Rev 1: September 2018

FSN Ref: **SFRI_FSN_I01SOL01_20220805**

FSCA Ref: **SFRI_FSCA_I01SOL01_20220805_DK**

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	IonoRef solution used for IONIX device calibration
1.	2. Commercial name(s)
	IonoRef Solution
1.	3. Unique Device Identifier(s) (UDI-DI)
	unknown
1.	4. Primary clinical purpose of device(s)*
	Not applicable
1.	5. Device Model/Catalogue/part number(s)*
	I01SOL01 – I01SOL01-01
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	LOT number 212901
1.	8. Associated devices
	IONIX analyzer reference A0408

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Presence of black particle in the solution
2.	2. Hazard giving rise to the FSCA*
	Mistaken results when using on IONIX analyser – risk to user only
2.	3. Probability of problem arising
	Rare
2.	4. Predicted risk to patient/users
	Risk evaluation from Risk analysis report = 2
2.	5. Further information to help characterise the problem
	Particle visible to the naked eye – nature of pollution could be microbiological (to be confirmed by analyses)
2.	6. Background on Issue
	Pollution was detected before shipping IonoRef solution REF I01SOL01 (250mL) from lot number 212901
2.	7. Other information relevant to FSCA
	Pollution was also detected by the customer before using IonoRef solution REF I01SOL01-01 (500mL) from lot number 212901

	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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer**	
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Action plan to be implemented in order to control the microbiological contamination of IonoRef solution	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
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?	
	Choose an item. Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
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	**Lieu-dit Berganton - 33127 St Jean d'Illac - France**
	c. Website address	www.sfri.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Hélène SERVAJEAN – Head of Quality**

SFRI
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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.