GLOBUS

LASER THERAPY

User Manual

PHYSIOLASER 1000

PHYSIOLASER 500

CE
0476

DEAR CUSTOMER

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

☐ Pysiolaser 1000 ☐ Physiolaser 500

The lasertherapy devices (**Pysiolaser 1000 e Pysiolaser 500**) are produced and distributed by:

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These products have been manufactured according to the technical regulations in force and are certified according to Directive 93/42/EEC updated by 2007/47 directive for medical devices, by Kiwa CERMET s.p.a. Body (authorization n. 0476), in order to ensure the products' safety.

Table of contents

TECHNICAL FEATURES

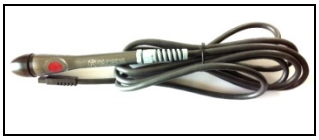
Device

Size: 160x99x35,4
Weight: 404 g.
Case: in food grade ABS
Protection level of the case: IP 22
Storage and transportation temperature: from -10°C to 45°C
Max. relative humidity: from 30% to 75%

Use conditions

Temperature: from 0°C to 35°C
Max. relative humidity: 15% to 93%
Atmospheric pressure: from 700 hPa to 1060 hPa

Technical features of the laser



Medical Device of II b class
Laser of IV Class
Nominal power (CEI EN 60825-1): Up to1000mW
Beam divergence: 13°
Power Density: up to 1 W/cm2 max (Physiolaser 1000)
500mW/cm2 max (Physiolaser 500)

NOHD: 0.27 m (1W)
0.18 m (500mW)
Spot size: 3.5 mm or 11.5 mm
Wave length: from 630 to 1064 nm 808 nm
(the wave length of the laser source is indicated on the handpiece)
Frequency: 8 – 10.000Hz
Operation mode: Continuous and Pulsed
Wave length of the guidance light (I class device): 660 nm

Accessories

Glasses for the patient (Physiolaser 1000)

Visual field PPE: >40
Length regulation and sidepiece inclination: jerky mechanism
Ventilation system: small holes in the lateral protections
Complete PPE weight: 34
Materials: polycarbonate
VLT%: 0,36
Color: green 7
Bend: Basic 6
Optical class: 2
Scale number: 7

Glasses for the operator

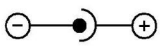
Visual field: >40
Frame weight: 28 g
Frame material: polyamide 6.6 varnished
Transmittance (%): 35
Bend: Basic 6
Optical class: 1
Minimum thickness: 2.0

Power supply unit

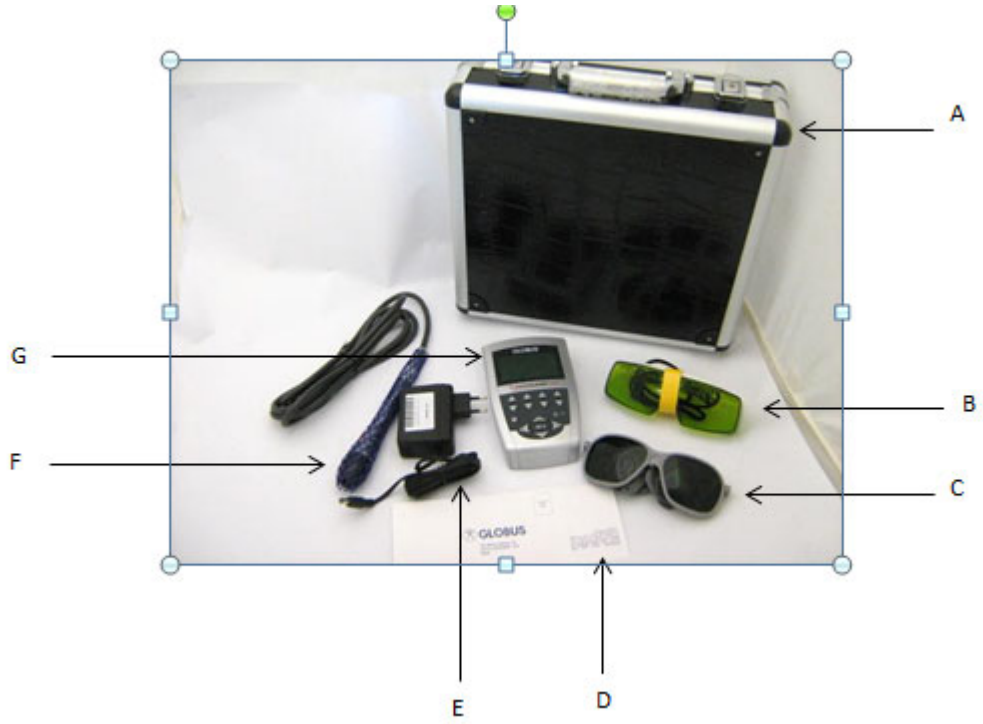
Brand GLOBTEK
model: GTM41060
PRI: 100-240V~ 50-60 Hz 600 mA
SEC: 12 V = 2,08 A

Battery

Battery pack: Ni-MH 7,2 V 1,8 Ah



EQUIPMENT



A: CARRYING CASE
B: GLASSES FOR THE OPERATOR
C: GLASSES FOR THE PATIENT
D: WARRANTY
E: POWER SUPPLY UNIT
F: LASER HANDPIECE
G: DEVICE

The device is supplied complete of laser handpiece, power supply unit, glasses for the operator and glasses for the patient; opening the package, it is necessary to check that the basic equipment is complete. If some elements should be missing, contact immediately the authorized retailer where you purchased the product.
Control carefully the integrity of the device and its accessories.

INTENDED USE

The after sales service is guaranteed for 5 years. We suggest having a check of the device every two years for the maintenance and to ensure the safety.

The Physiolaser is designed to be used in the following operating environments:

- home environment;
- clinics;
- physiotherapy centers;

- rehabilitation centers;
- general pain treatments (medical treatments);
- for beauty and sport purposes.

