California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

A L I Technologies Ltd Change Healthcare Cardiology Hemo and Hemodynamics software

Recall Date	Product Description	Recalling Firm	Recall Reason
01/16/2025	Change Healthcare Cardiology Hemo software Change Healthcare Cardiology Hemodynamics software McKesson Cardiology Hemo software	A L I Technologies Ltd	Software defect concerning autosave mechanism may result in the clinician administering incorrect medication(s).

Recall Class	Product Identification	Distribution	Affected Dates
II	Software version: 14.1.1 UDI: (01)17540262100020 Software version: 14.2 UDI: (01)17540262100037 Software version: 14.3 UDI: (01)17540262100044 Software version: 14.3.2 UDI: (01)17540262100051 Software version: 15.01 UDI: (01)17540262100105 Software version: 15.1 UDI: (01)17540262100129 Software version: 15.01 UDI: (01)17540262100129	20 units in California	December and prior

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	Software version: 13.1.2 UDI: No UDI Software version: 13.2.1 UDI: (01)80010939050010 Software version: 14 UDI: (01)80010939050027		

For additional information, please visit: FDA Website (Hemo), FDA Website (Hemodynamics), and FDA Website (McKesson).