NightWatch +

United States Version

Legal Manufacturer

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User Manual

EN

Thank you for choosing the nocturnal epileptic seizure detection and monitoring device,

NightWatch +

We at LivAssured | NightWatch understand that caring for persons suffering from epileptic seizures is highly demanding and stressful.
Seizures can be scary, as some of them can result in injuries or even sudden unexpected death in epilepsy (SUDEP) especially when a person suffering from seizures is unattended at night. NightWatch+ will warn you for the most dangerous seizures during sleep and it has been proven to reduce stress for the caregiver.

NightWatch was invented because multiple neurologists from the Dutch Academic Centre for Epileptology at Kempenhaeghe and Epilepsy Centre SEIN saw that there was a need for a reliable epileptic seizure detection device. These neurologists started a cooperation, a so-called consortium, of Dutch neurologists from Kempenhaeghe and SEIN, multiple universities, and patient organizations. This consortium invented, developed and clinically validated the first version of the NightWatch. LivAssured | NightWatch was founded and further developed the NightWatch in cooperation with the consortium. This resulted in the high-quality and reliable device in front of you today.

LivAssured | NightWatch has the mission to improve the lives of people living with epilepsy. We do this by developing products like NightWatch+ that support the daily care for people with epilepsy and which enable research into new and better treatments.
In this manual, we explain how to get started and use your NightWatch+.
We stand beside you with our product, as well as with help, advice and tips.

Contents

EN

1 General

1.1 About this Manual

This manual provides the information necessary to use the United States (US) version of the NightWatch+ safely and effectively. Please read the manual before using NightWatch+ US. In the following text the NightWatch+ US will be referred to as NightWatch+. If any part of this manual is unclear, please contact support. See Section 0 for contact details. The latest version of the User Manual is available at www.nightwatchepilepsy.com

1.2 Explanation of symbols used in the manual

WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in death or a serious injury.

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device.

PLEASE NOTE: A symbol used to emphasize information of which the user should be aware.

1.3 General warnings and cautions

CAUTION

- NEVER diagnose or treat yourself based on the readings of NightWatch+. ALWAYS consult with your physician.
- Do not accept and use the device if there are signs of piercing, manipulation, water damage or any other damage to the device, its packaging or label. Contact your supplier for help.
- Only use the power adapters as supplied by LivAssured. Using a different charger or cable could damage the device and/or affect its performance.

WARNING

- This product does not guarantee that 100% of the epileptic seizures will be detected, therefore there is a possibility that the caregiver is not warned of an epileptic seizure while using NightWatch+
- No modification of this equipment is allowed. Modifications to the device could lead to the hardware, algorithm, connectivity or communication to fail.
- Use of transducers and cables other than those specified or provided by LivAssured could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of NightWatch+, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Keep small parts away from children in the age range of 0 to 3 years. Spare and unassembled clips could pose a choking hazard when swallowed.
- Cords pose a strangulation hazard that may lead to death.

1.4 Symbols on labels

The instruction manual must be read before use of the Device

℞ Only — This device is a prescription only device

Li-ion — This part contains a Lithium Ion battery and should not be disposed with regular household waste

FCC ID: — This device complies with part 15 of the FCC Rules this means that the electromagnetic interference from the device is under the limits that are approved by the Federal Communications Commission

Applied part, type BF

USA YYYY-MM — Manufactured in the United States of America on manufacturing date

MD — This symbol indicates a medical device

SN — Serial number, production date followed by an identifier

Code to access the device monitoring data online

IP21 — Classification of ingress protection by enclosure for alarm station, meaning: *Protected against access to hazardous parts with a finger and vertically falling drops of water or condensation*

IP22 — Classification of ingress protection by enclosure for sensor, meaning: *Protected against access to hazardous parts with a finger and vertically falling drops of water when the enclosure is titled at any angle up to 15° on either side of the vertical*

0-3 — **WARNING**: Keep small parts away from children in the age range of 0 to 3 years. Spare and unassembled clips could pose a choking hazard when swallowed.

WARNING: Cords pose a strangulation hazard that may lead to death

Temperature limits (minimum + maximum)

Pressure limits (minimum + maximum)

Humidity limits (minimum + maximum)

Keep dry

Keep away from heat

Direct current

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2 NightWatch+

2.1 Indication for use

The US version of the NightWatch+ is a prescription only device that is indicated for use as an adjunct to seizure monitoring of children age 4 till 16 diagnosed with epilepsy having Nocturnal Epileptic Major Motor Seizures which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures, in home or residential facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures heart rate and motion data to detect patterns that may be associated with Nocturnal Epileptic Major Motor seizures in patients with epilepsy. When a seizure event is detected by the Sensor of the NightWatch+, it sends a command to the paired wireless alarm station of the NightWatch+ that is programmed to initiate an alarm to a designated caregiver. The system records and stores data from seizure events. The data can be viewed by the user in a cloud based data portal. The NightWatch+ is not intended to diagnose specific seizure types.

***CAUTION**: Requires prescription: United States (U.S.) law restricts the sale of the NightWatch+ in the U.S. by, or on the order of, a physician.*

2.2 Type of seizures NightWatch+ detects

Seizures taking place during the night/while sleeping are termed nocturnal seizures. Motor seizures are any type of seizures involving muscle activity, such as sudden stiffness or tension in the muscles of the arms, legs, or trunk during a tonic seizure, or leg pedaling movements during a hyperkinetic seizure.
The heart rate is controlled by the autonomic nervous system. Epileptic seizures affect this system in complex ways. Increases in heart rate are common during motor seizures but sudden decreases in heart rate are also observed. NightWatch+ uses these changes in heart rate to detect seizures.
NightWatch+ is intended to notify for the most dangerous nocturnal epileptic motor seizures associated with a risk of Sudden Unexpected Death in Epilepsy (SUDEP) or injury[1],

***CAUTION**: NightWatch+ is intended to monitor seizures during rest and not to monitor seizures during activities of daily living. The device has not been clinically validated for this purpose.*

which are the following seizure types[2]:

- Tonic-clonic
- Tonic (if clustered or prolonged >30 seconds)
- Hyperkinetic
- TC-like seizures

"TC- like" seizures, are defined as bilateral movements without classical TC pattern (i.e.,no tonic phase, pronounced asymmetry, short duration, or quick recovery).
These seizures are detected by combining and analyzing heart rate data, measured with a photoplethysmography (PPG) sensor, and movement data, measured with an accelerometer (ACC).

2.3 Operation mode

NightWatch+ is a wearable device consisting of a wireless sensor and an alarm station. The sensor is worn during sleep on the biceps of the upper arm. It includes a PPG sensor to track the heart rate, an ACC movement sensor, a microprocessor that processes the data from the sensors using a detection algorithm and a battery. NightWatch+ does not provide direct monitoring of the tracked heart rate or movement data. NightWatch+ is not a heart rate monitor.

The detection algorithm detects if the sensor readings match preprogrammed parameters that are associated with Nocturnal Epileptic Major Motor Seizures. If a match is detected, the epilepsy alarm is triggered and transmitted to the alarm station.
It is neither possible nor necessary to modify the algorithms or adjust any thresholds to influence the device's performance.
The sensor and alarm station communicate using a wireless DECT protocol. When an epilepsy alarm is transmitted from the sensor to the alarm station, the alarm station notifies caregivers with an audible alarm and a blinking red LED light. A caregiver can then go to the person with epilepsy and, if necessary, provide assistance according to their physician's instructions.
The alarm station also warns caregivers with alarm sounds and orange blinking LED lights in case the system is unable to detect seizures for technical reasons. Possible reasons include a depleted battery, a lost connection between the sensor and

[1] J. Arends, R. D. Thijs, T. Gutter, C. Ungureanu, P. Cluitmans, J. Van Dijk, J. van Andel, F. Tan, A. de Weerd, B. Vledder, W. Hofstra, R. Lazeron, G. van Thiel, K. C. B. Roes and F. Leijten, "Multimodal nocturnal seizure detection in a residential care setting: A long-term prospective trial," Neurology, vol. 91, no. 21, pp. e2010-e2019, 2018
[2] Nomenclature is based on the classification of epileptic seizures by the International League Against Epilepsy (ILAE): S. Fisher, J. H. Cross, C. D'Souza, J. A. French, S. R. Haut, N. Higurashi, et al. "Instruction manual for the ILAE 2017 operational classification of seizure types," Epilepsia, vol. 58, no. 4, pp. 531-542, 2017

alarm station (out of range), or the sensor being unable to track a PPG signal or movement data needed for seizure detection.

