Field Safety Notice

SBN-CPS-2017-008

CPS / Laboratory Integration
Version 1
02-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 Affected parts are not available in Singapore
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

One complaint was received referring to 5 position racks at the Output Unit were not being smoothly pushed out into the tray, possibly leading to spilling of the sample tube material. After internal investigation it was observed that a gap between the conveyor belt and the rack tray table (plastic part) may cause vibration of the 5 position racks during the transport. The rack vibration can be easily visually detected by the operator of the Output Unit.

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

An adjustment procedure which solves this issue is already available. All systems affected will be adjusted by a Roche Field Service Representative.

Actions to be taken by the customer/user

If a customer identifies their 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. Potentially affected sample tubes must be discarded according to local guidance.

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 other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Sincerely,

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