ECTOSENSE

Ectosense nv

NightOwl Software

Instructions for Use

NIGHTOWL

IFUNOS-B-EN-1.23 v2_MDD

18-11-2022

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP FOR FUTURE REFERENCE

DISCLAIMER

Ectosense shall not be held accountable in any way for any injury and/or property damage arising from operation or use of NightOwl Software other than that which strictly adheres to the instructions and safety precautions contained herein.

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The latest version of the device (V1.23) was created in 2022 (date of manufacture) and the device (version) expiry date is set at the immediate moment succeeding the launch of an incremental version intended to replace the expiring version, or, 2 years after the latest version release. The Instructions for Use herein refer to the device version V1.23.

The Instructions for Use herein are available in the following language(s):

- English

Note: The latest version of the NightOwl Software Instructions for Use in the abovementioned language(s) is available in electronic format in www.ectosense.com/eifu. A printed version can be requested by contacting the manufacturer through info@ectosense.com. Delivery will be made within 7 days after formal request and at no additional cost to the user.

(01)05430001742176

Medical Device

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Safety notices

⚠ **CAUTION**	**Contra-indication: device should not be used on patients with known severe ventricular extra-systole, as this is likely to lead to insufficient clean data segments**
⚠ **CAUTION**	**Total recording length of interpretable signal quality should be greater than 4 hours for diagnosis to be accurate**
⚠ **CAUTION**	**Beginning and end of signal recordings should preferably be close to time of going to bed and getting up, respectively**
⚠ **CAUTION**	**The NightOwl Software's Instructions for Use should be carefully studied by the device user and kept where it is easily accessible. Periodic review of the Instructions is recommended.**

1. General information

1.1. Scope

This IFU relates to the **NightOwl Software** stand-alone medical software device. It is the analytical engine that interprets signals from one or more physical sensor devices.

The NightOwl Software device has been validated to work with the **NightOwl Sensor** device, a separate medical device for the continuous recording of a patient's blood volume pulse waveform and motion during sleep or resting, in both the clinical and home environment. The sensor can be worn on the finger by adults or children aged 13 and over, without requiring direct supervision by a healthcare professional.

Diagnostic results of the NightOwl Software device, which this Instructions for Use manual exclusively relates to, are output by the NightOwl Software as a JSON data file.

1.2. Intended use

The NightOwl Software is a software application intended for the physiological signal retrieval, visualisation, report generation, automated analysis and interpretation for the area of direct diagnosis and monitoring of obstructive sleep apnoea, including SpO2 software module: to optionally derive Oxygen Saturation levels from the own manufactured electronic reflective photoplethysmogram (PPG) sensor.

1.2.1. Claims

The NightOwl Software device accurately diagnoses patients with obstructive sleep apnea based on an analysis of the peripheral arterial tonometry ('PAT'), amongst other channels. It provides an estimate of the AHI as well as additional parameters relevant for the diagnosis such as total sleep time and an indication of cardiac irregularities. It displays photoplethysmography-derived signals and actigraphy.

1.2.2. Intended User

The Healthcare Professional (HCP): The NightOwl Software device's output JSON data file (*cf. Section 3*) is interpreted by a healthcare professional with knowledge of the patient's symptoms and on how to interpret them.

1.2.3. Intended use environment

The Healthcare Professional will have access to the JSON data files in which the outputs of the NightOwl Software are stored.

1.2.4. Intended patient population

The intended population for the device usage encompasses all individuals aged 13 or older that are suspected of suffering from sleep disordered breathing.

1.2.5. Clinical indications for use

The device is to be used for the benefit of patients with sleep disorder symptoms and a high risk for sleep apnea and/or with sleep apnea symptoms.

The American Academy of Sleep Medicine (AASM) identifies the following risk factors and symptoms that warrant a sleep study (Epstein et al., 2009) (**Table 1**):

Table 1 Risk factors and symptoms of obstructive sleep apnea

High Risk for Sleep Apnea	Sleep Apnea Symptoms
Obesity (BMI > 35)	Witnessed apnea
Congestive heart failure	Snoring
Atrial fibrillation	Gasping/choking at night
Treatment refractory hypertension	Excessive sleepiness not explained by other factors
Type 2 diabetes	Non-refreshing sleep
Nocturnal dysrhythmias	Total sleep amount
Stroke	Sleep fragmentation/maintenance insomnia
Pulmonary hypertension	Nocturia
High-risk driving populations	Morning headaches
Preoperative for bariatric surgery	Decreased concentration
	Memory loss
	Decreased libido
	Irritability

1.2.6. Clinical contra-indications for use

The device should not be used on patients with known severe ventricular extrasystole (VES) as this is likely to lead to insufficient clean data segments and therefore a failed test, similar to the challenges faced by a polysomnographic examination of such patients. The inclusion of a patient with known and severe VES does not lead to a significantly increased risk related to the device.

