

USER MANUAL



RESTART

Recover faster, anytime anywhere

POWERED BY
I-TECH
MEDICAL DIVISION

WEPERE

Technical information

Manufacturer	4
Declaration of conformity	4
Classifications	5
Intended purpose and scope of use	5
Technical specifications	6
Device description and controls	7
Labelling	8
Pack contents	10

How To Use

Introduction to the technology	10
Contraindications	11
Warnings	12
Device use	12
Treatments	14

Looking after the device

Maintenance	14
Troubleshooting	15
Charging the battery	16
Disposal Information	16
Warranty	17
Support	18
Spare parts	18
Interference and electromagnetic compatibility tables	22

Manufacturer

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

via Enzo Ferrari 2 • 30037 Scorzè (VE) - Italy

Tel. 041.5401356 • Fax 041.5402684

Declaration of conformity



The manufacturer

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

via Enzo Ferrari 2 - 30037 Scorzè (VE) - Italy

declares under its own responsibility that the product

RESTART

Is conform to the dispositions of the electromagnetic compatibility Directive 2014/30/UE of the European Parliament and of the Council of the 26th February 2014, to the current TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2:2015 and the following rules applied:

EN 60601-1:2006 + A1:2013, EN 60601-1-2:2015, IEC 60601-2-5:2009, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, EN ISO 14971: 2012, ISO 10993-1: 2009, ISO 10993-5: 2009, ISO 10993-10: 2010, EN 62366: 2015.

Scorzè, 31/01/2022

Place, date

A handwritten signature in black ink, appearing to read 'Massimo Marcon', with a stylized flourish at the end.

MASSIMO MARCON

Legal Representative

Classifications

The RESTART device assumes the following classifications:

- class II with type BF applied part (Classif. EN 60601-1);
- device with IP22 protection degree against the penetration of solids and liquids into the machine body. IPX7 protection degree for the treatment head. **DEVICE NOT SUITABLE FOR USE IN IMMERSION.**
- equipment and accessories not subject to sterilisation;
- device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or with nitrous oxide;
- device intended for continuous operation;
- device not suitable for external use.

Intended purpose and scope of use

The RESTART device for ultrasound treatment is ideal for all muscle, tendon and ligament treatments including:

- Muscle contracture;
- Tendon cool-down;
- Relaxing massage;
- Tissue oxygenation;
- Pre-competition preparation;
- Post-workout recovery;
- Tissue recovery;
- Muscle relaxation.

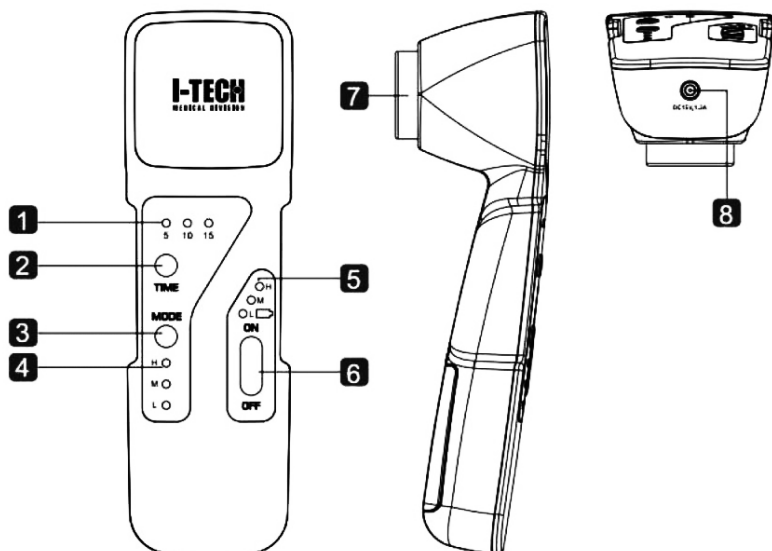
It is also recommended using the device for the following aesthetic treatments:

- Cellulite;
- Draining massage;
- Microlifting.

The user of the device can be either the user or a professional operator.

