EnsoSleep
Device Profile

Reference Document

Introduction

EnsoSleep is a software-only medical device that analyzes previously recorded physiological signals obtained during sleep. Users of EnsoSleep are consistent with the roles required to run a sleep clinic: sleep physicians, sleep technicians, clinic operations managers, and IT administrators. EnsoSleep can analyze at-home and in-lab sleep studies for both adult and pediatric patients who are at least 13 years old. Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of the following: respiratory events, sleep staging events, arousal events, movement events, cardiac events, derived signals, and calculated indices. This includes calculation of total sleep time.

EnsoSleep does not interpret the results, nor does it suggest a diagnosis. The device only marks events of interest for review by a physician who is responsible for diagnoses. The device does not analyze data that are different from those analyzed by human scorers.

The signals and automated analyses can be visually inspected and edited in EnsoViewer prior to the results being integrated into a sleep study report.

The software consists of 4 major components:

- The Application Platform runs on local clinic workstations and manages the detection, upload, and download of study records and scoring to and from the Storage Platform
- The Processing Platform accepts raw physiological signals as inputs in order to recognize events, derive signals, and calculate indices
- The Storage Platform facilitates file and database storage in the EnsoSleep cloud through an API
- The Dashboard is a web-based user interface to support configuration, clinic management, and sleep study scoring

Please read this document carefully before using the device. User information can be found in the instructions for use available within the device.

Indications for Use

EnsoSleep is intended for use in the diagnostic evaluation by a physician to assess sleep quality and as an aid for physicians in the diagnosis of sleep disorders and respiratory related sleep disorders in pediatric and adult patients as follows:

- Pediatric patients ages 13 years and older with polysomnography (PSG) tests obtained in a Hospital or Sleep Clinic
- Adult patients with PSGs obtained in a Hospital or Sleep Clinic
- Adult patients with Home Sleep Tests

EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas (OSA), central sleep apneas (CSA), and hypopneas.

All automatically scored events and physiological signals which are retrieved, analyzed, displayed, and summarized are subject to verification by a qualified clinician. Central sleep apneas should be manually reviewed and modified as appropriate by a clinician.

All events can be manually marked or edited within records during review.

Photoplethysmography (PPG) total sleep time is not intended for use when electroencephalograph (EEG) data is recorded. PPG total sleep time is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

Contraindications

There are no known contraindications.

Product Requirements

Computer Requirements:

- Operating System – Microsoft Windows Operating System version 10+
- Minimum 4 GB RAM, 16 GB RAM recommended
- Web Browser – Google Chrome (Mac or Windows) or Microsoft Edge (Windows)
- High Speed Internet connection - 12 Mbps or more recommended
- Patient Data File Formats – EDF or EDF+, HL7

Event Type	Event Subtypes	AASM Required Signals - minimum sampling rate; anatomical derivation Default system settings	AASM Recommended Signals - minimum sampling rate; anatomical derivation Optional system settings
Arousal Events	Arousals	3 channel EEG (200 Hz; Frontal, Central, and Occipital)	EOG (200 Hz; Outer Canthus) and/or EMG (200 Hz; Submental)
Cardiac Events	Bradycardia, Tachycardia	ECG (200 Hz; Lead II)	N/A
Movement Events	LM, PLMS	EMG (200 Hz; Anterior tibialis)	Actigraphy (1 Hz; Wrist)
Respiratory Events	OSA, CSA, MSA, Hypopnea, Cheyne-Stokes respiration, Periodic breathing	Airflow (25 Hz; Oronasal Thermal Sensor and/or Nasal Pressure Transducer) and Oximetry (10 Hz; Finger or Earlobe pulse oximeter)	RIP (25 Hz; Thoracic and Abdominal), PVDF (25 Hz; Thoracic and Abdominal), ECG (200 Hz; Lead II), Snoring Microphone (200 Hz), Peripheral Arterial Tonometry (200 Hz; Finger), and/or Esophageal Manometry (25 Hz)
Sleep Staging Events	Wake, N1, N2, N3, REM	3 channel EEG (200 Hz; Frontal, Central, and Occipital)	EOG (200 Hz; Outer Canthus) and/or EMG (200 Hz; Submental)
Sleep-Wake, Staging Events*	Wake, Sleep Light, Deep, REM	Photoplethysmogram (100 Hz), Airflow (25 Hz; Nasal pressure transducer) and RIP (25 Hz; Thoracic)	N/A

**Only intended to be used in the absence of EEG signals.*

Study Scoring

The EnsoSleep autoscoring software is based directly on the recommendations of the American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events designed to guide sleep study professionals through the technical aspects of polysomnography (PSG) testing.

