Ultrasound

Mio-Sonic

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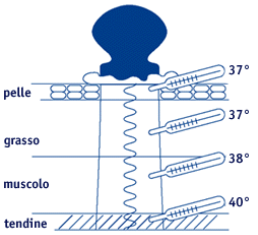
Summary

Summary 3
Introduction 4
Warnings 6
Contraindications 6
Side effects 7
Accessories and device description 7
Technical features 7
Labeling 8
Symbols description 9
Specifications 9
Purpose 9
Kit contents 10
How to use Mio Sonic 10
Analgesic and decontracting treatments 11
Beauty treatments 12
Cleaning 17
Carriage and storage 17
Disposal 18
Electromagnetic interferences and device safety 18
Assistance 18
Spare parts 19
Warranty 19

Introduction

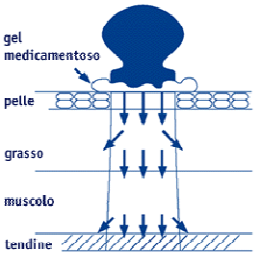
Mio-Sonic is an innovative and advanced medical device for ultrasound treatment. Thanks to its practicity it's ideal for home use.
The **sound** is given by a body vibration that expands in the air with a specific frequency and finally it reaches the ear. Sound frequency is measured in **Hertz (Hz)** and it is the number of oscillations (pressure variations) per second. The human ear can nominally hear sounds in a range from 20 Hz to 20000 Hz. Wavelength is the spatial period of the wave in a complete oscillation.
Ultrasounds are mechanical sound waves with frequencies higher than frequencies audible by the human ear.
Ultrasounds mechanical waves, generated by piezoelectric elements, are used in different industrial fields for years.
Thanks to the study of ultrasound waves in human application new diagnostic medical instrumentation has been built and they are widely used in gynecology, gastroenterology, hagiology and cardiology.
These instrumentations uses back-echo resulting from ultrasound beam that spreads in the human body and it is decelerated in different ways by anatomic structures. Each tissue has a specific acoustic impedance so ultrasound wave crossing through anatomic structures provokes different biological effects. **Thermal Effect** is the first effect that has a **pain-killer function** in orthopedics, sport medicine and in aesthetic fields for **cellulite** and **adipose tissue** treatment.

How do ultrasound waves generate heat?
Ultrasound waves loss energy when they cross through the tissues. The delivered energy is given to the crossed anatomic structure. Then energy to heat conversion increases significantly local temperature, in particular between tissues with different acoustic impedance (for example bone/soft tissues), and increases microcirculation. The bloodstream helps to dissipate the increased heat.



There are also **Not Thermal Effects** in ultrasound waves propagation.

The first are the **Mechanical Effects** caused by the ultrasound waves force on the cells that move toward low-pressure zones. As a consequence cells torsions and rotations with small vortexes happen in interstitial fluids (streaming).
These pressure variations can provoke **permeability alterations** of cells membranes (**biochemical and biological effects**). In case of adipose cells pressure variations promotes complex molecules liberation as fats that are released in circulatory system and subsequently they are eliminated through lymphatic system and micro-circulation.
Another aspect related to biochemical effect is the **Phonophoresis**, a technique that introduces drugs in tissues through the ultrasounds.
A non – thermal effect is the **Cavitation**.
In therapeutic field the ultrasounds are obtained in an artificial way. In fact some mineral crystals are able to dilate and condense when they are subjected to electric field action. Ultrasound irradiation creates some vibrations and a consequent intensive micro-massage on tissues in depth and as a consequence heat is generated (ultrasounds interaction with biological tissues has mechanical, thermal, chemical and cavitation effects).



Ultrasounds therapy is particularly indicated for locomotor apparatus **pathologies** in order to obtain an analgesic effect, in sciatic pain and neuritis, in periarticular calcifications, in Duplay's disease, in Dupuytren's disease, in hematomas and in heal tissues, in tendinitis, in muscle contractures. The ultrasounds can be used also in **cellulite** treatment by activating local circulation and by decreasing orange-peel effect. They promotes active substances penetration like essential oils, liposolubil vitamins (for example vitamin A and E) and water-soluble agents through skin by relaxing the tissues with great results in wrinkles treatment.

