Urgent Field Safety Notice

Notice Ref No:	***FSN_SB_RPD_2013_04***
Document Date:	**dd-mmm-2013**

PRODUCT AFFECTED:	**<control unit software>**
SYSTEM AFFECTED:	**<cobas 8000 modular analyzer series configurations which include cobas e 602 module>**
MATERIAL NUMBERS:	**See list below**
LOT NO (IF APPLICABLE):	**n/a**
SUMMARY OF ISSUE:	**An incorrect diluent may be used under certain circumstances when using automatic dilution on cobas e 602 module**
ACTION REQUIRED:	**Please follow the described workaround**
CONTACTS:	**Technical Services:** **Country:**

Products affected:
cobas 8000 modular analyzer series, control unit software versions 02-02 / 03-01 / 03-02 / 03-03 / 03-04:

SW version	GMMI No:
02-02	05846480001
03-01	06323600001
03-02	06450873001
03-03	06733794001
03-04	06912435001

Reason for notice:

To inform about a software bug leading to the possibility that an incorrect diluent may be used under certain circumstances when using automatic dilution on **cobas e** 602

module.

Dear Customer,

We regret to inform you that due to a software bug on the **cobas** 8000 modular analyzer series an incorrect diluent may be used under certain circumstances when using automatic dilution on **cobas e** 602 module.

In order that this happens, the following conditions must be fulfilled simultaneously:

- More than a total of 2000 reagents kits or diluents had been registered on the **cobas e** 602 modules within one configuration.
- Two or more different diluent types are available on board in parallel (e.g. Diluent Universal and Diluent MultiAssay).
- A different type of diluent (e.g. Diluent Universal) had been previously registered in the database with the identical key information as the current diluent of another type (e.g. Diluent MultiAssay). As an example, Diluent Universal had been registered with a specific key information (e.g. “55”: 1-2000 are possible) and 2000 reagent kits later (once the 2000 key information had been exceeded in the data base) the specific key information of “55” had been assigned to Diluent MultiAssay.

The root cause has been clearly identified and the problem will be fixed in the upcoming control unit software version 04-01.

Actions required:

Meanwhile, please follow the following workaround whenever a new diluent reagent pack for the cobas e 602 module is placed on board in case that more than one diluent type is used:

Check the assays listed as suitable for the newly placed diluent pack in Overview / Reagent Overview / Detail (see attachment cobas e 602 screen.pptx).

Each diluent package contains a note that informs which assay can be (auto-) diluted with the respective diluent (see attachment note diluent universal.pdf and diluent multiassay.pdf).

Compare the assays listed in the note and in the screen mentioned above.

If the assays listed in the note and on the screen match completely, there is no problem and no further action required.

If the assays listed in the note and on the screen differ (e.g. if TSH is listed for Diluent Universal instead of Diluent MultiAssay), following actions are required:

- Replace the diluent pack (which has more assays listed in the screen than in the note) by another diluent pack of the same lot. Please make sure afterwards

that the assays listed in the note and on the screen matches.

- If the assays listed in the note and on the screen still don’t match, it would be then necessary to replace this diluent pack by a diluent pack of a different lot.

- If no other diluent lot is available then in that case only one type of diluent pack (e.g. only Diluent Universal) must be placed in the reagent disk of the cobas e 602 module. As a consequence, manual dilution is required for all assays using a different diluent type.

We apologize for any inconvenience caused by that issue.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency (Closing paragraph)
Signature

Attachments:

<Supporting data>