



Impact of the Philips PAP Recall on Patient Care and Sleep Center Operations

June 18, 2021

American Academy of Sleep Medicine

American Academy of Neurology

American College of Chest Physicians

American Thoracic Society

Canadian Sleep Society/Canadian Thoracic Society



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Background

- On June 14, 2021, Philips initiated a voluntary recall notification in the United States for specific models of continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), and mechanical ventilator devices, stating that the recall is to “ensure patient safety in consultation with regulatory agencies.”
- The recall is to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound-abatement foam used in these devices.
- Foam degradation may happen over time; process seems to be accelerated by high heat/high humidity environments and use of ozone-based cleaning systems.

CPAP and BiLevel PAP Devices

All Affected Devices Manufactured Before 26 April 2021, All Device 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, S/T, AVAPS



OmniLab Advanced
Plus
In-Lab Titration Device

Non-continuous Ventilator



SystemOne
(Q series)



DreamStation
CPAP, Auto CPAP, BiPAP



DreamStation GO
CPAP, APAP



Dorma 400, 500
CPAP



REMStar SE Auto
CPAP

Mechanical Ventilators

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers

Continuous Ventilator



Trilogy 100
Ventilator



Trilogy 200
Ventilator



Garbin Plus, Aeris,
LifeVent
Ventilator

Continuous Ventilator, Minimum Ventilatory Support, Facility Use



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



A-Series BiPAP V30
Auto
Ventilator

What products are not affected and why?

Products that are not affected may have different sound abatement foam materials, as new materials and technologies are available over time. Also, sound abatement foam in unaffected devices may be placed in a different location due to device design.

Products not affected by this recall notification (U.S. only) / field safety notice (International Markets) include:

- Trilogy Evo
- Trilogy Evo OBM
- Trilogy EV300
- Trilogy 202
- BiPAP A40 EFL
- BiPAP A40 Pro
- M-Series
- DreamStation 2
- Omnilab (original based on Harmony 2)
- Dorma 100, Dorma 200, & REMStar SE
- All oxygen concentrators, respiratory drug delivery products, airway clearance products.

The recall notification (U.S. only) / field safety notice (International Markets) advises patients and customers to take the following actions:

For patients using life-sustaining mechanical ventilator devices:

- **Do not stop or alter your prescribed therapy until you have talked to your physician.** Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.
- If your physician determines that you must continue using this device, use an inline bacterial filter. Consult your Instructions for Use for guidance on installation.

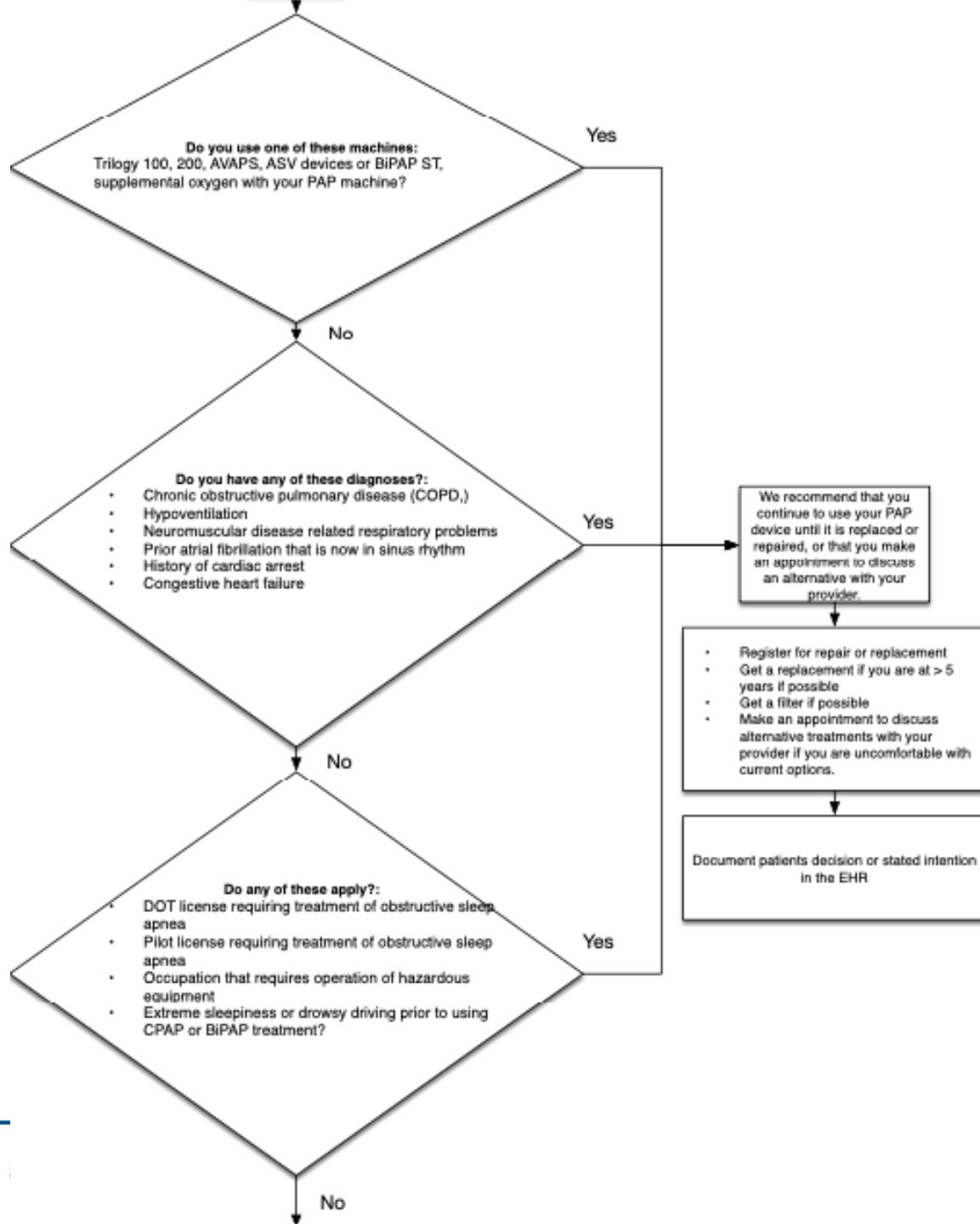
For patients using BiLevel PAP and CPAP devices:

- **Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.**

Notes from Philips re: Foam Degradation

- Absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
 - Toluene Diamine
 - Toluene Diisocyanate
 - Diethylene glycol
- To date, no reports of death as a result of these issues.
- Risk of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.
- The potential risks of chemical exposure due to off-gassing (VOCs) include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects.

<https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf>



How has your center adjusted to this recall?

- Contacting patients?
 - Personnel burden?
 - Using standardized language such as smart phrases?
 - Electronic communications?
 - Appointments?
- Implementing decision trees?
 - Which patients? Safety sensitive; comorbid; severity
- Lab operations if units affected?
 - Cancel or delay PAP studies?

What advice are you providing patients?

How are DME companies in your area coping?

- Communications
- Antibacterial filter requests?
- Requests to change machine?

Communications with referring providers?

Are your centers engaged in PAP research?
If so, how is this affecting things?

Besides manufacturer repair/replace, what is most needed right now?

- How can we best support our patients during this recall?

Questions?

- Email: recall@aasm.org
- AASM Engage: engage.aasm.org
 - Members Forum
 - AASM members can join the discussion!