Accession Number:	A37110 03	**ECRI Priority:**	Critical	**Published:**	01/28/2022
Channel:	Devices	**FDA:**	Class I	**Last Updated:**	02/03/2022

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

Product Identifier(s)

[Capital Equipment]

Product	Philips Respironics Inc Model	Material No.	UDI	Serial No.	Lot No.
Ventilators	Trilogy Evo	DS2110X11B, KR2110X15B	00606959051942, 00606959055483	H29069399D107, H29467106F5BE, H29467208F3A4, H29667046C054, H29669752BDEF, H29669926A6D8, H29670012A4AD, H29670055B772, H29670062E9A5, H29670066AF81, H29670089CD66, H29670099D4BE, H29670110DD63, H29670120F70B, H29670124B12F, H29670177FD0C, H29672248F981, H29672338EE55, H29672349B2D4, H29672401D5F9, H29672403F6EB, H29672456DFFE, H29674238FF13, H29770818C91E, H29784208BBAC, H29815437CFBC, H29815534A7FB, H29815680EA13, H29817188D328, H29818029D7F4, H29818206A90B, H29818225A820, H29818313BDA2, H29818528FFC0, H29818539F791, H29818898E417, H29819674B8CB, H29819705BE96, H29819715A74E, H31192401F7C3, H31192433FEB9, H31192470AB42, H31192474ED66, H31198653C37F, H31198703E71B, H31199129B193, H31200467A24A, H31200649CD3C,	N/A

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Ventilator Repair Kits	Trilogy Evo	1135257	N/A	N/A	210414 to 210524

Manufacturer(s)

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

Summary

Update Reason: Additional affected product, new Action Needed information. This Alert provides new information based on a January 26, 2022, Safety Communication and Medical Device Recall listing posted by FDA and FDA Center for Devices and Radiological Health (CDRH) source material regarding Alerts A37110 and A37110 02. FDA states that Philips sent an Urgent Medical Device Recall letter to Trilogy Evo ventilator customers on December 21, 2021, and an updated letter to clarify information on cleaning and filters on January 13, 2022.

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 Urgent Medical Device Recall letter(s) from Philips and/or reviewed the FDA January 26, 2021, Medical Device Recall listing and January 26, 2021, Safety Communication. FDA and Philips recommend the following:

- Create awareness of this safety information by forwarding it to your organization's personnel.
- Identify all of the affected devices purchased by your organization.
- Do not stop or change patient therapy unless the patient has consulted their healthcare provider or unless a replacement Trilogy Evo ventilator has been provided.
- Instruct patients and/or caregivers to closely monitor the bacteria filter for foam debris. Using an inline bacterial filter may help to filter out particles of foam. Additionally, after placement of an inline filter, instruct patients and/or caregivers to be aware of potential changes in breathing circuit resistance. Ventilator performance may change because of increase in resistance of airflow through the device after filter placement. Bacterial filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam.
- Inspect and clean the patient circuit and accessories per the instructions included with the letter.
- Philips will provide your facility with a replacement ventilator. Once the patient has been transitioned to the replacement ventilator, return the affected ventilator to Philips. Your Philips representative will provide a return authorization and any support needed to facilitate this return. See the packing instructions in Appendix A of the letter sent to your facility.
- Isolate and discontinue use of any affected repair kits. Contact Philips for return instructions. Philips will provide your facility with replacement kits.
- Determine whether any Trilogy Evo devices have been repaired using Trilogy Evo muffler assembly (part number 1135357) on or after April 14, 2021.
    - If the lot number used in repair is between 210414 and 210524, contact Philips. Philips will replace the device into which these parts were installed.
    - If the lot number used in a repair is unknown, assume it is affected and contact Philips for next steps. Philips will replace the device into which these parts were installed.
    - If lot number is known and is not an affected lot, no further action is required.

See the FDA Safety Communication for further recommendations.

For Further Information:

FDA
Tel.: (888) 463-6332
Philips
Tel.: (800) 722-9377
E-mail: Respironics.repair@philips.com
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), Argentina, Brazil, The Netherlands, Romania, 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:

- 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.
- Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls. Event ID: 89276. Philips Respironics, Inc. [online]. 2022 Jan 22 [cited 2022 Jan 27]. Available from Internet: Click here.
- Food and Drug Administration. Philips Respironics recalls certain Trilogy EVO ventilators for potential health risks from PE-PUR foam [online]. 2022 Jan 26 [cited 2022 Jan 27]. Available from Internet: Click here.
- Food and Drug Administration. Update: certain Philips Respironics ventilators, BiPAP, and CPAP machines recalled due to potential health risks: FDA safety communication [online]. 2022 Jan 26 [cited 2022 Jan 27]. Available from Internet: Click here.