Operative manual for diagnosis lamp

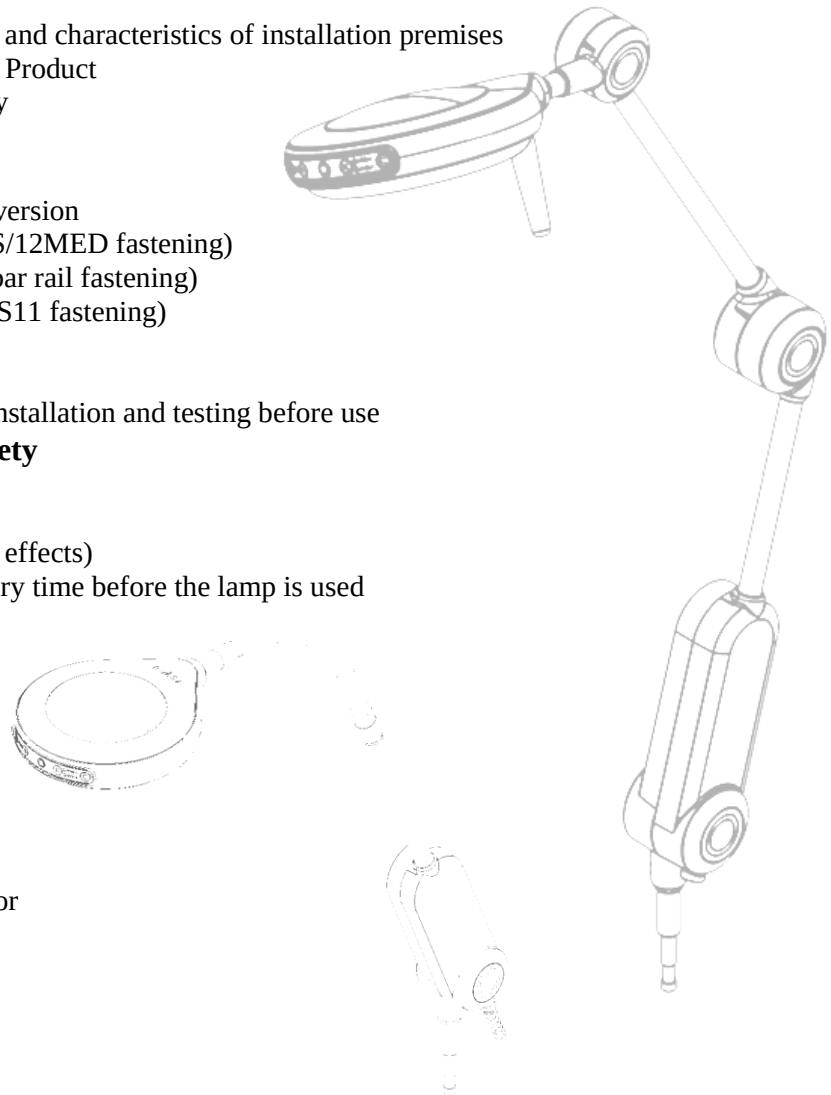
PRIMALED

PRIMALED-FLEX

GIMA

Via Marconi, 1 – 20060 GESSATE (MI) ITALIA
Tel. +39 02 953854209 Fax +39 02 95381167
http://www.gimaitaly.com e-mail: gima@gimaitaly.com

CONTENTS



Introduction

Dear User, you are kindly invited to read this manual carefully before proceeding to use the Product in order to safeguard yourself and other people from any injuries.
This appliance is a Class 1 medical device pursuant to European Directive on medical devices (MDD) 93/42/EEC (Annex IX) and 2007/47/EC.
The manufacturer declares that this Product is in compliance with Annex I (Essential requirements) of Directive 93/42/EEC and certifies such conformity by affixing the CE marking.
The Product is classified in risk group 1 according to IEC 62471 standard (Photobiological Safety of Lamps).
This operator's manual is valid for the **PRIMALED/ PRIMALED-FLEX** model.
The customer service is at your disposal in case of Product details, information concerning its use, identification of spare parts being required and for any other queries you might have concerning the appliance, for ordering spares and for matters relating to assistance and warranty.

