



TITLE: **Portable Devices Used for Home Testing in Obstructive Sleep Apnea**

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PORTABLE DEVICES USED IN HOME TESTING FOR OBSTRUCTIVE SLEEP APNEA

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum (CTAF) has been asked to update its review of the scientific literature on the safety and efficacy of portable devices used in the home to diagnose patients with obstructive sleep apnea. Home diagnostic devices for sleep apnea were last reviewed by the Forum in June 2005.¹ At that time, the recommendation of the systematic review was that portable devices did not meet CTAF criteria. Since that time, several new studies and reviews have been published and the Centers for Medicare and Medicaid Services (CMS) issued a national coverage decision supporting the coverage of continuous positive airway pressure (CPAP) based on home diagnosis of sleep apnea using portable devices. An updated review was considered in October 2008, but was tabled.

BACKGROUND

Obstructive Sleep Apnea (OSA)

Untreated, OSA is associated with significant morbidity and mortality including excessive sleepiness, poor memory, poor quality of life, hypertension, sudden death, stroke, congestive heart failure, myocardial infarction, and automobile and work-related accidents.²⁻¹⁰ Apnea is usually defined as a cessation of airflow for >10 seconds, and hypopnea, as a reduction of >50% in thoracoabdominal movements for >10 seconds or as a discernable reduction in respiratory airflow for >10 seconds and accompanied by a decrease of >4% in SaO₂ and/or an arousal¹¹. The apnea-hypopnea index (AHI) is calculated as the average number of apneas plus hypopneas per hour of sleep. The cut-off for the diagnosis of OSA for the AHI has varied from study to study. Recent studies using a “liberal” definition of OSA—an AHI of greater than five events per hour—have found that up to 24% of men and nine percent of women have OSA. Using a more “conservative” diagnostic criterion—an AHI of at least 15 events per hour plus a history of daytime somnolence—up to two percent to four percent of adults have obstructive sleep apnea syndrome.^{12, 13} Treatment of OSA syndrome with nasal continuous positive airway pressure (nasal CPAP), dental devices, surgery, and weight loss improves patient daytime somnolence, cognitive dysfunction, and overall survival^{3, 14-19} Although there have been few comparative studies, the consensus is that CPAP should be the first line therapy for OSA.

A major advance in the past decade has been the demonstration that CPAP does not need to be titrated in the sleep lab. Multiple studies have demonstrated the equivalence of automated home titration of CPAP (auto-CPAP) to in lab CPAP titration and guidelines have been written by sleep societies supporting its use.²⁰⁻³⁸

The diagnosis of OSA cannot be made accurately by clinical history or physical examination alone. The “gold standard” for diagnosis of OSA is polysomnography (PSG), a recording of at least seven parameters—electroencephalography (EEG, brain waves), electro-oculography (EOG, eye movements), chin electromyography (muscle activity), electrocardiography (ECG), respiratory effort, airflow, and blood oxygen saturation—that is performed by a trained technologist using dedicated equipment with the patient sleeping overnight in a sleep laboratory. Full PSG also allows calculation of the respiratory disturbance index (RDI), which is the number of sleep-disordered events per hour of sleep including respiratory effort related arousals that don’t qualify as hypopneas or apneas. Consensus standards exist for the proper use of the in-laboratory PSG in the diagnosis of OSA.³⁹⁻⁴¹ In-laboratory PSG is labor-intensive and long waiting lists are common in sleep laboratories⁴². Furthermore, single-night PSG is not perfect, and false-negative results have been reported⁴³. In addition, night-to-night variability of respiratory abnormalities has been well documented^{42,44} and may give rise to divergent RDIs, causing reclassification of the diagnosis in up to 43% of patients with lower RDIs (5-15 respiratory events/hour)⁴⁵. Some do not consider standard PSG to be the “gold standard” for the diagnosis of OSA⁴⁶; instead, they suggest that therapeutic response to treatment (e.g., with nasal CPAP) might be a better “gold standard”⁴⁷.

The American Academy of Sleep Medicine recommends using the following definition for the diagnosis of obstructive sleep apnea hypopnea syndrome.⁴¹ A patient must meet either criterion A or B plus criterion C:

- A. Excessive daytime sleepiness that is not better explained by other factors
- B. Two or more of the following that are not better explained by other factors:
 - a. Choking or gasping during sleep
 - b. Recurrent awakenings from sleep
 - c. Unrefreshing sleep
 - d. Daytime fatigue
 - e. Impaired concentration
- C. Overnight monitoring demonstrates five or more obstructed breathing events per hour during sleep

The report also recommends the following terminology for disease severity: mild = 5-15 events per hour; moderate = 15-30 events per hour, severe = more than 30 events per hour.⁴¹

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Portable Devices for Home Diagnosis of OSA

Over the past twenty years, numerous portable devices have been developed that can record sleep, nocturnal breathing and oxygenation at home. A large number of portable sleep monitors are now available⁴⁸⁻⁵¹ with different diagnostic goals. Simple, inexpensive devices have been developed to screen or to case-select patients with sleep-disordered breathing. More complex equipment has been developed to allow the performance of a study equivalent to full PSG in the home setting⁴⁸. A recent review identified an “incomplete list” of 36 portable monitors (PM).⁵²

The portable devices offer several potential advantages compared with in laboratory PSG^{53, 54}. Home studies might provide a more realistic appraisal of sleep-disordered breathing than can be obtained in the laboratory setting⁵⁵. The reduced number of monitors with portable devices may also help with better approximation of the patient’s usual sleep habits. The use of home devices could allow for wider access to sleep studies, as there are not enough sleep centers in the United States to perform full PSG on all at risk patients. In the past, waiting lists at some centers have been six months or longer⁵⁶, although recent increases in the numbers of sleep centers has decreased wait times in most areas of the United States.⁵⁷ The data from these portable devices are relatively easy to interpret and data analysis is less time-consuming⁵⁸.

Potential disadvantages include lack of feasibility due to patient disability or transportation problems; possible unsatisfactory results obtained because of faulty placing of sensors or poor quality signals^{58, 59}; inability to diagnose position dependant OSA; and inaccurate diagnoses. Most portable devices are not able to diagnose other sleep disorders such as narcolepsy and restless leg syndrome. Thus, most studies of portable devices exclude patients with a high likelihood of sleep disorders other than obstructive sleep apnea. In addition, many portable home monitoring devices do not actually monitor sleep itself, making it impossible to determine the frequency of apneas and hypopneas per hour of sleep (AHI)⁵⁸.



In 1994 and 1999, a Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine reviewed the role of portable recording devices in the diagnosis of OSA in adults. Ferber et al⁵⁵ subsequently published a comprehensive review of published literature concerning the validity, clinical utility, advantages, and limitations of portable sleep monitoring devices. In 1996, an updated summary was published by Broughton et al⁴⁸. More recently both the Agency for Health Care Research and Quality and a joint task force of the American Academy of Sleep Medicine, The American College of Chest Physicians, and the American Thoracic Society updated systematic reviews on home diagnosis of sleep apnea and were unable to identify any clearly effective portable home devices.^{50, 60-62} Many different (and constantly upgraded) systems employing different technologies to obtain, store, and analyze data have been marketed. These devices use various sensors in a variety of combinations; they measure different physiological parameters depending on the model. Because each portable device measures a unique set of parameters and use proprietary algorithms to calculate an approximation of the AHI, the devices should not be evaluated as a class. Each unique device should be evaluated on its own merits.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

There are many portable devices approved by the FDA through the 510K program as substantially equivalent to predicate devices. There are at least two devices specifically noted in this assessment:

The Remmers Sleep Recorder (formerly SnoreSat) (SageTech Electronics Inc., Calgary, Alberta) received FDA 510(k) clearance in June 2002.

The Apnea Risk Evaluation System (ARES, Advanced Brain Monitoring, Carlsbad, CA) received FDA 510(k) clearance in October 2004.

