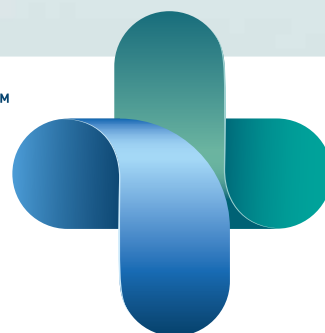




WatchPAT⁺ 300



Home Sleep Apnea Testing

Simple. Accurate. Reliable.



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WatchPAT™ 300

Home Sleep Apnea Testing

Simple. Accurate. Reliable.

WatchPAT 300 is an innovative diagnostic Home Sleep Apnea Test (HSAT) that utilizes the proprietary peripheral arterial tone signal (PAT). WatchPAT measures up to 7 channels (PAT signal, heart rate, oximetry, actigraphy, body position, snoring and chest motion) via three points of contact. Within one-minute post study, the raw data is downloaded and auto-scored differentiating obstructive and central events, providing an AHI, RDI and ODI based upon True Sleep Time and Sleep Staging. Both the AHI and RDI derived from the WatchPAT were clinically validated with an 89% correlation to PSG¹. The PAT signal is an approved measure in the 2017 AASM HSAT Clinical Practice Guidelines for Adults with OSA.

- **Simple**, 3 points of contact for outstanding patient compliance
- **Clinically reliable** with 98% success rate²
- **True Sleep Time** for accurate AHI
- **Sleep Architecture** for a comprehensive diagnosis
- **Central Sleep Apnea (CSA)** diagnostic capability with Central+ module
- **Scalable Cost Effective Solution** for high volume workflow with an automated report for immediate diagnosis and treatment decision
- **zzzPAT** software with an advanced automatic algorithm for scoring of respiratory events
- **CloudPAT™** cloud based IT solution for convenient sleep diagnosis and secure patient data transfer

WatchPAT's Clinical Parameters:

AHI

Apnea / Hypopnea Index

AHlc

Central Apnea/Hypopnea Index

RDI

Respiratory Disturbance Index

ODI

Oxygen Desaturation Index

Wake / Sleep

True Sleep Time

REM / Deep / Light - Sleep Stages

Complete Sleep Architecture

Body Position Indices

Snoring

Heart Rate

Chest Movement

Pulse Oximetry

Actigraphy

It's Simple.

Intuitive Design

- Modern intuitive design
- Improved comfort with lighter weight and flexible wristband
- Detachable design for easier cleaning

Improved Signals and User Interface

- Improved oximetry signal quality
- Enhanced user interface for improved ease of use

No More Waiting Time

- Rapid download (15 sec) for improved workflow
- One Stop processing with external battery

Central Plus Module

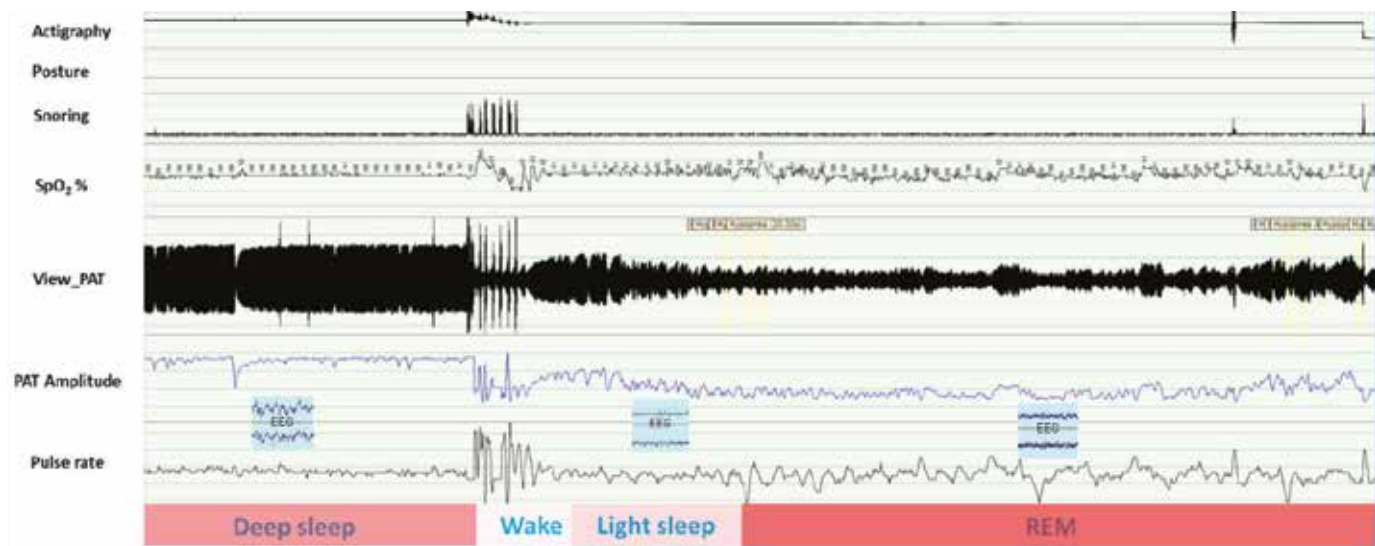
- Specific identification of Central Sleep Apnea



