URGENT: FIELD SAFETY NOTICE

Philips Respironics
CPAP and BiPAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. 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.

All Devices manufactured before 26 April 2021, All 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

Immediate Actions to be taken by You, the User:

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Please call Philips Hong Kong Sleep & Respiratory Care Service hotline: (852) 2873 1232 to register your device.

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 with 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:

Hong Kong Sleep & Respiratory Care Service hotline: (852) 2873 1232
www.philips.com/src-update

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care

緊急：醫療設備出廠後安全通知

Philips Respironics

持續正氣壓 (CPAP) 和 雙正氣壓(BiPAP) 裝置

隔音泡棉

易發生降解及釋放揮發性有機化合物

親愛的裝置客戶：

Philips Respironics 正自願召回下列裝置，因為發生兩 (2) 項與 Philips 連續型及非連續型呼吸器所使用的聚酯基聚氨酯 (PE-PUR) 隔音泡棉相關的問題：1) PE-PUR 泡棉可能會降解成微粒，而這些微粒可能會進入裝置的空氣管路並由使用者攝入或吸入，以及 2) PE-PUR 泡棉可能會釋放某些化學氣體。使用未經授權許可的清潔方法，例如臭氧，可能會使泡棉的降解加劇 (請參閱有關使用 Ozone 清潔劑的 FDA 安全性通知)，且在初始操作期間可能發生氣體釋放，也可能在裝置使用壽命期間持續發生。

這些問題可能導致嚴重受傷，可能會致命的、導致永久損害，及/或需要醫療介入以避免永久性損害。迄今為止，Philips Respironics 已收到一些關於空氣通道迴路中存在黑色碎片/微粒 (從裝置出口、加濕器、管路及面罩延伸而來) 的投訴。Philips 也已收到頭痛、上呼吸道刺激、咳嗽、胸悶和鼻竇感染的通報。微粒暴露的潛在風險包括：刺激 (皮膚、眼睛和呼吸道)、發炎反應、頭痛、氣喘、對其他器官 (例如腎臟和肝臟) 造成不良事件以及毒物致癌性影響。氣體釋放導致之化學物質暴露的潛在風險包括：頭痛/頭暈、刺激 (眼睛、鼻子、呼吸道、皮膚)、過敏、噁心/嘔吐、毒物致癌性影響。尚無因這些問題而導致死亡的通報。

所有 2021 年 4 月 26 日前製造的裝置， 所有序號	
連續型呼吸器，最低通氣支援，設施用	E30 (緊急使用授權)
連續型呼吸器，非維生用	DreamStation ASV
	DreamStation ST、AVAPS
	SystemOne ASV4
	C 系列 ASV

	C 系列 S/T 與 AVAPS
	OmniLab Advanced+
非連續型呼吸器	SystemOne (Q 系列)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

身為使用者的您應立即採取的行動：

1. 請停用您的裝置，並與您的醫生或耐用醫療設備 (DME) 提供者一起決定持續治療的最適當選項。若因缺少替代方案而需要繼續使用您的裝置，請諮詢您的醫生，以確認繼續治療的效益是否超過本文所述的風險。

2. 請撥打飛利浦香港睡眠和呼吸護理熱線：(852) 2873 1232 註冊您的設備及登記您的資料。

公司將採取的永久修正方法：

Philips 正在部署永久修正方法，以解決本安全通知中所述的兩 (2) 個問題。在上述註冊程序中，將會提供您實施永久解決方案的後續步驟資訊。

其他資訊：

如果您需要關於此問題的進一步資訊或支援，請聯絡支援專線或造訪網站：

飛利浦香港睡眠和呼吸護理熱線：(852) 2873 1232
www.philips.com/src-update

使用本產品時發生的不良反應或品質問題，可以透過線上、一般郵件或傳真通報給 FDA 的 MedWatch Adverse Event Reporting (不良事件回報) 計畫。

本公司已將本通知提報政府管理機關。

對於此問題所造成的不便，Philips 深表歉意。

敬祝　商祺

Rodney Mell
品質與法務主管
Philips Respironics - 睡眠與呼吸照護