cobas® 6000 analyzer series

*Interlock function **cobas c** 501 with ISE*

Table of contents

Publication information

Publication version	Software version	Revision date	Change description
1.0	02-01 – 02-07	March 2008	General update
1.1	02-01 – 02-07	June 2009	Document title
1.2		December 2014	Maintenance Replacing the ISE sipper tubing revised. Some other minor changes.
1.3	05-02 – 06-02	July 2018	Maintenance actions *Replacing the ISE pinch valve tubing* and *Replacing the ISE sipper tubing* revised.

Edition notice

Interlock function **cobas c** 501 with ISE of the **cobas**® 6000 analyzer series

This manual describes maintenance actions of the **cobas**® 6000 analyzer series that can only be performed by special trained person. Further maintenance sections are described in the Operator's Manual.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

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

Where to find information

The **Online Help** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- A software reference
- Configuration information
- Background information

The **Operator´s Manual** contains information about safety, hardware modules and operating the system as well as maintenance and troubleshooting.

The manual **Interlock function cobas c 501 with ISE** describes maintenance actions of the **cobas** 6000 analyzer series that can only be performed by special trained person.

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 instrument 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.

Images

The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, 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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UltraVNC is a piece of free software for all commercial uses. It is installed on the control unit PC of the **cobas** 6000 analyzer series.

You can redistribute the software and/or modify it under the terms of the GNU General Public License (version 2 or later), as published by the Free Software Foundation. A copy of the GNU General Public License (version 2) is stored on the control unit PC. The path for the license is C:\Program Files\uvnc bvba\UltraVNC.

The software is distributed without warranty. There is no implied warranty of merchantability or fitness for a particular purpose. For more information, see the GNU General Public License at http://www.gnu.org/licenses.

The source code for the software is stored on the control unit PC. The path for the source code is C:\DriversAndTools\UltraVNC.

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cobas 6000 analyzer series may include components or modules of commercial or open-source software. For further information on the intellectual property and other warnings, as well as licenses pertaining to the software programs included in **cobas** 6000 analyzer series, refer to the electronic distribution included with this product.

This open source and commercial software and **cobas** 6000 analyzer series as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the user manual and labeling.

Please note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to **cobas** 6000 analyzer series.

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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** 6000 analyzer series 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 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.

Compliance with the applicable directives is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

For in vitro diagnostic use.

Complies with the IVD directive 98/79/EC on in vitro diagnostic medical devices

Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Instrument approvals

Furthermore, the instrument is manufactured and tested according to the following international safety standards:

- IEC 61010-2-101
- IEC 61010-1

The instrument complies with the emission and immunity requirements described in standard IEC 61326-2-6/EN 61326-2-6.

The Operator's manual meets the European Standard DIN EN ISO 18113-3.

Fluorinated greenhouse gas

The product contains a fluorinated greenhouse gas in the hermetically sealed refrigeration.

Type	Charge weight (kg)	CO_2 equivalent (tonne)	Global warming potential
R-134a	0.102	0.14	1430

Contact addresses

Inside the European Union and EFTA member states

	Manufacturer of the **cobas**® 6000 analyzer series instrument	Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku, Tokyo 105-8717 Japan
	Authorized representative	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Outside the European Union and EFTA member states

Manufactured by:	Hitachi High-Technologies Corporation
Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

General safety information

Before operating with the **cobas**® 6000 analyzer series it is essential that the warnings, cautions, and safety requirements contained in this manual, as well as the explanation of safety labels on the system are read and understood by the user.

In this chapter *Chapter* 1

Table of contents

Safety classifications

This section explains how precautionary information is formatted in the manual.

For more information, see *Safety labels of the system* on page 17.

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

Warning

Indicates a possibly hazardous situation which, if not avoided, may result in death or serious injury.

Caution

Indicates a possibly hazardous situation which, if not avoided, may result in slight or minor injuries, and/or damage to equipment.

Important information which is not security relevant is indicated with the following symbol:

Note

Indicates additional information on correct usage of the system or useful tips.

Safety precautions

Particular attention must be taken of the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury. Each precaution is important.

Qualification of service personnel

Incorrect results or damage to the analyzer due to wrong operation

Service personnel are required to be licensed persons according to the country specific laws. They should have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Do not use the interlock release tool unless you have been trained by Roche Diagnostics.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Follow standard laboratory practices, especially when working with biohazard material.

Intended use


CAUTION

Intended use

This instrument is designed for immunological and clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids.

Please note that other analyses may not be applicable to this instrument.

Working with the analyzer

Electrical safety


WARNING

Electrical shock by electronic equipment

Do not attempt to work in any electronic compartment. Do not remove any cover of the instrument, other than specified in this Manual. Installation, service, and repair must only be performed by authorized and qualified personnel.

Electrical shock by electronic equipment

Removing the covers marked with this symbol  can cause electric shock, as there are high voltage parts inside. In addition, opening the top cover of the **c** 501 module and touching the ultrasonic mixing mechanism during operation can also cause electric shock.

- Do not remove any cover of the instrument, other than specified in this Manual
- Do not open the top cover and touch the ultrasonic mixing unit during operation or when the analyzer performs maintenance.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: R-5, R-7.

Mechanical safety


WARNING

Injury or damage to the analyzer due to contact with instrument mechanism

Do not put your hands into the pathway of any moving parts during instrument operation.

Personal injury due to contact with instrument mechanism

Contact with sampling mechanism or other mechanisms may result in personal injury and infection.

- Before starting operation or maintenance, be sure to close and lock the top and back covers whenever possible.
- When working with a open top cover of a module while the analyzer is performing maintenance, pay attention to the movement of the instrument mechanism.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: F-3, F-4, F-9, F-10, T-2, T-3, T-6, R-3.

Personal injury due to contact with pierce pin

A pierce pin for reagent cassettes is located adjacent to the reagent probe R1. Contact with the pierce pin may result in personal injury.

- Do not touch the pierce pin during cleaning.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: F-2.

Operation and maintenance

WARNING

Injury or damage to the analyzer due to contact with instrument mechanism

Do not touch any parts of the instrument other than those specified. During operation and maintenance of the instrument, proceed according to the instructions.

Damage to the analyzer due to the use of organic solvents for cleaning

Do not use organic solvents except for ethanol, which is used in operation and maintenance.

Fire and burns due to the use of ethanol

Ethanol is a flammable substance.

- Keep flammables away from the analyzer when conducting maintenance or checks using ethanol.
- When using ethanol on or around the instrument, use no more than 20 mL at a time.

CAUTION

Incorrect results due to missing cover of the ISE measuring compartment

If the cover of the ISE measuring compartment is not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurement, when the cover of the ISE measuring compartment is closed.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: T-11.

Damage to the analyzer due to remaining tools during maintenance

If the instrument power is turned ON when performing manual maintenance, parts or tools may contact the instrument mechanisms and damage the instrument.

- Make sure no parts or tools remain on the instrument before starting any maintenance action where mechanical parts of the analyzer are moved.

Handling samples, reagents, and waste

Reagents and other working solutions

WARNING

Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns. When handling reagents, be sure to wear protective equipment (like goggles, gloves) and observe the cautions given in the package insert.

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury. When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Material Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Infection due to contact with sample or waste solution

Contact with sample or waste solution may result in infection. All materials and mechanical components associated with the reaction system and the waste systems are potentially biohazardous.

- Be sure to wear protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: F-6, F-7, F-10, T-13, T-16, R-6, S-1.

Personal injury due to contact with cleaning solutions or reagents

Contact with cleaning solutions of the system or reagents may cause skin damage or inflammation.

- Be sure to wear protective equipment.
- Observe the cautions given on the bottles and cassettes and the package inserts.
- If cleaning solution comes into contact with your skin, wash it off immediately with water. Consult a physician.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: F-8, F-14, F-15, F-16.

CAUTION

Correct handling of reagents and other working solutions

- Reagents, calibrators and controls must be handled, stored and disposed of according to the instructions given in the package inserts.
- Samples and chemicals must be handled, stored and disposed of on your own responsibility and in accordance with the appropriate standards.

Spillage

CAUTION

Malfunction due to spilled liquid

Any liquid spilled on the instrument may result in malfunction of the instrument. If liquid does spill on the instrument, wipe it up immediately and apply disinfectant. Be sure to wear protective equipment.

Biohazardous materials


WARNING

Infection by biohazardous materials

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

- Follow standard laboratory practices, especially when working with biohazard material.
- Be sure to wear appropriate protective equipment, including, but not limited to, safety glasses with side shields, fluid resistant lab coat, and approved disposable gloves.
- Wear a face shield if there is a chance of splash or splatter.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or waste solution comes into contact with your skin, wash it off immediately with soap and water and apply a disinfectant. Consult a physician.

Infection and injury due to sharp objects

When wiping probes, use several layers of gauze and wipe in the direction from the top down.

- Be careful to not injure yourself.
- Be sure to wear appropriate protective equipment, for example gloves. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.

Waste


WARNING

Infection by waste solution

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.
- Observe the system safety labels illustrated from page 19 to 24 and in particular the following: F-6, F-7, F-19, S-1.

Contamination by waste solution and solid waste

The waste of the system is potentially biohazardous.

The system discharges two kinds of waste solutions:

- Concentrated waste solution, that contains highly concentrated reaction solution. This waste must be treated as infectious waste.
- Diluted waste: Rinsing water from cell wash or water from the incubation bath.

Dispose of any waste generated by the system according to the appropriate local regulations.

Miscellaneous safety precautions

Power interruption

CAUTION

Data loss or damage to the system due to voltage drop

By a power failure or momentary voltage drop the operation unit or software of this system may get damaged or data may be lost. Use only uninterruptible power supply.

Electromagnetic devices

CAUTION

Malfunction of instrument and incorrect results due to interfering electromagnetic fields

Devices that emit electromagnetic waves may cause the instrument to malfunction. Do not operate the following devices in the same room where the system is installed:

- Mobile phone
- Transceiver
- Cordless phone
- Other electrical devices that generate electromagnetic fields

Approved parts

CAUTION

Malfunction of instrument and incorrect results due to nonapproved parts

Use of nonapproved parts or devices may result in malfunction of the instrument and may render the warranty null and void. Only use parts and devices approved by Roche Diagnostics.

Third-party software

CAUTION

Malfunction of instrument and incorrect results due to third-party software

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

Safety labels of the system

Warning labels have been placed on the analyzer to draw your attention to areas of potential hazards. The labels and their definitions are listed below according to their location on the instrument.

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

If the labels are damaged, they must be replaced by Roche service personnel. For replacement labels, contact your local Roche representative.

Spillage warning

This label indicates the instrument may be damaged if a spillage occurs within the vicinity of this label. Do not place liquids in this area.

Protective equipment warning

This label indicates protective goggles and gloves should be worn when working within the vicinity of this label as there is a danger of coming into contact with corrosive material.

Warning

This label indicates there is a danger of hazardous situations within the vicinity of this label, which may result in death or serious injury. Refer to the Operator's Manual for safety operation.

Biohazard warning

This label indicates there are potential biohazards within the vicinity of this label. The relevant laboratory procedures on safe use must be observed.

Electrical warning

This label indicates there is a danger of coming into contact with electrical components when gaining access to parts of the system marked with this label.

Mechanical parts warning

This label indicates there is a danger of coming into contact with moving mechanical parts within the vicinity of this label.

Mechanical parts warning

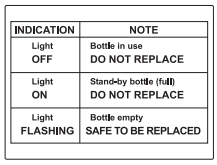
This label indicates there is a danger of coming into contact with moving mechanical parts within the vicinity of this label.

Hot surface warning

This label indicates the area within the vicinity of this label may be hot. Do not touch this area as you may be burned.

Maximum weight

This label indicates the maximum weight. Do not place anything heavier than the specified weight on the label.



INDICATION	NOTE
Light OFF	Bottle in use DO NOT REPLACE
Light ON	Stand-by bottle (full) DO NOT REPLACE
Light FLASHING	Bottle empty SAFE TO BE REPLACED

Green button light states

This label indicates the meaning of the status of the green button lights. DO NOT perform an action unless the correct state is indicated.

The following sections describe the meaning of the safety labels on the instrument in a short form.

