

Field Safety Notice Reference: FFID ECN_003504.

URGENT: FIELD SAFETY NOTICE

FUJIFILM DR-XD1000(FDR Nano) Countermeasure to strengthen the arm

Dear Customers,

We have identified a potential failure with our DR-XD1000 (FDR Nano).

We received a report that the arm part wobbled while moving this device and received reports that an arm broke during arm movement. To date, we have received no reports of any serious incidents.

FUJIFILM has developed a repair kit for strengthening the arm part that is the cause of such failure. FUJIFILM wishes to reduce any potential risk to patients as soon as possible.

This Field Safety Notice is intended to inform you about the following:

- what the problem is and under what circumstances it may occur;
- the actions that should be taken by the customer/user in order to prevent risks to patients;
- the actions planned by FUJIFILM to correct the problems.

This document contains important information for the continued safe and proper use of your equipment.

PLEASE READ AND FOLLOW THE INSTRUCTIONS

Please refer to the following page which provides the details of the problem and instructions for actions to be taken. **Please follow the instructions in the “ACTIONS TO BE TAKEN BY CUSTOMER/USER” section.** Please share this information with those who should be informed within your organization

We sincerely regret the inconvenience that this may cause you. FUJIFILM is committed to providing products and services of the highest quality. Your satisfaction with FUJIFILM products and with our response to this issue is very important to us.

If you have any questions about this matter, please contact your local FUJIFILM office.

Yours sincerely,

FUJIFILM

To all FUJIFILM subsidiaries, branch offices and dealers:

PLEASE TYPE YOUR LOCAL CONTACT HERE!

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URGENT: FIELD SAFETY NOTICE

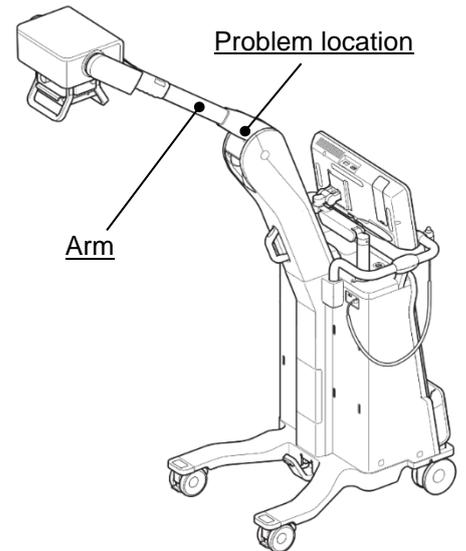
FUJIFILM DR-XD (FDR Nano)

AFFECTED PRODUCTS

DR-XD1000 Serial No. with last 4 numbers 1993 or less, see attachment for detailed instructions to identify the Serial Number of the DR-XD1000.

PROBLEM DESCRIPTIONS

We received a report that the arm part wobbled while moving this device and that an arm broke during arm movement. For this reason, we will carry out repairs to increase the strength of the arm. To date, we have received no reports of any serious incidents.



AFFECTED PRODUCTS

<fill in per country, or include attachment>

	Country	Product code	Serial No.

ACTIONS TO BE TAKEN BY CUSTOMER/USER

- 1) Please conduct a pre-use inspection according to **Attachment** to prevent any serious incident to patients and users. In addition, if any abnormality is found during the pre-use inspection, please stop using the product immediately and directly contact us.
- 2) Cooperate with the FUJIFILM Service Engineer to plan and schedule a visit to allow the measure of reinforcing the strength of the arm being implemented.
- 3) Complete the feedback form as relevant and email it back.

ACTIONS PLANNED BY FUJIFILM

FUJIFILM service engineer will contact all of the medical facilities where the applicable products have been installed to arrange a visit for this correction and implement the measures.

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FIELD SAFETY NOTICE

Customer Feedback Form

URGENT: PLEASE COMPLETE AND RETURN TO FUJIFILM AS SOON AS POSSIBLE

Via e-mail to **xxxx**

Customer/Facility Name:

Address:

Instrument Serial Number:

Product code	Serial No.

- I confirm that I have received and understand the attached notice.
- This notice does not apply to my facility.
- The device has been transferred to another organization.

