I-TECH
MEDICAL DIVISION

I-TECH UT1

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MEDICAL DIVISION

USER MANUAL

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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 UT1.

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;

- unauthorised 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.

SAFETY INFORMATION

Cautions

- Read carefully the contraindications.
- Respect the limitations and hazards associated with the use of the device. Pay attention to the labels and symbols placed on the unit. Always follow your prescribing doctor's or therapist's recommendations.
- Do not operate this unit in an environment where other devices are used that intentionally radiates electromagnetic energy in an unshielded manner.
- Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
- Before each use inspect applicators and cables integrity.
- The device should not be placed next to or on top of other devices. Should it prove necessary to place it next to or on top of other devices, supervision is essential at all times to control its normal functioning.
- Precautions must be taken regarding the electromagnetic compatibility of the device, which must be installed and commissioned in compliance with the EMC provided in this manual.

- Portable RF devices can affect the functioning of the device. Do not use mobile phones or other devices that emit electromagnetic fields nearby. This may result in incorrect operation of the unit.
- Only use the device for the recommended applications.
- Do not use the device in presence of inflammable anesthetic mixture and in environments with high concentrations of oxygen. I.A.C.E.R. will not be held responsible for any accident if the above instructions are not complied with in full.
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Warnings

- Make sure of the device connection to an electrical system in conformity with the current National laws.
- 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. Try to minimize this interference by not using other equipment in conjunction with I-TECH UT1.
- 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.
- To avoid the risk of electric shock disconnect the device from the electrical system before maintenance service.
- Use of accessories, transducers and cables other than those specified here (even as internal spare parts) may result in EM immunity reduction or in EM emissions increase.
- The device must not be used in the same environment where magnetic resonance devices are working or are installed.

Contraindications

- 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.
- 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.
- Do not direct the beam towards or near the eyes.
- This device should not be used over cardiac area.
- This device should not be used over neoplastic lesions.
- Do not use near testicles not to increase their temperature.
- The treatment with ultrasounds should be avoided in those areas affected by thrombophlebitis not to make the thrombus move. Avoid treating patients with deep vein thrombosis, embolism or arteriosclerosis..
- Tissues that have previously been treated with X rays or other radiations should not be treated with ultrasounds.
- Using ultrasounds on the stellate ganglion, on the spinal column after a laminectomy, on the area surrounding the main nerves or the cranium should be avoided.
- 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 a healing fracture.
- Avoid using ultrasounds near bone growth centres in kids/growing children.

Precautions

- 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.
- If the patient feels a deep and sharp pain during the treatment, the intensity must be reduced to a comfortable level.
- The tendency to bleed is increased by the heat as more blood flows in the area. Be careful when treating patients with bleeding disorders.
- We advise moving the head if the intensity is more than 0,5 W/ sq cm.
- Avoid heating or overheating the capsule in cases of acute and subacute arthritis.
- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- This device should not be used when cancerous lesions are present in the treatment area.
- Cautions should be used for patients affected by the following diseases: areas of the spinal column which underwent a laminectomy, anesthesised areas, patients with bleeding disorders.
- 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.
- Before using the device pay attention to the appllicators and head integrity in order to avoid the ingress of liquids.
- The ultrasound therapy controls unit is not designed to prevent the ingress of water or liquids. Ingress of water of liquids could cause malfunction of internal components of system and therefore create risk of injury to the patient/user.

Unwanted effects

- In case of undesired effects, suspend the therapy, stop using the device straight away and contact your doctor.
- Follow the instructions in order to minimise the undesired effects of the ultrasound therapy.

- 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.

USE

I-TECH UT1 is a device for ultrasound therapy.

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

Use: hospital and domestic use. it is recommended the use only by seasoned professional.

Expected lifetime (time after which we suggest sending the device to the manufacturer for safety checks): 2 years.

CONDITIONS OF USE and EQUIPMENT

Environmental conditions for use:

- Environment temperature: from +10° to +40°C;
- Relative humidity: from 30% to 85% without condensation;
- avoid direct sunlight, chemical products and vibrations.

