INSTRUCTIONS FOR USE
FESIA WALK

fesia

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These Instructions for Use can be visualized through any PDF viewer installed on your computer.

If you require the Instructions for Use printed, please contact your nearest distributor.

The latest version of this Instructions for Use can be found on the following link:
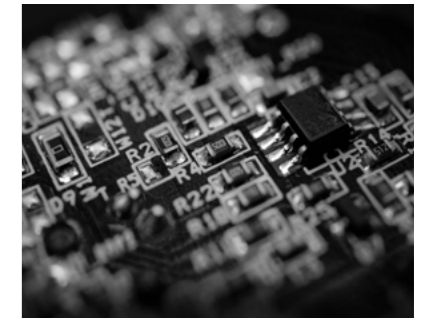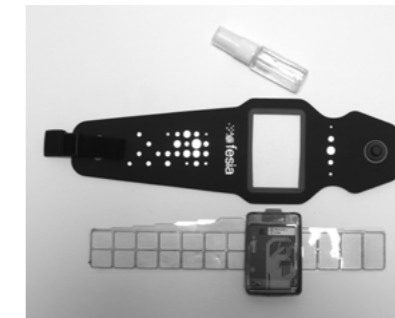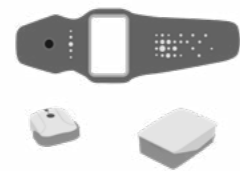*https://www.fesiatechnology.com/downloads/FesiaWalk_IFU_en.pdf*

01 02 03 04 05 06 07

01

GENERAL INFORMATION

INDICATIONS OF USE

Fesia Walk is a rehabilitation device designed to provide dorsal and plantar ankle flexion for people suffering from foot drop/equine as a result of a nervous system disease or injury. **Fesia** Walk stimulates the motor nerves of the affected leg by means of electrical currents, assisting the deficient movements, thus, improving the patient's gait. Functional electrical stimulation can also enhance motor relearning, improve spatiotemporal aspects of gait, strengthen muscles, increase local blood flow and/or increase range of motion.

CONTRAINDICATIONS

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

WARNINGS

- Do not use the device to **control machines, drive nor 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 leg only** as indicated in the manual.
- Do not use this **device simultaneously with other high frequency medical devices**. Ignoring this warning can result in skin burns in the electrode area and damage the stimulator.
- Do not use this device in **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 device nor 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 overused electrodes** could cause skin burns or loss of function of the device.
- Improper use or **use of a faulty device** could cause **skin burns, muscle damage or falls**.

PRECAUTIONS

- This device must be used **under the supervision of a rehabilitation specialist and must only be operated by personnel trained** specifically for this purpose.
- This device 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 sign of malfunction or if any of the components are in poor condition**.
- Must not be exposed to **liquids or splashes**.
- Must not be exposed to **extreme temperatures**.
- Must not be exposed to **direct sunlight**.
- Must not be used **near flammable products**.
- Store the device under **protection from humidity, dust and direct sunlight**.
- Use only the **electrodes supplied by Fesia**.
- Use only the **charger and charging cable supplied and approved by Fesia**.
- This device must be kept **out of reach of children**.
- **Caution** when using the device if you have **heart disease, epilepsy, or vascular or circulation problems** is recommended.
- Do not turn on the stimulator until it is properly placed.
- The **electrode is personal**, it should not be exchanged between different people.
- Make sure the **stimulator and sensor are 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.

> ⓘ Contact the clinical specialist in case of skin alterations, sensation of pain, worsening or any sudden change in the clinical picture.

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 blushed after removing the device**, this redness should disappear in about an hour.
- In some cases, electrical stimulation or gel contact with the skin **may cause irritation or allergic reaction** on the contact surface.
- The patient must **immediately stop using the device** when:
  - Redness or irritation in the area of stimulation lasts for more than one hour after removing the electrode.
  - Blisters or sores are shown within the area of stimulation.
  - Feeling a significant increase in muscle spasticity.
  - Suffering from tachycardia or cardiac stress during stimulation.
  - The extremity is swollen.

> ⓘ Any serious incident involving the use of this product must be informed to the manufacturer.

> ⓘ Specific training is required for the correct use of the device.

LEGEND

This user guide includes additional audio-visual material to ease comprehension and foster inclusive learning.

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

Symbol	Meaning
	This section includes a video.

SYMBOLS

Symbols	Meaning
	Caution
CE 0051	Complies with european regulatory requirements for medical devices
	Manufacturer
REF	Catalogue number
SN	Serial number
	Consult the instructions for use
	Double insulation (equivalent to Class II according to IEC 536)
	Type BF applied parts
	Single patient multiple use
	Continuous load current
	Non-ionizing radiation
	Keep out of sunlight
	Keep dry
	This product should not be disposed with other household products
	Low battery (red light)
	Stimulation is active (yellow light)
	Intensity increase button
	Intensity reduction button
	On/off button

02

FESIA WALK
DEVICE

The **Fesia** Walk device operation is based on superficial electrical stimulation to cause plantar flexion and dorsiflexion in the corresponding gait phases.

The main feature of this device is its multi-field electrode which allows better selection of movement and shorter setup time.

It is a multi-field electrode designed to cover both the posterior and lateral areas of the knee; thus, covering the entire area susceptible to stimulation.

GENERAL DESCRIPTION
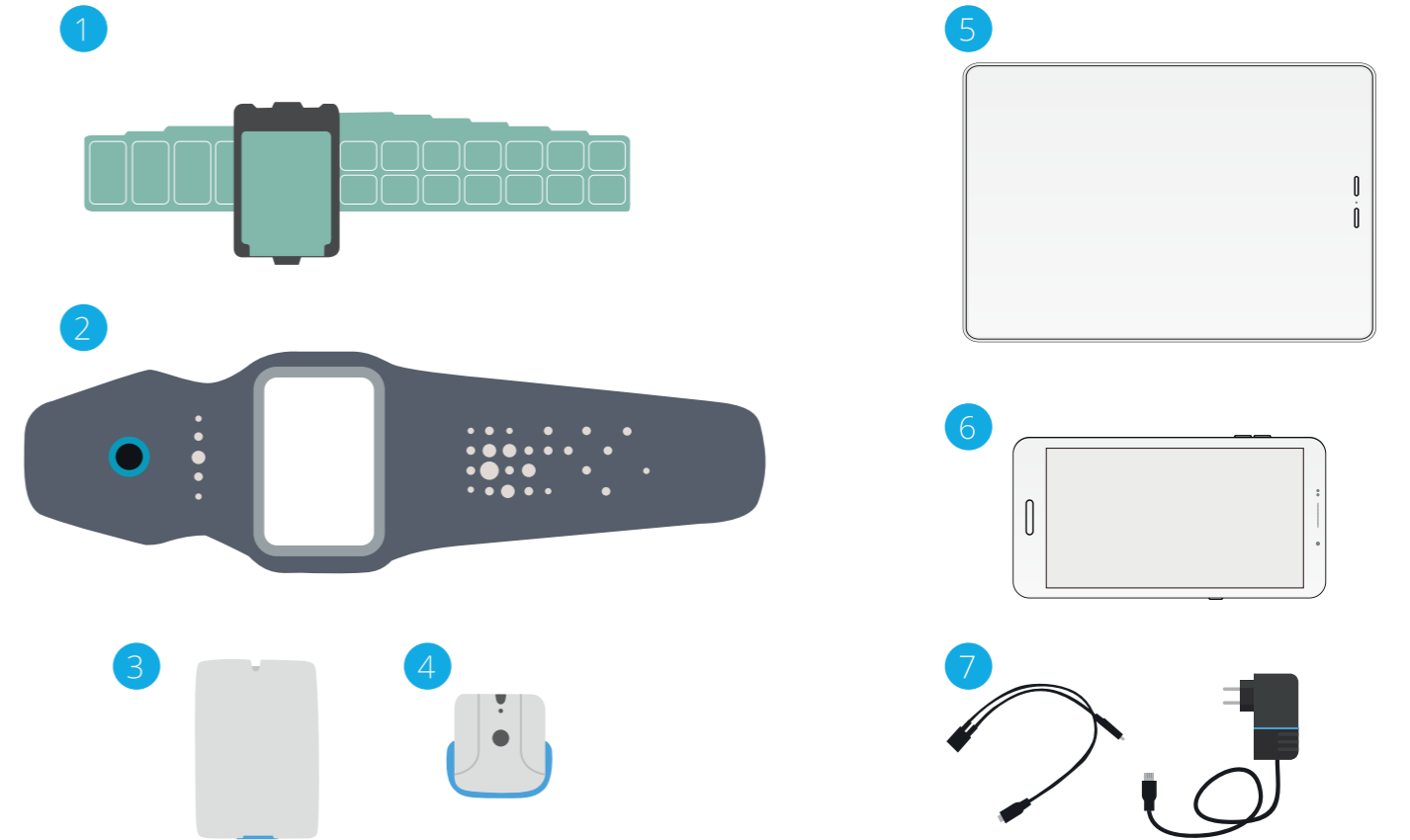
1. **Electrode:** It consists of 16 cathodes (output fields) and four anodes (return fields) that can be activated independently or in combination, thus allowing adaptation to the different people's anatomy. The multi-field electrode is personal and disposable.
2. **Textile garment:** The textile garment ensures proper electrode-skin contact and, on the other hand, serves as a support for both the stimulator and electrode.
3. **Stimulator:** The stimulator generates electrical pulses, which are transmitted to the skin through the multi-field electrode.
4. **Sensor:** It is an inertial sensor placed on the foot and has two functions: the search of optimal stimulation parameters (configuration) and detection of the gait phases. In the configuration phase the sensor is capable of measuring dorsiflexion, plantarflexion, eversion and inversion of the foot, and helps determining the optimum parameters and fields stimulation for each of these movements. During gait, the sensor is able to detect the takeoff and foot contact times in order to trigger the stimulation with the corresponding parameters.
5. **Fesia** Pro *app* (already installed in pre-configured tablets provided by Fesia): The device has a software application that allows, on the one hand, to control and configure the stimulation parameters and, on the other hand, to monitor the evolution of the different users in an easy and intuitive way. The application is specifically designed for healthcare personnel use.
6. **MyWalk** *app* (to be installed on Android mobile phone): The device has a software application that allows you to control and configure the stimulation parameters in an easy and intuitive way. The application is specifically designed to be used by the patient.
7. **Charger and splitter 2x1:** It is a charger approved for charging medical devices. It comes with a splitter that allows the simultaneous charge of both stimulator and sensor.

⊘ Make sure the received device includes all components.

INDICATORS

Bluetooth indicator

Stimulation indicator

Battery indicator

On/Off button

Reduce intensity button

1s. **Short press**: Increase intensity button.

2s. **Long press**: Automatic start of the Gait protocol to use the device without tablet.

Bluetooth indicator

Battery indicator

On/Off button
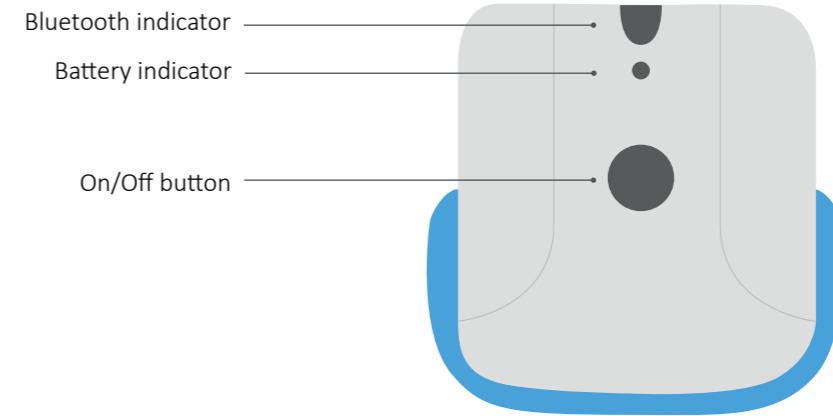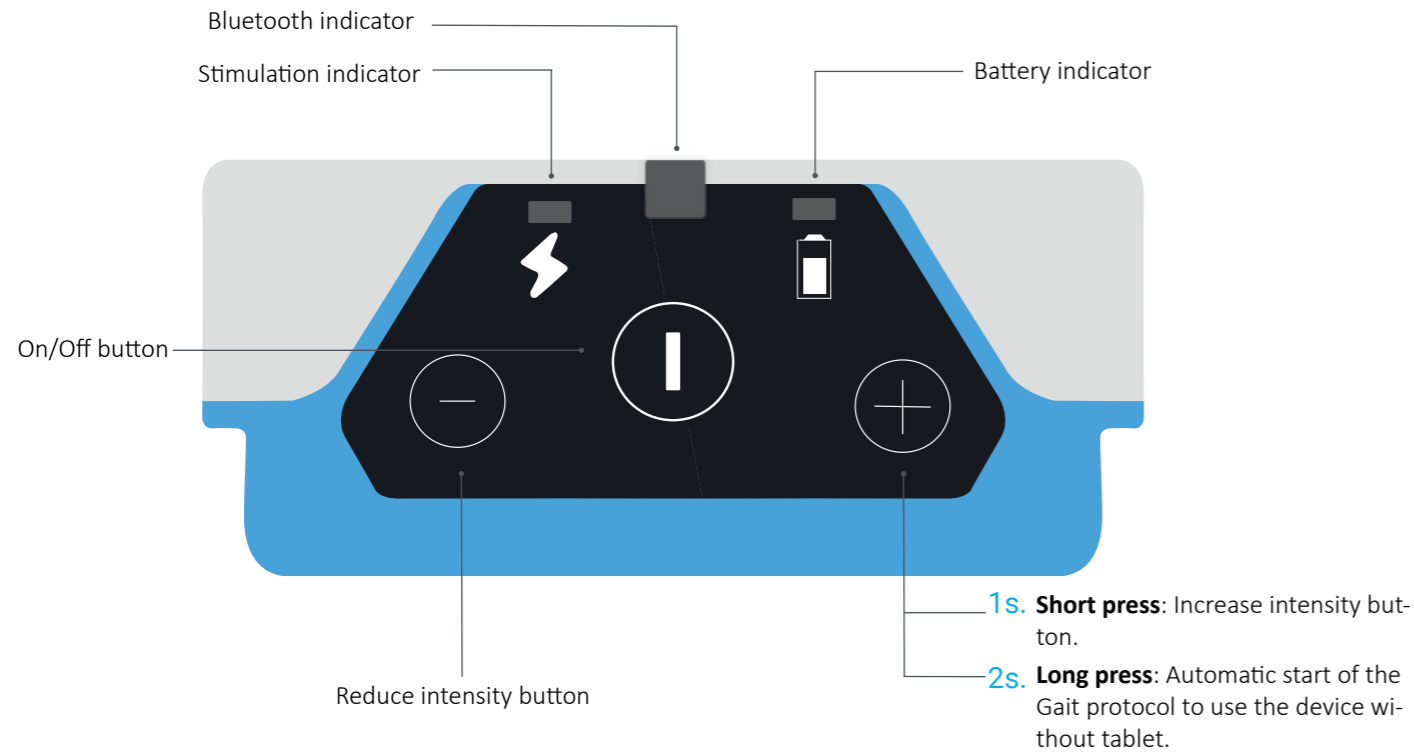
STIMULATOR INDICATORS	STATUS
Stimulation indicator	Stimulation on
	Stimulation off
Bluetooth indicator	Stimulator on
	Stimulator off
Battery indicator	Low battery level
	Adequate battery level
Beep. Pulse sound	Increase intensity button
	Reduce intensity button
Beep. Pulse sound	Start of the Gait protocol without tablet

SENSOR INDICATORS	STATUS
Bluetooth indicator	Sensor on
	Sensor off
Battery indicator	Low battery
	Adequate battery level

INITIAL CHECKS

1   **2**   **3**   **4**

3h

FULLY CHARGED

Before the first use, the device must be fully charged. This process takes about 3 hours. Connect the charger to the network and the connector to the stimulator and sensor. Ensure the plug is fully inserted. The red LED will light while charging and will turn off when the process is completed.

