ERS technical standards for using type III devices (limited channel studies) in the diagnosis of sleep disordered breathing in adults and children

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Abstract

For more than three decades, type III devices have been used in the diagnosis of sleep disordered breathing in supervised as well as unsupervised settings. They have satisfactory positive and negative predictive values for detecting obstructive and central sleep apnoea in populations with moderately high pre-test probability of symptoms associated with these events. However, standardisation of commercially available type III devices has never been undertaken and the technical specifications can vary widely. None have been subjected to the same rigorous processes as most other diagnostic modalities in the medical field. Although type III devices do not include acquisition of electroencephalographic signals overnight, the minimum number of physical sensors required to allow for respiratory event scoring using standards outlined by the American Academy of Sleep Medicine remains debatable. This technical standard summarises data on type III studies published since 2007 from multiple perspectives in both adult and paediatric sleep practice. Most importantly, it aims to provide a framework for considering current type III device limitations in the diagnosis of sleep disordered breathing while raising research- and practice-related questions aimed at improving our use of these devices in the present and future.

Introduction

In adults, the obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a highly prevalent disorder, which increases the risk of hypertension and cardiovascular mortality and is associated with impaired quality of life and traffic accidents [1–8]. The optimal diagnosis of OSAHS and the determination of its severity in individual patients is currently under debate [9] and includes discussion on how best to

integrate nocturnal breathing disturbances and the degree to which they directly impact on symptoms and comorbidities [10, 11]. Nevertheless, the apnoea/hypopnoea index (AHI) remains essential to the diagnosis of individuals with OSAHS. The current classification system defines OSAHS based on an AHI $\geqslant 5$ events·h^{-1} while asleep accompanied by symptoms of excessive daytime sleepiness, or with AHI $\geqslant 15$ events·h^{-1} of sleep [12]. The AHI is calculated according to the number of apnoea and hypopnoea events per hour of sleep, with an apnoea defined as a pause in respiration $\geqslant 10$ s and a hypopnoea defined as a ventilation reduction $\geqslant 30\%$ resulting in an arterial oxygen desaturation of $\geqslant 3\%$ or 4% or an arousal [13]. OSAHS severity is classified as mild, moderate or severe according to AHI score cut-offs and can determine the type of treatment offered to the patient.

OSAHS in adults is diagnosed using either in-lab or unattended polysomnography (PSG) or increasingly frequently by using type III devices (table 1). Type III devices, also referred to as home sleep apnoea testing (HSAT) if unattended, respiratory polygraphy or limited channel studies, use between three and seven sensors/channels to acquire electrophysiological signals during the sleep period without incorporating any electroencephalographic (EEG) data [14]. Although in use for more than three decades and initially designed as screening tools for sleep disordered breathing, there has never been any attempt to standardise or set agreed technical specifications for the sensors or algorithms utilised in acquiring data nor in the nomenclature, scoring criteria or cut-off values for diagnosing different types of sleep disordered breathing [15, 16]. Type III studies are primarily used as a "cheaper" and "more convenient" alternative to PSG in countless sleep centres worldwide, again based on limited evidence.

OSAHS is also common in children, particularly during early childhood in association with lymphoid tissue overgrowth and increasingly in the context of obesity [1]. Scoring criteria differ to those for adults, but the principles of investigation remain the same with type III studies increasingly used in the diagnosis of sleep disordered breathing in children, both in-hospital and at home. Apart from a document defining standards on using PSG and other devices for use in France [17], and the American Academy of Sleep Medicine (AASM) guidelines on scoring paediatric sleep, no attempts have been made to standardise type III device use in this group. The adolescent group is subject to most variation in assessment and no separate standards exist that are applied consistently. An AASM position paper [18] published in 2017 did not support the use of home sleep studies for the diagnosis of OSAHS in children due to insufficient validation and monitoring available for most devices (i.e. absence of carbon dioxide partial pressure, arousal monitoring and calculation of total sleep time). Since the publication of this position paper, a number of studies comparing type III devices to in-laboratory PSG in children have become available, making this evaluation necessary [18].

The aims of this task force were to examine and establish standards and specifications in the acquisition and scoring of respiratory events using limited studies in both adults and children and to call to attention the fact that very few technical standards exist at all with respect to terminology, quality and technical specifications of equipment used for acquiring the physiological signals, respiratory event scoring criteria and patient information provided.

Methods

The task force was comprised of experts in managing and scoring adult and paediatric PSG and respiratory polygraphy (table 1). In addition, two patient representatives were included. Members were assigned to working groups within the task force. The following areas were covered: technical specifications of type III devices, utility of type III devices in comparison to PSG for investigating sleep disordered breathing, scoring criteria for sleep-related breathing disturbances using type III devices in adults and scoring criteria for sleep-related breathing disturbances using type III devices in children.

The work was coordinated by email and through teleconference interactions, and no physical meetings of the full task force were held on account of the coronavirus disease 2019 (COVID-19) pandemic. Each

TABLE 1 The American Academy of Sleep Medicine, American College of Chest Physicians and the American Thoracic Society have divided portable monitoring into four types	
Type I	Full attended polysomnography (seven or more channels) in a laboratory setting
Type II	Full unattended polysomnography (seven or more channels)
Type III	Limited channel devices (four to seven channels)
Type IV	One or two channels, usually using oximetry as one of the parameters

working group completed the relevant section, which was integrated into a final report by the task force chairs (R.L. Riha, W. Randerath).

A systematic literature search (PubMed) from January 2007 to November 2021 was performed by a research assistant (Kelsea Stewart, University of Edinburgh, Edinburgh, UK) together with the members of each working group, and the respective publications were retrieved. Reference lists were systematically examined for relevant articles and included. Keywords were selected that were appropriate to the relevant working group, then, appropriate search words were added. Details of search criteria, keywords and comparisons can be found in the supplementary material. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowcharts were used to document the search results [19].

