Newly commercialized

Electroencephalography instrument/device*

Country of origin | Denmark
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 3500
Year of commercialization: 2023
Number of units distributed: 9
Currently marketed in: Kenya
Model: BC-1

Product description

BrainCapture's BC-1 technology is an affordable diagnostic solution that enables portable, hospital-grade electroencephalography (EEG) diagnoses without a neurologist or an EEG technician onsite. The BC-1 consists of:

(1) a low-cost device for capturing medical-grade EEG recordings, consisting of an amplifier and electrode cap (with 27 or 21 electrodes); (2) a proprietary smartphone application that can guide a non-expert to perform a medical-grade EEG test; and (3) a cloud-based telemedicine solution that allows secure transfer of patient data to be read by a remote expert and communication between experts and clinicians at the point of care.

Product details

Accessories: BC-1 Charger BC-1 Charging cable ECG electrodes instructions for use (IFU)27/21 pin cap adapter

Consumables: For easier, more comfortable recording, we recommend the following accessories and consumables: A syringe and needle to apply the conductive gel into the cap electrodes, a conductive gel to lower the resistance between the scalp and the cap electrodes. This improves measurement of brain signals. A measuring tape to find the proper cap size to fit the patient. Alcohol swabs to clean the wrists before putting on the ECG electrodes. A brush to clean the cap electrodes after use. A cap manikin for proper cap storage/display

Warranty duration: BrainCapture offers a 1-year warranty for the medical product BC-1. An extended warranty is available on request. A limited 6-month warranty is available for parts that have been replaced, which only applies to the scope of the replaced part. Support shall be given via email, telephone or Skype.

Lifetime: 3 years

Energy requirements: The BC-1 operates independently of the electrical grid once charged. It is equipped with a 3.7V 2000mAh lithium polymer battery, which enables the device to perform up to 30 recordings, each lasting 30 min, on a single battery charge. The following BC-1 charger specifications apply: Medical grade (2 x MOPP from input to output according to EN 60601-1:2006), Input (AC): 100–240 V, 50–60 Hz Output (DC): 5 V, 1.5 A The charger is a part of BC-1, and shall not be replaced by a different power source.

Facility requirements: Electrical power supply: To ensure compatibility and proper functioning of the BC-1, the facility should provide access to an electrical power supply within the range of 100–240 V and 50–60 Hz to support the BC-1 charger. Smartphone: A precondition for performing EEG recording is a smartphone with a BC-1 mobile application installed. The smartphone must have Android OS (10 or above) with at least 2GB of ram and 1600x720px resolution. Additionally, it requires free memory space (minimum 1 Gb) and Bluetooth 5.0 BLE with PHY2 capabilities. Internet Access: The BC-1 system requires access to the Internet for authentication, upload of data, access to EEG interpretation and patient administration. For upload of data, a stable minimum 500 Kb/s connection is recommended (either WiFi, or mobile data).Proximity between the BC-1 amplifier and smartphone: Since the BC-1 amplifier transmits signals to the user's smartphone app via Bluetooth (BLE 5.0), the maximum acceptable range between the amplifier and smartphone shall not exceed 30 m. Additionally, consideration should be given to any physical obstacles or other electronic devices that may interfere with BLE 5.0 connection. Environmental conditions: The BC-1 can be stored and operated optimally in indoor environments with temperatures of 10–40°C, humidity 15–95% and altitudes -500–3000 m above sea level.

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*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommend with caution

Epilepsy is a chronic neurological condition that requires prompt diagnosis and treatment to prevent significant morbidity. The cornerstone of epilepsy diagnosis and management is the EEG. Traditional EEG machines are cumbersome and sensitive devices, requiring highly skilled technicians for their operation. These constraints, coupled with the absence of qualified electrophysiologists for interpretation, means patients in rural and low-resource settings are often left undiagnosed and untreated.

This technology is a battery-operated and portable medical device composed of a recording tool that is connected to an electrode head cap. The device can be connected by Bluetooth to a smartphone, which allows upload of examinations to the cloud and subsequent remote evaluation by a physician. The app also provides an AI-based EEG interpretation software. Due to its ease of use, this device may significantly extend access to EEG examinations to currently underserved populations. However, the automated interpretation software's performance needs improvement, as agreement between the app and human interpretation is still significant, especially focalized epileptic activity.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed with caution

Pre-market: This product has obtained market approval in Kenya. The manufacturer has submitted the design verification and validation test reports and shared the list of standards to which the product conforms. On the basis of the certification and standards for the performance, the documentation submitted is adequate to demonstrate the product is safe and effective.

Post-market: The manufacturer did not submit complete post-market surveillance and vigilance documentation to monitor the safety and effectiveness of the product after placement in the market.

Quality management system (QMS): Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016, the product is safe, and performance is in accordance to the intended use.

Security: The manufacturer did not submit complete risk management documentation based on ISO14971:2019. The introduction of this technology leads to cybersecurity risk; software validation based on IEC62304 and risk management based on ISO14971 would have addressed these issues and mitigated this risk.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	Proceed	
Safety	Proceed	
Economy	Proceed with caution	
Organizational	Proceed with caution	
Legal	Proceed	
Social	Proceed with caution	
Ethical	Proceed with caution	
Green environment	Proceed with caution	

The BC-1 solution boasts various advantages including affordability that results in increased accessibility. As stated by the innovator, the technology has obtained market authorization from the Kenya Pharmacy and Poisons Board, with a pending CE mark approval. Innovation costs 3500 USD, in contrast to standard EEG equipment from leading vendors, which typically cost 200 000–350 000 USD Furthermore, its use does not require organizational changes or the adoption of additional legislation. As highlighted by the innovator, the BC-1 is environmentally friendly and sustainable due to its lower energy consumption and extended product lifespan; however, the only evidence provided was the innovator's claims.

Technology readiness level 9

Technology evidence assessment Recommend with caution

** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer has provided the necessary, well-detailed technical specifications mainly through the supporting technical documentation provided (i.e. instruction and user manual). At the time of this report creation, WHO technical specifications were not available to compare this type of technology.

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The Braincapture is a portable, battery-operated, and water-resistant device with a mobile app-based EEG acquisition device. It has a head cap containing electrodes prepositioned in standard EEG acquisition locations allowing untrained personnel to conduct examinations. The user must provide an Android smartphone for the acquisition app. A potential drawback is that interpretation of results may require Internet connectivity. Although AI is used for the interpretation of results, no study has been conducted to confirm the accuracy of the interpretation. However, results can be interpreted by human neurologists using the same software platform.

One advantage of the device is that it does not require preventive maintenance. However, it may require corrective maintenance, such as a battery replacement, which can only be performed by the manufacturer. Shipping the device back may pose a problem due to the high transportation costs associated with such returns. Even though spare parts are supplied by the manufacturer, they must be transported directly from the factory. Currently, local support is provided only in Kenya. The manufacturer states in the submitted report that physical, chemical, and biological safety testing has been conducted. The durability of the device cannot be fully verified since only one certificate indicates that testing has been performed.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyright and patents. The device uses proprietary software, and patents are pending. The use of all intellectual property will require clearance.

Local production: The technology has a compliant manufacturing process. However, the device is in an early phase of commercialization and hence might evolve further. The technology has a weak business case for end-to-end manufacture as the technology is highly import dependent, requires a comparatively high level of technical and quality control expertise, availability of a robust, consistent, and highly flexible supply chain in the region and related in-house manufacturing infrastructure.

WHO guidance

- Improving the lives of people with epilepsy: a technical brief. (2022). https://iris.who.int/bitstream/handle/10665/365270/9789240064072-eng.pdf?sequence=1