Urgent Field Safety Notice
SBN-CPS-2017-002

CPS / SWA High/Mid Volume Solutions
Version 1
22-Feb-2017

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

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

Dear Valued Customer,

We regret to inform you that we found discrepant information between the previous versions 4.2.1 and 5.0 **cobas®** 8000 operator's manuals (OM) for non-standard tubes (NSTs).

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. However, 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.

Furthermore, the just launched version 5.1 **cobas®** 8000 operator's manual (which supersedes version 5.0) now 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	∅ 11–16 mm x 63–102 mm Inner diameter > 10 mm (HbA1c: Inner diameter > 9.7 mm)	Sample only
	e 801, **e** 602	∅ 11–16 mm x 63–102 mm	Sample only

Non-standard tubes

If a sample tube with a too narrow diameter (<13 mm) is used on a **cobas e** 602 or **cobas e** 801 module, the implemented safety features on both these modules should ensure with a very 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.

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

These stated safety features are specifically:

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.

Correct information now 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	∅ 11–16 mm x 63–102 mm Inner diameter > 10 mm (HbA1c: Inner diameter > 9.7 mm)	Sample only
	e 801, **e** 602	∅ 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** to16 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 (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Best regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
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