ECTOSENSE

Ectosense nv

NightOwl Software

Instructions for Use

NIGHTOWL

IFUNOS-B-EN-1.21 v1

05-June-2020

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 (V1.21) was created in 2020 (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 V1.21. The NightOwl Software device is serviced for one year after expiry date.

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

- English
- French

Note: The latest version of the NightOwl Software Instructions for Use in the abovementioned language(s) is available in electronic format in hwww.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.

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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. You can operate the NightOwl Software device with, but also independently of, the NightOwl Sensor device.

Diagnostic results of the NightOwl Software device, which this Instructions for Use manual exclusively relates to, can be viewed in the **Ectosense Dashboard**, a portal made available through your web browser on dashboard.ectosense.com/nightowl. You can also view the diagnostic results independently of this portal, through the pdf format.

The Ectosense Dashboard incorporates other functionalities such as patient monitoring, diagnostic test ordering, and account management.

1.2. Intended use

The NightOwl Software is intended for physiological signal retrieval, visualisation, report generation, analysis and interpretation for the area of direct diagnosis and monitoring of obstructive sleep apnea.

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 report (*cf*. **1.1.1**) 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 software device will be operated in or from within an environment where no patients or physicians are present, namely, the Ectosense premises.

The Healthcare Professional will have access to the analysis results through the Ectosense Dashboard, developed to view the diagnostic results as well as to track patients and order new tests.

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 Failure Report, 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 Massie et al., 2018, Journal of Clinical Sleep Medicine.

The software further calculates or provides the parameters described in section 3.2

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 13485:2003
3.	Medical devices – Application of risk management to medical devices	EN ISO 14971:2012
4.	Medical devices – Symbols to be used with the medical device labels, labelling and information to be supplied. General Requirements	ISO 15233-1:2007
5.	Medical Device Directive	MDD 93/42/EEC MDD 2007/47/EC

1.5. CE compliance

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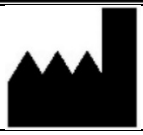
The product complies with MDD 93/42/EEC and amendments 2007/47/EC (Medical Device Directive) requirements.

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

1.8. Product labels

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 3.2. The NightOwl Software device outputs comprehensive reports of the overnight recordings, including the above parameters and graphic representation of the data and detected events. The full night data is displayed and can be visually analysed.

3. Diagnostic report interpretation

3.1. Report types

The NightOwl Software generates single-night diagnostic reports and summary diagnostic reports, the latter aggregating the results of multiple single-night reports.

The diagnostic reports are electronic documents in PDF format that have been optimized for printing.

3.2. Single night diagnostic report output interpretation

Table 2 Single-night diagnostic report parameters and interpretation

Parameter type	Parameter	Interpretation
Channel	Blood oxygen saturation (SpO_2(%))	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.
	Photoplethysmo-gram (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 displayed in a normalized form in

Parameter type		Parameter	Interpretation
			the reports and cannot be used to assess the general level of perfusion.
		Pulse Rate (PR(bpm))	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	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.).
Figure		Poincaré plot	This plot sets 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		Desaturations	Locations of the oxygen desaturation events are highlighted.
		Disconnections	Highlights recording episodes during which the sensor was disconnected.
Index	AHI	AHI	The AHI defined according to the 2012 AASM guidelines.
	SpO_2	ODI ($\geqslant$3%)	Number of $\geqslant$3% oxygen desaturations per hour of sleep (oxygen desaturation index).
		ODI ($\geqslant$4%)	Number of $\geqslant$4% oxygen desaturations per hour of sleep (oxygen desaturation index).
		Minimum SpO_2	Minimum observed blood oxygen saturation value
		Maximum SpO_2	Maximum observed blood oxygen saturation value.
		T90	The percentage of the interpretable recording time during which the SpO2 was below 90%.
	Pulse Rate	Mean PR	Mean pulse rate during the full recording.
		Pulse Rate > 100 bpm	Percentage of the pulse rate channel where the value was above 100 bpm.
		Pulse Rate < 40 bpm	Percentage of the pulse rate channel where the value was below 40 bpm.
		% of ectopic beats	The percentage of inter-beat-intervals that was labelled as ectopic.
	Total Sleep Time	TST	Estimated total amount of time spent sleeping (total sleep time) of the interpretable part of the recording.
		SE	Total sleep time divided by the total duration of the interpretable part of the recording.
	Other	Rejected recording	The percentage of the total recording that was rejected from the analysis because it was of insufficient quality for interpretation

4. Troubleshooting guide

Signal recording errors which arise during the operation of the NightOwl device are tracked by means of the output report. In case of an error, the report takes the form of a failure report. The failure report can contain one of the messages described in the following table. If an unknown error occurs, the manufacturer will also be notified to adopt the required measures to resolve the problem.

Table 3 Interpretation of possible failure reports and actions to undertake to resolve problem

Error Code	Error Message
EC01	No Examination report was generated since the total recording time was less than 4 hours. 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. We noticed that the signal quality was not optimal. Please explain the patient how to adequately apply the sensor.
EC02	No Examination report was generated since the total recording time was less than 4 hours. 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.
EC03	No Examination report was 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.
EC04	No Examination report was 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 Examination report was 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.

