

## **URGENT – Field Safety Notice**

To all users of the FUJIFILM DR-XD1000 (FDR Nano)

### **Re: FUJIFILM DR-XD1000 (FDR Nano) - Countermeasure to strengthen the arm & to replace the incorrectly installed mirror inside the Collimator Assembly**

Dear Customers,

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

The first issue was 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.

The second issue was incorrect mirror installation inside the Collimator Assembly causes a deficiency where the LED light does not reach the vicinity of the full open area of Light Irradiation Field and the device is unable to properly irradiate the Light Irradiation Field.

FUJIFILM has developed a repair kit for strengthening the arm part that is the cause of such failure and replacement kit to replace the mirror assembly in which the mirror has been incorrectly installed. 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

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FUJIFILM (Malaysia) SDN. BHD. (205535 K)  
No. 22, Jalan Jurunilai U1/20,  
Seksyen U1, Hicom Glenmarie Industrial Park,  
40150 Shah Alam, Selangor Darul Ehsan, Malaysia.  
Tel: 03-5569 8388 Fax: 03-5569 8288

## URGENT – Field Safety Notice

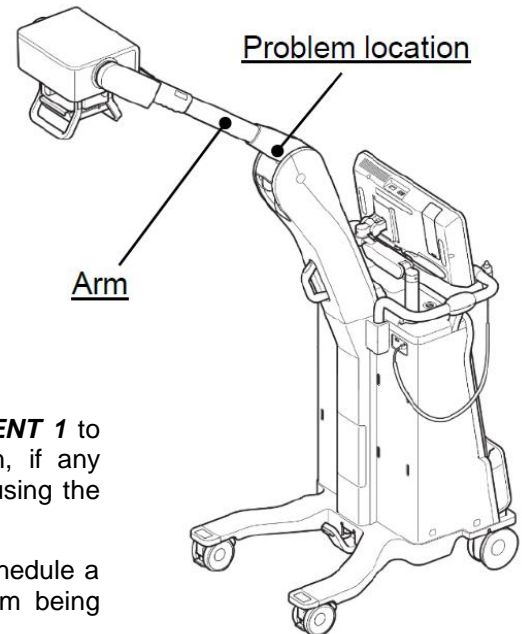
### 1. ARM ISSUE

#### Affected products

DR-XD1000 Serial No. with last 4 numbers 1993 or less, see **ATTACHMENT 1** 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.



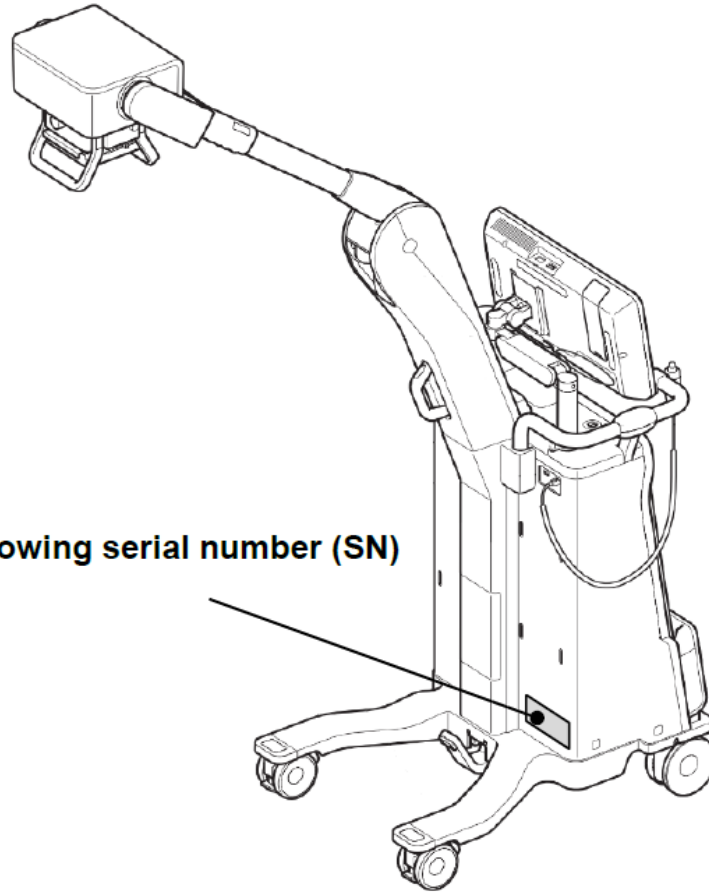
#### Action to be taken by Customer / User

- 1) Please conduct a pre-use inspection according to **ATTACHMENT 1** 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.



