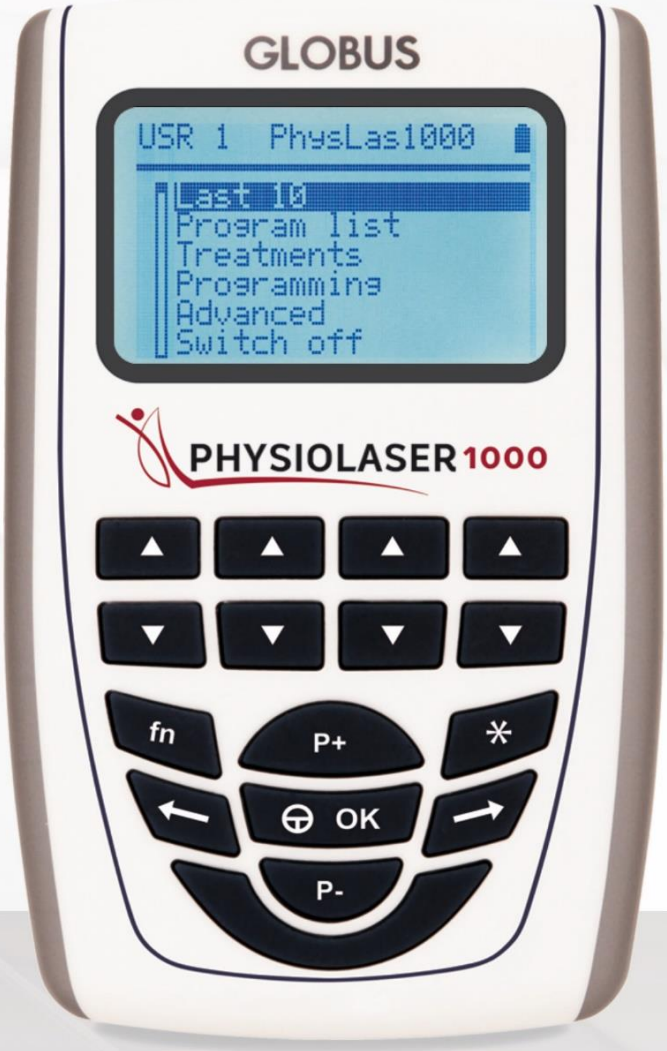
GLOBUS

ITALIAN EXCELLENCE

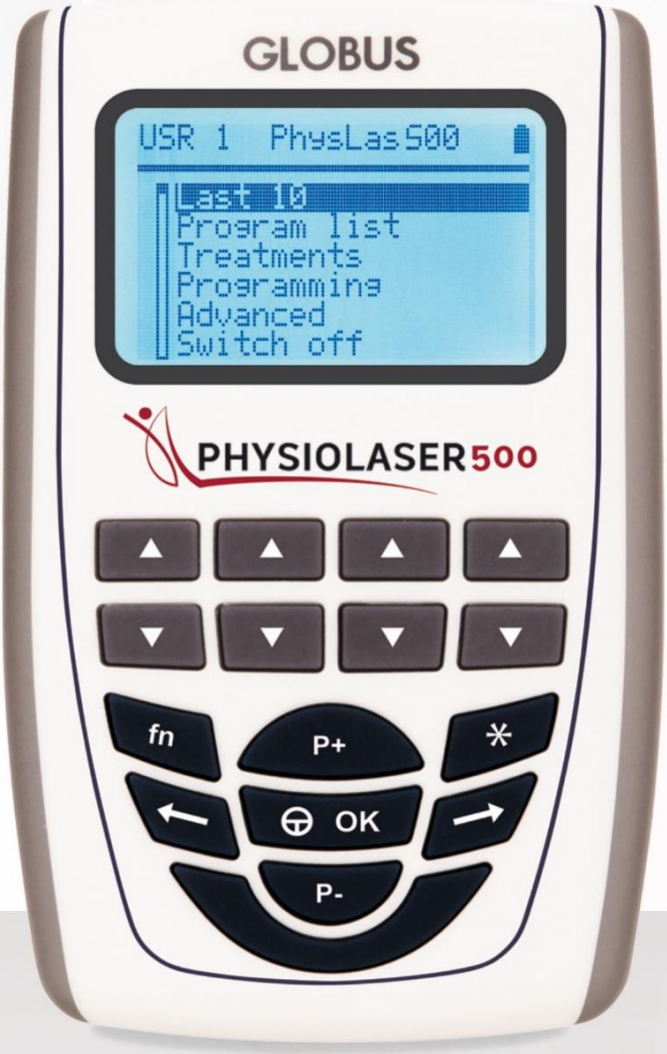
LASER THERAPY

User Manual

PHYSIOLASER 1000



PHYSIOLASER 500



CE 0476

DEAR CUSTOMER,

THANK YOU FOR CHOOSING A GLOBUS PRODUCT. WE REMAIN AT YOUR DISPOSAL FOR ANY ASSISTANCE OR ADVICE YOU MAY NEED.

DOMINO s.r.l.
via Vittorio Veneto 52
31013 - Codognè - TV - Italy
Tel. (+39) 0438.7933
Fax. (+39) 0438.793363
e-mail: info@globusitalia.com
www.globuscorporation.com

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TECHNICAL FEATURES

Device

Container	ABS Food grade
Protection level	IP20
Dimension	160 x 99 x 35.4mm
Weight	440 g
Certificates	CE MDD certificate
Laser class (CEI EN 60825-1)	IV

Laser handpiece for Physiolaser 1000 “Handpiece Green 808 nm”

Diode type	GaAlAs
Laser class (CEI EN 60825-1)	IV
Max RMS power (CEI EN 60825-1)	1 W ±20%
Optics spot dimension	11 mm – area 0,95 cm^2
Wave length	808 nm ± 10 nm
Operation	continuous (CW) and pulsed
Pulsed operation frequency	1 – 10,000Hz
Light guide wave length	660 nm 100mW (Laser Class I)
Beam divergence	0.23° with 11mm focal
NOHD	58.60m (focal 11mm, CW 0.8-1.2W)

Laser handpiece for Physiolaser 500 “Handpiece White 808 nm”

Diode type	GaAlAs
Laser class (CEI EN 60825-1)	IV
Max RMS power (CEI EN 60825-1)	0.5 W ±20%
Optics spot dimension	11 mm – area 0,95 cm^2
Wave length	808 nm ± 10 nm
Frequency	1 – 10,000Hz
Operation	continuous and pulsed
Light guide wave length	660 nm 100mW (Laser Class I)
Beam divergence	0.23° with 11mm focal
NOHD	36.95W (focal 11mm, CW 0.4-0.6W)

Power supply

Producer	GLOBTEK
Model	GTM41060-2512
PRI	100-240V~ 50-60Hz 600mA max
SEC	12V ⎓ 2.08A ⊕-◉-⊖

Battery

Battery pack	Ni-MH 7.2V 1.8Ah

Conditions of use and storage of the device

Temperature:	from 0°C to 35°C
Maximum relative humidity:	from 15% to 93%
Atmospheric pressure:	from 700 hPa to 1060 hPa
Storage and shipping temperature:	from -10°C to 45°C
Maximum relative humidity:	from 30% to 75%

INTENDED USE of the device

These laser therapy devices are used in physiotherapy and podiatry, for the treatment of pain, trauma and pathologies affecting the musculoskeletal system.
These devices are used in physiotherapy and podiatry, for applications in rehabilitation medicine, sports medicine, orthopedics in outpatient and hospital settings, in operational areas such as outpatient clinics, medical practices and rehabilitation centers.
The use of the device is permitted to doctors and physiotherapists.

