I-TECH
MEDICAL DIVISION

USER MANUAL

MNPG152 Rev. 03 03/07/15

Electrotherapy model

MIO-PERISTIM

I-TECH
MEDICAL DIVISION

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-PERISTIM is manufactured in conformity with Council Directive 93/42/EEC (MDD) dated 14 June 1993 (D. Lgs. 46/97 dated 24 February 1997 "Implementation of Directive"93/42/CEE concerning medical devices), 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-PERISTIM 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

Classifications

MIO-PERISTIM 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 when mixed with air or with oxygen or with nitrous oxide;
- Continuous operating mode equipment;
- Equipment not suited to be used in external.

Purpose

Clinical purpose: Therapeutic
Scope of use: ambulatory and domestic

MIO-PERISTIM is a stimulator designed and engineered for the treatment of pathologies affecting urogenital system, like urinary or faecal incontinence.

The treatment of incontinence is possible using protocols with specific waveforms, frequency and impulse width. A probe (vaginal probe for urinary incontinence in women, anal probe for faecal incontinence both for men and women) transmits the impulses to pelvic floor muscles or to sphincter, causing the contractions and strength recovery.

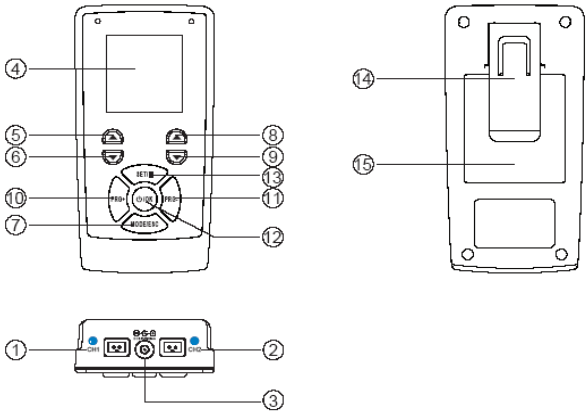
Thanks to its TENS protocols, MIO-PERISTIM is particularly suitable for pain therapy. TENS impulses can reduce and, in many patients, eliminate the pain generated from pathologies affecting muscles and tendons.

Technical specifications

Power supply	Rechargeable batteries 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
Dimension (mm)	140x70x30
Max output current	40mA, 1KΩ load for channel in REHA programs
	99mA, 1KΩ load each channel for the remaining programs
Waveform	Biphasic compensated square wave and monophasic square wave
Waveform frequency (Hz)	From 1 to 200
Impulse width (μs)	From 20 to 450
Timer	From 1to 90 minutes

WARNING. The equipment delivers current in excess of 10mA

Labelling



(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

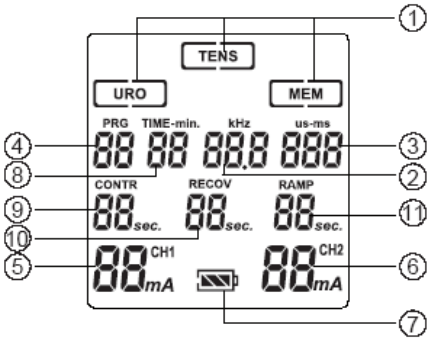
(11) Decrease program

(12) ON/OFF and OK button

(13) Set programs and therapy pause button

(14) Belt clip

(15) Battery compartment



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

(2) Wave frequency

(3) Wave impulse width

(4) Program number

(5) CH1 intensity

(6) CH2 intensity

(7) Battery status

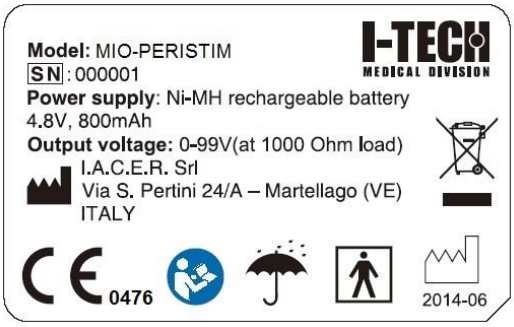
(8) Therapy time

(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
	Follow the instructions
	Applied part type BF
CE 0476	Compliance with Directive 93/42/EEC (MDD) (and following modifications)
	Manufacturing date (month/year)

