

## URGENT MEDICAL DEVICE CORRECTION

### TRUE METRIX®, TRUE METRIX® AIR and TRUE METRIX® GO Self-Monitoring Blood Glucose Systems – E-5 Error Code Instructions

#### Consumer Notice



Trividia is updating the **E-5 Error Code** in the “Messages” section of the **Owner’s Booklets/System Instructions for Use** to emphasize that users must seek medical attention immediately if they receive an E-5 error code and are experiencing symptoms of high glucose. Trividia Health will notify users of additional mitigation strategies as needed.

The system displays an E-5 error code for a very high blood glucose event (> 600 mg/dL) or when there is a test strip error. As currently written, the instructions could potentially lead to a delay in treatment if the user does not seek medical attention immediately when they receive an E-5 error code and are experiencing symptoms of high glucose. A delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose levels.

#### UPDATED E-5 INSTRUCTIONS for TRUE METRIX, TRUE METRIX AIR, and TRUE METRIX GO:

Display	Reason	Action
	<p>Very high blood glucose result (higher than 600 mg/dL), or Test Strip Error</p>	<p><b><u>WARNING!!</u></b>  <b>Retest with a new test strip.</b>  <b>If the error persists and you have symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.</b></p> <p><u>If you are not experiencing symptoms</u>, retest with a new test strip. If the error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST for assistance.</p>

**You may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced.**

If you have any questions, please call Trividia Health Customer Care Department toll-free at **1-888-835-2723** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail [trividia0126CC@trividiahealth.com](mailto:trividia0126CC@trividiahealth.com) or visit [www.trividiahealth.com/E-5productnotice](http://www.trividiahealth.com/E-5productnotice).