CONNECTIONS

Device

Power supply by electricity grid
The Physiolaser operates connected to the mains. To connect the power supply unit to the connector, plug it as shown below.

Handpiece Laser

To connect the cable of the handpiece to the device plug it into the appropriate inlet removing the sticker with the yellow symbol (see picture).

Battery: how to charge the batteries

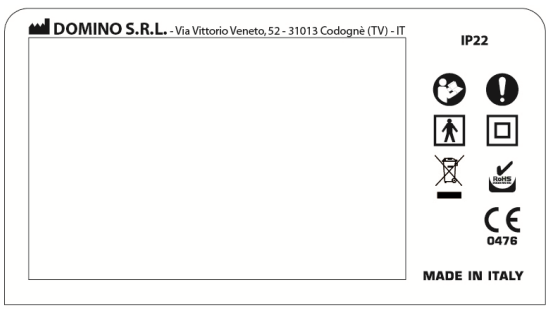
The device is supplied with a set of rechargeable nickel-metal hydrate batteries (7.2V, 1.5Ah), which have high performance without storage effect.
Recharge the batteries when the battery light on the display indicates ¼. To charge the batteries, turn off the device, then connect it to the power supply unit included by inserting the plug in the appropriate inlet (see picture).
Do not use a power supply unit different from the one provided with the device. To replace the device's batteries, contact an authorized service center.

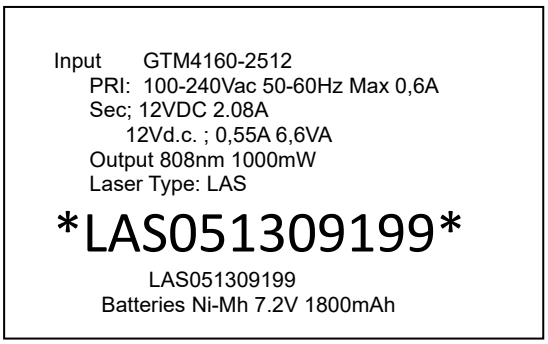
LABELLING AND SYMBOLS

	Warning
	This symbol on your device indicates that it complies with the directives on medical devices (93/42/CEE 47/2007CEE). The number of the notified unit is 0476.
	It indicates that this is a I class device.
	It indicates that this device has BF type parts.
	WEEE symbol (Waste of Electrical and Electronic Equipment). Recycling symbol. The WEEE symbol used for this product indicates that the device may not be disposed of as a household product. Properly dispose of the product to help protect the environment. For more information on recycling this product, contact the local competent department, the household waste management company or the store in which the product was purchased.
	It indicates that the product has been produced respecting the directive 2002/95/CE.
	It indicates the optimal temperatures for the storage and transportation of the product.
	It informs the operator that before using the device he must read the manual.
IP22	It indicates the water protection degree
	It informs the operator of a compulsory conduct
	It refers to the pressure of the environment where the device and its accessories are stored and shipped
	It refers to the humidity of the environment where the device and its accessories are stored and shipped
	It refers to the manufacturer
	It refers to the expiry date

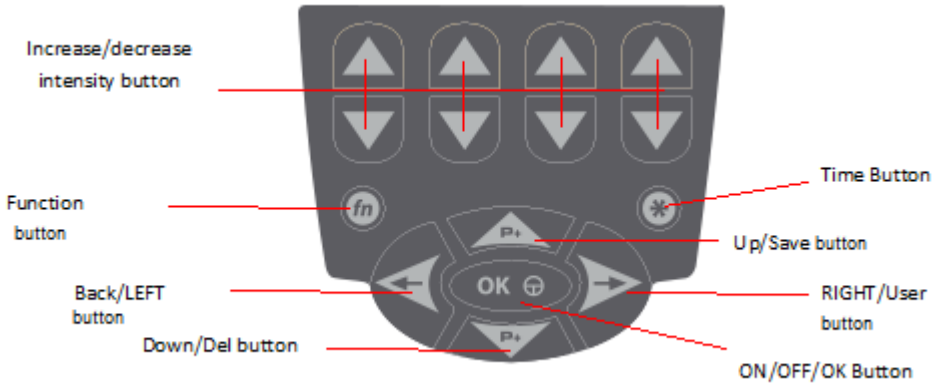
LOT	It refers to the production lot
RH	It refers to the percentage of storage humidity
	It refers to the interruption of the laser emission
	Attention danger laser emission not visible
	It identifies the risks related to the laser use and it classifies them
PRI	Mains voltage
SEC	Power supply voltage
Input	Input: It indicates the value of the mains voltage for the power supply unit
Output	Output: - it indicates the power supply unit outbound voltage - it indicates the maximum power value of the magnetic field emitted by the device - it indicates the range of frequencies of the magnetic field emitted by the device
Type	It indicates the device type
Power	It indicates he power supply unit model of the device
Battery	It indicates the battery pack inside the device

Device





Panel and keyboard



ON/OFF/OK Button (To turn on/off and confirm the treatment)
LEFT/BACK Button
P+ Button (to scroll the programs up)
P- Button (to scroll the programs down)
RIGHT Button
Up/Down left button to modify the power
Fn button to activate some special functions described in the "instructions for use"

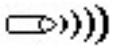
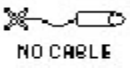
Display/Interface

ALARMS

Compliance

Certifications: CE MDD Certificate
The sound and acoustic signals are in compliance with the directive 60601-1-8.

Meaning

	Correct power emission: the treatment proceeds correctly, the laser emission is present.
	Cable not connected Verify that the cable is connected to the right 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

Warning sounds

If the Warning Sounds function is on, the device emits an acoustic signal while pressing the buttons.

If the Warning Sounds 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.