The year 2007 was used as the initial year for searches on account of the publication of the AASM's new technical specifications, rules and terminology for polysomnography testing and scoring [20], subsequently adopted internationally. For the technical specifications, the year 2011 was used on account of the publication of the Sleep, Cardiovascular, Oximetry, Position, Effort and Respiratory (SCOPER) paper, which discussed signal derivation from type III studies [21]. The criteria and flow charts for the literature searches for each working group are provided in the supplementary material. Inclusion criteria were articles in any language and data on human subjects; exclusion criteria were reviews, guidelines or case reports. Each working group extracted and analysed data as considered relevant to the technical standard.

The creation of this technical standard combined an evidence-based approach as far as was feasible with the expertise of the task force members. Discussion was undertaken within each working group initially, followed by review of the entire technical standard by the whole group. All members of the task force approved this document and reached consensus on the technical standards. Accordingly, this technical standard provides an overview of current knowledge and practice in the area in addition to clarifying limitations that require further attention and research to allow for future recommendations.

Results

Technical specifications for type III devices

The literature search retrieved 250 references (supplementary figure E1). After abstract and text screening, 82 references remained. Based on further evaluation of the reference lists of these 82 references, 61 references were finally included.

Evidence overview of sensors used to acquire physiological signals during sleep

The various sensors used to analyse breathing disorders during sleep have been reviewed and are summarised in supplementary tables E3–E23. Studies published since the SCOPER paper were included [21].

Measurement of respiratory flow signals

The pneumotachograph is the gold standard for accurate assessment of breathing flow [22–24]. Nasal cannulas are excellent surrogates, are used most frequently and have been validated extensively; all have their limitations (supplementary table E4). Thermistors are less sensitive in detecting hypopnoeas, but perform well in obligate mouth breathers and when there is reduced nasal patency. A new thermal-based sensor system has been developed for low airflow detection, with low-power dissipation, high linearity and of small dimensions [25]. Innovative sensors such as polyvinylidene fluoride film (PVDF) nasal flow sensors have been introduced, which are much more sensitive than thermistors while encompassing their advantages [26]. The tracheal sound sensor (PneaVoX) is a three-fold sensor and holds promise in optimising assessment while decreasing the number of sensors applied to the body; it allows for wireless recording, with response characteristics that are linear over a wide range of frequencies [27–30].

Characterisation of breathing during sleep

Full PSG with oesophageal pressure measurement is considered the gold standard for characterising sleep breathing events. In respiratory polygraphy, different surrogates are used, including thoraco-abdominal movements, pulse transit time, peripheral arterial tonometry (PAT)/photoplethysmography (PPG), jaw movement and suprasternal pressure. The most common surrogates used are the thoraco-abdominal bands, especially respiratory inductance plethysmography (RIP), while effort belts with PVDF may be used, just as RIP often is, as a "back-up" signal for detecting respiratory events when nasal pressure signals become artefactual or are lost [31]. RIP belts have replaced piezoelectric belts in more recent studies and can be used in a calibrated or uncalibrated manner. Algorithmic approaches can enhance the performance of piezoelectric belts [32]. PPG has been used extensively in recent years and can extract features from different frequencies of the RR interval signals to detect OSA as well as sleep stages [33–48]. Pulse transition time, which reflects changes in pleural pressure and detects autonomic arousals, is a useful tool

for distinguishing central from obstructive events. Different parameters and machine learning algorithms can improve its systemic accuracy [49]. Chest-worn accelerometry can be a robust and accurate method for the measurement of respiratory features, based on a single point of mechanical contact with the chest. Wrist-worn accelerometry can provide a degree of surrogate measurement of respiratory movement as well.

Quantification and measurement of snoring

The nasal cannula shows poor reliability and accuracy for measuring snoring, since it only detects frequencies up to 100 Hz, compared to the 4 kHz that a microphone can capture [50]. Microphone-based technologies can be optimised to perform automatic analysis of snoring, including determination of synchronisation with inspiration below a maximal frequency level (500 Hz) and exclusion of any noise resulting from movement [51]. Piezoelectric vibration sensors can provide data on snoring, as well as movement and heartbeat during sleep, profiting from new algorithms for automatic snoring detection [52].

Position sensing during sleep

Accelerometers make use of three-dimensional signals and identify the orientation of the device relative to the line of gravity, thus quantifying position shift [53–60] and indicating arousals.

Pulse oximetry

Pulse oximeters make use of photoplethysmography; they behave differently, depending on the sampling rate, the technology utilised as well as the measurement site (*e.g.* finger *versus* ear lobe).

A detailed overview of measurement techniques, their advantages and disadvantages is given in supplementary tables E3–E23.

Limitations and remarks regarding sensors used to record physiological signals during sleep

There have been considerable advances since 2011 in the development and refinement of noninvasive sensors and techniques for measuring respiratory and sleep variables. However, few have been standardised against each other or against an "ideal" acquisition signal. Variations in acquisition, sampling rates and sensitivity can affect signal quality and integrity, hence scoring and diagnostic outcomes.

Technical standards: type III device specifications

The nasal cannula is the best-validated surrogate for hypopnoea detection owing to its good frequency response, while the thermistor is the recommended sensor for apnoea detection. PVDF sensors and tracheal sound sensors deserve a more prominent role, given their high sensitivity.

RIP bands should be the standard technique used to discriminate between the types of respiratory events in a routine setting. Jaw movement, suprasternal pressure, accelerometers and use of indirect signals like peripheral arterial tonometry/photoplethysmography are alternatives that are less obtrusive, but require further validation.

The lack of consistency between snoring sensors affects future research on the clinical significance of snoring. Standardisation of objective snore measurements is necessary.

The acquisition parameters of pulse oximeters should be disclosed whenever oximetric data are reported, and efforts should be made to standardise them.

Scoring criteria for sleep-related breathing disturbances when using type III devices in adults

The literature search retrieved 991 references. After abstract and text screening, 286 references remained. Further evaluation of the references resulted in 48 references being included (supplementary figure E2).

