Accession Number:	A37110 04	**ECRI Priority:**	Critical	**Published:**	02/18/2022
Channel:	Devices	**FDA:**	Not Specified	**Last Updated:**	05/20/2022

Philips—CPAP and BiLevel PAP Devices and Mechanical Ventilators: Inhalation of Particles and Volatile Organic Compounds from Sound Abatement Foam May Cause Patient Harm [Update]

Product Identifier(s)

[Capital Equipment]

Product	Philips Respironics Inc Model
Ventilators	A-Series BiPAP A30, A-Series BiPAP A40, A-Series BiPAP Hybrid A30, A-Series BiPAP V30 Auto, Aeris, C Series, Dorma 400, Dorma 500, DreamStation, DreamStation GO, E30, Garbin Plus, LifeVent, OmniLab Advanced Plus, REMStar SE Auto, SystemOne, Trilogy 100, Trilogy 200

Manufacturer(s)

Philips Respironics Inc , 1001 Murry Ridge Ln, Murrysville, PA 15668, United States

Summary

Update Reason: New Action Needed information. This Alert provides new information based on a January 2022 Philips letter regarding Alerts A37110, A37110 02, and A37110 03.

Problem

In a November 12, 2021, News Release, FDA states that in response to the July 14, 2021, Philips Respironics recall of certain ventilators, continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BiPAP) machines (see Alert A37110), it conducted an inspection of a Philips Respironics manufacturing facility to determine what may have caused or contributed to the foam problems and assess adherence to the agency's requirements for quality manufacturing. During the inspection, the FDA investigator made several observations that are outlined in an inspection closeout report, also known as an "FDA Form 483." The FDA investigator provided a list of their observations to the company. An FDA investigator's list of inspection observations does not constitute a final FDA determination of whether any condition is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations. FDA will review the company's response and the totality of information available to the agency in determining appropriate next steps.

Following the initial recall, Philips Respironics developed a plan to repair the polyester-based polyurethane foam in the recalled CPAP and BiPAP devices with a different, silicone-based foam. FDA initially approved this plan based, in part, on testing the company provided to FDA in June on the new foam. However, during the manufacturing facility inspection, FDA obtained additional information regarding the silicone-based foam used in a singular, similar device marketed outside the U.S., which failed one safety test for the release of certain chemicals of concern, called volatile organic compounds (VOCs). Similar testing information provided by Philips Respironics to FDA on devices authorized for marketing in the U.S. had demonstrated acceptable results. FDA has requested that Philips Respironics retain an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by the silicone-based foam. FDA is aware that patients have already received devices with silicone-based foam as part of the repair and replace program. At this time, the agency does not have sufficient information to conclude whether the silicone-based foam being used in the repaired devices poses any risk to patients in the U.S. The manufacturer has not confirmed the information provided in the source material.

Action Needed

Identify any affected devices in your inventory. If you have affected devices, verify that you have received the January 2022 letter from Philips. Register for participation in the Philips recall and receive additional instructions to participate in corrective actions by visiting the Philips website. To begin the registration process, you will be asked to enter the account number and passcode listed on the notification enclosed with the letter sent to your facility. If you

are unable to locate the account number, call Philips at (877) 907-7508. During the registration process, you will have the option to manage the remediation process yourself or to have Philips manage the remediation process for you. For Philips to manage the remediation process for you, homecare patient information is required. Note that only durable medical equipment providers have this option. Hospitals and other institutions will be required to manage the remediation process themselves.
Talk to your healthcare provider to decide on a suitable treatment for your condition, which may include stopping use of your device; continuing to use your affected device, if your healthcare provider determines that the benefits outweigh the risks identified in the recall notification; and using another similar device that is not part of the recall or using alternative treatments for sleep apnea. Follow the manufacturer's instructions and recommended cleaning and replacement guidelines for your CPAP machine and accessories. Ozone cleaners may exacerbate the breakdown of the foam, and there are other potential risks associated with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories.
Do not stop or change ventilator use until you have talked to your healthcare provider. Alternative 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 in the judgment of the treating clinical team, the benefit of continued use of affected ventilators may outweigh the potential risks identified in the recall notification. Talk to your healthcare provider about using an in-line bacterial filter, which may help to filter out particles of foam. FDA does not have evidence of the safety and effectiveness of a filter for mitigating the foam risks, and its evaluation is ongoing. It is important to note the following considerations:

- Filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam.
- Filters may affect ventilator performance because they may increase resistance of airflow through the device.
- You should closely monitor for possible accumulation of foam debris on the filter or resistance-related problems in the breathing circuit after filter placement.
- Consult your instructions for use (IFU) for guidance on installation.

Devices should only be serviced by qualified technicians. They do not include user serviceable parts. Attempts to remove the sound abatement foam may render the device permanently inoperative. Devices damaged due to attempts by the user to remove the sound abatement foam will not be able to be remediated. Philips is deploying a permanent corrective action to address these problems. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website.
For Further Information:
Philips
Tel.: (877) 907-7508
Website: Click here

UMDNS Term(s)

Positive Airway Pressure Units [20742]
Positive Airway Pressure Units, Bi-Level [20743]
Positive Airway Pressure Units, Continuous [11001]
Ventilators, Noninvasive Positive Pressure [20746]

Geographic Region(s)

□□□(□Impact in additional regions has not been confirmed or ruled out at the time of this posting), U.S.

Suggested Distribution

Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Home Care, EMS/Transport

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:

- Philips. Sleep and respiratory care update. Medical device recall notification (U.S. only)/field safety notice (international markets) [online]. 2021 Jun 14 [cited 2021 Jun 14]. Available from Internet: Click here.