ECTOSENSE

Ectosense nv

NightOwl

Instructions for Use

Ectosense

REF IFUNOS-B-EN-1.2011-1

NIGHTOWL

Caution: **Sale is restricted to Member States of the European Union**

Caution: **Device output only to be provided to healthcare professionals**

3-Oct-18

IMPORTANT

READ CAREFULLY BEFORE USE

KEEP FOR FUTURE REFERENCE

CONFIDENTIALITY NOTICE

This manual and the information contained herein are confidential and are the sole property of Ectosense nv ("Ectosense"). Only Ectosense, its customers or its licensees have the right to use this information. Any unauthorised use, disclosure or reproduction is a direct violation of Ectosense's proprietary rights.

DISCLAIMER

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

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The latest version of the device (V1.2011) was created in 2018 (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 V1.2011. 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
- Portuguese
- French

Note: The latest version of the NightOwl 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. Delivery will be made within 7 days after formal request and at no additional cost to the user.

CE

1639

Record of Editions

Edition	Date	Description	Chapters	Pages	Responsible
V1	3 Oct 2018	Initial release			Mr. Bart Van Pee, Quality Manager

The version herein has not undergone any editions as of 3-Oct-18.

Note: the latest version of the NightOwl Instructions for Use is available in electronic format in the aforementioned language(s) at 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.

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SAFETY NOTES

⚠ **CAUTION**	**Device output only to be used by healthcare professionals**
⚠ **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'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-only 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 provider. 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 **NightOwl Dashboard**, a portal made available through your web browser on dashboard.ectosense.com. You can also view the diagnostic results independently of this portal, through the pdf format.

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

Throughout this document, the references 'NightOwl device', 'the software', 'NightOwl software device', and 'NightOwl software', are used to refer to the NightOwl medical device software that provides the diagnostic interpretation.

1.2. Intended use

The NightOwl is a computer program (software) 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 device accurately diagnoses patients with obstructive sleep apnea based on an analysis of the peripheral arterial tonometry ('PAT'), amongst other channels. It provides 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 NightOwl device has two user groups:

(1) The Ectosense Operator: The NightOwl device is intended to be operated by a person explicitly authorised and qualified to oversee the automated software analysis.
(2) The Healthcare Provider (HCP): The NightOwl device's output report (*cf*. **1.2.7**) is interpreted by a healthcare professional with knowledge of the patient's symptoms and on how to interpret them.

This IFU is developed for the latter user group only.

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 Provider will have access to the analysis results through the NightOwl Dashboard portal, 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. Data generated by the NightOwl device

The NightOwl device generates a diagnostic report containing information on the apnea-hypopnea index (AHI) severity category, the oxygen saturation index (ODI) using both the ≥3% rule and the ≥4% rule for the classification of desaturations (ODI3% and ODI4%, respectively),

the total sleep time (TST), the presence or absence of a substantial changes in peripheral arterial tone (PAT) caused by, for example, sympathetic activation, the presence of irregular heart rhythms. It also contains information on the location of desaturations and signal artifacts.

1.2.8. 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 Oxygen Desaturation Index (ODI), changes in the peripheral arterial tone (PAT), the blood oxygen saturation (SpO_2) from photoplethysmography as well as pulse rate and deterministic derivations thereof.

1.2.9. Precautions

- Ensure a total recording length of more than 4 hours.
- Ensure that the start and stop of the signal acquisition device is as close to the actual going to bed for sleep.
- The NightOwl 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 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 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

CE 1639

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

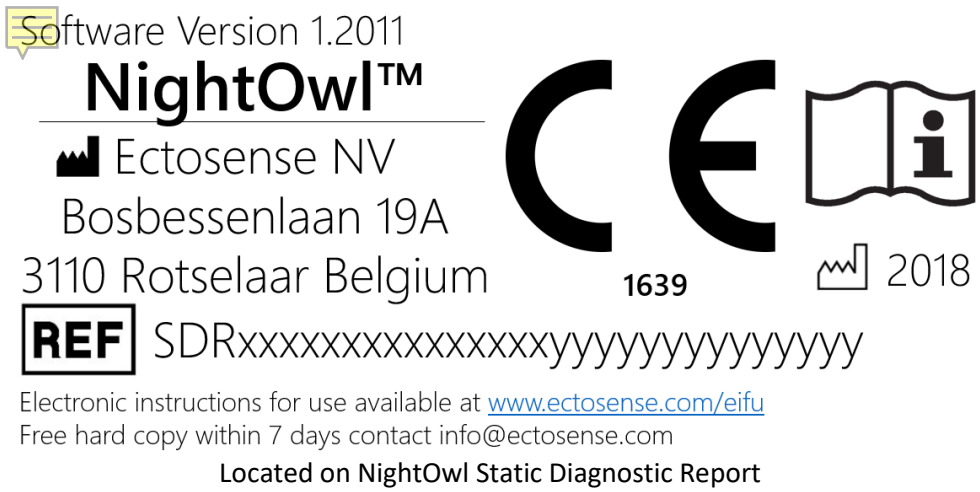
1.6. Conventions used in these instructions