Methods for estimating total sleep time
Evidence overview

Since type III studies do not include EEG measurement, the number of apnoeas and hypopnoeas cannot be expressed as being "per hour of sleep". Thus, total recording time is often used as the denominator to calculate respiratory event frequency or the oxygen desaturation index (ODI) [61–79]. The difference between the mean total recording time and mean total sleep time ranges between 1 h and 3 h based on the literature. Different techniques have been used to optimise total sleep time, by increasing the accuracy of start and stop times and/or by removing estimated wake periods. These include event markers [80–82], actigraphy or position sensors [63, 65, 83–87], sleep diaries [63] or combined use of actigraphy, position and questionnaires [88–91]. Total sleep time has also been obtained by eliminating episodes with poor signal quality [69, 83, 87, 90, 92–94]. Studies assessing the diagnostic accuracy of sleep time estimation

have shown improved agreement by removing periods of probable wakefulness based on heart rate, breathing pattern, movement, oximetry and activity [72], or by using an algorithm to identify sleep and wake periods based on single-lead EEG, airflow, actimetry, snoring, suprasternal pressure and thoracoabdominal belts [73] and a combination of movement and respiratory signals [95].

PAT devices have an algorithm that uses movements (actigraphy) for sleep/wake detection [34, 96–103]. Moderate agreement for sleep/wake classification has been shown [34, 36]. Manual editing can improve estimation of rapid eye movement (REM) sleep duration [104].

A detailed overview on methods used to estimate sleep time is given supplementary table E24.

Limitations and remarks on estimating total sleep time

There is no standardised definition to evaluate total sleep time. Total recording time, and thereby total sleep time, may vary as the device can be manually turned on and off when getting into bed or automatically at pre-specified times. The AASM recommends using the term "monitoring time", defined as total recording time minus artefact periods and awake time determined by actigraphy, body position, respiratory pattern or patient diary, as the denominator to calculate respiratory indices [13]. There is little evidence to advocate one method over another. These methods will have the highest impact in cases of low sleep efficiency, in the presence of artefacts or short sleep time and should be validated in different patient populations.

Technical standards for estimating total sleep time

Evidence suggests that monitoring time, incorporating removal of artefact and estimated wake periods from total recording time, is appropriate for use as the denominator to calculate event indices using type III devices. Methods used for estimating sleep time will vary by device and thus it is important to clearly state these methods in clinical reports and research studies and to highlight that the reported total sleep time is estimated (events per hour of monitoring time or events per hour of estimated total sleep time).

Scoring criteria for respiratory events

Apnoea: evidence overview

Most authors have used a 90% reduction in flow using nasal pressure [64, 70, 71, 74–77, 88–90, 95] or thermistor [84, 86, 87] for ⩾10 s. Cessation of airflow, for ⩾10 s [82, 105, 106] or without time specification [65, 68, 78, 81, 83, 85, 94], was also used for obstructive apnoea; 80% reduction has been used for automatic scoring [71].

Hypopnoea: evidence overview

Hypopnoea scoring criteria have varied over time for PSG and type III studies (supplementary table E2a and b). The major limitation in type III studies is the inability to undertake arousal scoring.

VAT et al. [62] evaluated four different type III hypopnoea criteria (3% or 4% desaturation with or without pulse-wave amplitude (PWA) drops as a surrogate arousal). The best diagnostic accuracy for mild and moderate OSA was shown using the hypopnoea criterion requiring ⩾3% desaturation without PWA drops. Incorporation of PWA drops only added accuracy in detecting severe OSA. The lack of diagnostic accuracy improvement for mild-to-moderate OSA was attributed to the poor correlation between PWA drops and EEG arousals. XU et al. [88] compared two different type III hypopnoea criteria (3% or 4% desaturation) to two different PSG hypopnoea criteria (3% desaturation + arousal or 4% desaturation + arousal). The mean difference in AHI between the type III and the PSG equivalent was -1.2 and -1.4 events·h^{-1} respectively, with narrow limits of agreement. At higher values, the type III scoring resulted in larger underestimates of PSG AHI. AYAPPA et al. [83] explored two different hypopnoea scoring techniques: 50% flow reduction + 4% desaturation and 50% flow reduction + 1% desaturation + surrogate arousal and reported good correlation with equivalent PSG indices.

Respiratory event type: evidence overview

A limited number of studies [76, 81, 85, 86, 88, 91, 105, 107] showed separate results for scoring central, obstructive and/or mixed apnoeas. Standard criteria were used to score these different apnoea types: presence of respiratory effort for obstructive apnoeas; absence of respiratory effort for central apnoeas; and absence of respiratory effort at the beginning and appearance of effort during the latter part of the respiratory events for mixed apnoeas. Most of these studies showed similar or good agreement for the scoring of central and/or mixed apnoeas compared to obstructive apnoeas. One study calculated an "obstructive ratio", defined as the obstructive apnoea index per apnoea index, also reporting good correlation with the ratio from PSG [107]. An even lower number of studies reported a distinction between

obstructive and central hypopnoeas [85, 88]. Criteria used for the scoring of central hypopnoeas were absence of snoring, flow limitation and paradoxical movement of the chest and abdomen. Nagubadi et al. [85] reported better accuracy of the type III device in hospitalised patients who did not have significant CSA.

Other respiratory events: evidence overview

PAT studies do not include any apnoea or hypopnoea scoring criteria [34, 36, 96–99, 101–104]. Respiratory events are derived from attenuation of the PAT signal, accompanied by heart rate increase and oxygen desaturation at the end of a "respiratory event" [34, 103, 104].

A detailed overview on scoring criteria for respiratory events is given in supplementary table E24.

Limitations and remarks on scoring respiratory events using type III devices

For scoring an apnoea, the majority of studies required ⩾90% reduction in airflow in line with the current AASM standard [41]. Of note, most studies used nasal pressure to detect apnoea, not a thermistor, which may result in event misclassification [108].

