
8071 - 8072	IfS calculation error (1) - (2)	UC calculation error (1) on interference sensor. Possible causes: • An incorrect calculation has occurred.	• Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S3 Fluid Pack A *Exchanging solutions and packs* (p. 280) • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
8073	IfS sensor signal unstable	Interference sensor signal cannot be reproduced. Possible causes: • Unsuitable sample type is being used • Measuring path contaminated • Interference signals in the measuring path during measurement acquisition • Interference signals via reference electrodes during measurement acquisition	• If you have an installed reference electrode for measuring urea on a **cobas b** 221<6> system, and this interference applies to the complete module, replace the reference electrode. *Changing the reference electrode* (p. 304) • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • Perform the stability monitor: **System > Diagnostics > Stability monitor** Then, select **Electrode slope** from the drop-down list and press the **Details** button. • If the MSS cassette is defective, replace it. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)
8074	IfS ref. point not OK	Problem at reference point of standby solution at interference sensor. Possible causes: • Error with the MSS standby solution aspiration • Error with the MSS reference solution aspiration	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Aspirate standby solution** from the **Routines** list, and press the **Start** button. • Perform another fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform the MSS wetting routine: **System > Utilities > Fluid actions** • Perform the contact path test for the MSS module with standby solution: **System > Component test > Control sensors > Contact path > MSS standby solution** • If the MSS cassette is defective, replace it. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)
8075	IfS ADC error		• Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
8076	IfS mean not OK	Final calibration value of an interference sensor is out of range. Possible causes: • S3 Fluid Pack A transponder error • Defective electrode • Incorrect baro value	• Perform an MSS system calibration: **System > Calibration > MSS system calibration** • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306) • Replace the S3 Fluid Pack A *Exchanging solutions and packs* (p. 280)
8077	IfS ADC >>>>>	Interference sensor signal is above ADC range Possible causes: • Reference system not filled • Leak in the electrode or missing electrode	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
8078	IfS ADC <<<<<	Interference sensor signal is below ADC range Possible causes: • Reference system not filled • Leak in the electrode or missing electrode	• Perform the fill routine: **System > Utilities > Fluid actions > Fill routines** Then, select **Fill ref. electrode MSS** from the **Routines** list, and press the **Start** button. • Perform **Calibration for "Ready"**: **Quick access > Calibration for "Ready"** • To make sure that there are no leaks from the electrode, check the electrode seating. If the electrode is leaking, replace the electrode. • Replace the MSS cassette. *Changing the MSS cassette (cobas b 221<6> system only)* (p. 306)
8080	Interferences (4)	Detected sample type is invalid. Possible causes: • Interferences • Unsuitable sample type used	• Follow correct preanalytical procedures before you perform measurement.s Make sure that your sample is not too old, partially hemolyzed, and not homogeneous, and that you use approved anticoagulants. *Preanalytics* (p. 145) • Repeat your measurement. • If this error persists, contact your Roche Service representative.
8081	Interferences (5)	The calculated COHb value is outside the permitted range. Possible causes: • Interferences • Unsuitable sample type used	• Follow correct preanalytical procedures before you perform measurement.s Make sure that your sample is not too old, partially hemolyzed, and not homogeneous, and that you use approved anticoagulants. *Preanalytics* (p. 145) • Repeat your measurement. • If this error persists, contact your Roche Service representative.
8082	Interferences (6)	The calculated SO_2 value is outside the permitted range. Possible causes: • Interferences • Unsuitable sample type used	• Follow correct preanalytical procedures before you perform measurement.s Make sure that your sample is not too old, partially hemolyzed, and not homogeneous, and that you use approved anticoagulants. *Preanalytics* (p. 145) • Repeat your measurement. • If this error persists, contact your Roche Service representative.
8083	Sample type conflict	Detected sample type is invalid. Possible causes: • Unsuitable sample type used	• Follow correct preanalytical procedures before you perform measurement.s Make sure that your sample is not too old, partially hemolyzed, and not homogeneous, and that you use approved anticoagulants. *Preanalytics* (p. 145) • Repeat your measurement. • If this error persists, contact your Roche Service representative.
8084	Invalid sample type	A blood type other than arterial or capillary blood was used.	• Use only arterial or capillary blood with your system.

Table 11-6 Status messages of measuring and calibration values

No.	Message	Cause	Action
9000	Calculation error (3)	PC calculation error. Possible causes: • An incorrect calculation has occurred.	• Remove the W Waste Container, S1 Rinse Solution, S2 Fluid Pack and S3 Fluid Pack A containers, and reinsert them. • Turn off the system, wait at least 3 minutes, and turn it back on. • If this error persists, contact your Roche Service representative.
9001	Not activated	Parameter is not activated for measurement (gray).	• Activate the parameter.
9002	Not calibrated	Parameter is not calibrated (red X).	• 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.	• Perform a system calibration: **System > Calibration > System calibration** • If this error persists, contact your Roche Service representative.

