Urgent Field Safety Notice

FSN-CPS-2020-003

CPS / Urinalysis

Version 3

July 2020

cobas 6500: possible sample mismatch software 2.2.0 – 2.2.8

Product Name	**cobas u** 701 microscopy analyzer **cobas u** 601 urine analyzer
System	**cobas**® 6500 urine analyzer series (**cobas u** 701 microscopy analyzer in combination with **cobas u** 601 urine analyzer)
GMMI / Part No **Device Identifier**	06390501 001 (**cobas u** 701 microscopy analyzer) 06390498 001 (**cobas u** 601 urine analyzer)
Production Identifier (Product name/Product code)	n/a
SW Version	Software 2.2.9 Modification codes: **cobas u** 701 microscopy analyzer: S_SU2020/003SBN Software version 2.2.9 **cobas u** 601 urine analyzer: S_SV2020/003SBN Software version 2.2.9
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

We are happy to inform you that software 2.2.9 the **cobas u** 601 urine analyzer and **cobas u** 701 microscopy analyzer has been released for installation on the analyzers with Software 2.2.0 – 2.2.8.

With that software the issue of a possible sample mismatch on the **cobas**® 6500 urine analyzer series is resolved.

After the installation of the software update, the precautions described in SBN-CPS-2020-003 version 1 are no longer needed.

Customers using already updated **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB), using standalone **cobas u** 601 urine analyzer or standalone **cobas u** 701 microscopy analyzer are not affected.

Due to the residual medical risk associated with this issue, customers have been informed using the FSN attached to the SBN-CPS-2020-003 version 1. With the upcoming software update, the issue can be considered as resolved.

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Actions to be taken by Roche Diagnostics

Development, verification and release of the corrected software version 2.2.9 (Windows Embedded POSReady 2009) for **cobas**® 6500 urine analyzer series has already been completed.

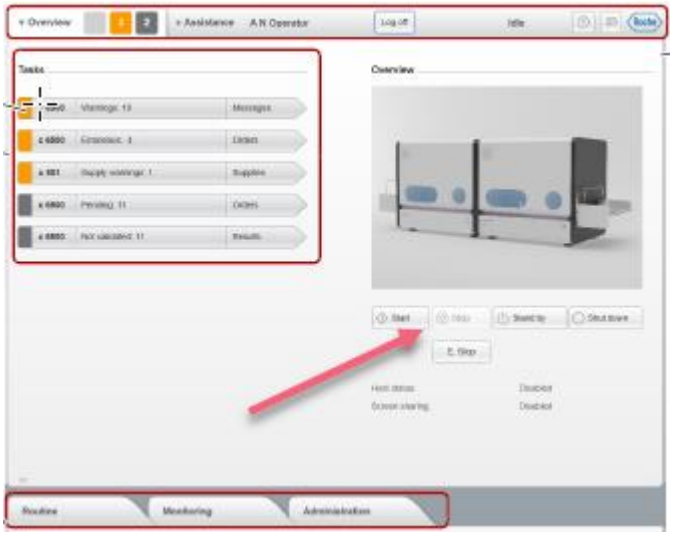
The following corrective actions have been initiated:

- Distribution and update of the corrected software version 2.2.9 (Windows Embedded POSReady 2009) for **cobas**® 6500 urine analyzer series by Roche service at customers side.

Actions to be taken by the customer/user

In order to update the affected analyzers, please contact your local Roche service.
The software update is mandatory only for users with **cobas**® 6500 urine analyzer series with software version 2.2.0-2.2.8, but not needed for already updated **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB), standalone **cobas u** 601 urine analyzer or standalone **cobas u** 701 microscopy analyzer.
Until completion of the update to software version 2.2.9 (Windows Embedded POSReady 2009), affected customers:

- shall empty the cuvette solid waste container every time a new cuvette cassette gets loaded onto the **cobas u** 701 microscopy analyzer.
- shall **not** use the *stop* button on the user interface of the **cobas**® 6500 urine analyzer series.



This advice is valid as long as the **cobas**® 6500 urine analyzer series with software versions 2.2.0 - 2.2.8 is in use. The issue will be resolved with the update to software version 2.2.9 or with the update of the **cobas**® 6500 urine analyzer series with software version 2.3.x (Windows 10 IoT Enterprise 2016 LTSB) together with new hardware.

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 where the devices have been distributed/supplied (if appropriate).

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

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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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com