Although hypopnoea rules are variable, the majority of studies used the current AASM recommended hypopnoea definition for HSAT [13], where hypopnoeas require ⩾30% airflow reduction and ⩾3% desaturation. The AASM recommended hypopnoea rule for PSG requires ⩾3% desaturation or EEG-based arousal. Since EEG-based arousal cannot be scored using type III devices, there is likely to be a reduction in the number of events per hour of monitoring time or estimated total sleep time *versus* PSG AHI.

Comparison studies against PSG suggest the inclusion of a surrogate arousal measure does not substantially improve agreement and diagnostic accuracy beyond that obtained using current AASM recommendations [62, 92].

Technical standards for scoring respiratory events using type III devices

At present, the recommended AASM scoring rules for apnoeas and hypopnoeas are appropriate. Although hypopnoeas defined using an arousal during PSG will not be scored during type III recordings, there is no compelling evidence to use surrogate arousal measures.

Methods used for arousal scoring

Evidence overview

Since type III devices do not record EEG, it is not possible to score respiratory events based on the presence of EEG-based arousal. Studies comparing type III devices to PSG have used alternative methods to detect the presence of arousals [62, 66, 83, 92, 95, 106]. Methods include a combination of changes in head position, pulse rate and snoring sounds [83, 106]; pulse oximetry derived heart rate increase [66]; sudden increase in amplitude or frequency of airflow or respiratory bands [92]; pulse wave amplitude drops [62]; and body movement indicated by an abrupt change in thoracoabdominal signals [95].

Conclusions based on comparison to PSG are limited, in that studies have compared type III scoring to outdated or custom scoring criteria [66, 83, 106] have used atypical OSA or population-based subject groups [62, 66], or have compared type III studies to PSG on a separate night [66]. Furthermore, comparisons with automatic algorithms [83, 106] are problematic, as algorithms may be updated without notification. The studies of Masa et al. [92] and Vat et al. [62] utilised respiratory event scoring criteria equivalent to current AASM recommended standards [13] with manual scoring of simultaneous type III and PSG recordings. Both studies reported minimal benefit in incorporating surrogate arousals into event scoring definitions.

A detailed overview on methods used for arousal scoring is given in supplementary table E24.

Limitations and remarks on scoring arousals using type III studies

Limitations noted for surrogate arousal methods include that movement-based methods may miss brief arousals without movement [95, 106] and heart rate methods may be affected in patients with heart disease, autonomic neuropathy or on a β-blocker [106]. Kinoshita et al. [97] reported that arterial stiffness due to ageing may attenuate the accuracy of PAT measurements.

It is difficult to draw conclusions about the superiority of one method over another, as there are no direct comparisons of methods in a single study; limited direct comparisons between surrogate and PSG scored arousals; and no studies assessing scorer reliability.

Technical standards for scoring arousals using type III devices

Inability to score EEG-based arousals is considered a limitation of type III devices, resulting in inability to score events that result in sleep disturbance without, or with minimal oxygen desaturation. Although several different surrogate arousal detection methods have been described for type III devices, there is no evidence to determine the superiority of one method over another, and very limited evidence to support general use.

Scoring of oximetry
Evidence overview

The presence of $\geqslant 3\%$ or $\geqslant 4\%$ desaturations has typically been used to score hypopnoeas, according to the different hypopnea scoring rules [62–79, 81–83, 85–95, 105, 107]. To *et al.* [106] also included 1% desaturation if the event was accompanied by changes in pulse rate, head position or snoring sounds, which implied arousals. The PAT devices use an incorporated algorithm to score respiratory events using 3% and 4% desaturations [34, 36, 84, 96–104].

CHANG *et al.* [89] found lower oxygen saturation values in type III recordings compared to simultaneous PSG in COPD patients, emphasising that different pulse oximeters could influence oxygen saturation findings and clinical decision-making. ODI was not significantly different from PSG, despite a denominator difference in total sleep time in the order of 90 min. POLESE *et al.* [81] showed no difference in oxygen saturation measures in elderly patients between PSG and simultaneous portable monitoring. For both studies, peripheral oxygen saturation (S_{pO_2}) differences between home portable monitoring and PSG were explained by different oximeter technology, but also by possible artefacts impacting home oxygen saturation values [81, 89]. AURORA *et al.* [76] showed a high correlation between automated and manually scored ODI values for two devices. BRIDEVAUX *et al.* [78] showed almost perfect agreements between ODI scores of different observers and automated scores.

A detailed overview on scoring of oximetry is given in supplementary table E24.

Limitations and remarks on scoring oximetry using type III devices

Due to relative measurement simplicity, it is likely that there is better agreement for oxygen saturation measures compared to the respiratory event index between PSG and type III recordings. However, different oximeter technology and artefact can lead to significant differences in oxygen saturation findings, particularly in patients with comorbidities. Additionally, the same issues impacting the respiratory event index regarding the denominator will also influence ODI. For ODI, although the AASM oxygen desaturation definition is not well defined, the AASM recommend using the term "monitoring time" as the denominator [13], and the term "per hour of estimated total sleep time" could also be used.

Technical standards for scoring oximetry

The use of "monitoring time in hours" or "estimated total sleep time in hours" is appropriate for use as the denominator to calculate ODI, as well as mean values and percentages of time with oxygen saturations less than a particular threshold, using type III devices. Be aware of differences across devices.

Utility of type III devices in comparison to PSG for diagnosing sleep disordered breathing in adults

The literature search retrieved 914 references. After abstract and text screening, 184 references remained. Based on further evaluation of the reference lists of these 184 references, 35 references were included (supplementary figure E3).

Diagnostic accuracy of type III devices in sleep disordered breathing
Evidence overview

Supplementary table E25 summarises the key results from prospective, single-blind studies published from January 2007 to November 2021 comparing commercially available type III devices with PSG in both attended (simultaneous with PSG) and unattended settings [71, 74–76, 80–84, 88, 89, 97, 98, 100–103, 105, 106, 109–122]. Sensitivity of in-lab PSG studies to detect apnoeas and hypopnoeas at various cut-offs compared to simultaneous attended studies using type III devices ranged from 80% to 100%, and specificity from 0% to 100%. When comparing type I and type II studies (PSG) to home/unattended type III studies, the diagnostic sensitivity ranged from 74% to 96% and specificity from 25% to 88% (dependent on AHI cut-off value). Comparing the number of respiratory events sored using the same rules in studies with type III devices *versus* in-lab PSG demonstrated both under- and over-reporting of severity of sleep disordered breathing. Type III device to manually scored PSG respiratory event indices also varied according to population examined, type of device, whether autoscoring was used and whether the studies were conducted simultaneously or separately in time.