Technical specification		
Feature	Specification	
Power Supply	IN: 100-240V~, 50/60 Hz, 0.6-0.2 A OUT: 15V === 1.2A	
Battery	Ni-MH AAA850mAh 4.8 V	
External dimensions (Length x Width x Height)	204 x 63 x 58mm	
Ingress protection rating IP	IP22 machine body IPX7 head	
Insulation (EN 60601-1)	II	
Applied parts (EN 60601-1)	BF	
Part applied to the user	Aluminium head of the device	
Operation	Continuous	
Wave form	Pulsed, continuous	
Carrier frequency of use	1MHz \pm 10%	
Modulation frequency	100Hz \pm 10%	
Duty cycle	5%, 50%, 100% (mains powered) 5%, 50%, 100% (battery powered)	
Power	Can be set in 3 steps L (low) - M (medium) - H (high)	
Maximum power density	1.6W/cm ² (mains powered) 0.8W/cm ² (battery powered)	
Maximum output power	6.4W (mains powered) 3.2W (battery powered)	
RBN(max)	5.0	
Head surface	5 cm ²	
Actual radiant area	4 cm ² \pm 20%	
Beam type	Collimated	
Head material	Aluminium	
Treatment time	5, 10, 15 minutes	
Usage conditions	Ambient temperature	From +5 to +40°C.
	Relative humidity	From 15 to 93%
	Atmospheric pressure	700-1060 hPa
Transport and storage conditions	Ambient temperature	From +5 to +40°C.
	Relative humidity	From 15 to 93%
	Atmospheric pressure	700-1060 hPa
Useful life of the device and its accessories: 3 years.		

Device description and controls



- 1 Treatment time indicator
- 2 Time button
- 3 Power adjustment button
- 4 Treatment power indicator
- 5 Battery indicator
- 6 Device ON/OFF button
- 7 Emitting head
- 8 Power supply connector

Model: Restart

Power supply

In: 100-240V~, 50/60 Hz, 0.6-0.2 A

Out: 15V ---1.2A

Battery: Ni-MH AAA850mAh 4.8 V

Ultrasound

Carrier frequency of use: 1MHz \pm 10%%

Duty cycle:

5%, 50%, 100% (mains powered)

5%, 50%, 100% (battery powered)

Maximum output power:

6.4W (mains powered)

3.2W (battery powered)

RBN (max): 5,0 Actual radiant area: 4 cm² \pm 20%

Wave form: pulsed, continuous

Beam type: collimated

Modulation frequency: 100Hz \pm 10%

Pulse duration: 0.5ms, 5ms



IP22

IPX7: for the device head only

I.A.C.E.R. Srl, via Enzo Ferrari 2
30037 Scorzè (VE) - Italy

SN XXXXXX

XXXX-XX

Gel labelling

GEL PER ULTRASUONO
ULTRASOUND GEL
IDROSOLUBILE
IMPORTANTE:
IMPORTANT:

Per ottenere il massimo dal vostro Gel per ultrasuoni è indispensabile utilizzare una quantità generosa di gel conduttore al fine di trasmettere le onde ad ultrasuoni.
To get the most out of your Ultrasound gel it is essential to use liberal amount of conductive gel in order to transmit the ultrasound waves.

Conservazione e riutilizzo
Storage and Multi-use

Pulire il tappo prima di richiuderlo. Conservare in luogo fresco e asciutto.
Wipe nozzle clean and recap after each use.Store in cool, dry place.

INGREDIENTI PRINCIPALI
MAIN INGREDIENTS

Acqua, Carbopoli, Glicerolo, Trolamine, Mentolo
Water, Carbopol, Glycerol, Trolamine, Menthol

 Solo per uso esterno, non usare su pelle danneggiata.
Interrompere l'uso se si verifica eruzione cutanea o irritazione. Leggere sempre l'etichetta. Utilizzare solo come indicato. Se i sintomi persistono consultare il medico.
For external use only, do not use on broken skin. Discon-
tinue use if rash or irritation occurs.
Always read the label. Use only as directed. If symptoms
persist please consult your doctor.

