SHIMADZU
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

Date: 22th. June 2026

FSN Ref: MRBR-26H056 FSCA Ref: MRBR-26H036

Urgent Field Safety Notice

- X-RAY HIGH VOLTAGE GENERATOR UD150B-40
- X-RAY HIGH VOLTAGE GENERATOR UD150V-40
- X-RAY HIGH VOLTAGE GENERATOR UD150L-40
- X-RAY HIGH VOLTAGE GENERATOR UD150G-40
- X-RAY HIGH VOLTAGE GENERATOR UD150L-40E
- X-RAY HIGH VOLTAGE GENERATOR UD150L-40F
- Digital Angiography System Trinias
- Digital Angiography System BRANSIST safire
- Digital Angiography System BRANSIST alexa
- RADspeed Pro
- Digital Radiography System RADspeed safire
- Radiography System RADspeed fit
- X-RAY TV SYSTEM SONIALVISION G4
- X-RAY TV SYSTEM SONIALVISION safire17
- X-RAY R/F SYSTEM FLUOROspeed
- REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION

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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Risk addressed by FSN

	1 Information on Affected Devices*
1.	1. Device Type(s)*
	1)Trinias, BRANSIST safire, and BRANSIST alexa are Digital Angiography Systems that include a high-voltage X-ray generator. 2)SONIALVISION safire17, SONIALVISION G4 and FLEXAVISION are a multi-purpose X-ray R/F system that include a high-voltage X-ray generator. 3)RADspeed fit and RADspeed Pro are X-ray radiographic system that include a high-voltage X-ray generator. 4)UD150B-40、UD150L-40、UD150V-40、UD150L-40E and UD150L-40F are X-ray high voltage generators. These medical devices are not supplied in a sterile condition.
1.	2. Commercial name(s)
	X-RAY HIGH VOLTAGE GENERATOR UD150B-40, X-RAY HIGH VOLTAGE GENERATOR UD150V-40, X-RAY HIGH VOLTAGE GENERATOR UD150L-40, X-RAY HIGH VOLTAGE GENERATOR UD150L-40E, X-RAY HIGH VOLTAGE GENERATOR UD150L-40F- Digital Angiography System Trinias- Digital Angiography System BRANSIST safire, Digital Angiography System BRANSIST alexa, RADspeed Pro, Radiography System RADspeed fit, X-RAY TV SYSTEM SONIALVISION G4, X-RAY TV SYSTEM SONIALVISION safire17, REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION
1.	3. Unique Device Identifier(s) (UDI-DI)*

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	See Table 1
1.	4. Primary clinical purpose of device(s)*
	1)Trinias, BRANSIST safire, and BRANSIST alexa are intended for Interventional procedures such as cardiology, interventional radiology and interventional neurology. 2)SONIALVISION safire17, SONIALVISION G4 and FLEXAVISION are suitable for radiographic and fluoroscopic examinations, including general radiography and pediatric examinations, excluding mammography.） 3)RADspeed fit and RADspeed Pro are suitable for radiography for each region of a patient in horizontal or vertical position (only RADspeed Pro) including pediatric examinations. 4)UD150B-40、UD150L-40、UD150V-40、UD150L-40E and UD150L-40F are used for radiography and fluoroscopy (optional) on patients combined with an X-ray tube unit, an X-ray collimator, and if necessary, an X-ray tube support, an X-ray radiography stand, an X-ray radiography table or an X-ray diagnostic table, and digital radiography system.
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 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

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	・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. ➢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.

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3.	2. By when should the action be completed?	3 years
3.	3. Particular considerations for: Choose an item. 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 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.

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Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	MRBR-25H137
FSN Date*	2026.6.22
Product/ Device name*	-X-RAY HIGH VOLTAGE GENERATOR UD150B-40 -X-RAY HIGH VOLTAGE GENERATOR UD150V-40 -X-RAY HIGH VOLTAGE GENERATOR UD150L-40 -X-RAY HIGH VOLTAGE GENERATOR UD150G-40 -X-RAY HIGH VOLTAGE GENERATOR UD150L-40E -X-RAY HIGH VOLTAGE GENERATOR UD150L-40F -Digital Angiography System Trinias -Digital Angiography System BRANSIST safire -Digital Angiography System BRANSIST alexa -RADspeed Pro -Digital Radiography System RADspeed safire -Radiography System RADspeed fit -X-RAY TV SYSTEM SONIALVISION G4 -X-RAY TV SYSTEM SONIALVISION safire17 -X-RAY R/F SYSTEM FLUOROspeed -REMOTE-CONTROLLED R/F SYSTEM −FLEXAVISION
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

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☐	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:	
☐	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	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

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.