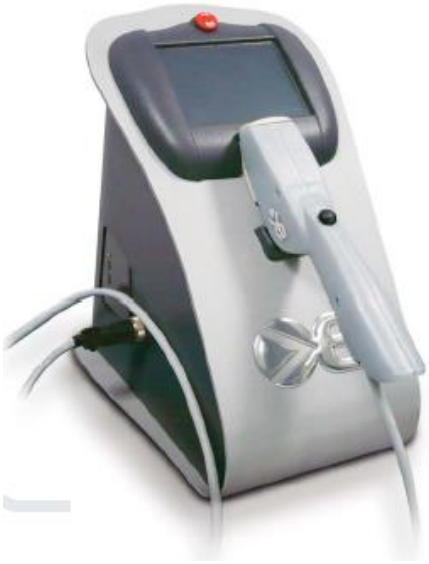
MULTI-OP®
EYE-SYSTEM®



EYE-LIGHT®
BE-LIGHT®

INSTRUCTION MANUAL

CE
0476

MAN 59 rev 02

Date 20/04/2017

INTRODUCTION

READ THIS MANUAL COMPLETELY BEFORE USE. COMPLY WITH THE SAFETY RULES AND THE RULES FOR PROPER USE AND MAINTENANCE OF THE EQUIPMENT.

THE MANUFACTURER WILL NOT BE HELD RESPONSIBLE UNDER ANY CIRCUMSTANCES FOR NON-COMPLIANCE WITH THE ABOVE.

THE EQUIPMENT IS A MEDICAL DEVICE

EQUIPMENT NAMED

EYE-LIGHT®
BE-LIGHT®
MULTI-OP®
EYE-SYSTEM®

ARE PROTECTED BY THE FOLLOWING

PATENT:

- International Patent N. 0711661.4

Espansione Marketing Spa is certified:
UNI EN ISO 9001-2008
UNI EN ISO 13485-2012
ISO 13485 :2003

SOMMARIO: **PAG.**

TECHNOLOGIES OF THE MEDICAL DEVICES DESCRIBED IN THIS MANUAL

The medical systems described in this manual, with OPE®(polychromatic light inducing thermal stimulation) and LIGHT MODULATION® (biostimulating monochromatic light (LED) technologies **are intended for therapeutic treatments in medical environment with professional personnel (doctor/dermatologist/ophthalmologist** with the following use destinations:

OPE® IPL 600nm
- Treatment of meibomian glands dysfunction (dry eye syndrome) in order to stimulate the secretion of the tear film lipid component of the patient

BLUE LED
- intended for treatment of moderate inflammatory conditions caused by Acne Vulgarise

YELLOW LED
- performs a precise action on the lymphatic system, stimulates the cellular metabolism by promoting a detoxifying and soothing effect in conditions of cutaneous oedema

RED LED
- supports tissue repair processes by penetrating skin in depth in cases of cutaneous ageing
- in combination with the infrared LED it stimulates the cellular mechanisms responsible for the repair of tissues and their regeneration in cases of deep cutaneous ageing
- In combination with the blue LED it helps acne treatment
- In the Dental version, it acts as an adjuvant to the standard non-surgical therapies in the treatment of inflammatory processes, stimulating tissue repair and regeneration in cases of parodontitites.
- It is indicated for the treatment of androgenetic alopecia also in combination with other therapies (plasma) and telogen effluvium in combination with laser therapy.
- It triggers an endogenous eyelid heating thanks to the LEDs emission.

INFRARED LED
- stimulates the cellular mechanisms responsible for the repair of tissues and their regeneration in cases of deep cutaneous ageing.
- supports the processes of repair and regeneration of tissue in both dermatology and dental

Equipment named EYE-LIGHT®; BE-LIGHT®; MULTI-OP® and EYE-SYSTEM® with OPE® and LIGHT MODULATION® technologies described in this manual are intended for following application and destinations of use:

- ✓ INDICATED ONLY FOR PROFESSIONAL USE (MEDICAL)
- ✓ FIELDS: DERMATOLOGICAL, DENTAL and OPHTHALMIC

PDT function allows PhotoDynamic Therapy commonly identified as PDT. In this case the light is used in the dermatological field for the activation of specific drugs prescribed and applied by the physician who carries out the treatment.

WORKING FIELDS
Devices named EYE-LIGHT®; BE-LIGHT®; MULTI-OP® and EYE-SYSTEM® are intended to be used in healthcare: medical clinic, professional office, medical facilities, etc ..

AUTHORIZED PERSONNEL
Devices named EYE-LIGHT®; BE-LIGHT®; MULTI-OP® and EYE-SYSTEM® are intended for use by health care professionals that:
* they know how to use the device;
* they are aware of the standard techniques for the use of OPE® and LIGHT MODULATION® (technologies available in the unit) for the execution of the treatments
* They are aware of the risks associated with the use of technologies of the unit: OPE® and LIGHT MODULATION®

INSTALLATION

1. INSTALLATION REQUISITES

Correct installation of the medical systems described in this manual, ensures the normal operation of the equipments. For this purpose, it is necessary that the following environmental conditions be ensured:

- The position of the machine does not result in it being exposed to heat sources or being in places subject to water or dampness.
- The space around the machine is no less than 50cm, in order to allow sufficient cooling of the internal parts.
- The electrical system is compliant with the IEC standards and the power source corresponds with that described in the machine's technical specifications.

For installation, follow the directions provided in chapter INSTALLATION INSTRUCTIONS (p.18)

2. UNPACKING AND INSPECTION

The medical systems described in this manual are supplied with their own packaging, inside which are placed all parts necessary for the normal operation of the machine and the related documents. The pack contains:

- The medical device
- A power cable
- Handpiece for OPE® and LIGHT MODULATION® Technologies
- Protective operator's glasses for OPE® Technology treatments
- Protective patient's goggles for OPE® Technology treatments
- This Instruction Manual for use of the device

OPE® 600nm cartridge and LIGHT MODULATION applicative terminals are supplied and packed separately according to customer requirements. Available accessories are:

CODE	DESCRIPTION
EYE LAMP/CE-XXX	OPE® 600nm Lamp
EYE MASK/CE-XXX	Light Modulation® Red Mask
MASK LM RED/CE-XXX	Light Modulation® Red Mask
MASK LM YELLOW/CE -XXX	Light Modulation® Yellow Mask
MASK LM BLU/CE -XXX	Light Modulation® Blue Mask
MASK LM IR/CE -XXX	Light Modulation® Infrared Mask
HAIR LM/CE-XXX	Light Modulation® Red Helmet
BAND LM/CE-XXX	Light Modulation® Body Bands

Always keep the original packaging in case of need for a transfer or return to the manufacturer for service.

After unpacking it is recommended to examine the contents of shipping box in order to ascertain the presence of any damage to the equipment. Should any damage be noted, immediately inform the distributor or the manufacturer. Please also check the different parts contained in the packaging against the shipping list in order to ascertain that all parts are present in the carton, and communicate any discrepancies.