WARNINGS AND CONTRAINDICATIONS

Mandatory behavior

For safety reasons, the device must be used in the prescribed manner and within the limits of use explained in this manual.
The manufacturer declines any responsibility due to a different use from what it is indicated in this manual.
No part of this manual (texts and/or photos) may be reproduced by electronic or mechanical means without the prior written authorization of the manufacturer.
If the package, the cable or the connector of the power supply unit show signs of wear or damage, replace them instantly.
The unit should be connected to the mains by its power supply unit. Before starting the treatment, make sure that the power system specifications comply with the directives in force within your country. Make sure that the power supply unit will be in a comfortable position and that it will be easy to be removed.
The device should be protected against a not authorized use.
It is forbidden to modify the device.

Warnings before the use

We suggest avoiding the use of the device together with other electronic devices, especially with those used to maintain vital functions. For a correct use of the Electromedical device, make reference to the tables attached. If it is necessary to use the device near or together with other devices, pay attention to its working.
- It is recommended to read carefully the entire operating manual before using the device; keep carefully this manual.
- Do not insert fingers or metallic objects into the emission holes to avoid injuries and/or damages to the optical section.
-The unit should be used only with the laser handpiece provided originally (or Globus branded) and according to the therapeutic modalities described.
- Before each use always check the integrity of the unit. This is a fundamental requirement for carrying out therapies, do not use the unit if either the buttons or cables are defective or malfunctioning.
- It is recommended to control the functioning of the pointing laser beam. This must always be present before executing the treatment; if it should be missing, it means that an anomaly occurs.
The device:
- should not be used in front of people who are not wearing the protection glasses.
- it must be used only from people over 18 who are able to understand and take action.

- it must be used following the indications and under the physician or physiotherapist's control.
- it must be kept out of the reach of children.
- if there is any health problem, it must be used only after seeing a doctor;
- once you have turned on the device, make sure that in the display the software version and the model of the device appear, it means that the device is working and it is ready to be used.
If not, or in the display all the segments do not appear, turn it off and on again. If the problem persists, contact the service center and do not use the device.
- An unexpected switching-off of the device means that the battery has run-down. Charge it according to the instructions in the paragraph: HOW TO CHARGE THE BATTERIES
- The use of controls or the execution of different procedures from what specified can cause a dangerous exposition to the laser radiation.

Warnings during the use

During the use of the Physiolaser some warnings should be followed:
- the device should be used wearing the included appropriate glasses for the operator and for the patient.
- In case of damaged cables, they must be replaced with original parts and not used anymore.
- The device must be kept out of the reach of any pet that could damage it and contaminate it with parasites.
- The cables of the laser handpiece and of the power supply unit should not be wrapped around people's neck to avoid any risk of strangulation and suffocation.
- The mobile and fixed radiocommunications devices could influence the functioning of the electromedical device: see the tables attached to this manual.
- The use of controls or the execution of different procedures from what specified can cause a dangerous exposition to the laser radiation.

Side effects and contraindications

Possible side effects of the lasertherapy are:
- photosensitization;
- rebound effect (the increase of the tenderness after the lasertherapy use);
- skin pigmentation.

Contraindications

Do not use the lasertherapy in the following cases:
- Do not carry out this treatment on pregnant women.
- On children under 15.
- 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.
- On noble organs (ovaries, heart, head, etc.).
- On epileptic patients.
- In case of fibrocystic mastitis.
- On patients who have photosensitization reaction.
- In case of fever.
– In case of patients with tumor diseases, see your physician or oncologist before using the lasertherapy.
- Do not irradiate the thyroid and other endocrine glands.

MAINTENANCE AND CLEANING

Maintenance and cleaning of the device

- In case of real or alleged malfunction, do not tamper with the device or try to repair it by yourself.
Do not intervene on the device and do not open it. Only specialized and authorized centers can repair it.
- Avoid violent impacts that may cause damage and malfunctions to the device even if undetectable immediately.
- Use this device in a dry environment and in an open space (not wrapped in any materials).
- Clean the device and its accessories only with disinfectant with sodium hypochlorite or quaternary ammonium salt diluted with distilled water equal to 0,2-0,3%. After cleaning/disinfecting it, dry the device and its accessories with a clean cloth.
- Use always the device and its accessories with clean hands.
- It is recommended to use the device in a clean room, to avoid the contamination of the device with dust and dirt.
- It is recommended to use the device in a ventilated space, with regular air change.
- It is recommended to clean/disinfect the parts after every use.

Battery

Battery info.
The device is equipped with a menu that can visualize the charge of the battery, the values and the conditions of the end of the charge.
It is recommended to access to this menu only after a complete charge of the batteries.
From the main menu choose "Advanced", then "Set-Up" and finally "Battery info".
Six codes will be visualized with the following meanings:
COD1 = 0 expected voltage threshold reached.
COD1 = 1 max. charge time reached.
COD2 value of the battery voltage at the start of the charge.
COD3 value of the battery voltage at the end of the charge.
COD4 charge duration (from 1 to 840 minutes, ideal time 720 minutes).
COD5 charger/power supply unit connection duration.
COD6 Battery pack voltage value.

According to the values above described, it is recommended to replace the battery when COD1 = 1 and COD3 < 7,4 volts. Or when COD3-COD2 >= 2 volts and COD4 <600. Or when COD6 is lower than 5,8 volts.
Furthermore it is recommended to replace the battery pack after 3 months in which the device has not been used. After that period, batteries usually loose their ability to charge making the recharge dangerous.

Disposal of the device

Do not throw the device or part of it in the fire, but dispose of the product in the specialized centers and respecting the directives in force within your country. When the product has to be disposed of, the user can give it back to the retailer when purchasing a new unit.
A correct separate waste collection or following what above mentioned contributes to avoid possible negative effects on environment and health and promotes the reuse and/or recycle of materials of which the device is composed. The illegal disposal of the product by the user involves the application of the administrative fines according to the current regulations.

INSTRUCTIONS FOR USE

Pin unlocking

The device, when not used, should be protected against a not authorized use. The PIN function has this objective; it consists of a SW code intended to impede the device use to not authorized staff.