1.2.7. Clinical performance data

In order to perform its intended function, the device must receive data collected from signal acquisition devices.

The NightOwl Software's accuracies for parameters such as the Apnea-Hypopnea Index (AHI) and total sleep time (TST) are described in *Van Pee et al. Sleep. 2022 PMID: 35554589.*

The software further calculates or provides the parameters described in section 3.

1.2.8. Precautions

- Ensure that the start and stop of the signal acquisition device is as close to the actual going to bed for sleep.
- The NightOwl Software device's Instructions for Use should be carefully studied by the healthcare professional and kept where it is easily accessible. Periodic review of the Instructions is recommended.

1.3. Medical device classification

The NightOwl Software device is a Class IIa medical device under Rule 10 of Annex X of MDD 93/42/EEC, amended by 2007/47/EEC.

1.4. Quality Assurance System

The Ectosense NightOwl Software device is compliant with the following standards.

	STANDARD TITLE	STANDARD NUMBER
1.	Medical Device Software – Software Life Cycle Processes	EN IEC 62304:2006
2.	Medical devices – Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2016
3.	Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
4.	Medical devices – Symbols to be used with the medical device labels, labelling and information to be supplied. General Requirements	ISO 15233-1:2021
5.	Medical Device Directive	MDD 93/42/EEC MDD 2007/47/EC

1.5. CE compliance

CE
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The product complies with MDD 93/42/EEC and amendments 2007/47/EC (Medical Device Directive) requirements.

1.6. Conventions used in these instructions

⚠ **WARNING**	**Warnings** are used to identify conditions or actions which, if instructions are ignored, may violate patient safety, or cause malfunction of the device, resulting in non-recoverable loss of data.
⚠ **CAUTION**	**Cautions** are used to identify conditions or actions which could impair study results.

1.7. Symbols used on the Instructions for Use and on the Product Labels

	ISO 7000-2493	Catalogue number
	ISO 7000-3082	Manufacturer

	ISO 7000-2497	Year of manufacture
	ISO 7000-1641	Consult Instructions for Use
	ISO 7000-0434A	Caution
	ISO 15223-1:2020 5.7.7	Medical Device

1.8. Product labels

NightOwl™
Version number: 1.23

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CE 1639 2022 MD

CAUTION	Contra-indication: device should not be used on patients with known severe ventricular extra-systole, as this is likely to lead to insufficient clean data segments
CAUTION	Total recording length of interpretable signal quality should be greater than 4 hours for diagnosis to be accurate
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(01) 05430001742152

Figure 1: Label located on NightOwl Software Operator interface

2. Overview

Affecting 4 to 7% of the general population, sleep apnea is a highly prevalent sleep disorder and is characterised by partial or complete collapse of the upper airway resulting in an interruption of breathing during sleep. This often leads to hypoxaemia and hypercapnia and/or autonomic arousals (sympathetic nervous system – SNS – activation).

Three main types of sleep apnea exist: obstructive sleep apnea (OSA – the vast majority of cases), central sleep apnea (CSA – a small proportion of cases) and mixed sleep apnea. The distinction between obstructive and central apnea is described by the presence or absence of respiratory effort during apnea, respectively.

The diagnosis of sleep apnea is typically based on the number of apnea and hypopnea per hour of sleep, i.e. the Apnea-Hypopnea Index (AHI). Other relevant parameters include, the oxygen desaturation index (ODI) and the total sleep time (TST).

Common consequences of sleep apnea include excessive daytime sleepiness, increased propensity to accidents and decreased productivity. Prevalent co-morbidities are chronic cardiovascular conditions (arterial hypertension, heart failure, cardiac ischaemia or cardiac arrhythmia) or metabolic conditions (diabetes mellitus or obesity).

The NightOwl Software device is used by providing it with two input signals. Specifically, it receives as an input:

- A double-wavelength photoplethysmography trace
- An accelerometer trace

The NightOwl Software device uses the above signals to derive the AHI and TST, among other parameters described in section 3. The NightOwl Software device outputs a JSON Data file from which a comprehensive report of the overnight recordings can be rendered by rendering software which is not a part of the NightOwl Software device.

