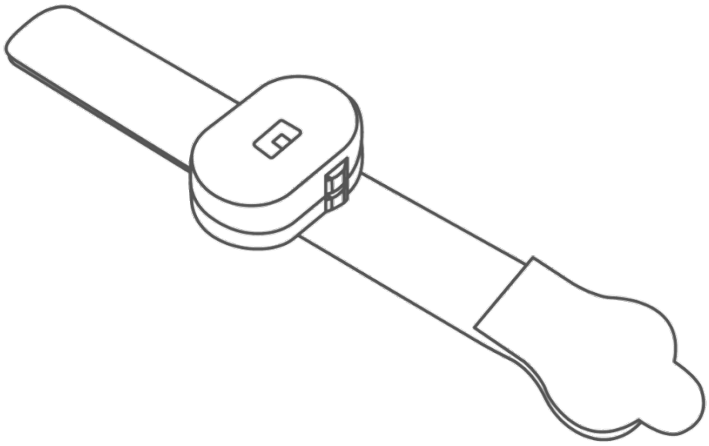
ECTOSENSE

NightOwl® Sensor

Healthcare Professional Manual



NIGHTOWL

1 Document information

These instructions for use were developed exclusively for the healthcare professional ('HCP') and shall not serve to inform patients on their usage of the NightOwl® Sensor.

This labeling information was developed exclusively for the following markets:

- Asia-Pacific: Australia, India, New Zealand, Singapore
- European Union member states

This labeling information is available in the following languages:

- English
- French

Consult Commercial Support (see below) if your required language or region is not listed, or if you are not the intended user of this document.
Store this document for future reference.

2 Contacting us

2.1 Technical support

Choose to contact Technical Support over Commercial Support for any questions related to technical documentation, troubleshooting, or malfunctioning of the sensor.

For support, consider creating a support ticket by contacting us online through www.ectosense.com/support, even if you have had prior direct contact with an Ectosense representative through other channels. Contacting Ectosense staff directly through other channels such as email always results into a longer response time.

For questions regarding a specific sensor, always specify the sensor serial number marked on the sensor device.

2.2 Commercial support

Choose to contact Commercial Support over Technical Support for any questions related to warranty or replacement programs, pricing, or adaptations of documentation according to your specific clinical pathway.

2.2.1 Product sourced from Ectosense

In case your product was purchased directly from Ectosense, follow the steps outlined under ***2.1 Technical support.***

2.2.2 Product sourced from distributors

In case your product was sourced from a distributor, contact your appointed sales or support representative directly.

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3 Introduction

The NightOwl® Sensor is a wireless device designed for comfortable, continuous data recording during an individual's sleep.

The device records two signals:

- Dual-wavelength photoplethysmography ("PPG"), from which oxygen saturation, peripheral arterial tone (PAT), and pulse rate channels can be derived.
- 3-axis accelerometry to capture motion-based activity from which total sleep time ("TST") and body position can be derived (depending on the sensor's placement).

The NightOwl® Sensor was supplied to you either as a stand-alone device or as part of a system for the diagnosis and monitoring of sleep apnea which further consists of several separate software devices, together referred to as the ***NightOwl® Diagnostic System*** as elaborated in ***3.4 Connection to the NightOwl® Diagnostic System*** below.

3.1 Intended use

The NightOwl® Sensor is intended to be used for the continuous recording of a patient's pulse waveform (also known as photoplethysmography, or 'PPG') and motion during sleep or resting, in both the clinical and the home environment.
The sensor can be worn on the finger, by adults or children aged 13 and over, without requiring direct supervision of a healthcare provider.

3.2 Intended use cases

1. The patient is provided with the NightOwl® Sensor by a healthcare professional who wishes to perform a recording of the patient's signals in the home environment as part of a disease management plan, such as with the NightOwl ®Diagnostic System, or,
2. An individual wishes to add the sensor data to a recording package for sleep patterns and sleep disturbances.

3.3 Claims

#	Claim
1	The recording of the optical blood volume pulse at spectral peak wavelengths of 660nm (red) and 880nm (infrared).
2	The recording of activity through accelerometry.

3.4 Connection to the NightOwl® Diagnostic System

Ectosense's software tools enable the automated analysis to support healthcare professionals in the diagnosis and monitoring of patients for sleep apnea, as well as provide means to set-up, manage, and track these patients.

