TRIPLE THERAPY

USE AND MAINTENANCE MANUAL

CE 1370

DISCLAIMER

Level S.r.l. disclaims any responsibility for damage to persons or property due to improper use of this product and failure to observe the indications, warnings, instructions and precautions contained in this user manual.

This user manual is provided in paper format only and must always accompany the Triple Therapy device.

Triple Therapy is manufactured by:

Level S.r.l.
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P.IVA - 05130100877

SUMMARY

1 GENERAL INFORMATION

Triple Therapy is a medical device that allows to perform therapeutic treatments through the emission of a scanning laser beam (laser therapy), which can be generated by two different sources (GaAlAs diodes): one with a wavelength of 808 nm and power maximum of 10 W and one with a wavelength of 1064 nm and maximum power of 15 W. There is also a red aiming laser beam (635 nm), which allows you to view the area radiated by the two nonvisible laser sources.
Triple Therapy is equipped with a system with 3 motors (stand, tilting and rotary), which allow, through the simple and intuitive controls on the touchscreen, to adjust and position the head from which the laser beam is emitted, allowing to irradiate correctly and easily any part of the body you want.
Triple Therapy is also equipped with 2 modes: “Programs”, which allows you to choose from the 40 pre-stored automatic programs by user, or “Manual”, with the possibility of independently adjusting time, power and emission mode (continuous or pulsed) of the 2 laser sources.
Triple Therapy is placed on a base with 5 swiveling wheels, which allow it to be transported and moved easily, and it can be closed when not in use, reducing its overall dimensions.

1.1 INTENDED USE

The intended use of the device object of this FT is the therapeutic-analgesic treatment, through the emission of a laser beam (laser therapy), of pathologies and related inflammatory states affecting the musculoskeletal and dermatological system, in various areas doctors (dermatology, pain therapy, aesthetic medicine, physiatry and rheumatology). The device provides for the emission of two laser beams from 2 different sources: one with a wavelength of 808 nm and a maximum power of 10 W and one with a wavelength of 1064 nm and a maximum power of 15 W.

1.2 CLASSIFICATION

Classification according to Directive 93/42/CEE Annex IX rule 9 class IIb.

WARNING!

THE DEVICE IS INTENDED TO BE USED BY APPROPRIATELY TRAINED MEDICAL AND / OR NURSING STAFF, INSIDE HOSPITAL
STRUCTURES, MEDICAL CLINICS AND IN PRIVATE CENTERS FOR REHABILITATION AND PHYSIOTHERAPY.

1.3 SYMBOLOGY

To make reading the manual comfortable and clear, the symbols used to manage the important warnings for a correct and safe use
of the device are shown below.

Requirement for proper use
This symbol identifies the presence of information for correct use of the device.

	
	**Information requirement** This symbol identifies the presence of useful and general information whose reading guides the user to a conscious use of the device and / or to the execution of actions.
CE 1370	Identifies that the product is manufactured, designed and manufactured in compliance with the safety requirements (RES) of the Medical Device Directive 93/42 / EEC (Class IIb medical device, in compliance with classification rule 9 as indicated by annex IX).

1.4 PRELIMINARY WARNINGS

Failure to observe the warnings below as well as the rules and precautions described in this user manual will result in the immediate forfeiture of any warranty on the Triple Therapy device. Level S.r.l. is not responsible for any damage to persons or property as a result of failure to comply with the rules or precautions listed below and reported in general in this user manual.

FAILURES OR NEGLIGENCIES IN FULFILLMENT OF THE FOLLOWING INSTRUCTIONS MAY CAUSE DEVICE MALFUNCTION, DAMAGE AND INJURY TO THE USER

WITH THE PURPOSE OF PREVENTING THE DANGERS OF ELECTRIC SHOCK, CONNECT THE DEVICE ONLY TO SOCKETS WITH PROTECTIVE EARTH AND TO ELECTRICAL SYSTEMS IN COMPLIANCE WITH STANDARD CEI 64-8 / 7

DO NOT USE THE DEVICE UNTIL IT HAS BEEN READ AND UNDERSTAND THIS USER MANUAL IN EVERY PART

NO MODIFICATION OF THE DEVICE IS ALLOWED AND / OR ITS PARTIES

USE OF THE DEVICE FOR PURPOSES DIFFERENT FROM THOSE INDICATED IN THIS USER MANUAL COULD EXPOSE THE PATIENT AND THE OPERATOR TO DANGERS

IN CASE OF SERIOUS ACCIDENTS WITH THE DEVICE, IMMEDIATELY CONTACT THE MANUFACTURER AND THE COMPETENT AUTHORITY

DO NOT USE THE DEVICE IN AN ENVIRONMENT WITH FLAMMABLE ANESTHETIC MIXTURES WITH AIR OR OXYGEN OR NITROUS OXIDE. USING LASER EMISSION IN THE PRESENCE OF FLAMMABLE MATERIALS, SOLUTIONS, OR GASES OR IN AN ENVIRONMENT RICH IN OXYGEN CAN CREATE A RISK OF FIRE AND / OR EXPLOSION

DO NOT USE IN THE PRESENCE OF LIFE SUPPORT EQUIPMENT OR RADIOFREQUENCY EQUIPMENT

DO NOT USE THE DEVICE ON INCLINED SURFACES, AS THE WHEELS UNDER THE BASE ARE NOT BLOCKING AND THE RISK OF OVERTURNING OR UNEXPECTED HANDLING MAY OCCUR

IT IS COMPULSORY FOR THE OPERATOR AND THE PATIENT TO WEAR THE PROTECTIVE GLASSES SUPPLIED BEFORE STARTING THE EMISSION OF THE LASER BEAM OR AIMING BEAM

	DO NOT POINT THE LASER BEAM TOWARDS THE EYES OR THYROID DO NOT USE THE DEVICE IN THE CASE OF PREGNANCY, EPILEPSY OR NEOPLASIA
	DO NOT USE THE DEVICE ON BODY PARTS WHERE AN ACTIVE IMPLANTABLE MEDICAL DEVICE (FOR EXAMPLE, A PACEMAKER) IS IMPLANTED
	IT IS COMPULSORY THAT THE PATIENT REMAINS VIGOR AND SENTIENT DURING THE WHOLE DURATION OF THE THERAPEUTIC TREATMENT, SO AS TO BE ABLE TO IMMEDIATELY STOP THE EMISSION OF THE LASER BEAM IN THE EVENT THAT THE PATIENT FEELS DISCOMFORT OR PAIN IN THE AREA
	THE USE OF THE DEVICE BY UNAUTHORIZED PERSONNEL IS FORBIDDEN: TO THIS PURPOSE IT IS RECOMMENDED TO REMOVE THE KEY FROM THE MAIN SWITCH WHEN THE DEVICE IS NOT USED AND TO STORE IT IN A SAFE PLACE
	IT IS COMPULSORY TO ALWAYS CONNECT THE PLUG OF THE INTERLOCK SAFETY DEVICE BEFORE TURNING ON THE DEVICE
	USE OF THE CONTROLS OR ADJUSTMENTS, OR PERFORMING PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS MANUAL MAY RESULT IN EXPOSURE TO HAZARDOUS RADIATION.

1.5 DEVICE COMPOSITION

Together with the Triple Therapy device (Code 10LS25), the packaging also includes:

- N. 1 Power cable (Code 10AX03);
- N. 2 Pairs of protective goggles (Code 10AL19);
- N. 2 spare fuses (Code 00FL08);
- N. 1 PVC cover bag (Code 00XL27);
- N. 1 key for the main switch;
- N. 1 Interlock socket
- N. 1 Table of plasticized application points

THE USE OF ELEMENTS NOT PART OF THE SYSTEM DESCRIBED ABOVE OR NOT SUPPLIED WITH THE DEVICE COULD HAVE AFFECT SAFETY AND EFFECTIVENESS.

WHEN OPENING THE PACKAGING, CHECK THE TOTAL INTEGRITY OF THE CONTENT.
IN THE EVENT OF EVIDENT SIGNS OF DAMAGE, CONTACT THE MANUFACTURER IMMEDIATELY.

If all the elements listed above have not been received, contact the manufacturer immediately

2 CONNECTION TO MAIN POWER AND SWITCH ON

BEFORE CONNECTING THE DEVICE TO THE ELECTRICITY NETWORK, CHECK THAT THE ELECTRICAL SYSTEM COMPLIES WITH THE REQUIREMENTS OF THE CEI 64-8 / 7 STANDARD

DO NOT POSITION THE DEVICE IN SUCH A WAY THAT IT IS DIFFICULT TO DISCONNECT THE PLUG FROM THE POWER SOCKET

PLEASE NOTE THAT PRODUCTS SUCH AS SMART-PHONES, MOBILE PHONES AND OTHER RF COMMUNICATION DEVICES COULD GENERATE DISTURBANCES TO THE MEDICAL DEVICE

DO NOT PLACE THE DEVICE EXCESSIVELY CLOSE TO OTHER ELECTROMEDICAL DEVICES

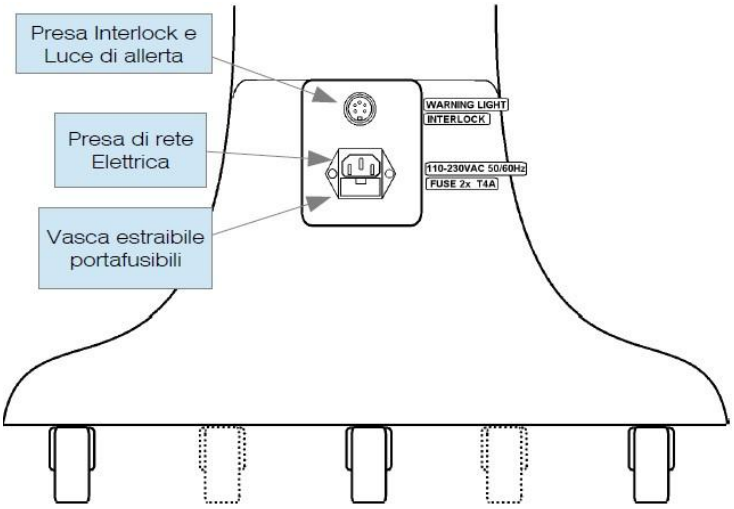
VERIFY THAT THE ENVIRONMENT OF USE IS COMPLIANT WITH WHAT INDICATED IN THE FOLLOWING CHAPTER "ELECTROMAGNETIC COMPATIBILITY"

VERIFY THAT THE AIR VENTS UNDER THE BASE OF THE DEVICE ARE FREE OF DUST OR ANY OBJECTS

WHEN HANDLING THE DEVICE PAY ATTENTION TO THE SWIVEL WHEELS TO AVOID THE RISK OF CRUSHING

To connect Triple Therapy to the mains and to switch on, follow the instructions below:

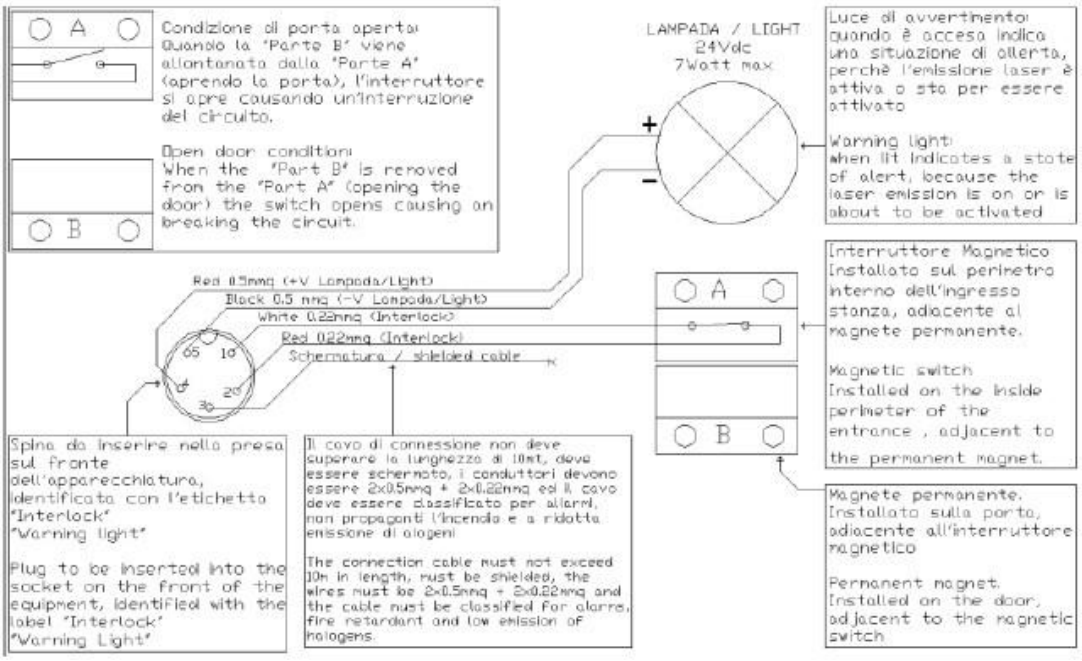
- Insert the supplied power cable into the appropriate socket.
- Connect the Interlock device as described in paragraph 2.1.
- Insert the key into the main switch and turn it clockwise: the device will emit a sound signal to communicate correct ignition.