Table 11-6 Status messages of measuring and calibration values

Status messages on the measurement report

Messages	Causes
(-)/(+)	Measurement value is outside (below (-)/above(+)) the normal range, within the critical range.
(--)/(++)	Measurement value is outside (below(--)/above(++)) the normal range, and outside the critical range.
Out of range (-)/(+)	Measurement value is outside (below (-)/above(+)) the measuring range.
# ... check Hct result	The Hct value is not plausible.
? ... 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.
I ...	30% or more of the detected signal from the Glu or Lac sensor comes from an interfering substance. Result may be compromised.

Table 11-7 Status messages on the measurement report

The **cobas b** 221 system provides stable and reliable results for MSS parameters through its interference detection and correction algorithm. An interference status message (I...) appears on the measurement report if 30% or more of the detected signal from the Glu or Lac sensor is caused by an interfering substance.

This status message is intended to warn the user that the signal from an interfering substance is high enough that there is a risk that the result may be compromised.

If this status message appears, verify the validity of your results with a medical specialist before any clinical decisions are made.

Barcode scanner troubleshooting

If you are having issues with your barcode scanner, follow the steps below:

To find possible issues with your barcode scanner

1. Try to scan in your target barcode again using different distances and angles between your barcode scanner and your target barcode.
2. Verify that your barcode scanner is securely connected to the interface connector of the instrument.

   To find the location of the interface connector on the rear panel of the instrument, see *Interfaces* (p. 39)
3. Inspect the condition of your barcode scanner cable. If it is damaged, contact your Roche representative.
4. Verify that the barcode scanner lens is not damaged and is free of dust and fingerprints. If you find damage to your barcode scanner lens, contact your Roche representative. If your barcode scanner lens is not clean, use a soft lens cloth to clean it.
5. Verify that there is an LED light visible inside the barcode scanner and the barcode scanner prompts a trigger tone when scanning barcodes.
6. Test the performance of your barcode scanner using the barcode scanner test feature on your system.

   To test the performance of your barcode scanner (p. 360)

   If the scanned barcode does not match the characters shown on your screen, unplug and plug the barcode scanner into the interface connector again.

   To find the location of the interface connector on the rear panel of the instrument, see *Interfaces* (p. 39)

   Then, perform the barcode scanner test.

   To test the performance of your barcode scanner (p. 360)
7. If you are still unable to solve your issues, reset the barcode scanner's configuration.

   To reset the barcode scanner's configuration (p. 360)
8. If your issues still persist, contact your Roche Service representative.

■

To test the performance of your barcode scanner

1 Press the following buttons:
System > Component test > PC components > Barcode

Figure 11-1 PC components screen in System mode

2 Scan a Roche-generated barcode, such as barcodes found on the packaging inserts of Roche QC materials or electrodes, with your barcode scanner.

3 Verify that the scanned barcode matches the characters shown on your screen.

4 To remove these characters from your screen, press **Delete.**

■

To reset the barcode scanner's configuration

1 Find and scan the Roche Configuration Barcode delivered with the barcode scanner.

This product insert is also available from your Roche representative on demand.

When you scan the Roche Configuration Barcode, your keyboard layout language is automatically set to English. If your keyboard layout language is German, change the keyboard layout language after scanning the Roche Configuration Barcode.

7. Change the keyboard layout language (optional) (p. 49).

2 Perform the barcode scanner function test.

To test the performance of your barcode scanner (p. 360)

■

Removing clogs in the W Waste Container piping

Clogs can occur in the region between the W Waste Container cap and its piping. Agglutinated blood collects in this region and stops the flow of waste into the container.

Signs that indicate there is a clog in the W Waste Container piping are:

- Waste separator errors
- Insufficient pressure in the vacuum system
- Fill level detection errors in the W Waste Container

WARNING

Cutting the piping in the W Waste Container may result in infection

Cutting the piping in the W Waste Container affects the accurate detection of the fill level in the W Waste Container. Contact with spilled contents from the W Waste Container may lead to a biohazardous contamination, resulting in personal injury and/or infection. In addition, spilled liquid may result in malfunction and/or damage to the system.

