LUX-WAVE

10W 808NM

10W 1064NM

USER'S MANUAL

CE 1370

DISCLAIMER

Level S.r.l. cannot be held liable for any injury to persons or damage to property due to misuse of this product and failure to comply with the indications, warnings, instructions and precautions given in this User's Manual.

Only a hardcopy of this User's Manual is provided and must always accompany the LUX-WAVE device.

LUX-WAVE is manufactured by:

Level S.r.l.
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Operating base - Zona Asi C/da Archi 98044 - San Filippo del Mela (ME), Italy
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CONTENTS

1. GENERAL INFORMATION

The device LUX-WAV has been designed and constructed in a quality system conformant with specific legislation for medical devices and with all the latest safety standards related to medical electrical equipment; it is therefore a totally safe and reliable therapy instrument in respect of both the patient and the operator.

The one-of-a-kind device LUX-WAVE in manual mode allows the power and treatment times of the 808nm or 1064nm laser source to be adjusted.

All the internal components are enclosed in an elegant compact housing mounted on an adjustable motorised stand with base fitted with pivoting castors. A readily accessible control panel and the key-operated master switch are incorporated at the rear.

The advanced electronic system is managed by an intelligent unit, the microprocessor, which constantly controls the keyboard and processes the operator's commands, showing them on the graphic display.

The device LUX-WAVE can tilt 110 degrees thanks to the support swivel.

The emission is vertical from the lower part of the housing and performs horizontal and vertical scanning within a 30 degree range
The basic version of the device LUX-WAVE fundamentally consists of:

- a 635 nm diode pointer with power of 3mW;
- a 808nm IR (Ga Al As) diode with maximum power of 10W (10LS27) or 1064nm with maximum power of 10W (10LS26) in CW aligned with the 635 nm diode pointer;

1.1 END USE

The end use of the device forming the subject matter of this TF is the therapeutic-antalgic treatment, through emission of a laser beam (laser therapy), of pathologies and related inflammatory states of the skeletal muscle and dermatological system, in various medical fields (dermatology, pain therapy, aesthetic medicine, physiatrics and rheumatology). Depending on the version, the device emits two laser beams from 2 different sources with wavelength 808 nm and maximum power 10 W (version 10LS27) and with wavelength 1064 nm and maximum power 10 W (version 10LS26) respectively.
The device is intended for use by specifically trained medical or healthcare personnel.

1.2 CLASSIFICATION

Classification in accordance with Directive 93/42/EEC Annex IX rule 9 class IIb.

CAUTION!

THE DEVICE IS INTENDED FOR USE BY SPECIFICALLY TRAINED MEDICAL AND/OR NURSING PERSONNEL IN HOSPITALS, MEDICAL PRACTICES AND IN PRIVATE CENTRES FOR REHABILITATION AND PHYSIOTHERAPY.

1.3 SYMBOLS

To make the manual easy and clear to read, the symbols used to indicate the important warnings for 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 abide by the warnings given below or the standards and precautions described in this User's Manual immediately invalidates any warranty for the device LUX-WAVE.
Level S.r.l. cannot be held liable for any injury to persons or damage to property due to failure to comply with the standards and precautions given in general in this User's Manual.

	NON-COMPLIANCE OR NEGLIGENCE IN COMPLYING WITH THE FOLLOWING INDICATIONS COULD RESULT IN DEVICE MALFUNCTION, DAMAGE AND INJURY TO THE USER
	TO PREVENT THE RISK OF ELECTRIC SHOCK, ONLY CONNECT THE DEVICE TO EARTHED/GROUNDED SOCKETS AND TO ELECTRICAL SYSTEMS IN CONFORMITY WITH THE STANDARD CEI 64-8/7
	DO NOT USE THE DEVICE UNTIL EVERY PART OF THIS USER'S MANUAL HAS BEEN READ AND FULLY UNDERSTOOD
	IT IS FORBIDDEN TO MAKE ANY CHANGE TO THE DEVICE OR ANY PART THEREOF
	USE OF THE DEVICE FOR ANY PURPOSE OTHER THAN THOSE INDICATED IN THIS USER'S MANUAL COULD EXPOSE THE PATIENT AND THE OPERATOR TO DANGER
	IF SERIOUS ACCIDENTS OCCUR WITH THE DEVICE, IMMEDIATELY CONTACT THE MANUFACTURER AND THE APPROPRIATE AUTHORITY
	DO NOT USE THE DEVICE IN ENVIRONMENTS WHERE THERE ARE ANAESTHETIC MIXTURES THAT ARE INFLAMMABLE WITH AIR OR OXYGEN OR NITROUS OXIDE. THE USE OF LASER EMISSION IN THE PRESENCE OF INFLAMMABLE MATERIALS, SOLUTIONS OR GASES OR IN AN OXYGEN-RICH ENVIRONMENT COULD INVOLVE A RISK OF FIRE OR EXPLOSION
	DO NOT USE IN THE PRESENCE OF LIFE-SUPPORT EQUIPMENT OR RADIOFREQUENCY EQUIPMENT
	DO NOT USE THE DEVICE ON SLOPING SURFACES SINCE THE CASTORS FITTED TO THE BASE ARE NOT SELF-LOCKING, WITH CONSEQUENT RISK OF OVERTURNING OR UNEXPECTED MOVEMENT OF THE DEVICE
	THE OPERATOR AND THE PATIENT MUST BE WEARING THE PROTECTIVE EYEWEAR PROVIDED BEFORE STARTING EMISSION OF THE LASER BEAM OR THE BEAM POINTER. SEE APPENDIX A FOR THE TYPE OF COMPULSORY PROTECTIVE EYEWEAR
	DO NOT DIRECT THE LASER BEAM TOWARDS EYES OR THE THYROID GLAND

