
USER MANUAL

Ultrasound therapy and electrotherapy

I-TECHUE



I.A.C.E.R. Srl

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Information on the user manual

This manual is addressed to:

- machine user;
- owner;
- managers;
- handling personnel;
- installers;
- users;
- maintenance personnel.

It contains general information on the operation, precautionary practices, and maintenance information of the device I-TECH UE.

This is an essential reference guide for users. It is essential to read the manual carefully before installing and using the device and to keep it at hand for quick reference.

Partial or complete non-observance of the recommendations may lead to malfunction and damage of the device, and therefore the warranty will no longer be valid.

Following the provisions and the recommendations supplied by the manufacturer scrupulously is the only way of achieving the best results and to benefit from a quick and efficient technical assistance if needed.

The limits of this manual:

- the user manual cannot replace actual user experience;
- for particularly demanding operations, this instruction manual only represents a remainder of the main operations.

This user manual must be considered an integral part of the equipment and must be preserved for future reference until the device is dismantled. The instruction manual must be available for reference at the place of use of the device and preserved carefully.

This manual reflects the current state of machine technology and shall not be considered obsolete solely because updated at a later date on the basis of acquired experience.

The manufacturer reserves the right to update the production and the manuals with no obligation to update previous versions.

The manufacturer declines all responsibility for:

- improper use of the machine;
- use contrary to specific national laws;
- incorrect installation;

- defective power supply;
- improper maintenance;
- unauthorized modifications and interventions;
- use of material or spare parts that are not specific for the model;
- partial or complete non-observance of the instructions supplied;
- exceptional events.

To get further information, consult the fabricant.

Manufacturer

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

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

Tel. 041.5401356 • Fax 041.5402684

IACER Srl. is an Italian manufacturer of medical devices (certified CE n° 0068/QCO-DM/235-2020 from the Notified Body n° 0068 MTIC InterCert S.r.l.).

Declaration of conformity

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

Via S.Pertini 24/A – 30030 Martellago (Ve), Italia
herewith declares under its own responsibility, that the product

I-TECH UE

UMDNS Code: **17908**

has been designed and manufactured according to the European Medical Device Directive 93/4/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



Compliance of the concerned product with the Directive 93/42/EEC has been assessed and certified by the Notified Body:

0068 – MTIC InterCert S.r.l.

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

Certificate no.: 0068/QCO-DM/235-2020

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

Martellago, 03/08/2020

Place, date

MASSIMO MARCON

Legal Representative

Classification

The I-TECH UTE has the following classification:

- class IIa equipment (Directive 93/42/CEE, Annex IX, rule 9 and following modifications/additions);
- class I applied part type BF (classif. EN 60601-1);
- IPX0 equipment not protected against liquid and dust penetration. IPX7 only for ultrasound head;
- equipment and accessories not subject to sterilization;
- equipment unsuitable for use in presence of a flammable anesthetic mixture containing air, oxygen and nitrous oxide;
- continuous operating mode equipment;
- equipment not suited to be used in external.

Purpose and scope

Clinical intended use: Therapeutic and aesthetic

Environmental intended use: Ambulatory

I-TECH UE is a medical device for ultrasound therapy combined with electrotherapy. The ultrasound modality allows an ideal treatment of the muscular and nervous pathologies and for the rehabilitation post-trauma, both in case of chronic and acute pathologies.

Ultrasound treatment is indicated for several chronic and sub-chronic treatments as:

- Muscle pains and contractures
- Contractures
- Capsulitis
- Bursitis
- Myositis
- Soft tissues diseases
- Tendinitis
- Tendinosis

In fact, the ultrasound therapy is indicated for the antalgic pathologies and the relax of the tensed musculature, in the treatment of neuritis and sciatica, articular calcifications, tendinitis, hematomas and contractures.

This modality is recommended a lot in the esthetic field, in particular for the cellulite blemishes, tissue regeneration, vascularization and lymphatic drainage. For more details, the pathologies that can be treated, the specific application modalities and programs use, refer to the paragraph dedicated to the use of the device.

The electrotherapy modality allows the application of electrical micro impulses, which create energy. Thanks to the modulation given by the different set of the parameters, this energy can lead to many results, from the pain reduction in case both of acute and chronic pathologies to the rehabilitation post-trauma, from muscle strengthening to drainage, from isotonic exercises to the treatment of the hematomas.

The device can be used both in clinics (on adult patients of both sexes, adults unless otherwise indicated by doctors), unless the operator is qualified to use such equipment and the conformity to the statements declared in the manual is respected.

Technical features

Characteristics		Specifications	
Power supply		Input: 100-240V, 47-63Hz, 1.35A Output: 15V DC, 3A max Dimensions: 143x73x40mm	
Classification (EN 60601-1)		Class I	
Applied part (EN 60601-1)		Type BF	
Dimensions (length x height x depth)		250x82x185mm	
Environmental conditions for use	Temperature	10÷40°C	
	Relative humidity	30÷85%	
	Atmospheric pressure	800÷1060hPa	
Environmental conditions for storage	Temperature	-10÷55°C	
	Relative humidity	10÷90%	
	Atmospheric pressure	700÷1060hPa	
Ultrasuond			
Output power (±20%)		0.5W-10.0W, when duty cycle ≥80% for 5cm ² ultrasound head 0.5W-15.0W, when duty cycle ≤70% for 5cm ² ultrasound head	

Characteristics	Specifications
	0.1W-2.0W, when duty cycle $\geq 80\%$ for 1cm^2 ultrasound head 0.1W-3.0W, when duty cycle $\leq 70\%$ for 1cm^2 ultrasound head
Ultrasound wave frequency	1MHz $\pm 10\%$, 3MHz $\pm 10\%$
Duty cycle	10÷100% a stepping 10%
Working frequency	100Hz $\pm 10\%$
Therapy time	Adjustable, max 60 minutes
Timer accuracy	$\pm 3\%$
Effective radiating area (Aer)	1.0cm ² $\pm 20\%$ 5.0cm ² $\pm 20\%$
Effective intensity	3.0W/cm ² $\pm 20\%$
Accuracy	$\pm 20\%$ for each setting above 10% of the maximum value
RBN (Max)	<8.0
Beam type	Collimated
Material of ultrasound head	Aluminum
IP Protection	IPX7 only for ultrasound head
Interferenziale 4 poli (IF-4P)	
Waveform Type	Biphasic compensated
Mode Selection	CC, constant current or CV, voltage current
Vector	Auto: 0÷100%, Manual: 0÷90°
Carrier frequency (C.F.)	4.0kHz
High frequency (Beat H.)	(Beat L.) – 150Hz
Low frequency (Beat L.)	1 – (Beat H.)
Output	0÷100mA (CC at 1kOhm load) 0÷100V (CV at 1kOhm load)
Therapy time	Adjustable 1÷60 minutes

Characteristics	Specifications
Interferential waveform 2 poles (IF-2P)	
Waveform Type	Biphasic compensated
Mode Selection	CC, constant current or CV, voltage current
Carrier frequency (C.F.)	2.5kHz
High frequency (Beat H.)	(Beat L.) – 150Hz
Low frequency (Beat L.)	1 – (Beat H.)
Output	0÷100mA (CC at 1kOhm load) 0÷100V (CV at 1kOhm load)
Therapy time	Adjustable 1÷60 minutes
Contraction/recovery (Cycle)	Continuous, 5s/5s, 4s/12s, 10s/10s, 10s/20s, 10s/30s, 10s/50s
Ramp	2 seconds
TENS and EMS	
Waveform Type	Monophasic or Biphasic compensated
Mode Selection	CC, constant current or CV, voltage current
Frequency	1÷250Hz
Frequency modulation (F.M.)	0÷249Hz
Burst rate (Burst)	1÷10Hz
Width impulse (P. Dur.)	30÷400µs
Amplitude modulation (A.M.)	0÷100%
Output	0÷100mA (CC at 1kOhm load) 0÷100V (CV at 1kOhm load)
Therapy time	Adjustable 1÷60 minutes
Contraction/recovery (Cycle)	Continuous, 4s/4s, 4s/8s, 7s/7s, 5s/5s, 4s/12s, 10s/10s, 10s/20s, 10s/30s, 10s/50s
Ramp	1 secondo

