cobas® 8100 automated workflow series

Addendum 1.0 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 graphics showing the centrifuge unit inside the ACU module were updated

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
Manufactured for	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany

Table of contents

General

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

- Chapter *Document information*:

  The specifications for the fluorinated greenhouse gas type R.448A was added.

- Chapter *System description*, sub-chapter *ACU module*:

  2 graphics showing the centrifuge unit inside the ACU module were updated.

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

Revision 1: Fluorinated greenhouse gas type R-448A added

In the chapter *Document information*, the specifications for the fluorinated greenhouse gas type R.448A have been added.

In the chapter *System Description*, sub-chapter *ACU module*, 2 graphics showing a label on the centrifuge unit inside the ACU module have been updated. The label contains information about the fluorinated greenhouse gas type.

Document information

Fluorinated greenhouse gas

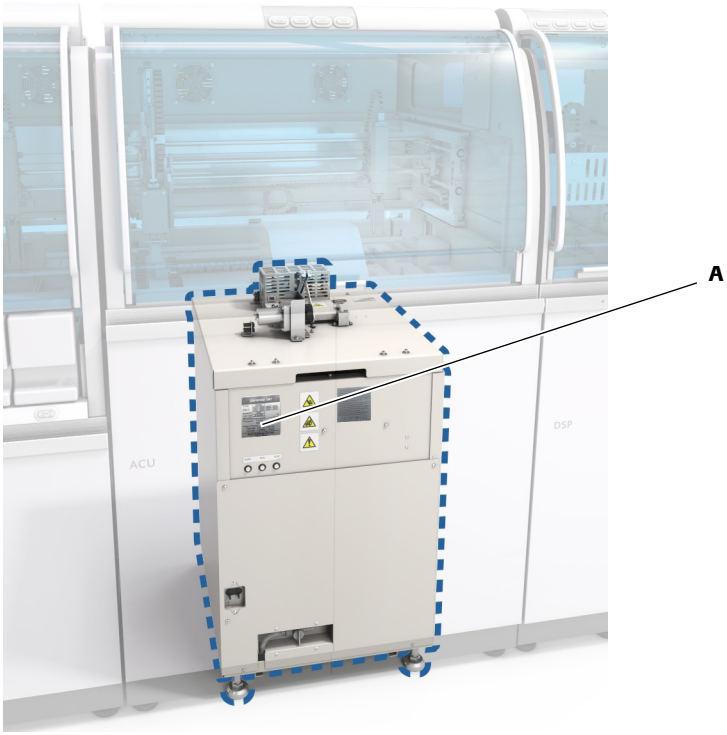
The product contains a fluorinated greenhouse gas in the hermetically sealed refrigeration.

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 3 Fluorinated greenhouse gas detail.

The distinction between the 2 fluorinated greenhouse gas types is made with a name label on the front of the ACU module.



A Name label

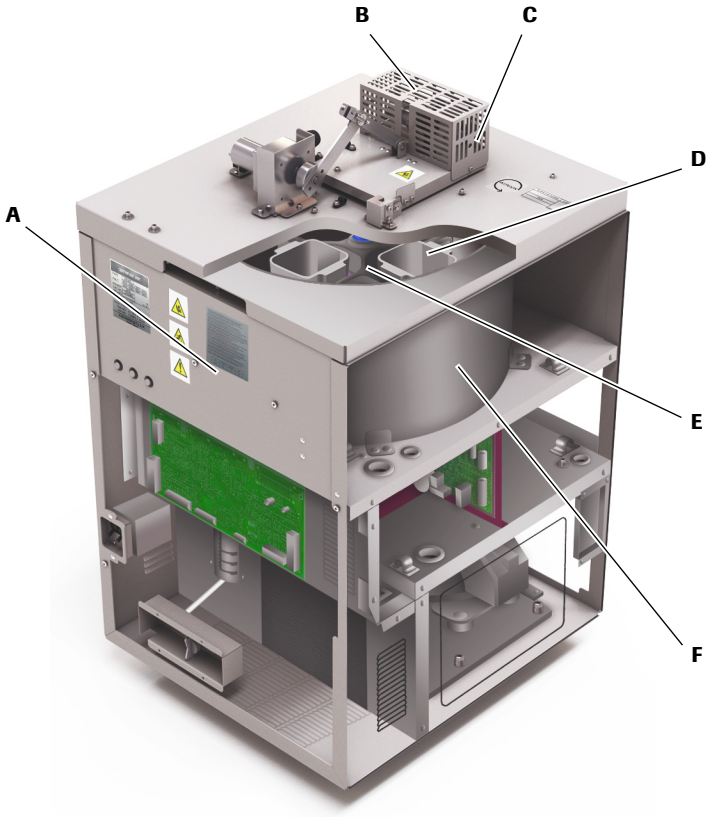
Figure 1 Fluorinated greenhouse gas label on the centrifuge unit inside the ACU module.

	Type: R-404A	Type: R-448A
Name label	CENTRIFUGE UNIT TYPE ME30C VOLT. 200V~50Hz 200V~60Hz 230V~50Hz 208V~60Hz POWER 2kVA CAT.NO. S102366 MFG.NO. S311617 Refrigerant R-404A 260g (0.573 lb) Design Pressure High-side 3.45 MPa (500 psi) Low-side 1.2 MPA (174 psi) Koki Holdings Co., Ltd. Tokyo Japan	CENTRIFUGE UNIT TYPE ME30C VOLT. 200V~50Hz 200V~60Hz 230V~50Hz 208V~60Hz POWER 2kVA CAT.NO. S102366 MFG.NO. S311801 Refrigerant R-448A 260g (0.573 lb) Design Pressure High-side 2.8 MPa (406 psi) Low-side 0.33 MPA (48 psi) Koki Holdings Co., Ltd. Tokyo Japan

Table 4 Name labels of different types of fluorinated greenhouse gas.

ACU module

Figure 2 Inside the ACU module - bottom compartment. Cutaway showing the centrifuge unit inside the ACU module.



A	Front of the centrifuge	**D**	Centrifuge bucket inside the rotor room
B	Centrifuge hatch	**E**	Hanging pins
C	Opening for hexagonal wrench	**F**	Rotor room

Figure 3 Cutaway diagram - inside the centrifuge