

Blood Glucose Monitor Recall: Trividia Health Issues Correction for TRUE METRIX Blood Glucose Monitoring Systems

This recall (</medical-devices/medical-device-recalls-and-early-alerts/what-medical-device-recall/>) **is an update to an Early Alert.** The FDA has identified this recall as Class I, the most serious type. This device may cause serious injury or death if the recommendations below are not followed.

The FDA has provided new recommendations for patients, caregivers, and health care providers. These recommendations can be found in the FDA Safety Communication “[Risks of Using TRUE METRIX Blood Glucose Monitoring Systems by Trividia Health](/medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication/) (</medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication/>)”.

Feedback

Affected Product



The FDA is aware that Trividia Health, Inc. has issued an Urgent Medical Device Correction to notify affected customers that all TRUE METRIX, TRUE METRIX AIR, and TRUE METRIX GO Self-Monitoring Blood Glucose Systems and TRUE METRIX PRO Professional Monitoring Blood Glucose Systems, including cobranded products sold under store or distribution partner names, have updated use instructions. Affected devices (collectively referred to as TRUE METRIX in this communication):

- TRUE METRIX Self-Monitoring Blood Glucose System
- TRUE METRIX AIR Self-Monitoring Blood Glucose System
- TRUE METRIX GO Self-Monitoring Blood Glucose System

- TRUE METRIX PRO Professional Monitoring Blood Glucose System

[Full List of Affected Product \(/media/191141/download?attachment\)](/media/191141/download?attachment)

What to Do

The FDA recommends that consumers and health care providers follow the recommendations provided in the FDA Safety Communication “[Risks of Using TRUE METRIX Blood Glucose Monitoring Systems by Trividia Health \(/medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication\)](/medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication)”, issued April 28, 2026.

Linked below you can also find the letter sent on February 6, 2026 from Trividia Health to notify affected customers of the issue.

Reason for Recall

This recall is for an issue with the E-5 error code and the instructions for the user in the “Messages” section of the Owner’s Booklets/System Instructions for Use and the online labeling and help guides. The TRUE METRIX meters display the same E-5 Error Code for two different types of issues: 1) a very high blood glucose event (> 600 mg/dL), and/or 2) when there is a test strip error. If a user receives an E-5 Error Code when they are having a very high glucose event, they may not seek appropriate treatment if they think it is a test strip error, or they may delay appropriate treatment as they try to determine what the error means. Alternately, if a user assumes the E-5 Error Code is due to a very high blood glucose event, but they actually have low or normal blood glucose, they may improperly treat themselves for high blood glucose when they actually have low or normal blood glucose. Either a delay in treatment or improper treatment may result in serious adverse health consequences, such as dehydration, altered mental status, loss of consciousness, or death, especially for users with very high or very low blood glucose levels.

As of January 16, Trividia Health has reported 114 serious injuries and one death associated with this issue.

Device Use

The TRUE METRIX devices are used for the quantitative measurement of glucose (sugar) in fresh whole blood samples.

Contact Information

Health Care Professionals and patients in the U.S. with adverse reactions, quality problems, or questions about this issue should contact Trividia Health at trividia0126CC@trividiahealth.com (<mailto:trividia0126CC@trividiahealth.com>) or 1-888-835-2723. Distributors, pharmacists, DME providers, and mail order/eCommerce providers in the U.S. with quality problems or questions about this issue should contact Trividia Health at trividia0126CS@trividiahealth.com (<mailto:trividia0126CS@trividiahealth.com>) or 1-800-588-1685.

Additional FDA Resources

- [FDA Safety Communication \(/medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication\)](/medical-devices/safety-communications/risks-using-true-metrix-blood-glucose-monitoring-systems-trividia-health-fda-safety-communication) [04/28/2026]
- [FDA Enforcement Report \(https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=98317\)](https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=98317).
- [CDRH Medical Device Recall Database \(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=98317\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=98317).

Additional Company Resources

Company-provided information is posted here by the FDA as a public service.

- [Firm Press Release \(https://www.trividiahealth.com/wp-content/uploads/2026/02/FINAL-TMX-product-notice-Press-Release-2-6-26_.pdf\)](https://www.trividiahealth.com/wp-content/uploads/2026/02/FINAL-TMX-product-notice-Press-Release-2-6-26_.pdf) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) [02/06/2026]
- [Firm-Issued Medical Device Correction Letter \(https://www.trividiahealth.com/wp-content/uploads/2026/02/FINAL-Trividia_TMX-Product-Notice-and-Response-2-6-2026.pdf\)](https://www.trividiahealth.com/wp-content/uploads/2026/02/FINAL-Trividia_TMX-Product-Notice-and-Response-2-6-2026.pdf) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) [02/06/2026]
- [Firm List of Impacted Products \(https://www.trividiahealth.com/wp-content/uploads/2026/01/List-of-Impacted-Productsv2_020426_For-Review-Only.pdf\)](https://www.trividiahealth.com/wp-content/uploads/2026/01/List-of-Impacted-Productsv2_020426_For-Review-Only.pdf) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) [02/06/2026]
- [Firm Medical Device Web Page \(https://www.trividiahealth.com/e-5productnotice/\)](https://www.trividiahealth.com/e-5productnotice/) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Unique Device Identifier (UDI)

The unique device identifier (UDI) helps identify individual medical devices sold in the United States from manufacturing through distribution to patient use. The UDI allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that devices can be identified, and problems potentially corrected more quickly.

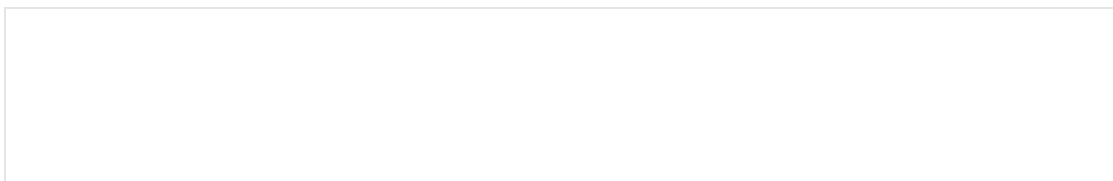
- [How do I recognize a UDI on a label? \(/medical-devices/unique-device-identification-system-udi-system/udi-basics\)](/medical-devices/unique-device-identification-system-udi-system/udi-basics)
- [AccessGUDID database - Identify Your Medical Device \(https://accessgudid.nlm.nih.gov/\)](https://accessgudid.nlm.nih.gov/)
- [Benefits of a UDI System \(/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system\)](/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system)

How do I report a problem?

Health care professionals and consumers may [report adverse reactions or quality problems \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Timeline of Communication Updates

Date	Actions
04/28/2026	The FDA updated this communication to inform the public that the FDA's current recommendations for this issue can be found in the FDA Safety Communication "Risks of Using TRUE METRIX Blood Glucose Monitoring Systems by Trividia Health". This update also notifies the public that this issue has been classified as a Class I Recall.
02/17/2026	The FDA issued an Early Alert communication to notify the public of a potentially high-risk device issue. Archived Communication: Early Alert: Trividia Health Issues Correction for TRUE METRIX Blood Glucose Monitoring Systems FDA (https://web.archive.org/web/20260310130411/https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-trividia-health-issues-correction-true-metrix-blood-glucose-monitoring-systems) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)



Was this page helpful? * (required)

Yes

No

Submit

 An official form of the United States government. Provided by [Touchpoints](#)