State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Phillips Respironics CPAP, BiPAP, and Ventilator Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
06/14/2021	**Continuous Ventilator, Minimum Ventilatory Support, Facility Use** **E30** Emergency Use Authorization **A-Series BiPAP V30** Auto Ventilator **Trilogy 100, 200** All serial numbers Manufactured before 4/26/21	**Phillips Respironics,** Murraysville, PA	Sound Abatement Foam (PE-PUR) susceptible to degradation and particle release, exacerbated by ozone cleaning.
06/14/2021	**Continuous Ventilator, Non-life Supporting** **DreamStation ASV** BiPAP autoSV **DreamStation ST, AVAPS** **SystemOne ASV4** BiPAP autoSV, BiPAP autoSV Advanced **C-Series ASV** **C-Series S/T and AVAPS** **OmniLab** All serial numbers Manufactured before 4/26/21	**Phillips Respironics,** Murraysville, PA	Sound Abatement Foam (PE-PUR) susceptible to degradation and particle release, exacerbated by ozone cleaning.
06/14/2021	**Noncontinuous Ventilator** **SystemOne (50,60-Series)**CPAP, Auto CPAP, BiPAP **DreamStation** CPAP, Auto CPAP, BiPAP **DreamStation Go** CPAP, APAP, Auto CPAP All serial numbers Manufactured before 4/26/21	**Phillips Respironics,** Murraysville, PA	Sound Abatement Foam (PE-PUR) susceptible to degradation and particle release, exacerbated by ozone cleaning.

Recall Class	Product Identification	Distribution	Affected Dates
I	Dreamstation series All serial numbers	Nationwide, including California	April 26, 2021 and earlier
Voluntary	E30, A-Series, Trilogy, OmniLab, C-Series, SystemOne All Serial Numbers	Nationwide, including California	April 26, 2021 and earlier

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE PHILLIPS WEBSITE or FDA

FOR DREAMSTATION 1 REMEDIATED DEVICES PLEASE VISIT MANUFACTURER PAGE