



Intelligent, Interactive Monitoring

Night Shift is worn around the neck or the chest; it uses and measures the effectiveness of vibration feedback to discourage back-sleeping.



Using the Night Shift:

- Prior to first use, completely charge the device.
- Fit the strap so it is adjusted evenly on both sides. If worn too tight, the magnetic clasp will detach during the night. If strap (or chest belt) is worn too loose, incorrect positional feedback will occur when not centered on the back of your neck (or front of your chest).
- Just after you turn the device on, it will provide feedback to confirm sufficient battery capacity to record and provide feedback for at least eight hours. Remember to recharge the battery at least once every three days.
- When the Night Shift recognizes you are sleeping on your back, it will vibrate with increasing intensity until you change position.
- Night Shift records your position, sleep quality, and snoring so you can print reports to monitor your response to positional feedback.

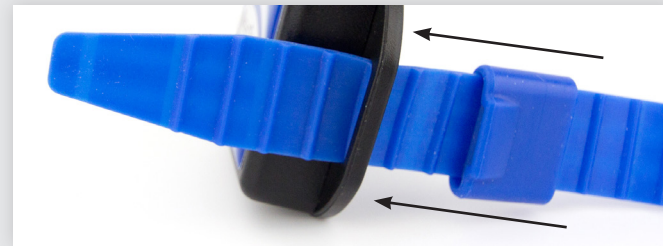
Fitting the Night Shift: Step-by-Step

The Neck Strap

- Retention Band
- Magnetic Clasp



- Begin by feeding one end of the strap through one of the slots on the side of the enclosure. The strap should be fed through from the back to the front of the device, and with the ridged side facing out.



- Loop the strap back and slide it through the retention band. Pull the strap through the band just enough to hold it in place. Repeat the process with the other side.



- With the blue label right-side up, center the Night Shift on the back of your neck. **The blue label must be facing away from the neck and the On/Off button facing down.**



- Re-fasten the magnetic clasp and tighten both sides of the strap evenly, keeping the enclosure centered on the back of your neck and the magnetic clasp centered on the front.



- The Night Shift strap should be just tight enough to prevent it from sliding around the neck. Two fingers on each side should fit between the strap and the neck without causing the magnets to release.



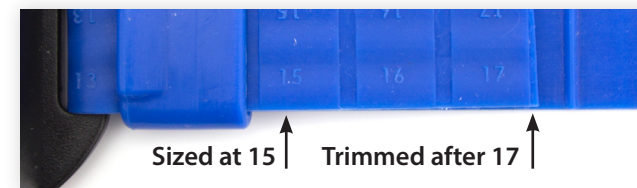
- Use the numbers provided on the strap as a guide to help even out each side.



- With the straps evened out, try the Night Shift on again and verify the fit is still comfortable and snug.



- Once a good fit is determined, excess length can be trimmed off the ends of the strap. Leave at least 2 extra sizes in case you need to loosen the strap later. The Night Shift is now properly fit.



- Unclasp the strap by bending at a 90° angle, like snapping a stick. To avoid damage, do not pull apart.



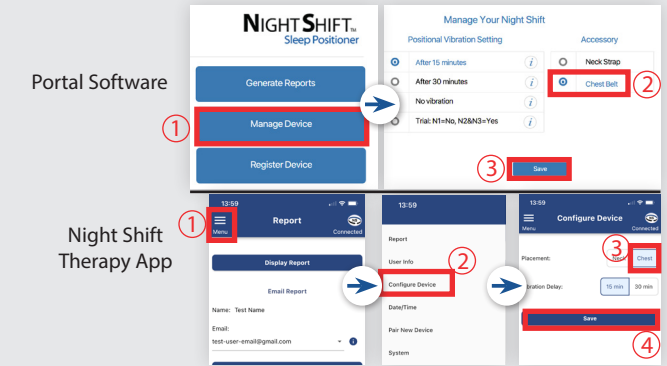
⚠ Caution: Replace the strap immediately if the clasps become demagnetized and do not retain during the night.

The Chest Belt

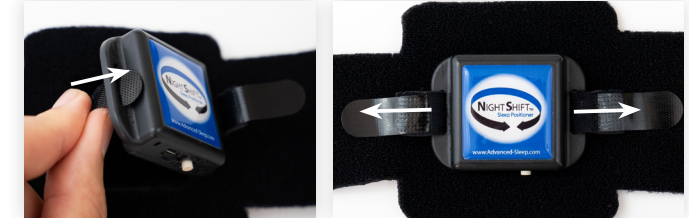
The chest belt is a Night Shift accessory that allows for alternative placement on the chest instead of the neck. The chest belt is available for purchase separately from your Night Shift healthcare provider. *Note: Behavioral Sleep/Wake information will not appear on reports for recordings made with the chest belt due to the movement of the chest during breathing. Snoring levels measured on the chest should not be compared to snoring levels measured on the neck.*



- Use the Night Shift software to change device setting from 'Neck Strap' to 'Chest Belt'.



- Affix the Night Shift to the chest belt by inserting the two Velcro tabs through the slots on each side of the device and then securing the Velcro tabs to the belt fabric.



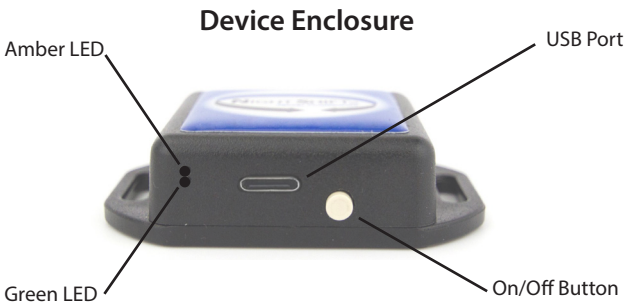
- Adjust the chest belt length so it remains centered during the night. Note that the chest belt is designed to be worn over a shirt or other nightwear.



- With the blue label right-side up, center the Night Shift on your chest. **The blue label must be facing away from the chest and the On/Off button facing down.**



Night Shift Features



Starting the Night

- Hold the On/Off Button down for 1-second.
- The LED indicator and vibration feedback patterns will confirm if there is sufficient battery capacity to record and provide feedback for the entire night:

Battery charge sufficient for	LED indicator pattern	Vibration feedback
3 nights	Green - 3 blinks	3 times
2 nights	Green - 2 blinks	2 times
1 night	Green - 1 blink	1 time
Needs charging	Amber - 1 blink per second	1 time every 5 seconds

- When the device is powered on for a study, the LED indicator will blink green for 5 min. After 5 min. the LED will become solid green.
- Put on the device and go to sleep.
- Vibration feedback will not begin for the first 15 minutes to allow adequate time to fall asleep.
- To turn the Device off, press the On/Off Button and the Green LED will turn off.
- Note: if the device has not been charged for a few weeks, the date and time may be incorrect; connect the device to the Night Shift software to correct the date and time.

Explanation of symbols:

Follow Instructions for Use

Adults Only

Dispose Properly

Keep Dry

GITEKI (MIC) Mark

Non-ionizing Electromagnetic Radiation

Operating Temperature

Operating Humidity

Operating Pressure

IP22

Limit Objects, Water Ingress

Charge Between Uses

CE 0482 European Conformity

Importer

Type BF Applied Part

Prescription required in USA

Catalog Number

Serial Number

Medical Device

REF

NS27-1005.LE

Manufacturer

Advanced Brain Monitoring, Inc.
2237 Faraday Ave, Suite 100, Carlsbad, CA, 92008, USA
760.720.0099 | nightshift@advanced-sleep.com

EC REP

MPS Medical Products Service GmbH
Bornhassse 20, 35619 Braunfels, Germany
MedEnvoy Global B.V. (EU)
Prinses Margrietplantsoen 33, Ste 123
2595 AM The Hague, The Netherlands

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Charging the Night Shift:

- See Warnings associated with charging the device.
- Insert the small cable connector into the USB port of the device.
- Connect the large cable connector into a computer or recommended USB wall charger (maximum 5 volts and 1.5 amps).
- If the device does not appear to charge or hold a charge, try using a new USB cable.

LED Indicators while Night Shift is charging	
Charging	Green on – for up to three hours and LED will turn off when charging is complete
Charging error	Green and amber on - check power supply and cable connections
Device failure	Amber on - return the devices for servicing

Cleaning the Night Shift:

The Night Shift should be cleaned regularly. When cleaned as described below, the Night Shift can be reused on the same or different patients.

Neck Strap / Chest Belt: Detach the neck straps / chest belt from the device. Wash each strap / chest belt separately by submerging in solution of 1 teaspoon (5 ml) of mild dish detergent (e.g. Dawn) per gallon (4 liters) of water. Agitate slightly for one to two minutes. Rinse with clear warm tap water for one minute. Dry with a clean paper towel. Ensure the straps / chest belt are completely dry before use.

Device: Wipe all surface areas of the device enclosure with a 70% isopropyl alcohol wipe. All surface areas should remain wet for at least 15 seconds. Using a new alcohol wipe, repeat the cleaning; allow to remain wet for 15-seconds. If any visible soil remains, repeat as needed. Allow to air-dry.

Technical Support and Replacement Parts:

Customers in the USA:

- For technical support, contact the Night Shift Support team at www.NightShiftTherapy.com and click Contact Us. Or call us at (760)720-0099 ext. 6020.
- To purchase replacement neck straps or chest belts, go to www.NightShiftTherapy.com and click Buy Now.

International Customers:

- For technical support, or to obtain a replacement neck strap / chest belt, please contact your Night Shift healthcare provider.

www.NightShiftTherapy.com

Using Night Shift Software on a computer:



From a computer (Windows or Mac), go to www.NightShiftTherapy.com and click on the “Report Portal” link to download/install the software.

With the Night Shift software, you can:

- Register your device
- Generate reports to monitor how often you’re sleeping on your back, how well you are sleeping, and how loudly you are snoring.
- Update date, time, and firmware on your device.
- Change the initial vibration delay from 15-minutes to 30-minutes.
- Change the device settings for use with the chest belt accessory.

