



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

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## PORTABLE DEVICES FOR HOME TESTING FOR OBSTRUCTIVE SLEEP APNEA

### INTRODUCTION

The California Technology Assessment Forum (CTAF) has been asked to review the scientific literature on the safety and efficacy of portable devices used in the home to diagnose patients with obstructive sleep apnea. The primary focus of this review will be Level III devices.

Home diagnostic devices for sleep apnea were last reviewed by the Blue Shield of California Medical Policy Committee on Quality and Technology in 2001. At that time, the recommendation of the systematic review was that only Level I devices met MPCQT Technology Assessment criteria.

### BACKGROUND

Untreated, obstructive sleep apnea (OSA) is associated with significant morbidity and mortality related to obesity, hypertension, stroke, congestive heart failure, myocardial infarction (He *et al.*, 1988; Peppard *et al.*, 2000) and automobile and work-related accidents (AASM, 2000). 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 SaO<sub>2</sub> and/or an arousal (Golpe *et al.*, 1999). 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 > 5 events per hour—have found that up to 24% of men and 9% of women have obstructive sleep apnea. Using a more “conservative” diagnostic criterion—an AHI of at least 15 events per hour plus a history of daytime somnolence—up to 2% to 4% of adults have OSA syndrome (Young *et al.*, 1993). Treatment of OSA syndrome with nasal continuous positive airway pressure (CPAP), dental devices, surgery and weight loss improves patient daytime somnolence and overall survival (ASDA, 1997; AASM, 2000).

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 allows calculation of the respiratory disturbance index (RDI), which is the number of sleep-

disordered events per hour of sleep. Consensus standards exist for the proper use of the in-laboratory PSG in the diagnosis of OSA (Block *et al.*, 1985; ATS, 1989). Of course, in-laboratory PSG is labor-intensive and long waiting lists are common in sleep laboratories (Portier *et al.*, 2000). Furthermore, single-night PSG is not perfect and false-negative results have been reported (Meyer *et al.*, 1993). In addition, night-to-night variability of respiratory abnormalities has been well documented (Le Bon *et al.*, 2000; Portier *et al.*, 2000) 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) (Mosko *et al.*, 1988). Some do not consider standard PSG to be the “gold standard” for the diagnosis of OSA (Teschler *et al.*, 1997); instead, therapeutic response to treatment (e.g., with nasal CPAP) might be a better “gold standard” (ATS, 1994).

Recently, portable devices have been developed that can record sleep, nocturnal breathing and oxygenation at home. A large number of portable sleep monitors are now available (Zimmerman *et al.*, 1992; Broughton *et al.*, 1996) 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 setting (Broughton *et al.*, 1996). Screening refers to use of a device in an unselected population of subjects who may or may not have symptoms, or in a high-risk population such as first-degree relatives of patients with sleep-disordered breathing. Case selection is the usual clinical application for portable sleep monitors and refers to the use of a device in a patient for whom there is a clinical suspicion of sleep-disordered breathing. Another possible clinical application for portable devices is to assess the efficacy of treatments for sleep apnea, such as nasal CPAP, oromandibular devices or upper airway surgery. Some devices allow for automatic adjustment of CPAP based on feedback from the home monitor (Fletcher *et al.*, 2000).

To assist in the evaluation of published studies, a Task Force of the Standards of Practice Committee of the American Sleep Disorder Association distinguished four levels of sleep monitor devices, shown in Table 1. Thus, in-home portable devices may record a single channel such as oximetry (Level IV devices); two or more channels that measure only cardiorespiratory variables (Level III devices) or multiple channels that allow for sleep staging as well as measurement of cardiorespiratory variables (Level II devices).

The portable devices offer some advantages (Chervin *et al.*, 1999; Boyer *et al.*, 2003). Home studies might provide a more realistic appraisal of sleep-disordered breathing than can be obtained in the laboratory setting (Ferber *et al.*, 1994). 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 at risk patients. Currently, waiting lists at many centers are six months or longer (Flemons *et al.*, 2004). The data from these portable devices are relatively easy to interpret and data analysis is less time-consuming (White *et al.*, 1995).

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 (White *et al.*, 1995; Parra *et al.*, 1997), 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. 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) (White *et al.*, 1995).

Perhaps due to the controversy surrounding use of these devices, there have been numerous recent reviews evaluating their use (Boyer *et al.*, 2003; Chesson *et al.*, 2003; Douglas *et al.*, 2003; Flemons *et al.*, 2003; Li *et al.*, 2003; Parra *et al.*, 2003; Mattei *et al.*, 2004; Tarasiuk *et al.*, 2004). 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 al.*, (1994) 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 al.*, (1996). 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 along with the American Thoracic Society, updated systematic reviews on home diagnosis of sleep apnea. Since then, 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. For example, Zimmerman *et al.*, (1992) described the technical features of 32 different sleep data monitoring systems manufactured by 17 different companies.