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



Located on NightOwl Static Diagnostic Report

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). Furthermore, a measure of SNS activation is informative: high sympathetic activation throughout the night despite a low AHI might indicate the presence of a sleep disorder other than sleep apnea.

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 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 device uses the above signals to derive the severity of sleep apnea (AHI severity category), the ODI, the TST. The NightOwl 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. Diagnostic report colour codes

The first page of the single-night diagnostic report provides a summary of the full diagnostic report in which a colour code is used. For future reference, the colour code is as specified by **Figure 5**.

Figure 1 Colour code used in the reports

The colours indicate a level of severity of certain aspects to take into consideration when diagnosing the patient. The colour of certain parts of the report thus depends on the type of information it concerns and the severity of certain parameters.

3.3. Single night diagnostic report output interpretation

Table 2 Single-night diagnostic report parameters and interpretation

Parameter type	Parameter	Interpretation
Trace	Blood oxygen saturation (SpO_2(%))	Blood oxygen saturation refers to the fraction of oxygen-saturated haemoglobin relative to the total amount of haemoglobin in the blood. It is expressed in percentage of total haemoglobin and physiological values are usually in the 95-100% range.
	Photoplethysmo-gram (PPG)	The PPG is an optically obtained volumetric measurement of an organ. It monitors the perfusion of blood in the dermis and subcutaneous tissue of the skin.
	Heart Rate (HR(bpm))	Because the skin is so richly perfused, it is easy to derive the pulsatile component of the cardiac cycle from the PPG. Each PPG peak corresponds to a systole while each PPG trough corresponds to a diastole. As such, heart rate is derived by detecting all peaks. Heart rate is expressed in beats per minute (bpm). Physiological values during sleep are usually in the 40-100 bpm range. HR values below 40 bpm

Parameter type		Parameter	Interpretation
			(bradycardia) or above 100 bpm (tachycardia) are considered pathological.
		Activity	Motion, in combination with PPG, is used to estimate sleep parameters and sleep/wake patterns. 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		Blood oxygen desaturations	Collapse of the upper airway reduces oxygen supply and decreases the percentage of saturated haemoglobin. The desaturations displayed over the SpO_2 trace correspond to ≥3% drops in oxygen saturation from pre-event baseline.
		Artifacts	Motion artifacts strongly affecting PPG and SpO_2 signal quality are flagged.
		Disconnections	Highlights recording episodes during which the sensor was disconnected.
Index	AHI	AHI Category (AASM)	The sleep apnea severity category as indicated by the AHI, following the 2012 AASM guidelines. The four possible values for this index are “Not relevant” (AHI below 5 events per hour), “Mild” sleep apnea (AHI of 5 or more and below 15 events per hour), “Moderate” sleep apnea (AHI of 15 or more and below 30 events per hour) and “Severe” sleep apnea (AHI of 30 events per hour or more)
		AHI	The AHI defined according to the 2012 AASM guidelines.
	SpO_2	ODI (≥3%)	Number of ≥3% oxygen desaturations per hour of sleep (oxygen desaturation index)
		ODI (≥4%)	Number of ≥4% oxygen desaturations per hour of sleep (oxygen desaturation index)
		Minimum SpO_2	Minimum blood oxygen desaturation value recorded during the full recording
		Maximum SpO_2	Maximum blood oxygen desaturation value recorded during the full recording
	Heart Rate	Mean HR	Mean heart rate during the full recording
		Beats > 100 bpm	Percentage of heart beats where the instantaneous heart rate was above 100 bpm
		Beats < 40 bpm	Percentage of heart beats where the instantaneous heart rate was below 40 bpm
		% of ectopic beats	The percentage of inter-beat-intervals that was labelled as ectopic
	Total Sleep Time	TST	Total amount of time spent sleeping (total sleep time)
		SE	Total sleep time divided by the total duration of the interpretable part of the recording.