It's Accurate. It's Reliable.

Sleep Architecture

WatchPAT's clinically validated Sleep Architecture provides information on sleep staging including sleep efficiency, sleep latency and REM latency³⁻⁴. It also provides the added value of detecting REM related sleep apnea with REM and non-REM AHI.



Deep sleep

Low PAT amplitude variability, low pulse rate variability

Light sleep

High PAT amplitude variability, high pulse rate variability

REM sleep

Very high PAT amplitude variability, very high pulse rate variability, attenuated PAT amplitude

True Sleep Time

The WatchPAT uses its advanced actigraphy to differentiate between wake and sleep periods to calculate True Sleep Time and uses the PAT amplitude and pulse rate to differentiate between non-REM and REM thereby creating a Sleep Architecture (Light, Deep, REM). WatchPAT calculates AHI and RDI using the patient's True Sleep Time rather than the recorded time used in most commercially available HSAT's. WatchPAT's True Sleep Time reduces the risk of misdiagnosis and misclassification that has been reported to be 20% with HSAT's using total recording time.⁵

Sleep Summary

Start Study Time:	9:43:01 PM
End Study Time:	6:04:59 AM
Total Study Time:	8 hrs, 21 min
Sleep Time	6 hrs, 7 min
% REM of Sleep Time:	21.4

WatchPAT⁺ 300



Comprehensive Automated Report Streamlines Workflow

Sleep Summary

- Recording Start and End Time
- Total Recording Time and True Sleep Time

Sleep Summary

Start Study Time:	11:09:35PM
End Study Time:	5:48:33AM
Total Study Time:	6 hrs, 38 min
Sleep Time	4 hrs, 50 min
% REM of Sleep Time:	14.4

Oxygen Saturation Statistics

Mean:	96	Minimum:	86	Maximum:	99
Mean of Desaturations Nadirs (%):	93				
Oxygen Desatur. %:	4-9	10-20	>20	Total	
Events Number	55	1	0	56	
Total	98.2	1.8	0.0	100.0	
Oxygen Saturation	<90	<88	<85	<80	<70
Duration (minutes):	0.8	0.3	0.0	0.0	0.0
Sleep %	0.3	0.1	0.0	0.0	0.0

Respiratory Indices

- pRDI – PAT Respiratory Disturbance Index
- pAHI – PAT Apnea-Hypopnea Index
- ODI – Oxygen Desaturation Index
- pAHIc – PAT Central Apnea Hypopnea Index
- %CSR – Percentage of Cheyne Stokes Respiration

Respiratory Indices

	Total Events	REM	NREM	All Night
pRDI:	124	47.1	22.0	25.6
pAHI:	91	47.1	14.0	18.8
ODI:	56	35.7	7.5	11.6
pAHIc:	4	0.8	0.8	0.8
%CSR	0.0			

Indices are calculated using valid sleep time of 4 hrs, 50 min.
pRDI/pAHI are calculated using oxl desaturations $\geq 3\%$