DEVICE CLASSIFICATION

The device has been manufactured in compliance with applicable technical standards and has been certified, in compliance with Directive 93/42/EEC as amended by directive 2007/47 / CE on medical devices, by the Notified Body Kiwa Cermet Italia, Via Cadriano 23, 40057 Granarolo dell'Emilia (BO) Italy N° 0476, in order to ensure product safety.

Physiolaser devices are classified as:

- Class IIb equipment (Directive 93/42/EEC, Annex IX, rule 9, as amended);
- Class II with Type B applied part (Classif. EN 60601-1 and EN 60601-1-2);
- RF Emissions of Class B Group I (Classif. EN 60601-1-2);
- Laser Class 4(Classif. EN 60825-1);
- Device and accessories not subject to sterilization.
- Device not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- Device for continuous operation.
- Device not suitable for outdoor use.

SAFETY PRECAUTIONS

For maximum safety, the device must be used following the rules and the limitations of the user manual.
The manufacturer declines all responsibility with reference to a different use from what is indicated in this manual.
The full or partial reproduction in any form and by any electronic or mechanical means of the texts and/or pictures contained in this manual without the written authorization of the manufacturer is forbidden.
If the package, the cable or the connector of the power supply show signs of wear or damage, replace it instantly.
The device should be connected to the mains with its power supply. Before starting this operation, make sure that the power system complies with the directives in force within your country. Make sure that the power supply can be easily unplugged.
Ensure that the device is not misused.
Do not modify the device.
Use laser handpiece with focal optics.

Warnings before the use

Do not use this device simultaneously with other electronic devices, especially if they maintain vital functions. In case it is necessary to use the device nearby or on other devices, make sure it works properly, please refer to annex 3 and to EMC accompanying documents.
- It is recommended to read carefully the entire operating manual before using the unit; keep carefully this operating manual.
- Do not insert fingers or objects into the connection sockets between the handpiece and the device.
- Do not damage the optics lenses with blunt objects.
- Please use the device only with the laser handpiece supplied with the original equipment (see the complete list of handpieces in the Accessories section) and following the therapeutic methods described.
- Checking the integrity of the device before each use is a fundamental requirement to perform the therapy; do not use the unit if the cables or the buttons are defective or malfunctioning.
- Please use the device only if wearing protection glasses.
- Once you have turned the device on, make sure the display shows the software version and the device model: it means that the device is working and ready to be used;
If it does not show that information or does not show all the segments, turn it off and on again. If the problem persists, contact the customer care and do not use the device.

- If the device is not connected to the mains, sudden shutdown shortly after switching on could indicate a low battery. Recharge as reported in the section "HOW TO CHARGE THE BATTERIES".
- Please make sure the guiding light is working. If it does not work please pay attention, as the device emits even if the light is not visible.
- Any misuse or mishandling of the device may lead to a dangerous exposure to laser radiation.
- Using the laser in presence of flammable materials, solutions, gases, or in an oxygen-rich environment may cause a risk of fire and / or explosion.
- High temperatures produced by the laser device in normal use can ignite some materials, such as oxygen-saturated cotton.
- Attention should also be paid to the fire hazards of endogenous gases.

Warnings during the use

- The device must be placed on a horizontal and safe surface, away from direct heat sources such as radiators or heating systems.
- In cables are damaged, they must be replaced with original parts and not used anymore.
- The device must be kept out of the reach of pets, which can damage it and contaminate it with parasites.
- The cables, the solenoids and the power supply must never be wound up around the neck, since it may lead to strangulation and suffocation.
- Mobile and fixed radio communication devices might affect the operation of the electromedical device. Please refer to Annex 3 on EMC accompanying documents.
- Any misuse or mishandling of the device may lead to a dangerous exposure to laser radiation.

Personal protection

- Both the user and the patient have to wear the protection glasses included in the package. If other people are present in the room where the treatment is carried out, they must wear protective glasses like the person being treated.
While using the device, the operator must wear protective gloves (for example latex).

Absolute contraindications

Do not use the device without wearing the special protective glasses for the operator and the patient.
Do not use lasertherapy:

• On the abdominal and uterine area in pregnant women. There is no scientific evidence that demonstrates potential risks to the fetus or mother, but for prudential purposes it is advisable to avoid direct irradiation on pregnant subjects.

• On patients with neoplasms. It is possible that the therapeutic application of the laser can accelerate carcinogenesis in cancer patients. In case of patients with tumor diseases, consult your physician or oncologist before using lasertherapy.

Relative contraindications

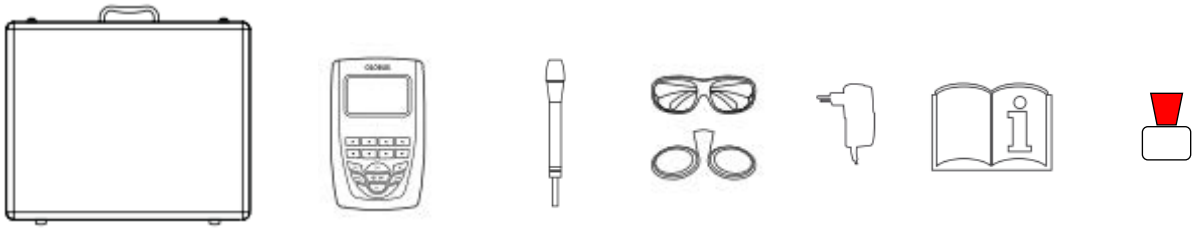
The following contraindications are listed to recommend extreme caution in using the laser in some situations.

- Do not point the laser on big moles or on dark areas that could absorb excessive quantity of energy. In this case we suggest covering these areas with a titanium dioxide or zinc cream.
- Avoid treatment on the heart area.
- Be careful with patients who have a marked sensitivity to light as photosensitization reactions may occur.
- On patients with fever.
- Do not irradiate the thyroid and other endocrine glands directly.

Side effects

The use of laser therapy can cause redness on the treated areas. Isolated cases of skin irritation may occur in subjects with particular epidermal sensitivity, in these cases it is advisable to suspend the treatment.

