

Urgent Field Safety Notice

SBN-CPS-2017-011

CPS / cobas 4000
Version 1
21-Jun-2017

cobas e 411 analyzer: Software malfunction in the database

Product Name	cobas e 411 analyzer (disk system) (GMMI 04775279001) cobas e 411 analyzer (rack system) (GMMI 04775201001)
Product Description	cobas e 411 analyzer for Immuno Chemistry
GMMI / Part No	cobas e 411 analyzer (disk system) (GMMI 04775279001)
Device Identifier	cobas e 411 analyzer (rack system) (GMMI 04775201001)
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that in very rare cases a software (SW) malfunction in the Sample&Control datafile can occur which may lead to a potential data mismatch. This SW malfunction only occurs:

- when the “Sample Data Clear” function is not performed daily as indicated in the Operator’s Manual, and
- when the Sample&Control datafile of the **cobas e 411** analyzer is filled with ≥ 2000 records.

All tests that are run on **cobas e 411** are potentially affected whereas the impact of the data mismatch cannot be predicted. Roche has received a total of four customer complaints for this issue.

The following alarms **should** be triggered by the SW and the “Sample Data Clear” tab in the “System Overview screen” **should** change its color as followed:

- When 1900 records are stored in the Sample&Control datafile -> **yellow** alarm; color changes from blue to yellow.
- When 2000 records are stored in the Sample&Control datafile -> **red** alarm; color changes from yellow to red.

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The alarms don't prevent the operator from ordering new samples. Please consider the counter does not always work correctly, however it doesn't cause a potential data mismatch.

Actions taken by Roche Diagnostics (if applicable)

The manufacturer Hitachi High Technologies Corporation (HHT) has confirmed this malfunction of the system. HHT will immediately start to fix this error in the Sample&Control datafile, with a new software version. This new software will prevent samples from being ordered and run on the **cobas e 411** analyzer when the Sample&Control datafile is full.

Distribution of the next software version is planned for Q4/2017. You will be informed accordingly.

Actions to be taken by the customer/user

The customer is advised to perform the following actions until the new SW has been installed:

- *Perform a "Sample Data Clear" daily*
"Sample Data Clear" is step no. 2 in the Work Flow Guide in the System Overview window
Please note:
A Sample Data Clear deletes all sample records and moves QC data to the QC view. It is recommended to perform the backup procedure on a regular basis, depending on data volume and the regulations at customer site. If your system is connected to a host, make sure that all data has been uploaded before performing a sample data clear.
- *When the new SW version is available it will be installed as a mandatory update to the system.*

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.

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:

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.

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Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com