I-TECH
MEDICAL DIVISION

USER MANUAL

Ultrasound therapy

MIO-SONIC

I.A.C.E.R. Srl
Via Enzo Ferrari 2 - 30037 Scorzè (VE) – Italia/Italy - Tel.: (+39) 041/5401356 - Email: iacer@iacer.it
PEC: iacer@pec.it - Web: www.itechmedicaldivision.com - Cod. Fisc./P.IVA/VAT N.: IT00185480274
R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.

Manufacturer

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

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

herewith declares under its own responsibility, that the product

MIO-SONIC

UMDNS Code**: 11248**

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

CE 0068

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

Certified number: 0068/QCO-DM/235-2020

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

Scorzè, 31/01/2022 — MASSIMO MARCON

Place, date — *Legal Representative*

Classification

The MIO-SONIC has the following classification:

- class IIa (Directive 93/42/EEC, Annex IX, rule 9, 10 and further amendments);
- class II with BF type applied part (classification EN 60601-1);
- unprotected device, IPX0 protection degree based on penetration of liquids and dust. Degree of protection IPX7 is for the treatment head. DEVICE NOT SUITABLE FOR USE WITH IMMERSION;
- equipment and accessories not subject to sterilization;
- equipment unsuitable for use in presence of a flammable anesthetic mixture containing air, oxygen and nitrous oxide;
- equipment suitable for continuous operation;
- equipment unsuitable for outdoors use.

Purpose and scope

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

The MIO-SONIC device for ultrasound therapy is ideal for the treatment of muscular and nervous pathologies and for the recovery of traumas, in case of both chronic and acute pathologies.
In fact, ultrasound therapy is indicated for antalgic treatments and relaxation of contracted muscles, in the treatment of neuritis and sciatalgia, joint calcifications, tendinitis, hematomas and contractures.
Very suitable also for applications in the aesthetic field, for the treatment of cellulite, tissue regeneration, vascularization and lymphatic drainage. For details, treatable pathologies, specific methods of application and use of the programs, see the chapter dedicated to the use of the device.
The population of patients for electrotherapeutic treatment
using the MIO-SONIC device includes patients of both sexes, men and women, adults (unless otherwise indicated). For more details, please refer to *Contraindications*

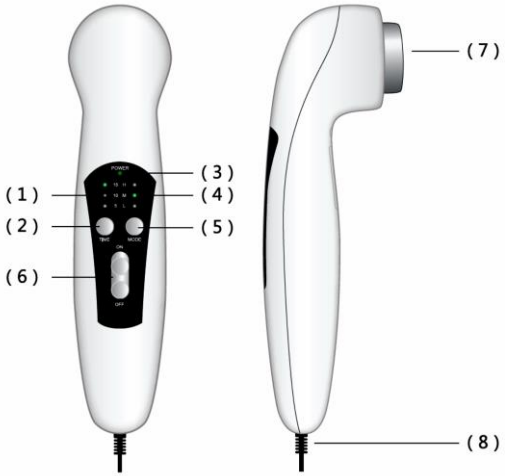
Technical features

Characteristics	Specifications
Power supply	Medical power model GJ24WA-1500120V Input: AC 100/240V, 50/60Hz Output: DC 15V, 1.2A

Characteristics	Specifications	
Isolation (EN 60601-1)	II	
Applied part (EN 60601-1)	BF	
Dimensions (length x height x depth)	202x490x700mm	
Weight	193g (power adapter not included)	
Functioning	Continuous	
Maximum power	6.4W ± 20% (modulation duty cycle at 100%)	
Effective power	1.6W/cm² ± 20% (modulation duty cycle at 100%)	
Frequency range	1MHz ± 10%	
Frequency modulation	100Hz ± 10%	
Waveform	Pulsed	
Modulation duty cycle	L: 5% M: 50% H: 100%	
Regolation intensity	Adjustable on 3 steps L-M-H	
Ultrasound head	5 cm²	
Effective radiant area	4 cm² ± 20%	
Ultrasonic beam	Collimated	
Head material	Alluminium	
Conditions of use	Environmental temperature	From +5° to +40°C
	Relative humidity	From 30% to 75%
	Atmospheric pressure	From 800 to 1060hPa
Storage and transportation conditions	Environmental temperature	From -10° to +50°C
	Relative humidity	From 20% to 93%
	Atmospheric pressure	From 700 to 1060hPa

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

Device and commands description



(1) Time indicator light
(2) Time button
(3) Power indicator light
(4) Intensity indicator light
(5) Mode button
(6) Power switch
(7) Ultrasound head
(8) AC/DC adapter connector

