

FSN ANSM 201504468 Safire 17

2015 June 15

FIELD SAFETY NOTICE
SHIMADZU SAFIRE 17 Digital Radiographic System

Dear Customer,

According to an information about a incident with the footrest of the Shimadzu Sonialvision Safire 17 Radiographic Table in France we asked you herewith to read the manual carefully and follow the described instructions.

The mentioned incident occurred because the operator didn't pay attention to the user manual of the Sonialvision Safire. The footrest was not fixed to the table as described in the operation Manual

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 review the following information with all members of
your staff who need to be aware of the contents of this
communication. It is important to understand the
implications of this communication.

Please retain a copy with the equipment Instruction for Use.

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.

We sincerely regret the inconvenience that this may cause you. Shimadzu is committed to providing products and services of the highest quality. Your satisfaction with Shimadzu products and with our response to this issue is very important to us. If you need any further information or support concerning this issue, please contact your local Shimadzu representative.

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Detlef Otten

Safety Officer
Medical Systems
Mail: do@shimadzu.eu



Klaus Engels

Safety Officer
Medical Systems
ken@shimadzu.eu

FSN ANSM 201504468 Safire 17

2015 May 15

<p style="text-align: center;">FIELD SAFETY NOTICE SHIMADZU SAFIRE 17 Digital Radiographic System</p>
--

AFFECTED PRODUCTS

Sonialvision SAFIRE 17

PROBLEM DESCRIPTION

The footrest slipped down because it was not fixed to the table as described in the Operation manual. Please refer to page 17 "Accessories and Options" of the Sonialvision Safire 17 Operation Manual.

ACTION TO BE TAKEN BY CUSTOMER

Attach accessories such as grip bars, shoulder rests and foot rest to the unit according to the patient's body position and physique.

After attaching the accessories or relocating them, vigorously shake them in both directions to confirm that they are secured to the unit completely.

If the footrest moves, start again the procedure of installation of the footrest according to the operation manual.

ADDED DOCUMENT

Page 17 "Accessories and Options" of the Sonialvison Safire 17 Operation Manual

FSN ANSM 201504468 Safire 17

2015 May 15

FIELD SAFETY NOTICE
SHIMADZU SAFIRE 17 Digital Radiographic System

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:

Phone number:

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

Customer/Facility Name:

Address:

Fax this completed form to 0049 203 765733
or by email to do@shimadzu.eu or ken@shimadzu.eu
Mr. Detlef Otten / Mr. Klaus Engels
Shimadzu Europa GmbH
Albert-Hahn-Strasse 6-10, 47269 Duisburg, Germany