

Philips Respironics Recall: June 2021

What You Need to Know

Overview

On June 14, 2021, Philips Respironics announced a voluntary recall of some CPAPs, BiLevel PAPs, and ventilators. This is because of possible health risks related to the sound-proofing foam used in the machines.

In 2020, Philips Respironics received complaints about the sound-proofing foam for a small number of machines (about 3 in 10 000, or 0.03%). The foam can:

- Break down into dust, which could be swallowed or breathed in.
- Create chemical vapours (a type of gas).

The risk of foam breakdown seems to be higher if:

- You clean your machine with ozone cleaning products.
- You have high heat or humidity in your home.

Philips Respironics states they are issuing a voluntary recall "out of an abundance of caution". At the time this info sheet was written, there were no reported serious harmful effects, hospitalizations, or deaths.

Health risks

The possible health risks from being exposed to the foam dust include:

- Irritation (redness or swelling) of the skin, eyes or airways
- Headache
- Asthma
- Kidney and/or liver problems
- Toxic effects that could lead to cancer

Does my machine have this problem?

This recall applies only to **some** models of Philips Respironics machines that were manufactured before April 26, 2021. They include:

- Dreamstation
- Dreamstation Go
- System One

See the full list of machines here: philips.ca/healthcare/e/sleep/communications/src-update

- Trilogy (some models only)
- A-series BiPAP

You may also notice black dust inside your humidifier, tubing, or mask. You may have headaches, airway irritation, cough, chest pressure or a sinus infection.

What do I need to do?

If you have one of the of Philips Respironics machines mentioned:

- Stop using ozone or UV light cleaning products to clean your equipment. Follow the manufacturer's cleaning instructions.
- Register on the MUHC webpage: muhc.ca/philipsrecall
 - After you register, we will be able to email you important updates on this recall.
- Register your machine(s) on the Philips website: philips.ca/healthcare/e/sleep/communications/src-update
 - o 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.

Do you use a CPAP, BiLevel PAP machine or ventilator for one of the reasons below? □ I am followed by the National Home Ventilatory Assistance Program/Programme National d'Assitance Ventilatoire à Domicile □ My ability to work depends on me using my machine (ex: truck driver, bus driver, pilot, operator of heavy machinery, taxi/Uber driver, etc.). □ I get very sleepy during the daytime (eg. while driving) if I don't use my machine. □ I have a severe heart condition (eg. Previous heart attack, irregular heartbeat, heart failure) □ I have breathing or a medical condition makes me need to use my machine (eg: severe asthma, COPD, neuromuscular problem, hypoventilation). □ I take strong opioid pain medication on a regular basis. YES NO

Do not stop your treatment until you have talked to your doctor.

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

Contact the clinic right away if:

- You notice foam dust in the humidifier, tubing or mask
- Have headaches, skin, eye or airway 0 irritation, cough, chest pressure or a sinus infection.

QUESTIONS?

If you see a respirologist at the MUHC Contact us at 514 934-4470 rappelphilips@muhc.mcgill.ca

Register on the MUHC website: muhc.ca/philipsrecall

We recommend that you continue using your machine. You can speak with your doctor to find the best option for you to continue your treatment.

The risk of continuing to use your machine is not clear.

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.

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, 0 chest pressure or a sinus infection.

This communication applies ONLY to patients using Philips Respironics breathing machines. It does NOT apply to patients using ResMed or Fisher-Paykel breathing machines.