USER MANUAL

Electrotherapy

MIO-PERISTIM

I.A.C.E.R. Srl
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R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.

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Manufacturer

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

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IACER S.r.l. is an Italian manufacturer of medical devices (certified CE n° 0068/QCO-DM/234-2020 from the Notified Body n° 0068 MTIC InterCert S.r.l.).

Declaration of conformity

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

Via Enzo Ferrari, 2 – 30037 Scorzè (Ve), Italia

herewith declares under its own responsibility, that the product

MIO-PERISTIM

UMDNS Code**: 13762**

has been designed and manufactured according to the European Medical Device Directive 93/42/EEC (transposed in Italy by the D.Lgs. 46/97), as modified by the Directive 2007/47/EC (D.Lgs.37/2010) and further modifications/integrations.

The product has been assigned to class IIa, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bears the mark

CE 0068

0068 – MTIC InterCert S.r.l.

Via G. Leopardi 14, Milano (MI) 20123, Italia

Certified number: 0068/QCO-DM/234-2020

following the certification procedure according to Annex II (excluding point 4) of the Directive 93/42/EEC.

Scorzè, 31/01/2022 — *Place, date*

MASSIMO MARCON — *Legal Representative*

Classification

The MIO-PERISTIM has the following classification:

- class IIa (Directive 93/42/CEE, Annex IX, rule 9 and further amendments);
- class II with BF type applied part (classif. EN 60601-1);
- equipment protection level IP22 against liquid and dust penetration;
- equipment and accessories not subject to sterilization;
- equipment unsuitable for use in presence of a flammable anesthetic mixture containing air, oxygen and nitrous oxide;
- equipment suitable for continuous operation;
- equipment unsuitable for outdoors use.

Purpose and scope

Clinical intended use:	Therapeutic
Environmental intended use:	Ambulatory and home

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 of the stimulation. 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.
The patient population intended for electrotherapy treatment using the MIO-PERISTIM device includes patients of both sexes, men and women, of age (unless otherwise indicated by medical doctors). For further details, please refer to the Contraindications section.
The CE0068 mark is only for the medical programs (see the following paragraphs related to the detailed description of the programs).

Caratteristiche tecniche

Characteristics	Specifications
Power supply	Rechargeable batteries AAA Ni-MH 4.8V 800mAh

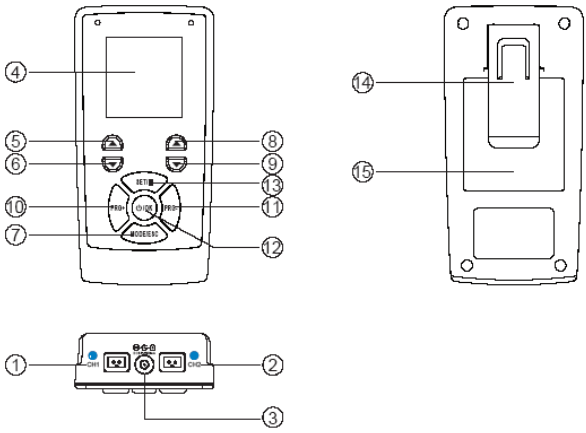
Characteristics	Specifications	
Recharger	power supply line AC 100-240V, 50/60Hz 200mA; Output DC 6.8V, 300mA max.*	
Isolation (EN 60601-1)	II	
Applied part (EN 60601-1)	BF	
Protection level	IP22	
Applied part to the patient	Electrodes	
Dimensions (length x height x depth)	260x176x60mm	
Weight main body	205gr including batteries	
Layout	ABS	
Number output channel	2 independent	
Functioning	Continuous	
Intensity	adjustable	
Max output current	99mA, 1KΩ load each channel in all the programs	
Impulse	Biphasic compensated square wave	
Frequency	From 1 to 200Hz	
Impulses's width	From 20 to 250μs	
Therapy	Time depending on the program (1-90 min)	
Display	Reflective and illuminated LCD display	
Command	ABS keyboard with 9 keys	
Conditions of use	Environmental temperature	From +5° to +40°C
	Relative humidity	From 30% to 75%
	Atmospheric pressure	From 700 to 1060hPa
Storage and transportation conditions	Environmental temperature	From -10° to +55°C
	Relative humidity	From 10% to 90%
	Atmospheric pressure	From 700 to 1060hPa

WARNING: the device has an output current over 10mA.

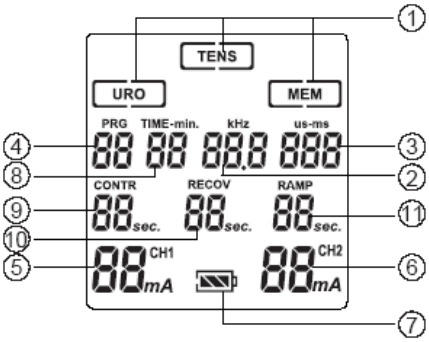
* Use only the battery recharger given by the manufacturer. The use of other recharger could seriously compromise the security and safety both of the patient and of the device.

Expected useful life of the device is set in 3 years, meanwhile the expected useful life of the electrodes is set in 10/15 uses.

