NightWatch +

US version

Legal Manufacturer

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User Manual United States, Version 1.3
Date of issue: DRAFT

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Contents

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Thank you for choosing the epilepsy 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 the 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 Center 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 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 treatment.
In this manual, we explain how to get started and use your NightWatch+. We stand beside you, with our product, as well as help, advice and tips.

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1 General

1.1 About this user manual

This manual provides the information necessary to use the US version of the NightWatch+ in a safe and effective manner and is available in multiple languages. Please read the manual before using the device. If any part of this manual is unclear, please contact support. See section 8.2 for contact details. The latest revision of the User Manual can be found at www.nightwatchepilepsy.com

1.2 Explanation of symbols used

1.2.1 Symbols in the user manual

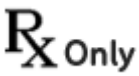
WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in death or a serious injury.

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.

1.2.2 Symbols on labels

The instruction manual must be read before use of the Device



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

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	Manufactured in the Netherlands, manufacturing date
	This symbol indicates a medical device
	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*
	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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1.3 General warnings and cautions

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 cause the hardware, algorithm, connectivity or communication to fail.
- Use of accessories, 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.

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 sensor and/or affect its performance.

2 NightWatch+

2.1 Indication for use

The NightWatch+ is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 4 and up in home or healthcare facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures hearth rate and motion data to detect patterns that may be associated with tonic-clonic, tonic (if cluster or prolonged), myoclonic (if clustered) or hyperkinetic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected by the Sensor of the NightWatch+, it wirelessly sends a command to the paired alarm station of the NightWatch+ which in turn alarms a designated caregiver. The system records and stores data from seizure events. The data can be viewed in a cloud based data portal.

***CAUTION**: Requires prescription: U.S. law restricts the sale of the NightWatch+ sale 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 as nocturnal seizures. Motor seizures are any type of seizures involving muscles in any way which can be 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 nerve system. Epileptic seizures affect this system in a complex way. Increases in heart rate are common during motor seizures but also sudden decreases in heart rates are seen. These changes in heart rate are used by NightWatch to detect seizures.

NightWatch+ is intended to alarm for the most dangerous nocturnal motor seizures associated with a risk on Sudden Unexpected Death in Epilepsy (SUDEP) or injuries[1] which are the following seizure types[2]:

- Tonic-Clonic
- Tonic (if cluster or prolonged)
- Myoclonic (if cluster)
- Hyperkinetic

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).

[1] Arends, JBAM. Movement-based seizure detection. Epilepsia. 2018; 59(S1): 30– 35.

[2] Nomenclature is based on the classification of epileptic seizures by the International League Against Epilepsy (ILAE): Fisher et al. 2017, Instruction manual for the ILAE 2017 operational classification of seizure types. Epilepsia, 58(4), 531–542.

2.3 Operation mode

NightWatch+ is a wearable device and consists of a wireless sensor and an alarm station. The sensor is worn during sleep on the biceps of the upper arm. The sensor consists of PPG (photoplethysmography) sensor to track the heart rate, an ACC (accelerometry) movement sensor, a microprocessor which 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 preprogramed parameters that are associated with Nocturnal Epileptic Motor Seizures, the epilepsy alarm is triggered and transferred to the accompanying alarm station. It is not possible or necessary to change the algorithms or set any thresholds to influence the performance of the device.
The sensor and alarm station communicate using the wireless DECT protocol. When an epilepsy alarm is transmitted from the sensor to the alarm station, the alarm station warns caregivers with alarm sounds and a red blinking LED light. A caregiver can then go to the person with epilepsy and, if necessary, assist according to instructions received by their physician.

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. Those reasons could be a depleted battery, a lost connection between sensor and alarm station (out of range) or when the sensor is unable to track a PPG signal or movements to perform seizure detection.

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

***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

2.4.1 Intended users

Users of NightWatch+ are people diagnosed with epilepsy aged 4 years and older, having Nocturnal Epileptic 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.*

2.4.2 Contra-indications

NightWatch+ has no contra-indications

2.4.3 Risk Factors

There are two risk factors which do not have to exclude a user but requires increased attention:

- 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+.*

2.4.4 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

It was observed for the previous generation of NightWatch+, the NightWatch Original (which consists of the same materials) that a small percentage of the users developed Skin irritation when wearing the sensor without the comfort patch. See chapter '3.2 Comfort patch'.

2.6 Clinical performance & benefits

Seizure detection sensitivity

Disease manifestation in the form of epileptic seizures can result in injuries, status epilepticus and even Sudden Unexpected Death in Epilepsy (SUDEP). Providing assistance during an epileptic seizure has been shown to decrease the risk on injuries for persons with epilepsy.

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 3 scientific studies, to detect these seizures[1,3,4].
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 median seizure detection sensitivity for the Nocturnal Epileptic Motor Seizures and for the tonic-clonic seizures in adult and pediatric cohorts being respectively:

- Adults: 86% Nocturnal Epileptic Motor seizures and 96% tonic-clonic seizures[1]
- Children: 100% Nocturnal Epileptic Motor seizures and 100% tonic-clonic seizures[4]

Using NightWatch+ leads to reduced stress for people with epilepsy and their caregivers.

[3] Lazeron, RH, Thijs, RD, Arends, J, Gutter, T, Cluitmans, P, Van Dijk, J, On behalf of the Dutch Tele-Epilepsy Consortium. Multimodal nocturnal seizure detection: Do we need to adapt algorithms for children? Epilepsia Open. 2022; 7: 406– 413.
[4] van Westrhenen, A., Lazeron, R.H.C., van Dijk, J.P., Leijten, F.S.S., Thijs, R.D. and (2023), Multimodal nocturnal seizure detection in children with epilepsy: a prospective, multicenter, long-term, in-home trial. Epilepsia.

***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+ can sometimes provide an epilepsy alarm when there is no epileptic seizure taking place or it alarms for a minor seizure which is a seizure with a very short duration. After an epileptic seizure alarm due to a minor seizure it could be that visibly it cannot be seen that there was an epileptic seizure. These occurrences are called false alarms.

NightWatch+ has a median false alarm rate for the Nocturnal Epileptic Motor Seizures detection in adult and pediatric cohorts being respectively:

- Adults: 0.03 per hour[1]
- Children: 0.04 per hour[3]

This means that most will experience less than 1 false alarm every 3-4 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 section 8.2 for contact details.*

Clinical Testing details

NightWatch was invented, developed and validated by a consortium of Dutch Neurologists from the Academic Centre for Epileptology at Kempenhaeghe and epilepsy center SEIN, multiple Universities and patient organizations. The device was tested in 3 studies of which the last 2 were performed in the home environment representative to the indicated use environment.

	Neurology®	Epilepsia Open™	Epilepsia
	Arends et al. 2018	Lazeron et al. 2022	Westrhenen et al. 2023
Patients	28	14	51
Age	15-67	3-17	4-16
Location	Institution	Institution/Home	Home
Nights	1826	497	3210
Seizures	809	384	552
Sensitivity Tonic Clonic seizures (median)	96%	98%	100%
Sensitivity All seizure types (median)	86%	93%	100%
False alarm rate/ hour (median)	0.038	0.078	0.040
Side effect mild, reversible skin irritation*	3	None	8

* *During these studies the device was worn directly on the skin without comfort patch. See chapter 2.5 possible side effects.*

