

Sleep and Respiratory Care Bulletin #4

May 2022

Field safety notice: 2021-05-A & 2021-06-A.

We know how important it is for you and your patients to be informed on all aspects of their sleep therapy and treatment. 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. We invite you to consult our website regularly to keep informed of updates and for additional information on this field safety notice: [Visit our clinician information page](#).

1. Biocompatibility testing results

At the time the field safety notice was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Since then, Philips Respironics has worked and will continue to work with independent partners to conduct extensive testing and analysis of results on affected devices, including biocompatibility evaluations.

[Visit this dedicated page](#) to access available testing results and third party confirmed conclusions on and findings from testing PE-PUR foam used in affected devices for volatile organic compounds (VOCs), particulate matter (PM), and other testing.

Please check this page for updates frequently as we will add new testing results documents as they become available.

The overall guidance for healthcare providers and patients in the field safety notice remains unchanged at this time.

2. Cleaning Guidance

Your patients need to be confident they are cleaning their device properly. For detailed information about caring for replacement devices, your patients are urged to refer to the device's User Manual and Accessory Cleaning and Inspection Instructions that come with the device. **It is important that they use only the cleaning methods approved for their device**, as unapproved cleaning methods¹ such as ozone may contribute to foam degradation.

1. Please note that both ozone and UV light cleaning products (including the Philips UV Light Sanitizer Box) are not currently approved cleaning methods for our devices or masks and do not remediate the current recall. Please refer to the [FDA safety communication](#) issued on February 27, 2020 and titled "Ozone and UV light: Potential Risks associated with the use of ozone and ultraviolet (UV) light for cleaning CPAP machines and accessories" for more information. The communication indicates that devices claiming to clean, disinfect or sanitize CPAP machines using ozone gas or UV light have not been FDA authorized

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To effectively complete the field safety notice ALL affected devices must be remediated regardless of the cleaning method used. Please refer to the June 2021 field safety notice on the philips.com/src-update page to determine if your patients' devices are affected by this field safety notice

3. Home ventilation updates

We recently received several competent authorities' authorisation to remediate the Trilogy 100 and 200 devices affected by the field safety notice. The full remediation process for Trilogy 100/200 repair kits will take approximately 6 to 7 months to complete.

Bacteria Filter or your patients on mechanical ventilators:

- We want to make sure as many patients as possible can continue with therapy. In circumstances where you determine that a patient should continue use of a registered affected Trilogy 100/200 and BiPAP A30/A40, Philips offers bacteria filters² to reduce exposure to sound abatement foam particulate in conjunction with the advice of a physician.
- Bacteria filters should be used in accordance with the affected device's Instructions for Use (IFU). While use of such filters may reduce exposure to degraded sound abatement foam particles, bacteria filters will not reduce exposure to potential volatile organic compounds ("VOCs").

In addition, the field safety notice provided us the opportunity to take a more comprehensive review of our products. As we optimise our processes and solutions, you may see additional updates, such as the information on the recent BiPAP A40 Pro and EFL software release and information on use of bacteria filters.

We want to make sure that you receive timely information on all the measures we take and the progress we make. If you have any questions, or would like more information on the content provided, please reach out to your Philips account manager.

2. Philips will provide customers who have registered recalled Trilogy 100/200 models on philips.com/src-update with inline bacteria filters to help them provide safer care for patients whose treating physicians advised that they continue therapy on affected devices. Customers who choose to opt-in to the program are eligible to order one (1) pack of inline bacteria filters (includes ten (10) filters) for each registered Trilogy 100/200 device for each ten-day period until that device is remediated. Please note, customers must first register recalled devices at philips.com/src-update indicating their patient will continue to use affected devices.

Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.



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