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Diagnostic Modalities in Sleep Disordered Breathing: Current and Emerging Technology and Its Potential to Transform Diagnostics

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ABSTRACT

Underpinned by rigorous clinical trial data, the use of existing home sleep apnoea testing is now commonly employed for sleep disordered breathing diagnostics in most clinical sleep centres globally. This has been a welcome addition for the field given the considerable burden of disease, cost, and access limitations with in-laboratory polysomnography testing. However, most existing home sleep apnoea testing approaches predominantly aim to replicate elements of conventional polysomnography in different forms with a focus on the estimation of the apnoea-hypopnoea index. New, simplified technology for sleep disordered breathing screening, detection/diagnosis, or monitoring has expanded exponentially in recent years. Emerging innovations in sleep monitoring technology now go beyond simple single-night replication of varying numbers of polysomnography signals in the home setting. These novel approaches have the potential to provide important new insights to overcome many of the existing limitations of sleep disordered breathing diagnostics and transform disease diagnosis and management to improve outcomes for patients. Accordingly, the current review summarises the existing evidence for sleep study testing in people with suspected sleep-related breathing disorders, discusses novel and emerging technologies and approaches according to three key categories: (1) wearables (e.g., body-worn sensors including wrist and finger sensors), (2) nearables (e.g., bed-embedded and bedside sensors), and (3) airables (e.g., audio and video recordings), and outlines their potential disruptive role to transform sleep disordered breathing diagnostics and care.

1 | Introduction

Obstructive sleep apnoea (OSA) is a highly prevalent chronic respiratory disorder characterised by repetitive partial (hypopnoea) or complete (apnoea) collapse of the upper airway during sleep [1]. The resultant breathing interruptions cause frequent arousals, sleep disruption, and intermittent hypoxia. When left untreated, the accompanying pathophysiological sequelae of OSA trigger intermediary mechanisms that impact multiple organ systems and contribute to a range of

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adverse health consequences. These include excessive daytime sleepiness [2], mood disturbances [3], neurocognitive impairment [4], hypertension [5], cardiovascular disease [6], diabetes [7], and an increased risk of motor vehicle accidents [8]. The global prevalence of OSA has been estimated to be close to 1 billion adults [1, 9, 10].

OSA diagnosis and severity classification is primarily based on the apnoea-hypopnea index (AHI), which quantifies the average number of upper airway collapse episodes lasting > 10 s per hour of sleep. Gold standard diagnostic approaches for OSA with in-laboratory polysomnography (PSG) are expensive, labour-intensive, and time-consuming. This can limit early patient access to care and lead to prolonged waiting times for sleep service provision. As a result, the vast majority of people with OSA remain undiagnosed and untreated, with estimates suggesting that only 20% of individuals with this sleep disorder have received a formal diagnosis [11]. To address the limitations of in-lab PSG testing and the global burden of undiagnosed OSA, a growing number of portable sleep study devices have been introduced. These can be used within a patient's own home, can have a reduced number of monitoring channels versus full PSG, and can be automatically scored using proprietary algorithms which have been incorporated into specialised software programs. In addition to traditional limited-channel sleep testing devices, there has been a rapid surge in the development and use of novel technologies with sleep monitoring capabilities. While several recent review articles have discussed various aspects of emerging technologies [12–20], the clinical utility of novel sleep tracking devices in the diagnosis of OSA currently remains unclear.

The aim of this current review is to summarise the existing evidence for sleep study testing in patients with suspected sleep-related breathing disorders, discuss the novel and emerging technologies and approaches, and provide insights into their potential role in the future of disease diagnosis and management.

2 | Existing Technology

2.1 | Classification of Sleep Study Types

Traditionally, sleep study devices have been categorised into one of the following four different "levels" or "types" depending on the number of monitoring leads/channels and whether testing is conducted in an attended (sleep laboratory) or unattended (e.g., home) setting [21]. A **level 1** sleep study refers to the gold standard, full PSG monitoring with the use of at least 7 recording channels (including electroencephalogram [EEG], electro-oculogram [EOG] and chin electromyogram [EMG] to determine sleep stages, airflow, respiratory effort, electrocardiogram [ECG], oximetry and body position), performed in a sleep laboratory with a sleep technician in attendance. Level 2–4 sleep studies describe testing conducted in an unattended, usually in-home setting, often referred to as home sleep apnoea testing (or "HSAT"). A **level 2** sleep study refers to the use of unattended, full PSG with at least 7 monitoring channels in the absence of an overnight sleep technician. **Level 3** sleep studies refer to the use of a limited-channel device in an unattended setting, with monitoring of at least 3 cardiorespiratory signals and typically lack EEG, EOG, and EMG signals to evaluate sleep. **Level 4** sleep studies utilise only 1–2 recording channels, often including oximetry.

With rapid advances in sleep study technologies, many of the newer monitoring devices, such as those that incorporate peripheral arterial tonometry (PAT), no longer fit neatly into the traditional categorisation scheme described above. As a result, alternative categorisation systems have been proposed, such as the "SCOPER" system [22] which provides details of Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory monitoring parameters.

2.2 | Evidence for HSAT vs. Level 1 PSG

2.2.1 | Diagnostic Accuracy

2.2.1.1 | Level 2 Studies. While there may be potential for slightly higher failure rates with unattended level 2 home PSG compared to attended in-lab PSG testing, diagnostic accuracy has been shown to be clinically comparable. Using Sleep Heart Health Study methodology, Iber and colleagues demonstrated that the median respiratory disturbance index (RDI) was similar (difference 0.27 [interquartile range − 3.7 to 5.3], $p = 0.41$) in 64 participants who underwent both unattended home and attended in-lab PSG testing [23]. A recent systematic review on portable monitoring devices for OSA by Khor and colleagues [17] included 7 studies that compared level 2 with level 1 PSG testing and found AHI/RDI differences of −5.1 to −0.5 (upper and lower limits: 32.1–36) events/h on Bland–Altman concordance analyses. The authors concluded that type 2 studies have adequate sensitivity to detect OSA (88%–100% for AHI cut-off of 5 events/h and 76.5%–86.7% for AHI cut-off of 15 events/h) with improved specificity with increased OSA severity (35.7%–71.4% to 89.8%–97.8% for AHI cut-offs of 5 and 15 events/h, respectively).