The WATCH-PAT 100 (Itamar Medical, Inc) received FDA 510(k) clearance in November 2001. Several updated versions of the WATCH-PAT have received FDA 510(k) clearance.

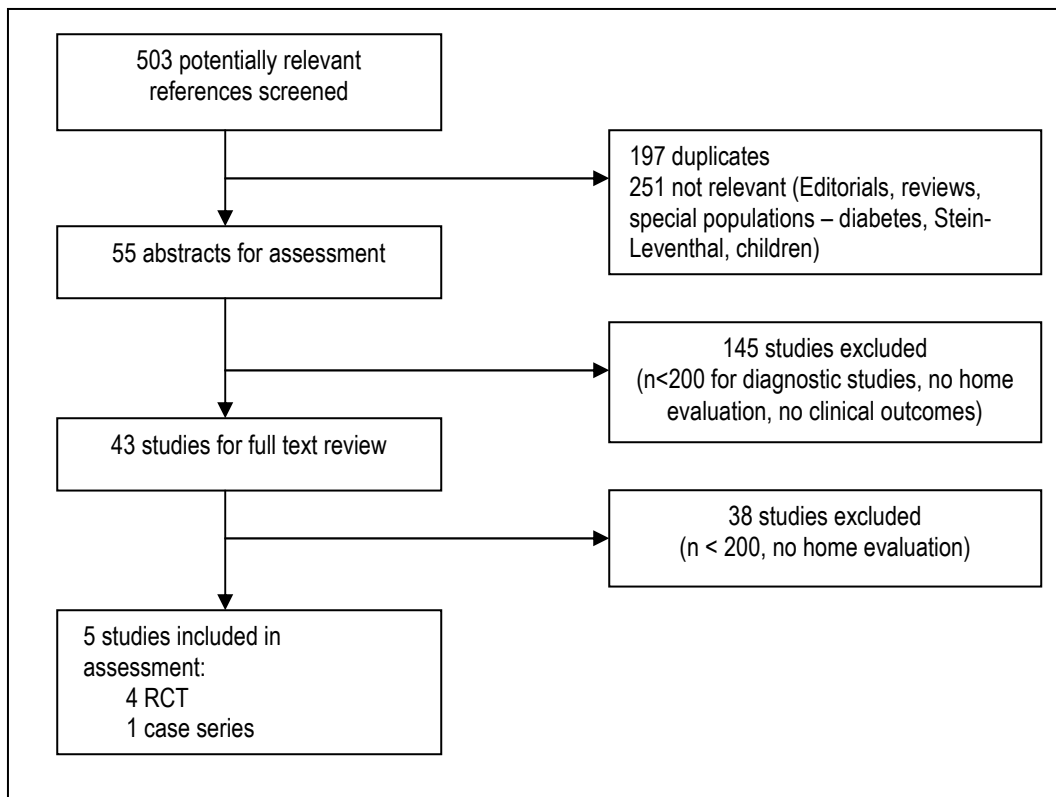
TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database, and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words sleep apnea, sleep study, polysomnography, home sleep study, home polysomnography, portable sleep study, portable polysomnography and sleep disorder breathing. The search was updated for the period from March 1, 2005 through January 21, 2008. The bibliographies of systematic reviews and key articles were manually searched for additional references.^{51, 52, 60-63} Further references were also solicited from the manufacturer, local experts and sleep societies. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

Full details of the search terms are included in Appendix 1. Figure 1 describes the search results. In brief, a total of 502 references were reviewed (199 from Embase, 128 from PubMed, 80 from the combined Cochrane databases, 95 from reference lists of articles and manufacturers).

Figure 1: Study Selection



Most studies of PM have had serious methodological flaws⁶⁴. First, often the validation data for these portable devices designed for unattended home use have been generated with the patient sleeping in the sleep laboratory in the presence of a technologist.^{55, 65, 66} The best validation studies compare data from portable devices used at home with data from full PSG as a “control” and have blinded the scoring of the full polysomnographic tracing to this study results of the home device under evaluation. Second, confounding some research studies are the long intervals between the full PSG and the home monitoring by portable devices. Third, studies have generally not included patients with few symptoms of OSA (and thus low pre-test probability of disease), so the utility of the devices as a screening tool in such cases cannot be determined.

In 1994, the American Sleep Disorders Association published standards⁴⁷ for the conduct of research studies investigating new diagnostic systems. These included: an independent, blind comparison with a reference standard; an appropriate spectrum of patients; avoidance of work-up bias; adequate detail regarding methods for performing the test; an adequate description of the study population; adequate sample size (estimated to be >200 patients); avoidance of selection bias; and an adequate description of the study setting. No new studies were identified comparing in laboratory PSG to home testing with at least 200 patients and the majority of studies evaluated in the prior study failed to meet this standard. The tables of studies evaluated in our 2005 review and the list of new, small studies investigating portable devices is included as Appendix 2.

Experts have noted a number of inherent difficulties in trying to compare one sleep diagnostic system to another. The most important problems are: (1) the lack of a true “gold standard” in assessing respiration during sleep and thus difficulties in detecting apneas and hypopneas; (2) the absence of a well-accepted cutoff for apnea-hypopnea frequency to make the diagnosis of obstructive sleep apnea; and (3) the night-to-night variability in measures of sleep and respiration that makes comparisons of home assessment versus in-laboratory evaluation difficult^{44, 58, 67, 68}. PSG results also can vary significantly from night to night. In one recent study, home monitoring had less variability over time than PSG.⁶⁹ Given the high night-to-night variability of in-lab PSG, it is clear that the results from home monitoring cannot be expected to precisely match those of PSG. The more important question is whether a home-based test and treat strategy can improve outcomes in patients with suspected obstructive sleep apnea to the same degree (or more) than a strategy based on in-lab polysomnography and CPAP titration.

The ideal study would randomize patients at multiple sites to either full PSG in the laboratory or home testing with a portable device and evaluate differences in the rates of motor vehicle accidents, sudden

death, strokes, myocardial infarctions, and total mortality. No such studies were identified. A much more feasible design would be to randomize patients as above and assess the short-term relative effects of the diagnostic approach on daytime somnolence, domains of cognitive function known to be associated with sleep apnea, quality of life, blood pressure, and measures of CPAP use. All patients should be evaluated, regardless of whether they were diagnosed with sleep apnea or received therapy with CPAP. Three new studies were identified that approximated this design.⁷⁰⁻⁷² One additional randomized trial was included in our 2005 review.⁷³ No comparative studies evaluating clinical outcomes using either concurrent controls or historical controls were identified, but we did include one case-series because it reported long-term clinical outcomes.⁷⁴

Level of evidence: 2 – 5 including studies from the prior reviews.

TA Criterion 2 is met.

TA Criterion 3: The technology must improve net health outcomes.

Randomized clinical trials

There have been four published randomized trials comparing the outcomes of a diagnostic strategy for OSA using a portable device designed for home use to that of a PSG-based strategy.⁷⁰⁻⁷³ See the Table below describing the studies and their principle findings. Two of the randomized trials (Whitelaw 2005 and Mulgrew 2007) used Remmers portable devices (formerly SnoreSat). The other two randomized trials (Townsend 2007 and Berry 2008) used the WatchPat device. Each of the studies is described in detail in the below Table.



