

# A summary of the clinical evidence of NightWatch

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<sup>1</sup> recommend the use of sufficiently validated WSDDs for people with uncontrollable Tonic-Clonic Seizures:



To decrease seizure morbidity and mortality

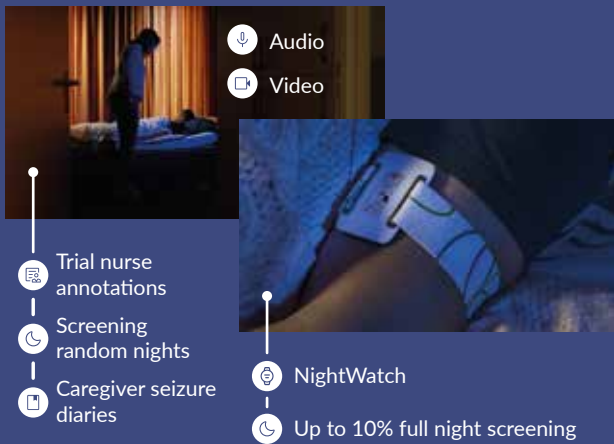


To obtain more objective quantification of seizures



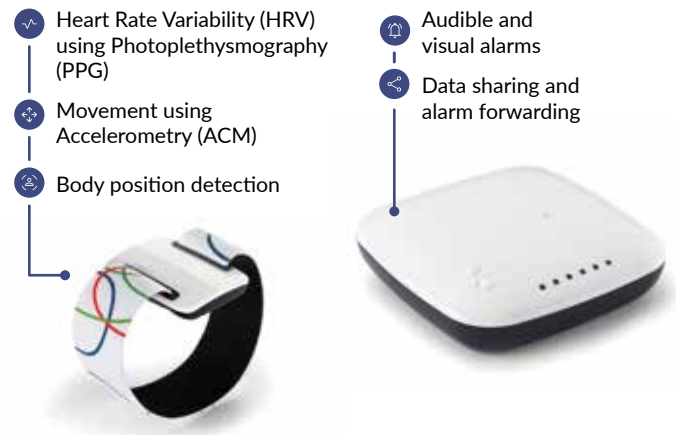
To support therapeutic decision-making

## Clinical research method



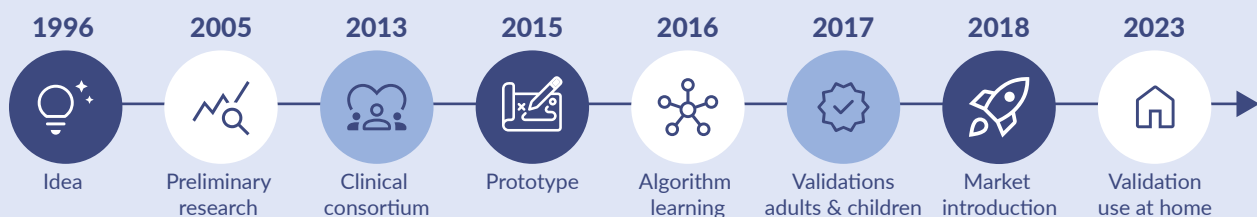
NightWatch has been validated in phase 3 and 4 prospective, multi-centered, video-controlled cohort trials in residential and home setting.

## 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

	Arends et al <sup>2</sup>	Lazeron et al <sup>3</sup>	Westrhenen et al <sup>4</sup>
Patients	26	14	51
Age	15 - 67	3 - 17	4 - 16
Location	Institution	Institution/Home	Home
Nights	1.716	497	2.310
Seizures	805	384	552
Sensitivity for Tonic-Clonic Seizures (median)	96%	98%	100%
Sensitivity for all seizure types (median)	86%	93%	99%
False alarm rate/ hour (median)	0,038	0,078	0,040

### Secondary outcomes (after 2 months intervention)<sup>2,3,4,5</sup>

- 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<sup>5</sup>

## NightWatch detection sensitivity for different major nocturnal motor seizure types

These are aggregated study results (Ahrends et al<sup>2</sup>, Lazeron et al<sup>3</sup>, Westrhenen et al<sup>4</sup>)

### Sensitivity per seizure type

#### Tonic-Clonic



#### Tonic (if cluster or prolonged)



#### Myclonic (if cluster)

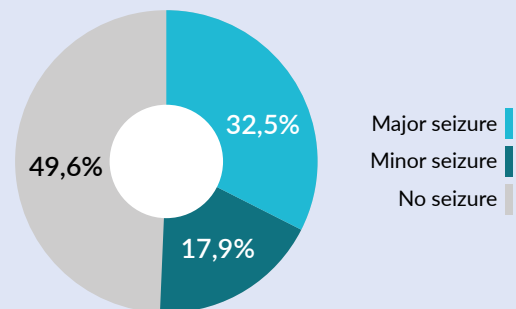


#### Focal impaired awareness with hyperkinetic movements



Seizures detected   
 Seizures missed   
 Median sensitivity per patient

### 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

- 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.
- 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
- Lazaron 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
- Westrhenen A. van, Lazaron 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.
- 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.