

INSTRUCTIONS FOR USE FESIA GRASP

MANUFACTURER



Fesia Technology S.L.
Pº Mikeletegi, 58
20009 Donostia / San Sebastián
Spain

COMERCIALIZED BY

Fesia Technology S.L.
Pº Mikeletegi, 58
20009 Donostia / San Sebastián
Spain

E-MAIL: support@fesia.net
WEB: www.fesiatechnology.com



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01

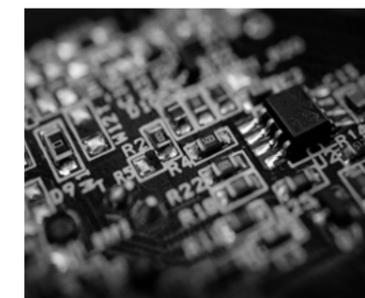
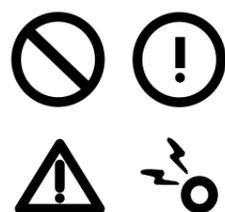
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01

GENERAL
INFORMATION

INDICATIONS OF USE

Fesia Grasp is a rehabilitation and assistive device designed to provide dorsal and plantar ankle flexion for people suffering from foot drop as a result of nervous system disease or injury. During gait, Fesia Grasp electrically stimulates the motor nerves of the affected leg to achieve dorsal and plantar flexion of the foot, so that the user's gait is improved. Functional electrical stimulation may also enhance motor relearning, muscle strength, prevent or slow down muscle atrophy, increase local blood flow and / or maintain / increase the range of motion.



CONTRAINDICATIONS

- Do not use the device with people with **cardiac pacemakers or other electrical or metallic implants**, unless recommended by a doctor or clinical staff.
- Do not use the device with people with **severe epilepsy** or a recent history of frequent seizures.
- Do not use the device with people with **tumors or cancerous lesions in the area** where electrical stimulation is applied.



WARNINGS

- Do not use the device to **control machines, drive or perform any activity** where an involuntary movement could pose a risk of injury.
- Do not place the electrode on the head, eyes, mouth, throat (carotid sinus), chest or back. Place the **electrode on the arm only** as indicated in the manual.
- Do not use the **device simultaneously with other medical devices**. Ignoring this warning can result in **skin burns** in the electrode area and could damage the stimulator.
- Do not use the device **less than one meter** away from shortwave or microwave therapy equipment. Ignoring this warning **could cause instability** in the output of the stimulator
- Electrode placement near the thorax may increase the risk of atrial fibrillation.
- Do not attempt to **repair the Fesia Grasp or open the stimulator under any circumstances**. In case of breakdown, contact a **Fesia** technician.
- **Prolonged use of the electrode** increases the risk of **skin irritation**.
- Use of **worn electrodes** could cause **skin burns or loss of function** of the system.
- Improper use or **use of a faulty device** may cause **skin burns or muscle damage**.



PRECAUTIONS

- The device must be used **under the supervision of a physician or clinician, physiotherapist or care giver** and may only be operated by personnel trained specifically for this purpose.
- The system should not be used if there is **presence of lesions and/or wounds of any kind** (skin, muscle, tendon, bone...) in the area and at the time of applying electrical stimulation.
- Do not use this device if you experience any **symptoms of malfunction** or if any of the components are in **poor condition**.
- Should not be exposed to **liquids or splashes**.
- Should not be exposed to **extreme temperatures**.
- Should not be exposed to **direct sunlight**.
- Should not be used **near flammable products**.
- Store the system under **protection from moisture, dust and direct sunlight**.
- Only use **electrodes supplied by Fesia**.
- Use only the **charger and charging cable supplied** and/or approved by **Fesia**.
- This device should be **kept out of reach of children**.
- Caution when using the system if you have **heart disease, epilepsy, or vascular or circulation problems** is recommended.
- **Do not turn on** the stimulator until it is **properly placed on the arm**.
- The **electrode is personal**, it should not be exchanged between different people.
- Make sure the **stimulator is charged** before each use.
- The long-term effects of chronic electrical stimulation are unknown.
- The **safety** of using electrical stimulation **during pregnancy** has not been determined.



ADVERSE REACTIONS

- Electrical stimulation could cause an **uncomfortable feeling or very mild pain** in the first uses until the feeling becomes familiar.
- It is normal for the **area** where stimulation has been applied to appear **red** after removing the device, this redness should disappear in about an hour.
- Electrical stimulation or **gel contact with the skin** may cause **irritation or allergic reaction** on the contact surface in some cases.
- The patient should immediately **stop using the system** in the following cases:
 - **Redness or irritation at the site** of application of stimulation for more than one hour after removing the electrode.
 - **Blisters or sores** within the area of stimulation application.
 - Feel a **significant increase** in muscle **spasticity**.
 - Suffer from **tachycardia or cardiac rhythm disturbances** during stimulation.
 - It has **swelling** of the forearm, wrist or fingers.



Manufacturer must be informed of any serious incident involving the use of this product.

LEGEND

This user guide includes additional audio-visual material to encourage inclusive and accessible learning for every person.

The legend of the symbology contained in this manual is shown below.

Symbol	Meaning
	This section includes a video.

SYMBOLS

Symbol	Meaning
	Caution
	Complies with European regulatory requirements for medical devices
	Manufacturer
	Device reference number
	Serial number FG-YYWWxx YYWW: YY(year)WW(week) of manufacturing xx: Correlative number of same lot
	Consult the instructions
	Double insulation (equivalent to Class II according to IEC 536)
	Type BF applied parts
	Continuous load current
	Non-ionizing radiation
	Keep out of sunlight
	Keep dry
	This product should not be disposed with other household products
	Indicates low battery (red light)
	Indicates that the stimulation is active (yellow light)
	Indicates the intensity increase button
	Indicates the intensity reduction button
	Indicates the button on/off system



02

FESIA GRASP
DEVICE

The **Fesia** Grasp device bases its operation on superficial electrical stimulation of the forearm muscles to provide flexion and extension of the wrist and fingers.

The main feature of this device is its multi-field electrode, which allows better selection of movements and reduces the time of device placement. It is a matrix electrode designed to cover both the anterior and posterior areas of the forearm to stimulate the flexor and extensor muscles of the wrist and fingers.

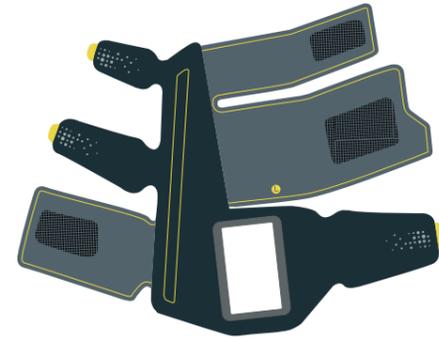


GENERAL DESCRIPTION

1



2

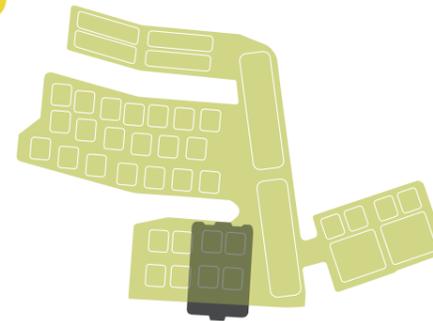


Available in 2 sizes:

S/M

M/L

3

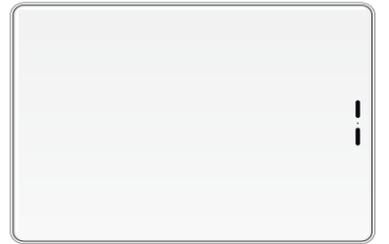


Available in 2 sizes:

S/M

M/L

4



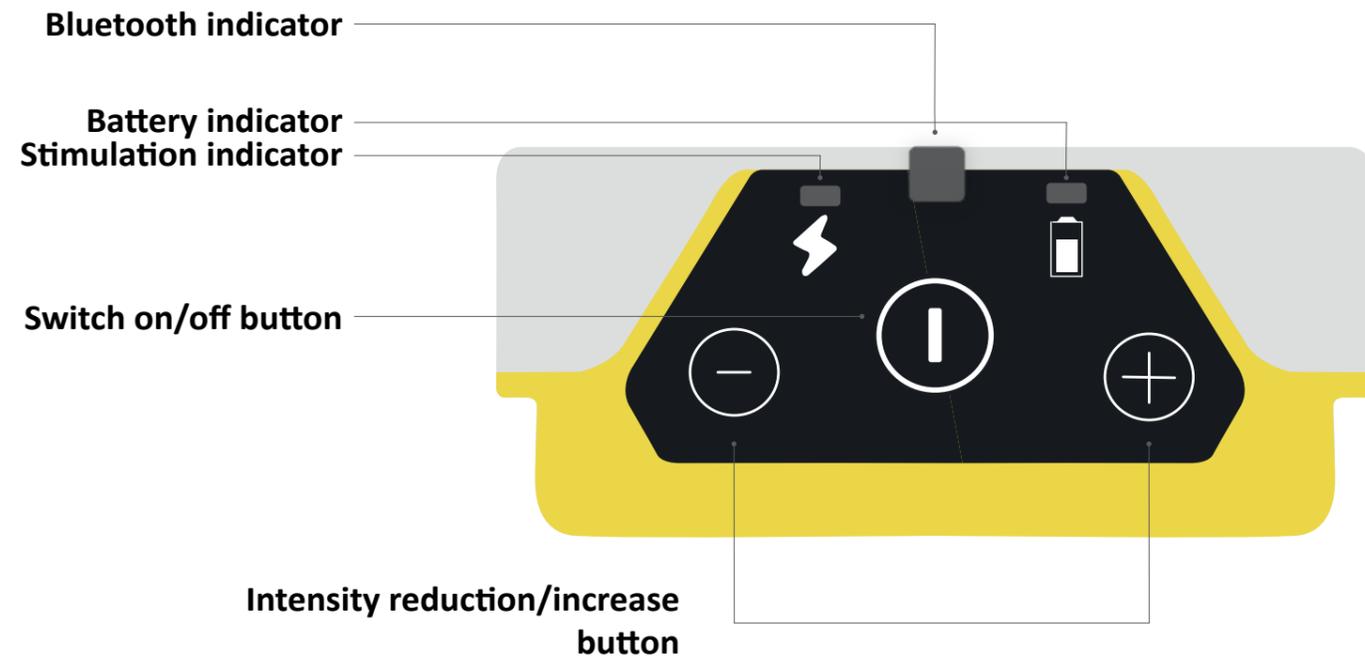
5



- 1. Stimulator:** The stimulator generates electrical pulses, which are transmitted to the skin through the multi-field electrode.
- 2. Textile garment:** The textile garment ensures proper electrode-skin contact and holds both the stimulator and the electrode. It is available in two sizes: S/M and M/L. To choose the garment size, see "[Size Selection Guide](#)".
- 3. Electrode:** It consists of 32 cathodes (output fields) and 8 anodes (return fields) that can be activated independently or in combination, thus allowing adaptation to the different patient physiology. The multi-field electrode is personal and disposable, with an estimated life of two weeks of daily use. It is available in two sizes: S/M and M/L. To choose the electrode size, see "[Size Selection Guide](#)".
- 4. Fesia Pro app (already installed in pre-configured tablets provided by Fesia):** Fesia Grasp has a software application that allows, on one hand, to control and configure the stimulation parameters and, on the other, to monitor the evolution of the different patients/users in an easy and intuitive way. The application is specifically designed for use by healthcare personnel.
- 5. Charger:** It is a charger approved for charging medical devices.

✓ Check the **Fesia** Grasp transport case and make sure that all the components are included.

INDICATORS

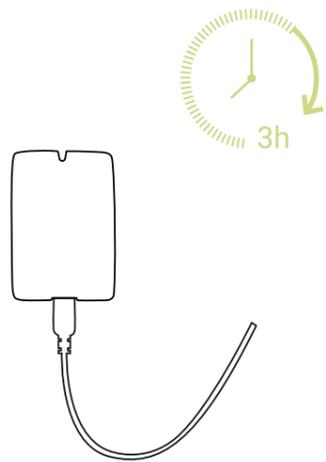


STIMULATOR INDICATORS	STATE
 Stimulation indicator	 Stimulation active  Stimulation no active
 Bluetooth indicator	 Stimulator conected to the Fesia Pro app  Stimulator switched off
 Battery indicator	 Low battery level  Adequate battery level
 Beep. Pulsed sound	 Intensity increase button  Intensity reduction button

INITIAL CHECKS



1

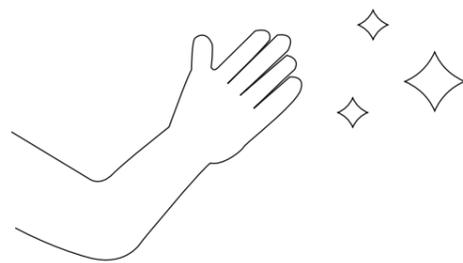


FULLY CHARGED

Before the first use, the battery must be fully charged. The charging process takes about 3 hours. Connect the charger to the network and the connector to the stimulator. Make sure that the plug is fully inserted. The red stimulator LED will light while charging and will turn off when charging is complete.

