



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Datascope Recalls Cardiosave Intraaortic Balloon Pump For Alarms During Therapy

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	<p>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</p>	<p>DATASCOPE CORP. Mahwah, New Jersey</p>	<p>Users were reporting instances of "Gas Loss in IAB Circuit" and "Gas Gain in IAB Circuit" alarms while providing therapy. An internal investigation of the complaints determined that there is a potential trigger for these alarms that was not listed in the IFU: Patient Movement (coughing, general movement, and swallowing). Blood in the circuit, kinks and abrasions of the tubing/catheter and certain patient conditions could also trigger these alarms. The HHE also identified hardware issues related to these alarms.</p>
9/6/2023	<p>Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP) Part Numbers 0998-00-0800-75, 0998-00-0800-83, 0998-00-0800-85</p>	<p>DATASCOPE CORP. Mahwah, New Jersey</p>	<p>Users were reporting instances of "Gas Loss in IAB Circuit" and "Gas Gain in IAB Circuit" alarms while providing therapy. An internal investigation of the complaints determined that there</p>

			is a potential trigger for these alarms that was not listed in the IFU: Patient Movement (coughing, general movement, and swallowing). Blood in the circuit, kinks/abrasions of the tubing/catheter and certain patient conditions could also trigger these alarms. The firm's HHE also identified hardware issues related to these alarms.
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Recall Class	Product Identification	Distribution	Affected Dates
I	Cardiosave Hybrid 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

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