

In April 2021, Philips reviewed data on potential health risks involving specific Philips CPAP, BiPAP and mechanical ventilators (to include some Trilogy ventilatory assist devices and all Dreamstation models, except for Dreamstation 2). In June, Philips determined that the sound abatement foam in the affected devices may degrade into particles, or the foam may off-gas certain chemicals, leading to an issuance of a recall of those devices. Philips is working with regulatory agencies to develop a plan to repair or replace the affected models; however, a specific plan to achieve this has not yet been announced. Our understanding is that to date, Philips has not received any reports of patient impact or serious harm as a result of this issue. Given the potential for patient harm, Philips is currently recommending that patients not use the affected devices.

Pulmonary Associates of Fredericksburg believes that it is important for patients who have the affected devices to be able to make an informed decision regarding whether or not to continue using the devices until they can be repaired.

Continued use of the affected devices require acceptance of seemingly low risks to include:

- Irritation of skin, eye and respiratory tract
- Inhalation or ingestion of materials that may increase the risk of developing cancer

Discontinuation of affected devices requires the acceptance of risks associated with untreated sleep breathing disorder to include:

- Heart arrhythmia
- Excessive daytime sleepiness that may increase the risk for automobile accidents
- Increase in blood pressure that may increase the risk of stroke or heart attack
- Increased blood sugar levels in patients with diabetes

PLEASE note: Any other method to clean your machine other than manufacturing recommendation is not recommended and may increase the degradation of the foam insulation.

We encourage you to gather additional information by contacting the recall support hotline or visiting the website: 1-877-907-7508 <http://www.philips.com/src-update>