HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Specific ResMed Ventilators with Adaptive ServoVentilation (ASV)

Priority 2 – Warning

HPRA Safety Notice: SN2015(10) **Issue Date: 25 May 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
ResMed Ltd	V24266

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. 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) that was circulated in May 2015.
2	Return confirmation form to confirm receipt of the FSN to ResMed.
3	Physicians managing patients with symptomatic chronic heart failure with reduced ejection fraction who are using ResMed ASV devices should contact their patients to discuss discontinuation of treatment. Physicians should be aware that new at risk patients should not use ASV. ASV therapy is now contraindicated in these at risk patients.

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 ResMed representative.
- Call the helpline: +44 800 917 9411
- Go to www.SERVE-HFfaqs.com for more information, including answers to frequently asked questions.

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. For further information about the clinical trial and recommendations for use of the device, please see the attached FSN from ResMed.

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:

ResMed Ltd
1 Elizabeth Macarthur Drive,
Bella Vista
NSW 2153
Australia

Telephone: +44 800 917 9411
Fax:
E-mail: asvsupport@resmed.co.uk
Website: www.resmed.com

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

PEI
M50 Business Park,
Ballymount Rd Upper
Ballymount,
Dublin 12

Telephone: 01 419 6900
Fax: 01 419 6999
E-mail: info@pei.ie
Website: www.pei.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