Parameter type		Parameter	Interpretation
	Other	Rejected recording	The percentage of the total recording that was rejected from the analysis because it was of insufficient quality for interpretation

3.4. Summary Diagnostic report

The summary diagnostic report contains straightforward aggregations of the parameters displayed in the single-night report.

4. Troubleshooting guide

Diagnostic errors which arise during the operation of the NightOwl device are tracked by means of the output report. In case of an error, this report will almost always be output, and takes the form of a failure report. The failure report can contain one of the messages described in the following table. When one of the described errors is met, perform the recommended actions.

Table 3 Interpretation of possible failure reports and actions to undertake to fix problem (for the operator and for the healthcare professional)

Error message	Possible reason	Action
The Red LED of the NightOwl Sensor is broken. Replace the device.	The Red data acquisition of the NightOwl Sensor is malfunctioning.	Replace the NightOwl Sensor
The IR LED of the NightOwl Sensor is broken. Replace the device.	The IR data acquisition of the NightOwl Sensor is malfunctioning.	Replace the NightOwl Sensor
The NightOwl Sensor has a functional defect. Replace the device.	There is a malfunctioning of the optical sensor.	Replace the NightOwl Sensor
The recording is too short to be interpreted.	There duration of the interpretable recording is less than 4 hours .	Ensure that the NightOwl Sensor was positioned and attached correctly
The total sleep time is too short. The recording cannot be interpreted.	The total sleep time was less than 1.5 hours.	Ensure that the NightOwl Sensor was positioned and attached correctly
The Accelerometer of the NightOwl Sensor is broken. Replace the device.	The Accelerometer of the NightOwl Sensor is broken.	Replace the NightOwl Sensor

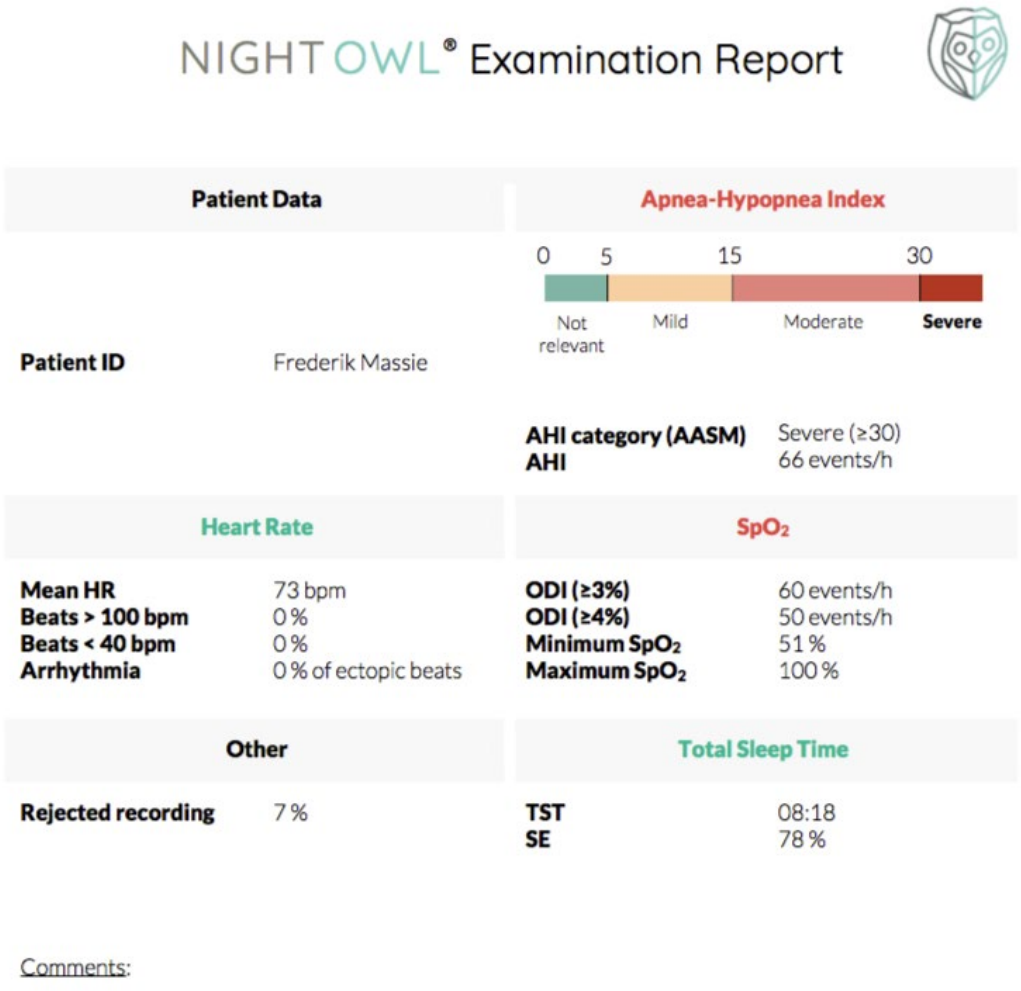
If an unknown error occurs, the manufacturer will also be notified and adopt the required measures to fix the problem. Contact the manufacturer to assess the problem fix status.

