

## **Update on the ERS 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 released a Field Safety Notification on 14 June, 2021 for a number of positive airway pressure (PAP) devices used for treatment of sleep apnoea and respiratory failure. The notification was published based on the recognition that volatile gas products or particles from the polyester-based polyurethane foam may be inhaled by users. Local airway irritation (due to particulates) or carcinogenic risk (due to volatile organic components (VOC)) were considered as a potential health risk. The degradation process of the sound abatement foam may have been accelerated by unapproved cleaning methods (e.g., ozone).

Based on this information, the European Respiratory Society (ERS) released a statement. This statement has been updated based on new information, in order to provide up-to-date guidance to respiratory, sleep and critical care teams, and patients.

Philips have performed additional testing and research to evaluate the potential risk. They produced a press release on the results on 23 December, 2021. In addition, ERS officers were provided with outcome information (as described in the next paragraphs) by direct communication with the company. Philips also informed European health authorities, including the Bundesinstitut für Arzneimittel und Medizinprodukte, Berlin (BfArM), about the data in detail.

Additional testing was performed by certified testing laboratories and qualified independent third-party experts, using ISO 18562 guidance. Toxicological risk assessments of the VOC were performed with Dream Station BiPAP and CPAP devices. The testing was conducted using new devices, devices with lab-degraded foam, and devices retrieved from the field. According to the information, the results showed that VOCs do not exceed safe exposure thresholds, specified in the applicable safety standards, and are not anticipated to result in long-term health consequences for patients. The testing suggests no increased risk for adverse health impact in the general patient population, nor the higher risk patient population because of VOC exposure. Toxicological experts of the BfArM acknowledged the interpretation of the results.

The testing did not focus on the potential harm of particulates or the additional use of ozone cleaning.

Philips continues with the recall and repair process, especially due to the remaining particulate inhalation as potential risk of irritation.

### **Statement of the European Respiratory Society**

- 1.** Due to the new independent testing, there is no evidence of potential carcinogenic risk due to volatile organic compounds. Foam degradation may in individual cases lead to transport of particulates into the tube or mask and may potentially be inhaled, leading to irritation.
- 2.** There have been a number of adverse event reports, describing features such as cough, headache and sinus infection in users. There is no confirmed evidence of a causal relationship to the conceivable inhalation of particulates. All these reports are checked and monitored by health authorities.
- 3.** The assessment of the situation has to balance the real and potential acute and chronic risk for the patient due to airway irritation on the one hand, against the acute and chronic risk of cessation of treatment of sleep apnoea or respiratory failure on the other.

4. Therefore, ERS confirms the previous statement that the patients **should not stop or change** their treatment, even if they receive notification from the manufacturer. The new findings support this previous statement substantially.
5. Patients should contact their physician/sleep team for advice.
6. The medical recommendation should take into consideration:
  - Patient impairment due to daytime sleepiness, accident risk at the workplace and when driving, and individual comorbidities.
  - 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 options:
  - 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, device therapy **should not be stopped or altered until comparable alternative is available**.
  - For patients with mild or moderate symptoms with or without respiratory and cardiovascular burden of the disease, therapy **should not be stopped or altered until a comparable alternative is available**. Patients and their caregivers can consider a swap to alternative therapy in case of perception of adverse reactions or visible particulates in the interface.
8. 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.
9. Although the recall of devices continues, due to the number of patients affected, it will be impossible to exchange devices using in-lab supervision immediately. However, swapping of non-invasive ventilators should 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.
10. In the meantime, patients are advised to continue with their current device; and the use of in-line bacterial filters (without humidifiers) is recommended.

#### Other resources

- A list of affected devices includes the first generation of DreamStation devices, though not the DreamStation-2-devices. Please refer to the [complete list](#).
- Philips created a registration process that allows patients to [look up their device serial number to see if their unit is affected](#).
- [Access the latest notification from Philips](#).