

Watch-PAT 100: Review of Evidence

David Barone, December 2003

TABLE OF CONTENT

Overview	1
Prior Guidelines for Unattended Sleep Studies	3
Validating the PAT Signal.....	4
Summary of Evidence	5
Proposed Guidelines for Using PAT Technology to Diagnose OSA	7
Summary.....	7
References	7

The references presented in this memorandum do not address all portable sleep studies, but rather focus on the evidence associated with a new technology utilizing a measurement of peripheral arterial tone (PAT), in conjunction with other physiological parameters, to detect sleep apnea events. The specific technology addressed in this report was developed in recent years, and was not available during prior reviews of medical literature analyzing the evidence for reliability, efficacy and outcomes associated with unattended sleep studies.

Overview

Obstructive Sleep Apnea

Obstructive Sleep Apnea (OSA) is a recognized disorder of sleep, characterized by recurrent airway obstruction, identified as apneic and hypopneic episodes. In view of its high prevalence, serious associated morbidity and recently shown mortality, sleep apnea has been recognized as a major public health problem¹. Persons with this disorder usually experience tiredness, fatigue, irritability and difficulty concentrating². Worse still, they are more likely to fall asleep at inappropriate times and have a higher rate of vehicular crashes and work-related accidents than other people³. Sleep apnea also affects the cardiovascular system. It is associated with increased blood pressure, cardiac arrhythmias during sleep, and it may contribute to atherosclerosis leading to myocardial infarction⁴, as well as to stroke⁵. The mortality among patients with severe untreated sleep apnea has been significantly higher than in patients

with a mild sleep apnea⁶. The National Sleep Commission on Sleep Disorders Research estimated that sleep apnea may be responsible for 38,000 cardiovascular deaths per year⁷.

OSA has been recognized as a clinical condition for over 25 years⁸, and since then, diagnostic tests identifying OSA as well as treatments have increasingly been provided to patients complaining of excessive sleepiness and other related symptoms. The prevalence of OSA, most common among middle-aged adults, is estimated to be up to 5% of the U.S. population⁹ (although some reports estimate the prevalence to be closer to 10%), and is in effect more prevalent than asthma. In certain high risk populations, the prevalence of OSA is even significantly higher. Over 50% of patients with CHF have been reported to suffer from sleep-disordered breathing¹⁰, and among morbidly obese patients, the incidents of OSA are at least 12 fold higher than in the general population¹¹.

Shortcomings of current state of the art OSA diagnostics and treatment

Patients with obstructive sleep apnea benefit from a number of effective therapies, such as continuous positive airway pressure (CPAP), oral appliance, also known as an intraoral mandibular advancement device, and for those failing or refusing the non-invasive treatment options, surgeries such as tonsillectomy and adenoidectomy. Other treatment options, including surgeries, are available for patients failing or refusing CPAP treatment. In spite of the availability of effective treatments for OSA, results from the Wisconsin Sleep Cohort indicate that over 10 million patients with sleep apnea remain undiagnosed¹². The major problem in the field is, therefore, not treatment but diagnosis: whom to test, how to identify the candidates for the test, how to test, and what are the implications of test results regarding the risk of serious clinical sequelae, as well as the economical related issues.

The most common diagnostic method for OSA is an overnight full polysomnography (PSG) test, which consists of measuring electroencephalogram (EEG), electrocardiogram (ECG), electrooculogram (EOG), electromyogram (EMG), respiratory airflow, chest and abdominal respiratory efforts, body position and blood oxygen saturation in a sleep laboratory. PSG is costly, and while considered as the “gold standard”, the interpretation of the data is complex and subject to significant variability¹³. The cost of full PSG for all suspected cases would be prohibitive, and will fall far short of providing an acceptable solution for

testing all patients suspected of sleep apnea. Thus, with so many people requiring testing for OSA, the availability of accurate, yet simpler and less costly alternatives for diagnosing sleep apnea, to augment the in-lab PSG, is highly desirable.

The PAT solution

On November 2001, the FDA approved a 510(k) application for the Watch-PAT100, a patient wrist-worn device to be used unattended during sleep in the home for the purpose of aiding in the diagnosis of obstructive sleep apnea syndrome. The device records a physiological measurement, Peripheral Arterial Tone (PAT) signal, which can be monitored non-invasively through a finger-mounted opto-pneumatic probe. In addition to the PAT probe, the device incorporates pulse oximetry measurement and an embedded actigraph for sleep/wake differentiation. PAT signal is a measure of arterial pulsatile volume changes in the fingertip brought about by varying sympathetic nervous system activity. Since respiratory disturbances during sleep are associated with sympathetic surges, they cause changes in the PAT signal as well. The PAT device can identify respiratory disturbances during sleep, utilizing a computer analysis program used with the PAT signal to analyze fluctuations in sympathetic tone.