EQUIPMENT



A B C D E F G

A: Carrying case
B: Device
C: Laser handpiece for Physiolaser 1000 “HANDPIECE GREEN 808 nm” (REF G5796) with 11 mm optics – area 0,95 cm^2
Laser handpiece for Physiolaser 500 “HANDPIECE WHITE 808 nm” (REF G5767) with 11 mm optics – area 0,95 cm^2
D: Operator glasses (REF G1462)
Patient glasses (REF G1461)
E: Power supply (REF G4048)
F: User manual
G: Emergency button (REF G6096)

The device is supplied with: laser handpiece, power supply, glasses for the operator and glasses for the patient; when opening the package, please check that the basic equipment is complete. If some elements should be missing, contact immediately the authorized retailer where you purchased the product.
Check that the device and its accessories are intact.

REF G6096 Emergency button

The emergency button is used to immediately stop the emission of the laser beam and must be placed so that it can be readily used by both the operator and the patient.

REF G1461 Patient glasses

Wave length 200-2000nm
V.L.T. <1%

REF G1462 Operator glasses

Model: SG-04B
Wavelength: 800-1100nm
L-rating: 808 – 980nm DIR L5, 1000-1070 DIR L7
Application: 808nm, 980nm laser diode protection, 1064nm YAG laser protection.
Transmittance: 60%

REF G5796 Laser handpiece "HANDPIECE GREEN 808 nm" + REF 5750 11 mm optic

Diode type	GaAlAs
Laser class (CEI EN 60825-1)	IV
Max RMS power (CEI EN 60825-1)	1 W ±20%
Optics spot dimension	11 mm – area 0,95 cm^2
Wave length	808 nm ± 10 nm
Operation	continuous (CW) and pulsed
Pulsed operation frequency	1 – 10,000Hz
Light guide wave length	660 nm 100mW (Laser Class I)
Beam divergence	0.23° with 11mm focal
NOHD	58.60m (focal 11mm, CW 0.8-1.2W)

REF G5796 Laser handpiece "HANDPIECE WHITE 808 nm" + REF 5767 11 mm optic

Diode type	GaAlAs
Laser class (CEI EN 60825-1)	IV
Max RMS power (CEI EN 60825-1)	0.5 W ±20%
Optics spot dimension	11 mm – area 0,95 cm^2
Wave length	808 nm ± 10 nm
Frequency	1 – 10,000Hz
Operation	continuous and pulsed

Light guide wave length	660 nm 100mW (Laser Class I)
Beam divergence	0.23° with 11mm focal
NOHD	36.95W (focal 11mm, CW 0.4-0.6W)

DEVICE OPERATION

In order to start the device, the following elements must be connected, ***pay particular attention to avoid damage to the connections.***

Device

Power supply by electricity mains. Physiolaser 1000 -500 can operate connected to the mains. Connect the power supply to the connector as shown in the figure (below).

Handpiece and emergency button connection

Insert the connector of the handpiece and the emergency button in the appropriate housings located in the upper part of the unit (see photo below). **The plug must be inserted with the grooves facing down.**

The handpiece must be inserted in the first output of the device.
The emergency button must be inserted in the third output of the device before starting a treatment with the laser.
Outputs 2 and 4 are used only during service and repair processes by qualified personnel.

Battery recharge

The device is supplied with a set of rechargeable nickel-metal hydrate batteries (7.2V, 1.8Ah) with high performance and without memory effect.
It is advisable to recharge the batteries when the battery indicator on the display indicates ¼. Turn the device off, connect it to the power supply included by plugging the connector into the specific inlet.
Do not use a power supply different from the one provided along with the device. Contact the customer service to replace the battery pack. At the end of the process, a message will communicate that the charging has been completed.

How to use the handpieces

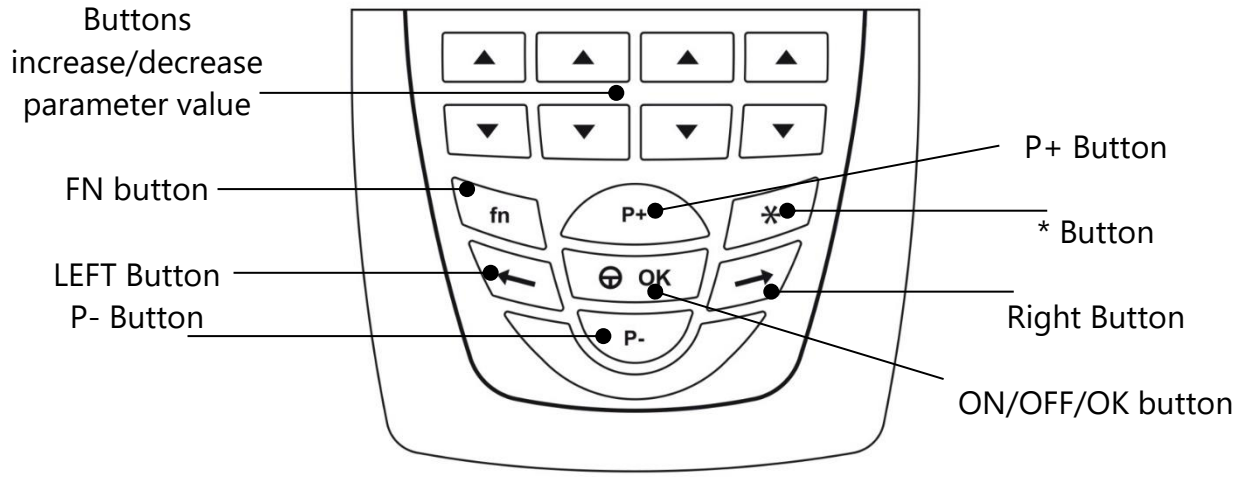
It is possible to choose whether to use the handpieces in monostable or bistable mode (option in the SETUP menu). In case we use the monostable mode, the laser beam will be emitted only by holding down the button on the handpiece and will stop by releasing it. In bistable mode, on the other hand, simply press once on the handpiece button to start the emission and then it will be possible to release it (the emission will continue automatically). To stop the emission, press again on the handpiece button or on the OK button of the device (thus pausing the program).

Laser unlock

If we are using the laser in point mode, we have the ability to manage the beam emission only from the handpiece button. To do this, enter the SETUP menu, then LASER UNLOCK and select the "Key off" option. In this way, it is not necessary to press "OK" on the keyboard to start the treatment of each point (situation that occurs with the "Key on" option), but simply press the activation key on the handpiece.

DESCRIPTION OF THE DEVICE

Below is a brief description of the keyboard and commands of the device.



ON/OFF/OK button..... Confirms the selection, starts and pauses the treatment. Pressed for 3 seconds, it allows switching on and off.

Left button..... Move to the left, return to main menu. Pressed for 3 seconds during the treatment, it allows to end the treatment.

Right button..... Move to the right.