	DO NOT USE THE DEVICE IN CASES OF PREGNANCY, EPILEPSY OR NEOPLASM
	DO NOT USE THE DEVICE ON PARTS OF THE BODY WHERE AN ACTIVE MEDICAL DEVICE HAS BEEN IMPLANTED (E.G. A PACEMAKER)
	THE PATIENT MUST REMAIN AWAKE AND SENTIENT THROUGHOUT THE WHOLE THERAPEUTIC TREATMENT, SO THAT EMISSION OF THE LASER BEAM MAY BE STOPPED IMMEDIATELY IF THE PATIENT FEELS DISCOMFORT OR PAIN IN THE TREATED AREA
	ONLY AUTHORISED PERSONNEL MAY USE THE DEVICE: IT IS THEREFORE RECOMMENDED THAT THE KEY BE REMOVED FROM THE MASTER SWITCH AND PUT IN A SAFE PLACE WHEN THE DEVICE IS NOT BEING USED
	THE INTERLOCK SAFETY DEVICE PLUG MUST BE CONNECTED BEFORE SWITCHING ON THE DEVICE
	USE OF THE CONTROLS OR MEANS OF ADJUSTMENT/SETTINGS, OR THE PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS MANUAL COULD RESULT IN EXPOSURE TO HARMFUL RADIATION.
	SHOULD BLEEDING OCCUR DURING TREATMENT, STOP IMMEDIATELY AND TREAT THE WOUND, THOROUGHLY DISINFECTING IT.

1.5 CONTRAINDICATIONS

Do not use in:
case of use of photosensitising drugs,
presence of neoplastic or precancerous lesions,
presence of Herpes Simplex in the area to be treated,
case of tendency to form keloids,
case of pregnancy,
case of epilepsy,
case of a very tanned skin
presence of serious metabolic alterations to the skin,
presence of wounds in the area to be treated,
case of use of drugs which can affect cutaneous metabolism (Accutane, Roaccutane).

1.6 LIMITATIONS OF USE

Only use on intact skin,
Do not treat around eyes or on eyelids.

1.7 SIDE EFFECTS

Some of the following adverse or side effects could occur:
Change in skin colour of the treated area
Surface erosion of the treated area
Onset of pain during treatment
Erythema and oedema
Scarring

1.8 INTENDED ENVIRONMENT OF USE

The device is intended for use inside hospital structures, medical practices and in private rehabilitation and physiotherapy centres.

1.9 PATIENT POPULATION

The device is intended for use solely on adult patients.

1.10 COMPOSITION OF THE DEVICE

The following are also supplied in the packaging together with the LUX-WAVE device:

- 1 Power cord;
- 2 Pairs protective eyewear;
- 2 Spare fuses;
- 1 master switch key;
- 1 Interlock plug;
- 1 "danger laser" sticker

LUX-WAVE is not fitted with accessories.

	THE USE OF ELEMENTS THAT ARE NOT PART OF THE ABOVE-DESCRIBED SYSTEM OR NOT SUPPLIED TOGETHER WITH THE DEVICE COULD JEOPARDISE ITS SAFETY AND EFFICACY.
	UPON REMOVING THE PACKAGING, CHECK THAT THE CONTENTS ARE INTACT. IN THE EVENT OF OBVIOUS SIGNS OF DAMAGE, IMMEDIATELY CONTACT THE MANUFACTURER.
	If you have not received all the above-listed elements, immediately contact the manufacturer

2 CONNECTION TO THE MAINS SUPPLY AND SWITCHING ON

⚠	BEFORE CONNECTING THE DEVICE TO THE MAINS POWER SUPPLY, CHECK THAT THE ELECTRICAL SYSTEM IS IN CONFORMITY WITH THE REQUIREMENTS OF STANDARD CEI 64-8/7
⚠	DO NOT PLACE THE DEVICE WHERE IT IS DIFFICULT TO PULL THE PLUG OUT OF THE POWER SOCKET
⚠	REMEMBER THAT PRODUCTS SUCH AS SMART-PHONES, MOBILE PHONES AND OTHER RF COMMUNICATION DEVICES COULD CAUSE INTERFERENCE IN RESPECT OF THE MEDICAL DEVICE
⚠	DO NOT PLACE THE DEVICE TOO NEAR OTHER MEDICAL ELECTRICAL DEVICES
⚠	CHECK THAT THE ENVIRONMENT OF USE IS COMPLIANT WITH THE INDICATIONS GIVEN IN THE SECTION "ELECTROMAGNETIC COMPATIBILITY"
⚠	CHECK THAT THE AIR INTAKES LOCATED UNDER THE BASE OF THE DEVICE ARE FREE OF DUST AND ANY OBJECTS
⚠	WHEN MOVING THE DEVICE, PAY ATTENTION TO THE SWIVEL WHEELS TO AVOID THE RISK OF CRUSHING

To connect LUX-WAVE to the mains power supply and to switch on, follow the instructions given below:

- Plug the power cord into the appropriate socket.
- Connect the Interlock device as described in section 2.1.
- Insert the key into the emergency switch and turn it clockwise, then press the primary push-button switch: the device will emit a sound signal to indicate correct switching on.

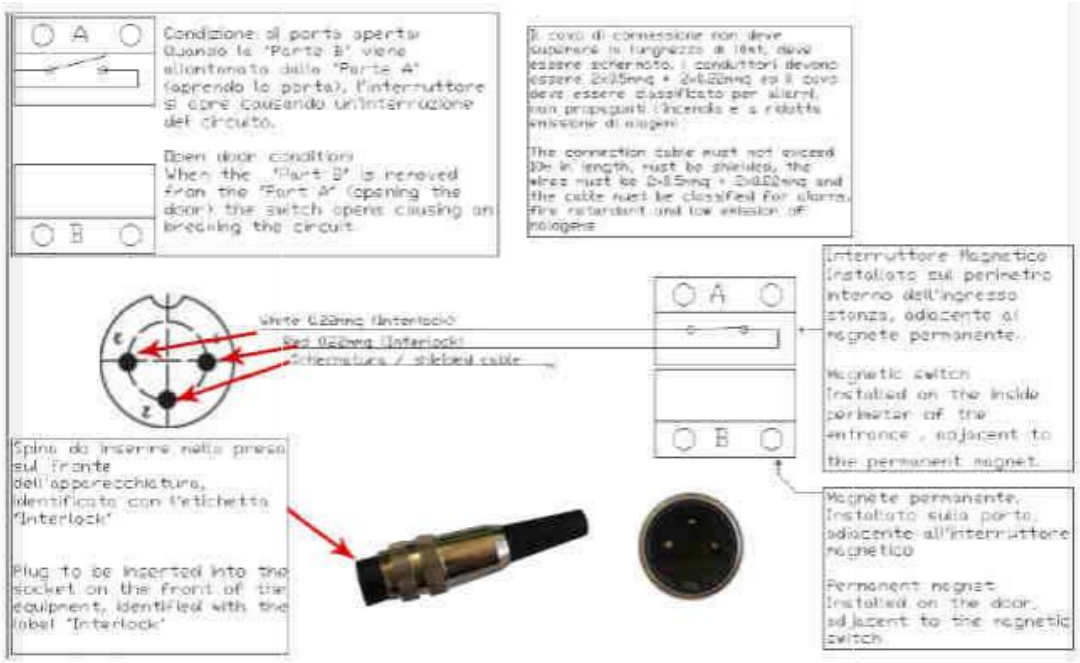
Figura 1

2.1 CONNECTION OF THE INTERLOCK DEVICE

The interlock device is a safety system, which stops laser emission whenever the door into the room where treatment is being carried out is opened. It is compulsory to connect the interlock device appropriately.

The interlock plug to be inserted into the relative socket on the laser equipment is supplied together with the laser equipment. Correct installation of the interlock device entails inserting the plug of the interlock device into the interlock socket on the equipment, as shown in the figure below. The interlock device consists of a plug connected through two electric cables (or single two-core cable with insulated wires) to a normally closed switch, which will be placed on the entrance door. The interlock device plug must be connected to the interlock socket, the two cables must be normal electric cables and the normally closed switch must be an electromagnetic, optical or mechanical circuit breaker with specifications 12 Vdc and 10mA. LEVEL S.r.l. may supply the complete interlock device kit upon request by the customer. Triggering of the interlock device due to unexpected opening of the entrance door to the room stops the equipment, which will remain in this state even after the door is closed. It is necessary for the operator to restart the device in accordance with the switching-on instructions given in the following sections.

IT IS COMPULSORY FOR THE INTERLOCK SAFETY DEVICE PLUG TO BE CONNECTED BEFORE SWITCHING ON THE DEVICE



3 METHOD OF USE

BEFORE PROCEEDING, CHECK THAT THE DEVICE IS INTACT

3.1 SWITCHING ON THE DEVICE AND SELF-DIAGNOSIS

After having inserted the key in the master switch and turned it, the display lights up and the "LEVEL" logo appears. The LUX-WAVE laser now starts self-diagnosis, during which the essential parts of the device are tested and checked for correct operation. Should there be any malfunction in even just one of these stages, the device will indicate the problem and will not allow any treatment to be started. It will therefore be impossible to use a piece of equipment that cannot guarantee absolute reliability and safety.

