cobas® 8000 modular analyzer series

Addendum 2.0 to Operator's Manual version 5.1

Publication information

Publication version	Revision date	Change description
1.0	May-2017	First version
2.0	December-2017	A safety message was added to all **c** 502 maintenance actions that involve handling of the cell cover above the ultrasonic mixers

Revision history

Edition notice

This addendum contains an addition to the **cobas**® 8000 Operator's Manual and is valid only for the **c** 701, **c** 702, **c** 502, and **e** 801 modules.

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Approvals

The **cobas**® 8000 modular 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 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.
To view the full text of the 2014/53/EU declaration of conformity, go to the Roche DiaLog Global Web Site (*https://dialog1.roche.com/*) and choose the eLabDoc link.
If you are unable to access Roche DiaLog, contact a Roche Service representative.

The full text of the 2014/53/EU declaration of conformity is available at the following internet address:
http://e-labdoc.roche.com

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 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 Intertek for Canada and the US.

Contact addresses

Inside the European Union and EFTA member states

Manufacturer of the instrument	Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku Tokyo 105-8717 Japan
Manufacturer of **cobas**® 8000 data manager	Roche Diagnostics GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Authorized representative	Roche Diagnostics GmbH Sandhofer Strasse 116 D-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

Table of contents

Revision 1: Specifications of radio equipment added

In the chapter Specifications, the specifications of the RFID readers of the **c** 701, **c** 702, and **e** 801 modules have been added.

Specifications of radio equipment

The following modules contain RFID readers:

	c 701 module	c 702 module	e 801 module
Frequency (MHz)	13.56	13.56	13.56
Maximum radio-frequency power (mW)	< 90	< 100	< 200
Number of RFID readers	2	1	8

Specifications of radio equipment

Revision 2: Maintenance of the c 502 module

During product surveillance, a risk of personal injury at the edges of the cell cover above the ultrasonic mixers was found. A safety message was added to all maintenance actions that involve handling of the cell cover above the ultrasonic mixers.

In this section

Cleaning the reaction cell covers of the c 502 module

To ensure that the reaction cell covers remain free of reagent and reaction mixture, you must clean them as well as the ultrasonic mixer covers.

⚠ Refer to the Safety Guide

- Infectious samples
- Skin inflammation or injury
- Infectious waste
- Moving parts
- Fire and burns
- Incorrect results may occur due to interruption of operation

⚠ CAUTION

Personal injury due to square shape on the cell covers

The square shape may lead to personal injury during replacing or cleaning.

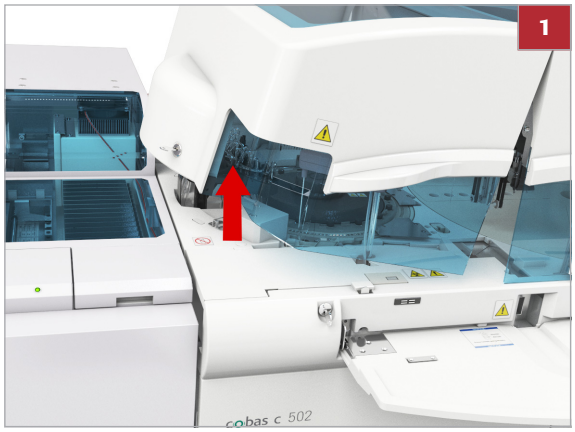
- Be careful not to be hurt by the square shape of cell covers.
- Take extra care when unscrewing the screws and removing the cell cover above the ultrasonic mixers.

Approximately 5 minutes per module

- ☐ Cotton swabs
- ☐ Lint-free cloth
- ☐ Alcohol (e.g., isopropanol or 70% ethanol)
- ☐ Deionized water

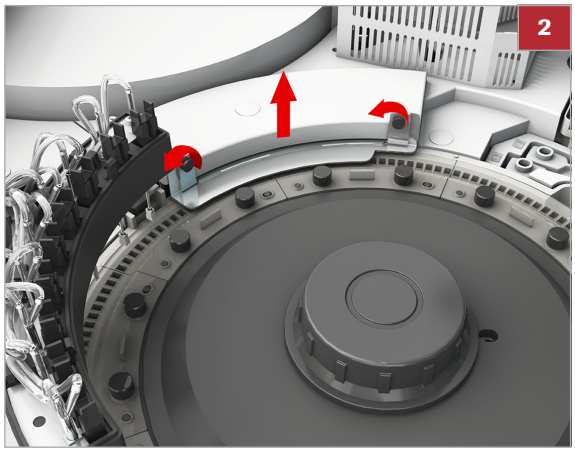
- ☐ The instrument or module is in **Standby** mode.
- ☐ Or: The instrument is powered off.
- Masking a module for background maintenance
- Powering off the instrument

