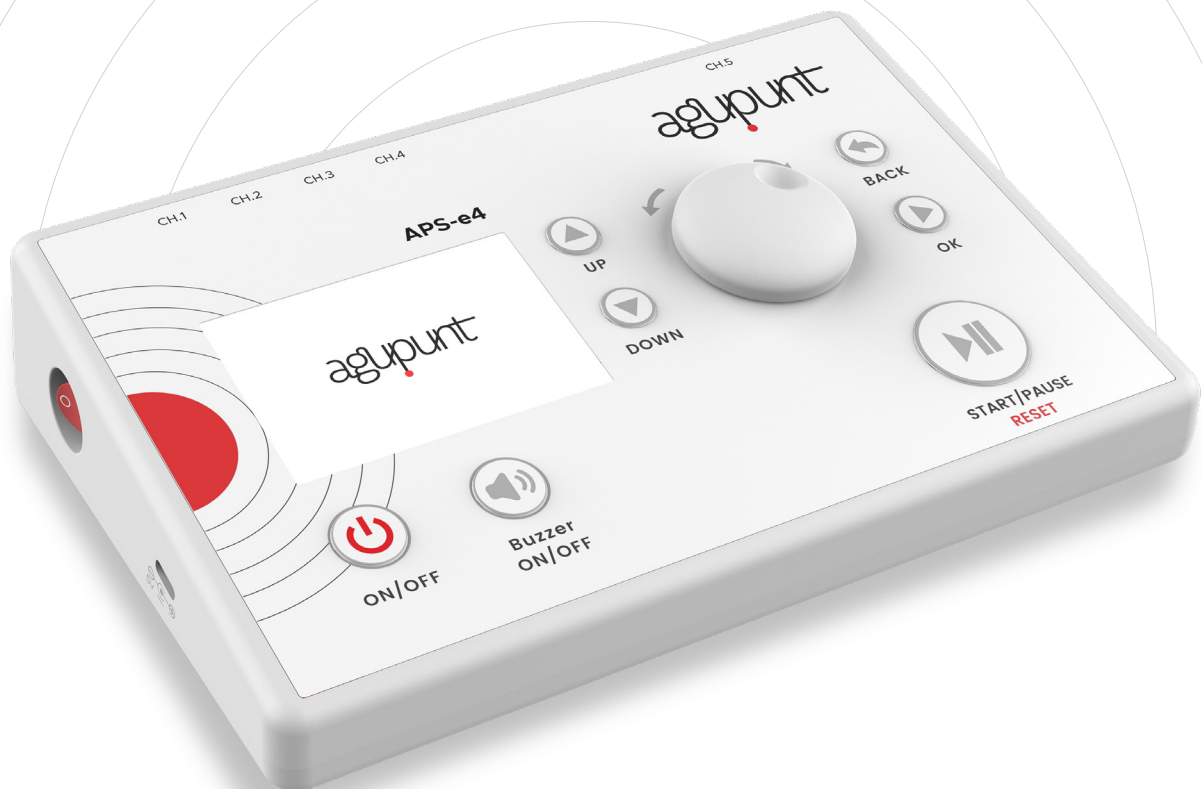


agupunt

You need it, we needle it.

APS-E4

USER MANUAL



FOR YOUR **SAFETY**, THAT OF YOUR PATIENTS, AND THAT OF YOUR **APSE4** DEVICE, IT IS STRONGLY RECOMMENDED THAT YOU CAREFULLY READ THIS **MANUAL**.

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I. SAFETY MEASURES

1. Safety Measures

- The equipment is intended for use in a professional healthcare environment.
- The **APSe4** device should not be used alongside or mounted on other equipment. If it is necessary to install it alongside or mount it on other equipment, it must be observed to verify its normal operation in the configuration in which it will be used.
- To prevent fires or risk of electric shock, both during use and storage, do not expose the unit to contact with water or excessive moisture.
- Avoid using the **APSe4** device in environments with flammable materials or flammable gases.
- To avoid electric shocks, do not open the **APSe4** device. Before subjecting the patient to any treatment, the operator must be familiar with the modes of use of the **APSe4** device as well as the therapeutic indications and contraindications.
- Ensure that this manual is available to all personnel authorized to operate this device.
- The location of use of the device complies with safety regulations.
- The device will be used in accordance with the instructions contained in the user manual.
- You can work with the **APSe4** device when the battery charger is connected.
- Do not use APSe4 device within 1.5 meters of a shortwave device or a microwave.
- Always use the cable with the handle provided by the manufacturer.
- The device has a 5V, 1.2Ah battery inside, which is estimated to have a lifespan of no less than 2 years, provided that the use is correct. After this time, the periods between charges will decrease. Battery replacement must be carried out by the manufacturer's technical service through **AGU-PUNT SL**.
- In accordance with clause 4 of the standard establishing particular requirements for the basic safety and essential performance of nerve and muscle stimulators, the equipment does not have specific elements of essential operation.
- Never charge the battery with a charger other than the one supplied by the manufacturer. In case of breakdown or loss of this, request an original replacement to maintain basic safety and essential operation related to EMC.
- The use of other cables and accessories different from those included and specified for the **APSe4** system could negatively affect the safety and electromagnetic compatibility of the equipment, causing malfunction.
- Prolonged exposure to electromagnetic disturbances may shorten the life of the bed. If the bed is located near transmission antennas (TV, AM, FM, etc.), necessary precautions should be taken to isolate it from such emissions.
- For any repair and/or maintenance work, you must go to the technical service authorized by **AGU-PUNT SL** to maintain basic safety and essential operation related to EMC.
- Do not recharge the battery in confined spaces (bags, briefcases, etc.).

- The stimulation should not be applied through or over the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or with electrodes placed on the chest and upper back or crossing the heart.

- The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could cause an increase in electromagnetic emissions or a decrease in electromagnetic immunity of this equipment and result in incorrect operation.
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of any part of the equipment, including cables specified by the manufacturer. Otherwise, it may result in degraded operation of this equipment.
- The **APSe4** equipment has no essential operation.

2. Intended use and contraindications

Intended use	Contraindications
<ul style="list-style-type: none"> - Patellar tendon. - Achilles tendon. - Pubalgia/hernia. - Lateral and medial APScondyle. - Rotator cuff. - Plantar fascia. - Skeletal muscle injuries. 	<ul style="list-style-type: none"> • Infectious arthritis. • Heart diseases. • Pregnancies. • Skin ulcers and other skin infections. • Endoprostheses and/or osteosynthesis. • Pacemakers. • Oncological processes. • Thrombophlebitis. • Endocrine glands. • Patients with altered sensitivity. • Patients with central nervous disorders. • Pediatric patients

3. Warnings

Warnings for the Safe Use of Invasive Physiotherapy Equipment

1. Device malfunction or performance issues

- Do not use the device if malfunctions are detected during startup, such as unstable current intensity, display errors, or any abnormal behavior.
- Immediately stop the treatment if the patient experiences unusual pain, burning, numbness, or any unexpected symptoms.
- Regularly inspect the device and do not use it if it shows signs of damaged cables, worn electrodes, or loose connections.
- Perform periodic calibrations and maintenance according to the manufacturer's instructions.