2.2.1.2 | Level 3 Studies. A systematic review and meta-analysis conducted by El Shayeb and colleagues [24] in 2014 to evaluate the diagnostic accuracy of level 3 devices versus level 1 PSG ($N = 5026$; 59 studies) demonstrated receiver operating characteristic (ROC) area under the curves (AUC) of between 0.85 and 0.99, sensitivities of 79% to 97%, and specificities of 60% to 93% across different OSA severities. Overall diagnostic accuracy improved with increased disease severity. The authors concluded that level 3 devices had good diagnostic performance in adults with a high pre-test probability of moderate–severe OSA and no unstable medical comorbidities. The technical failure rate of level 3 studies was 10.25% versus 0.44% for level 1 studies.

2.2.1.3 | Level 4 Studies. In 2018, Abrahamyan and colleagues published a systematic review and meta-analysis to compare the diagnostic capability of level 4 devices versus level 1 PSG ($N = 2068$; 24 studies). This study showed sensitivities of 0.68–1.0 and specificities of 0.25–1.0 for an AHI ≥ 5 events/h. Meta-analysis that included 6 studies that used the ApneaLink device, which consists of airflow, oximetry, and position sensors (ResMed Pty. Ltd., Australia), showed sensitivity (95% CI) of 88 (82–92)% and specificity of 64 (52–75)% for AHI/RDI ≥ 5

events/h, and sensitivity of 82 (69–90)% and specificity of 88 (83–91)% for an AHI/RDI ≥15 events/h. The authors concluded that the evidence was not strong for the use of level 4 studies as stand-alone devices in routine practice, but they suggested a potential role in populations with high demand, high rates of OSA underdiagnosis, and/or limited access to PSG testing to enable timely diagnosis and management.

2.2.1.4 | Peripheral Arterial Tonometry. Simplified testing devices which incorporate PAT technology are available for OSA diagnosis. However, they do not fit neatly into the traditional level 1–4 sleep study categorisation system. These devices measure changes in peripheral arterial tone and are a reflection of sympathetic nervous system activation which occurs with arousals and in REM versus non-REM sleep. When combined with other monitoring signals such as oximetry, heart rate, actigraphy, and respiratory movements, PAT devices can provide estimates of key traditional sleep study parameters, including AHI, oxygen desaturation index (ODI), total sleep time, and sleep stages. WatchPAT (Itamar Medical Ltd., Caesarea, Israel) is the most widely studied PAT device. Recent systematic reviews and meta-analyses provide conflicting conclusions regarding their diagnostic performance and clinical utility. For example, a recent systematic review by Moffa and colleagues [25] included 18 studies ($N=1049$) that compared WatchPAT to PSG. A high correlation for most parameters was reported including AHI, ODI, and oxygen saturation (SaO_2) with sensitivities of 87%–96% and specificities of 66%–80%. The conclusion was that WatchPAT was an effective and convenient tool for OSA diagnosis. Conversely, a meta-analysis by Iftikhar and colleagues [26] published 1 year earlier that included 17 studies ($N=1318$) reported a pooled mean AHI bias of 0.30 (SE 0.74) and percentage error of 230% in limit agreement in PAT-derived AHI versus PSG-AHI. These authors concluded that there was clinically significant discordance, significant misclassification in OSA severity, and poor diagnostic performance with WatchPAT.

2.2.2 | Clinical Effectiveness and Cost-Effectiveness Studies

Assessment of diagnostic accuracy using specified AHI cut-points and calculations of sensitivity/specificity may not be the best way to determine the clinical utility of limited-channel devices. Firstly, there is no single agreed AHI cut-point that defines clinically significant OSA, and clinicians will usually combine the findings from a single night sleep study with other pertinent clinical information such as patient symptoms and medical co-morbidities when making diagnostic and management decisions. Also, it is well established that there is significant night-to-night variability in OSA severity, which is not captured when measured with a single-night sleep assessment [1, 27, 28]. Lastly, there is considerable inter- and intra-scorer variability in OSA severity metrics including AHI, and inter-laboratory scoring rules can also vary. Thus, the evaluation of the clinical utility of HSAT devices against PSG should consider not only their diagnostic accuracy in terms of the agreement in the number of sleep-disordered breathing events, but also their impacts on long-term patient-related outcomes (e.g., OSA symptoms and quality of life), efficiency in providing patient care, and cost-effectiveness.

This has led to several randomised controlled trials (RCTs) [29–34] between 2008 and 2018 that aimed to evaluate the clinical and cost-effectiveness of level 3 and/or 4 sleep studies versus full PSG in specialist sleep clinics and general practice settings. The results have generally shown non-inferior/comparable patient outcomes. These include treatment-related improvements in Epworth Sleepiness Scale [ESS], Functional Outcomes of Sleep Questionnaire [FOSQ] and other quality of life measures, treatment adherence, and significant within-trial cost savings for HSAT (particularly level 3 studies) compared to full PSG. It is important to note that these RCTs tended to recruit symptomatic patients with a high pre-test probability of moderate-to-severe OSA and excluded those with significant medical comorbidities.

2.3 | Clinical Guidelines for Diagnosis of OSA

The AASM 2017 Clinical Practice Guideline for Diagnostic Testing for Adult OSA [35] recommends that a technically adequate HSAT (i.e., type 2 or 3 sleep study, or PAT device with oximetry and Actigraphy), administered by an accredited sleep centre, be used for the diagnosis of OSA in uncomplicated patients at high risk of moderate-to-severe OSA; that PSG be used instead of HSAT in patients with significant medical comorbidities (e.g., severe cardiorespiratory disease, suspected hypoventilation syndromes, chronic opioid use, previous stroke, or severe insomnia); and that type 1 PSG should be performed if the initial, single-night HSAT is negative, inconclusive, or technically inadequate. Similar recommendations for the use of portable sleep monitoring devices have been made in other international clinical guidelines for OSA diagnosis, including Australia [36], Spain [37], and Canada [38].

3 | New and Emerging Technology

In recent years, the development of non-invasive sleep tracking devices and digital tools has grown exponentially. Many of these innovations provide considerable potential to transform OSA diagnostics or are already being employed in screening for or diagnosis of OSA in certain regions. This section provides an overview of examples of emerging, simplified diagnostic modalities for OSA, which we have categorised into three groups [39]: wearables, nearables, and airables (Figure 1). Special emphasis is placed on devices and technologies available in the consumer space or accessible for clinical and research purposes as of November 2024 (Table 1). It is important to note that this is a rapidly evolving field with continuous ongoing advancements. Several alternative technologies and emerging approaches such as ingestibles (Celero Systems, USA) [40] and morphic sensors embedded into clothing to detect breathing motion [41] are in early developmental stages. These have potential for future implementation but are not covered extensively in the current review.

