

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merge Healthcare, Inc. VERICIS Merge Cardio

Recall Date	Product Description	Recalling Firm	Recall Reason
03/20/2025	VERICIS, Merge Cardio Model/Catalog Number: Version 9.x Software Version: 9.0.6 and 9.0.8 VERICIS, Merge Cardio Model/Catalog Number: Version 10.x Software Version: 10.0, 10.1.1.1, 10.1.2, 10.2.0, 10.2 P2, 10.3 VERICIS, Merge Cardio Model/Catalog Number: Version 11.x Software Version: 11.0.2, 11.0.3, 11.0.4, 11.1, 11.1.1 VERICIS, Merge Cardio Model/Catalog Number: Version 12.X Software Version: 12.0.1, 12.0.2 The VERICIS is an integrated cardiovascular information system classified as a picture archiving and communications system.	Merge Healthcare, Inc.	When following a specific less typical workflow in which the user remeasures using the ultrasound device or manually edits primitive or derived measurement values directly in Clinical Reporting, derived measurements may be inconsistent with the associated primitive measurements in the final patient report.

	Merge Cardio Model/Catalog Number: Version 12.X Software Version: 12.1, 12.1.1, 12.2, 12.3, 12.3.1, 12.3.2, 12.3.3, 12.4, 12.4.1, 12.4.2 Merge Cardio is a software medical device that is an integrated multi-modality image cardiovascular information management system.		
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Recall Class	Product Identification	Distribution	Affected Dates
II	The following versions were introduced prior to the implementation of UDI. Version Numbers: 9.0.6, 9.0.8 Part Numbers: 88-00061-00, 88-00062-00, 88-00063-00, 88-00054-00, 88-00064-00 Software Version: 10.0 Part Numbers: 88-00527-00, 88-00528-00, 88-00529-00, 88-00530-00, 88-00531-00, 88-00532-00, 88-00533-00, 70-00008-00 Software Version: 10.1.1.1 Part Numbers: 88-01094-00 Software Version: 10.1.2 Part Numbers: 88-01074-00, 88-01075-00, 88-01076-00, 88-01077-00, 88-01078-00, 88-01079-00, 88-00781-00, 88-00803-00, 88-01080-00, 70-00473-00 Software Version: 10.2.0 Part Numbers: 88-01115-00, 88-01116-00, 88-01117-00, 88-01118-00, 88-01119-00, 88-01120-00, 88-01121-00, 88-01122-00, 88-01123-00, 70-00491-00	26 units in California	February and prior

	Software Version: 10.2 P2 Part Numbers: 88-01203-00 Software Version: 10.3 P1 UDI: (01)00842000100041(10)10.3.0.2 009(11)170309 Software Version: 11.0.2 UDI: (01)00842000100416(10)11.0.2.1 523(11)180809 Software Version: 11.0.3 UDI: (01)00842000100416(10)11.0.3.1 601(11)181019 Software Version: 11.0.4 UDI: (01)00842000100416(10)11.0.4(1 1)210207 Software Version: 11.1 UDI: (01)00842000100751(10)11.1.0.1 054(11)181211 Software Version: 11.1.1 UDI: (01)00842000100751(10)11.1.1(1 1)190724 Software Version: 12.0.1 UDI: (01)00842000100768(10)12.0.1(1 1)200107 Software Version: 12.0.2 UDI: (01)00842000100768(10)12.0.2(1 1)201117 Software Version: 12.4.1 UDI: (01)00842000101123(10)12.4.1(1 1)240522 Software Version: 12.4.2 UDI: (01)00842000101123(10)12.4.2(1 1)250206 Software Version: 12.1 UDI: (01)00842000100928(10)12.1(11		
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	)210122 Software Version:12.1.1 UDI: (01)00842000100928(10)12.1.1(1 1)211220 Software Version: 12.2 UDI: (01)00842000100065(10)12.2.0(1 1)220713 Software Version: 12.3 UDI: (01)00842000101109(10)12.3.0(1 1)221114 Software Version:12.3.1 UDI: (01)00842000101109(10)12.3.0(1 1)221114 Software Version: 12.3.2 UDI: (01)00842000101109(10)12.3.2(1 1)230612 Software Version:12.3.3 UDI: (01)00842000101109(10)12.3.3(1 1)230913 Software Version: 12.4 UDI: (01)00842000101123(10)12.4.0(1 1)231220 Software Version: 12.4.1 UDI: (01)00842000101123(10)12.4.1(1 1)240522 Software Version: 12.4.2 UDI: (01)00842000101123(10)12.4.2(1 1)250206		
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For additional information, please visit: [FDA Website \(VERICIS 9.x\)](#), [FDA Website \(VERICIS 10.x\)](#), [FDA Website \(VERICIS 11.x\)](#), [FDA Website \(VERICIS 12.x\)](#), and [FDA Website \(Merge Cardio 12.x\)](#).