IBRAMED

QUESTÃO DE RESPEITO

Instructions Manual

SONOPULSE

Therapeutic Ultrasound 1 and 3 MHz

Manufactured by
Ibramed - Indústria Brasileira de Equipamentos Médicos EIRELI
Made in Brazil
1st edition (LASTREV_10/2019)

TABLE OF CONTENTS

Caution: Federal Law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

SYMBOL DEFINITIONS.....3
CARTON.....4
ABREVIATIONS GLOSSARY.....5
FIGURES GLOSSARY.....5
FOREWORD.....6
PRODUCT DESCRIPTION.....6
ESSENTIAL PERFORMANCE 6
SAFETY PRECAUTIONS.....7
PRECAUTIONARY DEFINITIONS 7
INDICATIONS, ADVERSE REACTIONS, CONTRAINDICATIONS AND PRECAUTIONS.....9
INDICATIONS 9
CONTRAINDICATIONS.....10
PRECAUTIONS.....10
RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT.....11
GENERAL EQUIPMENT CARE.....12
SHIPPING DAMAGE.....12
INSTALLATION, CARE AND CLEANING.....12
ENVIRONMENTAL PROTECTION.....13
ELECTRICAL FEED.....14
ELECTROMAGNETIC COMPATIBILITY GUIDANCE.....15
POTENTIAL ELECTROMAGNETIC INTERFERENCE.....15
SPECIFICATIONS.....22
SYSTEM SPECIFICATIONS.....22
ULTRASOUND SPECIFICATIONS.....23
NOMENCLATURE.....25
CONTROLS, INDICATORS AND CONNECTORS.....25
DEFINITION OF SYMBOLS.....28
ACCESSORIES USED.....30
OPERATION INSTRUCTIONS.....31
TRANSDUCER PROTECTION MESSAGES 33
TEMPERATURE SENSOR.....33
EQUIPMENT WITHOUT TRANSDUCER.....34
PROGRAMMING THE EQUIPMENT.....35
ULTRASOUND GUIDELINE.....36
PATIENT PREPARATION.....36
ULTRASOUND APPLICATION TECHNIQUE.....37
USING THE PROG/MENU BUTTON.....38
SELECTION OF LANGUAGE 38
USING THE MENU BUTTON.....38
USING THE PROG BUTTON. 39
SELECTION OF USER PROTOCOLS.....39
REFERENCES.....40
ACCESSORIES WHICH ACCOMPANY SONOPULSE.....42
REPLACEMENT ACCESSORIES 43
TROUBLESHOOTING 44
MAINTENANCE, CALIBRATION, WARRANTY AND TECHNICAL SUPPORT.....44
CEFAI – IBRAMED.....46

SYMBOL DEFINITIONS

BELOW ARE THE DEFINITIONS OF THE SYMBOLS USED ON THE EQUIPMENT AND THROUGHOUT THE INSTRUCTIONS FOUND IN THIS MANUAL. UNDERSTAND THESE SYMBOLS AND THEIR DEFINITIONS BEFORE OPERATING THIS EQUIPMENT


Caution! Refer to user manual.

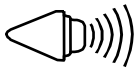

CLASS II Electrical equipment.

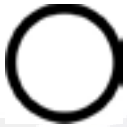
IPX1 Protected against dripping water.

IPX7 Protected against the effects of immersion.


TYPE BF Electrical Equipment.


Dangerous Voltage.


Transducer.


Off switch.


On swith.


Start treatment.


Stop treatment.

V~ Alternating Current.

SYMBOLS DEFINITIONS

CARTON

Fragile.

This side up.

Limits of temperature for storage and packaging in °C (Celsius Degrees).

Keep away from the rain.

Stacking up.

Do not use if the packaging is damaged.

Refer to operating instructions for correct product use.

Manufacturer’s name and address.

ABREVIATIONS GLOSSARY

MHz	Megahertz (million pulses (10^6) by second)
ERA	Effective Radiating Area
W	Watt (s)
W/cm²	Watt (s) per square centimeter
cm²	Square centimeter
VA	Volt Ampere
BNR	Beam Non-Uniformity Ratio
NTC	Negative Temperature Coefficient
min	Minute

FIGURES GLOSSARY

Figure 1. Upper view.....25

Figure 2. Rear view.....25

Figure 3. Frontal view.....26

Figure 4. Lower view.....26

Figure 5. Transducer of ultrasound with ERA of 7 cm² and 3 c m².....30

Figure 6. A, presentation message; **B**, standard/default **SONOPULSE** screen.....31

Figure 7. Application technique with ERA of 7 cm².....37

Figure 8. Application technique with ERA of 3 cm².....37

Figure 9. Message of selection of language.....38

This user manual allows the user to efficiently use the **SONOPULSE**.
Consult other resources for additional information regarding the uses of ultrasound before attempting any treatment on a patient. Users must read, understand and follow the information in this manual for each mode of treatment available, as well as the indications, contra indications, warnings and precautions.
The specifications and instructions in this manual are in effect at the time of its publication. These instructions may be updated at any time at the manufacturer's discretion. Visit our website for updates.

ESSENTIAL PERFORMANCE

SONOPULSE is a therapeutic ultrasound microcontrolled device in the frequencies of 1 MHz and 3 MHz, designed to be used for physiotherapy treatments. **SONOPULSE** allows the choice of ERA (Effective Radiating Area) of 7 cm^2 or 3 cm^2 , making it possible to select the 1 MHz frequency with the ERA 7 cm^2 or 3 cm^2 and the frequency of 3 MHz with the ERA of 7 cm^2. The average ultrasound output power is 21 Watts for the ERA of 7 cm^2 and 3 Watts for the ERA of 3 cm^2, therefore, the maximum average intensity is 3 W/cm^2 for the ERA of 7 cm^2 and 1 W/cm^2 for the ERA of 3 cm^2 . The ultrasound emission mode can be adjusted to continuous or pulsed. The pulsed mode has pulse repetition frequencies of 100 Hz, 48 Hz or 16 Hz, with pulse ratio of 1/2 (50%) or 1/5 (20%). **SONOPULSE** has a **PROG** key, which allows the user to choose a pre-programmed treatment.
Ultrasound delivered to the body using an efficient couplant provides deep heating effects to body tissues. Ultrasound delivered at a frequency of 1 MHz penetrates to a depth of approximately 5 centimeters while ultrasound at a frequency of 3 MHz penetrates tissue to a depth of approximately 1–2 cm.
This device must be used only under prescription and supervision of a licensed professional.

PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment prior to therapy session.

Text with a "CAUTION" indicator refers to potential safety infractions that could cause minor to moderate injury or damage to equipment.

Text with a "WARNING" indicator refers to potential safety infractions that could cause serious injury and equipment damage.

Text with a "DANGER" indicator refers to potential safety infractions that represent immediately life threatening situations that would result in death or serious injury.

- Read, comprehend and practice the precaution and operation instructions. Know the limitations and dangers associated with the use of any electrical stimulation. Observe the precaution and operation labels placed on this unit.
- Do not operate this unit in an environment where other devices intentionally radiate electromagnetic energy in an unprotected manner.
- Check the cables and connectors before each use.
- The **SONOPULSE** is not designed to prevent the penetration of water and other liquids. Penetration of water and other liquids may cause malfunction of the internal components of the system, and consequently, promote risk of injure to the patient.
- Disconnect the plug from the power outlet when the device is not used for long periods of time.
- The applicator should be operated only by the handle to avoid exposure to unwanted emission of ultrasound.
- **Caution-use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.**

WARNING

• In order to be protected from the risk of fire, use only spare fuses of the same type and class.
• Make sure the unit is grounded, connecting it to a grounded power outlet in conformity with the applicable local and national electrical codes.
• Before treating the patient, it is necessary to know the operational procedures for each treatment mode available, as well as the indications, contra indications, warnings and precautions. Refer to other sources to obtain additional information on electrotherapy applications.
• To avoid electrical shock, turn the device off the power supply line before any maintenance procedure.
• The ultrasound treatment must not be applied on swollen infected or inflamed areas, or on skin eruptions such as phlebitis, thrombophlebitis, varicose veins, etc.
• Ultrasound treatment must not be applied on or next to cancerous lesions.
• Complete handpiece skin contact should be ensured.
• The device should not be used stacked with or adjacent to other equipment.
• In addition, there should be adequate warning(s) to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.
• Burns have been reported with the use of ultrasound. If burns occur please seek medical care to minimize the signs and symptoms related to burning. The applicator should be moved continuously during the therapy to avoid discomfort and burn.
• This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

DANGER

• Patients with neurostimulation devices or implanted pacemakers must be distant from any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy and must not be treated with these on any part of their bodies.
• The diathermy energy (shortwave, microwave, ultrasound and laser) may be transferred through the implanted neurostimulation system, and it may cause damage to the tissues, and result in serious injury or death.
• Damage, injury and death may occur during diathermy therapy even if the implanted system is turned off.
• Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. Equipment is not the AP or APG category.

INDICATIONS

Therapeutic Ultrasound:

- Pain relief.
- Reduction of muscle spasm.
- Localized increase in blood flow.
- Increase range of motion of contracted joints using heat and stretch techniques.

CONTRAINDICATIONS

- Therefore, therapeutic ultrasound should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
- Therapeutic ultrasound must not be applied over neoplastic areas or over areas from which tumors have been removed.
- Therapeutic ultrasound must not be applied over the eyes.
- Therapeutic ultrasound must not be applied on ischemic tissues, where the blood supply may be incapable of following the increase in metabolic demand and result in necrosis.
- Therapeutic ultrasound must not be applied over bone growth centers.
- Ultrasound therapy is not recommended for patients with implanted electronic devices (cardiac pacemakers, deep brain stimulation devices).
- Do not apply ultrasound over areas previously treated with radiotherapy.
- Ultrasound must not be applied over the testes, to avoid increases in temperatures.
- Ultrasound must not be applied over the heart.
- Therapeutic ultrasound must not be applied over areas of thrombophlebitis deep vein thrombosis emboli and severe atherosclerosis.
- Ultrasound treatment must be avoided over the stellate ganglion, spinal cord after laminectomy, when great tissue resections have been performed, under subcutaneous major nerves and the cranium.

CONTRAINDICATIONS

• In an area of the body where a malignancy is known to be present.
• Over reproductive organs.
• Over open wounds or lesions, including severe or cystic acne.
• To the brain, spinal cord or large subcutaneous peripheral nerves.
• Treatment of acute infection of bone or tissue as the treatment could force areas of pus into surrounding tissue, thereby spreading infection.

PRECAUTIONS

• Ultrasound must not be applied in areas of reduced sensation or circulation or over anesthetic areas. Patients with reduced sensation are not capable of warning the professional in case there is discomfort and in patients with compromised circulation there may be an excessive buildup of heat in the treated area.

• Professionals operating the device on a daily basis must not be exposed to therapeutic ultrasound. The applicators handles have been developed to allow the professional to protect the hands from ultrasound when performing underwater treatment.

• If a patient complains of deep periosteal pain during ultrasound treatment, the intensity should be reduced to a comfortable level.
Heating must be avoided during the acute or sub-acute phase of arthritis.

• Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic ultrasound who have bleeding disorders. Examples of these are hemophilia, post acute trauma, long term steroid therapy, cumiden or heparin therapy.

• Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than 0.5W/cm^2 to assure even exposure of tissues to ultrasound.

• Electrical treatment tables or whirlpools which may come in contact with the patient during a treatment with the Sonopulse, should be adequately grounded and safety tested to insure safe operation with the Sonopulse.

• The use of therapeutic levels of ultrasound may delay or prevent callous formation in a healing fracture.

RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT

The use of electromedical equipment is restricted to a physician or under his command, the physical therapists or health professionals properly licensed. The professional will be responsible for properly licensed use and operation of the equipment. IBRAMED makes no representations regarding laws and federal, state or local laws that may apply to the use and operation of any electromedical equipment.

The physician or under his command, also the physical therapist or other professional health care licensed assumes total and full commitment to contact the local certifying agencies to determine any credential required by law for clinical use and operation of this equipment.

The use of electromedical equipment must comply with the local, state and federal country.

SHIPPING DAMAGE

Your **SONOPULSE** is shipped complete in one carton. Upon receipt, inspect carton and unit for visible and hidden damage. In case of damage, keep all shipping materials including carton and contact the shipping agent responsible for the delivery of the unit. All claims relating to damage during transport should be filed directly with them. The manufacturer will not be liable for any damage during shipping, nor allow for adjustments unless proper formal claim has been filed by the receiver against the carrier. The carton in which your **SONOPULSE** was received is specially designed to protect the unit during shipping. Please keep all shipping materials in case you need to return your unit for servicing.

INSTALLATION, CARE AND CLEANING

Installation Instructions

1. Connect the line cord to the back of the **SONOPULSE.**
2. Plug the line cord into a grounded wall outlet(100 -240V 50Hz/60 Hz).
3. Plug the ultrasound cables into the correct connections.
4. Turn on the equipment.

CAUTION

CORRECT EQUIPMENT INSTALLATION PREVENTS SECURITY RISKS

SONOPULSE Care Instructions

- Avoid areas subject to vibrations.
- Install the equipment on a firm and level surface, in open air.
- Do not block ventilation.
- Avoid humid, hot and dusty environments.
- Make sure the area around the network cable is free.
- Do not insert objects into device holes.

CAUTION

Proper installation, operation and maintenance of the equipment prevents security risks.

Cleaning the SONOPULSE

- Disconnect the system from the power source, wipe with a clean, lint free cloth moistened with water and mild antibacterial soap.
- If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.
- Do not place the system in liquids.

ENVIRONMENTAL PROTECTION

The **SONOPULSE** is an electronic device and has heavy metals such as lead. Thus, there are risks of contamination to the environment associated with the disposal of this equipment and its accessories at the end of their useful lives. The **SONOPULSE**, parts and accessories must be disposed of as waste. Contact your local distributor for information on rules and laws regarding the disposal of waste electrical, electronic equipment and accessories.

CAUTION

THE DEVICE AND ITS CONSUMABLE PARTS MUST BE DISPOSED OF, AT END OF LIFE, ACCORDING TO THE APPLICABLE FEDERAL AND/OR STATE AND /OR LOCAL REGULATIONS.

ELECTRICAL FEED

SONOPULSE is a protective CLASS II device with applied part type BF of safety and protection. **SONOPULSE** works in power supply tension in the range of 100 - 240 V 50/60 Hz. Just connect the device to the power line and it will perform the selection of power tension automatically. The connector cable to the power supply line is detachable. The device uses the power line plug as a resource to electrically separate its circuits in relation to the power supply line in all poles.

NOTES

In the rear part of **SONOPULSE** there is a protection fuse. To replace it, **turn the device off the power supply line** and with the help of a screwdriver, remove the protection lid, disconnect the fuse, perform the replacement and reinsert the lid.

Always use the fuses indicated by IBRAMED. Use a fuse for rated current of 5A, type 20AG and fast action 250V~ (interruption capacity: 50A).

SONOPULSE does not need any type of power stabilizer. Never use a power stabilizer.

Before turning on **SONOPULSE** make sure:

- The voltage and frequency of the local power supply line of the establishment where the device is installed are equal to the one described on the label describing characteristics of voltage and power located at the rear part of the device.
- To prevent electrical shock, do not use the plug in the device with extension cables, or any other types of sockets except the terminals connect perfectly in the receptacle.
- Cleansing and disinfection must always be performed with the power plug off of the power supply line.
- Maintenance and technical assistance of **SONOPULSE** must always be performed at unauthorized service, only by qualified technicians.

CAUTION

Inside the device there are dangerous tensions.
Never open the device.

• This unit is not designed to be used where there is explosion hazard, such as anesthesia departments or in the presence of an anesthetic flammable when mixed with air, oxygen or nitrous oxide.

• Using cables, electrodes and other accessories from other manufacturers and/or different from those specified in this manual as well as the replacement of internal components **SONOPULSE** may result in increased emissions or decreased immunity of the equipment.

• **SONOPULSE** equipment is intended for use only by health care professionals. The **SONOPULSE** may cause radio interference or disrupt equipment operations nearby. It may be necessary to adopt mitigation procedures, such as reorienting or relocating the equipment or shielding of the site.

• Portable and Mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Devices.

POTENTIAL ELECTROMAGNETIC INTERFERENCE

As for the limits of electromagnetic interference, **SONOPULSE** is an electromagnetic device of Group 1 Class A. The simultaneous connection from the patient to **SONOPULSE** and to high frequency surgical equipment may result in burns in the ultrasonic transducer application area and possible damage to the device. Short distance operation (1 meter, for example) of short wave or microwave therapy equipment may produce instability in the output of the device. To prevent electromagnetic interference, we suggest that one group of power supply line is used for **SONOPULSE** and another separate group is used for short wave or microwave equipment. We also suggest that the patient, **SONOPULSE** e and connection cables are installed at least 3 meters away from short wave and microwave therapy equipment.

Medical Electrical Devices requires special attention regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in the following tables.