IF AN ALARM SIGNAL IS TRIGGERED DURING THE SELF-DIAGNOSIS STAGE, IT IS MANDATORY TO SWITCH OFF THE DEVICE IMMEDIATELY AND CONTACT THE AFTER-SALES SERVICE CENTRE

Being medical electrical equipment, special attention has been paid to dependability and the possibility of easily identifying any malfunction. Every time LUX-WAVE is switched on, it therefore carries out a self-diagnosis procedure during which correct operation of all the main subsystems is tested. If any malfunction in any one of these stages occurs, LUX-WAVE will stop the procedure and a display page while at the same time audible signals are emitted and the detected error is shown on the display. It is therefore impossible to use an appliance that cannot guarantee absolute reliability and safety.

More commonly, upon completion of all the test stages, the main menu will appear on the display:

Figure 1

3.2 DEVICE SETTINGS

Upon clicking the setup key, the software will present the display page showing the possible adjustments and settings.
Each time the touchscreen is touched, the display highlights in green the selection made, activating the software so that it presents the display page related to the activity to be accessed. The following menu appears:

Figure 2

Click on the sun-shaped cursor to adjust screen brightness, ranging from low to high.
Changing the language is really simple, just click on the corresponding flag.
Two versions of software are available: ENGLISH/ITALIAN/SPANISH or GERMAN/FRENCH/PORTUGUESE
The boxes below the flags show the software version installed on the device and the firmware version of the touchscreen.
In this screen it is also possible to deactivate the acoustic signal emitted by the device during the emission of the therapeutic laser beam by clicking on the loudspeaker symbol
To return to the main menu, touch the relative key bottom right.

ALWAYS REMEMBER TO WEAR PROTECTIVE EYEWEAR DURING EMISSION OF THE LASER BEAM

3.3 MOTOR MOVIMENT

The device is delivered closed inside the packaging. After removing the packaging, the arm of the device must therefore be opened.
To do this, it is necessary to enter the menu for motor adjustment.

Figure 3

To access this menu, click on the second icon from the left - depicting a motor - and wait for the display page below to appear.

Figure 4

The pictorial menu makes it easy to distinguish the various functions:
Simply click on the open laser figure to activate the function that will open the arm, and on the closed laser figure to close it. The same applies to raising and lowering the column, which in turn raises and lowers the arm. Being a touchscreen, movement stops as soon as your finger is lifted from the display. In this way all possible positions can be achieved so that treatments can be carried out in every possible position.
Having found the optimum position of the device (there should always be approx. 30cm between the part to be treated and the laser beam point of exit), then decide whether to operate using a pre-set treatment or using the manual mode. The various functions are described in the following sections.

ALWAYS REMEMBER TO WEAR THE PROTECTIVE EYEWEAR WHEN EMITTING THE LASER BEAM

3.4 INFORMATION ON THE DEVICE

Information regarding the version of software can be found, as indicated previously, in the settings menu reached from the main menu.
It will display:

Figure 5

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.

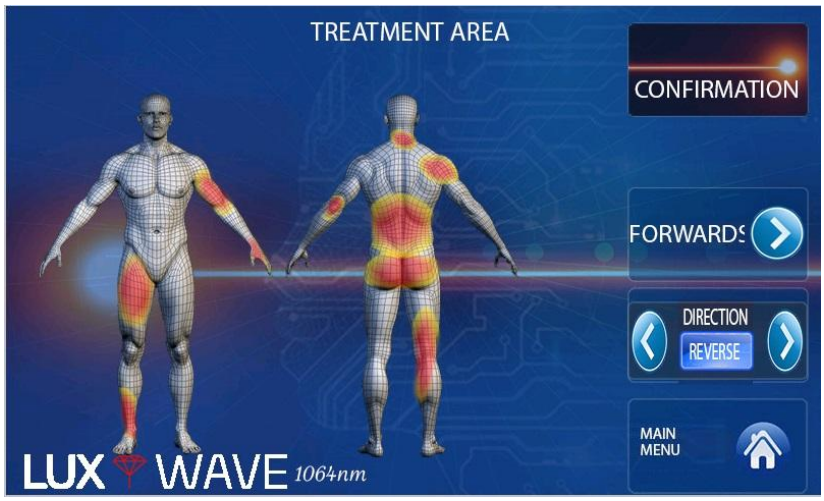


Figure 6

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.

