

Consumer Letter (Accu-Chek Guide Power Issues)



Urgent field safety notice

Important information on Accu-Chek® Guide blood glucose meters potentially having power related issues

Dear valued customers,

At Roche Diabetes Care, we strive for highest quality of our products and services and are committed to keeping you informed as soon as there is a potential issue you should be aware of. This is why we would like to inform you today about an issue that might occur in Accu-Chek® Guide blood glucose meters. As part of our ongoing quality monitoring and market surveillance processes, we have identified that Accu-Chek® Guide blood glucose meters may potentially:

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

Power issues such as those listed may result in a temporary meter unavailability for the user. Failure to test could cause a delay in therapy decisions and may potentially lead to a serious medical condition. As patient safety is our primary concern, we want to communicate to you the below mentioned notices to ensure optimal battery life performance.

In addition, we would also like to provide you with specific instructions on how to handle power issues of Accu-Chek® Guide blood glucose meters. This applies to meters with the defined serial numbers below XXX11000001, where "XXX" is the first 3 digits of the serial number. The serial number can be found on the back of the meter, indicated by the red rectangle in the photo below.



Please find below the following warning and important notices to ensure optimal battery life performance and recommendations on how to handle power issues.

- **Warning:**
 1. Always have a spare set of batteries.
 2. Battery life may vary due to factors such as temperature and battery manufacturer.
 3. Have a back-up testing method available.
- **If the meter is powered on and displaying an E-9 error or low battery icon:**

1. Move the meter to a more moderate environment to ensure optimal battery life performance.
 2. Turn the meter off, then turn the meter back on.
 3. If the problem persists, perform a meter reset by doing the following:
 - Remove the batteries
 - Press and hold the Power/Set/OK button for at least 2 seconds
 - Reinsert the batteries.
 4. 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.
 5. If replacing the batteries does not correct the situation, please contact our Accu-Chek[®] Customer Care line at 1-800-88-1313 to obtain further support.
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- **If the meter will not power on or has short battery life:**
 1. Move the meter to a more moderate environment to ensure optimal battery life performance.
 2. Perform a meter reset by doing the following:
 - Remove the batteries,
 - Press and hold the Power/Set/OK button for at least 2 seconds,
 - Reinsert the batteries.
 3. 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.
 4. If replacing the batteries does not correct the situation, please contact our Accu-Chek[®] Customer Care line at 1-800-88-1313 to obtain further support.

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

Your national competent authority, healthcare professionals and distributors and retailers have been informed about this field action. This information is also available on our website, www.accu-chek.com.my.

We sincerely apologise for any inconvenience this may cause and hope that the enhanced handling information provided with this communication supports you in a safe, reliable and satisfactory use of the Accu-Chek[®] Guide blood glucose meter.

Please call our Accu-Chek[®] Customer Care line at 1-800-88-1313, if you need any additional advice on the operation of Accu-Chek[®] Guide blood glucose meters 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.

Kind regards,

Roche Diagnostics (M) Sdn Bhd

A handwritten signature in black ink, appearing to read "Yip Siew Ping", with a stylized flourish at the end.

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A handwritten signature in blue ink, appearing to read "Koh Wai Chin", with a stylized flourish at the end.

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A handwritten signature in black ink, appearing to read "Heng Chai Yin", with a stylized flourish at the end.

Heng Chai Yin
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