

## **URGENT: MEDICAL DEVICE CORRECTION - UPDATED**

### **Trividia Health Correction for TRUE METRIX Blood Glucose Monitoring Systems**

May 1, 2026

Dear Valued Customer:

The purpose of this letter is to provide an important update on Trividia Health's ("Trividia" or "we"), medical device labeling correction that was announced on February 6, 2026, for all TRUE METRIX®, TRUE METRIX® AIR, TRUE METRIX® GO, and TRUE METRIX® PRO Blood Glucose Monitoring Systems (collectively, the "Products").

Since the February 6, 2026 communication, Trividia Health has been actively updating the labeling and providing messaging to ensure that users are aware of the updated instructions for the E-5 Error Code. Users will already be seeing the new E-5 Error Code message in TRUE METRIX Meter boxes and in test strip boxes.

In coordination with the U.S. Food and Drug Administration (FDA), we continue to develop our long-term corrective strategy and wish to communicate certain key updates to users.

#### **Message to People currently managing their Diabetes with TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO branded Blood Glucose Meters:**

Delayed recognition of extremely low or extremely high blood glucose levels could increase the risk of serious health complications or delays in treatment. Your safety is our top priority.

**For People with Diabetes**, if possible, consider transitioning to an alternative method of testing your blood glucose (blood sugar), otherwise you should continue using your TRUE METRIX meter. Patients continuing to use their TRUE METRIX device should follow the updated instructions if they receive an E-5 Error Code. People with Diabetes who rely on intensive insulin therapy, sulfonylureas, or glucose monitoring due to frequent hypo- or hyperglycemia events are at highest risk, and should consider transitioning to an alternative testing method until the updated TRUE METRIX blood glucose test system becomes available.

If you have questions or concerns as to whether TRUE METRIX is appropriate for you, based on an understanding of your individual risk factors, please discuss with your healthcare provider or pharmacist.

Contact Trividia Health's Customer Support Department to be provided with a TRUENESS® Blood Glucose Monitoring System (Meter and Test Strips), at no-charge, by calling toll-free at 1-888-943-2387 Monday-Friday 8AM-8PM EST (excluding holidays) or visit <https://truemetrixmeters.expertinquiry.com> to sign up to be contacted.

#### **Updated TRUE METRIX Meters and Future Upgrade Program:**

As part of its commitment to continuous improvement and patient safety, Trividia Health has determined that developing updated software for TRUE METRIX meters will provide the most effective long-term solution. In coordination with the FDA, we are diligently working on these updates.

We anticipate that updated meters will become available across the TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO and TRUE METRIX PRO branded Blood Glucose Meters in the near future, after which Trividia Health will initiate a comprehensive meter upgrade program. **Trividia Health will notify users when the upgrade program becomes available.**

This updated notice affects all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO and TRUE METRIX PRO branded Blood Glucose Meters distributed in the United States. This includes our cobranded products sold under store or distribution partner names. Please refer to the updated 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, customer notices and updated TRUE METRIX owner's booklets.

Additional information that can be found online includes a Serial Number search tool for impacted products.

## **WHAT YOU SHOULD CONTINUE TO DO:**

- **Distributors**: Please notify your customers immediately of this correction update. 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 by email to [Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com) or fax at: 1-888-965-6125**, to confirm that you have received this updated notice and have notified your customers. If you have any questions, please call our Customer Support Department toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays). **Products are not to be returned, and in accordance with the information noted above we will notify users of the product upgrade in the near future.**
- **Pharmacists/DME Providers**: Please notify your stores/providers immediately of this correction update. 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 by email to [Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com) or fax at: 1-888-965-6125**, to confirm that you have received this updated notice and have notified and/or posted the notice for your stores/locations. If you have any questions, please call our Customer Support Department toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays). **Products are not to be returned and in accordance with the information noted above we will notify users of the product upgrade in the near future.**
  - **RETAIL PHARMACIES**: Consider communicating this correction to your patients using a TRUE METRIX meter and post the updated “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on **page 5** in areas where the Products are sold.
- **Mail Order/eCommerce Providers**: Please notify your customers who use these Products immediately of this correction update. You may use the updated “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on **page 5**. **Complete and return the Acknowledgement form on page 4 by email to [Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com) or fax at: 1-888-965-6125**, to confirm that you have received this updated notice and have notified your customers. If you have any questions, please call our Customer Support Department toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays). **Products are not to be returned, and in accordance with the information noted above we will notify users of the product upgrade in the near future.**
- **Health Care Professionals**: Please notify your providers and patients who use these Products immediately of this correction update. You may use the updated “URGENT MEDICAL DEVICE CORRECTION” consumer notice provided on **page 5**. **Complete and return the Acknowledgement form on page 4 by email to [Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com) or fax at: 1-888-965-6125**, to confirm you have received this updated notice and have notified your patients. If you have any questions, please call our Customer Support Department toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays). **Products are not to be returned, and in accordance with the information noted above we will notify users of the product upgrade in the near future.**
  - **FOR FACILITIES WITH MULTIPLE PATIENTS**: Please post the updated “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.
- **For People with Diabetes**: If possible, consider transitioning to an alternative method of testing your blood glucose (blood sugar), otherwise you should continue using your TRUE METRIX meter. Patients continuing to use their TRUE METRIX device should follow the updated instructions if they receive an E-5 Error Code. People with Diabetes who rely on intensive insulin therapy, sulfonylureas, or glucose monitoring due to frequent hypo- or hyperglycemia events are at highest risk and should consider transitioning to an alternative testing method until the updated TRUE METRIX meter becomes available. If you have questions or concerns as to whether TRUE METRIX is appropriate for you, based on an understanding of your individual risk factors, please discuss with your healthcare provider or pharmacist.
  - Contact Trividia Health’s Customer Support Department to be provided with a TRUENESS® Blood Glucose Monitoring System (Meter and Test Strips), at no-charge, by calling toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays) or visit <https://truemetrixmeters.expertinquiry.com> to sign up to be

contacted. **Products are not to be returned, and in accordance with the information noted above we will notify users of the product upgrade in the near future.**

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.

