I-TECH
MEDICAL DIVISION

USER MANUAL

Pressotherapy

I-PRESS

I.A.C.E.R. Srl

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https://www.itechmedicaldivision.com

I-TECH
MEDICAL DIVISION

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Manufacturer

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

Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

IACER S.r.l. is an Italian manufacturer of medical devices (EU Certificate No. ITH 1344294 1 issued by the Notified Body No. 1936 TÜV Rheinland Italia S.r.l.).

EU Declaration of conformity

I.A.C.E.R. S.r.l
Via Enzo Ferrari, 2 – 30037 Scorzè (Ve), Italy
declares under its own responsibility that the devices

I-PRESS LEG2 M, I-PRESS LEG2 L, I-PRESS LEG1 M, I-PRESS LEG1 L, I-PRESS ARM1 M, I-PRESS ARM1 L

are designed and built in compliance with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and are marked

CE 1936

The devices are classified class IIa, according to Annex VIII, Comma III, paragraph 3, point 6.1 rule 9 of Regulation (EU) 2017/745 (and subsequent amendments).

The conformity of the products in question with the Regulation (EU) 2017/745 has been verified and certified by the Notified Body:

1936 - TÜV Rheinland Italia S.r.l.
Via Mattei 3, 20002 Pogliano Milanese (MI), Italy
Certificate No.: ITH 1344294 1

according to the certification process provided for in Regulation (EU) 2017/745, Annex IX.

Scorzè, 22/03/2024

MASSIMO MARCON

Place, date Legal representative

From now on, for simplicity, in this user manual, reference will be made to the I-PRESS device meaning the devices I-PRESS LEG2 M, I-PRESS LEG2 L, I-PRESS LEG1 M, I-PRESS LEG1 L, I-PRESS ARM1 M and I-PRESS ARM1 L.

Classifications

In compliance with article 2, point 1, of REGULATION (EU) 2017/745, I-PRESS device is a medical device as it consists of a device intended by the manufacturer to be used on humans for the treatment or mitigation of illnesses.

In compliance with point 1.2 of Annex VIII of REGULATION (EU) 2017/745, I-PRESS device is a type of device designed for continuous use for less than 24 hours, whose duration of use is therefore "short term". According to point 2.4 of the same annex, the device is an active therapeutic device as it depends on a source of electrical energy (active medical device), and is intended for the treatment of various types of pathologies (therapeutic device). In accordance with point 6.1 rule 9, annex VIII of regulation (EU) 2017/745, all therapeutic active devices intended to supply or exchange energy are classified as class IIa unless their characteristics are such as to allow them to supply energy to the human body or exchanging energy with the human body in a potentially dangerous form, taking into account the nature, density and point where the energy is applied, in which case they are in class IIb. Considering the fact that the type of (mechanical) energy used by the devices of the I-PRESS family is applied in a safe and controlled manner, it can be said that the energy exchanged by the device with the human body is absolutely not dangerous.

Therefore, I-PRESS device is a class IIa active medical device. With regard to point 3.5 of the aforementioned annex, which states "If different rules or, within the same rule, more sub-rules apply to the same device according to its intended use, the more stringent rule and sub-rules that involve the higher classification must be applied ", it is stated that there are no other stricter rules to apply to I-PRESS device.

Therefore, the classification is IIa

Basic UDI-DI: 8019781CLTH4CDEVDT
UDI-DI I-PRESS LEG2 M: 08019781405135
UDI-DI I-PRESS LEG2 L: 08019781708182
UDI-DI I-PRESS LEG1 M: 08019781506146
UDI-DI I-PRESS LEG1 L: 08019781809193
UDI-DI I-PRESS ARM1 M: 08019781607157

UDI-DI I-PRESS ARM1 L: 08019781900203

The I-PRESS device assumes the following classifications:

- class IIa device;
- Class II with type BF applied part (applicators, leg cuffs, arm cuff) (Classif. EN 60601-1);
- IP21 protection degree device in relation to the penetration of liquids and dust.
- Device and accessories supplied non-sterile and not subject to sterilisation;
- Device and accessories supplied do not contain or incorporate a medicine, including a derivative of human blood or plasma;
- Device and accessories supplied do not contain or incorporate tissues or cells of human origin, or their derivatives;
- Device and accessories supplied do not contain or incorporate tissues or cells of animal origin, or their derivatives;
- 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

Clinical purpose: Therapeutic
Scope of use: Outpatient Clinic/Hospital and home

The I-PRESS device for pressotherapy is ideal for the treatment of diseases affecting the circulatory system, in order to improve peripheral blood circulation. This type of device is designed for the following applications:

- Oedema
- Lymphedema
- Venous ulcers
- Venous insufficiency
- Muscle recovery

The device can be used by patients themselves. In this case they will also assume the role of operator during therapy. **In the case of home therapy, it is recommended to use the device exclusively on the recommendation of the doctor/therapist.**

The patient population intended for pressotherapy treatment using the I-PRESS device includes patients of both sexes, men and women, and adult

(unless otherwise indicated by medical practitioners). For further details, please refer to the Contraindications section.

In accordance with guidelines for medical devices, the manufacturer suggests a check of the efficiency and safety of the device every 24 months. Useful life of the device and its accessories (period after which it is suggested to send the device to the manufacturer):5 years

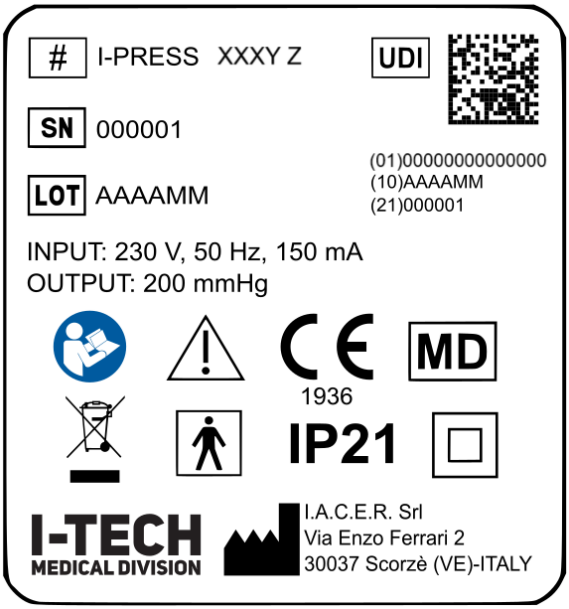
Technical specifications

Feature	Specification	
Power supply	Mains power supply 230V AC, 50Hz	
Fuses	T1A x1	
Total consumption	150mA max	
Insulation (EN 60601-1)	II	
Applied parts (EN 60601-1)	BF, applicators (leg cuff/cuffs, arm cuff)	
Dimensions (Length x Width x Height)	260 x 200 x 125 mm	
Weight	2 kg	
IP protection	IP21	
Pressure	200 mmHg (±20%)	
Treatment duration	0 ÷ 60 minutes (±15%)	
Operation	Continuous	
Conditions of use	Ambient temperature	From +5 to +40°C
	Relative humidity	From 15 to 90%
	Atmospheric pressure	700-1060 hPa
Storage/transport conditions	Ambient temperature	From -25 to +70°C
	Relative humidity	From 15 to 90%
	Atmospheric pressure	700-1060 hPa

Device description and controls

No.	Feature	Description
1	**Timer**	Time setting knob
2	**Pressure**	Pressure setting knob

Labelling

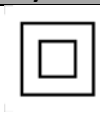


Where:

- XXX indicates the type of applicator present in the configuration (LEG for leg cuff, ARM for arm cuff);
- Y indicates the number of applicators present in the configuration;
- Z indicates the size of the applicator.