For more information about the safety labels on the instrument, see:
Front view on page 19
Side view on page 21
Top view on page 22
Rear view on page 24
Safety information for barcode readers on page 25

In addition to *safety labels* on the instrument there are *safety notes* in the corresponding parts of the Interlock function Manual, Operator's Manual and Online Help.

These safety notes give more detailed information about potentially hazardous situations in the context of all kinds of working procedures.

When working with the analyzer be sure to observe both safety labels on the instrument and safety notes in the Interlock function Manual, the Operator's Manual and Online Help.

Front view

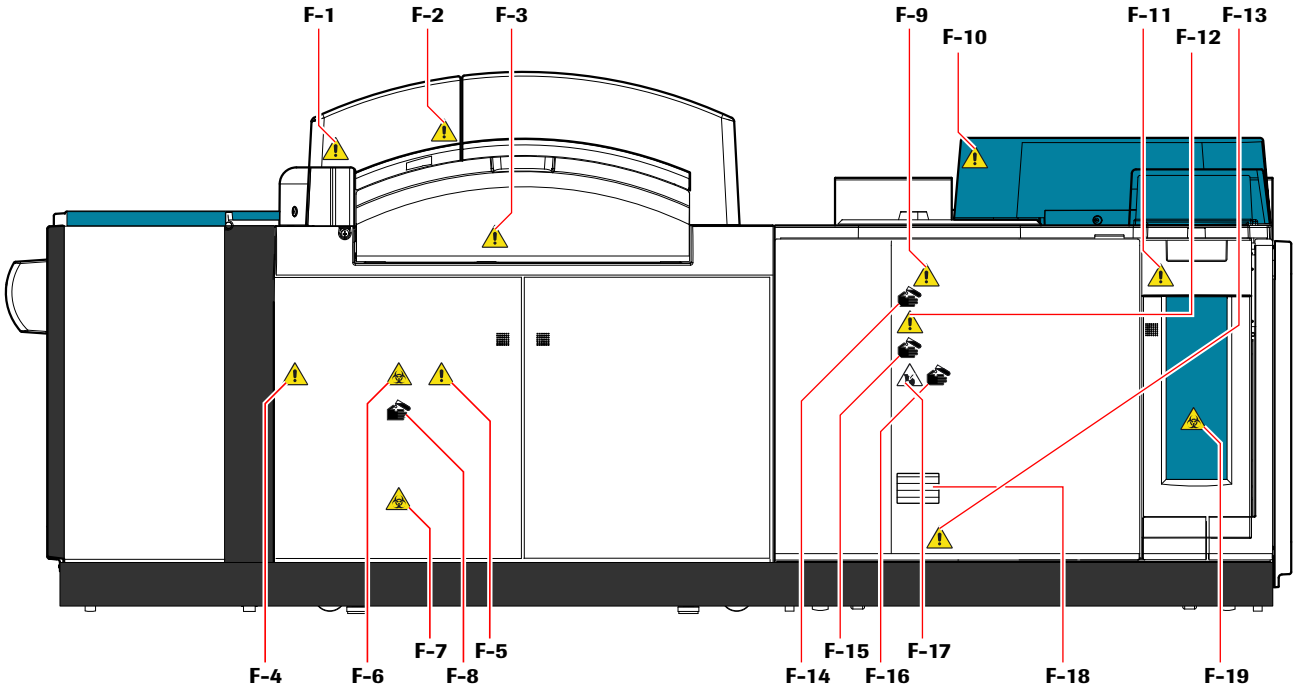
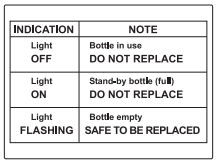


Figure 1 Front view of the analyzer

F-1		**Attention to interlock!**
F-2		**Caution against contact with pierce pin!**
F-3		**Caution against contact with mechanism!**
F-4		**Caution against pinch by syringe**
F-5		**Caution against false result due to loose nipple!**
F-6		**Caution against infection due to contact with sipper syringe!**
F-7		**Caution against infection due to contact with vacuum tank inside!**
F-8		**Caution against irritation by detergent and/or reagent!**
F-9		**Caution against pinch by syringe**

F-10		**Caution against injury and infection due to contact with mechanical parts!**
F-11		**Attention to handling the magazine drawer!**
F-12		**Attention to auxiliary reagent setting!**
F-13		**Attention to auxiliary reagent misplacement!**
F-14		**Caution against irritation by detergent and/or reagent!**
F-15		**Caution against irritation by detergent and/or reagent!**
F-16		**Caution against irritation by detergent and/or reagent!**
F-17		**Caution against injury by contact with needle!**
F-18		**Attention to the status of the green lights!**
F-19		**Caution against infection due to contact with tips and AssayCups!**

INDICATION	NOTE
Light OFF	Bottle in use DO NOT REPLACE
Light ON	Stand-by bottle (full) DO NOT REPLACE
Light FLASHING	Bottle empty SAFE TO BE REPLACED

Side view

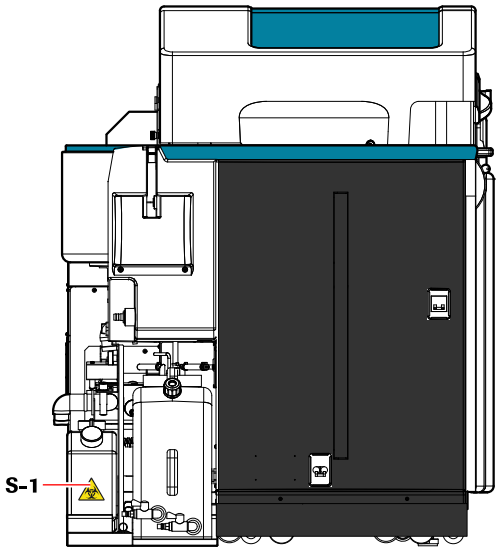


Figure 2 Right side of the analyzer

S-1		**Caution against infection due to contact with waste solution in waste solution tank!**

Top view

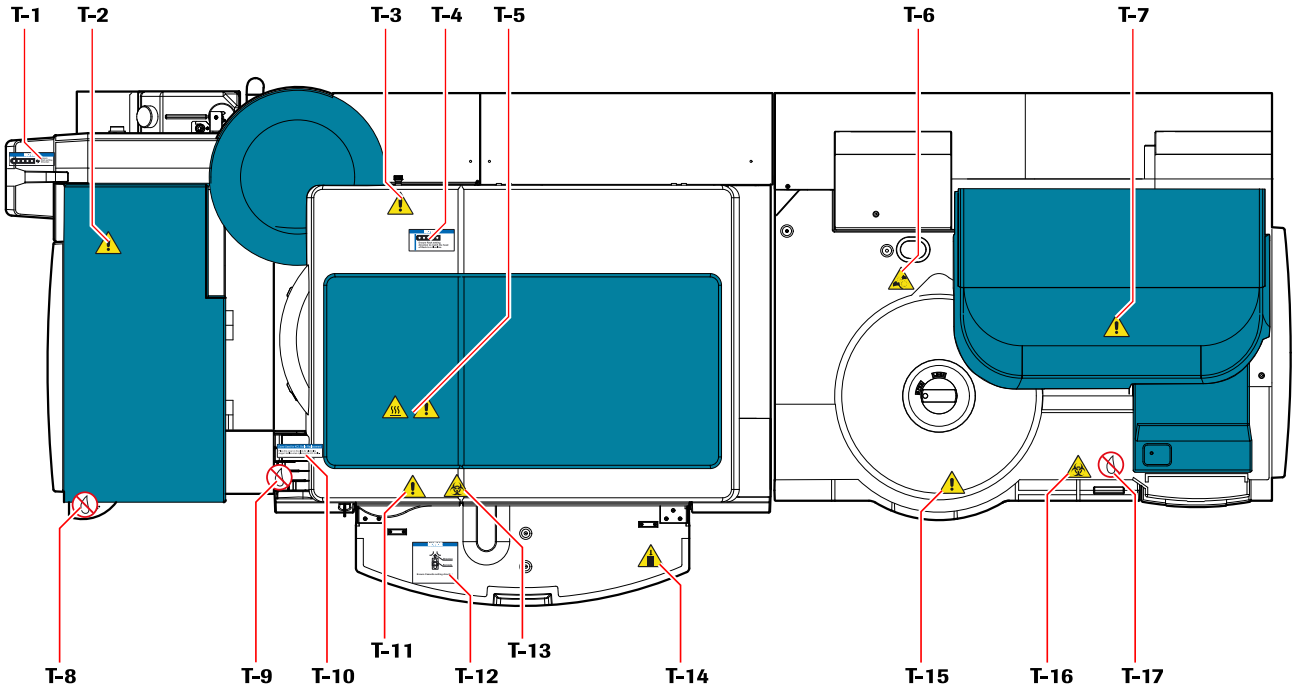
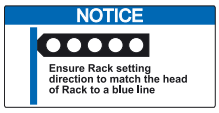
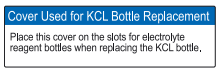
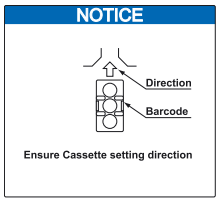


Figure 3 Top view of the analyzer

T-1		**Attention to rack direction when loading STAT port!**
T-2		**Attention to sampler cover!**
T-3		**Caution against pinch by rotor mechanism!**
T-4		**Attention to rack direction when loading backup operation port!**
T-5		**Caution against burn at photometer lamp replacement!**
T-6		**Caution against entanglement by reagent disk!**
T-7		**Attention during incubator maintenance!**
T-8		**Instrument damage by water!**
T-9		**Instrument damage by water!**

T-10		**Reminder to use cover for KCL bottle replacement**
T-11		**Attention when opening or closing ISE cover!**
T-12		**Attention to cassette direction when loading cassettes!**
T-13		**Caution against infection due to contact with parts of the ISE compartment!**
T-14		**Attention to cassette table maximum weight!**
T-15		**Attention when opening or closing reagent disk cover!**
T-16		**Caution against infection due to contact with mechanism!**
T-17		**Instrument damage by water!**

Rear view

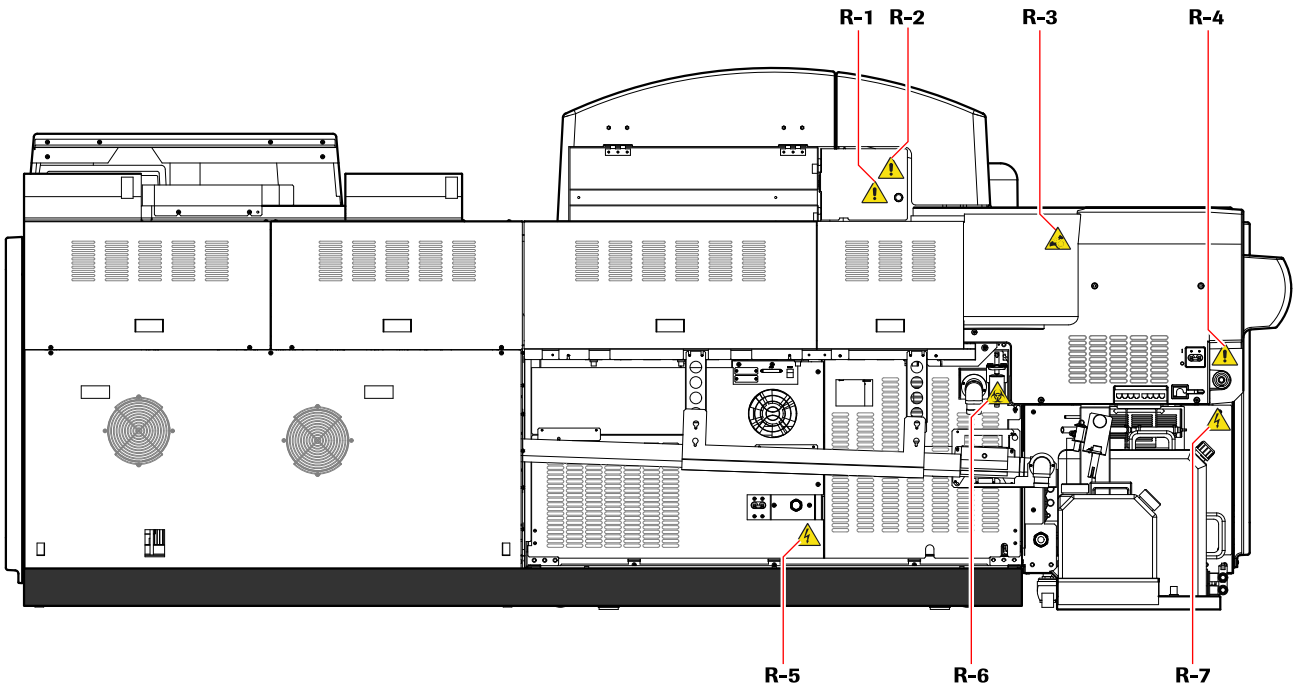


Figure 4 Rear view of the analyzer

R-1		**Caution against contact with mechanism!**
R-2		**Attention to cover with a key!**
R-3		**Caution against entanglement by rack rotor!**
R-4		**Attention during water filter maintenance!**
R-5		**Attention to electric shock at the back side of the instrument!**
R-6		**Caution against infection due to contact with ISE waste solution!**
R-7		**Attention to electric shock at the lower part of the rack sampler unit!**

Safety information for barcode readers

WARNING

Loss of sight

The intense light of a LED barcode reader may severely damage your eyes or result in hazardous radiation exposure.

