HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Philips Ventilators

Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, A-Series BiPAP Hybrid A30, A-Series BiPAP V30 Auto, A-Series BiPAP A40, A-Series BiPAP A30

Philips Sleep and Respiratory care devices

E30
DreamStation ASV
DreamStation ST, AVAPS
SystemOne ASV4
C-Series ASV
C-Series S/T and AVAPS
OmniLab Advanced+
SystemOne (Q-Series)
DreamStation
DreamStation Go
Dorma 400
Dorma 500
REMstar SE Auto

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2021(05 Version 2) **Update Issued: 20th July 2021**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips Respironics	V46723

ISSUE

The Health Products Regulatory Authority (HPRA) is issuing this Safety Notice to raise awareness of two issues identified with certain Philips Respironics ventilators, sleep and respiratory care devices (also known as 'CPAPs' or 'BiPAPs') manufactured before 26th April 2021.

Philips has advised that the two issues are due to the potential that polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices:
1) may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user and,
2) may emit certain chemicals.

A list of all affected models and further information on the issues is available in the accompanying field safety notices (FSNs) issued by Philips. Where certain device models may have been previously marketed under alternate names (eg. SystemOne REMstar) please contact Philips or your provider to establish if your device is within the scope of this issue. It is important to note that the FSNs advise not stopping or changing your prescribed therapy without first consulting your doctor.

ACTION OR RECOMMENDATIONS

The HPRA advises users to:

1. Identify whether your device is one of the impacted models listed in the accompanying FSNs.

   Based on the current information supplied by Philips, the Health Service Executive (HSE) recommends that all patients and device users continue to use their device as prescribed until a replacement device is supplied or the device repaired. Further details are available on the HSE website https://www.hse.ie/eng/services/news/newsfeatures/advice-philips-respironics-devices/

2. Register your device at https://www.philips.ie/healthcare/e/sleep/communications/src-update
   Call 1800 851 241 if you cannot visit the website or do not have internet access.
3. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSNs for further information in relation to this issue.
2. Acknowledge receipt of the FSNs if you have not already done so.
3. Refer to information provided by Philips for physicians and other medical care providers at https://www.philips.ie/healthcare/e/sleep/communications/src-update/information-for-physicians-and-providers
4. Report any adverse incidents associated with this device to the manufacturer and to the HPRA.

Note – This is an emerging issue, the HPRA is working with the HSE, hospital and community services to further assess this issue and the potential impact on patients in Ireland. As information becomes available, the up to date HSE advice will be published on their website https://www.hse.ie/eng/services/news/newsfeatures/advice-philips-respironics-devices/

The HPRA has also published a Special Topics webpage for this issue at https://www.hpra.ie/homepage/medical-devices/special-topics/philips-sleep-and-respiratory-care-devices

Suppliers are requested to forward a copy of this Safety Notice and the accompanying FSNs to all affected users and to any organisation / persons to which / whom these devices have been transferred.

TARGET GROUPS

Users of affected devices and their carers Respiratory consultants General practitioners Community care managers Paediatricians Risk managers Supplies managers	Outpatient clinics Intensive Care Units Neonatal Intensive Care Units Nursing Homes Sleep Centres Rehabilitation Units

BACKGROUND

Philips Respironics has initiated a global field safety corrective action and issued the accompanying FSNs to notify device users of the two issues outlined above. As described in these notices, the manufacturer has identified a number of potential risks, which may have significant effects on the users of these devices in the long term, including potential risks related to exposure to carcinogens.

To date, Philips has received several global complaints regarding the presence of black debris/particles within the air pathway 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.

Philips has advised that they are deploying a permanent corrective action to address these issues. Further information on this corrective action and the status of the field action are available at: https://www.philips.ie/healthcare/e/sleep/communications/src-update

MANUFACTURER / AUTHORISED REPRESENTATIVE / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Philips Respironics Inc, 312 Alvin Drive,	Telephone: E-mail:	1800851241 devicevigilanceuki@philips.com

New Kensington, 15068, USA	Website: https://www.philips.ie/healthcare/e/sleep/communications/src-update

Enquiries to the **authorised representative** should be addressed to:

Respironics Deutschland GmbH & Co. KG, Gewerbestr 17, Herrsching 82211, Germany	Telephone: E-mail:	1800851241 devicevigilanceuki@philips.com

Enquiries to the **distributors** should be addressed to:

Air Liquide 18 H Rosemount Business Park, Ballycoolin, Dublin 11	Telephone: E-mail: Website:	1800 740202 (Option 3) healthie@airliquide.ie www.airliquide.ie
Direct Medical Suite 2 Gateway Centre, Monksland, Athlone, Co. Roscommon, N37 CD77	Telephone: E-mail:	09064 90190 patient.support@directmedical.ie
Cardiac Services Unit 3a, Northern Cross Business Park, Finglas, Dublin 11, D11 WY11	Telephone: E-mail:	(01) 8307499 recalls@cardiac-services.com
BOC Healthcare Bluebell, Dublin 12	Telephone: E-mail:	1800 22 02 02 healthcareinfo.ie@boc.com
PAP Healthcare 18 Laburnum Park, Model Farm Road, Cork.	Telephone: E-mail:	(021) 419 3009 (Option 4) support@paphealthcare.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: E-mail: Website:	+353-1-6764971 devicesafety@hpra.ie www.hpra.ie