

Urgent Field Safety Notice



Accu-Chek® Aviva blood glucose meters

For attention of: **Users of Accu-Chek Aviva meters**

Manufacturer's reference: SB_RDC_2019_06

6th November 2019

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

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 a potential issue that might occur in Accu-Chek Aviva blood glucose meters. As part of our ongoing quality monitoring and market surveillance processes, we have identified that Accu-Chek Aviva blood glucose meters may potentially **have unexpected short battery life or not power on**.

Description of Situation

An issue was discovered during the manufacturing process of the meter where an internal component of the meter might have been damaged. In a small percentage of meters, this damage could cause an accelerated depletion of the meter's battery. Roche Diabetes Care implemented corrective actions to prevent this root cause from recurring in the future.

However, in the worst case, this issue may result in meter unavailability, and failure to test could cause a delay in therapy decisions, potentially leading to a serious medical condition. As patient safety is our primary concern, we would like to provide you with the detailed instructions on how to handle the issue if it were to occur.

Details on affected devices

The following products are affected:

Commercial Name	
Accu-Chek® Aviva blood glucose meters	serial numbers between XXX05000001 and XXX06335297 OR serial numbers between XXX20000000 and XXX23284925

Rationale giving rise to this corrective measure

The damage of the internal component of the meter may result in a meter unavailability, and failure

to test could cause a delay in therapy decisions potentially leading to a serious medical condition.

Actions taken by Roche Diabetes Care

Roche Diabetes Care implemented corrective actions to eliminate the root cause for the damage of the internal component.

Actions to be taken by users of the Accu-Chek Aviva blood glucose meters

In order to troubleshoot any power related issue, refer to the instructions in the user's manual on how to appropriately handle any errors that may occur. If the instructions provided in the user's manual are not solving the issue, please contact our Roche Diabetes Care Customer Careline on UK: 0800 701 000 Ireland: 1 800 709 600 to obtain further support.

Please find below the following warning and important notices regarding potential power issues.

- **Notice:**

If you use a meter with a serial number (where "XXX" is the first 3 digits of the serial number) in the defined serial number range, you may have a meter potentially impacted by the damaged component.

- Accu-Chek® Aviva: between XXX05000001 and XXX06335297 OR
- Accu-Chek® Aviva: between XXX20000000 and XXX23284925

- **If you believe you have a meter in the impacted serial number range, please consider the following warnings:**

1. Always have a spare set of batteries.
2. Have a back-up testing method available.

Communications of this Field Safety Notice

Your national competent authority has been notified about this field action. We sincerely apologise for any inconvenience this may cause and hope for your understanding and your cooperation.

Please call our Roche Diabetes Care Customer Careline on UK: 0800 701 000 Ireland: 1 800 709 600, if you need any additional advice on the handling of the Accu-Chek® Aviva blood glucose meters or have any further questions or concerns. We appreciate your time and attention to this important notification.

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