State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Datascope Recalls Cardiosave Intraaortic Balloon Pump For Device Charging

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	**Cardiosave Hybrid Intra-Aortic Balloon Pumps (Iabp)** Part Numbers 0998-00-0800-31, 0998-UC-0800-31, 0998-00-0800-32, 0998-00-0800-33, 0998-UC-0800-33, 0998-00-0800-34, 0998-00-0800-35, 0998-00-0800-45, 0998-00-0800-52, 0998-UC-0800-52, 0998-00-0800-53, 0998-UC-0800-53, 0998-00-0800-55, 0998-UC-0800-55, 0998-00-0800-65	**DATASCOPE CORP.** Mahwah, New Jersey	Users were reporting that the device was not charging as expected. It was discovered that users were unaware that the Cardiosave console was not completely inserted into the hospital cart. If the console is not fully inserted back into the cart the battery(ies) will not charge.
9/6/2023	**Cardiosave Rescue Intra-Aortic Balloon Pumps (Iabp)** Part Numbers 0998-00-0800-75, 0998-00-0800-83, 0998-00-0800-85	**DATASCOPE** Mahwah, New Jersey	Users were reporting that the device was not charging as expected. It was discovered that users were unaware that the Cardiosave console was not completely inserted into the hospital cart. If the console is not fully inserted back into the cart the battery(ies) will not charge.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiosave Hybrid Intra-Aortic Balloon Pumps (labp)** All Lot Numbers. Model: 0998-00-0800-31, UDI: 10607567109053; Model: 0998-UC-0800-31, UDI: N/A; Model: 0998-00-0800-32, UDI: 10607567111117; Model: 0998-00-0800-33, UDI: 10607567109008; …	9175 Units Nationwide	July 2023 and prior
I	**Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)** All Lot Numbers. Model: 0998-00-0800-75, UDI: 10607567112312; Model: 0998-00-0800-83, UDI: 10607567108407; Model: 0998-00-0800-85, UDI: 10607567113449	9175 Units Nationwide	July 2023 and prior

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