Error Code	Error Message
EC06	No Examination report was generated since the total recording time was less than 4 hours. Please advise the patient to attempt sleeping longer next night.
EC07	No Examination report was generated since there was less than 4 hours of analysable signal available. Please explain the patient how to adequately apply the sensor.
EC08	No Examination report was 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 Examination report was 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 Examination report was 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. Please explain the patient how to adequately apply the sensor.
EC11	No Examination report was 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. Please explain the patient how to adequately apply the sensor.

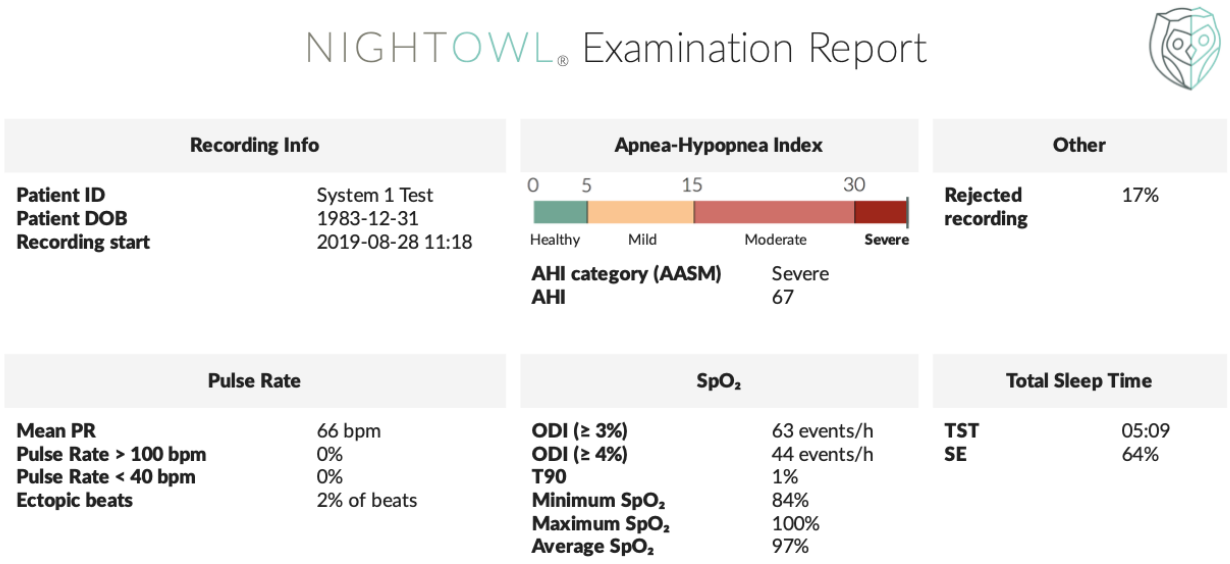
If an unknown error occurs, the manufacturer will also be notified and adopt the required measures to fix the problem. Contact the manufacturer to assess the problem fix status.

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.

