EnsoSleep PPG Device Profile

Reference Document

Introduction

EnsoSleep PPG™ processes physiological data obtained during sleep studies and applies a variety of analytical approaches to identify the occurrence of sleep events that relate to the presentation of sleep disorders. At the end of the analysis, the system generates a score report that includes tables and graphs typical of those generated following manual scoring of sleep studies by certified technologists. The results of the automated scoring may be displayed using commercially available sleep study viewer applications or it may be displayed within this device; both allow for manual editing of the results and generation of a revised score report.

It is a stand-alone software device, which can be accessed from a computer with a compatible operating system platform and operated without being attached to any other physical device or any direct or indirect contact with a patient.

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 PPG is a Software as a Medical Device (SaMD) that establishes sleep quality. EnsoSleep PPG automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep using compatible devices. EnsoSleep PPG is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults.

The EnsoSleep PPG output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional. The EnsoSleep PPG output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

EnsoSleep PPG is not intended for use with polysomnography devices.

Contraindications

There are no known contraindications.

Target Population

EnsoSleep PPG is indicated for use in adults 22 years old and above.

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

EnsoSleep PPG is compatible with medical purpose pulse oximetry devices cleared in your market and/or country that meet the data acquisition characteristics in this table:

Minimum Device Specification	Photoplethysmography	SPO2	Pulse /Heart Rate
Sampling Rate	16 Hz or greater	1 Hz	1 Hz
Digital Resolution	8 bit	n/a	n/a
Measurement Range	n/a	0 - 100%	30-250 BPM
Accuracy Range (70-100%)	n/a	+/- 3%	+/- 2%

Event Type	Event Subtypes	AASM Required Signals - minimum sampling rate; anatomical derivation, default settings
Respiratory Events	Sleep Disordered Breathing (Apneas, Hypopneas, RERAs)	Photoplethysmogram (16 Hz) and Oximetry (1 Hz; Finger)
Sleep-Wake Events	Wake, Light Sleep, Deep Sleep, REM, Arousals	Photoplethysmogram (16 Hz)

For a good user experience, EnsoData has identified the following as sources that have data acquisition characteristics and file formats meeting the system requirements:

Viatom Checkme O2 Max
Viatom Oxyfit PO6
Viatom O2 Ring PO2
ResMed NightOwl
Happy Health Happy Ring
Bodimetrics Circul
ABM Night Shift*

EDF files containing PPG data collected during sleep that are consistent with the acquisition characteristics mentioned above.

The above list is provided for informational purposes only and is correct at the time of issue; the list will be updated as additional data sources are identified and allowed by EnsoData. If your data source is not listed or does not meet the above acquisition characteristics, please email: support@ensodata.com.

*Only for body position.

Channels

The channels available for display in the device include:

- Photoplethysmogram (PPG)
  - Airflow*
  - Respiratory Effort*
  - Heart Rate Variability (HRV)
- Saturation of Peripheral Oxygen (SpO2)
- Pulse Rate
- Position
- Acoustic Flow**
- Snore**

*Surrogate signals extracted from the third-party device input signals.
**From Celeste+

Study Scoring

The autoscoring algorithm 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 sleep testing. The scoring results should be reviewed and edited as necessary.

The device identifies the following physiological events based on AASM guidelines:

- Apnea-Hypopnea Index (eAHI)
- Respiratory Disturbance Index (eRDI)
- Respiratory Events (Apneas or Hypopneas): Obstructive, Central, Respiratory Effort-Related Arousals (RERA)
- Sleep-Wake Events: Wake, Light Sleep, Deep Sleep, REM
- Arousals
- Total Sleep Time (TST)
- Total Recording Time
- Sleep Efficiency (SE)
- Sleep Latency (SL)
- Wake After Sleep Onset (WASO)

- Desaturation: Count, Index per Hour
- SpO2 / Oxygen Saturation: Minimum, Maximum, Mean, Percent of Time in Range
- Heart Rate: Minimum, Maximum, Mean, Variability, Percent of Time in Range

Advanced Metrics

The following are advanced metrics provided by the device that are for informational purposes only. The advanced metrics are based on the indicated peer-reviewed, published literature.

Desaturation: Hypoxic Burden

> 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).

Heart Rate: Variability

> Blanchard, M. *et al*. Association of Nocturnal Hypoxemia and Pulse Rate Variability with Incident Atrial Fibrillation in Patients Investigated for Obstructive Sleep Apnea. *Ann. Am. Thorac. Soc.* 18, 1043–1051 (2021).

Clinical Performance

Device performance compared automatically detected events results obtained by a two-thirds majority of three experienced sleep technologists. Performance in terms of sensitivity and specificity was assessed at an AHI cut-off of AHI >= 5. For more information about the clinical study, contact EnsoData or view the study information in the most recent device clearance.