Device and commands description

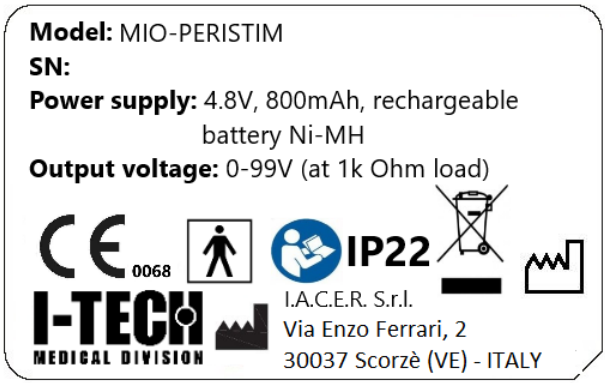


1. CH1 output
2. CH2 output
3. Battery charger connector
4. Display
5. Increase intensity CH1
6. Decrease intensity CH1
7. Mode operation button
8. Increase intensity CH2
9. Decrease intensity CH2
10. Increase program
11. Decrease program
12. ON/OFF and OK button
13. Set programs and therapy pause button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



1. Mode operation (TENS, URO, 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

Labels



Symbol	Description
	Manufacturer's logo.
	Product CE certification released by Notified Body n°0068.
	Applied part type BF according to EN 60601-1, 3rd edition.
	Manufacturer.
	Manufacturing date (YYYY-MM).
	Read instructions for use.
	The product must be disposed as "electronic waste", in accordance to WEEE Directive on waste electrical and electronic equipment.
IP22	Medical device protected against the penetration of solids (with a diameter *d≥12,5mm*) and against the vertical drops when the device is kept at 15° from its normal functioning position.
	Limits of relative humidity (relative humidity of the storage environment, on the package).
	Temperature humidity (temperature of the storage environment, on the package).

Packaging content

The MIO-PERISTIM pack contains:

- n° 1 MIO-PERISTIM device;
- n° 2 connection cables, for the transmission of electric impulses;
- n° 4 cable splitters;
- n° 1 packages containing 4 pre-gelled self-adhesive 41x41 mm electrodes (or 48x48mm);
- n° 1 packages containing 4 pre-gelled self-adhesive 40x80 mm electrodes (or 50x90mm);
- n° 1 battery pack (inside the device);

- n° 1 battery charger;
- n° 1 user manual;
- n° 1 user manual of the electrodes' positions;
- n° 1 bag for the transportation;
- n°1 anal probe;
- n°1 vaginal probe.

Introduction to the technology

MIO-PERISTIM is a portable generator of TENS and perineal rehabilitation currents. It is particularly indicated for muscle pain and for the treatment of urinary and faecal incontinence. 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. With MIO-PERISTIM, 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.

Contraindications

The device must not be used in presence of cancerous injuries in the area to be treated. The stimulation should not be applied to infected, swollen or inflamed areas and in case of rashes (phlebitis, thrombophlebitis, etc.), open wounds and dermatitis.
It is forbidden to use MIO-PERISTIM if the patient has a pacemaker, is cardiopathic, suffers from epilepsy, is a pregnant woman, is an anxious person, has severe disease, tuberculosis, juvenile diabetes, viral diseases (in the acute phase), mycoses of inguinal or abdominal hernias, carriers of magnetizable prostheses, acute infections, epileptics (except for different medical prescriptions). Do not use the device if the source of the pain is unknown or not diagnosed. **Use the device ONLY after having a diagnosis.** In the event of injury, muscle stress or any other health problem consult your doctor before using the device and only use it under medical supervision.

Side effects

No significant side effects are known. In some cases of particularly sensitive people, skin redness occurs at the electrodes after treatment: the redness normally disappears few minutes after treatment. If the redness persists, consult a doctor.
In some rare cases evening stimulation causes some difficulties in falling asleep. In this case, suspend the treatment and consult a doctor.

Warning

It is recommended:

- to control position and meaning of all the labels on the equipment;
- not to damage the connection cables to the electrodes and to avoid winding the cables around the device;
- to avoid the use of the device by persons who did not read carefully this manual. Keep the device away from children, it contains small pieces that could be swallowed;
- avoid use in damp environments;
- not to wear metal objects during treatment;
- to use the electrodes on clean and dry skin. When using the electrodes, follow the instructions given in the manual and on the package of the electrodes. Use only single-patient electrodes, supplied exclusively by the manufacturer, and take care to avoid the exchange of electrodes between different users. MIO-PERISTIM has been tested and guaranteed for the use only with the electrodes supplied by the manufacturer;
- to use ONLY accessories supplied by device manufacturer. Only use battery chargers supplied by the manufacturer; the use of battery chargers not supplied by the manufacturer will free the same from any responsibility related to damage to the equipment or user and will expose the user to risks such as short circuits and fire.

It is forbidden:

- to use the device in the presence of patient monitoring equipment, of electrosurgical (possible bruises and burns) or shortwave or microwave therapy equipment or other equipment that sends electrical impulses into the body and in general in combination to other medical devices, since it could cause problems to the stimulator;
- to use the device by persons known to be unsound-minded, or suffering from sensibility disorders, permanently or temporarily disabled unless assisted by qualified personnel (e.g. a doctor or therapist); by persons younger than 15 years old or not adequately educated about the device use by an adult person;
- to use the device close to flammable substances/gas/explosives, in environments with high concentrations of oxygen, with aerosol-therapy devices or in wet environments (use of the device is prohibited in bathroom or shower areas or while showering/bathing);
- to use the device in presence of signs of deterioration of the device itself, cables and accessories (electrodes, battery charger, etc.): please contact the dealer or the manufacturer following the instructions given in the

paragraph *Support*. Control carefully the integrity of the device before each use;

- to use the device while driving or during the operation and control of equipment/machinery;
- 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); however, electrodes can be positioned along the muscular fascia of the heart area, as used for pectoral strengthening. Danger of heart arrythmia;
- to position the electrodes 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;
- ***to position the electrodes on the carotid sinuses (carotid) or genitals, in particular in patient with a well-known sensibility on reflection of the carotid sinuses; to position the electrodes near genitals and in those areas that have poor sensibility;***
- ***to stimulate the thyroid or apply stimulation on the neck and mouth, as this stimulation could cause important muscle spasms that can obstruct the airways, creating difficulty in breathing and problems with the heart rhythm and blood pressure;***
- to use pointed or sharp objects on the device keyboard.

