

NOTICE of Voluntary Recall - Philips Respironics

The Ottawa Hospital Sleep Centre

July 02, 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:

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

Only “Phillips 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. Philips reports the foam-related complaint rate in 2020 was low (0.03%), 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, such as using Ozone and Ultraviolet (UV) Light cleaners that use disinfectants that may harm your unit.
- in 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.
- Please see the questionnaire below for more information.
- If you have any further questions and you want to seek medical advice on whether to stop or continue with your equipment, please contact your ventilatory medical provider:
 - For device registration and technical support, please contact as applicable:
 - Your CPAP vendor/supplier

Recommendations are based upon current information and may require further updates

- Your machine may be considered for replacement if it is malfunctioning, but may not be funded by the 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 Ottawa Hospital Sleep Center: phone number: 613-761-4636
 - If you saw your sleep physician more than two years ago, please ask your family physician to send a new referral to the Ottawa Hospital Sleep Center: fax number: 613-761-5211.
 - In the meantime, you can discuss this letter with your family physician, given the information provided below.
 - Please ensure that you brought the most recent summary report from your device (or requested your CPAP Vendor)

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 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 makes me need to use my machine (e.g., severe asthma, severe or very severe COPD)

YES

NO

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)

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.