<table>
<tr><th colspan="3">Manufacturer’s guidelines and declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">SONOPULSE is destined to be used in the electromagnetic environment specified below. The user of the equipment should be sure that it will be used in this environment.</td></tr>
<tr><th>Emission test</th><th>Conformity</th><th>Electromagnetic emissions</th></tr>
<tr><td>RF Emissions
NBR IEC CISPR 11
IEC CISPR 11</td><td>Group 1</td><td>SONOPULSE emits RF energy only for its internal functions. However, its RF emissions are very low and it is unlikely to cause any interference in nearby electronic equipments.</td></tr>
<tr><td>RF Emissions
NBR IEC CISPR 11
IEC CISPR 11</td><td>Class A</td><td rowspan="3">SONOPULSE is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/
flicker emissions

IEC 61000-3-3</td><td>Class A</td></tr>
</table>

Manufacturer's guidelines and declaration – Electromagnetic immunity			
SONOPULSE is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment.			
Immunity Test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment – orientations**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by air	The floor should be wooden, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV in the feeding lines ± 1 kV in the input/output lines	± 2 kV in the feeding lines ± 1 kV in the input/output lines	The quality of power supply should be that of a hospital environment a or typical commercial building.
Surge IEC 61000-4-5	± 1 kV modo diferencial ± 2 kV modo comum	± 1 kV diferencial mode ± 2 kV common mode	The quality of power supply should be that of a typical commercial or hospital environment.

Immunity test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment -orientations**
Voltage drops, short interruptions and voltage variations in power input lines IEC 61000-4-11	< 5% U (> 95% voltage drops in U) by 0,5 cycle 40% U (60% of voltage drops in U)by 5 cycles 70% U (30% of voltage drops in U) by 25 cycles < 5% U (> 95% of voltage drops in U) by 5 seconds	< 5% U (> 95 % voltage drops in U) by 0,5 cycle 40% U (60% of voltage drops in U) by 5 cycles 70% U (30% of voltage drops in U) by 25 cycles < 5% U (> 95% of voltage drops in U) by 5 seconds	The quality of power supply should be that of a typical commercial or hospital environment. If the user's equipment requires continued operation during power failure, it is recommended the equipment be powered by an uninterruptible power supply or battery.
Magnetic field at power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at power frequency should be at the level of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the C.A. voltage before applying the test			

Manufacturer's guidelines and declaration – Electromagnetic immunityw			
SONOPULSE is destined to be used in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such environment.			
Immunity test	**Test level IEC 60601**	**Conformity level**	**Electromagnetic environment – guidelines**
RF Conducted IEC 61000-4-6 RF Radiated IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Communication equipment of RF portable and mobile should not be used near any part of **SONOPULSE** including cable with separation distances smaller than the recommended, calculated from the equation applicable to the transmitter frequency Recommended separation distance d = 1.2 $\sqrt{P}$ 150 KHz to 80 MHz d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum nominal output power in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). It is recommended that the field intensity established by the RF transmitter, as determined by an electromagnetic inspection on the local, be smaller than the conformity level in each frequency range . Interference may occur around the equipment marked with this symbol:

NOTE 1: At 80 MHz and 800 MHz it is applied to the higher frequency range. NOTE 2: These guidelines may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a]Field strengths set by fixed transmitters, such as radio base stations, telephone (cellular / cordless) telephones and land mobile radios, amateur radio, AM / FM radio and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended an electromagnetic inspection on the place. If the measure of field strength at the location **SONOPULSE** is used exceeds the conformity level used above, the unit must be observed to see whether the operation is normal. If an abnormal performance is observed, additional procedures may be needed, such as reorientation or replacement of the equipment. Over the frequency range from 150 kHz to 80 MHz, the field strength must be less than 3 V / m.

Recommended separation distances between the communication equipment of RF portable and mobile and SONOPULSE

SONOPULSE is intended to be used in an electromagnetic environment in which RF disturbances are controlled. The user of the electro-stimulator can help to prevent the electromagnetic interference by maintaining the minimum distance between the portable communication equipment and mobile RF (transmitters) and, **SONOPULSE** as recommended below, according to the maximum power of communication equipment.

Maximum rated power output of the transmitter maximum nominal potency of transmitter output **W**	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	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 with a maximum nominal output power not listed above, the recommended separation distance in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum rated output in watts (W) According to the transmitter manufacturer.

NOTE 1: 80 MHz to 800 MHz, applies to the distance of separation for the higher frequency range.

NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SYSTEM SPECIFICATIONS

Dimensions

Width	14.1” in (36 cm)
Depth	12.4” in (31.5 cm)
Height	4.9” in (12.5 cm)
Standard Weight (with transducer)	2.2 kg

Power

Input	100 - 240V~ 50Hz/60 Hz
Input power	100 VA
Fuses	5A 250~ (20AG) Fast Action (Rated current of 5A, type 20AG and fast action 250V~ (interruption capacity: 50A)).
Electrical Class	CLASS II
Electrical Protection	TYPE BF

Conformity Regulations

IEC 60601-1

IEC 60601-1-2

IEC 60601-2-5

IEC 60601-1-4

Range of temperature during transportation and storage:

5 - 50°C/ 41- 122°F.

Range of operational environment temperature:

5 - 45 °C/ 41- 113 °F.

ULTRASOUND SPECIFICATIONS

Frequency	1.1 MHz, ± 10% 3.3 MHz, ± 10%
Effective radiating area (ERA)	7 cm^2; 3 cm^2
Mode	Continuous Pulsed
Duty Cycle	20% or 50%
Frequency of pulse repetition	100 Hz; 16 Hz; 48 Hz
Transducer of 7 cm^2	1.1 MHz ±10%; 3.3 MHz ± 10%
Transducer of 3 cm^2	1.1 MHz ± 10%
Treatment time	1-30 min
Output Power	
Transducer of 7 cm^2	0.1 to 3.0 W/cm^2; 1.1 MHz and 3.3 MHz
Transducer of 3 cm^2	0.1 to 1.0 W/cm^2; 1.1 MHz
Maximum Amplitude (7 cm^2)	21 W ± 20%
Maximum Amplitude (3 cm^2)	3 W ± 20%
BNR (Beam Non-Uniformity Ratio)	
Crystal of 7 cm^2	3
Crystal of 3 cm^2	8

Note: The equipment in pulsed mode shows values of peak power, average values are equivalent to pulsed selected percentage, ex:

Selected:
Rated power: 21 W
Duty cycle: 50%

Rated Power: 21 x 0.5 = 10.5 W

ULTRASOUND SPECIFICATIONS

Frequency	1.1 MHz ±10% 3.3 MHz ±10%
Modes	Continuous Pulsed-20% duty cycle and Pulsed-50% duty cycle
Pulse Repetition Rate	100Hz ±10% 48Hz ±10% 16Hz ±10%
Pulse Duration	2ms ±10% 20% duty cycle 100Hz 4ms ±10% 20% duty cycle 48Hz 12.5ms ±10% 20% duty cycle 16Hz 5ms ±10% 50% duty cycle 100Hz 10ms ±10% 20% duty cycle 48Hz 31ms ±10% 20% duty cycle 16Hz
Temporal Peak	5:1 ±10% 20% duty cycle 2:1 ±10% 50% duty cycle
Maximum output power	21W with a 7 cm^2 Applicator 3W with a 3 cm^2 Applicator
Maximum intensity	3W/cm^2 with a 7 cm^2 Applicator 1W with a 3 cm^2 Applicator
Indication accuracy	±10%
Piezoelectric discs	The output transducer utilizes a barium titanate disc with a specially coated face
Frequency effective radiating area	1.1 or 3.3 MHz ±10% 7 cm^2 ±10% 3 cm^2 ±10%
Maximum beam non-Uniformity ratio	Crystal of 7cm2 3:1 Crystal of 3cm2 8:1

CONTROLS, INDICATORS AND CONNECTORS

Figure 1. Upper view.

Figure 2. Rear view**.**

CONTROLS, INDICATORS AND CONNECTORS

Figure 3. Frontal view.

Figure 4. Lower view.

CONTROLS, INDICATORS AND CONNECTORS

1- ON/OFF switch.

2- Light Indicator of **ON** condition.

3- SET+ and **SET-** control keys for selecting parameters.

4- SET control keys – increasing or decreasing parameter values.

5- Alphanumerical liquid crystal display.

6- START/STOP control keys to start or stop treatment.

7- Control keys **PROG/MENU**. **PROG:** Selection of user protocols; **MENU:** Selection of language.

8- UP and **DOWN** control keys – increase or decrease ultrasound intensity.

9- Output Connection of transducer to ultrasound.

10- Protection fuse.

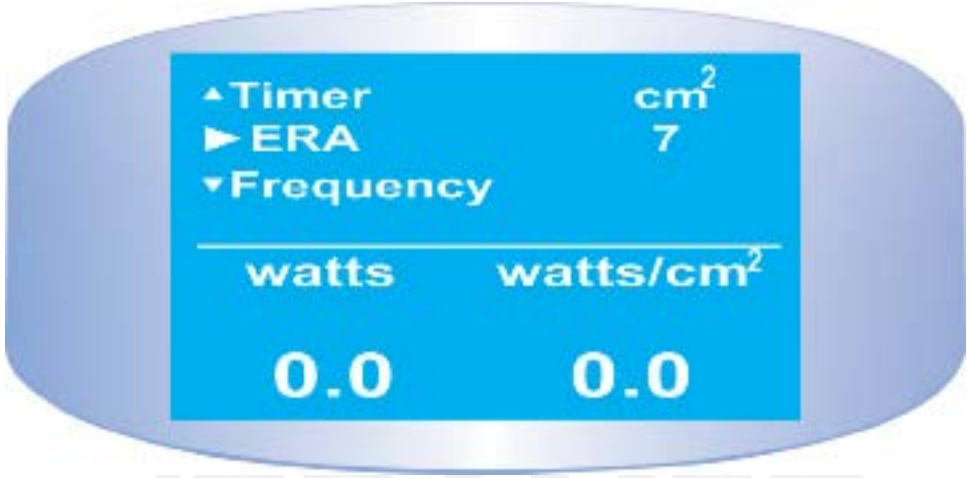
11- Connection of power cable.

12- General technical information.

13- Label with technical characteristics and serial number.

14- Federal Law warning (only for the USA).

Read and understand these symbols and their definitions before operating the equipment



Switch used to start or stop treatment. Always press the center of the switch.

Switch with double function: **PROG** – user protocols; **MENU** – Selection of language (Portuguese, English, Spanish or Russian).

Read and understand these symbols and their definitions before operating the equipment

SELECT: switch for the selection of ultrasound parameters.

SET: switch: selection of values of parameters.

UP and **DOWN**: switch: increase or decrease of da intensity: 0.1 to 3.0 W/cm^2.

1 and 3 MHz ULTRASOUND: Ultrasound transducer with ERA of 7 cm^2 for frequency of 1 and 3 MHz and with ERA of 3 cm^2 for frequency of 1 MHz. (Figure 5).

CAUTION

The screws of the transducer connector must be firmly fixed to the device.

Figure 5. Ultrasound transducer with ERA of 7 cm^2 and 3 cm^2.

Note: The ultrasound gel is not included in the accessories list and does not accompany the device. IBRAMED recommends the use of K102637 ultrasound gel FDA cleared with the SONOPULSE systems.

The user can obtaining the K102637 ultrasound gel FDA cleared by means of the website http://www.dynarex.com/product.php?family=Ultrasound_Gel&itmno=2190 or by contacting the Dynarex sales representative +1 (888) 396-2739.

PREPARING THE EQUIPMENT

Check if the power cable is connected to the power supply on the wall. Press the **ON/OFF** switch to the **ON** position. The display will show for a few seconds the presentation message which includes the model of the device and the programming software followed by the standard **SONOPULSE** screen (Figure 6).

