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 Corp. Cardiosave Rescue Intra-Aortic Balloon Pump for Inability to Charge Batteries

Recall Date	Product Description	Recalling Firm	Recall Reason
7/26/2023	**Cardiosave Rescue Intra-Aortic Balloon Pump** Model numbers 0998-00-0800-75 0998-00-0800-83 0998-00-0800-85	**Datascope Corp.** Mahwah, New Jersey	IABP may lose the ability to charge batteries in one or both bay slots. Therapy may be interrupted if batteries fail to charge, and the device is disconnected from AC power. Low battery alarms may alert the User to the issue prior to interruption of therapy.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiosave Rescue Intra-Aortic Balloon Pump** All Unit Serial Numbers Model UDI 0998-00-0800-75 10607567112312 0998-00-0800-83 10607567108407 0998-00-0800-85 10607567113449	4586 Units Nationwide	June 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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