MHRA Device Safety Information

Reference: MDSI2406 **Issued:** 28 August 2024 **Review Date:** 28 August 2025

Philips Respironics BiPAP A series ventilators: alarm malfunction and risk of therapy interruptions in ventilators not intended for life-support

Summary

Philips Respironics has issued a Field Safety Notice (FSN) relating to the Bilevel Positive Airway Pressure (BiPAP) A series ventilators. This relates to a Ventilator Inoperative alarm which could result in the potential loss of therapy to patients without warning.

Action for healthcare professionals

- Identify patients using the relevant devices listed in the FSN in both inpatient and community-based settings
- Follow the actions set out in the FSN
  - Assess if patients can tolerate interruptions to their therapy.
  - If patients cannot tolerate interruptions of therapy, prioritise and provide an alternative device appropriate to their level of ventilation dependency as soon as possible depending on local resources.
  - If patients can tolerate interruptions in therapy, consider the benefits and risks of continued use on an individual basis. Prioritise patients at higher risk to ensure an alternative device is provided at the earliest opportunity depending on local resources. Lower risk patients should also be provided with an alternative device when possible depending on local resources.
  - For patients using this device who have a backup device available, advise the patients / carers or caregivers or hospital staff that if the alarm occurs to immediately remove the device, and connect the patient to an alternative device.
  - Ensure community-based patients/carers or caregivers are provided with clear instructions for changing over their device (see MHRA recommendations on page 2).

As an additional measure, a forced restart of the device may temporarily restore function of the device if it has entered the inoperable state whilst waiting for a replacement device:

1. Power off the device by pressing the start/stop button. If the ventilator screen displays the “Power off” command, press the “Yes” button to shut off the device and silence the alarm
2. Unplug the power cord from the wall or from the device itself
3. Remove the battery from the ventilator device. If a detachable battery pack is used, open the battery compartment at the top of battery module accessory and lift out the battery using the release lever on top of the battery. If an external battery pack is used, unplug the battery pack cord from the back of the ventilator
4. Leave the battery disconnected from the ventilator for at least 30 seconds
5. Reconnect the applicable battery in use to the ventilator
6. Plug the power cord back in to the wall or the device itself
7. Power on the ventilator by pressing the Start/Stop button
8. Once the ventilator powers back, therapy may be restarted

Reporting adverse incidents

Direct any known or suspected adverse incidents to the Incident Reporting & Investigation Centre (IRIC) and to your local incident reporting and learning system.

Click this link to report an incident to IRIC.

For information only: actions MHRA has recommended for others

Patients / carers or caregivers

- Patients / carers or caregivers using these devices or caring for a patient who is, should follow the advice of the patient's healthcare professional who will make recommendations for treatment and may recommend an alternative device.
- Patients / carers or caregivers using these devices or caring for a patient who is, should be aware of possible symptoms associated with loss of therapy (see above list of symptoms).
- If the 'Ventilator Inoperative' alarm occurs, immediately remove the device and connect the patient to an alternative device if available. Contact your home care equipment provider for advice and / or an alternative device.

As an additional measure a forced restart of the device may temporarily restore function of the device while waiting for a replacement device:

1. Power off the device by pressing the start/stop button. If the ventilator screen displays the "Power off" command then press the "Yes" button to shut off the device and silence the alarm
2. Unplug the power cord from the wall or from the device itself
3. Remove the battery from the ventilator device. If a detachable battery pack is used, open the battery compartment at the top of battery module accessory and lift out the battery using the release lever on top of the battery. If an external battery pack is used, unplug the battery pack cord from the back of the ventilator
4. Leave the battery disconnected from the ventilator for at least 30 seconds
5. Reconnect the applicable battery in use to the ventilator
6. Plug the power cord back in to the wall or the device itself
7. Power on the ventilator by pressing the Start/Stop button
8. Once the ventilator powers back, therapy may be restarted
    - Patients / carers or caregivers that have concerns about continued use of these devices should discuss this with the patient's healthcare professional.
    - Seek urgent medical attention if patients feel unwell following the interruptions of therapy from the malfunction of these devices whilst awaiting a replacement.
    - Any patients experiencing a malfunction of this device and / or feel that they have been harmed by a medical device should inform their care team at the earliest possible opportunity and then report this via the Yellow Card scheme. Healthcare professionals receiving this information should report it to IRIC (see above) and to their local incident reporting and learning system.

