

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

#### Philips Respironics, Inc. Trilogy Evo Universal Ventilator

| Recall Date | Product Description                                                                                                                                                                                             | Recalling Firm            | Recall Reason                                                                                                                                                                                        |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11/13/2024  | Trilogy Evo Universal Ventilator. Intended for invasive and non-invasive ventilation of pediatric through adult patients weighing at least 2.5 kg in institutional, home, and non-emergency transport settings. | Philips Respironics, Inc. | Potential for in-line nebulizer configuration in certain locations to result in aerosol deposit accumulation on the device's internal flow sensor, which could lead to inaccurate flow measurements. |

| Recall Class | Product Identification                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Distribution                       | Affected Dates         |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------|
| I            | UDI-DI Number: 606959052000.<br>Model No. AU2110X15B, BL2110X15B, BL2200X15B, BR2110X18B, BR2200X18B, CA2110X12B, CA2200X12B, DE2100X13B, DE2110X13B, DE2200X13B, DS2000X11B, DS2100X11B, DS2110X11B, DS2200X11B, EE2100X15B, EE2110X15B, EE2200X15B, ES2100X15B, ES2110X15B, ES2200X15B, EU2100X15B, EU2100X19, EU2110X15B, EU2110X19, EU2200X15B, FP2100X10, FP2110X10, FR2100X14B, FR2110X14B, FR2200X14B, FX2100X15B, FX2200X15B, GB2110X15B, GB2200X15B, IA2100X15B, IA2110X15B, IA2200X15B, | 9,999 units Worldwide including CA | October 2024 and Prior |

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| IN2100X15B, IN2100X19,<br>IN2110X15B, IN2200X15B,<br>IT2100X21B, IT2110X21B,<br>IT2200X21B, JP2100X16B,<br>JP2110X16B, KR2110X15B,<br>KR2200X15B, LA2100X15B,<br>LA2110X15B, LD2110X23B,<br>ND2100X15B, ND2110X15B,<br>ND2200X15B, PP2110X10,<br>RDS2110X11B, SP2100X26B,<br>TR2110X15B, TR2200X15B,<br>UDS2110X11B, VT2110X24B;<br>UDI-DI: 606959051942,<br>606959051959, 606959051973,<br>606959051980, 606959051997,<br>606959052000, 606959052017,<br>606959052307, 606959052321,<br>606959054059, 606959054080,<br>606959054097, 606959054103,<br>606959054110, 606959054127,<br>606959054981, 606959055421,<br>606959055438, 606959055452,<br>606959055476, 606959055483,<br>606959055490, 606959055506,<br>606959055513, 606959055520,<br>606959055537, 606959055544,<br>606959055551, 606959055575,<br>606959055582, 606959055599,<br>606959055636, 606959055643,<br>606959055650, 606959055674,<br>606959055681, 606959055698,<br>606959056497, 606959057432,<br>606959057456, 606959058583,<br>606959058590, 606959058613,<br>606959058620, 606959058637,<br>606959058644, 606959058651,<br>606959058668, 606959058675,<br>606959058682, 606959058705,<br>606959058798, 606959060500,<br>606959060517, 606959061019,<br>606959061033, 606959062962; All<br>Serial No. |  |  |
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For additional information, please visit the [FDA Website](#).