2.1 CONNECTION OF INTERLOCK DEVICE SYSTEM

The Interlock device is a safety system that blocks the laser emission every time the access door to the premises where the treatment is carried out is opened. Please note that it is mandatory to properly connect the Interlock device.
The Interlock socket is also supplied with the laser equipment to be inserted into the appropriate socket of the laser equipment. The correct installation of the Interlock device involves inserting the plug of the Interlock device into the Interlock socket of the equipment, as shown in the figure below. The Interlock device consists of a plug connected through two electric cables (or a single cable with double conducting filament, with insulated filaments) to a normally closed switch that will be positioned on the entrance door. The plug of the Interlock device must be connected to the Interlock socket, the two electric cables must be normal electric cables and the normally closed switch must be a magnetoelectric, optical or mechanical switch with 12 Vdc and 10mA characteristics, while the signaling must be a 24 Vdc 7W maximum lamp, preferably yellow. At the customer's request, LEVEL S.r.l. can provide the complete device kit of Interlock and / or signaling light.
After the intervention of the "Interlock" device due to the unexpected opening of the door to the room, the equipment will lock and remain locked even if the door is then closed. It will therefore be necessary for the operator to restart the device, following the switch-on instructions in the following sections.

IT IS COMPULSORY TO ALWAYS CONNECT THE PLUG OF THE INTERLOCK SAFETY DEVICE BEFORE TURNING ON THE DEVICE



3 METHOD OF USE

CHECK THE INTEGRITY OF THE DEVICE BEFORE PROCEEDING WITH THE NEXT STEPS

3.1 SWITCHING ON THE DEVICE AND SELF-DIAGNOSIS

After inserting and turning the key in the main switch, the touchscreen turns on and the "LEVEL" logo is shown. At this point, the Laser Triple Therapy begins self-diagnosis, where the strategic parts of the device are tested and their correct functioning is verified. If a malfunction occurs in only one of these phases, the device will signal the problem and will not allow in any way to start a therapy. It will therefore not be possible to use an apparatus that is not able to guarantee absolute reliability and safety characteristics.

IF AN ALARM SIGNAL IS ACTIVATED DURING THE SELF-DIAGNOSIS PHASE, IT IS COMPULSORY TO IMMEDIATELY SWITCH OFF THE DEVICE AND CONTACT TECHNICAL ASSISTANCE

Since it is an electromedical device, particular attention has been paid to the safety of operation, and the possibility of identifying any malfunctions with extreme ease. For this purpose TRIPLE THERAPY at each ignition performs a self-diagnosis procedure in which all the main subsystems are tested in their correct operation. If a critical malfunction occurs, it will not be possible to start any therapy and the error warning accompanied by an acoustic signal will appear in the MAIN MENU screen (Figure 22). It will not be possible to use an device that is not able to guarantee absolute reliability and safety characteristics.
Most commonly, following completion of all the test phases the main menu will be displayed on the display:

3.2 DEVICE SETTINGS

By pressing the SETUP icon the software will present the general settings screen.
At each touch the touchscreen display will display in green the selection made by activating the software to present the screen related to the task to be called.
The following menu will appear

Drag the slider of the LIGHT bar' from left to right to adjust the brightness of the display from weak to stronger.
Changing the language becomes very easy, just click on the flag.
The software is available in two versions: ENGLISH/ITALIAN/SPANISH or ENGLISH/ITALIAN/GERMAN
In the boxes below the flags will report the version of the software installed on board the device and the firmware version of the touchscreen display.
To return to the main menu, tap the relevant button at the bottom right.

REMEMBER TO ALWAYS WEAR PROTECTIVE GLASSES DURING THE LASER BEAM EMISSION

3.3 HANDLING OF MOTORS

The device on delivery, after it has been unpacked, is closed. It is therefore necessary at this point to open the arm.
For this function we will need to enter the motors settings menu.

The second icon from the left, depicting an motor, allows access to this menu.
So proceed by clicking on it and wait for the screen to appear
ARM ADJUSTMENT AND TESTED.

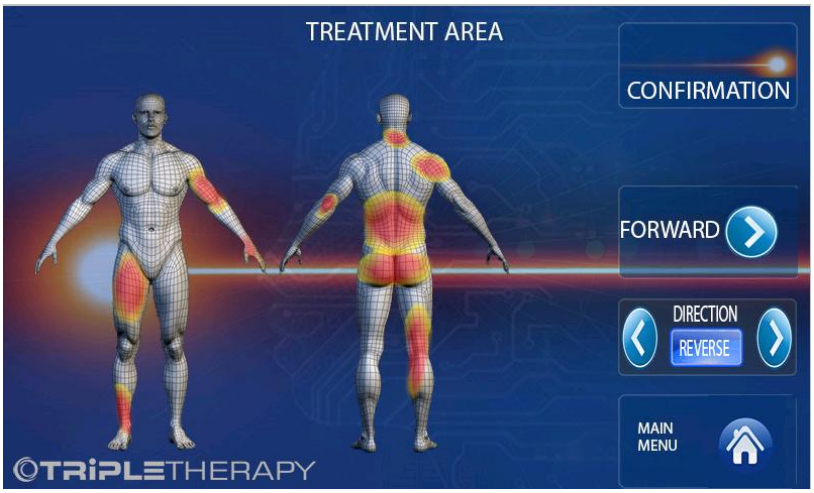
The illustrated menu makes it easy to distinguish the various functions:
just click and hold on the OPEN icon to activate the function that will open the arm, as well as pressing the icon ARM CLOSED the arm will close again. Similarly to raise and lower the column and then raise and lower the arm. Finally you can rotate the laser output up to a maximum angle of 90 by pressing on WHEEL 90 and return it to its normal position. The pressure comes from the touch, so it stops as soon as we remove the finger from the display. In this way the totality of the possible positions is reached and this will allow to perform therapies in any possible position.
Once the optimal position of the device is found (it should always be a distance of about 30cm between the part to be treated and the output of the laser beam) you can decide whether to operate using a therapy previously stored or through manual mode. The following paragraphs will describe the various functionalities

3.4 INFORMATION ABOUT THE DEVICE

The information related to the software version can be called up, as indicated above, in the settings menu accessible from the main menu.
It will display:

3.5 MANUAL MODE

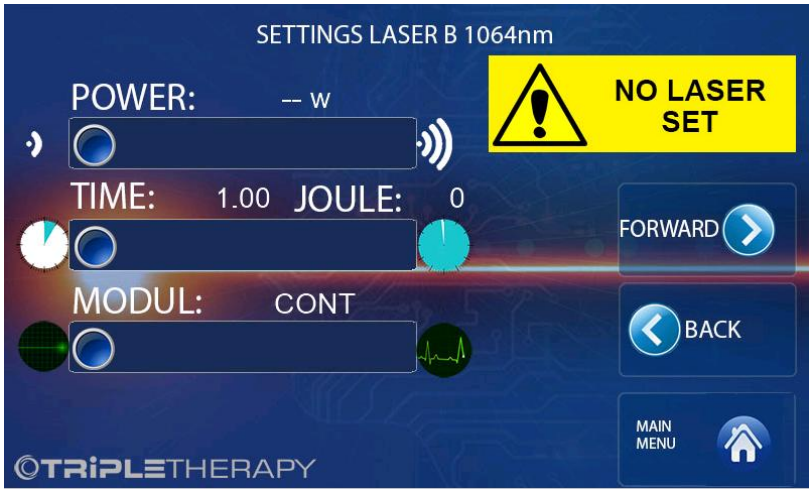
From the main menu, pressing the MANUAL START icon takes you to the following screen; from this by clicking on FORWARDS it is possible to access the adjustment screen of all emission parameters of the therapeutic treatment to perform (power, time and emission mode) otherwise it is possible to use preset parameters according to the anatomical area to be treated by clicking on the highlighted areas on the figure depicting the human body



Clicking on one of these anatomical areas causes the pointer to scan in a size proportional to the selected area; clicking on REVERSE DIRECTION causes the scan to change its direction from movement along the horizontal axis to vertical and vice versa. To confirm the preset parameters click on CONFIRM.
If you have opted for free parameter setting, then press FOWARDS to access the LASER SETTING screen:
The adjustment must be made first for laser source A (808 nm) and then for laser source B (1064 nm), through the interaction in succession with 2 identical screens, one for laser A and one for laser B.