GIMA TECHNICAL ASSISTANCE OFFICE FOR CLIENTS
Via Marconi, 1 – 20060 GESSATE (MI) ITALY
Tel. +39 02 953854209 Fax +39 02 95381167
http://www.gimaitaly.com e-mail: gima@gimaitaly.com

1 General information

THE EM (Electro-Medical) DEVICE to which this manual refers is a LAMP for diagnosis or observation. For ease of description, in this manual this EM EQUIPMENT will be called "Product".
This manual is an integral part of the Product as indicated by European Directives 93/42/EEC and 2007/47/EC. Always keep this operator's manual close to the lamp.
GIMA disclaims all liability for any injuries to persons or damage to things caused by the installation, maintenance or use of the Product by unqualified operators. By qualified operator is meant whosoever has attended a course relating to the installation, maintenance and use of the product organised by GIMA or, alternatively, whosoever has carefully read this installation manual. GIMA does not authorize third parties to perform special maintenance jobs. Should a problem arise, contact GIMA.
The end user is entirely responsible for Product installation activities; no costs or responsibilities relating to the installation and/or commissioning of the Product may therefore be traced back and/or in any case attributed to GIMA.
The ceiling or wall masonry works for Products to be installed on ceilings or walls, and the electrical works for supplying power to the Product shall be carried out in a workmanlike manner by suitably qualified personnel to ensure these are sturdy and safe.
By way of example only, the following professional figures are deemed as suitably qualified:
⇨ Construction Engineer, Draughtsman, Building firm duly registered in the professional Register (for the masonry works)
⇨ Electrical Engineer Electro-technical expert qualified to work as an electrician (for the electrical works)
The Product is an EM electro-medical equipment and therefore falls within the field of application of the EN 62353 standard. Consequently, any operation performed on the Product must be carried out in compliance with the EN 62353 standard, where applicable.

1.1 Operator qualification

This paragraph describes the requirements and qualifications which the operators involved in the various stages of Product life and use must possess.

Installation	Installer and/or qualified technician
Use	Professional medical personnel
Routine maintenance	Qualified technician with required technical-professional skills
Special maintenance	GIMA or authorized Dealer
Assistance	GIMA or authorized Dealer
Cleaning	Properly trained medical and paramedical personnel
Demolition	Comply with applicable laws on waste disposal. This product must not be disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through authorized channels so as to ensure correct recycling.

1.2 Packaging, transport, storage and characteristics of installation premises

Boxes containing the Product together with operator's manual
Transport is made by GIMA or any road-hauler as long as in compliance with the following characteristics:
Temperature (°C): -15 / +60; Humidity: 10 / 75 %; Atmospheric pressure (hPa): 500 / 1060.
The packaged Product must be stored (warehoused) in dry premises having the following characteristics:
Temperature (°C): -15 / +60; Humidity: 10 / 75 %; Atmospheric pressure (hPa): 500 / 1060.
The premises where the Product is started up must have the following characteristics:
Temperature (°C): +10 / +40; Humidity: 30 / 75 %; Atmospheric pressure (hPa): 700 / 1060.

1.3 Graphic symbols used on the Product

Description of the symbols on plates, product and in manual:

CE	Graphic symbol showing product bears CE marking		RECYCLING! The Product must be recycled separately
	Symbol indicating date of manufacture (month/year)	REF	Model
	Manual reading obligation	SN	Serial number
	Manufacturer's address		Top side of packaging
%	Humidity to be complied with (indicate max limit at top right and min limit at bottom left)		Fragile packaging
	Limit temperature (indicate max limit at top right and min limit at bottom left)		Pressure to be complied with (indicate max limit at top right and min limit at bottom left)
	Do not stack packaging		Weight of packaging
	Protect from rain		Functional earth
'I'	ON power		Protection earth
	Standby	'O'	OFF power
'L'	Line lead connection point	'N'	Neutral lead connection point

1.4 EC Declaration of Conformity of the Manufacturer

The company: **RIMSA P. LONGONI S.r.l. Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) – ITALY** declares under its own responsibility that the Product (Medical device for observation and diagnosis):

