US Announcement: Ascensia Diabetes Care issues Voluntary Recall for CONTOUR® NEXT Gen Blood Glucose Meters issued as part of one lot.

As the safety of our customers is our top priority, Ascensia Diabetes Care has announced a Voluntary Recall of **specific serial numbers of one lot** (DM01T033P) of CONTOUR® NEXT Gen Blood Glucose Meters in the United States due to Potentially Incorrect Units of Measurement. **No other Ascensia Diabetes Care blood glucose meters are affected.**

We have discovered that <u>specific serial numbers</u> (as listed below) of CONTOUR® NEXT Gen meters from lot number DM01T033P, item number: 90002902 (SKU 7917) distributed in the United States were packaged into the meter kit and had incorrect factory-set units of measurement where the meters display glucose results in mmol/L rather than mg/dL.

The values displayed by the meters in mmol/L 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 read as a lower blood glucose measurement than expected, and this may result in the patient's glucose level remaining high, which can potentially lead to an injury requiring immediate medical intervention.

Glucose readings in mg/dL are whole numbers in the range of 20 to 600, while readings in mmol/L always contain a decimal point and are in the range of 1.1 - 33.3. These numbers are very different and may result in the misunderstanding of the blood glucose measurement.

Consumers who have this meter should do the following:

- Confirm whether your meter is from lot number DM01T033P with item number 90002902 (SKU 7919) and contains a meter with serial numbers: 1057018, 1057019, 1057020, 1057023, 1057024, 1057025, 1057076 to 1057113, 1057115 to 1057150, 1058501 to 1058750, 1060751 to 1060755, 1060757 to 1061000. This information can be found on the back of the meter, and on the product outer packaging.
- 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 1-800-348-8100 Monday-Sunday, 8:00 AM-12:00 Midnight EDT or e-mail support@ContourNext.com and let the customer service team know you have received a meter that matches the recall information in a notice stating you have a CONTOUR® NEXT Gen meter with the incorrect unit of measurement.
- You will be requested to return your CONTOUR® NEXT Gen meter by following the instructions provided by Ascensia Diabetes Care Customer Service. Ascensia will expedite return and replacement of the meter kit containing a meter at no charge.
- 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 the US FDA has been informed about this issue.

About Ascensia

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 and the exclusive global distribution partner for the Eversense® Continuous Glucose Monitoring Systems from Senseonics. 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 125 countries. Ascensia has around 1,500 employees and operations in 31 countries.