Safety Action Notice

Reference **SAN2109** Issued **24 June 2021** Review Date **24 June 2022**

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

Summary

This alert updates advice issued in NatPSA/2021/005/MHRA. Attention is drawn to arrangements for registering affected devices with Philips.

Action

1. Identify all affected devices including those currently in use by patients and notify National Procurement (NSS) of this information by **16:00 on Wednesday 30 June 2021**.
2. Make your medical engineering team and your medical device safety officer aware of this issue.
3. Ensure clinicians are informed of the advice on continued use and prioritisation for alternative devices.
4. Share the suggested patient letter (appendix) with any patients that currently use a device covered by the Field Safety Notice.
5. Reassure patients that the risk involved with use of these products is very low and that they only need to be moved to an alternative where it is clinically necessary.
6. Register the device on behalf of patients using the link included in the FSN.
7. Arrange for an alternative device for patients that have occupational asthma related to isocyanates. Train staff and patients in the use of alternative devices. Verify competency and update training records.
8. Report any suspected or actual adverse incidents involving these devices through your local incident reporting system and to IRIC: report an incident

Equipment Details

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.

A visual guide to the devices affected and those not affected has been provided by the manufacturer: https://www.philips.co.uk/healthcare/e/sleep/communications/src-update

Problem / background

Philips has issued a Field Safety Notice (FSN) and MHRA (Medicines and Healthcare products Regulatory Agency) subsequently published National Patient Safety Alert NatPSA/2021/005/MHRA which NSS distributed in Scotland on 23 June 2021.

Philips identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in affected devices. Following testing, it was identified that this type of foam may degrade into particles which could enter the device's air pathway and be ingested / inhaled by the user. It is possible the foam may release certain chemicals in gaseous form. While there have been no complaints from users in the UK and a low complaint rate globally, the foam degradation may be exacerbated by use of unapproved cleaning methods, especially ozone, and environments with high heat and/or high humidity. It has been advised that ozone should not be used to clean these products.

Both the Field Safety Notice and the MHRA information recommend:

- that patients should continue to use affected products unless advised not to do so by their clinician and
- to seek clinical advice on circumstances where provision of an alternative device would be appropriate.

Philips will pause shipping these products to the NHS. Alternative products are being sought both to allow for patients that need to exchange their devices for clinical purposes and for new patients who need to start PAP therapy.

The FSN asks that devices are registered on the Philips website to allow for Philips to manage the repair and replacement of devices. However, it would not be appropriate for patients to provide their details directly to Philips. Therefore, clinical teams will need to register devices on behalf of patients and manage the repair process when Philips are in contact.

No adverse events have been reported in relation to these devices in the UK. From a clinical perspective, the risk of discontinuing therapy for the vast majority of patients far outweighs continuing therapy until a replacement device can be sourced or remedial action can be taken to rectify the issue. For most patients this means they should continue to use their device as normal.

The one exception to this guidance is patients with certain very rare forms of occupational asthma related to isocyanates who should be contacted to arrange an alternative device. This is a measure being undertaken as a precaution. Where there are patients that this may impact, alternative devices should be sourced through the normal supply route in the first instance. Where normal supply routes are unable to meet requirements, contact should be made with national procurement Customer Services. It should be noted that supply is likely to be constrained and demand management may need to be applied to support cases of greatest clinical need.

Philips have recommended that, if continuing to use some of the affected devices, patients should use an inline bacterial filter. A clinical assessment of each case should be made before inserting a filter, as for many patients there is a justification for not having a filter in the circuit.

Attached is a template letter for patients explaining the issue. Please can you arrange for this letter to be sent along with a copy of the relevant FSN to patients that have been impacted.

Manufacturer contacts

Philips support line 0800 249 4578 or website:
https://www.philips.co.uk/healthcare/e/sleep/communications/src-update

References

Philips field safety notices (FSNs)

- 2021-05A, Philips Respironics: Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series
- 2021-06A, Philips Respironics: CPAP and Bi-Level PAP Devices

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.

APPENDIX

Suggested patient letter template

We have been made aware of an issue with Philips Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices.

We are writing to you as you have one of these devices.

Philips has issued a Field Safety Notice. This notice says that under certain conditions the foam part of the machine can be damaged. This notice has been issued globally, so it is not specific to the UK. These conditions; very high temperatures, high humidity and the use of a non-approved cleaning solution, are rare in the UK.

NHS Scotland has been working closely with Philips and the Medicines & Healthcare products Regulatory Agency (MHRA) who are responsible for patient safety. There have been no known safety issues related to these products reported in the UK. No adverse events in the UK in relation to these devices have been reported to the MHRA.

For most patients the risk of stopping using these devices is far greater than the risk from the issue that Philips has reported. The MHRA (23-6-21) has advised that patients should continue to use these devices: https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-philips-ventilator-cpap-and-bipap-devices-potential-for-patient-harm-due-to-inhalation-of-particles-and-volatile-organic-compounds-natpsa-slash-2021-slash-005-slash-mhra

Some patients with certain very rare forms of occupational asthma related to isocyanates will need to be moved onto an alternative device. If this applies to you, please notify us at the earliest opportunity. If you are not contacted by your clinician, you do not need to change devices and you can continue to use your device as normal.

Philips will be gradually replacing the devices. The notice that they have issued asks patients to register their devices. However, NHS <<name of NHS Board>> will do this on behalf of patients, so please contact us at << insert local contact details >> and we will be able to register the device on your behalf.