2. Environmental conditions or foreseeable external influences

- Do not use the device near strong magnetic fields (such as those from MRI scanners) or sources of electromagnetic interference.
- Avoid using the device in environments with high humidity, extreme temperatures, or direct sunlight exposure.
- Ensure the device is properly grounded and protected against electrostatic discharges.
- Do not use the device in the presence of flammable gases or in areas where there may be a risk of explosion.

3. Risks of interference with other procedures or devices

- Maintain a safe minimum distance from other active electronic medical equipment to avoid electromagnetic interference.
- Contraindicated in patients with pacemakers or other implanted electronic devices.
- Verify that the use of the device does not interfere with ongoing diagnostic or therapeutic procedures (e.g., cardiac monitoring or neurostimulation).
- It is recommended to suspend the use of the device during clinical studies involving equipment highly sensitive to electromagnetic fields.

4. Where the needle should never be applied

- Blood vessels.
- Endocrine glands.
- Intra-articular cavities.
- Peritoneal region.

5. Precautions and Intended users

Precautions

Needles must be the original ones from **AGU-PUNT S.L.**, **APS** brand, and **APS IPEN**.

Needle handling must be done with gloves.

Do not bend the needle during insertion into the handle.

Do not apply electric current until the needle is inserted.

Do not reuse the needle.

Needles should be disposed of in authorized disposable containers or through the **APS Destroyer** needle destroyer.

Intended users

The equipment is intended for use in a professional healthcare environment (medical practitioners, physiotherapists,..).

II. INTRODUCTION

HISTORY

AGU-PUNT is a company with 40 years of experience developing products for physiotherapy and acupuncture.

In 2008, it focused on developing products for physiotherapy, specifically in the emerging field of invasive physiotherapy, being the first company to have a product development department for this technique. The first products were **APS** dry needling needles, followed by **APS IPEN** needles for electrotherapy treatments. Subsequently, an **APS Destroyer** needle destroyer and a **SKIN APS** chlorhexidine disinfectant were developed.

All products have evolved over time, thanks to our R&D department, which never rests, striving to achieve the best possible product at all times.

This allows us to now have a wide variety of needle models, depending on the application required. **APS regular**, **APS Superficial**, **APS Fascia**, **APS Safety Tube**, **APS CLICK**, and also our **APS Destroyer** needle destroyer.

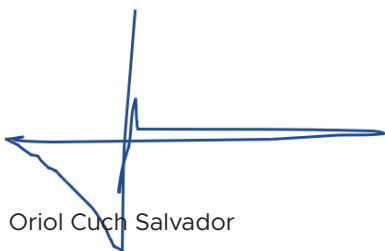
In 2013, the development of the first exclusive electrotherapy equipment for invasive physiotherapy began. Developing several equipment for other companies.

THE DEVICE

This 2024, we are pleased to present the evolution of the **APSe4** equipment, which has poured all the accumulated experience in the development of products for invasive physiotherapy, bringing together the functionalities for all the techniques currently used, and incorporating the latest technology available in the market.

The model update has been possible thanks to the recommendations and contributions of the best national and international professionals with whom **AGU-PUNT** collaborates.

We appreciate the trust you have placed in us by acquiring the **APSe4** device.



Oriol Cuch Salvador

CEO

1. Description of the material

- A. **APSe4** Equipment
- B. Handle with power on and off button
- C. 4 cables for channels 1-4
- D. Universal type C charging cable
- E. Pointer for handle
- F. 4 electrodes
- G. **APS IPEN** needles
- H. 8-output octopus-type cable



Figure 1

2. Description of the APSe4 Device

APSe4 is an intratissue percutaneous electrolysis (EPI) system designed to promote tendon restoration and regeneration, as well as the treatment of soft tissue injuries.

The device features a full-color 3.5" TFT screen and is equipped with a high-performance lithium-ion battery system.

It includes a working menu with preprogrammed treatments and parameters, which users can modify at any time during the session. It also offers open/custom programs for advanced users.

Emission of single-phase/biphasic currents (symmetric/asymmetric depending on the channel/program) pulsed, as well as continuous galvanic current.

3. Warranty and Useful life

The **APSe4** device is covered by a two-year warranty and has a five-year useful life. Accessories (cables, handpiece, and battery) have a six-month warranty.

The warranty with the seller takes effect on the date of the invoice or purchase document.

4. Maintenance

The user should not perform any repairs on the **APSe4** device or its accessories. Do not dismantle the APSe4 device or the battery charger.

AGU-PUNT SL disclaims all responsibility for damages resulting from opening, modifying, or repairing the device by unauthorized persons.

To clean the device, use a soft cloth and a solvent-free cleaning product to avoid affecting the transparent plastic covering the transparent screen.

The **APSe4** device requires mandatory calibration every 2 years from the date of purchase or from the last inspection, ensuring that the characteristics remain stable and do not vary under normal conditions of use.

5. Storage and Transport Conditions

The **APSe4** device contains a built-in rechargeable battery. During operation, environmental conditions must not exceed the following values:

Temperature: 5°C ~ 40°C.

Maximum relative humidity: 70% non-condensing

Atmospheric pressure: 86 kPa - 101 kPa.

Storage and transport conditions must not exceed the following values:

Temperature: -20°C ~ 55°C.
 Maximum relative humidity: 93% non-condensing
 Atmospheric pressure: 50 kPa - 106 kPa.

6. Disposal

For environmental protection and in accordance with current regulations, the device, battery, and its accessories must be disposed of in designated special containers.

7. Standards

The **APSe4** device is designed in accordance with DIRECTIVE EUROPEAN 93/42 CEE for medical devices. According to this directive, the **APSe4** device is classified as a Class IIa medical device.

The following standard regulations have been employed:

Electromagnetic Compatibility EMC according to standard:
 EN 60601-1-2:2015

Safety:
 EN 60601-1:2006+/A1:2013

Particular requirements for basic safety and essential performance:
 EN 60601-2-10:2015 + A1:2016

8. Symbols used in the device



Attention: under certain conditions, the effective voltage value may exceed 10mA or 10V. Please follow the information carefully



The **APSe4** device is a Class II appliance with internal power supply, with applied parts of BF type.



(Off) Power On/Off Button
 (On) Power On/Off Button



Manufacturer



Date of Manufacture (YEAR AND MONTH)



Serial Number



CE Marking with Notified Body Intervention

9. Safety Labels

Dimensions:

- Length: 220 mm.
- Width: 140 mm.
- Maximum Height: 45 mm.
- Weight: 400 g.
- Power Supply: Lithium Ion Battery.
- Rechargeable 5v \approx 1.2 A/h.

