I-TECH
MEDICAL DIVISION

USER MANUAL

MNPG151 Rev. 5del 11/11/15

Electrotherapy model

MIO-IONOTENS

Summary

Manufacturer

I.A.C.E.R. S.r.l.

Via S. Pertini, 24/a • 30030 Martellago (VE)

Tel. 041.5401356 • Fax 041.5402684

IACER S.r.l. is an Italian medical devices manufacturer (CE medical certificate n° MED 24021).

Declaration of Conformity

IACER S.r.l., headquartered in Italy, via S. Pertini 24/A 30030 Martellago (VE), declares on its own responsibility that MIO-IONOTENS is manufactured in conformity with Council Directive 93/42/EEC (MDD) dated 14 June 1993 (D. Lgs. 46/97 dated 24 February 1997 "Attuazione della Direttiva 93/42/CEE concernente i dispositivi medici), Annex II as modified by Directive 2007/47/CE dated 5 September 2007 (D. Lgs 37/2010 dated 25 January 2010).

Notified Body: Cermet, Via di Cadriano 23 – 40057 Cadriano di Granarolo (BO) Italy.

MIO-IONOTENS is a Class IIa equipment, with reference to Directive 93/42/EEC (MDD), annexed IX rule 9 (and following modifications).

Certification Path: Annex II

Martellago, 01/07/2014

Legal representative
Mario Caprara

Specifications

MIO-IONOTENS has the following specifications:

- Class IIa equipment (Directive 93/42/EEC, annexed IX rule 9 and following modifications);
- Class II, applied part type BF (Classif. EN 60601-1);
- Equipment not protected against liquids penetration;
- Equipment and accessories not subjected to sterilization;
- Use of the equipment is prohibited close to flammable substances or in environments with high concentrations of oxygen;
- Continuous operating mode equipment;
- Equipment not suited to be used in external.

Purpose

Clinical purpose : Therapeutic
Use: Clinic/Hospital and domestic use

MIO-IONOTENS is indicated for the treatment and the functional rehabilitation of the following pathologies and anatomical zones:

- wrist articulation
- hand articulation
- shoulder articulation
- foot articulation
- ankle articulation
- knee articulation
- skeletal motor apparatus
- arthrosis
- atrophies and muscular dystrophy
- bruises
- sprains
- neuralgias
- benign lesions and muscular tears
- tendinitis

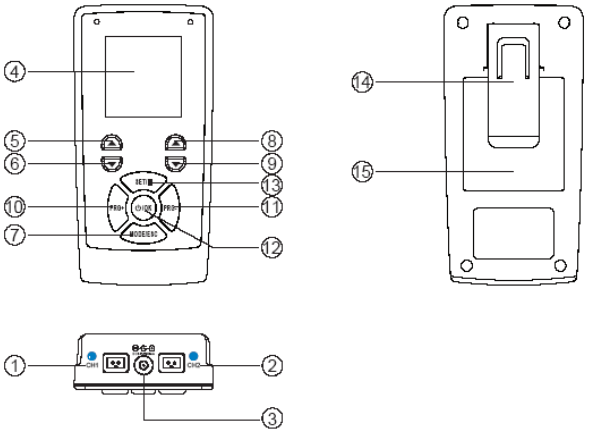
MIO-IONOTENS, thanks to its protocols TENS, is particularly suitable for the treatment of pain. TENS pulses are able to significantly reduce, and in some cases eliminate, the sensation of pain caused by diseases and / or problems indicated above.

MIO-IONOTENS has also specific ionophoresis protocols. Ionophoresis is an electrotherapeutic technique that uses continuous current to introduce drugs on pain or contracture area. The current promotes the migration of the drug ions: the drug passes through the pain area releasing its specific action. Ionophoresis has two great advantages: it avoids the administration of drugs by mouth and its treats directly the pain areas.
Ionophoresis is also used for the treatment of diseases affecting urogenital male apparatus, like IPP (Induratio Penis Plastic) or La Peyronie disease. Consult a specialist before start the therapy. Contact the manufacturer for other information.

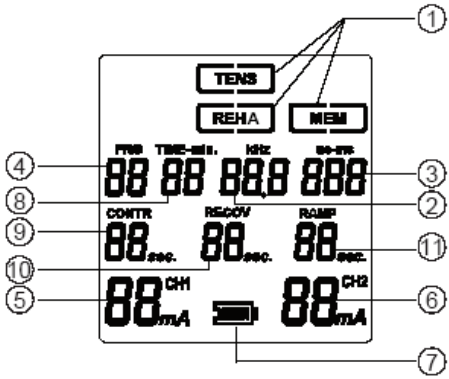
Specifications

Power supply	Rechargeable battery pack 4,8V 800mAh
Charger	Input 100/240VAC 50/60Hz 0.2A, output 6.8VDC 0.3A
Insulation class (CEI EN 60601-1)	II
Applied part (CEI EN 60601-1)	BF
Dimensions (mm)	140x70x30
Max output current	40mA su 1KΩ for each channel on REHA programs
	99mA su 1KΩ for each programs on the other programs
Waveform	Quadra compensated biphasic and monophasic square
Waveform frequency (Hz)	From 0.25 to 200
Impulse width (µs)	From 20 to 450
Timer	From 1 to 90 minutes

WARNING. The equipment delivers current in excess of 10mA.