***PLEASE NOTE**: Do not use this product in an environment where DECT signals may be blocked or interfered with by environmental properties or other equipment.*

2.4 User Profile

Intended users

Users of NightWatch+ are children diagnosed with epilepsy aged 4 till 16, having Nocturnal Epileptic Major Motor Seizures and caregivers thereof.

***PLEASE NOTE:** Patients using NightWatch+ can act as operator of the device during setup and usage, but someone has to be able to respond to alarms when a seizure is detected.*

Contra-indications

NightWatch+ has no absolute contraindications that make its use completely inadvisable. However, certain risk factors do not necessarily exclude a user but require increased attention and may make the use of NightWatch+ inadvisable.

- User with damaged skin on the upper arm(s)

***CAUTION**: NightWatch+ is found to be biological safe to be worn on intact skin. Wearing the device on damaged skin could cause (further) irritation or damage of the contact area.*

- User with cardiac arrhythmia

***CAUTION**: NightWatch+ detects seizures by measuring, among other parameters, sudden changes in heart rate. Cardiac arrhythmia could influence the performance of NightWatch+.*

- User aged younger than 4 years

***CAUTION**: NightWatch+ is not intended for children younger than 4 years old. For children younger than 4 years old, clinical data evaluating the possible risks and benefits of using the device is lacking.*

Intended use environment

NightWatch+ is intended to be used at home or at residential care facilities. NightWatch+ is not intended to be used in intensive care environments.

2.5 Possible side effects

For the previous generation of NightWatch+, the NightWatch Original (which consists of the same materials), it was observed that a small percentage of the users developed skin irritation when wearing the sensor without the comfort patch. See Chapter '4.2 Comfort Patch'.

2.6 Clinical performance & benefits

Epileptic seizures can result in injuries, status epilepticus, and even Sudden Unexpected Death in Epilepsy (SUDEP).

Scientific studies have shown that nocturnal tonic-clonic seizures are the most dangerous type that can lead to injuries or hospitalization. NightWatch+ uses advanced technology and algorithms, previously validated in multiple scientific studies, to detect these seizures which enables that assistance can be provided[2,3,4].

Using NightWatch+ was found to lead to reduced stress for caregivers of people with epilepsy[4].

Seizure detection sensitivity

How well a seizure detection device detects the type of seizures it is intended to detect is expressed in sensitivity also called Positive Percentage Agreement (PPA).

NightWatch+ has a seizure detection sensitivity for Nocturnal Epileptic Major Motor

[3] R. Lazeron, R. Thijs, J. Arends, T. Gutter, P. Cluitmans, J. Van Dijk, F. Tan, W. Hofstra, C. Donjacour and F. Leijten, "Multimodal nocturnal seizure detection: Do we need to adapt algorithms for children?," Epilepsia, vol. 7, no. 3, pp. 406-413, 2022

[4] A. van Westrhenen, R. Lazeron, J. van Dijk, F. S. S. Leijten and R. D. Thijs, "Multimodal nocturnal seizure detection in children with epilepsy: A prospective, multicenter, long-term, in-home trial," Epilepsia, vol. 64, pp. 2137-2152, 2023.

Seizures and for tonic-clonic seizures for children (ages 4-16 years) of

- Nocturnal Epileptic Major Motor seizures: Mean 90% [95% CI: 84%-95%]
- Tonic-clonic seizures: Mean 98% [95% CI: 94%- 100%]

An overview of Sensitivity metrics found during the study for the other seizure types can be viewed in the table under clinical testing details.

***WARNING**: This product does not guarantee that 100% of the epileptic seizures will be detected, therefore there is a possibility that the caregiver is not warned of an epileptic seizure while using NightWatch+.*

False alarm rate

NightWatch+ may sometimes trigger an epilepsy alarm when no epileptic seizure is occurring or it triggers an alarm for a minor seizure, which is a seizure of very short duration. When an epilepsy alarm was triggered by a minor seizure, it may not be visibly apparent that a seizure occurred. These occurrences are called false alarms.

NightWatch+ has a false alarm rate for Nocturnal Epileptic Major Motor Seizure detection children (ages 4-16 years) of median 0.04 per hour. A median false alarm rate of 0.04 per hour means that most users will experience fewer than 1 false alarm every 3 to 4 nights.

***CAUTION**: This device may also give seizure alarms if no seizure is taking place which could cause stress for the caregiver.*

***PLEASE NOTE:** Please contact LivAssured's service department when you have many false alarms to try to help you resolve this. See chapter 12 for contact details.*

Clinical Testing details

NightWatch was invented, developed, and clinically validated by a consortium of Dutch neurologists from the Academic Center for Epileptology at Kempenhaeghe and epilepsy center SEIN, multiple universities, and patient organizations.
The device was tested to determine its performance for the indicated users, children 4-16 years old, in the home environment in the following scientific study.

	Epilepsia[3]
	Westrhenen et al 2023 [4]
Patients	53
Age	4-16 years
Location	Home
Nr of Nights	2310
Nr of Seizures	552
Sensitivity Nocturnal Epileptic Major Motor Mean [95% CI]* Overall	 90% [95% CI: 84%-95%] 89%
Sensitivity tonic-clonic. Mean [95% CI]* Overall	 98% [95% CI: 94%- 100%] 94%
Sensitivity tonic(>30 seconds). Mean [95% CI]* Overall	 71% [95% CI: 43%- 100%] 53%
Sensitivity hypermotor. Mean [95% CI]* Overall	 58% [95% CI: 17%- 99%] 83%
Sensitivity Other major (TC-like). Mean [95% CI]* Overall	 87% [95% CI: 75%- 100%] 91%
False alarm rate/ hour, Median Mean [95% CI]* Overall	0.04 0.07 [95% CI:0.04–0.10] 0.06
Side effect mild, reversible skin irritation**	8

** 95% Confidence Interval (CI) means that if the same population were to be sampled on multiple occasions, for 95 percent of the cases the mean sensitivity will fall within the range*
*** During this study the device was worn directly on the skin without comfort patch. See chapter 2.5 possible side effects.*

***PLEASE NOTE:** The detection performance (sensitivity) found during the study of van Westrhenen et al. 2023 for tonic seizures (> 30 seconds) and hypermotor seizures were not as high as tonic clonic and other major TC-like seizures*

3 NightWatch+ package contents

1 Alarm station
- Includes built-in backup battery: Lithium-ion battery 3.7V, 450mAh, not replaceable

2 The FRIWO NEO006.0-I-X-05, 5VDC/1.4A power adapter with barrel jack for the alarm station (black)

3 Sensor clips (1 already in the sensor, 3 additional including 2 spare clips)

4 Comfort patches (3x)

5 Travel case

6 Sensor
- Operates on built-in battery: Lithium-ion battery 3.7V, 450mAh, not replaceable

7 Sensor elastic strap (1 meter)

8 The FRIWO NEO006.0-I-X-05, 5VDC/1.4A power adapter with USB-C connector for the sensor (black)

9 Manual

10 Quick guides

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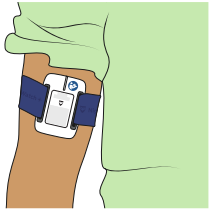
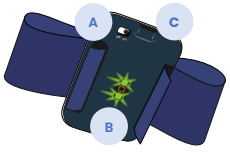
4 The different parts and how they work

4.1 Sensor with elastic strap

The sensor is worn on the upper arm and secured with an elastic strap. The optimal position for the sensor is around the upper arm on the front of the biceps, not on the side. This positioning helps prevent the wearer from lying on the sensor when turning onto their side, as doing so could interfere with heart rate tracking. The orientation of the indicator light, whether facing up or down, does not affect functionality.





A = ON/OFF switch

B = PPG sensor & LEDs

C = Charging port

D = Indicator light

ON/OFF switch

The dark grey underside of the sensor contains an ON/OFF switch (A). The position can be switched by sliding it to the side using a pointy object (pen).

The ON/OFF switch is usually only used for the first activation.

You can use the ON/OFF switch to turn OFF the sensor completely when the sensor cannot be charged and is not being used. This is to prevent the battery from depleting.

Heart rate and movement sensor

The sensor continuously tracks the wearer's heart rate and movement to detect epileptic seizures. It uses two green LEDs (B) on the dark grey bottom of the sensor to track the heart rate through Photoplethysmography (PPG).
PPG sensors use lights to measure small changes in blood volume in the capillaries just below the skin's surface. This technology works because blood is red, it reflects red light and absorbs green light. When your heart beats, blood flow increases, and more green light is absorbed. Between beats, blood flow decreases, and less green light is absorbed. By flashing its green LED lights hundreds of times per second, NightWatch+ can calculate your heart rate in beats per minute (BPM).

