PHILIPS

Sleep and Respiratory Care Bulletin #8

January 2023

Field Safety Notice: 2021-05-A & 2021-06-A.

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 clinician information page regularly for the most current information for you and your patients.

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

Based on the comprehensive testing and analysis that we have done over the past 18 months – working with five 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.

- **Philips Respironics has provided the data and analyses to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach different conclusions.**
- **Healthcare providers, patients, and other stakeholders should use the complete update, including information on the limitations of the testing, for any informed decision making and should not solely rely on the overview presented here.**
- **Philips Respironics' guidance for healthcare providers and patients remains unchanged.**
- **Philips Respironics will continue with the remediation program.**

We understand you, and your patients, may have questions about these latest findings, and we want to ensure you feel confident answering them.
An on-demand video is available **here**.

As mentioned in past bulletins, we are committed to providing additional data as it becomes available from on-going third-party testing in a more user-friendly version for patients. The summary document can be downloaded **here**.

(continued on next page)

For the most current information, visit our clinician information page
philips.com/src-clinician-update

2. CPAP/BiPAP Remediation Update

At the end of 2022, we have approximately 90 percent of 5.5 million replacement CPAP and BiPAP devices produced and shipped globally. Find the latest update for your specific country **here**. Your patients who are still waiting to receive their replacement device can expect to continue hearing from us as we work through some of the more complex challenges of the remediation, including ongoing efforts around communicating specific actions for patients who use System One and DreamStation Go.

3. Update to Trilogy 100/200 repairs

Following the preparations and relevant clearances, the repair of Trilogy 100/200 ventilators (approximately 3% of the registered affected devices globally) has started in recent months. To date, we have remediated a limited number of registered Trilogy devices.

Philips Respironics has detected two issues with these corrected Trilogy 100/200 ventilators following a limited number of complaints. Post market surveillance data indicate that silicone sound abatement foam installed in reworked Trilogy 100/200 devices may potentially separate from the plastic backing to which it is adhered. Separation of the foam could impact the performance of the device by potentially blocking the air inlet and thus lowering the inspiratory pressure.

This issue only affects the Trilogy 100/200 ventilators that have already been repaired. Additionally, Philips Respironics has observed residual PE-PUR sound abatement foam in some devices that were returned to the field. These cases were limited but further exposure to PE-PUR sound abatement foam should be avoided. These problems do not affect any of the DreamStation CPAP or BiPAP sleep apnea devices that have been remediated and distributed to patients or homecare providers.

While Philips Respironics works to resolve these issues, the company has temporarily suspended the repair of Trilogy 100/200 devices. Patient safety is our top priority, and we are steadfast in our commitment to quickly investigate, identify and address any potential corrections.

For more information regarding these identified issues, and to understand the actions you need to take, please visit the **dedicated webpage**. We will provide you with additional information as it is available.

4. Ensuring the safety of your patient's replacement device

Your patients may have questions regarding if their replacement CPAP/BiPAP device is safe to use. A short video has been added to the **patient device safety information page** for patients to understand the differences between the foam used in the affected versus new or recertified devices, how we replace device parts and how we deal with any cosmetic blemishes.

Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.

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