Labelling

Model: MIO-SONIC
Power supply: DC 15V, 1.2A
Frequency: 1MHz
Waveform: pulsed
Modulation wave: 100Hz
Duty cycle: 5%, 50%, 100%
RBN max: 5.0
Beam type: collimated
Effective power: 1.6W/cm2
Power: 6.4W
Effective area: 4.0cm2

IPX7 (only for the treatment head)

I-TECH MEDICAL DIVISION

I.A.C.E.R. S.r.l
Via Enzo Ferrari 2
30037 Scorzé (VE) - ITALY

0068

1MHz	LOT MED1032WHJ09/1
4.0cm²	SN 11020001

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
	Class II device
IPX7	Degree of protection from temporary immersion under water, up to 1m of depth and up to 30 minutes (only for the ultrasound head).
	Pay attention, Sign of danger

Package content

The MIO-SONIC package contains:

- n° 1 MIO-SONIC device;
- n° 1 medical power supply;
- n° 1 ultrasound gel;
- n° 1 transport bag;
- n° 1 user manual;
- n° 1 position manual.

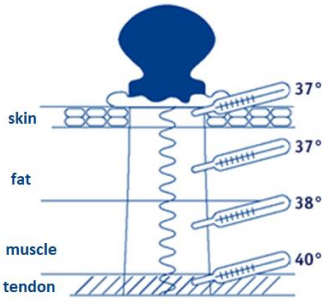
Introduction to the technology

The **sound** is given by a body vibration whose oscillation propagates in the air with a certain frequency and reaches the human ear. The number of oscillations (or pressure variations) per second is called sound frequency, measurable in cycles per second, **Hertz (Hz)**. For example, the human auditory field goes from 20Hz up to 20,000Hz. The wavelength, on the other hand, represents the space covered by the sound wave in a complete period of oscillation.

Ultrasounds are mechanical sound waves, whose frequencies are higher than those normally heard by a human ear. For years the mechanical waves of ultrasounds, specially generated through piezoelectric materials, used in various sectors of industry. In particular, the study of ultrasound wave propagation in humans has allowed the construction of eco-diagnostic medical instruments that have long been used in gynecology, gastroenterology, angiology and cardiology; these technologies in fact exploit the return echo deriving from an ultrasonic beam which propagates inside the human body and which is slowed down in a different way depending on the different anatomical structures it encounters.

Research has however shown that ultrasounds cause different biologic effects, precisely because of the different impedance characteristic of the various tissues. Among these effects, the **thermal effect** is the most known and is the one who first has determined the use of ultrasounds in orthopedics, physiatrist and sport medicine with **pain relief function** and in aesthetic field for **localized fat deposits** and **cellulite** treatment.

The thermal effect consists in the propagation of heat realized by the beam of ultrasonic waves: by penetrating in the biological tissues, the waves lose energy and yield it to the system they pass through; this energy transferred is converted into heat with a significant increase in local temperature, especially at interface level between tissues with different acoustic impedance (e.g. bone/soft tissue), and with a consequence increasing of the micro-

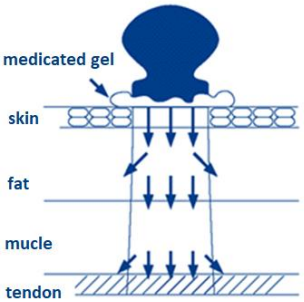


circulation, which allows the dissipation of one part of the heat produced.

After that there are also **non thermal effects** related to the propagation of ultrasonic waves: the **mechanical effects** are due to the strength applied by the sound waves on the cells that thus undergo micro-displacements towards areas with less pressure, getting into torsion and rotation phenomes, with consequent formation of small vortices in the interstitial fluids (*streaming*). These pressure variations generate **biochemical and biological effects**, that occur like possible **alterations of the permeability** of cellular membranes and, in the case of adipose cells, like the liberation of complex molecules such as the fats contained in them, beyond which are then placed into the circulatory system and largely disposed of through the lymphatic system and microcirculation.
Finally, closely related to the biochemical effect is **phonophoresis**, which consists of the ability of ultrasounds to introduce a drug into tissues.
Another non thermal phenomena is that of **cavitation**. Cavitation is a physical phenomenon which consists into formation of steam zones within the fluid.
The dissolved gasses within the fluid they aggregate as a result of the lowering of pressure realized by the ultrasound, forming bubbles or cavity containing vapor and subsequently they implode for the displacement in zones with a greater pressure. The energy which is then free produced reactions in the surrounding zones.

In therapeutic field ultrasounds are obtained in an artificial way using the proprieties of dilatation and compression of some mineral crystal when they are subject to the action of an electric field. So the ultrasonic irradiation generate vibrations and a consequent micro-massage of remarkable intensity, acting in depth into tissues. The heat is therefore generated by this micro-massage, whom consists in the impact and friction of the cellular and intracellular structures affected by the beam of ultrasonic waves.

