

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

GE Healthcare Finland Oy TruSignal Sensor for a Potential Reduction of Energy

Recall Date	Product Description	Recalling Firm	Recall Reason
7/12/2023	TruSignal Adult/Pediatric Sensor a) REF TS-AP-10, 10 pcs; b) REF TS-AP-25, 25 pcs	GE Healthcare Finland Oy Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	TruSignal AllFit Sensor a) REF TS-AF-10, 10 pcs; B) REF AF-25, 25 pcs; Oximeter	GE Healthcare Finland Oy Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	TruSignal Sensitive Skin Sensor REF TS-SE-3; Oximeter	GE Healthcare Finland Oy Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	TruSignal Wrap Sensor REF TS-W-D; Oximeter	GE Healthcare Finland Oy Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.

Recall Class	Product Identification	Distribution	Affected Dates
I	TruSignal Adult/Pediatric Sensor a) REF TS-AP-10, GTIN 00840682103220 b) REF TS- AP-25, GTIN 00840682103220	23,537 Units Nationwide	May 2023 and Prior
I	TruSignal AllFit Sensor a) REF TS-AF-10, GTIN 0840682103176 b) REF TS-AF- 25, GTIN 0840682103176	36,337 Units Nationwide	May 2023 and Prior
I	TruSignal Sensitive Skin Sensor GTIN 00840682103282	2,097 Units Nationwide	May 2023 and Prior
I	TruSignal Wrap Sensor GTIN 00840682103121	5,039 Units Nationwide	May 2023 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: <u>www.cdph.ca.gov</u>

