

## 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 Recalls MRI Software due to Slicing Error

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	SIGNA Premier 11 devices	<b>GE Healthcare LLC,</b> 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	<b>GE Healthcare LLC,</b>	Slices missing in 3D
	13 Devices	Waukesha, Wisconsin	Volume images.
10/27/2021	Discovery MR750 3.0T	<b>GE Healthcare LLC,</b>	Slices missing in 3D
	5 Devices	Waukesha, Wisconsin	Volume images.
10/27/2021	SIGNA Architect 2 Devices	<b>GE Healthcare LLC,</b> Waukesha, Wisconsin	Slices missing in 3D Volume images.
10/27/2021	Optima MR450w 1.5T	<b>GE Healthcare LLC,</b>	Slices missing in 3D
	13 Devices	Waukesha, Wisconsin	Volume images.
10/27/2021	SIGNA Voyager	<b>GE Healthcare LLC,</b>	Slices missing in 3D
	15 Devices	Waukesha, Wisconsin	Volume images.

Recall Class	Product Identification	Distribution	Affected Dates
II	SIGNA Premier	6 Devices in California	August 2021 and prior
11	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

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