(1) CH1 output
(2) CH2 output
(3) Battery charger connector
(4) Display
(5) Increase intensity CH1
(6) Decrease intensity CH1
(7) Mode operation button
(8) Increase intensity CH2
(9) Decrease intensity CH2
(10) Increase program
(11) Decrease program
(12) ON/OFF and OK button
(13) Set programs and therapy pause button
(14) Belt clip
(15) Battery compartment



(1) Mode operation (REHA, TENS, MEM)

(2) Wave frequency

(3) Wave impulse width

(4) Program number

(5) CH1 intensity

(6) CH2 intensity

(7) Battery status

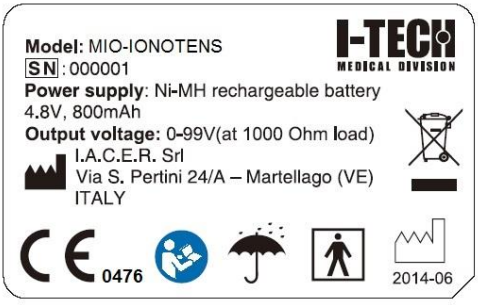
(8) Therapy time

(9) Contraction time

(10) Recovery time

(11) Up/down slope

Labelling details



Symbol description

	Keep dry. Avoid contact with liquids.
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment.
	Refers to operating instructions
	Internally powered device with type BF applied parts
CE 0476	This product complies with the European Community Directive 93/42/EEC (and subsequent mod.)
	Manufacturing date (month/year)

Contents of the package

MIO-IONOTENS contains:
n° 1 device;
n° 1 Rechargeable battery pack 4,8V 800mAh;
n° 2 cables for electrical stimulation;
n° 4 cable splitters;
n° 1 set of 4 pre-gelled electrodes 41x41mm (alternatively 48x48mm)
n° 1 set of 4 pre-gelled electrodes 40x80mm (alternatively 50x90mm);
n° 1 Iontophoresis kit (elastic band, 2 rubber electrodes, 2 sponges)
n° 1 belt clip;
n° 1 carriage bag;
n° 1 User manual.
n° 1 electrodes position manual

How to use

Warning

- Take care of position and meaning of the labels on MIO-IONOTENS;
- Do not damage the connection cables and avoid to roll up the cables around the device;
- Check the device and its accessories before use. Avoid the use in case of damage to the case or to the accessories (damaged cables): contact the manufacturer as mentioned in "Assistance" paragraph;
- Avoid the use of MIO-IONOTENS to people not educated through the reading of the manual;
- Avoid the use of MIO-IONOTENS in damp environments;
- Do not wear metallic objects during therapy;
- It is forbidden to position the electrodes in such a way that the current crosses the heart area (e.g. a black electrode on the chest and a red electrode on the shoulder blade);
- Use of the device is prohibited with electrodes positioned on or close to injuries or cuts;
- The electrodes must not be positioned on the carotid sinuses (carotid) or genitals;
- The electrodes must not be positioned close to the eyes; make sure that the current delivered does not cross the eyeball (one electrode diametrically opposite to the other in relation to the eye); keep a distance of at least 3 cm. from the eyeball;
- Insufficiently sized electrode sections can cause skin reactions or burns;
- Do not use electrodes when damaged, even if they stick to the skin well;

- Use only cables and electrodes supplied by device manufacturer;
- Electrodes must not be used when they no longer stick to the skin. Repeated use of the same electrodes can compromise the safety of the stimulation, in fact it can cause skin redness that can last for many hours after stimulation.

The manufacturer is responsible of the performances, safety and integrity of the device only if:

- Eventual additions, modifications and/or reparations are performed by authorized personnel;
- The electrical system is in compliance with the national laws;
- The device is used in compliance with the instructions of the user manual.

Electromagnetic Interference

The device does not generate and does not receive interference from other equipment. It 'should still use the device while holding the applicator at a distance of at least 3 meters away from televisions, monitors, cell phones or any other electronic equipment.

Contraindications

Patients in a state of pregnancy, tuberculosis, juvenile diabetes, viral diseases (acute), fungal dermatitis, patients with heart disease, arrhythmia or severe with pace-makers, children, denture wearers magnetisable, acute infections, open wounds, epileptics (unless otherwise prescriptions). There are no known significant side effects. In some cases of particularly sensitive people, after the treatment of skin rashes occur at the electrodes: the redness usually disappears a few minutes after treatment. If the redness persists, consult a physician. In rare cases, the stimulation evening causes a delay in falling on some subjects. In this case, avoid treatment in the evening.

How to use

MIO-IONOTENS is a portable and battery-powered device that generates TENS and IONOPHORESIS currents. It is particularly indicated for daily treatments of the most commons muscle diseases. I-TECH PHYSIO is provided with two independent and adjustable intensity channels.
MIO-IONOTENS has 14 preadjusted tens programs, 10 preadjusted programs REHA (including 3 programs iontophoresis) and 12 free memories adjustable by the user to create programs according to his needs. The program MEM 13 is a battery test.

