Medicines & Healthcare products Regulatory Agency

Device Safety Information (DSI)

Philips Respironics BiPAP A series ventilators: alarm malfunction and risk of therapy interruptions in ventilators not intended for life-support, DSI/2024/006

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.

Devices Details

Device Name: BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro
Affected lot numbers/serial numbers: **All** devices
Manufactured by: Philips Respironics

Explanation of identified safety issue

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 are 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 our 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 DSI. For further information on this separate issue and the affected model numbers, please refer to the manufacturer's FSN.

Actions

Actions 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.

- 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, 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

- There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
    - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Actions for 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.

Actions for 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

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.

Stakeholder engagement

- Department of Health & Social Care's National Supply Disruption Response team
- NHS England's National Operations Centre and product Clinical Reference Group, chaired by the National Clinical Director for Respiratory Disease
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- NHS Wales
- Northern Ireland Adverse Incident Centre for Northern Ireland

An advance copy for review was sent to all the devolved administrations for stakeholder engagement.