Field-safety notice by Royal Philips

On 14th June 2021, Philips Respironics issued a medical device recall notification (U.S. only) and field-safety notice (International Markets) for mechanical ventilator devices including continuous positive airway pressure (CPAP), and bi-level positive airway pressure (bi-level PAP) [1]. The firm had also provided a complete list of the affected devices. This was in response to potential health risks related to the sound abatement foam component in these devices.

On behalf of the company, Frans van Houten, CEO of Royal Philips issued a statement in the global press, "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety. In consultation with the relevant regulatory agencies and in close collaboration with our customers and partners, we are working hard towards a resolution, which includes the deployment of the updated instructions for use and a comprehensive repair and replacement program for the affected devices". An industry source confirmed to *BusinessToday (India)* "Following the recall notification issued by Philips in the US market, the Dutch medical equipment company will voluntarily recall impacted machines, including breathing devices and ventilators in India" [2]. They stated that the customers can also call its helpline number 18002587678 for support and more information.

The recall / field-safety notice is related to the type of foam used to reduce the noise made by the devices. Over time, the foam inside the machine may fall apart into black particles. These particles can enter the humidifier, tubing and mask. As a result, one may inhale these particles when using the device. Philips reports that the potential risks include headache, skin or eye irritation and asthma [3]. Testing by Philips also found that the foam can produce unsafe chemical levels. These "volatile organic compounds" (VOCs) are released as gases. Exposure to VOCs may cause problems such as irritation of the airway, headache or dizziness, skin, eye or nose irritation and nausea or vomiting. Philips reports that in 2020 the complaint rate for foam particles was low (0.03%). Philips has received no complaints related to chemical exposure. They also stated that there have been no reports of death.

1. Medical Device recall notification (U.S. only) / field safety notice (International Markets). https://www.usa.philips.com/healthcare/e/sleep/communications/src-update (Accessed on 23rd June 2021)

2. Philips India to recall faulty breathing devices, mechanical ventilators over safety. https://www.businesstoday.in/current/corporate/philips-to-recall-faulty-breathing-devices-ventilators-in-india-over-health-safety-issues/story/441802.html (Accessed on 22nd June 2021)

3. Philips PAP device recall: Guidance for patients. https://sleepeducation.org/philips-pap-device-recall-guidance-for-patients/ (Accessed on 23rd June 2021)