PRELIMINARY INSTRUCTIONS

1. CABLES AND ELECTRODES CONNECTION
   Position the electrodes on the skin (see the following paragraph), connect the electrostimulation cable jacks to the self-adhesive electrodes and then connects the cables to the outputs on the upper side of MIO-IONOTENS;
2. SWITCHING ON OF THE DEVICE
   Turn MIO-IONOTENS on using the ⏻/OK button;

PREADJUSTED PROGRAMS

Read the follow instructions to use the preadjusted programs of MIO-IONOTENS.

1. MENU AND PROGRAM SELECTION
   Select the menu by pressing MODE button (TENS, REHA, MEM).
   Select the program using PRG+ and PRG+ buttons (please make reference to "Programs list" to get all technical specifications);
2. INTENSITY SELECTION
   You can increase current intensity using CH1 and CH2 buttons (up-arrow). The value can be adjusted with stepping of 1 mA. Press CH1 and CH2 buttons (down-arrow) to decrease the intensity.
   MIO-CARE PRO recognize the electrodes connection: in case of faulty connection, when the intensity reaches 10 mA the value is resetted to zero.
   The remaining time is showed on the display of MIO-IONOTENS. An acoustic signal advises the user when the treatment is completed.

Press the SET/II button to pause the treatment. To restart the program press ⏻/OK button.

Turn off the device keeping pressed the ⏻/OK button for at least two seconds.
The device automatically switches off when no button is pressed for 2 minutes.

FREE MEMORIES (ADJUSTABLE PROGRAMS)
With I-TECH PHYSIO you can set the parameters according to your needs using the MEM programs.
Read the following instructions to adjust the parameters.

1. PROGRAM SELECTION
   Select MEM by pressing MODE/ESC button. Scroll the programs using PRG+ and PRG- buttons.
   Read the following instructions to adjust the program parameters (time, frequency and width impulse);
2. PARAMETERS ADJUSTEMENT
   - Adjust therapy time TIME-min pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons;
   - Press SET to confirm;
   - Adjust frequency Hz pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons;
   - Press SET to confirm;
   - Adjust width impulse us pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons;
   - Press OK to confirm;
3. INTENSITY ADJUSTEMENT
   Increase intensity current of two channels using CH1 and CH2 ▲ buttons. The value can be adjusted with 1mA stepping. Decrease the intensity pressing ▼ buttons.

TENS and ionophoresis

In TENS programs the intensity should be adjusted to a level between the thresholds of perception and pain: the maximum intensity level is the moment in which the muscles surrounding the area treated begin to contract. It is suggested to stop before that point.
The electrodes should be positioned to form a square surrounding the painful area using Channel 1 and Channel 2 as shown in illustration 1.
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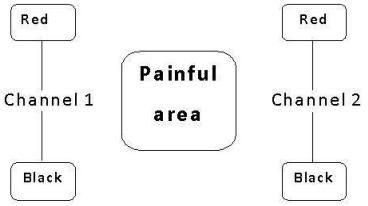

⚠ WARNING

Apply the electrodes forming a square over the painful area while maintaining a minimum distance of 4cm between an electrode and the other.

For ionophoresis programs set up an intensity value so to have "pins and needles" on treatment area. The used drug can have negative polarity, positive polarity or double polarity. The current induce the drug to run from one pole to the other, crossing the painful area and releasing the specific active ingredient.

WARNING: before starting the therapy, wet the sponge electrodes and wring them so to avoid dripping, then put the drug on the electrode as follow:

- Active polarity drug: dissolve this drug on the electrode connected to positive pole (red connector)
- Negative polarity drug: dissolve this drug on the electrode connected to negative pole (black connector)
- Double polarity drug: can be dissolved on positive pole or negative pole without distinction.

Position the electrode with the drug on painful area, and the other electrode on the other side.

At the end of the program, the skin could lightly turn bright red; the reddening usually vanishing few minutes after the end of program.

WARNING. Do not use ionophoresis program near metallic prosthesis.

LIST of the main drugs used in ionophoresis			
Drug	**Polarity**	**Pharmaceutical action**	**Indications**
Calcium chloride (Sol, 1% 2%)	Positive	Sedative and recalcifying	Osteoporosis, Spasmophilia, algodystrophic syndrome DO not use in cases of arteriosclerosis
Magnesium chloride (Sol. 10%)	Positive	Analgesic, sedative, Fibrolytic	Substitute for calcium chloride cases with arteriosclerosis
Potassium iodide	Negative	Sclerolytic, emollient	Scars, adhesions, Dupuytren's disease, cheloidis
Lysine acetylsalicylate	Negative	Analgesic	Arthrosis
Flectadol, Aspegic	Negative	Analgesic	Arthrosis extra/intra-articular rheumatisms
Local anaesthetics (Novocaine,lidocaine)	Negative		Local anaesthesia, trigeminal neuralgia
Benzydamine	Positive	Analgesic	Rheumatoid arthritis
Diclofenac sodium	Positive/Negative	Analgesic	Hematomas
Orudis, voltaren, Lometacen, Arfen, Tilcotil, Axera, Naprosyn	Negative	Anti-inflammatory	Degenerative and extra-articular rheumatisms, gout
Piroxicam, Feldene	Positive	Analgesic	Fractures
Sodium salicylate (1%-3%)	Negative	Analgesic	Articular rheumatism, myalgia
Ketoprofene	Positive/Negative	Anti-inflammatory	Arthrosis, arthritis

