# Addendum 1.0

*to Operator´s Manual Version 8.1*
**cobas**® *6000 analyzer series*
*Software Versions 05–02 / 06–02*

# Document information

*Revision history*

| Document version | Software version | Revision date | Changes |
|---|---|---|---|
| Addendum 1.0 to Operator's Manual Version 8.1 | 06-02[(a)] | January 2018 | |

(a) Also valid for software version 05-02 and 06-01

*Edition notice*

This addendum contains supplementary information for operators of the **cobas** 6000 analyzer series. It is meant to complement the Operator´s Manual Version 8.1.

Every effort has been made to ensure that all the information is correct at the time of publishing. However, Roche Diagnostics reserves the right to make any changes necessary without notice as part of ongoing product development.

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# Addendum

## In this addendum

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# General

This addendum introduces a new safety precaution for all maintenance actions on the **c** 501 module where the cell cover above the ultrasonic mixers is handled.

*Maintenance c 501 with ISE* on page 6

# Maintenance c 501 with ISE

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.

*Affected maintenance actions*

- *Cleaning the cell covers* on page 6
- *Cleaning the incubator bath* on page 8
- *Cleaning the ultrasonic mixers* on page 15
- *Replacing the photometer lamp* on page 19

## Weekly maintenance

In this section you find the revised maintenance for the **c** 501 module that must be performed at least once a week.

### Cleaning the cell covers

**⚠ 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.

Clean the cell covers of the reaction cells at least once a week. The cell covers serve to prevent contamination by reagent and reaction solution. If reagent adheres to the front or rear face of a cell cover, the analytical accuracy may decrease.

*Operator time* approximately 5 minutes

*Materials required*

- ☐ Cotton swabs
- ☐ Lint-free gauze pads
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)

