URGENT: FIELD SAFETY NOTICE

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

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 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 operation.

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	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Your local Philips representative, Celki International Limited, will contact you to arrange for the permanent corrective action once it is available. If you need any further information or support concerning this issue, please contact your local Philips representative:
   Celki International Limited
   Phone: +852 2268 9243
   Email: celki.cs@airliquide.com

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. 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 recall/issue, please contact the support hotline or visit the website:

Celki International Limited
Phone: +852 2268 9243
Email: celki.cs@airliquide.com
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

Trilogy 100、Trilogy 200、Garbin Plus、Aeris、LifeVent、BiPAP V30，以及 BiPAP A30/A40 系列裝置機型

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之聚酯基聚氨酯 (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)，且在操作期間可能發生氣體釋放。

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	Trilogy 100
	Trilogy 200
	Garbin Plus、Aeris、LifeVent

連續型呼吸器，最低通氣支援，設施用	A 系列 BiPAP Hybrid A30 (未在美國銷售)
	A 系列 BiPAP V30 Auto
連續型呼吸器，非維生用	A 系列 BiPAP A40
	A 系列 BiPAP A30

身為使用者的您應立即採取的行動：

1. 在您與醫生討論之前，請勿停止或改變您的處方治療。Philips 知道對於需要呼吸器進行生命維持治療，或是無法中斷治療的病患，可能不存在可用於治療的替代呼吸器選項，或者嚴重受限。在這些情況下，且由治療臨床團隊酌情決定，繼續使用這些呼吸器裝置的效益可能會超過其風險。

2. 如果您的醫生判斷您必須繼續使用本裝置，**請搭配內嵌式的細菌過濾器使用。**請參閱使用說明以取得安裝指引。

3. 您當地的 Philips 代表： 尚健國際有限公司將與您聯繫，並安排實施永久解決方案。如果您需要有關此問題的進一步信息或支援，請聯繫您當地的 Philips 代表：
   尚健國際有限公司
   電話: +852 2268 9243
   電郵:celki.cs@airliquide.com

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。Philips 或當地的 Philips 代表將會提供您實施永久解決方案的後續步驟資訊。

其他資訊：

如果您需要關於此安全通知/問題的進一步資訊或支援，請聯絡支援專線或造訪網站：

尚健國際有限公司
電話: *+852 2268 92*43
電郵:*celki.cs@airliquide.com*

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