A summary of the clinical evidence of NightWatch

Version 2.0 EN

The International League Against Epilepsy (ILAE) acknowledges the importance of automated Wearable Seizure Detection Devices (WSDDs).

Self-reporting of seizures is unreliable, with 86% of nocturnal seizures going unnoticed.

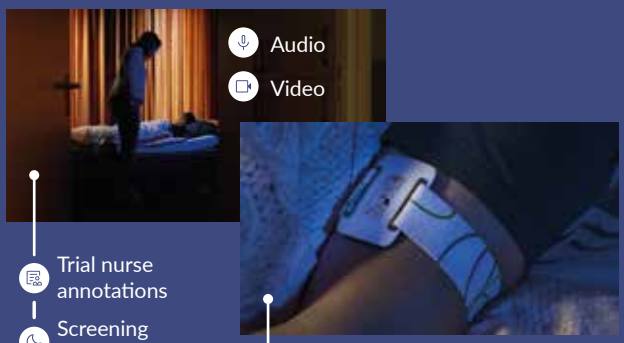
Timely intervention is important in preventing injuries and SUDEP (Sudden Unexpected Death in Epilepsy) associated with tonic-clonic seizures.

The unpredictability of seizures can lead to social isolation, distress and decreased quality of life.

The international guidelines[1] recommend the use of sufficiently validated WSDDs for people with uncontrollable tonic-clonic seizures:

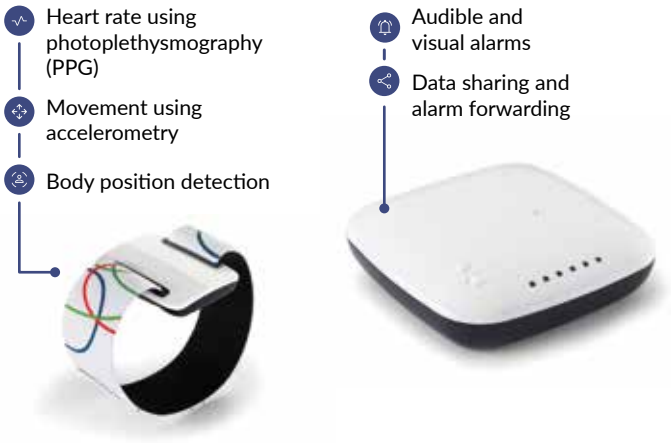
1. To decrease seizure morbidity and mortality
2. To obtain more objective quantification of seizures
3. To support therapeutic decision-making

Clinical research method



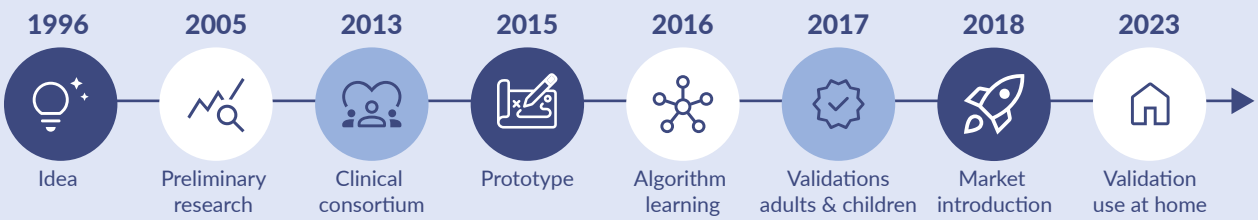
NightWatch has been validated in phase 3 and 4 prospective, multicenter, video-monitored cohort trials in residential and home settings.

NightWatch Multimodal Detection



NightWatch notifies caregivers on the occurrence of major nocturnal motor seizures in order to take appropriate caring measures.

NightWatch development and validation timeline



NightWatch was invented, developed and validated by a consortium of Dutch neurologists, patient organizations and universities and is part of our conjoined mission to reduce SUDEP and improve the quality of life of people with epilepsy and their caregivers.