Ultrasounds result very efficacious in **anti-inflammatory process** that re-generate tissues in case of acne, in fats movement for tissue metabolism promotion, with positive effects also on vascularization and lymphatic drainage.

Warnings

- The device doesn't produce or receive electromagnetic interferences from other devices. However it's recommended to keep a distance of at least 3 meters from televisions, monitor, mobile phones or other electronic devices.
- The device must not be used in the presence of patient monitoring equipment.
- Do not use the device with electrosurgical or shortwave or microwave therapy equipment.
- Use of the device is prohibited to persons known to be of unsound mind.
- Use of the device is prohibited in hyposensitive zones and on carotid sinus. Avoid neck and mouth treatment.
- Use of the device is prohibited to persons temporarily disabled unless assisted by qualified personnel (e.g. a doctor or therapist).
- Use of the device is prohibited in the presence of signs of deterioration of the device itself.
- Should any foreign matters penetrate the device contact the retailer or manufacturer immediately.
- If dropped, 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 (patients being treated in a centre must also be informed of the event).
- Use of the device is prohibited in combination with other medical devices.
- Use of the device is prohibited close to flammable substances or in environments with high concentrations of oxygen.
- Consult a doctor before using Mio-Sonic with metallic osteosynthesis devices.

Contraindications

Use of the device is prohibited to persons with a pace-maker, cardiopathic subjects, epileptics, pregnant women, anxious people or people suffering from heart disease, phlebitis, thrombophlebitis or serious illnesses.

Use of the device is prohibited to persons persons suffering from serious cardiovascular problems, tuberculosis, vertebral column diseases, malignant tumour, neoplasia or with metallic prosthesis carriers (different medical prescriptions excepted), acute infections, vein thrombosis, serious osteoporosis, arteriopathies, inflammations and to persons younger than 12 years old.

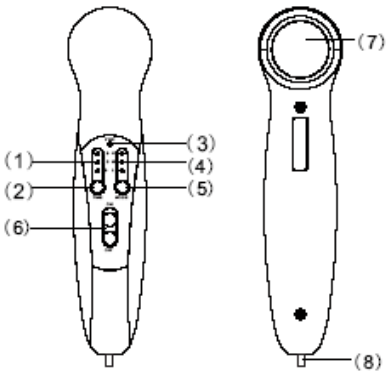
In the event of injury, muscle stress or any other health problem use the device only under medical supervision.

Avoid to position the device in a way that ultrasound beam hits the eye area or in presence of glands, near uterus and abdomen, or in thrombophlebitis and inflammation area.

Side effects

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

Accessories and device description



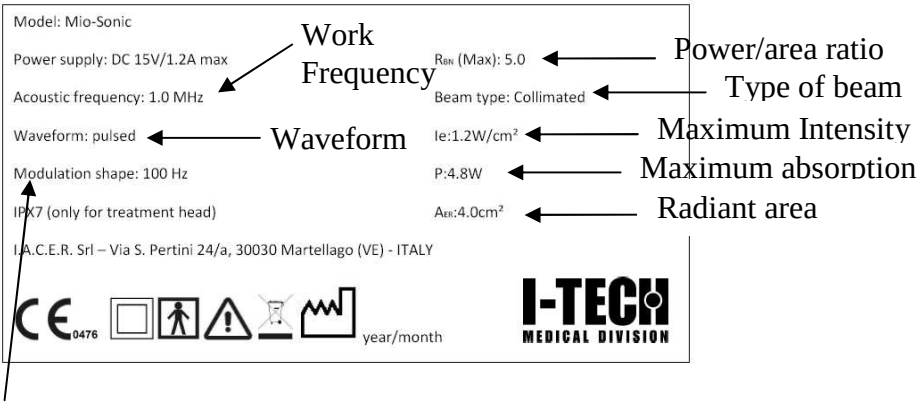
(1) Treatment time led
(2) Treatment time selector
(3) Switching on led
(4) Intensity indicator led
(5) Intensity selector
(6) ON/OFF
(7) Ultrasound head
(8) Power supply connector

Technical features

Power supply	100-240VAC, 50-60 Hz with MM1510 series power supply, output 15VDC 1 Amp. max

Insulation class (CEI EN 60601-1)	II
Applied part (CEI EN 60601-1)	BF
Dimensions (mm)	200x50x70
Maximum absorption	9.6 W ± 20% peak value (4.8 W ± 20% medium)
Effective absorption	2.4 W/cm^2 ± 20% peak value (1.2 W/cm^2 ± 20% medium)
Ultrasound frequency	1MHz ±10%
Modulation waveform	100Hz ±10%
Waveform	Pulsed
Ultrasound intensity levels	Adjustable on 3 levels L-M-H (20-30-50 % duty cycle)
Ultrasound head dimensions	5 cm²
Radiant area	4 cm² ± 10%
Type of ultrasound beam	Collimated
Ultrasound head (material)	Aluminum

Labeling



1MHz	LOT MED1032WHJ09/1
4.0cm²	SN 11020001

Symbols description

	Attention. Please read annex documents
	Product subject to WEEE regulations concerning separate waste collection of electronic equipment
	Class II equipment
	Applied part type BF
CE 0476	Product in compliance with Directive 93/42/EEC (MDD) (and following modifications Dir. 2007/47/EC)
	Manufacturing date (month/year)
S/N xxxxxx	Serial number

Specifications

Mio Sonic has the following specifications:

- Class IIa equipment (Directive 93/42/CEE, Annexed IX, rule 9 and following modifications);
- Class II applied part type BF (Classif. EN 60601-1);
- Equipment not protected against liquid penetration; IPX7 only for ultrasound head. NOT INDICATED FOR IMMERSION TREATMENTS.
- Equipment and accessories not subjected to sterilization;
- Use of the equipment is prohibited close to flammable substances or in environments with high concentrations of oxygen or nitrogen protoxide;
- Continuous operating mode equipment;
- Equipment not suited to be used in external.

Purpose

Clinical purpose: Therapeutic and aesthetic
Use: Clinic and domestic use

Mio Sonic is indicated for the treatment of muscular and nervous pathologies, for traumas recovery and also for chronic and acute pathologies.
Ultrasound therapy is particularly indicated for analgesic treatment and for contracted muscle relaxation, and in neuritis, sciatalgy, articular calcification, tendinitis, hematomas and contractures treatments.
Ultrasound therapy is also indicated for treatments in aesthetic field like for example in cellulite treatment, tissues regeneration, vascularization and lymphatic drainage.

Please read chapter "How to use Mio-Sonic" to get all information about treatments, applications details and programs.

Read and follow carefully user manual instructions for a secure and safe use of the device.

Kit contents

- Mio Sonic
- Medical Power Supply
- Ultrasound gel
- User manual
- Carriage bag

How to use Mio Sonic

Before and after using Mio Sonic clean and disinfect ultrasound head with a disinfectant solution.

Instructions

1. Connect the power supply plug to the device.

2. Put a good quantity of ultrasound gel on the area to be treated. The gel is an important factor in order to guarantee a right combination between the treated zone and the ultrasound head so finally the therapy efficacy.

3. Move the on ON/OFF switch on ON position: PWR led and L (low intensity) led will be switched on.
4. Put the ultrasound head on the area to be treated.
5. Select the intensity using the button MODE: middle intensity led (M) and high intensity led (H) will light up sequentially.
6. Select the treatment time using the button TIME: 5-10-15 leds will light up sequentially and the device will start to work.

ATTENTION: in ultrasound treatment we recommend an adjusted intensity equal to M. If you use intensities equal to H pay attention to keep ultrasound head in continuous movement. Intensity equal to L corresponds to 0,7 W/cm^2, M corresponds to 0,95 W/cm^2 and H corresponds to 1,2 W/cm^2.

ATTENTION: the device is equipped with a right combination detector between the ultrasound head and patient skin in order to guarantee patient safety. In case of wrong combination the treatment time led starts flashing.

ATTENTION: it's important to keep in continuous movement ultrasound head on the treated area during the therapy with slow and circular or vertical (at least of 7-8 cm) movements. It's forbidden to keep ultrasound head fixed in a point during the treatment.

Analgesic and decontracting treatments

In the imagines pain zones are illustrated by the **red color** and trigger points by the **blue color**.
Make reference to the figures in the attached table PAIN ZONES AND TRIGGER POINTS in order to get details and suggestions about treatable pathologies.

