Medical Device Advisory

Health Products Regulation Group
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PHILIPS CPAP AND BI-LEVEL PAP DEVICES - RISK OF INHALATION OR INGESTION OF PARTICLES OR VOLATILE ORGANIC COMPOUNDS

The Health Sciences Authority (HSA) would like to inform patients, users, and caregivers on the potential risk of inhalation or ingestion of particles or volatile organic chemicals associated with the use of certain models of Philips Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices. CPAP and Bi-Level PAP are medical devices intended to provide non-invasive positive airway pressure therapy, primarily to treat patients affected by obstructive sleep apnoea (OSA). CPAP delivers single pressure, while Bi-Level PAP delivers two pressure: an inhale and exhale pressure. CPAP and Bi-Level PAP devices that use a polyester-based polyurethane (PE-PUR) sound abatement foam are potentially affected by this issue.

Potential health risks of the PE-PUR foam in these devices

2 The potential risks of the PE-PUR foam found in the affected devices are particulate exposure which may lead to irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to the release of volatile organic compounds include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

3 To date, HSA has not received any local reports of serious adverse effects related to the use of Philips CPAP and Bi-Level PAP machines. However, Philips Respironics has received complaints from consumers overseas on the presence of black debris/particles within the airpath circuit of the devices and reports of headache, upper airway irritation, cough, chest pressure and sinus infection in some patients using these devices. There have been no reports of death as a result of these issues.

List of Affected Devices – All Devices Manufactured Before 26 April 2021, All Device Serial Numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Provisional Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV DreamStation ST, AVAPS SystemOne ASV4 C-Series ASV C-Series S/T and AVAPS OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series) DreamStation DreamStation Go Dorma 400 Dorma 500 REMstar SE Auto

Advisory and recommended actions

4 Philips Electronics Singapore Pte Ltd and their distributors will be reaching out to the local users to deploy a permanent corrective action to the affected devices, which would involve the replacement of the PE-PUR sound abatement foam.

5 Patients, users or caregivers with the affected CPAP and Bi-Level PAP devices should:

- Consult their doctors on their current clinical situation before considering alternatives or deciding to discontinue use of the device
- Refer to the Philips Respironics' website (accessible by the QR code below) for the latest updates and the 'Questions and Answers' section
- Contact Philips' customer support hotline at 1800-28-63-020 (9 am - 6 pm, Mon - Fri) for any issues or clarifications regarding this safety notice

6 HSA will continue to monitor the situation globally and work with Philips Electronics Singapore Pte Ltd to ensure that the permanent correction is implemented for local users once available.

Thank you.

Yours faithfully,

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