Lysine salt			
Thiomucase	Negative	Antiedemic	Post-trauma and post-surgical oedema due to venous insufficiency

If the drug used is not included in the above list, determine the polarity from the package or consult the prescribing doctor or dispensing pharmacist.

Programs list

TENS		REHA		MEM	
1	Conventional Tens (rapid)	1	Ionophoresis L (low)	1	Free TENS 1
2	Endorphinic Tens (delayed)	2	Ionophoresis M (medium)	2	Free TENS 2
3	Tens at maximum values	3	Ionophoresis H (high)	3	Free TENS 3
4	Anti-inflammatory	4	Microcurrent	4	Free TENS 4
5	Neck pain / headache	5	Hematoma	5	Free TENS 5
6	Backache/sciatic pain	6	Oedema	6	Free NEMS 1
7	Sprains / Bruises	7	TENS sequential	7	Free NEMS 2
8	Vascularization	8	TENS Burst	8	Free NEMS 3
9	Muscle relaxant	9	Atrophy prevention	9	Free NEMS 4
10	Hand and wrist pain	10	Atrophy	10	Free NEMS 5
11	Plantar stimulation			11	Alternated NEMS 1
12	Epicondylitis			12	Alternated NEMS 12
13	Epitroclea			13	Battery test
14	Periarthritis				

TENS Programs

Prg.	PHASE 1	PHASE 2	PHASE 3
T1	Total time 40 min frequency 90 Hz impulse width 50µs		
T2	Time tot 30 min frequency 1 Hz impulse width 200µs		
T3	Time tot 3 min frequency 150 Hz impulse width 200µs		
T4	Total time 30 min frequency 120 Hz impulse width 40µs		
T5	Total time 20 min frequency 90 Hz impulse width 60µs	Total time 5 min frequency 2 Hz impulse width 150µs	Total time 10 min frequency 90 Hz impulse width 60µs
T6	Total time 20 min frequency 90 Hz impulse width 50µs	Total time 20 min frequency 60 Hz impulse width 60µs	
T7	Total time 10 min frequency 110 Hz impulse width 50µs	Total time 10 min frequency 90 Hz impulse width 50µs	Total time 10 min frequency 70 Hz impulse width 60µs
T8	Total time 20 min frequency 2 Hz impulse width 200µs		
T9	Total time 10 min frequency 4 Hz impulse width 250µs	Total time 10 min frequency 6 Hz impulse width 200µs	Total time 10 min frequency 2 Hz impulse width 300µs
T10	Total time 15 min frequency 70 Hz impulse width 60µs	Total time 15 min frequency 90 Hz impulse width 50µs	Total time 10 min frequency 110 Hz impulse width 50µs
T11	Total time 15 min frequency 70 Hz impulse width 60µs	Total time 15 min frequency 2 Hz impulse width 150µs	Total time 10 min frequency 90 Hz impulse width 50µs
T12	Total time 20 min frequency 90 Hz impulse width 50µs	Total time 10 min frequency 70 Hz impulse width 60µs	Total time 10 min frequency 50 Hz impulse width 90µs
T13	Total time 20 min frequency 90 Hz impulse width 50µs	Total time 20 min frequency 70 Hz impulse width 60µs	
T14	Total time 1 min frequency 150 Hz impulse width 200µs	Total time 30 min frequency 90 Hz impulse width 60µs	Total time 10 min: (3Hz-200µs x 7sec 50%+ 1Hz 200µs x 3 sec 60% + 30Hz-200µs x 5 sec 50%) x 40 cycles

TENS 1 • Conventional TENS

Program used for analgesic purposes; its purpose is to induce the organism into blocking pain at the spine, in accordance with the "Gate Control Theory" by Melzack and Wall. Pain impulses leave part of the body (for example the hand) and run along the nerve tracts (through small-diameter nerve fibers) until they reach the central nervous system where the impulses are interpreted as pain. Conventional tens activates large-diameter nerve fibers, blocking the path of small-diameter nerve fibres at the spine. So action is mainly taken against the symptom: to simplify it further, the wire transmitting pain information is obstructed.

Treatment duration should be no less than 30/40 minutes. Conventional tens is a current that can be used to treat general everyday pain. The average number required to benefit from the treatment is 10/12 per day (there are no contraindications for up to double this amount).

The program has a duration of 40 minutes in a single phase. The program can be repeated at the end of the session for particularly persistent pain. The nature of the impulse means that the patient may experience an "addictive" effect due to which the impulse will be felt less and less: if necessary the intensity can be increased by one level to counter this effect.

Position of electrodes: form a square above the painful area as shown in illustration 1.

TENS 2 • Endorphinic TENS

This type of stimulation produces two types of effects according to how the electrodes are positioned: positioning the electrodes in the dorsal region, see photo 08 in the positions manual, promotes the endogenous production of morphine-like substances capable of raising the pain perception threshold; positioning the electrodes to form a square above the painful area as shown in illustration 1 produces a vascularizing effect. Vascularization increases arterial flow and consequently aids the removal of allogenic substances and helps to restore normal physiological conditions.

Treatment duration 30 minutes in a single phase, daily frequency.

Do not position the electrodes close to inflamed areas.

Intensity adjusted for good solicitation of the part stimulated, the sensation must be similar to that of a massage.

TENS 3 • TENS at maximum values

Very short duration, 3 minutes. Blocks pain impulses peripherally creating a proper anaesthetising effect in the area treated. This type of stimulation is suitable for injuries or bruises when rapid action is required. The intensity selected is the maximum tolerable value (well in excess of conventional tens, and therefore with considerable contraction of the muscles surrounding the area treated). That is the reason why such stimulation is undoubtedly the least tolerated but is extremely effective. This type of stimulation is not recommended for particularly sensitive people and in any case the electrodes should not be positioned in sensitive areas such as the face and genitals or close to wounds.

Position of electrodes: form a square above the painful area as shown in illustration 1.

TENS 4 • Anti-inflammatory

Program recommended for inflammatory conditions. To be applied until the inflammatory state is lessened (10-15 applications, once a day; the daily treatments can be doubled if required). Identify the area to be treated and position the electrodes as shown in illustration 1. Adjust the intensity until a tingling feeling is produced in the area treated; avoid contracting the surrounding muscles.

Program duration: 30 minutes.

TENS 5 • Neck pain / Headache

Specific program for the treatment of pain in the neck area.

The intensity should be adjusted to a level between the thresholds of perception and pain: the maximum intensity level is the moment in which the muscles surrounding the area treated begin to contract; over this limit stimulation does not become more effective, just more irritating, so it is best to stop before that point. The first benefits can be seen after 10 to 12 treatments carried out on a daily basis; proceed with the treatment until the symptoms pass. Position of electrodes: photo 25.

Warning: the device varies stimulation parameters during the program. The current may feel different: this is perfectly normal and is envisaged by the software: raise or lower the intensity according to your own sensitivity to reach a level of stimulation that is comfortable for you.

TENS 6 • Backache/Sciatic pain

Specific program for the treatment of pain in the lumbar area or along the sciatic nerve, or both. The intensity should be adjusted to a level between the thresholds of perception and pain: the maximum intensity level is the moment in which the muscles surrounding the area treated begin to contract; over this limit stimulation does not become more effective, just more irritating, so it is best to stop before that point. The first benefits can be seen after 15 to 20 treatments carried out on a daily basis; proceed with the treatment until the symptoms pass. Program duration: 40 minutes.

Position of electrodes: see photo 27 and 28 in the manual of positions.

TENS 7 • Sprains / Bruises

The program develops its effectiveness after this type of injury by inhibiting pain locally, producing three selectively acting, differentiated impulses. The intensity should be adjusted to a level between the thresholds of perception and pain:

Number of treatments: until pain is lessened, on a daily basis (even 2/3 times a day).

TENS 8 • Vascularization

Has a vascularizing effect on the area treated. Vascularization increases arterial flow and consequently aids the removal of algogenic substances and helps to restore normal physiological conditions. Do not position the electrodes close to inflamed areas.

Daily application is recommended, the number of applications is not defined; the program can be used to reduce pain.

Stimulation intensity should be between the thresholds of perception and slight discomfort.

Program duration: 20 minutes.

Position of electrodes: see photo 25 and 33 in the manual of positions.

TENS 9 • Muscle relaxant

Program used to speed up the recovery of muscle function after intense training or strain from work; the effect is immediate. Adjust the intensity for moderate muscle solicitation. Two treatments per day for three or four days. Program duration: 30 minutes. Position of electrodes: from photo 1 to 28.

TENS 10 • Hand and wrist pain

This program is suitable for all types of hand and wrist pain: aching caused by strains, arthritis in the hand, carpal tunnel syndrome, etc. Total program duration: 40 minutes. A combination of various

types of square-wave impulses has a general analgesic effect on the area to be treated (impulses at different frequencies stimulate different sized nerve fibres promoting an inhibitory action at spinal level). The intensity should be adjusted to a level between the thresholds of perception and pain, without causing muscle contraction:

Position of electrodes: form a square above the area to be treated as shown in illustration 1.

TENS 11 • Plantar stimulation

This program has a relaxing and draining effect on the limb stimulated. It is ideal for people suffering from a sense of "heaviness in the legs".

Duration: 40 minutes. Intensity: just above the threshold of perception.

Position of electrodes: 2 electrodes (one positive, the other negative) on the sole of the foot, one close to the toes, the other under the heel.

