Urgent Field Safety Notification

Increased Risk of Cardiovascular Death with Adaptive Servo-Ventilation (ASV) Therapy For Patients with Symptomatic Chronic Heart Failure with Reduced Ejection Fraction

Date: May 13, 2015

Distribution: Distributors of devices with ASV therapy
Medical and nursing staff in professional health care facilities
Health Care Providers (HCP)

Description of issue:

A serious safety concern has been identified during the preliminary primary data analysis from the SERVE-HF clinical trial. This trial investigated the effect of Adaptive Servo-Ventilation (ASV) therapy on the hospitalisation and mortality rate of 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).

Hazards involved:

The identified safety concern is a significant increase in the risk of cardiovascular death in patients with symptomatic, chronic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) being treated with Adaptive Servo-Ventilation.

Products affected:

The following ResMed devices are affected:

- AirCurve 10 CS PaceWave
- S9 VPAP Adapt
- S9 AutoSet CS-A
- S9 AutoSet CS
- S9 AutoSet CS eASV
- S9 VPAP Adapt PaceWave
- AutoSet CS-A
- S9 VPAP Tx
- VPAP Tx
- Lumis Tx
- AutoSet CS2
- AutoSet CS
- VPAP Adapt SV
- VPAP Adapt

Manufacturer:

ResMed Ltd
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Australia

Immediate action required:

Physicians managing patients' symptomatic chronic heart failure with reduced ejection fraction who are using ResMed ASV devices should contact their patients to discuss discontinuation of treatment.

Distributors / Suppliers of Medical Devices:

This Field Safety Notification needs to be provided to all health care providers or physicians who have prescribed ASV therapy, or all health care facilities which have purchased affected products.

Physicians:

The present data raises concerns with respect to patients with symptomatic, chronic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) who are on ASV therapy. This is the patient population studied in the SERVE-HF trial that is now considered at risk.

- For this at risk population there is a 33.5% increased risk of cardiovascular death, compared to equivalent patients who are not on ASV therapy (absolute annual risk: 10% in ASV patients vs. 7.5% in control group).
- The SERVE-HF study has identified no patient benefit from the use of ASV therapy in the at risk patient group with chronic systolic heart failure.
- New at risk patients should not use ASV. ASV therapy is now contraindicated in these at risk patients.
- 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.
- Physicians need to identify and reassess all patients with symptomatic chronic heart failure with reduced ejection fraction currently being treated with ASV devices with the aim of urgently stopping ASV therapy. The decision about current patients continuing on therapy should be made considering this significant increased risk of death and lack of observed patient benefit, and also considering:
    - The increased cardiovascular mortality is mainly attributed to death occurring out of hospital (likely "sudden cardiac death")

- Deaths attributed to use of this therapy may often occur without a preceding hospitalization or worsening symptoms
- The risk does not reduce with time on therapy
- The risk should be considered independent of perceived patient response to therapy

There has been no malfunction or technical fault with the operation of the device, it operates correctly to treat central sleep apnea. The identified risk is with the use of ASV in this identified at risk population.

Distributors, health care providers or medical staff who have questions about this Field Safety Notification should:

- Contact their ResMed representative
- Go to SERVE-HFfaqs.com for more information including answers to frequently asked questions

ResMed's primary focus is to provide safe and effective therapy for our patients. The SERVE-HF trial was initiated to understand the effect of ASV therapy in heart failure patients. As the preliminary data have identified an unexpected safety concern, we consider this urgent Field Safety Notification as necessary to enable physicians to reassess the use of ASV therapy in heart failure patients as soon as possible.

Yours truly,

Lionel King
Senior Vice President Global Quality Assurance and Regulatory Affairs