Update for patients on Field Safety Notice

August 2022

Philips Respironics Sleep and Respiratory Care devices - FSN 2021-05-A & 2021-06-A.

Dear Patient,

We understand the profound impact the field safety notice regarding certain of our sleep apnea and home ventilation devices has had on patients who are waiting for a remediated device. Progress cannot come quickly enough. Through this monthly patient newsletter, we want to keep you updated on our progress on the remediation effort and also share the latest test and research results, as well as any other updates. We have also included three videos in which I discuss these different topics.

Since announcing the field safety notice, our goal has been to remediate affected devices as quickly as possible. It is a significant task: we need to remediate 5.5 million devices across more than 100 countries. Throughout this process, I know we have not always met your expectations and realise how important it is for you to continue your treatment with confidence.

We sincerely apologise for the uncertainty this field safety notice has created and we are working very hard to resolve the situation.

Ongoing testing and research

Since June 2021, together with certified testing laboratories and other qualified third-party experts, we have been conducting a comprehensive testing and research program to understand potential health risks for patients specifically related to possible emission of particulates and of certain volatile organic compounds (VOCs) from polyester polyurethane foam.

In December 2021, we published research results that indicated that for the DreamStation 1 the volatile organic compounds should not cause any long-term health risks and that the measured levels are within the safety standards. In addition, further research was conducted. We inspected 1,360 DreamStation 1 sleep apnea devices in Europe. None of these devices showed degradation of the sound-abatement foam. This is important and encouraging news.

Additionally, independent and rigorous research was published online in May in the European Respiratory Journal[1] that concluded that the use of Philips CPAP devices, compared to devices of other manufacturers, was

1. Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnoea, European Respiratory Journal 2022, in press (https://doi.org/10.1183/13993003.00551-2022), Grégoire Justeau, Chloé Gervès-Pinquié, Marie Jouvenot, Thierry Pigeanne, Sandrine Launois, Laurene Leclair-Visonneau, Philippe Masson, Acya Bizieux-Thaminy, Sébastien Bailly, Nicole Meslier, Abdelkebir Sabil, Jean-Louis Racineux, Wojciech Trzepizur, and Frédéric Gagnadoux.

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not associated with an increased risk of cancer. Similar studies have been published in Canada and in other countries. You can read a summary and overview of these studies here.

The full results of these tests and epidemiological studies are technical, so we have created a summary of these studies for patients. You can find all patient updates on our website or watch the opposite video in which I explain the results.

Increasing our manufacturing speed

We have a dedicated team of over 1,000 people working directly on device remediation with many thousands more supporting the effort across the company. This has allowed us to more than triple our weekly production output compared to 2020, despite the ongoing global supply chain challenges, and we expect to continue at this pace until the remediation is complete. To date, more than 574,000 repair kits and replacement devices have been produced for Western Europe.

About the foam in the remediated devices

We know how important it is to feel confident that your therapy device is safe to use and have received questions about the foam in remediated devices. The affected devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component. The sound abatement foam in new and recertified CPAP, BiPAP and Trilogy devices is a silicone foam that has met all applicable industry testing standards, including particulate and Volatiles Organic Component (VOC) emissions testing.

A complex task: why this remediation process is different from others

The remediation process we are currently in is a very complex one, because of the very large number of devices, countries and relevant authorities involved and because of external factors such as the lack of certain materials to produce the devices. We created a guide outlining each step of the remediation process, so you can understand how we're handling the field safety notice and what to expect. To learn more about the process, please click here.

We are committed to being transparent with you throughout this process and will continue to share a monthly update by email and on the Information Hub.

We thank you for your understanding.

Dr. Jan Kimpen
Chief Medical Officer, Philips