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Table: Summary of Clinical Trials of Home Diagnosis for Obstructive Sleep Apnea

Study	Group	Age, years	F, %	BMI kg/m ²	ESS	AHI or RDI	OSA def.	OSA, %	CPAP attempted, %	CPAP continued, %	CPAP, hrs/night	Nights > 4 hours use, %	Residual AHI	Change ESS	Change FOSQ	Change SAQLI	
Randomized trials																	
Whitelaw 2005	Home	156	47	31.8	11.6	16.6	NA	NA	100	82	3.3	56	4.2	-3.4	NR	.82	
	PSG	132	47	32.1	11.6	26.0			100	82	3.8	62	5.7	-4.0		.92	
Mulgrew 2007	Home	33	55	21	39	14	27	RDI≥15	89	100	94	6.0	NR	2.5	-8.0	NR	1.9
	PSG	35	52	25	38	14	31			94	86	5.4	3.2	-10.0		2.2	
Townsend 2007	Home	50	44.1	22	34.2	14.3	28.3	RDI > 15 or RDI >5 and ESS > 10	86	70*	40*	4.0	NR	NR	-5.8	1.1	NR
	PSG	53	43.8	24	33.2	12.0	38.0		87	85	49	5.1		-6.0	1.8		
Berry 2008	Home	53	51.9	13	34.0	16.6	29.2	AHI≥5	96	85	75	5.2	72	3.5	-6.5	3.1	NR
	PSG	53	55.1	11	34.4	16.2	36.8		91	81	74	5.2	67	5.3	-7.0	3.3	
Cohort studies																	
Rice 2006	"Home"	106	59.9	0	33.5	13.1	31	AHI ≥ 5	90	87	77	NR	84	NR	-4.0	NR	NR

* 8 patients with oxygen saturation < 80% dropped from the home diagnosis group.

F	Female	OSA	Obstructive sleep apnea	PSG	Polysomnography
BMI	Body mass index	CPAP	Continuous positive airway pressure	NA	Not applicable
ESS	Epworth Sleepiness Scale	FOSQ	Functional outcomes of sleep questionnaire	NR	Not reported
AHI	Apnea-hypopnea Index	SAQLI	Sleep apnea quality of life index	RDI	Respiratory Distress Index

Whitelaw 2005

The goal of both PSG and the portable home devices is to identify patients who will benefit from treatment for OSA. Whitelaw et al⁷³ randomized patients referred to a sleep center to have either PSG or home monitoring. PSG was a standard full night diagnostic study. The primary outcome measure is unusual, making interpretation of the study difficult. The pre-defined definition of successful treatment was an improvement of at least 1.0 points on the Sleep Apnea Quality of Life Index (SAQLI). The home monitor was SnoreSat, Prior publications using Snoresat⁷⁵⁻⁷⁷ indicate that this is a Level IV device, although details of the methods used to define a positive test were not described in this article. After the diagnostic studies were performed, sleep specialists reviewed all data available for patients and predicted the likelihood of significant improvement with CPAP. Prediction was termed a success if the predicted success was <50% and the patient did not improve or if the predicted success was >50% and the patient did improve. It is not clear how patients with 50% predicted success were handled in the analyses. All patients then received four weeks of autoCPAP therapy at home. The machines included concealed compliance monitors. A total of 307 patients were randomized, but eight withdrew prior to the sleep studies and 11 others withdrew after learning their study results, but prior to CPAP (12% dropout). An additional 51 patients dropped out of the study prior to completing four weeks of CPAP, although 15 of these patients did complete a final SAQLI questionnaire. Of the 288 patients treated with CPAP, 132 were in the PSG group and 156 were in the home monitor group. The two groups were similar in age (47 years), body mass index (BMI) (32 kg/m²), neck circumference (41 cm) and score on the standard Epworth Sleepiness Scale (ESS) (11.6). Overall, 42% of patients met criteria for improvement (≥ 1 point increase in SAQLI). It is not clear from the paper how many patients were included in this analysis, but the maximum was 253 (82% of randomized patients). The correct prediction rate was 61% for patients who had PSG and 64% for patients who had home monitoring ($p=0.72$). There was no difference between the groups, but the ability to predict successful response to CPAP was poor in both groups.

The authors offer four reasons to explain the poor accuracy of predicting successful treatment with PSG or home monitoring. First, that the chain of events leading to success (low quality of life due to symptoms, symptoms due to OSA, patient tolerates CPAP, and benefits of treatment outweigh side effects) has so many uncertainties that predictive accuracy will always be poor. Second, there may be a placebo effect or regression to the mean. Third, patients judged to be at close to 50% probability of success are nearly impossible to predict successfully using the chosen definition of success. Finally, a one point improvement in the SAQLI may not be a good metric for successful treatment. The authors conclude that the home

monitor did as well as PSG and thus should replace PSG as the first step in evaluating patients with suspected sleep apnea.

The study suffers from many flaws. First, it appears that neither the participants, nor the investigators were blinded at any time during the study. No description of the randomization process was presented and there appears to have been no attempt at allocation concealment. At a minimum, patients could have been blinded to the results of their sleep studies until the completion of their CPAP trial, but the report indicates that some patients refused the CPAP trial after learning their sleep study results. Drop-out was also relatively high (23%) for a short clinical trial. Few details were given on the procedures for measurement and scoring of PSG and home monitoring. Finally, the predicted success rate was completely subjective: it appears that no objective guidelines were given to the physicians making the assessment. Many may also not agree with the study's definition of "successful treatment." However, the poor ability of PSG to predict successful treatment calls into question the utility of sleep studies to guide therapy.

Mulgrew 2007

Mulgrew et al reported the results of a randomized trial that compared the results of a diagnostic strategy based on home monitoring to laboratory PSG in patients at high risk for obstructive sleep apnea.⁷¹ Consecutive patients referred to a tertiary sleep center were screened for inclusion in the study. The primary inclusion criteria were a score on the ESS ≥ 10 and a Sleep Apnea Clinical Score ≥ 15 . Exclusion criteria included prior treatment for OSA, unwillingness to use CPAP, pregnancy, unstable angina, abnormal spirometry, unwillingness to sign the informed consent and significant psychiatric illness. All 81 of the potentially eligible patients were then evaluated with an awake CPAP trial: two were unable to tolerate the trial and were excluded from the study. The remaining 79 were screened overnight with the Remmers Sleep Recorder (formerly SnoreSat). Sixty-eight of these patients had an RDA ≥ 15 per hour and were willing to be randomized. The study randomized 35 patients to PSG for diagnosis and titration of CPAP and 33 patients to the ambulatory arm with autotitrating CPAP at home. The investigators used the same model of CPAP machine for patients in both arms of the study. After three months, 30 patients in the PSG arm and 31 patients in the ambulatory arm complete in lab PSG while receiving CPAP at their usual level. The primary outcome was the AHI on CPAP after three months of treatment. Secondary outcomes included changes in the scores on the ESS (higher is sleepier; 3 point change is clinically meaningful) and the Sleep Apnea Quality of Life Index (SAQLI; higher is better; 1 point change is clinically meaningful). The study was powered to demonstrate equivalence for final AHI with a minimum between group difference of less than

five events per hour. The investigators postulated that this would also give a minimum between group difference of less than one point on the SAQLI.

Among the patients eligible for randomization at baseline, 34 out of 36 (94%, 95% CI 81-99%) had an AHI > 15 per hour on PSG and thus met criteria for moderate to severe sleep apnea. After three months there was no difference in residual AHI on CPAP (polysomnography 3.2/hour; ambulatory 2.5/hour, $p=0.31$). The median decrease in sleepiness according to the ESS was clinically significant in both arms (PSG -10 points versus ambulatory -8 points, $p=0.26$). Quality of life using the SAQLI improved to a similar degree in both arms (2.2 versus 1.9, $p=0.69$). Compliance with CPAP was slightly worse in the PSG group (5.4 versus 6.0 hours per night, $p=0.021$), although the pressures required were nearly identical. All patients reported being satisfied with their treatment, although 62% of patients in the PSG group would have preferred home management compared to only six percent of the ambulatory group expressing a preference for management in the sleep laboratory.

Based on these results, the authors concluded that the PSG-based diagnostic and therapeutic approach offers no advantage over the ambulatory approach in the initial management of patients with a high probability of sleep apnea and may be inferior in terms of compliance with CPAP. They recommend that patients meeting criteria for this study ($ESS \geq 10$; $SACS \geq 15$; RDI by home monitoring ≥ 15 /hour) be treated with autotitrating CPAP adjusted at weekly intervals. Patients not meeting the above criteria or who don't improve with CPAP at two weeks would require PSG.