The ultrasonic therapy is particullary indicated for all the **patologies** of the **locomotor system** in which is desired an antalgic effect, i.e. in general in the sciatalgia and neuritis, in the periarticular calcifications, in the Duplay disease, in the Dupuyten disease, organized hematomas and scar tissues, tendinitis, muscle contractures.



The ultrasounds can also been used efficacy in the treatment of imperfections caused by

the **cellulite**, reactivated the local circulation and reducing the "orange peel" effect. They facilitate the absorption of active substance like essential oils, fat-soluble vitamins (e.g. A and E vitamin) and water-soluble agents through the epidemic layers, relaxing the tissue with appreciable results in the relaxation of the wrinkles.
Finally, considerable results occur in activation of **anti-inflammatory** processes that regenerate tissues in case of acne and furunculosis, in the fat mobilization with the restoration of the tropism of cellulitic tissue and the tissue balance, with positive impact on the lymphatic vascularization and drainage.

Contraindications

It is absolutely prohibited the use of MIO-SONIC in patients with severe arrythmia or has a pacemaker, with heart disease or severe cardiovascular problems, suffers from epilepsy, phlebitis in place, thrombophlebitis, in feverish state, anxiety or serious illnesses, vein thrombosis, severe osteoporosis, inflammation, arteriopathies (except in case of medical prescription). For treatment of children under 18 years of age, a medical prescription is required and in any case consult your doctor.

Side effects

By the use of ultrasound may arise momentary inflammations in the treated area, momentary increase of the pain, overdose injuries, reactions of the nervous system or blood clotting. If such symptoms persist suspend the therapy and consult your doctor.

Warnings

It is recommended:

- to use the device by keeping a distance of at least 3 meters from televisions, monitor, mobile telephones or any other elettronic device even if the devise doesn't generate and receive any electromagnetic interference by other devices.
- to avoid the use of the device by persons who did not read carefully this manual.
- not to wear metal objects during treatment;
- to use ONLY accessories supplied by device manufacturer.

It is forbidden:

- to use the device in the presence of patient monitoring equipment, of electrosurgical or shortwave or microwave therapy equipment or other equipment that sends electrical impulses into the body and in general in combination to other medical devices, since it could cause problems to the device;
- 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;
- to use the device in presence of signs of deterioration of the device itself, cables and/or ultrasound head: 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);
- 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. Also avoid using the device on the neck and mouth. Finally, avoid treatment with direct exposure of the eye to the ultrasonic beam;
- ***maintain the ultrasound head stationary on one point during the therapy;***
- to use pointed or sharp objects on the device keyboard.

Warning:

- 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.
- The device is not intended for outdoor use.

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

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

- the environmental electrical installation to which MIO-SONIC 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.

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

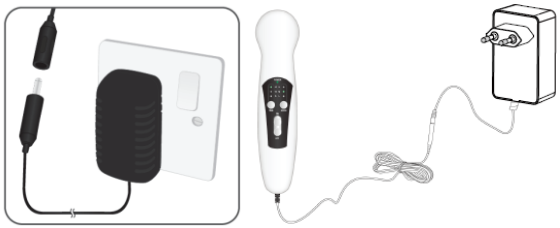
IF YOU HAVE ANY DOUBTS REGARDING THE DEVICE USE CONSULT YOUR DOCTOR.

Device use

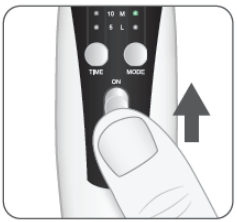
Clean and disinfect the ultrasound head with a disinfectant solution before and after the use.

To utilize MIO-SONIC:

1. connect the power supply to the device.



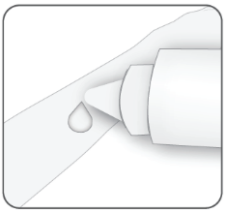
2. Move the switch to the **ON position**: the power indicator (under the written POWER) will illuminate, while the other six will begin to light up alternatively and the head will start to vibrate reporting that the device has automatically preheating mode. When the preset temperature is reached (after about 3 minutes) the six lights will flash 5 times, so the



device will enter in standby mode. If the warming feature is not needed, press both the **MODE** button and the **TIME** button simultaneously, in this way the device will go back to standby mode.
When the device is in **standby** mode, the modulation duty cycle is defaulted at 5% and the (L) indicator light will be illuminated.

⚠ DO NOT APPLY THE ULTRASOUND HEAD TO THE SKIN OF THE PATIENT during the warming period! The device will automatically exit the head warming feature if any load is detected in the preheating process.

