

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

ZOLL Medical Corporation Powerheart G5 AED

Recall Date	Product Description	Recalling Firm	Recall Reason
03/12/2025	Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5A-00A, (2) G5A-01A, (3) G5A-02A, (4) G5A-03A, (5) G5A-19A, (6) G5A-80A, (7) G5A-80A-TSO Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5A-80A, (2) G5A-80A-TSO. Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5A-80C, (2) G5A-80C-TSO Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5A-01C, (2) G5A-02C, (3) G5A-05C, (4) G5A-08C, (5) G5A-10C, (6) G5A-13C, (7) G5A-15C, (8) G5A-22C, (9)	ZOLL Medical Corporation	The potential for devices to fail their self-test as a result of prolonged exposure to extreme environments (temperature and/or humidity).

	G5A-41C, (10) G5A-85C, (11) G5A-90C (12) G5A-80-L Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5S-01C (2) G5S-02C (3) G5S-10C (4) G5S-11C Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: G5S-80C Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: (1) G5S-00A-TSO(2) G5S-01A (3) G5S-02A (4) G5S-05A (5) G5S-08A (6) G5S-10A (7) G5S-11A (8) G5S-80A-TSO (9) G5S-80-L (10) G5S-90A Software Version: NA Brand Name: ZOLL Product Name: Powerheart G5 AED Model/Catalog Number: G5S-80A Software Version: NA The Powerheart G5 automated external defibrillator (AED) is designed for treating life-threatening heart beat irregularities, such as ventricular fibrillation, that cause Sudden Cardiac Arrest (SCA). There are two models available fully automatic and semi-automatic. After the defibrillations pads are applied		
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	to the patient, the fully automatic model evaluates the heart rhythm and, if a shockable rhythm is detected, delivers a shock without any rescuer assistance. The semi-automatic model evaluates the heart rhythm and requires the rescuer to press the shock button if a shockable rhythm is detected. Both models have voice and text instructions that guide the rescuer through the entire defibrillation process. Note: Not all configurations described in this document are available in all areas.		
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Recall Class	Product Identification	Distribution	Affected Dates
II	Model/Catalog Number: (1) G5A-00A (2) G5A-01A (3) G5A-02A (4) G5A-03A (5) G5A-19A (6) G5A-80A (7) G5A-80A-TSO UDI-DI: (1) no UDI (2) 00812394021154 (3) no UDI (4) no UDI (5) 00812394022243 (6) 00812394021192 (7) 00812394021390 Serial Numbers: See additional information and product list below Model/Catalog Number: (1) G5A-80A (2) G5A-80A-TSO UDI-DI: (1) 00812394021192 (2) 00812394021390 Serial Numbers: See additional information and product list below	7,377 units in California	February and prior

	Model/Catalog Number: (1) G5A-80C (2) G5A-80C-TSO UDI-DI: (1) 00812394021208 (2) 00812394021406 Serial Numbers: See additional information and product list below Model/Catalog Number: (1) G5A-01C (2) G5A-02C (3) G5A-05C (4) G5A-08C (5) G5A-10C (6) G5A-13C (7) G5A-15C (8) G5A-22C (9) G5A-41C (10) G5A-85C (11) G5A-90C (12) G5A-80-L UDI-DI: (1) 00812394021161 (2) no UDI (3) no UDI (4) no UDI (5) no UDI (6) no UDI (7) no UDI (8) no UDI (9) no UDI (10) 00812394021208 (11) no UDI (12) 00812394021215 Serial Numbers: See additional information and product list below Model/Catalog Number: (1) G5S-01C (2) G5S-02C (3) G5S-10C (4) G5S-11C UDI-DI: (1) 00812394021246 (2) no UDI (3) no UDI (4) no UDI Serial Numbers: See additional information and product list below Model/Catalog Number: G5S-80C UDI-DI: 00812394021284 Serial Numbers: See additional information and product list below Model/Catalog Number: (1) G5S-00A-TSO (2) G5S-01A (3) G5S-02A (4) G5S-05A (5) G5S-08A (6) G5S-10A (7) G5S-11A (8) G5S-80A-TSO (9) G5S-80-L (10) G5S-90A UDI-DI: (1) no UDI (2) 00812394021239 (3) no UDI (4) no UDI (5) no UDI (6) no UDI (7) no UDI (8) 00812394021413		
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	(9) no UDI (10) no UDI Serial Numbers: See additional information and product list below Model/Catalog Number: G5S-80A UDI-DI: 00812394021277 Serial Numbers: See additional information and product list below		
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For additional information, please visit: [FDA Website \(G5A-00A\)](#), [FDA Website \(G5A-80A\)](#), [FDA Website \(G5A-80C\)](#), [FDA Website \(G5A-01C\)](#), [FDA Website \(G5S-01C\)](#), [FDA Website \(G5S-80C\)](#), [FDA Website \(GFS-00A-TSO\)](#), and [FDA Website \(G5S-80A\)](#).