The primary concern with this study is generalizing it to the clinic. As pointed out by Dr. Bloch and colleagues in a letter to the editor, only three percent of patients referred to the sleep clinic met the criteria for randomization.⁷⁸ Thus, use of this algorithm would have little impact on resource use as almost all patients would still require PSG. The authors replied that 15% of all patients would have met the eligibility requirements, but many declined participation in the study because of time and distance constraints. Thus, they argue that the results are applicable to an important percentage of patients referred to sleep centers and likely represent those with the most significant disease who are thus at greatest need for early intervention with CPAP. The study was not blinded, but allocation concealment was maintained until all baseline measurements were completed. Their primary outcome, three month AHI by PSG on CPAP, was objective and thus less likely to be affected by the lack of blinding. There were some dropouts after randomization, but the authors attempted to assess the potential impact by sensitivity analyses and the conclusions remained unchanged. The trial was also relatively small and thus may have been underpowered to detect clinically important differences between the groups. For example, the upper bound

of the 95% confidence interval for the change in the ESS was four, a potentially clinically meaningful decrease in sleepiness in favor of PSG-guided therapy. However, to the investigators credit, the 95% confidence interval for their primary outcome was less than their pre-specified cutoff for equivalence of five events per hour (between group difference 0.8, 95% CI -0.9 to 2.3) and the difference in the median SAQLI was less than one (between group difference -0.19, 95% CI -0.7 to 0.3).

Townsend 2007

Townsend et al reported the results of a randomized trial of a home-based diagnostic strategy using the Watch PAT device.⁷² They screened 303 new patients seen at a sleep center for enrollment in the trial. The primary reasons for exclusion from the study (n=200) were other sleep disorders suspected (19%), age <18 or > 59 years (18%), refusal to participate (12%), complex medical history (10%) and a prior diagnosis of OSA (8%). They randomized the remaining 103 patients to evaluation and treatment of suspected OSA using either PSG in a sleep laboratory (N=53) or home diagnosis and treatment (n=50). Unfortunately, the study protocol called for any patients in the home diagnosis group with oxygen desaturations below 80% (n=8, 16%) to be excluded from the study after randomization and scheduled for PSG. Thus, subjects with the most severe desaturations were excluded from the home diagnosis group, but not the PSG group. This fundamental violation of randomization calls into question the validity of any of the study results. There were no significant differences between the two groups in age (44 years), sex (23%), and body mass index (33.7 kg/m²).

The investigators' algorithm called for subjects in either arm who had an RDI > 15 to be treated with auto-CPAP or CPAP as well as any subjects with an RDI of 6 to 15 and an ESS > 10. Subjects who tolerated CPAP were evaluated at eight weeks and at six months using the ESS, the SF-36, the Functional Outcomes of Sleep Questionnaire (FOSQ), the Beck Depression Index (BDI) and measures of CPAP utilization.

Two subjects (4%) in the home diagnosis group had incomplete data collection, but one was able to successfully complete the home diagnosis on a second night. Six subjects in the home diagnosis group (12%) and seven in the PSG group (13%) did not have significant OSA (RDI ≤ 15 and ESS ≤ 10) and were not followed up in the study. An additional 19 patients in the PSG group failed CPAP or did not return for the eight-week evaluation. Similarly, 15 patients in the home diagnosis group failed CPAP or did not return for the eight-week evaluation. Thus, only 26 out of 53 (49%) subjects randomized to PSG had follow-up data at eight weeks and only 20 subjects at six months. Correspondingly, only 20 out of 50 (40%) subjects randomized to home diagnosis had follow-up data at eight weeks and only 14 subjects at six months.

The RDI at baseline was higher in the PSG group (38.0 versus 28.3, $p=0.03$). At eight weeks, the ESS had declined from 12.0 to 6.0 in the 26 subjects remaining in the PSG group and from 14.3 to 8.5 in the 20 subjects in the home diagnosis group ($p=0.05$ between the two groups). No other significant differences between the two groups were found at eight weeks or six months, eight subscales of the SF-36, five subscales of the FOSQ, or on the BDI. Hours of CPAP use were higher in the PSG group at eight weeks (5.1 versus 4.0, $p=0.04$).

In general, outcomes favored the PSG group, although the large numbers of exclusions and loss to follow-up at eight weeks and six months makes it difficult to draw any meaningful conclusions about outcomes with the two approaches to the diagnosis and treatment of OSA. Excluding the eight subjects with very low oxygen saturation overnight in the home testing group from inclusion in that group may have removed the subjects who would benefit the most from CPAP, thus biasing the results against the home treatment arm. Higher quality studies are needed to answer this question.

Berry 2008

Berry et al. published the most recent randomized trial of a home diagnostic strategy that also used the Watch PAT100 device to diagnose OSA.⁷⁰ All patients referred to a single sleep center for evaluation of suspected OSA were considered for inclusion in the study. Patients were eligible if they had significant daytime sleepiness ($ESS \geq 12$) and at least two of the following: habitual loud snoring, witnessed apneic episodes, or treatment for hypertension. Patients were excluded if they had congestive heart failure, chronic obstructive pulmonary disease, arrhythmias, used supplemental oxygen at night, used certain medications (potent narcotics, alpha blockers), suspected other causes for sleepiness, or if they lived more than 200 miles from the sleep center.

Patients randomized to the PSG group underwent CPAP titration if their AHI was ≥ 10 per hour during the first two hours of monitoring. Otherwise, patients with an AHI ≥ 5 per hour underwent CPAP titration on a second night. Patients randomized to the home diagnosis arm applied the Watch PAT device themselves at home. When they brought the device back, the AHI was calculated using a proprietary algorithm and patients with an AHI ≥ 5 per hour were fitted with a mask and sent home with an auto-titrating positive airway device. Both groups were then offered treatment with CPAP. Those accepting CPAP were treated using the same device (REMstar Pro with C-Flex and heated humidity). Patients with an AHI < 5 after their initial study were re-evaluated using the alternate diagnostic test. The primary outcome was a comparison of the mean hourly use of CPAP among patients still using CPAP after six weeks. The ESS and FOSQ were

measured at baseline and after six weeks on CPAP. Satisfaction with CPAP and the residual AHI were also assessed.

The study randomized 106 patients (53 to each group). The subjects were on average about 53 years old, 12% were female and the average BMI was about 34 kg/m². The mean ESS was just over 16 in both groups. There were no significant differences between groups at randomization or between the groups using CPAP at six weeks. Ten subjects did not have OSA when tested as randomized. Two of six patients randomized to PSG had an AHI < 5, but met criteria for OSA when re-assessed by home diagnosis. Similarly, one of four patients randomized to home diagnosis had an AHI < 5, but met criteria for OSA when re-assessed by PSG. Patients in the home diagnosis group were slightly more satisfied (6.5 versus 5.6, p NS). In the home diagnosis group, 51 out of 53 (96%) were diagnosed with OSA, 45 out of 53 (85%) accepted setup of CPAP, and 40 out of 53 (75%) completed follow-up through six-weeks. In the PSG group, 48 out of 53 (91%) were diagnosed with OSA, 43 out of 53 (81%) accepted setup of CPAP, and 39 out of 53 (74%) completed follow-up through six-weeks.

Outcomes in the two groups were similar at six weeks. The average number of hours per night of CPAP use was 5.2 hours in each group and the residual AHI was 3.5 per hour in the home diagnosis group compared to 5.3 per hour in the PSG group (p NS). The ESS score declined by 6.5 points in the home diagnosis group and by 7.0 points in the PSG group. Functional outcomes, assessed by the FOSQ, improved by 3.1 points in each group. None of the differences were statistically or clinically significant.

As in the previous studies, the vast majority of patients randomized in this study had OSA (93%), although several were missed on initial testing. The percentage diagnosed after the initial study was similar in each group as was the percentage accepting CPAP and continuing CPAP use. There were no significant differences between the home diagnosis group and the PSG group, although the authors do not present the 95% confidence intervals for the differences between groups and the sample size is relatively small. Thus, it is difficult to assess the range of potential differences between the two groups.