NOTES FOR CONSULTATION

ABBREVIATIONS
Unit = Medical equipment based on OPE® and LIGHT MODULATION® technologies
OPE® lamp/cartridge/terminal = applicative OPE® terminal
LM® terminal = Applicative Light Modulation® terminal (face masks, body bands, hair helmet)
Cod. = Code
Pag. = Page
Fig. = Figure
Pos. = Position

SYMBOLS

- **To ensure quick and rational reading** use has been made of symbols which draw attention to situations requiring the utmost care, practical suggestions or simple information.

- **These symbols** may be found placed alongside text (therefore they refer to that text only), alongside a figure (they refer to the subject illustrated in the figure and to the related text), or at the top of a page (they refer to all subjects covered on that particular page).

CAUTION ! Pay utmost attention to the meaning of symbols: their function is to avoid the need to repeat technical concepts or safety warnings, therefore they should be considered veritable 'reminders'. Consult this page whenever you are in doubt about their meaning.

	CAUTION ! Draws attention to an important description concerning technical action, hazardous conditions, safety warnings, prudential suggestions and/or information of utmost importance.
	**DISCONNECT POWER! Before working on the unit, disconnect from the power supply.**
	**SPECIALISED PERSONNEL! Any task highlighted by this symbol must be performed only by a specialised technician.**

LABELS

The system has a label which gives instructions and warnings; it is applied on the back of unit above the power socket and shows the data plate and applicable regulations (Fig. 1)

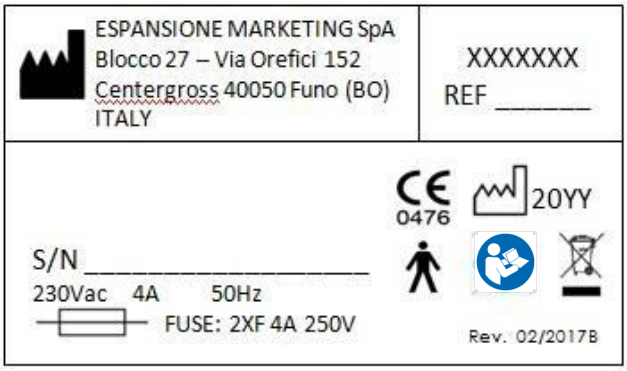


Fig. 1

XXXXXXX - IDENTIFIES THE DEVICE MODEL BETWEEN THOSE DESCRIBED IN THIS MANUAL, SUCH:
EYE-LIGHT®
BE-LIGHT®
MULTI-OP®
EYE-SYSTEM®

Symbols on the LABEL

MANUFACTURER
S/N SERIAL NUMBER
REF CODE NUMBER

FUSE

PART APPLIED TYPE B

READ THE USAGE MANUAL

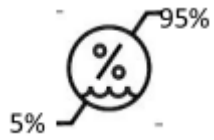
COMPLIANT WITH DIRECTIVE 93/42CEE

YEAR OF PRODUCTION

RAEE INDICATIONS

Other symbols on the packaging label of the device are the following

store at a temperature of -5 to 40° C



store at relative hunidity of 5-95%

SAFETY FEATURES

The unit includes a number of safety features realized in accordance with the specifications of the appropriate standards.

The unit was manufactured in line with:
The EN 60601-1 and EN 60601-1-2 harmonised European Standards

It therefore has the following safety standards required by the above-stated regulations:

- Autotest
- Acustic Indicator of light emission
- Protective housing.
- READY and WAITING modes for the light emission unit
- Location of controls.
- Compliance label.

The unit also has the following additional safety features:

- Auto test
- Interruption (with automatic return to WAIT mode)
- Control of voltage at lamp's opposite poles
- Power cut protection
- Temperature control
- Automatic switch-off of the application accessory during its replacement

LIMITATION OF LIABILITY

Espansione Marketing S.p.A. assumes responsibility as regards safety, reliability and performance of the medical systems described in this manual , provided that:

- The installation, modifications and service procedures are performed solely by authorised technical staff.
- The electrical system to which the machine is connected complies with the applicable IEC regulations.
- The system is installed and used in line with the instructions provided in this instruction manual.

Espansione Marketing SPA will not be held responsible under any circumstances

- for direct consequences caused by non-compliance with the general warranty conditions, during the warranty and at its expiry. For material damage or bodily accidents occurring following installation which is not compliant with the legal or regulatory provisions of the country in which the appliance is installed
- for material damage or bodily accidents occurring following an intervention not provided for in the usage manual of the manufacturer and/or performed by the user or a third party not authorized by the manufacturer.
- for material damage or bodily accidents deriving from use differing from the use destination stated in this usage manual
- the owner or lessee of the unit fulfils its obligation of annual maintenance as indicated in this manual.

MODIFICATIONS

Espansione Marketing S.p.A. reserves the right to carry out modifications to the unit and the related accessories, and also to the technical specifications of the product, giving its customers suitable notice of this.

⚠ WARNINGS ⚠

ATTENTION

To turn on units: EYE-LIGHT® - BE-LIGHT® - MULTI-OP® - EYE-SYSTEM® it is requested to enter a PASSWORD. The equipment must be protected against unauthorized use by means of proper management of the POWER-ON PASSWORD

By switching on the unit following page will appear (fig.2)

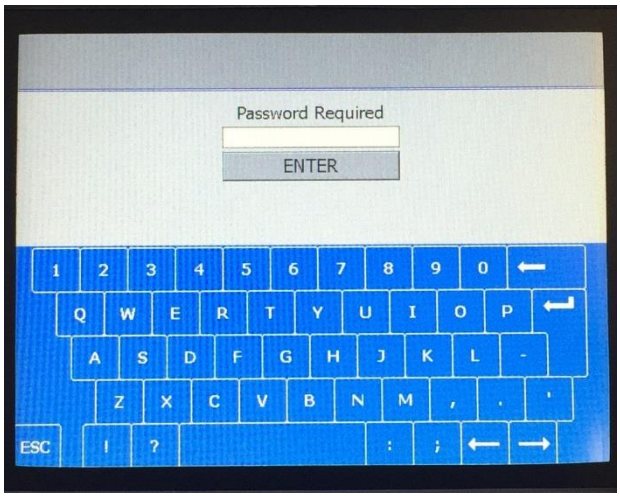


Fig. 2

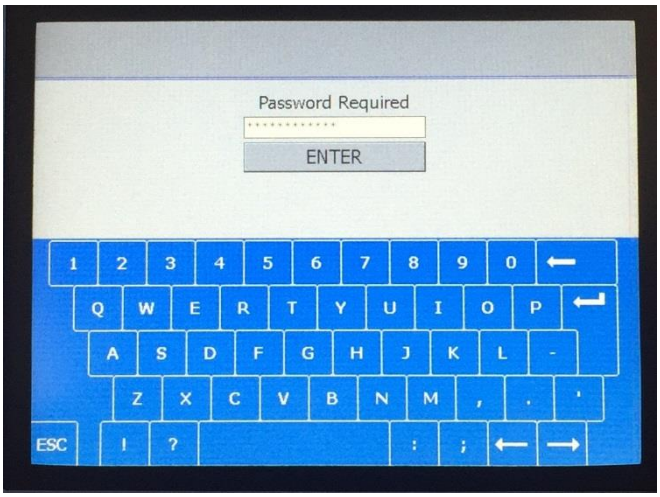


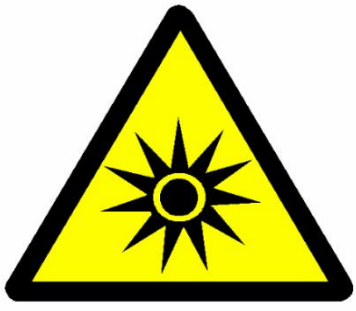
Fig. 3

User must enter the password provided when purchasing the unit and press ENTER to start the equipment operation (Fig 3)

