PHILIPS

# Sleep and Respiratory Care Bulletin #4-7

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. 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.

## Information from Philips Respironics

Philips Australia notes that the device manufacturer, Philips RS North America LLC (Philips Respironics), has periodically released on its US website communications (Clinical Bulletins) for physicians on recent developments as well as provide a status update on remediation efforts. The full set of Clinical Bulletins are available on the Philips RS North America Website here.

The information below in relation to device testing has been adapted from Clinical Bulletins #4, #5, #6 and #7 released by Philips RS North America (available in full at the website above). In addition, on 21 December, 2022 a further update relating to test results for first-generation DreamStation sleep therapy Electronics was released by Philips RS North America. The testing information referred to in this Bulletin and on the Philips Respironics site has not been separately verified by Philips Electronics Australia.

Further information in relation to device testing is also available on the following webpages maintained by Philips Respironics:

- US testing results webpage for patients
- US external studies summary webpage for patients

Please note that the Philips Respironics North America website also contains information specific to the CPAP, BiPAP and mechanical ventilator device recall in the USA, which may be different to and not relevant for Australia. This information has not been separately verified by Philips Electronics Australia.

## Biocompatibility testing results

At the time the product correction was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Since June 2021, together with certified testing laboratories and other qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope potential patient health risks related to possible emission of particulates from degraded foam and certain volatile organic compounds (VOCs).

*(continued on next page)*

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

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

Please check this page for updates frequently as new testing results documents are added by Philips Respironics as they become available.

## Independent analysis of health risks

In May 2022, an analysis was published online in the European Respiratory Journal** that concluded that sustained and adherent CPAP therapy of OSA using Philips Respironics devices, compared with other manufacturers' devices, was not associated with an increased risk of cancer after a median follow-up time of 7.2 years. The analysis and conclusion were based on data from a large multicenter cohort study involving 4,447 OSA patients on CPAP devices between 2007 and 2018, including 1,648 Philips Respironics CPAP users. Philips Respironics was not involved in the study or the analysis.

** Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnoea, European Respiratory Journal 2022, in press (https://doi.org/10.1183/13993003.00551-2022), Grégoire Justeau, Chloé Gervès-Pinquié, Marie Jouvenot, Thierry Pigeanne, Sandrine Launois, Laurene Leclair-Visonneau, Philippe Masson, Acya Bizieux-Thaminy, Sébastien Bailly, Nicole Meslier, Abdelkebir Sabil, Jean-Louis Racineux, Wojciech Trzepizur, and Frédéric Gagnadoux.

## Summary of Philips Respironics Testing Results available to date

Philips Respironics is committed to providing additional data as it becomes available from the on-going third-party testing such that healthcare providers have updated information to make informed decisions regarding the risk of continued use of affected products. An updated summary can be viewed/downloaded at the dedicated Testing Results page.

## Supporting patients with testing summaries

As mentioned in past bulletins, Philips Respironics is committed to providing additional data to the professional community as it becomes available from studies and testing. Philips Respironics has released 2 new documents.

- An independent systematic literature review of epidemiological studies to evaluate whether use of Continuous or Bilevel Positive Airway Pressure (PAP) devices increases the risk of cancer in obstructive sleep apnea (OSA) patients.
- Third-party testing results from the June 28, 2022 summary.

## Our approach to the correction

When we issued the voluntary recall/voluntary field safety notice***, we immediately focused our efforts to respond to this issue as quickly as possible. We expanded our production shifts, service and rework and replacement capacity in applicable manufacturing sites and intend to maintain this expansion until the correction program is completed. We are not currently selling these products and all corrected devices should be allocated to patients affected by the voluntary recall/field safety notice***.

*** Voluntary recall notification in the US and Australia /field safety notice for the rest of the world.

We thank you for your continued patience and trust and will continue to provide updates to you through this process.

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