Real-world efficacy of the mjn-SERAS device in EARLY SEIZURE DETECTION

For patients diagnosed with **drug-resistant epilepsy**, the **mjn-SERAS** device offers a predictive alert system before the onset of the seizures to **prevent accidents, enhance safety and promote independence**.

This post-market study, **SERAS-Home**, part of the **EIT Health Amplifier** project, showcases the initial application of the in-ear EEG medical device, **mjn-SERAS**, integrated with an **AI algorithm** in daily life activities.

METHODOLOGY

A **prospective, randomized, multicentre, postmarketing clinical study**, recruited 85 already diagnosed patients, recording 26.842 hours and 624 seizures, **assessing the device for minimum six months** and conducted between July 2022 and June 2025 in an **ambulatory setting**.

The **mjn-SERAS**, a CE-marked **wearable device** under the European Medical Device Regulation (MDR), continuously monitors patient data and transmits it to a **mobile application** for real-time analysis using advanced AI algorithms.

Simultaneously, the device uploads data to **cloud servers** to enhance our **machine learning** models, enabling the development of highly individualized **patient-specific** predictions.

STUDY DATA

26842 hours of EEG recordings

624 seizures recorded

6.8 average usage hours per day

VALIDATION SPLIT

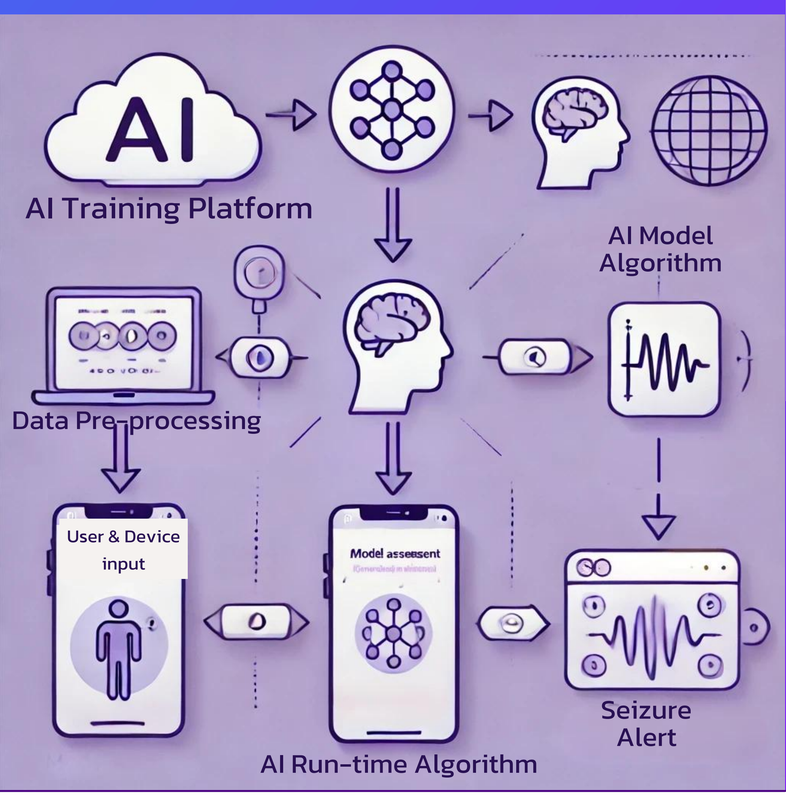
13112 hours of EEG recordings

286 seizures validated

94% ACCURACY

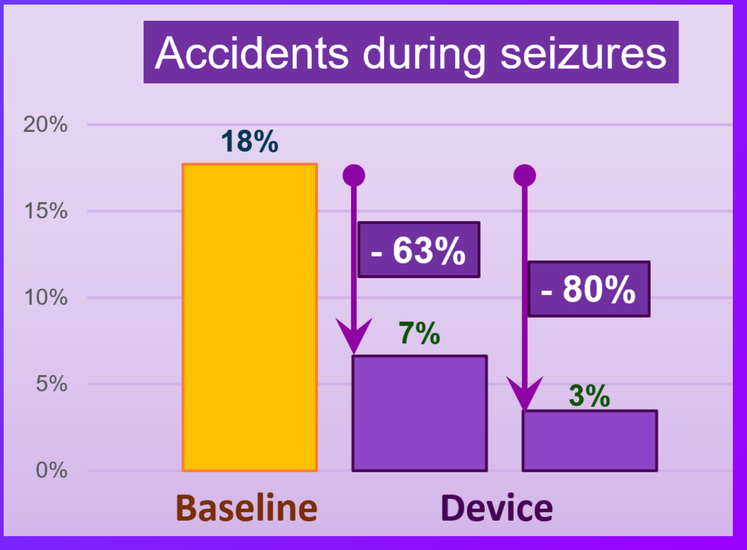
80% SENSITIVITY

99% SPECIFICITY

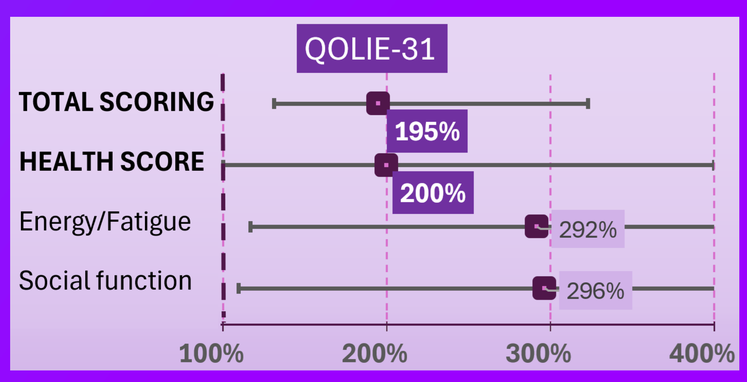


RESULTS

94% Accuracy with a **False Alarm Rate (FAR) per day at 0.20.**
Seizure-related accidents has been reduced up to 80%, with a severity reduction.



There is an **improvement in the quality of life QOLIE-31 of 23 points** representing a 195% (Power=93%, p-value<0.001) and perceived **health score increased in 21 points** representing 200%



CONCLUSIONS

The study reveals a significant impact of mjn-SERAS device, with a clear improvement in safety and quality of life for those patients reducing distress associated.

The availability of seizure prediction devices has the potential to enhance patients' sense of control and empowerment in managing seizures and risks.

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