

Patient Safety Advisory



Philips Respironics Voluntary Recall and FDA Safety Communication: Guidance for Patients and Providers/Care Teams

(Addendum to MHS Patient Safety Advisory 21-016*)

Philips Respironics Issues Recall Related to Sound Abatement Foam Component in Certain Sleep and Respiratory Care Devices

Philips Respironics announced a worldwide voluntary recall for certain BiLevel Positive Airway Pressure (BiLevel PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices due to reports of exposure to off-gas, fine dust and particles resulting from the breakdown of the foam used to reduce sound and vibration. Foam pads have been approved for the purpose of sound abatement in ventilators for over a decade. Off-gassing refers to chemicals released in vapor form in newly manufactured devices when opened (i.e., the smell one may notice when opening a new product that is made of foam or plastic). While in use, recalled devices may have very small foam particles or dust break loose and travel through the air hose. This breakdown may be related to exposure to extreme heat and humidity over time or be hastened by the use of unapproved cleaning devices. Of particular concern are commercial cleaning systems that use ozone. This recall affects devices manufactured prior to April 26, 2021.

The FDA released a Safety Communication on June 30, 2021. We will send out more guidance about this recall as more clinically relevant information becomes available.

Frequently Asked Questions – Patients

Why are certain Philips BiLevel PAP, CPAP, and Mechanical Ventilator devices being recalled?

The manufacturer has identified a problem due to a breakdown of the foam used to reduce sound and vibration in these devices. Very small particles or dust from the foam could break loose and come through the air hose. There was also a concern for exposure via off-gassing (detecting the scent of chemicals that are released in vapor form while the device is in use).

How do patients find out if their devices are part of the Philips BiLevel PAP, CPAP, or Mechanical Ventilator recall?

Patients can find out if a device is part of the recall by visiting the Philips website that allows patients, users, or caregivers to look up their device serial number and begin a claim if their unit is affected at:

<https://www.philipssrcupdate.expertinquiry.com> or by calling (877) 907-7508.

Should patients keep using their devices if they are part of the Philips recall?

The health risks of continuing to use affected CPAP devices are currently unknown, but appear to be low.

- **If a patient is using an affected BiLevel PAP and CPAP device:** Consider the risks and benefits of continued use of the CPAP versus discontinuing use as the Philips recall advises. If a patient struggles with daytime sleepiness, impaired concentration, sleepiness while driving, or poor quality of life when not using the CPAP, advise the patient to continue to use the current device until an option for a comparable replacement or repair is available. In the risk versus benefit analysis of continued CPAP use, factor into the equation the patient's job and need for a good night's sleep, such as those on flight status, those who operate hazardous equipment or firearms, or those in the medical field.

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- If a patient is using an affected life-sustaining mechanical ventilator device: Do not stop or alter the prescribed therapy. The benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

Patient safety is our top priority. Advise patients, users, or caregivers that if they notice any problems with the device or any new respiratory symptoms, to contact their care team immediately. Advise them to send a secure message to their provider or care team through Secure Messaging Portal: <https://app.tolsecuremessaging.com/> or call their care team directly for guidance if they are concerned about using the device. Additional guidance will be sent out as more clinically relevant information becomes available.

What cleaning products or devices should patients use/avoid?

Since each type and brand of CPAP machine is different, patients should follow the cleaning schedule and instructions from the company that made the CPAP machine. Refer to the device's owner's manual for approved cleaning methods. Most CPAPs can be cleaned with mild soap and water as described in the owner's manual for the machine. Some manufacturers recommend using diluted vinegar. Remember not to put any machine with an electrical cord into water or other liquids. Use a damp towel to clean the outside of the part of the CPAP machine that has an electrical cord. Find additional information on cleaning at: <https://www.fda.gov/consumers/consumer-updates/cpap-machine-cleaning-ozone-uv-light-products-are-not-fda-approved>.

Commercial CPAP cleaning devices that use ozone or ultra-violet light to clean, sanitize, or disinfect CPAP devices are a concern as well. The FDA previously published a safety communication to patients about them not being legally marketed for this use by the FDA in the United States; safety risks are unknown. See <https://www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or>.