Kit contents

n° 1 MIO-PERISTIM;
n° 1 battery pack;
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 belt clip;
n° 1 carry bag;
n° 1 User manual.
n° 1 electrodes position manual
n° 1 optional accessory:

- n° 1 anal probe;
- n° 1 vaginal probe;

How to use

Warnings

- Take care of position and meaning of the labels on MIO-PERISTIM;

- Do not damage connection cables and avoid to roll up the cable 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 the device to people not educated through the reading of the manual;
- Do not use MIO-PERISTIM 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 provided by the 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 produce and receive any interferences from others equipment. However it is recommended the use of the device at least 3 metres away from televisions, monitors, mobile phones or any other electronic equipment.

Contraindications

Patient in pregnancy, tuberculosis, juvenile diabetes, viral (in acute phase) illnesses, mycosis, dermatitis, cardiopathic subjects, serious arrhythmias or pacemaker carriers, children, metallic prosthesis carriers, acute infections, epileptics (different medical prescriptions excepted).
No significant side effects are known of. Some particularly sensitive people have reported skin redness in the area where the electrodes were positioned: the redness usually disappears a few minutes after the end of the treatment. Should the redness persist please consult a doctor.
In rare cases, stimulation carried out in the evening can cause some people to experience difficulty in falling asleep. If this occurs, suspend the treatment and consult a doctor.

How to use

MIO-PERISTIM is a portable and battery-powered device that generates TENS and perineal rehabilitation currents. It is particularly indicated for muscle pain and for the treatment of urinary and faecal incontinence. MIO-PERISTIM has two independent channels adjustable by the user.
MIO-PERISTIM has 14 stored TENS programs, 9 URO programs and 12 free memories that can be adjusted by the user to create programs according to specific needs. MEM 13 program is for battery test.

PRELIMINARY INSTRUCTIONS

1. ELECTRODES AND CABLES CONNECTION

Place the electrodes on the skin near the painful area (see next chapter for details), connect the electrodes to the cables and then connect the cables to CH1 and CH2 outputs on the upper side of MIO-PERISTIM;

2. SWITCHING ON

   Switch on the device pressing ⏻/OK button;

STORED PROGRAMS

Read the following instructions if you want to use stored programs on MIO-PERISTIM.

1. PROGRAM SELECTION
   Press MODE button to select the treatment (TENS, URO, MEM). Select the program using PRG+ e PRG – buttons (for the features of each program, make reference to the paragraph "List of Programs");
2. INTENSITY ADJUSTEMENT
   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-PERISTIM 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-PERISTIM. 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.

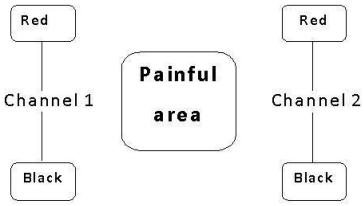
FREE MEMORIES (ADJUSTABLE PROGRAMS)

With MIO-PERISTIM 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 pelvic rehabilitation

For TENS programs, the intensity should be adjusted to a level between the thresholds of perception and pain. The maximum limit is reached when the muscles surrounding the area treated begin to contract. It is best to stay below that limit.
The electrodes should be positioned to form a square surrounding the painful area using Channel 1 and Channel 2 as shown in illustration 1.



⚠ WARNING

Create a square area with the electrodes, over the painful zone. Keep 4cm minimum distance between electrodes.

Regarding the use of probes for vaginal and anal stimulation, follow these simple steps:

- After connecting the cables to the probe electro stimulation, grease it lightly with suitable lubricants can be purchased at the pharmacy on the advice of your pharmacist / doctor in order to facilitate the introduction into the vagina or anus;
- Lay back and eventually take the gynaecological position with a pillow under your lower back. In any case, the best position to take is the one that creates less discomfort and annoyance, also in consideration of the fact that it must be maintained throughout the treatment time (maximum 30 minutes).
- Carefully insert the probe into the vagina or anus, taking care to place it at least up to two golden rings before starting the stimulation.

As reported in the tables relating to the programs, we advise you to associate with electro stimulation therapy appropriate training exercises that help the recovery of strength and muscle tone of the pelvic floor muscles.

It is precisely the weakening of the muscles that leads to the onset of disorders such as urinary incontinence and urogenital prolapse. Strengthening this muscle produces incredible improvements in symptoms of urinary incontinence and genital prolapse also blocking the advance of dysfunction. The pelvic floor rehabilitation must be the first line treatment in women with stress incontinence.