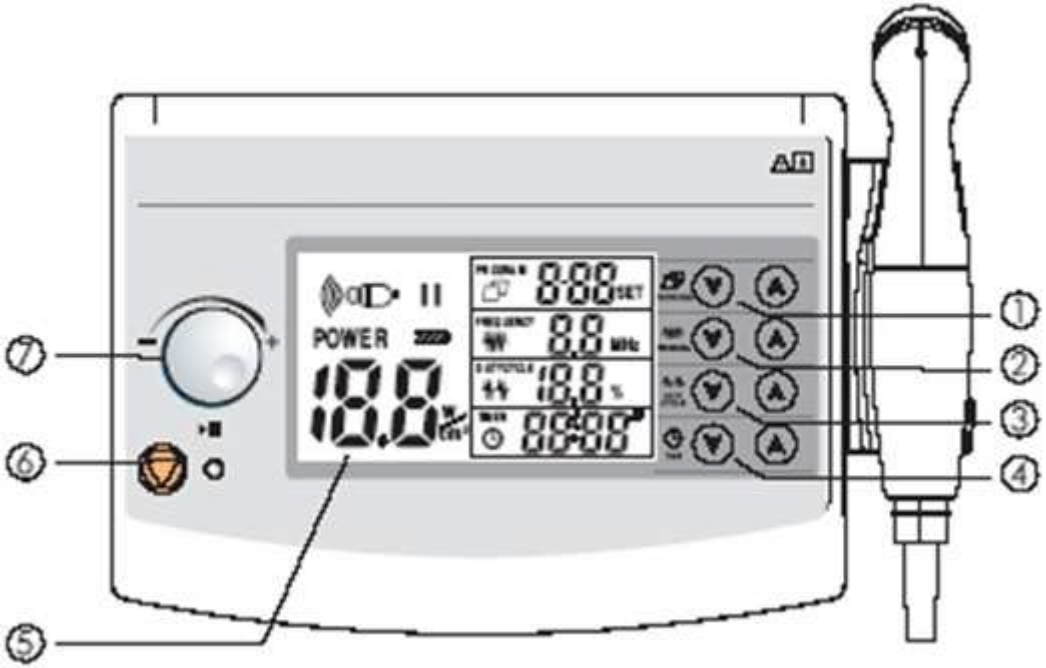
The device is equipped with the following accessories:

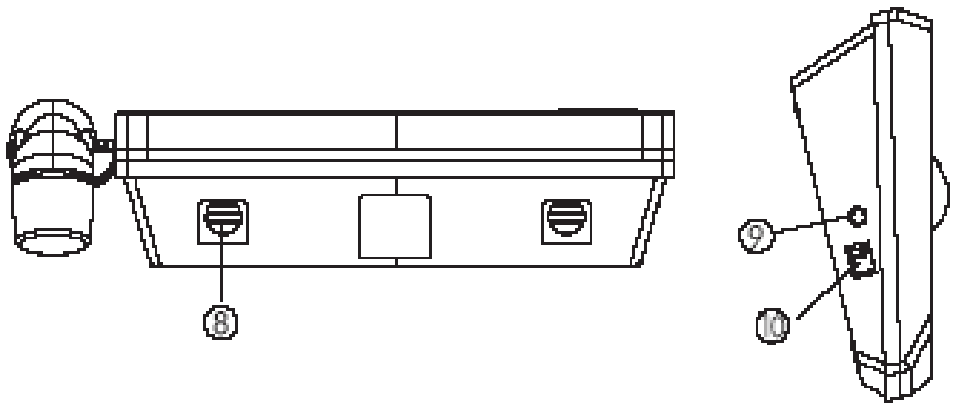
	Description	Kit
1	Power supply 15V 3A	1 piece
2	Power supply cable	1 piece
3	Ultrasound head with 5cmq area	1 piece
4	User manual	1 piece
5	Ultrasound gel	1 piece

All accessories are available on demand as spare parts.

Moreover the ultrasound head with 1 cmq area is available on demand.

