June 29, 2021

UPDATE

In light of Philips' recent recall for many of its sleep and respiratory care products, we want to reassure our patients that ResMed and Fisher & Paykel devices are safe to use and are not subject to Philips' recall. ResMed and Fisher & Paykel devices use a different material than what Philips uses in their recalled machines.

At this time, there has been a considerable increase in demand for CPAP machines. Our manufacturers are doing everything they can to increase the production of these products, however, many are currently on back order.

We are currently **accepting pre-orders for backordered units,** however, until our manufacturers have caught up with the production demand, we will only be allowing one unit per patient to ensure fair share allocation.

We will continue working closely and communicating directly with our patients and suppliers to help serve our patients across Canada.

Frequently Asked Questions

Is ResMed or Fisher & Paykel affected by Philips' June 2021 recall?
No. ResMed and Fisher and Paykel devices are not subject to Philips' June 2021 recall.

Are ResMed and Fisher & Paykel devices safe to use?
ResMed and Fisher & Paykel have not observed the issues that Philips is reporting with its devices; ResMed and Fisher & Paykel devices use different materials.

How do I know which brand my PAP or ventilator is?
Your device will have the manufacturer's logo on it. If you are unsure, email a photo of your device to philipsrecall@mrcsleep.com

Does ResMed have foam in its devices? How do I know my ResMed PAP device is safe?
ResMed devices use two foam materials that are different from the foam material Philips says are in its recalled machines. ResMed devices use polyETHER-urethane or silicone foams for sound abatement; Philips has said it uses PolyESTER-based polyurethane for sound abatement. The foams used by ResMed in its devices are safe for patients when following the device's instructions for use. ResMed devices are not subject to Philips' recall.

June 18, 2021

UPDATE: Medical Device Recall

Dear Patient,

We have recently learned that Philips Respironics is voluntarily recalling specific Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.

For more information regarding this recall, please click HERE.

Philips Respironics has opened up registration for devices manufactured in Canada. Please click HERE to find out if your machine is one of the affected devices being recalled.

How to register your unit

Step 1: Click the link below and scroll to the bottom on the page. Select "Patient/Device User/Caregiver" and choose Canada as your country, then click "Next"

Step 2: Enter your serial number in the field and click "Check Unit". You can find your serial number on the label on the bottom of your unit. It is the letters and numbers that follow the SN or S/N on the label. Click HERE if you need additional help locating your serial number.

Step 3: Fill out your personal information and submit. You will receive a confirmation number. Please keep note of your confirmation number for reference.

REGISTER MY UNIT ▶

June 17, 2021

FAQ PHILIPS Recall

Should I keep using my machine or stop using it?
For patients using BiLevel PAP and CPAP devices: Philips recommends to discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks. For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.

We would just like to reassure you that this recall has not been forced on Philips, but was done as a precautionary measure to ensure the safety of the end users of the positive airway pressure machines.

Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device instructions for Use for approved cleaning methods.The issues listed in the email may be a result of unapproved cleaning methods, such as ozone cleaners. If you have not been using an ozone cleaning device, this lowers the risk dramatically.

Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.

Can I deal with MRC regarding the recall/replacement directly instead of with Philips?
We are still awaiting further information from Philips as they are currently deploying a permanent corrective action to address the issues described in the Recall Notice. We will be sending out updates as soon as they come to us on how to proceed with the recalled units. Please keep an eye on your email for these updates.

My health is at risk, I have been using the machine for x years, why did guys announce the news so late?
This voluntary recall was brought to our attention by Philips Respironics on June 15, 2021. We are doing our best to be proactive in communicating and addressing it as we work tirelessly with Philips towards a resolution.

Does this affect my ResMed or Fisher and Paykel Machine?
This recall does not affect any machines that were not manufactured by Philips Respironics.

The Philips website says this recall is USA only, does this affect Canada?
This recall applies to Canada as well. Philips is currently implementing a process for Canadian units, and we will send this information to all our patients once it is available.

June 15, 2021

URGENT: Medical Device Recall

Dear Patient,,

We have recently learned that Philips Respironics is voluntarily recalling specific Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.

The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response,
headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects.

The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

Which devices are affected by the recall?

CPAP and BiLevel PAP Devices All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers:	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Products not affected by this recall notification include:

- Trilogy Evo
- Trilogy Evo OBM
- Trilogy EV300
- Trilogy 202
- BiPAP A40 EFL
- BiPAP A40 Pro
- M-Series
- **DreamStation 2**
- Omnilab (original based on Harmony 2)
- Dorma 100, Dorma 200, & REMStar SE
- **All oxygen concentrators**, respiratory drug delivery products, airway clearance products.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:
1-877-907-7508
www.philips.com/src-update

This notice has been reported to the appropriate Regulatory Agencies. Philips regrets any inconveniences caused by this problem.

We are still awaiting further information from Philips as they are currently deploying a permanent corrective action to address the issues described in the Recall Notice. We will be providing you further information as it becomes available to us.

Sincerely,

MRC Sleep