California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Philips Medical Systems Nederland B.V. Allura Xper FD10 Catalog, FD10/10, FD20, FD20 Biplane, FD20 OR Table, FD20/10, FD20/15, FD20/20, Azurion 3 M12, Azurion 5 M12, M20, and Azurion 7 B12, B20, M12, M20

Recall Date	Product Description	Recalling Firm	Recall Reason
02/04/2025	Allura Xper FD10 Catalog System Code: (1) 722003 (2) 722010 (3) 722026 Allura Xper FD10/10 System Code: (1) 722005 (2) 722011 (3) 722027 Allura Xper FD20 System Code: (1) 722006 (2) 722012 (3) 722028 Allura Xper FD20 Biplane System Code: (1) 722008 (2) 722013 Allura Xper FD20 OR Table System Code: (1) 722023 (2) 722035 Allura Xper FD20/10 System Code: (1) 722029 Allura Xper FD20/15 System Code: (1) 722058 Allura Xper FD20/20 System Code: (1) 722038	Philips Medical Systems Nederland B.V.	Potential safety issue with the AD7 and AD7X patient tables (both tilt and non-tilt versions) part of the Philips Allura and Azurion systems. During manual repositioning of the patient tabletop, a finger can get entrapped between the longitudinal guiding rails and the tabletop. This may result in an injury of the finger, applicable for operators and service personnel

	Azurion 3 M12 System Code: (1) 722063 (2) 722221 Azurion 5 M12 System Code: (1) 722227 (2) 722231 Azurion 5 M20 System Code: (1) 722228 (2) 722232 (3) 722281 Azurion 7 B12 System Code: (1) 722067 (2) 722225 (3) 722235 Azurion 7 B20 System Code: (1) 722068 (2) 722226 (3) 722236 Azurion 7 M12 System Code: (1) 722078 (2) 722223 (3) 722233 Azurion 7 M20 System code: (1) 722224 (2) 722079 (3) 722234 (4) 722282		

Recall Class	Product Identification	Distribution	Affected Dates
II	Allura Xper FD10 Catalog UDI: (1) 722003 00884838059191(10) (2) 722010 00884838059030(21) (3)722026 00884838054189(21) **474 units** Allura Xper FD10/10 UDI: (1) 722005 00884838059191(10) 00884838080805(10) (2) 722011 --- (3) 722027 00884838054196(21) **146 units**	Nationwide	January and prior

	Allura Xper FD20 UDI: (1) 722006 00884838055513(21) 00884838059115(21) 00884838059191(10) (2) 722012 00884838059054(21) (3) 722028 00884838054202(21) **1,528 units** Allura Xper FD20 Biplane UDI: (1) 722006 00884838055513(21) 00884838059115(21) 00884838059191(10) (2) 722012 00884838059054(21) (3) 722028 00884838054202(21) **66 units** Allura Xper FD20 OR Table UDI: N/A **1 unit** Allura Xper FD20/10 UDI: 00884838054219(21) **22 units** Allura Xper FD20/15 UDI: 00884838059115(21) **69 units** AlluraXper FD20/20 UDI: 00884838054226(21) **33 units** Azurion 3 M12 UDI: (1) 722063 00884838085275(21) (2) 722221 00884838099203(21) **9 units** Azurion 5 M12 UDI: (1) 722227 00884838099227(21) (2) 722231 00884838116740(21) **6 units**		

	Azurion 5 M20 UDI: (1) 722228 00884838099234(21) (2) 722232 00884838116757(21) (3) 722281 00884838110564(21) **68 units** Azurion 7 B12 UDI: (1) 722067 00884838085350(21) (2) 722225 00884838099265(21) (3) 722235 00884838116788(21) **90 units** Azurion 7 B20 UDI: (1) 722068 00884838085367(21) (2) 722226 00884838099272(21) (3) 722236 00884838116801(21) **251 units** Azurion 7 M12 UDI: (1) 722078 00884838085251(21) (2) 722223 00884838099241(21) (3) 722233 00884838116764(21) **324 units** Azurion 7 M20 UDI: (1) 722224 00884838099258(21) (2) 722079 00884838085268(21) (3) 722234 00884838116771(21) (4) 722282 00884838110571(21) **1,346 units**		

For additional information, please visit: FDA Website (Xper FD10 Catalog), FDA Website (Xper FD10/10), FDA Website (Xper FD20), FDA Website (Xper FD20 Biplane), FDA Website (Xper FD20 OR Table), FDA Website (Xper FD20/10), FDA Website (Xper FD20/15), FDA Website (Xper FD20/20), FDA Website (Azurion 3 M12), FDA Website (Azurion 5 M12), FDA Website (Azurion 5 M20), FDA Website (Azurion 7 B12), FDA Website (Azurion 7 B20), FDA Website (Azurion 7 M12), and FDA Website (Azurion 7 M20).