## 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.

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, PSG and sleep disorder breathing. These were cross-referenced with the keywords “sensitivity and specificity,” “screening,” “reproducibility of tests,” and “human”. The search was performed for the period from 1966 through April 2005. The bibliographies of systematic reviews and key articles were manually searched for additional references. 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.

Outcomes assessed in the various clinical trials summarized below include the sensitivity and specificity of each device in the detection of apnea, ideally in the home rather than the laboratory environment. Test sensitivity is the likelihood that a patient with OSA has a positive test. Test specificity is the likelihood that a healthy patient without OSA has a negative test. Evaluating these results is difficult because the criteria used to diagnose sleep apnea after full PSG varied from study to study and some studies reported results using multiple definitions. The lack of consensus in the field on the diagnosis of sleep apnea makes comparisons across studies difficult. Some studies have assessed how much each device adds to clinical prediction rules in the detection of cases. Several studies have reported feasibility and practicality of performing limited sleep studies unsupervised in patients’ homes (Whittle *et al.*, 1997).

All but one of the validation trials of home portable monitoring devices have been non-randomized or randomized comparative trials, comparing outcomes of portable devices with standard full PSG. Since this topic was last reviewed, an additional 16 studies of Level III devices were identified that provided sufficient data to estimate sensitivity and specificity compared with full PSG (see Table 3A). Studies without data on sensitivity or specificity were not included (Fletcher *et al.*, 2000; Bar *et al.*, 2003). One additional study randomized patients to evaluation and treatment based on the results of either full PSG or a home portable monitoring device (Whitelaw *et al.*, 2005)

Many, if not most, studies of portable monitors have had serious methodological flaws (Flemons *et al.*, 1996). 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 (Emsellem *et al.*, 1990; Ferber *et al.*, 1994; Man *et al.*, 1995). 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 the 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.

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 OSA; and (3) the night-to-night variability in measures of sleep and respiration that makes comparisons of home assessment versus in-laboratory evaluation difficult (Wittig *et al.*, 1984; Stoohs *et al.*, 1992; White *et al.*, 1995; Le Bon *et al.*, 2000).

In 1994, the American Sleep Disorders Association published standards (1994) 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; an adequate detail regarding methods for performing the test; an adequate description of the study population; an adequate sample size (estimated to be >200 patients); avoidance of selection bias; and an adequate description of the study setting. Several critics (Flemons *et al.*, 1996) have noted that most studies in the published literature do not meet all of these criteria, with notable exceptions (Douglas *et al.*, 1992; Series *et al.*, 1993).

Level of evidence: 2, 3, 4 and 5

TA Criterion 2 is met.

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

#### Level II Devices

Level II devices measure both respiratory and sleep variables. Respiratory variables are measured by inductance plethysmography, or nasal or oral thermistors. Sleep variables, including an electroencephalogram, electrooculogram and chin electromyogram, are measured as in standard laboratory PSG (Level I studies). Like Level I studies (but unlike Level III and IV), Level II studies permit calculation of the RDI.

Table 2 summarizes results from six published validation studies of Level II portable monitoring devices in the diagnosis of OSA, five of which (White *et al.*, 1995; Ancoli-Israel *et al.*, 1997; Whittle *et al.*, 1997; Portier *et al.*, 2000; Iber *et al.*, 2004) included patients studied unattended at home. In the 423 patients included in these six studies, the average sensitivity of the Level II portable devices was fairly high—92% compared to full in-laboratory PSG;

however, the average specificity of the Level II portable devices was considerably lower at 68%. This means that home studies would miss ~8% of patients who would be diagnosed as having OSA with full in-laboratory PSG. In addition, ~32% of healthy patients who do not manifest abnormalities on full in-laboratory PSG would be diagnosed with OSA on home studies.

Among the published validation studies of Level II devices, several of them have been conducted under in-laboratory, rather than home, conditions (Orr *et al.*, 1994; Mykytyn *et al.*, 1999). Several others (White *et al.*, 1995; Fry *et al.*, 1998; Portier *et al.*, 2000; Pelletier-Fleury *et al.*, 2001; Gagnadoux *et al.*, 2002) have provided polysomnographic data from the unattended home setting. However, Level II devices have not always been validated by studying patients suspected of OSA (Fry *et al.*, 1998; Mykytyn *et al.*, 1999).

White *et al.* (1995) compared the Healthdyne NightWatch System, a portable home Level II polysomnographic device, to standard PSG. Because the NightWatch system does not include an EEG, many reviewers consider it to be a Level III device. Two separate studies were completed. NightWatch was compared to a simultaneously obtained standard PSG both in the sleep laboratory in 30 patients (IN-LAB study); and NightWatch in the home was compared to laboratory standard PSG (HOME-LAB study) in 70 patients. The IN-LAB study revealed a high correlation ( $r = 0.94$ ) between NightWatch and standard PSG for AHI, with a sensitivity of 100% and specificity of 64% at an AHI threshold of  $\geq 10$ . The HOME-LAB study also demonstrated a high correlation between NightWatch and standard PSG for AHI of  $r = 0.92$ , with a sensitivity of 91% and a specificity of 70% at an AHI threshold of  $\geq 10$ . However, there was only a 79% diagnostic agreement between NightWatch and standard PSG in the HOME-LAB study, with NightWatch underestimating the AHI 4% of the time and overestimating it in 17% of cases.

