



OPERATION AND MAINTENANCE MANUAL

GIMAled81

MINOR SURGICAL LUMINAIRE (TREATMENT LAMP)



GIMA SPA VIA MARCONI 1 - GESSATE M



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Introduction

Marking (E

Compliance

Validity of manual

Customer Service

Copyright

Translations

Please read this manual carefully before using the Product, so as to protect "the Technical Service Personnel" and "the Operator" from any injury.

This appliance is a Class I medical device pursuant to REGULATION (EU) 2017/745 on medical devices (Annex VIII) as amended and integrated.

The manufacturer declares that this Product complies with Annex I (General Safety and Performance Requirements) of REGULATION (EU) 2017/745 as amended and integrated and certifies such conformity by affixing the CE marking.

This installation manual is valid for the following models:

• GIMAled81 in ceiling, mobile versions.

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.

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The original language of this manual is ITALIAN. For all translations, reference must be made to the original manual language.

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PRODUCT

OPERATOR

RESPONSIBLE ORGANIZATION

TECHNICAL SERVICE PERSONNEL

KEY

The ME (Medical Electrical) EQUIPMENT to which this manual refers is a **MINOR SURGICAL LUMINAIRE** (**TREATMENT LUMINAIRE**). For ease of description, in this manual this ME EQUIPMENT will be called "**Product**".

Professional medical personnel (e.g., professional health personnel, expert person assisting the patient).

Entity accountable for the use and maintenance of an ME equipment or ME system (e.g., a hospital, an individual doctor or a non-expert person). Preparation and awareness are included in use.

The personnel (individuals or entity accountable to the responsible organization) that installs, assembles, maintains or repairs the equipment. Under certain circumstances, the safety of such persons depends on their knowledge and awareness and ability to take appropriate precautions when gaining access to hazardous parts partially. By way of example only, the following professional figures are deemed as SERVICE PERSONNEL:

- ⇒ 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)

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1 GENERAL SAFETY INFORMATION

This manual is an integral part of the Product as indicated by REGULATION (EU) 2017/745 and subsequent amendments and supplements. Read and keep this Operation and Maintenance Manual close to the Product.

GIMA disclaims all liability for any injury to persons or damage to property caused by the USE or MAINTENANCE of the Product by persons who are not OPERATORS or TECHNICAL SERVICE PERSONNEL. The Product is an EM electro-medical equipment and therefore falls within the field of application of the IEC 62353 standard.

To avoid any risk of electric shocks, the Product must only be connected to mains supplies with earth protection.



Electric shock risk.

2 Importance of personal safety

2.1 Intended use

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

The Product is a medical device designed for use in operating theatres within the PATIENT AREA, with short-term duration, active, non invasive, designed to locally light up the patient's body for treatments and diagnosis which can be interrupted without any HAZARD for the PATIENT in case of failure of the light.

A combination of two or more surgical lamps used in the operating theatre and required for treatment and diagnosis makes up a SURGICAL LAMP SYSTEM.

The Product correctly lights up the operating range from a distance of about 70 – 140 cm from the patient area.

In the event of overlapping lamps, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.

In case of a reduction in blood flow with start of tissue dehydration, reduce light intensity.

Operating field

Undesired effects of overlapping light fields



Possibility of tissue dehydration and damage.

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Optical safety



Possibility of glare.

Electromagnetic disturbance

Incorrect use



Do not place objects on Product.

Improper use of mobile version



Pushing or resting on the Product is forbidden.

2.2 Safety conditions (secondary effects)

- Do not direct the light source into the patient's and/or operator's eyes.
- When Product use is restricted to the face (maxilla-facial surgery, plastic surgery, ear-nose-throat surgery) the patient's eyes must be covered with adequate protection.
 - Failure to follow such precautions could cause glare and potential damage to the retina.

To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments, refer to section 10 of the Manual.

- Never place and/or hang anything on the Product.
 Failure to follow such precaution could result in 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 to prevent overheating.
- Avoid the Product parts colliding with one another or other nearby equipment.

Knocks could cause the detachment of plastic parts or paint from the Product which could fall in the patient area.

In the case of the mobile version, do not rest, push or lie on the product. Failure to comply could result in damage to the product and to devices nearby and injury to staff members.

2.3 Environmental conditions

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or N_2O (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of inflammable 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.

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Use Cleaning Routine maintenance Special maintenance

Assistance Demolition

Patient population

Patient interaction

Operator interaction

3 General information

3.1 Operator qualifications

Qualification of personnel in charge of operating on the Product:

Professional medical personnel.

Properly trained medical and paramedical personnel.

Qualified technician with required technical-professional skills.

GIMA or technical service personnel, the latter only for the fuse change.

GIMA or authorized Dealer.

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.

3.2 Patient population and body interactions

The intended use makes the Product suitable for all types of population without constraints of age, weight, health or medical conditions. Patients can be awake or unconscious, in local or total anaesthesia. Patient population can also be made of animals.

An active patient could only accidentally touch the head and the swinging arm of the device, while this is not possible in case of unconscious or disable patients.

The operator touches the device necessary on the sterilisable grip and function control keyboard, and occasionally on the enclosure. In any case, he/she probably wears personal protective equipment (PPE) so it isn't a direct contact.

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3.3 Graphic symbols used in this operation and maintenance manual

The following safety measures must be put in place during Product installation, use and servicing.

To emphasize their importance, a number of safety precautions are repeated throughout the manual.

Follow the safety precautions before using or repairing the Product. Carefully abiding by the safety precautions improves the ability to use the Product safely and correctly and helps prevent incorrect maintenance which could be hazardous and cause damage. The safety measures are approximate and not exhaustive; the Operator, the Responsible Organization and the Technical Service Personnel must develop their capacities to upgrade and integrate them.

General warning signal

General mandatory code of conduct signal

General prohibition signal



Below are the symbols to be found on the Product:

CE marking indicating the Product complies with REGULATION (EU) 2017/745 and subsequent amendments and supplements

Date of manufacture (month and year)

Manufacturer's address

Fuses used in the device

Comply with the instructions for use

Medical Device

Reference number

Serial number

Disposal

Protection earth



























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'N'

'L'

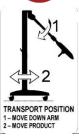
"l"

'O'









Operator Instructions

Neutral lead connection point

Line lead connection point

ON

OFF

Standby and switch-on

Pushing, resting on or lying on the product is forbidden

No stepping on surface

Only move the product after lowering the arm

4 Precautions for the Product operator

4.1 Personnel awareness obligation

The Responsible Organization must instruct the Operator on how to use, clean and service the Product.

The instructions must be provided in written form on the basis of this Manual.

4.2 Warranty and liabilities

GIMA disclaims all liability as regards unreliable Product operation in the following cases:

- The Product has not been used for its intended purpose and in conformity with the operating instructions.
- Authorized modifications and repairs have not been performed by TECHNICAL SERVICE PERSONNEL.

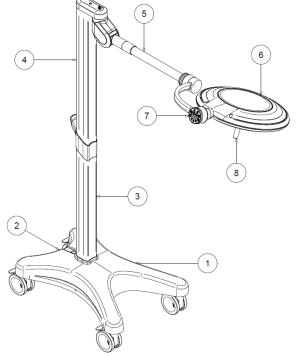
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Versions

3 3 2 8 7 5 6 9



Separable parts

5 Product description and operation

5.1 Product description

The Product is available in various versions:

- ceiling version
- mobile version

CEILING version: ceiling cover (1), ceiling anchor tube (2), supply unit (3), horizontal arm (4), swinging arm (5), yoke (6), lamp head (7), function control keyboard (8), sterilisable grip (9).

MOBILE version: base with wheels (1), power plug (2), lower stem (3), upper stem (4), swinging arm (5), lamp head (6), function control keyboard (7), sterilisable grip (8).

Sterilisable handpiece Refer to Section 6.4 for assembly/disassembly instructions.

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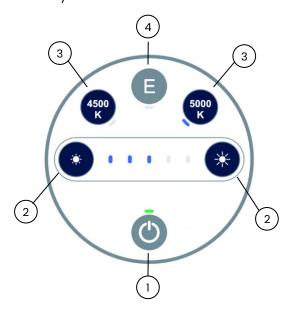




Main switch

CAUTION

Control keyboard



Light field adjustment

5.2 Description of operation

Mobile version lamps feature a green light switch for general switching on and off.

In case of single and double ceiling versions position the thermal magnetic switch near the Product so that it can be switched off in case of need.

In case of mobile version do not position the device so it is hard to reach and remove the power plug in case of an emergency.

The capacitive keyboard with touch technology is fitted on the Product yoke. By touching with your finger on the surface of the keyboard, the following functions can be activated:

- lamp switch-on and switch-off by means of the "I/O" key (1).
 With the lamp off, the green LED indicates the presence of power voltage in the Product;
- adjustment of light intensity by dragging your finger over the bar or touching the sun symbol keys (2). The level of intensity achieved is indicated by means of 5 blue microleds;
- selection of colour temperature between the 2 values by pressing the respective keys (3);
- enabling the "Endoled" function, using the key with the letter E (4). This function is only available with lamp off.

The mechanical adjustment of the light field can be performed by the sterilizable hand-piece.

By skimming the references on the handpiece light intensity can be increased or decreased. The handpiece is shaped so as to allow easily identifying the position of the sensors by means of a groove.

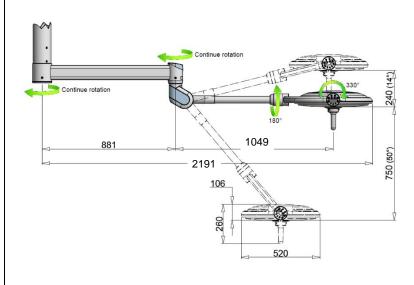
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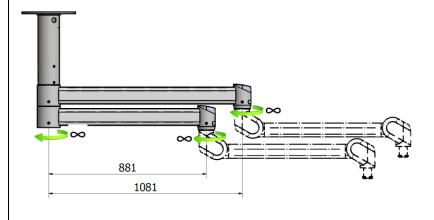
5.3 Product handling

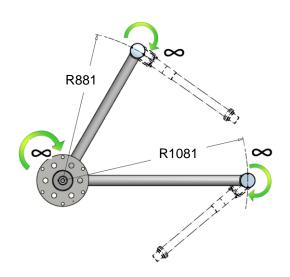
SINGLE ceiling model



Continue rotation R1051 Continue rotation

DOUBLE lamp model

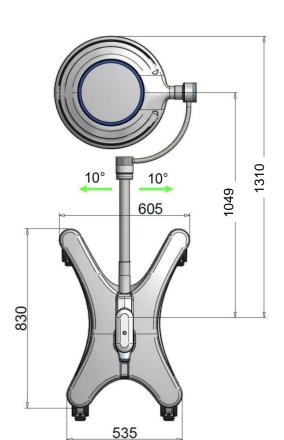




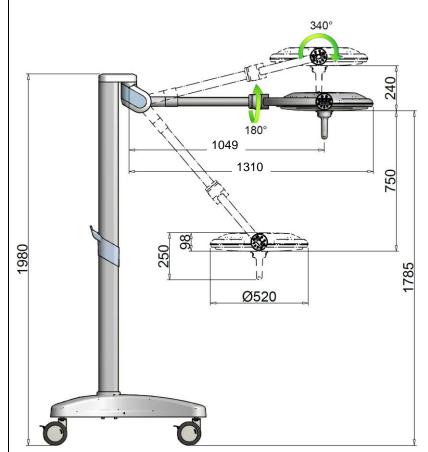
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Mobile model



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The Product can be moved using the sterilisable handpiece.



The Product can also be moved using the external contour.



By pressing the keys on the keyboard, the previously described control functions can be enabled.



By skimming the sensors on the handpiece as previously indicated, the light field can be adjusted.

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70cm

100cm

140cm



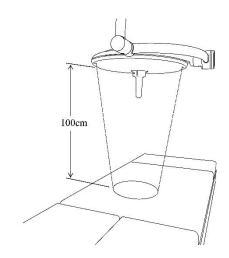
Max Ix

OPERATION AND MAINTENANCE MANUAL



RECOMMENDED WORK DISTANCE

To optimize light intensity, the product is best used at a distance of lm.



