

Philips device defect correction Patient information

Philips have notified medical regulators around the world of potential issues with the sound abatement foam in a large number of Philips CPAP and Bi-Level PAP devices.

The recalled machines include DreamStation and System One devices that are used to treat obstructive sleep apnoea, as well as Trilogy ventilators. Philips has begun a process to repair or replace affected devices.

The recall is related to foam used in the devices to reduce noise. Over time, the foam may deteriorate and result in the release of black particles which can enter the humidifier, tubing and mask. Inhaling these particles can result in symptoms including headache, eye irritation, asthma, irritation of the airway, nausea or vomiting. Philips reports that in 2020 the number of complaints related to foam particles was low (0.03% or 3 in 10,000 users). Testing by Philips also found that the foam can produce unsafe chemical levels (volatile organic compounds) which are released as gases.

The Therapeutic Goods Administration (TGA) in Australia has issued a product defect correction notice and noted that “To date, there is no definitive evidence of long-term harm and there have been no reported deaths as a result of these issues.” The TGA has also noted that “Stopping treatment suddenly could have an immediate and detrimental effect”.

People with affected devices should:

- Make an appointment with their physician or care provider before making any changes to their prescribed therapy
- Register their device for repair or replacement [online here](#) or call 1800 009 579 (toll-free) Mon-Fri 9:00am – 6:00pm AEST
- Stop using ozone cleaners on their machine if they have been used in the past.

It is not safe for patients to try to remove the foam from affected machines. Do not attempt this.

Links for more information:

- [Information from Philips regarding product defect correction](#)
- [Information from the TGA](#)
- [Information from the Australasian Sleep Association](#)