TENS 12 • Epicondylitis

Also known as "tennis elbow", it is an insertional tendinopathy concerning insertion of the elbow bone into the epicondylite muscles, those enabling finger and wrist extension (bending backwards). 15 applications once a day (even twice), until the symptoms pass. We recommend that you consult your doctor to identify the precise cause of the pain in order to prevent the condition from reoccurring.

Program duration 40 minutes, intensity adjusted above the threshold of perception.

Position of electrodes: photo 29.

TENS 13 • Epitroclea

Also known as "golfing elbow", it affects golfers but also those who carry out repetitive tasks or tasks involving frequent intense strain (for example carrying a particularly heavy suitcase). It causes pain in the flexor and pronator tendons inserted in the epitroclea. Pain is felt when bending or straightening the wrist against resistance, or when clenching a hard rubber ball in the hand. 15 applications once a day (even twice), until the symptoms pass. We recommend that you consult your doctor to identify the precise cause of the pain in order to prevent the condition from reoccurring.

Program duration 40 minutes, intensity set above the threshold of perception.

Position of electrodes: photo 29 but with all of the electrodes positioned on the inside of the arm (with a rotation of about 90°).

TENS 14 • Periarthritis

Scapulo-humeral periarthritis is an inflammatory condition affecting the fibrous tissues surrounding joints: tendons, serous sacs and connective tissue. These appear altered and can break into fragments and calcify. If neglected, this condition can become heavily crippling. For this reason, after carrying out a cycle of 15/20 applications once a day, we recommend that you consult your doctor for a cycle of specific rehabilitation exercises to reduce the pain.

The Tens17 program consists of various phases including Tens and muscle stimulation aimed at improving the tone of the muscles surrounding the joint.

Program duration 41 minutes, intensity set above the threshold of perception with small muscle contractions at the end of the program (10 minutes before the end).

ARTHROSIS

Arthrosis is a chronic-degenerative medical condition, appearing insidiously, developing over time and causing progressive degeneration of the joints (a joint is formed of two or more joint "heads", cartilage, ligaments, a synovial membrane, a joint capsule, tendons and muscles), limiting joint motility

increasingly over time. Arthrosis mainly causes progressive deterioration of cartilage (which is not capable of re-forming) and bone, with secondary deformation of the same, and production of excrescences, called "osteophytes", which mechanically obstruct joint movement; it also causes the joint capsule to thicken and stiffen, which together with contraction of the muscles surrounding the joint limits the "joint excursion" even further.
Tens therapy can lessen the pain caused by this condition, but cannot cure it!
Tens (Tens 1) can be combined with stimulation of the area to be treated using a low-frequency current (Tens 2) to relax the surrounding muscles.

Pathology	Program	No. of treatments	Treatment frequency	Position of electrodes
Arthrosis	TENS 1+ TENS 2	Until pain is lessened	Daily (TENS1 up to 2/3 times a day, TENS 2 once a day)	On the painful area
Neck pain	TENS 5	10/12	Daily, even twice a day	Photo 25
Cervicogenic headache	TENS 5	10/12	Daily, even twice a day	Photo 25
Back pain	TENS 6	10/12	Daily	Photo 25 but with all electrodes placed 10 cm lower
Backache	TENS 6	12/15	Daily	Photo 27
Sciatic pain	TENS 6	15/20	Daily, even twice a day	Photo 28
Cruralgia	TENS 6	15/20	Daily, even twice a day	Photo 18 with all electrodes placed on the inside of the thigh
Epicondylitis	TENS 12	15/20	Daily, even twice a day	Photo 29
Hip pain	TENS 1	10/20	Daily, even twice a day	Photo 30
Knee pain	TENS 1	10/20	Daily, even twice a day	Photo 31
Ankle sprain	TENS 3	5/7	Daily, up to 2/3 times a day	Photo 32
Carpal tunnel syndrome	TENS 1	10/12	Daily, even twice a day	Photo 33
Trigeminal neuralgia	TENS 1	10/12	Daily	Photo 24
Wryneck	TENS 1 + TENS 9	8/10	Daily, even twice a day	Photo 25
Periarthritis	TENS 14	15/20	Daily	Photo 26

Important: for all of these programs, stimulation intensity must be set between the threshold of impulse perception and the moment in which the impulse starts to cause discomfort. With the

exception of the "periarthritis" program, the muscles surrounding the area to be treated must not contract, they should only produce slight "vibrations".