The Product nevertheless also ensures a good light intensity at a distance between 70cm and 140cm.



5.3.1 Brakes for mobile version

The mobile version has 4 wheels with pedal brake. This are used to block the Product in the required position.

Press the brake pedal with your foot, without applying too much pressure.





Risk of damaging pedal.



Do not kick the brake pedal and do not press continuously once the stop position has been reached.

To disengage the brake, lift the pedal with your foot.

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Risk of lamp overturning.

5.3.2 Moving the stand

Whenever the stand has to be moved, make sure the swinging arm is moved downwards.

Failure to do so could cause the lamp to overturn.

5.4 Checks to be made every time before use

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 swinging arm maintains correctly its position;
- The cupola maintains correctly its position.

6 Cleaning and disinfecting

The responsible organization must comply with the rules (standards and directives) concerning hygiene, disinfection and sterilization laid down by the relevant national commission.

6.1 Application method

Before proceeding to clean / disinfect the Product, make sure it is off and cannot be switched back on.

Allow the lamp to cool down and only clean it when it is cold. Protect the Product from water spray and detergents and do not clean it in direct contact with liquids.

Do not spray detergent / disinfectant directly on Product.

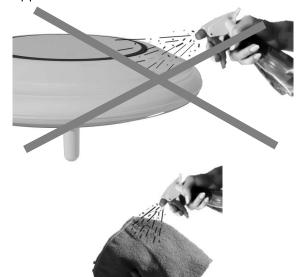


Interrupt the power supply before cleaning the Product.



Possibility of damaging the Product.

Application method



Spray the detergent / disinfectant on a cloth so as to dampen it.

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Afterwards wipe the product with the cloth.

Failure to comply with the above instructions could cause:

- detaching of paint with possible accidental dropping of such paint into the patient area;
- early ageing of the plastic parts with consequent weakening and the possibility of breakages;
- tarnishing of the protection screens and glass.

6.2 Cleaning the Product

We recommend you to clean the Product every day.

- Do not use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.
- Do not pour liquids directly on the Product.
- Clean the Product with a damp, but not wet, cloth.
- 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 detergents strictly according to the percentage indications shown on the manufacturer's technical sheet, being careful that no liquids penetrate into the joints of the various Product parts, with special care give to the reflector and supporting structure.

Frequency

Frequency



Possibility of damaging the Product.

Possibility of damaging the

Product.

6.3 Product disinfecting

We recommend you to disinfect the Product every time before use.

Disinfectants can contain substances that are harmful for the health; use disinfectants indicated by the national commission for hygiene and disinfection, according to the hygienic standards adopted by the Responsible Organization.

- Do not use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.
- Do not pour liquids directly on the Product.
- Disinfect the Product with a damp but not wet cloth.
- Use appropriate disinfectants with low alcohol content.
- To prevent damaging the stainless-steel and aluminium parts, use only disinfectants that do not contain chlorine or halogens.
- Dilute the disinfectants in strict accordance with the percentage indications on the manufacturer's technical data sheet, being careful no liquids penetrate into the joints of the various parts of the Product, with special attention for the reflector and supporting structures.

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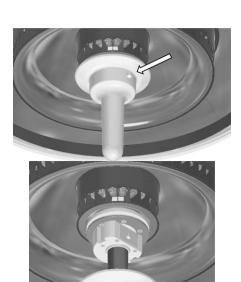




Frequency



Hazard for the patient.



6.4 Handpiece sterilization

The handpieces must be sterilized before use and can withstand up to 200 cycles.

The Operator must comply with the rules of the national commission for hygiene, disinfection and sterilization.

The handpieces are made of plastic material resistant to heat and knocks (PSU - Polysulfone).

Replace the hand-pieces as soon as these become cracked or deformed, as these could fall in the patient area.

Hand-piece fitting / removal:

- Press the hand-piece release button and remove it.
- Insert the handpiece in the support, following the guide provided until it is locked in position.

Clean and disinfect the handpieces in the traditional way before sterilization. They can be cleaned with a 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 polylsulfone (PSU). After disinfecting, rinse off the detergent residues with plenty of water.

The handpieces fit into a suitable sterilization pack (disposable sterilization pack, e.g., plastic/paper bags; single or double pack), before being sterilized.

The handpieces can withstand about 200 steam sterilization cycles in accordance with the following parameters:

- steam sterilization at 121°C and 1.3 bar for 25 to 30 minutes
- steam sterilization at 134°C and 2.3 bar for 4 minutes

Do not exceed a sterilization temperature of 134°C.

Strictly keep to the ISO 17665-1 standard.

When placing in the autoclave, make sure the open side of the handpieces is turned downwards. The handpieces must be free and not burdened by other material being sterilized.

Damaged handpieces must no longer be used.

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7.1 Swinging arm adjustment

The Product is sold already balanced and does not require further adjustment. In the event of the spring swinging arm becoming stiff or loose over time, mechanical intervention is possible by regulating the compression of the internal spring.

Manually move the cover (1) forwards. Looking at the lamp from the front, fit the adjustment pin (2) in the holes of the ring nut on the left of the arm (3) and turn in the direction indicated by the arrows to increase/decrease the load on the spring (a reference sticker is placed on the arm).

If the swinging arm drops, this means the elastic force of the spring is insufficient:

- turn the lever downwards and load the spring.

If the swinging arm lifts up, this means the elastic force of the spring is too high:

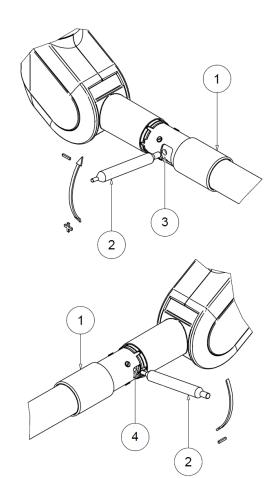
- turn the lever upwards and release the spring.

At the end of adjustment, manually reposition the cover (1) in its original position.

The swinging movement of the arm can also be adjusted upwards. The Product is sold with maximum set swinging movement. If the swinging movement is to be reduced upwards, manually move the cover (1) forwards. Looking at the lamp from the front, fit the adjustment pin (2) in the holes of the ring nut on the right of the arm (4). By turning the pin downwards, the swinging movement can be reduced until it is in horizontal position.

The swinging movement downwards cannot instead be changed.

At the end of adjustment, manually reposition the cover (1) in its original position.



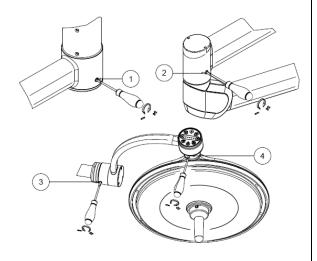
7.2 Clutch adjustment

The brakes are set during installation. Like all the other mechanical parts, the brakes are also subject to wear.

If the Product does not remain in a stable position, the braking force will have to be adjusted by means of the brake screws.

Use a flathead screwdriver to increase brake force, turning the screws (1) and (2) of the arm brake clockwise.

To increase the braking force at the head, turn the two brake screws (3 and 4) clockwise using a flathead screwdriver.



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Perform the Product electrical check.



Making any changes to this device is forbidden.



Interrupt the power supply before doing any maintenance jobs.



Check Product integrity.

7.3 Periodical checks to be performed on the Product

At the time of start up and after each maintenance job, perform electrical tests and jobs indicated in the IEC 62353 standard.

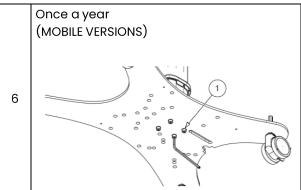
7.4 Routine maintenance

N.	Period	Action
1	Before using	Make sure there are no pieces or fragments of paint that could become detached and fall within the operating field. If there are any, remove them manually.
2	Before using	Make sure the light source protection screens are not damaged. If they are, contact the Customer Service.
3	Once a year	Check all the Product joints and make sure there are no noises or squeaks. If there are, lubricate the clutches involved with suitable grease for industrial use at a service temperature between -30°C and + 120°C, type OKS 470 or with similar properties.
4	Once a year	If the Product fails to maintain a regular position, adjust the clutches as indicated at points 7.1 and 7.2 (arm and clutch adjustment) .
5	Once a year (CEILING VERSION)	Make sure the bar retention screws (1) are tightened properly. Also check the bar horizontal arm retention screws (4). If these are not properly fastened, adequately tighten. To access the nuts (1), slide off the aluminium ring (2) downwards by loosening the screws and bar cover (3).

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Make sure the stem retention screws (1) under the base are tightened properly.

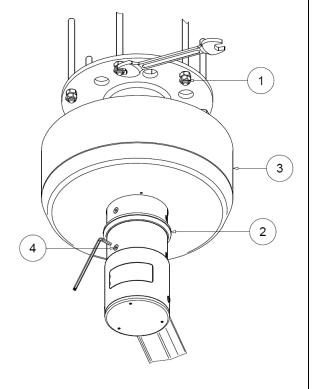
If these are not properly fastened, adequately tighten.



The Product must only be opened and repaired by the Technical Service Personnel for the fuse change. All other repairs to be done by the manufacturer.



Interrupt the power supply before doing any maintenance jobs.



7.5 Repairs

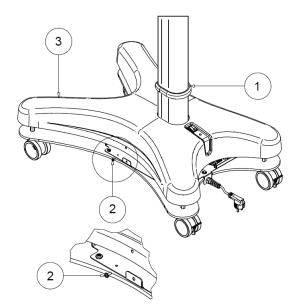
The only repair job with which the technical assistance personnel are charged is the fuse change.

To access the fuses in the ceiling version, open the bar cover as indicated in point 5 of paragraph 7.4.

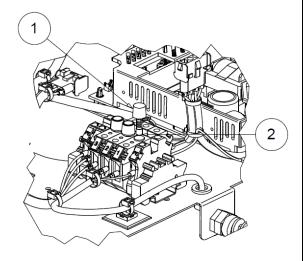
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To access the fuses in the mobile version, lift the ring (1), remove the screws (2) and lift the cover (3).



Remove the screw fuse carrier (1) from the terminal board and replace the fuse (2) making sure it is replaced with another of the same type.



Making any changes to this device is forbidden.

If necessary, GIMA will provide the wiring diagrams, the list of component parts, the descriptions, setting instructions or other information to assist the technical assistance personnel in repairing the parts of the Product indicated as reparable by the technical assistance personnel.

If the above indications are not enough to solve the problem, contact the after-sales service.

7.6 Disposal after use

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.

Disposal at end-of-life

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Only original spare parts must be used.

7.7 Spare parts list

Description	Order code
Sterilisable grip	Z400307-2
Electronic board	Z300632-PL81
Keyboard	Z300242
I/O switch (for mobile versions)	Z300016
Switching power supply unit	Z400629
Fuse T2AH 250V '5x20'	Z400195
Fuse T10AH 250V '5x20'	Z400217
Fuse T4AH 250V '5x20'	Z400215

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8 Technical properties

Technical details of light	GIMAled81
Illumination E _c at 1 m ± 10% [Lux]	160,000
Colour temperature [K]	4,000 – 4,600
Colour rendering index Ra [-]	95
R ₉ [-]	>90
Light field diameter d50 [mm] (D)	150
Light field diameter d₁₀ [mm] (D)	260
Light field adjustment – to – [mm]	110 – 350
Lighting depth L1+L2 [mm] at 60%	810
Max irradiance [W/m²]	556
Irradiance / Illumination [mW/m²lx]	3,47
Max radiation in UV [W/m²]	0.002
Power connection details	
Primary alternate voltage [Volt ac]	100 - 240
Frequency [Hz]	50 / 60
Absorbed power [VA]	65
Light source	№ 81 LED
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	25 - 100

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	General data			
Regulation		REGULATION (EU) 2017/745		
Classification of	Medical Device	Class I		
Standards		IEC 60601-2-41		
Classification of	Medical Device	Class I		
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the EM equipment s not vary by more than 20% during use; the colour temperature and colour rendering index shall stable and within the range 3000K-6700K and 85-100, respectively; E _c value shall be ≥ 40,000 lux ≤ 160,000 lux). Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm shall exceed 10 W/m²; and the total irradiance E _e in the lighted area shall not exceed 1000 W/m²			
Colour	distance of 1000 mm; E _c value	shall be ≥ 40,000 lux and ≤ 160,000 lux; E _e /E _c ≤ 6 mV/m²lx). RAL 9003		
IP degree of pro	tection	IP20		
Operating cond	itions	Continuous operation		
l Handniece steam sterilization		121°C and 1.3bar for 25 to 30 minutes. 134°C and 2.3bar for 4 minutes.		
Mains power vo	ltage insulation means	Outside the product (main switch) for ceiling versions. Main switch for mobile versions.		
	Dimensions			
Diameter of lam	np body [cm]	52		
Light emission s	urface [cm²]	567		
Weight of Product in ceiling, double ceiling, mobile [kg]		45, 75, 75		
Markings				
C€		In conformity with REGULATION (EU) 2017/745		
All technical light measurements are to be deel reasons		emed with a tolerance of ±6% for metrological and manufacturing		

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Possibility of interferences with nearby appliances.

