

Urgent Field Safety Notice



SBN-CPS-2020-013

RDS / Core Lab / Serum Work Area Systems

Version 2

March 2021

Rare occurrence of changed configuration settings on certain systems

| | |
|--|---|
| Product Name | cobas pro [®] sample supply unit cobas [®] 8000 Core Unit cobas c 513 analyzer |
| System | cobas pro integrated solutions cobas 8000 modular analyzer series cobas c 513 analyzer |
| GMMI / Part No Device Identifier | cobas pro sample supply unit: 08464502001 cobas 8000 Core Unit: 05641446001 cobas c 513 analyzer: 07649142001 |
| Production Identifier (Product name/Product code) | n/a |
| SW Version | cobas pro integrated solutions: version 02-01 Modification code: S_S22021/010Q pro_SW_02-01 cobas 8000 modular analyzer series version 06-08 Modification code: S_AG2021/024Q Install cu 06-08& dm 1.06.09 cobas c 513 analyzer version 02-05 Modification code: S_AW2021/023Q SW 02-05 |
| Type of Action | Field Safety Corrective Action |

Dear Valued Customer,

Description of Situation

We previously notified you of a very rare issue where, due to a software limitation, the instrument stopped reading barcoded samples with loss of the utility settings. Refer to the list of systems above for affected instruments.

With version 2 of this notification, we are pleased to inform you that the software solutions to resolve this issue are on track and will be rolled out over the coming weeks. With these updates the software limitation is resolved; barcoded samples can be processed without a loss of the Utility Settings.

The updates are expected to be available according to the time frames in Table 1 below:

| System | Software Version | Planned release |
|---|------------------|-----------------|
| cobas pro integrated solutions | 02-01 | March 2021 |
| cobas 8000 modular analyzer series | 06-08 | June 2021 |
| cobas c 513 analyzer commercial system | 02-05 | June 2021 |

Table 1: Availability of software updates

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After the installation of the respective software update, the precautions described in FSN-CPS-2020-013 version 1 are no longer needed for the affected systems.

The update will be performed by Roche field service engineers.

Actions to be taken by Roche Diagnostics

The described issue will be resolved after installation of the corresponding software versions (refer to the software release dates in Table 1).

The updates will be released after completion and documentation of the verification activities.

The update for all three systems will be performed by Roche field service engineers and is planned to be completed in 2022.

Actions to be taken by the customer/user

Until the software update has been completed, please continue to regularly check if the date is visible in the control unit software. Instrument-specific instructions were provided in the attachments to version 1 of FSN-CPS-2020-013.

The described precautions can be lifted for each system after completing the software update.

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>,

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Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com