To clean the reaction cell covers

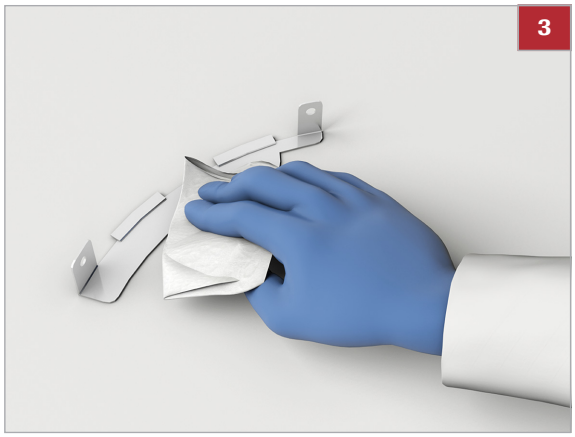


1 Open the top cover and the cover around the reagent probe.

ⓘ As the interlock function monitors the top cover, alarms are issued.



2 Remove the reaction cell covers above the ultrasonic mixers by unscrewing and removing the retaining screws.



3 Wipe the front and rear of all reaction cell covers using a lint-free cloth moistened with alcohol.

ℹ Take care not to splash alcohol into the reaction cells.
Do not place a lint-free cloth moistened with alcohol on the module surface as the finish may be damaged.

4 Put the reaction cell covers back in place.

5 Close the top cover.

6 If the module is masked, unmask it.

Related topics

- Replacing reaction cells and cleaning the incubation bath of the c 502 module
- Unmasking a module

Removing the reaction cells of the c 502 module

To clean the incubation bath, you must first remove the reaction cells.

⚠ Refer to the Safety Guide

- Infectious samples
- Skin inflammation or injury
- Infectious waste
- Moving parts
- Spilled sample
- Incorrect results may occur due to interruption of operation

⚠ CAUTION

Personal injury due to square shape on the cell covers

The square shape may lead to personal injury during replacing or cleaning.

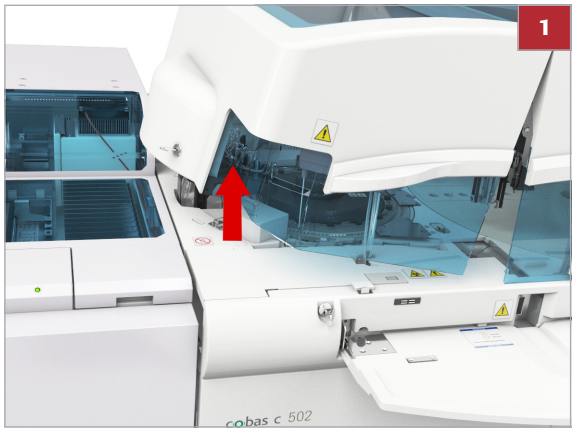
- Be careful not to be hurt by the square shape of cell covers.
- Take extra care when unscrewing the screws and removing the cell cover above the ultrasonic mixers.

Approximately 10 minutes

☐ The instrument or module is in **Standby** mode.

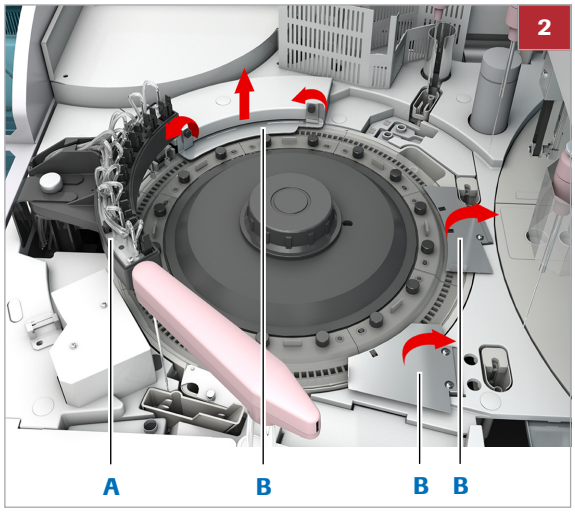
Masking a module for background maintenance

To remove the reaction cells



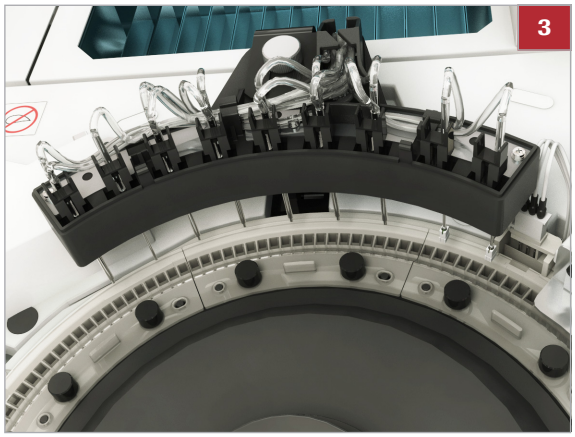
1 Open the top cover and the cover around the reagent probe.

