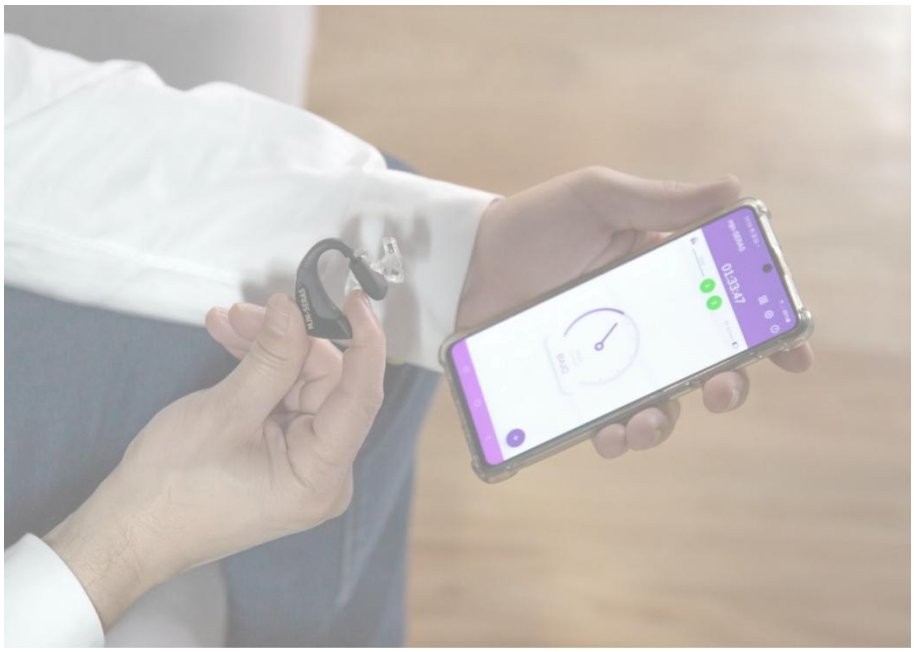
mjn·SERAS >EPILEPSY

Next step for seizure prediction



USER MANUAL

MDR_TD_SERAS.
Instructions for use. (TD_B-4)
Ver. 05
December 2025
UDI-DI: 8437024417064

CE 2797 UKCA 0086

MJN Neuroserveis S.L.

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mjn neuro

CONTENT

1. GENERAL INFORMATION

mjn-SERAS is a medical device product branded as EPISERAS in Europe.

mjn-SERAS or EPISERAS is a non-invasive, artificial intelligence (AI) powered solution designed to help people with epilepsy by providing early alerts of seizure risk. It consists of a discreet earpiece that continuously monitors brain activity, sending real-time data to its companion mobile app. When the system detects patterns that suggest a seizure may be approaching in the next few minutes, it notifies the user, giving the patient valuable time to take safety precautions.

mjn-SERAS or EPISERAS is classified as a Class IIa medical device and has obtained the CE Certificate of Conformity from Notified Body No. 2797 in accordance with Regulation (EU) 2017/745 on medical devices (MDR) and Spanish Royal Decree 192/2023.

The device is also UKCA marked in compliance with the UK Medical Devices Regulations 2002 (as amended), following the applicable conformity assessment procedure for Class IIa devices.

The manufacturer has appointed a UK Responsible Person in accordance with UK regulatory requirements, and the device is duly registered with the Medicines and Healthcare products Regulatory Agency (MHRA) prior to being placed on the Great Britain market.

The product is certified and clinically validated, ensuring compliance with the highest standards of safety, performance, and regulatory requirements in both the European Union and the United Kingdom. mjn-SERAS or EPISERAS proactive approach is expected to significantly reduce the risk of injuries, accidents, and other complications linked to unexpected episodes. Furthermore, by offering greater predictability, mjn-SERAS or EPISERAS aims to alleviate psychological burden often experienced by patient, including stress, anxiety, and uncertainty about when a seizure might occur. Overall, the device contributes to improving autonomy, safety, and quality of life for individuals living with epilepsy.

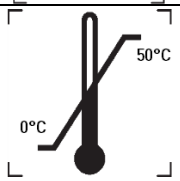
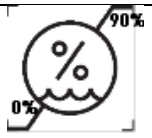
Key highlights:

- AI-powered early detection: Uses advanced algorithms to analyse patient's brain activity, detect patients' pre-ictal patterns, and adapt to patterns' changes over time.
- Real-time monitoring: Offers continuous surveillance to help detect seizure risk early.
- Discreet and comfortable: Designed to be worn like a regular earpiece, with no invasive sensors.
- Mobile app connection: Displays patient's risk level and alerts.

The manufacturer of this medical device is MJN Neuroserveis, SL.

The electronic instructions for use (IFU) comply with Regulation (EU) 2021/2226 and can be downloaded from the website: https://epilepsymanagement.mjn.cat/ifu-language/

1.1. NOTICES AND WARNINGS

	**Please consult the instructions for use** This manual accompanies a brand new, unused product. You can request them by email at info@mjn.cat, by telephone or in writing to the registered office of MJN Neuroserveis.
	**Non-sterile product**
	**Fragile, handle with care** Do not drop the device and protect it from impact.
	**Do not use if the packaging is damaged** If you receive the product with damaged labelling or packaging, please notify the manufacturer immediately and wait to use the device until instructed to do so by MJN Neuroserveis.
	**Keep dry** Do not expose the device to moisture, wet it or immerse it in water or other liquids.
	**Temperature limit 0 to 50°C** Do not expose to extreme temperatures. Protect the device from direct sunlight when not in use.
	**Humidity limit, in the absence of condensation, 0 to 90%**
	To ensure safe use of the device, observe the **care and maintenance** and **storage and transport conditions** in this manual. If you have any questions, concerns, or uncertainties regarding the use of this medical device, please consult your healthcare professional. You may also contact the device manufacturer for additional information or support.
	Do not attempt to open or repair the device or any of its components. All work, reworks or repairs must be performed exclusively by personnel certified by MJN Neuroserveis. Avoid excessive bending or improper handling to prevent damage. Clean the headset regularly with a damp cloth; do not use any other liquids. Do not insert objects into any openings of the device to avoid damaging the electronics, cables or electrodes.

Each time you put on the earpiece, ensure that communication with your smartphone is functioning properly (see Connecting To The Device section).

The device is safe for use by pregnant women and individuals aged 12 years and older. It is not suitable for children under 12 years of age.

Avoid exposing the device to electromagnetic fields or electrical voltages other than those specified in this manual.

Do not connect your smartphone to public or unsecured Wi-Fi networks.
Network requirements:

- *Use **only encrypted Wi-Fi networks** (WPA2 or higher)*
- ***Public/unsecured hotspots are NOT suitable** for operating this medical device*
- *Mobile data connections: At least 4G/LTE with device lock code enabled.*

User responsibility:

- *Enable the smartphone firewall*
- *Install security updates promptly after manufacturer release*
- *Do not use unauthorised apps on the connection device*

If you notice any malfunction of the device, report it immediately to the manufacturer at info@mjn.cat , so that appropriate action can be taken.

Any serious incident must also be reported to MJN Neuroserveis S.L., who will report to the competent national authority.

If the device overheats during charging or use, report this immediately to the manufacturer at info@mjn.cat, so that the appropriate action can be taken.

This medical device is electrical equipment and must not be disposed of as ordinary household waste at the end of its useful life. Under the Waste Electrical and Electronic Equipment Directive (WEEE) and corresponding national laws, this device must be collected separately.
Disposal options:

- Take the device to your local recycling centre or collection point for electronic waste
- Hand over the device to a certified waste management operator or authorized waste disposal company
- Contact the manufacturer for information about take-back systems or producer responsibility organizations

Keep the mjn-SERAS or EPISERAS app always updated to the latest available version. Do not delay updates without a valid reason, as unjustified delays may cause the solution to malfunction.

Do not expose the product to electromagnetic interference outside the permissible range, as this may cause communication failures and lead to device malfunction, compromising its intended purpose.
If such interference occurs and cannot be avoided, leave that environment as soon as possible.

	The device houses an internal battery that powers the equipment. A microUSB type B charger with constant voltage and current is required for charging. - Nominal voltage: 3.7 Vdc. - Charging voltage: 4.2 ± 0.05 Vdc. - Initial charging current: 30 - 60 mA. Do not expose the device to water; its protection rating is IP22. The earpiece should **always** be charged when not in use. **IMPORTANT: Charging the battery is incompatible with using the device.** The earpiece emits high-frequency wireless signal via Bluetooth BLE, compatible with ISM bands. Do not use the device if you have an ear canal infection. Do not use the device if you have a skin injury near the area of influence, or if you are undergoing treatment for the skin in that area. The earpiece should also not be used in cases of inflammation due to otitis, infection or ear injury. Please observe the specified conditions of use and storage. Carefully read this document (Instructions for Use) carefully and watch the video tutorials available in the Help menu of the mjn-SERAS or EPISERAS app to better understand the main operations. Avoid always knocking or dropping the product from any height. When beginning to use this device, please use it for a few hours per day and gradually increase the duration as you become comfortable with the earpiece. Initially, use the product for a maximum of 2 hours per day. Then, increase usage by up to 4 additional hours every 5 days, provided you do not experience discomfort or pain, until you reach the desired usage time. During the first few days of use, you may experience mild discomfort due to the presence of the earpiece in the ear canal; this is expected to diminish over time.
	**Multiple use by a single patient.** This product is for individual use only and must not be shared with other people.
	**Undesirable Side Effects** No undesirable side effects are expected. If you experience or suspect any adverse effects, contact the manufacturer (MJN Neuroserveis S.L.) immediately using any of the provided communication channels, and notify the competent national authority in your country. **IMPORTANT**: Whenever you remove the earpiece, you must turn off the mjn-SERAS or EPISERAS app. Failure to do so will cause the system to assume it is still recording the user's brain activity data, which may prevent accurate assessment of seizure risk.

1.2. CONTRAINDICATIONS

The device should not be used in the following situations:

- Presence of an ear canal infection.
- Skin injuries or ongoing dermatological treatment in the area of influence of the device.
- Inflammation caused by otitis, infection, or ear injury.

Usage restrictions: The device must be used only by individuals within the defined target population (see "Who it is For" subsection within "Preliminary Considerations" section). The functionality and effectiveness of the solution cannot be guaranteed for individuals outside the defined target population.

1.3. INTENDED PURPOSE

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The intended purpose of the mjn-SERAS is "The continuous assessment of the epilepsy seizure risk and the warning against a high risk of suffering it, in previously diagnosed patients".

This assessment is displayed in the app in two risk levels: **Low risk** and **High risk**.

1.4. PRELIMINARY CONSIDERATIONS

What it needs to work:

- A smartphone (Android or iOS) with Bluetooth Low Energy (BLE 4.2 or higher) and internet access.
- The mjn-SERAS or EPISERAS app installed on this smartphone.

Who it is for:

The user of the mjn-SERAS or EPISERAS medical device is a person already diagnosed with refractory epilepsy, according to international clinical standards. The age range is patients aged 12 years or older, up to and including 65 years, regardless of gender. Additionally, it is designed for individuals who experience epileptic seizures that:

- Last more than 5 seconds
- Show clear, observable clinical manifestations

mjn-SERAS or EPISERAS is not suitable for patients whose seizures are caused by psychotic outbreaks, high fever, or infections such as meningitis.

How mjn-SERAS or EPISERAS works:

mjn-SERAS or EPISERAS solution works by combining a wearable earpiece device and a mobile application to continuously monitor and assess seizure risk. Also, the solution embeds an AI algorithm that is patient-customized (personalized for each patient) trained in the cloud.

The process involves several steps:

1. **Signal Capture:** The earpiece records the patient's brain activity through ear-EEG sensors. These signals are digitalized and transmitted securely via Bluetooth to the patient's smartphone.
2. **Sending signal:** The smartphone sends the digitalized signal to mjn-SERAS or EPISERAS cloud. The application uses a pre-trained machine learning model that personalizes itself this individual data during the first days of use. Once personalization is complete, the model parameters stabilize and provide patient-specific assessments (see "What is the Training Period").
3. **Data Analysis:** The smartphone runs the trained machine learning AI algorithm developed by MJN Neuroserveis using Machine Learning, the most clinically validated AI technology. This allows us to make decisions based on signal characteristics, following clear and explainable recommendations provided by AI. The algorithm is previously customized for the patient. This algorithm processes the ear-EEG signals in real time, using statistical and mathematical models to identify temporal and frequency characteristics in the ear-EEG signal, that are associated with pre-ictal states (the period before a seizure).
4. **Risk Detection:** When the algorithm detects patterns that indicate a possible pre-ictal state (a signal that often precedes a seizure), it triggers the high risk level.
5. **Alert Activation:** If the risk is high, the system immediately triggers an alert in the app. The alert includes visual, audible, and vibration signals to help the patient take safety measures.
6. **Seizure Confirmation:** After an alert, the patient is prompted to indicate whether a seizure occurred. The model uses this manual seizure confirmation to further refine its performance. It also logs seizure events for medical review and to further personalize the algorithm.

