

Ultrasound therapy device

FISIOSONIC[®] PLUS

User manual



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User manual information

This document provides information regarding the putting into service and correct use of FISIOSONIC® PLUS ultrasound devices. It is an indispensable reference guide for the user: **before starting up and using the device, it is essential to read the manual carefully and keep it handy for quick reference.**

Writing Conventions

To highlight certain sections of the document, **bold** is used.

Note

The notes point out important information contained in the text.

WARNING














Warning messages appear before operations which, if the warnings are not observed, may cause damage to the machine and/or its accessories.



CAUTION

Caution messages indicate operations or situations which, if not known or not performed correctly, may cause problems for users.

SYMBOLS USED ON LABELS AND USER MANUAL

 <p>Manufacturer</p>	 <p>Date of manufacture</p>
 <p>Model reference</p>	 <p>Serial number</p>
 <p>type BF applied part</p>	 <p>Generic warning signal</p>
 <p>Read the Instruction Manual carefully before using the product</p>	 <p>Follow instructions for use</p>
 <p>Protective earthing</p>	 <p>CE marking in compliance with directive 93/42/EEC and further amendments.</p>
 <p>OFF (Power)</p>	 <p>ON (Power)</p>
 <p>Electro-medical device subject to separate collection</p>	

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FISIOSONIC PLUS: user manual

1 General information

FISIOSONIC® PLUS is a device for use in therapeutic activity which utilises acoustic pressure waves in the ultrasound frequency band. When applying ultrasounds, the operator sets the treatment mode and defines the skin area to be exposed to the ultrasound radiation.

The applicators, which can work with both 1MHz and 3.3MHz frequencies, are designed to be waterproof (IPX8) against liquids. This allows them to be used, should the operator deem it appropriate, in complete immersion.

FISIOSONIC® PLUS is equipped with a touch-screen display located on the front panel of the container, with which the user can set the appliance operating modes. The appliance also has an acoustic alarm.

For the purpose of further simplifying its use, FISIOSONIC® PLUS comes equipped with programs which can be easily called up by the operator.



The unit must be powered from the mains through the use of a suitable detachable power cord, which is supplied, and must be connected to the socket on the rear panel of FISIOSONIC® PLUS.

The FISIOSONIC® PLUS appliance is manufactured in compliance with the essential requirements of the European Economic Community Directive 93/42/EEC as amended by Directive 2007/47 EC concerning medical devices. In compliance with this Directive, the appliance features the following marking:



In compliance with current standards, the user is reminded that the user's manual is an integral part of the appliance it refers to. It should be thoroughly read and understood before using said device. The manual must be available to all personnel qualified to operate the device.

2 Data plate and technical features

<i>Constructor Manufacturer</i> 	Fisioline S.r.l. Borgata Molino 29 - 12060 Verduno (CN) Italy Tel. +39 0172.470432 – 0172.470433 Fax +39 0172.470891 e-mail: fisioline@fisioline.com
<i>Model</i>	FISIOSONIC® PLUS
<i>Grading of goods</i>	Electro-medical Appliance for Ultrasonic Therapy
<i>Medical device class</i>	II a (Dir. 93/42/EEC)
<i>Electrical protection class</i>	Class I and Type BF (according to IEC 60601-1)
<i>Mark</i>	
<i>Reference standard</i>	<ul style="list-style-type: none"> • Directive 93/42/EEC as amended by 2007/47/EC • EN 60601-1, IEC 60601-1 - Electro-medical equipment: general safety standards. • EN 60601-2-5, IEC 60601-2-5 Electro-medical equipment: particular requirements for the safety of ultrasonic therapy equipment • EN 60601-1-2, IEC 60601-1-2 – Electromedical equipment: electromagnetic compatibility. • EN 60601-1-6, IEC 60601-1-6- Electromedical equipment – Collateral standard. Usability.
<i>Power supply voltage</i>	230V ± 10% (115V optional)
<i>Network frequency</i>	50-60Hz
<i>Absorbed power</i>	80 VA
<i>Fuses</i>	1,6A delayed. (2 fuses, one per phase)
<i>Outputs</i>	4
<i>Emission frequencies:</i>	1MHz (±10%), 3.3MHz (±10%)
<i>Adjusting the average power density:</i>	Average power density can be adjusted from: 0.1W/cm ² to 3W/cm ² , at steps of 0.1 W/cm ² of the maximum power.

<i>35 mm diameter applicator</i>	freq. 1, 3.3MHz \pm 10%; BNR <8; max peak power density 3W/cm ²
<i>55 mm diameter applicator</i>	freq. 1, 3.3MHz \pm 10%; BNR <8; max peak power density 3W/cm ²
<i>21 mm diameter applicator (OPTIONAL)</i>	freq. 1, 3.3MHz \pm 10%; BNR <8; max peak power density 3W/cm ²
<i>Double three-disc scanning applicator (OPTIONAL)</i>	freq. 1, 3.3MHz \pm 10%; contact area 2x52cm ² ; max power density 3W/cm ²
<i>Rotary three-disc scanning applicator (OPTIONAL)</i>	freq. 1, 3.3MHz \pm 10%; contact area 32cm ² ; max power density 3W/cm ²
<i>Protection against humidity</i>	common IPX0 equipment
<i>Protection against flammable substances</i>	Appliance for use in environments where there are no flammable anaesthetics and/or flammable cleaning products
<i>Operating modes for high-frequency applicators</i>	<p>Pulsed output: the 1MHz or 3.3MHz carriers, which supply the transducer, are modulated by a 100Hz frequency square wave with duty cycle varying in the range 10 - 90%, in steps of 10%. The peak power density output is user-adjustable in the range of 0,1-3,0 W/cm² when setting a maximum duty cycle: Head diameter 35: up to 80% Head diameter 55: up to 50% Head diameter 21: up to 90%</p> <p>Continuous output: energy is continuously generated and the power density output is user-adjustable in steps of 0.1 W/cm². Maximum power density: Head diameter 35: 2.4 W/cm² total power output 12W at 1MHz Head diameter 55: 1.5 W/cm² total power output 15W at 1MHz Head diameter 21: 3 W/cm² total power output 3.6W at 1MHz, 0 W/cm².</p>
<i>Measurements</i>	320 x 430 x 980 mm
<i>Timer:</i>	The duration of treatment, ranging from 1 to 30 minutes, can be set by a timer with increments of 1 minute.
<i>Weight</i>	≈25 Kg

3 Intended use

FISIOSONIC® PLUS is a high-frequency ultrasound device for physiotherapy treatments in outpatient, hospital, medical practice and physiotherapy settings, and is mains-powered. FISIOSONIC® PLUS is a device which is restricted to operators (medical personnel, physiotherapists and paramedics, duly trained and qualified to use the device) who, by virtue of their professional training, can guarantee operation in complete safety and in compliance with the operating manual.

4 General principles of ultrasounds

Ultrasound waves are pressure waves with frequencies greater than the upper limit of human hearing (20 kHz). They can be produced artificially by the piezoelectric effect, using quartz or a disc made of ceramic material.

The piezoelectric effect is the mechanical deformation (expansion or compression) that a piezoelectric disc undergoes when subject to a variation in the applied voltage on both of its circular surfaces.

A device for ultrasonic therapy is therefore made up primarily of an alternating current generator (an oscillator operating at 1 MHz and/or 3 MHz) which, through an appropriate cable, supplies an applicator where a piezoelectric transducer is inserted, which is responsible for converting the electrical energy it receives into mechanical energy.

The therapeutic effect of ultrasounds is largely due to four different effects that are able to act in combination:

- **Thermal effect**, consisting of raising the temperature of the tissues affected by the treatment. This effect is due to both the absorption of mechanical energy associated with the ultrasound, by the tissues themselves, and the phenomena of acoustic wave reflection, which occur in the vicinity of an interface between tissues with different acoustic impedance.
- **Mechanical effect**, consists of a high-frequency micromassage, determined by the movement of particles in tissues that the ultrasonic waves pass through.
- **Chemical effect**, consisting of partially altering the local pH and the permeability of cell membranes. This effect is caused by the considerable accelerations that the cells affected by the acoustic wave are subject to.
- **Cavitation effect**, consisting of the generation, in a fluid, of small bubbles of the gas that is dissolved therein.

Unlike Marconi therapy and/or radar therapy devices, which only enable the treated tissues to be heated, the ultrasounds associate the heating with the mechanical action, resulting from the propagation of pressure waves generated by the applicator in the tissues themselves. Both heating and massage are techniques that have been used for centuries in treating soft tissue injuries. The use of ultrasound energy makes it possible to massage and/or heat the tissue at a greater depth than could be achieved manually.

The dosimetry of ultrasound radiation can be controlled by varying three main parameters: the ultrasound frequency, the power density produced by the applicator and the duration of exposure to the radiation.

The frequency of ultrasound radiation determines the way in which the energy is absorbed by the tissues. Generally, we can say that the higher the frequency of the radiation, the more rapid the decrease in power density with an increase in the depth of the radiation in the tissue.

In human soft tissue, it has been experimentally proven that the power density of ultrasounds at a frequency of 1 MHz is halved at a distance of 50 mm from the applicator, while at a frequency of 3 MHz, the power density is halved after only 15 mm. Frequencies significantly lower than 1 MHz are scarcely used because of the difficulty in focusing the beam of energy, while frequencies above 3 MHz are generally not very useful since they cause actions that are too superficial. For clinical effectiveness purposes, the frequency of radiation is not particularly critical and variations $\pm 10\%$ are generally considered acceptable.

The power density produced by the applicator must be limited to the value of $3\text{W}/\text{cm}^2$. This limit is imposed by applicable legislation (**IEC 60601-2-5**) and must be strictly respected in order not to cause damage to the tissues exposed to the radiation. For this reason, FISIOSONIC® PLUS delivers a maximum power density of up to 3 W/ cm^2 .

It must be possible for health personnel to determine the precise duration of exposure to radiation, taking into account the type of tissue being treated and the disorder.

In certain cases, it may be appropriate to exploit the micromassage effect produced by ultrasound vibrations, minimizing the heating effect of the tissues: this is made possible by the pulsed mode. When this operating mode is selected, the radio frequency carrier, responsible for the emission of ultrasound, is modulated by a low-frequency square wave and variable *duty cycle*. In this way, it is possible to regulate the average power delivered to the tissue, without changing the instantaneous peak power, with the result of being able to reduce the heating effects to a level that is virtually negligible, all the while maintaining the peak value of the mechanical pressure that provides the micro-massage.

5 Using ultrasounds

Ultrasound therapy can be carried out in either direct contact or scanning modes.

5.1 Direct contact mode

This mode consists in applying the emitter head in direct contact, with the skin interposing a substance (a special conductive gel for ultrasounds) whose purpose is to facilitate the transmission of the ultrasounds from the transducer to the skin of the patient being treated.

Using the manual method, the power density is freely adjustable from 0.1 to 3W/cm². The frequency of treatment is usually three times a week for the first two weeks and twice a week in subsequent weeks.

When using the head in manual mode, using small circular movements or movements that are perpendicular to each other, slide the applicator head along the skin on the surface to be treated.



CAUTION

In order to allow the transmission of the ultrasonic wave from the applicator to the skin, a layer of ultrasound gel must be placed between the two.

Do not use oils, talcum powder or creams as they prevent the correct transmission of the ultrasonic wave and can permanently damage the applicator, making it necessary to replace it.

5.2 Immersion method

The immersion method is used when it is necessary to treat skin areas that are irregular or too small or so painful that direct contact is not possible.

The part to be treated is therefore immersed in a container containing water together with an applicator. The head is placed approximately 2 cm from the skin surface. In order not to reduce the effectiveness of the treatment, the water must be kept at a temperature of approximately 37 degrees centigrade.

In the immersion method, power densities of about 1 – 2 W/cm² can be safely used. The treatment frequency is usually daily for a total of ten sessions. Each session lasts between 5 and 15 minutes. The continuous operating mode can be safely used in this case.

5.3 Scanning method

Scan mode is used if large areas are to be treated without the continuous intervention of an operator. The scanning applicators (single applicator or double applicator) must be secured to the treatment area using the special elastic straps supplied with the scanners themselves. Between the scanners and the skin, it is always necessary to apply a layer of the special conductive gel supplied. It is also necessary to ensure that the metallic surface of the applicators is in perfect contact with the skin. Each scanner has three transducers activated individually in sequence to simulate manual massage. It is possible to set the scan time from a minimum of one second to a maximum of 10 seconds (scan time).

**CAUTION**

In order to allow the transmission of the ultrasonic wave from the applicator to the skin, a layer of ultrasound gel must be placed between the two.

Do not use oils, talcum powder or creams as they prevent the correct transmission of the ultrasonic wave and can permanently damage the applicator, making it necessary to replace it.

6 Therapeutic indications

The use of ultrasounds is particularly indicated for analgesia in arthrosis and periarthritis, to facilitate the reabsorption of haematomas to stimulate tissue healing. It is also indicated to facilitate the resolution of muscle spasms, to increase the elasticity of connective tissue and in contractures; and is useful for promoting a more aesthetic and functional healing and also for reducing or eliminating tenuous calcifications.

The FISIOSONIC® PLUS device is used in Physiotherapy to treat:

- Tendon disorders: treatment aimed at relieving/healing pain and/or inflammation
- Ligament disorders: treatment aimed at relieving/healing pain and/or inflammation
- Muscle disorders thanks to the relaxant analgesic action and defibrotic and trophic effect
- Scar adhesions
- Stiffness and joint degeneration.
- Dupuytren's disease
- Epicondylitis
- Sciatic pain
- General neuritis
- Scapulohumeral periarthritis
- Muscle tendon calcifications. N.B.: calcifications of other nature are excluded, such as bladder, biliary and salivary kidney stones.



7 Contraindications, side effects and warnings

Ultrasonic therapy is not recommended for:

- Acute inflammatory processes not related to the musculoskeletal system
- Neoplasms
- Skin lesions in the area to be treated (healthy, undamaged skin)
- During pregnancy (near the abdominal or lumbar area)
- Directly on joint prostheses or metal synthesis devices
- Varices
- Phlebitis and thrombophlebitis
- Presence of pacemakers or other implanted electronic devices
- Sensitivity alteration
- Fertile women for treatments on the lumbar and abdominal regions, except for 10 days after menstruation
- Presence of hernias in the focal field to be treated
- Ongoing, on-site inflammation not related to the musculoskeletal system

WARNINGS AND SPECIAL PRECAUTIONS

In the case of irritable bowel syndrome, colitis, gastritis, diverticulitis, fibroids, ovarian cysts, intestinal inflammation, pelvic inflammatory diseases, etc. it is advisable not to treat the area directly and use reduced power. We also recommend plica treatment on these subjects.