For communicating a complaint, noting a malfunction of the device or a customer service query, healthcare professionals should contact the manufacturer by sending an e-mail to customers@ectosense.com. Technical assistance can also be provided by filling the contact form available at www.ectosense.com.

5. Appendix A: report illustrations

5.1. Single-night report

Index page



NIGHT OWL® Examination Report

Patient Data	
Patient ID	Frederik Massie

Apnea-Hypopnea Index

0 5 15 30

Not relevant | Mild | Moderate | **Severe**

AHI category (AASM)	Severe (≥30)
AHI	66 events/h

Heart Rate	
Mean HR	73 bpm
Beats > 100 bpm	0 %
Beats < 40 bpm	0 %
Arrhythmia	0 % of ectopic beats

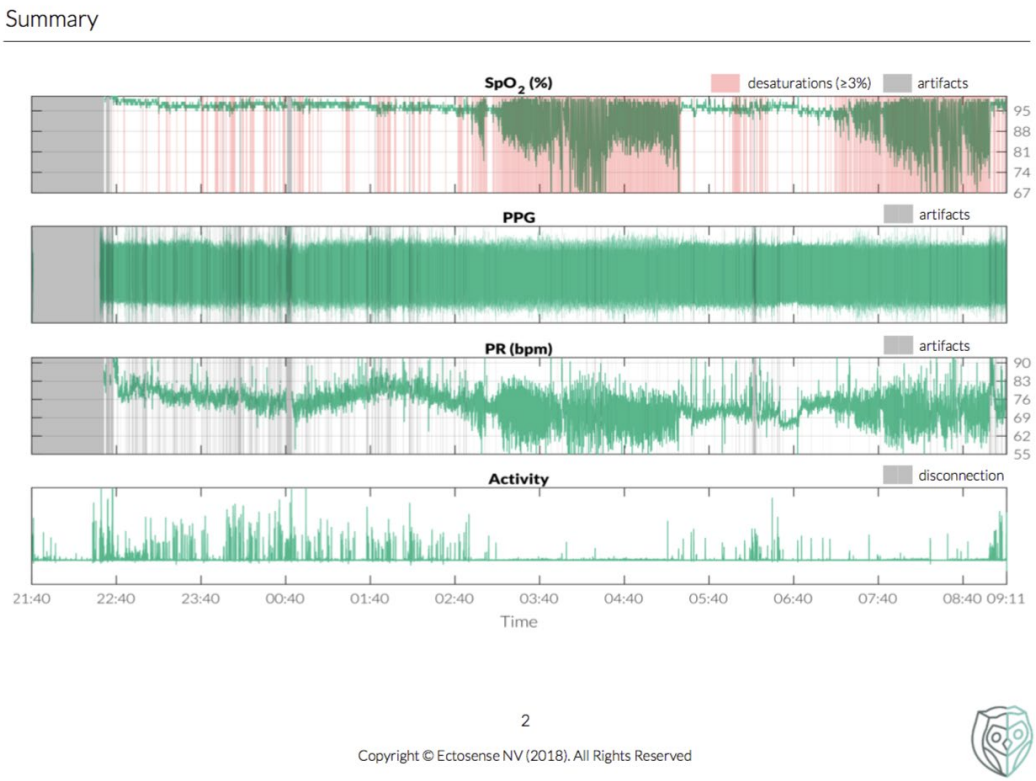
SpO_2	
ODI (≥3%)	60 events/h
ODI (≥4%)	50 events/h
Minimum SpO_2	51 %
Maximum SpO_2	100 %

