

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Philips Medical Systems Nederland B.V. Allura Xper FD10, FD10/10, FD20, FD20 Biplane, FD20 Biplane OR Table, FD20 OR Table, FD20/10, FD20/15, FD2020, Azurion 3 M12, M15, Azurion 5 M12, M20, and Azurion 7 B12, B20, M12, M20

Recall Date	Product Description	Recalling Firm	Recall Reason
02/20/2025	Allura Xper FD10 Catalog numbers: (1) 722003 (2) 722010 (3) 722026 Allura Xper FD10/10 Catalog numbers: (1) 722005 (2) 722011 (3) 722027 Allura Xper FD20 Catalog numbers: (1) 722006 (2) 722012 (3) 722028 Allura Xper FD20 Biplane Catalog numbers: (1) 722008 (2) 722013 Allura Xper FD20 Biplane OR Table Catalog numbers: (1) 722020 (2) 722025 Allura Xper FD20 OR Table Catalog numbers: (1) 722023 (2) 722035 Allura Xper FD20/10 Catalog numbers: 722029 Allura Xper FD20/15 Catalog numbers: 722058	Philips Medical Systems Nederland B.V.	Possibility of the patient falling from the table related to the mattress used on the patient table.

	Allura Xper FD20/20 Catalog numbers: 722038 Azurion 3 M12 Catalog numbers: (1) 722063 (2) 722221 Azurion 3 M15 Catalog numbers: (1) 722064 (2) 722222 Azurion 5 M12 Catalog numbers: (1) 722227 Azurion 5 M20 Catalog numbers: (1) 722228 Azurion 7 B12 Catalog numbers: (1) 722067 (2) 722225 Azurion 7 B20 Catalog numbers: (1) 722068 (2) 722226 (3) 722236 Azurion 7 M12 Catalog numbers: (1) 722078 (2) 722223 Azurion 7 M20 Catalog numbers: (1) 722079 (2) 722224 (3) 722234		
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Recall Class	Product Identification	Distribution	Affected Dates
I	Catalog numbers: (1) 722003 (2) 722010 (3) 722026 UDI-DI: (1) No UDI (2) 00884838059030 (3) 00884838054189 Serial Numbers: See additional information and product list below 474 units	Nationwide	January and prior

	Catalog numbers: (1) 722005 (2) 722011 (3) 722027 UDI-DI: (1) No UDI (2) 00884838059047 (3) 00884838054196 Serial Numbers: See additional information and product list below 147 units Catalog numbers: (1) 722006 (2) 722012 (3) 722028 UDI-DI: (1) No UDI (2) 00884838059054 (3) 00884838054202 Serial Numbers: See additional information and product list below 1,599 units Catalog numbers: (1) 722008 (2) 722013 UDI-DI: (1) No UDI (2) 00884838059061 Serial Numbers: See additional information and product list below 195 units Catalog numbers: (1) 722020 (2) 722025 UDI-DI: (1) No UDI (2) 00884838059108 Serial Numbers: See additional information and product list below 2 units Catalog numbers: (1) 722023 (2) 722035 UDI-DI: (1) 00884838059085 (2) 00884838054240 Serial Numbers: See additional information and product list below 1 unit Catalog number: 722029 UDI-DI: 00884838054219 Serial Numbers: See additional information and product list below 22 units		
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	Catalog number: 722058 UDI-DI: 00884838059115 Serial Numbers: See additional information and product list below 69 units Catalog number: 722038 UDI-DI: 00884838054226 Serial Numbers: See additional information and product list below 33 units Catalog numbers: (1) 722063 (2) 722221 UDI-DI: (1) 00884838085275 (2) 00884838099203 Serial Numbers: See additional information and product list below 25 units Catalog numbers: (1) 722064 (2) 722222 UDI-DI: (1) 00884838085282 (2) 00884838099210 Serial Numbers: See additional information and product list below 42 units Catalog numbers: (1) 722227 UDI-DI: (1) 00884838099227 Serial Numbers: See additional information and product list below 6 units Catalog numbers: (1) 722228 UDI-DI: (1) 00884838099234 Serial Numbers: See additional information and product list below 68 units Catalog numbers: (1) 722067 (2) 722225 UDI-DI: (1) 00884838085350 (2) 00884838099265 Serial Numbers: See additional information and product list below 90 units		
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	Catalog numbers: (1) 722068 (2) 722226 (3) 722236 UDI-DI: (1) 00884838085367 (2) 00884838099272 (3) 00884838116801 Serial Numbers: See additional information and product list below 251 units Catalog numbers: (1) 722078 (2) 722223 UDI-DI: (1) 00884838085251 (2) 00884838099241 Serial Numbers: See additional information and product list below 324 units Catalog numbers: (1) 722079 (2) 722224 (3) 722234 UDI-DI: (1) 00884838085268 (2) 00884838099258 (3) 00884838116771 Serial Numbers: See additional information and product list below 1,346 units		
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For additional information and product list, please visit: [FDA Website \(Xper FD10\)](#), [FDA Website \(Xper FD10/10\)](#), [FDA Website \(Xper FD20\)](#), [FDA Website \(Xper FD20 Biplane\)](#), [FDA Website \(Xper FD20 Biplane OR Table\)](#), [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 \(Azurion 3 M15\)](#), [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 \(Azurion 7 M20\)](#).