P + and P- buttons..... Move the menu selection up or down. During the treatment they increase or decrease the intensity.

FN button..... Used for some special functions.

Parameter buttons..... They allow to increase or decrease the parameter visible on the display corresponding to each pair of buttons. The first pair of buttons adjusts the average power, the second pair of buttons adjusts the peak power, the third pair of buttons adjusts the area on which we want to carry out the treatment, the fourth pair adjusts the duty cycle (in pulsed emission programs and scanning mode).

* button.....Allows to view the hidden parameters

DEVICE USE

General instructions

Turning the device on/off

To turn on or off, press and hold the ON / OFF / OK button until an acoustic signal is heard.

Unlock device with PIN code

When the device is not in use it must be protected against unauthorized use, for this purpose the PIN function is on. The PIN is a SW code designed to prevent the use of the device by unauthorized personnel.
In order to use the device, after switching on, you need to enter the PIN code.
Press P + 4 times (factory preset PIN sequence), then press the ON / OFF / OK button to confirm.

Emergency button

The emergency button is used to immediately stop the emission of the laser beam and must be placed so that it can be readily used by both the operator and the patient. Its pressure is a real EMERGENCY STOP that disconnects the power supply, without turning off the machine, preventing the diode emission. Delivery will stop immediately even if the icon on the display will appear with a few seconds delay to allow the software to double check. The system remains so until the button is reset. Once the button has been reset, to restore power to the diode, it is necessary to reactivate the output and increase the power again.

Choice of the phototype

Before starting any program, the user is asked to choose, based on the patient's skin color, the most appropriate phototype among 6 options, according to the Fitzpatrick scale:

Type I	Type II	Type III	Type IV	Type V	Type VI

Between one phototype and the next, the emission power is slightly reduced and the duration is increased, so as to guarantee the transfer of the same therapeutic dose. The choice of the phototype is particularly important in the case of dark skin or skin spots.

Emission type

The device allows 2 types of laser emission:
Continuous mode: continuous laser emission with 100% duty cycle.

Pulsed mode: laser emission with variable duty cycle and frequency that depends on the individual program (frequency that can be set for programs created by the user).

Program type

The device supports 2 types of programs:
Scanning mode: the treatment is carried out uniformly over one area.
Point mode: the treatment is performed by points using the handpiece statically on each point. After treating each point, the handpiece is moved to the next point to be treated.

How to carry out a preset program

- In the main menu, select PROGRAM LIST
- Chose the pathology area to treat
- Choose the anatomical area on which to perform the treatment
- Choose the program according to the patient's problem (arthritis, arthrosis,...) and press Start.
- Set the patient's phototype

How to adjust the intensity while running the program

The preset programs are ready for use and it is not necessary to increase the emission intensity. If it is deemed appropriate to make changes to the average and peak power, it is possible to do so in the following ways:

- press P +/P- to increase the average and peak power at the same time (the corresponding duty cycle will be maintained)
- press the arrows corresponding to the Average and Peak parameter to increase or decrease the single parameter. This adjustment will affect the duty cycle percentage and the treatment time
- press the Ok button to pause
- press the FORWARD or BACK button (for a few seconds) to end the treatment in advance.

Important

In the continuous emission programmes, the average and peak power correspond, therefore it will be possible to increase the intensity up to the maximum value of average power foreseen for the device (refer to the data reported in the technical characteristics chapter of this manual).
In the pulsed emission programmes it will be possible to adjust the average and peak power independently, until the two maximum values foreseen for the device are reached. The ratio between the two values will determine the duty cycle.

Both in the programs already in the library and in free programming, the power can be adjusted up to 60 minutes of treatment. With very low powers, the treatment duration timer may be updated every 2-3 seconds instead of second by second. This is completely normal and does not indicate a malfunction.

Switching from continuous to pulsed emission during a programme

The preset programmes are the result of a careful evaluation of the scientific literature, therefore we suggest to stick to the set parameters. In all continuous emission programmes we have seen that the average and peak power correspond and therefore can only be changed simultaneously. If, in certain therapeutic conditions, it is considered more appropriate to switch to a pulsed mode, in order to exploit the effect of the peak power, it is sufficient to keep the key for increasing the peak power pressed for 3 seconds. This will switch to treatment in pulsed mode. The frequency in Hertz will be set with a default value of 1000 Hz.

Energy, Area and Treatment Time

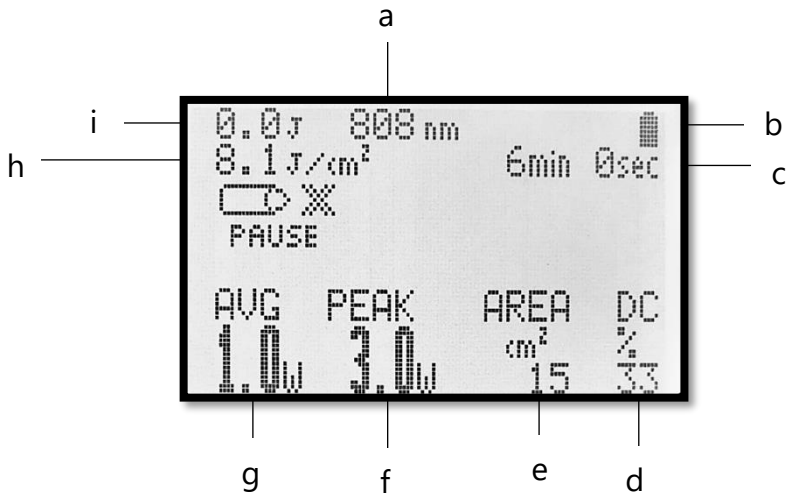
This device allows you to transfer a maximum of 6500 J in 60 minutes (you can view the total energy by pressing the * key).
In the case of a scanning program that provides for a lower amount of total Joules it will be possible to change the pre-set treatment area up to 250 cm^2.

APL function

If the ambient temperature in the place of use is particularly high or if the pause time between consecutive treatments is very short, the device will activate an intelligent protection system that will automatically adjust the power and duration of treatment in order to preserve the diode and ensure the effectiveness of the treatment. During this situation the icon "APL" (Automatic Power Limiting) will appear on the screen, the treatment time will increase slightly and it will be impossible to increase the emission power (it will be possible to decrease it). To find out the power output with the protection system active, press the asterisk key and refer to the figure marked P. The main screen will retain the setup value set by the user.