- ① - Use only the charger and charging cable supplied and/or approved by **Fesia**.
- The battery may only be replaced by authorized personnel.

2



CLEAN SKIN

The skin should be clean and dry to assure optimal placement of electrode. Lack of proper skin care and improper or prolonged use of electrical stimulation may result in skin irritation or an adverse skin reaction. Skin irritation may occur after approximately three months of use. Therefore, it is important to follow a daily skin care routine to use the system for a long time without damaging the skin.

- ① - Clean the skin where the electrodes are attached with a damp cloth before each use. If there is presence of oils or lotions on the skin, then wipe it off with soap and water.
- Always check for redness or rashes on the skin when placed or removed **Fesia** Grasp device.
- ① - Be sure to replace the electrodes at least every 15 sessions, even if they appear to be in good condition.
- Excessive body hair in the area where the electrodes are attached may reduce skin contact. If necessary, remove excess body hair in the place where electrodes are attached with scissors or wax. Do not use a razor blades, as they may irritate the skin.

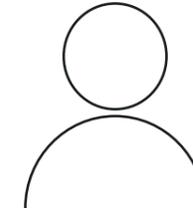
3



WIFI CONNECTION

Make sure you have a wifi connection in order to create an account.

4



ACCOUNT CREATED

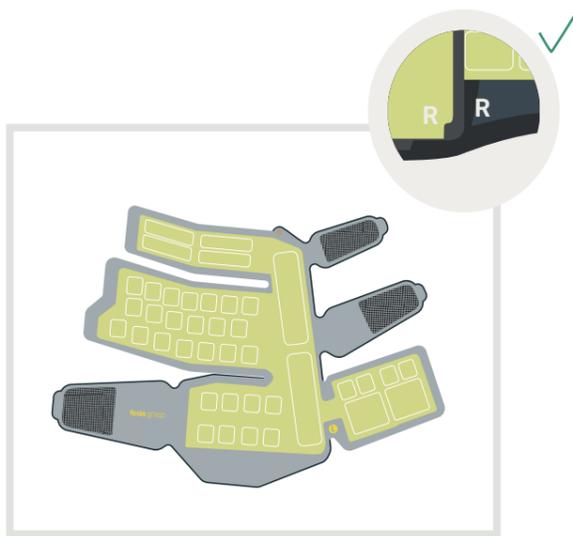
Create an account in **Fesia** Pro app and make sure you remember the user and the password.

- ① - Keep in mind that should select "save password" to ensure that it is stored in the backup copy.



Once you have gone through the previous steps, check that you have all the components for placement and performance of **Fesia** Grasp.

DEVICE PLACEMENT



- 1** Place the electrode on the garment matching the shape of the electrode with the shape of the garment. Pay attention to the laterality of the affected limb of the patient: take the electrode and the garment with indicator R (right) if working on the right side and L (left) if working on the left side.

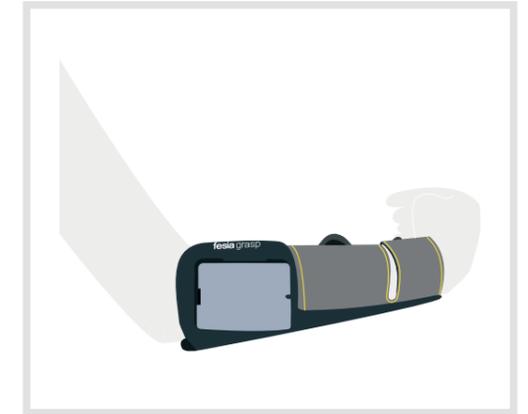
✓ To choose the garment and electrode size, see "[Size Selection Guide](#)".



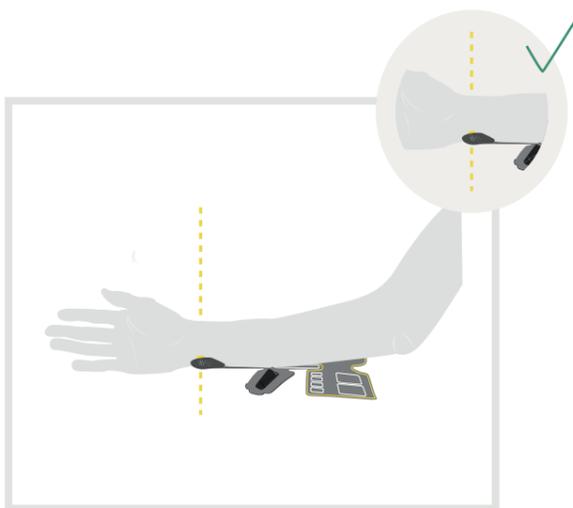
- 2** Carefully remove the electrode gel protective layer. Keep this protective layer as you will need it to store it at the end of its use. This layer protects the gel from dirt and dust.



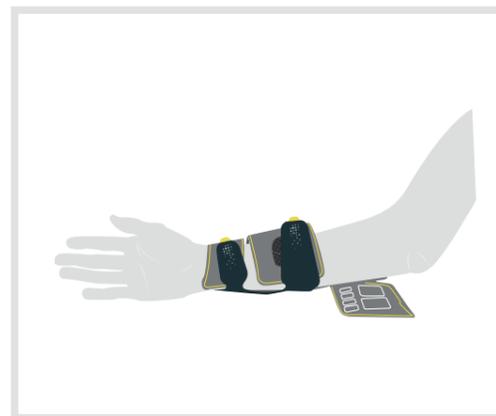
- 5** Insert the stimulator into the base of the electrode. Tighten until it clicks and make sure it is properly inserted.



- 6** Make sure that the hand remains completely free.



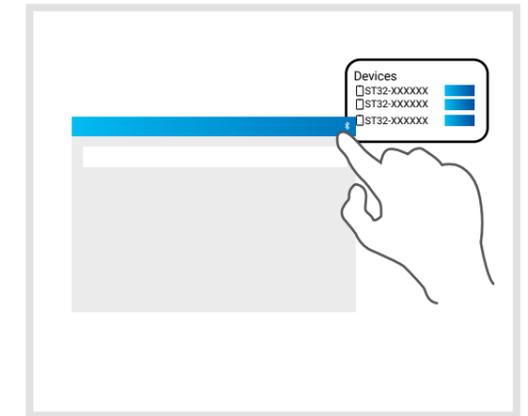
- 3** Place the electrode and the garment in the forearm. The ulnar diaphysis should be aligned with the yellow longitudinal indicator and the ulnar styloid process should be on the circular yellow indicator.



- 4** Close the three parts of the garment using the velcro fasteners.

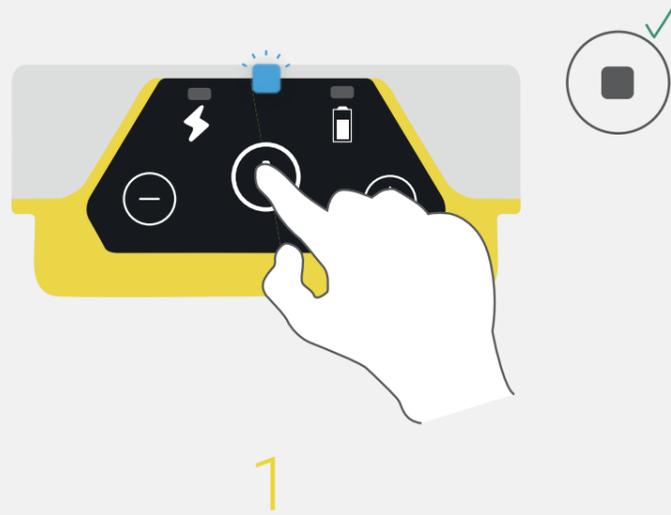


- 7** To switch the stimulator on, press and hold the On/Off button for two seconds. When the stimulator has been switched on, the blue LED will start flashing. It will remain flashing until it is paired with the sensor.



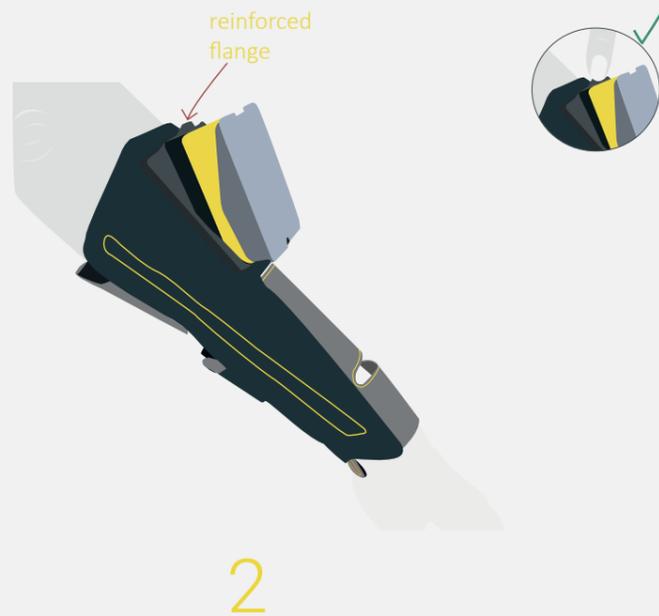
- 8** Once all the components are properly placed and turned on, open the **Fesia Pro** app and search the device serial number to connect it by Bluetooth. You can find the information regarding **Fesia Pro** app in chapter 3.

REMOVAL OF THE DEVICE



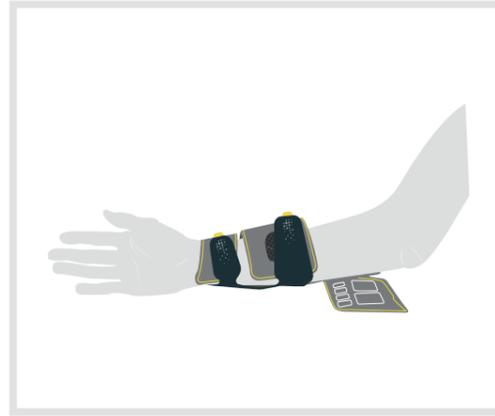
1

To switch off the stimulator, press and hold the On/Off button for a few seconds. When the stimulator is turned off, all LEDs will turn off.

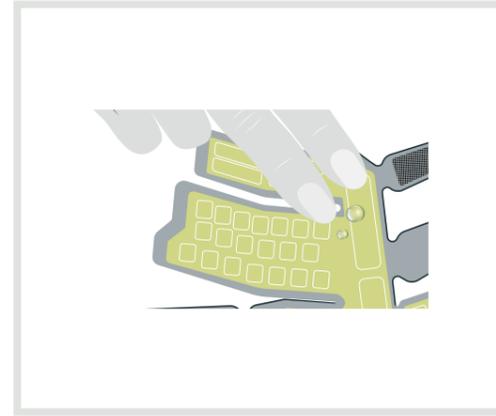


2

Once the stimulator is switched off, remove the stimulator using the reinforced flange.

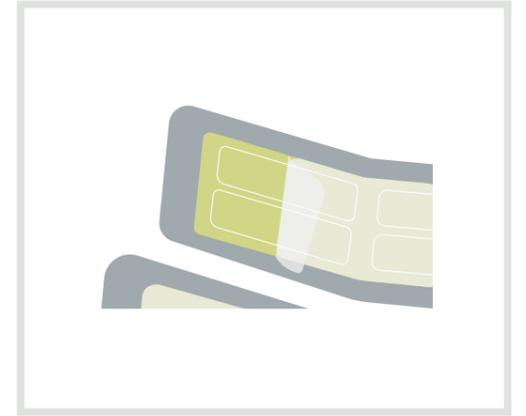


3 Then, remove both the textile garment and the electrode carefully.



4 If the electrode gel is dry, pour a few drops of water over it before placing the protective layers on it.

If the electrode gel is humid, carefully dry with a cotton thread gauze.

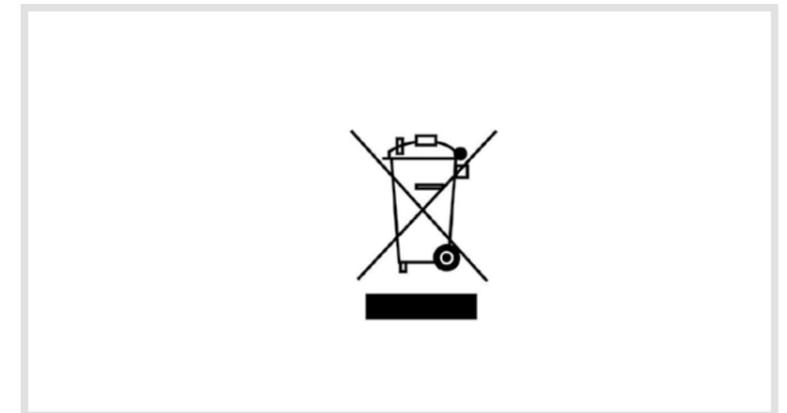


5 Finally, place the protective plastics back on the electrode gel. Make sure that the plastics are clean.

For more information on electrode maintenance, see "[Electrode Maintenance](#)".



