# cobas® 8000 modular analyzer series

*Addendum to Operator's Manual V4.0*
*Replacement pages V4.0.1*

Please replace the attached pages.

# cobas® 8000 modular analyzer series

*Operator's Manual*
*Software Version 04-01*

Replacement page

# Document information

| Document version | Software version | Revision date | Changes |
|---|---|---|---|
| 1.0 | 01-01 | Jun. 2009 | |
| 2.0 | 02-01 | Jan. 2010 | **cobas e** 602 module added |
| 3.0 | 03-01 | Oct. 2010 | **cobas c** 702 module added |
| 4.0 | 04-01 | Apr. 2013 | General update including, by way of example:<br>• New software features such as review of calibrator status, PT link, rack unloading, change rack priority, reagent pack masking<br>• Revised software features such as download of applications, calibrators and controls<br>• Hitergent was replaced by Ecotergent |
| 4.0.1 | 04-01 | May 2013 | Manual cleaning was revised. |

**Table 1** Revision history

*Edition notice*

This Operator's Manual is for users of the **cobas**® 8000 modular analyzer series.

The **cobas**® 8000 modular analyzer series is composed of two main components:

- The **cobas**® 8000 instrument includes the analytical modules, the control unit, and other core components.
- The **cobas**® 8000 data manager consists of a PC which coordinates data in real time between the instrument and the laboratory LIS.

  A separate Operator's Manual is available for the **cobas**® 8000 data manager.

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

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

*Intended use*

The **cobas**® 8000 modular analyzer series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitative in-vitro determinations using a wide variety of tests.

The **cobas**® 8000 modular analyzer series is an in-vitro diagnostic (IVD) medical equipment.

It is important that the user reads the Operator's Manual thoroughly before using the **cobas**® 8000 modular analyzer series.

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*Trademarks*

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# General information

**Relevant safety messages for operation**

- Make sure that you have read and understood the chapter *General safety information* (p. 19). The following safety messages in particular are relevant:
- **Warning messages:**
  - *Electrical shock from electronic equipment* (p. 25)
  - *Infection from samples and associated materials* (p. 25)
  - *Infection and injury due to sharp objects* (p. 25)
  - *Skin inflammation or injury caused by reagents and other working solutions* (p. 26)
  - *Infection from waste solution and solid waste* (p. 26)
  - *Contamination of the environment due to inappropriate treatment of waste* (p. 27)
- **Caution messages:**
  - *Personal injury due to contact with moving parts* (p. 28)
  - *Incorrect results due to incorrect reagent volume* (p. 28)
  - *Incorrect results and interruption of analysis due to contaminated samples* (p. 29)
  - *Incorrect results due to evaporation of samples or reagents* (p. 29)
  - *Incorrect results due to carryover* (p. 29)
  - *Fatigue due to long hours of operation* (p. 31)
  - *Spillage* (p. 31)
- Observe the safety labels illustrated in section *Safety labels on the instrument* (p. 33).

Before starting to work with the instrument, read the following safety messages carefully. If you ignore these safety messages, you may suffer serious or fatal injury.

# Safety messages (overall system)

**WARNING**

**Infection and injury due to contact with instrument mechanism**

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

- Whenever possible, keep all covers of the analytical modules closed.
- Do not open any cover while the module is operating.
- Do not touch any parts of the instrument other than those specified.
- Observe all instructions given in this manual very carefully.
- Observe in particular the following safety labels on the instrument:
  *T-1* (p. 36), *T-7* (p. 36), *T-14* (p. 37); *T-14* (p. 37), *T-16* (p. 37), *T-18* (p. 37);
  *F-1* (p. 39), *F-2* (p. 39), *F-4* (p. 39), *F-12* (p. 40);
  *R-1* (p. 43), *R-3* (p. 43), *R-7* (p. 43); *R-7* (p. 44).

CAUTION

**Interruption of operation due to interlock system**

The interlock system senses opening of the monitored covers and immediately stops operation by cutting off the power. All pipetted samples are lost and must be reloaded. Interlock covers are: The plexiglass cover above the sampling mechanism (**c** 701 / **c** 702) and the top cover (**c** 702 and **c** 502).