The Watch PAT 100 (WP100) is the first device to use PAT signal analysis to measure respiratory disturbance during sleep. A principal benefit of this measurement technique is its simplicity of use. Since PAT signal can be measured using a device worn comfortably on the wrist, it is ideal for studies performed outside of a sleep lab facility and does not require the full-night attendance of a technologist. Another primary benefit of the PAT measurement is the ability to detect and record even minute changes in peripheral vascular volume associated with arousals, and through this measurement, detect even subtle sleep disordered breathing events.

A further basic aspect of the PAT measurement that is of practical importance is that it also provides information about changes in pulse rate. While isolated spontaneous vasomotor tone and heart rate fluctuations are common and normal occurrences, it is in fact the specific combination of a characteristic pattern of vasoconstriction and a degree of transient relative tachycardia in close temporal proximity that serves as a highly sensitive and specific autonomic marker of OSA.

Despite the longstanding awareness that autonomic

activation accompanies apnea termination, prior to the introduction of the PAT technology, a reliable noninvasive marker of this was conspicuously lacking. A number of autonomic parameters have been evaluated as potential markers of OSA but their performance has been disappointing. For example, Pitson and Stradling reported an R value of 0.65 for the pulse transit time (PTT), and 0.51 for heart rate changes relative to standard PSG criteria of sleep disordered breathing indices¹⁴. In sharp contrast to these modest levels of correlation, PAT has been consistently found to provide R values within the 0.85- 0.95 range in several independent studies^{38,41,49}.

In addition to the PAT probe, the WP100 device incorporates pulse oximetry and an embedded actigraph. The WP100 software automatic algorithms uses features of the PAT signal, blood oxygen desaturation and pulse rate for respiratory disturbances detection, and the actigraphy signal for sleep/wake state detection. The WP100 is the only non-EEG ambulatory device having the capacity to reliably detect sleep/wake states, providing for diagnostic capability closer to PSG, rather than any conventional cardio-pulmonary ambulatory device (which have been used in unattended sleep studies), as it allows the detection of the respiratory events during the relevant sleep periods only and the assessment of sleep fragmentation that is often caused by OSA.

PAT testing represents a substantial technological advancement from other devices currently marketed for ambulatory sleep tests. Some technologies previously used in the unattended setting require cumbersome sensors interface, and as a result, they are susceptible to unreliable and inconsistent data acquisition. Many devices have failed to demonstrate consistent sensitivity and specificity. The new PAT technology records some of the same physiological parameters as other unattended devices (e.g. arterial oxygen saturation and pulse rate) but (i) by including the PAT signal, instead of the cumbersome airflow and efforts measurements, and (ii) by adding actigraphy to identify sleep states, it performs unique physiological analysis, different from the parameters monitored and recorded by other devices.

By utilizing these new capabilities, the PAT device is able to provide a higher level of informative diagnosis value, and to achieve a high level of reliability and accuracy. Through a direct measure of the arterial pulse volume changes – a demonstrated surrogate of arousal and sympathetic activation, the PAT has the ability to provide an ‘arousal context’ to the measurement of apnea or hypopnea events,

matching the ability of the full PSG study to diagnose OSA in an unattended home testing environment. Furthermore, the unique nature of the PAT events enables the effective use of distinct computer programs, now well-validated, in the analytic parts of the PAT-based procedure.

The WP100 is mounted to the wrist, and connects to external sensors placed on two fingers. This configuration, with minimal discomfort, if at all, makes the device particularly convenient to the patient. Eliminating the patient's intimidation and physical interference factor, and allowing for the recording to be conducted at the patient's natural home environment, provide for a much better reflection of patient's typical sleep, and unimpaired recording of sleep patterns.

