

# Guidance assessment consultation document for HTG10865 Software with artificial intelligence (AI)-derived algorithms to help interpret electroencephalograms (EEGs) for suspected epilepsy: early-use assessment

9 June 2026

## Guidance development process

NICE HealthTech guidance evaluates digital technologies, diagnostics and medical devices (including artificial intelligence). It provides evidence-based recommendations about how safe and effective these technologies are, and their cost effectiveness. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible treatments. NICE aims to promote innovations that meet the needs of patients and the healthcare system.

This guidance has been developed as early-use HealthTech guidance, for HealthTech products that could address an unmet need in the NHS and need more evidence to support routine use.

Find out more on the [NICE webpage on HealthTech guidance](#).

NICE is producing this guidance on software with artificial intelligence (AI)-derived algorithms to help interpret electroencephalograms (EEGs) for suspected epilepsy in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

**This document has been prepared for consultation with the stakeholders.** It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE

invites comments from the stakeholders for this evaluation and the public. This document should be read along with the [evidence](#).

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If the committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

**Note that this document is not NICE's final guidance on software with artificial intelligence (AI)-derived algorithms to help interpret electroencephalograms (EEGs) for suspected epilepsy. The recommendations in section 1 may change after consultation.**

More details are available in [NICE's HealthTech programme manual](#).

### **Key dates:**

Closing date for comments: 30 June 2026

Second committee meeting: 15 July 2026

# 1 Recommendation

1.1 More research is needed on the following software technologies with artificial intelligence (AI)-derived algorithms to help interpret electroencephalograms (EEGs) for suspected epilepsy before they can be funded by the NHS:

- BioEP
- encevis
- NeuroCenter EEG
- NeuroWorks
- Persyst 15.

## What this means in practice

There is not enough evidence to support funding for software with AI-derived algorithms to help interpret EEGs for suspected epilepsy in the NHS.

Access to the technologies should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

## What research is needed

### For software that helps review visual epileptiform activity on EEG

For encevis, NeuroCenter EEG, NeuroWorks and Persyst 15, more research, ideally from the UK, is needed on:

- diagnostic accuracy of healthcare professional EEG review with and without the software
- time to review and interpret EEGs with and without the software
- time to diagnosis and treatment with and without the software
- using the software for longer-term ambulatory EEGs

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- how the software helps in prioritising EEG review
- the proportion of people who have an EEG that is either inconclusive or shows an epileptic abnormality and who are then diagnosed with epilepsy
- healthcare resource use for people having an EEG (including the type of EEG for first and follow-up EEGs).

### **For software that estimates the likelihood of epilepsy on visually inconclusive EEGs**

For BioEP, more research, ideally from the UK, is needed on:

- diagnostic accuracy of epilepsy diagnosis made by healthcare professionals with and without the software
- time to diagnosis and treatment with and without the software
- how the software helps in prioritising EEG follow up
- healthcare resource use for people having an EEG (including the type of EEG for first and follow-up EEGs).

### **Why the committee made this recommendation**

These software technologies could support the diagnosis of epilepsy by:

- enabling healthcare professionals to review epileptic abnormalities on EEGs more quickly (encevis, NeuroCenter EEG, NeuroWorks, Persyst 15)
- providing healthcare professionals with supporting information about the likelihood of epilepsy on visually inconclusive EEGs (BioEP).

The results from 1 small study suggest that using the software to help detect epileptiform activity reduces healthcare professionals' review time of EEGs compared with no use of the software. But it is uncertain whether this time saving would be meaningful in NHS clinical practice. This is because the unmet need in the NHS is associated more with the varying availability of specialist healthcare professionals who diagnose and treat epilepsy than with the speed of interpreting EEGs or having additional information about the EEG.

There is no evidence on how having supporting information about the likelihood of epilepsy on visually inconclusive EEGs affects healthcare professionals' decision making on diagnosis, treatment or follow up. There is also no evidence on the effect of using the software on the time to diagnosis and treatment.

The results of the economic model suggest the software could be cost effective in some situations. But the plausibility of cost effectiveness is uncertain because there is not enough clinical evidence to support the model's assumptions.

So, more research is needed on all 5 software technologies. Ideally, research would be done in the UK. This is because current practice for investigating suspected epilepsy varies across countries. So, evidence from other countries may not be generalisable to NHS practice.

## **2 Information about the technologies**

2.1 This assessment included 2 types of software that help healthcare professionals interpret electroencephalograms (EEGs) recorded using scalp electrodes:

- 4 software technologies (encevis, NeuroCenter EEG, NeuroWorks, Persyst 15) that help healthcare professionals review and interpret EEGs by automatically detecting visual epileptiform activity (such as interictal epileptiform discharges or seizures) on EEGs
- 1 software technology (BioEP) that helps diagnose epilepsy by classifying EEG recordings without visual epileptiform activity (EEGs considered inconclusive for epilepsy) based on how likely they are to indicate epilepsy.