Hereunder please find labels affixed to the product with relevant explanations:

SAFETY LABELLING

a)



Hazard warning signal arasing from optical radiation (IEC 174/11)

b)

LIGHT SOURCE GROUP 3 ACCORDING TO NORM EN 62471

Classification of risk group according to standard EN62471: 2009 (Group 3)

c)

CAUTION
VISIBLE AND IR RADIATIONS EMITTED BY THIS DEVICE MAY BE HARMFUL TO THE EYES DO NOT LOOK INTO LIGHT SOURCE

CAUTION
VISIBLE AND IR RADIATIONS EMITTED BY THIS DEVICE CAN CAUSE EYE IRRITATION DO NOT LOOK INTO LIGHT SOURCE

CAUTION
VISIBLE AND IR RADIATIONS EMITTED BY THIS DEVICE CAN CAUSE INJURY TO THE EYES DO NOT LOOK INTO LIGHT SOURCE

The devices EYE-LIGHT® - BE-LIGHT® - MULTI-OP® and EYE-SYSTEM® emit a light radiation that can be hazardous to the eyes. It is therefore essential that the operator and the patient wear glasses/goggles with optical density greater than 6.5 in the emission spectrum (510-960nm).

c-bis)

CAUTION
DO NOT USE IN OXYGEN ENRICHED ATMOSPHERES

The devices EYE-LIGHT® - BE-LIGHT® - MULTI-OP® - EYE-SYSTEM ® should not be used in presence of flammable anesthesia or oxidizing gases. In case of use of solvents for cleaning or disinfection, wait for their complete evaporation before proceeding to treatments.

d)

OPTICAL RADIATION OPENING

It indicates the position from which optical radiation comes out

Image 1: rear of the unit with product label (fig.1) and plate c-bis)
Image 2: side of the unit with labels a), b) e c)
Image 3: handpiece with labels a) e d)

Image 1

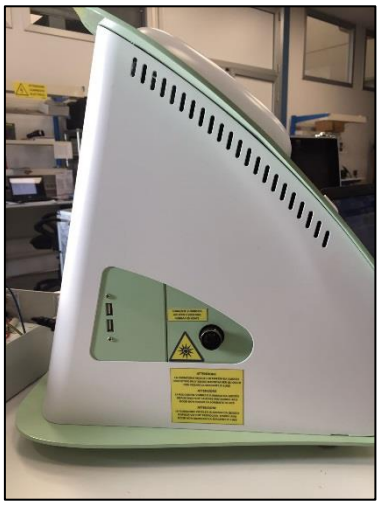


Image 2

Image 3

⚠ GENERAL WARNINGS ⚠

MUST READ BEFORE USING THE MEDICAL DEVICES DESCRIBED IN THIS MANUAL

Application of the unit is absolutely prohibited on pregnant women, persons fitted with pacemakers, pulse generator, internal defibrillator, metal, electrical or acoustic prosthetics, persons who suffer from epilepsy, cardiac frequency disorders, pyretic diseases underway, thrombophlebitis or acute phlebitis of legs, large-sized varicose veins, high blood pressure sufferers and severe diabetics, people with capillary fragility or spider veins.

- Keep the unit out of the reach of children.
- For every use condition, pay the utmost attention to the instructions stated below, some of which are repeated several times.
- Modifications and tampering, even slight, or the use of non-original spare parts or spare parts non-compatible with the manufacturer's quality standards relieve the manufacturer of responsibility under any circumstances and result in the withdrawal of the warranty rights.
- Do not leave the unit exposed to dust, dampness, temperatures below 15°C (if kept at lower temperatures, it is required that the unit acclimatises at a temperature of a minimum of 15°C at least 15 hours before use).
- The unit must never be kept below -5°C.
- It is advised not to use the unit near appliances such as microwave ovens, mobile telephones, ultrasound or high frequency generators.
- The unit must only be used by staff trained for its use.
- After each use, press the ON/OFF switch on the back of the unit to the OFF (O) position and if necessary disconnect the power cable.
- When the unit is not being used, it must be protected from non-authorized use.
- Do not deform, fold, tread on or knot the power cable or any of the cables connected to the unit. Replace these cables as soon as they show signs of deterioration, using only original parts.
- Do not obstruct the ventilation slits located on the bottom of the central unit.
- Do not rest on the receptacles containers with liquids.
- Any use other than the intended use relieves the manufacturer of responsibilities under any circumstances.
- The use of commands, controls or sequences of procedures other than those listed in this manual can cause damage to unit.
- Do not use the appliance on children under 7 years of age. A doctor's opinion is necessary if the appliance is to be used on children over 7 years of age.
- Do not use the unit in the event of fever, open wounds, recently healed wounds, serious and evolving diseases (cancer, AIDS, hepatitis, blood disease etc.), blood coagulation problems. Do not use the unit on persons who suffer or have suffered from phlebitis, have undergone an operation on veins (surgical or sclerotherapy in the past two months), who have varicose veins and/or tingling in the legs.
- Do not use the unit inside the mouth, on the mucous membranes, on genitals or on moles with an anomalous appearance.
- Do not use the unit on persons who suffer from epilepsy. The appliance must not be used on persons who suffer from mental disorders, excitation, recurring migraines.
- Inform patient's doctor in the event of intake of pharmaceuticals such as anti-inflammatory drugs, anticoagulants, antibiotics and antihistamines.
- It is advised to remove jewellery or piercing prior to treatment.
- The results obtained can vary according to the person's lifestyle (sports activities, diet and other factors) and morphology.
- Do not use in a dusty place.
- It is strongly advised to avoid the presence of reflective surfaces of any type in the system field of action.
- The unit must be used only on tissue which is completely visible. Do not use the unit if the area to be treated is not observable.
- The unit must not come into contact with injured parts or infected parts.

RISK OF ELECTRIC SHOCK

- Due to the high voltages present within the system and in particular the handpiece, it is absolutely prohibited to use the device in case some panels are open or appear not properly closed.
- Users are also reminded that all assembly or disassembly operations of parts of the system must be performed solely by authorized staff.
- The equipment is electrically connected to earth through the power cable; a good earthing system of the electrical system to which the machine is connected is a necessary condition for normal safety conditions.

REFLECTIONS

- Avoid placing reflective materials such as glass, mirrors, metals and reflective plastic in the range.