The Watch PAT100, which has been used clinically since early 2002, does not fit the definition of PSG, on one hand, but has clinical and technological features that are substantially advantageous to those associated with existing technologies for unattended sleep studies, on the other hand. CPT code 95806 describes unattended sleep studies, but the description of the service associated with this code refers to technologies predating the PAT. Due to certain limitations of such older technologies, some health plans have not reimbursed providers for conducting unattended studies. Approving reimbursement for sleep studies utilizing the PAT ambulatory technology, which represents significant improvement over prior devices, is consistent with the evolution of other medical practices. A number of procedures performed in the past only in a fixed facility setting, for example monitoring of cardiac and neurological parameters, have evolved to include home-based options, once ambulatory technologies for such applications have been properly validated. These ambulatory technologies have not replaced fixed site technologies, but rather provide additional diagnosis options for physicians and a valuable alternative for their patients. While the WP100 may not be appropriate for all patients being referred to the sleep lab, nor for the diagnosis of all sleep disorders, it will however, in the vast majority of cases, provide a definitive diagnosis to patients suspected of having sleep apnea.

Prior Guidelines for Unattended Sleep Studies

Various professional organizations, medical societies and health plans have assessed in the last ten years

the use of unattended sleep studies for OSA. Since such reviews were based on literature predating the introduction of the peripheral arterial tonometry technology, they do not address the PAT technology specifically.

Blue Cross Blue Shield – TEC

A TEC Assessment of portable sleep studies for diagnosis of obstructive sleep apnea syndrome was presented to the Blue Cross and Blue Shield Associations' Medical Advisory Panel on May 1996¹⁵. The report recognized that "portable sleep studies have been used in the home setting for diagnosis of obstructive sleep apnea. Portable sleep studies may be used as an initial diagnostic tool to avoid the inconvenience of PSG in a sleep laboratory; as a means for evaluating treatment; or as an alternative to PSG for making a definitive diagnosis of sleep apnea", but indicated that (based on the scientific data reviewed for that report published prior to 1996) the evidence was not sufficient to quantify the probability of incorrect diagnosis, redundant testing, or the beneficial outcome of avoiding the inconvenience of an unnecessary polysomnography. Based on the report findings, many of the Blue Cross and Blue Shield plans determined that unattended sleep studies should be considered investigational and therefore, not eligible for reimbursement (since then a number of Blue Cross plans have decided to reimburse providers for unattended sleep studies).

Agency for Health Care Policy and Research (AHCPR)

MetaWork's systematic literature review conducted in 1998 on behalf of the U.S. Agency for Health Care Policy and Research (AHCPR)¹⁶. The report found evidence that a full PSG may not be necessary to diagnose sleep apnea, but determined, based on literature published prior to November 1997, that there was not sufficient evidence that sleep studies devices can be used reliably in the home setting.

American Association of Sleep Medicine (AASM)

The Practice Committee of the American Sleep Disorders Association (name changed to American Academy of Sleep Medicine, or AASM) stated in 1994¹⁷ that unattended portable sleep recordings for OSA assessment is an acceptable alternative to PSG in the following situations:

- Patients with severe clinical symptoms indicative of OSA, when initial treatment is urgent, and standard PSG is not available.

- Patients unable to be studied in a sleep lab, such as non-ambulatory patients who cannot safely be moved. Such patients are likely to have disturbed sleep patterns, therefore the risk for false negatives and otherwise inaccuracy assessment is heightened.
- Evaluate response to therapy, using follow-up studies, when a diagnosis has been established by standard PSG, and therapy has been initiated.

Institute for Clinical Systems Improvement (ICSI)

The Minnesota-based organization, sponsored by the major health plans in the state, provides an evidence-based framework for the evaluation of treatment of patients. The 2003 ICSI guidelines¹⁸ indicate that “selection of appropriate diagnostic tests, as in all clinical situations, must take into account the estimated pre-test likelihood (prior probability) of the patient having OSA, the availability of credible diagnostic tests, and the local expertise in interpreting these complex physiological tests”. The guidelines state that in patients with a high pre-test likelihood of OSA, unattended portable recording for the assessment of obstructive sleep apnea is an acceptable alternative to standard polysomnogram in the same situations outlined by the AASM (above). The recommendation to reserve in-home ambulatory testing to patients for whom the probability of having moderate to severe obstructive sleep apnea is high, was justified by the number of false-negative results obtained by in-home studies when used in patients with mild to moderate apnea¹⁹.