### ► To clean the cell covers

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

2 Unlock and open the top cover of the module.

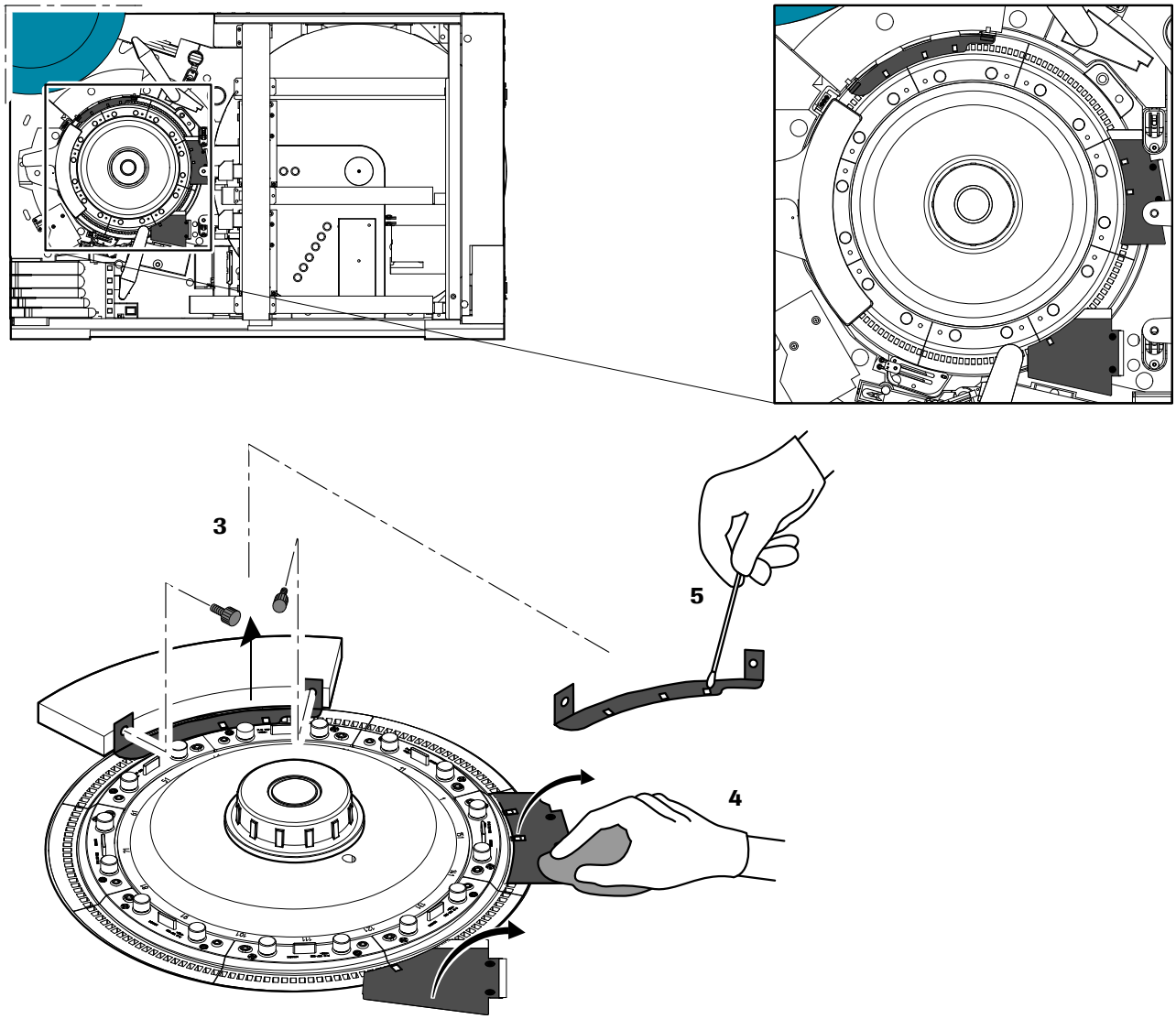


**Figure -1** Cleaning the cell covers

3 Loosen the screws and remove the cell cover above the ultrasonic mixers.

4 Wipe the front and rear faces of the cell covers using a gauze pad moistened with alcohol.

5 Wipe the openings of cell covers using a cotton swab moistened with alcohol.

Be careful not to splash alcohol in the reaction cells.

**6** Return the cell cover above the ultrasonic mixers.

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

**8** Switch on the analyzer, if the analyzer is in shutdown status.

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## Monthly maintenance

In this section, you find the revised maintenance for the **c** 501 module that must be performed at least once a month.

### Cleaning the incubator bath

**⚠ 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.

Contamination inside the incubator bath or on the photometric window will reduce the reproducibility of measurement results. Clean the incubator bath and photometric window at least once a month.

We recommend combining this maintenance with the weekly cleaning of the IS bath, the monthly replacement of reaction cells and with the quarterly cleaning of the ultrasonic mixers.

For more information, see:
*Removing and manually cleaning the IS bath* on page C-87
*Replacing reaction cells* on page C-90
*Cleaning the ultrasonic mixers* on page -15

Cleaning of the incubator bath can be performed either with the analyzer in shutdown status or with the module in incubator bath cleaning mode. These two states require different steps to be performed for this maintenance; these steps are described in two separate procedures in the remainder of this section.

For more information, see:
*To clean the incubator bath (in incubator bath cleaning mode)* on page -9
*To clean the incubator bath (in shutdown status)* on page -12.

*Operator time* approximately 15 minutes

*System time* approximately 25 minutes

*Materials required*
- ☐ Deionized water
- ☐ Cotton swabs
- ☐ Lint-free gauze pads

### ► To clean the incubator bath (in incubator bath cleaning mode)

**1** Put the analyzer in incubator bath cleaning mode:

- Choose **Utility** > **Maintenance**.
- Select **Maintenance** (1) from the **Maintenance Type** list on the left.
- Select **(10) Incubator Bath Cleaning** from the **Maintenance** items list on the right.
- Choose **Select** to open the **Incubator Bath Cleaning** window.
- Select the appropriate module. Selected modules are highlighted.
- Choose **Execute**.

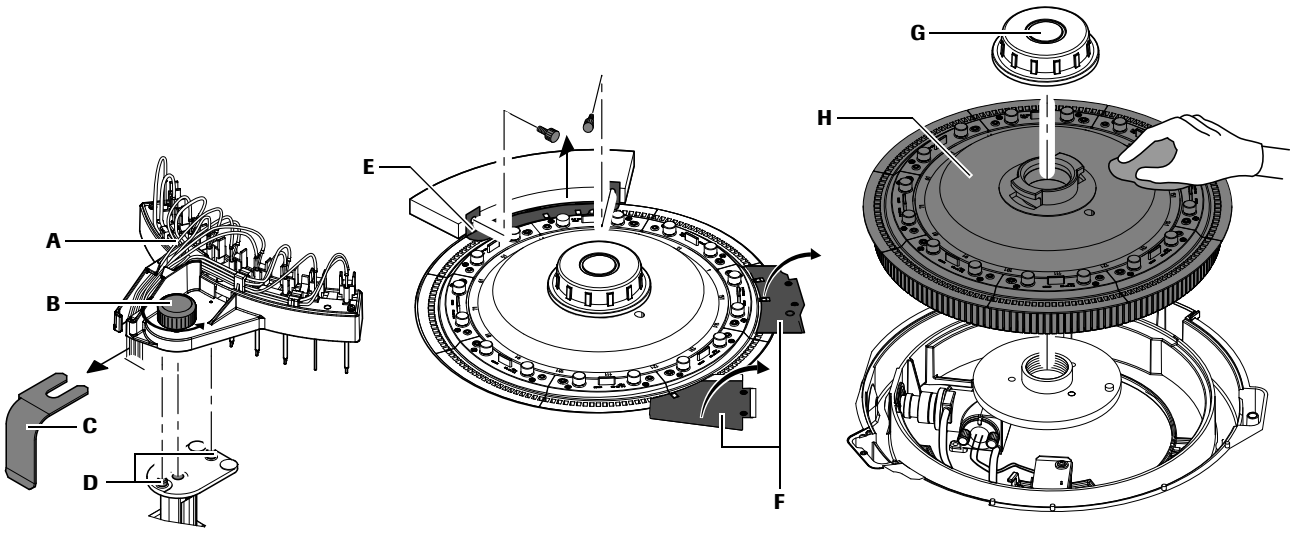
  The analyzer enters incubator bath cleaning mode and water is drained from the incubator bath.