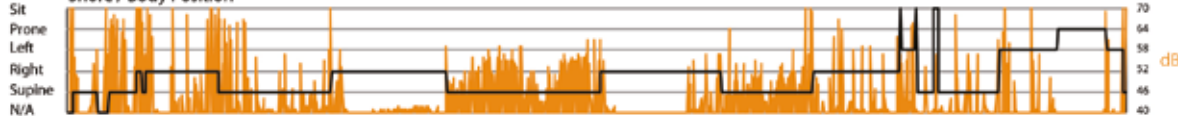
Pulse Rate Statistics during Sleep (BPM)

Mean:	55	Minimum:	N/A	Maximum:	75
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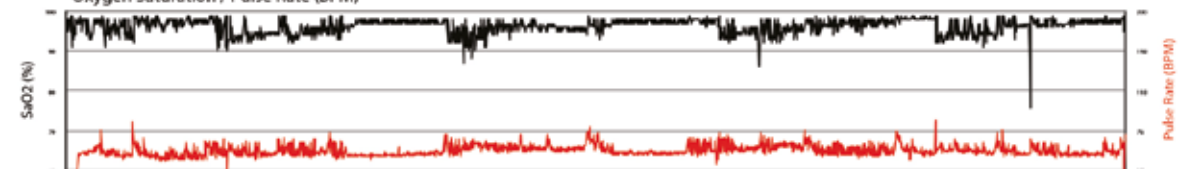
PAT Respiratory Events



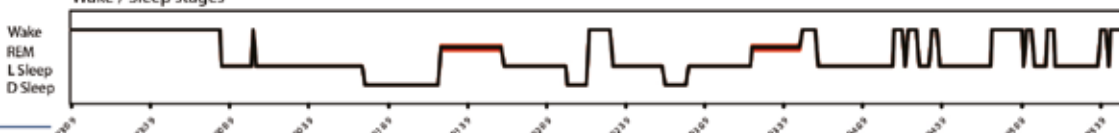
Snore / Body Position



Oxygen Saturation / Pulse Rate (BPM)



Wake / Sleep stages



Hypnogram

- All Respiratory Events
- Snore / Body Position
- Oxygen / Pulse Rate
- Sleep Stages

Oxygen and Pulse Information

- Oxygen Saturation Statistics
- Oxygen Desaturation %
- Oxygen Desaturation
- Pulse Rate Statistics

Body Position Statistics

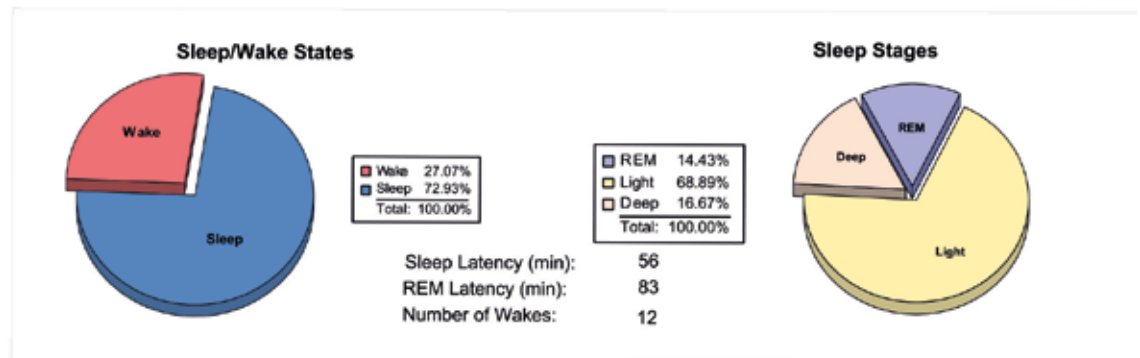
Position	Supine	Prone	Right	Left	Non-Supine
Sleep (min)	150.3	17.0	114.7	9.0	140.7
Sleep %	51.7	5.8	39.4	3.1	48.3
pRDI	33.6	0.0	19.4	N/A	17.1
pAHI	28.8	0.0	10.0	N/A	8.1
ODI	18.4	0.0	5.2	N/A	4.3



