



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



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

**Philips Respironics Recalls Trilogy Series Ventilators For
 Potential Underdelivery Of Oxygen**

Recall Date	Product Description	Recalling Firm	Recall Reason
4/12/2023	Trilogy Evo O2 And Lifeventevo2 Portable Electric Ventilator Model Numbers DS2100X11B, IN2100X15B, IN2100X19, FX2100X15B, JP2100X16B, AU2100X15B, LA2100X15B, CA2100X12B, CN2100X17B, BR2100X18B, KR2100X15B, IA2100X15B, PP2100X10, FP2100X10, FR2100X14B, ND2100X15B, IT2100X21B, ES2100X15B, DE2100X13B, BL2100X15B, GB2100X15B, EU2100X15B, EU2100X19, EE2100X15B, TR2100X15B, UDS2100X11B, RDS2100X11B, and SP2100X26B	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	The accuracy of delivered oxygen may deviate below the required tolerance of 5% from setpoint when providing high concentration oxygen therapy. Additionally, if equipped, the internal FiO2 sensor may indicate a value higher than the device is actually delivering. This may lead to under delivery of oxygen.
4/12/2023	Trilogy Ev300 Portable Electric Ventilator Model Numbers DS2200X11B, IN2200X15B, FX2200X15B, CA2200X12B, CN2200X17B, BR2200X18B, KR2200X15B, IA2200X15B, FR2200X14B, ND2200X15B, IT2200X21B, ES2200X15B, DE2200X13B, BL2200X15B, GB2200X15B, EU2200X15B, EU2200X19, EE2200X15B, TR2200X15B, RU2200X15B	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	The accuracy of delivered oxygen may deviate below the required tolerance
4/12/2023	Trilogy Evo Universal Portable Electric Ventilator Model Number DS2000X11B	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	The accuracy of delivered oxygen may deviate below the required tolerance

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Trilogy Evo O2 And Lifeventevo2 Portable Electric Ventilator</p> <p>UDI-DI: 606959051997, 606959054059, 606959055575, 606959061019, 606959055599, 606959055636, 606959062085, 606959055643, 606959055650, 606959055438, 606959054097, 606959054103, 606959055674, 606959055681, 606959055698. UDI-DI, Model Number: Serial numbers. 606959054103, DE2100X13B: H236054270DD5 - H800189696A38</p>	62826 Units Nationwide	March 2023 and Prior
I	<p>Trilogy Ev300 Portable Electric Ventilator</p> <p>UDI-DI: 606959052017, 606959056497, 606959061033, 606959052321, 606959058613, 606959058620, 606959058644, 606959058668, 606959058675, 606959058682, 606959058705, 606959058798, 606959052000. UDI-DI, Model number: Serial numbers 606959052017, DS2200X11B: H27990931E388 - H32724965A6AA. Model number RU2200X15B, no serial numbers provided.</p>	62826 Units Nationwide	March 2023 and Prior
I	<p>Trilogy Evo Universal Portable Electric Ventilator</p> <p>Model number: DS2000X11B, UDI-DI: 606959052000. Serial Numbers: H27736231F4BE -</p>	62826 Units Nationwide	March 2023 and Prior

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