

# **URGENT: MEDICAL DEVICE VOLUNTARY RECALL**

## **Trividia Health, Inc. Initiates Voluntary Recall for an Isolated TRUE METRIX AIR Blood Glucose Meter with Serial Number TA1548753**

April 20, 2020

Dear Valued Customer:

The purpose of this letter is to inform you that Trividia Health, Inc. has announced a voluntary product recall of one (1) TRUE METRIX AIR blood glucose meter. The company has determined that one (1) TRUE METRIX AIR blood glucose meter distributed in the United States was packaged into a TRUE METRIX blood glucose meter kit and has an incorrect factory-set unit of measure; the meter displays glucose results in mmol/L rather than mg/dL. If a consumer does not notice the incorrect unit of measure, it is possible that the meter glucose result will be read as a lower blood glucose result than expected, and this may result in the patient's glucose level remaining high, which can lead to serious injury or impairment with risk of death.

There is one (1) affected TRUE METRIX AIR meter (serial number TA1548753), packaged into a TRUE METRIX blood glucose meter kit (Kit Lot number KW0135) that was distributed nationwide in the United States in February 2019. We have not received any reports of patient injury or an adverse event related to this recall.

Follow the instructions below to determine if you have the affected meter and to have it replaced at no charge:

- People with Diabetes: Determine whether you have the affected meter by obtaining the serial number from the serial number label on the back of the meter (TA1548753) and visiting [www.TrividiaHealth.com/air-product-notice](http://www.TrividiaHealth.com/air-product-notice) or by calling **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST**. (See page 4 for images of the meter and meter labels). Trividia Health will verify the affected meter by serial number and will expedite return and replacement of the meter at no charge to you. **Discontinue use of the meter immediately if it is determined you have the affected meter.** You may continue to test blood glucose using any other Trividia Health blood glucose meter not included in this recall, while waiting for your replacement meter to arrive. Only use test strips that are intended for use with your meter.
- Health Care Professionals: Determine whether you have or may have the affected meter in inventory by examining the kit lot number (KW0135) and meter serial number (TA1548753) printed on the outer case/shipper label or on the side of the individual meter box. (See page 3 for images of these labels). If you have any product from lot KW0135, you may have the

affected meter. Please check your inventory and product labels to determine if you have meter serial number TA1548753. If you have this meter in inventory, please contact **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST** to expedite return and replacement of the meter. Please advise any patients who may have lot KW0135 or meter serial number TA1548753 to contact **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST**. Please advise patients that they may continue to test blood glucose using any other Trividia Health blood glucose meter not included in this recall while waiting for their replacement meter to arrive. Patients should only use test strips that are intended for use with their meters.

- Pharmacists/DME Providers: Determine whether you have or may have the affected meter in inventory by examining the lot number (KW0135) and meter serial number (TA1548753) printed on the outer case/shipper label or on the side of the individual meter box. (See page 3 for images of these labels). If you have any product from lot KW0135, you may have the affected meter. Please check your inventory and product labels to determine if you have meter serial number TA1548753. If you have this meter in inventory, please contact **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST** to expedite return and replacement of the meter. Please advise any patients who may have lot KW0135 or meter serial number TA1548753 to contact **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST**. Please advise patients that they may continue to test blood glucose using any other Trividia Health blood glucose meter not included in this recall while waiting for their replacement meter to arrive. Patients should only use test strips that are intended for use with their meters. If you receive inquiries from health care professionals or meter users, please reference the above instructions.
- Distributors: Determine whether you have or may have the affected meter in inventory by examining the lot number (KW0135) and meter serial number (TA1548753) printed on the outer case/shipper label or on the side of the individual meter box. (See page 3 for images of these labels). If you have any product from lot KW0135, you may have the affected meter. Please check your inventory and product labels to determine if you have meter serial number TA1548753. If you have this meter in inventory, please contact **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST** to expedite return and replacement of the meter. In addition, please notify your customers of this voluntary product recall immediately. Request that they return only the product identified as Lot KW0135 or return the meter box identified as Lot KW0135 with serial number TA1548753, following your normal return procedures. Once you have received all meters to be returned, please call **Trividia Health toll-free at 1-800-518-5726, Monday-Friday, 8AM-8PM EST** to obtain prepaid return labels.

This recall is being made with the knowledge of the Food and Drug Administration. Please complete and return the enclosed response form as soon as possible via email to **trividia0420CS@trividiahealth.com**. If you have any questions, please call Trividia Health toll free at **1-800-518-5726, Monday-Friday, 8AM-8PM EST**.