Description of the symbols (device and packaging)

Symbol	Meaning
I-TECH MEDICAL DIVISION	Manufacturer's logo.
CE 1936	This product complies with Regulation (EU) 2017/745 and subsequent amendments. Product certification issued by Notified Body No. 1936.
	Device with type BF applied part

Symbol	Meaning
	Class II device
	Manufacturer data.
	Consult the user manual.
	WEEE directive for the disposal of electronic and electrical waste.
	Serial number
IP21	Degree of protection against entry of solids, dusts and liquids (device protected against solid foreign bodies with a diameter of ≥12.5mm and against the vertical fall of water drops). IP21
	Caution, danger.
	Allowed temperatures (storage temperatures, on packaging)
	Relative humidity (storage relative humidity, on packaging)
	UDI vector for device traceability

Symbol	Meaning
	Unique device identifier. Affixed near UDI vector
	Model
	Batch number
	Medical device

Pack contents

The I-PRESS pack in all configurations contains:

- 1 I-PRESS device with applicators;
- 1 user manual
- Non-woven fabric strip 15x150 cm (see page 16 for further details)

The pack is supplied in 3 different versions depending on the type and also contains, integrating the above:

I-PRESSLEG2 -n.2 leg cuffs, n.2 4-chamber 4-ending tube, n.1 splitter, n.1 connector, n.2 pressure orthotics.
I-PRESS LEG1 – n.1 leg cuff, n.1 4-chamber 4-ending tube, n.1 connector, n.1 pressure orthotic.
I-PRESS ARM1 – n.1 arm cuff, n.1 4-chamber 4-ending tube, n.1 connector.

All these configurations are available in M or L options (for example I-PRESS LEG1 M or I-PRESS LEG1 L).

Leg extenders for large leg circumferences are also available as optional items.

Below are some example images in order to help identify the components mentioned above:

Device body

Non woven fabric strip (TNT)

Lef cuff

Arm cuff

4-chamber 4-ending tube

Connector

Splitter

Pressure orthotic

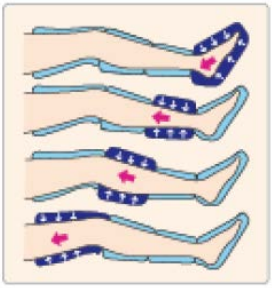
N.B.: it is recommended to interpose the non-woven fabric band between the foot and the orthotic.

Introduction to the technology

Pressotherapy is a useful method for treating diseases and conditions affecting the circulatory system, as it is able to promote correct venous circulation, reducing muscle tension caused by stress or chronic and acute pain. Thanks to its pump action, it actually promotes venous return (see figure below), increasing the blood supply of the tissues and their consequent correct physiological renewal.

Pressotherapy is therefore able to solve the problem of blood that could stagnate in damaged blood vessels or in any case in areas of the body that are not properly supplied.

External compression also allows excess interstitial fluids to return more easily to the circulatory system, so that they can be properly and quickly eliminated.



Contraindications

Undesirable effects may occur if the device is used in the following situations or in people suffering from the following diseases and conditions:

- people with implantable medical devices;
- people suffering from pulmonary oedema, heart attack, phlebocarcinoma, high blood pressure, high fever;
- people suffering from diseases or skin damage, such as burns, dermatitis, sores, purulent wounds, malignant tumors, etc.;
- people who have undergone skin surgery in the treatment area;
- people suffering from severe circulation disorders, such as hardening of the arteries, angina, previous heart attack, etc.;
- people with suspected blood clots;
- people with severe malformations or wearers of prostheses (or other fixation devices) in the treatment area;
- immediately after undergoing surgery for the treatment of varicose veins;

- patients who have just undergone surgery, pregnant women, children;

There are no known side effects related to the use of the device.

Warnings

It is recommended to read this user manual carefully before using the device. For any further information and in-depth analysis, we suggest you visit our website **www.itechmedicaldivision.com/en** in the section dedicated to pressotherapy. In this section, on the I-PRESS product page, a copy of the most up-to-date revision of this user manual can be consulted under the heading "User Manual"

It is recommended:

- to use the device keeping it 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 therapy, the user is advised not to wear metal objects;
- to pay attention to the use of connection cables in the presence of children/young people: potential strangulation hazard. Keep out of the reach of children;
- position the device so that the mains plug can be easily disconnected;
- use ONLY applicators supplied by the manufacturer.

