Urgent Field Safety Notice

SBN-CPS-2020-013

CPS / Serum Work Area Systems

Version 1

November 2020

Rare occurrence of changed configuration settings on certain systems

Product Name	**cobas**® 8000 Core Unit **cobas pro** sample supply unit **cobas c** 513 analyzer commercial system
System	**cobas** 8000 modular analyzer series **cobas pro** integrated solutions **cobas c** 513 analyzer commercial system
GMMI / Part No **Device Identifier**	**cobas** 8000 Core Unit: 05641446001 **cobas pro** sample supply unit: 08464502001 **cobas c** 513 analyzer commercial system: 07649142001
Production Identifier **(Product name/Product code)**	n/a
SW Version	**cobas** 8000 modular analyzer series: all versions **cobas pro** integrated solutions: all versions **cobas c** 513 analyzer commercial system: all versions
Type of Action	Field Safety Corrective Action

Dear Valued Customer,

Description of Situation

Roche has received one customer complaint for the **cobas** 8000 modular analyzer series where due to a software limitation the system stopped reading barcoded samples with loss of the Utility Settings. For **cobas pro** integrated solutions, two similar complaints have been received since launch.

Although no impact on patient results occurred, internal investigation revealed that for some settings under specific conditions, the occurrence of this situation may remain undetected and leads to deactivation of clotting and foam data flags. In case of poor sample quality, discrepant results may remain undetected due to absence of the associated data flags.

Trigger of this event is a very rare database timeout error, which impacts the settings stored on the SQL Server due to a software limitation. This can lead to a deactivation of some analyzer settings. Due to residual medical risk associated with this issue, customers using the affected products must be informed via FSN-CPS-2020-013.

Furthermore, this FSN describes how to identify this software limitation and provides a possible interim countermeasure for the customers.

Rare occurrence of changed configuration settings on certain systems

Actions to be taken by Roche Diagnostics

The described issue will be solved within **cobas**® 8000 modular analyzer series SW 06-08, **cobas pro** integrated solutions SW 02-01 and **cobas c** 513 analyzer commercial system SW 02-05. It is planned that the new SW versions will be available by Q3/2021.

Actions to be taken by the customer/user

Customers are advised to check regularly if the date is visible in the control unit software. Details are described in the attachment for each affected instrument.

This advice is valid until further notice. As soon as the aforementioned SW updates are available, we will update the communication.

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.

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

Rare occurrence of changed configuration settings on certain systems

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

Attachments

- Instructions FSN cobas® 8000
- Instructions FSN cobas pro
- Instructions FSN cobas c 513

cobas 8000

The affected settings

Affected important settings

Affected important settings	**Affected time**
Clot detection for ISE, c 502 and c 70x disabled	next operation starting from Standby
Foam detection for e 801 disabled	next operation starting from Standby

