

Urgent Field Safety Notice

Notice Ref No:	FSN RPD 17/2009
Document Date:	14 December 2009
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	Accu-Chek Inform
SYSTEM AFFECTED:	Accu-Chek Inform II
MATERIAL NUMBERS:	Mat. no. 05060303001, 05060311001
LOT NO (IF APPLICABLE):	not applicable
SUMMARY OF ISSUE:	Display foil cracks
ACTION REQUIRED:	Check meter for possible crack(s) and return to local affiliate once cracks are visible.
CONTACTS:	Technical Services: Country:

Dear Roche Customer,

This communication is being sent to you because, according to our records, you currently use an Accu-Chek Inform II system in your hospital system. Roche is investigating a limited number of complaints (<1% of the total number of 8,000 devices) regarding cracks in the plastic covering over the meter display of the Accu-Chek Inform II meter.

If cracks occur in the plastic covering of the Accu-Chek Inform II meter, there is a remote possibility that cleaning or disinfection may not adequately remove all contaminants. Therefore, we would ask you to check the Accu-Chek Inform II meters in your institution. If cracks occur in the plastic covering over the display, please return this device to Roche through the normal processes.

We can assure you that patient safety is our first priority. Therefore, we are taking this extra precaution to prevent any possible contamination.

For more information, please contact your local sales affiliate or sales representative to discuss this situation further.

Sincerely,

Roche Diagnostics

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