

Urgent Field Safety Notice



<Enter address here>

Location, Date 2014

Important notice:

Enhanced instructions for the proper handling of 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 substantially enhance its training and handling instructions for the Accu-Chek[®] Mobile system – giving them more visibility in the meter kit to ensure user awareness and education of how to appropriately use the system. This will enable users to obtain safe and reliable blood glucose (bG) readings at all times.

Please find attached the new training leaflet which is provided in the package of the Accu-Chek[®] Mobile kits and can be distributed to existing users. This will be accompanied by additional training measures for people with diabetes online and offline.

Actions required from you

- 1) Ensure that your customers are aware of the new training materials included within the packaging.
- 2) Ensure that your customers 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

Actions required from your customers

- 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 handling instructions, we have informed regulatory bodies, healthcare professionals and customers. You will also be able to access this information online via www.accu-chek.co.uk/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 people with diabetes 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 0800 040 7221 or your Roche representative.

Sincerely,
Roche Diabetes Care

Attachments: Training Leaflet, Acknowledgement form

Urgent Field Safety Notice



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.co.uk/mobileproPERTesting for UK and www.accu-chek.ie/mobileproPERTesting for ROI. This action only applies to users of Accu-Chek® Mobile and does not apply to any other Accu-Chek® device.

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 0800 040 7221 for UK and 1 800 931 078 for ROI or your Roche representative.

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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
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 - 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.co.uk/mobileproptesting. 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 0800 040 7221 or your Roche representative.

Sincerely,
Roche Diabetes Care

Attachments: Training Leaflet, Acknowledgement form

Urgent Field Safety Notice



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,

As a valued Accu-Chek[®] Mobile user, we would like to inform you that we are introducing enhanced handling instructions and training for the use of the Accu-Chek Mobile system.

As the strip-free Accu-Chek[®] Mobile blood glucose monitoring system offers a unique testing procedure, it also requires particular awareness of 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 your safety is our primary concern, Roche Diabetes Care has decided to substantially enhance its training and handling instructions for the Accu-Chek[®] Mobile system. This will help ensure you obtain safe and reliable blood glucose (bG) readings at all times. Please find attached the new training leaflet.

You can continue to use your Accu-Chek[®] Mobile device safely and reliably by carefully following the instructions that are described in your Accu-Chek[®] Mobile User Manual and which are also included in the new training leaflet

- 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

If you are concerned about the accuracy of a particular bG reading, please refer to the possible sources of error listed in the user manual and perform a test with a control solution. If all of the conditions for testing have been satisfied and you still feel concerned about a reading, please contact your healthcare provider and follow the individual advice.

To ensure maximum awareness of the enhanced handling instructions, we have informed regulatory bodies and healthcare professionals.

We thank you for your understanding and for your cooperation. Should you have any additional questions or seek clarification, please contact our Accu-Chek® Care Line on 0800 701 000 UK or 1 800 709 600 ROI or your Roche representative.

Sincerely,

Roche Diabetes Care

Attachments: Training Leaflet

Facebook / Web template

Urgent Field Safety Notice



Important notice:

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

Today, Roche Diabetes Care announced that the company is introducing enhanced instructions and training for the use of its Accu-Chek Mobile blood glucose monitoring system. The new and enhanced training materials will be included into the Accu-Chek® Mobile kits.

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 its primary concern, Roche Diabetes Care has decided to enhance training and handling instructions for the Accu-Chek® Mobile system. This will enable the users to obtain safe and reliable blood glucose (bG) readings at all times.

Patients can continue to use their Accu-Chek® Mobile device safely and reliably by carefully following the instructions included in the new training leaflet. 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.

The new training leaflet is provided in the package for the Accu-Chek® Mobile kits and can also be downloaded via [Insert country URL]. The training leaflet will be accompanied by additional training measures for people with diabetes online and offline.



Annex 1

URGENT FIELD SAFETY NOTICE

Roche Diagnostics Ref.: SB_RDC_2014_05

Acknowledgement Form / Faxback

Please submit this acknowledgement form to Roche Diagnostics via e-mail; or fax:; or postal address:.....

Herewith I acknowledge the receipt of the Field Safety Notice of xx. May, 2014 concerning the Accu-Chek® Mobile systems.

Name / title of person completing this form:

Company:

Phone #:..... Email:.....

Address:.....

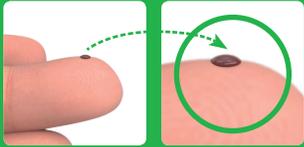
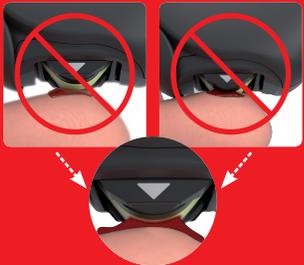
Date: Signature.....

Thank you!



Accu-Chek® Mobile – Proper Testing Instructions

Incorrect handling may lead to incorrect test results which can cause the wrong therapy recommendation to be made and so result in serious adverse health effects. Therefore, follow these instructions carefully to perform a blood glucose test correctly.

Do	Do not	Why
<p>1</p>  <p>Wash your hands with warm water and soap and rinse well. Dry your hands thoroughly with a clean towel before obtaining blood.</p>	 <p>Do not test when your fingers are unwashed, soiled or sticky (e. g. due to food or drink residue).</p>	<p>1</p> <p>Unwashed, soiled or sticky fingers can lead to falsely elevated blood glucose results and delivery of an inappropriately high insulin amount.</p>
<p>2</p>  <p>Always use a small, fresh and well-formed blood drop.</p>	 <p>Do not test with a smeared or spread blood drop. Do not smear the blood drop onto or across the test area.</p>	<p>2</p> <p>Testing with a spread blood drop or wiping the blood drop on the test area increases the risk of contamination of the testing site. This can lead to falsely elevated blood glucose results and delivery of an inappropriately high insulin amount.</p>
<p>3</p>  <p>Touch the test area gently and steadily when applying blood. Apply the blood drop to the centre of the test area.</p>	 <p>Do not press the test area onto the finger (especially if shaking or trembling).</p>	<p>3</p> <p>Pressing the test area onto the finger can lead to falsely elevated blood glucose results and delivery of an inappropriately high insulin amount.</p>
<p>4</p>  <p>Apply the blood drop to the test area immediately after you have obtained the blood drop. Remove your finger from the test area when the beep tone sounds and <i>Test in progress</i> is displayed. Note: You can only hear beep tones when they are turned on. See User's Manual for tone settings.</p>	<p>Do not wait before applying the blood drop to the test area. Do not hold your finger on the test area after the beep tone sounds and <i>Test in progress</i> is displayed.</p>	<p>4</p> <p>Not testing promptly can lead to evaporation of the blood drop. This can lead to falsely elevated blood glucose results and delivery of an inappropriately high insulin amount. The beep tone helps you to obtain a reliable test result.</p>

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V4/2 – vio_07299095001_01_EN – cyan

V4/3 – vio_07299095001_01_EN – magenta

V4/4 – vio_07299095001_01_EN – yellow

Proof print number: n/a

PDF-Certified Profile: Package-Insert_V5-0

Last Change of Indesign-File: 12-05-2014 15:31:00