

# Important Drug Safety Notice

## TO ALL PARTICIPATING PHARMACIES

### Circular Letter MC26-003-CG February 13, 2026

FDA announced that today that it is initiating a labeling correction which requires a modification of the Owner's Booklets/System Instructions for Use for all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO, and TRUE METRIX PRO Blood Glucose Monitoring Systems (collectively, the "Products") distributed in the United States, United Kingdom, Mexico, Australia, and the Caribbean.

### RECOMMENDATIONS

1. The company is sending the Product Notice to impacted customers with instructions on what to do, to post the notice where products are stored/sold, and to forward the notice to device users, if possible.
2. These customers include pharmacies, mail order companies, and distributors where the TRUE METRIX® meters are sold. Please refer to the Product Notice located at [www.trividiahealth.com/E-5productnotice](http://www.trividiahealth.com/E-5productnotice) for more information.
3. You may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced. This correction does not require removal of the Products from where they are used or sold. This labeling correction impacts the Owner's Booklets/System Instructions for Use that accompany the meters at purchase, as well as the online labeling and help guides located on Trividia Health's website. Trividia Health will notify users of additional mitigation strategies as needed.
4. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

### MC-Rx Pharmacy Services Department

## Trividia Health, Inc. Initiates Labeling Correction for all TRUE METRIX® Blood Glucose Monitoring Systems

### SUMMARY:

<b>Company Announcement Date:</b>	February 06, 2026
<b>FDA Publish Date:</b>	February 06, 2026
<b>Product Type:</b>	Medical Devices
<b>Reason for Announcement:</b>	As currently written, the Owner's Booklets/System Instructions for Use fails to emphasize that users must seek medical attention immediately if they receive an E-5 error code and are experiencing symptoms of high glucose.
<b>Company Name:</b>	Trividia Health, Inc.
<b>Brand Name:</b>	TRUE METRIX
<b>Product Description:</b>	Blood Glucose Monitoring Systems

### Company Announcement

(FT. LAUDERDALE, FL) – February 6, 2026 – Trividia Health, Inc., announced today that it is initiating a labeling correction which requires a modification of the Owner's Booklets/System Instructions for Use for all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO, and TRUE METRIX PRO Blood Glucose Monitoring Systems (collectively, the "Products") distributed in the United States, United Kingdom, Mexico, Australia, and the Caribbean.

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.

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.

Since August 2014, when TRUE METRIX was launched globally, there have been 114 reported serious injuries, and one (1) death associated with the E-5 Error Code.

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

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

**UPDATED E-5 INSTRUCTIONS for TRUE METRIX PRO:**

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

If you have any questions relating to the Owner’s Booklets/System Instructions for Use update, 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).

The correction affects all TRUE METRIX branded Blood Glucose Meters distributed in the United States, United Kingdom, Mexico, Australia and the Caribbean. This includes our cobranded

products sold under store or distribution partner names. Please refer to the Product Notice located at [www.trividiahealth.com/E-5productnotice](http://www.trividiahealth.com/E-5productnotice) for more information on the list of co-brand partners and affected product labeling.

The company is sending the Product Notice to impacted customers with instructions on what to do, to post the notice where products are stored/sold, and to forward the notice to device users, if possible. These customers include pharmacies, mail order companies, and distributors where the TRUE METRIX® meters are sold. Please refer to the Product Notice located at [www.trividiahealth.com/E-5productnotice](http://www.trividiahealth.com/E-5productnotice) for more information.

**You may continue to use the TRUE METRIX® Products.** Products are not to be returned or replaced. This correction does not require removal of the Products from where they are used or sold. This labeling correction impacts the Owner's Booklets/System Instructions for Use that accompany the meters at purchase, as well as the online labeling and help guides located on Trividia Health's website. Trividia Health will notify users of additional mitigation strategies as needed.

Trividia Health has notified the U.S. Food and Drug Administration (FDA) of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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