

EMIE[®]

ITALY

CRYSTAL YAG



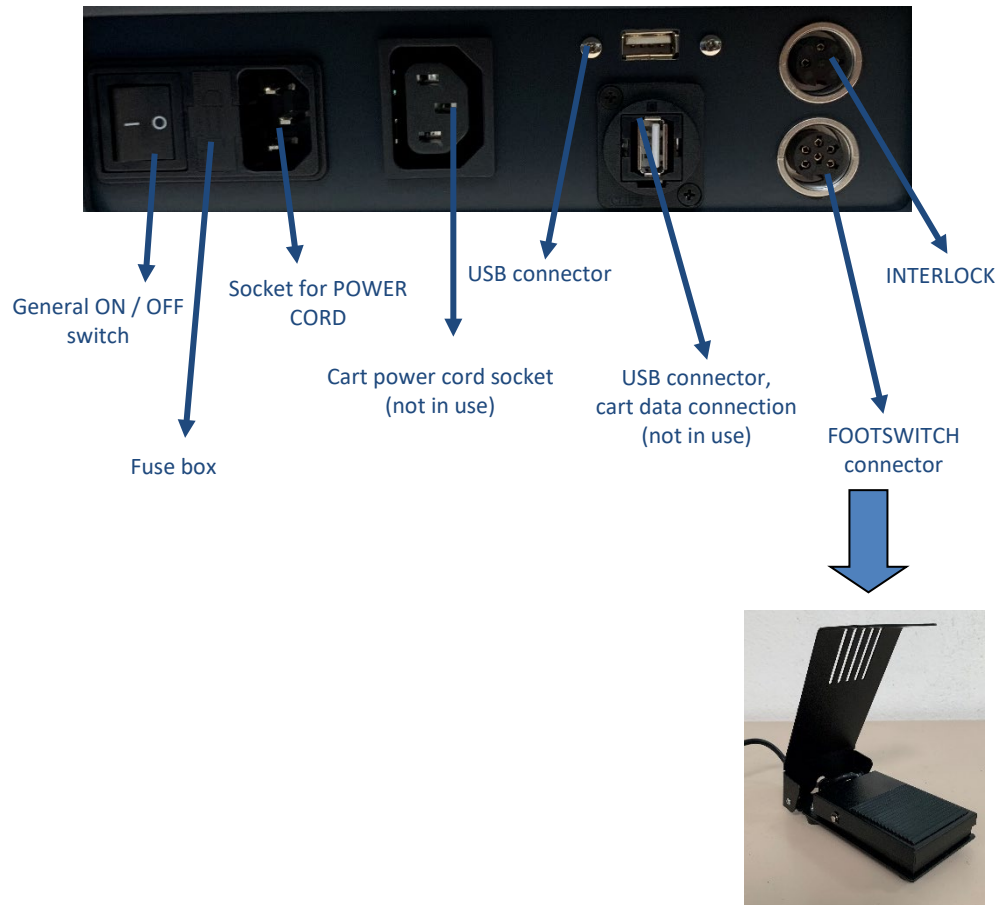
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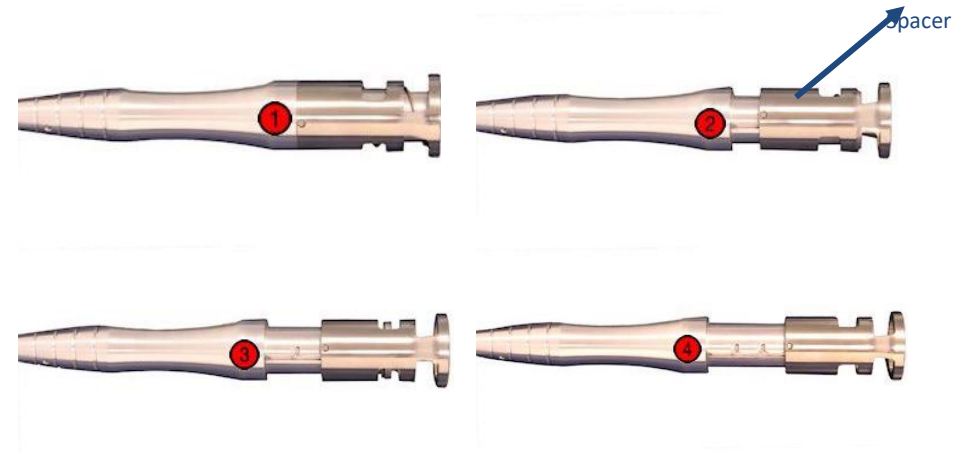
CE 1936



REAR PANEL



QUADRIFOCAL DEFOCUSSED LASER PROBE IN OPTICAL FIBER (4 positions)



The spacer is the final part of the handpiece, the one in contact with the patient. To change the size of the spot just pull and rotate the spacer until it fits into one of the three possible clicks.

