



2020-08-20

Field Safety Notice
FUJIFILM Medical Systems U.S.A., Inc.
Synapse PACS Software Versions 5.5 and 5.7

Dear Sir/ Madam:

FUJIFILM Europe GmbH is the authorised representative of products manufactured by FUJIFILM Medical Systems U.S.A., Inc. As such, it is our responsibility to inform you of a voluntary Field Safety Corrective Action affecting Breast Tomosynthesis in Synapse PACS Versions 5.5 and 5.7.

REASON FOR THE Field Safety Corrective Action

FUJIFILM has become aware of the possibility that the Lateromedial (LM) and Lateromedial Oblique (LMO) Orientation Markers may be displayed incorrectly on the 3D TOMO slider bar. In addition, the slice location of the image and/or the slice direction could be incorrect as well.

These issues have been identified in Synapse PACS Versions 5.5 and 5.7. Depending on the 5.5 version applied at your site the Orientation Markers may also be missing.

RISK TO HEALTH/ACTIONS TO BE TAKEN BY CUSTOMER/END USER

There have been no reported patient injuries associated with these issues. In an abundance of caution, FUJIFILM is recommending that you do not perform Tomosynthesis on these views until the correction is applied. In an effort to ensure the highest level of customer satisfaction, FUJIFILM is providing hotfixes for Synapse PACS Versions 5.5, 5.7.0, and 5.7.1 to resolve these issues.

We ask that you acknowledge receipt of this Field Safety Notice by completing and returning the Field Action Verification Form attached below. Providing the response is essential for ensuring appropriate action is taken. We will contact you to discuss next steps for installing the hotfix.

FUJIFILM regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. Please contact the undersigned or your Service representative if you have any further questions regarding this field action.

Sincerely,
FUJIFILM

[Name]
[Title]
[Company]

PLEASE COMPLETE AND RETURN TO FUJIFILM AS SOON AS POSSIBLE

Via e-mail to [Email] or facsimile to [Fax]

Synapse PACS Version 5.5 and 5.7 Field Action Verification Form

Product Identification

ACKNOWLEDGEMENT OF RECEIPT AND UNDERSTANDING OF LETTER

Please complete the response:

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

CUSTOMER NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

NAME (PRINT): _____ SIGNATURE: _____

TITLE: _____ EMAIL: _____

TEL.: _____ DATE: _____

NOTES: _____
