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Channel:	Devices	**FDA:**	Not Specified	**Last Updated:**	08/04/2021

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

Product Identifier(s)

[Capital Equipment]

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

Manufacturer(s)

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

Problem

The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a National Patient Safety Alert (NatPSA) warning healthcare workers of the risk of patient harm from degradation of the sound abatement foam in the above devices. There are two identified problems:

1. Degradation of foam causing particles to be blown into the patient's airway. MHRA states that there have been a small number of reports outside the U.K. of this problem causing minor, short-term effects such as irritation to the skin, eyes, and respiratory tract; an inflammatory response; headaches; asthma. Inappropriate use and decontamination can worsen the foam degradation.
2. Release of volatile organic compounds (VOC) including dimethyl diazene and phenol. Evidence suggests that these gases dissipate after 24 hours from first out-of-box use. There is a risk of short-term effects such as headache/dizziness; irritation of the eyes, nose, respiratory tract, and skin; hypersensitivity; nausea and vomiting. There have not been any reports of this to date.

MHRA also states that, although there is currently no definitive data showing long-term harm to patients, VOCs and degradation of the foam are associated with possible long-term effects such as genotoxicity, mutagenic and carcinogenic effects, hepatotoxicity, nephrotoxicity, and neurotoxicity. MHRA further states that the available evidence suggests the following:

- Volatile organic chemicals of concern (dimethyl diazine and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) are not detectable 24 hours after the first out-of-box use of the device.
- Levels of diethylene glycol detected were within an acceptable margin of safety.
- The degradation byproducts toluene diamine and toluene diisocyanate are classified by IARC as Group 2B carcinogens. This category is used for chemicals where there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals.
- Laboratory analysis found that as the foam degraded, it stuck to nearby surfaces as well as itself. This reduces the risk of respirable particles entering the breathing circuit.
- Degradation of the polyurethane foam can be accelerated by off-label use of ozone decontamination or use in environments with high humidity and temperature, neither of which apply in the U.K.
- Most degraded foam particles are too big to be inhaled.
- Diisocyanate is associated with isocyanate-induced asthma in a very small number of patients. For sensitized patients, even low concentrations can cause adverse effects.

MHRA states that the manufacturer issued two Field Safety Notice (FSN) letters regarding this problem. The manufacturer has not confirmed the information provided in the source material.

Action Needed

MHRA recommends the following:

- Identify whether you have any of the affected devices in your inventory or whether you have provided them to patients under your care.
- Notify all relevant personnel at your facility of the information in the FSNs. Ensure that clinicians read and follow the FSNs for each device.
- Implement and document a risk assessment process to determine the suitability of the continued use of these devices within one month. Refer to additional information section in the NatPSA for more information. Clinicians should do the following:
    - Determine whether risk assessments should be based on individual patients or patient groups, and
    - Contact affected patients and have a risk–benefit conversation about continued use. Advise that they can register their devices on the manufacturer's website.
- Source alternative devices where clinically appropriate. Guidance will be available through NHS Supply Chain in England (or national procurement services for Devolved Administrations).
- Train staff and patients, and verify competency, in using the alternative devices. Ensure that training records are updated.

Do not advise patients to stop using affected devices unless a risk assessment has concluded that the risks outweigh the benefits. Stopping treatment suddenly could have an immediate and detrimental effect on patient health. BiPAP devices are primarily used by patients with established type II respiratory failure. Withholding treatment may worsen the respiratory failure, resulting in the underlying condition getting worse and possible hospitalization. CPAP devices are primarily used by patients with obstructive sleep apnea (OSA), enabling them to carry out activities of normal daily living that they would be unable to do if they were to stop treatment (e.g., driving a vehicle). Withholding treatment could increase their risk of stroke, heart disease, and high blood pressure. This could require hospital admission and a more invasive method of treatment and have long-term health consequences. Inserting an inline filter into the breathing system of a ventilator between the patient and the device will greatly reduce the risk of patients inhaling particulates because of the size of the particles released during degradation (2.69 µm to 724 µm). The use of filters is only validated by Philips for the ventilator system and is recommended in the instructions for use. The use of filters is not validated by Phillips for their CPAP/BiPAP machines and is considered off-label use. The effect of introducing a filter to the breathing system on patient treatment is unknown. Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

For Further Information:

Philips
Website: Click here
MHRA
E-mail: devices.queries@mhra.gov.uk

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)

U.K.

Suggested Distribution

Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, 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:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. National Patient Safety Alert: Philips ventilator, CPAP and BiPAP devices: potential for patient harm due to inhalation of particles and volatile organic compounds [online]. London: Department of Health; 2021 Jun 23 [cited 2021 Aug 3]. (National Patient Safety Alert; no. NatPSA/2021/005/MHRA). Available from Internet: Click here.