Pain zones could be different from trigger points as it's illustrated in the figures.

First we recommend a daily treatment of 10 minutes for a period of 21 days. If the pain persists we suggest a therapy interruption

of 7 days and eventually you can start a new therapy cycle of 21 days.

Patholgy	Ultras. 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
Trapezius 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
Menstrual pains	L	daily
Phantom limb pain	L-M	daily
Hip pain	M-H	daily
Knee osteoarthritis pain	M	daily

Beauty treatments

Cavitation

Cavitation is a physical fenomena that consists in the formation of vapor zones within a fluid. The fluid dissolved gas forms vapor bubbles or cavities due to ultrasound pressure decrease. Then vapor bubbles collapses because of movement in high pressure zones. The delivered energy produces different reactions on the surrounding areas.

Cavitation applications

Acoustic waves with frequency from 1 to 16 Mhz are used in medical field both for diagnosis and dermatoligic purposes. In fact these waves produces a thermal and analgesic effect and also a cavitation effect than can be used for **kidney stones** removal (litotrissia). Microbubbles collapse destroys kidney stones and it pulverizes solid substances within the kidney. Moreover cavitation effect is used in **aesthetic medecine** in order to decrease or eliminate adiposities. This technique is called non-surgical liposuction.

Cellulite is a deasese affecting the hypoderma that is a tissue under the dermal tissue and with an adipose nature. The consequence is an increase of adipose cells volume, like so hydric retention and liquids stasis in the inter-cell spaces.

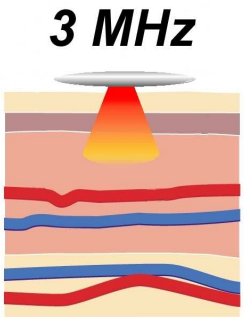
There are three kinds of cellulite desease:

- **Compact**: this type of cellulite causes an oedema that is a liquids concentration; it appears in adipose tissue in particular near the ankles, calfs, thighs and it's present also in persons with good health conditions and with tonic muscles.
- **Flaccid**: is found in middle-age persons with hypo-tonic muscles.
- **Edematous**: is the progression of compact cellulite and it appears in presence of circulatory pathologies.

Cavitation and aesthetic

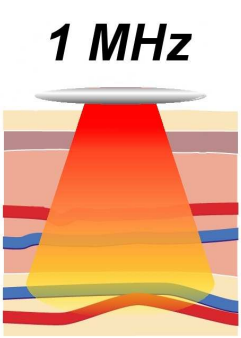
Aesthetic cavitation consists in low frequency (0,03-3 MHz) ultrasound waves application that generates vapor bubbles in adipose tissue. These bubbles rapidly implode delivering energy that breaks up adipose cell and transform localised fat in a form which can be easily eliminated by lymphatic system and urinary way and with the help of a right drainage.

In aesthetic field 3 MHz ultrasounds has been used for years. Recently new studies induce ultrasound devices manufacturers to decrease working frequencies since ultrasounds ability to penetrate in depth in tissues is in inverse proportion to the ultrasound beam frequency. Nowadays the marketing offers 3MHz,1MHz till 0,03MHz ultrasound devices.



3MHz beam, characteristically more collimated but with lower tissue penetration.

1MHz beam, characteristically less collimated but with higher tissue penetration.



Application

Ultrasound head has to work in a uniform way on the area to be treated in order to avoid adipose anti-aesthetic and solid masses on non-treated areas.

Ultrasound head has to be in continuous movement in order to avoid treated zone overheating.

Ultrasound head has to be in continuous contact with the treated zone through a conductive gel, better if it's a gel with active ingredient.

We always recommend to treat a maximum area of 20cmX20cm size for 10 minutes, afterwards treat an adjacent area in order to treat finally all interested area.

This kind of treatment can be done with hours or days intervals or consecutively between the different areas.

Cream or gel use with active ingredients promotes ultrasound action. In fact ultrasound action promotes substances and active principles penetration into the tissues (**Phonophoresis**). **As a consequence ultrasound effect will be amplified if you use a specific active principle.**

Cavitation purpose is to transform adipose cells (fat) in a form which can be easily eliminated by lymphatic system. After a cavitation treatment we heartily recommend to do optionally:

- a walk at a fast pace for 30/40 minutes
- a pressotherapy treatment for 20/30 minutes
- swimming for 20/30 minutes

in order to promote "liquid" fat elimination.

