INSTALLATION MANUAL

GIMAled29

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

Introduction

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

Marking CE

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

Compliance

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.

Validity of manual

This installation manual is valid for the following models:

- GIMAled29 in ceiling, wall and mobile versions;
- GIMAled29 in ceiling version with double yoke.

Customer Service

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

Copyright

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

Translations

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

Index of contents

KEY

PRODUCT

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**".

OPERATOR

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

RESPONSIBLE ORGANIZATION

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

TECHNICAL SERVICE PERSONNEL

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.

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 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.

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 masonry works to prepare the slab or wall, for Products to be installed on the ceiling or wall, and the electrical works to prepare the electrical system to power the Product must be carried out in a solid and safe manner according to the rules of art by TECHNICAL ASSISTANCE PERSONNEL.

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.

2 General information

2.1 Operator qualifications

Qualification of personnel in charge of operating on the Product:

Installation	Installer and/or qualified technician.
Use	Professional medical personnel.
Cleaning	Properly trained medical and paramedical personnel.
Routine maintenance	Qualified technician with required technical-professional skills.
Special maintenance	GIMA or technical service personnel, the latter only for the fuse change.
Assistance	GIMA or authorized Dealer.
Disposal	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

Packing

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

Transport

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

Storage

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

Installation premises

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

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:

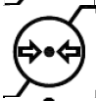
This side upwards

Fragile

Protect from rain

Max number of stackable boxes

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



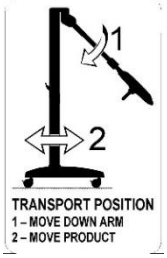
Pressure to be complied with (max limit at top right and min limit at bottom left)

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

Materials and composition

2.5 Graphic symbols used on the Product

Below are the symbols to be found on the Product:

CE	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
MD	Medical Device
REF	Model reference
SN	Serial number
CH REP	Swiss authorised representative
	Disposal
	Protection earth
'N'	Neutral lead connection point
'L'	Line lead connection point
'I'	ON
'O'	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

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

CAUTION

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 and wall version)

Carry out safe masonry works.

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.

Collapse of the building structure.

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

Make sure that ceiling or wall are adequate.

The ceiling must be able to withstand a weight of at least 300 kg/m^2 and have a thickness of at least 250 mm. For the wall version, the wall must be a supporting wall and be made of solid brick. Installation on walls made of hollow bricks and plasterboard is only allowed with the fitting of another plate on the opposite side of the wall (sandwich closing). 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.
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

Carry out safe electrical works.

Make sure that the electrical environment complies with the law.

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.

Main switch

Wall and 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.

CAUTION

In case of wall and 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 re-dispatched.

Personnel required:  (Two)

Necessary protection equipment:

- Safety eyewear
- Gloves
- Accident-prevention footwear

Special equipment:

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

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

4.1 Parts included in the package

Ceiling version

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.

Wall version

The Product is supplied complete with lamp head, sterilisable handpiece, swing arm, horizontal arm, wall plate with switchboard and HAM M6x50 wall plugs.

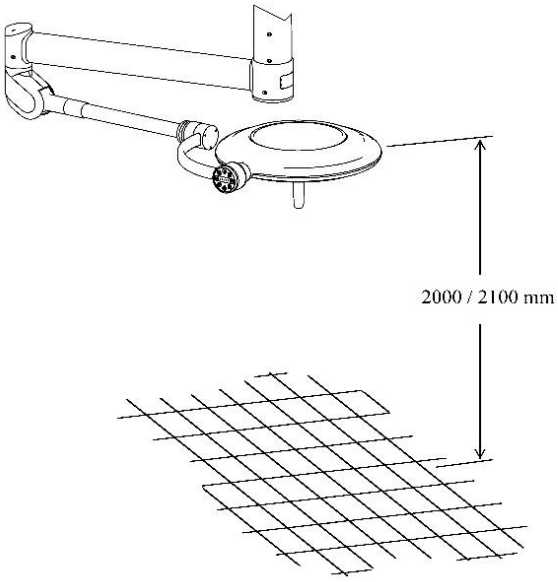
Mobile version

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

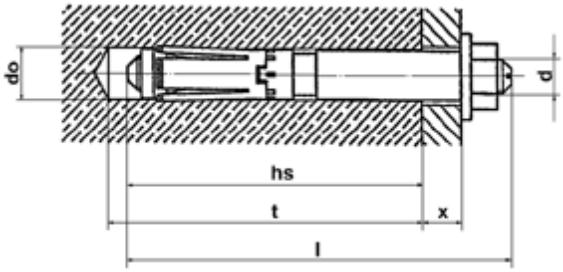
4.2 Ceiling drilling instructions

Fixing positions

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.



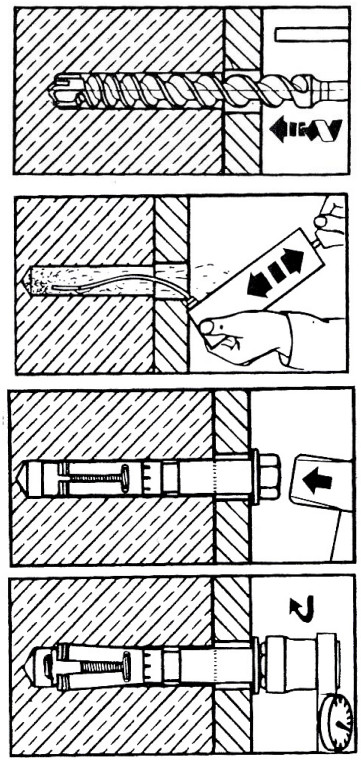
Reinforced concrete
Mechanical anchoring



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 (6 screw anchors HAM M6x50 for wall version) or other anchors with similar characteristics, carefully following the instructions provided by the anchor manufacturers and shown below for information purposes:

do	Nominal drill bit diameter	Mt	Closing bending moment
t	Minimum drilling depth	Sw	Wrench opening
hs	Minimum insertion depth	x	Fastening height
l	Anchor tie-rod length		

Anchor tie-rod	do (mm)	t (mm)	hs (mm)	l (mm)	Mt (Nm)	SW (mm)	x (mm)
HSL-3-G M 16/25	24	125	100	163	80	24	25
HAM M6x50	12	65	40	50	10	10	20



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/plate to the ceiling/wall and, using a hammer, insert the anchoring tie-rod in the hole.
   Attention!
   Check the fitting depth
5. 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.

Chemical anchoring

Drill the ceiling/wall 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 for ceiling versions and M8 for wall versions. Proceed to fasten the ceiling plate with nuts and locknuts for each tie-rod and tighten using the Allen key.

Hollow-core concrete

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.

Ceiling version

	**Do not install the Product on unsuitable ceilings.**

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.

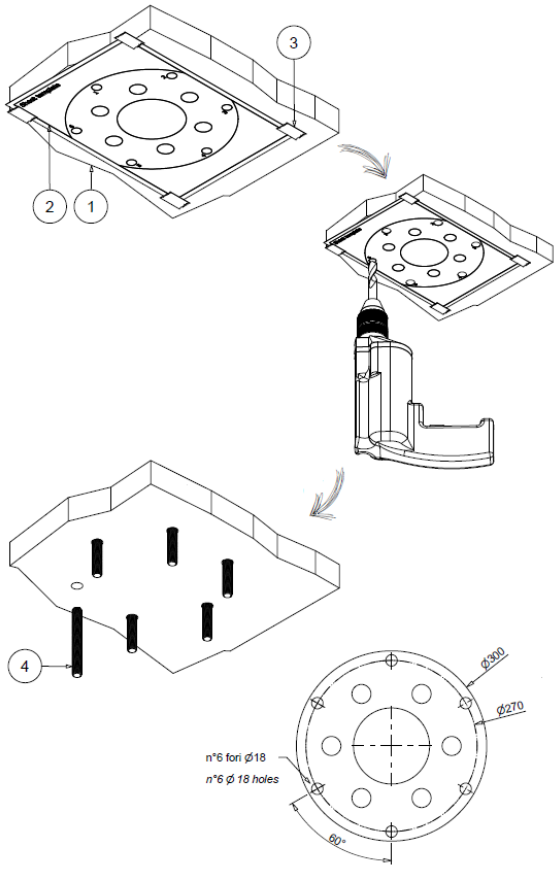
Wall version

	**Do not install the Product on unsuitable walls.**

The Product is supplied complete with wall plate and HAM M6x50 wall plugs.

4.3 Installation of Product in ceiling version

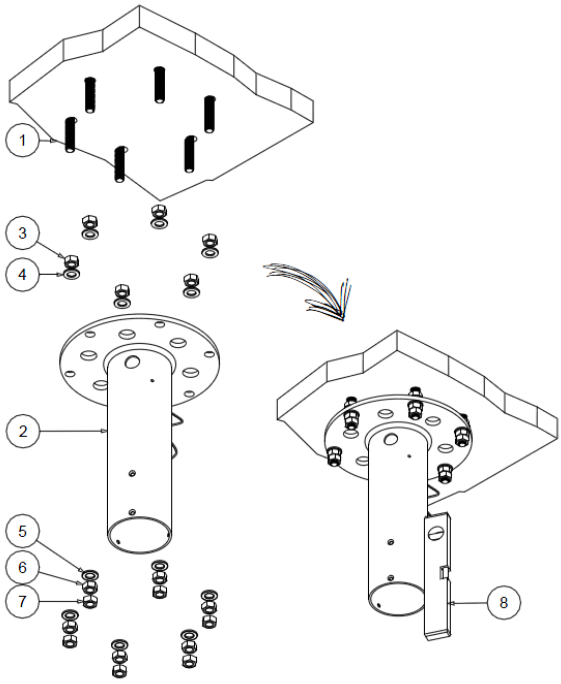
4.3.1 Installation of the ceiling plate, bar, power supply



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).

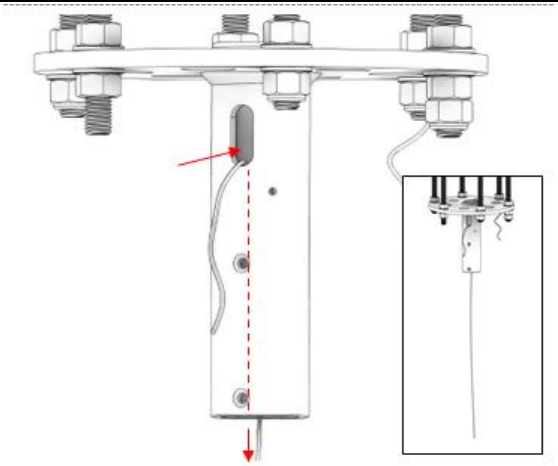
Drill the holes according to paragraph 4.2 and insert the 6 threaded bars M16 (4) into the ceiling.



On the threaded bars (or pre-prepared tie rods) insert the nuts (3), the washers (4) (secure them with adhesive tape on the anchoring tube to prevent them from falling) and insert the anchoring tube (2). Position the washers (5), nuts (6) and locknuts (7) from underneath. Using the nuts (6) and locknuts (7), position the anchoring 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.

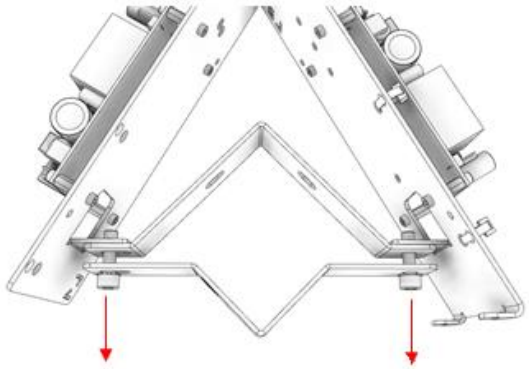
	Make sure the product is stable.

	Product falling hazard.

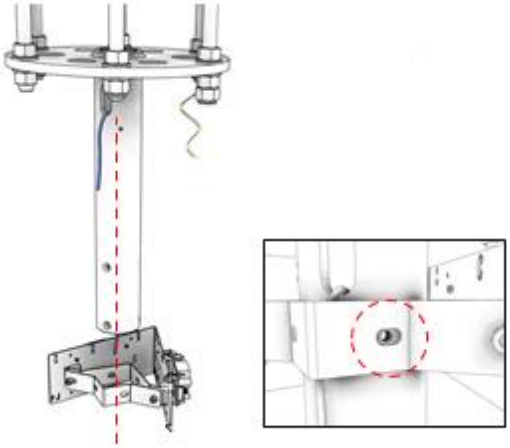


VERSION WITH COUNTER-PLATE
In case of counter-plate (optional), drill the holes as shown in paragraph 4.2 and fix it to the ceiling.
To fasten the anchoring tube to the counter-plate, follow the instructions given above.

Take a guide wire and insert it into vertical slot, making it coming out from bottom side of anchoring tube.



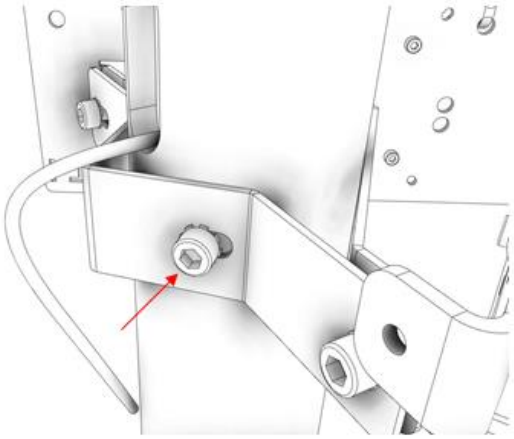
Take the electrical panel and loosen the 2 screws that secure the bent brackets, without removing them, so that the two brackets themselves can be distanced.



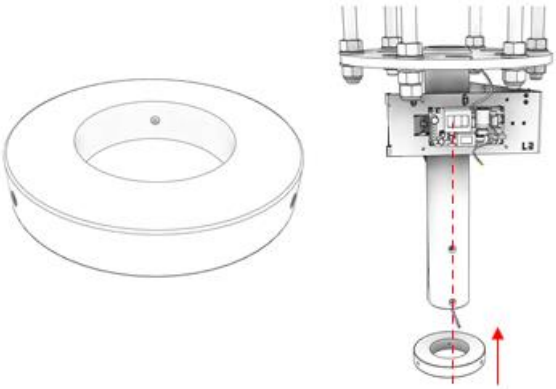
Orient the electrical panel so that the number labels on the connection terminals are facing downwards; then, insert the electrical panel by passing the anchoring tube between the two bent brackets.

!! Attention: carry out this operation with care to avoid damaging the anchoring tube!!

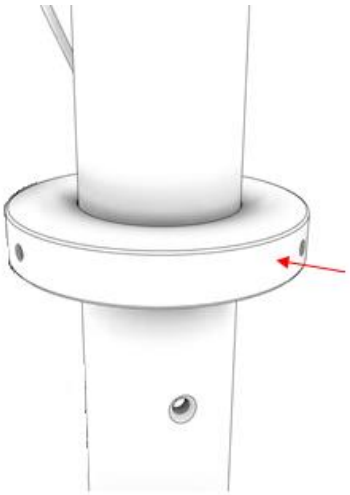
Insert the electrical panel until the slot on the bracket corresponds to the threaded hole of the tube.



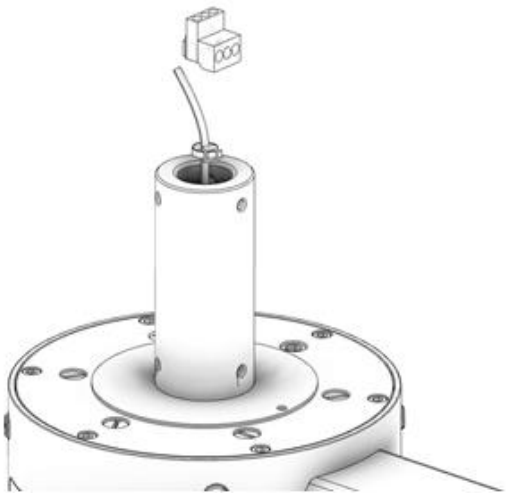
Tighten the 2 screws that fix the bent brackets so that they lock around the tube.
Then insert and tighten the safety screw in correspondence of the bracket slot and anchoring tube hole.



Take the adapter ring for the ceiling cover and insert it up the anchoring tube.

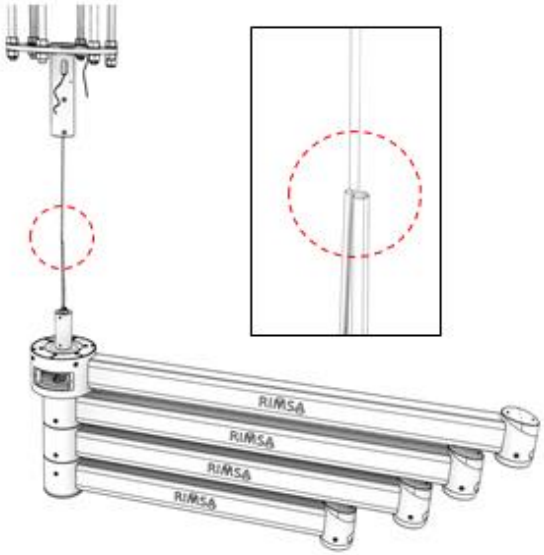


Position the ring just below the vertical opening so as not to interfere with the subsequent assembly phases of the structure.
To avoid the risk to ruin the tube with the grub-screws, stop the ring using a simple adhesive tape.

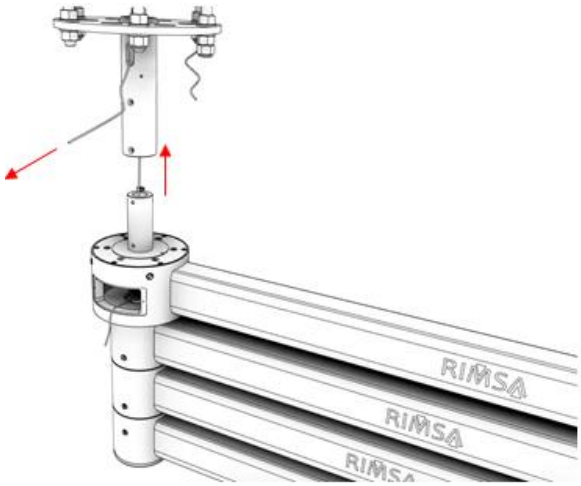


On top side of horizontal arm structure, remove the 'OW' wires connection terminal.

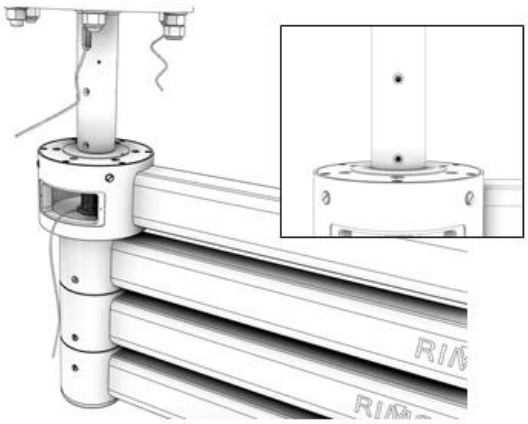
4.3.2 Installation of structure to bar



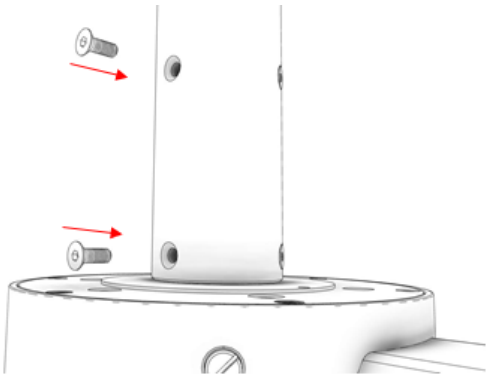
Take the horizontal arm structure and bring it close to the anchoring tube.
Join the guide cable coming from anchoring tube to all cables exiting by the pivot of horizontal arm structure, including the guide wire previously inserted.



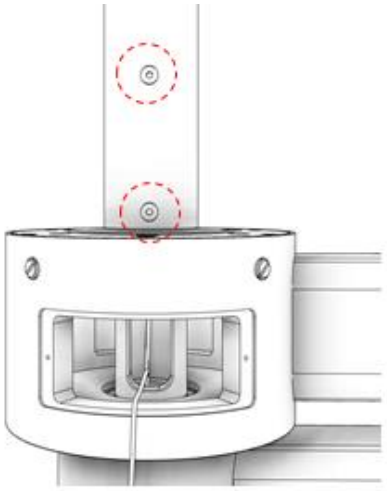
Align the horizontal arm structure pivot with the anchoring tube.
Insert the pivot into the tube, while pulling the guide wire out of the vertical opening of tube, so that all the wirings of the horizontal arm structure come out.



