

Rev 1: January 2025

FSN Ref: FSN-AN-2026-001

FSCA Ref: FSCA-AN-2026-001

Urgent Field Safety Notice (FSN)
TRUE METRIX AIR, TRUE METRIX GO
Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Owner's Booklets/System Instructions for Use for TRUE METRIX AIR and TRUE METRIX GO Blood Glucose Monitoring Systems
1	2. Commercial name(s)
.	TRUE METRIX AIR and TRUE METRIX GO Blood Glucose Monitoring Systems
1	3. Unique Device Identifier(s) (UDI-DI)*
.	Unknown
1	4. Primary clinical purpose of device(s)*
.	The TRUE METRIX AIR Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh, human whole blood taken from the fingertip or forearm (capillary) and from the vein(venous). The TRUE METRIX GO Blood Glucose Monitoring System is intended for the quantitative determination of glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous).
1	5. Device Model/Catalogue/part number(s)*
.	REA4i82-11; RF4i82-12BK
1	6. Affected serial or lot number range
.	Serial / Lot number not applicable. Affected are only the instructions for use: REA4UKT03 revision 55 and prior, RF4UKT16 revision 56 and prior

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Potential for user misinterpretation of the current E-5 Error Code instructions under certain high glucose-related conditions.
2	2. Hazard giving rise to the FSCA*
.	The correction involves the E-5 Error Code in the "Messages" section of the Owner's Booklet/System Instructions for Use. The system displays an E-5 error code for a very high blood glucose event (higher than 33.3 mmol/L) 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.
2	3. Probability of problem arising
.	Based on complaints for the E-5 error code from Aug. 2014 to December 2025 for TRUE METRIX family of meters (TRUE METRIX, TRUE METRIX PRO, TRUE METRIX AIR and TRUE METRIX GO) the likelihood of an occurrence or recurrence of the hazardous event is very low: $x < 1$ in 100,000 uses (10-5).
	4. Predicted risk to patient/users

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2	The overall probability of occurrence is considered very low; however, delayed treatment associated with misinterpretation of the E-5 instructions may result in serious adverse health consequences in certain high-risk users.
2	5. Further information to help characterise the problem
.	User may misinterpret E-5 error code instructions, which may cause a delay in treatment/obtaining a result.
2	6. Background on Issue
.	The correction involves the E-5 Error Code in the "Messages" section of the Owner's Booklet/System Instructions for Use. The system displays an E-5 error code for a very high blood glucose event (higher than 33.3mmol/L or higher than 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.

3. Type of Action to mitigate the risk*			
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None 1. End users should transition to an alternative method of testing their blood glucose (blood sugar). 2. Products are not to be returned. If you have any questions, please use the contact information listed on the attached customer letter from Boots or contact the manufacturer at E5Ireland@cc.trividiahealth.net.		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">2. By when should the action be completed?</td> <td>Right away.</td> </tr> </table>	2. By when should the action be completed?	Right away.
2. By when should the action be completed?	Right away.		
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td>Yes</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes		

3.	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☒ None Trividia Health has no plans for continued commercialization of TRUE METRIX GO and TRUE METRIX AIR in Ireland. End users should stop using the TRUE METRIX AIR and TRUE METRIX GO blood glucose meters and transition to an alternative method of testing their blood glucose (blood sugar).	
3	6. By when should the action be completed?	N/A
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? N/A, please see attached Customer Letter issued by Boots.	
	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	www.trividiahealth.com
4.	8. The Regulatory Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Boots Customer letter

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4.	10. Name/Signature	Alexandra Popelca Global Regulatory Affairs Project Manager
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	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.