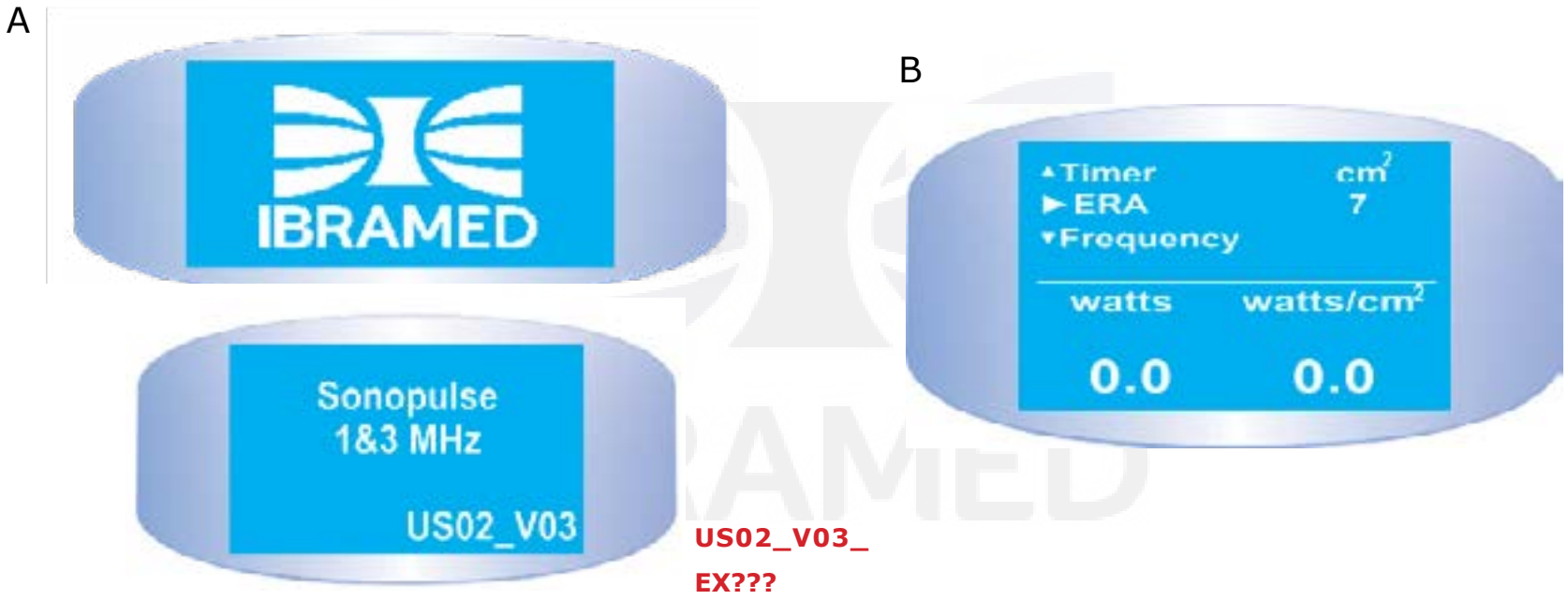


Figure 6. A, presentation messages; **B**, standard/default **SONOPULSE** screen.

Note that as the standard/default screen is shown, an arrow indicates the **ERA**. This arrow indicates the parameter to be programmed.

PREPARING THE EQUIPMENT

Selection of parameters

The **SELECT** switch allows you to select the parameters necessary for the treatment. Press **SELECT** switch up or down to move the indicating arrow to the next parameter or return to the previous parameter.

The **SET** switch allows the selection of values of each para meter necessary for treatment. Press the **SET** switch up or down to select the values

Programming treatment time

Program the desired session time. At the end of the programmed time, you will hear a sound beep indicating that the treatment session has been finalized. Press the **STOP** switch, so that the sound beep is discontinued. The equipment will return to the programming status.

START treatment

Press the Start button to begin the therapy sesion.

STOP treatment

To STOP treatment, press the Stop button once. The treatment will stop and the display will back to show the parameters selected to the treatment.

The treatment may be stopped at any time during the session by pressing the STOP button.

Initiating Treatment

Press the **START** switch to initiate treatment.

Stopping Treatment

Press the **STOP** switch to finalize therapy.

Intensity of ultrasound

The intensity of ultrasound can be increased before press the **START** key using the **UP** or **DOWN** switch. The intensity of ultrasound may be increased or decreased at any time during the session.

TEMPERATURE SENSOR

Inside the **SONOPULSE** transducer there is a temperature sensor which verifies and maintains the work temperature of the piezoelectric crystal, and consequently, the aluminum face of the transducer, which avoids the disagreeable sensation of excessive heat to the patient. This sensor is programmed so that the temperature in the aluminum never exceeds 41 degrees Celsius. During treatment, particularly when the couplant gel used is not of superior quality, the temperature may rise above 41 degrees Celsius. When that happens, the equipment will 'freeze' the programmed time and turn off the emission of ultrasound. At that moment, a sound beep will be emitted and the display will show:

The professional should continue to 'move' the transducer, because after a few seconds the temperature will return to normal. The equipment will automatically revert the 'frozen' time, resuming the original program.

EQUIPMENT WITHOUT TRANSDUCER

If the equipment is without its transducer, when the therapist press the **START** button, a protection circuit will be activated and the display will show:

Just connect the transducer so that the message disappears and the equipment will return to its original program.

Example: Suppose the clinical practice or literature suggest for a particular pathology, the following parameters:

Frequency: 3 MHz
ERA: 7 cm^2
Mode: Pulsed
Pulse Freq.: 100 Hz
Duty Cycle: 50%
Time: 10 minutes
Ultrasound energy: 1 Watts/ cm^2

1. Turn on the equipment to initiate the standard program described above. Note the cursor blinking on the **ERA** and **Intensity** field.

2. Using the **SELECT** and **SET** switches, go through the parameters and select the values shown in the example.

3. Press the **UP** or **DOWN** buttons to select the ultrasound intensity necessary for treatment.

4. Now press the **START** key to initiate the treatment. After press the **START** key, the transducer figure will appear on the display. It indicates that the ultrasound energy is activated. Now, the patient is receiving the ultrasound energy and the display will show:

5. At the end of the programmed time, the emission of ultrasound is interrupted and a sound beep will be emitted at the end of the treatment.

6. Press the **STOP** key to stop the sound beep. The equipment can now be turned off, the same program can be performed or a new program may be programmed.