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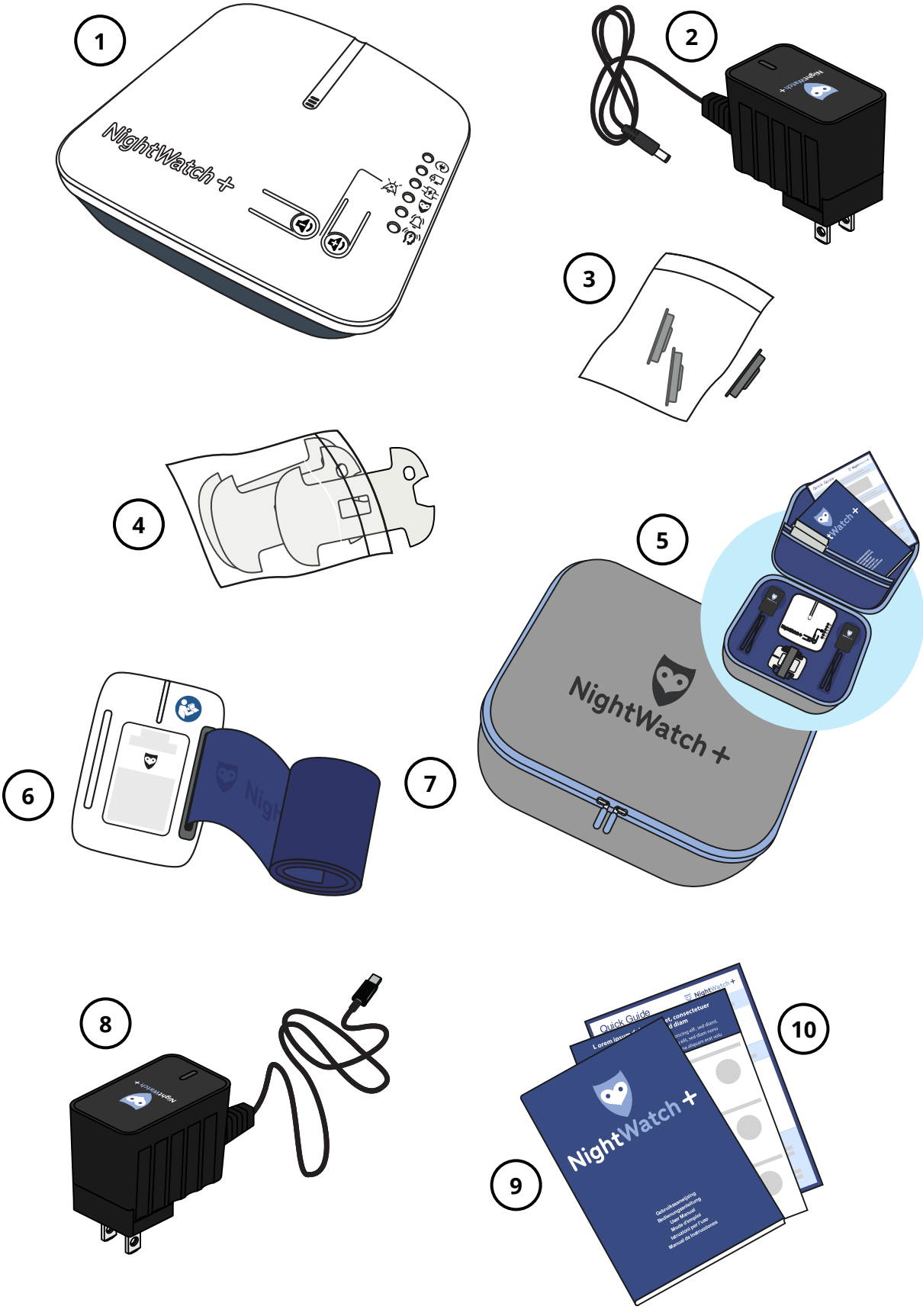
2.7 NightWatch+ package contents

The NightWatch+ package contains the following items:

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. Optional 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 (1m)
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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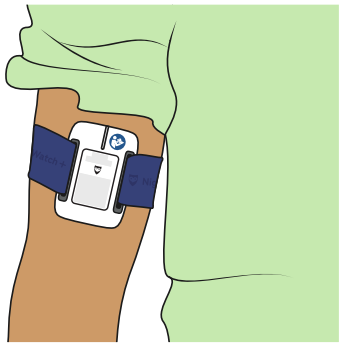
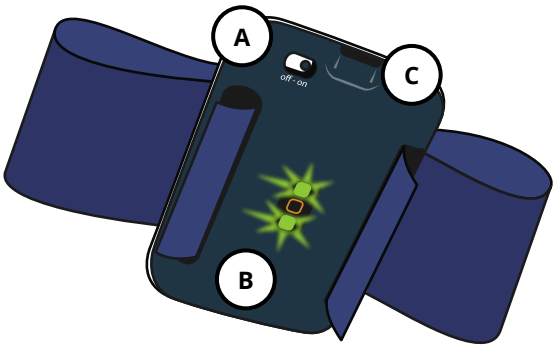
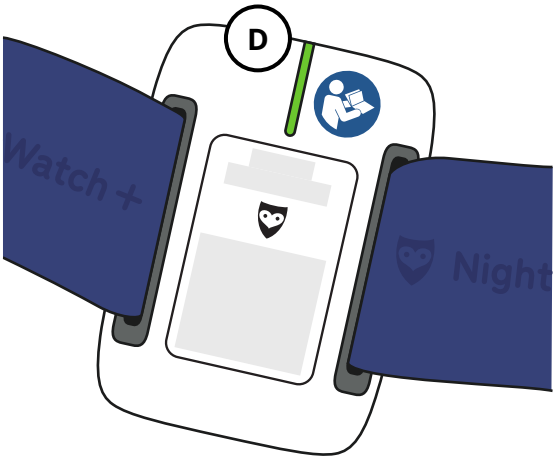
3 The different components and how they work

3.1 Sensor with elastic strap

The sensor is worn on the upper arm and held in place with an elastic strap. The best position for the sensor is around the upper arm on the front of the biceps, not on the side of the biceps. 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.







A = ON/OFF switch

B = PPG sensor & LEDs

C = Charging point

D = Indicator light

3.1.1 ON/OFF switch

The dark grey underside of the sensor contains an ON/OFF switch (A). The position can be switched 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.

3.1.2 Heart rate and movement sensor

The sensor continuously tracks the wearers heart rate and movement in order to detect epileptic seizures. The two green LEDs (B) on the dark grey underside of the sensor are used to track the wearer's heart rate. One green heart rate LED can shut itself off when there is too many environmental light. Both LEDs should turn on in the first seconds after you remove the sensor from the charger.

3.1.3 Charging port

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

3.1.4 Indicator light

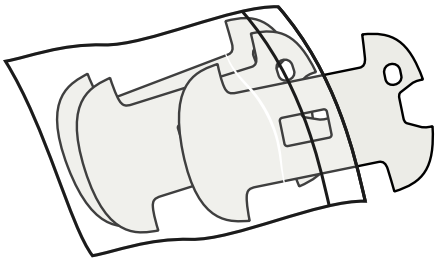
The notch on the white side of the sensor contains an indicator light (C). The brightness of this indicator is set for use in a darkened room and may consequently be more difficult to see in daylight / a brightly lit area. The indicator light is used for several signals. Read about these signals in Chapter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

3.2 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 latest 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 to replace it after one month. More comfort patches can be ordered via the website or by contacting LivAssured. See section 8 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.*

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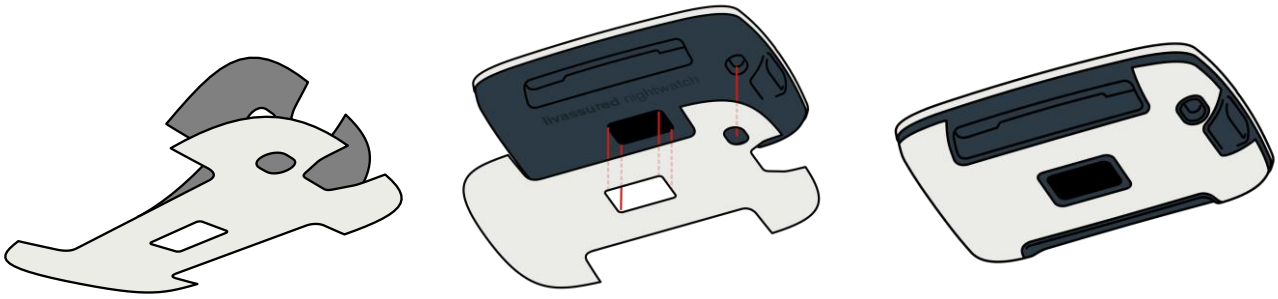
***CAUTION**: The sensor of NightWatch+ should only be worn on intact skin. Do not continue using the device on the same skin location in case the skin becomes red, itchy or if any pain is felt and place a comfort patch on the NightWatch+ sensor. Please contact LivAssured in this case. See section 8.2 for contact details.*

3.2.1 Applying the Comfort Patch

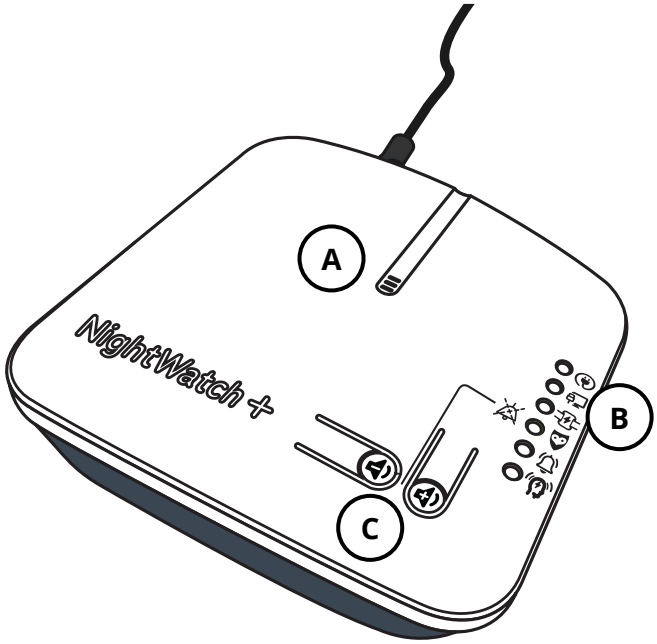
Remove the paper on the bottom of the patch and stick it over the dark side of the NightWatch+ sensor, using the middle hole and opening for the switch as position guides as shown in the figure below.



