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 of Loss of Pumping

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 reported "System Over Temperature" alarms associated with a loss of pumping and/or the Cardiosave system entering Standby mode.
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 CORP.** Mahwah, New Jersey	Users reported "System Over Temperature" alarms associated with a loss of pumping and/or the Cardiosave system entering Standby mode.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)** 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

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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