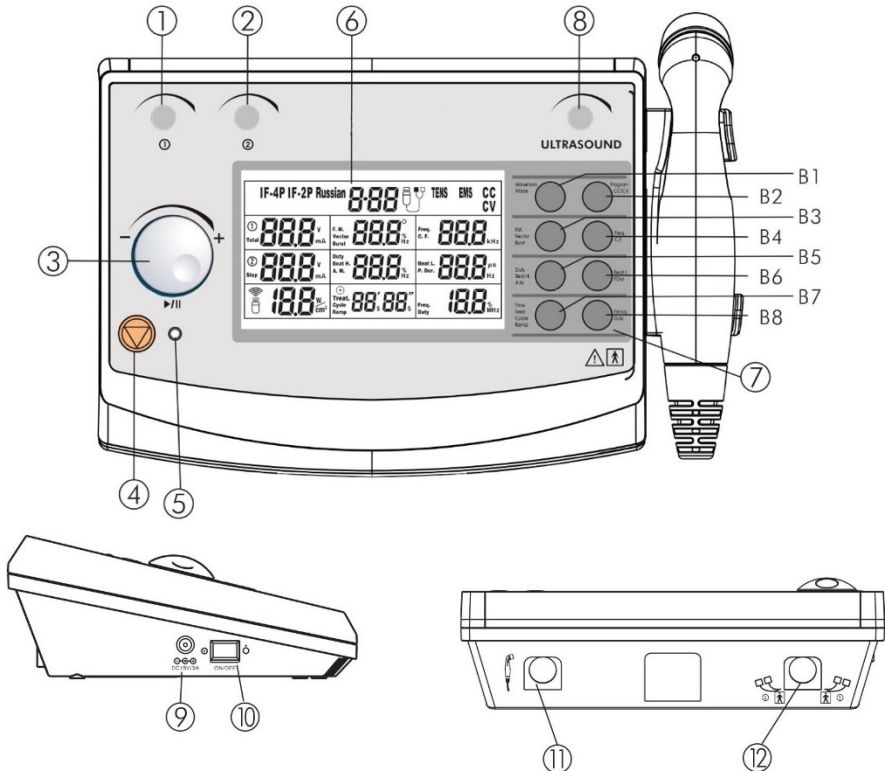
Characteristics	Specifications
Kotz waveform (Russian)	
Waveform Type	Biphasic compensated
Mode Selection	CC, constant current or CV, voltage current
Carrier frequency (C.F.)	2.5kHz
Burst Frequency (Freq.)	20÷100Hz
Output	0÷100mA (CC at 1kOhm load) 0÷100V (CV at 1kOhm load)
Duty cycle	10%, 20%, 30%, 40%, 50%
Therapy time	Adjustable 1÷60 minutes
Contraction/recovery (Cycle)	Continuous, 5s/5s, 4s/12s, 10s/10s, 10s/20s, 10s/30s, 10s/50s
Ramp	1, 2 e 5 seconds



WARNING! The device has an output current over 10mA or 10V over a period of 5 seconds.



Useful life of the device and its accessories: 2 years.

Device and commands description



- (1) Channel 1 intensity selection knob
- (2) Channel 2 intensity selection knob
- (3) Programs parameters control knob and PAUSE
- (4) Parameter confirm and STOP button
- (5) Led indicator
- (6) LCD display
- (7) Parameters selection buttons:
 - B1: mode selection (ultrasound, electrotherapy, combined) and waveform selection
 - B2: program selection
 - B3: Burst/vector/frequency modulation selection
 - B4: frequency/carrier frequency selection
 - B5: Duty cycle/high frequency/width modulation selection
 - B6: low frequency/impulse duration selection

- B7: therapy time/contraction-recovery cycle/ramp up selection
 - B8: frequency/ultrasound duty cycle selection
- (8) Ultrasound Intensity selection knob
 (9) Power supply socket
 (10) ON/OFF button
 (11) Handle socket
 (12) Electrostimulation cable socket

IF-4P IF-2P Russian			8.88		TENS	EMS	CC CV
①	88.8 V Total	F. M. Vector Burst	88.8 ° % Hz	Freq. C. F.	88.8 kHz		
②	88.8 V Step	Duty Beat H. A. M.	88.8 % Hz	Beat L. P. Dur.	88.8 μs Hz		
	18.8 W cm ²	Treat. Cycle Ramp	88' 88"	Freq. Duty	18.8 % MHz		

- CC – Constant current output mode
- CV – Constant voltage output mode
- F.M. – Frequency modulation
- Burst –Burst frequency
- Freq. – Frequency
- C.F. – Carrier frequency
- Duty – Duty cycle for Russian waveform (Kotz) for B5 button
- Beat H. – High beat frequency selection
- A.M. – Amplitude modulation
- Beat L. – Low beat frequency selection
- P.Dur. – Impulse duration
- Treat. – Therapy time
- Cycle – Contraction recovery cycle
- Ramp – Ramp time
- Duty – Duty cycle for ultrasound for B8 button
- Freq. – Ultrasound frequency









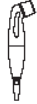




ON /OFF button

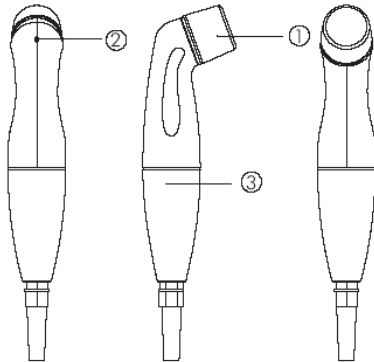


Polarity of Power Supply



Stop treatment (7)

	Start/Pause button (7)	
	Ultrasonic beam intensity (1)	
	Ultrasound handle state (handle/skin contact) (1)	
	Ultrasound intensity (5)	
	Ultrasound power	
	Therapy time	
	Socket for the handle connection	
IF-4P	Interferential waveform with 4 poles	
IF-2P	Interferential waveform with 2 poles	
Russian	Russian waveform (Kotz)	
TENS EMS	TENS/EMS waveforms	
	Electrotherapy channels indicators (1/2)	
	Electrotherapy/ultrasound/combined symbols	therapy
	Program in use	
	Parameter indicator	










1. Ultrasound head
2. LED for head/skin detection
3. Handle applicator

Labelling

<p>MODEL: UE</p> <p>ELECTRICAL STIMULATION</p> <p>Output intensity: 0-100mA (1000 ohm load)</p> <p>Frequency: 1-250Hz</p> <p>Beat frequency: 1-150Hz</p> <p>Power supply: DC15V/3.0A, Adaptor</p> <p> I.A.C.E.R.Srl, via S.Pertini 24/A 30030 Martellago(VE)-ITALY</p>	<p>ULTRASOUND</p> <p>Waveform: Pulsed</p> <p>Acoustic Frequency: 1.0MHz±10% 3.0MHz±10%</p> <p>Modulation wave shape: 100Hz±10%</p> <p>Duty factor: 10%~100%</p> <p>I_e: 3.0W/cm² ±20%</p> <p>R_{ms}(Max.): 8.0</p> <p>Beam type: collimated</p>
<p>I-TECH MEDICAL DIVISION SN:000001 2013-05 CE 0068 </p>	

