

## An update on the Philips Respironics remediation process

November 2022

Philips Respironics Sleep and Respiratory Care devices - FSN 2021-05-A & 2021-06-A.

Dear Patient,

Following our previous outreach, we want to ensure that we are keeping you updated on the remediation program. Read on for an introduction to the priorities of Philips' newly appointed CEO and the latest program updates, including a <u>reminder of key players involved in the remediation program</u>.

## New leadership focused on improving remediation execution

On October 15th, Roy Jakobs was appointed as President and CEO of Philips. His priority is to improve execution to ensure we're doing all we can to help patients.

"I am honored to have been given the responsibility to lead Philips and have started my new job excited and determined to turn things around. I am committed to serving you, the patients who rely on us, to working ever more closely with the doctors, nurses, and healthcare managers we partner with, and to enabling people everywhere to improve their health and well-being.

I am mindful of the pain caused when expected levels of care fall short. The recall notification of our Respironics sleep apnoea devices let down the many patients like you who relied on them, for which I am deeply sorry. I would like to assure you that we remain fully committed to providing a resolution to you as soon as possible."

## **Program update**

While we are making progress on shipping replacement devices, we understand that it is frustrating that you have not yet received your replacement device. Please be assured that we continue to work side-by-side with HCPs to get your remediated device to you. Our plan is guided by patient needs, specifically the prescribed care established between patients and their doctors and fulfilled by Home Care Providers (HCP). A reminder that we developed a helpful guide outlining each step of the remediation process, so you can understand how we are handling the remediation and what to expect. The guide can be found <a href="here">here</a>.

In addition, we continue to work with independent partners to conduct extensive testing and analysis of results on affected devices, including biocompatibility evaluations. The latest published testing results can be found <u>here</u>. We will continue to provide the latest information as new testing results become available.

## Insights from a sleep apnoea specialist

Prof Dr N. de Vries, ENT specialist with a special interest in OSA, seeks to reassure patients affected by the June 2021 field safety notice issued by Philips Respironics related to a component in a certain number of their sleep apnoea devices. His critical review of available major worldwide studies, tracking the health of over 50,000 patients, concludes that there is no statistically significant difference in overall cancer risk associated with the use of Philips Respironics PAP devices containing PE-PUR polyurethane foam when compared with other devices that do not contain PE-PUR foam.

Against the background of this evidence, he further reinforces the importance of continuation of PAP treatment to offset symptoms of OSA and reduce the likelihood of other severe health risks associated with untreated OSA. Please read the full article on following link.

Please continue to visit our information hub for the most current and accurate information.

We thank you for your continued patience and trust.

