

Urgent Field Safety Notice

SBN-CPS-2017-017

CPS / Serum Work Area
Version 2
16-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
Reason for Version 2	Updated information based on input from HHT. Changes highlighted in yellow, <i>[the yellow background can be removed in final local version]</i>
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We have informed you in the previous version of this document that we have identified a software limitation, which in rare cases resets your system settings of the control unit software to default. Roche Diagnostics received 6 (as of 29-Jul-2017) complaints in total regarding this issue. Due to new information received we would like to give you an update.

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

1. The date 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.

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For instruments which are connected to CLAS and/or are running in Barcode mode:

If the issue has happened and with starting the next Operation:

- Barcodes are not read anymore
- Rack loading from CLAS is not possible anymore

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 “System-Alarm Settings” and “System-Immune Analyzer Settings” unnoticed switched back to “default” may cause a risk for incorrect results.

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 is displayed in the Status Line of the User Interface at minimum on a daily basis (see Figure 1). Whenever the date is not displayed in the Status Line of the User Interface, the software limitation has occurred on this instrument.



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

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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.

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				
		GGT12	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	81	U/L				
		TRIGL	1.57	mmol/L				
		UREE	2.8	mmol/L				

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

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.

Hint:

Possible action to save the current System-Settings at customer site:

On daily base follow the description in the Operator Manual-Utility-Maintenance Chapter to perform the Utility-Maintenance item (14) Parameter Read/Write by selecting the “Parameter Write”.

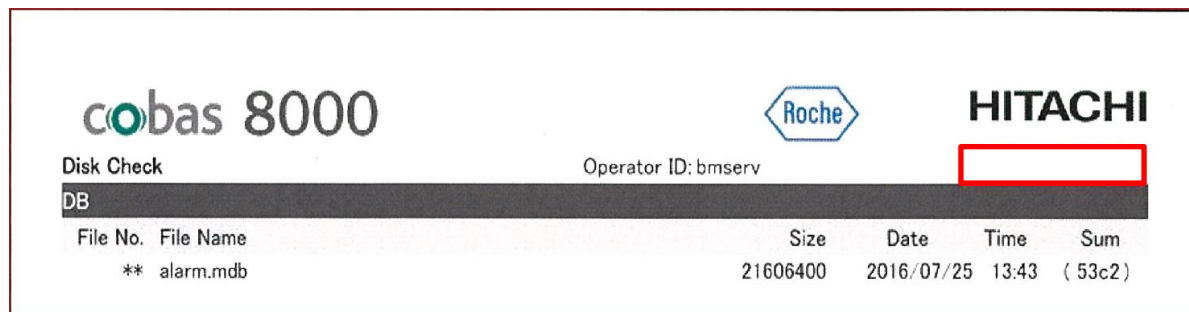
This will save the current System Settings of the instrument. Repeat this Maintenance function whenever a System setting is changed.

If the issue has happened on the instrument use the Utility-Maintenance item (14) Parameter Read/Write by selecting the “Parameter Read” to download the parameters to the system again

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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.



File No.	File Name	Size	Date	Time	Sum
**	alarm.mdb	21606400	2016/07/25	13:43	(53c2)

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.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com