It is important to stress that these exercises should be taught to the patient by a specialist (doctor, physiotherapist, midwife). This exercise involves the contraction of the vaginal and anal muscles without the use of the abdominal muscles and buttocks. The exercises are then repeated in different patterns always follow the doctor's orders.

Programs List

TENS		URO		MEM	
1	Conventional TENS (rapid)	1	Stress urinary incontinence and fecal 1	1	Free TENS 1
2	Endorphinic Tens	2	Stress urinary	2	Free TENS 2

	(delayed)		incontinence 2		
3	TENS at maximum values	3	Stress urinary incontinence 3	3	Free TENS 3
4	Anti-inflammatory	4	Urinary and fecal incontinence by urge 1	4	Free TENS 4
5	Neck pain/headache	5	Urinary incontinence by urge 2	5	Free TENS 5
6	Backache/sciatic pain	6	Urinary incontinence by urge 3	6	Free NEMS 1
7	Sprains / Bruises	7	Mixed urinary incontinence and fecal 1	7	Free NEMS 2
8	Vascularization	8	Mixed urinary incontinence 2	8	Free NEMS 3
9	Muscle relaxant	9	Mixed urinary incontinence 3	9	Free NEMS 4
10	Hand and wrist pain			10	Free NEMS 5
11	Plantar stimulation			11	NEMS alternated 1
12	Epicondylitis			12	NEMS alternated 2
13	Epitroclea			13	Battery test
14	Periarthritis				

Program Technical Specifications

TENS programs

Prog.	PHASE 1	PHASE 2	PHASE 3
T1	Total time 40 min frequency 90 Hz impulse width 50µs		
T2	Total time 30 min Frequency 1 Hz impulse width 200µs		
T3	Total time 3 min Frequency 150 Hz impulse width 200µs		
T4	Total time 30 min Frequency 120 Hz impulse width 50µs		
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	Total time 20 min Frequency 60 Hz	

	impulse width 50µs	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 cycle

TENS 1 • Conventional Tens

Program used to relieve pain; its action is to induce a body block pain at a spinal level, as claimed by the "gate theory" of Melzack and Wall. The pain impulses that start at a given point of the body (such as a hand) run through the nerve pathways (via nerve fibers of small diameter) to reach the central nervous system where the impulse is interpreted as pain. The conventional TENS activates nerve fibers of large diameter, at the spinal level, blocking the path of the fibers of small diameter. And 'therefore an action primarily on symptom: To further simplify the occluded is the thread that carries the information of pain.

The duration of treatment should not be less than 30/40 minutes. The conventional TENS is a current that can be used in the treatment of daily pain in general. The number of treatments required for an average experience of the benefits is 10/12 on a daily basis (no contraindication to double the dose).

The program has a duration of 40 minutes in a single step. In case of persistent pain particularly, at the end of a session to repeat the program. For the particularity of the pulse, during treatment you may experience an effect of "addiction" that he will feel less and less impulse to counteract this effect, it is sufficient, as needed, to increase the intensity level.

Location :: electrodes form a square above the painful area as Figure 1.

TENS 2 • Endorphinic TENS

This type of stimulation produces two effects in relation to the placement of the electrodes by placing the electrodes in the dorsal area with reference photos of the 08 positions manual, promotes the production of endogenous morphine-like substances that have the ability to raise the threshold of pain perception; positioning electrodes forming a square over the painful area as Figure 1, produces an effect vascularizing. The action of vascularization produces an increase in blood flow resulting in a positive effect on the removal of substances algogenic and a restoration of normal physiological conditions.

Duration of treatment 30 minutes in a single stage, daily frequency.

Do not place the electrodes in close proximity to areas prone to inflammation.

Intensity adjusted so as to produce a good part of the stress-stimulated, the feeling must be similar to a massage.

TENS 3 • TENS at maximum values

Very short duration, 3 minutes. It inhibits pain impulses peripherally causing a real local anesthetic effect. It 'a suitable type of stimulation in situations of trauma or bruising where you need to intervene quickly. The intensity selected is the maximum tolerable (well beyond the limits of conventional TENS, so with conspicuous contraction of the muscles surrounding the treated area). For this reason, this stimulation is certainly the least tolerated, but very effective. It is a type of stimulation that is not recommended for people who are particularly sensitive, and in any case to avoid placing the pads in sensitive areas like the face, genitals, near wounds.