ⓘ As the interlock function monitors the top cover, alarms are issued.

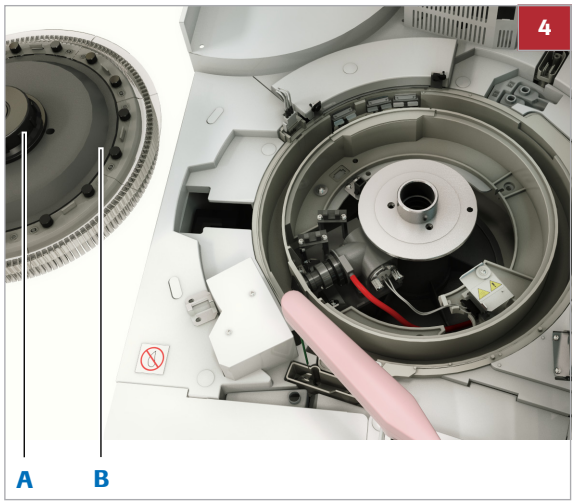


A Reaction cell rinse unit **B** Reaction cell covers

2 Remove all reaction cell covers.



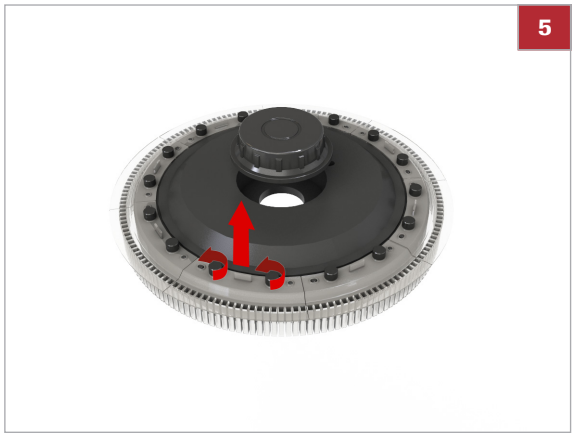
3 Remove the reaction cell rinse unit.



A Retaining nut
B Reaction disk

4 Remove the complete reaction disk by loosening the retaining nut.

ℹ Take care that the reaction disk stays upright and that reaction cells do not get scratched.



A Reaction cells

5 Remove the reaction cells that are to be discarded from the reaction disk.

ℹ Do not touch the surfaces of reaction cells that will be used again.

6 Discard the used reaction cells.

Reinstalling the reaction cells of the c 502 module

After having cleaned the incubation bath, you must reinstall the reaction cells.

⚠ Refer to the Safety Guide

- Infectious samples
- Skin inflammation or injury
- Infectious waste
- Moving parts
- Spilled sample
- Incorrect results may occur due to interruption of operation

⚠ CAUTION

Personal injury due to square shape on the cell covers

The square shape may lead to personal injury during replacing or cleaning.

- Be careful not to be hurt by the square shape of cell covers.
- Take extra care when unscrewing the screws and removing the cell cover above the ultrasonic mixers.

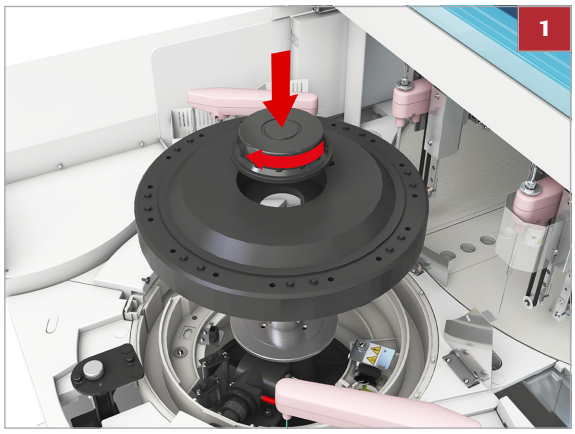
Approximately 10-15 minutes

☐ Reaction cells

☐ The instrument or module is in **Standby** mode.