Ultrasound therapy must be avoided in the cephalic region of the cranium, the genitalia, eyeballs and the uterus during pregnancy due to the possibility of cavitation phenomena occurring even at therapeutic dosages.

It is not advisable to use this appliance in the vicinity of metal synthesis devices and joint prostheses, as these are characterized by a higher absorption of the ultrasound wave and are therefore more exposed to possible deterioration.

Avoid the use of ultrasound in the vicinity of the heart muscle, due to the possibility of interference with the activity of cardiac muscle contraction. Do not apply ultrasound in the presence of pacemakers or other electronic equipment.

Particular caution should be used when performing treatments in the vicinity of the spinal cord, after a laminectomy. Avoid use in the vicinity of areas of the body affected by osteoporosis and anaesthetized areas, or in patients who are unable to communicate any sensations of pain or heat to the operator.

Do not treat articular cartilage areas on children and adolescents.

Operators must protect their hands from ultrasound waves with the use of rubber gloves when using immersion mode.

Applicators must always be handled with care to avoid damaging the ceramic piezoelectric translators that are inside them.

Do not use on persons who have undergone infiltrations to avoid local cavitation/overheating.

Do not use on patients with active hearing aids and/or hearing problems.

Do not treat patients with sensitive skin and/or intolerance to the conductive gel

8 Electrical safety and rules for proper use

Some operating instructions necessary for the purposes of protecting both the operators as well as the patients from any risks deriving from the use of the FISIOSONIC® PLUS appliance are set out below. It is extremely important that personnel using the instrument read and fully understand the following points.

The electrical system of the room where the device will be used must meet applicable IEC requirements and in particular **THE DEVICE MUST NOT BE USED IF THE GROUNDING CONNECTION IS MISSING OR INEFFICIENT.**

The device is built to meet applicable legislation and belongs to equipment class I type BF. As with all medical electrical devices, it is important to remember that both the performance of the device and its insulation tend to deteriorate over time. It is therefore evident that the correct functioning of the machine, its proper grounding and its electrical current leakage values must be periodically evaluated, as prescribed by applicable legislation and as indicated in the section below entitled PREVENTIVE MAINTENANCE.

It is the operator's responsibility to ensure that the device is plugged in without the use of extension cords, adapters or multiple plugs/sockets that may interrupt or render the grounding of the instrument unreliable.

If an electrical device is connected to an inadequate system, the electrical safety, and sometimes the proper functioning of the device itself are impaired.

In case of doubt or uncertainty about safety, how to use the equipment and the risks resulting from using one or more devices, the operator must consult the medical electrical equipment technicians, in order to prevent hazardous conditions that are not readily identifiable without specific technical skills.

8.1 Proper use of the applicators and relative warnings

The applicators must be kept in conditions of maximum cleanliness with the use of neutral soap and water and must be repaired if they present external damage. External surface damage can jeopardize the seal on the applicator itself and must therefore be promptly reported to technical assistance. Any surfaces that are not perfectly clean, but badly encrusted with deposits of poorly removed gel, greatly decrease the power output and can cause excessive burning sensations in area being treated. Conductors with damaged casing, plugs or sockets that do not work perfectly can pose a serious danger to operators and/or the people being treated.

When using the applicators, it is necessary to take into account the following warnings:

a) Do not leave the applicator on the same area of skin for too long.

In this case, in fact, there is the risk of raising the temperature of the skin being treated, due to the transformation of mechanical energy emitted by the head of the applicator into heat. It is therefore necessary to move the applicator on the area of skin being treated, in order to distribute the energy delivered to the tissue well over a larger region. It is therefore advisable to use the direct contact mode with a moving head technique. If the fixed head technique is used instead, it is recommended to reduce the average power delivered to the tissue by operating in pulsed mode.

b) Do not lift the applicator off of the skin for excessive periods of time.

In the second case there is an excessive rise in temperature of the applicator due to the fact that all of the energy delivered by the head is automatically transformed into heat, as it is not possible to emit ultrasound when the head is held in the air. To prevent this problem, the appliance is equipped with a sensor enabling supply interruption in the event that applicators do not come into contact with skin.

In any case, only use the applicator if there is a thick layer of ultrasound gel interposed between the radiating surface and the skin.

The gel for ultrasounds supplied with the appliance bears the CE marking in compliance with Directive 93/42/EEC as amended. The exclusive use of ultrasound gel with the characteristics reported above is recommended.



CAUTION

In order to allow the transmission of the ultrasonic wave from the applicator to the skin, a layer of ultrasound gel must be placed between the two.

Do not use oils, talcum powder or creams as they prevent the correct transmission of the ultrasonic wave and can permanently damage the applicator, making it necessary to replace it.

9 Putting the device into service

9.1 Unpacking the machine

The FISIOSONIC® PLUS device is packed and prepared for shipping with a box complete with filler material, designed for storage and safe transport.

To unpack the machine and accessories, place the box on a solid, flat surface and open the top (without the use of knives, cutters, etc.) removing the filler material.

9.2 Standard accessories

The package always contains:

- 1 x 1 and 3.3 MHz multifrequency applicator with 35 mm diameter
- 1 x 1 and 3.3 MHz multifrequency applicator with 55 mm diameter
- 1 x Applicator holder support
- 1 x Adjustable arm for diameter 55 mm applicator
- 2 x Bottles of ultrasound gel
- 1 x user's manual
- 1 x power cord
- 1 x 10mm adjustable spanner
- 1 x 6mm Allen key

Check the contents of the package.

If any parts are missing and/or faulty, contact FISIOLINE s.r.l. immediately.

**Keep the original packaging for the machine:
it must be used again in case the machine is sent back to the company.**

WARNING

Check thoroughly that the connections are set up correctly according to the instructions provided before operating the device.

Do not use accessories other than the original ones supplied as they could damage the device and will void the warranty.

If you experience problems or difficulties installing the machine and/or have special requests, please contact FISIOLINE s.r.l. technical support.

WARNING

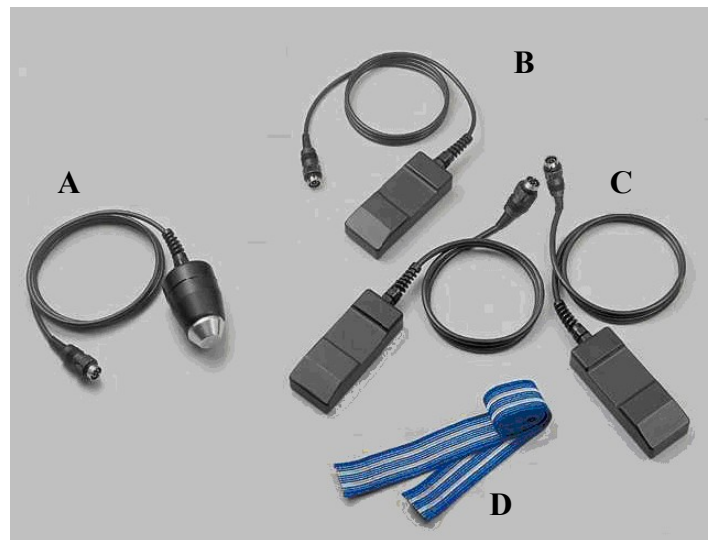
FISIOSONIC® PLUS FUNCTIONALITY
IS GUARANTEED

IN COMPLIANCE WITH THE ABOVE RULES FOR INSTALLATION AND PROPER USE,
ONLY WITH ORIGINAL ACCESSORIES AND REPLACEMENT PARTS.

9.3 Optional accessories

The optional accessories of the FISIOSONIC® PLUS device, which must be requested separately, are the following:

- 21 mm diameter multifrequency applicator
- Multidisc scanning applicator (3 discs)
- Double multidisc scanning applicator (3 +3 discs)
- Rotary scanning applicator
- Elastic strap 8x60 mm
- Elastic strap 8x100 mm



- (A) Applicator ϕ 21mm
(B) Multidisc 3-disc scanning applicator
(C) Double multidisc 3 +3 disc scanning disc
(D) Elastic strap

9.4 Choosing the installation site.

The installation of the appliance for ultrasonic therapy is simple, immediate and does not require particular attention. The environmental features recommended for installation of the FISIOSONIC® PLUS appliance and its accessories are the following:

- Room temperature: between +10 °C and +40 °C;
- relative humidity: between 45% and 60%, non-condensing;
- avoid direct exposure to sunlight, chemicals and vibrations.



WARNING

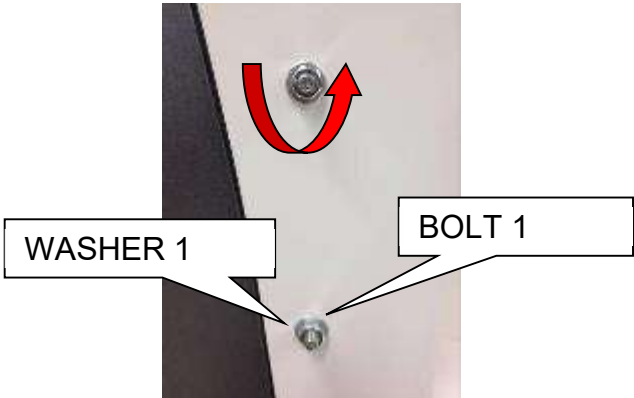

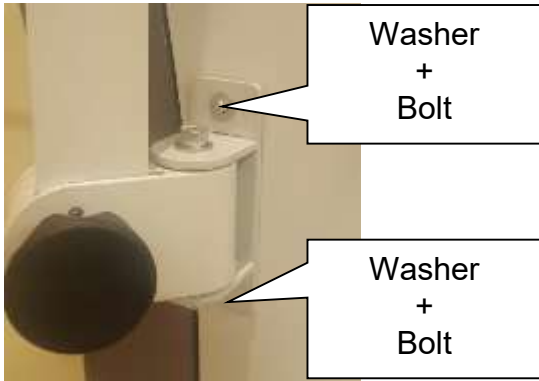
Do not use
FISIOSONIC® PLUS
in places where the equipment could get wet
either externally or internally (such as bathrooms, saunas etc.).

When transporting or storing the device, the recommended environmental conditions are:

- ambient temperature: between 5 °C and +45 °C;
- relative humidity: from 40% to 60%, non-condensing.

9.5 Assembling the adjustable arm

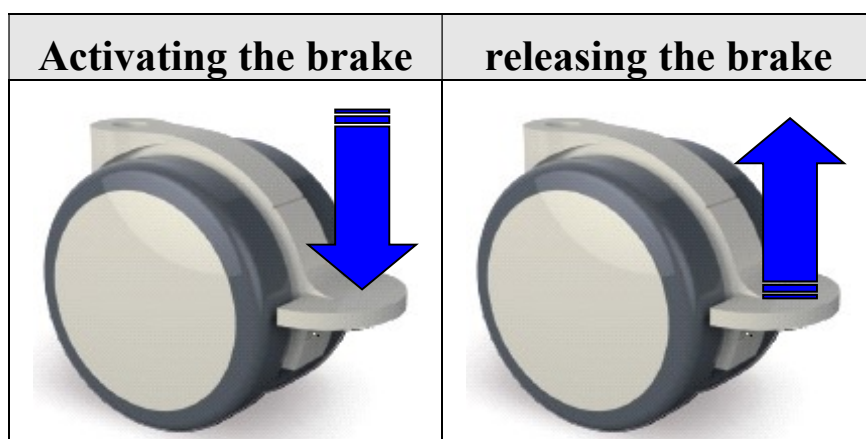
Equipment required	
10mm adjustable spanner Supplied	
6mm Allen key Supplied	

1	Unscrew the 2 bolts (anti-clockwise) using the 10 mm adjustable spanner supplied: the 2 bolts and 2 washers will be used to secure the handpiece holder.	
2	Position the arm support on the right side of the device.	
3	Position the two washers and the 2 fastening bolts and tighten (clockwise) using the 10 mm adjustable spanner supplied.	

9.6 Moving/stabilising the device

It is recommended that the device is used on a flat, solid surface (floor). The device features 4 swivel wheels that enable it to be moved, using the handle on the top of the device itself.

When the device has been positioned in its workstation, it is advised that you activate the brakes on the front wheels using the levers on the wheels themselves.



9.7 Connecting the device to the electric mains and applicators connection

On the rear panel, you will find the power connector, where you must connect the power cord.



WARNING

Before connecting the cable to the mains, make sure the device has not been damaged during transport and ensure that the characteristics of the power supply in the mains meet the data on the nameplate located on the bottom panel of the device.



CAUTION

For safety reasons the power cord is supplied with a plug with a grounding connection, for protection.