Table 1: Affected important settings

Detectability

1. The date is not displayed in the red rectangles shown in figure 1.

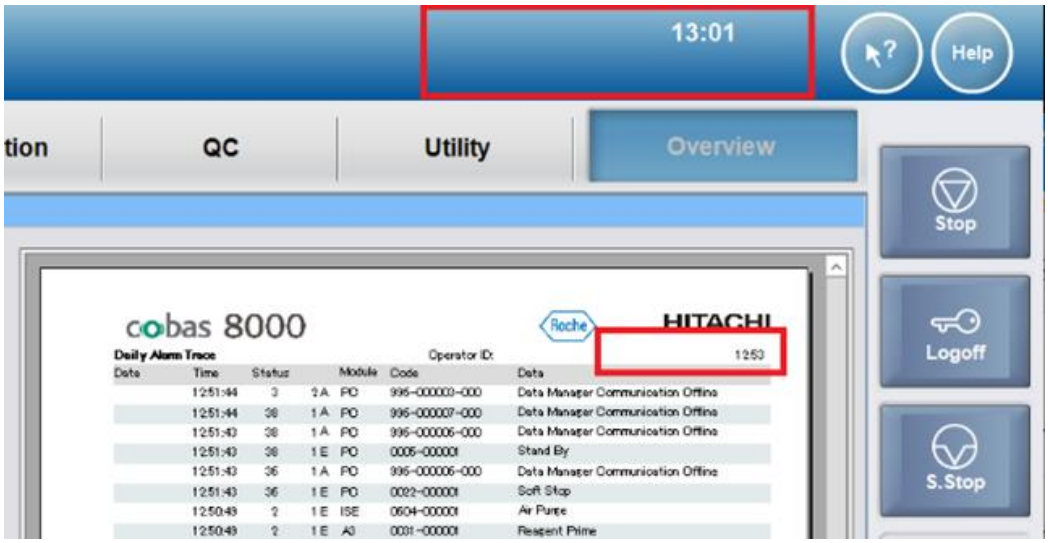


Figure 1: Date is not displayed in the red rectangles.

2. Newly loaded **barcoded** samples are not measured anymore and a system alarm (27-1 No Test Performed on Rack) is triggered.

Actions to be taken by the customers

Check if the date is displayed in the red rectangles shown in figure 1 before you click on the start button or at minimum on a daily basis. Whenever the date is not displayed, the software limitation has occurred on this instrument.

If the described software issue is present, stop the instrument by pressing the “Stop” button and call your Roche Service Representative for further instructions.

For systems running in sequence mode, it is recommended to measure those samples again which have been measured in the time frame from the issue occurrence until the instrument has been stopped.

In order to determine the estimated time when the issue occurred, follow the steps below:

1. Open the Print-History screen.

2. Search for the latest report which still displays the date in the red rectangle shown in figure 2. This is the estimated time before the issue occurred.

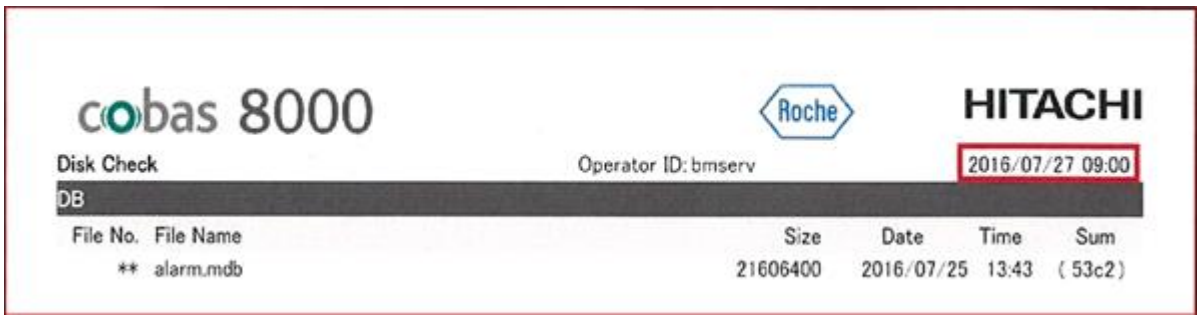


Figure 2: Report in Print- History

Note: For systems running in barcode mode, there is no need to rerun the barcoded samples which have been measured in the time frame from the issue occurrence until the instrument has been stopped, except those samples registered under Workplace- Test Selection- Barcode Read Error.

cobas c 513

The affected settings

Affected important setting

Affected important settings	**Affected time**
Sample probe 1 (S1) Clot Detection disabled (only active on system running Glucose)	next operation starting from Standby

