1.1 Overall synopsis of the clinical investigation

Title	Performance of BIOSERENITY AI SEIZURE EEG algorithm in the automatic detection of epileptic seizures in standard and long-term home EEG recordings: a retrospective validation study.
Short title	BIOSERENITY AI SEIZURE EEG – validation study
Version and date	Version 1.1 – 26/05/2026
EUDAMED Single Reference Number (SRN)	FR-MF-000039391
Sponsor	BIOSERENITY MEDICAL DEVICES GROUP 6/8 rue Jean Antoine de Baïf, 75013 Paris
Location(s) and participating country(ies)	Data will be collected from several hospitals in France or recordings at patients' homes through Neurophy, BioSerenity's tele-interpretation service.
Medical device name	BIOSERENITY AI SEIZURE EEG
Objective and Background	Electroencephalograms (EEGs), in conjunction with clinical assessment, are frequently used in neurological examinations, but they require highly specialized medical expertise. EEG remains the gold standard for detecting epileptic seizures, but manual real-time analysis of long EEG records is tedious. Because of this need for specific expertise, Artificial Intelligence (AI) could help healthcare professionals with their diagnoses and make EEG more accessible in hospitals. Several articles have been published on this topic to address the challenge of automatically detecting recordings using AI. Specifically, some researches have focused on AI algorithms capable of automatically identifying epileptic seizures in the EEGs of adult patients, whether during short-term routine EEGs or long-term monitoring (LTM). The goal of these researches is to improve early seizure detection (particularly non-convulsive seizures that are difficult to recognize clinically) and to lighten the workload of neurologists and technicians by identifying critical segments. Here, our study will be focused on BIOSERENITY AI SEIZURE EEG as an advanced algorithm designed to detect epileptic seizures. This clinical validation study aims to confirm the performance and safety of the BIOSERENITY SEIZURE EEG AI algorithm, ensuring that it meets or exceeds the standards set for medical devices.

Device under study and comparator	Clinical validation of the algorithm will be based on its ability and performance to automatically detect epileptic seizures in standard EEG recordings (approximately 20 minutes) and long-term home EEG recordings (approximately around 24 hours). This algorithm classification will be compared with the scoring provided by qualified physicians who have blind scored the records (3 physicians per record in order to achieve consensus). The consensus will be used as a reference to assess algorithm performance. Consensus will be achieved by 2/3 majority scoring, defined as double-blinded manual scoring by consensus between three (3) physicians. EEG recordings for which there is no consensus are excluded from the final validation database. The algorithm classification performance will be also compared to performance results of two selected similar devices (ENCEVIS 2.0 and Persyst 14).
Clinical development stage	Pivotal study
Study design	Retrospective, non-interventional, multicenter
Objectives and primary endpoint	To evaluate the performance of BIOSERENITY AI SEIZURE EEG algorithm in automatically detecting epileptic seizures compared to the detection performance of a consensus of neurologists versus the performance of similar devices (Encevis 2.0 and Persyst 14). The primary endpoint will be evaluated on all the database (standard and long-term EEG records) to validate that the algorithm performs consistently across multiple contexts of use. The primary endpoint will be measured across the entire database, to evaluate the sensitivity and the false positive ratio (FPR/h) on the consensus of physicians versus the performance of similar devices (Encevis 2.0 and Persyst 14).
Objectives and secondary endpoints	• Evaluation of: • The performance of BIOSERENITY AI SEIZURE EEG algorithm in detecting epileptic seizures compared to the detection performance of a consensus of neurologists versus the performance of similar devices (Encevis 2.0 and Persyst 14) on two separated sub-group of EEG records : standard and long-term EEG. • The consensus of physicians results by: - Determination of inter-scorer variability. - Determination of distance algorithm-consensus vs distance physicians – consensus. • The detection performance of the algorithm based on patient demographics (age, sex). • The detection performance of the algorithm according to seizures subtypes. • The detection performance of the algorithm according to seizures duration.

	• The detection performance of the algorithm on TUH and Siena databases.
Study population	The study population will include adult patients who performed an EEG for neurological clinical examination for several indications as epilepsy, dementia, coma, stroke. Patients included had performed a standard EEG exam of around 20 minutes in hospital or a long-term EEG exam of at least 24 hours at home.
Sample size	The objective of the study is to evaluate the performance of the study device in detecting EEG seizures during a standard EEG or long-term video EEG exam. Due to the great heterogeneity of population pathologies and the two use cases (standard and long-term exam) that will be studied and analyzed, around 300 patients with EEG records will be required in the study in order to collect around 1500 hours of EEG records.
Inclusion criteria	1- ≥18 years 2- Male or female 3- Neuronaute records 4- Having completed a standard EEG record (approx. 20min recording) or a long-term video EEG record (at least 24 hours recording) 5- Informed and non-opposed for the use of their personal data for the conduct of the research
Exclusion criteria	1- EEG lacking the 19 channels of the 10/20 positioning or for which some channels are non-functional / too artifactual 2- Traces with too many artifacts
Study duration	The target period for data collection will span from 27/05/2024 to 21/04/2026.
Statistical analyses	**Primary endpoint analysis** The primary endpoint will be evaluated on all the database (standard and long-term EEG records) to validate that the algorithm performs consistently across multiple contexts of use. Several thresholds will be applied directly to the model's output probabilities tested (from 0.05 to 0.95) to determine the threshold at which the algorithm performs satisfactorily. Across the entire database, computation of sensitivity and false positive ratio (FPR/h) of BIOSERENITY AI SEIZURE EEG is performed by considering the consensus of physicians as reference with 95%

	confidence intervals (CI). Results will be compared to the performance metrics (±10% for sensitivity and ±0.1 for FPR/h) of similar devices (Encevis 2.0 and Persyst 14) : sensitivity > 77.05% and FPR/h <0.4175. **Secondary endpoint analysis** • Computation of sensitivity and false positive ratio (FPR/h) of BIOSERENITY AI SEIZURE EEG on two separated sub-group of EEG records (standard and long-term EEG) will be compared to the performance metrics (±10% for sensitivity and ±0.1 for FPR/h) of similar devices (Encevis 2.0 and Persyst 14) : sensitivity > 77.05% and FPR/h <0.4175. on two separated sub-group of EEG records : standard and long-term EEG. • Evaluation of the consensus of physicians results by: o Determination of inter-scorer variability; o Determination of distance algorithm-consensus vs distance physicians – consensus. • Sensitivity and FPR/h of the algorithm will be evaluated on each demographic parameter (age, sex). • Sensitivity and FPR/h of the algorithm will be evaluated according to each seizures subtypes. • Sensitivity and FPR/h of the algorithm will be evaluated according to seizures duration. • Sensitivity and FPR/h of the algorithm will be compared to TUH and Siena databases.