

NightWatch

Epileptic seizure detection
during sleep



version 3.0 EN



NightWatch

NightWatch is a clinically validated seizure detection solution for nocturnal epileptic motor seizures

NightWatch is a CE certified medical device intended for persons with epilepsy from 4 years and older who are experiencing nocturnal epileptic motor seizures of the following types:

- > Tonic-clonic seizures
- > Hyperkinetic seizures
- > Tonic seizures (if clustered or prolonged)
- > Myoclonic seizures (if clustered)






NightWatch detects 9 out of 10 nocturnal epileptic motor seizures by combining data from a photoplethysmography (PPG) sensor to detect heart rate and an accelerometer to detect movement.

In case a seizure is detected, a wireless alarm signal is sent to the remote base station that warns a caregiver.

Benefits of NightWatch

The unpredictability of seizure occurrence, especially at night, is distressing for parents and caregivers since persons who experience seizures during sleep may need help, but are not able to call for help during seizures. Timely intervention by caregivers during nocturnal epileptic motor seizures can be crucial in preventing injuries, status epilepticus and SUDEP (Sudden Unexpected Death in Epilepsy).

NightWatch helps caregivers by detecting seizures during sleep that may need intervention. This has been shown to significantly reduce stress on caregivers and even the cost of care.

-  Detects seizure types that may lead to injuries, status epilepticus or SUDEP
-  Reduces caregiver stress
-  Reduces the cost of care
-  Suitable for home and professional use
-  Suitable for adults and children (4+)

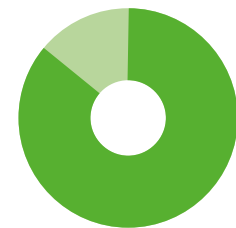


See hundreds of independent caregiver reviews on Kiyoh.

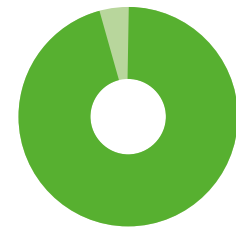


Clinical Validation of NightWatch

NightWatch has been clinically validated in phase 3 and 4 prospective, multicenter, video-monitored cohort trials in residential and home settings. ^{1, 2, 3)}

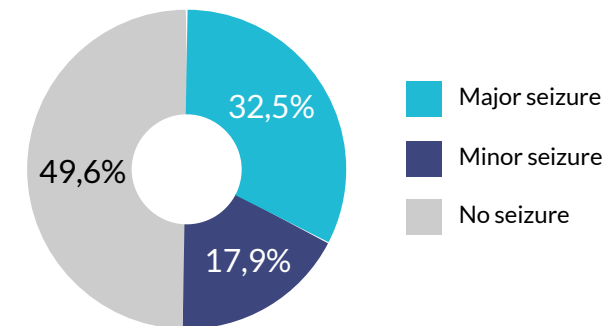


Median detection sensitivity range
86-100%
of all major motor seizures.



Median detection sensitivity range
96-100%
of all tonic-clonic seizures.

Positive predictive value of all NightWatch alarms



Minor seizures are epileptic seizures detected by NightWatch, that did not qualify as a major motor seizure.

Summary of clinical findings



Median sensitivity range of all tonic-clonic seizures: 96-100%



Median false positive: 0.04/hour



Median sensitivity range of all major nocturnal epileptic motor seizures: 86-100%



Long-term comparison showed better sensitivity (median difference of 58%) for NightWatch compared to a bed sensor



Significant stress reduction after 2-month intervention CSI score: 8.0 vs 7.1 ; $p = 0.032$



NightWatch can reduce societal costs by 775 EUR after 2-month intervention

Epilepsia^{® 1)}

Published: May 17, 2023

Multimodal nocturnal seizure detection in children with epilepsy: A prospective, multicenter, long-term, in-home trial.

Anouk van Westrhenen, Richard H. C. Lazeron, Johannes P. van Dijk, Frans S. S. Leijten, Roland D. Thijs, the Dutch Tele-Epilepsy Consortium

- 51 children aged 4-16 at home, 2310 nights, 552 major nocturnal epileptic motor seizures
- Sensitivity of 94% for TC, overall sensitivity for major nocturnal epileptic motor seizures 89.5%
- False alarm rate 0.04/h
- Significantly lower caregiver stress scores during NightWatch use



seizure²⁾

Published: August 16, 2022

An economic evaluation of the NightWatch for children with refractory epilepsy: Insight into the cost-effectiveness and cost-utility.

Anouk Engelgeer, Anouk van Westrhenen, Roland D. Thijs, Silvia M. A. A. Evers

- 41 families used NightWatch for two months
- Two months of NightWatch implementation showed a decrease in mean costs of €775
- Cost-effectiveness probability was 72% for NightWatch at a €50,000 cost-effectiveness threshold



Neurology^{® 3)}

Published: October 24, 2018

Multimodal nocturnal seizure detection in a residential care setting. A long-term prospective trial.

Johan Arends, Roland D. Thijs, Thea Gutter, Constantin Ungureanu, Pierre Cluitmans, Johannes van Dijk, Judith van Andel, Francis Tan, Al de Weerd, Ben Vledder, Wytske Hofstra, Richard Lazeron, Ghislaine van Thiel, Kit C. B. Roes, Frans Leijten and the Dutch Tele-Epilepsy Consortium

- 28 adults aged 15-67, 1826 nights, 809 major motor seizures
- Sensitivity of 96% for TC, overall sensitivity for major motor seizures 86%
- PPV 49%
- NightWatch showed a better sensitivity than the Emfit bed sensor (median difference 58%)



NightWatch Multimodal Seizure Detection



	Arm module	Base station
Environment	Home, care home, professional healthcare facility	
Weight	35 grams	90 grams
Dimensions	72mm x 52mm x 14mm	100mm x 100mm x 28mm
Grid voltage	100V-240V AC / 50Hz-60Hz	
Power usage	0.5A	2.0A
Motion measurements	3D accelerometry	
Heart rate	Photoplethysmography (PPG)	
Wireless connection	DECT Ultra Low Energy Indoor range max 15 meters	
Connectors	RJ-11 and RJ-45	
Registration	CE Medical device class I	
Body contact	Arm module class BF	

Parents and caregivers

Healthcare professionals

Patients living independently

Couples



Registered place of business:
LivAssured B.V.
Venusstraat 17
4105 JH Culemborg
The Netherlands



Notes:



LivAssured B.V.

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