3.1 | Wearables

Wearable devices require direct physical contact with the user. Sleep-tracking wearables range from small finger and wrist devices to adhesive patches, bands, masks, strips, smart clothing, or any other sensor type designed to be worn or attached to the body.

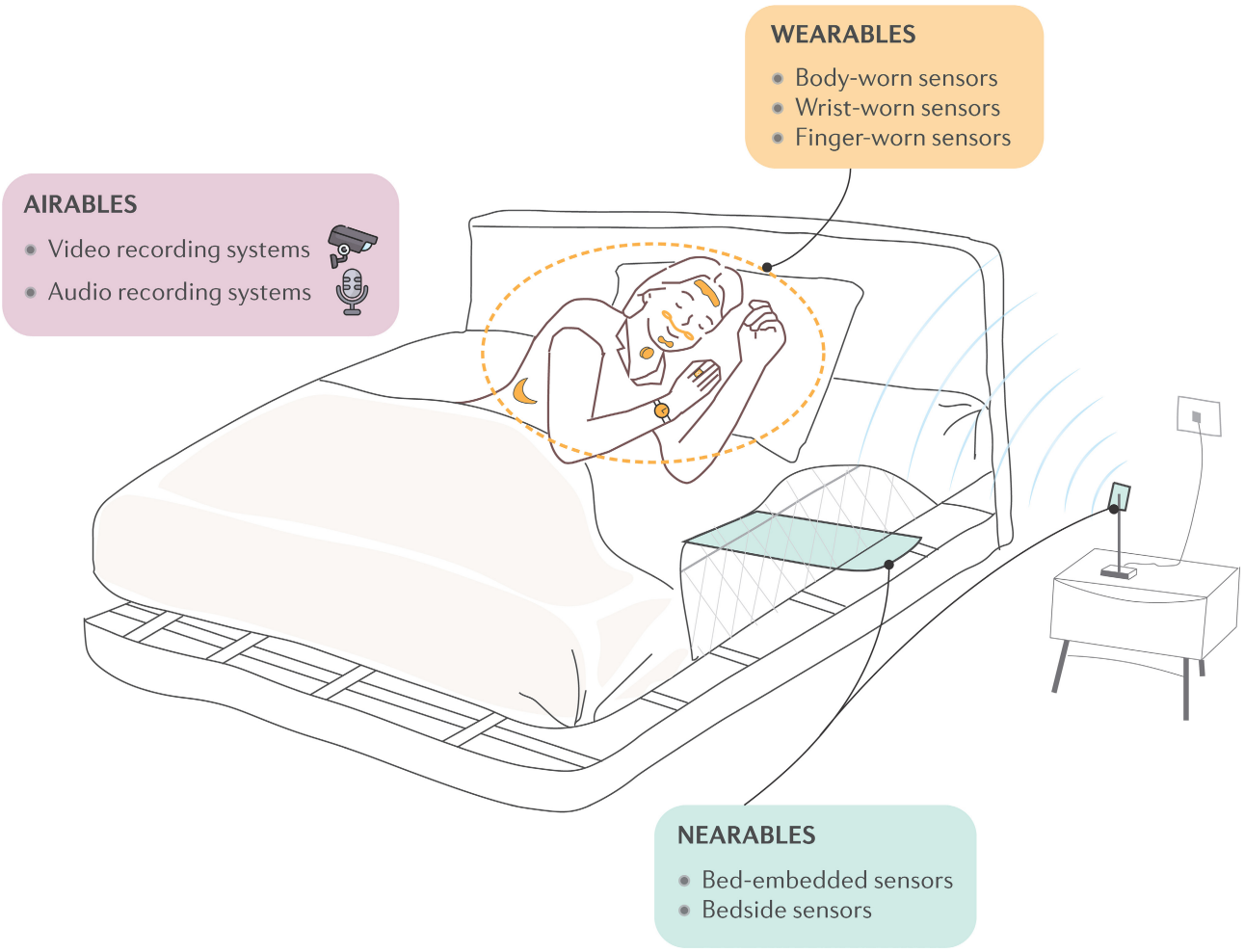

FIGURE 1 | Overview of emerging simplified approaches for in-home sleep apnoea detection. Wearable devices include any sensor type that requires direct physical contact with the user, such as adhesive patches or bands, wristbands, and rings. Nearables are non-contact devices that interact with the user from strategic locations within the sleeping environment, such as on the bed, under the mattress, or on a bedside table. Airable devices passively collect and transmit data from the surrounding environment via air-based recording sensors, such as microphones or cameras.

3.1.1 | Body-Worn Sensors

Early efforts to create simpler, lower-cost, and less intrusive wearables for in-home OSA screening led to the development of Sleepstrip (S.L.P. Ltd., Israel). This small, self-adhesive device worn underneath the nose and above the upper lip uses oral and nasal thermistors to provide an estimate of the AHI. An initial study conducted over 20 years ago that combined data from three validation cohorts across different countries ($N = 288$) reported an AUC of 0.810 to detect an AHI ≥ 10 events/h compared to PSG (AUC for AHI ≥ 20 events/h of 0.840) [42]. Sleepstrip received regulatory clearance as a pre-screening device for OSA. However, subsequent research to evaluate its reliability and validity has shown mixed results in terms of agreement with PSG [43–46].

Another early effort toward simplified, wearable-based OSA detection was the Apnea Risk Evaluation System or ARES (formerly Advanced Brain Monitoring, USA; now Watermark Medical, USA). This approach combines a head-mounted device, a self-administered questionnaire, and off-line analysis software. The device, known as Unicorder, is self-affixed to the forehead and acquires physiological data via a microphone, accelerometer, and optical sensors that measure reflectance oximetry. Automated software integrates the acquired physiological signals with questionnaire-based information on pre-existing risk factors to provide an overall estimated risk level for OSA. An initial multisite validation study against PSG that included 284 participants reported sensitivity and specificity values of 97.4% and 85.6%, respectively, in detecting an AHI > 10 events/h [47]. Another study that included 141 Chinese participants found accurate performance in identifying severe OSA, with lower agreement levels in classifying mild and moderate cases [48]. The Unicorder was later modified to include an airflow measurement via a nasal cannula connected to the forehead band. A prospective study with blinded analysis re-evaluated the device after this modification and showed good performance rates compared to simultaneous in-lab PSG and non-simultaneous home testing [49]. The device has also been validated to detect OSA specifically in pregnant women [50], and is currently cleared for the diagnostic evaluation of adult patients with suspected OSA.

