



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Brainlab recalls ExacTrac Dynamic Software for Incorrect Conebeam CT Positioning

Recall Date	Product Description	Recalling Firm	Recall Reason
2/25/2021	ExacTrac Dynamic Software model numbers: 20910-01, ETD Positioning and Moni. 1.0.0 INST; 20910-01A, ETD Positioning and Moni. 1.0.1 INST; 20910-01B, ETD Positioning and Moni. 1.0.2 INST; and 20910-01C ETD Positioning and Moni. 1.0.3 INST.	Brainlab AG Munich, Germany	The yaw angle may be incorrect for CBCT (conebeam CT) positioning workflows using setup beams with Varian LINACs (Linear Accelerator)

Recall Class	Product Identification	Distribution	Affected Dates
II	Software versions 1.0.0, 1.0.1, 1.0.2, 1.0.3, GTIN 04056481142315	7 Units within California	February 2022 and prior

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