2.2 The software also provides additional information and features to assist EEG review and interpretation.

**Table 1 Features of each software**

<b>Software (company)</b>	<b>Regulatory status</b>	<b>Software type</b>	<b>Intended age group</b>
BioEP (Neuronostics)	UKCA class I (EU MDR class IIa submission planned for 2027)	Assists epilepsy diagnosis by classifying EEG recordings without visual epileptiform activity based on how indicative they are of epilepsy	18 years and over
Encevis (AIT Austrian Institute of Technology GmbH)	CE class IIb	Assists reviewing and interpreting EEGs by automatically detecting and marking in EEG data: <ul style="list-style-type: none"> <li>• interictal epileptiform discharges</li> <li>• seizures.</li> </ul>	18 years and over
NeuroCentre EEG (Clinical Science Systems)	CE class I (EU MDR class IIa expected in 2026)	Assists reviewing and interpreting EEGs by automatically detecting and marking in EEG data: <ul style="list-style-type: none"> <li>• interictal epileptiform discharges</li> <li>• seizures.</li> </ul>	6 years and over
NeuroWorks (Natus Medical)	CE class IIa	Assists reviewing and interpreting EEGs by automatically detecting and marking interictal epileptiform discharges in EEG data	3 months and over
Persyst 15 (Persyst)	UKCA class IIa	Assists reviewing and interpreting EEGs by automatically detecting and	<ul style="list-style-type: none"> <li>• 1 month and over for spike detection</li> <li>• Neonates (conceptional</li> </ul>

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		marking in EEG data: <ul style="list-style-type: none"> <li>• interictal epileptiform discharges</li> <li>• seizures.</li> </ul>	age between 36 and 44 weeks and chronologic age less than 2 weeks) and 18 years and over for seizure detection
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## Sustainability

2.3 For information, Carbon Reduction Plans for UK carbon emissions for Natus Medical and Neuronostics are published here:

- [Natus Medical's Carbon Reduction Plan](#)
- [Neuronostics' Carbon Reduction Plan.](#)

Carbon Reduction Plans were not available for AIT Austrian Institute of Technology GmbH, Clinical Science Systems or Persyst.

## 3 Committee discussion

The diagnostics advisory committee considered evidence on software with artificial intelligence (AI)-derived algorithms to help interpret electroencephalograms (EEGs) for suspected epilepsy from several sources. This included evidence submitted by AIT Austrian Institute of Technology GmbH, Clinical Science Systems, Natus Medical, Neuronostics and Persyst, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the [project documents for this guidance](#).

### The condition

3.1 Epilepsy is a disease of the brain. In England and Wales, about 533,000 people, including 112,000 children and young people, have epilepsy. Some people have epilepsy for a short period in

their life, whereas others have it for many years or all their life.

Epilepsy is a common cause of people attending emergency departments. The [Epilepsy Research Institute's webpage on epilepsy statistics](#) states that there are about 100,000 epilepsy-related emergency department admissions each year. Epileptic seizures can result in injury and are associated with an increased risk of premature death, for example because of sudden unexpected death in epilepsy.

## Current practice

3.2 After someone has a suspected seizure, they are referred for a specialist assessment by a consultant neurologist, paediatrician or a consultant paediatric neurologist to find out if the event was caused by epilepsy. The assessment includes:

- a clinical history from the person who had the event, and ideally also from a witness, and a physical examination
- an assessment of alternative causes, such as cardiac-related conditions (assessment by a 12-lead ECG) or metabolic disturbances.

If this assessment suggests epilepsy, referral for an electroencephalogram (EEG) is considered.

The EEG is reviewed for evidence of seizures or epilepsy-related electrical brain activity that may appear between seizures, called interictal epileptiform discharges, by a clinical physiologist and a consultant clinical neurophysiologist. A clinical report on the EEG is returned to the referrer, who decides on any further tests, diagnosis and treatment.

A diagnosis of epilepsy is made based on the entire specialist

assessment, not just the conclusion from the EEG. The EEG result can:

- 'make' a diagnosis of epilepsy if a seizure is captured during the recording, but this is rare
- support the diagnosis if interictal epileptiform discharges are seen
- have little bearing on the diagnosis if the EEG is normal or shows non-specific changes.

Epilepsy can be diagnosed, and treatment can start, without an EEG.