Other forehead-mounted wearables developed to assess OSA include UMindSleep (EEGSmart Co. Ltd., China) and Somfit (Compumedics Ltd., Australia). UMindSleep employs a

TABLE 1 | New simplified diagnostic modalities for sleep apnoea.

Device	Placement	Sensor technology	Estimated OSA metric	Validation[a]	Performance[b]	Clearance[c]
Wearables						
Body-Worn Sensors						
SleepStrip S.L.P. Ltd., Israel	Below-nose adhesive	Airflow	AHI	$N = 288$ [42]	Sensitivity = 86.0% Specificity = 57.0% AUC = 0.810 (vs. PSG-AHI ≥ 10 events/h)	Yes
ARES Formerly Advanced Brain Monitoring, USA Now Watermark Medical, USA	Forehead band (plus nasal cannula on later versions)	Acc, PPG, and acoustic (plus airlow on later versions)	RDI	$N = 284$ [47]	Sensitivity = 97.4% Specificity = 85.6% (vs. PSG-AHI ≥ 10 events/h)	Yes
UMindSleep EEGSmart Co. Ltd., China	Forehead adhesive patch	EEG	ODI	$N = 169$ [51]	Sensitivity = 93.4% Specificity = 88.9% (vs. PSG-ODI ≥ 10 events/h)	No
Somfit Compumedics Ltd., Australia	Forehead adhesive patch	Acc, PPG, and acoustic	AHI		Unavailable	Yes
ANNE Sleep Sibel Inc., South Korea	Suprasternal notch and index finger adhesives	Acc and ECG (chest) and PPG (finger)	AHI	$N = 225$ [52]	Sensitivity = 89.7% Specificity = 97.5% AUC = 0.950	Yes
SANSA Huxley Medical, USA	Chest patch	Acc, ECG, and PPG	AHI	$N = 340$ [54] (conference paper)	Sensitivity = 88.2% Specificity = 87.3%	Yes
Sunrise Sunrise S.A., Belgium	Mentolabial sulcus adhesive	Acc and gyroscope (plus PPG and airflow on later versions)	RDI	$N = 376$ [56]	Sensitivity = 92.0% Specificity = 84.0% AUC = 0.930 (vs. PSG-RDI ≥ 15 events/h)	Yes
Wesper Lab Wesper Inc., USA	Chest and abdomen adhesive patches and finger pulse oximeter	Acc and RIP	AHI	$N = 45$ [60]	No performance metrics Pearson correlation = 0.951	Yes
BresoDx BresoTec Inc., Canada	Face frame (replaced by suprasternal notch patch on later versions)	Acoustic (plus Acc on later versions)	AHI	$N = 206$ [63]	Sensitivity = 59.0% Specificity = 96.0% AUC = 0.861	Yes

(Continues)

TABLE 1 | (Continued)

Device	Placement	Sensor technology	Estimated OSA metric	Validation[a]	Performance[b]	Clearance[c]
AcuPebble Acurable Ltd., UK	Suprasternal notch adhesive	Acoustic	AHI	$N = 150$ [67]	Sensitivity = 92.7% Specificity = 96.8% (vs. RP-AHI ≥ 15 events/h)	Yes
Wrist-Worn Sensors						
Apple Watch Apple Inc., USA	Smartwatch (wrist)	Acc	Binary risk estimate		Unavailable	Yes
Galaxy Watch Samsung Eletronics Co. Ltd., South Korea	Smartwatch (wrist)	PPG	Binary risk estimate		Unavailable	Yes
Finger-Worn Sensors						
NightOwl Formerly Ectosense, Belgium Now ResMed Pty. Ltd., Australia	Adhesive patch (middle finger fingertip)	Acc and PPG	AHI	$N = 167$ [77]	Sensitivity = 94.0% Specificity = 95.0%	Yes
Belun Sleep System Belun Technology Company Ltd., Hong Kong	Ring (proximal index finger)	Acc and PPG	AHI	$N = 84$ [79]	Sensitivity = 91.0% Specificity = 88.0% AUC = 0.960	Yes
SleepImage System MyCardio LLC, USA	Ring (thumb or index finger)	PPG	AHI	$N = 39$ [81]	Sensitivity = 87.0% Specificity = 69.0% AUC = 0.904	Yes
Go2Sleep SLEEPON, China	Ring (position not specified)	PPG	AHI	$N = 20$ [82]	Sensitivity = 42.0% Specificity = 88.8% AUC = 0.610 (vs. RP-AHI ≥ 15 events/h)	No
Nearables						
Bed-Embedded Sensors						
SD101 Kenzmedico Co. Ltd., Japan	On the mattress (sheet-type)	Pressure	RDI	$N = 201$ [84]	Sensitivity = 89.7% Specificity = 90.5%	No

(Continues)

TABLE 1 | (Continued)