Completely insert the pivot till to make correspond the 6 holes for fixing.



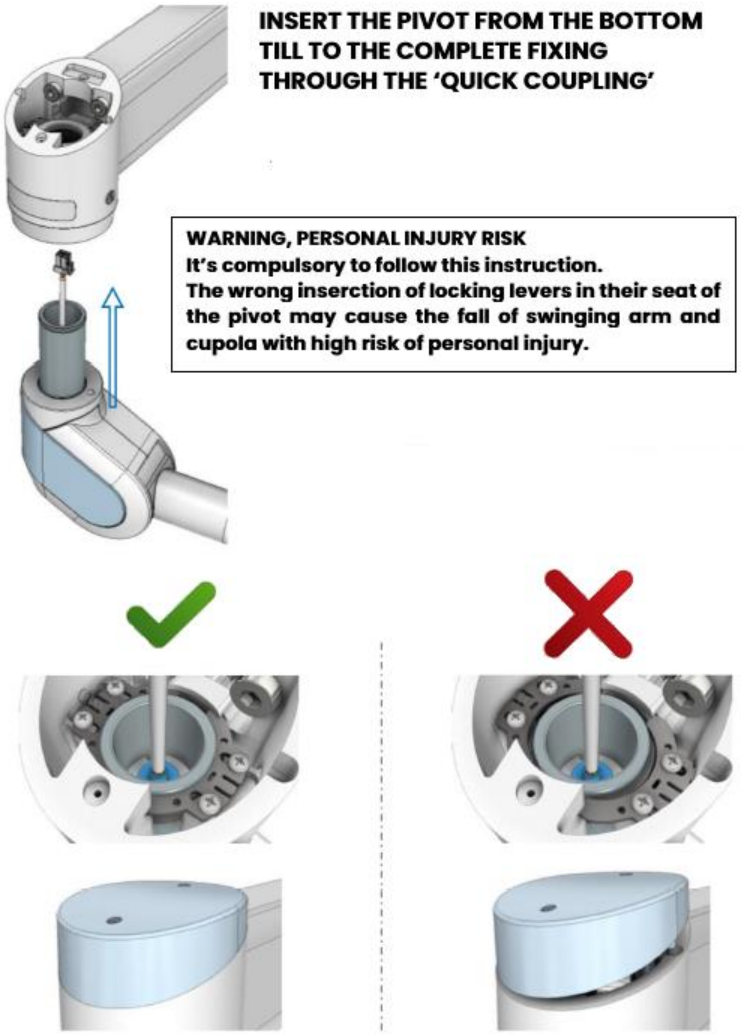
Fix the pivot to the tube by screwing the 6 M6x16 countersunk head screws.
Do not tighten the screws. Just screw-in them without locking them against the tube.

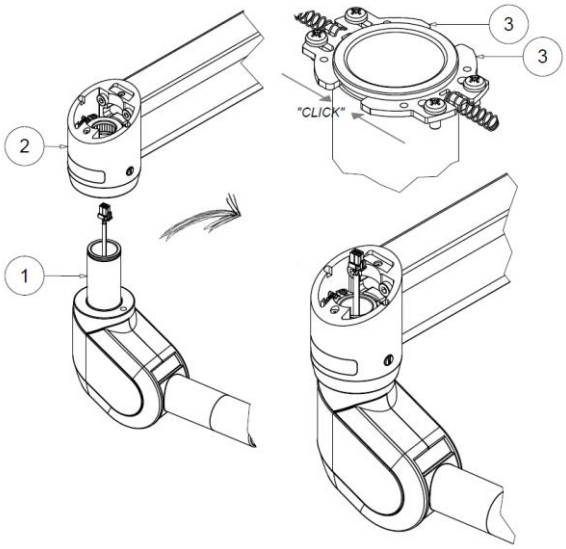


Definitively fix the pivot by first tightening 2 screws on the same vertical axis.
Then proceed to tighten the remaining 4 screws.

⚠	**Product falling hazard.**

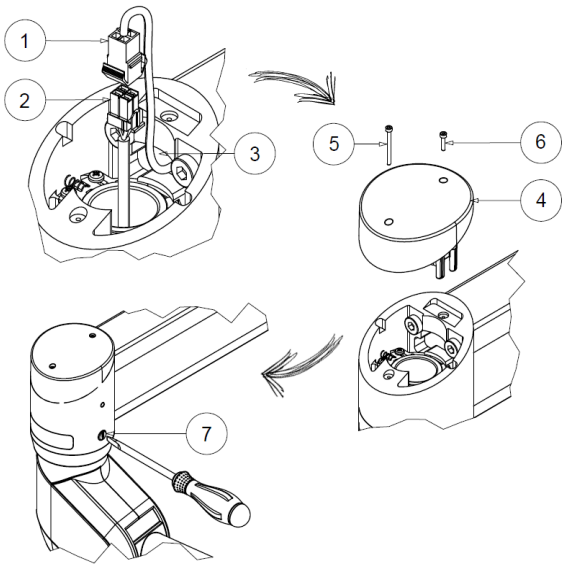
4.3.3 Installation of swinging arm





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.

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



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.

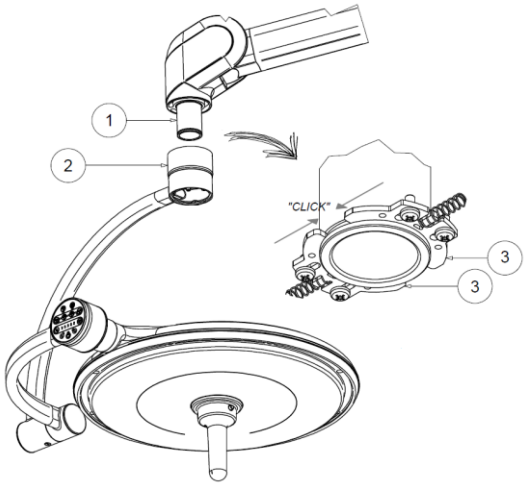
⚠	**Before proceeding, make sure the plastic cap is correctly positioned and in contact with the horizontal arm and that the screws are well tightened.**

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

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

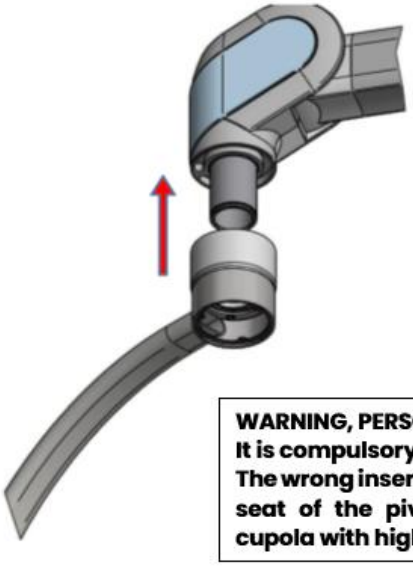
⚠	**Product falling hazard.**

⚠	**To make assembly easier, keep one hand on the swinging arm and push it downwards.**

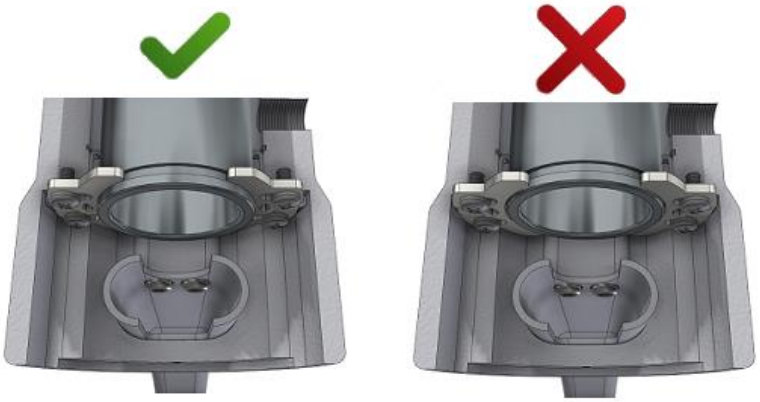


4.3.4 Installation of cupola (DOUBLE YOKE)

INSERT THE YOKE FROM THE BOTTOM TILLTO THE COMPLETE FIXING THROUGH THE 'QUICK COUPLING'

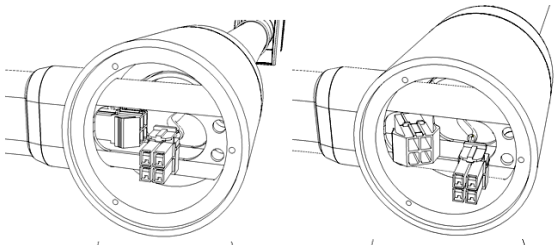


WARNING, PERSONAL INJURY RISK
It is compulsory to follow this instruction. The wrong insertion of locking levers in their seat of the pivot may cause the fall of cupola with high risk of personal injury.

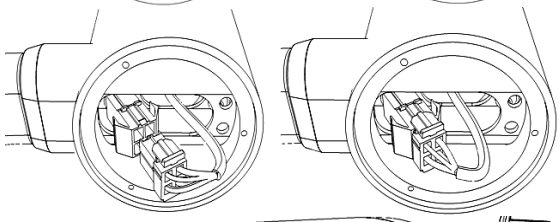


Align and fit the yoke hub (2) on the pin of the swinging arm (1) (keep one hand on it and push it downwards) until the two locking levers (3) automatically engage and produce a "CLICK", and lock the arm in place.

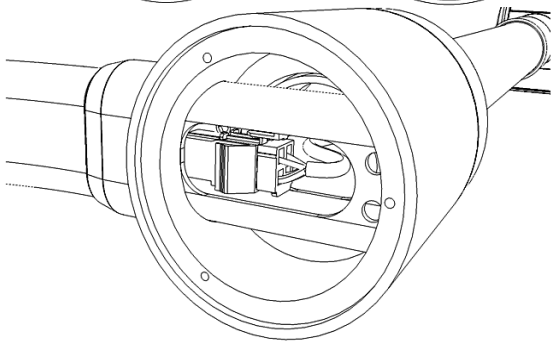
⚠	**Before continuing with the assembly, check with yoke rotation that the locking levers are in place in the pin slot.**



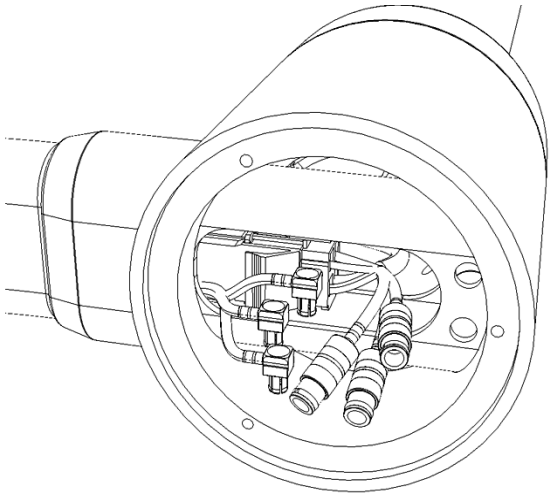
To ease the cables connection, first slightly extract the white connector coming from the swinging arm and then the one coming from the yoke.



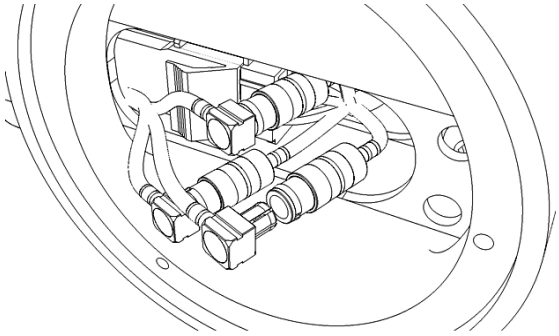
Connect the white connectors together as shown in the images to the side.



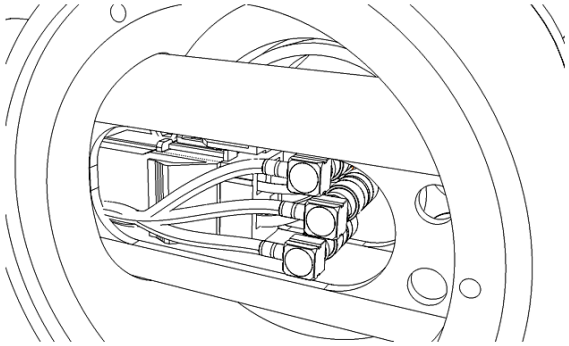
Then reposition the connectors inside the yoke, taking care not to crush cables.



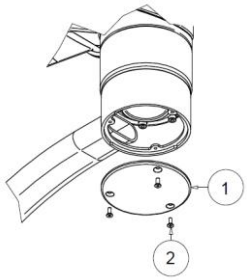
In case of a lamp equipped with CCTV, in addition to the power connector, there will also be video signal connectors.



Connect the connectors in accordance with the letters.



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



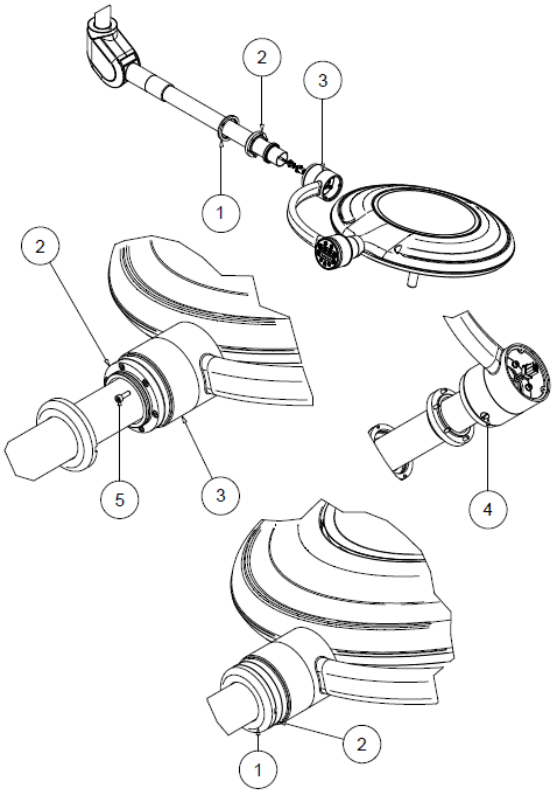
Once the connection is complete fasten the closing cap (1) using the three screws (2).

4.3.5 Installation of cupola (SINGLE YOKE)

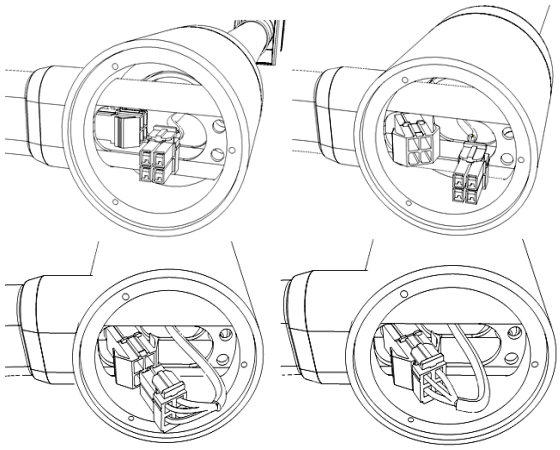
Install the swinging arm as indicated in point 4.3.3 above.

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

⚠	**Product falling hazard.**

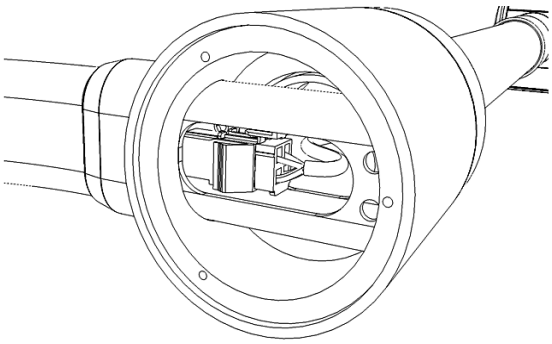


Before positioning the cupola, as indicated in the drawing, position the yoke lock covering (1) and the yoke lock (2) on the swinging arm tube.
Insert the head of the Product with the yoke (3) on the swinging arm and bring the surfaces into contact. Now the head is able to maintain the position autonomously, 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.

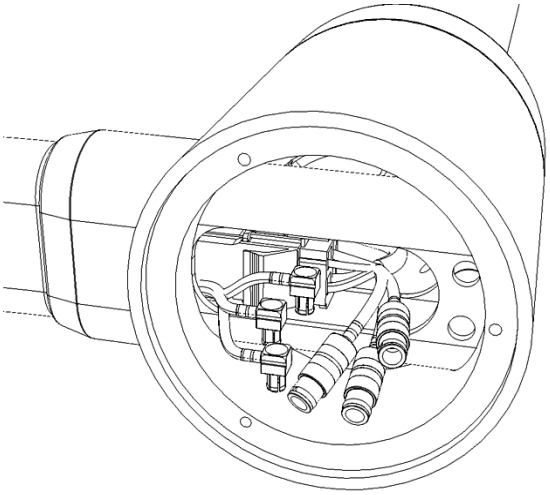


To ease the cables connection, first slightly extract the white connector coming from the swinging arm and then the one coming from the yoke.

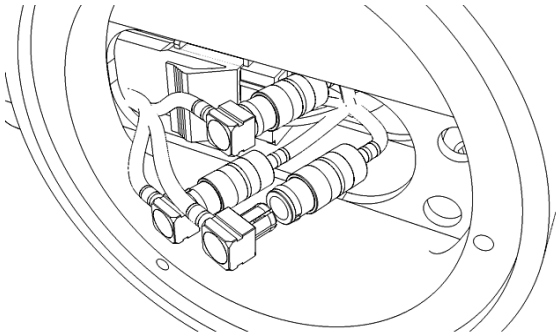
Connect the white connectors together as shown in the images to the side.



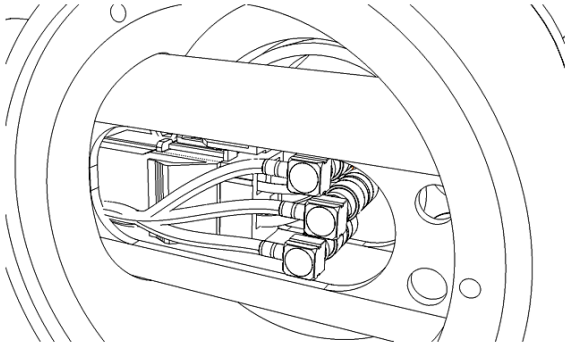
Then reposition the connectors inside the yoke, taking care not to crush cables.



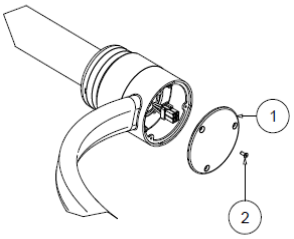
In case of a lamp equipped with CCTV, in addition to the power connector, there will also be video signal connectors.



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).

4.3.6 Electrical connection

	Electric shock hazard.

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.

Prime the fuses in the switchboard terminal box after 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.

	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.

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.

	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.

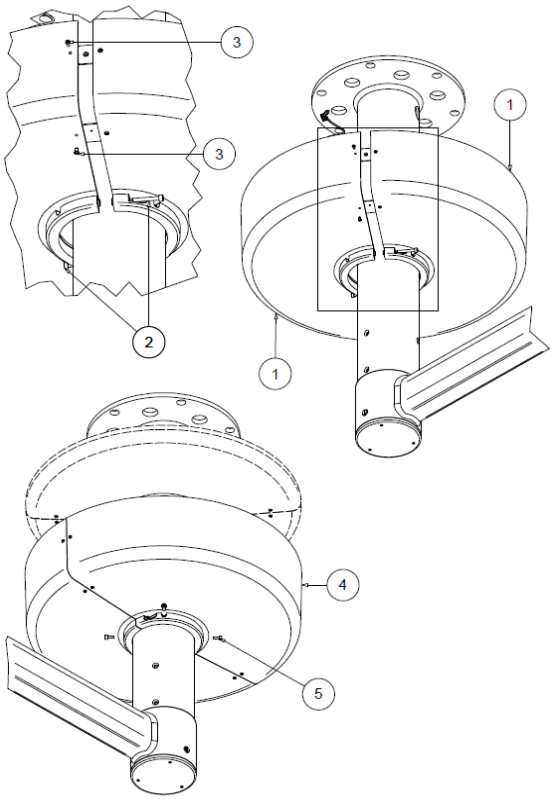
Always connect earthing cables (⏚) of lamp and net into the related terminals.

