August 13, 2021

Health Canada: UPDATE

Philips Respironics recalls several models of CPAP and BiLevel PAP machines and mechanical ventilators

Summary

- Product: Philips Respironics Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines and mechanical ventilators
- Issue: Philips Respironics is recalling several models because of reports of the sound-reducing foam breaking down, which could pose potential health risks. There is no definitive link to adverse health effects based on the company's preliminary assessments.
- What to do:
    - Talk to your physician or medical device provider first before stopping or changing how you use your product, as the benefits of using these devices may outweigh the risks for many users.
    - Register your device on the Philips recall website or call 1-877-907-7508. Philips has established a registration process where you can look up your device serial number and begin a claim if your unit is affected.
    - Clean your device only according to the manufacturer's Instructions for Use, as the use of non-validated cleaning methods could contribute to potential issues.

Issue

Philips Respironics (Philips) has recalled several models of its Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines and mechanical ventilators in Canada and internationally. The devices include a foam component that reduces sounds from the device. This foam may degrade (break down) into particles which may be inhaled or swallowed by users, or release volatile organic compounds (VOCs) that may be inhaled, which could lead to negative health effects.

Preliminary laboratory analysis by Philips determined that extreme operating temperatures and ozone cleaning methods may increase the breakdown of the foam. The company recommends against product use in temperatures outside of the labelled operating conditions, and the use of non-validated cleaning methods, such as ozone.

Philips has issued letters to customers, patients, and distributors with instructions for the recall. Philips indicates it will replace the foam component with a material that is not affected by this issue, or it will replace affected devices altogether.

Philips reports that they have received a relatively low number of complaints, some of which relate to black debris in the device air path, including the tubing and mask. Some users have reported headache, upper

airway irritation, cough, chest pressure, and sinus infection, but it has not yet been determined if degraded foam particles or VOCs were the cause.

Health Canada considers the benefits of using the affected devices to outweigh the risks for many users, and recommends that users not stop or alter their prescribed therapy before having a discussion with their health care professional.

For ventilators only, Health Canada cautions the use of in-line bacterial filters to mitigate foam particles, as they will not protect against VOC emissions and airflow can be negatively affected if the filter becomes clogged with debris.

What you should do

- Register your device on the Philips recall website or call its recall hotline at 1-877-907-7508. Philips has established a registration process where you can look up your device serial number and begin a claim if your unit is affected.
- If you have an affected product talk to your physician, or medical device provider first before stopping or changing how you use your product, as the benefits of using these devices may outweigh the risks for many users.
- Be sure to clean your device only according to the manufacturer's Instructions for Use, as the use of non-validated cleaning methods (e.g. ozone) could contribute to potential foam degradation.
- Do not attempt to remove or replace the foam yourself.
- Report any health product-related side effects or complaints to Health Canada.

What Health Canada is doing?

Health Canada is monitoring the recall and the availability of devices in Canada. The Department continues to work with the manufacturer to further assess potential health risks, any future design or material changes that may be proposed, and the appropriateness of the company's corrective actions.

The Department is also working with Philips to identify strategies to address any device shortages. If additional products or safety concerns are identified, Health Canada will take appropriate action and inform Canadians.

Affected products

Philips Respironics Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines and mechanical ventilators

Product description

The recall affects several models manufactured before April 26, 2021. Device photos are available on the company's recall website.

Product	Model or catalog number
BIPAP A30 SYSTEM-VENTILATOR	1076577 1111147
BIPAP A30 SYSTEM-VENTILATOR & SYSTEM ONE A-SERIES HEATED HUMIDIFIER	1076578 1111148
BIPAP A40, CANADA	1076579 1111173
BIPAP A40, CANADA, CORE PACKAGE	1111174
BIPAP AUTO BI-FLEX, WITH HUMIDIFIER, WITH SMARTCARD, CANADA	CA751HS CA761HBT CA761HS CA761NTS CA761TBT CA761TS
BIPAP AUTO BI-FLEX, WITH SMARTCARD, CANADA	CA751S CA761BT CA761S
BIPAP AUTOSV ADVANCED SYSTEM ONE	CA951HS CA951S CA961HS CA961NTS CA961S CA961TS CA961XHS CA961XS CA961XTS
BIPAP AUTOSV ADVANCED/ENCORE SMARTCARD	1044288
BIPAP AUTOSV ADVANCED/ENCORE SMARTCARD/HEATED HUMIDIFIER	1044289
BIPAP AUTOSV WITH SMARTCARD INT	1044114