- Choose **OK** to confirm the message of the confirmation window.
- Choose **Monitor** to open the **Maintenance Monitor** window.
- Wait until the message **Incubation Bath Cleaning (Wait Restart)** is displayed.

**Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.**

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

**2** Unlock and open the top cover of the module.




**A** Cell rinse unit
**B** Retaining screw
**C** Tube retainer
**D** Guide pins
**E** Cell cover of the ultrasonic mixers
**F** Cell covers
**G** Retaining nut
**H** Reaction disk

**Figure -2** Dismount the cell rinse unit and the reaction cells

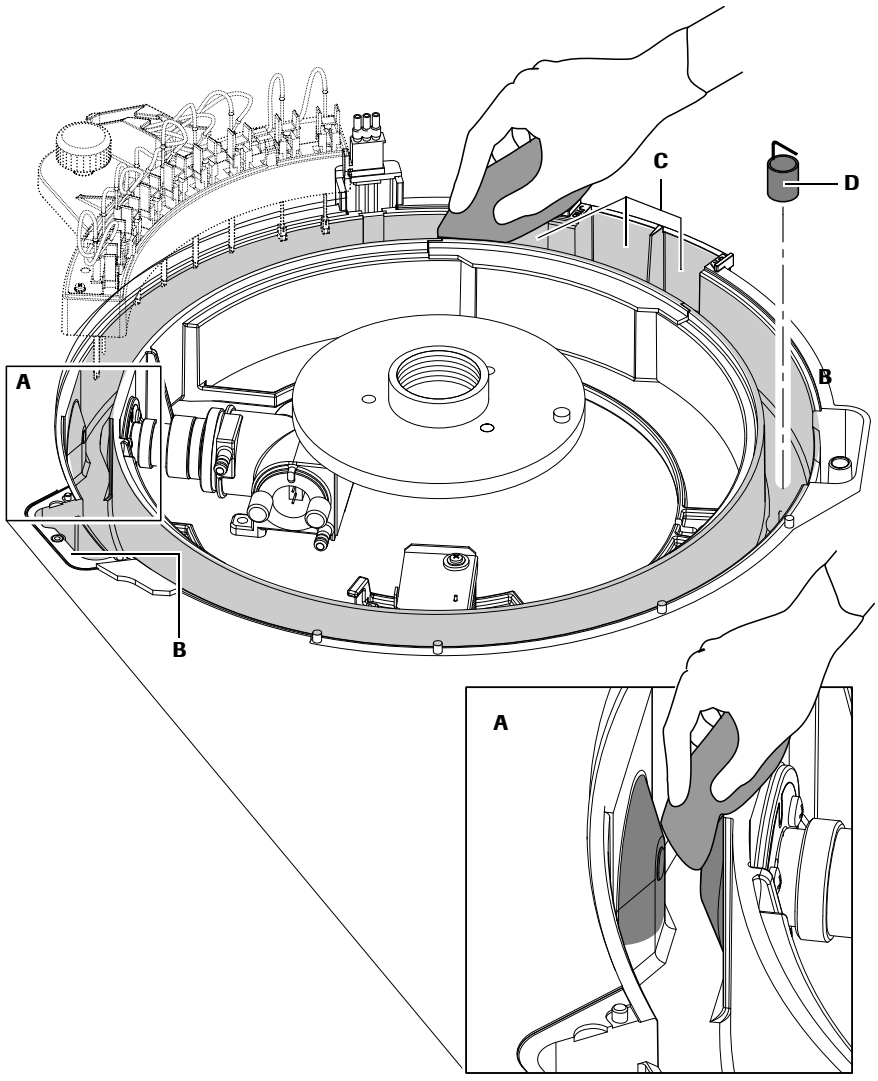
**3** Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

**4** Remove the cell cover above the ultrasonic mixers (**E**). Lift the cell covers (**F**) and leave them vertical.

**5** Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.

**Damage to the photometer windows**

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.




**A** Photometer windows
**B** IS bath location
**C** Ultrasonic mixer positions
**D** Drain filter

**Figure -3** Wipe the inside surfaces of the incubator bath

**6** Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.

**7** If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.

For instructions, see *To remove and manually clean the IS bath* on page C-87.

**8** Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.

For instructions, see *To clean the surface of the ultrasonic mixer* on page -16.

**9** Remove the incubator bath drain filter (**D**). Grasp the filter by the handle and pull up to remove.

**10** Clean and rinse the filter with deionized water and return it in place.

**11** If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.

See *To replace reaction cells* on page C-91.

**12** Reinstall the reaction disk (inclusive reaction cells), the cell cover of the ultrasonic mixer and the cell rinse unit.

**13** Turn down the cell covers for the reagent probes.

**14** Close the top cover of the module and lock it.

**15** Choose Continue on the **Utility** > **Maintenance** >**Incubator Bath Cleaning** window to end the incubator bath cleaning mode.

