

Urgent Field Safety Notice – Update 1

Notice Ref No:	FSN RPD 19/2010
Document Date:	9. February 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 + RF
MATERIAL NUMBERS AND LOT NO:	05060311011 (< serial no. UU12500419) 05060303001 (< serial no. UU12500419)
SUMMARY OF ISSUE:	Unintended measuring unit switch from mmol/L to mg/dL
ACTION REQUIRED:	Update to new software version necessary
CONTACTS:	Technical Services: Country:

Dear Accu-Chek Inform II customer,

With this letter, we apologize for any inconvenience that this problem may cause and inform you about the matter that led to this Urgent Field Safety Notice.

Background information

There is the rare possibility of an automatic configuration switching that can occur with Accu-Chek Inform II meters. This switching results in a change of measurement units from mmol/L to mg/dL.

Affected customers

This automatic configuration switching was observed only with customers using the measurement unit mmol/L. Nevertheless, all customers may be potentially affected.

Thus, all Accu-Chek Inform II meters (with serial number lower than UU 12500419) have to be updated with a new meter software version, especially at customers where reading is used in mmol/L.

Occurrence Rate

According to information available to Roche at time of writing, the automated unit switch has been observed only two times on a worldwide basis. In both cases observed, the automatic configuration change did not result in a wrong clinical decision.

Implications

In a worst case scenario, for a patient presenting with a severe hypoglycaemia, the device would display a mg/dL result in the 2-digit range (e. g. 25) which could mistakenly be interpreted as a high mmol/L-glucose value. As a clinical consequence insulin may be injected instead of administering carbohydrates which would worsen the hypoglycaemia.

Root Cause

An investigation of potential failures of the meters revealed that a loss of flash memory in the database of the meter may lead to the error reported about by two customers. In this case, the meter software may load the manufacturer's default configuration to keep the instrument working and no error message may be generated. Also, in the default configuration there would not be a request for user authentication and the results were displayed in mg/dL.

Solution and Prevention

As consequence of the two cases reported and the consecutive analysis, additional preventive measures were implemented in a new meter software version to prevent unintended unit switch by using the customer's settings as the default value for the situation that the meter's database needs to be restored.

Until the software update is implemented, the measuring units should be checked prior to every use to ensure that the meter is reading in the correct units.

For questions about the software versions mentioned above, please contact your Roche representative. 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.

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

Signature