Cohort studies

Rice 2006

Rice et al published data from a cohort of 106 patients at the Veterans Administration (VA) that used unattended PM as part of their diagnostic algorithm for OSA.⁷⁴ A pulmonary specialist assessed patients referred for a sleep evaluation. Patients with a high likelihood of OSA and no evidence suggesting another

sleep disorder or severe cardiopulmonary disease were offered overnight evaluation with the portable Embletta device, although all studies were performed at an outpatient center at the VA rather than at the subject's home. The Embletta device is a type 3 monitor with an oral thermistor, a nasal flow sensor, a snore microphone, a pulse oximeter and strain gauges to measure thoracic and abdominal expansion. Patients with an AHI < 5 per hour were referred to the sleep center for possible PSG. All subjects were men and their mean age was 60 years. Their BMI averaged 33.5 kg/m² and their average ESS was 13.1. Patients with an AHI ≥ 5 per hour were diagnosed with OSA (average AHI 31 per hour) and sent home with auto-CPAP for titration and then a CPAP machine with settings based on the auto-CPAP results. In the cohort, 95 out of 106 (90%) were diagnosed with OSA, 92 out of 106 (87%) accepted setup of CPAP, and 82 out of 106 (77%) completed follow-up through six-months. The ESS score declined by an average of 4 points in subjects evaluated at six months and 69 out of 82 (84%) reported good adherence to CPAP. At one year, 23% of patients reported that their symptoms were much better and an additional 67% reported that their symptoms were slightly or moderately better. Only ten percent reported that their symptoms had not improved. Among the subjects with an AHI < 5 per hour using the portable device, two of the seven (29%) had an AHI > 5 on PSG testing and were offered CPAP therapy. The number of subjects diagnosed with OSA when evaluated a second time were similar to those reported by Berry et al⁷⁰ and likely reflect expected night to night variation in the severity of OSA.

This study does not help with direct comparisons of the efficacy of home-based OSA diagnosis to that of PSG-based diagnosis, but it does report the longest follow-up and describes one organization's response to the demand for sleep studies given limited resources. Unfortunately, the investigators do not describe their procedures for deciding who should receive portable testing in sufficient detail to replicate their approach at other sites. As in the randomized trials described above, the proportion of patients in the study eventually diagnosed with OSA was quite high (>85% in all studies). The similarity of the CPAP acceptance rate and improvements in ESS (see Table) for subjects in this study to those in the randomized trials suggest that this diagnostic and treatment strategy might be viable alternative to one based on PSG.

Summary

The randomized trial published by Mulgrew et al⁷¹ defines a clear population of patients to assess at home with the PM (those with ESS ≥ 10 and SACS ≥ 15, no other cause of somnolence). Those patients with an RDI ≥ 15 measured using the Remmers Sleep Recorder at home would then be offered autotitrating CPAP. All patients not meeting these criteria and those failing auto-CPAP would be referred for full PSG. In the randomized trial, patients randomized to this ambulatory approach had similar quality of life and sleepiness

outcomes at three months and were slightly more compliant with use of CPAP when compared with treatment based on PSG. This trial adds to the findings of the randomized trial described in the prior review, which found that the results of home monitoring with the SnoreSat (earlier version of Remmers Sleep Recorder) was as useful as PSG in predicting which patients would respond to CPAP.

Similarly, there are two randomized trials using the WatchPat device.^{70, 72} The trial of Berry et al is of much higher quality, but both studies find that patients treated for OSA diagnosed with a portable device at home have significant reductions in daytime sleepiness by the ESS and improvements in functional outcomes assessed by the FOSQ. All four studies used a combination of validated questionnaires and clinical criteria to identify patients with a low likelihood of an alternate cause for sleep disturbance who were at very high risk for OSA. More than 90% of patients in all four of the studies were eventually diagnosed with OSA. The utility of home diagnosis in more complex patients or patients at lower risk for sleep apnea remains unclear.

TA Criterion 3 is met for the Remmers Sleep Recorder when used in conjunction with the ESS and SABCS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 3 is met for the WatchPat 100 when used in conjunction with the ESS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 3 is not met for any other portable devices when used to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The major established alternative to home studies is full PSG. The published data summarized in this and the prior review suggest that Level II, Level III, and Level IV portable devices used unattended at home do not achieve results comparable to full in-laboratory PSG in the diagnosis of OSA. However, it is widely acknowledged that PSG is an imperfect gold standard. The results are not highly correlated with symptoms or response to CPAP.⁷⁹⁻⁸² There is often significant variability from night to night using the same PSG equipment^{45, 83-85} and significant variability in trained readers' interpretation of the PSG data.⁸⁶⁻⁸⁸

However, the goal of both PSG and the portable home devices is to identify patients who will benefit from treatment for OSA. As described above, four clinical trials⁷⁰⁻⁷³ randomized patients referred to a sleep center



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to have either PSG or home monitoring. They found no important between group differences in rates of diagnosis of OSA, use of CPAP, daytime sleepiness, quality of life, and functional outcome measures from one to twelve months after randomization. The primary problem with the Mulgrew trial⁷¹ was the wide confidence intervals around estimates of effectiveness due to the small sample size. Some clinically important differences in outcome could not be ruled out. Furthermore, the results only apply to a limited portion of the patients referred to sleep centers (3% in trial; 15% of all patients according to the investigators) and it was performed at one tertiary care center. The fact that three additional randomized trials studies confirmed that home diagnosis is comparable to management based on PSG suggests that the devices used in the trials can be used to diagnose OSA in high risk patients. Further study is needed to evaluate whether home testing can be extended to more complex patients or those at lower risk for sleep apnea. It also remains unclear whether any diagnostic study is necessary in these very high risk patients as the AHI, even by PSG, is a poor predictor of response to CPAP. Some investigators have argued for and evaluated a strategy of instituting auto-titrated CPAP in high risk patients without any diagnostic strategy other than being a sleepy person (ESS \geq 8) who snores and has been referred for a sleep study.⁸⁹ Additional comparative studies need to be performed to identify the optimal approach for different subgroups of patients.

Decision Analysis

In the absence of large, randomized clinical trial evidence, decision analysis is often performed to model the relative risks and benefits for alternative diagnostic or therapeutic pathways. Several studies were evaluated for the last review and that consistently found PSG to be the preferred approach, even with unrealistically high estimates for the sensitivity and specificity of portable monitoring in the home.^{54, 90, 91} However the trials in patients at high risk for OSA suggest that similar proportions of patients will be adequately treated with CPAP, regardless of the diagnostic approach. Thus, some of the assumptions underlying these models may be flawed. In particular, some of these studies assumed that there are no false negatives with PSG. This is clearly not true. The false negative rate from a single night of PSG is at least 20% and has been reported to be as high as 43%.^{45, 92, 93} Given the uncertainty of the inputs into the decision analytic models at this time, little weight should be placed on their results.

TA Criterion 4 is met for the Remmers Sleep Recorder when used in conjunction with the ESS and SABCS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 4 is met for the WatchPat 100 when used in conjunction with the ESS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.



TA Criterion 4 is not met for any other portable devices when used in conjunction with the ESS to identify and institute treatment in patients at very high risk for obstructive sleep apnea.

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

Portable home monitoring devices have been used in dozens of studies in a wide variety of clinical settings. There are some problems with failure to acquire data when monitors are incorrectly applied or become detached during home monitoring. However, the comparative trials suggest that this limitation can be overcome for the vast majority of patients. Most of the trials have been single center trials at sites with extensive experience with the use and interpretation of portable devices. Until further data is available, use of these devices should be limited to centers with expertise in home monitoring using the devices studied in the clinical trials.

TA Criterion 5 is met.