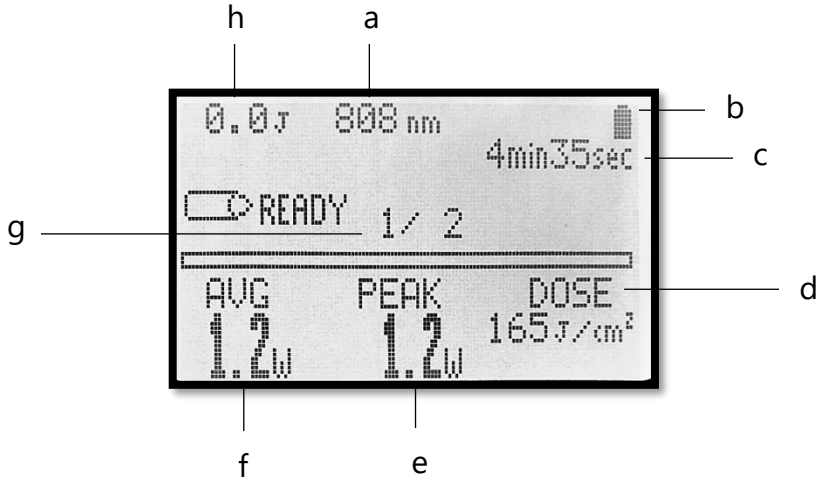
Screenshots of a running treatment program

Scanning mode:



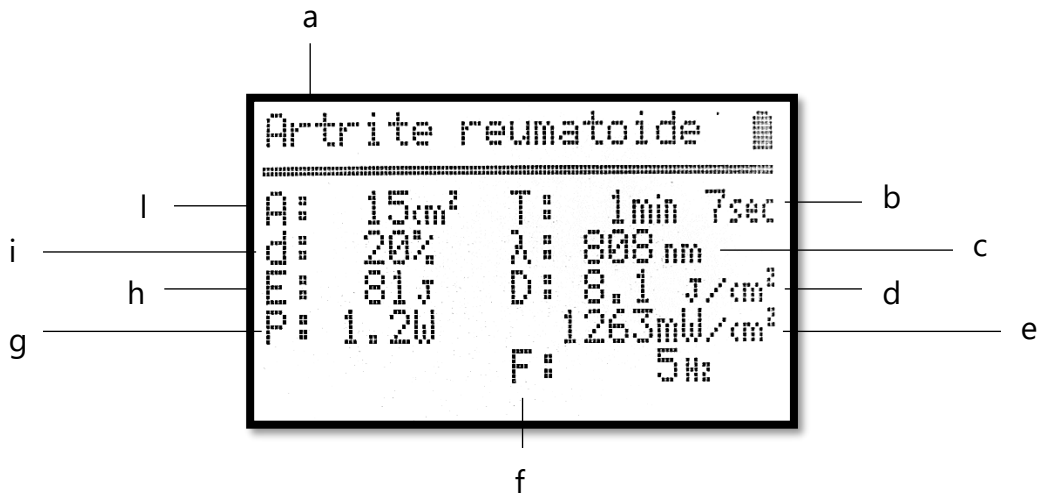
a	Wave length	f	Peak power
b	Battery status	g	Average power
c	Remaining program time	h	Dosage per cm²
d	Duty Cycle	i	Total dosage transferred
e	Treatment area		

Point mode:



a	Wave length	f	Average power
b	Battery status	g	Point number/total points
c	Remaining program time	h	Total dosage transferred
d	Dosage per cm^2		
e	Peak power		

By keeping the * key pressed, you go to the screen-page that usually characterizes a laser therapy protocol. The following screen-page will appear with the specific parameters of the program being executed:



a	Name of the program	f	Frequency
b	Battery status	g	Average power
c	Remaining program time	h	Emitted energy
d	Wave length	i	Duty Cycle
e	Dosage per cm^2 and Power density	l	Treatment area

How to save a program to easily find it for a new use

- In the main menu, select PROGRAM LIST and select the desired program.
- Choose SAVE TO FAVORITES
- Start the treatment. For a new use we will find the program in the FAVORITES section (Folder) of the main menu. In FAVORITES we will also easily find the programs included in PROGRAMMING (New)

PROGRAMMING

How to create a new program

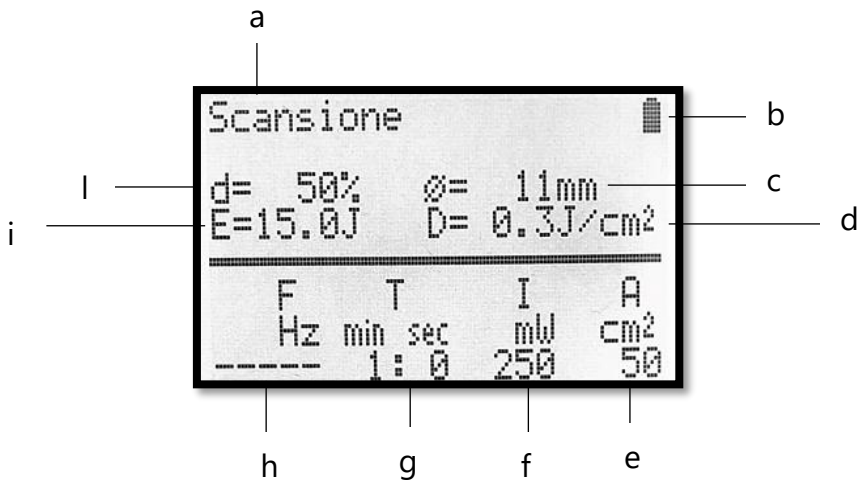
- In the main menu, select PROGRAMMING
- Scroll with P + and P- until you find a free memory (the word Empty will appear) and confirm with OK.
- Using P +, P-, BACK and FORWARD, rename the program and confirm with OK
- Choose the type of emission (continuous or pulsed)
- Choose the mode of use (scanning or point)
- Using the pairs of arrows below the display, change the corresponding parameters. Then confirm with OK
- Confirm or not to save the program
- Press OK to start the treatment
- Once the program is finished, it will be saved in PROGRAMMING and it will be possible to repeat it, modify it (fn + P +) or delete it (fn + P-).

Important: when creating a new programme, the power that can be set is referred to the average power, therefore the maximum limit depends on the maximum average power foreseen for the device.

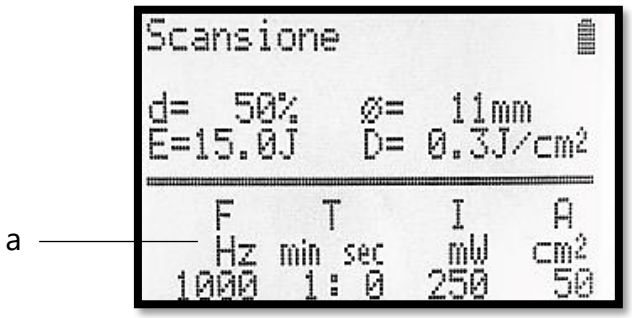
Screenshots of programs in the Programming section

Scanning mode

Choosing the scan mode, this screen will appear:



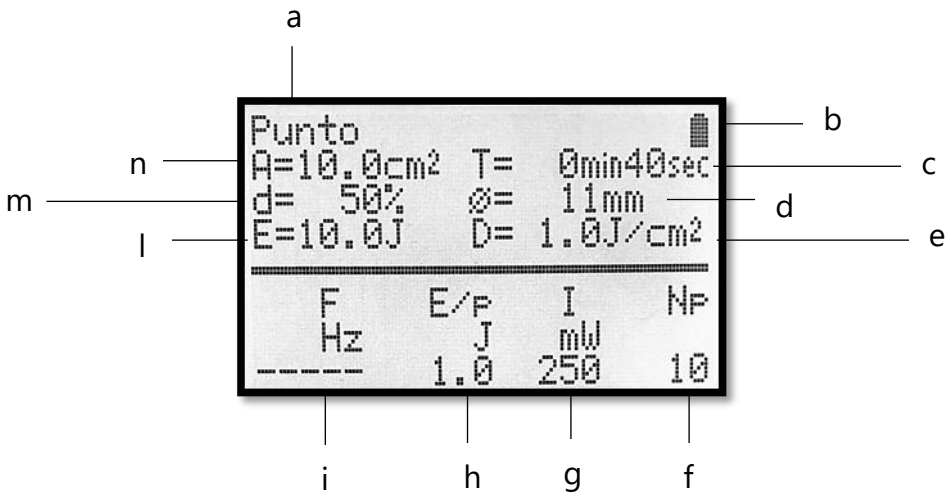
a	Mode	f	Intensity
b	Battery status	g	Remaining program time
c	Optic diameter	h	Continuous emission
d	Dosage per cm^2	i	Emitted energy
e	Treatment area	l	Duty cycle



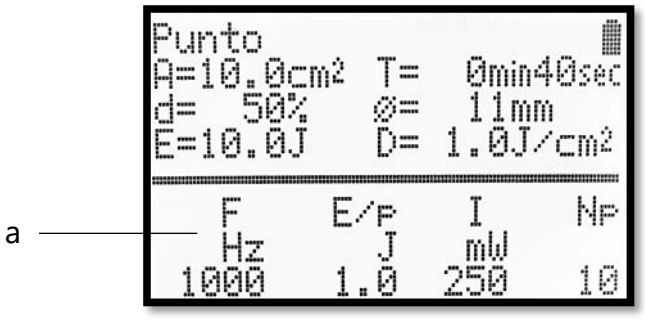
a	Pulsed emission

Point mode

Choosing the point mode, instead, this screen will appear:

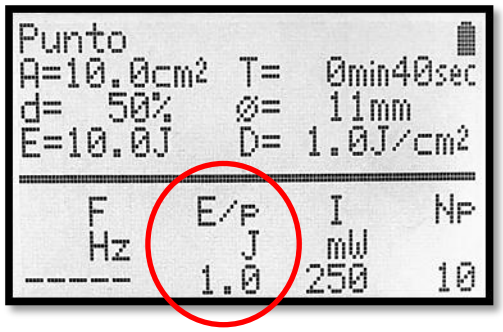


a	Mode	g	Intensity
b	Battery status	h	Energy per point
c	Remaining program time	i	Continuous emission
d	Optic diameter	l	Emitted energy
e	Dosage per cm^2	m	Duty cycle
f	Point number/total points	n	Treatment area



a	Pulsed emission

Using the adjustment keys, you can set the frequency (if the pulsed emission mode has been chosen), the energy per point, the power intensity and the number of points.
By pressing the * key, the parameter "D" (Power density) in J / cm^2 is displayed at the bottom and, with the adjustment keys, it can be changed.



Also in this case, by acting on the four Up and Down buttons, it is possible to modify the frequency (if the pulsed emission mode has been chosen), the program duration, the power intensity and the size of the area to be treated, combining them in order to obtain the desired protocol. By pressing the * key, the parameter "D" (Power density) in J / cm^2 is displayed at the bottom and, with the adjustment keys, it can be changed.

Possible problems

If the connected handpiece does not have an adequate wavelength for the laser model purchased, it will not be possible to use the device (the program list will not appear).

How to customize the functions of the device

From the main menu, choose the SETUP option where you can change:

a. **Lighting time:** allows to vary the duration of the backlight in stand by.
b. **Contrast:** Allows to vary the contrast level of the display. It should be used when the writings on the display cannot be read well.
c. **Auto shut-off time:** The user can choose the inactivity period after which the device automatically shuts down. Press P+ and P- to set the time in minutes.
d. **Language selection:** Allows to choose between the different navigation languages with the P + and P- keys. Confirm the selection by pressing OK.
e. **Sounds of service:** It allows to enable (YES) or disable (NO) the beeps the device emits.
f. **Handpiece button:** Allows to select 2 modes: monostable and bistable. Monostable: hold the handpiece button down to make the device emit; release the button to stop the emission. Bistable: press the button on the handpiece one time to make the device emit; press the button again to stop the emission.

g. **Laser unlock:** It is possible to activate or deactivate the safety function during the “point” laser treatment. The device is supplied with the “Key on” function, i.e. during the point treatment, to start the treatment of each point it is necessary to press the “OK” key on the keyboard and then press the activation button on the handpiece. If the "Key off" function is on, it is not necessary to press "OK" on the keyboard to start the treatment on each point, but simply press the activation key on the handpiece.
h. **Edit PIN:** Allows to change the current PIN. Enter the current PIN, then the new PIN, confirm and press OK, at this point the new PIN is enabled.
i. **Battery management:** see section MAINTENANCE AND CLEANING

Medical programs List: HEALTH-REHAB

X = Program available in the device

Health	Physiolaser 500	Physiolaser 1000
Arthrosis	X	X
Ankle sprain	X	X
Knee pain	X	X
Ankle sprain edema	X	X
Meniscus pain		X
Knee osteoarthritis		X
Achilles tendon inflammation		X
Finger pain		X
Myofascial shoulder pain		X
Articular shoulder pain	X	X
Epicondylitis	X	X
Frozen shoulder		X
Carpal tunnel		X
Chronic back pain	X	X
Acute back pain		X
Back pain with radiculopathies		X
Neck pain	X	X
Neck pain with radiculopathies		X
Myofascial neck pain		X
Neck osteoarthritis		X
Temporo-Mandibular pain		X
Tendinopathies	X	X
Injuries		X
Total Programs	9	23

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa Cermet Italia. Body n. 0476 according to the 93/42/EEC EU directive for medical devices. The certification covers clinical applications.

Program List AESTHETICS - FITNESS (non-medical treatments)

X = Program available in the device

Beauty	Physiolaser 500	Physiolaser 1000
FACE AESTHETIC		
Wrinkles	X	X
Acne	X	X
Dehydrated skin		X
Skin rejuvenation	X	X
Face skin - lifting	X	X
Expression Wrinkles	X	X
Neck wrinkles		X
Rosacea	X	X
Teleangectasie		X
BODY AESTHETIC		
Breast stretch marks	X	X
Cell. Thighs, hips and gluteus edematous cellulite	X	X
Thighs, hips and gluteus fibrous cellulite		X
Body fat and spread cellulite	X	X
Stretch marks	X	X
Epilation		X
Scars	X	X
Loc. lymphatic stasis		X
Total Programs	11	17

CE0476 does not refer to non-medical treatments.