What is the Training Period:

The Training Period is the first stage of using mjn-SERAS or EPISERAS and is essential for the initial personalization of the risk assessment and training the solution to the patient's unique brain activity.

The system records brain signals and user manually logs seizures in order to configure the validated algorithm to that specific user. Seizure logging is key for finding each patient personalized parameters to be configured, and to foster accurate detection.

During the initial Training Period the risk assessment alerting is not activated yet in the app, as this can only be done after the initial training.

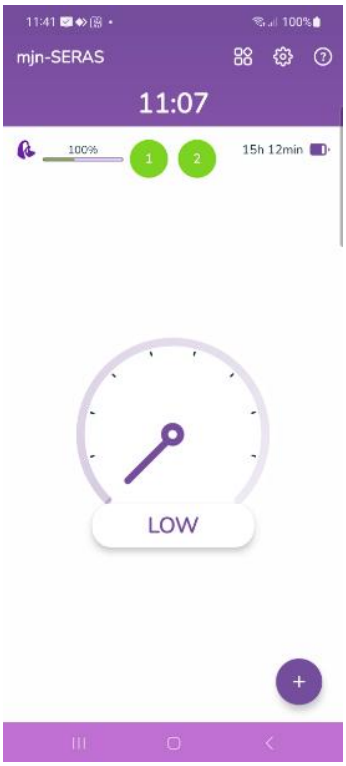
There are no seizure warning or alerts during this period.

When the patient begins using mjn-SERAS or EPISERAS and during the Training Period:

- The system continuously records brain signals No risk detection neither alerts are triggered during the Training Period.
- The patient must log each seizure manually in the app.
- At least 5 seizures must be recorded correctly while using the device, meaning the Training Period duration depends on the patient's epilepsy seizures' frequency and varies from patient to patient.
- This data allows the algorithm to learn the patient's specific patterns and adjust its parameters for accurate seizure risk assessment.

The Training Period is critical because the quality and quantity of recorded seizures directly influence the reliability of the alerts. The more accurate the information manually logged in the app, the better the system can predict seizure risk. The mathematical model is parametrized by the technical team at MJN Neuroserveis. Once the algorithm has been activated with the optimised patient model parameters, the Training Period ends and the Seizure Risk Assessment Period begins.

What is the Seizure Risk Assessment Period:



Once the algorithm is configured to detect individual pre-ictal patterns and enabled in the patient's app user, the app begins assessing seizure risk and issuing visual and audible alerts when pre-ictal patterns are detected. This alerts are displayed to the user through the app and indicate the user's possible risk of seizure compared to the patterns initially trained in the algorithm.

The enabled algorithm performance is continuously monitored throughout mjn-SERAS or EPISERAS use, at the time that patient's brain signals are continuously being used to refine the algorithm configuration for the patient.

If the performance drops, new personalized parameters can be enabled to patient app for immediate use – this allows mjn-SERAS or EPISERAS to be continuously adapting to patients' condition over time.

Additional Regulatory and Safety Information:

- Clinical Validation and Compliance: The safety and efficacy of the mjn-SERAS or EPISERAS have been clinically validated.
- MJN Neuroserveis S.L. considers that the software of its medical device (part of the device mjn-SERAS or EPISERAS) is legal (CE marked under MDR), ethical (deep principle of social action and knowledge of the problems of patients and their carers) and robust (any new

version of the software has been verified and validated based on EN 62304 and EN 82304 standards).

- Data Protection: All data transmitted is anonymized and linked only to the device's UDI number, never to personal identifiers. MJN Neuroserveis applies a Data Protection Methodology in accordance with Regulation (EU) 2016/679 (GDPR) and implements additional measures to prevent unauthorized access.
- Secure Storage: Raw EEG data is stored on secure servers in a proprietary format that can only be processed by MJN Neuroserveis technology.
- Device Lifetime and Environment: The expected useful life of the device is 3 years. It is designed for use in home healthcare setting; for special environments, please consult MJN Neuroserveis through the available contact channels.

1.5. CLINICAL BENEFIT

The clinical benefit of the mjn-SERAS device is a monitoring of brain electrical activity for a measure of a high probability of an epileptic seizure, generating a warning to the user prior to the seizure.

This is expected to lead to an improvement in the user's quality of life as a result of an expected reduction in accidents and injuries.

The mjn-SERAS medical device is intended to lead to an improvement in the user's uncertainty, stress and anxiety in relation to the possibility of suffering an epileptic seizure without prior warning, as well as to related accidents

2. USE AND OPERATION

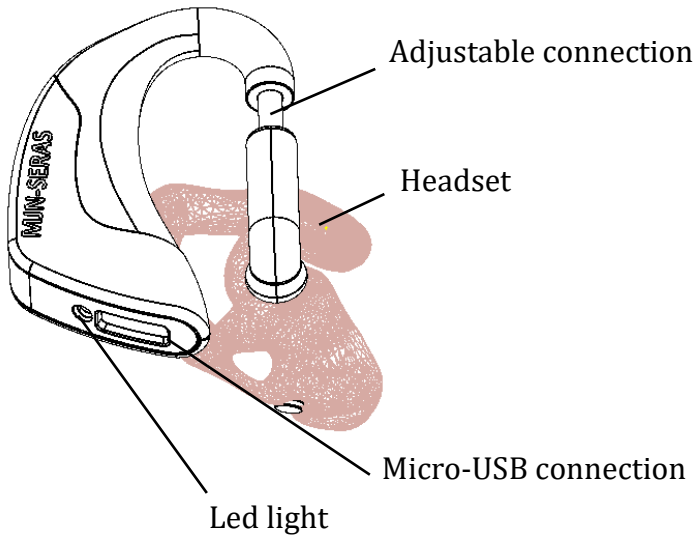
2.1. PACKAGE CONTENTS

- 1 **mjn-SERAS or EPISERAS** earpiece
- 1 USB Type A to microUSB Type B **charging cable**
- 1 Quick start guide
- 1 **User card,** featuring on the front: a QR code providing access to the User Manual (eIFU), along with support and sales contact details; and on the back: the **UDI** code and the earpiece **pairing code**.

The box is shipped with a quality assurance label, serving as confirmation that:

- All applicable quality tests have been successfully completed.
- The product has been officially released.
- The authenticity of the product is certified.

⚠ **The device must not be used if the seal is broken, missing, or otherwise compromised. In such cases, contact the manufacturer without delay.**



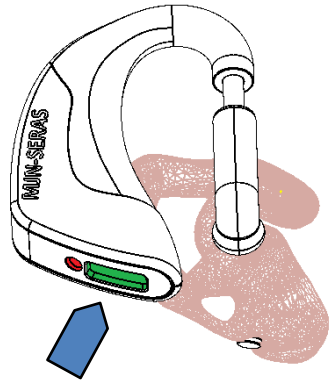
2.2. REQUIRED ACCESSORIES (NOT INCLUDED)

- An Android or iPhone smartphone compatible with the mjn-SERAS or EPISERAS app is required(see APP Compatibility section).
- A standard 5Vdc, 1A USB mobile phone charger together with the supplied USB cable to recharge the mjn-SERAS or EPISERAS device.

⚠ Do not use any USB cable other than the one provided with the device, as doing so may result in malfunction or damage.

2.3. INITIAL SET-UP

2.3.1. Charging the battery

	1. **Connect the micro-USB cable:** Insert the micro-USB connector into the port located at the bottom of the device. 2. **Plug into a charger:** Insert the other end of the cable into the USB port of a standard 5 V mobile phone charger. 3. **Check the LED indicator:** The device's LED will illuminate **solid red** while charging. 4. **Wait for full charge:** Charging is complete when the red LED turns **off**. 5. **Disconnect the cable:** Once fully charged, unplug the charging cable from both the device and the charger.

2.3.2. Download and install the App

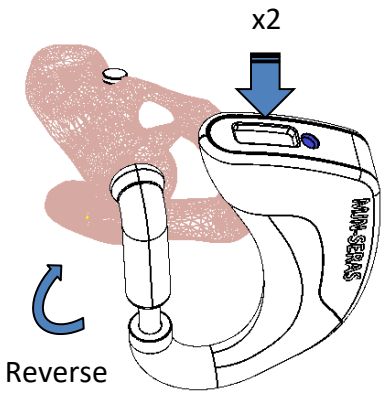
To use the mjn-SERAS or EPISERAS device, you must install the mjn-SERAS or EPISERAS App on your mobile phone. Before installation, verify your device meets the compatibility requirements for operating system and Bluetooth connectivity.

Google Play Store	**For Android Smartphones** Option 1: 1. Scan the QR code provided in the user documentation. 2. Download and install the mjn-SERAS or EPISERAS App. Option 2: 1. Open the Google Play Store on your smartphone. 2. Search for "mjn-SERAS". 3. Download and install the app.
Apple App Store	**For Apple (iOS) Smartphones** Option 1: 1. Scan the QR code provided in the user documentation. 2. Download and install the mjn-SERAS or EPISERAS App. Option 2: 1. Open the Apple App Store on your smartphone. 2. Search for "mjn-SERAS". 3. Download and install the app.

2.4. GETTING STARTED

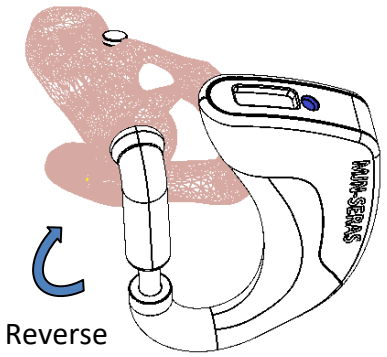
Once your mjn-SERAS or EPISERAS device is fully charged and the mjn-SERAS or EPISERAS App has been downloaded and installed on your mobile phone, you are ready to begin using the device.

2.4.1. Starting the device



1. **Reverse the device position** so that the micro-USB connector is facing upward.
2. **Tap the connector area twice quickly** in succession.
3. The **LED will illuminate green for three seconds,** indicating that the device is starting.
4. **Return the device to its normal position,** with the micro-USB connector facing downward. The green LED will turn off, confirming the device is now running.

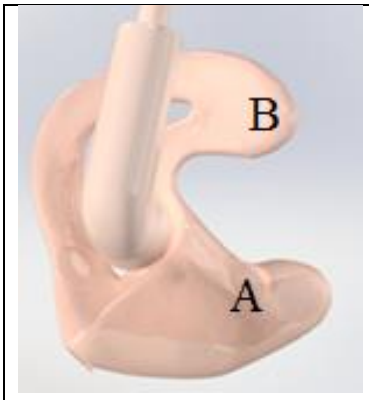
2.4.2. Check if the device is switched on



1. **Reverse the device position** so that the micro-USB connector is facing upward.
2. If the device is powered on, **the LED will remain green** while the device stays in this inverted position.

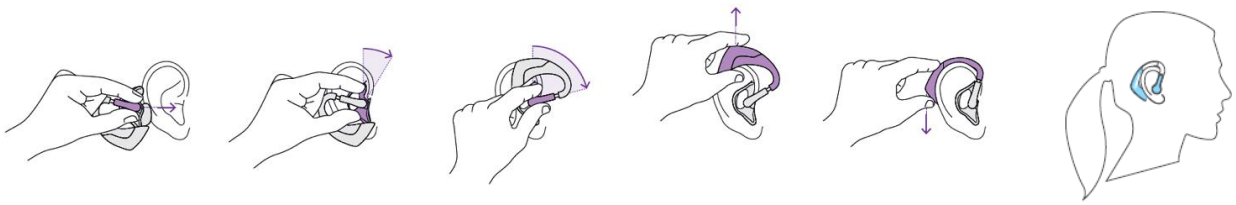
⚠	When handling the device in an inverted position, it may power off. Only turn it over if you intend to check whether it is switched on. If the green LED flashes three times, this indicates that the device is about to power off. In that case, you will need to turn it back on.

2.4.3. Positioning the device



1. **Bring the device close to the ear for which it is intended** (right or left, depending on the patient).
2. **Insert Part A** of the earpiece **into the ear canal.**
3. **Position Part B (the helix)** of the earpiece **into the outer fold of the ear.**
4. **Place the plastic casing securely behind the outer ear.**

The following diagram illustrates the **correct sequence for fitting the mjn-SERAS or EPISERAS device** to ensure proper placement and comfort:



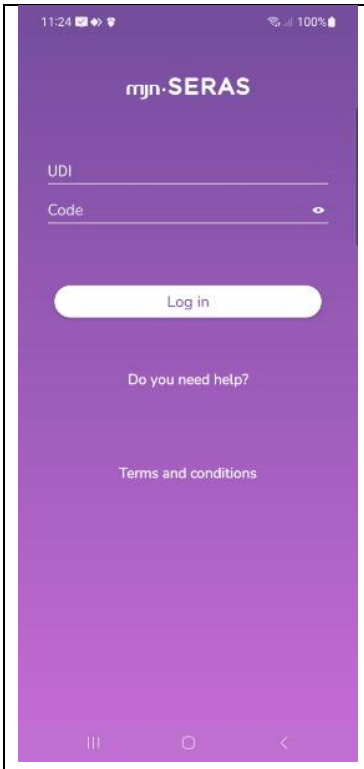
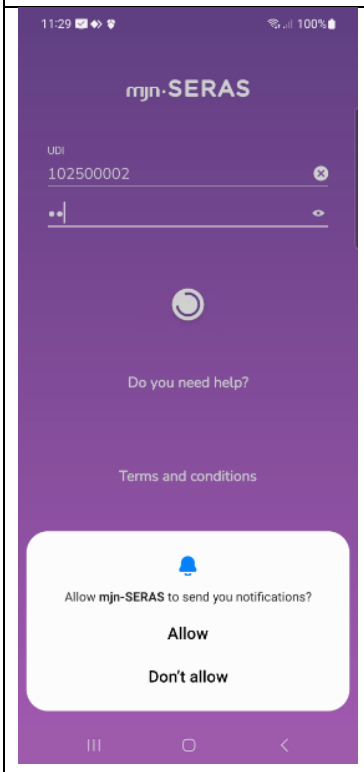
The device has been custom-made using a mould of one of the user's ears. It is essential that it is inserted only into the corresponding ear.