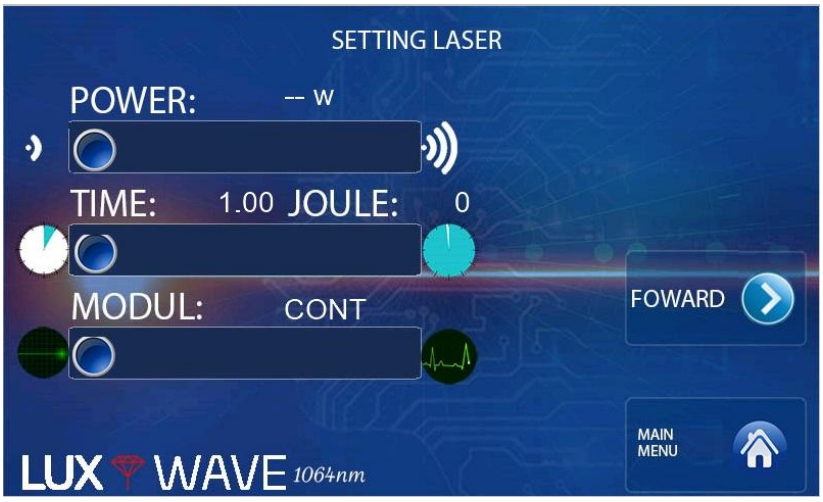


Figure 7

The emission parameters that can be adjusted are:

- Power: by pressing the icons at the end of the POWER bar, or by directly dragging the bar cursor to the right or left, you can adjust the emission power up to a maximum of 10 W. If no power value is set for and the FORWARD icon is pressed, the warning NO LASER SET will appear on the screen.

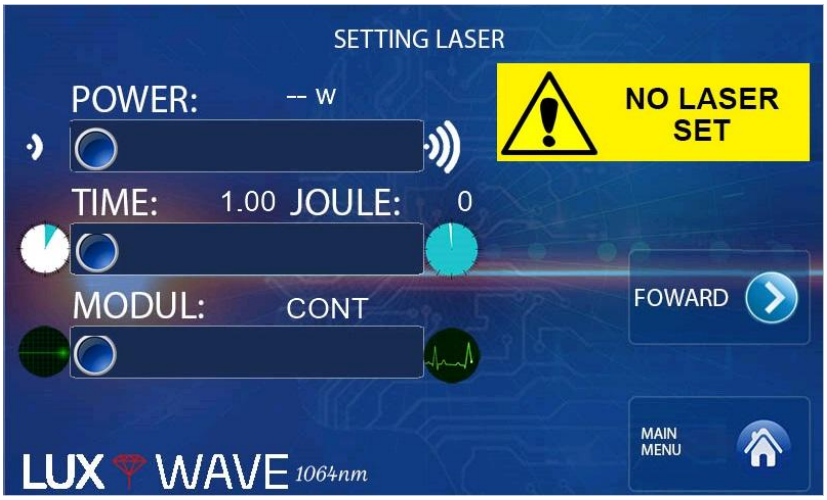


Figure 8

To continue, therefore, set the power values for laser sources

- Time: By pressing the icons at the end of the TIME bar, or by directly dragging the bar cursor to the right or left, you can set the emission duration for a maximum time is 20 minutes. The counting starts at the same time as the therapy is started. Depending on the set power value, the software will automatically calculate the energy that will be delivered during the therapy as the duration changes.
- Frequency: It is possible to operate the laser source in CONTINUOUS or PULSED mode at the set frequency with fixed duty-cycle at 50% of the period. To have "continuous" operation the cursor on the MODULATION bar must be all the way to the left, dragging it to the right instead switches to the pulsed mode starting from the frequency value of 1 Hz up to the maximum frequency of 10KHz when the cursor is all the way to the 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 the parameters have been set, pressing the FORWARD icon takes you to the motor 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 keeping a distance of 30 cm

Figure 9

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

3.6 SCANNING ADJUSTMENT

THE OPERATOR AND THE PATIENT MUST BE WEARING THE PROTECTIVE EYEWEAR PROVIDED BEFORE STARTING EMISSION OF THE LASER BEAM OR THE POINTER (ALSO EMITTED DURING SCANNING ADJUSTMENT)

From the SCAN AJUSTMENT screen, it is possible to change the size of the scanning area detected by the laser guide beam and reverse the scanning direction

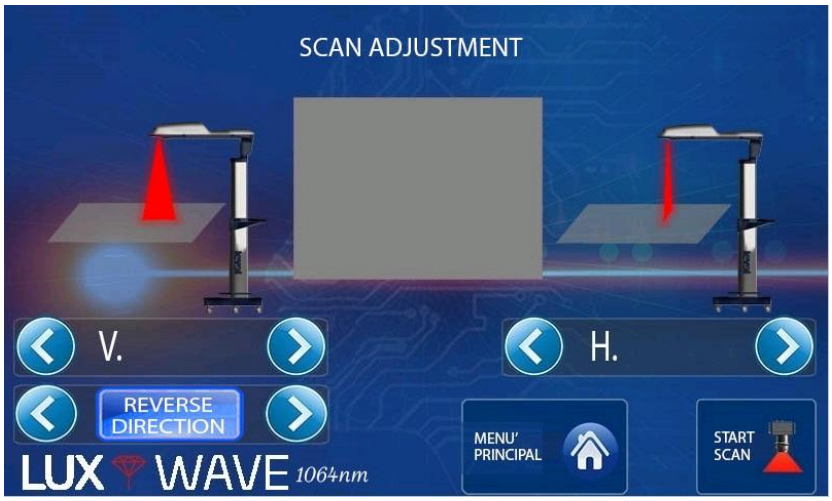


Figure 10

Acting on the arrow icons in the V. and H. fields changes the scanning area along the horizontal and vertical directions respectively
Acting on the arrows in the REVERSE DIRECTION field reverses the direction of scanning from the horizontal to the vertical axis and vice versa. In this screen it is also still possible to adjust the angle of the laser output by acting on the RIGHT and LEFT icons
To confirm the set settings and move on to the next screen, press the START SCAN icon, which gives access to the summary screen of all settings and from which it is possible to give consent to start therapy.