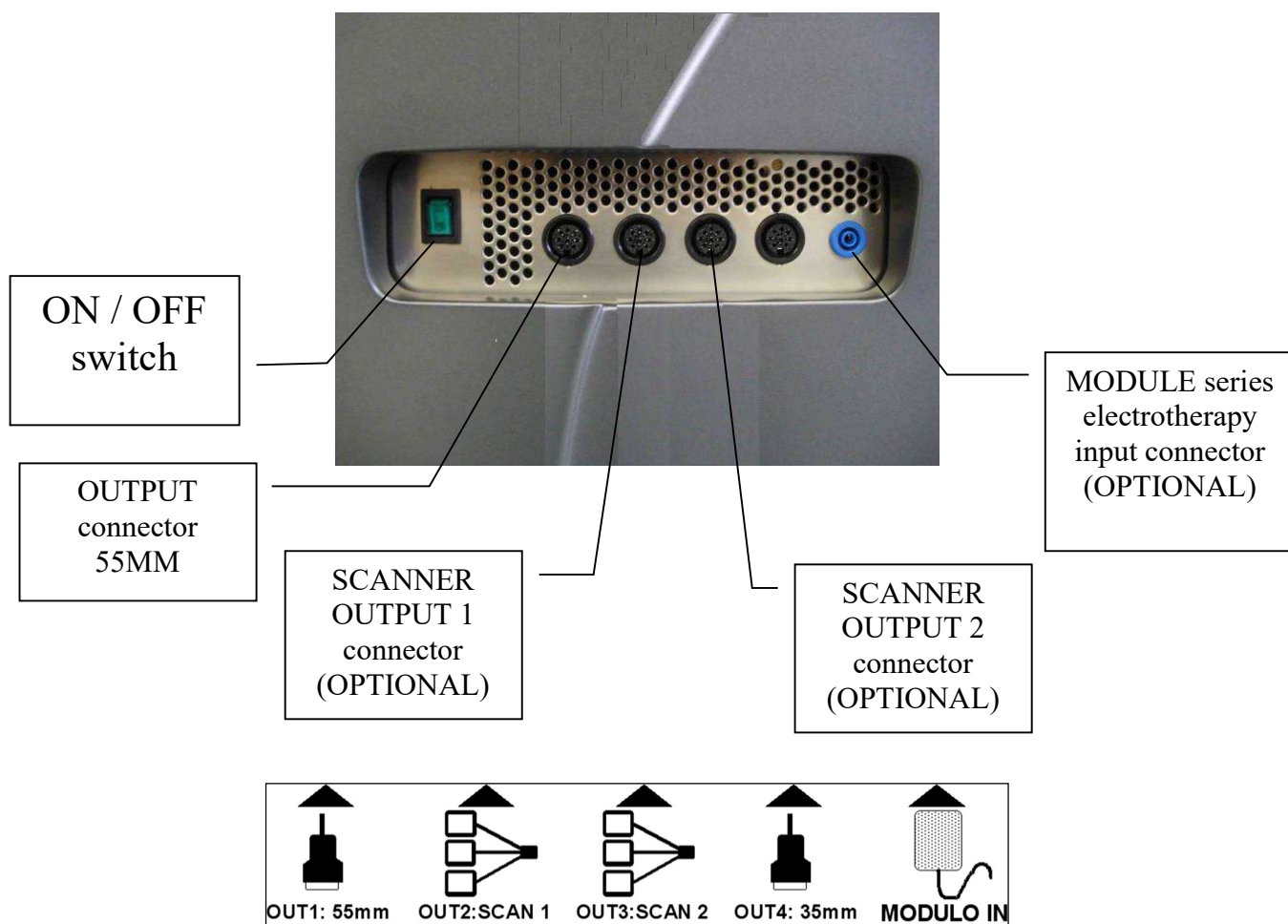
Use only suitable grounded power outlets.

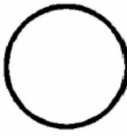


The unit should only be connected to regulation electrical systems

Do not use extension cords.

Failure to observe this warning could cause danger to persons as well as damage the device itself.

After you have finished checking that the installation and assembly have been carried out correctly as specified in the paragraphs above, proceed as described in chapter 11 “Instruction for Use”.

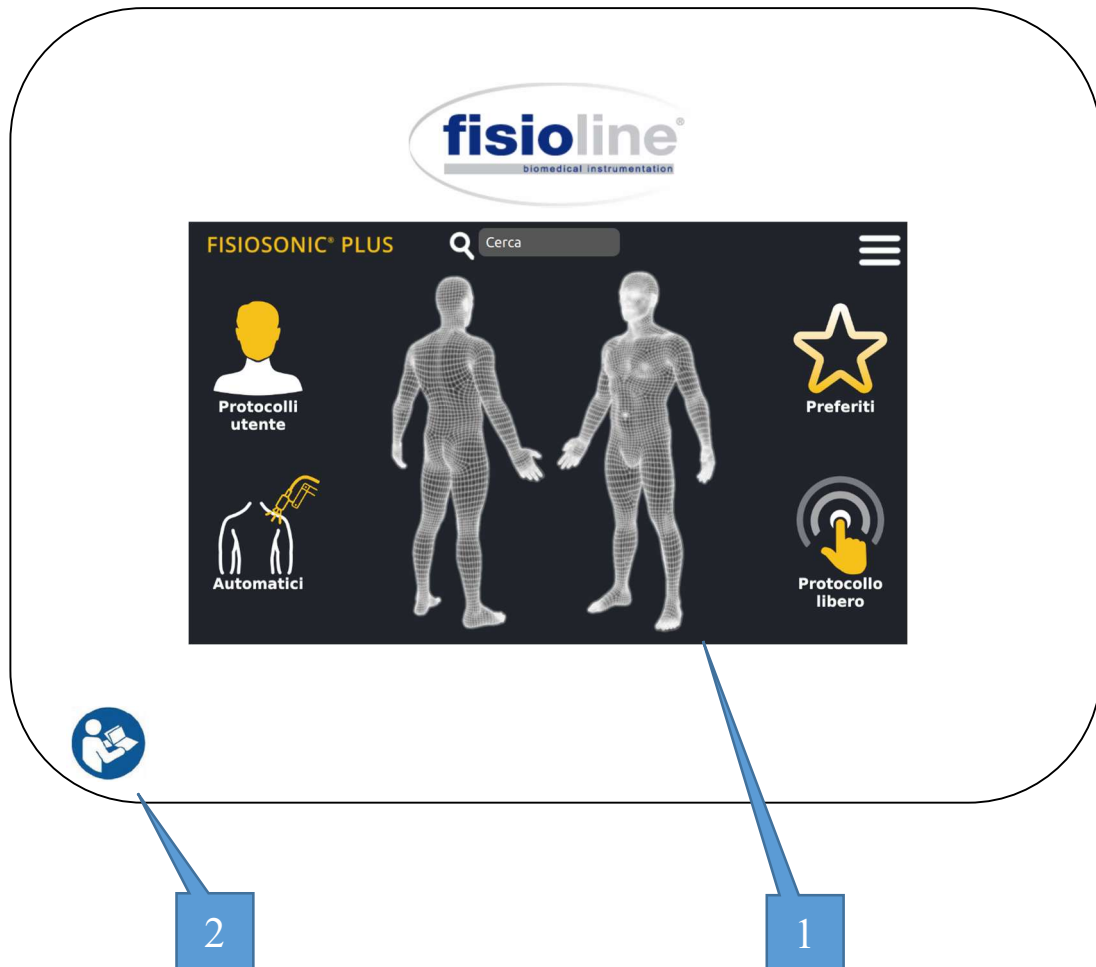


ON/OFF GENERAL SWITCH		
Switch position 0 →device off (green light off)		
Switch position 1 →device on (green light on)		

10 Device description

10.1 Front panel: FISIOSONIC® PLUS controls

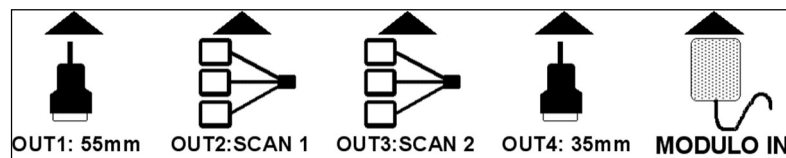
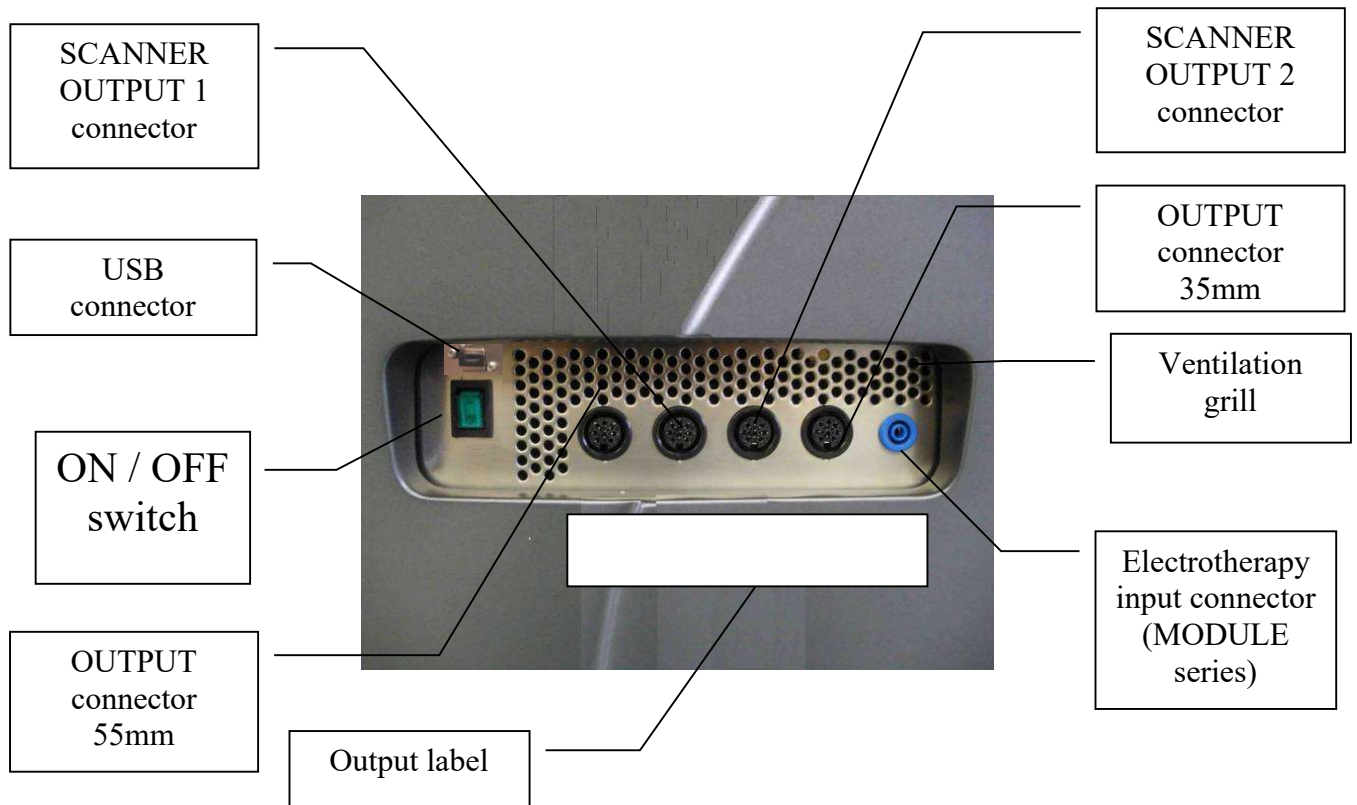
The appliance control panel with its corresponding touch-screen is located on the upper inclined top of the This positioning ensures immediate, easy device use with prompt display and operation of necessary commands.



Legend:

- 1) Touch-screen display for indication and adjustment of treatment parameters
- 2) For the symbols, see the identification plate data.

10.2 Rear panel

















WARNING

Connect the applicators in accordance with the above instructions.



10.3 Device data plate

 fisioline <small>biomedical instrumentation</small>	<table><tr><td>SN</td><td>XXXXYY</td></tr><tr><td colspan="2">230Vac 50Hz 80VA</td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2">2xT1.6 A 250V</td></tr></table>	SN	XXXXYY	230Vac 50Hz 80VA				2xT1.6 A 250V		REF: FISIOSONIC® PLUS    0051  MM YYYY 
SN	XXXXYY									
230Vac 50Hz 80VA										
										
2xT1.6 A 250V										

	Generic warning signal. Symbol no. 14, table D 1 of the CEI 62-5 standard: caution, consult accompanying documentation
	Symbol 20 of table D 1 of standard CEI 62-5: Type LF applied part
	CE marking in compliance with Directive 93/42/EEC and subsequent amendments
 	Electro-medical appliance subject to separate collection

11

Instructions for use

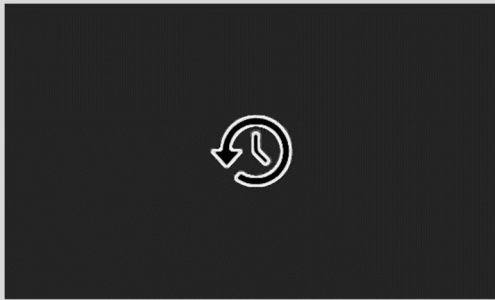




CAUTION: The use of commands or regulations or procedures different than those specified here, can cause expositions at dangerous radiation levels.

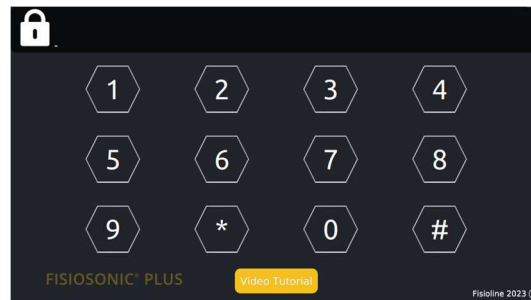


CAUTION: We point out to the user that, before using the device, must follow the precautions specified in the section “Safety and norms for correct use”.

When the device is turned on, the following screen videos are sequentially displayed:

Activation system: about 40 seconds	
The logo of the Manufacturer: about 5 seconds	
The reference of the model: about 5 seconds	









After displaying the sequence of previous screens, the device requires the access code (PIN):



Access is blocked until the correct code is entered (4 digits, default 1,2,3,4). When the access code is being entered, each digit will be indicated by a bullet point. From here you can access the main device menu.

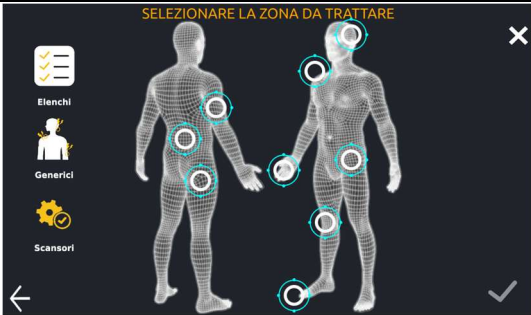
Press anywhere on the screen to access the main screen, otherwise you will be sent there after about 5 seconds.

