NIGHTWARE

DIGITAL THERAPEUTIC

TAKE SLEEP BACK. MOVE LIFE FORWARD.

Please refer to page 7 for safety and indication information. The IFU can be found at www.NightWare.com.

NIGHTMARE DISORDER

There have been no FDA-cleared options for sleep disturbance related to nightmares for adults who suffer from Nightmare Disorder or PTSD/PTS*, until NightWare. The majority of patients with PTSD report sleep disturbances, mostly nightmares and insomnia. Frequent nightmares disrupt sleep and may lead to chronic sleep deprivation, which may lead to other long term problems.[1]

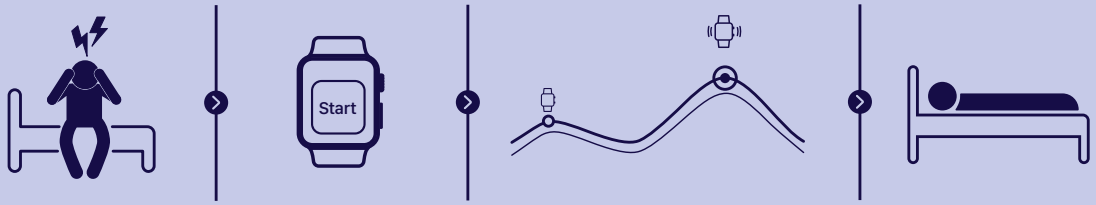
Key Facts about Nightmare Disorder:

- Nightmares affect 2–8% of the general population[1]
- 72% of patients with PTSD have comorbid nightmares[1]
- Nightmares are present in many patients with depression, insomnia, and especially PTSD[1]
- Frequent nightmares are independent risk factors for suicide[2]

Current nightmare treatments[3]

1. A medication approved to treat high blood pressure is used for sleep disturbance related to Nightmare Disorder but is not FDA approved for this purpose
2. Imagery Rehearsal Therapy and other forms of rescripting therapy
3. Cognitive Behavioral Therapy

When a patient presents with Nightmare Disorder or is having recurring nightmares from trauma such as PTSD that causes sleep disturbance, 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 Apple Watch application

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

Patient gets better quality of sleep

* For many Veterans, the use of the word "Disorder" serves as a barrier to receiving care. They believe that the symptoms associated with the trauma they experienced are not a "Disorder." For the purpose of supporting the needs of all Veterans, Nightware recognizes that many use PTS instead of PTSD.

WHAT IS NIGHTWARE?

NightWare is the first and only FDA cleared therapy to interrupt nightmares and improve sleep quality.

- Non-pharmaceutical and non-invasive treatment option with a low risk safety profile
- Granted FDA breakthrough status reflecting the severity of Nightmare Disorder and the lack of available effective treatment options
- Has shown temporary reduction of sleep disturbance related to nightmares in a randomized clinical trial
- Has been used across a variety of specialties including psychiatry, social work, sleep medicine, psychology, and family medicine

PATIENT BENEFITS

NightWare improves sleep in those with Nightmare Disorder and PTSD-associated nightmares. It functions as a 'digital therapeutic' that helps to reduce the cycle of sleep deprivation.

Key NightWare benefits:

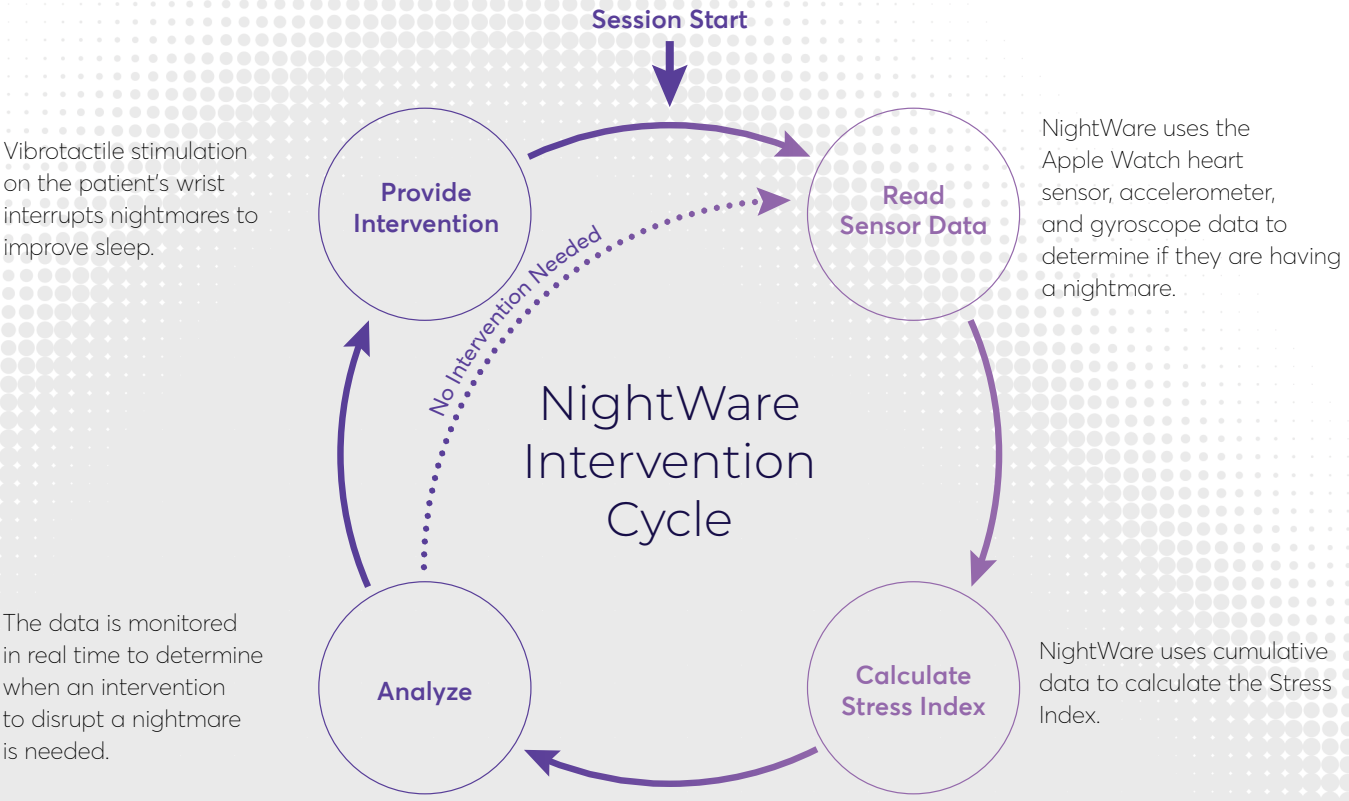
- Helps improve sleep in a few days to a few weeks
- Proprietary Artificial Intelligence customized treatment for each patient
- Reduction in sleep disturbances in adults 22 years and older
- Very low risk of side effects. NightWare should not be used in people who act out their nightmares (i.e. sleepwalking, violence)
- Can be used with existing treatments

HOW NIGHTWARE WORKS

NightWare improves sleep by interrupting nightmares when they happen. It provides a treatment option for patients with sleep disturbances related to Nightmare Disorder or nightmares associated with PTSD.

- Uses the Apple Watch heart rate monitor sensor, accelerometer, and gyroscope to continuously monitor and analyze the patient for physical signals consistent with a nightmare
- NightWare uses artificial intelligence algorithms to calculate a patient's unique "stress index"† using the patient's heart rate and movement, creating an individualized treatment for each patient
- Interrupts nightmares via vibrotactile feedback on the Apple Watch

By interrupting nightmares at the time they occur, sleep quality has been shown to improve using the clinically validated standard to assess sleep quality, the Pittsburgh Sleep Quality Index (PSQI).



Vibrotactile stimulation on the patient's wrist interrupts nightmares to improve sleep.

NightWare uses the Apple Watch heart sensor, accelerometer, and gyroscope data to determine if they are having a nightmare.

The data is monitored in real time to determine when an intervention to disrupt a nightmare is needed.

NightWare uses cumulative data to calculate the Stress Index.

† Stress Index is a device-specific measurement and does not represent a clinically validated measure of stress.

CLINICAL EVIDENCE

JOURNAL ARTICLE SUMMARY 1

"A randomized sham-controlled clinical trial of a novel wearable intervention for trauma-related nightmares in military veterans"

Journal of Clinical Sleep Medicine: Volume 19, No.2 (2023)

DOI: 10.5664/jcsm.10338

https://pubmed.ncbi.nlm.nih.gov/36305584/

Insights

- A randomized, sham-controlled study was conducted to determine efficacy of the NightWare system. Study enrollment was terminated due to the COVID-19 pandemic. In all, 72 of a target 210 Veterans (age 22 years and older) were enrolled. A final sample size of 65 Veterans completed the study.
- Changes in sleep quality and other measures were evaluated, but statistically significant differences between the active and sham groups were not achieved.
- A post-hoc analysis was conducted to determine if interim results underestimated the treatment effect due to underutilization of NightWare. Eight subjects in the 'Active' group and nine subjects in the 'Sham' group were excluded due to usage between 0 and 50% of nights.
- Within the 'High Utilization' subset, median usage in the Active and Sham groups was 74% and 75%, respectively.
- Increased utilization of the NightWare system by the Active group resulted in a statistically significant improvement, with a large effect size, on the PSQI (Pittsburgh Sleep Quality Index) and NWL (NightWare Likert Scale), compared to the Sham group.
- Increased utilization of the Sham device had little effect on sleep quality. In contrast, higher usage of the Active (NightWare) system was more effective in improving sleep quality.
- The areas of greatest sleep quality improvement were decreased sleep latency and fewer sleep disturbances.
- NightWare was associated with approximately one additional hour of sleep on average in the Active group. No change was observed in sleep duration in the Sham group.