6 Transport equipment should always be in the case provided for this purpose and provided respecting environmental conditions described in chapter 5.



7 At the end of life of this device, follow local regulations and never dispose the product or batteries with normal household waste.

This symbol means that the product contains electrical appliances that must be disposed separately from household waste. There are separate collection systems for recycling in the EU.



03

FESIA PRO

APP

GENERAL DESCRIPTION

The **FESIA** Pro Software Application connects wirelessly via Bluetooth to **Fesia** Grasp. This is an Android app that can be run in any tablet that complies with the minimum requirements specified in next section.

Principal functions:

-  **Fesia** Grasp configuration
-  Patients' management
-  System status monitoring (battery level, connectivity, operating mode, etc.)

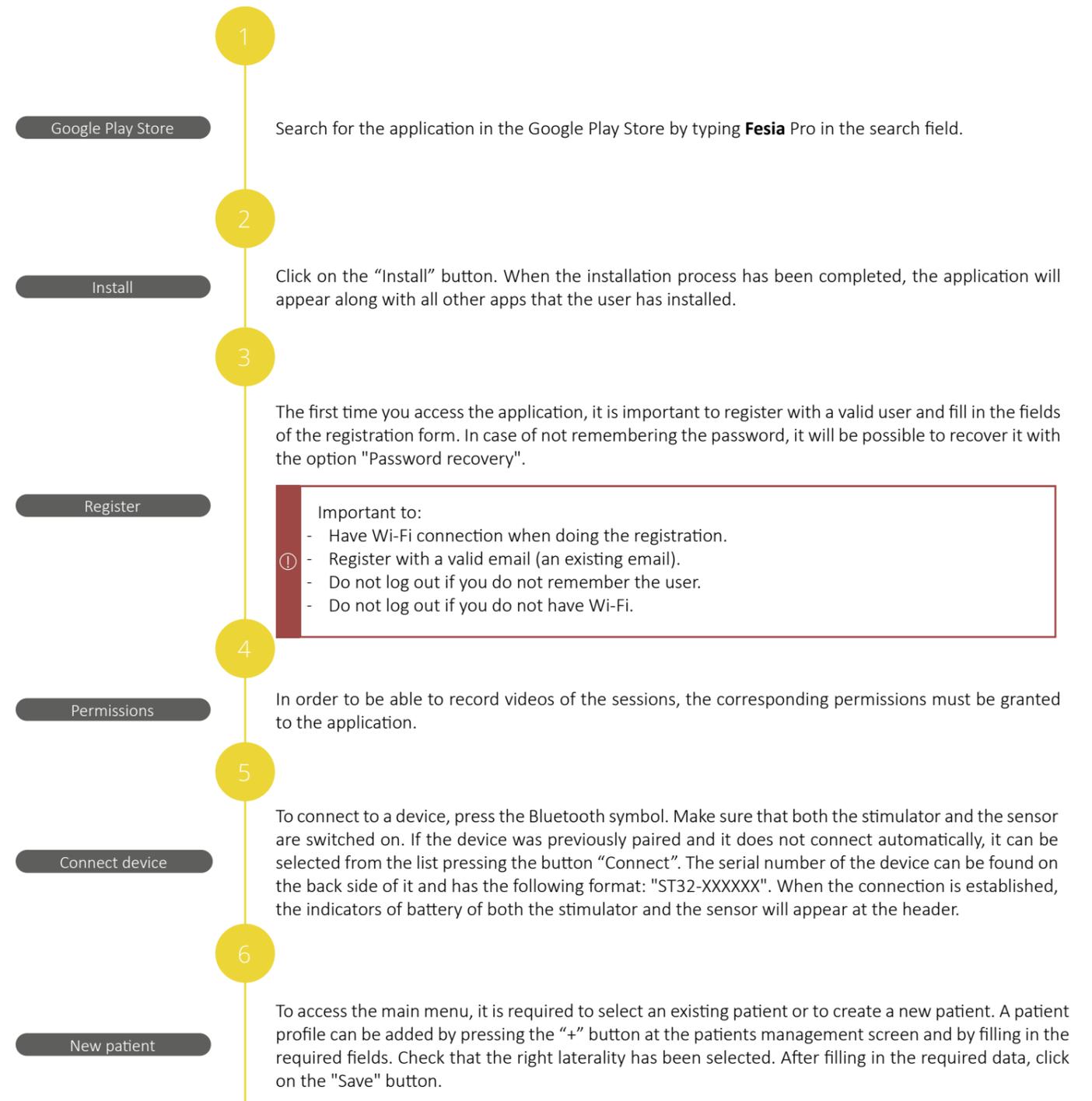


INSTALLATION AND REGISTRATION

The device on which the application is installed must meet the following requirements:

- Operating system Android 5.1 and up
- V.2.0 Bluetooth connection and up
- Minimum screen size 10 "

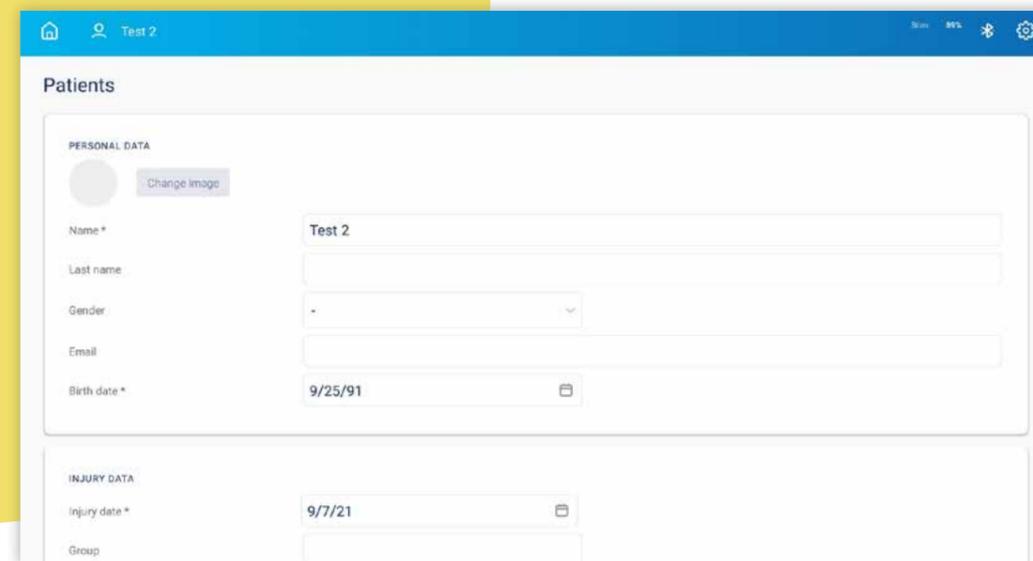
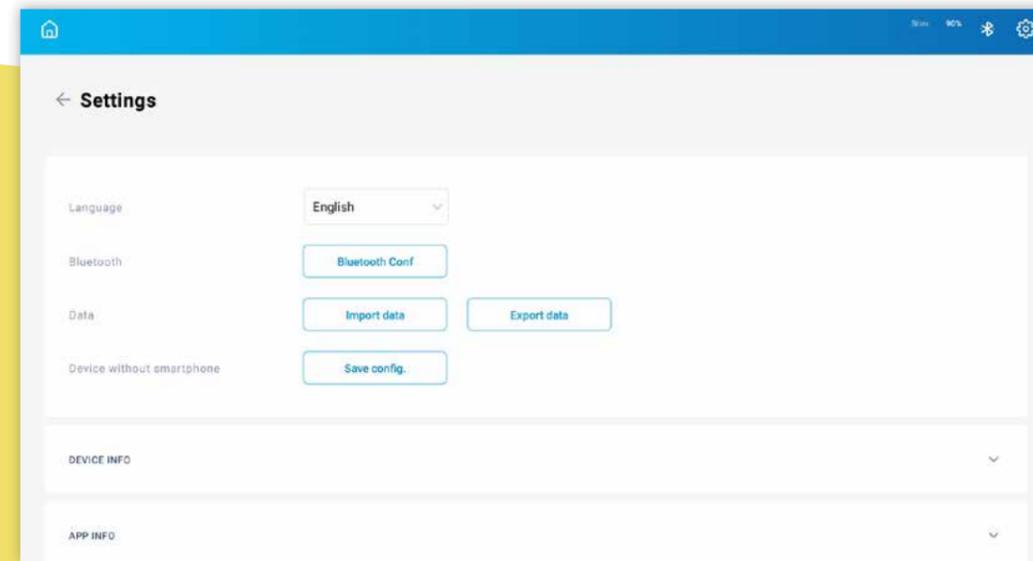
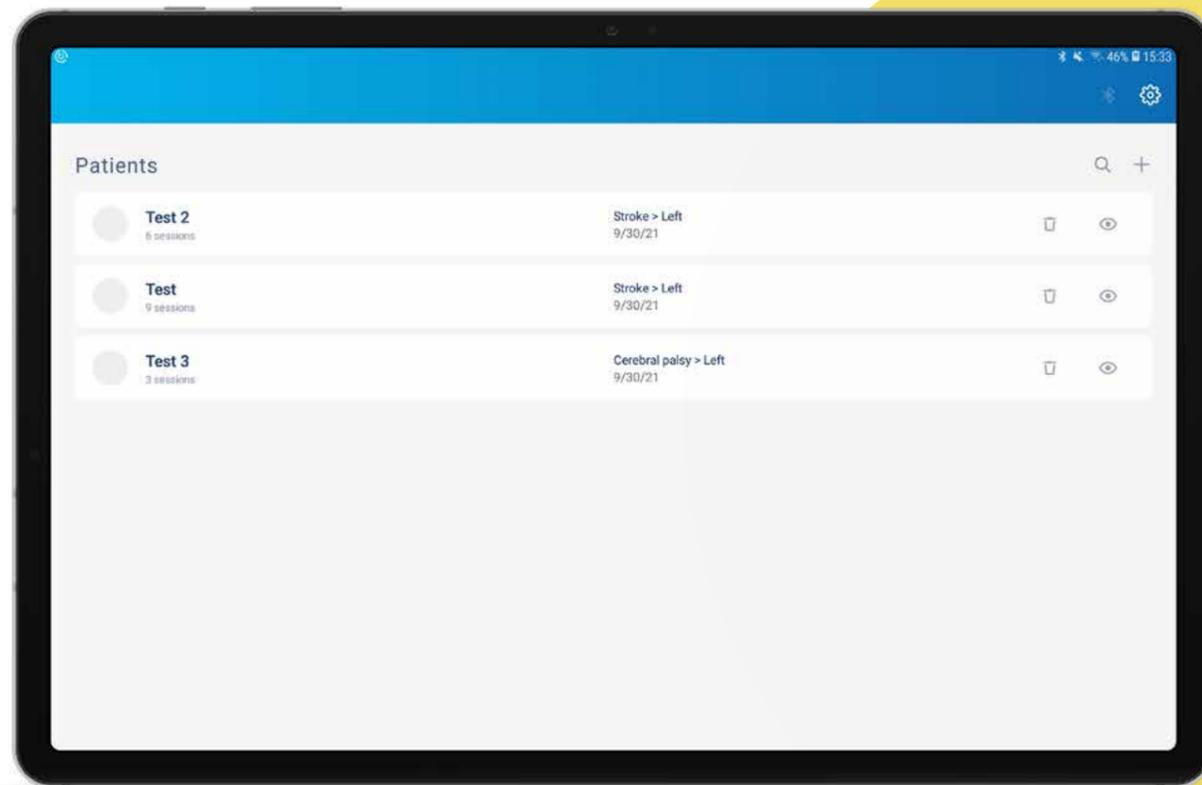
It is important to ensure not to use the application more than 50 meters away from the stimulator (in open free space) to avoid losing the connection.



MAIN MENU

In the main menu you can:

- Establish the Bluetooth connection with the device (this option is available from any of the windows in the app).
- Access the application Settings.
- Create a new patient.
- See the list of patients and access their profile and sessions.



Bluetooth Connection

Choose the ID of the stimulator from the device list and click on the button "Connect".

Settings

- In the "Settings" menu, the user can:
- Select the language of the application.
 - Change Bluetooth device.
 - Export / Import data from another tablet.
 - Check the device information.
 - Save the configuration in the stimulator.
 - Log out.

+ Create patients

Click on the "+" icon to create a patient. Fill in your profile details. The mandatory fields are indicated with an asterisk.