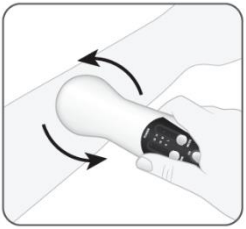
To restart the warming feature, you will have to power off the device and turn it back on again.



3. Wash the area to be treated so that it is free of oil and dirt. Apply a generous layer of ultrasound transmission gel on the treatment area. The gel is fundamental to ensure a correct fit between the treated area and the ultrasound head and so the efficiency of the therapy.

4. Press several times the **MODE** button to select the modulation duty cycle. The mode button has three levels, Low (L, preset), Medium (M) and High (H).

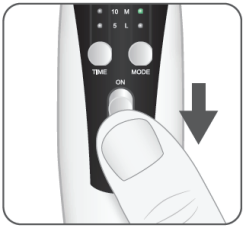
5. Press several times the **TIME** button: the lights will light up in seuqnce related to the 5-10-15 minutes of therapy and the device will start working. Set the time, the device will start automatically the treatment.



6. Place the ultrasound head on treatment area: is important perform therapy **moving continuously and uniformly the ultrasound head around the treatment area, with slow and circular or vertical movements of at least 7-8 cm**. PROHIBITED MAINTAIN THE

ULTRASOUND HEAD STATIONARY IN ONE POINT DURING THE THERAPY.

7. At the end of the therapy all the time lights indicator will shut off. Move the switch on the **OFF** button and unplug the device from its power supply.



8. Clean the ultrasound head from the gel before storing the device and its accessories in the bag. DO NOT IMMERSE THE DEVICE IN WATER!

N.B. before storing the device and its accessories in the bag, disconnect the cables. If this does not do, the cables may take excessive folds near the connectors, that can cause a damage of the cables.

ATTENTION: it is recommended to use the ultrasound with the intensity set on M. for H intensity is recommended maximum attention in maintaining in continuous moving the ultrasound head. The intensity L corresponds approx. to 0,08W/cm², the intensity M approx. to 0,80W/cm² and intensity H approx. to 1,6W/cm².

ATTENTION: to ensure the safety of the patient, the device is equipped with a recognition system of correct coupling between the ultrasound head and the patient skin. **In case of non-correct coupling or inadequate contact, the light related to the period of therapy will start light up.**

ATTENTION: to ensure the safety of the patient, the device is also equipped of a system for regulating the temperarure. **In the case the ultrasound head excees 42°C, the device will stop the treatment and time indicator light will flash two times**; it will not be possible continue the treatment program until the temperature is below 40°C.

Antalgic and de-contracting treatments

For the details and suggestions about the treatable pathologies with ultrasound please refer to 1-2-3 pages of the PAIN ZONE AND TREATMENTS POINT card included in the manual. In the figures of the table are indicated in **red color** the pain areas, with **blue color** the treatment points (trigger points). *The pain areas may not match with the treatment points, as it is evidenced in some illustrations*.

It is recommended to execute a daily cycle of therapy, with an average duration of 10 minutes each, for a maximum period of 21 days. In case the pain persists, stop for 7 days the treatment and eventually restart another therapy cycle of 21 days.

Pathology	Intensity	Frequency
Headache	L	Daily
Face pain	L	Daily
Mononeuropathy	L-M	Daily
Muscle pain	M-H	Daily
Cervical Rizopathy	L-M	Daily
Neuralgia	M-H	Daily
Sciatalgy	M-H	Daily
Knee pain	M-H	Daily
Trapezium pain	M-H	Daily
Lumbalgy	M-H	Daily
Thigh pain	M-H	Daily
Neck pain	L-M	Daily
Shoulder pain	L-M	Daily
Elbow pain	L-M	Daily
Rheumatic pains	L-M	Daily
Intercostal pains	L-M	Daily
Mestrual pains	L	Daily
Phantom limb pain	L-M	Daily
Hip pain	M-H	Daily
Knee osteoarthritis pain	M	Daily

Beauty treatments

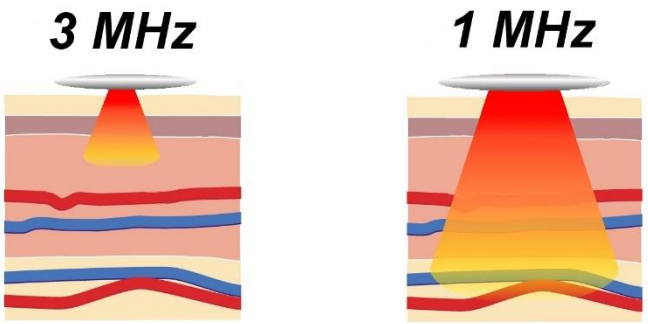
Cavitation and aesthetics

In medical field, for dermatological diagnosis and applications, is used sound waves frequencies between 1 and 16MHz for both thermal **antalgic** effect who can produce, for both controlled cavitation to use to remove the **kidney stone** (shock wave lithotripsy), which are crushed right through the formation of micro-bubbles which imploding erode solid formations inside the kidneys. Furthermore, cavitation is also used in **aesthetic medicine** to eliminate or reduce adiposities, a technique that has been called non-surgical liposuction.

In particular the **cellulite** is a disturb that affects the ipoderm, a tissue which is found under the derm and that has a mainly adipose nature; the conseguence is the increase of the volume of the adipose cells, of the water retention and of the stasis of liquids in the intercellular spaces.
The cellulite can be divided:

- **Compact**: it creates an edema that is an accumulation of liquids and it is present in the adipose tissue, especially arround the ankles, the calves and it affects subjects with a good health and with a tonic musculature.
- **Flaccid**: is manifested in middle-age people, with a ipotonic musculature.
- **Edematous**: is the evolution of the compact cellulite and is manifested in presence of circulation pathologies.

The cavitation used in aesthetic field consists inth eapplication of particula low frequencies sound waves (0,03-3MHz) which generate inside the adipose tissue vapour bubbles that implodes, releasing energy that disintegrates the adipose cells and so transforms the local fat in an easly eliminable form with the help of a correct dreinage of the lymphatic system and of the urinary tract.
If from many years the application of ultrasound was used with 3MHz frequencies, more recently the development of knowledge induced the producers of ultrasounds and cavitation equipments to reduce the frequencies of employment, because the ability of ultrasounds to penetrate in depth is inversely proportional at the beam of ultrasound frequency; consequently today 3MHz, 1Mhz, up to 0.03MHz devices are commercially available.



3MHz beam, typically more collimated but with less tissue penetration.

Application

The ultrasound head must evenly act on the treated zone, so as to evitate that in the untreated area remain substantial and unsightly adipose formations.

IT MUST ALSO BE MAINTAINED IN A CONTINUOUS MOVEMENT TO PREVENT THE OVERHEATING OF THE TREATED AREA.

The ultrasound head it must be maintained in a continuous contact with the treated area with the use of a conductive gel, better if the gel has an active substance.

Always act on an area of up to 20x20cm for about 10 minutes for then pass in nearly area, until have treated all the affected area (a complete thigh treatment depends of the thigh dimentions and will vary from 20 to 30 minutes). This job can be performed at intervals of hours or days between an area and the adjacent one or in rapid sequence.

The use of lotions or gel containing active principles, promotes the action of the ultrasound.

One of the peculiarities of ultrasound is to favor the penetration of substances and active substances under the skin (**phonophoresis**). **If therefore a specific active principle is used, the effect of the ultrasound will be amplified**.

The **purpose of cavitation** is therefore to transform the fat cells (fat) into a form easily eliminated by the organism that can expel it thanks to the lymphatic system. It is recommended, after the cavitation session, carry out as desired:

- hard walking for 30/40 minutes;
- a pressotherapy session for 20/30 minutes;

- swimming for 20/30 minutes,

in order to favorite the disposal of fat “became liquid”.
Thanks to the effects that the product (thermal, chemical, mechanical, cavitation), ultrasounds are useful for their ability to:

- stimolation of the local circulation system,
- improvement of skin trophism,
- cellular oxygenation.

Treatment

The major areas indicated fot the draining/anticellulite treatment with the ultrasounds are:

- thighs;
- calfs;
- hips (pads);
- ankles;
- knee;
- gluteus;
- arms;
- abdomen (with maximum ultrasound intensity at M).

Programs

Area	Intensity	N° app. tot	Frequency
Thighs drainage	M-H	20	Daily
Thighs compact cellulite	M-H	30	Daily
Thighs flaccid cellulite	M-H	40	Daily
Thighs edematous cellulite	H	40	Daily
Calfs drainage	M-H	20	Daily
Calfs compact cellulite	M-H	25	Daily
Calfs flaccid cellulite	M-H	30	Daily
Calfs edematous cellulite	H	30	Daily
Pads drainage	M	20	Daily
Pads compact cellulite	M	25	Daily
Pads flaccid cellulite	M	30	Daily
Pads edematous cellulite	M-H	30	Daily
Ankles and knees drainage	L-H	15	Daily
Ankles and knees compact cellulite	L-H	20	Daily
Ankles and knees flacid cellulite	L-H	25	Daily

Area	Intensity	N° app. tot	Frequency
Ankles and knees edematous cellulite	L-H	30	Daily
Gluteus drainage	M-H	20	Daily
Gluteus compact cellulite	M-H	25	Daily
Gluteus flaccid cellulite	M-H	30	Daily
Gluteus edematous cellulite	H	30	Daily
Arms drainage	L-M	15	Daily
Arms compact cellulite	L-M	20	Daily
Arms flaccid cellulite	L-M	20	Daily
Arms edematous cellulite	L-M	20	Daily
Abdomen drainage	L-M	20	Daily
Abdomen compact cellulite	L-M	25	Daily
Abdomen flaccid cellulite	L-M	30	Daily
Abdomen edematous cellulite	M-H	30	Daily
Acne / Pimples	L	10/20	Daily

REMEMBER:

- keep always in movement ultrasound head;
- use a good amount of gel to ensure contact;
- in 10 minutes act on an area of 20x20cm;
- if the area to be treated is more than 20x20cm, divide it into 2 or more parts and treat it in succession;;
- act with uniformity on the treated area.

Maintance

If used following the instructions given in this user guide, the equipment does not require any particular kind of maintenance.
It is recommended that the manufacturer carries out a functional test every 24 months. The manufacturer does not consider the MIO-SONIC 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 MIO-SONIC 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 strains can be removed using a sponge soaked in solution of water and alcohol.
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.

TRANSPORTATION AND STORAGE

Precaution for the transportation

There is no particular precaution to be taken during transportation of the device, since MIO-SONIC is a portable device. In any case it is recommended to store MIO-SONIC 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.
Don't place any heavy objects on the device.

Precaution for the storage

The appliance is protected up to the following environmental conditions:
In operation

temperature	from +5 to + 40 °C
relative humidity	from 30 to 75%

pressure from 800 to 1060hPa

Inside the supplied carrying bag

temperature from –10 to +50 °C
relative humidity from 20 to 93%
pressure from 700 to 1060hPa

Troubleshooting

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

PROBLEM	POSSIBLE CAUSE	SOLUTION
POWER LED fails to light up	The plug of the adaptor is not inserted into the socket properly.	Check the socket operation.
	Network cable not correctly inserted in the registered connector.	Insert the plug and cable correctly into the device connector.
	Network cable worn out and interrupted.	Replace the network cable.
	Power swith non set to ON.	Check that the switch has been ON.
Il LED d'accensione funziona correttamente ma non viene erogato alcun output	Time and intensity not set correctly.	Check and reset the desired values.
Some comands 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 MIO-SONIC 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 MIO-SONIC 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.*
Should you need to return the goods then please pack the device and all the accessories so that it won't be damaged during transportation. In order to be

entitled to the warranty assistance, the purchaser must enclose to the device a copy of the purchasing receipt, proving origin and purchasing date.
For more information on the warranty please contact the distributor or vendor, in order to check the norm and standard in force in your Country, or ultimately the manufacturer IACER Srl.

Warranty conditions

1) Should assistance be needed, enclose the purchasing receipt when sending the device to the manufacturer.
2) The warranty period is valid only on the electronic parts. The warranty will be granted by the shop or directly by the manufacturer.
3) The warranty covers only the product damages, which causes its malfunctioning.
4) Warranty means that only the manufacturing defect components or material are covered by reparation or free substitution, hand work included.
5) Warranty is not applied to damages caused by negligence or use not compliant to the given instructions, by intervention on the device from personnel not authorized, accidental causes or negligence form the purchaser.
6) Warranty is not applied in case of damages caused by unsuitable power supplies.
7) Warranty does not apply to wearing parts.
8) Warranty does not include transportation costs which have to be covered by the purchaser.
9) After the warranty period, the warranty is no more applicable. In this case all the assistance interventions will be performed by debiting the costs of the substitution of the parts, the hand work and the transportations costs.
10) The court of Venice has exclusive jurisdiction over any dispute.

Support

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

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

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

Spare part

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

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

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

Electromagnetic interferences and electromagnetic compatibility tables

The MIO-SONIC equipment has been designed and manufactured according to the TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY legislation EN 60601-1-2:2015 with the aim of providing adequate protection from harmful interference when installed in homes and health establishments.

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.

Edition: MNPG71-06 of the 31/01/2022

TABELLE DI COMPATIBILITÀ ELETTROMAGNETICA – ELECTROMAGNETIC COMPATIBILITY TABLES

<table>
<tr><th colspan="3">Guida e dichiarazione del costruttore – EMISSIONI ELETTROMAGNETICHE – PER TUTTI GLI APPARECCHI ED I SISTEMI
Guidance and manufacturer's declaration – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS</th></tr>
<tr><td colspan="3">Il MIO-SONIC è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore di MIO-SONIC deve garantire che esso venga usato in tale ambiente.
The MIO-SONIC is intended for use in the electromagnetic environment specified below. The customer or the user of the MIO-SONIC should assure that it is used in such an environment.</td></tr>
<tr><td>Prova di emissione
Emissions Test</td><td>Conformità
Compliance</td><td>Ambiente elettromagnetico – Guida
Electromagnetic environment - guidance</td></tr>
<tr><td>Emissioni RF
RF emissions
CISPR 11</td><td>Gruppo 1
Group 1</td><td>Il MIO-SONIC utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini
The MIO-SONIC uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Emissioni RF
RF emissions
CISPR 11</td><td>Classe B
Class B</td><td rowspan="3">Il MIO-SONIC è adatto per l'uso in tutti i locali compresi quelli domestici e quelli collegati direttamente ad un'alimentazione di rete pubblica a bassa tensione che alimenta edifici usati per scopi domestici.
The MIO-SONIC is suitable for domestic establishment and in establishment directly connected to the public low-voltage power supply network that supplis buildings used for domestic purposes.</td></tr>
<tr><td>Emissioni armoniche
Harmonics emissions
IEC 61000-3-2</td><td>Classe A
Class A</td></tr>
<tr><td>Emissioni di fluttuazioni di tensione/flicker
Voltage fluctuation/flicker emissions
IEC 61000-3-3</td><td>Conforme
Compliant</td></tr>
</table>

Guida e dichiarazione del costruttore – IMMUNITÀ ELETTROMAGNETICA – PER TUTTI GLI APPARECCHI ED I SISTEMI ***Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS***			
Il MIO-SONIC è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore di MIO-SONIC deve garantire che esso venga usato in tale ambiente. *The MIO-SONIC 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*			
Prova di immunità ***Immunity test***	**Livello di prova** ***Test level*** **IEC 60601**	**Livello di conformità** ***Compliance level***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - guide***
Scarica elettrostatica (ESD) *Electrostatic discharge (ESD)* IEC 61000-4-2	±8kV a contatto/ *in contact* ±15kV in aria/ *on air*	±8kV a contatto/ *in contact* ±15kV in aria/ *on air*	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno 30%. *Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.*
Transitori/treni elettrici veloci *Electrical fast transient/burst* IEC 61000-4-4	±2kV per le linee di alimentazione di potenza *for power supplies lines*	±2kV per le linee di alimentazione di potenza *for power supplies lines*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a typical commercial or hospital environment.*
Sovratensioni *overvoltage* IEC 61000-4-5	±1kV linea(e) – linee / *Line(s) to line* ±2kV linea(e) – terra / *Line(s) to earth*	±1kV linea(e) – linee / *Line(s) to line* ±2kV linea(e) – terra / *Line(s) to earth*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a typical commercial or hospital environment.*
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione	<5% U_T (>95% buco in / *dip in* U_T) per / *for* 0,5 cicli / *cycles*	<5% U_T (>95% buco in / *dip in* U_T) per / *for* 0,5 cicli / *cycles*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore di MIO-SONIC richiede un funzionamento continuato

Guida e dichiarazione del costruttore – IMMUNITÀ ELETTROMAGNETICA – PER TUTTI GLI APPARECCHI ED I SISTEMI
Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS

Il MIO-SONIC è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore di MIO-SONIC deve garantire che esso venga usato in tale ambiente.
The MIO-SONIC 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

Prova di immunità ***Immunity test***	**Livello di prova** ***Test level*** **IEC 60601**	**Livello di conformità** ***Compliance level***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - guide***
Voltage dips, short interruptions and voltage variations on power supplì input lines IEC 61000-4-11	40% U_T (60% buco in / *dip in* U_T) per / *for* 5 cicli / *cycles* 70% U_T (30% buco in / *dip in* U_T) per / *for* 25 cicli / *cycles* <5% U_T (>95% buco in / *dip in* U_T) per/ *for* 5s	40% U_T (60% buco in / *dip in* U_T) per / *for* 5 cicli / *cycles* 70% U_T (30% buco in / *dip in* U_T) per / *for* 25 cicli / *cycles* <5% U_T (>95% buco in / *dip in* U_T) per/ *for* 5s	anche durante l'interruzione della tensione di rete, si raccomanda di alimentare il MIO-SONIC con un gruppo di continuità (UPS) o con batterie. *Main power quality should be that of a typical commercial or hospital environment. If the user of MIO-SONIC requires continued operation during power mains interruptions, it is recommended that MIO_SONIC be powered from an uninterruptible power supply (UPS) or a battery.*
Campo magnetico a frequenza di rete (50/60 Hz) *Power frequency (50/60 Hz) magnetic field* IEC 61000-4-8	30A/m	30A/m	I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in ambiente commerciale o ospedaliero. *Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment*

Nota: U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova.
Note: U_T is the A.C. mains voltage prior to application of the test level.