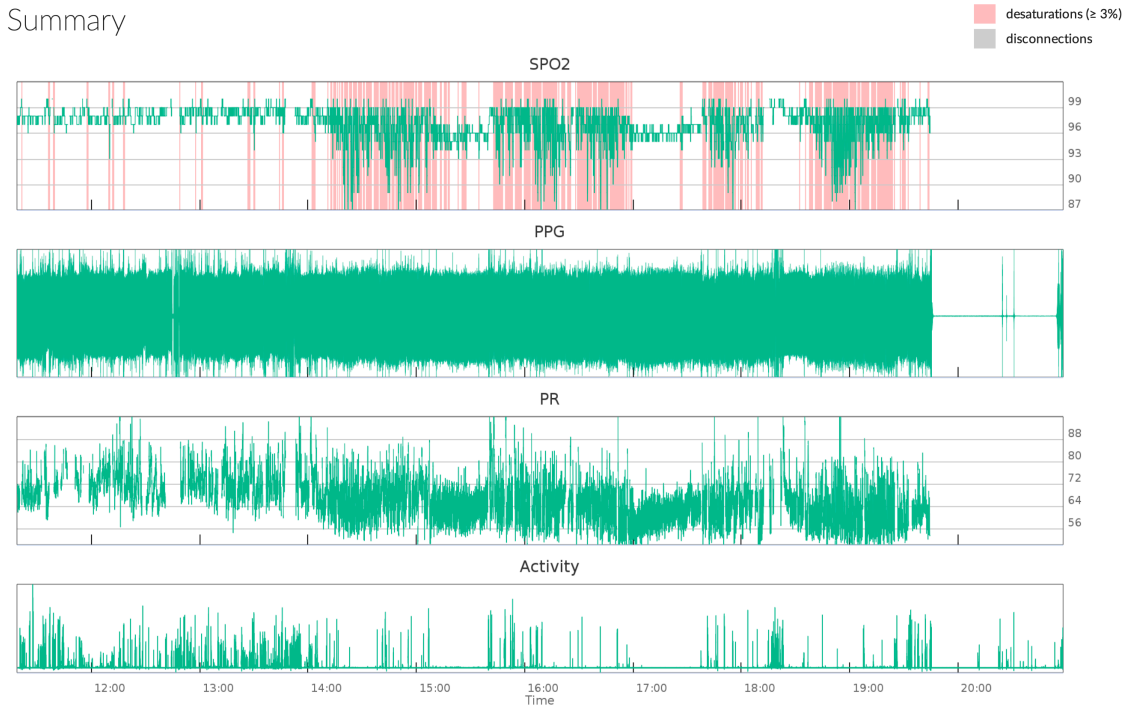
5. Appendix A: report illustrations

5.1. Single-night report

Index page

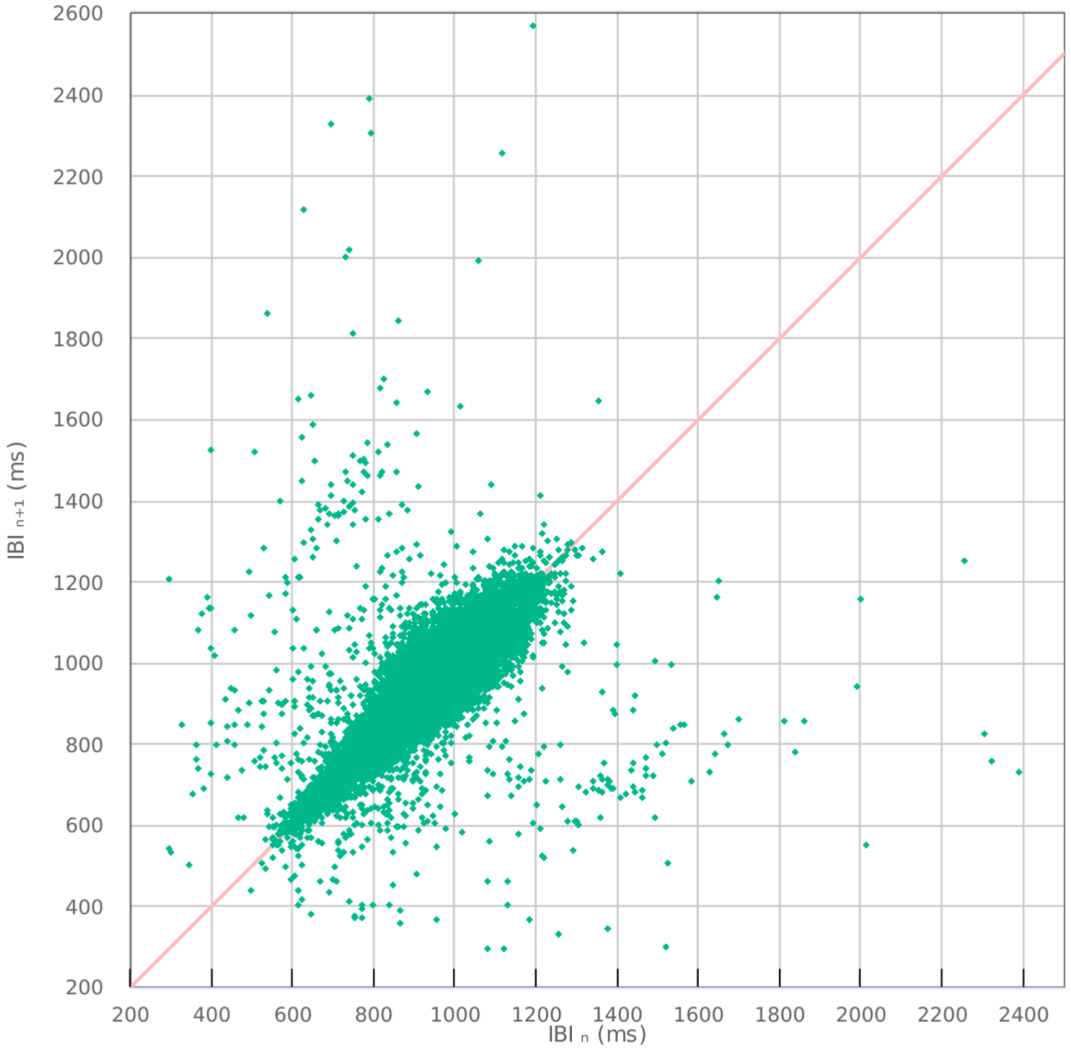


Trace summary page



One-hour trace page

Poincaré plot page



Failure report

NIGHTOWL® Error Report

There was an error when performing the analysis. The details of this error are described below. Please act accordingly as to fix the error or contact technical assistance at info@ectosense.com.

Patient ID: System 1 Test
Recording start: 2019-08-21 22:26

Error: No diagnostic report was generated since there was less than 4 hours of analyzable signal available