Warning:

- insufficiently sized electrode sections can cause skin reactions or burns;
- do not use damaged electrodes even if they well adhere to the skin;
- be sure that the electrodes well adhere 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;
- pay attention to use connection cables with children/young people: strangulation danger;
- do not mix connection cables up with earphones or other devices and do not connect the cable to other equipment;
- keep right distance between electrodes: the contact between electrodes could cause wrong stimulations or irritations/burns;
- ***stimulation intensity and electrodes position should be suggested by the prescriber doctor.***

The manufacturer considers himself responsible for the performances, reliability, safety and security of the device only if:

- any addition, modification and/or repair are carried out by authorized personnel;

- the environmental electrical installation to which MIO-PERISTIM is connected is compliant to the national laws;
- the instructions for use contained in this manual are strictly followed.

Should any foreign materials penetrate the device contact the retailer or manufacturer immediately. If dropped down, check that the housing is not cracked or damaged in any way; if so, contact the retailer or manufacturer.
Should you notice any changes in the device's performance during treatment, interrupt the treatment immediately and consult the retailer or manufacturer.


If the stimulation is uncomfortable decrease intensity. If the problem persists consult a doctor.


Some patients could suffer from skin irritation or oversensitivity due to stimulation or gel. If the problem persists, suspend the stimulation and consult a doctor.


Consult a doctor before using MIO-PERISTIM with metallic osteosynthesis devices.

IF YOU HAVE ANY DOUBTS REGARDING THE DEVICE USE CONSULT YOUR DOCTOR.

Patient preparation

Before using MIO-PERISTIM clean the skin of the area to be treated; with the cable disconnected from MIO-PERISTIM, connect the electrostimulation cable jacks to the self-adhesive electrodes; position the self-adhesive electrodes on the skin (see photos of electrode positions in the *Positions manual*); connect the impulse transmission cables to the relative jacks (Channel 1 and/or Channel 2), then turn MIO-PERISTIM on.
Splitting leads use: please use splitting leads if you want to double electrodes number for each channel. Connect the splitting cable jacks to the self-adhesive electrodes, with the cable disconnected from MIO-PERISTIM; position the self-adhesive electrodes on the skin (see photos of electrode positions in the *Positions manual*); connect the splitting leads cables to the impulse transmission cables that are connected to the relative jacks (Channel 1 and/or Channel 2), then turn MIO-PERISTIM on.


Make sure that MIO-PERISTIM is switched off **before disconnecting the electrodes** at the end of the treatment.

Device use

MIO-PERISTIM has 14 preadjusted TENS programs, 9 preadjusted URO programs and 12 free memories adjustable by the user to create programs according to his needs. The program MEM 13 is a battery test.

Operating instructions

It is recommended reading the entire user manual before using.
To start the therapy, turn MIO-PERISTIM on using the ⏻/OK button.

PREADJUSTED PROGRAMS

Read the follow instructions to use the preadjusted programs and start the therapy:

1. Select the program group using the **MODE/ESC** button (TENS, URO, MEM).
2. Select the program using **PRG+** and **PRG-** buttons (make reference to the follow sections to get all technical specifications).
3. Increase current intensity for the channels using CH1 and CH2 (▲) buttons. The value can be adjusted with stepping 1mA. Press CH1 and CH2 (▼) buttons to decrease the intensity.MIO-PERISTIM recognize the electrodes connection: in case of faulty connection, when the intensity reaches 15mA the value is resetted to zero.
4. The remaining time is showed on the display of MIO-PERISTIM. An acoustic signal advises the user when the treatment is completed.
5. Turn off the device keeping pressed the ⏻/OK button for at least two seconds.

FREE MEMORIES (ADJUSTABLE PROGRAMS)

With MIO-PERISTIM you can set the parameters according to your needs or indicated by the doctor/physical therapist using the MEM programs.
Read the following instructions to adjust the parameters:

1. Select **MEM** by pressing **MODE/ESC** button. Scroll the programs using **PRG+** and **PRG-** buttons to display the preadjusted technical specifications. Read the following instructions to adjust the chosen program parameters: time, frequency and width impulse.
2. Adjust therapy time **TIME-min**, pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons by increasing and decreasing the time value. Press SET to confirm.
3. Adjust frequency **HZ**, pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons by increasing and decreasing the frequency value. Press SET to confirm.
4. Adjust width impulse **µs**, pressing ▲(increase) and ▼(decrease) CH1 or CH2 buttons by increasing and decreasing the width impulse value.
5. Press OK to confirm.

6. Increase intensity current of two channels using CH1 and CH2 (▲) buttons. The value can be adjusted with 1mA stepping. Decrease the intensity pressing CH1 e CH2 (▼) buttons.

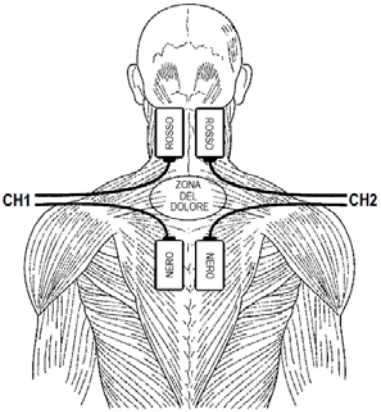
Stop program command: press the SET/II button to pause the treatment. To restart the program press ⏻/OK button.