Location electrodes forming a square over the painful area as Figure 1.

TENS 4 • Anti-inflammatory

Recommended program in inflammatory states. Application to the reduction of the inflammatory state (10-15 applications 1 time per day, with the possibility of doubling the daily treatments). Having identified the part to be treated as square to place the electrodes Fig. 1. The intensity should be adjusted so as to produce a slight tingling on the treated area, avoiding the contraction of the surrounding muscles.

Duration of program: 30 minutes.

TENS 5 • Neck pain/headache

Specific program for the treatment of pain in the cervical area. Duration 35 minutes.

Intensity adjusted between the perception threshold and the threshold of pain: the maximum intensity is represented by the time when the musculature surrounding the treated area begins to contract; beyond this limit the stimulation does not increase its effectiveness but only the sense of annoyance, so it's good to pause before this threshold. The number of treatments to achieve the initial benefits is between 10 and 12 daily, continue in treatment until the symptoms have disappeared. Position of electrodes: photo n ° 25.

Note: During the program the unit varies the parameters of stimulation. You may have feelings of current different: what is normal and expected in the software: To raise or decrease the intensity according to their sensitivity to reach the comfort of their own stimulation.

TENS 6 • Backache/sciatic pain

Specific program for the treatment of pain in the lumbar area or along the sciatic nerve, or both. Intensity adjusted between the perception threshold and the threshold of pain: the maximum intensity is represented by the time when the musculature surrounding the treated area begins to contract; beyond this limit the stimulation does not increase its effectiveness but only the sense of annoyance, so it's good to pause before this threshold. The number of treatments to achieve the initial benefits is between 15 and 20 daily, continue in treatment until the symptoms have disappeared. Duration of program: 40 minutes.

Position of electrodes: refer to the picture of the positions 27 and 28.

TENS 7 • Sprains / Bruises

After this type of injury, the program develops its effectiveness with a pain inhibitory action at the local level, producing three different pulses with selective action. Intensity adjusted from the perception threshold and pain threshold. Programme duration 30 minutes.

Number of treatments: up to pain reduction, on a daily basis (even 2/3 times a day).

TENS 8 • Vascularization

Vascularizing produces an effect in the treated area. The action vascularizing produces an increase in blood flow resulting in a positive effect on the removal of substances algogenic and a restoration of normal physiological conditions. Do not place the electrodes in close proximity to areas prone to inflammation.

The frequency of application is suggested daily, the number of applications is not defined; the program can be used to reduce the pain itself.

The intensity of stimulation suggested should be between the perception threshold and the threshold of slight discomfort.

Duration of program: 20 minutes.

Position of electrodes: refer to the picture of the positions from 25 to 33 photos.

TENS 9 • Muscle relaxant

Program shown to accelerate the process of functional recovery of the muscle after an intense workout or an effort to work; performs an immediate action. Intensity adjusted so as to produce a discrete solicitation muscle. Two daily treatments for three or four days. Programme duration 30 minutes. Position of electrodes: photos from 1 to 28.

TENS 10 • Hand and wrist pain

This program is recommended in case of pains of various kinds to the hand and wrist soreness stress, arthritis in the hand, carpal tunnel, etc.. Total duration of 40 minutes. Combining different types of pulse square wave produces a generalized analgesic action on the area to be treated (pulses at different frequencies stimulate the nerve fibers of different caliber favouring the inhibitory action at the spinal level). Intensity adjusted from the perception threshold and the pain threshold without producing muscle contractions.

Location electrodes forming a square over the area to be treated as in Figure 1.

TENS 11 • Plantar stimulation This program is able to produce a relaxation effect and draining along the limb stimulated. Ideal for people who suffer from "heavy legs".

The duration is 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 near the toes of one foot, the other under the heel

TENS 12 • Epicondylitis

Also known as "tennis elbow" is an insertional tendinopathy involving the insertion of the bone of the elbow epicondylar muscles which are those that allow the extension (bending backwards) of the fingers and wrist. 15 applications once a day (even 2 times), until disappearance of the symptoms. In general it is advisable to consult your doctor to check the precise source of pain, in order to avoid the recurrence of the disease.