- Do not cut the piping in the W Waste Container.
- If any content from the W Waste Container is spilled, wipe it up immediately and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

To remove clogs in the W Waste Container piping

WARNING

Inappropriate handling and disposal of the contents inside the W Waste Container may cause infection and environmental harm

The W Waste Container contains liquid and/or solid waste. Inappropriate handling of this waste may lead to the transmission of blood or urine borne pathogens. In addition, inappropriate disposal may contaminate the environment.

- Treat the contents inside the W Waste Container as chemcial and biohazardous waste and dispose it accordingly. In addition, decontaminate the W Waste Container after disposing its contents according to the local regulations. For more information, contact your Roche Service representative.
- Wear appropriate personal protective equipment, such as laboratory clothing, protective gloves, safety glasses, face masks, and safety visors, during disposal to prevent direct contact.
- If you spill contents from the W Waste Container, wipe it up immediately and apply a disinfectant.
- If contents from the W Waste Container come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.
- Regularly replace the W Waste Container and its screw cap. Roche recommends replacing the W Waste Container and its screw cap after emptying it 5 times.

1 Open the bottle compartment.

2 Open the docking mechanism, hold the W Waste Container by the grip recesses, and W Waste Container remove carefully.

3 Empty the W Waste Container. Do not screw the cap back onto the container.

To empty the W Waste Container (p. 284)

4 Inspect the screw cap and the piping for agglutinated blood. If you find agglutinated blood, flush it out with plenty of water.

5 Inspect the screw cap again for agglutinated blood. If you still find agglutinated blood, remove it with a moist cloth.

■

Appendix

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Available accessories and consumables

In this chapter, all available accessories and consumables, and their order numbers are listed.

In this chapter

Chapter **12**

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Available accessories and consumables

Below is a list of globally available accessories and consumables. For ordering information, contact your Roche Service representative.

Electrodes and sensors

	Parameter								
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	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	-	+
Reference Contact (RCon) 03112071180	-	-	-	-	-	-	-	-	+
Sensor Contact (SCon) 03260909184	X	X	X	X	X	X	X	-	-
Micro Electrode Dummy 03111849035	+	+	+	+	+	+	+	-	+
GLU/LAC/UREA (BUN) Cassette(2) 03261085184	-	-	-	-	-	-	-	-	X
GLU/LAC Cassette(2) 03260887184	-	-	-	-	-	-	-	-	X
GLU Cassette(2) 03260895184	-	-	-	-	-	-	-	-	X
MSS Dummy Sensor(2) 03351262001	+	+	+	+	+	+	+	-	+

Table 12-1

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

(2) **cobas b** 221<6> system only

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

Solutions

	Parameter								
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	COOX/Bili	MSS
S1 Rinse Solution 03260917184	X	X	X	X	X	X	X	X	X
S2 Fluid Pack 03260925184	X	X	X	X	X	X	X	X	X
S3 Fluid Pack A 03260933184	X	X	X	X	X	X	X	X	X
W Waste Container(1) 03144054001	X	X	X	X	X	X	X	X	X
Hb-Calibrator 03110923035	-	-	-	-	-	-	-	X	-

Table 12-2

(1) The W Waste Container is an empty container only.

X	Has to be installed
-	n/a

QC material

	Parameter								
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	COOX/Bili	MSS
AUTO-TROL PLUS B, Level 1 03321169190	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 2 03321177190	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 3 03321185190	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 1(1) 03321169001	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 2(1) 03321177001	O	O	O	O	O	O	O	O	O
AUTO-TROL PLUS B, Level 3(1) 03321185001	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 1 03321193190	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 2 03321207190	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 3 03321215190	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 1(1) 03321193001	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 2(1) 03321207001	O	O	O	O	O	O	O	O	O
COMBITROL PLUS B, Level 3(1) 03321215001	O	O	O	O	O	O	O	O	O
COOX/MSS Verification Material, Level 1-3 03354628001	O	O	O	O	O	O	O	O	O

