PHILIPS

Sleep and Respiratory Care Bulletin #11

We are committed to supporting clinicians through the correction* process and will provide 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 correction efforts as they become available. Please find below some recent information that we wanted to bring to your attention. Be sure to visit our Australian clinicians information page regularly for the most current information for you and your patients.

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

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

On 21 December 2022, Philips Respironics announced that additional test results and assessments had been completed for the first-generation DreamStation devices. These tests were conducted over a period of 18 months working with five independent certified laboratories, as well as third party experts and physicians.

Philips Respironics had already communicated earlier that the 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.

(continued on next page)

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

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

By clicking the link below you are now accessing a website of Philips RS North America LLC, the legal manufacturer. Information on that site is provided and verified by Philips RS North America LLC only.

Register to view an on-demand webinar here.

Updated reports and resources can be viewed here. This includes the latest testing update published by Philips Respironics on 21 December 2022.

2. Useful information for your patients

Ensuring the safety of replacement devices: We understand correcting 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. Our replacement device safety information page highlights the differences between the foam used in affected devices vs. replacement devices which contain the new silicone foam.

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