Diameter of the spot incident on the skin of the treated patient	Position n. 01 (contact)	10mm
	Position n.02	15mm
	Position n.03	20mm
	Position n. 04	25mm
Area dello spot incidente sulla pelle del paziente trattato	Position n. 01 (a contatto)	0.78 cm ²
	Posizione n.02	1.76 cm ²
	Position n. 03	3.14 cm ²
	Position n.04	4.90 cm ²

HOW TO USE THE DEVICE

This chapter provides important information on the correct use of CRYSTAL YAG high power laser therapy devices.

All the control functions and the entire functional set-up of the machine are managed and coordinated by a microprocessor: in addition to the task of making the application programs already stored available, it allows an optimal and safe use of the device in a personalized way.

The dialogue interface with the user is carried out by a large and clear backlit liquid crystal graphic display (LCD): it displays all the operational messages of interest to the operator, the functional status of the machine during normal therapeutic activity, any error messages.

The following paragraphs illustrate the operations that must be carried out by the operator to make the most of the potential and technical peculiarities of the CRYSTAL YAG equipment.

The different options are covered, from the selection of a pre-stored program for setting a specific therapy, to the determination of the correct working parameters for a "customized" application.

OPERATION

CRYSTAL YAG can work in CONTINUOUS mode, emitting a power up to 18W (9W), or in PULSED DUTY CYCLE mode.

The delivered power is conveyed using the OPTICAL FIBER which guarantees high efficacy and full handling of application.

One of the peculiar characteristics of the CRYSTAL YAG is represented by the HANDPIECE. It is a special device that allows you to defocus the beam to have the possibility of acting on portions of fabric of different sizes, from 0.78 cm² to 4.90 cm².

This special HANDPIECE therefore allows to have a greater and more specific range of action based on the anatomical area to be treated.

The operator has the ability to select the value of the treatment parameters according to their needs.

The stored programs proposed are the result of the operational experience gained over years of support from professionally experienced users and will be useful as a guiding suggestion for starting treatment. The ability to modify the parameters according to

the operator's needs guarantees versatility of use which is essential in medical contexts.

Once the window relating to the chosen work program appears on the display, you can go directly to its execution simply by pressing the START key and following the procedure described in this manual.

CRYSTAL YAG gives the possibility to save personalized programs and patient cards in the memory support called USER MEMORY in which both personalized protocols and patient cards can be stored.

The standard therapeutic suggestion protocols are saved in an additional fixed internal memory of the machine. This memory is not manageable by the user, the data cannot be deleted or formatted, to make any changes made available, they must be stored on one of the alternative media by creating a customized protocol.

PATIENT PREPARATION

Before applying laser therapy, the patient's skin must first be prepared. This will allow the laser light to reach the targeted areas better and reduce the risk of skin irritation.

To prepare the patient's skin for therapy, do the following:

1. Thoroughly wash the skin on which you intend to place the laser head with soap and water or clean with alcohol.
2. Dry the skin well.

FREE PROCEDURE

By pressing the FREE PROCEDURE button, a screen appears (fig. 3) in which you can:

- modify the processing data, proceeding as indicated in MODIFICATION;
- save any modified parameters proceeding as indicated in SAVE;
- upload a personalized treatment as indicated in CHARGE;
- start the treatment, following the START procedure.

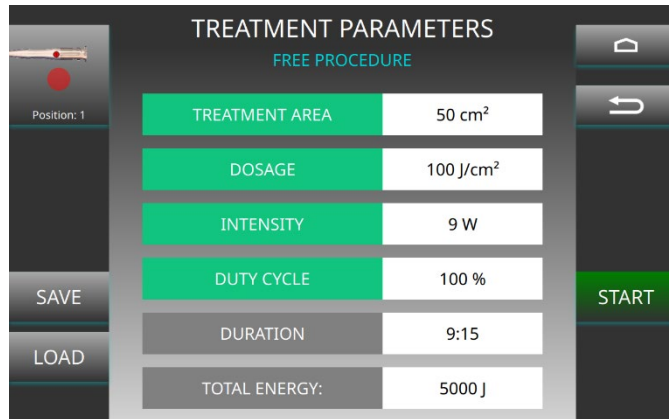


fig. 3

MODIFY

In this section it is possible to modify the treatment parameter values set by default in the machine in order to create customized programs.

