carecentrix

Provider Newsflash
April 2026

FDA Safety Communication – Trividia Health TRUE METRIX

Purpose of this communication:

We are writing to inform you that Trividia Health has issued an Urgent Medical Device Correction for all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO, and TRUE METRIX PRO Blood Glucose Monitoring Systems, and that the FDA has subsequently issued a Safety Communication on April 28. The correction updates the Instructions for Use related to the E-5 Error Code, which may appear during very high blood glucose levels (>600 mg/dL) or due to test strip errors. The FDA has determined that prior labeling may have contributed to delays in seeking appropriate medical treatment when users experiencing symptoms of severe hyperglycemia received an E-5 message. While Trividia revised the instructions to clearly emphasize the need for urgent medical care when symptoms are present, the FDA now recommends that patients transition to an alternative method of blood glucose testing when possible. TRUE METRIX systems may be used temporarily while an alternative is arranged, and users experiencing symptoms with an E-5 error should seek immediate medical attention.

As of January 16, 2026, Trividia Health has reported 114 serious injuries and one death associated with this issue.

What do I need to do?

- Please review the following FDA Safety Communication here.
- Notify impacted patients of the updated labeling and FDA Safety Communication. TRUE METRIX Products may continue to be purchased and used temporarily; however, the FDA recommends transitioning to an alternative blood glucose testing method when possible. Products do not need to be returned or replaced.
- Confirm if you have any CareCentrix patients affected by this FDA Safety Communication and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.

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