9 EMC Declaration

The Product has been tested according to IEC 60601-1-2 standard to ensure correct electromagnetic compatibility.

Portable and mobile communication appliances can affect the Product. The product should not be used close to another device and if this is inevitable, the product must be checked to make sure it is working properly.

The use of accessories other than those supplied/recommended by the manufacturer could increase the level of emissions and lower the level of immunity of the appliance.

The Product has been designed to be used in the electromagnetic environments described below.

The Responsible Organization or Operator is responsible for making sure the Product is used in a compatible environment.

It could occur that if the Product is affected by radiations in the range of 80 MHz – 1 GHz or bursts, it will no longer respond to the commands both as regards the lamp and the camera.

If this does occur, essential performance will in any case be ensured, but to restore normal operation it will be necessary to de-energize the master switch.

Immunity test	Compliance	Electromagnetic environment - directives	
RF Emissions CISPR 11	Group 1	The Product only uses RF energy for internal operation. Consequently its RF emissions are very low and should not cause any interference to nearby electronic appliances.	
RF Emissions CISPR 11	Class A	The Product is suitable for use in all environments except in domestic environments and those directly connected to a low-	
Harmonic emissions IEC 61000-3-2	Class A	voltage public mains supply which supplies buildings used for domestic purposes, as long as the following precaution is followed. Warning: This Product is intended for use by professional health personnel only. This Product can cause radio-interference or disturb	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Conforming	the operation of nearby appliances. Measures may have to taken to reduce such disturbance, such as Product re-positioning or shielding of premises.	

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR II class A). If it is used in a residential environment (for which CISPR II class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives		
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV at contact +/- 15 kV in air	+/- 8 kV at contact +/- 15 kV in air	Floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must at least be equal to 30%.		
Rapid impulse electric transistors IEC 61000-4-4	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	Mains voltage quality should be that of a typical commercial or hospital environment.		
Overvoltage IEC 61000-4-5	+/-1kV Between phases +/-2kV Between phases and earth	+/- 1 kV Between phases +/- 2 kV Between phases and earth	Mains voltage quality should be that of a typical commercial or hospital environment.		
Voltage dips, short interruptions and variations on the power supply input lines IEC 61000-4-11	<5% U _T (drop >95% of U _T) For 0.5 cycles <40% U _T (drop = 60% of U _T) For 5 cycles <70% U _T (drop = 30% of U _T) For 25 cycles <5% U _T (drop >95% of U _T) For 5 s	<5% U _T (drop >95% of U _T) For 0.5 cycles <40% U _T (drop = 60% of U _T) For 5 cycles <70% U _T (drop = 30% of U _T) For 25 cycles <5% U _T (drop >95% of U _T) For 5 s	Mains voltage quality should be that of a typical commercial or hospital environment. If the Product user requires continued function during mains power supply interruptions, the Product should be supplied by a UPS unit or batteries.		
Magnetic field at electrical mains frequency (50/60Hz)	30 A/m	30 A/m	The magnetic fields at mains frequency should have the characteristic levels of a typical locality in a commercial or hospital environment.		
NOTE: U _T mains voltage in AC before application of test level.					

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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 2.7 GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Products, 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} \] 800 MHz to 2.7 GHz \[\text{where } P \] 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 and people.

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Test frequency (MHz)	Band a) (MHz)	Service ^{q)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)}	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	18 Hz FM ^{c)} ± 5kHz deviation 1 kHz sine	2	0.3	28
710			Pulse			
745	704-787	LTE Band 13, 17	modulation ^{b)}	0.2	0.3	9
780			217 Hz			
810		GSM800/900,	Pulse			
870	800-960	TETRA 800, iDEN 820,	modulation ^{b)}	2	0.3	28
930		CDMA 850, LTE Band 5	1 18 17			
1720		GSM 1800; CDMA 1900;	Pulse			
1845	1700-1990	GSM 1900;	modulation ^{b)}	2	0.3	28
1970		DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz	_	-1.5	
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID	Pulse modulation ^{b)}	2	0.3	28
		2450, LTE Band 7	217 Hz			
5240			Pulse			
5500	5100-5800	WLAN 802-11 a/n			0.3	9
5785		,	217 Hz			

NOTE: If necessary, to achieve the IMMUNITY TES LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1m test distance is permitted by IEC 61000-4-3.

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a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.





Recommended separation distance between portable and 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 $d = 1,2\sqrt{P}$	Da 80 MHz a 800 MHz $d = 1,2\sqrt{P}$	Da 800 MHz a 2.7 GHz $d = 1,2\sqrt{P}$	
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 and people.

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10 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.).
- 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 all 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 Product 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.

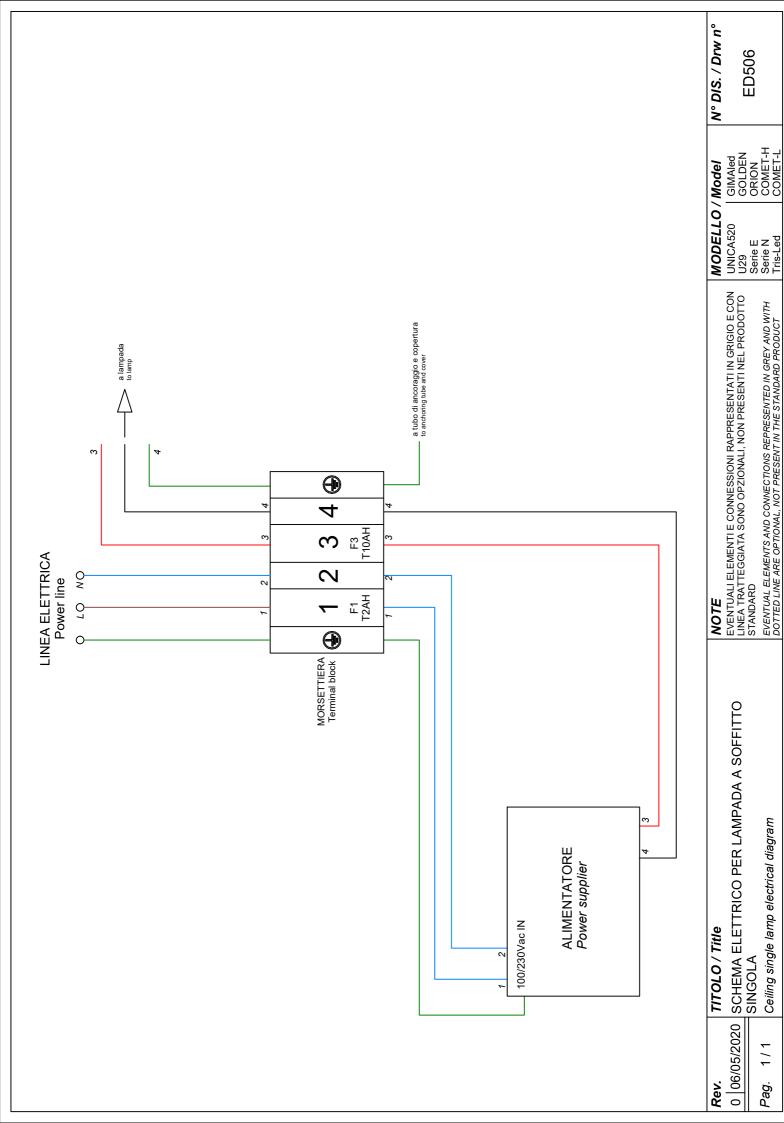
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Notes

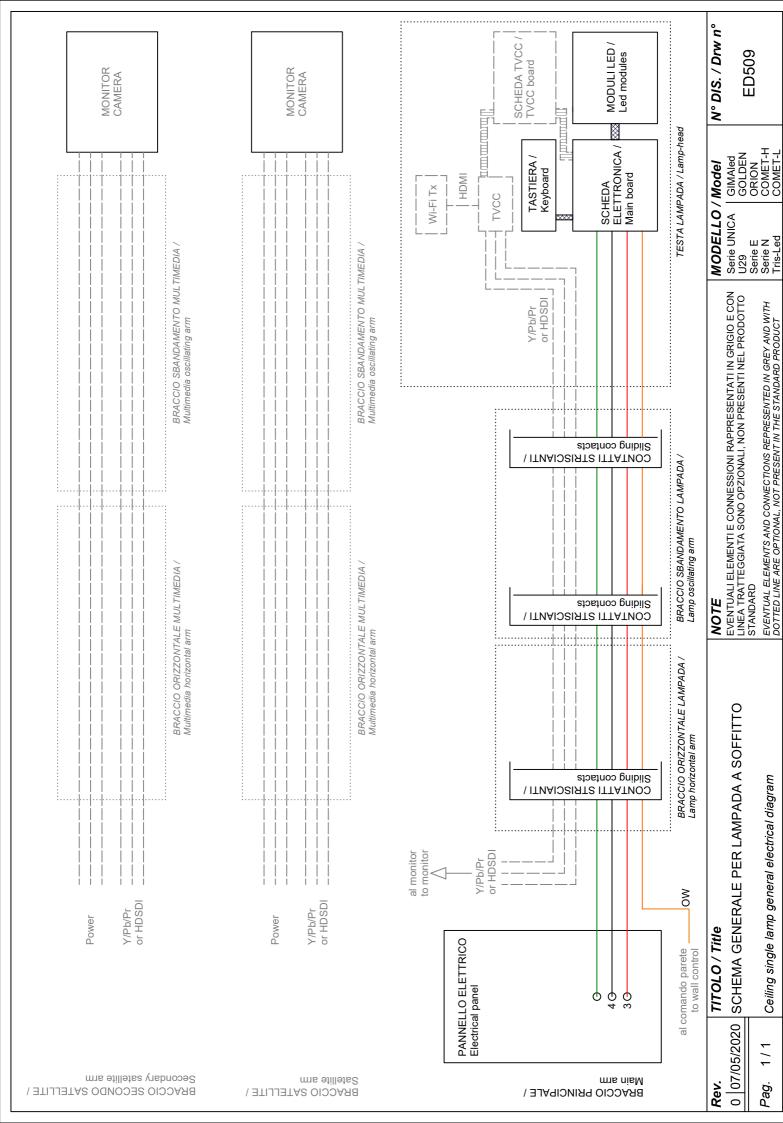
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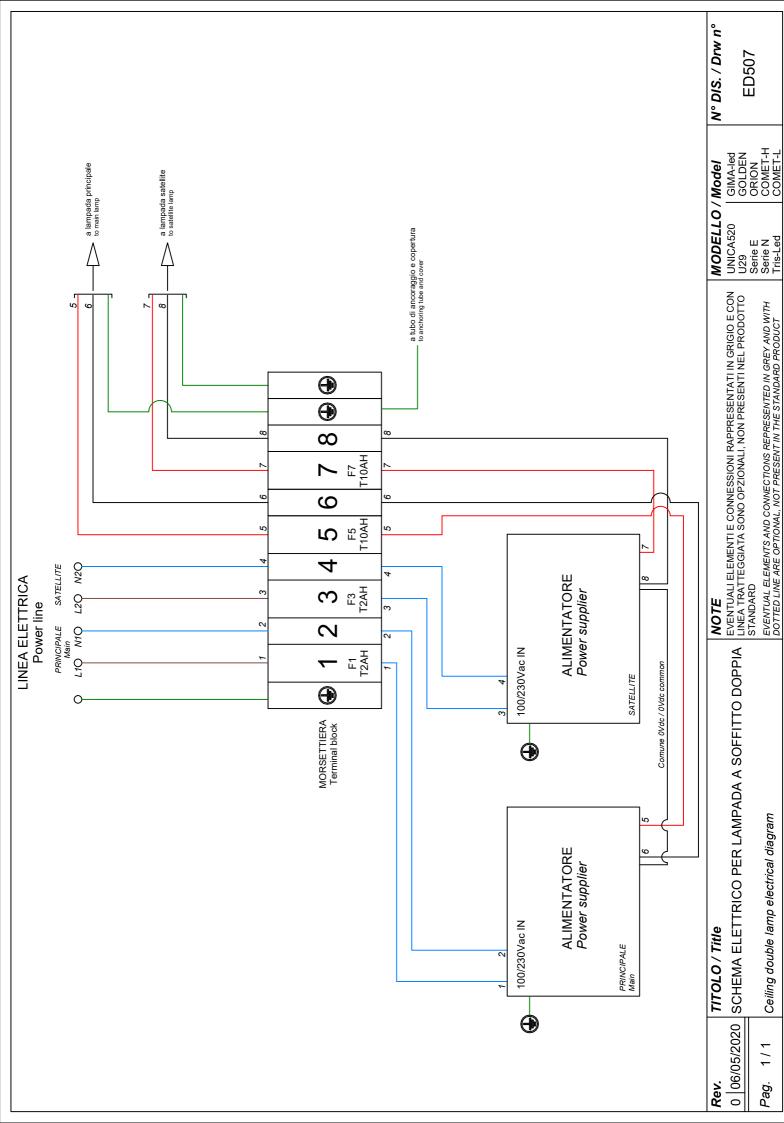