The incubator bath is filled with water and the analyzer returns to standby.

**16** Perform maintenance item (4) Cell Blank Measurement.

Perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows and replacing the reaction cells.

For instructions, see *To perform a cell blank measurement* on page C-82.

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### ► To clean the incubator bath (in shutdown status)

**1** Put the analyzer in shutdown status.

**2** Unlock and open the top cover of the module.

**3** Loosen the retaining screw of the cell rinse unit and lift off the entire unit.

**4** Remove the cell cover above the ultrasonic mixers. Lift the other cell covers and leave them vertical.

Do not let all the water drain. Leave a small amount of water to just cover the bottom of the incubator bath. Close the drain by moving the tap to the Operation position.

**5** Turn the tap located on the rear of the analyzer to the DRAIN position and drain the incubator bath. After draining, turn the tap back to its OPERATION position.

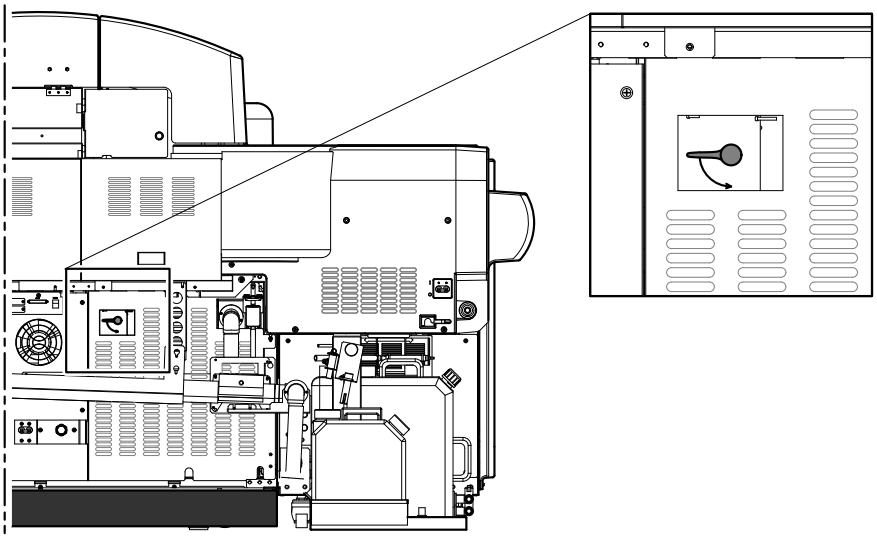
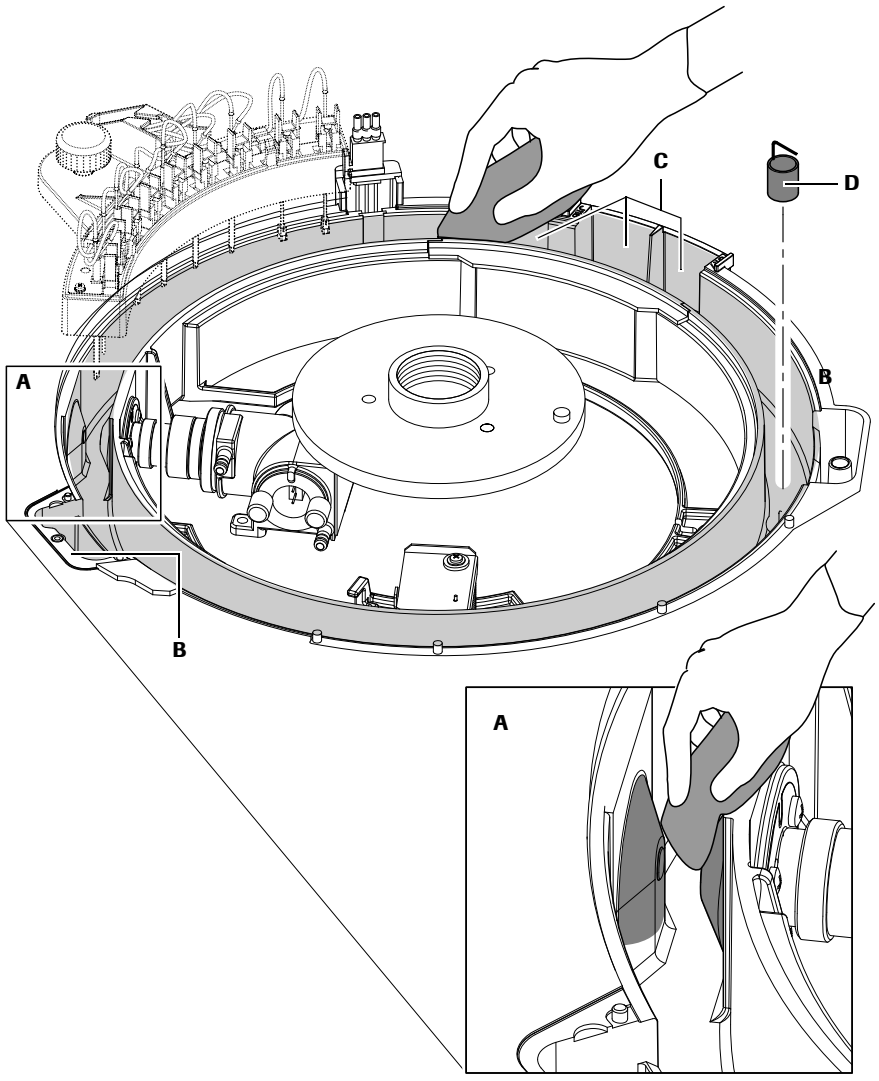


