ResMed ASV Devices:

Recall for Product Correction

FAQs

Please make sure that you check back here frequently as we will keep these FAQs up-to-date as more information becomes available that we can share with you.

1. **Are the ResMed ASV devices being recalled by Therapeutic Goods Australia (TGA)?**
   - No. A product recall is a permanent removal of an affected therapeutic good from supply or use in the market. TGA has issued a 'Recall for Product Correction' for the ResMed ASV devices.

2. **What is a TGA 'Recall for Product Correction'?**
   - A recall for product correction means there is a requirement for repair, modification, adjustment or re-labeling of a therapeutic good.

3. **Why is there a 'Recall for Product Correction" for the ResMed ASV devices?**
   - TGA has issued the 'Recall for Product Correction' for the ResMed ASV devices to all health care providers and prescribers regarding the identified risk of using ResMed ASV therapy for treating patients with symptomatic, chronic heart failure with reduced left ventricular ejection fraction and moderate to severe predominant central sleep apnea.
   - For further medical and technical information, please refer to the following links:
     - http://www.resmed.com/au/en/consumer/news-and-information/news-releases/2015/phase-iv-serve-hf-study.html
     - https://www.tga.gov.au/alert/resmed-devices-use-adaptive-servo-ventilation-therapy
     - http://www.resmed.com/au/en/consumer/news-and-information/news-releases/2015/phase-iv-serve-hf-study.html

4. **Is the device malfunctioning?**
   - There has been no malfunction or technical fault with the operation of the device; it operates correctly to treat central sleep apnea.

5. **Which devices are affected?**
   - The list of ResMed ASV devices affected by this issue are:
     - AutoSet CS
     - AutoSet CS2
     - VPAP Adapt SV
     - S9 VPAP Adapt
     - VPAP Adapt

- AirCurve 10 CS PaceWave

- Each of the above devices is a ResMed ASV device. Do not be confused by the use of the word "VPAP" as ResMed's bi-level devices are not included in this recall.

6. Does this apply to all PAP therapy (e.g., CPAP and APAP)?

- No. This warning **does not** apply to any of the ResMed CPAP, APAP or VPAP devices not listed in FAQ #5.
- This particular warning only applies to specific ResMed devices called ASV, and only to people with a certain type of heart failure and a certain type of sleep apnea.

7. What if I use a ResMed CPAP or ResMed APAP device?

- You do not need to do anything.
- The study and this warning **does not** apply to ResMed CPAP or APAP devices.

8. Does this apply to the Philips BiPAP Auto SV devices?

- Philips has initiated an expedited review of possible implications for the recommended use of their own product lines.
- SNORE Australia will advise of any further recommendations or actions following this review.
- If you are concerned about the use of another brand of ASV therapy, please contact your physician to discuss your individual treatment.

9. What is SNORE Australia doing about this recall for product correction?

- We will notify each physician that has recommended an ASV titration study to someone that has attended one of our clinics
- We will provide each physician with a list of people that have attended/ are yet to attend (but have been booked) for an ASV titration study at one of our clinics

10. What should I do if I have purchased an affected ResMed ASV device?

- You should contact your physician to discuss your individual care plan.