For a correct connection of the product it is necessary to proceed as follow:

- Connect the handpiece to the relative output of the device;
- To turn on the device, press and hold the ON/OFF (OK) button for approximately 3 seconds until a sound signal is heard.

Pin unlocking procedure

Press 4 times the P+ or "Save" buttons.

To switch-off, press and hold the ON/OFF (OK) button until a sound signal is heard.

With the Up and Down buttons of the joypad, you can move inside the main Menu, on the following entries: "Last 10", "Program List", "Treatments", "Programing", "Advanced", "Switch-off".

By pressing the OK button on "Last 10" you access to the Menu: the last 10 executed programs are shown.

Program selection from the "Program List" menu

Use the UP and DOWN buttons to place the cursor on "Program List" and confirm by pressing the OK button.

Area selection

By using the Up and Down buttons, place the cursor on the area you want to select. Press OK to confirm.

Program selection

Select the desired program by using the Up and Down buttons.

Press OK to confirm.

Press and hold the left (Back) button for 3 seconds to return to the previous screen.

Select START to start the treatment.

Select SAVE IN TREATMENTS to save the program and execute it later (see paragraph about "Treatments").

Phototype selection

Once you have chosen the program, you were asked to set the skin phototype of the subject to treat:

Phototype setting
Light (A)
Dark (B)

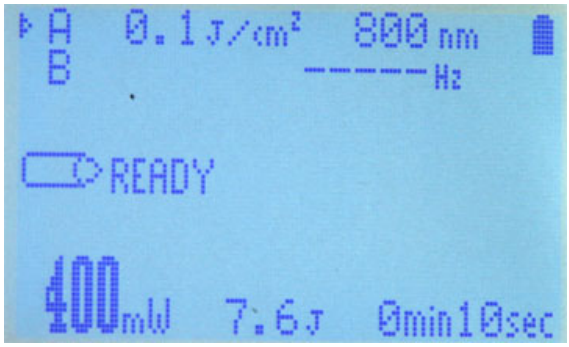
By choosing the phototype B, the emission intensity will be automatically reduced and the duration of the treatment will be increased, both of 20 %.

Light phototype= for light/normal skin

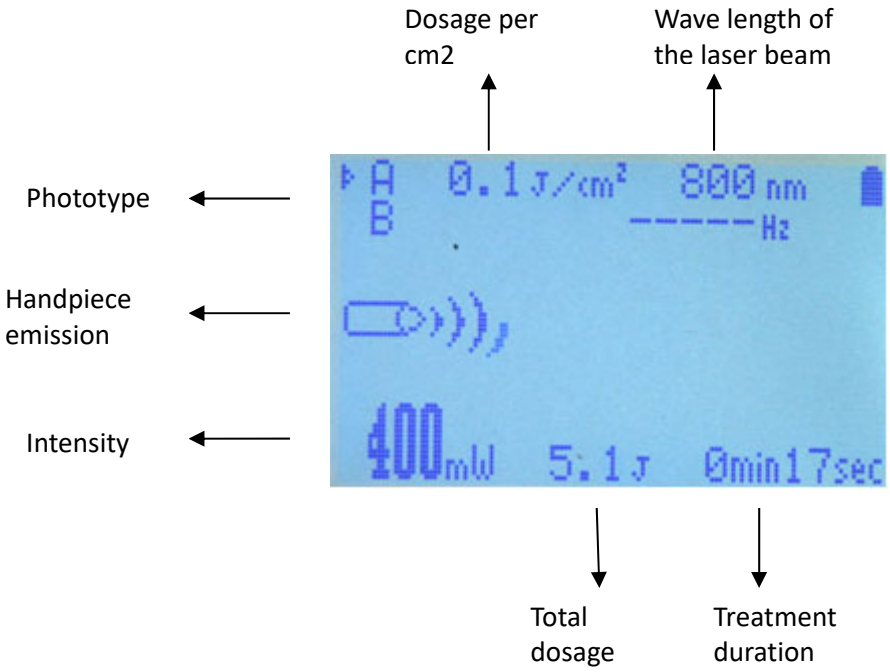
Dark photype= for dark skins or dark marks.

How to start the program

After selecting the program, the display will show the message "ready". At this point put the handpiece on the area to be treated and press and hold the emission button . The handpiece emits only if the button has been pressed, if not, the device does not emit.



Visualization during a program execution



Visualization of the parameters during the execution

By holding the * button, the screen will show you the visualization normally characterizing a lasertherapy protocol. The following screen with the specific values of the ongoing program will appear:

How to pause/stop the program

To pause the program, press the OK button. Press OK again to return to the program. During the pause the message PAUSE will appear on the screen.

How to exit from the program

To stop the program before the end of the treatment, press the Back button.

How to change the working phase parameters

After starting the program, the power of the treatment can be modified by using the P+ and P- buttons. By increasing or decreasing the power, the duration of the treatment will change.

Special Functions

"Last 10" Function

The device stores the last 10 executed programs, so that these are available for a rapid and easy execution.
The storage occurs automatically at the end of each program; when the memory is full, older programs are automatically deleted.
When the device turns on, select "Last 10" and then confirm with OK

Treatments

The device allows the user to block the device and to execute only the treatments saved with the "Save in treatments" function in the screen previously to the execution of the same program. This function is especially thought for the rent of the unit to inexpert users and/or to patients that have to carry out only some special programs that have been chosen by the specialist.

Activation of the STIM LOCK function

Press and hold the buttons fn and --> (RIGHT button) for at least 3 seconds until the area where the treatments have been saved appears.
After the activation of the STIM LOCK function, the functions of the unit will have limited functionalities.

Deactivation of the STIM LOCK function

Press and hold the fn and <-- buttons (LEFT button) for at least 3 seconds until the main menu appears.

NOTE: If, when the unit is turned on, the main menu does not appear, verify that the STIM LOCK function is not activated. Try to deactivate it.
If the problem persists, contact the customer service.

