Instructions for Use - epihunter 3.0(en)

Version 1

This Instruction For Use (IFU) is available on https://www.epihunter.com/hubfs/IFU/Instructions_for_Use-epihunter_3-0(en)_rev_1.pdf

UDI	(01)05430005150007(8012)3.0.0
	Farow NV Kempische Steenweg 303/200 3500 Hasselt, Belgium www.epihunter.com - info@epihunter.com
MD	epihunter 3.0

Product Description

Product Name

epihunter 3.0

General Description

epihunter 3.0 is an artificial intelligence based software solution that analyses EEG data from a consumer grade EEG headset to automatically detect absence seizures. Upon seizure detection, the event is signaled to the people around (via light/sound) and the event is logged in an automated electronic seizure diary. Optionally, a video is automatically recorded, including a short period before seizure onset and after the seizure has ended. The person with (suspected) absence seizures or their caregivers can add extra information.

Potential Benefits

The system may provide the following benefits for persons with (suspected) absence seizures and/or their caregivers:

- Increased awareness of absence seizure events that may otherwise be unnoticed or difficult to detect.
- Improved understanding of seizure occurrence and patterns over time through systematic event logging.
- Increased confidence in identifying possible seizure events, which may support daily activities and quality of life.
- Reduced burden on caregivers associated with continuously monitoring for potential absence seizures.

Support in Daily Life and Social Context

The epihunter 3.0 solution may support users and caregivers in their daily activities in several ways:

- Automated documentation of detected events, which may help reduce the effort required for manual reporting and support communication among caregivers, family members, teachers, and other relevant individuals.
- Assistance for caregivers in observing and recording possible absence seizure episodes in a structured manner.

System Components

The epihunter 3.0 system consists of the following components:

- **EEG headset:**
  A headset equipped with dry frontal EEG sensors designed for ease of use. The headset can also be integrated into a sports cap, beanie or alike.
- **epihunter Core App:**
  A mobile application that connects to the EEG headset via Bluetooth® and runs on a compatible Android smartphone.
- **Smartphone holder (optional):**
  A holder to place the smartphone upright to improve usability during operation.
- **epihunter Companion App (optional):**
  An optional smartphone App for Android and iPhone smartphones that allows lay user / caregivers to get an overview of logged absence seizure events and allows the caregiver to add manual annotations to the seizure diary.
  It displays:
  - Usage
  - Seizure time
  - Seizure duration
  - Videos recorded
  - Manual annotations

  Epihunter Companion App can be downloaded from the Apple App Store or Google Play Store.

Intended Purpose

Epihunter 3.0 is an assistive software device that analyses EEG headset data to support people with (suspected) absence seizures and their caregivers by automatically detecting, signaling, video recording and logging absence seizures in real time during daily life at home, work or at school and to self-manage their disease.

Epihunter 3.0 is not be used as a monitoring device for serious events, e.g. to warn family or caregivers of such serious events. It is not intended for direct diagnosis, nor for monitoring of the EEG or any other physiological process.

Intended Users

Lay persons

- Persons with (suspected) absence seizures
- Caregivers of people with (suspected) absence seizures

Intended User Environment

The EEG headset and Android mobile app will be used at home, work or at school.
Epihunter 3.0 can be used daily, at day time, when the person with (suspected) epilepsy is active. It is to be used preferably during periods when users expect higher probability of seizure occurrence.

Patient Population

Children from 4 years up and adults.
Head circumference should be compatible with the EEG headset (40-70cm).