MAINTENANCE AND CLEANING

Maintenance and cleaning of the device

- In case of real or alleged malfunctioning, do not tamper with the device and do not try to repair it by yourself.
Do not try to repair the device and do not open it. Only specialized and authorized centers can repair it.
- Avoid violent impacts that may damage the device and cause malfunctioning, also not immediately detectable.
Use this device in a dry, open-space environment (not wrapped in any materials).
- Clean the device and the accessories only with disinfectant with sodium hypochlorite or quaternary ammonium salt (percentage: 0.2-0.3%) diluted with distilled water. After cleaning/disinfecting the device and its accessories, dry them perfectly with a clean cloth.
- It is recommended to use the device and the accessories in a clean environment to avoid contamination with dust and dirt.
- It is recommended to use the device in a ventilated, well-aired space.
- The parts should be cleaned/disinfected after every use, unless otherwise indicated.

Usable life of the device

The product has an estimated usable life of 5 years. It is advisable to return the device to the producer and/or the authorized center to perform security and maintenance checks every 2 years.
The device can be used continuously when connected to the mains. The numbers of treatments depends on the battery charge. The estimated duration of the battery is of 6 months. Thereafter, it is advisable to replace it.

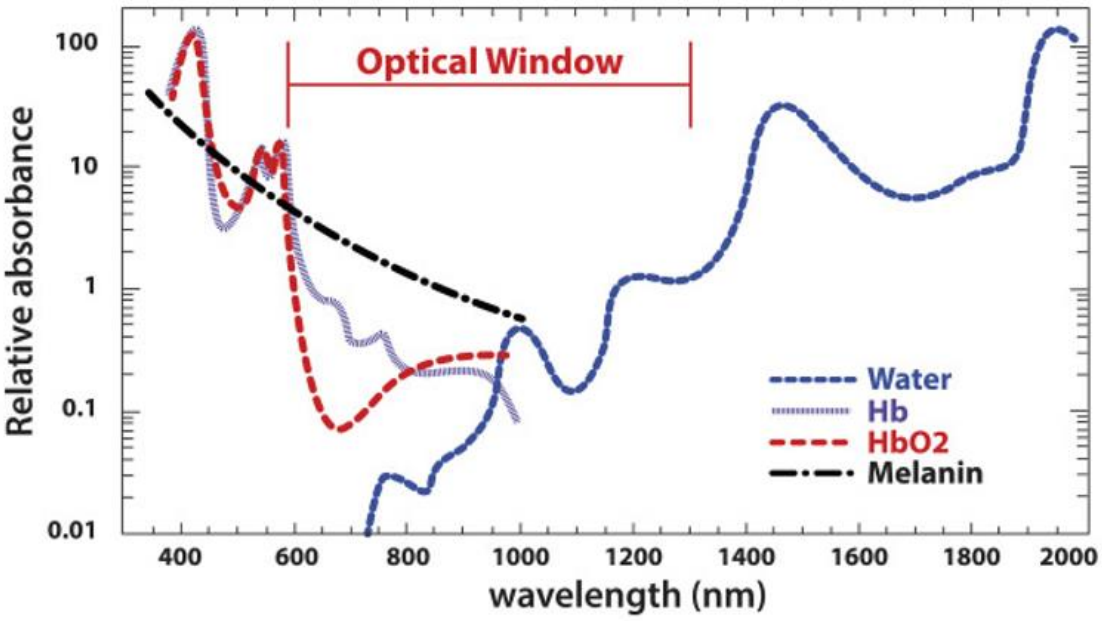
Disposal of the device

Do not throw the device or parts of it into the fire; dispose of the product in the specialized centers and respecting the regulations in force in your country. When the product has to be disposed of, the user can give it back to the retailer when purchasing a new device.
Correct waste separation or following the above-mentioned procedure contribute to avoiding possible negative effects on environment and health and promote the reuse and/or recycle of the materials that compose the device. The illegal disposal of the product entails the application of administrative fines in accordance with applicable regulations.

APPLICATION METHOD

Functionalities

The main goal of laser therapy treatment is to exploit the analgesic and anti-inflammatory effects that laser radiation has on human tissue.
The laser light is absorbed by the different molecules normally present within the surface layers of biological tissues, called chromophores.
This absorption is lower in the near infrared region, the wavelengths present in this range are therefore able to better penetrate the soft tissues through the skin and muscles; for this reason it is called "therapeutic window" (see Figure 1)



Mechanism of Low Level Laser Therapy - Hamblin 2006

Figure 11: Therapeutic window

Therapeutic effects of laser therapy

- Anti-inflammatory effect: the laser is able to influence the mechanisms of inflammation.
- Anti-edema effect: by inducing active hyperemia, it increases the permeability of the lymphatic vessels and capillaries with a release of pre-inflammatory substances. They stabilize the cell membrane of mast cells, which produce histamine.
- Analgesic effect: blocking the action potential of the superficial nociceptive terminations, through modifications of the permeability of the membranes. Promotes

the drainage of algogenic substances. It interacts with the activity of large-caliber myelinated fibers, modulating the perception of pain.

- Biostimulating effect: metabolic activation of fibroblasts, increase in ATP, increase in the supply of nutrients and growth factors, necessary for tissue regeneration.

Use method

To activate the laser radiation, the button on the handpiece must be pressed. The handpiece should be kept at a distance of about 1cm and perpendicular (90 °) to the skin. In this way, the best energy transfer is obtained and reflection and refraction phenomena are minimized. It is recommended to use spots suitable for the width of the area to be treated.
The laser can deliver energy both in continuous and pulsed mode. In the first case the thermal effect prevails, with greater results on muscle spasm and a decrease in tissue viscosity.
In the pulsed treatment, energy can be delivered by decreasing the thermal effect, which is useful for exploiting the biostimulating effect in chronic diseases.

Accessory functions

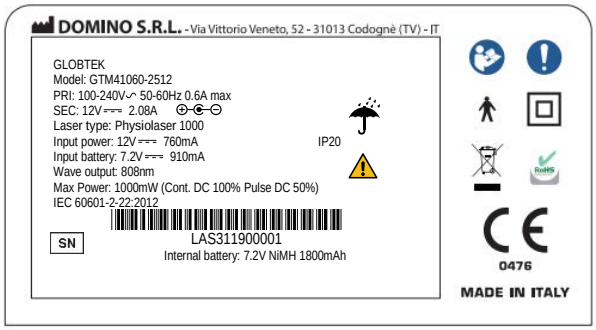
In addition to the use of the laser in the pathologies indicated in each individual program, the laser can be used to take advantage of the stimulation effects on cellular metabolism, which is deficient in all inflammatory processes, or pain relief through the gate control effect. These applications are at the discretion of the individual operator and can be used through customized programs.