One of the accessories provided is a USB cable splitter, with which using a single charger, you can charge the two elements (stimulator and sensor).

> - Use only the charger and charging cable supplied and/or approved by **Fesia**.
> - Ensure the device is charged before its first use.
> - The battery may only be replaced by authorized personnel.

CLEAN SKIN

The skin should be clean and dry to assure optimal placement of electrode. The skin must not have residues of lotion, oils or similar. Lack of proper skin care and improper or prolonged use of electrical stimulation may result in skin irritation or in an adverse skin reaction. Skin irritation may occur up to three months after its use. Therefore, it is important to follow a daily skin care routine to use the device for a long time without damaging the skin.

> - 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, wipe it off with soap and water.
> - Always check for redness or rashes on the skin when the device is placed and removed.
> - Make 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 it with a beard trimmer or scissors. Do not use razor blades, as they may irritate the skin.
> - When placing the garment, ensure the electrodes are in contact with the skin evenly.
> - Remove the garment and electrode for at least 15 minutes every 3 to 4 hours to let the skin breathe.

WIFI CONNECTION

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

ACCOUNT CREATED

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

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

Once you have gone through the previous steps, check you have all the components for placement and operation of the device.

> In case the received package is damaged, unintentionally opened before use or exposed to environmental conditions outside of those specified, contact Fesia Support.

DEVICE PLACEMENT

1 Insert the electrode in the garment matching the shape of the electrode with the shape of the garment. To assure proper placement, check the left (L) and right (R) electrode and textile garment indicators match.
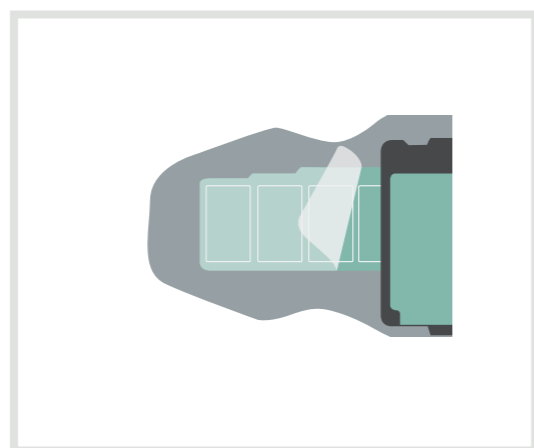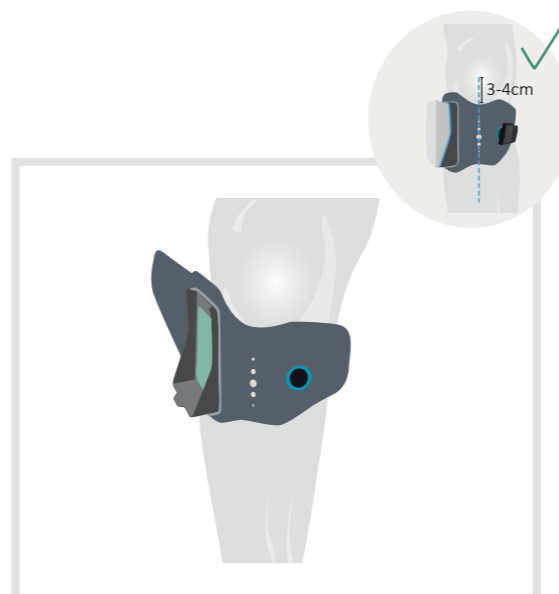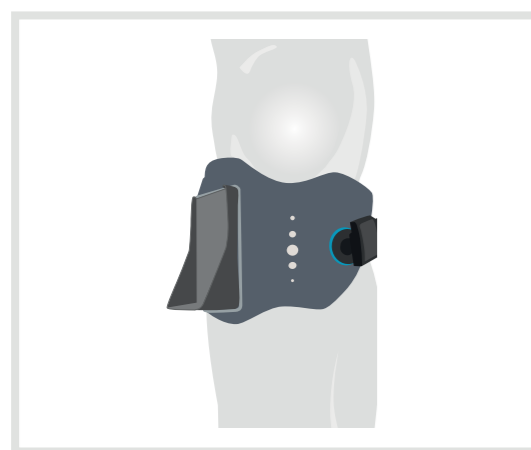

2 Carefully remove the electrode gel protective layer. Keep this protective layer as you will need it to store it at the end of its use. This layer protects the gel from dirt and dust.

3 Place the central axis reference of the garment three or four centimeters below the patella.

4 Close the garment using the magnetic fastener and adjust to suit.
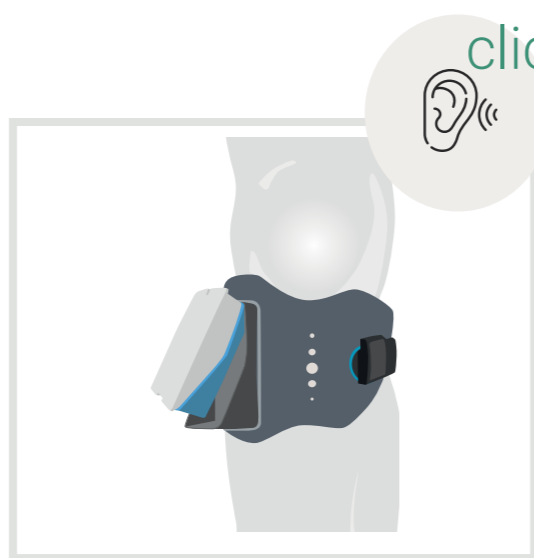
click!

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

6 Place the sensor on the foot. Assure the blue part of the sensor is upwards, as shown in the picture.
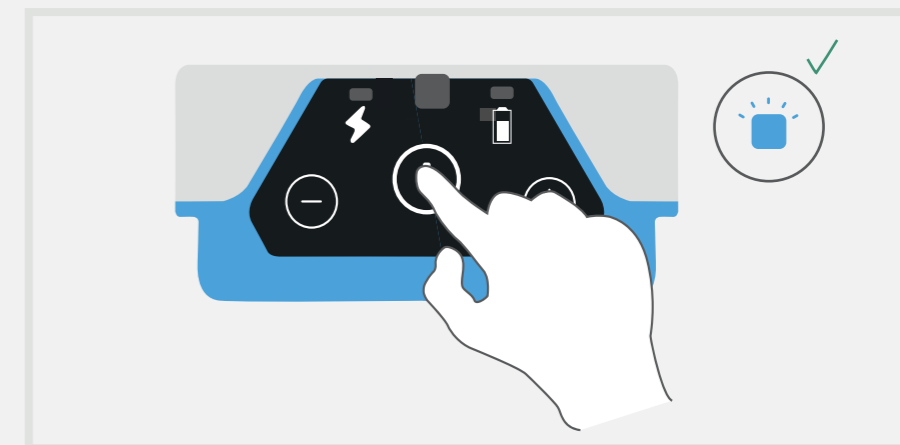
7

SWITCH ON THE STIMULATOR
Press and hold the On/Off button for two seconds. When the stimulator is on, the Bluetooth LED indicator will start flashing. The flashing will slow down once it is paired with the sensor.
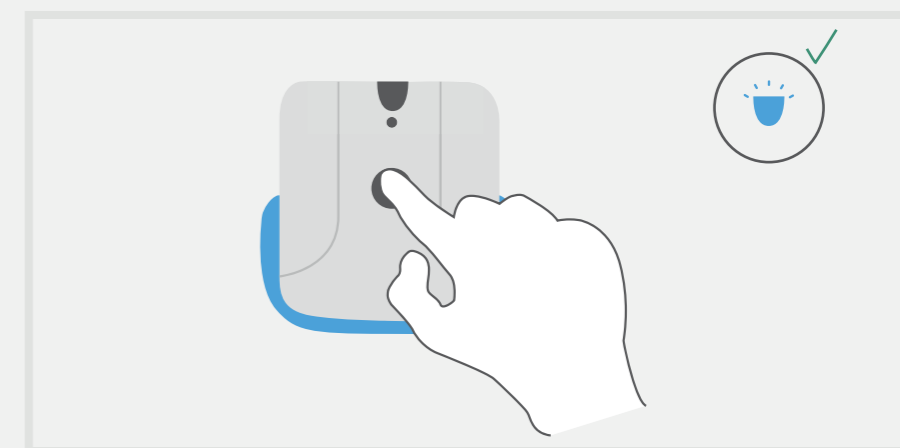
8

SWITCH ON THE SENSOR
Press and hold the On/Off button for two seconds. When the sensor is on, the Bluetooth LED indicator will start flashing. The flashing will slow down once it is paired with the stimulator.

Devices
ST16-XXXXXX
ST16-XXXXXX
ST16-XXXXXX

9

CONNECT TO THE APP
Once all the components are properly placed and switched on, open the **Fesia** Pro or MyWalk app and choose a Bluetooth device to connect. Before starting, read the information on the app described in Chapter 3 and 4.

REMOVAL OF THE DEVICE
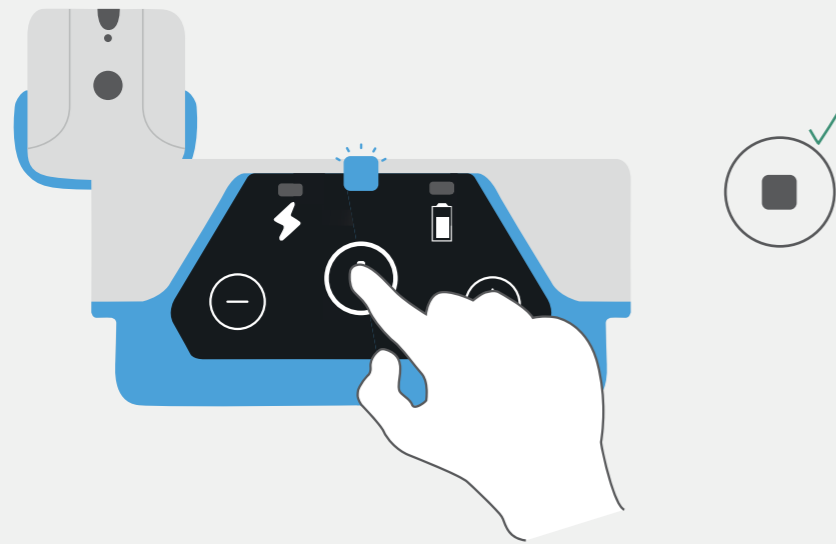
1

SWITCH OFF THE DEVICE
To switch off the device, press and hold the On/Off button of the stimulator for a few seconds. When the stimulator is turned off, the sensor and all LEDs will turn off automatically.
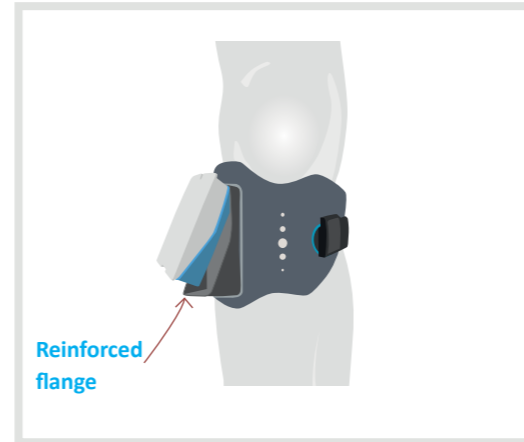
Reinforced flange

2   Remove the stimulator using the reinforced flange.
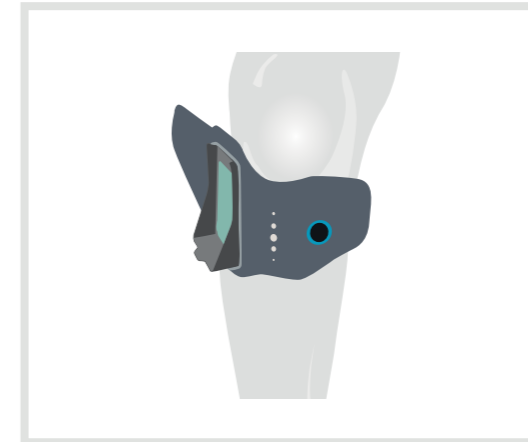
3   Remove both the textile garment and the electrode carefully.
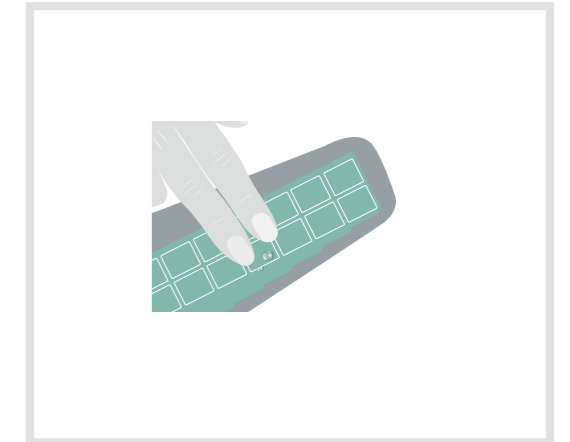
4   If the electrode gel is dry, pour a few drops of water over it before placing the protective layers on it. Use the spray included in the case.

If the electrode gel is humid, carefully dry with a cotton thread gauze.
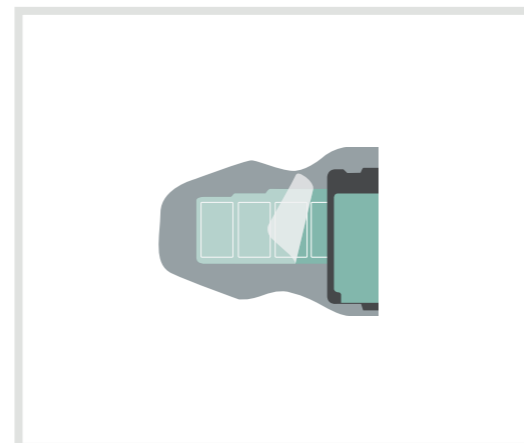
5   Finally, place the protective plastics back on the electrode gel. Make sure that the plastics are clean.

For more information on electrode maintenance, see "Electrode maintenance".

6   Transport of the equipment should always be in the case provided for this purpose and provided respecting environmental conditions described in chapter 6.
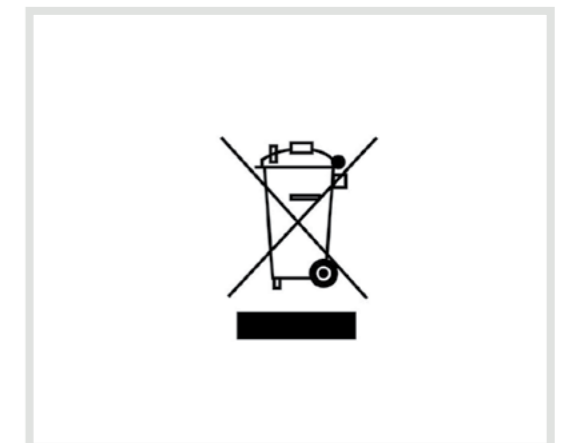
7   At the end of life of this device, follow local regulations and never dispose the product or batteries with normal household waste.