The "Programming" function

The “Programming” function is activated only when the laser pointer is connected. The device offers the possibility to create/modify new programs. This makes the device flexible and adaptable to all users' requirements.
From the "Programming" entry of the main menu, it is possible to create new programs (when the message EMPTY appears) and to execute already personalized programs. These programs can be modified at any time. The programs created in the “Programming” menu are the same for all USERS and cannot be stored in the "Last 10" list.

How to create a new program

From the main menu, move the cursor on "Programming" using the UP and DOWN buttons and confirm with OK.
Use the DOWN button to scroll down the memory list (from 1 to 15) and confirm with OK. The free memories are the ones where the message “EMPTY” appears.
NOTE: If the program has already been created, see "How to modify a program".

Insertion of the program's name

Use the LEFT and RIGHT buttons to select letters and confirm with OK. To delete a letter, move the cursor on DELETE and confirm with OK.

Parameter insertion

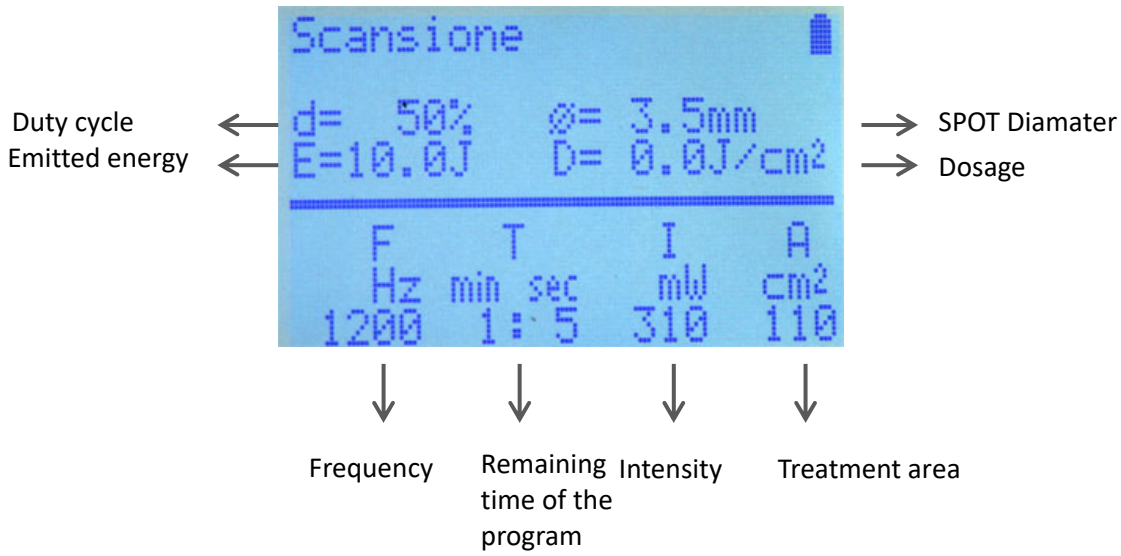
After selecting the program name you should select the desired carrier:

- Continuous (duty cycle 100%)
- Pulsed (duty cycle 50%)

After that, you were asked to choose to execute a program in multi spot mode or in scanning mode.

Scanning mode

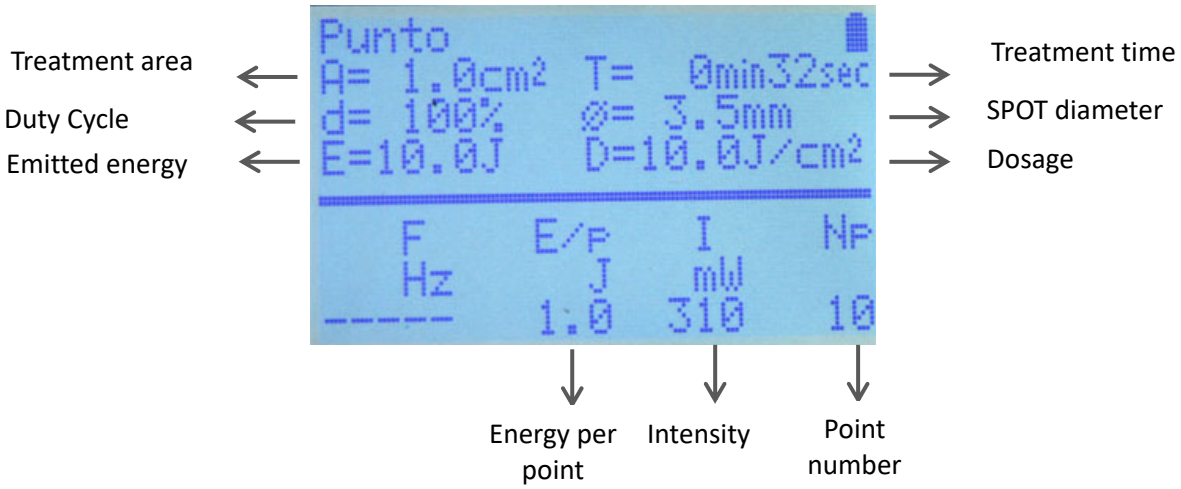
When you choose the scanning mode, the following screen appears:



By using the Up and Down buttons you can modify the frequency (only in pulsed mode), the program duration, the intensity and the size of the area to be treated, and you can combine these parameters in order to have the desired protocol. In the upper part of the screen both the emitted total dosage and the dosage per cm2 will appear.

Multi spot mode

When you choose the multi spot mode, the following screen appears:



By using the regulation buttons you should set the desired intensity for the treatment, by choosing the point number and the dosage per point.

By pressing the * button you can visualize and modify the information “E/p” Energy per point or the information “D (dosage) in J/cm²”.

This allows the operator to choose the parameter he wants to set.

How to modify a program

Inside the “Programming” menu, select the program number you wish to modify and press at the same time the “fn” + UP” buttons.

How to delete a program

Inside the “Programming” menu, select the created program you wish to delete and press at the same time the “fn” + Down" buttons.
The deleted program cannot be recovered.