APPLY
LABEL

made by RIMSA P.LONGONI S.r.l., complies with Annex VII of Directive 93/42/EEC dated 14/05/1993, enforced in Italy by Legislative Decree No. 46 dated 24 February 1997 and subsequent amendments (including Directive 2007/47/EC dated 05/09/2007, enforced in Italy by Legislative Decree No. 37 dated 25 January 2010) and with the following standards:

- IEC 60601-1 (Part 1: General requirements for basic safety and essential performance)
- IEC 60601-2-41 (Part 1: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis)
- IEC 60601-1-2 (Part 2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)

Classification with reference to article 9 and Annex IX of Directives 93/42/EEC and 2007/47/EC	
DURATION:	Short term duration (Annex IX, Par.1 "Definitions", art.1, subsection 1.1)
DESCRIPTION:	Non-invasive medical device (Annex IX, Par.1 "Definitions", art.1, subsection 1.2) Active medical device (Annex IX, Par.1 "Definitions", art.1, subsection 1.4)
CLASS I:	(Annex IX, Par.3 "Classification", art.3, subsection 3.3, Rule 12) and (Annex IX Par.3 "Classification", art.1, subsection 1.1 Rule 1)

- Reference to technical file Code RIM-FT023.
- The conformity assessment is developed with reference to article 11 of Directive 93/42/EEC and 2007/47/EC.
- The RIMSA Quality System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).
- The Medical Device to locally light up the patient's body is marketed in **NON-STERILE** form.

Name: Paolo Longoni
Position: Managing Director

1.5 Warranty Certificate

1. The Product is covered by an 18-month warranty, including electrical parts
2. The warranty begins on the date of product shipment from the GIMA warehouse to the buyer.
3. In case of disputes, the date indicated on the "transport document" attached to the goods shall be deemed valid.
4. The warranty only covers the sending of Product spare parts to the buyer or, in the event of GIMA considering the replacement of spare parts not feasible, the replacement of the entire product, after fabrication faults have been properly ascertained at the undisputable judgement of GIMA . The warranty does not therefore cover any other costs or expenses (including, by way of example but without limitation, labour costs, packaging costs and transport costs, etc.).
5. The guarantee does not include the components subject to normal wear, such as halogen bulbs, LEDs, fuses, relays, ball bearings, etc.)
6. The warranty does not cover:
   - malfunctions due to failure to comply with the instruction manuals;
   - malfunctions due to installation and/or maintenance errors;
   - malfunctions or faults caused by carelessness, negligence, incorrect use or other causes not attributable to GIMA;
   - malfunctions or faults due to the fact that the electrical system of the premises where the device is installed is not in compliance with CEI 64-8 standards (standards for electrical systems in premises used for medical purposes) and similar standards.
7. GIMA shall repay direct damages suffered by the buyer and which are documented as attributable to its product, caused within the warranty period, for an amount not above 40% of the net value of the product as indicated on the buyer's invoice. GIMA's liability is expressly ruled out for indirect damages or consequential damages (including cases of the lamp not being used) deriving from the supply.
8. This warranty certificate replaces legal warranties for faults and non-conformities and rules out any other possible liability of GIMA originating from the supplied products.
9. The payment of any damages to persons or things due to product malfunction or faults shall be limited to the maximum amount of GIMA's insurance coverage for civil liability.
10. The warranty shall be automatically invalidated in the event of:
    - the Product having been tampered with or modified by the buyer or third parties;
    - the Product having been repaired by the buyer or third parties, without following the instructions in the instruction manuals;
    - the Product serial number having been cancelled, defaced or removed;
    - the buyer not being up to date with payments.
11. For jobs to be done under warranty, the buyer shall contact GIMA only.
12. The component parts replaced under warranty must only be returned to GIMA, if so requested by GIMA, carriage free and suitably packed.
13. In case of failure to return a part requested by GIMA, the cost of the component part will be charged.
14. GIMA cannot accept returns from end users or in any case from parties other than the buyer.
15. Products returned to GIMA must be complete with documentation authorising such return and another document describing the malfunction.
16. For everything not indicated on this warranty certificate, reference shall be made to the laws of Italy.
17. For all disputes deriving from or related to the orders to which this warranty certificate applies and which cannot be amicably settled between the parties, the only competent law court shall be that of Milan.