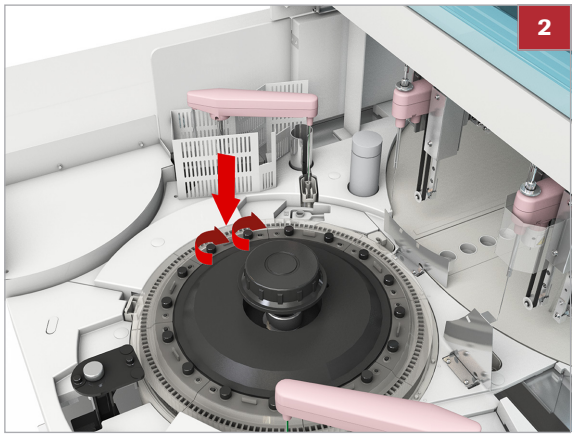
Masking a module for background maintenance

To reinstall the reaction cells

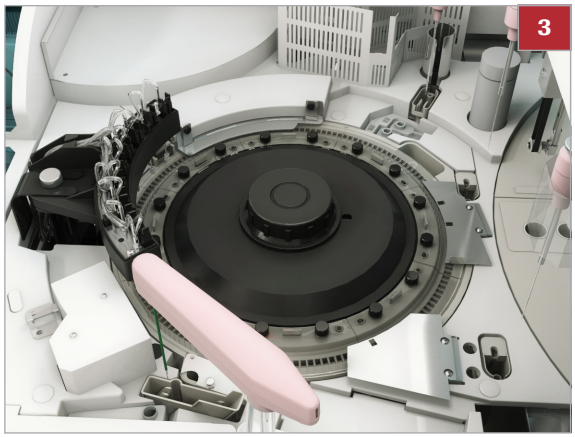


A Reaction cells

1 Reinstall the reaction disk back into the analyzer.



2 Insert all reaction cells segments onto the reaction disk.



3 Rotate the reaction disk by hand.

ⓘ Make sure that the bottoms of the reaction cells do not touch the incubation bath drain filter.

4 Return the reaction cell covers and the reaction cell rinse unit ensuring that the reaction cell rinse unit is correctly aligned.

5 Close the top cover of the module.

Cleaning the ultrasonic mixers of the c 502 module

To prevent contamination and precipitation on the surface of the ultrasonic mixers leading to inaccurate results, you must clean the ultrasonic mixers.

⚠ Refer to the Safety Guide

- Electric shock
- Infectious samples
- Infectious waste
- Moving parts
- Incorrect results may occur due to interruption of operation

⚠ CAUTION

Personal injury due to square shape on the cell covers

The square shape may lead to personal injury during replacing or cleaning.

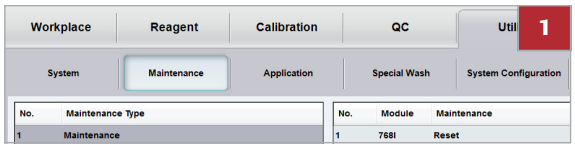
- Be careful not to be hurt by the square shape of cell covers.
- Take extra care when unscrewing the screws and removing the cell cover above the ultrasonic mixers.

- Operator time: approximately 5 minutes per module
- System time: approximately 2 minutes for draining the incubation bath; 18 minutes for refilling the incubation bath; 3 minutes for (9) Cuvette Mixing check

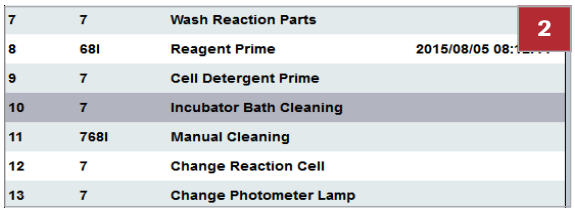
- ☐ 2% ECO-D solution
- ☐ Deionized water
- ☐ Cotton swabs

- ☐ The instrument or module is in **Standby** mode.
- ☐ Or: The instrument is powered off.
- Masking a module for background maintenance
- Powering off the instrument