**ATTACHMENT 1**



**Nameplate showing serial number (SN)**

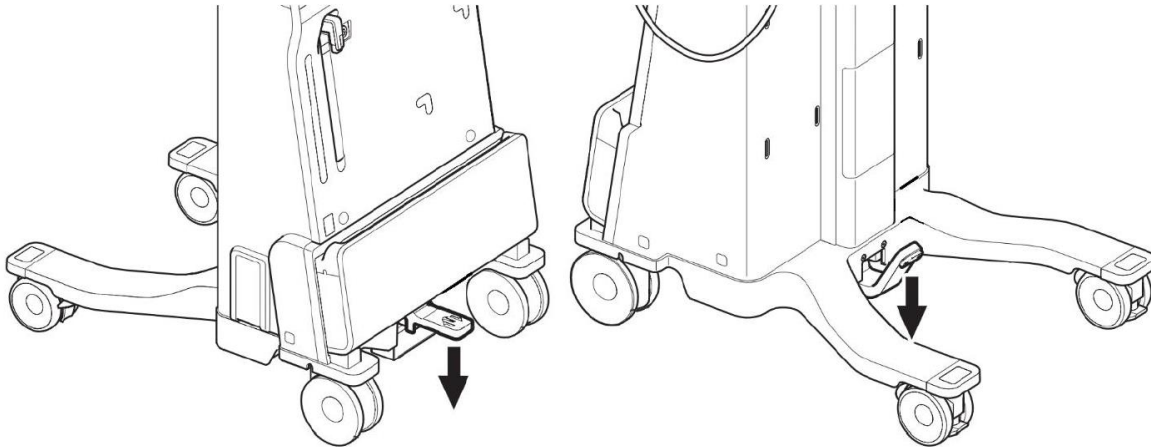
**Nameplate**

 <p>Manufacturer <b>FUJIFILM Corporation</b></p>	<p>26-30, NISHIAZABU 2-CHOME, MINATO-KU, TOKYO 106 8620 JAPAN</p>	<p>405N200797A MADE IN JAPAN</p>
<p>MOBILE DIGITAL X-RAY SYSTEM MODEL : DR-XD 1000</p>	<p>MOBILE X-RAY UNIT DR-XD 1000PX 50-60 Hz 100-240 V ~ 8-3.33 A</p>	<p>Maximum load condition of the number of exposures : 160 shot/h</p>
	<p>The maximum permissible value for apparent resistance of supply mains : 0.5 Ω</p>	<p>Maximum exposures ON time : 1 s Minimum exposures OFF time : 10 s</p>
	<p>Mass of the mobile ME equipment including its safe working load : 98 kg</p>	<p></p>
	<p>Maximum load condition of the tube voltage : 100 kV</p>	<p> nnnnXXXX</p>
	<p>Maximum load condition of mAs : 400 mAs/h</p>	<p></p>
<p> 0123 </p>	<p> <small>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 E488258</small></p>	<p> </p>

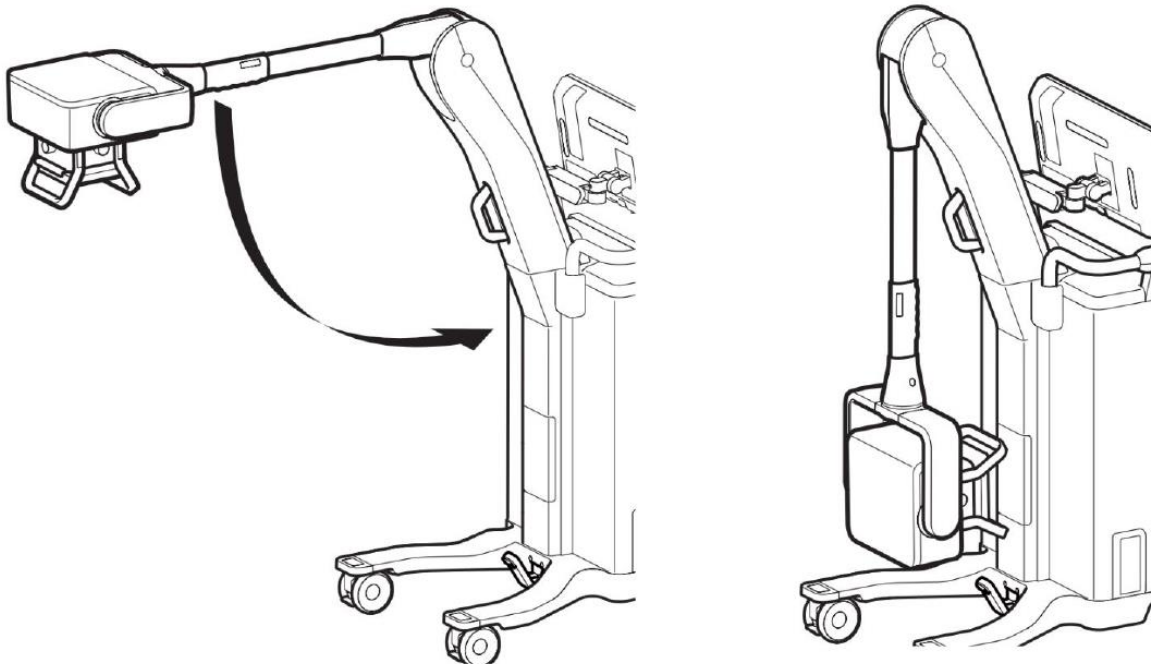
Equipment whose  has the last four digits (XXXX) of 1993 or less is subject to this FSCA. Equipment with the last 4 digits of  (XXXX) of 1994 or higher is not covered by the FSCA.