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
APPLICATION

GENERAL DESCRIPTION

The **Fesia** Pro Software Application connects wirelessly via Bluetooth to the device. It is an Android app that can be run in any tablet that complies with the minimum requirements specified in the next section. This app is intended for clinical use of the device.

Main functions:

- **Fesia** Walk configuration

- Patients' management

- Device status monitoring (battery level, connectivity, operating mode, etc.).

INSTALLATION AND REGISTRATION

It is not required to read this section if you have received a pre-configured tablet by **Fesia**.

✓ The device on which the application is installed must meet the following requirements:
- Operating system Android 5.1 or superior
- v.3.0 Bluetooth connection or superior
- Minimum screen size 10 "

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

1

Google Play Store

Search for the application in the Google Play Store by typing "**Fesia** Pro" in the search field.

2

Install

Click on the "Install" button. The installation process will start automatically once the consent to give permissions to the application is accepted.

3

Register

The first time you access the application, it is important to register with a valid email and fill in the fields of the registration form. In the case of not remembering the password, it will be possible recover it with the option "Password recovery".

⚠ Important to:
- Have Wi-Fi connection when doing the registration.
- Register with a valid email.
- Do not log out if you do not remember the user.
- Do not log out if you do not have wifi.

4

Permissions

In order to be able to record videos of the sessions, the corresponding permissions must be granted to the application (camera, microphone, storage and location).

5

Connect device

To connect to a device, press the Bluetooth symbol. Make sure the device is switched on. The serial number of the device can be found on the back side of the stimulator and has the following format: "ST16-XXXXXX". Select the device you want to pair and press "Connect". When the connection is established, the indicator of battery of the stimulator and sensor will appear at the header.

6

New patient

To access the main menu, it is required to select an existing patient or to create a new patient. A patient profile can be added by pressing the "+" button and by filling in the required fields. Check that the laterality has been selected correctly. After filling in the required data, click on the "Save" button.

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".
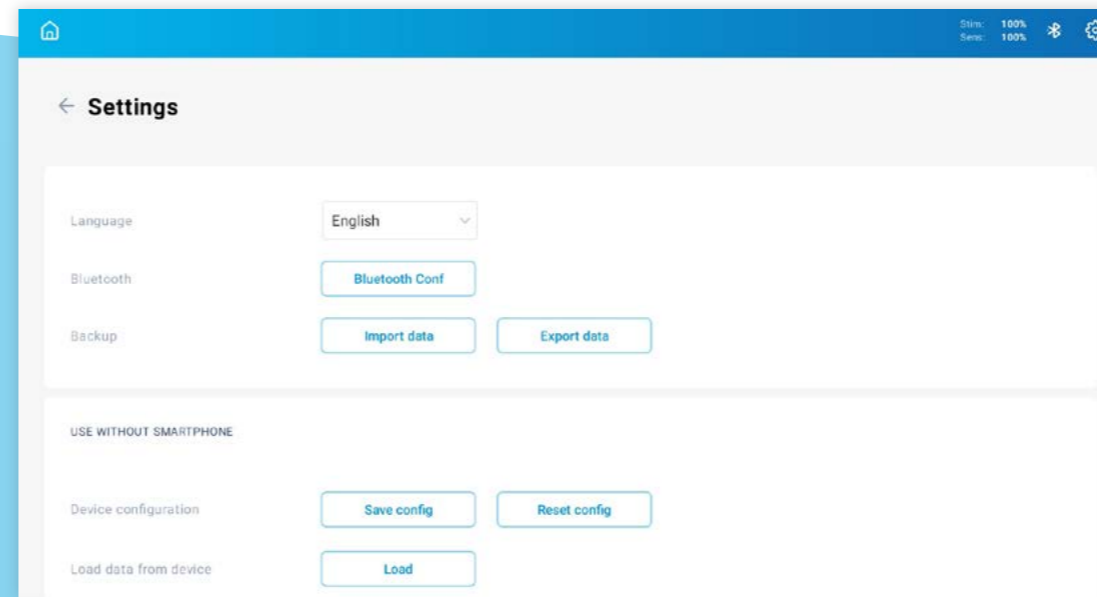
⚙ Settings
In the "Settings" menu, the user can:

- Select the language of the application.
- Change Bluetooth device.
- Export/Import data from another tablet.
- Save configuration in the stimulator to use the **Fesia** Walk without tablet and import the sessions performed.
- Report an issue to **Fesia** Support.
- Check the device information.
- Log out.

＋ Create patients
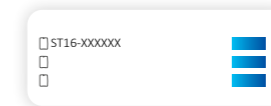Click on the "+" icon to create a patient and fill in the profile details. The mandatory fields are indicated with an asterisk.

Make sure 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
- By clicking on the "See patient" icon, you will access to the patient's configuration.

🗑 Delete patient
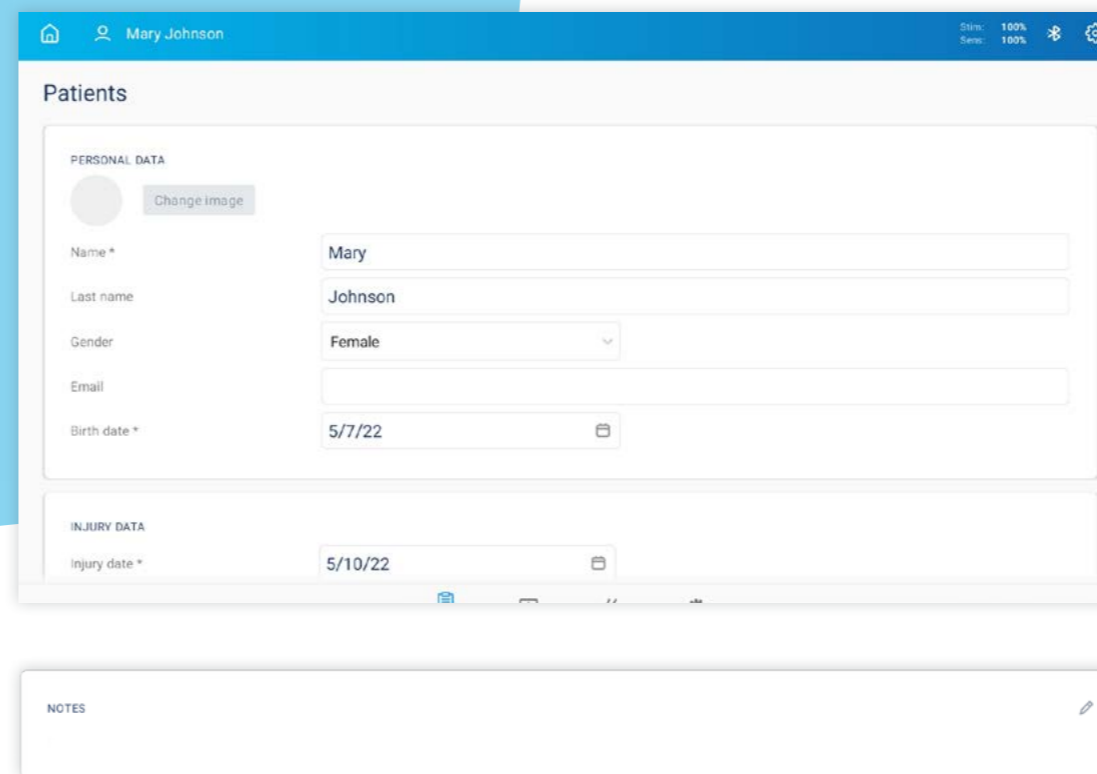- By clicking on the "Delete" icon, all patient data and sessions are deleted.

PATIENT'S 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 through the menu at the foot of the screen:
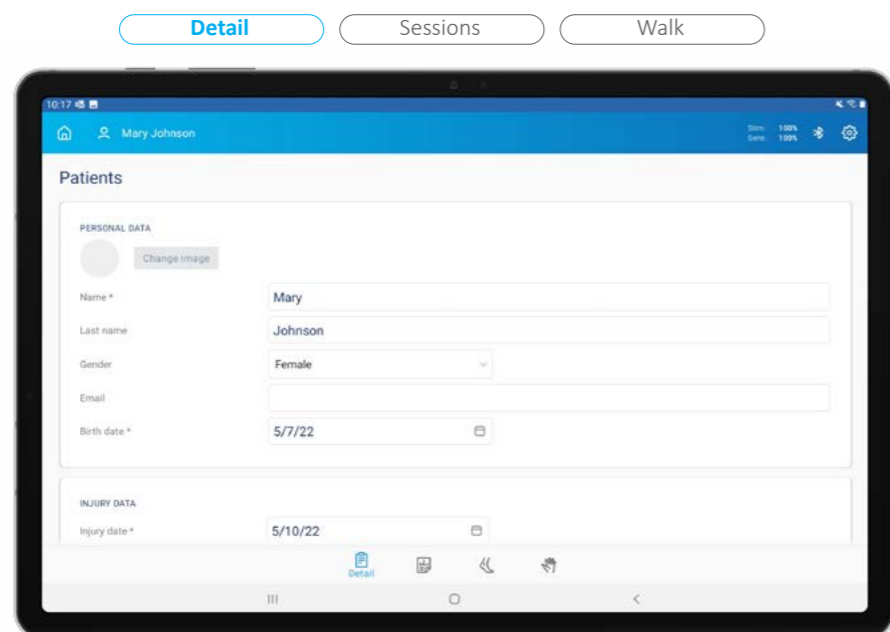
The patient's data will be shown in the "Detail" menu. The mandatory fields are indicated with an asterisk.

The records of the sessions will be shown in the "Sessions" screen. It can be filtered by product and protocol.

👁 See Session Report

Clicking on the "Session report" icon, you can see: the details of each session, session's notes, video recordings and the evolution chart. Session data can be exported to a .CSV or .PDF document by clicking on the "Export" button.

Click in any other part of the session to repeat it.

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

There, the user can select between the following 6 protocols:

1. Habituation
2. Tone Reduction
3. Gait
4. Repetitive training
5. External assistance
6. Balance training

INTERFACE

HEADER

Check the battery level and access to the main menus of the application:
- Patients menu 🏠
- Patient menu 👤
- Bluetooth connection ✳
- Settings ⚙

CONFIGURATION BAR

Configure the parameters of the stimulation:
- Election of scanning/configuration.
- Edition of stimulation parameters (by clicking on the "Expand options" button) ⟩ .
- Activation of the ramp function (for dorsal + plantar flexion).
- "Play" and "Stop" buttons.
- Configuration of all movements.
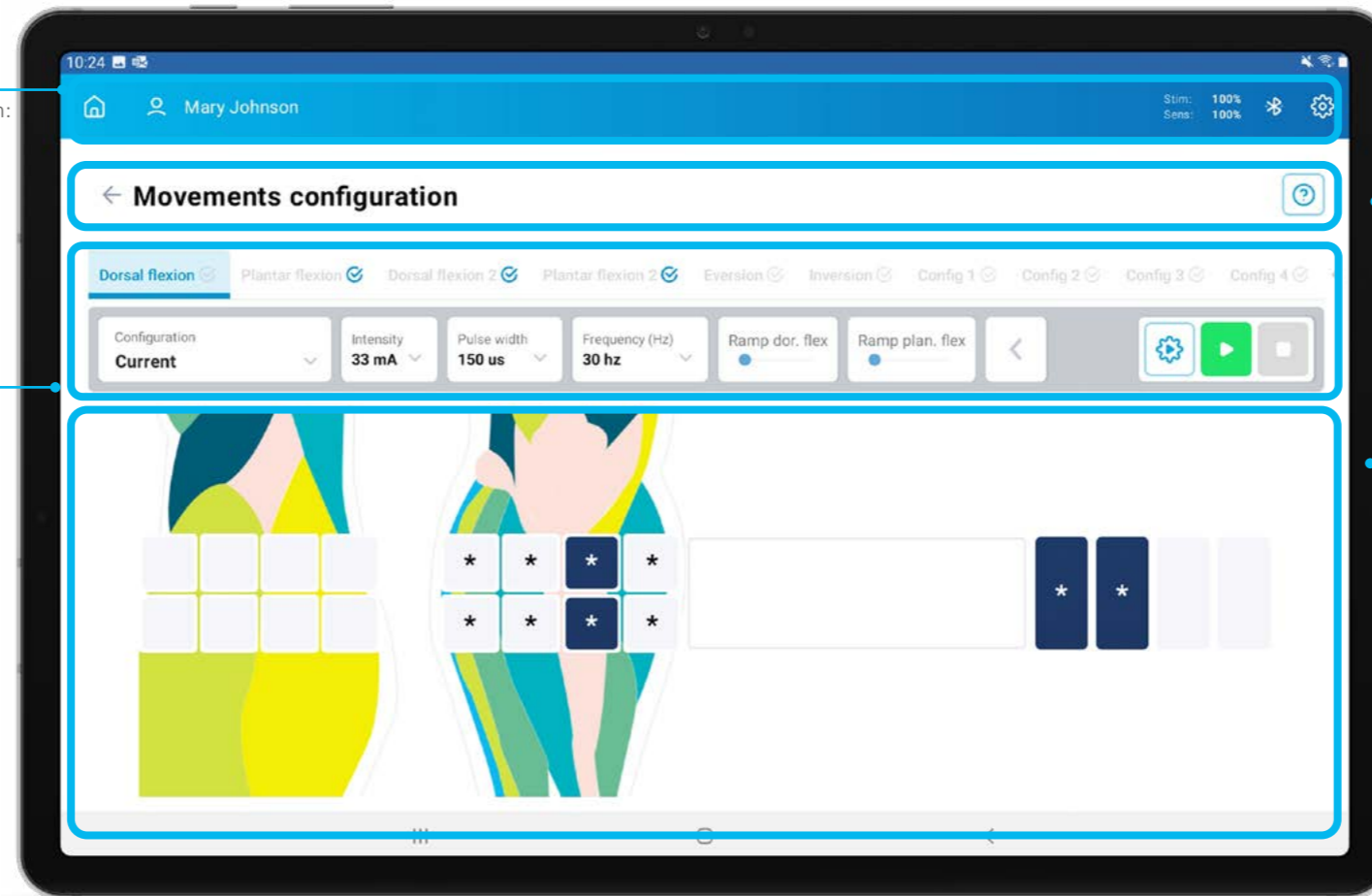
NAVIGATION BAR

Access the different screens of the protocol.

INTERACTIVE VIRTUAL ELECTRODE

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

Clicking on the "Play" button the stimulation is activated and the configuration is automatically saved.

Clicking on the "Stop" button the stimulation is stopped.

Clicking on the "Record" button it is possible to record a video of the session.

Clicking on the "Notes" button it is possible to write down notes of the session.

Clicking on the "Help" button a window opens with clarifications on the usability of the screen and clinical guidelines.

