

NIGHTWARE BACKGROUND

NightWare Description and Indication

NightWare is a digital therapeutic system that temporarily reduces sleep disturbance related to nightmares. NightWare provides customized medical treatment for dysfunctional nightmares and is the only FDA-cleared treatment for this disorder.

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.

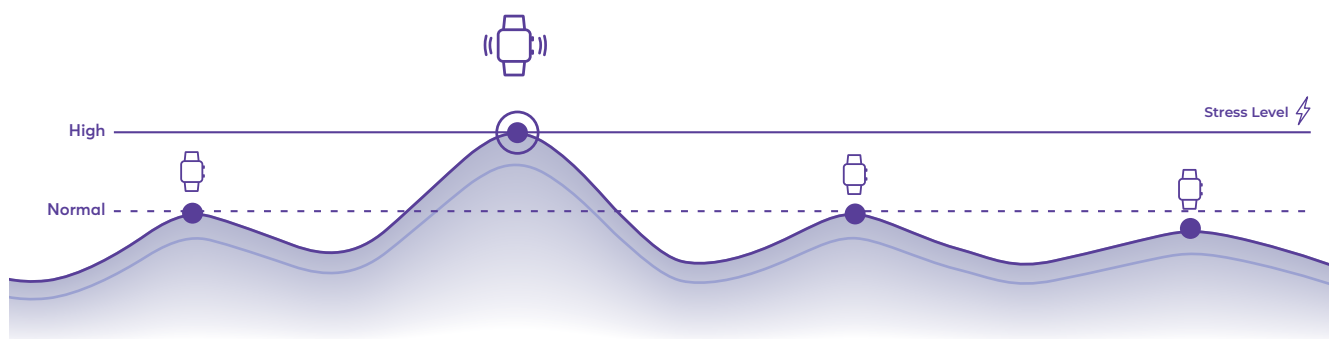
NightWare Specifications

NightWare consists of a backbone of cloud-based artificial intelligence and delivers its intervention through the Apple Watch and an iPhone®. The phone and watch are secured and only function to deliver the NightWare therapy. The phone is necessary for connecting to data servers.

Using artificial intelligence, NightWare first learns the patient's physiologic patterns over a period of 2–20 hours. After this learning period, NightWare will continually evaluate the user's stress index*by tracking heart rate and movement data obtained from an Apple Watch. NightWare uses a combination of the patient's heart rate, accelerometer, and gyroscope data to determine when a patient has a high stress index. As the patient's stress index changes, the device can update the information that it has, and new "set points" for the patient's stress index can be determined. In this way, NightWare is continually updating its information about a particular patient. Artificial Intelligence is needed for this application because the data is highly granular and continual evaluation is required to make the individualized decision to intervene in sleep.

FIGURE A

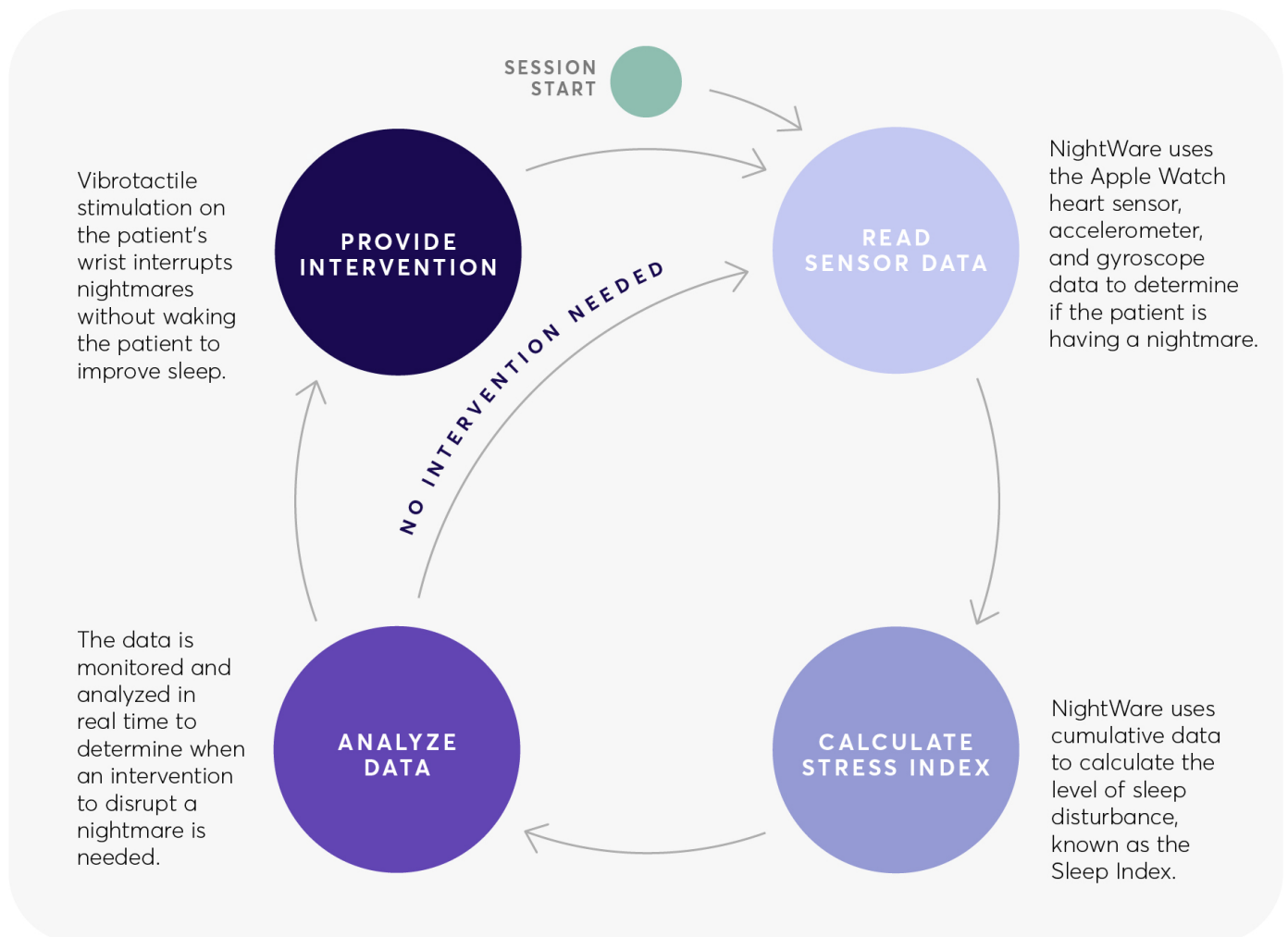
How NightWare Treatment Produces A Better Night's Sleep



When NightWare detects an increased stress index past the intervention level for a patient, a series of customized vibrations interrupt the nightmare. There are 3 intervention levels of increasing intensity and 9 vibration patterns that NightWare can apply. The minimum time between interventions can also vary from 1–5 minutes, depending on the individual patient. Based on the response to the interventions in the past, NightWare will increase, maintain, or decrease the intervention level. In the clinical studies of NightWare, these interventions did not awaken patients, but rather, they interrupted nightmares and improved sleep. NightWare is personalized treatment for nightmares.

NightWare continuously monitors sleep and provides personalized interventions to improve sleep in patients with dysfunctional nightmares.

FIGURE B
NightWare Intervention Cycle



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.

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