A product lifespan of 5 years is anticipated, in line with the type of technology used in its design and the current state of development of the materials used.

All electrical specifications are given for a load range between 500 and 2000 Ω .

APSe4 CC Output Signal _____	Pulsed
Frecuency _____	1-150 Hz
Pulses _____	10-700 μ s
HVPC- Emission Mode _____	Sweep
Maximum APSe4 CC Voltage _____	19 V
Maximum Current _____	20 mA
Initial Minimum Current _____	0.01 mA
Minimum Incremental Current Step _____	0.01 mA
Maximum Incremental Current Step _____	0.2 mA
Maximum Electrical Charge per Session _____	60 C
Subtypical Signal Onset Time _____	3 s

12. Descripción del menú de trabajo

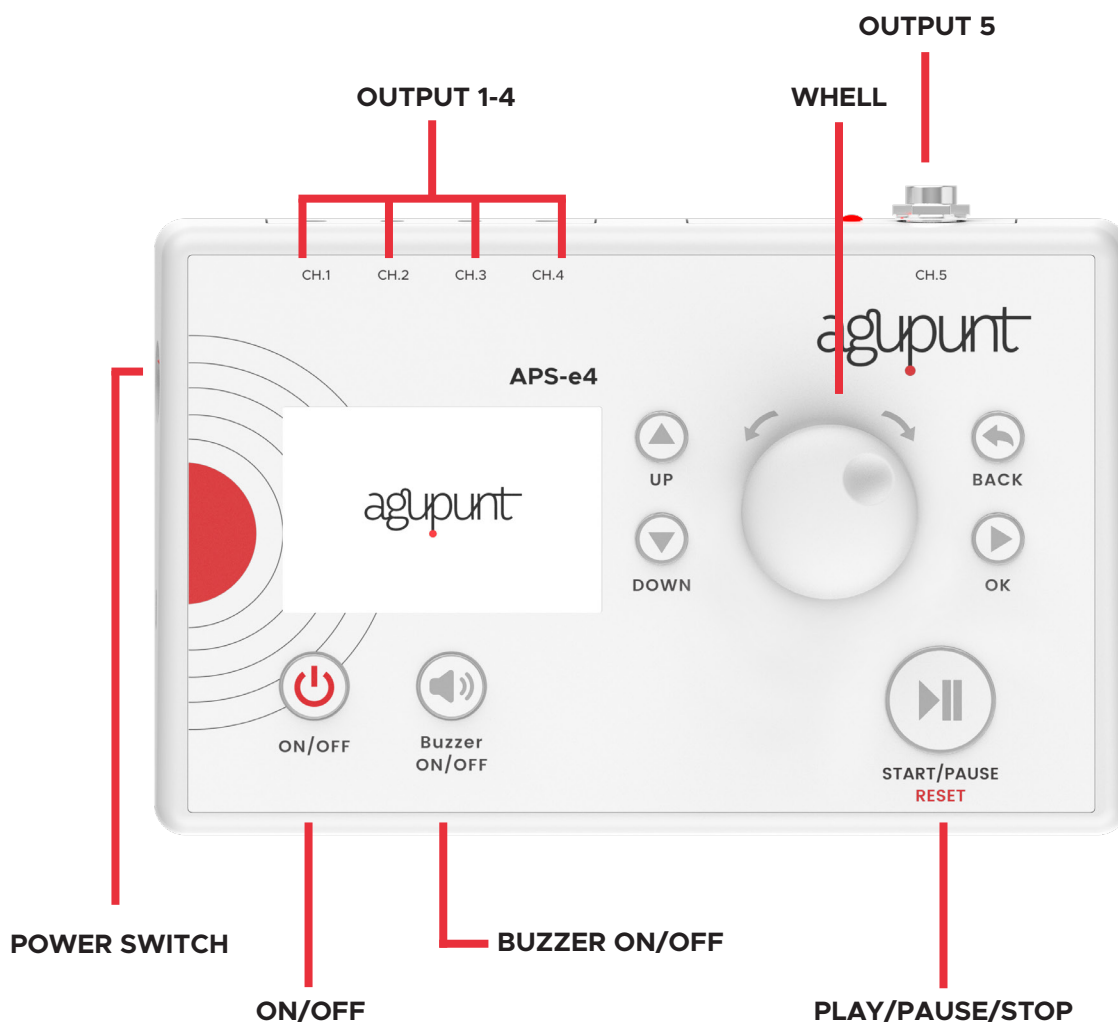


Figure 6

NOTE: The equipment can only be used by properly trained professionals.

BUTTONS, USAGE, AND FUNCTIONS

ON/OFF SWITCH

ON position for equipment operation.
OFF position for complete shutdown/restart of the equipment.

ON/OFF BUTTON


Long press with equipment off turns on the equipment.
Long press with equipment on turns off the equipment.

BUZZER ON/OFF BUTTON

Activates or deactivates the buzzer (except emergency sounds).

PLAY/PAUSE/STOP BUTTON:

In "STOP" state, a short press starts the treatment.

In  state, a short press pauses the treatment.

In "PAUSE/STOP" state, a long press resets the treatment.

In "PAUSE" state, a short press resumes the treatment.

UP/DOWN:

Press to navigate through different menu options and/or treatment program parameters.

BACK:

Press to go back on the menu screens.

OK:

Press to proceed on the menu screens and/or treatment program parameters.

WHEEL:

Rotate to navigate the menu and/or modify parameters in treatment programs.

In Microcurrent and IPEN programs, press and hold on the intensity parameter (mA) to switch to μ A.

In memory programs, hold down until a beep is heard to save new parameters.

Press on the intensity parameter to modify decimals.

Press on time parameter to switch from seconds to minutes.

III. USE MODE

1. Description of the APSe4 device

GENERAL STARTUP

1. Place the switch in the ON position (Fig. 5).
2. Power on using the ON/OFF button. The AGUPUNT logo and version appear on the screen (Fig. 6).
3. Select desired program (Fig. 6).
4. Modify current parameters: intensity, frequency, pulse, time, and pulse train time* (Fig.6).
**This can be done live and with the program in STOP.*

MICROCURRENT, NEUROMODULATION, MSUN, TENS PROGRAM

1. Select program.
2. Determine treatment time*, frequency and pulse width.
3. Determine current intensity.
4. Press PLAY/PAUSE/STOP button.
**At the end of the treatment, three beeps will sound.*

ELECTROPUNCTURE PROGRAM

1. Select desired program.
2. Determine treatment time*, frequency, pulse width, and pulse time.
3. Determine current intensity.
4. Press PLAY/PAUSE/STOP button.
**At the end of the treatment, three beeps will sound.*

IPEN PROGRAM

1. Select IPEN program.
2. Determine treatment time* and current intensity.
3. Press PLAY/PAUSE/STOP button or handpiece on/off button.
**An extended beep signal will appear in "open circuit" errors, and three beeps will sound at the end of the treatment time.*

POINTER PROGRAM (Fig. 6)

1. Select Pointer program.
2. Determine frequency and pulse width.
3. Determine current intensity.
4. Determine time.
5. Press PLAY/PAUSE/STOP or handpiece on/off button.