Table 1: Affected important setting

Detectability

1. Date and Logon ID is not displayed in the red rectangles shown in figure 1.

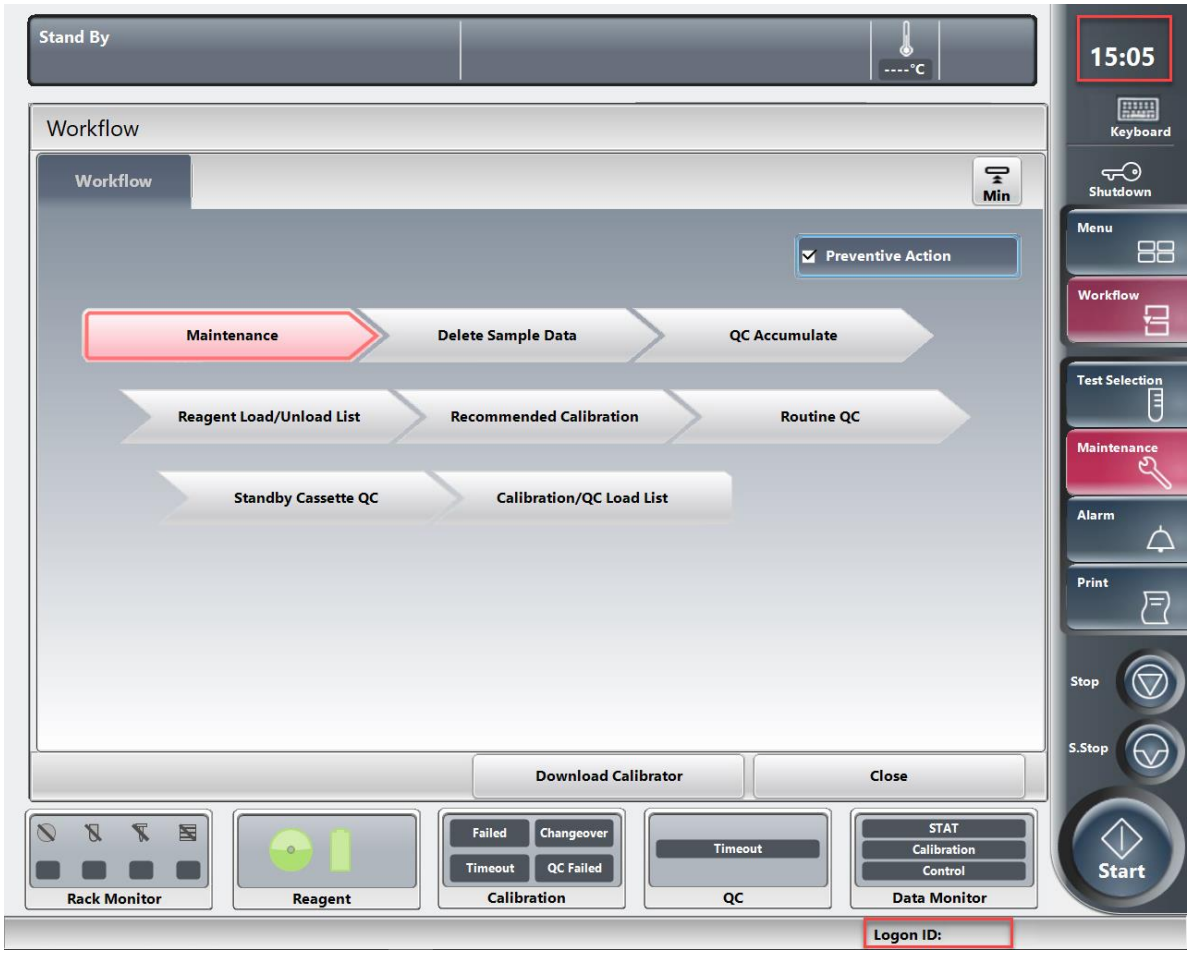


Figure 1: Date and Logon ID (in the red rectangles) is not displayed on the User Interface

2. System alarm 471-000001 without alarm name occurs.

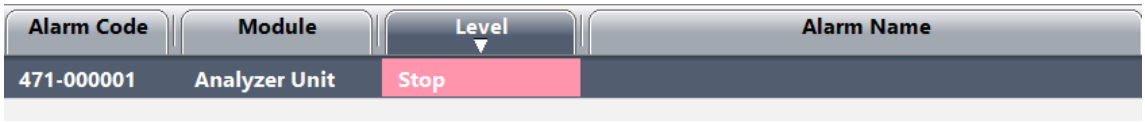


Figure 2: System alarm 471-000001 without alarm name

Actions to be taken by the customer

Check if the date is displayed in the red rectangle shown in figure 1 before you click on the start button or at minimum on a daily basis. Whenever the date is not displayed, the software limitation has occurred on this instrument.

