IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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TO: Hospitals
Healthcare Providers

FROM: Office of Preparedness and Response

Re: **URGENT** – Medical Device Recall

Date: June 29, 2021

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators. The PR-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user and the PE-PUR foam my off-gas certain chemicals. The foam degradation may also be exacerbated by use of unapproved cleaning methods. These issues can result serious injury which can be life threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Further details are provided in the attached recall notice and additional information regarding immediate actions to be taken by the User can be found here.