



# **cobas® 8100 automated workflow series**

Addendum 1.0 to Operator's Manual version 2.9.6

## Document information

Document version	Revision date	Changes
1.0	September 2020	Initial version (only valid for software version 04-02), revision history and chapter <i>What is new in publication version 2.9.6</i> 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.

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*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.



The **cobas**® 8100 automated workflow series instrument complies with IVD Directive 98/79/EC.



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, IEC 61010-2-020, IEC 60825-1:2007, and IEC 60825-1:2014.



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 <sub>2</sub> 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.

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

## Contact addresses

### Inside the European Union and EFTA member states

*Manufacturer of cobas® 8100  
automated workflow series  
instrument*



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Japan

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### Outside the European Union and EFTA member states

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## General

This addendum provides the following changes to the **cobas**® 8100 Operator's Manual version 2.9.6:

- Chapter *Document information*:  
The revision history has been updated.
- Chapter *What is new in publication version 2.9.6*, section *Update to Windows 7*:  
The section has been replaced by the section *Update to Windows 10*.

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

## Revision 1: Update to Windows 10

In the chapter *Document information*, the revision history has been updated.

In the chapter *What is new in publication version 2.9.6*, the section *Update to Windows 7* has been replaced.

### Document information

Manual version	Software version	Revision date	Changes
2.9.6 Add. 1.0	04-02	September 2020	Update to Windows 10 (SW 04-02). •  <i>What is new in publication version 2.9.6</i> (p. 7)

**Table 3** Revision history

### What is new in publication version 2.9.6

*Update to Windows 10* The software version 04-02 is functional identical to version 03-11 but has been designed for Windows 10 computers.