cobas® 8100 automated workflow series

Addendum 2.0 to Operator's Manual version 2.9.4

Document information

Document version	Revision date	Changes
1.0	July 2019	Initial version (only valid for software version 03-09)
2.0	July 2019	Added warning message of sharps, rough edges, and moving parts

Table 1 Revision history

Edition notice This publication is intended for operators of the **cobas**® 8100 automated workflow series.

The **cobas**® 8100 automated workflow series consists of processing modules, connection components, and a control unit PC, that combine to create an automated processing system.

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.

Trademarks The following trademarks are acknowledged.

COBAS, COBAS C, COBAS INTEGRA, ELECSYS, and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

System approvals The **cobas**® 8100 automated workflow 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.
- Directive 2014/30/EU of the European Parliament and Council of 26 February 2014 relating to electromagnetic compatibility (EMC).
- 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.

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

Compliance is demonstrated by the marks below.

CE	The **cobas**® 8100 automated workflow series instrument complies with IVD Directive 98/79/EC.
RoHS	The **cobas**® 8100 automated workflow series instrument complies with RoHS Directive 2011/65/EU.

Instrument approvals

The **cobas**® 8100 automated workflow series complies with the emission and immunity requirements described in standard IEC 61326-2-6 / EN 61326-2-6.

Furthermore, the **cobas**® 8100 automated workflow series instrument is manufactured and tested according to the international safety standards IEC 61010-2-101:2002, IEC 61010-2-020:2006, and IEC 60825-1:2007.

Issued by TÜV Rheinland for Canada and the US.

Fluorinated greenhouse gas

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

The insulation of the chamber includes foam blown with fluorinated greenhouse gas.

Type	Charge weight (kg)	CO_2 equivalent (tonne)	Global warming potential
R-404A	0.260	1.02	3920
R-448A	0.260	0.36	1387

Table 2 Fluorinated greenhouse gas detail.

Contact addresses

Inside the European Union and EFTA member states

*Manufacturer of **cobas**® 8100 automated workflow series instrument*		Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku, Tokyo 105-8717 Japan
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Outside the European Union and EFTA member states

Manufactured by	Hitachi High-Technologies Corporation
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General

This addendum provides the following changes to the **cobas**® 8100 Operator's Manual version 2.9.4:

- Chapter *System description*, sub-chapter *Warning messages*:

  A warning message of sharps, rough edges, and moving parts was added.

Roche recommends that you familiarize yourself with the new or revised content provided in this addendum.

Revision 1: Warning message of sharp edges added

In the chapter *System Description*, sub-chapter *warning messages*, a warning message of sharps, rough edges, and moving parts has been added.

Warning messages

WARNING

Personal injury and infection due to sharps, rough edges, and/or moving parts

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use.

Some areas of the instrument may have sharps, rough edges, and/or moving parts.

- Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument.
- Your personal protective equipment should be appropriate to the degree and type of potential hazard, e. g. suitable lab gloves, eye protection, lab coat, and footwear.