Warning: the device automatically switches off when no button is pressed for 2 minutes to preserve battery by emitting an acoustic signal.

TENS programs

TENS, an acronym standing for *Transcutaneous Electrical Nerve Stimulation*, is a therapeutic technique mainly used for analgesic purposes to counter the effects (usually pain) of a wide variety of medical conditions. For this purpose, it finds application in treating everyday ailments troubling mankind: neck pain, arthrosis, myalgia, neuritis, back pain, periarthritis, heaviness in legs, muscle weakness, just to mention a few.
On an academic level, TENS can be divided into various categories according to the mechanism used to reduce the pain. The main types are: conventional TENS (or fast analgesic), training TENS (or delayed analgesic), which is similar to the effect of the electro acupuncture, TENS at maximum values with antidromic action and consequently an immediate local anaesthetic effect.
The rehabilitative action of TENS is represented by its power to reduce pain thereby restoring physiological conditions; most of the time this allows the patient to regain normal motor function. Consider a patient suffering from irritating periarthritis; the patient usually resorts to use analgesics or learns to live with the pain, which often makes even the simplest movements impossible. Immobility reduces metabolic activity making it impossible to eliminate allogenic substances. So, a vicious circle begins. In addition to relieving pain, TENS causes induce muscle stimulation increasing metabolic activity and blood flow and improving tissue oxygenation with an intake of nutritional substances. Therefore, the positive effect can be amplified by combining TENS with muscle stimulation of the area concerned.

Electrodes' positioning and intensity levels



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

Figure 1 – Electrodes' positioning.

The electrodes have to be positioned to form a square over the painful zone by using the channel 1 and 2 as shown above in *Figure 1* (red or black up or down are not important for the therapy purposes, follow the indications in the *Positions manual*). 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 treated area begin to contract; over this limit the stimulation does not become more effective, just more irritating, so it is best to stop before that point.

Programs specifications

Prg	Medical prg. Yes/No	Description	PHASE 1	PHASE 2	PHASE 3
1	Yes	Conventional Tens (fast)	Total time 40 min frequency 90 Hz impulse width 50µs		
2	Yes	Endorphinic Tens (delayed)	Total time 30 min frequency 1 Hz impulse width 200µs		
3	Yes	Tens at maximum values	Total time 3 min frequency 150 Hz		

Prg	Medical prg. Yes/No	Description	PHASE 1	PHASE 2	PHASE 3
			impulse width 200µs		
4	Yes	Anti-inflammatory	Total time 30 min frequency 120 Hz impulse width 40µs		
5	Yes	Neck pain/headache	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
6	Yes	Backache/sciatic pain	Total time 20 min frequency 90 Hz impulse width 50µs	Total time 20 min frequency 60 Hz impulse width 60µs	
7	Yes	Sprains/bruises	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
8	Yes	Vascularization	Total time 20 min frequency 2 Hz impulse width 200µs		
9	Yes	Muscle relaxant	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

Prg	Medical prg. Yes/No	Description	PHASE 1	PHASE 2	PHASE 3
10	Yes	Hand and wrist pain	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
11	Yes	Plantar stimulation	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
12	Yes	Epicondylitis	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
13	Yes	Epitroclea	Total time 20 min frequency 90 Hz impulse width 50µs	Total time 20 min frequency 70 Hz impulse width 60µs	
14	Yes	Periarthritis	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 + 1Hz-200µs x 3 sec + 30Hz-200µs x 5 sec)

The indications of the electrodes' positioning are available in the *Positions manual.*

TENS1 • Fast TENS (medical program)

Program also called **conventional TENS**, 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 fibres) until they reach the central nervous system where the impulses are interpreted as pain. Conventional TENS activates large-diameter nerve fibres, blocking the path of small-diameter nerve fibres at the spine. Therefore, this action is mainly taken against the symptom: to simplify it further, the wire transmitting pain information is obstructed.

Conventional TENS is a current that can be used to treat **general daily pain**. The average number required to benefit from the treatment is 10/12 per day (no contraindications in doubling this amount).

The program can be repeated at the end of the session for particularly persistent pain. Due to the nature of the impulse the patient may experience an addictive effect, meaning that the impulse will be felt less and less: if necessary, the intensity can be increased by one level to counter this effect.

Session duration: 40 minutes (no less than 30/40 minutes), in a single phase.

Electrodes' positioning: form a square above the painful area as shown in *Figure1*.

Intensity: to be adjusted in order to have a good solicitation of the stimulated part, but not over the pain threshold.

TENS2 • TENS endorfinico (programma medicale)

Questo tipo di stimolazione produce due effetti in relazione al posizionamento degli elettrodi: posizionando gli elettrodi in zona dorsale con riferimento foto 08 del *Manuale posizioni*, favorisce la produzione endogena di sostanze morfinosimili che hanno la proprietà di innalzare la soglia di percezione del dolore. Con posizionamento elettrodi formando un quadrato sopra la zona dolente come *Figura 1*, produce un effetto vascolarizzante; l'azione di vascolarizzazione produce un aumento della portata arteriosa con un conseguente effetto positivo sulla rimozione delle sostanze algogene ed un ripristino delle condizioni fisiologiche normali.

Durata: 30 minuti in una sola fase, frequenza giornaliera.

Posizione elettrodi: foto 08 del *Manuale delle posizioni* o come in *Figura 1*, attorno l'area da trattare; non posizionare gli elettrodi in prossimità di aree soggette a stati infiammatori.

Intensità: regolata in modo da produrre una buona sollecitazione della parte stimolata, la sensazione deve essere simile ad un massaggio.