2 Product installation

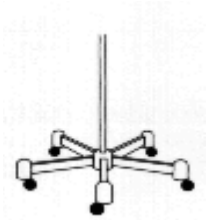
Before proceeding to install the Product, first of all check the presence of all the packaging and that this is in good condition and has not been damaged during transport.
Claims will only be taken into consideration if the seller or carrier has been immediately notified. All claims must be made in writing. Goods always travel under the responsibility and at the risk of the buyer.
Keep the original packaging in case the Product has to be re-dispatched.

The product is supplied with 4 different support systems, to be selected as required:

- 'RL' Floor lamp consisting of upright and 5 wheels with pedal-operated lock system;
- 'S12 MED' wall-fastening clamp;
- 'Z400072' rail bar clamp, 'Z400075' rail bar supplied with 1 metre bar length, 3 spacers, 3 wall anchors and 3 screws for fastening the anchors to the bar;
- 'S11' wing-nut vice for fastening to table.

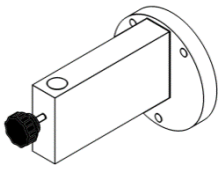
The package also contains a sterilizable handpiece.

2.1 Installation of 5-spoke floor version



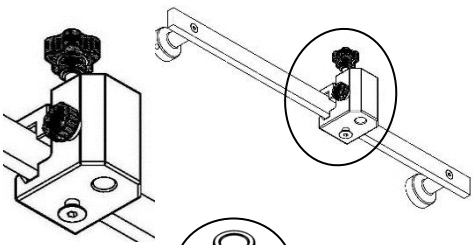
1 Fit the lamp in the hole located in the top part of the stand rod.
2 Screw up the threaded knob, making sure this fits into the mill hole of the lamp pin in such a way as to prevent it accidentally coming out.
3 Insert the pin situated in the end of the power cable in the power socket (IMPORTANT: to avoid the risk of electric shocks, this appliance must only be connected to mains supplies with earth connection).

2.2 Installation of wall version (S/12 MED fastening)



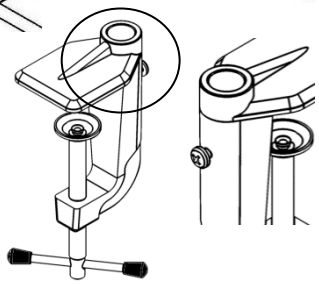
1. Fasten the clamp S12 MED to the wall. GIMA does not supply screws.
   The wall must be a supporting wall and be made of solid brick. Installation on walls of perforated bricks and plasterboard is only allowed with the fitting of a plate on the opposite side of the wall (sandwich closing). GIMA suggests using M5 screws.
2. Fit the lamp in the hole located in the top part of the S11 clamp.
3. See points 2 and 3 of paragraph ***2.1***.

2.3 Installation of wall version (bar rail fastening)



1. Fasten the bar rail according to attached instructions MO002i.
2. Fit the clamp on the bar and tighten the lower knob.
3. Fit the lamp in the hole located on the clamp.
4. See points 2 and 3 of paragraph ***2.1***.

2.4 Installation of table version (S11 fastening)



1. Fasten the S/11 clamp to the table by tightening the threaded pin.
2. Fit the lamp in the hole located in the top part of the S/11 clamp.
3. With the aid of a screwdriver, tighten the screw on the back of the clamp.
4. See point 3 of paragraph ***2.1***.

2.5 Handpiece fitting

To fit the handpiece, turn it clockwise inside the threaded hole provided until it is up against the headpiece and rotation remains blocked.

2.6 First switch-on

At this point, the Product can be switched on to make sure it works properly.
Follow the instructions below:
1- Press the green switch on the base;
2- Press the I/O keyboard located on the front part of the reflector.
3- Make sure all LEDs and functions are working properly.

2.7 Check the result of Product installation and testing before use

The following instructions are to be deemed mandatory during the installation inspection phase, as they prove that all the various jobs referred to have been correctly done. Hence each single step must be ticked.