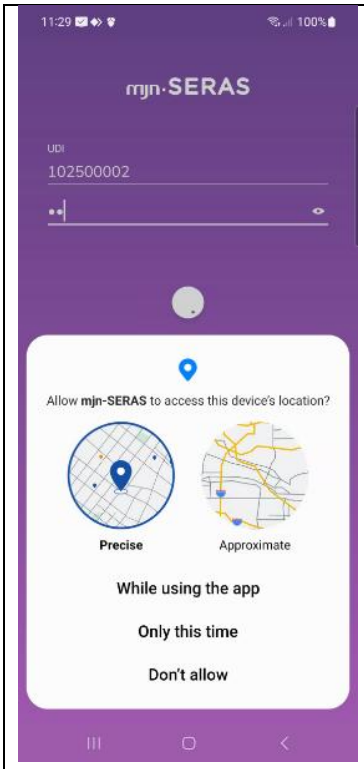
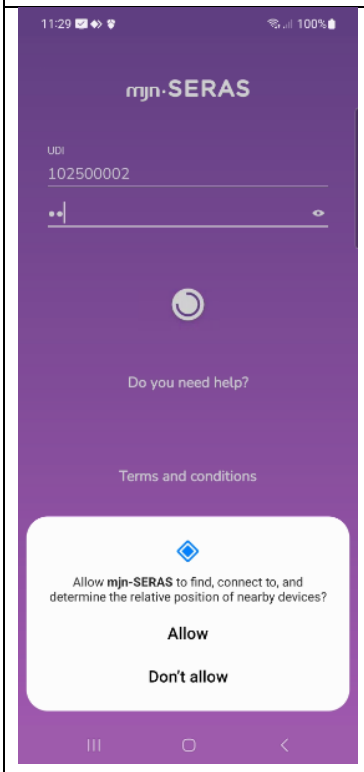
2.4.4. Link the device to the app

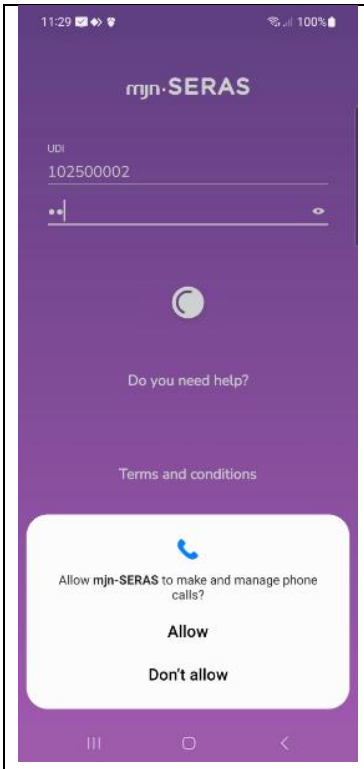
Open the mjn-SERAS or EPISERAS app on your mobile phone. During the first set-up:

- The app will prompt you to grant the necessary permissions for proper functionality.
- You will be asked to review and accept the terms and conditions of use

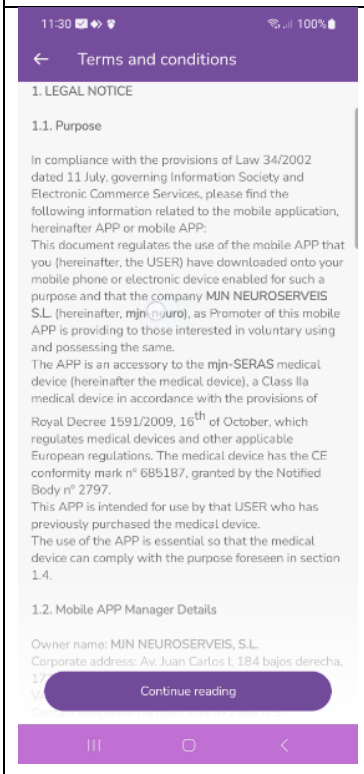
Follow the step-by-step instructions below to complete the linking process.

	1. Log in to the mjn-SERAS or EPISERAS App by entering the UDI and pairing code from the user card, then press 'Log in'. This action will link your device to your mobile phone.
	2. Allow the mjn-SERAS or EPISERAS App to send notifications.

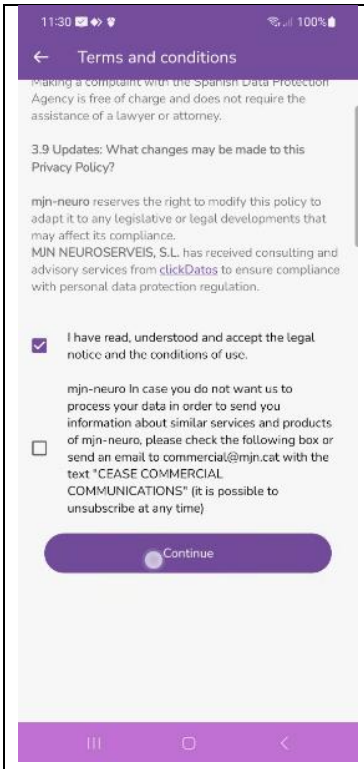
	3. Allow the mjn-SERAS or EPISERAS App to access your location while using the application.
	4. Allow the mjn-SERAS or EPISERAS App to search for, connect to, and determine the relative position of nearby devices.



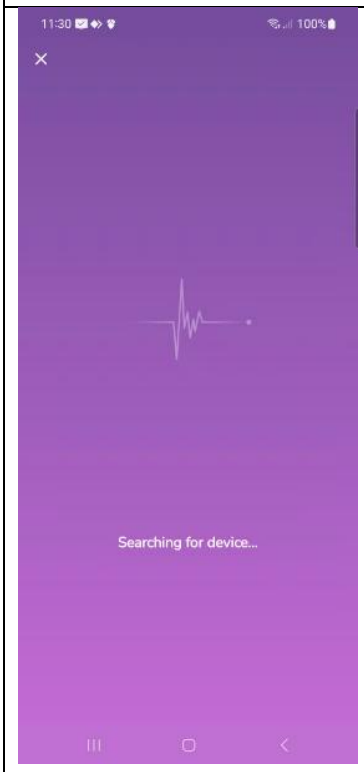
5. Allow the mjn-SERAS or EPISERAS App to make and manage calls.



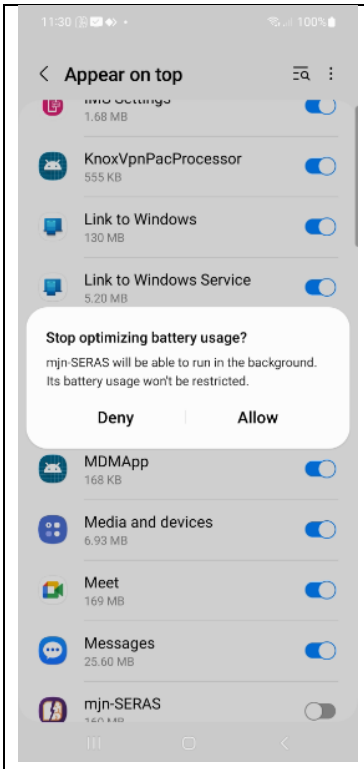
6. Read the Terms and Conditions. Once done, please press 'Continue reading' button placed at the end.



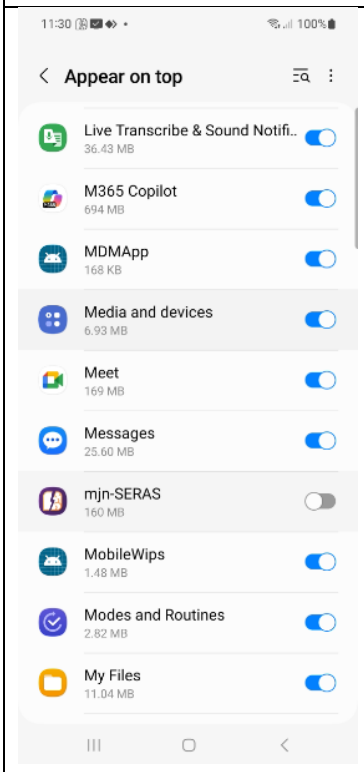
7. Read the legal notice. Check the box to confirm that you have read and understood it, together with the Terms and Conditions.
8. If you are interested to do so, check the box to receive commercial information.
9. Finally press the 'Continue' button.



10. Now the App will search for the associated mjn-SERAS or EPISERAS device.

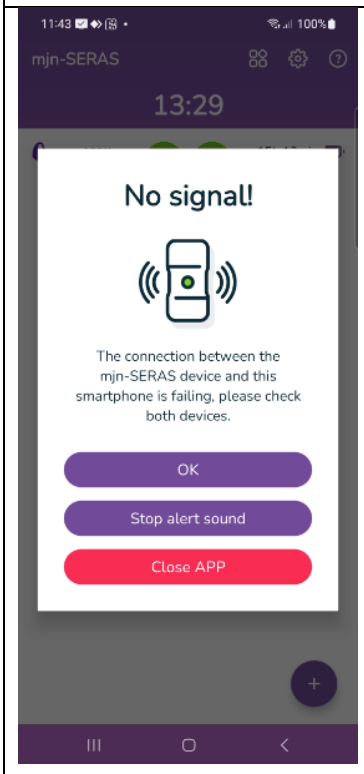


11. For Android smartphones specifically, allow the mjn-SERAS or EPISERAS App to always run in the background without limiting battery usage.



12. For Android smartphones specifically, allow the mjn-SERAS or EPISERAS App to be displayed on top of other apps. This will prioritize the alerts being triggered independently that other app is used.

13. The App should now find the mjn-SERAS or EPISERAS device. Now the Training Period will start. Remember that during this initial period, the brain activity is recorded and the AI algorithm is learning your specific patterns, meanwhile no seizure risk alerts are triggered. Please ensure you read carefully the "What is the Training Period" subsection under section 1.4.



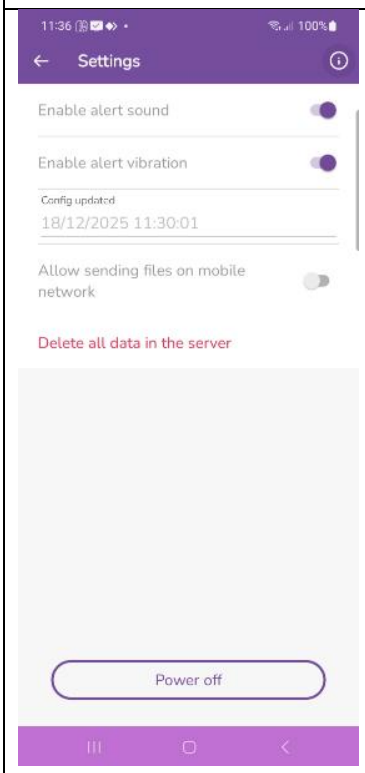
14. If the app is not able to find your mjn-SERAS or EPISERAS device, ensure the device is turned on (section 2.4.2) and less than 1 metre away from your mobile phone.
15. From now on and if the App is functioning, whenever the App loses the signal of your mjn-SERAS or EPISERAS device it will trigger an alert. If the device is off, turn it on and the App will detect it automatically.
    If this alert triggered because you are now not using the device and you forgot to close the App as recommended in the preliminary considerations, you can do it so by clicking 'Close App' button in this screen.

2.5. SHUTDOWN PROCESS

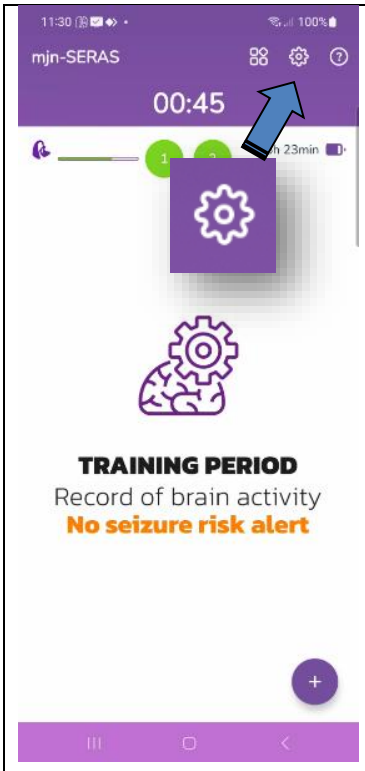
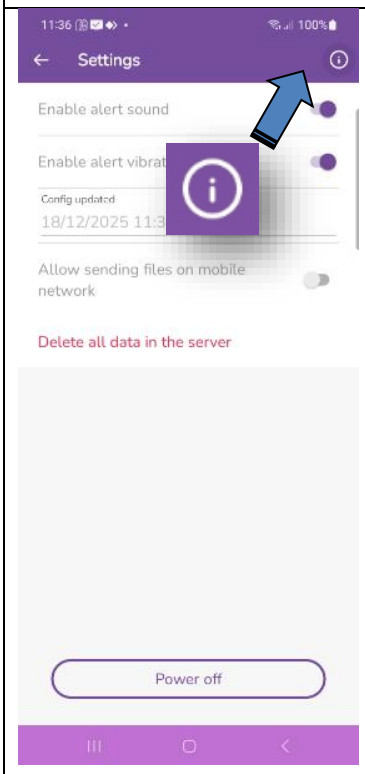
Before removing the device from your ear, ensure mjn-SERAS or EPISERAS is powered off through the app.

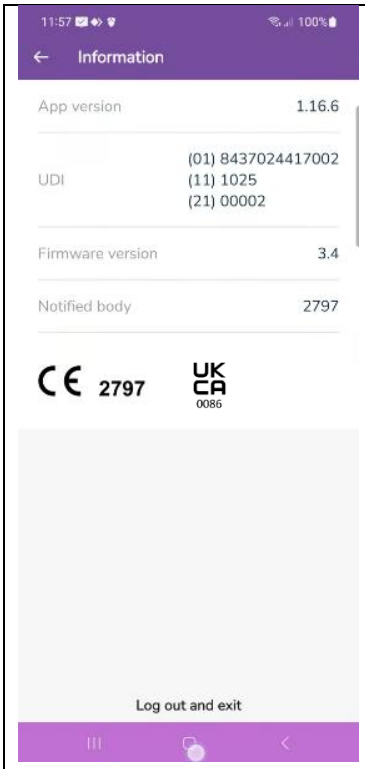
2.5.1. Turning off the device

The device must be powered off using the mjn-SERAS or EPISERAS app on the paired mobile phone before removal.

	1. On the top right corner of the main screen of the mjn-SERAS or EPISERAS application, select the Settings button.
	2. Tap "**Power Off**" and confirm the action. 3. The green LED on the mjn-SERAS or EPISERAS device will flash three times, indicating that the device is shutting down.

You can also disconnect the device by closing the current session. If you choose this option, you will need to re-enter the **UDI** and **pairing code** the next time you use the device.

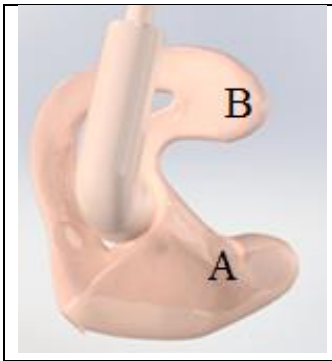
	1. On the top right corner of the main screen of the mjn-SERAS or EPISERAS application, select the Settings button.
	2. To access the logout option in the Settings menu, tap the Information button.



3. Tap the Log out and Exit button and confirm the action.
4. The green LED on the mjn-SERAS or EPISERAS device will flash three times, indicating that the device is shutting down.

IMPORTANT : Whenever the headset is removed, the mjn-SERAS or EPISERAS application must be turned off. If the app remains active, the system will assume it is still recording brain activity data, which may prevent accurate seizure risk assessment.

2.5.2. Remove the device



1. Gently move the plastic casing forward, toward the front of the ear.
2. Carefully remove the earpiece:
   a. First, **detach Part B** (the helix).
   b. Then, with a **slight twist toward the back**, remove the rest of the earpiece from the ear canal.
3. Once removed, you can safely store the device.

2.6. HOW THE APPLICATION WORKS

The mjn-SERAS or EPISERAS application is the central interface for monitoring seizure risk and managing device functionality. It operates in conjunction with the earpiece to process brain activity data and provide real-time insights.

The app's main functions include:

- **Seizure Risk Assessment**: Uses an AI algorithm with a model customized to the patient's brain patterns to evaluate seizure risk based on the detection of patient pre-ictal patterns. During the initial **Training Period**, the algorithm is inactive whilst learning the patient pre-ictal patterns, and no alerts are generated. Once the **Seizure Risk Assessment Period** begins, the model is personalized, and app displays two possible states: *Low Risk* or *High Risk*.

- **Seizure Logging**: Allows the patient to manually record seizures at any time, which is essential for algorithm personalization and ongoing accuracy.
- **Reports and History**: Provides access to seizure reports and trends, which can be exported for medical review.
- **Epilepsy educational Resources**: Offers information on epilepsy management and best practices.
- **Settings and Legal Information**: Enables configuration of alerts, review of legal notices, and management of data privacy options.
- **Help and Support**: Includes tutorials, quick guides, and contact details for assistance.
- **Alerts**: Issues visual, audible, and vibration alerts when a high seizure risk is detected.
- **Other notifications**: such as connection loss, low battery, or signal errors.

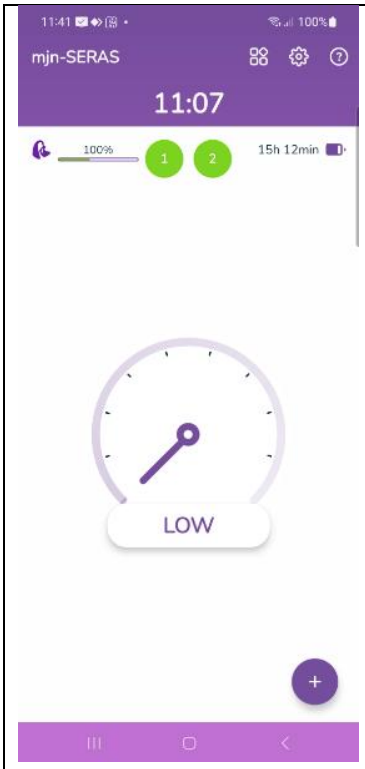
The mobile app ensures secure data transmission and storage, complying with GDPR and medical device regulations. Continuous updates and customization improve accuracy and maintain optimal performance.

2.6.1. Seizure risk assessment

The mjn-SERAS or EPISERAS application evaluates the risk of an epileptic seizure using an Artificial Intelligence (AI) algorithm specifically designed for epilepsy management. This algorithm continuously analyses brain activity data captured by the earpiece and transmitted to the app in real time. It is processing all information with the goal to identify patterns that typically occur before a seizure (pre-ictal state) and provide early warnings to the patient.

The algorithm enters the **patient personalization phase during the Training Period**, where it learns the patient's unique statistical patterns for that person. It is important to take into consideration that:

- At least five seizures must be correctly recorded for the model to adapt effectively.
- Manual seizures must be logged in by the patient.
- No alarms are triggered during this period.



Once training is complete, the personalized model is enabled in the patients' linked app (see section 2.7) and runs in real time, continuously assessing risk.

The app will correctly assess the seizure risk level once the **Seizure Risk Assessment Period** has been activated by MJN technicians in 1-2 business days after the 5 correctly recorded seizures.

The app displays two possible states:

- **Low Risk**: No potential pre-ictal pattern detected by the algorithm.

- **High Risk**: Patterns detected suggesting a seizure may occur within the next few minutes.

When high risk is detected, the app triggers **visual, audible, and vibration alerts**, giving the patient time to take safety measures. Accuracy improves over time as the patient logs seizures (see section 2.6.2).

Alerts are based on a statistical risk link to pre-ictal pattern detection, so occasional false alarms or missed detections may occur.

2.6.2. Seizure logging

Recording seizures in the mjn-SERAS or EPISERAS application is essential for the personalized initial set-up (Training Period) and highly recommended during the Seizure Risk Assessment Period.

- **During the Training Period:** Manual seizure logging is crucial and mandatory. The algorithm relies on these entries to learn the patient's unique brain activity patterns and

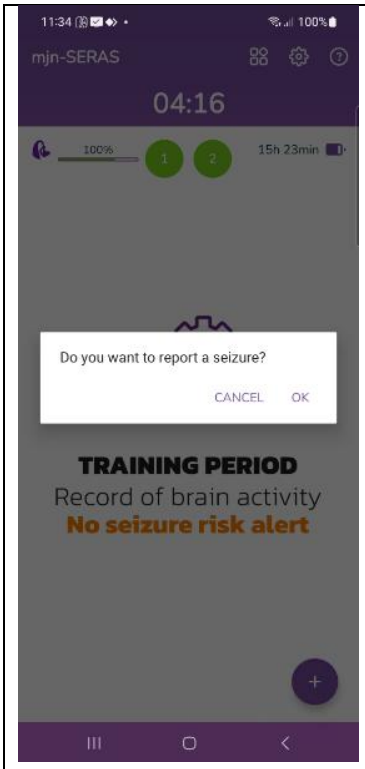
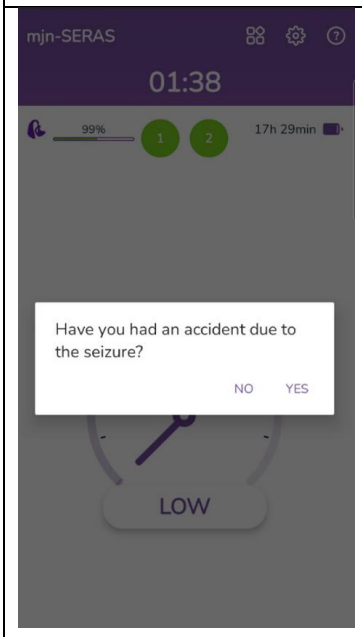
accurately distinguish pre-ictal states. At least five seizures must be recorded before the system can activate risk assessment and alerts.

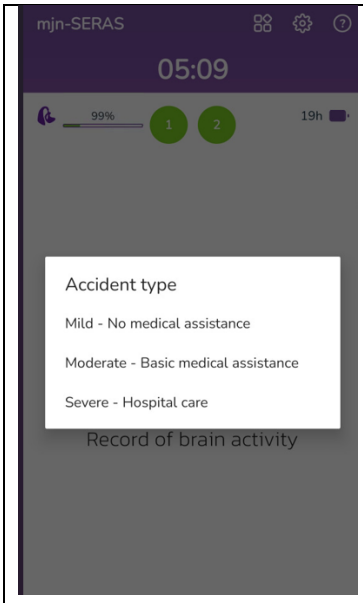
- **During the Seizure Risk Assessment Period:** Although the algorithm is already enabled, continuing to log seizures is mandatory. Each new entry helps refine the personalized model, improving prediction accuracy and reducing false alerts over time. This ongoing customization ensures the system adapts to changes in the patient's condition and provides the most reliable warnings.

Maintaining accurate seizure records not only enhances model performance but also provides valuable data for medical review, helping healthcare professionals better understand the patient's condition.

See below the steps to record a seizure on the main screen of the mjn-SERAS or EPISERAS App.

	1. Select the '+' button on the right bottom of the main screen of the app. It is available in both "Training period" and "Seizure risk assessment period" of the app.

	2. A confirmation prompt appears to report a seizure. Select OK if a seizure occurred and needs to be reported. Next, a confirmation message will appear to continue reporting the seizure. To proceed, select OK.
	3. Have you had an accident due to the seizure?" Select Yes or No to continue.

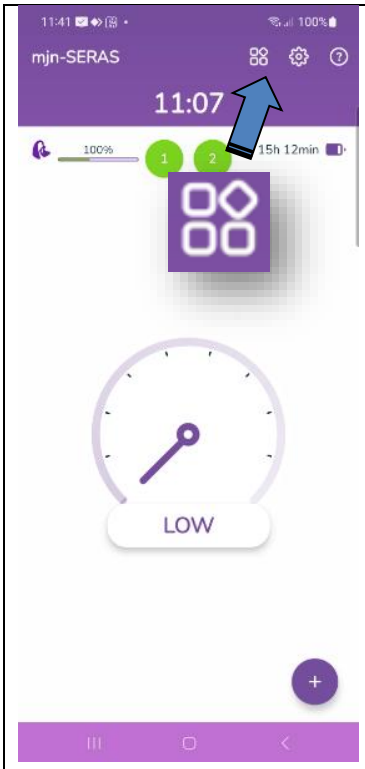
	4. In case you selected yes, select the accident type you had: mild, moderate, severe.