More recently, Portier *et al.* (2000) reported a study in which 103 patients received two polysomnograms, one at home and one in the laboratory, in a random fashion. Results suggested that home Level II PSG was not feasible for 33% of patients because of disability or transportation difficulties. In addition, data loss was higher with home studies (20%) than with in-laboratory studies (5%). There was no evidence of a better quality of sleep or tolerance of the recording at home. The sensitivity of the home polysomnogram compared to the in-lab polysomnogram was 31/37 (84%). Overall, 45 patients had discordant RDIs ( $>5$  events/hour) by the two tests, and 8 of the 45 were classified differently as normal, mild or moderate sleep apnea versus severe sleep apnea. The authors concluded that further investigations were needed to define clearly the type of patients who could benefit from home PSG and the optimal conditions under which to undertake it.

Fry and colleagues (Fry *et al.*, 1998) reported that 26% of pre-selected patients did not qualify for home PSG either because of disability or transportation difficulties. Gagnadoux *et al.* (2002) reported loss of 23.4% of data from studies at home. Both Fry and Portier reported that the majority of patients actually preferred in-laboratory PSG to home testing.

### Level III Devices

Level III devices measure cardiorespiratory variables, but do not record EEG, EOG, or chin EMG, and therefore cannot evaluate sleep stages.

Table 3 summarizes results from 10 published validation studies of Level III portable monitoring devices in the diagnosis of OSA, five of which (Ancoli-Israel *et al.*, 1981; Redline *et al.*, 1991; Man *et al.*, 1995; Parra *et al.*, 1997; Whittle *et al.*, 1997) included patients studied unattended at home. In the 559 patients included in these 10 studies, the average sensitivity of the Level III portable devices was fairly high—91% compared to full PSG; again, however, the average specificity of the Level III portable devices was lower at 86%. This means that home studies would miss ~9% of patients who would be diagnosed as having OSA with full PSG. In addition, ~14% of healthy patients who do not manifest abnormalities on full PSG would be diagnosed with OSA on home studies.

Parra and colleagues (Parra *et al.*, 1997) studied 89 patients with suspected OSA in two settings: in the sleep laboratory using full-PSG and at the patient's home using a portable monitor. In the home setting, 50 patients were assisted by a technician and 39 were unattended. OSA (defined as an AHI >10 events/hour by full PSG) was diagnosed in 75 (84%) of the 89 patients. Agreement obtained between the AHI measured by full polysomnogram and portable monitor was good, with the clinical therapeutic decision taken after portable monitoring agreeing with that determined by full PSG in 79 (89%) patients. Overall 10% of the unattended home studies needed repetition.

Whittle *et al.* (1997) conducted a validation study with 23 subjects who underwent in-laboratory full PSG and a home study using the Edentec 3711 Level II device on successive nights. All subjects with an AHI >15 on full PSG had an AHI of >30 on their home study. The home study AHI correlated significantly with the full PSG ( $r=0.8$ ,  $p<.001$ ). However, in a subsequent prospective trial involving 150 subjects who had a home study as the initial investigation, a further sleep study was required for diagnostic reliability in 56% of cases (Whittle *et al.*, 1997). In the validation trial, 13% of home recordings were uninterpretable and in the prospective trial, 18% of home studies were not interpretable.

### Level III Devices – Identified Since Prior Review

Table 3A. summarizes the results of 16 additional studies of Level III devices (White *et al.*, 1995; Schafer *et al.*, 1997; Ballester *et al.*, 2000; Verse *et al.*, 2000; Claman *et al.*, 2001; Ficker *et al.*, 2001; Marrone *et al.*, 2001; Calleja *et al.*, 2002; Golpe *et al.*, 2002; Dingli *et al.*, 2003; Pillar *et al.*, 2003; Reichert *et al.*, 2003; Pittman *et al.*, 2004; Quintana-Gallego *et al.*, 2004; Su *et al.*, 2004). Two novel technologies are employed in some of these new studies. Wrist actigraphy, which measures arm movement, can be used to better estimate the actual awake and sleep periods during the night. Peripheral arterial tonometry (PAT) is an indirect measure of autonomic arousal assessed by

monitoring changes in peripheral blood flow. Autonomic arousal has been postulated to be a better measure of clinical significant arousals than decreases in arterial oxygen saturation.

The publications report on 669 patients studied with portable sleep monitors concurrently with PSG in the sleep lab and more importantly, on an additional 446 patients studied with a portable device in the home. The overall prevalence of sleep apnea was high in these studies (59%) reflecting the fact that essentially all of these studies evaluated patients referred to sleep centers with suspected OSA. Thus, the results of the studies should apply to patients who meet criteria of suspected sleep apnea, but may not apply to the general population. The quality of the studies was generally good – essentially all of the studies reported that the person scoring the PSG studies was blinded to the results of the portable device readings and that the person scoring the portable device data was blinded to the results of PSG.

