URGENT FIELD SAFETY NOTICE
IMMEDIATE ACTION REQUIRED

Ref No:	**POCFSN18 Increase in Strip Errors due to reagent and electrode cracking SBN_RDC_2018_02**
Date:	**03/05/2018**
Type of Action:	**Field Safety Corrective Action (FSCA)**

Product Affected:	ACCU-CHEK INFORM II test strips
System Affected:	**Accu-Chek®** Inform II **Accu-Chek®** Performa

Software Version: n/a

Product No	Material No	Lot Nos
ACCU-CHEK INFORM II Test Strips	5942861018	476614, 476617, 476618, 476340, 476605, 476638, 476639, 476653

Summary of Issue

Important information on selected lots of Accu-Chek® INFORM II test strips potentially showing an increased number of strip errors prior to dosing or biased results

Reason for Notice

At Roche Diagnostics we hold our products to the highest standards of quality and are committed to communicating any issues impacting the operation of our products. This is why we would like to inform you today about an issue that might occur in certain lots of the ACCU-CHEK INFORM II test strips. As part of our ongoing quality monitoring and market surveillance processes, we have identified certain test strip lots that potentially show an increase in strip errors prior to dosing. Due to the designed fail-safe in the blood glucose meter, the issue can be identified by the error message displayed on the meter upon strip insertion or through the device not recognizing the test strip, respectively. However, in a very limited number of cases the test strip can produce a biased result i.e. a falsely too high or too low value, which might not be detected easily and which could lead to erroneous therapy adaptations.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

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As patient safety is our first priority, we would therefore like to ask you to

▪ check the lot numbers of the test strip supply against the complete list of lot numbers in the attachment. The lot number can be found on the top flap of the vial packaging as well as on the label of each test strip vial as shown in the picture below.

▪ discontinue using strips from the affected lots immediately and please use other testing supplies and equipment to monitor your patients' glucose levels.

▪ Please dispose of any affected lots immediately as per your reagent disposal process.

Replacements will be automatically processed at no extra cost. Please contact our Customer Services line 0808 100 9998 (UK), or 1800 509 586 (ROI) if you have any queries about this replacement process.

We have thoroughly investigated this issue to identify the root cause of this potential error and have already started to implement the appropriate corrective measures. Please be assured that this issue only affects the ACCU-CHEK INFORM II test strips. Other Accu-Chek blood glucose test strips available in your market are not impacted by this issue.

Your national competent authority, users of the affected blood glucose monitoring systems, distributors and retailers have been informed about this field action.

Please call our Point of Care Technical Team on 0808 100 1920 (UK) and 1 800 40 9564 (ROI) , if you need any additional advice on the operation of Accu-Chek blood glucose meters and test strips or have any further questions or concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions. We appreciate your time and attention to this important notification.

Please complete and return the Acknowledgement Form which accompanies this Field Safety Notice by 17/05/2018

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Please bring this notice to the attention of all personnel in your hospital or Health Care facility who need to be aware of this safety issue.

If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

Attachments

SB_RDC_2018_02_FSN Appendix A lot Numbers

SBN_RDC_2018_02_FSN Aknowledgement Form

This action is being conducted with the knowledge of the Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

Roche Diagnostics operates a vigilance system that complies with the IVD Directive 98/79 EC

A copy of this notice can also be found on the Roche Dialog Portal

If you require any further information please contact our

Technical Support Hotline

UK: 0808 100 19 20

Ireland: 1800 40 95 64

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