Urgent Field Safety Notice
SBN-CPS-2016-015

CPS / ClinChem fully automated
Version 1
14-Sep-2016

Measurement Timing Error 7002: 108000572

Product Name	**cobas c** 111 analyzer **cobas c** 111 analyzer with ISE
Product Description	**cobas c** 111 analyzer
GMMI / Part No **Device Identifier**	04528778001 **cobas c** 111 analyzer 04777433001 **cobas c** 111 analyzer with ISE
Production Identifier **(Lot No./Serial No.)**	All instruments with respective software version.
SW Version	All software versions **up to and including**: · 3.0.3 · 4.1.0 · 4.2.0
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

We would like to emphasize the importance of following the here given instructions in case the described software error occurs in order to avoid potentially erroneous results. A final solution will be provided with fixed SW versions in Q4/2016.

Description of Situation

We have become aware of a software issue that may lead to erroneous results on **cobas c** 111 analyzer (without ISE unit) in very rare cases. **cobas c** 111 analyzer with ISE unit are not affected as long as the ISE is in status 'Ready'. To date, no field issue has been reported where the identified software error actually produced wrong results.

Under very rare constellations of already used and unused cuvettes remaining on the **cobas c** 111 analyzer rotor a measurement timing error "7002: 108000572 A software error occurred" might be produced. Immediately after occurrence of the error all ongoing tests are stopped. Depending on open test orders the system might restart processing using an already consumed cuvette and hence, producing a potentially erroneous result.

We have identified measures to ensure the detectability for measurements that may have yielded erroneous results.

Measurement Timing Error 7002: 108000572

The measures are described below. Final solutions will be provided with fixed SW versions respecting the different hardware configurations in the field.

Actions taken by Roche Diagnostics

Software versions where the issue is solved will be made available in Q4/2016.

Actions to be taken by the customer/user

In case the alarm LED shines red / the alarm button on the right hand side of the analyzer becomes red, the operator has to act as described in the operator's manual (section, Reacting to alarm messages).
Whenever the here reported error "7002: 108000572 A software error occurred" is listed in the message list the following procedure shall be applied:

- Watch alarms indicated by the red alarm LED/alarm button on the instrument carefully (see Attachment 1)
- Once the alarm LED shines red / the alarm button becomes red, the alarm code needs to be identified and if the timing error 7002: 108000572 occurred the workaround as described in Attachment 1 must be started
- Results run after the timestamp of the error 7002: 108000572 should be questioned and a re-run should be considered

For further explanation and illustration see Attachment 1.

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.

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.

Best regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com