Trividia Health, Inc. Issues Nationwide Voluntary Recall for an Isolated True Metrix® Air Blood Glucose Meter with Serial Number TA1548753

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Trividia Health, Inc. today announced it is initiating a nationwide voluntary recall of one (1) True Metrix® Air Blood Glucose Meter distributed in the United States to one customer (AssuraMed). The meter was not packaged into store-brand or retail branded packaging.

The company has determined that one (1) isolated True Metrix Air Blood Glucose Meter was packaged into a True Metrix Blood Glucose Meter kit and has an incorrect factory-set unit of measure; the meter displays glucose results in mmol/L rather than mg/dL. If a consumer does not notice the incorrect unit of measure, it is possible that the meter glucose result will be read as a lower blood glucose result than expected, and this may result in the patient’s glucose level remaining high, which can lead to serious injury or impairment with risk of death.

There is one (1) affected True Metrix Air meter with serial number TA1548753 that was packaged into a True Metrix Blood Glucose Meter Kit with the Lot number KW0135 and with UDI number (01)00021292006075(17)200831(10)KW0135(21)TA1548753. It has been determined that this kit was distributed nationwide in the United States (US) in February 2019. Trividia Health has not received any reports of patient injury or an adverse event related to this voluntary recall.

Consumers who have or may have the recalled True Metrix Air meter are instructed by the manufacturer to do the following:

- Check to confirm if you have the affected True Metrix Air meter by obtaining the meter serial number (TA1548753) from the serial number label located on the back of the meter, and then visit www.TrividiaHealth.com/air-product-notice or call Trividia Health toll-free at 1-800-518-5726, Monday - Friday, 8 AM – 8 PM EST.

- If you have the affected True Metrix Air meter, please stop using the meter and call Trividia Health immediately to verify the serial number, and to expedite return and replacement of the affected True Metrix Air meter at no charge.
• Consumers may continue to test blood glucose using any other Trividia Health blood glucose meter not included in this voluntary recall while waiting for their replacement meter to arrive. Use only the test strips that are intended for use with your blood glucose meter.

Notifications will be sent to US pharmacies, durable medical equipment providers and distributors who may have received this device from Trividia’s customer.

Patient safety is a top priority at Trividia Health. The company has notified the US Food and Drug Administration (FDA) of this voluntary product recall and is working with the customer who received the affected meter to quickly resolve this matter.

Users within the US may report adverse reactions or quality problems experienced with the use of this product to the FDA’s MedWatch Adverse Event Reporting program either online or by phone.

• Complete and submit the report Online
• Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the US FDA.

Company Contact Information

Consumers:
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1-800-518-5726

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