To clean the surface of the ultrasonic mixer

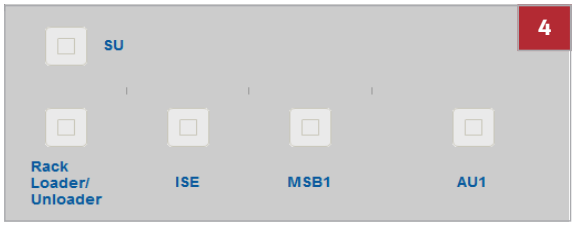


1 Choose **Utility > Maintenance > Maintenance**.



2 Choose the **(10) Incubator Bath Cleaning** option.

3 Choose the **Select** button.

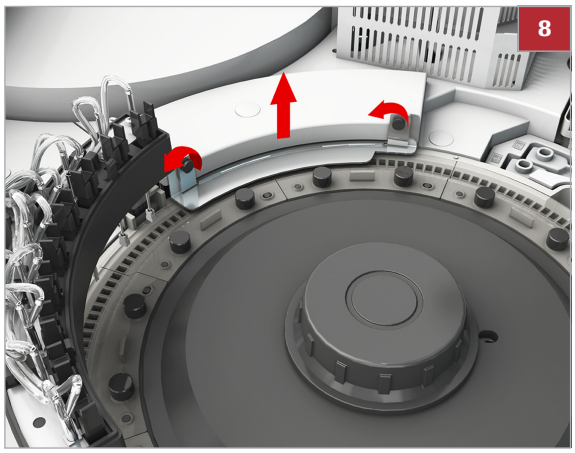


4 Select the desired module.

5 Choose the **Execute** button.
- ➔ The water drains from the incubation bath.
- ➔ A confirmation window appears.

6 Wait until the **Continue** button is active (black).

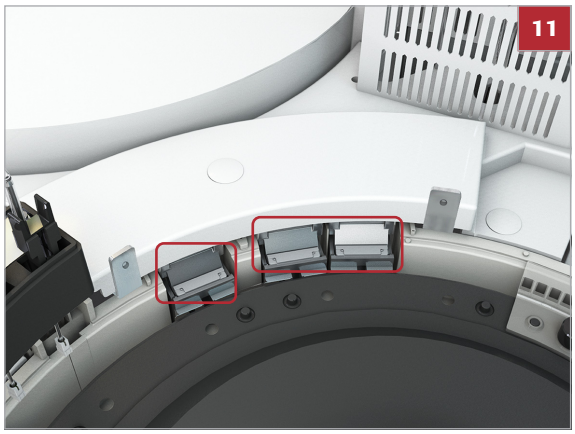
7 Open the top cover of the module.



8 Remove the reaction cell covers above the ultrasonic mixers by unscrewing and removing the retaining screws.

9 Remove the reaction cells near the ultrasonic mixers (at least 3 reaction cell segments).
- ❶ Do not to touch the surfaces of reaction cells.

10 Dilute the 100% ECO-D solution to a 2% solution.



11 Carefully wipe the surface of the ultrasonic mixers using cotton swabs moistened with 2% ECO-D solution.

12 Wipe off the wash solution using cotton swabs moistened with deionized water.

13 Return the removed sections of reaction cells to the same positions.

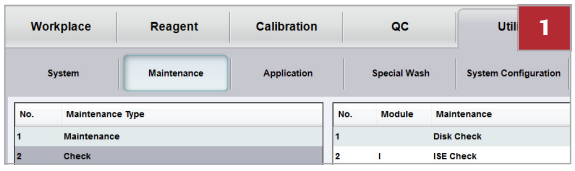
ℹ If the reaction cells are not returned to the same positions, then a cell blank measurement must be performed.

14 Return the reaction cell covers.

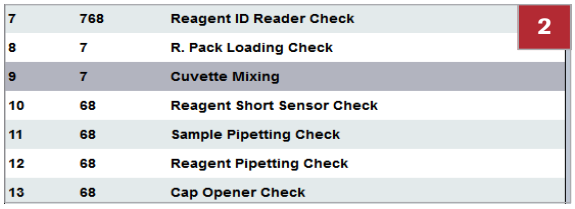
15 Close the top cover.

16 To terminate incubator bath cleaning, choose the **Continue** button.

To check the intensity of the ultrasonic output

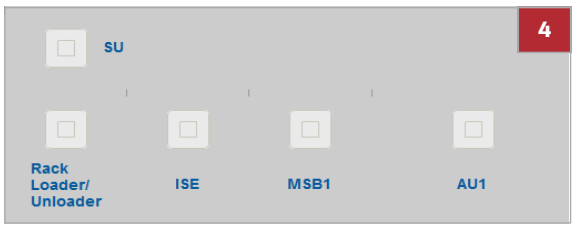


1 Choose **Utility > Maintenance > Check**.

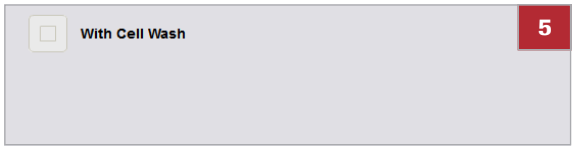


2 Choose the **(9) Cuvette Mixing** option.

3 Choose the **Select** button.



4 Select the desired module.



5 Clear the **With Cell Wash** check box.

ℹ If selected, it would rinse all reaction cells prior to the check.

