

URGENT NOTIFICATION



Roche Diabetes Care
201 Armand-Frappier Blvd, Laval, Quebec, H7V 4A2

RRDC202402

Important information related to the Accu-Chek® Guide system: Voluntary recall of meters showing incorrect measurement unit

Product name	Impacted meter's serial numbers	Product no.	UPC	Affected lot number
Accu-Chek Guide	93040301566 93040304746 93040300107	07400934119	064562111697	406670

According to Health Canada Medical Devices Regulations, we are required to provide the following information to all potential users. Additionally, in order to comply with this regulation, an answer to this urgent notification is **required by June 4, 2024**. Please refer to the section **What you should do**. According to the Medical Devices Regulations, an answer to this urgent notification is required and mandatory.

[Click here to fill out the form and certify that you have read the document and understood the issue at hand.](#)

At Roche, we strive for the highest quality of our products and services and are committed to keeping you informed promptly of any issue associated with our products. Today, we would like to notify you of a voluntary corrective measure that we are initiating concerning our Accu-Chek Guide blood glucose meter. In Canada, only three (3) individual Accu-Chek Guide blood glucose meters were configured incorrectly and thus show the results in mg/dL instead of mmol/L.

Please be assured that all other Accu-Chek and Accu-Chek Guide meters not included in this voluntary corrective action are not impacted by this issue and are safe to be used as intended.

Description of the situation

Since safety is our top priority, we would like to provide more information about the potential risk resulting from the above-described issue. The issue arises when a blood glucose measurement is taken and the result is displayed in the wrong measuring unit (i.e., mg/dL instead of mmol/L). If it goes unnoticed, the incorrectly displayed blood glucose value may result in inappropriate therapy decisions, including the administration of insulin, and could potentially result in severe consequences. Such possible consequences range from no clinical impact to adverse health events including hypoglycemia.

Action taken by Roche Diabetes Care

We have conducted an in-depth evaluation of the underlying root cause of the above-described issue and have adapted our manufacturing and quality control processes to prevent the issue from recurring.

Instructions to identify the three (3) individual impacted meters

- For people living with diabetes, please check your Accu-Chek Guide meter(s) to see if the display shows the same measuring unit as the label on the backside of the meter.
- Please compare the serial number of your meter with the list below to determine if it is impacted by this issue. The serial number can be found at the bottom of the Accu-Chek Guide meter packaging or the backside of the meter.

Serial number location 1:
Sticker at the bottom of Accu-Chek Guide meter packaging

Serial number location 2:
Backside of Accu-Chek Guide meter



Affected serial numbers **SN**:

93040301566
93040304746
93040300107

What you should do if you locate one of the three (3) individual impacted meters:

- Please stop using the meter / do not distribute the meter.
- Please contact our Accu-Chek Care Customer line at 1-800-363-7949, Monday - Friday 9 a.m. - 6 p.m. (ET) to receive instructions **to send it back to us** and to receive your replacement meter free of charge. It is very important to recuperate impacted meters.

To comply with the Medical Devices Regulations, you must confirm that you have read and understood this Urgent Notification by **June 4, 2024**.

[Click here to fill out the form and certify that you have read the document and understood the issue at hand.](#)

Should you need more information, please do not hesitate to contact Accu-Chek Customer Care line at 1-800-363-7949 or also by e-mail at laVal.info_line@roche.com

Roche Diabetes Care thanks you for your continued support.