California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Trividia Health, Inc. Recalls TRUE METRIX PRO Professional Monitoring Blood Glucose System

Recall Date	Product Description	Recalling Firm	Recall Reason
3/12/2026	Owner's Booklets and Instructions for Use that are used with the following blood glucose measurement devices. Description/Item: TRUE METRIX PRO Meter Only/RE4H01P-40, TRUE METRIX PRO Starter Kit/RE4H01P-43, PROCURE TRUE METRIX PRO Meter Only/RE4212P-00, Henry Schein TRUE METRIX PRO Meter Only/RE4099P-40, Henry Schein TRUE METRIX PRO Kit/RE4099P-43, McKESSON TRUE METRIX PRO Meter Only/RE4051P-00, Moore Medical TRUE METRIX PRO Meter Only/RE4068P-01	Trividia Health, Inc. Fort Lauderdale, FL	The system labeling (user manual and online labeling) did not provide adequate directions for lay users to act on the E-5 error code. The error code description and recommended actions for the E-5 error code in the labeling do not: (a) clearly emphasize that an E-5 error code could represent a very high blood glucose level, and (b) prominently convey the appropriate immediate actions, such as contacting a healthcare professional. This could lead to a delay in treatment if the user does not seek medical attention immediately when receiving an E-5

			error code and experiencing symptoms of high glucose.

Recall Class	Product Identification	Distribution	Affected Dates
I	Device Item/UDI-DI: RE4H01P-40/21292006099, RE4H01P-43/21292006105, RE4212P-00/10840330705681, RE4099P-40/21292014919, RE4099P-43/21292008673, RE4051P-00/20612479197217, RE4068P-01/607415261097. Owner's Booklet or IFU Description/Part and Revision: TRUE METRIX PRO Owners Booklet/RE4TVHP03 Rev 56 and prior, McKesson Med Surg TRUE METRIX PRO Owners Booklet/ RE4SUNP03 Rev 56 and prior, Device serial numbers: Prefix "TP" followed by a seven-digit numeric sequence	1,001,534 Units Worldwide	February 2026 and prior

For additional information, please visit the FDA website