PHILIPS

Sleep and Respiratory Care Bulletin #5

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 field safety notice: Visit our Clinicians information page.

1. Trilogy 100/200 News

The rework of affected Trilogy 100/200 devices has begun at Philips Service Centers and designated remanufacturing sites. The full remediation process for Trilogy 100/200 repair kits will take approximately 12-14 months to complete.

Customers with registered devices will be contacted in the following weeks with further details of the process, including signing a Recalled Device Services Agreement for Trilogy to authorize customer payment for return and set up as well as the opportunity to clarify where your remediated devices should be shipped, required packaging, serial numbers prepared for return, etc.

2. Independent analysis of health risks

In May 2022, an analysis was published online in the European Respiratory Journal[1] 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.

[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.

3. An update on our approach to 60 Series devices

The approach to Philips Respironics 60 Series devices, most of which are significantly past their warranty period, and their operating life, has been revised. As part of our efforts to ensure that devices outside of their useful life are no longer in use, we are creating alternative ways to support our customers.

Depending on your market, this includes repair and replace or a financial payment to compensate for returned 60 Series devices.

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4. Useful information for your patients

We continue to work to ensure that your patients are provided with information needed to feel confident in using their replacement device, including:

- While recalled devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in all new and recertified devices is a silicone foam which has been allowed for use by the FDA in DreamStation 2 devices.
- All recertified devices include a new blower and air pathway and are cleaned and disinfected.
- The recertified device may show some external cosmetic blemishes and a different manufacturing date than your original device, it has undergone rigorous verification and validation procedures to ensure that standards of safety, performance and quality are met.
- The replacement device's manufacturing warranty has been adjusted accordingly. This warranty covers all labor and materials to repair the replacement device free of charge.