**Figure -4** Tap for manually draining the incubator bath

**6** Loosen the retaining nut and remove the reaction disk inclusive reaction cells from system. Be careful not to touch the optical surfaces.

**Damage to the photometer windows**

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.




**A** Photometer windows
**B** IS bath location
**C** Ultrasonic mixer positions
**D** Drain filter

**Figure -5** Wipe the inside surfaces of the incubator bath

**7** Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.

**8** If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.

For instructions, see *To remove and manually clean the IS bath* on page C-87.

**9** Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.

For instructions, see *To clean the surface of the ultrasonic mixer* on page -16.

**10** Remove the incubator bath drain filter (**D**). Grasp the filter by the handle and pull up to remove.

**11** Clean and rinse the filter with deionized water and return it in place.

**12** If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.

See *To replace reaction cells* on page C-91.

**13** Reinstall the reaction disk (inclusive reaction cells) and the cell rinse unit.

**14** Reinstall the cell cover of the ultrasonic mixer and **remove one** section of reaction cells.

**15** Turn down the cell covers for the reagent probes.

**16** Gradually pour about 500 mL of deionized water into the incubator bath and mount the missing section of reaction cells. Be careful not to allow water to overflow from the incubator bath.

**17** Close the top cover of the module and lock it.

**18** Start up the analyzer.

**19** Perform maintenance items (5) Incubation Water Exchange and (4) Cell Blank Measurement.

Make sure to perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows.

For instructions, see *To perform a cell blank measurement* on page C-82.

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# Every three months maintenance

In this section, you find the revised maintenance for the **c** 501 module that must be performed at least once every three months.

## Cleaning the ultrasonic mixers

**⚠ 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.

Clean the ultrasonic mixers every 3 months or after 225.000 tests (whatever comes first). Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results.

If the ultrasonic mixer cleaning coincides with the monthly incubator bath cleaning, the procedure can be performed together.

**Replacement of ultrasonic mixer**

The ultrasonic output intensity is continually monitored during measurement. If the data alarm <Mix occurs frequently, replacement of the ultrasonic mixer is required. Contact your Roche service representative for the replacement.

This maintenance comprises the following procedures and maintenance items:

1. To clean the surface of the ultrasonic mixer
2. To check the intensity of the ultrasonic output

*Operator time* approximately 6 minutes

*System time* approximately 7 minutes

*Materials required*

- ☐ 2% EcoTergent solution
- ☐ Deionized water
- ☐ Cotton swabs

### ► To clean the surface of the ultrasonic mixer

**1** Put the analyzer in incubator bath cleaning mode:

- Choose **Utility** > **Maintenance**.
- Select **Maintenance** (1) from the **Maintenance Type** list on the left.
- Select **(10) Incubator Bath Cleaning** from the **Maintenance** Items list on the right.
- Choose **Select** to open the **Incubator Bath Cleaning** window.
- Select the appropriate module. Selected modules are highlighted.
- Choose **Execute**.

  The analyzer turns to incubator bath cleaning mode and water is drained from the incubator bath.
- Choose **OK** to confirm the message of the confirmation window.
- Choose **Monitor** to open the **Maintenance Monitor** window.
- Wait until a message about the Incubator bath cleaning mode is displayed.

**Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.**

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

**2** Unlock and open the top cover of the module.

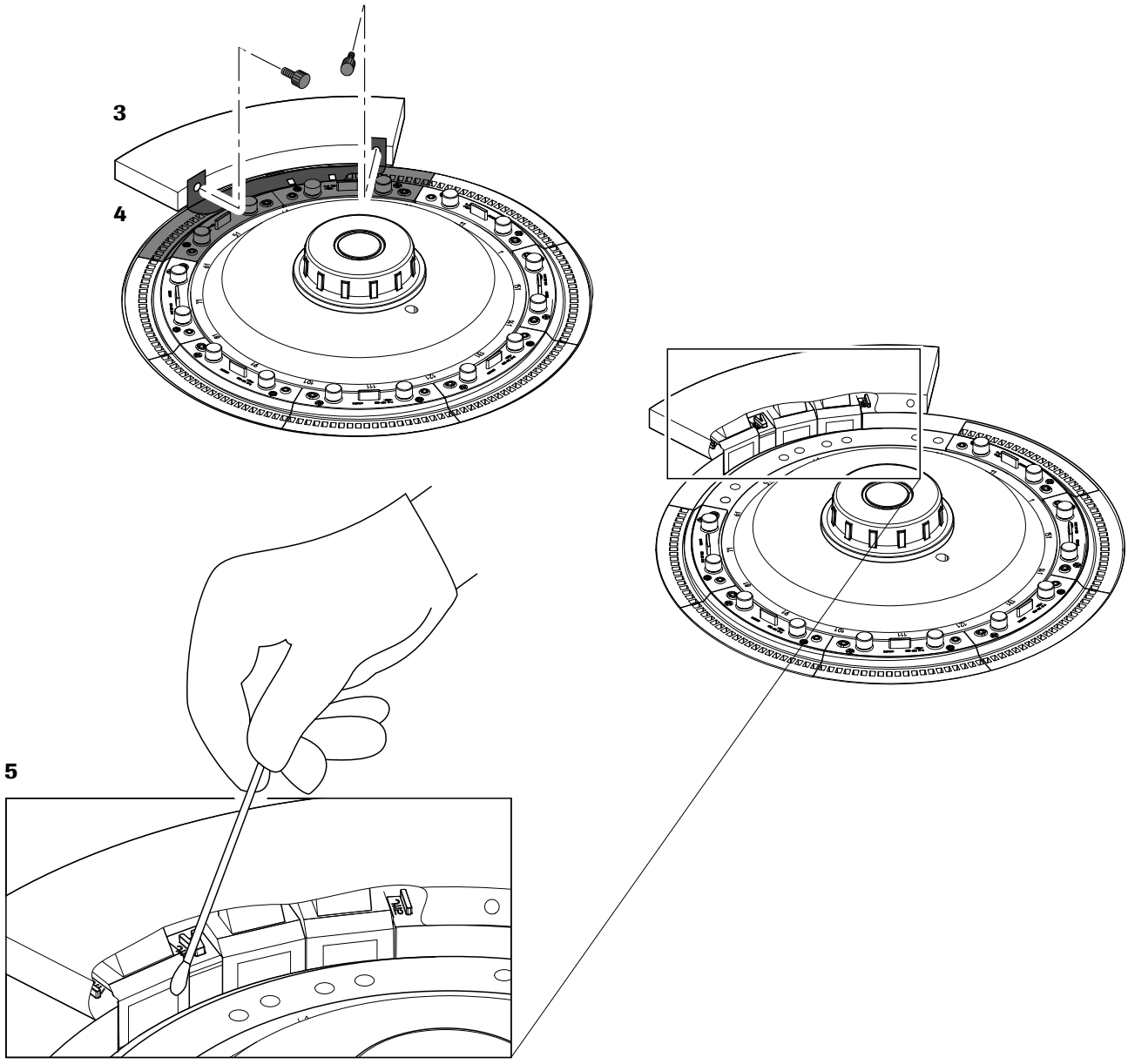


**Figure -6** Cleaning surface of ultrasonic mixer with cotton swabs

**3** Remove the cell cover.

**4** Loosen and remove the thumbscrews on two or three sections of reaction cells near the ultrasonic mixers. Lift the reaction cells out of the reaction disk. Be careful not to touch the optical surfaces.

**5** Gently wipe the surface of the ultrasonic mixers with cotton swabs moistened with 2% EcoTergent solution. Then, wipe off the detergent with cotton swabs moistened with deionized water.

**6** Return the removed sections of reaction cells.

**7** Return the cell cover.

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

9 Choose **Start** (global button) > **Start** to release the incubator bath cleaning mode.

Water is poured into the incubator bath.

■

### ► To check the intensity of the ultrasonic output

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

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

3 Select **(7) Cuvette Mixing** from the **Maintenance** Items list on the right.

4 Choose **Select**, to open the **Cuvette Mixing** window.

5 Select a module (selected modules are highlighted), and verify the **Cell Wash** check box is not selected.

Selecting the **Cell Wash** check box would rinse all reaction cells prior to the actual intensity check.

6 Choose **Execute**.

■

# Every six months maintenance

In this section, you find the revised maintenance for the **c** 501 module that must be performed at least once every six months.

## Replacing the photometer lamp

**⚠ 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.

The reproducibility of measurement will decrease if the photometer lamp deteriorates. Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.

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

This maintenance comprises the following procedures and maintenance items:

1. To check the light intensity
2. To remove the photometer lamp
3. To install a new photometer lamp

*Operator time* approximately 5 minutes

*System time* approximately 20 minutes

*Materials required*

- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Lint-free gauze pads
- ☐ Photometer lamp

### ► To check the light intensity

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

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

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

**4** Choose **Select** to open the **Photometer Check** window.

**5** Select a module. Selected modules are highlighted.

**6** Select **Execute**.

Water is injected from the rinsing mechanism into reaction cell no. 1 and the absorbance of the water is measured for each available wavelength.

**7** After the photometer check select **Print** (global button) to open the **Print** window.

**8** Select **Print** to print a **Photometer Check** report and check the absorbance values of the current photometer check.