Device	Placement	Sensor technology	Estimated OSA metric	Validation[a]	Performance[b]	Clearance[c]
Sonomat Sonomedical Pty Ltd., Australia	On the mattress (mattress-type)	Piezoelectric and acoustic	AHI	$N=60$ [87]	Sensitivity = 88.0% Specificity = 91.0% AUC = 0.966	Yes
EarlySense EarlySense Ltd., Israel	Under the mattress (chest height)	Piezoelectric	AHI	$N=96$ [98] (conference paper)	Sensitivity = 88.0% Specificity = 78.0%	No
Sleeptracker-AI Fullpower Technologies, USA	Under the mattress (chest height)	Piezoelectric	REI	$N=102$ Volunteers [99]	Sensitivity = 81.8% Specificity = 93.4%	No
Emfit QS Emfit Ltd., Finland	Under the mattress (chest height)	Piezoelectric	No OSA metrics	Unavailable		No
Nemuri SCAN Paramount Bed Co., Japan	Under the mattress (chest height)	Pressure	REI	$N=70$ [101]	Sensitivity = 90.9% Specificity = 76.9% AUC = 0.860	No
Withings Sleep Analyser/ Sleep Rx Withings Health Solutions, France	Under the mattress (chest height)	Pneumatic and acoustic	AHI	$N=118$ [102]	Sensitivity = 88.0% Specificity = 88.6% AUC = 0.926	Yes
Bedside Sensors						
SleepMinder BiancaMed, Ireland	Bedside table (distance from bed < 1 m)	Radar	AHI	$N=74$ [109]	Sensitivity = 90.0% Specificity = 92.0% AUC = 0.970	No
Sleepiz One Sleepiz AG, Switzerland	Bedside table (distance from bed 40–50 cm)	Radar	AHI	$N=100$ [112]	Sensitivity = 85.4% Specificity = 88.1%	No
XK300 Xandar Kardian, USA	Bedside table (distance from bed 40–50 cm)	Radar	ABI	$N=94$ [113]	Sensitivity = 93.0% Specificity = 84.0%	No
OrbSense Megahealth Medical Inc., China	Bedside table (distance from bed < 1 m)	Radar	REI	$N=359$ [114]	Sensitivity = 87.1% Specificity = 89.7% AUC = 0.942	No
Somnofy VitalThings, Norway	Bedside table or wall (distance not specified)	Radar	REI	Unavailable		No

(Continues)

TABLE 1 | (Continued)

Device	Placement	Sensor technology	Estimated OSA metric	Validation[a]	Performance[b]	Clearance[c]
Airables						
Audio Recording						
OSAnet Not commercially available	Voice recorder (distance from bed < 1 m)	Acoustic recording	AHI	*N* = 194 [126]	Sensitivity = 95.8% Specificity = 88.5% AUC = 0.981	No
Drowzle App Resonea Inc., USA	Smartphone (distance from bed < 1 m)	Acoustic recording	Binary risk estimate	*N* = 91 [132]	Sensitivity = 93.7% Specificity = 63.0% AUC = 0.874	Yes
SleepCheckRx App ResApp Health, Australia	Smartphone (on a nightstand)	Acoustic recording	Binary risk estimate	Unavailable		Yes
Video Recording						
SleepWise Not commercially available	Digital camera facing thorax (distance from bed 60 cm)	Video recording	AHI	*N* = 50 [136]	Sensitivity = 88.2% Specificity = 81.3% AUC = 0.847	No

Note: Summary of the reviewed sleep apnoea detection systems, including details on device placement, sensor technology, estimation metrics, validation and performance data (if available), and regulatory status for market authorisation as of November 2024.

Abbreviations: ABI, abnormal breathing index; Acc, accelerometer; AHI, apnoea-hypopnoea index; AUC, area under the curve; ECG, electrocardiograph; EEG, electroencephalograph; EU-MDR, European Union Medical Device Regulation; FDA, US Food and Drug Administration; ODI, oxygen desaturation index; OSA, obstructive sleep apnoea; PPG, photoplethysmograph; PSG, polysomnography; RDI, respiratory disturbance index; REI, respiratory event index; RIP, respiratory inductance plethysmograph; RP, respiratory polygraphy; TGA, therapeutic goods administration.

[a]Referral to the sleep clinic for suspected OSA, unless otherwise specified.

[b]Performance metrics are compared to same-night AHI cut-off of ≥ 15 events/h evaluated with gold-standard level 1 PSG, unless otherwise specified.

[c]Clearance by at least one major medical device regulatory body (FDA/TGA/EU-MDR) for pre-screening or diagnostic evaluation of OSA.

single-channel forehead EEG and provides oximetry metrics including an estimated ODI. A study that tested its performance against PSG reported a sensitivity of 93.4% and specificity of 88.9% to predict an ODI cut-off of > 10 events/h [51]. However, regulatory clearance and validation studies specific to AHI-based OSA detection are currently lacking for this device. Conversely, Somfit provides an AHI estimate via forehead-based PAT technology. This device has been cleared as a diagnostic aid for the detection of sleep-related breathing disorders, although validation data on its performance is currently not available. Another cleared PAT-based device is ANNE Sleep (Sibel Inc., South Korea). This device uses a flexible, wireless dual-sensor system with adhesive patches on the index finger and suprasternal notch. The chest unit contains an accelerometer, single-lead ECG, and temperature sensors, while the finger unit consists of a photoplethysmography (PPG) sensor to measure SaO_2 and PAT. The device has good performance to detect moderate-to-severe OSA compared to both in-lab PSG (AUC = 0.950; $N = 225$) [52] and level 3 HSAT (AUC = 0.900; $N = 46$) [53]. SANSA (Huxley Medical, USA) offers an alternative approach with a single chest patch that uses reflective PPG, single-lead ECG, and accelerometer to derive an estimate of AHI. This device was recently cleared to aid in the evaluation of suspected OSA. Results from a conference abstract show sensitivity of 88.2% and specificity of 87.3% to identify an AHI > 15 events/h [54].

Other technological advancements in wearable devices for OSA assessment focus on the analysis of respiratory effort, such as Sunrise (Sunrise S.A., Belgium) and Wesper Lab (Wesper Inc., USA). The Sunrise system includes an inertial measurement unit embedded in a small sensor attached to the chin to allow detection of mandibular jaw movement as a surrogate for respiratory effort [55]. Combined with an automated machine learning-supported analysis, the device calculates an estimate of respiratory disturbances during sleep. An initial validation study in > 370 participants reported an AUC of 0.930 compared to PSG to detect an RDI > 15 events/h [56]. Further studies have confirmed its performance characteristics in both adult [57] and paediatric [58] cohorts. The subsequent version, Sunrise2, incorporates airflow and SaO_2 measurements within the single-point contact chin sensor and has been cleared as a home-care aid in the diagnosis of OSA. Conversely, Wesper Lab acquires respiratory inductance plethysmography (RIP) signals from a set of two patches affixed to the chest and abdomen, which measure respiratory effort and derived airflow. Two proof-of-concept studies in relatively small cohorts have shown a high correlation between the AHI derived by the device and PSG-AHI [59, 60]. Wesper Lab has been cleared for use in adult sleep studies in conjunction with finger pulse oximetry, although clinical validation studies to evaluate its diagnostic performance are not yet available.