REHA Programs

Prg.	PHASE 1	PHASE 2	PHASE 3
R1	Total time 30 min frequency 800 Hz impulse width 100µs		
R2	Total time 30 min frequency 1000 Hz impulse width 100µs		
R3	Total time 30 min frequency 1200 Hz impulse width 100µs		
R4	Total time 30 min frequency 90 Hz impulse width 20µs		
R5	Total time 30 min (5 sec 30 Hz – 200 us + 5 sec 50 Hz – 150 us + 5 sec 100 Hz – 120 us) x 120 cycles		
R6	Total time 30 min (6 sec 100Hz – 175 us + 6 sec 2-100Hz modulated – 250 us + 6 sec 150Hz – 60-200 us)		
R7	Total time 30 min (6 sec 100Hz – 175 us + 6 sec 2-100Hz mod modulated – 250 us + 6 sec 150Hz – 60-200 us modulated)		
R8	Total time 30 min frequency 2 Hz impulse width 80 us Burst impulses		
R9	Total time 4 min frequency 6 Hz impulse width 250us	Total time 10 min (10 sec 3Hz – 250us 80% + 5 sec 20Hz – 250us 80%) x 40 cycles	Total time 10 min (10 sec 3Hz – 250us 80% + 5 sec 30Hz – 250us 80%) x 40 cycles
R10	Total time 4 min frequency 6 Hz impulse width 250us	Total time 15 min (10 sec 3Hz – 250us 80% + 5 sec 40Hz – 250us 80%) x 40 cycles	Total time 10 min (10 sec 3Hz – 250us 80% + 5 sec 50Hz – 250us 80%) x 40 cycles

REHA 1-2-3 • Ionophoresis 1-2-3

The intensity must be strong enough to produce a relevant perception, near pain, till the muscles surrounding the area treated begin to contract.

Electrodes position: place the electrode with the drug on painful area and the other electrode on the opposite side.

Channel 2 is disconnected.

REHA 4 • Microcurrent

The use of microcurrent is very similar to conventional Tens, the only difference being the very fine electric impulse used that is sometimes more suitable for the sensibility of slightly anxious people or the more delicate parts of the body.

It can generally be applied for everyday pains, bearing in mind that you should always consult your doctor to identify the cause of the pain.

It is considered a good all-purpose analgesic current, as it does not have any side effects (except slight skin redness after long applications), and has very few contraindications (those specified in the paragraph at the beginning).

Program duration: 30 minutes. Intensity set above the threshold of perception.

Position of electrodes: above the painful area as shown in illustration 1.

REHA 5 • Hematomas

Consult a doctor before using this program to treat hematomas. Total program duration: 30 minutes. Few applications carried out within a few hours of the bruise. A combination of various types of square-wave impulses has a graduated draining effect on the area to be treated (impulses at different frequencies drain the area at different depths). The intensity should be adjusted to a level between the thresholds of perception and pain, without causing muscle contraction:

Position of electrodes: form a square above the area to be treated as shown in illustration 1.

REHA 6 • Oedema

Program similar to REHA 5. Intensity should be adjusted to a level between the thresholds of perception and pain without muscle contractions.

Position of electrodes: form a square above the area to be treated as shown in illustration 1.

REHA 7 • TENS sequential

During stimulation, this program modifies by itself the frequency and impulse width. This results in a more comfortable stimulation compared to the one with constant frequency and width impulse.

Program indicated for pain treatment and massage effect on muscles as trapezium.

Position of electrodes: form a square above the area to be treated as shown in illustration 1.

REHA 8 • TENS Burst

This program produces a TENS training effect using the frequencies of conventional TENS. Useful for pain therapy. The action is similar to the one of endorphinic TENS.
Position of electrodes: form a square on the painful area as shown in illustration 1.

REHA 9 • Atrophy prevention

Program created to maintain muscle trophism.

This treatment concentrates on muscle toning, paying particular attention to slow-twitch fibres. Particularly indicated for patients recovering from an accident or an operation. Prevents the reduction of muscle trophism caused by physical inactivity. The muscle area concerned can be stimulated with daily applications of medium intensity; if you increase the intensity, leave a day of rest between applications to allow the muscles to recover. The intensity of this program must be adjusted to produce good muscle contraction in the area treated. Position of electrodes from photo 1 to photo 20.

Program duration: 24 minutes.

REHA 10 • Atrophy

This program acts selectively on slow-twitch fibers. Ideal for recovering muscle trophism after a long period of inactivity or an accident.

Program to be carried out when loss of muscle tone has already occurred. Apply with caution (at low intensity, enough to produce light muscle contractions) in the first 2/3 weeks. Increase intensity progressively over the next 3/4 weeks. Application on alternate days. Position of electrodes from photo 1 to photo 20.

Program duration: 29 minutes.

MEM Programs

Prg.	PHASE 1
M1-M5	TENS Free memories Total time 1-90 min frequency 1-200 Hz impulse width 20-250 µs
M6-M10	NEMS Free memories Total time 1-90 min frequency 1-200 Hz contraction time 1-10 sec slope 0-5 sec Recovery time 0-30 sec impulse width 50-450µs
M11-M12	NEMS Free memories alternate channel 1 and 2 Total time 1-90 min frequency 1-200 Hz contraction time 1-10 sec slope 0-5 sec Recovery time 0-30 sec impulse width 50-450µs
M13	Battery Test

M1-M5 • TENS Free memories

Free memories for antalgic TENS treatment.

M6-M10 • NEMS Free memories

Free memories for muscle recovery and training.

M11-M12 • NEMS Alternated free memories

Free memories for muscle recovery and/or training with alternated impulses on channel 1 and 2.

M13 • Battery test program (only for I.A.C.E.R. assistance centre)

Program for battery test.