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Photometer Check 8:20

| PREVIOUS DATA | | CURRENT DATA | |
|---|---|---|---|
| c501 DATE | 05/12/1 8:20 | DATE | 05/12/2 8:18 |
| 340 nm | 10386 | 340 nm | 10386 |
| 376 nm | 10358 | 376 nm | 10358 |
| 415 nm | 9534 | 415 nm | 9534 |
| 450 nm | 9275 | 450 nm | 9275 |
| 480 nm | 9195 | 480 nm | 9195 |
| 505 nm | 9130 | 505 nm | 9130 |
| 546 nm | 8984 | 546 nm | 8984 |
| 570 nm | 8967 | 570 nm | 8967 |
| 600 nm | 8929 | 600 nm | 8929 |
| 660 nm | 8676 | 660 nm | 8676 |
| 700 nm | 8657 | 700 nm | 8657 |
| 800 nm | 8594 | 800 nm | 8594 |

**Figure -7** Photometer check report

If the current data exceed 14000, check the following points and then replace the photometer lamp:

- Verify there are no contamination or bubbles in incubator bath or photometric windows.
- Verify reaction cell no. 1 is not scratched, cracked or damaged.

If the current data value is quite different from the previous one, check for the cause!

### ► To remove the photometer lamp

**1** Put the analyzer in shutdown status.

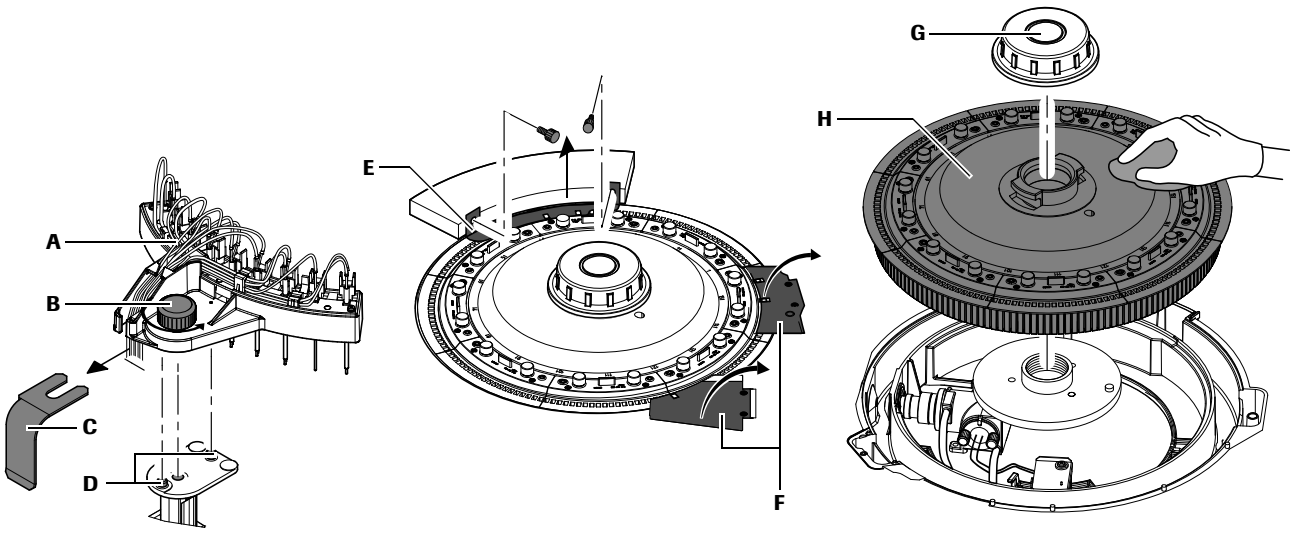
👁 See *To shutdown the analyzer* on page C-6.

Alternatively, cut off the photometer lamp's power supply by executing the maintenance item (39) Change Light Source Lamp from the **Maintenance** Items list on **Utility** > **Maintenance**.

Alternatively, you can combine the incubator bath cleaning with the changing of the photometer lamp.

CAUTION! You may be burned if you touch any part of the photometer lamp unit. Wait about 30 minutes for the lamp and lamp housing to cool down.

**2** Unlock and open the top cover of the module.




**A** Cell rinse unit
**B** Retaining screw
**C** Tube retainer
**D** Guide pins
**E** Cell cover of the ultrasonic mixers
**F** Cell covers
**G** Retaining nut
**H** Reaction disk