One green heart rate LED can shut itself off when there is too much environmental light. Both LEDs should turn on in the first seconds after you remove the sensor from the charger.

Charging port

The charging port (C) is used to charge the sensor with the supplied USB-C power adapter.

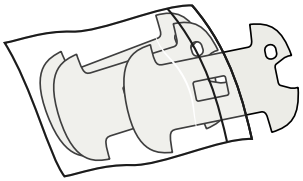
Indicator light

The notch on the white side of the sensor contains an indicator light (D). The brightness of this indicator is set for use in a darkened room and may consequently be more difficult to see in daylight / a brightly lit area. The indicator light is used for several signals. Read about these signals in Chapter 6.

4.2 Comfort Patch

The highest-grade materials were selected when NightWatch+ was designed. The sensor and strap have been subjected to biocompatibility analysis and have been found biologically safe for its use according to the ISO 10993 standard. It is therefore unlikely that you'll develop an allergic reaction from NightWatch+.

However, it was observed for the previous generation of NightWatch+, the NightWatch Original (which consists of the same materials) that less than 3.5% of the users developed skin irritation when wearing the sensor without the comfort patch. We therefore recommend applying the comfort patch to offer the highest comfort while wearing the sensor.



Please make sure to replace the comfort patch regularly when it becomes loose, damaged or dirty. We recommend replacing it after one month. More comfort patches can be ordered via the website or by contacting LivAssured. See section 12 for contact details.

***CAUTION**: Please make sure to replace the comfort patch regularly when it becomes loose, damaged or dirty. Due to the buildup of sweat and bacteria on the comfort patch, skin irritation is more likely to occur.*

***CAUTION**: The sensor of NightWatch+ should only be worn on intact skin. Do not continue using the device on the same skin location in case the skin becomes red, itchy or if any pain is felt and place a comfort patch on the NightWatch+ sensor. Please contact LivAssured in this case. See section 012 for contact details.*

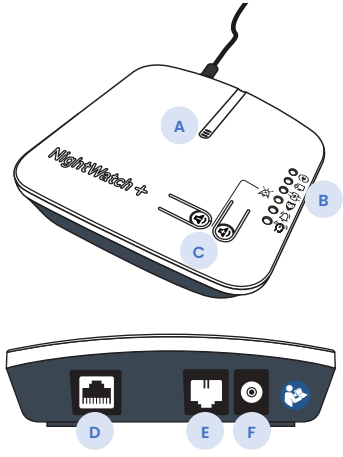
Applying the Comfort Patch

Remove the backing paper from the bottom of the patch and adhere it to the dark side of the NightWatch+ sensor. Use the middle hole and the opening for the switch as position guides, as shown in the figure below.

- Make sure that the charging port remains free for charging.
- Make sure that the ON/OFF switch of the sensor remains free.
- Make sure the patch does not cover the black sensor area in the middle.

4.3 Alarm station

The square white box is the alarm station. It emits both light and sound signals. The alarm station should be placed indoors near a power outlet.



A = Loudspeaker

B = LED indicator lights

C = Volume controls

Decreases the volume

Increases the volume

D = Network connection (RJ45 port)

E = RJ11 port (disabled, professional use only)

F = Power supply

Alarm station icons

LED 1 (blue)	– Alarm station power status
LED 2 (blue)	– Network status
LED 3 (blue)	– Sensor charging status
LED 4 (green)	– Audio paused state / Operation mode
LED 5 (orange)	– Technical alarm
LED 6 (red)	– Epilepsy alarm

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5 Using your NightWatch+

Scan this QR code to watch a video online explaining the setup of the NightWatch and how to start using it.

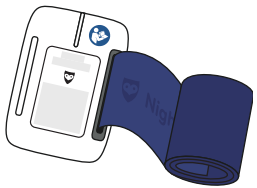
5.1 Preparing for first use

Step 1: Adjust the sensor strap

You will need:

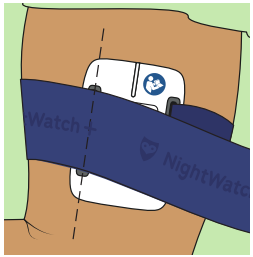
- Elastic strap, with clip inserted in sensor
- Additional clip
- Sensor
- Ballpoint pen/pencil
- Sharp (fabric) scissors

1



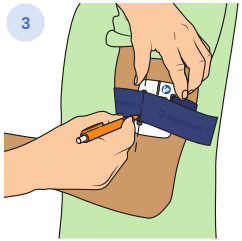
The elastic strap should be adjusted to the size of the upper arm of the wearer. One side of the elastic strap has already been fitted into the sensor.

2



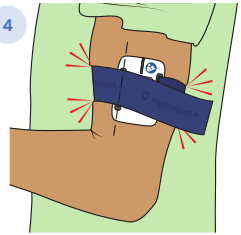
Use the remaining end of the elastic strap to measure the circumference of the wearer's arm above the biceps in a bent position. Do not stretch the strap.

3



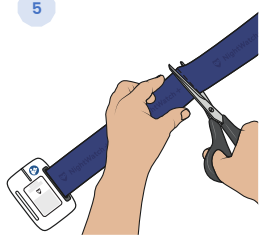
Mark the elastic strap where it overlaps the second sensor clip entrance and cut the elastic strap at the marked point.

4



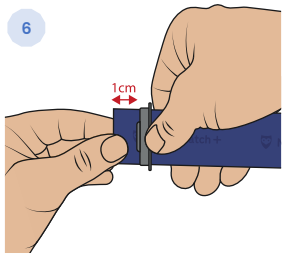
The sensor must not fit too tight but should fit snugly against the skin.

5



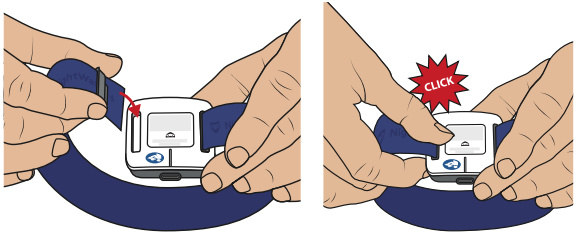
Cut the strap on the marked location.

6



Attach a clip to the remaining end of the strap by pushing one corner of the elastic strap through the flat side of the clip. Pull the strap through the clip until it sticks out at a length of around one centimeter.

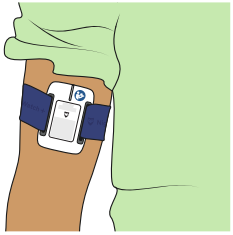
7



Push the clip into the remaining slot of the sensor and make sure that the end of the strap is protruding from the bottom of the sensor.

8

Place the sensor around the wearer's upper arm on the front of the biceps, not to the side. This ensures that the wearer is unlikely to lie on the sensor when turning onto his/her side. Lying on the sensor could disrupt tracking the heart rate. It does not matter if the indicator light is facing up or down.



PLEASE NOTE: *In order to achieve as accurate detection as possible of any epileptic seizures, the sensor should be worn on the upper arm (biceps) and directly on the skin. If the wearer is wearing a pajama top or other long-sleeved garment, please ensure the sleeve is wide enough to wear the sensor underneath or else seizure detection is not possible.*

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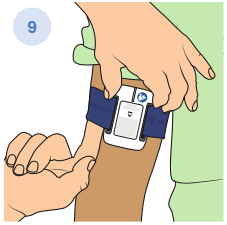

Check the tightness of the strap. The correct fit allows for just about one finger underneath the strap.

If the elastic strap feels too loose:
Pull the elastic strap further through the clips. Try again.

If the elastic strap feels too tight:

a. Using a fingernail, press the clips from below to remove them from the sensor.
b. Adjust the clips to make the space between the clips on the elastic strap longer.
c. Place the clips back into the slots and try again.

Adjust the strap until it is both comfortable for the wearer and fits snugly around the arm. Finally, cut off the excess ends of the strap with scissors to ensure it does not cover the green PPG LEDs and sensor.

There is no cause for concern if the sensor leaves an imprint on the arm after a sleep cycle, as long as this imprint fades by itself within hours.

PLEASE NOTE: *Please ensure the sensor has been adjusted to the correct size for the patient before use. If it fits too tight or too loose, seizure detection may be less accurate.*
Please ensure that the protruding ends of the elastic strap do not cover the green LEDs of the PPG sensor or seizure detection may be less accurate.

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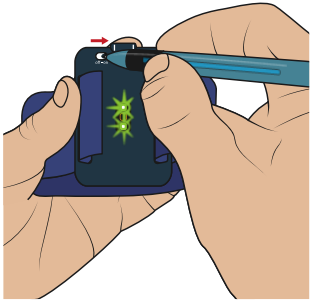
Step 2: First activation of the sensor

1. Take a pointed object or a pen/pencil
2. The dark underside of the sensor houses an ON/OFF switch. Use a pencil to slide this switch toward the middle of the sensor to switch it ON.
3. As soon as you activate the sensor via the switch (ON), seizure detection will begin. Two green PPG LEDs will light up brightly on the dark underside. One LED may turn off automatically when there is too much environmental light.
4. You can now connect the sensor to the charger and plug it into a power supply to stop seizure detection.

   Disconnecting the sensor from the charger starts the seizure detection.



If you wish to turn the sensor OFF to prevent the battery from running out, use the ON/OFF switch to turn the sensor OFF. The sensor cannot charge when it is switched OFF.

Step 3: Using the alarm station

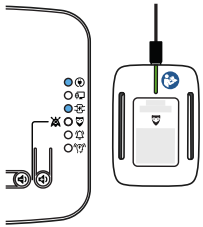
Placement

Position the alarm station where you want to receive alarms. It is important that the sound signals from the alarm station are clearly audible. The recommended location is in the bedroom of the operator or caregiver.

The distance between the alarm station and a worn sensor is limited and depends on the structure of the building where NightWatch+ is used. The typical range is approximately 15 meters. Be aware that wearing the sensor and especially blocking the signal with your body decreases the range. The alarm station will trigger a technical alarm if the sensor is out of range. If this happens, move the alarm station closer to the sensor, or ensure that the signal does not have to pass through too many walls.

Start-up

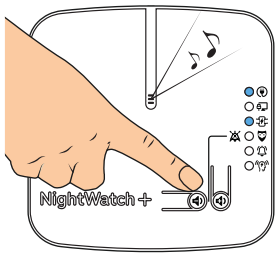
Ensure that the activated sensor is connected to the charger and that the alarm station is plugged into a power supply. Approximately 30 seconds after connecting the alarm station to a power supply, blue LED 3 on the alarm station will begin blinking ('sensor charging'). Once the sensor is fully charged, blue LED 3 will remain steadily lit.



Adjusting the volume

When no alarm is active, the volume of the alarm station can be adjusted as needed using the volume controls and (see Section 5.3). Ensure that the sound signal from the alarm station is audible and loud enough to wake you while sleeping.

Your system is now ready to use.



Testing the alarm system

Remove the sensor from the charger and verify that within five seconds the alarm station begins blinking the technical alarm LED (orange) and emits an alarm sound indicating that no heart rate has been tracked yet. Notice that the alarm station responds when the sensor is removed from the charger, confirming that they are connected. When the sensor is reconnected to the charger, the alarm will stop within five seconds.

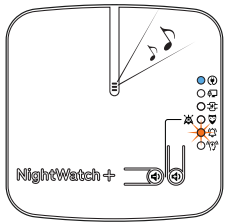
CAUTION: *Only use the power adapters as supplied by LivAssured. Using a different charger or cable could damage the device and/or affect its performance.*

PLEASE NOTE: *The alarm station power supply plug and the sensor charging supply plug are the disconnecting devices from the electricity from the outlet. Make sure that the power supplies are always accessible.*

5.2 Daily use

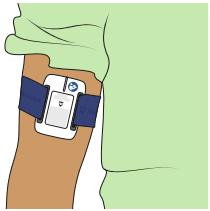
1 Disconnect the sensor from the charger. NightWatch+ is now in standard detection mode, where rapid shaking movements or a low heart rate are required to trigger an epilepsy alarm.

2 The alarm station will begin blinking the technical alarm LED (orange) and emit an alarm sound indicating that no heart rate has been tracked yet. This signal also confirms that the sensor and alarm station are communicating properly and that the alarms are audible.

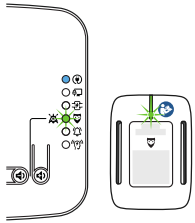


WARNING*: If the alarm station does not emit an alarm when disconnecting the sensor from the charger, it will not be able to notify you when a seizure event is detected. Please contact LivAssured in this case. See section 012 for contact details.*

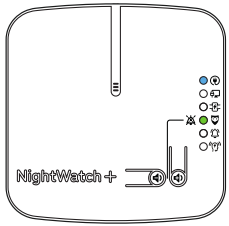
3 Place the sensor directly on the skin around the upper arm, on the thickest part of the biceps, with the sensor facing forward to prevent the wearer from lying on it when sleeping on their side. Lying on the sensor could disrupt tracking the heart rate. It does not matter if the indicator light is facing up or down.



4 The alarm station and sensor will blink green when the heart rate is tracked.

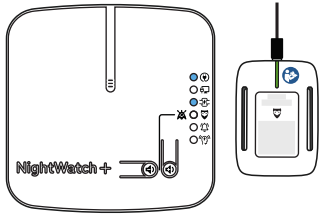


5 The wearer will now go to sleep. Once the wearer is lying down and the sensor has detected very little to no movement for two minutes, the more sensitive epilepsy detection algorithms become active. When this occurs, the blinking green LED changes to a steady green LED. NightWatch+ is now in rest mode and will also produce epilepsy alarms when vibrating movements or heart rate increases occur.



As soon as the wearer rises or gets out of bed, NightWatch+ automatically switches back to standard mode until the wearer lies down with no movement again for two minutes.

6 When the wearer wakes up, place the sensor back on the charger to stop detection. Once the sensor is fully charged, it will be ready for a new daily use cycle.



See chapter 6 for a list of all NightWatch+ alarms

PLEASE NOTE: *When the sensor is switched ON and removed from the charger, both green PPG LEDs will light up. Both green LEDs should have the same light intensity. After a while, one of the green LEDs may switch itself off due to environmental light to optimize the heart rate tracking, this is normal.*

PLEASE NOTE*: As soon as the sensor is disconnected from the charger, the alarm station will emit an alarm sound until the heart rate has been tracked. Once the heart rate has been tracked, LED 4 (green) will start to blink or light up continuously. Check this regularly.*

WARNING: *Please ensure the alarm station is not covered during use as this can result in inaudible alarms.*

WARNING: *Damage to or degradation of the PPG sensor can result in the sensor not tracking heart rate. If the sensor cannot track the heart rate while wearing the sensor, please contact LivAssured. See section 012 for contact details.*

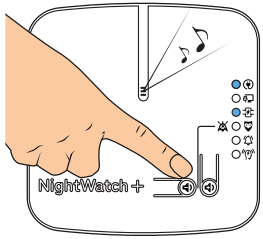
WARNING: *Please ensure that the alarm station is powered before the sensor is removed from the charger or you won't be able to hear if the alarm station is properly working.*

5.3 Managing alarm sounds

The volume buttons and allow you to adjust the volume of the alarms emitted by the alarm station as well as to pause the audio of an alarm. You can change the volume when no alarm is currently active.

Adjusting the volume

- The buttons and can be used to adjust the alarm volume. You will hear the epilepsy alarm volume increase or decrease. Release the button at the desired volume. The selected volume setting is now saved and will remain unchanged even if the alarm station is disconnected from the power supply.



Pausing the audio of an alarm

- Either button can be pressed to pause the audio during an alarm.
- When the alarm audio is paused, a flashing green LED will appear on the alarm station.
- For epilepsy alarms, the flashing green light indicates that you have acknowledged the epilepsy alarm. Seizure detection will automatically resume three minutes after the onset of the alarm.

Resuming the audio of an alarm

- You can manually resume a paused alarm by pressing either button again.
- If a technical alarm is paused but remains active after 10 minutes, the alarm audio will automatically resume. For example, if you pause a technical alarm due to 'no heart rate found', the alarm will sound again if no heart rate is detected after 10 minutes.

WARNING*: Ensure that the alarm sound of the alarm station is set to an audible sound level during use, or you will not be notified of an alarm sound.*

CAUTION: *Very loud sounds can trigger epileptic seizures in some people. Make sure that the signals can be heard clearly by the person who needs to respond to them but are not too loud for the person wearing the sensor.*

5.4 Charging the sensor

The sensor is powered by a rechargeable battery and can be charged by connecting the supplied USB-C power adapter to the charging port. When the sensor is connected to the charger, the green PPG LEDs will turn off. The sensor is designed to remain on the charger for extended periods. When NightWatch+ is not in use, leave the sensor switched ON and connected to the charger. It will automatically stop charging when the battery is full and cannot overcharge. Seizure detection is disabled during charging.
The sensor will only charge when switched ON. The sensor will not charge if the ON/OFF switch is set to OFF.

When the sensor is not in use and cannot be connected to a charger, for example during transport, the ON/OFF switch should be set to OFF to prevent battery depletion.

Sensor battery life:

- Battery charging time: Approximately 2 hours.
- Fully charged battery life: At least 12 hours.

WARNING: *Do not wear the sensor while it is charging because seizure detection is disabled while charging.*

CAUTION: *Contact LivAssured to replace the sensor if a fully charged battery of the sensor is empty before the end of a single cycle of use.*

CAUTION: *Always keep the sensor connected to the charger until use or the device may not be able to detect seizures during the full use cycle.*

CAUTION: *The sensor cannot charge when it is switched OFF. Always leave the sensor switched ON when it is connected to the charger.*

PLEASE NOTE*: The system starts automatically as soon as the sensor is removed from the charger. It is not possible to 'overcharge' the sensor.*

PLEASE NOTE: *Charging the sensor in the maximum operating temperature of 35°C may cause the contact surface to become 45°C, do not hold the sensor for longer than 10 minutes if it feels hot. Keep the sensor away from radiators and other sources of heat.*

5.5 Maintenance & cleaning

NightWatch+ does not require periodic maintenance. However, for hygiene reasons, the sensor should be cleaned regularly with a damp cloth and disinfectant. Replace the comfort patch when it becomes dirty, damaged, or starts to come loose.

CAUTION: *Clean the sensor regularly to reduce the risk of the wearer developing skin irritation.*

CAUTION: *Do not use excessive water to clean the device. Do not submerge the device or parts of the device in water. Do not wear the device in the rain, bath or in shower. This can damage the device.*

5.6 Reuse

If NightWatch+ is to be used by a different person, the sensor should be cleaned with a damp cloth and disinfectant. A new piece of elastic strap should be used to fit the sensor to the new user, following the instructions in Section 012.
Data from the device is stored only in the NightWatch Portal if the device was connected to the internet. The data stored in the Portal consists of recorded device data and is not linked to any individual. If the Portal was used, you can delete the data before the device will be used by another person. See Chapter **Error! R eference source not found.** for instructions on how to delete data from the Portal.

CAUTION: *If the sensor is to be worn by a different user, it is recommended to be cleaned with a damp cloth and a disinfectant or else skin irritation can occur.*

5.7 Transport or storage

When storing NightWatch+ or taking it along while traveling, both the alarm station and sensor should be switched OFF to prevent battery depletion. Disconnect the power supply from the alarm station. The "power lost" alarm will sound. Press one of the volume buttons to stop the 'power lost' alarm, and the alarm station will turn off. On the sensor, use a pointed object or a pen/pencil to slide the ON/OFF switch to OFF to prevent battery depletion.

CAUTION: *The sensor and alarm station should be powered OFF during transport or storage or else the battery may be damaged. If you wish to use the system again, you can use the ON/OFF switch to switch the sensor back ON and charge it.*

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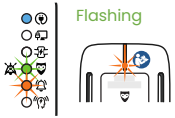
6 Signals from the sensor and the alarm station

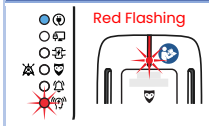
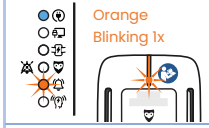
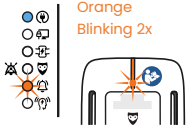
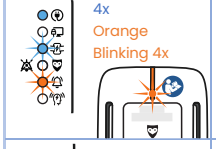
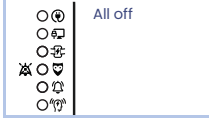
Both the sensor and alarm station display signals indicating the system's status. The sensor has a light in the notch on the (white) top. The brightness of this indicator is optimized for use in a darkened room and may be more difficult to see in daylight or a brightly lit area. The alarm station uses both light and sound signals. These signals are explained in the following section.

- LED 1 (blue) – Power
- LED 2 (blue) – Network connection
- LED 3 (blue) – Sensor charging status
- LED 4 (green) – Audio paused state / Operation mode
- LED 5 (orange) – Technical alarm
- LED 6 (red) – Epilepsy alarm

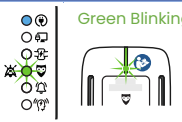
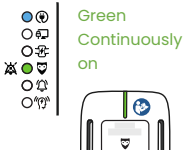
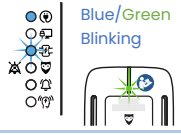
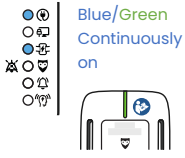
6.1 Alarm signals

Light Indicator	Pausing alarm audio signals
 Flashing	*Except for the "no power" alarm, all alarm audio signals can be paused by pressing one of the volume buttons on the alarm station.* *A flashing green light, along with the existing alarm lights, will indicate that the alarm is paused. New alarms will be audible.*

Example: Pressing one of the volume buttons while the "out of range" alarm is sounding will cause the alarm station lights to display as shown above. The flashing green audio-paused signal light will indicate that the alarm is paused, while the orange alarm light will continue to blink twice repeatedly until the issue is resolved.

Light indicator	Sound	Meaning
 Red Flashing	**Fast** beeping melody 	**Epileptic seizure detected** Check on the wearer and provide assistance as needed, following your doctor's instructions. Press either button to acknowledge the alarm and pause the audio. Seizure detection will automatically resume after three minutes.
 Orange Blinking 1x	**Monotone** melody of three beeps 	**Unable to track heart rate** Check if the sensor is worn correctly. Press either button to pause the audio.
 Orange Blinking 2x	**Falling** melody of three beeps 	**Out of range** The distance between the alarm station and the sensor is too great, or the sensor is switched OFF. Press either button to pause the audio.
 Blue Blinking 4x Orange Blinking 4x	**Rising** melody of three beeps 	**Sensor battery low** Charge the sensor. Press either button to pause the audio.
 All off	**Continuous** tone 	**The alarm station has no power** Check the power connection. Note: Pressing either button will turn the alarm station OFF.

6.2 Information signals

Light indicator	Sound	Meaning
 Green Blinking	None	**The heart rate is tracked**
 Green Continuously on	None	**The heart rate is tracked while the wearer has been at rest** The wearer remained at rest (no movement) in a horizontal position for two minutes. NightWatch+ is now operating in rest mode for seizure detection.
 Blue/Green Blinking	None	**The sensor is connected to the charger and is charging**
 Blue/Green Continuously on	None	**The sensor is connected to the charger and is fully charged.** Disconnect the sensor from the charger to begin seizure detection.

Operating modes
NightWatch+ has two modes for seizure detection: standard mode and rest mode. **Standard mode** *When the sensor is removed from the charger, NightWatch+ operates in standard mode for seizure detection. Seizure alarms will be triggered by shaking movements or a detected low heart rate.* **Rest mode** *When the wearer's heart rate is tracked in a horizontal position (angle lower than 45 degrees) and minimal or no movement is detected for two minutes, the green indicator light will remain continuously on. This indicates that NightWatch+ is operating in rest mode.* *In rest mode, seizure detection becomes more sensitive. NightWatch+ will also respond to smaller movements and increases in heart rate. If the sensor detects a vertical position, for example when the wearer gets out of bed, or when an alarm sounds, NightWatch+ will switch back to standard mode.*

⚠ ***CAUTION**: Be aware that if the sensor is not horizontal during sleep, NightWatch+ will stay in standard mode increasing the possibility that the caregiver is not warned of an epileptic seizure while using NightWatch+.*

6.3 Responding to alarms

Simultaneous alarm conditions

NightWatch+ epilepsy and technical alarms are assigned a priority. If multiple alarm conditions occur at the same time, NightWatch+ announces the highest priority alarm.

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Epilepsy alarm

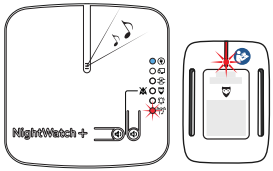
Blinking red: Epilepsy alarm

Sound: Fast beeping melody

Priority: high

Epilepsy alarm!

A possible epileptic seizure has been detected. Check on the wearer and, if necessary, provide aid as instructed by your physician. This alarm will remain active until someone presses one of the volume buttons. When pressed, NightWatch+ will automatically resume seizure detection within a maximum of three minutes.

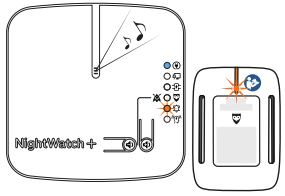


NightWatch+ may have triggered an epilepsy alarm for one of the following reasons:

Type	Description
Rhythmic movements	Rhythmic movements have been detected, which could indicate epileptic activity.
Vibrating movements	Vibrating or muscle tension movements have been detected, which could indicate epileptic activity.
Shaking movements	Intense shaking movements have been detected, which could indicate epileptic activity.
Heart rate increase	The average tracked heart rate rose suddenly, which could indicate epileptic activity.
High heart rate	The tracked heart rate is significantly higher than before, which could indicate epileptic activity.
Low heart rate	The tracked heart rate is low, which could indicate epileptic activity.

Technical alarms

Blinking orange: Technical alarm



There are 3 types of technical alarms:

Sound	Alarm LED 5 (orange)	Priority	Technical alarm
1 **Falling** melody	Blinking 2x repeatedly	High	Sensor out of range or sensor switched off
2 **Monotone** melody	Blinking 1x repeatedly	Medium	Sensor unable to track heart rate
3 **Rising** melody	Blinking 4x repeatedly	Low	Sensor battery low

PLEASE NOTE: *If the alarm station makes a sound not described in the manual, please contact LivAssured. See section 012 for contact details.*

1. Out of range

There is no connection between the sensor and the alarm station. Several causes are possible:

- The sensor and alarm station are too far apart. Move the alarm station and sensor closer together.
- The sensor is switched OFF. Turn the sensor ON by sliding the ON/OFF switch. At least one green LED at the bottom of the sensor should illuminate when the sensor is ON and disconnected from the charger.
- The alarm station is not connected to a power supply.
- The sensor displays a continuous (non-blinking) orange LED in the notch. If this occurs, press and hold both volume buttons on the alarm station for 20 seconds. The sensor should automatically reconnect to the alarm station.

2. Unable to track heart rate

You will hear this alarm as soon as you remove the sensor from the charger. The alarm will stop as soon as NightWatch+ tracks a heart rate. Hold still to allow the heart rate to be tracked more quickly. This alarm will sound again if the sensor fails to track both heart rate and movement for at least two minutes. Please note that NightWatch+ is not a heart rate monitor but uses heart rate tracking alongside movement detection to notify for seizures.

As described under "how things work", the NightWatch+ uses a technology called photoplethysmography (PPG). PPG sensors use lights to measure small changes in blood volume in the capillaries just below the skin's surface.
There are multiple factors that can affect the PPG heart rate detection. Skin characteristics such as perfusion (how much blood flows through your skin) and skin color are factors that can affect the absorption rate of the light. Skin perfusion varies significantly from person to person and can also be impacted by the environment. If you're sleeping in the cold with your arm above the covers, for example, the skin perfusion will be lower and it can be more difficult for the heart rate sensor to get a good reading.

Permanent or temporary changes to the skin, such as tattoos, can also have an impact. The ink, pattern, and saturation of some tattoos can block the light from the sensor, making it difficult to get reliable readings. The tightness of the strap is another factor. The strap should be setup as described in the Instructions for use. The strap is properly tight when you can move the Sensor, and the skin underneath moves with it. If the strap is too loose, the Sensor may slide around, creating a gap between the ppg and your skin that can interfere the detection. If it's too tight, it can restrict blood flow which also affects detection.

To sum up, there are multiple reasons for temporary failure to track a reliable heart rate which can be prevented:

- The PPG sensor is not correctly positioned on the skin. Ensure that the green LEDs on the underside of the sensor make direct contact with the skin.
- The sensor may be too loose, have slid off, or has been removed. If so, tighten the elastic strap slightly.
- The wearer may be lying on the sensor, making heart rate detection difficult. Adjust the sensor position to prevent the wearer from lying on top of it. Try placing it on top of the bicep muscle, closer to the inside of the arm (near the armpit) rather than the outer side.

3. Sensor battery low

This alarm indicates that the sensor battery is nearly empty. NightWatch+ will no longer function until the sensor is charged. Connect the sensor to the charger.
If this alarm persists despite correct and sufficient charging, please contact 'Service and support'. See Section 012 for contact details.

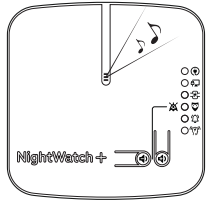
Power loss alarm

● No LED on

♪ Sound: constant beep: Power loss

Priority: high

When the alarm station loses power, a 'power loss' alarm will sound. Restore power to the alarm station to stop the alarm, or press one of the volume buttons to turn off the alarm station completely.



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7 Seizure monitoring

7.1 The NightWatch Portal

It is not necessary to connect NightWatch+ to the internet in order for NightWatch+ to function correctly. Although, whenever it is connected to the internet during use, the data captured by the device along with the alarms will be sent to the Portal. This data can be viewed via the **portal.nightwatchepilepsy.com** website.

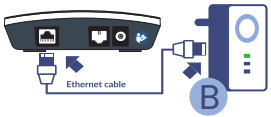
The Portal can provide insight into what happened while sleeping and helps to better understand why NightWatch did or did not provide alarms. Furthermore, it can be used as input for a diary to track seizure frequency and to share this data together with your experiences with your neurologist. It is also helpful for troubleshooting.
The alarm station does not store any data internally. The alarm station will only send data to the Portal when it is recording and connected to the internet via a cabled internet connection.

7.2 How to connect your NightWatch+ to the internet

To connect to the NightWatch Portal, the NightWatch+ alarm station must be permanently connected to the internet via a wired connection to a network access point, such as a router.

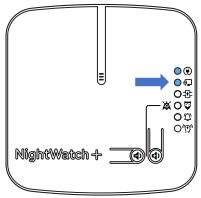
1. Find the nearest internet access point—typically your router (A)—and connect it to the NightWatch+ alarm station using an Ethernet cable.

2. If the nearest access point is too far for a direct cable connection, we recommend using a powerline adapter (B) or mobile router to bridge the connection.



3. Once NightWatch+ is connected to the internet, the second blue indicator LED on the alarm station will illuminate, confirming the internet connection.

4. After a recording has been made while NightWatch+ was connected to the internet, your data can be viewed using **portal.nightwatchepilepsy.com**



7.3 Getting started using the NightWatch Portal

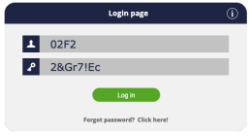
You can access the NightWatch Portal via: **portal.nightwatchepilepsy.com**

You need two unique numbers of your NightWatch+ to access the data of your device on the Portal.

MAC code:	Last 4 numbers/letters of the MAC address
Connection code:	The code indicated with the symbol

Your unique numbers can be found on the white label on the back of your alarm station. Find the number that starts with MAC. Your MAC code for the portal consists of the last 4 characters. So in the example below, the unique MAC code is 02F2 and the connection code is 2&Gr7!Ec.

Example

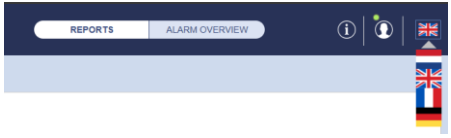


After you set up your account, you can navigate through different recordings, create overviews or zoom in on specific moments to gain more insight into the recorded events. For interpretation of recorded events and event overviews, consult a healthcare professional.

7.4 What's there to view?

Language

You can set your preferred language from the options in the top right corner of the screen.



Once you enter the Portal, you will find yourself on the 'Reports' page. In addition to this page, you can also navigate to the 'Alarms overview' page by clicking on the 'Alarm overview' button at the top of the page.

Reports page

This page shows an overview of all the reports made in a specific month. Each line provides a summary of the report, including details such as the total number of seizures and technical alarms recorded. Notes can be added to a report by clicking on the grey pen under 'Note'. Clicking on a report of a certain date on the left will open the corresponding graphs.
All recordings made between 12 noon and 12 noon the following day are combined into one recording. If there is a break between two recordings, a flat line between these recordings will be shown.

There are symbols in the overview and graphs for the alarm types:

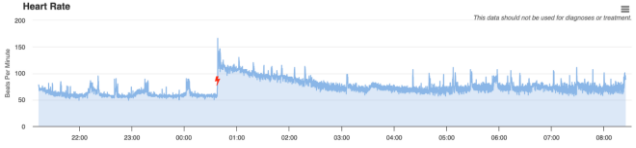
Technical Alarm

Epilepsy Alarm

When hovering over a graph or alarm with the cursor, the values at that point in time can be seen. It is also possible to zoom in on the graphs. Click and drag in the graph to zoom in.
When clicking the link shown above the graph, it will launch in a new browser window. This window is designed to automatically refresh every 5 minutes, ensuring that any new data is updated automatically if you monitor the graphs during a recording.

Blue graph: Heart rate

The blue graph shows the PPG (photoplethysmography) signal translated to beats per minute (BPM). The peaks in a PPG signal represent estimated heart beats and therefore the graph represents an estimated heart rate in beats per minute. The blue graph also shows icons for alarms and descriptions of the alarm conditions.



***CAUTION**: The PPG sensor in NightWatch+ is not intended to function as a heart rate monitor. The PPG data is used solely for the detection of epileptic seizures and is suitable for this purpose. Do not use this data to draw conclusions about the cardiovascular health of the wearer. If you have concerns about the wearer's health, consult with your healthcare provider.*

Green Graph: Motion Signal.

The green graph shows the intensity of motions detected. The intensity of the motion graph is measured by vibrating movements (zero crossings) and the speed of these movements. When the movements are subtle, the graph will reach a lower value than when the sensor is shaken wildly. To illustrate this, when someone turns over in bed a low movement value will be depicted, but when the sensor detects zero-crossings because of shaking movements, the motion value will be increased. The degree of intensity is indicated on a 0-15 scale.

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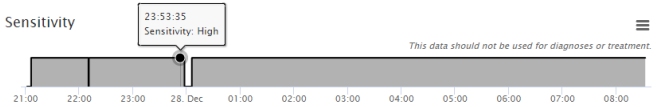
Black and Grey Graph: Detection mode

This graph shows if NightWatch+ is operating in standard mode or in rest mode.



The graph remains high when NightWatch+ is in rest mode and low when NightWatch+ operates in standard mode. The standard and rest modes are designed in order to reduce false alarms when someone leaves the bed at night or upon waking up. The modes of NightWatch+ cannot be changed.

Detection modes

NightWatch+ has a standard mode and a rest mode for seizure detection.

Standard mode

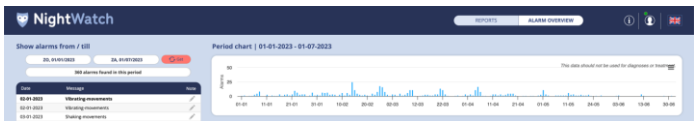
When the sensor is removed from the charger, NightWatch+ is in standard mode for seizure detection. Seizure alarms will be triggered by shaking movements or a low tracked heart rate.

Rest mode

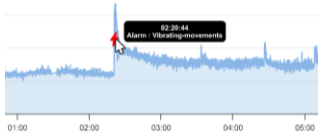
When the wearer's heart rate is tracked in a horizontal position (angle lower than 45 degrees) and minimal or no movement is detected for 2 minutes, the light indicator will be continuously green. This indicates that NightWatch+ is operating in rest mode. When in rest mode, seizure detection becomes more sensitive. It will also respond to smaller movements and increases in heart rate. When the sensor detects a vertical position, for instance when the wearer gets out of bed, NightWatch+ will switch back to standard mode.

'Alarm overview' page

On this page you can generate an overview of all seizure alarms recorded within a specific period of your choice. The period can be selected at the top left. This can be used to compare the number of seizure alarms between different periods.



The left column shows all alarms registered within the selected period. These alarms can be clicked, after which the graph for that day will open.



'Settings' page

On the settings page you can change the following settings for your NightWatch+ Portal account:

- Change the time zone in which NightWatch+ Portal displays your data.
- Delete all of your historic recordings.

Alarms of NightWatch+ in the Portal

The epilepsy alarms and technical alarms raised by your NightWatch+ are visible on the blue heart rate graphs. Epilepsy alarms are depicted with the red epilepsy alarm symbol (lightning bolt) and technical alarms are depicted with the orange technical alarm symbol (bell). When hovering over the alarm symbol, a description is given of the alarm reason.

NightWatch+ could have raised an epilepsy alarm based on the following reasons:

Type	Description
Rhythmic movements	Rhythmic movements have been detected which could be the result of epileptic activity
Vibrating movements	Vibrating/muscle tension movements have been detected which could be the result of epileptic activity
Shaking movements	Wild shaking movements have been detected which could be the result of epileptic activity
Heart rate increase	The average tracked heart rate rose suddenly, which could be the result of epileptic activity
High heart rate	The tracked heart rate is high compared to a moment before, which could be the result of epileptic activity
Low heart rate	The tracked heart rate is low which could be the result of epileptic activity

The algorithm thresholds that trigger an alarm cannot be modified.

The portal also shows when a technical alarm occurred:

Type	Description
Unable to detect heart rate	The sensor was unable to reliably detect a heart rate for a few minutes. Check if the sensor is placed correctly and that the wearer is not lying on top of it.
Sensor Connection lost	The alarm station lost connection with the sensor. Most probably the sensor is out of range or switched OFF.
Sensor battery low	The battery of the sensor is almost empty. Recharge the sensor.
Sensor switched off	The sensor was switched OFF while being placed on the charger. Please switch ON the sensor.
Accelerometer error	The movement sensor of the sensor is defect.

For explanation of the technical alarm conditions see section 6 in the user manual.

***PLEASE NOTE**: The Portal displays all alarms which include epilepsy alarms which were false alarms.*

***CAUTION**: NEVER diagnose or treat yourself based on the readings of NightWatch+. ALWAYS consult with your physician.*

Annotating Alarms

The Portal shows all alarms provided by NightWatch+. This includes epilepsy alarms that did not arise from an epileptic seizure. The Portal provides the possibility to add annotations or notes to each recording. Notes can be made by clicking the 'pen icon' on the recording line. To protect the privacy of the wearer, we advise against including privacy-sensitive information such as the identity of the sensor wearer in these notes.

7.5 Does the NightWatch+ Portal respect my privacy?

If your NightWatch+ remains connected to the internet during use, it automatically sends recordings to the NightWatch+ Portal. This data contains information about heart rate, movements and alarms. The data contains no information about the identity of the wearer and is stored encrypted and anonymously. NightWatch+ Portal does not ask to enter personal data like your name or address. You can always ask our customer support to remove your data or you can remove your own historic recordings at the settings page of the Portal.

7.6 Connecting NightWatch+ to alarm systems

NightWatch+ offers two different methods for connecting to information or alarm systems. These options are available only for professional use upon request.

- The RJ-11 port allows connection to a Distributed Information System
- The RJ-45 port allows connection to a Distributed Alarming System.

No other interconnections are possible. For more information, please contact LivAssured. See Section 012 for contact details.

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8 Specifications

8.1 Technical Specifications

Operating mode	[Sensor]: Body worn
Weight	[Sensor]: 35g [Alarm station]: 90g
Dimensions (L x W x H)	[Sensor]: 72 mm x 52 mm x 14 mm [Alarm station]: 100 mm x 100 mm x 28 mm
Supply voltage	[Sensor]: FRIWO NEO006.01-X-05, 100V–240V AC, 50Hz–60Hz, IEC60601-1 protection class II, 5VDC/1.4A. Lifetime: 20 years at continuous use. [Alarm station]: FRIWO NEO006.01-X-05, 100V–240V AC, 50Hz–60Hz, IEC60601-1 protection class II, 5VDC/1.4A Lifetime: 20 years at continuous use.
Current consumption	[Sensor]: 0.1A (RMS) max. [Alarm station]: 0.2A (RMS) max.
Internal transmitters	DECT, operating frequency (send/receive) 1880-1900MHz, 23 dBm
Casing protection	[Sensor]: IP21 - This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops. [Alarm station]: IP22 - This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops when enclosure tilted up to 15°
Applied part	Sensor, type BF
Battery	[Sensor] Built-in Lithium-ion battery 3.7V, 450mAh, not replaceable [Alarm station] Built-in Lithium-ion battery 3.7V, 450mAh, not replaceable Both batteries comply to IEC62133-2:2017 and UN38.3
Sound pressure range	40 to 80 dBA for all alarms (1m radius)
Alarm condition delay	2 seconds max.
Pulse rate accuracy	(30 – 210 bpm) ± 1.31 bpm (RMS)
Pulse rate acc. method	Electronic pulse simulator

CAUTION: *Batteries inside NightWatch+ cannot be replaced. Trying to replace the batteries can damage NightWatch+ which could result in its incorrect operation. Under normal use conditions the batteries service life is 5 years. Please contact LivAssured if you think the battery is not working properly. See section 012 for contact details.*

8.2 Environmental conditions

Operating conditions

- Temperature range of +5°C to +35°C
- Relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50hPa
- Atmospheric pressure range of 700hPa to 1060hPa

