

## Sleep and Respiratory Care Bulletin #10

June 2023

Field Safety Notice: 2021-05-A & 2021-06-A.

We are committed to supporting you through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients. The clinical bulletin will continue to offer news and updates on the PE-PUR foam voluntary FSN and will also be expanded to help address common topics and concerns on additional topics. Please find below some recent information that we wanted to bring to your attention.

### 1. PE-PUR foam voluntary FSN news and updates

#### Update on completed set of test results for CPAP/BiPAP sleep therapy devices

Building on past reports, the risk assessments have now been completed for the CPAP/BiPAP sleep therapy devices, including the first-generation DreamStation, System One and DreamStation GO devices. These devices represent approximately 95% of the registered devices globally. The assessments built on the December 2021, June 2022 and December 2022 reports. Additionally, tests and analyses have been completed for first-generation DreamStation devices that have been exposed to ozone cleaning.

The completed set of test results and analyses for the CPAP/BiPAP sleep therapy devices indicate that potential patient exposure to foam particulates and volatile organic compounds (VOCs) from the polyester-based polyurethane (PE-PUR) foam within the breathing gas pathway of these devices is unlikely to result in an appreciable harm to health in patients. The test and research program has been conducted together with five independent, certified testing laboratories, and the results have been reviewed and assessed by third-party qualified experts and Philips Respironics, as well as an external medical panel.

Philips Respironics has provided the completed set of test results and analyses for the CPAP/BiPAP sleep therapy devices to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach different conclusions.

Healthcare providers, patients, and other stakeholders should use the complete May 16, 2023 update (including information on the limitations of the testing) for any informed decision making and should not solely rely on the overview.

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**Completion of the test and research program, as well as the remediation program remain Philips Respironics' highest priorities. Philips Respironics' guidance for healthcare providers and patients using devices that have not been remediated yet, remains unchanged.**

As of April 30, 2023, a total of 955,997 devices have been corrected across Western Europe, of which approximately 90,259 devices are in the United Kingdom. Patients with any remaining sleep therapy device currently in use that has not been remediated yet and not registered yet, are requested to register their product to facilitate the remediation of their devices.

## **Patients to hear from David Ferguson, Business Leader, Sleep and Respiratory Care**

This month, David Ferguson shared [an update with patients](#) on the changes that have been put in place to reinforce patient safety, an overview of recent test results, and what they can expect from Philips Respironics in the future.

## **2. Useful Links**

### **PE-PUR foam voluntary field safety notice News and Updates for clinicians**

Be sure to visit our [Clinician information page](#) regularly for the most current information for you and your patients.

Patients may still have questions about their replacement device: the page [Learn more about your replacement device](#) can help them to quickly and easily find the support they need.

### **Masks and magnets updates**

You have additional questions about Philips Respironics masks and magnets? Learn more, [here](#).

### **Ventilation updates**

For the latest ventilation news and updates, please visit [this page](#).

*Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.*



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