	Strictly follow the wiring diagram for the correct connection.

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.

4.3.7 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).

4.4 Installation of Product in wall version

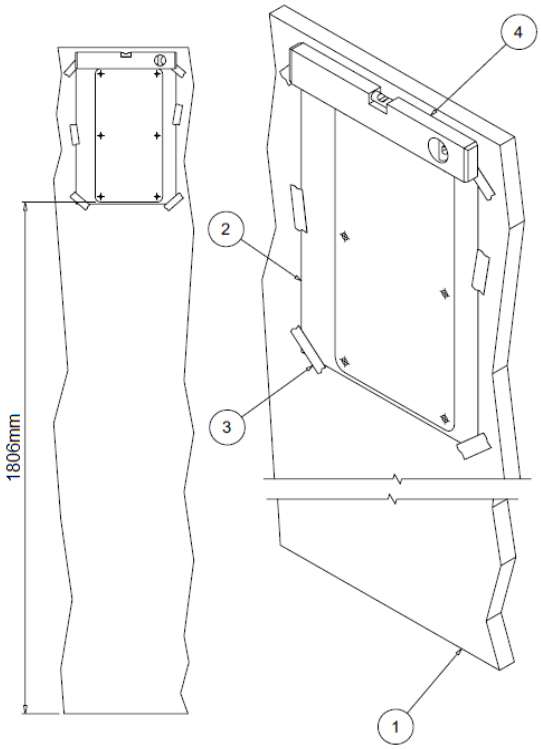
4.4.1 Installation of plate with wall switchboard

Make sure the product is stable.

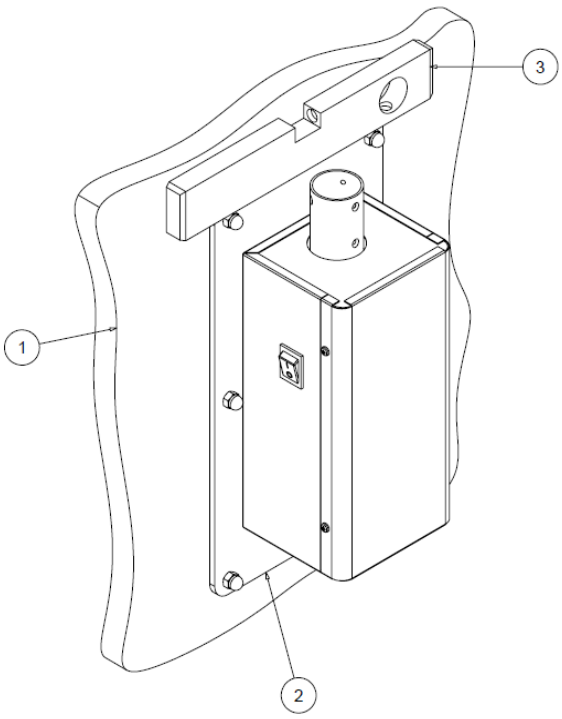
Make sure the wall plate is fastened level, so the Product is in stable position.

Position the template sheet (2) (drawing 11) on the wall (1) and fasten it with adhesive tape (3), with the aid of a spirit level (4) to ensure levelling.
Make the holes as indicated in paragraph 4.2.

It is recommended to fix the plate at a height of about 1806 mm.

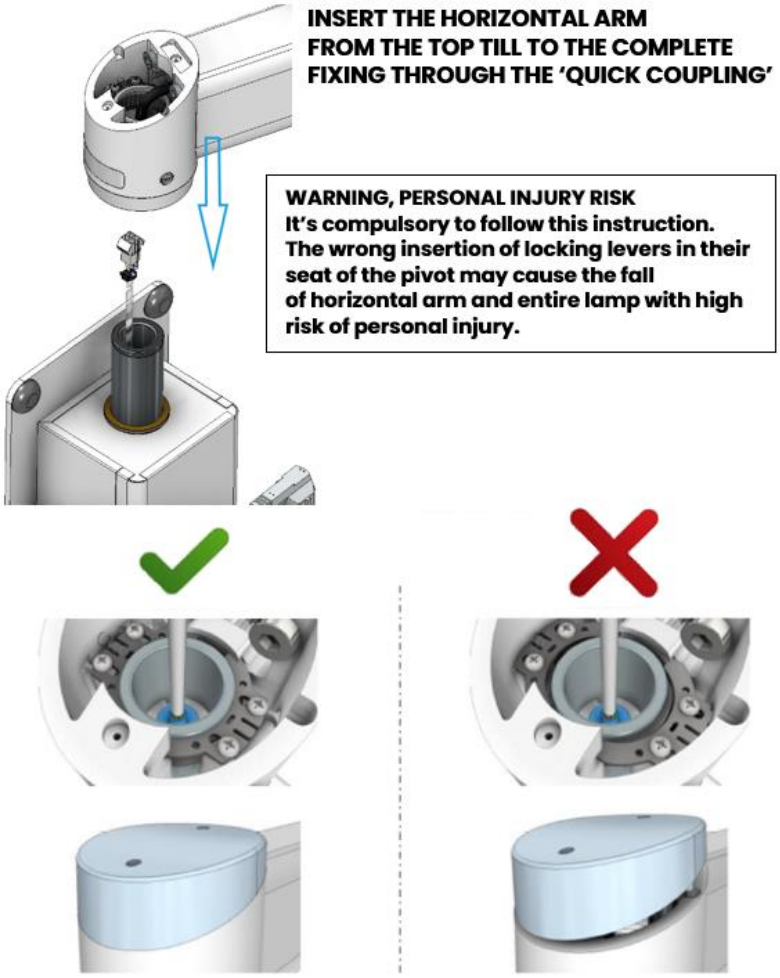


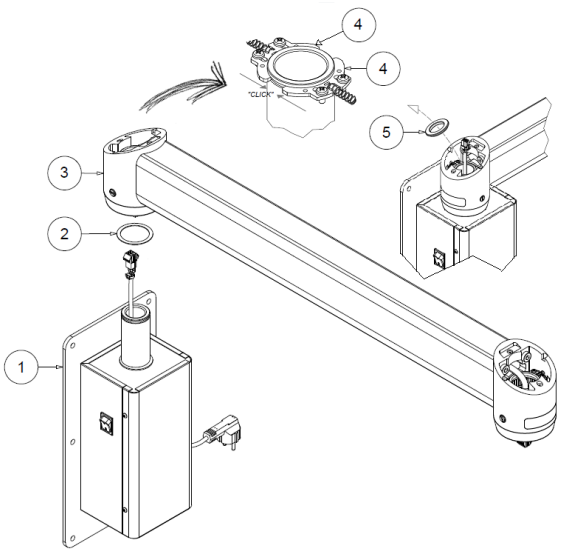
Fasten the plate (2) to the wall (1) with the aid of a spirit level (3).



⚠	**Product falling hazard.**

4.4.2 Installation of structure to plate

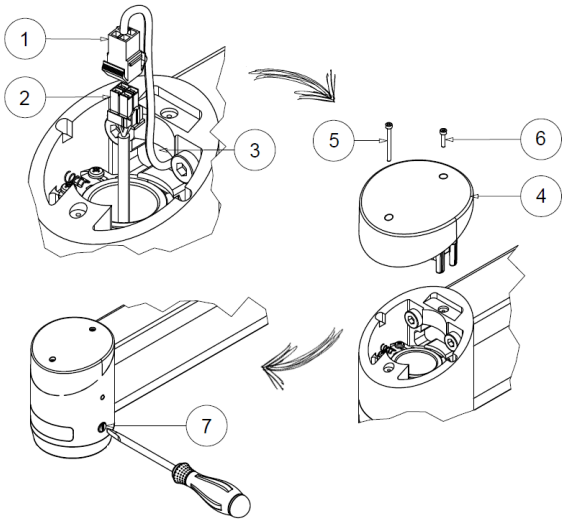




Insert in the wall box pin (1) the bronze washer (2).
Afterwards, align the horizontal arm (3) with the box pin and insert it until the two locking levers (4) automatically engage and produce a "CLICK", and lock the arm in place.
During insertion the assembly ring (5) will be automatically ejected. It is only designed to guide and facilitate assembly.
It is recommended to keep it in case of future installation of the Product.

⚠	**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 horizontal 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.**

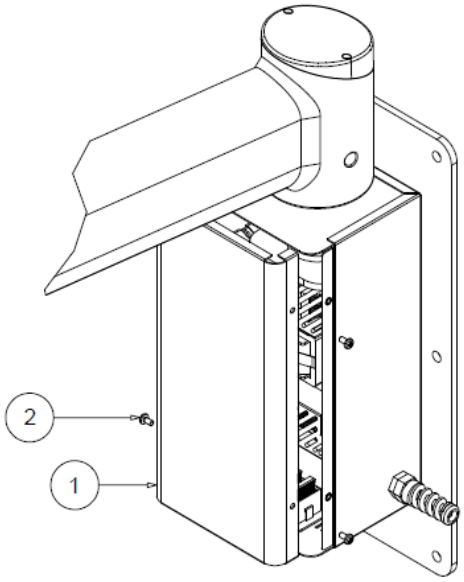
Join together connectors (1) and (2). In case of a standard lamp only one locking connector will be available.
In case of a lamp equipped with CCTV, the supply will include power connectors, to be connected according to colours, and video signal connectors, to be connected according to letters. These 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.

4.4.3 Installation of swinging arm

See the previous point 4.3.3.

4.4.4 Installation of cupola

See the previous point 4.3.5.

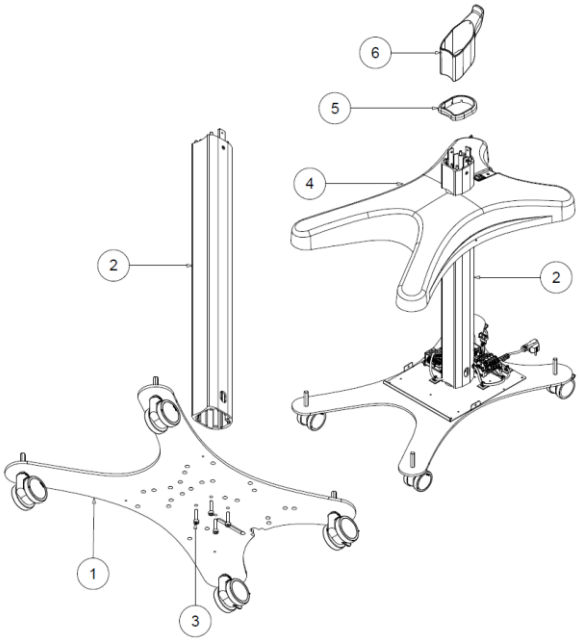


4.4.5 Electrical connection

Remove the cover (1) of the wall box by loosening the screws (2). Engage the fuses and reposition the wall box cover (1) in place and tighten the screws (2).

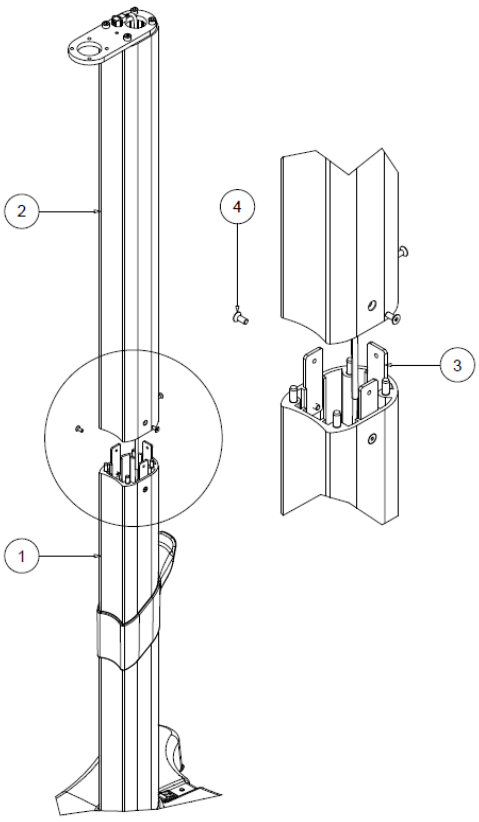
4.5 Installation of Product in mobile version

4.5.1 Installation of lamp stem

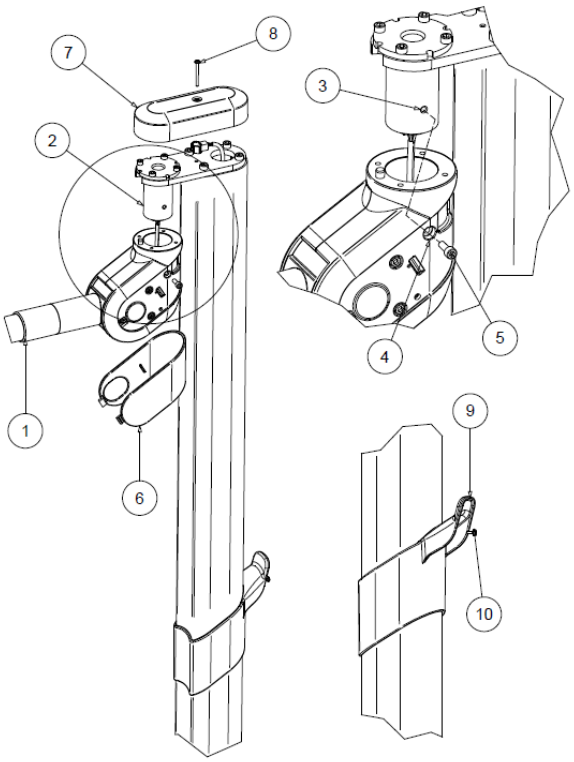


Position the lower stem (2) in the base housing (1) and tighten it with the 4 screws (3).
Adequately tighten the 4 screws (3) to avoid any risk of instability and possible Product overturning.
Insert from the top of the stem (2) the stand cover (4), the closing ring (5) and the stem cover (6) in the 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).

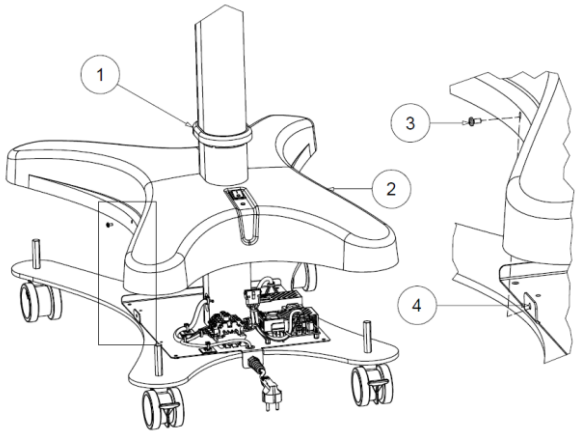


4.5.2 Installation of swinging arm

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.

4.5.3 Installation of cupola

See point 4.3.5 above.



4.5.4 Electrical connection

Lift the closing ring (1) and the stand cover (2) by 30-40 cm in order to access the power section. Join the connectors coming from the stem and switch. Return the cover and seal to original position and faster the cover (2) by means of the screws (3) to be fastened to the threaded bush (4). In the case of a battery lamp, also connect the battery faston that is disconnected.
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.

Fuses

4.6 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 WALL MODEL:
n°1 T2AH (L-N) 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)

4.7 Handpiece fitting

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

4.8 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.

4.9 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 and Wall versions only;
3. Close the switch upstream of the system;
4. Move the Product switch located on the electrical box for the wall-mounted version and on the base cover for the mobile version to position "I" (ON);
5. Press the ⏻ 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.

4.10 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/wall is suitable for Product installation. ☐
2. Using a spirit level, make sure the bar is perpendicular with the ceiling or that the wall plate is horizontal with the wall. ☐
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 and wall versions*). ☐
5. Check that the locking levers are in place and the cap with the 4 tips is inserted correctly (*ceiling and wall 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 position. ☐
10. Make sure the Product emits light. ☐

Stamp and signature of TECHNICAL SERVICE PERSONNEL:

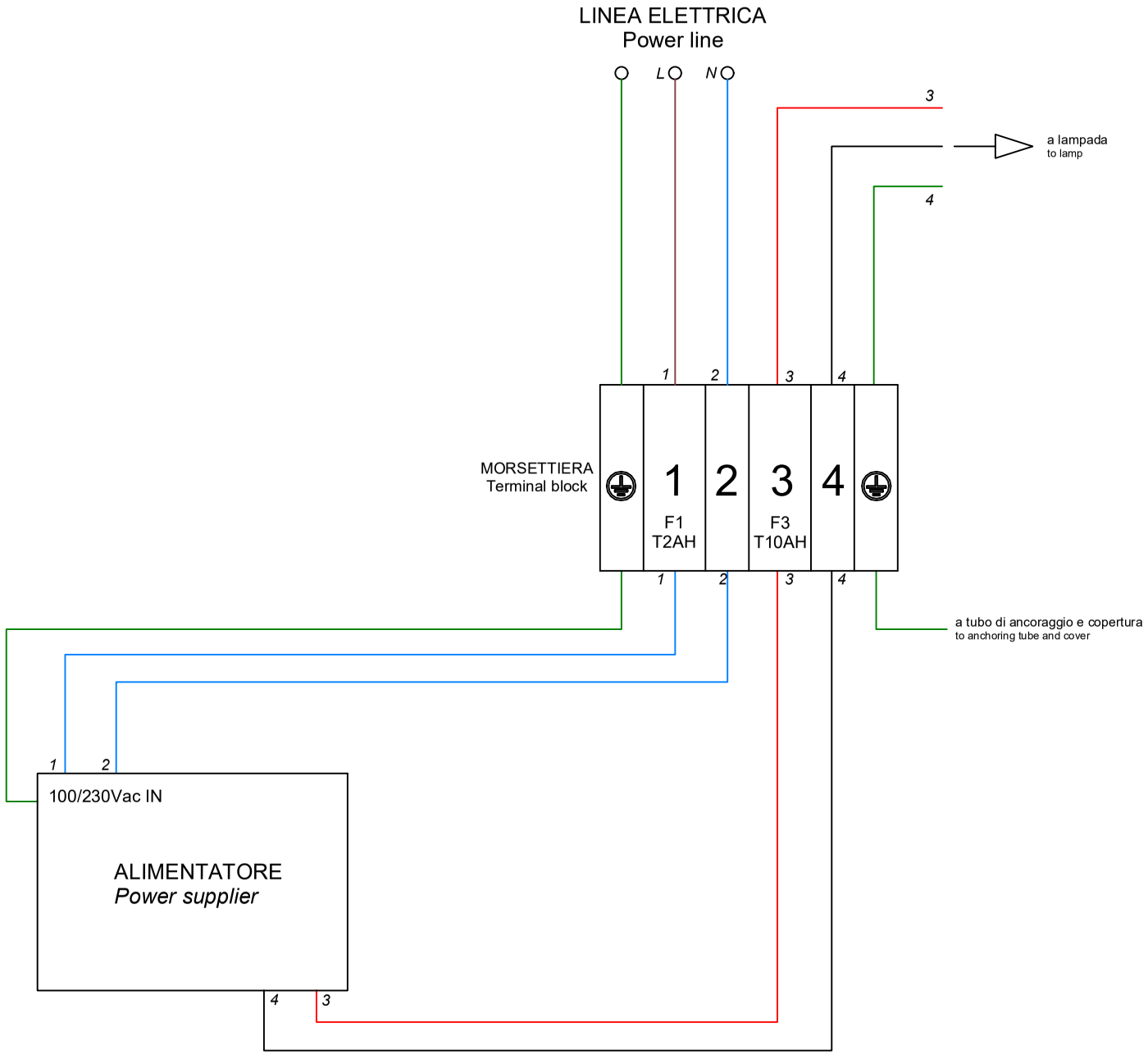
_____

5 Troubleshooting

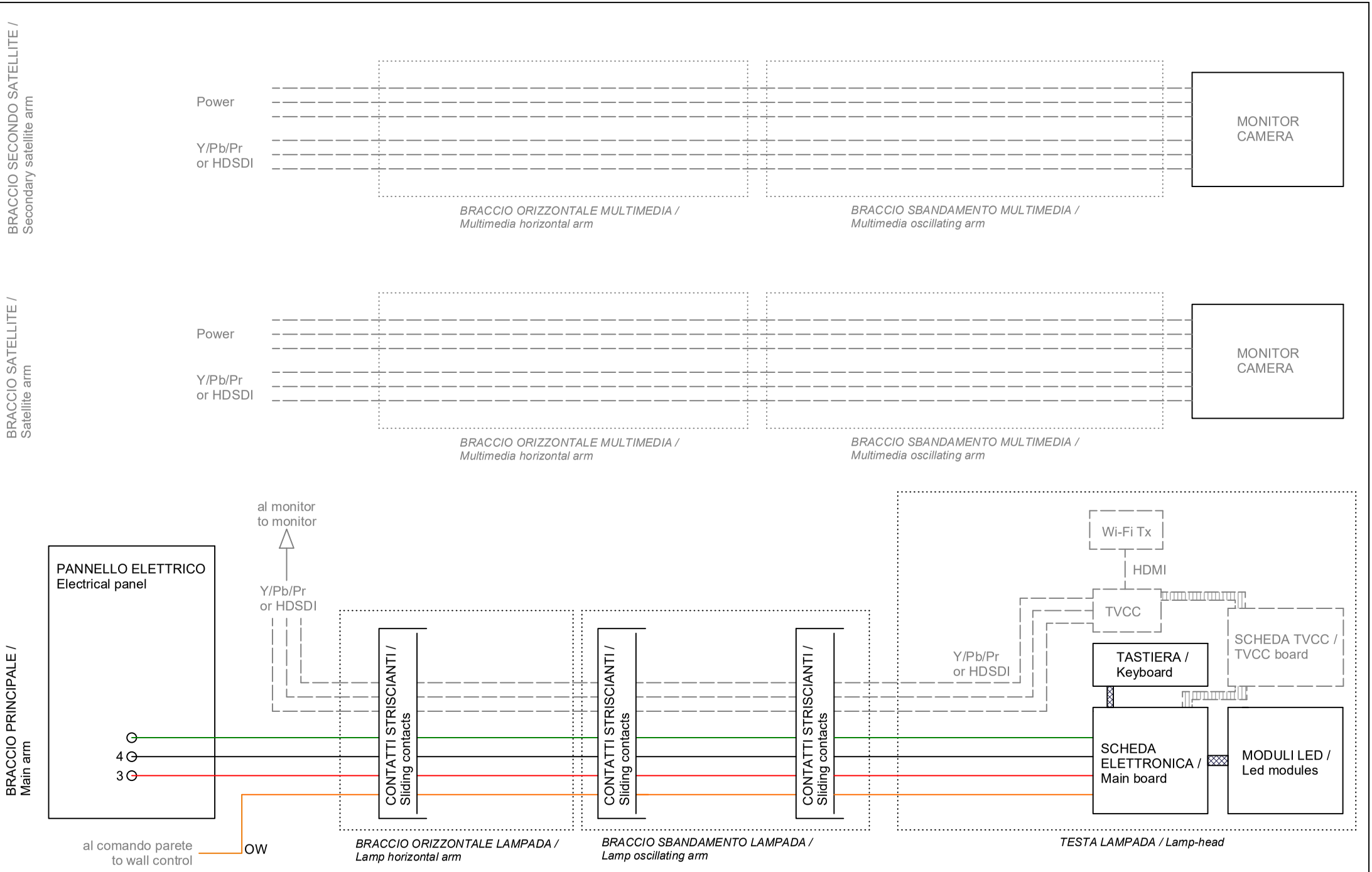
Possible Product damage.

Presence of dangerous voltage.

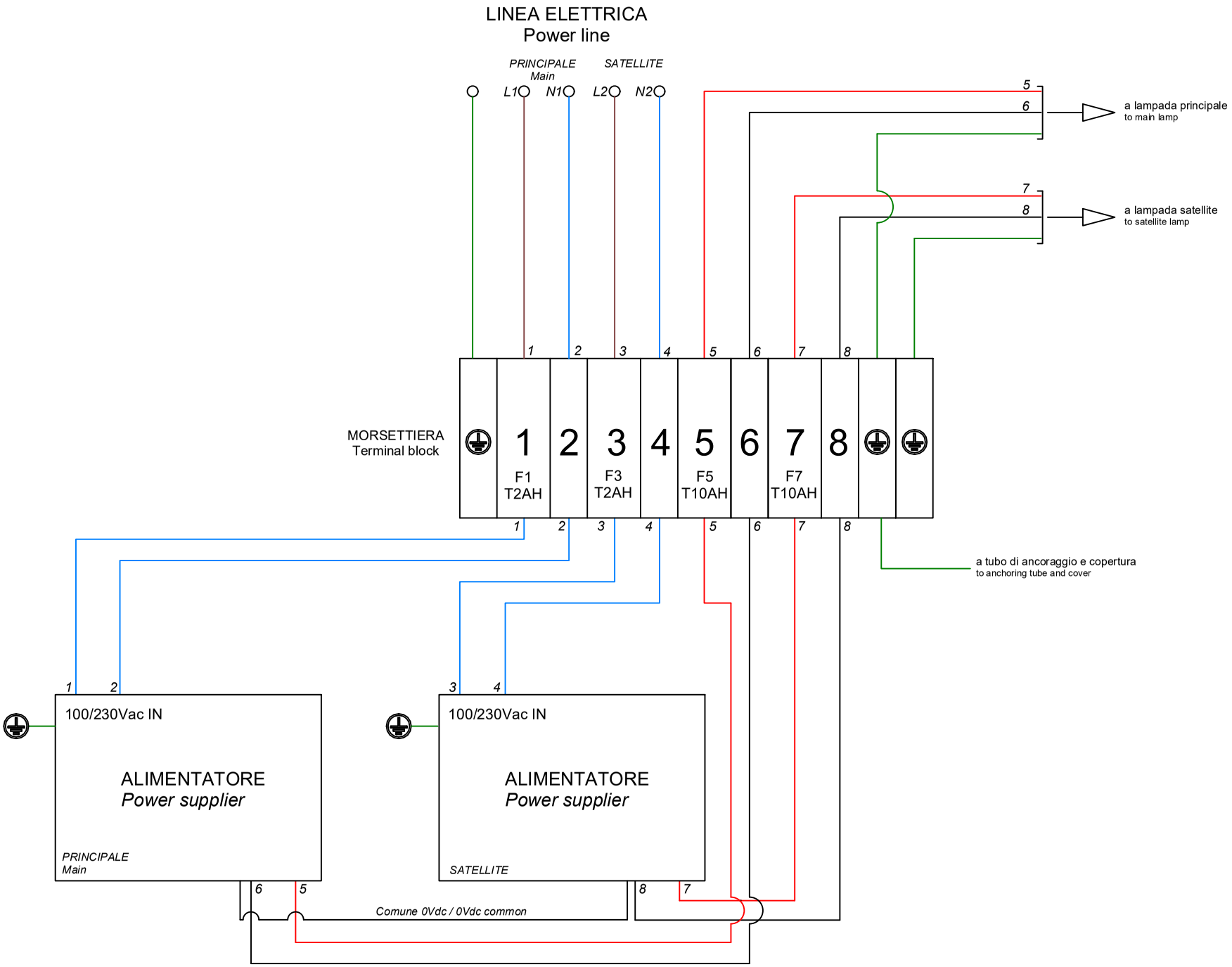
N.	Problem	Solution
1	The Product fails to remain in stable position	Make sure the instructions in this manual, in the "Product installation" paragraph, have been correctly followed. Refer to setting instructions in the operation and maintenance manual.
2	The Product fails to work	Make sure fuses have 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.



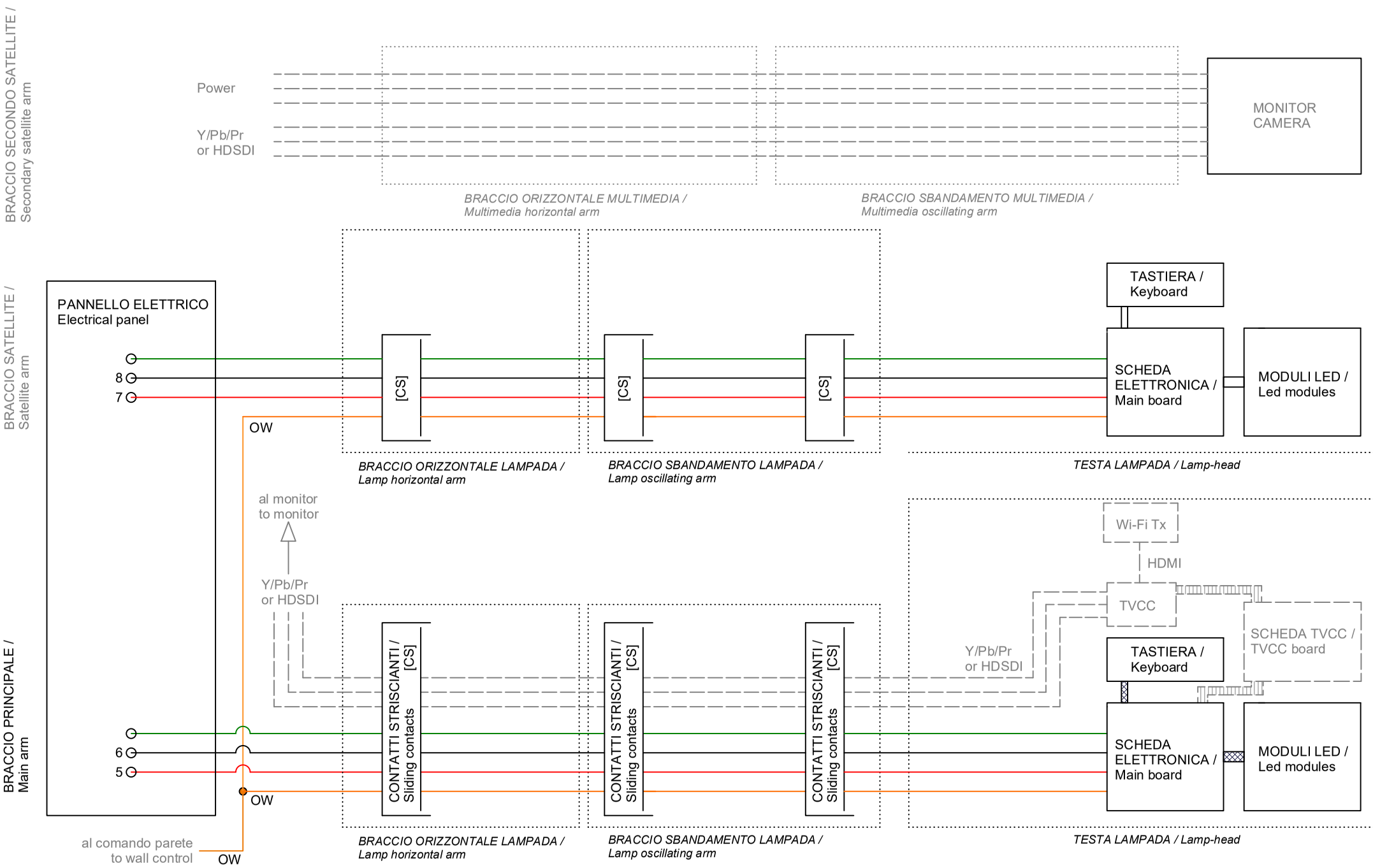
Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO SINGOLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Serie E Serie N Tris-Led	GIMAled GOLDEN ORION COMET-H COMET-L	ED506
Pag. 1 / 1	*Ceiling single lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



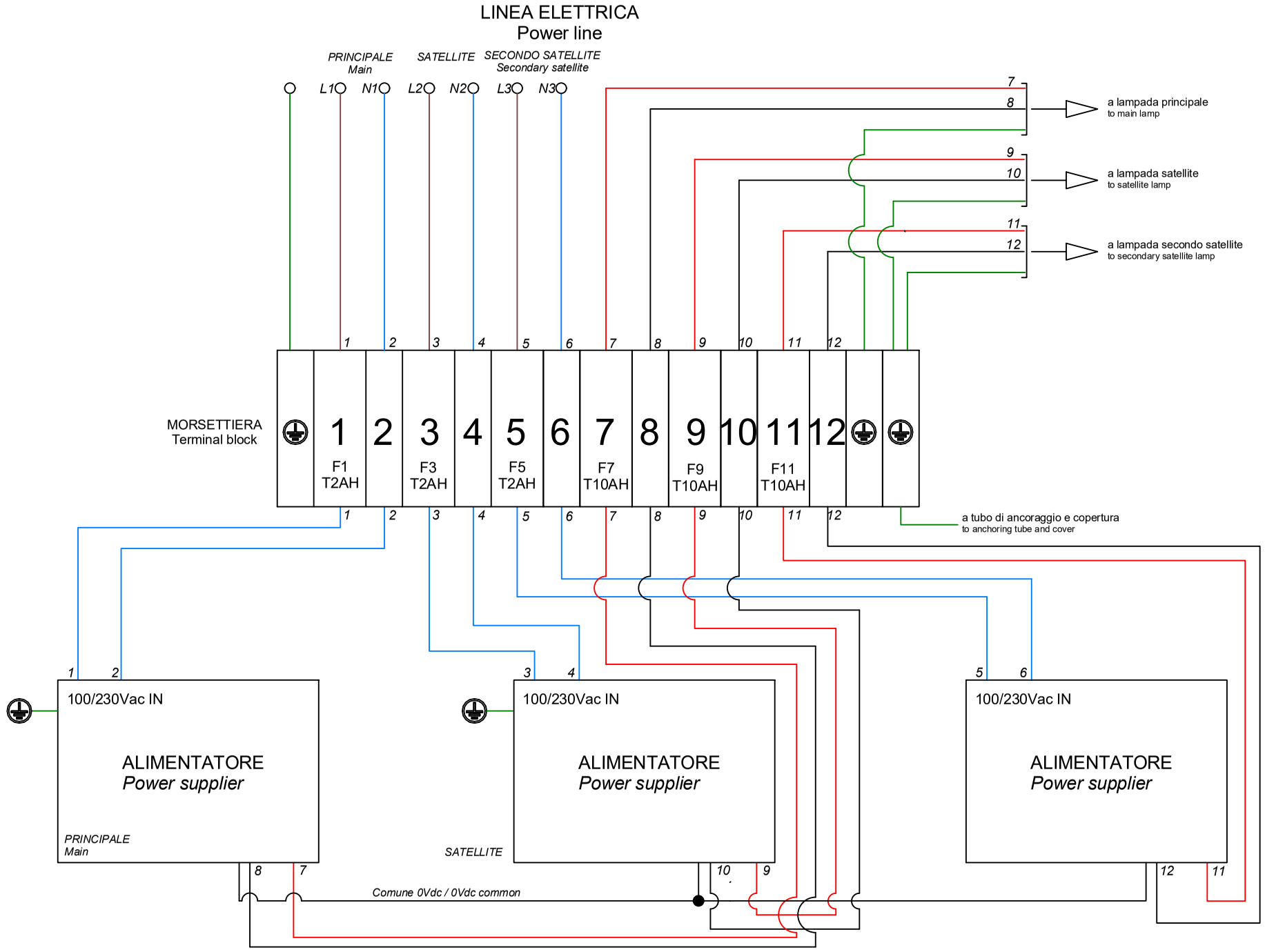
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION COMET-H COMET-L	ED509
Pag. 1 / 1	*Ceiling single lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



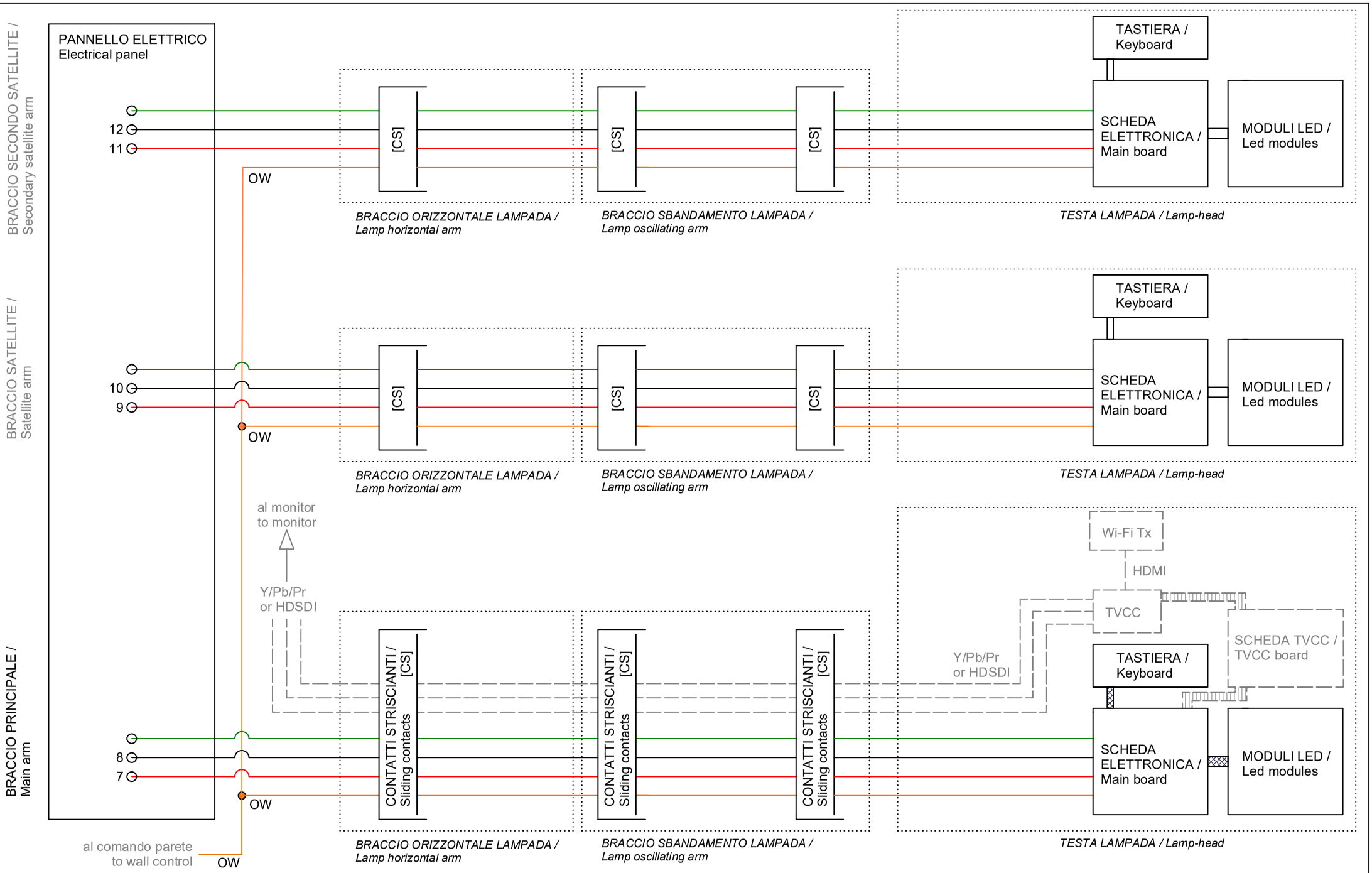
Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520	GIMA-led	ED507
Pag. 1 / 1	*Ceiling double lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*	U29 Serie E Serie N Tris-Led	GOLDEN ORION COMET-H COMET-L	



