cobas® 8100 automated workflow series

Addendum 2.0 to Operator's Manual version 2.9.6

Document information

Document version	Software version	Revision date	Changes
1.0	04-03	January 2021	*Safety message Multiple barcode labels* replaced. Section on selective barcode reading added.

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, 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_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.

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*		Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku, Tokyo 105-8717 Japan
Authorized representative		Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany

Outside the European Union and EFTA member states

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Table of contents

General

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

- A new safety message entitled *Incorrect results due to multiple barcode labels* replaces the safety message entitled *Multiple barcode labels*.

  This update is necessary because processing a sample tube with multiple barcode labels is now possible.

- The section *Selective barcode reading* has been added to the following chapter: *Overview of the system > Sample and holder identification > Barcodes*.

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

Revision 1: Safety message Multiple barcode labels replaced

A new safety message entitled *Incorrect results due to multiple barcode labels* replaces the safety message entitled *Multiple barcode labels*.

CAUTION

Incorrect results due to multiple barcode labels

The barcode reader with default settings cannot process a sample tube with multiple barcode labels. Multiple barcode labels on sample tubes can cause the system to misidentify samples, leading to wrongly reported results.

- Label each tube with only one barcode label.
- Check each barcode label against information from the LIS.
- Remove incorrect barcode labels.
- If necessary, print a new barcode label.
- If you use more than one type of barcode label in your laboratory, the barcode reader must be configured to read only one type of barcode.

  Contact your Roche Service representative.

The safety message is used on the following pages of the **cobas**® 8100 Operator's Manual version 2.9.6: p. 26, p. 210, p. 231, p. 236, and p. 237.

Revision 2: Section on selective barcode reading added

In the chapter *Overview of the system* > *Sample and holder identification* > *Barcodes* a section on selective barcode reading has been added.

Selective barcode reading is available starting from software version 04-03.

Selective barcode reading

Sample tubes should be labeled with only one barcode label. A barcode reader with default settings cannot process a sample tube with multiple barcode labels. If you use multiple barcode labels in your laboratory, selective barcode reading must be applied.

The relevant barcode to be read by the barcode reader and forwarded to the analyzer must be a different type from all other barcodes on the sample tube. The barcode reader can be configured to read only the relevant barcode type and to neglect all others.

This configuration is done by Roche Service representatives.