# NightWatch+



#### Legal Manufacturer



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# 1 General

## 1.1 About this manual

This the NightWatch Portal manual which provides the information necessary on how to connect your device and use NightWatch Portal. It is complementary to the NightWatch+ User Manual. Please read the NightWatch+ User Manual before using NightWatch+. If any part of this manual is unclear, please contact support. The latest revision of the User Manual can be found at <u>www.nightwatchepilepsy.com</u>

## 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.

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**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.



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.
- Cords pose a strangulation hazard that may lead to death.

# 2 Seizure monitoring

## 2.1 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.

## 2.2 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.

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



 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.

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Ţ	Ethernet cable		Ξ
		B	

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



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

## 2.3 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 <b>Carro</b> 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.





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.

### 2.4 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.



#### **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.

🦁 Nig	ghtWatch	IEPOETS ALAAM OVERVEN	0 0 =
Show alarn	ns from / till	Period chart   01-01-2023 - 01-07-2023	
20,	0100/2023 DA 00/07/2023 O 00	to This data about not be sam	d for diagnoses or beatment.
	360 alarms feand in this period		-
Owne	Nessage	a second calls and the second second second	
02-01-2023	Vibrating movements		
02-01-2023	Worating movements	81-01 11-01 21-01 21-01 10-02 20-02 02:00 12:00 22:00 01-04 11-04 21-04 01-05 11-05 24-05 00	106 13-06 20-06
05-01-2023	Shaking movements		

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.

antingurostatutu aphtinguquettatungu		42-230-44 Alarm : Vibrating movements		-

#### '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:

Туре	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:

Туре	Description
Unable to detect	The sensor was unable to reliably detect a heart rate
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	The alarm station lost connection with the sensor. Most
lost	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	The movement sensor of the sensor is defect.
error	

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.



## 2.5 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.

# 3 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.

# 4 Contact information

Service and support



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