The emission parameters that can be adjusted are:

- Power: by pressing the icons at the end of the POWER bar, or directly dragging the bar cursor to the right or left, the emission power can be adjusted up to a maximum of 10 W for source A (808 nm) and 15 W for source B (1064 nm). If you decide not to use one of the two laser sources, do not set any unused laser power and press the NEXT button (If by mistake no power value is set for both sources and you press the icon NEXT will appear in the screen the warning NO LASER SET.



To be able to continue, therefore, set the power values for the desired laser sources

- Time: by pressing the icons at the end of the TIME bar , or by directly dragging the cursor of the bar to the right or left , you can set the emission duration for a maximum time is 20 minutes for each individual laser source. If both laser power sources are active, during the therapy two separate timers will be scaled and the count will be finished independently of each other with the due indication of the end of therapy. The counts start at the same time that the therapy is initiated. Depending on the power value set for a given laser source, the software will automatically calculate the energy that will be delivered from that source during therapy to vary the duration set.

- Frequency: it is possible to use the laser sources in CONTINUOUS DISPENSING mode or in PULSED DISPENSING mode at the frequency set with fixed duty cycle at 50% of the period. To have the operation "continuous" the cursor of the bar MODULATION must be all left , dragging it instead to the right you switch to pulsed mode starting from the frequency value of 1 Hz until you get to the maximum

frequency of 10khz when the cursor is all right in the relevant bar.
The frequency increment steps are as follows:
1, 2, 3, 4,5, 6, 7, 8, 9, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 200, 300, 400, 500,
600, 700, 800, 900, 1000, 2000, 3000, 4000, 5000, 6000, 7000, 8000, 9000, 10000 Hz.
For the same power and duration of therapy, the energy delivered in pulsed mode is half that in continuous mode than in continuous mode

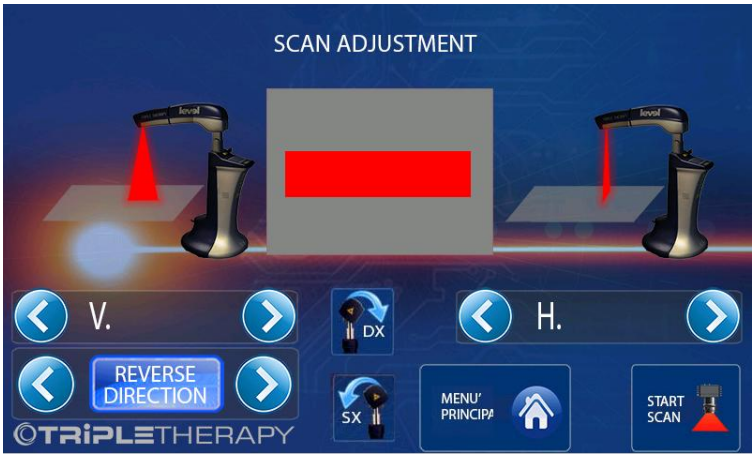
Once you have set the parameters of both laser sources by pressing the icon FORWARD you access the engine adjustment screen to set the optimal position of the laser output according to the position of the patient and the anatomical area to be treated.

Once the position of the laser output has been adjusted, pressing the icon SCAN CONTROL you switch to the screen activation and adjustment of the scan; from this point on is activated the scan by the laser beam guide.

3.6 SCAN ADJUSTMENT

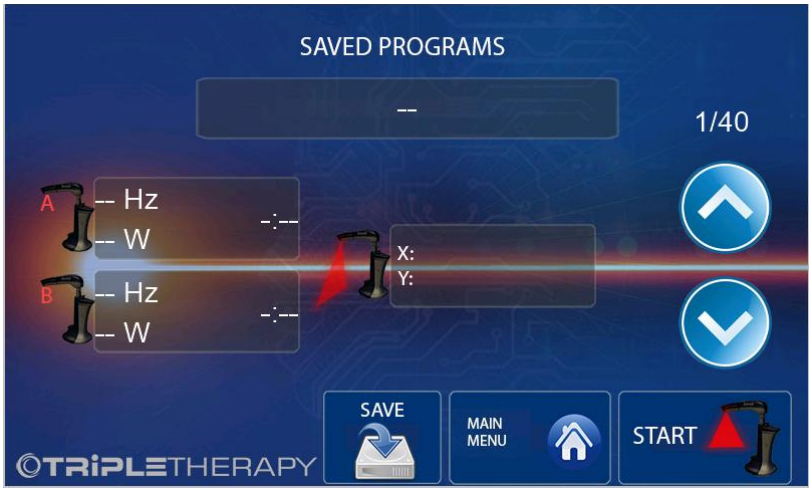
IT IS COMPULSORY FOR THE OPERATOR AND THE PATIENT TO WEAR THE PROTECTIVE GLASSES PROVIDED BEFORE STARTING THE EMISSION OF THE LASER BEAM OR THE POINTING BEAM (ALSO ISSUED DURING SCAN ADJUSTMENT)

From the SCAN adjustment screen you can vary the size of the scanning area detected by the laser beam guide and reverse the scanning direction



Acting on the arrow-shaped icons of the fields V. and H. you vary the scanning area respectively along the horizontal and vertical direction
Acting on the arrows of the field INVERT DIRECTION inverts the direction of the scan from the horizontal to the vertical axis and vice versa.
In this screen you can also still adjust the angle of the laser output by acting on the icons DX and SX
To confirm the settings and move to the next screen press the START SCAN icon that gives access to the summary screen of all settings and from which you can give consent for the start of therapy

This screen is useful to verify the correct insertion of all parameters (power and emission mode and scanning area) before starting the therapy and allows you to save such settings in the form of a therapeutic program to perform the same type of therapy in the future without the need to reset the various therapy parameters again. Inside the screen is displayed the warning ATTENTION TO WEAR SAFETY GLASSES (mandatory for the patient and the operator).
So if you opt for saving the therapy you must press the icon SAVE , so you can access the screen PROGRAMS IN MEMORY where you can save up to 40 therapeutic programs



To save the therapy choose one of the 40 positions available by pressing on the icons in the shape of an arrow until you reach the desired position (by default the first position is set) and press the SAVE icon to access the virtual keyboard to type the name to be assigned to the therapy you are saving.

