California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fujifilm Healthcare Americas Corporation Synapse PACS Software

Recall Date	Product Description	Recalling Firm	Recall Reason
03/20/2025	Synapse PACS Software Version 7.4.x; Software Versions: 7.4.000, 7.4.001, 7.4.010, 7.4.100, 7.4.110, 7.4.200.	Fujifilm Healthcare Americas Corporation	The incorrect computed patient age is showing in VX for patients less than 3 months old.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model numbers: Synapse PACS 7.4.000, 7.4.001, 7.4.010, 7.4.100, 7.4.110, 7.4.200 Software Version Numbers: Synapse PACS 7.4.000, UDI: (01)00854904006008(10)0704000; Synapse PACS 7.4.001, UDI: (01)00854904006008(10)0704001; Synapse PACS 7.4.010, UDI: (01)00854904006008(10)0704010; Synapse PACS 7.4.100, UDI: (01)00854904006008(10)0704100; Synapse PACS 7.4.110, UDI: (01)00854904006008(10)0704110; Synapse PACS 7.4.200, UDI: (01)00854904006008(10)0704200.	4 affected Synapse PACS Software Version 7.4.x systems were distributed in California, specifically versions 7.4.010 and 7.4.200 The corresponding UDIs are: Version 7.4.010: (01)00854904006008(10)0704010 Version 7.4.200: (01)00854904006008(10)0704200	March 2025 and Prior

For additional information, please visit the FDA Website.

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