DESCRIPTION OF OUTPUTS

Outputs 1 to 4: Pulsed currents (monophasic and biphasic) from 0 to selected value according to selected pulse and frequency.

Output 5:

- IPEN: Galvanic current for percutaneous electrolysis application.
- Current: Asymmetric biphasic pulse at 10Hz frequency and 300ms pulse (adjustable). For verifying needle positioning in neuroactive points, for neuromodulation, or at the motor point for muscle electrostimulation.

The device includes 15 different programs, The different modes/programs will be selected by the physiotherapist:

PROGRAM TABLE

	Nº	Name	Description
ELECTROPUNCTION	1	Low combined frequency	Freq = 2/2 Hz, Pulse = 180/250 µs, Time = 1 seg - 59 min 59 seg
	2	Low single frequency	Freq = 2 Hz, Pulse = 40 µs, Time = 1 seg - 59 min 59 seg
	3	High combined frequency	Freq = 80/80 Hz, Pulse = 180/250 µs, Time = 1 seg - 59 min 59 seg
	4	High single frequency	Freq = 100 Hz, Pulse = 40 µs, Time = 1 seg - 59 min 59 seg
	5	Low/high frequency combination	Freq = 2/80 Hz, Pulse = 200/200 µs, Time = 1 seg - 59 min 59 seg
	6	Memory 1 (Simple)	Freq = 1-150 Hz, Pulse = 10-700 µs, Time = 1 seg - 59 min 59 seg. Saved
	7	Memory 2 (Simple)	Freq = 1-150 Hz, Pulse = 10-700 µs, Time = 1 seg - 59 min 59 seg. Saved
	8	Memory 3 (Combined)	Freq = 1-150 Hz (2 etapas), Pulse = 10-700 µs (2 etapas), Time = 1 seg - 59 min 59 seg. Saved
	9	Memory 4 (Combined)	Freq = 1-150 Hz (2 etapas), Pulse = 10-700 µs (2 etapas), Time = 1 seg - 59 min 59 seg. Saved
	-	Neuromodulation	Freq = 2 Hz, Pulse = 250 µs, Time = 1 seg - 59 min 59 seg
	-	- MSUN (Segmental Stimulation)	Freq = 30 Hz, Pulse = 210 µs, Time = 1 seg - 59 min 59 seg
	-	TENS	Freq = 1-150 Hz, Pulse = 10-700 µs, Time = 1 seg - 59 min 59 seg
	-	Microcurrents	Freq = 1-150 Hz, Pulse = 10-700 µs, Time = 1 seg - 59 min 59 seg
	-	POINTER	Freq = 10 Hz, Pulse = 300 µs, Time = 1 seg - 59 min 59 seg
	-	- IPEN (Electrolysis)	Intensity 0,01-20 mA, Time: 1 seg - 59 min 59 seg

- Monophasic or biphasic symmetric (pulsed) currents
- Monophasic (pulsed) currents
- Asymmetric biphasic currents
- Symmetric biphasic currents
- Galvanic (continuous) currents

Figure 7

2. Needle insertion into the device

Needle insertion into the device

Use gloves for needle manipulation (Fig. 8 and 9).

Avoid contact with the needle body by holding it by the head to prevent product contamination. Press the button on the handle to insert the needle.

The needle head should be carefully inserted into the handle until a stop is felt.

After performing the technique, remove the needle by pressing the handle button again.



Figure 8



Figure 9



Figure 10

3. Description of the APSe4 Device Programs

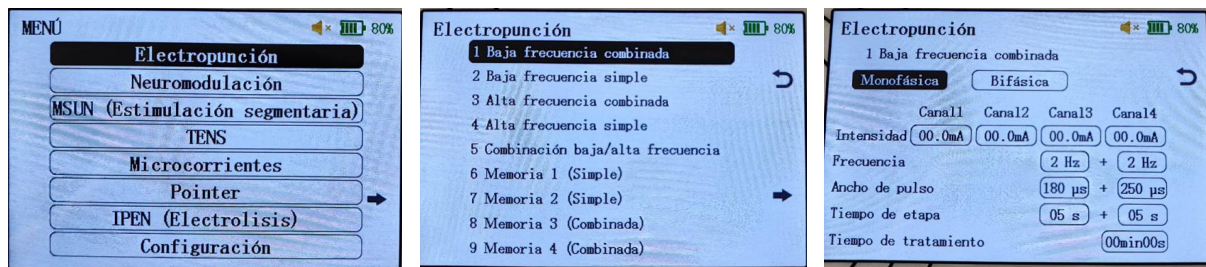
The **APSe4** is designed to offer a wide range of treatments in invasive physiotherapy, focusing on the management of cervical pain, tendinopathies, and trigger point stimulation.

Below is a description of the different programs available on the device:

3.1. ELECTROPUNCTURE PROGRAM

This program allows the electrical stimulation of myofascial trigger points. It is used to modulate muscle tone, reduce pain, and facilitate muscle activation. The **APSe4** offers preset programs and the possibility to adjust parameters according to the patient's needs, allowing work with high or low frequencies depending on the therapeutic goal.

COMBINED FREQUENCY ELECTROPUNCTURE PROGRAM

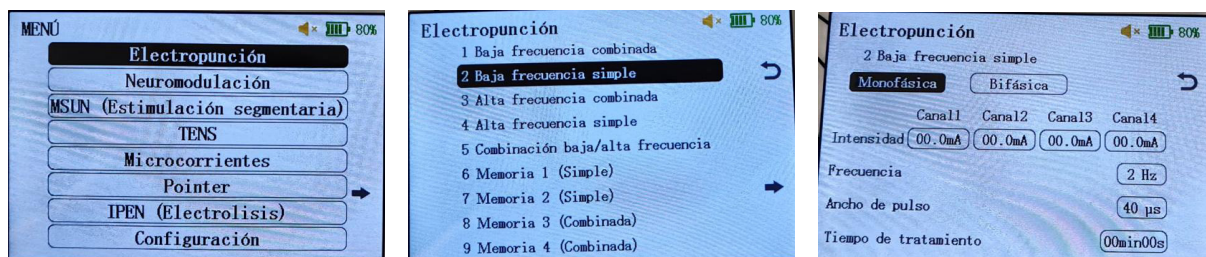


Preset **Low Frequency** Program:
 First stage: 2Hz / 180µs / 5sec
 Second stage: 2Hz / 250µs / 5sec

Preset **High Frequency** Program:
 First stage: 80Hz / 180µs / 5sec
 Second stage: 80Hz / 250µs / 5sec

- Ability to work with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.
- Off time setting (by setting Hz or µs to 0).
- Display of the current stage time in progress.