To confirm the name entered and simultaneously store the therapy press the button with the image depicting a floppy-disk and you will return directly to the summary screen of the settings from which you can start the therapy

3.7 STARTING THE THERAPY

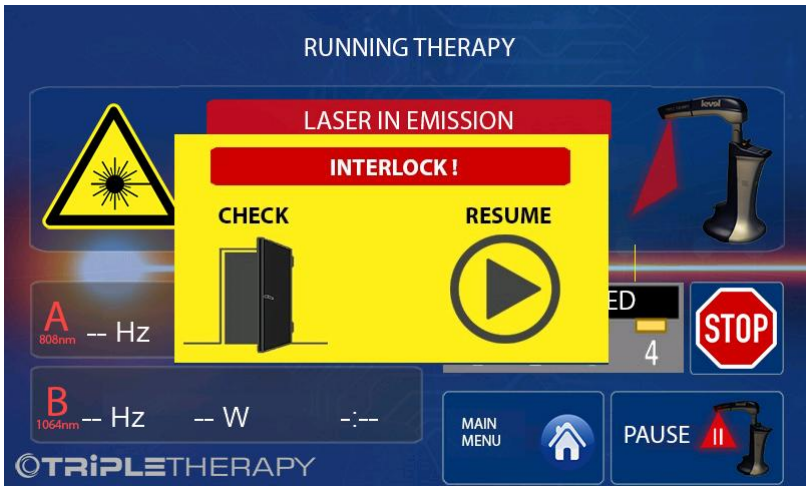
Pressing then on START in the summary screen settings starts the therapy and the screen is displayed RUNNING THERAPY

In this screen for each activated laser source are displayed the parameters set and the time countdown at the end of the emission and you can select the desired scan speed among the four available by pressing on the icons marked by numbers 1 to 4 (Speed 1 is selected by default).
At any time you can pause the therapy and then stop the emission by clicking on the corresponding icon ; countdowns are blocked and the message PAUSE THERAPY will appear from which you can then resume the therapy or quit it permanently, with return to the main menu and switch off the guide beam, respectively pressing the icons RESUME or QUIT

You can also stop permanently and emergency , with return to the main menu screen, the therapy running pressing on the STOP icon.

IT IS POSSIBLE TO INTERRUPT THERAPY AT ANY TIME ALSO BY PRESSING THE EMERGENCY LOCK BUTTON. THIS OPERATION REQUIRES THE RESTART OF THE DEVICE BY THE OPERATOR

The therapy will also be automatically paused following the opening of the access door to which the INTERLOCK device is connected and the following screen will be displayed to alert us to the opening.



To resume the therapy it is necessary to close the door and press on the icon RESUME.
The following controls are active during the duration of the broadcast

- Interlock safety device: If the door is opened, the output is interrupted. Once the door is closed, the operator must manually intervene to resume the therapy.

- Check the status of the galvanometers: in case of a failure of the galvanometers (which regulate the scanning of the laser beam), the emission is interrupted and an error message is displayed on the screen. Contact the manufacturer for Technical Assistance.

- Temperature control of the laser source: if the maximum temperature is exceeded, the emission Is interrupted. Contact the manufacturer for Technical Assistance.

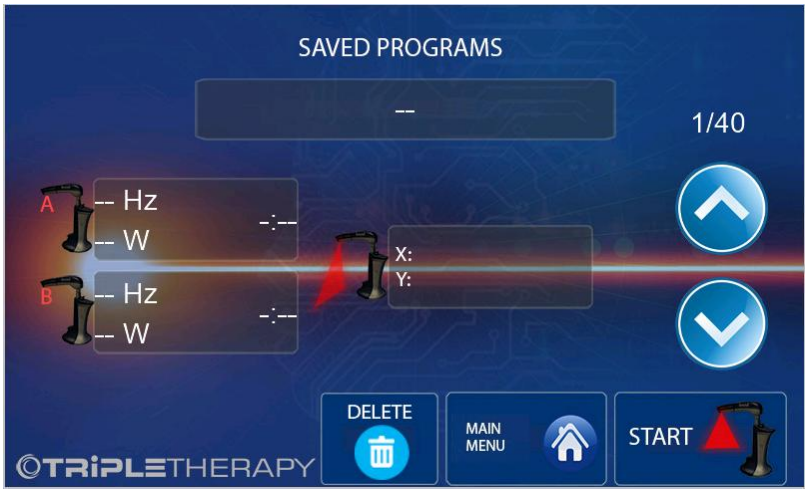
- Emission power control: If the emission power differs by more than 20 % from the set value the emission is interrupted. Contact the manufacturer for Technical Assistance.

FUMES AND / OR VAPORS PRODUCED BY THE BEAM MAY CONTAIN PARTICLES OF VITAL TISSUE

Once the timer is over, the therapy is over, the laser beam emission is interrupted and the shutter is reactivated. The device returns to the home screen and, if the laser output does not was in a perpendicular position, the Laser Triple Therapy provides for the automatic repositioning of the rotating head in a perpendicular position

3.8 PROGRAMS MODE

Selecting the PROGRAMS mode from the main menu leads to the following screen where You can view the list of previously stored therapies and their emission characteristics.



To scroll through the stored therapies press on the arrows until the therapy you want to start and confirm it by pressing the START icon, you will have direct access to the screen ARM AND HEAD ADJUSTMENT of manual mode (figure 9) from which to continue as already explained
To delete a stored therapy from the list press the DELETE icon.

3.9 REPORTS OF WARNINGS AND ERRORS

- WARNING CLEAN FILTER

When the TRIPLE THERAPY device is switched on in the MAIN MENU screen, it can appear, after a certain period of use, the warning CLEAN FILTER that reminds us the need to perform a periodic cleaning of the air filter placed under the floor of the TRIPLE THERAPY near the pivoting wheels.

To remove the filter box simply pull it down with your hands and free the filter sponge and retina from dust accumulation.
Cleaning the air filter is of fundamental importance to preserve the life and proper functioning of the laser sources and avoid possible overheating and permanent failures.
It is possible to postpone the cleaning of the filter at a later time by clicking directly on the pop-up but it is recommended to clean the filter immediately as soon as possible.

