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Excellence in Science

Medical Regulatory Policy Department
Post Market Surveillance Section

1,Nishinokyo-Kuwabaracho,Nakagyo-ku,Kyoto 604-8511, Japan Phone: +81-75-823-1928 Fax: +81-75-823-2530

Rev 1: September 2018
FSN Ref: MRBR-26H048 FSCA Ref: MRBR-26H049

Date: 14.07.2026

Urgent Field Safety Notice
- FDR Visionary Suite

For Attention of*:Dear Customer（For details, see the attached customer list.）

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name:

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Urgent Field Safety Notice (FSN)
FDR Visionary Suite

Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	The FDR Visionary Suite are digital X-ray general imaging systems that include a high-voltage X-ray generator. This medical devices is not supplied in a sterile condition.
1.	2. Commercial name(s)
	The FDR Visionary Suite
1.	3. Unique Device Identifier(s) (UDI-DI)
	See Table 1
1.	4. Primary clinical purpose of device(s)*
	The FDR Visionary Suite is intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. The FDR Visionary Suite enables radiographic exposures of the whole body of all ages including pediatric patients. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. The FDR Visionary Suite uses portable or integrated flat panel detectors to generate diagnostic images by converting x-rays into electronic signals. The device is also designed to be used with conventional film/screen or computed radiography (CR) cassettes. The device is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/trained professionals. The device is not intended for mammographic applications.
1.	5. Device Model/Catalogue/part number(s)*
	See Table 1
1.	6. Software version
	Not involved in this matter
1.	7. Affected serial or lot number range
	See Table 1
1.	8. Associated devices
	—

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	After the radiological technologist turned off the power to the equipment body, smoke was coming out of the high-voltage generator cabinet.Therefore, the radiological technologist turned off the breaker in the distribution board.As a result of the investigation, it was confirmed that the contacts of the electromagnetic contactor had welded. As a result, it is believed that even when the power to the device was turned off, current continued to be

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	supplied to the power circuit, and the discharge resistor in the circuit continued to overheat the nearby capacitor, causing the temperature inside the capacitor to rise, opening the explosion-proof valve and causing the electrolyte inside to spray out.
2.	2. Hazard giving rise to the FSCA*
	・There is a possibility that overheating inside the cabinet could damage the internal components.・If although the parts around the power resistor inside the cabinet were burned, the internal wiring, printed circuit board, exterior cover, etc. are made of flame-retardant materials, so the fire will not spread.・There was no opening below the melted parts, so the fire will not spread to the floor of the facility.・It cannot be denied that overheating could cause the electrolyte inside the capacitor to eject, setting off a fire alarm. [Severity : 4 (Based on ISO14971:2019)]
2.	3. Probability of problem arising
	・The total number of existing devices since its release in 2003 was 29,257 (including the UD/ZUD-40 series, which has the same structure as the UD150BC-40). ・There were three incidents. ・The probability of occurrence obtained by dividing the number of malfunctions by the number of devices x number of years of operation is as follows (however, calculations are based on the assumption that 10% of devices are discarded after the 11th year of operation).Probability of occurrence: 1.20 × 10^-5. [Probability : 2 (Based on ISO14971:2019)]
2.	4. Predicted risk to patient/users
	Risk acceptability: III [Unacceptable] (Based on ISO14971:2019)
2.	5. Further information to help characterise the problem
	–
2.	6. Background on Issue
	There was no sufficient risk analysis carried out for the occurrence of unacceptable risks in the case of a single fault condition in which the electromagnetic contactor contacts welded together, and fail-safe mechanisms, etc., which would be necessary risk reduction measures, were not installed.
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
	・Pay attention to the following points until the work is completed.

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	□ For safety reasons, turn off the breaker of the distribution board to which the power cord of the unit is connected after turning off the power of the unit according to the operation manual. □ Do not forget to turn off the breaker of the distribution board until the replacement of the contactor is completed.	
3.	2. By when should the action be completed?	3 years
3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No This case does not affect the patient's diagnostic results.	
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 We will install a protective circuit to ensure that no current flows through the discharge resistor even if the electromagnetic contactor's contacts weld together. (Some electromagnetic contactors do not have contacts for the protective circuit, so these will also need to be replaced.)	
3	6. By when should the action be completed?	MM, YYYY (36 months)
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.	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	—
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	—
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SHIMADZU Corporation
	b. Address	1 Nishinokyokyo-Kuwabaracho, Nakagyo-ku
	c. Website address	https://www.shimadzu.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Takeshi Yamamoto

	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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Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.