Clinical Results

	Neurology® Arends et al.[2] 2018	Epilepsia Open™ Lazeron et al.[3] 2022	Epilepsia Westrhenen et al.[4] 2023
Patients	28	14	51
Age	15 - 67	3 - 17	4 - 16
Location	Institution	Institution/Home	Home
Nights	1826	497	2310
Seizures	809	384	552
Sensitivity for tonic-clonic seizures (median)	96%	98%	100%
Sensitivity for all seizure types (median)	86%	93%	100%
False alarm rate/ hour (median)	0.038	0.078	0.040

Secondary outcomes (after 2 months intervention) [2,3,4,5]

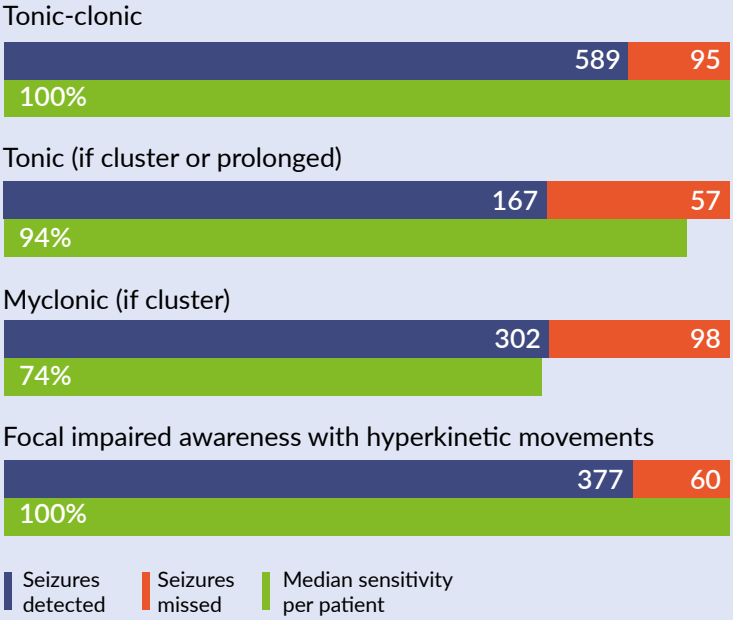
→ Significant stress reduction (mean total Caregiver Strain Index (CSI) score 8.0 vs 7.1 ; p = 0.032)
→ Easy to use for caregivers
→ Timelier response

Calculated cost of care reduction in 2 months by using NightWatch = € 775[5]

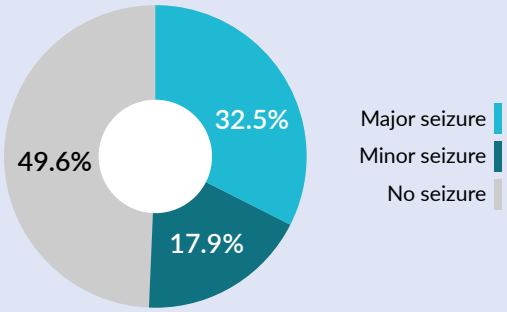
NightWatch detection sensitivity for different major nocturnal motor seizure types

These are aggregated study results (Arends et al.[2], Lazeron et al.[3], Westrhenen et al.[4])

Sensitivity per seizure type



Positive Predictive Value of all NightWatch Alarms



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

Sources

1. Beniczky S., Wiebe S., Jeppesen J. et al. Automated seizure detection using wearable devices: A clinical practice guideline of the International League Against Epilepsy and the International Federation of Clinical Neurophysiology. Clin Neurophysiol. 2021 May;132(5):1173-1184. doi: 10.1016/j.clinph.2020.12.009. Epub 2021 Mar 5.
2. Arends J., Thijs R.D., Gutter T. et al. Multimodal nocturnal seizure detection in a residential care setting: A long-term prospective trial. Neurology 2018; 91:1-10. doi:10.1212/WNL.0000000000006545
3. Lazeron R.H.C., Thijs R.D., Arends J. et al. Multimodal nocturnal seizure detection: Do we need to adapt algorithms for children? Epilepsia Open 2022; doi: 10.1002/epi4.12618
4. Westrhenen A. van, Lazeron R.H.C., Dijk J.P. van et al., Multimodal nocturnal seizure detection in children with epilepsy: a prospective, multicenter, long term, in-home trial. Epilepsia 2023; May 17. doi:10.1111/epi.17654.
5. Engelgeer A., Westrhenen A. van, Thijs R.D. et al. An economic evaluation of the NightWatch for children with refractory epilepsy: Insight into cost-effectiveness and cost-utility. 2022 Oct;101:156-161. doi: 10.1016/j.seizure.2022.08.003. Epub 2022 Aug 17.

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