Rev 1: September 2018
FSN Ref: FSN-2021-0003 FSCA Ref: FSN-2021-0003

Date: 19/05/2021

Urgent Field Safety Notice
ARIS HiQ

For Attention of*:

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
Low resistance heaters

	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)
	V4000
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 N002 to 753/R01 N025 and 753/R02 N001 to 753/R02 N029
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 heaters on a limited number of ARIS HiQ instruments are out of specification (with low resistance).
2.	2. Hazard giving rise to the FSCA*
	This could potentially cause overheating and failure of internal components followed by an interlock failure
2.	3. Probability of problem arising
	Occasional
2.	4. Predicted risk to patient/users
	Interlock failure means the internal fans remain powered when the access door is opened, which could lead to an injury. In particular, risk of injury to a Service Engineer during servicing is higher
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Out of specification low resistance heater parts supplied
2.	7. Other information relevant to FSCA

	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
3.	2. By when should the action be completed?
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No No impact to results as this is an instrument safety issue
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? — ASAP
3.	7. Is the FSN required to be communicated to the patient /lay user? — No
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:	
	N/A	
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	**.....** **Vice President, Quality and Regulatory, MBD**
	Signature	[redacted]

	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*	FSN-2021-0003			
FSN Date*	19 May 2021			
Product/ Device name*	ARIS HiQ			
Product Code(s)	V4000			
Batch/Serial Number (s)	753/R01 N002 to 753/ R01 N025 and 753/R02 N001 to 753/R02 N029			
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 or **N/A**	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete. **(EDIT WHEN NECESSARY)**	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Qty	Credit ☐ Replacement ☐	
		Comments:		
☐	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			
Deadline for returning the reply form*	19 June 2021			

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.