TENS3 • TENS at maximum values (medical program)

This program blocks pain impulses peripherally creating a proper anaesthetizing effect in the treated area. This type of stimulation is suitable for injuries or bruises when rapid action is required. That is the reason why such stimulation is undoubtedly the least tolerated, but it 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.

Session duration: very short, 3 minutes in a single phase.

Electrodes' positioning: form a square above the painful area as shown in *Figure1*.

Intensity: it is the maximum tolerable value (well in excess of conventional TENS, and therefore with considerable contraction of the muscles surrounding the area treated).

TENS4 • Anti-inflammatory (medical program)

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).

Session duration: 30 minutes.

Electrodes' positioning: identified the area to be treated, position the electrodes as shown in *Figure 1*.

Intensity: to be adjusted until a tingling feeling is produced in the area treated; avoid contracting the surrounding muscles.

TENS5 • Neck pain/Headache (medical program)

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

Session duration: 35 minutes.

Electrodes' positioning: photo 25 of the *Positions manual*.

Intensity: to 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 treated area begin to contract; over this limit the stimulation does not become more effective, just more irritating, so it is best to stop before that point.

WARNING: the device varies stimulation parameters during the program. The current may be felt 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.

TENS6 • Back/Sciatic pain (medical program)
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 treated area begin to contract; over this limit the 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 daily; proceed with the treatment until the symptoms pass.
Session duration: 40 minutes.
Electrodes' positioning: photo 27 and 28 in the *Positions manual*.
Intensity: to be adjusted between the threshold of perception and pain.

TENS7 • Sprains/Bruises (medical program)
The program develops its effectiveness after this type of injury by inhibiting pain locally, producing three selectively acting, differentiated impulses. Until pain is lessened, the treatment is recommended daily (even 2/3 times a day).
Session duration: 30 minutes.
Electrodes' positioning: form a square above the painful area as shown in *Figure1*.
Intensity: to be adjusted between the threshold of perception and pain.

TENS8 • Vascularization (medical program)
Has a vascularizing effect on the treated area. Vascularization increases arterial flow and consequently aids the removal of allogenic 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.
Session duration: 20 minutes.
Electrodes' positioning: photo from 25 to 33 in the *Positions manual*; do not position the electrodes close to inflamed areas.
Intensity: to be adjusted between the perception threshold and slight discomfort.

TENS9 • Muscle relaxant (medical program)
Program used to speed up the recovery of muscle function after intense training or strain from work; the effect is immediate. Two treatments per day for three or four days are recommended.
Session duration: 30 minutes.
Electrodes' positioning: photo from 01 to 28 in the *Positions manual*.
Intensity: to be adjusted in order to have a moderate muscle solicitation.

TENS10 • Hand and wrist pain (medical program)
This program is suitable for all types of hand and wrist pain: aching caused by strains, arthritis in the hand, carpal tunnel syndrome, etc. A combination of various types of square-wave impulses has a general analgesic effect on the area to be treated, in fact impulses at different frequencies stimulate different sized nerve fibres promoting an inhibitory action at spinal level.
Session duration: 40 minutes.
Electrodes' positioning: form a square above the area to be treated as shown in *Figure 1*.
Intensity: to be adjusted between the threshold of perception and pain, without causing muscle contraction.

TENS11 • Plantar stimulation (medical program)
This program has a relaxing and draining effect on the stimulated limb. It is ideal for people suffering from a sense of "heaviness in the legs".
Session duration: 40 minutes.
Electrodes' positioning: 2 electrodes on the sole of the foot (one positive, the other negative), one close to the toes and the other under the heel.
Intensity: just a little bit over the perception threshold.

TENS12 • Epicondylitis (medical program)
Also known as "tennis elbow", it is an insertional tendinopathy concerning insertion of the elbow bone into the epicondylar muscles, those enabling finger and wrist extension (bending backwards).
It is recommended 15 applications once a day (even twice), until the symptoms pass. First it is recommended that you consult your doctor to identify the precise cause of the pain in order to prevent the condition from reoccurring.
Session duration: 40 minutes.
Electrodes' positioning: photo 29 in the *Positions manual*.
Intensity: to be adjusted above the perception threshold.

TENS13 • Epitrochlea (medical program)

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 epitrochlea. Pain is felt when bending or straightening the wrist against resistance, or when clenching a hard rubber ball in the hand.
It is recommended 15 applications once a day (even twice), until the symptoms pass. First it is recommended that you consult your doctor to identify the precise cause of the pain in order to prevent the condition from reoccurring.
Session duration: 40 minutes.
Electrodes' positioning: photo 29 in the *Positions manual,* but with all the electrodes positioned on the inside of the arm (with a rotation of about 90°).
Intensity: to be adjusted above the perception threshold.

TENS14 • Periarthritis (medical program)

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, it is recommended that you consult your doctor for a cycle of specific rehabilitation exercises to reduce the pain.
This program consists of various phases including TENS and muscle stimulation aimed at improving the tone of the muscles surrounding the joint.
Session duration: 41 minutes.
Electrodes' positioning: photo 26 in the *Positions manual.*
Intensity: to be adjusted above the perception threshold with small muscle contractions at the end of the program (10 minutes before the end).

Treatment programs for TENS therapy

Pathology	Progr.	No. of treatments	Frequency of treatments	Electrodes' positioning reference
Arthrosis	TENS1 + TENS2	Until pain reduction	Daily (TENS1 up to 2/3 times per day, TENS2 once a day)	On the painful are
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	REHA 4	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

The indications of the electrodes' positioning are available in the *Positions manual.*

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 **TENS14** program, the muscles surrounding the area to be treated must not contract, they should only produce slight “vibrations”.

N.B. read the specific instructions on TENS14.