Advanced Menu

By selecting the Advanced Menu you can access to an area intended for the special functions.

“User Selection”

The "User Selection" in the advanced menu function permits to use the special functions ("Last 10 " and “Treatments”) in a personalized manner.

NOTE: Every time the device is turned on, the last user will be displayed.

SETUP

- **Backlight time FUNCTION**

The backlight time function in the setup menu allows to modify the duration of the light during the stand-by phases using the Up and Down buttons.

- **Contrast FUNCTION**

The contrast function in the setup menu allows to modify the display contrast by pressing the UP/DOWN buttons.

- **Auto shutdown FUNCTION**

The "Auto shutdown" function in the setup menu permits to choose, using the UP and DOWN buttons, a period of time (in minutes) after which the device, if not used, automatically turns off.

- **Language selection FUNCTION**

The "Language Selection" function in the setup menu permits to choose among 4 different languages for the navigation using the UP and DOWN buttons. Confirm the selection with OK.

- **Warning sounds FUNCTION**

The "Warning sounds" function in the setup menu permits to enable (ON) or disable (OFF) the acoustic tones emitted by the unit.

- **“Handpiece button” FUNCTION**

The handpiece button function permits to select two modes (monostable and bistable).

Monostable: The device emits while pressing and holding the handpiece button; the device does not emit releasing the button.

Bistable: By pressing once the handpiece button the device emits, and by pressing another time the button the device does not emit.

- **“PIN change” FUNCTION**

The “PIN change” function present in the Setup area permits to modify the current PIN.

- Insert the current pin and press OK.

- Insert the new pin and press OK.

- Confirm the new pin and press OK.

The new pin is enabled.

- “Diameter spot laser” FUNCTION

In this section it is possible to set the diameter spot of the handpiece to use during the treatment. This value is indicated in the table with the program list in the end of the manual.

When choosing the 3.5 diameter you should remove the lens from the handpiece unscrewing it in a counterclockwise sense.

- “Battery info” FUNCTION (see the chapter “MAINTEINANCE AND CLEANING”)

APPLICATION MODE: THERAPEUTIC AND BEAUTY EFFECTS

The biological changes caused by the laser light, determine the following effects:

1) *Biostimulating effect.* The biostimulating effect of the laser accelerates the cicatrization of ulcers and sores. The laser light stimulates the mitochondris and accelerates the ATP production. The increased production of APT recharges the cells of energy so that, if the cells are damaged because of inflammatory, traumatic or regenerative causes, they restart to execute their physiological functions.
2) *Activation of microcirculation.* The lasertherapy has an intense vasoactive action on the microcirculation. The activation of microcirculation favors a greater nutritional contribution and a better drainage of catabolites from the tissues.
3) *Antalgic effect.* The laser has an analgesic effect because it increases the excitement of receptors and it creates an antiphlogistic action.

Application method

To carry out lasertherapy sessions it is necessary to follow these indications:

1) It is obligatory for the operator and the patient to wear protective glasses for the retina and to install the device in environments without reflecting surfaces.

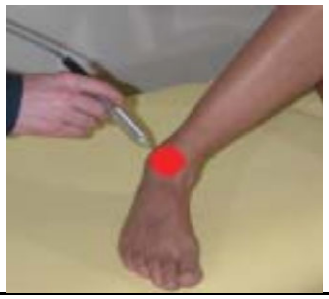
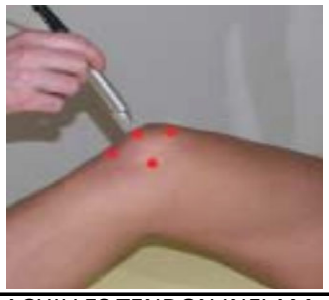
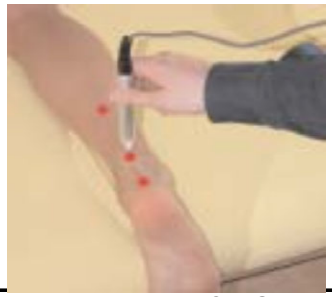
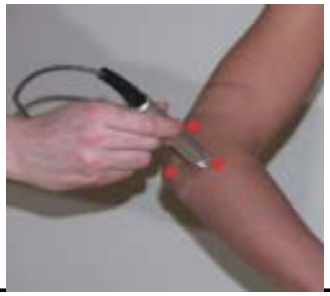
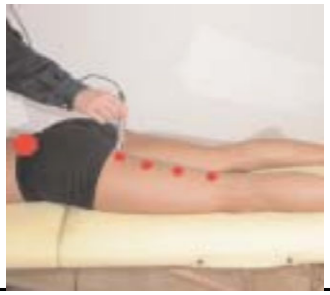
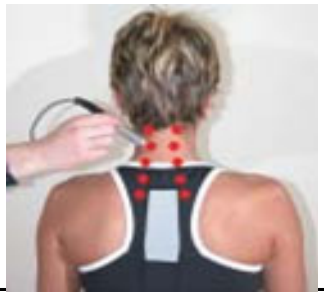
2) The body area should not be covered with clothes and the skin has to be cleaned with alcohol. The presence of superficial fat could cause reflecting phenomena of beam obstructing its penetration.

3) During the treatment the handpiece must be put in contact with the skin and the ray must have a 90° of incidence. The more you go away from the skin, the bigger the treatment area is and the less the power density is. Only the operator can use the handpiece unit. The laser handpiece must be moved with a circular movement or with a grid scansion movement.

4) The treatment time for each cm^2 of surface changes in relation to the type of used laser, to the emission methods (continuous or pulsed) and to the average power.

5) The total number of therapeutic sessions is correlated to the type of pathology to be treated (acute or chronic); it can vary from 10 to 20 sessions.