## Unmet need

- 3.3 Faster access to diagnosis and treatment for epilepsy is needed. The patient and carer experts highlighted that quicker diagnosis and treatment after suspected seizures would enable access to support, and improve safety and quality of life.

Specially trained healthcare professionals carry out and interpret EEGs for suspected epilepsy. The test generates large amounts of data that takes time to interpret. The specialist capacity available to do and interpret EEGs varies across the country, so the waiting time for a routine EEG can range from a few weeks to 12 months.

Both the patient and clinical experts explained that it is not only the capacity of the specialist healthcare professionals who review EEGs that varies across the country, but also the capacity of specialist healthcare professionals who diagnose and treat epilepsy. Faster access to EEG or being provided with additional information about EEGs, may help reach answers faster, but it could still take a long time to have an appointment with a healthcare professional who diagnoses and treats epilepsy. The

committee recalled that epilepsy can be diagnosed, and treatment can start, without an EEG. The committee concluded that the unmet need is associated more with access to healthcare professionals than with the speed of interpreting EEGs.

## **Innovative aspects**

- 3.4 The software in this assessment uses AI-derived algorithms to automatically detect visual epileptiform activity on EEG recordings or to calculate digital biomarkers from the EEG recordings that are not visible to the human eye.

## **Clinical effectiveness**

### **Diagnostic accuracy**

- 3.5 Five studies reported on the accuracy of healthcare professionals using the software to help review EEGs for interictal epileptiform discharges or seizures. Some of these studies reported similar or improved accuracy. But some also reported lower sensitivity to detect interictal epileptiform discharges and seizures. The EAG noted that some of the studies used older versions of the software. NeuroWorks had only accuracy studies that used the software on its own, not alongside healthcare professional EEG review as intended. All 5 studies were done outside the UK.

One study reported on the accuracy of BioEP to identify epilepsy in people with inconclusive EEGs. The EAG noted that this study used the software on its own, not to help the EEG epilepsy diagnosis by a healthcare professional as intended. The committee recalled that in practice EEG is only 1 possible component of the overall diagnostic process. The diagnosis of epilepsy is made based on the entire specialist assessment, not just the conclusion from the EEG.

The committee concluded that the diagnostic performance of the current versions of all 5 software technologies, used as intended in UK clinical practice, is uncertain.

## **EEG review and reporting time**

3.6 One small study (Kural et al. 2022) compared the time for healthcare professional EEG review with and without encevis (an older version called DeepSpike) or Persyst (an older version, Persyst 13). This study showed a time saving in routine EEG review with both encevis (mean saving of less than 1 minute) and Persyst (mean saving of less than 2 minutes) for each EEG. The committee noted that, in this study, the mean speed of the healthcare professional EEG review without the software was less than 3 minutes. The clinical experts advised that, in the NHS, each EEG is typically reviewed first by a clinical physiologist and then by a consultant neurophysiologist. The review and reporting of a routine EEG takes usually around 20 to 30 minutes. So, the review times in the study may not be reflective of NHS practice. The committee recalled that it may also take some time for an appointment to become available with a healthcare professional who diagnoses and treats epilepsy. So, it is uncertain whether the reported time saving would be meaningful in NHS practice.

The clinical experts noted that longer-term ambulatory or telemetry EEG, which produce days' worth of data for review, are where the largest time savings could be made. But if the software does not integrate with existing EEG systems, using it could add time to the EEG review and limit these potential time savings. The experts also acknowledged that in the NHS, fewer longer-term EEGs than routine EEGs are done. The committee concluded that data comparing healthcare professional time to review and interpret EEGs with and without the software in the UK is needed. Studies

should also include the time it takes to use the software. Studies in longer-term EEGs would be particularly useful.

### **Time to diagnosis and treatment**

3.7 One small study (Tittensor et al., preprint, 2024), reported on the impact of BioEP score on 2 reviewers' beliefs on how likely people with suspected epilepsy are to have a second seizure. The study did not collect data on final clinical diagnosis, treatment or follow up. The committee concluded that it is uncertain how using the software would affect clinical decision making and the care pathway. Data on time to diagnosis and treatment comparing clinical decision making with and without the software is needed to better understand this.

The committee noted that using the software to help with prioritising EEG review may help reduce time to diagnosis. One small study (Charles et al. 2026) reported on the diagnostic yield when using BioEP scores to prioritise follow-up EEGs for people with suspected epilepsy and an inconclusive routine EEG result. When half of the follow-up EEGs were done, 10% more people had received an epilepsy diagnosis than when follow-up EEGs were done without prioritisation. The study did not collect data on time to diagnosis. The committee also noted that some of the software that helps healthcare professionals review EEGs could be used to prioritise EEG recordings for review. But there was no evidence on how this could help. The committee concluded that it would be useful to have data on the effect of using the software for prioritising EEG review or follow up.