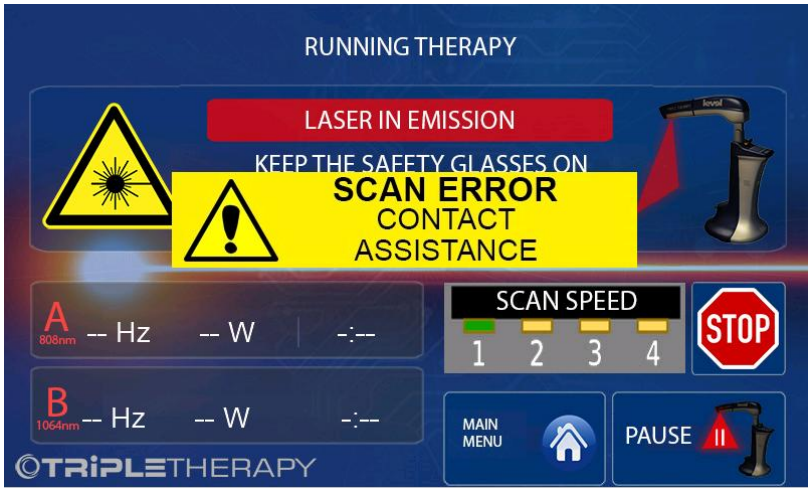
- OVERHEATING WARNING

This warning may appear during the execution of a therapy and indicates the overheating of laser sources which may be due to an excessively high ambient temperature or a malfunction of the cooling system of laser sources: in this case the emission of laser sources is interrupted and you will need to return to the main menu via the STOP icon.

Should this occur, wait for it to cool down with the device switched on for about ten minutes and try the start of therapy again. If the problem persists contact technical support

- SCAN ERROR

  This error may occur when scanning is active and indicates a malfunction of the scanning system; if the pop-up occurs in the screens prior to the start of therapy, return to If the error is due to an occasional malfunction, it will be possible to use the Triple Therapy device for the execution of a new therapy.

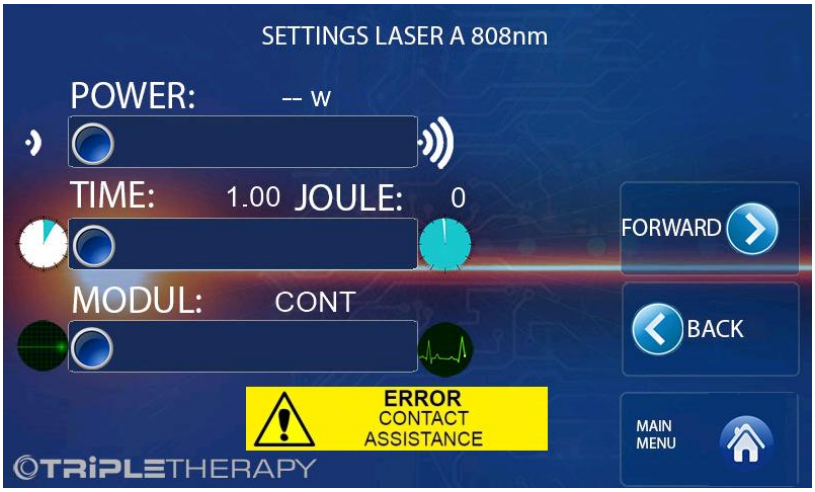


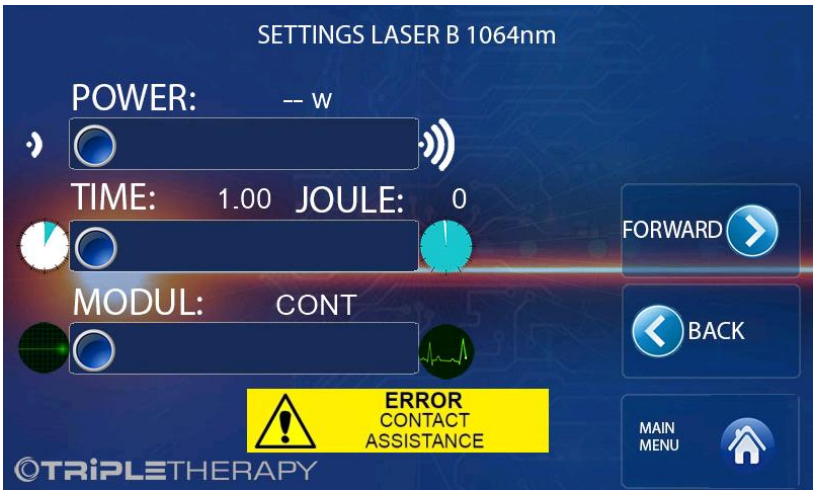
If, on the other hand, the malfunction is permanent, the pop-up **SCAN ERROR CONTACT ASSISTANCE** will appear in the main menu; the device is no longer able to execute any therapy and only the MOTORS, SETUP and GUIDE functions remain active.

- LASER ERROR

his error may occur during therapy and indicates a malfunction of one or both laser sources, in which case the emission of the laser sources is interrupted and it will be necessary to return to the main menu via the STOP icon.

If the error is due to an occasional malfunction, it will be possible to use the TRIPLE THERAPY device to carry out a new therapy, whereas if the fault is permanent for only one of the two laser sources, it will still be possible to use the TRIPLE THERAPY to start a new therapy with only the working source; the source that is no longer working is identified in the relative LASER SETTING screen following the selection of the manual mode in the main menu and it is no longer possible to set its operating parameters. Here the error reminds us to contact technical assistance as soon as possible so that the TRIPLE THERAPY can be restored to its full functionality





Use the NEXT icon to proceed to the next screens.

During therapy, the failed source status is constantly displayed .

If the fault is permanent for both sources, the ERROR CONTACT TECHNICAL ASSISTANCE pop-up will appear in the main menu; the device is no longer able to perform any therapy and only ENGINE, SETUP and DRIVING functions remain active.

4 MAINTENANCE

ALWAYS CHECK THAT THE DEVICE IS DISCONNECTED FROM THE ELECTRIC NETWORK BEFORE PERFORMING ANY OPERATION DESCRIBED BELOW

DO NOT POINT THE LASER BEAM TOWARDS THE EYES OR THYROID

The useful life of the device if properly maintained and used is 10 years

4.1 ORDINARY MAINTENANCE AND CLEANING

Triple Therapy does not require special maintenance. To ensure the efficiency of the equipment, make sure that the air vents under the base of the instrument are free from dust / objects that could obstruct the normal flow of air and clean the device periodically. Triple Therapy can be cleaned of dust using a soft dry cloth. More resistant stains can be removed using an aqueous solution of soap or a sponge soaked in a hydroalcoholic solution. For disinfection, Triple Therapy can be treated with all the aids normally used for electromedical equipment.
There is no danger of flammability of the materials normally used for cleaning the appliance (alcohol or other detergents), given the low temperature reached by the laser emission. The device has no parts subject to sterilization..

4.2 EXTRAORDINARY MAINTENANCE AND REPAIRS

Extraordinary maintenance consists of a six-monthly check of earth leakage currents by competent technical personnel for protection against direct and indirect contacts. In addition, a periodic check is provided for the verification and calibration of the laser emission, measuring the emission power according to the procedure described in section 3.2 "Device settings".

Triple Therapy is equipped with a mechanical safety shutter that blocks any uncontrolled emissions from Class 4 IR laser sources (CEI EN 60825-1).
For safety reasons, the user is recommended to carry out a check at least once a year, sending the equipment to LEVEL S.r.l., to proceed with the maintenance of this shutter. This ensures the perfect functioning of the device.

