NIGHTWARE



TAKE SLEEP BACK. MOVE LIFE FORWARD.

WHAT IS NIGHTWARE¹

NightWare is the first and only FDA cleared digital therapeutic to interrupt nightmares and help 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® and iPhone® 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



NIGHTWARE DATA SECURITY

NightWare is a non-pharmacologic category of product called a digital therapeutic, and many people are curious about how their data is used and if it's secure. NightWare has implemented various protections to guard patient data and guard against outside attacks.²

Some of the safeguards NightWare uses:

- Access to the device is limited by using authentication protocols that are different based on the user type.
- NightWare restricts or disables other applications that could compromise the security and data on the device.
- The Google Cloud platform monitors NightWare servers, algorithms, and data exchange to detect any security breaches.
- NightWare only shares personal health information with the patient's clinician so they can monitor the NightWare device interventions.
- NightWare never shares personal health information with external 3rd parties not directly involved in the treatement of a patient.
- NightWare uses a two factor authentication process to ensure access is granted only to authorized users when sensitive data is involved.

IMPORTANT SAFFTY 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

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



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