Given the variety of devices evaluated, variations in the PSG systems used, differences in the AHI cutoff used to define clinically significant sleep apnea and the data driven decisions about the best RDI cutoff to use, it is inappropriate to pool the data. The pooled numbers were calculated to give some general reference values and to see how they have changed. In the prior report, the mean sensitivity was 91% and mean specificity was 86%. The pooled sensitivity (90%) and specificity (90%) for the in-laboratory studies is very similar. When the same devices were evaluated at home, the pooled sensitivity remained 90%, but the specificity dropped to 76%. It is important to note that these values overestimate the true sensitivity and specificity of test performance in the home setting as 0% and 33% of the studies were not useable due to lost data. The Watch PAT 100 was designed to be particularly easy to use at home. Preliminary data in just 29 patients had no loss of data at home and a remarkable 95% sensitivity and 100% specificity (Pittman *et al.*, 2004). Larger studies are needed to determine whether this was a chance finding in a small study or a real advance in portable home monitoring.

Several studies took a more thoughtful approach to classifying patients based on the results of portable home devices. They reported 2 cut points: a lower bound below which almost all patients were at very low risk for significant OSA and a higher bound above which most patients had significant OSA. For instance, Dingli *et al.*, (2003) defined a positive study with the Embletta device with an RDI  $\geq 20$ , a negative study with an RDI  $< 10$  and an indeterminate study as an RDI between 10 and 19. In their home validation study, all 23 patients with positive home studies had OSA on PSG defined as an AHI  $\geq 15$ . Similarly, all nine patients with negative home studies were determined not to have significant OSA by PSG. Unfortunately, 18% of the home studies were technically inadequate and an additional 30% were indeterminate. Thus, almost half (48%) of the patients would have required PSG.

## Level IV Devices

Some centers use portable pulse oximetry alone to test for OSA. The oximetry studies have been quite variable, with some reporting excellent results (Series *et al.*, 1993) and others reporting quite poor and inconsistent data (Williams *et al.*, 1991). An early comparison of data from eight published studies of pulse oximetry indicate that the predictive value is usually considerably less than that of devices that also monitored variables such as airflow, heart rate and chest expansion (Ferber *et al.*, 1994; Chervin *et al.*, 1999).

Table 4 summarizes results from 22 published validation studies of Level IV portable monitoring devices in the diagnosis of OSA. In general, the site of study is not specified in the published oximetry studies. In the 2,082 patients included in these 22 studies, the average sensitivity of the Level IV portable devices was low at 86%, compared to full PSG, and the average specificity of the portable Level IV devices was even lower at 72%. This means that home studies would miss ~14% of patients who would be diagnosed as having OSA with full PSG. In addition, ~28% of healthy patients who do not manifest abnormalities on full PSG would be diagnosed with OSA on home studies.

As many as 14% of OSA patients can be missed if only oximetry is used (Golpe *et al.*, 1999). Thus, oximetry may not reliably rule out OSA even in patients with a high pre-test probability of the disease (Rauscher *et al.*, 1993; Golpe *et al.*, 1999). In addition, up to half of patients cannot be classified with oximetry alone (Golpe *et al.*, 1999). Finally, in one study, of 87 apparent desaturations during home studies, 29 (33%) were found to be artifactual (Brouillette *et al.*, 1995; Lafontaine *et al.*, 1996). Therefore, some authors recommend that all patients with at least moderate symptoms of obstructive apnea have a full polysomnogram done, irrespective of the results of any home study, in order to avoid missing true positive cases and to avoid long-term treatment of false-positive cases (Golpe *et al.*, 1999).

Series *et al.* (1993) studied 240 patients with home oximetry in direct comparison to sleep lab PSG (of course, not on the same night). Based on the results of the PSG, 110 patients had sleep apnea. Home oximetry testing had a sensitivity of 98.2%, a specificity of 47.7%, a positive predictive value of 51.4% and a negative predictive value of 96.9%. The authors concluded that a negative home oximetry test result was helpful in ruling out the diagnosis of sleep apnea in patients clinically suspected of it, because a negative test result reduced the probability from 54.1% to 3.1% in their patients. However, a positive oximetry test increased the probability from 46% to 61.4% in their patients.

Both of the two largest published series of oximetry in comparison to PSG evaluated 300 patients. In a group of 300 patients referred with excessive daytime somnolence, Yamashiro *et al.* (1995) found the sensitivity of oximetry in screening for sleep- and breathing-disorders was 94% and the specificity was 75%. The authors concluded that home oximetry may not have sufficient sensitivity and specificity to detect breathing disorders reliably during sleep

and is useless for other sleep disorders. Zamarron *et al.* ( 2003) performed spectral analysis on the pulse oximetry data gathered on 300 patients and reported similar sensitivity (94%), but improved specificity (82%).