1. Make sure the wall is suitable for Product installation ☐
2. Make sure the stand pin has been correctly fitted in its fastening point ☐
3. Make sure movement mechanisms are working properly. Check mechanical operation by means of direction and rotation movements ☐
4. After switch-on, the Product must emit light from the reflector ☐

Installer's stamp and signature:

_____

3 Importance of personal safety

3.1 Intended use

The Product has been designed to light up the area of the patient undergoing observation and diagnosis and is intended for use in doctors' surgeries.
The Product correctly lights up the operating field from a minimum distance of 40 cm and a maximum distance of about 70 cm, from the point of light emission.
The Product, in conformity with the IEC 60601-2-41 standard, is defined as a lamp for diagnostics:
- A lamp for diagnostics is a lamp used to locally light up the body of a patient, in order to make diagnosis or treatment easier. These can be interrupted without any danger for the patient in case of the light going off. (The Product is not intended for use in operating theatres).

3.2 Environmental conditions

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are flammable mixes of anaesthetics with air, oxygen or NO_2 (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of flammable agents.
- During operation, the ambient temperature must be between 10°C and 40°C.
- Relative humidity must be between 30% and 75%.
- Atmospheric pressure must be between 700 and 1060hPa.

3.3 Safety conditions (secondary effects)

- Do not direct the light source into the patient's and/or operator's eyes.
- Obligation to adequately protect the patient's eyes.
  Failure to follow such precautions could cause glare and potential damage to the retina.
- Never place and/or hang anything on the Product.
  Unless this precaution is taken, positioning will not be reliable and the danger exists of such objects falling in the operating area.
- Never hang on the Product with the body weight of a person.
  Failure to follow such precaution could damage the Product structure.
- Never cover the head of the Product during operation.
  Failure to comply could prevent heat exchange with the environment and the Product could overheat.
- Avoid knocking the rocker arms and Product head.
  A violent knock could damage the Product and pieces of paint could chip off and fall onto the operating field in the patient area.
- To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments, see section 9 of the manual.

3.4 Controls to be performed every time before the lamp is used

To make sure the Product is safe and provides a correct diagnosis, every time before use, the operator must check:
- The lamp has been correctly disinfected;
- The emitted light is stable and of adequate intensity;
- The flexible arm remains in the selected position, without falling.

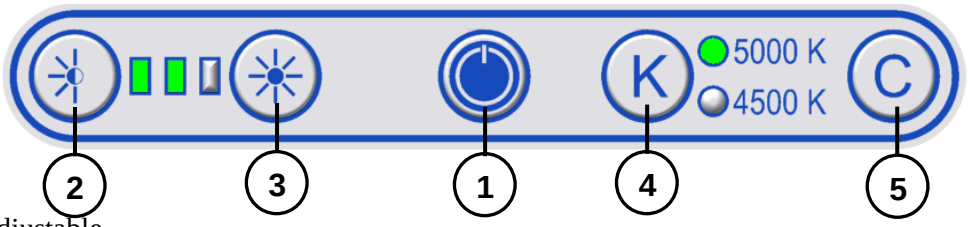
4 Description and operation

4.1 Description

The Product locally lights up the patient's body thanks to 9 LEDs focalized by means of specific lenses. 3 non-focalized LEDs are also fitted to permit using a courtesy or reading light.
Positioning the light beam is made easy thanks to the articulated arm (PRIMALED) or flexible arm (PRIMALED-FLEX). Such positioning is to be done manually. By means of the membrane keyboard on the reflector, the various product functions can be easily controlled.

4.2 Operation

To switch on the Product, use the "I/O" green light master switch on the Product base.
IMPORTANT: do not position the device so it is hard to reach and remove the power plug in case of an emergency.
The following functions can be controlled by means of the keyboard:
Switch the lamp on and off by means of the standby key (1), adjust light intensity by pressing keys (2) and (3), with display of the level of intensity achieved by means of 3 green positions micro-LEDs. Select the colour temperature by means of the "K" key (4) with display by means of 2 green micro-LEDs, and select the courtesy light by means of the "C" key, which permits switching on the 3 LEDs without lens, not to be used for observation (5). To select the courtesy light, the lamp must be switched off. In courtesy position, only the light intensity can be adjusted, while temperature change is not possible. To return to normal operating position, the standby key (1) must be pressed.