MAIN SCREEN	
	Pre-set Rehabilitative Medicine protocols (anatomic search)
	User Protocol
	Automatic protocols that use the 55 mm applicator mounted on the adjustable arm
	Favourite protocols
	Free Protocol
	Advanced menu
	Find protocol

 ADVANCED MENU	
	
	Device safety lock
	Settings menu
	Tutorial videos
	Information
	Switching off the device
	Go back to the Main Menu

11.1 Pre-set protocols

BODY AREA SELECTION



1

Body Area Selection

Go back to the Main Menu




2

Confirm Selection

Go back to the previous screen

Confirm Selection

PROTOCOL FILTERS

	Textual category protocol lists
	General protocols (not associated with a body area)
	Protocols with scanning applicators

SELECTION OF THE WORKING PROTOCOLS

1 Indication of previous selection

2 Program selection keys

3 Selected program

4 Program application video

5 Confirm Selection

6 Applicator Program

Go back to the Main Menu

Addition into the FAVOURITE category

Addition in the FAVOURITE category

Go back to the previous screen

Creation of a new user program

DISPLAY and EDITING of PROGRAM PARAMETERS

32 TENDINITE INSERZION.RETTO ANT.

Potenza 1,2 W/cm²

Tempo 10' 00"

Energia 288,0J/cm²

Duty-cycle 40%

OFF

Applicatore: Ø 55mm

Tempo fase: 10' 00"

Modulazione: 100Hz

Fase 1

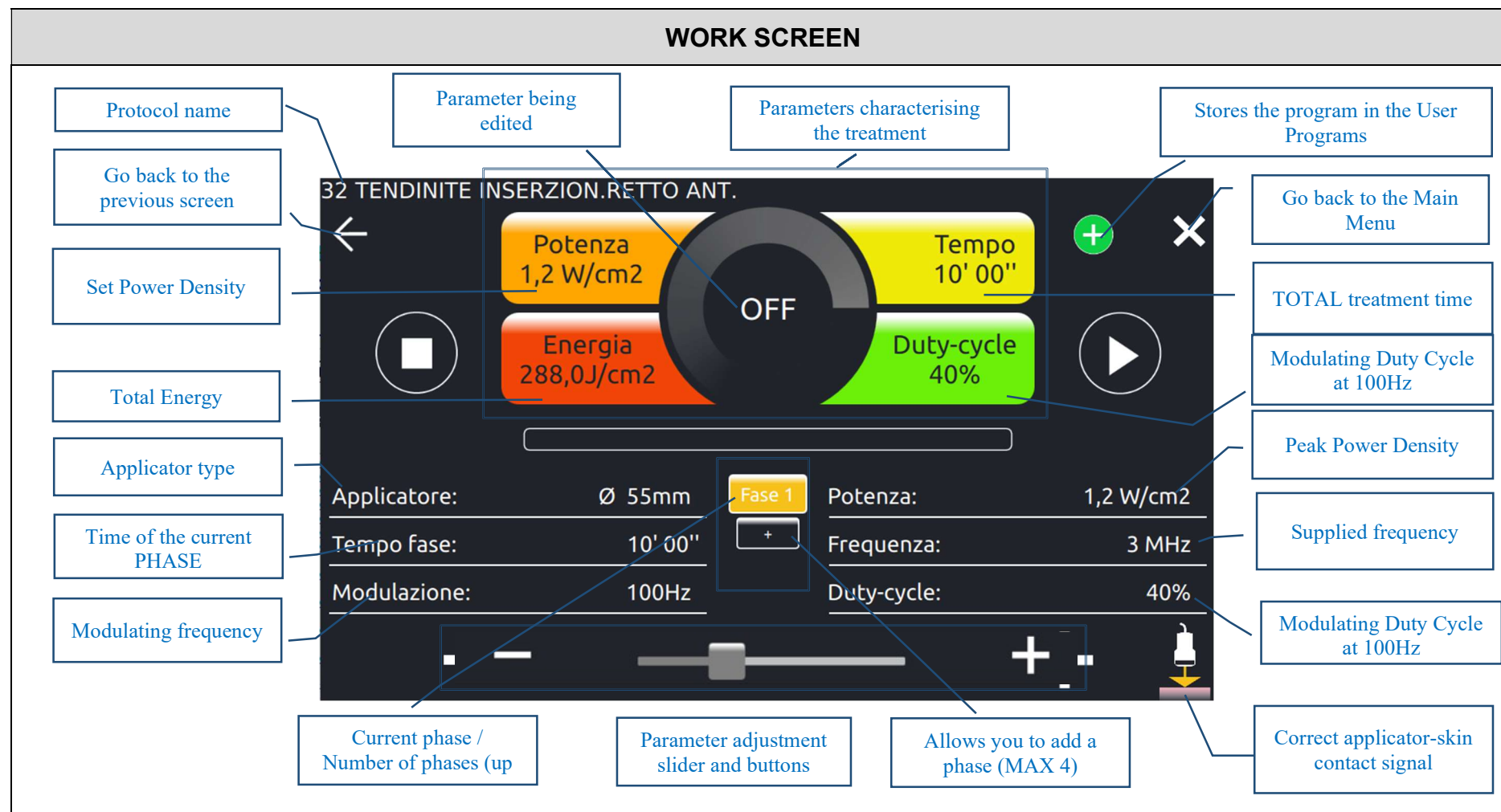
Potenza: 1,2 W/cm²























Frequenza: 3 MHz

Duty-cycle: 40%

11.2 Display and Editing of program parameters

On this screen you can freely modify the parameters to create a User Program and store it in the relevant category or simply start the treatment.







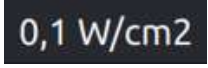




	<div>START key: activates the US generator</div> <table><tr><th>OFF state</th><th>READY state</th><th>ON state*</th></tr><tr><td><div><div>→ START</div></div></td><td><div><div>→ START</div></div></td><td><div></div></td></tr></table> <div>* It is the task of the operator to adjust the US power appropriately and gradually depending on the feedback from the treated subject and the technique and speed of movement of the handpieces/applicators on the skin.</div>	OFF state	READY state	ON state*	<div><div>→ START</div></div>	<div><div>→ START</div></div>	<div></div>
OFF state	READY state	ON state*					
<div><div>→ START</div></div>	<div><div>→ START</div></div>	<div></div>					
	<div>STOP key: switches off US emission</div> <table><tr><th>OFF state</th><th>READY state</th><th>ON state</th></tr><tr><td><div><div>← STOP</div></div></td><td><div><div>← STOP</div></div></td><td><div></div></td></tr></table>	OFF state	READY state	ON state	<div><div>← STOP</div></div>	<div><div>← STOP</div></div>	<div></div>
OFF state	READY state	ON state					
<div><div>← STOP</div></div>	<div><div>← STOP</div></div>	<div></div>					
	No skin contact						
	Skin contact present						






11.3 Parameter adjustment




CAUTION: the manufacturer discharges his responsibility on the creation of user programs with parameters that are wrong or can damage skin or other tissues.

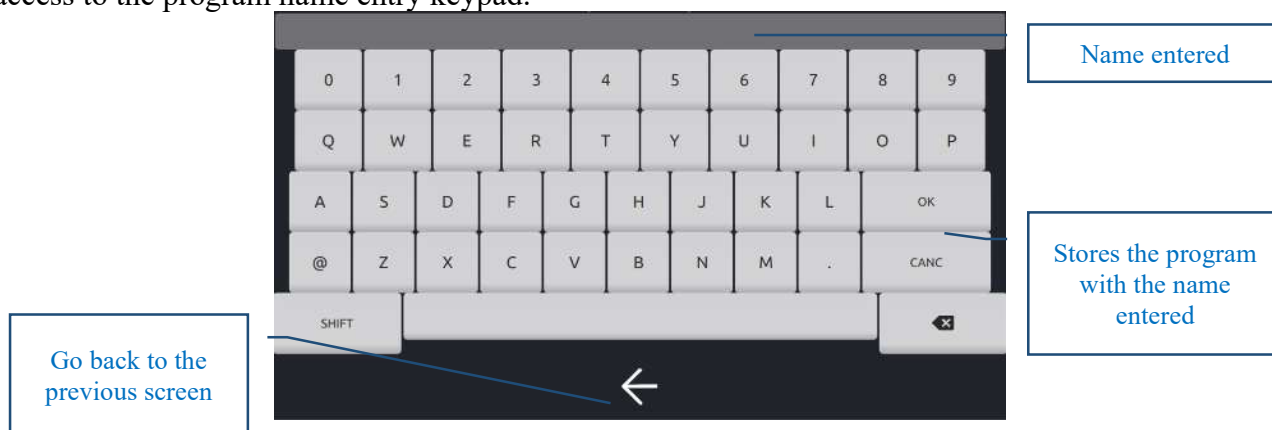
The parameter adjustment range is shown in the following table:


Setting range		
Working frequency	Applicator diameter 55, 35 and 21	Fixed frequency at 1 MHz or 3 MHz Or automatic 1-3MHz frequency switch 2s 1M – 3s 3M With indication of the seconds of output at 1MHz and seconds of output at alternating 3MHz. The cycle is repeated throughout the treatment time
	Scanning applicators	1 MHz, 3 MHz with indication of scanning time: 1MHz 1sec indicates 1 second of emission for each scanning disc.
Applicators		Multifrequency applicator diameter 55
		Multifrequency applicator diameter 35
		Multifrequency applicator diameter 21 (optional)
		Scanning applicators (optional)
Power (adjustable in the ON state)		55 mm diameter applicator: from 10% to 50%: 3W/cm ² from 60% to 80%: 1.8W/cm ² from 90% to 100%: 1.5W/cm ² 35 mm diameter applicator: from 10% to 80%: 3W/cm ² from 90% to 100%: 2.4W/cm ² 21 mm diameter applicator: from 10% to 80%: 3W/cm ²
Modulation		Range 10% ÷ 100% step 10%. This range varies depending on the applicator and the set Power Density (refer to the Power Density setting). PULSED MODE: 10% ÷ 90% CONTINUOUS MODE: 100 %
Number of phases		Number of phases from 1 to 4. Example of a program consisting of two phases and the parameters displayed are those of the first phase. Using the “+” key to set a time other than 0 will insert a new phase into the program.
Phase time Total time	 	Phase time range 1 sec ÷ 30 min. step 1sec Total time (sum of active phase times)


1	Selection of the parameter to regulate by pressing the corresponding box on the touch-screen	 → 
2	Parameter adjustment using the arrow keys or via scroll bar	
3	De-selection of the parameter to be adjusted by pressing on the touch-screen or selection of an additional parameter to be adjusted	 → 

11.4 Free protocol and Create program

Any program can be freely edited and, if necessary, stored by means of the button  which provides access to the program name entry keypad:

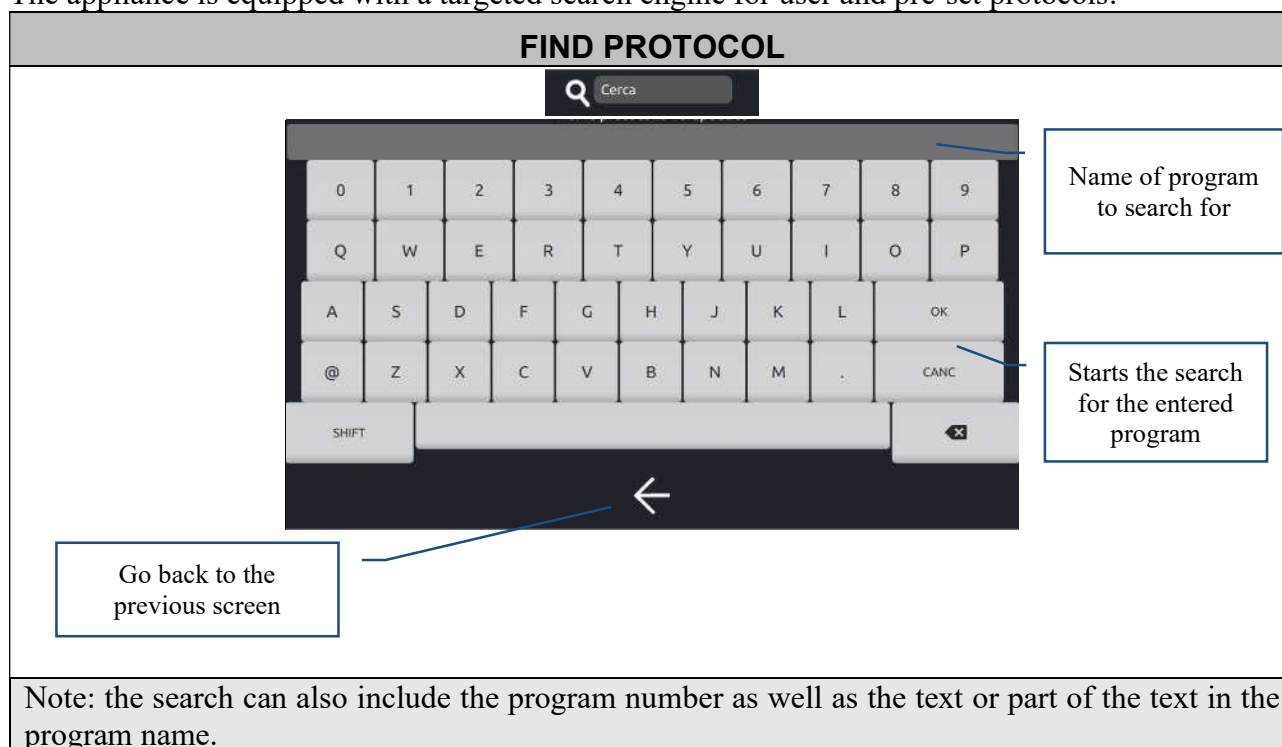


The program is then stored in the User Protocols section accessible from the icon indicated in the Main Menu .

