

Reference number: 20250217SP74X

March 2025

## **URGENT: FIELD SAFETY NOTICE**

### **Synapse PACS 7.4.x**

#### **Dear Customer:**

We would like to inform you that FUJIFILM Healthcare Americas Corporation (FUJIFILM) is conducting a voluntary correction for Synapse PACS v7.4.x at customers using the Synapse PACS 7.4.x with Viewer Extension (VX) client.

#### **AFFECTED PRODUCTS**

Model Number      Synapse PACS  
SW version          7.4.000, 7.4.001, 7.4.010, 7.4.100, 7.4.110 and 7.4.200

#### **PROBLEM DESCRIPTIONS**

Fujifilm became aware that a patient's age for patients younger than 18 years of age can show incorrectly in the Synapse PACS Viewer EXtension (**VX**) Client - Image Viewer. For instance, under these circumstances an infant patient's actual age of 26 days may appear incorrectly as 5 days in Synapse VX. However, in such event, the patient's age appears correctly in Synapse PACS Zero Viewer/Thin Viewer and Series Viewer within VX.

In the event a patient's age is relevant to a diagnosis or treatment decisions and an incorrect age is displayed in Synapse VX, the diagnosis or treatment plan could be incorrect.

#### **ACTIONS BY FUJIFILM**

Fujifilm will issue corrections for all impacted 7.4.x versions. The following patch releases will be made available:

7.4.020 for 7.4.0x versions

7.4.120 for 7.4.1x versions

7.4.210 for 7.4.2x versions

#### **ACTIONS REQUIRED BY CUSTOMERS**

To prevent any issue, Synapse PACS VX can safely be used by the end-user as long as; 1] the end-user is aware of the issue and, 2] takes appropriate actions when rendering a diagnosis for patients under 18 years of age. The following precautions need to be taken;

- 1) The image acquisition date and date of birth are displayed on the Image. The end-user can use the dates to verify the age or,
- 2) Open the Series Viewer by double clicking on the thumbnail displayed on top the Synapse VX Image viewing window or the worklist. The Series Viewer Window will render the image on the server using the Server-side rendering (Zero Viewer component) which will calculate the age correctly. Alternatively, the user can switch to the Synapse PACS Zero Viewer/Thin Viewer (Server-side Rendering). The Synapse PACS Zero Viewer/Thin Viewer calculates the age correctly

**ACTIONS TO BE TAKEN BY THE CUSTOMER/END-USER**

Please complete and return the Customer Feedback Form attached to this communication. Responding with the information requested is essential for ensuring appropriate action is taken.

FUJIFILM Service Engineer will contact your organization shortly to schedule an appointment for installing the required Software Update.

Fujifilm regrets any inconvenience this action may cause and appreciates your understanding and cooperation. Please contact your local distributor in case if you have any further questions regarding this field action.

Sincerely,

FUJIFILM Healthcare Europe GmbH

Balcke-Dürr-Allee 6

40882 Ratingen, Germany

[Vigilance\\_hceu@fujifilm.com](mailto:Vigilance_hceu@fujifilm.com)

## FIELD SAFETY NOTICE

### Customer Feedback Form

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

Via e-mail to [vigilance\\_hceu@fujifilm.com](mailto:vigilance_hceu@fujifilm.com)

Customer/Facility Name:

Address:

Instrument Serial Number:

Product code	Serial No.

☐ 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 email this completed form to:**

**FUJIFILM Healthcare Europe GmbH**

**Balcke-Dürr-Allee 6**

**40882 Ratingen, Germany**

**Email: [vigilance\\_hceu@fujifilm.com](mailto:vigilance_hceu@fujifilm.com)**