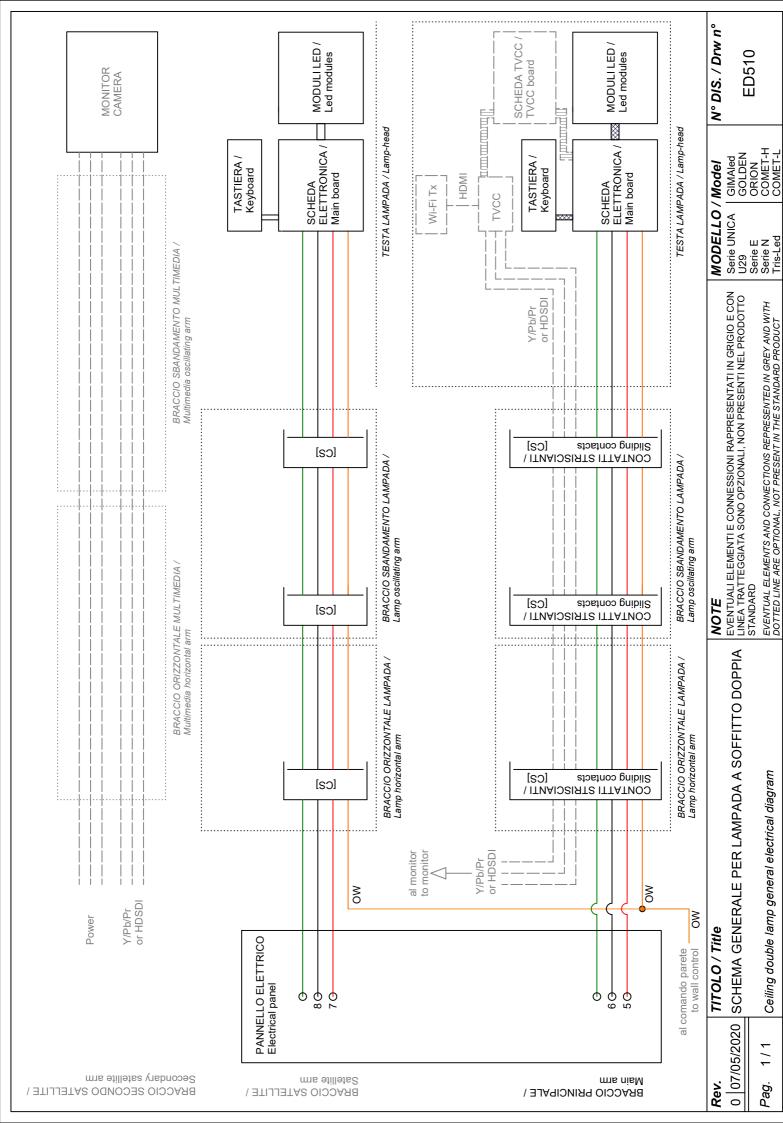
EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

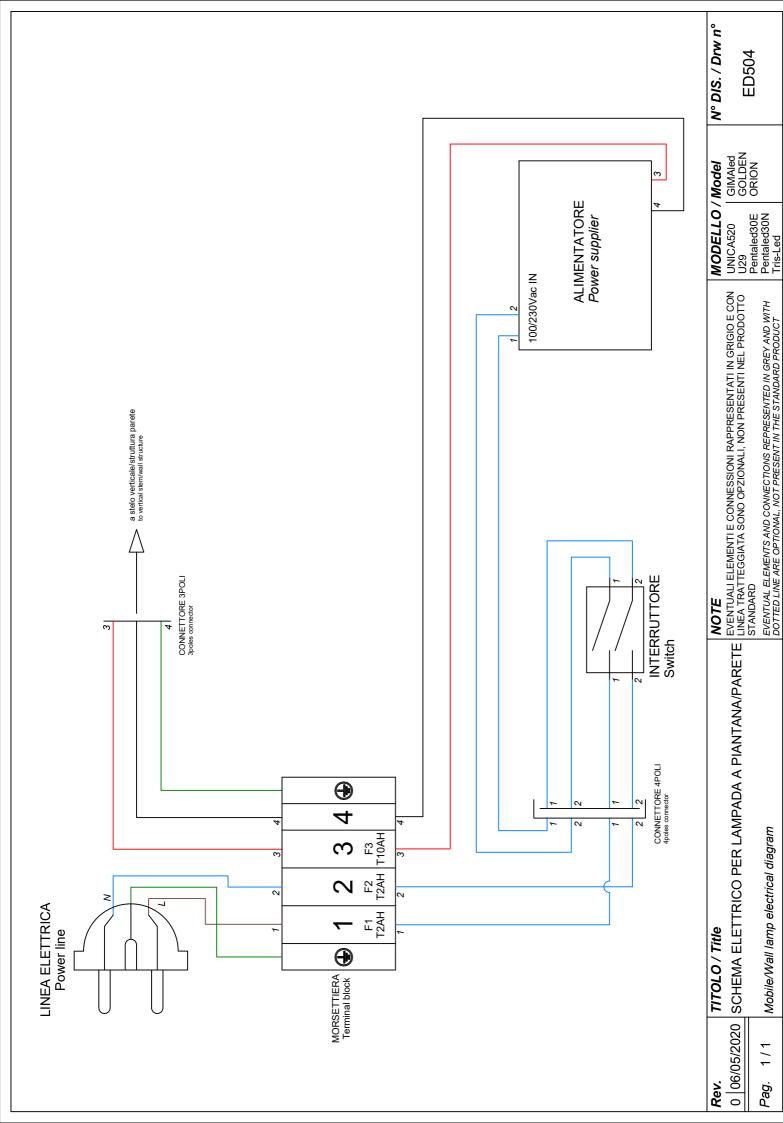
Ceiling single lamp electrical diagram

Pag. 1/1





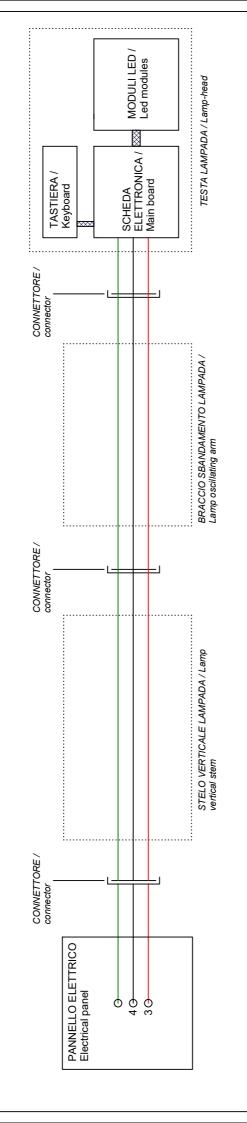




EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

Mobile/Wall lamp electrical diagram

Pag. 1/1

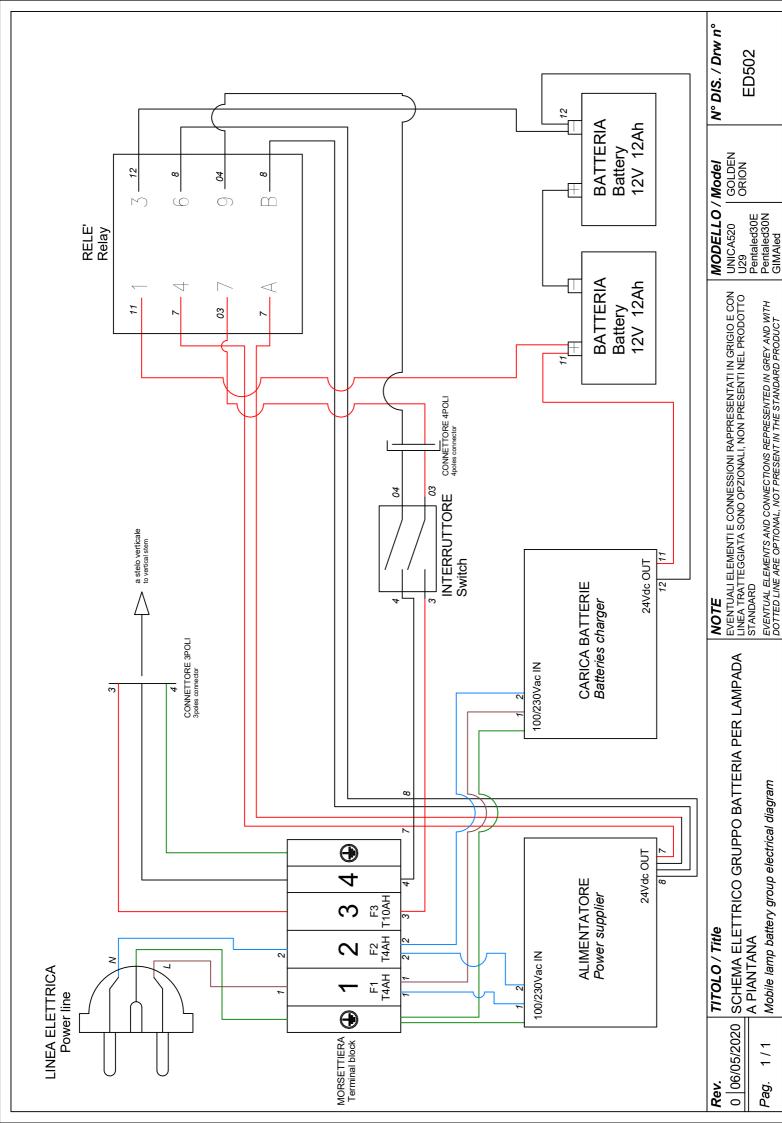


0 |07/05/2020 | SCHEMA GENERALE PER LAMPADA A PIANTANA Mobile lamp general electrical diagram TITOLO / Title Pag. 1/1 Rev.

NOTEEVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

MODELLO / Model
UNICA520 GIMAled
U29 GOLDEN
Pentaled30E Pentaled30 N
Tris-Led

N° DIS. / Drw n° GIMAled GOLDEN ORION







INSTALLATION MANUAL

GIMAled81

MINOR SURGICAL LUMINAIRE (TREATMENT LAMP)



GIMA SPA VIA MARCONI 1 - GESSATE MI



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Introduction

Marking (E

Compliance

Validity of manual

Customer Service

Copyright

Translations

Please read this manual carefully before using the Product, so as to protect "the Technical Service Personnel" and "the Operator" from any injury.

This appliance is a Class I medical device pursuant to REGULATION (EU) 2017/745 on medical devices (Annex VIII) as amended and integrated.

The manufacturer declares that this Product complies with Annex I (General Safety and Performance Requirements) of REGULATION (EU) 2017/745 as amended and integrated and certifies such conformity by affixing the CE marking.

This installation manual is valid for the following models:

• GIMAled81 in ceiling, mobile versions.

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 S.p.A.
- Via Marconi, 1
- I-20060 Gessate -MI-
- Tel.: +39 02 953854209 / 221 / 225
- Fax: +39 02 95381167
- E-mail: gima@gimaitaly.com

The reproduction and translation, including partial, of any part of this manual is forbidden without the written permission of GIMA.

The original language of this manual is ITALIAN. For all translations, reference must be made to the original manual language.

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J	

26/05/2021





BG	За да поискате наръчника на този език, изпратете имейл на адрес info@rimsa.it.			
CS	Chcete-li si vyžádat příručku v tomto jazyce, zašlete e-mail na adresu info@rimsa.it.			
DA	Hvis du ønsker at få manualen på dette sprog, bedes du sende en e-mail til info@rimsa.it.			
DE	Um das Handbuch in dieser Sprache anzufordern, senden Sie bitte eine E-Mail an info@rimsa.it.			
EL	Για να ζητήσετε το εγχειρίδιο σε αυτή τη γλώσσα, στείλτε μήνυμα ηλεκτρονικού ταχυδρομείου στη διεύθυνση info@rimsa.it.			
ES	Para solicitar el manual en este idioma, envíe un correo electrónico a info@rimsa.it.			
ET	Selles keeles käsiraamatu tellimiseks saatke palun e-kiri aadressile info@rimsa.it.			
FI	Jos haluat käsikirjan tällä kielellä, lähetä sähköpostia osoitteeseen info@rimsa.it.			
FR	Pour demander le manuel dans cette langue, veuillez envoyer un e-mail à info@rimsa.it.			
GA	Chun an lámhleabhar sa teanga seo a iarraidh, seol r-phost chuig info@rimsa.it.			
HR	Da biste zatražili priručnik na ovom jeziku, pošaljite e-mail na info@rimsa.it.			
HU	A kézikönyv ezen a nyelven történő igényléséhez kérjük, küldjön e-mailt a info@rimsa.it címre.			
LT	Norėdami prašyti vadovo šia kalba, siųskite el. laišką adresu info@rimsa.it.			
LV	Lai pieprasītu rokasgrāmatu šajā valodā, lūdzu, sūtiet e-pastu uz adresi info@rimsa.it.			
MT	Biex titlob il-manwal f'din il-lingwa, jekk joghġbok ibgħat e-mail lil info@rimsa.it.			
NL	Om de handleiding in deze taal aan te vragen, kunt u een e-mail sturen naar info@rimsa.it.			
PL	Aby zamówić podręcznik w tym języku, należy wysłać wiadomość e-mail na adres info@rimsa.it.			
PT	Para solicitar o manual nesta língua, envie por favor um e-mail para info@rimsa.it.			
RO	Pentru a solicita manualul în această limbă, vă rugăm să trimiteți un e-mail la info@rimsa.it.			
SK	Ak chcete požiadať o príručku v tomto jazyku, pošlite e-mail na adresu info@rimsa.it.			
SL	Če želite zahtevati priročnik v tem jeziku, pošljite e-pošto na naslov info@rimsa.it.			
SV	Om du vill ha handboken på detta språk skickar du ett e-postmeddelande till info@rimsa.it.			

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PRODUCT

OPERATOR

RESPONSIBLE ORGANIZATION

TECHNICAL SERVICE PERSONNEL

KEY

The ME (Medical Electrical) EQUIPMENT to which this manual refers is a **MINOR SURGICAL LUMINAIRE** (**TREATMENT LUMINAIRE**). For ease of description, in this manual this ME EQUIPMENT will be called "**Product**".

Professional medical personnel (e.g., professional health personnel, expert person assisting the patient).

Entity accountable for the use and maintenance of an ME equipment or ME system (e.g., a hospital, an individual doctor or a non-expert person). Preparation and awareness are included in use.

The personnel (individuals or entity accountable to the responsible organization) that installs, assembles, maintains or repairs the equipment. Under certain circumstances, the safety of such persons depends on their knowledge and awareness and ability to take appropriate precautions when gaining access to hazardous parts partially. By way of example only, the following professional figures are deemed as SERVICE PERSONNEL:

- ⇒ 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)

For the installation phase, as regards assembly operations only, a qualified person is deemed whosoever has attended a course organized by GIMA or, alternatively, whosoever has carefully read the manual.

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1 GENERAL SAFETY INFORMATION

This manual is an integral part of the Product as indicated by REGULATION (EU) 2017/745 and subsequent amendments and supplements. Read and keep this manual close to the Product.

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or N₂O (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of inflammable agents.

GIMA disclaims all liability for any injury to persons or damage to things caused by the Product having been installed by persons who are not "TECHNICAL SERVICE PERSONNEL".

The RESPONSIBLE ORGANIZATION 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 masonry works for Products to be installed on ceilings, and the electrical works for supplying power to the Product shall be carried out in a workmanlike manner by TECHNICAL SERVICE PERSONNEL to ensure these are sturdy and safe.



Electric shock hazard.

The electrical system in the premises must conform to IEC:60364-7-710 standard and any national regulations. A master switch must be installed with fuse or thermal magnetic circuit breaker to be able to interrupt power to the Product.

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Installation

Use

Cleaning

Routine maintenance

Special maintenance

Assistance

Demolition

Packing

Transport

Storage

Installation premises

2 General information

2.1 Operator qualifications

Qualification of personnel in charge of operating on the Product:

Installer and/or qualified technician.

Professional medical personnel.

Properly trained medical and paramedical personnel.

Qualified technician with required technical-professional skills.

GIMA or technical service personnel, the latter only for the fuse change.

GIMA or authorized Dealer.

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.

2.2 Packaging, transport, storage and characteristics of installation premises

Cardboard boxes containing Product. Dispose of these in compliance with national directives applicable for waste disposal.

Product transport is done by land, sea or air according to the following characteristics:

Temperature (°C): -15 / +60

Humidity: 10 / 95 %

Atmospheric pressure (h/Pa): 500 / 1060

The packaged Product must be stored (warehoused) in dry premises having the following characteristics:

Temperature (°C): -15 / +60

Humidity: 10 / 95 %

Atmospheric pressure (h/Pa): 500 / 1060

The premises where the Product is started up must have the following characteristics:

Temperature (°C): +10 / +40

Humidity: 30 / 75 %

Atmospheric pressure (h/Pa): 700 / 1060

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2.3 Graphic signs and symbols used in the installation manual

The following safety measures must be put in place during Product installation, use and servicing.

To emphasize their importance, a number of safety precautions are repeated throughout the manual.

Follow the safety precautions before using or repairing the Product. Carefully abiding by the safety precautions improves the ability to use the Product safely and correctly and helps prevent incorrect maintenance which could be hazardous and cause damage. The safety measures are approximate and not exhaustive; the Operator, the Responsible Organization and the Technical Service Personnel must develop their capacities to upgrade and integrate them.

General warning signal

General mandatory code of conduct signal

General prohibition signal

2.4 Graphic symbols used on packaging

List of symbols on packaging boxes:

This side upwards

Fragile

Protect from rain

Do not stack packaging

Weight of packaging

Humidity to be complied with (max limit at top right and min limit at bottom left)

Pressure to be complied with (max limit at top right and min limit at bottom left)

Limit temperature (max limit at top right and min limit at bottom left)









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2.5 Graphic symbols used on the Product

Below are the symbols to be found on the Product:

CE marking indicating the Product complies with REGULATION (EU) 2017/745 and subsequent amendments and supplements

Date of manufacture (month and year)

Manufacturer's address

Fuses used in the device

Comply with the instructions for use

Medical Device

Reference number

Serial number

Disposal

Protection earth

Neutral lead connection point

Line lead connection point

ON

OFF

Standby and switch-on

Pushing, resting on or lying on the product is forbidden

No stepping on surface

Only move the product after lowering the arm

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2.6 Warranty and liabilities

GIMA disclaims all liability as regards unreliable Product operation in the following cases:

- Installation, authorized modifications and repairs have not been performed by TECHNICAL SERVICE PERSONNEL.
- The Product has not been used for its intended purpose and in conformity with the operating instructions (see operation manual).
- The premises have not been approved for healthcare activities.
- The premises are not built in conformity with the law and applicable regulations.
- The electrical system in the premises is not in compliance with appropriate requirements.

2.7 Structural changes or variations

No arbitrary structural changes or variations to the Product are admitted. Any modifications must have the prior written authorization of GIMA. In case of the Product having been tampered with, the warranty shall be invalidated and the manufacturer disclaims all liability for any injuries or damage caused to the OPERATOR, the RESPONSIBLE ORGANIZATION and the TECHNICAL SERVICE PERSONNEL.

3 Instructions on how to prepare the premises mechanically and electrically

3.1 Preparing the premises mechanically (ceiling version)

The masonry works for preparing the ceiling to install the Product must be sturdy and safe and performed in a workmanlike manner according to applicable building regulations.

By way of example only, the professional persons charged with completing the masonry works are: Construction Engineer, Draughtsman, Building firm, duly registered in a professional register.

In case of wrong perforation of the Product supporting wall (e.g., the breakage of a reinforced-concrete ceiling iron) always inform the building manager as this could affect the stability of the building.

The ceiling must be able to withstand a weight of at least 300 kg/m² and have a thickness of at least 250 mm.

The Product installation premises must conform to local building standards.

After making sure the premises used for medical purposes are in conformity with the above requirements, proceed to mechanically anchor the ceiling plate, assessing the type of building and making all consequent adaptations.

CAUTION



Carry out safe masonry works.



Collapse of the building structure.



Make sure that ceiling is adequate.

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0

Carry out safe electrical works.



Make sure that the electrical environment complies with the law.

Main switch

CAUTION

The TECHNICAL SERVICE PERSONNEL has all technical, civil and legal responsibility relating to correctly and suitably performing Product anchoring and installation operations in a workmanlike manner.

3.2 Correctly wiring up the premises

The premises used for medical purposes must be safely wired up in a workmanlike manner by TECHNICAL SERVICE PERSONNEL to power the Product.

Before installing the Product, the TECHNICAL SERVICE PERSONNEL must make sure the following conditions exist:

- The wiring system of the environment (premises) in which installation is made must be in conformity with regulations for premises used for medical purposes and with applicable national laws and/or regulations.
- The electrical system must have a certificate of conformity issued by whosoever installed it.

The earth system must be certified as required by applicable regulations.

Mobile version lamps feature a green light switch for general switching on and off.

In case of single and double ceiling versions position the thermal magnetic switch near the Product so that it can be switched off in case of need.

In case of mobile version do not position the device so it is hard to reach and remove the power plug in case of an emergency.

4 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 redispatched.

Personnel required:



Necessary protection equipment:

- Safety eyewear
- Gloves
- Accident-prevention footwear

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Special equipment:

- Drill (ceiling version only)
- Set of hexagon spanners
- Screwdriver
- Circlip pliers
- Ladder (ceiling version only)
- Standard manual tools
- Set of drill bits (ceiling version only)

After installation, the Product must be tested by Technical Service Personnel before being used.

4.1 Parts included in the package

The Product is supplied complete with lamp head, sterilisable handpiece, swing arm, horizontal arm, bar, bar cover with relative safety ring, structure retention screws with glue, switchboard. GIMA does not provide any kind of anchoring for fastening the plate to the ceiling. Such equipment must all be provided by the installer.

