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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

Date: 28.01:2026

Urgent Field Safety Notice
Digital Angiography System Trinias

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

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

Urgent Field Safety Notice (FSN)
Digital Angiography System Trinias
Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Trinias is intended for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational angiography, multi-purpose angiography and whole body radiographic/fluoroscopic procedures. This medical device is not supplied in a sterile condition.
1.	2. Commercial name(s)
	Digital Angiography System Trinias
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	Trinias is an angiographic X-ray system, which is used for diagnostic imaging and interventional procedures. Trinias is intended to be used for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational angiography, multi-purpose angiography and whole body radiographic/fluoroscopic procedures.
1.	5. Device Model/Catalogue/part number(s)*
	563-79821-26
1.	6. Software version
	Not involved in this matter
1.	7. Affected serial or lot number range
	1) M1EFC6E83001, 2) M1EFC6E83002, 3) M1EFC6E82001
1.	8. Associated devices
	—

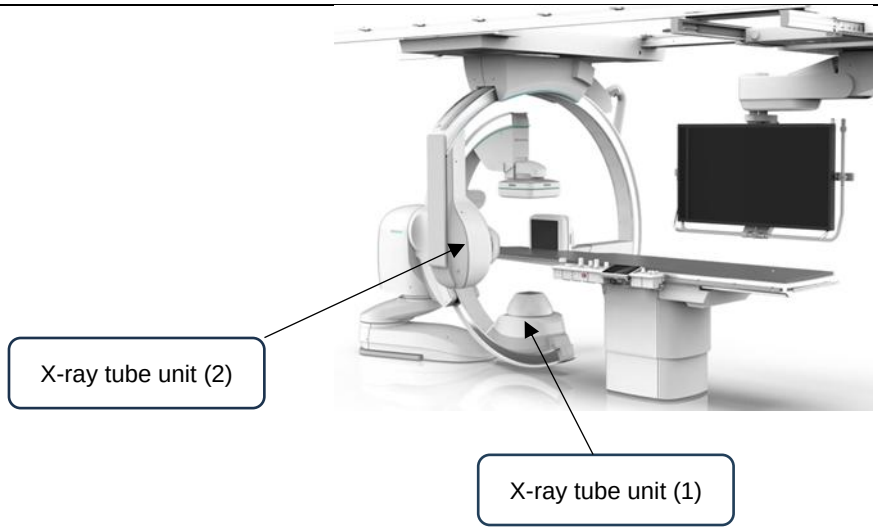
2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	In the biplane type (refer the figure below) of the Digital Angiographic System Trinias, when a specific operation is performed, a problem occurs rarely in which X-rays are emitted by the X-ray tube unit (2) even though the X-ray tube unit (1) is selected.

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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

	
2.	2. Hazard giving rise to the FSCA*
	For the following reasons, the severity level is "3" of "serious". ・The X-ray image is correctly collected even on the side of the unintended radiation plane, and the user can easily notice it and consider the increase of the dose in the treatment. ・In the next radiography, the unnecessary exposure is not caused by selecting the radiography protocol again, and the device can be used without any problem. ・The increase of the exposure dose is not large, and it is not at the level of "temporary injury or failure that does not require medical or surgical intervention." ・However, the risk of harm to the patient cannot be denied if the user feels uneasy about this failure and stops the examination and treatment.
2.	3. Probability of problem arising
	The number of shipments of the Trinias biplane system is approximately 100 units. 12 years have passed since the release of this device, and assuming an average of 6 years of use, the number of radiographs so far is approximately 10 times/clinical x 5 cases x 200 days x 6 years x 100 units = 6 million times. Considering the past record of 2 occurrences, the probability of occurrence per 1 patient is considered to be 6 million times/10 times/2 times = 1 in 300,000 cases. Therefore, it falls within the range of "1/100, 000 (10^-5) or Less to Over 1/1, 000, 000 (10^-6)".Therefore, the possibility of the occurrence of harm due to unnecessary patient exposure was set as “1” in “Unlikely”. In addition, based on the discussion at the Safety Committee, we examined the possibility that the user might feel uneasy about this event and interrupt the test. There have been no cases in which the test was interrupted, and especially since fluoroscopy works normally, it is unlikely that the test would be interrupted in a dangerous situation, which is lower than the above probability. Therefore, the possibility that a problematic event occurs in one patient and the test is interrupted, and then harm occurs, was set as “1” in “Unlikely”.
2.	4. Predicted risk to patient/users
	Based on the severity level of 3 (Serious) and the probability of occurrence of 1 (Unlikely), the risk assessment is II.
2.	5. Further information to help characterise the problem
	—
	6. Background on Issue

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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

2.	It was found that this issue occurs at a low probability when both “switching the X-ray tube unit used for radiography” and “switching radiography method" are set as reservation operations for the next procedure during fluoroscopy, fluoroscopy is terminated, and radiography is performed. Note that this issue does not occur by “switching the X-ray tube unit used for radiography” and “switching radiography method” in a state where fluoroscopy is not performed, or by only one operation of either the "switching the X-ray tube unit used for radiography” or the “switching radiography method” under fluoroscopy.
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 ・This issue occurs when switching from a bi-plane to a single-plane during fluoroscopy. Until countermeasures are completed, Please avoid this issue by switching planes after fluoroscopy.	
3.	2. By when should the action be completed?	As soon as possible
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 update the software for the target device so that the X-ray tube unit can be switched correctly.	

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

3	6. By when should the action be completed?	Jun 30, 2026
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.	

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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

	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.*

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

Rev 1: September 2018
FSN Ref: MRBR- MRBR-26H022 FSCA Ref: MRBR-26H021

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