

Field Safety Notice

SBN-CPS-2016-015

CPS / ClinChem fully automated
Version 1
15-Sep-16

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 <u>up to and including</u> : • 3.0.3 • 4.1.0 • 4.2.0
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

With reference to QN-CPS-2016-201 version 1 (Prevent Measurement Timing Error 7002: 108000572), 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' mode. To date, no field issue has been reported where the identified software error produced wrong results.

When a run is started as a first action, the instrument checks the number of free cuvettes and its location around the rotor. In addition, a check is performed to determine whether the number of free cuvettes is sufficient for the scheduled run. If there are sufficient free cuvettes available, the run is started. Otherwise, the operator is requested to replace used cuvette segments.

In very rare instances where a certain mixture of used and free cuvettes on the **cobas c** 111 analyzer rotor may lead to a measurement timing error "7002: 108000572 A software error occurred" might be produced. The occurrence of the error will cease all ongoing tests. However, depending on the open test orders, the system may reschedule an aborted test in a used cuvette, producing a potentially erroneous result.

Measurement Timing Error 7002: 108000572

We have identified measures to ensure the detectability for measurements that may have yielded erroneous results. The measures are described below. Resolution will be in the next software version, which will be available in Q4/2016.

Actions taken by Roche Diagnostics

Software versions that resolve the issue will be available in Q4/2016.

Actions to be taken by the customer/user

When the alarm LED shines red / the alarm button on the right side of the analyzer becomes red, the user has to act as described in the operator's manual (section, Reacting to alarm messages).

If the measurement timing error "7002: 108000572 A software error occurred" appears in the message list, the following procedures should be carried out:

- Look for alarm LED / alarm button that appears red (Refer to Attachment 1)
- Once this is observed, identify the alarm code. If the timing error 7002: 108000572 has occurred, the workaround solution described in Attachment 1 needs to be initiated.
- Results obtained after the timestamp of the error 7002: 108000572 should be reexamined and a re-run should be considered

For further explanation and illustration, please refer to Attachment 1.

Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche.com

Attachment 1 to “Measurement Timing Error 7002: 108000572”

D) Identification of the Timing Error:

In case the LED shines red / the alarm button on the right hand side of the instrument becomes red (Fig. 1 / 1.1), the operator has to act as described in the respective operator's manual (section 'Reacting to alarm messages').

Example for instruments with old types of displays

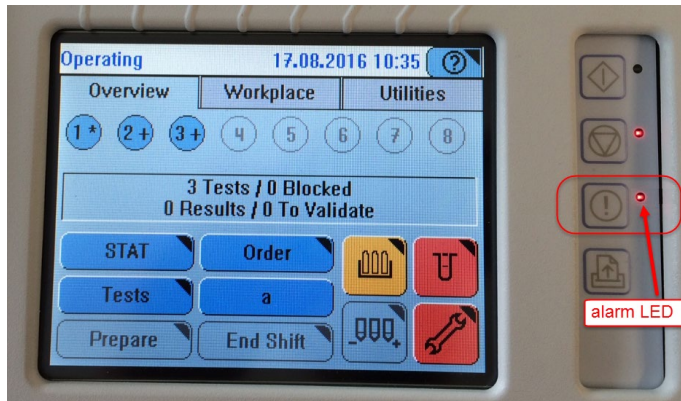


Fig 1: General overview of the display, global action buttons and LEDs.

Example for instruments with an 8.4” display

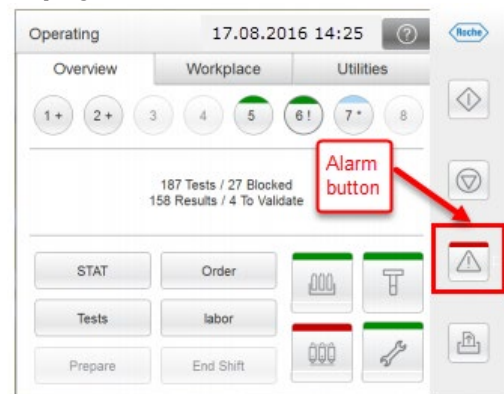


Fig 1.1: General overview of the display and global action buttons.

The timing error is indicated by the alarm code “7002: 108000572” incl. its timestamp:

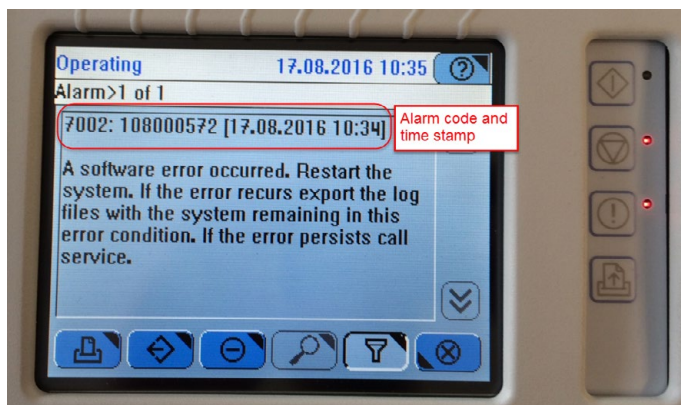


Fig 2: Detailed alarm message on instruments with old screen versions.

