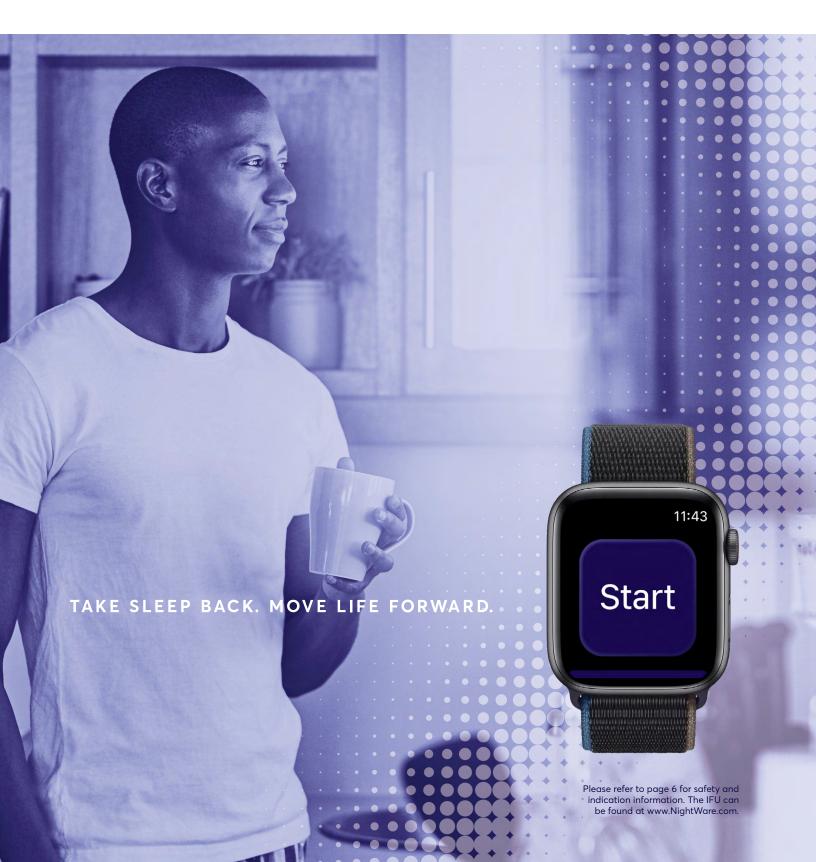
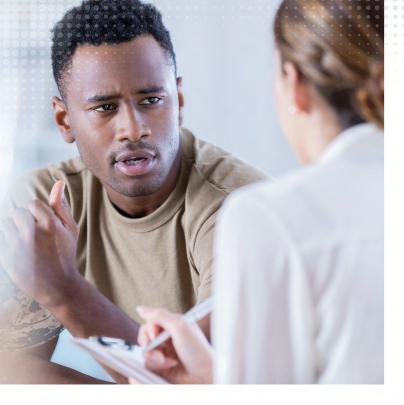


# DIGITAL THERAPEUTIC





#### Key Facts about Nightmare disorder:

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

## NIGHTMARE DISORDER

There have been no FDA-cleared options for Nightmare disorder and Nightmare disorder associated with PTSD/ PTS\*, until NightWare. The majority of patients with PTSD report sleep disturbances, mostly nightmares and insomnia. Frequent nightmares disrupt sleep and often lead to chronic sleep deprivation. This sleep deprivation is associated with considerable social, financial, and health-related costs.<sup>1</sup>

#### Current nightmare treatments<sup>3</sup>

- A drug indicated for hypertension is the most commonly prescribed treatment for nightmares.
- 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, NightWare can be prescribed to help improve the patient's sleep quality. NightWare is designed to disrupt nightmares and improve sleep.



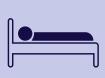
Patient with nightmares experiencing poor quality of sleep and distress



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<sup>1</sup>

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

- NightWare's platform uses patented artificial intelligence algorithms to interrupt nightmares
- It pairs cloud-based AI with the easy-to-use Apple Watch<sup>®</sup> and iPhone<sup>®</sup> ecosystem
- Senses physiological signals that are consistent with a nightmare utilizing the hardware's heart rate sensor, accelerometer, and gyroscope
- Non-pharmaceutical treatment option with a low risk safety profile

