

# External studies summary of the risk of cancer for Philips Respiroics users was not higher compared to other brands

In June 2021, Philips Respiroics issued a field safety notice for specific CPAP and BiPAP devices due to an issue related to the polyester-based polyurethane (PE-PUR) foam that is used to decrease the sound within the devices. The foam may degrade into particles that might enter the device and then possibly be ingested or inhaled. It had been originally thought that volatile organic compounds (VOCs) may have been emitted, which after additional testing has been found to have no harm to health.

Healthcare providers have been reviewing their patient databases to determine if anyone who had used a Philips Respiroics PAP device have increased health issues, including cancer. Analysis from Canada<sup>1</sup> and France<sup>2</sup> that included about 13,000 patients, compared the incidence of cancer in those that were treated with a PE-PUR foam device versus a non-PE-PUR foam device. **In these two publications, the risk of cancer for Philips Respiroics users was not higher compared to other brands.**

As part of our commitment to supporting our patients and sharing further detail and clarity on the latest research and analysis, below we have provided a brief summary of each of these studies:

## **An Association between Positive Airway Pressure Device Manufacturer and Incident Cancer? A Secondary Data Analysis**

Tetyana Kendzerskam MD., et al, *Journal of Respiratory Critical Care Medicine*

Dr. Tetyana Kendzerska and colleagues did not find a higher risk of incident cancer among patients with obstructive sleep apnea (OSA) who had a Philips Respiroics CPAP device compared to those who had devices from other manufacturers. The researchers used data from 6,903 patients in the province of Ontario who purchased a positive airway pressure device since 2012 and who were free of cancer at the start of OSA treatment. Over an average follow-up of 7.5 years, 5.4% of patients developed cancer. There were no significant differences in incident cancer between different PAP device manufacturers, including ResMed and Fisher&Paykel, compared to Philips Respiroics.<sup>1</sup>

## **Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnoea** Gregoire Justeau, MD., et al, *European Respiratory Journal*

In the study from France, Dr. Gregoire Justeau and associates reported that sustained CPAP therapy of OSA using Philips Respiroics devices containing PE-PUR foam, was not associated with an increased risk of cancer after an average follow-up time of 7.2 years. The group analysed data from 4,447 patients who had not been diagnosed

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with cancer at the time of their sleep study or within 1 year afterwards. Using Philips Respironics devices was not associated with all-cancer frequency compared to using devices from other manufacturers. Additionally, the use of Philips Respironics devices was not associated with new cases of lung cancer.<sup>2</sup>

**There are 11 other studies that provide minimal additional insights, but show there is no increased risk of cancer when using a CPAP device.**<sup>3-14</sup>

Philips Respironics is committed to further testing and reporting as we work through the repair and replacement program for affected CPAP, BiPAP and mechanical ventilator devices.

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

## References

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