

FDA Early Alert – Trividia Health TRUE METRIX

Purpose of this communication:

We are writing to inform you that Trividia 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. The company has updated the device instructions to correct guidance related to the E-5 Error Code, which appears during very high blood glucose readings (>600 mg/dL) or test strip errors. Current labeling may delay appropriate treatment if users experiencing high-glucose symptoms do not seek immediate medical attention. To prevent this risk, Trividia has revised the E-5 instructions to clearly emphasize the need for urgent medical care when symptoms are present. Additional mitigation updates will be communicated to users as needed.

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

What do I need to do?

- Please review the following Early Alert notice from the FDA [here](#).
- Notify impacted patients regarding the labeling correction, according to the guidelines issued by the manufacturer in the FDA notification in the above link. Customers may continue to purchase and use the TRUE METRIX Products. Products are not to be returned or replaced.
- Confirm if you have any CareCentrix patients affected by this FDA Early Alert 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.