



Position Statement from the Canadian Thoracic Society, Canadian Sleep Society and the Canadian Society of Respiratory Therapists Phillips Respironics Device Recall

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This position statement aims to provide rapid guidance to physicians and medical device distributors (MDD) (i.e., positive airway pressure providers/vendors) with regard to the recent recall notice. This document was based on the consensus of the authors, who are members of the Guideline Committees (Sleep Disordered Breathing, Home Mechanical Ventilation and Pediatric Assemblies) of the Canadian Thoracic Society (CTS), the Canadian Sleep Society (CSS) and the Canadian Society of Respiratory Therapists (CSRT). The recommendations are informed by a limited body of evidence and statements from other international and provincial bodies. These recommendations are subject to change as more information regarding the recall becomes available, and we recommend periodically checking the CTS/CSS/CSRT websites for updates.

WHAT WE KNOW:

- Philips Respironics issued a voluntary recall notification in the USA for many of their positive airway pressure (PAP) devices and ventilators on June 14, 2021. This was due to possible harm secondary to breakdown of the polyester based polyurethane (PE-PUR) sound abatement foam.
- On June 23, 2021 Health Canada posted a medical device recall for the same products. The hazard classification is type II, defined as a situation in which the use of, or exposure to, a product may cause

temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

- A variety of devices are potentially affected including: several Continuous Positive Airway Pressure (CPAP - including DreamStation), Auto-CPAP, Bi-Level Positive Airway Pressure (Bi-Level PAP) devices, Adaptive-servo-ventilators (ASV), Average volume-assured pressure support devices (AVAPS), OmniLab and Trilogy ventilators; a list of affected and unaffected devices can be found on the Phillips and the Health Canada websites:

https://www.philips.ca/healthcare/e/sleep/communications/src-update#section_2

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75887r-eng.php>

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- At the time of publication of this statement, Phillips Oxygen Concentrators, Respiratory Drug Delivery Products, Airway Clearance Products, and a variety of PAP devices (e.g., DreamStation 2, M-series) do not appear to be affected by the recall.
- Timelines for replacement or repair of devices by Philips are unclear but may take many months. Discontinuing treatment for prolonged time periods while waiting for replacement or repair may not be appropriate or feasible in many patients.
- Globally, the number of units affected is in the millions. Therefore, despite the efforts of PAP manufacturers, we would expect future problems with PAP supply.
- According to information from their websites, devices from other manufacturers widely used in Canada (i.e., ResMed, Fisher and Paykel) are not affected by the recall as different materials are used in these devices:

<https://www.resmed.com/en-us/other-manufacturer-recall-2021/>

<https://www.fphcare.com/en-ca/our-company/about-us/cpap-notice/>

Potential Risks:

- Breakdown of the foam may result in generation of particulate matter and volatile organic compounds (VOC) that can pass through the tubing system. This breakdown may be worsened by ambient heat/humidity (i.e., not related to the use of heated humidifiers within the device) and use of non-authorized cleaning methods (e.g., ozone, ultraviolet light).
- According to Phillips, the potential risks of degraded foam include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver), and toxic carcinogenic effects. The company has received several complaints regarding the presence of black debris/particles within the airpath circuit. Philips also has received reports of headache, upper airway irritation, cough, chest pressure, and sinus infection.

- It is possible that foam breakdown has occurred, even in the absence of visible particles.
- 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.
- There are risks associated with stopping CPAP or Bi-Level PAP abruptly in sleep apnea patients with significant comorbidities and/or substantial sleepiness and patients treated for hypoventilation syndromes. This includes reemergence of excessive daytime somnolence and associated complications such as worsening sleep quality, quality of life, daytime function, and motor vehicle crash risk. There is also potentially worsening cardiovascular risk or respiratory failure.

GUIDING PRINCIPLES FOR THIS DOCUMENT:

- The nature and magnitude of the risk of recalled devices and how these might be affected by factors such as duration of exposure or type of device are presently uncertain.
- The decision to continue or interrupt treatment must be individualized and consider disease severity, symptoms without treatment, risks of continued potential exposure to foam degradation products, and medical risks of interruption in treatment.
- There should be shared decision-making between the patient, their family or other supports, and physicians to carefully balance risks of continuing versus interrupting the use of affected devices, and consideration of alternative treatments/devices available. The decision to continue prolonged use of a recalled device needs to be individualized and documented in the medical record.
- This document should not replace direct consultation with physicians with expertise in clinical care of patients with ventilators, CPAP, and Bi-Level devices.