6 Choose the **Execute** button.

Replacing the photometer lamp of the c 502 module

To ensure reproducibility of measurement, you must replace the photometer lamp.

We recommend combining this maintenance action with the monthly cleaning of the incubation bath.

⚠ Refer to the Safety Guide

- Infectious samples
- Infectious waste
- Moving parts
- Fire and burns
- Incorrect results may occur due to interruption of operation

⚠ CAUTION

Personal injury due to square shape on the cell covers

The square shape may lead to personal injury during replacing or cleaning.

- Be careful not to be hurt by the square shape of cell covers.
- Take extra care when unscrewing the screws and removing the cell cover above the ultrasonic mixers.

7

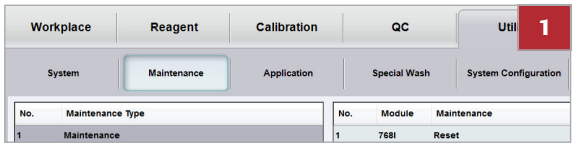
If the photometer lamp has been used for more than 6 months (or 750 hours of power-on time) or if the photometer check value exceeds 14 000 absorbance units.
The total power-on time is displayed on the cumulative operation list. You can view this list via **Print > Utility > Cumulative Operation List**.

- Operator time: approximately 5 minutes per module
- System time: approximately 3 minutes for (3) Photometer Check; 30 minutes waiting for lamp to cool down; 30 minutes waiting for lamp stabilization; 15 minutes for (4) Cell Blank Measurement

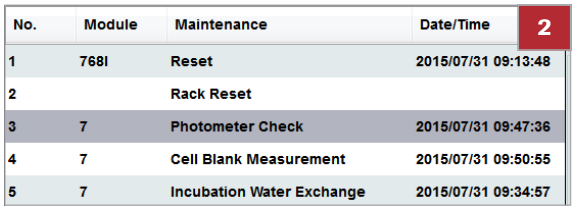
- ☐ Alcohol (e.g., isopropanol or 70% ethanol)
- ☐ Lint-free cloth
- ☐ Photometer lamp

- ☐ The instrument is in **Standby** mode.
- Masking a module for background maintenance

To check the light intensity

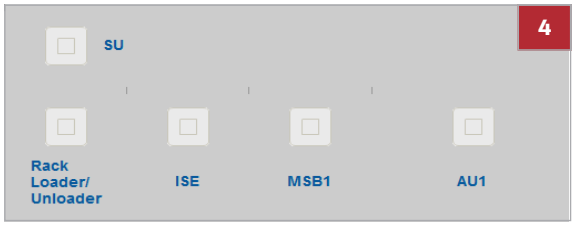


1 Choose **Utility > Maintenance > Maintenance**.



2 Choose the **(3) Photometer Check** option.

3 Choose the **Select** button.



4 Select the desired module.

5 Choose the **Execute** button.
➔ Water is injected from the rinsing mechanism into reaction cell no. 1 and the absorbance of the water is measured for each available wavelength.

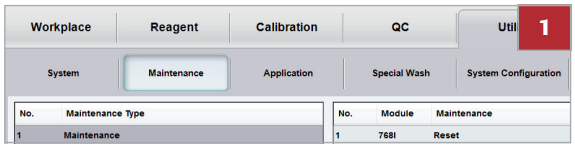
6 Choose **Print > History**.

7 Choose the **Photometer Check** option.

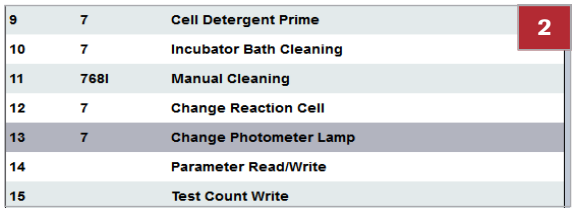
8 Check the absorbance values in the photometer check report.
If the readings exceed 14 000 absorbance units at 340 nm, or if the readings are different from the previous one, do the following:

- Verify that the reaction cells, the incubation bath, and the photometer windows are free of contamination or air bubbles.
- Verify that the reaction cells are not scratched or cracked. Verify that the reaction cells are at least half filled with water.
- If the results do not improve, replace the photometer lamp.

