Rev 1: March 2021

FSN Ref: FSN_2021_01_EN FSCA Ref: FSCA_210301C01

Date: 04:03:2021

Urgent Field Safety Notice
Intuition

For Attention of*:

- Person at company distributing the product who is accountable for communication of safety information related the product to end-users.

- Everyone that carry out or oversees cleaning routines of the manoeuvre handle and/or manoeuvre display of the product.

Contact details for distributor
Arcoma AB, service@arcoma.se, +46 470 706900

Contact details for end-user
Contact person at the company distributing the product.

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Urgent Field Safety Notice (FSN)
Intuition
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Intuition; versions with touch display
	
1.	2. Commercial name(s)
	Intuition, Aceso, Omnera 400T
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	The system is a stationary X-ray system, intended to emit ionizing radiation for diagnostic and interventional radiology by obtaining radiographic images of various portions of the human body in a clinical environment. The system is not intended for mammography.
1.	5. Device Model/Catalogue/part number(s)*
	0180/Intuition
1.	6. Software version
	All
1.	7. Affected serial or lot number range
	All

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Cleaning of the manoeuver handle or the manoeuver display with excessive amount of disinfectants containing certain components pose a risk of causing a short circuit due to ingress of liquid, which in turn could cause uncontrolled up- or down movement of the overhead tube crane (OTC). Examples of components which could result in a risk of uncontrolled movement are quaternary ammonium compounds (e.g. benzalkonium chloride, alkyl dimethylbenzyl ammonium chlorides and alkyl dimethyl ethylbenzyl ammonium chlorides)- L-lactic acid- Citric acid- pH adjusting compounds and stabilizers (commonly present in disinfectants containing hydrogen peroxide).
2.	2. Hazard giving rise to the FSCA*
	The potential hazard of the above-mentioned risk is uncontrolled movement of the OTC. Either after a z-button has been released or spontaneous movement without pressing a z-button to activate the movement.
2.	3. Probability of problem arising
	The probability of an uncontrolled z-movement of the OTC is estimated to be 0,02 times per year and system.
	4. Predicted risk to patient/users

2.	The probability for a squeezing hazard to occur is assessed to be below 0,005% of all examinations.
2.	5. Further information to help characterise the problem
	By not following the recommended cleaning routines and cleaning agents, the risk of uncontrolled movement is estimated to increase by more than 450 %.
2.	6. Background on Issue
	Arcoma has received increasing number of customer complaints of uncontrolled movements in the last year. None of these have reported a squeezing hazard. Root cause of the uncontrolled movement has been identified as cleaning of the manoeuver handle and the manoeuver display with excessive amounts of disinfectants containing e.g. quaternary ammonium compounds (e.g. benzalkonium chloride, alkyl dimethyl benzyl ammonium chlorides and alkyl dimethyl ethylbenzyl ammonium chlorides), L-lactic acid, citric acid and pH adjusting compounds and stabilizers (commonly present in disinfectants containing hydrogen peroxide). Arcoma has received reports of uncontrolled movement only for the type of display unit referred to under section 1.1.
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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	2021-08-31
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Not required since the potential hazard is not related to the indented use of the medical device.	
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 Provide further details of the action(s) identified.		
3	6. By when should the action be completed?	2021-04-30	
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?		
	N/A	N/A	

	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:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
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	Arcoma AB
	b. Address	Annavägen 1, 35246 Växjö, Sweden
	c. Website address	www.arcoma.se
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	Updated IFU (not available yet)
4.	10. Name/Signature	Katja Kristensson Manager Quality and Regulatory

	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.