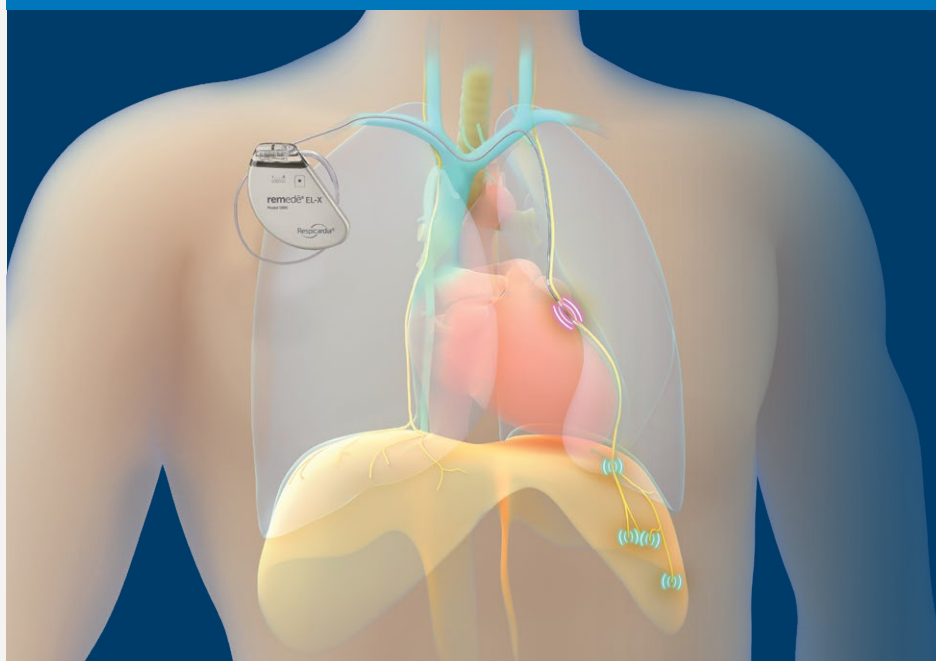


Transvenous Phrenic Nerve Stimulation (TPNS) recommended as a treatment option in the 2025 AASM CSA guidelines



Make sure your patients with central events know remedē is an option

Summary of AASM's 2025 guidelines for Adults with Central Sleep Apnea¹

NEW
to the
guidelines

Intervention	Strength of recommendation	Certainty of Evidence	Critical Outcomes Meeting Clinical Significance Threshold ²		
			Excessive sleepiness	Disease severity	Cardiovascular Disease
TPNS ³	Conditional for	⊕○○○	✓	✓	✓
CPAP ⁴	Conditional for	⊕⊕○○		✓	
BPAP w/ backup rate ⁵	Conditional for	⊕○○○	✓	✓	✓
BPAP w/o backup rate ⁴	Conditional <u>against</u>	⊕○○○		✓	✓
ASV ⁴	Conditional for	⊕⊕○○		✓	
Low-flow oxygen ⁶	Conditional for	⊕⊕○○		✓	
Acetazolamide ⁴	Conditional for	⊕⊕○○	✓	✓	

¹ Does not include central sleep apnea due to high altitude

² Excluded hospitalizations, sleep quality, and mortality, for which no intervention met the Clinical Significance Threshold or could not be assessed

³ Primary CSA and CSA due to heart failure

⁴ Primary CSA, CSA due to HF, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder

⁵ Primary CSA, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder

⁶ CSA due to heart failure

⊕○○○ GRADE certainty of evidence: very low

⊕⊕○○ GRADE certainty of evidence: low

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The new AASM CSA guidelines...

Highlight **two major changes since last guideline update**: Availability of TPNS (remedē) and updates to ASV data

"The period since the last AASM guidelines on CSA was notable for two important developments featured in these guidelines. The first is the development of the TPNS... The second is the publication of a trial addressing the safety and efficacy of a peak flow based ASV device in patients with HFrEF."

Encourage the focus on **patient reported outcomes** over disease process metrics

"Clinicians must prioritize optimizing therapy for the conditions contributing to central apneas and improving patient-reported outcomes rather than solely focusing on eliminating disordered breathing events"

Recommend the **consideration of alternative therapies** for patients where central events persist

"Persistence of central respiratory events should prompt re-evaluation of the underlying risk factors and consideration of alternative treatment options."

Recognize the **benefits of TPNS**

"The study found improvements in central event indices, desaturation index, quality of life, and several sleep architecture measures."

The conditional recommendation **suggests most patients** in the appropriate population **should be offered TPNS** as an option.

"Most patients should be offered the suggested course of action" (Table 1—Implications of strong and conditional recommendations)

Contact us at remede.zoll.com or call us at 952-592-1343

Important Safety Information

The remedē[®] System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the remedē System is appropriate. The remedē[®] System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the remedē System MRI guidelines manual. The remedē System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The remedē System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all the risks and benefits associated with the implantation of the remedē System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Contraindications:** The remedē System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events. **Rx Only.** The remedē[®] System, remedē[®] EL System, and remedē[®] EL-X System have received FDA approval. The remedē[®] System model 1001 has received CE Mark approval.

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