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

**URGENT: MEDICAL DEVICE CORRECTION – UPDATED May 1, 2026**

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

I have read and understand the updated product notice instructions provided in the May 1, 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 below or by e-mail:  
[Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com)

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**Distributors/Pharmacies/DME Providers/Mail Order/eCommerce/Health Care Professionals:**

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.

**PLEASE COMPLETE ALL FIELDS REQUIRED BELOW:**

Signature:	Date:
Print Name & Title	
<b>Company/Facility Name</b>	
Distribution Center	
Address	
Telephone	
Email	

**PLEASE SEND THE COMPLETED RESPONSE FORM TO:**  
[Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com) or fax to: 1-888-965-6125

**URGENT: MEDICAL DEVICE CORRECTION – UPDATED May 1, 2026**  
**TRUE METRIX® TRUE METRIX® AIR and TRUE METRIX® GO Self-Monitoring Blood Glucose**  
**Systems – E-5 Error Code Instructions**

**Consumer Notice**



Delayed recognition of extremely low or extremely high blood glucose levels could increase the risk of serious health complications or delays in treatment. Your safety is our top priority.

**For People with Diabetes**, if possible, consider transitioning to an alternative method of testing your blood glucose (blood sugar), otherwise you should continue using your TRUE METRIX meter. Patients continuing to use their TRUE METRIX device should follow the updated instructions if they receive an E-5 Error Code. People with Diabetes who rely on intensive insulin therapy, sulfonylureas, or glucose monitoring due to frequent hypo- or hyperglycemia events are at highest risk and should consider transitioning to an alternative testing method until the updated TRUE METRIX meter becomes available.

If you have questions or concerns as to whether TRUE METRIX is appropriate for you, based on an understanding of your individual risk factors, please discuss with your healthcare provider or pharmacist.


Contact Trividia Health’s Customer Support Department to be provided with a TRUENESS® Blood Glucose Monitoring System (Meter and Test Strips), at no-charge, by calling toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays) or visit <https://truemetrixmeters.expertinquiry.com> to sign up to be contacted.

**Continued Labeling Updates:**

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.

You will already be seeing the new E-5 Error Code message in Meter boxes and in TRUE METRIX test strip boxes.

**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	<b>WARNING!!</b> Retest with a new test strip. <b>If the error persists and you have symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.</b>  <i>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.</i>

**Updated TRUE METRIX Meters and Future Upgrade Program:**

As part of its commitment to continuous improvement and patient safety, Trividia has determined that developing updated software for TRUE METRIX meters will provide the most effective long-term solution. In coordination with the FDA, we are diligently working on these updates.

We anticipate that updated meters will become available in the near future, after which **Trividia Health will notify users when the upgrade program becomes available.**

If you have any questions, please call our Customer Support Department toll-free at 1-888-943-2387 Monday-Friday 8AM-8PM EST (excluding holidays) or visit <https://truemetrixmeters.expertinquiry.com> to sign up to be contacted.

**URGENT: MEDICAL DEVICE CORRECTION – UPDATED May 1, 2026**

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

**Healthcare Professional Notice**




**For your patients with Diabetes, especially those who rely on intensive insulin therapy, sulfonylureas, or glucose monitoring due to frequent hypo- or hyperglycemic events,** delayed recognition of extremely low or extremely high blood glucose levels could increase the risk of serious health complications or delays in treatment. Safety is our top priority. For your patients with diabetes, if possible, consider transitioning to an alternative method of testing your blood glucose (blood sugar), otherwise you should continue using your TRUE METRIX PRO meter. Continuing to use the TRUE METRIX PRO device should follow the updated instructions if you receive an E-5 Error Code. Alternative testing methods will only be required until the updated TRUE METRIX PRO meter becomes available.

**Continued Labeling Updates:**

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.

You will already be seeing the new E-5 Error Code message in meter boxes and in TRUE METRIX PRO test strip boxes.

**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	<b><u>WARNING!!</u></b> Retest with a new test strip. <b>If the error persists, and the patient has symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.</b>  <u>If the patient has no symptoms,</u> retest with a new test strip. If the error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST-for assistance.

**Updated TRUE METRIX Meters and Future Upgrade Program:**

As part of its commitment to continuous improvement and patient safety, Trividia has determined that developing updated software for TRUE METRIX PRO meters will provide the most effective long-term solution. In coordination with the FDA, we are diligently working on these updates, which are intended to make high-glucose warnings more prominent and intuitive for users.

We anticipate that updated meters will become available in the near future, after which **Trividia Health will notify users when the upgrade program becomes available.**

If you have any questions, please call our Customer Support Department toll-free at **1-888-943-2387** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail [Trividia4036@sedgwick.com](mailto:Trividia4036@sedgwick.com).