

## Sleep and Respiratory Care Bulletin #2

March 2022

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 continue to visit our website, [Information for Physicians and other medical care providers](#), for additional information on this field safety notice as it becomes available.

### 1. Safety of the replacement foam

Providing patients with safe and high-quality therapy devices is our primary focus. We want your patients to feel confident that their therapy device is safe to use. 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<sup>1</sup>.

When we rework affected devices that have been examined and in good working order, we replace the sound abatement foam and associated air pathway blower with brand new parts. We also thoroughly clean and disinfect them.

Please remind your patients not to try to remove the foam from their device. This could affect the prescribed therapy and devices damaged due to attempts to remove the sound abatement foam will not be able to be remediated. 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.

### 2. Cleaning guidance

Your patients need to be confident they are cleaning their device properly. For detailed information about caring for replacement devices, your patients are urged to refer to the device's User Manual and Accessory Cleaning and Inspection Instructions that come with the device. It is important that they use only the cleaning methods approved for their device, as unapproved cleaning methods<sup>2</sup> such as ozone may contribute to foam degradation.

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1. Excludes Trilogy Evo loaner devices, they are designed with a different foam

2. Please note that both ozone and UV light cleaning products (including the Philips UV Light Sanitizer Box) are not currently approved cleaning methods for ur devices or masks and do not remediate the current recall. Please refer to the FDA safety communication issued on February 27, 2020 and titled "Ozone and UV light: Potential Risks associated with the use of ozone and ultraviolet (UV) light for cleaning CPAP machines and accessories" for more information. The communication indicates that devices claiming to clean, disinfect or sanitize CPAP machines using ozone gas or UV light have not been FDA authorized.

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

To effectively complete the recall all affected devices must be remediated regardless of the cleaning method used. Please refer to the June 2021 FSN on the [philips.com/src-update](https://philips.com/src-update) page to determine if your patients' devices are affected by this recall.

### **3. DreamStation 2 Auto CPAP Advanced: Information for your patients who have received a DreamStation 2 as a replacement for their existing CPAP device**

We understand that adjusting to a new therapy device does not happen overnight and can raise questions from your patients or feel stressful. The new device will have been set to comparable prescription settings and ready for use by your clinician. Even so, if your patients are accustomed to using a DreamStation CPAP device and have received a DreamStation 2 Auto CPAP Advanced, they may notice some differences.

The DreamStation 2 Auto CPAP Advanced was designed with patient comfort in mind, and to provide a simplified user experience.

- **Ramp Plus starting pressure**

Ramp Plus offers flexibility in allowing the patient to pick a comfortable starting pressure when falling asleep. Unlike the DreamStation CPAP device, the DreamStation 2 Auto CPAP Advanced device features the Ramp Plus functionality where the patient can select a comfortable start pressure. This set pressure will be delivered constantly for a given period of time (default 30 min) unless an event is detected where the pressure will automatically increase as needed. After the Ramp Plus time has concluded, the pressure will then return to the prescribed pressure.

Once set, the device will automatically start at the selected Ramp Plus pressure with all future therapy sessions. Your patient no longer needs to tap a Ramp button every night to start at the desired pressure. This means they can set the Ramp Plus pressure once and there is no need to restart/activate it each night. Even, Auto ON is enabled so that all they have to do is put their mask on and start breathing.

[Click here](#) for more information on Ramp Plus.

- **Adaptive Humidification**

Fully integrated and adaptive, the humidification automatically adjusts the humidifier heater plate temperature to maintain a constant level of relative humidity in a patient's mask. The device uses adaptive humidification when a water chamber is attached. Once humidification is set, it will be saved and automatically activated for future therapy sessions, with the ability to also adjust heated tube temperature settings.

If you have any questions, or would like more information on the content provided, please reach out to your Philips account manager.



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