PHILIPS

Sleep and Respiratory Care Bulletin #11

We are committed to supporting clinicians through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients. 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. Be sure to visit **our clinicians information page** regularly for the most current information for you and your patients.

1. Update on completed testing for first-generation DreamStation devices

On December 21, 2022, Philips Respironics announced that based on the comprehensive testing and analysis that we have done over the past 18 months – working with 5 independent certified laboratories, as well as third party experts and physicians – we now have a complete set of results for the first-generation DreamStation devices.

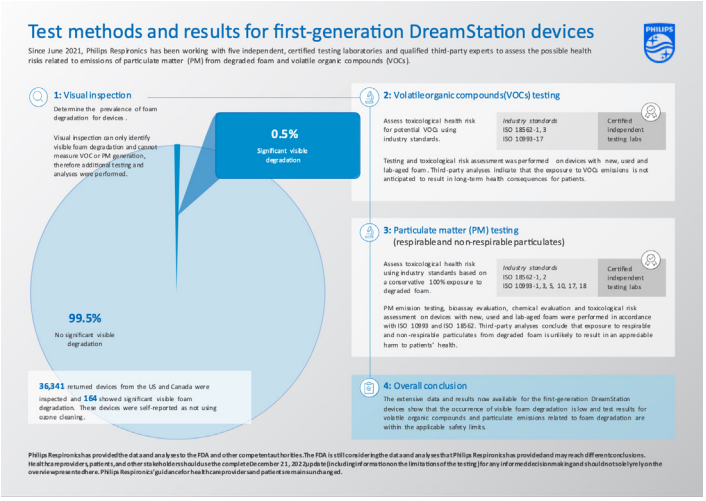
We had already communicated earlier that our visual inspection results to date indicate that the prevalence of visible foam degradation is low, and that test results for volatile organic compound and particulate emissions for both new and used first-generation DreamStation devices are within the applicable safety limits.

This latest third-party chemical evaluation and toxicological risk assessment of degraded foam concluded that for the first-generation DreamStation devices, exposure to foam particulates is unlikely to result in an appreciable harm to health in patients.

We understand you and your patients may have questions about these latest findings, and we want to ensure you feel confident answering them.

Register to view an on-demand webinar **here**.

Updated reports and resources can be viewed **here**.



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2. Useful information for your patients

Ensuring the safety of replacement devices: We understand recalling your patients' CPAP, BiPAP or ventilator device may make them question whether their replacement device is safe to use. We want patients to feel confident in using their new device and the steps we take to ensure their safety. We've added a **new video** to our replacement device safety information page, which highlights the differences between the foam used in affected vs. new or recertified devices, how we replace device parts and how we address cosmetic blemishes.

3. Auto-CPAP Remediation Program

As Philips Respironics progresses through the recall, there is a population set of exception patients for which we have not been able to obtain prescription information as of yet and thus cannot send a replacement device. We continue to look for and develop a way to ensure remediation for all patients.

With that goal in mind, Philips Respironics, in consultation with our medical team, will be starting an Auto CPAP remediation program on registered devices for your patients that do not have a DME registration or valid prescription settings in Care Orchestrator. Patients will be advised to contact you, as their physician, to discuss whether Auto CPAP mode is appropriate and ensure that the pressure settings are correctly adapted to their therapy needs.

Eligible devices, sent with a setting range of 4-20 cmH2O and the OptiStart feature enabled, will include System One 50 Series CPAP/Auto CPAP, System One 60 Series CPAP/Auto CPAP and DreamStation CPAP/Auto CPAP.

Additional information on the Auto CPAP program can be found **here**.

For more information, visit Philips.com/src-update