

URGENT: FIELD SAFETY NOTICE
FUJIFILM CR-IR363(PROFECT CS PLUS)
Countermeasure against Residual Images

Dear Customers,

We have identified a potential failure with our FCR PROFECT CS Plus.

When imaging plates are read successively, images may not be erased due to the unlit erasure lamp. [In such a case, residual images are produced, requiring re-exposure.](#)

FUJIFILM has corrected the software 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!**

URGENT: FIELD SAFETY NOTICE
FUJIFILM CR-IR363(PROFECT CS PLUS)**AFFECTED PRODUCTS**

CR-IR363 Serial No. 97172001~97172010

PROBLEM DESCRIPTIONS

When IPs are read successively, images may not be erased due to the unlit erasure lamp.
A software bug which causes this failure is corrected.

HAZARD INVOLVED

If an image is not erased, it is overlaid with the image obtained in the following exposure, leading to creation of a residual image (dual image). If such a phenomenon occurs, re-exposure is needed.

AFFECTED PRODUCTS

	Country	Product code	Serial No.
2	UNITED KINGDOM	CR IR 363 RU P2 E	97172002
3	UNITED KINGDOM	CR IR 363 RU P2 E	97172003
4	UNITED KINGDOM	CR IR 363 RU P2 E	97172004
5	UNITED KINGDOM	CR IR 363 RU P2 E	97172005

ACTIONS TO BE TAKEN BY CUSTOMER/USER

- 1) Please contact your local FUJIFILM office.
- 2) Until the modified software is applied perform the step below when using CR-IR363(PROFECT CS PLUS) of serial number xxx72001 or later:
Perform the primary erasure processing for IPs before performing exposures.
- 3) Cooperate with the FUJIFILM service personnel to upgrade the software from V10.1 to V10.2.
- 4) Complete the feedback form as relevant and email it back

ACTIONS PLANNED BY FUJIFILM

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

FIELD SAFTY NOTICE

Customer Feedback Form

Please complete the feedback form as relevant and fax or email it back.
Thank you for your co-operation.

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:

To all FUJIFILM subsidiaries, branch offices and dealers:

FAX: PLEASE TYPE RELEVANT NUMBER HERE

Email: PLEASE TYPE RELEVANT ADDRESS HERE