Company	Compumedics
Device	 Somfit/Somfit-D
Website	compumedics.com
Description	The Somfit platform uses reflectance forehead oximetry at 0.1% resolution sampling at 78 Hz to return SPO_2 and peripheral arterial tone—an optimal place due to the presence of 3 large peripheral arteries (supratrochlear artery, supraorbital artery, and front branch of the superficial temporal artery), all near surface depth. The cranium acts as a reflective backstop from further light penetration, preventing signal distortion from tissues such as light-scattering adipose tissue.
Regulatory Status	FDA 510(k) K231546
Form Factor	forehead-attached
Peripheral Arterial Tone Measurement Site	forehead
Optical Light Source Power - Red (mW)	[not provided]
Optical Light Source Power - Infrared (mW)	[not provided]
Wavelengths (nw)	red: 660, IR: 940
Additional Light-Related Details	Standard wavelengths offer advantages over using the isosbestic point, which has a reduced signal dynamic range due to declining molar extinction coefficients of oxygenated and deoxygenated blood. The dual IR and R wavelengths have increased dynamic range, allowing a stronger signal-to-noise ratio and better assessment of artifact comparing being able to assess the changes in IR/R returns individually and their relationship to each other. The isosbestic point having the same molar extinction coefficient regardless of oxygenation produces relatively small absolute absorbance changes, potentially reducing signal-to-noise ratio in low-perfusion states.
Sampling Rate for Peripheral Arterial Tone Signal (Hz)	78
Optical Architecture	reflectance
Operational Model	rent, lease, buy, clinic-distributed
ARMS	1.46 in the 70%-100% range
Mean AHI Bias vs PSG	mean difference 1.35, 95% CI [-1.13, 3.84], mean difference and mean bias are functionally equivalent as measures of systemic bias in Bland-Altman analysis
How System Detects, Manages Signal Quality Issues	A proprietary convolution neural-network AI tool assesses SpO_2 and peripheral arterial tone quality. Peripheral arterial tone signal is normalized and not subjected to filtering in presence of artifact to create signals; only the raw data is shown. Signals are presented as raw data and, where appropriate, marked by the AI tool as artifact. SpO_2 and peripheral arterial tone signal will drop out when signal-to-noise or artifact conditions exist that prevent the accurate separation of the AC pulsatile returns from the IR and R channels. (Peripheral arterial tone is the AC return of a pulse oximeter, so artifact and metrics of accuracy are related.)
How System Mitigates Venous Blood Pooling	N/A—relevant primarily to sampling in the limbs. Venous blood pooling is not a concern with forehead oximetry except in the presence of head trauma or sleeping on an inversion table while inverted at a negative angle.
How System Determines Wake Vs Sleep	Convolution deep-neural network AI-based analysis of channels including EEG, EMG, EOG, and motion through accelerometer.
Sleep Staging Technology	Convolution deep-neural network AI analysis of EEG, EMG, and EOG
Validation Evidence	McMahon M, Goldin J, Kealy ES, et al. Evaluating Somfit's pulse arterial tonometry for detection of obstructive sleep apnoea. *Sleep Biol Rhythms.* 2024 Nov 27;23(2):145-52. doi: 10.1007/s41105-024-00559-4.
Skin-Tone Diversity in Validation Cohorts	SpO_2 accuracy testing cohort: 58% classified as medium-dark.

Information for this guide based on data submitted by sleep technology companies. Sleep Review *strives for accuracy in all data but cannot be held responsible for claims made by other organizations. All options may not be included. Email editor@sleepreviewmag.com to be considered for the next update.*

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Company	EnsoData
Device	 EnsoHST
Website	ensodata.com/ensohst
Description	EnsoHST is an interoperable software as a medical device (SaMD) solution that measures peripheral arterial tone by analyzing the photoplethysmography (PPG) signal recorded by an FDA-cleared pulse oximeter. EnsoHST provides multi-night home sleep testing using a mobile app to collect data for AI analysis and scoring and deliver accurate, diagnostic reports for clinician review.