It is forbidden:

- for the device to be used by people of unsound mind, who suffer from sensitivity disorders, or temporarily unfit if not assisted by qualified personnel; people under the age of 18 or in any case those not adequately trained in the use of the device by an adult;
- to use the device if you find any damage or signs of deterioration to it or to the applicators 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 sharp objects on the device.

Warning:

- it is forbidden to use the device in combination with other devices that monitor/support vital functions.
- do not crush, bend or damage the electric cable. Electrical shock hazard.
- do not immerse the device in liquids.
- be careful when closing the zip to avoid entangling hair or clothing.
- avoid knocking or dropping the device.
- do not move when you are using the device.

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 I-PRESS is inserted complies with national laws;
- the devices is used in strict compliance with the instructions reported in this manual.

If foreign substances get into the device, contact the retailer 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.

Electromagnetic interference

It is advisable to use the device at a distance of at least 3 meters from televisions, monitors, mobile phones, WI-FI routers or any other electronic equipment as these devices could affect the operation of the device.

The device must be operated in accordance with the electromagnetic compatibility information contained in this manual. See also the paragraph EMC tables.
The device should not be used near or placed on top of other equipment and, if it is necessary to use it near or placed on top of other equipment, it should be observed to check normal operation in the configuration in which it is used.

Patient preparation

1. Select the appropriate applicator for the area being treated.

1.1. Leg cuffs

1.1.1. **Use of two leg cuffs**

a) Connect the connector to the splitter, paying attention to the correct direction of insertion (as in figure 1-2): the correct connection will be confirmed by the click of the two side fins;
b) Connect the two 4-chamber 4-ending tube to the splitter, paying attention to the correct direction of insertion (as in figure 3-4);

1.1.2. **Use of one leg cuff**

a) Connect the connector to the 4-chamber 4-ending tube, paying attention to the correct direction of insertion (as in figure 1-2): the correct connection will be confirmed by the click of the two side fins;

1.1.3. Put on the leg cuffs (or the single leg cuff) and close the zip up to the top;

1.1.4. Insert the pressure orthotics at the lower ends of the leg cuffs, under the sole of the foot.

N.B.: it is recommended to cut the non-woven fabric band according to the shape of the pressure orthotics and place it between the foot and the pressure orthotics.

1.1.5. Connect the tubes to the 4 inlets on each leg cuff, making sure to connect the longer tube to the topmost connector (darker in colour) on the leg cuff (thigh) (figure 5).

1.1.6. After connecting the tubes, connect the connector to the clutch on the machine.

1.2. Arm cuff

1.2.1. Connect the connector to the 4-chamber 4-ending tube, paying attention to the correct direction of insertion (as in figure 1-2): the correct connection will be confirmed by the click of the two side fins;

1.2.2. Put on the arm cuff and connect the tubes to the inlets on the cuff, taking care to connect the longest tube to the (darker) connector located higher on the arm cuff;

1.2.3. After connecting the tubes to the cuff, connect the connector to the clutch on the machine.

USING EXTENSIONS

The extensions for the leg cuffs are an optional extra that allows you to increase the size of the leg cuffs and can be requested by the customer at any time.
For correct use of the leg cuffs, use the zips on the leg cuffs and on the extensions to join the two elements.

Use of device

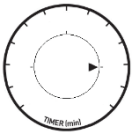
To use the I-PRESS device:

1. Plug the power cable into the mains socket.

2. Put on the applicators suitable for the treatment you intend to perform according to *Patient preparation* paragraph and connect the connector to the device body.

3. Adjust the pressure: the pressure can be adjusted from 0 to 200mmHg (± 20%), i.e. the maximum pressure that can be set, by slowly turning the knob clockwise.