Validating the PAT Signal

OSA testing using the new physiological marker, peripheral arterial tone, has been studied and reported in the literature since 1999. There is a growing body of published evidence that demonstrates that measurement and analysis of peripheral arterial tone, in conjunction with pulse rate, blood oxygen Saturation, body movement and related physiological indicators, provides accurate assessment of OSA, comparable in most instances to that of in-lab PSG. The new procedure utilizing PAT technology can monitor and identify overnight patterns of arousal and cardio-respiratory pathophysiology, and provide the physician with reliable information to accurately diagnose sleep apnea and other subtle sleep disordered breathing pathologies in the patient’s natural home setting

The studies of Schnall et al²⁰ and Lavie et al²¹ based on 42 OSA suspected adults demonstrated that (i) terminations of apnea events are associated with marked attenuation of pulse wave amplitude and transient relative tachycardia; (ii) PAT attenuations were associated with alpha activity coinciding with the onset of the vasoconstriction phase of PAT; and (iii) mean Apnea-Hypopnea Index (AHI) score, as measured by conventional PSG and by the PAT, correlates well, with $R=0.92$ ($p<0.001$). Taken together, these studies showed that the use of the specialized PAT finger plethysmograph facilitates the non-invasive detection of peripheral vascular responses to arousals in sleep disordered breathing.

Ding et al²² validated vasoconstriction response to apnea by the PAT signal, by measuring it simultaneously with PSG, while administering oxygen and intraarterial infusion of alpha-receptor antagonist (phentolamine) during sleep stages 1 and 2.

Grote, Hedner et al^{23,24} concluded that PAT allows for a continuous and non-invasive measurement of digital blood flow changes, which are determined by adrenergic alpha-receptor activation. The study validated the PAT’s utility in detecting autonomic sympathetic nervous system activation, and showed that sleep disordered breathing induced an arousal-related attenuation of pulse wave amplitude. This study further demonstrated that vasomotion in the forearm vasculature is mediated by both alpha (constrictory) and beta (dilatatory) sympathetic effectors, and is thus potentially capable of ambiguous and unpredictable response patterns during sympathetic activation due to the opposing vasomotor influences of the alpha and beta adrenergic effectors at the forearm. In contradistinction to this, the vascular bed of the finger is characterized by a tonic and phasic alpha-receptor mediated control, allowing accurate and unambiguous identification of arousals mediated sympathetic activation by pulse wave amplitude.

O’Donnell et al²⁵ conducted a validation study demonstrating that the magnitude of reduction in PAT signal amplitude is dependent on the degree of airflow obstruction during sleep, and thus, greater obstruction is reflected in a greater reduction in PAT amplitude. Furthermore, the study also demonstrated that the PAT signal shows marked attenuation during the arousal from sleep, immediately after nasal pressure is restored, while the signal amplitude shows non-significant decrease in the absence of arousal.

Summary of Evidence

Approval from the appropriate government regulatory bodies:

FDA has issued 510(k) clearance authorizing clinical use and commercial distribution of the Watch-PAT 100, consistent with its labeled indication. FDA's determination was issued on November 6, 2001, reference number K010739.

The approved indications for use are: *The Watch PAT 100 is a non-invasive home care device, intended for use as an aid in the detection of sleep related breathing disorders. It is indicated in cases of suspected sleep disorders. The Watch PAT 100 is not indicated for children less than 17 years old. The Watch PAT 100 is contraindicated for patients with latex allergy.*

The effect of the technology on health outcomes:

In a published position statement by the AASM²⁶, the authors refer to the many retrospective and matched control studies pointing to the fact that mortality appears to be related in a graded fashion to the severity of sleep-disordered breathing (SDB). Numerous papers reported that SDB also plays causal or contributing role in the development of comorbidities, such as hypertension and cardiovascular events. Untreated OSA is also associated with increased risk of motor vehicle and work accidents.

In a two year study of 97 untreated sleep apnea patients, hospitalization days increased 2.8-fold compared to the control group. During that period, the OSA patients also incurred hospital costs of \$100,000-\$200,000 higher than the control group, and double the physician costs²⁷. Another study of 238 patients with OSA, compared to age and gender matched control subjects, showed that the magnitude of medical costs correlated with the severity of OSA, with mean medical cost prior to diagnosis of \$2,720 for sleep apnea patients vs. \$1,384 for control subjects²⁸.

A study by Bahamman et al²⁹ analyzed saving realized following medical intervention in 344 patients with OSA. The author reported that in the two years following treatment, physician costs fell 33%, compared to the two years period prior to intervention, and that duration of hospital days for OSA patients dropped from 1.27 days per-patient-year to 0.54 days per-patient-year (p=0.01).