GENERAL ADVICE:

- MDD providers should advise and support patients to use the Phillips registration site to look up serial numbers of devices to determine if they are subject to the recall; if so, they should register their device and begin a claim as appropriate to obtain a replacement/repaired device.
See: <https://www.philippsrcupdate.expertinquiry.com/?ulang=en>
- For all devices, we would recommend using the cleaning methods described in their device's instructions and discontinuing all unauthorized cleaning methods (e.g., ozone such as SoClean or ultraviolet light products). Please see United States Federal Drug Administration statement: <https://www.fda.gov/news-events/press-announcements/fda-reminds-patients-devices-claiming-clean-disinfect-or-sanitize-cpap-machines-using-ozone-gas-or>

FOR ADULT PATIENTS:

GUIDANCE FOR MEDICAL DEVICE DISTRIBUTORS:

- **For patients using affected devices that are considered life-sustaining**, where discontinuation of the device would result in rapid deterioration of breathing and/or overall health status, we would recommend not discontinuing the existing device. These could include patients with neuro-muscular diseases, severe respiratory diseases, obesity hypoventilation syndrome, and other causes of respiratory failure. The risks of stopping ventilatory support likely far outweigh the risks identified in the recall notification. Patients need to consult with their physician as soon as possible to determine the best course of action.
- **For patients using affected CPAP or Bi-Level devices at night for obstructive sleep apnea**, we would advise contacting their physician in a timely fashion to decide on the best course of action and continuing using their device in the meantime.
- **For patients who develop symptoms compatible with irritation** from foam degradation particles such as cough, headaches, sinus infections that started after starting on PAP treatment OR who notice particles in their humidifier chamber, tubing or mask; they should contact their physician as soon as possible to discuss options and they should be considered a priority for clinical decision-making.

GUIDANCE FOR PHYSICIANS:

These represent general suggestions and should not supersede clinical judgment. The decision on the best course of therapy should represent a joint decision between the physician and patient/caregiver.

For patients using affected devices that are considered life-sustaining (see above for description) physicians should discuss risks and benefits with their patients as soon as possible to determine the best course of action. For life-sustaining devices, this would very likely involve obtaining a comparable non-recalled device or, if this is not possible, to continue the recalled device until repair/replacement. Other experts involved in the care of these patients (such as respiratory therapists) could be helpful in these discussions, but the ultimate decision about continuing or stopping therapy remains with the physician and patient. If the device is changed to a non-recalled device or any modifications are made to the circuit (e.g., addition of a filter - see below), close follow-up and optimization of therapy (e.g., potentially changing pressures, triggering sensitivities) are necessary to ensure continued adequate ventilatory support and patient comfort.

For patients using affected CPAP or Bi-Level devices at night for obstructive sleep apnea, therapeutic decisions should be individualized. Discussion between patient and physician might also provide an opportunity to reconsider indications and effectiveness of therapy. This does not represent an exhaustive list, but we believe the following factors should be considered in clinical decision-making:

- the severity of sleep apnea and nocturnal desaturation
- the negative impact of untreated sleep apnea on comorbidities. These include:

- cardiovascular comorbidities (e.g., heart failure, prior myocardial infarction, angina, stroke, valvular heart disease, difficult to control hypertension, arrhythmias including atrial fibrillation, aortic aneurysm)
 - pulmonary diseases (e.g., significant COPD, hypercapnia, pulmonary hypertension)
 - neurologic disorders (e.g., seizures, dementia and other neurodegenerative diseases)
 - other conditions (e.g., pregnancy)
- extent of improvement in daytime sleepiness, quality of life, cognitive performance, driving ability with therapy and/or recurrence of these symptoms with CPAP or Bi-Level interruption
 - risk of occupational injury/accident especially for patients in safety critical occupations (e.g., professional pilots/drivers, heavy equipment operators)
 - adherence to therapy

For patients with mild to moderate OSA without substantial comorbidities and symptoms, interruption of therapy until the repaired/replacement machine is available may be reasonable. Patients in whom therapy is interrupted or discontinued should be followed closely for possible adverse effects.

For any patient from the above categories in whom it is felt that treatment cannot be withheld for a prolonged time period, the following are potential options:

- Obtaining a CPAP or Bi-Level device not subject to recall, while continuing the recalled device until that new device becomes available. The new device should be Health Canada approved, preferably from a company that has verified the safety of their products with respect to the recall.
- Considering alternatives to CPAP (e.g., dental appliances in patients with mild/moderate sleep apnea, positional therapy). Close follow-up is required if CPAP is discontinued.
- Continuing the recalled device until replaced/repaired by the manufacturer. The decision to continue using a recalled device for a prolonged time period needs to be individualized after discussion between the patient and physician, and documented in the record. These patients need to be closely monitored for possible symptoms from foam degradation products.

Patients with symptoms that could represent irritation from foam degradation should be evaluated as soon as possible by a physician so that a clinical decision can be made promptly. For patients in whom therapy has been interrupted due to symptoms believed to be due to irritation from foam degradation, close follow-up should be instituted to assess for progression/resolution of these symptoms. These cases should be reported to Health Canada and Phillips:

- <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>,
- Phillips: 1-800-345-6443 or canadian.customerservice@philips.com

PEDIATRIC PATIENTS:

GUIDANCE FOR MEDICAL DEVICE DISTRIBUTORS:

Many pediatric patients using CPAP, Bi-Level, and life-sustaining ventilator devices tend to have complex medical issues. As such, we recommend that children continue using these devices until their physician has been consulted.