Thanks to their effects (thermal, chimical, mechanical, cavitation) ultrasounds are indicated for:

- local sanguine circulation stimulation
- skin trophism improvement
- cell oxygenation.

Treatments

Ultrasound treatments for drainage/cellulite problems concern the following body areas:

- Thigh
- Calfs
- Hips (pads)
- Ankles
- Knees
- Gluteus
- Arms
- Abdomen (with M level as maximum ultrasound intensity)

Cellulite and drainage: each treatment has to be done on a maximum area 20x20 cm size for 10 minutes. Consequently a thigh complete treatment will depend on thigh dimension and it will last from 20 to 30 minutes.

PROGRAMS

ZONE	Intensity	N° appl.	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 flaccid cellulite	L-H	25	daily
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

ATTENTION:

- Keep always in movement ultrasound head
- Use a good dose of gel in order to guarantee the contact
- Treat a maximum area 20x20cm size during a therapy session
- If the area is bigger than 20x20 cm size do more treatments in succession on smaller zones
- Treat in a uniforme way the interested area

CONTRAINDICATIONS:

- Phlogosis
- Neoplasia
- Pregnancy

- Metal materials near the treated area
- Heart area (directly on the chest)
- Persons with a pace maker
- Arteriopathies
- Serious osteoporosis
- Thrombophlebitis
- Near genital and eyes area
- Tumors
- Growing bones (younger than 12 years old)
- Vertebral column (it's forbidden to treat area on spinal cord)

Cleaning

Clean the equipment from the dust using a dry soft cloth.
Resistant stains can be removed using a sponge soaked in solution of water and alcohol.

Carriage and storage

Carriage precautions

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

Storage precautions

Mio-Sonic is protected till following environmental conditions:

Outside of the packaging

temperature	from +5 to + 40 ℃
humidity	from 30 to 85%
pressure	from 800 to 1060 hPa

Inside of the packaging

temperature	from –10 to +50 ℃
humidity	from 20 to 93%
pressure	from 700 to 1060 hPa

Disposal

The equipment is subjected to WEEE regulations (see the symbol  on the label) concerning separate waste collection: when disposing this product, please use the designed areas for disposing electronic waste or contact the manufacturer.

Electromagnetic interferences and device safety

The device doesn't produce and doesn't receive interferences from other equipments. However, it's opportune to use the instrument keeping it at least at 3 meters from televisions, monitors, cellular telephones or any other electronic equipment.
The device is manufactured in compliance with EC 60601-1-2:2001/DIN VDE 0750 Part 1-2.
The device is also in compliance with IEC/EN 60601-1, IEC/EN 60601-2-5 and IEC/EN 60601-2-10.

Assistance

Every intervention on device must be performed by manufacturer or national distributor. For any assistance intervention contact:

I.A.C.E.R. S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE) - Italy
Tel. +39 041 5401356 • Fax +39 041 5402684

You can get any technical documentation on spare parts but only prior business authorization.

Spare parts

Contact the manufacturer or the national distributor for original spare parts at following address:

I.A.C.E.R. S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE) - Italy
Tel. +39 041 5401356 • Fax +39 041 5402684

To preserve product warranty, functionality and product safety we recommend to use only original spare parts.

Warranty

Make reference to the national laws for any warranty conditions by contacting the national distributor (or directly the manufacturer IACER).

EMC Compliance

Electromagnetic emission		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions Cispr 11	Group 1	**Mio-Sonic** device uses RF Energy only for its internal function. Therefore its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions Cispr 11	**Class B**	**Mio-Sonic** device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A Complies	
Voltage Fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
Mio-Sonic is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient /burst EN 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode	±1kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (>95% dip in U_T) For 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) For 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Mains frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic field should be that of a typical commercial or hospital environment.

r.f. Electromagnetic immunity			
Mio-Sonic is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part oft he device, including

RF Radiata EN 61000-4-3	3 Veff da 80MHz a 2,5GHz	3 Veff da 80MHz a 2,5GHz	cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 			

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

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