State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Resmed Ltd. Recalls Astral 100 And Astral 150 Ventilators For Sudden Power Loss

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	**Astral 100 And Astral 150 Ventilators**	**RESMED LTD.** Bella Vista, Austrailia	If ventilator is on internal battery, not intended to serve as a primary power source, low/critically low battery alarms will sound, but a fault leads to sudden power loss. If power fails, then ventilation stops and a Total Power Failure (TPF) alarm should sound, but it's powered by a supercapacitor, which degrades over time, which may cause TPF alarm to sound for less than 2 minutes or not at all

Recall Class	Product Identification	Distribution	Affected Dates
I	**Astral 100 And Astral 150 Ventilators** All devices manufactured between 2013 and 2019 Astral 100, UDI: 00619498003259 Astral 150, UDI: 00619498003266	16634 Units Nationwide including California	13 September 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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