TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

URGENT: MEDICAL DEVICE CORRECTION

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

February 6, 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 labeling 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 labeling correction impacts the Owner's Booklets/System Instructions for Use included with the meter at purchase and the online labeling and help guides at www.trividiahealth.com. 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.

The correction involves the **E-5 Error Code** in the "Messages" section of the Owner's Booklets/System Instructions for Use. 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.

Trividia is updating the **E-5 Error Code** actions 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.

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

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

Display	Reason	Action
	**Very high blood glucose result (higher than 600 mg/dL),** or Test Strip Error	**WARNING!!** **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.

UPDATED E-5 INSTRUCTIONS for TRUE METRIX PRO:

Display	Reason	Action
	**Very high blood glucose result (higher than 600 mg/dL),** or Test Strip Error	**WARNING!!** **Retest with a new test strip.** **If the error persists and the patient has symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.** If the patient has no symptoms, retest with a new test strip. If the error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST-for assistance.

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

This labeling correction affects all Products sold in the United States, United Kingdom, Mexico, Australia, and the Caribbean, including co-branded products sold under the following store or distribution partner names. The full list of impacted Owners Booklets and System IFUs is provided on page 7.

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

WHAT YOU SHOULD DO:

- **Distributors**: Please notify your customers immediately of this correction. Include this letter in your notification and ask that they notify their customers or facilities if they have further distributed the Products. Complete and return the Acknowledgement form on page 4 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. **Customers 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. Include this letter in your notification and ask that they notify their customers or facilities if they have further distributed the Products. Complete and return the Acknowledgement form on page 4 to confirm 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. **Customers 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 5 in areas where the Products are sold to notify patients of this labeling correction. **Customers 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 customers who use these Products immediately of this correction. Complete and return the Acknowledgement form on page 4 to confirm you have received this notice and have notified your customers. You may use the "URGENT MEDICAL DEVICE CORRECTION" consumer notice provided on page 5. **Customers 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 5. **Patients may continue to use the TRUE METRIX® Products. Products are not to be returned or**

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

replaced. If you have any questions, please call Trividia Health Customer Care at **1-888-835-2723** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0126CC@trividiahealth.com

- **FOR MULTIPLE PATIENT FACILITIES**: Please post the "URGENT MEDICAL DEVICE CORRECTION" HCP notice provided on page 6 in areas where the Products are stored within your facility to notify 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:** Please follow the updated **E-5 error code** instructions in the "URGENT MEDICAL DEVICE CORRECTION" consumer notice on page 5 or visit www.trividiahealth.com for links to the updated Owner's Booklets and help resources. **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 at **1-888-835-2723** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0126CC@trividiahealth.com.

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.

Regular Mail or Fax: Download form 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.

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

Sincerely,

Trividia Health

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

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 February 6, 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 by e-mail: trividia0126CC@trividiahealth.com

_____

_____

Distributors/Pharmacies/DME Providers/Mail Order/eCommerce:

Please acknowledge the following (check all that apply):

☐ I have notified all customers/stores who were shipped or may have been shipped these products:
Date notification was sent : _____
Method of notification *(e.g. email, telephone)*: _____

☐ I have notified/posted the notices for providers/patients who may use these products:
Date notification was sent : _____
Method of notification *(e.g. email, telephone)*: _____

☐ I have questions. Please have Customer Service contact me.

Signature:	Date:
Print Name & Title	
Company Name	
Distribution Center	
Address	
Telephone	
Email	

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

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

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
	**Very high blood glucose result (higher than 600 mg/dL),** or Test Strip Error	**WARNING!!** **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.

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/E-5productnotice.

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

URGENT MEDICAL DEVICE CORRECTION

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

Healthcare Professional Notice

Trividia is updating the **E-5 Error Code in the "Messages" section of the Owner's Booklets** to emphasize that users must seek medical attention immediately if they receive an E-5 error code and the patient is 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 the patient is experiencing symptoms of high glucose. A delay in treatment may result in serious adverse health consequences or death, especially for patients with very high blood glucose levels.