1. Click on the parameter to be modified, the modification screen appears showing the name of the parameter to be modified and it is possible to increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the value is reached desired;
2. For the **TREATMENT AREA** (cm²) parameter, increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (figure 4). It is possible to vary the TREATMENT AREA parameter between 1 and 200.
 - o Click on **CONFIRM** (green tick) to save the parameter set value and return to the main screen;
 - o Click **BACK** (gray x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

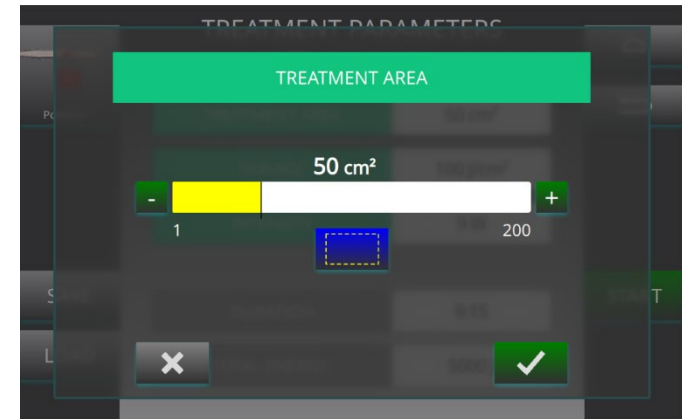


fig4

3. For the **DOSING** (J / cm²) parameter, increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (figure 5).
 - o Click on **CONFIRM** (green tick) to save the parameter set value and return to the main screen;
 - o Click **BACK** (gray x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

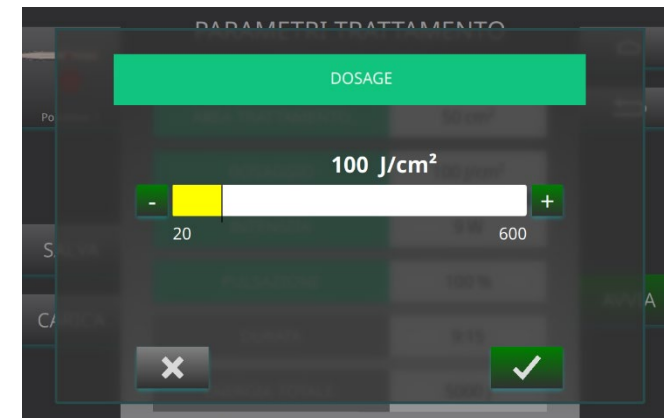


fig. 5

4. For the **INTENSITY** (W) parameter, increase or decrease the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached (Figure 6). It is possible to vary the INTENSITY parameter between 0.2W and 18W for CRYSTAL YAG and between 0.2W and 9W for CRYSTAL YAG SP.

- Click on **CONFIRM** (green tick) to save the parameter set value and return to the main screen;
- Click **BACK** (gray x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

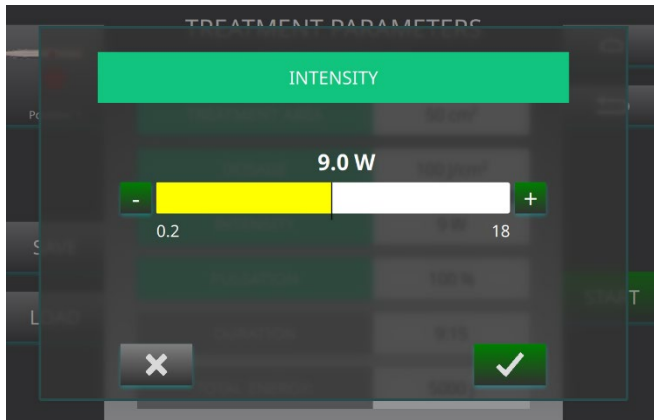


fig. 6

- For the **PULSATION** parameter it is necessary to set the PULSATION WORK CYCLE (%) and PULSATION FREQUENCY (Hz) parameters by increasing or decreasing the value using the + or - buttons or by scrolling the cursor to the right or left until the desired value is reached. (figure 7).
 - Click on **CONFIRM** (green tick) to save the parameter set value and return to the main screen;
 - Click **BACK** (gray x) to cancel the parameter modification operation, you return to the main screen without having made any changes.

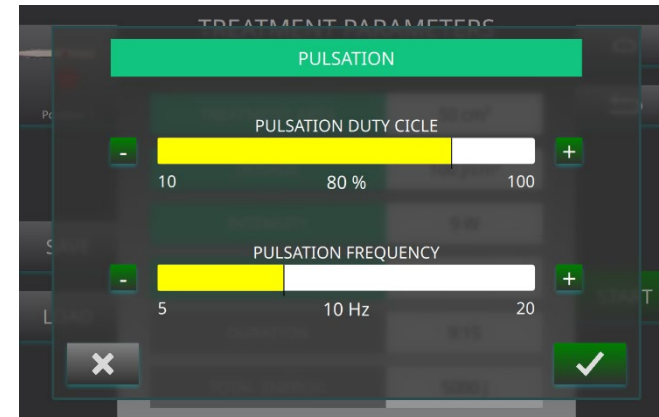


fig. 7

- Click on the image of the handpiece to select the spot area: POS1 - 0.78 cm², POS2 - 1.76 cm², POS3 - 3.14 cm², POS4 - 4.90 cm². Each press changes the spot size.

- Check that the spot area set is the same as that set in the handpiece.

The DURATION and TOTAL ENERGY parameters are parameters that cannot be directly modified but vary directly as the other parameters vary:

- DURATION varies depending on the TREATMENT AREA, DOSE and INTENSITY;
- TOTAL ENERGY varies according to the TREATMENT AREA and DOSE;

SAVE

To save any changes made to the parameters and store a personalized therapy program:

- Click the **SAVE** button;

NB: It is possible to save the protocols only in the INTERNAL MEMORY of the machine. It is not possible to store personalized treatments on the USB.

- Enter the name to be assigned to the created therapy program on the virtual keyboard;
- Click on CONFIRM (green check) to continue with the program saving operation;
 - Otherwise, click on BACK (gray x) to cancel saving the therapy program, the screen with the modified treatment parameters will reappear;
- To start the saved customized program proceed as described in the START section.

Allows you to modify and save the general basic settings in the internal memory which will be automatically recalled each time the machine is turned on.

By pressing the **SETTINGS** button , a screen appears in which you can select:

– LANGUAGE

By pressing the LANGUAGE button you can select the language settings of the machine.

To select the desired language:

1. Click directly on the flag representing the language of interest and press CONFIRM;

The selected language will be automatically enabled: all machine messages and commands will be displayed in the chosen language.

– DATE / TIME

By selecting the DATE / TIME button you can adjust the date and time of the machine:

1. Press the “+” or “-” buttons to set the day, month, year, hours and minutes. Then press SET DATE / TIME to confirm.

– SOUND

By selecting the SOUND button you can change the volume of the machine sounds (screen touch sound, system sounds, treatment sounds).

HISTORICAL

The historical section shows a list of all the treatments carried out with the machine, identifying the date and time.

DEVICE MAINTENANCE

In this section it is possible to change some settings of the machine by pressing on GENERAL or to access information on the maintenance of the CRYSTAL YAG using the LASER MAINTENANCE key

Pressing the GENERAL key is possible:

- MODIFY THE ACCESS PASSWORD;

To change the access code proceed as follows:

1. Click on the CHANGE PASSWORD button;
2. Enter the current password using the numeric keypad on the screen and click confirm (green tick);
3. Type the new access password and click confirm (green tick);
4. To confirm the new password, enter it for the second time and click confirm (green tick).

The insertion of the new password will be confirmed on the screen with the message "PASSWORD CHANGED".

- RESET THE FACTORY SETTINGS:

This function allows you to restore all the values bringing them to the default ones present in the device at the time of purchase.

Furthermore, all customizations performed including patient records and customized protocols will be deleted.

To access this section, enter the access password.

The password has been set by default to 12345: to enter it, simply press the 5 numeric buttons in sequence and then the OK button.

