

NOTICE of Voluntary Recall - Philips Respironics

The Sleep Disorders Clinic (SDC) at The Royal

September 23, 2021

Dear Patients and Family/Support Members:

Health Canada is aware of the **voluntary recall** of certain Philips Respironics Continuous and Non-Continuous Ventilators, including Continuous Positive Airway Pressure (CPAP), BILEVEL, and Continuous Ventilator devices. For most patients at The Royal SDC, this affects CPAP, APAP and BiPAP devices made by Philips Respironics:

- <https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75889r-eng.php>
- <https://healthykanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75887r-eng.php>

Only “Philips Respironics” units are being recalled. If you have a ResMed or Fisher & Paykel machine, you are not affected.

This recall is voluntary. Information continues to be gathered, and individuals with affected devices can expect to be contacted by their CPAP Vendors/suppliers. The Ontario Ventilator Equipment Pool (VEP) was notified of an issued recall and safety notification by Philips for specific ventilator devices. The VEP is working to identify all affected devices. The VEP will notify any users by mail, if they have an affected unit. You can also visit philips.com/SRC-update and www.sleepeducation.org/philips-pap-device-recall-guidance-for-patients/.

Why is there a voluntary recall?

The voluntary recall surrounds two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in some models of Philips Respironics Continuous and Non-Continuous Ventilators.

1. This foam may degrade into irritant particles that may enter the device’s air pathway and be ingested or inhaled by the user.
2. The PE-PUR foam may emit volatile gas products, which the user may inhale.

What are the symptoms and risks?

According to the manufacturer, inhalation of the particles could cause symptoms such as headache, upper airway and eye irritation, cough, chest pressure and sinus infections or asthma. Other potential effects include adverse effects to other organs (e.g. kidneys, and liver), inflammatory responses, toxic carcinogenic effects and other issues that can result in serious injury which can be life threatening and/or cause permanent impairment. Philips reports the foam-related complaint rate in 2020 was low (0.03% of users), and it has received no accounts of patient impact related to chemical emissions. **There have been no deaths reported.**

Foam degradation may be exacerbated by the following:

- use of unapproved cleaning methods that may harm your unit, such as Ozone, Ultraviolet (UV) Light, or cleaners that include disinfectants.
- high heat and high humidity environments (unrelated to the humidity from the device).

What are the next steps?

- Stop using ozone or UV light cleaning products to clean your equipment. Follow the manufacturer’s cleaning instructions.
- Register your machine(s) with your CPAP Vendor or on the recall website: www.philips.ca/healthcare/e/sleep/communications/src-update
 - The website will give you up-to-date information on the status of the recall and how to access the permanent solutions or fixes that will be put into place to solve this problem.
 - Call 1-877-907-7508 if you cannot visit the website.

- For device registration and technical support, please contact as applicable:
 - Your CPAP vendor/supplier (your machine may be considered for replacement if it is malfunctioning, but may not be funded by the Ontario Assistive Devices Program for the recall issue alone).
 - Ontario's Ventilator Equipment Pool: Phone: 613-548-6156; <https://ontvep.ca/>
- For medical advice:
 - If you saw your sleep physician within the last two years, please book your appointment at the Sleep Disorders Clinic at The Royal: phone number: 613-722-6521, x6226
 - If you saw your sleep physician more than two years ago, please ask your family physician to send a new referral to the Sleep Disorders Clinic at The Royal: fax number: 613-798-2980.
 - In the meantime, you can discuss this letter with your family physician, given the information provided below.
 - Please bring to your doctor's appointment at the Sleep Disorders Clinic the most recent summary report from your device (or request this from your CPAP Vendor). See the questionnaire below for more information:

Do you use a CPAP, BiLevel PAP machine or ventilator for one of the reasons below?

- Your machine is from the ventilator equipment pool in Kingston
- I have been told by a health professional that my breathing and overall health status would rapidly deteriorate and I could be at risk of death by the sudden removal of this treatment (e.g., neuromuscular diseases, such as ALS, myasthenia gravis, diaphragm weakness or paralysis)
- Severe sleep apnea
- My ability to work depends on me using my machine (e.g., truck driver, bus driver, pilot, operator of heavy machinery, taxi/Uber driver, etc.)
 - Stopping CPAP/Bilevel may result in report to the Ministry of Transportation
- I get sleepy when I drive
- I get very sleepy when I do not use my machine
 - You can stop using your machine for a few days to confirm that you feel sleepy off treatment.
- I have a severe heart condition (e.g., previous heart attack, irregular heartbeat, heart failure)
- I have breathing or a medical condition that requires me to use my machine (e.g., severe asthma, severe or very severe COPD)

YES

Do not stop your treatment until you can get a replacement machine. If you want to discuss the risk to benefit rationale for this recommendation, please request a follow-up or new referral to your sleep doctor.

In your case, the benefits of continuing to use your machine may outweigh the health risks mentioned in the recall notice.

If your device was replaced, you do not need to see your sleep doctor for reassessment if you feel good on a new machine and your sleep apnea is under control (AHI<5)

NO

The risk of continuing to use your machine is not clear. It may be safer to stop using your machine for a short time until replacement parts are available.

We recommend you speak with your doctor and your machine's supplier to find the best option for you to continue your treatment.

If you choose to stop using your machine

- Do not have alcohol or muscle relaxants at bedtime.
- Keep your head elevated when you sleep (use extra pillows)
- Sleep on your side (wear a backpack filled with towels).
- Do not drive for more than 30 minutes without taking a break.
- Consider pre-manufactured oral appliances (e.g., ApneaRx)

If you choose to continue using your machine

Stop using your machine and contact the clinic right away if:

- You notice foam dust in the humidifier, tubing or mask.
- Have headaches, skin, eye or airway irritation, cough, chest pressure or a sinus infection.