



# NIGHTWARE

## ***NightWare Digital Therapeutic Patient Instructions for Use***

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## **Description of the NightWare Product**

The NightWare device includes a software application and the NightWare server. The device uses an Apple Watch® and an Apple iPhone® for its platform. These components monitor your sleep behavior and, using a proprietary formula, creates a unique sleep profile to help you get a better night's sleep. NightWare is designed to monitor your heart rate and movement throughout the night and occasionally provide vibrotactile interventions (haptic feedback) through the Apple Watch while you are sleeping. These interventions will occur when NightWare detects that you have exceeded a certain threshold and will disrupt the phenomena consistent with a nightmare at the time that it is occurring. The first night you use NightWare, the watch will not provide any of these interventions because it is gathering enough data to create your unique sleep profile. The data that NightWare collects from the Apple Watch includes:

- Heart Rate
- Body Movement (Acceleration)
- Body Position (Rotation)

This information is securely sent to the NightWare servers and processed to help you improve the quality of your sleep.

## **NightWare Indications for Use, Contraindications, Warnings and Precautions**

### **INDICATIONS 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 been known to "act out" your nightmares (i.e.: sleepwalking, violence), do not use NightWare and contact your Healthcare Provider.

### **WARNINGS:**

The NightWare digital therapeutic is not a standalone therapy for PTSD. This device can 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 Healthcare Provider.
- If the watch vibrations cause awakenings not associated with your nightmares, 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 could disturb your bed-partner's sleep if they are in contact with the watch when it vibrates. 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, but 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.
- NightWare is not intended for use by individuals under age 22.
- The long-term safety and effectiveness of the device has not yet been established.

**PRECAUTIONS:**

- Caution: Federal law restricts this device to sale by or on the order of a Healthcare Provider.
- NightWare is intended to be used under the supervision of a Healthcare Provider.
- Do not drop or crush the smartphone or watch.
- Be sure to charge the smartphone and watch every day.

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**Contents of the NightWare Kit:**



*Apple Watch*



*Apple iPhone*



*Velcro Watch Band*



*Dual USB-A port Wall Adapter  
Charging Brick*



*Apple Watch  
Power Cable*



*Apple iPhone Power Cable*

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## 4

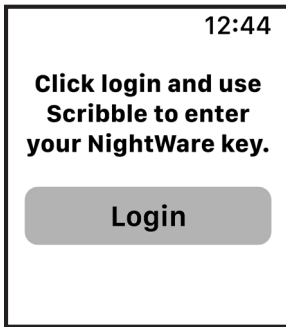
### Configuring the Apple Watch and iPhone

When you receive your NightWare Kit, the Apple Watch and iPhone will already be configured and logged into the application. However, at times, such as during a software update, restarting the phone, or accidentally hitting the logout button, you may become logged out of the application. If this occurs, these instructions will help you log back into your device.

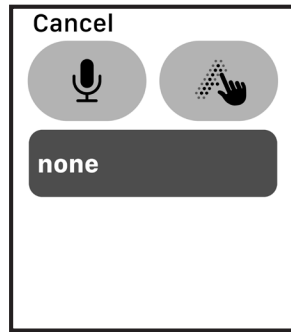
Each user is assigned a unique log-in code (NightWare ID). The NightWare ID is used to identify users and their profile settings. The NightWare key is a 5-digit number followed by a hyphen and a six-digit alphabetical code. An example of this NightWare ID is 11111-AAAAAA. The NightWare ID can be found on the back of the iPhone. If a user loses their code, they should contact NightWare at [support@nightware.com](mailto:support@nightware.com) or **1-833-44-NIGHT** to retrieve their NightWare ID.

#### STEPS TO RE-ESTABLISH YOUR LOGIN TO THE NIGHTWARE DEVICE:

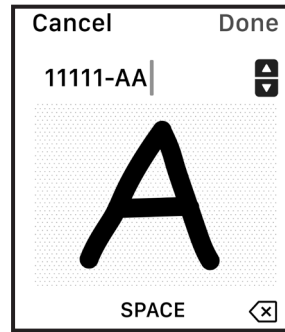
1. On the Apple Watch, select the LOGIN button.



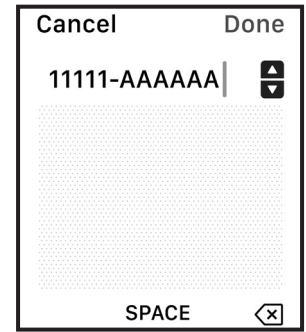
2. Press the SCRIBBLE ICON in the upper right corner of the application.



3. With your finger, draw each digit one at a time in the grid. Be sure to include the hyphen:



4. Press DONE in the top right corner once your NightWare key is completely entered.



This should re-establish your login to the NightWare application. If this does not re-establish your login to NightWare, please contact NightWare Technical Assistance (see Section 9).

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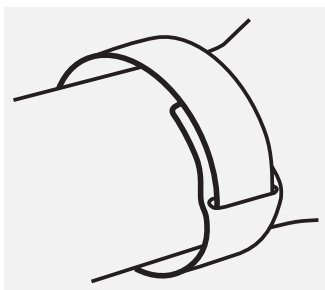
### How to Apply the Apple Watch

Optimal performance for your NightWare watch relies on accurate readings using the sensors on the Apple Watch. To ensure you are getting the best readings from the optical heart rate sensor, we suggest you follow these recommendations from Apple for using the Apple Watch:

#### A better fit means better readings:

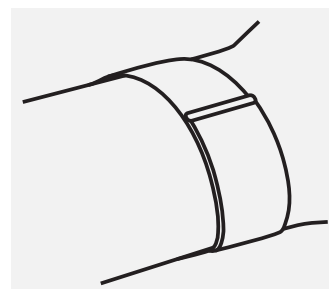
For best results, the back of your Apple Watch needs skin contact for features like Wrist Detect, the Taptic Engine, and the electrical and optical heart sensors. Wearing your Apple Watch with the right fit—not too tight, not too loose, and with room for your skin to breathe—keeps you comfortable and let the sensors do their jobs.

**IMPORTANT:** the sensors will work only if you wear your Apple Watch on the top of your wrist.



#### TOO LOOSE

If your Apple Watch does not stay in place, or the sensors are not reading your heart rate, tighten the band a bit.



#### JUST RIGHT

Your Apple Watch should be snug but comfortable.

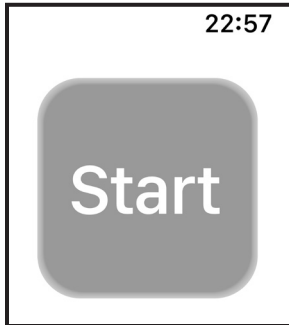
To ensure that you have the appropriate tightness on your Apple Watch, NightWare has included a Velcro wrist strap that will allow for more adjustments than the standard adjustable watch band typically shipped with the Apple Watch.

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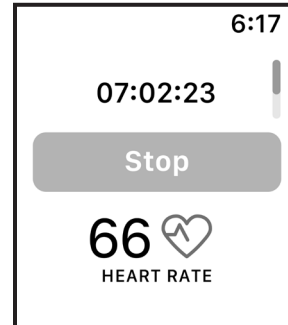
## 6

### How to Use the NightWare Application

For the NightWare application to function optimally, it needs to be monitoring your full night of sleep. You should begin using the application when you are trying to fall asleep.



1. To begin the application, press the purple START button on the Apple Watch.



2. In the morning, when you are getting up to begin your day, press the purple STOP button.

#### Important things to consider:

- You should NOT stop the application if you get up in the middle of the night to go to the bathroom.
- You should NOT start the application if you are doing other activities in bed. Examples Include:
  - Reading a book.
  - Watching a television show
  - Checking email/messages or other activities on a phone/laptop/tablet.

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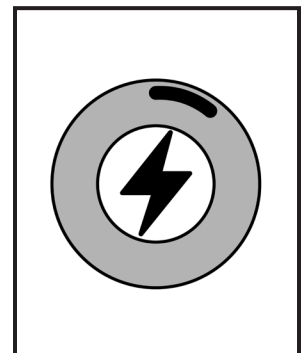
### Charging Your Devices

NightWare is using the Apple Watch sensors throughout the night. Doing this requires a full battery at the beginning of the night. To ensure that NightWare is working properly, you should charge both the iPhone and the Apple Watch during the day so that they have a full charge at night.

To charge your Apple Watch, place the back of the watch onto the magnetic charging platform. (See photo of the Apple Watch power cable, Section 3, above) Only one side of this charging platform will connect to the back of the watch. Once the watch and the charger are in contact, you will know that the watch is charging when you see the charging icon on the watch:

The iPhone requires that you plug the lightning cable into the bottom of the phone. (See photo of iPhone power cable, Section 3, above).

Both the Apple Watch power cable and the iPhone power cable can be plugged into the provided Dual USB-A port wall adapter charging brick which is plugged into a 120v power receptacle.



## How to Care for Your NightWare Devices

### APPLE WATCH CARE:

Keeping your Apple Watch and bands—as well as your skin—clean and dry maximizes comfort and prevents long-term damage to the watch. This is especially important after exposure to liquids such as sweat, soap, sunscreen, and lotions that can cause skin irritations.

Below are instructions from Apple on how they recommend you keep your watch, the watch band, and your skin clean to minimize skin irritation and optimize accurate readings from the watch's sensors.

Using a 70 percent isopropyl alcohol wipe or Clorox® Disinfecting Wipes, you may gently wipe the exterior surfaces of your Apple Watch, Sport Band, or metal band. Don't use this on fabric or leather bands. Don't use bleach. Avoid getting moisture in any openings, and don't submerge your Apple Watch in any cleaning agents.

### CLEAN AND DRY YOUR APPLE WATCH:

Keep your Apple Watch clean and dry. Soaps, cleaning products, abrasive materials, compressed air, ultrasonic cleaning, and external heat sources can cause damage and should not be used with your Apple Watch.

### To clean your Apple Watch, follow these steps:

1. Turn off your Apple Watch and remove it from the charger.
2. If you have a leather band, remove it from your Apple Watch.
3. Wipe your Apple Watch clean with a nonabrasive, lint-free cloth. If necessary, lightly dampen the cloth with fresh water. Or you can hold your Apple Watch under lightly running, warm, fresh water for 10 to 15 seconds. Soaps and other cleaning products shouldn't be used.
4. Dry your Apple Watch with a nonabrasive, lint-free cloth, including the surface of the back crystal.

### Clean and dry the reset button on the Apple Watch ("Digital Crown"):

If the Digital Crown gets stuck or won't move, check for debris and wipe down your Apple Watch. If you find substances like dust or lotion around the Digital Crown, follow these steps to clean it, and repeat as needed:

1. Turn off your Apple Watch and remove it from the charger.
2. If you have a leather band, remove it from your Apple Watch.
3. Hold the Digital Crown under lightly running, warm, fresh water from a faucet for 10 to 15 seconds. Soaps and other cleaning products shouldn't be used.
4. Continuously turn and press the Digital Crown as water runs over the small gap between the crown and the housing.
5. Dry your Apple Watch with an absorbent, non-abrasive, lint-free cloth. Be sure to wipe the surface of the Digital Crown, the space between the Digital Crown and the watch case, and the surrounding surfaces, removing any water.

### Clean and dry your band:

First remove the band from your Apple Watch before cleaning.

1. Place your Apple Watch face down over a clean surface like a lint-free, micro-fiber cloth or soft padded mat.
2. Hold down the BAND RELEASE button, then slide the band across to remove it.
3. If the band does not slide out, press the BAND RELEASE button again and make sure that you hold it down.
4. Make sure that the text on the band is facing you, then slide the new band in until you feel and hear a click.



This cleaning information applies to Apple-branded bands only. For all other bands, follow the care information provided with the band.

**For all other bands, buckles, and closures:**

1. Wipe the band clean with a nonabrasive, lint-free cloth. If necessary, lightly dampen the cloth with fresh water.
2. Dry the band with a nonabrasive, lint-free cloth before you attach it to your Apple Watch.


**Tips to avoid skin irritation, or if you have allergies or skin sensitivities:**

- Wearing your Apple Watch with the right fit—not too tight, not too loose, and with room for your skin to breathe—will keep you comfortable.
- Keeping your Apple Watch and bands—as well as your skin—clean and dry will maximize comfort and prevent long-term damage to the watch. This is especially important after workouts or exposure to liquids such as sweat, soap, sunscreen, and lotions that can cause skin irritations.

**IPHONE CARE:**

The following are recommendations from Apple to care for the iPhone:

Clean the iPhone immediately if it comes in contact with anything that may cause stains, or other damage—for example, dirt or sand, ink, makeup, soap, detergent, acids or acidic foods, or lotions. To clean:

- Disconnect all cables, then do one of the following to turn off iPhone:
  - *On an iPhone with Face ID:* Simultaneously press and hold the side button and either volume button until the sliders appear, then drag the top slider.
  - *On an iPhone with a Home button:* Press and hold the side button or Sleep/Wake button (depending on your model), then drag the slider.
  - *All models:* Go to Settings  > General > Shut Down, then drag the slider.
- Use a soft, slightly damp, lint-free cloth—for example, a lens cloth.
  - Avoid getting moisture in openings.
  - Do not use cleaning products or compressed air.

iPhone has a fingerprint-resistant oleophobic (oil-repellant) coating. This coating wears over time with normal usage. Cleaning products and abrasive materials will further diminish the coating and may scratch iPhone.

**Exposure to liquid and dust**

If liquid splashes on iPhone or dust gets on it, wipe it off with a soft, lint-free cloth (for example, a lens cloth). Minimize exposing iPhone to soap, detergent, acids or acidic foods, and any liquids—for example, salt water, soapy water, pool water, perfume, insect repellent, lotion, sunscreen, oil, adhesive remover, hair dye, and solvents. If iPhone meets any of these substances, follow the instructions above in the Cleaning section.

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**Cybersecurity of your NightWare Digital Therapeutic System**

NightWare’s processes and technologies are intended to make use of various platforms in order to provide you an easy to use, reliable and safe therapeutic device. The NightWare Digital Therapeutic System is built on the Apple Watch platform and utilizes features and security built into the infrastructure of both the Apple Watch and the included iPhone. This protects patient information from security threats and enables convenience of things like upgrades and configuration backup.

Specifically, this infrastructure enables data privacy compliance performance as it applies to the components of NightWare digital therapeutic. This included the mobile client applications from Apple.

**A. PRODUCT SPECIFICATIONS RELATED TO CYBERSECURITY**

1. The NightWare Digital Therapeutic System runs on Apple iPhones that are locked to and provisioned by NightWare’s Apple Profile Manager. Devices provided by NightWare are prevented from running any software that is not

provided by NightWare. The underlying iOS operating system is also preconfigured and user driven changes are prevented as well. You are able to connect the devices to your home network. We advise you to use Wi-Fi secured by WPA2 if possible. You are also required to set up a six digit passcode on your device.

2. You do not have to provide anti-virus software or be concerned about setting up firewalls on the home network, the equivalent of these features are built into iOS.
3. Even with this built in infrastructure of cyber protection, breaches are still possible. The device has been designed to be failsafe for this occurrence. All data is encrypted and cannot be tied to any individual.

## **B. BACKUP AND RESTORE**

1. iPhone configurations for the NightWare Digital Therapeutic System are managed by the Apple Profile Manager. NightWare user settings are stored on the NightWare server and are transmitted upon the first login of the application, and any subsequent logins should a logout occur.
2. The configuration set by a user of NightWare Digital Therapeutic System will be stored on the NightWare server ('backed up') and if a device needs to be restored to a configuration, or a new device is provided due to hardware failure, the patient's NightWare user settings will be restored on the device upon login.

## **C. INFRASTRUCTURE REQUIREMENTS**

1. You will need a source of power by the bedside, such that the iPhone charger will remain plugged in to a power outlet with the iPhone connected to the charger enough of the time to be charged and operational through the night.
2. The Apple Watch must be charged during the day by its charger such that it is fully charged when placed on the wrist in the evening prior to sleep. You will also need a reliable Wi-Fi internet connection such that the iPhone is able to be connected continually through the period of use. Loss of internet connectivity will not disrupt the function of the Apple Watch through the night. However, loss of internet connectivity will disrupt the immediate transmission of data to the NightWare secure cloud.
3. Any data not transmitted during a period of internet connectivity loss will be securely stored on the iPhone and securely transmitted when the phone reconnects. We advise you to secure your home Wi-Fi with a WPA2 password if possible.

## **D. SECURE CONFIGURATION**

The NightWare Digital Therapeutic System provides users with a secure configuration that has built in protection that are utilized with the iOS of the Apple products. This eliminates the need for you to provide firewalls on your home network or put in place provides anti-malware features.

## **E. DOWNLOADING NEW VERSIONS OF SOFTWARE**

1. All updates related to the iPhone and Apple Watch are completed using the Apple Profile Manager. New versions of software will be automatically installed on your NightWare Digital Therapeutic System.
2. You will not receive device prompts or emails asking you to update, nor will you need to do anything to enable the use of the updated software, which will work automatically. This software upgrade process enables only authorized NightWare users to upload a new version, with a second authorized NightWare user required to push the update to user devices. This process is secured by Apple's software distribution system security, using usernames, passwords, and two-factor authentication devices.

## **F. SECURITY ALERTS**

1. The NightWare Digital Therapeutic System utilizes features of the Google Cloud Platform to check for network anomalies.

If the Apple Watch is unable to communicate with the server, a message will be displayed to you.

## **G. SECURITY LOGGING**

1. Any configuration change to your NightWare Digital Therapeutic System, network anomalies and anomalous traffic that might represent a security breach, are monitored continuously by NightWare through the Google Cloud Platform.

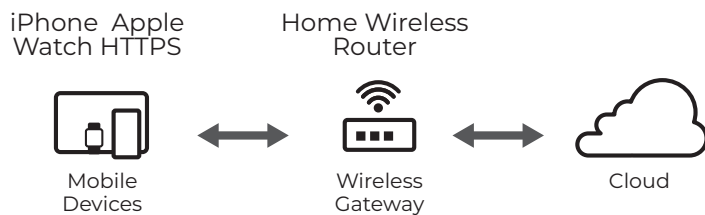


## H. DATA RECOVERY FROM NIGHTWARE

1. All data related to your NightWare Digital Therapeutic System are backed up and securely stored in Google's Datastore. If needed, any data can be retrieved by NightWare and restored from Google Cloud Storage.
2. For other Backup / Restore information, please see section 9(b). Device configuration settings are updated using the Apple Profile Manager. NightWare completes regular database backups that can be restored by a NightWare administrator.

## I. SYSTEM DIAGRAMS

1. System diagram for your NightWare Digital Therapeutic System are shown below.
  - a. The NightWare Digital Therapeutic System communicates with the Google Cloud Platform through the internet. All requests that pass through Google Cloud Platform are monitored.
  - b. App Engine handles authentication and authorization.
  - c. While in use, the NightWare application sends biometric data along with a unique user token that is used by App Engine to validate user authentication. Upon validation, the biometric data is stored in Google Cloud Datastore.



## J. WHAT TO DO IF A BREACH OCCURS

1. If NightWare detects any cybersecurity breach of its services, you will be contacted immediately by NightWare using the contact information you have provided and NightWare will advise you of its findings and recovery efforts.
2. If you think you had a cybersecurity problem with your NightWare Digital Therapeutic System, discontinue use immediately and then please contact NightWare technical support by email at:  
**support@nightware.com**  
as soon as possible to alert NightWare of the issue.

3. In addition to contacting NightWare, you can also report the problem through the FDA's MedWatch Voluntary Reporting Form:

**<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>**

## K. CYBERSECURITY PRODUCT LIFETIME / SUPPORT

1. Your NightWare Digital Therapeutic System will be continually updated for any known or potentially concerning cybersecurity threats. This support currently has no planned end date and is anticipated to continue for many years. Apple and Google provided the cybersecurity infrastructure support to NightWare. At such a point where Apple or Google inform NightWare that security updates will no longer be available to NightWare Digital Therapeutic System, NightWare will notify you of the impact to your device and establish a plan. At that point, NightWare may no longer be able to reasonably provide security patches or software updates. If your NightWare Digital Therapeutic System remains in service following any end of support notifications, the cybersecurity risks can be expected to increase over time.

## L. MINIMUM OPERATING REQUIREMENTS

The NightWare digital therapeutic requires an iPhone 7 or newer, Apple Watch 3 or newer, iOS 13 or newer, WatchOS 6 or newer.

## Contact Us

If you run into any technical problems with the NightWare Digital Therapeutic System, please contact us.

Contact NightWare by email at [support@nightware.com](mailto:support@nightware.com)

Website: [NightWare.com](http://NightWare.com)


Toll Free: 833-44-NIGHT

NightWare, Inc.

8900 Excelsior Blvd

Hopkins, MN 55343

## Symbols Glossary

Symbol	Symbol Title [Reference Number]	Description
	Consult instructions for use [5.4.3] <sup>1</sup>	Indicates the need for the user to consult the instructions for use.

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1. ISO 15223-1:2016 – Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.

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