HAZARDS

- Many non-metallic materials can catch fire when exposed to high densities of luminous radiation. Therefore remember that the majority of plastics, paper and wood are readily inflammable.
- In addition, do not use the unit in rooms or areas in which easily inflammable liquid or gaseous substances or substances with high concentrations of oxygen are present. The use of inflammable anaesthetic gases or oxidising gases such as nitric oxide (N2O) and oxygen must be avoided. Some materials e.g. cotton wool, when saturated with oxygen, can catch fire because of the high temperature generated in the normal use of the light emission unit. Glue solvents and inflammable solutions used for cleaning and disinfection should be left to evaporate before using the light emission unit. Pay attention to the fire risks of endogenous gases**.**

RISK OF FIRE OR EXPLOSION

- The emission of light by the system does not present significant risks such as to cause the ignition of non-metallic materials. However, considering the relatively high temperatures reached by the handpiece, we recommend to keep the operating area clear of flammable material objects such as paper, cotton wool, plastic, wood or similar non-metallic materials.
- Set the light beam onto the area to be treated only.
- Always deactivate the unit when it is unattended.

OPE® TECHNLOGY WARNINGS

The person undergoing the treatment must be warned that during the application there could be complications such as:

- slight pain
- hyperpigmentation
- hypopigmentation

Cover any nevi or other dark spots with a white patch or white pencil

ACCIDENTAL EXPOSURE

A light technology based system emits very intense light that may cause, **if not adequately protected,** temporary disturbances to the eyes. For this reason, all persons in the system's operating area must wear the protective glasses/goggles provided and must not look directly at the opening of the handpiece during the discharge. Espansione Marketing S.p.A. will accept liability only for its own protective glasses/goggles provided with the system and which are suitable for the wavelengths used.
Protective glasses/goggles must be used for OPE® mode (OPE® technology), by both those undergoing and those performing the treatment.
A potential danger is represented by accidental reflections that can deflect the light emitted in a completely unpredictable way; it is therefore recommended to avoid reflective surface of any type in the working area.

Take all necessary protective measures in areas where the unit is used. All staff present in the room where the unit operates including those undergoing the treatment, must use protective eyewear appropriate to the wavelength used by the unit. Do not observe in any case the lamp filter during the flash output.
Direct the light beam of the unit only on the area to be treated.
Always turn off the unit when it is unattended.

Proceed with caution in the treatment until the operator is not fully aware of the biological mechanisms of interaction between the power of the unit and the skin.
If high fluence values are used, it could cause damage to the skin. Use low fluences until you have not fully understood the full capacity of the instrument and the response of the patient's skin to be treated

EYE DAMAGE

Exercise extreme caution when working near the eyes.

All staff must wear special glasses to prevent the risk of accidental damage to the eyes. The person being treated must therefore also wear the above-stated goggles otherwise it is required that the eyelids be covered with a gauze.
All protective glasses/goggles must be specific against radiations emission in continued wavelength in the range of 600-1100nm.
The use of optical accessories and means of magnification can lead to ocular exposure in excess of safety values and should therefore be submitted for the approval of local authorities in charge of the subject.

BURNS

Accidental irradiation of substances or materials other than skin tissue may cause burns.

REFLECTIONS

Avoid placing reflective materials such as glass, mirrors, metals and reflective plastic in the range.

LIGHT MODULATION® TECHNOLOGY WARNINGS

EXPOSURE TIME TO THE LIGHT MODULATION® LIGHT

Treatment time must not exceed 30 minutes.
Keep the unit out of the reach of children.

⚠ CONTRAINDICATIONS ⚠

The unit must be used solely in conditions in which its use is suitable and of proven effectiveness and only in full compliance with the conditions set out in this manual. In no event must it ever be used other than with the direct supervision of expert staff specifically trained in its use.
Application of the unit is absolutely prohibited on pregnant women, persons fitted with pacemakers, metal, electrical or acoustic prosthetics, persons who suffer from epilepsy, cardiac frequency disorders, pyretic diseases underway, thrombophlebitis or acute phlebitis of the legs, large-sized varicose veins, high blood pressure sufferers and severe diabetics.

GENERAL SPECIFICATIONS

GENERAL SPECIFICATIONS OF EQUIPMENT	
Operating mode	Continuous / Pulsed
Control unit weight	25 Kg
Power Voltage	230 VAC 50 Hz
Fuses (two)	4 A, 250 Volt
External container:	Varnished metal and Derlin
Handpiece	A.B.S.
Insulation	Class I, Part applied Type B
Control panel with touch screen computer	Incorporated
Environmental conditions allowed for transport, storage and working:	Temperature -5 to + 40° - Humidity 5 - 95% Pressure from 500° 1060° hPa Working temperature: 15 - 30° C Relative humidity: 5 - 95%
Useful life of the device	10 years
OPE® TECHNOLOGY FEATURES	
Source type	IPL
Maximum optical radiance of the unit	65 Joule
Emission wavelength	600nm
Spot area in cm	2, 5 cm x 4,5 cm Total 11,25 cm2 – spot reducers and heat absorption filter are supplied with the lamp
Function mode	Impulsed (P)
Cooling system	Air (internally forced)
Impulse duration	From 10 to 30 ms
Power indication	YES – on the screen
Information about filter under use	YES – on the screen
Limitation of maximum emission	YES
Risk free distance (distance at which the radiance value is within the limits of the group 0)	3mt
LIGHT MODULATION® TECHNOLOGY FEATURES	
The device produces increased blood flow in the treated part, causing a sensation of heat	
Source type	LLLT
Duration of treatment	Manageable by the operator up to a maximum of 30 min.
LED FEATURES	
RED	Supports tissue repair processes by penetrating deeply into skin in the case of cutaneous ageing In combination with the infrared LED it stimulates the cellular mechanisms responsible for tissue repair and tissue regeneration in cases of deep cutaneous ageing In combination with the blue LED it helps acne treatment In the Dental version it acts as an adjuvant to the standard non-surgical therapies in the treatment of inflammatory processes, stimulating tissue repair and regeneration in cases of parodontites. It is recommended for the treatment of male and female Androgenic Alopecia also in combination with other therapies (plasma) and of Telogen Efflivium in combination with laser therapy.
YELLOW	Performs a precise action on the lymphatic system, stimulates the cellular metabolism by promoting a detoxifying and soothing effect for cutaneous oedema conditions
BLUE	Intended for the treatment of moderate inflammatory conditions caused by Acne Vulgaris

INFRARED	Stimulates the cellular mechanisms responsible for tissue repair and tissue regeneration in cases of deep cutaneous ageing. It supports tissue repair and regeneration both in dermatological and dental field.

DESCRIPTION OF THE UNIT

COMPONENTS

The unit basically consists of two components:

- The control unit that encloses all the control electronics of microprocessor, power supply and cooling units
- The handpiece for releasing energy to the tissue, which encloses lamp, filter and ventilation system

FRONT PANEL CONTROLS

All main operations of unit are managed by the touchscreen computer. The options are selectable by pressing the keys on the screen.
Instructions on where to press the keys to perform specific tasks will be given in this manual.

HANDPIECE

The energy release system consists of a handpiece that contains lamp, filter and ventilation system.

INSTALLATION INSTRUCTIONS

Remove the unit from the packaging, being careful not to scratch the body of the machine with scissors or cutters.

