PHILIPS

Sleep and Respiratory Care Bulletin

Philips knows 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 update you on recent developments as well as provide a status update on correction efforts. Please continue to visit our website, Information for Physicians and other medical care providers, for additional information on this Product Correction.*

Overall correction effort status update

In early 2022, Philips provided an update that the current recall action is expected to impact approximately 5.2 million sleep and respiratory devices globally based on registrations so far. To date, globally, Philips Respironics has produced a total of approximately 1.5 million repair kits and replacement devices – of which approximately 750,000 have reached customers – and aims to complete the repair and replacement program globally in the fourth quarter of 2022.

*Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand.

1. Latest patient safety information

At the time the Product Correction was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Since then, additional testing and assessments were performed. Review of this assessment by an outside medical panel and Philips Respironics has determined that exposure due to off-gassing (Volatile Organic Compounds, or VOCs) identified to date for the first-generation DreamStation devices is not typically anticipated to result in long-term health consequences for patients.*

These findings support a better understanding of potential long-term impact on health but do not change the current course of our product correction.

*It is important to note that the tested DreamStation devices were not exposed to ozone cleaning. Additionally, this new assessment is limited to the evaluation of VOCs for first-generation DreamStation devices and does not evaluate the risks of potential foam particulates or cover other devices affected by the recall. Further health risk assessments are ongoing.

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For more information, visit philips.com/SRC-update.

2. What to know about replacement foam

While affected DreamStation devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in all corrected DreamStation devices is a silicone foam.

If your patient has an affected device, we urge that they do not try to remove the foam from their device. This could affect the prescribed therapy.

3. Prioritising correction efforts

To make sure patients with the greatest needs receive a replacement device as timely as possible, we are able to prioritise correction efforts around certain patients upon prioritisation from prescribers. In addition to this prioritisation, the shipment of the repaired or replaced devices happens as inventory is available and Philips collects the information needed to transfer existing therapy settings to the repaired or replaced device.

4. Change of address

Getting corrected devices into the hands of patients as quickly and efficiently as possible is our priority. To do so, it is critical to ensure we have the best address on file for patients who may have relocated since they originally registered for the correction. For this reason, your patients may receive a communication (text message, phone call, letter or email) requesting they confirm their current address just prior to sending their replacement device.* We know that patients must carefully assess the legitimacy of any communication requesting their personal information, and so we are letting you know of this effort in case patients come to you with any questions or concerns about this information being requested again.

*In some cases, patients may be managed by their Homecare Provider and will not receive the communication from Philips.

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