Table 12-3

(1) Will be phased out

O	Can be used

Accessories

	Parameter								
	Cl^-	Na^+	K^+	Ca^{2+}	PCO_2	PO_2	pH	COOX/Bili	MSS
Deproteinizer 03110435180	O	O	O	O	O	O	O	O	O
Adapter for Capillaries 03069931001	O	O	O	O	O	O	O	O	O
Ampoule Adapter 03066762001	O	O	O	O	O	O	O	O	O
Clot Catcher(1) 03112012180	O	O	O	O	O	O	O	O	O
Cleaning Kit for Cl^- Electrode 03112098035	O	-	-	-	-	-	-	-	-
Adapters for Sample Containers 03112101180	O	O	O	O	O	O	O	O	O
Caps for Roche MICROSAMPLER 03112152180	O	O	O	O	O	O	O	O	O
Thermo Printer Paper 03113361180 (HP0107)	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER PROTECT, non sterile 05772494001 (200 pcs.)	O	O	O	O	O	O	O	O	O
Roche MICROSAMPLER PROTECT, sterile 05772583001 (50 pcs.)	O	O	O	O	O	O	O	O	O
Capillary Tubes, ~ 200 µL 03113477180 (MC0024)	O	O	O	O	O	O	O	O	O
BS2 Blood Sampler (sterile) 03113493035 (MC0028)	O	O	O	O	O	O	O	O	O
Capillary Tubes, ~ 115 µL 03113507035(MG0002)	O	O	O	O	O	O	O	O	O
tHb Cuvette Packed 03086879001	-	-	-	-	-	-	-	O	-
Caps for Capillary Tubes 03113647035 (RE0410)	O	O	O	O	O	O	O	O	O
Customer Accessory Kit(2), for **cobas b** 221<2>/<4>/<6> system 04975626001	O	O	O	O	O	O	O	O	O

Table 12-4

(1) The Clot Catcher is not suitable for measurements in syringe mode and in “Aspiration from syringe” mode.

(2) The Customer Accessory Kit is a spare part collection kit for customers.

O	Can be used
-	n/a

Glossary

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

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

Acid-base Diagram A graphical representation of acid-base physiology in a patient based on the Henderson-Hasselbalch equation. pH and PCO_2 measurements are used to identify acid-base physiology disorders, such as metabolic and respiratory acidosis and alkalosis.

Alkaline Basic, or a solution, whose pH value is greater than 7

Analyzer mode Software mode for sample and QC measurements, system functions, calibration and quick access.

A_{rate} The assisted breathing rate when a patient is on a ventilator.

Arterial blood Blood taken from the artery

ASTM A protocol for data transfer.

AutoQC module A unit that automatically takes QC measurements programmed by the user.

AUTO-TROL PLUS B AutoQC material for controlling BG, ISE, Glu, Lac, Urea/BUN and COOX/Bilirubin

Barcode scanner PS2 hand-held scanner with integrated decoder for simple input of QC and electrode data, and patient and operator information.

BG measuring chamber Responsible for measuring pH values and blood gas values PO_2 and PCO_2

Bilirubin Yellow decomposition product of the red blood pigment, hemoglobin

Bottle compartment Holds the W Waste Container, the S1 Rinse Solution, the S2 Fluid Pack (with the solutions for BG and ISE) and the S3 Fluid Pack A (with the solutions for Glu, Lac and Urea/BUN - for **cobas b** 221<6> system). It also contains docking mechanisms for transporting the fluids into or out of the system.

Bottle tool Used to open the screw cap of the W Waste Container and the S1 Rinse Solution.

Bypass nipple Connection between the sample inlet path and the sample distributor

Calibration for "Ready" A calibration type that brings all activated parameters into the "Ready" condition.

Clot Catcher Coagulum catcher for use with syringes and capillaries

COMBITROL PLUS B QC material for controlling BG, ISE, Glu, Lac, Urea/BUN and COOX/Bilirubin

Contact clip Fixes the MSS cassette in the correct position inside the MSS measuring chamber

COOX module Consists of the hemolyzer and the COOX measuring chamber. It is an optical sensor module for determining bilirubin (Bili), total hemoglobin (tHb), and hemoglobin derivatives oxyhemoglobin (O_2Hb), deoxyhemoglobin (HHb), carboxyhemoglobin (COHb) and methemoglobin (MetHb).

Docking mechanism The interface between packs or bottles and the fluid channels in the system

Dummy electrode A flow-through electrode that acts as a placeholder electrode, which has no measuring functions.

Electrodes Flow-through electrodes with a visible sample channel.

Fill port Enables a sample to be injected or aspirated from syringes, Roche MICROSAMPLER PROTECT, capillaries and ampoule adapters.

Fixation lever Fixes the sensor in the measuring chamber

FMS Makes sure that the correct mixture of CAL A and CAL B calibration solutions from the S2 Fluid Pack for the next calibrations, with the aid of the VM and V19 valves.

Glass tube see *Sample inlet path (SIP)* (p. 376)

Hematocrit The ratio of blood cell volume (mainly from red blood corpuscles) to the total blood volume.

Hemoglobin Main component of erythrocytes and serves for transporting oxygen.

Hemolyzer It applies a strong ultrasound field to samples to destroy the cell membranes of erythrocytes. This releases hemoglobin for analysis.

Heparin salts The only permitted anticoagulant for use with the system

Input unit Collects samples for analysis into the system. It is made up of the T&D module and the sample drip tray.