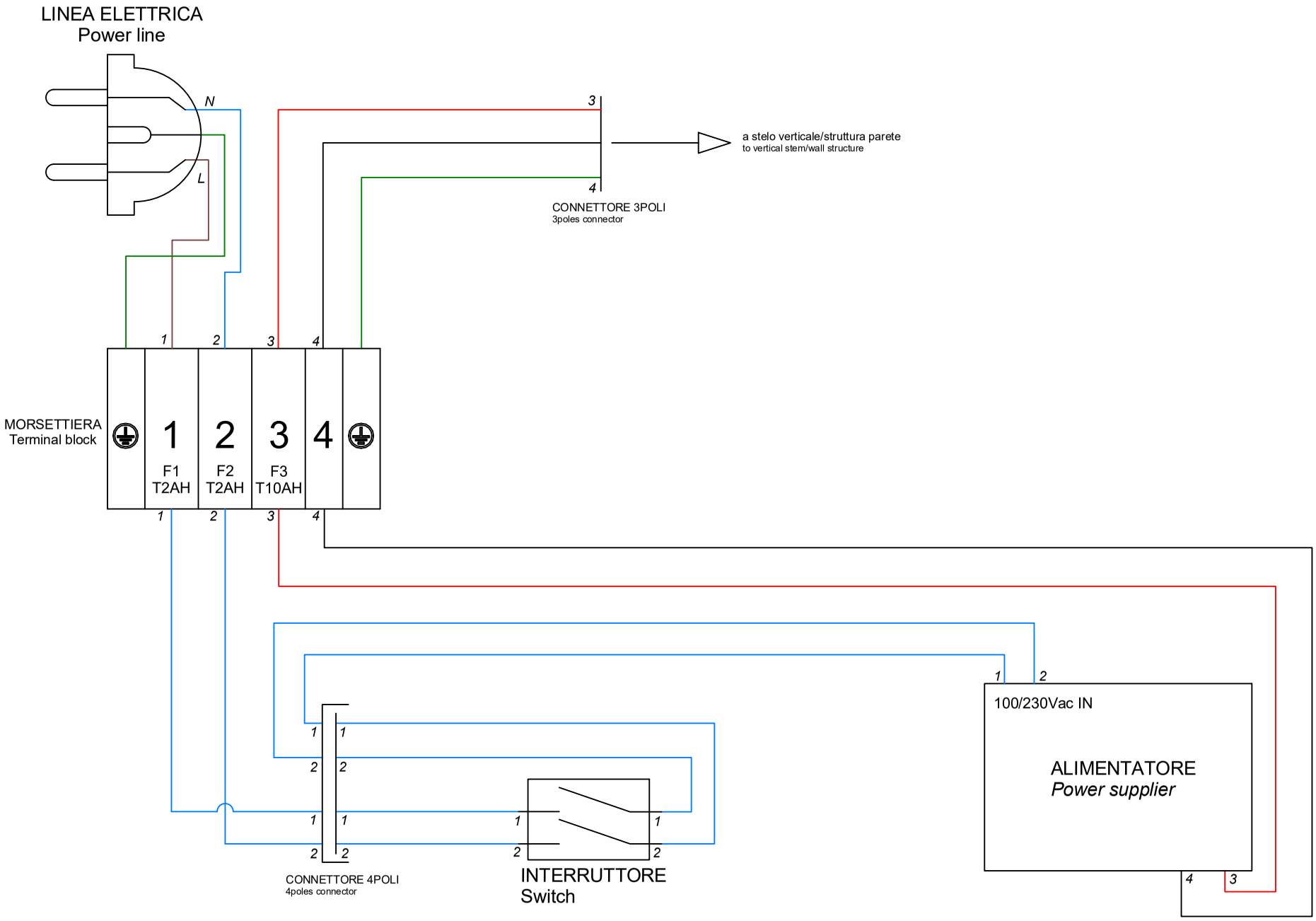
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION COMET-H COMET-L	ED510
Pag. 1 / 1	*Ceiling double lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



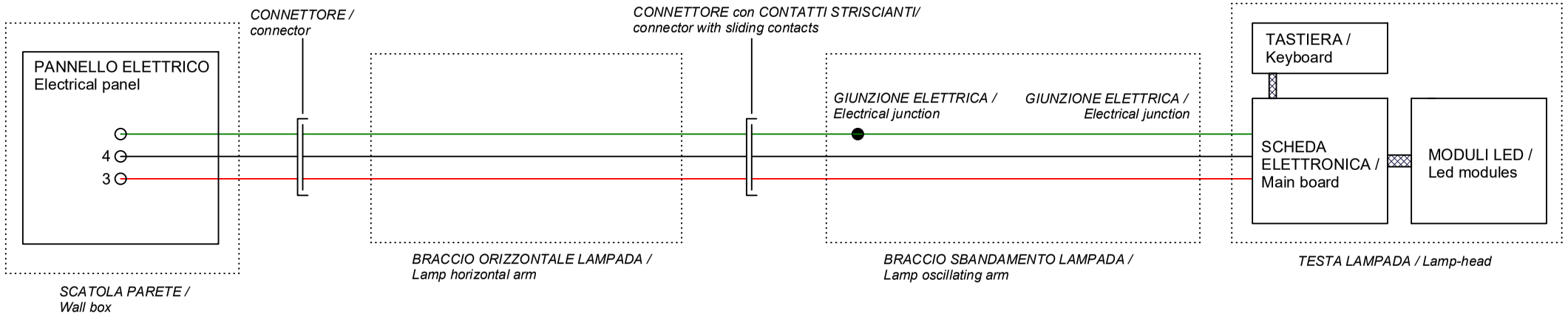
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO TRIPLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Serie E Serie N Tris-Led	ED508
Pag. 1 / 1	*Ceiling triple lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



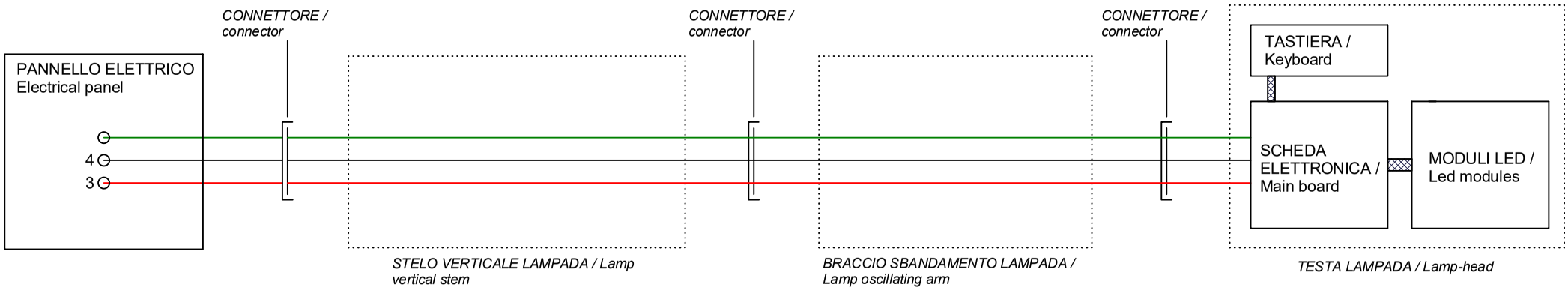
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO TRIPLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION	ED511
Pag. 1 / 1	*Ceiling triple lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A PIANTANA/PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Pentaled30E Pentaled30N Tris-Led	GIMAled GOLDEN ORION	ED504
Pag. 1 / 1	*Mobile/Wall lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 26/08/2020	SCHEMA GENERALE PER LAMPADA A PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled30E Pentaled30N TRIS-LED GOLDEN ORION40	ED517
Pag. 1 / 1	*Wall lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A PIANTANA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Pentaled30E Pentaled30 N Tris-Led	GIMAled GOLDEN ORION	ED512
Pag. 1 / 1	*Mobile lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			

OPERATION AND MAINTENANCE MANUAL

GIMAled29

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

Introduction

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

Marking CE

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

Compliance

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.

Validity of manual

This installation manual is valid for the following models:

- GIMAled29 in ceiling, wall and mobile versions;
- GIMAled29, in ceiling double yoke version.

Customer Service

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

If the device causes the death or serious deterioration of the patient's or user's health conditions, contact the manufacturer and the competent state authority where the event occurred.

Copyright

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

Translations

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

Index of contents

KEY

PRODUCT

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**".

OPERATOR

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

RESPONSIBLE ORGANIZATION

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.

TECHNICAL SERVICE PERSONNEL

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)

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 ME Medical Electrical 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.

Operating field

Undesired effects of overlapping light fields

	**Possibility of tissue dehydration and damage.**

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

2.2 Safety conditions (secondary effects)

Optical safety

	**Possibility of glare.**

- 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.

Electromagnetic disturbance

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.

Incorrect use

	**Do not place objects on Product.**

- 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.

Improper use of mobile version

	**Pushing or resting on the Product is forbidden.**

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.

3 General information

3.1 Operator qualifications

Qualification of personnel in charge of operating on the Product:

Use	Professional medical personnel.
Cleaning	Properly trained medical and paramedical personnel.
Routine maintenance	Qualified technician with required technical-professional skills.
Special maintenance	GIMA or technical service personnel, the latter only for the fuse change.
Assistance	GIMA or authorized Dealer.
Disposal	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

Patient population	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.
Patient interaction	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.
Operator interaction	The operator touches the device necessary on the sterilisable grip and function control keyboard, and occasionally on the enclosure.

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

3.4 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

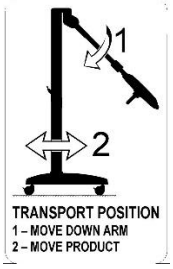
Medical Device

Model reference

Serial number

Swiss authorised representative

Disposal

	Protection earth
‘N’	Neutral lead connection point
‘L’	Line lead connection point
‘I’	ON
‘O’	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

Operator Instructions

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.

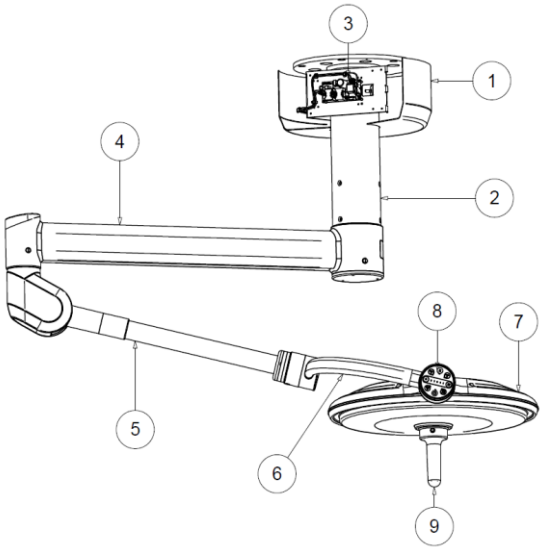
5 Product description and operation

5.1 Product description

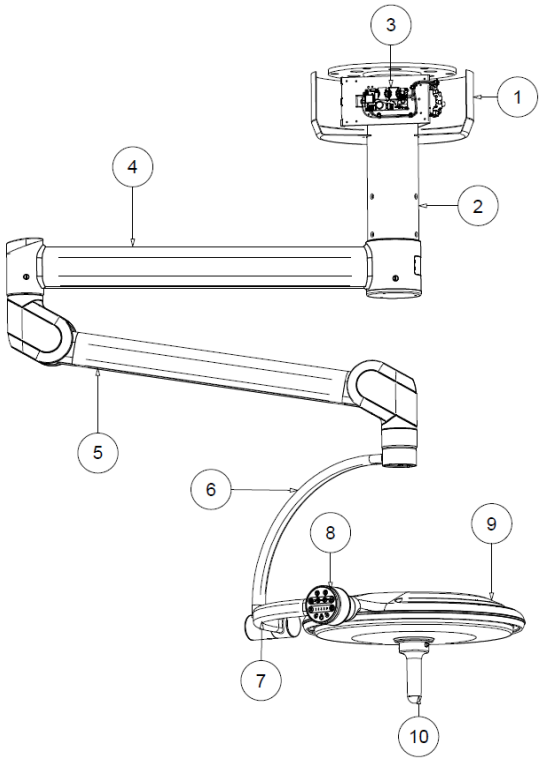
Versions

The Product is available in various versions:

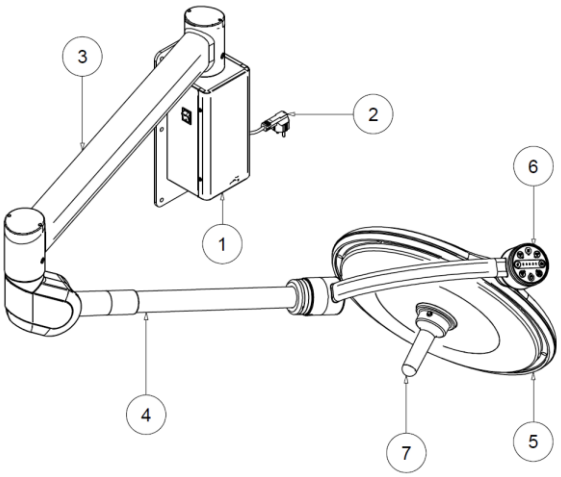
- **ceiling version**
- **ceiling version with double-yoke**
- **wall version**
- **mobile version**



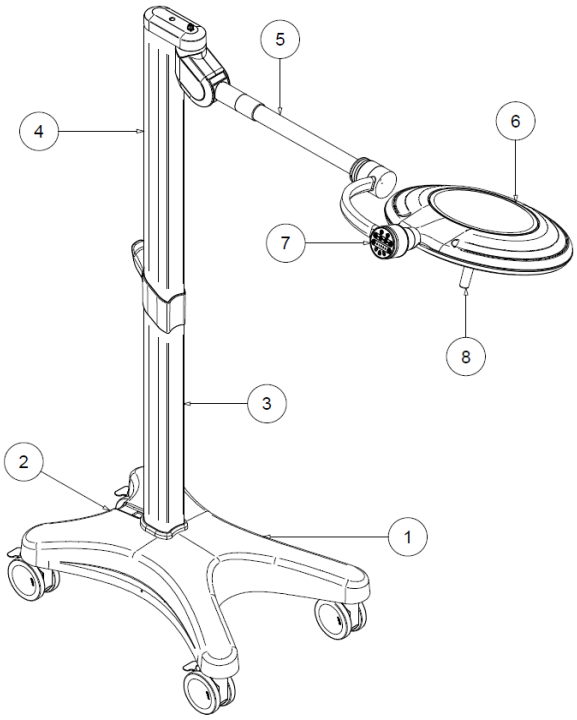
CEILING version with SINGLE YOKE: ceiling cover (1), ceiling anchor tube (2), supply unit (3), horizontal arm (4), swinging arm (5), yoke (6), lamp head (7), function control keyboard (8), sterilisable grip (9).



CEILING version with DOUBLE YOKE: ceiling cover (1), ceiling anchor tube (2), supply unit (3), horizontal arm (4), swinging arm (5), external yoke (6), internal yoke (7), function control keyboard (8), lamp head (9), sterilisable grip (10).



WALL version: wall box (1), power plug (2), horizontal arm (3), swing arm (4), lamp head (5), control keyboard (6), sterilisable handle (7).



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).

Separable parts

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

5.2 Description of operation

Main switch

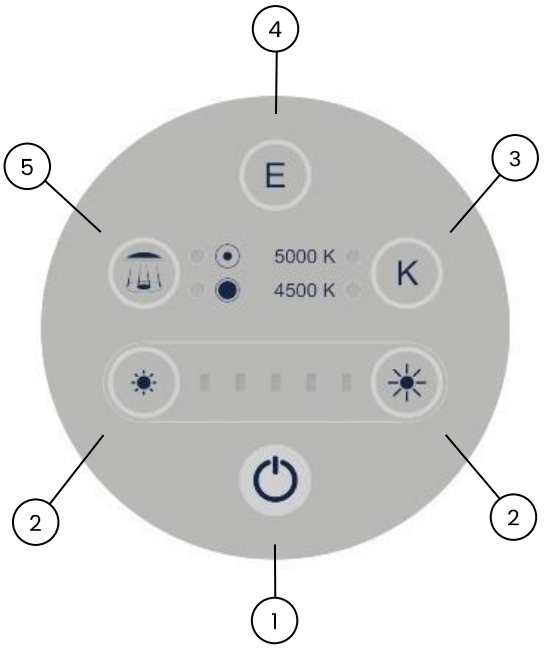
Wall and mobile version lamps feature a green light switch for general switching on and off.
In case of single and double ceiling versions position the thermal magnetic switch near the Product so that it can be switched off in case of need.

CAUTION

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

5.2.1 GIMAled29 control keyboard

GIMAled29 control keyboard



The membrane keyboard is located on the yoke. It can control:

- lamp switch-on and switch-off by means of the "I/O" key (1);
- 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 green microleds;
- selection of colour temperature between 2 values: 4500K and 5000K by pressing the keys with the letter K indicating the value (3);
- enabling the "Endoled" function, using the key with the letter E (4). This function is only available with lamp off;
- adjustment of light range (increase-decrease) by means of key (5) which increases or reduces the range.

Lighted area

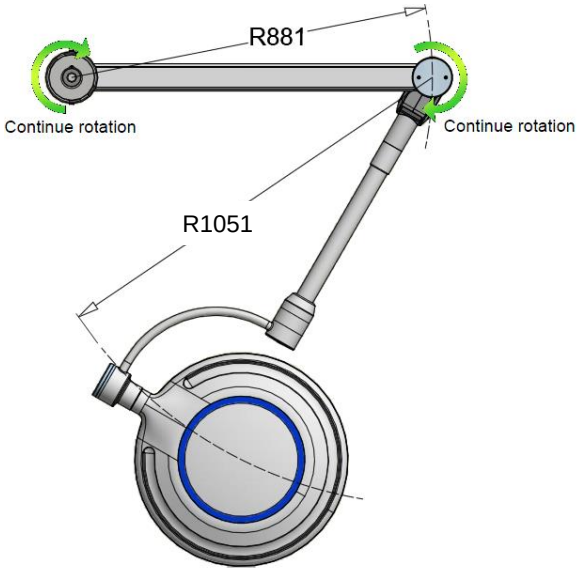
The Product has been designed to be able to regulate the light diameter electronically by means of the key (5) provided.

System desynchronization/synchronization

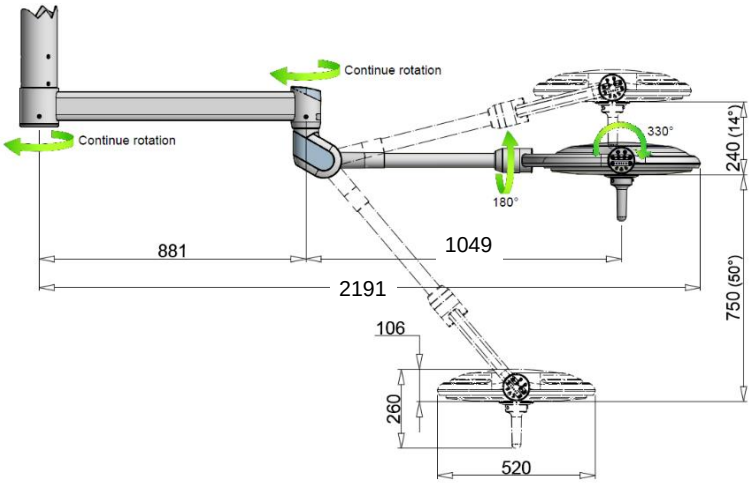
In case of multiple lamps, it's possible to desynchronize/synchronize the system:

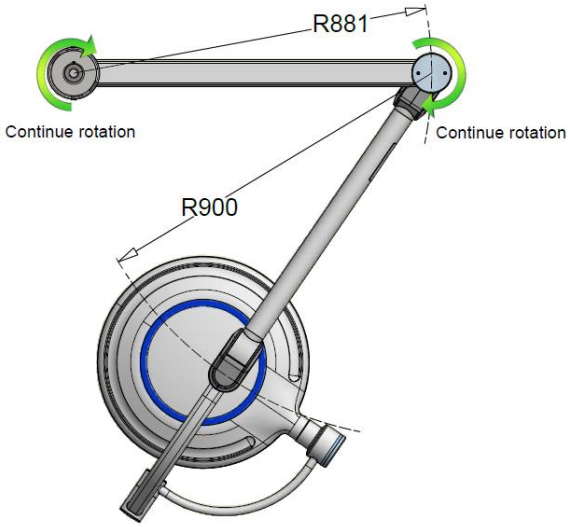
- press and keep pressed the key with the letter K (3) until indicator led flashes;
- repeat previous steps on remaining lamp-heads of the system.

