

USER MANUAL

Pressotherapy

I-PRESS



TABLE OF CONTENTS	I
TECHNICAL INFORMATION	3
MANUFACTURER	3
DECLARATION OF CONFORMITY	3
CLASSIFICATIONS	4
INTENDED PURPOSE AND SCOPE OF USE	4
TECHNICAL SPECIFICATIONS	5
DEVICE DESCRIPTION AND CONTROLS	6
LABELLING	7
<i>Pack contents</i>	9
HOW TO USE THE DEVICE	10
INTRODUCTION TO THE TECHNOLOGY	10
CONTRAINDICATIONS	10
WARNINGS	11
PATIENT PREPARATION	12
USE OF DEVICE	14
RECOMMENDED THERAPY SETTINGS	16
LOOKING AFTER FOR THE DEVICE	17
MAINTENANCE	17
TROUBLESHOOTING	18
DISPOSAL INFORMATION	19
WARRANTY	20
<i>Support</i>	21
<i>Spare parts</i>	21
INTERFERENCE AND ELECTROMAGNETIC COMPATIBILITY TABLES	22

Manufacturer

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

Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

IACER S.r.l. is an Italian manufacturer of medical devices (CE certificate No. HD60134521 issued by the Notified Body No. 1936 TÜV Rheinland Italia srl).

Declaration of conformity

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

Via S.Pertini 24/A – 30030 Martellago (Ve), Italy
declares under its own responsibility that the product

I-PRESS

UMDNS code: **10969**

is designed and built in compliance with the essential requirements of Annex 1 of Directive 93/42/EEC concerning medical devices (implemented in Italy with Legislative Decree 46/97), as amended by Directive 2007/47/EC (Legislative Decree 37/2010) and subsequent amendments/additions.

The device is classified class IIa, according to Annex IX, rule 9 of Directive 93/42/EEC (and subsequent amendments/additions) and is marked



The conformity of the product in question with the Directive 93/42/EEC has been verified and certified by the Notified Body:

1936 - TÜV Rheinland Italy

Via Enrico Mattei 3, 20010 Polignano Milanese (MI), Italy

Certificate No.: HD60134521

according to the certification process provided for in Directive 93/42/EEC, Annex II (excluding point 4)

Martellago, 31/07/2020

Place, date

MASSIMO MARCON

Legal representative

Classifications

The I-PRESS device assumes the following classifications:

- class IIa device (Directive 93/42/EEC, annex IX, rule 9 and subsequent amendments/additions);
- Class II with type BF applied part (Classif. EN 60601-1);
- IP21 protection degree device in relation to the penetration of liquids and dust.
- device and applicators 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

Clinical purpose: Therapeutic
Scope of use: OutpatientClinic/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.

The minimum age for patients to use the device is 18 years.

Technical specifications

Feature	Specification	
Power supply	Mains power supply 230V AC, 50Hz	
Fuses	T1A x1	
Total consumption	100mA max	
Insulation (EN 60601-1)	II	
Applied parts (EN 60601-1)	BF	
Dimensions (Length x Width x Height)	260 x 200 x 125 mm	
Weight	2 kg	
IP protection	IP21	
Pressure	200 mmHg ($\pm 20\%$)	
Treatment duration	0 ÷ 30 minutes	
Operation	Continuous	
Conditions of use	Ambient temperature	From +5 to +40°C
	Relative humidity	From 15 to 93%
	Atmospheric pressure	700-1060 hPa
Storage/transport conditions	Ambient temperature	From +5 to +40°C
	Relative humidity	From 15 to 93%
	Atmospheric pressure	700-1060 hPa

Useful life of the device: 3 years.

Device description and controls



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

MODEL: I-PRESS

SN : XXXXXX

Power supply: 230 Vac, 50 Hz, 100 mA




Output: 200 mmHg












IP21



I.A.C.E.R. Srl,
via S. Pertini 24/a
30030 Martellago

Symbol	Meaning
	Manufacturer's logo.
	Product certification issued by notified body No. 1936.
	Device with type BF applied part according to EN 60601-1 ed. III.

Symbol	Meaning
	Class II device
	Manufacturer data.
	Date of manufacture (YYYY-MM).
	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 $\geq 12.5\text{mm}$ and against the vertical fall of water drops). IP21
	Caution, danger.
	Allowed temperatures (storage temperatures, on packaging)
	Relative humidity (storage relative humidity, on packaging)

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 13 for further details)

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

LEG2 - right leg cuff, left leg cuff, 4-chamber 8-ending tube, two pressure orthotics.

LEG1 - leg cuff (right or left), 4-chamber 4-ending tube, one pressure orthotic.

ARM1 - arm cuff (right or left), 4-chamber 4-ending tube.

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

Also available as optional items are the leg cuff extensions for wide legs.

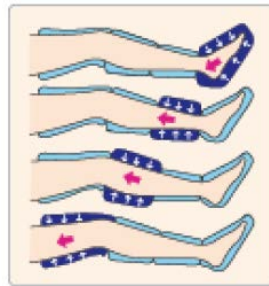
N.B.: it is recommended to interpose the non-woven fabric band between the foot and the orthotic.

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 burns, dermatitis, purulent wounds, malignant tumours, etc .;
- people who have undergone skin surgery in the treatment area;
- people with severe circulation problems, such as hardening of the arteries, angina, 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;

CONSULT YOUR DOCTOR BEFORE STARTING TREATMENT WITH THE DEVICE.

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 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; children under the age of 12 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.

