TRINIDAD NAVARRO
COMMISSIONER

STATE OF DELAWARE DEPARTMENT
OF INSURANCE

DOMESTIC & FOREIGN BULLETIN NO. 126

TO: **ALL DOMESTIC AND FOREIGN INSURERS WRITING HEALTH INSURANCE IN DELAWARE**

RE: **PHILIPS SLEEP & RESPIRATORY CARE PRODUCTS RECALL**

DATED: **August 2, 2021**

The purpose of this bulletin is to:

- Inform health insurance carriers of a recall of certain Philips sleep & respiratory care products; and
- Strongly encourage carriers to work closely with their insureds concerning coverage for replacement machines.

On June 14, 2021, Philips issued a recall notification for specific Philips Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (Bi-Level PAP) devices, and Mechanical Ventilators, due to potential adverse health risks related to exposure to degraded sound abatement foam used in these devises. The affected devises are tabulated on the next page of this bulletin.

The Department is aware that most health insurance plans do not cover the cost of replacement of devises that are less than five years old. However, the Department strongly encourages health insurance carriers to make an exception to cover the replacement of these life-saving devises.

Philips advises that the possible health risks if recalled devises remain in use include exposure to degraded sound abatement foam and exposure to chemical emissions from the foam material.

For more information, visit the Philips website at Philips.com/SRC-update. Questions concerning this Bulletin should be emailed to: consumer@delaware.gov.

This Bulletin shall be effective immediately and shall remain in effect unless withdrawn or superseded by subsequent law, regulations, or bulletin.

Trinidad Navarro
Delaware Insurance Commissioner

NOTE: This Bulletin is intended solely for informational purposes. It is not intended to set forth legal rights, duties, or privileges, nor is it intended to provide legal advice. Readers should consult applicable statutes and rules and contact the Delaware Department of Insurance if additional information is needed.

TABLE OF DEVISES PER PHILIPS' FAQ SHEET

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<tr><th colspan="2">Products Affected by Recall</th><th>Products NOT affected by Recall</th></tr>
<tr><td colspan="2">CPAP and BiLevel PAP Devices
(All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers)</td><td rowspan="3">Trilogy Evo
Trilogy Evo OBM
Trilogy EV300
Trilogy 202
A-Series Pro and EFL
M-Series
DreamStation 2
Omnilab (original based on Harmony 2)
Dorma 100, Dorma 200, & REMStar SE
V60 Ventilator
V60 Plus Ventilator
V680 Ventilator
All oxygen concentrators, respiratory drug delivery products, airway clearance products.</td></tr>
<tr><td>Continuous Ventilator, Minimum Ventilatory Support, Facility Use

Continuous Ventilator, Non-life Supporting

Noncontinuous Ventilator</td><td>E30 (Emergency Use Authorization)

DreamStation ASV
DreamStation ST, AVAPS
SystemOne ASV4
C-Series ASV
C-Series S/T and AVAPS
OmniLab Advanced+

SystemOne (Q-Series)
DreamStation
DreamStation Go
Dorma 400 Dorma 500
REMstar SE Auto</td></tr>
<tr><td colspan="2">Mechanical Ventilators
(All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers)</td></tr>
<tr><td>Continuous Ventilator

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

Continuous Ventilator, Non-life Supporting</td><td>Trilogy 100
Trilogy 200
Garbin Plus, Aeris, LifeVent

A-Series BiPAP Hybrid A30 (not marketed in the US)
A-Series BiPAP V30 Auto

A-Series BiPAP A40 (not marketed in the US)
A-Series BiPAP A30 (not marketed in the US)</td><td></td></tr>
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