PLEASE NOTE: *Charging the sensor in the maximum operating temperature of 35°C may cause the contact surface to become 45°C, do not hold the sensor for longer than 10 minutes if it feels hot. Keep the sensor away from radiators and other sources of heat.*

CAUTION*: Using NightWatch+ in an environment above 35°C may cause the contact surface of the sensor to become hot and unsuitable to wear.*

Transport and storage condition limits

- Temperature range of -25°C to +70°C
- Relative humidity range of 15% to 90%, non-condensing
- Atmospheric pressure range of 700hPa to 1060hPa

Recommended storage conditions

- Temperature range -20°C to +25°C for a maximum of 3 months with the sensor turned off

CAUTION*: Storage temperatures above 25°C will increase the rate of self-discharge, reducing the available capacity of the battery. A reduced capacity of the battery may cause the sensor to be empty before the end of a single cycle of use and will not be able to detect seizures during the full use cycle.*

8.3 Electromagnetic environment conditions

NightWatch+ is intended for use in the electromagnetic environment specified below. The operator should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The above listed models use RF energy only for its internal function. Therefore, its RF emissions are ultra low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The above listed models are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Enclosure Port			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±,8 kV Contact ± 2,4,8,15 kV Air	±8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz – 2,7 GHz	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
	385MHz (18Hz Pulse Modulation)	27 V/m	
	450MHz (FM+/- 5KHz deviation 1kHz sine or 18Hz Pulse Modulation)	28 V/m	
	710MHz (217Hz PM)	9 V/m	
	745MHz (217Hz PM)	9 V/m	
	780MHz (217Hz PM)	9 V/m	
	810MHz (18Hz PM)	28 V/m	
	870MHz (18Hz PM)	28 V/m	

EN

	930MHz (18Hz PM)	28 V/m	
	1720MHz (217Hz PM)	28 V/m	
	1845MHz (217Hz PM)	28 V/m	
	1970MHz (217Hz PM)	28 V/m	
	2450MHz (217Hz PM)	28 V/m	
	5240MHz (217Hz PM)	9 V/m	
	5500MHz (217Hz PM)	9 V/m	
	5785MHz (217Hz PM)	9 V/m	
RATED power frequency magnetic fields IEC 61000-4-8	50Hz or 60Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	30 kHz (CW)	8 A/m	Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
	134,2 kHz (2,1 kHz PM)	65 A/m	
	13,56 MHz (50 kHz PM)	7,5 A/m	

Input a.c. power PORT			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrical fast transient/bursts IEC 610004-4	± 2 kV 100kHz Repetition frequency	± 2 kV	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
Surges IEC 61000-4-5	± 0,5kV, ±1 kV line(s) to line(s)	± 1 kV, Differential mode	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
Conducted RF induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz also 6 Vrms ISM and Amateur Radio Bands a) 80% AM 1kHz	3 Vrms 150 kHz - 80 MHz also 6 Vrms ISM Radio Bands a) 80% AM 1kHz	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0°,45°,90°,135°,180°,225°,270°,315° 0% U_T; 0° 0% U_T; 70% 0% U_T; 0%	0,5 Cycles 1Cycle 25/30 Cycles (50/60Hz) 250/300 Cycles (50/60Hz) (5s)	Mains power quality should be that of a professional healthcare facility environment and home healthcare environment. If the user of the above listed models requires continued operation during power mains interruptions, it is recommended that the

			above listed models are powered from an uninterruptible power supply or battery.

Comment:
a) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Signal input/output parts PORT			
Immunity test	**Test Condition**	**IEC 60601 Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±,8 kV Contact ± 2,4,8,15 kV Air	±8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/bursts IEC 610004-4	± 1 kV 100kHz Repetition frequency	± 1 kV	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment.
Conducted RF induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz also 6 Vrms ISM and Amateur Radio Bands a) 80% AM 1kHz	3 Vrms 150 kHz - 80 MHz also 6 Vrms ISM and Amateur Radio Bands a) 80% AM 1kHz	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment.

Comment:
a) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

⚠ ***CAUTION**: Using NightWatch+ in electromagnetic environments outside these descriptions may cause disturbances leading to a loss of connection between the sensor and the alarm station.*
***CAUTION**: NightWatch+ has not been tested for use in airplanes and should not be operated in such environments.*

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8.4 Regulatory and Compliance

NightWatch+ is in compliance with the following standards for medical devices and radio equipment and has been subject to specific laboratory testing to assess its safety, electromagnetic compatibility, usability, and biocompatibility.

Basic safety and essential performance	IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EMC requirements	IEC 60601-1-2:2014+A1:2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests ETSI EN 301 489-1 V2.2.3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility EN 301 489-6 V2.2.1 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 6: Specific conditions for Digital Enhanced Cordless Telecommunications (DECT) equipment;
DECT	ETSI EN 301 406 V2.2.2 (2016-09) Digital Enhanced Cordless Telecommunications (DECT); Harmonised Standard for access to radio spectrum; Part 1: DECT, DECT Evolution and DECT ULE
Home care use	IEC 60601-1-11:2015+A1:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical Systems used in the home healthcare environment
Medical Alarm systems	IEC 60601-1-8:2006+A1:2012+A2:2020 Medical Electrical equipment Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General Requirements, tests and guidance for alarm systems in medical electrical equipment.
FCC	FCC 47 CFR Part 15 Radio Frequency Devices
Biocompatibility	ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices, Part 5: EN Tests for in vitro cytotoxicity ISO 10993-10:2021 Biological evaluation of medical devices, Part 10: Tests for skin sensitization ISO 10993-23:2021 Biological evaluation of medical devices, Part 23: Tests for irritation
Risk Management	ISO 14971:2019 Application of risk management to medical devices
Medical Device Software	IEC 62304:2006+A1:2015 Software life-cycle processes
Cybersecurity	IEC 81001-5-1:2021 Health software and health IT systems safety effectiveness and security Part 5-1: Security Activities in the product lifecycle AAMI TIR57:2016/(R)2023 Principles for medical device security - Risk management
Labelling and symbols	ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirement
Usability	IEC 60601-1-6:2010+A1:2013+A2:2020 Medical electrical equipment Part 1-6 General requirements for basic safety and essential performance- Collateral standard: Usability EN 62366-1:2015+A1:2020, Medical devices -- Part 1: Application of usability engineering to medical devices

8.5 FCC compliance

Both the Sensor and the Alarm Station comply with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation (FCC Title 47, Subpart A, Part 15.19(3)).
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

Radio interference

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult a representative of LivAssured or an experienced radio/TV technician for support

Radio power exposure

The Alarm Station is tested for radio power exposure limits at a minimum distance of 20cm from the body. When installing and operating the Alarm station a minimum distance of 20cm should be maintained.

8.6 Cybersecurity

LivAssured works according to the latest standards for security risk management to keep your data safe. The alarm station and sensor do not store any health data internally. Data recorded by the sensor is recorded for no more than 5 minutes.

The alarm station and the sensor are connected via DECT Ultra Low Energy (ULE). DECT has been standardized for the purpose of cordless telephony and ULE provides enhanced encryption. A connection according to the DECT standard uses subscription, authentication and encryption techniques to secure the data stream and uses a dedicated radio frequency for high stability. The DECT connection used by the NightWatch+ has been tested according to the latest standards for DECT.

Connecting to the NightWatch Portal is entirely optional, the system is fully functional without this connection. When connected, communication between the alarm station and the Portal is encrypted. The data is stored at a partner with ISO 27001:2022 certification, an international security standard that ensures having and maintaining a high security level of the data. Moreover, the data that the Portal displays is anonymous device recorded data and cannot be identified to any person.

9 Incident reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the country in which the user is established.

10 Service life and guarantee

NightWatch+ has a 2-year guarantee. In the event NightWatch+ is not working or seems to be working incorrectly, please contact LivAssured. See chapter 12 for contact details. The expected service life of NightWatch+ including the parts shipped with the device in case of daily use is 5 years.

11 Disposal

At the end of its useful life, NightWatch+ (with its battery) must be disposed of in accordance with local law and the local code concerning the disposal of electrical and electronic equipment including lithium-ion batteries. Do not discard NightWatch+ in a standard trash bin.

12 Contact information

Service and support

LivAssured
Schipholweg 103
2316 XC Leiden
Netherlands

NightWatch+ US is supplied by:
Unitron MedX, LLC
1941 Evans Road
Cary, NC27513-2041
USA

Support: +1 (919) 694-6670
Email: contact-us@nightwatchepilepsy.com

www.nightwatchepilepsy.com

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