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

3.3 Alarm station

The square white box is the alarm station. It is able to emit both light and sound signals. The alarm station can be placed anywhere in a home near a power outlet.

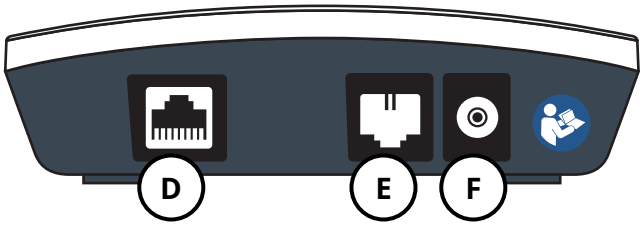


A = Loudspeaker

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

3.3.1 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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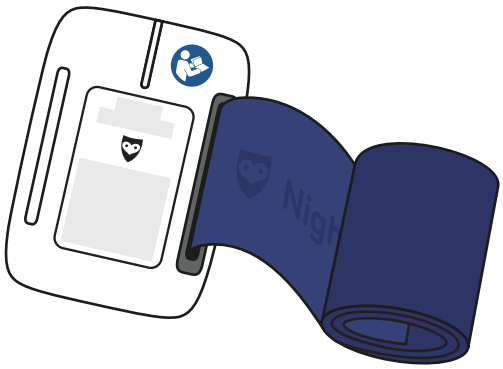
4 Using your NightWatch+

4.1 Preparing for first use

Step 1: Adjust the sensor strap

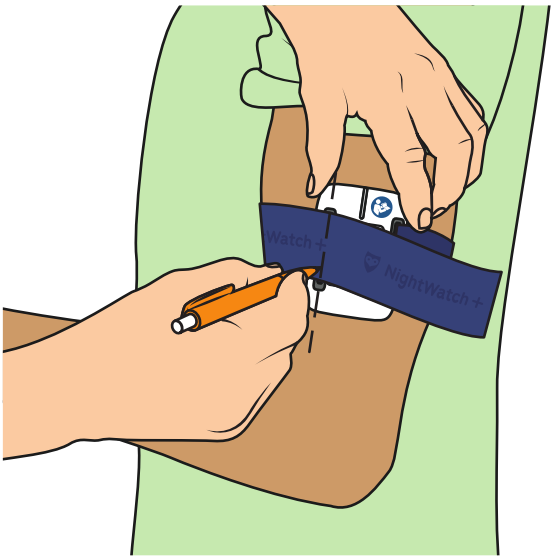
You will need:

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

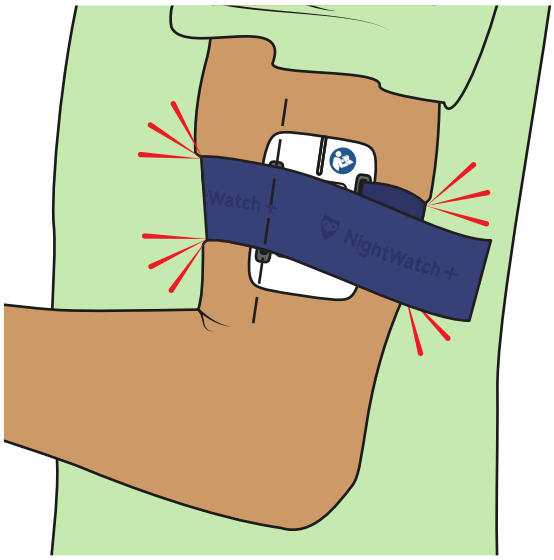


The elastic strap should be adjusted to the size of the upper arm of the wearer. One side of the elastic strap has already been fitted into the sensor.

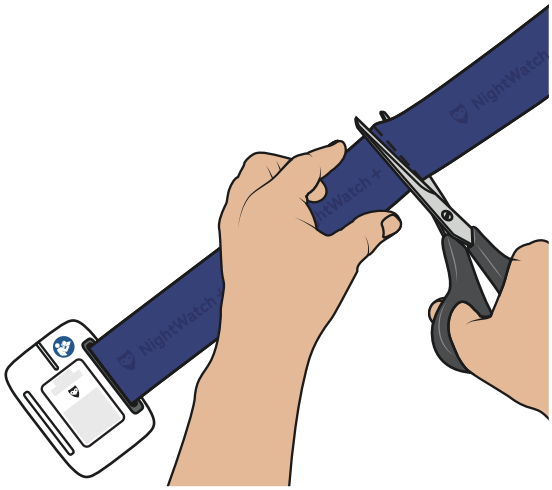
Use the remaining end of the elastic strap to measure the circumference of the wearer's arm above the biceps in a bent position. Do not stretch the strap.



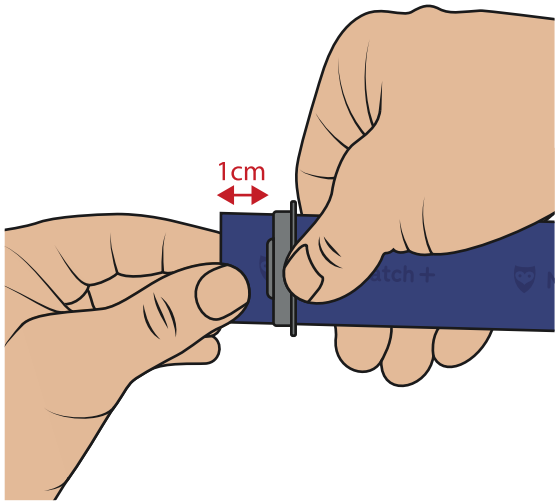
Mark the elastic strap where it overlaps the second sensor clip entrance and cut the elastic strap at the marked point.



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



Cut the strap on the marked location.



Attach one clip to the remaining end of the strap. Push one corner of the elastic strap through the clip and then pull the strap through the clip until it sticks out at a length of around one centimeter.

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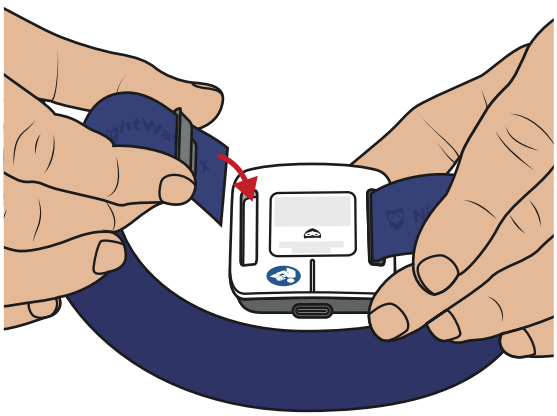
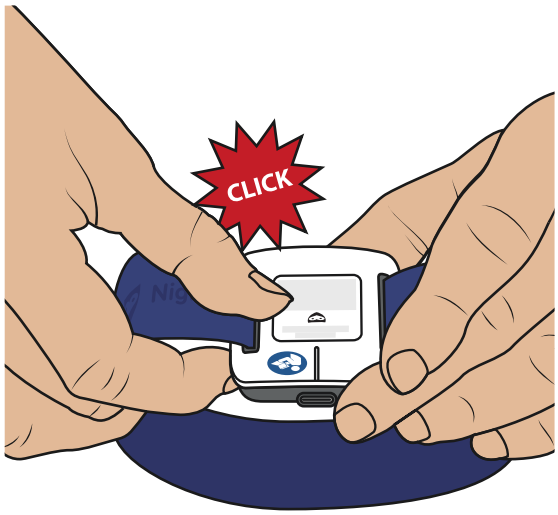
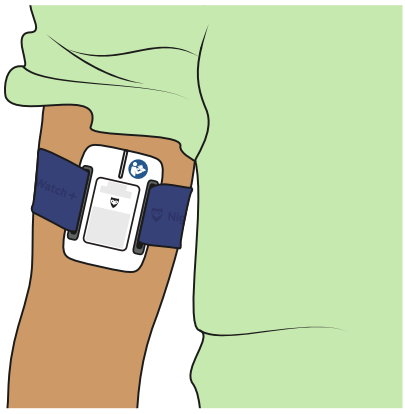




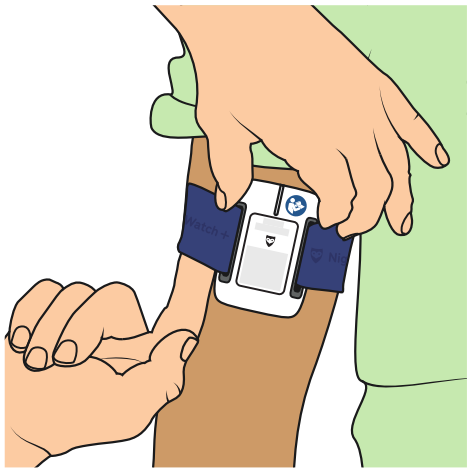
Attach the clip into the remaining slot of the sensor in a downward motion and make sure that the end of the strap is protruding from the lower end of the sensor.

