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WEINMANN medical technology

Important Safety Information

To whom it may concern

Hamburg, May 29th, 2015

Increased risk of cardiovascular death with use of adaptive servo-ventilation (ASV) therapy for patients with symptomatic chronic systolic heart failure and reduced ejection fraction

Dear Sir or Madam,

Quality and safety are our highest priority. For this reason it is important for us to provide you with the following safety information in relation to the Weinmann devices SOMNOvent CR and prismaCR.

Sender:
Weinmann Geräte für Medizin GmbH + Co.KG

Addressee:
Users and operators of devices for adaptive servo-ventilation therapy

Identification of the devices concerned:

SOMNOventCR	Article numbers: 23470; 24720; 247320HL0; 24785;
prismaCR	Article numbers: 29960-2110; 29960-2111; 29960HL-4110

The safety information applies to all serial numbers.

Description of the problem and the identified cause:
The medical device manufacturer ResMed has published safety information, in which it reported results of the SERVE-HF study which indicate a significant increase in the annual death risk in patients who have received adaptive servo-ventilation (ASV) therapy. According to the results, patients with symptomatic chronic heart failure, a left ventricular ejection fraction (LVEF) of ≤ 45% and central sleep apnea who were treated with the devices used in the study were at a higher risk of death than patients in the control group. Although the individual ASV algorithms used by the 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 a deterioration in the state of health of at-risk patients with the clinical symptoms stated above.

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USt-IdNr. DE 118051598
WEEE-Reg.-Nr. DE 63391140
Zertifiziertes QM-System
EG-Richtlinie 93/42/EWG, Anh. II
(EN ISO 13485 / EN ISO 9001)

Komplementär
Verwaltungsgesellschaft Weinmann
Geräte für Medizin GmbH, Hamburg
Registergericht
Amtsgericht Hamburg, Abt. B, Nr. 8678
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Action by customers/operators
Until the assessment has been concluded, please inform all your patients who use ASV therapy that they 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 (NYHA 2-4) and reduced LVEF of ≤ 45% and moderate to severe predominant central sleep apnea. Where appropriate, treatment should be discontinued. It is not advisable to terminate treatment with ASV without taking into consideration the situation of the individual patient. Previous examinations must be reviewed and, if necessary, repeated in light of the criteria (severity of heart failure, severity of central portion).

Furthermore, you should, wherever possible, advise the attending physicians and prescribers of ASV therapy to contact the affected patients, inform them of the risks, and consider discontinuing or changing the therapy.
Until the assessment has been concluded, we recommend that no new patients in this risk group should be treated with SOMNOvent CR or prismaCR devices.

The instructions for use of the Weinmann SOMNOvent CR and prismaCR devices have, until further notice, been amended to include the contraindication *Symptomatic chronic systolic 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).* The supplement to the instructions for use is appended to this letter.

Acknowledgment
Please confirm that you have received this letter and have forwarded it to the relevant persons by completing the attached confirmation of receipt.

Distribution of the information provided
In your organization, please make sure that all users of the above devices and other persons who need to be informed have received notification of this **Safety Information**. If you have passed on these devices to third parties, please forward a copy of this information to them or inform the contact person given below.

Weinmann regrets any inconvenience caused by this action.

Sincerely,

Thomas Weber

Head of Quality Management and Regulatory Affairs

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-Confirmation of Receipt-

Increased risk of cardiovascular death with use of adaptive servo-ventilation (ASV) therapy for patients with symptomatic chronic systolic heart failure and reduced ejection fraction

Original letter was sent to:

Please fill out this Confirmation of Receipt and return it by fax, e-mail or mail to:

Fax: **+49 (0)40 547 02-476**
E-mail: **customerservice-HC@weinmann.de**

Weinmann Geräte für Medizin GmbH + Co.KG
Sicherheitsbeauftragter für Medizinprodukte
(Safety Officer for Medical Devices)
Kronsaalsweg 40
22525 Hamburg
Germany

Please complete fully in block letters:

☐ **Company details are <u>identical</u> to the above address field.**

☐ **Company details are <u>different</u> from the above address field. The correct details are as follows:**

Your customer number: _____

Company name + address: _____

_____

_____

☒ **I hereby confirm receipt of the Safety Information** and that I have **read and understood the contents**. **All users of this device and other persons in my organization who need to be informed have been made aware of this letter**.
If we have passed on the devices to third parties, a **copy of this letter has been forwarded to them.**

_____ _____
Name (in block letters) **Date & signature**

_____
Position

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