HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Philips ventilators BiPAP autoSV, BiPAP autoSV Advanced, OmniLab Advanced, OmniLab Advanced + and HeartPAP devices

Priority 2 – Warning

HPRA Safety Notice: SN2015(12) **Issue Date: 02 June 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Philips	V24344

ISSUE
ResMed has identified a risk of increased cardiovascular death in patients with symptomatic chronic heart failure with reduced left ventricular ejection fraction being treated with Adaptive Servo-Ventilation (ASV) mode on ResMed ventilators. This issue was highlighted in a field safety notice (FSN) that was circulated by the manufacturer in May 2015 and was the subject of the HPRA safety notice SN2015(10). Philips is actively evaluating the information provided by ResMed and examining if this might impact the medical care of patients who use the Philips devices listed above. Until their investigation has been completed, based on the ResMed announcement, Philips is strongly recommending clinicians adhere to the recommendations given in the attached FSN. Philips has also issued a press release alerting the healthcare community of this issue. Please refer to the attached FSN for additional details on the issues affecting the devices and the actions proposed by the manufacturer.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Ensure that you have read and followed the instructions that were provided in the manufacturer's field safety notice (FSN).

2 Return confirmation form to confirm receipt of the FSN to Philips.

3 Physicians are advised not to place new patients with symptomatic chronic heart failure (NYHA 2-4) and reduced LVEF≤45%, AND moderate to severe predominant central sleep apnea on ASV therapy. Before putting patients on ASV, each patient should be assessed for Heart Failure. In case of signs and symptoms of Heart Failure an objective assessment of LVEF should be performed. Current patients should be evaluated and a discussion about whether to discontinue ASV therapy should occur if a current patient is found to be in the at-risk population. If it is unknown whether a current patient falls within the at-risk population, the patient should be evaluated to determine if ASV therapy should continue.

4 Forward this HPRA Safety Notice to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

5 Ensure that relevant personnel receive a copy of the attached FSN.

6 Health care providers or medical staff who have questions about this FSN should:

- Contact their Philips representative.
- Call the helpline: +44 800 1300845. Local IE number 1850 240202

TARGET GROUPS

HSE Hospital Staff	Risk Managers
Private Hospital Staff	Purchasing Managers
Hospice Staff	Supplies Managers
Clinical Engineers/Medical Physics	Home Care Providers

BACKGROUND

ResMed has identified a serious safety concern during preliminary primary data analysis from the SERVE-HF clinical trial. The data analysis shows that patients with symptomatic, chronic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea (AHI ≥ 15/h, CAHI/AHI ≥ 50% and CAI ≥ 10/h) are at a 33.5% increased risk of cardiovascular death when undergoing AdaptiveServo Ventilation (ASV) therapy when compared to equivalent patients who are not on ASV therapy. The SERVE-HF study has identified no patient benefit from the use of ASV therapy in the at risk group with chronic systolic heart failure.

Further information about the clinical trial and the action being recommended by ResMed can be found in HPRA safety notice SN2015(10).

The HPRA is communicating this Safety Notice at this time to ensure that all users of the device are aware of the issue.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Philips Healthcare
Chichester Business Park
City Fields Way
Tangmere, Chichester
West Sussex, UK
PO20 2FT

Telephone: ++44 800 1300840
Fax: ++44 800 1300841
E-mail: rukcustomerservices@philips.com
Website: www.philips.co.uk/healthcare

Enquiries to the **distributor** should be addressed to:

Baywater Healthcare Ltd
Unit 18H Rosemont Business Park
Dublin 11
Ireland

Telephone: 1850 240202
0800 328 5875 (Northern Ireland Only)
Fax: +353 (0)1 829 3966
E-mail: healthie@baywater.ie
Website: www.baywater.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie