

Special Article

Australasian Sleep Association 2024 guidelines for sleep studies in adults

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Abstract

Executive summary: This document is a consensus statement of a subcommittee of experienced sleep physicians and scientists, tasked to review the literature and formulate recommendations on the indications, performance, and reporting of sleep studies, to update clinical practice from the 2017 Australasian Sleep Association (ASA) guidelines for sleep studies in adults (Douglas JA, Chai-Coetzer CL, McEvoy D, et al. Guidelines for sleep studies in adults - a position statement of the Australasian Sleep Association. *Sleep Med.* 2017;36(Suppl 1):S2–S22. doi:10.1016/j.sleep.2017.03.019). This document moves the focus beyond important discussions outlined in the 2017 guidelines, particularly surrounding the sensitivity and specificity of validated questionnaires and home sleep studies. The 2024 guide outlines the performance of the broad range of sleep testing available for the investigations of sleep disorders in adults including indications, strengths, limitations, and reporting standards.

Key words: polysomnography; sleep standards; actigraphy; sleep reporting; sleep studies

Statement of Significance

Sleep measurement is one important component of the assessment and diagnosis of sleep disorders. This document outlines the breadth of sleep studies available in Australia and New Zealand and reviews the literature regarding the indications, limitations, and advantages of each modality. This document provides the minimum reporting requirements for physicians reporting sleep studies.

The key changes compared with the 2017 Australasian Sleep Association (ASA) guideline [1] include:

- Normative values must now be used in reporting Type 1 diagnostic testing (see Normative values).
- Table 4 shows a concise outline of the mandatory and optional measures and reporting requirements for Type 1–4 diagnostic studies.
- A reporting structure is provided to guide documentation when commencing therapy with an auto-titrating positive airway pressure (APAP), based on the findings of the device download (see Interpretation and minimum reporting requirements for APAP initiation report).
- The requirements for reporting Continuous Positive Airway Pressure (CPAP) and bi-level studies are listed in detail (see Interpretation and minimum reporting requirements in CPAP studies for CPAP and Interpretation and minimum reporting requirements for bi-level studies).
- Vigilance testing requirements must be in keeping with the 2021 American Academy of Sleep Medicine recommended

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protocols for the Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT) [2] (see Vigilance Testing).

- Requirements for reporting actigraphy are now provided (see Tests of Activity).
- The requirements for sleep laboratory facilities and personnel have been detailed (see Facilities for Conducting Sleep Studies).
- Quality control and quality assurance requirements have been clarified (see Documentation and Quality Control Procedures).
- Data management policies and procedures required in a sleep service have been detailed (see Data Management).

Introduction and Scope of Guidelines

Measurement of sleep using sleep studies is an important component in the assessment and management of people with sleep disorders. As such it is imperative that patients can expect to receive high-quality diagnostic services when being evaluated for sleep disorders. This document aims to outline minimal standards for performance of sleep studies in adults, to help ensure that patients in Australia and New Zealand who are seeking assessment for sleep disorders receive high-quality services.

Sleep measurement is only one component in the assessment and diagnosis of sleep disorders. Sleep studies need to be combined with clinical assessment by clinicians, to appropriately diagnose and manage people with sleep disorders. Sleep measurement alone does not constitute a diagnosis, nor allow formulation of a personalized management plan in isolation. Comparing the 2017 ASA guide [1], this updated ASA guideline does not include a flow algorithm for the diagnosis of suspected obstructive sleep apnea (OSA). This committee has deliberately done so in this update, as flow charts often by their nature turn choices for diagnosis and management into binary decisions, whereas the diagnosis and management of sleep disorders require more complex decision-making, considering the advantages and disadvantages of tests when making a clinical decision. The details of these advantages and limitations are outlined for each study type in this document.

Sleep is at the nexus of physical and mental health, and changes in sleep are common accompaniments of many conditions. As such, the measurement of sleep via performance of a sleep study is much broader than solely for the quantification of breathing disturbances during sleep. Sleep studies have broad indications as diagnostic tools in the evaluation of respiratory and non-respiratory sleep disorders such as parasomnia, movement disorders, and disorders of hypersomnolence. A sleep study provides a rich physiological dataset, showing the interaction between different physiological systems, assisting with the understanding of interaction, causation, and impact which are critical to developing management plans for individuals. As such, it is important that the ability to perform comprehensive and high-quality measurement of sleep such as type 1 polysomnography is retained and seen as the gold-standard of sleep measurement.

Sleep studies are commonly used, together with clinical assessment, to diagnose sleep-disordered breathing including OSA. Simplified pathways with ambulatory sleep studies can be utilized for the evaluation of OSA. As research in this area matures and the role of new technologies becomes clearer, we

anticipate there will be changes to how sleep measurement is used to screen for, diagnose, and monitor sleep disorders such as sleep-disordered breathing. The role of screening questionnaires in the assessment of OSA was extensively discussed in the 2017 [1] version of this document; there have not been significant updates in the literature in this area since the previous edition.

Like any diagnostic test, sleep studies of varying types/levels have strengths and weaknesses. Clinicians ordering, performing, and interpreting sleep studies should be aware of the relative strengths and weaknesses of individual tests and match the test to the clinical question being asked. There is no “one size fits all” approach to applying a single type of sleep study across all clinical questions and patient situations. Hence, there is a need for appropriate pretest clinical assessment, to ensure that the test being performed will inform the diagnostic formulation of the treating clinician.

Although this paper outlines the indices to be reported as part of sleep studies in adults, a sleep study is much more than distilled indices or numerical values. An important part of performing sleep studies is reviewing physiological signals and combining this with the derived indices and numerical values to prepare a written report. This interpretation is then combined with a clinical assessment of the individual patient, to make a diagnosis and formulate an individualized management plan.

It is an exciting and challenging time in the measurement of sleep. There is a constant flow of new technologies that may allow sleep to be measured less intrusively and for longer periods. However, these are often promoted without adequate validation or research to confirm improvements in long-term patient sleep-related outcomes. We hope guidelines such as these will help to guide the development of new technologies alongside existing sleep measurements, move the field forward, and deepen our understanding of sleep; ultimately helping us to provide better outcomes for those with sleep disorders.

The guideline highlights the findings of several updated systematic reviews and international practice guidelines, which are referenced throughout ([3–13]). The guideline extends and revises the 1994, 2005, and 2017 Thoracic Society Australia and New Zealand (TSANZ)/ ASA position statement [1] and National Association of Testing Authorities (NATA) guide [14].

The committee was empaneled by the ASA. Individual conflicts of interest were declared before the review began. Individual conflict of interest statements were vetted by the ASA Board and were declared to all other committee members.

Questionnaires

There are a number of validated screening questionnaires that can be utilized for patients with OSA. These questionnaires are useful for stratifying the risk and to guide the type of sleep study to request. The 2017 ASA guide [1] undertook a detailed review of OSA screening tools and discussed the evidence base for these questionnaires. Since the last review, there have not been significant new questionnaires developed for OSA screening thus the guideline authors recommend reference to the previous guide [1] for a thorough evidence-based review.

However, since the previous review screening questionnaires have been introduced in Australia to determine the eligibility of sleep studies requested by primary care providers for Medicare funding. The three screening questionnaires to detect sleep apnea syndrome that have been adopted for usage within the Australian

primary care screening setting, are the Berlin Questionnaire [15], STOP-Bang [16], and OSA-50 [17].

In isolation, these questionnaires have poor specificity and low sensitivity in diagnosing OSA: Berlin questionnaire (specificity 59% and sensitivity 65%), STOP-Bang (specificity 36% and sensitivity 81%), and OSA-50 (specificity 21% and sensitivity 86%) [18]. Adding a measurement of sleepiness, in the form of the Epworth Sleepiness Scale [19] (ESS) greater than 8/24 improves the specificity of the STOP-Bang and OSA-50 to 94%–95% [18], however sensitivity remains low. Therefore, this combination of questionnaires is good at ruling in, but not ruling out OSA.

Attended Diagnostic Investigations During Sleep

Type 1 diagnostic sleep studies

General description of Type 1 diagnostic studies.

Attended sleep studies are complex multichannel recordings performed in a dedicated sleep laboratory setting by trained staff. They allow the continuous simultaneous recording of multiple physiological variables allowing an understanding of the complex interaction between sleep, cardiac, and respiratory function, and motor activity throughout sleep. Attended polysomnography, or Type 1 sleep studies, have been widely used in clinical and research settings with a large body of evidence supporting their reliability and accuracy. For simplification within this document, studies will be referred to by their “Type,” however the term “Type” and “Level” can be used interchangeably. Due to the complex nature of attended polysomnography, it is important that they are performed by appropriately trained staff. Training of staff and staffing requirements are described elsewhere in this document (Staffing Requirements for Conducting Sleep Studies) and in the ASA Standard for Sleep Disorder Services which is accompanied by the NATA accreditation program documentation [14, 20].

Indications for Type 1 diagnostic study.

Attended polysomnography is useful for the diagnosis of a range of sleep disorders including, but not limited to, OSA, central sleep apnea (CSA), movement disorders during sleep, disorders of hypersomnolence, parasomnias, and insomnia. A strength of attended polysomnography is the simultaneous recording of data representing multiple physiological systems, allowing analysis of the interaction of these systems in complex sleep disorders, or where sleep disorders may coexist, which is common in clinical practice. For example, while attended polysomnography is not routinely indicated in the diagnosis of insomnia, OSA coexists in 30%–50% of insomnia patients, so in treatment-resistant insomnia, Type 1 attended polysomnography should be considered [7, 21]. Another advantage of attended polysomnography is the presence of trained sleep scientists to ensure excellent quality of the physiological signals and observe sleep directly in real-time. Throughout this document, we have used the term “sleep scientist” to refer to staff attending polysomnography overnight, as it is typical of sleep laboratory staff in Australia and New Zealand to have a bachelor of science/biomedical sciences degree from university. The real-time detailed measurement is especially invaluable for the diagnosis of non-OSA sleep disorders (e.g. disorders of hypersomnolence, restless legs, parasomnias, and nocturnal seizures).

Measurement involved in Type 1 diagnostic studies.

Attended polysomnography allows the measurement of a range of variables. Detailed guidelines for recording methodology can be found in the American Academy of Sleep Medicine (AASM) manual for the scoring of sleep and associated events and an accompanying commentary from the ASA [22, 23]. In summary, the minimum recording channels must include:

- Electroencephalography (EEG)—minimum of 3 channels.
- Electro-oculogram (EOG)—2 channels.
- Electromyogram (EMG).
 - Chin—1 channel.
 - Legs EMGs—2 channels.
- Electrocardiogram (ECG)—modified lead II.
- Oximetry.
- Airflow—nasal pressure, oronasal thermal airflow sensor, PAP device flow.
- Rib cage and abdominal movements.
- Body position.
- Snoring—sound level meter.
- Digital video—is helpful in verifying body or head position, which is important in assessment of sleep-disordered breathing [23–25]. Furthermore, it has considerable value in the diagnosis or exclusion of parasomnia or seizures [23].

The ASA recommends adoption of the technical and digital specifications for routine PSG recordings (including impedances, digital resolution, sampling rates, and filter settings) as published in the AASM manual and an accompanying commentary from the ASA and Australia and New Zealand Sleep Science Association [22, 23].

In some clinical situations, additional measurements can be used:

- Transcutaneous carbon dioxide ($TcCO_2$) measurement: in the investigation of sleep-related hypoventilation, $TcCO_2$ is required, as oxygen saturation alone is not a direct reflection of the degree of hypoventilation.
- Arterial blood gas (ABG) measurements: Together with $TcCO_2$ measurements, ABGs can be a useful adjunct and can allow calibration of $TcCO_2$ so that values throughout the attended polysomnography are aligned more closely to true arterial values. Measurement of arterial blood gases taken as soon as possible after lights on also allows estimation of the magnitude of any drift in transcutaneous carbon dioxide calibration across the night [23, 26]. Alternatively, capillary blood gas can be considered if repeated measures are needed or where arterial blood gases are not possible [22].
- Extended EEG montage:
 - Seizure disorder: in the evaluation of seizure disorders during sleep, extended EEG montages can be used.
 - Research: there is also an emerging role, currently in research, for high-density EEG recordings during sleep to integrate the spatial and temporal resolution of EEG activity throughout sleep. Currently, this is a research tool and its usefulness in clinical settings is under evaluation.
- Additional EMG electrodes:
 - Parasomnias: when looking at parasomnias, particularly REM behavior disorder, additional EMG electrodes can increase diagnostic yield. One such protocol (SINBAR) has

been described with simultaneous recording of mentalis, flexor digitorum superficialis, and extensor digitorum brevis muscles [27].

- Bruxism: if bruxism is of clinical interest, additional masseter electrodes may be placed [22].

Interpretation and minimum reporting requirements for Type 1 diagnostic studies.

The ASA recommends the adoption of the adult scoring rules for sleep staging, arousals, cardiac events, PLMS, and respiratory events as published in the AASM manual and an accompanying commentary from the ASA and Australia and New Zealand Sleep Science Association [22, 23]. Definitions of Respiratory Events including apneas, hypopneas, respiratory effort-related arousals (RERA), hypoventilation, and Cheyne-Stokes breathing must be adopted without modification. Hypopneas must be scored using the AASM recommended definition. Scoring of hypopneas as obstructive or central is optional [22, 23]. It is noted that the scoring of central versus obstructive hypopneas is an emerging area within the literature, but that the differentiation is difficult and current AASM definitions may be inadequate as they can result in event misclassification [28]. Table 1 shows some important terminology.

As attended polysomnography is a complex diagnostic test incorporating multichannel recordings, it is important that the reporting and interpretation reflect this. There must be a summary that integrates and interprets these recordings. The parameters which must be reported as part of a sleep study report are outlined in detail in the Australasian commentary on the AASM manual for the scoring of sleep and associated events [23] and are summarized below in Table 4.

A written report must be issued at the completion of all Type 1 sleep studies detailing:

- (a) Date of testing.
- (b) The variables measured.
- (c) Sleep staging, including total sleep time (TST), sleep efficiency, wake after sleep onset, sleep latency, stage R sleep latency, percentage of time in the various sleep stages, and frequency of arousals.
- (d) Frequency and type of abnormal respiratory events (e.g. central or obstructive).
- (e) Relationships of disordered breathing to posture, sleep stage, or treatment intervention when relevant.
- (f) Oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals. The following oxygen saturation values must be reported: mean stable baseline prior to sleep onset, mean during stable NREM, duration and/or percentage of sleep time $\leq 90\%$ and $\leq 88\%$. See the 2020 ASA commentary on the AASM manual for scoring sleep and associated events for more detail [23].
- (g) Transcutaneous PCO_2 (PtcCO_2) trends, where measured and a conclusion as to the occurrence of hypoventilation must be reported. The baseline value prior to sleep onset, maximum value in NREM and REM must be commented on where PtcCO_2 is measured.
- (h) Any disturbance of cardiac rate or rhythm, and its relationship to abnormal respiratory events, if measured. Include mean heart rate asleep.
- (i) The frequency of periodic limb movements and any associated sleep fragmentation.

Table 1. Important Terminology

Respiratory Disturbance Index (RDI) = Apnea Hypopnea Index (AHI) + Respiratory Effort-Related Arousals (RERA) Index
Oxygen desaturation Index (ODI) = $\geq 3\%$ arterial oxygen desaturations/hour of sleep/monitoring time

Adapted from AASM guide [22]

- (j) Medications (including sedatives), caffeine, and alcohol that may have influenced the results.
- (k) Technical comment including signal quality and behavioral factors.
- (l) Scoring definitions used and supporting references, including normative reference range utilized.
- (m) The physician's interpretation/conclusions must provide a summary of the relevant normal and abnormal findings from a review of the raw study data, together with the above summary data, including comments on sleep staging, respiratory scoring, cardiac abnormalities, any abnormal behaviors or movements, and effectiveness of any applied therapy. The conclusion should provide a clear diagnosis and severity rating for diagnostic studies, and only make relevant recommendations regarding therapy from intervention studies.
- (n) Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).

The committee notes that NATA accreditation standards advise that an absolute *minimum* of 12 minutes per study is required for the sleep physician to assimilate the clinical data, review the raw sleep study data, take into consideration scientist/physiologist comments, and observations and prepare a report [14]. For most studies, a longer period of time will be required to interpret the data.

Normative values.

Normative values must be used as a reference point in the interpretation of PSG parameters. There must be reference made to the source and awareness of the limitations of the data set used.

Normative values can be derived from local control data, if available, or existing datasets such as Boulous et al. [5]. Limitations of existing normative values are important to acknowledge. There is no normative data currently available for Type 2 and portable studies. Boulous et al. [5] is the largest meta-analysis to date of normative data; however, the sample size even in this systematic review is small, particularly for adults >80 years (only one study of 10 males provides the data in over 80 years group [5]) and the data included has a high level of clinical heterogeneity. Furthermore, the respiratory events, particularly the apnea-hypopnea index (AHI) in this series are based on the previous definitions of AHI, which does limit the applicability with updated scoring criteria.

Minimum data required for Type 1 diagnostic studies.

Attended polysomnography is a complex investigation, and while the presence of appropriately qualified and trained staff with real-time monitoring of data allows for replacement or adjustment of electrodes in real-time, it is difficult to have high-quality recordings of all channels for an entire night.

The minimum amount of data required will depend upon the clinical question being addressed. Comments must be made on the severity of sleep-disordered breathing (where relevant), the oxygenation, and influencing factors, as described in more detail below. Responsibility for determining whether there are sufficient data to answer the clinical question should rest with the interpreting physician.

Note: in Australia for Medicare billing purposes a minimum of 8 hours (including patient setup time and actual period of recording) is required.

Sleep-disordered breathing.

Historically, sleep apnea severity has been arbitrarily divided into stratified severity groups based on the AHI which is a simple metric quantifying the number of apneas and hypopneas per hour of sleep. Values less than 5 events per hour have been considered normal, with values between 5 and 15 events per hour representing mild OSA, 15–30 events per hour moderate OSA and greater than 30 events per hour severe OSA [22]. However, these thresholds have not changed over many years, despite increases in sensitivity of measurement, such as with the introduction of nasal pressure, and changes in scoring definitions [29–31]. Given this, while the AHI must be reported as part of attended polysomnography, comments on the severity of sleep-disordered breathing should be reserved for the interpreting physician as these thresholds need to be used with caution and interpreted in the clinical context of individual patients, testing techniques, and scoring definitions used.

Oxygen saturation and desaturation.

A detailed discussion of parameters to report is provided in the Australasian commentary on the AASM manual for the scoring of sleep and associated events [23]. Oxygen desaturation criteria should be standardized with reporting of $\geq 3\%$ desaturations. The percentage of sleep time (Type 1 and 2 studies) or percent of MT (types 3 and 4 studies) spent with $\text{SpO}_2 \leq 88\%$ must be reported consistent with Thoracic Society of Australia and New Zealand nocturnal oxygen requirement guidelines [32]. Reporting percent of sleep/MT spent with oxygen saturation $\leq 90\%$ has evolving literature with regards to cardiovascular risk, so reporting must also include percent total sleep/MT with $\text{SpO}_2 \leq 90$ [33]. As an explanatory note, the literature often reports oxygen saturation as $< 90\%$, whereas in this ASA updated guideline there has been the decision to specify $\text{SpO}_2 \leq 90\%$. This is to provide less ambiguity and increase precision in sleep study reporting. However, the use of either of the two variables ($\text{SpO}_2 < 90\%$ or $\leq 90\%$) would currently be acceptable in clinical practice, dependant on software measurement capabilities, provided that laboratories must be clear about what cutoff threshold they specify in reports.

Respiratory effort-related arousals.

A strength of attended polysomnography is the ability to measure RERAs which are much harder to score on ambulatory sleep studies where EEG and airflow signals may be noisier. A RERA is a sequence of breaths lasting ≥ 10 seconds with increasing respiratory effort or flattening of the inspiratory portion of the nasal pressure tracing and without meeting the criteria for a hypopnea or apnea, that is terminated by an arousal. While the clinical utility of reporting RERAs is not well established, scoring and reporting RERAs may provide additional information,

particularly in women and non-obese [34] and is therefore recommended in the Australasian commentary.

If RERAs are scored then grading of severity must be made on the AHI, not the RDI

Influencing factors.

A range of factors can impact sleep architecture, sleep-disordered breathing, and motor activity during sleep. These include body position, alcohol consumption, and medications taken around the time of the sleep study. The presence of these factors should be included in the report, together with any technical factors which may have impacted the quality of data recording.

Ambulatory/Unattended Diagnostic Sleep Studies

The earliest portable monitoring guidelines and practice parameters for OSA investigation described a four-tier scheme [35, 36], where portable devices are classified into levels/types 2, 3, and 4 studies. Subsequently, there was recognition that the type and number of signals recorded by devices varied widely and therefore devices may not fit well within the original device classification recommendations [37, 38]. Hence the development of the “Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory” SCOPER classification scheme [38], where devices are described based on measurements obtained and measurement levels (e.g. for sleep scoring S1 = sleep by 3 EEG channels + EOG and chin EMG; S3 = sleep surrogate such as actigraphy).

Wrist-worn devices utilizing peripheral arterial tone (e.g. Tondo et al. [39]), where respiratory events are derived from attenuation of peripheral arterial tone in combination with heart rate increase and oxygen desaturation, are an example of devices that do not fit well into the traditional four-tier classification. Other types of wearable devices or non-contact devices, such as biotion sensors [40], are also becoming more common. However, despite the introduction of increasingly diverse devices for OSA investigation and the introduction of the SCOPER categorization scheme, the categorization of devices using the traditional scheme remains widespread [9, 13, 41, 42].

There is no clinical definition of what defines an *adequate* or *inadequate* Type 2, 3, or 4 study. Thus, reporting clinicians should ensure there is sufficient data that is free from artifacts available for interpretation, especially when reporting types 3 and 4 studies.

Recommendations for the use of unattended/ambulatory diagnostic sleep studies

There are number of documents published since the previous Australasian guidelines [1] relevant to portable monitoring which are largely consistent with past Australasian recommendations and have been summarized as recommendations below.

These documents include:

- Clinical Practice Guideline for Diagnostic Testing for Adult OSA: An American Academy of Sleep Medicine Clinical Practice Guideline [9]
- Endorsement of: “Clinical practice guideline for diagnostic testing for adult OSA: An American Academy of Sleep Medicine clinical practice guideline” by the World Sleep Society [8]
- Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement [13]

Indications/patient evaluation when using unattended/ambulatory diagnostic sleep studies

From the above documents, the following should be considered when utilizing ambulatory studies in the evaluation of a patient with a suspected sleep disorder:

- (1) Diagnostic testing for OSA (including portable monitoring) must be conducted as part of a comprehensive evaluation and follow-up [9, 13] by a licensed, suitably trained medical practitioner [8, 13]. The overseeing practitioner must have a clear understanding of device and setting (home vs. laboratory) advantages and limitations [8].
- (2) Test ordering must be conducted by a suitably trained medical practitioner [13].
- (3) To use caution with the use of limited, single-channel Type 4 tests (e.g. oximetry) due to the need for high-level clinical proficiency for patient selection and result interpretation [8].
- (4) Portable monitoring with a technically adequate device can be used for diagnosis of uncomplicated adult patients with increased risk of moderate to severe OSA [8, 9].
- (5) Attended Type 1 PSG must be conducted, rather than portable monitoring, in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation, or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia [9] (as summarized in Table 2 above). A caveat to this recommendation is where PSG is unavailable in the jurisdiction. Additionally, Type 2 home testing can be considered for severe insomnia given the difficulty some patients have with sleeping in an unfamiliar environment [8].
- (6) Diagnostic and treatment decisions must not be based solely on automatically scored portable monitoring data [13].
- (7) Review and interpretation of raw data must be performed by a suitably trained medical practitioner [13].
- (8) Attended Type 1 PSG, as well as repeat clinical evaluation [8], must be performed where portable monitoring testing for OSA is inconclusive, technically inadequate, or if testing is negative [9], particularly if clinical suspicion for OSA remains.
- (9) Situations where repeat testing with a portable device may be warranted include where no polysomnography is available in a jurisdiction, or where no or minimal sleep was achieved during PSG, noting that there may be billing restrictions for repeat testing [8].

Type 2 studies

General description of Type 2 studies.

Type 2 portable sleep studies are described as comprehensive, portable PSG, without the need for the presence of trained personnel to intervene [35], including a minimum of seven channels (electroencephalogram, electro-oculogram, electromyogram, electrocardiogram or heart rate, airflow, respiratory effort, and oxygen saturation) [36].

Limitations of Type 2 studies.

The main disadvantage of Type 2 recordings, compared to PSG, is that they are unattended, increasing the risk of signal loss and study failure. The large population-based Sleep Heart Health Study and a New Zealand clinical-based study reported

Table 2. Patients Unsuitable for Ambulatory Studies

Patients who may be unsuitable for ambulatory studies include:

1. Those with a low-pretest probability of moderate to severe OSA.
2. Patients reporting symptoms suggestive of a condition other than sleep disordered breathing which will require more extensive monitoring (examples include parasomnias, narcolepsy, periodic limb movement disorder, and nocturnal epilepsy).
3. Patients with any of the following (where nocturnal hypoventilation or central sleep apnea is likely):
 - a. Neuromuscular disease.
 - b. Severe COPD or restrictive lung disease.
 - c. Hypoxia and/or hypercapnia at rest or requiring supplemental oxygen therapy.
 - d. Significant obesity and/or suspected obesity hypoventilation syndrome.
 - e. Significant cardiovascular disease, i.e. recent hospitalization for acute MI, unstable angina, heart failure, and atrial fibrillation.
 - f. Chronic narcotic use.
4. Inability to perform overnight oximetry in a non-monitored environment. For example, significant active psychiatric disease, cognitive dysfunction, or physical limitation.

failure rates in the order of 5%–10% [9, 43] where studies were setup by trained professionals in the patient's home. Failure rates may be larger if studies are setup in the laboratory and the patient is sent home, or by patients themselves under instruction [37]. Light sensors are not typically incorporated into portable monitoring and patient-reported estimates may not be accurate, with one study showing inaccuracy > 5 minutes for 25% of home PSGs (light off time mean difference: 13 minutes), and 92% of hospital PSGs (light off time mean difference: 18 minutes) [44]. Additionally, EEG recorded with limited channels or alternative electrode placement compared to PSG may alter distribution of sleep stages and arousal indices [45, 46]. These issues highlight the need for transparent reporting of alternative methodologies.

Advantages of Type 2 studies.

An important advantage of Type 2 sleep studies over other portable studies is that they record electroencephalography (EEG). Like Type1 PSG this allows for the assessment of sleep quality, the use of TST in the denominator of event indices, the measurement of sleep disruption by cortical arousal, and scoring of respiratory events associated with cortical arousal. However, there may be some subtle differences in sleep efficiency and sleep latency reported by Type 2 studies compared to Type1 PSG if, for example, a recording is manually commenced with a button press, or automatically at prespecified times, or if time is available for sleep (total dark time) is estimated from patient report, or movement or position sensors.

Accuracy of Type 2 studies compared with attended Type 1 studies.

Early portable monitoring guidelines did not assess performance of Type 2 studies due to insufficient data [36, 37]. Additionally, the latest AASM position statement on Home Sleep Apnea Testing [13] did not address Type 2 studies, possibly based on the assumption they are not in common use [42]. Previous Australasian Guidelines for sleep studies in adults suggested that Type 2 studies could be

used to “rule in” or “rule out” sleep apnea [1]. This was largely based on the comprehensive evaluation and use of Type 2 studies in the Sleep Heart Health Study [47–49] and its application in a small New Zealand clinical OSA population [50]. It should be noted, however, that a recent systematic review [3] found only eight studies evaluating the accuracy of Type 2 portable monitoring studies in adults and none since the previous Australasian Guidelines for PSG in Adults [1]. Those studies generally show a small negative AHI bias compared to PSG with wide limits of agreement, with no clear advantage over other study categories [3].

Interpretation and minimum reporting requirements for Type 2 ambulatory/unattended diagnostic study.

A written report must be issued at the completion of all Type 2 sleep studies detailing:

- (a) Date of testing.
- (b) The variables measured.
- (c) Sleep staging, including TST, sleep efficiency, wake after sleep onset, sleep latency, stage R sleep latency, percentage of time in the various sleep stages, and frequency of arousals.
- (d) The method used to determine time available for sleep (total dark time).
- (e) Frequency and type of abnormal respiratory events (e.g. central or obstructive).
- (f) Relationships of disordered breathing to posture, sleep stage, or treatment intervention when relevant.
- (g) Oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals. The following oxygen saturation values must be reported: mean stable baseline prior to sleep onset, mean stable during stable NREM, duration and/or percentage of sleep time $\leq 90\%$ and $\leq 88\%$. See the 2020 ASA commentary on the AASM manual for scoring of sleep and associated events for more detail [23].
- (h) Any disturbance of cardiac rate or rhythm, and its relationship to abnormal respiratory events, if measured. Include mean heart rate asleep.
- (i) The frequency of periodic limb movements and any associated sleep fragmentation.
- (j) Medications (including sedatives) and alcohol that may have influenced the results.
- (k) Technical comment including signal quality and behavioral factors.
- (l) Scoring definitions used and supporting references, including normative reference range utilized.
- (m) The physician’s interpretation/conclusions must provide a summary of the relevant normal and abnormal findings from a review of the raw study data together with the above summary data, including comments on sleep staging, respiratory scoring, and cardiac abnormalities. The conclusion should provide a clear diagnosis and severity rating.
- (n) Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).

Type 3 studies

General description of Type 3 studies.

Type 3 portable studies have traditionally been described as having at least four channels as a minimum (two respiratory

channels, ECG or HR, and oxygen saturation) [35, 36], or usually 4–7 channels with at least airflow, respiratory effort, and blood oxygenation recorded [37]. They are sometimes referred to as respiratory polygraphy.

Advantages of Type 3 studies.

The key advantage of Type 3 studies relates to relative simplicity compared to Types 1 and 2 devices, which may lead to increased accessibility, reduced application and analysis staffing costs, as well as improved patient acceptance [42].

Limitations of Type 3 studies.

A significant limitation is the lack of EEG data, such that sleep staging and cortical arousal scoring are not possible [41, 51]. TRT rather than TST has often been used as the denominator for event indices for Type 3 studies. Differences in TRT from Type 3 studies and TST from PSG in the order of 1–3 hours have been reported [41].

Current scoring standards recommend the term respiratory event index (REI) using monitoring time (MT) as the denominator to distinguish from the AHI in PSG with TST as the denominator [22]. Important terminology is shown in Table 3.

MT is defined as the TRT, minus periods of artifact and time the patient was awake, as determined by actigraphy, body position sensor, respiratory pattern, or patient diary. However, as methods to determine MT differ between devices, and between sleep centers, the method used must be clearly reported [22]. These methods have been shown to improve REI/AHI agreement and diagnostic/severity classification [41]. It is perhaps an oversight that there is no equivalent term to the REI for the oxygen desaturation index (ODI) when MT is used as the denominator.

As EEG-based cortical arousals are not scored using Type 3 studies, the Arousal Index cannot be calculated; however, the scoring of respiratory events is also impacted. Current PSG hypopnea scoring standards allow for hypopnea scoring with minimal or no desaturation, provided the hypopnea is associated with cortical arousal [22]. Events of this nature cannot be scored using Type 3 devices resulting in a reduction in the AHI [52]. Despite this, a recent European Taskforce reported that when considering studies consistent with current AASM criteria, inclusion of surrogate arousal measures in hypopnea definitions did not substantially improve agreement and diagnostic accuracy [41]. More recently a significant improvement in Type 3 device diagnostic and clinical decision accuracy was reported when heart rate acceleration was used as a surrogate marker of arousal for hypopnea scoring [52].

Similar to current PSG standards [22], early portable monitoring guidelines recommended that oronasal thermal sensors be used to detect apnea and nasal pressure transducers be used to detect hypopneas, and that ideally both sensors should be used [37]. In reality, nasal pressure only is commonly used to monitor airflow in Type 3 studies [41] which on average will elevate apnea index and REI/AHI values [53].

Table 3. Important Terminology for Type 3 Studies

Respiratory Event Index (REI) = [Apneas + hypopneas]/
monitoring time (hours)

Adapted from AASM guide [22]

Accuracy of Type 3 studies compared with attended Type 1 studies.

A European Taskforce recently assessed the diagnostic accuracy of Type 3 studies for sleep-disordered breathing versus Type 1 PSG, reviewing studies conducted between 2007 and 2021 [41]. Limitations in comparing such studies were noted, including number and types of sensors utilized, scoring rules utilized, differing severity and diagnostic cut-points, differing populations examined, manual versus automated scoring, and whether assessments were conducted simultaneously or on separate nights. Nevertheless, they reported Type 3 device sensitivities at various respiratory event cutoffs of 80%–100% and specificities of 0%–100% against simultaneous in-laboratory PSG. For home/unattended Type 3 studies sensitivities of 74%–96% and specificities of 25%–88% were reported. In general, the Taskforce reported reasonable diagnostic sensitivity and specificity for adults with a high pretest OSA probability in an attended setting, even when comorbidities were present. Lower sensitivities and specificities were reported for unattended/home studies, as well as higher technical failure rates.

Manual scoring was recommended, as this was shown to improve diagnostic accuracy compared with automated scoring alone [41]. Additionally, due to the lack of sleep monitoring the Taskforce recommended Type 1 or 2 PSG for patients found to have no or mild OSA on home-based Type 3 studies where the patient has a high pretest probability of OSA/hypopnea syndrome.

Finally, the Taskforce recommended that experienced sleep healthcare providers apply, interpret, and follow-up Type 3 studies. For patients with symptoms of OSA (snoring, witnessed apneas, or excessive daytime sleepiness) and no contraindications to ambulatory sleep studies (as outlined above in Table 2), an Australian randomized controlled trial has demonstrated non-inferiority of Type 3 studies with regards to OSA treatment outcomes [54]. In this trial Type 3 studies (performed in laboratory and manually scored) were compared with Type 1 studies for the investigation of OSA. Type 3 studies were found to be non-inferior with respect to Functional Outcomes of Sleep Questionnaire (FOSQ) scores, ESS, and CPAP use at 4 months [54]. It should be noted that this study was performed in expert tertiary referral centers and may not be directly translatable to the general community, particularly in settings where patients would have to apply the equipment themselves.

Interpretation and minimum reporting requirements for Type 3 sleep studies.

Type 3 study reports must include the following:

- (a) Date of testing.
- (b) Type of device used.
- (c) The variables measured.
- (d) Duration of test recording.
- (e) REI and total number of respiratory events. The criteria used for apneas & hypopneas should be defined.
- (f) The denominator used to calculate event indices (TRT or MT). If relevant, the method used to estimate MT (sleep diaries, actigraphy, etc.).
- (g) Oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals. The following oxygen saturation values must be reported: mean stable baseline, duration, and/or percentage of sleep time $\leq 90\%$ and $\leq 88\%$. See the 2020 ASA commentary on the AASM manual for scoring of sleep and associated events for more detail [23].

- (h) Heart rate during the recording period.
 - (a) Provide mean, minimum, maximum, and acute heart rate changes (e.g. >6 and 12 bpm) as markers of autonomic arousal [52]
- (i) Technical comment including signal quality and behavioral factors.
- (j) Scoring definitions used and supporting references, including reference range utilized.
- (k) Interpretation (based upon test results and clinical information), including at a minimum whether the test results support a diagnosis of OSA or not.
- (l) Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).

Type 4 studies

General description of Type 4 studies.

A Type 4 study is one that incorporates only one or two measured parameters [35]; typically including oxygen saturation or nasal airflow [36, 37]. The data acquired by Type 4 devices is downloaded and analyzed by software to provide oxygen saturation and heart rate parameters (or potentially airflow) and a digital display from which interpretation is made. At least 4 hours of data must be recorded.

Advantages of Type 4 studies.

In general, such studies are inexpensive, portable, durable, and simple to operate. Some have automatic artifact detection software built in. In some circumstances, Type 4 devices can be mailed to the patient in rural locations. Technically they could also be remotely monitored. For oximetry-based Type 4 devices, the accuracy of oximetry is estimated to be $\pm 2\%$ between the arterial oxyhemoglobin saturation range of 70%–100% and can accurately track change. Technical factors such as adequate signal acquisition, averaging time, and storage sampling frequency are crucial to the reliability of oximetry [55].

Type 4 devices such as the ApneaLink which measure nasal flow, have been compared with Type 1 PSG in a recent systematic review and meta-analysis; across 13 studies of 2045 patients, the sensitivity for detecting AHI > 5 events/hour ranged from 64.5% to 100% for AHI/RDI [3]. The specificity varied between scoring methods, with the default setting having lower specificity than using manual analysis [3].

Limitations of Type 4 studies.

Despite the relative simplicity of Type 4 studies, caution is still required due to the need for expertise in patient selection and interpretation [8]. The accuracy of oximetry measurement is impacted by a low pulse volume, atrial fibrillation, hemoglobinopathies, significant peripheral vascular disease (e.g. scleroderma and Raynaud's phenomena) and darker skin pigmentation, and nail pigmentation (shellacking of finger nails) [55].

Given that the recording time of a Type 4 device is similar or longer than the TST when measured by simultaneous polysomnography (Type 1 device), the ODI from a Type 4 study is generally less (in which the denominator is total recording time [TRT]) than an AHI (in which denominator is TST) for the same patients measured simultaneously [3]. MT, which can take into account periods of artifact or device disconnection, can be used as the denominator to reduce this difference [22].

Accuracy of Type 4 studies compared with attended Type 1 studies.

Despite these limitations, the sensitivity and specificity of oximetry for identifying OSA, as defined by ODI, is 48%–97% and 63%–100%, respectively, for Type 1 PSG AHI/RDI cutoff values of 5–15 events/hour [3]. The variability is explained by the benchmark AHI threshold ($AHI \geq 5$, ≥ 15 , or ≥ 30) and the pre-test probability of OSA. In terms of clinical decision-making and clinical outcomes, an Australian randomized controlled trial demonstrated non-inferiority when comparing oximetry/ODI to Type 1 PSG with respect to FOSQ scores at 4 months when used to investigate symptomatic patients [54]. However, ODI did not perform as well as Type 1 PSG when considering changes in ESS, CPAP use, and physician confidence in the diagnostic process [54].

Interpretation and minimal reporting requirements.

- Data collected by Type 4 devices needs to be downloaded and analyzed by software to provide a graphic display (usually SpO_2 and heart rate versus time) plus an analysis of the data to provide recording time, SpO_2 , and HR variables.
- The graphic display of SpO_2 and heart rate are usually the maximum and minimum of 3–12 second epochs. The epochs can usually be set at a shorter period (3 seconds) to provide greater fidelity for identifying 10-second apneas, whereas longer epochs (12 seconds) are useful where motion artifact is apparent.

Type 4 study reports must include the following:

- (a) Date of testing.
- (b) Type of device used.
- (c) The variable/s measured.
- (d) Duration of test recording.
- (e) REI and total number of respiratory events if a marker of airflow is measured. The criteria used for apneas-hypopneas should be defined.
- (f) Method used to determine MT.
- (g) Oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals. The following oxygen saturation values must be reported: mean stable baseline duration and/or percentage of recording time $\leq 90\%$ and $\leq 88\%$. See the 2020 ASA commentary on the AASM manual for scoring of sleep and associated events for more detail [23].
- (h) Location of testing (home, hospital, and other).
- (i) Technical comment including signal quality and behavioral factors.
- (j) Heart rate during the recording period.
 - Provide mean, minimum, maximum, and acute heart rate changes (e.g. ≥ 6 bpm) as markers of autonomic arousal [52]
- (k) Scoring definitions used and supporting references, including reference range utilized.
- (l) Interpretation (based upon test results and clinical information), including at a minimum whether the test results support a diagnosis of OSA or not.
- (m) Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).

Other parts of the report to consider include:

- Whether data were edited.
- Concurrent positive pressure airway device use (or supplemental oxygen).
- Questionnaire responses (including a patient's estimate of sleep quality on that night).
- Body weight and height.
- An estimate of frequency of heart rate change (>6 bpm) can also be commented upon as a marker of autonomic arousal.

Summary of reporting requirements for diagnostic studies

Table 4 is not exhaustive and should be used in combination with the text above and the AASM manual [22] and an accompanying commentary from the ASA and Australian and New Zealand Sleep Science Association [23]. See separate Table 7 for the recommended and optional components of a vigilance test report.

In keeping with the AASM scoring manual [22], items listed as “Recommended” must be included in a sleep study report to meet NATA accreditation requirements. Items listed as “Optional” may be performed at the discretion of the clinician or scientist.

Attended Treatment Studies

Continuous positive airway pressure studies

General description of CPAP titration studies.

As for attended diagnostic polysomnography, appropriately trained staff are important to support people using CPAP in attended sleep laboratory settings. In addition to the requirements for measurement during the night, clinical interaction is needed to help with mask fitting and troubleshooting any problems with CPAP prior to commencing the sleep period and during the night. Further details on staffing and environmental requirements are in Facilities for Conducting Sleep Studies and Staffing Requirements for Conducting Sleep Studies of this document.

Indications/contraindications for CPAP titration studies.

While people with uncomplicated OSA may be commenced on CPAP using auto-titrating devices in the home, (see More Recent Studies below), where there are significant cardiorespiratory comorbidities or CSA, attended CPAP implementation is recommended. All patients prior to CPAP titration must receive adequate education, mask fitting, and acclimatization prior to titration as this increases uptake and adherence with CPAP going forward [56].

Specific caution is needed in those susceptible to the effects of elevated intrathoracic pressure such as previous pneumothorax and conditions with reduced cardiac output. CPAP titration studies are contra-indicated in the context of unstable severe medical comorbidity (e.g. decompensated heart failure, active exacerbations of pulmonary disease), active infectious respiratory disease, severe nausea, recent aerodigestive system surgery, recent trauma to face/aerodigestive system [57]. In these situations, the study should be delayed until there has been stabilization or resolution of the contra-indication.

Method of titration for CPAP studies.

A number of methods are available for titrating CPAP in an attended setting. Titrations can be done manually by experienced sleep scientists or by using auto-titrating devices. If local

Table 4. Items That Must be Included in a Study Report According to Diagnostic Study Sub-type

Parameter(s)	Type 1	Type 2	Type 3	Type 4
Service information	Recommended	Recommended	Recommended	Recommended
Patient demographics	Recommended	Recommended	Recommended	Recommended
Date of testing	Recommended	Recommended	Recommended	Recommended
Recording device and software version use.	Recommended	Recommended	Recommended	Recommended
Variables measured	Recommended	Recommended	Recommended	Recommended
Sleep staging	Recommended	Recommended	—	—
Method used to determine time available for sleep (total dark time or monitoring time)	Recommended	Recommended	Recommended	Recommended
Frequency and type of respiratory events	Recommended	Recommended	Recommended	Recommended
Overall	Recommended	Recommended	Recommended	Recommended
By sleep stage (REM, non-REM, and other)	Recommended	Recommended	—	—
By body position	Recommended	Optional*	Optional*	Optional *
Oxygen saturation	Recommended	Recommended	—	—
Mean stable SpO ₂ prior to sleep onset and mean SpO ₂ during stable NREM	—	—	Recommended	Recommended
Mean stable SpO ₂ at beginning of monitoring time	Recommended	Recommended	Recommended	Recommended
SpO ₂ nadir	Recommended	Recommended	—	—
Duration and/or % of sleep with SpO ₂ ≤ 90% and ≤ 88%	—	—	Recommended	Recommended
Duration and/or % monitoring time with SpO ₂ ≤ 90% and ≤ 88%	Recommended	Recommended	Optional	Optional
ODI 3%	Optional	Optional	Optional	Optional
ODI 4%	Optional	Optional	Optional	Optional
PtcCO ₂				
Trends graphically	Optional*	—	—	—
Presence-absence of hypoventilation	Recommended	—	—	—
Average wake TcCO ₂ (or equivalent) prior to sleep onset	Recommended	—	—	—
Maximum value in REM and NREM sleep	Recommended	—	—	—
Average wake TcCO ₂ morning after study	Optional*	—	—	—
Arterial blood gas results	Optional*	—	—	—
Cardiac	Recommended	Recommended	Recommended	Recommended
Average heart rate during sleep and awake	Optional**	Optional**	Optional**	Optional**
Highest and lowest heart rate during sleep	Recommended	Recommended	Optional*	Optional*
Disturbance of cardiac rhythm and relationship to respiratory events if present	Recommended	Optional*	—	—
PLM and associated sleep fragmentation	Recommended	Recommended	Recommended	Recommended
Medications, caffeine, and alcohol	Recommended	Recommended	Recommended	Recommended
Technical comment including signal quality and behavioral factors	Recommended	Recommended	Recommended	Recommended
Location of recording (home, hospital, and other)	Recommended	Recommended	Recommended	Recommended
Scoring definitions	Recommended	Recommended	Recommended	Recommended
Denominator used to calculate event indices	Recommended	Recommended	Recommended	Recommended
Normative values used	Recommended	α	α	α
Interpretation and conclusion including comment on diagnosis and severity	Recommended	Recommended	Recommended	Recommended
Signature of reporting Sleep Medicine Specialist with date of report	Recommended	Recommended	Recommended	Recommended

Recommended items MUST be included to meet National Association of Testing Authorities (NATA) accreditation requirements.

Optional may be performed at the discretion of the clinician or scientist.

Items marked with a * symbol must be included in the report if they are measured and **indicates a divergence from the commentary from the Australasian Sleep Association and Australia and New Zealand Sleep Association [23] of the AASM manual [22]. α indicates there are no current normative data in the literature.

See Limitations of Type 3 studies for discussion of the difference between monitoring time compared with total sleep time.

expertise is available, manual titration is preferable, aiming to find a balance between sufficient CPAP to eliminate respiratory events, while minimizing emergence of CPAP-related side effects. Each sleep service must have a written protocol for the titration methodology used.

Measurements required in CPAP studies.

As for diagnostic polysomnography plus description of the PAP settings, the device used, and mask leak encountered (including if the mask was changed or chin straps added through the night). As noted for diagnostic studies, additional measurements of transcutaneous carbon dioxide and ABGs should be used when there is significant risk for hypoventilation.

Interpretation and minimum reporting requirements in CPAP studies.

In addition to the reported variables for diagnostic polysomnography, the final report of CPAP studies must include details on the equipment used, the treatment parameters trialed, and the most effective mask interface and treatment parameters.

Bi-level studies

General description of bi-level studies.

Bi-level ventilation is a more complex therapy than CPAP and additional factors need to be considered including inspiratory and expiratory pressures, inspiratory, and expiratory times and patient-ventilator factors including the ability to trigger (switch from expiratory to inspiratory pressures) and cycle (inspiratory to expiratory pressures) between breaths.

Indications for bi-level studies.

Chronic (home) bi-level ventilation is indicated in conditions where pressure support (with a higher inspiratory than expiratory pressure) is required to augment a patient's spontaneous tidal volume. The most common indications for home ventilation in Australasia are neuromuscular diseases and obesity hypoventilation syndrome [58]. Bi-level ventilation may also be indicated when high airway pressures are required to control upper airway obstruction that cannot be delivered by a CPAP device.

Method of titration required in bi-level studies.

Outpatient initiation of therapy is non-inferior to hospital inpatient initiation [59–61]. Determination of therapy settings is commonly performed either by overnight polysomnography or daytime titration in wakefulness. There are limited quality data comparing the two methods, but there are indications that polysomnography is associated with lower patient-ventilator asynchrony, improved nocturnal oxygenation, and improved sleep architecture [62, 63], but variable effects on diurnal gas exchange. One study suggested that polysomnography may improve therapy usage in patients initiated on therapy by daytime titration [62]. Patients who appear clinically stable on home bi-level ventilation may still have respiratory events related to upper airway obstruction, glottic closure due to therapy, and unstable ventilatory drive which are only apparent on polysomnography [64]. In stable patients on home ventilation, studies have demonstrated persistent hypoventilation in up to 70% [65] and evidence of patient-ventilator asynchrony events > 10–20 per hour in 21%–71% (> 100 per hour in 17%) [65, 66]. These issues were not detected on clinical evaluation, overnight oximetry, or wakeful ABG measurements and highlight the importance of transcutaneous carbon dioxide measurements [65].

Auto-titrating bi-level therapy has been developed similarly to auto-titrating CPAP therapy. These devices use proprietary algorithms which adjust inspiratory and expiratory pressure support to maintain a pre-set target ventilation and some also utilize algorithms to automatically adjust the expiratory pressure (EPAP) which responds to indirect features of upper airway obstruction. There are a small number of studies comparing these devices to standard, fixed-pressure bi-level therapy. Most studies have shown that auto-titrating bi-level therapy is non-inferior to standard therapy [67–70]. However, these studies are limited by small participant numbers, short follow-up, and the primary outcome measures used. Most used single-night polysomnographic measures such as mean oxygen saturation. One study evaluated arterial carbon dioxide partial pressure at 3 months [70]. Long-term outcomes have not been reported.

Recommendations when performing bi-level studies include:

- (1) Settings for bi-level ventilation can be determined either by overnight polysomnography or daytime (wakeful) titration.
- (2) Polysomnography should be considered if patient-ventilator asynchrony is suspected.
- (3) Polysomnography should be considered if outcome measures (including arterial carbon dioxide pressures or symptoms) do not improve with therapy.
- (4) Polysomnography should be considered in patients with poor usage and/or tolerance of therapy, where settings were determined by daytime titration.
- (5) Auto-titrating bi-level ventilation appears promising but verification of efficacy is required including nocturnal oximetry, assessment of device-derived data and ideally overnight transcutaneous carbon dioxide measurements.

Measurements required in bi-level studies.

As for CPAP polysomnography and measurements of transcutaneous carbon dioxide must be performed. ABGs should be performed when there is significant hypoventilation. Measurement of air leaks (preferably unintentional air leaks but total air leak is acceptable), pressures (inspiratory and expiratory), and flow must be performed. The following channels may be useful to display in real-time on the PSG montage: estimated tidal volume and information on triggering and cycling (i.e. patient versus ventilator initiated), depending on device outputs.

Interpretation and minimum reporting requirements for bi-level studies.

Given the complexity of the therapy and the study measurements, attending staff and reporting clinicians of bi-level sleep studies require additional specific training, and services providing this investigation must have documented training, competency, and maintenance of competency procedures. The AASM recommends scoring of respiratory events from the device-calculated flow signal using the same criteria as in a diagnostic sleep study [22]. However, respiratory events are influenced by patient factors, ventilator settings, and patient-ventilator interaction [71]. Therefore, scoring of respiratory events is recommended but qualitative description of respiratory abnormalities is acceptable if features of upper airway obstruction and patient ventilatory effort are described in sufficient detail to justify the final recommendation(s). In all cases, the presence and effects of unintended air leaks, patient-ventilator asynchrony must be considered.

The final report must include:

- (1) Device used during the study.
- (2) Calculated the frequency of respiratory events or detailed description of respiratory events, including hypoventilation if present.
- (3) Measured unintentional or total leaks.
- (4) Settings used during the study. The duration at each setting, frequency of breathing events, oxygen saturation, and transcutaneous carbon dioxide measurement are desirable.
- (5) Use of supplemental oxygen during the study.
- (6) Interface or interfaces used during the study.
- (7) Final recommended settings, including inspiratory pressure, expiratory pressure, rate (if appropriate), rise time, duty cycle (inspiratory and expiratory times), trigger and cycling sensitivities, or settings.

Adaptive servo-controlled ventilation studies

General description of an adaptive servo-controlled ventilation study.

Requirements are the same as for both diagnostic and CPAP implementation attended sleep studies. However, as patients requiring adaptive servo-controlled ventilation (ASV) generally present with more complex cardiorespiratory comorbidities, it is important there is adequate clinical support and experienced staff to manage these complex titrations. Important ASV terminology is shown in [Table 5](#).

Indication for ASV study.

ASV is an effective form of positive airway pressure therapy for reducing CSA. However, the clinical indication for ASV is not clear, with recent research aiming to find subgroups of patients with heart failure and CSA who may derive benefit from ASV [72, 73]. ASV should not be used for the treatment of CSA in patients with a left ventricular ejection fraction $\leq 30\%$ [74, 75] and with caution for those with left ventricular ejection fraction $< 45\%$ – 30% [76].

Method of ASV titration.

Performing ASV titrations is challenging as the difference between expiratory and inspiratory pressures is constantly changing. A general approach is to adjust end-expiratory pressure settings to stabilize the upper airway while allowing the device to vary the difference between inspiratory and expiratory pressures. Modern ASV devices also have the ability to auto-adjust the expiratory pressure setting in response to upper airway obstruction. Each patient should have a specific titration plan based on the clinical circumstances and the purpose of using ASV in that individual.

Measurements required in ASV studies.

Requirements are the same as for both diagnostic and CPAP implementation attended sleep studies. The final report must include:

- (1) Device used during the study.
- (2) Calculated frequency of respiratory events or detailed description of respiratory events.
- (3) Measured unintentional or total leaks.
- (4) Settings used during the study. The duration at each setting, frequency of breathing events, and oxygen saturation are desirable.
- (5) Interface or interfaces used during the study.
- (6) Final recommended settings, including maximum pressure support (cmH₂O), minimum pressure support (cmH₂O), and end-expiratory pressure.

Interpretation and minimum reporting requirements for ASV studies.

As for diagnostic and CPAP implementation attended polysomnography with addition of optimal expiratory pressure settings to stabilize the upper airway and range of inspiratory pressures used.

Attended assessment of non-PAP interventions for OSA

General description for non-PAP treatment studies.

Requirements are the same as for diagnostic attended polysomnography.

Indication for non-PAP treatment studies.

When using non-PAP treatments for sleep-disordered breathing, it is important to assess effectiveness of treatment, particularly if sleep-disordered breathing is severe. In cases of mild OSA, relying on improvement in clinical symptoms is adequate, reserving non-PAP treatment studies for cases where clinical response is sub-optimal. Use of attended polysomnography to assess effectiveness of treatment is appropriate when assessing moderate—severe OSA. Non-PAP treatments include, but are not limited to, oral appliances (e.g. mandibular advancement splints), weight loss, surgery including hypoglossal nerve stimulators, oxygen, and positional therapy.

Measurements in non-PAP treatment studies.

As for diagnostic polysomnography with documentation of the device used.

Interpretation and minimum reporting requirements in non-PAP treatment studies.

As for diagnostic polysomnography with the addition of specific measures relevant to the treatment being assessed. For example, in the case of a mandibular advancement splint the degree of mandibular advancement, or when using a hypoglossal nerve stimulator, the device settings.

Split-night sleep studies

General description of split-night studies.

Requirements are the same as for both diagnostic and CPAP implementation attended sleep studies. However, the decision to go ahead with a split study requires assessment of the degree of sleep-disordered breathing during the night. Overnight staff should have sufficient clinical experience to decide whether to proceed with a split-night study or complete the study as a diagnostic study and must document the trigger which prompted the change from diagnostic to treatment study.

Table 5. Terminology in ASV

Inspiratory positive airway pressure = IPAP
Expiratory positive airway pressure = EPAP
Pressure support = PS
= IPAP—EPAP
End-expiratory pressure = EEP

Indication for split-night studies.

Split diagnostic and CPAP titration studies may be considered where there is limited access to attended polysomnography and a high pretest probability of severe OSA. During the initial diagnostic portion of the study, there should be an AHI of at least 40 events per hour over a minimum of 2 hours [77]. A split-night study may be considered at an AHI of 20 to 40, based on clinical judgement [77]. If considering a split-night study, the patient must have adequate education around CPAP prior to the study, as familiarization and education about CPAP is a strong predictor of future uptake of CPAP treatment [56].

Method of titration in split-night studies.

As time for titration is limited, it is important that staff are experienced in CPAP titration and able to titrate CPAP for at least 3 hours including during REM and non-REM sleep and preferably REM sleep in the supine position.

Measurements in split-night studies.

As for diagnostic and CPAP implementation attended polysomnography.

Interpretation and minimum reporting requirements in split-night studies.

As for diagnostic and CPAP implementation attended polysomnography. However, the report must be divided into diagnostic and titration sections to allow separate evaluation of sleep architecture and respiratory parameters under each of these conditions.

Multi-night electroencephalography studies

For the evaluation of complex seizure disorders, there is a role for attended multi-night electroencephalography (EEG) recording. This is usually undertaken in a dedicated neurology service with staff experienced in epilepsy and seizure management and neurologists experienced in the interpretation of EEG recordings in relationship to seizures. As technologies evolve, there is increasing ability to perform multi-night EEG recordings in an ambulatory setting. The simplified nature of these devices may extend their clinical use to areas such as insomnia, particularly where there is suspected sleep state misperception.

Ambulatory Treatment: CPAP Initiation Using Auto-Titration Devices

General description of APAP initiation

Many brands of auto-titrating pumps report either the 90th or 95th percentile of pressure over a period of APAP usage. This pressure can be used to determine the pressure at which to set standard CPAP pump when commencing therapy. The 2017 ASA Guidelines [1] concluded there was insufficient evidence to recommend either home auto-titrating, or attended CPAP titration over the other, when a patient with minimal medical comorbidities commences therapy.

Since that time, an AASM Taskforce has conducted a systematic review and meta-analysis [4] to evaluate the role of ambulatory CPAP commencement utilizing auto-titrating devices. They found ten studies from 2000 to 2018 that compared initiating CPAP treatment for OSA with manual CPAP titration during a sleep study in a sleep laboratory with home auto-titrating CPAP. The sleep studies in sleep laboratories were for 1 night, although some were part of split diagnostic and treatment studies over 1 night. Auto-titration CPAP was used at home for 2 to 7 nights.

There was no difference in the outcomes of sleepiness (from 1 to 3 months), quality of life (after 3 months), and adherence with CPAP (from 1 to 6 months).

AASM recommendation

On the basis of the 2019 systematic review and meta-analysis [4] the AASM 2019 [10] recommendations were formulated. In that guideline, there is a strong recommendation that CPAP treatment in adults should be initiated with a method of determining an appropriate pressure using either auto-titrating CPAP at home, or with manual titration during a sleep study in a sleep laboratory. They did not prefer one method over the other.

More recent studies

More recent published studies do not change the conclusions that can be drawn from the AASM 2019 meta-analysis. For example, a study from Brazil published in 2021 [78] found that initiating CPAP with auto-titrating CPAP and then changing to fixed CPAP was cost-effective. However, cost-effectiveness is very much dependent on local funding factors, even within Australia and New Zealand, and such a conclusion cannot be applied generally.

The caution with using auto-titrating CPAP initially in those with a degree of CSA was reinforced in a study showing that those with a proportion of central apneas are less likely to have their AHI reduced to below five with auto-titrating CPAP [79]. They also showed that mask leak is also a factor limiting the reduction in AHI.

A retrospective review of manual CPAP titration during laboratory polysomnography compared with subsequent auto-titrating CPAP showed slightly higher pressures on average with manual titration (11.4 ± 2.6 compared with 10.3 ± 2.4 cmH₂O, $p = .013$) [79]. This was more likely in those with a higher BMI. A German study [80] added follow-up with telemetry to auto-titration and compared this combination with laboratory manual titration over two nights. Telemetry data were reviewed weekly by a specialist nurse who dealt with any problems that were identified. There were no differences in CPAP usage or sleepiness between the two groups over 6 months.

Indications for CPAP auto-titration to initiate CPAP

Practical issues still apply and can determine which patients would not be suitable for unattended auto-titration. Those who may find it difficult to put on and take off the mask initially, may be better starting CPAP in a sleep laboratory, in which assistance and training can be readily provided. Ultimately, however, patients will need to fend for themselves at home (unless they have a carer who can assist). Relative contraindications to auto-titrating CPAP at home initiation are detailed in Table 6.

Table 6. Relative ContraIndications to Auto-Titrating CPAP at Home Initiation

Auto-titrating CPAP initiation at home is not recommended in patients with:
– OSA and comorbidities in which central sleep apnea is often present (e.g. heart failure and/or use of opiate drugs).
– Conditions that might lead to prolonged nocturnal hypoxemia such as lung diseases, neuromuscular conditions, and obesity hypoventilation syndrome.
– Past history of uvulopalatopharyngoplasty.

Patients who have marked night-to-night variability in their OSA due to factors such as body position and variable alcohol consumption, may be better using auto-titrating CPAP for a period of time at home rather than a single night in a sleep laboratory.

Practical considerations such as comfort sleeping at home or at the laboratory, ability to get to and from the sleep laboratory or to and from the center for the auto-titrating device, and of course costs, which will vary depending on the clinical situation. Whether the clinician intends to continue auto-titrating CPAP in the long-term will also influence the decision-making. Waiting times for either method also vary, and these can be important, especially for those who are commercial drivers.

Education about the use of CPAP, appropriate mask fitting, and support in the first few weeks of treatment are all important and must be considered, but they do not specifically relate to the method of initiating CPAP.

Interpretation and minimum reporting requirements for APAP initiation report

Where PAP therapy is initiation via auto-titration, a report must be generated following a minimum of two nights trial. From this APAP trial, a laboratory-directed or industry-directed report must be generated, and the following must be included in the report:

- (a) The machine used.
- (b) The duration of the trial.

- (c) The mask(s) used over the trial.
- (d) Presence of any additional channels of measurement used (e.g. effort bands, oximetry) and the results of these where appropriate.
- (e) Machine-derived AHI.
- (f) Machine-derived leak.
- (g) Machine-derived 90th or 95th centile pressure.
- (h) Technical comments.
- (i) Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).

Access to CPAP treatment

Providing timely and affordable CPAP to patients who need it will be an important factor in determining which method to use to find the best pressure for each patient.

Vigilance Testing

Objective tests such as the MSLT and MWT to assess daytime sleepiness and alertness are an important part of the investigation of patients with a variety of sleep disorders associated with hypersomnolence. Normative data and clinical indications for the tests are found in the 2005 AASM review paper [81], which is supported by this guideline. In 2021 the AASM published an update to the recommended protocols for the MSLT and MWT [2]. Table 7 below

Table 7. Summary of Parameters to be Reported for MSLT and MWT

Parameter(s)	Status MSLT	Parameter(s)	Status MWT
Service information		Service information	
Name, address, and contact details of sleep service	Recommended	Name, address, and contact details of sleep service	Recommended
Site where the MSLT was performed (if a multi-site sleep service)	Recommended	Site where the MSLT was performed (if a multi-site sleep service)	Recommended
Patient demographics		Patient demographics	
Name	Recommended	Name	Recommended
Date of birth	Recommended	Date of birth	Recommended
Gender	Recommended	Gender	Recommended
Unique medical record number	Recommended	Unique medical record number	Recommended
Body mass index	Recommended	Body mass index	Recommended
Alerting and sedating medications administered within last 24 hours	Recommended	Alerting and sedating medications administered within last 24 hours	Recommended
Height, weight, neck circumference	Optional	Height, weight, neck circumference	Optional
Subjective measure of sleepiness (e.g. Epworth Sleepiness Scale)	Optional	Subjective measure of sleepiness (e.g. Epworth Sleepiness Scale)	Optional
Test information		Test information	
Test date	Recommended	Test date	Recommended
Treating clinician	Recommended	Treating clinician	Recommended
Sleep scientist/technologist	Recommended	Sleep scientist/technologist	Recommended
Recording parameters (e.g. EEG derivations)	Recommended	Recording parameters (e.g. EEG derivations)	Recommended
Referring clinician	Optional	Referring clinician	Optional
Aim of test	Recommended	Aim of test	Recommended
Vigilance test summary statistics		Vigilance test summary statistics	
Mean sleep latency	Recommended	Mean sleep latency	Recommended

Table 7. Continued

Parameter(s)	Status MSLT	Parameter(s)	Status MWT
Number of SOREMPs	Recommended	Mean sustained sleep latency	Optional
Individual trials		Individual trials	
Lights off time, lights on time	Recommended	Lights off time, lights on time	Recommended
Sleep latency	Recommended	Sleep latency	Recommended
REM sleep latency	Recommended		
Sleep time	Recommended	Sleep time	Recommended
Pre-nap trial rating of subjective sleepiness (e.g. Stanford Sleepiness Scale)	Optional	Sustained sleep latency	Optional
Post-nap trial experience (e.g. sleep achieved, dream recall, etc.)	Optional	Subjective sleep latency	Optional
Graphical summary	Optional	Graphical summary	Optional
Preceding PSG/therapy/sleep scheduling information		Preceding PSG/therapy/sleep scheduling information	
Total sleep time	Recommended	PAP therapy compliance in preceding 2 weeks	Recommended
AHI and/or RDI	Recommended	PAP therapy residual AHI in preceding 2 weeks	Recommended
SOREMP occurrence	Recommended	Tool used to assess sleep schedule prior to test (e.g. sleep diary and/or actigraphy)	Recommended
PAP therapy compliance in preceding 2 weeks (if applicable)	Recommended	Average sleep time in the 2 weeks before testing	Recommended
PAP therapy residual AHI in preceding 2 weeks (if applicable)	Recommended	TST	Optional
Tool used to assess sleep schedule prior to test (e.g. sleep diary and/or actigraphy)	Recommended	AHI and/or RDI	Optional
Average sleep time in the 2 weeks before testing	Recommended		
Report information		Report information	
Date of final report	Recommended	Date of final report	Recommended
Report template version	Recommended	Report template version	Recommended
Reference criteria/data used (e.g. sleep scoring, normative data)	Recommended	Reference criteria/data used (e.g. sleep scoring, normative data)	Recommended
Clinical/technical observations about conduct of study	Recommended	Clinical/technical observations about conduct of study	Recommended
Urine drug screen results	Recommended	Urine drug screen results	Recommended
Interpretative summary statement	Recommended	Interpretative summary statement	Recommended
Name and signature of interpreting/reporting clinician	Recommended	Name and signature of interpreting/reporting clinician	Recommended
Page number and total number of pages (for multi-page reports)	Recommended	Page number and total number of pages (for multi-page reports)	Recommended

provide a summary of the parameters to be reported in MSLT and MWT, respectively.

MSLT guidelines

Indications

- (1) The MSLT is indicated as part of the clinical evaluation for central disorders of hypersomnolence.
- (2) A repeat MSLT is indicated if the initial MSLT was rendered ambiguous or uninterpretable due to external factors.
- (3) A repeat MSLT is indicated if the initial MSLT result does not match with a strong clinical history that suggests a central disorder of hypersomnolence.

Contraindications

- (1) The MSLT is not indicated for the clinical evaluation of sleepiness in medical/neurological disorders other than central disorders of hypersomnolence.
- (2) The MSLT is not indicated for the clinical evaluation of sleepiness in the diagnosis of OSA.
- (3) The MSLT is not indicated for the clinical evaluation of sleepiness after commencing treatment for OSA.

The committee agrees with the AASM recommended protocol for the MSLT [2] with the following exceptions/additions:

Clinical guidance and patient preparation

- (1) An information sheet must be provided to the patient. This sheet must provide:
 - a. MSLT protocol details.
 - b. Expected finishing time.
 - c. Reference to any medication/caffeine tapering protocols.
 - d. Appointment details or an indication of when to expect the test results.
- (2) A written plan regarding use of prescription medication, OTC agents, herbal remedies, and other substances for the 2 weeks before the MSLT must be provided to the patient.
 - a. Medications including selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors can suppress REM sleep. Clinicians should assess and discuss with their patients the risks or benefits of ceasing/continuing such medications. Where SSRI/SNRI cessation has been deemed appropriate, these agents should be ceased for 2 weeks before testing. Abrupt cessation of most selective serotonin reuptake inhibitors and SNRI risks withdrawal symptoms [82], thus a tapering schedule customized to the individual patient, medication, and dose should be considered.
 - b. Medication cessation is not always possible if there are significant risk in ceasing relevant medications. As such, medication use prior to MSLT should be assessed in each case and clearly documented so that any medication effects can be factored into the interpretation of MSLT results.
- (3) A caffeine tapering protocol should be discussed with the patient if they regularly consume ≥ 400 mg of caffeine per day or notice withdrawal symptoms (e.g. headache, nausea, etc.) during caffeine abstinence.
 - a. As it takes approximately ten hours for the elimination of caffeine from the system, it is recommended that a caffeine tapering protocol must include no caffeine ingestion on the day of the PSG in addition to the day of the MSLT.
- (4) In patients who are undergoing an MSLT for persistent sleepiness despite treatment of a sleep disorder such as OSA, determination of therapy effectiveness during the PSG should take into account night-to-night variability in pressure requirements [83, 84].

General testing procedures.

Since acute withdrawal from alcohol and marijuana may be associated with reduced REM latencies and REM rebound [85], patients should:

- Abstain from alcohol for 24 hours prior to their PSG and until the end of the MSLT.
- Abstain from marijuana use for one week prior to their PSG and until the end of the MSLT.

In addition,

- (1) Mobile phones and tablets must be either powered down or switched to silent mode before each nap trial. This is to prevent any inadvertent calls or SMS texts during the nap trial.

- (2) Urine drug screens must occur and should include screening for amphetamines, benzodiazepines, buprenorphine, cannabinoids, cocaine, methadone, and opioids.
 - a. If a sample is positive for any of the above substances, it is suggested that high-performance liquid chromatography be requested to confirm the positive result.
- (3) The treating clinician must be consulted if the sleep scientist is concerned about the MSLT patient's level of sleepiness and its possible effect on driving safety.
- (4) Audio-visual recordings should be retained with the PSG and MSLT for medicolegal purposes.

Interpretation and minimum reporting requirements in MSLT.

MSLT Reports must contain the following data and interpretation:

- Demographics including name, date of birth, medical record number, test date, and body mass index (BMI).
- Name of referring clinician and sleep scientist.
- Documentation of available pre-study data including sleep diary, actigraphy, and PAP download.
- Documentation of alerting and sedating medications used within 24 hours of and during the MSLT and any changes to medications within the last 2 weeks.
- Results of drug screen testing performed.
- Appropriate pre-study data including sleep diary, actigraphy, and PAP download must be available and documented at the time of MSLT. There must be specific comments with respect to:
 - Adequacy and consistency of sleep in the 2 weeks prior to the MSLT. Less than 6 hours of sleep per night prior to the MSLT is considered inadequate.
 - Alignment of sleep diary with actigraphy if both are available.
 - Average PAP adherence and residual AHI (if available) in the 2 weeks prior to the MSLT must be reported.
- Results from prior night PSG, including TST, sleep efficiency, REM sleep latency, and AHI.
- Recorded parameters for each trial including start time, end time, TST, sleep latency (20 minutes is SL for a trial where no sleep occurs), and REM latency. Where CPAP was used the settings must be reported.
- Calculated results for mean sleep latency and number of naps with REM sleep episodes.
- Any deviations from ideal testing times and conditions must be documented by the sleep scientist.
- Interpretation of study findings in terms of sleepiness, clinical significance and relationship to clinical question (or diagnosis) being queried by referring clinician.
- Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).
- References to procedure guidelines and methodology employed, in addition to normative values used.

MWT guidelines

Indications

- (1) The MWT is indicated to assess a patient's ability to remain awake when this ability is crucial for public or personal safety.

- (2) The MWT is indicated to assess response to treatment in patients with a history of excessive sleepiness.

Contraindications.

The MWT is not indicated for the routine evaluation of sleepiness after commencing treatment for OSA.

The committee agrees with the AASM recommended protocol for the MWT [2] with the following exceptions/additions:

Clinical guidance and patient preparation

- (1) An information sheet must be provided to the patient. This sheet must provide:
 - a. MWT protocol details.
 - b. Expected finishing time.
 - c. Reference to any medication/caffeine tapering protocols.
 - d. Appointment details or an indication of when to expect the test results.
- (2) A written plan regarding use of prescription medication, OTC agents, herbal remedies, and other substances for the 2 weeks before the MWT must be provided to the patient.
- (3) A clinical judgment must be made by the requesting clinician regarding the use of caffeine during a MWT and this plan must be documented.
 - a. If MWT is to be performed without caffeine, a caffeine tapering protocol must be discussed with the patient and documented, if they regularly consume ≥ 400 mg of caffeine per day or notice withdrawal symptoms (e.g. headache, nausea, etc.) during caffeine abstinence.

General testing procedures

- (1) If PSG will not be occurring prior to the MWT, the patient must have a sleep diary and/or actigraphy completed for the 2 weeks prior to the MWT (ideally this should be completed for all patients undergoing MWT).
- (2) In addition to abstaining from alcohol, marijuana, and other sedating substances on the day of the test, patients should also reduce consumption in the days prior to the test.
- (3) Mobile phones and tablets must be either powered down or switched to silent mode before each trial. This is to prevent any inadvertent calls or SMS texts during the trial.
- (4) A white light source with an illuminance of no more than 1 lux at the corneal level is mandatory [86].
- (5) Urine drug screen must occur and should include screening for amphetamines, benzodiazepines, buprenorphine, cannabinoids, cocaine, methadone, and opioids. a. If a sample is positive for any of the above substances, it is suggested that high-performance liquid chromatography be requested to confirm the positive result.
- (6) The treating clinician must be consulted if the sleep scientist is concerned about the MWT patient's level of sleepiness and its possible effect on driving safety.

Additional measurements are required as part of MWT.

Appropriate pre-study data including sleep diary, actigraphy, and PAP download, must be available and documented. There must be specific comments with respect to:

- Adequacy and consistency of sleep in the 2 weeks prior to the MWT. Less than 6 hours of sleep per night prior to the MWT (on PSG or actigraphy) would be considered inadequate.
- Alignment of sleep diary with actigraphy if both are available.
- Average PAP adherence and residual AHI (if available) in the 2 weeks prior to the MWT must be reported.
- MWT reports must also include the TST and AHI from the prior night PSG (if performed).
- Audio-visual recordings should be retained with the MWT (and PSG if performed) for medicolegal purposes.

Interpretation and minimum reporting requirements in MWT.

MWT Reports must contain the following data and interpretation:

- Demographics including name, date of birth, medical record number, test date, and BMI.
- Name of referring clinician and sleep scientist.
- Documentation of available pre-study data including sleep diary, actigraphy, and PAP download.
- Documentation of medications used within 24 hours of and during the MWT and any changes to medications within the last 2 weeks.
- Results of drug screen testing performed.
- Results from prior night PSG (if performed), including TST, sleep efficiency, and AHI.
- Recorded parameters for each trial including start time, end time, TST, sleep latency of each wake trial (40 minutes is SL for a trial where no sleep occurs).
- Microsleep episodes may optionally be scored and reported.
- Calculated results for mean sleep latency averaged over the four wake trials.
- Any deviations from ideal testing times and conditions must be documented by the sleep scientist.
- Interpretation of study findings in terms of ability to maintain wakefulness, clinical significance and relationship to clinical question (or diagnosis) being queried by referring clinician.
- Signature of reporting Sleep Medicine Specialist (signatures may be hard copy or electronic, provided the electronic signature can be authenticated).
- References to procedure guidelines and methodology employed, in addition to predicted values used.

Tests of Activity

Longitudinal measurement of sleep can provide clinicians with important information in the diagnosis and management of sleep disorders.

Sleep diary

General description of sleep diaries.

Sleep logs also referred to as sleep diaries are self-report tools, completed by patients to record daily sleep patterns. While there are many templates available, the consensus sleep diary [87] was developed by international experts and can be freely used for clinical purposes (for example, Consensus Sleep Diary with all optional items [drcoleencarney.com]).

The limitations of sleep diaries include over-estimation of time in bed, TST, and sleep efficiency compared with PSG [88] related to recall bias. The mean difference in a study of 323 adults indicated over estimation of time in bed 20.1 minutes, TST 13.7 minutes, sleep efficiency 7.8 minutes and wake after sleep onset underestimated by 37.6 minutes compared with PSG [88].

Indications for a sleep diary.

Sleep diaries can be useful for:

- (1) The diagnosis and management of suspected circadian rhythm disorder such as delayed sleep–wake phase disorder, advanced sleep–wake phase disorder, irregular sleep–wake phase disorder and non-24 hour sleep–wake phase disorder.
- (2) In the management of insomnia with cognitive behavioral therapy.
- (3) In the investigation of hypersomnolence of central origin disorders, to exclude insufficient sleep syndrome, and
- (4) Prior to MSLT to confirm sufficient sleep prior to test.

Actigraphy

Description of actigraphy.

Actigraphs are small portable biosensors, from which sleep–wake patterns can be estimated [89]. These devices record several parameters, including motion via accelerometers, light (including type of light spectrum) and sound. These devices are usually worn on the wrist.

Compared with gold-standard PSG, there is high-quality evidence that actigraphy accurately measures TST, sleep latency, wake-after-sleep onset, and sleep efficiency [11, 90]. The accuracy is summarized in Table 8 below. It should be noted that performance characteristics will depend on the type of device and algorithm used. In general, actigraphs are more accurate at detecting sleep than wakefulness (therefore have a bias towards overestimating sleep) and are more accurate in “good” sleepers compared to those with poor sleep quality [12].

Indications and contraindications for actigraphy.

Actigraphy provides reliable, objective measurement of sleep–wake patterns in

- Insomnia.
- Circadian rhythm sleep–wake disorders.
- Excessive daytime sleepiness where central disorders of hypersomnolence are suspected and prior to MSLT or MWT
- Suspected insufficient sleep syndrome [11].

Table 8. Mean Difference in Actigraphy Compared With Polysomnography

	Mean difference	95% CI	Quality of evidence
TST	10.14 min	8.07 lower to 27.05 minutes higher	High
SOL	6.17 min	2.29 to 9.07 minutes lower	High
WASO	1.5 min	3.68 lower to 19.54 minutes higher	Moderate
SE	1%	4.9% lower to 3.0% higher	Moderate

TST, total sleep time; SOL, sleep onset latency; WASO, wake after sleep onset; SE, sleep efficiency.
Adapted from [11].

While actigraphy is not required for a diagnosis of insomnia, it can be utilized where objective measurement of sleep is desired for decision-making (e.g. to monitor treatment response in cognitive behavioral therapy for insomnia) [11]. The longitudinal measurement from actigraphy is convenient and has low patient burden; however, is more costly than self-reported sleep logs.

Actigraphy is useful in the diagnosis of circadian rhythm sleep–wake disorders, particularly where patients find completing sleep logs for extended duration cumbersome.

Prior to MSLT, actigraphy was recommended in addition to sleep diaries to objectively measure TST, as evidence suggests that actigraphy can define unrecognized insufficient sleep syndrome [11].

Contraindications for actigraphy are infrequent but include where skin break down is likely or where the device would need to be applied to irritated skin. Actigraphy is not recommended in the measurement of periodic limb movements [11].

Measurements required in actigraphy.

Duration of measurement is recommended to be a minimum of 72 hours to 14 consecutive days [11]. Actigraphs can be applied to the non-dominant wrist, ankle, or waist, depending on the device.

Interpretation and minimum report requirements for actigraphy.

Actigraphy data may be expressed graphically (as actograms) and a table numerically, to estimate sleep latency, TST, number of awakenings, duration of wake after sleep onset, and sleep efficiency. Each actigraphy brand has proprietary specific software from which the recorded data are downloaded to score “wake” and “sleep.”

Reporting must include comments on:

- Indication for the actigraphy.
- Quality or technical factors of concern.
- Duration of monitoring, whether weekdays or weekends were included in the measurement.
- Presence of discrepancies between sleep diary and actigraphy recorded data, if present.
- Average TST, sleep onset latency, wake after sleep onset, and sleep efficiency.
- Presence of circadian rhythm shift—advanced, delayed, erratic, non-24 hours.
- Presence and number of sleep periods (“naps”) and duration where present
- Inter day variability/stability.

Consumer Grade Devices

Consumer sleep technology (CST) has greatly expanded since the 2017 guidelines, and technology rapidly changes. CST ranges from devices worn on the body (“wearables”), phone applications (“App”), to those placed on or by the bed to monitor sleep (“nearables”). These are generally devices that do not have an approval as a medical device through the Therapeutic Goods Administration.

Wearables generally are wrist-worn and measure movement with accelerometers, heart rate, oximetry, and temperature to infer sleep–wake patterns. Nearables are more varied in their technology, some estimating sleep–wake patterns from heart rate and respiratory rate via ballistocardiography. Generally, the results of App sleep reports are the least validated of CST [91]; however, the technology evolves rapidly. Apps as part of online

CBTi with self-reported sleep diaries; however, have an important role in insomnia management.

Advantages of CST include improved patient-clinician engagement, longitudinal data collection for long-term pattern observation, easy and low-cost accessibility.

CST is not recommended for diagnostic purposes, as sufficient validation and regulatory approvals generally are not present. Disadvantages are that these unvalidated technologies may trigger patient worry and anxiety that require resource utilization to clarify a true underlying diagnosis. Conversely, patients may be falsely reassured and underestimate the severity of sleep disorders if devices underestimate the presence of a sleep disorder [92].

Future technological directions

As technology evolves, new techniques for measuring sleep are constantly emerging. These techniques may be incorporated with existing sensors, or used as a stand-alone device. New technologies may allow for ambulatory multi-night recordings.

Any new technology or technique used to measure sleep should be validated for the purpose for which it is being used. This requires validation of the sensor's ability to measure the physiological variable it is designed to measure. In addition, validation of the overall system for the purpose it is being used is required. For example, a sensor designed to measure respiratory events as part of assessment of sleep-disordered breathing, should be validated to measure respiratory events and to accurately classify severity of sleep-disordered breathing. In addition, any new sensor, device, or system should have full disclosure of recorded data and ability to review, score, and edit data as well as being able to exclude sections of data where data quality is poor, or artifact is present. Any device being used for clinical purposes requires approval through the Therapeutic Goods Administration.

Facilities for Conducting Sleep Studies

Adequate space and facilities must exist for the service to meet its objectives and comply with statutory requirements. All laboratory testing and scientific work areas must comply with institutional and/or national Work, Health, and Safety guidelines and be confirmed as fit for purpose and safe for resuscitation of patients.

The site and equipment must have appropriate facilities and equipment for the service it provides.

- (1) The site must meet the standards of safety consistent with State workplace health and safety regulations, including:
 - a. infection control,
 - b. handling of gas cylinders,
 - c. fire and electrical safety and
 - d. general safety procedures
- (2) Electrical supply to the monitoring room and the bedrooms of the site must be, at a minimum, at body-protected standard (class B [AS specification]).
- (3) Monitoring equipment must be listed on the Australian Register of Therapeutic Goods as a medical device and the public summary must indicate that the equipment is suitable for use.
- (4) The service must be identified by signage, telephone, and stationery so that it can be easily found and/or accessed.
- (5) The site must be regularly cleaned.
- (6) The facility must provide adequate access to bathrooms, a supply of drinking water, and storage of personal equipment and food for staff.

- (7) There must be adequate storage space for the safe and secure storage of records, consumables, and equipment.
- (8) Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies.

Attended (in-laboratory) services

- (1) The service must have a reception area and waiting room that conform to generally accepted standards for medical suites in size, appearance, privacy, lighting, and furniture.
- (2) The sleep service must have comfortably furnished bedrooms conducive to sleep and of sufficient size (minimum approximately 2.5 × 3.5 meters) to allow access in an emergency, with adequate lighting, soundproofing, exclusion of light during the study, quiet bedroom, air conditioning, emergency oxygen and suction, resuscitation equipment, and security.
- (3) The rooms must conform to local regulations with respect to entrances, exits, and fire precautions.
- (4) There must be a separate bedroom for each patient with comfortable bedding, storage for patient personal effects, and adequate lighting (including for reading).
- (5) There must be conveniently located and adequate toilet and shower sites.
- (6) The monitoring room must be near the bedrooms and a patient call system must be available from bedrooms to the monitoring room.
- (7) Attending staff must be able to visualize/monitor the live recording of all physiological signals for all studies simultaneously.
- (8) For positive airway pressure (titration) studies, staff must be able to adjust device settings from the monitoring room.
- (9) The facility must have office space with adequate space, furniture, lighting, and privacy for analysis of sleep studies.
- (10) A complete range of resuscitation equipment (including automated external defibrillation, AED) must be available to the service for the duration of the studies, including oxygen and suction at the bedside.

In-center home-based services

There are a number of models of home-based diagnostic services, each with advantages and disadvantages; local factors will determine the optimal model for a given sleep service. These include:

- Complete setup in laboratory/center
- Partial setup in laboratory/center
- Scientist setup at patient's home
- Patient setup at patient's home

The setup time for a home-based ambulatory diagnostic study should be as close as possible to the patients' usual sleep time. Local factors influencing the model will include staff shift timing, distance between the patient's house and the laboratory/center, presence of home support and many more.

In services with a laboratory or in-center completed study setup, the service must have:

- (1) A reception area and waiting room that conform to generally accepted standards for medical suites in size, appearance, privacy, lighting, and furniture.

- (2) Appropriately furnished private room(s) in which to setup patients for their home study.
- (3) Room(s) should be an adequate size for the function with adequate lighting, air conditioning, and security and appropriately furnished for the activity.
- (4) Rooms which conform to local regulations with respect to entrances, exits, and fire precautions.
- (5) Adequate space, furniture, lighting, and privacy for administrative tasks and analysis of sleep studies.

Infection control

Sleep laboratories raise very specific infection control issues and adequate understanding and commitment to minimizing risk of cross-infection is essential. Clearly defined infection control procedures must be developed in accordance with current state and/or national standards. Where there is a hospital infection control department they must be engaged in the development and endorsement of these procedures.

All laboratory testing and scientific work areas must be formally assessed by the local infection control department (where available) in accordance with institutional and national guidelines and confirmed as fit for purpose.

Infection control procedures must include, but not necessarily be limited to, addressing the following issues:

- (1) Cleaning and/or sterilization of all patient testing equipment
- (2) Use of in-line bacterial filters
- (3) Procedures for storage of re-usable equipment
- (4) Policies with regard to single-patient use equipment
- (5) Special procedures for patients with known infectious diseases including multi-resistant organisms
- (6) Laboratories should resource recyclable items when possible.
- (7) Laboratories must have a procedure for Standard Infection Control Precautions for all care provided to patients. This must include hand hygiene, personal protective equipment (including gloves, gowns, and facemasks).
- (8) Laboratories must have a procedure for routine environmental cleaning and handling of laundry, as well as safe disposal of waste (including sharps).
- (9) Laboratories must have a procedure for prevention of spread of airborne micro-organisms to other patients and staff (e.g. COVID-19), noting that positive pressure studies may be a source of respirable airborne micro-organisms (i.e. aerosol-generating procedures).

Performing sleep studies during a surge of respiratory communicable diseases is covered in separate ASA position statement [93].

Staffing Requirements for Conducting Sleep Studies

The laboratory must be appropriately staffed to achieve its objectives.

- (1) All staff members must be appropriately qualified for their tasks by education, training, and/or experience.
- (2) Staff must have access to education programs that maintain and develop their knowledge and skills.

- (3) Provision must be made for advice and medical emergencies. These should include an on-call roster for medical staff in appropriate facilities.
- (4) The service must ensure that all clinical and technical staff are appropriately trained in basic life support.

Patient:Staff ratios

Facilities must utilize a system to anticipate the medical complexity and care needs for patients attending on any given night and adjust staff accordingly. Such a system must consider patient history including comorbidities, falls risk, mobility, cognitive or behavioral challenges, infection control issues, carer requirements, and the complexity of the sleep study required.

For Type 1 attended studies, it is recommended that facilities observe patient-to-overnight staff ratios as follows:

- (1) Facilities providing Type 1 sleep studies should utilize a 3:1 patient: overnight staff ratio as the base model.
- (2) Facilities should have the capacity to decrease their patient: overnight staff ratio (i.e. 2:1 and 1:1) from this base model in response to identified patient complexity and requirements for overnight staff.

During setup periods there may also be a requirement for a decreased patient: overnight staff ratio (i.e. 2:1 or 1:1) from the 3:1 base model in response to identified patient complexity and requirements for overnight staff.

Sleep study analysis

A minimum of 1.5 hours of analysis must be allowed for the analysis of Types 1 and 2 sleep studies. Portable studies have significant device diversity and therefore the analysis time will vary according to variable complexity.

Documentation and Quality Control Procedures

Undertaking regular quality control activities and having a regularly implemented quality assurance program with clearly documented laboratory protocols are the cornerstones of quality scientific testing. A detailed guide for the requirements of sleep services is outlined in the ASA Standard for Sleep Disorders Services third edition [20] and the National Association for Testing Authorities position statements [14] on the accreditation of sleep disorders services. These guides call on all laboratories to develop local quality management systems and outline mandatory minimum requirements.

Other standards are relevant to this section and worthy of cross-reference—MSLT [81, 94], MWT [95], diagnostic testing generally [9].

Document control

- (1) All service documents, including policies, procedures, equipment manuals, computer software and templates, calibration records, forms, informational documents, and educational guides, must be managed under a document control system.
- (2) Services must maintain a master list, or equivalent document, identifying the current revision status and distribution of documents.
- (3) Documents must be uniquely identified, to include:

- a. Title
- b. Edition or current revision date, or revision number, or all of these
- c. Page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5")
- d. Authority for issue.
- (4) Services must ensure that:
 - a. Only current authorized versions of appropriate documents are available for use
 - b. Documents are periodically reviewed, revised when necessary, and approved by authorized staff
 - c. Invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use
 - d. Obsolete documents retained for legal or knowledge preservation purposes are suitably marked.
- (5) The service must describe how amendments to documents are made, including the process for hand amendments (if allowed) and the issue of revised documents.