<p>1 MHz, 3 MHz</p> <p>1.8cm²</p> <p>IPX7</p>	<p>A_{is}: 1.0cm²±20%</p> <p>P: 3.0W±20%</p> <p>R_{ms}(Max.): 8.0</p> <p>Beam type: collimated</p> <p>LOT</p> <p>SN</p>
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<p>1 MHz, 3 MHz</p> <p>7.0cm²</p> <p>IPX7</p>	<p>A_{is}: 5.0cm²±20%</p> <p>P: 15.0W±20%</p> <p>R_{ms}(Max.): 8.0</p> <p>Beam type: collimated</p> <p>LOT</p> <p>SN</p>
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Symbols	Description
	Manufacturer's logo
	Product CE certification released by Notified Body n°0068
	Manufacturer
	Manufacturing date (YYYY-MM)
	Read instructions for use
	WEEE Directive for the disposal of electronic waste
	Applied part type BF
IPX7	Degree of protection of the head of the ultrasound handle from the entry of liquids and dusts
LOT	Ultrasound handle lot
SN	Serial number of ultrasound handle

Package content

The I-TECH UE package contains:

- n° 1 I-TECH UE device;
- accessories:
 1. n° 2 silicone conductive electrode 60x90mm;
 2. n° 2 silicone conductive electrode 70x110mm;
 3. n° 2 sponge for silicone electrode 70x100mm;
 4. n° 2 sponge for silicone electrode 80x120mm;
 5. n° 2 set of electrodes 50x50mm;
 6. n° 2 set of electrodes 50x100mm;
 7. n° 1 elastic belt for electrodes fastening 75x1200mm;
 8. n° 1 elastic belt for electrodes fastening 75x600mm;

- 9. n° 2 electrical stimulation cables with 2 derivations red/black;
- 10. n° 1 medical power supply;
- 11. n° 1 power supply cable;
- 12. n° 1 electrotherapy cable;
- 13. n° 1 single plug cable for combined electrotherapy;
- 14. n° 1 ultrasound head with 5cm² area;
- n° 1 ultrasound gel;
- n° 1 transport bag;
- n° 1 user manual;
- n° 1 position manual.



All the accessories are available as spare parts. It is also available under request the ultrasound handle of 1cm².

Contraindications

Do not use I-TECH UE (in any mode) if the source of the pain is unknown or not diagnosed. Use the device ONLY after having a diagnosis.

It is absolutely forbidden to use I-TECH UE for ULTRASOUND THERAPY in those areas affected by thrombophlebitis not to make the thrombus move. Avoid treating patients with deep vein thrombosis, embolism or arteriosclerosis or that have previously been treated with X rays or other radiations. This device should not be used near testicles or over neoplastic lesions, on the carcinogenic areas and over a healing fracture. Do not use ultrasounds on the stellate ganglion, on the spinal column after a laminectomy, on the area surrounding the main nerves or the cranium, over cardiac area and in anesthetized areas or in patients with bleeding problems. This device should not be used on ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result. This device should not be used over the thoracic area if the patient is using a cardiac pacemaker in order to avoid interferences between the ultrasound device and the pacemaker.

Avoid using ultrasounds near bone growth centers in kids/growing children. Ultrasound therapy must not be performed near the uterus on pregnant women or those who suspect they might be pregnant. Therefore, the ultrasound beam should not be used in this area without ensuring that the patient is not pregnant.

I-TECH UE for ELECTROTHERAPY should not be used over, or in proximity to, cancerous lesions. Do not apply stimulation over open wounds or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins). Is forbidden to use the device on patient who have a cardiac pacemaker, suffers from epilepsy, heart-related pathologies, anxiety or serious illnesses, abdominal or inguinal hernias, on pregnant women (except in case of medical prescription). Use caution if stimulation is applied over the menstruating or pregnant uterus and over areas of skin that lack normal sensation. Electrical stimulation is ineffective for treatment pain of central nervous system.

Side effects

If the handpiece moves too slowly the patient may experience sharp and/or deep peripheral pain. If it moves too quickly, or if the handpiece is not held correctly, the therapeutic effects of the ultrasound might be reduced.

Some patients might be particularly sensitive to ultrasound and might therefore experience undesired reactions such as hot flushes in the treated area. Check the treated area before, during and after the treatment and suspend it in case of undesired effects.

Make sure that the handpiece is in contact with the skin using a specific ultrasound gel. Any substance used for this purpose must be highly conductive. Air is a terrible conductor of ultrasound waves.

Patients with arterial or venous thrombosis or thrombophlebitis are at risk of developing embolisms when electrical stimulation is applied over or adjacent to the vessels containing the thrombus.

With ultrasound therapy inflammation temporary increases can happen in treatment area, and so pain temporary increase, traumas due to more dosage, nervous system reactions, sanguine coagulation. If this occurs, suspend the treatment and consult a doctor.

The long-term effects of chronic electrical stimulation are unknown. Pay attention, electrical stimulation is not a substitute for pain medications and other pain management therapies.

Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.

No significant side effects related to electrotherapy are known. In some cases of particularly sensitive people, after the treatment, redness of the skin near the electrodes: the redness usually disappears a few minutes after the treatment. If the redness persists, consult a doctor.

Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes, head and face. In some rare cases evening stimulation causes some difficulties in falling asleep. In this case, suspend the treatment and consult a doctor.

Warnings

It is recommended:

- to control position and meaning of all the labels and symbols on the equipment;
- the device doesn't produce or receive electromagnetic interferences from other devices. However, it's recommended to keep a distance of at least 3 meters from televisions, monitor, mobile phones or other electronic devices (which can lead to abnormal device behavior). Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment;

- to avoid the use of the device by persons who did not read carefully this manual;
- not to wear metal objects during treatment (both for the operator and both for the patient);
- 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;
- to use **ONLY** accessories supplied by device manufacturer. **It is recommended to use the device only with the supplied power supply MPU50-160.** I-TECH UE is tested and guaranteed for use with the supplied accessories.

It is forbidden:

- to use the device in the presence of MRI equipment and 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;
- 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 12 years old or not adequately educated about the device use by an adult person;
- ultrasounds should not be used on areas with reduced sensitivity or circulation. Patients experiencing reduced sensitivity may not be able to warn their therapist/doctor when the ultrasound is too intense. Patients experiencing circulation problems may suffer from an excessive increase of temperature in the treated area;
- to use the device in presence of signs of deterioration of the device itself, cables and/or accessories: 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 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);
- absolutely use a device that has been wet or has come into contact with liquids before it has been checked by the manufacturer and / or service center. Take care to prevent liquids from entering the ventilation slots;

- to use the device while driving or during the operation and control of equipment/machinery;
- the use of the device in hyposensitive areas, on the carotid sinuses (carotid), genitals, near the uterus and abdomen, in the area of the body in which glands are present, on cancerous lesions. Do not direct the beam towards or near the eyes;
- 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 arrhythmia;
- 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 3cm 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;***
- ***maintain the ultrasound head stationary on one point during the therapy.*** We advise moving the head if the intensity is more than 0,5W/cm²;
- to use the device when the patient is sleeping;
- to use pointed or sharp objects on the ultrasound head and the control panel of the device.