A detailed overview of the diagnostic accuracy of type III devices in sleep disordered breathing, is given in supplementary table E24.

Limitations and remarks regarding the diagnostic accuracy of type III devices

There were significant differences across commercial devices in terms of number of sensors utilised as well as the AASM scoring rules over time. Airflow, heart rate, oximetry and respiratory effort were considered integral to acquiring and scoring sleep disordered breathing events. Although classified as a type III device, the PAT device lacks measurement of airflow and one study in >500 patients suggested that inbuilt autoscoring systems alone would result in 30–50% misclassification of OSA [118]. Since 2007, there have been no published data on severity classification of sleep disordered breathing using type III devices. Previous studies using older equipment and devices (again, not standardised) have suggested that apnoeas + hypopnoeas per estimated hours asleep (or hours in bed) of >15 was consistent with a diagnosis of moderate to severe sleep disordered breathing [123]. However, type III devices showed reasonable diagnostic sensitivity and specificity for adults with a high pre-test probability of OSA in attended settings even in the presence of comorbidities (table 1). Manual scoring was recommended by authors who compared manual to automatic scoring [71, 88, 118]. Algorithms for automated scoring were not disclosed. In all cases, type III device data led to either over- or underestimation of the total number of breathing disturbances, but this was not always significant. Unattended/home type III studies resulted in significantly lower sensitivity and specificity for detecting sleep disordered breathing and higher technical failure rates (data loss ranging from 3.5% to 61%).

Technical standards for optimising the diagnostic accuracy of type III devices

The recommended minimum number of signals to score respiratory events accurately using current AASM criteria include heart rate, oximetry, nasal airflow signals and respiratory effort bands [14]. A position sensor should be used to differentiate supine from non-supine respiratory event severity. Peripheral arterial tonometry does not measure airflow and may lead to misclassification of OSA at higher and lower rates of sleep disordered breathing. Its utility is probably greatest in a younger population with high pre-test probability of OSA and no significant comorbidities as a screening tool. Diagnostic accuracy of OSA severity is significantly lower when using type III devices in an unattended setting and failure rates can be high. Keeping a record of study failures, reasons for failure and information on study quality is recommended. Manual scoring is recommended, and manual editing of automated scoring programmes should be possible. Most studies suggest that the sensitivity and specificity for diagnosing OSA in an attended setting is sufficiently high with an AHI >10 events·h^{-1} irrespective of scoring criteria utilised. The task force agrees that an in-lab PSG/attended polygraphy is required to ensure diagnostic accuracy (determination of sleep efficiency) in patients with no or mild OSA on a home-based type III study, but high clinical probability of OSAHS.

The term AHI should not, by virtue of the absence of the EEG, be used to describe the summary of breathing events acquired using type III devices. More suitable terms include one of the following: apnoeas + hypopnoeas per estimated hours asleep [124], respiratory events index (per estimated hours asleep) [13] or apnoeas + hypopnoeas per estimated hours of monitoring time.

Patient and healthcare professional experience of using and scoring type III devices

Patient perspective: evidence overview

Most studies reviewed were undertaken in patient populations presenting at a sleep centre with a raised pre-test probability of OSAHS, predominantly male, predominantly middle-aged (30–60 years) and with an average body mass index of 30 kg·m^{-2}. No studies were naturalistic; all were part of a trial with inherent selection bias. Three studies were done in a group of patients with COPD [80, 89, 120]. Three studies included patients with heart failure [76, 110, 124]. One study examined people with neuromuscular disorders [109] and one study was undertaken in pregnant women [102]. Most of the studies undertaking home type III studies provided information to patients on how to wear the type III devices in an unattended setting/home. Six studies requested patient feedback on the experience [80, 89, 109, 114, 116, 121].

Scoring type III studies: evidence overview

Level of qualification of the scoring staff ranged from experienced technician to a formal North American qualification of registered polysomnographic technician [74, 75, 103, 112, 114, 117, 119, 120, 124]. No studies commented specifically on whether the type III software was user-friendly. Only two studies undertook intra- and inter-scoring concordance [74, 112]. There was no mention in any study on how equipment was cleaned and re-used, and the specific infection control procedures required by type of device used. Manual scoring or manual editing of automated scoring improved diagnostic accuracy compared with automated scoring alone. Ideally, type III devices should be capable of displaying the raw

data for review by the scorer, in order to allow assessment of the quality of the data. Data from the entire duration of the study should be available to review, rather than just an automated summary of the data.

Economic aspects of using type III studies: evidence overview

Masa et al. [93] documented costs and found that it was ⩾40% more expensive to do PSG than unattended type III studies for equal efficacy; patient costs were higher for unattended type III studies compared to PSG. No other studies examined cost to the sleep service overall, impact of technical failure on diagnostic pathway, time taken to hand out/mail out a type III device, give patient-specific instructions and support patients undertaking home studies or the time taken to score or repeat a study in either an attended or unattended setting. Formal assessment of the economic impact of using type III devices using appropriate tools (e.g. EQ-5D, calculation of quality-adjusted life-years) was not undertaken in any study and has not been reported on since 2007.

Limitations and remarks concerning population applicability and practical aspects of performing type III studies

Published information on the acceptability, sensitivity and specificity of type III studies in populations other than obese, middle-aged men with symptoms consistent with OSA is limited. The economic aspects of high failure rates in unattended type III studies have not been explored in any depth. Information on user-friendliness and scoring ease was not cited in the published literature, but should be a criterion for choosing a type III device for clinical use.

