California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Natus Neurology DBA Excel Tech., Ltd. (XLTEK) Recalls OBM00002 OBM DAB (Digital Acquisition Box)

Recall Date	Product Description	Recalling Firm	Recall Reason
6/9/25	Brand Name: OBM00002 OBM DAB (Digital Acquisition Box) Product Name: OBM00002 OBM DAB (Digital Acquisition Box) Model/Catalog Number: OBM00002 OBM DAB (Digital Acquisition Box) Software Version: N/A Product Description: OBM00002 OBM DAB (Digital Acquisition Box) Component: No	Natus Neurology DBA Excel Tech., Ltd. (XLTEK)	Electrode placement labels on the Digital Acquisition Box (DAB) were applied backwards. This may ultimately lead to misdiagnosis of seizure location in neonates monitored with this device.

Recall Class	Product Identification	Distribution	Affected Dates
II	I-DI 00382830010825 Serial Numbers 001 through OBM00002H3613. Note earlier version serial numbers did not contain the sequence of "OBM"	182 Units in California	May 2025 and prior.

For additional information, please visit the FDA Website.