MHRA Device Safety Information

Reference: MDSI2406U **Issued:** 18 October 2024 **Review Date:** 18 October 2025

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

This alert notifies an update that MHRA has added to advice it provided in the form of a web page on 28 August 2024. The original web page, with MHRA's update added on 02 October 2024, can be accessed here.

Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) has updated the webpage on which MDSI2406 was based on 02 October 2024.

MHRA update

The MHRA has issued the following update:

> Philips Respironics have now published a further Field Safety Notice (FSN) on actions they will be taking to address this issue. This includes updates to the instructions for use (IFU) for the BiPAP A40 and A40 Pro devices, and financial/replacement options for affected users. Please see the FSN for further information. Patients should continue to follow the advice of their healthcare professional.
>
> The advice within this DSI remains unchanged.

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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