Technical standards on applicability and practical deployment of type III devices in a clinical setting

When incorporating type III devices in the diagnostic pathway of a sleep centre, all aspects of using the device including quality of the sensors and scoring software, disposable and non-disposable consumables, cleaning protocols, patient acceptability and device reliability must be considered. Patients should be asked to document their experience with the device, the quality of their sleep and any disruptions or difficulties with using the device on the night of their study. Patients should be advised of the risk of having to repeat the study or undertake PSG to make an accurate diagnosis particularly if the study is unattended. All type III studies undertaken in subjects outwith a published demographic must be assessed strictly in the clinical context in which the study is being undertaken. Competence in scoring type III studies should be standardised at least nationally through specific accredited sleep training pathways.

Manual scoring or manual editing of automated scoring of limited studies is recommended in order to improve diagnostic accuracy. Finally, the application, interpretation, and follow-up of type III studies are best handled by experienced sleep healthcare providers.

Type III devices for diagnosing sleep disordered breathing in children

The literature search retrieved 981 references. After abstract and text screening, 45 references remained. No articles were excluded after further evaluation of the references (supplementary figure E4).

Differences across currently available type III devices and technology utilised; specifications required to acquire signals in a regulated fashion
Evidence overview

Technical differences across currently available type III devices that have been utilised in children are summarised in supplementary table E26. Type III devices are usually set up in the child's home by trained staff or by the parents. Repositioning of sensors is not possible during the night if the corresponding signals are lost or they are inadequate for analysis.

A few type III devices have been compared to full PSG in paediatric patients (supplementary table E27) [125–131]. Other reports have included results of respiratory polygraphy with type III devices in paediatric patients without comparison to PSG (supplementary table E28) [132–167]. Full PSG equipment is used in many paediatric sleep centres across the world for performance of respiratory polygraphy by omitting placement of the EEG, electro-oculography (EOG) and electromyography (EMG) channels [131, 138, 141, 145, 161, 162]. Devices with only two channels, i.e. airflow via nasal pressure transducer and pulse oximetry, have also been used in paediatric populations [127, 152, 155].

Michelet et al. [133] demonstrated that >80% of polygraphs performed either in the hospital or at home are interpretable and the main reasons of noninterpretability were poor S_{pO_2} signal (80%), poor nasal cannula signal (41%), poor abdominal belt signal (29%) and poor thoracic belt signal (18%). Scalzitti et al. [130] showed that in-lab portable monitor set-ups were technically acceptable (term not defined by the authors) in 93.9% of patients and 75% had interpretable data on three channels for ⩾360 min. For

polygraphs completed at home, 88.9% were technically acceptable and 67% had interpretable recordings. In a retrospective investigation by GUDNADOTTIR et al. [168], the requirement of 3 h of valid data for an acceptable study was not fulfilled for nasal airflow in 40% and for S_{pO_2} in 19% of cases, while in 11% of patients both parameters were missing. Moreover, in 5% of polygraphs other problems were noted, such as the caregiver misunderstanding the instructions, or the equipment batteries malfunctioning [168].

SCALZITTI et al. [130] studied 33 children with simultaneous laboratory PSG and polygraphs (portable monitor). 20 patients also underwent home studies, with 16 having two nights of monitoring. AHI by polygraphy performed in the sleep laboratory or at home was significantly different from that obtained by PSG. The sensitivity of the portable monitor for diagnosing OSAHS was best for in-lab use.

LESSER et al. [128] used a portable device to screen for OSAHS in obese adolescents in the sleep laboratory. The device had a high negative predictive value for ruling out OSAHS while automatic scoring using the device software was found to be as accurate as manual scoring in this age group.

A detailed overview on differences across currently available type III devices and technology utilised is given in supplementary tables E26–E29.

Limitations and remarks on the heterogeneity of type III devices using in paediatric sleep medicine

Approximately 70% of polygraphs performed at home are interpretable, and this frequency is higher when the study is performed in the sleep laboratory. Most common technical problems are poor S_{pO_2} or nasal airflow tracings.

Technical standards on the use of type III devices in the diagnosis of sleep disordered breathing in children

Type III devices can be used at home for the diagnosis of sleep disordered breathing in children, with a high rate of success in obtaining adequate signals. Type III devices and PSG systems without EEG can be used, when more advanced equipment is not available or in an attempt to reduce the time required for setting up and interpreting the sleep study, respectively.

Type III devices should incorporate RIP technology for detecting thoracic and abdominal wall movements. This approach has the added benefit of RIP flow tracing as loss of airflow signal is the most frequently encountered problem in children while performing polygraphy at home. The addition of actigraphy to the polygraph channels might increase the reliability of the obtained tracings and facilitate recognition of wakefulness.

Scoring criteria for sleep related breathing disturbances using type III devices in children
Evidence overview

Various rules have been used for automatic or manual scoring of obstructive, central and mixed apnoeas and hypopnoeas in type III devices, but in most cases the 2012 or 2007 AASM scoring rules have been applied (supplementary tables E26 and E27) [125–128, 131, 133–136, 140, 143, 145–149, 156, 158, 159, 169–172]. Automated scoring of polygraphy in children was reliable only for central apnoeas in a study by BLANC et al. [135]. In another study by ØRNTOFT et al. [166], AHI was consistently overestimated by automatic analysis. In contrast, MASOUD et al. [129] demonstrated that automatic analysis after exclusion of poor tracings had a very good sensitivity with low specificity for OSAHS defined as an AHI $\geqslant$1.5 events·h^{-1} (95.5% and 66.7%, respectively). LESSER et al. [128] also demonstrated that automatic scoring and manual analysis of polygraphy provided similar results.

GUDNADOTTIR et al. [168] evaluated the inter-rater reliability of polygraph scoring. They also explored whether the calibrated RIP flow signal could be used for the scoring of respiratory events when the airflow tracing is unreliable. They reported moderate agreement between the scorers when nasal airflow was present while the scoring of respiratory events alone based on the RIP flow signal was scorer-dependent.

