

THE WATCH-PAT™ IN THE SLEEP LABORATORY

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Most sleep labs utilize Polysomnography (PSG) as their sole methodology to diagnose obstructive sleep apnea (OSA) and other sleep breathing disorders. Some sleep labs may also use, or have used in the past, ambulatory test (a/k/a 'home study' or 'Level III' study). A number of mostly independent providers conduct unattended, home-based studies on a routine basis, utilizing simpler equipment, typically with four channels of recorded data. The growing interest of many physicians in diagnosing OSA through their own practice, using simplified unattended sleep studies, has stimulated an active debate about the efficacy of such tests. While this debate will undoubtedly be further pursued by clinicians and researchers, it is apparent that clinical needs, shifts in healthcare environment and technological developments will lead to growing acceptance of simpler diagnostic options, requiring all sleep labs to assess their services and determine how to respond to the shifting landscape.

Even proponents of in-lab PSG studies agree that a significant number of OSA patients can be diagnosed in alternate settings and with less than full PSG montage, especially if such studies are overseen by sleep specialists. Thus, ambulatory testing that are properly utilized and operated by skilled professionals can add to the arsenal of diagnostic options available to practitioners who are entrusted to manage patients' healthcare. The Minneapolis-based Institute for Clinical Systems Improvement (ICSI) has recognized the importance of this issue, and in its recent guidelines published in May 2004¹ stated that:

"In patients with a high pretest probability of OSA, unattended portable recording for the assessment of obstructive sleep apnea is an acceptable alternative to standard polysomnogram in the following situations: (1) patients with severe clinical symptoms that are indicative of a diagnosis of obstructive sleep apnea and when limitation of treatment is urgent and standard polysomnography is not available, (2) for patients unable to be studied in the sleep laboratory, and (3) for follow-up studies when diagnosis has been established by standard polysomnography and therapy has been initiated."

"Polysomnography is not available in some rural areas. Some patients decline to undergo a study in a sleep laboratory. For those and other reasons, some physicians are interested in expanding the use of in-home, unattended portable recording beyond the three situations listed above. At present the evidence supporting this expansion is limited and at times conflicting, but employment of portable monitoring as a second-best option is not likely to result in harm to patients with a high pretest probability of OSA, and may result in less risk than leaving the condition undiagnosed. Portable monitors should not be used in an unattended setting in patients with "Atypical or Complicating Symptoms". In a patient with suspected OSA, a negative study must be followed by a polysomnographic test. The patient and physician must discuss fully the limitations of portable monitoring before employing this strategy."

While many studies documented acceptable sensitivity and specificity of tests conducted with four-channel devices, some practitioners still perceive the quality of data gathered during an unattended study as potentially compromised due to poor data acquisition resulted from improper sensors' interface. Questionable data can leave the interpreting physician with the uncomfortable choice of incurring the cost of a repeat study and inconveniencing the patient, or relying on limited data to establish a diagnosis. The

¹ ICSI, Diagnosis and Treatment of Obstructive Sleep Apnea, Second Edition, May 2004

inability of most ambulatory testing devices to detect sleep/wake states results in additional impairment of the study's results, as assessment of the effect of the disorder on the patient's sleep architecture cannot be made and an objective measure of actual sleep time is not available.

The Watch-PAT is the first significant technology introduced to the sleep market in recent years to overcome such limitations. The technology, developed by Itamar Medical Ltd., is based on the system's ability to sense minute changes in peripheral arterial vasomotion caused by each apnea event. Coupled with the advanced actigraphy-based algorithms that enable the reliable detection of sleep/wake/REM states, and together with measures of heart rate and saturated blood oxygen, the Watch-PAT provides a remarkable new method to diagnose OSA. The Watch-PAT has undergone multiple validation studies which have demonstrated the reliability of the device, its ability to recognize sleep and wake states, and to provide an accurate measure of apneic events when used either in the lab or at the patient's home. With its innovative ergonomics and sophisticated algorithms, the Watch-PAT provides a number of unique benefits:

- All sensors and electronics are incorporated into a very simple-to-use wearable device, and with only two finger-mounted probes, patients are free of interfering wires. Furthermore, by avoiding the head and face sensors, patients can sleep in their natural position and in their own environment, emulating their regular sleep, even when undergoing the test.
- The minimal and simple interface to the patient provides for a high degree of signal acquisition reliability.
- Identifying actual sleep allows the device to normalize the number of apnea and hypopnea events to an index better resembling PSG studies.
- The sophisticated data analysis allows for an accurate and rapid detection of respiratory events, as well as sleep, wake and REM states, speeding up the turnaround time for the study and enhancing the consistency of the corresponding analysis. Yet, full disclosure capabilities enable the technologist or physician to review each episode and mark events manually.

In spite of growing interest in home sleep studies, not all third party payers cover such procedures. To reduce potential revenue loss even when reimbursement for home studies is not universally available, the sleep lab may identify those patients that qualify clinically and meet one of the following categories: Patients covered by plans that do reimburse for home studies; Patients with significant co-pay or deductibles who may in effect lower their expense when tested with Watch-PAT; Self-pay patients, and patients with no-coverage at all (courtesy studies).

