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 CardiosaveIntraaortic Balloon Pump for Unexpected Shutdown

Recall Date	Product Description	Recalling Firm	Recall Reason
3/15/2023	**Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP), Containing Coiled Cord cable** (part number 0012-00-1801, Model Numbers 0998-00-0800-31, 0998-00-0800-32, 0998-00-0800-33, 0998-00-0800-34, 0998-00-0800-35, 0998-00-0800-45, 0998-00-0800-52, 0998-00-0800-53, 0998-00-0800-55, 0998-00-0800-65, 0998-UC-0800-31, 0998-UC-0800-33, 0998-UC-0800-52, 0998-UC-0800-53, 0998-00-0800-55)	**Datascope Corp.** Mahwah, New Jersey	An unexpected shut-down of the IABP may occur due to a failure of the conn-ection between the Coiled Cord cable and the Cable Ass-embly backplane to the Coiled Cord cab-le which provides the communication bet-ween the display head and base unit.
3/15/2023	**Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP), Containing Coiled Cord cable** (part number 0012-00-1801, Model Numbers 0998-00-0800-75, 0998-00-0800-83, 0998-00-0800-85)	**Datascope Corp.** Mahwah, New Jersey	An unexpected shut-down of the IABP may occur
3/15/2023	**Cardiosave Hybrid** Model Nos. 0998-00-0800-31 0998-00-0800-32 0998-00-0800-33 0998-00-0800-34 0998-00-0800-35 0998-00-0800-45 0998-00-0800-52 0998-00-0800-53 0998-00-0800-55 0998-00-0800-65	**Datascope Corp.** Mahwah, New Jersey	An unexpected shut-down of the IABP may occur

3/15/2023	**Cardiosave Rescue** Model Nos. 0998-00-0800-75 0998-00-0800-83 0998-00-0800-85	**Datascope Corp.** Mahwah, New Jersey	An unexpected shut-down of the IABP may occur

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiosave Hybrid Intra-Aortic Balloon Pumps (IABP), Containing Coiled Cord cable** All serial numbers. Model 0998-00-0800-31, UDI-DI 106075671-09053; Model 0998-00-0800-32, UDI-DI 10607567111117; Model 0998-00-0800-33, UDI-DI 1060-7567109008; Model 0998-00-0800-34, UDI-DI 1060756711-1940; Model 0998-00-0800-35, UDI-DI 10607567109107; Model 0998-00-0800-45, UDI-DI 1060-7567108421; Model 0998-00-0800-52, UDI-DI 1060756710-8438; Model 0998-00-0800-53, UDI-DI 10607567108391; Model 0998-00-0800-55, UDI-DI 1060-7567108414; Model 0998-00-0800-65, UDI-DI 1060756711-3432	4062 Units Nationwide	February 2023 and prior
I	**Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP), Containing Coiled Cord cable** All serial numbers. Model Number 0998-00-0800-75, UDI-DI 10607567112312; Model Number 0998-00-0800-83, UDI-DI 10607567108407; Model Number 0998-00-0800-85, UDI-DI 10607567113449	4062 Units Nationwide	February 2023 and prior

I	**Cardiosave Hybrid** UDI 0998-00-0800-31 10607567-109053 0998-00-0800-32 1060-7567111117 0998-00-0800-33 10607567109008 0998-00-0800-34 10607567111940 0998-00-0800-35 10607567109107 0998-00-0800-45 10607567108421 0998-00-0800-52 1060756710-8438 0998-00-0800-53 1060756-7108391 0998-00-0800-55 1060-7567108414 0998-00-0800-65 10607567113432 0998-UC-0800-31* N/A 0998-UC-0800-33* N/A 0998-UC-0800-52* N/A 0998-UC-0800-53* N/A 0998-00-0800-55* N/A All serial numbers	4502 Units Nationwide including California	February 2023 and prior
I	**Cardiosave Rescue** UDI 0998-00-0800-75 1060756-7112312 0998-00-0800-83 10607-567108407 0998-00-0800-85 106-07567113449 All serial numbers	4502 Units Nationwide including California	February 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE