



Intelligent, Interactive Monitoring

Night Shift is worn around the neck; 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 worn too loose, incorrect positional feedback will occur when not centered on the back of your neck.
- 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.

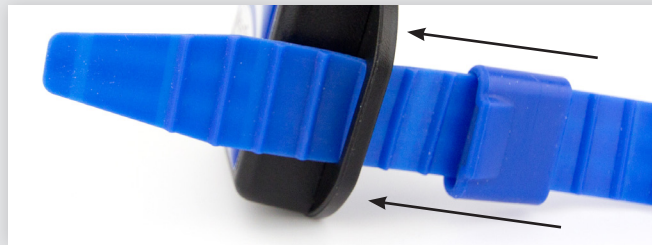
Fitting the Night Shift: Step-by-Step

The Strap

- a. Retention Band
- b. Magnetic Clasp



1 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.



2 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.



3 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.**



4 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.



5 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.



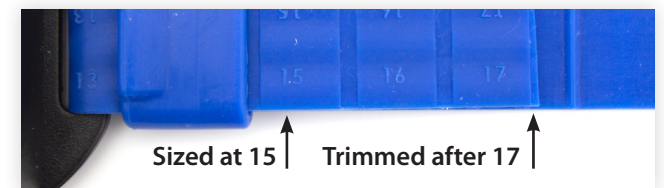
6 Use the numbers provided on the strap as a guide to help even out each side.



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



8 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.



9 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.

Night Shift Features



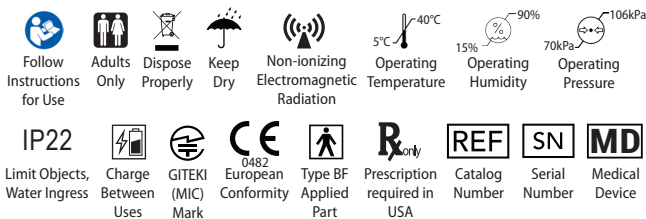
Starting the Night

- 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	Yellow - 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.
- Place the device on the neck 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 portal and follow the on-screen instructions to adjust the date and time.

Explanation of symbols:



Advanced Brain Monitoring, Inc.
2237 Faraday Ave, Suite 100, Carlsbad, CA, USA 92008
Manufacturer P 760.720.0099 | F 760.476.3620 | nightshift@advanced-sleep.com

European Representative:
MPS Medical Products Service GmbH,
Borngasse 20, 35619 Braunfels, Germany

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

www.NightShiftTherapy.com

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 yellow on - check power supply and cable connections
Device failure	Yellow 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.

Strap: Detach the straps from the device. Wash each strap 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.

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.

Using Night Shift Software:

From a computer, go to www.NightShiftTherapy.com and click the "Portal" link. Or, if using a Night Shift LE device, download the "Night Shift Therapy" mobile app on an iOS/Android device. Then 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 optional chest belt accessory.



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.

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.
- 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 too loose – position feedback will be inaccurate if the device is NOT on the center of your neck.
- 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.
- Dispose of the device that includes a Lithium Polymer battery properly.
- 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 your local EU competent authority.

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 strap. 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 strap should be inspected regularly for signs of deterioration due to normal wear and tear. It is recommended that the strap be replaced every six months.

Treatment outcome	Pre-treatment				95% Confidence Interval
	>5 AHI <15	>15 AHI <30	AHI > 30	Total	
	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