2.6.3. Reports and history

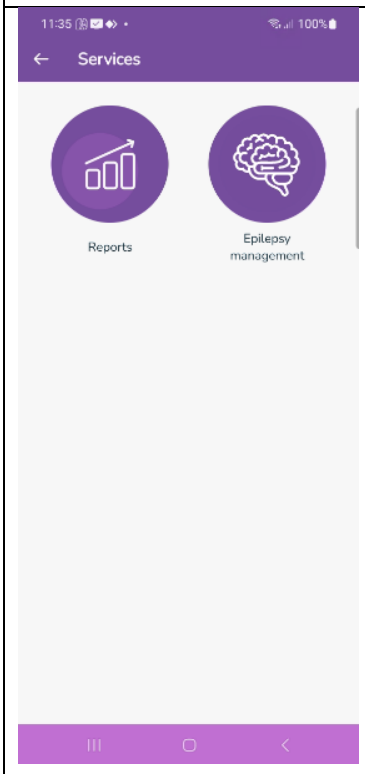
The mjn-SERAS or EPISERAS App provides an overview of the user's seizure records. This feature allows patients to review their history, monitor trends, and share the information with healthcare professionals. Reports include details such as the number of seizures, their timing, and patterns over selected periods.

Accessing these reports is highly beneficial for both the patient and their medical team, as it supports informed decision-making and helps optimize treatment plans. Reports can also be exported in PDF format for easy sharing during consultations.

To access these reports, the patient must be logged in to the app, and the mobile phone must have an Internet connection. See the steps below for more information.

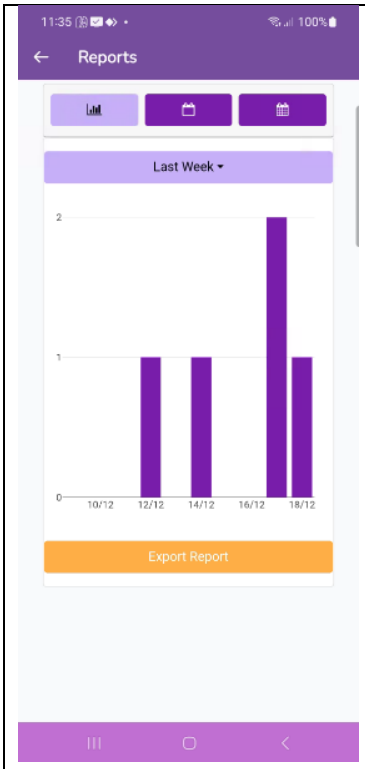


1. Select the Services button on the top right of the main screen of the app.
2. To return to the main screen, click on the arrow in the left top corner.



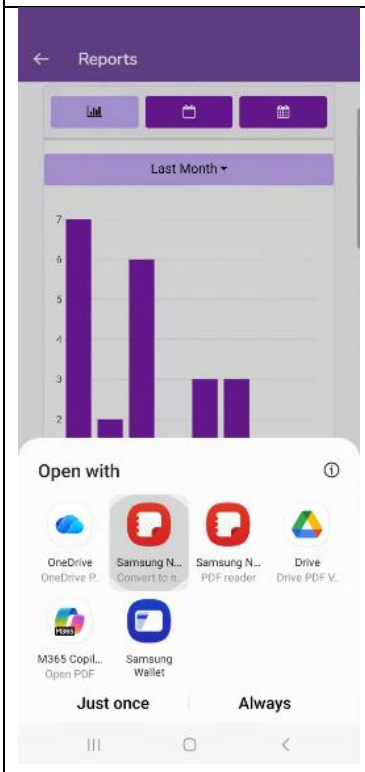
3. Choose Reports from the Services menu.

   To return to the Services screen, click on the arrow 



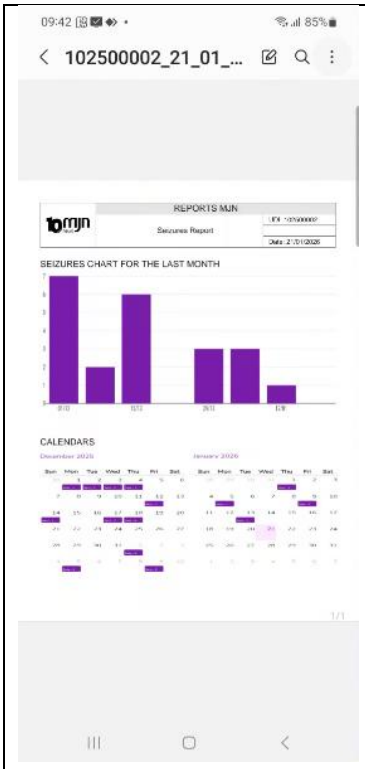
4. Select the period you wish to view from the selectable and predefined list, in order to display a graph showing the number of daily seizures.
5. Optionally, export and download the report in PDF format to share with your doctor by clicking 'Export Report' button.

   To return to the Services screen, click on the arrow

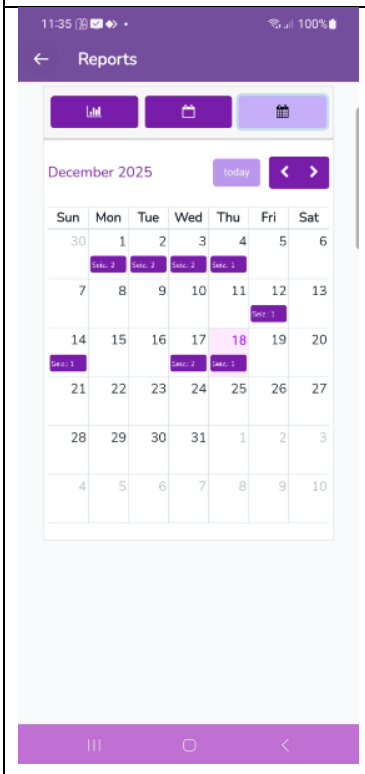


6. If you select "Export Report," the smartphone's operating system will display options to read and save the PDF.

   To return to the Services screen, click on the arrow



7. After selecting the exact tool to read and save the document, the PDF report is shown.



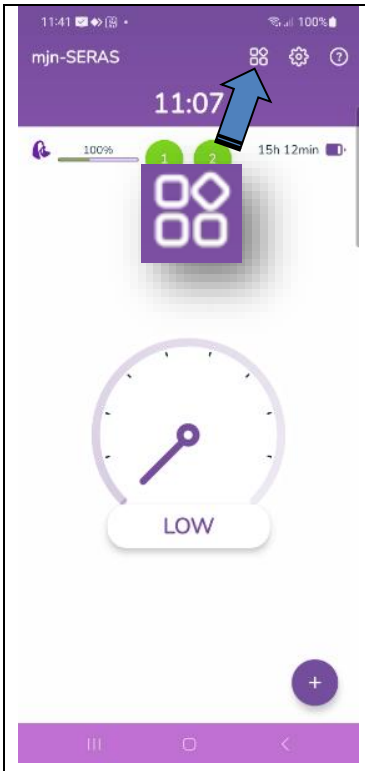
8. Tap on the calendar icon to view the daily seizures in calendar monthly format.

   To return to the Services screen, click on the arrow 

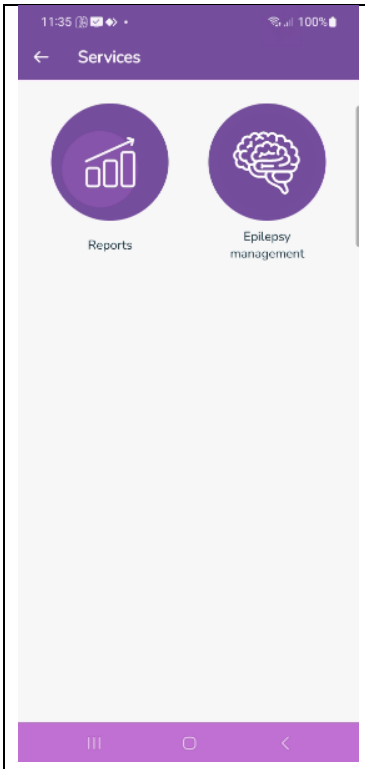
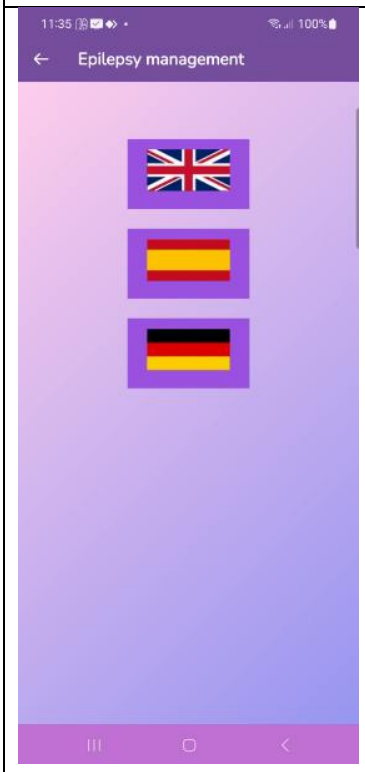
2.6.4. Epilepsy educational resources

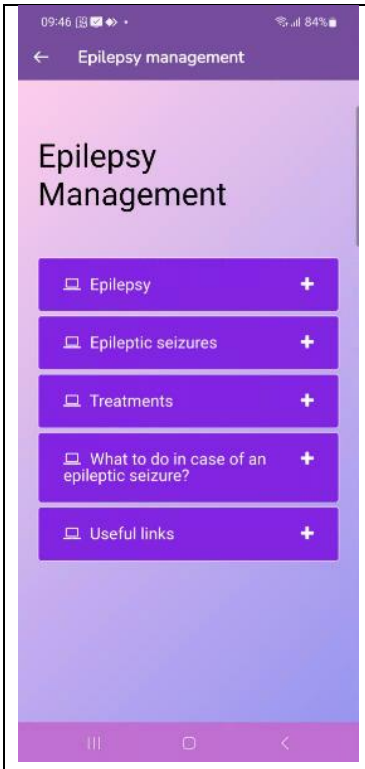
The mjn-SERAS or EPISERAS application provides access to information and practical resources to help patients better understand epilepsy and manage their condition. These educational materials include guidance on lifestyle considerations, seizure management strategies, and general knowledge about epilepsy.

To access these resources, the user needs to be logged in the app and the mobile phone connected to the Internet. Information is available in multiple languages and organized into easy-to-navigate sections for quick reference.



1. Select the Services button on the top right of the main screen of the app.
2. To return to the main screen, click on the arrow in the left top corner.

	3. Choose Epilepsy Management from the Services menu.
	4. Click on the language you want to read the information.



5. The information is presented in sections that are expanded once clicking them. The current available sections are shown in the selected language, and are:
    - Epilepsy
    - Epileptic seizures
    - Treatments
    - What to do in case of an epileptic seizure
    - Useful links: of global interest and of country-interest.

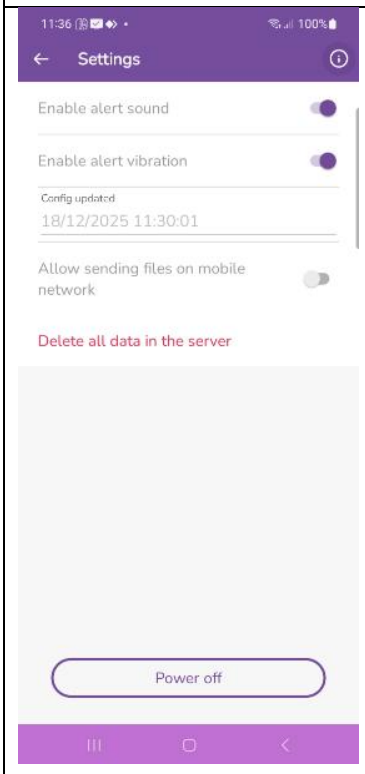
2.6.5. Settings and Legal information

The mjn-SERAS or EPISERAS application includes a dedicated section for configuring operational preferences and accessing essential legal details about the device. From this menu, users can adjust alert settings (sound and vibration), review the date of the last configuration update, and manage data transmission options.

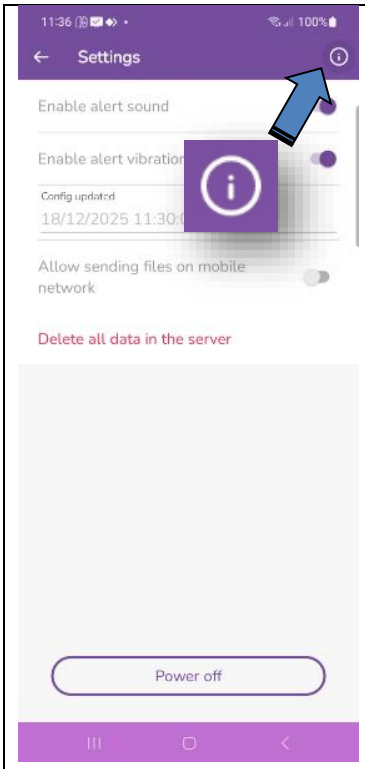
This section also provides access to important regulatory information, including the device's unique identifier (UDI), firmware version, CE marking, and compliance details. Users can exercise their data rights, request data deletion, and review terms and conditions directly within the app.

To access the settings and legal information, see the instructions below.

