PHILIPS

Sleep and Respiratory Care Bulletin #10

We are committed to supporting clinicians through the complete 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. Please find below some recent information that we wanted to bring to your attention. Be sure to visit our Australian clinician's 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. CPAP/BiPAP Correction Update

Philips Australia expects to have completed the replacement program by the end of 2022 for the majority of devices where, by 12 December 2022, patients (1) registered a device type listed below; and (2) provided their device settings preference to Philips. The device types are:

- DreamStation CPAP, Auto CPAP and Auto BiPAP
- DreamStation ASV
- DreamStation AVAPS
- System One CPAP, CPAP Auto and BiPAP Auto (50 and 60 Series)
- System One ASV4 (50 and 60 Series)
- C Series S/T and AVAPS
- A-Series BiPAP (A40 and A30)

For patients who registered their DreamStation Go, Philips Australia commenced the replacement program for DreamStation Go devices in December 2022 and it will continue into Q1 2023.

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

2. Update to Trilogy 100 repairs

Following the preparations and relevant clearances, the repair of Trilogy 100 ventilators (approximately 0.5% 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 ventilators following a limited number of complaints.

Post market surveillance data indicate that silicone sound abatement foam installed in reworked Trilogy 100 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 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 apnoea 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 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 click here. We will provide you with additional information as it is available.

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