- Before starting operation or maintenance, be sure to close and lock all covers. Operation will not start if an interlock cover is open.

  See: *Interlock function* (p. 48).
- Do not open interlock covers during operation. Open the interlock covers only when the module is in Standby or when specifically instructed to do so in the maintenance procedures.
- Observe in particular the following safety labels on the instrument: *F-1* (p. 39), *R-2* (p. 43).

CAUTION

**Injury or damage to the instrument due to contact with rack transfer mechanism**

The rack transfer mechanism may hurt you and lead to personal injury.

- Only load or unload racks when the green status LEDs at the rack loading area are on.
- Do not insert your fingers or any objects into the rack loading/unloading area while the instrument is operating.
- Keep all covers closed and in place while the instrument is operating.
- Observe in particular the following safety labels on the instrument: *R-3* (p. 43); *R-3* (p. 44).

CAUTION

**Incorrect results due to sample contamination**

If foreign material falls inside the rack loading area, samples may get contaminated.

- Keep the cover of the rack loading area closed while the instrument is operating.
- Do not place anything on the cover of the rack loading area.

CAUTION

**Incorrect results due to expired reagents or mixing reagents**

Results obtained using expired reagents are not reliable. Mixing new reagent and residues of old reagent may cause concentration changes or carryover, leading to incorrect results.

- Do not use reagents, diluents or detergents that have exceeded their expiration dates.
- Do not replenish reagents, diluents, or detergents. When a container is empty, replace it with a new one.

CAUTION

**Incorrect results due to sample mismatch in non-barcode mode**

- When operating in non-barcode mode, make sure to load the samples according to the **Requisition List** provided by the instrument.
- Avoid empty positions within the racks. Do not place nonregistered samples in any empty rack position.
- When manually assigning positions, ensure the position is not already assigned.

CAUTION

**Incorrect results due to incorrect definition of sample cup size**

When using standard cups or micro cups, the correct sample cup size must be selected. Otherwise, the sample pipetting may be inaccurate and thus lead to inaccurate measurement results.

- Be sure to specify the sample cup size for standard cups and micro cups.

### To power off a specific module

1 Make sure that the complete instrument is in Standby or the module is masked and in Standby.

2 Choose **Utility** > **System Configuration** > **Module Settings**.

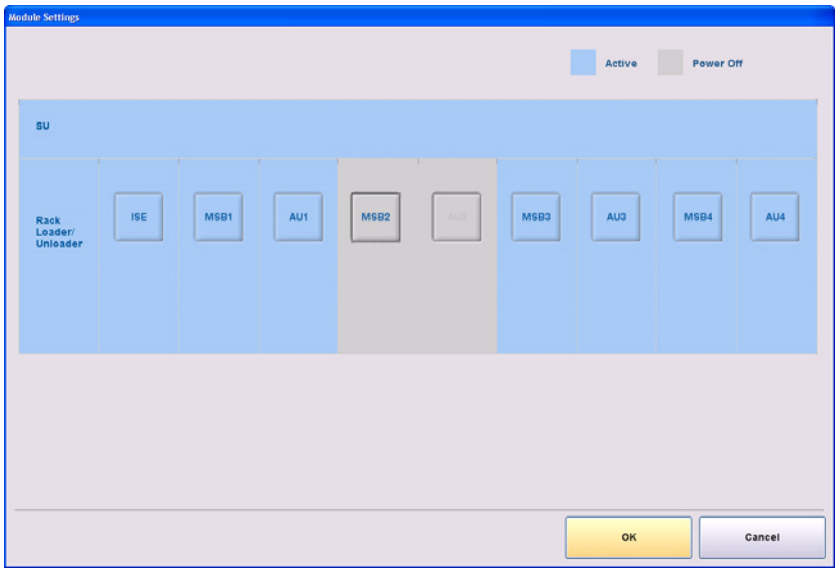



**Figure 20-1** **Module Settings** window

3 Select the desired module from the system layout to be powered off.

4 Choose **OK** to apply the assigned settings.

5 Turn off the module power switch at the rear of the module.

**CAUTION**

**Injury when the system is restarted accidentally**

If the instrument is restarted accidentally by a third person during replacement of parts, this may cause injury or damage to the system.