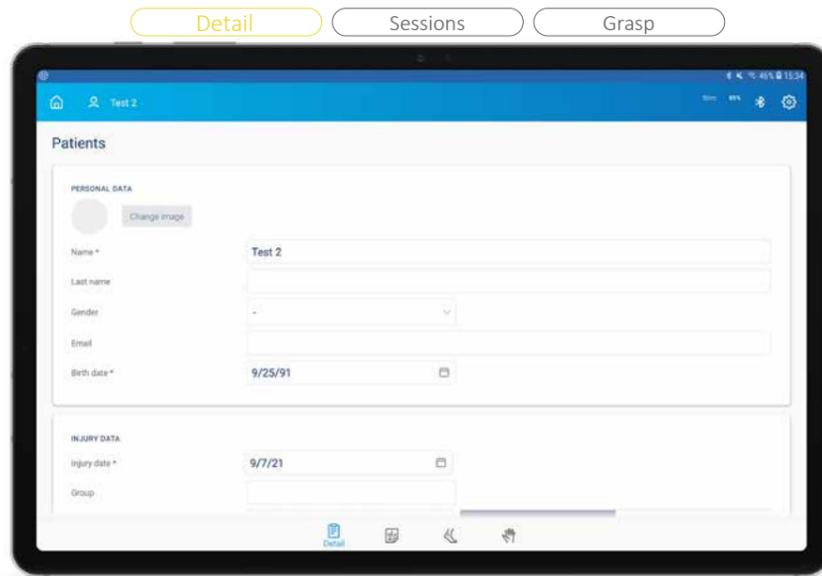
Make sure that the chosen laterality is correct. The affected limb must be chosen, that is, the side where the device is going to be placed.



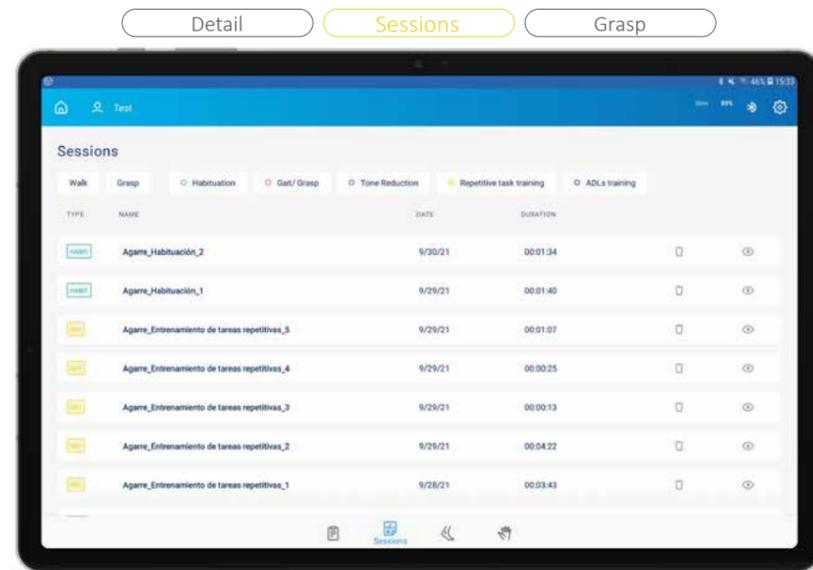
- See patient**
 - Click on the "+" icon to create a patient. Fill in your profile details. The mandatory fields are indicated with an asterisk.
- Delete patient**
 - By clicking on the "Delete" icon, all patient data and sessions are deleted.

PATIENT MENU

To start a new session, select an existing patient by clicking on the name. Then, the user will be able to access to patient's data, sessions, and different protocols surfing the menu at the foot of the page.



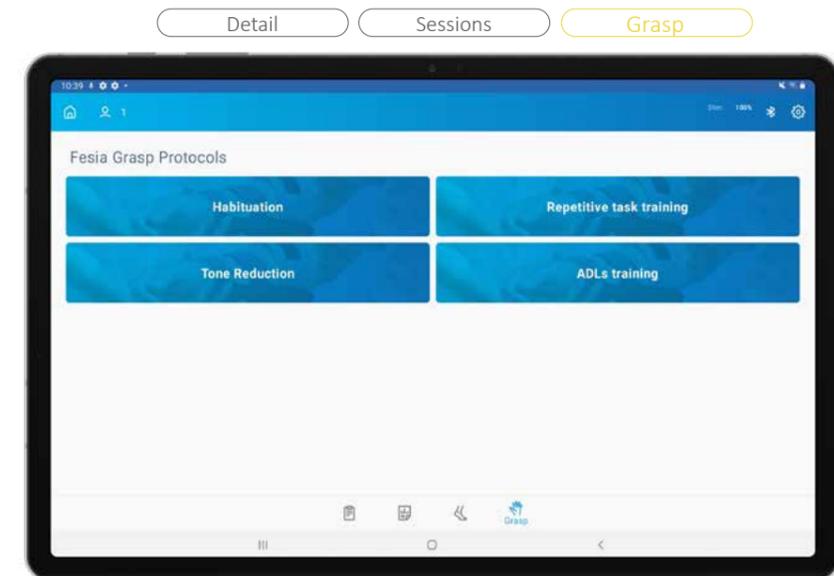
The patient's data will be shown in the "Detail" menu. The mandatory fields are indicated with an asterisk.



The sessions will be shown in the "Sessions" screen

 See Session Report

In the "Session Report" menu, you can see: the report of each session, session notes and video recordings. Session data can be exported to an excel by clicking on the "Export" button.



To access the protocols, select the "Grasp" icon in the patient navigation menu.

Once in the menu, you can choose the following protocols:

- Habituation
- Tone Reduction
- Repetitive Task Training
- AVD Training

INTERFACE

HEADER

Through the application header, it is possible to check the battery level and access to the main menus of the application:

- Patients' menu
- Patient menu
- Bluetooth connection
- Settings

CONFIGURATION BAR

Through the Configuration Bar it is possible to access:

- Election of scanning/configuration.
- Editing of stimulation parameters (by clicking on the button "Expand options")
- "Play" and "Stop" buttons.
- Configuration of all movements.

NAVIGATION BAR

Through the navigation bar you can access the different screens of the protocol.

INTERACTIVE VIRTUAL ELECTRODE

It allows to visualize and interact with the multi-field electrode in real time. The cathodes are represented over the corresponding images of the affected limb.

The cathodes indicated with an asterisk are the optimal candidates to achieve a motor response in the movement that is being configured.



- Clicking on "Play" the stimulation is activated and the configuration is automatically saved.
- Clicking on "Stop" the stimulation is stopped.
- By clicking on "Record" it is possible to record a video of the session that will be stored with the session data.
- Clicking on "Notes" it is possible to write down notes of the session that will be saved with the data of the session.
- Clicking on "Help" a window will open with help on the usability of the screen and clinical guidelines.
- Movements config.** By clicking on "Movements configuration" it is possible to access the movements configuration screens.

CLICK! CLICK!

Non activated cathode Activated cathode Blocked cathode

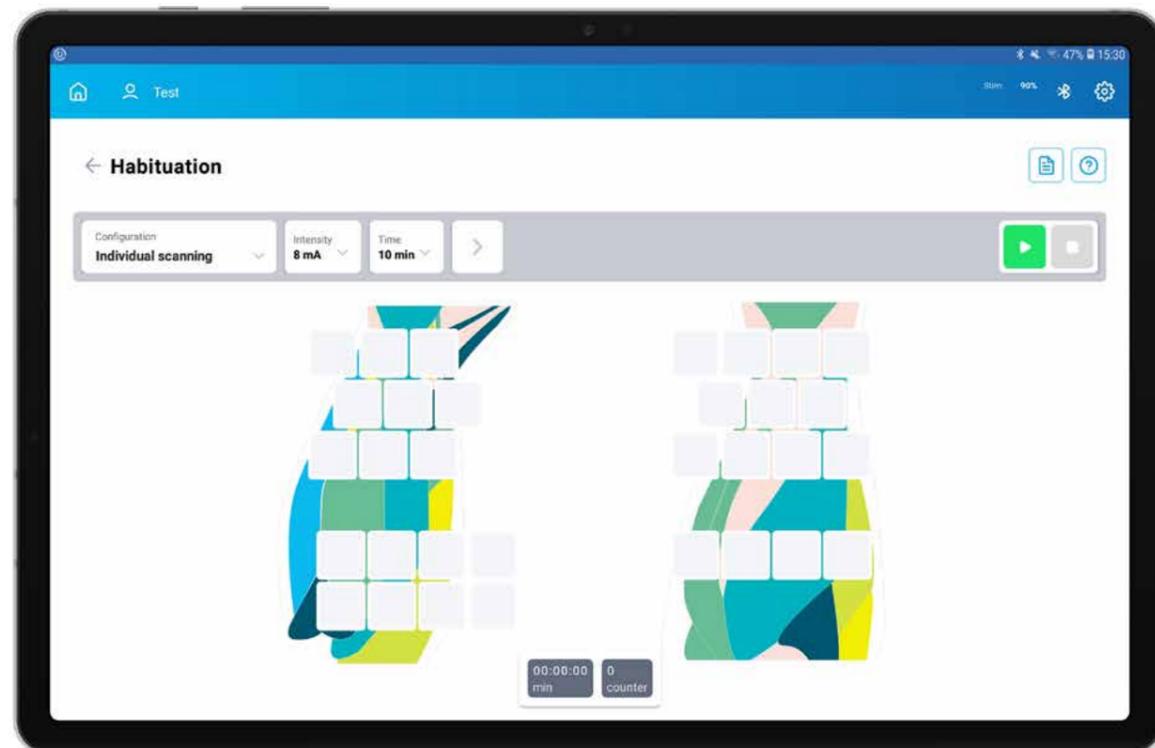
LONG TOUCH

By doing a long touch on the cathodes, it is possible to stimulate in real time while testing motor response.

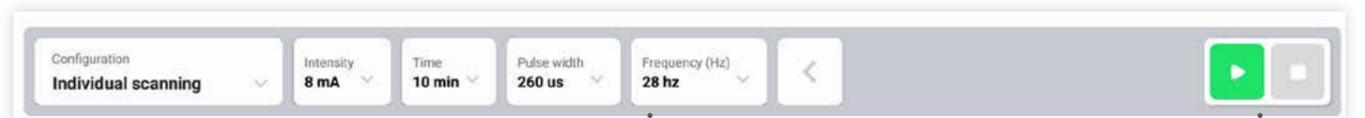
HABITUATION PROTOCOL

This protocol should be used in the following cases:

1. The very first time that the user uses the device with a new patient, to become familiar with it.
2. In acute/sub-acute cases, with no concrete functional objectives. It can be used to: increase / maintain range of motion, prevent muscle atrophy, delay the onset of spasticity, ...
3. In patients whose motor threshold is above the pain threshold, to increase the pain threshold, and to be able to generate movements without producing an unpleasant sensation.



CONFIGURATION BAR

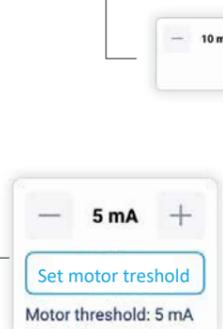


Individual scanning

All the pads will be activated sequentially, one by one, alternating flexors and extensors.

Couple scanning

All the pads will be activated sequentially in pairs, alternating flexors and extensors.



Intensity/motor treshold

Clicking on the "Set Motor Treshold" button, the intensity value will be saved and afterwards in the movement configuration screen will be possible to upload.

Stimulation parameters

Time

It is possible to set:

- A specific duration editing the default value (the counter will be displayed like a countdown).
- An undefined duration clicking on the "Loop" button (the counter will start from 0).

Start / Stop stimulation

Select configuration

Edit intensity

Play

Stop

1

Select the configuration and the stimulation time.

2

Edit the intensity by increasing the value progressively. When a motor response is achieved, it will be possible to "Define motor threshold" and load it later in the movement settings configuration.

3

Stimulation parameters can be edited (frequency, pulse width) by clicking on the "Expand" button

4

To start with the stimulation, click on the green button "Play" (the configuration will be saved automatically).

Once the session is finished, click on the red "Stop" button.

When going "back" in the navigation bar, a message will appear in which you must choose between "Save session" or "Exit without saving".



It is highly recommended to edit the intensity with caution!