 Shenzhen Dongdaixin Technology Co., Ltd.
Floor 1-2, No.3 Building, Fanshan Xusheng
Industrial Estate, Xixiangbaomang 518108
Nanshan District, Shenzhen P. R. China













  Shanghai International Holding Corp.
GmbH (Europe) Elffestraße 80,
20037 Hamburg Germany

  xxxxx-xx

85gr 

 2 Anni a confezione integra /
2 year's sealed condition

I-TECH
MEDICAL DIVISION

	Follow the "instructions for use"
	WEEE Directive
	Type BF applied part
	Class II device
	In compliance with Directive 2014/30/UE
	Serial number
	Allowed temperatures (storage temperatures, on packaging)
	Relative humidity (storage relative humidity, on packaging)
	Date of manufacture (YYYY-MM)
	Power supply
	Warning, see the documents accompanying the product
IP22	Device protected against the penetration of solids (with diameter d≥12.5mm) and against the fall of vertical drops of water when the device is held at 15° from the normal operating position.
	Expiry date

Pack contents

The RESTART pack contains:

- 1 RESTART device;
- 1 medical power supply;
- 1 battery charger;
- 1 gel for ultrasound;
- 1 carry bag;
- 1 user manual.

Introduction to the technology

Ultrasound treatment represents a method that is based on the transfer of energy into the tissues which results in thermal and non-thermal biological effects.

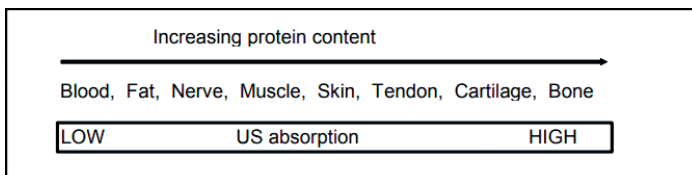
This treatment is based on the contact between the head of the device and the tissues being treated. The optimal coupling of these two surfaces is ensured by the use of a water-based ultrasound gel. Through the contact described the transmission of general mechanical waves from the piezoelectric present inside the head of the device takes place. In order for there to be maximum transmission of energy from one medium to another, the impedance of the two must be the same. Obviously in the case of the human body, such condition hardly occurs.

The greater the impedance difference between the two media, the greater the reflection and consequently the smaller the amount of energy that will be transferred. The impedance difference is greatest with aluminium-air interface, which is the first that ultrasound waves would have to overcome to reach the body. To reduce this difference, a coupling substance must be used. If there is a small amount of air between the transducer and the skin, the proportion of ultrasound waves that would be reflected would reach 99.998%, i.e. there would be no transmission.

In addition to the phenomenon of reflection, if the wave does not hit the separation surface between the media at 90°, refraction occurs. In practice, the direction of the ultrasound beam through the second medium will be angled. The critical angle for ultrasound waves at the skin surface appears to be 15°. If the device head is oriented at a 15° angle to the surface, most of the beam will propagate through the epidermal tissues parallel to the skin rather than perpendicular to the tissues.

The absorption of the energy released by the ultrasound waves follows an exponential trend, in fact much more energy is absorbed in superficial tissues rather than in deep ones.

Precisely due to the trend of absorption, theoretically there is no point where all the energy is absorbed, but there is certainly a point where these levels are not sufficient to produce a therapeutic effect. Generally tissues with the highest protein content will absorb more, unlike tissues with high water and low protein content, which will absorb a minimal amount of energy (blood and fat, for example).



Contraindications

It is strictly prohibited to use RESTART in users with severe arrhythmias or with pacemakers, with heart disease and severe cardiovascular problems, who suffer from epilepsy, with ongoing phlebitis, thrombophlebitis, in feverish states, tuberculosis, malignant tumours and neoplasms, local infections, metal implants (possible after consulting a doctor), venous thrombosis, severe osteoporosis, arteriopathies (except medical prescriptions).



Consult your doctor before using RESTART with metallic osteosynthesis devices.

Warnings

It is recommended:

- to use the device keeping the applicator at least 3 metres away from televisions, monitors, mobile phones or any other electronic equipment even if the device does not generate or receive any electromagnetic interference from other equipment;
- to avoid use of the device by people who are not properly trained and who have not read this manual;
- during treatment, the user is advised not to wear metal objects;
- to use ONLY the accessories supplied by the manufacturer.