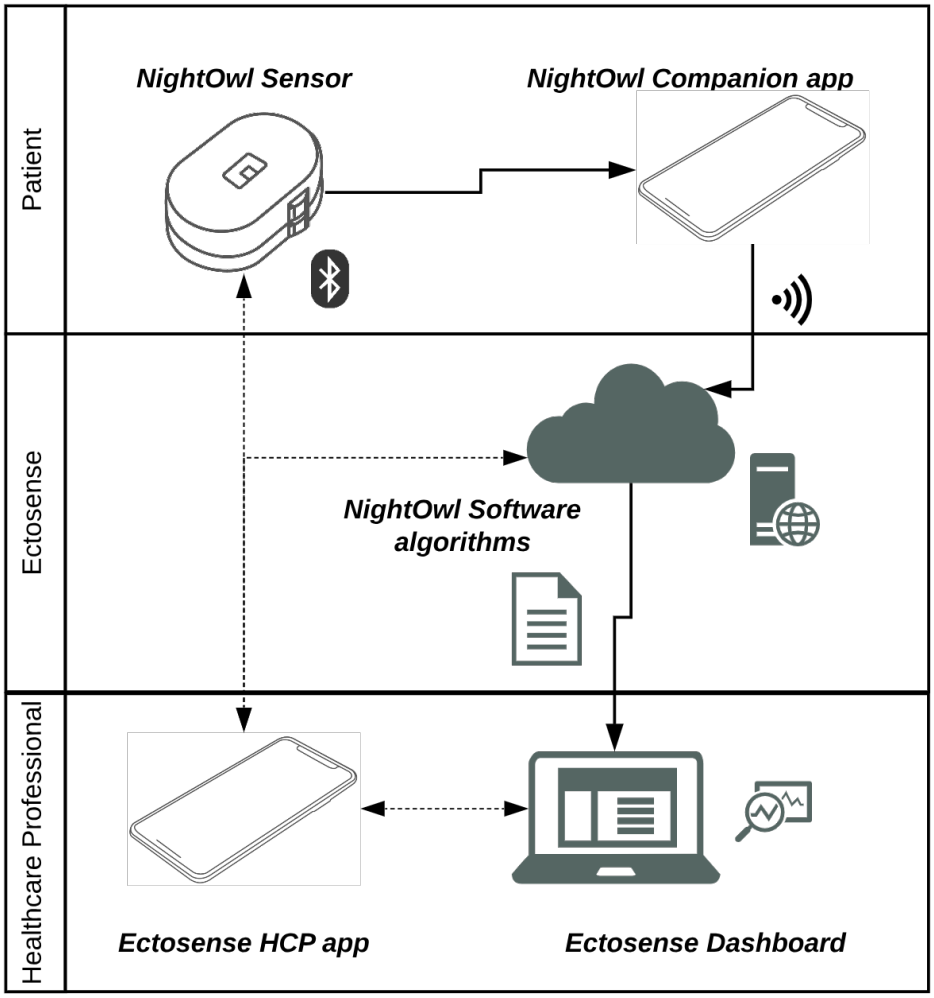
Together, these tools constitute the *NightOwl® Diagnostic System*. The NightOwl® Sensor can be used as part of that system, although it is a medical device on its own and available for other uses as well.

The *NightOwl® Diagnostic System* is further described in its manual which can be found at:

www.ectosense.com/nightowl-documentation

Where throughout this document reference is made to functionalities of other elements of the *NightOwl® Diagnostic System*, a blue text box is shown as illustrated below.

For compatibility of the NightOwl® Sensor with the *NightOwl® Diagnostic System*, ensure that the sensor is placed on the finger.



3.4.1 NightOwl® Companion app

- Description: iOS and Android smartphone application available for download in the respective app stores
- Intended User: patients
- Intended Use:
  - Links patient with the test provider and test configuration by means of a code or unique link
  - Provides patient with instruction for set-up
  - Receives data over Bluetooth® Low Energy (BLE) from the NightOwl® Sensor, and sends it to the NightOwl® Software's cloud environment
  - Optional: Push questionnaires to patients

3.4.2 NightOwl® Software algorithms

- Description: cloud-based algorithm that generates diagnostic reports based on the data captured by the NightOwl® Sensor.
- Intended User: Ectosense runs these algorithms on request of healthcare professionals
- 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.
- Claims:
  - The *NightOwl® Software* 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, and (optionally) snoring traces.
- Medical device Class IIa (Europe).

3.4.3 Ectosense Healthcare Professional app

- Description: iOS and Android smartphone application available for download in the respective app stores
- Intended User: the test provider
- Intended Use:
  - Configure offline tests for patients that do not use a smartphone, by linking a patient to a NightOwl® Sensor.
  - Download data stored on the NightOwl® Sensor after usage in which no smartphone was involved and send it along to the *NightOwl® Software* algorithms.

