



NightWare

FDA-cleared prescription digital therapeutic system using an Apple Watch and AI to reduce sleep disturbance from nightmares related to Nightmare Disorder or PTSD.

<https://nightware.com>

Overview

NightWare is the first and only FDA-cleared, prescription-only digital therapeutic system indicated 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 classified as a Class II medical device.

The system utilizes a proprietary, patented artificial intelligence (AI) algorithm running on a dedicated, closed-system kit that includes a preprogrammed Apple Watch and iPhone. The Apple Watch monitors the user's body movement (accelerometer, gyroscope) and heart rate in real-time. The AI analyzes this biometric data to create a unique sleep profile and calculate a "stress index." When the system detects the onset of a nightmare, it delivers a gentle, vibrotactile intervention (vibration) through the Apple Watch to interrupt the nightmare without fully waking the user.

NightWare is intended for home use and should be used in conjunction with prescribed medications and other recommended therapies for PTSD, as it is not a standalone treatment. Clinical trial data has demonstrated that NightWare can help patients with Nightmare Disorder improve their sleep quality, with improvements seen in as little as two weeks. The company primarily targets healthcare providers and payers, including the VA and DoD, to provide access to patients, especially veterans and active-duty service members.

Key Features

- FDA-cleared Class II Medical Device
- AI-powered personalized therapy (Machine Learning)
- Vibrotactile feedback to interrupt nightmares without waking the user

- Real-time heart rate and movement monitoring
- Dedicated closed-system Apple Watch and iPhone kit
- Non-pharmacological treatment option
- Improves sleep quality in as little as two weeks

Pricing

Model: subscription

Prescription-only, all-inclusive kit (preprogrammed Apple Watch and iPhone) is required. The estimated out-of-pocket cost is approximately \$7,000, though the company is actively seeking insurance coverage and has coverage with Highmark Health BCBS, VA, and DoD.

Starting at: USD \$7000

Target Company Size: enterprise

Integrations

Apple Watch, iPhone, Google Cloud Platform

Compliance & Certifications

FDA Class II Medical Device, FDA Breakthrough Device Designation

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