### Problems with Portable Devices

Limited home studies can fail to identify some subjects with severe sleep apnea on full PSG. A combination of factors is probably responsible for this discrepancy, including the night-to-night variation in respiratory abnormalities in any sleep study (Mosko *et al.*, 1988; Redline *et al.*, 1991; Meyer *et al.*, 1993), which is more marked in those with sleep apnea syndrome (Wittig *et al.*, 1984); the tendency of limited home studies to underestimate the frequency of sleep-related abnormalities in patients who are awake part of the night; and the different techniques for recording respiratory variables (Whittle *et al.*, 1997).

Many of the published studies cited above comment on the difficulty of accurately distinguishing different types of apnea (central, obstructive, mixed) when using the unattended portable monitoring devices. Portable device recordings are more frequently affected by data loss than are standard polysomnograms, with losses of 4%-33% reported in various studies (Ancoli-Israel *et al.*, 1981; Gyulay *et al.*, 1987; Jacobs *et al.*, 1989; Emsellem *et al.*, 1990; Stoohs *et al.*, 1990; Redline *et al.*, 1991; Stoohs *et al.*, 1992; Issa *et al.*, 1993; Ferber *et al.*, 1994; White *et al.*, 1995; Kiely *et al.*, 1996; Whittle *et al.*, 1997; Pelletier-Fleury *et al.*, 2001; Gagnadoux *et al.*, 2002). In addition, there appears to be much more home versus sleep-lab variability in results of portable monitoring than there is in simultaneous recording, emphasizing the importance of validating these monitoring devices at home in the setting in which they are intended to be used (Flemons *et al.*, 1996).

Several of the studies compared manual scoring of the portable device data to automatic scoring based on a machine algorithm. In all cases, manual scoring was significantly more accurate than automatic scoring (Esnaola *et al.*, 1996; Calleja *et al.*, 2002; Dingli *et al.*, 2003).

TA Criterion 3 is not met.

<b>TABLE 1. American Sleep Disorders Association levels for portable recording equipment for sleep - disordered breathing</b>				
	Level I 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

Table 2. Published Validation Studies of Level II Portable Monitoring Devices in Diagnosis of OSA																
First Author,	No.	Device;	Parameters	% Data Loss	OSA Diagnosis						TP	FP	FN	TN	LR+	LR-
Year	Patients	Site, Protocol	Measured		AHI	Sensitivity	Specificity	Prevalence								
Orr, 1994	40	Sleep I/T	EEG, EOG, EMG,		≥15/h	100%										
		In-lab attended	tracheal noise, S <sub>a</sub> O <sub>2</sub> ,													
			chest, abdominal movement,													
			wrist activity													
Whittle, 1995	70	Nightwatch	EOG, leg movements,		> 10/h	91%	70%									
		In-lab attended	S <sub>a</sub> O <sub>2</sub> , nasal-oral airflow,													
		Versus	chest, abdominal movement,													
		Home unattended	body position, HR													
White, 1995		Nightwatch;	EOG, EMG, S <sub>a</sub> O <sub>2</sub> ,													
	30	In-lab attended	nasal-oral airflow, chest,		> 10	100%	64%									
		Versus	abdominal movement, HR													
	70	Home unattended			> 10	91%	70%									
Ancoli – Israel, 1997	34	Nightwatch;	EOG, EMG, chest,													
		Home unattended	abdominal movement,		>10	100%	66%									
			nasal airflow, S <sub>a</sub> O <sub>2</sub> ,													
			body position, HR													
Portier, 2000	103	Minisomno at	EEG, EMG, EOG,	20%	> 15/h	84%										
		home versus	nasal-oral airflow, chest,													
		Respisomnograph	abdominal movement, S <sub>a</sub> O <sub>2</sub>	5%												
		In-lab														
Iber, 2004	76	PS-2	EEG, ECG,	16%	>26.8	90%	63%	75%	43	6	5	10	2.4	0.17		
		Home unattended	nasal-oral airflow, chest,													
			abdominal movement, S <sub>a</sub> O <sub>2</sub>													
<b>AVERAGE (MEAN)</b>						<b>92%</b>	<b>68%</b>									
<b>Note:</b>	<b>AHI = Apnea – hypopnea index</b>		<b>TP = True positive</b>		<b>LR+ = Positive likelihood ratio</b>											
	<b>OSA = Obstructive sleep apnea</b>		<b>FP = False positive</b>		<b>LR- = Negative likelihood ratio</b>											
	<b>RDI = Respiratory disturbance index</b>		<b>FN = False negative</b>		<b>SaO2 = Arterial oxygen saturation</b>											
			<b>TN = True negative</b>		<b>HR = Heart rate</b>											