SINGLE FREQUENCY ELECTROPUNCTURE PROGRAM

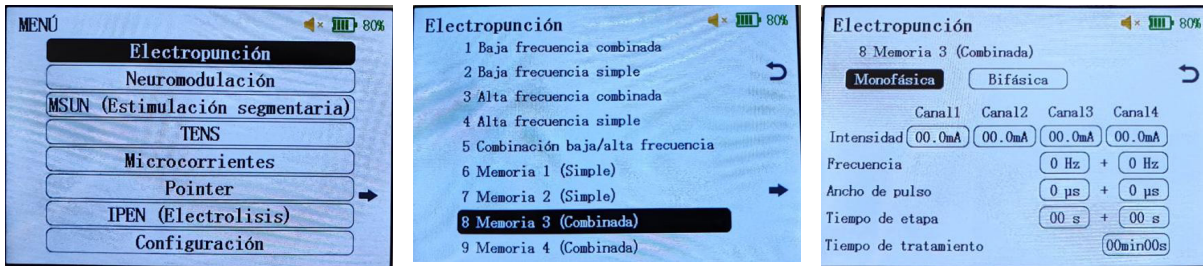


Preset **Low Frequency** Program:
Single stage: 2Hz / 40µs

Preset **High Frequency** Program:
Single stage: 100Hz / 40µs

- Ability to operate with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.

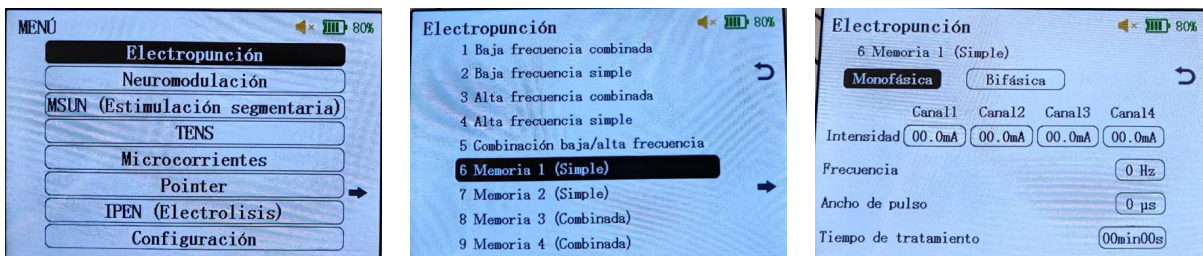
COMBINED MEMORY ELECTROPUNCTURE PROGRAM



Non-preset Combined Memory Program:
First stage: determined by the therapist
Second stage: determined by the therapist

- Option to save the treatment program settings.
- Ability to work with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.
- Off time setting (by setting Hz or µs to 0).
- Display of the current stage time in progress.

SINGLE MEMORY ELECTROPUNCTURE PROGRAM

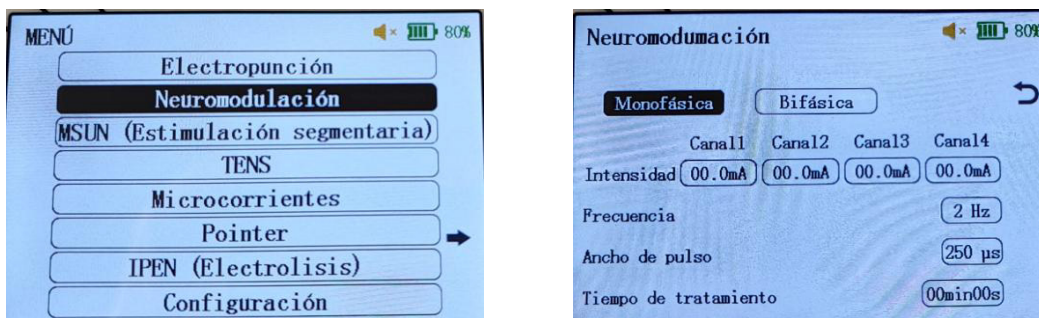


Non-preset Single Memory Program:
First stage: determined by the therapist

- Ability to work with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.

3.2. NEUROMODULATION PROGRAM

In this mode, the device allows electrical neuromodulation over dermatomes, myotomes, and sclerotomes related to pain perception. The program has a preset configuration but is also adjustable, enabling customization of intensity, frequency, and stimulus duration.

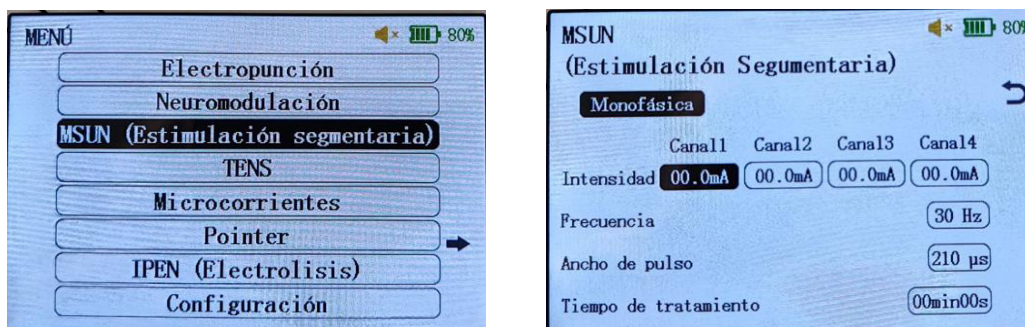


Preset **Neuromodulation** Program:
Single stage: 2Hz / 250µs

- Ability to work with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.

3.3. MSUN PROGRAM (SEGMENTAL STIMULATION)

Designed specifically for the stimulation of trigger points in deep muscles, this program uses safe and effective parameters to reach hard-to-access tissues. It features a preset program optimized for clinical use.

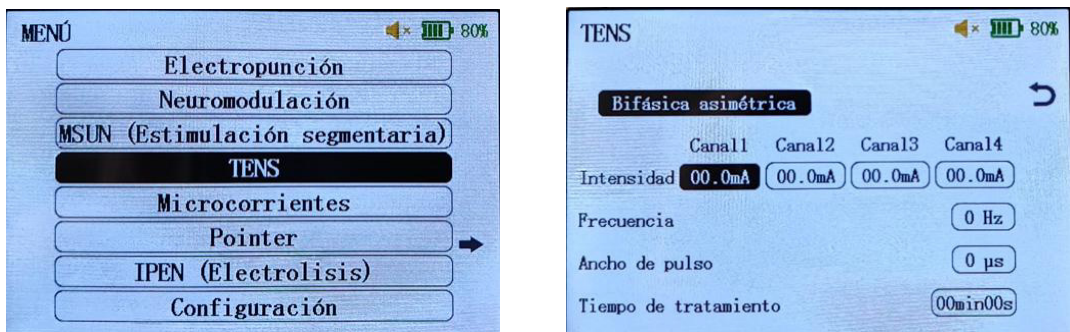


Preset **MSUN** Program:
Single stage: 30Hz / 210µs

- Program for the treatment of deep muscles.
- Ability to work with monophasic or symmetrical biphasic current.
- Parameter adjustment during the treatment.

