

Watch-PAT



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The Watch-PAT is a portable sleep diagnostic system to diagnose obstructive sleep apnea (OSA) without the attendance of a technologist. It is a small wrist-mounted device which fulfills the unmet need for an ambulatory, reliable and patient friendly diagnostic evaluation tool that is accessible to the great number of undiagnosed OSA patients. The Watch-PAT is a cost effective means for follow up treatment of patients on CPAP, Oral Appliances and post ENT surgery. The Watch-PAT opens new clinical avenues for the practice of sleep medicine – patients can be diagnosed in the comfort of their own home.

The Watch-PAT utilizes Peripheral Arterial Tonometry (PAT) in addition to other common physiological measurements. Unlike other portable devices, the Watch-PAT provides in addition to quantifiable apnea information, extensive sleep information, clinically comparable to sleep data obtained in a sleep lab. While providing more clinical information than any other Level III or Level IV devices, the Watch-PAT provides for the simplest and most reliable data acquisition in a non-attended setting.

The data acquired by the Watch-PAT is analyzed by Itamar Medical's proprietary user friendly software – zzzPAT which is installed on a computer. The sophisticated algorithm is automatic and thus eliminates the need for subjective scoring of respiratory events providing a complete report of the study within minutes after downloading the data. This method of immediate report generation, when compared to weeks in most other hospital-based settings, enables patients to initiate treatment on the same day and without delay.

How accurate is the Watch-PAT in comparison to PSG?

Numerous validations studies demonstrated high degree of correlation in RDI & AHI between same setting Watch-PAT and PSG sleep studies with $R = 0.85 - 0.96$. The RDI & AHI scores are highly reproducible, showing correlation between home and in laboratory sleep studies. The Watch-PAT device has an excellent reliability with minimal failure rate ($< 2\%$) during data acquisition or data analysis, and minimal technician time when compared with PSG.

- Bar A, Pillar G, Dvir I, Sheffy J, Schnall RP, Lavie P. Evaluation of a portable device based on arterial peripheral tonometry (PAT) for unattended home sleep studies. *Chest*, March 2003, 123(3): 695-703.
- Pittman DS, Ayas NT, MacDonald MM, Malhotra A, Fogel RB, White D. Using a Wrist Worm Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation. *Sleep* 2004, Vol.27 (5), 923-933.
- Ayas N. TA, Pittman S, MacDonald M, White D. Assessment of a Wrist-worn Device in the Detection of Obstructive Sleep Apnea. *Sleep Medicine* 2003, Vol. 4, (5), 435-442.
- Zou D, Grote L, Peker Y, Lindblad U, Hedner J. Validation a Portable Monitoring Device for Sleep Apnea Diagnosis in a Population Base Cohort Using Synchronized Home Polysomnography *Sleep* 2006: 29(3): 367-374.
- S.D. Pittman, G. Pillar, RB Berry, A Malhotra, MM MacDonald, DP White. Follow-Up Assessment of CPAP Efficacy in Patients with Obstructive Sleep Apnea using an Ambulatory Device Based on Peripheral Arterial Tonometry. *Sleep and Breathing*, 2006.

How does the Watch-Pat detect apnea, hypopnea & RERA events?

The Watch-PAT utilizes Peripheral Arterial Tone (PAT), a physiological signal that mirrors changes in the autonomic nervous system caused by respiratory disturbances during sleep. The automatic algorithm of the Watch-PAT analyzes the PAT signal amplitude along with the heart rate, and oxygen saturation to identify respiratory events. Using specific signal patterns, the algorithm provides two indices – AHI and RDI.



The Watch-Pat's unique clinical features:

- Real Sleep Time
- RDI and AHI
- ODI (Oxygen Desaturation Index)
- Heart Rate
- Body Position
- Snoring Intensity (dB)
- Sleep Stages and Architecture (wake/light/deep)
- REM/nonREM Sleep
- Sleep Fragmentation
- Sleep statistics

The Watch-Pat measures 6 channels

- PAT (Peripheral Arterial Tone)
- Oximetry
- Actigraphy
- Heart Rate
- Body Position
- Snoring

How do the Watch-PAT detect REM?

REM sleep is associated with considerable attenuation of the PAT signal and physiology coupled with specific variations in the PAT amplitude and rate. Based on this specific variability in the PAT and Pulse rate signals, REM sleep stage differs from non REM sleep. In addition, it is differentiated from the wake state by the advanced actigraphy algorithms of the Watch-PAT.

How does the Watch-PAT detect sleep architecture?

The sleep/wake detection is based on data recorded by the built-in actigraph. The propriety software's automatic actigraph algorithm discriminates between sleep and wake states in normal subjects and OSA patients. This algorithm makes the Watch-PAT superior to any other actigraph devices as most of them fail in OSA subjects. The sleep/wake algorithm has been validated and published in peer-reviewed journal. The results show close agreement between actigraphy and PSG in determining sleep efficiency, total sleep time, and sleep latency (agreement 86% in normal subjects, 86%-mild OSA, 84%-moderate OSA, 80%-severe OSA).

- Hedner J, Pillar G, Pittman DS, Zou D, Grote L, White D. A Novel adaptive wrist actigraphy algorithm for Sleep-Wake assessment in sleep apnea patients *Sleep*, 2004, 27(8):1560-6

How do the Watch-PAT differentiate between light and deep sleep?

The zzzPAT algorithm is based on 14 features extracted from two time series of PAT amplitudes and inter-pulse periods (IPP). Those features were then further processed to yield a prediction function that determines the likelihood of detecting a deep sleep epoch stage during Non-REM sleep periods. Together with the already existing algorithms for REM and wake detection

the zzzPAT is able to detect full stage detection method based solely on the PAT and actigraphy signals.

- Ma'ayan Bresler, Koby Sheffy, Giora Pillar, Meir Preiszler, Sarah Herscovici *Differentiating between light and deep sleep stages using an Ambulatory Device Based on Peripheral Arterial Tonometry. Physiol Meas.* 2008; 29(5): 571-584.

Why is it an advantage to use sleep time vs. study time?

One of the biggest problems with the vast majority of ambulatory devices is the lack of "real sleep" monitoring (*they record both sleep and awake time*). These devices provide only "total study time" in which case the respiratory disturbances index (RDI) is calculated by dividing the total number of respiratory events by a substantially longer time period, thus providing a lower RDI (or AHI) than the real one. The actual sleep time is essential to determine the true RDI. Because the Watch-PAT detects the sleep/wake state and REM sleep stage along with "total sleep time," it provides an accurate estimation of sleep architecture. The Watch-PAT's automatic sleep time detection is determined by:

$$\text{total recording time} - \text{the wake time and time of invalid signals} = \text{total sleep time}$$

Can the raw data of the sleep study be edited?

All raw data provided by the zzzPAT software can be edited and over-written by the physician. While we do not suggest that this be done as the accuracy of the algorithms have been proved, the physician has a free reign over all collected data.



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