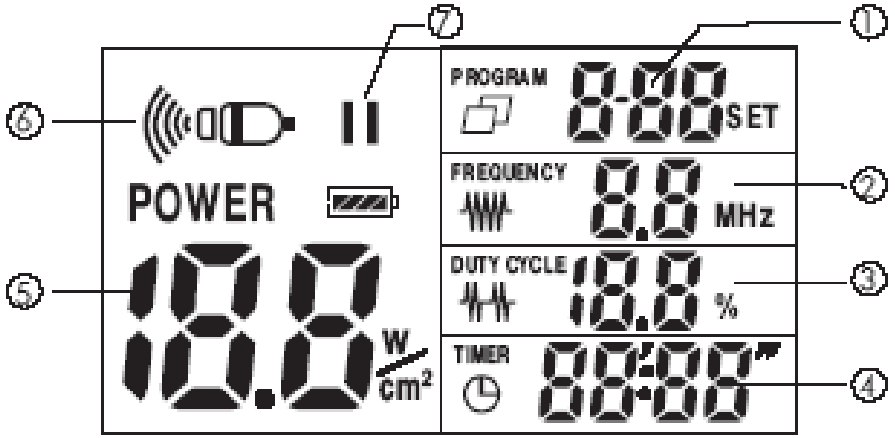
DEVICE DESCRIPTION





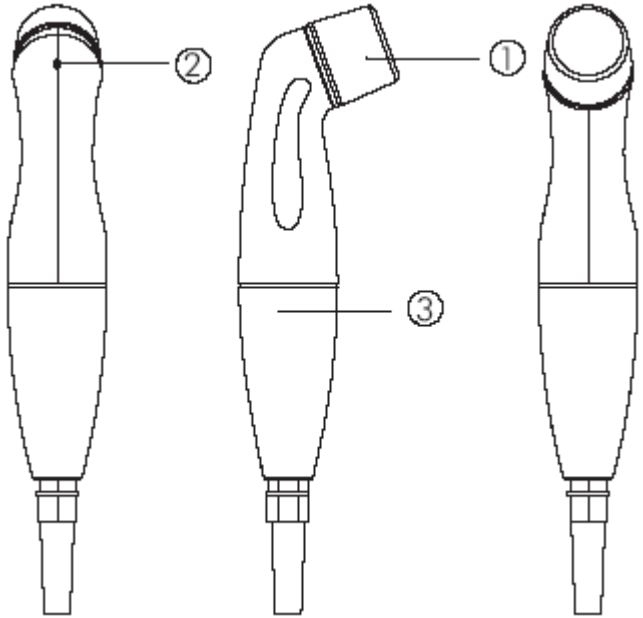
1. Program selection button
2. Frequency selection button 1/3MHz
3. Duty cycle selection button
4. Timer selection button
5. LCD display
6. STOP button
7. Intensity selection knob and PAUSE
8. Handle socket (5 cmq and 1 cmq)
9. Power supply socket
10. ON/OFF button

DISPLAY LCD



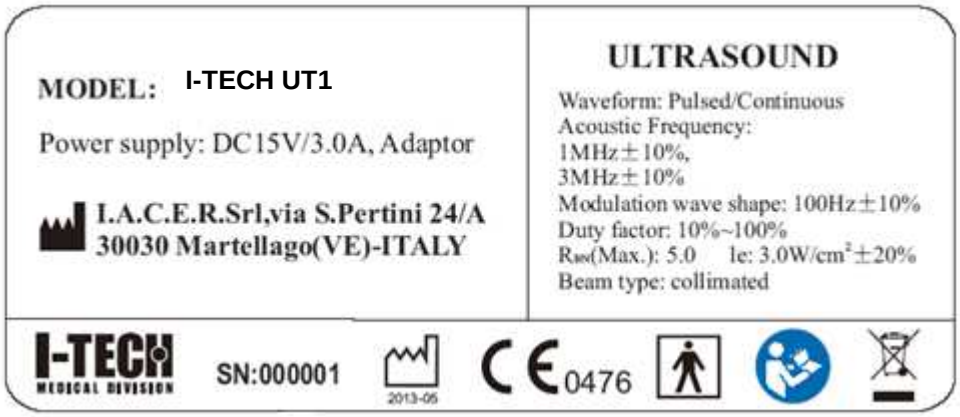
1. Program indicator
2. Frequency indicator 1/3MHz
3. Duty cycle indicator
4. Timer indicator
5. Output intensity/power indicator
6. Ultrasound head detector
7. PAUSE therapy indicator

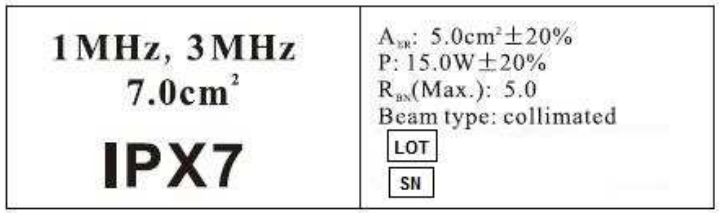
MANIPOLI



1. Ultrasound head
2. LED for ultrasound head detector
3. Handle applicator

LABELS





⊙/○	ON /OFF button
⊖⊙⊕	Polarity of Power Supply
▽	Stop treatment
▶/II	Start/Pause button
IPX7	Protected against the effects of immersion: for ultrasound handle

	WEE Regulations
	Applied part type BF
CE 0476	Product in compliance with Directive 93/42/EEC (MDD)
	Ultrasound intensity
	Ultrasound applicator state (contact head/skin)
	Indicator of connection socket of treatment head
W/cm²	Ultrasound output intensity
W	Ultrasound output power
	Treatment time
	Fabricant name and address
	Manufacturing date (month/year)

	Attention. Consult operating instructions
LOT	Ultrasound handle lot
SN	Serial number of ultrasound handle

INSTALLATION

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

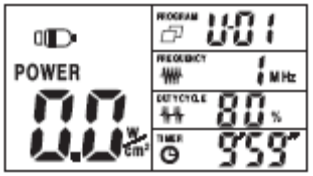
Before the installation and the connection of the device to the mains supply, check that the voltage and frequency correspond with the available mains supply and indicated in this user manual. We recommend that you use the MPU50-160 type power supply.

Follow the instructions below for a correct installation:

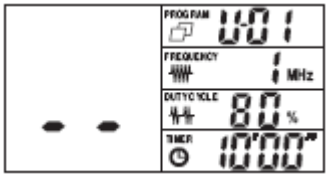
- Connect the power supply cable to the power supply
- Connect the power supply to the device connector
- Connect the power supply plug to the wall socket

Press on ON/OFF button to switch on the device.

If it is connected correctly, display will show the picture below.



If it is connected in wrong way, display will show the picture below.



PRELIMINARY OPERATIONS

Immediately after switching on, the device carries out a self-test. At the end of the self-test a beep is heard and display shows the picture as described in previous paragraph. When an error is found an error code will appear on the display: please read the paragraph “Operation troubles” to get more details.

Before starting treatment please pay attention to the following suggestions:

- Put the patient in a comfortable position. The area to be treated should be properly supported and exposed and perfectly relaxed.
- Inform the patient on the purpose of the treatment and the sensation he will perceive during the treatment.
- Ensure there are no contraindications to treatment.
- Inspect the patient's skin accurately for any abrasions, inflammation, surface veins etc.
- Clean the area to be treated with a 70% alcohol or soap.
- It is suggested to shave areas of excessive hair-growth.

Durante il trattamento:

1. The ultrasound-head has to be moved constantly when intensity is higher than 0,5 W/cmq.
2. Ask the patient about his/her sensation during the 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.

ATTENTION:

- The treatment should be performer 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.

ULTRASOUND TREATMENT

After performing the preliminary operations listed in the previous paragraph, start the session making sure to follow these steps:

1. Press PROGRAM keys 

to select the program: scroll up/down the programmes with the arrows.

2. Select the frequency 1 or 3 MHz by pressing the button FREQUEN. 

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3. Select duty cycle (10-100%) by pressing the buttons DUTY CYCLE 

(up arrow and down arrow)

4. Select therapy time (1-30 minutes) by pressing the buttons TIME (

up arrow and down arrow.

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

6. Regulate the intensity of the treatment using the knob (7). Press any of the PROGRAM, FREQUEN., DUTY CYCLE or TIME buttons during the treatment to visualise W (Watts) or W/cm² (Watt/sq cm).

7. 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.

8. 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. The system is not available on the 1cm head because of the reduced contact area: 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.

9. It's possible to stop temporary the therapy at any time pressing the knob (7). Press again the knob to continue the treatment.

10. Press the orange button  to stop immediately the treatment in progress.

We advise handling the handpieces with care in order to preserve them.