3.4. TENS PROGRAM

This program provides analgesia through neuromodulation, helping to reduce pain by stimulating specific nerve fibers. Although it is based on a general protocol, the user can modify the parameters to suit the individual characteristics of the patient.

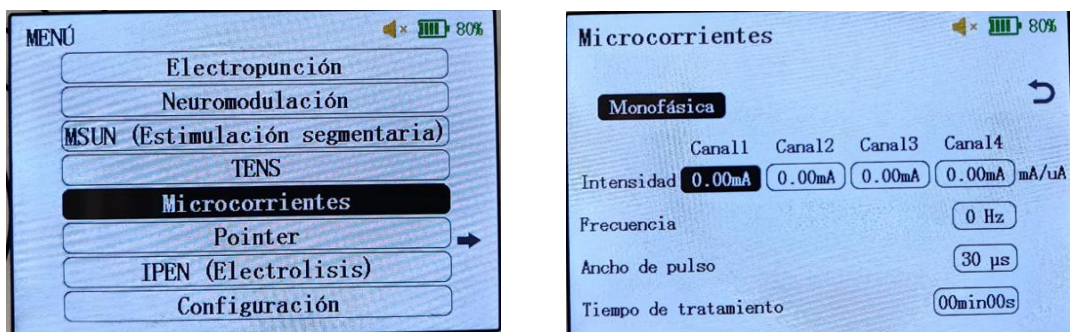


Non-preset TENS program:
Single stage: determined by the therapist

- Program for the relief or blocking of chronic or acute pain.
- It operates with asymmetrical biphasic current.
- Parameter adjustment during the treatment.

3.5. MICROCURRENT PROGRAM

It is used for the stimulation of trigger points with very low intensities. This program is fully adjustable, allowing adaptation according to the patient's sensitivity and the treated area.

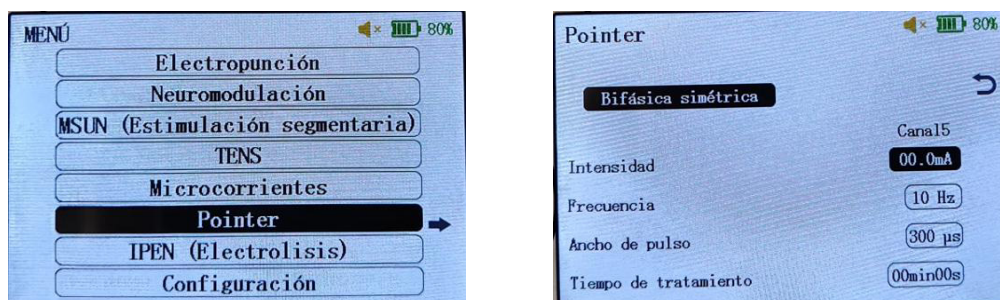


Non-preset MICROCURRENT program:
Single stage: determined by the therapist

- Ability to operate in mA or en μA .
- Maximum power: 1mA / 1000 μA
- Works with monophasic current.
- Parameter adjustment during the treatment.

3.5. POINTER PROGRAM

The Pointer mode is used for direct and precise stimulation of the target tissue (trigger point) with a single needle. It allows for localized intervention and can be configured using preset or adjustable programs, depending on the therapeutic approach.

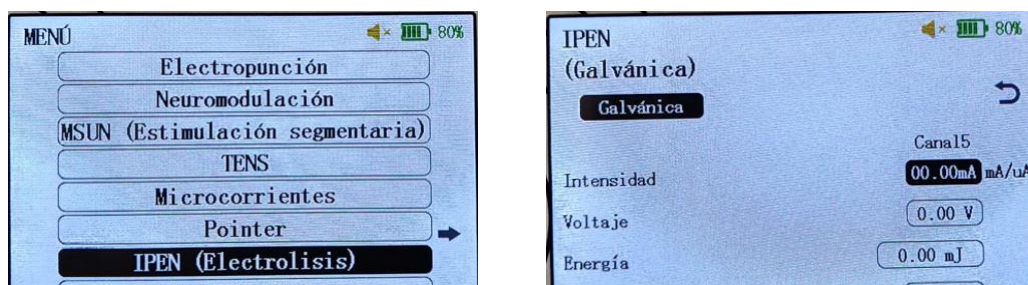


Preset **Pointer** Program:
Single stage: 10Hz / 300µs

- Program for the verification or stimulation of the target tissue.
- Operates with symmetrical biphasic current.
- Parameter adjustment during the treatment.

3.6. IPEN PROGRAM

This program applies controlled galvanic current and is specifically indicated for the treatment of tendinopathies. The **APSe4** allows modification of the program parameters, adapting the electrolysis dose to the treatment progression and the patient's tolerance.



Non-preset IPEN Program:
Single stage: determined by the therapist

- Program for the electrolysis technique.
- Operates with galvanic current.
- Parameter adjustment during the treatment.
- Real-time voltage display.
- Real-time accumulated energy display.

IV. APPLICATION OF TREATMENT

1. Treat the patient in a supine position.
2. Attach the positive electrode to the patient, as close as possible to the area to be treated.
3. Identify the region to be treated through relevant clinical tests.
4. Determine the area to be treated.
5. Calculate the optimal intervention dose.
6. Prior to applying the needle electrode, disinfect the patient's skin area to be treated in each treatment session using a disinfectant composed of benzalkonium chloride with a broad spectrum as a bactericide, fungicide, tuberculicide, microbactericide, and virus inactivator (HBV and HIV).
7. Determine the angle of needle insertion into the tissue.
8. The **APS** needles (CE 1639 certified and compliant with quality and safety standards corresponding to applicable regulations).
9. Different manufacturing sizes are for single-use, sterile, and disposable.
10. A single needle is used in each intervention, and it should be disposed of in authorized disposable bins at the end of the intervention.
11. The handle must be disinfected in each intervention using 2% peracetic acid, such as **Helix**®, which has potent sporicidal, bactericidal, fungicidal, and virucidal properties.
12. Press the button to start the treatment.

List of Cables and Accessories accompanying the APSe4 device

- Universal Type-C charger cable.
- Applicator handle with needle holder.
- Return electrode.
- 4 sets of cables (1.5 meters in length each).
- **APS iPEN** needles (percutaneous electrolysis needle).
- 8-way octopus cable.