Customer Name:

Position:

Signature:

Date:

Phone number:

If we have the wrong contact information for you, please correct below:

Customer/Facility Name:

Address:

Please FAX or email this completed form to:

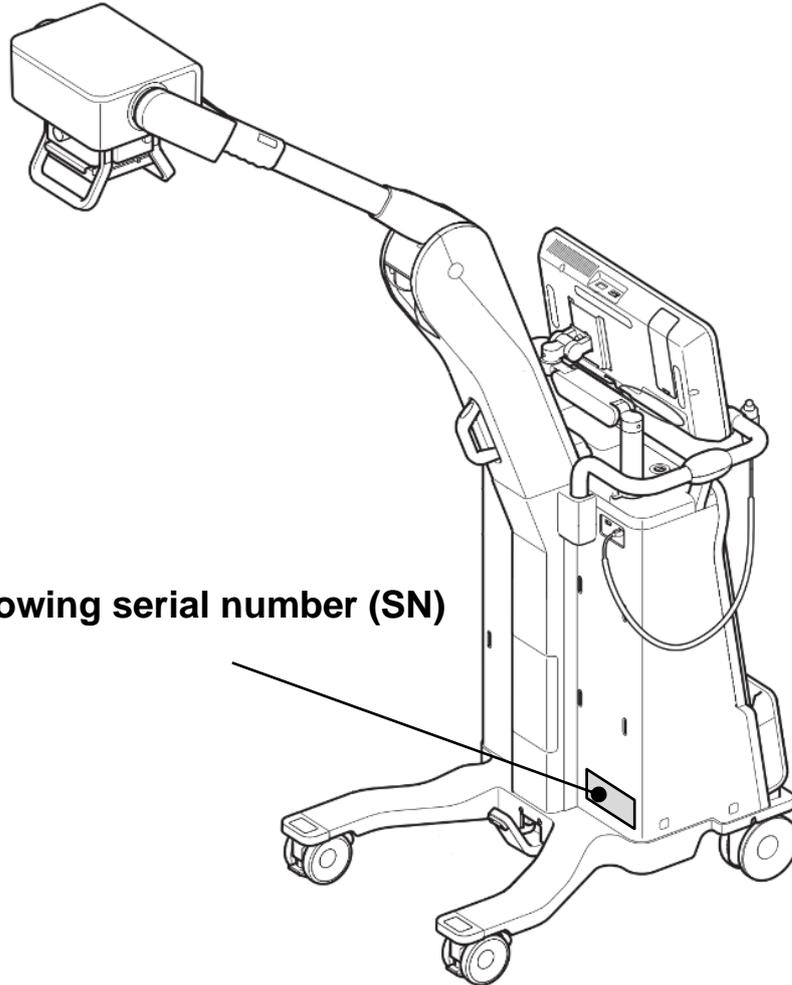
To all FUJIFILM subsidiaries, branch offices and dealers:

FAX: PLEASE TYPE RELEVANT NUMBER HERE

Email: PLEASE TYPE RELEVANT ADDRESS HERE

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ATTACHMENT



Nameplate showing serial number (SN)