What impact will this recall have on a patient scheduled for a sleep study?

Due to the volume of units affected, sleep centers may have to reschedule sleep study appointments until replacement devices are purchased or current equipment is repaired. Diagnostic sleep studies such as home sleep testing and in-laboratory polysomnography are not affected by the recall. Laboratories that use Philips devices affected by the recall for CPAP and BIPAP titrations may be impacted. Patients should talk to their physician about balancing the risks of using a PAP device for one night in the laboratory to optimize diagnosis and treatment settings against exposure risks that are likely minimal (i.e., exposure to a recalled device for several hours during a sleep study).

Will the patient's Philips BiLevel PAP, CPAP, or Mechanical Ventilator be replaced or repaired?

Encourage patients to register their device through the Philips Respironics patient portal at: <https://www.philipssrcupdate.expertinquiry.com> or call 877-907-7508 to see if the particular device is part of the recall and to begin a claim if the unit is affected. The website and contact will provide the patient with information for repairing or replacing the device if affected by the recall. Most likely, current models of devices will be replaced and repairs would be targeted to older model devices that are no longer manufactured.

Will TRICARE pay for a new, non-recalled device?

As per TRICARE Policy Manual, the TRICARE health plan allows patients to receive a new, non-recalled device when their medically necessary device has been recalled. Patients will need a new prescription from their provider (or referral for durable medical equipment) to receive a new device. Patients may need to pay appropriate co-pays or cost shares based upon their TRICARE plan. Due to the recall and national demand, new devices may not be readily available.

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How long will it take to get a replacement or get the device repaired? What should be done in the interim?

It will likely be some time before replacement machines are available from Philips. Please refer to the Philips website, register, and/or call (877) 907-7508 for more information. We will send out additional guidance as more clinically relevant information becomes available.

Does this issue only impact devices purchased by Military Medical Treatment Facilities?

No. This impacts all Philips CPAP and BiLevel PAP devices manufactured by Philips prior to April 26, 2021.

Where are the latest updates regarding the Philips device recall?

More information is available at <http://www.philips.com/src-update>, or contact Philips at 877-907-7508.

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Frequently Asked Questions – Providers/Care Teams

What is the magnitude of the patient risk related to recalled device issues?

The magnitude of the risk to patients is not currently known. Of the 16.5 million devices in use worldwide, Philips has received 1,304 complaints of soundproofing foam disintegration resulting in particles entering the air tube and possibly reaching the patient. Philips has reported 11 incidents of mild or minor health effects including cough, headache, and airway irritation requiring bronchodilators, but no reported serious illness or deaths. These reports were collected over more than a decade.

The foam has chemicals that are classified as carcinogens. The FDA notes that particulate and chemical exposure may have carcinogenic effects to internal organs such as kidneys and liver. Foam disintegration is more likely in high heat and humidity situations and may be related to after-market ozone cleaners.

What actions is the Military Health System (MHS) taking to respond to this recall?

The scale of this recall and its impact on patient care is unprecedented and the situation will continue to evolve as more is learned. The MHS is meeting regularly with federal partners and TRICARE Managed Care Support Contractors for a coordinated, evidence-based approach.

How do I determine if continuing therapy with a recalled Philips BiLevel PAP, CPAP, or Mechanical Ventilator outweighs potential risks?

It is presently unclear what the health risks are of continuing to use affected CPAP devices, but it appears that the risks are low. Therefore, consider your patient's risks and benefits of continued use of CPAP versus discontinuing use as the Philips recall advises. If a patient struggles with daytime sleepiness, impaired concentration, concerns about driving safety, or poor quality of life when they do not use their CPAP, then we would advise the continued use of the patient's current device until an option for replacement or repair is available. In addition, if your patient works in a high-risk career field such as security forces/ medical/ aviation/ transportation/ hazardous equipment operation, we recommend continued use of their device. Instruct patients to clean their devices as described in the manufacturer's owner's manual.