Maintenance

Battery charging

Display will show low battery indicator  only when battery is low**.** In this case it may not be possible to undertake the therapy session, or not being able to complete it.
To proceed with the charging follow the steps below:

- Make sure that the device is switched off or switch off the device pressing the ⏻/OK button;
- Connect the battery charger to the plug of the unit and connect the battery charger into the power socket.

The display will show the battery blinking icon. After 4 hours the recharge automatically finishes and the display shows the recharge total time.
At the end of battery charging, disconnect the charger from power supply and store it in the carriage bag.

Battery replacement

To proceed with battery replacement follow the steps below:

- Remove the clip belt;
- Open the battery compartment;
- Disconnect the cable and take away the battery;
- Connect the cable of the new battery;
- Close the battery compartment and insert the belt clip.

It is recommended to remove the battery in case of prolonged inactivity.
Batteries have to be handled by adult persons: keep them out of children's reach.
Dispose the battery according to the current regulations.

ATTENTION: the life of the battery depends on the number of charge/recharge cycles.
We suggest the following precautions for a battery longer duration:

- Recharge the battery once in a month even if the device is not used;
- Discharge the battery as much as possible before the recharging;
- Use only the original battery charger or in any case the battery charger supplied by the fabricant/distributor. Not open or modify the battery charger.

Cleaning

Clean the equipment from the dust using a soft cloth.
Resistant stains can be removed using a sponge soaked in solution of water and alcohol.
Device not subjected to sterilization.

Carriage and storage

Precautions for transportation
MIO-IONOTENS is a portable device, so it does not need any particular carriage precautions.

However we recommend to put away MIO-IONOTENS and its accessories in their own bag after every treatment.
Storage precautions
MIO-IONOTENS is protected till following environmental conditions:
In operation

Temperature	from +5 to+ 40 °C
Rel. humidity	from 30 to 75%
Pressure	from 700 to 1060 hPa

Inside of the packaging

Temperature	from –5 to +55 °C
Rel. humidity	from 10 to 90%
Pressure	from 700 to 1060 hPa

Disposal

The equipment is subjected to WEEE regulations (see the symbol  on the label) concerning separate waste collection: when disposing this product, please use the designed areas for disposing

electronic waste or contact the manufacturer.

Troubleshooting

If it is used in accordance with the instructions of the user manual, MIO-IONOTENS does not need a particular regular maintenance.
If you find any malfunctioning using MIO-IONOTENS, please follow these instructions:

- **MIO-IONOTENS does not turn on and/or the display does not light up.** Check the battery status and replace it if it is necessary (make reference to chapter "Battery replacement"). If the problem persists contact the manufacturer.
- **MIO-IONOTENS does not transmit electric impulses**. Check that the cable jacks have been inserted in the electrodes and that the plastic protection has been removed from the electrode. Check that the cables have been connected correctly (connector well inserted in the device). Check that the cables and the electrodes are not damaged. If the problem persists contact the manufacturer.
- **MIO-IONOTENS transmits low intensity or intermittent impulses.** Check the cables and the electrodes are in good condition and replace them if it is necessary. If the problem persists contact the manufacturer.
- **MIO-IONOTENS switches off during the operation**. It is suggested to replace the battery and start a new treatment. If the problem persists contact the manufacturer.
- **MIO-IONOTENS does not allow the intensity adjustment or not keep the adjusted value and reset.** It is suggested to replace the battery and start a new treatment. If the problem persists contact the manufacturer.

Assistance

Every intervention on device must be performed by manufacturer. For any assistance intervention contact the National Distributor or the manufacturer at the following address:

I.A.C.E.R. S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel. 041.5401356 • Fax 041.5402684

Technical documentation concerning the spare parts can be supplied by the manufacturer but only prior business authorization and specific training.

Spare parts

For original spare parts contact the National Distributor or the manufacturer at following address:

I.A.C.E.R. S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel. 041.5401356 • Fax 041.5402684

To preserve product warranty, functionality and product safety we recommend to use only original spare parts.

Warranty

Make reference to the national laws for any warranty conditions by contacting the national distributor (or directly the manufacturer IACER).

EMC Tabels

Electromagnetic emission		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions 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 emissions Cispr 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic immunity			
The device is inteded for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in suche environment			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%
Mains power electromagnetic field EN 61000-4-8	3 A/m	3 A/m	Mains power quality should be at that of a typical commercial or hospital environment

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such environment			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \cdot \sqrt{P}$ 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ 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 metres (m).
RF Radiata EN 61000-4-3	3 Vrms 80MHz to 2,5GHz	3 Vrms 80MHz to 2,5GHz	
Field strangths from fixed RF transmitters, are determined by an electromagnetic site survey, should be less than the complicance level in each frequency rage. Interference may occur in the vicinity of equipment marked with the following symbol: 			
Recommended separation distances between portable and mobile communications equipment and the device			
The device is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.			

Rated maximum power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	150kHz to 80MHz d = 1,2 ·√P	80MHz to 800MHz d = 1,2 ·√P	800MHz to 2GHz d = 2,3 ·√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Note:
(1) At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Tel +39 041 5401356 - Fax +39 041 5402684

Sede legale:
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