Positive diagnosis of OSA enables physicians to initiate treatment. The most common and first choice treatment for patients diagnosed with sleep apnea is CPAP, a highly effective, noninvasive treatment. CPAP has been shown to reduce physiological and psychological associated morbidities in patients with sleep apnea. A study at Yale³⁰ evaluated the impact of CPAP on quality of life of patients, showing marked improvement in vitality, social functioning and mental health. Other studies reported that treating OSA patients with CPAP may substantially reduce the negative effect on the cardiovascular system³¹. A recently published multi-center randomized clinical trial on 24 patients with CHF demonstrated improved heart function, decreased heart size, decreased blood pressure and decreased heart rate in the group treated with CPAP and medication, as compared to the group treated with medication alone, which showed no improvement at all³². Another study concluded that the magnitude of drop in blood pressure two months after starting CPAP treatment is predicted to reduce coronary heart disease event risk by 27% and the risk of cerebrovascular accident by 56%³³.

Chervin et al³⁴ analyzed the cost benefits of conducting sleep study for the detection of OSA. The study concluded that compared to other medical procedures, the advantage gained by sleep study seems to be well worth the cost. The use of PSG costs less than \$40,000 per quality-adjusted-life-year (QALY), compared to the cost of screening asymptomatic patients for carotid stenosis at \$120,000 per QALY, and the cost of renal dialysis at \$47,200 per QALY.

Technology impact on health outcome

Various portable monitors, predating the PAT technology, have been reported to lose data in 9% to 33% of studies. Portier et al³⁵ reported that in a series of 103 patients undergoing PSG at home and in the lab, 20% of home studies recordings were voided because of lost, or due to poor quality of recorded data, compared to 5% of data collected in the lab, and that for 33% of patients, home sleep studies were not feasible. Another study reported on a more recent technology used in attended sleep studies, and pointed to the fact that the device limits the information available to the diagnosing physician to summary data only, without providing visibility to the specific breath-by-breath data³⁶.

Reporting on a study of 37 adults, randomly selected from a population based cohort of 400 subjects, Grote et al³⁷ reported a correlation of R=0.83 (p<0.001) between RDI measured by the WP100, and standard PSG. Sensitivity and specificity for the diagnosis of

OSA (defined in the study as $AHI > 20$) by the PAT device were 92% and 70% respectively.

Another study by Pillar et al³⁸, including 35 OSA suspected patients, reported that the PAT can distinguish OSA with sensitivity of 100% and specificity of 80%. The correlation between the RDI measured by PSG and PAT was $R=0.93$ during Non-REM sleep and $R=0.79$ during REM sleep.

Pittman and Pillar³⁹ reported the results of a multi-center in-lab validation study of the WP100, including a sub-group of patients which was also evaluated in an unattended home setting. Data collected at patients' home was analyzed by the automatic algorithms built into the WP100 system. Each home study was followed by one PSG overnight study in the lab as a control. PSG scoring followed AASM criteria. The results showed that RDI measured by the PAT device in the home correlated well with RDI measured in the lab, using PSG ($R=0.74$, $p < 0.0001$). This seemingly not very high R value should be considered in light of the inherent inter-night variability of the number of sleep disordered breathing events⁴⁰, and the fact that the in-lab PSG studies and the at-home PAT studies were conducted on different nights. Using $RDI > 12$ to define OSA, sensitivity and specificity of the PAT device were 93% and 80%, respectively.

Benefit of the technology in comparison to established alternatives

Bar et al⁴¹ studied 76 adults, including 69 previously diagnosed patients with OSA and 7 normal volunteers. Study consisted of simultaneous PSG and WP100 recorded in a sleep lab. The results showed high degree of correlation in RDI between the two modalities of sleep studies, with $R=0.90$ ($p < 0.0001$).

Schnall et al¹⁷ studied 42 adult patients with suspected OSA, and using an automatic analysis of the PAT signal and the pulse rate derived from the WP100, demonstrated high correlation between mean conventional AHI and mean PAT AHI, with $R=0.92$ ($p < 0.0001$).

Ayas et al⁴² compared indices of autonomic arousal derived from standard PSG variables, and those measured by the WP100, are found the latter to better predict (i) subjective day-time sleepiness, as measured by Epworth Sleepiness Scale, (ii) quality-of-life, as measured by Functional Outcomes of Sleep Questionnaire, and (iii) decrements in performance, as measured by Psychomotor Vigilance Test.