- Do not stare into the LED barcode reader.
- Do not perform maintenance work on the barcode reader. If problems concerning the barcode reader occur, contact your local Roche representative.
- Do not perform other maintenance work than described in Chapter 2 *Interlock function cobas c 501 with ISE*.

The following figure shows the position of the barcode readers and the directions of the LED apertures used by the **cobas**® 6000 analyzer series:

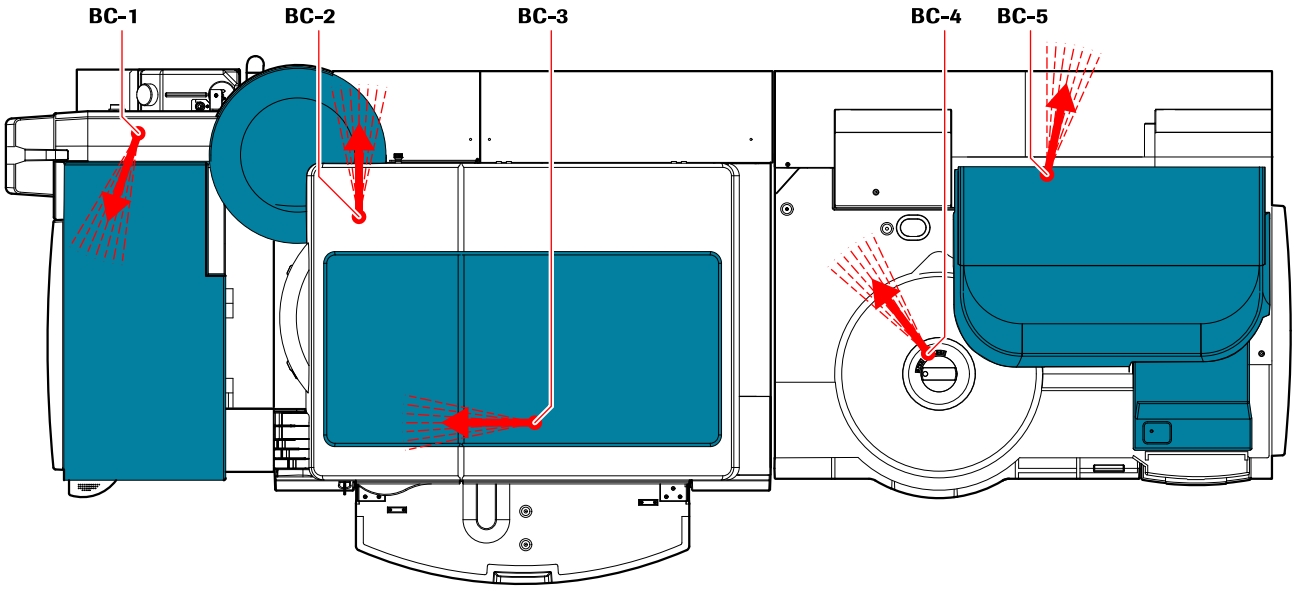


Figure 5 Top view of the analyzer - localization of barcode readers

The following table gives technical information about the intensity of the barcode readers:

Barcode no.	Module	Barcode reader used for	Maximum LED radiation output power	LED class / Classified standard
BC-1	**cu** 150	Rack ID and sample ID	10 µW	Class 1 LED product
BC-2	**c** 501	Rack ID and sample ID	10 µW	IEC 60825-1, +A2:2001
BC-3		Reagent	10 µW	
BC-4	**e** 601	Reagent	102,92 µW	
BC-5		Rack ID	10 µW	

Table 1 Barcode readers of the **cobas**® 6000 analyzer series

Interlock function cobas c 501 with ISE

This chapter describes the maintenance actions required for correct and efficient running of the **c** 501 module. The maintenance of both ISE unit and photometric unit is shown. The schedule of required periodic maintenance actions (daily, weekly, monthly…) is provided as well as maintenance actions that are performed as needed.

This manual describes maintenance actions that can only be performed by specially trained person. Further maintenance sections are described in the operator's manual.

In this chapter *Chapter* 2

Table of contents

General information on performing maintenance

In the following chapters the *operator time* and the *system time* for each maintenance work are mentioned.

Operator time The operator time is the estimated time that a trained person requires to perform this maintenance work.

System time The system time is the approximate time that the system requires to perform the required maintenance items. As most maintenance works can be performed in standby or shutdown status, the system time for shutdown of the analyzer (approximately 3 minutes) and for switching on the analyzer (approximately 12 minutes) is not included in the calculation of the system time.

Analyzer status during maintenance For most maintenance actions, either a module has to be in standby or the analyzer has to be in shutdown status. This section explains what shutdown status is, how to put the analyzer in shutdown status, how to restart the analyzer, and how to return the analyzer in standby status after interlock function has generated an error message.

Shutdown status Shutdown status is the condition where analytical module(s) and control unit are disconnected and the operation power switch is switched off. Power for keeping the reagents cool, however, is still supplied.

Interlock function When opening the top cover, the interlock function of the **c** 501module switches off the current to all moving parts below the top cover. However, it is required to open the top cover and check how some maintenance actions are performed. Therefore, this manual includes how to cancel the interlock function with the interlock release tool and perform maintenance actions. The interlock release tool is given only to the service personnel who have received the training to handle the instrument and get enough knowledge of potential hazard.

Interlock release tool If the interlock release tool is inserted into the interlock switch box, the analyzer control does not detect that the top cover is open. All moving parts on the analyzer are activated even when the top cover is opened. So you can check how the maintenance action is performed with the top cover opened.

► To release and to activate the interlock function

CAUTION

Usage of the interlock release tool

Use the interlock release tool only after receiving the training to handle the instrument, and get enough knowledge of potential hazard and correct operation.

Do not give the interlock release tool to operators that are not trained.

1 Unlock and open the top cover of the module.

2 Insert the interlock release tool to the interlock switch box.

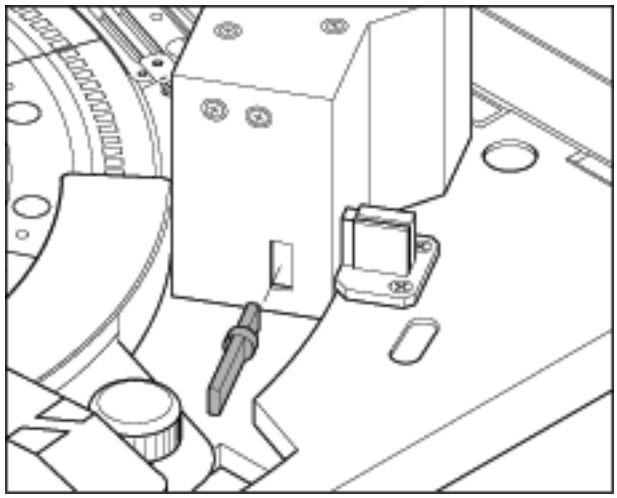


Figure 6 To insert the interlock release tool

3 Turn the interlock release tool 90°.

The interlock is released.

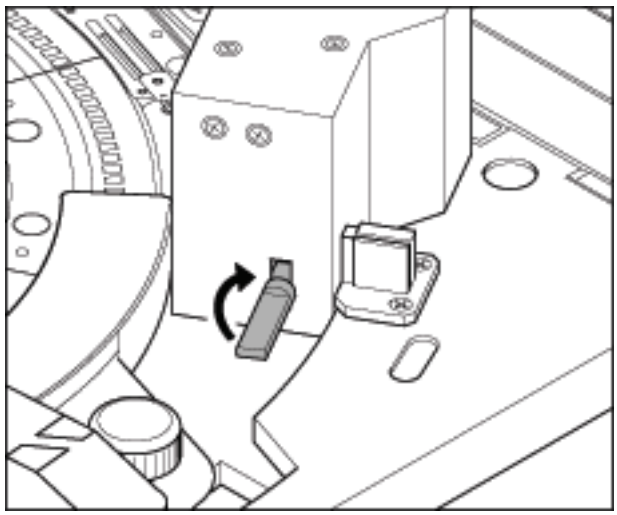


Figure 7 To turn the interlock release tool

4 Perform the necessary checks or maintenance.

5 Return the interlock release tool its insertion position.

6 Remove the interlock release tool.

7 Close the top cover of the module and lock it.

► To release the analyzer in standby status after interlock

1. Close the top cover of the c 501 module and lock it.
2. If an error message is displayed in the alarm list (Alarm global button), indicating that the top cover was opened, delete the message.
3. Choose Utility > Maintenance.
4. Select Maintenance (1) from the Maintenance Type list on the left.
5. Select (1) Reset from the Maintenance Items list on the right.
6. Choose Select to open the Reset window. Select the c 501 module to be reset.
7. Choose Execute.

► To shutdown the analyzer

System time approximately 3 minutes

1. Choose Shut down (global button) to display the Shutdown window.
2. Select the Shutdown option and choose OK to confirm the shutdown.
3. Wait until the computer power supply turns off. Then, switch off the monitor and the printer.
4. Switch off the operation power switch on the left of the rack sampler unit.

If the power of the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start properly when power is supplied again.

- Make sure the monitor indication has changed from shutdown to a state where nothing is displayed.
- Then, switch off the analyzer power switch.

► To switch on the analyzer

System time approximately 12 minutes

1 Switch on the analyzer's operation power switch located on the left of the rack sampler unit.

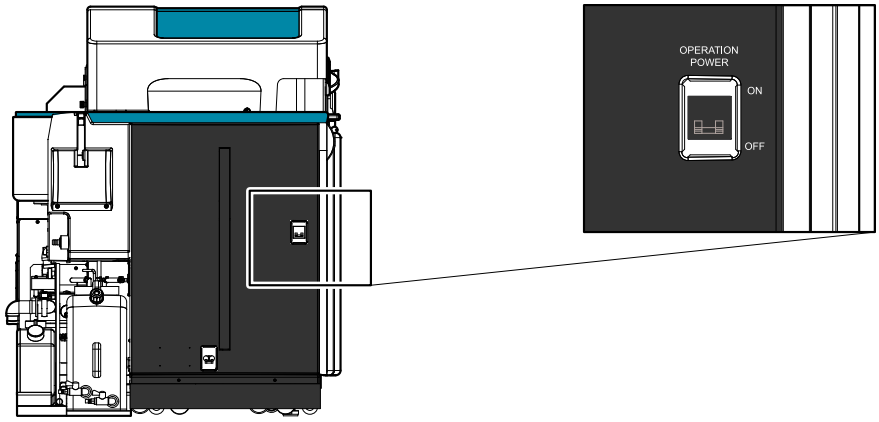


Figure 8 Operation power switch

The system starts the initialization routine.

2 Switch on the computer of the control unit, the monitor, and the printer.

3 After initialization, the Logon screen displays. Enter your operator ID and password to log on.

4 Choose OK to gain access to the software and begin system operation.

Maintenance schedule

The recommended intervals for maintenance and checkup are based on a usage of the analyzer for 5 hours a day, 25 days a month. Maintenance and checkup should be conducted in accordance with the list.

The maintenance actions colored in red are described in this manual. For other maintenance actions refer to the Operator's Manual.