3.4.4 Ectosense Dashboard

- Description: browser-based dashboard at dashboard.ectosense.com/nightowl
- Intended User: the test provider

- Intended Use:
  - Initiate testing and configure tests
  - Inspect status of tests and final diagnostic reports
  - Optional: Order logistical fulfilment by Ectosense
  - Admins only: Oversee billing and enrollment of related healthcare professionals into a joint working unit

3.5 Intended Application

The device is intended to be in contact with non-injured skin at the following body site(s):

- The distal phalanges (fingertip)

Body application can last for 15 hours or more and application can be repeated daily.
The sensor is re-usable and is supplied with single-use biocompatible adhesives for attachment of the sensor to the body site.

3.6 Contra-indications

3.6.1 General

- Do not use the sensor on regions of the skin that are tattooed, heavily blemished, or rough.

3.6.2 Clinical

- Do not use on individuals in critical care.
- Any physical or operating condition that restricts blood flow, such as use of a blood pressure cuff, may cause an inability to determine high quality photoplethysmografic readings.
- Do not use on patients with dyes introduced into their bloodstream, such as methylene blue, indocyanine green, indigo carmine, or fluorescein.

3.7 General warnings and precautions 

The following are general warnings and cautions. Further specific warnings, precautions, and notes appear next to the relevant instruction in the manual, further accompanied with the cautions symbol.

3.7.1 Precautions

A **precaution** explains special measures for the safe and effective us of the device.

- Do not expose the NightOwl® Sensor to excessive forces, such as caused by fall, shock, or impact.
- The power plug is designed to be used within 110-240V AC, 50-60Hz. Check if the required voltage is available before connecting the adapter to the socket.

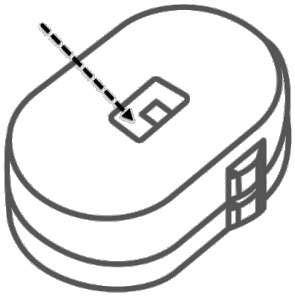
- Always transport and store the sensor, charging cradle, power plug, or charging cable in the original packaging to ensure that no damage to the components may arise during transportation and storage.
- The finger wrap for adhesion of the sensor should be disposed of after each use.

3.7.2 Warnings

A **warning** alerts you to possible injury.

- Choking hazard! Keep the device and its accessories away from children.
- Do not charge or use the device if it is cracked, damaged or if the internal components are visible.
- Do not expose the sensor and accessories to temperatures over +60° Celsius (140° Fahrenheit).
- Do not eat, swallow, drop, hit, abuse, open, incinerate, burn or short circuit the sensor, its accessories, or its components.
- Electrical Interference from other devices: The sensor has been designed to work satisfactorily in the presence of mobile phones, laptops or wireless routers. If the sensor data is not being received by the qualified app on the mobile device, move a short distance to a new location to remove any possible influence of another strong radio emitter and then retry the data transfer.
- Allergic Reaction: prolonged use may cause an allergic reaction in some users. If an allergic reaction occurs at the sensor placement site, immediately stop the use.

4 NightOwl® Sensor system content



The NightOwl® Sensor system includes:

1. Casing with NightOwl® logo, which contains all the elements listed below;
2. Sensor, containing the Optical Module that emits red and infra-red light (see arrow in the picture above)
3. Charging cradle (USB-C)

4. Disposable finger wraps (single-use)
5. Charging cable (USB-A to USB-C) to connect the charging cradle with the power plug;
6. Power plug with USB-A port (optional, depending on your geography).

⚠ Do not use the Sensor with accessories that are not expressly indicated by Ectosense as fit for use as this may cause damage, injuries, loss of performance, and voidance of the warranty.

In particular, pay attention not to use the charging cradle with a power plug that does not output 5 VDC 700mA nominal, 1A max.

4.1 Modes and configurations

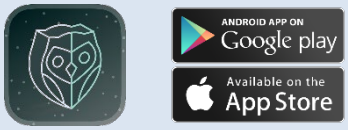
The NightOwl® Sensor can operate in two modes. Selection of modes is automatic and will not require active operator intervention.

1. **Streaming Mode**

When the sensor is turned on, it will first seek to establish a Bluetooth® Low Energy (BLE) connection with a nearby smartphone with a qualified smartphone app installed (see blue box below).
Upon such connection and subsequent start of the recording, the sensor will stream its data to the smartphone in real-time, without storing this data on the sensor itself.

