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: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update
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: www.mountsinai.org/cpaprecall
• We are meeting with Philips for ongoing updates and will share more info once available

• 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)
Patients should also be advised to stop using ozone or UV based cleaners (such as SoClean).
• **Additional Resources:**

- Press Release: [FDA Reminds Patients that Devices Claiming to Clean, Disinfect or Sanitize CPAP Machines Using Ozone Gas or UV Light Have Not Been FDA Authorized](https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/)
- Consumer Update Video: Watch This Before You Consider Using Ozone Gas or UV Light CPAP Cleaning Devices External Link Disclaimer
- **Ozone Overview** – The National Institute for Occupational Safety and Health (NIOSH)
- **Ozone Generators that are Sold as Air Cleaners** – United States Environmental Protection Agency (EPA)
- **UV Radiation** – The Centers for Disease Control and Prevention (CDC)
- [https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/](https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/)