Substantial advances in breathing sound signal processing have enabled the development of innovative acoustic-based wearable systems for the evaluation of OSA. These include BresoDx (BresoTec Inc., Canada) and AcuPebble (Acurable Ltd., UK). The initial version of BresoDx featured a tracheal sound-capturing module embedded within a face frame with no external wires. This devices incorporated validated algorithms to process the recorded data and calculate an automated estimation of the AHI [61, 62]. An RCT that enrolled adults with suspected OSA randomised participants to BresoDx followed by PSG (one-night apart) or vice versa. This study reported that the sensitivity of BresoDx-informed clinical diagnosis against PSG was between 0.86 and 0.89, but specificity varied between 0.38 and 0.44 [63]. Subsequent versions of the device (BresoDX1) replaced the face frame with a patch attached to the suprasternal notch, which, in addition to the microphone, included an accelerometer to derive trachea-sternal motion [64]. BresoDX1, in combination with a finger pulse oximeter [65], received regulatory clearance for use as an aid in the diagnosis of moderate to severe OSA in adults. Similarly, AcuPebble is a small neck sensor that uses a piezoelectric microphone to record tracheal sounds related to breathing, cardiac rhythms, and movements. The first version, AcuPebble SA100, was equipped with a compact sensor attached anywhere between the laryngeal prominence of the thyroid cartilage and the supra-sternal notch. The device is accompanied by an app with automated analysis software. After a preliminary proof-of-concept study to evaluate a device prototype [66], AcuPebble SA100 provided good performance results with sensitivity values > 92% and specificity > 96% to detect moderate to severe OSA in comparison to domiciliary respiratory polygraphy [67] and in-clinic PSG [68]. Both the SA100 and the following version, which also includes a finger pulse oximeter (AcuPebble Ox100), have received clearance to aid in the evaluation of suspected OSA.

3.1.2 | Wrist-Worn Sensors

The widespread adoption of wearable wrist devices such as smartwatches and fitness wristbands has facilitated continuous monitoring of a diverse array of physiological signals in daily life. This technology has attracted significant interest from both researchers and industry. Consumer-grade wrist-worn devices are currently capable of inferring sleep patterns and providing estimates of various key sleep metrics. In the context of OSA detection, a substantial body of research supports the potential to estimate the AHI based on reflectance PPG and accelerometry data gathered from wrist-based sensors, such as bracelets or watches [69–74].

Newer smartwatches are not only equipped with built-in sensors and algorithms which have the capability to detect breathing interruptions during sleep, but some also incorporate software-based medical functions that analyse the collected data and notify users when breathing patterns suggestive of OSA are identified. Two smartwatches have received regulatory clearance for this over-the-counter medical application, with the caveat that they are not intended to provide standalone diagnosis, assist clinicians in diagnosing sleep disorders, or function as an OSA monitor. The latest versions of the Apple Watch (Apple Inc., USA) incorporate a feature that uses accelerometer data to calculate nightly breathing disturbance values which are used to classify the risk of OSA as either "Elevated" or "Not Elevated". A notification is sent to the user if breathing patterns consistent with moderate-to-severe OSA are identified within a 30-day evaluation window. Similarly, the Galaxy watch (Samsung Eletronics Co. Ltd., USA) introduces an analogous mobile medical application designed to identify signs of OSA. This feature outputs an OSA risk

estimation metric based on PPG-measured blood oxygen data collected over two-day intervals. Results are reported as either "Did" or "Didn't" detect signs of moderate-to-severe OSA. However, validation studies for these functionalities have yet to be published.

3.1.3 | Finger-Worn Sensors

The development of wireless, ring-like sensors has become an area of growing interest to enable portable and convenient OSA assessments [75]. Currently, three finger-worn devices have received medical-grade clearance for HSAT upon physician prescription. Among the first was NightOwl (formerly Ectosense, Belgium; now ResMed Pty. Ltd., Australia), a small sensor that is self-attached to the fingertip by means of an adhesive patch. This device acquires accelerometer and reflectance PPG data from which its incorporated software derives an estimated AHI metric based on PAT. Since its initial performance evaluation against PSG [76], it has further shown good agreement findings in a multicentre validation study with a sensitivity of 94.0% and a specificity of 95.0% to detect moderate-to-severe OSA [77]. Belun Ring (Belun Technology Company Ltd., Hong Kong) is an artificial intelligence (AI)-powered system that analyses reflectance PPG and accelerometer signals from the proximal phalanx of the index finger to estimate AHI based on SaO_2 analysis. Following an initial proof-of-concept study [78], the introduction of second-generation deep learning algorithms to the system led to an AUC for moderate-to-severe OSA detection of 0.960 [79]. This device also performed well in the detection of OSA beyond the sleep clinic setting, as per results of another study from a cohort of 127 patients with essential hypertension and high cardiovascular risk factors (AUC = 0.961 vs. PSG-derived AHI ≥ 15 events/h) [80]. Additionally, SleepImage (MyCardio LLC, USA) is a software-based system that uses a single-lead ECG or PPG signals to automatically estimate the AHI based on the cardiopulmonary coupling (CPC) technique. In a study of 39 participants, this medical-grade software incorporated into an oximetry ring (SleepImage Ring) showed an AUC of 0.904 to detect moderate-to-severe OSA when CPC data are combined with PPG-assessed pulse oximetry [81]. Finally, a study that evaluated the diagnostic performance of another consumer-available but not yet cleared ring-shaped device, Go2Sleep (SLEEPON, China), showed an accuracy of 60% to detect moderate-to-severe OSA compared with home cardiorespiratory polygraphy [82].

3.2 | Nearables

Nearable devices interact with the user without the need for direct physical contact. Depending on the type of sensor technology, sleep nearables can be placed in different locations within the sleeping environment, such as on the bed, under the mattress, or on a nearby surface like a bedside table (Figure 1).

3.2.1 | Bed-Embedded Sensors

There has been interest in the development of non-invasive and unobtrusive bed sensors to monitor respiration and movement during sleep for decades [83]. However, recent advances in technology have yielded increased attention and popularity for these approaches. One of the earliest bed-embedded sensors designed to detect sleep-disordered breathing was SD101, later renamed SD102 (Kenzmedico Co. Ltd., Japan). This sheet-shaped device, placed on a mattress, uses pressure sensors to track gravitational changes in the body caused by respiratory movements, which are then analysed to quantify breathing patterns during sleep. The accuracy of this device compared to PSG showed a predictive value of ~90% for both sensitivity and specificity [84]. Two external validation studies further reported close agreement between the device-estimated RDI and the PSG-derived AHI [85, 86]. Another device that is also positioned directly on the mattress is Sonomat (Sonomedical Pty Ltd., Australia). This recording system, which has received clearance for OSA assessment, consists of a thin piece of foam that uses vibration and acoustic sensors to measure breathing movements and breath sounds. Results from a validation study in adults showed high accuracy with PSG (AUC > 0.93 for mild, moderate, and severe OSA thresholds; $N = 60$) [87]. Subsequent investigations have evaluated the reliability of this device to detect OSA in children with good agreement with PSG in two independent paediatric cohorts [88, 89].

