



FUJIFILM Medical Systems U.S.A., Inc.  
81 Hartwell Avenue, Suite 300  
Lexington, MA 02421

January 16, 2019

ATTN: Director of Radiology, Recalls  
Department

**FUJIFILM Medical Systems U.S.A., Inc., Modality Solutions**

**URGENT: MEDICAL DEVICE CORRECTION AND REMOVAL**

**RE: Fujifilm FDR Go PLUS**

Dear Director of Radiology:

This letter is to inform you that FUJIFILM Medical Systems U.S.A., Inc., Modality Solutions (FMSU) is conducting a voluntary field action affecting Fujifilm's FDR Go PLUS.

**Reason for the voluntary recall**

FMSU has become aware of the possibility that the braking mechanism might not be engaged in all cases when the driving handle has been released. This potential issue has been identified in models manufactured from January to May 2018 (S/N# MQ0001281001 – MQ0001285004).

During this field action, you can continue to use your current FDR Go PLUS by following these additional instructions:

1. Do not release the driving handle while the device is in motion
2. Do not release the driving handle while the device is on an inclined surface
3. In the event that the device starts to move unintentionally, press the red emergency STOP switch

**Risk to health / Actions to be taken by customer**

There have been no reported patient injuries, or adverse events associated with this incident. However, in an abundance of caution, please complete and return the Field Action Verification Form attached on page 3 of this communication. Upon receipt of the Field Action Verification Form, Fujifilm service personnel will contact you to schedule a visit to correct your device(s).

Fujifilm regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. In an effort to ensure the highest level of customer satisfaction, Fujifilm will correct your affected device(s) by replacing the driving handle, at no cost to you.

Please contact our field action coordinator, Jeffrey Wan, via phone at 201-675-8947 or email at [jeffrey.wan@fujifilm.com](mailto:jeffrey.wan@fujifilm.com), if you have any further questions regarding this field action.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Vader". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping tail.

Randy Vader

Vice President, Regulatory and Quality Affairs & Corporate Compliance Officer

Enclosures

**PLEASE COMPLETE AND RETURN TO FUJIFILM AS SOON AS POSSIBLE**

Via e-mail to [fmsuregulatoryaffairs@fujifilm.com](mailto:fmsuregulatoryaffairs@fujifilm.com) or fax to 781-372-1040

**FDR Go PLUS Field Action Verification Form**

**Product Identification**

**Acknowledgement of receipt / Understanding of the field action notification**

Please check/complete the response:

- We have read and understand the field action described in this letter.

**Actions to be taken by customer**

Please check/complete the appropriate response:

- We do NOT have the affected product.
- We have the affected FDR Go PLUS and would like to schedule a visit by FUJIFILM service personnel to correct our device.

Product	Number of Affected Units	Serial Number(s)
FDR Go PLUS	«Number_of_Units»	«Serial»

ACCOUNT NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP CODE: \_\_\_\_\_

NAME (PRINT): \_\_\_\_\_ SIGNATURE: \_\_\_\_\_

TITLE: \_\_\_\_\_ EMAIL: \_\_\_\_\_

TEL.: \_\_\_\_\_ DATE: \_\_\_\_\_