The light field is not adjustable.
To move the lamp use the sterilisable handpiece.
IMPORTANT: in the floor version, operate all 5 wheel brakes during operation to ensure stability.
After use, to safely switch off the Product, press 'O' on the light switch. To disconnect from the mains, remove the plug.

5 Cleaning and disinfecting

5.1 Cleaning the Product

Switch off the Product by detaching the plug and make sure it cannot be switched back on. Protect the Product from water spray and detergents and do not clean it with liquids. Leave the lamp body to cool down. Only clean the lamp body when it is cold. Clean with suitable detergents with low alkaline content and chlorine free.
Do not use abrasive products, petrol, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes;
dose the cleaning agents so no liquids penetrate inside the lamp elements and into the support arm system.
Clean the Product with a damp, but not wet, cloth.
CAUTION: Failure to comply with the instructions could cause the paint to come off with possible accidental dropping of such paint into the patient area, the early ageing of the plastic parts with consequent weakening and the possibility of breakages, and the tarnishing of glass.
The product is best cleaned at least once a day when used. To clean the lamp, the support need not be removed.

5.2 Disinfecting

Switch off the Product by detaching the plug and make sure it cannot be switched back on.
Protect the Product from water spray and detergents and do not clean it with liquids.
Leave the lamp body to cool down. Only disinfect the lamp body when it is cold.
Disinfectants can contain substances which are harmful for the health - only use disinfectants in accordance with the rules on hygiene established by the hospital; the Product operator must comply with the rules established by the national commission for hygiene and disinfection.
To prevent damaging parts in stainless steel or aluminium, only use disinfectants which are chlorine and halogen free; to prevent the plastic parts becoming fragile, use only disinfectants with low alcohol content; dose the disinfectants so no liquids penetrate inside the lamp elements and into the support arm system.
Clean the Product with a damp, but not wet, cloth.
The Product is best disinfected every time before use. To clean the lamp, the support need not be removed.

5.3 Handpiece sterilization

Replace the handpieces as soon as these become cracked or deformed, as these could fall in the patient area.
The Product operator must comply with the rules established by the national commission for hygiene and disinfection.
Handpiece fitting / removal:
- turn the handpiece anti-clockwise and remove it.
- turn the handpiece clockwise until it is up against the headpiece and rotation is blocked.

Cleaning, disinfection and sterilization of the handpiece:
The handpieces are made of plastic material resistant to heat and knocks (PPSU - Polyphenylsulphone).
They can be cleaned with a mild o mid-alkaline detergent free of active chlorine.
To disinfect the handpieces, we suggest using alcohol or aldehyde-based products. The disinfectants must be approved by the manufacturer for use on polyphenylsulfone (PPSU).
Rinse the handpieces before sterilization.
The handpieces can withstand about 200 steam sterilization cycles in accordance with the following parameters:
- steam sterilization at 121°C 1.3 bar from 25 to 30 minutes,

or
- steam sterilization at 134°C 2.3 bar for 4 minutes.

Position the handpieces in straight position with open side downwards.
Do not exceed a sterilization temperature of 134°C.
Avoid the handpieces coming into contact with other objects during the sterilization process.
Strictly keep to the ISO 17665-1 standard.

Each Product, over time, is subject to a certain amount of wear. Product safety and operation must therefore be checked during inspection and maintenance intervals.

6 Adjustments

6.1 Yearly inspections by operator

Keep to the yearly inspection schedules and inspect the product according to IEC 62353 standard.

6.2 Repairs

The Product must only be opened and repaired by the manufacturer. Contact customer service as indicated on page 1 in case of need.
CAUTION: Making any changes to this appliance is forbidden.

6.3 Adjustments

The Product is sold already balanced and does not require further adjustment. If the Product becomes unstable over time and fails to remain in position, see section 10. If, after adjustment, the product still fails to remain in position, contact the GIMA after-sales service.