4. Adjust the therapy time: the therapy time can be set from 0 to 60 minutes (±15%).



WARNING! The device will immediately begin delivering pressure into the worn applicators.

WARNING! Once the therapy has started, do not force the timer by turning it anticlockwise. Wait for the end of the therapy to set the desired time again.

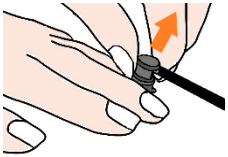
5. Press the ON/OFF switch on the device body so that it is ON.

6. At the end of the therapy, press the ON/OFF switch OFF.

7. It takes about 2 minutes for the air to flow into the chambers inside the applicators. Only when ALL the air has escaped from the chambers, unplug the power cable from the mains socket.

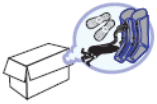
8. Disconnect the connector from the device body.

9. Remove the tube connection inlets from the applicators.



To avoid damaging the applicators, we recommend holding the coupling on the applicator with one hand and extracting the hose connection socket with the other.

10. Store the device and all its applicators in their box.



Recommended therapy settings

Condition	Pressure (mmHg)	Time (min)	Recommended applicator	Therapy cycle
Oedema	50	50	Leg cuff(s)	30 days
Lymphoedema	50	30	Leg/Arm cuff	30 days
Venous ulcers	50	60	Leg cuff(s)	30 days
Venous insufficiency	50	60	Leg cuff(s)	30 days
Muscle recovery	85	20	Leg cuff(s)	30 days

If n.2 4-chamber 4-ending tube are by connecting both leg cuffs, it is suggested to set the therapy pressures as follows:

Condition	Pressure (mmHg)	Time (min)	Therapy cycle
Oedema	100	50	30 days
Lymphoedema	100	30	30 days
Venous ulcers	100	60	30 days
Venous insufficiency	100	60	30 days
Muscle recovery	170	20	30 days

You should always consult your doctor before using the device.
You should not excessively increase the pressure more the suggested values, in order to avoid possible injuries.

Oedema: dedicated program for the reduction of oedema and resulting inflammation.

Lymphedema: dedicated program for reducing the volume of the lymphedematous limb.

Venous ulcers: dedicated program for the treatment of venous ulcers in order to speed up the healing process and reduce local pain.

Venous insufficiency: dedicated program for increasing blood perfusion in the limbs.

Muscle recovery: dedicated program for the treatment of muscle pain and stiffness after physical activity.

Looking after for the device

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 I-PRESS device to be repairable by personnel outside the company itself. Any operation in this sense 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 I-PRESS at the end of each therapy session, as well as to remove the cables from the appropriate connectors.

WARNING: device cleaning must not be performed while the device is in operation. Disconnect the device from the mains, disconnect all connection cables and perform cleaning with the device switched off.

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.
To clean the cuffs, use a soft cloth dampened if necessary, with a solution of water and alcohol.
Wait until completely dry before using the device and applicators again.
The device does not require sterilisation.
Notes:

- Never use solvents or chemicals 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.

Follow the above instructions only, for any other cleaning/maintenance operations contact the manufacturer.

TRANSPORT AND STORAGE

Transport precautions
There is no particular care to be taken during transport as I-PRESS is a portable device. However, it is recommended to put I-PRESS and the relative applicators in the holder supplied 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
Environmental operating conditions:

ambient temperature	from +5 to + 40°C
relative humidity	from 15 to 90%
pressure	from 700 to 1060 hPa

Environmental storage conditions:

ambient temperature	from -25 to + 70°C
relative humidity	from 15 to 90%
pressure	from 700 to 1060 hPa

