HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

SOMNOventCR and prismaCR

Priority 2 – Warning

HPRA Safety Notice: SN2015(16) **Issue Date: 7th July 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Weinmann	V24554

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). Due to the results of the study conducted by ResMed, Weinmann is also recommending that patients who use ASV therapy should contact their physician in order to urgently and critically review the individual indication for adaptive servo-ventilation on the basis of the criteria of symptomatic chronic heart failure and reduced LVEF of ≤ 45%. Although individual ASV algorithms used by manufacturers differ widely, at the present time the possibility cannot be ruled out that treatment with the Weinmann devices SOMNOvent CR and prismaCR for adaptive servo-ventilation could cause deterioration in the state of health of at-risk patients with the clinical symptoms stated above. 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 Weinmann.

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 Weinmann on +49 40 547020 or customerservice-HC@weinmann.de

TARGET GROUPS

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

BACKGROUND

Affected Devices:
SOMNOventCR - Article numbers: 23470; 24720; 247320HL0; 24785;
prismaCR - Article numbers: 29960-22110; 29960-22111; 29960HL-4110

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:

Weinmann	Telephone:	+49-40-547 020
Kronsaalsweg 40	Fax:	+49-40-547 02-461
22525 Hamburg	E-mail:	info@weinmann.de
Germany	Website:	www.weinmann.de

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

Respicare	Telephone:	01 8904020
Medical Centre,	Fax:	01 8904021
Applewood Village	E-mail:	sales@respicare.ie
Swords		
Dublin		

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	devicesafety@hpra.ie
Earlsfort Terrace	Website:	www.hpra.ie
Dublin 2		