URO programs

For the correct use of the vaginal and anal probe, please follow the steps here below:

- Connect the probe to the cables and then lubricate it with a specific cream (consult your doctor or your pharmacist) to avoid the insertion in the anus or vagina;
- Lay on the bed with the legs wide apart, if necessary with a pillow under the back. Anyway, the better position is the one which causes less discomfort, considering the fact that it has to be maintained for the whole treatment time (max 30 minutes);
- Gently introduce the probe in the anus or vagina, taking care to introduce the probe at least till the two golden rings before start the therapy.

As reported in the list of programs up above we suggest to associate electrostimulation with specific training exercises that can help the recovery of muscular strength of pelvic floor muscles.
The weakening of floor pelvic muscles lead to problems like urinary incontinence and urogenital prolapse. Strengthening these muscles lead to great improvements in urinary incontinence and urogenital prolapse symptomes, also blocking disease progress. Pelvic floor rehabilitation must be first therapeutic approach to stress incontinence in women.
It is important to point out that these exercises must be taught by a specialist (medician, physiotherapist, obstetric). In this kind of training, vaginal and anal muscles contraction occur without the use of abdominal muscles and gluteus. The exercises have to be repeated following specific steps suggested by medician.

Prg	Medical prg Yes/No	Description	PHASE 1
1	Yes	Stress urinary incontinence and faecal 1	Total time 25 min Frequency 40 Hz Impulse width 180µs contraction / recovery 3/7 sec
2	Yes	Stress urinary incontinence 2	Total time 25 min Frequency 45 Hz Impulse width 180µs contraction / recovery 6/9 sec
3	Yes	Stress urinary incontinence 3	Total time 25 min Frequency 50 Hz Impulse width 180µs contraction / recovery 8/12 sec
4	Yes	Urinary and faecal incontinence by urge 1	Total time 30 min Frequency 8 Hz Impulse width 180µs
5	Yes	Urinary incontinence by urge 2	Total time 30 min Frequency 10 Hz Impulse width 180µs
6	Yes	Urinary incontinence by urge 3	Total time 30 min Frequency 12 Hz Impulse width 180µs
7	Yes	Mixed urinary incontinence and faecal 1	Total time 25 min Frequency 20 Hz Impulse width 180µs contraction / recovery 3/7 sec
8	Yes	Mixed urinary incontinence 2	Total time 25 min Frequency 22 Hz Impulse width 180µs contraction / recovery 6/9 sec
9	Yes	Mixed urinary incontinence 3	Total time 25 min Frequency 25 Hz Impulse width 180µs contraction / recovery 8/12 sec

URO1-2-3 • Stress urinary incontinence and faecal (medical program)
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.

URO4-5-6 • Urge urinary incontinence and faecal (medical program)
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.

URO7-8-9 • Mixed urinary incontinence and faecal (medical program)
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

Prg	Medical prg. Yes/No	Description	PHASE 1
1-5	Yes	Free memoriesTENS	Total time 1-90 min frequency 1-200 Hz width impulse 20-250 µs
6-10	No	Free memories NEMS	Total time 1-90 min frequency 1-200 Hz contraction time 1-10 sec slope 0-5 sec recovery time 0-30 sec width impulse 50-450µs
11-12	No	Free memories NEMS alternated CH1/CH2	Total time 1-90 min frequency 1-200 Hz contraction time 1-10 sec slope 0-5 sec recovery time 0-30 sec width impulse 50-450µs
13	No	Battery test	

M1-M5 • TENS Free memories (medical program)
Free memories for antalgic TENS treatment.

M6-M10 • NEMS Free memories (non-medical program)
Free memories for muscle recovery and training.

M11-M12 • NEMS Alternated free memories (non-medical program)
Free memories for muscle recovery and/or training with alternated impulses on channel 1 and 2.

M13 • Battery test program (non-medical program)
Battery calibration program for the exclusive use of the manufacturer.

Maintenance

If used following the instructions given in this user guide, the equipment does not require any particular kind of maintenance.
It is recommended that the manufacturer carries out a functional test every 24 months. The manufacturer does not consider the MIO-PERISTIM device repairable by any personnel outside the company. Each operation of the kind perpetuated by personnel not authorized by the manufacturer will be considered as tampering the device, freeing the manufacturer from granting warranty and from any danger that the user or the operator may be exposed to.

CLEANLINESS

Clean the device using only a dry soft cloth. Resistant strains can be removed using a sponge soaked in solution of water and alcohol, do not use detergents or other aggressive agents.
Remove the battery before proceeding with the cleanliness of the device.
Device not subject to sterilization.
Note:

- Never use solvents for cleaning. Cleaning agents cause damage to the device.
- Attention to the need for periodic maintenance, especially:
  - inspection of main body for cracks, which may allow the ingress of conductive fluid;
  - inspection of the main cable and associated connectors.

TRANSPORTATION AND STORAGE

Precaution for the transportation

There is no particular precaution to be taken during transportation of the device, since MIO-PERISTIM is a portable device. In any case it is recommended to store MIO-PERISTIM and its accessories in the supplied carrying bag after each treatment. Protect the device from high temperature, direct daylight and liquids.

Precaution for the storage

Store the device in a cool, well-ventilated place. Do not store heavy objects on the device.
It is recommended to switch off MIO-PERISTIM at the end of each treatment and to remove the cables from the connectors. MIO-PERISTIM should be kept in the supplied carrying bag, together with the rest of the equipment supplied

and carefully stored on a secure surface. The performances of the equipment are granted if it is stored according to the following conditions:

Outside the carrying bag:

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

Inside the supplied carrying bag:

Temperature	from -10 to +55°C
Relative humidity	from 10 to 90%
Pressure	from 700 to 1060 hPa

N.B. Disconnect the cables, before storing the device into its carrying bag. If not, the cables could bend excessively near the connectors. It could severely damage the cables.

