

Urgent Field Safety Notice

SBN-CPS-2017-008

CPS / Laboratory Integration
Version 2
25-May-2017

cobas® connection modules (CCM) – Output Unit Rack vibration during transport

Product Name	OUTPUT UNIT
Automation System	cobas® connection modules (CCM)
GMMI / Part No Device Identifier	07667574001
Production Identifier (Lot No./Serial No.)	All Serial Numbers
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

After the initial complaint previously informed by the first version of this notice an additional complaint from the same customer was received reporting that the adjustment procedure provided to address the rack vibration issue on the Output Unit was performed and decreased the rack vibration. However it was subsequently identified that it did not completely solve the issue at this customer. The rack vibration can be easily visually detected by the operator of the Output Unit.

Internal investigation showed that the main factor which may cause the rack vibration is a gap between the conveyor belt and the rack tray table (plastic part). There are, however, additional factors that may contribute to the issue as the leaning of the rack into the guide rail and the friction between the tray table and the rack.

While no complaints of sample carry over have been received, cross-contamination caused by spillage can lead to erroneous increased/positive results; whereas the extent of bias cannot be assessed. Considering the poor detectability of the sample cross-contamination, and the unknown extent of erroneous results, relevant medical risk cannot be entirely excluded.

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Actions taken by Roche Diagnostics

As a workaround, an adjustment procedure is available which must be implemented on all Output Units by a Roche Field Service Representative.

Additionally, a modification kit is currently being developed and planned to be released by September 2017 to address the issue.

Actions to be taken by the customer/user

If you identify that your unit is affected by the rack vibration and the samples are required for further processing, the unit should not be used until the Roche Field Service Representative performs the adjustment procedure. If the rack vibration persists, samples coming from the affected output position must not be used for further processing until implementation of the modification kit. Potentially affected sample tubes must be discarded according to local guidance.

Once the modification kit is available, implementation is mandatory.

Communication of this Field Safety Notice

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.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com