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MEDICAL INFORMATION [IN] YOUR FINGERTIP

sleep-pat

The PAT™ signal has the potential to provide new screening, diagnostic, treatment assessment and patient follow-up possibilities in the medical management of sleep-related breathing disorders. Itamar Medical's non-invasive, ambulatory ***sleep_PAT***™ *system is designed to offer added value to sleep centers, and to open new clinical avenues for the practice of sleep medicine.*

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Waking Up to a New Tomorrow

With the incidence of SAS increasing, and some 90 percent of current SAS sufferers in the U.S. going undiagnosed, there is a very significant and growing need for a new paradigm to provide screening, diagnostic, treatment assessment and patient follow-up solutions.

sleep_PAT for Better Healthcare

- ***Non-invasive window to the autonomic nervous system***
- ***Ambulatory for comfortable and convenient home use***
- ***Non-intrusive***
- ***e-Healthcare compatible***
- ***Applicable in clinics, hospitals, home or sleep centers***

MEDICAL INFORMATION [IN]

Sleep-Related Breathing Disorders and Our Daily Lives

The ramifications of sleep-related breathing disorders go well beyond the short-term effect of feeling tired upon awakening and during the day. Sufferers endure much more serious consequences, such as increased morbidity from coronary artery disease and increased risk for hypertension and depression. Moreover, inadequate sleep is associated with increased incidences of road and work accidents and significant loss of productivity in the workplace.

Sleep Apnea Syndrome (SAS)– The Most Common Disorder

Sleep apnea impairs an individual's ability to achieve sound sleep due to frequent transient arousals. These are brought on by a cessation of the airflow at the nose and mouth. The halted airflow, usually caused by a collapse in the upper airway, results in oxygen deprivation or nocturnal hypoxemia as well as hypercapnia. These changes trigger momentary arousal, as sufferers inhale for air – though they are unaware of what is happening. These brief arousals result in sleep fragmentation.

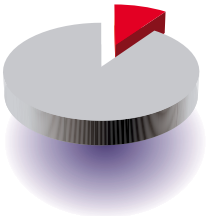
A Growing Population of SAS Sufferers

Recent research by the National Institute of Health in the U.S. estimates that SAS affects some 15 million Americans, yet less than 2 million are successfully diagnosed and treated. Furthermore, the overall prevalence of SAS is projected to rise due to the continuing increases in the number of aged and obese persons in the U.S. Both of these groups are at increased risk for suffering from SAS.

Why is this the case?

Although the number of diagnosed patients is growing rapidly and is expected to continue to grow in light of increased patient and physician awareness, traditional screening and diagnostic measures are costly, time-consuming and cumbersome.

Itamar Medical's sleep_PAT system is designed to meet this challenge.



Only a small percentage of SAS sufferers are currently diagnosed

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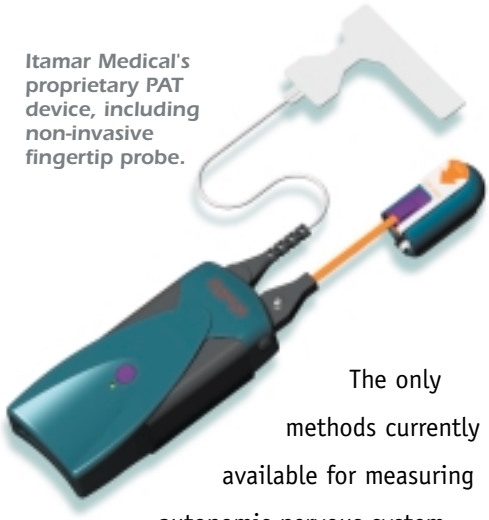


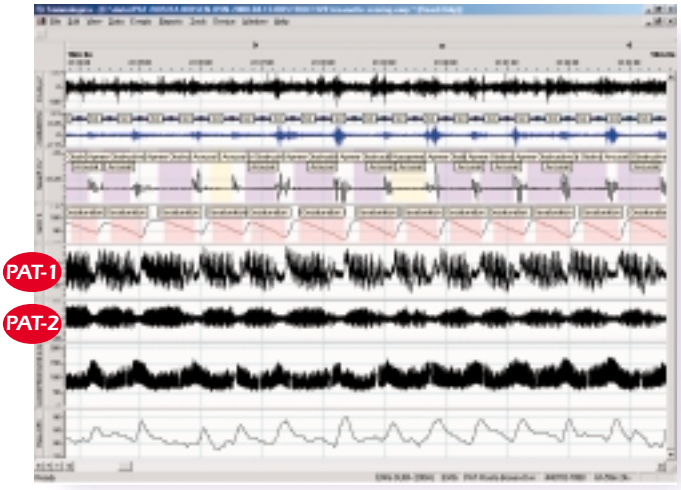
Itamar Medical's proprietary PAT device, including non-invasive fingertip probe.

Itamar Medical's sleep_PAT system is an innovative new paradigm being tested for application in the screening, diagnosis, treatment assessment and patient follow-up of sleep-related breathing disorders. The proprietary sleep_PAT system is based on the PAT (Peripheral Arterial Tone) neurosvascular signal, discovered by Itamar Medical.