Movements config. Clicking on the "Movements configuration" button it is possible to access the movements configuration screens.
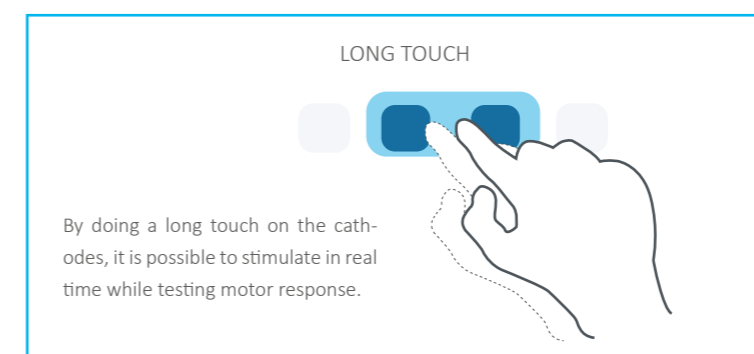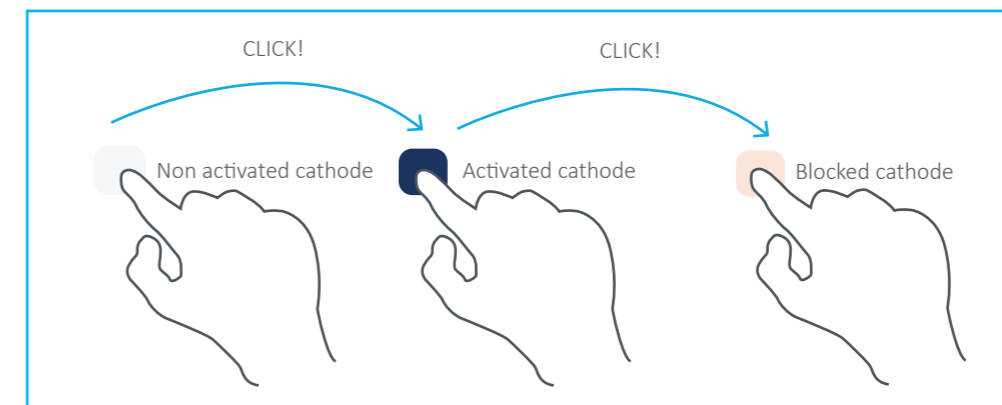
CLICK!   CLICK!

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

The Habituation protocol can be used while sitting or lying and it does NOT require the sensor to be on.

This protocol should be used in the following cases:
1. The very first time that the patient uses the device, to get used to the sensation.
2. In patients without ambulatory capacity.
3. In patients whose motor threshold is above the pain threshold. This protocol can be used to lower the motor threshold to eventually generate movement more comfortably.

CONFIGURATION BAR

Individual scanning:
All the pads will be activated sequentially, one by one.
Couple scanning:
All the pads will be activated sequentially in pairs.

Stimulation parameters

Start/Stop stimulation

Time
Can be 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).

Intensity/motor treshold
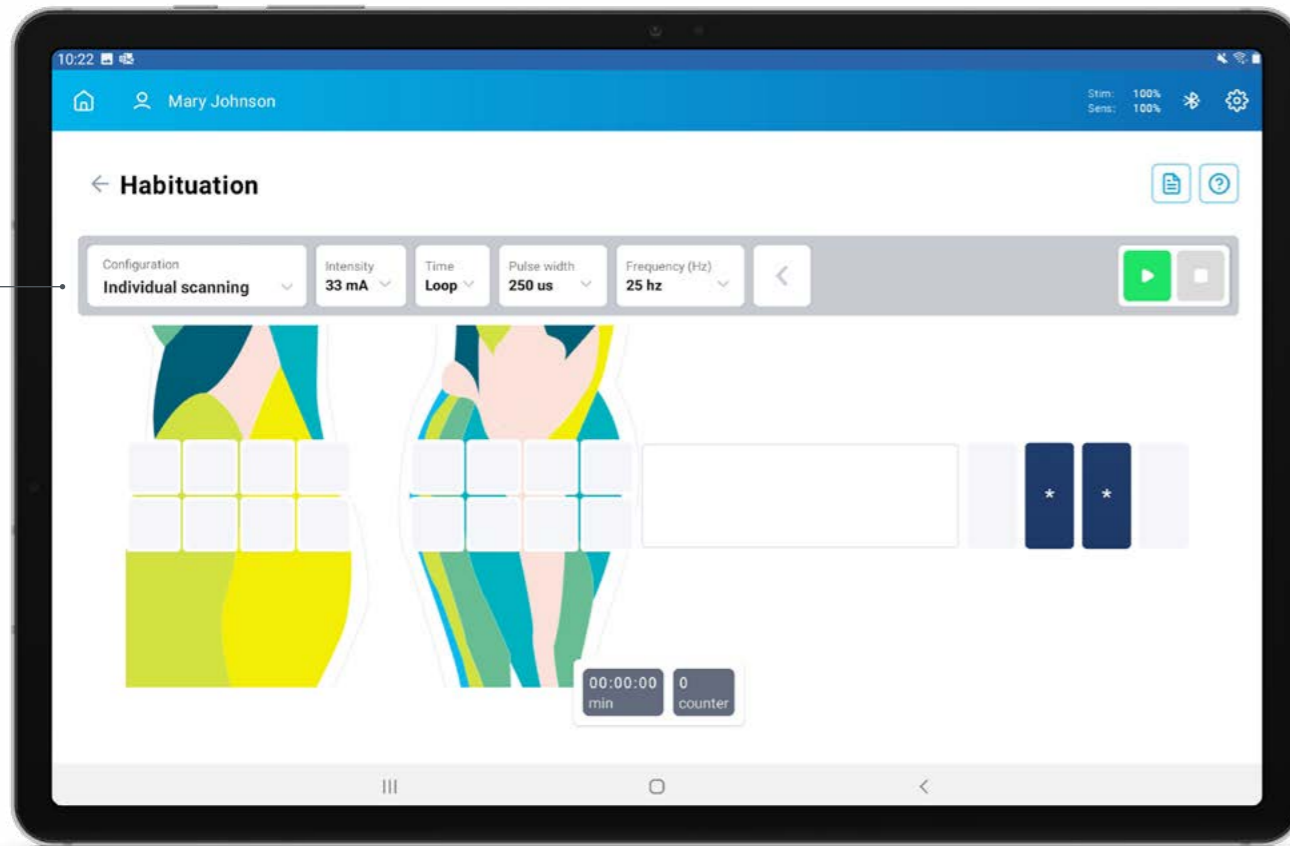Clicking on the "Set Motor Threshold" button, the intensity value will be saved so that you can use it later in the configuration screen.

1

Select configuration

Select the configuration and the stimulation time.

2

Edit intensity

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

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

3

Play

Press "Play" to start the stimulation and the configuration will be saved automatically.

4

Stop

Press "Stop" to finish the session.

5

Save session

When going "back" in the navigation bar, a message will appear in which you must choose between "Save session" or "Exit without saving".
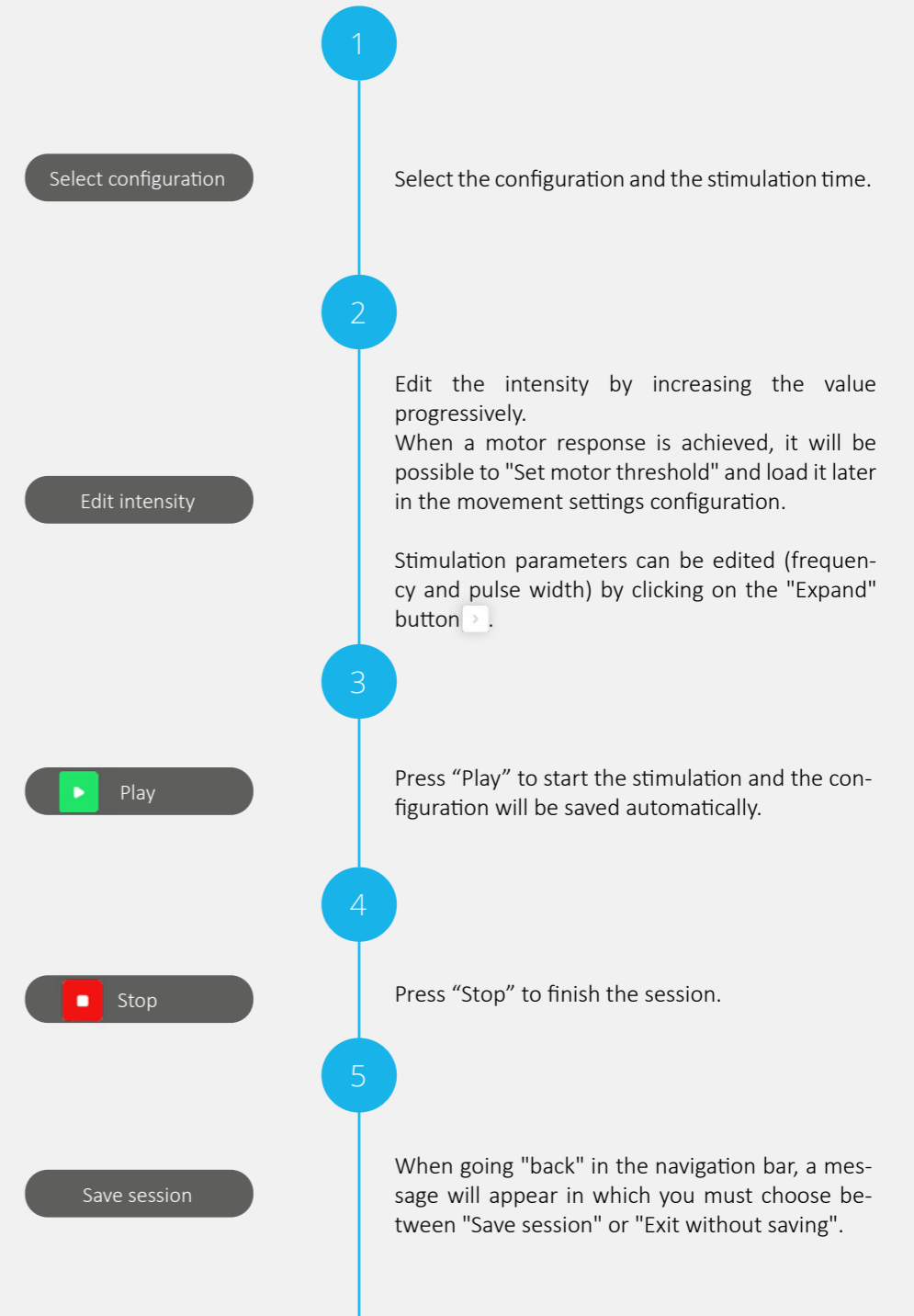
It is highly recommended to edit the intensity with caution!

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:

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

This protocol consists of two tabs: Dorsal Flexion and Plantar Flexion. Therefore, it is possible to stimulate both flexions 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 selected by the users are activated.

Intensity edition

Time
Can be 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).

Stimulation parameters

Start/Stop stimulation

---

1 Select movement — Select the desired movement (Dorsal flexion, Plantar flexion).

2 Select configuration — Select the desired configuration and stimulation time.

3 Edit intensity — Edit the intensity by increasing the value progressively.
Stimulation parameters can be edited (frequency and pulse width) by clicking on the "Expand" button.

4 Play — Press "Play" to start the stimulation and the configuration will be saved automatically.

5 Stop — Press "Stop" to finish the session.

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

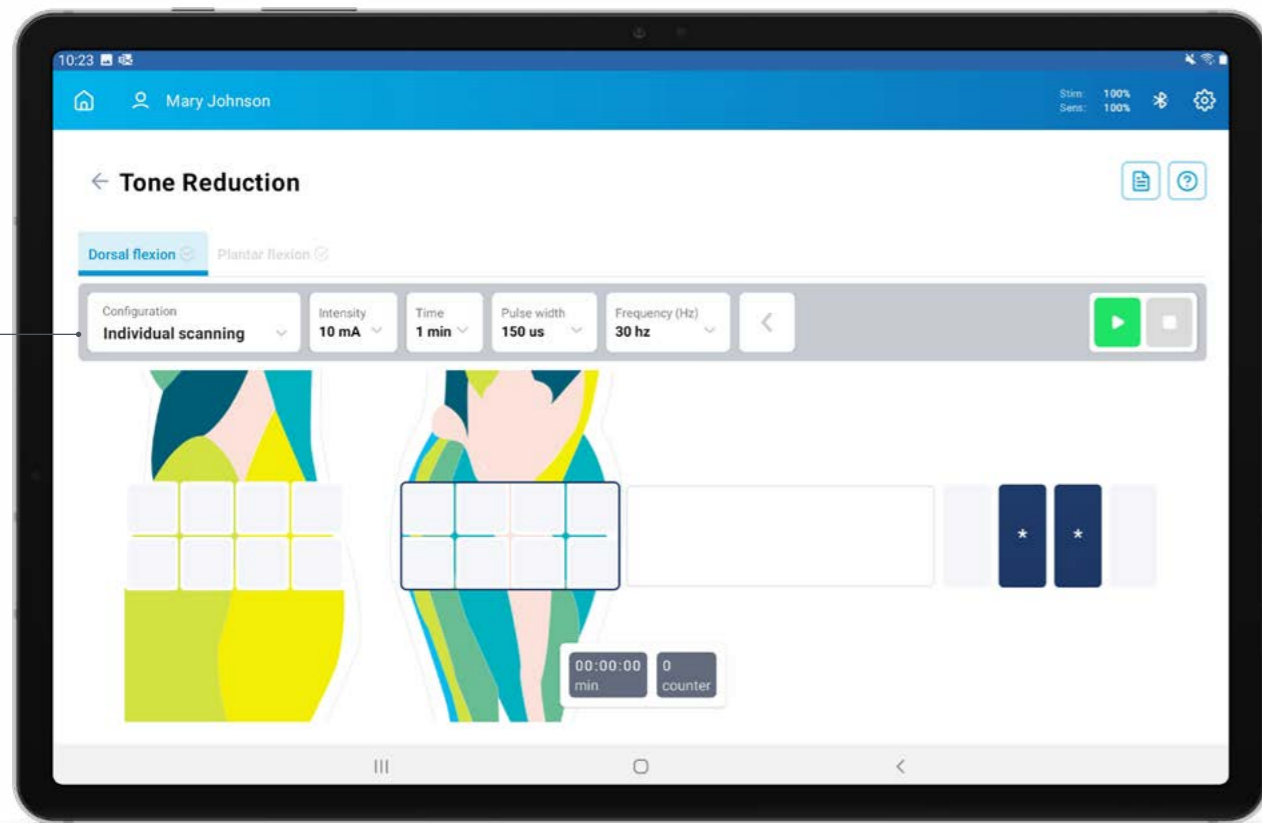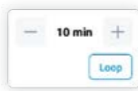> It is highly recommended to edit the intensity with caution!
>
> This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.
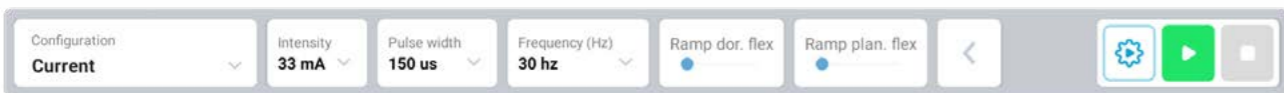
CONFIGURATION

In this screen, you will be able to configure the movements used in the protocols Gait, Repetitive training, External Assistance and Balance. The configuration can be done in two ways:

1. Automatic configuration: A sequential sweep of all fields will start, one by one, excluding the prohibited ones. The motor effect of the stimulation will be checked and, according to this, at the end of the sweep the device will suggest a configuration.
2. Manual configuration: selecting the pads and the intensities for the different functions and checking manually different cathodes until the desired motor response is identified.