Since total sleep time can only be estimated with respiratory polygraphy, total recording time is usually used in the denominator for calculating the frequency of respiratory events [126]. Total sleep time can be approximated when respiratory polygraphy is completed in the hospital with PSG equipment by using the sleep technologist's notes and the video recording of the sleeping child [141, 173].

A detailed overview on scoring criteria for obstructive, central and mixed apnoeas and hypopnoeas and terminology with type III devices in children is given in supplementary tables E26–E29.

Limitations and remarks on scoring sleep related breathing disturbances using type III devices in children

When polygraphy is performed, it is unknown whether the child has had adequate sleep time, and in particular, REM sleep during which most obstructive events may occur, because sleep scoring is not possible. The inability to score arousals may lead to underestimation of the number of hypopnoeas and central apnoeas associated with arousals from sleep (without accompanying hypoxaemia). Moreover, the lack of arousal scoring results in inability to evaluate the degree of sleep fragmentation. Use of total recording or calculated sleep time instead of the actual total sleep time leads to underestimation of the various respiratory event indices, because time is included in the denominator.

Technical standards: sleep related breathing disturbances using type III devices in children

Very limited evidence indicates satisfactory correlation between the AHI obtained from automatic analysis and AHI calculated by manual scoring of the tracing obtained using a type III device. The task force agrees on manual scoring, based on the current AASM scoring rules in order to limit over- or underestimation of the respiratory polygraphy parameters.

Cut-off values for the frequency of apnoeas and hypopnoeas scored using a type III device along with sensitivity and specificity for diagnosing sleep disordered breathing in children

Description of the frequency of obstructive and mixed apnoeas and hypopnoeas using a type III device

The frequency of obstructive and mixed apnoeas and hypopnoeas is calculated by dividing the total number of scored obstructive and mixed apnoeas and hypopnoeas by the total recording time or total calculated sleep time [141]. It should be noted that the OSAHS severity category (mild, moderate or severe) cannot be defined using the traditional AHI 5 events·h^{-1}, 15 events·h^{-1} and 30 events·h^{-1} cut-off values applied in adults. In the European Respiratory Society statement on the diagnosis and management of obstructive sleep-disordered breathing in 2–18-year-old children, the AHI cut-off values 1 event·h^{-1} and 5 events·h^{-1} have been proposed for defining mild and moderate-to-severe OSAHS, respectively [174].

Evidence overview

A small number of studies have compared various type III devices used at home or in the sleep laboratory against fully attended PSG (supplementary table E27) [125–131]. In a study by ALONSO-ÁLVAREZ et al. [126], scoring of recordings obtained from a type III device systematically overestimated the actual AHI. In two other paediatric studies, overestimation of the AHI was attributed to 1) events scored during wakefulness and 2) pseudo-events related to either reduced amplitude of the nasal airflow channel resulting from mouth breathing and/or artefactually reduced flow post-arousal [125, 127]. ALONSO-ÁLVAREZ et al. [126] used the eXim Apnea Polygraph in combination with the 2007 AASM scoring rules to evaluate otherwise healthy children with OSAHS symptoms. The investigators showed that an obstructive AHI ⩾3 events·h^{-1} using in-home polygraph had a sensitivity of 72.5% and specificity of 90% for detecting obstructive AHI ⩾1 events·h^{-1} in PSG. In addition, an obstructive AHI ⩾6.7 events·h^{-1} using polygraphy detects obstructive AHI ⩾5 events·h^{-1} in PSG with sensitivity 81.8% and specificity 92.9%.

In a study by IKIZOGLU et al. [125] utilising PSG as the gold standard, the NoxT3 portable monitor used at home had a high sensitivity (100%) for detecting an AHI ⩾1 events·h^{-1} in children with Down syndrome, but very low specificity, positive and negative predictive values (<40%). The monitor also overestimated the true AHI in this patient group; an AHI ⩾3 events·h^{-1} in polygraphy was predictive of an AHI ⩾1 events·h^{-1} on PSG with a sensitivity 100% and specificity 85%. MASOUD et al. [129] reported strong agreement between AHI obtained from PSG and the respective index calculated from polygraphy.

TAN et al. [131] compared attended PSG in the sleep laboratory without EEG channels (respiratory polygraphy) to fully attended PSG. They found that the AHI is underestimated mostly due to underscoring of hypopnoeas which are accompanied by arousals without desaturations [131].

Various cut-off values for defining OSAHS have been adopted in studies of type III devices without comparison to PSG (supplementary table E29). BROCKMANN et al. [170] obtained polygraph recordings in 37 healthy full-term infants at the ages of 1 month and 3 months that were analysed using the 2012 AASM scoring rules. The 95th percentile for the frequency of obstructive and mixed apnoeas and hypopnoeas per hour of estimated sleep time was 5.8 events·h^{-1} at 1 month and 3.4 events·h^{-1} at 3 months of age. The respective values for the oxyhaemoglobin desaturation (⩾3%) index were 24.9 events·h^{-1} and 24 events·h^{-1}. In a Canadian cohort including healthy infants who underwent polygraphy at the age of 1 year, the 90th percentile was 0.5 events·h^{-1} for the obstructive apnoea index, 7.1 events·h^{-1} for the central

apnoea index, 15.8 events·h^{-1} for the AHI (obstructive, central and mixed apnoeas and hypopnoeas per hour of estimated sleep time) and 10.7 events·h^{-1} for the ODI ($\geqslant$3%) [134].

A detailed overview on cut-off values for the frequency of apnoeas and hypopnoeas scored using a type III study along with sensitivity and specificity for diagnosing sleep disordered breathing in children is given in supplementary tables E26–E29).

Limitations and remarks regarding cut-off values for diagnosing severity of sleep disordered breathing scored using a type III study in children

The appropriate cut-off value of the frequency of apnoeas and hypopneas for diagnosing OSAHS with a type III device is affected by its technical specifications and the setting in which the study is performed (attended in-laboratory *versus* unattended at home). Thus, the measured AHI may overestimate or underestimate the real AHI. As a result, the AHI cut-off value to define OSAS in studies involving type III devices varied from 1 events·h^{-1} to 5 events·h^{-1} (supplementary table E29).