Using Night Shift Software on a Smartphone or Tablet:



The Night Shift LE device (identified by “LE” on the device label) can be wirelessly connected to a compatible iOS or Android phone or tablet using the Night Shift Therapy application. The Night Shift Therapy app can be downloaded from the Google Play Store or Apple App Store, or by scanning the QR Code on the right.



The wireless feature of the Night Shift LE device must be on in order to wirelessly connect to the Night Shift Therapy app. The wireless feature will only be turned on when the Night Shift LE device is charging or for the first 15 minutes after the Night Shift LE device is turned off via the On/Off button. The wireless feature is never on when the Night Shift LE device is on. The app provides instructions for connecting to the Night Shift LE device.

With the Night Shift Therapy app, you can:

- Generate reports to monitor how often you’re sleeping on your back, how well you are sleeping, and how loudly you are snoring.
- Update date, time, and firmware on your device.
- Change the initial vibration delay from 15-minutes to 30-minutes.
- Change the device settings for use with the chest belt accessory.

Night Shift Efficacy Data:

The treatment efficacy of Night Shift was demonstrated in a study of 27 patients diagnosed with positional obstructive sleep apnea with a pre-treatment non-supine apnea-hypopnea index (AHI) < 20. The results showed:					
	Pre-treatment				95% Confidence Interval
	5<AHI<15	15<AHI<30	AHI>30	Total	
Treatment outcome	n = 11	n = 10	n = 6	n = 27	
AHI >50% decrease, % (n)	81.8 (9)	80.0 (8)	100.0 (6)	85.2 (23)	71.8–98.6
AHI >35% decrease, % (n)	9.1 (1)	0.0 (0)	0.0 (0)	3.7 (1)	-3.4–10.8
Non-responder, % (n)	9.1 (1)	20.0 (2)	0.0 (0)	11.1 (3)	-0.8–23.0

Indications for Use:

The Night Shift is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index <20, and to reduce or alleviate snoring. It records position, movement, and sound so that positional changes in sleep quality and snoring can be assessed.

Contraindications: None

⚠ Warning: Do not wear the device while it is being charged. To avoid permanent damage: a) charge with a medical IEC 60601.1 compliant wall charger (maximum 5 volts and 1.5 amps), b) do not use rapid/fast USB wall chargers or wall outlets with USB ports, and c) do not use USB cables with exposed wires or bent pins.

⚠ Cautions:

- Night Shift users should **NOT**:
 - have Cardiac Arrhythmia corrected with an artificial pace-maker;
 - have skin sensitivity or an open wound around their neck;
 - have a neck size that is very small (less than 12 inches/30 cm) or very large (greater than 22 inches/55 cm);
 - sleep with their head in a near-upright position;
 - suffer from tics or tremors of the head.
- The Night Shift device generates localized magnetic fields (less than 0.02 mT) that must be kept at least 6 inches (15 cm) from an implanted medical device of the user or bed partner.
- You may initially feel more tired during the day if your sleep is disrupted while you learn to respond to the vibrations.
- The measured signal will be influenced by a loud snoring bed partner.
- Do not wear the Night Shift upside down – the reported sleep time on your left and right sides will be reversed.
- Do not wear the strap / chest belt too loose – position feedback will be inaccurate if the device is NOT on the center of your neck / chest.
- Do not wear the strap too tight – the strap may become detached during the night.
- US Federal law restricts this device to sale by or on the order of a physician.
- The device contains a Lithium Polymer battery and must be disposed of properly. Follow local guidance for proper disposal.
- To avoid damage not covered by warranty, keep the device dry and clean, and out of reach of children and pets.
- Selection of an appropriate pillow for non-supine sleep may reduce the occurrence of neck, shoulder, or back pain. Discontinue use of the device and contact your physician or the device manufacturer in case of any significant pain.

In the event of a serious incident, notify the manufacturer and, if applicable, your local EU competent authority.

Expected Service Life: The battery, haptic motors, neck strap, and chest belt are considered to be replaceable components and are expected to require replacement during the three-year service life of the Night Shift device. The battery has an expected useful life of two years; the user can substantially compromise the useful life by continuously leaving the device on a charger for extended periods when the battery is fully charged. The user can detect when the battery must be replaced; when fully charged, the device is unable to acquire data for >10hours. The haptic motors have an expected service life of 30 hours of vibration. The neck strap and chest belt have an expected service life of 6 months when used every day. The expected service life is not a guarantee (see warranty information below).

Warranty: Twenty-four (24) month warranty for assembly workmanship and electronic components, twelve (12) month warranty for haptic motors and battery, and six (6) month warranty for neck strap / chest belt. Warranty does not cover damage attributed to improper use by the customer. The warranty will be voided if an attempt is made to open the enclosure or change the battery. The neck strap / chest belt should be inspected regularly for signs of deterioration due to normal wear and tear. It is recommended that the neck strap / chest belt be replaced every six months.

For information on Night Shift technical specifications, reference the *Night Shift Technical Details* available at: www.NightShiftTherapy.com/software-help.