Snoring Statistics

Snoring Level (dB)	>40	>50	>60	>70	>80	>Threshold (45)	Mean: 42 dB
Sleep (min)	95.5	21.5	1.7	0.0	0.0	40.0	
Sleep %	32.8	7.4	0.6	0.0	0.0	13.7	

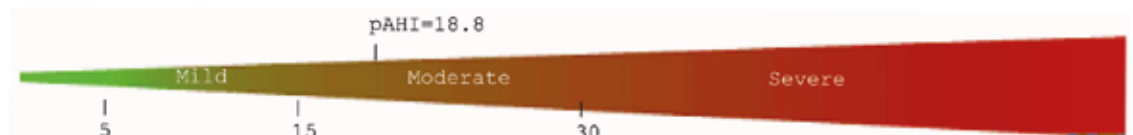
Sleep Stages Chart



Sleep Stages and Efficiency

Sleep Latencies and Sleep Stage Percentages

Respiratory Indices Graph

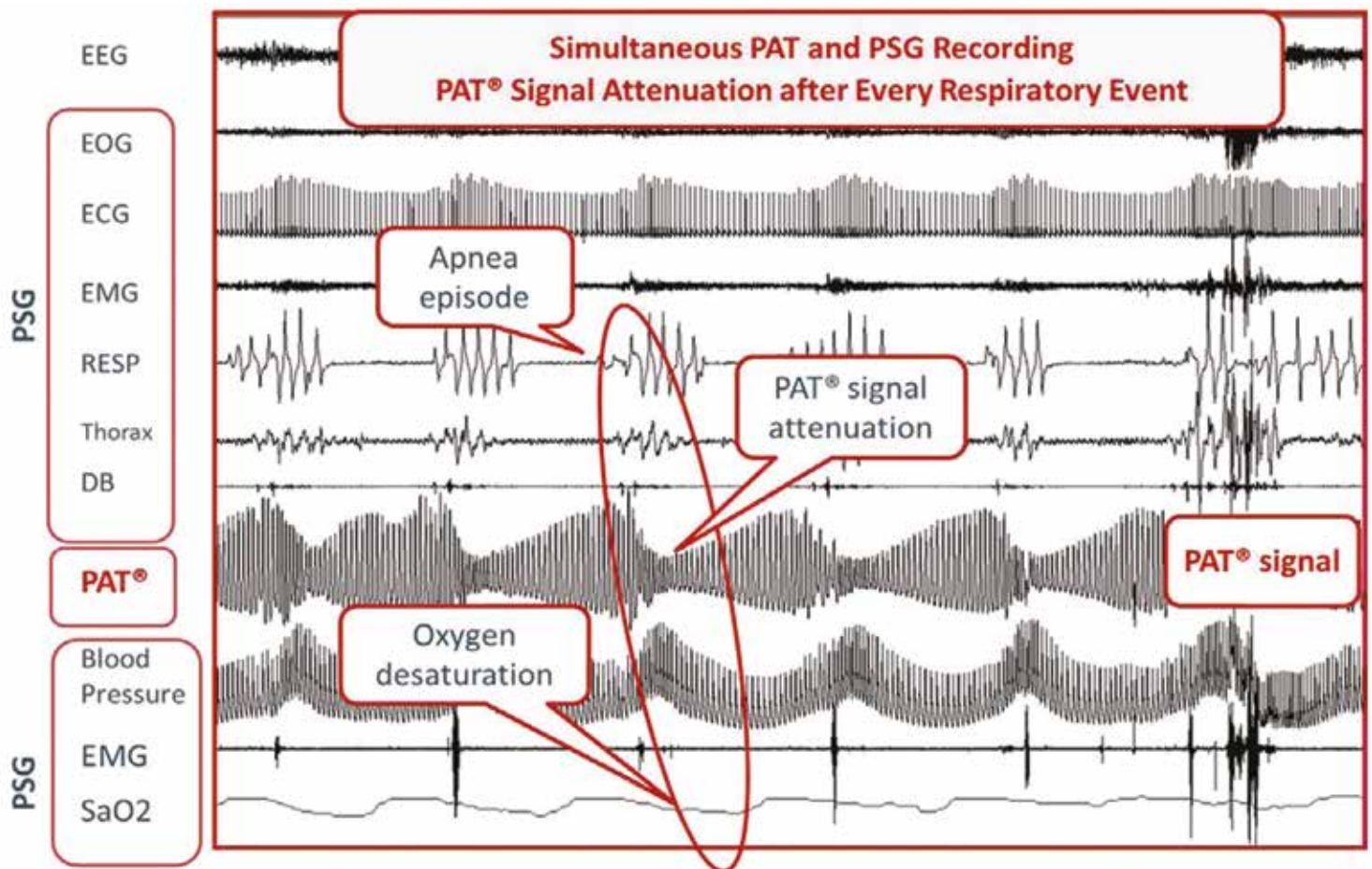


* Reference values are according to AASM guidelines

PAT Signal Explained

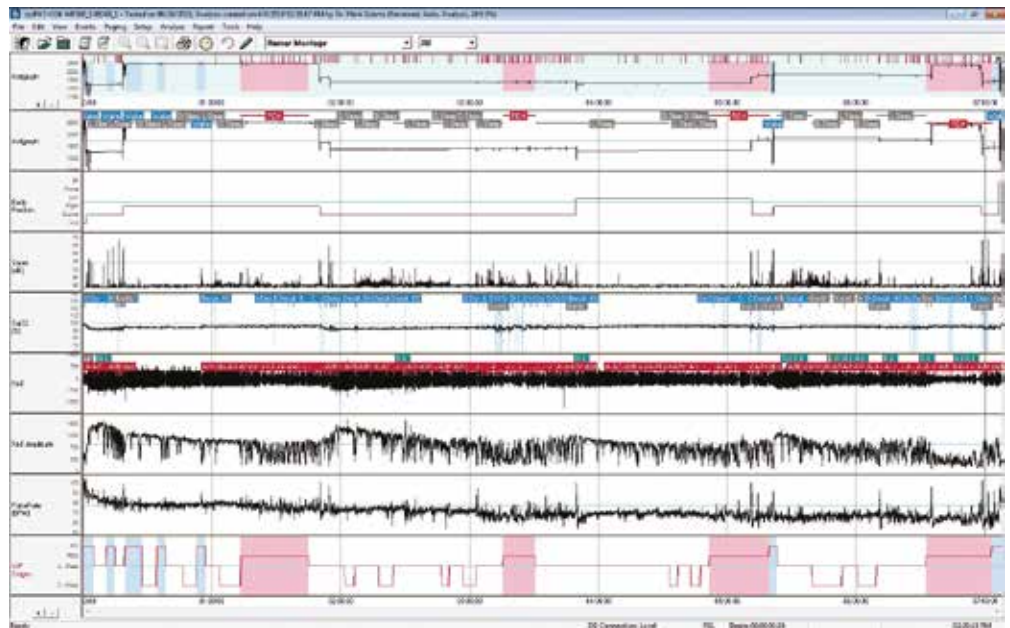
The proprietary PAT signal is a non-invasive measure of the arterial pulsatile volume changes at the fingertip.

The PAT signal attenuation and accelerated pulse rate has been shown to reflect sympathetic activation which is a clinically validated surrogate for autonomic arousals and micro-arousals found in sleep disordered breathing¹. Combined with oximetry desaturations or re-saturations, the proprietary WatchPAT algorithm accurately classifies the SDB events into AHI, RDI and ODI, providing the physician with a comprehensive assessment of the patient.