It is forbidden:

- to use the device in the presence of equipment for monitoring the user's vital functions, equipment for electrosurgery or for short wave or microwave treatment or other devices that send electrical impulses to the body and in general in combination with other medical devices;
- for the device to be used by people of unsound mind, suffering from sensory processing disorders, temporarily unfit unless assisted by qualified personnel;
- to use with consumers under the age of 18;
- to use the device if you find any damage or signs of deterioration to it or to the accessories and/or cables: contact the retailer or the manufacturer as indicated in the Support paragraph. Check the condition of the device before each use;
- to use the device near flammable substances, gases, explosives, in environments with high oxygen concentrations, in the presence of aerosols or in very humid environments (do not use in the bathroom or while showering/bathing);
- to use the device while driving vehicles or while operating and controlling equipment/machinery;

- to use the device in hyposensitive areas, on carotid sinuses, genitals, near the uterus and abdomen, in areas of the body where there are glands. Also avoid using the device on the neck and mouth. Finally, avoid treatment with direct exposure of the eye to the ultrasonic beam;
- ***keep the treatment head fixed in one place during treatment;***
- to use sharp objects on the device head.

Warning:

- pay attention to the use of connection cables in the presence of children/young people: potential strangulation hazard;
- do not confuse the connection cables with headphone cables or other devices and do not connect the cables to other devices.
- The device is not intended for outdoor use.

The manufacturer is to be considered responsible for the safety, reliability and performance of the device provided that:

- any additions, modifications and/or repairs are carried out by authorised personnel;
- the electrical system of the environment in which RESTART is installed complies with national laws;
- the device is used in strict compliance with the instructions given in this manual.

Should any foreign substances get into the device, contact the dealer or manufacturer immediately. Should the device fall, check that there are no cracks in the container or damage of any kind; if there are, contact your dealer or manufacturer.

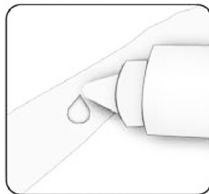
In the event of any change in performance during treatment, stop treatment immediately and contact your dealer or manufacturer immediately.

Device use

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

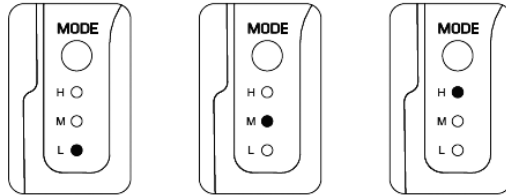
To use RESTART:

1. connect the power supply to the device if the device is not battery operated.
2. Before starting treatment, make sure to clean the treatment area with a 70% alcohol solution or mild soap. It is recommended to remove excessive hair in the treatment area.
3. Apply a good amount of ultrasound gel in the treatment area (**ONLY USE GEL WITH CE MARKING**). Gel is essential to ensure a correct coupling between the treatment area and the head and therefore the effectiveness of the treatment.

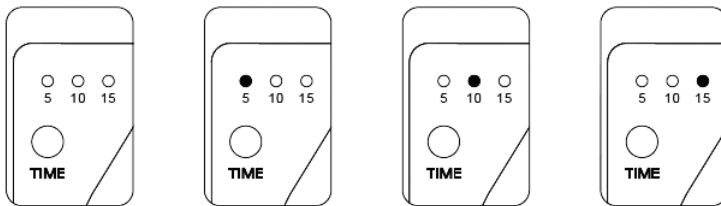


WARNING: do not apply the gel directly on the head. The device may interpret this as skin-to-head contact and emit ultrasound energy, damaging the device.

- Turn on the device by moving the switch to the ON position. The ultrasound intensity indicator will display L (Low, preset), whereas the battery level indicator will indicate the battery capacity: low (L-Low preset), medium (M-Medium) and high (H-High).
- Select the desired intensity by repeatedly pressing the **MODE** key. There are three levels of intensity selectable in order: low (preset L – Low), medium (M – Medium) and high (H – High).