Input signals used to derive outputs include:

Electroencephalogram (EEG)

Electrocardiogram (ECG)

Electro-oculogram (EOG)

Electromyogram (EMG)

Peripheral arterial tone (PAT)*

Actigraphy

Airflow

Oximetry

Saturation of Peripheral Oxygen (SpO2)

Respiratory Inductance Plethysmogram (RIP)

Polyvinylidene Fluoride (PVDF)

Photoplethysmogram (PPG)

Pulse Rate

Snoring Microphone

Esophageal Manometry

*Display and manual scoring only.

The EnsoSleep autoscoring algorithm identifies the following physiological events and indices. Scoring results may be reviewed and edited as necessary.

Respiratory Events

- Obstructive Sleep Apneas (OSA)
- Central Sleep Apneas (CSA)
- Obstructive Hypopneas
- Central Hypopneas
- Cheyne-Stokes
- Periodic Breathing

Sleep Staging Events

- Wake
- N1
- N2
- N3
- REM (rapid eye movement)
- Light (N1, N2)
- Deep (N3)
- Sleep (N1, N2, N3, REM)

Arousal Events

- Arousals
- Respiratory Effort-Related Arousal (RERA)

Movement Events

- Leg Movements (LM)
- Periodic Leg Movement Series (PLMS)

Cardiac Events

- Bradycardia
- Tachycardia

Apnea-Hypopnea Index (AHI)

Sleep Architecture

Sleep Efficiency (SE)

Arousal Index (ArI)

Sleep Latency (SL)

REM Latency (RL)

EnsoTST (total sleep time for home sleep studies)

TST (total sleep time for in-clinic studies)

Periodic Leg Movements (PLMS) Index

Hypoxic Burden*

*This is an advanced metric for informational purposes only. It is based on the following peer-reviewed, published literature:

Azarbarzin, A. *et al.* The hypoxic burden of sleep apnoea predicts cardiovascular disease-related mortality: the Osteoporotic Fractures in Men Study and the Sleep Heart Health Study. *Eur. Hear. J.* 40, 1149–1157 (2018).

The following events are supported for manual scoring.

Lights

- Lights On
- Lights Off

REM Behavior Disorder

Respiratory Events

- Mixed Apneas
- Mixed Hypopneas
- Central Respiratory
- Obstructive Respiratory

General (unclassified) Respiratory

- Hypoventilation
- Hypercapnia
- Respiratory Event
- Desaturation
- Snore

Cardiac Events

- Sinus Tachycardia
- Narrow Complex Tachycardia
- Wide Complex Tachycardia
- Asystole
- Premature Atrial Contraction
- Premature Ventricular Contraction

Movement Events

- Bruxism

- Alternating Leg Muscle Activiation
- Hypnagogic Foot Tremor
- Excessive Fragmentary Myoclonus
- Rhythmic Movement Disorder

Treatment Events

- Continuous Positive Airway Pressure (CPAP)
- Bilevel Positive Airway Pressure (BiPAP)
- Automatic Positive Airway Pressure (APAP)
- Nasal Positive Airway Pressure (NPAP)
- Variable Positive Airway Pressure (VPAP)
- Adaptive Servo Ventilation
- Auto Ventilation
- Oxygen
- Phrenic Nerve Stimulator
- Hypoglossal Nerve Stimulator
- Oral Appliance

Position Events

- Upright
- Supine
- Prone
- Left
- Right

General

- Unstaged
- Bad Data
- Inadequate
- Adequate
- Comment

Clinical Performance

Device performance in a clinical study compared automatically detected sleep staging events, sleep disordered breathing events, apnea-hypopnea index, apnea events, obstructive apnea events, arousal events, and leg movement events to polysomnography results obtained by a two-thirds majority of three experienced sleep technologists. For more information about the clinical study, contact EnsoData or view the study information in

the most recent device clearance.