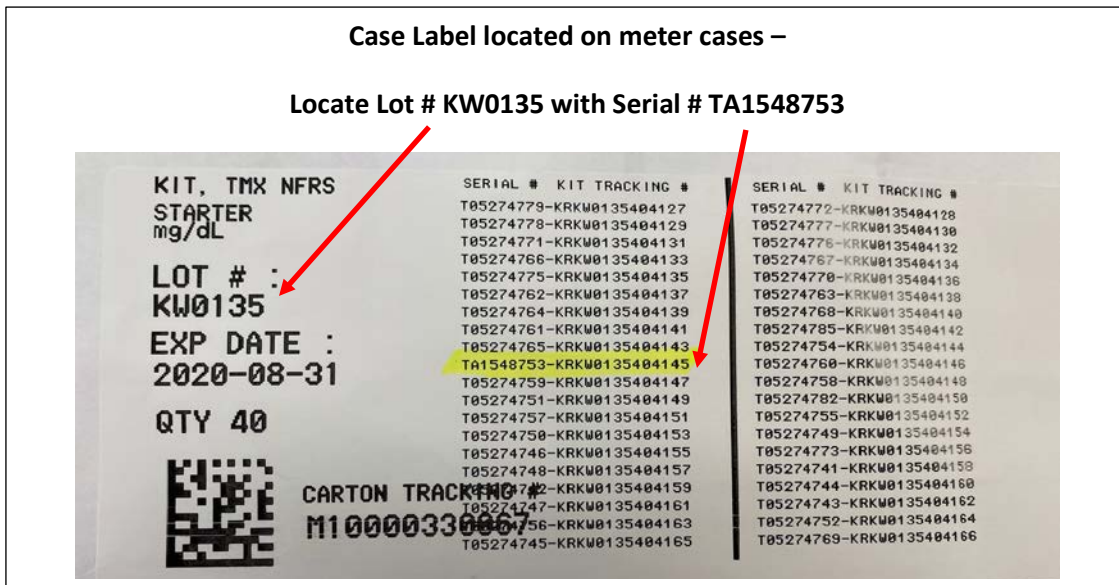
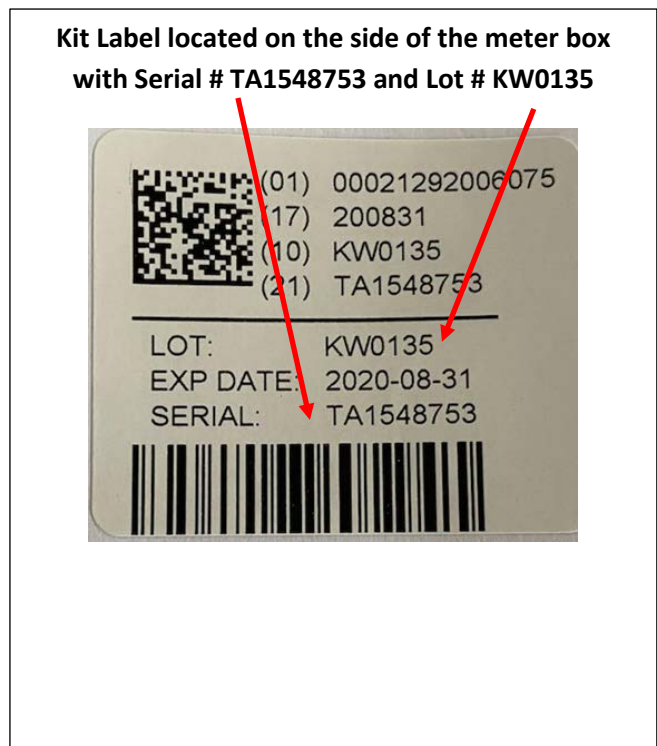
Patient safety is a top priority at Trividia Health, and we apologize for any inconvenience this voluntary recall may cause you.

Users within the USA may report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online or by phone.

- Online at <http://www.fda.gov/safety/medwatch/howtoreport/default.htm> (form available to fax or mail), or
- Call FDA 1-800-FDA-1088

Sincerely,  
Trividia Health

**EXAMPLES OF WHERE TO FIND SERIAL NUMBER OR LOT NUMBER**



**MEDICAL DEVICE VOLUNTARY RECALL RETURN RESPONSE**  
**Acknowledgement and Receipt Form**  
**Response is Required**

**TRUE METRIX BLOOD GLUCOSE METER LOT KW0135**  
**(METER SERIAL NUMBER TA1548753)**

I have read and understand the recall instructions provided in the April 20, 2020 letter.  
Yes \_\_\_ No\_\_\_

Any adverse events associated with recalled product? Yes \_\_\_ No\_\_\_

If yes, please explain:

---

---

---

| Product/Brand Names       | Manufacturer's Product Number/Catalog Number | Lot/Serial Number shipped to Customer | Quantity in inventory | Quantity returned |
|---------------------------|--|---------------------------------------|-----------------------|-------------------|
| TRUE METRIX AIR meter     | n/a  | TA1548753                             |                       |                   |
| TRUE METRIX meter box(es) | RE4H01-43                                    | KW0135                                |                       |                   |

UDI on the meter kit box is listed as:

(01)00021292006075

(17)200831

(10)KW0135

(21)TA1548753

**Return Response Box:**

**Please provide any additional information, if applicable.**

Distributors:

I have checked my stock and have quarantined inventory consisting of \_\_\_\_\_ <select one: units, cases, etc.>.

I have identified and notified my customers who were shipped or may have been shipped this product by (**specify date \_\_\_\_\_ and method of notification \_\_\_\_\_**);

<or>

Attached is a list of customers (provide in Microsoft Excel) who received/may have received this product. Please notify my customers. (Please do not include consumer information)

**Questions: (when applicable)**

Please have Customer Service contact me.

Signature of Receipt \_\_\_\_\_

|               |  |
|---------------|--|
| Name/Title    |  |
| Telephone     |  |
| Email address |  |

PLEASE E-MAIL THIS COMPLETED RESPONSE FORM TO: [trividia0420CS@trividiahealth.com](mailto:trividia0420CS@trividiahealth.com)

If you have any questions, please call **Trividia Health toll free at 1-800-518-5726.**