5.3 Product handling

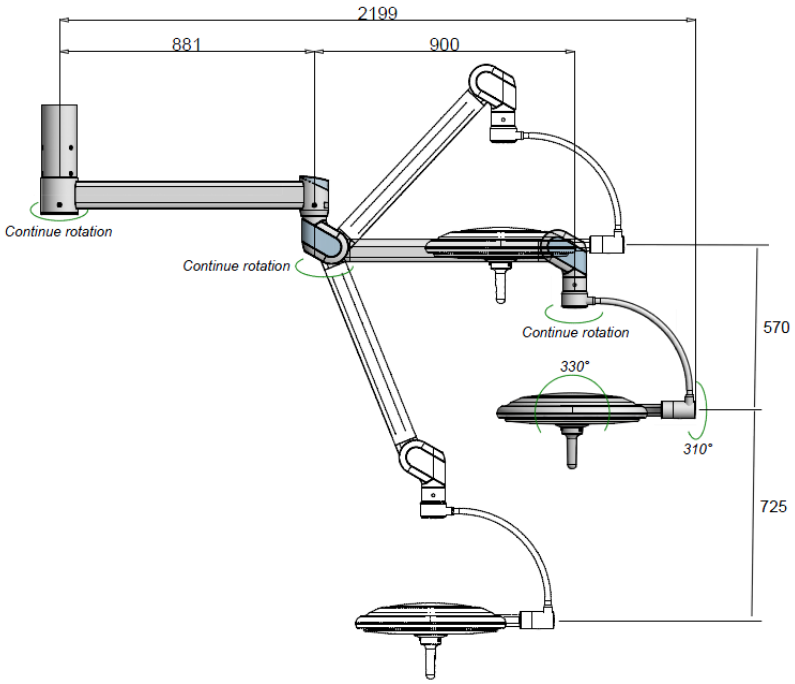


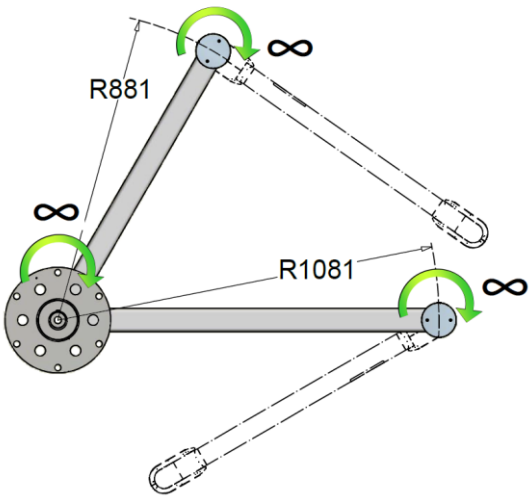
SINGLE ceiling model UNICA 520 and U29

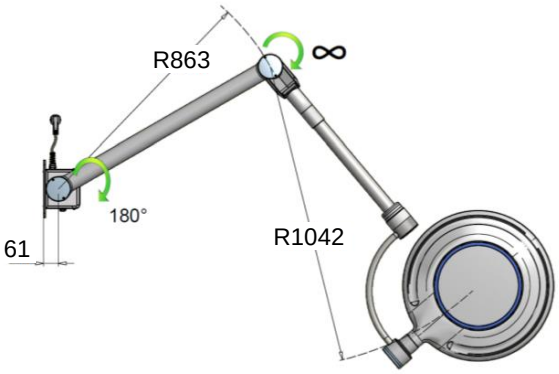




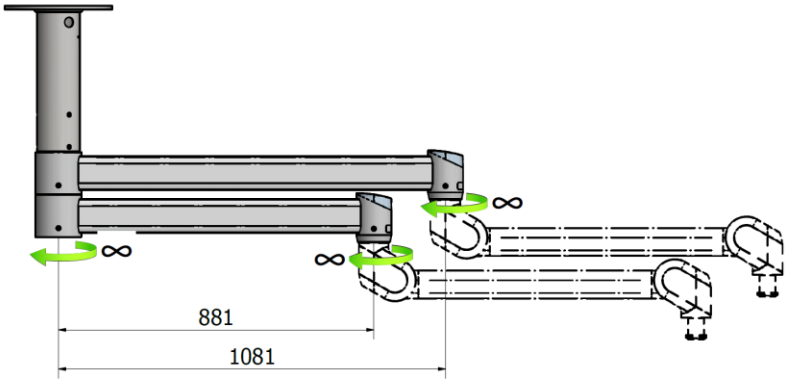
Ceiling model with double yoke



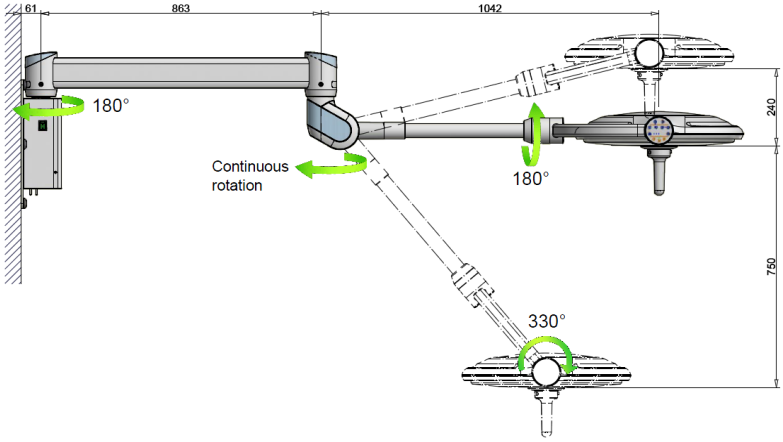


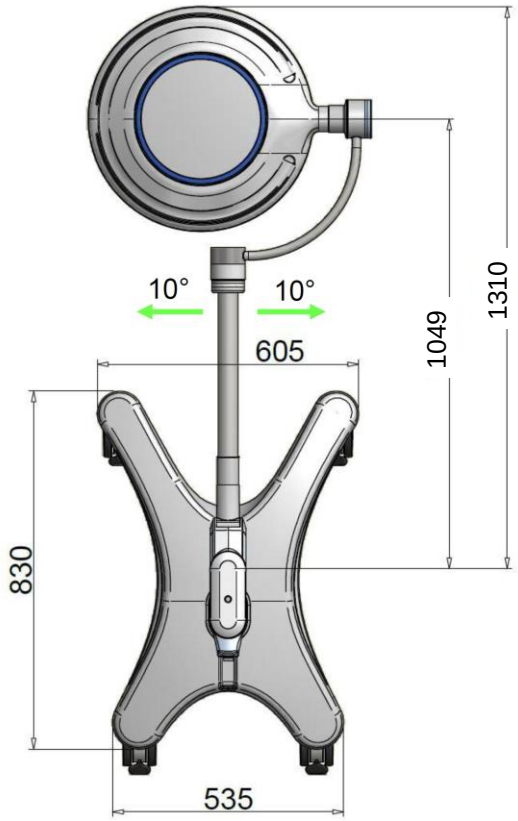


DOUBLE lamp model

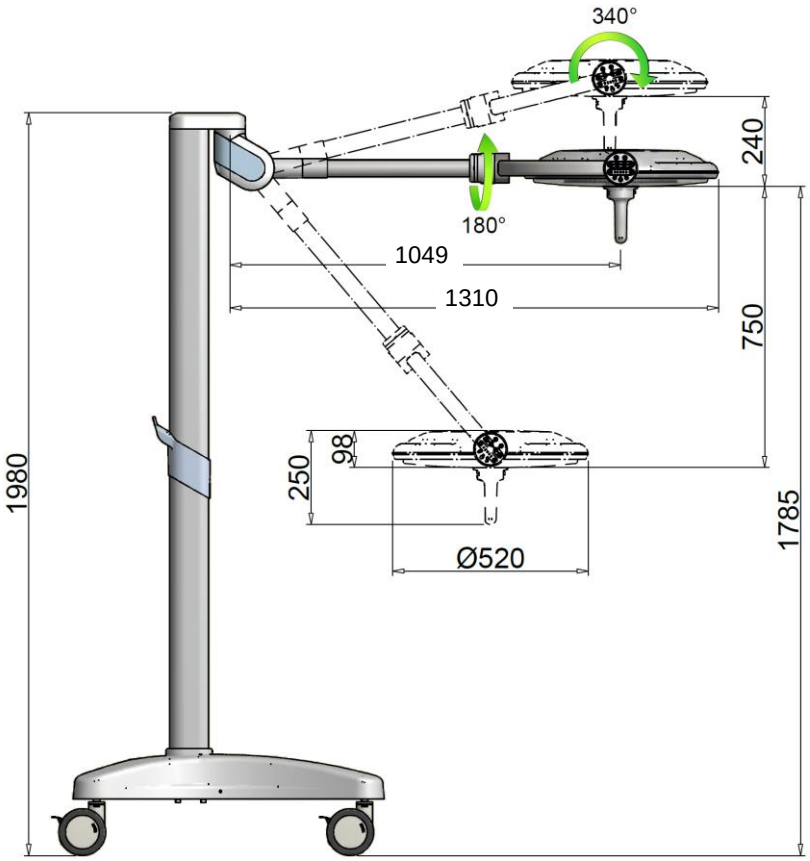


Wall model

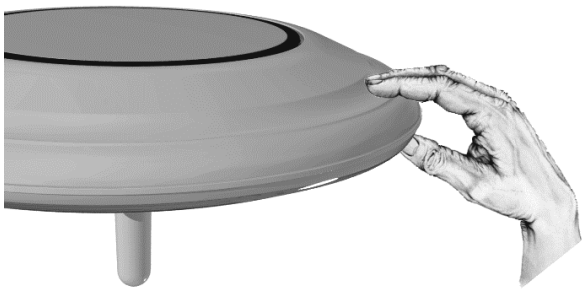




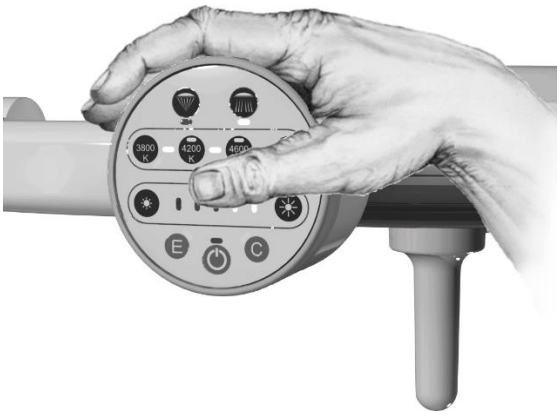
Mobile model



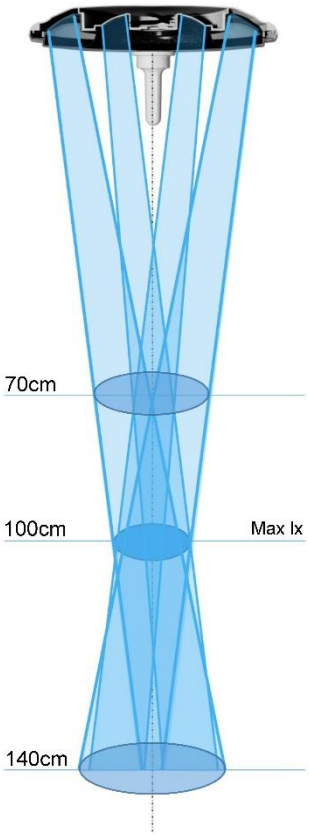
The Product can be moved using the sterilisable handpiece.



The Product can also be moved using the external contour.

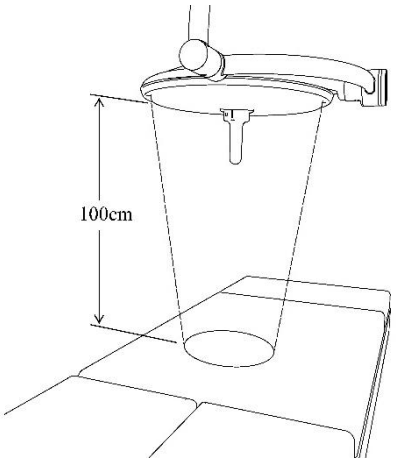


By pressing the keys on the keyboard, the previously described control functions can be enabled.



RECOMMENDED WORK DISTANCE

To optimize light intensity, the product is best used at a distance of 1m.



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.

5.3.2 Moving the stand

⚠	**Risk of lamp overturning.**

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:

- Clean/disinfect the Product according to the rules laid down by the relevant national commission;
- Check the emitted light is stable and of adequate intensity;
- Check the swinging arm maintains correctly its position;
- Check the cupola maintains correctly its position.

6 Cleaning and disinfecting

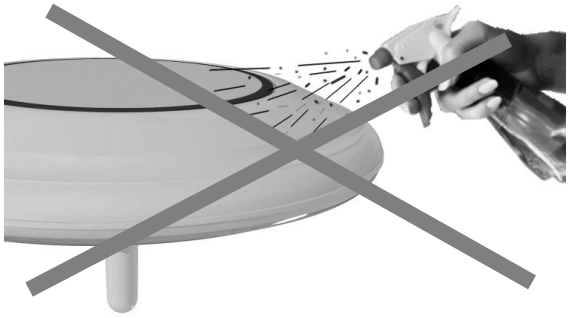
The responsible organization must comply with the rules (standards and directives) concerning hygiene, disinfection and sterilization laid down by the relevant national commission.

6.1 Application method

	Interrupt the power supply before cleaning the Product.
	Possibility of damaging the Product.

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.

Application method



Do not spray detergent / disinfectant directly on Product.

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

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

Frequency

We recommend you to clean the Product every day.

	**Possibility of damaging the Product.**

- 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.

6.3 Product disinfecting

Frequency

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

	**Possibility of damaging the Product.**

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.

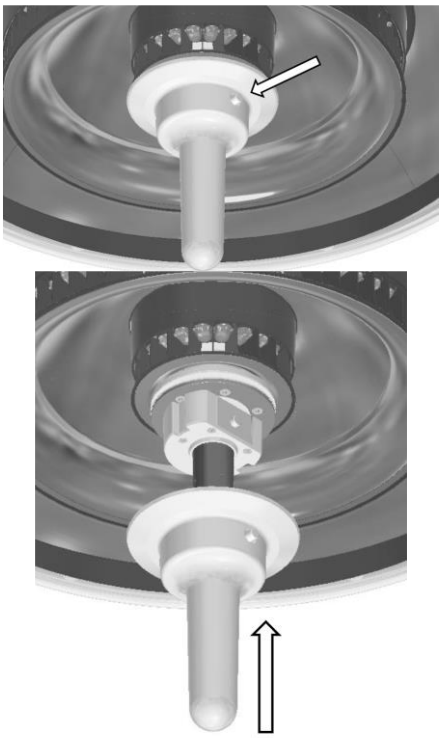
6.4 Handpiece sterilization

Frequency

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.

	**Hazard for the patient.**

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:

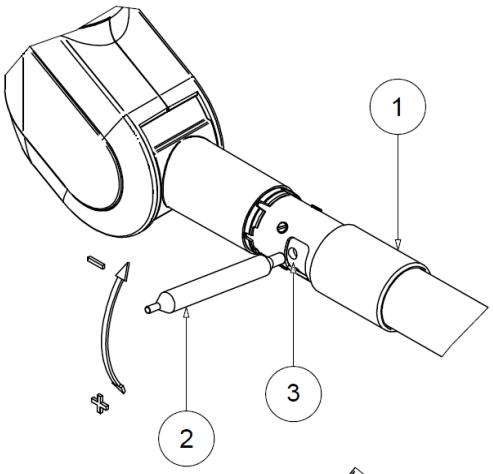
- steam sterilization at 121°C and 1.3 bar for 25 to 30 minutes
- steam sterilization at 134°C and 2.3 bar for 4 minutes

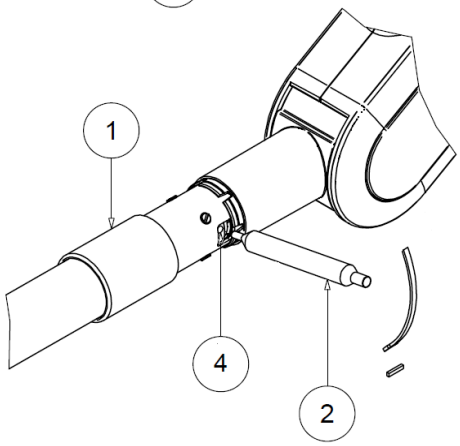
Do not exceed a sterilization temperature of 134°C.
Strictly keep to the ISO 17665-1 standard.
When placing in the autoclave, make sure the open side of the handpieces is turned downwards. The handpieces must be free and not burdened by other material being sterilized.
Damaged handpieces must no longer be used.

7 Adjustment and maintenance

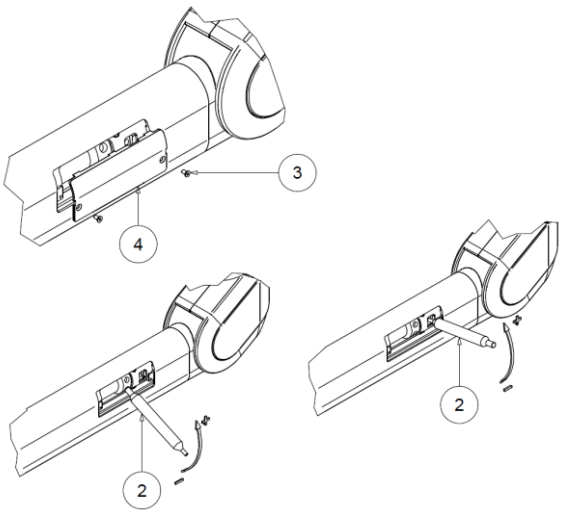
7.1 Swinging arm adjustment

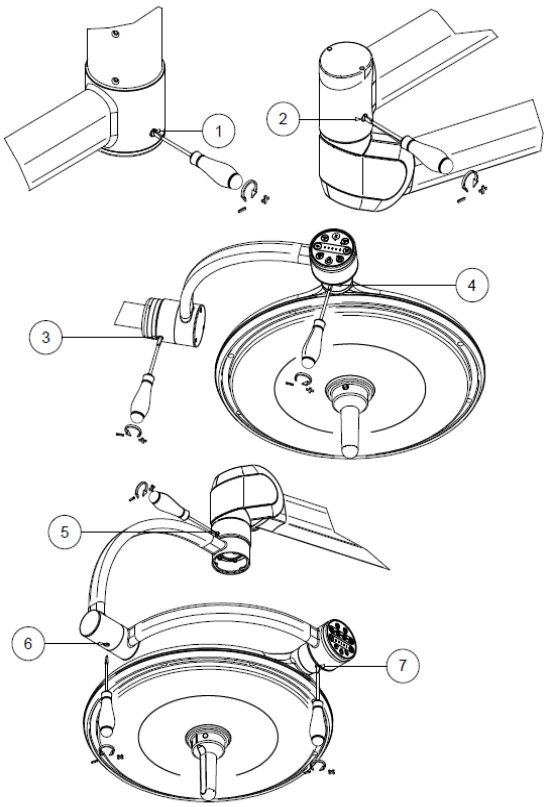
The Product is sold already balanced and does not require further adjustment. In the event of the spring swinging arm becoming stiff or loose over time, mechanical intervention is possible by regulating the compression of the internal spring.
Manually move the cover (1) forwards. Looking at the lamp 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.





In the double yoke version, remove the screws (3) and the cover (4) in order to access the adjustment ring nut. To make the adjustments, by means of the pin provided (2) rotate the large ring nut to adjust the spring, and the small one to adjust the swing in the same way shown above.





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.
In the double yoke version, adjust the brake force by means of the three screws (5, 6 and 7) of the brakes using a flathead screwdriver.

7.3 Periodical checks to be performed on the Product

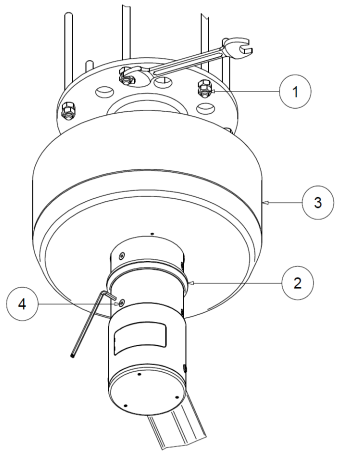
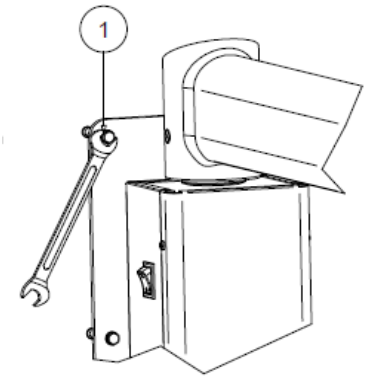
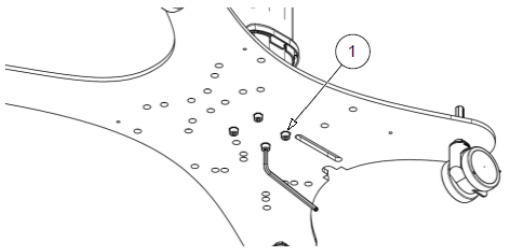
At the time of start up and after each maintenance job, perform electrical tests and jobs indicated in the IEC 62353 standard.

	Perform the Product electrical check.
	Making any changes to this device is forbidden.

7.4 Routine maintenance

	Interrupt the power supply before doing any maintenance jobs.
	Check Product integrity.

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.

