



California Device Recall Information Sheet

Philips Respironics Inc. Recalls Ventilator Software For Issue With Power Alarm Resulting In Potential Loss Of Ventilation

Recall Date	Product Description	Recalling Firm	Recall Reason
4/24/2024	Aeris Evo All software versions except 1.05.06.00. Ventilator for pediatric and adult patients. (sold outside US)	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
4/24/2024	Garbin Evo All software versions except 1.05.06.00. Ventilator for pediatric and adult patients. (sold outside US)	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
4/24/2024	Lifeventevo2 All software versions except 1.05.06.00. Ventilator for pediatric and adult patients. (sold outside US)	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
4/24/2024	Trilogy Ev300 all software versions except 1.05.06.00. Ventilator for pediatric and adult patients.	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.

4/24/2024	Trilogy Evo O2 all software versions except 1.05.06.00. Ventilator for pediatric and adult patients.	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
4/24/2024	Trilogy Evo all software versions except 1.05.06.00. Ventilator for pediatric and adult patients.	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
4/24/2024	Trilogy Evo Universal Ventilator All software versions except 1.05.06.00. Ventilator for pediatric and adult patients.	PHILIPS RESPIRONICS, INC. Murrysville, Pennsylvania	Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.

Recall Class	Product Identification	Distribution	Affected Dates
I	Aeris EVO Model No. VT2110X24B, UDI-DI: 606959062962; Serial No. H31910535835D to H32365121602B. See attached link for complete serial numbers.	775 Units Worldwide	March, 2024 and prior
I	Garbin EVO Model No. LD2110X23B, UDI-DI: 606959057432; Serial No. H252356907DD7 to H2981481031AB. See attached link for complete serial numbers.	1233 Units Worldwide	March, 2024 and prior
I	LifeVentEVO2 Model No. SP2100X26B, UDI-DI: 606959057456; Serial No. H25691987749F to H80018499168F. See attached link for complete serial numbers.	1002 Units Worldwide	March, 2024 and prior

I	<p>Trilogy EV300 Model No. BL2200X15B, BR2200X18B, CA2200X12B, EE2200X15B, EU2100X15B, EU2100X19, EU2200X15B, FR2200X14B, DE2200X13B, GB2200X15B, FX2100X15B, FX2200X15B, IN2100X15B, IN2100X19, IN2200X15B, IT2200X21B, JP2100X16B, KR2200X15B, LA2100X15B, ND2200X15B, ES2200X15B, TR2200X15B, DS2100X11B, DS2200X11B, UDI-DI: 606959058668 to 606959052017; All units except those with software version 1.05.06.00. See attached link for complete UDI numbers.</p>	56012 Units Worldwide	March, 2024 and prior
I	<p>Trilogy Evo O2 Model No. EE2100X15B, FR2100X14B, DE2100X13B, ES2100X15B, IA2100X15B, IT2100X21B, ND2100X15B; UDI-DI: 606959055698, 606959055643, 606959054103, 606959054097, 606959055636, 606959055438, 606959055650; Serial No. H800104584B7E to H26375405C98F. See attached link for complete serial numbers.</p>	789 Units Worldwide	March, 2024 and prior
I	<p>Trilogy Evo 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, FR2100X14B, FR2110X14B, FR2200X14B, FX2100X15B, FX2200X15B, GB2110X15B, GB2200X15B, IA2100X15B,</p>	76713 Units Worldwide	March, 2024 and prior

	<p>IA2110X15B, IN2100X15B, IN2100X19, IN2110X15B, IN2200X15B, IT2100X21B, IT2110X21B, IT2200X21B, JP2100X16B, JP2110X16B, KR2110X15B, KR2200X15B, LA2100X15B, LA2110X15B, LD2110X23B, ND2100X15B, ND2110X15B, ND2200X15B, RDS2110X11B, SP2100X26B, TR2110X15B, TR2200X15B, UDS2110X11B, VT2110X24B; UDI-DI: 606959051980 to 606959060500; All units except those with software version 1.05.06.00. See attached link for complete UDI numbers.</p>		
I	<p>Trilogy Evo Universal Ventilator Model No. DS2000X11B; UDI-DI: 606959052000; All units except those with software version 1.05.06.00.</p>	9999 Units Worldwide	March, 2024 and prior

For additional information, please visit the FDA website [Aeris EVO](#), [Garbin EVO](#), [LiveVentEVO2](#), [Trilogy EV300](#), [Trilogy Evo O2](#), [Trilogy Evo](#), [Trilogy EVO Universal](#)

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