To remove the photometer lamp

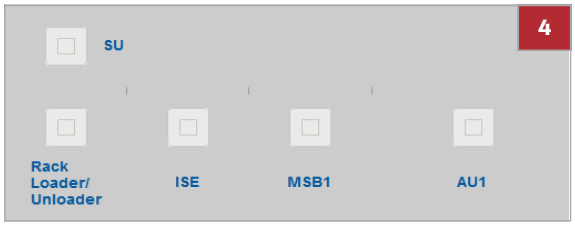


1 Choose **Utility > Maintenance > Maintenance**.



2 Choose the **(13) Change Photometer Lamp** option.

3 Choose the **Select** button.



4 Select the desired module.

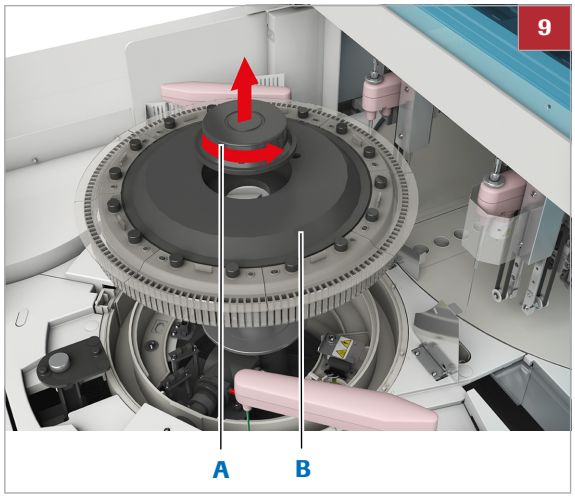
5 Choose the **Execute** button.
➔ The power supply to the photometer lamp is switched off during the execution of the maintenance action (13) Change Photometer Lamp.

6 CAUTION! Burns due to hot surface of the photometer lamp unit.
Check that the photometer lamp unit has cooled down before replacing the lamp.

Wait about 30 minutes for the photometer lamp and lamp housing to cool down.

7 Open the top cover of the module.

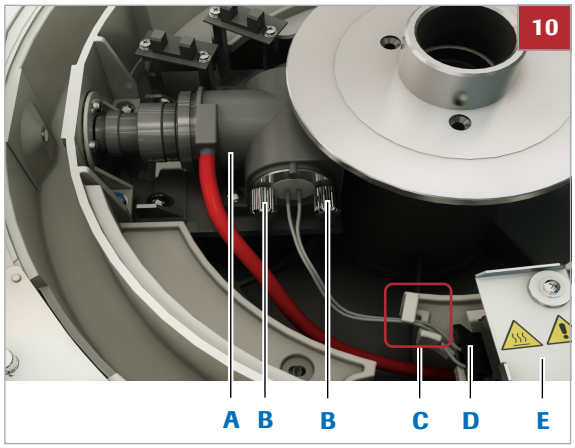
8 Lift up or remove all reaction cell covers.



A Retaining nut **B** Reaction disk

9 Remove the reaction disk including reaction cells from the module by loosening the retaining nut.

ℹ Take care not to touch the optical surfaces. An alarm is issued if water drops adhering to the outside of the reaction cells drip onto components.



A Photometer housing **D** Connector
B Retaining screws **E** Connector cover
C Cable clip

10 Loosen the photometer lamp cable from the cable clip.

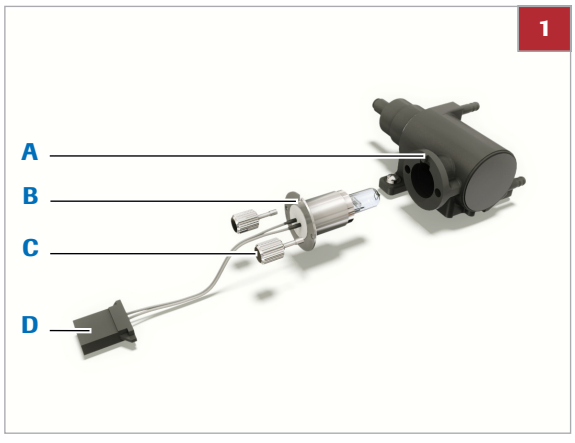
11 Rotate the connector cover and disconnect the connector of the photometer lamp cables.

12 Take out the photometer lamp by loosening both retaining screws.

13 Remove the retaining screws from the photometer lamp.

ℹ The retaining screws are used to install a new photometer lamp.

