

Urgent Field Safety Notice



SBN-CPS-2020-013

RDS / Core Lab / Serum Work Area

Systems

Version 3

February 2023

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 8000 modular analyzer series version 06-09: Modification code S_AG2022/003Q Install cu 06-09& dm 1.06.10 v06-09 cobas 8000 modular analyzer series version 06-10 Modification code S_AG2023/012Q Install CU 06-10 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.

Recently, we received feedback from the customers regarding several technical issues with versions 06-08 and 06-09. Although those issues are convenience only, without safety impact, we would like to inform you about the upcoming software update 06-10, which will be available from May 2023.

With this FSN, we want to reinforce that both updates – 06-08 and 06-09 – fix the software limitation; barcoded samples can be processed without a loss of the Utility Settings. Customers experiencing configuration and other technical issues with these SW versions are advised to update to the version 06-10 as soon as available.

For **cobas pro** integrated solutions and for **cobas c** 513 the measures and actions described in the previous versions of this FSN remain valid.

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.

Rare occurrence of changed configuration settings on certain systems



The update will be performed by Roche field service engineers.

Actions to be taken by Roche Diagnostics

The issue described in this Field Safety Notification **was resolved** after installation of one of the software versions 06-08 **or** 06-09. **To address technical issues with both versions 06-08 and 06-09, SW version 06-10** will be available in May 2023.

The updates will be performed by Roche field service engineers and are planned to be completed **by the end of 2023**.

Actions to be taken by the customer/user

Until the software update of the respective systems 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 attachment to SBN-CPS-2020-013 v1.

The described precautions can be lifted for each system after completing the software update version 06-08, 06-09 **or 6-10**. All actions for customers were described in the previous versions of the FSN-CPS-2020-013.

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

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com