The zzzPAT Software

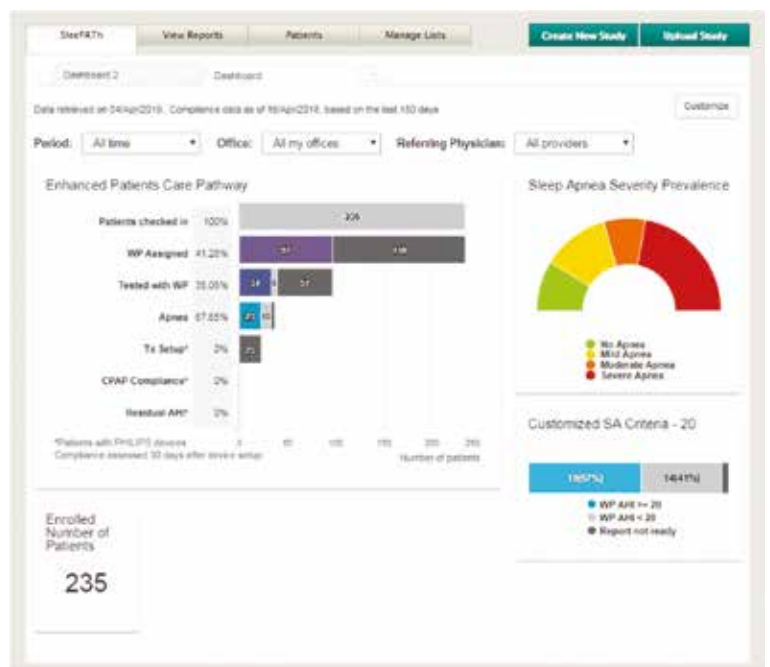
The zzzPAT software uses an advanced algorithm for the scoring of respiratory events and delineation of sleep stages. After a study is downloaded, an automated report is generated detailing sleep architecture, sleep efficiency, sleep latency, REM and non-REM related apnea events. If required zzzPAT's flexibility allows the user to manually score an event or study.



The CloudPAT® Platform



The CloudPAT® platform is a HIPAA-compliant, cloud-based IT solution for secure patient data transfer and convenient sleep study interpretation and diagnosis. SleepPATH™ expands the CloudPAT platform with a dashboard to assist physicians in monitoring patient compliance throughout the entire patient care pathway.





WatchPATTM

True Sleep TimeTM

decreases the risk of misdiagnosis
in up to **20%** of patients*

+ Understanding the Importance of True Sleep Time

Most HST devices as well as laboratory polysomnography (PSG) calculate AHI/RDI based on total recording time, which has shown to lead to a misdiagnosis and misclassification in up to 20% of patients tested.

WatchPAT, an innovative Home Sleep Test (HST), calculates AHI based on the patient's True Sleep Time, providing the physician with the most accurate and reliable diagnosis of the patient's AHI and RDI which are critical in managing the entire sleep apnea disease spectrum.

The WatchPAT also detects all sleep stages including wake, light sleep, deep sleep and REM. Coupled with undiluted respiratory events, the WatchPAT enables a more sensitive and accurate sleep disorder diagnosis.

Such highly sensitive and accurate diagnosis is especially important for patients with REM related sleep apnea, for patients who wake up numerous times during the night and for patients suffering from insomnia.

Sleep Summary

Start Study Time:	9:43:01PM
End Study Time:	6:04:59AM
Total Study Time:	8 hrs, 21 min
Sleep Time	6 hrs, 7 min
% REM of Sleep Time:	21.4 hrs

+ WatchPAT - the simplicity of pulse oximetry, the accuracy of PSG

WatchPAT is an FDA cleared portable sleep diagnostic system to diagnose sleep related breathing disorders. It is a small wrist-mounted device which allows testing to be done in the comfort of the patient's own home.

The WatchPAT's unique mode of action is based on the proprietary PAT® (Peripheral Arterial Tone) signal which measures the arterial volume changes in the fingertip, and is a reflection of sympathetic nervous system activation.

WatchPAT consistently demonstrates a high degree of correlation as compared with PSG.