Correct installation of the system ensures the normal operation of the equipment. For this purpose it is required that the following environmental conditions be ensured:

- The position of the machine does not result in it being exposed to heat sources or being in places subject to water or dampness.
- The space around the machine is no less than 50cm in order to allow sufficient cooling of the internal parts.
- The electrical system is compliant with the IEC standards and the power source corresponds with that described in the machine's technical specifications.

NOTE: Always keep the original packaging in case of need for a transfer or return to the manufacturer for servicing.

Remove the unit from the packaging, being careful not to scratch the body of the machine with scissors or cutters. Extract the unit paying attention to its weight and place it on the workbench. Remove now the handpiece supplied and connect the connector at its ends by screwing it into the seat in the unit (Figures 2 and 3).

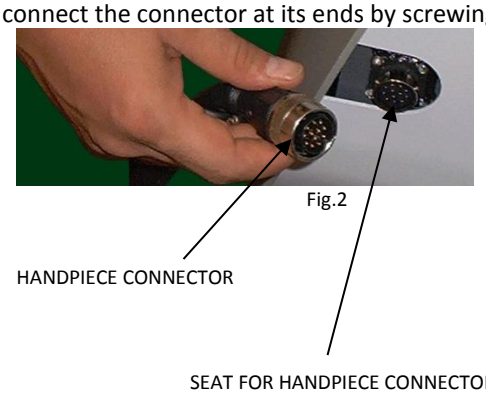


Fig.2

Fig. 3

Now remove the lamp supplied from the packaging and insert it as far down as it will go into the handpiece as per Fig.4/B. Be careful not to leave finger marks and not to dirty the filter located above the lamp. If the filter does get marked, clean it with a soft and dry cloth (of type used for soil glasses lenses).

Fig. 4A

Fig. 4B

Now insert the handpiece into its seat located in front of the central unit as per Fig. 5/A and Fig. 5/B until you hear the click.

Fig. 5A

Fig. 5B

Handpiece is provided with a NEUTRAL CARTRIDGE namely a blind cartridge, designed to be able to insert the handpiece into its seat. You should always replace the operating cartridges with the neutral one when not using the equipment, so as to avoid accidental breakage.

LIGHT MODULATION® systems (face masks) are connected through blind cartridges that activates the monochromatic light (Fig. 4C and 4D)

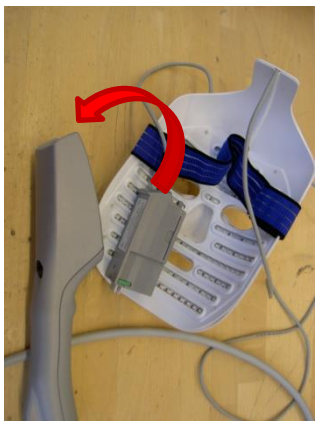


Fig. 4C

Fig. 4D

By inserting the blind cartridge of the mask into the handpiece as indicated with the red arrow in fig. 4C, mask will be activated (fig. 4D)

Now connect the power cable to the back of the control unit in the position indicated by arrow 1 in Fig.6 and 7 and turn the switch ON/OFF to the ON or 1 position as indicated by arrow 2.

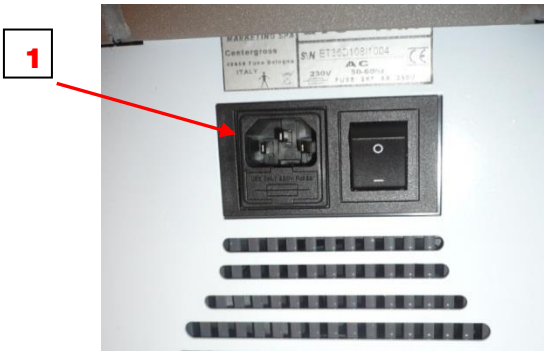


Fig. 6

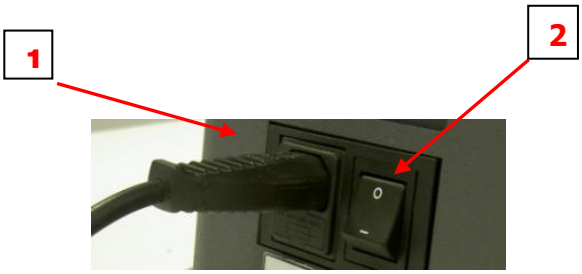


Fig.7

At unit switch-on you will hear the fan of the control unit start running. Should this not happen, check the power cable and that the ON/OFF switch has been pressed.
Should this check not give a successful outcome, disconnect the power cable from the electrical socket and check the 2 fuses inserted in the drawer placed between the switch and the cable in the position shown by arrow 2 in Fig.7 and 8. The kit includes 2 new fuses for replacing fuses which may be damaged.

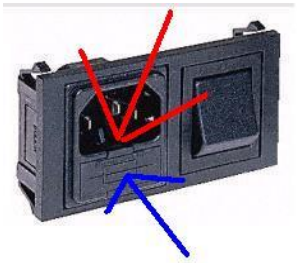


Fig. 8

Now press the ON/OFF switch on the back of the unit and wait for the screen to activate.
Now follow the instructions shown on the display.
The touch screen is a true screen to be used with a finger pression or a palmtop PC type pointer.

GENERAL PRECAUTIONS

The unit must be used solely by operators specially trained for its use and only after reading all parts of this manual.
The information supplied in this section is not intended to cover all problems and/or take the place of the operator's knowledge and experience. Please contact ESPANSIONE MARKETING for training courses on the use of this instrument.
Although it is difficult to specify the effects which the use of the unit can have on every single individual, it is useful to take into consideration the points described below.

1. The specific effect depends on the type of tissue treated and the products possibly used in synergy
2. There are recommended treatment times, however the defining of personal protocols is left up to the operator, depending on his/her experience and clinical judgement of the results obtained by the treatment.

The unit has been tested by specialists in the field, for suggestions on its use please contact the service centre using the telephone number to be found in this manual.
The unit must be used only on tissue which is completely visible. Do not use the unit if the area to be treated is not observable.

The unit must not come into contact with injured parts or infected parts.

COMPLICATIONS

The potential complications of treatment with the unit are identical to any complication which can be found in the field of normal procedures in medical/aesthetic treatments. Do not vehiculate skin products for which the side effects are not known.

⚠ PRECAUTIONS IN THE USE OF OPE® TECHNOLOGY ⚠

- The specific effect depends on the fluence value and of course on the type of tissue treated.
- The pulsed light may cause harm if it is improperly used.
- The appropriate precautions such as a correct evaluation of the tissue must therefore be taken during treatment and fluence must be used appropriately.
- Starting with low fluence values is a correct approach for an in-depth evaluation of pulsed light effectivencess.
- The operator must start with low values to observe the effect on the skin tissue and increases the fluence values until the required effect is obtained.
- Recommended fluence values are given. It is nevertheless up to the operator to define the personal protocols according to his experience and clinical assessment of results obtained in the specific treatments.

The light emission stability of the handpiece is guaranteed, under normal conditions of use, by production features of OPE® cartridges and by the emission control SW. For this purpose the device contains an internal control system that ensures the correspondence between the pulse energy set by the operator and the actual energy stored and released from the system in the output of OPE® handpiece. At the same time every OPE® cartridge contains internally an EEPROM memory in which an identifier ID is stored. Through this ID The device will identify the allowed parameters of use in order to ensure that the use conditions of OPE® cartridge matches with those expected from ESPANSIONE MARKETING. These features are the same in all types of accessories available.

