



Neuronostics

Enhancing neurological care with
digital biomarkers

BioEP

Service Definition Document for G-Cloud 15

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1. About Neuronostics

Neuronostics is a pioneering MedTech company transforming neurological care through advanced computational analysis of EEG data. Spun out from the University of Exeter in 2018, Neuronostics is built on over a decade of world-class academic research.

The company's mission is to deliver objective, data-driven insights that enable faster and more accurate clinical decision-making. Neuronostics' first product, BioEP, is a patented, UKCA-marked digital biomarker that unlocks the hidden value in clinically non-contributory EEGs, addressing a major diagnostic gap in the epilepsy care pathway.

ISO 13485–certified and supported by a clear regulatory strategy for key international markets, including the United States, Neuronostics is positioned to significantly enhance the diagnosis and management of neurological conditions worldwide.

2. Overview of the BioEP Service

BioEP is a UKCA-marked Software as a Medical Device designed to support the diagnostic pathway for adults with suspected epilepsy. It analyses resting-state EEG data collected as part of routine clinical care and deemed clinically non-informative by a reporting clinician.

BioEP generates a structured, categoric output indicating the degree to which an EEG resembles patterns observed in patients with confirmed epilepsy versus non-epileptic conditions. The output is provided via a clear clinical report and is intended to be used strictly as an adjunct to standard clinical assessment, not as a standalone diagnostic or automated decision-making system.

BioEP analyses the underlying dynamics of the brain's network activity using advanced computational methods. Proprietary algorithms extract a set of eight computational features from short, resting-state segments of a standard 19-channel EEG. These features quantify aspects of the brain's spectral, network, and model-based properties to generate a single, objective digital biomarker reflecting the brain's propensity for seizure generation.

This methodology enables BioEP to provide a quantitative risk score even when an EEG appears visually normal on standard clinical review. In doing so, BioEP addresses a critical clinical question frequently encountered in epilepsy services: where no epileptiform abnormalities are visible, what is the patient's underlying risk of epilepsy?

3. Intended Use, Users and Care Settings

BioEP is intended for use by qualified healthcare professionals involved in the epilepsy care pathway, including neurologists, epileptologists, clinical neurophysiologists, epilepsy nurses, and appropriately trained clinical scientists.

The service is designed for deployment within NHS secondary care Neurology and Neurophysiology services, and may support decision-making in onward referral pathways within primary care. BioEP integrates into existing EEG workflows without requiring changes to EEG acquisition hardware or clinical practice.

4. Clinical Context and Benefits to the NHS

Diagnosis of epilepsy can be complex and prolonged, particularly where standard EEG recordings are clinically non-informative. BioEP addresses this challenge by providing additional, objective information derived from computational analysis of EEG data.

Key benefits to the NHS include improved diagnostic confidence, reduced diagnostic delay, more efficient use of specialist neurophysiology and neurology resources, and improved patient experience through earlier diagnostic clarity. BioEP supports safer, more consistent decision-making while preserving clinical autonomy.

BioEP is a clinical decision-support tool designed to address a critical diagnostic gap in the epilepsy care pathway. Its primary value proposition is the ability to provide an objective, quantitative assessment of epilepsy risk from routine EEGs that are deemed clinically inconclusive or non-contributory due to the absence of visible epileptiform activity.

This is particularly significant given that approximately 70% of routine EEGs fall into this category, leaving clinicians with limited objective evidence to support diagnostic decision-making. This diagnostic uncertainty contributes to delays in diagnosis and misdiagnosis rates estimated to be between 20–30% in epilepsy services.

Unlike conventional artificial intelligence approaches that focus on automating the detection of overt abnormalities such as interictal epileptiform discharges, BioEP uniquely analyses background brain activity that appears visually normal on standard EEG review.

5. Service Functionality

BioEP is delivered as a secure, cloud-based web application. Core functionality includes:

- Secure user authentication with role-based access control and multi-factor authentication
- Creation and management of patient records for clinical traceability
- Upload of individual or bulk EEG files in standard EDF format
- Automated computational analysis of EEG data
- Generation of structured clinical reports, accessible online and downloadable as PDFs
- Comprehensive audit logging of user activity and data processing events.

