

Philips Respironics Medical Device Field Safety Notice Information

Support, at every step of the way

While we work to provide replacement devices as quickly as possible, we want to share the steps we are taking to ensure your replacement device is safe to use so you can be confident in your new device.



- While affected devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in all new and recertified devices is a silicone foam that has met all applicable industry testing standards, including particulate and Volatiles Organic Component (VOC) emissions testing, and is authorized as part of our remediation.
- All recertified devices include a new blower and air pathway and are cleaned and disinfected.
- While your recertified device may show some external cosmetic blemishes and a different manufacturing date than your original device, it has undergone verification and validation procedures to ensure that applicable standards of safety, performance and quality are met.
- Your device's manufacturing warranty has been adjusted to cover all labor and materials to repair your replacement device free of charge.
- All replacement devices will include a label at the bottom showing REV15 or higher. This indicates that the device has been remediated and includes silicon foam and that is safe to use.



Regular device cleaning and maintenance is important for your therapy

- We want you to be confident you are cleaning your device properly. For detailed information about caring for replacement devices, please refer to the device's User Manual and Accessory Cleaning and Inspection Instructions that come with the device.
- It is important that you use only the cleaning methods approved for your device. Ozone and UV light cleaning products are not currently approved cleaning methods for sleep apnea devices or masks and should not be used. Please also refer to the FDA safety communication titled: "Ozone and UV light: Potential Risks associated with the use of ozone and ultraviolet (UV) light for cleaning CPAP machines and accessories."



Need further assistance?

Please contact the Philips Customer Service team directly at +34 900 831 781 for more assistance.