Figure 11

This screen is useful for checking that all parameters (power, emission mode and scanning area) have been entered correctly before starting therapy, and allows these settings to be saved as a therapy programme for performing the same type of therapy in the future without the need to reset the various parameters again. The screen displays a alert WARNING TO WEAR PROTECTION GLASSES (mandatory for patient and operator).

If you choose to save the therapy, press the SAVE icon , this will take you to the PROGRAMMES IN MEMORY screen where you can save up to 40 therapy programmes.

To save the therapy choose one of the 40 available positions by pressing on the arrow-shaped icons until the desired position is reached (by default the first position is set) and press the SAVE icon to access the virtual keyboard for typing the name to be assigned to the therapy being saved.

Figure 12

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

Figure 13

3.7 STARTING THE TREATMENT

Pressing START on the settings summary screen starts the therapy and the THERAPY IN PROGRESS screen appears.

Figure 14

This displays the set parameters and the time countdown to the end of emission, and it is possible to select the desired scanning speed from the four available by pressing the icons marked by the numbers 1 to 4 (speed 1 is selected by default).

At any time it is possible to pause the therapy and thus interrupt the emission by clicking on the corresponding icon; the countdowns are blocked and the message THERAPY IN PAUSE will appear from which it is then possible to resume the therapy or to abandon it definitively by returning to the main menu and switching off the guide beam, by pressing the RESUME or LEAVE icons respectively

Figure 15

It is also possible to permanently and emergency stop, with return to the main menu screen, the therapy in progress by pressing the STOP icon

STOP THE TREATMENT AT ANY TIME BY PRESSING THE EMERGENCY STOP BUTTON. AFTER THIS ACTION THE OPERATOR NEEDS TO RESTART THE DEVICE

The therapy will also be automatically paused when the access door to which the INTERLOCK device is connected is opened, and the following screen will be displayed to warn of the opening.

Figure 16

To resume therapy, close the door and press the RESUME icon.
The following controls are active during the duration of the broadcast:

- Interlock safety device: if the door is opened, emission is interrupted. Once the door is closed again, the operator must intervene manually to resume therapy.
- Galvanometer status check: if a fault occurs in the galvanometers (which control the scanning of the laser beam), emission is interrupted and an error message is displayed on the screen. Contact the manufacturer for Technical Service.
- Temperature control of the laser source: if the maximum temperature is exceeded, emission is interrupted. Contact the manufacturer for Technical Service.
- Checking the emission power: If the emission power differs by more than 20 % from the set value, emission is stopped. Contact the manufacturer for Technical Service.

SMOKE, FUMES OR VAPOURS PRODUCED BY THE BEAM MAY CONTAIN PARTICLES OF VITAL TISSUE

3.8 PROGRAM MODE

Selecting the PROGRAM mode from the main menu takes you to the following screen where you can view previously stored therapies and their emission characteristics.

Figure 17

To scroll through the memorised therapies, press the arrows until the therapy you wish to start is displayed and confirm it by pressing the START icon; you will then have direct access to the ARM AND HEAD ADJUSTMENT screen of the manual mode (figure 9) from which you can continue as illustrated above
To delete a stored therapy, display it using the arrows and press the DELETE icon

3.9 REPORTING WARNINGS AND ERRORS

- OVERHEATING WARNING

This warning may appear during the execution of a therapy and indicates overheating of the laser sources, which may be due to an excessively high ambient temperature or a malfunction of the laser source cooling system, 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.

Figure 18

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 the main menu screen by pressing the relevant icon, if it occurs during therapy execution the laser emission will be automatically interrupted and it will be necessary to return to the main menu screen by pressing the STOP icon.

Figure 19

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 LUX WAVWS device for the execution of a new therapy; if, on the other hand, the malfunction is permanent, the pop-up ERROR CONTACT TECHNICAL 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

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

Figure 20

4 MAINTENANCE

ALWAYS CHECK THAT THE DEVICE IS DISCONNECTED FROM THE MAINS ELECTRICITY SUPPLY BEFORE CARRYING OUT ANY OPERATION DESCRIBED BELOW

DO NOT DIRECT THE LASER BEAM TOWARDS EYES OR THE THYROID GLAND

If correctly maintained and used, the working life of the device is 10 years

4.1 ROUTINE MAINTENANCE AND CLEANING

LUX-WAVE requires no special maintenance. To guarantee equipment efficiency, make sure that the air intakes under the base of the device are free from dust/objects that could hinder the normal flow of air and periodically clean the device.
Use a soft, dry cloth to dust LUX-WAVE. Remove stubborn marks using an aqueous soap solution or a sponge soaked in a hydroalcoholic solution. LUX-WAVE may be disinfected with all the products normally used for medical electrical equipment.
There is no flammability risk in respect of materials normally used to clean the appliance (alcohol or other detergents), given the low temperature reached by the laser emission. The device has no parts requiring sterilisation.