Warning:

- recent fractures should not be treated in order to avoid unwanted motion. Stimulation should not be applied immediately after a trauma or to tissues susceptible to hemorrhage. Use caution when the patient tends to bleed internally, such as following an injury or fracture;
- before administering any treatment to a patient, you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of ultrasound;

- ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity control does properly adjust the intensity of the ultrasonic power output in stable manner. Also, determine that the treatment time control does actually terminate ultrasonic power output when the timer reaches zero;
- handle the handpiece with care to preserve its characteristics;
- the tendency to bleed is increased by the heat as more blood flows in the area. Be careful when treating patients with bleeding disorders;
- avoid heating or overheating the capsule in cases of acute and subacute arthritis.;
- 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.

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 I-TECH UE 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. In case of undesired effects, suspend the therapy, stop using the device straight away and contact your doctor.



The ultrasound therapy controls unit is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of system and therefore create risk of injury to the patient/user.



If the patient feels a deep and sharp pain during the treatment, the intensity must be reduced to a comfortable level



Consult a doctor before using I-TECH UE with metallic osteosynthesis devices.

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

Installation

Remove the device and its accessories from shipping cartons. Check the device equipment.

Before the installation and the connection of the device to the mains supply, check that the voltage and the frequency correspond with the available mains supply and with the information in this user manual.

Follow the instructions below for a correct installation:

- connect the power supply cable to the power supply;
- connect the power supply to the device connector;
- connect the power supply plug to the wall socket.

Use in the ultrasound therapy mode

Patient preparation

Before starting the ultrasound treatment, please, check the following indications:

- make sure that the patient is in a comfortable position. The treatment area should be completely exposed and relaxed.
- Inform the patient about the objective of the treatment and the sensation he/she should feel during therapy.
- Make sure that there are no contraindications to therapy.
- Inspect accurately the treatment area for abrasion, irritation, surface veins, etc.
- Clean the treatment area with a soap or alcohol at 70%. In case of excessive hairy skin, it is suggested to shave the zone to get optimal treatment.

During treatment:

1. The ultrasound head has to be moved constantly when intensity is higher than $0.5W/cm^2$.
2. Ask about his/her sensation during treatment. If necessary, adjust ultrasound intensity, by reducing it if the treatment is not comfortable.

3. In case of indications of wrong contact, it is recommended to add the contact gel or reposition the ultrasound-head.
4. During the treatment if the ultrasound head works correctly, the applicator LED will light; if there is no contact, the applicator LED will blink light. When the treatment is in PAUSE, the applicator LED will be turned off and the countdown will also be stopped.



WARNING:


- The treatment should be performed with a regular movement of the ultrasound head, not too slow to avoid inducing heat, not too fast to prevent a bad contact which would reduce the effectiveness of the treatment.
- If it is needed to replace the handle, turn the power switch off and disconnect the device from power supply.



After the treatment clean the skin of the treated area as well as the ultrasound head by using a dry towel. The ultrasound-head should be cleaned up with a 70% alcohol solution. Check the patient conditions and the treated area (pain, circulation, etc.).

The patient should reveal any complaint/reaction before starting the treatment after.

Operative instructions

Follow the steps below to perform an ultrasound therapy treatment:

1. Connect the ultrasound handle to the socket (11) placed on back side of the device. Connect the cable only when the device is switched off.
2. Switch on the device pressing **ON/OFF** button placed on lateral side, next to power supply plug.
3. Immediately after switching on, the device carries out a self-test (10 seconds duration). At the end the display will show the last performed treatment.
4. Press **WAVEFORM MODE** (B1) button until it is shown the icon : this icon indicates ULTRASOUND treatment.
5. Press **B8** button to regulate ultrasound working frequency between 1 and 3MHz by using the **knob** (3).
6. Press again **B8** button to regulate the duty cycle: it's possible to adjust the value from 10% to 100% stepping by 10 using the **knob** (3).

7. Press **B7** button to regulate therapy time: it's possible to adjust therapy time from 1 to 30 minutes (by steps of 1 minute) by using the **knob** (3).
8. Put a good quantity of conductive gel on the area to be treated or on the ultrasound head. It is recommended to use the conductive gel supplied by the manufacturer or at least a gel bearing the CE mark.
9. Regulate the treatment intensity using the **knob** (8). Press the **knob** to adjust unit of measurement W (Watt) or W/cm² (Watt/cm²).
10. Keep the head in constant contact with the skin and make sure that the part is covered in gel so that the therapy can be effective. The green LED located next to the head on the handpiece lights up when the device is working.
11. The device is provided of a head/skin coupling system for safety reasons. If the contact is not correct and if the intensity is set above 0,5W, the LED on the handpiece and the symbol on the display will start flashing. The system is not available on the 1cm head because of the reduced contact area, therefore the device emits an ultrasound beam even if the head is not in contact with the skin. This is not a defect but rather a technical choice, as it would be impossible to perform therapies on small and irregular areas like toes or fingers with such a system.
The image shows a small LED symbol consisting of a central dot with radiating lines, and a digital display showing the number '0.5' followed by the unit 'W/cm²'.
12. It's possible to stop temporary the therapy at any time by pressing the **knob** (3). Press again the **knob** to continue the treatment.
13. Press the **orange button**  to stop immediately the ongoing treatment.

It is recommended to carefully manage the handles in order to preserve their integrity and performances.

Always use a proper conductive means so that the energy is correctly transmitted from the ultrasound head to the skin. In fact, the air stops and reflects completely the ultrasound beam. The best solution is using the gel: it is the best means for the ultrasound energy transfer; therefore, it must be applied to all the treatment area. Move the ultrasound head in circles; the area to be treated has to be at least twice the area covered by the head.

If the area is not regular or if it does not allow a proper contact with the head (as ankles or feet for instance) or in case the direct contact has to be avoid (acute pain) it is possible to conduct the treatment under water. Use two liters of water, with a temperature not higher than 25 ° C. The water should be

degassed (by previous boiling) in order to prevent air bubbles that could decrease the effectiveness of the treatment.



WARNING. Do not apply directly on the head of the handle the gel: it could emit the ultrasound beam, therefore ruining the head itself. Always use a CE marked gel.



WARNING. In order to guarantee the patient safety, the device stops emitting the ultrasound beam and alerts the users with the blinking LED when the head exceeds the 42°C. The device will emit again when the temperature drops under 41°C.



WARNING. Only in the ultrasound mode the handpiece can be used for immersion treatments. The handpiece and its cable are the only parts protected against water damage with an IPX7 level.

Programs features and main applications

Refer to the following table for programs features. All parameters are adjustable by the user.

