

NOTICE of Voluntary Recall - Philips Respironics
Specified Devices Manufactured BEFORE April 26, 2021

June 28, 2021

Dear Patients, Clients and Family/Support Members,

Manitoba's Health Service Delivery Organizations are aware of the **voluntary recall** of certain Philips Respironics Continuous and Non-Continuous Ventilators, including CPAP, BILEVEL and Continuous Ventilator devices used in Canada. **Only "Philips Respironics" units are being voluntarily recalled. If you have a ResMed 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 supplier.

Affected Mechanical Ventilators

Devices Manufactured BEFORE April 26, 2021	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus
	Aeris
	LifeVent
BILEVEL	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30
	A-Series BiPAP V30 Auto
BILEVEL	
Continuous Ventilator, Non-Life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Affected CPAP and BiPAP Devices

Devices Manufactured BEFORE April 26, 2021	
BILEVEL	
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
CPAP	
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

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 which 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 cleaners that use disinfectants that may harm your unit. The "SoClean" brand is an example of an Ozone cleaner. **Please stop using any such cleaning systems and instead refer to your CPAP or BiPAP device instructions for approved cleaning methods:**
usa.philips.com/c-e/hs/better-sleep-breathing-blog/better-sleep/keeping-it-clean-cpap.html
- in high heat and high humidity environments unrelated to the humidity from the device

What are the next steps?

Manitoba clinical leaders are working with all health regions, provincial supply chain representatives, local distributors and Manitoba Health and Seniors Care to determine the most appropriate course of action for Manitobans.

For more information about next steps, please refer to the adult or children information sheets.

For **adult patients** with questions about your equipment's warranty, replacement or repair, please contact your vendor who is working closely with Philips Respironics.

MediGas: 204-786-4719

VitalAire: 1-855-309-8301

NOTICE of Voluntary Recall - Philips Respironics Information for ADULT patients

For patients using life-sustaining devices (e.g. patients with neuro-muscular diseases and other causes of respiratory failure who require a ventilator to breathe at night and parts of the day):

- If you are on treatment with Trilogy 100 or Trilogy 200 or affected BiLevel systems (BiPAP, AVAP, ASV) **do not discontinue** use of your existing device while waiting for replacement of your unit, even if you receive notification from Philips. **The risks of stopping ventilatory support outweigh the risks identified in the recall notification.**
- Filters may be beneficial in some situations to reduce exposure to degraded foam particles, however they should only be used with the recommendation and supervision of your equipment provider.
- For individuals on life-sustaining devices, followed by the Long Term Ventilation Program, it is strongly suggested that any shift to a new device/model be done with clinical assessment and supervision.
- For BiPAP or ASV users in this group, who are currently being followed by the Sleep Disorder Centre (SDC), follow up may be required once you switch to a replacement device.

Work is underway to replace your affected equipment as soon as possible.

For patients using affected CPAP or BiLevel devices (BiPAP, ASV) at night for sleep apnea, the following is suggested:

- For moderate to severe sleep apnea: As there is no evidence of acute, life-threatening incidents in patients using the recalled equipment, in the following situations the risk versus benefit of continuing with your current PAP system likely favours continuing treatment (not stopping or changing) until a replacement for your machine becomes available:
 - Severe sleep apnea
 - Moderate sleep apnea (with mild to moderate symptoms) *and* other medical disorders including: COPD, cardiac disease (such as coronary artery disease, arrhythmia, heart failure, or pulmonary hypertension), stroke, seizures and other neurologic disorders (such as Parkinson's disease, Multiple Sclerosis)

- Sleep apnea with impairment in daytime performance and/or significant daytime sleepiness that improved on CPAP
- Sleep apnea and safety critical occupation, e.g. truck or transit driver, taxi/uber driver, pilot, operator of heavy equipment, etc. (accident risk in workplace or driving due to sleepiness or impaired performance)
- For mild sleep apnea: interruption of the treatment (discontinuing use of the affected units) until the device can be replaced can be considered. Other options for treatment can be discussed with your sleep medical team.
- For patients with symptoms that could be compatible with the irritation from degradation foam particles: if you have significant symptoms (e.g. upper airway or eye irritation, cough, headaches, sinus infections) that started after you started on CPAP treatment, or you notice foam dust in the humidifier, tubing or mask, discontinuation of CPAP treatment and a switch to another form of treatment can be considered until a replacement device is available.

Work is underway to secure new devices as soon as possible.

For any questions or advice on whether to stop or continue using your recalled device, please contact your ventilatory medical provider:

Sleep Disorder Centre (Misericordia Health Centre): 204-788-8570

For updates, please visit: [misericordia.mb.ca/programs/acute-care/sleep-disorder-centre](https://www.misericordia.mb.ca/programs/acute-care/sleep-disorder-centre)

Long Term Ventilator Program (Health Sciences Centre): 204-787-3163

For questions about the recall and your medical device replacement or warranty, please contact your supplier directly.

Your supplier has the serial numbers of all affected equipment and is working closely with Philips Respironics.

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VitalAire: 1-855-309-8301

You can also visit [philips.com/SRC-update](https://www.philips.com/SRC-update) or call 1-877-907-7508.

There is no need to register your device online at this time as this is a vendor responsibility.