Rev 1: September 2018
FSN Ref: FSN-2022-002 FSCA Ref: FSN-2022-002

Date: 4 March 2022

Urgent Field Safety Notice
ARIS HiQ

For Attention of Lab Manager:

Contact details of local representative (name, e-mail, telephone, address etc.)*
E.mail : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

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Urgent Field Safety Notice (FSN)
ARIS HiQ

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD Instrument
1.	2. Commercial name(s)
	ARIS HiQ
1.	3. Unique Device Identifier(s) (UDI-DI)
	+M578V40000
1.	4. Primary clinical purpose of device(s)*
	The Thermo Scientific™ Sensititre™ ARIS HiQ™ System is part of the Sensititre™ AST system and is an automated plate management device containing an incubator and embedded OptiRead™ module.The Thermo Scientific™ Sensititre™ ARIS HiQ™ System is designed for use with the Thermo Scientific™ Sensititre™ SWIN™ Software System. The ARIS HiQ™ and SWIN™ systems work together to read Sensititre™ (18–24 hr) susceptibility plates and identification plates, generating minimum inhibitory concentration (MIC), interpreting breakpoint (BP) results and performing microbial identification for non-fastidious and fastidious microorganisms.
1.	5. Device Model/Catalogue/part number(s)*
	V4000
1.	6. Software version
	2.10.016 to 2.12.018
1.	7. Affected serial or lot number range
	753/R01 N001 to 753/R01 N025 and 753/R02 N001 to 753/R02 N078
1.	8. Associated devices
	None

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal investigation has confirmed that the transfer arm PCB is missing 2 capacitors.
2.	2. Hazard giving rise to the FSCA*
	If an ESD pulse from a build-up of static electricity is discharged on the HiQ front door it can cause the instrument to go into an error state. In worst case this state may not present an error screen immediately but rather over a minute later. The heating of plates still continues but no robotic movement and therefore no reading of plates occur until someone clears the error.
2.	3. Probability of problem arising
	Unlikely
2.	4. Predicted risk to patient/users
	Potential delayed diagnosis
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	N/A
2.	7. Other information relevant to FSCA
	N/A

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 **Please arrange for a replacement of the PCB for the transfer arm**	
3.	2. By when should the action be completed?	As soon as possible
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Only impacted if unit statistic builds up and the HiQ stops working	
3.	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	
3	6. By when should the action be completed?	As soon as possible
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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?	
	Choose an item. Choose an item.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
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	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Trek Diagnostic Systems Ltd.
	b. Address	Units 17-19 Birches Industrial Estate East Grinstead West Sussex RH19 1XZ
	c. Website address	www.trekds.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Customer Response Form
4.	10. Name	… **Director, Quality EMEA**
	Signature	

	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.*

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Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*	2022-002			
FSN Date*	4 March 2022			
Product/ Device name*	ARIS HiQ			
Product Code(s)	V4000			
Batch/Serial Number(s) Range	753/R01 N001 to 753/ R01 N025 and 753/R02 N001 to 753/R02 N078			
2. Customer Details				
Account Number				
Organisation Name*				
Organisation Address*				
Department/Unit				
Shipping address if different to above				
Contact Name*				
Title or Function				
Telephone number*				
Email*				
3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I performed all actions requested by the FSN.			
☐	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete **N/A**	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete. **N/A**	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Qty	Credit ☐ Replacement ☐	
		Comments: Please arrange for a replacement of the PCB for the transfer arm.		
☐	No affected devices are available for return/ destruction			
☐	Other Action (Define):			
☐	I do not have any affected devices.			
☐	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*				
Signature*				
Date*				

4. Return acknowledgement to sender	
Email	MBD.vigilance@thermofisher.com
Telephone Number & Fax	Tel : +44(0) 1256 841144 / Fax :+44(0) 1256 479525
Postal Address	
Deadline for returning the reply form*	**1 April 2022**

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.