In case of failure it is recommended to carry out the following checks:

- • Check the connection with the mains socket;
- • Make sure the equipment is working in a room with an ambient temperature below 28 ° C.
- • Check that the key has been correctly inserted in the safety switch;
- • Check the connection of the interlock plug;Verificare lo stato dei fusibili di rete e procedere eventualmente alla loro sostituzione;
- Check that all operations have been carried out correctly; If the problem is not solved, call the Technical Assistance service.

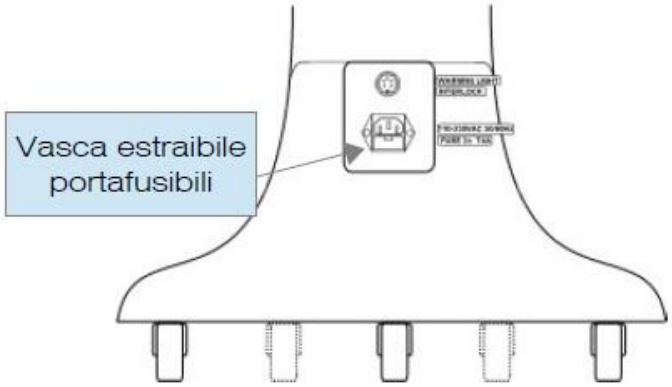
4.3 THECNICAL ASSISTANCE

If the appliance requires Technical Assistance, before sending the product to our service center, you must have authorization. Therefore, please contact our office or the nearest authorized center (see the list on the website www.level-laser.com) and fill out the technical assistance request form.
LEVEL S.r.l., unless otherwise indicated by the company itself, for reasons of safety and maintenance of the characteristics of the products even after interventions, is the sole agent for assistance on its products. Any technical documentation concerning repairable parts can be provided, but only with company authorization and only after giving adequate instruction to the personnel assigned to the interventions.
Please note that the products sent for assistance must be previously and compulsorily sanitized for the protection of the health of the staff involved in providing the service.

4.4 FUSES REPLACEMENT

To replace the fuses, follow the instructions below:

- Switch off the appliance and disconnect the mains plug;
- Remove the fuse holder tray located on the mains socket by acting on the special tab.
- Replace the fuses using the spare ones supplied with the equipment; • Reinsert the fuse holder;
- Reactivate the system.



5 DISPOSAL

Do not dispose of this product and its accessories as general waste. Prepare the product for recycling or separate collection pursuant to Legislative Decree of 14 March 2014, n. 49 "Implementation of Directive 2012/19 / EU, on waste electrical and electronic equipment (WEEE)".

In case of use in hospitals, follow the internal rules for the disposal of electrical and electronic waste.

6 THECNICAL CHARACTERISTICS

Main Supply	230 Vac; 1.1 A Max.; 50 Hz
Absorbed power	215 W Max.
Motors	N°3 (Stativo, Basculante e Rotativo)
Display	LCD (touch-screen) with resolution 800x480 pixel
Mode	Continue or pulse (Frequency da 1 a 10000 Hz)
Frequency and scan XY angle XY	36 Hz, da -14° a +14° (±5%)
Dimensions	60x65x122 cm

Weight	40 Kg

Terapeutic laser beam A	
Diode	GaAlAs CW
Wave lenght	805/811 nm
Power max	10 W ± 10%
DNRO (Nominal Ocular Risk Distance)	23.4 m ± 20%
Spot dimensions	22 mm ± 20% (Diameter)
Divergence	21 x 49 milliradianti ± 20%

Terapeutic laser beam B	
Diode	GaAlAs CW
Wave lenght	1061/1067 nm
Power max	15 W ± 10%
DNRO (Nominal Ocular Risk Distance)	23.4 m ± 20%
Spot dimensions	22 mm ± 20% (Diameter)
Divergence	21 x 49 milliradianti ± 20%

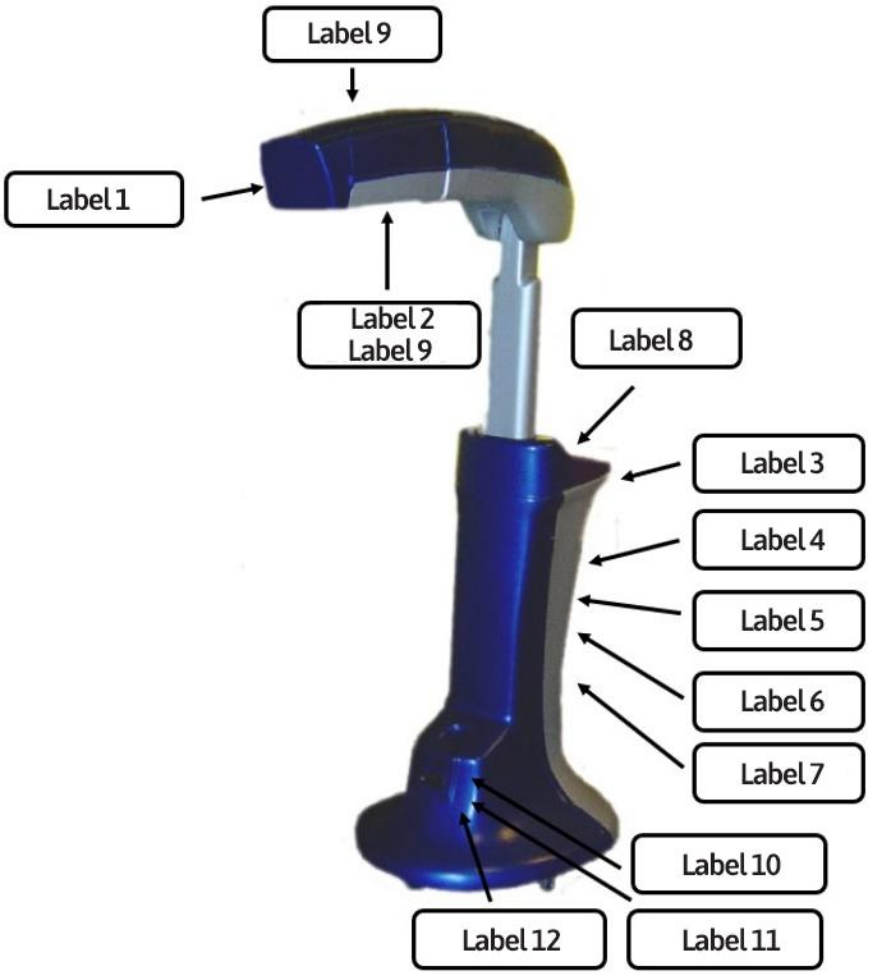
Aiming beam	
Power	<3 mW
Wave lenght	635 nm
DNRO (Nominal Ocular Risk Distance)	12.44 m ± 20%

Spot dimensions	2x2 mm ± 20%
Divergence	0.3 x 0.9 milliradianti ± 20%

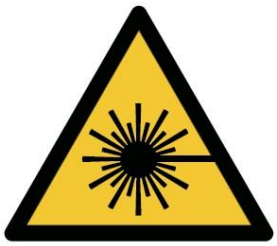
Ambiental Conditions	Temperature	Use	+0°C - +40°C
		storage / transport	-40°C - +70°C
	Humidity	**Use**	+10 - 95% Ur senza condensazione
		storage / transport	+10 - 95% Ur
	Atmospheric Bar	**Use**	700 - 1060 hPa
		storage / transport	500 - 1060 hPa