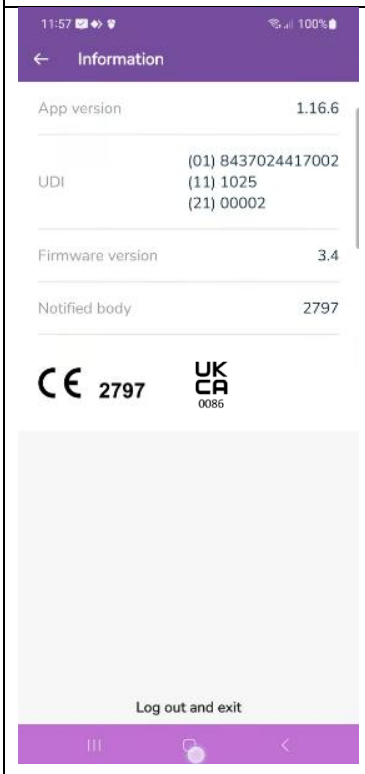
1. On the top right corner of the main screen of the mjn-SERAS or EPISERAS application, select the Settings button.



2. From the Settings screen, users can manage key preferences and access important legal details:
   - **Alerts**: Enable or disable sound and vibration notifications according to your preference.
   - **Configuration Updates**: View the date of the last update to your personalized settings.
   - **Data Transmission:** Allow or restrict data transfer via the mobile network.
   - **Data Rights**: If you decide to stop using the device, you can submit a request from this screen to delete all data stored on the server.
   - **Device Control**: Turn off both the device and the app by pressing the "Power Off" button.
3. To return to the main screen, click on the arrow in the left top corner.



4. Tap the Information button.

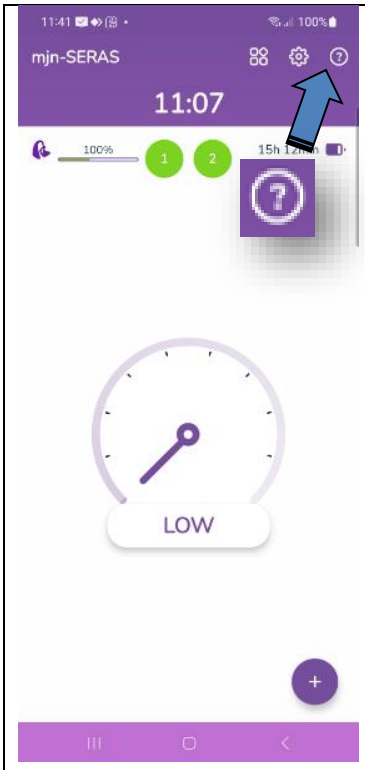


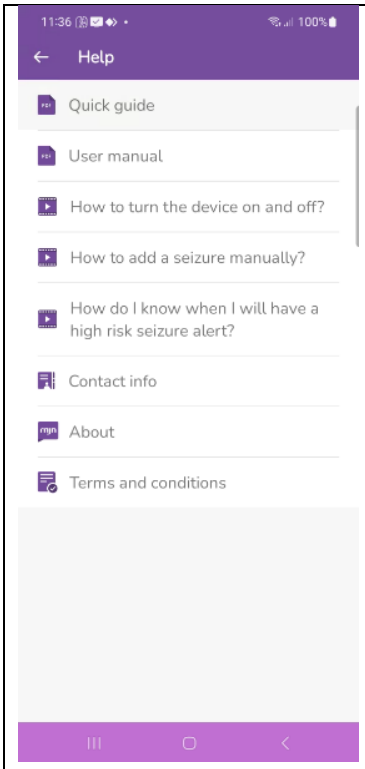
5. From this screen, you can:
   - **Check the App version**, the legal unique device identifier (UDI), the firmware version, and verify the CE marking along with the code of the notified body that certifies compliance.
   - **Log out, turn off the device, and exit** by selecting the option at the bottom of the screen.
     Important: If you choose this option, the next time you access the device you will need to re-enter your User Card details (UDI and pairing code).

2.6.6. Help and support

The mjn-SERAS or EPISERAS application includes a dedicated **Help** section designed to assist users with device operation and troubleshooting. This area provides quick access to essential resources such as the user manual, video tutorials, and a quick-start guide. It also includes contact details for technical support and legal information, ensuring users can resolve issues promptly and operate the device safely.

To access these online resources, the user must be logged in and the mobile phone connected to the Internet.

	1. Select the help button on the top right corner of the main screen of the App.

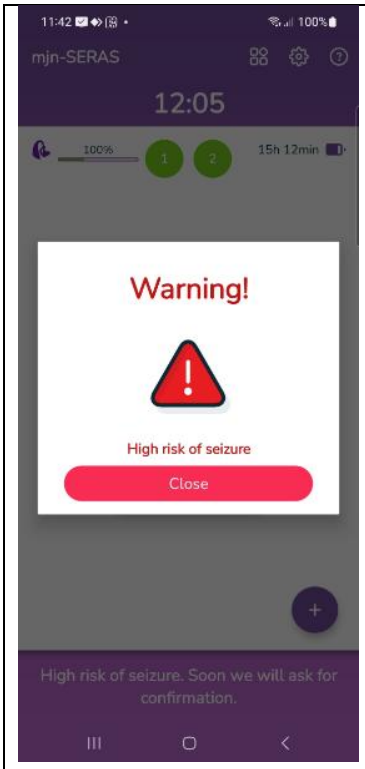


2. From this help screen, you can access:
   - Quick guide to the device
   - User manual
   - Tutorials
   - Contact information
   - About
   - Terms and conditions
3. To return to the Main screen, click on the arrow of the left top corner of the screen.

2.6.7. Alerts

During the Seizure Risk Assessment period, when the algorithm detects a high risk of seizure, the mjn-SERAS or EPISERAS application immediately issues an alert to warn the user. This alert is designed to be noticeable and includes visual, audible, and vibration signals, ensuring the user can take precautionary measures . The alert remains active until the user acknowledges it.

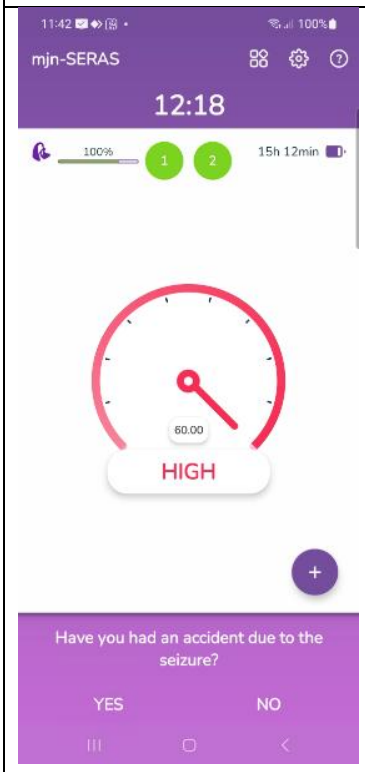
See the step by step explanation below.



1. When a **high seizure risk** is detected, the app displays a prominent alert with visual, audible, and vibration signals to prompt the user to move to a safe place.
2. The alert remains active until the user closes it by pressing the "**Close**" button."

3. After the high-risk alert is closed, the app displays a reminder message at the bottom of the screen.
   The patient should take all necessary precautions and remain in a safe environment for at least 15 minutes.

4. 15 minutes after a high-risk alert, the app will prompt the user to confirm whether a seizure actually occurred, helping classify the alert as accurate or a false positive.
   No additional alerts will be issued during this period until the confirmation is completed.

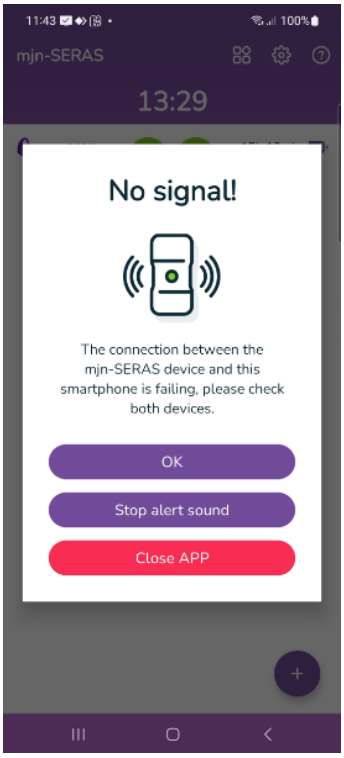


5. If seizure is confirmed, the app will prompt the patient to indicate whether the seizure resulted in an accident.

2.6.8. Other notifications

In addition to seizure risk alerts, the mjn-SERAS or EPISERAS application provides various notifications to ensure proper device functionality and user safety. These notifications inform the patient about connection status, signal quality, battery levels, and maintenance requirements. Each notification is accompanied by clear instructions to help the user resolve issues promptly and maintain optimal performance of the system.

Loss of connection



If the app loses connection with the device, it will trigger an audible and vibration alert to notify the user. When the mjn-SERAS or EPISERAS device is not connected to the mobile phone, brain activity cannot be recorded.

This issue may occur if:

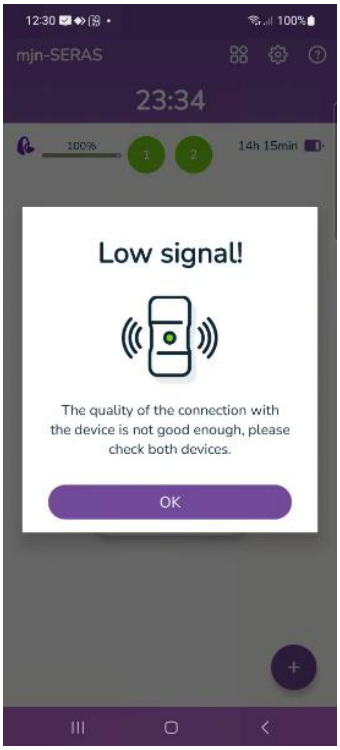
- The device is too far from the phone
- The device has been turned off (e.g., due to low battery)

The connection will automatically restore once the device is switched on and within range.

Available actions:

- **OK** – Reset the alert
- **Stop alert sound** – Silence the alarm
- **Close App** – Turn off the application

Low signal

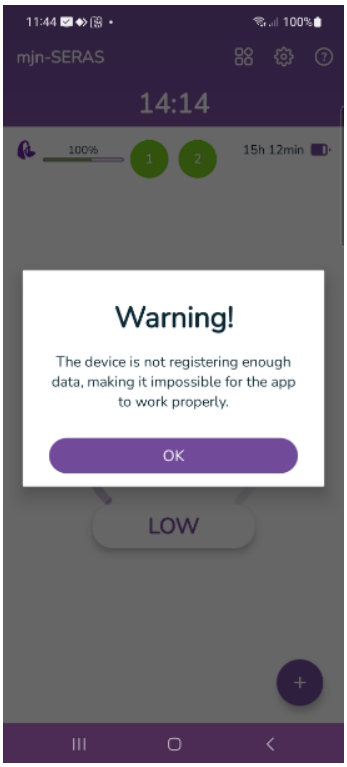


If the connection between the device and the mobile phone is weak, the App will activate an audible and vibration alert.

This may happen because the device is too far from the phone.

The connection will automatically restore when distance is reduced.

Data recording error

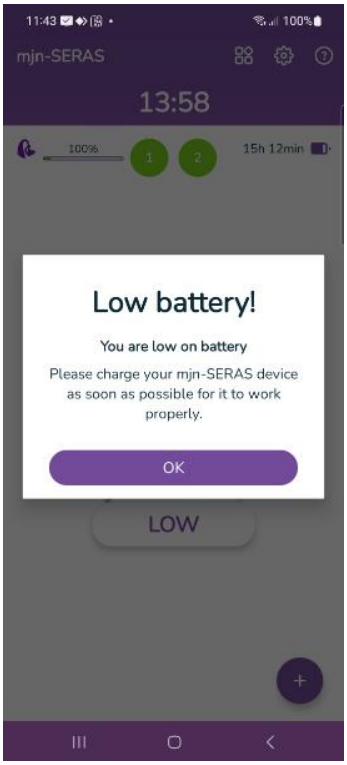


This warning is displayed when the device cannot record sufficient signal data, preventing proper brain activity recording.

The alert will clear automatically once signal recording resumes.

If the problem persists after restarting the device and the app, contact the manufacturer.

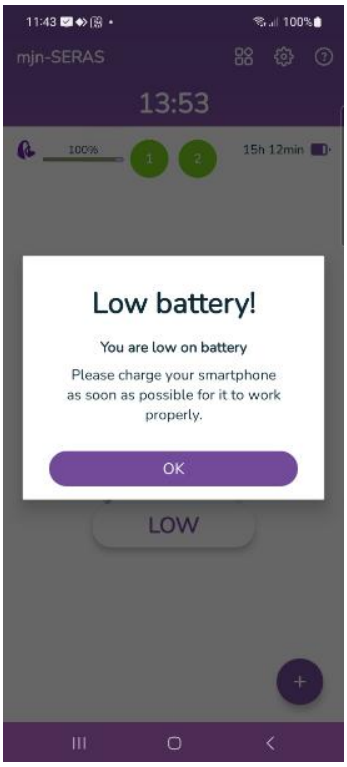
Low device battery



If the device battery is too low, the app will trigger an audible and vibration alert.

Do switch off the device, remove it from your ear, and recharge it using the provided USB cable.