NightOwl® Diagnostic System

Ectosense makes available the *NightOwl Companion* app for patients to connect with the Sensor.



Upon completion of a recording, the *NightOwl Companion* app automatically uploads the transferred data to the *NightOwl Software* for further analysis through WiFi or via an available mobile network connection.

2. **Offline Mode** [functionality not enabled yet]

If no qualified smartphone application is found after turning on the sensor (see Streaming Mode), the Sensor will automatically switch to its Offline Mode. In this mode, the Sensor will store up to 30 hours of recording on its internal memory, after which the operator is required to download the data through an active Bluetooth® Low Energy (BLE) connection.
A time-stamp is added to the recording based on the internal clock of the sensor device.

⚠ In Offline Mode, memory is constrained to 30 hours of recording.
After 10 hours, the sensor will automatically turn off to preserve memory. Upon reaching full memory, the sensor will overwrite the oldest recording present on the memory.

NightOwl® Diagnostic System

Ectosense makes available the *Ectosense Healthcare Professional* app to download the data off the Sensor over a BLE 5 connection using an Android smartphone or tablet.

This app also allows to associate the sensor with a patient.

5 Using the NightOwl® Sensor

5.1 Turning the sensor on and off

Turn on the sensor by firmly pressing the push button using your nails for at least 0.5 seconds. The sensor will vibrate and the Optical Module will start to emit red light.
The indicator light will briefly turn green (0.5 seconds) to indicate that no data is left on its memory. If this light appears, the sensor can be provided to a new patient without the risk of overwriting prior recording sessions still stored on the memory.
If the indicator light blinks purple, the sensor does not contain a sufficient battery charge for a 10 hour recording and will require to be recharged first (see ***16 Charging***).
Turning the sensor on will put the sensor in Streaming Mode in which it will try to establish a BLE connection with a qualified smartphone app. Absent such connection, it will automatically proceed to Offline Mode and start loggings data on the sensor memory. Upon establishing a Bluetooth connection, the indicator lights will turn blue for 2 seconds.
Turn off the sensor by firmly pressing the button until the Optical Module ceases to emit red light.

NightOwl® Diagnostic System

In Online Mode and using the *NightOwl® Companion* app, the sensor will be turned off automatically when the patient indicates on the app to be awake, and there is no further need to turn the sensor off manually.

5.2 Recording configuration and association

The configuration of recordings and associating the sensor with a patient or test is optional and takes place within the *NightOwl® Diagnostic System*.

NightOwl® Diagnostic System

Healthcare professionals can use the Ectosense Dashboard to create a test and input patient details, or leave it to the patient to input further details in the *NightOwl® Companion* app.

Streaming Mode

The following parameters can be configured in the Ectosense Dashboard for each test:

- Amount of testing nights
- Questionnaires [optional]

These parameters will be applied to the recording when the patient downloads the app through a unique link embedded in the email sent to that patient upon creation of a test.
Note that these patient-specific parameters will not apply if no email address was provided into the Ectosense Dashboard. If you do not enter the patient's email, or if you supply the patient with physical instruction papers which include a different activation code, your standard unit settings will be applied, and any patient-specific deviations therefrom are not possible.

Offline Mode

In the Offline Mode, patients do not use a smartphone and therefore a different method is required to associate a patient or test with a recording from the NightOwl® Sensor.
When using our *Ectosense Healthcare Professional* app, you will be required to link a test that you have previously created in the *Ectosense Dashboard* with a unique sensor by establishing a BLE connection with that sensor. At this time, the app will prompt you to associate it with patient information. If you do not associate the sensor with patient information at that time, you will be prompted to do so when you download the data off that sensor using a Bluetooth connection again (see ***5.4 Data retrieval***).

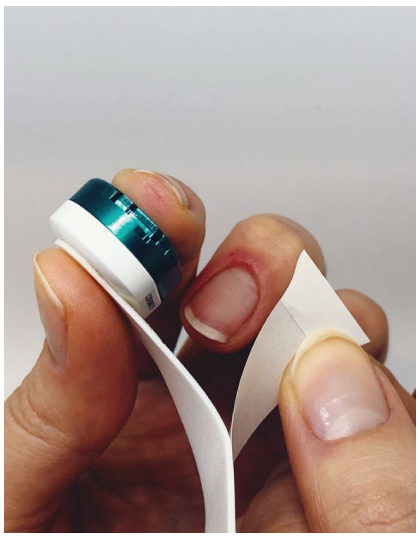
For further information on the workings of the *NightOwl® Diagnostic System* and how to configure tests, consult the *NightOwl® Diagnostic System Manual* available at:
www.ectosense.com/nightowl-documentation