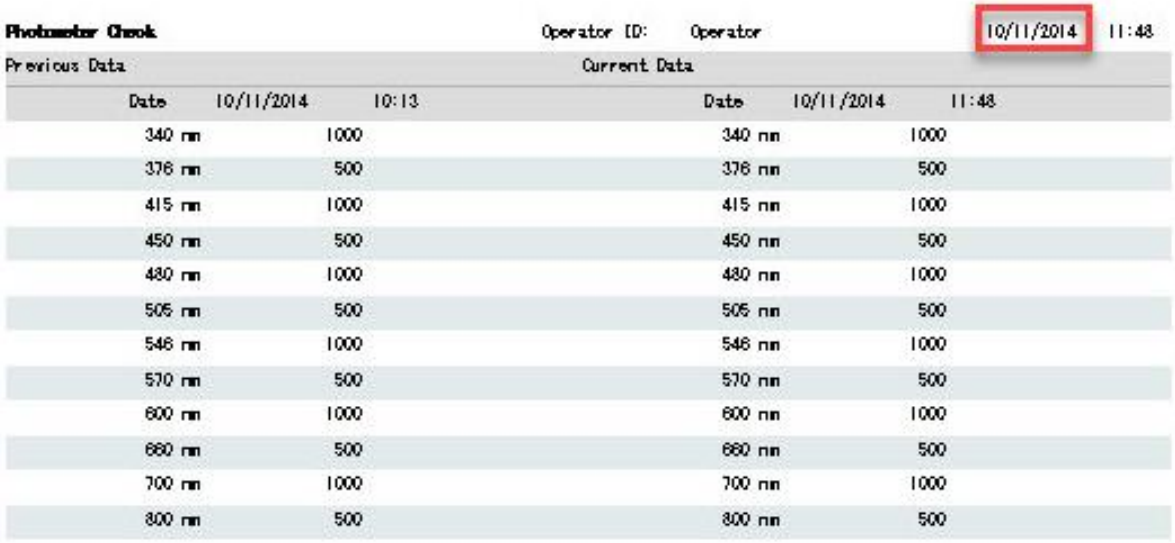
If the described software issue is present, stop the instrument by pressing the “Stop” button and call your Roche Service Representative.

For systems running in sequence mode, it is recommended to measure those samples again which have been measured in the time frame from the issue occurrence until the instrument has been stopped.

In order to determine the estimated time when the issue occurred, follow the steps as below.

1. Open the Print-History screen.

2. Search for the latest report which still displays the date in the red rectangle shown in figure 3. This is the estimated time before the issue occurred.



Photometer Check — Operator ID: Operator — 10/11/2014 11:48

Previous Data		Current Data	
Date	10/11/2014 10:13	Date	10/11/2014 11:48
340 nm	1000	340 nm	1000
376 nm	500	376 nm	500
415 nm	1000	415 nm	1000
450 nm	500	450 nm	500
480 nm	1000	480 nm	1000
505 nm	500	505 nm	500
546 nm	1000	546 nm	1000
570 nm	500	570 nm	500
600 nm	1000	600 nm	1000
660 nm	500	660 nm	500
700 nm	1000	700 nm	1000
800 nm	500	800 nm	500

Figure 3: Report in Print- History

For systems running in barcode mode, there is no need to rerun the barcoded samples which have been measured in the time frame from the issue occurrence until the instrument has been stopped, except the samples registered under Workplace- Test Selection-Barcode Read Error.

cobas pro

The affected settings

Affected important settings

Affected important settings	Affected time
Clot detection for ISE and c 503 sample probe disabled	next operation starting from Standby
Abnormal reagent aspiration for c 503 disabled	next operation starting from Standby
Foam detection for e 801 disabled	next operation starting from Standby
High altitude function disabled	next operation starting from Standby

Table 1: Affected important settings

Detectability

1. Message “The remaining sequence number … is 59999…” pops up on the start condition screen, when the start button is pressed.