PO	Power OFF
SB	Stand By
CIB	Cleaning Incubator Bath
CLSL	Change Light Source Lamp

	Procedure	Mode	Operator time (min.)	System time (min.)	Page
Daily	Processing green wash rack		5	15[(a)]	
	Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle	SB/PO	2		
	Cleaning cell rinse nozzles	SB/PO	2		
	Cleaning the drain port for high concentrated waste	SB/PO	1		
Weekly	Rinsing the reaction system	SB	2	55	
	Cleaning the cell covers	SB/PO	5		
	Cleaning the rinse stations	SB/PO	5		
	Removing and manually cleaning the IS bath	SB/PO	5		
Monthly	Cleaning the ISE Ref. (KCl) aspiration filter	SB/PO	5	3	
	Replacing reaction cells	CIB/SB/PO	10	55	
	Cleaning the incubator bath	CIB/PO	15	25	
	Cleaning the detergent aspiration filters	SB/PO	5	7	
	Cleaning the filters behind the front doors	SB/PO	10		
Every 2 months	Replacing ISE measuring cartridges (Cl^-, K^+, Na^+)	SB/PO	20	15	34
Every 3 months	Cleaning the ultrasonic mixers[(c)]	CIB	6	7	
	Replacing the ISE pinch valve tubing	SB/PO	4	5	40
	Replacing the ISE sipper tubing	SB/PO	4	10	43
Every 6 months[(b)]	Replacing the photometer lamp[(d)]	CLSL/PO	5	20	
	Replacing the ISE reference cartridge	SB/PO	5	12	45
As needed	Replacing sample, ISE and reagent probes – elimination of blockages	SB/PO	7	15	48
	Replacing nozzle tips on cell rinse nozzles	SB/PO	6		
	Draining the vacuum tank	SB/PO	5		
	Cleaning instrument surfaces	SB/PO	5		

Table 2 Maintenance schedule **c** 501

(a) When **Green Rack during Operation** is enabled for a 24 hour shift

(b) All maintenance actions described as 6 monthly or as needed can be covered by appropriate service contract actions.

(c) Every 3 months or after 225.000 tests (whatever comes first)

(d) Every 6 months, after 750 hours or if the photometer check value exceeds 14000 (whatever comes first)

Adjustment of probes and ISE sipper nozzle after cleaning

At the end of analysis each day, the outside of the pipetter probes (sample probe, reagent probes, ISE probe) and of the ISE sipper is cleaned to remove residual solution and precipitation. Positional adjustment can be required after cleaning the probe. The positional adjustment is described in the chapter Replacing sample, ISE and reagent probes – elimination of blockages. If it is necessary to adjust a probe or the ISE sipper, go through the following procedures before you resume routine operation:

- To check the probe's alignment
  To check the probe's alignment on page 55
- To perform an air purge and check the operation of the probe
  To perform an air purge and check the operation of the probe on page 57
- To perform a Mechanisms Check
  To perform a Mechanisms Check on page 58

Every two months maintenance

In this section, you find maintenance for the ISE unit of the **c** 501 module that is to be performed at least once every two months.

Replacing ISE measuring cartridges (Cl^-, K^+, Na^+)

The electrical response level and the slope value (sensitivity) of each measuring cartridge decreases slowly with time and use. Replace an ISE measuring cartridge if one of the following criteria is met:

- The cartridge has been in service beyond 2 months.
- The test count has reached 9000 tests.
- The slope value of the cartridge falls outside of the normal range.

In the latter case, an alarm is issued as described in the figure below.

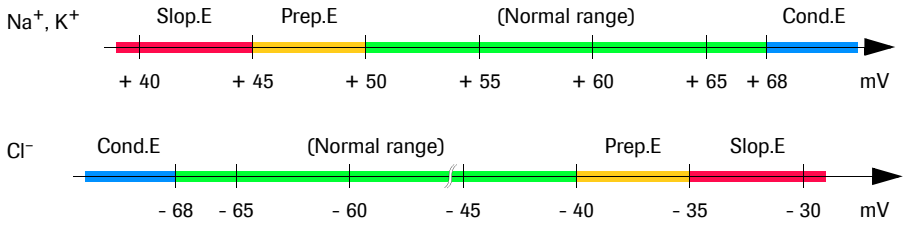


Figure 9 ISE data alarms and corresponding slope values (EMF values)

Judgement on ISE measuring cartridge replacement

- If the alarm “Preparation abnormal (Prep.E)” appears during calibration, you may continue the day’s analyses, if the QC are within the limits, but replace the cartridges at the end of the day or before the beginning of the next routine analyses.
- If the alarm “ISE slope error (Slop.E)” appears, replace the cartridges at once.
- Normally, the slope values decrease slowly over time and use. If there is a large change, the cause may be other than the electrodes. Check for air bubbles in or leakage from the flow path, an error in substitution of standard solution or calibrators, contamination of the flow path, etc.

This maintenance comprises the following procedures and maintenance items:

1. To replace ISE measuring cartridges
2. To prime lines and check connections
3. To perform ISE Check and calibrate the ISE unit

Operator time approximately 20 minutes.

System time approximately 15 minutes.

Materials required

- ☐ Sodium (Na^+) cartridge
- ☐ Potassium (K^+) cartridge
- ☐ Chloride (Cl^-) cartridge
- ☐ O-ring
- ☐ Lint-free gauze pads
- ☐ Forceps

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page 14
- *Personal injury due to contact with instrument mechanism* on page 12
- *Incorrect results due to missing cover of the ISE measuring compartment* on page 13

► To replace ISE measuring cartridges

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

3

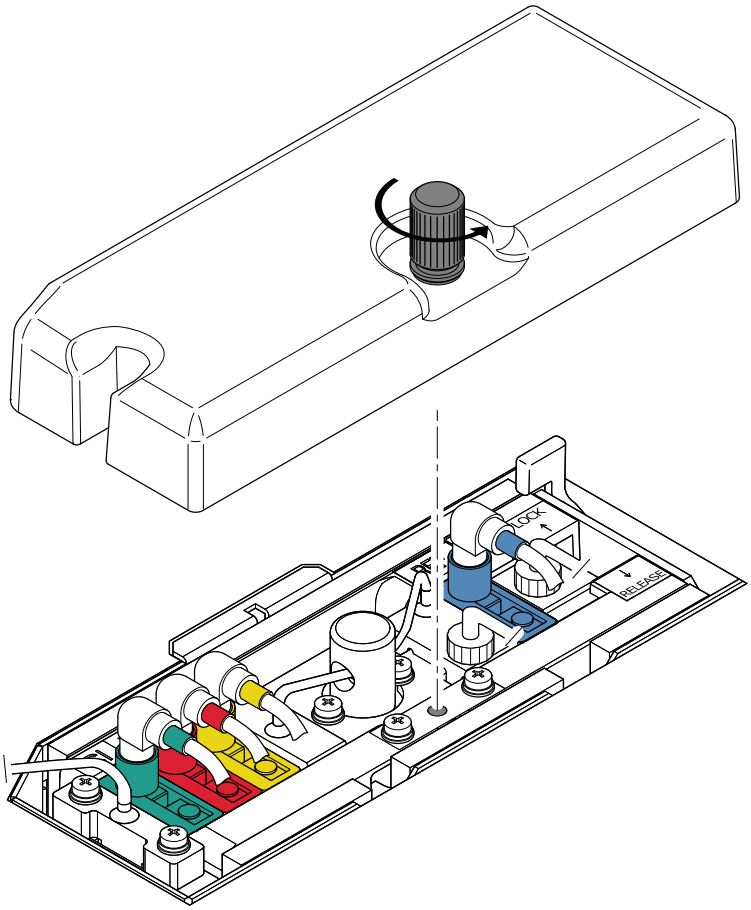


Figure 10 Remove the cover of the ISE measuring compartment

3 Remove the cover of the ISE measuring compartment.

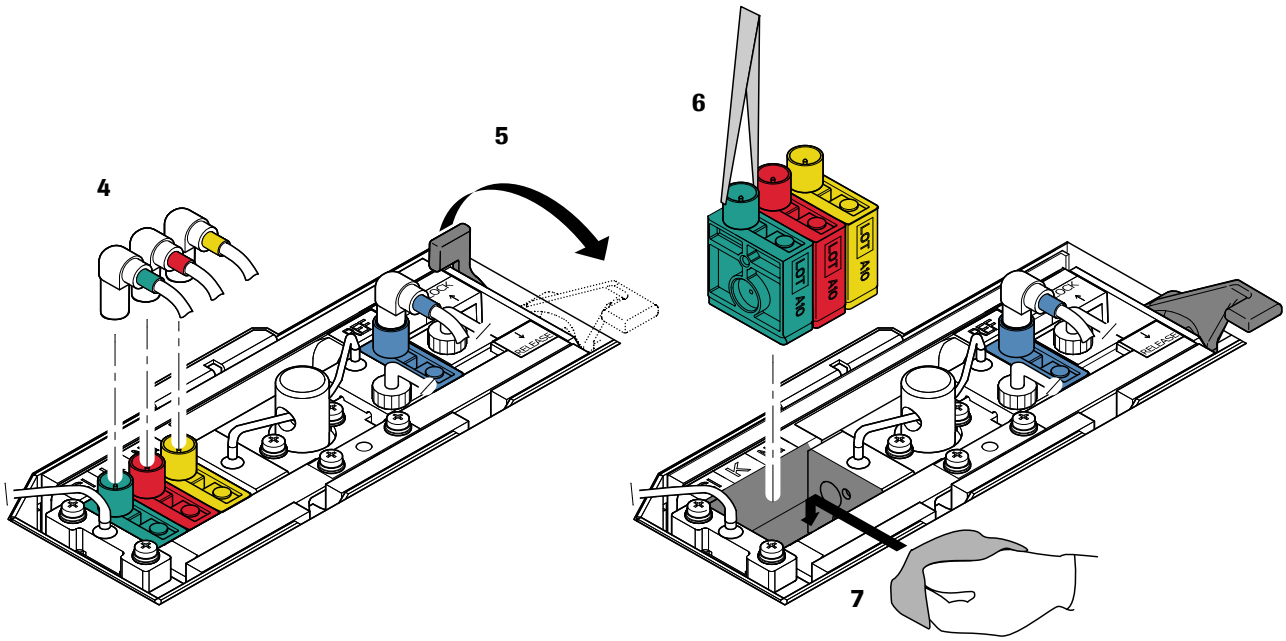


Figure 11 Replace ISE measuring cartridges

4 Disconnect the color-coded wires attached to the ISE measuring cartridges.

5 Pull the release lever toward the RELEASE position to loosen the cartridges in the mounting block.

6 Use large forceps to remove the cartridges from the mounting block.

7 During the replacement, thoroughly wipe up any spilled liquid or liquid adhering to connecting parts.

8 Attach new cartridges in the order of Cl (green), K (red), and Na (yellow) from the left, and set them in the cell holder while holding the lever at RELEASE.

Verify that the connecting part and cartridges are provided with O-rings, but be sure to remove the black rubber protectors that are located over the O-ring receptacles on the new cartridges.

9 Set the lever at LOCK to fasten the cartridges, then reconnect the color-coded wires to their respective cartridges.

CAUTION

Incorrect results due to interchanged wires

Verify that the color-coded wires are connected to their respective cartridges.

10 Switch on the analyzer, if the analyzer is in shut down status.

► To prime lines and check connections

1 Insert the interlock release tool.

See *To release and to activate the interlock function* on page 30

2 Choose Utility > Maintenance.

3 Select Maintenance (1) from the Maintenance Type list on the left.

4 Select (8) Reagent Prime from the Maintenance Items list on the right.

5 Choose Select to open the Reagent Prime window.

6 Select a module. Selected modules are highlighted.

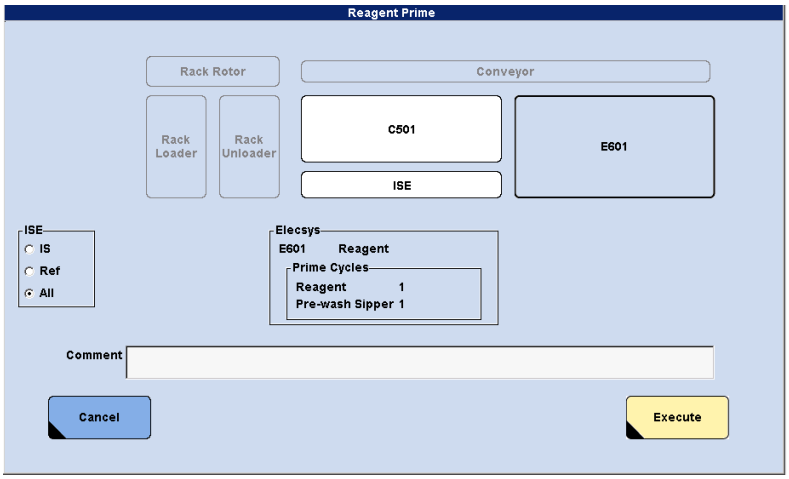


Figure 12 Reagent Prime window

7 Choose ALL in the ISE area.

8 Choose Execute.

The prime is complete when the system returns to standby.

