State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Phillips North America Recalls Panorama 1.0T HFO Magnetic Resonance System For Structural Integrity Failure During Excessive Helium Pressure Buildup

Recall Date	Product Description	Recalling Firm	Recall Reason
12/20/2023	**Panorama 1.0t Hfo** Magnetic Resonance (MR) System; Model Numbers 781250 and 781350. Philips Magnetic Resonance (MR) systems are Medical Electrical Systems for use as a diagnostic device.	**Philips North America Llc** Cambridge, Massachusetts	Firm was informed of an event in which the structural integrity of the MR system components failed due to unintended excessive pressure buildup of helium gas during a magnet quench. If the system is unable to contain the pressured helium gas due to an unforeseen blockage in the system, risks to patients and/or operators that may lead to injury or death include chemical exposure (i.e. helium gas) that may expand to surrounding rooms, contusion caused by debris, and asphyxia.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Panorama 1.0t Hfo** All serial numbers	150 Units Nationwide including California	November 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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