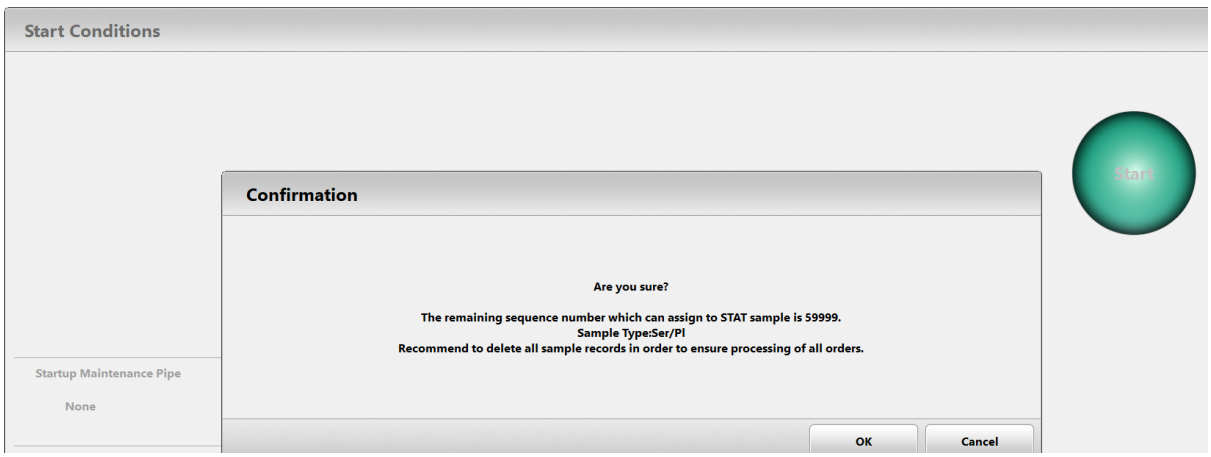


Figure 1: Pop-up message on the start condition screen

2. System alarms such as “Replace photometer lamp/ Reaction cells”, "Wash Sippers Flow Paths Recommendation" are issued, and countdown values in the red rectangles shown in

figure 2 become zero.

