Raymed Imaging AG

FSN Ref: 20200204_FSN FSCA Ref: 20200204_FSCA

Date: 04.02.2020

Urgent Field Safety Notice

Raymat AS1

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*
Raymed Imaging AG, Mr. Pirmin Meier, Grenzstrasse 1a, CH 6214 Schenkon, +41 58 433 03 03, pirmin.meier@raymed.com

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The X-ray system Raymat AS1 is designed for general radiography applications. The tripod consists of a wall column, on which a cross arm is attached, which carries the X-ray tube and a detector. The weight of the cross arm is balanced by a tension spring. As a result, the cross arm is balanced in the entire vertical area and is fixed to the desired position by means of a brake on the pulley.
1.	2. Commercial name(s)
	Raymat AS1
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	The universal tripod is used in X-ray diagnostics. It can carry out practically all conventional X-ray settings that are made in a doctor's office.
1.	5. Device Model/Catalogue/part number(s)*
	AS1
1.	6. Software version
	NA
1.	7. Affected serial or lot number range

000-05.00006	001-08.00090
001-05.00001	001-08.00094 - 001-08.00104
001-05.00003 - 001-05.00023	001-09.00105 - 001-09.00108
001-06.00024 - 001-06.00029;	001-09.00110 - 001-09.00119
001-06.00031 - 001-06.00045	001-10.00002 - 001-10.00003
001-07.00046 - 001-07.00048	001-10.00005
001-07.00050 - 001-07.00070	001-10.00120 - 001-10.00128
001-07.00072 - 001-07.00075	001-11.00129 - 001-10.00135
001-08.00001	03-14404-001
001-08.00076 - 001-08.00088	P01-04.00001

1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	For many devices on the market the pull rope of the tripod has not been replaced during maintenance after 10 years of operation. However, this is mandatory as it is requested in manufacturer's technical documentation. There is the danger that the pull rope brakes due to wear if it stays in operation for more than 10 years. If this happens the cross arm with X-ray tube and detector will fall down and may injure patient and/or medical assistant.
2.	2. Hazard giving rise to the FSCA*
	Recently the pull rope of a Raymat AS1 tripod broke after 12 years of operation. This happened when the medical assistant tried to rise the cross arm for a next exposure. Due to its weight the cross arm fell down immediately. The emergency brake could not stop the cross arm in this case. Fortunately neither the patient nor the assistant were injured during this incident.
2.	3. Probability of problem arising
	If the pull rope is not exchanged after latest 10 years as requested in the Instructions for Use, the probabilty of a rope tore will continuously increase due to the mechanical stress on the pull rope.
2.	4. Predicted risk to patient/users
	In the risk management the probability of such an incident happens was estimated as 2 "far imaginable" (on a scale from 1 to 5) and the severity as 4 "disastrous" (on a scale from 1 to 4).
2.	5. Further information to help characterise the problem
	Out of eight hundred devices in the field, the breaking of rope occurred so far in six cases. In each of those cases the rob was not exchanged in the prescribed time period.
2.	6. Background on Issue
	The Root cause of the problem is the continuous bending of the rope under load. This inevitably leads to breaking of the rope. If the rope is not exchanged after 10 years as requested by the manufacturer, the probability of incidents increases to 3 "occasional" (on a scale from 1 to 5) an the overall risk becomes 12 "intolerable"..
2.	7. Other information relevant to FSCA
	NA

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?	as soon as possible, latest 30.06.2021

3.	3. Particular considerations for: *Diagnostic Imaging device* Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? *	Yes , by 30.3.2020
3.	5. **Action Being Taken by the Manufacturer** ☐ Product Removal ☒ **On-site device modification/inspection** ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None For all tripods Raymat AS1 in operation and older than 10 years, a rope change shall be carried out immediately. In the course of this activity the braking plate of the falling break and all bearings of the vertical carriage shall be replaced as well for enhanced safety. If the maintenance/replacement of the pull rope is not completed within reasonable time, the product must be removed.	
3	6. By when should the action be completed?	30.06. 2021
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) *Local distributors in EU:*	
	a. Company Name	Primax International
	b. Address	30-34 Avenue Henri Matisse, F-6200 Nice
	c. Website address	http://www.primax.fr/primaxinter/
	a. Company Name	Primax France SA
	b. Address	2 Place Gustave Eiffel - CS 20280, F-94518 RUNGIS CEDEX 1
	c. Website address	https://primax.fr/
	a. Company Name	Sorer Imagerie Médicale
	b. Address	2 place d'Italie, F-31400 Toulouse
	c. Website address	
	a. Company Name	Primax Berlin GmbH
	b. Address	Meeraner Straße 17e, D-12681 Berlin
	c. Website address	http://primax-berlin.de/d/index.htm
	a. Company Name	K & S Röntgentechnik
	b. Address	Barhöfter Strasse 37, D-18445 Klausdorf
	c. Website address	

	a. Company Name	SIA "A.MEDICAL"
	b. Address	Varkalu iela 13a, Riga, LV-1067, Latvija
	c. Website address	http://www.amedical.eu/en/
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * : YES	
4.	4. List of attachments/appendices:	NA
4.	5. Name/Signature	**Pirmin Meier** **Leiter Technik**

	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.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	20200204_FSN
FSN Date*	04.02.2020
Product/ Device name*	Raymat AS1
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

2. Customer Details	
Account Number	
Healthcare 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.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	

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☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	**pirmin.meier@raymed.com**
Customer Helpline	NA
Postal Address	**Raymed Imaging AG, Mr. Pirmin Meier, Grenzstrasse 1a, CH 6214 Schenkon**
Web Portal	NA
Fax	NA
Deadline for returning the customer reply form*	30.03.2020

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.