Other	
Rejected recording	7 %

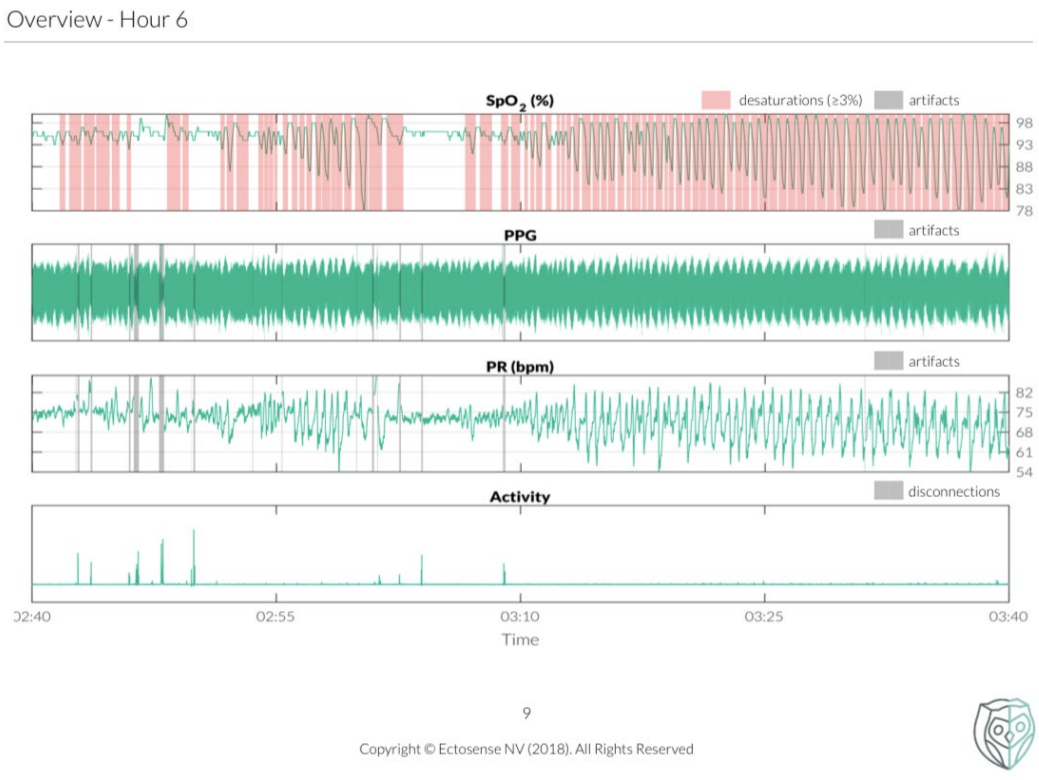
Total Sleep Time	
TST	08:18
SE	78 %

Comments:

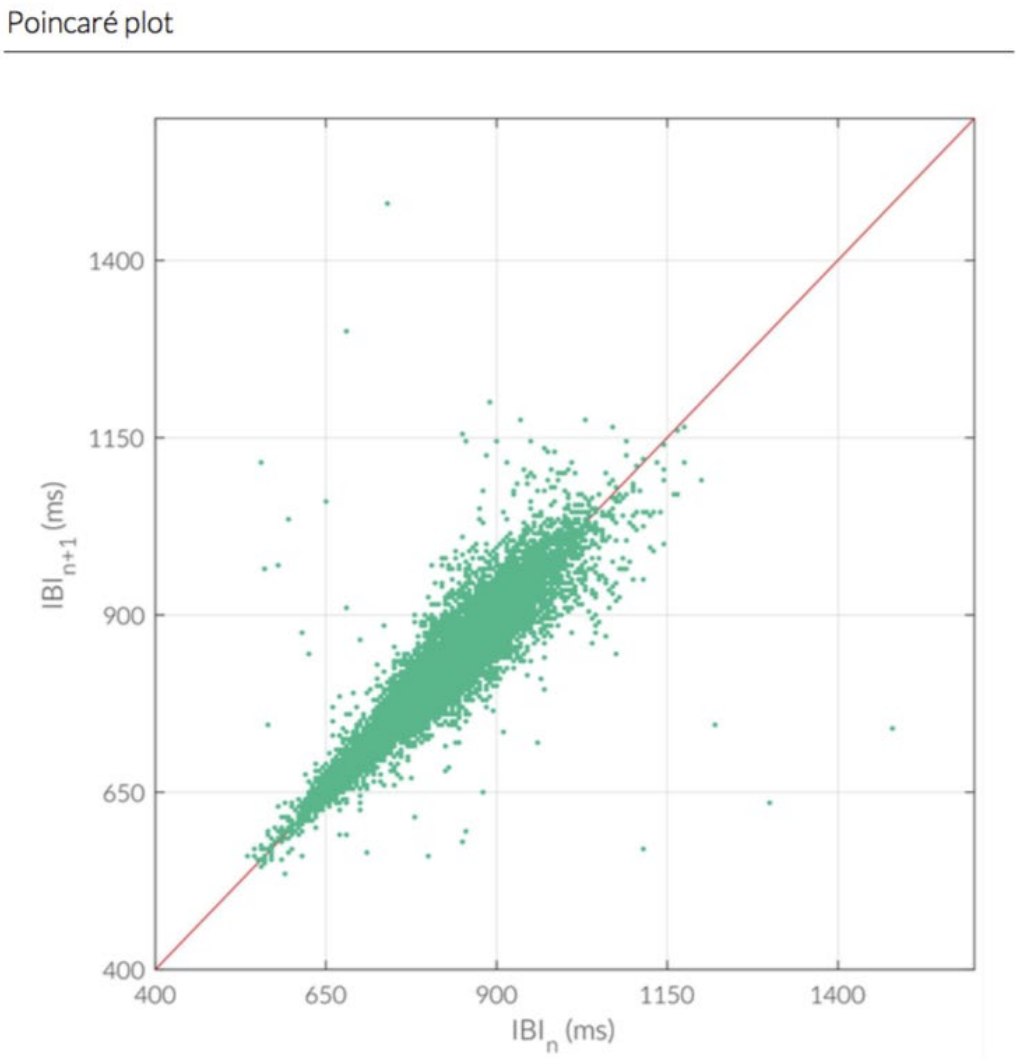
Trace summary page



One-hour trace page

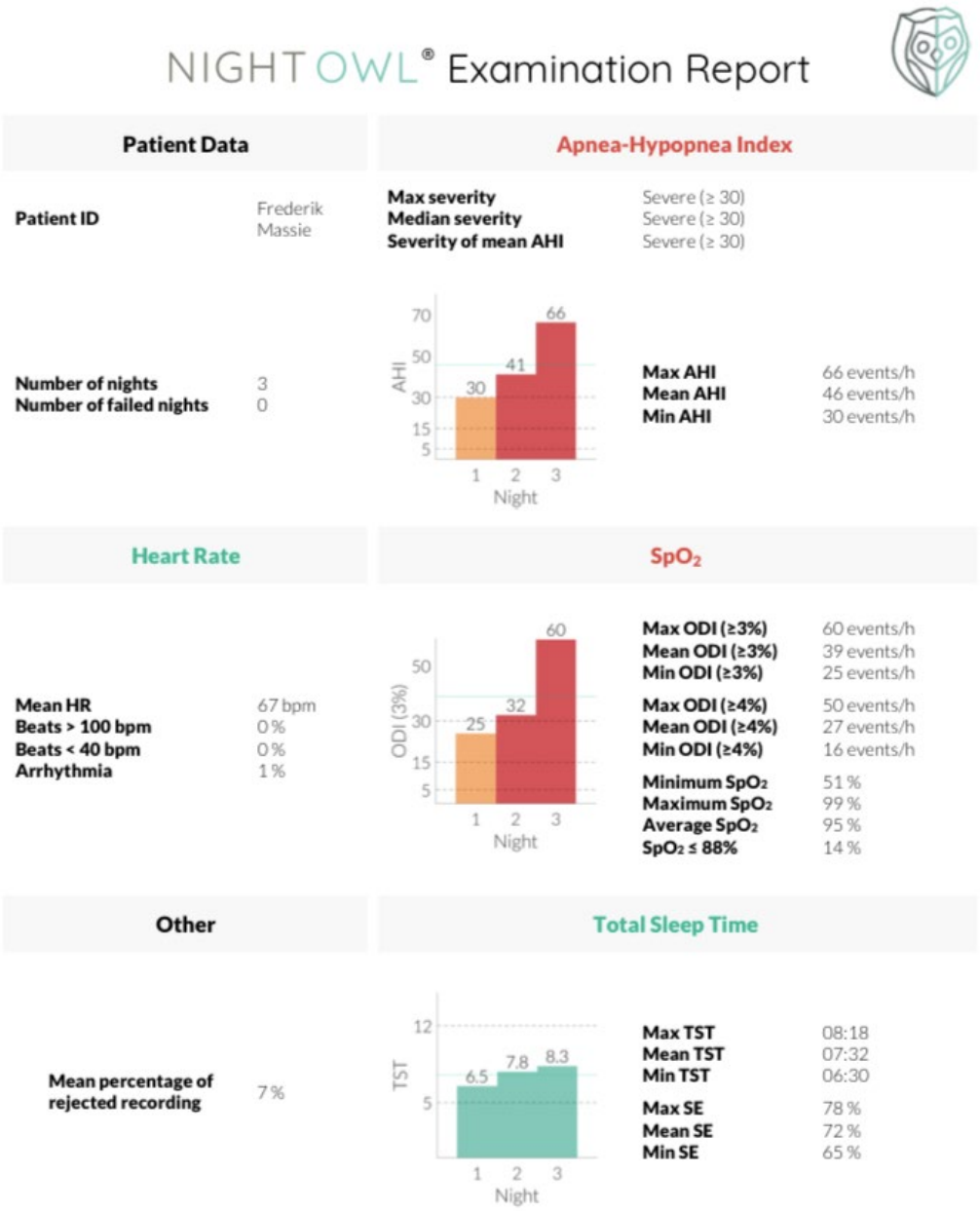


Poincaré plot page

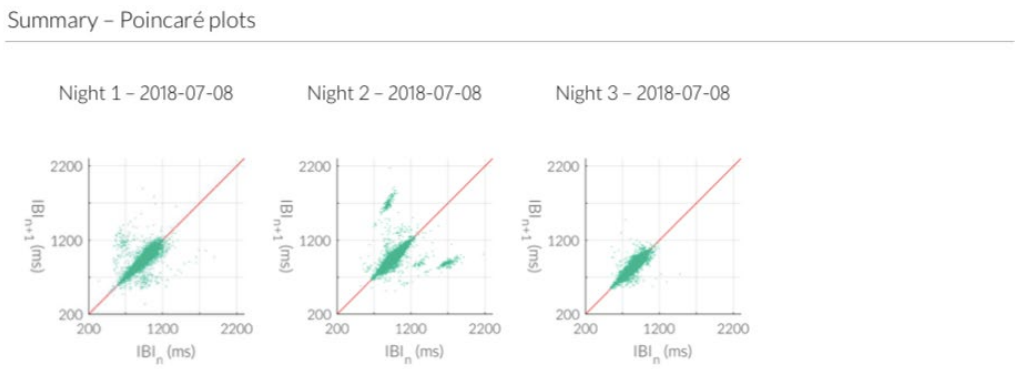