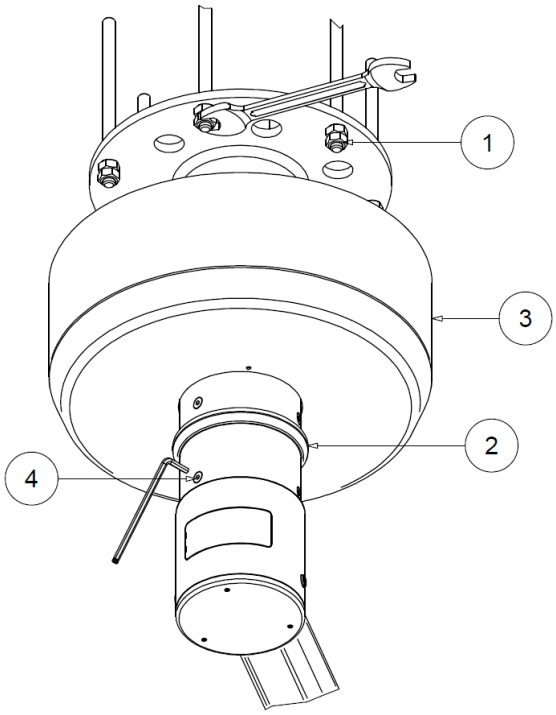
2	Before using	Make sure the light source protection screens are not damaged. If they are, contact the Customer Service.
3	Once a year	Check all the Product joints and make sure there are no noises or squeaks. If there are, lubricate the clutches involved with suitable grease for industrial use at a 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).
6	Once a year (WALL VERSION) 	Make sure the wall retention screws (1) are tightened properly. If these are not properly fastened, adequately tighten.
7	Once a year (MOBILE VERSION) 	Make sure the stem retention screws (1) under the base are tightened properly. If these are not properly fastened, adequately tighten.

7.5 Repairs

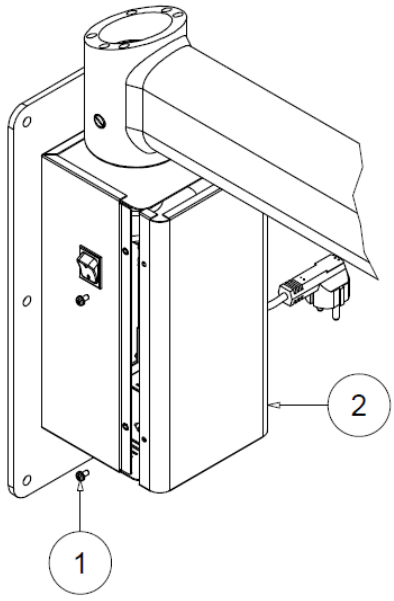
The only repair job with which the technical assistance personnel are charged is the fuse change.

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.

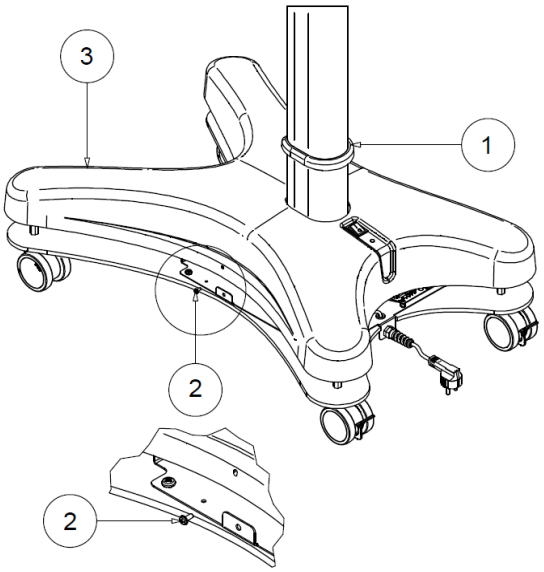
Interrupt the power supply before doing any maintenance jobs.



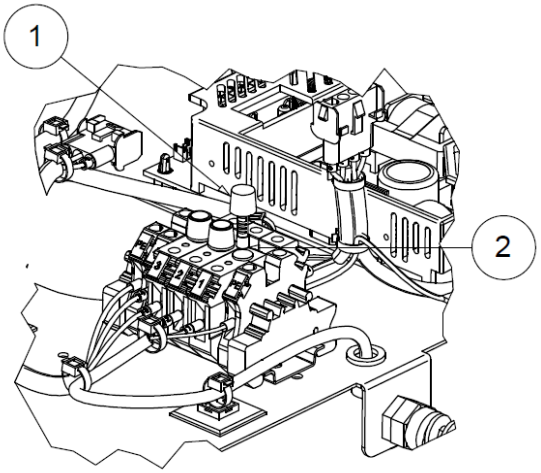
To access the fuses in the ceiling version, open the bar cover as indicated in point 5 of paragraph 7.4.



To access the fuses in the wall version, remove the 4 screws (1) and the closing box (2).



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

Disposal at end-of-life

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.

7.7 Spare parts list

Only original spare parts must be used.

Description	Order code
Sterilisable grip	Z400307-4
Electronic board	Z300632-PL30E
Keyboard	Z300227
I/O switch (for wall and mobile versions)	Z300016
Switching power supply unit	Z400629
Fuse T2AH 250V ‘5x20’	Z400195
Fuse T10AH 250V ‘5x20’	Z400217
Fuse T4AH 250V ‘5x20’	Z400215

8 Technical properties

Technical details of light	**GIMAled29**
Illumination E_c at 1 m ± 10% (d) [Lux]	160,000
Illumination E_c at 1 m ± 10% (D) [Lux]	160,000
Colour temperature [K]	4,500 – 5,000
Colour rendering index R_a [-]	93
R_9 [-]	>90
Light field diameter d_{50} [mm]	110
Light field diameter d_{10} [mm]	200
Lighting depth L1+L2 [mm] at 60%	490
Lighting depth L1+L2 [mm] at 20%	1350
Max irradiance [W/m²]	580
Irradiance / Illumination [mW/m²lx]	3.68
Max radiation in UV [W/m²]	0.04
E_c 1 mask [%]	64
E_c 2 masks [%]	44
E_c with cylinder [%]	100
E_c with cylinder and 1 mask [%]	65
E_c with cylinder and 2 masks [%]	46
Power connection details	
Primary alternate voltage [Volt ac]	100 - 240
Frequency [Hz]	50 / 60
Absorbed power [VA]	60
Absorbed power battery version [VA]	150
Light source	N° 29 LED
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	20 - 100

General data		
Regulation		REGULATION (EU) 2017/745
Classification of Medical Device		Class I
Standards		IEC 60601-2-41
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the EM equipment shall not vary by more than 20% during use; the colour temperature and colour rendering index shall be stable and within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).	
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm shall not exceed 10 W/m^2; and the total irradiance E_e in the lighted area shall not exceed 1000 W/m^2 at a distance of 1000 mm; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m^{2}lx).	
Colour		RAL 9003
IP degree of protection		IP42
Operating conditions		Continuous operation
Handpiece steam sterilization		121°C and 1.3bar for 25 to 30 minutes. 134°C and 2.3bar for 4 minutes.
Mains power voltage insulation means		Outside the product (main switch) for ceiling versions. Main switch for wall and mobile versions.
Dimensions		
Diameter of lamp body [cm]		52
Light emission surface [cm^2]		468
Weight of Product in ceiling, double ceiling, wall, mobile, mobile battery versions [kg]		45, 75, 33, 50, 60
Markings		
CE		In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons		
D = with big diameter selected; d = with small diameter selected		

9 EU Declaration of conformity

In accordance with Article 19 and Annex IV of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturer: **RIMSA P. LONGONI S.r.l.**
Address of registered place of business: Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) – ITALY
Single registration number (SRN): IT-MF-000009224

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Basic UDI-DI: **++B880LUMINAIREPM**

Product and trade name: **U29 (GIMAled29)**
Model reference: U29 (GIMAled29)
Configurations:

U29PA (GIMAled29)	LAMP MODEL U29 (GIMAled29) WALL
U29PI (GIMAled29PI)	LAMP MODEL U29 (GIMAled29) MOBILE STAND
U29SO (GIMAled29SO)	LAMP MODEL U29 (GIMAled29) CEILING
U29+29 (GIMAled29+29)	LAMP MODEL U29 (GIMAled29) DOUBLE CEILING

Intended purpose: MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

Risk class of the device in accordance with the rules set out in Annex VIII of REGULATION (EU) 2017/745: **CLASS I**
Explanation: Duration: Short term (Annex VIII, CHAPTER I, point 1. DURATION OF USE)
Description: Non-invasive medical device (Annex VIII, CHAPTER III, point 4. NON-INVASIVE DEVICES, par. 4.1 Rule 1)
Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, par. 6.2 Rule 10)

The manufacturer declares that the device is in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and with the following standards:

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

The conformity assessment procedure is developed with reference to premise (60) and Article 52 of REGULATION (EU) 2017/745.

RIMSA Quality and Environmental System complies with UNI EN ISO 9001, UNI CEI EN ISO 13485 and ISO 14001 standards and is certified by IMQ S.p.A. (certificates n. 9120.RMS1, n. 9124.RMS2 and n. 0833.2023).

Name: Paolo Longoni
Position: Managing Director

10 EMC Declaration

	**Possibility of interferences with nearby appliances.**

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.

<table>
<tr><th>Immunity test</th><th>Compliance</th><th>Electromagnetic environment - directives</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Product is suitable for use in all environments except in domestic environments and those directly connected to a low-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 the operation of nearby appliances. Measures may have to be taken to reduce such disturbance, such as Product re-positioning or shielding of premises.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations /flicker emissions

IEC 61000-3-3</td><td>Conforming</td></tr>
<tr><td colspan="3">NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 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.</td></tr>
</table>

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	+/- 1 kV Between phases +/- 2 kV 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	10 ms – 0% a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	10 ms – 0% a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	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) IEC 61000-4-8	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.			

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz 6 V ISM Frequencies	3 Veff 150 kHz to 80 MHz 6 V ISM Frequencies	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 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	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.			

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

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.

[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.

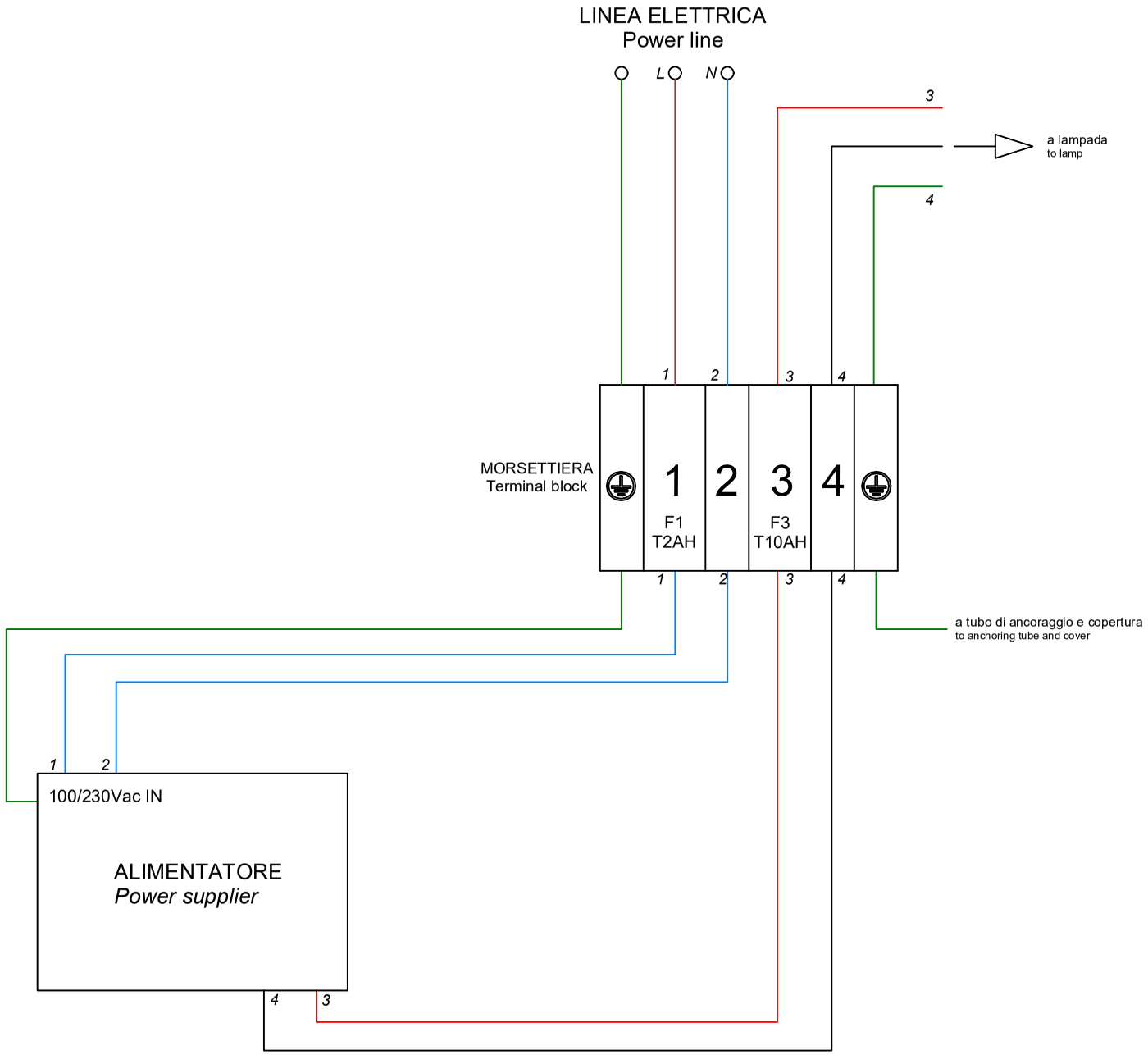
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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 and people.

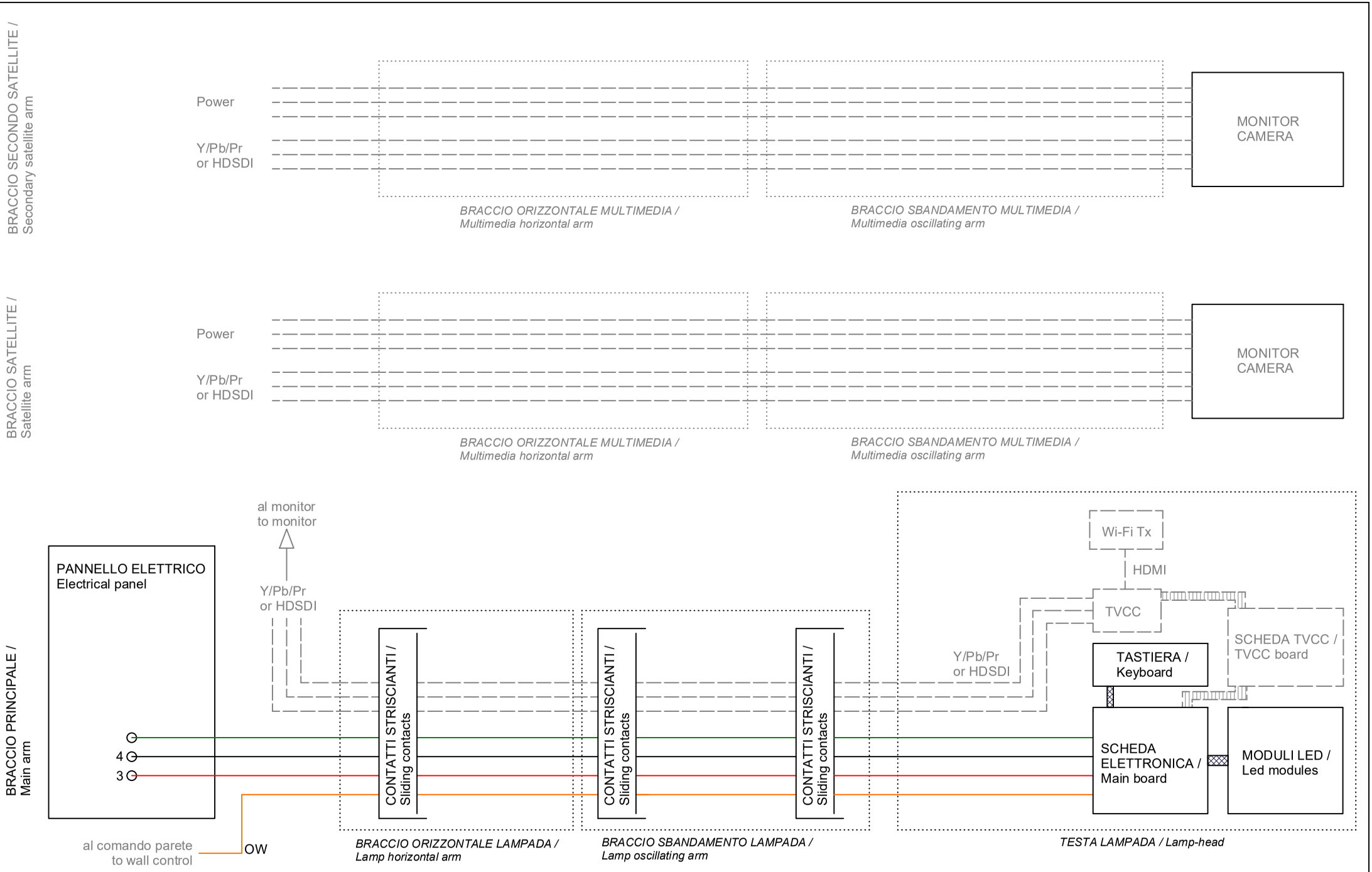
11 Warranty Certificate

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 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 IEC 60364-7-710 standard (standard 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.