Test procedures

Each test and its procedure must be separately described with the following detail included or cross-referenced from other sources, preferably under appropriate subheadings:

- (1) The purpose of the test.
- (2) A description of the equipment used, with special reference to its specifications and their applicability to the measurement.
- (3) The equipment verification procedure.
- (4) The procedure for performance of the test.
- (5) Troubleshooting: problems that may be encountered in the performance of each test and their appropriate remedies.
- (6) Specific quality assurance, including details of quality control steps required for the method.
- (7) Cleaning and maintenance.
- (8) Infection control and other safety requirements.
- (9) Records and Reports (with samples, including interpretation of the results).
- (10) Normal values and prediction equations used to interpret the results.

Quality procedures

- (1) The service must have a documented procedure for the management of complaints or other feedback received from clinicians, patients, service staff, or other parties.
- (2) The service must have a documented procedure for what happens when it detects any aspect of the service's activities which does not conform to service requirements.
- (3) The service must have a documented procedure for the identification and elimination of nonconformities and their causes (i.e. corrective actions). This procedure must address:
 - a. Determining the root causes of nonconformities.
 - b. Evaluating the need for corrective action to ensure that nonconformities do not recur.
 - c. Determining and implementing corrective action needed (appropriate to the effects of the nonconformities encountered)

- d. Recording the results of corrective action taken.
- e. Reviewing the effectiveness of the corrective action taken.
- (4) The service must have documented procedures for the identification and elimination of potential nonconformities to prevent their occurrence (i.e. preventive actions).
 - a. Reviewing service data and information to determine where potential nonconformities exist.
 - b. Determining the root cause(s) of potential nonconformities.
 - c. Evaluating the need for preventive action to prevent the occurrence of nonconformities (appropriate to the effects of the potential problems).
 - d. Determining and implementing preventive action needed.
 - e. Recording the results of preventive action taken.
 - f. Reviewing the effectiveness of the preventive action taken.
- (5) The service must have a documented procedure for the planning and conduct of evaluations and internal audits. These internal audits demonstrate if the pre-study, study, post-study and supporting processes meets the needs and requirements of referrers and patients and improve the effectiveness of the quality management system. These audits must:
 - a. Ensure that the types of sleep studies provided by the service are clinically appropriate for the referrals received.
 - b. Elicit staff suggestions for the improvement of any aspect of the service.
 - c. Be conducted at planned intervals.
 - d. Be conducted by suitably trained staff.
 - e. Be objective and impartial.
 - f. Evaluate the impact of procedures and potential failures on study results, and must modify processes to reduce or eliminate the identified risks and document decisions and actions taken.
- (6) The service must conduct a management review of the service at planned intervals to ensure its continuing suitability, adequacy and effectiveness, and support of patient care. The input to management review must include information from the results of evaluations of at least the following:
 - a. periodic review of referrals, and suitability of procedures.
 - b. assessment of referrer and patient feedback.
 - c. staff suggestions.
 - d. internal audits.
 - e. risk management.
 - f. quality indicators.
 - g. reviews by external bodies or assessors.
 - h. results of external proficiency testing.
 - i. monitoring and resolution of complaints.
 - j. performance of suppliers.
 - k. identification and control of nonconformities.
 - l. results of continual improvement including current status of corrective actions and preventive actions.
 - m. follow-up actions from previous management reviews.
 - n. changes in the volume and scope of work, staff, and premises that could affect the service.
 - o. recommendations for improvement.

Equipment/Signal verification and checking

- (1) The service must have a documented procedure for the verification or checking of polysomnography equipment

and sensors as well as other equipment that directly or indirectly affects results. This procedure must include:

- a. Conditions of use and the manufacturer's recommendations/instructions
 - b. Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals.
 - c. Safeguards to prevent adjustments or tampering that might invalidate results.
 - d. The date at which verification was performed and the results of each verification must be recorded.
 - e. Results of each verification must be monitored for trends that may indicate equipment drift or malfunction.
 - i. Action must be taken and recorded where required.
- (2) The service must conduct biological signal verification (i.e. biocalibrations) for polysomnography.
- a. All signals should be checked but EEG, EOG, chin EMG, leg EMG, respiration, position and sound must be checked.
 - b. The service must have a documented process in place to verify signal quality when biological signal verification cannot be performed.
- (3) The service must conduct equipment signal quality verification to ensure that all equipment used produces consistent and reliable data, and where appropriate, traceable results.
- a. EEG/EOG/EMG signals should be verified against an externally applied square wave voltage of appropriate frequency and voltage.
 - b. Quantitative signals (e.g. pulse oximetry, sound level meters, positive airway pressure, transcutaneous carbon dioxide monitors and position sensors) should be verified/adjusted against a standard.
 - c. Qualitative signals (e.g. nasal pressure sensors, oronasal thermal sensors, respiratory inductive plethysmographic sensors, microphones and video monitors) should be verified for satisfactory performance.
- (4) The service must define an equipment signal verification interval (e.g. weekly, monthly, quarterly, and annually) that takes into account:
- a. history of stability.
 - b. frequency of use.
 - c. accuracy required.
 - d. requirement for traceability of measurement.
 - e. ability of staff to perform in-house verifications.

Proficiency/competency testing

- (1) Training records must be maintained that are sufficiently detailed to demonstrate training in relevant aspects of the service. These records include:
 - a. Proof of qualifications, membership of professional societies and hours of attendance at the service.
 - b. Evidence of recognition of overseas qualifications.
- (2) Following appropriate training, the service must assess the competence of each person to perform assigned tasks according to established criteria.
- (3) Ongoing competence must be assessed periodically.
- (4) All staff who conduct analysis of clinical sleep studies must participate in a proficiency testing program(s) appropriate to the sleep studies performed. An external proficiency

test [96] is preferable; however, if not available, the service must have an alternative documented approach and provide objective evidence for determining the acceptability of study results. It is recommended that proficiency testing:

- a. Occur at least twice per year per eligible staff member as the minimum standard.
- b. The service must monitor the results of the proficiency testing program(s) and implement corrective actions when predetermined performance criteria are not fulfilled.

Validation of accuracy of equipment and software

- (1) The service must verify and document that equipment meets all necessary performance characteristics before commission (i.e. new equipment) and re-commission (i.e. repaired equipment returned to service). This includes all equipment owned by the service and any equipment provided on loan.
- (2) The service must have a documented procedure that describes how new methodologies and technologies are introduced into the service. This includes:
 - a. nonstandard methods.
 - b. Service developed or modified methods.
 - c. Methods used outside their intended scope.
 - d. Validate methods subsequently modified.
 - e. These records must include:
 - i. A description of the validation/verification studies
 - ii. The results obtained from these studies
 - iii. A summary of the suitability and limitations of the method
- (3) The service should keep a collection of polysomnograms to ensure that the introduction of new software or new software versions does not inadvertently result in calculation and report errors.

Equipment maintenance and repair

- (1) The service must have a documented program of preventive maintenance which, at a minimum, follows the manufacturer's instructions.
- (2) Equipment must be maintained in a safe working condition and in working order. This must include examination of electrical safety, emergency stop devices (where they exist) and the safe handling and disposal of chemical and biological materials by authorized persons.
- (3) Whenever equipment is found to be defective, it must be taken out of service and clearly labeled. The service must ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The service must examine the effect of any defects on previous studies and institute immediate action or corrective action.
- (4) The service must take reasonable measures to decontaminate equipment before service, repair, or decommissioning, provide suitable space for repairs, and provide appropriate personal protective equipment.
- (5) When equipment is removed from the direct control of the service, the service must ensure that its performance is verified before being returned to use.

Performance quality indicators

- (1) The service must have quality control procedures for monitoring the validity of tests and services provided.
- (2) Quality indicators must be established to monitor and evaluate performance throughout critical aspects of pre-study, study (methods), and post-study processes.
- (3) Pre-study quality indicators could include measures such as:
 - a. Waiting times for urgent studies.
 - b. Waiting times for routine diagnostic PSG and CPAP titration.
 - c. Adequacy of clinical information provided.
 - d. Appropriate pre-study identification of patients.
- (4) Study quality indicators could include parameters such as:
 - a. Time from test request to test completion.
 - b. Biological signal verification quality.
 - c. Duration of sleep study recording (in hours).
 - d. Signal quality and timeliness of interventions.
 - e. PAP Titration quality.
 - f. Time from diagnostic study to initiation of PAP treatment
 - g. Completion of urine drug test, sleep diary, and/or actigraphy with MSLT or MWT
 - h. Medication plans completed for MSLT and MWT studies.
 - i. Patient and staff satisfaction.
 - j. Clinical care quality (e.g. falls prevention, clinical hand-over, and medication safety).
- (5) Post-study quality indicators could include measures such as:
 - a. Analysis and reporting turnaround times.
 - b. Physician reporting concordance.
- (6) Therapy quality indicators could include parameters such as:
 - a. Therapy uptake (after a defined period).
 - b. Therapy adherence.
 - c. Therapy adverse events and/or side effects.
 - d. Pre-post symptom changes (e.g. ESS, FOSQ, and insomnia severity index).

Equipment

- (1) The service must have a documented procedure for the selection, purchasing and management of equipment.
- (2) The service must operate with all equipment capable of performing polysomnography consistent with established standards and relevant guidelines.
- (3) Records must be maintained (for the life of the equipment plus 7 years or other legislative requirement—whichever is longer) for each item of equipment that contributes to the performance of studies. These equipment records must include, but not be limited to, the following:
 - a. Identity of the equipment.
 - b. Manufacturer's name, model and serial number or other unique identification.
 - c. Contact information for the supplier or the manufacturer.
 - d. Date of entering into service.
 - e. Location.
 - f. Condition when received (e.g. new, used, or reconditioned).
 - g. Manufacturer's instructions.

- h. Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the service.
 - i. Maintenance carried out and the schedule for preventive maintenance.
 - j. Equipment performance records that confirm the equipment's ongoing acceptability for use.
 - k. Damage to, or malfunction, modification, or repair of the equipment.
- (4) The service should have a documented procedure for the storage and inventory management of consumables.
 - (5) Polysomnography software must allow for the recording and full disclosure of the raw signals
 - (6) In-lab audio-visual monitoring of patients (by infrared or low light video) is recommended.
 - (7) The service must replace equipment as needed to ensure the quality of procedure results.
 - (8) Each item of equipment (excluding consumables) must be uniquely labeled, marked or otherwise identified.

Data Management (Security and Confidentiality of Data)

Data management is an important concern for sleep services, particularly considering the volume and type of data collected, the increasing reliance on electronic medical records, and the rapid technological advancement in access to positive airway pressure device data.

The sleep service must establish documented processes and policies, to manage the retention, security, integrity, and confidentiality of all data relating to a patient's episode of care. This includes but is not limited to: PSG records, treatment information (including device data), records of clinical consultations, correspondence, technical information, surveys and questionnaires, and reports.

These processes/policies must encompass:

- patient identification (in-person and recorded in software or on documentation).
- data back-up and recovery.
- retention of various forms of data including scored PSG records/raw data, video (where required for diagnostic or medicolegal purposes) and reports. The data retention must be undertaken in a way that is in keeping with the relevant local institutional, state, and federal requirements.
- safeguards to prevent unauthorized access, misuse, modification, or disclosure of data, including secure access to data limited to authorized staff that have a specific need for access.
- patient access to data and records.
- report authorization, release, and amendment.

Patient privacy and confidentiality requirements may vary by jurisdiction and so sleep services are required to comply with institution policies as well as relevant state and federal legislation. There are particular considerations for device data and so for a detailed discussion the reader is directed to the ASAs position statement on CPAP data management [97].

Conclusions and Take Away Messages

This document has outlined the general description, indications, measurements, and reporting requirements for a broad range of

measurements of sleep. The measurement of sleep requires skill and precision with considerable expertise to maintain data reliability, quality, and integrity. This document has outlined the minimum standards for the performance and interpretation of sleep studies.

Crucial to the management of sleep disorders, is the skill of utilizing the correct type of sleep study in the correct clinical context. For many patients with sleep-disordered breathing, an ambulatory/unattended measurement of sleep approach has a strong evidence base. However, for those patients with complex medical comorbidities or symptoms of non-respiratory sleep disorders, an in-laboratory attended study is required to make the correct diagnosis or implement appropriate care.

As such, the measurement of sleep does not replace clinical care and clinicians practicing in this field. Specialist skills and expertise are essential to ensure that the correct clinical context, test, and treatment are joined to achieve optimal outcomes for patients with sleep disorders.

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Data availability

No new data were generated or analyzed in support of this research.

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