Adult Sample Pooled-Epochs EnsoSleep vs 2/3 Majority Sleep Staging Performance

(N=100, 84,408 PSG epochs)		Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=2000)		
Overall	Total	Positive	Negative	Overall
Wake	23,596	93.5% (93.1%, 93.8%)	97.2% (97.1%, 97.4%)	96.1% (96.0%, 96.3%)
N1	4,406	37.0% (35.6%, 38.5%)	98.3% (98.2%, 98.4%)	95.0% (94.8%, 95.1%)
N2	37,890	88.3% (87.9%, 88.6%)	89.3% (89.0%, 89.6%)	88.8% (88.6%, 89.0%)
N3	6,513	80.0% (79.0%, 81.0%)	96.3% (96.2%, 96.5%)	95.0% (94.9%, 95.2%)
REM	9,400	90.9% (90.4%, 91.5%)	99.3% (99.2%, 99.3%)	98.3% (98.2%, 98.4%)
Total	81,805	86.6% (86.4%, 86.9%)		
None	2,603	-		

Pediatric Sample Pooled-Epochs EnsoSleep vs 2/3 Majority Sleep Staging Performance

(N=47, 38,568 PSG epochs)		Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=2000)		
Overall	Total	Positive	Negative	Overall
Wake	7,867	93.1% (92.5%, 93.6%)	99.2% (99.1%, 99.3%)	97.9% (97.8%, 98.1%)
N1	1,263	43.2% (40.4%, 45.9%)	98.8% (98.7%, 99.0%)	97.0% (96.8%, 97.1%)
N2	17,542	92.6% (92.3%, 93.0%)	89.4% (89.0%, 89.8%)	90.9% (90.6%, 91.2%)
N3	6,852	92.3% (91.6%, 92.9%)	97.5% (97.3%, 97.7%)	96.6% (96.4%, 96.7%)
REM	4,278	80.9% (79.6%, 82.0%)	99.1% (99.0%, 99.2%)	97.0% (96.8%, 97.2%)
Total	37,802	89.7% (89.4%, 90.0%)		
None	766	-		

EnsoSleep vs 2/3 Majority Sleep Apnea Diagnostic Agreement

-	Adult		Pediatric			
	AHI >= 5	AHI >= 15	AHI ≥ 1	AHI >= 5	AHI >= 10	AHI >= 15
Sample size (N)	100	100	47	47	47	47
Positive Agreement (PA)	94.4% (89.0%, 98.7%)	94.0% (85.7%, 100.0%)	94.4% (85.3%, 100.0%)	90.5% (75.0%, 100.0%)	78.6% (45.5%, 100.0%)	85.7% (44.4%, 100.0%)
Negative Agreement (NA)	89.7% (75.8%, 100.0%)	96.3% (90.9%, 100.0%)	77.8% (50.0%, 100.0%)	100.0% (100.0%, 100.0%)	94.9% (86.5%, 100.0%)	100.0% (100.0%, 100.0%)
Overall Agreement (OA)	93.0% (88.0%, 97.0%)	95.0% (90.0%, 100.0%)	89.4% (80.9%, 97.9%)	95.7% (89.4%, 100.0%)	91.5% (83.0%, 97.9%)	97.9% (93.6%, 100.0%)
Likelihood ratio (+)	9.146 (3.879, ∞)	25.458 (10.154, ∞)	4.190 (1.892, ∞)	∞ (∞, ∞)	15.692 (5.067, ∞)	∞ (∞,∞)
Likelihood ratio (-)	0.062 (0.014, 0.127)	0.062 (0.000, 0.151)	0.070 (0.000, 0.205)	0.095 (0.000, 0.250)	0.222 (0.000, 0.578)	0.143 (0.000, 0.556)

Adult Sample Overall-Epochs EnsoSleep vs 2/3 Majority Event Detection Performance

(N=100, 84,408 PSG epochs)		Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=2000 resamples)		
Events	Total Epochs	Positive Agreement (PA)	Negative Agreement (NA)	Overall Agreement (OA)
Sleep Disordered Breathing	8108	75.4% (74.5%, 76.3%)	97.0% (96.9%, 97.2%)	94.9% (94.8%, 95.1%)
Hypopnea	4420	66.3% (64.9%, 67.6%)	97.1% (97.0%, 97.2%)	95.5% (95.4%, 95.6%)
Obstructive Apnea	1659	74.1% (72.1%, 76.1%)	99.3% (99.2%, 99.3%)	98.8% (98.7%, 98.8%)
Central Apnea	1505	65.3% (63.1%, 67.6%)	99.5% (99.5%, 99.6%)	98.9% (98.8%, 99.0%)
Arousal	9047	73.6% (72.7%, 74.5%)	95.6% (95.5%, 95.7%)	93.2% (93.1%, 93.4%)
Leg Movement	6018	82.0% (81.0%, 83.0%)	92.4% (92.2%, 92.6%)	91.7% (91.5%, 91.8%)

