



Sleep Technology: TECHNICAL GUIDELINE

330 N. Wabash Ave. Ste. 2000 Chicago, IL 60611

aastweb.org

Out of Center Sleep Testing (OCST) - Updated July 2012

SUMMARY: Out of center sleep testing (OCST) can be used as an alternative to full, attended polysomnography (PSG) for the diagnosis of obstructive sleep apnea (OSA) in adult patients meeting clinical eligibility criteria. In order to determine eligibility, a comprehensive sleep evaluation is necessary. OCST may be used as an alternative to polysomnography for the diagnosis of OSA when there is a high pretest probability of moderate to severe OSA. Unattended OCST studies can be used for hospital or other facility inpatients, or in the home. Often the determination for OCST to be used in place of attended PSG is initiated by the insurance carrier, but approved by a board certified sleep specialist. OCST can be used when attended in the sleep center PSG is not possible because of immobility, or other safety or medical factors. OCST can also be used to monitor non-PAP treatments for sleep apnea, such as oral appliances. Because some comorbid medical conditions confound the interpretation of the data received from a limited number of physiological recordings, they exclude patients from OCST for the diagnosis of OSA. There are a large and growing number of portable monitoring (PM) devices available to be used for OCST in alternative settings; but for the diagnosis of OSA, airflow, respiratory effort, and blood oxygenation must be monitored. The technical requirements for these channel types should meet the standards set by the American Academy of Sleep Medicine (AASM) (1).

Sleep technologists work under the direction of the medical director of the sleep center to conduct OCST. Sleep technologists are trained in patient interaction, age related competencies, facilitating patient education and the diagnostic and therapeutic modalities used in sleep technology. As such, they are well suited for the dispensing of PM devices. Interaction with the sleep technologist for instruction on how to successfully use the device, the symptoms and consequences of OSA, and the benefits of treatment can set the stage for long-term compliance. The technical skill and experience of the sleep technologist also ensures a low OCST failure rate. It is essential that a sleep technologist experienced in acquiring and scoring Type 1, fully attended polysomnography tests (≥ 7 channels) scores the PM tests in order to accurately identify normal and abnormal breathing and artifact. The 2007 American Academy of Sleep Medicine (AASM) *Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients* indicate that an experienced sleep technologist or technician, preferably a registered sleep technologist (RST, RPSGT) or respiratory therapist (RRT-SDS, CRT-SDS), must apply the sensors or directly educate patients in sensor application, as well as manually review and score or edit the scoring of the raw data (1).

KEY DEFINITIONS

Portable monitor (PM) A device that can be used for sleep disorder testing in a variety of settings alternative to the in-sleep PSG. These small portable devices record physiological data that is uploaded or transmitted back to the sleep center for scoring and interpretation. The specific use of each device is limited by the data channels available and used.

Respiratory disturbance index (RDI) In the context of type 3 and 4 portable monitoring devices, RDI refers to an index of recording time rather than sleep time.

Portable monitoring device classification Portable monitoring (PM) devices were originally classified based on the number of recording channels, type of recordings and the circumstances in which the device was used,

closely mirroring the current CPT codes. The most recent classification utilizes sleep, cardiovascular, oximetry, position, effort and respiratory (SCOPER) parameters to categorize PM devices (2).

Type 2 PM: full unattended polysomnography (≥ 7 channels)

Type 3 PM: limited channel devices (usually 4–7 channels)

Type 4 PM: 1 or 2 channels usually including oximetry as one of the parameters

1.0 SCOPE

This guideline is intended to provide guidance for the technologist performing and scoring OCST studies in accordance with the AASM *Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients* (1). The scope of this guideline is restricted to adult patients with a high pretest probability of moderate to severe OSA, determined by a board certified sleep specialist to be eligible for portable monitoring.

1.1 Indications for OCST

OCST is indicated for adult patients with a high pretest probability of moderate to severe OSA, patients for whom in-center PSG is not possible by virtue of immobility, safety, or critical illness, and for monitoring patient response to non-CPAP treatments for obstructive sleep apnea, including oral appliances, upper airway surgery, and weight loss.

1.2 Contraindications for OCST

OCST is not appropriate and is contraindicated for pediatric patients, patients with comorbid medical conditions including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure, and patients suspected of having other sleep disorders, including central sleep apnea, periodic limb movement disorder (PLMD), insomnia, parasomnias, circadian rhythm disorders, or narcolepsy. OCST is also contraindicated for patients with medical or cognitive issues that impact the safety of a patient using the device unattended. OCST should not be used for general screening.

2.0 INSTRUMENTATION

The PM device used for OCST by a sleep center should be chosen carefully for its intended purpose by the technical staff and medical director. Factors to consider are ease of use by the patient, recording parameters, transmittance of the data, the ability to customize the raw data view, the ability to customize reports, the cost of the device, the cost of consumables (cannulas, disposable sensors), database features, and the availability of technical support.

There are a wide variety of PM types and manufacturers. It is imperative to read and follow manufacturer guidelines and instructions for use.

2.1 Initializing the PM Device

Most PM devices require re-charging or replacing the batteries, and previous study results must be cleared before a new recording can be acquired. Once the device is connected to a computer and the manufacturer's software, patient information can be entered and the device initialized to collect new data. Devices can be set to start at a preset time, or can be manually started by the patient at bedtime. It is important to know the maximum recording time capability, which might range from one to seven or more nights of recording time. When chain of custody features are required to verify the identity of the patient's data that is recorded, a security cable, non-removable sensor, or other feature may need to be applied on site.

2.2 Physiological and Recording Parameters

For Type 2 devices only:

EEG electrodes should be placed according to the International 10-20 system of Electrode Placement (3). The recommended EEG derivation is F₄-M₁, C₄-M₁, and O₂-M₁ recorded at a minimum sampling rate of 200 Hz with impedances of 5 K Ω or less. The recommended sampling rate is 500 Hz; filter settings for this parameter are LFF 0.3 Hz and HFF 35 Hz.

EOG electrodes should be placed at E₁ and E₂ according to *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications* standards (4). The recommended EOG derivation is E₁-M₂, E₂-M₂ recorded at a minimum sampling rate of 200 Hz with impedances of 5 K Ω or less. The recommended sampling rate is 500 Hz filter settings for this parameter are LFF 0.3 Hz and HFF 35 Hz.

Chin EMG electrodes should be placed above and below the mandible on the mental and submental muscles of the chin as specified in the *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications* standards. The derivation for recording chin EMG consists of a submental electrode referred to the electrode placed above the mandible on the mental muscle. The minimum sampling rate is 200 Hz. The recommended sampling rate is 500 Hz. Filter settings for this parameter are LFF 10 Hz and HFF 100 Hz.

For Type 2-4 devices:

A nasal air pressure transducer is the most common mode of recording airflow in portable monitoring. Use of an oronasal thermal sensor is recommended but optional for PM. Using a thermal sensor does make the detection of apneas more accurate, since mouth breathing can appear as apneic respiration when measured by nasal-only sensors. The recommended respiratory effort sensor is calibrated or un-calibrated respiratory inductance plethysmography (RIP). The minimum acceptable sampling rate for the collection of respiratory data is 25 Hz. The preferred sampling rate is 100 Hz, which improves the ability to assess artifact and visualize cardiogenic oscillations. Filter settings for the respiratory data parameters are LFF 0.1 Hz, HFF 15 Hz.

The recommended blood oxygen sensor is a pulse oximeter with an averaging time of < 3 seconds. Finger probes can be reusable or disposable, but in both cases secure attachment is important. A slipped or disconnected oximeter probe is one of the more common reasons for PM failure. The minimum recommended sampling rate is 10 Hz. The preferred sampling rate is 25 Hz, which improves the ability to recognize artifact.

The minimum acceptable sampling rate for recording body position using a body position sensor is 1 Hz.

A pulse rate is generally obtained from the pulse oximeter. The minimum acceptable sampling rate is 10 Hz. The preferred sampling rate is 25 Hz, which improves the ability to recognize artifact. When it is used in conjunction with the oximetry signal, the pulse rate signal may assist with oximeter artifact detection.

Modified Lead II is the recommended placement for recording the electrocardiogram (ECG). The minimum acceptable sampling rate is 200 Hz. The recommended sampling rate of 500 Hz improves waveform definition. Filter settings for ECG are LFF 0.3 (which minimizes waveform distortion), HFF 70 Hz.

Snoring can be derived from the nasal air pressure transducer signal, or can be recorded as a separate channel with a piezo sensor or microphone device with or without decibel meter output. The minimum acceptable sampling rate for the collection of snoring sound or vibration data is 200 Hz. The preferred sampling rate is 500 Hz, which improves waveform definition. Filter settings are LFF 10 Hz, HFF 100 Hz.

3.0 METHODOLOGY FOR PATIENT EDUCATION AND INSTRUCTION

The visit in which the patient picks up the PM device and is instructed how to apply it at home is an opportunity to engage them in their sleep health. Providing information on OSA symptoms, health consequences, and the benefits of treatment can help set the stage for a successful test and acceptance and compliance with treatment.

The instruction on how to apply the PM device can be performed using multiple modalities. Written instructions with pictorial diagrams of each component and step in the process should be given to the patient to take home. Many manufacturers provide video instruction accessible online or on a pre-recorded disk. A demonstration on video or by the technologist educator can be followed by having the patient apply the device and sensors themselves. This allows for questions to come up and for the technologist educator to correct anything that is incorrectly applied.

Dispensing the device, patient education and complete instruction can be performed using one to one instruction, in a group setting, or by mail if the patient is unable to get to the sleep center. Face to face patient interaction is preferable to mail to home, because it allows for physical exploration of the device and components, and the opportunity for the patient to ask questions. When devices must be mailed, all information normally supplied by the technologist educator, should be made available in printed and/or recorded materials. It is important for the patient to be given a 24-hour access phone number for technical support if any questions or problems arise.

4.0 DOCUMENTATION

As with full attended polysomnography, the sleep technologist is responsible for ensuring that all required documentation (history, physical exam, previous test results, referral and insurance information, physician's orders, etc.) is available and reviewed prior to dispensing the PM device for testing.

Patient ID verification and insurance verification should be completed at intake, as well as the documentation that the privacy notice was made available to the patient. The sleep center may require the patient to sign a return agreement stating when and where to return the device that includes device replacement or late fee terms.

A form that includes pre-sleep and post-sleep questions should be dispensed to the patient with the device and returned for the interpreting physician's review.

A comprehensive database should be kept to track OCST procedures, diagnosis codes, turnaround time, and failure rates. Optimally, this data should be tied to patient outcomes.

5.0 DEVICE RETURN AND DATA UPLOAD

Timely return of the device is desired to enable it to be available for subsequent use, and to expedite test interpretation, diagnosis, and treatment. If possible, the data should be checked for minimal adequacy (required signals recorded for a minimum time set by the center) and re-dispensed at the same visit when a failure is detected. The device is connected to the manufacturer's software and uploaded for manual review by the scoring technologist. The raw data may also be made available remotely on a secured website or server.

6.0 PM SCORING

The scoring technologist evaluates whether the minimum data collection requirement has been met (set by the sleep center). The manufacturer may provide an automated analysis of the raw data, although an experienced and qualified technologist must manually edit and verify the results. At minimum, respiratory events by type, oxygen desaturations, and fail periods must be accurately marked. Scoring should be performed in accordance with the AASM scoring manual (3). The expertise of a sleep technologist who has conducted and scored full

polysomnographic studies is necessary to evaluate when the patient might be awake and moving, or mouth breathing, so that these episodes are not mistaken for sleep disordered breathing. The scorer prepares a scoring report, which should indicate that the study was manually edited, and communicates any limitations to the recorded data, including failures. The scoring report and scored raw data is then made available to the interpreting sleep specialist for interpretation.

