

COBAS INTEGRA 400 plus analyzer

Cedex Bio HT Analyzer

Instruction to clean the internal water reservoir

Version 1.0

Software version 3.6/5.1

Publication information

Revision history

Publication version	Software version	Revision date	Change description
1.0	3.6/5.1	November 2017	First version

☰ Revision history

Edition notice

This publication is for Roche trained laboratory technicians of the COBAS INTEGRA 400 plus analyzer and the Cedex Bio HT Analyzer. It explains how to clean the internal water reservoir for instruments with the following serial numbers:

- COBAS INTEGRA 400 plus analyzer: 420001 or higher
- COBAS INTEGRA 400 plus analyzer (without ISE module): 520001 or higher
- Cedex Bio HT Analyzer: 620001 or higher

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.

Where to find information

The **User Manual** or **Operator's Manual** for the respective analyzer focuses on operation, maintenance, troubleshooting, and basic configuration of the analyzers. They also contain important safety information. You must read the Safety chapter before operating the analyzer.

The **Online Help** includes all information of the Operator's Manual. In addition it contains all error messages and a complete software reference.

General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- ▶ Pay particular attention to all safety notices.
- ▶ Always follow the instructions in this publication.
- ▶ Do not use the software 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 hardware images in this publication have been added exclusively for illustration purposes.

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

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

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

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This open source and commercial software and the COBAS INTEGRA 400 plus analyzer or Cedex Bio HT Analyzer as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the respective Operator's 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 the COBAS INTEGRA 400 plus analyzer or Cedex Bio HT Analyzer.

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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.

Contact addresses



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Approvals for COBAS INTEGRA 400 plus analyzer

The COBAS INTEGRA 400 plus analyzer 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.

RoHS compliant from Serial No. 410001 (with ISE module) and 510001 (without ISE module).

Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.



Complies with the provisions of the applicable EU directives.



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

Approvals for Cedex Bio HT Analyzer

The Cedex Bio HT Analyzer meets the requirements laid down in:

Directive 2014/30/EU of the European Parliament and Council of 26 February 2014 relating to electromagnetic compatibility (EMC).

Directive 2014/35/EU of the European Parliament and Council of 26 February 2014 relating to electrical equipment designed for use within certain voltage limits.

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.

RoHS compliant from Serial No. 610001.

Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:



Complies with the provisions of the applicable EU directives.



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Intended use for COBAS INTEGRA 400 plus analyzer

The COBAS INTEGRA 400 plus analyzer is a fully automated, computerized chemistry analyzer. It is intended for in vitro quantitative or qualitative determination of a wide range of analytes in various body fluids.

Intended use for Cedex Bio HT Analyzer

The Cedex Bio HT Analyzer is a fully automated, computerized analyzer for professional use. It is intended for determination of a wide range of analytes in various aqueous solutions like cell culture and fermentation media.

For use in quality control/manufacturing process only.

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product name	Descriptor
COBAS INTEGRA 400 plus analyzer	instrument
Cedex Bio HT Analyzer	instrument

☰ Product names

Abbreviations

The following abbreviations are used.

Abbreviation	Meaning
ISE	Ion Selective Electrode
PCB	Printed Circuit Board
RoHS	Restriction of Hazardous Substances

☰ Abbreviations

Instructions

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Cleaning the internal water reservoir

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Cleaning the internal water reservoir



Clean the internal water reservoir only when advised by Roche.



30 minutes



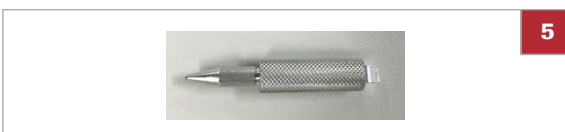
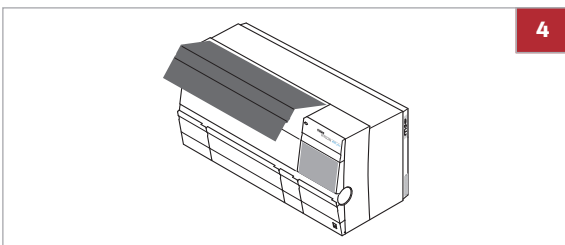
- Unlock rack tool
- 0.6% sodium hypochlorite solution
- Reagent grade type 1 water
- Paper tissues
- 70% ethanol solution
- Clean protective gloves



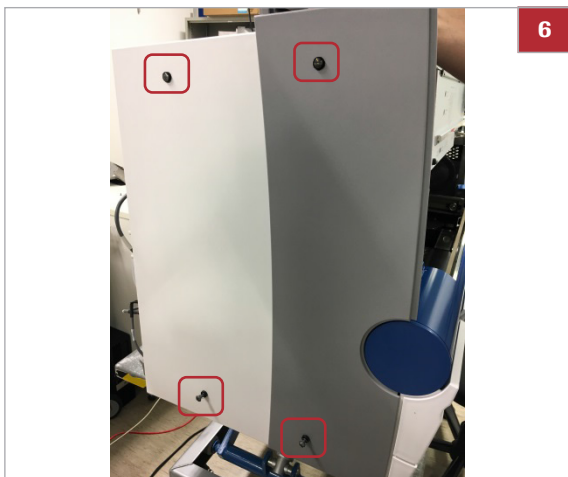
- Your instrument has one of the following serial numbers: COBAS INTEGRA 400 plus analyzer 420001 or higher; COBAS INTEGRA 400 plus analyzer (without ISE module) 520001 or higher; Cedex Bio HT Analyzer 620001 or higher.
- This instruction must be performed only by laboratory technicians trained by Roche in this procedure.

