

Urgent Field Safety Notice

SBN-CPS-2017-003

CPS / Laboratory Integration
Version 1
20-Feb-2017

cobas[®] 8100 BRF and URF with Software Version 02-xx: Buffering May Cause Specimen Spillage

| | |
|---|--|
| Product Name | cobas [®] 8100 automated workflow series |
| Product Description | BRF for cobas [®] 8100 URF for cobas [®] 8100 |
| GMMI / Part No | BRF for cobas 8100 GMMI 07439954001 |
| Device Identifier | URF for cobas 8100 GMMI 07441657001 |
| Production Identifier (Lot No./Serial No.) | Not applicable |
| SW Version | Software version 02-xx |
| Type of Action | Field Safety Corrective Action (FSCA) |

Dear Valued Customer,

Description of Situation

We regret to inform you that a rack crash may occur on the cobas[®] 8100 reformatter modules URF and BRF with software versions 02-xx. This can only occur, if rack buffering is activated and the rack buffer is completely full. To solve this issue, it is mandatory to upgrade the system software to version 03-01 onwards until June 30, 2017.

As a workaround, rack buffering has to be deactivated until the software is upgraded.

Depending on local regulations, the workaround can be applied by a Roche Service Representative either on-site or remotely, or by an authorized operator (instructions see below).

Root cause:

This issue is caused by an incorrect mechanical control sequence based on a limitation in software versions 02-xx.

This issue has led to sample spillage, posing a potential risk to involved operators / laboratory staff due to exposure to potentially infectious material. However, relevant medical risk for trained operators is unlikely, since the appropriate handling of sample spillage is described in the operator's manual.

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This issue can also lead to cross-contamination of samples in the affected racks. Further processing of contaminated samples can lead to erroneous results due to sample carry-over. Since cobas[®] 8100 can be used with different analyzers (clinical chemistry, immunology, coagulation, urine analysis and hematology), erroneous increased / positive results because of the sample carry over can occur in any of these areas, whereas the extent of bias cannot be assessed. Considering the poor detectability of the sample cross-contamination, and unknown extent of erroneous results, relevant medical risk cannot be entirely excluded.

Actions taken by Roche Diagnostics (if applicable)

To solve this issue Roche will release the software version 03-01. There is an immediate mandatory workaround that ensures that this system failure cannot occur. The rack buffering option in all BRF and URF modules is required to be disabled until the software version 03-01 is installed.

Actions to be taken by the customer/user

In case of major spillage on the cobas[®] 8100, affected modules should be set offline. A Roche Service Representative should check and clean the modules before they can return to routine operation (see Operator's Manual V2.6, "Major spillage"). Affected samples / racks should be carefully inspected. If cross-contamination cannot be excluded, affected samples should be handled according to local regulations incl. the decision whether previously generated results should be reviewed.

The rack buffering for all BRF and URF modules is required to be disabled in the configuration of the Control Unit, until software version 03-01 is installed. Once version 03-01 is installed the rack buffering for all BRF and URF modules can be re-activated.

Depending on local regulations, the workaround can be applied by a 1) Roche Service Representative either on-site or remotely, or 2) by an authorized operator (instructions see below):

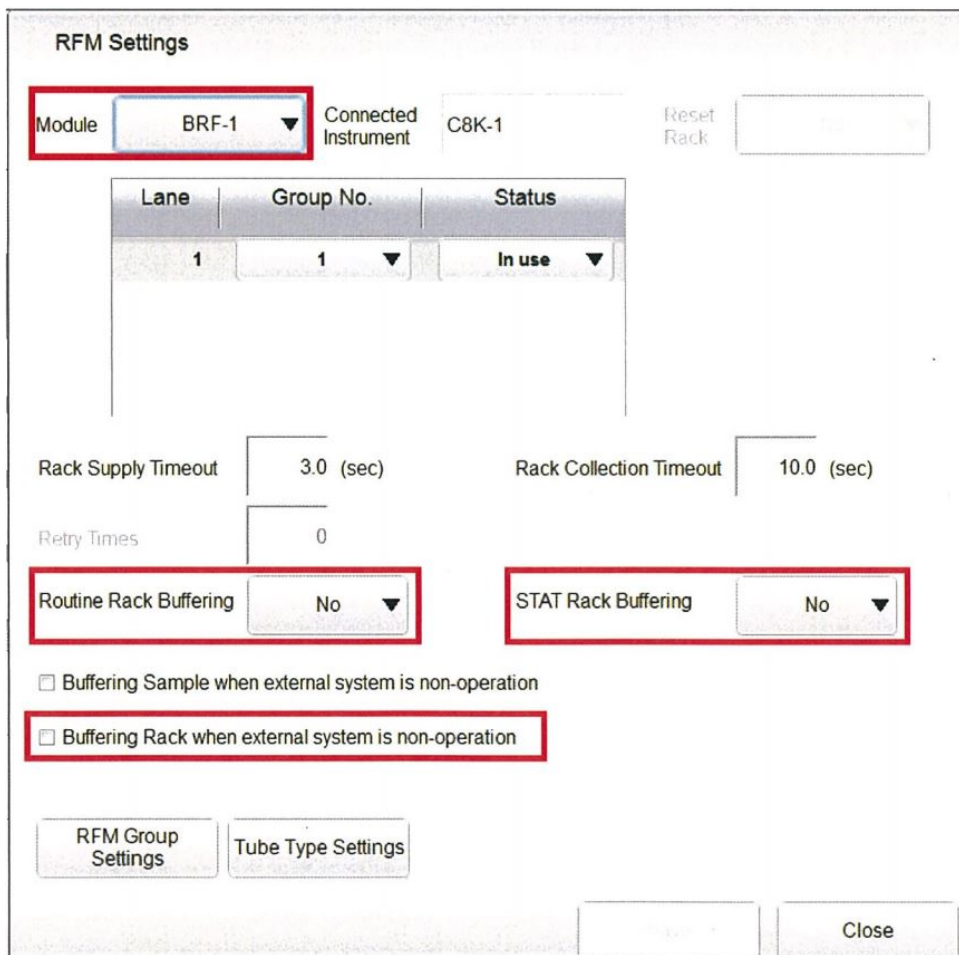
If 1) applies: Please contact Roche Diagnostics for further steps [if applicable add local contact details].

If 2) applies: If you are an authorized operator please follow the workaround as stated below:

To prevent this issue, rack buffering has to be deactivated until the software is upgraded to version 03-01 onwards. Please refer to the following procedure to disable rack buffering:

- Open the RFM Setting Screen.
- Choose BRF and URF from the pull-down menu for "Module".
- Set "Routine Rack Buffering" to "No".
- Set "STAT Rack Buffering" to "No".
- Uncheck "Buffering Rack when external system is in non-operation".
- Press "Save" button.
- Repeat steps 2 to 6 for all connected BRF and URF modules.
- Reboot the system.

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RFM Settings

Module: **BRF-1** Connected Instrument: C8K-1 Reset Rack: []

| Lane | Group No. | Status |
|------|-----------|--------|
| 1 | 1 | In use |

Rack Supply Timeout: 3.0 (sec) Rack Collection Timeout: 10.0 (sec)

Retry Times: 0

Routine Rack Buffering: **No** STAT Rack Buffering: **No**

Buffering Sample when external system is non-operation

Buffering Rack when external system is non-operation

[RFM Group Settings] [Tube Type Settings] [] [Close]

(Fig 1: English version of screen)

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.

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The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: 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