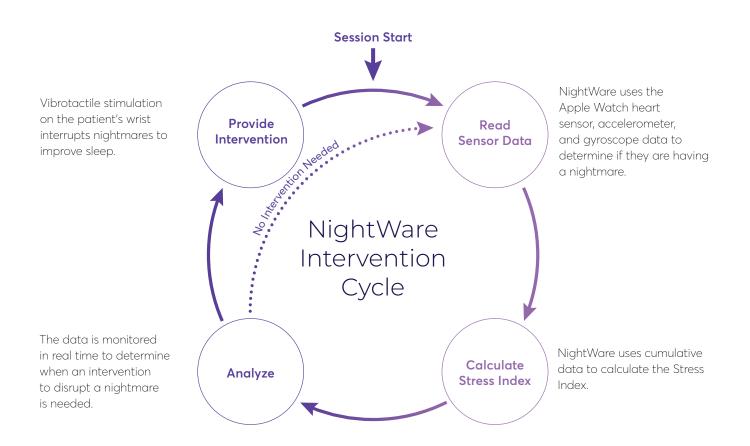


### HOW NIGHTWARE WORKS<sup>1</sup>

NightWare improves sleep by interrupting nightmares when they happen. It provides a treatment option for nightmare disorder or nightmares from PTSD.

- NightWare uses artificial intelligence algorithms to calculate a patient's heart rate and movement to create a custom sleep profile
- Calculates a patient's unique "stress index" to develop an individualized treatment for each patient
- Uses the Apple Watch heart rate monitor sensor, accelerometer, and gyroscope to continuously monitor and analyze the patient for signals of nightmare
- 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).



## PATIENT BENEFITS

NightWare disrupts nightmares and improves sleep. It functions as a 'digital therapeutic' that helps to end the cycle of sleep deprivation.

#### Key NightWare benefits<sup>3</sup>:

- Helps improve sleep in a few days to a few weeks
- Proprietary Artificial Intelligence customizes
  patient treatment
- Reduction in sleep disturbances
- Can be used with existing treatments



# CLINICAL SUPPORT

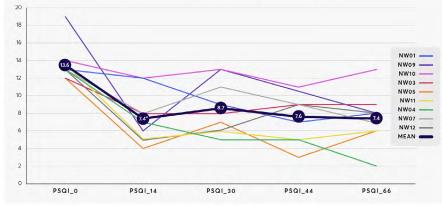
#### NightWare demonstrated efficacy in placebo-controlled clinical trials<sup>1</sup>

NightWare's safety and efficacy is supported by a double-blind, sham controlled, randomized clinical trial (NW101002). 70 participants were enrolled in the trial. Patients in the sham group wore the device, but no vibratory stimulation was provided. The evidence demonstrated the probable benefits outweighed the probable risks.

#### Summary:^

- The primary measure of relative efficacy was the difference in mean PSQI change between NightWare and placebo arms. The difference observed between the active and sham groups was 1 point.<sup>+</sup>
- 3.2-point improvement on the Pittsburgh Sleep Quality Improvement Scale in an ongoing randomized controlled trial\*
- Exceeds the minimal clinically important difference
- The PSQI-A improvement was more than double that of the sham device\*
- PSQI-A measures important differences in sleep quality directly related to PTSD

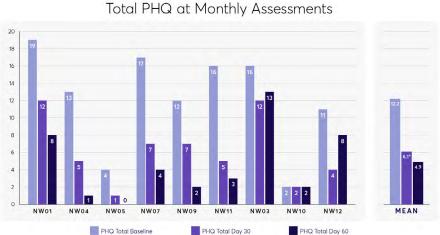
In an open-label pilot study<sup>4</sup> of NightWare in 9 subjects, there was a large effect size of a 6-point improvement in the Pittsburgh Sleep Quality Index (PSQI), a well-validated measure of sleep quality [Figure 1].



#### FIGURE 1 Total PHQI at Biweekly Assessments

\*While there was a 3.2 range in the PSQI for NightWare and the Sham was 2.2, there was no statistical significance between the two. The PSQI-A was also not statistically significant.

FIGURE 2



Additionally, the Patient Health Questionnaire 9 (PHQ-9), a standard questionnaire to measure the severity of depressive symptoms demonstrated

<sup>^</sup>These are interim data. Clinical trials are ongoing.

<sup>+</sup> These results were not statistically significant

a 6-point improvement [Figure 2].

\* While there was a 3.2 range in the PSQI for NightWare and the Sham was 2.2, there was no statistical significance between the two. The PSQI-A was also not statistically significant.

### 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

- 1. NightWare. (2020). Provider Instructions for Use: FDA Instructions for Use. Hopkins, MN. NightWare.
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- 4. Data on file at NightWare.



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