5.3 Device set-up

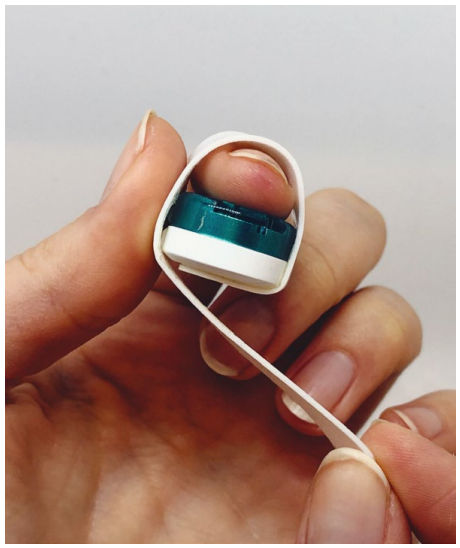
3. Turn on the sensor.
4. Place the sensor with the white side up.
5. Take a new adhesive and remove its top liner on the round sided end.
6. Adhere the round, sticky side of the adhesive on top of the white side of the sensor

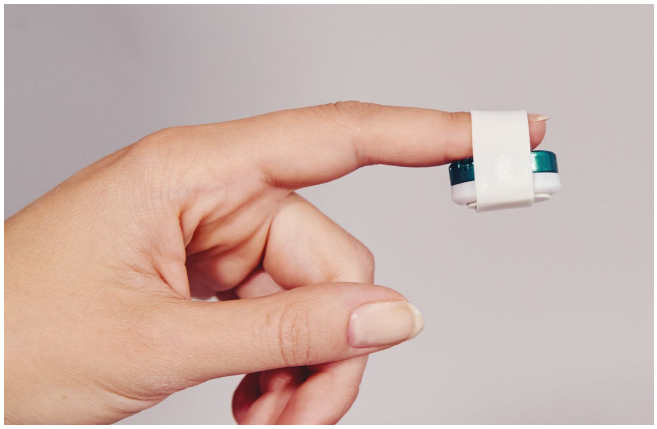
1. Place the finger on the green side of the sensor. Make sure the finger is aligned with the sensor and it rests flat on the sensor.
2. Preferably, the sensor is worn on the index finger of your non-dominant hand to minimize signal distortion due to motion.

8. Remove the second part of the liner
9. If the wrap breaks or gets damaged during the application, just take a new one.



7. Wrap the adhesive snugly around the finger, so that it does not move around. If ever the adhesive feels uncomfortably tight, rewrap it more loosely.





10. The sensor is now correctly applied.

NightOwl® Diagnostic System

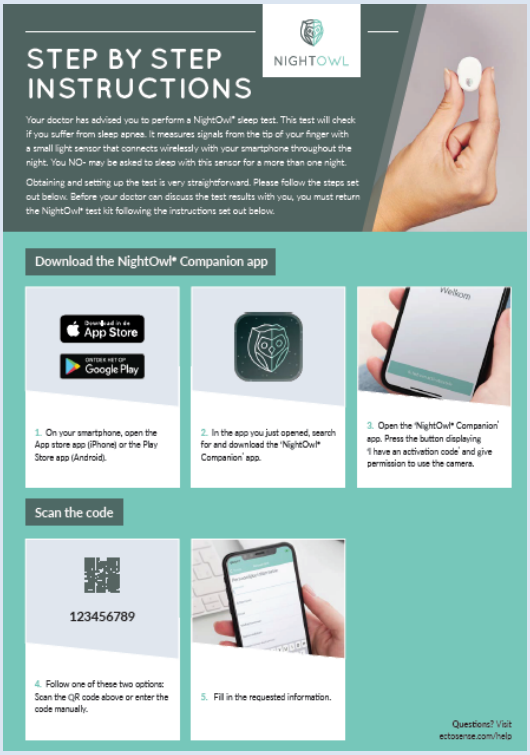
Online Mode

Patients using the Online Mode will be guided through extensive instruction videos on the smartphone application which introduce all the above-mentioned steps.

Ectosense also provides paper-based *Step-by-Step Instructions (Online Mode)* that can be further tailored to your process and pathway and can aid in explaining the test to your patients (see example to the right).