The Product is supplied complete with lamp head, sterilisable handpiece, swing arm, stems, wheeled base and base cover.

4.2 Ceiling drilling instructions

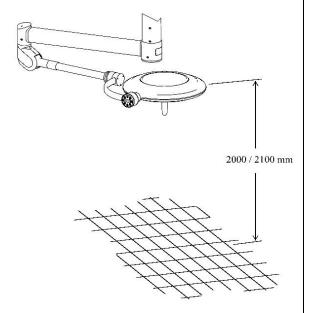
For ceiling installation, the length of the bar varies according to the height of the premises in which the Product is installed.

The length of the bar is calculated to install the Product at a finished height off the floor of around 2000/2100 mm (as per drawing below), unless otherwise requested by the RESPONSIBLE ORGANIZATION.

Ceiling version

Mobile version

Fixing positions

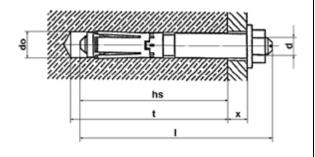


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Reinforced concrete Mechanical anchoring

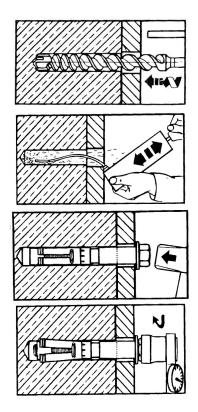


By way of example only, below is a list of some types of walls: Proceed to fasten the ceiling plate using Hilti HSL-3-G M16/25 screw anchors or other anchors with similar characteristics, carefully following the instructions provided by the anchor manufacturers and shown below for information purposes:

do	Nominal diameter	drill bit	Mt	Closing bending moment
t	Minimum drilling depth			Wrench opening
hs	Minimum depth	insertion	x	Fastening height

Anchor tie-rod	do	t	hs	l	Mt	sw	x
	(mm)	(mm)	(mm)	(mm)	(Nm)	(mm)	(mm)
HSL-3-G M 16/25	24	125	100	163	80	24	25

Anchor tie-rod length



- 1. Apply the paper template at the Product installation point and mark the fastening hole points with a pencil.
- 2. Make the holes in the ceiling in accordance with the anchoring tie-rod manufacturer's specifications.
- 3. Using a pump or a vacuum cleaner, remove the drilling residues and dust from the hole.
- 4. Fasten the Bar to the ceiling and, using a hammer, insert the anchoring tie-rod in the hole.

Attention!

Check the fitting depth

- Using a torque wrench, tighten the anchorage to the tightening force indicated by the screw anchor manufacturer.
 The anchorage will immediately bear the weight.
- 6. Proceed in the same way for the remaining anchors.
- 7. After one hour, again tighten the tie-rods to the prescribed tightening torque.

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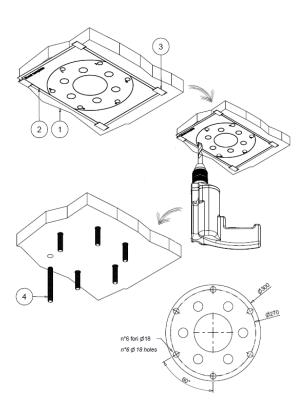
EN

Chemical anchoring

Hollow-core concrete



Do not install the Product on unsuitable ceilings.



Drill the ceiling using the template provided. Insert the resin inside the 6 drilled holes and fill the hole, carefully following the manufacturer's instructions. GIMA recommends using HILTI HIT-HY 270 resin or similar products.

Fit 6 threaded bars into the holes. GIMA recommends M16 bars. Proceed to fasten the ceiling plate with nuts and locknuts for each tie-rod and tighten using the Allen key.

In this case the ceiling must be sandwich closed by means of the ceiling plate and counter-plate, being careful to include at least one rafter.

The plate and counter-plate must be fastened together using suitable M16 threaded steel bars, with ultimate tensile strength of at least 800 MPa, blocked at the top and bottom ends by relative washers, nuts and locknuts.

4.3 Instructions for ceiling version of Product

4.3.1 Installation of the ceiling plate, bar, power supply

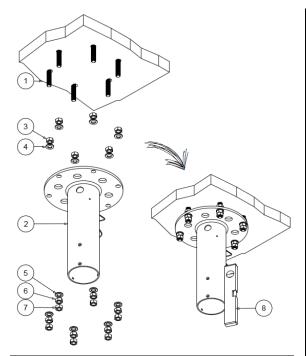
VERSION WITH PRE-PREPARED TIE RODS OR CHEMICAL ANCHORAGE If the tie rods are not prearranged in advance, place the template (drawing 12) (2) on the ceiling (1) and secure it with adhesive tape (3)

Drill the holes according to paragraph 4.2 and insert the 6 threaded bars M16 (4) into the ceiling.

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On the threaded bars (or pre-prepared tie rods) insert the nuts (3), the washers (4) (secure them with adhesive tape on the tiges (bar) to prevent them from falling) and insert the tiges (2).

Position the washers (5), nuts (6) and locknuts (7) from underneath. Using the nuts (6) and locknuts (7), position the tiges tube vertically, making sure it is correctly aligned using a spirit level (8).

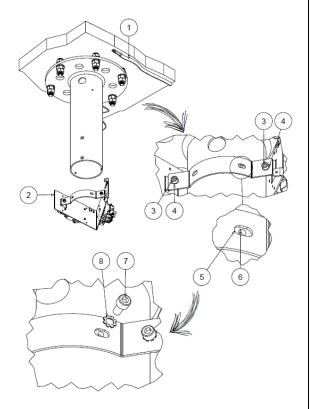
Once in the balanced position, tighten the upper nuts (3) so that everything is stable.



Make sure the product is stable.



Product falling hazard.



VERSION WITH COUNTER-PLATE

In case of counter-plate (optional), drill the holes as shown in paragraph 4.2 and fix it to the ceiling.

To fasten the tiges to the counter-plate, follow the instructions given above.

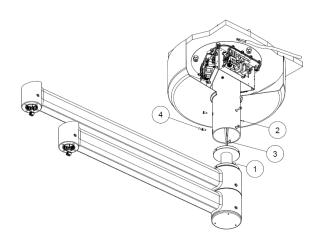
Make sure the mains power cable (1) can reach the lamp power board without creating interferences with the Bar.

Fit the switchboard (2) on the Bar tube and tighten the two screws (3) and their toothed washers (4). Position the switchboard so the slot (5) of the retention bracket coincides with the hole M6 (6) on the fastening tube. Make sure the switchboard is secure by tightening the screw (7) and its toothed washer (8).

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4.3.2 Installation of structure to bar

Align the pin of the horizontal arm (1) with the ceiling plate (2). Fit the connection cables (3) in the tube so that they come out from the side hole, in order to connect them to the power board. Insert the pin in the tube until the 3+3 holes at 120° of the pin coincide with the 3+3 holes at 120° of the tube.

- Insert all 6 screws (4).
- Strongly tighten ONLY two screws of a same side in vertical the one to the other.
- Now tighten the remaining screws.

This way the loosening over time will be avoided during continuous Product rotation.

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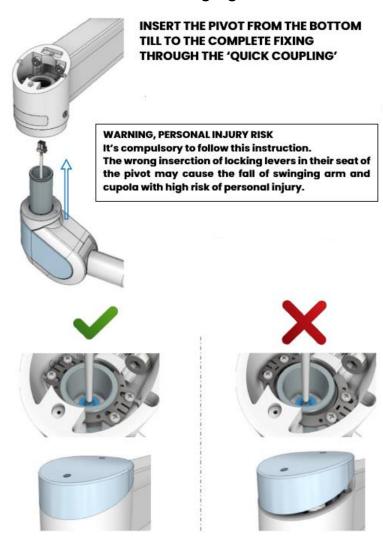


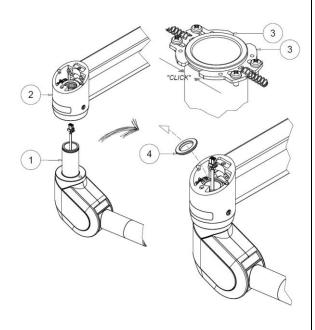




Product falling hazard.

4.3.3 Installation of swinging arm





Align the swinging arm pin (1) and insert it into the horizontal arm (2) until the two locking levers (3) automatically engage and produce a "CLICK", and lock the arm in place.

During insertion the assembly ring (4) will be automatically ejected. It is only designed to guide and facilitate assembly.

It is recommended to keep it in case of future installation of the Product.

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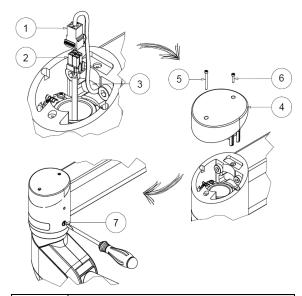




If the assembly ring comes out before the pin is inserted, assembly is not possible. In the event of this coming out, it must be repositioned in its seat.



Before continuing with the assembly, check with swinging arm movements that the locking levers are in place in the pin slot.





Before proceeding, make sure the plastic cap is correctly positioned and in contact with the horizontal arm and that the screws are well tightened.



The correct closure of the plastic cap ensures that the locking levers are locked.

Join together connectors (1) and (2). In case of a standard lamp only one locking connector will be available.

In case of a lamp equipped with CCTV, the supply will include power connectors, to be connected according to colours, and video signal connectors, to be connected according to letters. These connectors need to be screwed together.

Put the wires into the horizontal arm slot (3).

Place the plastic cap (4) on the upper part of the horizontal arm making sure that the 4 tips fit into their respective seats and close with the screws (5–6).

Tighten the clutches (7) in order to make the arm position stable.

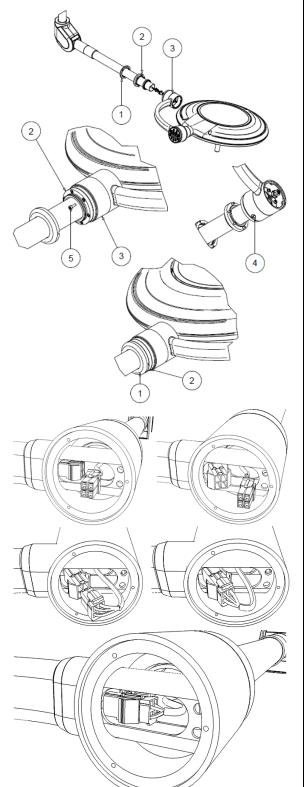
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To make assembly easier, it is best to assemble the swinging arm first, and then the cupola.



4.3.4 Installation of cupola

Before positioning the cupola, as indicated in the drawing, position the yoke lock covering (1) and the yoke lock (2) on the swinging arm tube.

Insert the head of the Product with the yoke (3) on the swinging arm and bring the surfaces into contact. Now the head is able to maintain the position autonomously, without any support.

Pay attention to place the Product head and the arm in the same position, as indicated in the drawing, with the yoke to the left of the arm and the friction screw (4) turned downwards.

Push the yoke hub lock (2) onto the yoke hub (3), and rotate it in order to match the corresponding 6 holes.

Screw the 6 screws (5) to lock the hub and lock.

Then position the cover (1) on the lock (2) in order to cover the screws.

To ease the cables connection, first slightly extract the white connector coming from the swinging arm and then the one coming from the yoke.

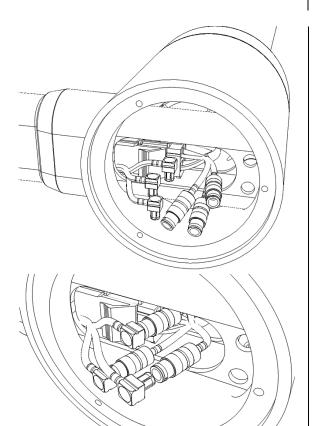
Connect the white connectors together as shown in the images to the side.

Then reposition the connectors inside the yoke, taking care not to crush cables.