CONCLUSION

The validation trials of home portable monitoring devices are difficult because of known night to night variability in the AHI measured by full PSG, known first night effects when patients are monitored, probable differences between sleep patterns in the laboratory and at home, and the limited correlation of AHI with health outcomes and response to CPAP. In fact, portable home testing may be better at predicting which patients will respond to treatment with CPAP or other interventions for OSA. Published reports of diagnostic accuracy are difficult to compare as they use many different recording devices and different definitions of RDI to define OSA. Many of the studies present analyses using multiple cutpoints for AHI to define sleep apnea and determine optimal cutpoints for the portable device based on data obtained in the study. Such results almost always provide overly optimistic estimates for sensitivity and specificity when the cutpoint is validated in an independent study.

Four randomized trials using two different portable devices (Remmers Sleep Recorder; Watch PAT) compared outcomes of therapeutic interventions (e.g., nasal CPAP) based on home studies to those based on full in-laboratory PSG. The studies were small, each from a single center, and did not evaluate the most important outcomes associated with OSA (motor vehicle accidents, strokes, sudden death, myocardial infarctions). However, each study demonstrated equivalence of an ambulatory strategy incorporating portable home monitoring to PSG for the following outcomes: AHI on CPAP, sleepiness, and quality of life or functional status. All of these studies excluded patients with other potential explanations for their sleepiness



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and used a variety of strategies to ensure a high pre-test probability for obstructive sleep apnea. In the four studies, more than 90% of the patients had a final diagnosis of obstructive sleep apnea.

It is likely that other PMs have a role in the efficient diagnosis of OSA. Further trials comparing the sensitivity and specificity of these devices to the imperfect gold standard, PSG, will never be sufficient to demonstrate their clinical utility. Rather, studies should focus on identifying those patients in whom treatment guided by home monitoring gives results that are equivalent to PSG. Ideally randomized clinical trials will demonstrate that these techniques can rival or exceed the outcomes achieved by laboratory-based PSG.

RECOMMENDATION

It is recommended that the use of two portable home devices (Remmers Sleep Recorder, WatchPat) to diagnose OSA meets technology assessment criteria 1 through 5 for safety, effectiveness, and improvement in health outcomes in patients at very high risk for OSA and unlikely to have another cause for their sleepiness.

March 11, 2009

This technology was previously reviewed by the California Technology Assessment Forum in June 2005

The California Technology Assessment Forum panel voted to accept the recommendation as presented.



RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center Medical Advisory Panel has not conducted a formal review of this topic.

Centers for Medicare and Medicaid Services (CMS)

The CMS issued a National Coverage Determination on March 3, 2009 which allows for coverage of Type 1, II, III or IV devices for the diagnosis of Obstructive Sleep Apnea.

<https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=227&>

American Academy of Sleep Medicine (AASM)

From the AASM web site:

Using evidence review and a consensus process, the AASM task force developed clinical guidelines that were approved by the AASM board of directors and published in the December 15, 2007, issue of the *Journal of Clinical Sleep Medicine*. The guidelines recommend the use of PM by AASM-accredited sleep disorders centers and labs under the direction of a board-certified sleep specialist for the diagnosis of OSA in select adults. The guidelines are available at:

<http://www.aasmnet.org/Resources/ClinicalGuidelines/030713.pdf>

California Thoracic Society (CTS)

A CTS representative attended the meeting to provide opinion and participated in discussion regarding this technology.

American College of Cardiology, California Chapter (CA ACC)

A CA ACC representative attended the meeting to provide an opinion regarding the use of this technology.

Agency for Healthcare Research and Quality (AHRQ)

An AHRQ Technology Assessment: Obstructive Sleep Apnea-Hypopnea Syndrome: Modeling different diagnostic strategies dated December 4, 2007 is available at:

<http://www.cms.hhs.gov/determinationprocess/downloads/id50TA.pdf>



ABBREVIATIONS USED IN THIS REVIEW

CTAF	California Technology Assessment Forum	VA	Veteran’s Administration
CMS	Centers for Medicare and Medicaid Services	ARES	Apnea Risk Evaluation System
CPAP	Continuous positive airway pressure		
OSA	Obstructive sleep apnea		
AHI	Apnea-hypopnea index		
PSG	Polysomnography		
EEG	Electroencephalography		
EOG	Electro-oculography		
ECG	Electrocardiography		
RDI	Respiratory disturbance index		
PM	Portable monitors		
DARE	Database of Abstracts of Reviews of Effects		
BMI	Body mass index		
ESS	Epworth Sleepiness Scale		
SAQLI	Sleep Apnea Quality of Life Index		
FOSQ	Functional Outcomes of Sleep Questionnaire		
BDI	Beck Depression Index		

Appendix 1: Detailed search criteria

Pubmed Search

PubMed, run date Jan 21, 2009, data file pubmed_128.txt

Search	Most Recent Queries	Time	Result
#18	Search #3 OR #6 OR #15 NOT REVIEW[PT] Limits: Publication Date from 2005/03 to 2009, English	17:38:04	128
#17	Search #3 OR #6 OR #15 Limits: Publication Date from 2005/03 to 2009, English	17:37:54	144
#16	Search #3 OR #6 OR #15	17:37:30	633
#15	Search #4 AND #14 AND (AMBULATORY[TI] OR HOME[TI] OR HOMES[TI] OR PORTABLE*[TI] OR DOMICIL*[TI]) AND (IN PROCESS[SB] OR PUBLISHER[SB] OR PUBMEDNOTMEDLINE[SB] OR SLEEP APNEA, OBSTRUCTIVE/PHYSIOPATHOLOGY)	17:37:15	23
#14	Search OBSTRUCTIVE SLEEP APNEA OR OBSTRUCTIVE SLEEP APNOEA*	17:36:14	10161
#6	Search #1 AND #4 AND #5	17:30:52	467
#5	Search AMBULATORY OR HOME OR HOMES OR PORTABLE* OR DOMICIL*	17:30:42	250410
#4	Search POLYSOMNOGRAPHY OR POLYSOMNOGRAPH* OR ELECTROCARDIOGRAPHY OR OXIMETRY	17:30:30	175828
#3	Search #1 AND #2	17:30:13	563
#2	Search AMBULATORY CARE[MH] OR HOME CARE SERVICES[MH] OR MONITORING, AMBULATORY[MH] OR HOME OR HOMES OR PORTABLE* OR DOMICIL*	17:29:56	211157
#1	Search SLEEP APNEA, OBSTRUCTIVE/DI OR SLEEP APNEA SYNDROMES/DI[MH:noexp] OR APNEA/DI[MAJR:noexp]	17:29:41	5094

Embase Search



run date Jan 21, 2009, datafile embase_199.enw

No.	Query	Results	Date
#2	'sleep apnea syndrome'/de OR 'sleep disordered breathing'/mj OR 'sleep disorder'/mj OR 'obstructive sleep':ti OR 'apnea'/dm_di/mj	26,515	21 Jan 2009
#3	'polysomnography'/de OR 'electrocardiography'/exp OR 'electrocardiography monitoring'/de OR 'oximetry'/exp OR 'instrumentation'/de OR 'electrocardiography monitoring'/de OR 'monitor'/de	321,751	21 Jan 2009
#4	ambulatory OR home OR homes OR portable* OR domicil*	267,018	21 Jan 2009
#5	#2 AND #3 AND #4	775	21 Jan 2009
#6	#2 AND #3 AND #4 AND [english]/lim AND [2005-2009]/py	222	21 Jan 2009
#7	#2 AND #3 AND #4 AND [english]/lim AND ([review]/lim OR [short survey]/lim) AND [2005-2009]/py	23	21 Jan 2009
#8	#6 NOT #7	199	21 Jan 2009

Cochrane Search:

Cochrane Library (Issue #1, 2009), run date Jan 22, 2009, datafiles CLtrials62, CLhta2, CLhta16

ID	Search	Hits	Edit	Delete
#1	(SLEEP APNEA* OR SLEEP APNOEA* OR OBSTRUCTIVE SLEEP APNEA* OR OBSTRUCTIVE SLEEP APNOEA* OR SLEEP DISORDER*) and (AMBULATORY OR HOME OR HOMES OR PORTABLE* OR DOMICIL*) and (DIAGNOS* OR MONITOR* OR POLYSOMNOGRAP*) , from 2005 to 2009	144	edit	delete
#2	"obstructive sleep" , from 2005 to 2009 in Technology Assessments	16	edit	delete

