Accession Number:	A37110 02	**ECRI Priority:**	High	**Published:**	11/17/2021
Channel:	Devices	**FDA:**	Not Specified	**Last Updated:**	02/01/2022

Philips—CPAP and BiLevel PAP Devices and Mechanical Ventilators: FDA Provides Information Regarding Health Risks Caused by Sound Abatement Foam [Update]

Product Identifier(s)

[Capital Equipment]

Product	Philips Respironics Inc Model	Manufacture Date	Serial No.
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	< 2021 Apr 26	All

Manufacturer(s)

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

Summary

Update Reason: Additional Problem and Action Needed information. This Alert provides new information based on a November 12, 2021, FDA News Release regarding Alert A37110.

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 reviewed November 12, 2021, FDA News Release. FDA does not currently recommend that patients who have participated in the repair and replace program discontinue use of their product. At this time, FDA has determined that discontinuing use of one of these devices may be more harmful to a patient's health and quality of life. The results from the

independent testing are needed to determine if the silicone-based foam used in the repaired devices does in fact present any risks to patients, and FDA will communicate those results to the public as soon as they are available. Patients who have additional concerns should talk to their healthcare provider about the plan for their care and treatment. FDA recommends that patients currently using a recalled device that has not yet been repaired and replaced consult with their healthcare provider if they have additional questions or concerns to further determine whether patients should continue using the device, switch to another product or stop use. See the FDA Frequently Asked Questions to for more information regarding this problem.

For Further Information:

FDA
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Philips
Tel.: 44 (2080) 893822 or (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:**

- United States. Food and Drug Administration. FDA news release—FDA provides update on recall of certain Philips Respironics breathing assistance machines [online]. 2021 Nov 12 [cited 2021 Nov 17]. Available from Internet: Click here.