For patients who require the Trilogy 100 and 200 mechanical ventilator devices for emergency, life-sustaining therapy, if an alternate option for therapy does not exist, Philips advises that the benefit of continued usage of these devices may outweigh the risk.

Clinical Subject Matter Experts across the MHS, in conjunction with the Veterans Health Administration, have developed guidance to assist teams with these decisions. Attached to this Advisory is a process for prioritizing which patients should continue CPAP/BIPAP due to the risks associated with untreated sleep apnea. These guidance documents will continue to be updated as more clinically relevant information becomes available.

May a patient use in-line bacterial filters to make these devices safe for continued use by blocking the flow of particles or dusts? Would this be a solution for many of our patients?

In most cases, no. While inline bacterial filters can offer a potential physical barrier to particle transition (they trap particles larger than 0.3 microns, and the size of particles released from foam breakdown in CPAP devices is on the order of 3 microns), they have the potential to reduce the effective delivered pressure which could result in inadequate respiratory support that might be harmful to the patient. Per the FDA, "filters may affect ventilator performance because they may increase resistance of air flow through the device. Filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam. Filters should be monitored closely for possible accumulation of foam debris." Also, heat and humidity can affect these in-line bacterial filters, and most CPAP/BIPAP devices use heated tubing and humidifiers.

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In-line filters may be an option that could be considered in a select group of patients, such as patients requiring ongoing use of a recalled ventilator for respiratory failure that are experiencing airway symptoms thought to be due to breakdown of foam, but for whom stopping ventilator therapy would be life-threatening. Before electing use of these in-line filters, we recommend consulting with the specific equipment vendor.

What other resources are available for providers/care teams and patients?

- Provider and care team information materials will soon be available at <https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/Home.aspx> and updated as needed.
- DHA will soon be publishing a letter to the patients at <https://tricare.mil/>.
- Patients who are using a Philips device should register their device and their contact information at <https://www.philipssrcupdate.expertinquiry.com> or call Philips at 877-907-7508.
- Visit <http://www.philips.com/src-update> for the latest updates regarding this Philips device recall.
- Check <https://tricare.mil/> for updates.

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References:

Philips Respironics Company Announcement:

<https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf>

Philips Respironics Recall Information: <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update>

Images of Affected Devices: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2

Device Registration Process: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_3

Information for Physicians and Other Medical Care Providers:

<https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-physicians-and-providers>

FDA Company Announcement on Philips Respironics Recall: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam>

FDA Guidance on Cleaning CPAP: <https://www.fda.gov/consumers/consumer-updates/cpap-machine-cleaning-ozone-uv-light-products-are-not-fda-approved>

FDA Reminder Regarding Commercial Cleaners: <https://www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or>

American Association of Sleep Medicine (AASM): <https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices>

FDA Safety Communication: <https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks?>

Additional References:

European Respiratory Society Statement: <https://mk0ersnetorgsavg5whs.kinstacdn.com/wp-content/uploads/2021/06/ERS-statement-on-Philips-devices.pdf>

American Academy of Sleep Medicine Statement: <https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/>

American Thoracic Society Statement: <https://www.thoracic.org/patients/patient-resources/recommendations-for-sleep-and-critical-care-medicine-professionals-regarding-philips-recall-notice.php>

American College of Chest Physicians Statement: <https://www.chestnet.org/News/CHEST-News/2021/06/CHEST-Issues-Joint-Statement-in-Response-to-Philips-Device-Recall>

Australian Government Department of Health Statement: <https://www.tga.gov.au/alert/philips-recall-action-cpap-bi-level-pap-devices-and-mechanical-ventilators>

Resources:

Secure Messaging Portal: <https://app.tolsecuremessaging.com/>

Philips Device Recall Contact Support: Call 877-907-7508

AASM Impact of Recall Video: <https://www.youtube.com/watch?v=Mj6Tamcd6zc>

DHA Updates: <https://tricare.mil/>

* MHS Patient Safety Advisory [21-016] Philips Recall Due to Sound Abatement Foam Component:

https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/Alerts1/PSAC%20Alerts/MHS_Patient_Safety_Advisory-Philips_Recall_Sound_Abatement_June2021_21-016.pdf