MAIN AREAS TO BE TREATED

SHOULDER PAIN		ANKLE SPRAIN
		
KNEE ARTHROSIS/OSTEOARTHRITIS		FINGER PAIN
		
ACHILLES TENDON INFLAM.		EPICONDILYTIS
		
BACK PAIN WITH RADICULOPATHIES		NECK PAIN
		
CARPAL TUNNEL		TEMPORO/MANDIBULAR PAIN
		

Program list HEALTH- REHABILIATION

In compliance with the last regulations of the Ministry of Health, medical treatments are indicated in the below list

The following programs are medical

Health	Physiolaser 500	Physiolaser 1000	Session/ week	# weeks	Ø Spot mm
Arthrosis	x	x	5	2	11,5
Ankle sprain	x	x	5	2	11,5
Knee pain	x	x	5	2	11,5
Ankle sprain edema	x	x	5	2	11,5
Meniscus pain		x	5	2	11,5
Knee osteoarthritis		x	2	4	11,5
Achilles tend inflam.		x	5	3	11,5
Finger pain		x	3	3	11,5
Myofacial shoulder pain		x	5	2	11,5
Articular shoulder pain	x	x	5	2	11,5
Epicondilytis	x	x	2	4	11,5
Frozen shoulder		x	2	4	11,5
Carpal tunnel		x	5	2	11,5
Chronic back pain	x	x	5	2	11,5
Acute back pain		x	5	2	11,5
Back pain with radiculopathies		x	5	4	11,5
Neck pain	x	x	2	7	11,5
Neck pain with radiculopathies		x	5	3	11,5
Myofacial neck pain		x	5	2	11,5
Neck osteoarthritis		x	5	2	11,5
Temporo-Mandibular pain		x	2	5	11,5
Tendinopathies	x	x	5	2	11,5
Injuries		x	2	5	11,5

Because of the presence of clinical programs, this product is a medical device. Therefore it is certified by the Kiwa CERMET s.p.a n°. 0476 according to 93/42/CEE directive for medical devices. The certification covers clinical applications.

Program list BEAUTY – FITNESS
(non medical treatments)

X = Available program

Beauty	**Physiolaser 500**	**Physiolaser 1000**
FACE BEAUTY		
Wrinkles	x	x
Acne	x	x
Dehydrated skin		x
Skin rejuvenation	x	x
Skin – face lifting	x	x
Expression wrinkles	x	x
Neck winkles		x
Couperosis	x	x
Telangieactasias		x
BODY BEAUTY		
Breast stretch marks	x	x
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		
Scares	x	x
Loc. lymphatic stasis		x

CE0476 does not refer to non-medical treatments.

WARRANTY CONDITIONS

The device is guaranteed to the first user for a period of twenty-four (24) months from the date of purchase against defects in materials or of the manufacturing, provided that it is used properly and maintained under normal operating conditions.

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

1. The products, and all accessories, to be repaired must be sent by and at the expenses of the customer in their original packages.
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 warranty expiry date 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 where the fault has been caused by: impacts, falls, erroneous or improper use of the product, use of non-original power supplies or charger, accidental events, alteration, replacement/detachment of the warranty seals and/or tampering with the product. The warranty does not cover damages caused during transportation when unsuitable packages are used (see point 1).
6. The warranty does not cover the inability to use the product, other incidental or consequent costs or other expenses incurred by the purchaser.

NOTE: Before returning the device for repairs, we recommend to read carefully the user instructions contained in the manual.
In case of any faults caused to the device, refer to your retailer.
The manufacturer reserves the right to make all necessary modifications at any time in order to improve the aspect and quality of the product.

Emc tables

TABELLA 1 *TABLE 1*		
GUIDA E DICHIARAZIONE DEL COSTRUTTORE – EMISSIONI ELETTROMAGNETICHE – PER TUTTI GLI APPARECCHI ED I SISTEMI ***GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS***		
Il dispositivo PHYSIOLASER 1000 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del PHYSIOLASER 1000 deve garantire che esso viene usato in tale ambiente. *The* PHYSIOLASER 1000 *is intended for use in the electromagnetic environment specified below. The customer or the user of the* PHYSIOLASER 1000 *should assure that it is used in such an environment.*		
Prova di emissione ***Emissions Test***	**Conformità** ***Compliance***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - Guidance***
Emissioni RF *RF emissions* CISPR 11	Gruppo 1 *Group 1*	Il PHYSIOLASER 1000 utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. *The* PHYSIOLASER 1000 *uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
Emissioni RF *RF emissions* CISPR 11	Classe B *Class B*	Il PHYSIOLASER 1000 è adatto per l'uso in tutti i locali compresi quelli domestici e quelli collegati direttamente ad un'alimentazione di rete pubblica a bassa tensione che alimenta edifici usati per scopi domestici. *The PHYSIOLASER 1000 is suitable for use in all establishments, includine domestic establishments and those directly connected to the public low-voltage power supplì network that supplies buildings used for domestic purposes*
Emissioni armoniche *Harmonics emissions* IEC 61000-3-2	Classe A *Class A*	
Emissioni di fluttuazioni di tensione/flicker *Voltage fluctuation/flicker emissions* IEC 61000-3-3	Conforme	

TABELLA 2
TABLE 2

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER TUTTI GLI APPARECCHI ED I SISTEMI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS

Il PHYSIOLASER 1000 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del PHYSIOLASER 1000 deve garantire che esso viene usato in tale ambiente.