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-
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 <sub>a</sub> O <sub>2</sub> , HR,										
				body movement										
Salmi, 1989	55		SCSB, themistor	Body movement, air flow,	0%	>5	100%	86%						
			and pulse oximetry	S <sub>a</sub> O <sub>2</sub>										
Emsellem, 1990	67		Edentrace 2700;	Nasal/oral airflow, chest	6%	>5	95%	96%						
			In-lab attended	wall movement, S <sub>a</sub> O <sub>2</sub> , HR										
Svanborg, 1990	77		SCSB and pulse oximetry;	Respiratory movement, S <sub>a</sub> O <sub>2</sub>	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 <sub>a</sub> O <sub>2</sub> , HR,										
			Home unattended (5)	body movement										
Stoohs, 1992	56		MESAM 4;	S <sub>a</sub> O <sub>2</sub> , 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 <sub>a</sub> O <sub>2</sub> ,		> 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 <sub>a</sub> O <sub>2</sub> , 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 study r = 0.8 , p < .001							
			In-lab attended	movement, ECG, S <sub>a</sub> O <sub>2</sub>										
			plus											
			Home unattended											
	149		Edentrace 3711;		18%	>30								
			Home unattended											
<b>AVERAGE (MEAN)</b>							<b>91%</b>	<b>86%</b>						

**Note:** AHI = Apnea-hypopnea index OSA = Obstructive sleep apnea RDI = Respiratory distress index SCSB = Static-charge-sensitive bed

Table 3A. Recently 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,	Measured	Loss	AHI	Sensitivity	Specificity	TP	FP	FN	TN	LR+	LR-
			Protocol											
<b>HOME</b>														
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 <sub>2</sub> , HR, eye movement,										
				leg movement										
Shafer, 1997	114	70%	MESAM 4	Body position,	0%	>10	95%	41%	76	20	4	14	1.6	0.12
				SaO <sub>2</sub> , HR, sound/snoring										
Golpe, 2002	44	52%	ApnoeScreen I	Nasal/oral airflow, body	20%	>10	78%	71%	18	6	5	15	2.7	0.30
			Home	position S <sub>a</sub> O <sub>2</sub> , HR,	33%									
			w/wo tech set-up	wrist actigraphy										
Dingli, 2003	50	82%	Embletta	Nasal/oral airflow, chest	18%	≥10	93%	100%	38	0	3	9	∞	0.07
			Home	movement, abdominal movement,										
				SaO <sub>2</sub> , 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, S <sub>a</sub> O <sub>2</sub> , HR,										
			Unattended	sound/snoring										
Fietze, 2004	18	61%	MESAM-4	Sleep diary, body	0%	>15	91%	57%	10	3	1	4	2.1	0.16
			Home	position, S <sub>a</sub> O <sub>2</sub> , HR,										
				sound/snoring										
Pittman, 2004	29	76%	Watch PAT 100	PAT, SaO <sub>2</sub> ,	0%	≥15	95%	100%	21	0	1	7	∞	0.05
			Lab attended	HR, wrist actigraphy										
Quintana-Gallego, 2004	75	39%	ApnoeScreen II	Nasal/oral airflow, body	9%	≥10	79%	98%	23	1	6	45	36.5	0.21

	75	25%	Home	position S <sub>a</sub> O <sub>2</sub> , HR, chest		≥15	68%	95%	13	3	6	53	12.8	0.33
			w/ tech set-up	movement, abdominal movement,										
				wrist actigraphy										
<b>Total Home pooled</b>	446	61%					90%	76%	245	42	26	133	3.8	0.13
<b>LAB</b>														
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
				SaO <sub>2</sub> , 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, S <sub>a</sub> O <sub>2</sub> , 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 movement,		>10	92%	96%	23	1	2	27	25.8	0.08
				SaO <sub>2</sub> , 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, S <sub>a</sub> O <sub>2</sub> , 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, S <sub>a</sub> O <sub>2</sub> , 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
			Lab attended	movement, abdominal movement,										
				SaO <sub>2</sub> , 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,										
				SaO <sub>2</sub> , 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,										
				SaO <sub>2</sub> , HR, body position										
Pillar, 2003	68	59%	Watch PAT 100	PAT, SaO <sub>2</sub> ,	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, S <sub>a</sub> O <sub>2</sub> , HR,										
				sound/snoring										
Pittman, 2004	29	76%	Watch PAT 100	PAT, SaO <sub>2</sub> ,	0%	≥15	91%	86%	20	1	2	6	6.4	0.11
			Lab attended	HR, wrist actigraphy										
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, S <sub>a</sub> O <sub>2</sub> , HR,		≥15	84%	76%	26	7	5	22	3.5	0.21
				sound/snoring										
<b>Total Lab pooled</b>	669	57%					90%	90%	345	29	39	256	8.8	0.11
<b>Note:</b>	<b>AHI = Apnea - hypopnea index</b>			<b>TP = True positive</b>			<b>LR+ = Positive likelihood ratio</b>							
	<b>OSA = Obstructive sleep apnea</b>			<b>FP = False positive</b>			<b>LR- = Negative likelihood ratio</b>							
	<b>RDI = Respiratory disturbance index</b>			<b>FN = False negative</b>			<b>SaO<sub>2</sub> = Arterial oxygen saturation</b>							
	<b>PAT= Peripheral arterial tone</b>			<b>TN = True negative</b>			<b>HR = Heart rate</b>							

