

Urgent Field Safety Notice



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Location, Date 2014

Important notice:

Enhanced instructions for proper testing with the Accu-Chek® Mobile system to avoid the potential of falsely elevated blood glucose readings

Dear Customer,

We would like to inform you that we are introducing enhanced instructions and training for the use of the Accu-Chek Mobile system. The new and enhanced training materials will be included into the Accu-Chek® Mobile kits and will be available for you to distribute to current Accu-Chek Mobile users.

As the strip-free Accu-Chek® Mobile blood glucose monitoring system offers a unique testing procedure, it requires particular awareness of people with diabetes regarding its proper handling. Being in close contact with its customers worldwide, Roche Diabetes Care has identified that a small number of people with diabetes using the Accu-Chek® Mobile device have experienced falsely elevated blood glucose readings when using the system as a result of not following the described and labelled handling instructions. Such improper handling can include, for example, unclean hands contaminated with glucose-containing substances, pressing the finger too hard and too long on the test field or smearing the blood while performing a test.

As patient safety is our primary concern, Roche Diabetes Care has decided to enhance its training and handling instructions for the Accu-Chek® Mobile system – increasing their visibility in the meter kit to ensure people with diabetes' understanding of how to appropriately use the system. This will enable the users to obtain safe and reliable blood glucose (bG) readings at all times.

Attached you will find new training leaflet that is provided in the package for the Accu-Chek® Mobile kits. This will be accompanied by additional training measures for people with diabetes online and offline.

Actions required from you

- 1) Ensure that your patients are aware of the new training materials included within the packaging.
- 2) Ensure that your patients understand how they should use Accu-Chek® Mobile properly to get accurate results, according to the specified instructions:
 - Wash your hands with warm water and soap. Dry your hands thoroughly before obtaining a blood sample
 - Form a proper blood drop and apply it to the centre of the test field
 - Immediately apply the blood gently to the test field after you have created the blood drop.
 - Do not press against the test field on the tape
 - Touch the test area gently and remove your finger immediately after having applied the blood
 - Your finger should be removed from the test field when the beep tone sounds and/or “test in progress” is displayed
- 3) Do not recommend the Accu-Chek Mobile system to patients who are obviously not able to follow the specified instructions as being able to test gently and with a steady hand is an important requirement of Accu-Chek Mobile.

Actions required from your patients

- 1) Patients can continue to use their Accu-Chek® Mobile device safely and reliably by carefully following the instructions included in the new training leaflet.
- 2) If patients have concerns about the accuracy of a bG reading, they should refer to the possible sources of error listed in the user manual and perform a test with a control solution or they should contact their healthcare provider and follow the individual advice.

To ensure maximum awareness of the enhanced instructions, we have informed regulatory bodies, distributors, retailers and customers. You will also be able to access this information online via www.accu-chek.ie/mobileproPERTesting. This action only applies to users of Accu-Chek® Mobile and does not apply to any other Accu-Chek® device.

Could you please sign and date the attached acknowledgment form and send it back to us using either the self addressed envelope provided or the fax number on the form. We thank you for your understanding and for your cooperation in helping patients to get accurate readings from Accu-Chek® Mobile. We apologize for any inconvenience this issue may cause you. Should you have any additional questions or seek clarification, please contact our Accu-Chek® customer care team on 1800 931 078 or your Roche representative.

Sincerely,
Roche Diabetes Care

Attachments: Training Leaflet, Acknowledgement form