Pediatric Sample Overall-Epochs EnsoSleep vs 2/3 Majority Event Detection Performance

(N=47, 38,568 PSG epochs)		Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=2000 resamples)		
Events	Total Epochs	Positive Agreement (PA)	Negative Agreement (NA)	Overall Agreement (OA)
Sleep Disordered Breathing	1480	72.7% (70.4%, 74.9%)	98.6% (98.4%, 98.7%)	97.6% (97.4%, 97.7%)
Hypopnea	1046	68.8% (66.0%, 71.6%)	98.9% (98.8%, 99.0%)	98.0% (97.9%, 98.2%)
Obstructive Apnea	105	45.5% (36.0%, 54.8%)	99.7% (99.6%, 99.7%)	99.5% (99.5%, 99.6%)
Central Apnea	277	68.9% (63.5%, 74.1%)	99.7% (99.7%, 99.8%)	99.5% (99.4%, 99.6%)
Arousal	3018	78.6% (77.1%, 80.0%)	97.0% (96.8%, 97.2%)	95.5% (95.3%, 95.7%)
Leg Movement	1247	66.0% (63.4%, 68.6%)	95.5% (95.3%, 95.7%)	94.5% (94.3%, 94.8%)

Per-Patient Adult, Pediatric and RR Sample Total Sleep Time vs 2/3 Majority Scoring Sample

-	Two-sided 95% bootstrapped median percentile confidence interval (R=2000 resamples)			
	EnsoSleep PPG-TST vs RR Sample	EnsoSleep EEG-TST vs RR Sample	EnsoSleep EEG-TST vs Adult Sample	EnsoSleep EEG-TST vs Pediatric Sample
Deming Regression Slope ß1	0.964 (0.860, 1.067)	0.984 (0.925, 1.023)	1.037 (0.974, 1.201)	1.006 (0.988, 1.018)
Deming Regression Intercept ß0 [hrs]	0.089 (-0.484, 0.663)	0.156 (-0.071, 0.504)	-0.181 (-1.101, 0.182)	0.021 (-0.034, 0.134)
Bland-Altman mean difference (MD) [min]	5.380 (2.372, 8.475)	-4.785 (-6.131, -2.237)	0.515 (-4.173, 2.331)	-3.255 (-4.411, -1.472)
Bland-Altman upper limit (ULOA) 95% [min]	73.463 (68.332, 78.743)	32.922 (30.625, 37.269)	57.750 (49.751, 60.849)	10.654 (9.310, 12.728)
Bland-Altman lower limit (LLOA) 95% [min]	-62.703 (-67.835, -57.423)	-42.492 (-44.789, -38.145)	-56.720 (-64.718, -53.621)	-17.164 (-18.508, -15.091)

Safety - Warnings and Cautions

- EnsoSleep is a prescription device used under supervision of a physician in the United States.
- The device is intended for analysis of sleep data acquired from patients 13 years old and up.
- Capnography data is not supported or displayed.
- The tachycardia and bradycardia outputs are not for use for cardiovascular monitoring or diagnosis, nor does the device detect arrhythmias.
- The device neither interprets results nor suggests a diagnosis or recommendations for treatment.
- The device aims to identify physiological events according to the latest sleep scoring rules, procedures, and definitions under the current standards of care as recommended by the AASM Manual for the Scoring of Sleep and Associated Events, industry-standard published papers, and methods cleared for this device.
- Clinics using the API have the ability to send a link to view and edit a single study. The link can be sent to and used by persons for whom the link was not intended. Follow your clinic guidelines and your country regulations on privacy and access of patient data.
- The scoring provided by the device must be reviewed, edited as necessary, and approved by a qualified

healthcare professional.

- Any preliminary or preexisting score reports should be regenerated after review and rescoring of EnsoSleep studies to ensure any/all scoring changes are reflected in final reports.
- Notify EnsoData and the appropriate government agencies if an adverse event has occurred that is related to use of this product.

EnsoData

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