



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Canon Medical System, USA, Inc. Recalls MRI Systems Vantage Titan and Vantage Orian For SFG Maximum Values Being Too Low

Recall Date	Product Description	Recalling Firm	Recall Reason
3/13/2024	MRI System: Vantage Titan Model: MRT-1504	CANON MEDICAL SYSTEM, USA, INC. Tustin, California	This device is being recalled due to some of the maximum Spatial Field Gradient (SFG) values displayed in "System Information" of the operation window and some of the maximum SFG values described in the safety manual being lower than the correct values, potentially causing discomfort for patients with an MR conditional device during the MRI scan.
3/13/2024	MRI System: Vantage Orian Model: MRT-1550	CANON MEDICAL SYSTEM, USA, INC. Tustin, California	This device is being recalled due to some of the maximum Spatial Field Gradient (SFG) values displayed in "System Information" of the operation window and some of the maximum SFG values described in the safety manual being lower than the correct values, potentially causing discomfort for

			patients with an MR conditional device during the MRI scan.
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Recall Class	Product Identification	Distribution	Affected Dates
II	<p>Mri System: Vantage Titan UDI-DI: 04987670102400. Serial Numbers: U4B15Y2102, U5B15Z2001, U4B1492080, U4B1582100, U4B1582099, U4B1522091, U4B1512089, U4B1432067, U4B1522093, U4B1452073, U4B1442069, U4B1442068, U4B1642106, U4B1432066, U4B15X2101, U4B14Y2083, U4B1452071, U4B1512087, U4B1652107, U4B1552097, U4B1482078, U4B1512090, U4B1552098, U4B1442070, U4B14Y2082, U4B1482076, U4B14Z2085, U4B14Z2086, U4B1512088, U4B1612103, U4B1472075, U4B1422065, U4B1462074, U4B14Y2084, U4B1632105, U4B1452072, U4B1492081, U4B1482079, U4B1612104, U4B1482077</p>	2 Units in California California	March, 2024 and prior
II	<p>Mri System: Vantage Orián UDI-DI: 04987670102400. Serial Numbers: U4B15Y2102, U5B15Z2001, U4B1492080, U4B1582100, U4B1582099, U4B1522091, U4B1512089, U4B1432067, U4B1522093, U4B1452073, U4B1442069, U4B1442068, U4B1642106, U4B1432066, U4B15X2101, U4B14Y2083, U4B1452071, U4B1512087, U4B1652107, U4B1552097, U4B1482078, U4B1512090, U4B1552098, U4B1442070, U4B14Y2082, U4B1482076, U4B14Z2085, U4B14Z2086, U4B1512088, U4B1612103, U4B1472075, U4B1422065, U4B1462074,</p>	1 Units in California California	March, 2024 and prior

	U4B14Y2084, U4B1632105, U4B1452072, U4B1492081, U4B1482079, U4B1612104, U4B1482077		
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE [Vantage Titan](#) , [Vantage Orian](#)

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