

Urgent Field Safety Notice

Notice Ref No:	FSN RPD 11/2011
Document Date:	25. October 2011
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	Accu-Chek Inform II
SYSTEM AFFECTED:	Accu-Chek Inform II meter Accu-Chek Inform II meter with RF-card
MATERIAL NUMBERS:	05060311011 05060303001
SOFTWARE VERSION:	03.02.01 and 03.03.00
SUMMARY OF ISSUE:	Unexpected behavior noticed with Accu-Chek Inform II meters configured to allow to add new patient ID
ACTION REQUIRED:	Update to new software version necessary
CONTACTS:	Your Roche Representative

Dear Accu-Chek Inform II customer,

With this letter, we apologize for any inconvenience caused with the matter described herein, and inform you about the matter that led to this Urgent Field Safety Notice.

Background information

Roche has recently received one complaint concerning Accu-Chek Inform II meters with software versions 03.02.01 or 03.03.00 showing a problematic behavior when configured to allow the operators to add new patient IDs.

The problematic behavior is seen **only** with SW 03.02.01 and 03.03.00 and **only** when following settings have been chosen in the data management system used in your hospital, like the cobas IT 1000 application:

- Patient ID Validation: "List - allowed to add new"
- Patient Entry: all possible entry modes are affected

Scanning a new patient ID via Barcode scanner will lead the Accu-Chek Inform II meter to suggest a patient ID that was previously used. The operator has then the possibility to accept or reject the suggestion. In case no previous entry exists, a measurement will still be possible, but the result is displayed and transferred to the data management system without patient ID.

Affected Accu-Chek Inform II meters

Only Accu-Chek Inform II meters available in the market, which have been recently upgraded to software version 03.02.01 or 03.03.00, might be affected. Accu-Chek Inform II meters with software version 03.01.01 or lower are not affected. Also, newly produced and shipped Accu-Chek Inform II meters are not affected because these are still being produced with software version 03.01.01.

Affected Customers

Customers affected are only those who have installed software version 03.02.01 or 03.03.00, and configured the data management system, like the cobas IT 1000 application to use the following specific setting:

- Patient ID Validation: "List - allowed to add new"
- Patient Entry: all possible entry modes are affected

Occurrence Rate

According to information available to Roche at time of writing, the problematic behavior relating to displaying test results and to transferring these to the respective data management system without patient ID or under the patient ID of a different patient has been observed only one time on a worldwide basis. In this case, the problematic behavior did not result in a wrong clinical decision.

Implications

In the worst case, there is remote probability that the issue will cause medically reversible or transient adverse health consequences as the issue can lead to false treatment (e.g. with insulin) based on results of a different patient.

Root Cause

Root Cause analysis is ongoing.

The investigation so far has shown the problematic behavior only when using the barcode scanner as an entry method and if the scanned patient ID is not available on the list of the meter. Scanning such a patient ID will lead the meter to suggest the previous patient ID (in case available in the meter), which either can be accepted or rejected. If there was no previous entry a measurement will still be possible, however the result will be recorded without the new patient ID.

Solution and Prevention

As consequence of the one case reported, a new software update has been issued to resolve the problematic behavior described in this Urgent Field Safety Notice. Upon availability of this new software version, all Accu-Chek Inform II meters with either software version 03.02.01 or 03.03.03 have to be updated. Respective information will be made available by your Roche representative in due course. If you do not already have contact details, visit our website on www.roche.com. Select "Roche Worldwide" at the top of the page and then select your country to find the appropriate local office contact information.

Until the availability of this new software update, you are not allowed to upload Accu-Chek Inform II meters with software version 03.02.01 or 03.03.00.

If you have already upgraded your Accu-Chek Inform II meter to software version 03.02.01 or 03.03.00, use any patient ID validation method but the following:

- Patient ID Validation: "List - allowed to add new"
- Patient Entry: all possible entry modes are affected

In case measurements need to be run for unknown patients, you are advised to use the patient ID validation mode "lengths" for the time being.

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

Signature