PATIENT PREPARATION

• Examine the skin for any wounds and clean the treatment area, rubbing the skin with medical use alcohol.

• Before applying the ultrasound, clean the area with and soap and water to remove the oil and possible skin fragments, thus reducing the difficulty of passage of the ultrasound through the skin.

• Clean the applicator with soap and water before each therapy session.

• Apply conductor gel over the patient's treatment area.

• Move the ultrasound transducer constantly during the session in circular moves. Examine the skin again after treatment.

• **BIOCOMPATIBILITY** of the materials in contact with the patient (ISO 10993-1): The ultrasound transducer provided with the equipment does not invoke allergic reactions. The user may purchase any FDA approved therapeutic ultrasound coupling gel. The transducer and gel must be only be placed in contact with intact surface of the skin, respecting duration limit time of this contact of 24 hours. There is no risk of harmful effects to the cells, nor is there any allergic reaction or of sensitivity. The transducer (material that it is made from) do not invoke potential irritation on the skin.

Position of the ultrasound transducer for the application with ERA of 7 cm^2 (figure 7).

Figure 7. Application technique with ERA of 7 cm^2.

Position of ultrasound transducer for the application with ERA of 3 cm^2 (figure 8).

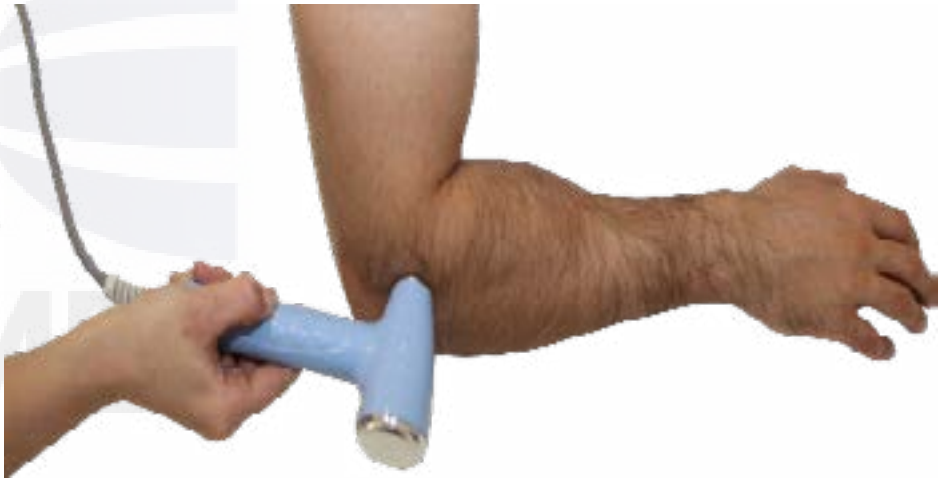


Figure 8. Application technique with ERA of 3 cm^2.

USING THE MENU BUTTON SELECTION OF LANGUAGE

The **MENU** button is used to select the language. Press the **MENU** button until you hear three sound beeps. Select the desired language: "Portuguese", "Spanish", "English" or "Russian". Press the **MENU** button again to define the chosen language (figure 9).

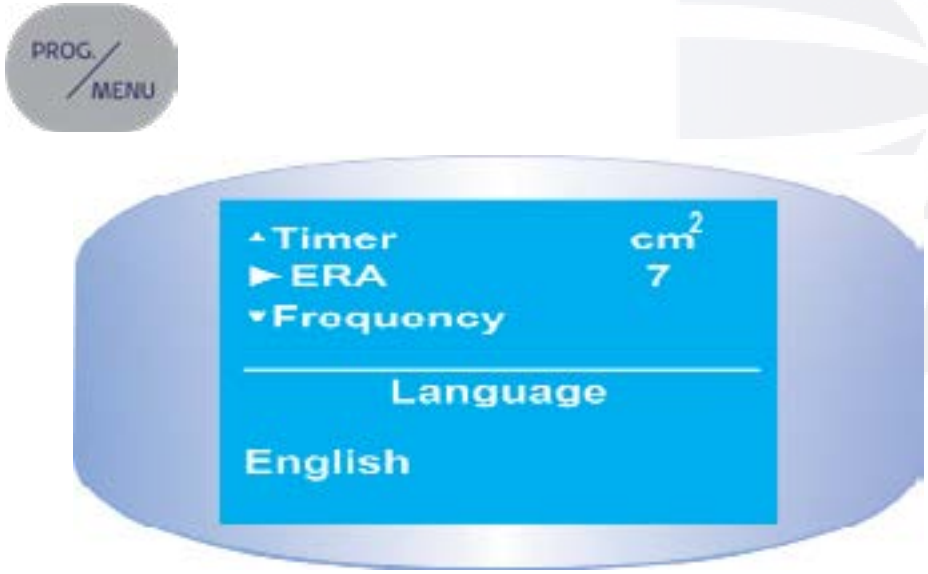


Figure 9. Message of selection of language.

USING THE PROG BUTTON SELECTION OF USER PROTOCOLS

To program user protocols, briefly press the PROG button. With the SET + or SET - buttons choose one of the available protocols from User. Enter the parameters according to therapeutic needs including the intensity. Press START. The last set parameters will be recording in the device memory. To access protocols saved by the user, simply select the PROG button and the SET+ or SET- buttons to choose the protocol number desired.

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ACCESSORIES WHICH ACCOMPANY SONOPULSE

SONOPULSE contains accessories conceived to satisfy the demands of electromagnetic compatibility – accessories coded **03018108** and **02049001.**

CODE	QTT	DESCRIPTION OF ITEM
03018108	01	CABLE PP 2 X 0.75 WITH 1.50MT BLACK PLUG 180° NEMA 2P WITH PLUG 180° FDA
03026009	01	PROTECTION FUSE CARD
03019012	01	20 AG FUSE OF 5A
03040052	01	DIGITAL INSTRUCTIONS MANUAL SONOPULSE 1 AND 3 MHZ FDA
02049001	01	SONOPULSE 1 AND 3 MHZ HANDPIECE KIT

WARNING

The use of accessories, ultrasound transducer and cables and electrodes different from the ones for which the device was designed may significantly degrade the performance of emissions and immunity. Therefore, DO NOT USE accessories, ultrasound transducer, cables and electrodes of **SONOPULSE** in other equipment or electromedical systems.

