Philips Respironics PAP Devices Recall: An Update

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- Conflict of Interest: None

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Philips Respironics PAP Devices Recall: An Update Objectives

Discuss the rationale and type of PAP devices recalled

Review the FDA Guideline for the recall

Approach to managing patients on PAP

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Safety Recall from Philips: June 14,2021

- **April 26, 2021:** Philips advised of potential health risk related to polyester-based polyurethane (PE-PUR) sound abatement foam used to dampen device vibration and sound during routine operation
- Analysis of **potential health** risks was ongoing:
  - **Particles** from degraded foam
  - **Chemical emissions** from degraded foam
- Limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection may have been associated with foam
- No reports of life-threatening injury or death due to this issue
- **June 14, 2021:** Philips decided to issue a recall for all the PAP devices that had this foam

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Potential Hazards from Foam Degradation

- **Degraded foam particles** may enter the devices air pathway and be **Ingested or inhaled**

  Environmental factors that may contribute to foam degradation

  High temperatures and humidity in certain regions

  Use of unauthorized cleaning methods such as ozone-based cleaning devices may accelerate potential degradation

- **Volatile Organic Compounds (VOC):**

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Potential Hazards from Foam Degradation

- **Volatile Organic Compounds (VOC): Two compounds outside safety threshold**

  Dimethyl Diazine

  Phenol, 2,6-bis(1,1-methylethyl)-4-(1-methylpropyl)-

VOCs may cause both short-term and long-term effects

Short-term exposure- irritation and inflammation of airways may impact patients with underlying lung disease

Chemical exposure due to off-gassing may include headaches/dizziness, irritation of eyes, nose airway and skin, hypersensitivity, nausea/vomiting, toxic and carcinogenic effects

To date Philips has not received any reports of patient harm resulting from chemical emissions

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Safety Recall from Philips: June 30, 2021

- **Bilevel PAP and CPAP Devices:**
  Discontinue the use of all the affected devices and consult with your physician to make further decision

- **Life-Sustaining Devices Trilogy 100, 200**
  Continue with treatment and consult with physician

All Devices: Register at the website: Philips.com/src-update
1 877 907 7508

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Philips Respironics Recalled Products

- **Continuous Ventilator:** Trilogy 100, Trilogy 200 Garbin plus, Aeris, Lifevent
- **Continuous Ventilator, Minimum Ventilator Support:**
  Facility use E 30 with Humidifier
- **Continuous Ventilator, Non-Life Supporting Devices:**
  Dream Station ASV, ST, AVAPS, System One ASV 4, C-Series A
  C-series S/T and AVAPS, Omni Lab Advanced+
- **Noncontinuous Ventilators:**
  System One(Q-Series), Dream Station, Dream Station Go, Dorma 400 and Dorma 500, and REM Star SE Auto

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FDA Urgent Medical Device Recall Notice: July 22, 2021

- **Class I recall-** the most serious type of recall
- Identified more than 1200 complaints and more than 100 injuries
- **Identified Who may be affected:**
  - People using these devices
  - Health care providers
  - DME and sleep laboratories

Guidelines: Stop using your device

- Consider another similar device from a different manufacturer
- Consider alternative treatments such as OMD, positional therapy

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Impact of Recall on DME Providers: Frequently Asked Questions

- Medicare beneficiary's adherence metrics in the first 90 days
- Adherence metrics if they receive a new PAP device within 90 days
- Temporary replacement must be provided if billing is continued.
- Billing must be stopped if patient wishes to return and wait for a new machine – capped rental duration will be accommodated
- Billing a rental unit under HCPCS code K0462 (TEMPORARY REPLACEMENT FOR PATIENT OWNED EQUIPENT BEING REPAIRED, ANY TYPE) is allowed

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FDA: Potential Risks Associated with Use of Ozone and UV Light Products for Cleaning CPAP: 2/27/2020

- **Ozone (O3)** also considered as **" activated oxygen"** can kill harmful bacteria

➢ Ozone effectiveness, however, is dependent on higher levels of ozone concentration

➢ Ozone can be an irritant: cough, SOB, nasal congestion

➢ **Ozone leaks** can take place at the multiple connection sites and **residual ozone** may remain in the CPAP machine and tubing

Use of Ultraviolet Light: Not as effective as ozone cleaners

➢ Exposure to UV light **harmful effects** on skin/eye and skin cancer risk

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Philips Respironics: Supplemental Clinical Information for not using the Bacterial Filters

- Filters are designed as bacterial and small particle filters for the **main line outlet** on **Trilogy devices used for invasive therapy** and need to be monitored
- **Do not** provide protection from **chemical emissions**
- Bacterial filters need to be **replaced periodically**
- Bacterial filters change the **resistance of the circuit**, negatively impacting the max airflow, dynamic and static airway pressure
- Auto CPAP and other advanced PAP devices algorithms that rely on **pressure sensing sensors** may not work
- Humidification on the CPAP/BiPAP machines will have **negative impact** on the filter performance

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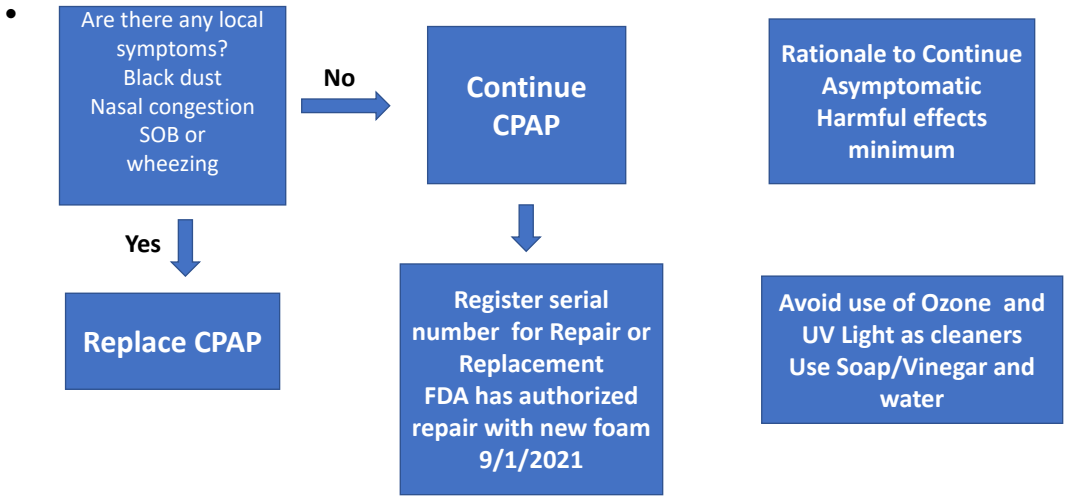
Clinical Approach to Managing Patients on PAP



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