



# URGENT FIELD SAFETY NOTICE

## IMMEDIATE ACTION REQUIRED

**Ref No:** CFSN cobas 8000 core unit SBN-CPS-2017-017  
**Date:** 24/07/2017  
**Type of Action:** Field corrective action

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**System Affected:** cobas® 8000

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**Software Version:** 05-02, 06-02 and 06-03

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Product Name	Material No	Lot No
Cobas 8000 core unit	05641446001	

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### Summary of Issue

AU not visible on the Data Review screen

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### Reason for Notice

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

Roche Diagnostics  
Charles Avenue  
Burgess Hill  
West Sussex  
RH15 9RY

Ö	Immediate Action Required
	Action Required
	Information Only

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### 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.

### 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.

### Action Required

#### 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

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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.

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.

cobas 8000		Roche		HITACHI	
Disk Check		Operator ID: bmserv		2016/07/27 09:00	
DB					
File No.	File Name	Size	Date	Time	Sum
**	alarm.mdb	21606400	2016/07/25	13:43	( 53c2 )

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## IMMEDIATE ACTION REQUIRED



Please complete and return the [Acknowledgement Form](#) which accompanies this [Field Safety Notice](#) by Friday 4<sup>th</sup> August 2017.

Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

### Attachments

CFSN cobas 8000 core unit SBN-CPS-2017-017 Acknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the [Roche Dialog Portal](#)

If you require any further information please contact our

**Technical Support Hotline**

**UK: 0808 100 19 20**

**Ireland: 1800 40 95 64**

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# ACKNOWLEDGEMENT

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### IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: CFSN cobas 8000 core unit SBN-CPS-2017-017

Acknowledgement Form

Date: 24/07 /2017

Type of Action: Field Corrective action

Kindly complete and return this form to the e mail address shown on the footer before Friday 4<sup>th</sup> August 2017.

**System:** cobas 8000 core unit

**Customer Name & Dept:**

**Address:**

Are the above contact details correct? *(Please circle)* Yes No *(If no please insert correct details below)*

**Contact Name:**

**Department:**

**Telephone:**

*If you require an electronic copy of this field safety notice in addition to the hard copy please print your e-mail address below:*

**Email:**

Please acknowledge receipt of information and awareness of any required actions described within the accompanying **Field Safety Notice**.

Please bring this notice to the attention of all personnel in your hospital or healthcare facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Roche Diagnostics  
Charles Avenue  
Burgess Hill  
West Sussex  
RH15 9RY

Registered No 571546

**email to [burgesshill.centralisedsolutions@roche.com](mailto:burgesshill.centralisedsolutions@roche.com)**



# ACKNOWLEDGMENT

## URGENT FIELD SAFETY NOTICE

### IMMEDIATE ACTION REQUIRED

**I acknowledge receipt of this Field Safety Notice and have read, understood and implemented its content.**

Name:

Signed:

Date:

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