A summary of the clinical evidence of NightWatch

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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.[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)]

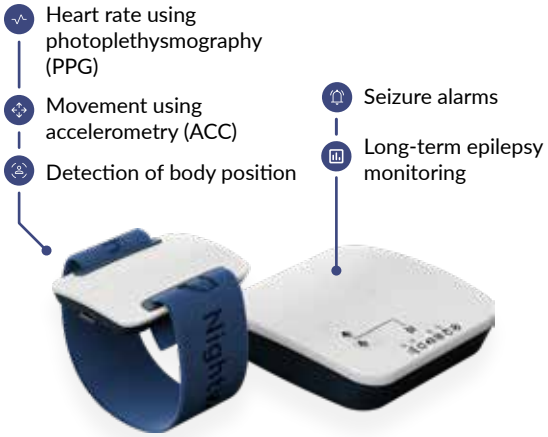
The international guidelines[2,4)] recommend the use of sufficiently validated WSDDs for people with uncontrollable tonic-clonic seizures when safety concerns exist:

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

Clinical research method

NightWatch has been validated in phase 3 and 4 prospective, multicenter, video-monitored cohort trials in residential and home settings.[5,6,7)]

NightWatch+ Multimodal Detection



NightWatch+ notifies caregivers on the occurrence of major nocturnal motor seizures to take appropriate care measures.

NightWatch development and validation timeline

1996	2005	2013	2015	2016	2017	2018	2023	2025
Idea	Preliminary research	Clinical consortium	Prototype	Algorithm learning	Validations adults & children	Market introduction NightWatch	Validation use at home	Market introduction NightWatch+

NightWatch was developed and validated in close cooperation with neurologists and scientists from the epilepsy clinics Kempenhaeghe, UMCU, SEIN, and patient organizations. It is part of a conjoined mission to reduce SUDEP and improve the quality of life of people with epilepsy and their caregivers.

Clinical Results

	Neurology® Arends et al.[5] 2018	Epilepsia Westrhenen et al. [6] 2023
Patients	28	53
Age	15 - 67	4 - 16
Location	Institution	Home
Nights	1826	2310
Seizures	809	552
Sensitivity (median) tonic-clonic seizures	96% (95% CI*: 80%-100%)	100% (95% CI*: 100%-100%)
Sensitivity (median) all seizure types	86% (95% CI*: 77%-93%)	100% (95% CI*: 87%-100%)
False alarm rate/hour (median)	0.03	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)[5,6]

- 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)*

Calculated cost of care reduction in 2 months by using NightWatch = € 775[8]

Sources

1. Hoppe C, Poepel A, Elger CE. Epilepsy: Accuracy of patient seizure counts. Arch Neurol [Internet]. 2007;64(11):1595–9. Available from: http://dx.doi.org/10.1001/archneur.64.11.1595
2. Beniczky S, Wiebe S, Jeppesen J, Tatum WO, Brazdil M, Wang Y, 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 [Internet]. 2021;132(5):1173–84. Available from: http://dx.doi.org/10.1016/j.clinph.2020.12.009
3. Fisher RS, Blum DE, DiVentura B, Vannest J, Hixson JD, Moss R, et al. Seizure diaries for clinical research and practice: limitations and future prospects. Epilepsy Behav [Internet]. 2012;24(3):304–10. Available from: http://dx.doi.org/10.1016/j.yebeh.2012.04.128
4. Larsen PM, Beniczky S. Non-electroencephalogram-based seizure detection devices: State of the art and future perspectives. Epilepsy Behav [Internet]. 2023;148(109486):109486. Available from: http://dx.doi.org/10.1016/j.yebeh.2023.109486
5. Arends J, Thijs RD, Gutter T, Ungureanu C, Cluitmans P, Van Dijk J, et al. Multimodal nocturnal seizure detection in a residential care setting: A long-term prospective trial. Neurology [Internet]. 2018;91(21):e2010–9. Available from: http://dx.doi.org/10.1212/WNL.0000000000006545
6. van Westrhenen A, Lazeron RHC, van Dijk JP, Leijten FSS, Thijs RD, Dutch TeleEpilepsy Consortium. Multimodal nocturnal seizure detection in children with epilepsy: A prospective, multicenter, long-term, in-home trial. Epilepsia [Internet]. 2023;64(8):2137–52. Available from: http://dx.doi.org/10.1111/epi.17654
7. Lazeron RHC, Thijs RD, Arends J, Gutter T, Cluitmans P, Van Dijk J, et al. Multimodal nocturnal seizure detection: Do we need to adapt algorithms for children? Epilepsia Open [Internet]. 2022;7(3):406–13. Available from: http://dx.doi.org/10.1002/epi4.12618
8. Engelgeer A, van Westrhenen A, Thijs RD, Evers SMAA. An economic evaluation of the NightWatch for children with refractory epilepsy: Insight into the cost-effectiveness and cost-utility. Seizure [Internet]. 2022;101:156–61. Available from: http://dx.doi.org/10.1016/j.seizure.2022.08.003

www.nightwatchepilepsy.com

NightWatch is a Class I and NightWatch+ is a Class IIa medical device under the EU Medical Device Regulation 2017/745.
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