3. JSON Data file contents

The NightOwl Software generates single-night JSON Data files containing the below enumerated information.

Table 2 JSON Data file contents

Parameter type	Parameter name	JSON field code	Interpretation
Channel	Blood oxygen saturation (SpO_2(%))	J.SpO2	Blood oxygen saturation refers to the fraction of oxygen-saturated hemoglobin relative to the total amount of hemoglobin in the blood. It is expressed in percentage of total hemoglobin and physiological values are usually in the 95-100% range. Sudden decreases (desaturations) followed by a return to baseline (resaturation) lasting for more than 10 seconds are typically associated with apneic events

Parameter type	Parameter name	JSON field code	Interpretation
	Photoplethysmo-gram (PPG)	J.PPG	PPG is defined as an optical measure of pulsatile volume changes. The amplitude of the PPG is defined as the height of a PPG systolic peak. Sudden decreases in the amplitude of the PPG are indicative of a sympathetic nervous system-initiated vasoconstriction of the arteries in the peripheral tissue. During apneic events, such vasoconstrictions would frequently occur. Note: the PPG signal is included in a normalized form in the JSON file and cannot be used to assess the general level of perfusion
	Pulse Rate (PR(bpm))	J.PR	Pulse rate is expressed in beats per minute (bpm) and is computed from the distance between the systolic peaks of the PPG. Physiological values during sleep are usually in the 40-100 bpm range. During apneic events, sudden increases in PR would typically occur
	Activity	J.activity	Motion, in combination with PPG, is used to estimate sleep parameters and is derived from a 3-axis accelerometer. Spikes in the activity trace should be interpreted as detected motion (e.g. limb movement, position changes etc.)
	Positionality	J.Position	Sleeping position (upright, supine, prone, left, right) throughout the night
Figure	Poincaré plot	J.IBI	Parameter allows to set out the time interval between two neighbouring PPG pulse peaks on the horizontal axis to the subsequent neighbouring PPG pulse peaks on the vertical axis
Events	Respiratory events	J.RespEventLocations	Locations of the respiratory events tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		J.RespEventLocations4	Locations of the respiratory events tuned to the 2012 AASM 1B rule for the scoring of hypopnea (4% Rule)
		J.RespEventLocationsRDI	Locations of the respiratory events and respiratory event related arousals (RERAs) tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
	Desaturations	J.desats	Locations of desaturations of at least 3%
	Disconnections	J.disconnects	Locations of episodes during which the sensor was disconnected
	Major artifacts	J.MajArt	Locations of episodes during which the SpO_2 could not be determined due to insufficient PPG data quality

Parameter type		Parameter name	JSON field code	Interpretation
		Minor artifacts	J.MinArt	Locations of episodes during which the PR could not be determined due to insufficient PPG data quality
Index	pAHI	pAHI (3%)	J.AHI	The pAHI tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		pAHI (4%)	J.AHI4	The pAHI tuned to the 2012 AASM 1B rule for the scoring of hypopnea (4% Rule)
		Respiratory disturbance index (RDI)	J.RDI	The RDI tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		pAHI (3%) severity category	J.AHICategory	The severity category (Normal, Mild, Moderate, Severe) of the pAHI tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		pAHI (4%) severity category	J.AHICategory4	The severity category (Normal, Mild, Moderate, Severe) of the pAHI tuned to the 2012 AASM 1B rule for the scoring of hypopnea (4% Rule)
		RDI severity category	J.RDICategory	The severity category (Normal, Mild, Moderate, Severe) of the RDI tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		Number of respiratory events (3%)	J.Apneas	The total number of respiratory events with respiratory event detection tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		Number of respiratory events (4%)	J.Apneas4	The total number of respiratory events with respiratory event detection tuned to the 2012 AASM 1B rule for the scoring of hypopnea (4% Rule)
		Number of respiratory events (3%) and RERAs	J.ApneasRDI	The total number of respiratory events and respiratory event related arousals (RERAs) with respiratory event detection tuned to the 2012 AASM 1A rule for the scoring of hypopnea (3% Rule)
		AHIc Flag	J.AHIcFlag	The value of this parameter is 1 when a presence of 10 or more central or mixed respiratory events per hour of sleep were detected and 0 otherwise. Its value is defined as 'NaN' when the data was of insufficient quality to determine the output
	SpO_2	ODI ($\geqslant$3%)	J.ODI3	Number of $\geqslant$3% oxygen desaturations per hour of sleep (oxygen desaturation index)