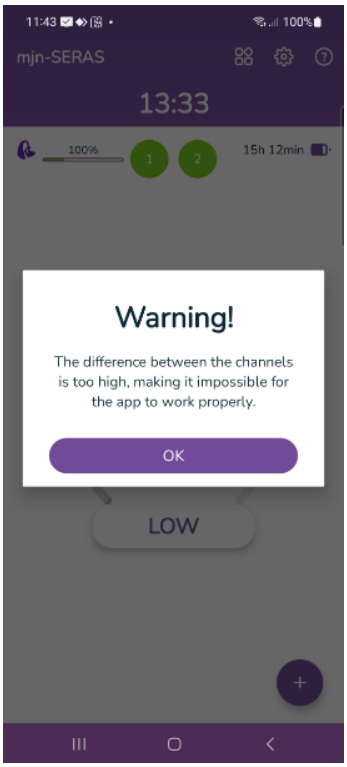
Low mobile phone battery



If the mobile phone battery is too low, the app will trigger an audible and vibration alert.

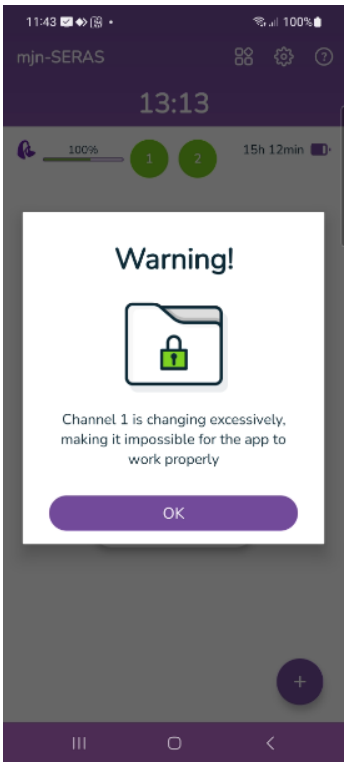
Switch off the device, remove it from your ear and charge your mobile phone promptly to maintain proper operation.

Signal errors



Occurs when the **difference between signal channels is excessive**, preventing the correct recording of brain activity and the correct functioning of the device, possibly due to electrical interference or electromagnetic disturbances.

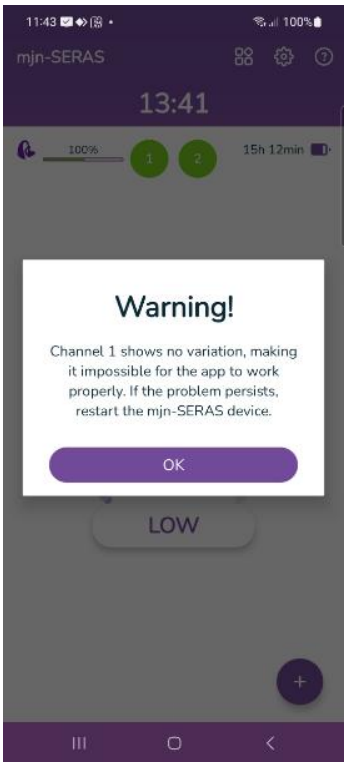
Ensure the device is positioned correctly and move away from interference sources. The alert clears automatically when signal levels normalize.



Occurs when any of the signal channels shows sudden, excessive changes which may result from interference or incorrect earpiece positioning. This prevents the correct recording of brain activity and the proper functioning of the device.

This may occur due to electrical interference or electromagnetic disturbances, or because the earpiece is not positioned correctly in the ear.

Reposition the earpiece back to its proper place, and/or eliminate interference sources.

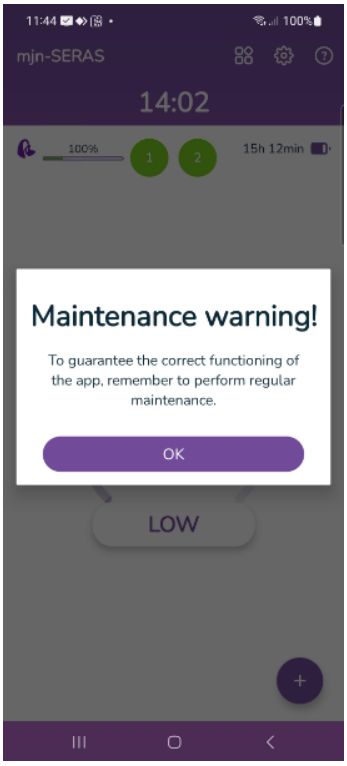


Occurs when one of the signal channels remains static, preventing the correct recording of brain activity and the correct functioning of the device.

Check the earpiece placement and restart both device and app. Then, the warning should disappear and the device automatically returns to normal operation.

If the problem persists after resetting the device and the app, contact the manufacturer.

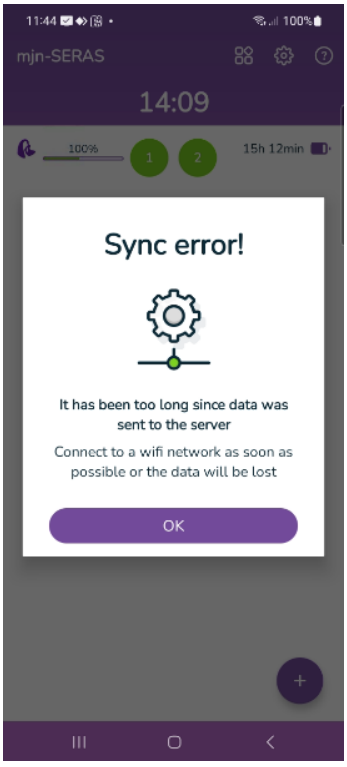
Maintenance warning



This maintenance warning is displayed periodically as a reminder to clean the device.

Switch off the device, remove it from your ear and clean the device according to the instructions in the "Care and Maintenance" section of this manual.

Synchronisation error

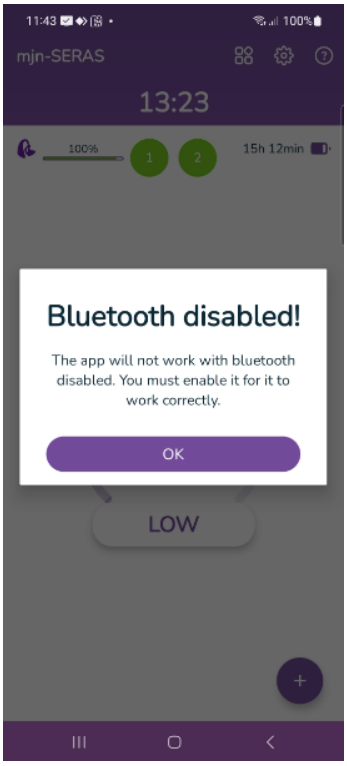


This warning appears when data has not been uploaded to the cloud within a set time limit.

Although the device and the app can operate autonomously for some time, it is highly recommended to always keep the Internet connection active via WiFi or mobile network to send and store brain activity and seizure records on the servers. This prevents the risk of data loss.

Ensure an active internet connection to prevent data loss.

Bluetooth error



This warning appears when Bluetooth is disabled on the mobile phone.

For the system function, the smartphone must be connected to the earpiece via Bluetooth Low Energy (BLE).

Enable Bluetooth on your mobile phone to restore connectivity between earpiece and smartphone, and the warning will automatically disappear.

2.7. COMMISSIONING

This procedure is carried out by MJN Neuroserveis S.L. technicians with the user's assistance. The goal is to ensure the device operates with maximum accuracy and reliability for the patient.

Once received, the device is ready for use and for continuous recording of the user's electrical activity. For the algorithm customisation to be effective, the device must be used daily and a minimum of 5 seizures must be recorded.

This customisation consists of adjusting the software parameters to the user's specific seizures. With this adjustment, a personal configuration is created that the application downloads when it starts operating.

This customisation may need to be performed more than once, depending on the type of seizures recorded and the information about the seizures provided by the user. The more accurate and truthful this information is, the better the risk assessment algorithm can be customised.

2.8. USE OF DATA

The mjn-SERAS or EPISERAS solution processes and stores brain activity data in strict compliance with Regulation (EU) 2016/679 of 27 April 2016 (GDPR) to all personal data and applicable medical device regulations. All data is handled securely, anonymized, and linked only to the device's unique identifier (UDI), never to personal identifiers.

The brain activity data collected by the application is classified into two types:

1. Raw data:

- Direct EEG signals captured by the device sensors before any processing, that cannot be interpreted by algorithms.
- Used exclusively by MJN Neuroserveis technical team for troubleshooting and algorithm improvement.
- Stored in encrypted format for 1 year, then permanently deleted.

2. Processed data:
   - Data analysed by the algorithm to assess seizure risk, includes extracted features and seizure logs.
   - Stored in encrypted, pseudonymized format for 10 years to support clinical review and continuous improvement

Purpose of Data Use:

- Personalization of the AI algorithm for accurate seizure risk assessment
- Continuous optimization of device performance
- Generation of seizure reports for medical review
- Compliance with regulatory and safety requirements

Data Security Measures:

- Secure HTTPS/TLS 1.3 transmission
- Encrypted storage on certified servers
- Access restricted to authorized personnel only
- Regular security updates and audits

2.9. MAINTENANCE

The mjn-SERAS or EPISERAS device requires minimal maintenance to ensure proper functioning and safety. No preventive maintenance is necessary beyond the care and cleaning instructions provided in the Care and Maintenance section. To consider:

- All repairs or servicing must be performed exclusively by personnel certified by MJN Neuroserveis S.L.
- Do not attempt to open or repair the device yourself, as this may compromise safety and void the warranty
- Routine maintenance is limited to regular cleaning (see section 2.10) and proper storage of the device
- If any anomalies occur, refer to the Anomaly/Cause/Solution section 5, for troubleshooting. In summary, request service if you encounter the following situations:
  - Persistent signal errors or data recording issues
  - Physical damage to the device or its components
  - Battery charging problems that cannot be resolved by replacing the cable or charger

2.10. CARE AND MAINTENANCE

Proper care and maintenance are essential to ensure the longevity and safe operation of the mjn-SERAS or EPISERAS device. Follow these guidelines for general care:

- Store the device in a safe, clean and dry environment when not in use

- Keep the equipment protected from excessive impact and pressure.
- Do not leave it outdoors, as the internal circuits could get wet.
- Avoid exposure to direct sunlight when not in use, as it could overheat.
- Do not immerse the device in water or any liquid, neither expose it to moisture beyond its IP22 protection rating.
- Never attempt to open or modify the device.

2.10.1. Cleaning

- Regularly clean the headset and electrodes using a soft, damp cloth.
- Do not insert objects into any openings of the device.
- For deeper cleaning, use a cloth lightly moistened with alcohol.
- Avoid cleaning with aggressive products or abrasive materials.
- Ensure the device is dry before use.

3. STORAGE AND TRANSPORT CONDITIONS

Proper storage and transport are essential to maintain the integrity and functionality of the mjn-SERAS or EPISERAS device. Following these guidelines helps prevent damage and ensures the device remains safe and effective for use.

Storage guidelines:

- Store the device in a safe, clean, dry environment free from unsanitary conditions.
- Storage temperature range: 0 to 50 °C.
- Maximum relative humidity: 0 to 90%, without condensation. Avoid exposure to direct sunlight when not in use.

Transport guidelines:

- Ensure product packaging remains intact, avoiding damage or destruction.
- Ensure labelling is not damaged.
- Protect the device from excessive shock, vibration or pressure.
- Sterile conditions are not required, but the transport environment must be clean and free from unsanitary conditions.

4. TERMS AND CONDITIONS

You can consult the full terms and conditions of sale at https://mjn.cat/en/terms-conditions/

5. ANOMALY/CAUSE/SOLUTION

5.1. DEVICE

Common anomalies related to the device, their causes and recommended solutions.

Anomaly	Cause	Solution
Device cannot be started	Battery may be discharged	Double-tap connector upside down; check battery status
Battery cannot be charged	Faulty cable or charger	Check cable and charger; ensure proper connection; do not use if cannot charge
Device has stopped	Battery depleted or lost connection	Check battery and app connection; recharge if needed
Device is too hot	Prolonged heat exposure or malfunction	Remove from ear; allow cooling; avoid high temperatures

5.2. APPLICATION

Issues related to the app and troubleshooting steps.

Anomaly	Cause	Solution
App cannot be installed	No Internet or incompatible OS	Check Internet; download from store; verify OS compatibility; update or try another device
App cannot be started	Installation incomplete or OS issue	Reinstall app; check OS compatibility; try another phone
Unable to connect to device	Bluetooth disabled or device off	Enable Bluetooth; restart device and app; enter UDI and pairing code
Bluetooth connection failure	Distance too great or Bluetooth issue	Keep within 1m; check Bluetooth settings
APP stopped working	App running in background or crash	Restart app; reinstall if needed

5.3. OPERATION

Operational anomalies and corrective actions.

Anomaly	Cause	Solution
App not collecting data	Distance too great or memory full	Keep within 1m; check Bluetooth; free phone memory
App generates alarms continuously	Electromagnetic interference or poor positioning	Remove interference; reposition earpiece; restart app and device
App does not generate alarms	System in Training Period or device disconnected	Check app status; verify device connection; clean electrodes
Problems reading visual alerts	Low screen resolution	Try another phone with higher resolution

5.4. MOBILE TELEPHONE

Mobile smartphone-related issues and solutions.