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.*

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:

1. Using a fingernail, press the clips from below to remove them from the sensor.
2. Adjust the clips to make the space between the clips on the elastic strap longer.
3. 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 the excess ends off the strap with a scissor so that they do 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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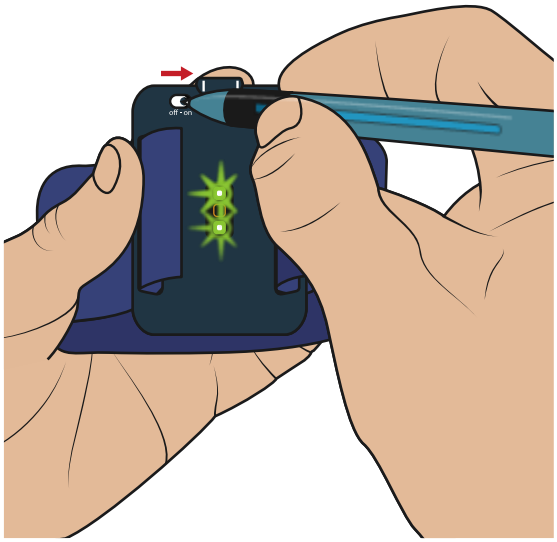
Step 2: First activation of the sensor

- Take a pointy object or pen/pencil
- The dark grey underside of the sensor houses an ON/OFF switch. Use a pencil to move this switch to the middle of the sensor to switch it ON.
- As soon as you have activated the sensor via the switch (ON), two green PPG LEDs will light up brightly on the dark underside. One LED can shut itself off when there is too much environmental light.
- You can now connect the sensor to the charger and plug it into a power supply to stop the seizure detection.
- Disconnecting the sensor from the charger starts the seizure detection.



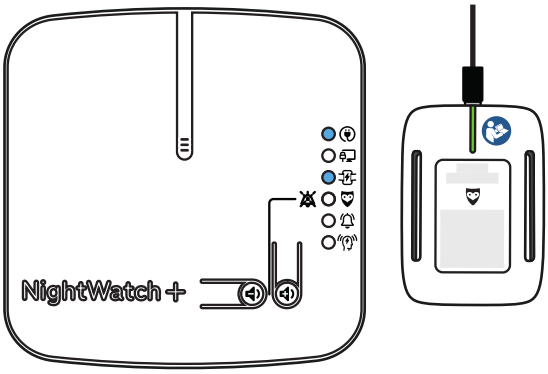
If you wish to turn the sensor OFF to prevent the battery from running out, use the ON/OFF switch to turn the sensor OFF. The sensor cannot charge when it is switched OFF.

Step 3: Using the alarm station

Placement
Position the alarm station where you want to receive the alarms. It is important that you can hear the sound signals from the alarm station. 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 in which NightWatch+ is used. It will usually be 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 that happens, move the alarm station closer to the sensor, or make sure the signal does not have to pass through too much walls.

Start-up
Ensure that the (activated) sensor is connected to the charger and that the alarm station is connected to the power supply. Approximately 30 seconds after connecting the alarm station to a power supply, blue LED 3 on the alarm station will start to blink ('sensor charging'). Once the sensor is fully charged, blue LED 3 will be lit continuously.



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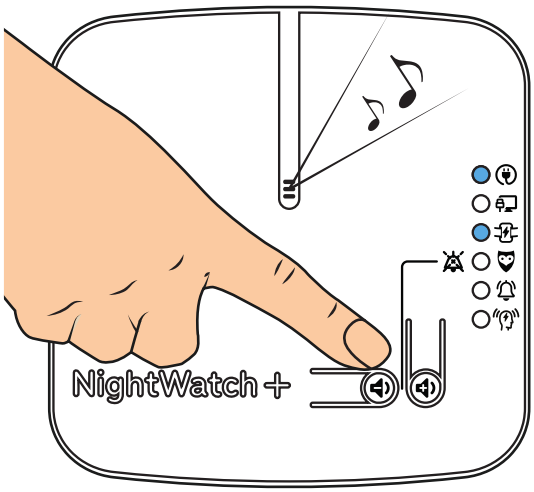
Adjusting the volume

When there is no active alarm, the volume of the alarm station can be adjusted as required using the volume controls and (see section 7.3). Ensure that you can hear the sound signal from the alarm station and that it is loud enough to wake you up while sleeping.



Your system is now ready to use.

Testing the alarm system

Remove the sensor from the charger and verify that the alarm station starts showing a blinking LED (orange) and emits an alarm sound indicating that no heart rate has been tracked yet. Notice that the alarm station is responding to the sensor, indicating that they are connected. Connect the sensor to the charger to stop the alarm.

CAUTION: *Only use the power adapters as supplied by LivAssured. Using a different charger or cable could damage the sensor 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.*

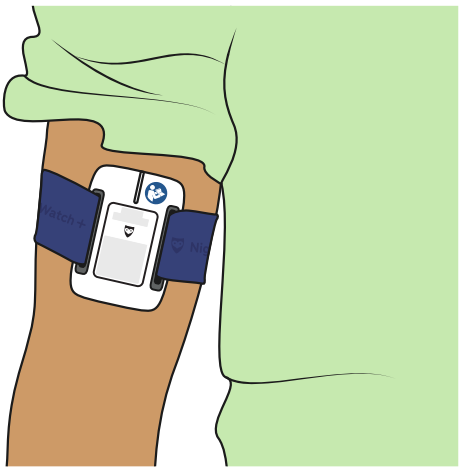
4.2 Daily use

1. Disconnect the sensor from the charger.

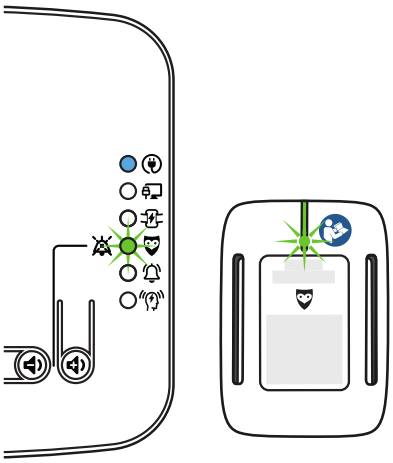
The alarm station will start showing a blinking LED (orange) and emit an alarm sound indicating that no heart rate has been tracked yet. This signal also confirms that the sensor and alarm station are responding to each other and that the alarms are audible.

***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 8.2 for contact details.*

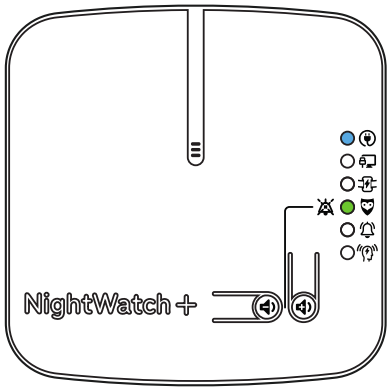
2. Place the sensor directly on the skin around the upper arm, on the thickest part of the biceps, with the sensor facing forward so that the wearer will not lie on it when lying on its side. Lying on the sensor could disrupt tracking the heart rate. It does not matter if the indicator light is facing up or down.



The alarm station and sensor will blink green when the heart rate is tracked. NightWatch+ is now in a low sensitivity state, where rapidly shaking movements or a low heart rate are required to trigger an epilepsy alarm.

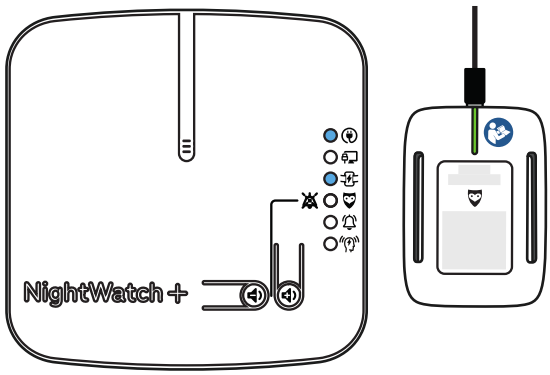


3. The wearer will now go to sleep. Once the wearer is lying down quietly and the sensor has detected very little to no movement for two minutes, the more sensitive epilepsy detection algorithms become active. When this occurs, the blinking green LED changes to a continuous green LED. NightWatch+ is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



As soon as the wearer rises or gets out of bed, NightWatch+ automatically switches to the low sensitivity state, until the wearer is lying down quietly again for two minutes.

4. When the wearer awakes, place the sensor back on the charger to stop the detection. As soon as the sensor is 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 low sensitivity state is not reached when wearing the sensor, please contact LivAssured. See section 8.2 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.*

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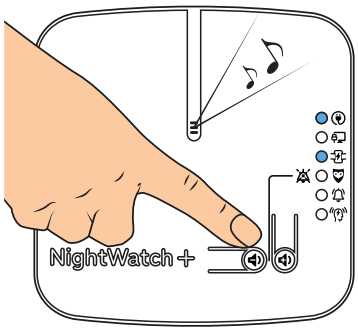
4.3 Managing alarm sounds

Touch buttons and allow you to regulate 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.



- Adjust 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 volume level is now saved and will not change when you disconnect the alarm station from the power supply.

- Pausing the audio of an alarm
  - Either button can be pressed if you wish to pause the audio during an alarm.
  - When an alarm audio is paused, a green flashing LED will be shown on the alarm station.
  - For epilepsy alarms the green flashing light means that you have acknowledged the epilepsy alarm. Epilepsy detection will resume automatically within 3 minutes after the acknowledging the alarm.

- Resuming the audio of an alarm
  - You can resume paused alarm audio manually by pressing either button again.
  - When a technical alarm is paused but still present after 10 minutes, the alarm audio will automatically become active again. For instance, if you pause a technical alarm because of 'no heart rate found', the alarm will sound again if the heart rate is still not found 10 minutes later.

***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.*

4.4 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 point. When you connect the sensor to the charger, the

green PPG LEDs will turn off. The sensor is designed to stay on the charger for long periods. When NightWatch+ is not in use, leave the sensor switched ON and connected to the charging unit. It will automatically stop charging when the battery is full and it cannot overcharge. During charging seizure detection is disabled

The sensor will only charge when switched ON. The sensor will not charge if the ON/OFF switch is switched OFF.

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

Sensor battery life:

- Battery charging time: approximately 2 hours.
- A fully charged battery should last 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 the 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.*

4.5 Maintenance & cleaning

NightWatch+ does not require periodic maintenance. For hygiene reasons, however, the sensor should be cleaned regularly with a damp cloth and a disinfectant. In case the comfort patch is used, please replace it with a new one when it is dirty, damaged or when it comes 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 device or parts of the device in water. Do not wear device in rain, bath or in shower. This can damage the device.*

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4.6 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 section 4.1.
Data from the device is stored only in the data portal if the device was connected to the internet. The data stored in the portal is data recorded by the device and not linked to any person. If the data portal was used it can be requested to delete the data before the device will be used by another person. See chapter 6.4.4 on how to delete the 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.*

4.7 Transport or storage

When NightWatch+ is stored or will be taken along while traveling, the alarm station and sensor have to be switched OFF to protect the battery from depleting.

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 now turn off.

On the sensor, use a pointy object or pencil/pen to switch the ON/OFF switch to OFF.

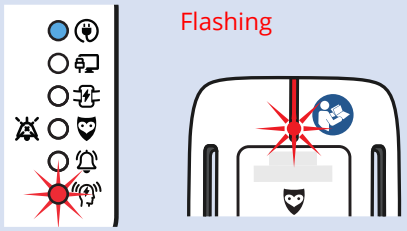
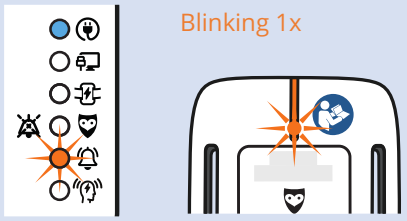
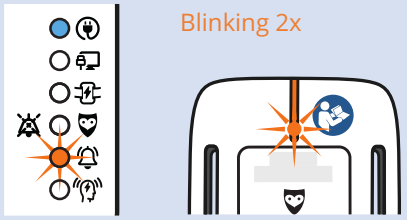
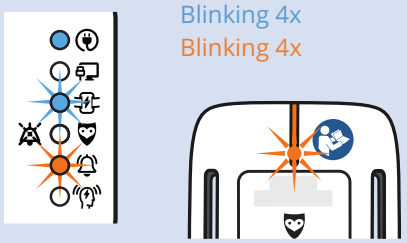
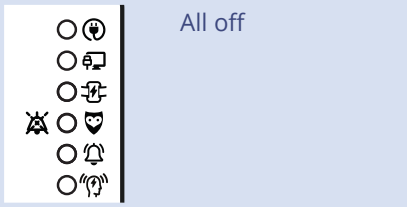
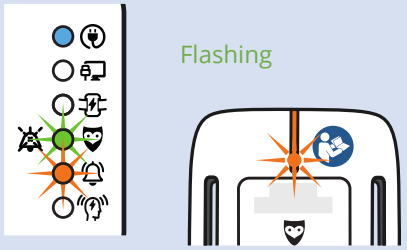
CAUTION: *The sensor and alarm station should be powered OFF during transport or storage or else the battery may be damaged. If you wish to use the system again, you can use the ON/OFF switch to switch the sensor back ON and charge it.*

5 Signals from the sensor and the alarm station

Both sensor and alarm station display signals about the status of the system. The sensor uses a light in the notch on the (white) top. 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 alarm station uses 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

5.1 Alarm signals

Light indicator	Sound	Meaning
 Flashing	**Fast** beeping melody 	**Epileptic seizure detected**, possible epileptic seizure, check on the wearer and when required provide aid when required according to your healthcare provider! Press either button to acknowledge the alarm and pause the audio. After 3 minutes the seizure detection automatically resumes.
 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.
 Blinking 2x	**Falling** melody of three beeps 	**Out of range**, the distance between the alarm station and sensor is too great or the sensor is switched OFF. Press either button to pause the audio.
 Blinking 4x 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.
 Flashing	**Pausing alarm audio signals** *Except for the "no power" alarm, all of the above alarm audio signals can be paused by pressing one of the volume buttons on the alarm station. A green flashing light, together with the already signaling alarm lights, will indicate this alarm is paused. New alarms will be audible.* *Example: When pressing one of the volume buttons while the "out of range" alarm is sounding, the alarm station lights will look as shown on the left. The green audio paused signal light will flash and the orange alarm light will continue to blink 2x repeatedly until the problem is solved.*	

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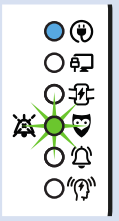
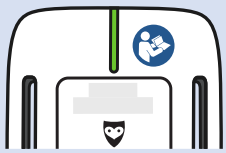
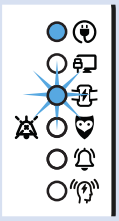
5.2 Information signals

Light indicator	Sound	Meaning
 Continuously on 	None	**Wearer is in rest and heart rate is tracked.** The wearer has been at rest (no movement) in a horizontal position for 2 minutes. NightWatch+ is in its highest sensitivity setting for detecting seizures.
 Blinking 	None	**Wearer is not in rest and heart rate is tracked.** The wearer has not been at rest in a horizontal position for 2 minutes yet or has recently become upright. NightWatch+ is in a lower sensitivity setting for detecting seizures but is operational.
 Continuously on 	None	**The sensor is connected to the charger and is fully charged.** Disconnect the sensor from the charger to start recording.
 Blinking 	None	**The sensor is connected to the charger and is charging.**

NightWatch+ has a low sensitivity and a high sensitivity state for seizure detection.

Low sensitivity
When the sensor is removed from the charger and the heart rate is tracked, the green light indicator will blink. NightWatch+ is now in a low sensitivity seizure detection state, seizure detection will be triggered by bigger movements and low tracked heart rate only.

High sensitivity
When the sensor is reading a heart rate , is lying down in an angle lower than 45 degrees and limited to no movement is detected for 2 minutes, the green light indicator will be continuously on. This is interpreted by NightWatch+ that the patient is in rest. NightWatch+ is now in a high sensitivity seizure detection state, seizure detection will trigger on smaller movements and/or on heart rate changes. Only when a seizure alarm is given or when the wearer gets out of bed or into an upright position, the sensitivity will drop to low.

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

5.3 Responding to alarms

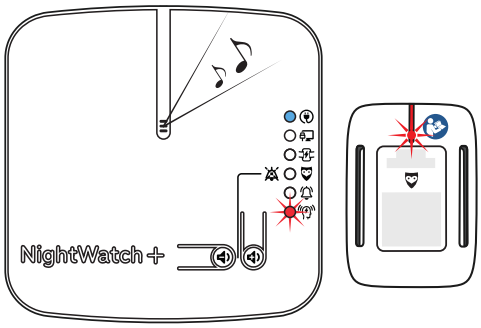
5.3.1 Simultaneous alarm conditions

NightWatch+ alarms are assigned a priority. If multiple alarm conditions occur at the same time NightWatch+ announces the highest priority alarm. All technical alarms are medium priority. If multiple technical alarm conditions are active at the same time, NightWatch+ announces the most severe.

5.3.2 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 when required provide aid as instructed by your physician. This alarm remains active until someone presses one of the buttons. When pressed, NightWatch+ will automatically continue tracking seizures after 3 minutes maximum.



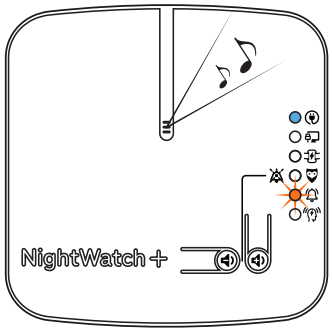
NightWatch+ could have raised an epilepsy alarm based on the following reasons:

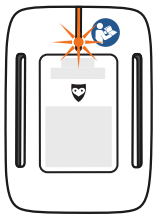
Type	Description
Rhythmic movements	Rhythmic movements have been detected which could be the result of epileptic activity
Vibrating movements	Vibrating/muscle tension movements have been detected which could be the result of epileptic activity
Shaking movements	Wild shaking movements have been detected 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

5.3.3 Technical alarms

Blinking orange: Technical alarm
Priority: medium

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





PLEASE NOTE: *If the alarm station makes a sound not described in the manual, please contact LivAssured. See section 8.2 for contact details.*

Unable to track heart rate
You will hear this alarm as soon as you remove the sensor from the charger. This alarm will stop as soon as NightWatch+ tracks a heart rate. Hold still for the heart rate to be tracked quicker. This alarm will sound again when the sensor is not tracking heart rate and movement for at least 2 minutes. Please remember that NightWatch+ is not a heart rate monitor, but tracks the heart rate besides movement to detect seizures.

There are several possible causes of a temporary or permanent failure to track a reliable heart rate:

- The PPG sensor is not correctly positioned on the skin. Make sure that the green LEDs on the underside of the sensor make direct contact with the skin.
- The sensor may fit too loose, have slid off, or been taken off. In that case, tighten the elastic strap a little.
- The wearer may be lying on the sensor, which complicates registration. Change the position of the sensor so that the wearer will not lie on top of it so easily. Try to place it on the bicep muscle, not on the outside of the arm, but more towards the inside (arm pit).

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

- The sensor and the alarm station are too far apart. Place the alarm station and sensor closer together.
- The sensor is switched OFF. Switch the sensor ON by using 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 is showing a continuously (not blinking) orange LED in the notch. If this is the case, press and hold both volume buttons on the alarm station for 20 seconds. The sensor should automatically connect with the alarm station again.

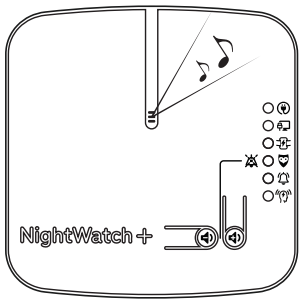
Sensor battery low
This alarm means that the sensor battery is nearly empty. You will no longer be able to use NightWatch+. Connect the sensor to the charger.

If this alarm appears repeatedly despite correct and sufficient charging, please contact 'Service and support'. See section 8 for contact details.

5.3.4 Power loss alarm

No LED, constant beep: Power loss
Priority: high

When the alarm station has no power, a 'power loss' alarm sounds. Power the alarm station to stop the alarm, or press one of the volume buttons to turn off your alarm station completely.



6 Seizure monitoring

6.1 The Online 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 system along with the alarms will be sent to the Portal. This data can be viewed via the portal.nightwatchepilepsy.com website.

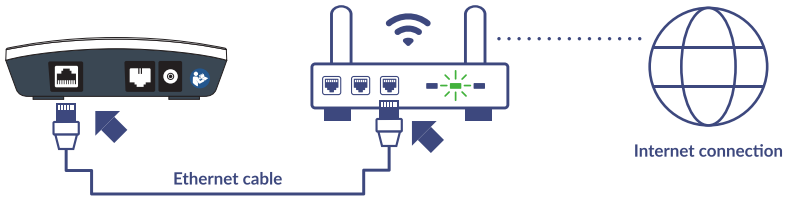
The Portal can provide insight into what happened while sleeping and helps to better understand why NightWatch did or did not give alarms. Furthermore, it can be used as input for a diary to track seizure frequency and to share this data together with your experiences with your neurologist. It is also helpful for troubleshooting.

The base station does not store any data internally. The base station will only send data to the Portal when it is recording and connected to the internet via a cabled internet connection.

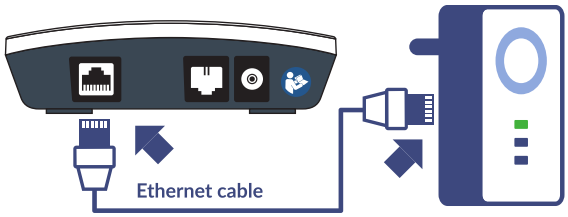
6.2 How to connect to the Online Portal

1. A permanent wired connection from the NightWatch+ alarm station to an internet access point like a router needs to be established.

2. Find an internet access point (router) closest to the NightWatch+ alarm station and use an ethernet cable to connect both.

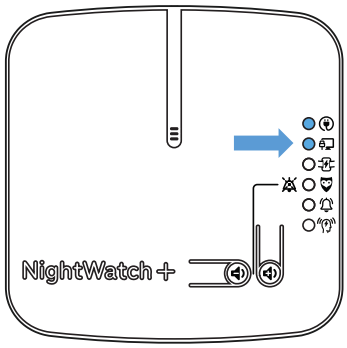


3. If the nearest access point is too far away for a cable connection, we recommend bridging the connection with a powerline adapter, WiFi repeater or mobile router.



4. Once NightWatch+ is connected to the internet, the second blue indicator LED on the base station will light up, confirming the internet connection.

5. Once a recording has been made while NightWatch+ was connected to the internet, an account for the device will automatically be created. Following this step, you can access the Portal through the website.



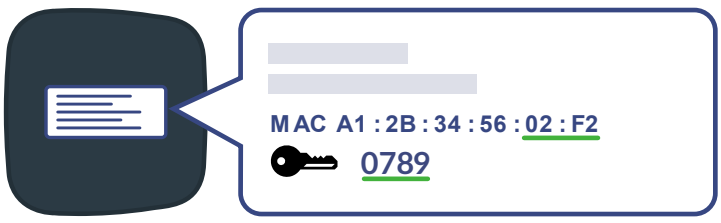
6.3 Getting started using the Online Portal

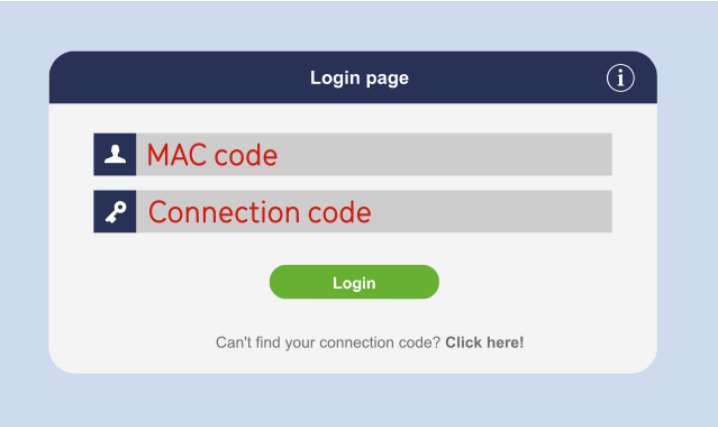
You need two unique numbers of your NightWatch+ to access the data of your device on the Online Portal.