Parameter type		Parameter name	JSON field code	Interpretation
		ODI (⩾4%)	J.ODI4	Number of ⩾4% oxygen desaturations per hour of sleep (oxygen desaturation index)
		Minimum SpO_2	J.minSpO2	Minimum observed blood oxygen saturation value
		Maximum SpO_2	J.maxSpO2	Maximum observed blood oxygen saturation value
		Average SpO_2	J.avgSpO2	Average observed blood oxygen saturation value
		Baseline SpO_2	J.baseSpO2	Baseline observed blood oxygen saturation defined as the most frequently occurring SpO_2 value
		Lowest desaturation	J.LowestDesaturation	The depth of the deepest desaturation
		TXX	J.T90, J.T89, J.T88, J.T85, J.T80, J.T70	The percentage of the interpretable recording time during which the SpO_2 was below XX%
		Hypoxic burden index	J.HBI	The total area between the SpO_2 curve during desaturations of at least 2% and the straight line between the pre and post desaturation SpO_2 values, divided by the TST
		Desaturation counts	1. J.NumOfDesaturations 2. J.NumOfDesaturations3to3 3. J.NumOfDesaturations4to9 4. J.NumOfDesaturations10to20 5. J.NumOfDesaturations21	Number of desaturations of respectively: 1. At least 3% 2. 3% 3. 4% to 9% 4. 10% to 20% 5. 21% or more
		Desaturation percentages	1. J.PercOfDesaturations 2. J.PercOfDesaturations3to3 3. J.PercOfDesaturations4to9 4. J.PercOfDesaturations10to20 5. J.PercOfDesaturations21	Percentage of desaturations of respectively: 1. At least 3% 2. 3% 3. 4% to 9% 4. 10% to 20% 5. 21% or more

Parameter type		Parameter name	JSON field code	Interpretation
	Pulse Rate	Mean PR	J.HRM	Mean pulse rate
		Minimum PR	J.HRMin	Minimum observed pulse rate value
		Maximum PR	J.HRMax	Maximum observed pulse rate value
		Pulse Rate > 100 bpm	J.HRT	Percentage of the pulse rate channel where the value was above 100 bpm
		Pulse Rate < 40 bpm	J.HRB	Percentage of the pulse rate channel where the value was below 40 bpm
		% of ectopic beats	J.percEct	The percentage of inter-beat-intervals that was labelled as ectopic
	Total Sleep Time	TST for pAHI determination	J.TST	Estimated total amount of time spent sleeping (Total Sleep Time) of the interpretable part of the recording. The pAHI is determined by dividing the number of respiratory events by this value.
		TST	J.TST_full	Estimated total amount of time spent sleeping (Total Sleep Time) of the recording. Episodes of sensor disconnection from the smartphone or detachment from the finger are excluded.
		Total REM Time	J.TRT	Estimated total amount of time spent in REM sleep of the interpretable part of the recording
		Extrapolated Total REM Time	J.TRT_full	J.TRT extrapolated by multiplying it by J.TST_full divided by J.TST
		Total REM Time as a percentage of Total Interpretable Time	J.percREMtit	J.TRT/J.TIT * 100
		Total REM Time as a percentage of Total Sleep Time used for pAHI determination	J.percREMsleep	J.TRT/J.TST * 100

Parameter type		Parameter name	JSON field code	Interpretation
		Extrapolated Total REM Time as a percentage of the total time the sensor was connected to the smartphone and attached to the finger	J.percREMtit_full	J.TRT_full divided by the total time the sensor was connected to the smartphone and attached to the finger, multiplied by 100 to express the value as a percentage.
		Extrapolated Total REM Time divided by Total Sleep Time	J.percREMsleep_full	J.TRT_full/J.TST_full
		Sleep efficiency version 1	J.SE	J.TST divided by J.TIT
		Sleep efficiency version 2	J.SE_full	J.TST_full divided by the total recording time minus the time during which the sensor was disconnected from the smartphone or detached from the finger
	Body position statistics	Sleep time in each position	J.TSTSupine; J.TSTProne; J.TSTLeft; J.TSTRight; J.TSTNonsupine	A breakdown of the total sleep time in each body position
		Sleep % in each position	J.percTSTSupine; J.percTSTProne; J.percTSTLeft; J.percTSTRight; J.percTSTNonsupine	A breakdown of the percentage of time spent asleep in each body position
		pAHI in each position	J.AHISupine; J.AHIProne; J.AHILeft; J.AHIRight; J.AHINonsupine	A breakdown of the pAHI in each body position
		ODI	J.ODISupine; J.ODIProne; J.ODILeft; J.ODIRight; J.ODINonsupine	A breakdown of the ODI in each body position
		Positionality failed	J.positionalityFail	The value of this parameter is equal to 1 when the positionality information could not be determined due to inadequate data quality and 0 otherwise