Offline Mode

You will need to distribute the paper-based *Step-by-Step Instructions (Offline Mode)* to your patients. These instructions will contain all the above-mentioned steps.



For more information and examples, consult the *NightOwl® Diagnostic System Manual* and the available paper-based Step-by-Step Instructions at the following web page:

www.ectosense.com/nightowl-documentation

5.4 Data retrieval

Recordings performed in the Online Mode do not require further data retrieval.

Recordings performed in the Offline Mode are stored internally on the sensor and require further data retrieval. This data download is to be performed over BLE and requires a qualified smartphone or tablet app.
Whether data is still present on the sensor can be checked by turning the device on: if a short green light does not immediately appear, data is still available for downloading.

NightOwl® Diagnostic System

Ectosense provides the *Ectosense Healthcare Professional* Android smartphone/tablet app to download data stored on the Sensor over a BLE 5 connection.
Downloading data over the smartphone will automatically clear the memory of the sensor afterwards.

5.5 Charging

5.5.1 When is charging required?

The sensor requires at least 10 hours of recording capacity before it can start to record data. If the battery does not meet that criterium, the sensor will emit a continuous purple light and should be charged.

When fully charged, the battery of the sensor lasts at least 30 hours.
We recommend that you advise your patients to recharge the sensor after each (nightly) recording. Doing so ensures that the sensor is returned to you in a state that does not require recharging before dispensing it to another patient, and can save valuable time to the operator.

While in Online Mode, battery depletion will break the connection with the smartphone app.
In Offline Mode, battery depletion will end the recording but all data will remain stored on the memory of the sensor. A small recharge will subsequently be required prior to being able to download the data off the sensor.
To preserve battery and battery storage capacity, in Offline Mode the sensor will automatically shut down after 10 hours.

5.5.2 How to recharge the sensor

⚠ The power plug is designed to be used within 110-240V AC, 50-60Hz. Check if the required voltage is available before connecting the adapter to the socket. Failure to do so can lead to damage to the sensor, charging cradle, power plug, or charging cable.

The sensor can only be charged using the supplied wireless charging cradle.

To bring a depleted battery up to 10 hours of usage requires approximately 60 minutes of charging. A complete recharge requires approximately 4 hours.

To charge the sensor:

1. Find a power source and connect the power plug and charging cable to it.
2. Connect the charging cable to the charging cradle.
3. Position the sensor into the charging cradle with its green side up such that the sensor fits in the charging cradle's cavity. A blue indicator light will appear on the charging cradle to indicate that the sensor is charging.
4. The sensor is fully charged when the blue indicator light on the charging cradle switches off. Make sure this is not due a disconnection with the electricity source.

ⓘ It is safe to leave the sensor on the charging cradle even when charging is complete.

6 Care and maintenance

Regular cleaning and maintenance should be carried out on the NightOwl® Sensor as described below.

6.1 Cleaning

⚠
- Never use abrasive agents, chlorine-containing substances, acetone, or other solvents to clean the device.
- Do not immerse the sensor or charging cradle and ensure that no fluids penetrate the products.
- Do not attempt to sterilize the device, as this could cause unobservable damage to the inside of the unit.

1. Turn off the sensor and ensure the charging cradle, charging cable, and power plug are disconnected from any source of power.
2. Clean the following parts with a damp cloth and a mild liquid soap: sensor and charging cradle. Ensure that no liquid enters the USB-C port of the charging cradle.
3. Leave the cleaned parts to dry.

It is recommended to subject the sensor to cleaning as described above in between use by different patients. Recommend patients to perform such cleaning at home when the sensor remains with them for an extended period of time.

6.2 Disinfecting

After cleaning the sensor as instructed above, disinfect the device as follows:

1. Apply undiluted disinfectant to a clean non-dyed disposable cloth.
2. Wipe all surfaces of the sensor.
3. Leave the disinfectant on the sensor for five minutes.
4. Wipe residual disinfectant from the sensor with a clean, dry, undyed disposable cloth.

The following disinfectants can be used on the sensor:

- 70% Ethyl alcohol or isopropyl alcohol (IPA)
- Mikrozid
- Cavicide

6.3 Maintenance and servicing

Other than routine cleaning, there is no additional maintenance or calibration required.

There are no user serviceable parts. Do not attempt to open the device or any of its components

Any device failure should be communicated to Technical Support (see ***2 Contacting us***) after carefully reading the ***7 Troubleshooting*** section of this document.

6.3.1 Firmware updates

The embedded software on the sensor ("firmware") can be updated over a BLE connection with a qualified smartphone app.