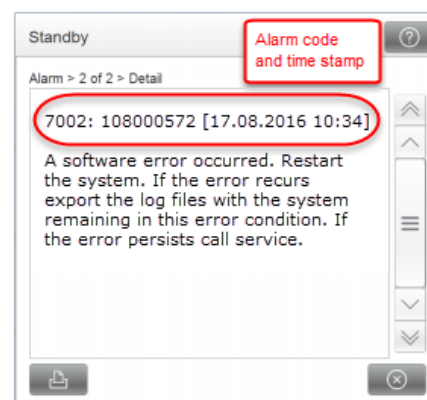


Fig 2.1: Detailed alarm message on instruments with 8.4” displays.

II) Actions to be taken by the Customer / User:

Whenever the here reported error “7002: 108000572 A software error occurred” (Fig 2 / 2.1) is listed in the message list the following procedure shall be applied:

1. Review the timestamp of the error message (see Fig 2 / 2.1)
2. Review the samples being processed since that exact time (Fig. 3 and 4 / 3.1 and 4.1)

All samples processed since this time stamp need to be re-measured.

In this example:

- the time stamp of result generation of sample 11 GLU2 is 10:46
- the error occurred at 10:34
- the result of 0.61 mmol/L for GLU2 might be affected and should be re-tested

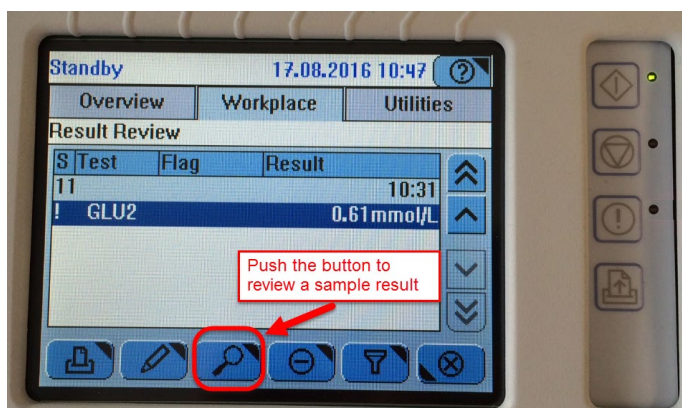


Fig 3: Result Review window on instruments with old screen versions.

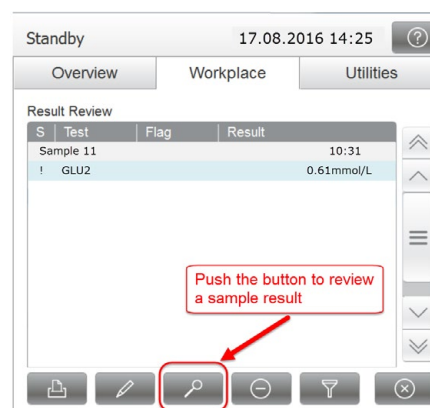


Fig 3.1: Result Review window on instruments with 8.4” displays.

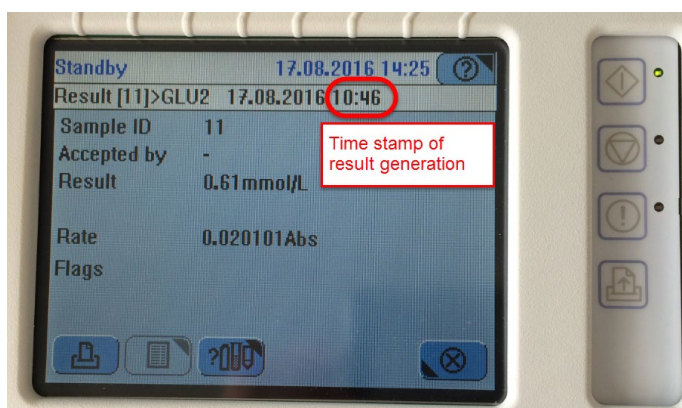


Fig 4: Review the time stamp of a sample result.

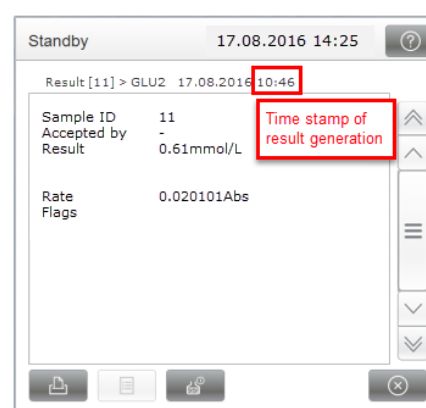


Fig 4.1: Review the time stamp of a sample result on an 8.4” display.

3. Restart the system
4. Re-measure all the tests of respective samples in order to guarantee absence of potentially erroneous results