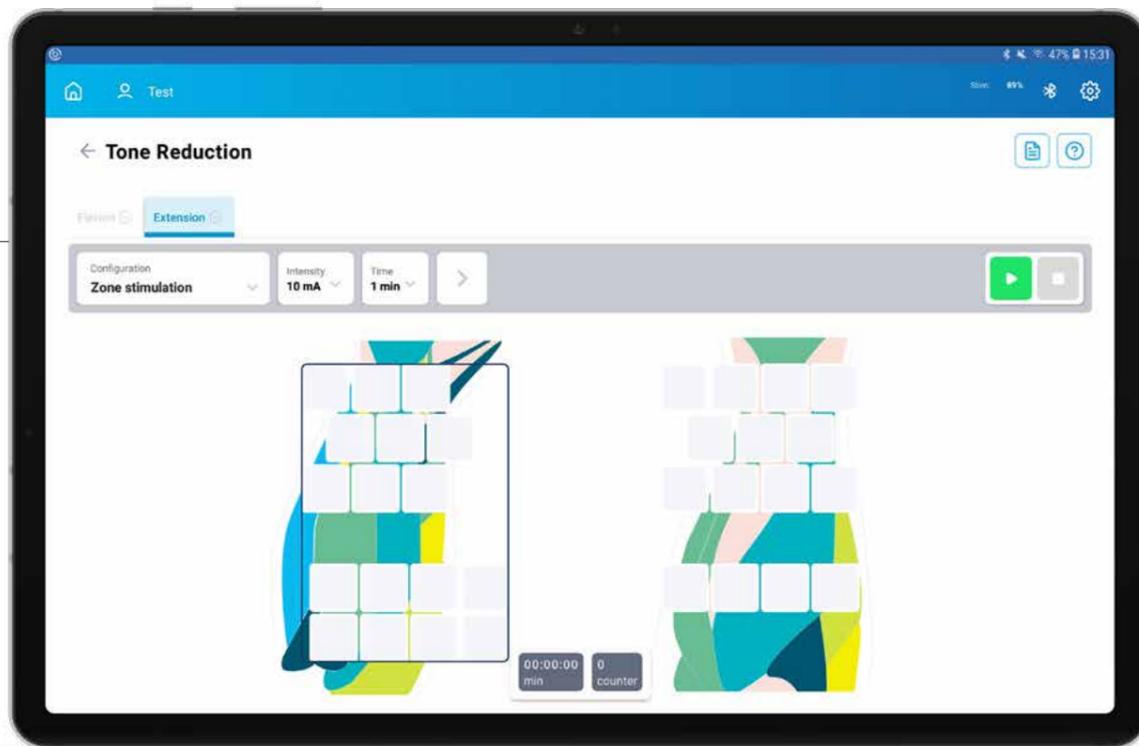
- ⓘ This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.

TONE REDUCTION PROTOCOL

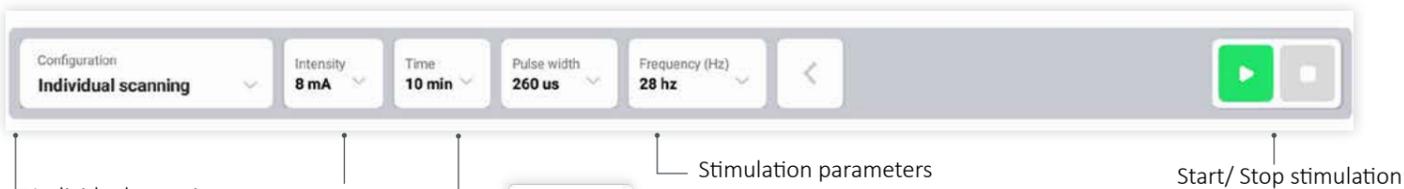
This protocol can be used in the following cases:

- The patient has a generalized hypertonia in the limb.
- The patient has localized hypertonia in specific muscle groups.

This protocol consists of two tabs: Flexion and Extension. Therefore, it is possible to stimulate the flexor and extensor muscles independently. In this protocol, the stimulation pattern is longer and the ramps are progressive.



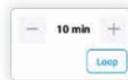
CONFIGURATION BAR



Individual scanning
All the pads will be activated sequentially, one by one, going through the cathodes of the corresponding muscle groups.

Area stimulation
The pads activated by the users are activated.

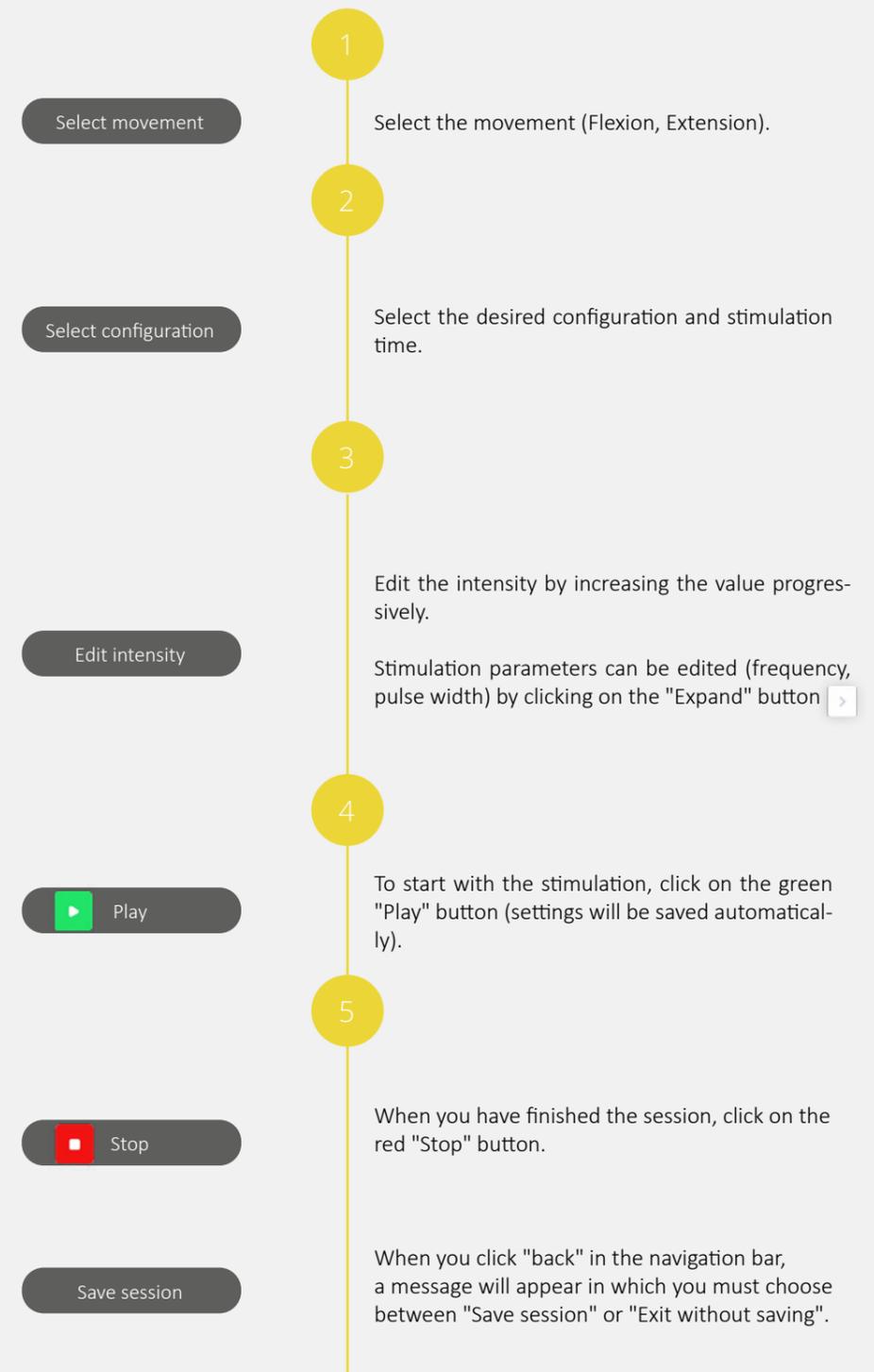
Intensity edition



Stimulation parameters

Time
It is possible to set:
- A specific duration editing the default value (the counter will be displayed like a countdown).
- An undefined duration clicking on the "Loop" button (the counter will start from 0).

Start/ Stop stimulation



It is highly recommended to edit the intensity with caution!

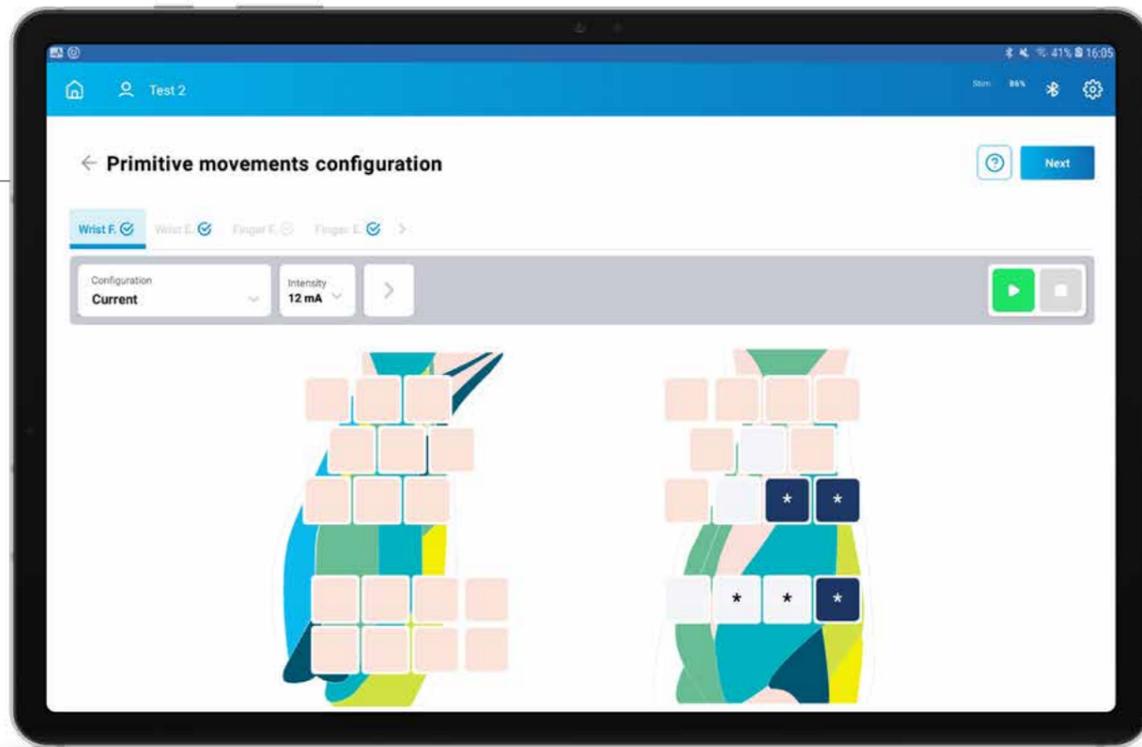
① This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.

CONFIGURATION | Primitive Movements

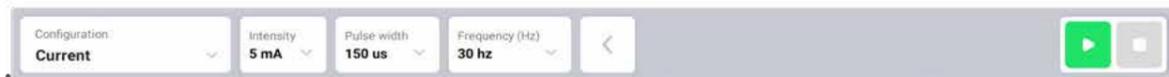
Primitive movements configuration is required for the Repetitive Task Training and AVD Training protocols. In both protocols, it is possible to access the movement configuration.

In the Configuration screen, you will be able to configure the 8 primitive movements and additional personalized movements.

- Wrist flexion and extension.
- Thumb flexion and extension.
- Flexion and extension of fingers 3, 4 and 5.
- Index flexion and extension.
- Primitive personalized movements.



CONFIGURATION BAR



Last session

It loads all the configuration of the last session (from both primitives and complex movements).

Habituation

It loads the intensity value set as motor threshold and frequency and pulse width defined in the Habituation protocol.

By default

It loads all the standard electro-parameters values for the specific pathology selected for the patient.

Current

Current configuration value. It will always change to this state.

Stimulation parameters

Collective

Clicking on the "+" and the "-" the intensity of all the cathodes is edited at the same time.

Individual

By clicking "Edit intensities" the intensity of the cathodes is edited independently. To do this, the cathodes must be selected one by one in the virtual electrode.

Start / Stop stimulation

Select/ create movement

Select configuration

Edit intensity

Select cathodes

Play

Next

1

Select the primitive movement to configure.

A personalized primitive movement can be created by clicking on "Config1" and "Config2" options. To change the title and image, make a long touch on the title.

2

Select the configuration to load. By default, except for the first time, the last configuration made for that patient will be loaded.

3

Edit the intensity by increasing the value progressively.

Stimulation parameters can be edited (frequency, pulse width) by clicking on the "Expand" button

4

Select the cathodes. Start with the cathodes with an asterisk and if there is no motor response, continue with the gray cathodes.

There are two options for selecting cathodes:

- 1) Select the cathodes and hit "Play".
- 2) Make a long touch on the cathodes with the Long Touch function.

5

To start with the stimulation, click on the "Play" button. The configuration will be saved automatically.

6

To continue with the Complex Movement Configuration, click on "Next" button.



