California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fisher & Paykel Healthcare, Ltd. Recalls PT301US Airvo 3 Respiratory Support Device

Recall Date	Product Description	Recalling Firm	Recall Reason
9/25/2024	PT301US Airvo 3 Respiratory Support Device with software version 1.2.0 and/or 1.5.1 The Airvo 3 is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals and sub-acute facilities.	Fisher & Paykel Healthcare, Ltd.	Due to a software issue, affected devices that are set up with High Pressure Oxygen (HPO), if the flow alignment alarm occurs, the device will deliver room air only. If this happens, a patient my experience oxygen desaturation that could lead to hypoxia.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model Number: PT301US UDI-DI code: 09420012466662 Lot/Serial Numbers:	186 Units in California	September 2024 and prior.

For additional information, please visit the FDA Website.