6.4 Troubleshooting

No.	Problem	Solution
1	The Product fails to work	Contact the after sales service
2	The Product does not remain in position	See par. 10. If, after adjustment, the product still fails to remain in position, contact the after-sales service.
3	The light flickers	Contact the after sales service
4	The light beam is not focalised	Contact the after sales service

6.5 Routine maintenance

No.	Interval	Action
1	Once a year	Perform complete movements of all Product joints and make sure movement is smooth. If the Product fails to maintain its position or its movements are hard, see par. 10.
2	Once a year	Make sure the retention screws of connections are tightened properly. If these are not properly fastened, adequately tighten.
3	Once a year	Check the condition of the Product paint. Make sure there are no paint pieces that could fall in the patient area. If any paint pieces deemed hazardous are found, contact the after-sales department.

6.6 Spare parts list

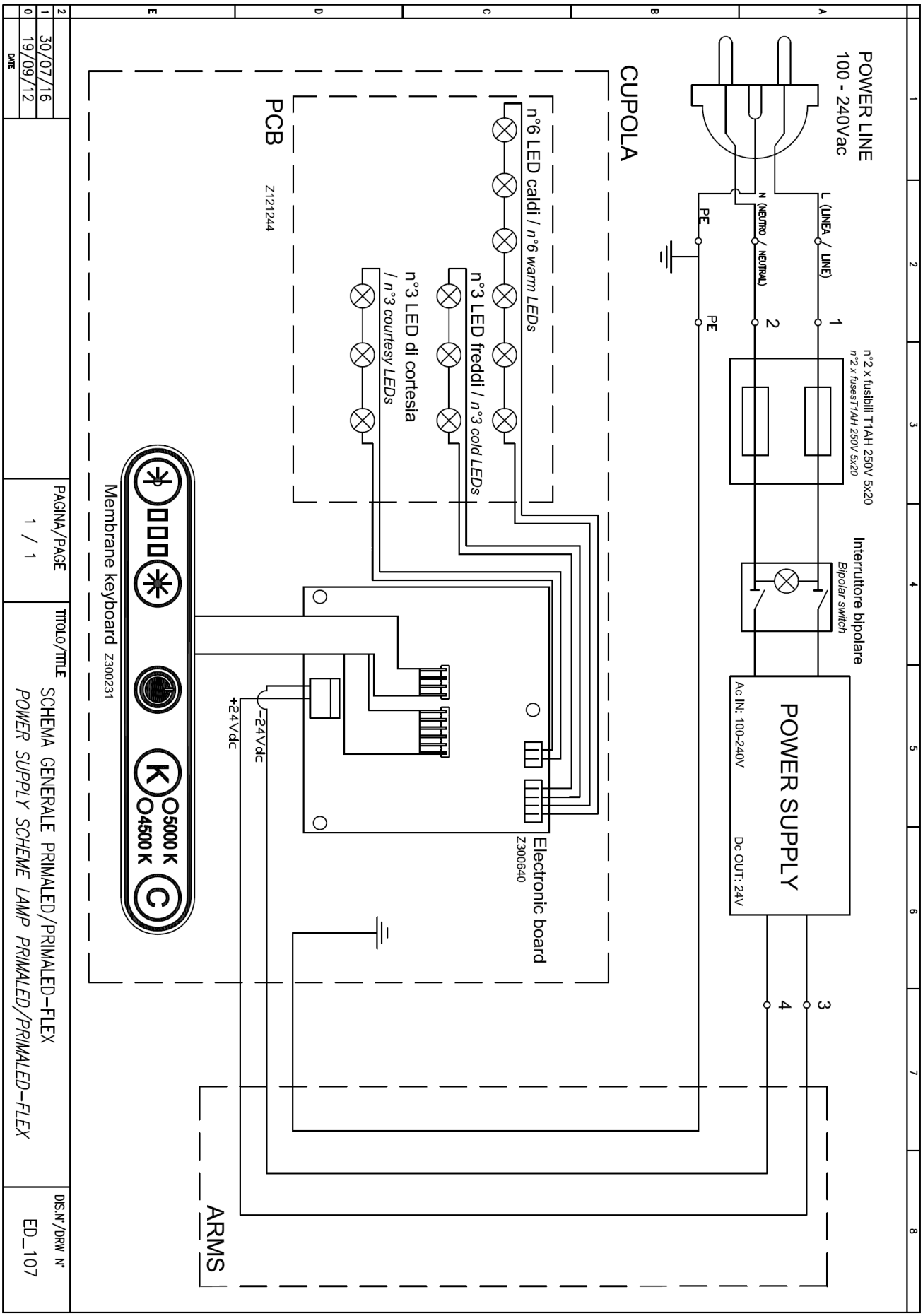
WARNING: only use original GIMA parts

Description	Order Code
Sterilisable grip	Z100848

7 Technical properties

Technical properties	PRIMALED/ PRIMALED-FLEX
Illumination Ec at 50cm distance ± 10% [Lux]	80,000 / 86,000
Colour temperature (±5%) [K]	4,500 / 5,000
Colour rendering index Ra [-]	95
Max irradiation [W/m2]	225
Irradiation / Illumination [mW/m2lx]	2.8
Max irradiation in UV [W/m2]	0.001
Focalization from grip	No
Power connection details	
Primary alternate voltage [Volt ac]	100-240
Frequency [Hz]	50/60
Power input [VA]	22 (100V) – 30 (240V)
Light source	N°9 Led x 1.4W
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50,000
Light intensity control [%]	25 –100
General data	
Colour	RAL 9003
Directive	2007/47/EC
Standards	IEC 60601-2-41
Classification of Medical Device	Class I
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively)
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m^2 and the total irradiance Ee in the lighted area does not exceed 1000 W/m^2 at a distance of 500 mm).
IP Classification	IP20
Operating conditions	Continuous operation
Mains power voltage insulation means	Integrated power plug
Integrated fuses	T1AH 250V, 5x20
Handpiece steam sterilization	121°C 1.3 bar from 25 to 30 minutes 134°C 2.3 bar for 4 minutes.
Dimensions	
Diameter of lamp body [cm]	19.5
Lens diameter [cm]	3.2
Light emission surface [cm2]	65
Lamp weight (Primaled / Primaled-Flex) [Kg]	3.5 / 3.3
Markings	
CE	In conformity with Directive 93/42/EEC (and 2007/47/EC)
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons	

8 Wiring diagram



9 EMC Declaration

The Product has been tested according to EN60601-1-2 standard to ensure correct electromagnetic compatibility.
Portable and mobile RF-communications equipment can affect the Product. The Product should not be used adjacent with other equipment and that if adjacent use is necessary the Product should be observed to verify normal operation.
