

Philips Respironics Recall Patient Brochure

The recommendations contained in this document apply **ONLY** to patients using Philips Respironics breathing devices.

It does **NOT** apply to patients using ResMed or Fisher-Paykel breathing devices.

1

What is happening?

On June 14 2021, Philips Respironics announced a voluntary recall of a number of Continuous and Non-Continuous Ventilators (certain CPAP, Bi-Level PAP and Ventilator Devices) due to a potential health risk related to the sound abatement foam used in these devices.

In 2020, Philips Respironics received complaints for about 3 in 10 000 devices (0.03%) regarding this foam which may:

- Breakdown into dust that may be ingested or inhaled.
- Produce chemical vapours (volatile organic compounds (VOC) type of gas).

The risk of breakdown of this foam inside the device seems to increase with:

- The use of ozone cleaning products.
- Exposure to high heat and/or with humidity in the home (not within the device itself).

2

How to know if your device is affected?

This voluntary recall applies to some of the following models of Philips Respironics devices manufactured before April 26, 2021.

- Dreamstation
- Dreamstation Go
- System One
- Trilogy (not all of them)
- A-Series BiPAP

You may notice the presence of black dust inside your humidifier, tubing, and/or mask.

You may experience headaches, upper airway irritation, cough, chest pressure and sinus infection, but this may also be due to a respiratory infection or condition.

3

What are the risks?

Philips Respironics states the voluntary recall is issued "out of an abundance of caution". At the time of creation of this information sheet, there have been no reported serious harmful effects or hospitalizations.

However, the potential risks from being exposed to the foam dust include:

- Irritation (skin, eyes, and respiratory tracts)
- Headache
- Asthma
- Kidney and/or liver problems
- Toxic carcinogenic effects

The real risks are still unknown as current testing suggests foam particles are not likely to get trapped in the lungs and the VOC levels are not outlined. We are exposed to VOCs daily both inside and outside our dwellings and higher levels of VOCs may be present on the streets. To learn more click [here](#).