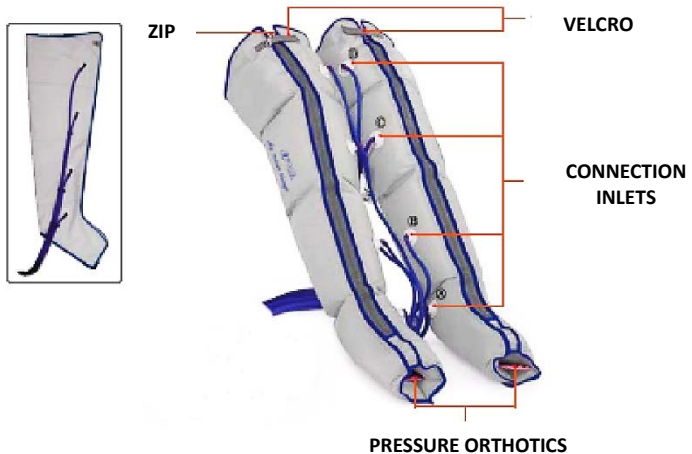
In the event of any change in performance during treatment, stop treatment immediately and contact your dealer or manufacturer immediately.

Patient preparation

1. Select the appropriate applicator for the area being treated.
1.1. Leg cuffs



- 1.1.1. Attach the connector relating to the tube with 8 endings (for using two leg cuffs) or the connector relating to the tube with 4 endings if using a single leg cuff;
- 1.1.2. Put on the leg cuffs (or the single leg cuff) and close the zip up to the top, then close the Velcro fastener; if it is necessary to increase the circumference of the leg cuffs, add the extenders for leg cuffs available on request;



- 1.1.3. 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.
- 1.1.4. When wearing the leg cuffs make sure that the connection inlets of the tubes is always on the inside of each leg cuff; if only one leg cuff is used, the position of the connection inlets does not matter.
- 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).

1.2. Arm cuff

- 1.2.1. Put on the arm cuff and connect the tubes to the inlets on the arm cuff itself, making sure to connect the longer tube to the topmost connector (darker in colour) on the arm cuff;

- 1.2.2. After connecting the tubes to the arm cuff, connect the tubes to the air outlet connector on the machine.

USING EXTENSIONS

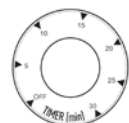
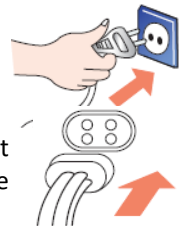


The extensions for the leg cuffs are an optional extra that allows you to increase the size of the leg cuffs and can be requested by the customer at any time. For correct use of the leg cuffs, use the zips on the leg cuffs and on the extensions to join the two elements, as shown in the figure above.

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 and connect the relative connector to the device body.
3. Adjust the pressure: the pressure can be adjusted from 0 to 200mmHg ($\pm 20\%$), 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 30 minutes.





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



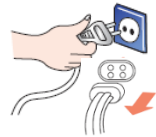
WARNING! Once the therapy has started, do not force the timer by turning it anticlockwise. Wait for the end of the therapy to set the desired time again.

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 applicator connectors from the device body.



9. Remove the tube connection inlets from the applicators.

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 the 8-ending tube is used 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 93%
pressure	from 700 to 1060 hPa

Environmental storage conditions:

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 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	<ol style="list-style-type: none"> 1. Check the connection to the mains. 2. Check the power ON/OFF button. 3. Check the power cable is not damaged.

Problem	Solution
I-PRESS emits a strange hiss similar to leaking air	<ol style="list-style-type: none"> 1. Check for damage and/or holes in the tubes and connectors 2. Check the applicators are correctly connected 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	<ol style="list-style-type: none"> 1. Check the applicator 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	<ol style="list-style-type: none"> 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.

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 (pressure band) 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.

As established by the Medical Device Directive 93/42/EEC, the manufacturer is obliged to trace at any time the equipment supplied to intervene promptly, if necessary, as a result of manufacturing defects.

The warranty conditions are those described in the following paragraph Warranty conditions. The warranty is provided by IACER.

WARNING! In the event of non-shipment, the manufacturer declines all responsibility, if corrective action on the equipment is necessary.

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 S. Pertini, 24/a • 30030 Martellago (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

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 S. Pertini, 24/a • 30030 Martellago (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, 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

Guidance and manufacturer's declaration - ELECTROMAGNETIC EMISSIONS - 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.		
Emission Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	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
RF emissions CISPR 11	Class B	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker IEC 61000-3-3	Complies	

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	± 1kV line - line	Mains power quality should be that of a typical commercial or hospital environment.
	± 2kV line - ground	± 2kV line - ground	
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 0.5 cycles	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.
	<5% U_T (>95% dip in U_T) for 1 cycle	<5% U_T (>95% dip in U_T) for 1 cycle	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T	<5% U_T	

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
	(>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.
Note: U_T 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
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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	3V _{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
	6V _{eff} from 150kHz to 80MHz for ISM band	6V _{eff} ([V ₁] V)	
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)				
	<i>from 150kHz to 80 MHz</i>	<i>from 150kHz to 80 MHz for ISM band</i>	<i>from 80MHz to 800 MHz</i>	<i>from 800MHz to 2,7GHz</i>	<i>from 800MHz to 6GHz (to radio frequency wireless communication equipment)</i>
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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Edition: MNPG338-00 of the 12th October 2020



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Capitale Sociale / Share Capital: € 110.000,00 i.v.

