



INSTALLATION MANUAL

PENTALED 30E LIGHT

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

MI_027 Rev.2 08/07/2022 Page 1 of 30





Introduction

Marking C E

Compliance

Validity of manual

Customer Service

Copyright

Translations

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

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

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

This installation manual is valid for the following models:

PENTALED 30E LIGHT in single ceiling, double ceiling, wall and mobile versions.

The customer service is at your disposal in case of Product details, information concerning its use, identification of spare parts being required and for any other queries you might have concerning the appliance, for ordering spares and for matters relating to assistance and warranty.

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

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

MI_027 Rev.2 08/07/2022 Page 2 of 30





Index of contents

KEY	
1 GENERAL SAFETY INFORMATION	5
2 General information	
2.1 Operator qualifications	
2.2 Packaging, transport, storage and characteristics of installation premises	 A
2.3 Graphic signs and symbols used in the installation manual	0
2.4 Graphic symbols used on packaging	<i>7</i> 7
2.5 Graphic symbols used on the Product	γ Ω
2.6 Warranty and liabilities	q
2.7 Structural changes or variations	g
3 Instructions on how to prepare the premises mechanically	and
electrically	0 0
3.1 Preparing the premises mechanically (ceiling and wall version)	
3.2 Correctly wiring up the premises	3 10
4 Product installation	O
4.1 Parts included in the package4.2 Ceiling and wall drilling instructions	II
4.2 Centrig and wait ariting instructions	I
4.3.1 Installation of the ceiling plate and bar	
4.3.2 Arrangement bar ceiling version	
4.3.3 Installation of bar, switchboard and cover ceiling version	
4.3.4 Installation of structure to bar ceiling version	
4.3.5 Arrangement bar double ceiling version	
4.3.6 Installation of bar, switchboard and cover double ceiling version	
4.3.7 Installation of structure to bar double ceiling version	
4.3.8 Electrical connection	
4.4 Installation of Product in wall version	
4.4.1 Installation of plate with wall switchboard	
4.4.2 Installation of structure to plate	
4.4.3 Electrical connection	
4.5 Installation of Product in mobile version	24
4.5.1 Installation of lamp base	
4.5.2 Installation of swinging arm and head	25
4.5.3 Electrical connection	27
4.6 Protection fuses	
4.7 Handpiece fitting	27
4.8 Mechanical adjustments	27
4.9 First switch-on	28
4.10Check the result of Product installation and testing before use	
5 Troubleshooting	. 30



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PRODUCT

OPERATOR

RESPONSIBLE ORGANIZATION

TECHNICAL SERVICE PERSONNEL

KEY

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

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

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

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

- ⇒ Construction Engineer, Draughtsman, Building firm duly registered in the professional Register (for the masonry works)
- ⇒ Electrical Engineer Electro-technical expert qualified to work as an electrician (for the electrical works)

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

MI_027 Rev.2 08/07/2022 Page 4 of 30





GENERAL SAFETY INFORMATION

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

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

RIMSA 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 RIMSA.

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

Electric shock hazard.

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

08/07/2022 MI_027 Rev.2 Page 5 of 30





Installation

Use

Cleaning

Routine maintenance

Special maintenance

Assistance

Demolition

Packing

Transport

Storage

Installation premises

2 General information

2.1 Operator qualifications

Qualification of personnel in charge of operating on the Product: Installer and/or qualified technician.

Professional medical personnel.

Properly trained medical and paramedical personnel.

Qualified technician with required technical-professional skills.

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

RIMSA or authorized Dealer.

Comply with applicable laws on waste disposal. This product must not be disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through authorized channels so as to ensure correct recycling.

2.2 Packaging, transport, storage and characteristics of installation premises

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

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

Temperature (°C): -15 / +60

Humidity: 10 / 95 %

Atmospheric pressure (h/Pa): 500 / 1060

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

Temperature (°C): -15 / +60

Humidity: 10 / 95 %

Atmospheric pressure (h/Pa): 500 / 1060

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

Temperature (°C): +10 / +40

Humidity: 30 / 75 %

Atmospheric pressure (h/Pa): 700 / 1060

MI_027 Rev.2 08/07/2022 Page 6 of 30





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)

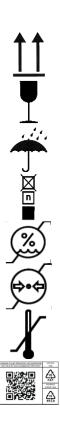
Limit temperature (max limit at top right and min limit at bottom left)