Check connections!

Make sure no air bubbles enter the system from the connecting parts and there is no liquid leaking inside the ISE measuring compartment.

9 Replace the cover of the ISE measuring compartment and secure its retaining pin.

10 Remove the interlock release tool.

11 Close the top cover of the module and lock it.

After installing new ISE cartridges, perform maintenance check (2) ISE Check to condition the electrodes and then calibrate the ISE device before you resume routine analysis.

► To perform ISE Check and calibrate the ISE unit

1 Choose Utility > Maintenance.

2 Select Check (2) from the Maintenance Type list on the left.

3 Select (2) ISE Check from the Maintenance Items list on the right.

4 Choose Select, to open the ISE Check window.

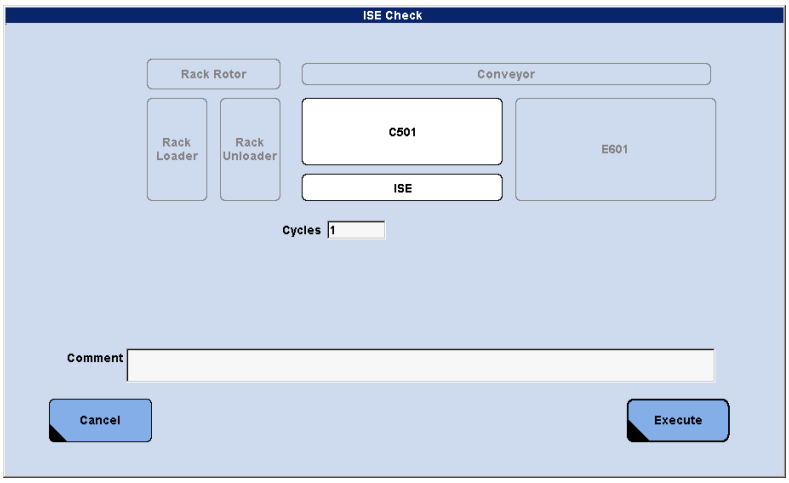


Figure 13 ISE Check window

5 Select a module. Selected modules are highlighted.

6 Enter 10 at Cycles and choose Execute.

The electromotive force (EMF) values of the internal standard solution are printed 10 times for each electrode. At this point, the results can be ignored.

7 After waiting ten minutes, execute another ISE check (10 cycles).

Make sure the printed EMF values of the internal standard solution are normal and the difference in successive values for the same electrode are stable within ± 0.2 mV.

ISE Check 02/02/06 14:27

MODULE	C6				
NO	NA EMF	K EMF	CL EMF	KCL EMF	IS
1	-32.8	-34.5	103.5	-0.2	IS1
2	-31.9	-34.3	105.3	-0.3	IS1
3	-31.6	-34.3	109.0	-0.3	IS1
4	-31.7	-34.4	112.3	-0.2	IS1
5	-31.8	-34.4	115.3	-0.2	IS1

Figure 14 ISE Check report

8 Finally, calibrate the ISE unit.

Quarterly maintenance

In this section, you find maintenance for the ISE unit of the **c** 501 module that is to be performed at least once every three months.

👁 This section discusses the following maintenance actions:
Replacing the ISE pinch valve tubing on page 40
Replacing the ISE sipper tubing on page 43

Replacing the ISE pinch valve tubing

After long use, the tubing will gradually wear out and the accuracy of sample aspiration will decrease. Replace the ISE pinch valve tubing once every three months.

Operator time approximately 4 minutes

System time approximately 5 minutes

Materials required ☐ Pinch valve tubing

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page 14
- *Incorrect results due to missing cover of the ISE measuring compartment* on page 13

► To replace the ISE pinch valve tubing

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

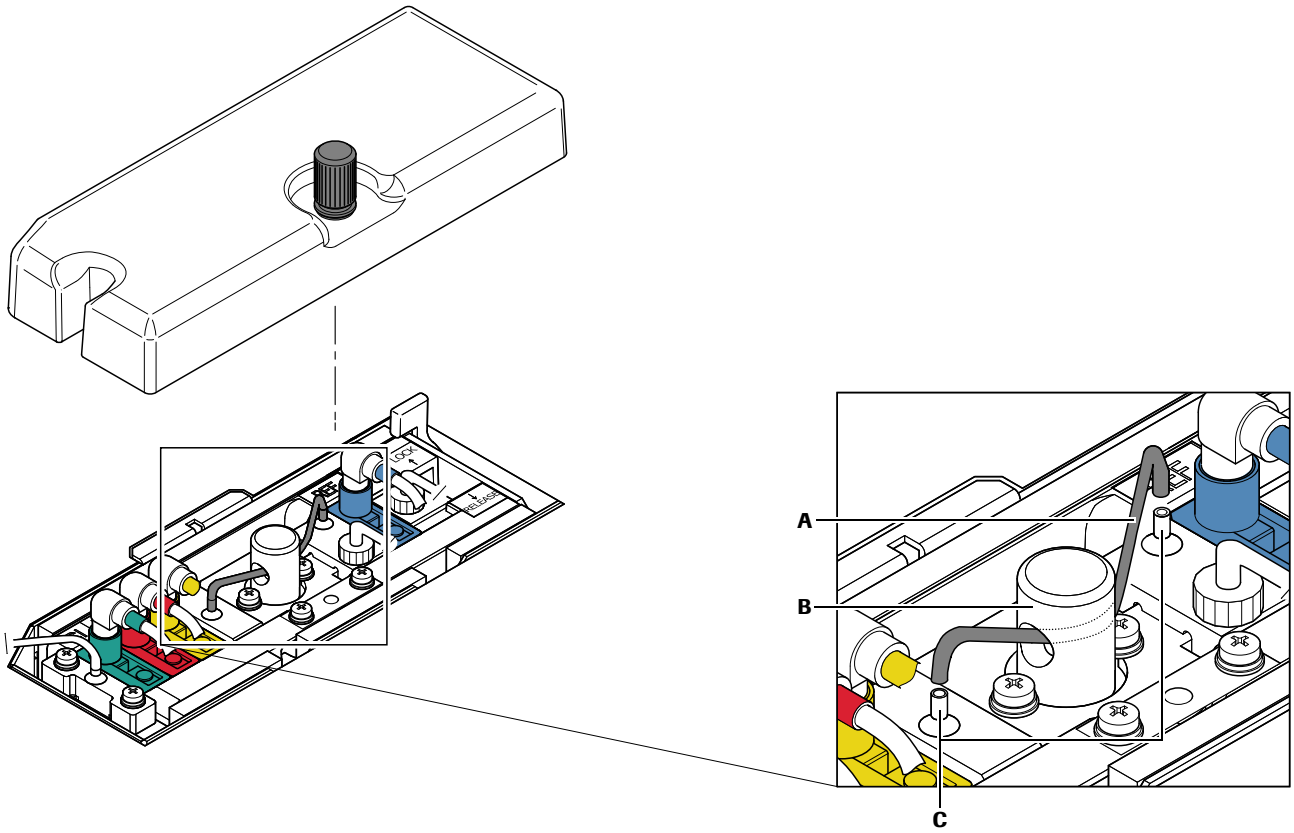


Figure 15 Replacing the ISE pinch valve tubing

3 Remove the cover of the ISE measuring compartment.

4 Gently remove both ends of the tubing (**A**) from the connectors (**C**) and remove the tubing from the pinch valve (**B**). Discard the old tubing.

5 Insert the new tubing through the pinch valve and attach both ends of the tubing to the connectors.

6 Switch on the analyzer, if the analyzer is in shut down status.

7 Insert the interlock release tool.

8 Perform maintenance item (6) Air Purge.

See *To perform an air purge* on page 42

9 Perform maintenance check (2) ISE Check (two times, 10 cycles) and then calibrate the ISE device before you resume routine analysis.

See *To perform ISE Check and calibrate the ISE unit* on page 39.

10 Reattach the cover of the ISE measuring compartment.

11 Remove the interlock release tool.

12 Close and lock the top cover.

► To perform an air purge

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with instrument mechanism* on page 12

1 Choose Utility > Maintenance.

2 Select Maintenance (1) from the Maintenance Type list on the left.

3 Select (6) Air Purge from the Maintenance Items list on the right.

4 Choose Select to open the Air Purge window.

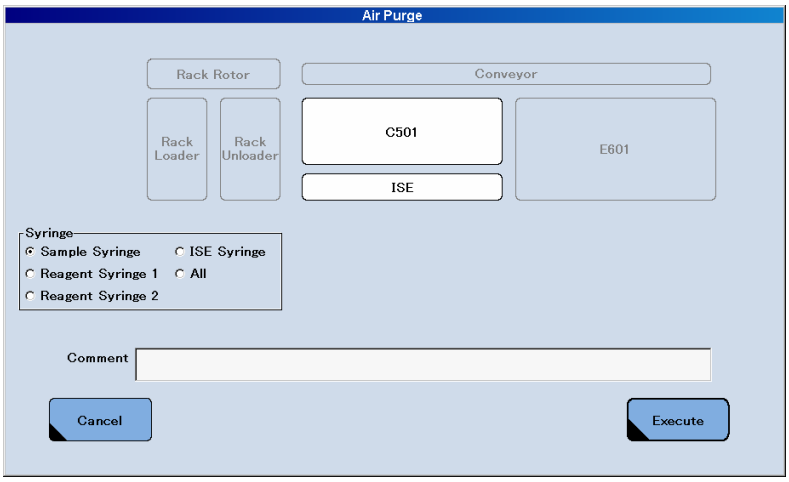


Figure 16 Air Purge window

5 Select the appropriate module. Selected modules are highlighted.

6 In the Syringe area select ISE Syringe.

7 Choose Execute to initiate the air purge.

The pipetter will operate.

Check connections!

Make sure no air bubbles enter the system from the connectors and there is no liquid leaking inside the ISE measuring compartment.

8 Check if water is dispensed from the tip of the probe in a straight flow.

Replacing the ISE sipper tubing

After long use, the tubing will gradually wear out and the accuracy of sample aspiration will decrease. Replace the ISE sipper tubing once every three months.