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 0789.

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





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.

6.4 What's there to view?

6.4.1 Language

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

Once you enter the Online 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.

6.4.2 Reports page

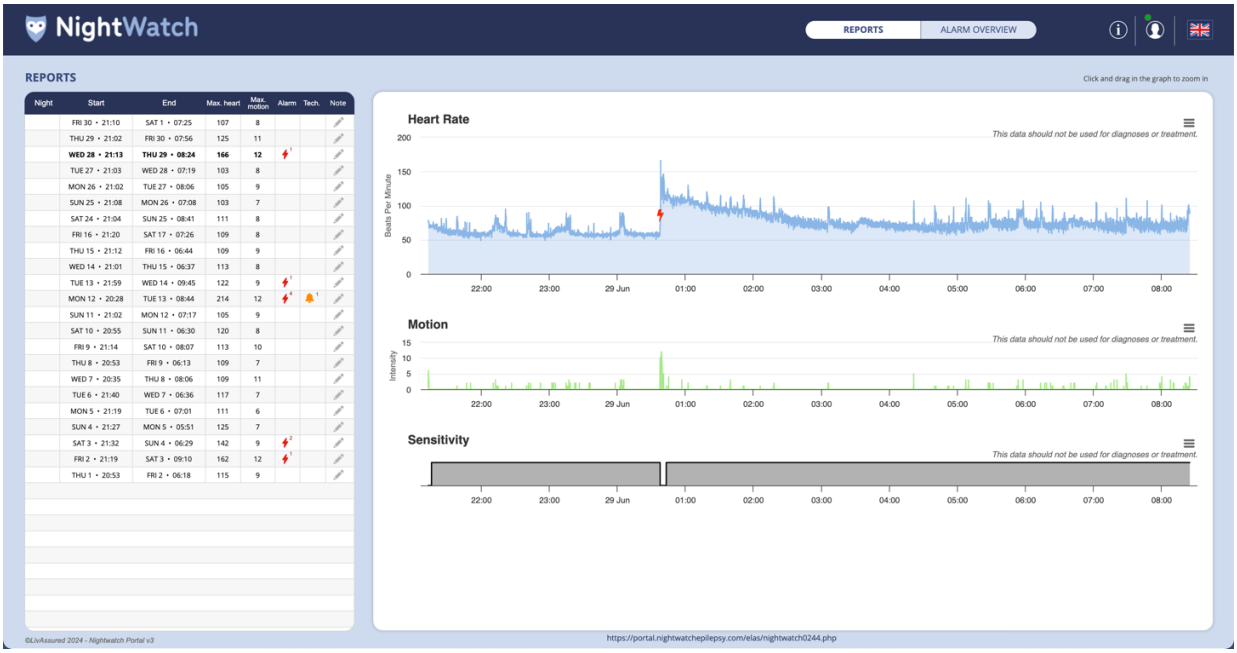
This page shows an overview of all the reports made in a specific month. Each line provides a summary of the report, including details such as the total number of seizures and technical alarms recorded. Notes can be added to a report by clicking on the grey pen under 'Note'. Clicking on a report of a 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

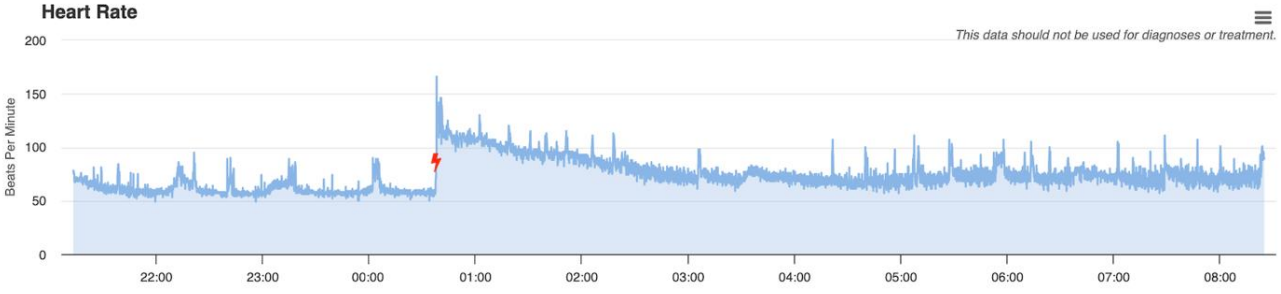


When hovering over a graph or alarm with the cursor, the values at that point in time can be seen. It is also possible to zoom in on the graphs. Click and drag in the graph to zoom in.

When clicking the link shown above the graph, it will launch in a new browser window. In this window, you will remain logged in without being automatically logged out after a short period. Additionally, this window is designed to automatically refresh every 5 minutes, ensuring that any new data is updated in real time as you monitor the graphs live during 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.

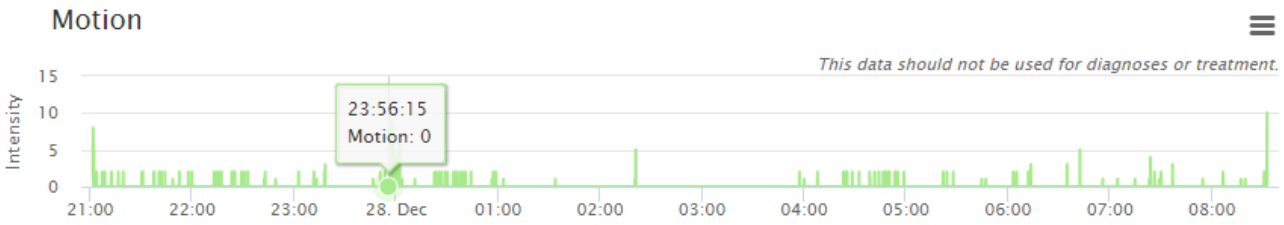


EN

***CAUTION**: The PPG sensor in NightWatch+ is not intended to perform as a heart rate monitor. The PPG data is solely used to identify an epileptic seizure and is fit for this purpose. Do not use this data to draw conclusions on the cardiovascular health of the wearer. If you suspect something wrong then deliberate with your healthcare provider.*

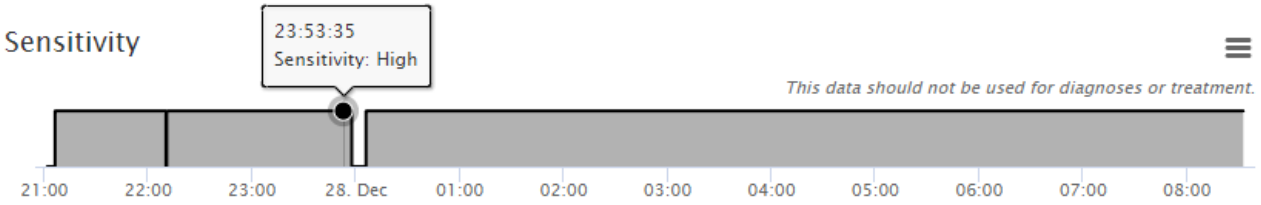
Green Graph: Motion Signal.

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 arm module is shaken wildly. To illustrate this, when someone turns over in bed a low movement value will be depicted, but when the arm module detects zero-crossings because of shaking movements, the motion value will be increased. The degree of intensity is indicated on a 0-15 scale.



Black and Grey Graph: Sensitivity state

The sensitivity graph shows if NightWatch+ is operating in a 'low sensitivity' mode or in a 'high sensitivity' mode.



The high and low sensitivity states are designed in order to reduce false alarms for when someone leaves the bed during the night or while waking up. The sensitivity settings of NightWatch+ cannot be changed.

