

Urgent Medical Device Correction

19-002

November 06, 2019



Accu-Chek® Aviva Plus blood glucose meters with serial numbers either between 45505000001 and 45506335297 or between 45520000000 and 45523284925

Purpose of this Notification:

The purpose of this notification is to advise you that Roche Diabetes Care is voluntarily recalling Accu-Chek Aviva Plus blood glucose meters with serial numbers either between 45505000001 and 45506335297 or between 45520000000 and 45523284925. This notification provides guidance to users with meters in the serial number range listed above experiencing short battery life or not powering on.

Reason for the Notification:

As part of our ongoing quality monitoring and market surveillance processes, we have identified that Accu-Chek Aviva Plus blood glucose meters may potentially **have unexpected short battery life or not power on**. An issue was discovered in which an internal component might have been damaged during the manufacturing process. In a small percentage of meters, this damage could cause an accelerated depletion of the meter's battery, which could result in the meter not powering on.

Risk to Health:

Unexpected power issues with the Accu-Chek Aviva Plus 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.

Affected Product:

The following product is affected:

| Commercial Name | Serial Number Range |
|---|--|
| Accu-Chek Aviva Plus blood glucose meters | serial numbers either between 45505000001 and 45506335297 OR between 45520000000 and 45523284925 |

Please see picture to the right for an illustration of where to find the serial number on the back of the meter.

Note: This notice only applies to Accu-Chek Aviva Plus blood glucose meters in the serial number ranges noted above.



Actions to be taken by the user:

If you have a meter in the impacted serial number range:

- Always have a spare battery. The meter requires one (1) size CR2032 battery.
- Have a back-up testing method available.

In order to resolve power related issues, refer to the **Maintenance and Troubleshooting** section in the user's manual for how to appropriately handle any errors that may occur. The user's manual can be found at: <http://www.accu-chek.com/meters/aviva-meter>

If the instructions provided in the user's manual are not solving the issue, contact our Accu-Chek Customer Care team through our website ([accu-chek.com](http://www.accu-chek.com)), email address (accu-chek.care@roche.com), or call (1-800-858-8072).

Actions taken by Roche Diabetes Care:

In addition to this communication, Roche Diabetes Care implemented corrective actions to eliminate the root cause of the damage to the internal component.

ACCU-CHEK AVIVA PLUS 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.