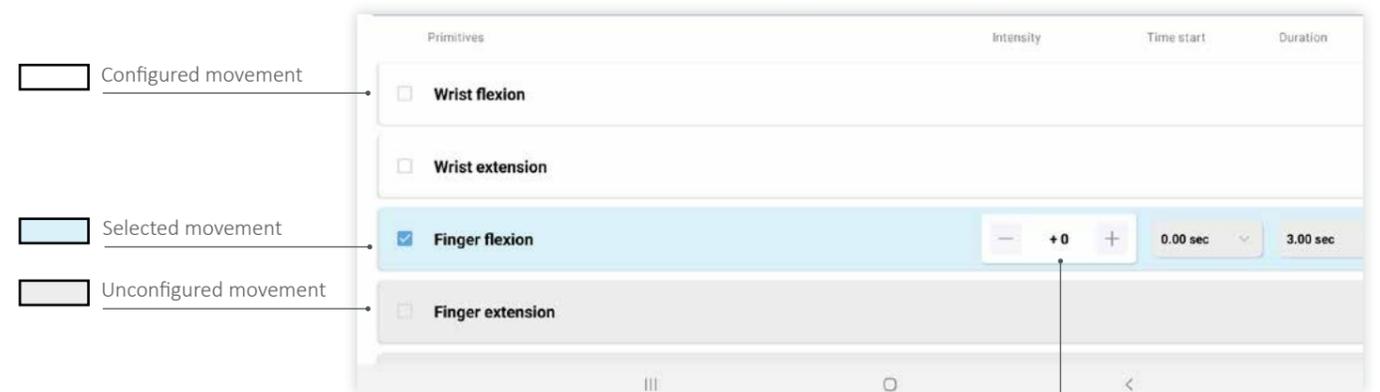
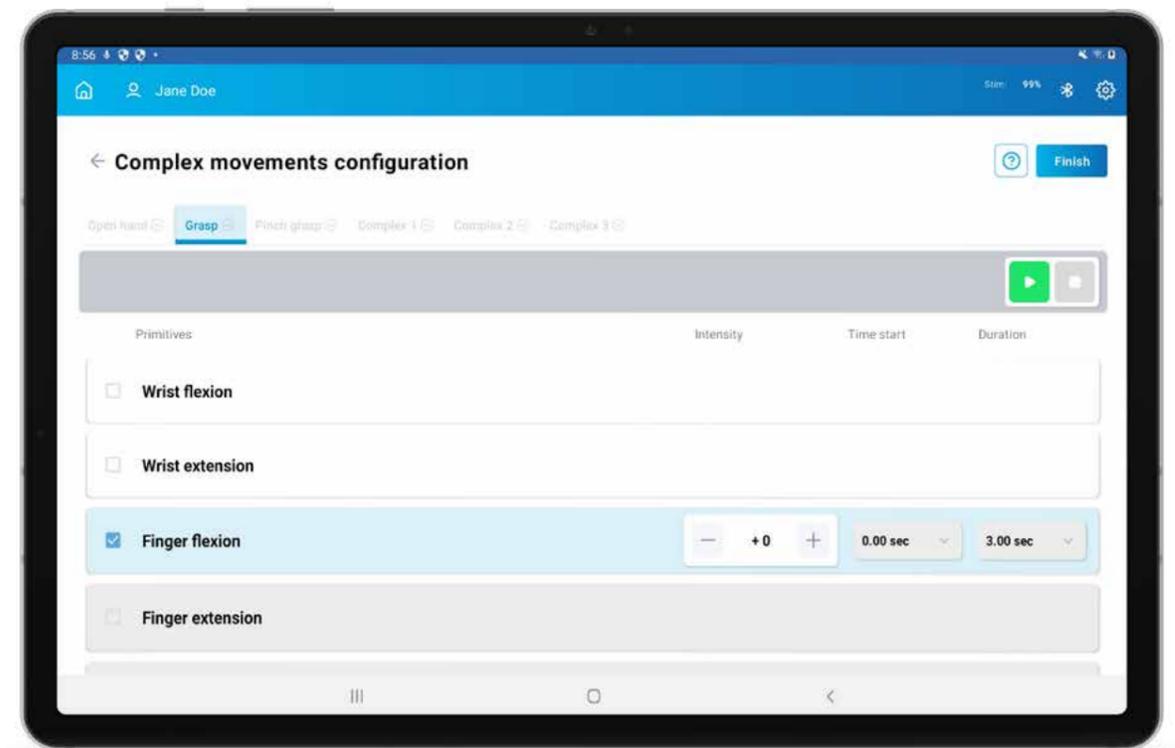
It is highly recommended to edit the intensity with caution!

This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.

CONFIGURATION | Complex Movements

Complex movements configuration is required for the Repetitive Task Training and AVD Training protocols. In both protocols, it is possible to access the movement configuration. In the second "Configuration" screen you can configure the 3 predefined complex movements as well as personalized complex movements:

- Open hand.
- Grasp.
- Pinch grasp.
- Personalized complex movements.



Edit start and end times of each primitive

7

Select the complex movement to configure.

Personalized complex movements can be created clicking on the options "Complex 1", "Complex 2", "Complex 3". To change the title and image, make a long touch on the title.

Select/Create movement

In case of choosing predefined complex movements (Open hand, Grip, Palm grip) it is not possible to choose additional primitive movements.

In the case of creating new personalized complex movements, all primitive movements configured in the previous screen can be selected (they will be shown in white).

8

It is possible to edit the intensity for each of the movements selected.

Edit intensity

①

Remember that the intensity value is being modified relative to the intensity value set on the previous screen.

9

To start with the stimulation, click on the "Play" button. The settings will be saved automatically.

Play

10

To finish the configuration, click on the "Finish" button.

①

It is important to click on "Finish" so that the configuration is saved and updated in the protocols.

Stop

It is highly recommended to edit the intensity with caution!

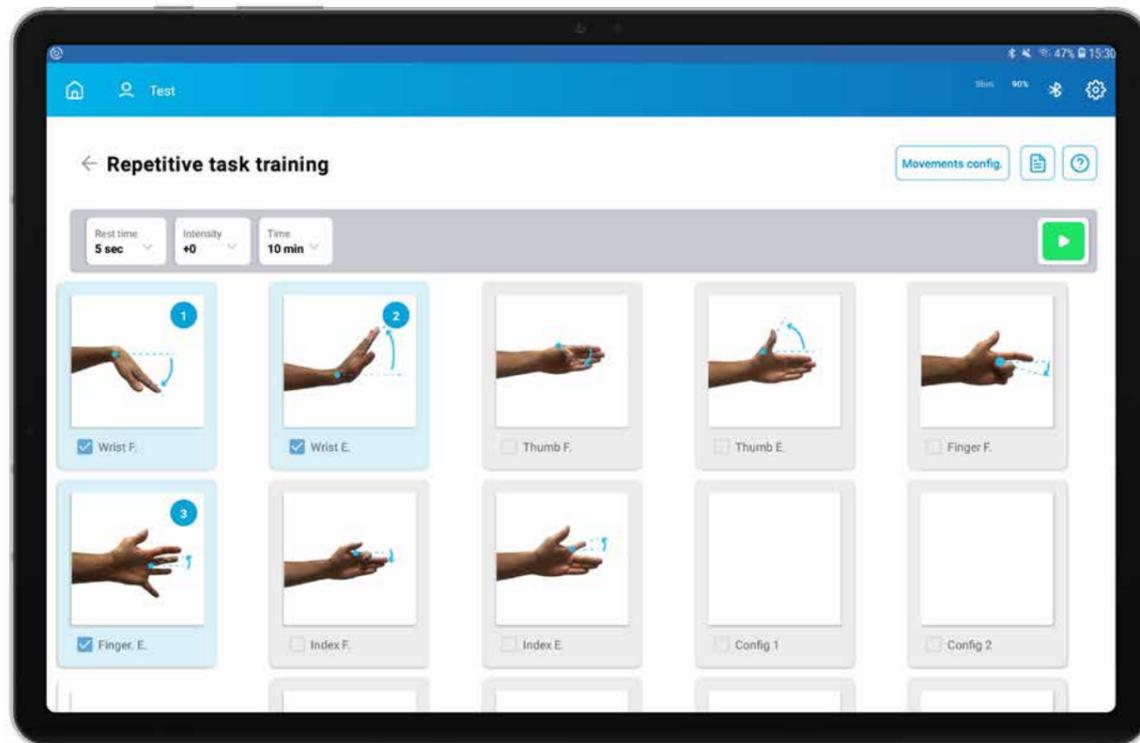
①

This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.

REPETITIVE TASK TRAINING PROTOCOL

This protocol can be used to perform repetitive training of different movements:

- Analytically, stimulating movements in isolated joints.
- In an integrated way, stimulating motor patterns composed of different analytical movements.



Select movements

Select parameters

Play

1

Select the desired movements in the order in which you want to perform the training.

2

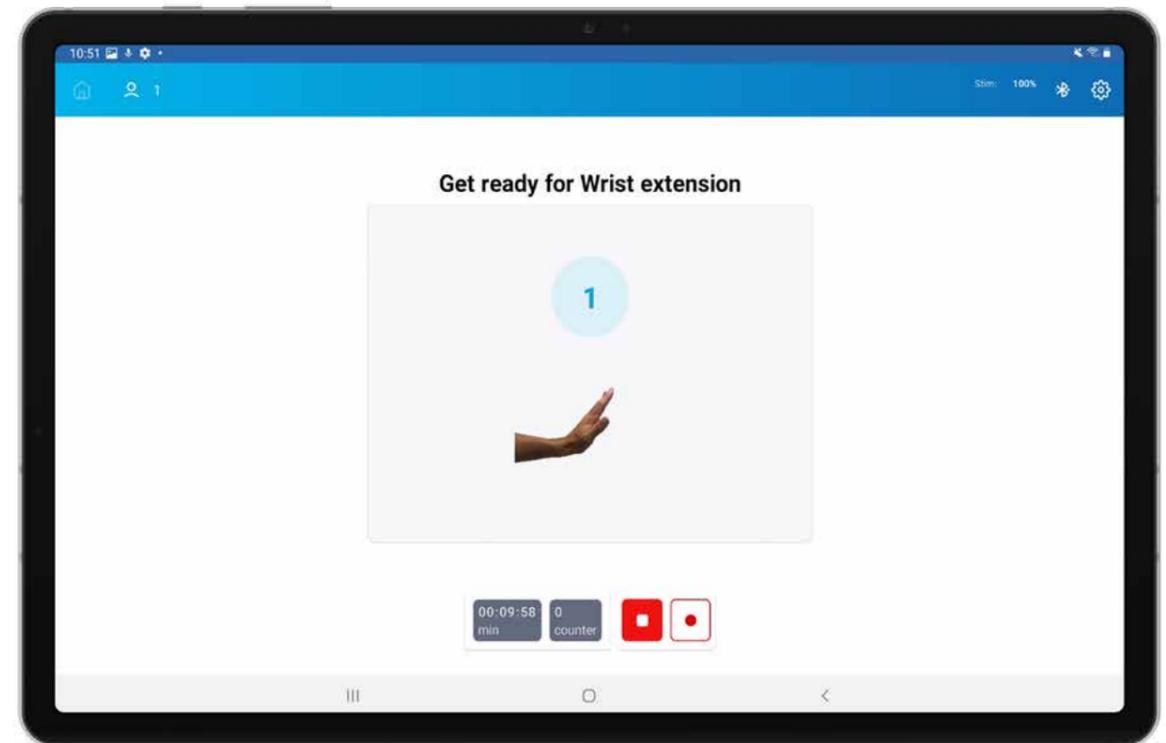
Select in the Configuration Bar:
- Rest time: It is the rest time between one movement and another.
- Intensity: Increase in relative intensity for all movements.
- Time duration of the entire exercise.

3

To start stimulation, click on the "Play" button.

①

Remember the intensity is increasing relative to the intensity value configured in the Movements Configuration screens.



Perform movement

Stop

4

The movements will appear full screen in the order of choice.

There are 3 phases:

- Preparation: A 3-second countdown and a dynamic image of the movement to be performed are shown.
- Realization: A descriptive static image of the movement is displayed as visual feedback of the movement performed by the stimulation at that moment.
- Rest: Rest time established in the previous screen.