The supplied cables and accessories are intended for use with the **APSe4** device only, and their use with any other **APSe4** device or system is not recommended

The use of other cables and accessories not included and specified for the APSe4 system could adversely affect the safety and electromagnetic compatibility of the equipment, leading to malfunctioning.

1. Intended purpose

The proposed device is an intratissue percutaneous electrolysis system intended to apply galvanic currents to tissues producing an electrolysis which activates the regenerative process.

2. Troubleshooting

Device does not power o

- Check that the switch is in the "on" position.
- Connect to power in case the device's battery is depleted

Blank screen

- Appears when an error in the initialization system is detected, as a safety mechanism. Restart the equipment with the switch.

3. Population and related medical conditions

The **APSe4** is intended for use in adults (of all ages and genders) suffering from tendon pathologies and soft tissue injuries (in the patellar tendon, Achilles tendon, pubalgia/hernia, lateral and medial epicondylitis, rotator cuff, plantar fascia, and musculoskeletal injuries).

4. Side Effects

Occasional side effects that may occur during treatments:
Side effects are defined as “an unexpected or unusual reaction, in addition to the normal expected physiological or psychological effects.”

CUTANEOUS	Rash Irritation Unexpected redness Burns Blister formation Cracks Exfoliation
SYMPTOMS	Discomfort Pain Nausea Headache Dizziness Fainting Vomiting Diarrhea
CARDIORESPIRATORY	Dyspnea
NEUROLOGICAL	Numbness Tingling Changes in muscle tone
MUSCULOSKELETAL	Joint pain Muscle pain Pain

Side effect / Residual risk	Description and possible cause	Estimated frequency	Action / Recommended measure
Mild local erythema or redness	Transient skin irritation from electrical stimulation or electrode contact	Occasional (1–10 %)	Self-limited; no treatment required. Stop session if persistent.
Tingling or mild warmth during use	Normal sensory response to electrical stimulation or tissue conductivity variation	Frequent (10–30 %)	Expected effect; reduce intensity if discomfort appears.
Mild pain at needle insertion site	Local reaction or controlled microlesion due to percutaneous technique	Occasional (1–10 %)	Self-limited; apply local cold if needed.
Mild itching or skin irritation after treatment	Mild hypersensitivity or residue from contact materials	Rare (<1 %)	Clean area, apply neutral cream; discontinue if persists.
Superficial hematoma or bruising	Minor capillary lesion during insertion	Rare (<1 %)	Apply light pressure; resume treatment once fully resolved.
Transient muscle fatigue or weakness	Repeated stimulation or excessive intensity	Very rare (<0.1 %)	Reduce intensity or treatment time in future sessions.
Serious adverse event (burn, severe pain, syncope, infection)	Incorrect use, out-of-range parameters, or application in contraindicated area	Extremely rare (<0.01 %)	Stop treatment immediately; contact technical service or medical assistance.

Note:

All listed effects are **temporary and reversible**, based on clinical experience and literature for percutaneous electrotherapy.

Operators must **interrupt treatment** and report any unexpected or severe reaction according to local vigilance procedures.

5. Manufacture’s guide and declaration. Electromagnetic emissions

The **APSe4** device has been tested according to standard EN 60601-1-2:2015. However, like all electro-medical equipment, it requires special precautions regarding EMC (Electromagnetic Compatibility), and the instructions provided in this section must be followed.

Portable and mobile radiofrequency communication equipment (e.g., walkie-talkies, mobile phones) may affect the proper functioning of the device. Also, avoid using it adjacent to or stacked with other electronic equipment to prevent possible interference that may cause malfunction of the device.

The use of accessories other than those specified could cause device malfunction or increase emissions or decrease device immunity. Always use those recommended in these instructions.

Emission Testing	Compliance	Electromagnetic environment
RF Emissions	Group 1	The APSe4 device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and unlikely to cause interference with nearby electronic equipment.
RF Emissions	Class B	The APSe4 device is suitable for use in all types of residential installations and those directly connected to the low-voltage public network supplying residential buildings.
The APSe4 device should not be used alongside or mounted on other equipment. If it is necessary to install it alongside or mount it on other equipment, it should be observed to verify its normal operation in the configuration in which it will be used.		
WARNING: The use of cables and/or accessories other than those specified may cause an increase in EMISSIONS or a decrease in the immunity of the equipment. Use only original cables and/or accessories, or original spare parts, supplied by the manufacturer.		

V. BIBLIOGRAPHY

Abat. F, Valles. SL, Paredes Brunet- P, Polidori. F, Gelber PE, Monllau. JC, Sanchez-Ibáñez JM. Estudio experimental sobre los mecanismos moleculares de reparación tras tratamiento con electrólisis percutánea intratisular en la tendinopatía rotuliana producida en ratas Sprague Dawley. RECOT 2014.

Abat F, Gelber P, Polidori F, Monllau JC, Sánchez Ibáñez JM.- Clinical results after ultrasound - guided intratissue percutaneous electrolysis and eccentric exercise in the treatment of patellar tendinopathy over a 10- year follow - up. *Knee Surgery, Sports Traumatology, Arthroscopy*, January 2014. DOI 10.1007/s00167 -0142855-2.

A.K. Vijh, Electrochemical treatment of tumors (ECT): electroosmotic dewatering (EOD) as the primary mechanism, *Dry ing Technol.* 17 (1999) 585– 596.

Balogun JA, Tang S, He Y, Hsieh JM, Katz JS. Effects of high - voltage galvanic stimulation of ST36 and ST37 acupuncture points on peripheral blood flow and skin temperature. *Disabil Rehabil.* 1996 Oct;18(10):523- 8.

Balogun JA, Biasci S, Han L. The effects of acupuncture, electroneedling and transcutaneous electrical stimulation therapies on peripheral haemodynamic functioning. *Disabil Rehabil.* 1998 Feb; 20(2):41- 8.

Bernateck M, Becker M, Schwake C, Hoy L, Passie T, Parlesak A, Fischer MJ, Fink M, Karst M. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: a randomized controlled trial. *Auricular acupuncture and autogenic training in rheumatoid arthritis. Forsch Komplementmed.* 2008 Aug; 15(4):187 -93

Dyrehag LE, Widerström - Noga EG, Carlsson SG, Andersson SA. Effects of repeated sensory stimulation sessions (electro - acupuncture) on skin temperature in chronic pain patients. *Scand J Rehabil Med.* 1997 Dec;29(4):243- 50.

Dong, B., Liang, P., Yu, X., Su, L., Yu, D., Cheng, Z., Zhang, J. Percutaneous sonographically guided microwave coagulation therapy for hepatocellular carcinoma: results in 234 patients. *AJR Am. J. Roentgenol.* 2003, 180(6):1547 1555.