With use OPE® cartridge is subject to usury and to a consequent degradation of the emitted light radiation performance. ESPANSIONE MARKETING fixed the limit to which the accessory can be used in complete safety and efficacy. For this purpose, also the real use, is saved inside the OPE® cartridge. The device disabilities output exhaustion of that parameter.

Although still usable, the OPE® cartridge must be sent to ESPANSIONE MARKETING, to be verified, in case of:

-Strong trauma (eg. falls, overheating, etc.).
-After prolonged periods of non-use (eg. 1 year)

⚠ PRECAUTIONS IN THE USE OF LIGHT MODULATION® TECHNOLOGY ⚠

Carry out a careful anamnesis of the patient before exposing him or her to application of the technology, being careful to find out if the patient has been subjected to antibiotic or photo sensitising therapy. In this case, the doctor will be responsible for the decision on whether or not to use the technology. Analyse the area to be treated carefully, ascertaining that the skin is intact. In the event of wounds which have not yet healed, delay the treatment until healing is complete.

DESCRIPTION OF OPE® APPLICATIVE TERMINALS

OPE® technology is used by following applicative terminal:
OPE® lamp with 600nm filter: dry eye treatment

DESCRIPTION OF LIGHT MODULATION® APPLICATIVE TERMINALS

LIGHT MODULATION® can be used by means of one of the following applicators:

FACIAL MASK

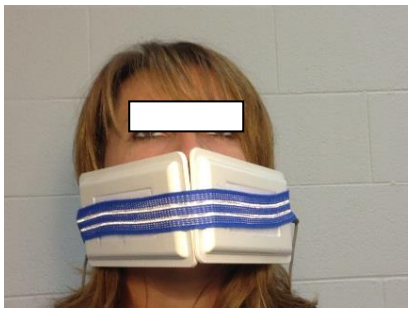
The facial mask is rested on the face and its internal structure is such that the LED do not come into direct contact with the skin, as it is kept at the optimal distance of 5-10 mm from the skin to be treated. Application of the mask is done without the operator's help, as self-treatment by the patient. It is available in the following variants: red, yellow, blue, infrared.

BODY BAND

The body band is rested on the skin to be treated and its internal structure is such that the LED do not come into direct contact with the skin, as it is kept at the optimal distance of 5-10 mm from the skin to be treated. Application of the body band is done without the operator's help, as self-treatment by the patient. It is available in the following variant: red and infrared.

DENTAL BAND

The dental band is placed on the dental part to be treated and its internal structure is designed in such a way that the LEDs do not come into direct contact with the skin, as it is maintained at an optimal distance of 5 to 10 mm from the skin to be treated. The application of the dental band is performed with the aid of the operator. It's available in the red and infrared variant.



HAIR HELMET

The Hair Helmet allows application of the luminous beam directly on the head. It is worn easily and comfortably by the patient. The form of the helmet allows uniform distribution of light on the scalp, lighting up a very large area at the same time. Special spacers keep the LED distanced from the skin of the patient. The helmet contains monochromatic light (red LED).

CONNECTION AND REPLACEMENT OF OPE® AND LIGHT MODULATION® TERMINALS

All the terminals are connected to the central unit by means of inserting OPE cartridge or blind cartridge of LIGHT MODULATION terminal into the LIGHT HANDPIECE. Insert lamps and cartridges as indicated in the "INSTALLATION INSTRUCTION" section

Lifetime of OPE® lamps is measured in number of flashes, that of **LIGHT MODULATION®** applicative terminals is measured in hours. Software advises when termination is approaching.

APPLICATIVE PROTOCOLS

GENERAL INSTRUCTIONS

1. Before beginning any treatment it is necessary to find out if the patient has, or has suffered from in the past, any skin disease or is following antibiotic, cortisone or photosensitising therapy. In this case the doctor will be the sole judge to decide when to begin the treatment.
2. Analyse the area to be treated carefully, checking that the skin is not damaged. Cleanse the area to be treated.
3. It is possible to apply to the part to be treated a specific product for the treatment being performed. At the end of the treatment a specific product can be massaged into the treated part.

GUIDELINES

Operators who use this equipment need to have knowledge of its use and of the principles on which OPE and Photobiostimulation therapies are are based. Consequently the qualified staff designated for the different treatments must assume responsibility for correct applicative diagnosis.

The purpose of this manual is to supply guidelines aimed at the correct use of monochromatic light emission equipment for non invasive applications.

The medical system contains:

- **OPE® TECHNOLOGY** (pulsed light or IPL) polychromatic light for dry eye deseases
- **LIGHT MODULATION® TECNOLOGY** (photobiomodulation, LLLT) monochromatic biostimulationg light (LED) for treatments for the face and body and for hair thickening

PREPARATION FOR THE TREATMENT

Select the treatment from the menù and press ENTER. You can go back to the previous screen by using the ESC button.
Based on the selected treatment, the software will indicate the sequence of technologies to be used.

PREPARATION FOR THE TREATMENT WITH OPE® TECHNOLOGY

- cover all nevi or dark spots with a white patch or white pencil
- Insert the cartridge 600nm, as shown in the menu of the software, and press ENTER.
- Set the required parameters: FEATURES and PIGMENTATION

For a more correct interpretation of skin pigmentation, we advise you to consider the following Fitzpatrick skin scale.

FITZPATRICK SKIN SCALE

Skin Type	Objective classification	Colour
I	Always gets burned under the sun does not suntan, very sensitive skin to sun exposure	White
II	Easily gets burned under the sun gets slightly suntanned, very sensitive skin to sun exposure	White
III	Sometimes can get burned under the sun. Gradually gets suntanned to reach a light/medium brown colour sensitive skin to sun exposure	White / Asian
IV	Seldom gets burned under the sun constantly sun tunned skin very minimally sensitive skin to sun	Medium brown
V	Rarely gets burned under the sun suntans very easily, non-sensitive skin to sun	Dark brown
VI	Never gets burned under the sun, deep pigmentation, non-sensitive skin to sun.	Black

In the application phase of OPE® PATENTED TECHNOLOGY, parameters of use are already set and protocolled; the software suggests recommended fluence values and milliseconds based on treatment selection. Fluence values and milliseconds can be changed by the operator. Fig. 9 shows an example of an operative screen of the Patented OPE® Technology

