PHILIPS

Sleep and Respiratory Care Bulletin #10

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. CPAP/BiPAP Remediation Update

As we approach the end of 2022, we expect to have approximately 90 percent of 5.5 million replacement CPAP and BiPAP devices produced and shipped globally. 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:

1. Helping patients without a Durable Medical Equipment (DME) provider or device connectivity move forward in the remediation process.
2. Connecting with yourselves to obtain their prescription information.
3. Communicating specific actions for patients who use System One and DreamStation Go.

2. 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.

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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 read the complete Field Safety Notice here.** We will provide you with additional information as it is available.

An on-demand video on the Trilogy 100/200 repairs can be viewed **here**.

3. Phone numbers for you and your patients

Philips has available several phone lines that are for both you and your patients to be able to utilize whenever questions may occur. Please share these numbers with your patients if needed.

	Audience	Phone Number
Recall Registration Questions	DME, Patient	1-877-907-7508
Recall Post Remediation Questions	Patient	1-833-262-1871
Prescription Assistance	Physician, Patient	1-888-511-2797
Mask Magnet Recall	DME, Patient	1-877-387-3311
General Complaints	DME, Patient	1-800-345-6443

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