Troubleshooting

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

Problem	Solution
I-PRESS does not turn on	1. Check the connection to the mains; 2. Check the power ON/OFF button; 3. Check the power cable is not damaged.
I-PRESS emits a strange hiss similar to leaking air	1. Check for damage and/or holes in the tubes and connectors; 2. Check the applicators are correctly connected to the connector/splitter and the connector to the device; 3. Check that the tubes are not bent or squashed.
There is no pressure or the air is not reaching the applicators	1. Check the connector is correctly connected to the device; 2. Check that the tubes are not bent or squashed; 3. Check that the air chambers inflate rhythmically and gradually.
Air continues to enter the chambers and/or an air leak is detected in the applicators	Check for holes or damage in the air chambers. If no air leaks are found, turn off the device, turn it back on and see if it operates correctly.
Pressure is too strong and/or the patient feels discomfort	1. Reduce the pressure using the appropriate knob. 2. Turn off the device and detach the applicators to remove air from the chambers.

Disposal Information

I-PRESS 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 subject of energy saving.

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

Correct disposal of obsolete equipment, applicators 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.

Incident reporting

In compliance with the provisions of Regulation (EU) 2017/745, the manufacturer places the need to report any incident or serious incident occurring in relation to the device to the attention of the user.
The report must be addressed:

- To the Manufacturer of the device:

I.A.C.E.R. Srl
Via Enzo Ferrari 2 – 30037
Scorzè (VE) ITALY
Tel. +39 041 5401356 – Fax +39 041 5402684
e-mail: iacer@iacer.it

Warranty

IACER Srl guarantees a warranty period from the purchasing date for I-PRESS device, unless information contained in this manual regarding installation, use and maintenance is strictly adhered. The parts subject to wear and tear (applicators) 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.
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 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)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

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

For information on spare parts and their availability, contact the manufacturer:

I.A.C.E.R. S.r.l.
Via Enzo Ferrari, 2 • 30037 Scorzè (VE)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

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 I-PRESS electrotherapy device is designed and built in compliance with the current TECHNICAL STANDARD on ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2:2015/A1:2021, with the aim of providing reasonable protection against harmful interference in residential, civil and healthcare settings. Based on their operating principle, the devices do not generate significant radio frequency energy and have 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, therapy 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 therapy device at an appropriate distant from critical equipment for monitoring patients' vital functions and to use caution in therapeutic applications on patients 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.

ELECTROMAGNETIC COMPATIBILITY TABLES

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - ELECTROMAGNETIC EMISSIONS - FOR ALL EQUIPMENT AND SYSTEMS</th></tr>
<tr><td colspan="3">I-PRESS is designed to work in the electromagnetic environment specified below. The customer or the user of I-PRESS must ensure that it is used in such an environment.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>I-PRESS uses RF energy only for its internal operation. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">I-PRESS is suitable for use in all premises including domestic settings and those directly connected to a public low voltage mains supply which supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Emission of voltage fluctuations/flicker
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR ALL EQUIPMENT AND SYSTEMS			
I-PRESS is designed to work in the electromagnetic environment specified below. The customer or the user of I-PRESS must ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV, +8kV contact ±8kV, +15kV air	±6kV, +8kV contact ±8kV, +15kV air	Floors should be wood, concrete or ceramic tile. -
Electrical Fast Transient/Burst IEC 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 IEC 61000-4-5	± 1kV line - line ± 2kV line - ground	± 1kV line - line ± 2kV line - ground	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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles <5% U_T (>95% dip in U_T) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% U_T	<5% U_T (>95% dip in U_T) for 0.5 cycles <5% U_T (>95% dip in U_T) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the user of I-PRESS requires continued operation even during mains voltage failure, it is recommended to power I-PRESS with an uninterruptible power supply (UPS) or with batteries.

