



State of California—Health and Human Services Agency
California Department of Public Health



[Food and Drug Branch – Device Recalls](#)

California Device Recall Information Sheet

Medtronic Navigation, Inc. Recalls O-arm O2 Imaging System

Recall Date	Product Description	Recalling Firm	Recall Reason
6/12/2024	O-Arm O2 Imaging System Mobile x-ray system designed for 2D fluoroscopic and 3D imaging for adult and pediatric patients	MEDTRONIC NAVIGATION, INC. LITTLETON, MA	Potential for an electrical component of the O-arm" O2 Imaging System to intermittently shut off, failure can cause the potential for surgical delay, additional imaging, cancellation and rescheduling of surgery, or completion of surgery without the benefit of image guidance.

Recall Class	Product Identification	Distribution	Affected Dates
II	O-Arm O2 Imaging System UDI-DI 00763000616564	2 Units in California	June 2024 and prior

For additional information, please visit the [FDA website](#).

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