PROG.	Medical prg. YES/NO	FREQ.	DUTY CYCLE	TIME	SUGGESTED INTENSITY
P-01	Yes	1MHz	50%	14min	1.0W/cm ²
P-02	Yes	1MHz	50%	20min	1.0W/cm ²
P-03	Yes	1MHz	50%	20min	1.0W/cm ²
P-04	Yes	1MHz	50%	30min	0.5W/cm ² 1.0W/cm ²
P-05	Yes	3MHz	50%	16min	1.0W/cm ²
P-06	Yes	1MHz	50%	14min	1.0W/cm ²
P-07	Yes	1MHz	50%	14min	1.0W/cm ²
P-08	Yes	1MHz	50%	14min	1.0W/cm ²
P-09	Yes	1MHz	50%	14min	1.0W/cm ²
P-10	Yes	3MHz	50%	14min	1.0W/cm ²

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATION NUMBER
Acne	P-01/10	Affected area	3MHz	30%	15min	5cm ²	1.5W/cm ²	Free
Muscle fatigue	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ²	2-3
Algodystrophy	P-01/10	Affected area	1MHz	50%	10min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Anti-inflammatory	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Arthritis	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1,5W/cm ²	10-15
Fingers arthritis	P-01/10	Hand fingers	1MHz	40%	15min	5cm ²	1.5W/cm ² - 2W/cm ²	10-15
Arthrosis	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.5W/cm ² - 2W/cm ²	10-15
Bursitis	P-01/10	Affected area	1MHz	30%	15min	5cm ²	2W/cm ²	10-15
Brachialgia	P-01/10	Trapezium and arm	1MHz	30%	15min	5cm ²	2W/cm ²	10-15
Capsulitis	P-01/10	Shoulder	1MHz	30%	15min	5cm ²	2W/cm ²	10-15
Cavitations	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ² - 3W/cm ²	20-30
T-T headache	P-01/10	Cervical area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
T-T headache	P-01/10	Massetere	1MHz	50%	15min	5cm ²	1.5W/cm ²	10-15
Cervicalgias	P-01/10	Cervical area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATION NUMBER
Whiplash	P-01/10	Cervical and dorsal + front zone	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Condriopathy	P-01/10	Affected area	1MHz	60%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Muscle contractures	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ²	4-6
Coxarthrosis	P-01/10	Hip	1MHz	60%	15min	5cm ²	2W/cm ²	10-15
Cramps	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ²	4-6
Cruralgy	P-01/10	Internal thigh	1MHz	40%	15min	5cm ²	2W/cm ²	10-15
Discopathy	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Strains	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Articular pain	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Intercostal pain	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Menstrual pain	P-01/10	Abdomen	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Muscle pain	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Rheumatic pain	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATION NUMBER
Dorsalgia	P-01/10	Dorsal area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Drainage	P-01/10	Affected area	1MHz	60%	15min	5cm ²	2W/cm ²	30
Eczemas	P-01/10	Affected area	3MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Oedemas	P-01/10	Affected area	1MHz	30%	15min	5cm ²	2W/cm ²	10-15
Hematomas	P-01/10	Affected area	1MHz	40%	15min	5cm ²	2W/cm ² - 3W/cm ²	10-15
Epicondylitis	P-01/10	Elbow	1MHz	40%	15min	5cm ²	1.0W/cm ² - 1.2W/cm ²	10-15
Epitrocleitis	P-01/10	Internal elbow	1MHz	40%	15min	5cm ²	1.0W/cm ² - 1.2W/cm ²	10-15
Slipped disc	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Gonarthrosis	P-01/10	Knee	1MHz	50%	15min	5cm ²	1.5W/cm ² - 2W/cm ²	10-15
Lymphoedema	P-01/10	Affected area	1MHz	30%	15min	5cm ²	2W/cm ²	10-15
Lypolisis	P-01/10	Affected area	1MHz	60%	15min	5cm ²	2W/cm ²	30
Lumbago	P-01/10	Lumbar area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Massage	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ²	Free

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATION NUMBER
Mialgy	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Mononeuropathy	P-01/10	Pain zone	1MHz	50%	15min	5cm ²	1.5W/cm ²	12-15
Neuralgia	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Periarthritis	P-01/10	Shoulder	1MHz	70%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Pubalgia	P-01/10	Internal thigh (upper zone)	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Radiculitis	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Muscle recovery	P-01/10	Affected area	1MHz	70%	20min	5cm ²	2W/cm ²	Free
Rizarthrosis	P-01/10	Thumb area	1MHz	30%	15min	5cm ²	1.5W/cm ²	10-15
Rizopathy	P-01/10	Dorsal area	1MHz	60%	15min	5cm ²	1.5W/cm ²	10-15
Wrinkle	P-01/10	Affected area	3MHz	30%	15min	5cm ²	1.5W/cm ²	Free
Sciatalgy	P-01/10	Affected area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Stretch marks	P-01/10	Affected area	3MHz	40%	15min	5cm ²	2W/cm ²	Free
Venous stasis	P-01/10	Extremities limbs	1MHz	50%	15min	5cm ²	2W/cm ²	Free
Sprains	P-01/10	Affected area	1MHz	40%	15min	5cm ²	2W/cm ²	4-6

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATION NUMBER
Muscle sprains	P-01/10	Affected area	1MHz	40%	15min	5cm ²	2W/cm ²	8-10
Tallonitis	P-01/10	Heel	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Tendinitis	P-01/10	Affected tendons	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Stiff neck	P-01/10	Cervical area	1MHz	50%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Carpal tunnel syndrome	P-01/10	Internal wrist	1MHz	40%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	10-15
Vascularisation	P-01/10	Affected area	1MHz	60%	15min	5cm ²	1.0W/cm ² - 1.5W/cm ²	Free
Active principle vehiculation	P-01/10	Affected area	1MHz	60%	15min	5cm ²	2W/cm ²	Free



Indications regarding intensity and number of sessions can vary depending on the opinion of your personal doctor or therapist.

In particular, the indications on intensity do not consider the width of the area to be treated. If this is very wide, the intensity of the ultrasound can be increased by 20% with respect to what indicated above or, vice versa, it can be reduced, if the area is small. Similarly, the movement on the area must be appropriate to the heat felt by the patient: the slower it's been moved, the stronger the heat. If the patient complains about the heat, we advise reducing the intensity or moving the head faster.

REMEMBER TO:

- keep moving the ultrasound head and uniformly apply the treatment on the overall area;
- use enough gel in order to guarantee a proper contact.

Use in the electrotherapy mode

Electrodes



Use only CE marked electrodes and strictly follow the user instructions on the packaging.

The electrodes supplied by the manufacturer are top-quality, pre-gelled and ready to be used, particularly indicated for the electrostimulation treatments. Their wide flexibility allows an easy application over the different areas of treatment. Take away the protective plastic, position on the skin as indicated in the user manual and, after using, reposition the protective plastic.

The useful lifetime of an electrode is determined by the pH of the skin. **THE ELECTRODES ARE TO BE CONSIDERED FOR A SINGLE-USE.** Using the same electrodes over and over will affect the safety of the stimulation, for this reason it is forbidden to use the same electrodes when they do not adhere anymore on the skin; it can lead to skin redness that can last also a few hours after the end of the treatment. In such cases consult a doctor.

Refer to the indications given on the electrodes' packaging and at the *Warnings* paragraph.

Patient preparation

Before starting the treatment, pay attention to the following indications:

- ensure there are no contraindications to treatment.
- Ensure there are no abrasions or irritations in the area to be treated.
- Clean the skin with neutral soap or alcohol (70%). If the skin is hairy, it is suggested to shave the area for an optimal treatment.
- Test the heat sensibility of the treatment area.
- Guarantee a good contact between electrodes and skin.
- Check that the electrodes are correctly placed on the skin during treatment.
- Examine the skin after the treatment.
- Choose the electrodes' dimensions taking into consideration the area to be treated.
- Follow electrodes manufacturer's instructions.
- To avoid skin irritation due to high current density, do not use electrodes smaller than 25cm².



WARNING:

- Keep at a proper distance the electrodes during treatment. Electrodes that come in contact with each other could lead to unwanted stimulations and/or burns.
- The current intensity depends on the electrodes' dimensions. Improper application can lead to damage to the patient. In case of any doubts on the proper electrodes' size, consult a physician/therapist specialized in electrostimulation.

This device is supplied with 50×50mm and 50×100mm adhesive electrodes. You can select the correct adhesive electrodes according to the treatment area and output current density.