The device was designed and tested under the following standards and guidelines:

- EN ISO 13485 Third Edition 2016/A11 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes

Apnea Hypopnea Index (eAHI)			
Desaturation	Sample Size (n)	Sensitivity	Specificity
3%	158	92.6% (87.2%, 97.2%)	71.6% (59.2%, 83.7%)
4%	158	89.4% (81.6%, 96.1%)	76.8% (67.1%, 85.4%)

Clinical trial performance in terms of sensitivity and specificity was assessed at an AHI cut-off of AHI >= 5. The following table is supplemental information.

	Apnea Hypopnea Index (eAHI) Supplemental Information			
Desaturation	eAHI Cutoff	Sample Size (n)	Sensitivity	Specificity
3%	15	158 (n=70 AHI≥15, n=88 AHI≤15)	74.1% (64.3%, 84.3%)	92.0% (86.4%, 96.6%)
4%		158 (n=40 AHI≥15, n=118 AHI≤15)	70.1% (55.0%, 82.6%)	95.8% (92.4%, 99.2%)
3%	30	158 (n=38 AHI≥30, n=120 AHI≤30)	53.0% (36.8%, 68.4%)	100% (100%, 100%)
4%		158 (n=13 AHI≥30, n=145 AHI≤30)	84.8% (61.5%, 100%)	98.6% (96.6%, 100%)

Sleep Staging			
Category	Sample Size (n)	Sensitivity	Specificity
Wake	52,622	86.7% (86.5%, 87.0%)	93.5% (93.4%, 93.7%)
Light Non-REM	69,438	80.9% (80.6%, 81.2%)	85.5% (85.2%, 85.7%)
Deep Non-REM	10,195	63.4% (62.4%, 64.3%)	95.9% (95.7%, 96.0%)
REM	14,459	83.6% (83.0%, 84.2%)	97.5% (97.4%, 97.5%)

Sleep Profile and Oxygen Saturation					
Category	Deming Regression		Bland-Altman		
	Slope ß1	Intercept ß0	Mean Difference (MD)	Upper Limit (ULOA)	Lower Limit (LLOA)
eAHI (3%) [events/hour]	0.936 (0.853, 1.033)	0.023 (-1.185, 1.122)	1.000 (0.630, 1.367)	14.575 (13.779, 15.363)	-12.574 (-13.371, -11.786)
eAHI (4%) [events/hour]	0.982 (0.903, 1.130)	1.219 (0.116, 1.985)	-1.039 (-1.326, -0.749)	9.307 (8.692, 9.931)	-11.386 (-12.001, -10.763)
Total Sleep Time [hours]	1.159 (1.035, 1.318)	-0.695 (-1.576, -0.005)	-0.093 (-0.132, -0.059)	1.145 (1.060, 1.216)	-1.330 (-1.414, -1.259)
Sleep Efficiency [hours/hours]	1.154 (1.031, 1.317)	-0.088 (-0.205, 0.003)	-0.011 (-0.017, -0.007)	0.163 (0.151, 0.173)	-0.185 (-0.198, -0.176)
Sleep Latency [hours]	1.114 (0.997, 1.290)	-0.023 (-0.185, 0.090)	-0.129 (-0.154, -0.089)	0.884 (0.831, 0.970)	-1.143 (-1.196, -1.057)

Sleep Profile and Oxygen Saturation					
Category	Deming Regression		Bland-Altman		
	Slope ß1	Intercept ß0	Mean Difference (MD)	Upper Limit (ULOA)	Lower Limit (LLOA)
Wake After Sleep Onset [hours]	1.073 (0.938, 1.219)	-0.271 (-0.436, -0.121)	0.167 (0.140, 0.196)	1.131 (1.073, 1.193)	-0.797 (-0.855, -0.735)
Oxygen Desaturation Index [events/ hours]	0.962 (0.896, 1.056)	1.667 (0.330, 2.847)	-1.046 (-1.417, -0.677)	13.223 (12.426, 14.015)	-15.315 (-16.111, -14.522)

Safety - Warnings and Cautions

- EnsoSleep PPG is a prescription device used under supervision of a physician in the United States.
- The device is not for patients with unstable cardiopulmonary conditions, current opiate or other narcotic drug use, or using home supplemental oxygen therapy, non-OSA respiratory ventilatory support therapy, diaphragmatic pacing, or cardiac stimulation therapy devices.
- The device is intended for analysis of sleep data acquired from adult patients.
- Capnography data is not supported or displayed.
- 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 standard 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.
- 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 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

This product is approved for sale and distribution in the United States of America (USA) and Canada. Do not use, resell, or distribute this product outside of the USA or Canada.

Published in the United States of America.

Manufactured by:
EnsoData, Inc.
10 E Doty Street, Suite 449
Madison, WI USA 53703

Phone: 608-889-3676 (ENSO)
Email: support@ensodata.com

Part Number: REF0025-A-ENG
Publication Date: June 2025
Software Version: 8.1+