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	S <sub>a</sub> O <sub>2</sub>	>5	80%	71%							
Bonsignore, 1990	83	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>20	74%	100%							
Williams, 1991	40	Pulse oximetry	S <sub>a</sub> O <sub>2</sub> , Clinical score	>10	58%	100%							
Cooper, 1991	41	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>5	60%	95%							
				>15	75%	86%							
				>25	100%	80%							
Douglas, 1992	200	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>5	92%	67%							
				>10	97%	53%							
				>15	97%	46%							
				>20	99%	36%							
Series, 1993	240	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>10	98%	48%							
				>20	100%	39%							
Rauscher, 1993	116	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>10	94%	45%							
				>20	95%	41%							
Gyulay, 1993	98	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>15	40%	98%	4% desaturations						
			Clinical score		79%	50%							
Issa, 1993	120	Snorestat	Snoring, S <sub>a</sub> O <sub>2</sub>	>7-20	84-90%	95-98%							
Bradley, 1995	31	ResCare AutoSet	Nasal airflow, S <sub>a</sub> O <sub>2</sub>	>15	100%	92%							

Gugger, 1995	27	ResMed	Nasal airflow,	>20	82%	90%										
		Autoset	S <sub>a</sub> O <sub>2</sub>													
Ryan, 1995	69	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>15	31%	100%										
				desats												
Yamashiro, 1995	300	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>5	94%	73%										
Sivan, 1996	58	Videotape	Snoring, arousals,	---	94%	68%										
		recording	apneas, chest wall													
			movement													
Fleury, 1996	44	ResMed	Nasal airflow,	>20	100%	88%										
		Autoset	S <sub>a</sub> O <sub>2</sub>													
Gugger, 1997	67	ResMed	Nasal airflow,	>20	97%	77%										
		Autoset	S <sub>a</sub> O <sub>2</sub>													
Epstein, 1998	100	Pulse oximetry	S <sub>a</sub> O <sub>2</sub>	>10	96%	85%										
		In lab														
Golpe, 1999	116	Pulse oximetry	S <sub>a</sub> O <sub>2</sub> ;				9% of data excluded									
			DI 4%		r = 0.60		r = correlation between AHI									
			RI 3%		r = 0.58		&									
			CT 90%		r = 0.50		Various desaturations indices.									
Wiltshire, 2001	84	Biox 3740	S <sub>a</sub> O <sub>2</sub> ;	>10	41%	100%		13	0	19	52	infinity	0.59			
				>15	35%	100%		8	0	15	61	infinity	0.65			
Hussain, 2003	30	Pulse oximetry	S <sub>a</sub> O <sub>2</sub> ;	>15			Negative studies by pulse			12	18	n/a	n/a			
							oximetry									
							referred for polysomnography									
Zamarron, 2003	300	Pulse oximetry	HR, S <sub>a</sub> O <sub>2</sub>	≥10	94%	82%		159	23	10	108	5.4	0.07			
		In lab	Power spectral													
			analysis													
<b>AVERAGE</b>					<b>86%</b>	<b>72%</b>										
<b>(MEAN)</b>																
<b>Note: DI 4% = desaturations index of ≥ 4% ; RI 3% = resaturations index of ≥ 3%; CT 90% = cumulative percentages of time at saturations below 90%.</b>																

**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 Tables 2-4 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.

The goal of both PSG and the portable home devices is to identify patients who will benefit from treatment for OSA. One clinical trial (Whitelaw *et al.*, 2005) 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 Snoresat (Issa *et al.*, 1993; Vazquez *et al.*, 2000) 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 auto CPAP therapy at home. The machines included concealed compliance monitors. A total of 307 patients were randomized, but 8 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 (32 kg/m<sup>2</sup>), neck circumference (41 cm) and score on the standard Epworth Sleepiness Scale (11.6). Overall, 42% of patients met criteria for improvement ( $\geq 1$  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, 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 1-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. Dropout 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.

### 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. Chervin *et al.* (1999) applied decision analytical techniques to the published data to model the diagnosis of OSA by standard full PSG, home study and no sleep testing. Their model included a wide range of pretest probabilities of OSA, from 35% to 95%. Their base case estimates for the diagnostic test characteristics of portable home monitoring were 95% sensitivity and 96% specificity. The results suggested that full PSG usually provides improved quality-adjusted life years over both home studies and no testing. At the authors' own center, the positive predictive value of the home study was quite high (99%), but the negative predictive value was considerably lower (only 77%). This means that 23% of patients with negative results could be left with untreated OSA. In addition, at centers with a lower pretest probability of OSA, the negative predictive value of the home study might be higher but the positive predictive value would be lower and the preference for PSG over home study would be maintained (Chervin *et al.*, 1999). Two subsequent studies using data from more recent studies came to similar conclusions (Reuven *et al.*, 2001; Tarasiuk *et al.*, 2004).

TA Criterion 4 is not met.