NightOwl® Diagnostic System

The firmware can be updated automatically prior to a patient starting a recording if he or she is using the *NightOwl® Companion* app, or can be manually updated using the Ectosense Healthcare Professional app under the assistance of a technical representative.

7 Troubleshooting

7.1 Indicator lights under normal usage

Indicator light	Meaning
Online Mode	
Purple blinking	The battery is too low – recharge the sensor.
Blue 2 seconds	A connection with a qualified smartphone app was established successfully.
Blue blinking	The sensor was previously connected to an app, and has now lost connection. It is possible that you moved too far away from the smartphone. Upon getting closer to the smartphone, the connection should re-establish automatically leading the blue light to disappear.
Offline Mode	
Green 0.5 second flash	The memory does not contain any data and you can proceed with a new test without risking any overwrite.
Green blinking	The sensor is in the process of clearing data stored on its internal memory after an Offline Mode recording, as commanded by the Ectosense Healthcare Professional app.
Purple blinking	The battery is too low – recharge the device.
Charging cradle indicator lights	
Blue continuous	Charging and sensor is not fully charged yet.

7.2 Issues

If any problems arise while using the NightOwl® Sensor, take the following actions. If the problem cannot be solved, contact Technical Support (see ***2 Contacting us***), unless specified otherwise.

Prior to investigating the problem further, it is advised to reset the sensor by pressing the button for 20 seconds. Upon rebooting, the indicator lights will turn blue three times.

Problem/Possible cause	Action
My sensor does not turn on	1. Press longer than 0.5 seconds.
The sensor does not vibrate when turning on	1. Report the issue to Technical Support.
The indicator lights turned red for 30 seconds	1. The sensor is in error state. 2. Reset the sensor.
Charging cable/power plug/NightOwl casing is	1. Contact Technical Support within the

defective	warranty term, or Commercial Support when outside of it.
My sensor is heating while charging, resulting in the sensor having an uncomfortable temperature	1. Remove the sensor from the charging cradle and abstain from using the sensor. 2. Report the issue to Technical Support.
The sensor vibrates when turning on, but the Optical Module does not start to emit light	1. Abstain from further using the sensor. 2. Report the issue to Technical Support.
After sensor application, the user's skin has become irritated.	1. Abstain from further using the sensor. 2. Ask the user for any known allergies. 3. Report the issue to Technical Support, citing any relevant known allergies.
Connection between sensor and *NightOwl® Companion* or *Ectosense Healthcare Professional* app is not possible	1. Consult the *NightOwl® Diagnostic System Manual*.
The Optical Module emits green light instead of red	1. Abstain from further using the sensor 2. Report the issue to Technical Support – it is likely that your sensor will require a firmware upgrade.
The push button no longer works or requires an excessive amount of force.	1. Report the issue to Technical Support. 2. If you manage to turn on the sensor regardless, the sensor is safe for continued use while you are being helped.
The serial number on the sensor is no longer visible.	1. Download the Ectosense Healthcare Provider app on an Android device and log in with your Ectosense Dashboard account details. 2. Contact Technical Support for further instructions on how to identify the sensor by establishing a Bluetooth connection.

8 Technical Specifications

8.1 Device and accessories

Signals and samples rates	Photoplethysmography of wavelengths 660nm (red) and 880nm (infrared) at 50 Hz. Accelerometry at 25 Hz.
Recording time	30 hours (3 x 10 hours)
Power supply	Rechargeable lithium-ion battery (graphite layered metal oxide $LiNi_xMn_yCo_zO_2$), 3.7V, 60mAh, cycle life (80%) >500. UN 38.3, UL 1642, IEC 62133 passed.
Weight	Sensor: $^{7}/_{32}$ oz (6 grams) Charging cradle: $^{13}/_{16}$ oz (23 grams)
Adhesives biocompatibility	Combination of polyethylene foam and polyester film with acrylic adhesive layer. Biocompatibility testing performed according to ISO 10993.
Environmental conditions	Operating temperature: 41°F to 104°F (5°C to 40°C) Operating humidity: 10% to 90% non-condensing Storage and transport temperature1: -13°F to 158°F (-25°C to 70°C) Storage and transport humidity: 10% to 95% non-condensing Operating air pressure: 700 hPa to 1,060 hPa
Interfaces	Sensor: Bluetooth® Low Energy 5 (downward compatible with 4.2 and 4.1) Charging cradle: USB-C
Dimension	Sensor (length x width x height): 1 $^{1}/_{16}$" x $^{3}/_{4}$" x $^{25}/_{64}$" (27 x 19 x 10 mm) Charging cradle (l x w x h): 1 $^{15}/_{16}$" x 1 $^{1}/_{2}$" x $^{9}/_{16}$" (4.9 x 3.8 x 1.4 cm)
System compatibility	The NightOwl® Sensor device has been validated to work within the intended use and conform two-way interfacing requirements of the software devices in the *NightOwl® Diagnostic System* (see ***3.4 Connection to the NightOwl® Diagnostic*** System) under the below condition(s): 1. Restrict sensor placement to overnight recordings on the finger
EMC	This device meets the requirements of the Electromagnetic Compatibility (EMC), pursuant to IEC 60601-1-2 for residential, commercial, and light industry environments.
FCC	This equipment complies with FCC radiation exposure requirement. The device can be used in portable exposure conditions without RF restriction. 1. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

2. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/ TV technician for help.

(a) The interference potential of the device or system
(b) Maintenance of the system
(c) Simple measures that can be taken by the user to correct interference.
(d) Manufacturers of RF lighting devices must provide an advisory statement, either on the product packaging or with other user documentation, similar to the following: This product may cause interference to radio equipment and should not be installed near maritime safety communications equipment or other critical navigation or communication equipment operating between 0.45-30 MHz. Variations of this language are permitted provided all the points of the statement are addressed and may be presented in any legible font or text style.

Serial labeling Serial numbers are written on the side of the sensor and on the bottom of the charging cradles according to the following format: AYYBCXYZ in which

- A = model
- 20YY = year of manufacture
- BC = batch code
- XYZ = serial of that year

8.2 Disposal

Dispose of the finger wraps in ordinary household waste.
Disposal of an end-of-life sensor, charging cradle, power plug, charging cable, and the packaging must be carried out in accordance with applicable national laws and regulations.
The crossed-out wheeled bin symbol indicates that the product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal. This requirement for separate disposal is based on the European Directive 2012/19/EU for electrical and electronic equipment, and the European Directive 2006/66/EC for batteries. You can hand in the product at a municipal collection point, for example. This reduces the impact on natural resources and prevents contamination of the environment through the release of hazardous substances. Disposal of the rechargeable batteries must be carried out with the national regulations and statutory provisions applicable.

8.3 Symbols used on the product labels

CE labelling in accordance with EC Directive 93/42/EEC, Class I

Manufacturer

WEEE Directive 2012/19/EU concerning waste electrical and electronic equipment (EEE). See ***8.2 Disposal*.**

Serial number

9 Warranty and replacement

9.1 Limited Warranty

If you have contracted directly with Ectosense *nv*, Belgium, you have been supplied Sales Conditions that specify the warranty and shall supersede what follows.
In case you have not been provided with such Sales Conditions, Ectosense *nv* warrants that your NightOwl® Sensor product shall be free from defects in material and workmanship from the date of purchase for a period of 2 years.

If the product fails under conditions of normal use, Ectosense will repair or replace, at its discretion, the defective product or any of its components.
This Limited Warranty does not cover: a) any damage caused as a result of improper use, abuse, modification, or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by Ectosense *nv* to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar, or other smoke, and d) any damage caused by water being spilled on or into the electronics of the charging cradle, or on or into the electronics of the sensor after an impairment of its button.
Warranty is void on product sold, or resold, outside the region of original purchase.
Warranty claims on defective product must be made by the initial customer at the point of purchase.
Subject to no separate Sales Conditions stipulating warranty limitations between you and Ectosense *nv*, this warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.
Ectosense shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation, or use of any Ectosense product.

Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

9.2 Outside warranty replacements

9.2.1 Lost sensor or charging cradle

Ectosense or its distributors offer a lost devices program that allows operators to acquire a replacement sensor or charging cradle at a significantly reduced cost in the following geographies:

- United States

Contact Commercial Support for further information (see ***2 Contacting us***).

9.2.2 Loss of other components

Ectosense or its distributors offer restocking at reduced cost of the power plug, charging cable, and NightOwl casing if they are deteriorated in regular use or if they are lost in operation.
Contact your sales representative for further information.

ECTOSENSE

Manufacturer: Ectosense *nv*, Bosbessenlaan 19A, 3110 Rotselaar, Belgium, info@ectosnese.com, www.ectosense.com
Distributors: No other entities than the manufacturer above can distribute the product.
MRP: Maximum Retail Price in India not to exceed 1.6 lakh Rupees.
Disclaimer: Ectosense shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of the NightOwl® Sensor other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto.

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