The accessories, electrodes and cables described in these instructions of use and manufactured by IBRAMED are for the sole use with **SONOPULSE** equipment.

REPLACEMENT ACCESSORIES

The replacement accessories are designed for use with **SONOPULSE**. As you order them, provide the respective codes, description and quantity desired.
The use of accessories, cables and transducer Other than the ones destined for this specific equipment may degrade significantly the performance and immunity. Do not use accessories, cables and transducer of **SONOPULSE** in other equipment or electromedical systems.

What may initially appear to be a problem not always is really a defect. Therefore, before turning to technical assistance, check the items described in the table below.

PROBLEM	SOLUTION
The equipment does not turn on 1	Is the power cable properly connected? If it is not, connect it. Also check the power outlet on the wall.
The equipment does not turn on 2	Have you checked the protection fuse? Check if they are **properly connected**. Check also if the value is in accordance with the indicated in the operation instructions.
The equipment is on but does not perform the function.	Have you followed the recommendations and instructions in the operation manual correctly? Check and go over the steps indicated in the item about **controls**, **indicators** and **connections**; and in the item **operation instructions**.

MAINTENANCE

For the safe use of the equipment, we recommended to have it inspected and undergo preventive maintenance at IBRAMED or an authorized technical center **every 12 months**.
IBRAMED manufacturer only assumes liability for the technical features and equipment safety provided the unit is used according to the instructions for use contained in the manual, when maintenance, repairs and modifications are undertaken solely by the factory or authorized agents, and in the event of a breakdown when the components that can cause a security risk to the appliance are replaced by original spare parts. If requested, IBRAMED will provide technical documentation (circuit diagrams, lists of parts and components etc.) necessary for the repair of any equipment.
We assume no responsibility for repairs without prior explicit written permission from IBRAMED.

CALIBRATION REQUIREMENTS

Calibrating Ultrasound Applicator

Annual factory calibration is required for the ultrasound applicator from the date placed in service. The device and the applicator should be sent to the factory or a certified service technician from IBRAMED for this procedure.

WARRANTY

IBRAMED, Indústria Brasileira de Equipamentos Médicos EIRELI, here identified to the consumer through the following address and telephone number: Av. Dr. Carlos Burgos, 2800, Jd Itália, Amparo/SP; Tel.: +55 19 3817 9633 provides product-warranty for eighteen (18) months insofar as the conditions set for warranty terms are followed by the user as mentioned below.

WARRANTY TERMS

1) IBRAMED warrants that this product is free of manufacturing defects for eighteen (18) continuous months provided the set terms presented in these instructions for use are followed.

2) The warranty period takes effect from the date of purchase and applies to the original purchaser only, even in the event of a product being transferred to a third party. The warranty covers the replacement of component parts and labor required to repair defects whenever the presence of such manufacturing defects can be determined.

3) Customer Service during the warranty period will be provided exclusively at IBRAMED sale points by IBRAMED itself or another agent designated by the manufacturer.

4) The warranty does not cover damage caused to the product resulting from:

a) Failure to follow the specifications and recommendations detailed in these instructions for use during installation or use of the product.

b) Accidents or acts of God, connections to electrical system with inappropriate voltage and/or subjected to excessive fluctuation or overcharge.

c) Misuse, lack of reasonable care, product alterations, modifications or repairs undertaken by individuals or entities not authorized by IBRAMED.

d) Removal or adulteration of the equipment serial number.

e) Damage during Transport.

5) The legal warranty does not cover: expenses incurred during product installation or transport to the plant or sale point, labor, materials, parts and adjustments necessary to the readiness of the premises in view of the installation of the device, such as but not limited to electric net, masonry, hydraulic network, grounding system, as well as their requirements.

6) The warranty does not cover parts subjected to natural wear, such as but not limited to control buttons, control keys, handles and moving parts, cables, connectors, device cabinets.

7) The selling points are neither authorized to alter the conditions mentioned in this document nor to take any commitment on behalf of IBRAMED.

Do not alter this equipment. Any unauthorized modification can affect the safety of this equipment.
Never make unauthorized repairs.

TECHNICAL ASSISTANCE

If you have any doubts or problems related to the operation of your equipment, please contact:

United Regulatory LLC
Address: 7541 NW 112th Ave Unit 103
Doral, FL 33178 - USA
Tel. / Fax: +1 (786) 600-1081
info@unitedregulatory.com

CEFAI – IBRAMED Center for Education and Advanced Training

IBRAMED Equipment goes beyond technology. It also provides knowledge! Science constitutes our differential value and we effectively take advantage of its benefits in order to ensure patient safety and thereby maximize results.

IBRAMED develops products with scientific support of the most recent medical studies published in major scientific journals in the areas of biological, health and exact.

Access to the knowledge database is guaranteed by CEFAI (IBRAMED Center for Education and Advanced Training) whose goal is to provide technical and scientific support as well as current literature on therapies and their applicability while our treatment choices are always thoroughly selected according to the best and latest clinical criteria. CEFAI takes into account the personal and professional development of all its partners and customers.

CEFAI invites both students and professionals in the fields of Physical Rehabilitation, Esthetics, Physiotherapy, Dermatology and Esthetic Medicine to take part in free courses, workshops, and the best Postgraduate Lato Sensu courses in the areas of physical rehabilitation and esthetics.

Special attention is also given to those interested in visiting our structure. Whatever your professional development needs, we'll be right by your side to provide you with unconditional support.

We are happy to assist you!

Contact – **cefai@conexaocefai.com.br**
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Thanks,

IBRAMED – A matter of respect!

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QUESTÃO DE RESPEITO

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