GUIDANCE FOR PHYSICIANS:

- Life-sustaining ventilator users will need to continue using the affected machines until such time as a replacement machine unaffected by this recall can be obtained or the affected device can be repaired/replaced.
- For children with hypoventilation, impaired respiratory drive, and/or severe upper airway obstruction, discontinuation of CPAP and Bi-Level therapy is not advisable.
- Potential risks of temporarily discontinuing CPAP and Bi-Level therapy include daytime dysfunction, severe daytime sleepiness, decreased mood or mood lability, inattention, hyperactivity, learning dysfunction, behavioral disturbance and/or respiratory failure.
- The improvement in daytime function with CPAP and Bi-Level therapy is an important consideration in decision-making.
- A decision to interrupt CPAP or Bi-Level therapy temporarily while awaiting a replacement/repared device may affect long-term adherence, and may result in children discontinuing these treatments altogether.
- The impact of temporary CPAP and Bi-Level interruption on comorbidities such as neuromuscular diseases, chronic lung diseases, cardiovascular diseases, neurologic diseases, and pulmonary hypertension needs to be considered.
- Where appropriate, clinicians should provide guidance on alternative therapies.
- If after discussion with their physician, a decision is made to interrupt CPAP and Bi-Level therapy until a replacement device is available, close follow-up and monitoring of children is imperative to identify any clinical deterioration related to device discontinuation.
- The decision to continue using a recalled device for a prolonged time period needs to be individualized after discussion with their physician, balancing risk and benefits, and documented in the record. These children need to be closely monitored for possible symptoms from foam degradation products.

OTHER CONSIDERATIONS:

- For in-laboratory titration studies, we would recommend not using recalled devices. If there is no alternative (e.g., in-home titration) and an urgent in-laboratory titration is required, we would suggest frank discussion

with patients in terms of risks and benefits and consultation with local legal and risk management experts for guidance.

- In-line bacterial filters can reduce particulate matter exposure and can be considered in some devices (i.e., Trilogy 100 and 200 according to Phillips). Use of these filters in these devices may necessitate changes in settings (e.g., trigger sensitivities) and patients should be monitored carefully. Of note, the *filter will not reduce VOC exposure*. How these filters should be used in other devices (i.e., CPAP, Bi-Level) is not clear; filters may affect pressure delivery and use is not recommended with a humidifier in these devices.
- For patients switched from one device to another model, there should be close follow-up. We would not expect substantial issues with switching from one CPAP or auto-CPAP device to another. However, for patients with more advanced devices (e.g., AVAPS, ASV, ventilators) there may be significant differences in the devices and patients should be monitored very closely.
- We hope that insurance providers will be understanding of this unprecedented situation and flexible in terms of helping to obtain alternative devices in those who cannot wait safely for a manufacturer replacement/repaired device.
- It is likely that supply of PAP will be affected. If devices do become scarce, triaging of the devices for both replacement and new prescriptions might become necessary. We recommend that triage decisions be equitable and consider factors such as disease severity and comorbidities.

OTHER USEFUL LINKS:

- ❖ American Academy Sleep Medicine (AASM) Statement, Information, and Webinars:
 - https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices?utm_source=MarketingCloud&utm_medium=email&utm_campaign=AASM+guidance+in+response+to+Philips+recall+of+PAP+devices&utm_content=complete+guidance&utm_term=00341000014122NAAQ
 - <https://aasm.org/wp-content/uploads/2021/06/Philips-PAP-recall-SAMPLE-pediatric-assessment.pdf>
 - https://www.youtube.com/watch?v=H80vyhFb5vc&ab_channel=AmericanAcademyofSleepMedicine
 - https://www.youtube.com/watch?v=Mj6Tamcd6zc&ab_channel=AmericanAcademyofSleepMedicinehttps://aasm.org/event/impact-philips-pap-recall-vulnerable-populations/
 - <https://sleepeducation.org/philips-pap-device-recall-guidance-for-patients/>
- ❖ European Respiratory Society (ERS) Statement:
 - <https://www.ersnet.org/news-and-features/news/announcement-ers-releases-statement-on-the-philips-recall-notice/>
- ❖ American Thoracic Society (ATS) Statement:
 - <https://www.thoracic.org/patients/patient-resources/recommendations-for-sleep-and-critical-care-medicine-professionals-regarding-philips-recall-notice.php>

❖ Information from Phillips:

- <https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html>
- <https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf>
- [Supplemental clinical information for physicians and providers for specific CPAP, Bi-Level PAP, and mechanical ventilator devices](#)