URGENT - Field Safety Notice

Use of auto servo ventilation (ASV) devices on patients with symptomatic chronic heart failure (NYHA 2-4) and reduced LVEF≤45%, AND moderate to severe predominant central sleep apnea

BiPAP autoSV Advanced System One (60 Series, 30 cm):
BiPAP autoSV Advanced System One (60 Series):
BiPAP autoSV Advanced System One (50 Series):
BiPAP autoSV Advanced w/SmartCard (SV3):
BiPAP autoSV w/SmartCard (SV2):
OmniLab Advanced +:
OmniLab Advanced:
BiPAP autoSV
HeartPAP

Dear Customer,

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

ResMed has issued an Urgent Field Safety Notice that described a statistically significant 2.5 percent absolute increased annual risk of cardiovascular mortality for those randomized to a ResMed adaptive servo ventilation (ASV) therapy compared to the control group. In the patient population with reduced left ventricular ejection fraction (LVEF ≤ 45%), 10.0 percent of the ASV group experienced a cardiovascular death each year compared to 7.5 percent of the control group, representing a 33.5 percent relative increased risk of cardiovascular mortality (HR=1.335, 95%CI=(1.070, 1.666), p-value= 0.010).

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 we complete our investigation, based on the ResMed announcement, we strongly recommend clinicians adhere to the following recommendations:

Do not 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.

No other patient populations have been identified as at-risk for adverse outcomes.

Philips has issued a press release alerting the healthcare community of this issue.

Should you have any questions or need further information regarding this communication, please do not hesitate to contact us at (877) 387-3311. UK contact: 0800 1300845

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This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by these recommendations.

Sincerely,

Jonathan W. Demarest,
Head of Quality & Regulatory, SRC, Philips

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AFFECTED PRODUCTS	BiPAP autoSV Advanced System One (60 Series, 30 cm): BiPAP autoSV Advanced System One (60 Series): BiPAP autoSV Advanced System One (50 Series): BiPAP autoSV Advanced w/SmartCard (SV3): BiPAP autoSV w/SmartCard (SV2): OmniLab Advanced +: OmniLab Advanced: BiPAP autoSV HeartPAP
PROBLEM DESCRIPTION	ResMed has issued an Urgent Field Safety Notice that described a statistically significant 2.5 percent absolute increased annual risk of cardiovascular mortality for those randomized to a ResMed adaptive servo ventilation (ASV) therapy compared to the control group. In the patient population with LVEF ≤ 45%, 10.0 percent of the ASV group experienced a cardiovascular death each year compared to 7.5 percent of the control group, representing a 33.5 percent relative increased risk of cardiovascular mortality (HR=1.335, 95%CI=(1.070, 1.666), p-value= 0.010).
HAZARD INVOLVED	The use of ASV in patients with symptomatic chronic heart failure (NYHA 2-4) and reduced LVEF≤45%, AND moderate to severe predominant central sleep apnea, could potentially represent a safety risk.
HOW TO IDENTIFY AFFECTED PRODUCTS	The device serial number label, located in the bottom enclosure of the device, will identify the device.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until we complete our investigation, based on the ResMed data, we strongly recommend clinicians adhere to the recommendations cautioning against the use of ASV therapy in patients with symptomatic chronic heart failure (NYHA 2-4) and reduced LVEF≤45%, AND moderate to severe predominant central sleep apnea. Physicians prescribing ASV therapy are recommended to not place new patients in the at-risk population on the devices and to evaluate current patients; a discussion about whether to discontinue ASV therapy should occur if a current patient is found to be in the at-risk population. Therefore, as a precaution, physicians should assess individual risks before prescribing therapy with the Philips devices listed above for the at-risk patient population. No other patient populations have been identified as at-risk for adverse outcomes. Based on this, we are requesting that you contact the prescribing physician and/or the patient and alert them about this issue.
ACTIONS PLANNED BY PHILIPS	A press release was issued by Philips HealthTech regarding this issue. This FSN will alert the consignees that received the products covered by this notice.
FURTHER INFORMATION AND SUPPORT	Should you have any questions or need further information regarding this communication, please do not hesitate to contact us at (877) 387-3311. UK contact: 0800 1300845