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

Studies have not yet unequivocally demonstrated in the investigational setting the efficacy of portable home monitoring devices in leading to therapeutic interventions to improve symptoms and other outcomes of OSA. Whether portable home monitoring devices will be effective in improving health outcomes when used to diagnose individuals with OSA when used in the community setting under conditions of usual medical practice remains to be demonstrated.

TA Criterion 5 is not met.

## CONCLUSION

All systematic reviews to date, including the recent update of the review by the highly respected Agency for Healthcare Research and Quality, agree that none of the portable devices for home sleep studies have been shown to improve net health outcomes compared with standard PSG. The validation trials of home portable monitoring devices have been non-randomized or randomized comparative trials, comparing outcomes of portable devices with standard full PSG. The task is particularly difficult because of known night to night variability in the AHI measured by full PSG, known first night effects when patients are monitored and probable differences between sleep patterns in the laboratory and at home. Published reports 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 cut points for AHI to define sleep apnea and determine optimal cut points 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 cut point is validated in an independent study. Studies have not compared outcomes of therapeutic interventions (e.g., nasal CPAP) based on home studies to those based on full in-laboratory PSG. Furthermore, the majority of the studies have been conducted in the laboratory setting rather than in the home under unattended conditions. There remains uncertainty about the ability of unattended portable sleep monitoring devices to acquire and reproduce required physiological data in a sufficiently consistent manner to permit accurate clinical assessments (Ferber *et al.*, 1994). Data loss is frequent with home studies: up to 33% of home studies using Level III devices failed to provide data of sufficient quality for evaluation

Even when data is collected, it appears that its use in the home setting will miss cases of OSA that would be detected by traditional laboratory PSG. The published data summarized in Tables 2-4 suggest that Level II, Level III and Level IV portable devices used unattended at home do not achieve results comparable to full in-laboratory (Level I) PSG in the diagnosis of OSA. Standard full PSG has a higher sensitivity and specificity than home testing. Symptomatic patients with negative results or uninterpretable studies on a home study may need to undergo second home studies or full PSG. Finally, decision analyses suggest that even if portable home monitoring is assumed to have unrealistically high sensitivity (95%) and specificity (96%) for sleep apnea, the quality adjusted life years gained is still greater with PSG than with portable home monitoring (Chervin *et al.*, 1999).

There was one randomized trial (Whitelaw *et al.*, 2005) that directly compared PSG to home monitoring using an unusual outcome measure: the accuracy of sleep specialists prediction of the response to CPAP compared with the patient's actual response. Predictions based on clinical data, plus either full PSG or home monitoring, were both equally poor (61% versus 64% accuracy compared to 50% accuracy expected by chance alone). The authors argue that this is evidence that home monitoring should replace PSG. However, it could also be argued that a more efficient and clinically relevant approach would be a therapeutic trial of CPAP.

Future refinements in-home study equipment may yield health-outcome-related advantages for home diagnostic testing of OSA. Ideally randomized clinical trials will demonstrate that these techniques can rival or exceed the advantages of laboratory-based PSG.

TA Criteria 3-5 are not met.

#### DRAFT RECOMMENDATION

It is recommended that the use of Level III portable home devices to diagnose OSA does not meet Technology Assessment Criteria 3, 4 or 5 for safety, effectiveness and improvement in health outcomes.

June 15, 2005

*The California Technology Assessment Forum panel voted unanimously to accept the recommendation as written.*

## 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 an updated National Coverage Determination on May 6, 2005 which notes in part that “there is not sufficient evidence to conclude that unattended portable multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy \_ \_ \_ \_ \_ “  
([http://www.cms.hhs.gov/Manuals/pm\\_trans/R35NCD.pdf](http://www.cms.hhs.gov/Manuals/pm_trans/R35NCD.pdf)).

### American Academy of Sleep Medicine (AASM)

In November 2003, the American Association for Sleep Medicine, the American Thoracic Society and the American College of Chest Physicians issued a joint statement entitled *Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults*. These practice parameters do not generally endorse the use of Level III devices in an unattended setting. This document is included in the agenda book.

Representatives of the AASM attended the meeting.

### California Thoracic Society (CTS)

A CTS representative was not able to attend the meeting. However, CTS did provide opinion in support of the recommendation.

### Agency for Healthcare Research and Quality (AHRQ)

In September 2004 the AHRQ released an updated Technology Assessment titled *Effectiveness of Portable Monitoring Devices for Diagnosing Obstructive Sleep Apnea: Update of a Systematic Review*. This 130-page document is available at the following web site: (<http://www.cms.hhs.gov/coverage/download/id110e.pdf>).

## ABBREVIATIONS USED IN THIS REVIEW

OSA	Obstructive sleep apnea
AHI	Apnea-hypopnea index
RDI	Respiratory disturbance index
EEG	Electroencephalography
EOG	Electro-oculography
ECG	Electrocardiography
CPAP	Continuous positive airway pressure
PSG	Polysomnography
PAT	Peripheral arterial tonometry
SAQLI	Sleep Apnea Quality of Life Index

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