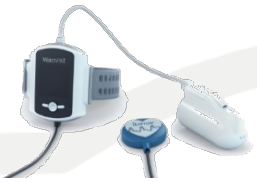
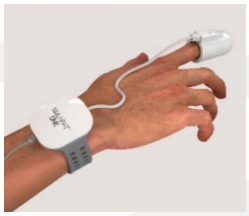
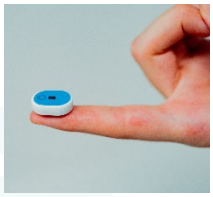
Comparison sheet of FDA-cleared HSAT devices based on peripheral arterial tonometry (PAT)[i]

Device	**WatchPAT 300** 	**WatchPAT One** 	**NightOwl®** 	**NightOwl® Mini** 
Legal manufacturer	Itamar Medical (Israel)		Ectosense (Belgium)	
Description	Multi-use, wrist-mounted HSAT	Disposable, single-night use variant	Rechargeable, finger-mounted HSAT	Disposable, multi-night use variant
FDA cleared since	2017	2019	2020	
Technology	Peripheral arterial tonometry (PAT) measurement based on the PPG signal[ii] acquired through the uPAT probe.		Peripheral arterial tonometry (PAT) measurement based on the PPG signal processed with patent-pending signal processing.[iii]	
Reimbursement code[iv]	Diagnostic exam codes CPT 95800 or G0400 as a peripheral arterial tonometry (PAT) – based HSAT			
Pediatrics	>12 years old		US: >21 years old; RoW: > 12 years old	
Portal access	Contact Itamar Medical for access to CloudPAT on cloudpat.precisemd.com.		Fast self-signup on the NightOwl Portal on signup.nightowl.care	
Clinical				
AASM compliant[v]	Yes, example report.		Yes, example report (US).	
pAHI[vi], TST, REM	Yes			
pOSA	Yes		Available in EU and APAC	Not at this time
CSA, Snoring	Yes, with extension	Yes	Not at this time	
Multi-night testing	 Up to 3 nights, each requiring a new probe.[vii]	No	Up to 7 nights without additional cost.[viii]	10 nights on 1 disposable device.
Dynamic test length[ix]	No	N.A.	A minimum, default, and maximum number of nights can be specified.	
In-app surveys	No		Yes	
pAHI accuracy against PSG	On the AASM recommended scoring rules: • Auto-scoring, accuracy: 58% (n = 278)[x] • Auto-scoring, correlation: 78% (n= 552)[xi]		On the AASM recommended scoring rules[xii]: • Auto-scoring, accuracy: 72% (n = 264) • Auto-scoring, correlation: 91% (n=264)	
Financial terms (United States)[xiii]				
Commitments	Monthly minimum use of probes when consigned[xiv]	None	2 tests/year under device consignment	None
Acquisition price	$4,277[xv] (excl. extension)	/	Typically on consignment	/
Per-patient price	$40 per night when the device is also acquired[xvi]	$70-90 for 1 night[xvii]	$45 for up to 7 nights[xviii]	$80 for up to 14 nights[xix]
Failure rate	5% - 8%[xx]	Not reported[xxi]	<3% multi-night[xxii] with testing cost waived[xxiii]	

[i] This comparison sheet is not intended to be an exhaustive comparison between the different devices cited. For a more detailed description of the device and services offered, consult its respective Instructions for Use and manufacturer. The information contained in this comparison sheet is provided as was known to Ectosense at the time of writing. If you believe this overview does not fairly represent the different devices cited herein, write to info@ectosense.com with your concerns.

[ii] Source: Watch-PAT300 FDA Summary (K180775) "[the device] records the PAT signal and blood oxygen saturation levels by a finger-mounted probe based on an optical plethysmographic method' (optical plethysmography synonymous to photo-plethysmography).

[iii] PAT measurement technology protected by several pending patent families.

[iv] Individual payor guidelines may vary in their use or acceptance of CPT 95800, G0400, PAT-based testing, or coverage of the NightOwl. Always check reimbursement coverage with your payor first.

[v] Compliance against the specifications and definitions in the AASM Scoring Manual v2.6 (January 2020).

[vi] pAHI is a surrogate for REI (Respiratory Event Index), which in turn is a surrogate for AHI for devices that do not contain an EEG measurement (AASM Scoring Manual v2.6, January 2020).

[vii] Source: Operation Manual WatchPAT300 (US) (REF: OM2196381), page 28

[viii] Each night a new disposable adhesive is required, which is supplied with the multi-night test credit at no additional cost. Sales Conditions apply.

[ix] A dynamic test length protocol allows the test provider to automatically extend a test's length in case of failed recording

[x] Sample-weighted average of all published studies on WatchPAT devices that report sleep apnea severity category accuracies and are benchmarked against a PSG scored according to the latest AASM recommended scoring rules. Studies retained (2): Loachimescu et al., 2020; Choi et al., 2018. N = total numb er of patients included across studies cited.

[xi] Sample-weighted average of all published studies on WatchPAT devices that report pAHI correlations and are benchmarked against a PSG scored according to the latest AASM recommended scoring rules. Studies retained (5): Loachimescu et al., 2020; Zhang et al., 2020; Pillar et al., 2020; Choi et al., 2018; Gan et al., 2017. N = total number of patients included across studies cited.

[xii] Multi-center study with data submitted to the FDA for NightOwl's clearance and AHI category / correlation evaluated against gold-standard PSG analyses according to the latest AASM recommended scoring rules and NightOwl's most recent algorithms. For a publication on a subset of this data, see Massie et al., 2018, Journal of Clinical Sleep Medicine (2018). N = total number of patients included across studies. See also the Instructions for Use / User Manual document for a discussion of clinical performance data.

[xiii] Prices as listed publicly. For most up to date pricing and other financial conditions, contact the other manufacturers. Prices listed are only for direct purchases from the respective manufacturers.

[xiv] Contracts with Itamar Medical involving use of the Watch-PAT 300 typically include minimum rotation conditions when the device is consigned and not acquired by the customer.

[xv] Watch-PAT 300, Publicly available price list for the U.S. Department of VA, link

[xvi] 12 White WatchPAT300 uPAT Probes at $482.03, Publicly available price list for the U.S. Department of VA, link

[xvii] 12 WatchPAT One devices at $1,025.13, Publicly available price list for the U.S. Department of VA, link. Other public comments and price extensions.

[xviii] Up to 7 nights of testing on a single patient within one week of starting the first night.

[xix] Up to 112 recording hours, can be spread over a period of 5 years on a single patient.

[xx] Data captured in highly controlled clinical studies in Zou et al., Sleep, 2006 and Garg et al., JCSM, 2014

[xxi] As of July 2020, no studies on the WatchPAT One have been reported in the scientific literature that would allow to evaluate the end-to-end failure rate of the WatchPAT One that differs materially in user experience due to the requirement for a Bluetooth® connection with the patient's own smartphone device.

[xxii] Based on end-to-end successful completion (incl. activation on patients' own smartphone, interrupted sleep studies etc.) and a minimum requirement of 4 hours of interpretable signal. The probability of not capturing at least 1 successful test in a 3-night testing protocol is 2.3%. The probability of failing the first night is 10.4%. Data internal to Ectosense.

[xxiii] Ectosense waives the charge for a NightOwl re-usable sensor test, and provides a new NightOwl Mini sensor free of charge for every failed test with such device when used on patients for an initial diagnosis, regardless of reason of failure. Sales Conditions apply.