Pillar et al⁴³ studied 26 patients, presumably well treated with CPAP. Simultaneous recording of PSG and WP100 showed that (i) the WP100 accurately detected respiratory breathing disorders while the patient is on CPAP, and (ii) that 20% of the patients with moderate or severe OSA required a re-titration of their CPAP pressure. The authors suggested that considering the technical inherent difficulty in measuring nasal air flow while the patient is breathing through a CPAP nasal mask, the WP100 would be an ideal device to conduct reassessment of treatment efficacy.

Penzel et al⁴⁴ studied 20 adults with suspected OSA, comparing changes in the PAT signal to the World Health Organization (WHO) criteria, and reported that PAT signal followed closely apnea-related changes in blood pressure.

Pillar et al⁴⁵, following a study including 68 adult patients, confirmed that the automatic analysis of the PAT signal derived from the WP100 device identifies arousals during sleep. Simultaneous overnight recordings of PSG and PAT signal showed a correlation of $R=0.87$ ($p < 0.001$) between arousals determined by sleep specialists analyzing PSG recordings using criteria defined by the AASM, and the arousals identified by the WP100.

In another study including 24 adults, Pillar, Shlitner et al⁴⁶ concluded that the PAT detects sympathetic activations associated with microarousals during sleep. Arousals identified by PSG, using AASM criteria, and arousals recognized by PAT, highly correlated with $R=0.95$ ($p < 0.01$).

The improvement is attainable outside the investigational setting

Duntly et al⁴⁷ reported on a validation study using the WP100 device at the home setting. 56 subjects, tested in two separate centers, have undergone PSG and PAT study in a sleep lab (control), followed by unattended studies at home. PAT RDI was highly correlated to PSG RDI with $R=0.87$ ($p < 0.0001$). Home studies were successfully collected in 91% of recordings, with Positive Predictive Value of 0.97 and Negative Predictive Value of 0.80.

Another study, reported by Ayas et al⁴⁸, compared the results of 28 randomly selected patients undergoing unattended home sleep study using the PAT device, to results obtained for same patients in both PSG and in-lab PAT studies. The study concluded that the WP100 provides an accurate method to differentiate patients with and without OSA. Using $RDI > 16$ to

define OSA, sensitivity was 85% and specificity 87.5%. The study also documented 100% reliability of the PAT device, with no failure during data acquisition or data analysis.

Proposed Guidelines for Using PAT Technology to Diagnose OSA

Sleep studies can be done at patient's home, without a technologist in attendance, as long as the study incorporates the following elements:

1. Identification of respiratory disturbances through the monitoring of sympathetic activation and measurement of changes in peripheral arterial tone.
2. Simultaneous measurements of arterial oxygen saturation and heart rate.
3. Detection of sleep/wake states.

The PAT technology should be an acceptable method for conducting sleep studies in an unattended setting, in the following cases:

1. Rule out a questionable OSA diagnosis and thereby eliminate the need for polysomnography.
2. Affirmatively diagnose suspected OSA and refer a patient for immediate treatment.
3. When standard polysomnography is not readily available, and patient's symptoms are severe, strongly suggesting a diagnosis of OSA requiring immediate treatment.
4. When testing in a sleep laboratory is not possible because of the patient's condition (e.g., patient is non-ambulatory or obese).
5. As a follow-up study to evaluate the response to therapy after initiation of treatment or after a period of time to evaluate the stability of the treatment
6. When testing by a sleep laboratory is not readily available in the patient's locale.

Summary

The PAT technology has been studied extensively, with essentially all published studies reaffirming the efficacy of the technology in diagnosing OSA. Ten published studies, including a total of 743 patients, report mean correlation of $R=0.86$ between RDI measured by PSG and in studies using the WP100. The new technology has now been used in multiple

clinical settings since its approval by the FDA in November 2001, demonstrating significantly better performance compared to previous devices used in unattended tests for OSA. Recording non-invasively Peripheral Arterial Tone (PAT) signal, together with simultaneous measurements of pulse oxymetry, heart rate and an embedded actigraph, enables reliable detection of sleep respiratory disturbances, as well as sleep/wake differentiation. These capabilities, coupled with a patient-friendly interface with the sensors and the device itself, have demonstrated in multiple reports close to 100% success in data acquisition in the unattended setting, with average reported sensitivity and specificity of 93% and 80%, respectively.

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