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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-25H025 FSCA Ref: MRBR-25H033

Date: DD:MMM:YYYY.

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.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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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 ceiling-mounted X-ray tube suspension, and the CH-200 and CH-200M are ceiling-mounted X-ray tube suspensions that make up this system. These medical devices are not supplied in a sterile condition.
1.	2. Commercial name(s)
	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*
	The CEILING TUBE SUPPORT CH-200 and CH-200M, which are components of the equipment described in the Affected Product, consist of a ceiling suspension mechanism and an X-ray Tube Support Section (Hereinafter, the “support”) for mounting the X-ray

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	tube assembly. It also has a rotating mechanism in which the shaft of X-ray tube support (Hereinafter, the “shaft”) of the ceiling suspension mechanism is inserted into the rotating bearing of the support so that the X-ray tube can be rotated for positioning. In the above equipment, It was found that the shaft for mounting the X-ray tube unit on the support may break. In addition, it was found that the support might come off if the handle of the support was lifted and pulled to the user side when the shaft broke. The shaft which was separated this time was made of a material which had been found in the past to have a very rare possibility of cracking with aging, and if these cracks grow, the retaining shaft may eventually break. In addition, From the production of September 2018, the material has been changed to a stronger material and there is no possibility of cracking over time. In addition, protective parts are installed to prevent the holder from falling off even if the shaft is broken. In most cases, the added protective parts works effectively when the shaft breaks, but as a result of the reproduction of the occurrence situation at the factory based on the hearing information at the site, it was found that the protective parts might not work effectively only when the shaft was broken while being operated toward the front while lifting.
2.	2. Hazard giving rise to the FSCA*
	The Support weighs approximately 40 kg, and if it falls off and comes into contact with the subject or the operator, Critical injury of the target audience is assumed as the worst case. [Severity : 5 (Based on ISO14971:2019)]
2.	3. Probability of problem arising
	① The number of horizontal rotation operations during the expected life of the equipment (10 years) is 1.95X105, but the number of horizontal rotation operations of the equipment where the incident occurred is estimated to be 3.9X105. It is believed that there are few customers who use the equipment in a manner that greatly exceeds the expected number of operations. ②When the fracture surface of the recovered shaft was inspected, no blow holes were found, indicating no manufacturing problems. ③Even if the shaft breaks, the support part will not come off immediately because there is a part that prevents it from coming off. However, it was found that the support part will only come off if the shaft breaks while the handle of the support part is being lifted and operated forward. ④This device is to be used by medical professionals, who will constantly monitor the device for abnormalities while it is in use, and if necessary, take appropriate measures such as stopping the device's operation in a safe state for the subject. Thus, the possibility of serious adverse health effects is extremely low. [Probability : 1 (Based on ISO14971:2019)]
2.	4. Predicted risk to patient/users
	Risk acceptability : II [Acceptable] (Based on ISO14971:2019)
2.	5. Further information to help characterise the problem
	After the countermeasure parts were installed, the shaft broke, and the countermeasure parts did not function properly in 1 unit out of 11,303 units. No incident arising from this case has occurred.
2.	6. Background on Issue
	In December 2023, a customer experienced an issue in which the shaft broke, and the countermeasures did not function, causing the support to fall off.
2.	7. Other information relevant to FSCA
	—

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	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 ・Perform the daily inspection described in the CH-200/CH-200M operation manual to check for wobbles or shakes, misalignment of the light irradiation position, etc. If any abnormality is found, discontinue use and contact our service provider. When rotating the X-ray tube unit, do not hit the stopper at the end. If the stopper is hit hard, in the unlikely event that a crack has already occurred, a large impact may be applied, and the growth of the crack may be accelerated. In the case of electric rotation, it is controlled by software and does not hit the stopper. ・Do not rotate the X-ray tube over or near the patient.	
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 take measures to add parts that will prevent the X-ray tube support from coming off even if the retaining shaft.	
3	6. By when should the action be completed?	MMM, YYYY (18 months)
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

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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.