Sensitivity mode	State enabled	Seizure detection mode	Indicator on base station
Low sensitivity	The sensor wearer is not in a horizontal position or has not been motionless for 2 consecutive minutes in the past.	NightWatch+ will only alarm for epileptic seizures after detecting wild shaking movements or a low heart rate	Green blinking LED

EN

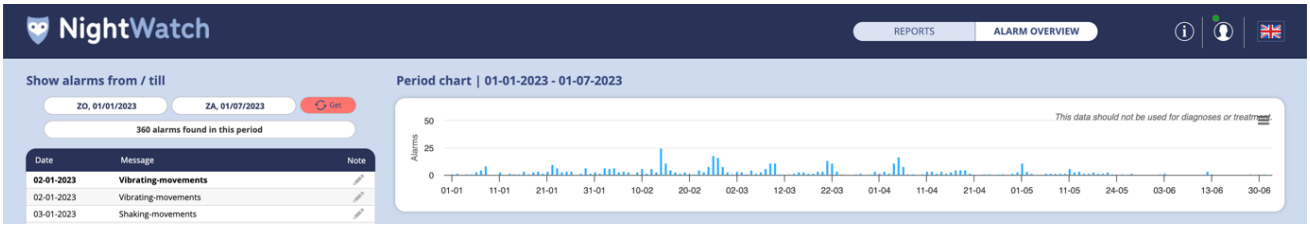
High sensitivity	The sensor wearer is in a horizontal position and has been motionless for 2 consecutive minutes somewhere in the past.	All seizure detection algorithms are active while NightWatch+ operates in 'high sensitivity' mode	Continuous green LED

High sensitivity:
This means that the sensor wearer is resting in a horizontal position. As soon as the wearer of the sensor is in a horizontal position and has not been moving for 2 consecutive minutes, the sensitivity will automatically change to 'high'. All seizure detection algorithms are active while NightWatch+ operates in 'high sensitivity' mode. The system will show a continuous green LED when this mode is active. The sensitivity of NightWatch+ will only decrease to 'low' when the wearer transitions to an upright position or when a seizure alarm is triggered. An upright position indicates that the arm module is positioned at an angle greater than 45 degrees, such as when the wearer has risen from bed or is raising their hands in the air.

Low sensitivity:
Low sensitivity mode means that the sensor wearer is not in a horizontal position or not yet in rest i.e. less than 2 minutes of no movement. When NightWatch+ is operating in low sensitivity, it will only alarm for epileptic seizures after detecting wild shaking movements or a low heart rate. On the base station the 'low sensitivity' mode can be recognized by a green blinking LED. The sensitivity settings of NightWatch+ cannot be changed. Please contact LivAssured if seizures are missed because of long periods of low sensitivity.

6.4.3 'Alarm overview' page

On this page you can make an overview of all seizure alarms registered during a certain period that you can choose. The period is 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.

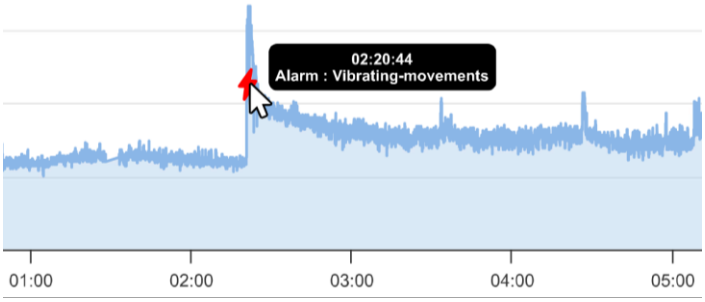
6.4.4 'Settings' page

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.

6.4.5 Alarms of NightWatch+ in the Online 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 that match epileptic activity
Vibrating movements	Vibrating/muscle tension movements have been detected that match epileptic activity
Shaking movements	Wild shaking movements have been detected that match epileptic activity
Heart rate increase	The average tracked heart rate rose suddenly, matching epileptic activity
High heart rate	The tracked heart rate is high compared to a moment before, matching epilepsy indicators
Low heart rate	The tracked heart rate is low

The algorithm and heart rate thresholds that trigger an alarm cannot be modified.

***PLEASE NOTE**: The Online 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.*

The portal also shows when a technical alarm occurred:

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

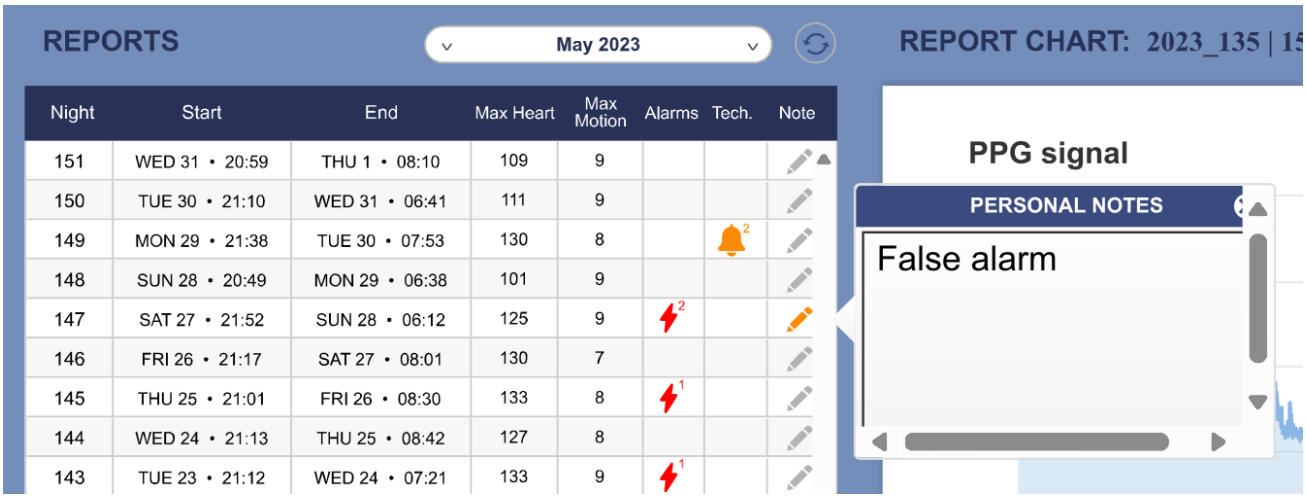
For explanation of the technical alarm conditions see section 0.

EN

6.4.6 Annotating Alarms

The Online Portal shows all alarms provided by NightWatch+. This includes epilepsy alarms that did not arise from an epileptic seizure. The Online 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.



6.5 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.

6.6 Integration of NightWatch+ with other devices

The device offers two different ways to connect to third party information systems or alarm systems. These are only available for professional use upon request. It involves the RJ-11 port for connection to a Distributed Information System and the RJ-45 port for connection to a Distributed Alarming System. There are no other interconnections possible. Please contact LivAssured for more information.

7 Technical specifications

7.1 Specifications NightWatch+

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	45 to 85 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 8 for contact details.*

7.2 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

EN

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

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.*

7.3 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	
	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/burst s 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 this descriptions may cause disturbances leading to a loss of connection between the sensor and the alarm station.*

7.4 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. 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 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 27001:2013 certification, an international security standard that ensures having and maintaining a high security level of the portal data. Moreover, the data that the portal displays is anonymous device recorded data and cannot be identified to any person.

8 Regulatory and Compliance

8.1 Laboratory testing

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. Tests have been performed according to the following standards:

Basic safety and essential performance	EN 60601- 1:2005/(R)2012 + A1:2012 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 EN 301 489-1 V2.2.0 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU 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; Harmonised Standard covering the essential requirements of article 3.1(b) of the Directive 2014/53/EU
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
Specific Absorption Rate (SAR)	EN 50566:2017/A1:2023 Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body
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	EN 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.
Biocompatibility	EN ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-5:2009 Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity EN ISO 10993-10:2021 Biological evaluation of medical devices, Part 10: Tests for skin sensitization EN ISO 10993-23:2021 Biological evaluation of medical devices, Part 23: Tests for irritation
Risk Management	EN ISO 14971:2019 Application of risk management to medical devices AAMI TIR57:2016/(R)2023 Principles For Medical Device Security—Risk Management
Medical Device Software	EN 62304:2006/A1:2015 Software life-cycle processes
Cybersecurity	EN 81001-5-1:2021 Health software and health IT systems safety effectiveness and security Part 5-1: Security Activities in the product lifecycle
Labelling and symbols	EN 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	EN 60601-1-6:2010/A2;2021 Medical electrical equipment Part 1-6 General requirements for basic safety and essential performance- Collateral standard: Usability EN 62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices
FCC	FCC 47 CFR Part 15 Radio Frequency Devices

8.2 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.

9 Contact information

Service and support
LivAssured Schipholweg 103 2316 XC Leiden Netherlands Email: info@nightwatchepilepsy.com Website: www.nightwatchepilepsy.com

10 Incident reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA via MedWatch.

11 Service life and guarantee

NightWatch+ has a 2-year guarantee. In the event the device is not working or seems to be working incorrectly, please contact LivAssured. See section 8 for contact details.

The expected service life including the parts and accessories shipped with the device in case of daily use is 5 years.

12 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 in a standard trash bin.

End of document