

MHRA Device Safety Information

Reference: MDSI2406U2 Issued: 29 May 2025

Review Date: 29 May 2026

Philips Respironics BiPAP A series ventilators: alarm malfunction and risk of therapy interruptions in ventilators not intended for life-support – UPDATE 2

Summary

This alert notifies a further update that MHRA has added to an alert it previously issued in the form of a web page on 28 August 2024. The alert was distributed in Scotland in document format by IRIC.

The document-based alert issued in Scotland by IRIC can be found <u>here</u>. The original MHRA web-based alert with updates added on 02 October 2024 and May 2025, can be found <u>here</u>.

MHRA update: May 2025

Philips Respironics have published a <u>Field Safety Notice (FSN)</u> to further clarify the patient population who cannot tolerate interruptions or loss of therapy. Please see the <u>FSN</u> for further information. The advice within this DSI remains unchanged. Patients should continue to follow the advice of their healthcare professional.

Information about IRIC

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

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 <u>CEL 43 (2009)</u>, Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities, issued 30 October 2009.

To find safety alerts: scan the QR code or <u>click</u> this link to visit our website



To report an incident: scan the QR code or <u>click</u> this link to visit our website



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