PHILIPS

Sleep and Respiratory Care Bulletin #3

April 2022

We know how important it is for you and your patients to be informed on all aspects of their sleep and respiratory 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 field safety notice: Visit our Clinicians information page.

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.

Our aim is to complete the repair and replacement program by the end of 2022. We keep increasing our repair capacity worldwide which will further increase our monthly output. To minimise impact on our product plans and overall timeline, we continue to encourage customers and their patients to finalise registration as soon as possible.

2. American Journal of Respiratory and Critical Care Medicine (AJRCCM) Independent study

Independent of Philips Respironics, in December 2021, an analysis was published in the American Journal of Respiratory and Critical Care Medicine[1] 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.

1. 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

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3. Home ventilator updates

We recently received the FDA's conditional approval to remediate the Trilogy 100 and 200 devices affected by the field safety notice. We are now preparing ourselves to begin the remediation process for the Trilogy 100 and 200.

In addition, as we focus on providing clear and transparent communications with our customers, you may see additional updates in the coming months.

We will ensure that you receive timely information on all the measures we take and the progress we make. These communications will be shared via this monthly letter or via additional letters as applicable.

4. Recent communications to your OSA patients

While we work to provide your OSA 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 field safety notice 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 remediate devices. A patient reviewing the step-by-step pathway 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 account manager.

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