The PHYSIOLASER 1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the PHYSIOLASER 1000 *should assure that it is used in such an environment.*

Prova di immunità ***Immunity Test***	**Livello di prova IEC 60601** ***IEC 60601 test level***	**Livello di conformità** ***Compliance level***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - Guidance***
Scarica elettrostatica (ESD) *Electrostatic discharge (ESD)* IEC 61000-4-2	±6 kV a contatto_*contact* ±8 kV in aria_*air*	±6 kV a contatto_*contact* ±8 kV in aria_*air*	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno 30%. *Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.*
Transitori/treni elettrici veloci *Electrical fast transient/burst* IEC 61000-4-4	±2 kV per le linee di alimentazione di potenza_*for power supply lines* ±1 kV per le linee di ingresso/uscita_*for input/output lines*	±2 kV per le linee di alimentazione di potenza_*for power supply lines* ±1 kV per le linee di ingresso/uscita_*for input/output lines*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power qualità should be that of a typical commercial or hospital environment.*
Sovratensioni *Surge* IEC 61000-4-5	±1 kV linea – linea *line-line* ±2 kV linea - terra *line - earth*	±1 kV linea – linea *line-line* ±2 kV linea - terra *line - earth*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power qualità should be that of a typical commercial or hospital environment.*
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso	<5% U_T (>95% buco in_*dip in* U_T) per_*for* 0,5	<5% U_T (>95% buco in_*dip in* U_T) per_*for* 0,5	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore del PHYSIOLASER 1000 richiede un funzionamento continuato

dell'alimentazione *Voltage dips, short interruptions and voltage variations on power supply input lines* IEC 61000-4-11	cicli_*cycle* 40% U_T (60% buco in_*dip in* U_V) per_*for* 5 cicli_*cycles* 70% U_T (30% buco in_*dip in* U_T) per_*for* 25 cicli_*cycles* <5% U_T (>95% buco in_*dip in* U_T) per_*for* 5 sec	cicli_*cycle* 40% U_T (60% buco in_*dip in* U_V) per_*for* 5 cicli_*cycles* 70% U_T (30% buco in_*dip in* U_T) per_*for* 25 cicli_*cycles* <5% U_T (>95% buco in_*dip in* U_T) per_*for* 5 sec	anche durante l'interruzione della tensione di rete, si raccomanda di alimentare il PHYSIOLASER 1000 con un gruppo di continuità (UPS) o con batterie. *Mains power quality should be that of a typical commercial or hospital environment. If the user of the* PHYSIOLASER 1000 *requires continued operation during power mains interruptions, it is recommended that the* PHYSIOLASER 1000 *be powered from an uninterruptible power supply or a battery*
Campo magnetico a frequenza di rete (50/60 Hz) *Power frequency (50/60 Hz) magnetic field* IEC 61000-4-8	3 A/m	3 A/m	I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in ambiente commerciale o ospedaliero. *Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment*
Nota_e U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova *U_T is the a.c. mains voltage prior to application of the test level*			

TABELLA 4

TABLE 4

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

Il PHYSIOLASER 1000 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del PHYSIOLASER 1000 deve garantire che esso venga usato in tale ambiente.

The PHYSIOLASER 1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the PHYSIOLASER 1000 should assure that it is used in such an environment.

Prova di immunità ***Immunity Test***	**Livello di prova IEC 60601** ***IEC 60601 test level***	**Livello di conformità** ***Compliance level***	**Ambiente elettromagnetico – Guida** ***Electromagnetic environment - Guidance***
			Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte del PHYSIOLASER 1000 compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore *Portable and mobile RF communications equipment should be used no closet to any part of the PHYSIOLASER 1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.* **Distanza di separazione raccomandata** ***Recommended separation distance*** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
RF condotta *Conducted RF* IEC 61000-4-6	3 Veff_Vrms da 150 kHz a 80 MHz	3 V	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ da 80 MHz a 800 MHz

RF irradiata *Radiated RF* IEC 61000-4-3	*150 kHz to 80 MHz* 3 V/m da 80 MHz a 2,5 GHz *80MHz to 2,5 GHz*	3 V/m	*80 MHz to 800 MHz* $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ da 800 MHz a 2,5 GHz *800 MHz to 2,5 GHz*
			ove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e *d* è la distanza di separazione raccomandata in metri (m). *Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).* Le intensità di campo dei trasmettitori a RF fissi, come determinato da un'indagine elettromagnetica[a] del sito potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza[b] *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].* Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: *Interference may occur in the vicinity of equipment marked with the following symbol:* 

Note_s:

(1) A 80 MHz e 800 MHz; si applica l'intervallo di frequenza più alto.

At 80 MHz and 800 MHz, the higher frequency range applies.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Le intensità di campo per trasmettitori fissi come le stazioni base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoricamente e con precisione. Per valutare un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa un PHYSIOLASER 1000, supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale del PHYSIOLASER 1000. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione del PHYSIOLASER 1000.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PHYSIOLASER 1000 is used exceeds the applicable RF compliance level above, the PHYSIOLASER 1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PHYSIOLASER 1000.

b L'intensità di campo nell'intervallo di frequenza da 150 kHz a 80 MHz dovrebbe essere minore di [V_1] V/m

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

TABELLA 6
TABLE 6

DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATILI E MOBILI E PHYSIOLASER 1000 PER APPARECCHI O SISTEMI CHE NON SONO DI SOSTENTAMENTO DELLE FUNZIONI VITALI

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PHYSIOLASER 1000 FOR EQUIPMENT AND SYSTEM THAT ARE NOT LIFE-SUPPORTING

Il PHYSIOLASER 1000 è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore del PHYSIOLASER 1000 possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e il PHYSIOLASER 1000 come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

The PHYSIOLASER 1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PHYSIOLASER 1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PHYSIOLASER 1000 as recommended below, according to the maximum output power of the communications equipment.

Potenza di uscita massima del trasmettitore specificata ***Rated maximum output power of transmitter*** ***W***	**Distanza di separazione alla frequenza del trasmettitore (m)** ***Separation distance accordino to frequency of transmitter (m)***		
	Da 150 kHz a_*to* 80 MHz	**Da 80 MHz a_*to* 800 MHz**	**Da 800 MHz a_*to* 2,5 GHz**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,20	1,20	2,30
10	3,80	3,80	7,30
100	12,00	12,00	23,00

Per i trasmettitori specificati per una potenza massima di uscita non riportata sopra, la distanza di separazione raccomandata d in metri (m) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, ove P è la potenza massima d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Nota_e

(1) A 80 MHz e 800 MHz, si applica l'intevallo della frequenza più alto.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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