

URGENT: MEDICAL DEVICE CORRECTION

Voluntary Labeling Correction for all TRUE METRIX® brand of Blood Glucose Monitoring Systems

January X, 2026


Dear Valued Customer:

The purpose of this letter is to inform you that Trividia Health, Inc. ("Trividia" or "we"), the manufacturer of TRUE METRIX® branded blood glucose monitoring systems, has initiated a voluntary medical device correction for TRUE METRIX, TRUE METRIX AIR, and TRUE METRIX GO Self-Monitoring and TRUE METRIX PRO Professional Monitoring Blood Glucose Systems (collectively, the "Products"). This medical device correction impacts the Owner's Booklet labeling only. The meter, test strips, and control solution are not impacted.

The Products may continue to be used and sold. This correction does **not** require removal of the Products from where they are used or sold.

Trividia is updating the description for the **E-5 Error Code in the "Messages" section of the Owner's Booklets** (i.e., Instructions for Use), to highlight that users must contact their healthcare professional immediately if they receive an E-5 error message and are having diabetic symptoms. In such circumstances, as currently written, the E-5 error code description may potentially lead to a delay in treatment. In rare instances, a delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose (higher than 600 mg/dL).

UPDATED INSTRUCTIONS:

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

The correction affects all Products sold in the United States, UK, Mexico and the Caribbean, including co-branded products sold under store or distribution partner names:

Care One (Ahold)	Meijer
CenterWell (Humana)	ProCure (WynnMed)
CVS	Publix
Discount Drug Mart	Relion (Walmart)
Foster & Thrive/Sunmark/Healthmart (McKesson)	Rite Aid
Good Neighbor Pharmacy (Cencora)	Signature Care (Albertsons)
HEB	Top Care (TopCo)
Henry Schein	Walgreens
HyVee	Farmacia Benavides (Mexico)
Leader (Cardinal Health)	Farmacia Del Ahorro Mexico)
McKesson (Med Surg)	

WHAT YOU SHOULD DO:

- **Distributors:** Please notify your customers immediately of this correction and include this letter in your notification. Complete and return the enclosed Acknowledgement form on page 3 to confirm you have received this notice and have notified your customers. If you have any questions, please call Trividia Health Customer Service at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0126CS@trividiahealth.com. **Patients may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.**
- **Pharmacists/DME Providers:** Please notify your stores/providers immediately of this correction and include this letter in your notification. Complete and return the enclosed Acknowledgement form on page 3 to let us know you have received this notice and have notified and/or posted the notice for your stores/locations. If you have any questions, please call Trividia Health Customer Service at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0126CS@trividiahealth.com. **Patients may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.**
 - **FOR RETAIL PHARMACIES:** Please post the “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on page 4 in areas where the Products are sold to advise patients of this labeling correction. **Patients may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.**
- **Mail Order/eCommerce Providers:** Please notify your patients who use these Products immediately of this correction. You may use the “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on page 4. **Patients may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.** If you have any questions, please call Trividia Health Customer Service at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0126CS@trividiahealth.com.
- **Health Care Professionals:** Please notify your providers and patients who use these Products immediately of this correction. You may use the “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on page 4. **Patients 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 or visit www.trividiahealth.com/productnotice
 - **FOR MULTIPLE PATIENT FACILITIES:** Please post the “URGENT MEDICAL DEVICE CORRECTION” HCP notice provided on page 5 in areas where the Products are stored within your facility to advise personnel of this labeling correction. **You may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced.**
- **People with Diabetes:** **You may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced.** Please follow the updated E-5 error message instructions in the consumer notice on page 4 or visit www.trividiahealth.com/productnotice for more information. If you are experiencing diabetic symptoms and you are receiving an E-5 error message, contact your healthcare professional immediately. If you have any questions, please call Trividia Health Customer Care Department toll-free at **1-88-835-2723** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0126CC@trividiahealth.com or visit www.trividiahealth.com/productnotice

This correction is being conducted in coordination with the U.S. Food and Drug Administration (“FDA”).

Adverse reactions or quality problems experienced with the use of the Product may be reported to the FDA's MedWatch Safety and Adverse Event Reporting Program at <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda> or call 1-888-INFO-FDA (1-888-463-6332).

Patient safety is our top priority, and we apologize for any inconvenience this correction may cause you.

Sincerely,

Trividia Health

URGENT MEDICAL DEVICE CORRECTION

TRUE METRIX brand of Blood Glucose Monitoring Systems Acknowledgement and Receipt Form – **Response Required**

I have read and understand the product notice instructions provided in the January **X**, 2026 letter.
Yes ____ No ____

Are you aware of any adverse events associated with the Product? Yes ____ No ____

If yes, please explain and provide details to the Trividia Health Customer Care Department via e-mail: trividia0126CC@trividiahealth.com

Distributors/Pharmacies/DME Providers:

Please acknowledge the following (check all that apply):

☐ I have notified all of my customers/stores who were shipped or may have been shipped these products by (**specify date notification was sent** _____ **and method of notification** _____);

☐ I have notified/posted the notices for providers/patients who may use these products by (**specify date notification was sent** _____ **and method of notification** _____);

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Company Name	
Telephone	
Email address	

PLEASE SEND THE COMPLETED RESPONSE FORM TO TRIVIDIA HEALTH CUSTOMER SERVICE
DEPARTMENT VIA E-MAIL TO: trividia0126CS@trividiahealth.com

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 description for the **E-5 Error Code** in the “Messages” section of the **Owner’s Booklets** (i.e., Instructions for Use), to highlight that users must contact their healthcare professional immediately if they receive an E-5 message and are having diabetic symptoms. In such circumstances, as currently written, the E-5 error code description may potentially lead to a delay in treatment. In rare instances, a delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose (higher than 600 mg/dL).

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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 or visit www.trividiahealth.com/productnotice

URGENT MEDICAL DEVICE CORRECTION


TRUE METRIX® PRO Professional Monitoring Blood Glucose System – E-5 Error Code Instructions

Healthcare Professional Notice



Trividia is updating the description for the **E-5 Error Code** in the “Messages” section of the **Owner’s Booklets** (i.e., Instructions for Use), to highlight that users must contact their healthcare professional immediately if they receive an E-5 message and are having diabetic symptoms. In such circumstances, as currently written, the E-5 error code description may potentially lead to a delay in treatment. In rare instances, a delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose (higher than 600 mg/dL).

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You may continue to use the TRUE METRIX® PRO Professional Blood Glucose Monitoring System. Products are not to be returned or replaced.

- If your patient is experiencing diabetic symptoms and you are receiving an E-5 error message, contact their healthcare provider immediately or follow your facilities’ procedures.
- 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 or visit www.trividiahealth.com/productnotice