

Canada Announcement: Ascensia Diabetes Care issues Voluntary Recall for CONTOUR® NEXT GEN Blood Glucose Meters issued as part of six (6) lots.

As the safety of our customers is our top priority, Ascensia Diabetes Care has announced a Voluntary Recall of **specific serial numbers from lots PH24110007, PH24110008, PH24110009, PH25010003, PH25010004, and PH25020014** of CONTOUR® NEXT GEN blood glucose meters in Canada due to potentially incorrect units of measurement.

No other Ascensia Diabetes Care blood glucose meters are affected.

We have discovered that specific serial numbers (as listed below) of **CONTOUR® NEXT GEN blood glucose meters** (item number: 90009743, SKU 7923 and item number: 90009742, SKU 9672) distributed in Canada were packaged into the meter kit and had incorrect factory-set units of measurement where the meters display glucose results in mg/dL rather than mmol/L.

All glucose readings include units of measurement, either mg/dL or mmol/L, depending on the country. The standard unit of measurement for Canada is mmol/L. Glucose readings in mmol/L always contain a decimal point and are in the range of 0.6 - 33.3 while readings in mg/dL are whole numbers in the range of 10 to 600.

The values displayed by the impacted meters in mg/dL are accurate. However, if a consumer does not notice the incorrect unit of measurement, it is possible that the meter's glucose measurement will be misinterpreted as a higher blood glucose measurement than expected, and the consumer may attempt to lower blood glucose levels by using glucose lowering medication, potentially leading to signs and symptoms of hypoglycemia. To date, we have not received any reports of patient injuries or adverse events related to this recall.

Consumers who have this meter should do the following:

Confirm whether your meter is from:

Item Number: 90009743

SKU: 7923

Lot Number: PH24110007

Serial numbers: 1BF5165, 1C02222, 1C02422 (3 meters)

Lot Number: PH24110008

Serial numbers: 1C05234, 1C08762, 1C08806, 1C12716, 1C12733, 1C12801, 1C12885, 1C13081, 1C13173, 1C13255, 1C13295, 1C13358 (12 meters)

Lot Number: PH24110009

Serial numbers: 1C13934, 1C14261, 1C14935, 1C15472 (4 meters)

Lot Number: PH25010003

Serial numbers: 1C54087, 1C54120, 1C54180, 1C55090, 1C55096, 1C55278, 1C55718, 1C55890, 1C56140, 1C56213 (10 meters)

Lot Number: PH25010004

Serial numbers: 1C57272, 1C57332, 1C59079, 1C59081 (4 meters)

Item Number: 90009742

SKU: 9672*

Lot Number: PH25020014

Serial numbers: 1CB9462, 1CC0884, 1CB9672 (3 meters)

- This information can be found on the back of the meter, and on the product's outer packaging. (please see example images below)
- If the lot number, item number and SKU number on the meter kit match this notice and contain a meter with serial numbers listed above, stop using the CONTOUR® NEXT GEN blood glucose meter immediately.
- Please contact **Ascensia Diabetes Care Customer Service** at 1-800-268-7200 from 9:00 a.m. to 6:00 p.m. EST, Monday to Saturday or e-mail questions@ascensia.com.
- When you reach out, let the team know you have a CONTOUR® NEXT GEN blood glucose meter affected by the recall due to a potentially incorrect unit of measurement.
- You will be requested to return your CONTOUR® NEXT GEN blood glucose meter by following the instructions provided by Ascensia Diabetes Care Customer Service. A **replacement meter kit** will be sent to you **at no cost**, and the return and replacement process will be expedited.
- Consumers may continue to test blood glucose using any other Ascensia Diabetes Care blood glucose meters not included in this voluntary recall while waiting for their replacement meter kit containing a meter to arrive.

Please note that Health Canada has been informed about this issue.

*Three (3) additional meters belonging to SKU 9672 were added based on additional findings, after the notification was initially posted.

Examples of where to find Serial Number, Item Number and LOT Number:



About Ascensia Diabetes Care

Ascensia Diabetes Care is a global company focused entirely on helping people with diabetes. Our mission is to empower those living with diabetes through innovative solutions that simplify and improve their lives.

We are home to the world-renowned CONTOUR® portfolio of blood glucose monitoring systems. These products combine advanced technology with user-friendly functionality to help people with diabetes manage their condition and make a positive difference to their lives. As a trusted partner in the diabetes community, we collaborate closely with healthcare professionals and other partners to ensure our products meet the highest standards of accuracy, precision and reliability, and that we conduct our business compliantly and with integrity.

Ascensia is a member of PHC Group and was established in 2016 through the acquisition of Bayer Diabetes Care by PHC Holdings Corporation. Ascensia products are sold in more than 100 countries. Ascensia has around 1,400 employees and operates in 29 countries.