UPDATED E-5 INSTRUCTIONS for TRUE METRIX PRO:

Display	Reason	Action
	**Very high blood glucose result (higher than 600 mg/dL),** or Test Strip Error	**WARNING!!** **Retest with a new test strip.** **If the error persists, and the patient has symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.** If the patient has no symptoms, retest with a new test strip. If the error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST-for assistance.

You may continue to use the TRUE METRIX® PRO Professional Blood Glucose Monitoring System. 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/E-5productnotice.

TRIVIDIA HEALTH
2400 N.W. 55TH COURT
FORT LAUDERDALE, FL 33309 U.S.A.

List of Affected Labeling & Online Resources

Affected Labeling:

Description	Part# & Revision
US Labeling:	
TRUE METRIX Owner's Booklet	RE4TVH03 Rev 56 and prior
TRUE METRIX Owner's Booklet (English)	RE4TVH35 Rev 51 and prior
TRUE METRIX Owner's Booklet (Spanish)	RE4TVH35S Rev 51 and prior
TRUE METRIX AIR Owner's Booklet	REA4TVH03 Rev 57 and prior
TRUE METRIX AIR Owner's Booklet (English)	REA4TVH35 Rev 51 and prior
TRUE METRIX AIR Owner's Booklet (Spanish)	REA4TVH35S Rev 51 and prior
TRUE METRIX GO Owner's Booklet	RF4TVH03 Rev 57 and prior
TRUE METRIX GO Owner's Booklet (English)	RF4TVH35 Rev 51 and prior
TRUE METRIX GO Owner's Booklet (Spanish)	RF4TVH35S Rev 51 and prior
TRUE METRIX PRO Owners Booklet	RE4TVHP03 Rev 56 and prior
Relion (Walmart) TRUE METRIX AIR Owners Booklet	REA4RLN03 Rev 52 and prior
Relion (Walmart) TRUE METRIX AIR Owner's Booklet - English	REA4RLN35 Rev 52 and prior
McKesson Med Surg TRUE METRIX Self Monitoring Owners Booklet	RE4SUN03 Rev 55 and prior
McKesson Med Surg TRUE METRIX PRO Owners Booklet	RE4SUNP03 Rev 56 and prior
INTERNATIONAL Labeling:	
Caribbean	
TRUE METRIX Blood Glucose Monitoring System IFU Trividia House Brand	RE4ITV16 Rev 53 and prior
TRUE METRIX AIR Owner's Booklet International Trividia House Brand	REA4ITV03 Rev 55 and prior
TRUE METRIX GO Blood Glucose Monitoring System IFU Trividia House Brand	RF4ITV16 Rev 55 and prior
United Kingdom	
TRUE METRIX System Instructions for Use (IFU) for Trividia Health UK Limited	RE4UKT16 Rev 55 and prior
TRUE METRIX AIR Owners Booklet for Trividia Health UK Limited	REA4UKT03 Rev 55 and prior
TRUE METRIX GO System Instructions for Use (IFU) for Trividia Health UK Limited	RF4UKT16 Rev 56 and prior
Mexico	
Trividia Health LATAM- TRUE METRIX System IFU mg/dL	RE4LAT16 Rev 50 and prior
Trividia Health LATAM- TRUE METRIX AIR Owners Booklet	REA4LAT03 Rev 51 and prior
Trividia Health LATAM- TRUE METRIX GO System IFU	RF4LAT16 Rev 51 and prior
Australia	
TRUE METRIX System Instructions for Use (IFU) for Trividia Health Australia	RE4AUT16 Rev 56 and prior
TRUE METRIX AIR Owners Booklet for Trividia Health Australia	REA4AUT03 Rev 58 and prior
TRUE METRIX GO System Instructions for Use (IFU) for Trividia Health Australia	RF4AUT16 Rev 57 and prior

For a list of impacted Products, including UPC/UDI, go to: www.trividiahealth.com/E-5productnotice.

Online resources:

TRUE METRIX Owner's Booklet – RE4TVH35r52_020426.pdf
TRUE METRIX AIR Owner's Booklet – REA4TVH35r52__020426.pdf
TRUE METRIX GO Owner's Booklet – RF4TVH35r52_020426.pdf
TRUE METRIX PRO Owner's Booklet – RE4TVHP03r57_020426.pdf
E-5 Troubleshooting Guide – E-5_020526.pdf