	CAUTION: the manufacturer discharges his responsibility on the creation of user programs with parameters that are wrong or can damage skin or other tissues.
-------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------

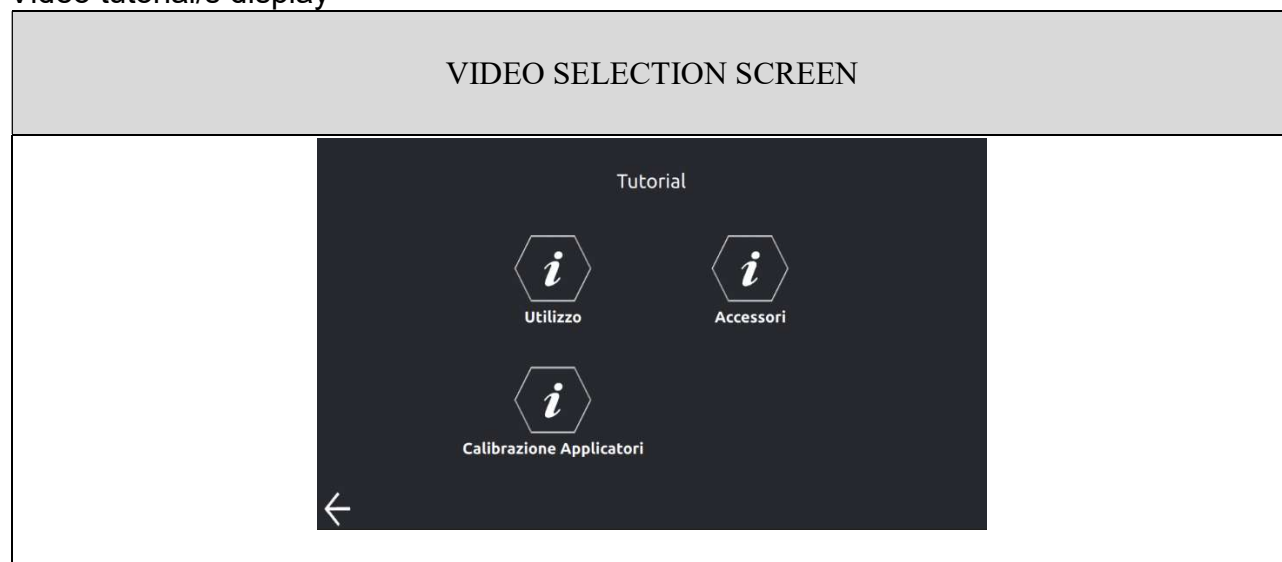
11.5 Find protocol

The appliance is equipped with a targeted search engine for user and pre-set protocols:

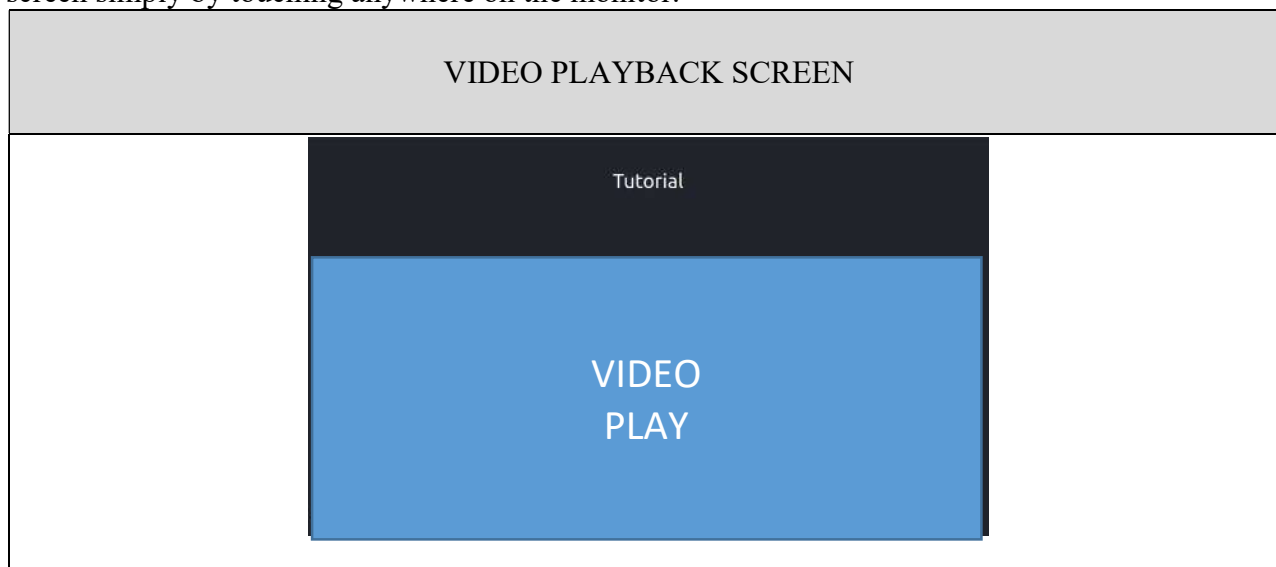


11.6 Tutorial Videos












Video tutorial/s display



During playback of the selected video, it is possible to stop it at any time and go back to the previous screen simply by touching anywhere on the monitor.



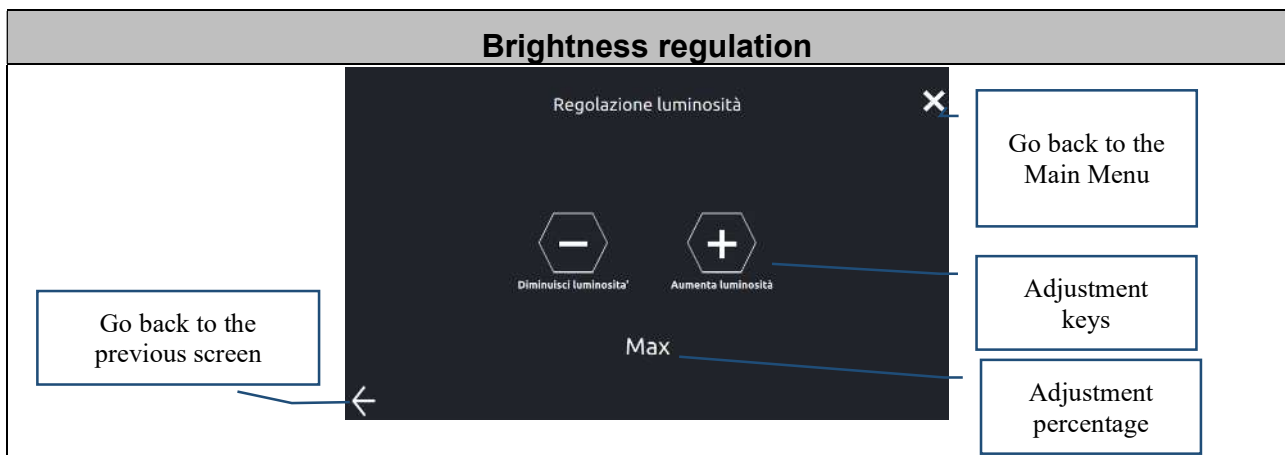
12 Settings

SETTING SCREEN	
	
	Language setting
	Adjust screen brightness
	Adjust tutorial video/application video playback volume
	Activation  / Deactivation  of the right contact sensor
	Information Display
	Change access password Ref Chapt.13 Modify PIN code
	Technical menu
	Software update

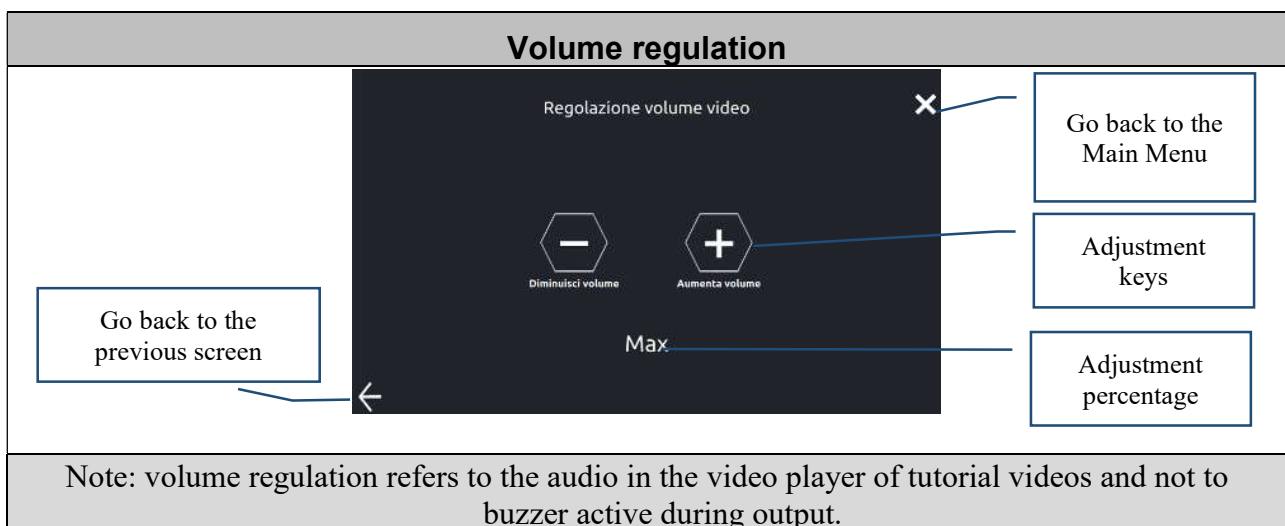
12.1 Language setting



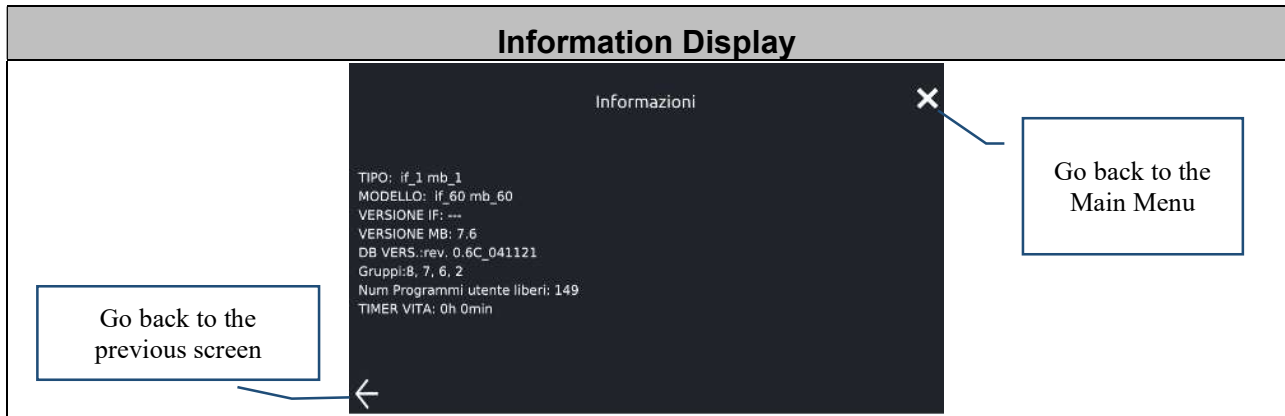
12.2 Adjust screen brightness



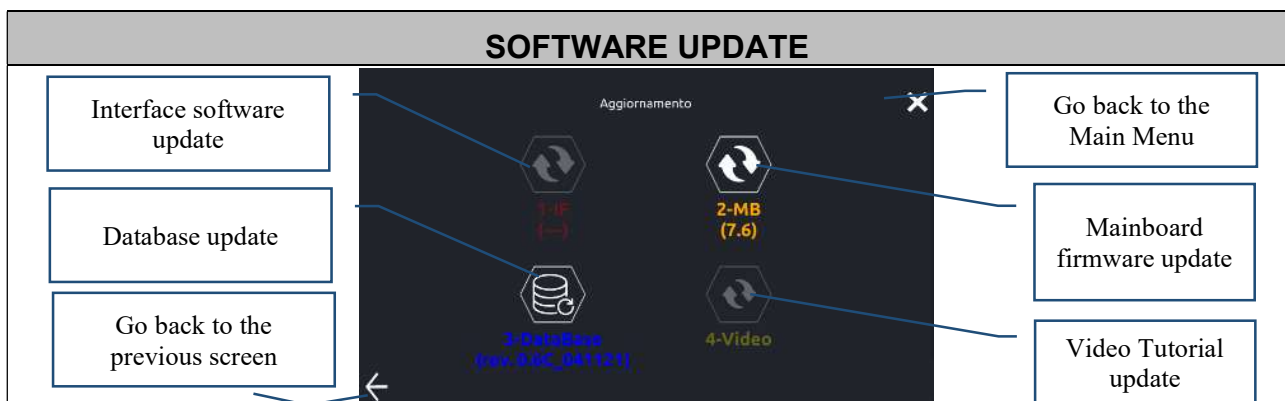
12.3 Adjust tutorial video playback volume



12.4 Information



12.5 Software update



Note: when it is required a software update, previously agreed with Fisioline, it is necessary to:

1. Via the PC (WINDOWS XP or later), download the software update received on the USB pen drive supplied.
2. Insert the USB key in the corresponding connector on the rear device panel
3. Press one of the following buttons:
 - Update IF: user interface update
 - Update MB: device firmware update
 - Update Database: pre-set protocol update
4. Wait for device to re-start (this may take a few minutes)

13 Switching the device off



CAUTION: Do not switch off the appliance from the switch without following the procedure below

13.1 Via interface

Select the ADVANCED MENU icon and then the shut-down button in the list.



The device switches off the display and starts emitting an intermittent sound.
It is possible to proceed to completely turn the appliance off by means of the main switch.



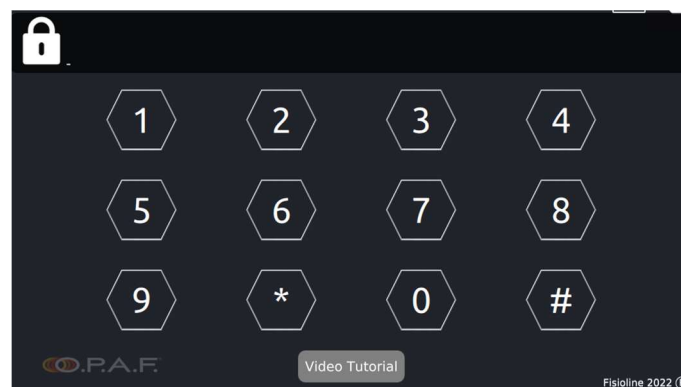
14 Security PIN code



WARNING: We suggest modifying the code and making it available EXCLUSIVELY to personnel authorised to use the device.

14.1 PIN code entry

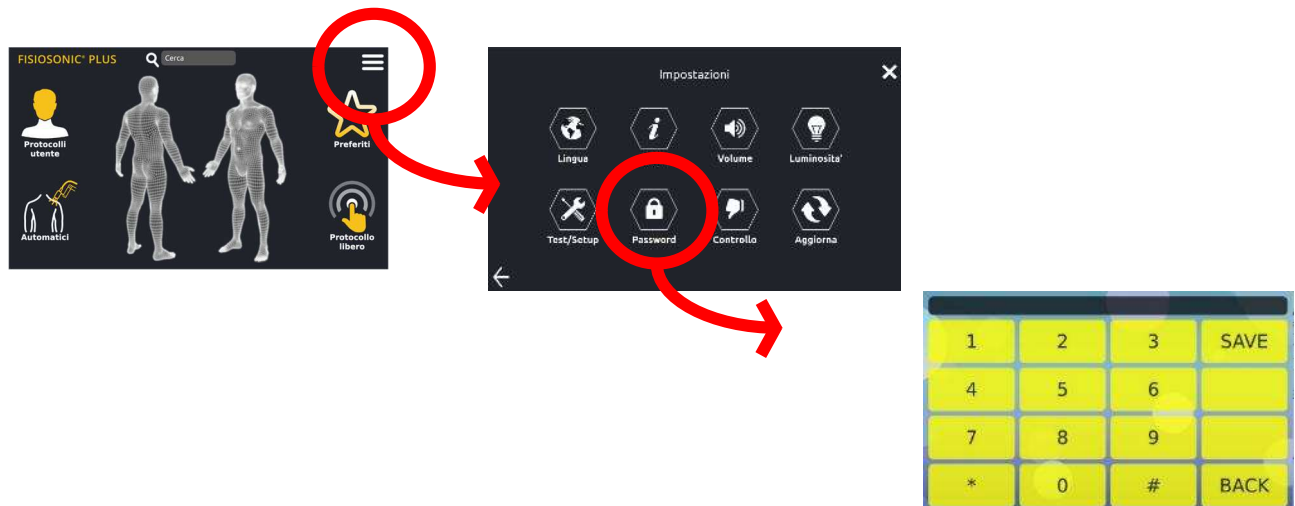
Every time the appliance is switched on a 4-digit PIN code is requested to prevent the device use from use by unauthorized personnel:



Manufacturing code 1,2,3,4.

