



Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Datascope Corp. Recalls Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP)

Recall Date	Product Description	Recalling Firm	Recall Reason
10/2/2024	<p>Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) Electromechanical system used to inflate and deflate intra-aortic balloons.</p>	<p>DATASCOPE CORP. Mahwah, NJ</p>	<p>Firm has developed a software correction (Revision D.00) outside the US to mitigate product problems that pose a risk of hemodynamic instability and failure of transmission of clinical data in Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump devices.</p>
10/2/2024	<p>Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) Electromechanical system used to inflate and deflate intra-aortic balloons.</p>	<p>DATASCOPE CORP. Mahwah, NJ</p>	<p>Firm has developed a software correction (Revision D.00) outside the US to mitigate product problems that pose a risk of hemodynamic instability and failure of transmission of clinical data in Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump devices.</p>

10/2/2024	Cardiosave Rescue Intra-Aortic Balloon Pump (Iabp) Electromechanical system used to inflate and deflate intra-aortic balloons.	DATASCOPE CORP. Mahwah, NJ	Firm has developed a software correction (Revision D.01) for outside the US to mitigate product problems that pose a risk of hemodynamic instability and failure of transmission of clinical data in Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump devices.
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Recall Class	Product Identification	Distribution	Affected Dates
I	Cardiosave Hybrid Intra-Aortic Balloon Pump (Iabp) UDI: 10607567109053, 10607567111117, 10607567109008, 10607567111940, 10607567109107, 10607567114187, 10607567108421, 10607567108438, 10607567108391, 10607567108414, 10607567113432; Lot No. ALL LOTS.	5,475 units Units Nationwide including California	October 2024 and Prior
I	Cardiosave Hybrid Intra-Aortic Balloon Pump (Iabp) UDI: 10607567112312, 10607567108407, 10607567113449; Lot No. ALL LOTS.	5,475 units Units Nationwide including California	October 2024 and Prior
I	Cardiosave Hybrid Intra-Aortic Balloon Pump (Iabp) UDI: 10607567112312, 10607567108407, 10607567113449; Lot No. ALL LOTS.	5,475 units Units Nationwide including California	October 2024 and Prior

For additional information, please visit the [FDA website](#)

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