In order to ensure efficient transfer of energy, a contact means is required between the ultrasound head and the body. Air causes virtually total reflection of the ultrasound energy. The best means for the transfer of ultrasound energy is the ultrasound gel.

Put a quantity of conductive gel on the area to be treated. Move the ultrasound head during therapy session in a circular motion. The treated area should be twice the ultrasound head area.

If the body surface is very irregular, making it difficult to obtain good contact between the ultrasound head and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles that could decrease the effectiveness of the treatment.

ATTENTION. The handpiece and its cable are the only parts protected against water damage with a IPX7 grade.

ATTENTION. Never apply the gel to the ultrasound head. The treatment head will register this as contact and may emit ultrasound energy, which could damage the ultrasound head. Always use the gel certificated with the requirements of the medical, such as with CE mark.

Programs features and main applications.

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

PROG.	FREQ.	DUTY CYCLE	TIME	SUGGESTED INT.
U-01	1MHz	80%	10 min.	1.0W/cm²
U-02	1MHz	50%	10 min.	1.0W/cm²
U-03	1MHz	50%	20 min.	1.5W/cm²
U-04	1MHz	50%	15 min.	1.0W/cm² 1.5W/cm² 2.0W/cm²
U-05	3MHz	80%	15 min.	1.0W/cm²
U-06	1MHz	30%	15 min.	1.5W/cm²
U-07	1MHz	80%	15 min.	1.0W/cm² 1.5W/cm²
U-08	1MHz	80%	8 min.	1.5W/cm²
U-09	1MHz	50%	12 min.	1.5W/cm²
U-10	3MHz	80%	10 min.	1.0W/cm²

TREATMENT	PRG	HANDLE POSITION	FREQ	DUTY CYCLE	TIME	HEAD	SUGGESTED INTENSITY	APPLICATIONS NUMBERS
Acne	U-01/10	Affected area	3MHz	30%	15 min	5 cmq	1,5W/cm²	Free
Muscle fatigue	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2 W/cm²	2-3
Algodystrophy	U-01/10	Affected area	1MHz	50%	10 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Anti-inflammatory	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Arthritis	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Fingers arthritis	U-01/10	Hand fingers	1MHz	40%	15 min.	1 cmq	1.5W/cm² - 2W/cm²	10-15
Arthrosis	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.5W/cm² - 2W/cm²	10-15
Bursitis	U-01/10	Affected area	1MHz	30%	15 min.	5 cmq	2W/cm²	10-15
Brachialgia	U-01/10	Trapezium and arm	1MHz	30%	15 min.	5 cmq	2W/cm²	10-15
Capsulitis	U-01/10	Shoulder	1MHz	30%	15 min.	5 cmq	2W/cm²	10-15
Cavitations	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2W/cm² - 3W/cm²	20-30
T-T headache	U-01/10	Cervical area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
T-T headache	U-01/10	Massetere	1MHz	50%	15 min.	5 cmq	1.5W/cm²	10-15
Cervicalgias	U-01/10	Cervical area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Whiplash	U-01/10	Cervical and dorsal + front zone	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Condropathy	U-01/10	Affected area	1MHz	60%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Muscle contractures	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2W/cm²	4-6

Coxarthrosis	U-01/10	Hip	1MHz	60%	15 min.	5 cmq	2W/cm²	10-15
Cramps	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2W/cm²	4-6
Cruralgy	U-01/10	Internal thigh	1MHz	40%	15 min.	5 cmq	2W/cm²	10-15
Discopathy	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Strains	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Articular pain	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Intercostal pain	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Menstrual pain	U-01/10	Abdomen	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Muscle pain	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Rheumatic pain	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Dorsalgy	U-01/10	Dorsal area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Drainage	U-01/10	Affected area	1MHz	60%	15 min.	5 cmq	2W/cm²	30
Eczemas	U-01/10	Affected area	3 MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Oedemas	U-01/10	Affected area	1MHz	30%	15 min.	5 cmq	2W/cm²	10-15
Hematomas	U-01/10	Affected area	1MHz	40%	15 min.	5 cmq	2W/cm² - 3W/cm²	10-15
Epicondylitis	U-01/10	Elbow	1MHz	40%	15 min.	5 cmq	1.0W/cm² - 1,2W/cm²	10-15
Epitrocleitis	U-01/10	Internal elbow	1MHz	40%	15 min.	5 cmq	1.0W/cm² - 1,2W/cm²	10-15
Slipped disc	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Gonarthrosis	U-01/10	Knee	1MHz	50%	15 min.	5 cmq	1.5W/cm² - 2W/cm²	10-15