14.2 Modify PIN code

To modify/reset the PIN code, use the following procedure:



Enter the new 4 number code and press the **SAVE** key to save.

The **BACK** key allows you to go back to the previous screen without changing the current code.

15 Optimal FISIOSONIC® PLUS use



CAUTION

Before using the appliance, the operator must read and understand this manual, particularly Chapter o "Contraindications".

WARNING

It is important to bring the operator's attention to the need to verify whether the electrical installation of the device has been set up correctly before turning on the electrical switch.

WARNING

In addition to possible compatibility problems with the connectors, the device does not work properly with applicators that are not specifically manufactured to be used with FISIOSONIC® PLUS.
Attempting to use different types of applicators, in addition to causing possible damage to the machine, automatically voids your right to a warranty.



CAUTION

In order to allow the transmission of the ultrasonic wave from the applicator to the skin, a layer of ultrasound gel must be placed between the two.
Do not use oils, talcum powder or creams as they prevent the correct transmission of the ultrasonic wave and can permanently damage the applicator, making it necessary to replace it.

Operations required for rapid use of FISIOSONIC® PLUS are indicated with the following phases:

1. **Preliminary:** include the insertion of the power plug into the mains outlet and moving the main switch to position 1 (appliance on).
2. **Preparing the patient for treatment:** It is necessary to apply a thin layer of the special gel for ultrasounds between the clean skin and the radiating surface of the applicator.
3. **Selecting the working mode/program:**
 - PRE-SET PROTOCOLS: divided into REHABILITATIVE MEDICINE groups
 - USER PROTOCOL: customized programs created, named and stored by the user.
 - FREE PROTOCOL enables the user to set parameters that characterize ultrasonic treatment:
4. **Starting treatment:** see *Errore. L'origine riferimento non è stata trovata. Errore. L'origine riferimento non è stata trovata.*



16 The “right contact” sensor

The FISIOSONIC® PLUS appliance has a system that makes it possible to check whether the applicator is in contact with the skin or not. This appliance is useful for preventing the treatment head from overheating if left out of contact for a certain period. This device is not enabled on heads where this problem does not occur.

The applicators for which the right contact sensor is enabled are

- 35mm diameter applicator
- 55mm diameter applicator

When the applicator is held in the air, the device regulates the duty cycle and the power to 10%, regardless of the values set by the user. This condition is shown on the display:

<i>Applicator “in the air” (not in contact with skin)</i>	<i>Applicator in contact with skin</i>
	
No contact	Contact present

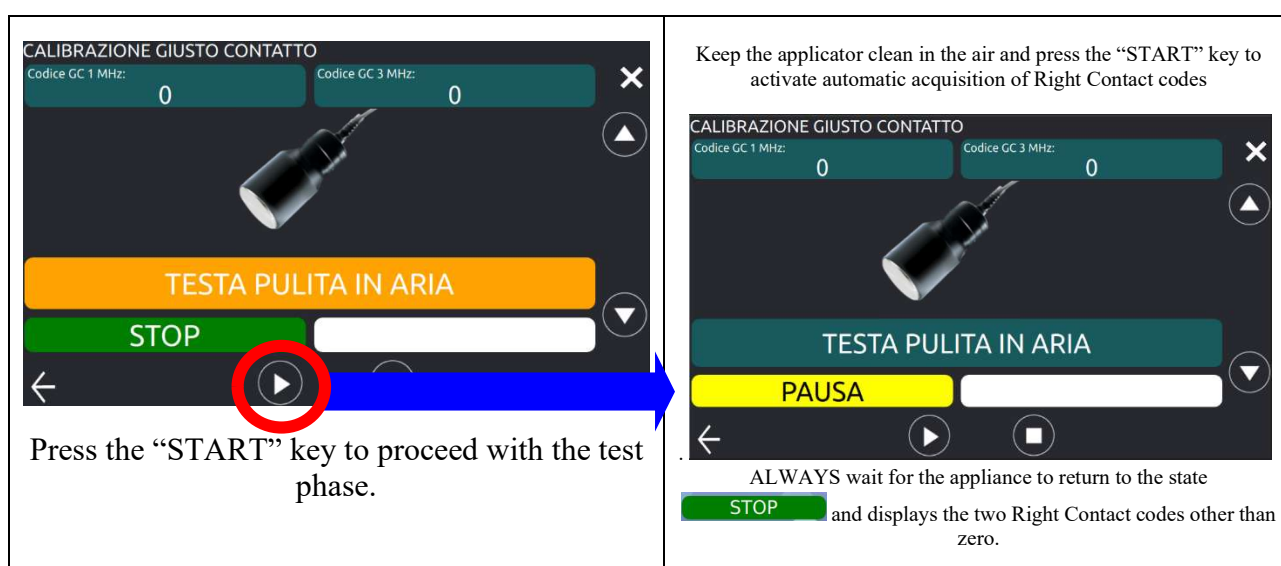
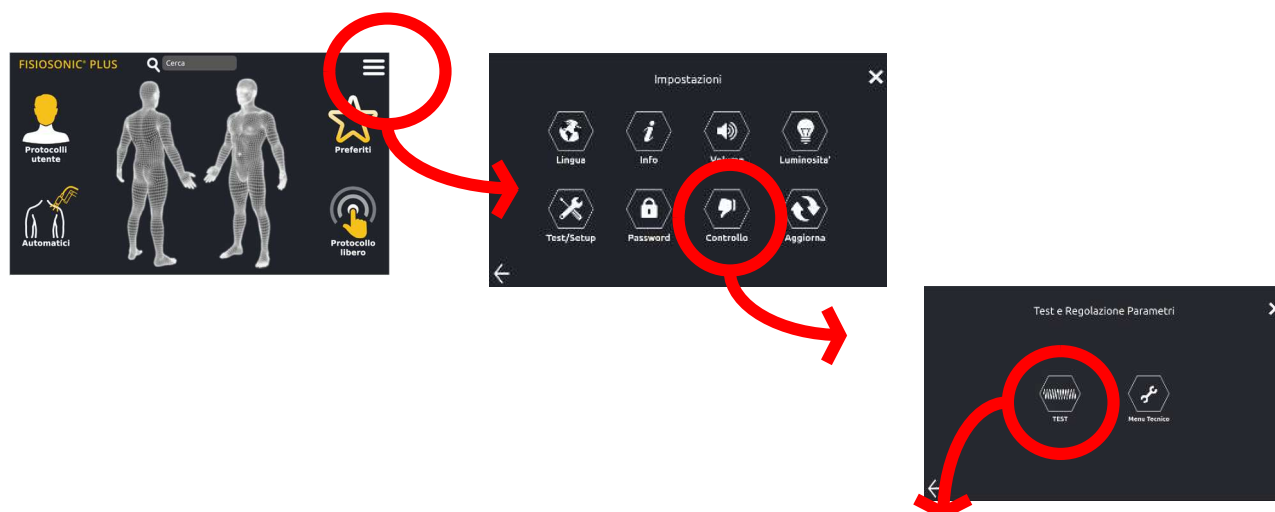
CAUTION:
the duty cycle and power shown are still the values set by the operator.

As soon as the head is immersed or placed in contact with the skin (provided there is a suitable layer of water or gel for ultrasounds) the appliance emits a short beep and sets the duty cycle power as shown on the display.

16.1 Calibration of the right contact

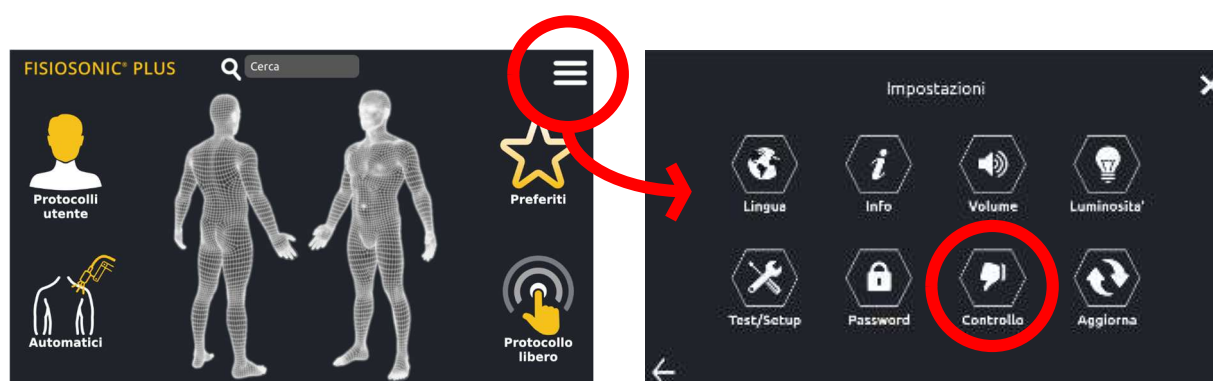
CAUTION:
Only perform this operation if strictly necessary and only perform it with the applicator clean, in air and cooled down (if necessary wait at least 5 minutes). Do not repeat the calibration operation in succession; if it is necessary to repeat it, wait at least 5 minutes.

It is possible to perform self-calibration on the applicator, which means that correct sensor operation can be resumed if any malfunctioning occurs caused by aging or modifications to the characteristics of the applicator itself.



Note: DO NOT disconnect the applicator from the appliance during this procedure as this would cause irreversible damage to the internal memory of the applicator.

16.2 Excluding/Enabling the right contact



Right Contact ACTIVATED



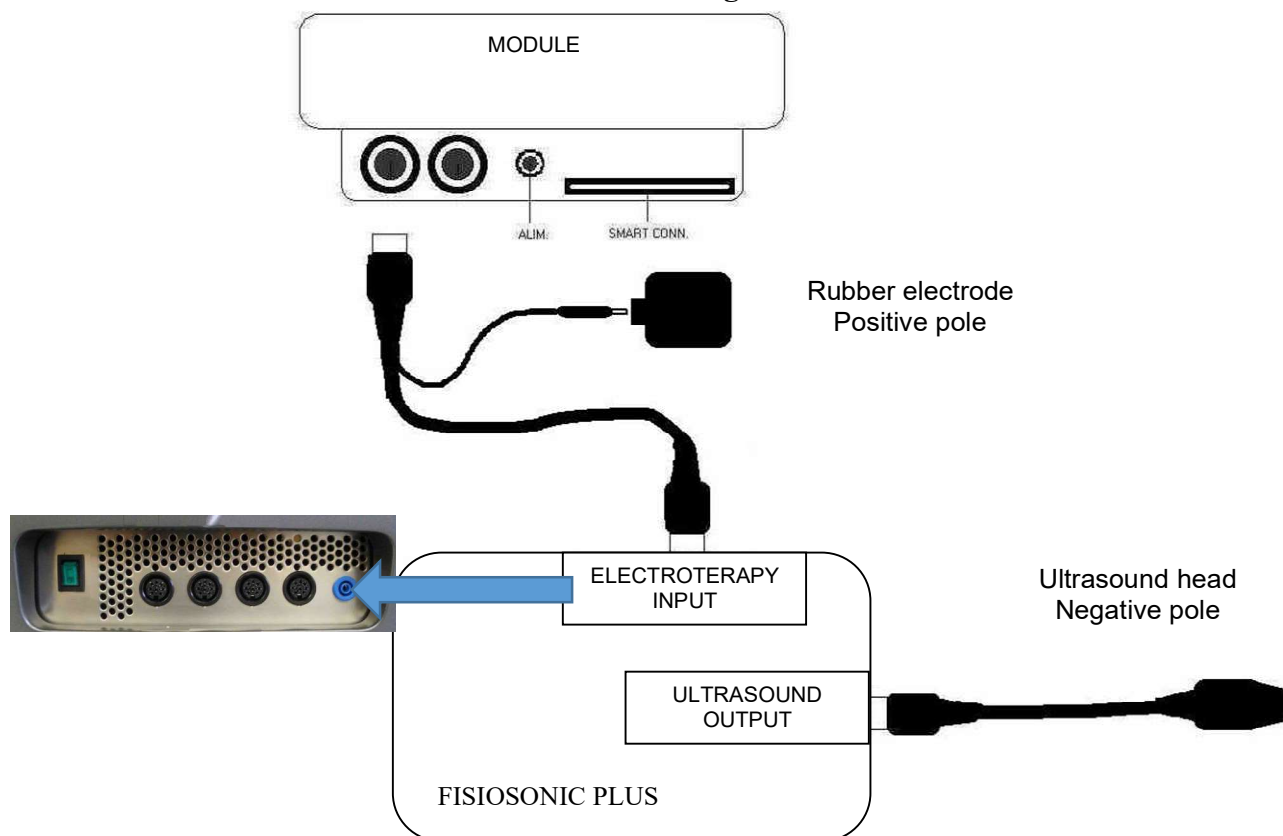
Right Contact DEACTIVATED



17 Connection with electrotherapy

FISIOSONIC PLUS can be operated in combination with an electrotherapy equipment model MODULO/ MODULO PLUS by means of the corresponding KIT CABLES.

Connecting the devices



Combination therapy uses only one channel as FISIOSONIC® PLUS model ultrasound therapy devices allow working with one head at a time. The reference channel of the stimulator is 1 CH1. The waveforms used in combination with the ultrasound are typically VOLTAGE-CONTROLLED CV to enable manual treatments that usually involve moving the ultrasound head with possible temporary detachment of the head from the skin.