Troubleshooting

Any type of work on MIO-PERISTIM must be carried out exclusively by the manufacturer or by an authorized dealer. In any event, any presumed malfunction of MIO-PERISTIM must be verified before sending the device to the manufacturer.

Here below are some typical situations:

- **MIO-PERISTIM cannot be turned 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 PHYSIO 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

Battery charging

MIO-PERISTIM is supplied by internal rechargeable Ni-MH 800mAh battery with new long-lasting technology.
When during the treatment many intensity increases is needed or the device turns off, it indicates a low battery state. **In this case, the display will show low battery indicator**  . 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 before charging with the ⏻/OK button;
- make sure that the device is NOT being used by patient (disconnect cables and electrodes);
- connect the battery charger to the plug on the upper side of MIO-PERISTIM and connect the battery charger into the power socket.

The display will show the battery blinking icon and the **TIME-min** icon (which takes account of the charging time) on the display. 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.

WARNING: at the end of the charge wait at least 30 minutes before switching on the device; in order to allow the cooling of the battery pack, overheated during charging and the closure of the integrated safety system that prevents the device from turning on.

Do not immerge the battery in water or other liquids and do not expose it to heat sources.
Do not dispose of dead or defective batteries with domestic waste; dispose of in an authorized waste collection bin or in any case according to the underlying norm (WEEE).
Only adults should be managing the battery. Keep out of children's reach.
Do not use the battery charger if:

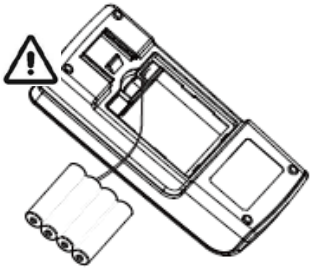
- the plug is damaged or parts of it are broken;
- it has been exposed to rain or any other type of liquid;
- the components have been damaged by a fall.

Use a dry cloth to clean the battery charger.

Do not open the battery charger: it does not contain repairable parts.

Battery substitution

Remove the clip belt, then open the battery compartement on the back side of the device. Disconnect the cable and take away the battery. Connect the cable of the new battery, close the battery compartment and insert the belt clip.



WARNING. Remove the battery in case of prolonged inactivity (over two months).

Batteries have to be handled by adult persons: keep them out of children's reach.

WARNING. 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.

Disposal

MIO-PERISTIM was designed and engineered to have minimal negative environmental impact, in consideration of its performance and safety requirements, following the disposition given by the European Directive 2012/19/EU, regarding the waste of electrical and electronic equipment.
Rigorous standards were followed in order to minimize the amount of waste, use of toxic materials, noise, non-required radiation and energy consumption. A deep research on the optimization of machine performances guarantees a significant consumption's reduction, in accordance to the saving energy principles.

This symbol means that the product shall not be disposed as domestic waste.

The correct disposal of obsolete equipment, accessories and most of all of batteries contributes in preventing possible negative consequences on human and environmental health.
The user must dispose of scrap equipment by taking it to a recognized center for recycling of electrical and electronic equipment.
For further information on the obsolete equipment disposal please contact the dedicated disposal service or the shop in which the device was bought.

Warranty

IACER Srl guarantees a warranty period from the purchasing date for MIO-PERISTIM device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The wearing parts (batteries and electrodes) are not included in the warranty, unless of visible manufacturing defects. The warranty is void in case of tampering of the device and in case of intervention on the same by personnel not authorized by the manufacturer or by the authorized dealer.
As established by the Medical Device Directive 93/42/EEC, the manufacturer is obliged to trace at any time the equipment supplied to intervene promptly, if necessary, as a result of manufacturing defects.
The warranty conditions are those described in the following paragraph Warranty conditions*. The warranty is provided by IACER.*
Should you need to return the goods then please pack the device and all the accessories so that it won't be damaged during transportation. In order to be entitled to the warranty assistance, the purchaser must enclose to the device a copy of the purchasing receipt, proving origin and purchasing date.
For more information on the warranty please contact the distributor or vendor, in order to check the norm and standard in force in your Country, or ultimately the manufacturer IACER Srl.

Warranty conditions

1) Should assistance be needed, enclose the purchasing receipt when sending the device to the manufacturer.
2) The warranty period is valid only on the electronic parts. The warranty will be granted by the shop or directly by the manufacturer.
3) The warranty covers only the product damages, which causes its malfunctioning.
4) Warranty means that only the manufacturing defect components or material are covered by reparation or free substitution, hand work included.
5) Warranty is not applied to damages caused by negligence or use not compliant to the given instructions, by intervention on the device

from personnel not authorized, accidental causes or negligence form the purchaser.

6) Warranty is not applied in case of damages caused by unsuitable power supplies.
7) Warranty does not apply to wearing parts.
8) Warranty does not include transportation costs which have to be covered by the purchaser.
9) After the warranty period, the warranty is no more applicable. In this case all the assistance interventions will be performed by debiting the costs of the substitution of the parts, the hand work and the transportations costs.
10) The court of Venice has exclusive jurisdiction over any dispute.

Support

The manufacturer is the one and only allowed to operate with technical assistance. For any technical assistance contact:

I.A.C.E.R. S.r.l.
Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Tel. 041.5401356 • Fax 041.5402684

Technical documentation related to repairable parts could be attached, but only with previous authorization from the manufacturer and only after giving proper training to the staff employed in technical assistance.