#1 Show Results in:

~~Cochrane Reviews [66]~~ | ~~Other Reviews [5]~~ | [Clinical Trials \[62\]](#) | [Methods Studies \[0\]](#) | [Technology Assessments \[2\]](#) | ~~Economic Evaluations [3]~~ | ~~Cochrane Groups [6]~~
(Strikethrough – refs not relevant & not exported)

#2 Show Results in:

[Technology Assessments \[16\]](#)

Appendix 2: Tables from 2005 review and diagnostic studies since March 2005

TABLE 1. American Sleep Disorders Association levels for portable recording equipment for sleep-disordered breathing				
	Level 1 standard	Level II comprehensive	Level III modified portable	Level IV continuous
	polysomnography	portable polysomnography	sleep apnea testing	single - or dual- bioparameter recording
Parameters	Minimum of seven, including EEG (C4-A1 or C3-A2), EOG, chin EMG, ECG, airflow, respiratory effort, oxygen saturation	Minimum of seven, including EEG (C4 -A1 or C3-A2), EOG, chin EMG, ECG or heart rate, airflow, respiratory effort, oxygen saturation	Minimum of four, including ventilation (at least two channels of respiratory movement or respiratory effort or airflow), heart rate, ECG, oxygen saturation	Minimum of one, e.g., oxygen saturation
Body position	Documented or objectively measured	May be objectively measured	May be objectively measured	Not measured
Leg movement	EMG or motion sensor desirable but optional	EMG or motion sensor desirable but optional	May be recorded	Not recorded
Personnel	In constant attendance	Not in attendance	Not in attendance	Not in attendance
Interventions	Possible	Not possible	Not possible	Not possible



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Table 2. Published Validation Studies of Level II Portable Monitoring Devices in Diagnosis of OSA

First Author, Year	No. Patients	Device; Site, Protocol	Parameters Measured	% Data Loss	OSA Diagnosis									
					AHI	Sensitivity	Specificity	Prevalence	TP	FP	FN	TN	LR+	
Orr, 1994	40	Sleep I/T	EEG, EOG, EMG,		>15/h	100%								
		In-lab attended	tracheal noise, SaO ₂ ,											
			chest, abdominal movement, wrist activity											
Whittle, 1995	70	Nightwatch	EOG, leg movements,		> 10/h	91%	70%							
		In-lab attended	SaO ₂ , nasal-oral airflow,											
		Versus	chest, abdominal movement, Home unattended body position, HR											
White, 1995	30	Nightwatch;	EOG, EMG, SaO ₂ ,											
		In-lab attended	nasal-oral airflow, chest,		> 10	100%	64%							
		Versus	abdominal movement, HR											
Ancoli – Israel, 1997	70	Home unattended			> 10	91%	70%							
		Nightwatch;	EOG, EMG, chest,											
		Home unattended	abdominal movement, nasal airflow, SaO ₂ , body position, HR		>10	100%	66%							
Portier, 2000	103	Minisomno at	EEG, EMG, EOG,	20%	> 15/h	84%								
		home versus	nasal-oral airflow, chest,											
		Respisomnograph	abdominal movement, SaO ₂	5%										
Iber, 2004	76	In-lab												
		PS-2	EEG, ECG,	16%	>26.8	90%	63%	75%	43	6	5	10	2.4	
		Home unattended	nasal-oral airflow, chest, abdominal movement, SaO ₂											
AVERAGE (MEAN)						92%	68%							
Note: AHI = Apnea – hypopnea index			TP = True positive	LR+ = Positive likelihood ratio										
OSA = Obstructive sleep apnea			FP = False positive	LR- = Negative likelihood ratio										
RDI = Respiratory disturbance index			FN = False negative	SaO₂ = Arterial oxygen saturation										
			TN = True negative	HR = Heart rate										



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Table 3. Published Validation Studies of Level III Portable Monitoring Devices in Diagnosis of OSA

First Author,	No.	Prevalence	Device;	Parameters	%	OSA Diagnosis								
Year	Patients	OSA	Site, Protocol	Measured	Data Loss	AHI	Sensitivity	Specificity	TP	FP	FN	TN	LR+	LR-
Ancoli - Israel, 1981			Medilog;	Chest wall movement,										
	36		In-lab attended (36);	leg movement, body	23%	>30/night	100%	97%						
	36		Home unattended (36)	movement	25%	>30/night	78%	92%						
Gyulay, 1987	14		Vitalog PMS - 8;	Chest wall movement,	15%	>5	100%	83%						
			In-lab attended	respiratory paradox, S _a O ₂ , HR,										
				body movement										
Salmi, 1989	55		SCSB, themistor	Body movement, air flow,	0%	>5	100%	86%						
			and pulse oximetry	S _a O ₂										
Emsellem, 1990	67		Edentrace 2700;	Nasal/oral airflow, chest	6%	>5	95%	96%						
			In-lab attended	wall movement, S _a O ₂ , HR										
Svanborg, 1990	77		SCSB and pulse oximetry;	Respiratory movement, S _a O ₂	0%	>5	100%	67%						
			In-lab attended											
Redline, 1991	25		Edentrace 4700 ;	Nasal/oral airflow, chest	9%	>10	95%	100%						
			In-lab attended (20)	wall movement, S _a O ₂ , HR,										
			Home unattended (5)	body movement										
Stoohs, 1992	56		MESAM 4;	S _a O ₂ , HR , snoring,	0%	>10	92%	97%						
			In-lab attended	body position										
Man, 1995	104		Poly G	Oronasal flow, chest,		>15	86%	95%						
			In-lab attended	abdominal movement, S _a O ₂ ,		> 5	83%	92%						
				ECG, body position				83%						
Parra, 1997	89		Endentrace 3711;	Nasal /oral airflow, chest	10%	>23	63%	93%						
			Home attended (50)	wall movement, S _a O ₂ , HR,		>18	73%	80%						
			Home unattended (39)	snoring, body position		>8	95%	33%						
Whittle, 1997	23		Edentrace 3711;	Nasal / oral airflow, chest wall	13%	>20	Correlation of home with in-lab							
			In-lab attended	movement, ECG, S _a O ₂			study r = 0.8 , p < .001							
			plus											
			Home unattended											
	149		Edentrace 3711;		18%	>30								
			Home unattended											
AVERAGE (MEAN)							91%	86%						

Table 3A. Recently Published Validation Studies of Level III Portable Monitoring Devices in Diagnosis of OSA														
First Author,	No.	Prevalence	Device;	Parameters	% Data	OSA Diagnosis								
Year	Patients	OSA	Site, Protocol	Measured	Loss	AHI	Sensitivity	Specificity	TP	FP	FN	TN	LR+	LR-
HOME														
White, 1995	70	61%	NightWatch	Nasal/oral airflow, chest	3%	>10	91%	70%	39	8	4	19	3.1	0.13
	70	41%	Home	movement, abdominal movement,		>20	86%	83%	25	7	4	34	5.0	0.17
			Tech set-up	SaO ₂ , HR, eye movement, leg movement										
Shafer, 1997	114	70%	MESAM 4	Body position, SaO ₂ , HR, sound/snoring	0%	>10	95%	41%	76	20	4	14	1.6	0.12
Golpe, 2002	44	52%	ApnoeScreen I	Nasal/oral airflow, body	20%	>10	78%	71%	18	6	5	15	2.7	0.30
			Home	position SaO ₂ , HR, w/wo tech set-up	33%									
Dingli, 2003	50	82%	Embletta	Nasal/oral airflow, chest	18%	≥10	93%	100%	38	0	3	9	∞	0.07
			Home	movement, abdominal movement, SaO ₂ , HR, body position										
Reichert, 2003	46	48%	NovaSom QSG	Nasal/oral airflow, chest	12%	≥15	91%	83%	20	4	2	20	5.5	0.11
			Home	wall movement, SaO ₂ , HR, Unattended										
Fietze, 2004	18	61%	MESAM-4	Sleep diary, body	0%	>15	91%	57%	10	3	1	4	2.1	0.16
			Home	position, SaO ₂ , HR, sound/snoring										
Pittman, 2004	29	76%	Watch PAT 100	PAT, SaO ₂ , Lab attended	0%	≥15	95%	100%	21	0	1	7	∞	0.05
			ApnoeScreen II	Nasal/oral airflow, body	9%	≥10	79%	98%	23	1	6	45	36.5	0.21
Quintana-Gallego, 2004	75	39%	Home	position SaO ₂ , HR, chest		≥15	68%	95%	13	3	6	53	12.8	0.33
			w/ tech set-up	movement, abdominal movement, wrist actigraphy										
Total Home pooled	446	61%					90%	76%	245	42	26	133	3.8	0.13



