



www.nightshifttherapy.com

## Intelligent, Interactive Monitoring

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

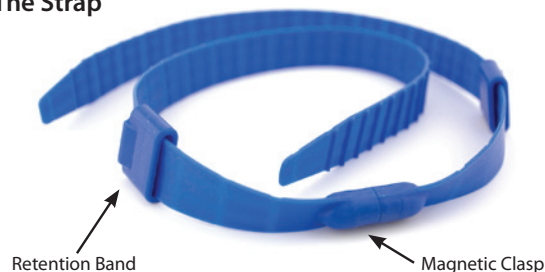


## Using the Night Shift:

- 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

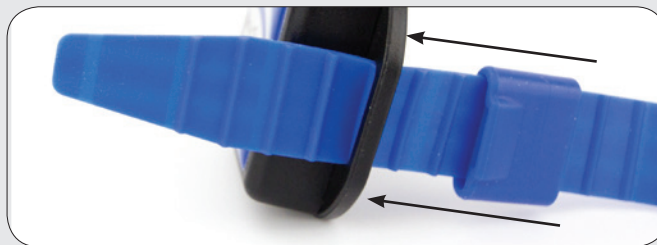
### The Strap



Retention Band

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.



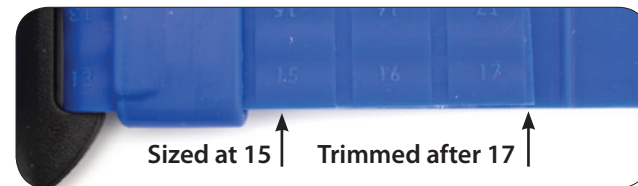
- 6** Use the numbers provided on the strap as a guide to help even out each side.



- 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-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, quick-press the On-Button and the Green LED will turn off.
- Note: if the device has not been used for more than 29 days 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  
Manufactured by P 760.720.0099 | F 760.476.3620 | info@advanced-sleep.com

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

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

[www.NightShiftTherapy.com](http://www.NightShiftTherapy.com)

## Charging the Night Shift:

- DO NOT wear the Night Shift while it is charging.
- Insert the small cable connector into the USB port of the device.
- Connect the large cable connector into a computer or USB wall charger (medical IEC 60601.1 compliant).

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:

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 [www.NightShiftTherapy.com](http://www.NightShiftTherapy.com):

Go to [www.NightShiftTherapy.com](http://www.NightShiftTherapy.com) and click the Portal link to register the device. Then you can:

- Generate and print daily, monthly, or annual 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 delay of delivery of positional feedback from 15-minutes after the device is powered on to 30-minutes.

## 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.

**Cautions:**

- Night Shift users should **NOT**:
  - have Cardiac Arrhythmia corrected with an artificial pacemaker;
  - 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 a 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 not sleep on your back.
- The measured signal will be influenced by a 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.

**Warranty:** Twenty-four (24) month warranty for assembly workmanship and electronic components and twelve (12) month warranty for haptic motors and battery. Warranty does not cover the strap or 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.

Treatment outcome	Pre-treatment			Total n=27	95% Confidence Interval
	>5 AHI <15 n = 11	>15 AHI <30 n = 10	AHI ≥ 30 n = 6		
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