Technical standards for diagnosing severity of sleep disordered breathing scored using a type III study in children

The term AHI should not, by virtue of the absence of the EEG, be used to describe the summary of breathing events acquired using type III devices. More suitable terms include one of the following: apnoeas + hypopnoeas per estimated hours asleep [124]; respiratory events index (per estimated hours asleep) [13]; or apnoeas + hypopnoeas per estimated hours of monitoring time.

Polygraphy in children performed using a type III device at home provides a frequency of apnoeas and hypopnoeas per estimated hours of monitoring time which is greater than the true AHI, *i.e.* AHI obtained from full in-lab video PSG. This discrepancy has been attributed to 1) events scored during wakefulness and 2) pseudo-events related to either reduced amplitude of the nasal airflow channel during mouth breathing and/or artefactually decreased flow post-arousal. In contrast, when polygraphy is performed in the sleep laboratory using a PSG system without recording the EEG, EOG and EMG channels, the calculated frequency of apnoeas and hypopnoeas is lower than the true AHI obtained from full PSG for two main reasons: 1) underscoring of hypopnoeas that are accompanied by arousals but not desaturations, and 2) use of total recording or calculated sleep time instead of the actual total sleep duration leads to underestimation of the various respiratory event indices because time is included in the denominator.

The frequency of apnoeas and hypopnoeas per estimated hours of monitoring time $\geqslant$3 events·h^{-1} in a type III device-based study is a reasonable predictor of AHI $\geqslant$1 events·h^{-1} in PSG.

Conclusion

Evaluation of the available evidence has shown that there are no universally defined technical standards in place for one of the most frequently used technologies in sleep practice in adult populations and particularly in paediatric populations. Application of the equipment, acquisition of signals and scoring of the signals and terminology for reporting is also not standardised, leading to huge variation in outcomes and treatment choices across centres which may carry significant financial implications. This is of importance not only to the individual patient but also for research studies, epidemiological studies, and the health economy overall. As diagnostic tools used exclusively for capturing sleep disordered breathing during sleep, type III devices are at their most specific and sensitive when there is high a pre-test probability clinically of such a disorder being present. For patients with lower pre-test probability of sleep disordered breathing as the source of their symptoms, an unclear differential diagnosis or suspected additional sleep disorders, PSG remains the diagnostic test of choice. Type III monitors are a diagnostic tool that must be tailored to a specific diagnostic problem. As such, they are also subject to additional considerations determining their use, including access to PSG, waiting list times, concerns regarding operator error in unattended settings, the preferences and practices of the medical institution and reimbursement and insurance issues.

With regard to the type of device deployed clinically (in the context of the almost universal adoption of AASM criteria for scoring respiratory events [13]), there are additional questions regarding the number of sensors required to record data. On the basis of this statement, and a recent review of the literature in a similar vein, it is currently suggested that a minimum of three sensors that attach directly to the body are necessary to obtain the minimal physiological signal dataset required to accurately score respiratory events [175].

At present, generalising the cut-offs for classifying mild, moderate or severe OSA using unattended type III studies remain unclear in both adult and paediatric populations and may also be specific to each device and the setting in which the study is undertaken. In populations with moderate to high pre-test probability of OSAHS, no unstable comorbid conditions as well as reasonable sleep efficiency in an attended setting, diagnostic capability is reasonably reliable. The nomenclature for reporting the number of breathing pauses per estimated hours asleep needs to be differentiated from the AHI, which should strictly remain in use for PSG studies only. We recommend either apnoeas + hypopnoeas per estimated hours asleep, or respiratory events index per estimated hours asleep, as suggested by the AASM [13] or apnoeas + hypopnoeas per estimated hours of monitoring time.

Manual scoring of events by qualified and registered sleep technologists is recommended as well as the facility to override/correct automated algorithms that are incorporated into most commercially available devices. Firstly, the criteria can change considerably over time depending on the standards adopted by the AASM, and secondly, many devices may have data signal acquisition limitations in respect of the reliability of their sensors that make their inbuilt automatic scoring algorithms unreliable.

Innovation is unstoppable. New technologies incorporating artificial intelligence are in constant development; their adoption could contribute to improved algorithms for extracting sleep stages from ECG, pulse wave detection, respiratory dynamics and movement sensors. They could thus overcome the current weaknesses of type III systems. An increase in the processing and integration capacity of electronic devices, as well as advances in low-power wireless communications, has also enabled the development of unwired intelligent sensors with a wide set of applications (supplementary material) [27–30, 176]. However, consideration should also be given to the "black box" of their unique scoring algorithms that cannot be manually examined or altered with time. Reflecting on the very disparate results recorded in the studies reviewed in this article, standardising clinical testing protocols is to be encouraged [177]. Thorough validation of such devices and extensive testing in both adult and paediatric subjects is essential and should in the very least include power and effect size calculations, failure rates and their reasons, side-effects of wearing the devices and patient feedback, as well as trials in a variety of clinical settings and populations.

The COVID-19 pandemic has had a major impact on sleep medicine [178]. Problems with hygiene (cleaning and disinfection of devices) as well as limited access to sleep laboratories have raised questions about the technical equipment utilised. For example, single-use devices (disposables) could play a role in the future; however, disadvantages for the environment could be considerable. Device manufacturing companies should be encouraged to develop contactless monitoring and evaluate its efficacy in both attended and unattended settings. Although this could include "nearables", at present they are devised largely for the consumer market and cannot be classified strictly as type III devices. There is an urgent need for standardised telehealth options for screening, diagnosis and follow-up of patients suspected of having sleep disordered breathing. Significant hurdles to such progress comprise legal and ethical dilemmas regarding data ownership and curation, scientific robustness in trialling new equipment, the lack of universally defined standards for physiological signal acquisition and processing and the future implications for financial resources as well as reimbursement in increasingly stretched healthcare systems. At the time of writing this technical standard, data on any developments concerning these issues were either unavailable or outside the defined search period.

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