Field Safety Notice

FSN-CPS-2017-017

CPS / Serum Work Area
Version 1
10-Aug-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 that a software limitation has been identified in the **cobas**® 8000 modular analyzer series. In rare cases, the software resets the control unit's (CU) settings to default. Roche Diagnostics has received 6 complaints regarding this issue.

The reset to default of the control unit (CU) settings (under Utility-System, see Figure 1) is indicated by 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. It is however displayed in the Test Review screen.
3. The year/month/date/time of the Printout Preview on the History screen is not displayed.

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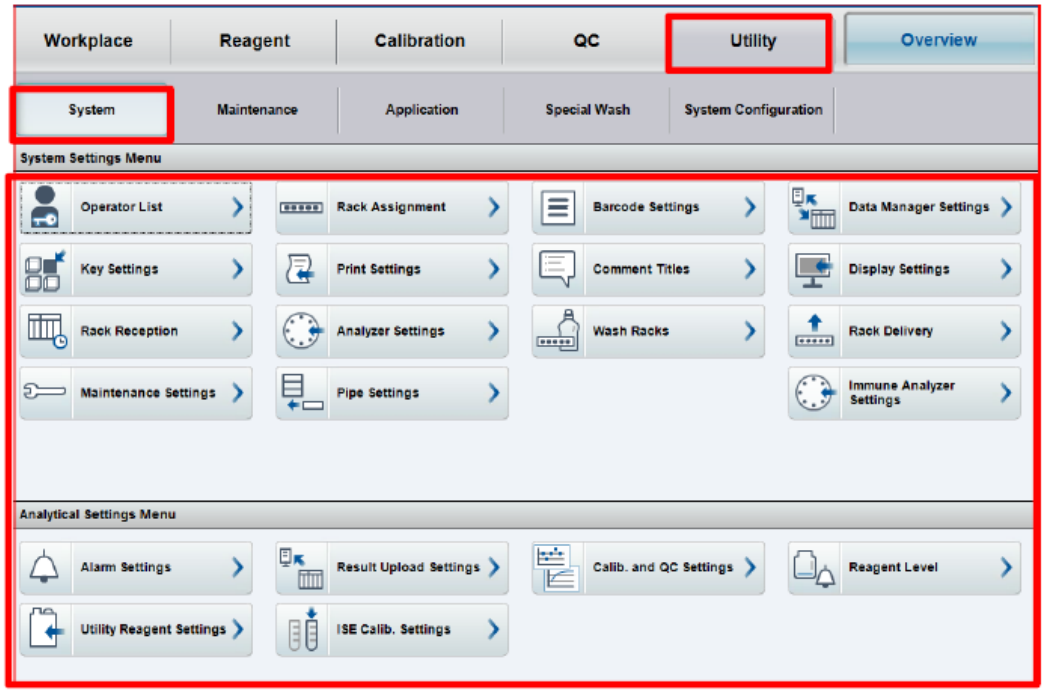

Figure 1: System settings that are changed.

Note:

The risk depends on which system setting(s) has/have been reset to default and the changes may lead to a risk for incorrect results.

Actions taken by Roche Diagnostics

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

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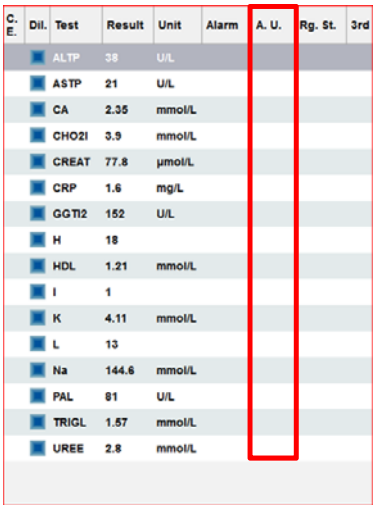
Actions to be taken by the customer/user

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

Indicator 1:
No display of the date and time in the Status Line of the User Interface (see Figure 2).

Figure 2: Date and time (in the red box) are not displayed in the Status Line of the User Interface

Indicator 2:
No Analytical Unit (AU) information on the Data Review screen (see Figure 3).



C. E.	Dil.	Test	Result	Unit	Alarm	A. U.	Rg. St.	3rd
		ALTP	38	U/L				
		ASTP	21	U/L				
		CA	2.35	mmol/L				
		CHO2I	3.9	mmol/L				
		CREAT	77.8	µmol/L				
		CRP	1.6	mg/L				
		GGTI2	152	U/L				
		H	18					
		HDL	1.21	mmol/L				
		I	1					
		K	4.11	mmol/L				
		L	13					
		Na	144.6	mmol/L				
		PAL	91	U/L				
		TRIGL	1.57	mmol/L				
		UREE	2.8	mmol/L				

Figure 3: Missing A.U. information (marked by the red box) in the Data Review screen

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If the indicators are observed, please stop the instrument. Your respective application support person will help with the reconfiguration of the system.

It is recommended that rerun of measured samples be done after the reconfiguration of the system. See below on how to identify the samples to be reran.

Estimation on date/time of the phenomenon:

1. Open the Print-History screen
2. Search for the oldest printout which does not show the year/month/day/time (indicated by empty red box in Figure 4)

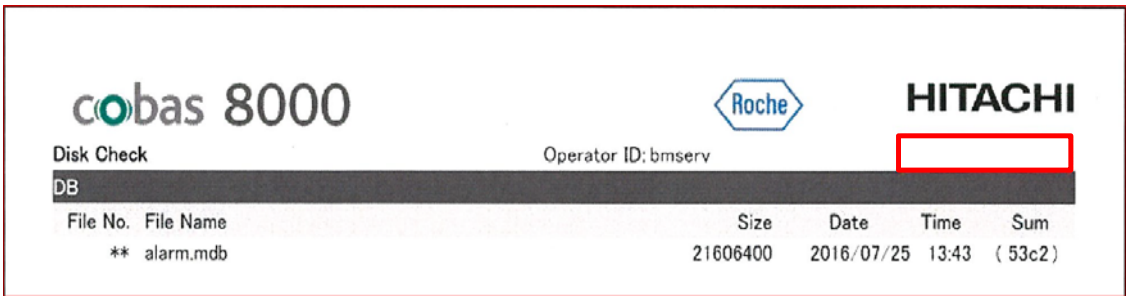

Figure 4: Missing year/month/day/time (empty red box) in the Print-History screen

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Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.
Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for inconvenience caused and thank you for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd
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