Configure "Dorsal Flexion 2" and "Plantar Flexion 2" with alternative cathodes to enable the fatigue reduction mode in the Gait protocol.
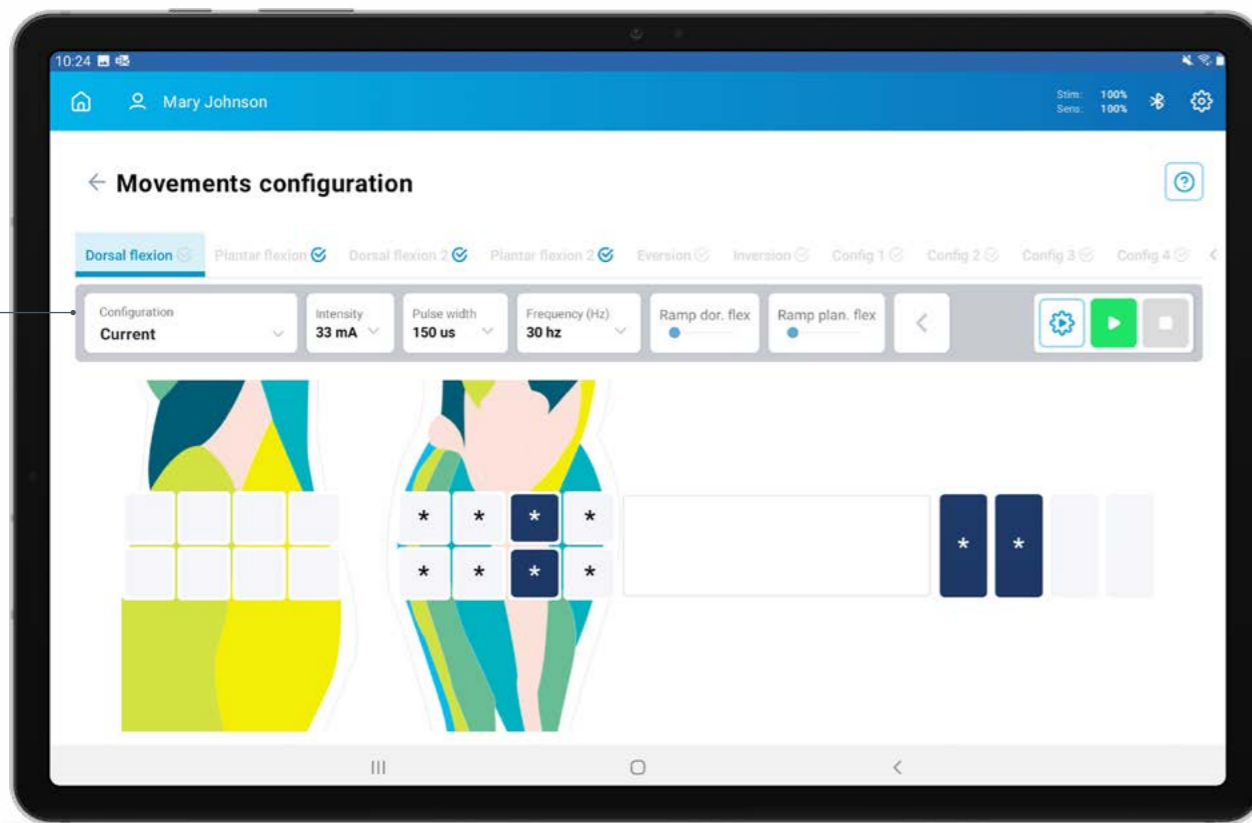
CONFIGURATION BAR

Last session:
It loads all the configuration of the last session.

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

By default:
It loads all the standard electro-parameter values for the specific pathology selected for the patient.

Current:
It loads the current configuration values. It will always change to this state when you modify any parameter of the loaded configuration.

Stimulation parameters

Ramp function activation and time configuration

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

Automatic configuration

1 Select movement

Select the movement you want to configure. A personalized primitive movement can be created by clicking on the "Config1" to "Config4" options. To change the title and image of the personalized movement, make a long touch on the title.

2 Select configuration

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

3 Edit intensity

Edit the intensity increasing the value progressively.

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

4

AUTOMATIC CONFIGURATION

5 Play Auto

Click on the "Automatic Configuration" button. The sequential sweep of all fields will begin, except the prohibited ones.
The motor effect of the stimulation will be checked and, according to this, at the end of the sweep the device will suggest a configuration (that will always be editable).

The optimal cathodes will be shown with 1,2,3 arrows based on the quality of the movement identified. The 3 arrows being the best movement and the E for eversion detected.

6 Select cathodes

Select the desired cathodes taking the suggested ones into account. Check and save the configuration clicking on the "Play" button.

MANUAL CONFIGURATION

5 Select cathodes

Select the desired cathodes.

To do so you can:
1) Select the cathodes and press "Play".
2) Make a long touch over the cathodes.

Repeat until the desired movement is found.

6 Play

Press "Play" to start the stimulation. The configuration will be saved automatically.

GAIT PROTOCOL

When started, the corresponding stimulation will be delivered according to the phase of the gait detected by the sensor. In this protocol, you can activate the 'Fatigue reduction' mode. To do so, you must have previously configured the movements Dorsal Flexion 2 and Plantar Flexion 2. The session can be started/stopped when desired.

| Edit intensity	Play	Stop
1	2	3
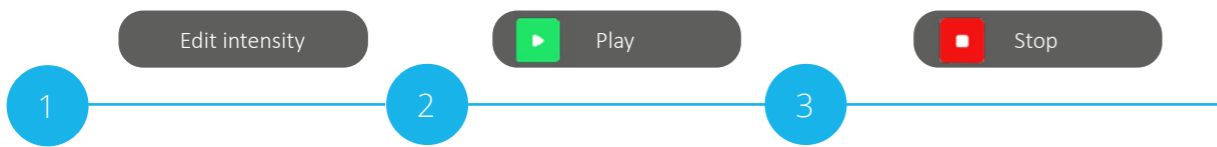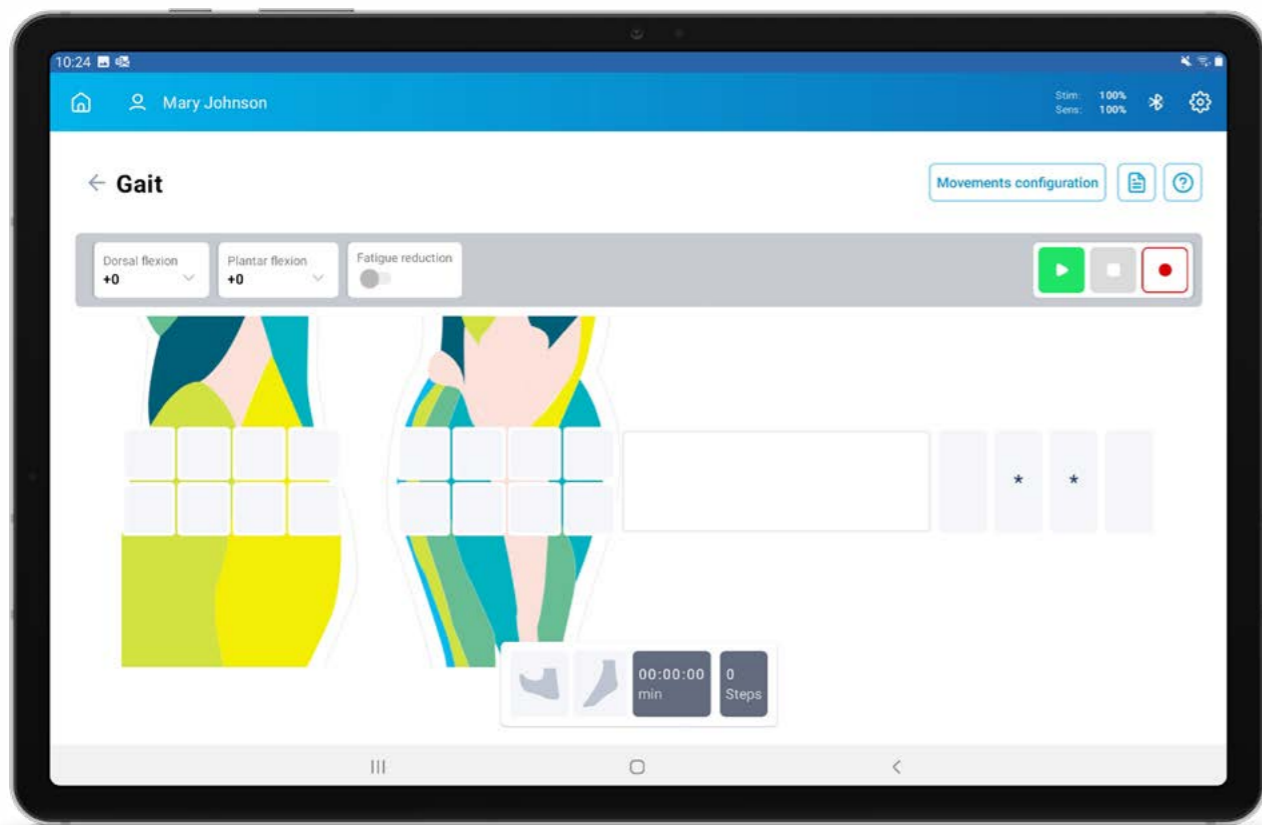
1. Edit the relative intensity if desired.

2. Press "Play" to start the stimulation. The configuration will be saved automatically.

3. Press "Stop" to finish the session.

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

> ⓘ Remember that the relative intensity is being increased over the intensity value set in the previous screen.
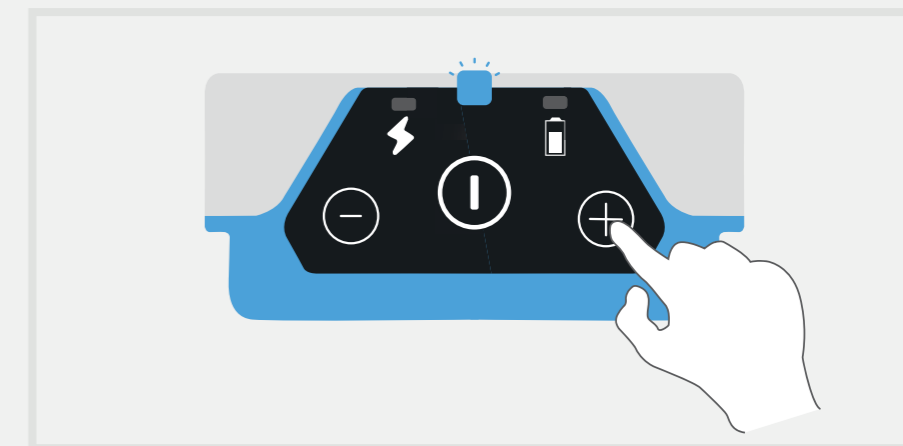
USE WITHOUT TABLET

This protocol can be used without a tablet. To do so:
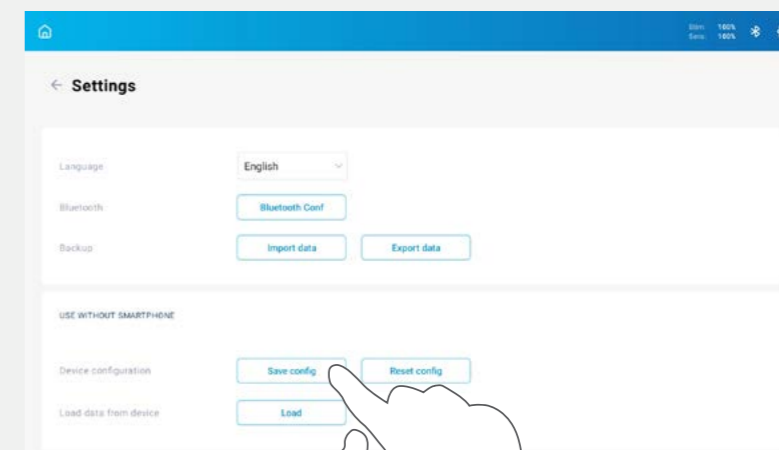
1

SAVE THE CONFIGURATION

Once the movements are configured, in the Settings window, click on the "Save Configuration" option. The configuration will then be saved in the stimulator.

2

START GAIT

When the stimulator and sensor are switched on and the LEDs are flashing at the same time, long press the '+' button on the stimulator. A long beep will be heard and all 3 lights will flash at the same time, then the gait protocol will start directly.

Each time the stimulator is switched off after this mode has been activated, a session will be saved in the device, which can be uploaded to the tablet using the "Load" button on the "Settings" screen.

> ⓘ Remember to check that the configuration has been carried out correctly by restarting the device and verifying that, after activating the gait mode without tablet, the yellow light flashes when the sensor is moved.

REPETITIVE TASK TRAINING PROTOCOL

This protocol can be used to perform repetitive training of different movements with or without voluntariness.

Different levels of assistance can be programmed during the session to promote the participation of the user.
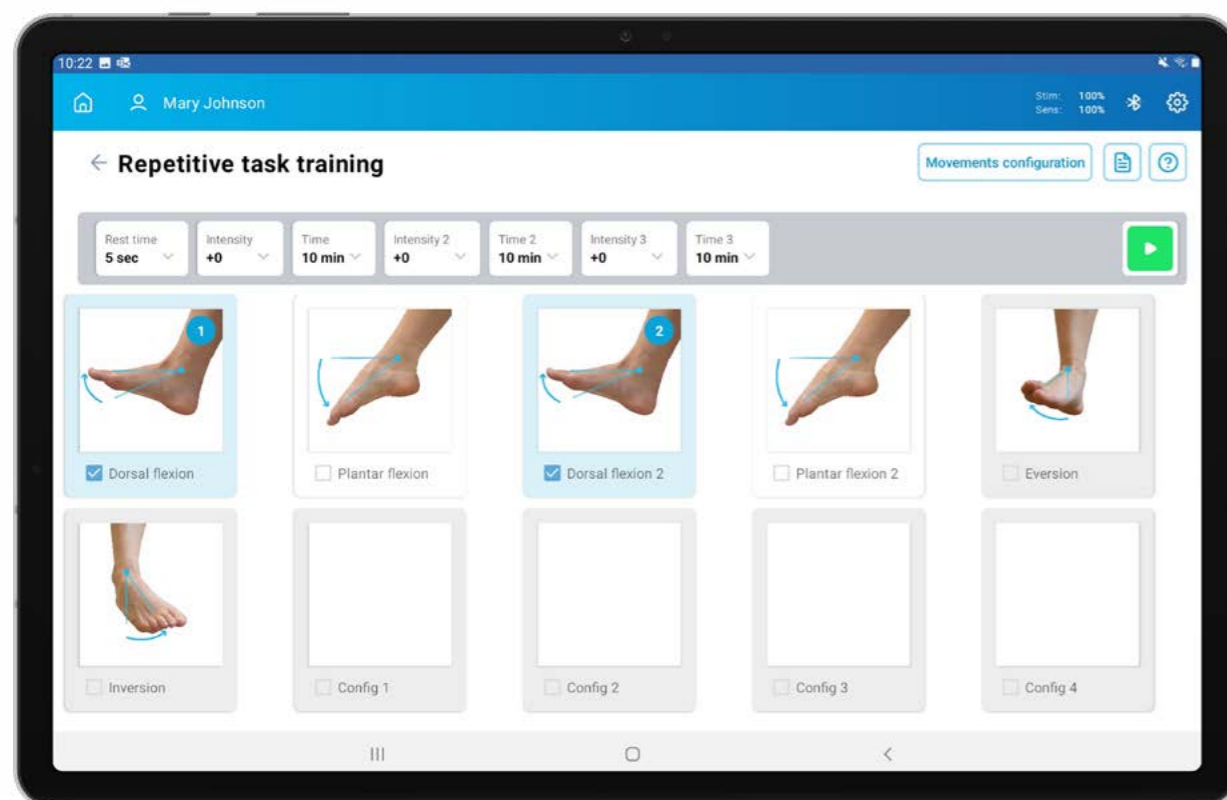
| Select movements | Select parameters | ▶ Play |

**1** Select the desired movements in the order you want the training to be performed.

2 Select in the configuration bar:
- Rest time: between one movement and another.
- Intensity: Modify the relative intensity for all movements.
- Time: Duration of the entire exercise.

