PHILIPS

Sleep and Respiratory Care Bulletin #7

November 2022

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

We are committed to supporting clinicians through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients. 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. Be sure to visit our clinician information page regularly for the most current information for you and your patients.

1. New leadership focused on improving remediation execution

On October 15th, Roy Jakobs was appointed the President and CEO of Royal Philips. His priority is to improve execution to ensure we're doing all we can to help you and your patients. Delivering on this requires us to urgently improve things where it has not met your expectations. This includes further strengthening our patient safety and quality initiatives, to ensure we're doing all we can to help you.

2. Manufacturing progress

We have tripled our production capacity compared to pre-FSN[1] levels and at the end of September, approximately 700,000 replacement devices and repair kits had been produced for Western Europe . We are on track to meet our goal of completing around 90 percent of the production of replacement devices to customers in 2022. Find the latest update **here**.

3. Are there any updates with regard to patient safety and risk related to the Field Safety Notice?

In December 2021, we provided an update specifically relating to the test results and assessment of the Volatile Organic Compound (VOC) emissions of the first-generation DreamStation devices, which represent the majority of the affected devices. At that time, those results to date determined that exposure to the level of VOCs for these first-generation DreamStation devices is not typically anticipated to result in long-term health consequences for patients. It is important to note however, that the overall guidance for physicians and patients in the Field Safety Notice remains unchanged. Testing continues on the DreamStation 1 and other devices affected by the Field Safety Notice: an update has been published in June 2022 and we will continue to publish updated results as they become available.

1. FSN: Field Safety Notice

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Independent of Philips Respironics, in December 2021, an analysis was **published** in the American Journal of Respiratory and Critical Care Medicine that did not find a higher risk of incident cancer among obstructive sleep apnoea (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.

In May 2022, an analysis was **published** online in the European Respiratory Journal that concluded that sustained and adherent CPAP therapy of OSA using Philips Respironics devices, compared with other manufacturers' devices, was not associated with an increased risk of cancer after a median follow-up time of 7.2 years. The analysis and conclusion were based on data from a large multicenter cohort study involving 4,447 OSA patients on CPAP devices between 2007 and 2018, including 1,648 Philips Respironics CPAP users. Philips Respironics was not involved in the study or the analysis.

4. New Patient Information Service Material to answer safety related questions

Prof. Dr N. de Vries, ENT specialist with a special interest in OSA, seeks to reassure patients affected by the June 2021 field safety notice issued by Philips Respironics related to a component in a certain number of their sleep apnoea devices. **His critical review** of available major worldwide studies, tracking the health of over 50,000 patients, concludes that there is no statistically significant difference in overall cancer risk associated with the use of Philips Respironics PAP devices containing PE-PUR polyurethane foam when compared with other devices that do not contain PE-PUR foam.

Against the background of this evidence, he further reinforces the importance of continuation of PAP treatment to offset symptoms of OSA and reduce the likelihood of other severe health risks associated with untreated OSA.

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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