► To clean the internal water reservoir

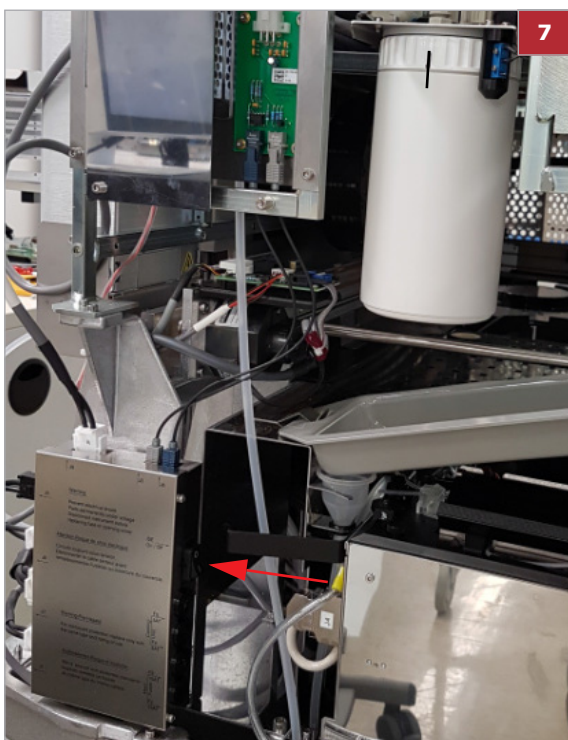
- 1 Choose **File > Shut Down**.
- 2 Switch off the instrument at the main switch.
- 3 Unplug the instrument from the power source.
- 4 Open the main cover, be sure to lift it as far as it will go.



- 5 Take out the unlock rack tool.



- 6** To remove the left side cover, unlock the four screws using the unlock rack tool.

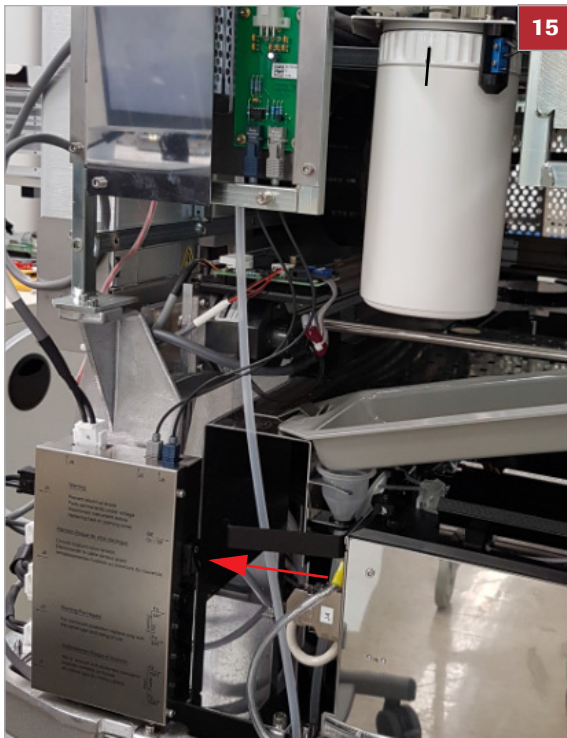


- 7** On the PCB voltage selector, switch off the power of the ISE power supply.



- 8** Unscrew the internal water reservoir.
 - ❶ The internal water reservoir may be full. Take care not to spill any water.
- 9** Empty the internal water reservoir and clean it with 0.6% sodium hypochlorite solution.
- 10** Rinse the internal water reservoir thoroughly with water four times.
 - ❶ Use only reagent grade type 1 water.
- 11** Clean the internal water reservoir level switch and the suction pipes using a tissue moistened with 70% ethanol.
- 12** Rinse thoroughly with water.
- 13** Replace the liquid filters (Filter Ligacon) at the end of the suction pipes.
 - ❶ Wear clean protective gloves so that you do not contaminate the filters.
- 14** Reinstall the clean empty internal water reservoir.
 - Make sure that both black marks fit.





- 15 Switch on the ISE power supply.
- 16 Put back the left side cover and lock the four screws using the unlock rack tool.
- 17 Return the unlock rack tool and close the main cover.
- 18 Plug in the power cord and switch on the instrument and the control unit.
- 19 Log on as a regular user.
 - The internal water reservoir is filled. After filling, a first priming of the fluid system starts automatically. This can take up to eleven minutes. Make sure that the instrument is in **Standby** mode. If the instrument is running, click **Stop**.
- 20 Perform the **Prime fluid system** service action twice.