Medical Conditions

Epileptic absence seizures

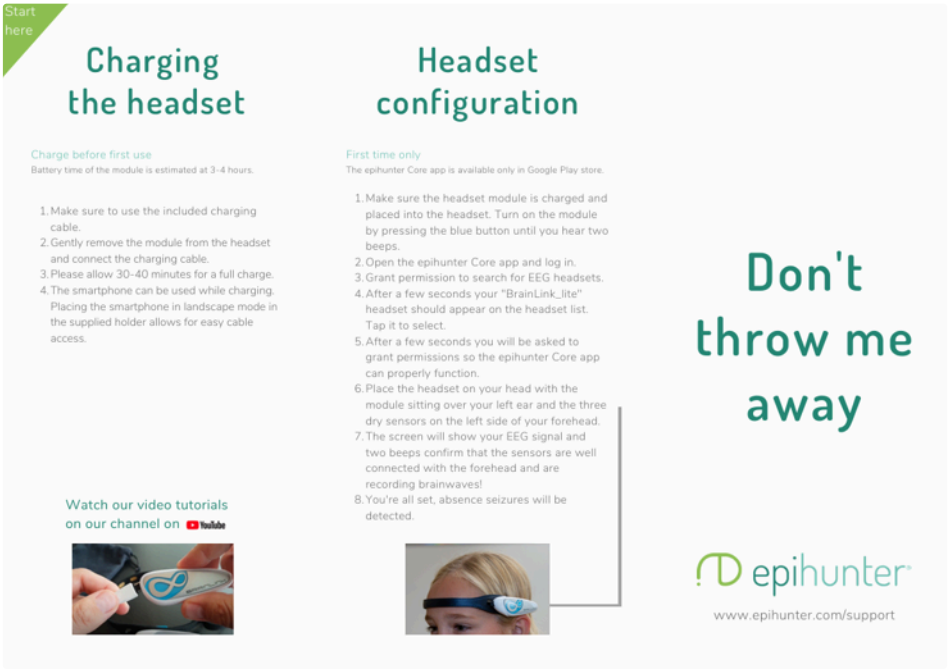
Contra-indications

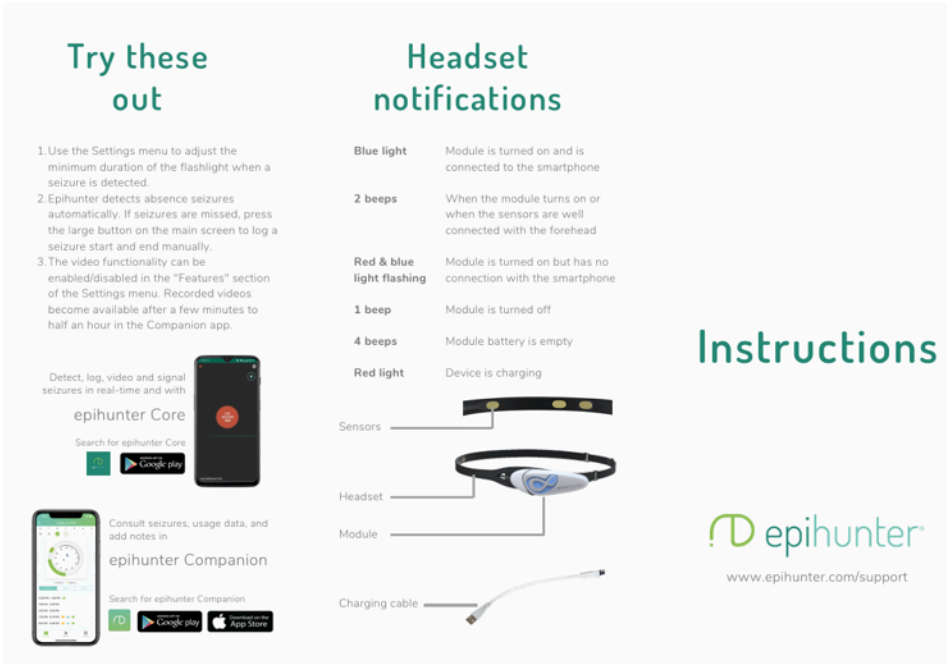
The EEG headset uses electrodes to collect the EEG signal. People who are hyper-sensitive or allergic for metals used must be cautious using the device.

Performance

Our validation research has shown that epihunter 3.0 detects absence seizures with a duration of 5 seconds and longer with a median sensitivity of 92,9%. Numbers can vary from person to person and are dependent on the epilepsy syndrome, type and how the epilepsy manifests itself. For more information, see Japaridze *et al.* : *Automated detection of absence seizures using a wearable electroencephalographic device: a phase 3 validation study and feasibility of automated behavioral testing* (https://doi.org/10.1111/epi.17200).

How to Use?





Information for safety

⚠	*Despite all precautions, a remaining risk exists that the epihunter 3.0 might lead to an inadequate measurement (false positives or false negatives).*

⚠	*The EEG headset uses metal electrodes to measure the EEG signal. Individuals with known metal hypersensitivity or allergies should use the*

	device with caution.

⚠	*User needs to be able to operate a smartphone and have basic computer and internet knowledge.*

⚠	*It is recommended to set the settings in the Play Store so that the Application is automatically updated when a new update becomes available. If not, please update to the newest version as soon as possible*

⚠	Users are expected to take adequate measures to mitigate cybersecurity risks on local hardware and data, including installation of security updates, device access authentication methods and timely installation of available platform software updates.

⚠	Epihunter 3.0 continuously monitors the EEG signal quality that it receives from the EEG headset and notifies the user when the data quality is not sufficient. Users must check and adjust the fit and positioning of the headset until acceptable signal quality is restored.

⚠	When fitting the EEG headset on your head, make sure that the headset transceiver module is on the left side of your head, and all 3 sensors are pressing against your forehead firmly.

⚠	The user must make sure that the battery of the EEG headset is sufficiently charged when using the device. When the LED light flashes and beeps 4 times, it means the battery of your BrainLink Lite ran empty.

⚠	The epihunter Core app smartphone must remain with a range of 5 meters to the person wearing the BrainLink Lite EEG headset and in the same room to ensure proper EEG signal transmission .

Data Protection and Data Security

Farow uses industry-standard encryption protocols to secure all products and data in transfer and at rest. The data is stored on secure, encrypted servers. A continuous backup system is used to make sure all data is secure. Other technical and organizational measures are in place to keep the data safe and accessible.

You, as a user, can also improve the safety of your data. For this, it is important to keep in mind the following recommendations:

- Use a complex and unique password for your login
- Be careful to never share your credentials
- Only use your own or a dedicated device (smartphone, computer)
- Use a secured internet connection

Furthermore, as a user, you have several rights with regards to your data. These rights are explained in our Privacy Notice. For all questions and concerns regarding the security of your data, please contact us at the address provided above.

Incident Reporting

In case any serious incident occurs in relation to the device, this should be reported to the manufacturer and competent authority of your country.

Incidents must be reported via e-mail to address info@epihunter.com.

Technical Description

Required hardware	**epihunter Core App** Recent Android phone **epihunter Companion App** Recent Android phone or iPhone
EEG headset	The application has been validated with the Brainlink Lite BL002 V2.0 headset from Macrotellect (BrainLink Lite | Healthy Brainwaves for Everyone-brainwave headset/EEG device/EEG headband).

Symbols

The following symbols are used on epihunter 3.0 labeling:

	Unique Device Identifier
	Release date
	Manufacturer
	URL that points to the location of the electronic IFU

MD	Medical Device
CE	CE marking to indicate conformity to EU legislation with reference to the notified body that granted the CE mark.