



TAKE SLEEP BACK. MOVE LIFE FORWARD.



Please refer to page 4 for safety and indication information.
The IFU can be found at www.NightWare.com.

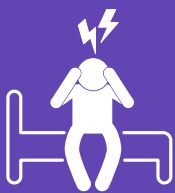
WHAT IS NIGHTWARE AND HOW DOES NIGHTWARE WORK¹?

NightWare is the first and only FDA cleared digital therapeutic to interrupt nightmares and help improve sleep quality.

- NightWare must be prescribed by a physician. It is not an app available for download.
- NightWare's platform uses artificial intelligence (AI) algorithms to interrupt nightmares
- It pairs cloud-based AI with the easy-to-use Apple Watch[®] and iPhone[®] provided in the kit
- The Apple Watch's heart rate sensor, accelerometer and gyroscope collect signals that are consistent with a nightmare
- NightWare calculates a patient's unique "stress index"^{*} to develop personalized treatment
- Interrupts nightmares via vibrotactile feedback through the prescribed Apple Watch



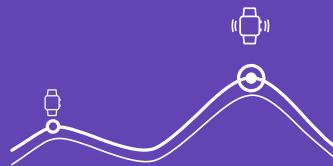
When a patient presents with recurring nightmares, NightWare can be prescribed to help improve the patient's sleep quality. NightWare is designed to disrupt nightmares and improve sleep.



Patient with nightmares
experiencing poor quality
of sleep and distress



Prescribed NightWare which
delivers therapy through the
iPhone and Apple Watch
provided in the kit



Patient data collected and evaluated to
create custom sleep profile that provides
interventions to interrupt nightmares



**Patient gets better
quality of sleep**

^{*} Stress Index is a device-specific measurement and does not represent a clinically validated measure of stress.