Parameter type		Parameter name	JSON field code	Interpretation
	Data quality	Rejected recording	J.rejection	The percentage of the total recording that was rejected for the analysis of respiratory events due to inadequate data quality
		Sensor disconnection or detachment	J.rejection_full	The percentage of the total recording that was rejected due to sensor disconnection from the smartphone or detachment from the finger
		Total interpretable time	J.TIT	the total recording time that was accepted for the analysis of respiratory events due to adequate data quality

4. Troubleshooting guide

Signal recording errors which arise during the operation of the NightOwl device are tracked by means of the presence of an error code in the JSON file. When an error code is present, no valid NightOwl Software output parameters could be calculated.

Table 3 Interpretation of possible JSON error codes and actions to undertake to resolve problem

Error Code	Interpretation
EC01	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. We noticed that the patient's smartphone had forced the NightOwl Sensor data acquisition to shut down. Please advise the patient to use a different smartphone or tablet next night. We noticed that the signal quality was not optimal. Please explain the patient how to adequately apply the sensor.
EC02	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. We noticed that the patient's smartphone had forced the NightOwl sensor data acquisition to shut down. Please advise the patient to use a different smartphone or tablet next night.
EC03	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. We noticed issues with the stability of the Bluetooth connection between the patient's smartphone and the NightOwl sensor. Please advise the patient to either make sure that the phone is within 2 meters of the sensor for the large majority of the night or to use a different smartphone if this was already the case. We also noticed that the signal quality was not optimal. Please explain the patient how to adequately apply the sensor.

Error Code	Interpretation
EC04	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. We noticed issues with the stability of the Bluetooth connection between the patient's smartphone and the NightOwl sensor. Please advise the patient to either make sure that the phone is within 2 meters of the sensor for the large majority of the night or to use a different smartphone if this was already the case.
EC05	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. We noticed that the signal quality was not optimal. Please explain the patient how to adequately apply the sensor.
EC06	No valid NightOwl Software outputs were generated since the total recording time was less than 4 hours. Please advise the patient to attempt sleeping longer next night.
EC07	No valid NightOwl Software outputs were generated since there was less than 4 hours of analysable signal available. Please explain the patient how to adequately apply the sensor.
EC08	No valid NightOwl Software outputs were generated since there was less than 4 hours of analysable signal available. We noticed issues with the stability of the Bluetooth connection between the patient's smartphone and the NightOwl sensor. Please advise the patient to either make sure that the phone is within 2 meters of the sensor for the large majority of the night or to use a different smartphone if this was already the case.
EC09	No valid NightOwl Software outputs were generated since there was less than 4 hours of analysable signal available. We noticed that the patient's smartphone had forced the NightOwl Companion App to shut down. Please advise the patient to use a different smartphone or tablet next night.
EC10	No valid NightOwl Software outputs were generated since there was less than 4 hours of analysable signal available. We noticed that the patient's smartphone had forced the NightOwl sensor data acquisition to shut down. Please advise the patient to use a different smartphone or tablet next night. Please explain the patient how to adequately apply the sensor.
EC11	No valid NightOwl Software outputs were generated since there was less than 4 hours of analysable signal available. We noticed issues with the stability of the Bluetooth connection between the patient's smartphone and the NightOwl sensor. Please advise the

Error Code	Interpretation
	patient to either make sure that the phone is within 2 meters of the sensor for the large majority of the night or to use a different smartphone if this was already the case. Please explain the patient how to adequately apply the sensor.

If an unknown error occurs, the manufacturer will also be notified and adopt the required measures to fix the problem. Contact the manufacturer to assess the problem fix status.

For communicating a complaint, noting a malfunction of the device or a customer service query, healthcare professionals should contact the manufacturer through www.ectosense.com/support.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.