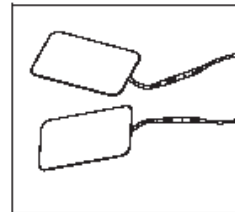
It is recommended to use only electrodes supplied by the manufacturer, to guarantee the highest level of contact with the area to be treated and the right current density in relation with the prescribed treatment. Properly dispose of electrodes after the use.

In case of doubts about the electrodes' integrity, it is suggested to replace them with new ones.

Do not start the treatment before the electrodes are correctly placed on the skin. Do not take away the electrodes during the ongoing therapy.

Pre-gelled electrodes positioning

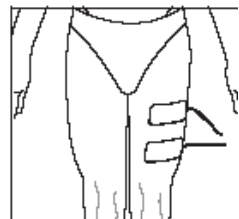
1. Insert the cable with the Red (+) connector into one adhesive electrode. Insert the cable with the Black (-) connector into one adhesive electrode. Make sure that the connectors are inserted completely and there are no metal parts of the pins exposed.



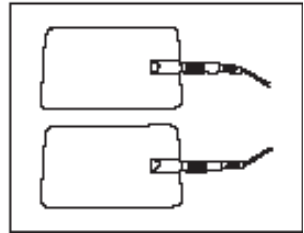
2. Remove the adhesive electrodes from the protective backing and place on the treatment area. Make sure that the entire electrode surface is in contact with patient skin.

As an alternative you can use silicon electrodes for electrotherapy treatments, in two different ways:

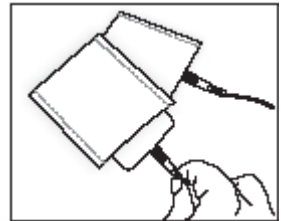
- with the use of wet sponges;
- with the silicon electrodes and conductive gel.



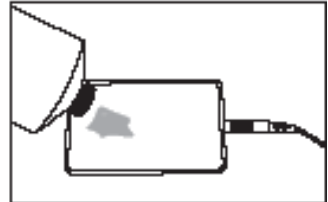
- The electrodes should be placed on the treatment area and hold down using the elastic belt supplied with the device. Insert the cable with the Red (+) connector into one rubber electrode. Insert the cable with the Black (-) connector into the other rubber electrode. Make sure that the connectors are inserted completely into the electrode.



OPTION 1: Insert the rubber electrode into the wet electrode sponge.



OPTION 2: Put conductive gel on the rubber electrode surface before placing it on the skin. Note: use only CE marked gel or supplied by the manufacturer.



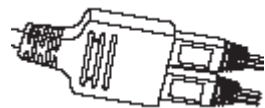
- Use elastic belts to keep the electrodes in the right position.



Operative instructions


Pay attention to the follow indications to start electrotherapy treatment:

- Connect the black/red cables to the sockets on the electrotherapy cables and connect this cable to the socket (12) on the back side of the device.
- Connect the electrodes to the electrotherapy cables following the instructions of the previous paragraph.
- Switch on the device pressing **ON/OFF** button placed laterally, next to power supply socket.



4. 4. Immediately after switching on, the device carries out a self-test (around 10 seconds). At the end of the self-test display shows the last performed treatment.



5. Press **WAVEFORM MODE (B1)** button to show  : this icon indicates **ELECTROTHERAPY** treatment.

6. Select waveforms by using the **knob (3)**: TENS, EMS, IF-4P (Interferential 4 poles), IF-2P (interferential 2 poles), RUSSIAN (Kotz). The icon related to the selected waveform starts flashing.

7. Select the program (from P01 to P10) by pressing the **PROGRAM CC/CV (B2)** button: the symbol P (or S) of the program starts flashing on the display. There are two type of programs you can select: programs with one phase (P) or with three phases (S). You can select the program by keeping pressed **PROGRAM CC/CV** button for at least 5 seconds.



In the S programs display shows the phases total number and the number of the phase you want to set the parameters: press **B3-B7 buttons** and the **knob (3)** to select programs parameters (contraction, recovery, width impulse, frequency, etc.) for each phase (please see the following instructions regarding each parameter). Press the **knob** to confirm the value for each phase

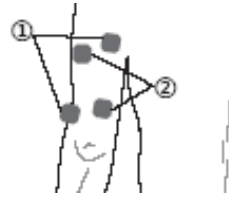


8. Select CONSTANT CURRENT (CC) or CONSTANT VOLTAGE (CV) by pressing again **PROGRAM CC/CV** button. The unity of measurement changes from mA (milliAmpere) to V (Volts).
9. Select the waveform features by pressing **B3-B7 buttons** (each waveform has different technical features):

- B3: select frequency modulation/vector/Burst
- B4: select frequency/carrier frequency
- B5: select duty cycle/high frequency/width modulation
- B6: select low frequency/impulse duration
- B7: select therapy time/contraction-recovery cycle / slope

Press the button of the selected parameter and regulate the value by using the **knob (3)**.

10. Place the electrodes on the area to be treated following the instructions of electrodes position manual. In case of treatment with 4 poles interferential waveform place the electrodes as shown in the picture on the right.
11. Select the two channels intensity by using the **knobs** (1-2) placed on the left upper side of the front panel.



ATTENTION. The device has a current supply safety system and the identification of the connected load: in case of disconnected electrodes/cables or damaged electrodes if the intensity is set above 10mA/10V the device emits an acoustic signal and the intensity value on the display starts flashing.

It's possible to stop temporary the therapy at any time pressing the **knob** (3). Press again the **knob** to continue the treatment.

12. Press the **orange button**  to stop immediately the treatment in progress.



ATTENTION. For safety patient, the device is equipped with a protection system against high temperatures. The device will stop electrical stimulation when the feature board temperature reaches 80° C. The device cannot work again unless the temperature is below 60°C.

Programs features and therapeutic indications

Interferential waveform with 4 poles – IF-4P

Prg	Phase	CC/ CV	Vector (Auto)	Vector (Manual)	Carrier Freq. (C.F.)	High Freq. (Beat. H)	Low Freq. (Beat. L)	Time
1	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	0min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	0min
2	1	CC	0	45°	4.0kHz	150Hz	100Hz	10min
	2	CC	0	45°	4.0kHz	150Hz	100Hz	0min
	3	CC	0	45°	4.0kHz	150Hz	100Hz	0min
3	1	CC	0	45°	4.0kHz	50Hz	50Hz	15min

Prg	Phase	CC/ CV	Vector (Auto)	Vector (Manual)	Carrier Freq. (C.F.)	High Freq. (Beat. H)	Low Freq. (Beat. L)	Time
	2	CC	0	45°	4.0kHz	50Hz	50Hz	0min
	3	CC	0	45°	4.0kHz	50Hz	50Hz	10min
4	1	CC	0	45°	4.0kHz	150Hz	90Hz	15min
	2	CC	0	45°	4.0kHz	150Hz	90Hz	0min
	3	CC	0	45°	4.0kHz	150Hz	90Hz	0min
5	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	0min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	0min
6	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	15min
7	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	15min
8	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	15min
9	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	15min
10	1	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	2	CC	0	45°	4.0kHz	110Hz	100Hz	15min
	3	CC	0	45°	4.0kHz	110Hz	100Hz	15min