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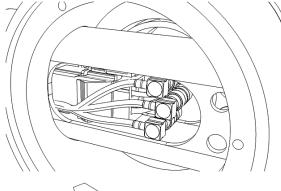




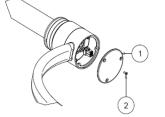


In case of a lamp equipped with CCTV, in addition to the power connector, there will also be video signal connectors.

Connect the connectors in accordance with the letters.



Then also reposition these connectors inside the yoke, taking care not to crush cables.



Once the connection is complete fasten the covering disc (1) in front of the yoke by screwing the three screws (2).



Electric shock hazard.

4.3.5 Electrical connection

Before completing the installation, it is necessary to connect the electrical system. To avoid any risk of electric shocks, the Product must only be connected to mains supplies with earth protection.

Before making the Product power connections, make sure the mains supply line has been interrupted.

GIMA does not supply the mains supply cables.

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For wiring connections in the ceiling version, use a cable suitable for at least 105°C and connect the ground lead to the terminal provided.



Comply with the line and neutral connection indications. An inverted connection would lead to the lack of fuse protection.



Failure to connect the earth cables would prevent the safety of the Product.



Strictly follow the wiring diagram for the correct connection.

Prime the fuses in the switchboard terminal box <u>after</u> the mechanical and electrical assembly of the Product. Priming the fuses too early could permanently damage the Product. If the Product is not used for long periods of time, remove the fuses.

According to the different cases, the electronic panel could be installed on the anchoring tube or in the false ceiling.

The line and neutral cables (L, N) from the power line have to be connected into the terminal 1 and 2 for single light head lamps and for double light heads to the terminals 1 and 2, 3 and 4.

Connect the wires (red and black) to the 3 and 4 terminals in case of single light head lamps and in case of double light head lamps to the terminals 5 and 6, 7 and 8. Follow always the colors and numbers on cables and terminals.

Always connect earthing cables ($\textcircled{\blacksquare}$) of lamp and net into the related terminals.

Out of every lamp there is always a communication cable (OW) connected to a forbox. In case of double light head lamp the cables (OW) of both lamps are connected to the same forbox.

This OW cable is needed for the communication between the lamps and to the optional wall control.

The cable (OW) of the wall control panel (if supplied) has to be connected to the forbox in order to allow the communication.

If the lamp isn't equipped with wall control panel, do not consider forbox connection

4.3.6 Installation of ceiling cover

Once the electrical connections have been completed, the installation can be completed by positioning the ceiling cover.

Depending on the type of ceiling (with false ceiling or not), a cover is provided split into two halves, which can be high or low.

To install, position the two halves (1) in line with the ceiling anchoring tube. Close them by tightening the two screws of the ring (2) and the 4 screws of the cover (3).

Fasten the ring earth lead in the respective terminal.

Bring the complete cover (4) up against the ceiling / false ceiling and secure it in position by fully tightening the 4 screws (5).

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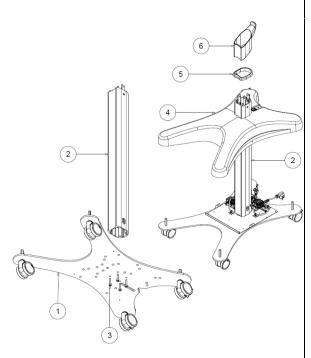


4.4.1 Installation of lamp stem

Position the lower stem (2) in the base housing (1) and tighten it with the 4 screws (3).

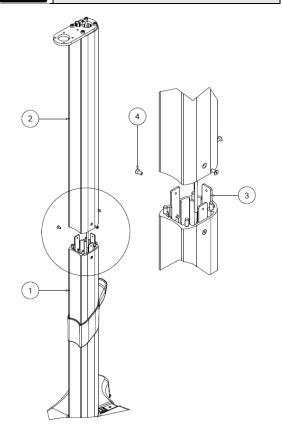
Adequately tighten the 4 screws (3) to avoid any risk of instability and possible Product overturning.

Insert from the top of the stem (2) the stand cover (4), the closing ring (5) and the stem cover (6) in the indicated order.





Instability and overturning hazard.



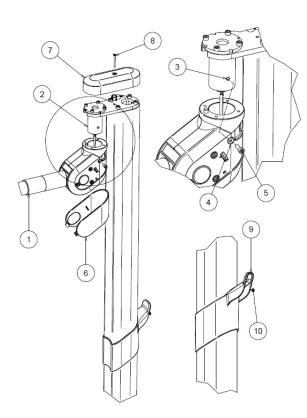
Insert the cables inside the top stem (2) and position it vertically above the lower stem (1). Make the two extremities coincide using the guides (3).

Fasten the two stems by means of the screws (4).

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4.4.2 Installation of swinging arm

Position the swinging arm (1) in front of the stem and in correspondence with the pivot (2).

Match the threaded hole of pivot (3) with the hole located on the hub (4).

Insert the swinging arm (1) into the pivot (2) and fastening it by tightening the screw (5).

Insert the plastic cover (6) from the bottom, widening it if required to make insertion easier. Fasten the cover by inserting the fasteners in the hub recesses.

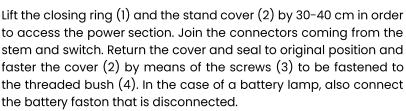
Join the wiring connectors and fasten the upper cover (7) with the screw (8).

Position the cover (9) and secure it with the screw (10) in line with the threaded hole.

4.4.3 Installation of cupola

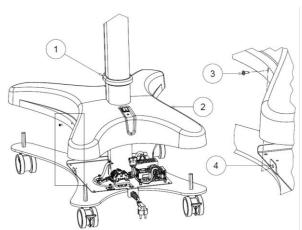
See point 4.3.4 above.





After making the connection, engage the fuses.

The Product power connection is by means of a plug integrated in the supply cable supplied with the Product, placed on the box.



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Fuses

4.5 Protection fuses

Product power protection is ensured by input fuses (L, N) and one output fuse (24V) of the TXAH 250V 5x20 type (where X is the fuse value). Only one input fuse (L) for ceiling versions.

FOR CEILING MODELS:

n°1 T2AH (L) and n°1 T10AH (+ 24VDC)

FOR MOBILE MODEL:

n°2 T2AH (L-N) and n°1 T10AH (+ 24VDC)

FOR MOBILE BATTERY MODEL:

n°2 T4AH (L-N) and n°1 T10AH (+ 24VDC)

4.6 Handpiece fitting

Insert the grip in the housing provided until the catch clicks into and is blocked in the handpiece hole.

4.7 Mechanical adjustments

The Product is supplied correctly clutched and balanced. To make movement adjustment, refer to the setting instructions shown in the operation and maintenance manual.

4.8 First switch-on

To ensure the Product operates correctly, proceed as follows:

- 1. Make sure the power rating of the premises corresponds to that of the Product;
- 2. Fit the plug in the power socket of the premises Mobile versions only;
- 3. Close the switch upstream of the system;
- 4. Move the Product switch located on the base cover for the mobile version to position "I" (ON);
- 5. Press the O keyboard positioned on the lower part of the Product cupola.
- 6. Make sure all LEDs and functions are working properly.

At the time of commissioning, perform the electrical tests and prescriptions indicated in the IEC 62353 standard.

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4.9 Check the result of Product installation and testing before use

Ticking the requirements listed below, if applicable to the Product version, is mandatory to ensure correct installation.

1.	Make sure the ceiling is suitable for Product installation.	
2.	Using a spirit level, make sure the bar is perpendicular with the ceiling.	
3.	Make sure the switchboard is correctly fastened to the Bar by means of the threaded hole provided.	
4.	Make sure the screws sustaining the horizontal arm are tight (ceiling versions).	
5.	Check that the locking levers are in place and the cap with the 4 tips is inserted correctly (ceiling versions).	
6.	Make sure the stand is correctly fitted in the base (mobile version).	
7.	Check the Product earth connection and make sure the earth terminals are well tightened.	
8.	Check the correct rotation of the articulated joints and mechanical movements.	
9.	Adjustment and rotation movements must be carefully clutched to ensure the Product is stable and maintains its	
10.	position. Make sure the Product emits light.	
Stc	ımp and signature of TECHNICAL SERVICE PERSONNEL:	

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5 Troubleshooting



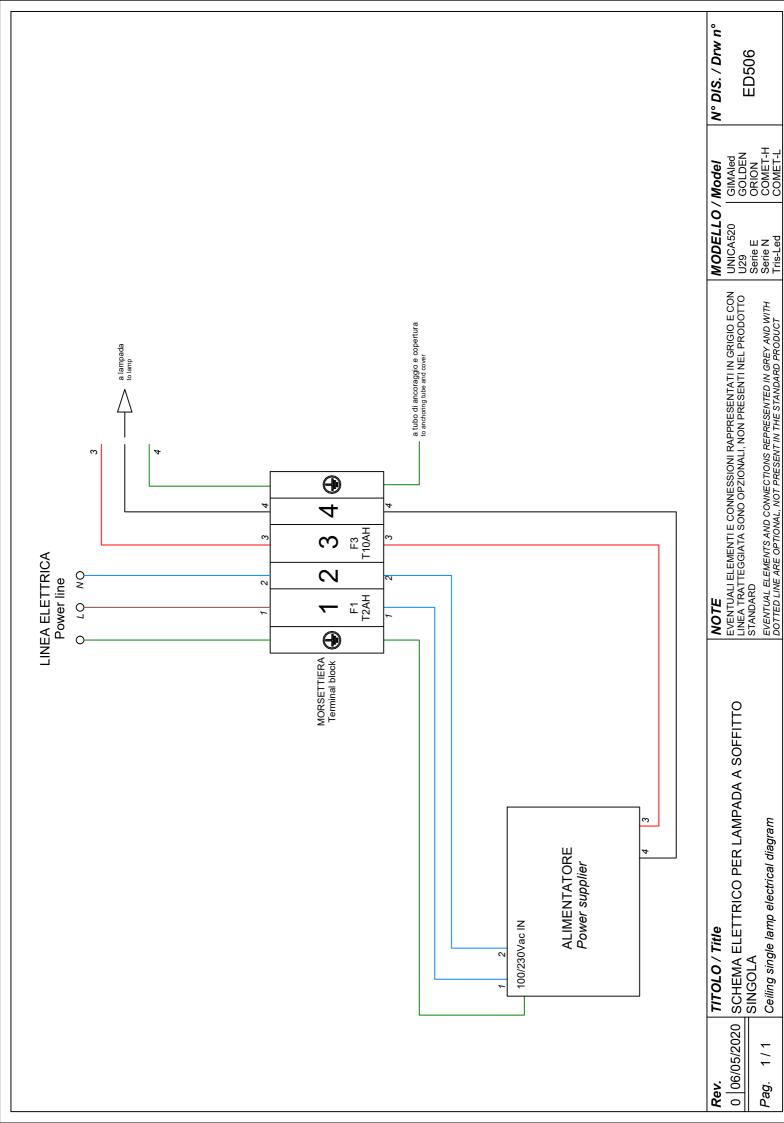
Possible Product damage.



Presence of dangerous voltage.

N.	Problem	Solution
1	The Product fails to remain in stable position	Make sure the instructions in this manual, in the "Product installation" paragraph, have been correctly followed. Refer to setting instructions in the operation and maintenance manual.
2	The Product fails to work	Make sure fuses have been fitted inside the terminal board. Make sure the electrical connectors are fitted. Check if there is voltage inside the Product.
3	The fuse continues to burn out	Check the specifications of the fitted fuses.
4	The light flickers and produces a stroboscopic effect	Contact the after sales service.
5	The Product does not switch on	Check the supply power voltage and check the fuses. The electronics are faulty: contact the after-sales service.