An alternative form of bed-based sleep trackers is devices that operate beneath the mattress. These devices leverage highly sensitive sensors to detect small variations in movement and pressure from which key physiological information such as respiration, cardiovascular function, and body motion can be inferred. The recorded signals undergo digital processing to estimate a range of sleep-related variables including OSA metrics through ballistography-based algorithms. Multiple sensor technologies have been tested in under-the-mattress devices, including piezoelectric, pneumatic, force, hydraulic, and fibre optic-based sensors, among others [90]. Despite a growing body of research investigation with under-the-mattress sleep monitoring systems for OSA detection [91–97], only a limited number of devices are currently commercially available.

One of the earlier under-the-mattress devices to become commercially available was the piezo-electric sensor EarlySense (EarlySense Ltd., Israel). A conference paper that evaluated its performance to screen for OSA reported a sensitivity of 88.0% and specificity of 78.0% to detect an AHI of ≥ 15 events/h with 100% of severe cases correctly classified [98]. Similarly, Sleeptracker-AI (Fullpower Technologies, USA), another piezo-electric sensor, achieved sensitivity and specificity rates of 81.8% and 93.4% respectively, for moderate-to-severe OSA [99]. However, this study was conducted largely among healthy volunteers (~10% of the cohort had an AHI ≥ 15 events/h). Therefore, its effectiveness in sleep clinic settings remains to be investigated. Another available piezoelectric under-mattress sleep monitor that has been broadly used for different research purposes is Emfit QS (Emfit Ltd., Finland). To test its potential for OSA detection, an exploratory study compared Emfit-derived parameters with PSG-measured AHI. Results showed that the percentage of sleep time with obstructive periodic breathing patterns was the device-estimated parameter that had the best correlation with AHI (AUC = 0.978 to predict an AHI ≥ 15 events/h) [100]. However, prospective validation studies to evaluate its diagnostic performance are needed to confirm these findings.

Pressure-sensitive under-the-mattress sensors have also shown encouraging performance results. Nemuri SCAN (Paramount Bed Co., Japan), commercially available in Japan, achieved an AUC of 0.860 to detect an AHI ≥15 events/h compared to in-lab PSG based on a validation study that included 70 participants [101]. Additionally, the pneumatic sensor Withings Sleep Analyser/Sleep Rx (Withings Health Solutions, France) was validated for OSA detection and had an AUC of 0.926 for moderate-to-severe OSA [102] with similar performance characteristics reported in a separate independent validation study [1]. This technology has since been used widely in OSA research [1, 103–105]. This device has received regulatory clearance to aid in OSA diagnosis and is available in the U.S. by prescription as part of clinical sleep management or remote patient monitoring programs.

An earlier pooled meta-analysis that included studies up to 2017 showed that, among different categories of portable screening devices for OSA, bed/mattress-based sensors were found to have the best sensitivity overall (95% CI) [0.921 (0.870 to 0.953)], as well as the best sensitivity to detect moderate and severe cases [106]. In addition, other emerging bed-related products such as smart pillows [107], may also have a future role in OSA screening/diagnosis and management.

3.2.2 | Bedside Sensors

The technology that underpins the currently available bedside sensors for OSA is based on the Doppler effect. These devices use radio wave reflections to monitor breathing movements and identify respiratory events from a distance via sophisticated signal processing algorithms. One of the first biomotion sensors introduced in this field was SleepMinder (BiancaMed, Ireland) [108]. This device emits ultra-low-power radio-frequency waves and captures the reflected electromagnetic energy using a Doppler radar sensor to continuously map movements related to respiration and position changes of the individual in bed. In an initial validation study against PSG over a decade ago, it showed a sensitivity of 90% and a specificity of 92% to detect moderate-to-severe OSA in a sleep clinic setting [109]. Subsequent independent studies have evaluated its performance in high-risk populations, such as patients with heart failure [110] and those with established hypertension [111], and showed good agreement with in-lab PSG (AUC = 0.850 for predicting AHI ≥15 events/h). Other commercially available bedside devices that employ radar technology have also been validated to detect moderate-to-severe OSA, including Sleepiz One (Sleepiz AG, Switzerland) [112] and XK300 (Xandar Kardian, USA) [113], with sensitivity values of 85% and 93% and specificity of 88% and 84%, respectively.

Another biomotion sensor, OrbSense (Megahealth Medical Inc., China), which uses an impulse radio ultrawideband radar system, showed close agreement with in-lab PSG in a cohort of >350 participants (AUC = 0.942 for moderate-to-severe OSA) [114]. An alternative commercially available device based on the same sensor technology, Somnofy (VitalThings, Norway), has also been proposed as a potential tool to detect OSA events when used in combination with pulse oximetry [115]. However, while this biomotion sensor has been validated for respiratory rate measurement and sleep stage classification, there is currently no evidence to evaluate its clinical effectiveness for OSA screening/diagnosis.

Other technologies that use non-contact devices positioned next to the bed have been proposed for OSA detection. One such example is the fibre-grating vision sensor technique, which tracks respiratory movements by measuring the displacement of laser spots on the body surface [116]. Another example is the use of inaudible sonar to monitor chest and abdomen movements during sleep. This technique, integrated into smartphones, has been used to build mobile apps designated to automatically detect sleep-related respiratory events without any dedicated hardware beyond the transformed smartphone [117–119]. Biomotion analysis using active 3D-depth sensing cameras represents another potential instrument to measure respiratory and whole-body movements during sleep [120]. However, despite substantial advancements, none of these bedside technologies currently qualify as a medical device for OSA screening or diagnosis.

3.3 | Airables

Airables refer to technologies that passively collect and transmit data from the surrounding environment through air-based interfaces. These devices can monitor environmental parameters (e.g., air quality, temperature, humidity), as well as capture biometric and physiological information via built-in sensors such as microphones or cameras.