Gogia PP, Marquez RR, M inerbo GM. Effects of high voltage galvanic stimulation on wound healing. *Ostomy Wound Manage.* 1992 Jan-Feb;38(1):29-35

Jaak, B., Daniel, S. Electrochemical aspects of treatment of tissue with direct current.

Eur. J. Surg. Suppl. 1994, 574:111 - 115.

Landry MD, Scudds RA. The cooling effects of electroacupuncture on the skin temperature of the hand. *J Hand Ther.* 1996 Oct- Dec;9(4):359 – 66.

Liu W, Mukherjee M, Sun C, Liu H, McPeak LK. Electroacupuncture may help motor recovery in chronic stroke survivors: A pilot study. *J Rehabil Res Dev.* 2008; 45(4):587- 96,

Mawson AR, Siddiqui FH, Connolly BJ, Sharp CJ, Stewart GW, Summer WR, Biundo JJ Jr.

Effect of high voltage pulsed galvanic stimulation on sacral transcutaneous oxygen tension levels in the spinal cord injured. *Paraplegia.* 1993 May;31(5):311-9

Mi WL, Mao - Ying QL, Liu Q, Wang XW, Wang YQ, Wu GC. Synergistic anti-hyperalgesia of electroacupuncture and low dose of celecoxib in monoarthritic rats: involvement of the cyclooxygenase activity in the spinal cord. *Brain Res Bull.* 2008 Sep 30; 77(2 -3):98 -104.

Nordenstrom, B.E.W. Survey of mechanisms in electrochemical treatment (ECT) of cancer.

Eur. J. Surg. Suppl. 1994., 574:93-109.

Robertson GS, S.A. Wemyss-Holden, A.R. Dennison, P.M. Hall, P. Baxter, G.J. Maddern, Experimental study of electrolysis -induced hepatic necrosis, *Br. J. Surg.* 85 (1998) 1212– 1216.

Samuelsson L, L. Jonsson, Electrolyte destruction of lung tissue. Electrochemical aspects, Acta Radiol, Diagn. Stockh. 21 (1980)711 –714.

Samuelsson L, Jönsson L, Ståhl E. Percutaneous treatment of pulmonary tumors by electrolysis. tumors by electrolysis. Radiologe. 1983 Jun; 23(6):284 -7

Sánchez - Ibáñez JM (2008): “ Ultrasound guided percutaneous electrolysis in patients with chronic insertional patellar tendinopathy: a pilot study”. Knee Surg Sports Traumatol Arthrosc.

May;16 :220-221

Sánchez Ibáñez, JM-. Fisiopatología de la regeneración de los tejidos blandos. En: Vila E; Sureda Seds. Fisioterapia del Aparato Locomotor. Ed Mc Graw Hill., 2005.

Sánchez -Ibáñez, JM. ¿Fascitis o Fasciosis plantar?. Bases biológicas de su tratamiento mediante electrólisis percutánea intratisular. Podología Clínica., 2004; 5(1) pags.22 -29.

Sánchez-Ibáñez JM: Treatment of painful chronic patellar tendinopathy in sportsmen through Intratendon Electrical Stimulation”. XIV International Congress on Sports Rehabilitation and Traumatology, 2005. Bologna Italy.

Sánchez - Ibáñez, JM. Ultrasound guided percutaneous electrolysis in patients with chronic insertional patellar tendinopathy: a pilot study “. 13th ESSKA 2000 Congress -2008, May 21-24.

Sánchez - Ibáñez, JM. Tratamiento de las tendinopatías mediante electrólisis percutánea intratendinosa “. XXX Congreso Nacional de la Sociedad Española de Reumatología, 2004. Barcelona.

Sánchez -Ibáñez, JM. (2003). Tratamiento de la entesopatía rotuliana en deportistas mediante microregeneración endógena guiada (MEG). Análisis de supervivencia dependiendo de la clasificación Victorian Institute of Sport Assessment (VISA). Memoria de Tesis Doctoral por la Universitat Internacional Cataluña.

Sánchez, JM , Oregui O, Gonzalez I . Terapia de Neuromodulación Percutánea (TNP) en la evolución del hombro doloroso hiperagudo”. En el Third European Congress of Sports, Medicine and Science in Tennis, 2001. Barcelona.

Shiotani A, Tatewak i M, Hoshino E, Takahashi T. Effects of electroacupuncture on gastric myoelectrical activity in healthy humans. Neurogastroenterol Motil. 2004 Jun; 16(3):293-8.

Sun, C.J., Chen, G.F. Primary trial of inhibiting effect of electrothermal needles therapy in mice bearing transplantable S180. J. Zhejiang Med. University, 1986, 15(3):107 -108.

Von Euler, H., Nilsson, E., Olsson, J.M., Lagerstedt, A.S. Electrochemical treatment (EChT) effects in rat mammary and liver tissue. In vivo optimizing of a dose planning model for EChT of tumors. Bioelectrochemistry, 2001. 54(2):117-12.

Von Euler H, E. Nilsson, - A.S. Lagerstedt, J.M. Olsson, Development of a dose-planning method for electrochemical treatment of tumors. A study of mammary tissue in healthy female CD- rats, Electro -Magnetobiol. 18 (1999) 93 -105

Wang F, Tian DR, Han JS. Electroacupuncture in the treatment of obesity. Neurochem Res. 2008 Oct; 33(10):2023-7.

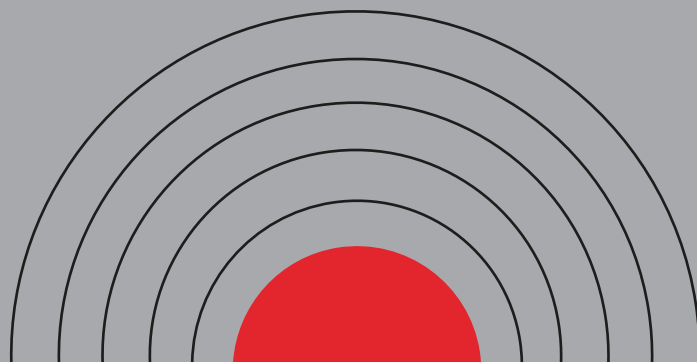
Yao -chi W, Bi meng- Z, Chong - miao - W, Junfeng Z, Ping- S, Liu GZ. Observation on short-term and long-term therapeutic effect of electroacupuncture at Houxi (SI 3) on acute lumbar sprain. Zhongguo Zhen Jiu. 2007 Jan; 27(1):3-5.

Zhang RX, Lao L, Wang L, Liu B, Wang X, Ren K, Berman BM. Involvement of opioid receptors in electroacupuncture -produced anti-hyperalgesia in rats with peripheral inflammation. Brain Res. 2004 Sep 10; 1020(1-2):12-7.

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