Commercial partners:

1. **What is SERVE-HF?**

SERVE-HF is a multinational, multicenter, randomized controlled Phase IV study designed to assess whether treatment of moderate to severe predominant central sleep apnea with adaptive servo-ventilation (ASV) therapy, in addition to optimized medical care, could reduce mortality and morbidity in patients with symptomatic chronic heart failure with reduced ejection fraction (Left Ventricular Ejection Fraction [LVEF] ≤ 45%).*

2. **What was found in the study?**

- SERVE-HF did not meet its primary endpoint as there was no statistically significant difference in the primary endpoint between those patients with symptomatic chronic heart failure with reduced ejection fraction who were randomized to ASV therapy, and those in the control group.
- However, SERVE-HF showed a safety signal with a statistically significant increased risk of cardiovascular death in people with symptomatic chronic heart failure with reduced ejection fraction and moderate to severe predominant central sleep apnea, who were randomized to ASV therapy compared to the control group patients with the same condition.*
- There have been no issues associated with the performance of the ASV therapy device.

3. **Which of my patients may be at risk?**

Only those people with a certain type of heart failure who are on ASV therapy should be concerned: That is, those who have predominant central sleep apnea and what's called symptomatic chronic heart failure with reduced left ventricular ejection fraction equal or below 45%. We are recommending that they contact their doctor immediately to see if they are at risk and to discuss their therapy.*

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

- This particular warning only applies to specific ResMed ASV therapy devices, and only to people with a certain type of heart failure and a certain type of sleep apnea. We can provide you with a list of devices by serial number.
- This warning does not apply to ResMed CPAP or APAP devices.

6. **Am I required to notify my patients or physicians?**

- The safety notice requires you to notify healthcare providers and physicians who have prescribed ASV or purchased affected devices.
- You are not required to reach out to patients at this point in time, as we expect that our efforts to educate physicians, and the public announcements we have made, will alert patients. However, because the primary goal of the notice is patient safety, you may independently decide to reach out to patients that have heart failure and are on ASV therapy, who you suspect may be at risk. You can let patients know that the best course of action is to contact their physician to discuss their individual care plans.

* ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2–4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnoea

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United States	1-800-478-9010
France	0805408804
UK	0800 917 9411
Ireland	
Germany	0800 2770400
Austria	+49 89 9901 0565
Sweden	+46 8477 10 00
Switzerland	0800 00 25 00
Norway	+47 800 33 100
Finland	+358 45 77310405
Italy	+39 344 0488702
Spain	+33426100349
Portugal	+33805408804
Czech Republic	+420 244 471 299
Poland	+48 22 121 6423
Netherlands	+441235 437580
Belgium	+33805408804 (Fr) +441235 437580 (NL + ENG)
Luxemburg	+33805408804 (Fr) +441235 437580 (NL + ENG)
India	+91 9958030808

Australia New Zealand	Australia: 1800 647 259 New Zealand: 0800 737 635
China	China hotline 400 810 6016 (toll free) Taiwan hotline +886 2 25568707
Singapore	+65 9128-8850
Malaysia	+60 16-688-5271
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