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Supplemental clinical information for physicians and providers for specific CPAP, Bi-Level PAP, and mechanical ventilator devices with the use of bacteria filters

This document is intended to provide an overview of particulate characterization and bacteria filter performance for CPAP devices.

On June 14, 2021, Philips issued a recall notification for the US only/field safety notice for the rest of the world for specific sleep and respiratory care devices due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain Philips continuous and non-continuous ventilators: 1) the PE-PUR foam may degrade into particulates which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may emit certain chemicals.

Chemical emissions from the PE-PUR foam

Emission of certain chemicals from the foam has been identified, resulting from trace amounts of organic compounds associated with the production process of the foam. Based on standard ISO 18562-3 testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl).

Foam Degradation

Despite a complaint rate of 0.03% (i.e. 3 in 10,000) in 2020 [1], Philips has determined from user reports and lab testing that the PE-PUR foam may slowly degrade – through a process called hydrolysis – and produce particulates which may enter the device's air pathway where they could be ingested or inhaled by the user of impacted Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (Bi-Level PAP) and mechanical ventilator devices.

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The foam degradation may be accelerated by the environmental conditions of high temperatures and humidity. Unauthorized cleaning methods such as ozone cleaning may exacerbate potential degradation.

According to an analysis performed by Philips, particles are of various sizes, however, the majority of particulates are of a size (>8 µm) that are unlikely to penetrate the deep lung tissue. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size captured by the bacteria filter was 2.69 µm. Additional testing is ongoing.

Bacteria Filters for CPAP

Due to an influx of questions, additional information is being provided about the use of bacteria filters with CPAP/BiLevel devices. According to FDA regulation 868.5260, bacteria filters are medical devices that are intended to remove microbiological and particulate matter from the gases in the breathing circuit. Philips does not recommend using bacteria filters outside of their normal intended use. Therefore, these bacteria filters should not be used on CPAP/BiLevel devices as a means of mitigating risk of PE-PUR foam chemical emission or particulate matter for the following reasons:

- Bacteria filters do not provide protection from the chemical emissions resulting from manufacturing or continued foam degradation. Furthermore, possible gas emission of the degraded foam has not been fully characterized yet throughout the life of the CPAP/BiLevel device.
- In-line bacteria filters are not intended to be used under the current affected CPAP/BiLevel devices use cases.
- Federal law (USA) restricts bacterial filters for sale under the order of a physician.
- In-line bacteria filters are specified to be used where they can be monitored by a medical professional.
- Bacteria filters need to be replaced frequently as referenced in the bacteria filter manuals, or as deemed necessary upon inspection by a medical professional.

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- Bacteria filters increase the resistance to airflow and will impact device performance of CPAP/BiLevel devices. Filters alter device performance by negatively impacting the maximum airflow, dynamic pressure and static pressure delivered by the CPAP/BiLevel devices. The extent of performance degradation will vary dependent upon prescribed therapy settings and air leakage which are different for each patient. Because of this, device performance may not meet the approved device's specifications.
- When an inline bacteria filter is used with a CPAP/BiLevel device the pressure reported by the device may be different than the prescribed pressure as well as the pressure received by the patient.
- Certain circuits are unable to be used with bacteria filters due to an increased airway resistance that can affect device performance: 12mm circuit or heated humidifier circuit.
- Bacteria filters may alter algorithms that govern therapy on many CPAP/BiLevel devices. Different modes (AutoCPAP, ASV, AVAPS, AVAPS-AE, Flex) require airflow sensing and demonstrate varying degrees of performance impact. Individual patients may experience varying degrees of performance impact.
- Therapy device performance reporting in Care Orchestrator may be impacted. There may be an impact on event detection, and the prescribed pressure may not accurately reflect the pressure received by the patient.
- Use of humidification, common to CPAP/BiLevel devices, will negatively impact the bacterial filter performance.
- Fixed mode humidification cannot be used with bacteria filters as the humidification may increase condensation within the filter.
- In-line bacteria filters specifications vary by manufacturer and the filters should be with accordance with the manufacturer's labeling.

Affected CPAP/BiLevel Devices that are not recommended to be used with a Bacteria Filter

- SystemOne
- SystemOne ASV4
- DreamStation (CPAP, AutoCPAP, BiPAP)
- DreamStation GO (CPAP, AutoCPAP)
- DreamStation ASV
- DreamStation S/T, AVAPS
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- C Series (ASV, AVAPS, S/T)
- OmniLab Advanced Plus

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Background on Bacteria Filters for mechanical ventilators

Bacteria filters are a part of the normal use of the Trilogy ventilators. Trilogy ventilator labeling recommends that a main line outlet bacteria filter be used on Trilogy devices whenever the device is used for invasive therapy or if the ventilator may be used on multiple patients in a monitored environment.

As mentioned above, bacteria filters are medical devices that are intended to remove microbiological and particulate matter from the gases in the breathing circuit. As indicated by the intended use of the bacteria filters for affected mechanical ventilator devices, exposure to particulates may be partially mitigated using a bacteria filter. However, please note that the use of the bacteria filter will not mitigate the harm of the chemical emissions.

The filter specification indicates a minimum efficacy of 99.97% on an inert test with particulate sizes of 0.3 µm or greater. Based on the available information to date on estimated particulate size range, the bacteria filter may effectively filter out some foam particulates that could make its way up the patient circuit.

Notes and references

[1] *486 foam-related complaints in 2020 for 1.56 million devices shipped in that year, representing a complaint rate of 0.03%.*

[2] *Lattuati-Derieux, A., Thao-Heu, S. & Lavédrine, B.; Assessment of the degradation of polyurethane foams after artificial and natural ageing by using pyrolysis-gas chromatography/mass spectrometry and headspace-solid phase microextraction-gas chromatography/mass spectrometry; J. Chromatogr. A 1218, 4498–4508 (2011).*

Additional information

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