cobas® 8100 automated workflow series

Addendum 1.0 to Operator's Manual versions 2.9 to 2.9.6
Software versions 03-07 to 03-12

Publication information

Publication version	Software version	Revision date	Change description
1.0	03–07 to 03–12	October 2023	Revised chapter 'System does not start'

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.
  To view the full text of the 2014/53/EU declaration of conformity, go to the Roche DiaLog Global Web Site (*www.dialog.roche.com*) and choose the eLabDoc link.
  If you are unable to access Roche DiaLog, contact a Roche Service representative.

Compliance with the applicable directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

CE	Complies with the provisions of the applicable EU directives.
RoHS	Complies with the directive 2011/65/EU on RoHS.

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 newer ACU modules use the flammable HFO-1234yf as refrigerant.

Type	Charge weight (kg)	CO_2 equivalent (tonne)	Global warming potential	Refrigerant used by serial number of ACU module
R-404A	0.260	1.02	3920	≤ 1970-10
R-448A	0.260	0.36	1387	1971-01 to 21A4-10
HFO-1234yf (R-1234yf)	0.094	0.000094	1	≥ 21A5-01

Table 2 Fluorinated greenhouse gas detail

To identify the refrigerant used on your instrument by serial number, refer to eLabDoc on the Roche DiaLog website:

www.dialog.roche.com

For more information, contact your local affiliate or Roche Service representative.

The distinction between the 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 the instrument	Hitachi High-Tech Corporation 1-17-1 Toranomon Minato-ku, Tokyo, 105-6409 Japan
	Authorized representative	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Outside the European Union and EFTA member states

	Manufactured by:	Hitachi High-Tech Corporation
	Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany
	Distributed in USA by:	Roche Diagnostics 9115 Hague Road Indianapolis, Indiana, USA

Roche affiliates A list of all Roche affiliates can be found at:

www.roche.com/about/business/roche_worldwide.htm

eLabDoc Electronic user documentation can be downloaded under eLabDoc on the Roche DiaLog website:

www.dialog.roche.com

For more information, contact your local affiliate or Roche Service representative.

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Revision of the chapter ’System does not start’

In the Operator’s Manual, the chapter '*Troubleshooting > Troubleshooting problems with the system > System does not start*' describes the possible problem resolutions you can take in case the system does not start.

The 'Notice' safety precaution, which was previously described before the procedure, has been moved and can now be found as info in the procedure. Minor corrections have been made such as terminology changes.

System does not start

The instrument does not start when you press the **ON** button.

Follow the procedure below and perform the recommended problem resolutions as necessary. If all problem resolutions are unsuccessful, contact your Roche Service representative.

▶ To troubleshoot system startup

If you are unable to starting the system, follow this procedure.

1 Are the main circuit breaker and the module circuit breakers on the rear of the instrument switched OFF?

- If yes, go to step 2.
  or,
- If no, go to step 3.

2 Switch on all the circuit breakers on the rear of the instrument.

3 Is the mains cable disconnected at either the instrument or the power outlet?

- If yes, go to step 4.
  or,
- If no, go to step 5.

4 Connect the mains cable.

The instrument must only be connected to a power supply source with the specified mains cable and by trained personnel. The instrument may be damaged by using an improper power connection.
Ensure that the main circuit breaker of the instrument is in the off position before plugging in the mains cable.

5 Is the main power outlet working?

- If yes, go to step 8.
  or,
- If no, go to step 6.

6 Ask your facility electrician to check the circuit breaker of the laboratory distribution box.

7 Ask your facility electrician to check the line voltage is adequate.

8 If you continue to experience problems, contact your Roche Service representative.