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LAB															
White, 1995	30	63%	NightWatch	Nasal/oral airflow, chest	0%	>10	100%	64%	19	4	0	7	2.8	0.00	
	30	43%	Lab attended	movement, abdominal movement,		>20	77%	88%	10	2	3	15	6.5	0.26	
				SaO2 , HR, eye movement,											
				leg movement											
Ballester, 2000	116	24%	Sibel Home 300	Nasal/oral airflow, chest	0%	>10, RDI>6	89%	92%	25	7	3	81	11.2	0.12	
			Lab attended	wall impedance, SaO2 , body											
				position, sound/snoring											
Verse, 2000	53	43%	POLY-MESAM	Nasal/oral airflow, chest	0%	>5	87%	97%	20	1	3	29	26.1	0.13	
	53	47%	Lab attended	wall movement, abdominal wall		>10	92%	96%	23	1	2	27	25.8	0.08	
				movement, SaO2 , HR, body position											
				ECG, sound/snoring											
Claman, 2001	42	50%	Bedbugg	Nasal/oral airflow, chest	0%	>15	86%	95%	18	1	3	20	18.0	0.15	
			Lab attended	wall movement, SaO2 , HR,											
				sound/snoring											
Ficker, 2001	60	58%	SomnoCheck	Nasal/oral airflow, body	0%	≥10	97%	100%	34	0	1	25	∞	0.03	
	60	40%	Lab attended	position, SaO2 , HR,		≥20	75%	100%	18	0	6	36	∞	0.25	
				sound/snoring											
Marrone, 2001	50	84%	POLY MESAM	Nasal/oral airflow, chest	0%	≥10	95%	100%	40	0	2	8	∞	0.05	



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			Lab attended	movement, abdominal movement,											
				SaO2 , HR, body position											
				ECG, sound/snoring											
Calleja, 2002	79	81%	MERLIN	Nasal/oral airflow, chest	8%	≥10	91%	87%	58	2	6	13	6.8	0.11	
			Lab unattended	movement, abdominal movement,											
				SaO2 , HR, body position											
				sound/snoring											
Dingli, 2003	38	74%	Embletta	Nasal/oral airflow, chest	3%	≥10	82%	100%	23	0	5	10	∞	0.18	
			Lab attended	wall movement, abdominal wall											
				movement,											
				SaO2 , HR, body position											
Pillar, 2003	68	59%	Watch PAT 100	PAT, SaO2 ,	0%	≥20	80%	79%	32	6	8	22	3.7	0.25	
			Lab attended	HR, wrist actigraphy											
Reichert, 2003	44	48%	NovaSom QSG	Nasal/oral airflow, chest	0%	≥15	95%	91%	20	2	1	21	11.0	0.05	
			Lab attended	wall movement, SaO2 , HR,											
				sound/snoring											
Pittman, 2004	29	76%	Watch PAT 100	PAT, SaO2 ,	0%	≥15	91%	86%	20	1	2	6	6.4	0.11	
			Lab attended	HR, wrist actigraphy											



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Su, 2004	60	68%	SNAP	Nasal/oral airflow, chest	0%	≥10	88%	74%	36	5	5	14	3.3	0.17	
	60	52%	Lab attended	wall movement, SaO ₂ , HR, sound/snoring		≥15	84%	76%	26	7	5	22	3.5	0.21	
Total Lab pooled	669	57%					90%	90%	345	29	39	256	8.8	0.11	
Note: AHI = Apnea - hypopnea index				TP = True positive		LR+ = Positive likelihood ratio									
OSA = Obstructive sleep apnea				FP = False positive		LR- = Negative likelihood ratio									
RDI = Respiratory disturbance index				FN = False negative		SaO₂ = Arterial oxygen saturation									
PAT= Peripherlal arterial tone				TN = True negative		HR = Heart rate									



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Table 4. Published Validation Studies of Level IV Portable Monitoring Devices in Diagnosis of OSA

First Author, Year	No. Patients	Device; Site, Protocol	Parameters Measured	OSA Diagnosis			Comments	TP	FP	FN	TN	LR+	LR-
				RDI	Sensitivity	Specificity							
Farney, 1986	54	Pulse oximetry	Sa O2	>5	80%	71%							
Bonsignore, 1990	83	Pulse oximetry	Sa O2	>20	74%	100%							
Williams, 1991	40	Pulse oximetry	Sa O2 , Clinical score	>10	58%	100%							
Cooper, 1991	41	Pulse oximetry	Sa O2	>5	60%	95%							
				>15	75%	86%							
				>25	100%	80%							
Douglas, 1992	200	Pulse oximetry	Sa O2	>5	92%	67%							
				>10	97%	53%							
				>15	97%	46%							
				>20	99%	36%							
Series, 1993	240	Pulse oximetry	Sa O2	>10	98%	48%							
				>20	100%	39%							
Rauscher, 1993	116	Pulse oximetry	Sa O2	>10	94%	45%							
				>20	95%	41%							
Gyulay, 1993	98	Pulse oximetry	Sa O2	>15	40%	98%	4% desaturations						
				Clinical score	79%	50%							
Issa, 1993	120	Snorestat	Snoring, SaO2	>7-20	84-90%	95-98%							
Bradley, 1995	31	ResCare	Nasal airflow,	>15	100%	92%							
		AutoSet	SaO2										
Gugger, 1995	27	ResMed	Nasal airflow,	>20	82%	90%							
		AutoSet	SaO2										
Ryan, 1995	69	Pulse oximetry	SaO2	>15	31%	100%							
				desats									
Yamashiro, 1995	300	Pulse oximetry	SaO2	>5	94%	73%							



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Sivan, 1996	58	Videotape recording	Snoring, arousals, apneas, chest wall movement		94%	68%									
Fleury, 1996	44	ResMed Autoset	Nasal airflow, SaO2	>20	100%	88%									
Gugger, 1997	67	ResMed Autoset	Nasal airflow, SaO2	>20	97%	77%									
Epstein, 1998	100	Pulse oximetry In lab	SaO2	>10	96%	85%									
Golpe, 1999	116	Pulse oximetry	SaO2; DI 4% RI 3% CT 90%		r = 0.60 r = 0.58 r = 0.50		9% of data excluded r = correlation between AHI & Various desaturations indices.								
Wiltshire, 2001	84	Biox 3740	SaO2;	>10 >15	41% 35%	100% 100%		13 8	0 0	19 15	52 61	infinity infinity	0.59 0.65		
Hussain, 2003	30	Pulse oximetry	SaO2;	>15			Negative studies by pulse oximetry referred for polysomnography				12 18	n/a n/a	n/a n/a		
Zamarron, 2003	300	Pulse oximetry In lab	HR, SaO2 Power spectral analysis	≥10	94%	82%		159	23	10	108	5.4	0.07		
AVERAGE (MEAN)					86%	72%									
Note: DI 4% = desaturations index of > 4% ; RI 3% = resaturations index of > 3%; CT 90% = cumulative percentages of time at saturations below 90%.															

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