Interferential waveform with 2 poles – IF-2P

Prg	Phase	CC/ CV	Carrier Frequency (C.F.)	High Frequency (Beat. H)	Low Frequency (Beat. L)	Time
1	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	0min
	3	CC	2.5kHz	110Hz	100Hz	0min
2	1	CC	2.5kHz	150Hz	100Hz	10min
	2	CC	2.5kHz	150Hz	100Hz	0min
	3	CC	2.5kHz	150Hz	100Hz	0min
3	1	CC	2.5kHz	50Hz	50Hz	15min
	2	CC	2.5kHz	50Hz	50Hz	0min
	3	CC	2.5kHz	50Hz	50Hz	10min
4	1	CC	2.5kHz	150Hz	90Hz	15min
	2	CC	2.5kHz	150Hz	90Hz	0min
	3	CC	2.5kHz	150Hz	90Hz	0min
5	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	0min
	3	CC	2.5kHz	110Hz	100Hz	0min
6	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	15min
	3	CC	2.5kHz	110Hz	100Hz	15min
7	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	15min
	3	CC	2.5kHz	110Hz	100Hz	15min
8	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	15min
	3	CC	2.5kHz	110Hz	100Hz	15min
9	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	15min
	3	CC	2.5kHz	110Hz	100Hz	15min
10	1	CC	2.5kHz	110Hz	100Hz	15min
	2	CC	2.5kHz	110Hz	100Hz	15min
	3	CC	2.5kHz	110Hz	100Hz	15min

TENS

Prg.	Phase	CC/CV	Freq.	Width impulse (P. Dur.)	Time
1	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	0min
	3	CC	120Hz	70µs	0min
2	1	CC	200Hz	60µs	20min
	2	CC	200Hz	60µs	0min
	3	CC	200Hz	60µs	0min
3	1	CC	10Hz	180µs	20min
	2	CC	10Hz	180µs	0min
	3	CC	10Hz	180µs	10min
4	1	CC	80Hz	100µs	30min
	2	CC	80Hz	100µs	0min
	3	CC	80Hz	100µs	0min
5	1	CC	180Hz	30µs	16min
	2	CC	180Hz	30µs	0min
	3	CC	180Hz	30µs	0min
6	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
7	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
8	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
9	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
10	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min

EMS

Prg.	Phase	CC/CV	Freq.	Width impulse (P. Dur.)	Time
1	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	0min
	3	CC	120Hz	70µs	0min
2	1	CC	200Hz	60µs	20min
	2	CC	200Hz	60µs	0min
	3	CC	200Hz	60µs	0min
3	1	CC	10Hz	180µs	20min
	2	CC	10Hz	180µs	0min
	3	CC	10Hz	180µs	10min
4	1	CC	80Hz	100µs	30min
	2	CC	80Hz	100µs	0min
	3	CC	80Hz	100µs	0min
5	1	CC	180Hz	30µs	16min
	2	CC	180Hz	30µs	0min
	3	CC	180Hz	30µs	0min
6	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
7	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
8	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
9	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min
10	1	CC	120Hz	70µs	14min
	2	CC	120Hz	70µs	14min
	3	CC	120Hz	70µs	14min

Russian waveform or Kotz

Prg	Phase	CC/ CV	Carrier freq. (C.F.)	Freq	Duty cycle	Contraction/ Recovery	Ramp	Time
1	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	0min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	0min
2	1	CC	2.5kHz	50Hz	50%	4s/12s	1s	10min
	2	CC	2.5kHz	50Hz	50%	4s/12s	1s	0min
	3	CC	2.5kHz	50Hz	50%	4s/12s	1s	0min
3	1	CC	2.5kHz	50Hz	50%	4s/12s	1s	10min
	2	CC	2.5kHz	50Hz	50%	4s/12s	1s	0min
	3	CC	2.5kHz	50Hz	50%	4s/12s	1s	0min
4	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	0min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	0min
5	1	CC	2.5kHz	50Hz	50%	5s/5s	1s	20min
	2	CC	2.5kHz	50Hz	50%	5s/5s	1s	0min
	3	CC	2.5kHz	50Hz	50%	5s/5s	1s	0min
6	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
7	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
8	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
9	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
10	1	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	2	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min
	3	CC	2.5kHz	50Hz	50%	10s/10s	1s	10min


Use in the electrotherapy mode

Operative instructions

Follow the indications below to start the combined treatment.

1. In combo mode ultrasound probe works as negative of channel 2, you should connect electrotherapy cable with 1 derivation (red cable) to the green cable on the output 2. **The channel 1 is turned off.**
2. Connect the green cable to the **socket** (12) placed on the back side of the device.
3. Connect the **electrode** to the **red cable** for electrotherapy.
4. Place the electrode on the treatment area following the instruction of the previous paragraphs. The electrode should be placed near the painful zone, approximately 10/15 cm far from the painful point where the ultrasound head is moved.
5. Connect the ultrasound handle to the **socket** (11) placed on the back side of the device. Connect the cable when the device is switched off.
6. Switch on the device pressing **ON/OFF** button placed laterally, next to power supply socket. IT IS RECOMMENDED TO TURN OFF THE DEVICE BEFORE CONNECTING ALL THE CABLES!
7. Immediately after switching on, the device carries out a self-test (around 10 seconds). At the end of the self-test display shows the last performed treatment.



8. Press **WAVEFORM MODE (B1)** button to show  : this icon indicates the COMBINED ULTRASOUND/ELECTROTHERAPY treatment mode.
9. Select waveforms by using the **knob** (3): IF-2P, TENS, EMS and RUSSIAN (Kotz).
10. As indicated in the paragraph related to treatment with electrotherapy, each waveform has 10 stored programs (see the related tables on the previous pages). Select the program by pressing the **B2 PROGRAM CC / CV** button and turn the **knob** (3) on the chosen program. As in the electrotherapy mode, also in the combined mode it is possible to choose between single-phase P or three-phase S programs, by keeping pressed **PROGRAM CC / CV** button for at least 5 seconds.

11. In the S programs display shows the phases total number and the number of the phase you want to set the parameters: press **B3-B7** buttons and the **knob** (3) to select programs parameters (contraction, recovery, width impulse, frequency, etc.) for each phase (please see the following instructions regarding each parameter). Press the knob to confirm the value for each phase.



12. Select CONSTANT CURRENT (CC) or CONSTANT VOLTAGE (CV) by pressing again **PROGRAM CC/CV** button. The unity of measurement changes from mA (milliAmpere) to V (Volts).



13. Select the waveform features by pressing B3-B7 buttons (each waveform has different technical features):

- B3: select frequency modulation/vector/Burst/
- B4: select frequency/carrier frequency
- B5: select duty cycle/high frequency/width modulation
- B6: select low frequency/impulse duration
- B7: select therapy time/contraction-recovery cycle / slope

Press the button of the selected parameter and regulate the value by using the knob (3).

14. Press **FREQ. DUTY (B8)** button and select the working frequency (1 or 3 MHz) by using the **knob** (3).

15. Press **B8** button to regulate the duty cycle: it's possible to select the value from 10% to 100% (stepping of 10) by using the **knob** (3).

16. Press **B7** button to select therapy time: it's possible to select therapy time from 1 to 30 minutes (stepping of 1) by using the **knob** (3).

17. Put a good quantity of conductive gel on the area to be treated. It is recommended to use a CE conductive gel.

18. Select electrotherapy intensity by using the **knob** (2) of the Channel (2).

19. Select treatment intensity by using the **knob** (8). Press the **knob** (3) to select the unity of measurement W (Watt) or W/cm² (Watt/cmq).


20. Keep the head in constant contact with the skin and make sure that the part is covered in gel so that the therapy is effective. The green LED located next to the head on the handpiece lights up when the device is working. Move the handpiece at a distance of 10/15cm from pre-gelled electrode.