Operator time approximately 4 minutes

System time approximately 10 minutes

Materials required ☐ ISE sipper tubing

WARNING

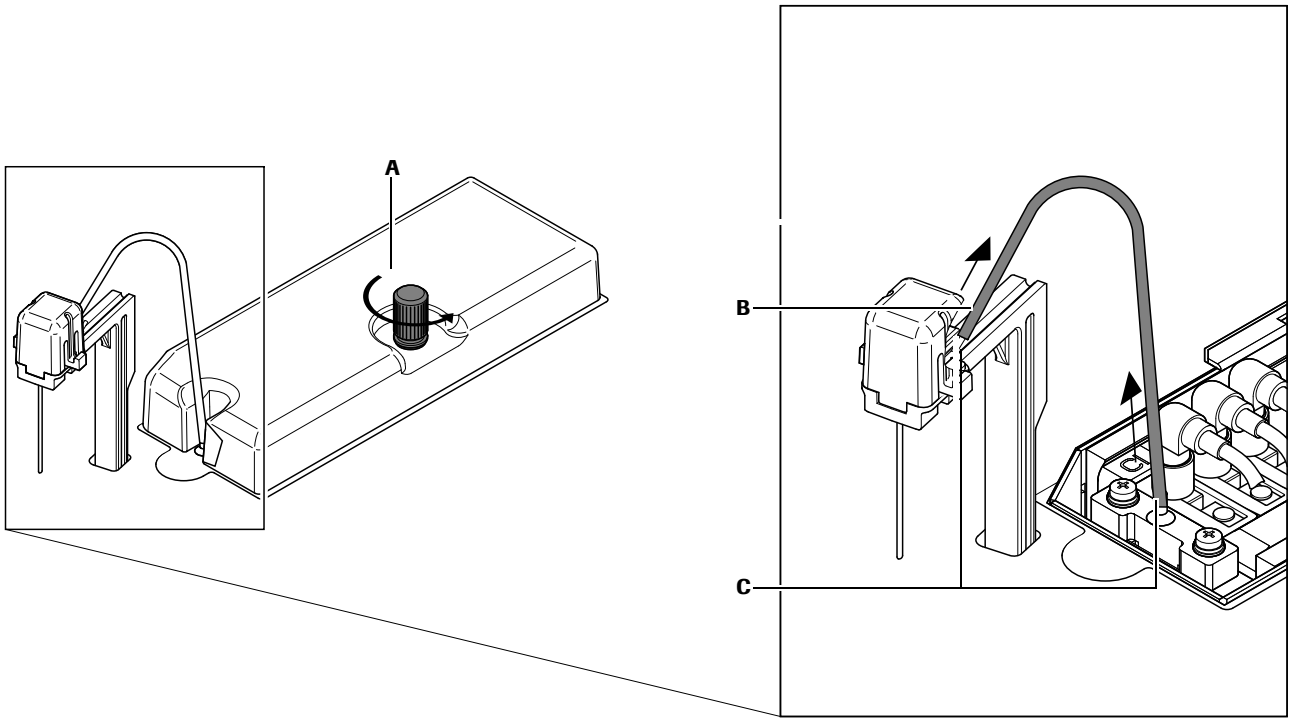
Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page 14
- *Incorrect results due to missing cover of the ISE measuring compartment* on page 13

► To replace the ISE sipper tubing

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.



A ISE measuring compartment cover

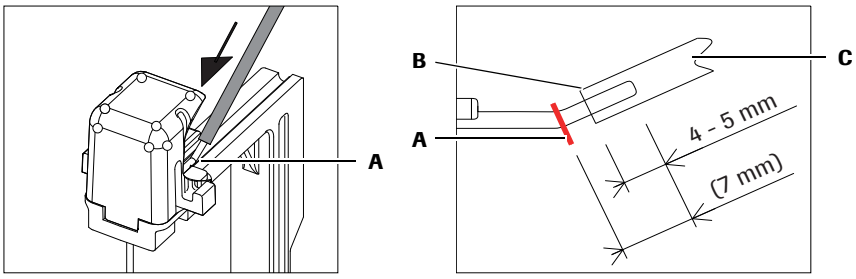
B Sipper tubing

C Connectors

Figure 17 Replacing the ISE sipper tubing

3 Remove the cover (**A**) of the ISE measuring compartment.

4 Gently remove both ends of the ISE sipper tubing (**B**) from the connectors (**C**).



A Insertion limit at the bending part of the sipper nozzle
B Insertion position
C Sipper tube

Figure 18 Attaching ISE sipper tubing

5 Attach both ends of the new tubing to the connectors.

To attach the tubing to the connector of the sipper, insert the tubing onto the sipper connector for 4 to 5 mm.

Do not exceed insertion limit

Inserting the tubing beyond the insertion limit (**A**) may influence the tip position of the sipper nozzle. The position of the sipper nozzle affects the ISE analysis result.

6 Switch on the analyzer, if the analyzer is in shut down status.

7 Insert the interlock release tool.

8 Perform maintenance item (6) Air Purge.

See *To perform an air purge* on page 42

9 Perform maintenance check (2) ISE Check (two times, 10 cycles) and then calibrate the ISE device before you resume routine analysis.

See *To perform ISE Check and calibrate the ISE unit* on page 39.

10 Reattach the cover of the ISE measuring compartment.

11 Remove the interlock release tool.

12 Close and lock the top cover.

Every six months maintenance

In this section, you find maintenance for the ISE unit of the **c** 501 module that is to be performed at least once every six months.

Replacing the ISE reference cartridge

Like any ISE cartridge, the ISE reference cartridge slowly deteriorates with time and use. Eventually, the electromotive force (EMF) values of all cartridges may become unstable. Therefore, replace the reference cartridge every six months.

Operator time approximately 5 minutes.

System time approximately 12 minutes.

Materials required

- ☐ ISE reference cartridge
- ☐ O-ring
- ☐ Lint-free gauze pads
- ☐ Forceps

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page 14
- *Personal injury due to contact with instrument mechanism* on page 12
- *Incorrect results due to missing cover of the ISE measuring compartment* on page 13

► To replace ISE reference cartridge

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

3

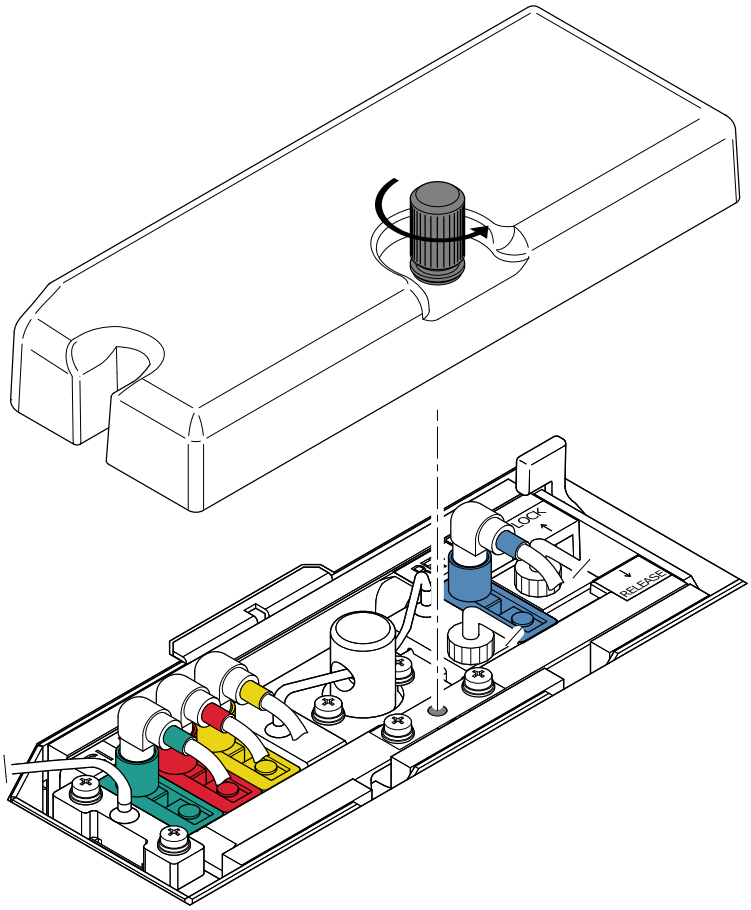


Figure 19 Remove the cover of the ISE measuring compartment

3 Remove the cover of the ISE measuring compartment.

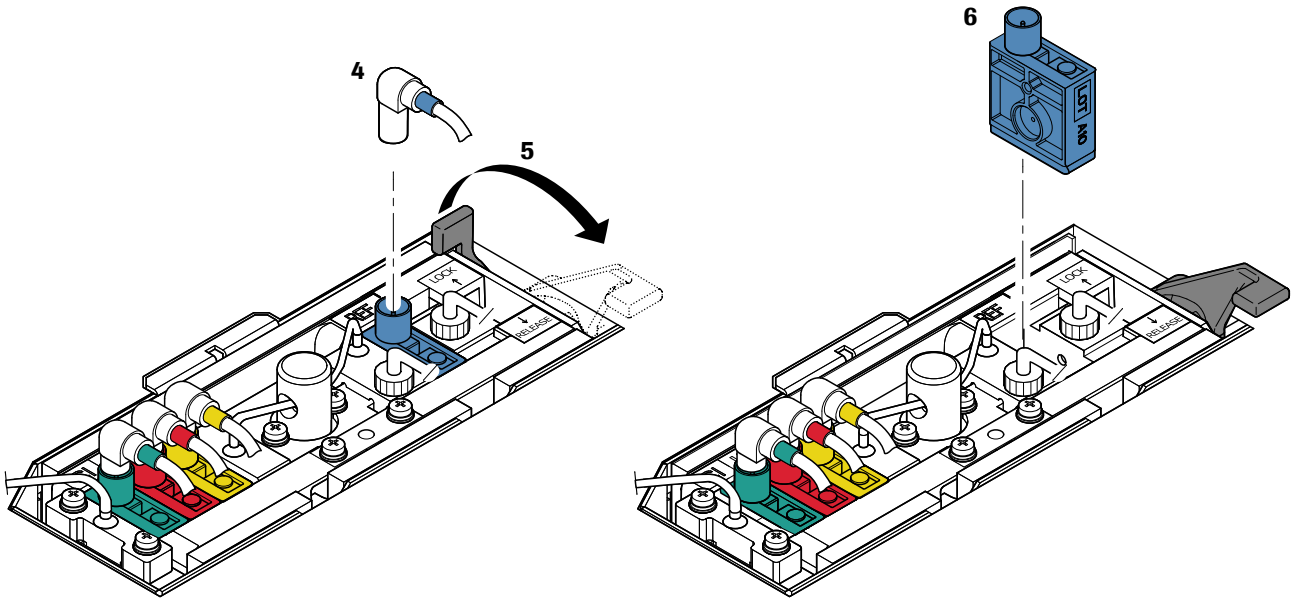


Figure 20 Replace ISE reference cartridge

4 Disconnect the wire attached to the ISE reference cartridge.

5 Pull the lever toward the RELEASE position to loosen the cartridges in the mounting block.

During the replacement, thoroughly wipe up any spilled liquid or liquid adhering to connecting parts.

6 Remove the reference cartridge.

7 An O-ring should be on the cartridge that just came out of the ISE measuring compartment. However, sometimes the O-ring stays inside the ISE measuring compartment. If this is the case, use forceps and remove it. If reference solution leaks, carefully clean to avoid crystallization.

8 Insert the new ISE reference cartridge. Ensure that the O-ring is all the way up against the collar on the new cartridge.

9 Set the lever at LOCK to fasten the cartridge, then reconnect the wire to the cartridge.

10 Switch on the analyzer, if the analyzer is in shut down status.

After installation of the new ISE reference cartridge, follow the procedure recommended for ISE measuring cartridges, before you resume routine operation.

For further instructions, see:
To prime lines and check connections on page 38
To perform ISE Check and calibrate the ISE unit on page 39

As needed maintenance

In this section, you find maintenance for **c** 501 module that is to be performed as needed.

Replacing sample, ISE and reagent probes – elimination of blockages

It is necessary to detach the probes to clean its inside, eliminate blockages, as well as for replacement. Replace the sample, ISE or reagent probe when it is bent or otherwise damaged.