Materials and composition









MI_027 Rev.2 08/07/2022 Page 7 of 30





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'N'

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11′

'O'





2.5 Graphic symbols used on the Product

Below are the symbols to be found on the Product:

CE marking indicating the Product conforms to 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

Disposal

Protection earth

Neutral lead connection point

Line lead connection point

ON

OFF

Standby and switch-on

No stepping on surface

MI_027 Rev.2 08/07/2022 Page 8 of 30





2.6 Warranty and liabilities

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

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

2.7 Structural changes or variations

No arbitrary structural changes or variations to the Product are admitted. Any modifications must have the prior written authorization of RIMSA. 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)

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

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

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

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

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).

CAUTION



Carry out safe masonry works.



Collapse of the building structure.



Make sure that ceiling or wall is adequate.

MI_027 Rev.2 08/07/2022 Page 9 of 30





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.

Carry out safe electrical works.



Make sure that the electrical environment complies with the law.

Main switch

CAUTION

3.2 Correctly wiring up the premises

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

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

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

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

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.

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

4 Product installation

Before proceeding to install the Product, first of all check the presence of all the packaging and that this is in good condition and has not been damaged during transport.

Claims will only be taken into consideration if the seller or carrier has been immediately notified. All claims must be made in writing. Goods always travel under the responsibility and at the risk of the buyer.

Keep the original packaging in case the Product has to be redispatched.

Personnel required:



MI_027 Rev.2 08/07/2022 Page 10 of 30





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
- Saw with metal blade (ceiling version only)
- 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

The Product is supplied complete with lamp, sterilisable handpiece, bar tube 1100mm long, bar plate, counter-plate for fastening to the ceiling, bar cover with relative safety ring and nuts for bar fastening. RIMSA does not provide any kind of anchoring for fastening the plate to the ceiling. Such equipment must all be provided by the installer.

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

The Product is supplied complete with lamp, sterilisable handpiece, stem, wheeled base and plastic base cover.

4.2 Ceiling and wall drilling instructions

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

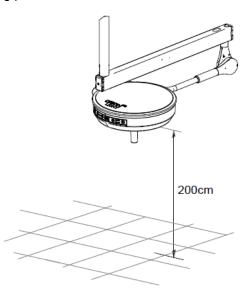
The length of the bar is calculated to install the Product at a finished height off the floor of around 200 cm (as per drawing next), unless otherwise requested by the RESPONSIBLE ORGANIZATION.

Ceiling version

Wall version

Mobile version

Fixing positions

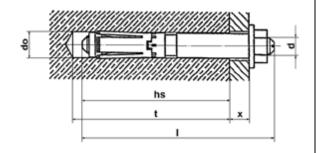


MI_027 Rev.2 08/07/2022 Page 11 of 30



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Reinforced concrete Mechanical anchoring

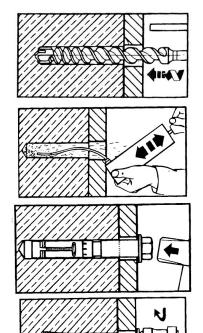


By way of example only, below is a list of some types of walls: Proceed to fasten the wall plate using 8 x Hilti HSL-3-G M8/20 screw anchors (6 x HAM M6x50 anchors for the wall version) or other anchors with similar characteristics, carefully following the instructions provided by the anchor manufacturers and shown below for information purposes:

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

I 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 8/20	12	80	60	98	25	13	20
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

- 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.

MI_027 Rev.2 08/07/2022 Page 12 of 30



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Chemical anchoring

Hollow-core concrete

Ceiling version



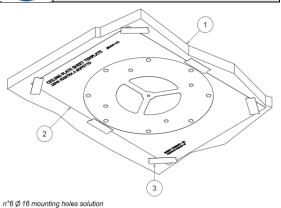
Do not install the Product on unsuitable ceilings.

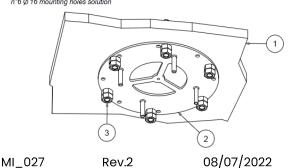
Wall version



Do not install the Product on unsuitable walls.

Make sure the Product is stable.





7. After one hour, again tighten the tie-rods to the prescribed tightening torque.

Drill the ceiling/wall using the template provided. Insert the resin inside the 8/6 drilled holes and fill the hole, carefully following the manufacturer's instructions. RIMSA recommends using HILTI HIT-HY 270 resin or similar products.

