National Patient Safety Alert

MHRA

Philips ventilator, CPAP and BiPAP devices: Potential for patient harm due to inhalation of particles and volatile organic compounds

Date of Issue:	23/06/2021	Reference No:	NatPSA/2021/005/MHRA

This alert is for action by: all Hospital Trusts and Health Boards providing NHS and private healthcare, including community care.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by a senior member of staff such as the Head of Respiratory Medicine and head of Procurement/supplies or equivalent roles

Explanation of identified safety issue:

Philips have issued 2 FSNs about selected ventilators and CPAP and BiPAP devices: See additional information section for affected models.

These devices are primarily used in patients with Obstructive Sleep Apnoea (OSA) and type 2 respiratory failure

There is a risk of patient harm from degradation of the sound abatement foam found in these devices.

Reports of incidents related to this issue are rare, and no incidents of harm have been reported in the UK.

There are 2 identified issues:

1. Degradation of foam causing particles to be blown into the patient's airway. There have been a small number of reports outside the UK of this causing minor, short-term effects such as: irritation to the skin, eye, and respiratory tract; an inflammatory response; headaches; asthma.

Inappropriate use and decontamination can worsen the foam degradation. Devices should be used and decontaminated as stated in the manufacturer's instructions for use.

2. Release of volatile organic compounds (VOC) including Dimethyl diazene and Phenol. Evidence suggests these gases dissipate after 24 hours from first 'out of box' use.

There is a risk of short-term effects such as: headache/dizziness; irritation of the eyes, nose, respiratory tract and skin; hypersensitivity; nausea and vomiting. There have not been any reports of this to date.

Patients with known allergies or sensitivities to these VOCs should be prioritised for an alternative device if available.

There is currently no definitive data showing long-term harm to patients, but VOCs and degradation of the foam are associated with possible long-term effects such as: genotoxicity; mutagenic and carcinogenic effects; hepatotoxicity; nephrotoxicity; neurotoxicity.

Actions required

NOTE:
Do not advise patients to stop using the devices unless a risk assessment has concluded that the risks outweigh the benefits.

Actions to be complete by 17 December 2021

1. Identify whether you have any of the affected devices in your organisation, or if you have provided them to patients under your care.

2. Send the FSNs to all relevant departments. Ensure clinicians read and follow the manufacturer's FSNs for each device within 2 days.

3. Implement and document a risk assessment process to determine the suitability of the continued use of these devices within 1 month. Refer to additional information section below for more information.

   Clinicians should:

   a) Determine whether risk assessments should be based on individual patients or patient groups and
   b) Contact affected patients and have a risk–benefit conversation about continued use. Advise that they can register their devices on the manufacturer's website.

4. Source alternative devices where clinically appropriate. Guidance will be available through NHS Supply Chain in England (or national procurement services for Devolved Administrations).

5. Train staff and patients, and verify competency, in using the alternative devices. Ensure training records are updated.

Additional information:

Risks involved in stopping treatment
Stopping treatment suddenly could have an immediate and detrimental effect on patient health. BiPAP devices are primarily used by patients with established type II respiratory failure. Withholding treatment may worsen the respiratory failure, resulting in the underlying condition getting worse and possible hospitalisation.

CPAP devices are primarily used by patients with Obstructive Sleep Apnoea (OSA), enabling them to carry out activities of normal daily living e.g. driving a vehicle, that they would be unable to do if they were to stop treatment. Withholding treatment could increase their risk of stroke, heart disease and high blood pressure. This could require hospital admission and a more invasive method of treatment and have long-term health consequences.

Filters for ventilator systems (not applicable to CPAP/BiPAP)
Inserting an inline filter into the breathing system of a ventilator between the patient and the device will greatly reduce the risk of patients inhaling particulates, due to the size of the particles released during degradation (2.69UM-724UM). The use of filters is only validated by Philips for the ventilator system and is recommended in the instructions for use.

The use of filters is not validated by Phillips for their CPAP/BiPAP machines and is considered off-label use. The effect of introducing a filter to the breathing system on patient treatment is unknown.

Biological safety risk assessment (based on the currently available data)
The available evidence suggests:

- Volatile organic chemicals of concern (Dimethyl Diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) are not detectable 24 hours after the first ‘out of box’ use of the device.
- Levels of diethylene glycol detected were within an acceptable margin of safety.
- The degradation by-products Toluene Diamine and Toluene Diisocyanate are classified by IARC as Group 2B carcinogens. This category is used for chemicals where there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals.
- Laboratory analysis found that as the foam degraded it tended to stick to nearby surfaces as well as itself. This reduces the risk of respirable particles entering the breathing circuit.
- Degradation of the polyurethane foam can be accelerated by off-label use of ozone decontamination or use in environments with high humidity and temperature, neither of which apply in the UK.
- Available evidence suggests that most degraded foam particles are too big to be inhaled.
- Diisocyanate is associated with isocyanate-induced asthma in a very small number of patients. For sensitised patients even low concentrations can cause adverse effects.

The available evidence suggests that the risks to patients of ceasing to use these devices significantly outweigh the biological safety risks if patients do not have ready access to an alternative.

Affected devices: All devices manufactured before 26 April 2021 are affected. This includes all device models and serial numbers listed below.

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

Mechanical 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.

Stakeholder engagement:
DHSC Supply resilience
NHSE/I – including National Clinical Director for Respiratory Disease
Devolved Administrations
Cross-system Incident Management Team
International regulators

Report any suspected or actual adverse incidents involving these devices through your healthcare institution’s local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Department of Health www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

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 issuing a Field Safety Notification about 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 emit 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). Emission of chemicals 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 effects. The potential risks of chemical exposure due to emission of chemicals 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. Register your device(s) on the field action website: https://www.philips.co.uk/healthcare/e/sleep/communications/src-update

    a. The website provides you current information on the status of the field action and how to receive permanent corrective action to address the two (2) issues.
    b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    c. Call 0800 249 4578 if you cannot visit the website or do not have internet access.

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 Field Safety Notification. 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 support hotline or visit the website:

0800 249 4578

https://www.philips.co.uk/healthcare/e/sleep/communications/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

URGENT: FIELD SAFETY NOTICE

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is issuing a Field Safety Notification about 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 emit 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). Emission of chemicals 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 emission of chemicals 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. Please contact your physician or care provider before making any changes to your prescribed therapy. While the risks identified in this letter have resulted in Philips recommending discontinued use, it is important that you consult with your physician to determine the most appropriate options for continued treatment. Together with your physician determine if the benefit of continuing therapy with your device outweighs the risks identified.

2. Register your device on the field action website:
   https://www.philips.co.uk/healthcare/e/sleep/communications/src-update

   a. The website provides you current information on the status of the field action and how to receive permanent corrective action to address the two (2) issues.
   b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
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