

Recommendations for respiratory, sleep and critical care medicine professionals and patients regarding the Philips recall notice

Note: The information provided may be updated as further details become available.

Philips Respironics released a Field Safety Notification on 14.06.2021 for a number of positive airway pressure (PAP) devices used for treatment of sleep apnoea and respiratory failure. According to the manufacturer, the polyester-based polyurethane foam used in their devices may degrade into particles and volatile gas products, which the user may inhale. This may result in potential health risks for the user, including local airway irritation. In animal trials, some of the volatile chemicals have been shown to be a possible carcinogenic risk. Further information on the potential risks of degraded foam exposure are listed on [the manufacturer's website](#). The degradation may be accelerated by unapproved cleaning methods (e.g. ozone). We currently lack concrete information on the toxicity and clinical relevance of particulate matter and volatile gases over the short or long term.

A variety of devices are affected and include the first generation DreamStation devices, though not the DreamStation 2 devices. Please refer to [the complete list](#).

Philips is creating a registration process that will allow patients to look up their device serial number to see if the unit is affected. [Read the Philips press release for more information](#).

Statement of the European Respiratory Society (ERS)

1. The assessment of the situation has to balance the real and potential acute and chronic risk for the patient due to physical or chemical injuries on the one hand, against the acute and chronic risk of cessation of treatment of sleep apnoea or respiratory failure on the other.
2. This decision should be taken on an individual basis.
3. We have no evidence of acute life-threatening incidents with patients using PAP treatment. There have been a small number of adverse event reports, describing features such as cough, headache and sinus infection in users.
4. Therefore, the patients **should not stop or change** their treatment, even if they receive notification from the manufacturer.
5. Patients should contact their physician/sleep team for advice.
6. The medical recommendation should take into consideration:
 - a. Patient impairment due to daytime sleepiness, accident risk at the workplace and when driving, and individual comorbidities.
 - b. Severity of the disease based on parameters like AHI, hypoxic load, objective impairment in daytime performance and hypercapnia.
7. Examples for possible decisions may vary between the following extremes:
 - a. For patients with severe breathing difficulties, excessive daytime sleepiness, ventilatory failure using non-invasive or invasive ventilation, significant pulmonary, cardiovascular or neurological comorbidities, or accident risk at their workplace or when driving, therapy should **not be stopped or altered until a comparable alternative is available**.

- b. For patients with mild to moderate symptoms and respiratory and cardiovascular burden of the OSA, a swap to alternative therapy such as mandibular advancement splint or position modifier device might be appropriate.
- c. For patients with mild symptoms of OSA and disease burden, interruption of the treatment until the device can be replaced can be considered.

These decisions should be kept under regular clinical review and take into account patient views. It is acknowledged that precise quantitation of risk of each treatment option is impossible. Patients have the right to up-to-date information so that they can fully participate in decision-making.

- 8. Due to the high number of patients affected, it will be impossible to exchange devices under in-lab supervision immediately. However, swapping of non-invasive ventilation must not be performed without supervision. Exchanges of sleep apnoea devices may be reasonable without supervision in individual cases. The evaluation should be performed at the earliest possible date.
- 9. As long as patients are advised to continue with their current device, the use of in-line bacterial filters is recommended.

Due to the limited information, this statement can only be preliminary. Updates will be provided when possible.

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