June 20, 2021

UPDATE: Medical Device Recall

Dear Client,

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 affected 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 20, 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.

Philips is also 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 InspiAIR regarding the recall/replacement directly instead of with Philips? We are still waiting 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.

My health is at risk, I have been using the machine for years, why was the news announced 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 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 20, 2021

Dear Patient,

URGENT: Medical Device Recall

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

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 will be providing you further information as it becomes available to us.

Yours truly,

InspiAIR Team