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Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
	(>95% dip in U_T) for 5s	(>95% dip in U_T) for 5s	
Magnetic field at power frequency (50/60Hz) IEC 61000-4-8	30A/m	30A/m	The magnetic fields at power frequency should be at levels typical of a commercial or hospital environment.
Immunity to proximity magnetic fields (9 KHz to 150 KHz) IEC 61000-4-39	8 A/m, 30 KHz, CW modulation, 60s	8 A/m, 30 KHz, CW modulation, 60s	Mains power quality should be that of a typical commercial or hospital environment.
Immunity to proximity magnetic fields (9 KHz to 150 KHz) IEC 61000-4-39	65 A/m, 134.2 KHz, 2.1 KHz pulsed modulation, 60s	65 A/m, 134.2 KHz, 2.1 KHz pulsed modulation, 60s	Mains power quality should be that of a typical commercial or hospital environment.
Immunity to proximity magnetic fields (150 KHz to 26 MHz) IEC 61000-4-39	7.5 A/m, 13.56 MHz, 50 KHz pulsed modulation, 60s	7.5 A/m, 13.56 MHz, 50 KHz pulsed modulation, 60s	Mains power quality should be that of a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR EQUIPMENT AND SYSTEMS NOT SUPPORTING VITAL FUNCTIONS			
I-PRESS is designed to work in the electromagnetic environment specified below. The customer or the user of I-PRESS must ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Portable and mobile RF communications equipment should not be used near any part of the device, including cables, except when respecting the recommended separation distances calculated from the equation applicable to the transmitter frequency.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	$3V_{eff}$ from 150kHz to 80MHz $6V_{eff}$ from 150kHz to 80MHz for ISM band	$3V_{eff}$ ([V_1] V) $6V_{eff}$ ([V_1] V)	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = d = \left[\frac{12}{V_1}\right]\sqrt{P}$ for ISM band
Radiated RF IEC 61000-4-3	3V/m from 80MHz to 2.7GHz	3V/m [E_1] V/m	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ from 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ from 800MHz to 2.7GHz
Radiated RF for radio communication devices IEC 61000-4-3	3V/m from 80MHz to 6GHz	3V/m [E_1] V/m	$d = \left[\frac{6}{E_1}\right]\sqrt{P}$ from 80MHz to 6GHz

Guidance and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY - FOR EQUIPMENT AND SYSTEMS NOT SUPPORTING VITAL FUNCTIONS
I-PRESS is designed to work in the electromagnetic environment specified below. The customer or the user of I-PRESS must ensure that it is used in such an environment.
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). The field strength from fixed RF transmitters, as determined by an electromagnetic[a] site survey a, may be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes: (1) At 80MHz and 800MHz; the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.
a) Field strengths from fixed transmitters, such as base stations for radio (mobile/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. In order 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 where an I-PRESS is used exceeds the applicable compliance level above, normal operation of the I-PRESS should be observed. If abnormal performance is noted, additional measures may be required such as reorienting or relocating the I-PRESS device. b) The field strength in the frequency range 150kHz to 80MHz should be less than [V_1] V/m.

Recommended separation distances between portable and mobile radiocommunication equipment for I-PRESS which are not supporting vital functions

I-PRESS is intended to operate in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of I-PRESS can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications devices (transmitters) and I-PRESS, as recommended below, according to the maximum output power of the radio communication devices.

Maximum Specified Transmitter Output Power (W)	**Separation distance according to frequency of transmitter (m)**				
	$from\ 150kHz\ to\ 80\ MHz$	$from\ 150kHz\ to\ 80\ MHz$ for ISM band	from $80MHz\ to\ 800\ MHz$	$from\ 800MHz\ to\ 2{,}7GHz$	$from\ 800MHz\ to\ 6GHz$ (to radio frequency wireless communication equipment)
0.01	0.12	0.2	0.12	0.23	–
0.1	0.38	0.63	0.38	0.73	–
0.2	–	–	–	–	0.9
1	1.20	2.0	1.20	2.30	–
1.8	–	–	–	–	2.7
2	–	–	–	–	2.8
10	3.80	6.3	3.80	7.30	–
100	12.00	20	12.00	23.00	–

For transmitters rated at a maximum output power not listed above, the recommended $d$separation distance in metres (m) can be calculated 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.

Notes

(1) At 80MHz and 800MHz; the higher frequency range applies.

(2) At 80MHz and 800MHz; the higher frequency range applies. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.

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