Distributors

- Review your inventory and determine if affected ventilators are present in your stock
- Quarantine affected stock and contact Philips Respironics for instruction
- Distribute a copy of the FSN to customers with affected ventilators
- Complete the response form attached to the FSN and return it to Philips Respironics

Equipment details

Manufacturer name:	Philips Respironics
Device name:	BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro
Serial numbers:	All devices

Background information

Philips BiPAP ventilator devices are primarily used to treat patients with obstructive sleep apnoea (OSA), respiratory insufficiency or respiratory failure. These devices are not intended for life support (patients who are dependent on artificial ventilation for their immediate life support) as indicated in the device instructions for use (IFU).

In May 2024, Philips released an FSN relating to an error causing interruptions or loss of therapy in the above named BiPAP ventilators.

An internal error in affected devices will trigger a Ventilator Inoperative alarm and the device will shut down if the cause of the error indicates the device cannot deliver therapy. The alarm silence button will flash red, and a message will appear on the device screen displaying “Ventilator Inoperative”. Please refer to the FSN for an example of what this message looks like.

This alarm can occur when 3 device restarts have occurred in a 24 hour period or it can occur spontaneously without a previous restart.

Interruption and / or loss of therapy may lead to adverse events including respiratory insufficiency or potentially death.

Interruption of therapy may present as symptoms of:

- nausea and vomiting,
- fragmented and unrefreshing sleep,
- tiredness (fatigue) or lethargy,
- shortness of breath,
- increased effort to breathe,
- dizziness,
- slow, shallow or laboured breathing,
- bluish skin, lips or nails (cyanosis),
- coughing and wheezing,
- headaches,
- confusion,
- paranoia,
- unusual jerking or shaking movements.

In the context of a worldwide use of over 100 million potential uses, the overall likelihood of a malfunction occurring is very low. At the current time, there have been 888 reports worldwide, 10 reports of suspected serious injury and 7 reports of death associated with this issue.

The MHRA has received reports of incidents related to an issue with the Ventilator Inoperative alarm in these devices and is continuing to investigate these reports in collaboration with the manufacturer Philips Respironics.

Any changes to the current advice will be communicated to users as soon as possible and posted onto MHRA’s website.

Users of these devices should also be aware of a second FSN, released by Philips Respironics in July 2024, regarding an alarm malfunction linked to the oxygen sensor inside specific model numbers of the A30 EFL, A40 PRO and A40 EFL ventilators. This issue does not cause interruptions or loss of therapy and is therefore of lower risk to patients than the Ventilator Inoperative alarm issue covered in this Medical Device Safety Information (MDSI). For further information on this separate issue and the affected model numbers, please refer to the manufacturer's FSN.

Additional information

NHS England has circulated a system letter to inform healthcare professionals that a clinical reference group has been set up to guide decision making in England and to perform a stocktake of affected devices.

For queries or more information, please contact Info@mhra.gov.uk.

Enquiries - manufacturer or supplier contact details

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Phone: 0800 026 0086
Email: ukisfco@philips.com

Suggested onward distribution (may not include all affected departments)

Care homes
Device Managers
District nursing
Emergency Departments
General Practitioners
Health & Safety
Health Centres
Hospices
Hospital at home
Medical high dependency
Medical Physics
Paediatrics
Respiratory Medicine
Risk Management
Sleep services
Supplies/Procurement
Surgical high dependency
Wards

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure NHS National Services Scotland, Tel: 0131 275 7575, email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

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scan the QR code or click this link to visit our website

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/