Should you wish to work with the ultrasound head in manual mode and combine the therapy with a personalized electrotherapy program, the control should be set in CV voltage, rather than CC current. If this setting is not respected, the first time the head is detached from the skin, current delivery is interrupted and the ERR1 error is shown on the display, corresponding to a fault with the electrode. Should voltage controlled wave shapes be used, ERR1 on display would correspond to an overload to be attributed to a contact (short circuit) between the ultrasound head and the return electrode of the stimulator.

Do not use the FISIOSONIC® PLUS appliance to make combined therapy when the ultrasound is used through dipping methodology

18

Applicator operation check

18.1 Checking diameter 21, 35 and 55mm applicators

1. Insert the applicator on the corresponding output.
2. Select the free program item in the main menu.
3. Set the following parameters:
 - **Treatment time:** 20 minutes
 - **Emission frequency:** “1 MHz”
 - **Duty Cycle:** 30%
4. Holding the applicator in your hand positioned vertically with the radiant surface (metal part) upwards, place a few drops of tap water in the centre of the radiant surface.
5. Press the START key and just the power density up to 1.0W/cm².
6. You should observe the mechanical action of the ultrasound. The right contact sensor may intervene.



CAUTION

If the water is not affected, the applicator is probably not working. Do not use the applicator and contact FISIOLINE technical assistance.

18.2 Scanning applicator check

1. Insert the scanning applicators in the corresponding outputs.
2. Select the free program item in the main menu.
3. Set the following parameters:
 - **Treatment time:** 20 minutes
 - **Emission frequency:** “1 MHz ”
 - **Modulating duty cycle:** 30%
4. Resting the applicators on a flat surface with the radiant surface (metal part) upwards, place a few drops of tap water in the centre of the radiant surface of each scanner.
5. Press the START key and just the power density up to 1.0W/cm².
6. You should observe the mechanical action of the ultrasound in sequence (one at a time) on all scanners.



CAUTION

If the water is not affected on one or more scanners, the applicator is probably not working. Do not use the applicator and contact FISIOLINE technical assistance.

WARNING


The applicators must NOT be removed. This tampering, apart from damaging the features and reliability of the accessory, immediately voids the warranty.

Any calibration, tare, repair and/or replacement of damaged parts MUST be carried out by FISIOLINE TRAINED AND AUTHORISED PERSONNEL using ORIGINAL PARTS only.

19 Maintenance

In order to minimize the potential for device malfunction and exposing users and operators to electrical hazards arising from use of faulty equipment, certain routine maintenance procedures must be carried out.

Some of these operations can be carried out by operators themselves, while others must be performed by technical personnel. Lastly, there are some procedures that must be performed by technicians that are specifically authorized and approved by FISIOLINE.

	<p>CAUTION</p> <p>For safety reasons, before carrying out any maintenance or cleaning procedure on the device, IT IS NECESSARY to turn it off using the switch on the rear panel and unplug the power cord from the outlet.</p>
-----------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Below is a list of the main periodic operations to be carried out on the device, together with an indication of time intervals:

OPERATOR	FREQUENCY	MAINTENANCE PROCEDURES
HEALTH PERSONNEL	EVERY TIME IT IS USED	Check that the connectors on the applicators connecting the EQUIPMENT are secure. DO NOT use the applicator if the connector is broken.
HEALTH PERSONNEL	EVERY TIME IT IS USED	After use, thoroughly clean the emitting surface of the applicators with a clean, soft cloth dampened with warm water. If necessary, add a few drops of a neutral liquid soap directly on the cloth. Do not use any solvents (acetones, trichloroethylene, jet gasoline, ether, alcohol, etc.) as they may corrode the applicator surface and the device container. Always replace the handpieces in their holders after each treatment. <u>Ensure any flammable substances used for cleaning and/or disinfecting evaporate before using the device.</u>
HEALTH PERSONNEL	EVERY TIME IT IS USED	Make sure the air intake of the rear device panel is free and not blocked by any foreign bodies. Remove any foreign bodies.
HEALTH PERSONNEL	EVERY THREE MONTHS	Carry out a visual inspection of plug and power cable. In the event that the plug or lead is damaged (cuts, cracks, abrasions etc.), replace the power cord. N.B.: replacing the power supply conductor wire with a longer one or one with a smaller section may compromise earth connection effectiveness. Replace any damaged plug and/or power lead with original components supplied by the manufacturer.
HEALTH PERSONNEL	EVERY THREE MONTHS	Check the surface of the applicators to detect any cracks.
HEALTH PERSONNEL	EVERY THREE MONTHS	Visually check the conditions of the touch-screen display and connectors.
TECHNICAL STAFF	EVERY TWELVE MONTHS	Check the leakage currents from the casing and in the patient and ensure that the values fall within those specified by law. Request immediate technical assistance if the readings exceed the limit.

Any calibration, tare, repair and/or replacement of damaged parts MUST be carried out by FISIOLINE TRAINED AND AUTHORISED PERSONNEL using ORIGINAL PARTS only.

WARNING

The applicators must NOT be disassembled. This tampering, apart from damaging the features and reliability of the accessory, immediately voids the warranty.

19.1 Cleaning the device and the applicators/accessories

Cleaning the device: the exterior of the device, when necessary, must be cleaned exclusively with a soft cloth dampened with warm water. If necessary, add a few drops of a neutral liquid soap directly on the cloth. Never use solvents (acetone, triline, avgas, ether, alcohol, etc.) as some of them may damage the container of the device, made of plastic. During cleaning, always unplug the power cord from the wall.

Caution: use caution when cleaning the front panel to avoid scratching the transparent liquid crystal display window.

Do not spray nor pour liquid on the outer casing of the FISIOSONIC® PLUS appliances.

Do not immerse the device in water.

After any external cleaning of the container, dry all parts thoroughly before turning the device back on.

WARNING

For routine cleaning, there is NO NEED to dismantle the device, and in any case any procedures requiring it to be opened must be performed exclusively by qualified technical personnel authorized by FISIOLINE.

Cleaning the applicators: the applicators must be cleaned regularly with water and non-corrosive detergents only, making sure all parts are thoroughly dry before use.

In order to avoid the transmission of skin infections, it is necessary to disinfect the applicators using a cloth soaked in a neutral disinfectant.

Cleaning the elastic straps: DO NOT wash the elastic straps with hot water. Use cold or warm water instead. If using detergents, rinse thoroughly.

20 Operational problems and solutions

The FISIOSONIC® PLUS device has been designed and manufactured adopting advanced technological solutions and quality components.

Should any operational problems arise, please consult the following guide before calling FISIOLINE technical assistance.

WARNING

Internal device components
may only be accessed by technical personnel
authorized by the manufacturer.

For repairs and more information,
contact
FISIOLINE s.r.l.



CAUTION

DO NOT OPEN the device:
inside, there are
HIGH VOLTAGES
which may be DANGEROUS.

When the following conditions occur, unplug the device from the power supply and contact FISIOLINE s.r.l. technical support.

- The power cord is frayed or damaged.
- There is liquid in the device.
- The unit has been exposed to rain.
- The device has suffered a serious fall.

20.1 Replacing the applicators



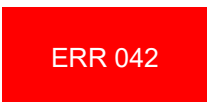
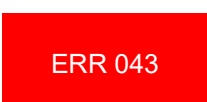
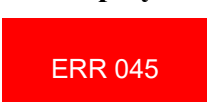
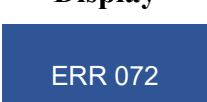

The FISIOSONIC® PLUS ultrasound device is manufactured with particular care in order to make it quick and simple to replace the supplied applicators which have been damaged during normal use.

The applicator sent in replacement is tested by the manufacturer on a sample FISIOSONIC® PLUS appliance, a standard against which all appliances on the market may not differ in performance, if not within the range of tolerance declared by the manufacturer.

During this stage, a specialized technician will “fine tune” the working frequency and the input voltage of the “fixed unit - applicator” system, so that the overall system performance (power output and RIGHT CONTACT) fall within the stated range of tolerance.

20.2 Troubleshooting chart

PROBLEM	POSSIBLE CAUSE	SOLUTION
The device does not deliver (verified by placing drops of water on the head).	Faulty connection of the applicators. Applicator cable disconnected or incorrectly connected. Output cable frayed and/or contacts uncertain. Defect in the electronic circuit of the device.	Carefully check that the output connection is correct and intact. Replace faulty applicators presenting obvious signs of wear on the external surface coating and cable. Contact FISIOLINE s.r.l. technical assistance.
The device is running as usual, but you notice a considerable drop in the level of effectiveness of the treatment (verified by placing drops of water on the head)	The connection of the output circuit of the applicators is not perfectly efficient. Damaged applicator Mechanical damage (due either to falling or violent impact) to the applicators, particularly at the connection point of the power cord. Interruption of the internal conductors of the applicators. Possible failure of the device's circuit.	Perform the maintenance procedures described in chapter 14. Install and position the device as described in chapter 10. Check that the device cable and connector are intact. Contact FISIOLINE s.r.l. technical assistance.

POSSIBLE ERRORS INDICATED ON THE DISPLAY		
PROBLEM	PROBABLE CAUSE	REMEDY
Display 	Communication error between interface system and source control system.	<ol style="list-style-type: none"> 1. Switch the device on and off again. 2. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis
Display 	Output power lower than that expected.	<ol style="list-style-type: none"> 1. Switch the device on and off again. 2. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis
Display 	Overheating	<ol style="list-style-type: none"> 1. Make sure the ventilation slots are free. 2. If working with high power, wait a few minutes with the appliance on and in STAND-BY and then re-start device use. 3. Contact FISIOLINE assistance
Display 	Control error	<ol style="list-style-type: none"> 1. Switch the device on and off again. 2. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis
Display 	Overload	<ol style="list-style-type: none"> 1. Switch the device on and off again. 2. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis
Display 	Error applicator not recognised	<ol style="list-style-type: none"> 1. Disconnect and re-connect the applicator 2. Switch the device on and off again. 3. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis
Display 	Error applicator not connected	<ol style="list-style-type: none"> 1. Disconnect and re-connect the applicator 2. Switch the device on and off again. 3. Contact the Fisioline technical support centre if the problem recurs on a continuous or frequent basis

WARNING

In the event that described interventions do not resolve problems, contact FISIOLINE technical assistance to request intervention.

Any calibration, tare, repair and/or replacement of damaged parts MUST be carried out by FISIOLINE TRAINED AND AUTHORISED PERSONNEL using ORIGINAL PARTS only.

20.3 Electromagnetic interferences

The CE marking also covers compliance with Directive 2014/30/CE concerning electromagnetic compatibility.

According to their operating principle the FISIOSONIC® PLUS model ultrasound devices generate an acceptable amount of radiofrequency energy and have an adequate level of immunity to radiating electromagnetic fields: in such conditions interferences cannot arise which would be harmful to radio-electric communications, to the functioning of other machines such as electronic office devices like computers, printers, photocopiers, fax machines, etc., and to any electric or electronic devices used in such environments which conform to the electromagnetic compatibility directive.

In any case, to avoid any interference problems, we recommend running ultrasound devices at a sufficient distance from any critical equipment.

21 Safety Guarantee

FISIOLINE equipment is insured for product liability with UNIPOL-SAI.

22 Manufacturer responsibility



The manufacturer shall be held responsible for the performance, reliability and safety of the device if and only if:

- a) Any additions, recalibration requiring the device to be opened, modifications and/or repairs are carried out by explicitly authorized personnel;
- b) The electrical system of the room where the appliance is located is in compliance with IEC requirements;
- c) The device is used in strict accordance with the operating instructions contained in this manual.

23 Package and transportation

The FISIOSONIC® PLUS device is delivered to the purchaser with suitable packaging in order to prevent damage to the device during transport. If you wish to transport the instrument a long way or entrust it to a carrier, we recommend to pack the instrument by re-using the same package and packing material supplied by the manufacturer for its delivery. **We therefore recommend conserving the original device packaging with care.**

24 Disposal

	CAUTION! Appliances subject to separate collection.
	

In reference to Directives 2011/65/EU and 2012/19/EU concerning the reduction of the use of hazardous substances in the electrical and electronic equipment as well as the disposal of wastes (WEEE)", **the disposal of WEEE (Waste Electrical and Electronic Equipment) as urban waste is prohibited and therefore said waste requires separate collection.**

This appliance contains substances which, if released into the environment due to improper use or incorrect disposal, could be hazardous and/or dangerous to the environment itself and to human health.

The disposal of this appliance and its accessories can be carried out by a collection centre authorised for WEEE waste or delivered to the Seller/Distributor upon purchase of another equivalent product.

Illicit disposal is sanctioned according to local legal provisions.

25

Pre-set programs

WARNING!
DO NOT TREAT BROKEN SKIN.

Note: the following protocols should be considered as guidelines only and **MUST ALWAYS** be personalised based on the anatomical variations, the disorder phase, the feed-back of the patient and the application technique.

