

Date: 5/04/2026

Product Information	
Product Description	CVS TRUE METRIX METER
Product SKUs	985464, 608419, 329479, 173140
Product UPCs	50428275283, 50428354766, 21292007010, 50428560402
Lot Codes	All Lots
Reason for Product Notice	Trividia, a CVS supplier, has notified CVS Pharmacy of an update to a recent device correction issued by FDA for all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO, and TRUE METRIX PRO Blood Glucose Monitoring Systems. <b>The FDA recommends all TRUE METRIX users transition to an alternative method of testing their blood glucose (blood sugar), when possible. Users should continue testing their blood glucose and should not stop using their TRUE METRIX meter until they have an alternative method available for testing.</b>
Additional Information	It is especially important for those users at highest risk, including those who are on intensive insulin therapy, sulfonylureas, or who have frequent hyper- and hypo- glycemic events, to transition to an alternative glucose monitoring system. Users should continue to use their TRUE METRIX device until they can access an alternative method to test blood glucose and if receiving an E-5 error code, users should follow the Updated E-5 Instructions provided by Trividia and the FDA outlined below. Additional information can be found here: <a href="https://www.trividiahealth.com/E-5productnotice/">https://www.trividiahealth.com/E-5productnotice/</a> . We anticipate that updated meters will become available across the TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO and TRUE METRIX PRO branded Blood Glucose Meters in the near future, after which Trividia Health will initiate a comprehensive upgrade program to replace meters currently in the field. <b>Trividia Health will notify users of the future Upgrade Program when it is available.</b> Alternatively, customers may return product purchased at CVS directly to store. For more information please contact the Trividia Customer Support Department toll-free at, 1-888-943-2387 (Monday-Friday 8AM-8PM EST) or visit <a href="#">Risks of Using TRUE METRIX Blood Glucose Monitoring Systems by Trividia Health: FDA Safety Communication   FDA.</a>


**URGENT MEDICAL DEVICE CORRECTION**

**E-5 Error Code Message update**

The correction involves the E-5 Error Code in the "Messages" section of the Owner's Booklets/System Instructions for Use. The system displays an E-5 error code for a very high blood glucose event (> 600 mg/dL) or when there is a test strip error. As currently written, the instructions could potentially lead to a delay in treatment if the user does not seek medical attention immediately when they receive an E-5 error code and are experiencing symptoms of high glucose. A delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose levels.

Trividia is updating the E-5 Error Code actions to emphasize that users must seek medical attention immediately if they receive an E-5 error code and are experiencing symptoms of high glucose.

**UPDATED INSTRUCTIONS: FOR TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO**

Display	Reason	Action
	Very high blood glucose result (higher than 600 mg/dL), or Test Strip Error	<b>WARNING!!</b> Retest with a new test strip. If the error persists and you have symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately. If you are not experiencing symptoms, retest with a new test strip. If the error persists call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

You may continue to use the TRUE METRIX® Products.

If you have any questions, please call Trividia Health Customer Care Department toll-free at 1-800-803-6025 Monday-Friday 8AM-8PM EST.

RE4TVH36 Rev. 1


## CORRECCIÓN URGENTE EN DISPOSITIVO MÉDICO

### Actualización de mensaje de código de error E-5

La corrección corresponde al código de error E-5 en la sección "Mensajes" del Manual del usuario/ Instrucciones de uso del sistema. El sistema muestra un código de error E-5 en caso de un evento de glucosa en la sangre muy alto (>600 mg/dl) o cuando ocurre un error de la tira de prueba. De la forma en que están redactadas en la actualidad, las instrucciones podrían potencialmente derivar en un retraso en el tratamiento si el usuario no busca atención médica de inmediato cuando recibe un código de error E-5 y tiene síntomas de glucosa alta. La demora en el tratamiento puede ocasionar consecuencias graves para la salud o la muerte, en especial para los usuarios con niveles de glucosa en la sangre muy altos.

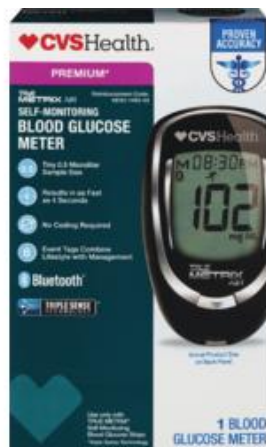
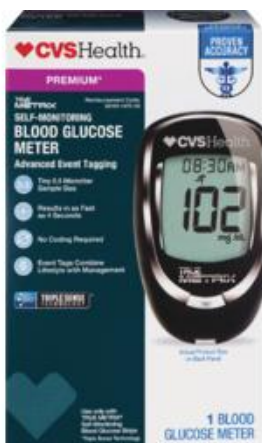
Trividia está actualizando las acciones correspondientes al código de error E-5 para enfatizar que los usuarios deben buscar atención médica de inmediato si reciben un código de error E-5 y tienen síntomas de glucosa alta.

#### INSTRUCCIONES ACTUALIZADAS: PARA TRUE METRIX, TRUE METRIX AIR y TRUE METRIX GO

Pantalla	Motivo	Acción
	Resultado de glucosa en la sangre muy alto (mayor que 600 mg/dl) o Error de la tira de prueba	<b>¡ADVERTENCIA!</b> Repita la prueba con una tira nueva. Si el error persiste y usted tiene síntomas como fatiga, micción excesiva, sed o visión borrosa, busque atención médica de inmediato. <u>Si no tiene síntomas</u> , repita la prueba con una tira nueva. Si el error persiste, llame al 1-800-803-6025, de lunes a viernes, de 8 a. m. a 8 p. m., EST.

Puede seguir usando los productos TRUE METRIX®

Si tiene alguna pregunta, llame a la línea gratuita del Departamento de Atención al Cliente de Trividia Health al 1-800-803-6025, de lunes a viernes, de 8 a. m. a 8 p. m., EST.



Product packaging may vary. Please review the product information above carefully.