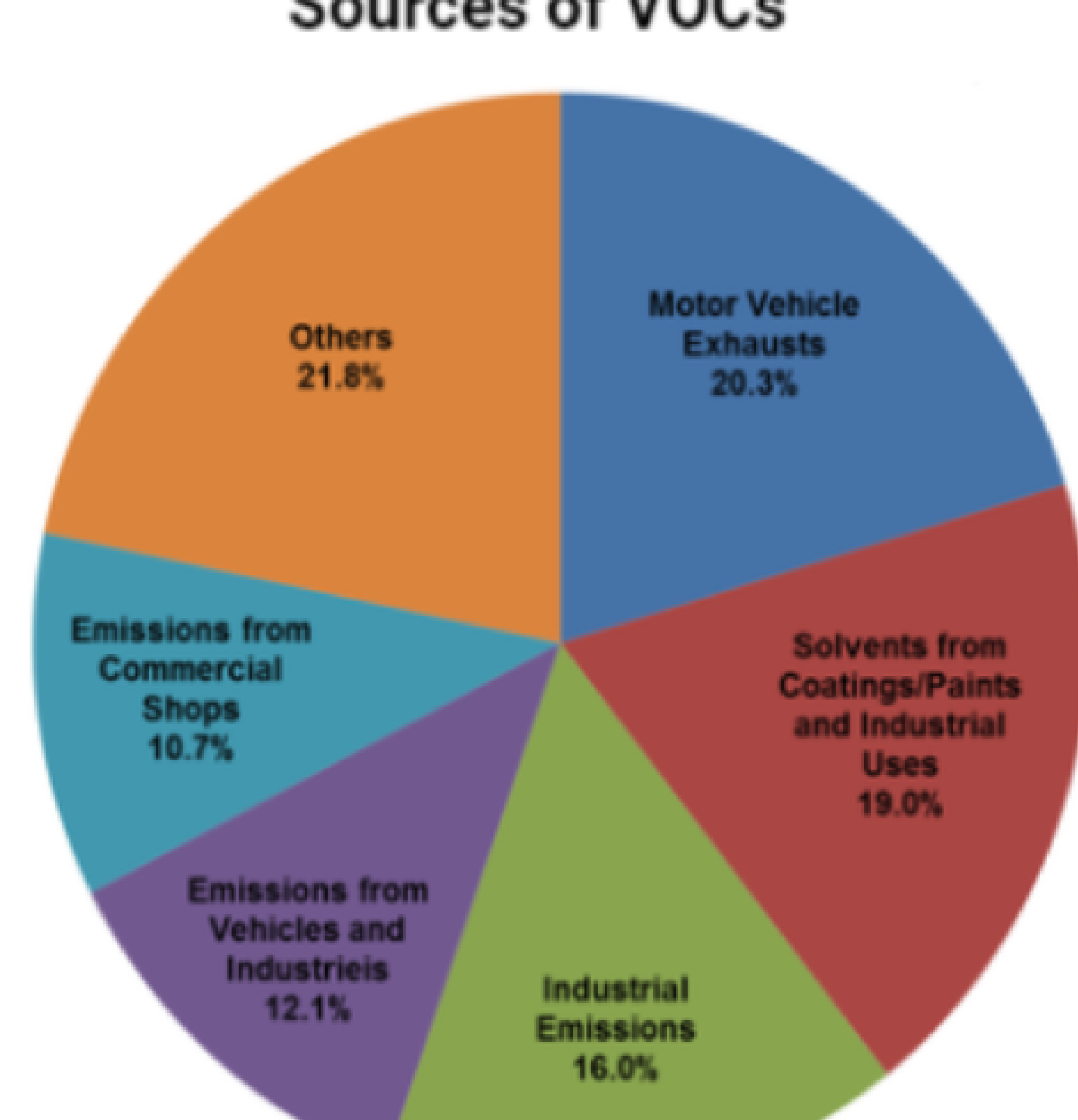


VOCs explained (Volatile organic compounds)

We are all exposed to **VOCs** on a daily basis and the greater the level of VOC exposure, the greater the health risks and the concern about increasing the risk of the development of cancer. We do not currently know the amount of VOCs released in these units or if all of them are involved.

VOCs are released from vehicles, burning wood, cigarettes and other smoked substances, household cleaning materials and even evergreen trees, so some exposure in our daily living is unavoidable. We will update our website if more information is provided by Philips Respironics about the possible exposure risks. Here is the typical finding of exposure to VOCs in an American city and where these compounds come from.

Sources of VOCs



We DO NOT recommend discontinuation of treatment without seeking your physician's advice as the risks of discontinuing therapy may be more dangerous than its continuity.

Here are some of the considerations that your physician may take into account in deciding to continue therapy:

- **Occupation Risk:** your occupation depends on you using your device (e.g., professional pilots, bus drivers, taxi/uber drivers, truck drivers or heavy equipment operators)
- **Quality of life:** extent of improvement in daytime sleepiness, quality of life, cognitive performance
- **Cardiovascular comorbidities:** you have a heart condition (e.g., heart failure, prior myocardial infarction, angina, stroke, valvular heart disease, difficult to control hypertension, arrhythmias including atrial fibrillation, aortic aneurysm)
- **Pulmonary comorbidities:** you have a breathing or medical condition that requires you to use your device to maintain your health (eg. severe asthma, COPD, neuromuscular disease, hypoventilation)
- **Neurologic disorders:** (e.g., seizures, dementia and other neurodegenerative diseases)
- **Other considerations:**
 - Pregnancy
 - You need nighttime breathing support because you are using narcotic medications
 - You have been told that your sleep apnea is severe where treatment is critical/very important
 - Adherence to therapy

Everyone should do the following:

- Stop using ozone cleaning products to clean your equipment.
- Follow the manufacturer's instructions for cleaning your equipment.
- Visit our website to "**acknowledge**" that you are aware of the recall and frequently check for updates

If you continue using your current device

- If you notice foam dust within the humidifier, tubing, mask or if you experience headache, skin or eye irritation, airways irritation, cough, chest pressure or sinus infection, please contact your physician immediately.

If after talking to your physician you discontinue the use of your device, you should:

- Avoid alcohol /muscle relaxants or sedatives at bedtime
- Elevate the head of the bed to a more head-up position
- Sleep on your side with a bumper belt/sleep noodle/anti snore shirt
- Avoid driving long distances or driving if sleepy

4

What about the use of filters?

Please be advised that similarly to Philips Respironics instructions, we DO NOT recommend the use of filters with CPAP/Bi-Level PAP/APAP devices as they do not mitigate the risk identified in this recall and they may impair performance of your device.

Limited availability of repaired/replacement devices

Please be aware that there is a global shortage of devices as a result of this recall which will impact the timeline for remedying this situation. Philips Respironics is working to remedy this situation, however, please expect a delay in replacing or repairing your device. In addition, this situation has also placed strain on the pool of loaner devices and as such, there are no more devices available to be loaned/rented to patients.

Confirm that you are aware of the recall by filling the online acknowledgement form.

For any additional questions, please contact our dedicated assistance hotline available 9:00 to 16:00 (local time) at 1 844 726-2727

Key References

- Health Canada - [Indoor Air Reference Levels for Chronic Exposure to VOC Compounds](#)
- Health Canada - [Air Quality](#)
- Health Canada - [Volatile organic compounds](#)
- Philips Respironics recall [notification](#)
- [Position Statement](#) from the Canadian Thoracic Society, Canadian Sleep Society and the Canadian Society of Respiratory Therapists Philips Respironics Device Recall

Co-Authors

Dr. Raymond Gottschalk (MB ChB, FRCPC, FCCP, D, ABIM, D, ABSM Sleep) Sleep Medicine Expert

Dr. Sean A. Gilman (MD, FRCPC, ABIM) Sleep Medicine Specialist