5.2. Summary report

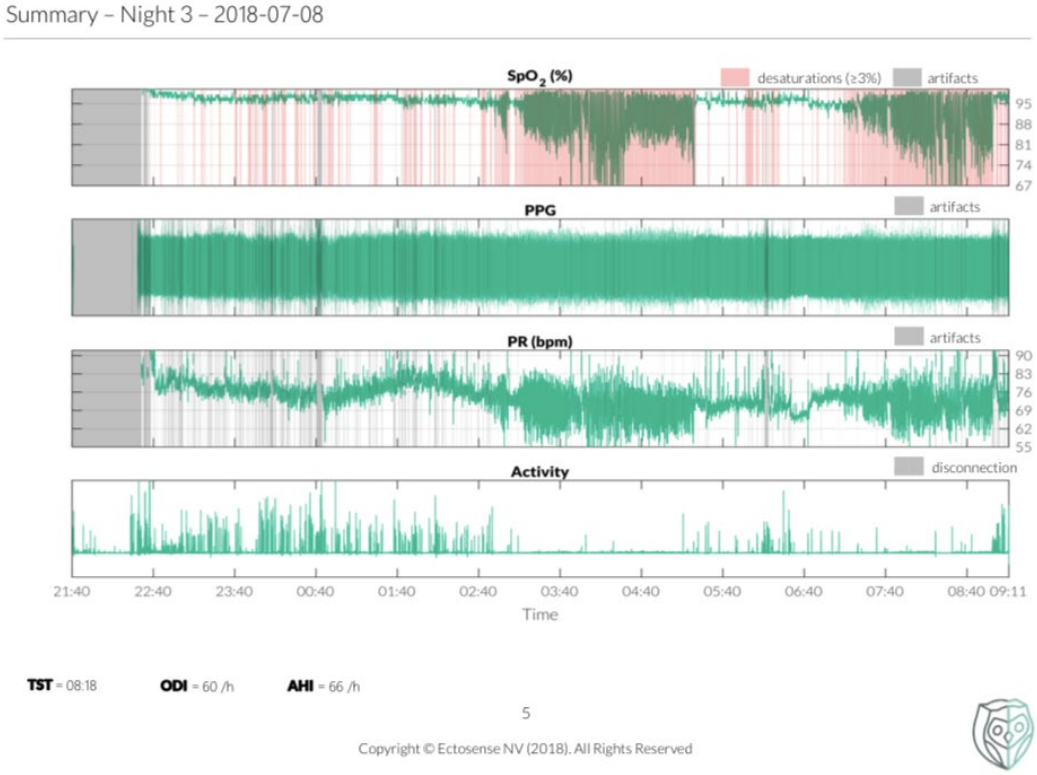
Index page



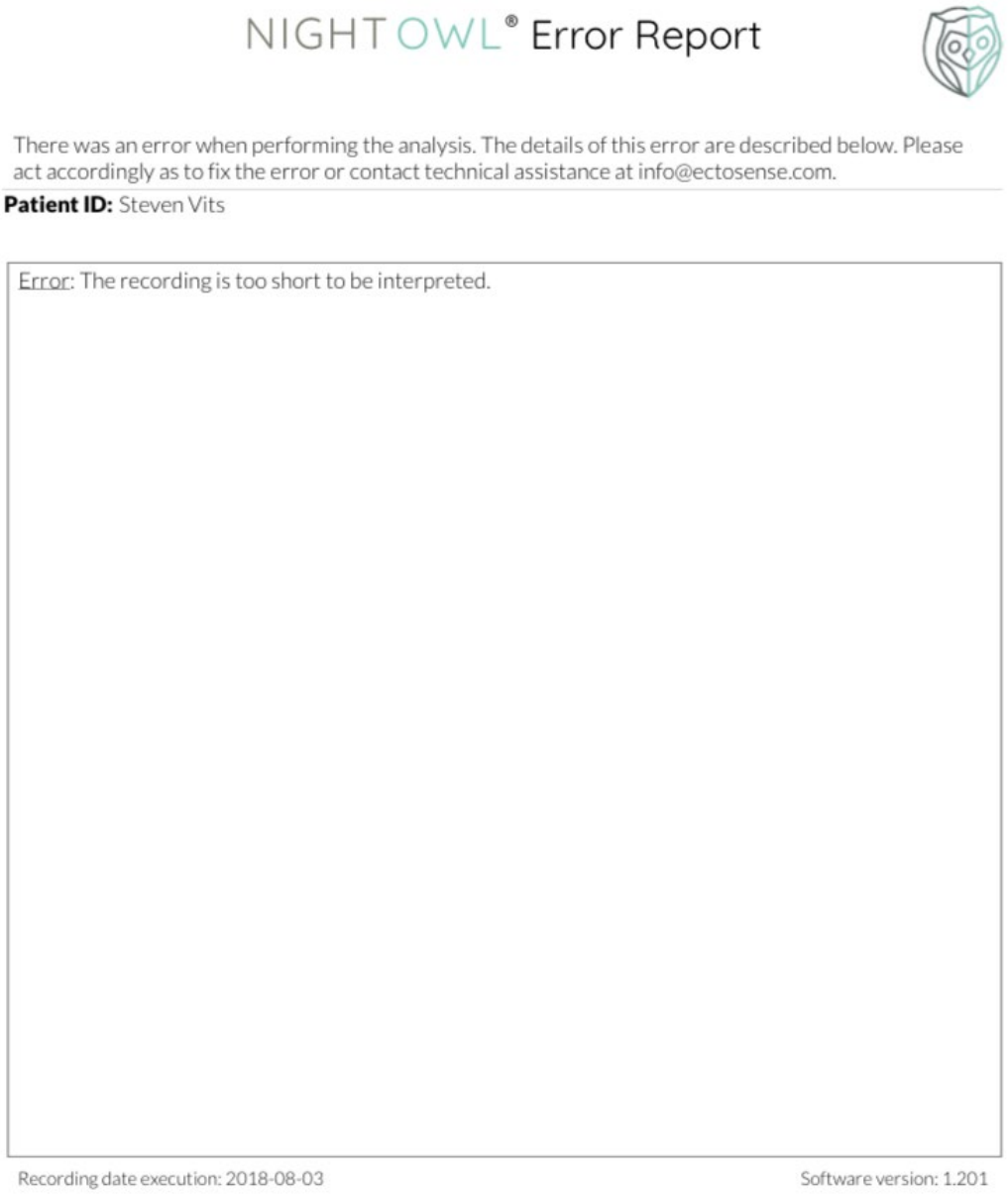
Poincaré plots page



Single-night summary page



Error report


NIGHT OWL® 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: Steven Vits

Error: The recording is too short to be interpreted.

Recording date execution: 2018-08-03

Software version: 1.201