3 Press "Play" to start the stimulation. The configuration will be saved automatically.

ⓘ - Remember the intensity is increasing relative to the intensity value configured in the Movements Configuration screens.
- Up to 3 periods with different levels of assistance can be configured by modifying the 3 time and intensity fields.
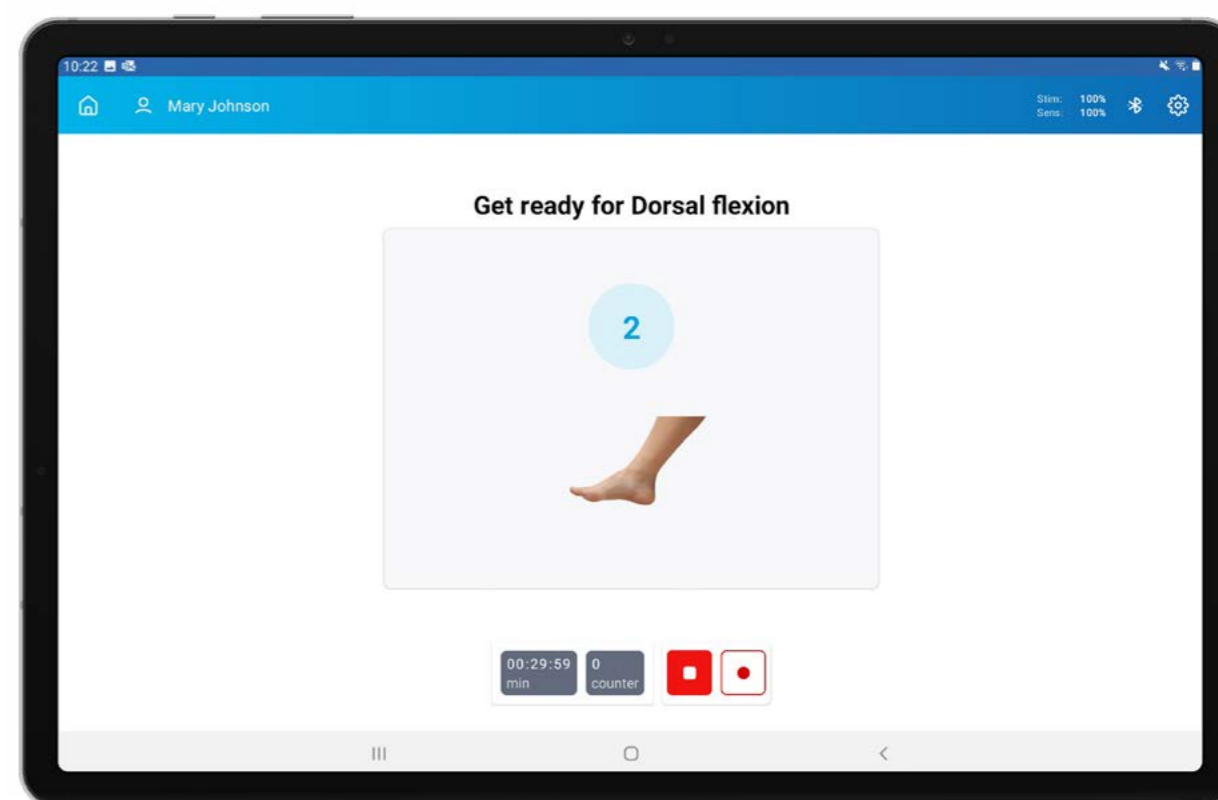
| Perform movement | ■ Stop |

4 The movements will appear full screen in the selected order.
There are 3 phases:
1. Preparation: A 3 second countdown and a dynamic image of the movement to be performed are shown.
2. Realization: A descriptive static image of the movement is shown as visual feedback of the movement performed by the stimulation at that moment.
3. Rest: Rest time established in the previous screen.

5 Press "Stop" to finish the session.

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

EXTERNAL ASSISTANCE PROTOCOL

This protocol can be used when the aim is to integrate movements provided by electrical stimulation in activities of daily life, compensating for movements that the patient cannot perform.
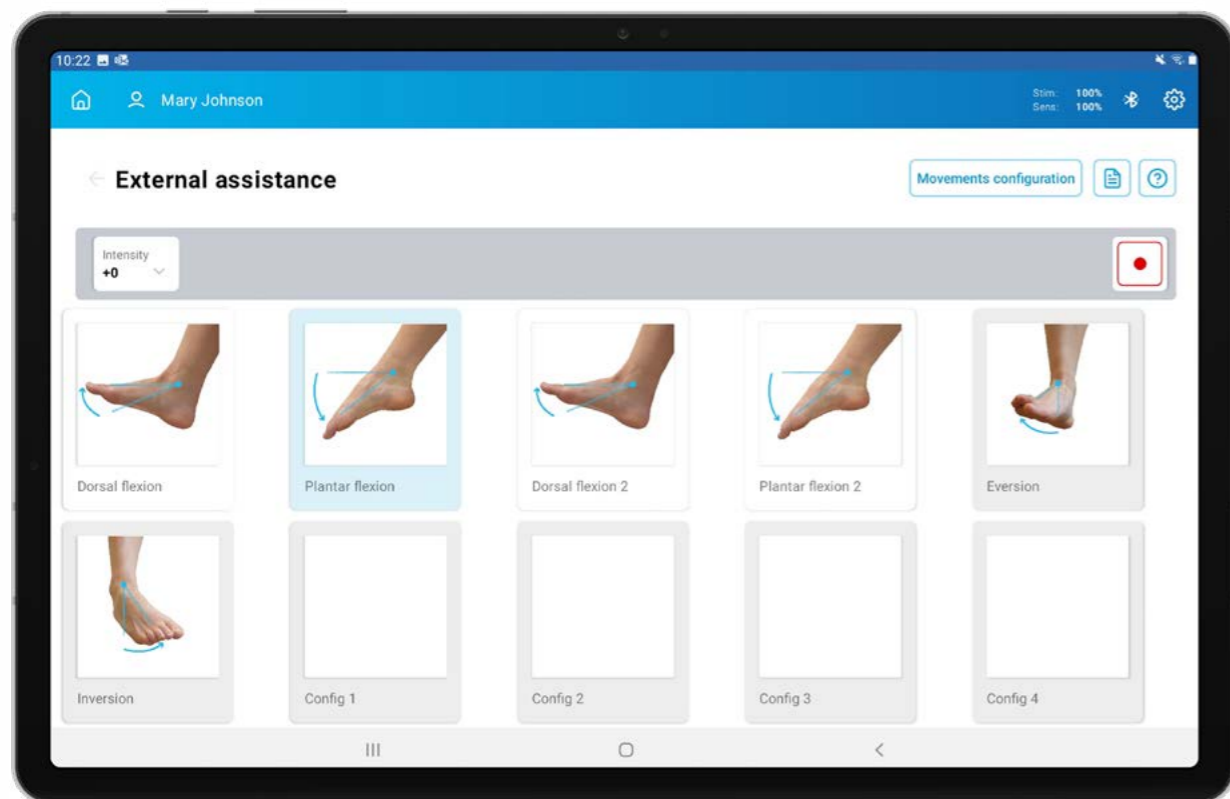
| Select movement | Stop/select movement | Save session |

1 Select the movement willing to perform clicking on its image.

2
- Stop the movement clicking on the same image.
- Select the next move clicking on its image.

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

ⓘ If the intensity is modified, remember that it is increasing relative to the intensity value configured in the Movements Configuration screens.

TOGGLE KEYPAD

The Toogle 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

CLICK!   CLICK!
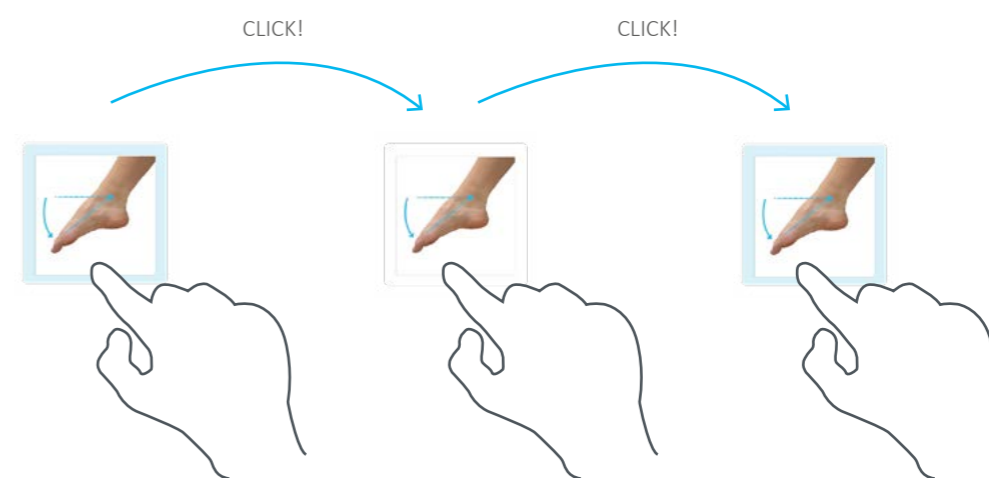
B. ACTIVATE/DEACTIVATE VARIOUS MOVEMENTS

CLICK!   CLICK!
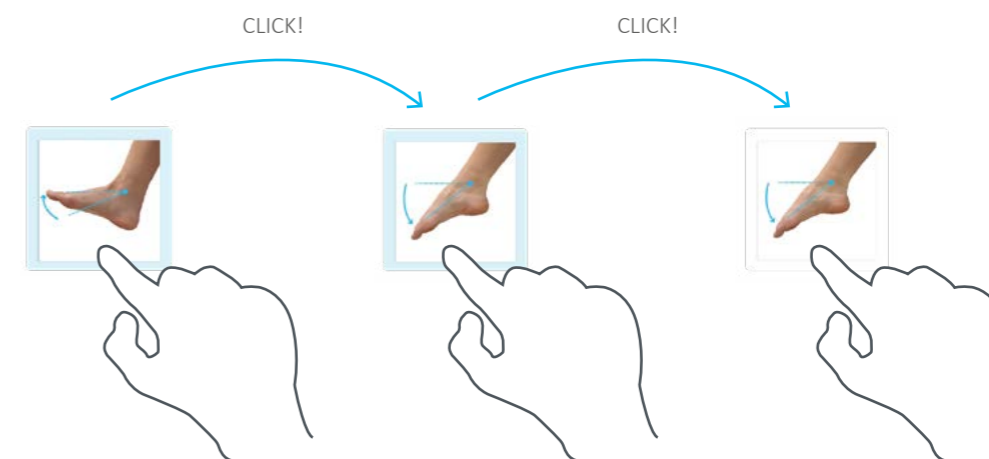
BALANCE TRAINING PROTOCOL

This protocol can be used to train balance with perturbations in 2 different modes:

1. Manual: to provide the disturbances at the exact time deemed appropriate.
2. Programmed: to program a series of random or defined perturbations in time and order.

Manual

Select movement	Stop/select movement	Save session

1 Select the movement willing to perform clicking on its image.

2 - Stop the movement clicking on the same image.
- Select the next move clicking on its image.

3 When going back in the navigation bar a message will appear in which you must choose between "Save session" or "Exit without saving".
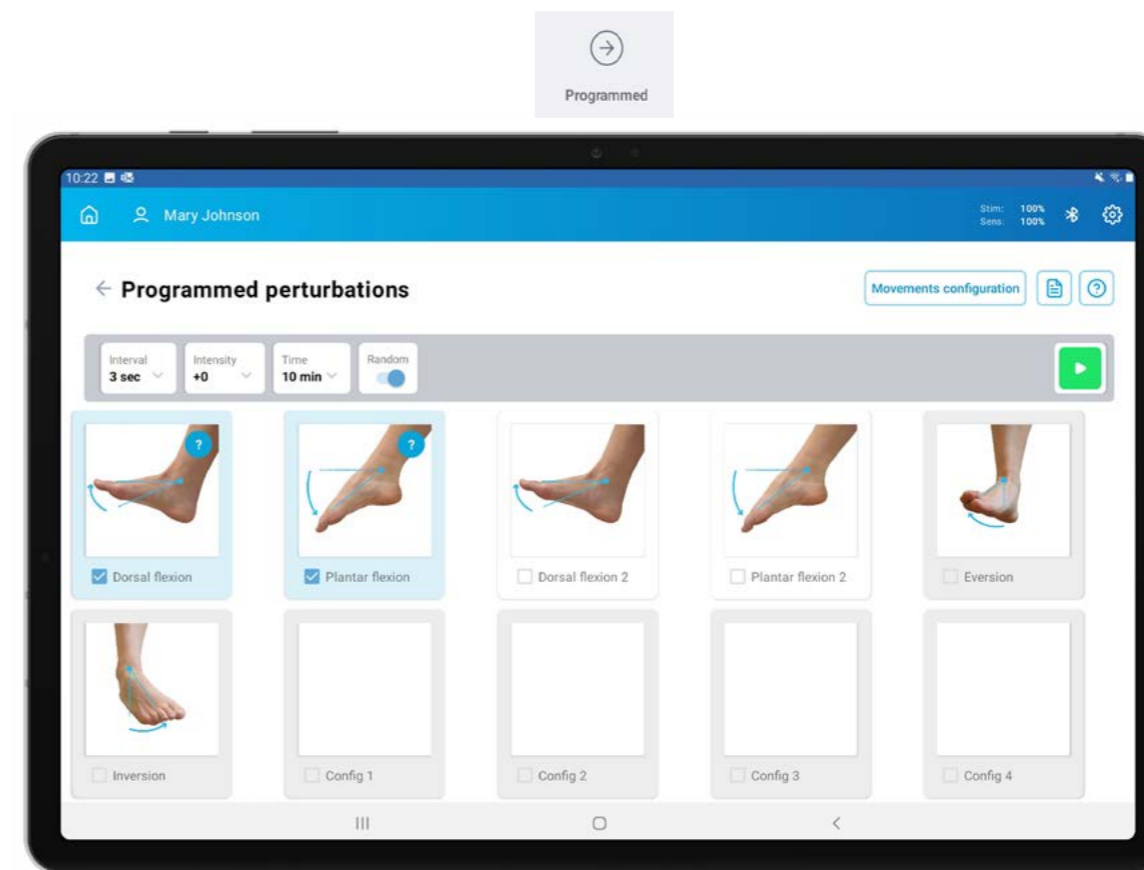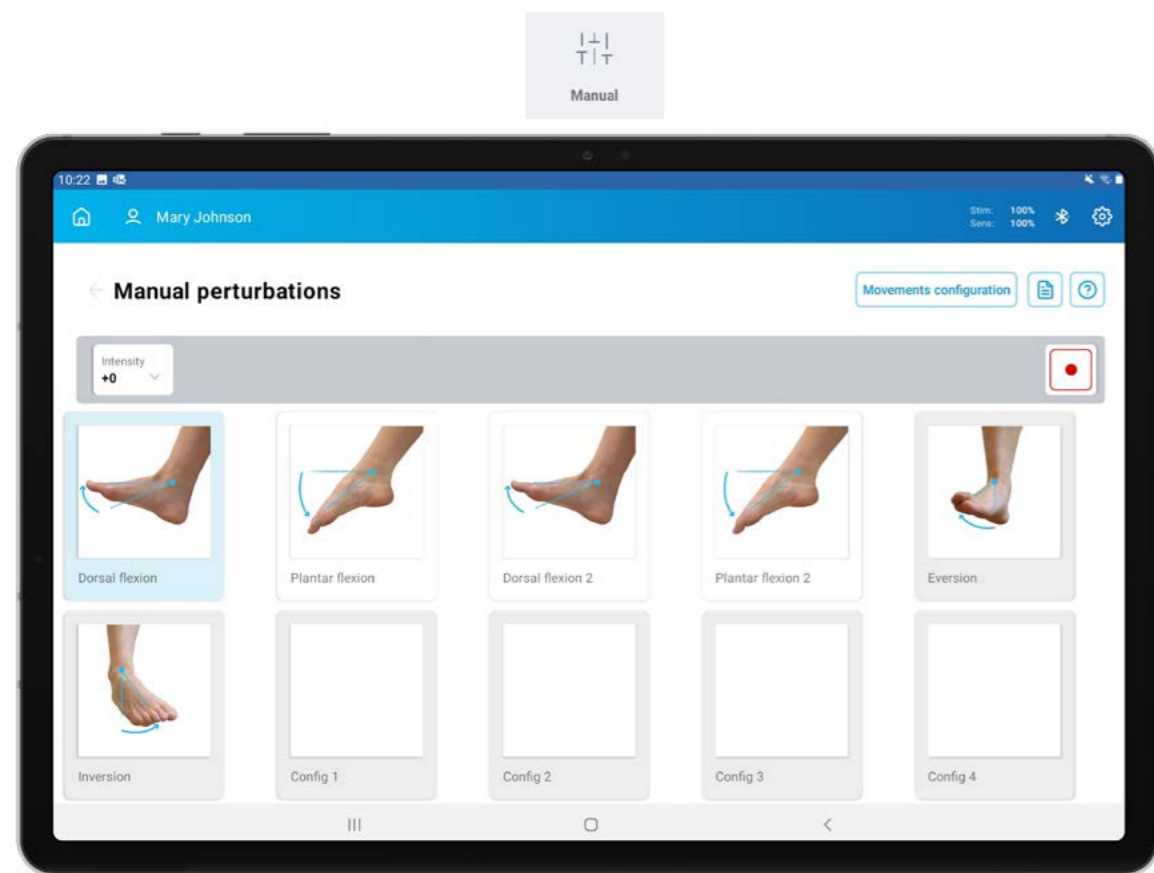
⊙ If the intensity is modified, remember that it is increasing relative to the intensity value configured in the Movements Configuration screens.

