

Field Safety Notice

SBN-CPS-2017-002

CPS / SWA High/Mid Volume Solutions
Version 1
01-Mar-2017

cobas® 8000 Operator's Manual version 5.0: Incorrect non-standard tube specification

Product Name	cobas e 602 module cobas e 801 module
Instrument/System Affected	cobas® 8000 modular analyzer series
GMMI / Part No Device Identifier	05990378001 07682913001
SW Version	N.A.
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We would like to inform you that a discrepant information on non-standard tubes (NSTs) was found between cobas® 8000 operator's manuals (OM) versions 4.2.1 and 5.0

The version 5.0 OM incorrectly states that 11 to 16 mm diameter NSTs may be used on cobas e 602 and cobas e 801 modules. We stress that only NST diameters of 13 to 16 mm are permitted on these modules.

IMPORTANT

Only the version 5.0 cobas® 8000 OM was incorrect for minimum NST diameter on the cobas e 602 and cobas e 801 modules. All previous OM versions correctly specified a 13 to 16 mm NST diameter for the cobas e 602 module.

The just launched version 5.1 cobas® 8000 operator's manual (which supersedes version 5.0) correctly states that only 13 – 16 mm diameter NSTs may be used on cobas e 602 and cobas e 801 modules.

cobas® 8000 Operator's Manual version 5.0: Incorrect non-standard tube specification

Description of Situation

Incorrect information previously provided on version 5.0 cobas® 8000 operator's manual, chapter "Specifications of containers", section "List of non-standard tubes":

Container	On module	Specifications	Use
Non-standard tubes	ISE, c 701, c 702, c 502	Ø 11–16 mm x 63–102 mm Inner diameter > 10 mm (HbA1c: Inner diameter > 9.7 mm)	Sample only
	e 801, e 602	Ø 11–16 mm x 63–102 mm	Sample only

Non-standard tubes

If a sample tube with a < 13 mm diameter is used on a cobas e 602 or cobas e 801 module, the implemented safety features on both these modules should ensure with a high probability that a sample result is not generated in the event of the sample probe coming into contact with the inner wall of the tube during sample aspiration.

While the actual risk can be considered low, a wrong result cannot be ruled out with 100% certainty in the event of NSTs with < 13 mm diameters being used on cobas e 602 and cobas e 801 modules as the safety features are designed to work specifically and optimally with NSTs of 13 mm to 16 mm diameter (and not 11 mm).

The safety features are:

1. A pressure sensor detection during sample aspiration
2. A liquid-level detection check before, during, and immediately after sample aspiration
3. An abnormal descent movement detection
4. A special sample detection algorithm that includes several checks using a combination of all the hardware safety measures described above

Actions taken by Roche Diagnostics

As of February 6, 2017, the corrected version 5.1 cobas® 8000 operator's manual is available. Replacements of the version 5.0 cobas® 8000 operator's manual will be arranged for affected laboratories.

Correct information provided on version 5.1 cobas® 8000 operator's manual, chapter "Specifications of containers", section "List of non-standard tubes":

Container	On module	Specifications	Use
Non-standard tubes	ISE, c 701, c 702, c 502	Ø 11–16 mm x 63–102 mm Inner diameter > 10 mm (HbA1c: Inner diameter > 9.7 mm)	Sample only
	e 801, e 602	Ø 13–16 mm x 63–102 mm	Sample only

Non-standard tubes

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Actions to be taken by the customer/user

Ensure that only tubes with a diameter of 13 to 16 mm are used on cobas e 602 and cobas e 801 modules.

Replace any available version 5.0 cobas® 8000 operator's manual by the version 5.1 cobas® 8000 operator's manual, which states the correct non-standard tube specifications.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Respectfully yours,

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com