SIMPLE

ACCURATE

FAST

RELIABLE



Complete Sleep Architecture with the WatchPAT

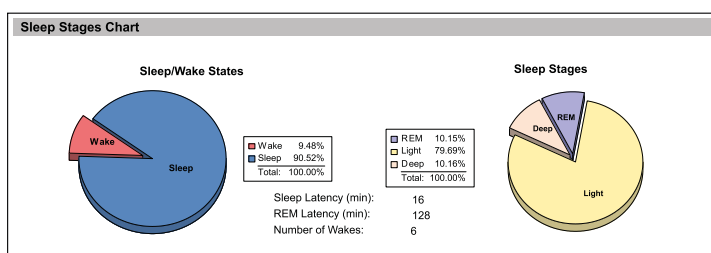
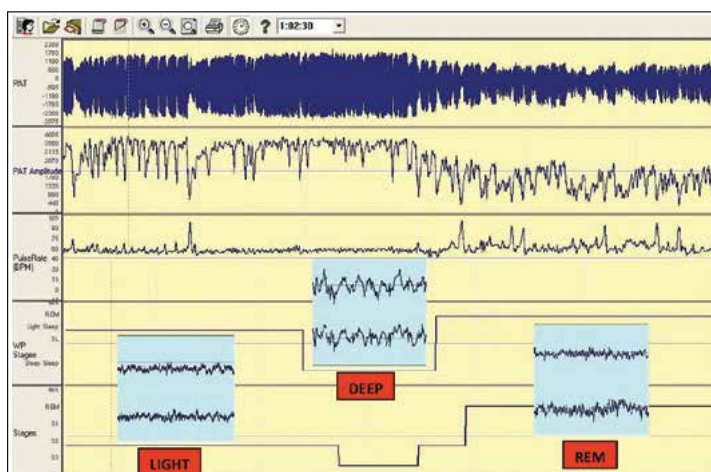
The WatchPAT software provides a clinically validated algorithm that provides the clinician both True Sleep Time and the Complete Sleep Architecture via the fingertip sensor.

WatchPAT is FDA cleared to measure sleep stages: light, deep and REM sleep. Each stage was clinically validated, both independently and then in combination.

First the advanced actigraphy differentiates wake from sleep; then a combination of the PAT signal amplitude and variability coupled with heart rate variability differentiates REM sleep from non-REM sleep and ultimately light from deep sleep.

The Complete Sleep architecture provides information on sleep quality including sleep efficiency, sleep latency and REM latency. The Complete Sleep architecture also provides further specificity in the diagnosis of REM sleep related apnea with a separate REM and non-REM AHI.

The WatchPAT, with its True Sleep Time together with the Complete Sleep Architecture, provides the clinician an accurate diagnosis that is simple and reliable.



* Sources:

- Rodin et al. Comparison of AHI using recording time versus sleep time Schutte. J Sleep Abs suppl 2014, p. A373
- Hedner J. et al. A Novel Adaptive Wrist Actigraphy Algorithm for Sleep-Wake Assessment in Sleep Apnea Patients. SLEEP, Vol. 27, No. 8, 2004 :1560-1566
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- Hedner J. et al. Sleep Staging Based on Automimcal Signals: A Multi-Center Validation Study. JCSM. Journal of Sleep Medicine, Vol. 7, No. 3, 2011: 301 - 306

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Itamar Medical is a leading medical device company that develops and markets products utilizing its proprietary PAT technology to diagnose and manage Sleep Disordered Breathing. The company has pioneered innovative solutions to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare costs.

Itamar Medical has offices and distribution channels around the world.



References:

- 1 Yalamanchali S, Farajian V, Hamilton C, Pott TR, Samuelson CG, Friedman M. Diagnosis of obstructive sleep apnea by peripheral arterial tonometry: meta-analysis. JAMA Otolaryngol. Head Neck Surg. December 2013;139(12):1343-1350
- 2 Data on file
- 3 Hedner J. et al. A Novel Adaptive Wrist Actigraphy Algorithm for Sleep-Wake Assessment in Sleep Apnea Patients. SLEEP, Vol. 27, No. 8, 2004 :1560-1566
- 4 Hedner J. et al. Sleep Staging Based on Automimcal Signals: A Multi-Center Validation Study. JCSM. Journal of Sleep Medicine, Vol. 7, No. 3, 2011: 301 – 306
- 5 Comparison of AHI using recording time versus sleep time Schutte – Rodin et al., J Sleep Abs suppl 2014, p. A373

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