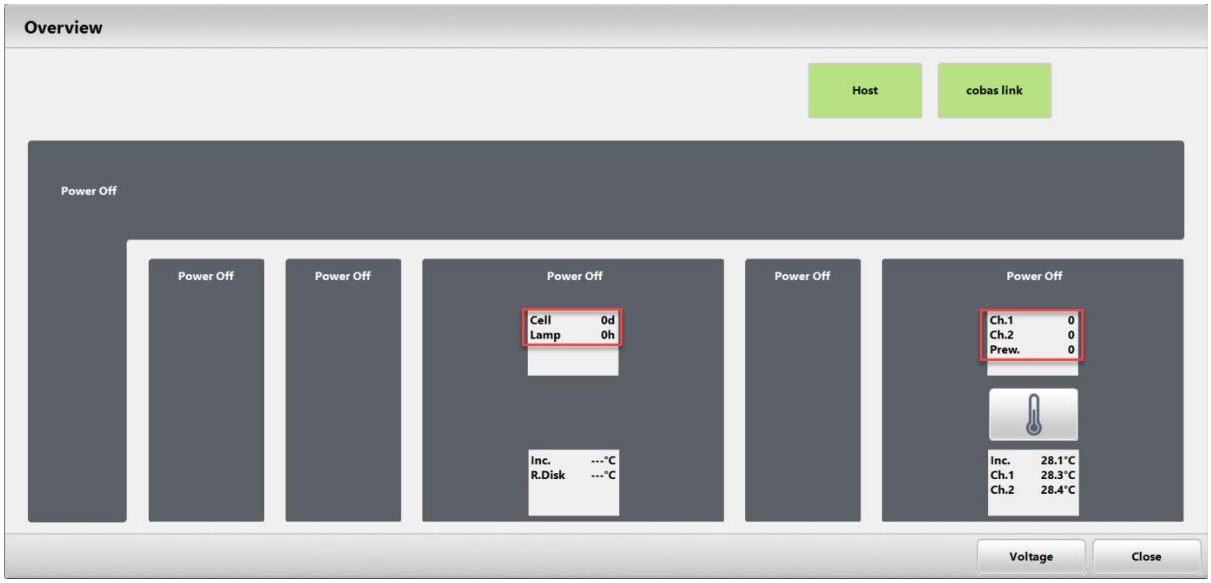


Figure 2: Overview screen with zero countdown values

3. The date is not displayed in the red rectangles shown in figure 3.

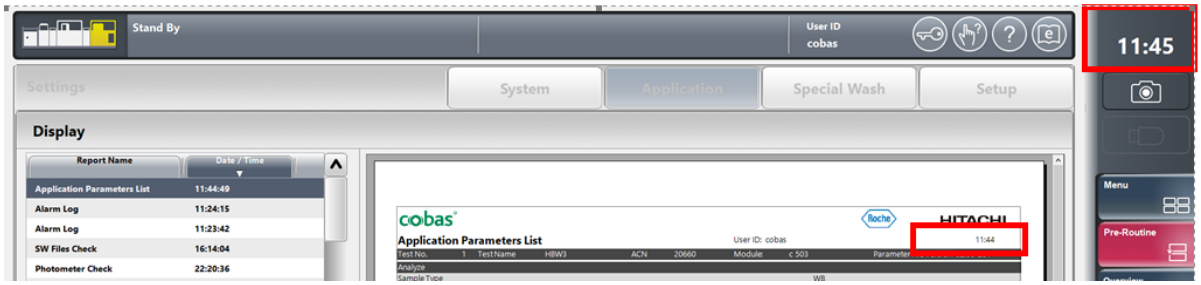


Figure 3: Date is not displayed in the red rectangles

Actions to be taken by the customers

Check if the date is displayed in the red rectangles shown in figure 3 before you click on the start button or at minimum on a daily basis. Whenever the date is not displayed, the software limitation might have occurred on this instrument.

If the described software issue is present, stop the instrument by pressing the “Stop” button and call your Roche Service Representative.

For systems running in sequence mode, it is recommended to measure those samples again which have been measured in the time frame from the issue occurrence until the instrument has been stopped.

In order to determine the estimated time when the issue occurred, follow the steps below.

1. Open the Report-Display screen.

2. Search for the latest report which still displays the date in the red rectangle shown in figure 4. This is the estimated time before the issue occurred.

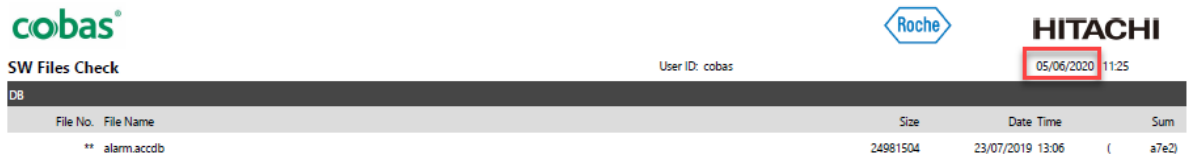


Figure 4: Report in Report- Display screen

For systems running in barcode mode, there is no need to rerun the barcoded samples which have been measured in the time frame from the issue occurrence until the instrument has been stopped, except the samples registered under Routine- Order Tests-Barcode Read Error.