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

Position of electrodes: photo 29.

TENS 13 • Epitroclea

Also known as "golfer's elbow", affecting not only golfers but also those who perform repetitive tasks that involve frequent or intense efforts (for example, carry a very heavy suitcase). You feel pain in the tendons and flexor pronator inserted sull'epitroclea. It's a pain that is felt when bending or prone wrist against resistance, or when clutches a hard rubber ball. 15 applications once a day (even 2 times), until disappearance of the symptoms. In general it is advisable to consult your doctor to check the precise source of pain, in order to avoid the recurrence of the disease.

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

Location electrodes: photo 29 but with the electrodes all moved toward the inside of the arm (with a rotation of about 90 °).

TENS 14 • Periarthritis

The humeral periarthritis is an inflammatory disease that affects the tissues surrounding the joint fibrous type: tendons, connective tissue and serous bags. These appear altered and fragmented and may calcify. It is a disease which, if left untreated, it can become very disabling. For this reason, after running a cycle of 15/20 applications once a day, to reduce the pain, you may want to start a cycle of rehabilitation consists of exercises specific consulting your doctor.

The program is composed of various steps including the steps of TENS and muscle stimulation in order to improve the tone of the muscles surrounding the joint.

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

ARTHROSIS

Arthrosis time and causing a progressive degeneration of the joints (joint is formed by two or more "heads" of bone, cartilage, ligaments, synovial membrane, articular capsule , tendons and muscles), thus causing a limitation of increasing joint mobility. The main action of osteoarthritis is to cause a progressive deterioration of cartilage (which is not able to reform) and bone, with secondary deformation of the same and manufacture of growths, called "osteophyte", which mechanically hinder the movement articulate; it also causes a thickening and stiffening of the joint capsule, which, together with the contraction of the muscles around the joint, further contribute to the limitation of "'range of motion".

TENS is a treatment that soothes the pain caused by this disease, but it is not a therapy practitioner!

Together with the TENS (TENS 1) can stimulate the area to be treated with a low-frequency current (TENS 2) in order to cause a de-contraction of the muscles

Pathology	Program	Number of treatment	Frequency Treatment	Electrodes position
Arthrosis	TENS 1+ TENS 2	Up to pain reduction	Dayily (TENS1 up to 2/3 times per day, TENS 2 daily)	On the painful area
Neck pain	TENS 5	10/12	Once or twice a day	Picture 25
Cervicogenic headache	TENS 5	10/12	Once or twice a day	Picture 25
Back pain	TENS 6	10/12	Daily	Picture 25 but with all electrodes placed 10 cm lower
Backache	TENS 6	12/15	Daily	Picture 27
Sciatic pain	TENS 6	15/20	Once or twice a day	Picture 28
Cruralgia	TENS 6	15/20	Once or twice a day	Picture 18 with all electrodes placed on the inside of the thigh

Epicondylitis	TENS 15	15/20	Once or twice a day	Picture 29
Hip pain	TENS 1	10/20	Once or twice per day	Picture 30
Knee Pain	TENS 1	10/20	Once or twice a day	Picture 31
Ankle sprain	TENS 3	5/7	Daily, up to 2/3 times a day	Picture 32
Carpal Tunnel	TENS 1	10/12	Once or twice a day	Picture 33
Trigeminal neuralgia	TENS 18	10/12	Daily	Picture 24
Wryneck	TENS 1 + TENS 9	8/10	Once or twice a day	Picture 25
Periarthritis	TENS 17	15/20	Daily	Picture 26

Important: In all of these programs, the stimulation intensity to be adjusted between the perception threshold of the pulse and the time when the impulse begins to cause discomfort. With the exception of the "periarthritis" the muscles surrounding the treated area should not shrink but only produce slight "vibrations".

