

Sleep and Respiratory Care Bulletin #3

We know how important it is for you and your patients to be informed on all aspects of their sleep therapy and treatment. This bulletin was created to help address common questions and concerns as well as provide a status update on remediation efforts as they become available. Please find below some recent information that we wanted to bring to your attention. We invite you to consult our website regularly to keep informed of updates and for additional information on this voluntary recall notification*: [Visit our Clinicians information page.](#)

*Voluntary recall notification in the U.S. / field safety notice outside the U.S.

1. Our Progress

Despite the global shortage of components which continues to cause delays, providing patients with safe and high-quality devices remains our priority.

At the end of February 2022, we reached a significant milestone in the remediation process, with currently over **1 million devices returned to customers** and on their way to patients. We expect the remaining affected devices to be remediated by end of 2022 for the vast majority of patients.

2. OSA Patient prioritization

For United States OSA patients whose remediation is directly managed by Philips, data collected throughout the patient registration process are now used to help to prioritize remediation of those patients at higher risk.

OSA patients who have already registered their device for remediation received an email that outlines the option to provide additional prioritization information¹ on the [patient portal](#). We have begun distributing devices based on prioritization as prior registrants have been given an opportunity to update their registration information.

While Philips cannot implement this prioritization outside of the US due to the remediation service model, we support homecare providers and other partners who wish to implement a similar strategy as needed for their affected OSA patients. As such, Philips can provide a detailed breakdown of the input variables to assist in any such efforts.

To date, Philips has been working to increase production capacity and ship replacement devices to our customers and patients as inventory becomes available.

[Click here](#) for more information about patient prioritization.

¹ The types of information requested include age, related health conditions including obstructive sleep apnea (OSA) severity, pregnancy, occupation associated with public safety, history of car accidents related to falling asleep while driving, identification of foam particulates in affected device and whether ozone products have been used for device cleaning purposes.

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3. AJRCCM Independent study

Independent of Philips Respironics, in December 2021, an analysis was [published](#) in the American Journal of Respiratory and Critical Care Medicine² that did not find a higher risk of incident cancer among obstructive sleep apnea (OSA) patients who used a Philips Respironics PAP device as compared to OSA patients who used a PAP device from other manufacturers, or OSA patients without treatment. The analysis and conclusion were based on data from a large multicenter cohort study involving 6,900 OSA patients on PAP devices between 2012 and 2020, including 1,200 Philips Respironics PAP users. Philips Respironics was not involved in the study or the analysis.

² Kendzerska, Tetyana et al, An Association between Positive Airway Pressure Device Manufacturer and Incident Cancer? A Secondary Data Analysis; American Journal of Respiratory and Critical Care Medicine, 2021, Volume 204, Issue 12 pp. 1484–1488

4. Ventilator updates

In response to the steps we are taking around the remediation of mechanical ventilators, we will be creating a [ventilation-specific news and updates page](#) on the information hub. This will include the latest updates related to ventilation.

As we continue to make progress on ventilator remediation in the coming months, please note that we may also share separate communications updates to your ventilation patients. We will continue to provide regular updates to you through this process.

5. Recent communications to your OSA patients

While we work to provide your patients with a replacement device as quickly as possible, we are also committed to ensuring transparency throughout the remediation process. We want your patients to understand how we're handling the recall and know what to expect, that they feel informed about each step of the remediation process, and confident in their new device.

To that end, we have created a [step-by-step pathway](#) on the information hub to help make it simpler for OSA patients to understand the remediation process.

This step-by-step pathway is intended to act as a process map and allowing your OSA patients to identify what steps Philips is taking to remedy devices. A patient reviewing the infographic should be able to say, "I've completed these steps, and now I know what to expect next."

Thank you for your continued patience and trust. If you have any questions, or would like more information on the content provided, please reach out to your Philips sales representative.



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