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Frequently Asked Questions about the WatchPAT200

When is it worn and where is it worn?
Itamar Medical's WatchPAT is only worn on the wrist with probes on two (2) fingers when the patient is sleeping. The simplicity of the WatchPAT200 offers the patient and practitioner the most reliable home sleep testing (HST) device in the market with a failure rate of less than 2%.

What is Peripheral Arterial Tone (PAT)?
PAT is a physiological signal that mirrors changes in the autonomic nervous system caused by respiratory disturbances during sleep. The PAT signal is automatically analyzed utilizing a clinically validated algorithm along with heart rate, and oxygen saturation to identify respiratory events. Using specific signal patterns, the algorithm provides two indices used in determining the degree of sleep apnea – Apnea-Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI).

Why is the PAT probe inflated?
The probe is inflated in order to clamp it on the finger and apply a uniform pressure field around the finger that is required for an accurate measurement of the PAT signal.

Can I re-use the PAT probe?
NO! The probe is one time use only and once it is applied on the finger it can't be re-used. Once inflated the probe loses its ability to maintain the elasticity properties of the inner membrane, which are necessary for an accurate measurement of the PAT signal. In addition the PAT probe can't be sterilized (the very fine membrane will be damaged).

How does the PAT pick up 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 WatchPAT 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 snore sensor enables the clinician to determine if the respiratory events are obstructive and the body position sensor enables the clinician to determine if there is a positional component to the sleep apnea.

How does the WatchPAT detect sleep and wake?
The sleep/wake detection is based on data recorded by the built-in actigraph and the specific signal patterns associated with the PAT signal. The propriety software zzzPAT automatic actigraph algorithm discriminates between sleep and wake states in normal subjects and OSA patients. This algorithm makes the WP superior to any other actigraph devices as most of them fail in OSA subjects due to the frequency of movement at the termination of the events.

How do the WP and zzzPAT detect REM?
REM sleep is associated with considerable attenuation of the PAT signal 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 no-REM sleep. In addition, it is differentiated from the wake state by the advanced actigraphy algorithms of the WP.

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Are there published studies that clinically validate the WatchPAT technology?
The WatchPAT has been scientifically validated **more than any ambulatory sleep diagnostic device** currently or previously available (~40 peer-reviewed articles) based on over 3,000 PSG studies simultaneously with WatchPAT. More than 230,000 tests have been performed worldwide using WatchPAT. Regarding long-term, multi-centered controlled studies, it is one of only 2 devices approved by Blue Cross' California Technology Assessment Forum as "**improving health outcomes.**"

Why is it an advantage to use sleep time vs. study time?
One of the biggest problems with HST devices is the lack of real sleep monitoring providing only total study time in which case the respiratory disturbances index is calculated by dividing the total number of respiratory events to what might be a substantial longer time period and thus providing a lower RDI (or AHI) than the real one. The actual sleep time is essential to determine the true RDI/AHI. The Watch PAT detects sleep/wake state and REM sleep stage along with total sleep time to minimize the number of potential false negatives.

Is an HST with the WatchPAT200 reimbursable?
Yes; in January 2011, the US Centers for Medicare Services CPT committee approved a new CPT code (95800) specific to HST devices that utilize PAT technology to determine the degree of sleep apnea and amount of sleep time that is recorded during a patient's HST. Commercial insurance payors are rapidly reimbursing for the new code, but some continue to use G codes (G0400) for 2011.

Who can interpret an HST?
In order for therapy to be reimbursed, most insurance payors, including Medicare (CMS), require that the HST is interpreted by a licensed medical doctor who is board certified or board eligible (awaiting examination) in sleep medicine. Alternatively, a physician that sits on the physician panel of an American Academy of Sleep Medicine (AASM) and/or JCAHO accredited sleep center may interpret an HST. Itamar Medical has a close working relationship with an interpreting service that meets these requirements.

Is there a warranty?
Yes. The WatchPAT200 offers a one year warranty against manufacturing defects, which means you can have full confidence in the product. Each additional year is $400.

Are there any exclusion criteria for the using the WP?

The exclusion criteria for using the WP include:

- Age less than 17 years old.
- Using one of the following medications:
  - Alpha blockers (if taken less than 24 hours before the study).
  - Short acting nitrates (less than 3 hours before the study).
- Permanent pacemaker.

What are the costs to conduct a home sleep study (HST) using the WatchPAT200?
The cost to conduct a study are $50 for a probe, $1.50 for adhesives, and the capital depreciation costs that approximate $15 per study for a total cost of approximately $66.50 per study.