The PAT Signal - What it Tells Us

The PAT signal mirrors changes or anomalies in autonomic nervous system activity and related vascular events. The PAT signal measures circulatory responses based on the magnitude and time course of changes in arterial pulsatile blood flow in the fingertip, which have been shown in clinical evaluations to provide a veritable window to the autonomic nervous system.

It is well established that the autonomic nervous system is a key factor in regulating many physiological systems. It has been shown that certain diseases, such as obstructive sleep apnea, myocardial ischemia, congestive heart failure, endothelial dysfunction, stress and a plethora of related conditions both effect and are effected by the autonomic nervous system.



Typical PAT signal attenuations during SAS, coinciding with the resumption of breathing and an increase in blood pressure. PAT-2 is filtered and PAT-1 is not. Note the breathing effort signature in the PAT signal.

The only methods currently available for measuring autonomic nervous system function are either painful, invasive procedures that carry with them certain risks, or are inaccurate and unreliable. Because of these factors, as well as the associated costs, regular, or even periodic screening of autonomic nervous system indicators has not been a viable clinical option.

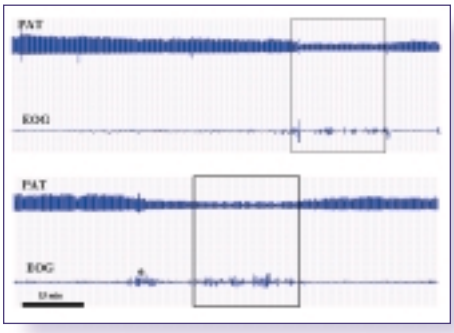
Itamar Medical devices based on the PAT signal are designed to provide a window to autonomic nervous system function by reliably and non-invasively measuring the associated changes in the magnitude and time course of changes in pulsatile arterial blood flow in the fingertip. The PAT signal can thus potentially provide a wealth of information about many medical conditions - including various sleep-related breathing disorders and cardiovascular problems - from a completely new perspective.

The sleep_PAT System

The ambulatory sleep_PAT system includes a non-invasive finger probe that measures the PAT signal. Attached to a wrist device, it can be worn comfortably during sleep. Readings can be stored in a remote CPU unit, or transferred in real-time to e-healthcare logistics centers for professional interpretation.

In clinical trials, sleep_PAT has shown profound, transient vasoconstriction at the end of each apneic event, which are related to a transient arousal. Given the fingertip's high density of alpha-adrenergic sympathetic innervation and its high degree of blood flow rate lability, the PAT signal is a reliable mirror of peripheral vascular responsiveness to SAS. sleep_PAT has also shown distinct sustained vasoconstriction during REM sleep, which is related to the well-known activation of the sympathetic branch of the autonomic nervous system during REM sleep. This opens new ways to detect REM sleep without the aid of the conventional EEG, EOG and EMG recordings which are difficult to apply outside the sleep laboratory environment.

On-going clinical studies are demonstrating that pulsatile finger blood flow patterns as measured by the PAT signal can serve as a reliable diagnostic indicator of SAS, as well as providing valuable insight into the related cardiovascular consequences.



Compressed records of the PAT signal and EOG during the transition time from non-REM to REM and back to non-REM sleep, in two subjects. Note the gradual decrease in PAT amplitude starts at least 30 minutes before the beginning of the traditionally scored REM sleep. From: Lavie et al, Nature Medicine, 2000, 6, 606.

SAS Follow-Up – Uncharted Territory

While the practice of sleep medicine is growing constantly and becoming more advanced, one very vital area has remained virtually untouched - patient follow-up. Because existing diagnostic procedures and tools are costly and cumbersome, most SAS sufferers are not referred back to sleep centers for follow-up and for assessing the efficacy of the treatment, such as CPAP usage or surgical intervention.

sleep_PAT is being tested as a cost-effective paradigm for physicians so that they will be able to not only screen potential patients, but also to provide a reliable, ambulatory alternative for follow-up on the efficacy of treatment protocols.

sleep_PAT is designed to open new avenues for the delivery of sound sleep medicine.

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About Itamar Medical

Itamar Medical Ltd. is pioneering the introduction to medicine of a non-invasive window to the autonomic nervous system – the PAT™ (Peripheral Arterial Tone) neurovascular signal. The Company's researchers are developing proprietary technologies, including non-invasive finger probes and advanced digital signal processing algorithms, to apply peripheral arterial tonometry in a number of important clinical applications, including various aspects of cardiology and sleep medicine.
The initial PAT screening, diagnostic, treatment assessment and patient follow-up products are now undergoing evaluations in leading clinical centers.
Itamar Medical was established in 1997 and is headquartered in Caesarea, Israel.

This information is provided to inform the scientific community of research and clinical developments associated with a recently discovered new medical signal- the PAT signal. It is not intended to promote any device or to suggest that any PAT based device, or any use of the PAT signal, has been proven safe or effective for any purpose.

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