

# 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 remediation efforts. Please continue to visit our website, [Information for Physicians and other medical care providers](#), for additional information on this recall notification\* as it becomes available.

## Overall remediation effort status update

In early 2022, Philips provided an update that the current recall is expected to impact approximately 5.2 million sleep and respiratory devices globally based on registrations so far. To date, 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 in the fourth quarter of 2022.

\*Voluntary recall notification in the U.S. / field safety notice outside the U.S.

## 1. Latest patient safety information

At the time the recall notification 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.\*

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For more information, visit [philips.com/SRC-update](https://philips.com/SRC-update).

[These findings](#) support a better understanding of the long-term impact on health but do not change the current course of our recall. Our most recently updated guidance for all patients can be viewed [here](#); we are continuing the recall efforts as planned.

\*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.

## 2. What to know about replacement foam

While recalled DreamStation devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in all new and remediated DreamStation devices is a silicone foam.\* When we refurbish the affected devices with a new blower and air pathway, we also clean and disinfect them.

If your patient has been affected by this recall, we urge that they do not try to remove the foam from their device. This could affect the prescribed therapy and may void the warranty. We have trained service professionals who can make sure that the affected foam is completely and safely removed and that the new silicone foam is inserted correctly.

\*Excludes Trilogy Evo loaner devices; they are designed with a different foam that has already been cleared for safe use.

## 3. Order processing (U.S. only)

To make sure patients with the greatest needs receive a replacement device as timely as possible, we will be prioritizing remediation efforts around certain patients as requested by the Food and Drug Administration. For US patients whose remediation is directly managed by Philips, data collected throughout the patient registration process will be used to help to prioritize remediation of those patients at higher risk. In addition to this prioritization, the shipment of replacement devices happens as inventory is available and Philips collects the information needed to transfer existing therapy settings to the replacement unit.

In the coming weeks, patients will receive an email that outlines the option to provide additional prioritization information. The types of information you may provide include patient age, history of other health conditions including obstructive sleep apnea (OSA) and its severity, pregnancy status, occupation associated with public safety, history of car accidents related to falling asleep while driving, and use of ozone for device-cleaning purposes.

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#### 4. Change of address

Getting replacement devices into the hands of patients as quickly and efficiently as possible is our top 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 recall. For this reason, your patients may receive an 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.

\*Only patients managed directly by Philips will receive a confirmation email; patients managed by their home care provider may not receive this.

#### 5. Receiving repaired / replacement devices

Providing patients with safe and high-quality therapy devices is our primary focus. Upon receipt of the affected device, in accordance with our repair and replacement process, we replace the sound abatement foam and associated air pathway blower with brand new parts. We will then thoroughly clean and decontaminate the device air pathway, update the firmware, test, and repackage it with a "refurbished" sticker to show that it is ready for use. By working with your patient to ensure they return their original device, you can help to make sure that it can be repaired for future use by another patient.



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