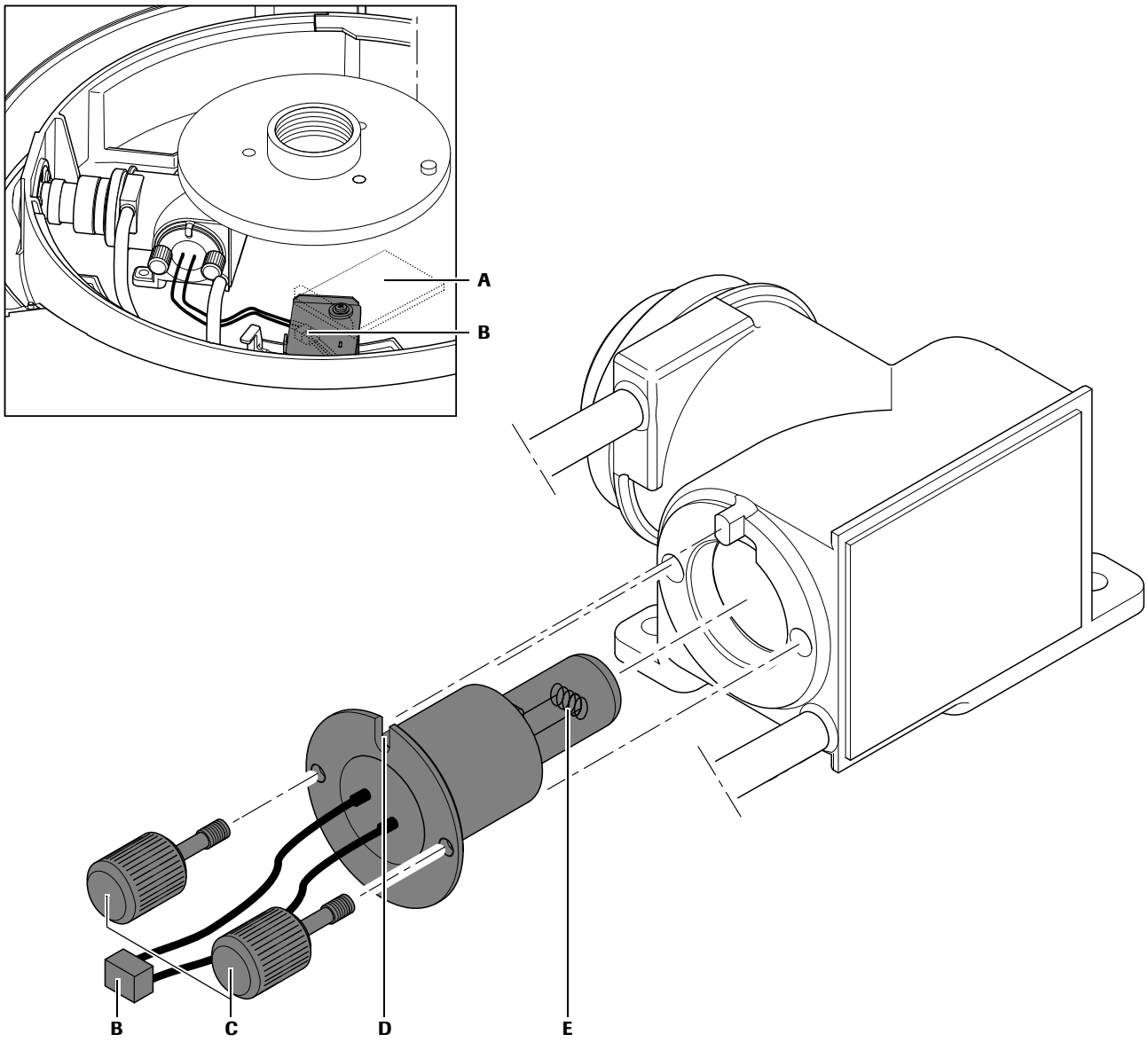
**Figure -8** Dismount the cell rinse unit and the reaction cells

**3** Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

**4** Remove the cell cover above the ultrasonic mixers (**E**). Lift the cell covers (**F**) and leave them vertical.

**5** Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.

If the reaction disk is detached with the reaction cells left in place, water drops adhering to the outside of the reaction cells may drip onto the detector, causing an alarm to be issued.




**A** Cover of the connector
**B** Connector
**C** Retaining screws
**D** Pin hole of the lamp base
**E** Photometer lamp

**Figure -9** Replacing photometer lamp

CAUTION! You may be burned if you touch any part of the photometer lamp unit. Check that the photometer lamp unit has cooled down before replacing the lamp.

**6** Rotate the connector cover (**A**) and disconnect the connector (**B**) of the lamp wire.

**7** Loosen two lamp retaining screws (**C**) and pull out the photometer lamp (**E**).

When the screws become easy to turn, the lamp can be detached.

**8** Carefully remove the retaining screws from the lamp base. These are needed to install the new lamp.

**9** Dispose of the photometer lamp according to local regulations.

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### ► To install a new photometer lamp

**1** Insert the retaining screws in the new lamp.

**2** Insert the new photometer lamp:

- Align the pin hole (**D**) in the lamp base with the guide pin of the lamp housing
- Tighten the two lamp retaining screws (**C**).

If you have touched the glass part of the new photometer lamp, wipe it off with a gauze pad moistened with alcohol.

**3** Connect the connectors of the lamp wires.

Do not let the lamp wires float up from the unit.

**4** Reinstall the reaction disk with the reaction cells and close the cell covers.

**5** Mount the cell rinse unit to its original position.

**6** Close the top cover of the module and lock it.

**7** Start up the analyzer again or—if maintenance item (39) Change Light Source Lamp has been executed without shutting down the analyzer—choose **Cancel Maintenance** on the **System Overview** screen.

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

Finally, perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity.

For instructions, see *To perform a cell blank measurement* on page C-82.

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