3.3.1 | Audio Recording

The possibility to detect OSA using recorded snoring and breathing sounds has been a research focus for many years [121–125]. Despite significant progress, most audio recording-based classifier prediction models for OSA have not undergone rigorous validations and therefore remain unsuitable for clinical use. A notable exception is a two-phase validation study that used a convolutional neural network named OSAnet to detect apnoeic events via analysis of sleep sounds recorded with a non-contact voice recorder. This method showed good agreement with PSG to identify moderate-to-severe OSA with sensitivity of 88.5% and specificity of 95.8% [126]. However, this deep-learning algorithm is not yet commercially available.

Mobile phones are powerful and accessible tools equipped with a range of embedded sensors that can be used to monitor different aspects of sleep. Over the past few years, several studies have tested the ability of the internal microphones of smartphones to quantify breathing pauses and snoring during sleep [127–129]. Several smartphone applications based on audio recording have been developed [130, 131]. Two have currently been cleared to screen for OSA (under prescription only use), named DROWZLE (Resonea Inc., USA) and SleepCheckRx (ResApp Health, Australia). Both use smartphone-captured sound signals to provide a binary estimate of OSA risk via proprietary algorithmic calculations. One key difference is that the first one uses a combination of sound plus symptom data to provide the estimated score, while the second is based solely on audio processing. The diagnostic ability of the DROWZLE app has been evaluated in

a two-phase clinical validation study with an AUC of 0.874 to detect moderate-to-severe OSA compared to in-lab PSG [132]. Performance data for the acoustic-based SleepCheckRx app are currently unpublished.

3.3.2 | Video Recording

Respiratory monitoring during sleep using passive video recording has also gained attention in recent years. Early developments in video-based OSA detection have tested the use of thermal, infrared, and digital red, green, and blue (RGB) cameras [133–135]. Notably, a system called SleepWise, which is based on the analysis of images captured by a conventional digital video camera equipped with infrared LEDs, has shown high accuracy in detecting moderate-to-severe OSA (sensitivity = 88.2%; specificity = 81.3%; $N = 50$) [136]. This technology has been further validated against HSAT in a cohort of 38 sleep clinic outpatients with consistent and concordant results across different nights for the same patient [137]. However, this video-based system is not yet commercially available.

4 | Conclusions and Future Perspectives

The evolution of multimodal forms of sleep technology aimed at OSA screening, detection/diagnosis, or monitoring has expanded exponentially in recent years. Backed by clinical trial data, the use of existing HSAT in different forms that has largely aimed to replicate various key components of in-lab PSG signals is now commonly used for OSA diagnostics in most clinical sleep centres globally. This has been a welcome addition for the field, given the considerable burden of disease and the limitations of in-lab PSG, including cost and access.

However, as OSA detection and monitoring technology evolves, so too must the regulatory and guideline framework. For example, initial attempts to categorise OSA testing into four different levels based on whether testing is performed in a comprehensively monitored setting (level 1) through to increasingly reduced numbers of key signal types from traditional PSG in an unattended setting (levels 2–4) are no longer fit for purpose. This is because innovations in technology now go beyond simply replicating varying numbers of PSG signals in the home setting.

Indeed, as outlined in the current review, we have grouped emerging technologies into three key categories: wearables, nearables, and airables (Figure 1, Table 1). These cover body-worn sensors including wrist and finger sensors, bed-embedded sensors, bedside sensors, and audio and video recording-based systems. In general, these various forms of emerging technology all tend to show good performance characteristics with AUC and/or sensitivity/specificity characteristics of > 80% when compared to PSG in the research setting (Table 1). As was previously the case for existing HSATs, the challenge for widespread clinical implementation/translation of new and emerging disruptive technology is ensuring validation through rigorous clinical trials, including comparative effectiveness studies to directly compare new approaches to current models of care. Theoretically, if these technologies continue to perform with the accuracy outlined in the initial validation studies in appropriately designed prospective trials, there is considerable potential for diagnostic cost savings and increased access to testing. These remain major challenges for the field.

In addition, implementation of minimally or non-invasive technology also has the potential to overcome other major limitations with the current diagnostic approach that relies on single-night testing. Due to measurement and night-to-night physiological variability in OSA severity [103, 105], conventional single-night OSA diagnostics result in considerable disease misclassification rates of 20%–50% [1, 138]. High misclassification rates with the current single-night testing model are estimated to result in high rates of both under (~30%) and over-treatment (~15%) for people with suspected OSA [139]. High disease misclassification rates with single-night testing may explain, at least in part, the high failure rates to improve important health outcomes such as cardiovascular outcomes in OSA treatment trials [104]. Thus, implementation of cost-effective, accurate technology with multi-night testing capability is a priority for the field and has the potential to transform OSA diagnostics and monitoring. Simplified OSA diagnostic technology with multi-night capability also has the potential to be used at the population screening level or as part of clinical triage testing. For example, this technology could be used to identify who may need immediate treatment if conducted over multiple nights with adequate accuracy and coupled with consistent clinical features of OSA, or used to identify who may require more detailed diagnostic testing where clinical uncertainty remains (e.g., in cases where they may be confounding co-morbidities).

A shift away from human-based sleep study scoring toward automated and AI-based approaches may help to reduce a key source of measurement error with conventional testing [140, 141]. Indeed, this is a priority for the field. A recent meta-analysis that included studies up to March 2024 evaluated the effectiveness of wearable AI-based OSA detection systems and showed a pooled mean (95% CI) sensitivity and specificity of 0.938 (0.89 to 0.97) and 0.752 (0.63 to 0.86), respectively, from the 13 included studies [142]. Many of the emerging simplified technologies also have the potential to be used for cost-effective long-term disease and treatment monitoring, which has not previously been possible for non-continuous positive airway pressure therapies. Ultimately, newer diagnostic approaches and smarter use of current signals that attempt to capture relevant physiological information beyond the conventional AHI may provide better predictive markers of adverse disease consequences [143] and help tailor treatment selections to specific individual needs via a personalised treatable trait approach [144–146].

Author Contributions

Lucía Pinilla: conceptualization (equal), writing – original draft (equal), writing – review and editing (supporting). **Ching Li Chai-Coetzer:** conceptualization (equal), writing – original draft (equal), writing – review and editing (supporting). **Danny J. Eckert:** conceptualization (equal), writing – original draft (equal), writing – review and editing (lead).

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