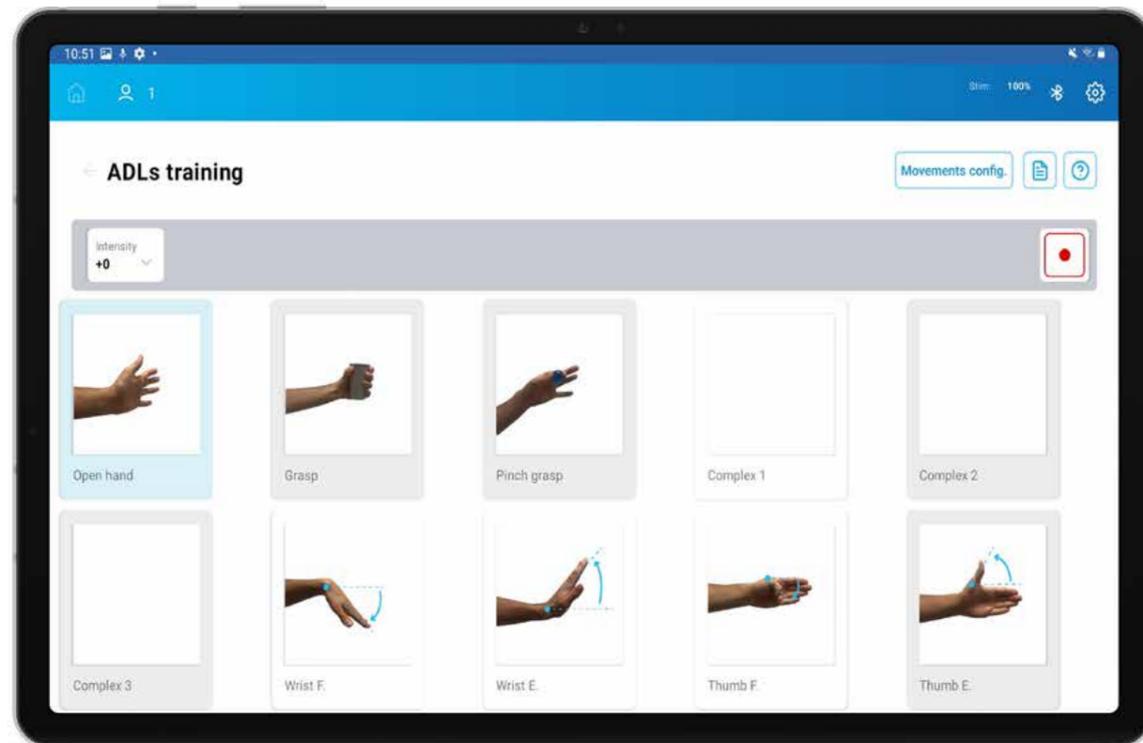
5

When you have finished the session, click on the "Stop" button.

Click "back" in the navigation bar, it will appear a message where you must choose "Save session" or "Exit without saving".

ADL TRAINING PROTOCOL

This protocol can be used when the objective is to integrate movements provided by electrical stimulation in activities of daily life, compensating for movements that the person cannot perform through electrical stimulation.



Select movement

Stop/select movement

Save session

1

Select the movement you want to perform by clicking on the image of the desired movement.

2

-Stop the movement by clicking on the same image.
-Select the next move clicking on the image of the desired movement.

3

Click on "back" arrow in the navigation bar. A message will appear in which you must choose between "Save session" or "Exit without saving".

①

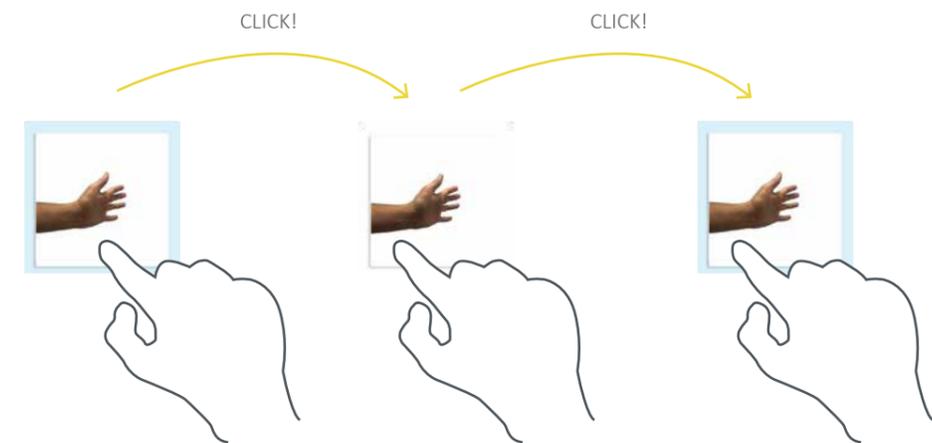
Remember the intensity is increasing relative to the intensity value configured in the Movements Configuration screens.

TOGGLE KEYPAD

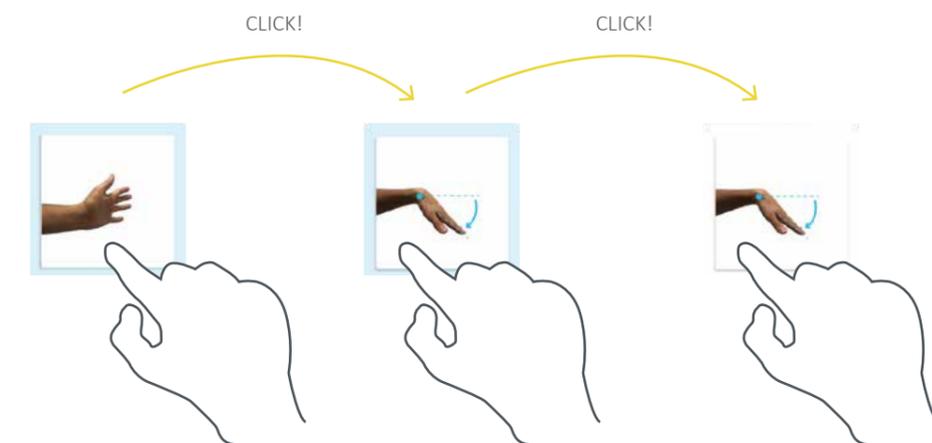
The Toggle keypad acts as a button and trigger for stimulation. By clicking directly on the image of the desired movement, stimulation is activated instantly and in real time.

We can:

A. ACTIVATE/DEACTIVATE MOVEMENT



B. ACTIVATE/DEACTIVATE VARIOUS MOVEMENTS





04

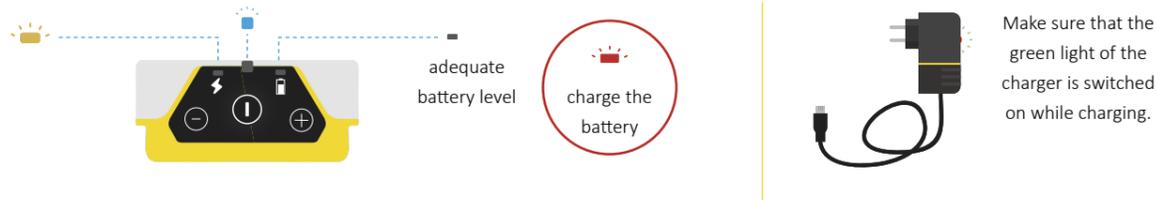
TECHNICAL
SUPPORT

TROUBLESHOOTING

Make sure you have checked the following steps before contacting **Fesia**:

1 Check that you do not have any pending update of the **Fesia** Pro app (Google Play Store, Select "Menu", "Apps and games").

2 Check all the device indicators. If battery indicator is blinking red, please charge the battery.



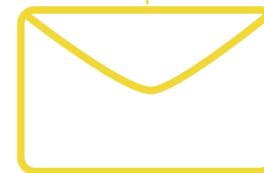
3

Issue	Action
The stimulator doesn't turn on.	- Check the stimulator is properly attached and charged.
The stimulator unit beeps during configuration and shows the following error message "ERROR: Open circuit detected".	- Check the electrode is completely attached to the forearm. - Check the electrode is in a good condition. - Substitute the electrode. - Check the cathodes configuration is appropriate.
The stimulation is not felt and the yellow light turns on.	- Check that the stimulator is properly placed in the socket of the electrode. - Check that the electrode is completely attached to the limb. - Check you have removed the protective plastic layer. - If the problem persists, replace the electrode and check the previous steps again.
The software is not responding or won't connect to the stimulator/sensor.	- If there is a communication failure in the app, restart the app. If it is not solved, restart the tablet. - If you cannot have the app connected to the stimulator: Switch off and on and try again.
Bluetooth connection is lost.	- Check the battery level. - Restart the device again.
An ERROR message appears at the bottom of the tablet screen.	- Please try again, if the error persists after restarting the device and tablet, contact Fesia Support with the exact error message.

CONTACT WITH FESIA SUPPORT



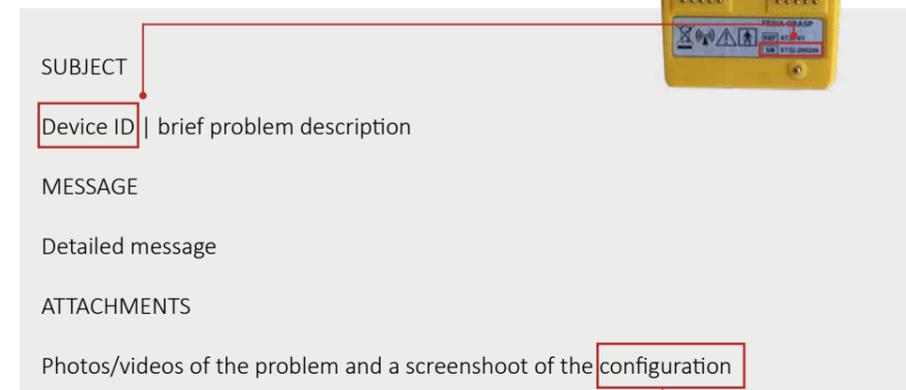
Once you have taken the previous steps, if your problem is not already solved, you can contact **Fesia** on: support@fesia.net or +34 613 009 533.



It is very important to provide a detailed description of the problem so that Technical Support team can solve it as fast as possible. Find the information we kindly ask you to include in your message:



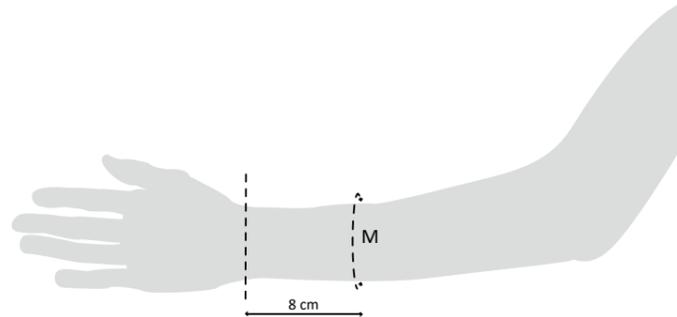
You can find the ID in the back-side label of the stimulator.



Make a screenshot or take a photo of the configuration screen and include it as an attached document in the email.

SIZE SELECTION GUIDE

- 1 Measure the diameter of the arm at the point indicated on the image and write down the value of M.

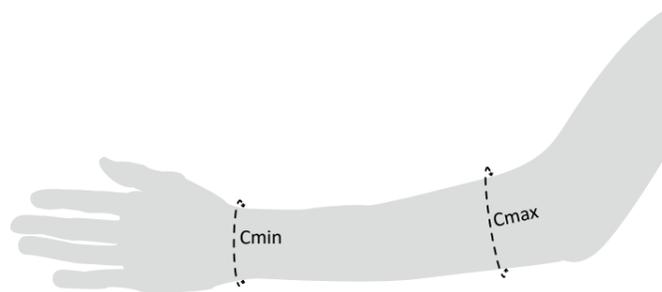


If $M < 19,5$ cm.....**CHOOSE THE S/M SIZE**

If $M > 21$ cm.....**CHOOSE THE M/L SIZE**

If $19,5$ cm $< M < 21$ cm.....**GO TO STEP 2**

- 2 Measure the diameter of the arm at the areas indicated on the image and write down the values of Cmin and Cmax.



If the arm is tube shaped ($C_{min} / C_{max} \geq 0,7$).....**CHOOSE THE S/M SIZE**



If the arm is cone shaped ($C_{min} / C_{max} < 0,7$).....**CHOOSE THE M/L SIZE**

If after choosing the S/M size, the textile does not close correctly at some points:

1. Change the textile to size M/L and keep the electrode size S/M.



If after choosing the M/L size, the textile does not close correctly at some points:

1. Provide additional fastening to the velcro (adhesive or elastic tape).
2. Use the electrode without the textile garment (only if it adheres to the skin correctly).

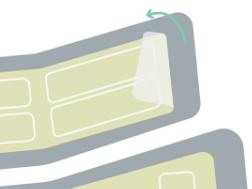


05

MAINTENANCE

ELECTRODE MAINTENANCE

DO



Before donning the device, carefully separate the plastic protecting the gel.

Keep the protective layer to store the electrode at the end of its use.



After using the electrode, spray it with a few drops of water, letting it dry at air or with a cotton gauze.

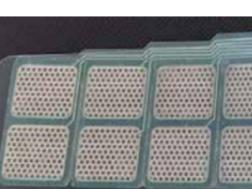
Hydrate the electrode and reposition the protective plastic.

In cases of excessive sweating, dry the electrode with a cotton gauze.

15 max

Change the electrode every 15 sessions.