Spare part

The manufacturer makes available at any time the original spare parts for the equipment. Please contact:

I.A.C.E.R. S.r.l.
Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Tel. 041.5401356 • Fax 041.5402684

In order to preserve the warranty, the functionality and the security and safety of the product, it is highly recommended to use exclusively the spare parts given by the manufacturer.

Electromagnetic interferences and electromagnetic compatibility tables

The MIO-PERISTIM equipment has been designed and manufactured according to the TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY

legislation EN 60601-1-2:2015 with the aim of providing adequate protection from harmful interference when installed in homes and health establishments. The equipment does not generate significant radio frequency energy and is adequately immune to radiated electromagnetic fields. Therefore, it does not detrimentally interfere with radio-electric communications, electro-medical equipment for monitoring, diagnosis, therapy and surgery, office electronic devices such as computers, printers, photocopiers, fax machines, etc. or any electric or electronic equipment used in these environments, as long as the equipment complies with the ELECTROMAGNETIC COMPATIBILITY directive.
In general, the use of accessories other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of the MIO-PERISTIM and result in improper functioning.
In any case, in order to avoid any interference problems, it is recommended to use the therapy equipment enough far away from critical equipment for monitoring vital patient functions, and to be careful when applying therapy to patients with pacemakers. In any case it is recommended to use the equipment at least at 3 meters away from televisions, monitors, cellphones or any other electronic equipment, in particular portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30cm (12 inches) to any part of the device, including the cables specified by the manufacturer; otherwise, it could lead to degradation of the performance of the MIO-PERISTIM.
In conclusion, the use of MIO-PERISTIM adjacent to or stacked with other equipment should be avoided, since it could cause improper functioning. If such use is necessary, the MIO-PERISTIM and the other equipment should be constantly observed to verify that they are operating normally.
When MIO-PERISTIM is used in an environment relatively dry, strong electromagnetic interferences usually occur. At this time, the device may be affected as follows:

- the device stops supplying;
- the device turns off;
- the device restarts.

The above phenomena do not affect the basic safety and essential performance of the device, which can be normally used according to the instructions given in this manual. If you want to avoid the above phenomena, please use the device according to the environment's conditions specified in the manual.

For more details, please see the EMC tables at the end of this manual.

ELECTROMAGNETIC COMPATIBILITY TABLES

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS</th></tr>
<tr><td colspan="3">MIO-PERISTIM is intended for use in the electromagnetic environment specified below. The customer or the user of MIO-PERISTIM should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>MIO-PERISTIM 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">MIO-PERISTIM is suitable for domestic establishment and in establishment directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonics emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker emissions
IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS			
MIO-PERISTIM is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV in contact ±2Kv, ±4kV, ±8kV; +15kV on air	±8kV in contact ±2Kv, ±4kV, ±8kV; +15kV on air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supplies lines	±2kV for power supplies lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1kV for input/output lines	±1kV for input/output lines	
Impluses IEC 61000-4-5	±0.5kV, ±1kV Line(s) to line(s)	±0.5kV, ±1kV Line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	±0.5kV, ±1kV, ±2kV Line(s) to earth	±0.5kV, ±1kV, ±2kV Line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supplì input lines IEC 61000-4-11	0% U_T a 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for 0,5 cycles 0% U_T for 1 cycle and 70% U_T for 25/30 cycles at singular phase 0°	% U_T a 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for 0,5 cycles 0% U_T for 1 cycle and 70% U_T for 25/30 cycles at singular phase 0°	Main power quality should be that of a typical commercial or hospital environment. If the user of MIO-PERISTIM requires continued operation during power mains interruptions, it is recommended tha MIO-PERISTIM be powered from an uninterruptible

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS			
MIO-PERISTIM is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment - guide**
	0% U_T for 250/300 cycles	0% U_T for 250/300 cycles	power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING</th></tr>
<tr><td colspan="4">MIO-PERISTIM is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Test level EN 60601</th><th>Conformity level</th><th>Electromagnetic environment - guide</th></tr>
<tr><td colspan="4">Portable and mobile RF communications equipment should not be used near any part of the device (including cables) except when the recommended separation distance is respected. This distance is calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td colspan="4">Recommended separation distance</td></tr>
<tr><td>Conducted RF

IEC 61000-4-6</td><td>$3V_{eff}$
from 150kHz to 80MHz

$6V_{eff}$
in ISM band and radio bands between 150kHz and 80MHz</td><td>$3V_{eff}$
from 150kHz to 80MHz

$6V_{eff}$
in ISM band and radio bands between 150kHz and 80MHz</td><td>$d = 1{,}2\sqrt{P}$
from 150kHz to 80MHz
$d = 1{,}2\sqrt{P}$
from 80MHz to 800MHz</td></tr>
<tr><td>Radiated RF

IEC 61000-4-3</td><td>10V/m
from 80MHz to 2,7GHz</td><td>10V/m
from 80MHz to 2,7GHz</td><td>$d = 2{,}3\sqrt{P}$
from 800MHz to 2,7GHz</td></tr>
<tr><td colspan="4">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).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td colspan="4">Note
(1) At 80 MHz and 800 MHz At 80 MHz and 800 MHz, 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.</td></tr>
<tr><td colspan="4">a) Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MIO-PERISTIM is used exceeds the applicable RF compliance level above, MIO-PERISTIM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating MIO-PERISTIM.
b) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment for MIO-PERISTIM that are not life-supporting			
MIO-PERISTIM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MIO-PERISTIM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MIO-PERISTIM as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of the transmitter (m)**		
	from 150kHz to 800 MHz	from 80MHz to 800 MHz	from 800MHz to 2,7GHz
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 determined 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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I-TECH
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