Fit 8/6 threaded bars into the holes. RIMSA recommends M8 bars and M6 for wall versions. Proceed to fasten the ceiling plate with nuts and locknuts for each tie-rod and tighten using the Allen key.

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

The plate and counter-plate must be fastened together using suitable M8 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.

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

4.3 Instructions for ceiling version of Product

4.3.1 Installation of the ceiling plate and bar

Make sure the bar (anchoring tube) is perfectly level to ensure the Product is stable.

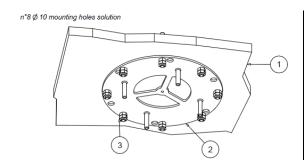
Position the template (drawing 51) (2) on the ceiling (1) and secure it with adhesive tape (3).

Make the holes according to indications in paragraph 4.2.

Unscrew the counter-plate from the plate, hence fasten the counter-plate (2) to the ceiling (1) using the nuts and locknuts (3).

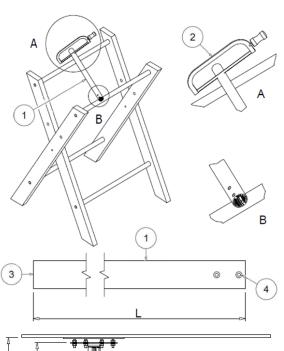


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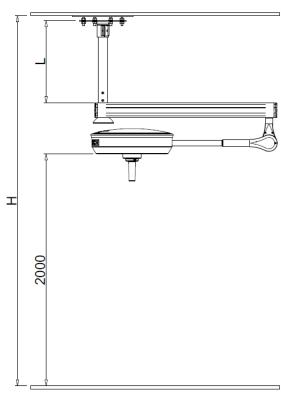
4.3.2 Arrangement bar ceiling version

The bar (1) is supplied in standard length 1100 mm. Using the saw (2), cut the tube to the desired size according to the height of the room (make the cut on the side of the tube (3), opposite to that bearing the fastening holes (4) of the horizontal arm).



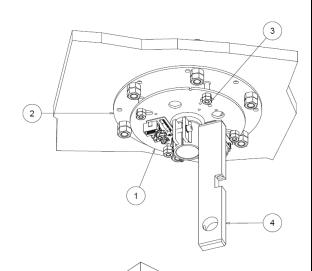
To determine the correct length of the tube, use the chart shown (suggested installation height is 2000 mm). It is not advisable to cut the bar to a length below 300 mm to avoid covering installation problems.

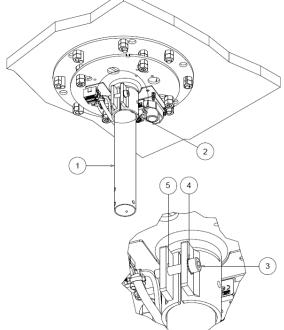
H [mm]	L [mm]
2565	300
2665	400
2765	500
2865	600
2965	700
3065	800
3165	900
3265	1000
3365	1100











Product falling hazard.

4.3.3 Installation of bar, switchboard and cover ceiling version

Fasten the plate (1) to the threaded pins of the ceiling counter-plate (2) using the nut and locknut (3). Using a spirit level (4), make sure the plate is correctly fastened.

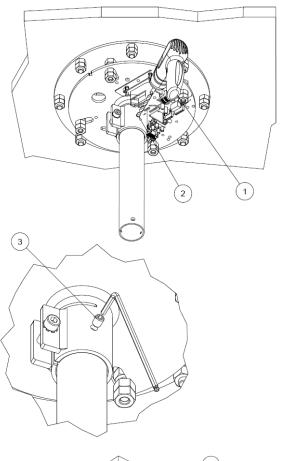
Insert the connection cables coming from the switchboard into the anchoring tube (1) (with cut side upwards) and the anchoring tube (1) flush with the ceiling plate hub (2).

To block the tube, tighten the screw (3) with the toothed washer (4) in the threaded hole (5). Tightened this way, the hub will ensure that the tube is sealed.

MI_027 Rev.2 08/07/2022 Page 15 of 30



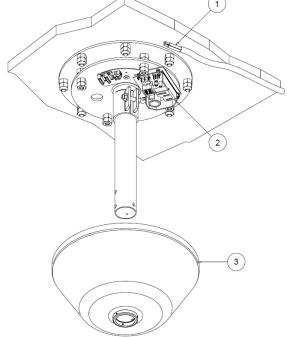




Using a drill (1), make a 6 mm diameter hole on the tube where the M8 hole (2) is located on the plate hub. Then fit and tighten the tapered tip M8 dowel (3) until this presses on the previously made hole.

