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 21 February 2022

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.

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