7.0 QUALIFICATIONS OF SLEEP TECHNOLOGISTS

Sleep technologists performing OCST studies must demonstrate knowledge of the application and limitations of the device. The sleep technologist educates and instructs patients and caregivers in the application of the PM device in the home environment, or may apply the device directly. The scoring technologist must be able to accurately mark events, identify artifact, and prepare a scoring summary.

7.1 Training of Sleep Technologists

All technical personnel must be trained by the Medical Director of the sleep center, a board certified sleep specialist, or a registered sleep technologist with the RST or RPSGT credential.

8.0 SLEEP CENTER ORGANIZATION AND RECORD KEEPING

Sleep technologists performing OCST studies should follow the sleep center departmental policy and procedure manual guidelines. Patient charts, in either print or electronic format, should be organized and available for use in the sleep center. HIPAA guidelines should be followed to meet documentation and confidentiality requirements. Records and recordings should be secure, retrievable and stored in accordance with state guidelines for the length of time designated by the statutes (generally a seven year minimum).

8.1 Quality Assurance

Scoring accuracy should be assessed against the reference sleep specialist once per quarter according to AASM OCST standards.

Failure rate, re-test rate, CPAP compliance at 12 weeks and turnaround time should be tracked and maintained at benchmarks set by the sleep center.

9.0 EQUIPMENT SAFETY

Equipment and sensor use and maintenance should meet manufacturer standards. All equipment used for OCST must be visually inspected and maintained, and those actions must be regularly logged and documented by a sleep technologist. Electronic equipment used in conducting OCST must be tested for safety by a credentialed biomedical engineer or electrician at least annually.

10.0 INFECTION CONTROL

Sleep technologists must use universal precautions to prevent the spread of infectious disease. Frequent hand washing is essential for protection of both patient and technologist, and should be performed before and after all patient contact and after glove removal. The technologist must wear gloves when handling contaminated equipment (5).

10.1 Equipment Decontamination

All equipment and sensors that come into contact with the patient are handled as contaminated per sleep center policy and procedure. Clean and dirty equipment must be kept in distinct areas designated as clean or dirty. All dirty equipment must be cleaned and disinfected after each use according to manufacturer guidelines. Single use items must be discarded after each use. Adhesive residue must be removed from sensors and the device container should also be cleaned and disinfected.

REFERENCES

1. Collop NA, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *Journal of Clinical Sleep Medicine*, 2007;3:737-47.
2. Collop, NA; Tracy, SL; Kapur, V; Mehra, R; Kuhlmann, D; Fleishman, SA; Ojile JM. Obstructive sleep apnea devices for out-of-center (OOC) testing: technology evaluation. *Journal of Clinical Sleep Medicine*, 2011;7(5):531-548.
3. Klem GH, Luders HO, Elger C. The ten-twenty electrode system of the International Federation. The International Federation of Clinical Neurophysiology. *Electroencephalography and Clinical Neurophysiology*, Suppl. 1999;52:3-6.
4. Iber C, Ancolia-Israel S, Chesson AL, Quan SF; American Academy of Sleep Medicine. *The AASM manual for the scoring of sleep and associated events: Rules, terminology and technical specifications*. Westchester, (IL): American Academy of Sleep Medicine; 2007.
5. Siegel JD, Rhinehart E, Jackson M, Chiarello L. Healthcare Infection Control Practices Advisory Committee. 2007 guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings. Atlanta (GA): Centers for Disease Control and Prevention; 2007 [cited 2011 Feb 27]. Available at <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf> Accessed March 25, 2012.