Make sure the mains power cable (1) reaches the Product power board (2).

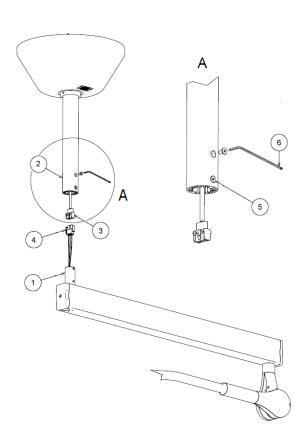
Before proceeding position the cover (3).



MI_027 Rev.2 08/07/2022 Page 16 of 30







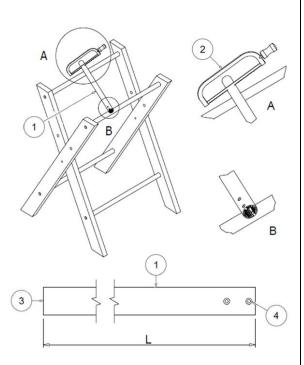
4.3.4 Installation of structure to bar ceiling version

Align the pin of the horizontal arm (1) with the bar (2) and make the electrical connections (3) and (4).

Fit the pin (1) in the tube (2), making it coincide with the retention holes and, using a hexagon spanner (6) secure it with screws (5).

4.3.5 Arrangement bar double ceiling version

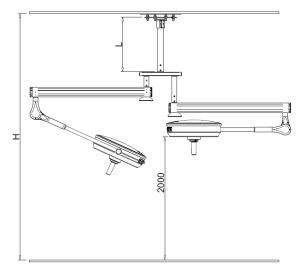
The bar (1) is supplied in standard length 1100 mm. Using the saw (2), cut the tube to the desired size according to the height of the room (make the cut on the side of the tube (3), opposite to that bearing the fastening holes (4) of the horizontal arm).



MI_027 Rev.2 08/07/2022 Page 17 of 30







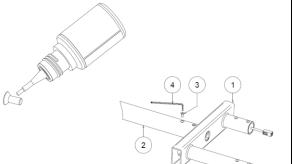
To determine the correct length of the tube, use the chart shown (suggested installation height is 2000 mm). It is not advisable to cut the bar to a length below 200 mm to avoid covering installation problems.

H [mm]	L [mm]
2695	200
2795	300
2895	400
2995	500
3095	600
3195	700
3295	800
3395	900
3495	1000
3595	1100

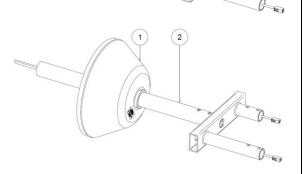
4.3.6 Installation of bar, switchboard and cover double ceiling version

Place the anchoring tube (1) and the double joint (2) on a protected surface.

Insert the cables and the double joint (2) into the anchoring tube (1).



Using a hexagonal spanner (4), fix the double joint (1) to the anchoring tube (2) by tightening the four screws (3). It is recommended add some glue to fix the screws.

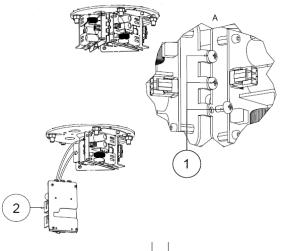


Insert the cover of the electrical panel (1) on the anchoring tube (2).

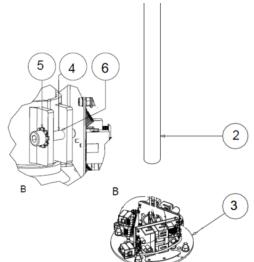
MI_027 Rev.2 08/07/2022 Page 18 of 30



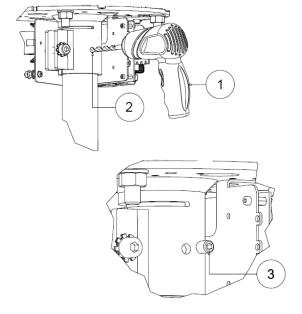




Place the electrical panel next to the top of the anchoring tube. Unscrew the 3 screws of the switchboard (1) and leave the plate with the power supply to one side (2).