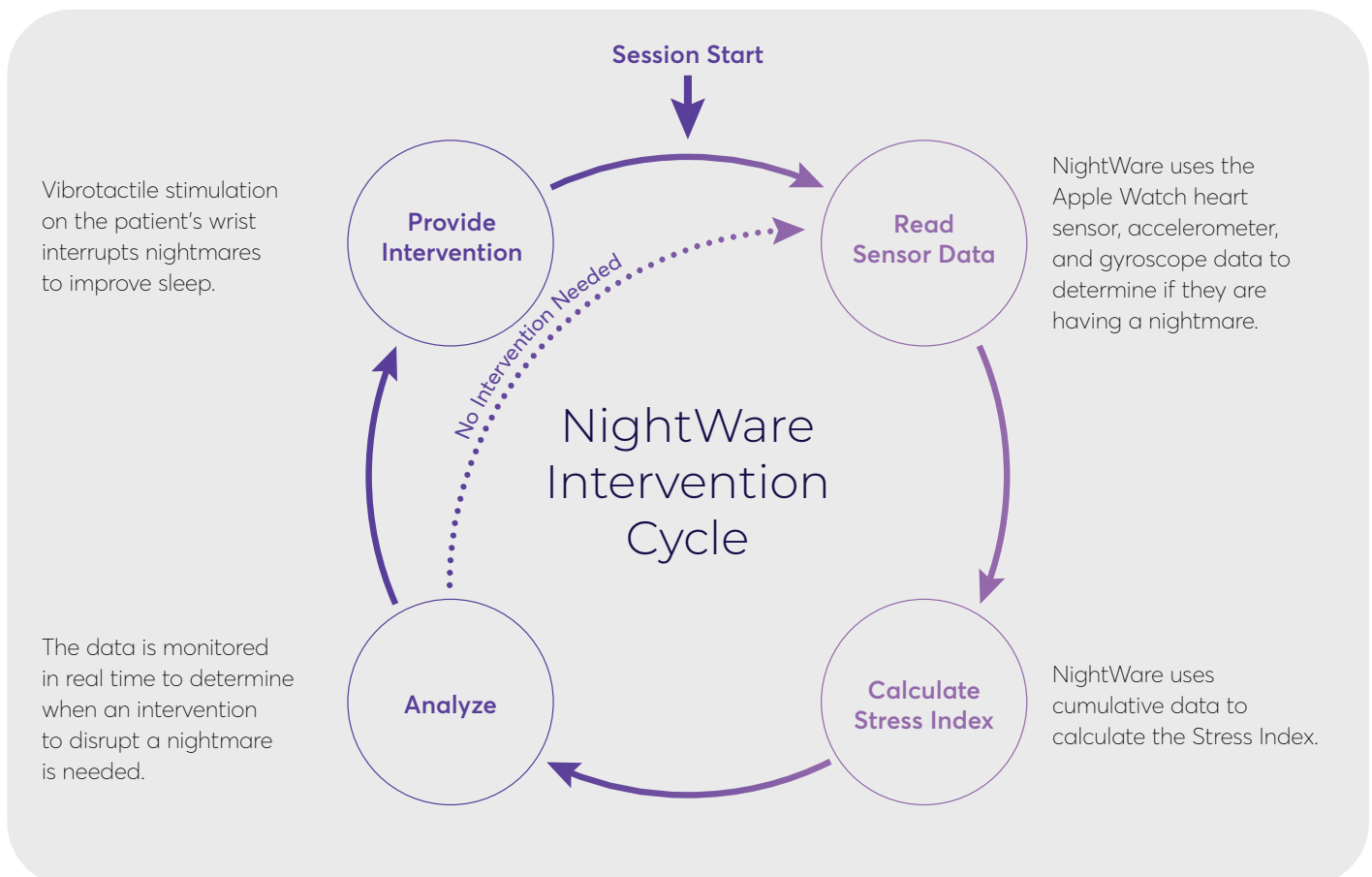
DIAGNOSTIC CRITERIA FOR NIGHTWARE

- Recurrent episodes of extended, extremely dysphoric, and well-remembered dreams that usually involve efforts to avoid threats to survival or security or physical integrity.
- On waking from the nightmare, the individual rapidly becomes oriented and alert.
- The episodes cause significant distress or impairment in social, occupational, or other areas of functioning.
- The symptoms cannot be explained by the effects of a drug or abuse or medication.
- The nightmares cannot be attributed to another mental disorder (i.e., posttraumatic stress disorder, delirium) or medical condition.

Associated Features Supporting Diagnostics

- Sweating
- Palpitations, pounding heart, or accelerated heart rate
- Trembling or shaking
- Sensations of shortness of breath or smothering
- Rapid or shallow breathing
- Feeling of choking
- Chills or hot flashes
- Chest pain or discomfort

NightWare improves sleep by interrupting nightmares when they happen. It is a non-invasive treatment option for those suffering from persistent nightmares.



IMPORTANT SAFETY INFORMATION

INTENDED USE/INDICATION FOR USE

The NightWare digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from post-traumatic stress disorder (PTSD). It is intended for home use.

CONTRAINDICATIONS

If you have acted out your nightmares (i.e. sleepwalking, violence) do not use NightWare and contact your Healthcare Provider.

WARNINGS

- NightWare is not a standalone therapy for PTSD. The device should be used in conjunction with prescribed medications for PTSD and other recommended therapies for PTSD-associated nightmares and nightmare disorder, according to relevant consensus guidelines.
- If daytime sleepiness occurs, contact your Healthcare Provider.
- If you feel drowsy, do not drive or operate heavy machinery. Contact your health care provider.
- If the watch vibration causes awakenings not associated with nightmares, please contact your Healthcare Provider.
- If nightmares persist, worsen, or recur, contact your Healthcare Provider.
- If skin irritation occurs, discontinue use of the watch and contact your Healthcare Provider.
- Your watch may disturb your bedpartner. Try not to expose your bedpartner to the watch at night.

- Do not wear the watch too tightly, it should feel comfortable and snug, not tight on your wrist.
- Wear the watch only when you are planning to go to sleep; do not wear it while reading or watching TV in bed as this may trigger false alerts.
- Use the NightWare watch every night.
- Not intended for use by individuals under age 22.
- The long term safety and effectiveness of the NightWare device has not been established.
- The long term effects of the NightWare device use on the sleep architecture have not been established.

PRECAUTIONS:

- Do not drop or crush the smartphone or watch.
- Be sure to charge the smartphone and watch every day.

REFERENCES

See the Provider Instructions for Use for complete information.

NightWare. (2020). Provider Instructions for Use: FDA Instructions for Use. Hopkins, MN. NightWare.

1. Sjöström N, Hetta J, Waern M. Persistent nightmares are associated with repeat suicide attempt: a prospective study. *Psychiatry Res.* 2009;170(2-3):208–211.



NIGHTWARE

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