

URGENT PRODUCT DEFECT CORRECTION



Consumer Letter

(Accu-Chek® Guide & Accu-Chek Performa Power Issues)

ACCU-CHEK® GUIDE and ACCU-CHEK PERFORMA blood glucose meters potentially having power-related issues TGA Ref. No.: RC-2019-RN-01601-1		
Product Description	Serial Numbers	ARTG No.
Accu-Chek Guide meters	Below 92911000001	190250
Accu-Chek Guide meter kit		273957
Accu-Chek Performa meters	Between 68920000000 and 68925525056	190250

Dear Valued Customer,

As part of our ongoing quality monitoring and market surveillance processes, it has recently come to our attention that a patient's Accu-Chek Guide or Accu-Chek Performa blood glucose meter may:

- Display E-9 Errors (indicating batteries need to be replaced); and/or
- Unexpectedly display the low battery icon; and/or
- Have short battery life; and/or
- Not power on.

If you notice one or more Battery Matters you must immediately follow our instructions below. If ignored, this may result in temporary meter unavailability that could cause a delay in therapy decisions which in turn may potentially lead to a serious medical condition.

The Battery Matter(s) have been reported in **Accu-Chek Guide meters with serial numbers below 92911000001 only** and **Accu-Chek Performa meters with serial numbers between 68920000000 and 68925525056 only**. The serial number can be found on the back of the meter, indicated by the red rectangle in the adjacent photos.

What to do if you notice a Battery Matter(s)

We would also like to provide you with the following warning and instructions to ensure optimal battery life performance and recommendations on how to handle a Battery Matter(s):

- **Warning:**
 1. Always have a spare set of high quality batteries such as Panasonic.
 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 Accu-Chek Guide or Performa User's Manual. Use high quality batteries in the meter, such as Panasonic.
 - 5. If replacing the batteries does not correct the situation, please contact our **Roche Diabetes Care Enquiry line at 1800 800 535** to obtain further support.
- **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 Accu-Chek Guide or Accu-Chek Performa User's Manual. Use high quality batteries in the meter, such as Panasonic.
 4. If replacing the batteries does not correct the situation, please contact our **Roche Diabetes Care Enquiry line at 1800 800 535** to obtain further support.

We have thoroughly investigated the Battery Matter(s) to identify the root cause and have already started to implement the appropriate corrective measures. This includes design improvements in new models to make the meters more robust against battery performance issues. The Therapeutic Goods Administration (TGA) has been notified of this action.

Your healthcare professionals, distributors and retailers have been informed about the Battery Matter(s). Additionally, we are placing notifications on the following webpages: Australian Diabetes Society (ADS), Australian Diabetes Educator Association (ADEA), Australian Practice Nurse Association (APNA) and Diabetes Australia (DA).

This information is also available on our website, www.accu-chek.com.au.

We sincerely apologise for any inconvenience this may cause you.

Please call our **Roche Diabetes Care Enquiry line at 1800 800 535**, if you need any additional advice on the operation of Accu-Chek Guide or Accu-Chek Performa 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 Diabetes Care Australia Pty Limited