California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Physio-Control, Inc. LIFEPAK 15 V4/Masimo Rainbow Sensors

Recall Date	Product Description	Recalling Firm	Recall Reason
02/19/2025	LIFEPAK 15 V4/Masimo Rainbow Sensors: Masimo¿ RD rainbow Adt 8¿ SpCO, SpO2, and SpMet, Adult Adhesive Sensors REF 11996-000515 Masimo¿ LNCS-II rainbow¿ DCI 8¿ SpCO, Adult Reusable Sensor REF 11996-000519 Masimo¿ LNCS-II rainbow¿ DCI 8¿ SpCO, Pediatric Reusable Sensor REF 11996-000520 The LIFEPAK¿ 15 Monitor/Defibrillator (LP15) is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols. RD rainbow" 8¿ SpCO sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO¿), and methemoglobin saturation (SpMet¿) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-	Physio-Control, Inc.	Due to an error message that prevents users from utilizing carboxyhemoglobin saturation and methemoglobin saturation sensors on their monitor/defibrillator system.

	type facilities, mobile, and home environments.		

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number: 11996-000515 UDI-DI/GTIN code: 00843997010863 Lot Number: 23G79 Catalog Number: 11996-000519 UDI-DI/GTIN code: 00843997015608 Lot Numbers: 23HER 23HPT 23JBN 23JTA Catalog Number: 11996-000520 UDI-DI/GTIN code: 00843997015615 Lot Numbers: 23HNV 23JBP	72 units in California	January and prior

For additional information, please visit the FDA Website.