4.2 EXTRAORDINARY MAINTENANCE AND REPAIRS

Extraordinary maintenance consists of the six-monthly check of earth leakage currents by qualified technical personnel to ensure protection against direct and indirect contact. A periodic control should also be carried out to check and calibrate the laser emission, measuring the emission power according to the procedure described in section 3.2 "Device settings".

LUX-WAVE is fitted with a mechanical safety shutter, which stops any uncontrolled emissions of Class 4 IR laser sources (CEI EN 60825-1).
For safety reasons, it is recommended that the user has a check carried out at least once a year, sending the equipment to LEVEL S.r.l. for maintenance of the shutter. This will ensure trouble-free operation of the device.

In the event of malfunction, carry out the following controls:

- check the connection to the mains power socket;
- make sure that the equipment is operating in a room with ambient temperature below 28°C;
- check that the key has been inserted correctly into the safety switch;
- check the connection of the interlock plug;
- check the state of the fuses and if necessary replace them;
- check that all actions have been performed correctly.

If the problem persists, call the Service Centre.

4.3 SERVICING

Whenever the appliance needs servicing, it is necessary to obtain authorisation from us before sending the product to our Service Centre. You are therefore kindly requested to contact our offices or your nearest authorised centre (see the list on our website www.level-laser.com) and to fill in the servicing request form.
For safety reasons and to maintain the characteristics of the products also after work carried out on them, unless otherwise indicated by LEVEL S.r.l., the latter has sole and exclusive rights to service its products. Only after having obtained company authorisation and only after suitable training has been given to maintenance personnel may technical documentation regarding repairable parts be supplied.
Please note: products must be sanitised before sending them for servicing so as to protect the health of personnel providing the service.

4.4 FUSE REPLACEMENT

To replace the fuses, follow the instructions given below.

- Switch off the equipment and pull the plug out of the mains power socket.
- Remove the fuse tray located in the mains power socket, pulling back the relative tab.
- Replace the fuses, using the spare ones provided with the equipment.
- Re-insert the fuse tray.
- Restart the system.

5 DISPOSAL

Do not dispose of this product or its accessories as general waste. Prepare the product for recycling or for separated collection in accordance with the relevant legislation in the country of use, in Implementation of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

In the case of use in hospital structures, comply with the internal rules on disposal of electrical and electronic waste.

6 SPECIFICATIONS

Main Supply	230 Vac; 1.1 A Max.; 50 Hz
Absorbed current	0.8 A Max.
Motors	2 (Stand up/down,Tilt)
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
Ideal distance from laser source to treatment surface	**From 30 to 40 cm**
Scanning area size (max)	**X = 14 cm - Y = 18 cm**

Terapeutic laser beam	
Diode	GaAlAs CW
Wavelength	808 nm (Code 10LS27) or 1064nm (Code 10LS26)
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%
Pointer	
Power	<3 mW

Wavelength	635 nm
DNRO (Nominal Ocular Risk Distance)	12.44 m ± 20%
Spot dimensions	2x2 mm ± 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 LABELLING

7.1 SAFETY LABELS

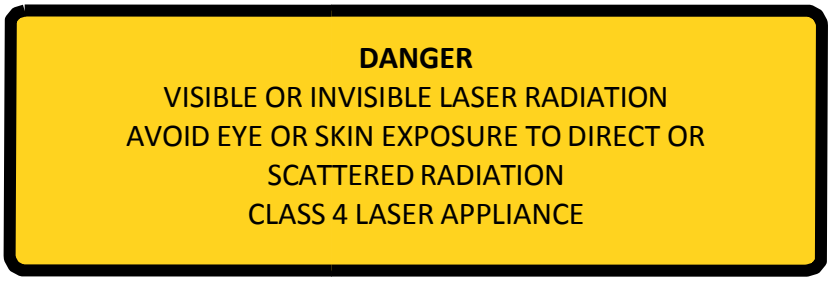
LABELLING PLAN

7.1.1 LABEL 1

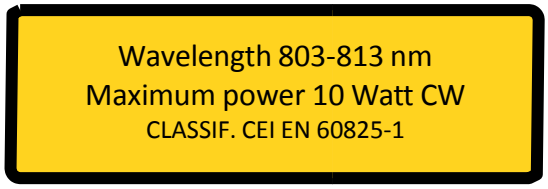
Warning sign – Laser radiation hazard

7.1.2 LABEL 2

7.1.3 LABEL 3



7.1.4 LABEL 4 ONLY ON 808NM VERSION (PRODUCT CODE 10LS27)



7.1.5 LABEL 5 ONLY ON 1064NM VERSION (PRODUCT CODE 10LS26)

7.1.6 LABEL 6

Wavelength 635 nm
Maximum power 3 mW CW

7.1.7 LABEL 7

Classif. CEI EN 60825-1 2009-07

7.1.8 LABEL 8

Around the mushroom-head emergency button.

