

# UCLA

## UCLA Previously Published Works

### Title

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

### Permalink

<https://escholarship.org/uc/item/08f573nj>

### Journal

Journal of Clinical Sleep Medicine, 13(10)

### Authors

Rosen, Ilene

Kirsch, Douglas

Chervin, Ronald

et al.

### Publication Date

2017-10-15

### DOI

10.5664/jcsm.6774

Peer reviewed

## SPECIAL ARTICLES

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

Ilene M. Rosen, MD, MS<sup>1</sup>; Douglas B. Kirsch, MD<sup>2</sup>; Ronald D. Chervin, MD, MS<sup>3</sup>; Kelly A. Carden, MD<sup>4</sup>; Kannan Ramar, MD<sup>5</sup>; R. Nisha Aurora, MD<sup>6</sup>; David A. Kristo, MD<sup>7</sup>; Raman K. Malhotra, MD<sup>8,9</sup>; Jennifer L. Martin, PhD<sup>10</sup>; Eric J. Olson, MD<sup>5</sup>; Carol L. Rosen, MD<sup>11</sup>; James A. Rowley, MD<sup>12</sup>;  
American Academy of Sleep Medicine Board of Directors

<sup>1</sup>Division of Sleep Medicine, Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania; <sup>2</sup>Carolinas Healthcare Medical Group Sleep Services, Charlotte, North Carolina; <sup>3</sup>University of Michigan Sleep Disorders Center, University of Michigan, Ann Arbor, Michigan; <sup>4</sup>Saint Thomas Medical Partners - Sleep Specialists, Nashville, Tennessee; <sup>5</sup>Division of Pulmonary/Sleep/Critical Care, Mayo Clinic, Rochester, Minnesota; <sup>6</sup>Johns Hopkins University, School of Medicine, Baltimore, Maryland; <sup>7</sup>University of Pittsburgh, Pittsburgh, Pennsylvania; <sup>8</sup>SLUCare Sleep Disorders Center; <sup>9</sup>Department of Neurology, Saint Louis University, St. Louis, Missouri; <sup>10</sup>Veteran Affairs Greater Los Angeles Health System, North Hills, California and David Geffen School of Medicine at the University of California, Los Angeles, Los Angeles, California; <sup>11</sup>Department of Pediatrics, Case Western Reserve University, University Hospitals - Cleveland Medical Center, Cleveland, Ohio; <sup>12</sup>Wayne State University, Detroit, Michigan

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 physician can diagnose medical conditions such as OSA and primary snoring. Throughout this statement, the term “physician” refers to a medical provider who is licensed to practice medicine. 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 physician, either in person or via telemedicine; an HSAT is a medical assessment that must be ordered by a physician 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, Chervin RD, Carden KA, Ramar K, Aurora RN, Kristo DA, Malhotra RK, Martin JL, Olson EJ, Rosen CL, Rowley JA, American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an American Academy of Sleep Medicine position statement. *J Clin Sleep Med.* 2017;13(10):1205–1207.

## 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 physician and objective testing. (Throughout this statement, the term “physician” refers to a medical provider who is licensed to practice medicine.) 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.

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>5,6</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>7</sup>

## POSITION

It is the position of the AASM that:

- Only a physician 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 physician, either in person or via telemedicine.
- An HSAT is a medical assessment that must be ordered by a physician 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.
- 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, an HSAT produces an estimate of severity (ie, respiratory event index or REI) based on monitoring time. 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>8</sup>

Although it is less sensitive than polysomnography in the detection of OSA, an HSAT can be ordered by a physician for the diagnosis of OSA when the physician 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>8</sup> The management of OSA also may include a follow-up HSAT ordered by a physician to collect objective data that can help improve or confirm treatment efficacy.<sup>9</sup> Data are insufficient to support the use of HSAT devices for general screening of asymptomatic populations.<sup>10</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>11</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, sleep-related hypoxia) 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>12,13</sup> These data should be interpreted by the physician in the context of the patient's medical history.

## CONCLUSIONS

HSAT devices are diagnostic medical tools that help physicians to provide high quality, patient-centered care for select adult patients who are suspected to have OSA. A physician'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 physician 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.

## REFERENCES

1. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
2. Punjabi NM. The epidemiology of adult obstructive sleep apnea. *Proc Am Thorac Soc*. 2008;5(2):136–143.
3. Young T, Finn L, Peppard PE, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep*. 2008;31(8):1071–1078.
4. Fu Y, Xia Y, Yi H, Xu H, Guan J, Yin S. Meta-analysis of all-cause and cardiovascular mortality in obstructive sleep apnea with or without continuous positive airway pressure treatment. *Sleep Breath*. 2017;21(1):181–189.
5. Code of Federal Regulations. Title 21, Volume 8. Part 868 – Anesthesiology Devices. Subpart C – Monitoring Devices. Sec. 868.2375 Breathing frequency monitor. U.S. Food & Drug Administration website. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfctr/CFRSearch.cfm?fr=868.2375>. Updated April 1, 2017. Accessed August 31, 2017.
6. What does it mean for FDA to “classify” a medical device? U.S. Food & Drug Administration website. <https://www.fda.gov/aboutfda/transparency/basics/ucm194438.htm>. Updated December 28, 2015. Accessed August 31, 2017.
7. Parthasarathy S, Subramanian S, Quan SF. A multicenter prospective comparative effectiveness study of the effect of physician certification and center accreditation on patient-centered outcomes in obstructive sleep apnea. *J Clin Sleep Med*. 2014;10(3):243–249.
8. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(3):479–504.

9. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. *J Clin Sleep Med*. 2015;11(7):773–827.
10. US Preventive Services Task Force; Bibbins-Domingo K, Grossman DC, et al. Screening for obstructive sleep apnea in adults: US Preventive Services Task Force recommendation statement. *JAMA*. 2017;317(4):407–414.
11. Berry RB, Brooks R, Gamaldo CE, et al.; for the American Academy of Sleep Medicine. *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications*. Version 2.4. Darien, IL: American Academy of Sleep Medicine; 2017.
12. Zhao YY, Weng J, Mobley DR, et al. Effect of manual editing of total recording time: implications for home sleep apnea testing. *J Clin Sleep Med*. 2017;13(1):121–126.
13. Claman D, Sunwoo B. Improving accuracy of home sleep apnea testing. *J Clin Sleep Med*. 2017;13(1):9–10.

## ACKNOWLEDGMENTS

The AASM board of directors thanks Mr. Thomas Heffron and other staff members who assisted with the development of this position statement

## SUBMISSION & CORRESPONDENCE INFORMATION

**Submitted for publication September 8, 2017**

**Submitted in final revised form September 8, 2017**

**Accepted for publication September 9, 2017**

Address correspondence to: Ilene M. Rosen, MD, MS, Penn Sleep Center, 3624 Market Street, Suite 205, Philadelphia, PA 19104; Tel: (215) 662-7772; Fax (215) 615-4874; Email: irosen@aasmnet.org

## DISCLOSURE STATEMENT

This position statement was developed by the board of directors of the AASM to help physicians and other health care 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.