Annex 1: SYMBOLS and LABELING of medical devices

	It refers to the manufacturer
	Warning
	Keep the device dry
	This symbol on your device indicates that it complies with the requirements of the directives on medical devices (93/42/EEC 47/2007EEC). The number of the notified body is 0476.
	It indicates that this is a class II device.
	It indicates that this device has B-type applied parts.
	WEEE symbol (Waste of Electrical and Electronic Equipment). Recycling symbol. The WEEE symbol used for this product indicates that it cannot be treated as a household waste. The proper disposal of the product will contribute to protecting the environment. For further information on the recycling of this product, please contact the concerned office of your local body, the household waste management company or the store where the product was purchased.
	It indicates that the product has been produced in compliance with the directive 2011/65/EEC.
	It informs the operator that s/he must read the manual before using the device.
	It indicates a compulsory procedure
	It indicates the ideal temperature for the storage and transportation of the product.
	It indicates the pressure of the environment in which the device and the accessories are transported and stored.
	It indicates the humidity of the environment where the device and the accessories are used and stored.
	It refers to the production lot

	It refers to the manufacturing date.
	It refers to the expiry date of the product
IP	It indicates water or dust protection
Model	It indicates the power supply model
PRI	Output electric features of the power supply
SEC	Output electric features of the power supply
Laser type	It indicates the device type
Input power	Input electric features of the device with external power supply.
Input battery	Features of electric power supply from internal battery
Wave output	Laser emission wave length
Max power	Laser emission power
	It indicates the serial number of the device.
Internal battery	Indicates the features of the battery pack inside the device
	Symbol for polythene

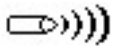
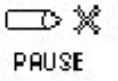
Device



SN The first 4 digits of the serial number indicate the week and year of manufacture of the device you purchased (for example, if the code is *** 2319 *****, it means that the device was produced in the 23rd week of 2019).

Annex 2: INFORMATION SIGNS

Information signals visible on the display

	Correct power emission: The treatment is going on properly. Laser emission.
	Cable not connected: Ensure that the cable is connected to the correct output.
	*Device in pause:* Press OK to continue the treatment.
	The device is in stand-by mode: Press the button on the handpiece to start the emission.
	*Device in Automatic Power Limiting mode* Diode in protection, power reduction
	*Overheating:* when this icon appears, the device will stop the emission due to overheating of the handpiece. Leave the device inactive for a few minutes to help it cool down
	*Lock connector not inserted or inserted in the wrong output*: check having inserted the lock connector in the third output of the device
	*Handpiece not compatible with the device model in use:* this icon indicates an error in the choice of the handpiece inserted in the device being used. Replace the handpiece with one that is compatible with the laser model in use.

Acoustic information signals

Sound signals comply with the EN 60601-1-8 directive.
If the Sound Signal function is on, the device emits an acoustic signal when the buttons are pressed.
In addition, the device emits an acoustic signal repeatedly while the laser emission is active.
If the Sound Signal function is off, the acoustic signal that indicates the start and the end of the treatment and the start and the stop of the laser emission are still present.
If during the treatment the laser handpiece is suddenly disconnected from the connector, the device will emit an acoustic signal.

WARRANTY CONDITIONS

The device is guaranteed to the first user for 12 months from the purchase date against defects in materials or manufacturing, provided that it is used properly and kept in normal conditions of efficiency.

Warranty coverage is limited in the following cases:

- six (6) months for accessories subject to wear, e.g. power supplies, handpieces, cables etc.

In order to take advantage of the warranty service, the user must comply with the following warranty clauses:

1. The products have to be sent for repairs by and at the expenses of the Customer in their original packages and with their full original equipment.
2. The product's warranty is subject to the production of a fiscal document (fiscal receipt, receipted bill or sale invoice), attesting the product's purchase date.
3. The repair work shall have no effect on the original expiry date of the warranty and shall neither renew nor extend it.
4. If no defects are found, during the repair work, the costs related to inspection times shall in any case be charged.
5. The warranty becomes void if the damage is caused by impacts, falls, erroneous or improper use of the product, use of non-original external charger/power supply, accidental events, alteration, replacement/detachment of the warranty seals and/or tampering with the product. Moreover, the warranty does not cover damages caused during transportation due to unsuitable packages (see point 1).
6. The warranty does not cover the impossibility to use the product, other incidental or consequent costs or other expenses incurred by the purchaser.

N.B. Before returning the device for repairs, we suggest reading carefully the user manual and consulting the Globus website.

If you have to return the product for repair, please contact your dealer or the Globus customer service.

Annex 3: EMC accompanying documents

Essential performance

PERFORMANCE	CONDITION	RISK	ACCEPTED EVENT
Laser	External disturbance (Burst).	Display information no longer readable.	The machine must stop the laser emission.
			The machine must maintain the emission and accept the commands.
	Lack of internal power supply.	Interruption of the treatment.	The machine must signal the battery exhaustion and the interruption of the treatment.
	Lack of external power supply.	Interruption of the treatment.	The device, if equipped with a battery, must continue the treatment signaling that operation is carry out in battery mode.
	Probe disconnected or internal connections interrupted	Failure to recognize the handpiece, with incorrect emission of light energy.	The device must constantly monitor the status of the handpiece and stop dispensing if it is not correctly identified.
	Breakage of the laser source	Treatment ineffectiveness.	The device should constantly monitor the status of the handpiece and interrupt the treatment.
	Breakage of the guiding light	Treatment of unaffected areas.	The device should constantly monitor the status of the handpiece and interrupt the treatment.
Loading of the programs from the memory.	Error in the data from the memory.	Execution of an incorrect program.	The machine must check the correctness of the data of the programs. In case an error is detected, the device must restart.
Change of settings.	Setting data memory error.	Operation error.	The device must check the correctness of the settings data and in case of errors it must load the default settings present in copy in the memory and must indicate on the display that the reset has been carried out.
		Display information no longer readable.	The device must check the contrast value. If it is out of range, the device must reset the value to the default one.
Battery charge.	Battery overheating.	Damaging of the device, display information no longer readable, explosion, fire.	The device must monitor the temperature of the battery, if a certain threshold is exceeded, the battery charging must be interrupted.

In compliance with:

EN 60601-1: 2006 + A1: 2013
EN 60601-1-2: 2015
EN 60601-2-22: 2013

Warning: radiofrequency communication devices (including accessories like antennas or antenna cables) must be used at least 3 meters away from every part (including the cables and the accessories) of the device. Otherwise, the performance of PHYSIOLASER can be affected.

GLOBUS

ITALIAN EXCELLENCE

DOMINO S.R.L. - Via Vittorio Veneto, 52 - 31013 Codognè (TV) - Tel. (+39) 0438.7933

globuscorporation.com