



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Philips Ultrasound Recalls 3D9-3v Transducer for Components Disassembling

Recall Date	Product Description	Recalling Firm	Recall Reason
9/13/2023	3D9-3v Transducer Product1 details accessory to Philips Ultrasound Systems: EPIQ Elite; Affiniti 30, 50, and 70; ClearVue 850; HD15; iU22; and Compact 5000	Philips Ultrasound, Inc. Bothell, Washington	Transducer, an ultrasound system accessory, consists of two parts that are bonded together that may come apart due to chassis bonding issue, which may pose risk to users and patients of tissue damage, and electric shock if the built-in safety measures to prevent electric were to also fail.

Recall Class	Product Identification	Distribution	Affected Dates
II	3D9-3v Transducer UDI-DI:00884838061545, Serial Numbers: F07VBZ, F083JP, F086Z5, F088QC, F08JPF, F08K4H, F08VLP, F08VLY, F08W1C, F08W1D ...	449 Units Nationwide including California	30 June, 2023, and prior

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