**Pre-Use Inspection**

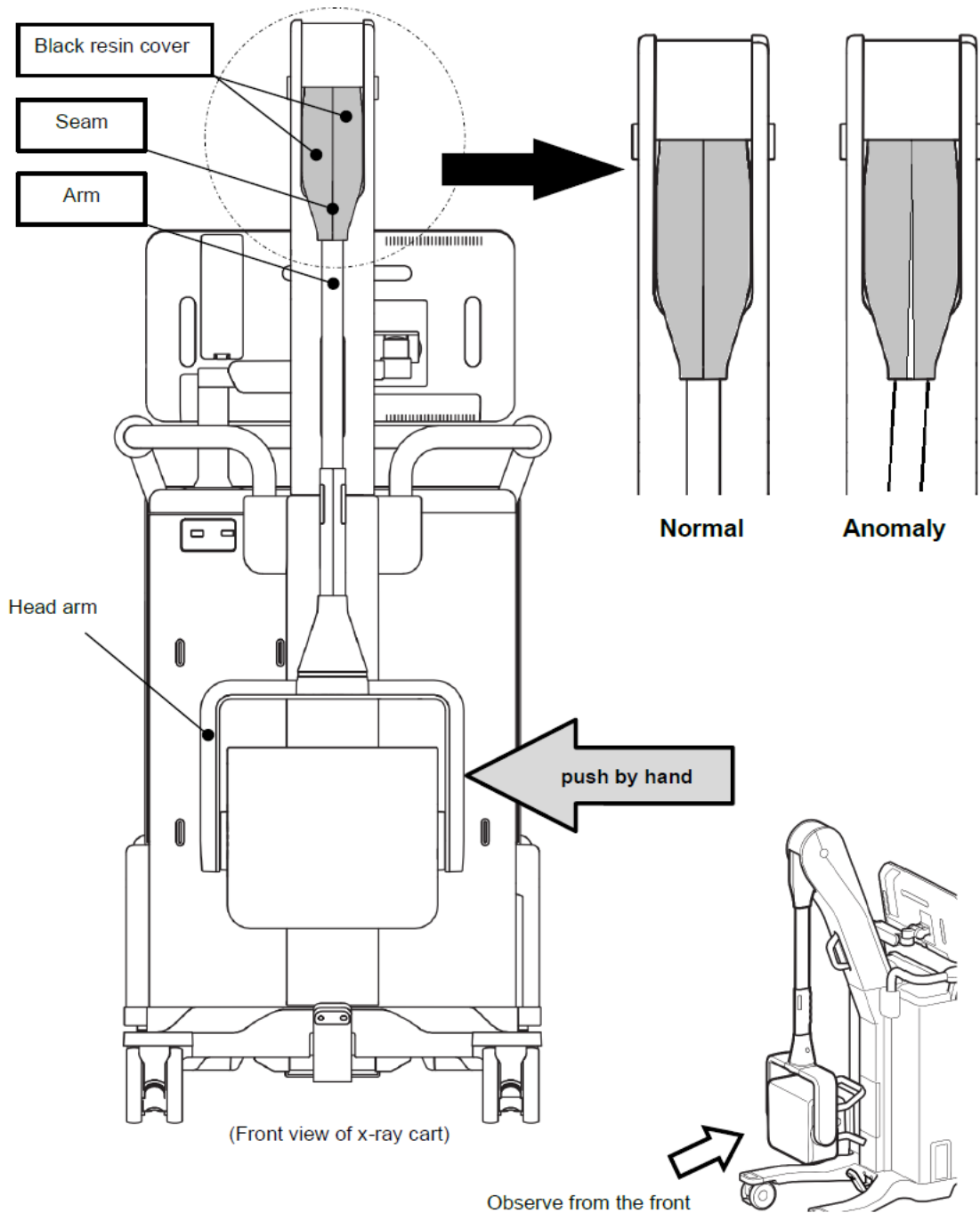
1. Set the caster lock pedal position to [Down] and secure the X-ray cart.



