

## URGENT FIELD SAFETY NOTICE

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

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 Blood Glucose Monitoring Systems (collectively, the “Products”). This labeling correction impacts the Owner’s Booklets and System Instructions for Use included with the meter at purchase and the online labeling located on the company’s website ([www.trividiahealth.co.uk](http://www.trividiahealth.co.uk)). 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 (higher than 33.3 mmol/L ) 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. None of those incidents were from the UK.

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

Display	Reason	Action
	<p><b>Very high blood glucose result (higher than 33.3 mmol/L)</b>                      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, contact for assistance.</p>

The list of UK impacted Owners Booklets, System IFUs and products is provided on [page 5](#).

**WHAT YOU SHOULD DO:**

- **Wholesalers/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 and Receipt” form on **page 3** to confirm you have received this notice and have notified your customers. If you have any questions, please e-mail [trividia0126CS@trividiahealth.com](mailto:trividia0126CS@trividiahealth.com). **Customers may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.**
- **Pharmacies/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 and Receipt” form on **page 3** 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 e-mail [trividia0126CS@trividiahealth.com](mailto:trividia0126CS@trividiahealth.com). **Customers may continue to purchase and use the TRUE METRIX® Products. Products are not to be returned or replaced.**
- **eCommerce Providers:** Please notify your customers who use these Products immediately of this correction. Complete and return the “Acknowledgement and Receipt” form on **page 3** to confirm you have received this notice and have notified your customers. You may use the “Consumer Notice” provided on **page 4**. **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 e-mail [trividia0126CS@trividiahealth.com](mailto:trividia0126CS@trividiahealth.com).
- **Health Care Professionals:** Please notify your providers and patients who use these Products immediately of this correction. You may use the “Consumer Notice” provided on **page 4**. Please also post the “Consumer Notice” provided on **page 4** in areas where the Products are stored within your facility to notify personnel of this labeling correction. **You and your patients may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced.** If you have any questions, please e-mail [trividia0126CC@trividiahealth.com](mailto:trividia0126CC@trividiahealth.com)
- **People with Diabetes:** Please follow the updated **E-5 error code** instructions in the “Consumer Notice” provided on **page 4** or visit [www.trividiahealth.co.uk](http://www.trividiahealth.co.uk) for links to the updated Owner’s Booklets/System Instructions For Use. **You may continue to use the TRUE METRIX® Products. Products are not to be returned or replaced.** If you have any questions, please e-mail [trividia0126CC@trividiahealth.com](mailto:trividia0126CC@trividiahealth.com).

Trividia Health has notified the UK MHRA of this action.

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

Sincerely,



Trividia Health

## URGENT FIELD SAFETY NOTICE

### 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 24, 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](mailto:trividia0126CC@trividiahealth.com)

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**Wholesalers/Distributors/Pharmacies/DME Provider/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](mailto:trividia0126CS@trividiahealth.com)**

## URGENT FIELD SAFETY NOTICE

### TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO 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** and **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 (higher than 33.3 mmol/L) 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.

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Visit [www.trividiahealth.co.uk](http://www.trividiahealth.co.uk) for links to the updated Owner’s Booklets/System Instructions for Use.

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

If you have any questions, please e-mail [trividia0126CC@trividiahealth.com](mailto:trividia0126CC@trividiahealth.com)

### List of Affected Labeling

Description	Part# & Revision
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

### List of Impacted Products

Item Number	Description	UDI-DI/GTIN	UPC
<b>TRUE METRIX</b>			
RE4i82-11	TRUE METRIX Kit (United Kingdom - mmol/L)	00021292012205	021292012205
RE4i82-12	TRUE METRIX Starter Kit (United Kingdom - mmol/L)	00021292009977	021292009977
<b>TRUE METRIX AIR</b>			
REA4i82-11	TRUE METRIX AIR Kit (United Kingdom - mmol/L)	00021292012212	021292012212
REA4i82-12	TRUE METRIX AIR Starter Kit (United Kingdom - mmol/L)	00021292009991	021292009991
<b>TRUE METRIX GO</b>			
RF4i82-11BK	TRUE METRIX GO Kit (United Kingdom - mmol/L)	00021292012229	021292012229
RF4i82-12BK	TRUE METRIX GO Starter Kit (United Kingdom - mmol/L)	00021292009984	021292009984