

Urgent Medical Device Correction



19-001

October 23, 2019

Accu-Chek® Guide blood glucose meters with serial numbers below 92311000001.

Issue:

As part of our ongoing quality monitoring and marketing surveillance processes, Roche has identified that Accu-Chek Guide blood glucose meters may:

- Display E-9 Errors (indicating batteries need to be replaced)
- Show unexpected low battery icons
- Have short battery life
- Not power on

We have thoroughly investigated this issue to identify root cause and have begun implementing appropriate corrective measures. This includes design improvements to make the meters more robust against battery performance issues.

Clinical Significance:

Unexpected power issues with the Accu-Chek Guide blood glucose meters may result in temporary meter unavailability that could lead to a delay in treatment and/or therapy decisions. Such a delay may potentially lead to an adverse medical event or consequence. **Serious injuries have occurred or could occur due to the failure mode associated with this recall. We have reports of two serious injuries.**

Affected Product:

Accu-Chek Guide blood glucose meters with a serial number below **92311000001**. The serial number can be found on the back of the meter, where indicated by the red rectangle in the photo below.

Note: No other Accu-Chek products are affected.

Actions for users of Accu-Chek Guide blood glucose meters:

- 1) Always have a spare set of batteries. The meter requires two (2) size CR2032 batteries.
- 2) Be aware that battery life may vary due to factors such as temperature and battery manufacturer.
- 3) Have a back-up testing method available.
- 4) If you have questions regarding this notification or you need further support, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).
- 5) If there is a Business Reply Card enclosed with this mailing, please complete and return it as instructed on the Business Reply Card.
- 6) Keep a copy of this notification for your records.



If you are currently experiencing a power issue with your Accu-Chek Guide meter, follow the instructions below.

If the meter is powered on and displaying an E-9 error or low battery icon:

- a. Move the meter to a more moderate environment, such as ambient room temperature, to ensure optimal battery performance.
- b. Turn the meter off, then turn the meter back on.
- c. If the problem persists, perform a meter reset by doing the following:
 - i) Remove the batteries.
 - ii) Press and hold the Power/Set/OK button for at least 2 seconds.
 - iii) Reinsert the batteries.
- d. If the problem still occurs after performing a meter reset, then replace the batteries with new ones according to the instructions in the user manual. Use high quality batteries in the meter, such as Panasonic. The meter requires two (2) size CR2032 batteries.
- e. If replacing the batteries does not correct the situation, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).

If the meter will not power on or has short battery life:

- a. Move the meter to a more moderate environment, such as ambient room temperature, to ensure optimal battery performance.
- b. Perform a meter reset by doing the following:
 - i) Remove the batteries.
 - ii) Press and hold the Power/Set/OK button for at least 2 seconds.
 - iii) Reinsert the batteries.
- c. If the problem still occurs after performing a meter reset, then replace the batteries with new ones according to the instructions in the user manual. Use high quality batteries in the meter, such as Panasonic. The meter requires two (2) size CR2032 batteries.
- d. If replacing the batteries does not correct the situation, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).

Actions for Distributors:

1. Provide a copy of this notification to your customers.
2. No product returns are required as part of this notification.
3. If you have questions regarding this notification, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).
4. If you received a Fax-back form with this notification, please complete and return it as instructed on the Fax-back form.
5. Keep a copy of this notification for your records.

Actions for Retailers:

1. Make this notification available to your customers.
2. No product returns are required as part of this notification.
3. If you have questions regarding this notification, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).
4. If you received a Fax-back form with this notification, please complete and return it as instructed on the Fax-back form.
5. Keep a copy of this notification for your records.

Actions for Healthcare Professionals:

1. Make this notification available to your patients using an Accu-Chek Guide blood glucose meter.
2. No product returns are required as part of this notification.
3. If you have questions regarding this notification, please contact our Accu-Chek Customer Care team through our website (accu-chek.com), email address (accu-chek.care@roche.com), or call (1-800-858-8072).
4. If you received a Fax-back form with this notification, please complete and return it as instructed on the Fax-back form.
5. Keep a copy of this notification for your records.

ACCU-CHEK GUIDE is a trademark of Roche.

This notification is being made with the knowledge of the Food and Drug Administration (FDA). You may also report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Events Reporting Program online at www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call the FDA 1-800-FDA-1088.

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