7.1.9 LABEL 9

DANGER - CLASS 4 VISIBLE OR INVISIBLE
LASER RADIATION WHEN OPEN
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION

7.1.10 LABEL 10

INTERLOCK
WARNING LIGHT

7.1.11 LABEL 11

230 V AC 50 HZ

7.1.12 LABEL 12

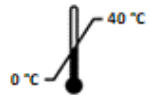
FUSE 2 X T 4 A

7.2 LABEL AFFIXED ON DEVICE

Version 808nm Product code 10LS27

Version 1064nm Product code 10LS26

7.3 IDENTIFICATION OF SYMBOLS USED

	Identification of the Manufacturer
	Product identification code
	Serial number
	Warning, refer to the User's Manual. Safety information
	Consult the User's Manual
	Year of manufacture
	Disposal in accordance with WEEE regulations
	Environmental operating temperature
 1370	The 4-digit code indicates the certification body of the 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.			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m EN 60601-1-2 Test level	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** $d = 1.2 \times P\sqrt{}$ 80 MHz to 800MHz

Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V EN 60601-1-2 Test level	$d = 2.3\times\sqrt{P}$ 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: 
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.			
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**
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.			

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		

9 APPENDICES

9.1 APPENDIX A – PROTECTIVE EYEWEAR TO BE USED

As indicated in the warnings in section 1.4 of this manual, it is compulsory to put on protective eyewear before starting the treatment. Before any emission, the software brings up a message that protective eyewear must be worn. Only use the eyewear provided: one for the operator of the device and one for the patient.

If either of the two pairs of glasses is damaged, replace with an equivalent pair.

The technical details of the preferred eyewear to be used are shown below.

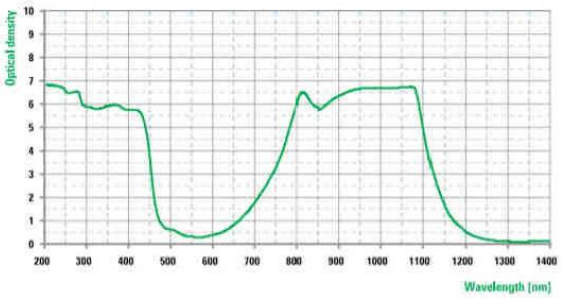
This protective eyewear provides adequate protection for our wavelengths.

If it is necessary to replace the eyewear, check the filter code and in particular the lens response.

The datasheet of the model we use is given below. Use this datasheet in the event of purchasing a replacement model. IT IS IMPORTANT THAT THE EYEWEAR HAS THE SAME CHARACTERISTICS AS THOSE GIVEN ON THE NEXT PAGE.

FILTER CODE: **UL-1005**

Filter	Full protection
Colour	Green
Material	Polycarbonate
VLT	42%
Alignement laser wavelength T%(λ) >10%	470-650 nm



Wavelength		OD	561	562	559G
			○ 561H.00.00.309 ● 561H.00.01.309	○ 562H.00.00.309 ● 562H.00.01.309	559G.00.00.309
190	315	5	D LB5 IR LB3	D LB5 IR LB3	D LB5 IR LB3
315	430	5	DIR LB5	DIR LB5	DIR LB5
750	1100	3	DIR LB3	DIR LB3	DIR LB3
775	1100	4	DIR LB4	DIR LB4	DIR LB4
790	1090	5	DIR LB5	DIR LB5	DIR LB5
920	1075	6	DIR LB6 M LB6Y	DIR LB6 M LB6Y	DIR LB6 M LB6Y
1000	1070	7	D LB6 IR LB7 M LB7Y	D LB6 IR LB7 M LB7Y	D LB6 IR LB7 M LB7Y
1030	1065	8	D LB6 IR LB8 M LB7Y	D LB6 IR LB7 M LB7Y	D LB6 IR LB8 M LB7Y
10600		6	DI LB4	DI LB4	DI LB4

Wavelength		OD	546	5X7
			546L.00.10.551	5X7L.00.00.651
745	1115	3	DIR LB3	DIR LB3
770	1100	4	DIR LB4	DIR LB4
785	1085	5	DIR LB5	DIR LB5
800	825	6	DIR LB6	DIR LB6
885	1075	6	DIR LB6	DIR LB6
1000	1070	7	D LB6 IR LB7 M LB7Y	D LB6 IR LB7 M LB7Y
1030	1065	8	D LB6 IR LB8 M LB7Y	D LB6 IR LB8 M LB7Y
9000	11000	6	DI LB4	DI LB4