Regulatory Status	FDA 510(k) K231355; also cleared in Canada and compatible with medical-purpose pulse oximeters cleared in US & Canada
Form Factor	finger probe
Peripheral Arterial Tone Measurement Site	finger
Optical Light Source Power - Red (mW)	7.5-10.5
Optical Light Source Power - Infrared (mW)	6.0-9.0
Wavelengths (nw)	red: 650-670, IR: 930-950
Additional Light-Related Details	
Sampling Rate for Peripheral Arterial Tone Signal (Hz)	16 (min for PPG); 1 (min for oximetry)
Optical Architecture	transmissive
Operational Model	buy, clinic-distributed, direct-to-patient shipping
ARMS	1.866%
Mean AHI Bias vs PSG	average difference of +/- 1 eAHI when compared to simultaneously recorded PSG
How System Detects, Manages Signal Quality Issues	Several methods ensure data quality: established filtering practices mitigate motion artifacts, environmental noise, and recording artifacts like baseline wander; an artifact detection module is employed to assess the technical adequacy of key data channels; while the raw data is preserved, artifact events are annotated, and these segments are excluded when calculating diagnostic report metrics such as eAHI and total sleep time.
How System Mitigates Venous Blood Pooling	[not provided]
How System Determines Wake Vs Sleep	A machine learning (ML)-based module that leverages a combination of convolutional neural networks, long short-term memory networks, dense neural networks, and other related deep learning methods to extract useful nonlinear signal data representations for the classification of sleep vs wake. The ML module was trained on recordings of PPG signals extracted from a historical database of over 1 million in-lab PSG and type III HSAT studies collected using 9 different sleep systems manually scored by RPSGTs.
Sleep Staging Technology	A ML-based module that leverages a combination of convolutional neural networks, long short-term memory networks, dense neural networks, and other related deep learning methods to extract useful nonlinear signal data representations for establishing sleep stages (Light Sleep, Deep Sleep, and REM). The ML module was trained on recordings of PPG signals extracted from a historical database of over 1 million in-lab PSG and type III HSAT studies collected using 9 different sleep systems that were all manually scored by RPSGTs.
Validation Evidence	Validation of an artificial intelligence based single-channel photoplethysmography (PPG) home sleep apnea test (HSAT). *JCSM*, accepted manuscript (preprint), December 2025: ensodata.com/research/validation-of-an-artificial-intelligence-based-single-channel-photoplethysmography-ppg-home-sleep-apnea-test-hsat; Poster: Prospective clinical performance validation of AI for PPG-based sleep staging: ensodata.com/research/prospective-clinical-performance-validation-of-ai-for-ppg-based-sleep-staging; EnsoHST Device Profile - ensodata.com/security-compliance
Skin-Tone Diversity in Validation Cohorts	The poster "Prospective clinical validation of AI for PPG-based OSA detection utilizing standardized skin color assessments" found no statistically significant differences or bias in AHI or sleep staging performance in relation to skin color, including the darkest skin tones, as measured by standardized skin pigmentation assessment using the Munsell Color Scale.

Company	SleepImage
Device	 SleepImage System
Website	sleepimage.com
Description	SleepImage utilizes cardiopulmonary coupling (CPC), a frequency-based analysis of coupling and coherence between pulse rate variability and tidal volume variability, to measure sleep states and stages. By combining the CPC-output with oxygenation information (SpO_2), a PSG-equivalent AHI is generated.
Regulatory Status	FDA 510(k) K182618
Form Factor	finger probe, ring
Peripheral Arterial Tone Measurement Site	finger
Optical Light Source Power - Red (mW)	0.8
Optical Light Source Power - Infrared (mW)	1.2
Wavelengths (nw)	red: 660, IR: 940
Additional Light-Related Details	
Sampling Rate for Peripheral Arterial Tone Signal (Hz)	125
Optical Architecture	transmissive
Operational Model	buy, clinic-distributed
ARMS	[not provided]
Mean AHI Bias vs PSG	1.9
How System Detects, Manages Signal Quality Issues	Independent of the reason for signal loss, the quality of the input signal is presented as a color-coded indicator (green, yellow, red) representing the strength of the signal quality. Frequent or complete signal loss is presented as red, intermittent signal loss as yellow, and no signal loss as green. Periods of complete signal loss will show areas of blank spectrogram output. This gives the user certainty that the signal is not extrapolated to produce output.
