PHILIPS

Sleep and Respiratory Care Clinical Bulletin #12 – 13

In this bulletin, you'll notice that along with news and updates on the Philips Respironics PE-PUR foam product correction*, we will also explore topics related to ventilation devices and masks with magnets. Please find updates below.

PE-PUR Foam Product Correction* News and Updates

1. Dr. Jan Kimpen, Senior Medical Advisor, Royal Philips answers key questions from patients

As we continue to make progress on shipping replacement devices, Philips Respironics caught up with Dr. Jan Kimpen, to explore some of the most common questions Philips Respironics are hearing from patients, from device safety to the latest testing and research results.

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

Questions and answers provided by Philips Respironics can be found here.

Ventilation News and Updates

2. Trilogy Evo Platform of Ventilators Urgent Product Defect Correction in Australia (Recall for Product Correction in New Zealand)

In March and April 2023, following consultation with the Therapeutic Goods Administration (TGA) and Medsafe, Philips Australia and New Zealand announced an Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand for Trilogy Evo, Trilogy Evo 02 and Trilogy EV300 (together the **Trilogy Evo platform of ventilators**).

With regard to the Trilogy Evo platform of ventilators, Philips Respironics has identified two problems that could pose a risk for patients if not mitigated:

- **Accuracy of FiO2 Delivery** in Trilogy EV300 and Trilogy Evo O2 devices
- **Environmental Contamination of Device Sensor** in Trilogy Evo, Trilogy Evo O2 and Trilogy EV300 devices

The Urgent Product Defect Corrections provide important information for the continued use of the Trilogy Evo platform of ventilators. If you require a copy of these correction notifications, please contact Philips on 1800 830 517 in Australia (toll-free) or + 61 2 9151 0289 in New Zealand.

Please note, Philips Respironics recommends, when the mitigating actions specified in each applicable Trilogy Evo platform of ventilators Urgent Product Defect Correction notifications are taken, the Trilogy Evo continues to be an alternative for Trilogy 100 devices. Trilogy 100 devices are impacted by an issue related to sound abatement foam.

We encourage you to visit this page for more information.

To learn more please visit the ventilation page.

(continued on next page)

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

Masks with Magnets News and Updates

Following our communications in September 2022 announcing updated instructions and labelling of specific sleep therapy masks that contain magnetic headgear clips, a study on masks with magnets has been released in the Journal of Clinical Sleep Medicine and can be found on the JCSM website here.

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.

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