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 Hybrid & Rescue Intra-Aortic Balloon Pumps (IABP) due to Unexpected Shutdown

Recall Date	Product Description	Recalling Firm	Recall Reason
1/25/2023	**Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP)** Model Numbers 0998-00-0800-31 - 0998-UC-0800-55	**Datascope Corp.** Mahwah, New Jersey	The Cardiosave IABP may shut down unexpectedly due to blood entering in the Cardiosave IABP when therapy is provided with a compromised intra-aortic balloon catheter.
1/25/2023	**Cardiosave Rescue Intra-Aortic Balloon Pump (IABP)** Model Numbers 0998-00-0800-75, 0998-00-0800-83, 0998-00-0800-85	**Datascope Corp.** Mahwah, New Jersey	May shut down unexpectedly

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiosave Hybrid IABP** All Serial Numbers. May also be designated as part number D998 etc. Model Number, UDI-DI: 0998-00-0800-31, 10607567109053; 0998-00-0800-32, 10607567111117; 0998-00-0800-33, 10607567109053; 0998-00-0800-34, 10607567111940; 0998-00-0800-35, 10607567109107; 0998-00-0800-45, 10607567108421; 0998-00-0800-52, 10607567108438; 0998-00-0800-53,	8759 Devices Worldwide	December 2022 and prior

	10607567108391; 0998-00-0800-55, 10607567108414; 0998-00-0800-65, 10607567113432; 0998-UC-0800-31, no UDI; 0998-UC-0800-33, no UDI; 0998-UC-0800-52, no UDI; 0998-UC-0800-53, no UDI; 0998-UC-0800-55, no UDI.		
I	**Cardiosave Rescue IABP** All Serial Numbers. May also be designated as part number D998 etc. Model Number, UDI-DI: 0998-00-0800-75, 10607567112312; 0998-00-0800-83, 10607567108407; 0998-00-0800-85, 10607567113449.	8759 Devices Worldwide	December 2022 and prior

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