2. Store the arm in the home position.



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) 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



## 2. INCORRECT MIRROR INSTALLATION

### Reason for the Field Action

Fujifilm has become aware that the positional deviation between the light field indicator and the X-ray irradiation field may exceed the standard (within 2% of the SID). Since the deviation does not comply with "IEC60601-2-54 203.8.102.6 Accuracy of Indication with a Light Field-Indicator".

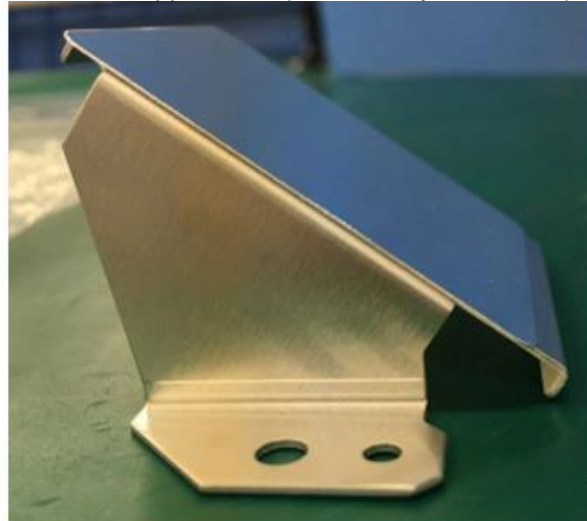
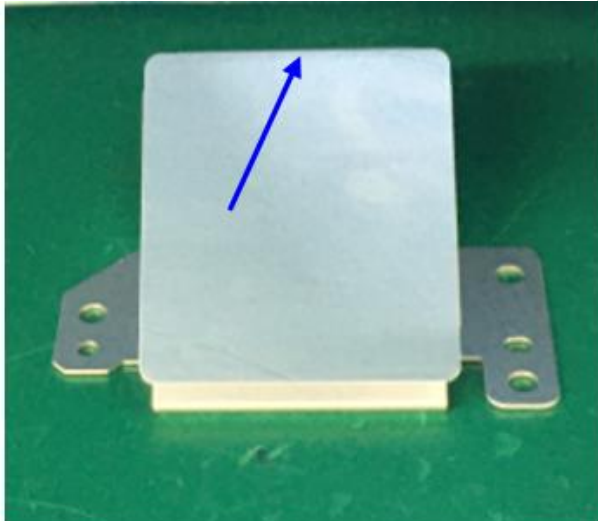
### Problem Descriptions

In DR-XD 1000, incorrect mirror installation inside the Collimator Assembly causes a deficiency where the LED light does not reach the vicinity of the full open area of Light Irradiation Field and the device is unable to properly irradiate the Light Irradiation Field.