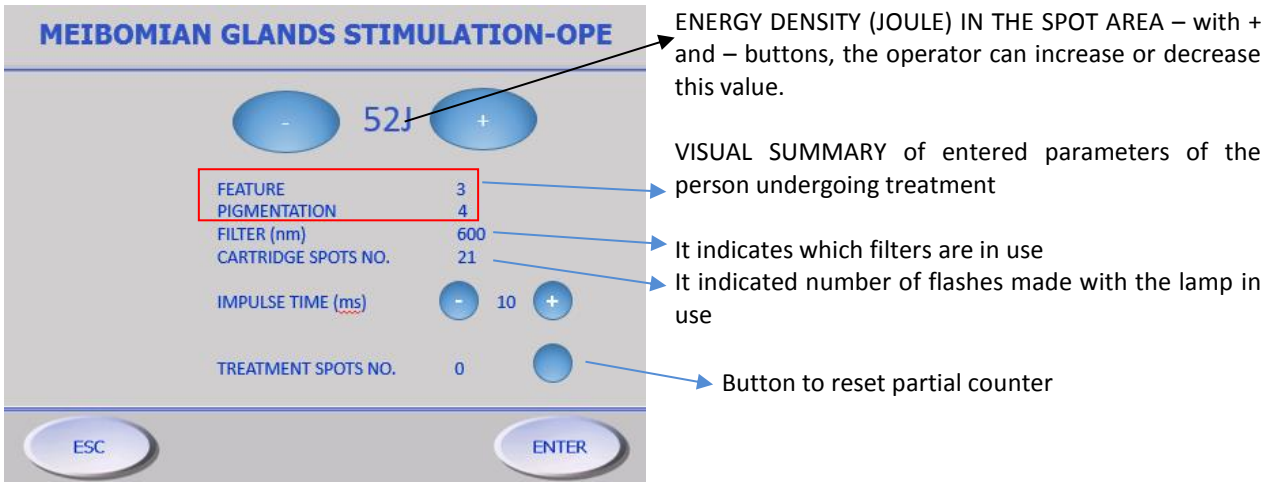


Fig. 9

Before pressing ENTER, prepare the patient undergoing the treatment.

Before treatment the skin must be cleaned, without make up.

For dry eye treatment, advise patient to remove contact lenses, in case they are wearing them. Make 5 flashes in the area under the eye as indicated in Fig. 10

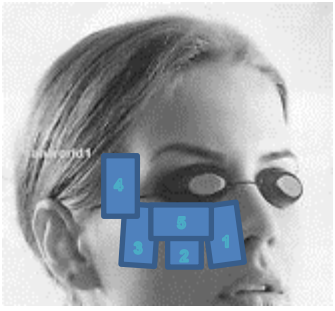


Fig. 10

BEFORE EMITTING THE FLASH

Check that all people, including those undergoing the treatment inside the room where the pulsed light is used, are wearing glasses or goggles to protect their eyes.

If you are not yet familiar with using the light, use lower fluences.
The emission of the pulsed light must be perpendicular to the work surface to prevent any reflections reaching the eyes.

⚠ FLASH EMISSION ⚠

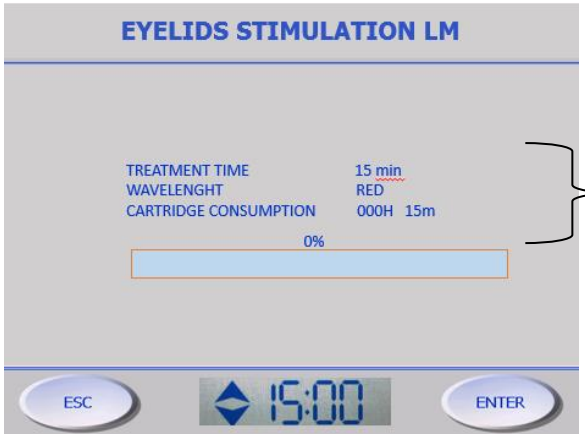
Place the handpiece on the area to be treated, press the ENTER button on the display and wait for the confirmation tone (beep) that activates the lamp.
Now press the button.
Avoid two consecutive flashes the same exact area.

If erroneously the button is steadily pressed the lamp does not emit any flash: between one emission and the other the operator must lift his finger off the button (and wait for the beep)
Prolonged use can cause an heat block of the unit for over-temperature, interrupting the light emission. This block is an automatic safety feature, after a few minutes of cooling the system will reactivate.
In case of failure please report the unit's serial number. The serial number is located on the identification label in the rear side of the unit. For at least 15 days after the complete treatment, sun exposure is not recommended.

PREPARATION FOR THE TREATMENT WITH LIGHT MODULATION® TECHNOLOGY

Follow steps as indicated by the software:

Prepare the **LIGHT MODULATION®** applicative terminal as requested by the software and press ENTER
Treatment time must not exceed 30 minutes.
An example of an operating screen of the **LIGHT MODULATION®** technology:



The screen shows the duration of the treatment, the wavelength/colour used and the cartridge consumption.

The bar shows the time elapsed, and at around 80% the continuous mode changes to pulsed.

OPERATOR TRAINING

The information necessary for the safe use of the equipment are contained in this manual and are displayed on the touch screen.
Operators are required to consider the following training:

- Accredited course with qualified professional instructors
- Direct training by professionals designated by the manufacturer.

ANTICLONE SYSTEM

The unit has an anticlone system and therefore each lamp/accessory must be 'unlocked' the first time it is used. To activate a lamp or another accessory (mask, band etc.) please contact customer service and quote the DEVICE ID and LAMP ID as shown on the monitor.

MAINTENANCE

This comprises all tasks for maintaining electrical, mechanical, aesthetic and functional features of the unit and of its accessories.

Before use:
When the unit is delivered the parts that come into contact with the skin are clean but not sterile.

After each session:
- switch off the unit
- remove the plug

EXTRAORDINARY MAINTENANCE

The unit is designed for operating with minimal maintenance. However, extraordinary maintenance includes repair and replacement of worn parts that are of exclusive competence of qualified and authorized personnel. In these cases, contact the service center (Service is available from 8.30 to 12.30 and from 13.30 to 17.30 Monday to Friday).

PERIODIC CHECKS

Keep this instruction manual and read it carefully before using the device. Before each use check the intactness of the device. Pay attention to the condition of wear of insulation (casing and cables), of central unit before connecting it to the power supply. Check the condition of wear of terminal connection cables before connecting them to the central

unit. Should you notice any damage or signs of wear, even only partial, stop the application and contact the manufacturer. Any replacement of parts or accessories with non-original parts may cause hazards to things and people or damage the unit itself, with resulting forfeiture of the warranty and the responsibility of the manufacturer.

ANNUAL MAINTENANCE OBLIGATION

The Standard IEC 62353 defines the aspects for maintenance, storage and safe use of medical equipment. For the equipment of this manual (Class IIa Directive 93/42 / EC) it is defined that maintenance should be annual.

DISINFECTION

After using the unit, it is absolutely necessary to disinfect all parts coming into contact with skin.
Do not use solvents to clean parts.
If the unit is not used and it is not expected any use in the short term, it is recommended to store it in its box.

