PHILIPS

Sleep and Respiratory Care Clinical Bulletin #14 – 16

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 updates below.

PE-PUR Foam Product Correction* News and Updates

1. Update from Philips Respironics on completed set of test results for CPAP/BiPAP sleep therapy devices.

16 May 2023 Testing Report

Building on past reports, the risk assessments have now been completed by Philips RS North America LLC (**Philips Respironics**) for the CPAP/BiPAP sleep therapy devices, including the first-generation DreamStation, System One and DreamStation Go devices. These devices represent approximately 95% of the registered devices globally. The assessments built on the December 2021, June 2022 and December 2022 reports. Additionally, tests and analyses have been completed for first-generation DreamStation devices that have been exposed to ozone cleaning.

Philips Respironics has stated that, the completed set of test results and analyses for the CPAP/BiPAP sleep therapy devices indicate that potential patient exposure to foam particulates and volatile organic compounds (VOCs) from the polyester-based polyurethane (PE-PUR) foam within the breathing gas pathway of these devices is unlikely to result in an appreciable harm to health in patients. The test and research program has been conducted together with five independent, certified testing laboratories, and the results have been reviewed and assessed by third-party qualified experts and Philips Respironics, as well as an external medical panel.**

Click here for a copy of the 16 May 2023 testing results released by Philips Respironics.

By clicking the link above you are now accessing information of Philips RS North America LLC, the Legal manufacturer. Information on that site is provided and verified by Philips RS North America LLC only.

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*Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand.
**This information has not been separately verified by Philips Electronics Australia Ltd.

24 July 2023 Testing Report

Philips Respironics has also released the latest results and conclusions on the comprehensive test and research program to assess potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in specific sleep therapy and ventilator devices under the voluntary June 2021 recall/field safety notice. Philips Respironics has stated as follows:

The impact of ozone cleaning on foam degradation in System One and DreamStation Go sleep therapy devices:

- Exposure to VOC emissions from the assessed devices treated with ozone cleaning is unlikely to result in an appreciable harm to health in patients.
- Exposure to PM emissions from the assessed devices treated with ozone cleaning is unlikely to result in an appreciable harm to health in patients.

Additional visual inspection of the foam in used first-generation DreamStation devices from the US and Canada confirms the low prevalence of significant visual foam degradation:

- An additional analysis using an algorithm to assess collected images of foam within a representative random sample of 100,000 used devices from the US and Canada (devices were selected to represent different manufacture dates) showed that 2,011 devices (~2%) were identified as having significant visual degradation/volume reduction.
- A comparison of ozone use among these devices found that devices for which the user self-reported ozone use were approximately 17 times more likely to have significant visual foam degradation/volume reduction (1,368 out of 14,971 or 9.1%) than those where the user reported no ozone use (357 out of 68,702 or 0.5%).

Click here for a copy of the 24 July 2023 testing results released by Philips Respironics.

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Philips Respironics has provided the completed set of test results and analyses for the CPAP/BiPAP sleep therapy devices 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 16 May 2023 and 24 July 2023 testing updates (including information on the limitations of the testing) for any informed decision making and should not solely rely on the overview.

Completion of the test and research program, as well as the remediation program remain Philips Respironics' highest priorities. Philips Respironics' guidance for healthcare providers and patients using devices that have not been remediated yet, remains unchanged.

Patients who have not yet registered their sleep therapy device are requested to do so to facilitate the correction of their device.

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What can you do to assist in progressing the correction?

1. Ask your patient to check if their device has been registered for the correction. This is via the link on www.philips.com/src-update. If their device is not registered, request them to do so.
2. Encourage your patients to provide device settings promptly in response to Philips' request for this information.
3. We recommend that you check in with your patient after they receive their replacement device. Upon using their device, if patients feel the settings are different, we recommend they reach out to their prescriber for support or contact Philips on the number 1800 830 517 in Australia (toll-free) or +61 2 9151 0289 in New Zealand.

2. Patients to hear from David Ferguson, Global Business Leader, Sleep and Respiratory Care, Philips Respironics.

Recently, David Ferguson, shared an update with patients on the changes that have been put in place to reinforce patient safety, an overview of recent test results, and what they can expect from Philips Respironics in the future. Click here to review the update.

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Useful links

PE-PUR Foam Product Correction* News and Updates for Clinicians

Be sure to visit our Australian clinicians information page regularly for the most current information for you and your patients.

Patients may still have questions about the correction process or may need additional support once they have received their replacement device. We have recently created our Contact and Support page to help patients quickly and easily find the support they need.

Masks and Magnets Updates

Do you have additional questions about Philips Respironics masks and magnets? Learn more, here.

Ventilation Updates

For the latest ventilation news and updates, please visit this page.

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

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