Urgent Field Safety Notice
SBN-CPS-2017-017

CPS / Serum Work Area
Version 1
20-Jul-2017

cobas 8000 core unit: AU not visible on the Data Review screen

Product Name	**cobas** 8000 core unit
GMMI / Part No Device Identifier	**cobas** 8000 core unit (GMMI 05641446001)
Instrument/System Affected	**cobas®** 8000 modular analyzer series
SW Version	05-02, 06-02 and 06-03
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that we have identified a software limitation, which in rare cases resets your system configuration of the control unit software to default.
Roche Diagnostics received 6 complaints in total regarding this issue.

The control unit (CU) settings under Utility-System are reset to the default settings, under the following conditions:

1. The date and time in the Status Line of the User Interface is not displayed
2. The information about the “Analytical Unit” (AU) is not displayed in the Data Review screen (however, it is still displayed in the Test Review screen)
3. The year/month/date/time of the Printout Preview on the History screen is not displayed

Note:
The described software issue may initialize the system setting information database and consequently resets relevant system settings.

The risk depends on the default settings which are unknowingly activated. Especially “alarm settings” and “analyzer settings” that when unnoticed are switched back to the "default" settings which can lead to a risk for incorrect results.

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Actions taken by Roche Diagnostics

A new software version is being developed in order to solve this limitation that will be available by November 2017.

Actions to be taken by the customer/user

There are two indicators that will identify if the described software issue has occurred.

Indicator 1:
Please check if the date and time is not displayed anymore in the Status Line of the User Interface at minimum on a daily basis (see Figure 1).

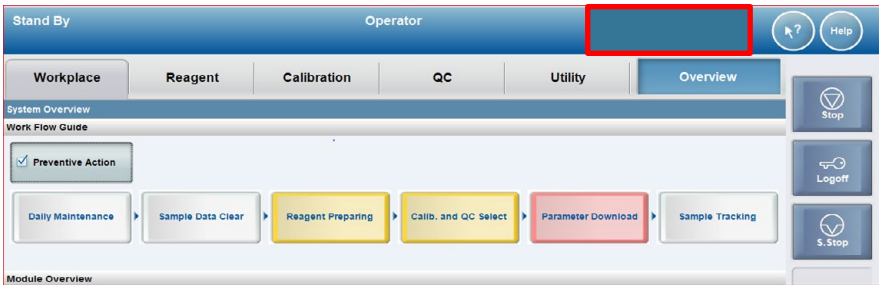

Figure 1: Date and time (in the red box) not displayed in the Status Line of the User Interface

Indicator 2:
Whenever the information about the Analytical Unit is not visible on the Data Review screen (see Figure 2 below, red mark), the software limitation has occurred on this instrument.

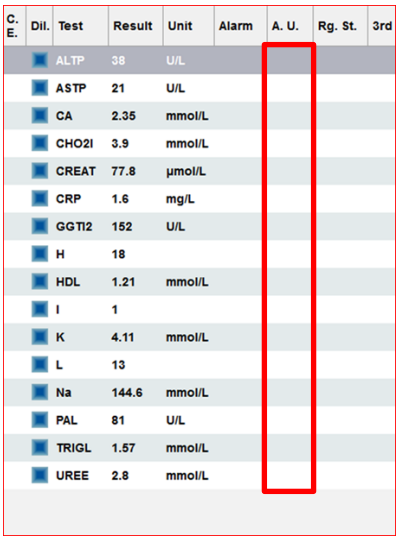

Figure 2: Missing A.U. information (in the red box) in the Data Review screen

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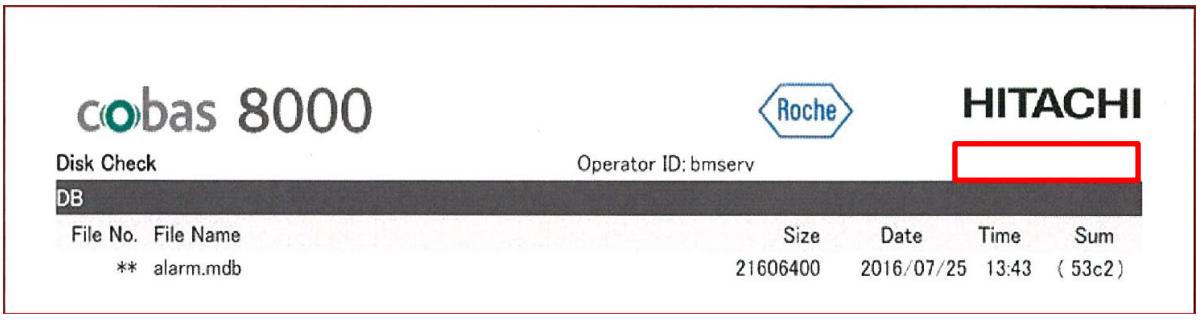
If the described software issue is present, please stop the instrument by using the "Stop" button and call your Roche Diagnostics contact, in order to get the appropriate support to have your system reconfigured.

Rerun of already measured samples after the issue occurred (to be performed **only** after all settings are set again):
It is recommended to measure those samples again which have been measured in the time frame from the issue occurrence till the instrument has been stopped.

Estimation about date/time of the occurrence of the phenomenon:
1. Open the Print-History screen
2. Search for the oldest printout which does not show the year/month/day/time in the Print-History screen.



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 (if appropriate).

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

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

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.

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Best regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com