Programmed

Select movements	Select parameters	▶ Play

1 Select the desired movements in the order you want the training to be performed.

2 Select in the configuration bar:
-Perturbation interval: between perturbations. It can be random.
-Intensity: modify the relative intensity for all movements.
-Time: duration of the entire exercise
-Random: the perturbations will be applied in a random order.

3 Press "Play" to start the stimulation. The configuration will be saved automatically. The movements will be displayed full screen in the selected order, in the same way as in the Repetitive Tasks protocol.

⊙ - Remember the intensity is increasing relative to the intensity value configured in the Movements Configuration screens.
- The feedback windows can be hidden from the patient to increase the challenge.

04

MYWALK
APPLICATION

GENERAL DESCRIPTION

MyWalk Software Application connects wirelessly via Bluetooth to the device. It is an Android app that can be run in any mobile phone that complies with the minimum requirements specified in the next section. This app is intended for personal use of the device in everyday life.

Main functions:

- **Fesia** Walk configuration

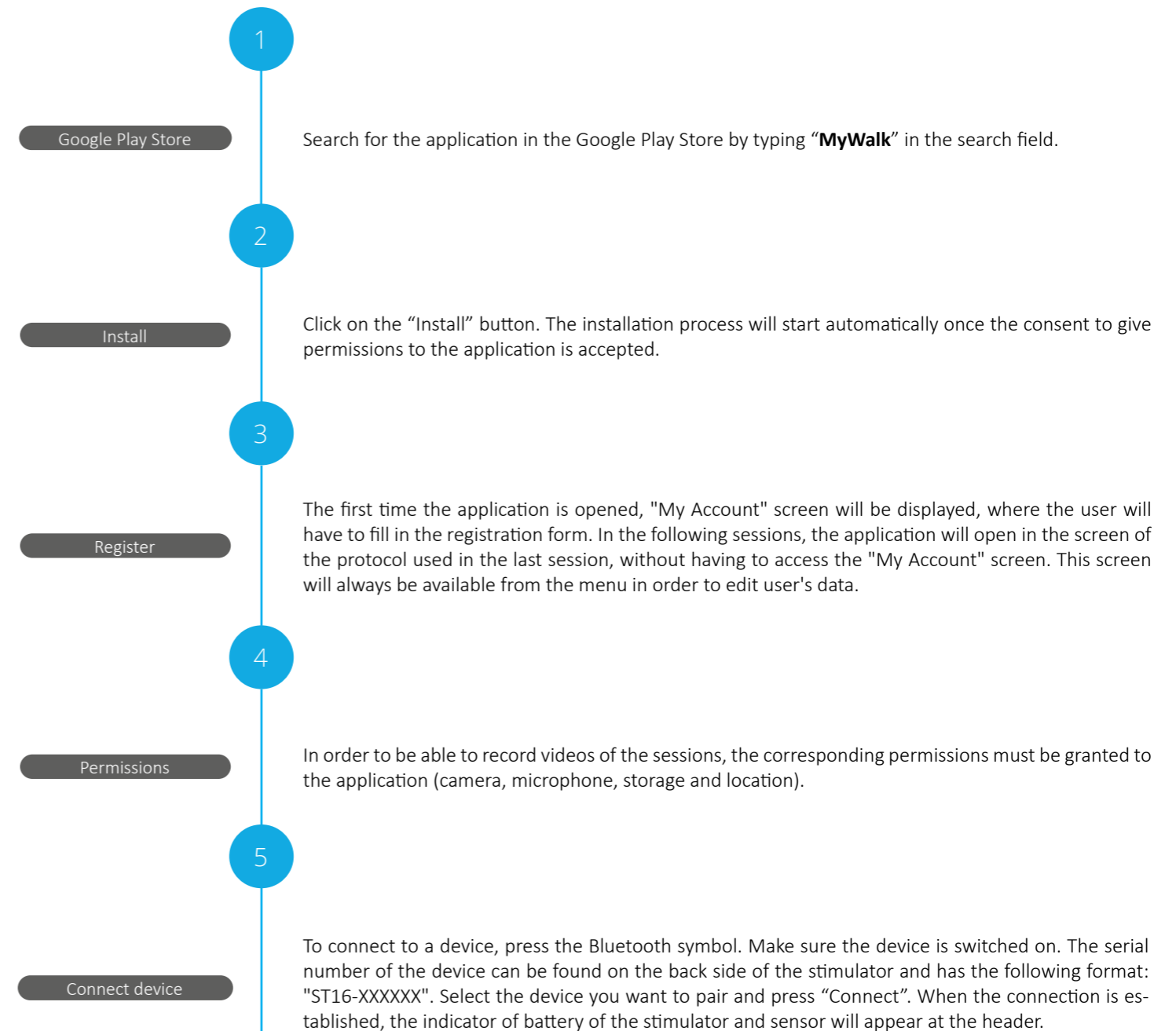- Device status monitoring (battery level, connectivity, operating mode, etc.).

INSTALLATION AND REGISTRATION

⊘ The device on which the application is installed must meet the following requirements:
- Operating system Android 5.1 or superior
- v.3.0 Bluetooth connection or superior
- Minimum screen resolution 720x1600px

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

1

Google Play Store

Search for the application in the Google Play Store by typing "**MyWalk**" in the search field.

2

Install

Click on the "Install" button. The installation process will start automatically once the consent to give permissions to the application is accepted.

3

Register

The first time the application is opened, "My Account" screen will be displayed, where the user will have to fill in the registration form. In the following sessions, the application will open in the screen of the protocol used in the last session, without having to access the "My Account" screen. This screen will always be available from the menu in order to edit user's data.

4

Permissions

In order to be able to record videos of the sessions, the corresponding permissions must be granted to the application (camera, microphone, storage and location).

5

Connect device

To connect to a device, press the Bluetooth symbol. Make sure the device is switched on. The serial number of the device can be found on the back side of the stimulator and has the following format: "ST16-XXXXXX". Select the device you want to pair and press "Connect". When the connection is established, the indicator of battery of the stimulator and sensor will appear at the header.

MAIN MENU

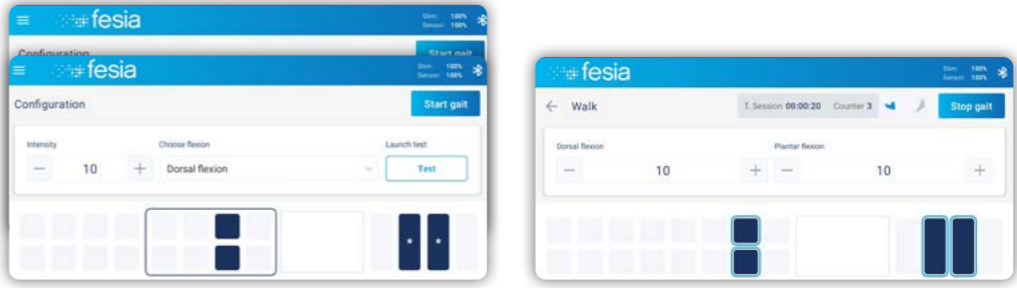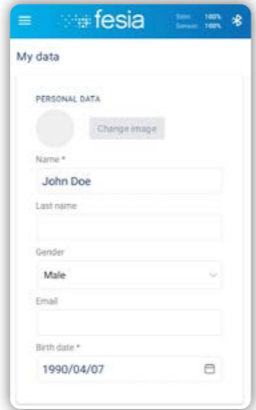Once the Bluetooth connection is established, press the icon with the three horizontal lines ☰ at the top left to access the main menu. This option will be available from all the screens of the application.

Configuration and gait
This protocol is detailed later on. Is composed by two screens:
- Plantar and dorsal flexion configuration.
- Gait: the stimulation corresponding to the gait phase detected by the sensor will be generated.

Habituation
This protocol is detailed in the following section.

Stimulation parameters
The clinician can:
- Modify the pulse width, frequency and maximum intensity.
- Activate/deactivate the ramp function in plantar and dorsal flexion.
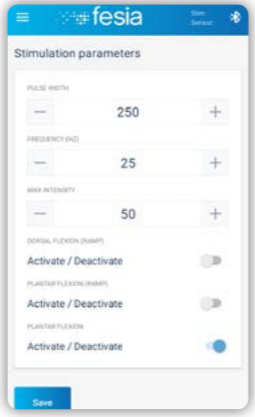- Activate/deactivate plantar flexion.

My account
The first time the application is opened, you will be directed to this screen to fill in the patient's details. The only mandatory fields are those marked with an asterisk.
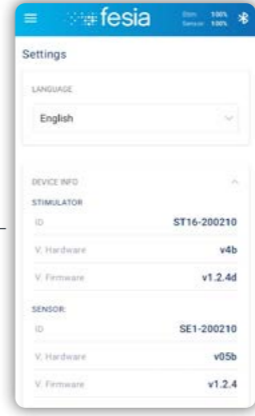
⚠ Make sure the chosen laterality is correct. The affected limb must be chosen, that is, the side where the device is going to be placed.

Settings
The user can:
- Select the app language.
- Check the device information: basic information about the device connected to the app and the version of the application.

HABITUATION PROTOCOL

The Habituation protocol can be used while sitting or lying, and it does NOT require the sensor to be on.

This protocol should be used in the following cases:
1. The very first time that the patient uses the device, to get used to the sensation.
2. In patients without ambulatory capacity.
3. In patients whose motor threshold is above the pain threshold. This protocol can be used to lower the motor threshold to eventually generate movement more comfortably.

Individual scanning
All the pads will be activated sequentially, one by one.

Column scanning
All the pads will be activated sequentially, by columns.

Area stimulation
The pads selected by the users are activated.

Intensity edition

Session time/Counter

Play/Stop Stimulation

Scanning repetitions
A certain value of repetitions can be set by editing the default value or the loop option can be selected to have unlimited scanning.

Cathodes

- Non activated cathode
- Activated cathode
- Blocked cathode

Anodes

- Non activated anode
- Activated anode

1

Select stimulation

Select the desired stimulation mode.

2

Edit intensity

Edit the intensity by increasing the value progressively.

3

Select repetitions

Edit the default value of repetitions or activate looping repetitions without predefined time.

4

Play/Stop

Press "Play" to start the stimulation and the configuration will be saved automatically.

Press "Stop" to finish the session.

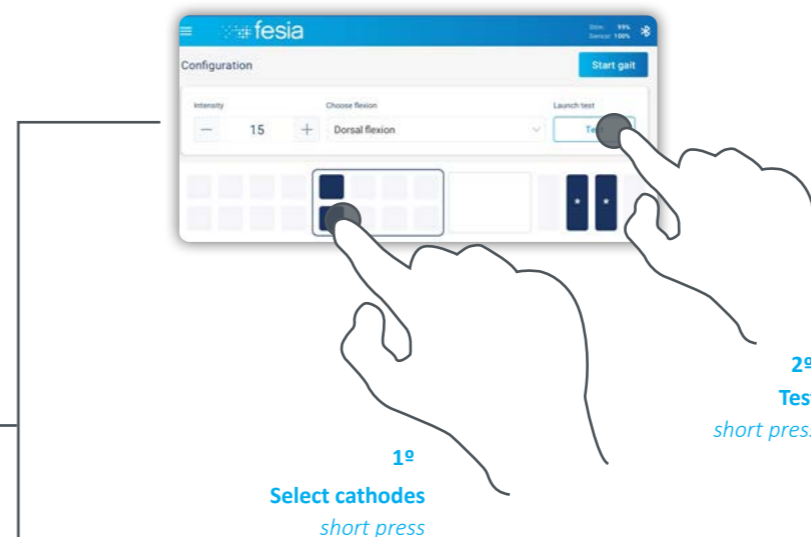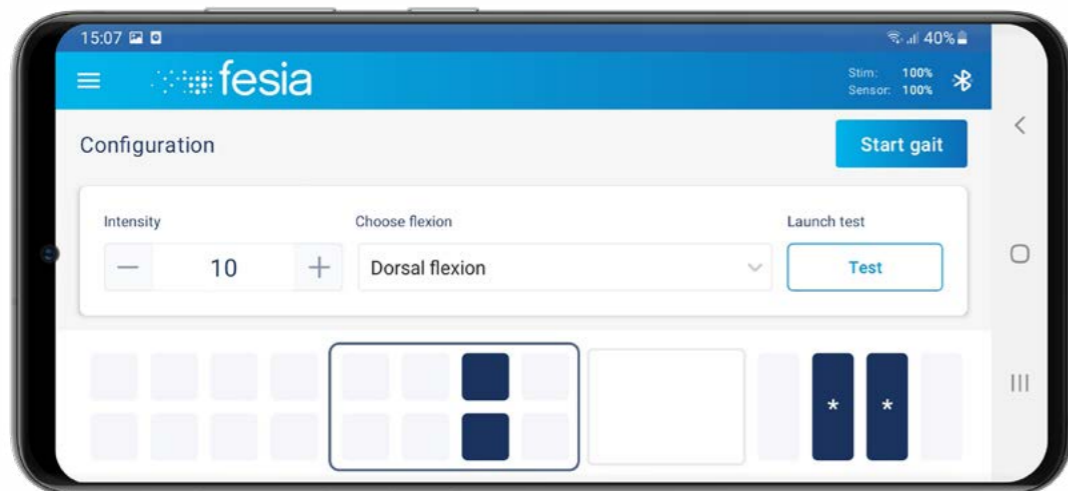> ⓘ It is highly recommended to edit the intensity with caution!
>
> This parameter is related to the comfort and safety. Then, it is highly recommended to increase it gradually taking the motor threshold into account.