Lymphoedema	U-01/10	Affected area	1MHz	30%	15 min.	5 cmq	2W/cm²	10-15
Lypolisis	U-01/10	Affected area	1MHz	60%	15 min.	5 cmq	2W/cm²	30
Lumbago	U-01/10	Lumbar area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Massage	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2 W/cm²	Free
Mialgy	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Mononeuropathy	U-01/10	Pain zone	1MHz	50%	15 min.	5 cmq	1.5W/cm²	12-15
Neuralgia	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Periarthritis	U-01/10	Shoulder	1MHz	70%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Pubalgy	U-01/10	Internal thigh (upper zone)	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Radiculitis	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Muscle recovery	U-01/10	Affected area	1MHz	70%	20 min.	5 cmq	2 W/cm²	Free
Rizarthrosis	U-01/10	Thumb area	1MHz	30%	15 min.	5 cmq	1,5W/cm²	10-15
Rizopathy	U-01/10	Dorsal area	1MHz	60%	15 min.	5 cmq	1,5W/cm²	10-15
Wrinkle	U-01/10	Affected area	3MHz	30%	15 min	5 cmq	1,5W/cm²	Free
Sciatalgy	U-01/10	Affected area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Stretch marks	U-01/10	Affected area	3MHz	40%	15 min	5 cmq	2W/cm²	Free
Venous stasis	U-01/10	Extremities limbs	1MHz	50%	15 min.	5 cmq	2W/cm²	Free
Sprains	U-01/10	Affected area	1MHz	40%	15 min.	5 cmq	2W/cm²	4-6
Muscle sprains	U-01/10	Affected area	1MHz	40%	15 min.	5 cmq	2W/cm²	8-10

Tallonitis	U-01/10	Heel	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Tendinitis	U-01/10	Affected tendons	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Stiff neck	U-01/10	Cervical area	1MHz	50%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Carpal tunnel syndrome	U-01/10	Internal wrist	1MHz	40%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	10-15
Vascularisation	U-01/10	Affected area	1MHz	60%	15 min.	5 cmq	1.0W/cm² - 1,5W/cm²	Free
Active principle vehiculation	U-01/10	Affected area	1MHz	60%	15 min.	5 cmq	2W/cm²	Free

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

In particular, indications on intensity do not consider the width of the area to be treated. If it is very wide, the intensity can be increased by 20% with respect to what indicated and it can be reduced if it is a small area.

Similarly, the movement on the area must be appropriate to the heat felt by the patient. The slower it moves, the stronger the heat. If the patient complains about the heat, we advise reducing the intensity or moving the head faster.

CLEANING, MAINTENANCE AND STORAGE

Before cleaning switch off the device and disconnect it from the mains supply. Disconnect all cables and accessories.

The dust can be removed with a dry cloth. To clean persistent dirt use a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

ATTENTION.

Do not immerse the device into liquids. Should the device accidentally become submersed, contact the fabricant and/ or Authorized Service center immediately. Do not attempt to use a system that has been wet inside until inspected and tested by the fabricant or the Service Technician Certified by Authorized Service center. Do not allow liquids to enter the ventilation holes in the optional modules.

In case of irritations or reddening, suspend the treatment and consult a doctor .

Clean the contact surface immediately after each treatment using a soft cloth or paper cloth, lightly wet if needed. Make sure that no ultrasound gel remains on the ultrasound head. Aggressive clearing agents could damage the rubber insulation and shorten the life of the cables.

Store the handpiece/applicators/cables with care at the end of each treatment.

To get more information about the original accessories and spare parts, contact I.A.C.E.R. Srl authorized centers.

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

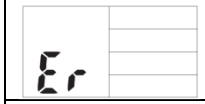
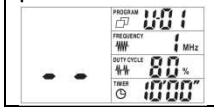
Do not disassemble the device to clean or check it: there is no need to clean the inside of the machine and in any case this operation should be performed by skilled technical personnel authorised by I.A.C.E.R. srl.

When not using the device for a long time, place it together with all its accessories in a dry place away from dust, direct sunlight and protected from the weather. Do not place other objects on top of the device.

OPERATION TROUBLES

I-TECH UT1was designed and manufactured using advanced technological solutions and high-quality components for an efficient and reliable use.

Anyway, should there be any problems during functioning, please refer to this guide before contacting an authorised service centre.

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.
Display shows the following error 	Error during the self-test	Remove any applicators, switch the apparatus off and on again. If the problem persists, contact the fabricant.
Display shows the following picture 	No handle is connected	Check the connection of applicator/s to the socket/s. . If the problem persists, contact the fabricant.

ENVIRONMENT PROTECTION

I-TECH MEDICAL DIVISION devices are designed and manufactured to have minimum negative impact on the environment in compliance with the functioning and safety needs.

We follow the criteria to minimise waste, toxic material, noise, undesired radiations and energy consumption.

A careful research on the performance of the device guarantees a significant reduction of consumption, in line with the concept of energy saving.

This symbol indicates that the product must not be disposed of with normal domestic waste.

Please dispose of the device in accordance with the directive 2002/ 96/EC WEEE (Waste Electrical and Electronic Equipment).

TECHNICAL FEATURES

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Power supply	Input: 100V-240V, 47Hz-63Hz, 1.35A Output: 15VDC, 3A max Dimensions: 143mmx73mmx40mm
Device	Dimensions: 250mmx185mmx82mm
Environmental conditions for use	Temperature: from 10°C to 40°C Relative humidity: 30%-85% Atmospheric pressure: 800-1060hPa
Environmental conditions for storage	Temperature: from -10°C to 55°C Relative humidity: 10%-90% Atmospheric pressure: 700-1060hPa
Maximum adjustable therapy time	30 minutes
Timer accuracy	+/-3%
Classification EN 60601-1	Class I
Applied part	Type BF

Ultrasound features

Ultrasound wave frequency	1MHz +/-10% 3MHz +/-10%
Duty cycle	10%-100% a stepping 10%
Working frequency	100Hz+/-10%
Therapy time	Adjustable, max. 30 minutes
Output power (+/-20%)	0.5W-10.0W, when duty cycle ≥ 80% for 5 cmq ultrasound head 0.5W-15.0W, when duty cycle ≤ 70% for 5cmq ultrasound head 0.1W-2.0W, when duty cycle ≥ 80% for 1cmq ultrasound head 0.1W-3.0W, when duty cycle ≤ 70% for 1cmq ultrasound head
Effective radiating area (Aer) (+/-20%)	1.0cmq (optional) 5.0cmq
Effective intensity	3.0W/cmq +/-20%
Accuracy	+/-20% (when value > 10% maximum value)
Rbn (Max)	5.0
Beam type	Collimated
Material of ultrasound head	Aluminium
IP Protection	IPX7 only for ultrasound head

SYMBOLS

	ON /OFF button
	Polarity of power supply
	Stop treatment
	Start/Pause button
IPX7	Protected against the effects of immersion: for ultrasound handle
	WEE Regulations
	Applied part type BF
CE 0476	Product in compliance with Directive 93/42/EEC (MDD)
	Device can supply a current > 10mA r.m.s. or 10V r.m.s. for a period of 5 seconds
	Fabricant name and address
	Manufacturing date (month/year)
	Attention. Consult operating instructions
LOT	Ultrasound handle lot
SN	Serial number of ultrasound handle

EM COMPATIBILITY – EMC TABLES

Use the I-TECH UT1 device at least 3 metres away from televisions, monitors, mobile phones, WIFI routers or any other electronic device as they may affect its functioning.

The device must be installed and commissioned in compliance with the information on electromagnetic compatibility supplied in this manual. Also see the EMC Charts paragraph.

Using accessories, transducers and cables other than those specified, except for those transducers and cables sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased immunity of the device.

The device should not be placed next to or on top of other devices. Should it prove necessary to place it next to or on top of other devices, supervision is essential at all times to control its normal functioning.

Guidance and manufacturer's declaration – electromagnetic emissions **FOR ALL EM DEVICES**		
The I-TECH UT1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the I-TECH UT1 should assures that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The I-TECH UT1 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 CISPR11	Class B	The I-TECH UT1 device is suitable for use in all establishments other than domestic and those directly connected to the public l o w - v o l t a g e p o w e r s u p p l y network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N.A.	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N.A.	
Guidance and manufacturer's declaration-electromagnetic Immunity		
The I-TECH UT1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the I-TECH UT1 should assure that it is used in such an environment.		

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	± 6kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 8kV air	± 8kV air	

Guidance and- manufacturer's declaration. Electromagnetic immunity

FOR EM DEVICES THAT ARE NOT INTENDED FOR LIFE SUPPORT

The I-TECH UT1 device is intended for use in. the electromagnetic environment specified below. The customer or the user of the I-TECH UT1 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Portable and mobile RF communications equipment should be used no closer to any part of the I-TECH UT1 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Electromagnetic environment - guidance
Conducted RF lEC 61000-4-6	3V effective from 150kHz to 80MHz	3V (V_1)	Portable and mobile RF communications equipment should be used no closer to any part of the I-TECH UT1 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d = 1,2 ·√P from 150kHz to 80MHz d = 1,2 ·√P from 80 MHz to 800 MHz d = 2,3 ·√P from 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the.
Radiated RF lEC 61000-4-3	3V/m from 80MHz to 2,5GHz	3V/m (E_1)	
Transmitter manufacturer and *d* Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site a survey, should be less than the compliance level b in each frequency range. Interference may occur In the vicinity of equipment marked with the following.: 			
NOTE I At 80 MHz ends 800 MHz. the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

*1: Field strengths from fixed 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 du to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the I-TECH UT1 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the I-TECH UT1.

*2: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V] V/m.

Recommended separation distances between portable and mobile rf communications equipment and the em devices that are not intended for life support

The I-TECH UE device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the I-TECH UE device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 frequency of transmitter (m)		
	From 150kHz to 80MHz d = 1,2 ·√P	From 80MHz to 800MHz d = 1,2 ·√P	From 800MHz to 2GHz d = 2,3 ·√P
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1:
At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARRANTY

The device has a 2 year warranty starting from the purchase date covering electric and electronic parts for household use. In case of purchase from professional operators (purchase with an invoice), the warranty is 12 months. All of the parts subject to normal wear and tear (ultrasound head) are not covered by warranty as well as all the parts that are defective due to negligence, improper maintenance, tampering or repair work carried out by personnel that has not been authorised by the manufacturer or the authorised dealer.
The warranty conditions are those described under "Warranty Regulations".

In accordance with the Medical Devices Directive 93/42/EEC, the manufacturer must be able to trace the devices at any time in order to intervene promptly in case of manufacturing faults.

In the event of future repairs under warranty, the equipment must be packaged to prevent damage during transport and sent to the manufacturer together with all of the accessories. The purchaser only has the right to repair under warranty when the equipment is returned to the manufacturer complete with the receipt or invoice proving the correct origin of the product and purchase date.

Warranty regulations.

1. *In the event f repairs under warranty, the purchaser must include in the package the receipt or invoicing proving the purchase date.*
2. The electronic parts are covered by a 24-months (12 months for professional user) warranty. The warranty is given through the point of sale or directly from the manufacturer.
3. The warranty covers exclusively product damage causing operational defects.
4. The warranty covers exclusively the repair or replacement free of charge, including labour, of components found to be defective in terms of manufacture or material.
5. The warranty does not apply to damage caused by neglect or use not complying with the instructions provided, damage caused by work carried out by unauthorized personnel or damage caused by accidental causes or the buyer's negligence, with particular reference to external parts.
6. The warranty does also not apply to damage to the equipment caused by incompatible power supplies
7. Parts subject to wear after use are excluded from the warranty.
8. *The warranty does not include transport costs to be paid by the purchaser in relation to the method and speed of transport.*
9. *The warranty empire after 24 months (12 months for professional user).. After such time repair work will be carried out at the rates currently in force for the parts replaced and the labour and transport costs.*
10. Any controversy will fall within the exclusive jurisdiction of the Venice courts.

I-TECH

MEDICAL DIVISION

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