Neuronostics BioEP

September 2024

Device Overview

BioEP, developed by Neuronostics, is used to support the diagnosis of epilepsy. [1] Epilepsy is traditionally diagnosed using a variety of methods, including electroencephalogram (EEG) tests, which capture the brain's electrical activity over a period of time and allow for observation of any potential abnormalities. However, EEGs only capture seizures that occur during testing, meaning the majority of EEGs do not yield clinically significant results. [1]

In as little as 15 minutes, BioEP "can use apparently normal, background EEG to identify the likelihood of future seizures," potentially circumventing the need for multiple EEGs to capture epileptiform activity. [1] Moreover, Neuronostics is currently researching BioEP's ability to distinguish between epilepsy and other neurological conditions such as Non-Epileptic Attack Disorder (NEAD). [1] BioEP aims to improve the quality of life for people with epilepsy by preventing delays in diagnosis. [1]

FDA Approval

Neuronostics aims to receive FDA approval for BioEP by the end of 2024.

Actions for Consideration

PARTNER

IDENTIFY STAKEHOLDERS
Engage subject matter experts including neurologists, neurosurgeons, epileptologists, neurodiagnostic leadership, and quality management teams.

DETERMINE NEED
Work with team members to understand current obstacles in diagnosing epilepsy and which patient populations may benefit.

CONSIDER COST
Value analysis team members will help to evaluate the financial impact of this technology.

CONNECT

SEEK CLINICAL IMPACT
Consider trial period to assess impact to outcomes and determine adoption of technology. Review data to support improved quality of care, patient outcomes, and compare efficacy.

CONDUCT ANALYSIS
Compare the benefits and drawbacks of traditional EEG monitoring and BioEP. Include cost, reimbursement, and potential outcomes impact.

DETERMINE POPULATION
Work with key stakeholders to determine appropriate patient population and settings.

COMMUNICATE

EDUCATE AND TRAIN
Provide thorough education and training for staff related to adoption of new technology, testing capabilities, and trial results. Identify any changes to workflow. Engage supplier for support.

PLAN AHEAD
Share available evidence, trials, and peer insights with key clinical stakeholders for discussion. Share plan for ongoing communications about product, use, & outcomes.

FOLLOW-UP FOR FEEDBACK
Report key metrics and solicit feedback at a regular cadence.

Clinical Insights: HealthTrust Physician Advisors

A panel of neurosurgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to BioEP. [2] Their previous familiarity with BioEP varied.

Physician Advisor Insights

- Epilepsy diagnosis takes a long time and is extremely variable between patients.
- BioEP's "algorithmic approach" and prospective ability to discern between epilepsy and "pseudo-seizures" were cited as potential benefits.
- The risk of misdiagnosis and false negatives/positives were cited as potential drawbacks for BioEP.
- There are pros and cons to artificial intelligence-based technology in epilepsy, but the true role of this technology needs to be further explored.
- There is potential use for this technology in recognizing other electrodiagnostic modalities and in intraoperative monitoring.
- BioEP may be beneficial for patients with traumatic brain injuries or infrequent seizures, as well as those in a minimally conscious state.
- Inpatient epilepsy monitoring unit (EMU), critical care/intensive care unit (ICU), and outpatient neurology were listed as settings best suited for BioEP
- A trial period at a multidisciplinary epilepsy clinic was also recommended.
- Further validation is needed to confirm the efficacy of BioEP as advertised.

Clinical Evidence

BioEP has been mentioned as a "breakthrough study" and "commercialization prize" through the Epilepsy Foundation, but there is a lack of published studies specific to BioEP. The Epilepsy Foundation lists BioEP as a new diagnostic tool under its pipeline tracker here. It refers to a small pilot study in idiopathic generalized epilepsy (IGE) patients, but results are not reported on this site. [3]

While there are currently no published studies on BioEP, there is published evidence on the use of biomarkers in epilepsy for diagnosis and prognosis. Below is an example of one study on the use of biomarkers for EEG analysis.

Schmidt et al. (2016) conducted an analysis of 30 patients with IGE and 38 control patients. An EEG technician analyzed each EEG recording to remove artifacts and normalize data. Using "group-level differences" in those with IGE and in control patients, the "global (between-channel) network structure and local (within-channel) coupling strength" were incorporated into a model which determined the "local coupling biomarker." Each node in the network was placed in a synchronous state, and the "level of emergent synchrony across the whole network" was assessed to determine seizure potential. Additionally, a "leave-one-out" approach determined the threshold of the biomarker for the "highest level of sensitivity at 100% specificity" and "highest level of specificity at 100% sensitivity." [4]

The thresholds were used to determine whether activity is normal, IGE, or unknown. Using these parameters, the authors reported 56.7% sensitivity and 65.8% specificity. Of those 30 patients with IGE, 17 were confirmed, 10 were unknown, and 3 were incorrectly classified. Of the 38 control patients, 25 were confirmed and 13 were unknown. This local coupling biomarker was significantly better at classifying patients with IGE and control patients ($p<0.001$ for both) versus other biomarkers. When compared to other measurements (such as average power or mean degree), the biomarker was significantly more accurate in classification (average power; IGE: $p<0.001$; control: $p=0.007$ and mean degree; IGE: $p<0.001$; control: $p<0.001$). [4]

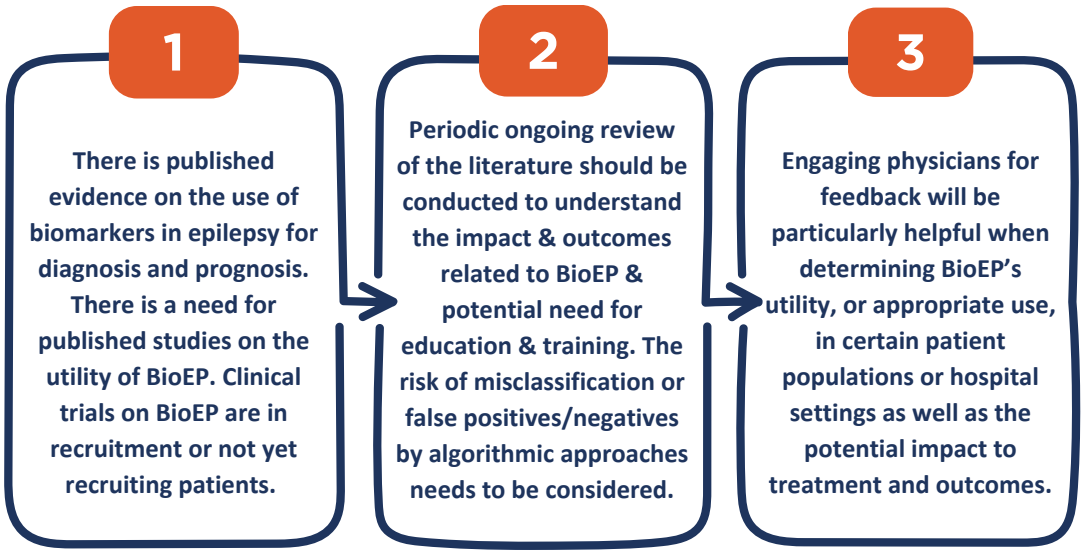
Clinical Trials

Research to support biomarkers in epilepsy are published on the Neuronostics website here. [5]

BioEP studies in progress may be searched via ClinicalTrials.gov found here [6], including a Neuronostics sponsored randomized controlled trial comparing BioEP to standard care (NCT06097195). [7]

See Reference section for complete listing of research sources.

Summary



References

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