### **Equality considerations**

3.8 The committee noted that of the 7 studies using software to help healthcare professionals, 3 included children (1 of which included children only). The key studies did not report subgroup data on

people with conditions that make it difficult to interpret the EEG (such as neurodevelopmental conditions, neuropsychiatric disorders, cognitive impairment, learning disabilities or medication that could influence electrical activity in the brain). The EAG noted that these groups appeared underrepresented or were not reported in the data the software's AI-derived algorithms were trained on. The committee agreed that developing and validating software that is representative of the intended population and reporting on this is important.

The committee noted that people in the most deprived areas of the UK are more likely to have epilepsy than people in the least deprived areas. The availability of healthcare professionals who are epilepsy specialists varies geographically. People who live in areas where epilepsy specialists are less available may have less access or wait longer for services.

## **Cost effectiveness**

### **Exploratory short-term model**

3.9 The EAG developed an early exploratory decision tree model that included an EEG, and review and reporting of the EEG. The model focused on staff time spent reviewing and reporting on EEGs. For BioEP, the EAG explored the potential for reduced need for follow-up EEGs. The EAG noted that there was no data available on the type of EEG for the first EEG or whether and what type of follow-up EEGs are done. The model did not include further steps in the diagnostic pathway (such as other diagnostic testing or diagnosis) or all potential consequences of unidentified epilepsy (such as further seizures resulting in emergency department attendance or injury). The committee concluded that data on healthcare resource use for people having an EEG (including the type of EEG for the

first and any follow-up EEGs) is needed to better capture the potential benefits of the software in a future model.

### **Clinical model inputs**

3.10 The key clinical inputs to the short-term model were the accuracy to detect epileptic abnormalities (interictal epileptiform discharges or seizures) or likelihood of epilepsy on EEG, and the prevalence of abnormalities on EEG. Because the evidence on the accuracy of the EEG review and epilepsy diagnosis done by the healthcare professional with and without support from the software was limited, the accuracy estimates were informed by experts. In the base case, the EAG assumed that there was a small increase in sensitivity (0.1%) when the EEG review or epilepsy diagnosis was supported by the software. For the prevalence of abnormalities on EEG, the EAG felt that clinical expert advice could be more reflective of features seen in NHS practice than data from the populations in the studies on the software. So, the prevalence of abnormalities on EEG was also informed by expert opinion.

### **Resource use inputs**

3.11 Resource use in the model included reviewing and reporting of the EEG, and epilepsy treatment-related healthcare use during a 1-year follow-up period. The base case assumed the time to review and report EEG was shorter when encevis, NeuroCenter EEG, NeuroWorks or Persyst 15 was used to assist the review. There was no EEG review time data reflective of NHS practice. So, the time estimates were based on expert opinion.

To explore some potential benefits and harms, the model assumed that people who had an EEG indicative of epilepsy diagnosis receive a diagnosis of epilepsy and included 1 year of antiseizure treatment. The EAG noted that this match between the EEG conclusion and epilepsy diagnosis and treatment was an

assumption that does not fully reflect current practice. The model made this assumption because no data was available on how the EEG conclusion with or without the software affects diagnostic decision making. The committee concluded that data on the proportion of people having an EEG (inconclusive or with an epileptic abnormality) diagnosed with epilepsy is needed.

### **Plausibility of cost effectiveness**

3.12 The exploratory modelling explored a variety of scenarios in which, when compared with standard care, all the software could be cost effective. The software to help with EEG review (encevis, NeuroCenter EEG, NeuroWorks and Persyst 15) appeared to dominate compared with standard care in many scenarios that assumed a reduction in review time. The software to help with diagnosing epilepsy (BioEP) appeared cost effective if the accuracy of diagnosing epilepsy in standard care was assumed lower than estimated in the base case. The committee recalled that no comparative EEG review time data reflective of NHS practice was available. There was also no data on how the EEG conclusion with or without the software affects diagnostic decision-making or what proportion of people may already be having treatment before an EEG is available. The committee concluded that the model's results, and therefore the plausibility of cost effectiveness, were uncertain because there is not enough clinical evidence to support the model's assumptions.

## **4 Committee members and NICE project team**

This topic was considered by [NICE's diagnostics advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of each committee meeting](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

## **Chair**

### **Thomas Clutton-Brock**

Chair, diagnostics advisory committee

## **NICE project team**

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

### **Suvi Härmälä**

Technical lead

### **Kimberley Carter**

Technical adviser

### **Catherine Pank**

Project manager

### **Lizzy Latimer**

Associate director

ISBN: [\[to be added at publication\]](#)