

NightWatch+ Multimodal Seizure Detection

Heart rate using
photoplethysmography (PPG)



Movement using
accelerometry (ACC)



Detection of
body position



Seizure alarms



Long-term epilepsy
monitoring



Alarm
forwarding

The US version of the NightWatch+ notifies caregivers on the occurrence of nocturnal epileptic major motor seizures, the seizure types associated with increased risk of morbidity and mortality that may require immediate assistance, including:

- Tonic-Clonic seizures (TC)
- Tonic seizures (if clustered or prolonged >30 seconds)
- Hyperkinetic seizures
- TC-like seizures

NightWatch, a Legacy of Collaborative Innovation

The technology of NightWatch is the result of over 15 years of dedicated research and development, originating from a shared mission to reduce SUDEP and improve the quality of life for families living with epilepsy. Rather than a standalone commercial effort, the NightWatch algorithm was engineered through the Tele-Epilepsy Consortium, a premier collaboration between neurologists, scientists, and engineers from:

- World-renowned epilepsy centers: SEIN and Kempenhaeghe
- Multiple Universities: University Medical Centre Utrecht & Maastricht, and Eindhoven University of Technology
- National patient advocacy organizations

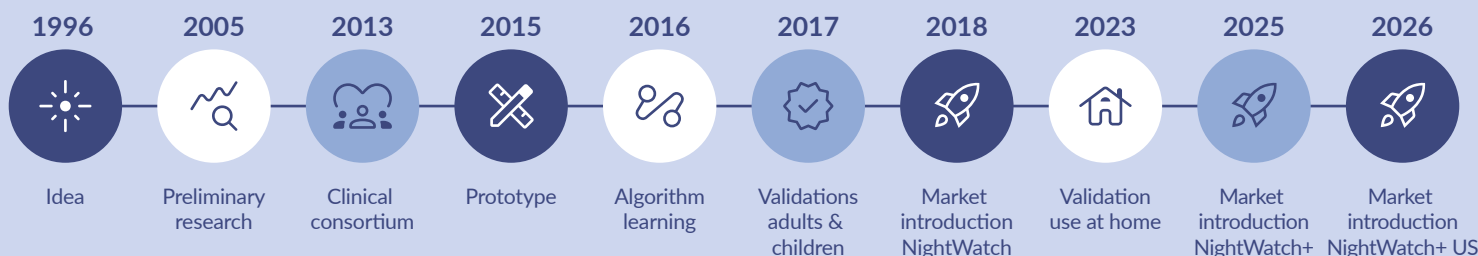
SEIN

Kempenhaeghe

UMC Utrecht

Maastricht UMC+

TU/e Eindhoven University of Technology



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



Self-reporting of seizures is unreliable, with 86% of nocturnal seizures going unnoticed.¹⁾



Timely intervention is essential in preventing injuries and SUDEP (Sudden Unexpected Death in Epilepsy) associated with tonic-clonic seizures.²⁾



The unpredictability of seizures can lead to social isolation, distress and decreased quality of life.³⁾

The international guidelines^{2,4)} recommend the use of sufficiently⁵⁾ validated seizure detection devices for people with uncontrolled tonic-clonic seizures when safety concerns exist.



To decrease seizure morbidity and mortality



To obtain more objective quantification of seizures



To support therapeutic decision-making



Clinical research method

The performance of NightWatch has been evaluated across multiple,^{6,7,8)} prospective, multi-centered, video-controlled cohort trials in residential and home settings. These include advanced phase 3 and 4 studies^{6,8)}, with the definitive phase 4 trial serving as the basis for the device's FDA clearance.⁸⁾



Trial nurse annotations



Screening random nights



Caregiver seizure diaries

Clinical Results

Neurology[®]

Arends et al.⁶⁾
2018



Epilepsia Open[®]

Lazeron et al.⁷⁾
2022



Epilepsia

Westrhenen et al.⁸⁾
2023



Patients	28	14	53
Age	15 - 67	3 - 17	4 - 16
Location	Institution	Institution / Home	Home
Nights	1826	497	2310
Seizures	809	384	552
Sensitivity (median) tonic-clonic seizures	96%	98%	100%
Sensitivity (median) all seizure types	86%	93%	100%
False alarm rate/hour (median)	0.03	0.08	0.04

* The 95% Confidence Interval (CI) means that if the same population were to be sampled on multiple occasions, the (median) sensitivity would fall within the range for 95 percent of the cases.

Secondary outcomes (after 2 months intervention)^{6,8,9)}



Significant stress reduction*



Easy to use for caregivers



Timelier response

* (mean total Caregiver Strain Index (CSI) score 8.0 vs 7.1 ; p = 0.032)

Sources

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Note: NightWatch+ US is an FDA-cleared device (K243199) for seizure monitoring of Children aged 4-16 years. The clinical data generated may include findings or use cases that differ from the specific cleared indications for use in the United States. Healthcare professionals should refer to the official User Manual for full instructions and warnings.



NightWatch
LivAssured