It is important to respect the time of use of the electrodes in order to avoid skin irritation.

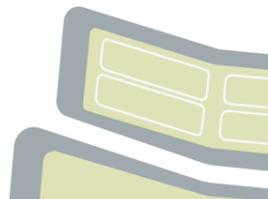


Check the electrodes visually at the end of the session and regularly.



Store the electrodes in the original packaging and close it with zip or tape for its correct conservation.

DON'T



Do not place the device with the protective plastic.

Do not throw the protective plastic in the trash.



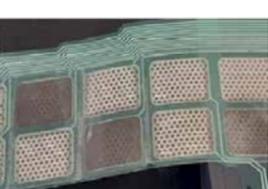
Do not pour too much water on the electrode.

In case of excessive sweating, do not moisturize the electrode.

>15 max

Do not use the electrode for more than 15 sessions.

Do not to extend the life of the electrodes using products not approved by **Fesia**, such as gels of other types of devices.



Do not use the electrodes if the cathodes are blackened (even if the 15 sessions have not been exceeded). Replace them.



Do not leave the electrode without a bag directly in the case or a bag other than the original one.

GARMENT CLEANING



Hand wash with a soft cloth on both sides.



Do not iron.



Do not use bleach.



Do not use the dryer.

Maintenance

Clean with a damp cloth on both sides. Then, disinfect in a 1% hydrogen peroxide solution for up to 5 minutes.

Deep cleaning

Immerse in hot water (50-60 degrees) using a large container without bending the garment. Rub with a soft cloth and dry at air.

Disinfection

To disinfect it, immerse in a 1% hydrogen peroxide solution for 5 minutes. If possible, use a UV device to disinfect the surface. Make sure to place it on both sides. Regarding the drying time, check with the supplier of the UV equipment.

SKIN CARE

When using FES, irritation can sometimes occur. In most cases, it can be treated and prevented from returning.

WHAT DOES SKIN IRRITATION LOOK LIKE?



- A slight reddening is normal under the electrodes after use, due to increased blood supply to the area.
- This should fade within an hour or so of removing the electrode.
- If the red mark is still there the next day, it may be skin irritation.

① If you get a skin irritation, STOP using your FES and contact your FES clinician.

HOW CAN I GET RID OF SKIN IRRITATION?



Do not use FES until the skin has completely healed.



Once the skin has healed, we may need to try alternative electrode positions.



Ask your FES clinician for advice.

** If your skin is slow to heal, weak steroid creams can be used following advice from your GP or Pharmacist.

WHAT CAUSES SKIN IRRITATION?

Can occur when the skin's natural barrier is broken. This can be due to:

- ⊘ Scratching the skin too hard.
- ⊘ Placing the electrode over a cut, rash, spot or insect bite.
- ⊘ Shaving the skin using a razor.
- ⊘ Using old, dried out, damaged or dirty electrodes.

** Very occasionally, irritation can be due to an allergic reaction to the materials within the device/electrode.

HOW DO I PREVENT SKIN IRRITATION?

1  Regulate the dosage of FES during the first sessions and increase it according to your evolution.

2  15 sessions
Make sure you change the electrodes every 15 sessions or, if you take proper care of them, before the adhesive stops being sticky.

3  Rehydrate the electrodes at the end of each use, by applying one or two sprays to the electrode.

4  Make sure the electrodes are stored on the plastic backing sheet and placed in their foil bag, when they are not in use.
NOTE: Always take off the electrode after its use.

5  Do not shave the skin using a razor to avoid scratches. Instead use a beard trimmer or clippers.

If you have any questions please contact your FES clinician:
☎
If you are in any doubt, stop using your FES device and wait to speak to your FES clinician.



06

TECHNICAL
INFORMATION

STIMULATOR SPECIFICATIONS

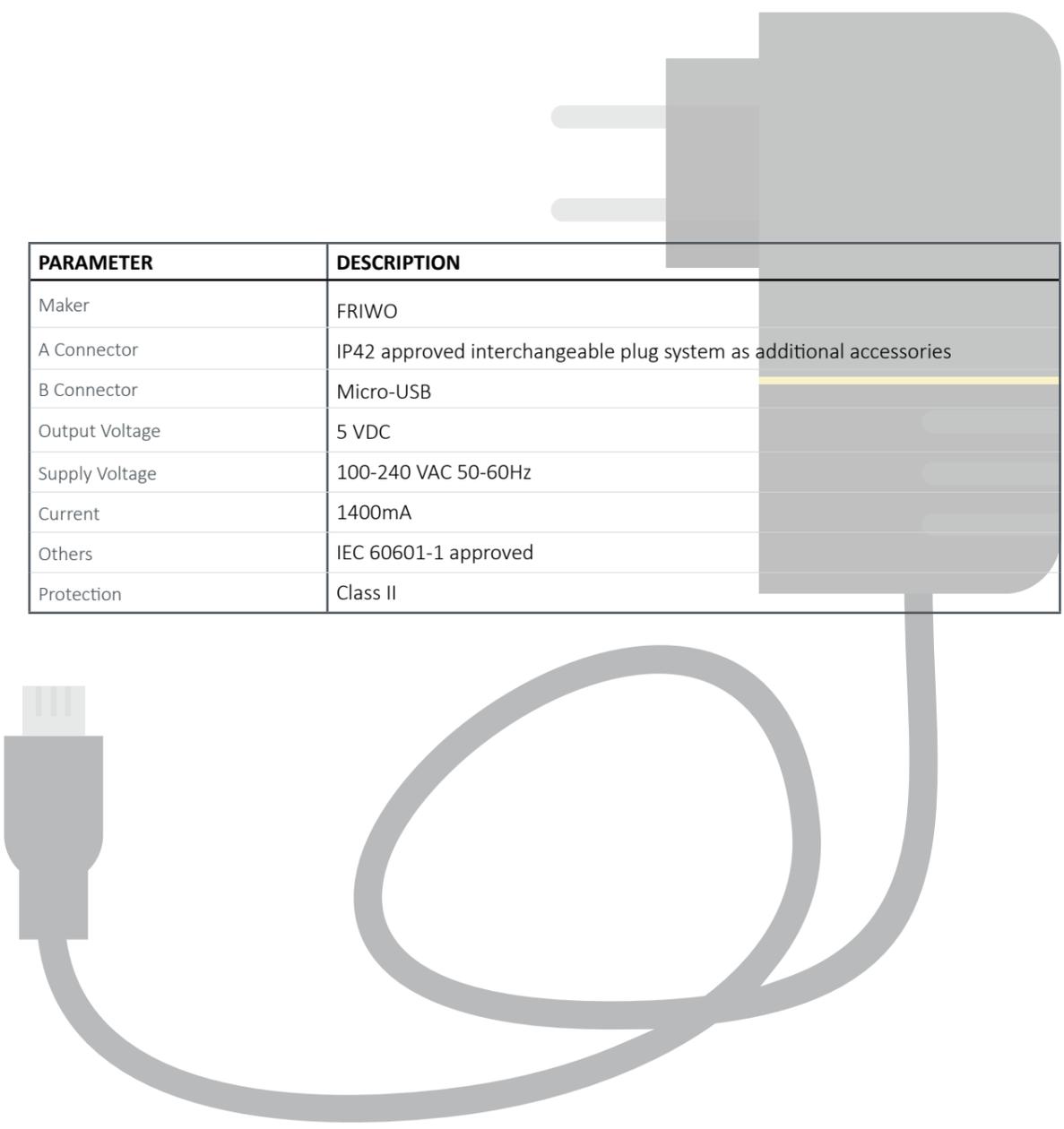
PARAMETER	DESCRIPTION
Classification	Internal power, continuous operation with applied parts type BF
Battery Type	Rechargeable Lithium-Polymer 3,7V, 1400mAh
Operating Modes	Primitive movements, configuration and standby
Controls	On / off button Intensity increase button (+) Intensity decrease button (-)
Indicators	Three status LEDs <ul style="list-style-type: none"> • Communication (Blue) • Battery / Alarms (Red) • Active stimulation (Yellow) Audio (buzzer)
Dimensions	26 mm x 76 mm x 52 mm
Weight	91 gr.
Load Characteristics	5V – 0.5A
Environmental conditions	Operating temperature: 5°C to 40°C Charging temperature: 5 ° C to 40 ° C Transport and storage temperature:-20 to 60 ° C Relative humidity: 15% to 90% Atmospheric pressure: 700hPa to 1060hPa
Wireless Communication	Two Bluetooth modules: Bluetooth 3.0 and Bluetooth 4.0- Dual mode
Maximum Load	5000Ω
Maximum Output Power	1,5W
Protection	IP22

GENERATED PULSE PARAMETERS	DESCRIPTION
Pulse type	Symmetrical biphasic or compensated biphasic
Pulse intensity	0- 60mA, 1mA resolution (for loads <5000Ω)
Pulse width	150us-. 300 us, resolution of 10us
Pulse frequency	1- 40Hz resolution of 1 Hz
Maximum output voltage	180V
Maximum output frequency	1KHz

ELECTRODE SPECIFICATIONS

PARAMETER	DESCRIPTION
Models	Right Fesia Grasp v01 Left Fesia Grasp v01
Materials	Base: 100um PET Fields electrode: silver ink bio-medical supports. Contacts: protected graphite
Hydrogel	0.9mm thick (approx.) pH 4.2 (± 0.5%) Approved tests: Cytotoxicidad, Primary Skin Irritation, Delayed Hypersensitivity
External Dimensions	270mm x 140mm
Cathodes	32 Area: 270mm ² (18mm x 15mm)
Anodes	8 Area: 600mm ² (30mm x 20mm).
Environmental Conditions	Operating temperature: 5°C to 40°C Transport and storage temperature: 0 to 40 Optimum temperature for long-term storage: 5°C to 27°C Recommended storage time: 3 months (sealed) Expiration time: 3 years (sealed) Relative humidity: 35% to 50% Atmospheric pressure: 700hPa to 1060hPa

CHARGER SPECIFICATIONS



PARAMETER	DESCRIPTION
Maker	FRIWO
A Connector	IP42 approved interchangeable plug system as additional accessories
B Connector	Micro-USB
Output Voltage	5 VDC
Supply Voltage	100-240 VAC 50-60Hz
Current	1400mA
Others	IEC 60601-1 approved
Protection	Class II

EMI TABLES

SYSTEM CHARACTERISTICS	MODULE 1
Function	Stimulator Main
Module	Lairdtech BT900
Frequency (MHz)	2402-2480
Max. declared output power (dBm)	8
Max. antenna gain (dBi)	+0,5
Max. E.I.R.P (dBm)	8,5
Max. E.I.R.P (mW)	7,08

GUIDANCE AND MANUFACTURER'S DECLARATION– ELECTROMAGNETIC EMISSIONS

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The Fesia Grasp device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Harmonic emissions IEC 61000-3-2 Voltage fluctuations/Flickers emissions IEC 61000-3-3	Class B Class A Fulfill	The Fesia Grasp device is suitable for use in establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

The equipment must not be used next to or mounted above or below another piece of equipment. If this cannot be avoided, the equipment should be checked for normal operation in the configuration in which it will be used.

The use of accessories other than those specified for the equipment is not recommended. This could result in an increase in emissions or a decrease in the immunity of the equipment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The **Fesia** Grasp device is intended for use in the electromagnetic environment specified below. The customer or user of this device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be Wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/bursts IEC 61000 4-4	±2 kV for Power supply lines ±1 kV for I/O lines (input/output)	±2 kV for Power supply lines ±1 kV for I/O lines (input/output)	Mains power quality should be that of a typical commercial and/or hospital environment.
Surges IEC 61000 4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000 4-11	<5% Ut (>95% dip in Ut) for 0,5 cycles <40% Ut (>60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles >5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0,5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles >5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the Fesia Grasp device requires continued operation during power mains interruption, it is recommended that the be powered from an uninterruptible power supply.
Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000 4-6	3 vrms 150 kHz to 80 MHz	3 Vrms	d = 1,17 VP 150 kHz to 80 MHz
Radiated RF IEC 61000 4-3	3 v/m 80 MHz to 2,5 GHz	3 V/m	d =1,17VP 80 MHz to 800 MHz d=2,33VP 800 MHz to 2,5 GHz

Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m).^b
 Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b
 Interference may occur in the vicinity of the equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies
 Note 2: Ut is the AC mains voltage prior to application of the test level.
 Note 3: 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 broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the **Fesia** Grasp device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the **Fesia** Grasp device.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE FESIA GRASP DEVICE

The **Fesia** Grasp device is intended for use in a electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the **Fesia** Grasp device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the **Fesia** Grasp device as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	150 kHz to 80 MHz d = 1,17 VP	80 MHz to 800 MHz d =1,17VP	800 MHz to 2,5 GHz d=2,33VP
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,74
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **p** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- Between 80 MHz and 800 MHz, the separation distance is applied in the highest frequency range.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.