25.1.1 Programs for 55mm and 35mm applicators

GENERAL

N 55	No. 35	Name	Frequency MHz	Duty cycle %	Recommended peak power density W/cm ²	Recommended average power density W/cm ²	Time in minutes
1	101	Calcifications	5sec 1M -5 s 3M	20	1,8	0,4	15
6	106	Fibro-adherences/Decontracting	1	10	3,0	0,3	15
7	107	Tendinitis	1	60	1,2	0,7	12
8	108	Bursitis	1	70	0,6	0,4	12

HEAD

9	109	Temporomandibular joint pain	3	40	0.6	0.2	10
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BACK-SHOULDER

10	110	Scapulohumeral periarthrititis	1	40	1,2	0,5	10
11	111	Trapezius myalgia	1	60	0,6	0,4	12
12	112	Pain in the parascapular region	1	60	1,2	0,7	12
13	113	Biceps and rotator cuff tendinopathy	1	70	0,6	0,4	12
14	113	Adhesive capsulitis of the shoulder joint	1	60	0,6	0,4	15
15	115	Subdeltoid bursitis	1	80	0,9	0,7	15

ARM-ELBOW

N 55	No. 35	Name	Frequency MHz	Duty cycle %	Recommended peak power density W/cm2	Recommended average power density W/cm2	Time in minutes
16	116	Triceps brachii muscle disorders	1	100	0,9	0,9	12
17	117	Epicondylitis and medial epicondylitis	2" 1MHz- 4" 3MHz	20	3,0	0,8	15
18	118	Distal tendinopathy	1	80	0,9	0,7	12
19	119	Olecranon bursitis	1	40	0,6	0,2	11
20	120	Distal triceps brachii tendonitis	1	40	0,6	0,2	11
27	127	Myotendinous disorders of the forearm	1	60	0,6	0,4	12

HANDS

21	121	Hand flexor extensor tendinitis	1	80	0,6	0,5	12
22	122	De Quervain's Tendinitis	1	70	0,6	0,4	12
23	123	Radial and ulnar styloiditis	1	70	0,6	0,4	12
24	124	Rheumatoid arthritis	1	80	1,8	1,4	12
25	125	Trapeziometacarpal osteoarthritis	1	80	0,6	0,5	12
26	126	Dupuytren's disease	1	70	0,9	0,6	12

LOWER BACK

28	128	Lower back pain	1	60	0,6	0,4	15
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GROIN-HIPS

29	129	31 Pain in the sacroiliac region	1	100	0,9	0,9	15
30	130	32 Bursitis enthesitis of the greater trochanter	1	80	1,8	1,4	11
31	131	33 Pain from coxartrosis	1	100	1,2	1,2	15

LEGS

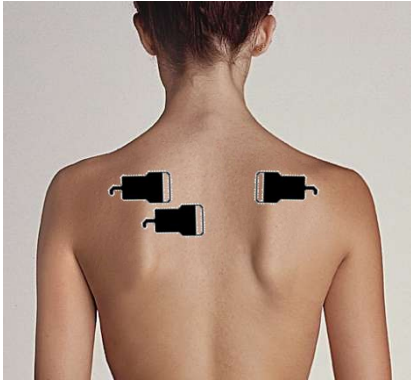
32	132	Insertional tendinitis of the rectus femoris	3	40	1,2	0,5	10
33	133	Proximal tibial tendinitis	1	40	1,2	0,5	11
34	134	Disorders of the flexor muscles treatment aimed at relieving/healing pain and/or inflammation	1	60	0,9	0,5	11
38	138	Tendinitis of the patellar and femoral quadriceps	3	60	1,2	0,7	10
41	141	Tendinopathy of the popliteal ligaments	1	70	1,2	0,8	12
42	142	Triceps surae muscle disorder treatment aimed at relieving/healing pain and/or inflammation	1	80	1,2	1,0	15

25.1.2 Programs for the scanning applicators

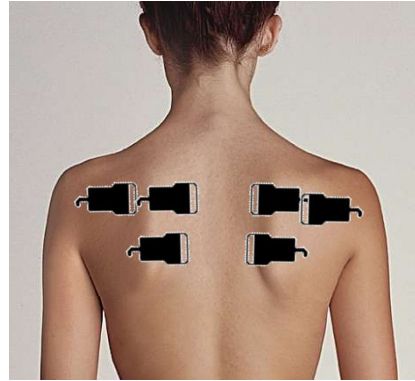
N	Disorder	Frequency MHz	Frequency & Modulating Duty cycle	Power density W/cm ²	Time in minutes
201	Calcifications	1MHz scan 5sec	100Hz 20%	1,8	15
202	Fibrous adhesions	1MHz scan 5sec	100Hz 10%	1,8	15
203	Tendinitis	1MHz scan 5sec	100Hz 40%	0,9	12
204	Bursitis	1MHz scan 5sec	100Hz 20%	1,5	12
205	Scapulohumeral periarthritis	1MHz scan 5sec	100Hz 40%	1,2	10
206	Trapezius myalgia	1MHz scan 5sec	100Hz 50%	0,6	15
207	Adhesive capsulitis of the shoulder joint	1MHz scan 5sec	100Hz 60%	0,6	15
208	Subdeltoid bursitis	1MHz scan 5sec	100Hz 60%	0,6	12
209	Triceps brachii muscle disorders	1MHz scan 5sec	100Hz 60%	0,6	15
210	Epicondylitis and medial epicondylitis	1MHz scan 5sec	100Hz 40%	0,6	15
211	Distal tendinopathy	1MHz scan 5sec	100Hz 60%	0,9	15
212	Olecranon bursitis	1MHz scan 5sec	100Hz 40%	0,6	11
213	Distal triceps brachii tendonitis	1MHz scan 5sec	100Hz 40%	0,6	12
214	Hand flexor extensor tendinitis	1MHz scan 5sec	100Hz 40%	0,6	10
215	De Quervain's Tendinitis	1MHz scan 5sec	100Hz 40%	0,6	14
216	Radial and ulnar styloiditis	1MHz scan 5sec	100Hz 40%	0,6	12
217	Rheumatoid arthritis	1MHz scan 5sec	100Hz 50%	0,9	15
218	Trapeziometacarpal osteoarthritis	1MHz scan 5sec	100Hz 50%	0,6	12
219	Dupuytren's contracture	1MHz scan 5sec	100Hz 50%	0,6	11
220	Lower back pain	1MHz scan 5sec	100Hz 20%	1,5	12
221	Pain in the sacroiliac region	1MHz scan 5sec	100Hz 30%	0,9	13
222	Ligament disorders	1MHz scan 5sec	100Hz 20%	1,2	12
223	Femoral-tibial arthrosis	1MHz scan 5sec	100Hz 60%	0,6	13
224	Distal tendinopathy	1MHz scan 5sec	100Hz 50%	0,6	11
225	Tendinopathy of the popliteal ligaments	1MHz scan 5sec	100Hz 30%	1,2	12
226	Triceps surae muscle disorder	1MHz scan 5sec	100Hz 60%	0,6	15
227	Sprains	1MHz scan 5sec	100Hz 40%	1,0	11
228	Plantar Fasciitis metatarsalgia	1MHz scan 5sec	100Hz 20%	1,5	12
229	Hallux valgus	1MHz scan 5sec	100Hz 60%	0,6	12

26 Application examples

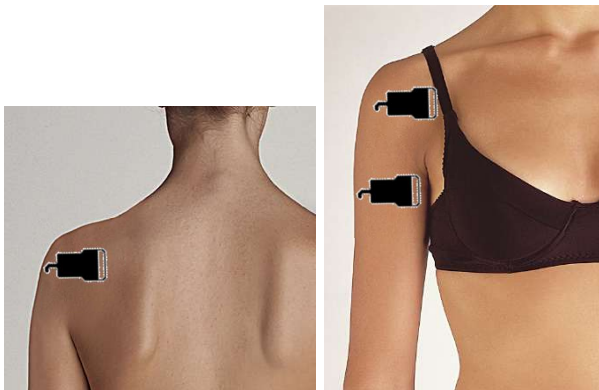
Trapezius myalgia



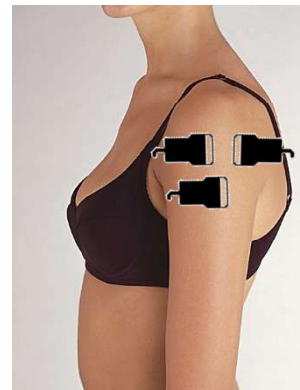
Pain in the parascapular region



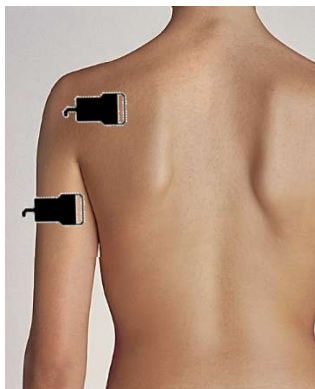
Biceps and rotator cuff tendinopathy



Subdeltoid bursitis



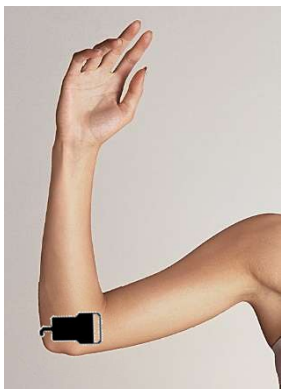
Triceps brachii muscle disorders



Epicondylitis



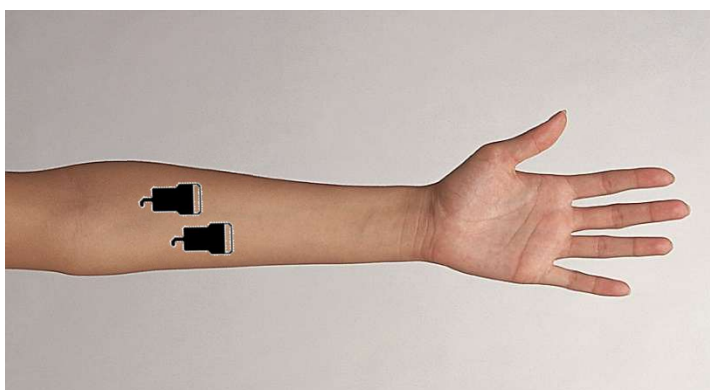
Medial epicondylitis



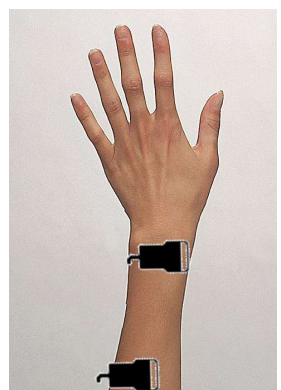
Distal tendinopathy of the brachial biceps

Retro-olecranal bursitis distal
tendonitis of the brachial triceps

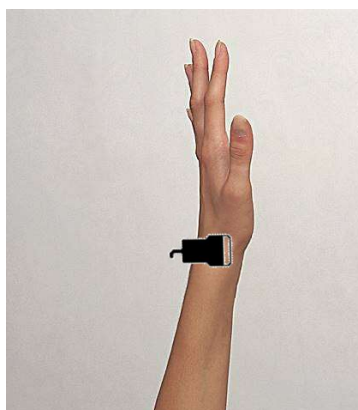
Myotendinous disorders of the forearm



Hand extensor tendinitis



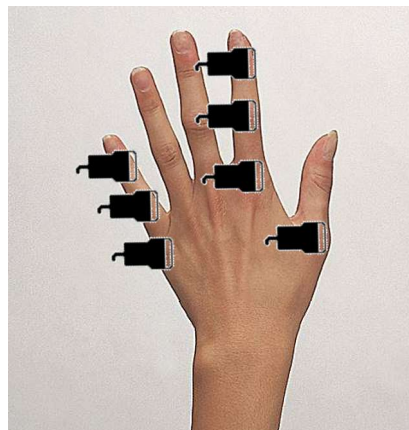
De Quervain's radial Tendinitis



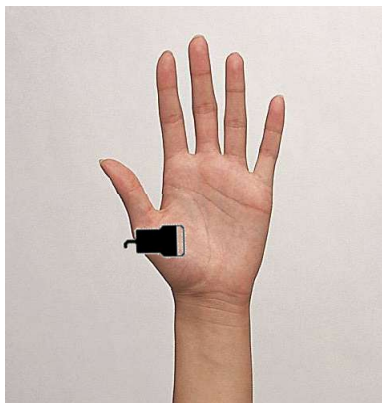
Hand flexor tendinitis



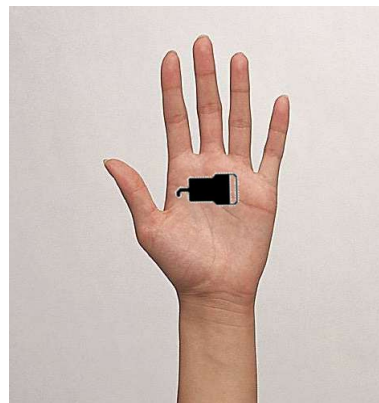
Rheumatoid arthritis



Trapeziometacarpal osteoarthritis



Dupuytren's disease



Lower back pain



Pain in the sacroiliac region



Insertional tendinitis of the rectus femoris



Bursitis-enthesis of the greater trochanter

Pain from coxarthrosis



Disorders of the quadriceps muscle



Disorders of the flexor muscles



Patellar tendonitis Prepatellar and under patellar bursitis



Tendinitis of the femoral quadriceps



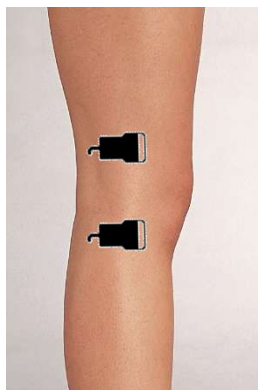
Patellofemoral chondropathy
Femoral-patellar arthrosis



Tendonitis-bursitis of the pes anserinus tendons



Collateral ligament and iliotibial band disorders - Femoral-tibial arthrosis



Medial collateral ligament disorder
Femoral-tibial arthrosis

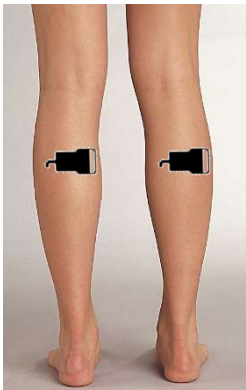



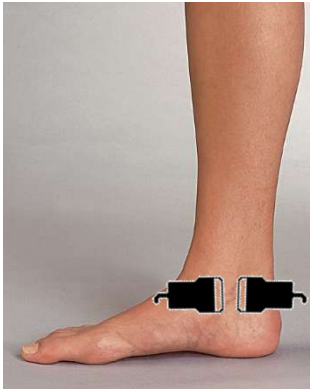
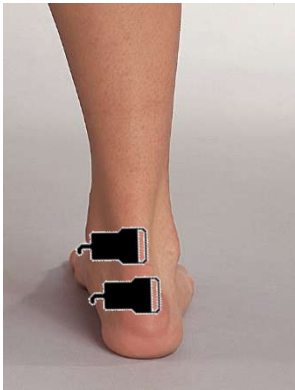


Distal tendinopathy of the femoral biceps



Tendinopathy of the popliteal ligaments



<p>Tendinopathy of the surae triceps muscle</p> 	<p>Proximal tendinitis of the anterior tibial</p> 
<p>Peroneal tendonitis</p> 	<p>Ankle side compartment disorder</p> 
<p>Ankle medial compartment disorder</p> 	<p>Retro achilles bursitis Achilles tendonitis</p> 

Distal tendinitis of the anterior tibial



Extensor tendinitis

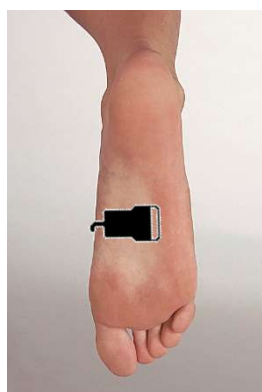
Hallux valgus



Plantar Fasciitis



Metatarsalgia



Temporomandibular joint pain

