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Supplemental clinical information for physicians and providers for specific CPAP/Bi-Level PAP 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 Friday July 2 2021, following consultation with the Therapeutic Goods Administration (TGA) and Medsafe, Philips Australia and New Zealand announced it is conducting an Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand 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

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. However, there is a risk these particulates may be ingested. 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.

Philips cannot recommend using bacteria filters outside of their normal intended use. Filter usage outside of the normal intended use should not be implemented without the consultation of a physician.

The following information must be taken into consideration regarding any proposed use of bacteria filters with CPAP/Bilevel devices:

- 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.
- Philips has no evidence demonstrating that the in-line bacteria filters are effective in filtering Volatile Organic Compounds.
- Your local regulations may restrict bacteria filters for sale under the order of a physician.
- In-line bacteria filters are widely used on multi-patient applications where they likely will be monitored by a medical professional.

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- Bacteria filters need to be replaced frequently as referenced in the bacteria filter manufacturer's manuals/instructions for use and as deemed necessary upon inspection by a medical professional.
- Bacteria filters increase the resistance to airflow and will impact device performance of CPAP/BiLevel devices. Bacteria 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, performance of the device may be affected.
- 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 and may also be different from the pressure received by the patient.
- 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 that attempt to use such filters 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 and instructions for use.

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