Anomaly	Cause	Solution
Battery does not charge	Dirty connector or damaged cable	Clean connector; handle cable carefully; try another cable
Screen or touch control not working	Device condition or incompatibility	Check compatibility; request service if needed

6. ESSENTIAL PERFORMANCE

The medical device mjn-SERAS or EPISERAS requires for its working, the user smartphone support (with Android or iOS operating system, according to chapter Compatibility) and the specific application, as monitoring tool and warning transmission.

According to the results of the clinical research clinical developed for the validation of the medical device, it is possible to expect (in a hospital environment, ideal conditions) a total sensitivity of the device of 94.7% (number of seizures detected by the medical device in relation to those clinically confirmed by Gold-standard, Video-EEG), a specificity of 97.0% (measure of true negatives - actual absence of seizures - in 15-minute time windows) and an accuracy of 95.5% in relation to those clinically confirmed by video-EEG.

Under normal living conditions (daily routine, home environments), MJN Neuroserveis S.L. has clinically validated that these values are corrected with a ratio of 0.7, i.e., sensitivity of 66.3%, specificity of 67.9% and accuracy of 66.8%.

The accuracy of the medical device has been validated in clinical research.

The device has been developed to detect epileptic seizure risk and warn when there is an elevated risk of suffering a seizure in previously diagnosed patients.

However, a false warning when the patient is not suffering a seizure is not considered a risk for the patient/user.

Keep in mind that severe electromagnetic interference may impair the device's ability to detect seizure risk or issue alerts, compromising its essential performance. The user must take all necessary precautions to avoid this type of interference.

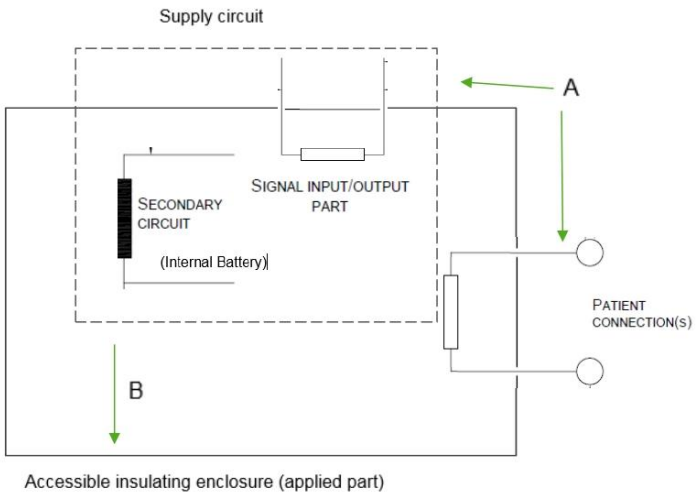
To guarantee or improve RF communications (Bluetooth), keep always a distance equal to or greater than 30 cm with the source of disturbances.

No additional maintenance is required to preserve the device's safety properties and essential performance against electromagnetic disturbances throughout its lifetime, provided that the warnings in this document are observed and advise is followed, and ensuring that there is no damage to the structure and casing of the device.

6.1. CLASSIFICATION UNE-EN 60601-1: Electromedical equipment

	Device protected against electric shock, in accordance with UNE EN 60601-1, with type BF classification.
Applicable protected part: metal sensors installed in the device for measuring the brain's electrical activity. Device power supply: internal power supply. Watertight device that prevents accidental ingress of liquids into the equipment (IP22). Installation and use of the device: portable equipment for continuous operation, installed in the user's ear canal by the user themselves, no intervention by specialised personnel or personnel with previous experience is required. Simply insert into the ear canal in the most ergonomic way (the mould has been custom-made for the user's ear canal), in accordance with the instructions contained in this document.	

Insulation diagram



7. CHARACTERISTICS AND TECHNICAL SPECIFICATIONS

7.1. General:

- **Size:** H 50 x W 55 x D 25 mm
- **Weight:** 9.5 grams (± 2 grams depending on size)
- **Operating temperature range:** 0 to 50 °C
- **Charging temperature range:** 0 to 45 °C
- **Certificates:** Bluetooth Smart and CE marking.
- **Warranty:** 2 years
- **Material:** Thermoplastics, DLP
- **Package contents:** 1 x mjn-SERAS or EPISERAS, 1 x microUSB type B charging cable
- **Waterproof:** No
- **Visual warning:** Yes
- **Protection rating:** IP22

Protection against medium-sized solid objects	Protection against vertically dripping water
Protection against contact between fingers and internal moving parts. Protection against the ingress of solid objects with a diameter greater than 12.5 mm.	Water droplets falling at an angle of up to 15° from the vertical from any direction should not cause damage.

7.2. Sensor technology

- **Sensor type:** 3 x electrodes, 1 x 3-axis accelerometer
- **Parameters:** 2 brain activity channels
- **Data rate:** 125 Hz
- **Wireless technology:** Bluetooth Low Energy (BLE4.2 or higher)

7.3. EEG Sensor

- **Sensor Type:** Ag/AgCl Electrodes
- **Measurement Method:** Silver chloride electrode for electrochemical measurements; the electrode is in contact with the skin; the principle is the conversion of ion current on the surface of human tissue to electron current in the electrode
- **Measurement accuracy:** ± 2 µV
- **Measurement range:** 0 to 2000 µV

7.4. Accelerometer

- **Sensor type:** 3-axis linear accelerometer
- **Measurement accuracy:** ± 0.1962 m/s2
- **Range:** -39.24 to +39.24 m/s2

7.5. Bluetooth / Communication

- **Version:** Bluetooth Low Energy (BLE 4.2 or higher)
- **Frequency:** ISM band 2.4 - 2.485 GHz
- **Transmission power:** 4 dBm
- **Signal distance:** approx. 10 m
- **Number of simultaneously connected devices:** 1 device
- **Data rate:** 50 Hz
- **Supported profiles:** Battery service, information device, EEG-type monitoring
- **Cloud storage:** secure HTTPS/TLS1.3 connection and transmission, encrypted storage, secure user and password-protected access

7.6. Battery

- **Type:** 1x internal rechargeable 3.7V lithium-ion battery
- **Duration:** approximately 18 hours
- **Charging time:** approximately 1 hour
- **Standby time:** over 24 hours
- **Battery charger:** 5VDC USB charger
- **Connector type:** micro-USB type B

7.7. App compatibility

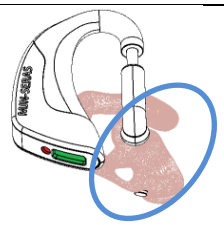
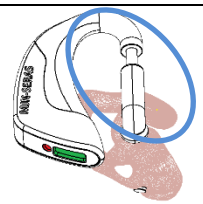
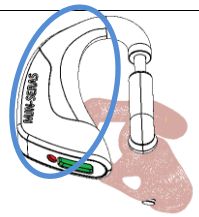
- **Android 10 or higher**
- **iOS 16 or higher**

7.8. App software

- **Audible alert:** Yes
- **Visual alert:** Yes
- **Vibration alert:** Yes
- **Data storage:** Yes
- **Cloud synchronisation:** Yes

7.9. Biocompatibility

- All plastic materials in direct contact with the user's skin are made from biocompatible material, in accordance with UNE-EN ISO 10993-1.

	Part	Manufacturing material
	DLP mould	Resin
	RC rubber + axis	TPE
	Axis + rear case + cover	PC

7.10. Electromagnetic compatibility (EMC)

The device maintains basic safety and essential functionality when used in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.		
Emissions test	**Compliance level**	**Electromagnetic environments - Guidance**
RF emissions CISPR 11	Group 1	The device uses radio frequency (RF) energy only for its internal operation. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies domestic buildings.

The device maintains basic safety and essential performance when used in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Immunity testing	**IEC 60601 Level**	**Compliance level**	**Electromagnetic environments - Guidance**
Electromagnetic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±15 kV	Indirect contact: ±2 kV, ±4 kV, ±6 kV, ±8 kV Contact: ±2 kV, ±4 kV, ±6 kV, ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Frequency (50/60 Hz) magnetic fields IEC 61000-4-8	30 A/m	30 A/m	The device is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies domestic buildings.
Radiated RF IEC 61000-4-3 & Immunity to nearby fields (EN 60601-1-2 Table 9)	10 V/m 80 MHz to 2.7 GHz AM modulation & 9–28 V/m 385 MHz to 5.785 GHz FM modulation Pulse modulation	10 V/m 80 MHz to 2.7 GHz AM modulation & 3 V/m 1 GHz to 6 GHz AM modulation & 9–28 V/m 385 MHz to 5,785 GHz FM modulation & Pulse	RF communications equipment should not be used at a distance less than the recommended separation distance calculated from the equation applicable to the transmitter frequency. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz, where P is the maximum transmitter output power in watts (W) as specified by the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strengths of fixed RF transmitters, as determined by an electromagnetic environment survey A, should be less than the compliance level in each frequency range B. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
A) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To evaluate the electromagnetic environment due to fixed RF transmitters, an electromagnetic environment survey should be considered. If the field strength measured at the location where the device is used exceeds the applicable RF compliance level above, normal operation of the device should be monitored. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the device.

8. DOCUMENT REVISIONS

Ver. 1	13-01-2023	First version compliant with MDR.
Ver. 2	15-12-2023	Second version. A subchapter entitled "Clinic al benefit" (R-017_23_00010) has been added.
Ver. 3	10-06-2024	Third version, updated: - Added a specification of compliance with Regulation (EU) 2021/2226 (electronic instructions for use) according to R-017_23_00011. - A safety warning has been added: "Avoid connecting your smartphone to public or unsecured Wi-Fi networks." - Several specifications have been added to ESSENTIAL PERFORMANCE and PRELIMINARY CONSIDERATIONS to provide information to the user in accordance with R-017_24_00012
Ver. 4	06/02/2025	Fourth version. - Once CE marking under MDR was obtained, we removed any mention of documents in progress or draft versions. - The link to download the electronic instructions for use has been updated. - The wording of the clinical benefit of the medical device has been improved(R-017_23_00010_rev_1), making it more accurate in relation to the conclusions reached in the CER (current version, MDR_TD_SERAS_Part_G-2_24_00003). - The wording regarding the IA has been improved in the *preliminary considerations* chapter (R-017_24_00012_rev_1).

Ver. 5	22/12/2025	Fifth version.
		- The name EPISERAS is added as a complementary name to mjn-SERAS or EPISERAS (throughout the document) in accordance with change control CH-012 and the agreement with Neuraxpharm.
		- The document sections have been numbered for improved readability.
		- The link to the EMA in the Warnings and Precautions chapter has been removed.
		- New notices and warnings added.
		- New chapters:
		  ○ REQUIRED ACCESSORIES (NOT INCLUDED)
		  ○ FIRST STEPS: new subchapters
		  ▪ Charging the battery
		  ▪ Download and install the APP
		  ○ START-UP: warnings added
		  ▪ Positioning the device
		  ▪ Connect the device to the APP
		  ○ SHUTDOWN PROCESS
		  ▪ Switch off the device
		  ▪ Remove the device
		  ○ APPLICATION OPERATION: new subchapters
		  ▪ Crisis log
		  ▪ Viewing crisis reports
		  ▪ Consult information about epilepsy

		▪ Settings and legal information ▪ Help ▪ User alerts: content is updated and divided into the different alerts that may appear - The general information section refers to the device manufacturer - iOS is introduced as a compatible operating system - The risk levels are: low risk and high risk; the moderate risk level is removed - The PRELIMINARY CONSIDERATIONS section has been updated: it specifies that BLE4.2 or higher is required and introduces the terms Training Period and Seizure Risk Assessment Period - The APP Compatibility chapter has been updated. - In the APP software section: vibration alerts and synchronisation with the Cloud are added - The INSTRUCTIONS FOR USE AND OPERATION chapter has been updated - In the DATA USE chapter, it is mentioned that the data is stored in encrypted form - The Cleaning subchapter indicates that no objects should be inserted into the device's openings. - The ANOMALY/CAUSE/SOLUTION chapter has been updated - "Consult with the Healthcare or MJN-Neuroserveis in case of doubt" has been added - Wording has been refined throughout the document.

Created by:	**Reviewed by:**	**Approved by:**
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Position: COO	Position: TM - PRRC MJN-Neuroserveis	Position: Manager, MJN-Neuroserveis
Signature and date: Jesus Valls Firmado digitalmente por Jesus Valls Fecha: 2025.12.22 11:06:28 +01'00'	Signature and date: ATIENZA GARCIA FERNANDO - 47458607Q Firmado digitalmente por ATIENZA GARCIA FERNANDO - 47458607Q Fecha: 2025.12.22 11:31:58 +01'00'	Signature and date: 43678831Z DAVID BLANQUEZ (R: B55209241) Firmado digitalmente por 43678831Z DAVID BLANQUEZ (R: B55209241) Fecha: 2025.12.22 15:59:19 +01'00'