7 LABELING

7.1 SAFETY LABELS



7.1.1 LABEL 1



Meaning: Warning plate - Danger from laser radiation source

7.1.2 LABEL 2

LASER OUTPUT

7.1.3 LABEL 3

ATTENTION
VISIBLE AND INVISIBLE LASER RADIATION
CLASS 4
IN THE EVENT OF OPENING AVOID EXPOSING EYES
AND SKIN TO DIRECT OR DIFFUSED RADIATION

7.1.4 LABEL 4

Wavelenght 805-811nm
Maximum power 10 Watt CW
CLASSIF. CEI EN 60825-1

7.1.5 LABEL 5

Wavelenght 1061-1067nm
Maximum power 15 Watt CW
CLASSIF. CEI EN 60825-1

7.1.6 LABEL 6

Wavelenght 635nm
Potenza massima 3 mW CW

7.1.7 LABEL 7

Classif. CEI EN 60825-1 2009-07

7.1.8 LABEL 8

Around the mushroom of the emergency button.

7.1.9 LABEL 9

VISIBILE AND INVISIBLE LASER RADIATION
AVOID EXPOSING EYES AND SKIN
TO DIRECT OF DIFFUSED RADIATION
LASER EQUIPMENT CLASS 4

7.1.10 LABEL 10

INTERLOCK
WARNING LIGHT

7.1.11 LABEL 11

230 V AC 50 HZ

7.1.12 LABEL 12

FUSE 2 X T 4 A

7.1.13 LABEL13

ON/OFF POWER

7.2 LABEL PLACED ON THE DEVICE

TRIPLE THERAPY	Level S.r.l. HeadQuarter: Via Perugia, 10 - 95129 Catania (CT), Italy Operational Site: Zona Asi C/da Archi 98044 - San Filippo del Mela (ME), Italy
REF 10LS25	Power supply: 230 V AC 50 Hz - 1.1 A Fuses 2 x T 4A AL230V
SN [Serial number	
Operating temp. 0 °C 40 °C	
[Year]	1370 CE

7.3 IDENTIFICATION OF THE SYMBOLS USED

Manufacturer identification

REF	Product identification code
SN	Serial number identification of the production serial number
	Attention, refer to the user manual. Safety information
	Consult the user manual
	Production year
	Disposal according to the WEEE regulation

 Operating temp.	Operating ambient temperature
CE 1370	Compliant with Council Directive 93/42 / EEC and subsequent amendments DM Class IIb. The 4-digit code indicates the certification bo device.

8 ELECTROMAGNETIC COMPATIBILITY

8.1 EMC WARNINGS

The appliance complies with the collateral standard CEI EN 60601-1-2 Standard applicable to the product and relating to electromagnetic compatibility.

	THE EQUIPMENT MUST BE INSTALLED AND PUT IN SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THIS SECTION.
	THE EQUIPMENT CAN BE AFFECTED BY COMMUNICATION EQUIPMENT AND MOBILE PHONES.
	THE EQUIPMENT CANNOT BE EQUIPPED WITH CABLES DIFFERENT FROM THOSE SPECIFIED BY THE MANUFACTURER
	THE DEVICE MUST NOT BE USED NEAR OR OVERLAPPING WITH OTHER EQUIPMENT IN ORDER TO AVOID INTERFERENCE IN NORMAL OPERATING CONDITION.

8.2 TABLES OF EVALUATION 60601-1-2

Table 1 (numerazione 60601-1-2)

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment**

RF emissions CISPR 11	Group 1	Device in which RF energy in the 9kHz-400 GHz range is not intentionally generated and not used in the form of electromagnetic radiation, capacitance and / or inductive coupling, for the treatment of materials or inspection.
RF emissions CISPR 11	Class A	Device suitable in all buildings except domestic ones and those connected directly to a low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Conforme	
CISPR 14	Not applicable	
CISPR 15	Not applicable	

Table 2 (numerazione 60601-1-2)

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD)	± 8 kV contact	EN 60601-1-2 Test level	Floors must be wood, concrete or ceramic tiles. If floors are
EN 61000-4-2	±2 kV;±4 kV;±8 kV;±15 kV air		covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV 100 kHz repetition frequency	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Surge EN 61000-4-5	± 0,5 kV, ± 1 kV (line-toline) ± 0,5 kV, ± 1 kV, ± 2 kV (line-to-ground)	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	EN 60601-1-2 Test level	The type of mains power supply must be that typical of a commercial, hospital or domestic environment.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2 Test level	The magnetic fields emitted at mains frequency should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.

Table 4 (numerazione 60601-1-2)

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

<table>
<tr><th>Immunity Test</th><th>EN 60601-1-2 Test level</th><th>Compliance level</th><th>Electromagnetic Environment</th></tr>
<tr><td>Radiated RF
EN 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m
EN 60601-1-2
Test level</td><td rowspan="2">Portable and mobile RF communications equipment should not be placed at any part of the [equipment or system], including cables, less than the separation distance calculated using the equation applicable to the transmitter frequency.

Recommended separation distance $d = 1.2 \times \sqrt{P}$ 80 MHz to 800MHz

$d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz
Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Conducted RF
EN 61000-4-6</td><td>3 V
150 kHz to 80 MHz</td><td>3 V
EN 60601-1-2
Test level</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>EN 60601-1-2 Test level</th><th>Compliance level</th><th>Electromagnetic Environment</th></tr>
<tr><td colspan="4">a) Fields generated by fixed transmitters, such as base stations for radiotelephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be accurately evaluated through calculations. To assess the electromagnetic environment generated by fixed RF transmitters, the need to make measurements in the field of application must be considered. If the field strength measured in the place where the device is used exceeds the established V / m field strength, observe the device to verify that normal operation is maintained. In the event of abnormal operation, additional protective measures must be taken, such as moving the device from the emitting element or using a place of use more shielded from RF radiation and / or using a more effective filter
b) Over the frequency range 150 kHz to 80 MHz, the field strength should be less than [V1] V / m.</td></tr>
</table>

Table 6 (numerazione 60601-1-2)

Recommended separation distance for devices not intended for life support and intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications devices (transmitters) and the device as recommended below, based on the maximum output power of the RF communications equipment. communication.		
Potenza massima di uscita del trasmettitore (W)	**Distance of separation in accord with the transmitter (m)**	
	80MHz to 800MHz $d = 1.2 \times P$	**800MHz to 2.5GHz** $d = 2.3 \times P$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters with maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated with the equation applicable to the transmitter frequency, where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer. Note: (1) 800 MHz, the separation distance for the higher frequency range (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people NB The system has not been tested for electromagnetic immunity to radiated RF over the entire frequency range from 80 MHz to 2.5 GHz		