

NIGHTOWL

BY ECTOSENSE 

FDA APPROVED



Package content

- 1 NightOwl Sensor®
- 10 single-night disposable finger wraps

Battery life

The battery life of the NightOwl® is limited to **10 nights** of recordings.

Turn the device off

To turn off the device, press the button for **5 seconds**.



Intended use

The NightOwl® is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).

Cleaning

Only clean the sensor with a damp cloth or an isopropyl alcohol wipe, and allow it to dry before use

Sleep test

You have been scheduled to perform a NightOwl® sleep test. This test will check whether you suffer from sleep apnea by measuring signals during your sleep.

You will need to attach the NightOwl Sensor® to the tip of your index finger. This sensor shines light onto your finger and records the reflected light from your skin. It connects to your smartphone via Bluetooth(r).

Preparing for your test is straightforward and will only take a few minutes of your time. The steps below will guide you through the process.

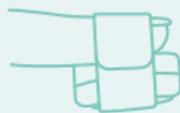
1

Open the email titled “NightOwl® sleep test setup instructions” on your smartphone and follow the included instructions. The email contains a unique link to download and activate the NightOwl Companion app®.



2

When you are ready to go to bed, the NightOwl Companion app® will explain how to set up and attach the sensor correctly to your finger.



3

Every morning, the NightOwl Companion app® will stream your sleep data to the cloud where it will be analyzed by the NightOwl Software®. The results of the analysis are communicated to your healthcare provider.



4

The test may be repeated for multiple nights, the exact number of nights will be highlighted in the NightOwl Companion app®.



5

After concluding the test, please hold on to the sensor as you could be asked to repeat the test at some point in the future.



Technical specifications

	Refer to the NightOwl Companion App® for more information on the Device's compliance with FCC Rules Part 15.
	Emits radio frequency radiation. Bluetooth, IEEE 802.15, with a maximum range of 10m (33 ft) Can be used in any country world-wide. For best Quality of Service, keep the NightOwl® and smartphone within 3m (10 ft) of each other and other home RF emitters (WLAN, DECT handset, other smart phones) at least 0.5m (18 inches) away from the NightOwl® .
	Contains electrical components, only dispose of in recognized recycling handling facilities.
Operating	5°C (41°F) – 40°C (104 °F) (20% - 95% RH)
Storage/ transport	-20°C (-4°F) – 60°C (140 °F) (20% - 95% RH)
Sensor	IP rating: IP55; Weight: 5.67g (0.2oz)
	Not sterile and can be re-used.
	Device conforms to the Medical Device standards for home use, IEC60601-1:2012 for electrical safety, and IEC60601-1-2:2014 for EMC.
	Type BF applied part.[MOU1]

Cautions

- Do not expose the NightOwl Sensor® to excessive forces, such as caused by fall, shock, or impact.
- The finger wrap for adhesion of the sensor should be disposed of after each use. Reuse of the finger wrap can result in a failed recording.
- Do not use the sensor on regions of the skin that are tattooed, heavily blemished, broken, or rough skin.
- Maximum application should not exceed 24 hours. Before reapplication, inspect that the skin is not broken, blemished or rough

Warnings

- Choking hazard! Keep the device and its accessories away from children.
- Do not expose the sensor and accessories to temperatures over 140° Fahrenheit (60° Celsius).
- Do not eat, swallow, drop, hit, abuse, open, incinerate, burn or short circuit the sensor, its accessories, or its components.
- There are no user serviceable parts.
- Electrical Interference from other devices: The sensor has been designed to work satisfactorily in the presence of mobile phones, laptops or wireless routers.
- 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.
- Read IFU fully before use.
- Follow the Screen Display information carefully during Use.



Device compliant with FCC Rules Part 15.

FCC ID: 2ASBE-DEV00104

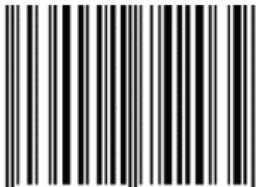


prescription only



Ectosense nv

Bosbessenlaan 19A,
3110 Rotselaar,
Belgium



5 430001 742039 >

REF NightOwl Mini

2024-04-01



(01) 05430001742039(11)YYMMDD

FCC STATEMENT

- 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.**

FCC Radiation Exposure Statement:

The device has been evaluated to meet general RF exposure requirement.
The device can be used in portable exposure condition without RF striction.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital, 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 the 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.