URO PROGRAMS

Prg.	Phase 1
U1	Total time 25 min Frequency 40 Hz Impulse width 180µs contraction / recovery 3/7 sec
U2	Total time 25 min Frequency 45 Hz Impulse width 180µs contraction / recovery 6/9 sec
U3	Total time 25 min Frequency 50 Hz Impulse width 180µs contraction / recovery 8/12 sec
U4	Total time 30 min Frequency 8 Hz Impulse width 180µs
U5	Total time 25 min Frequency 10 Hz Impulse width 180µs
U6	Total time 25 min Frequency 12 Hz

	Impulse width 180µs
U7	Total time 25 min Frequency 20 Hz Impulse width 180µs contraction / recovery 3/7 sec
U8	Total time 25 min Frequency 22 Hz Impulse width 180µs contraction / recovery 6/9 sec
U9	Total time 25 min Frequency 25 Hz Impulse width 180µs contraction / recovery 8/12 sec

URO 1-2-3 • Stress urinary incontinence and faecal

Programs suitable for the treatment of stress urinary incontinence in women and faecal humans (only U1), designed to strengthen and tone the muscles of the pelvic floor and perineal who have lost force and contractile capacity, or the sphincter muscles with weak contractile capacity. The stimulation should be as strong as possible without being painful. In addition, it helps a patient's participation in acts voluntary muscle during stimulation. It is suggested to be associated with the appropriate therapy training exercises for strengthening the muscles themselves. Applications: 3-5 sessions per week. Use the vaginal probe for the treatment of urinary incontinence in women and anal probe for faecal incontinence in both men and women.

URO 4-5-6 • Urge urinary incontinence and faecal

This program is suitable for the treatment of urge incontinence in women and faecal humans (only U4). Low frequency stimulation that helps to relax the bladder in case of hyperactivity. The stimulation should be as strong as possible without being painful. In addition, it helps a patient's participation in acts voluntary muscle during stimulation. Applications: 2-5 sessions per week. Use the vaginal probe for the treatment of urinary incontinence in women and anal probe for faecal incontinence in both men and women.

URO 7-8-9 • Mixed urinary incontinence and faecal

Programs suitable for the treatment of urinary incontinence in women and mixed faecal humans (only U7). The stimulation should be as strong as possible without being painful. In addition, it helps a patient's participation in acts voluntary muscle during stimulation. It is suggested to be associated with the appropriate therapy training exercises for strengthening the muscles themselves. Applications: 3-5 sessions per week. Use the vaginal probe for the treatment of urinary incontinence in women and anal probe for faecal incontinence in both men and women.

MEM Programs

Prog.	PHASE 1
M1-M5	Free memories TENS Total time 1-90 min

	Frequency 1-200 Hz Impulse width 20-250 µs
M6-M10	Free memories NEMS Total time 1-90 min Frequency 1-200 Hz Contraction time1-10 sec slope 0-5 sec recovery time 0-30 sec Impulse width 50-450µs
M11-M12	Free memories NEMS alternated on channel 1 and 2 Total time 1-90 min Frequency 1-200 Hz Contraction time11-10 sec slope 0-5 sec recovery time 0-30 sec Impulse width 50-450µs
M13	Battery test program

M1-M5 • TENS Free memories

Free memories for antalgic TENS treatment.

M6-M10 • NEMS Free memories

Free memories for muscle recovery and / or training.

M11-M12 • NEMS Alternated Free memories

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

Carriage precautions
MIO-PERISTIM is a portable device, so it does not need any particular carriage precautions.
However we recommend to put away MIO-CARE PRO and its accessories in their own bag after every treatment.

Storage precautions
MIO-PERISTIM is protected till following environmental conditions:
In operation

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

Inside of the packaging

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

Information for 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-CARE PRO does not need a particular regular maintenance.
If you find any malfunctioning using MIO-CARE PRO, please follow these instructions:

- **MIO-PERISTIM 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-PERISTIM 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-PERISTIM 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-PERISTIM 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-PERISTIM 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 Tables

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 sholud be wood, concrete or ceramic tile. If floor are covered with syntethic 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 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**
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 $d = 1,2 \cdot \sqrt{P}$	**80MHz to 800MHz** $d = 1,2 \cdot \sqrt{P}$	**800MHz to 2GHz** $d = 2,3 \cdot \sqrt{P}$
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

I.A.C.E.R S.r.l.
Sede operativa:
30030 Martellago (VE) - Via. S. Pertini 24/A
Tel +39 041 5401356 - Fax +39 041 5402684

Sede legale:
S. Marco 2757 - 30124 Venezia
Cod. Fisc./P.IVA IT 00185480274
R.E.A. VE N. 120250 - M. VE001767
Cap.Soc. € 110.000,00 i.v.
www.iacer.it - iacer@iacer.it