

Ascensia – Recall of Contour® Next Gen Blood Glucose Meters

• On June 21, 2023, <u>Ascensia Diabetes Care announced</u> a voluntary consumer-level <u>recall</u> of specific serial numbers of one lot of <u>Contour Next Gen Blood Glucose Meters</u> due to potentially incorrect units of measurement. The recalled meters had incorrect factory-set units of measurement where the meters display glucose results in mmol/L rather than mg/dL. No other Ascensia Diabetes Care blood glucose meters are affected.

Product Description	Lot Number	Serial Number
CONTOUR NEXT Gen Blood Glucose Meters	DM01T033P	1057018, 1057019, 1057020, 1057023, 1057024, 1057025, 1057076 to 1057113, 1057115 to 1057150, 1058501 to 1058750, 1060751 to 1060755, 1060757 to 1061000

- The values displayed by the recalled meters in mmol/L are accurate, however, if a patient 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.
 - The standard unit of measurement for the U.S. is mg/dL. 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.
- The erroneous decision of a user to increase blood glucose levels based on misleading information on the meter display by consuming carbohydrates and/or omitting glucose lowering medication might further increase blood glucose levels. This might cause early signs and symptoms of hyperglycemia such as hyperuricemia, thirst, blurred vision, and tiredness.
- In rare cases, where a patient continues to misinterpret meter results and units over a prolonged period of time after experiencing hyperglycemia, a ketoacidosis could occur with symptoms such as abdominal pain, nausea, vomiting, tachypnea, and confusion requiring immediate medical intervention.
- To date, Ascensia has not received any reports of patient injury or an adverse event related to this recall.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled blood glucose meter.
- Anyone with the affected glucose meter on hand should stop use and contact Ascensia for return and replacement information. Patients should continue to test blood glucose using any other blood glucose meters not included in this recall, while waiting for the replacement meter.

Contact Ascensia at 1-800-348-8100 or by email at support@ContourNext.com for questions regarding this recall.



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