To install a new photometer lamp



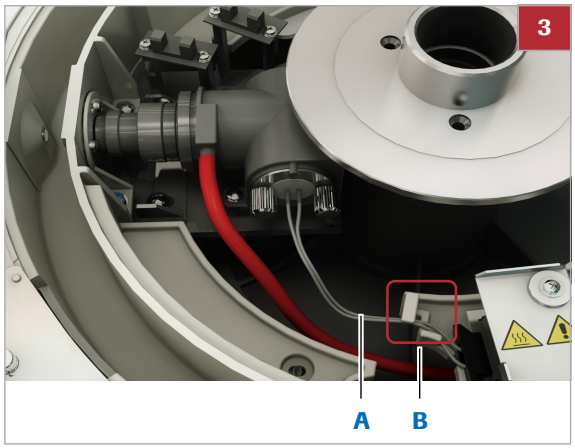
A Guide pin **C** Retaining screws
B Pin hole **D** Connector

1 Insert the retaining screws from the old photometer lamp into the new photometer lamp.

2 Insert the new photometer lamp:

- Align the pin hole in the photometer lamp base with the guide pin of the photometer lamp housing.
- Tighten the 2 photometer lamp retaining screws.

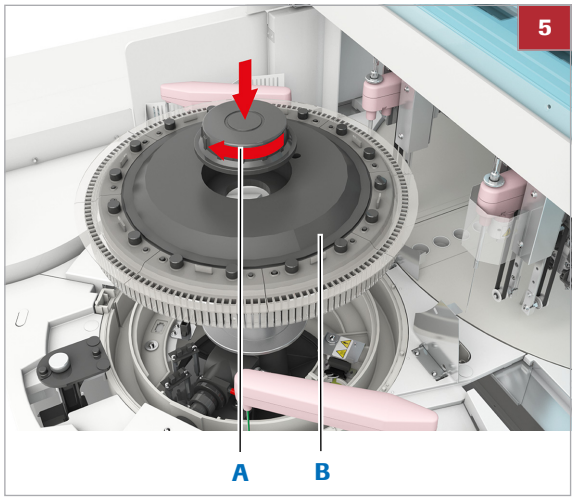
ℹ Be careful not to touch the glass part of the new photometer lamp. If you do touch the glass, wipe it off with a lint-free cloth moistened with alcohol.



A Photometer lamp cables **B** Cable clip

3 Secure the photometer lamp cables with the cable clip.

4 Plug in the connector.



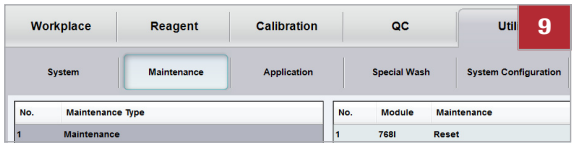
A Retaining nut **B** Reaction disk

5 Reinstall the reaction disk including reaction cells and tighten the retaining nut.

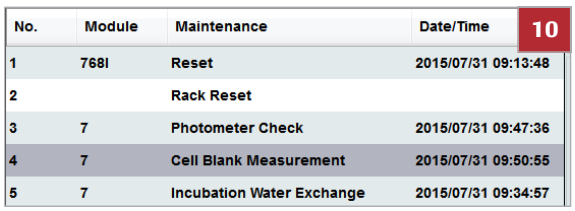
6 Close the covers of the module.

7 Choose the **Cancel Maintenance** button.

8 Wait about 30 minutes for the photometer lamp to stabilize.



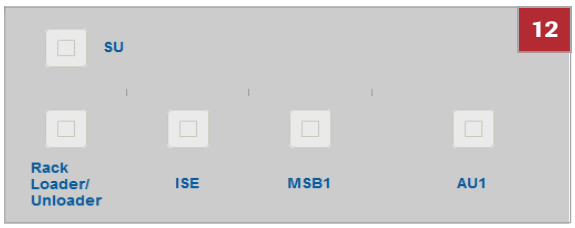
9 Choose **Utility > Maintenance > Maintenance**.



10 Choose the **(4) Cell Blank Measurement** option.

ℹ A cell blank measurement is necessary to compensate for a possible change in light intensity.

11 Choose the **Select** button.



12 Select the desired module.

13 Choose the **Execute** button.

14 To view the recent cell blank measurement report, choose **Print > History**.

15 Check if any reaction cells are listed in the **Abnormal Cell List** report:

- If no reaction cells are listed in the abnormal cell list, you can continue without any further action.
- If reaction cells are listed in the abnormal cell list, replace all reaction cells by new ones.

Related topics

- Washing the reaction parts of the c 502 module
- Reinstalling the reaction cells of the c 502 module (10)