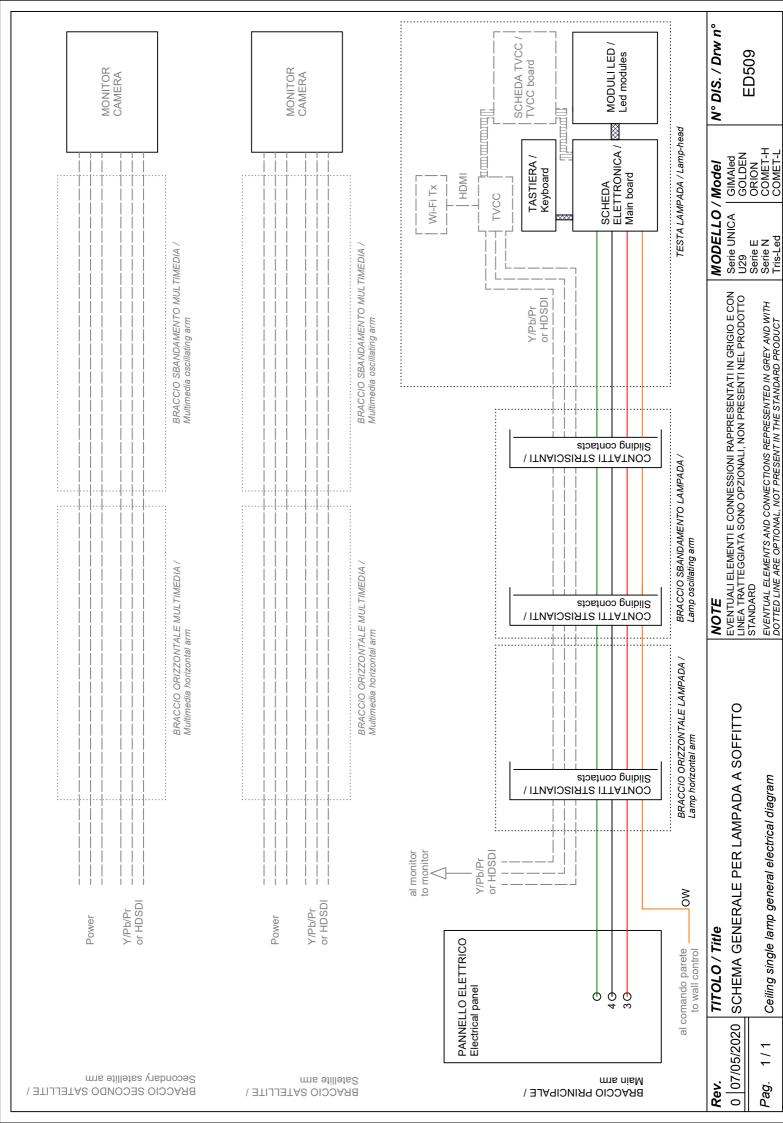
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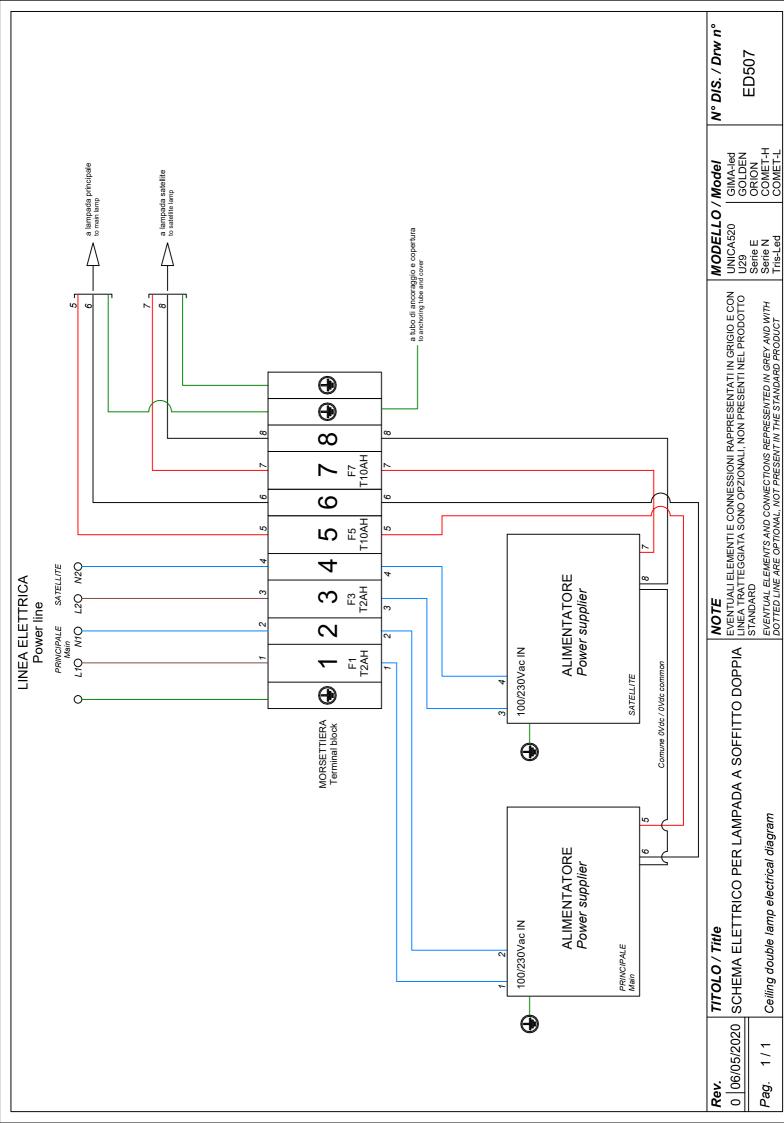


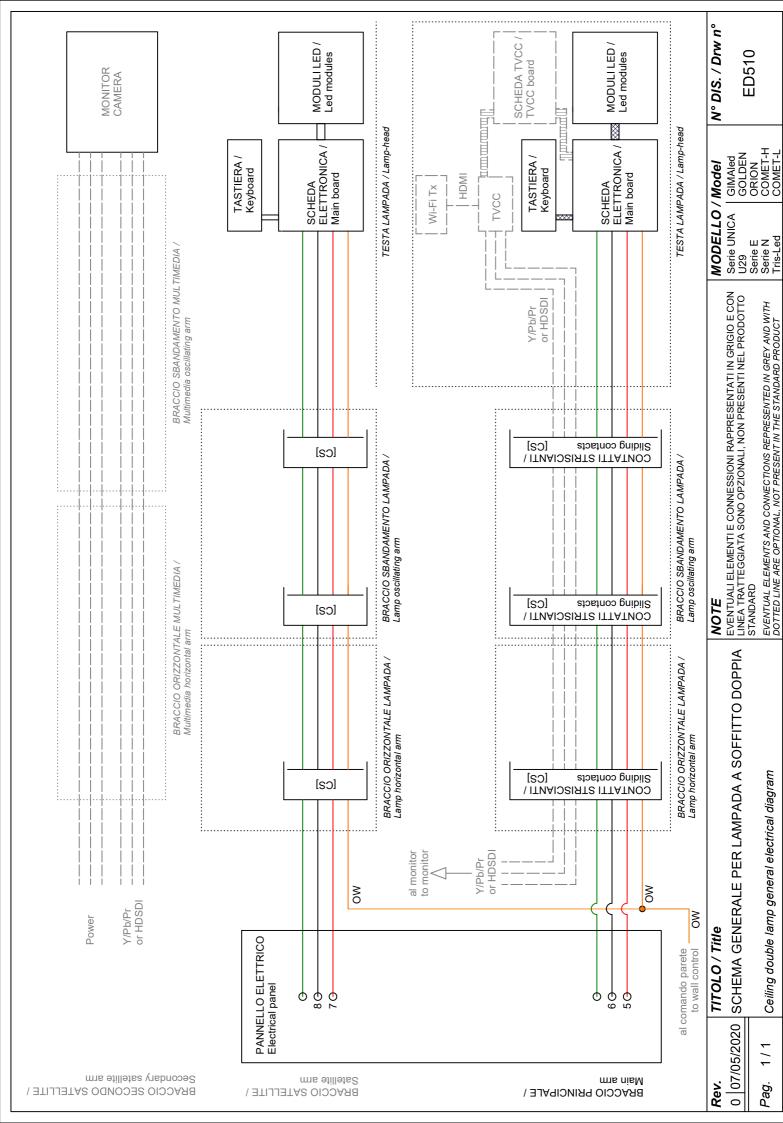
EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

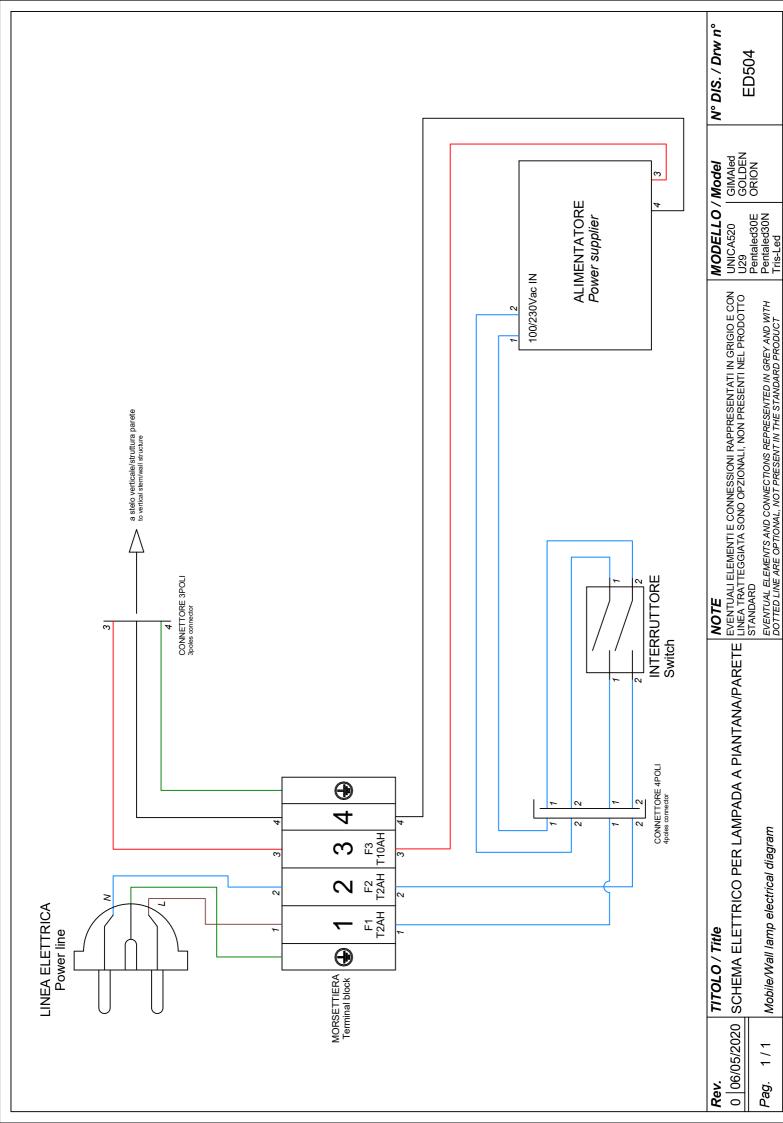
Ceiling single lamp electrical diagram

Pag. 1/1





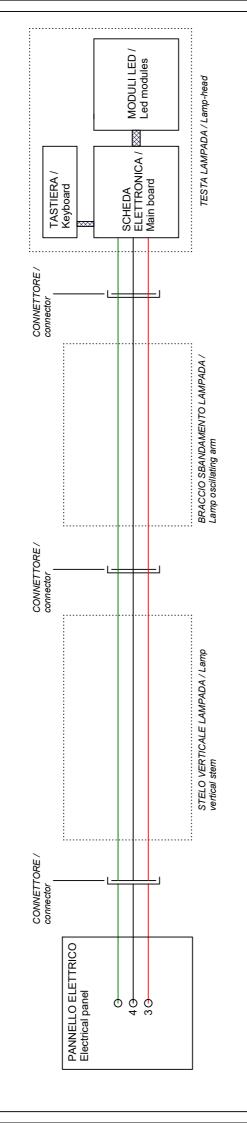




EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

Mobile/Wall lamp electrical diagram

Pag. 1/1



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MODELLO / Model
UNICA520 GIMAled
U29 GOLDEN
Pentaled30E Pentaled30 N
Tris-Led

N° DIS. / Drw n° GIMAled GOLDEN ORION

