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Philips Respironics Recall Information

On June 23, 2021 the Government of Canada published a recall of Philips Respironics CPAP, Bi-Level Positive Airway Pressure (BiPAP), and Mechanical Ventilators manufactured before April 26, 2021. This action follows a Field Safety Notice in Canada and a Medical Device Recall in the USA. (Tennant, 2021, p.1)

Philips has stated that the concern relates to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips continuous and Non-continuous Ventilators. This PE-PUR foam may degrade into particles which enter the device's air pathway and be ingested or inhaled by the user causing respiratory problems, and the PE-PUR foam may off-gas certain chemicals that may be cancerous with long term exposure. (Tennant, 2021, p.1-2)

The foam degradation may be accelerated by high ambient heat/humidity (i.e. not related to the use of heated humidity attached to the machine) and use of non-authorized cleaning methods (e.g. ozone, ultraviolet). (Ayas et al., 2021, p.2)

The potential risks of degraded foam include irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., liver and kidneys), and toxic carcinogenic effects. (Aya et al., 2021, p.2)

The risks of continued use of recalled devices are uncertain, but the number of complaints for particulate-related issues to the manufacturer has been low (3 per 10, 000 patients in 2020). No deaths have been reported. (Ayas et al., p.3)

There are risks associated with stopping therapy abruptly, especially in patients with significant comorbidities and/or substantial sleepiness and patients being treated for hypoventilation syndromes. These risks include reemergence of daytime sleepiness, worsened sleep quality, quality of life,

daytime function, and motor vehicle crash risk. There is also potential for worsening cardiovascular risk or respiratory failure. (Ayas et al., 2021, p.3)

Recommendations for effected device users:

- Register your serial number and begin the recall process as soon as possible. This can be done via web or phone:
  www.philips.com/src-update OR 1-877-907-7508

- For all devices we recommend only using cleaning methods as described in the manufacturer's manuals. Use of ozone or ultraviolet light cleaning methods (e.g., soClean, Lumen etc.) should be discontinued.

- Discuss whether to discontinue therapy or not with your family physician.

Given the scale of this recall (estimated 4 to 6 million device worldwide, and over 250, 000 devices in Canada) and the current global semiconductor shortage, Philips or other manufacturers cannot supply sufficient devices to effect replacements in a timely manner, without significant impact on patient's health. Current estimates are that it will take months before any replacement units would be made available to patients, and the length of this process could extend up to two years. (Tennant, 2021, p.2).

If you require more information from us, please call our office at 403-329-9153 or email info@chinookrespiratorycare.com.

We thank you in advance for your patience, understanding and continued support of our locally owned and operated business. We will continue to provide the best service possible.

Kindest regards,

Chinook Respiratory Care

References

Ayas, N. T., Fordyce, L., Giannouli, E., Kaminska, M., Katz, S., Kendzerska, T., MacLean, J., McCoy, C., Morrison, D., Pendharkar, S., Skomro, R., & Steward, C. (2021). Position Statement from the Canadian Thoracic Society, Canadian Sleep Society, and the Canadian Society of Respiratory Therapists Phillips Respironics Device Recall. *Canadian Thoracic Society*, 1-8. https://cts-sct.ca/guideline-library/

Tennant, D. (2021). *Request to Consider Recommendations Following the Recall of Medical Devices* (1). Respiratory Homecare Association of Alberta.