This maintenance comprises the following procedures and maintenance items:

1. To detach the sample or ISE probe
2. To detach the reagent probes
3. To eliminate blockages
4. To reattach the sample or ISE probe
5. To reattach the reagent probes
6. To check the tubing system for leakage
7. To check the probe's alignment
8. To perform an air purge and check the operation of the probe
9. To perform a Mechanisms Check

Operator time approximately 7 minutes

System time approximately 15 minutes

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Infection due to contact with sample or waste solution* on page 14
- *Personal injury due to contact with instrument mechanism* on page 12

Materials required

- ☐ Cleaning wire 0.2 mm and 0.5 mm diameter
- ☐ Deionized water
- ☐ Lint-free gauze pads
- ☐ Required probes

► To detach the sample or ISE probe

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

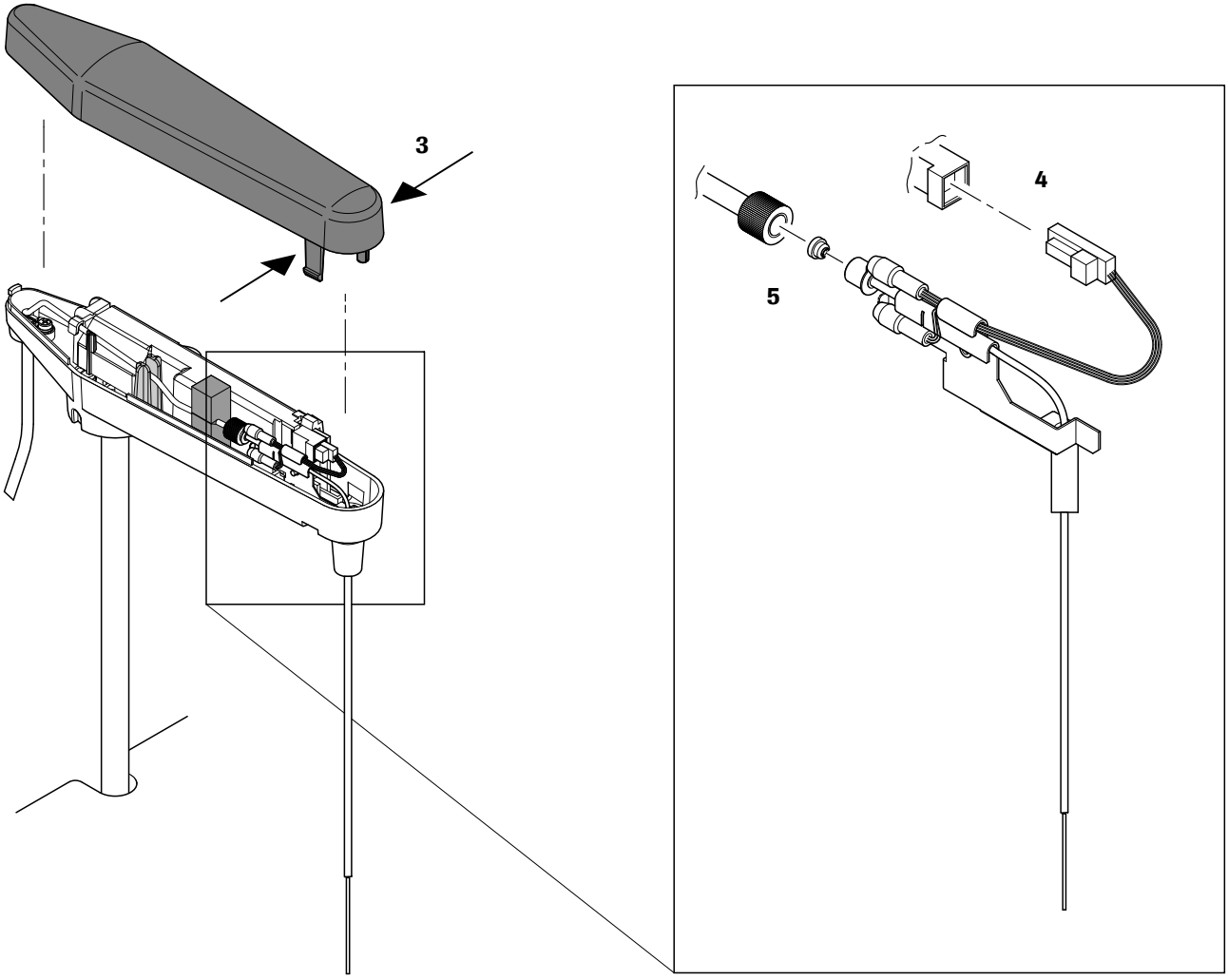


Figure 21 Removing the arm cover of the sample pipetter

3 Remove the arm cover by pressing the arm cover releases on either side and gently lifting up the cover. This exposes the wires and the tubing.

4 Disconnect the wire of the liquid level sensor.

5 Loosen the tubing from the probe by unscrewing it, taking care not to drop and lose the probe seal. Locate the probe seal either on the end of the probe tubing or in the retaining nut.

6 Lift the probe from the probe arm.

► **To detach the reagent probes**

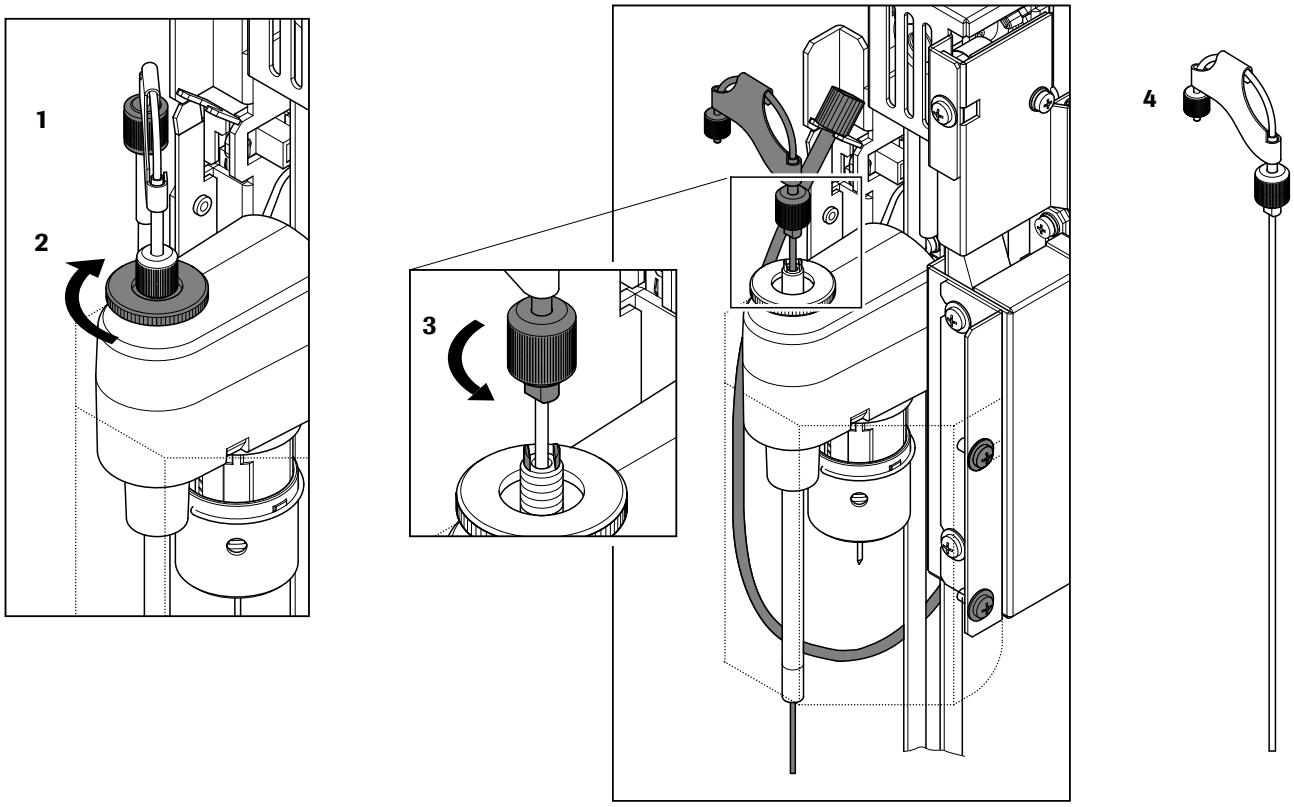


Figure 22 Removing the arm cover of the reagent pipetter

1 Disconnect the tube socket of the reagent tubing.

2 Loosen the knurled counternut by turning it clockwise.

3 Loosen the probe retaining nut by turning it counter clockwise.

4 Lift the probe from the probe arm.

► **To eliminate blockages**

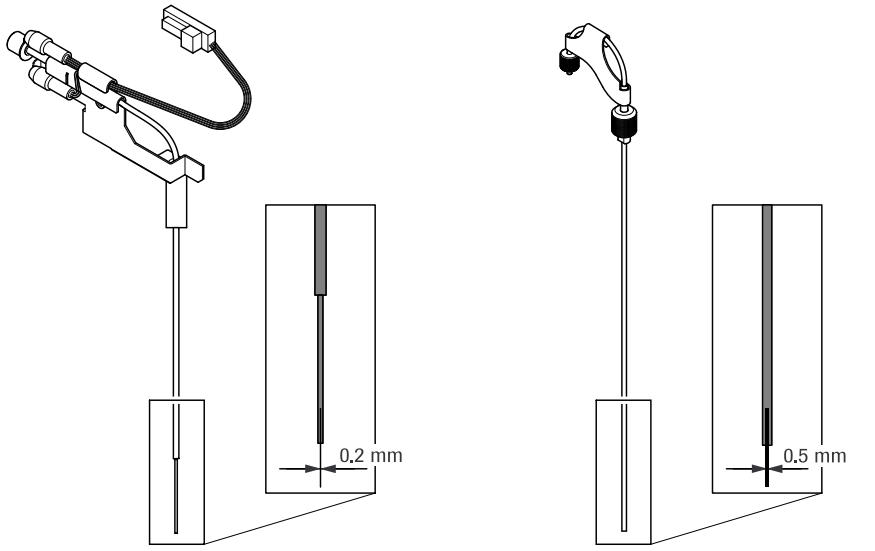


Figure 23 Eliminate blockages from the probes

1 For the sample and ISE probe use a probe cleaning wire (stainless steel) of 0.2 mm diameter. For reagent probes use a probe cleaning wire of 0.5 mm diameter.

2 Insert the probe cleaning wire into the probe tip and run it through the probe.

3 Rinse the inside of the probe thoroughly with deionized water, then wipe the probe with clean lint-free gauze pads.

► To reattach the sample or ISE probe

1 To reattach the sample probe, follow the instructions for detaching in the reverse order.

👁 *To detach the sample or ISE probe* on page 49

Observe the following notes when reattaching the sample probe:

- When placing the probe into the pipetter arm, the tab on the probe must slide into the holding slot on the pipetter arm to assure proper alignment.
- A probe seal, once pulled out, should not be reused since the edge will be deformed. A new probe always comes with a new seal.
- Reconnect the tubing making sure the probe seal is in place.
- Make sure, that the tube fits in the tube guide (foam block) as shown in the following figure.
- Replace the arm cover; the rear section first and then the front section.

