24-001 May 13, 2024

URGENT MEDICAL DEVICE REMOVAL

Accu-Chek® Guide system: Meters showing incorrect measurement unit (mmol/L rather than mg/dL)

This Urgent Medical Device Removal (UMDR) only applies to the following products:

Affected Meter Serial Number	Product Description	Product REF Number	Product Device Identifier (UDI / GTIN)	Product Lot Number
92339920445	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207482
92339955415	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207482
92340116052	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340117408	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340120006	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340120057	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92339920116	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207526
92339094787	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207545
92339744998	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207454

Issue:
Roche Diabetes Care has received three customer complaints, including one US complaint, in which the meter was reading in the incorrect unit of measure. The complaints were reported to FDA as quality issues via the Medical Device Reporting program. The resulting Roche complaint investigations indicated that the above Accu-Chek Guide systems were configured incorrectly, and thus show the results in mmol/L rather than in the labeled measuring unit, mg/dL. It becomes visible once a blood glucose measurement is taken and the user could recognize that the result is displayed mmol/L rather than mg/dL.
Roche Diabetes Care has conducted an in-depth evaluation of the underlying root cause of the above-described issue and has corrected the issue to prevent recurrence.

Risk to Health:
This misconfiguration may result in customers perceiving wrong units of measure, and/or interpreting a result as approximately 18 times lower than the actual blood glucose. In the worst case, these misleading displayed results, in the wrong unit of measure, may trigger an inappropriate treatment decision (consumption of carbohydrates) with potentially severe consequences.

Reason for the Notification:
Investigations have revealed that the nine meters listed above were configured incorrectly and thus show the results in a different than labeled measuring unit. This notification is to inform customers of the issue and to instruct customers to discontinue use of the Accu-Chek Guide blood glucose meters with the serial numbers listed above and contact Accu-Chek Customer Care at 1-800-858-8072 to arrange for return and replacement.

Actions Required by End Users

We ask all users of the Accu-Chek Guide blood glucose monitoring system to

- Please check your meter to see if the display shows the appropriate measuring unit (mg/dL)

- Please compare the serial number of your meter with the listed affected serial numbers to determine if it is impacted by this issue. Please see the affected serial numbers below.

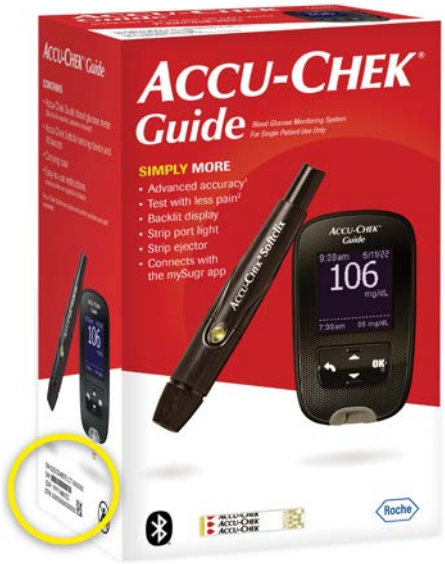
92339920445	92340117408	92339920116
92339955415	92340120006	92339094787
92340116052	92340120057	92339744998

- Please stop using your Accu-Chek Guide meter if you notice that your product shows an incorrect measuring unit or the serial number is one of the listed impacted products and:
- Please visit http://accu-chek.com/notices/UMDR-24-001 and enter your serial number. The form will provide instruction on how to proceed. Otherwise, you may contact our Roche Diabetes Care Accu-Chek Customer Care line at 1-800-858-8072 (Monday – Friday from 8:00 a.m. ET - 8:00 p.m. ET).
- Please keep this UMDR for future reference.

Actions Required for Distributors/Retailers

- Read this UMDR (24-001).
- Please check meters remaining in your stock for impacted serial number.

Affected Meter Serial Number	Product Description	Product REF Number	Product Device Identifier (UDI / GTIN)	Product Lot Number
92339920445	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207482
92339955415	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207482
92340116052	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340117408	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340120006	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92340120057	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207519
92339920116	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207526
92339094787	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207545
92339744998	Accu-Chek® Guide (SC) Kit	08453071001	00365702729100	207454



- If you identify an Accu-Chek Guide blood glucose meter with one of the serial numbers noted above, remove it from your inventory and contact our Roche Diabetes Care Accu-Chek Customer Care line at 1-800-858-8072 (Monday – Friday from 8:00 a.m. ET - 8:00 p.m. ET) to arrange for return and replacement.
- If you have distributed the products noted above to other suppliers, provide a copy of this UMDR to those suppliers whom you have shipped products from the above listed Product Lot Numbers.
- If you have distributed products of the lots noted above to consumer customers, make the UMDR available to those customers.
- Complete all sections of the enclosed distributor faxback form (24-001) and fax or email it according to the instructions on the form.
- Contact your Roche Account Manager or your distributor if you have questions regarding the information in this UMDR.
- Please keep this UMDR for future reference.

For questions regarding this UMDR or other questions related to your Roche Diabetes Care products, please contact your Roche Account Manager or contact Accu-Chek Customer Care at 1-800-858-8072.

ACCU-CHEK GUIDE and ROCHE DIABETES CARE are trademarks of Roche. ART-10333570001

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.