

How NightOwl™ works

You have been scheduled to perform a NightOwl™ sleep test. This test will help evaluate whether you suffer from sleep-related breathing disorders.



Activating your test – You received an email from noreply@nightowl.resmed.com with instructions on how to install and activate the NightOwl Companion app on your smartphone or tablet.



Getting ready for bed – In the app, you will be shown simple instruction videos on how to connect the sensor to your smartphone and attach it to your index finger.



Going to sleep – While you're asleep, the sensor will emit a light onto your skin to capture signals indicative of your sleep quality. This data will be sent to your smartphone throughout the night.



Waking up – In the morning, the app will upload this data for analysis by your healthcare provider.



Repeat as needed – The app will indicate the number of nights required to complete your test.



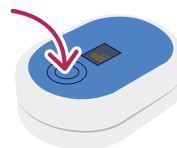
Next steps - After their evaluation, your healthcare provider will reach out to share your sleep test results.

Contents

- 1 NightOwl sensor
- 10 single-night disposable finger wraps

Turning off the sensor

In the morning, turn off the sensor automatically by tapping the 'Wake up' button in the NightOwl Companion app.



If you have accidentally turned on the sensor, you can turn it off by pressing and holding the button for 5 seconds until the red light turns off.

? Contact

For any medical questions related to your sleep study, contact your sleep test provider. For technical questions about the sensor or the NightOwl Companion app, visit nightowl.care/patientsupport.

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).

Technical specifications



The battery life of the NightOwl sensor is limited to 10 nights of recording.



Device compliant with FCC Rules Part 15. Operation subject to: (1) device may not cause harmful interference, (2) device must accept any interference received, including interference that may cause undesired operation. FCC ID sensor: 2ACHL-NOMLEN



Emits radio frequency radiation. Bluetooth with a maximum range of 33 ft. Can be used in any country worldwide. For the best service quality, keep the NightOwl sensor and smartphone within 10 ft of each other and other home RF emitters (e.g. WLAN, DECT handset, or other smartphones) at least 18 in away from the NightOwl sensor.



Contains electrical components, only dispose of in recognized recycling handling facilities.



Operating: 41°F – 104°F (20% - 95% RH)
Storage/ transport: -4°F – 140°F (20% - 95% RH)



Not sterile and can be re-used by the same patient.



Single patient multiple use.



Type BF applied part.

Device conforms to the Medical Device standards for home use, IEC60601-1:2020 for electrical safety, and IEC60601-1-2:2020 for EMC.

IP rating: IP45; Weight: 0.11 oz



CAUTION

- Do not expose the NightOwl sensor to excessive force caused by events such as fall, shock or impact.
- The adhesive finger wraps should be disposed of after each use.
- Do not use the sensor on regions of the skin that are tattooed, heavily blemished, broken or rough.
- Maximum application should not exceed 24 hours. Before reapplying, inspect that the skin is not broken, blemished or rough.

WARNING

- Choking hazard! Keep the device and its accessories away from children.
- Do not expose the sensor and its accessories to temperatures over 140° Fahrenheit.
- 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.

Rx Only

HOME SLEEP TEST MEDICAL DEVICE

NightOwl™