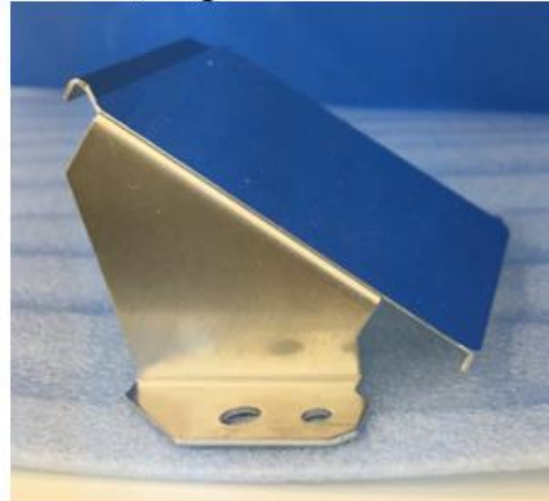
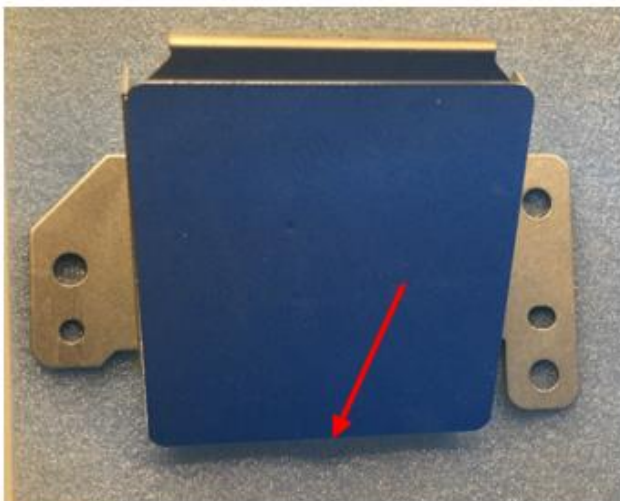
### ◇Detailed explanation of the deficiency

Inside the Collimator Assembly, the mirror is attached to the bracket incorrectly.

**Correct:** The mirror is attached to the bracket, aligned with the upper bend (indicated by blue arrow).

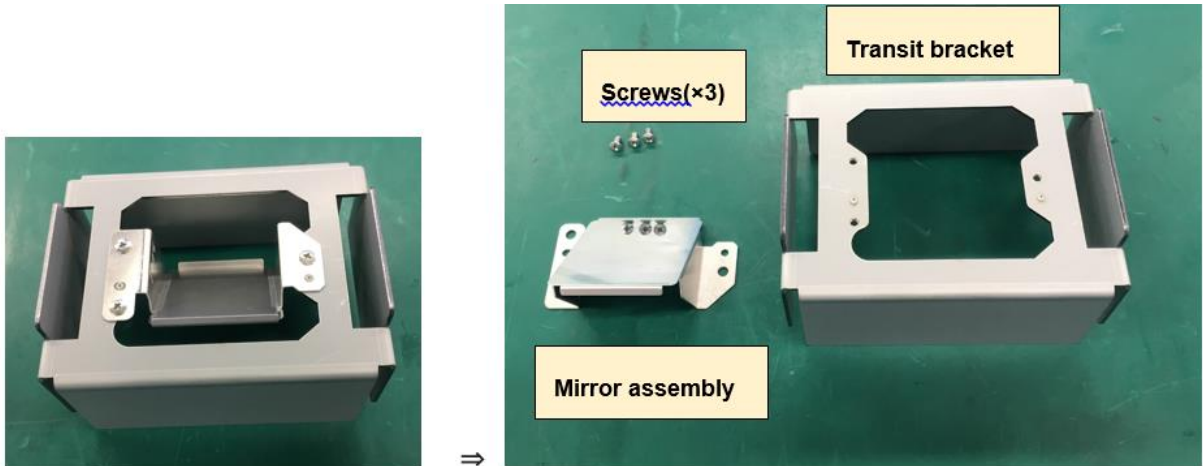


**Incorrect:** The mirror is attached to the bracket, aligned with the lower bend (indicated by red arrow).



◇Description of the countermeasure kit

- Countermeasure Kit No. : EXZT1004
- Contents  
Mirror assembly (in transit bracket)



**Risk to Health**

Since the X-ray irradiation field is wider than the light field indicator, there is no loss of areas in the captured X-ray image.

**Action to be taken by Customer / User**

- 1) Please contact your local FUJIFILM office.
- 2) Coordinate with the Fujifilm service engineer to schedule the correction of your device when contacted. The Fujifilm Service Person will contact you in order to repair at your facility.
- 3) Please complete and return the feedback form as relevant of this communication. Responding with the information requested is essential for ensuring appropriate action is taken.

**Actions Planned by Fujifilm**

A Fujifilm service engineer will contact your facility to arrange a visit to repair your affected unit(s).

# FIELD SAFETY NOTICE

## Customer Feedback Form

**URGENT: PLEASE COMPLETE AND RETURN TO FUJIFILM AS SOON AS POSSIBLE**  
Via e-mail to: [fmal.medical@fujifilm.com](mailto:fmal.medical@fujifilm.com)

Customer/Facility Name:

Address:

Instrument Serial Number:

- 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:**

**FUJIFILM (Malaysia) SDN. BHD. (205535 K)**  
No. 22, Jalan Jurunilai U1/20, Seksyen U1,  
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