Philips Respironics Recall 2021

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

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• June 14, 2021

- Philips issued a RECALL of specific Philips Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators
- Reason: potential health risks related to polyester-based polyurethane (PE-PUR) sound abatement foam used to dampen device vibration and sound during routine operation.
- Details available at:

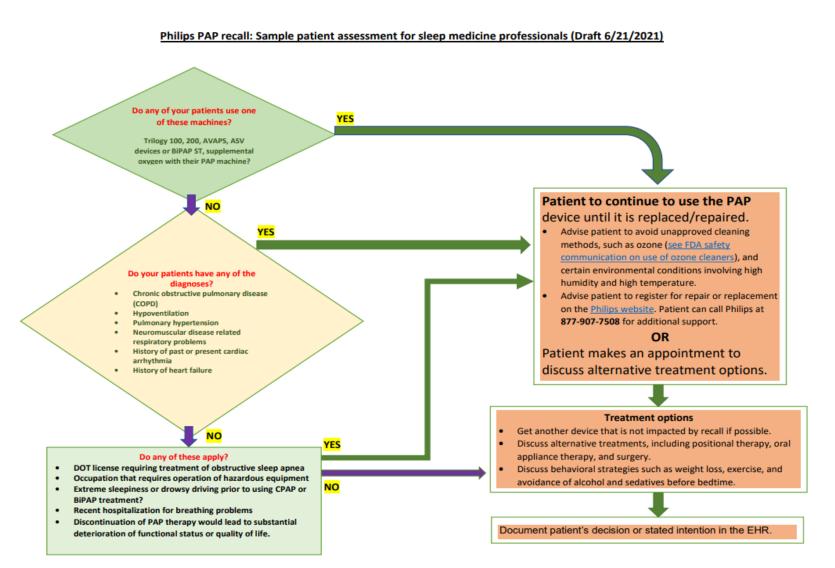
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What Happens Next:

- Philips is in charge of replacing/repairing affected units
 - Patients should register their device on the Philips website or call Philips
- We have shared a letter advising patients of this recall
- Patients can also get more info and contact their provider via: <u>www.mountsinai.org/cpaprecall</u>
- We are meeting with Philips for ongoing updates and will share more info once available
- <u>Providers will need to discuss options with patients and analyze risks of discontinuing therapy versus continuation of treatment until repair or replacement is available (see guidance on next slide)</u>

AASM Recommendations for Providers

(American Academy of Sleep Medicine) Shared Decision Making Process



 Patients should also be advised to stop using ozone or UV based cleaners (such as SoClean)

• Additional Resources:

- Press Release: <u>FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize</u> <u>CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized</u>
- Consumer Update: <u>Continuous Positive Airway Pressure (CPAP) Machine Cleaning</u>
- Consumer Update Video: <u>Watch This Before You Consider Using Ozone Gas or UV Light</u> <u>CPAP Cleaning Devices External Link Disclaimer</u>
- <u>Ozone Overview</u> The National Institute for Occupational Safety and Health (NIOSH)
- Ozone Generators that are Sold as Air Cleaners United States Environmental Protection Agency (EPA)
- <u>UV Radiation</u> The Centers for Disease Control and Prevention (CDC)
- <u>https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/</u>
- <u>https://www.thoracic.org/patients/patient-resources/recommendations-for-sleep-and-critical-care-medicine-professionals-regarding-philips-recall-notice.php</u>