TABLE 1

Mean (SD) Change in 'High Usage' Subsample Between Baseline and Primary Outcome Visit at 30 Days for Each Outcome Measure

Baseline Outcome Measure		NightWare (n = 21)	Sham (n = 27)	p-value
PSQI	Pittsburgh Sleep Quality Index	**-4.1 (3.4)**	**-1.9 (2.9)**	*0.016*
PHQ-9	Patient Health Questionnaire-9	**-2.5 (3.0)**	-0.6 (3.9)	0.067
PCL	PTSD Checklist	**-9.9 (14.8)**	**-5.9 (10.3)**	0.264
TRNS	Trauma-Related Nightmare Scale	**-6.1 (8.1)**	**-2.5 (5.1)**	0.063
FOSQ	Functional Outcomes of Sleep Questionnaire	**1.5 (3.0)**	1.0 (2.4)a	0.483
PSQI-A	Pittsburgh Sleep Quality Index Addendum	-1.2 (4.7)	-0.9 (3.1)	0.778
NWL	NightWare Likert Scale	**6.1 (3.9)**	**2.7 (3.5)**	*0.002*

P-values reflect a two-sample t-test.

Values in italic represent significance (P < .05) after correction for multiple comparisons. Values in bold represent significant changes from baseline (1-sample t-test, P < .05).

[a]n = 26 Sham due to missing baseline data.

JOURNAL ARTICLE SUMMARY 2

"Retrospective Assessment of Smart Watch Haptic Feedback to Treat Nightmares in the U.S. Military"

Journal of Psychiatry and Psychiatric Disorders 7 (2023): 186-191.

DOI:10.26502/jppd.2572-519X0199

Background

NightWare has been prescribed to more than 1,300 active-duty service members since 2021. Providers have been trained to prescribe NightWare to patients who meet specific patient selection criteria. The recommended criteria are:

- Disturbed sleep because of nightmares
- At least 3 nightmares each week
- Sympathetic activation symptoms such as, but not limited to, increased heart rate, sweating, feelings of choking, and panic attacks associated with the nightmares

Key Findings

1. Patient Feedback: Feedback was requested from active-duty United States military patients who used NightWare as part of their regular clinical care. Responses from all 630 patients who provided feedback were included in this study. This provided valuable insights into the device's real-world effectiveness.
2. High Effectiveness: The study reported that 68.4% of patients experienced a good or excellent response to the NightWare treatment. Additionally, 92.9% of patients noted at least some improvement in sleep quality and/or a reduction in nightmares.
3. Low Disruption Rate: Only 6.8% of patients reported that the device was disruptive to their sleep or ineffective.

Significance

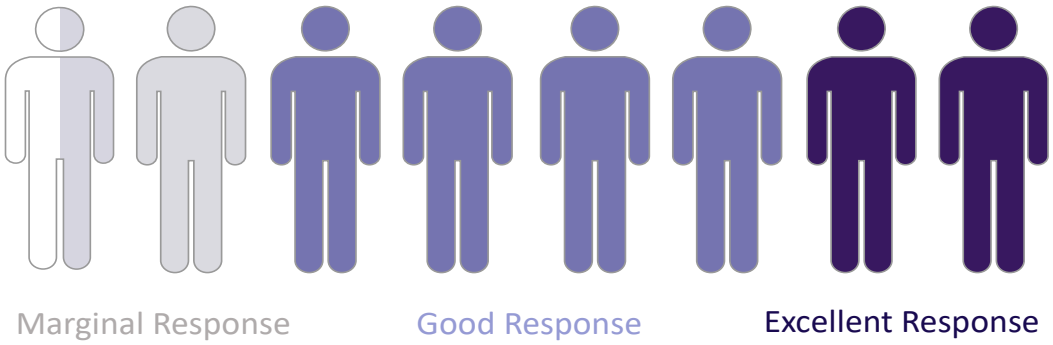
- This study demonstrates the practical application and benefits of NightWare in a real-world setting, particularly among a military population known to have a higher prevalence of PTSD and associated sleep disturbances.
- The results highlight the potential of NightWare as a non-invasive, accessible alternative to traditional treatments for nightmare disorders, which often include medication and psychotherapy.

Limitations and Future Directions

- The study acknowledges certain limitations such as the retrospective nature of the analysis and the lack of a representative control group.
- Future research could focus on additional controlled clinical trials and the evaluation of NightWare in conjunction with other treatments.
- The patient selection criteria training provided to prescribers may have resulted in NightWare being used in a patient population experiencing more severe nightmares, potentially yielding the high rates of treatment success.

FIGURE A

Patient Reported Response to NightWare Treatment



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, no not drive or operate heavy machinery. Contact your Healthcare 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 bed partner. Try not to expose your bed partner 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 the age of 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

1. NightWare. (2020). Provider Instructions for Use: FDA Instructions for Use. Hopkins, MN. NightWare.
2. 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.
3. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guidelines for the management of posttraumatic stress disorder and acute stress disorder. 2017. https://www.healthquality.va.gov/guidelines/MH/ptsd/VADoDPTSDCPGFinal.pdf Accessed 25 Apr 2020.
4. Data on file at NightWare.

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