- Select the treatment time by repeatedly pressing the **TIME** key: the LEDs relating to the 5-10-15 minutes of treatment will light up in sequence, as shown in the figure. When in use, the chosen treatment time indicator will be constantly lit until the set time has elapsed.



- Once the application time has been set and the head has been placed in contact with the skin, the treatment will begin: it is important to perform the treatment **by continuously and uniformly moving the head around the application area, with slow and circular movements**. The treated area should be twice the applicator diameter. If there is poor transmission of ultrasound energy, it is recommended to add more gel or reposition the ultrasound head.



Head movement should not be too slow to avoid inducing heat; nor too fast to prevent bad contact which would reduce the effectiveness of the treatment.

- At the end of the treatment all the indicator lights will turn off. Turn the switch to **OFF** and disconnect the device from the power supply (not needed if you are using the device with battery).
- Clean any gel off the head before storing the device and its accessories in the bag provided.
Make sure there is no gel left on the head. DO NOT SUBMERGE IN WATER!

N.B. disconnect the cables before putting the device in the bag. If this is not done, the cables can be excessively bent near the connectors, which can damage the cables.



WARNING: to ensure user safety, the device is equipped with a system that detects correct coupling between the ultrasound head and the user's skin. **In the event of incorrect coupling or bad contact, the treatment time LED will start flashing and the ultrasound intensity will be reduced.** Once head/skin contact is restored, the intensity will automatically increase slowly, up to the previously set level.



WARNING: to ensure user safety, the device is also equipped with a temperature regulation system. **If the head temperature exceeds 42°C, the device will end the treatment and the time indicator LED will flash twice;** it will not be possible to resume treatment until the head reaches a temperature below 40°C.

Treatments

Below is the list of treatments suggested by the manufacturer:

Treatment	Intensity	Minutes
Muscle	H - Power supply/Battery	15
Tendon/Ligament	L/M - Power supply M - Battery	10 – 15
Aesthetic	L - Power supply L/M - Battery	5 – 10



REMEMBER TO:

- keep the ultrasound head always in motion;
- use a good amount of gel to ensure contact;
- act evenly on the treated area.

Maintenance

If used in accordance with the information reported herein, this device requires no particular routine maintenance operations.

It is advisable to carry out a functional check of the device at the Manufacturer every 24 months. The manufacturer does not consider the RESTART device to be repairable by personnel outside the company itself. Any such operation by personnel not authorised by the Manufacturer will be considered tampering with the device, thereby avoiding the manufacturer's warranty and freeing it from liability for any hazards to which the operator or user may be subjected.

CLEANING

It is advisable to switch off the RESTART at the end of each treatment session, in addition to removing the power cable. Use a soft dry cloth to remove any dust from the device. In case of hard-to-remove dirt, use a cloth soaked in water and alcohol.

The device does not require sterilisation.

Notes:

- Never use solvents for cleaning. Cleaning agents can damage the device.
- Carry out routine maintenance, in particular:
 - inspect the body of the device for cracks or fissures, which may allow liquids to enter;
 - inspect the cables.

TRANSPORT AND STORAGE

Transport precautions

There is no particular care to be taken during transport as RESTART is a portable device. However, it is recommended to put RESTART and its accessories in the bag provided after each use. Protect the device from intense heat, direct sunlight and liquids. Store the device in a cool and well ventilated environment. Do not place heavy objects on top of the device.

Storage precautions

The storage location should have the following characteristics:

During operation	ambient temperature from +5 to + 40°C
	relative humidity from 15 to 93%
	pressure from 700 to 1060 hPa
In the bag provided	ambient temperature from +5 to +40 °C
	relative humidity from 15 to 93%
	pressure from 700 to 1060 hPa

Troubleshooting

Any type of work on RESTART must only be carried out by the manufacturer or authorised dealer. In any case, before sending RESTART to the manufacturer, it will be necessary to ascertain the exact nature of the RESTART malfunction. Check the following:

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device does not turn on	Adapter contact error	Make sure the adapter is connected. Check the following contacts: <ul style="list-style-type: none">• All contacts are fine• All contacts are not broken• The battery is 0
	The device does not work	
	The battery is damaged	
The LED indicators do not light up	Mains plug not inserted correctly in the power socket.	Check the operation of the power socket.
	Mains cable not correctly inserted in the connector of the device.	Insert the plug and cable correctly into the connector of the appliance.
	Mains cable worn and broken.	Replace the mains cable.