- Before replacing any parts, be sure to power off the instrument or the module.

6 You may now perform any of the manual maintenance tasks listed in the maintenance schedules.

See *Combined maintenance schedules (all modules)* (p. 609).

### To power on a specific module

1 Switch on the module power switch at the rear of the module.

2 Choose **Utility** > **System Configuration** > **Module Settings** to switch selected modules to the **Active** status.

Wait at least for about one minute before resuming operation.

## Manual cleaning

The motors of the selected module are switched off. Use this maintenance item to move different parts manually for cleaning purposes, such as the pipetter probes, without having to power off the instrument.

### To put a module in Manual Cleaning mode

1 Make sure that the complete instrument is in Standby or the module is masked and in Standby.

2 Choose **Utility** > **Maintenance** > **(11) Manual Cleaning**.

3 Choose **Select** to open the **Manual Cleaning** window.

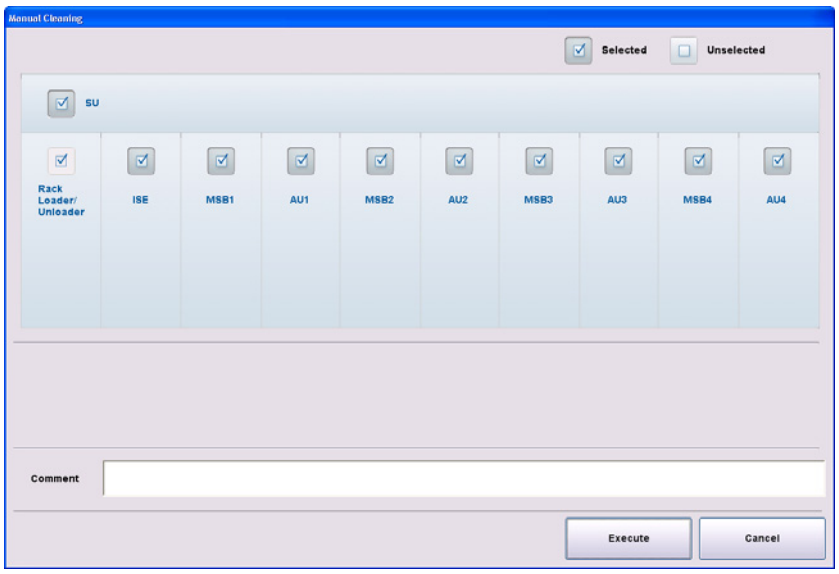



**Figure 20-2** Manual Cleaning window

4 Deselect the ISE and any **c** 502 modules. These modules have an interlock cover that allows the probes to be moved for cleaning when the top cover is opened.

Note that the ISE and the first module cannot be selected at the same time for manual cleaning.

5 Choose **Execute**. The probes on the selected modules move to their cleaning positions.

6 Choose **Maintenance Monitor** to check that the module is in Manual Cleaning mode.

4 After processing the green wash rack, perform a full calibration.

**CAUTION**

**Incorrect results due to missing calibration**

- After processing the green wash rack all ISE tests must be calibrated.
- Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.

See *To request an ISE calibration* (p. 338).

If washing is interrupted for some reason, perform (7) Wash Reaction Parts followed by (4) Cell Blank Measurement. Afterwards, perform (8) Reagent Prime (ALL) (only required for ISE modules).

## Washing with green rack during continuous operation

The **cobas** 8000 instrument offers a function to perform this washing procedure during operation. The function must be activated on **Utility** > **System** > **Wash Racks**.

**Notes for working with the Green Rack during Operation function**

- A full calibration of the ISE tests is required after the washing procedure. Therefore, we recommend processing the green wash rack immediately before the regular daily calibration.
- The instrument must not be in Standby when this function is activated.
- It is possible to load any other rack together with the green wash rack.
- During the washing procedure, ISE tests must be masked (**P.Mask**). Only photometric and immunological tests can be processed. Do not load any samples with ISE requests. If you load samples with ISE requests, the ISE requests cannot be processed until ISE tests are unmasked again.
- Samples with open ISE requests that were registered before masking the ISE tests will be unloaded. You must reload these samples after processing the green wash rack.