The service is accessed via modern web browsers on desktop or laptop computers and does not require local software installation.

BioEP's analytical pipeline operates on short resting-state EEG segments and applies proprietary computational algorithms to derive multiple quantitative features, which are combined into a single digital biomarker score presented within the clinical report.

BioEP employs a transparent, feature-engineered methodology grounded in peer-reviewed research. It applies three complementary analytical approaches to reveal digital biomarkers associated with seizure susceptibility:

- Signal analysis, which quantifies subtle alterations in the frequency and amplitude characteristics of the EEG signal;
- Network connectivity analysis, which uses graph theory to map patterns of communication between brain regions and identify disruptions characteristic of epilepsy; and
- Dynamic modelling, which applies computational models of brain networks to assess the underlying propensity for seizure generation.

Outputs from these analyses are integrated within a machine learning framework to produce a simple, intuitive five-point rating indicating the degree of support for an epilepsy diagnosis. This rating provides clinicians with an additional, objective piece of evidence to inform their level of clinical suspicion and guide subsequent decision-making early in the diagnostic pathway.

BioEP is provided as a cloud-based software service and is available to authorised users on a best-efforts basis. Neuronostics aims to maintain service availability during UK business hours (09:00–17:00, Monday to Friday, excluding public holidays). User support is provided during UK business hours via email and/or secure support channels. Planned maintenance will be communicated in advance where reasonably practicable.

6. Implementation, Onboarding and Training

Neuronostics provides a structured onboarding process designed to minimise operational and IT burden on NHS organisations. Implementation typically includes account configuration, confirmation of local information governance arrangements, and user access setup.

All users must complete mandatory BioEP training prior to use. Training includes review of the Instructions for Use, completion of a mandatory training video, and confirmation of understanding. Training completion is auditable within the platform, supporting local clinical safety and governance.

7. Clinical Safety and Regulatory Compliance

BioEP is a UKCA-marked Software as a Medical Device and is developed, validated, and maintained under Neuronostics' ISO 13485-certified Quality Management System.

Neuronostics is fully compliant with the NHS Digital Technology Assessment Criteria (DTAC). Evidence of DTAC compliance across clinical safety, data protection, technical security, interoperability, and usability is available to commissioning organisations upon request.

Clinical risk management activities are conducted in accordance with DCB0129 for manufacturers of health IT systems. NHS organisations deploying BioEP retain responsibility for local clinical safety management in line with DCB0160.

8. Data Protection, Security and Information Governance

BioEP processes personal and special category (health) data solely for the purpose of supporting direct patient care. NHS Health Boards and Trusts act as data controllers, while Neuronostics acts as a data processor under a formal Data Processing Agreement compliant with Article 28 of the UK GDPR.

The lawful basis for processing is Article 6(1)(e) (public task) and Article 9(2)(h) (medical diagnosis and healthcare provision). Processing for direct care relies on implied consent under the common law duty of confidentiality.

BioEP is hosted on Amazon Web Services (AWS) infrastructure located within the United Kingdom. All data are encrypted in transit using TLS 1.2 or higher and encrypted at rest using AES-256. Access is controlled through role-based permissions, multi-factor authentication, inactivity timeouts, and full audit logging. Neuronostics maintains compliance with the NHS Data Security and Protection Toolkit (DSPT) and Cyber Essentials.

9. Data Flows and Processing

EEG recordings (EDF format) and associated clinical metadata are uploaded to BioEP by authorised clinicians within NHS Neurology and Neurophysiology services. Data are transferred securely to the BioEP platform for analysis.

Following processing, BioEP generates a clinical report which can be reviewed online and downloaded as a PDF for inclusion in the patient record. No data are transferred outside the UK, and no third parties access patient data beyond Neuronostics and its UK-based cloud infrastructure provider.

10. Data Retention and Deletion

The NHS Health Board or Trust, as data controller, determines retention periods for patient data in line with the NHS Records Management Code of Practice.

Neuronostics retains patient-identifiable data only for the minimum period necessary to perform BioEP analysis, support audit and traceability, and meet contractual obligations. Upon completion of processing or contract termination, data are securely deleted or anonymised in accordance with agreed retention policies.