The LED indicators do not light up	Switch not turned ON.	Check that you have turned the switch ON.
The power LED is working fine but there is no output	Time and intensity set incorrectly.	Check and reset the desired values.
Some controls do not work properly..	Defective buttons or keys.	Contact the manufacturer
	Electronic control circuit failure.	
The device works as normal, but there is a noticeable drop in the effectiveness of the treatment.	Possible head fault.	Contact the manufacturer
	Possible failure of the appliance's power generator circuit.	
All battery indicators flash	The battery is damaged	Change the battery
	There is no battery	

Charging the battery

The device can be powered by the internal battery: when the battery level indicators are all off or the battery charge indicator is flashing to L (Low), it is necessary to charge the battery by connecting the adapter to the device.

When the device is charging: the battery indicator will flash from L-M-H in sequence. Once charging is complete, the battery charge indicator will light up as H (High).



WARNING: the battery life cycle depends on the charge/discharge cycles to which it is subjected and on the number of them.

Take the following precautions to increase battery life:

- Recharge the battery once a month, even when not using the device;
- Drain the battery as much as possible during use.

Replacing the Battery

The battery must only be replaced by personnel authorised by the manufacturer and not by the user. In addition, the batteries are disposed of in accordance with current regulations (WEEE).

Therefore, for replacement, contact IACER s.r.l. support directly (Support paragraph).

Disposal Information

RESTART devices, in line with operating and safety requirements, have been designed and built to have a minimum negative impact on the environment, following the provisions of the European



Directive 2012/19/EU relating to the disposal of waste electrical and electronic equipment. The criteria followed are those of minimising the amount of waste, toxic materials, noise, unwanted radiation and energy consumption.

Careful research into optimising machine performance guarantees a significant reduction in consumption, in accordance with the concept of energy saving.

This symbol indicates that this product should not be disposed with other household waste.

Correct disposal of obsolete equipment, accessories and especially batteries helps to prevent possible negative consequences on human health and the environment.

The user must dispose of the equipment to be scrapped by taking it to the collection centre indicated for the subsequent recycling of electrical and electronic equipment.

For more detailed information on the disposal of obsolete equipment, contact your local council, waste disposal service or shop where you purchased the product.

Warranty

RESTART is covered by a 2 (two) year warranty, starting from the date of purchase, on the electronic parts, when used in accordance with the instructions provided in this manual. The parts subject to wear and tear are excluded from the warranty unless there are obvious manufacturing defects. The warranty will lapse if: the device is modified in any way or operated by staff not authorised by the manufacturer or by the authorised dealer.

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.

Warranty terms and conditions

- 1) Any warranty claim must be accompanied by the receipt or invoice, that will be sent together with the goods to the manufacturer.
- 2) The warranty period is 2 years (two) and covers the electronic parts of the device. The warranty claim can be addressed to the dealer from which you have purchased the device or directly to the manufacturer.
- 3) The warranty only covers damage to the product that causes it to malfunction.
- 4) The warranty is understood to be the free repair or replacement of components recognised as faulty due to manufacturing or material defects, including labour.
- 5) The warranty does not apply in case of damage caused by negligence or use that does not comply with the instructions provided, damage caused by operations carried out by unauthorised persons, damage due to accidental causes or negligence of the purchaser, with particular reference to external parts.
- 6) The warranty does not cover any damage caused by incorrect power supply to the device.
- 7) The parts subject to wear and tear once the device has been used are excluded from the warranty.
- 8) The warranty does not include transport costs that will be borne by the buyer in relation to the modes and times of transportation.

- 9) The warranty automatically expires after 2 years. In this case, any assistance operations will be performed by charging for the replaced parts, labour costs and transport costs according to the current rates.
- 10) Any disputes that may arise shall be settled exclusively before the court of Venice.