### To perform washing during operation

1 Choose **Start** > **Masking** and select **P.Mask** for the ISE tests.

2 Request a full calibration for all ISE tests on **Calibration** > **Status**.

**CAUTION**

**Incorrect results due to missing calibration**

- After processing the green wash rack all ISE tests must be calibrated.
- Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.

See *To request an ISE calibration* (p. 338).

3 Place the racks in the following sequence into the rack loading area on the same tray:

- Green wash rack
- Calibrator rack containing the ISE calibrators
- QC rack containing the controls for ISE tests

4 Choose **Start** > **Start** to start the washing procedure.

5 Check the results for calibration and QC.

6 If the analyzer has generated a valid calibration and the QC results are okay, unmask the ISE tests.

Now the analyzer is ready to process routine samples again.

## Cleaning the ISE sample probe

Each day at the end of analysis, clean the outside of the ISE sample probe to remove residual solution and precipitation.

**Additional cleaning of the sample probe**

When a sample aspiration error occurs, perform maintenance item (18) Sample Probe Wash. If clogging cannot be eliminated by this maintenance item, the sample probe must be detached and cleaned manually.

A sample probe must be replaced if it is bent or damaged. Positional adjustment is required afterwards.

See *To perform a sample probe wash* (p. 668)
*Replacing the ISE sample probe – elimination of clogging* (p. 667)

*Operator time* approximately 1 minute

*Materials required*
- ☐ Alcohol (e.g., isopropyl alcohol or ethanol)
- ☐ Lint-free gauze pads
- ☐ Paper towel

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

- *Infection from samples and associated materials* (p. 25)
- *Infection and injury due to contact with instrument mechanism* (p. 571)
- *Fire and burns due to the use of alcohol* (p. 571)
- *Interrupt of operation due to interlock system* (p. 48)

***NOTICE***

**Damage to the probes**

- Do not bend or damage the lower end of the probes during cleaning.
- Move the arm gently. Do not move it up or down.

### To clean the outside of the probe

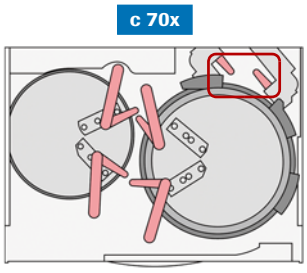
1 Ensure the instrument is in Standby.

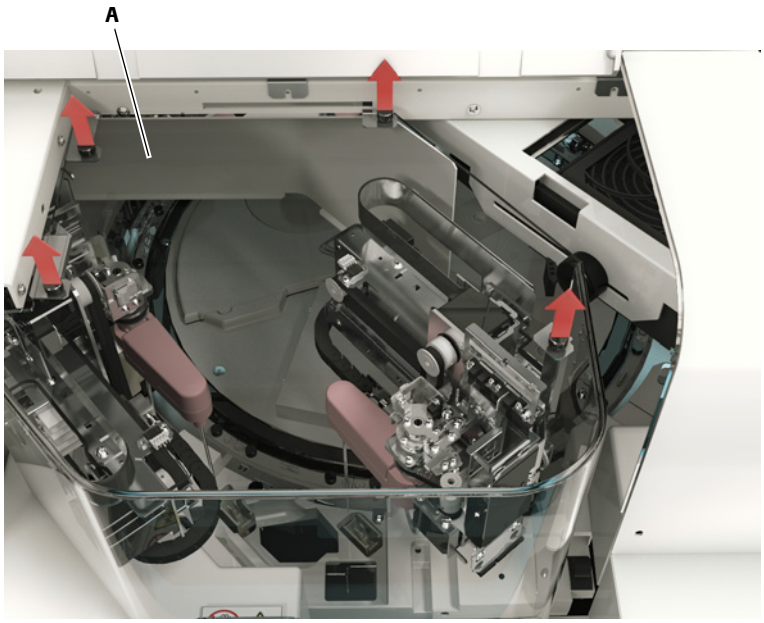
Or: Mask the module (**Start > Masking > Module Masking**) and wait until it is in Standby.

