

cobas® 8100 automated workflow series

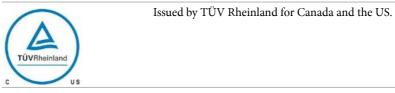
Addendum 2.0 to Operator's Manual version 2.7

Document information

| Document versio | on Revision date | Changes | | |
|-----------------|------------------|--|--|--|
| 1.0 | April 2017 | Initial version (only valid for software version 03-03) | | |
| 2.0 | June 2017 | Added statement of conformity to the Directive 2014/53/EU and radio equipment specifications | | |
| 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. | | |
| | Copyright | © 2017, Roche Diagnostics GmbH. All rights reserved. | | |
| | 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: <i>http://e-labdoc.roche.com</i> . | | |
| | | 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.



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.

| Туре | Charge weight (kg) | CO ₂ equivalent (tonne) | Global warming potential |
|---------|--------------------|------------------------------------|--------------------------|
| R-404A | 0.260 | 1.02 | 3920 |
| Table 2 | Fluorinated greenh | ouse 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 |
|--|----------|---|
| Authorized representative | ECREP | Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany |

Outside the European Union and EFTA member states

| Hitachi High-Technologies Corporation | |
|--|--|
| Roche Diagnostics GmbH | |
| Sandhofer Strasse 116 68305 Mannheim, Germany | |
| | |

| Table of contents | |
|---|---|
| General | 6 |
| Revision 1: Specifications of radio equipment added | 7 |
| Specifications of radio equipment | 7 |

General

This addendum provides the following changes to the **cobas**^{*} 8100 Operator's Manual version 2.7:

• Chapter *Document information*:

The statement of conformity to the Directive 2014/53/EU was added to this chapter.

• Chapter System description, sub-chapter Sample and holder identification:

The sub-chapter Specifications of radio equipment was added to this chapter.

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

Specifications of radio equipment

Revision 1: Specifications of radio equipment added

In the chapter *System Description*, the specifications of the radio equipment have been added.

Specifications of radio equipment

This instrument includes some RFID readers/writers with the following specifications for reagent information handling.

| Module | Frequency (MHz) | Maximum radio-frequency power (mW) | Number of RFID readers / writers |
|--------|-----------------|---------------------------------------|-------------------------------------|
| ACU | 13.56 | < 200 | 4 |
| АОВ | 13.56 | < 200 | 8 |
| AQM | 13.56 | < 200 | 5 |
| BCL | 13.56 | < 200 | 4 |
| BRF | 13.56 | < 200 | 7 |
| CLO | 13.56 | < 200 | 5 |
| CLW | 13.56 | < 200 | 5 |
| CRO | 13.56 | < 200 | 3 |
| CRW | 13.56 | < 200 | 5 |
| DSP | 13.56 | < 200 | 3 |
| IPB | 13.56 | < 200 | 13 |
| OBS | 13.56 | < 200 | 19 |
| RFX | 13.56 | < 200 | 7 |
| RSF | 13.56 | < 200 | 3 |
| RSS | 13.56 | < 200 | 3 |
| SCM | 13.56 | < 200 | 4 |
| SLL | 13.56 | < 200 | 2 |
| SLR | 13.56 | < 200 | 2 |
| TIJ | 13.56 | < 200 | 6 |
| UCU | 13.56 | < 200 | 6 |
| URF | 13.56 | < 200 | 5 |

Table 3

Specifications of radio equipment