

SPECIAL ARTICLES

## Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement

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The diagnosis and effective treatment of obstructive sleep apnea (OSA) in adults is an urgent health priority. It is the position of the American Academy of Sleep Medicine (AASM) that only a medical provider can diagnose medical conditions such as OSA and primary snoring. Throughout this statement, the term “medical provider” refers to a licensed physician and any other health care professional who is licensed to practice medicine in accordance with state licensing laws and regulations. A home sleep apnea test (HSAT) is an alternative to polysomnography for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. It is also the position of the AASM that: the need for, and appropriateness of, an HSAT must be based on the patient’s medical history and a face-to-face examination by a medical provider, either in person or via telemedicine; an HSAT is a medical assessment that must be ordered by a medical provider to diagnose OSA or evaluate treatment efficacy; an HSAT should not be used for general screening of asymptomatic populations; diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety; and the raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

**Keywords:** home sleep apnea test, HSAT, obstructive sleep apnea, OSA

**Citation:** Rosen IM, Kirsch DB, Carden KA, Malhotra RK, Ramar K, Aurora RN, Kristo DA, Martin JL, Olson EJ, Rosen CL, Rowley JA, Shelgikar AV; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine position statement. *J Clin Sleep Med.* 2018;14(12):2075–2077.

### INTRODUCTION

The American Academy of Sleep Medicine (AASM) is the leading professional society dedicated to promotion of sleep health. The AASM improves sleep health and fosters high quality, patient-centered care through advocacy, education, strategic research, and practice standards. The AASM endeavors to advance sleep health policy that improves the health and well-being of the general public.

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder that is characterized by repetitive episodes of complete or partial upper airway obstruction during sleep.<sup>1</sup> Untreated, OSA is a potentially lethal disease that increases the risk of numerous health complications, including hypertension, congestive heart failure, atrial fibrillation, coronary artery disease, stroke and type 2 diabetes.<sup>2</sup> Data also suggest that untreated OSA is associated with an increased risk of all-cause and cardiovascular mortality, and this risk can be reduced with effective treatment.<sup>3,4</sup> Therefore, the diagnosis and effective treatment of OSA in adults is an urgent health priority.

As snoring is a cardinal symptom of OSA, primary snoring and OSA are distinguishable only after evaluation by a medical provider and objective testing. Throughout this statement, the term “medical provider” refers to a licensed physician and any other health care professional who is licensed to practice medicine in accordance with state licensing laws and regulations. Polysomnography is the standard medical test for the diagnosis of OSA in adult patients when concern arises for OSA, and a home sleep apnea test (HSAT) is an alternative medical test for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.<sup>5</sup> HSAT devices (ie, cardiorespiratory portable monitors) are classified by the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) as Class II medical devices, which have moderate risk associated with them and are subject to increased regulatory controls to provide reasonable assurance of safety and effectiveness.<sup>6,7</sup> Most HSAT studies, including randomized controlled trials that are most generalizable to clinical practice, have involved accredited sleep centers and the clinical

expertise of board-certified sleep medicine physicians. Data suggest that sleep medicine accreditation and certification are associated with higher quality care for patients with OSA.<sup>8</sup>

In November 2017, the American Medical Association (AMA) House of Delegates adopted a policy that emphasizes that a licensed physician must be involved in determining the need for, and appropriateness of, ordering objective tests to diagnose OSA or evaluating treatment efficacy in patients with OSA. In addition, the AMA policy recognizes that objective tests for diagnosing OSA are medical assessments that must be ordered and interpreted by a licensed physician.<sup>9</sup> The AASM supports this policy specifically as it relates to the use of HSATs by licensed medical providers for diagnosing OSA as well as assessing treatment efficacy in patients treated for OSA in the manner further delineated in the statements that follow.

## POSITION

It is the position of the AASM that:

- Only a medical provider can diagnose medical conditions such as OSA and primary snoring.
- The need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a medical provider, either in person or via telemedicine.
- An HSAT is a medical assessment that must be ordered by a medical provider to diagnose OSA or evaluate treatment efficacy.
- An HSAT should not be used for general screening of asymptomatic clinical populations.
- Diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety.
- The raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

## DISCUSSION

Historically, HSAT devices have been classified (eg, Type III or Type IV) according to the number and type of sensors that are utilized. In contrast to polysomnography, HSAT devices typically do not include electroencephalography (EEG), electrooculography (EOG) or electromyography (EMG) sensors, all of which are required to define sleep versus wake. While polysomnography identifies the severity of sleep-disordered breathing (ie, apnea-hypopnea index or AHI) based on actual sleep time, most HSAT devices produce an estimate of severity (ie, respiratory event index or REI) based on monitoring time.<sup>10</sup> The conventional sensors used in HSAT devices also are unable to detect hypopneas that are only associated with cortical arousals. Due to these limitations, an HSAT may underestimate the severity of OSA.<sup>5</sup>

Although it is less sensitive than polysomnography in the detection of OSA, an HSAT can be ordered by a medical provider for the diagnosis of OSA when the medical provider has determined that the patient does not have other medical conditions or risk for other sleep disorders that would preclude the use of an HSAT and has identified signs and symptoms that indicate an increased risk of moderate to severe OSA, rather than mild OSA.<sup>5</sup> The management of OSA also may include a follow-up HSAT ordered by a medical provider to collect objective data that can help improve or confirm treatment efficacy.<sup>11</sup> Data are insufficient to support the use of HSAT devices for general screening of asymptomatic clinical populations.<sup>12</sup>

The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications includes scoring criteria for HSAT data and recommends that HSAT devices have the ability to display raw tracings in detail for review, manual scoring or editing of events.<sup>10</sup> The limitations of current automatic scoring algorithms restrict their diagnostic accuracy, and these algorithms are not set up to detect other abnormal findings (eg, hypoventilation) that may be indicative of underlying pulmonary disease. Therefore, it is essential for the raw HSAT data to be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.<sup>13,14</sup> Once interpreted, these results should guide the decisions made by the medical provider—in the context of the patient's symptomatology, comorbid medical conditions and physical examination—to make appropriate care management decisions.

## CONCLUSIONS

HSAT devices are diagnostic medical tools that help medical providers deliver high quality, patient-centered care for select adult patients who are suspected to have OSA. A medical provider's diagnosis of OSA is based on a patient's medical history, symptoms from a medical evaluation, and findings from either polysomnography or an HSAT. Decisions to treat OSA, and assessment of treatment efficacy, require the medical judgment of a medical provider and must take into consideration the patient's symptoms, other medical conditions, and the severity of OSA determined by objective medical testing. The accurate diagnosis and effective treatment of OSA can improve individual health, promote public safety, and reduce overall health care expenses.

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## ACKNOWLEDGMENTS

The board of directors thanks AASM staff members who assisted with the development of this position statement.

## SUBMISSION & CORRESPONDENCE INFORMATION

**Submitted for publication November 16, 2018**

**Submitted in final revised form November 16, 2018**

**Accepted for publication November 16, 2018**

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## DISCLOSURE STATEMENT

This position statement was developed by the board of directors of the AASM to help physicians and other medical providers make decisions about the appropriate evaluation of patients with suspected OSA. It is published by the AASM as an advisory that is to be used for educational and informational purposes only.