(Or: Power off the instrument or the module.)

The ISE module has an interlock cover that allows the probe to be moved for cleaning when the top cover is opened.

**4** Open the rear cover of the module.




**A** Plexiglass cover

**Figure 23-2** Removing the plexiglass cover above the sample probes

**5** Remove the plexiglass cover.

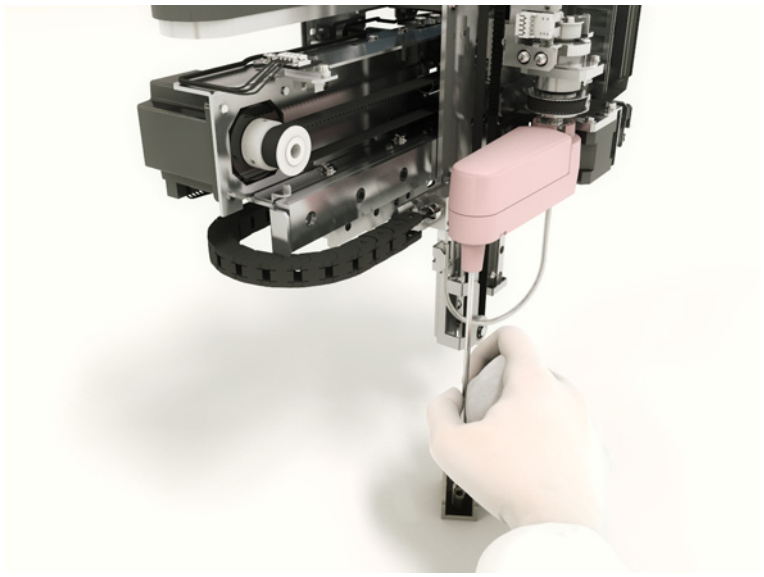


**Figure 23-3** Cleaning the outside of the **c** 701 / **c** 702 sample probes

**6** Move the sample probe by hand to an accessible position.

**7** Wipe the outside of the sample probe with a gauze pad moistened with alcohol:

- Always wipe from top to bottom.
- Hold the pipetter arm with one hand and wipe with the other.

***NOTICE***

**Damage to instrument surfaces**

▶ Do not place a gauze pad moistened with alcohol on the instrument surface as the finish may be damaged.

**8** Reattach and close all covers.

**9** To terminate Manual Cleaning mode, choose **Cancel Maintenance** from the **Overview** menu. Afterwards perform maintenance item (1) Reset for the module concerned.

Additionally perform a reagent registration via **Reagent > Setting > Reagent Registration**.

*To terminate Manual Cleaning mode* (p. 583)

**Alignment and replacement of pipetter probes**

Sample probes must be replaced if they are bent or damaged.

- Adjust the probe alignment after replacement or whenever the probe is not centered above the pipetting positions.

See:
*Replacing the pipetter probes – elimination of clogging* (p. 732)
*To check the horizontal alignment of a probe* (p. 736)

### To clean the outside of the c 701 / c 702 reagent probes and all c 502 probes

**1** Select one of these statuses, which both allow to move the pipetter probes to better accessible positions:

- **c** 701 / **c** 702: Manual Cleaning mode (described here)
- **c** 502: Standby
- Power off (instrument or module)

The **c** 502 module has an interlock cover that allows the probes to be moved for cleaning when the top cover is opened.

**2** Ensure the instrument or the module is in *Standby* (by masking the module). Then put the module into Manual Cleaning mode (**Utility > Maintenance > (11) Manual Cleaning**;).

See *To put a module in Manual Cleaning mode* (p. 582)

**3** Choose **Maintenance Monitor** to check that the module is in Manual Cleaning mode.

Do not use Standby to perform this maintenance procedure. This would end up in an E.Stop (emergency) alarm for all modules. Then the system would require either a complete power off or at least a reset (**Utility > Maintenance**) to resume normal operation.

**4** For **c** 701 / **c** 702 modules: Open the top cover.