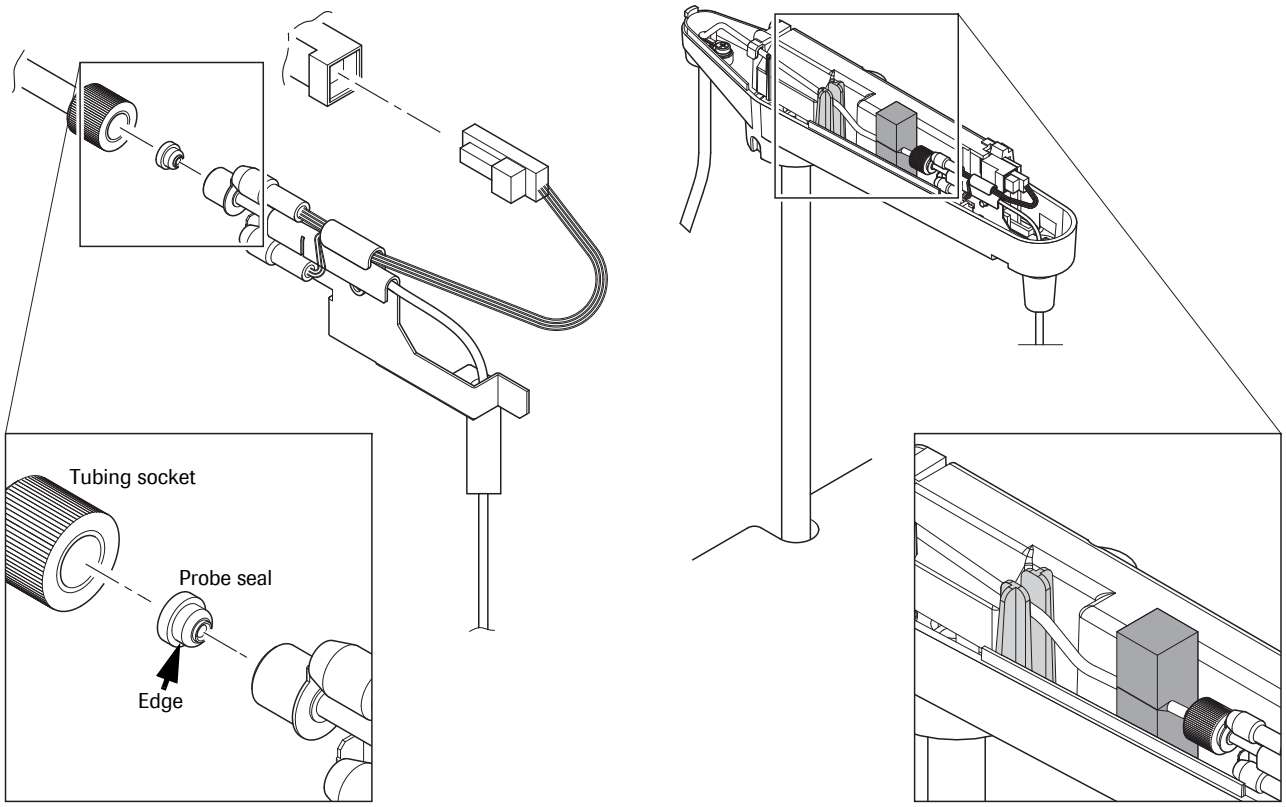


Figure 24 Location of the probe seal, correct position of the tube

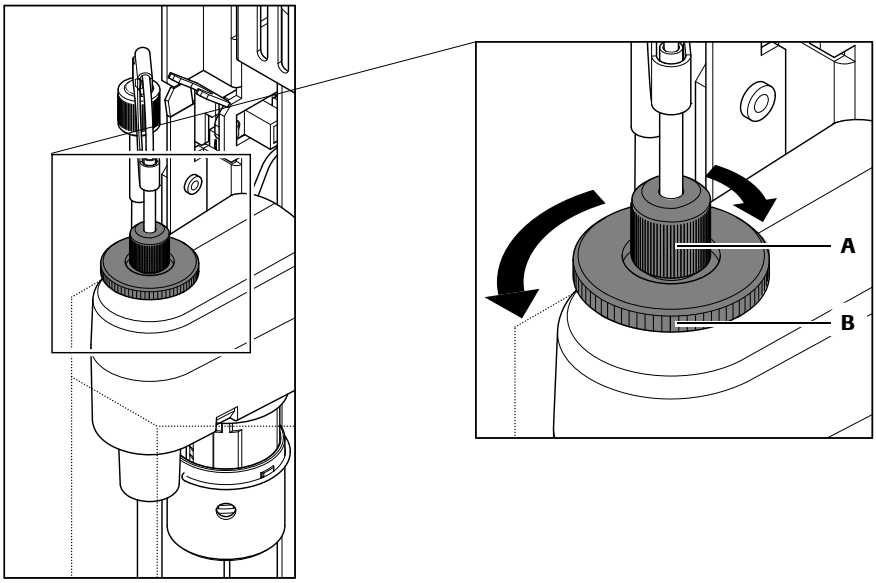
► To reattach the reagent probes

1 To reattach the reagent probe, follow the instructions for detaching in the reverse order.

👁 *To detach the reagent probes* on page 50

Observe the following notes when reattaching the reagent probe:

- Tighten the probe retaining nut by turning it clockwise.
- Tighten the knurled counternut by turning it counter clockwise to the stop.



A Probe retaining nut
B Counternut

Figure 25 Reattaching the reagent probes

► To check the tubing system for leakage


WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with instrument mechanism* on page 12

1 If the system was in shutdown, start the analyzer.

2 Insert the interlock release tool.

👁 See *To release and to activate the interlock function* on page 30

3 When the initial operation is completed, check the tubing system of the probes for leakage.

- Sample pipetter and ISE pipetter:
  Detach the arm cover of the sample pipetter and the ISE pipetter and check for any water leakage from the connecting parts.
- Reagent pipetter:
  Check for any water leakage from the connecting parts.

4 If there is a leak, stop the analyzer, remove the interlock release tool, wipe up the leaked water, and reattach the retaining nut.

5 Then, start the analyzer and check again.

6 Reattach the arm cover of the sample pipetter and ISE pipetter, the rear part first and then the front part.

7 Go through the following procedures before you resume routine operation:

- To check the probe's alignment
  👁 *To check the probe's alignment* on page 55
- To perform an air purge and check the operation of the probe
  👁 *To perform an air purge and check the operation of the probe* on page 57
- To perform a Mechanisms Check
  👁 *To perform a Mechanisms Check* on page 58

► To check the probe's alignment

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with instrument mechanism* on page 12

1 Choose Utility > Maintenance.

2 Select Maintenance (1) from the Maintenance Type list on the left.

3 Select (18) Probe Check from the Maintenance Items list on the right.

4 Choose Select to open the Probe Check window.

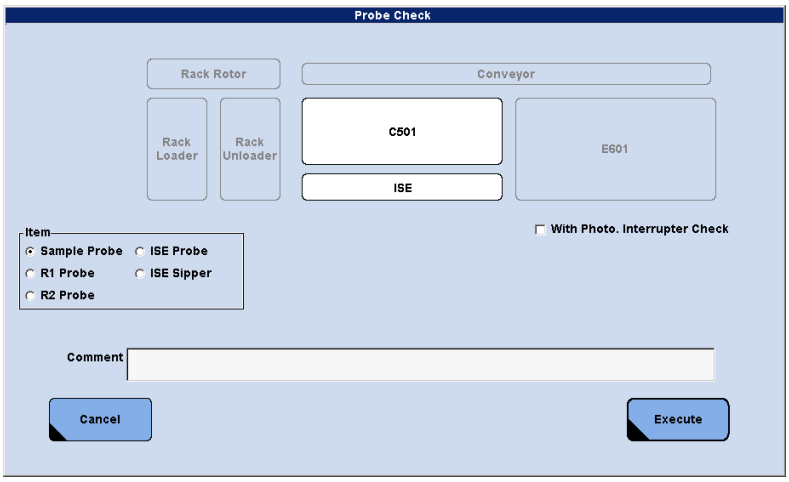


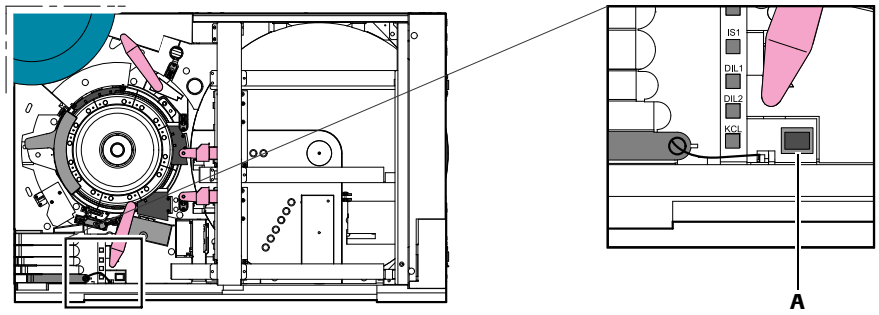
Figure 26 Probe Check window

5 In the Item area, choose pipetter probe that needs to be checked (Sample Probe, R1 Probe, R2 Probe…) and select the module. Selected modules are highlighted.

Danger of collision!

When pressing the maintenance key and at the completion of Probe Check, be careful not to contact the sample probe, reagent probe, ISE reagent probe, or sipper.

6 Press the maintenance key to move the probe.



A Maintenance key

Figure 27 Location of maintenance key next to ISE reagent compartment

Repeated pressing of the maintenance key moves the probe to the following positions:

Position #	Sample probe	R1 probe	R2 probe	ISE probe
1	Sample probe rinse station	R1 rinse station	R2 rinse station	ISE rinse station
2	Sampling position	Liquid volume check position	Drying cylinder	Sampling position
3	Reaction cell	Drying cylinder	Reaction cell	Reaction cell
4	Height control	Reaction cell		IS bath
5	Detergent 1 aspiration			EcoTergent
6	Detergent 2 aspiration			Incubator bath
7	Drying cylinder			

Table 3 Target positions for probe movements using the maintenance key

7 Move the probe to its reaction cell position. If the probe is not centered over the reaction cell, carefully adjust it:


CAUTION

Damage to the probe

Do not bend the probe sharply. This can crimp the probe, thereby requiring replacement.

- The correct alignment of all probes is critical for proper functioning of the system.
- Failure to correctly align all probes can result in damage to the system and/or incorrect test results.

Firmly hold the pipetter arm and gently bend the probe over its entire length in an arc to manually adjust the position.

8 Press the maintenance key again and verify the positional accuracy at each stop.

9 To terminate this maintenance item, choose Stop (global bottom).
The Stop window opens; choose Yes. A confirmation window opens; choose Yes.

► To perform an air purge and check the operation of the probe

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with instrument mechanism* on page 12

1 Choose Utility > Maintenance.

2 Select Maintenance (1) from the Maintenance Type list on the left.

3 Select (6) Air Purge from the Maintenance Items list on the right.

4 Choose Select to open the Air Purge window.

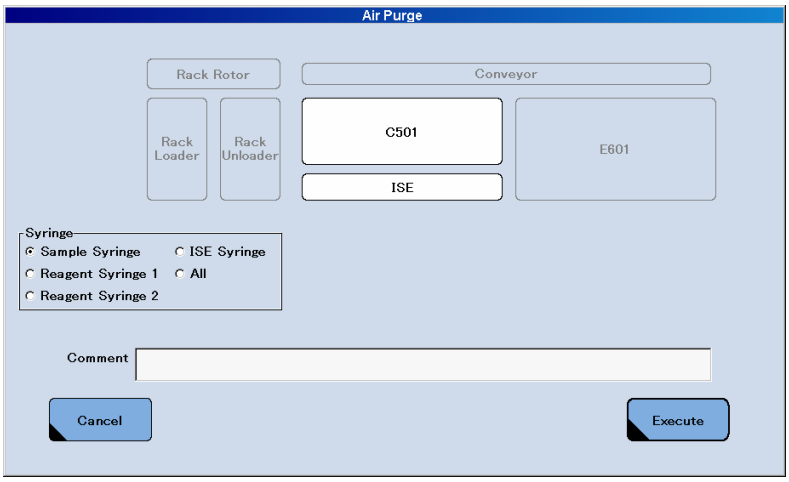


Figure 28 Air Purge window

5 Select the appropriate module. Selected modules are highlighted.

6 In the Syringe area select the appropriate option (Sample Syringe, Reagent Syringe 1, Reagent Syringe 2…).

7 Choose Execute to initiate the air purge.

The pipetter will operate.

8 Check if water is dispensed from the tip of the probe in a straight flow.

Now, continue with the mechanism check.

► To perform a Mechanisms Check

WARNING

Before performing this maintenance action, observe the following safety precautions:

- *Personal injury due to contact with instrument mechanism* on page 12

1 Choose Utility > Maintenance.

2 Select Check (2) from the Maintenance Type list on the left.

3 Select (3) Mechanisms Check from the Maintenance Items list on the right.

4 Choose Select to open the Mechanisms Check window.

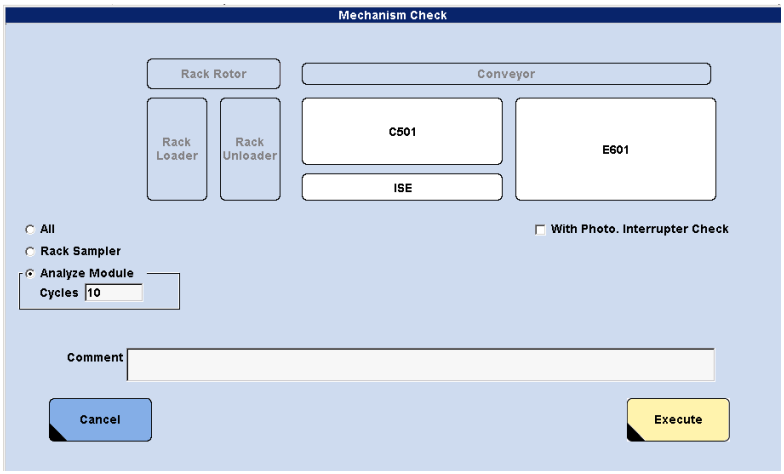


Figure 29 Mechanisms check window

5 Select the Module option and select a module. Selected modules are highlighted.

6 Enter 10 at Cycles and choose Execute.

All mechanisms of the module selected will operate.

7 Check for the following conditions:

- Probes descend into the center of the reaction cells.
- Probes do not contact any other parts.
- The outside of each probe is rinsed with water at the rinse stations.
- Check that reagent probes are correctly dried.

8 Remove the interlock release tool.

9 Close the top cover of the module and lock it.