ISE measuring chamber Responsible for measuring hematocrit values and electrolyte values Na^+, K^+, Ca^{2+} and Cl^-.

Levey-Jennings diagram Illustrates QC statistics to find errors in how the system performs measurements.

Linear bracket White plastic part of the peristaltic pump.

Measuring chamber cartridge Transports samples and calibration solutions to the waste system after a measurement and/or calibration and for adding the reference and S1 Rinse Solution.

Module stop Issues that affect specific modules of the system. During a module stop, other modules can still be used for measurements.

MSS cassette A multi-parameter sensor for measuring Glu, Lac and Urea/BUN

MSS measuring chamber Measures glucose, lactate and urea/BUN.

MSS polarization Wets and prepares the MSS cassette for use in the system

Multirules Decision criteria used for determining whether a parameter falls inside or outside of the specified range for a quality control run. It is based on Westgard rules.

NIST standards Defines precise sera with certified expected values.

Patient Trend Diagram Software feature in the system that is designed to graphically show trends in patient results over time

Plasma Liquid part of blood that contains water, salts, enzymes, antibodies and other proteins. Plasma samples are collected by centrifuging heparinized whole blood.

Pleural fluid Serous fluid produced by the pleura. Pleura are thin membranes that line the lungs and the chest cavity, which keeps the lungs moist to allow for proper breathing

Pleural space The thin space between the two pleural layers

Polychromator Light is refracted and focused onto the surface of a photosensitive receiver (CCD).

Printer A low-noise thermoprinter with an integrated paper cutter.

Pumps Responsible for transporting sample and operating fluids in the system. Up to three peristaltic pumps are found on the system, depending on its configuration.

QC material see *AUTO-TROL PLUS B* (p. 375), *COMBITROL PLUS B* (p. 375)

Quality control A process used to verify that a system's output is not affected by issues with the instrument. This is done by measuring a certified sample with the instrument, and testing the results against the sample's specifications

RCon Used in **cobas b** 221<6> system to replace the reference and dummy electrodes.

Ready screen Main window of the Analyzer mode.

Reference electrode Counter electrode for measuring electrodes.

S1 Rinse Solution Wash solution

S2 Fluid Pack Calibration solutions for BG and ISE parameters

S3 Fluid Pack A Calibration solutions for Glu, Lac and Urea/BUN parameters

Sample distributor System component responsible for controlling the temperature and delivery of samples and other liquids to the measurement modules

Sample distributor cartridge System component that contains the tube lines and valve heads that control the distribution of samples and other liquids

Sample drip tray Prevents contaminating the bottle compartment

Sample inlet path (SIP) Glass tube that transports fluids from the T&D disk via the needle to the sample distribution block

Sample sensor Optical sensors that detect the location of samples and other liquids on the system

Sample throughput Number of samples per hour

Sample volume limit Maximum aspiration volume from a sample container.

SCon Monitors the filling of measuring chambers with fluid, and measures temperature in the measuring chamber

Screen/PC unit Serves as a graphic user interface. Information, such as results and system messages, is displayed on the screen. The screen consists of a color LCD that is covered with a touch-sensitive film.

S_{rate} The spontaneous breathing rate when a patient is breathing on a ventilator.

System calibration Consists of the wavelength 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. It is carried out every 8, 12 or 24 hours (default).

System stop Issues that affect the general operation of the system. In a system stop, scheduled tasks are no longer performed.

System warnings Warning or indication that does not require any direct action.

T&D module Distributes samples, QC materials, and fluids from the S1 Rinse Solution, S2 Fluid Pack and S3 Fluid Pack A to the measuring modules.

Tension lever Plexiglass cover on the peristaltic pump

tHb calibrator Solution used for calibrating parameters measured by the COOX module.

Tonometered whole blood Whole blood is set with the aid of precision gas to expected values to be calculated for PO_2 and PCO_2.

Urea End product of the metabolism of nitrogen compounds (e.g. amino acids) produced in the urea cycle and then excreted in the urine.

USB An industrial standard for connecting external devices to a computer.

Vacuum pump Washes and dries all tubing in the system, except inside the measuring chambers

Vacuum pump protection A safety container that captures waste contents in the system in the event of a vacuum pump malfunction.

Valve V19 Air mixing valve

Valve VM Mixing valve for CAL A and CAL B calibration solutions from S2 Fluid Pack.

W Waste Container Waste container

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Revisions

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Revisions

Use this section of the manual as a repository for updates to the **cobas b** 221 system Instructions for Use. You can also use this section to insert your own notes about the system so that all information about the system is in one place.

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Revision

Currently, there are no revisions to the Instructions for Use.

Revision