A growing number of sleep labs that until recently employed only traditional PSG equipment have identified various ways to benefit from using the Watch-PAT. Some examples to how the Watch-PAT may be utilized by sleep labs are outlined below:

- **Reducing waiting time.** Many labs struggle with growing demand for services that extends waiting time for patients suspected of sleep apnea to weeks and even months, frustrating patients and referring physicians alike. Any lab faced with increasingly longer wait time can quickly reduce it by identifying patients that can be tested at home, applying its own clinical criteria for the Watch-PAT testing.
- **Addressing special needs.** Many patients referred to a sleep lab fail to schedule a study, either because they are intimidated by the experience, or consider the need to spend an entire night in an outside testing facility too inconvenient. Other patients may have special medical or physical needs that limit their ability to undergo a study in a sleep lab, or simply prefer to be tested at the privacy of their homes. Cumulatively, such cases may represent a significant case load of patients

that otherwise will not be seen at all by the lab, and now may be studied using the Watch-PAT, and subsequently, treated in accordance with standard protocols.

- **Maximizing limited resources.** Chronic shortage of sleep technologists affects the ability of labs to meet requested service volume. The situation deteriorates following turnover of techs, or even when techs are sick or on vacation. Labs cannot alleviate the situation by increasing the ratio of patients to a technologist, as such practice is contrary to the guidelines established by the American Academy of Sleep Medicine. Since the use of Watch-PAT requires minimal technician involvement for each study, the lab can utilize a number of Watch-PAT systems with even the limited number of available techs. When faced with shortage of staff, a lab can optimize its resources by utilizing the Watch-PAT for many of the diagnostic evaluations, either as home studies or in-lab studies, while reserving the available technologists to monitor titration studies and the more complex diagnostic evaluations.
- **Responding when immediate results are required.** A sleep lab with considerable waiting time can also use the Watch-PAT in situations requiring quick turnaround time (e.g. pre-operative evaluations, out-of-town patients, high risk cases, etc.), without having to reshuffle existing schedules.
- **Supporting inpatient studies.** Many hospital-based sleep labs are called periodically to conduct a sleep study on an inpatient located in an ICU, a CCU or on one of the patients' wards. The ability to set-up sleep studies for such patients within minutes and without interfering with other support systems is unique to the Watch-PAT. Furthermore, the auto-analysis software available with the Watch-PAT provides the diagnostic results within minutes following the completion of the test itself, enabling the hospital's staff to quickly incorporate the results of such to the ongoing management of the patient.
- **Expanding outreach programs to referring physicians.** Cardiologists, family practice physicians and other specialists are gaining appreciation of the importance of testing patients for sleep breathing disorders. Labs incorporating the Watch-PAT are able to better market their services to referring cardiologists, ENT's, bariatric surgeons and to other specialists and even to general practitioners that prefer a simpler and faster test for some of their patients.
- **An alternative to fixed-bed satellites.** A growing number of labs are setting satellite operations, consisting of smaller labs, distant to the main facility. While these facilities enable the organization to capture additional referrals, they do come at a financial cost for setting-up and operating these units, and at times, may also stretch already thin staff. An alternative method to testing patients in remote areas is to utilize the Watch-PAT, at least for the initial diagnosis of such patients. The Watch-PAT may be especially suitable in rural areas, as low population density cannot justify a local sleep lab staffed by qualified technicians.
- **Employee screening.** Some labs consider expansion of their programs to the employer market, offering screening and diagnosis services to shift workers, employees in critical and risky occupations, etc. The portable and user-friendly Watch-PAT is an ideal technology for this emerging market.
- **Conducting follow-up studies.** Many patients require periodic testing to confirm the need for continuing intervention, or to determine an adjustment in treatment parameters. Presently, due to the over-extension of sleep labs and the reluctance of many patients to come to the lab for additional studies, most patients are under-managed following initial intervention. Employing the Watch-PAT for an annual evaluation, or otherwise, when medically indicated, may optimally address such needs.

- **Evaluating pre-operative patients.** Recognizing OSA prior to surgical intervention may reduce anesthesia-related complications. In most instances, ruling-out OSA needs to be done a short time prior to surgery, and the lengthy wait time in labs is not practical. Rather than ignoring these clinical cases or losing such patients to services that offer quick unattended studies, labs can retain this business by offering Watch-PAT tests.

Adding the Watch-PAT to the sleep lab can be accomplished painlessly and for a minimal investment. Other than the acquisition cost of the Watch-PAT system itself, there are virtually no other up-front costs. Training sleep lab technologists and other support staff can be accomplished within a few hours, and while the system provides for full disclosure of data, the automatic scoring and report generation enable existing staff to absorb significant incremental volume of Watch-PAT studies. Operating expenses for the Watch-PAT are also minimal, and other than procuring the disposable sensors, there are virtually no incremental per-study costs. Compared to other unattended testing devices, the additional labor cost associated with Watch-PAT studies is negligible, and the user-friendly and most simple patient interface eliminate the need for multi-nights studies and minimize the number of cases in which repeat tests are required.

Thousands of studies have already been conducted with the Watch-PAT over the last few years. Established sleep labs, including academically-affiliated and community-based, hospital-owned and stand-alone facilities, as well as government and private centers, are already using or are in process of incorporating the Watch-PAT to meet some of the applications outlined above. Although home studies do not enjoy yet universal reimbursement, every sleep lab can start integrating the Watch-PAT to augment its current services, and achieve tangible operational and marketing advantages, strengthen its competitive position within its service market, improve its financial results, and most important, enhance and expand quality patient care.

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