By pressing the LASER MAINTENANCE button it is possible to view:

- The type of source mounted in the device;
- The serial number of the laser box
- The operating time of each laser source (one or two) mounted on the device

The RESET TIME or LASER CALIBRTION keys require the entry of a password and are only for authorized technical personnel.

TECHNICAL FEATURES

Mains power supply of the machine	230 Vac, 50-60 Hz, ±10%	
	115 Vac, 50-60 Hz, ±10% *	
Maximum power absorbed by the network	115 VA	
Double delayed protection fuse on the network (T)	230 Vac	1 A-T
	115 Vac	2 A-T
Socket for Interlock / Safety key (normally closed contacts)	Pres a DIN a 3 Contatti	
Backlit LCD display, for viewing ed control of operating parameters	Graphic color display 10.1" TOUCH SCREEN	
Configuring the laser handpiece:	Laser emission transmission via optical fiber (320 µm)	
	Defocused	
	Integral connection to the machine	
Source type	diode	
Emission wavelength of the laser source	1064 nm	
Nominal power	20 W	
Maximum power delivered	CRYSTAL YAG	18 W max ±20%
	CRYSTAL YAG SP	9W± 20%
Laser power delivered by the machine	CRYSTAL YAG	0.2W – 18W
	CRYSTAL YAG SP	0.1W - 9W
Pulse rate programmable	(10 – 1000) Hz	
Laser risk classification according to the standard EN 60825-1	4	
Numerical opening of the source	0.22	
Divergence	25.4°	
DNRO (direct light)	2.61 m	
Limit MPE	50 W/m ²	
Accessible issue	34,2 kW/ m2	
DO (Optical density)	2,8 (0,1 m of distance)	
Adjustable pulsed (Duty cycle)	(10-100) %	
Adjustable pulsed (Frequency)	5-20Hz	

Programmable treatment time	(1÷30) minutes	
Command of implementation of the treatment	Via protected footswitch	
Emission	CONTINUE and PULSED	
Output channels	1	
Diameter of the spot incident on the skin of the treated patient	Position n.01 (in contact)	10mm
	Position n.02	15mm
	Position n.03	20mm
	Position n.04	25mm
Area of the spot incident on the skin of the treated patient	Position n.01 (in contact)	0.78 cm ²
	Position n.02	1.76 cm ²
	Position n.03	3.14 cm ²
	Position n.04	4.90 cm ²
Classification according to directive 93/42 / EEC	II B	
Insulation class / applied parts according to EN 60601-1 standard	I / BF	
Degree of protection from the ingress of liquids according to the EN 60601-1 standard	IPX0	
Therapeutic suggestions can be stored in user memory	200	
Patient cards can be stored in the user memory	200	
Type of container	Table configuration	
External dimensions (Width x Height x Depth)	41x35x19 cm	
Machine body weight	7,5 Kg	
Terms of use	room temperature	(+10 : +35) °C
	relative humidity	(10 : 80) % without condensation
Storage / transport conditions	room temperature	(-40 : +70) °C
	relative humidity	(10 : 100) % senza condensa
	Atmospheric pressure	(500 : 1060) hPa

*The nominal voltage at 115Vac does not cover European countries.

DICHIARAZIONE DI
CONFORMITÀ ALLA
DIRETTIVA 93/42/CEE
SUI DISPOSITIVI MEDICI

EME
ITALY

Aesthetic & Medical Technologies

DECLARATION OF
CONFORMITY TO THE
93/42/CEE DIRECTIVE
ON MEDICAL DEVICES

Il Fabbricante / *The manufacturer*

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

**dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :**

Apparecchiature per laser terapia /
Equipment for laser therapy :

CRYSTAL YAG

è conforme ai requisiti essenziali della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche
(Allegato I), recepita in Italia con

D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche,
e la classe di rischio è la IIb secondo la regola 9.

*is in compliance with the essential requirements of 93/42/CEE Directive and the following integrations and
modifications (Annex I, implemented in Italy
following the D.L. N° 46 directive issued on 24 february 1997,
and the risk class is IIb according to the rule 9.*

Certificato n. HD 60139851 / Certificate n. HD 60139851

Allegato II escluso punto 4 / *Annex II except point 4*

La macchina è marcata / *The equipment is marked:*

CE 1936

Organismo Notificato / *Notified Body*
TÜV Rheinland Italia S.r.l.

Pesaro, 28/04/2020

EME srl
L' Amministratore unico / ~~Administrator~~

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