



CALIFORNIA DEVICE RECALL INFORMATION SHEET

GE Healthcare Recalls MRI Software due to Slicing Error

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	SIGNA Premier 11 devices	GE Healthcare LLC, Waukesha, Wisconsin	Under certain conditions, some slices may be missing which can lead to a gap of anatomy in the 3D Volume images.
10/27/2021	Discovery MR750w 3.0T 13 Devices	GE Healthcare LLC, Waukesha, Wisconsin	Slices missing in 3D Volume images.
10/27/2021	Discovery MR750 3.0T 5 Devices	GE Healthcare LLC, Waukesha, Wisconsin	Slices missing in 3D Volume images.
10/27/2021	SIGNA Architect 2 Devices	GE Healthcare LLC, Waukesha, Wisconsin	Slices missing in 3D Volume images.
10/27/2021	Optima MR450w 1.5T 13 Devices	GE Healthcare LLC, Waukesha, Wisconsin	Slices missing in 3D Volume images.
10/27/2021	SIGNA Voyager 15 Devices	GE Healthcare LLC, Waukesha, Wisconsin	Slices missing in 3D Volume images.

Recall Class	Product Identification	Distribution	Affected Dates
II	SIGNA Premier	6 Devices in California	August 2021 and prior
II	Discovery MR750w 3.0T	3 Devices in California	August 2021 and prior

II	Discovery MR750 3.0T	2 Devices in California	August 2021 and prior
II	SIGNA Architect	1 Devices in California	August 2021 and prior
II	Optima MR450w 1.5T	1 Devices in California	August 2021 and prior
II	SIGNA Voyager	1 Devices in California	August 2021 and prior

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