Impact of the Philips PAP Recall on Vulnerable Populations
JUNE 25 @ 3:00 PM - 4:00 PM EDT

Multi-Society Discussion Group
American Academy of Sleep Medicine
American Academy of Neurology
American Thoracic Society
American College of Chest Physicians
Canadian Thoracic Society
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 ASV, S/T, AVAPS
- C Series ASV
- REMStar SE Auto CPAP
- SystemOne (Q series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation GO CPAP, APAP
- Dorma 400, 500 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
- OmniLab Advanced Plus
  In-Lab Titration Device
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.**
Thinking about allocation of resources, how can we approach vent-dependent patients such as those with NMD?
Triaging respiratory assist devices and home ventilators in patients with chronic respiratory failure

***Discuss with your local DME providers on inventory, availability of Evo and non-Philips ventilators and RADs***

Does your patient use one of these respiratory devices?
- Dream Station BiPAP ST (RAD)
- Dream Station BiPAP AVAPS (RAD)
- Trilogy 100 / 200 (Ventilator)

Do your patients have one of the following medical conditions?
- Chronic Respiratory Failure
- Neuromuscular Disease or Chest Wall Restriction
- Hypercapnic COPD
- Obesity Hypoventilation Syndrome
- *Tracheostomy with invasive mechanical ventilation support*

**YES**

DO NOT stop treatment

- Trilogy 100/200 - add in-line HEPA/bacterial filter
- BiPAP/RAD – add in-line filter if integrated humidifier is not used

**NO**

Discuss options with patient
Re-evaluate diagnosis and necessity for home mechanical ventilation support

Is your patient on Care Orchestrator?
Obtain recent download report from device (~30 days)

- Analyze report
- Determine hours of usage, dependence
- Determine mode and pressure requirement

Triage dependence on NIV (Trilogy or BiPAP)
Request DME provider to prioritize patients with tracheostomy and those with highest usage

*Tracheostomy - use a non-Philips ventilator, including older ventilator models (e.g. LTV) if needed

**Trilogy 100/200**
- >10-12 hours usage, or advanced/rapidly progressive disease (e.g. ALS) – switch to Philips Evo or non-Philips ventilator
- <10-12 hours usage – consider switch to ResMed RAD (e.g. Aircurve 10 ST/ST-A)

**BIPAP/RAD**
- >10-12 hours, or advanced/rapidly progressive disease – consider switch to Evo or non-Philips ventilator
- <10-12 hours – consider switch to ResMed RAD
How is this similar/different than concerns facing practices early in the pandemic?
What about transitioning vent-dependent patients from hospital to home?

…and from home to hospital?
## Hospital Questions

### Acute Care to Homecare for Respiratory Failure

#### OHV

- **Acute Care** –
  - OK to use device bilevel with filter in house
- **Send them home** –
  - Send home on NIV
  - ENCOURAGE – system wide plans to assure devices for new starts
  - ENCOURAGE - PSG titration at 3 months to see if you can back down therapy to CPAP

#### NMD

- **Acute Care** –
  - OK to use device bilevel with filter in house
- **Send them home** –
  - Send home on NIV
  - ENCOURAGE – system wide plans to assure devices for new start
  - Include local ALS and MDA programs
  - AVOID the use of two devices – only in response to the crisis
Hospital Questions

Sleep apnea – medical admission

• Allow pt’s to use their own devices
• Fight the use of oxygen in lieu of CPAP

NIV Chronic on Home equipment

• Allow pt’s to use their own devices
• OK to use device on recall with filter – The risk benefit is high in stopping therapy
  A) may need a triggering adjustment

Trach / Vent – Chronic on Home equipment

• Allow pts to use their own devices
• Get old devices out of moth balls – LTV’s, transport vents and MRI vents
What about other conditions requiring ventilatory support, such as COPD and OHS?
Respiratory therapy in hospitals – how are you navigating hospital needs due to the recall of the A/ V-Series facility–based devices?
Hospital Questions

Why V 30

• This device may be the most challenging to replace. There are very limited choices if you need a device that has both ALL available modes and the ability to interface with monitoring systems.
• The devices can be extended with filters – but this is an imperfect solution.
• Alternatives:
  A) Respironics / The V60 and Trilogy 202 are not on the recall- limited modes
  B) Breas / The Vivo’s have nurse call systems – with cable or blue tooth- limited modes
  C) ResMed / The Lumis TX has all modes but no call system.
  D) Consider using pulse ox as an alternative to monitoring the PAP device

Peri- Op Sleep Apnea

• Use of CPAP for naïve pt’s is over rated
• Alternatives:
  A) Allow pt’s to use their own devices
  B) Consider using high flow on RA
  C) Consider monitoring pulse ox only
     – Position changes may help these pt’s – elevated HOB as well as side sleeping
What are some of the unique issues facing pediatrics, and how should approaches be adjusted to take these into account?
Does the child have any of these diagnosis/comorbidities?

- Neuromuscular disorder with hypoventilation
- CSA or Hypoventilation Disorder (e.g. CCHS, ROHHAD, Rett syndrome, Prader-Willi Syndrome, Chiari Malformation)
- Chronic Lung Disease with chronic respiratory failure
- Cardiovascular disease and/or Pulmonary Hypertension requiring PAP therapy
- Severe Upper Airway Obstruction with gas exchange abnormalities

Yes

Suggest to continue using PAP device until it is replaced or repaired, or make an appointment to discuss alternative treatment options with child and family

No

Does child have significant daytime dysfunction related to untreated sleep disordered breathing?

Yes

- Register for repair or replacement
- Get a replacement device if device is > 5 years old
- Assess routine cleaning regimen at home with recommendation to discontinue any ozone based cleaning or other nonapproved sanitizing methods
- For ventilator devices (e.g. Trilogy), consider inline bacterial filter to mitigate risks related to solid foam debris. Of note, filters are not thought to be effective against volatile organic compounds.

No

- Suggest to discontinue device
- Register for repair or replacement
- Get a replacement device if device is > 5 years old
- Discuss alternative treatments with child/family if they are uncomfortable with current options
- Offer a school note to family/child about PAP therapy suspension

- Document patients decision or stated intention in medical chart or EHR
Research trials – how have you approached ethically navigating the recall for those enrolled in clinical trials?

- Are these AEs/UPs if no participants have reported symptoms?
- Notifying participants, IRB, and DSMB
- What are the risks of stopping therapy in at-risk participants?
- Pausing randomization of new participants
- Trials that are PAP adherence interventions: is following the instructions to stop using actually demonstrating good adherence?
Allocation of limited supplies – how can we approach prioritizing the most urgent need the limited supply of devices for patients needing them?
Questions?

• Email: recall@aasm.org

• AASM Engage: engage.aasm.org
  – Members Forum
    • AASM members can join the discussion!