Support

The manufacturer is the only point of contact for technical support regarding the device. For all technical support matters, please contact:

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

Technical documentation concerning repairable parts may be provided, but only with prior company authorisation and only after giving proper training to the maintenance personnel.

Spare parts

Original spare parts for this device can be ordered at any time from the manufacturer. To order them contact:

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

Use only original spare parts supplied by the manufacturer; if non-original spare parts are used, the operation and safety of the product might be affected and the warranty will be null and void.

Interference and electromagnetic compatibility tables

The RESTART ultrasound treatment device is designed and built in compliance with the current TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2:2015, with the aim of providing reasonable protection against harmful interference in residential, civil and healthcare settings.

Based on its operating principle, the device does not generate significant radio frequency energy and has an adequate level of immunity to radiating electromagnetic fields. Under these conditions, harmful interference cannot occur to radioelectric communications and to the operation of electro-medical devices used for monitoring, diagnosis, treatment and surgery, to the operation of electronic office devices such as computers, printers, copiers, faxes, etc. and to any electrical or electronic appliance used in such environments, provided that they comply with the ELECTROMAGNETIC COMPATIBILITY directive.

In any case, to prevent any problem with interference, it is recommended to operate any treatment

device at an appropriate distant from critical equipment for monitoring users' vital functions and to use caution in therapeutic applications on users with pacemakers. However, it is advisable to use the device keeping a distance of at least 3 metres from televisions, monitors, mobile phones or any other electronic equipment.

For more details consult the compatibility tables at the end of the manual.

RESTART. All rights reserved. **RESTART** and the logo **I-TECH**
MEDICAL DIVISION are the exclusive property of
I.A.C.E.R.S.r.l. and are registered trademarks.
Issue: MNPG417-01 of 31/01/2022

ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration
ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS

The RESTART is intended for use in the electromagnetic environment specified below.
The customer or the user of the RESTART should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RESTART uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RESTART is suitable for domestic establishment and in establishment directly connected to the public lowvoltage power supply network that supplis buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	
Voltagefluctuation/flicker emis- sions IEC 61000-3-3	Compliant	

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

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

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	8kV contact 15kV on air	8kV contact 15kV on air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2kV for power supplies lines	2kV for power supplies lines	Mains power quality should be that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	1kV Line(s) to line 2kV Line(s) to line	1kV Line(s) to line 2kV Line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power suppli input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Main power quality should be that of a typical commercial or hospital environment. If the user of RESTART requires continued operation during power mains interruptions, it is recommended that MIO_SONIC be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: U_T is the A.C. mains voltage prior to application of the test level.

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

The 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.

Immunity test	Test level IEC 60601	Conformity level	Electromagnetic environment - guide
---------------	-------------------------	------------------	---

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.

Recommended separation distance

Conducted RF IEC 61000-4-6	$3V_{\text{eff}}$ from 150kHz to 80MHz	$3V_{\text{eff}}$ from 150kHz to 80MHz	$d = 1,2 \sqrt{P}$ from 150kHz to 80MHz
RF irradiate IEC 61000-4-3	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	$d = 2,3 \sqrt{P}$ from 80MHz to 800MHz $d = 1,2 \sqrt{P}$ from 800MHz to 2,7 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 surveya, should be less than the compliance level in each frequency rangeb.
Interference may occur in the vicinity of equipment marked with the symbol above:



- Note:
- (1) At 80 MHz and 800 MHz, the higher frequency range applies.
 - (2) Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- a) Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which RESTART is used exceeds the applicable RF compliance level above, RESTART should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating RESTART.
- b) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment for RESTART that are not life-supporting

RESTART is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of RESTART can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and RESTART as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	$d = 1,2 \sqrt{P}$ from 150kHz to 80MHz	$d = 1,2 \sqrt{P}$ from 80MHz to 800MHz	$d = 2,3 \sqrt{P}$ from 800MHz to 2,7 GHz
0.01	0.12	0.12	0.23
0.01	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- Note:
- (1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
 - (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WEPERE

www.wepere.com

I.A.C.E.R. Srl

via Enzo Ferrari 2 - 30037 Scorzè (VE) - Italy