GAIT PROTOCOL

This protocol consists of two screens:
1. The movement configuration screen (dorsal and plantar flexion).
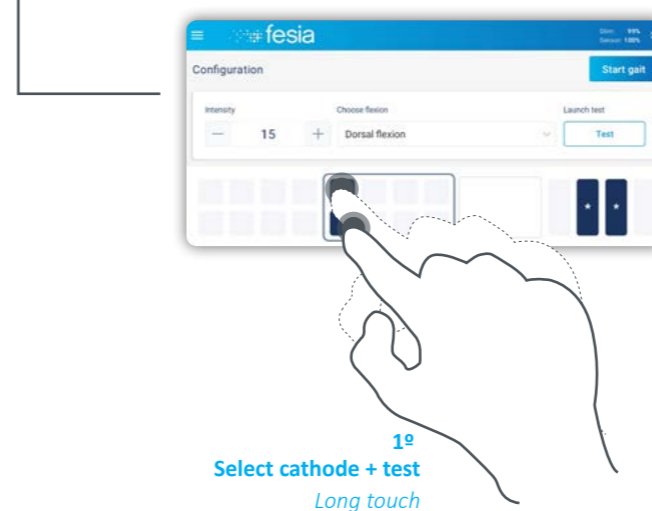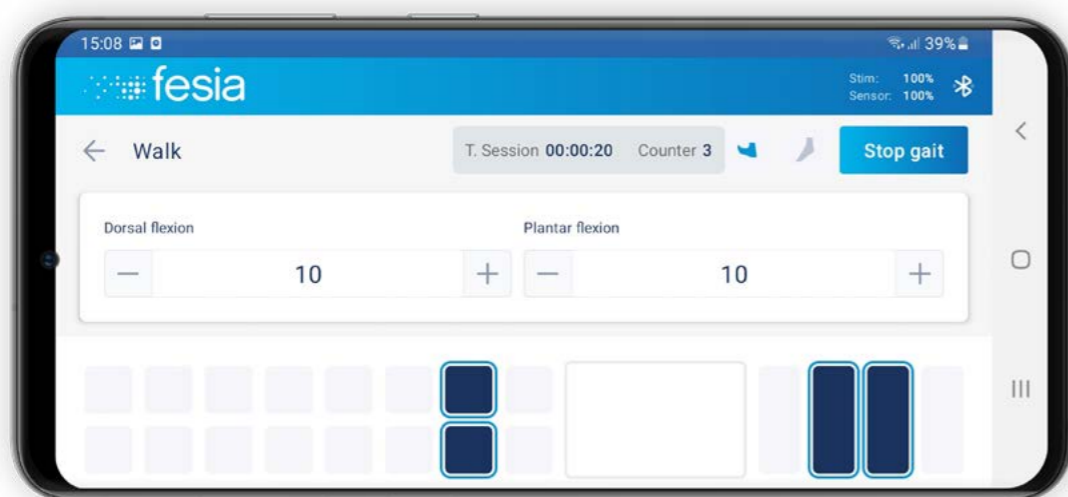2. The gait screen.

1.

The configuration of both functions (dorsal and plantar flexion) can be done in two ways, as shown in the right.

Plantar flexion configuration is optional and can be activated and deactivated from the "Stimulation Parameters" screen.

2.

By pressing "Start Gait", the gait screen is accessed. The relative intensity can be edited with the -/+ buttons at any time. When the gait is started, the stimulation corresponding to the gait phase detected by the sensor will be generated. The session can be started/stopped at any time.

2º
Test
short press

1º
Select cathodes
short press

1º
Select cathode + test
Long touch

1

Select movement

Select the movement you want to configure.

2

Select cathodes

Select the desired cathodes and anodes.

3

Test

By pressing "Test", the stimulation will start.

Repeat the process until the desired movement is found.

4

Start gait

Once the desired cathodes are selected, press "Start gait" to proceed to the next screen.

1

Select movement

Select the movement you want to configure.

2

Long touch

By sliding the finger over the cathodes (without lifting the finger from the screen), it is possible to stimulate in real time while testing motor response.

When the desired movement is found, lift the finger from the screen and the last pressed cathodes will automatically be selected and shown in blue.

3

Start gait

Once the desired cathodes are selected, press "Start gait" to proceed to the next screen.
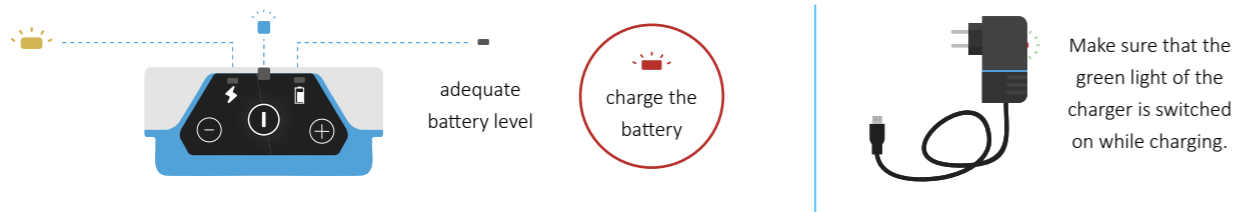
05

TECHNICAL
SUPPORT

TROUBLESHOOTING

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

1 Check that your Fesia Pro app or MyWalk app are updated (Google Play Store, "Menu", "Apps and games").

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

adequate battery level

charge the battery

Make sure that the green light of the charger is switched on while charging.

3

Issue	Action
The stimulator doesn't turn on.	- Check that the stimulator is properly attached to the electrode and charged.
The stimulator beeps during configuration and shows the following message "ERROR: Open circuit detected" .	- Check that the stimulator is properly placed in the socket of the electrode. - Check that the electrode is completely attached to the extremity. - Check that the protective plastic layers have been removed. - Check that the electrode is in good conditions. If the problem persists, replace the electrode and check the previous steps again.
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 extremity. - Check that the protective plastic layers have been removed. If the problem persists, replace the electrode and check the previous steps again.
The software is not responding or won't connect to the device.	- 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 device: 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.

(!) Remember to periodically back up the data to an external device.

In the Settings screen, click on the "Export data" button. Then, copy the ".fesiadb" file, found in the downloads folder, to another device or mail it to your device for storage.
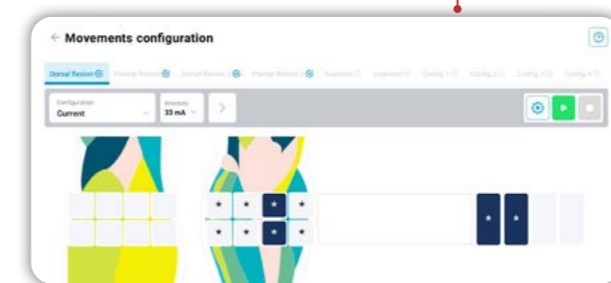
CONTACT WITH FESIA SUPPORT
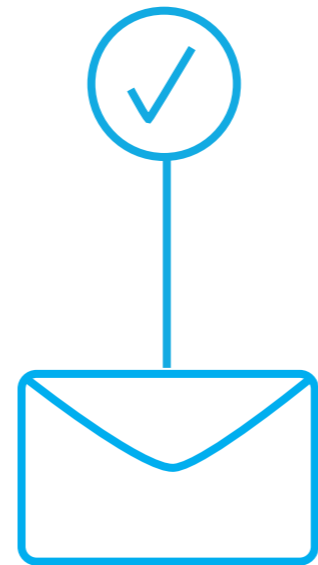
Once you have taken the previous steps, if your problem is not already solved, you can contact Fesia with the 'Support' button at the Settings screen preferably. Otherwise, send an email to support@fesia.net or through our Whatsapp service at the number +34 943 560 162.

It is very important to provide a detailed description of the problem so that the Technical Support team can solve it as quickly as possible. Therefore, it is recommended to use the "Support" button.

Otherwise, the content to be included in the message is shown below:

You can find the device ID in the backside label of the stimulator.

SUBJECT

Device ID | Brief problem description

MESSAGE

Detailed message

ATTACHMENTS

Photos/Videos of the problem and a screenshot of the configuration

Make a screenshot or take a photo of the screen where the problem occurred and the configuration being used and attach it to the email.

06

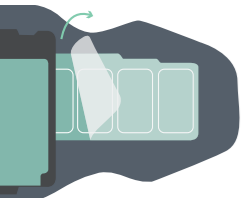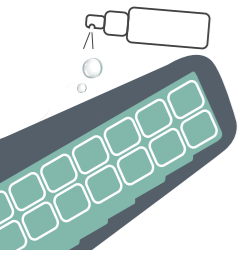## MAINTENANCE

ELECTRODE MAINTENANCE

DO

DON'T

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.

Do not place the device with the protective plastic.

Do not throw the protective plastic in the trash.

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.

Do not pour too much water on the electrode.

In case of excessive sweating, do not moisturize the electrode.
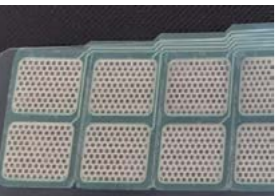
Check the electrodes visually at the end of the session and regularly.

Do not use the electrodes if the cathodes are blackened or if the gel does not adhere to the skin. Replace them.

Store the electrodes in the original packaging and close it with zip or tape for its correct conservation.
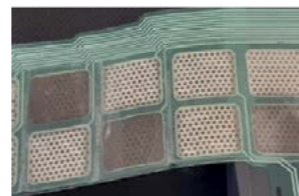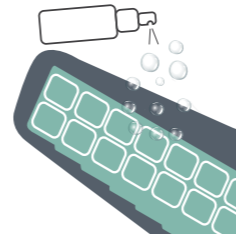
Do not leave the electrode without a bag directly in the case or a bag other than the original one.
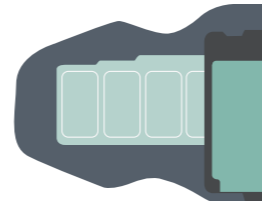
GARMENT CLEANING

Hand wash with a soft cloth on both sides.
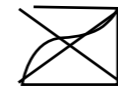
Do not iron.
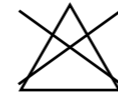
Do not use bleach.
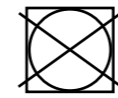
Do not use the dryer.

Maintenance

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

Deep cleaning

Immerse in hot water (max. 40ºC) 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.

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
Make sure to change the electrode if the cathodes are blackened or the adhesive no longer adheres to the skin.

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

4
Make sure the electrodes have the protective layers and are stored in their 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 scissors.

If you have any questions please contact your FES clinician:

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If you are in any doubt, stop using your FES device and wait to speak to your FES clinician.

07
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	Gait, configuration and standby
Controls	On/off button Intensity increase button (+) Intensity decrease button (-)
Indicators	Three status LEDs • 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: 5ºC to 40ºC Charging temperature: 5ºC to 40ºC Transport and storage temperature:-20ºC to 60ºC Relative humidity: 15% to 90% Atmospheric pressure: 700hPa to 1060hPa
Wireless Communication	Bluetooth 3.0 and Bluetooth 5.0
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-300us, resolution of 5us
Pulse Frequency	1- 40Hz resolution of 1 Hz
Maximum Output Voltage	180V
Maximum Output Frequency	1KHz

BATTERY LIFE

USE CASE	BATTERY LIFE (Time)	BATTERY LIFE (Strides[1])
Stimulator off	+ 1 year	N/A
Stand by	16h	N/A
Intensive use[2]	7h	20.000
Low intensity use[3]	11h	30.000

[1]Measured at 45 strides per minute.

[2]Dorsal and Plantar Flexion or only Dorsal Flexion, 4 cathodes, 40mA.

[3]Dorsal and Plantar Flexion or only Dorsal Flexion, 2 cathodes, 20mA.

SENSOR SPECIFICATIONS

PARAMETER	DESCRIPTION
Classification	Internal power, continuous operation (without applied parts)
Battery Type	Rechargeable Lithium-Polymer 3.7V, 660mAh
Operating Modes	Gait, Configuration and Hold
Controls	On/off button
Indicators	Two status LEDs • Communication (Blue) • Battery / Alarms (Red)
Dimensions	43 mm x 46 mm x 16 mm
Weight	22 gr.
Load Characteristics	5V – 0.5A
Environmental Conditions	Operating temperature: 5ºC to 40ºC Charging temperature: 5ºC to 40ºC Transport and storage temperature:-20ºC to 60ºC Relative humidity: 15% to 90% Atmospheric pressure: 700hPa to 1060hPa
Wireless Communication	Bluetooth 5.0
Protection	IP22

ELECTRODE SPECIFICATIONS

PARAMETER	DESCRIPTION
Models	Right **Fesia** Walk Left **Fesia** Walk
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	16
Anodes	4
Environmental Conditions	Operating temperature: 5ºC to 40ºC Transport and storage temperature: 0ºC to 40ºC Optimum temperature for long-term storage: 5ºC to 27ºC 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
Manufacturer	FRIWO
A Connector	IP42 approved interchangeable plug system
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

PARAMETERS	MODULE 1	MODULE 2	MODULE 3
Function	Stimulator Main	Stimulator-Sensor	Sensor-Stimulator
Module	Lairdtech BT900	u-blox ANNA-B112	u-blox ANNA-B112
Frequency (MHz)	2402-2480	2400-2480	2400-2480
Max. declared output power (dBm)	8	5	5
Max. antenna gain (dBi)	+0,5	+0,7	+0,7
Max. E.I.R.P (dBm)	8,5	5	5
Max. E.I.R.P (mW)	7,07	3,16	3,16

GUIDANCE AND MANUFACTURER'S DECLARATION– ELECTROMAGNETIC EMISSIONS

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emmisions CISPR 11	Group 1	The 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 emmisions CISPR 11 Harmonic emissions IEC 61000-3-2 Voltage fluctuations/Flickers emissions IEC 61000-3-3	Class B Class A Fulfill	The 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 device 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 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 en Ut) for 25 cycles >5% Ut (>95% dip en Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0,5 cycles 40% Ut (60% dip en Ut) for 5 cycles 70% Ut (30% dip en Ut) for 25 cycles >5% Ut (>95% dip en Ut) for 5 sec	Mains power quality should be that of a typical commercial and/or hospital environment.
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	$d = 1,17 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000 4-3	3 v/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,17\sqrt{P}$ 80 MHz to 800 MHz $d = 2,33\sqrt{P}$ 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: Ut is the AC mains voltage prior to application of the test level.

Note 2: At 80 MHz and 800 MHz, the higher frequency range applies.

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 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the device.

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

RECOMMENDED SEPARATION DISTANCE

The device is intended for use in a electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the 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 $d = 1,17 \sqrt{P}$	80 MHz to 800 MHz $d = 1,17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,30

For transmitters rated at a maximum output power nor 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.