CLEANING AND DISINFECTION

After any treatment, check that the front window of the OPE® lamp is clean. Check that the window placed in front of the lamp is shiny and free from dust, debris and fingermarks. Use a lens-cleaning cloth slightly dampened with pure acetone to clean the window
After every treatment, clean the LIGHT MODULATION® systems with a soft cloth dampened with a disinfectant solution which does not contain alcohol. Take great care not to wet the led.
To clean the outside of the machine, use a clean cloth dampened with neutral soap dissolved in water. Do not use solutions which contain ammonia. Dry immediately

TROUBLESHOOTING

The following list shows some technical problems which could occur, their causes and recommended solutions:

PROBLEM	CAUSE	SOLUTION
The machine does not light up	The electrical system is not under power	Check that there is network power
	The power cable is not inserted correctly.	Disconnect and reconnect the cable
	The main switch is in the OFF position.	Put it in the ON position
	Check that the fuses are intact	Replace them if necessary
	Check the emergency button	Turn it in order to turn on the unit
	The system is not in OPERATE status	Press the ENTER key to switch from Standby to Operate

For any malfunction of the system not shown in the list, stop the application and contact the manufacturer.
Before using the device again, ensure that the breakdown has been repaired and that the appliance is operating perfectly.
The operator must not open the unit for any reason. Any intervention carried out by unauthorized staff may constitute a serious hazard or damage the machine, with the resulting voiding of the warranty.
Use the following procedure if calibration of the touch screen is necessary:
At switch-on of the machine, when Windows screen appears (image 1) keep a point on the screen pressed (for approximately 20 seconds) until the white calibration screen appears (image 2).

image 1

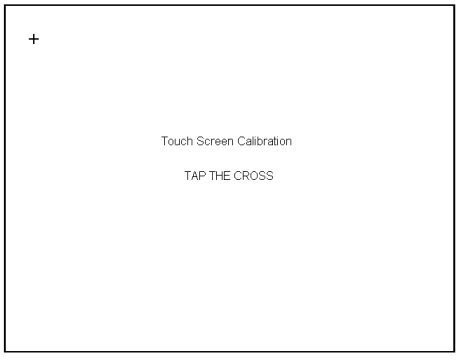


image 2

Use a rounded point to press on the centre of the cross (top left corner). The cross will then move to the bottom left: press on the centre of the cross again.
Do the same thing when the cross moves to the other two corners. When this procedure is finished the programme will continue normally.

DISPOSAL OF THE PRODUCT

At the end of the product's lifecycle, the light emission unit must be disposed of in accordance with the regulations in force or returned to the manufacturer.

	INFORMATION FOR USERS Pursuant to 27 March 2014 Legislative Decree "Implementation of Directives 2011/65/UE related to the reduction in use of hazardous substances in electrical and electronic equipment" and n. 49 March 2014 "Implementation of Directives 2012/19/CE related to the disposal of waste of electric and electronic equipment (RAEE)" The crossed refuse bin symbol shown on the equipment or on its packaging indicates that at the end of the product's useful life it must be collected separately to other waste. Differentiated waste collection of this equipment is organized and managed by the manufacturer at the end of its life. A user who owns similar equipment and wishes to dispose of it can therefore contact the manufacturer and follow the instructions the latter has adopted to allow separate collection of the equipment. Illegal disposal of the product by the holder entails the application of the penalties provided for in the regulations in force.

EMC WARNINGS

	The device complies with EN60601-1-2 EMC standards, but to guarantee patient safety it is advisable to forbid mobile phones and in general all portable and mobile RF communication equipment in the environment where the unit is used, as it can affect the operation of the device.
	The device requires special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in the EMC features tables.
	The device should not be used on patients together with other equipment or near other equipment.
	DANGER: the use of a power cord other than the one supplied may degrade the device performance in terms of emissions or immunity of EMC equipment. Always use the cable provided by the manufacturer.

EMC FEATURES

EMC Emissions		
The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the equipment should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromegnetic environment**

RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmnic emissions EN 61000-3-2	Class A	
Voltage fluctuazions/ Flicker emissions IEC 61000-3-3	Compliance	

EMC Immunity			
The device is suitable for use in the specified electromagnetic environment. The purchaser or user of the equipment should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance Level**	**Electromagnetic Environment**
Electromagnetic discherge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	En 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3m	En 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	1 kV differenzial mode 2 kV common mode	En 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	0% U_n for 0,5 cycles 40% U_n for 5 cycles 70% U_n for 25 cycles 0% U_n for 5 s	En 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	En 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment			
Immunity Test	**EN 60601-1-2 Test level**	**Compliance Level**	**Electromagnetic Environment**
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz

Conduced RF EN 61000-4-6	3 V 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
			Where *P* is the maximum output rating of the transmitter in Watts (W) according to the transmitter manufacturer an *d* is the recommended separation distance in meter (m). Field strengths for fixed RF transmitter, as determined by an electromagnetic site survey, should be less then the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device . b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.			

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

Rate maximum output power of the transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance *d* in meter (m) cam be estimated the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer.

Note:

(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applied.

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

WARRANTY

You have recently purchased on of our appliances. The purchase of this appliance entails the acceptance, with full rights, by the purchaser/professional user of these general terms and conditions. In the event that the appliance was sold by an authorized distributor of the manufacturer, the user shall make reference to its supplier's general terms and conditions of warranty. Those terms and conditions can in no case require an increase in the commitment made by the manufacturer as this warranty. This warranty can be activated and is valid from the delivery date. The manufacturer guarantees this appliance for defects of construction or raw materials. This warranty is valid for a one year period for the first user. During this period we undertake to replace or repair free of charge those parts which we consider to be defective, without the need to completely replace the appliance. Replacements and/or repairs under warranty which do or do not give rise to the immobilization of the instrument in no event have the effect of extending the duration of the warranty. No compensation shall be given for lack of enjoyment. The expenses of moving and if necessary transporting the appliance and spare parts to and from the service department's workshops are excluded from this warranty. Replacements and repairs as the warranty, which may or may not entail the immobilization of the appliance, shall in no event extend its duration.
The parts which are replaced shall become the manufacturer's property. The purchaser is required to give us the necessary time and means to proceed with the required repairs and delivery of the replaced spare parts. If this is not the case we shall be relieved from the warranty obligation. By express agreement we shall not be held responsible in the event of a use which is outside the framework of professional qualification or the incompetent use of the appliance. In the event of any dispute the sole competent courts shall those located in the district of the manufacturer's registered office, this being notwithstanding a different clause of assignment of jurisdiction which may appear on the commercial invoices of the contracting parties.

The warranty is excluded in the following cases:

- Damage occurring during transport. This appliance travels at the addressee's risks and perils. It rests with the latter to check that it is in perfect condition, prior to proceeding with the shipment;
- Failure to comply with the rules of installation and use prescribed in the manufacturer's usage manual, lack of maintenance of the appliance and cleaning, connection to an electric line which is defective or lacking an earth connection or of different electrical power from that stated on the appliance's plaque.

Limitation and exemption from liability.

Espansione Marketing SPA will not be held responsible under any circumstances

- for direct consequences caused by lack of compliance with the general terms and conditions of warranty, during and on expiry of the warranty. For material damage or bodily accidents occurring following installation which is not compliant with the legal or regulatory provisions of the country in which the appliance is installed
- For material damage or bodily accidents occurring following an intervention not provided for in the manufacturer's usage manual and/or performed by the user or by a third party not authorized by the manufacturer.
- For material damage or bodily accidents deriving from use other than the use destination stated in this usage manual

VIEWED
THE PURCHASER

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Copies are available from the manufacturer on request.

TECHNICAL SERVICE CENTRE
TEL. +39 051 89.01.611