How System Mitigates Venous Blood Pooling	[not provided]
How System Determines Wake Vs Sleep	[not provided]
Sleep Staging Technology	[not provided]
Validation Evidence	Al Ashry HS, Hilmisson H, Ni Y, Thomas RJ; APPLES Investigators. Automated apnea-hypopnea index from oximetry and spectral analysis of cardiopulmonary coupling. *Ann Am Thorac Soc.* 2021 May;18(5):876-83. doi: 10.1513/AnnalsATS.202005-510OC; Hilmisson H, Berman S, Magnusdottir S. Sleep apnea diagnosis in children using software-generated apnea-hypopnea index (AHI) derived from data recorded with a single photoplethysmogram sensor (PPG): Results from the Childhood Adenotonsillectomy Study (CHAT) based on cardiopulmonary coupling analysis. *Sleep Breath.* 2020 Dec;24(4):1739-49. doi: 10.1007/s11325-020-02049-6; Lu M, Brenzinger L, Rosenblum L, et al. Comparative study of the SleepImage ring device and polysomnography for diagnosing obstructive sleep apnea. *Biomed Eng Lett.* 2023 Jul 17;13(3):343-52. doi: 10.1007/s13534-023-00304-9.
Skin-Tone Diversity in Validation Cohorts	[not provided]

Company	ZOLL Itamar
Device	 WatchPAT ONE/WatchPAT 300
Website	itamar-medical.com
Description	WatchPAT measures peripheral arterial tonometry at the fingertip due to the high vasomotor changes in observed as a result of sympathetic nervous system activation (high ratio of alpha receptors). A finger probe covers the distal part of the finger with a uniform pressure field, allowing partial unloading of arterial wall tension that significantly improves the dynamic range of the PAT signal while reducing venous blood pooling and artifacts. The optic component measures the changes of the pulsatile blood volume in capillaries and small arteries using an isosbestic wavelength to prevent amplitude change related to the level of oxygenation. The probe also measures, from separate light sources, the blood oximetry.
Regulatory Status	FDA 510(k) K222331, K180775, K223675, K183559
Form Factor	finger probe
Peripheral Arterial Tone Measurement Site	finger
Optical Light Source Power - Red (mW)	27.5
Optical Light Source Power - Infrared (mW)	18.75
Wavelengths (nw)	red: 660, IR: 910, PAT: 800
Additional Light-Related Details	Third light source at isosbestic wavelength of 805 nm and 13 mW.
Sampling Rate for Peripheral Arterial Tone Signal (Hz)	100
Optical Architecture	transmissive
Operational Model	rent, buy, clinic-distributed, direct-to-patient shipping
ARMS	oximetry: 2.0 in the 70%-100% range (24 patients tested according the ISO 80601-2-61:2017 and FDA guidelines against blood gases)
Mean AHI Bias vs PSG	-0.5 (20 patients with and without CVD in multicenter study; DOI: 10.1253/circrep.CR-20-0097)
How System Detects, Manages Signal Quality Issues	The device adapts the gain and the light source power to improve signal in all conditions. The pressure field in the probe ensures superior dynamic range and reduces artifacts. The algorithms identify and exclude artifacts from reported calculations.
How System Mitigates Venous Blood Pooling	Uniform pressure field allows partial unloading of arterial wall tension that improves the dynamic range of the measured signal while preventing venous blood pooling and reducing retrograde venous shock wave propagation.
How System Determines Wake Vs Sleep	Wrist actigraphy with sampling rate of 100 Hz.
Sleep Staging Technology	PAT amplitude and pulse rate
Validation Evidence	Yalamanchali S, Farajian V, Hamilton C, et al. Diagnosis of obstructive sleep apnea by peripheral arterial tonometry: meta-analysis. *JAMA Otolaryngol Head Neck Surg.* 2013 Dec;139(12):1343-50. doi: 10.1001/jamaoto.2013.5338; Schnall RP, Sheffy JK, Penzel T. Peripheral arterial tonometry-PAT technology. *Sleep Med Rev.* 2022 Feb;61:101566. doi: 10.1016/j.smrv.2021.101566.
Skin-Tone Diversity in Validation Cohorts	Oximetry tested according to ISO 80601-2-61:2017 and FDA guidelines and accuracy were calculated per 3 group of skin tones:--For Light Skin Pigmentation (MST 1-3 and ITA > 30) ARMS was 2.0, bias was 1.0. --For Medium Skin Pigmentation (MST 4-7 and 30 ≥ ITA ≥ -30) ARMS was 2.2, bias was 1.3. --For Dark Skin Pigmentation (MST 8-10 and ITA < -30) ARMS was 1.6, bias was 0.6. Also, the WatchPAT was validated in large number of validation studies over the years, in the US, Europe, Middle East, and Asia including cohorts of multiple skin tone and ethnicity. ●