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that is used in such an environment.

Immunity test	Conformity	Electromagnetic environment - directives
RF Emissions CISPR 11	Group 1	The Product 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.
RF Emissions CISPR 11	Class A	The Product is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Product or shielding the location.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Conforming	

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	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 IEC 61000-4-4	+/- 2 kV for power supply unit +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	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 IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or battery.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is is the a.c mains voltage prior to application of the test level.			

Immunity test	**Test level to IEC 60601-1-2**	**Conformity level**	**Electromagnetic environment - directives**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Product, included cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{P}$ 150 KHz to 80 MHz $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 80 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and *d* is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance leave 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 an people.			

Recommended separation distance between portable an mobile RF communications equipment and the Product

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

Rated maximum output power of 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	0.24
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 a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.
Note 1: at 80 MHz and 800 MHz, the separation distance for 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 an people

10 Clutch adjustment

The Product is sold balanced and does not require further adjustment. Nevertheless, if the movements of the arms around the rotation joints becomes too stiff or too loose over time, such as to prevent the device remaining in position, the different clutch systems can be adjusted to restore correct stability.

Use the Allen key to adjust clutch force at the rotation joints and, therefore, the consequent movement of the small moving arms.

ROTATION JOINTS

The different device versions have a different number of joints and therefore of clutches:

Table version

Table version with flexible arm

ADJUSTMENT PROCEDURE

Using the Allen key, adjust the screw alongside the joint in question.

Turn clockwise to increase the force of the clutch and stiffen movement.

Turn anti-clockwise to reduce the force of the clutch and loosen movement.

After making adjustment, movement should be smooth and uniform.