BIPAP AUTOSV WITH SMARTCARD INT, CORE PKG	1044235
BIPAP AVAPS CORE PACKAGE, NORTH AMERICA	1029750
BIPAP AVAPS VENTILATORY SUPPORT SYSTEM-CANADA	CA1060486 CA1161X CAX1130S12
BIPAP AVAPS VENTILATORY SUPPORT SYSTEM-CORE PKG, CANADA	CA1061419 CA1161XTS CAX1130H12 CAX1130H12C CAX1130H12W CAX1130T12 CAX1130T12C
BIPAP AVAPS, C SERIES VENTILAROTY SUPPORT SYSTEM-CORE PKG, DOMESTIC	1061418
BIPAP AVAPS, C SERIES VENTILATORY SUPPORT SYSTEM-DOMESTIC	1060485
BIPAP PRO BI-FLEX, WITH HUMIDIFIER, WITH SMARTCARD, CANADA	CA651HS CA661HBT CA661HS CA661NTS CA661TBT CA661TS
BIPAP PRO BI-FLEX, WITH SMARTCARD, CANADA	CA651S CA661S
BIPAP ST, C SERIES VENTILATORY SUPPORT SYSTEM, CORE PKG, CANADA	CA1061423
BIPAP ST, C SERIES VENTILATORY SUPPORT SYSTEM-CANADA	CA1061421
BIPAP ST, C SERIES VENTILATORY SUPPORT SYSTEM-CORE PKG, DOMESTIC	1061422
BIPAP SYNCHRONY VENTILATORY SUPPORT SYSTEM WITH SMARTCARD	1029756 CA1029756

BIPAP SYNCHRONY VENTILATORY SUPPORT SYSTEM WITH SMARTCARD-CORE PACK	CA1029759
DREAMSTATION BIPAP PRO	CAX600H12 CAX600H12C CAX600H12W CAX600S12 CAX600T12 CAX600T12C
DREAMSTATION AUTO BIPAP	CAX700H12 CAX700H12C CAX700H12W CAX700S12 CAX700T12 CAX700T12C CAX700T12W
DREAMSTATION AUTO CPAP	CAX500H12 CAX500H12C CAX500H12W CAX500S12 CAX500T12 CAX500T12C CAX500T12W
DREAMSTATION BIPAP AUTO SV W/HUMID/HEATED TUBE, CA	CAX900T12 CAX900T12C
DREAMSTATION BIPAP AUTOSV, CA	CAX900S12
DREAMSTATION BIPAP AUTOSV, W/HUMIDIFIER, CA	CAX900H12
DREAMSTATION CPAP	CAX200H12 CAX200S12C CAX200T12
DREAMSTATION CPAP PRO	CAX400H12 CAX400H12C CAX400H12W CAX400S12 CAX400T12 CAX400T12C CAX400T12W

DREAMSTATION EXPERT	CAX501H12 CAX501H12C CAX501T12 CAX5O1T12C CAX5O1T12W
DREAMSTATION GO AUTO CPAP	CAG500S12
DREAMSTATION GO AUTO CPAP WITH HUMIDIFIER, CANADA	CAG500H12
DREAMSTATION GO CPAP	CAG400S12
DREAMSTATION GO CPAP WITH HUMIDIFIER, CANADA	CAG400H12
OMNILAB ADVANCED, DOMESTIC	1111122
OMNILAB ADVANCED, DOMESTIC CORE	1111123 1111124
REMSTAR AUTO WITH HUMIDIFIER, WITH SD CARD, A-FLEX, CANADA	CA551HS CA561HBT CA561HS CA561NTBT CA561NTS CA561TBT CA561TS
REMSTAR AUTO WITH SD CARD, A-FLEX, CANADA	CA551S CA561BT CA561S
REMSTAR PLUS WITH HUMIDIFIER, WITH SD CARD, C-FLEX, CANADA	CA251HS CA261HS CA261NTS CA261TS
REMSTAR PLUS WITH SD CARD, C-FLEX, CANADA	CA251S CA261S

REMSTAR PRO WITH HUMIDIFIER, WITH SD CARD, C-FLEX +, CANADA	CA451HS CA461HBT CA461HS CA461NTBT CA461NTS CA461TBT CA461TS
REMSTAR PRO WITH SD CARD, C-FLEX +, CANADA	CA451S CA461BT CA461S
REMSTAR, WITH SMARTCARD, CANADA	CA151S
REMSTAR, WITH HUMIDIFIER, WITH SMARTCARD, CANADA	CA151HS
TRILOGY 100 VENTILATOR, CANADA	CA1054096 CA1054096B U1054260
TRILOGY 100 VENTILATOR-INTERNATIONAL	1054096 U1054096
TRILOGY 200, CANADA	CA1032800 CA1032800B

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 effects.

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