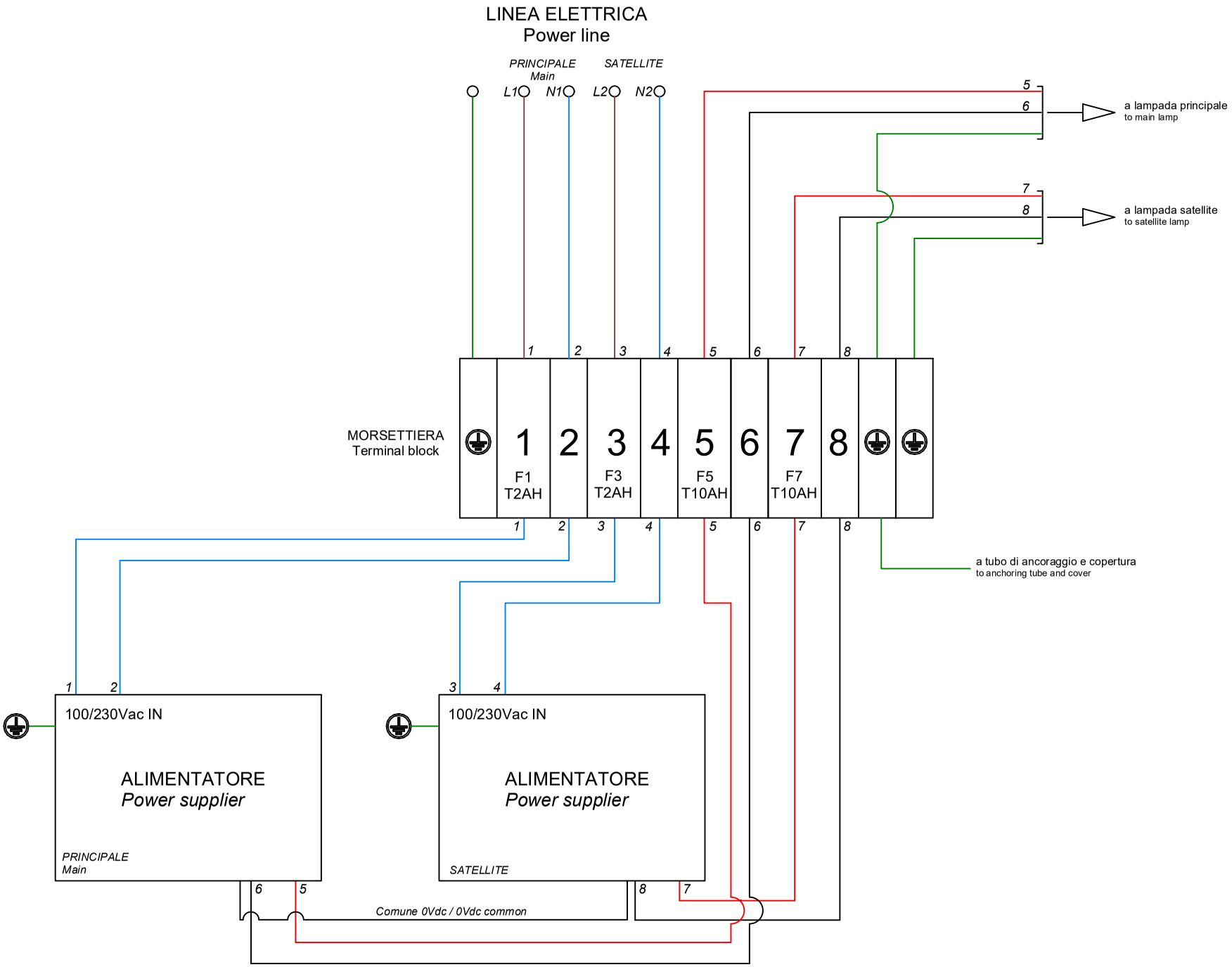
Notes



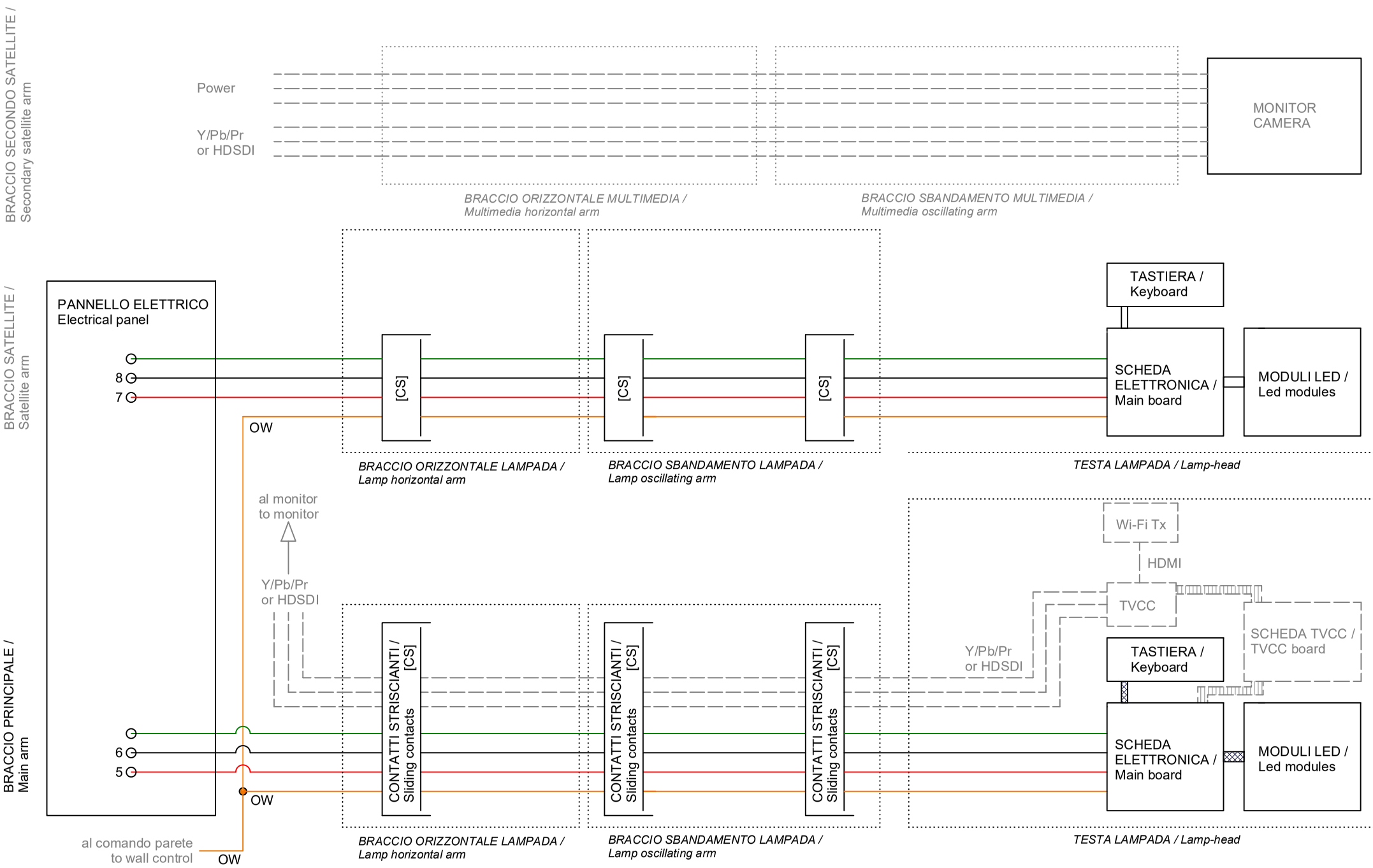
Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO SINGOLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Serie E Serie N Tris-Led	GIMAled GOLDEN ORION COMET-H COMET-L	ED506
Pag. 1 / 1	*Ceiling single lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



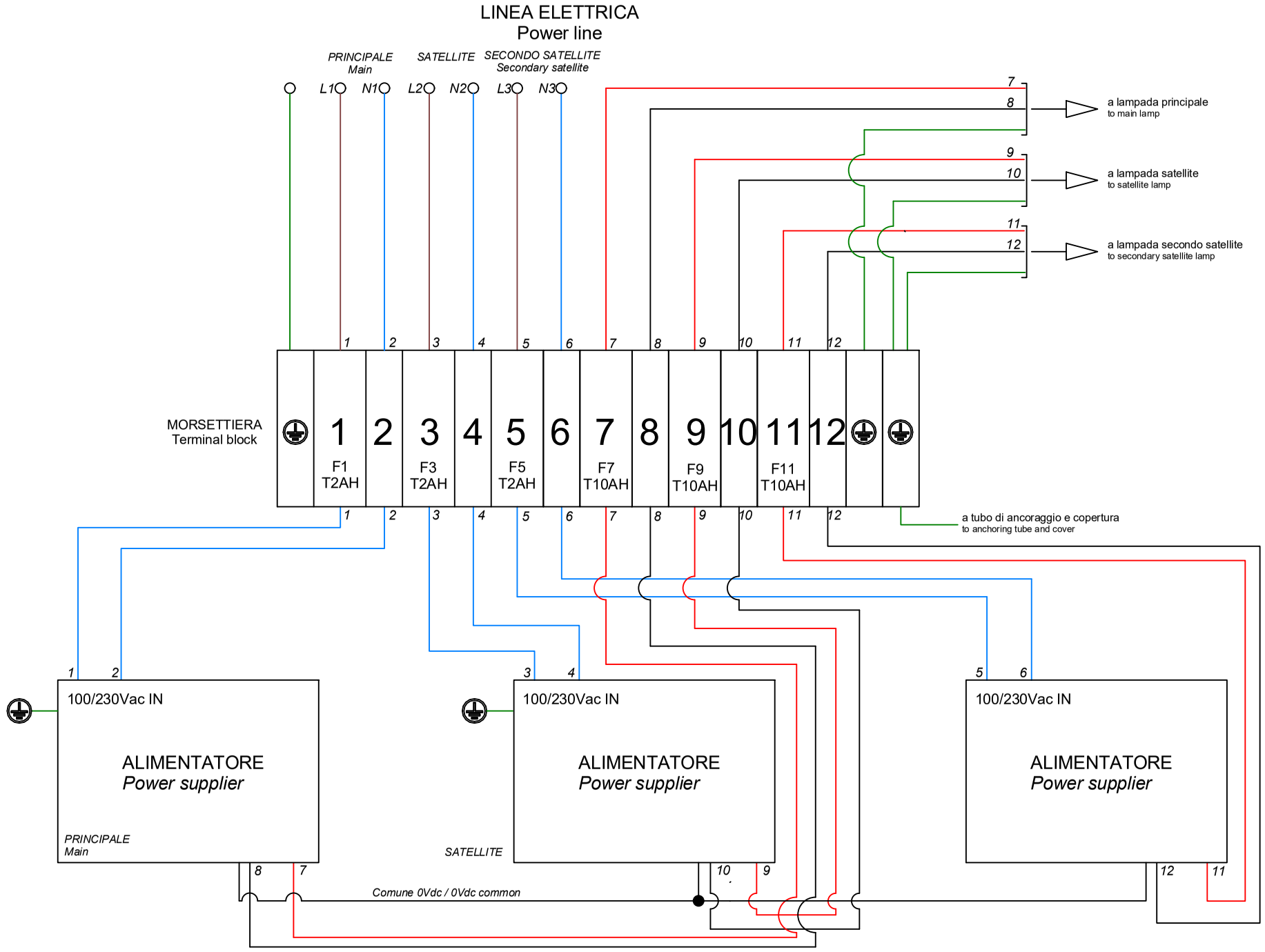
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION COMET-H COMET-L	ED509
Pag. 1 / 1	*Ceiling single lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



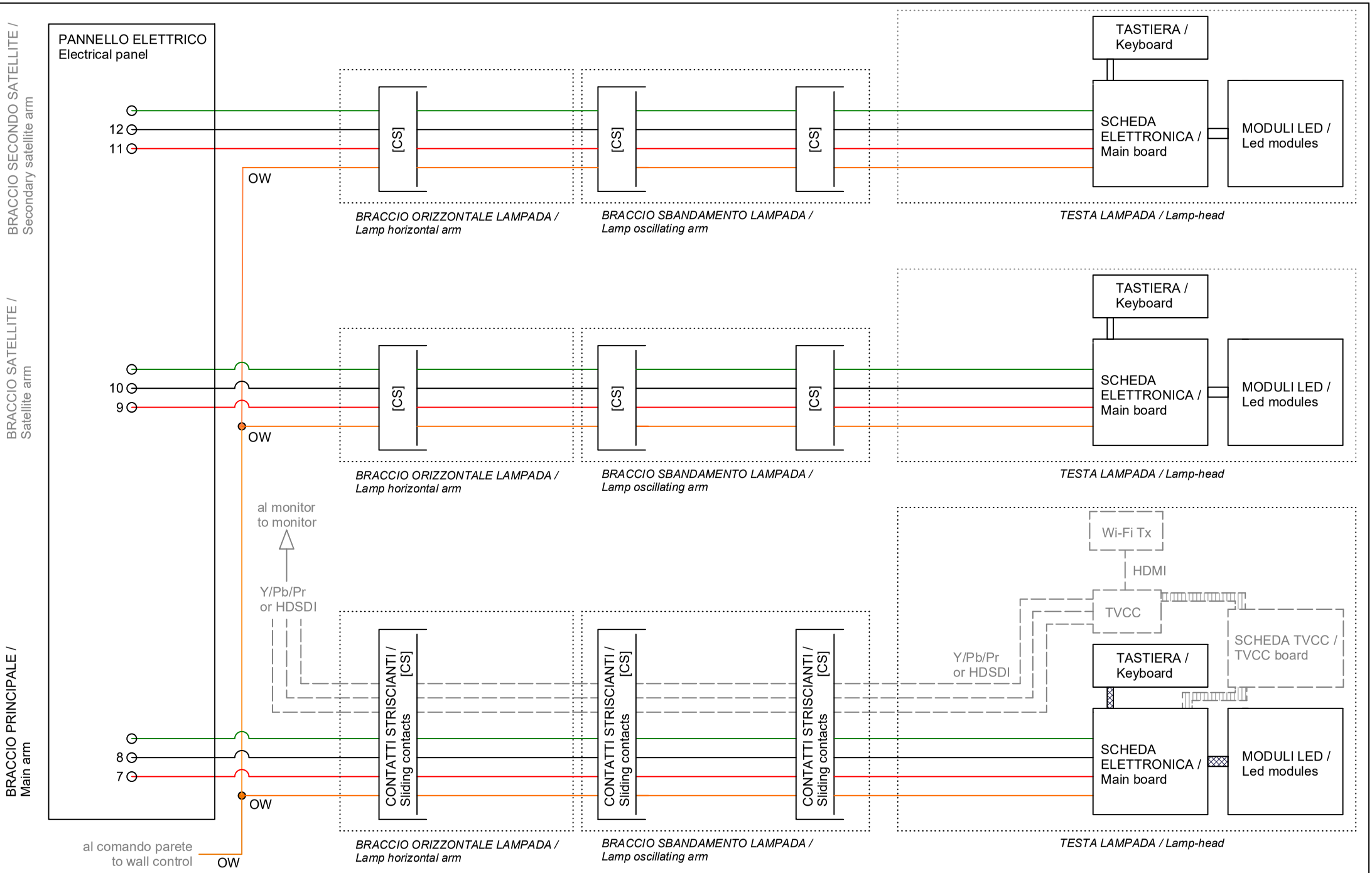
Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520	GIMA-led	ED507
Pag. 1 / 1	*Ceiling double lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*	U29 Serie E Serie N Tris-Led	GOLDEN ORION COMET-H COMET-L	



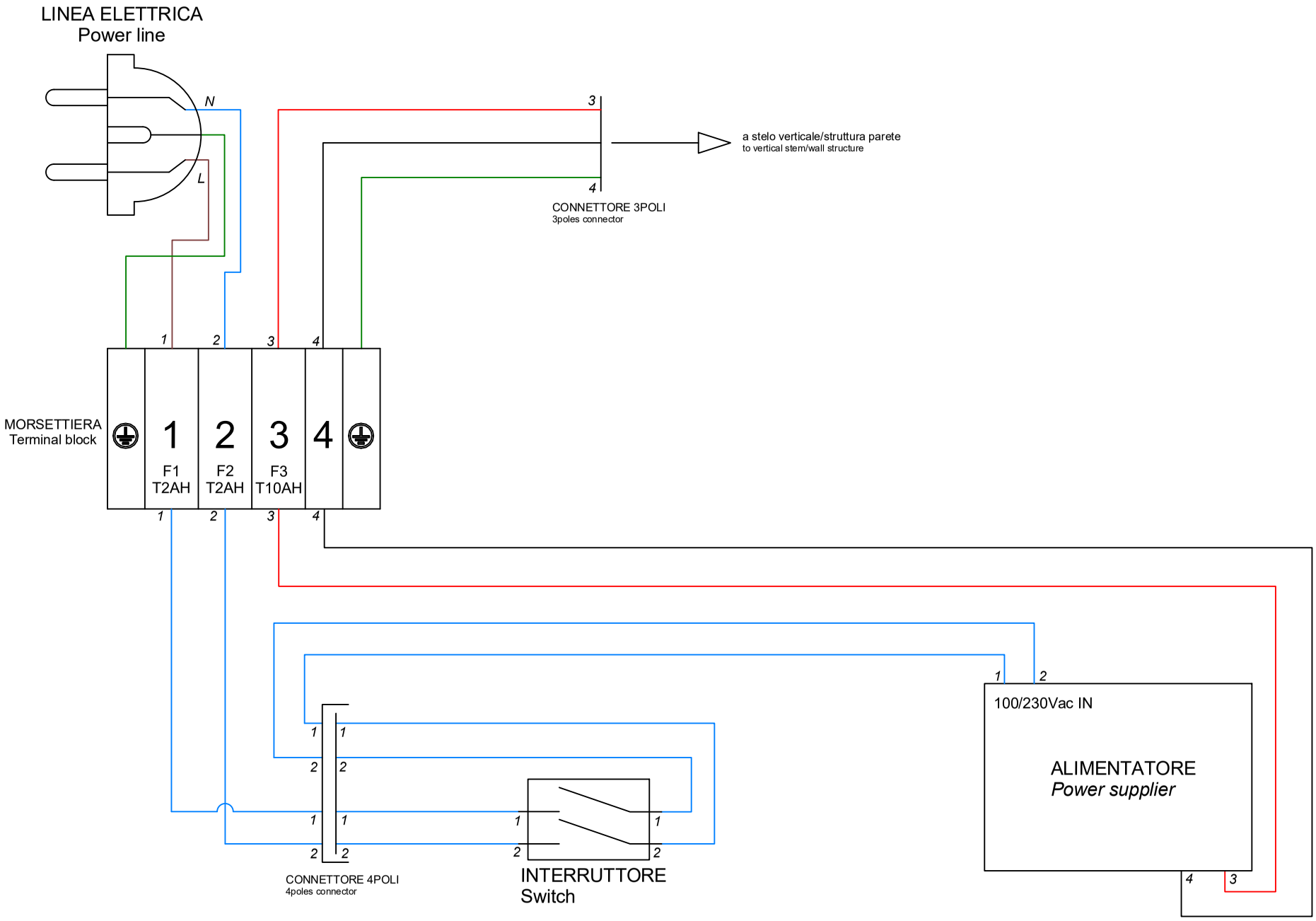
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION COMET-H COMET-L	ED510
Pag. 1 / 1	*Ceiling double lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



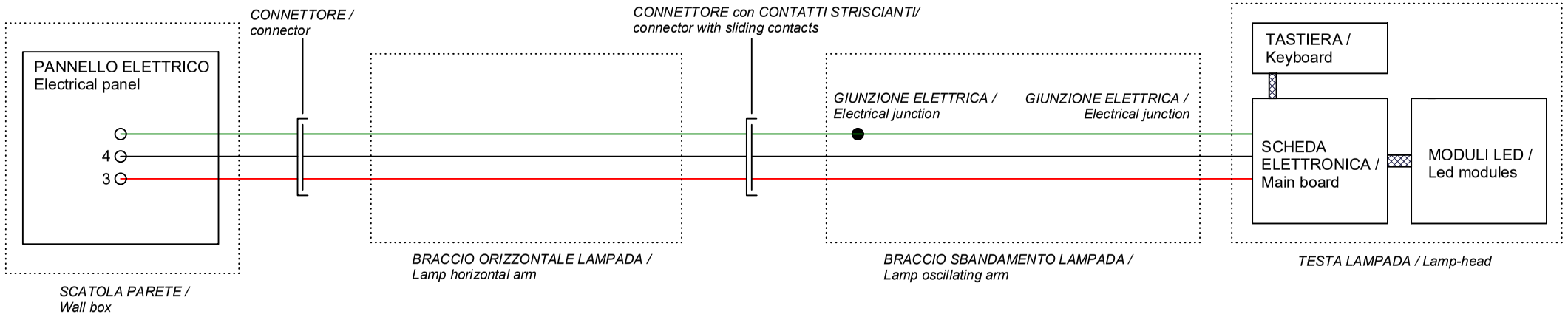
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO TRIPLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Serie E Serie N Tris-Led	ED508
Pag. 1 / 1	*Ceiling triple lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



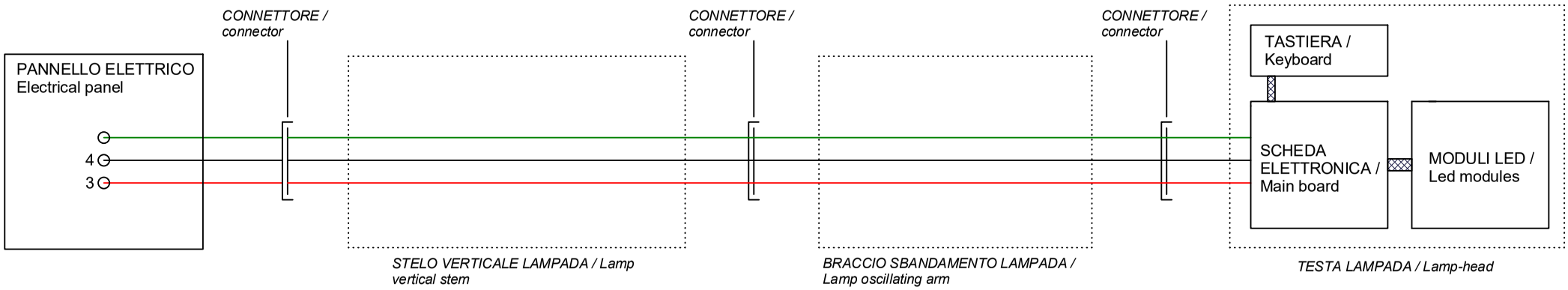
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO TRIPLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA U29 Serie E Serie N Tris-Led GIMAled GOLDEN ORION	ED511
Pag. 1 / 1	*Ceiling triple lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A PIANTANA/PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Pentaled30E Pentaled30N Tris-Led	GIMAled GOLDEN ORION	ED504
Pag. 1 / 1	*Mobile/Wall lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 26/08/2020	SCHEMA GENERALE PER LAMPADA A PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled30E Pentaled30N TRIS-LED GOLDEN ORION40	ED517
Pag. 1 / 1	*Wall lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A PIANTANA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	UNICA520 U29 Pentaled30E Pentaled30 N Tris-Led	GIMAled GOLDEN ORION	ED512
Pag. 1 / 1	*Mobile lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			