21. The device has a head/skin coupling system for safety reasons. If the contact is not correct and if the intensity is set above 0,5W, the LED on the



handpiece and the symbol on the display will start flashing.

22. It's possible to stop temporary the therapy at any time pressing the **knob** (3). Press again the knob to continue the treatment

23. Press the **orange button**  to stop immediately the treatment in progress.



ATTENTION. For safety patient, the device is equipped with a protection system against high temperatures. The device will stop electrical stimulation when the feature board temperature reaches 80° C. The device cannot work again unless the temperature is below 60°C.

Moreover, for patient safety, the device will stop ultrasound treatment and LED starts flashing on the handle if the temperature is above 42°C. It will start again when the temperature goes down to 41°C.

NOTE: for more information's about electrodes refer to the previous paragraph *Electrodes*.

Reset

To reset parameters and return the device to the factory settings on the device follow the instructions below:

- switch off the device;
- keeping pressed simultaneously the **knobs** of electrotherapy channels 1 and 2 (1/2);
- switch on the device by using **ON/OFF** button;
- keeping pressed the **knobs** (1) and (2): the device emits a prolonged signal for around 5 seconds and the set-up frame will showed on the display.

In this way the device is reset and all the custom settings are eliminated.

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 I-TECH UE 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

Switch off I-TECH UE after each therapy session, as well as remove the cable by the specific connector.

Clean the device from dust using a dry soft cloth. Resistant stains can be removed using a sponge soaked in solution of water well squeezed.

ATTENTION! No alcohol content solution. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

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.

Clean periodically the connecting cables for electrotherapy using a cloth dampened and mild soap and carefully dry them. Aggressive clearing agents could damage the rubber insulation and shorten the life of the cables.

Clean the ultrasound head to remove gel AFTER EACH USE using a soft cloth or paper cloth, lightly wet if needed. Aggressive clearing agents could damage the rubber insulation and shorten the life of the cables.

After cleaning the external box, dry all of the parts carefully before turning on the device.

Do not disassemble the device to clean or check it: there is no need to clean the inside of the machine and in any case this operation should be performed by skilled technical personnel authorized by I.A.C.E.R. Srl.

TRANSPORTATION AND STORAGE

Precaution for the transportation

There is no particular precaution to be taken during transportation of the device, since I-TECH UE is a portable device. In any case it is recommended to store I-TECH UE and its accessories in the supplied carrying bag after each treatment. Protect the device from high temperature, direct daylight and liquids. Keep the device in a fresh and well-ventilated environment. Place the device together with all its accessories in a dry place away from dust, direct sunlight and protected from the weather, chemical products and vibrations. Do not place other objects on top of the device.

Precaution for the storage

The appliance is protected up to the following environmental conditions:

In operation

temperature	10÷40°C
relative humidity	30÷85%
pressure	800÷1060hPa

Inside the supplied carrying bag

temperature	-10 ÷ +55°C
relative humidity	10÷90%
pressure	700÷1060hPa

Troubleshooting

I-TECH UE was designed and manufactured using advanced technological solutions and high-quality components for an efficient and reliable use.

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

Check the following:

PROBLEM	POSSIBLE CAUSE	SOLUTION
Display does not switch on	Wrong/failed connection with power supply.	Check if the mains adapter is connected to the device and to power supply.
		Check the integrity of all plugs/sockets and connection cables.
The stimulation is weak.	Damaged/broken electrodes.	Replace the electrodes.

PROBLEM	POSSIBLE CAUSE	SOLUTION
	Electrodes not correctly placed on the skin.	Check the electrodes position according to electrodes positions user manual. The distance between the electrodes should be at least of 5 cm.
The stimulation is ineffective.	Improper electrodes.	Reposition or replace the electrodes.
	Unknown.	Consult the doctor.
Display shows the error E1 or E2.	Hardware problem.	Restart the device, if the problem persists contact the fabricant.
Display shows the error E3.	Temperature sensor failure.	The device will stop treatment automatically, please wait at least 30 minutes before restart treatment.
Display shows the error E4.	Excessive temperature of internal parts.	The device will stop treatment automatically, please wait at least 30 minutes before restart treatment.
Display shows the error E5.	Internal memory error.	Restart the device, if the problem persists contact the fabricant.
The stimulation is ineffective.	Improper electrodes.	Reposition or replace the electrodes.
Some commands don't work regularly.	Defective keys and buttons.	Contact the manufacturer
	Failure electronic control circuit.	
The device works properly, but there is a noticeable drop in the effectiveness of the treatment.	Possible head failure.	Contact the manufacturer
	Possible failure of the device current generator circuit.	

Disposal

The I-TECH UE, device 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 I-TECH UE device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The wearing parts 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.

WARNING! In the event of non-shipment, the manufacturer declines all responsibility, if corrective action on the equipment is necessary.

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 from 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 S. Pertini, 24/a • 30030 Martellago (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 S. Pertini, 24/a • 30030 Martellago (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 I-TECH UE equipment has been designed and manufactured according to the TECHNICAL NORM 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.

According to operating principles the device does not generate significant radio frequency energy and is adequately immune to radiated electromagnetic fields: under such conditions it does not detrimentally harmful 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 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.

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

ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS		
The I-TECH UE device is intended for use in the electromagnetic environment specified below. The customer or the user of the I-TECH UE should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The I-TECH UE 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 I-TECH UE device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS			
The I-TECH UE 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 ±15kV on air	±8kV in contact ±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 ±1kV for input/output lines	±2kV for power supplies lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer’s declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS


The I-TECH UE 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
overvoltage IEC 61000-4-5	±1kV line(s) to line ±2kV line(s) to earth	±1kV line(s) to line ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power suppli input lines IEC 61000-4-11	<5% U _T (>95% dip in U _T) for 0,5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5s	<5% U _T (>95% dip in U _T) for 0,5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5s	Main power quality should be that of a typical commercial or hospital environment. If the user of I-TECH UE requires continued operation during power mains interruptions, it is recommended that I-TECH UE be powered from an uninterruptible power supply (UPS) 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.

Guidance and manufacturer’s declaration – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

The I-TECH UE device is intended for use in the electromagnetic environment specified below. The customer or the user of the I-TECH UE should assure that it is used in such an environment.

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment – guidance
Portable and mobile RF communications equipment should be used no closer to any part of the I-TECH UE device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Recommended separation distance			
Conducted RF IEC 61000-4-6	3V _{eff} from 150kHz to 80MHz	3V _{eff} from 150kHz to 80MHz	$d = 1.2\sqrt{P}$ from 150kHz to 80MHz
Radiated RF IEC 61000-4-3	10V/m from 80MHz to 2,7GHz	10V/m [E ₁] V/m	$d = 1.2\sqrt{P}$ from 80MHz to 800MHz $d = 2.3\sqrt{P}$ from 800MHz to 2,7GHz
<p>ove P è la potenza massima nominale d’uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e d è la distanza di separazione raccomandata in metri (m). Le intensità di campo dei trasmettitori a RF fissi, come determinato da un’indagine elettromagnetica^a del sito potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza^b</p> <p>Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: </p>			
<p>Note:</p> <p>(1) At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>(2) Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 I-TECH UE is used exceeds the applicable RF compliance level above, I-TECH UE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating I-TECH UE.</p> <p>b) Over the frequency range 150kHz to 80MHz, field strengths should be less than [V₁] V/m.</p>			

Recommended separation distances between portable and mobile radio equipment for I-TECH UE not sustaining vital functions			
I-TECH UE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of I-TECH UE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and I-TECH UE 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	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
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 80MHz and 800MHz, 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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