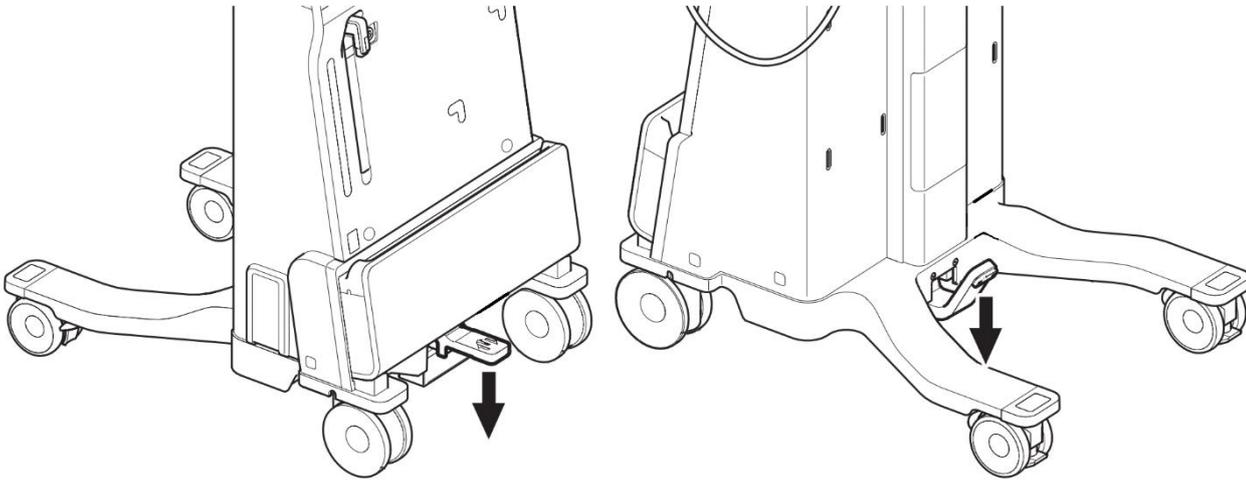
Nameplate

 Manufacturer FUJIFILM Corporation	26-30, NISHIAZABU 2-CHOME, MINATO-KU, TOKYO 106 8620 JAPAN	405N200797A MADE IN JAPAN
MOBILE DIGITAL X-RAY SYSTEM MODEL: DR-XD 1000	MOBILE X-RAY UNIT DR-XD 1000PX 50-60 Hz 100-240 V ~ 8-3.33 A	Maximum load condition of the number of exposures: 160 shot/h
The maximum permissible value for apparent resistance of supply mains: 0.5 Ω	Maximum exposures ON time: 1 s	
Mass of the mobile ME equipment including its safe working load: 98 kg	Minimum exposures OFF time: 10 s	
Maximum load condition of the tube voltage: 100 kV		
Maximum load condition of mAs : 400 mAs/h	 nnnnXXXX	
 0123 	 CLASSIFIED MEDICAL-APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA-C22.2 NO.60601-1-14 E485258	  

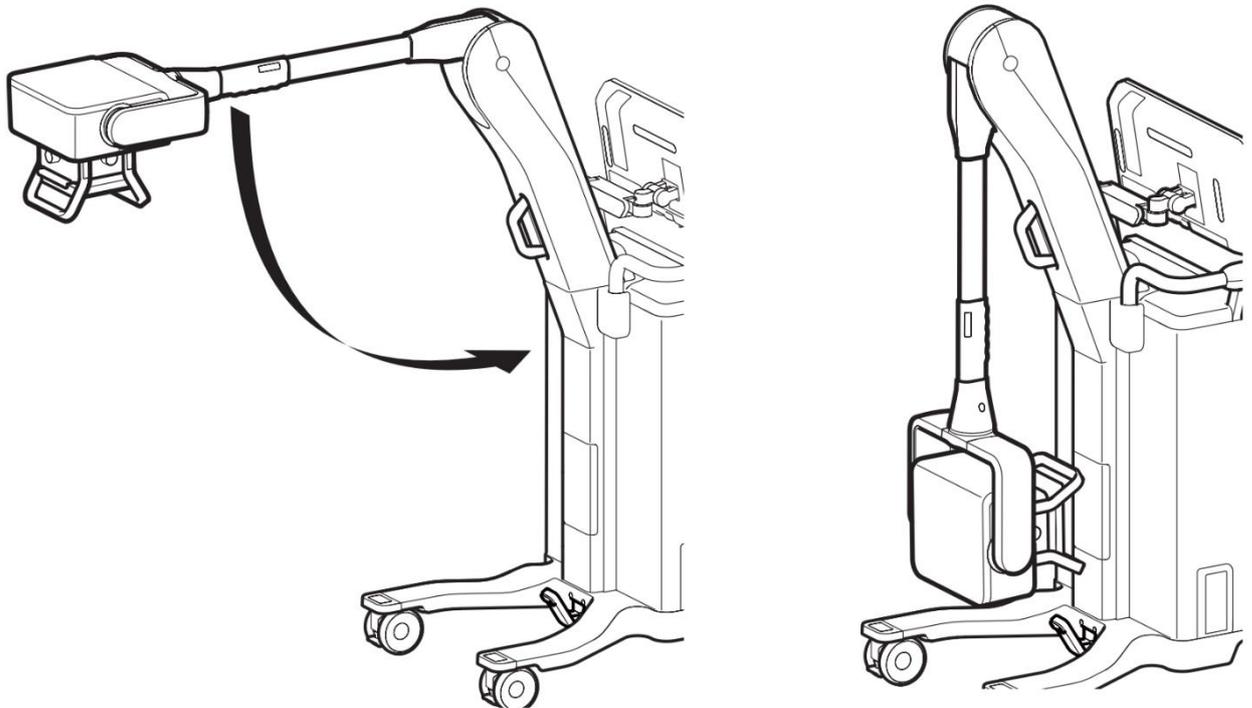
Equipment whose **SN** has the last four digits (XXXX) of 1993 or less is subject to this FSCA. Equipment with the last 4 digits of **SN** (XXXX) of 1994 or higher is not covered by the FSCA.

Field Safety Notice Reference: FFID_20200908(Fujifilm ID)

1. Set the caster lock pedal position to [Down] and secure the X-ray cart.



2. Store the arm in the home position.



Field Safety Notice Reference: FFID_20200908(Fujifilm ID)

3. Push the head arm from the side and check the following from the front.
If there is any abnormality, please stop using it and contact the contact information listed on page 1.
 - (1) Make sure that the gap between the seams of the resin cover does not widen.
 - (2) Make sure that the arm does not tilt against the resin cover.

