State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Heartsine Technologies Ltd Recalls Samaritan Public Access Defibrillator For Being Shipped In Test Configuration

Recall Date	Product Description	Recalling Firm	Recall Reason
2/21/2024	**Heartsine Samaritan PAD (Public Access Defibrillator)** Type/Catalog: SAM 350P/350-UNIT-US-10, 350-STR-US-10, 350-STR-UK-10; SAM 360P/360-STR-JA-10, 360-STR-DE-10, 360-STR-UK-10; SAM 450P/450-UNIT-US-08, ; SAM 500P/500-BAS-UK-10	**HEARTSINE TECHNOLOGIES LTD** Belfast, United Kingdom	Automated external defibrillators were shipped in their test configuration so there is a potential to have incorrect language, and CPR duration resulting in the device prompting users to perform CPR for 5-seconds, and it could analyze heart rhythm and instruct users to deliver a shock every 5-seconds if a shock-able heart rhythm is detected, potentially leading to no therapy or delayed therapy.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Heartsine Samaritan Pad (Public Access Defibrillator)** Type/UDI-DI or GTIN/Serial Number: SAM 350P/05060167120671, 05060167127670, +M727SAM350P0/$$+7/17D00023014, 18D00020508, 19D00017655, 20D00006524, 21D91081653, 22D91152391; SAM 360P/05060167127687,	1 Unit in California	February, 2024 and prior

	05060167127311,50601671229 27/21E91049810, 23E90001379, 23E90010409; SAM 450P/05060167129773, +M727SAM450P0/$$+7, +M727SAM450P0/$$+7/17G00 001893, 18G00001553; SAM 500P/05060167122453/22B910 71233		

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