Guida e dichiarazione del costruttore – IMMUNITÀ ELETTROMAGNETICA – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI
Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

Il MIO-SONIC è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del MIO-SONIC deve garantire che esso venga usato in tale ambiente.
The device 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.

Prova di immunità ***Immunity test***	**Livello di prova** ***Test level*** **IEC 60601**	**Livello di conformità** ***Conformity level***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - guide***
Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati vicino a nessuna parte del dispositivo, compresi i cavi, eccetto quando sono rispettate le distanze di separazione raccomandate, calcolate dall'equazione applicabile alla frequenza del trasmettitore. *Portable and mobile RF communications equipment should not be used near any part of the device, including cables, except when the recommended separation distance is respected, calculated from the equation applicable to the frequency of the transmitter.*			
			Distanza di separazione raccomandata – *Recommended separation distance*
RF condotta *Conducted RF* IEC 61000-4-6	$3V_{eff}$ da 150kHz a 80MHz *from 150kHz to 80MHz*	$3V_{eff}$ da 150kHz a 80MHz *from 150kHz to 80MHz*	$d = 1{,}2\sqrt{P}$ $da\ 150kHz\ a\ 80MHz$ $from\ 150kHz\ to\ 80MHz$
RF irradiate *Radiated RF* IEC 61000-4-3	10V/m da 80MHz a 2.7GHz *from 80MHz to 2,7GHz*	10V/m da 80MHz a 2.7GHz *from 80MHz to 2,7GHz*	$d = 0{,}35\sqrt{P}$ $da\ 80MHz\ a\ 800MHz$ $from\ 80MHz\ to\ 800MHz$ $d = 0{,}7\sqrt{P}$ $da\ 800MHz\ a\ 2{,}7GHz$ $from\ 800MHz\ to\ 2{,}7GHz$

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] Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo:

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
Interference may occur in the vicinity of equipment marked with the symbol above:

Note:
(1) A 80MHz e 800MHz; si applica l'intervallo di frequenza più alto.
At 80 MHz and 800 MHz, the higher frequency range applies.

Guida e dichiarazione del costruttore – IMMUNITÀ ELETTROMAGNETICA – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI ***Guidance and manufacturer's declaration – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING***
Il MIO-SONIC è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del MIO-SONIC deve garantire che esso venga usato in tale ambiente. *The device 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.*
(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone. *Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*
a) Le intensità di campo per trasmettitori fissi come le stazioni base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoricamente e con precisione. Per valutare un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa un MIO-SONIC, supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale del MIO-SONIC. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione del MIO-SONIC. *Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MIO-SONIC is used exceeds the applicable RF compliance level above, MIO-SONIC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating MIO-SONIC.* b) L'intensità di campo nell'intervallo di frequenza da 150kHz a 80MHz dovrebbe essere minore di 3V/m. *Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.*

Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili e mobili per MIO-SONIC che non sono di sostentamento delle funzioni vitali
Recommended separation distances between portable and mobile RF communications equipment for MIO-SONIC that are not life-supporting

Il MIO-SONIC è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore del MIO-SONIC possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e il MIO-SONIC come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.
MIO-SONIC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of MIO-SONIC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and MIO-SONIC as recommended below, according to the maximum output power of the communications equipment.

Potenza di uscita massima del trasmettitore specificata (W) ***Rated maximum output power of transmitter (W)***	**Distanza di separazione alla frequenza del trasmettitore (m)** ***Separation distance according to the frequency of the transmitter (m)***		
	$d = 1{,}2\sqrt{P}$ $da\ 150kHz$ $a\ 80MHz$ $from\ 150kHz$ $to\ 800\ MHz$	$d = 0{,}35\sqrt{P}$ $da\ 80MHz$ $a\ 800MHz$ $from\ 80MHz$ $to\ 800\ MHz$	$d = 0{,}7\sqrt{P}$ $da\ 800MHz$ $a\ 2{,}7GHz$ $from\ 800MHz$ $to\ 2{,}7GHz$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

Per i trasmettitori con potenza nominale massima di uscita sopra non riportata, la distanza di separazione raccomandata d in metri (m) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, dove P è la potenza massima nominale d'uscita del trasmettitore in watt (W) secondo il fabbricante del trasmettitore.
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) A 80MHz e 800MHz, si applica l'intervallo della frequenza più alto.
At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.
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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