

**FIELD SAFETY NOTICE**  
**SHIMADZU SAFIRE 17 Digital Radiographic System**

Dear Customer,

It has been brought to our attention an incident with serious clinical consequences following the involuntary fall of the footrest.

During the swing in position upright of the table, the footrest not having been fixed in the rules, this footrest is descended brutally until its mechanical stop, and this movement has surprised a mom who held her child.

This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the user in order to prevent risks for patients

**This document contains important information  
for the continued safe and proper use of your equipment,  
PLEASE READ AND ACTION.**

Please refer to the following pages which provide instructions for actions to be taken. Follow the **“Actions to be taken by Customer”** section of the instructions.

This issue has been reported to the appropriate regulatory agencies.

I 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.

Contact your FUJIFILM Account Manager if you have any questions or concerns or our QA/RA manager, Mr PASCAL Philippe

Yours sincerely,

Philippe PASCAL

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Quality Manager  
Quality Assurances and Regulatory Affairs  
FUJIFILM MEDICAL SYSTEMS France

# FIELD SAFETY NOTICE

## SHIMADZU SAFIRE 17 Digital Radiographic System

### AFFECTED PRODUCTS

SAFIRE 17

### PROBLEM DESCRIPTION

At the time of the realization of an examination of the abdomen on a baby of 1 month, the table SAFIRE 17 was moved from position laid down towards the position upright. The footrest, not having been fixed normally and not being blocked on its position, is descended brutally until mechanical blocking in low position. This movement, involuntary, has surprised the mom who released her baby, involving a cranial traumatism with this newborn.

### HAZARD INVOLVED

The fall unexpected of the footrest can surprise, to involve inopportune reactions, to wound by its weight the patient, or to involve the fall of a patient standing up on a footrest not fixed.

### AFFECTED PRODUCTS

**France has 47 units concerned with this alarm.**

### ACTION TO BE TAKEN BY CUSTOMER

Even when the footrest is not used as support, as at the time of the laid down position, please always block this last in its position. You have to ensure of the blocking of the footrest while following the operation manual, i.e. while trying to make slip the footrest fixed of before behind. If this last is normally fixed, displacement is impossible. If the footrest moves, start again the procedure of installation of the footrest according to the operation manual.

### ADDED DOCUMENT

You will find in enclosures an extract of the operation manual of the SAFIRE indicating the procedure to be respected during the fixing of the footrest.

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**Feedback Form**

We kindly ask you to fax back the attached information as soon as possible.  
Thank you for your co-operation.

Customer/Facility Name:

Address:

**Notice Reference:**

**Product Reference:**

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:** [Click here to enter a date.](#)

**Phone number:**

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

**Customer/Facility Name:**

**Address:**

**Fax this completed form to 01 78 91 07 99**  
**or email us on [philippe\\_pascal@fujifilm.eu](mailto:philippe_pascal@fujifilm.eu)**  
**or letter to : Mr Philippe PASCAL**  
**Fujifilm Medical Systems France**  
**Immeuble Objectif II, 2 rue Louis Armand 92607 ASNIERES cedex**