Insert the anchoring tube (2) in the ceiling plate hub (3). To block the anchoring tube (2), tighten the screw (4) with the toothed washer (5) in the threaded hole (6). Tightened this way, the hub will ensure that the tube is sealed.

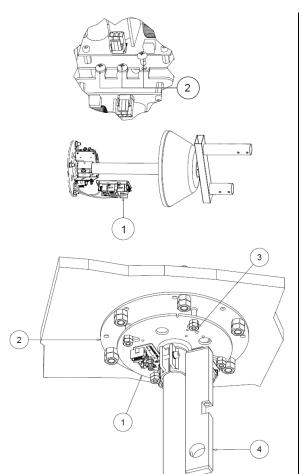


Using a drill (1), make a 6 mm diameter hole on the tube where the M8 hole (2) is located on the plate hub; then fit and tighten the tapered tip M8 dowel (3) until this presses on the previously made hole.

MI_027 Rev.2 08/07/2022 Page 19 of 30





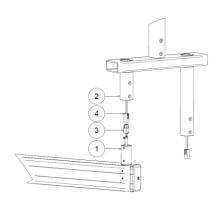


Then put back in place the plate with the power supply (1) and screw the 3 screws of the switchboard (2).

Fasten the plate (1) to the threaded pins of the ceiling counter-plate (2) using the nut and locknut (3). Using a spirit level (4), make sure the structure is correctly fastened.



Product falling hazard.



4.3.7 Installation of structure to bar double ceiling version

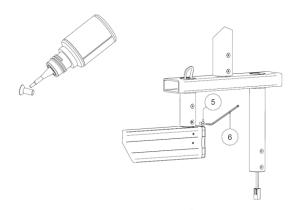
Align the pin of the horizontal arm (1) with the hub of the anchoring tube (2).

Connect the connectors (3) and (4).

MI_027 Rev.2 08/07/2022 Page 20 of 30





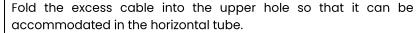


Fit the pin in the tube, making it coincide with the retention holes and, using a hexagon spanner (4) secure it with screws (3).

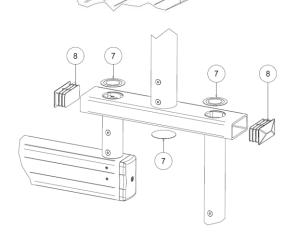
Use a hook to pull the cables out of the top hole.

It is recommended to add some glue to fix the screws.

Repeat the procedure for the second arm of the Product.



Repeat the procedure for the second arm of the Product.



After completing installation, close the openings using adhesive labels (7) and plastic caps (8).



Electric shock hazard.



Strictly follow the wiring diagram for the correct connection.



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.

4.3.8 Electrical connection

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

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

RIMSA does not supply the mains supply cables.

The power unit is fixed to the tiges plate.

Connect the cables (red and black) coming out of the lamp in the respective positive and negative terminals (+ and -) of electrical panel.

In case of double lamp, carry out the operation respecting the distinction of the cables in "cable A" and "cable B" on the cable and on the terminal board.

MI_027 Rev.2 08/07/2022 Page 21 of 30



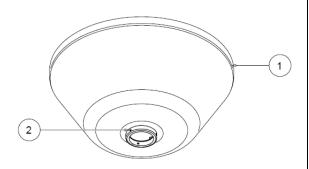




comply with the line and neutral connection indications. An inverted connection would lead to the lack of fuse protection.



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



Connect the line and neutral cables (L and N) coming from the power supply network to terminals such as L and N. In case of double lamp, carry out the operation for both connected devices.

Connect the earth cable(s) (ⓐ) coming from the network to the dedicated screw.

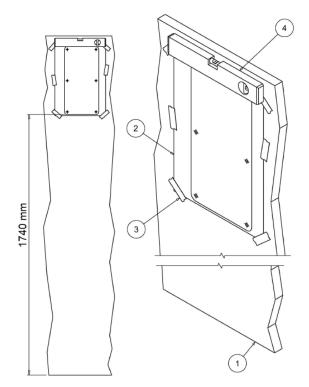
Finally, connect the earth cable () coming from the lamp and the cover to the same dedicated screw.

In case of double lamp, make sure you have connected the earth cables (((a))) from both lamps A and B and the cover to the same dedicated screw.

Once the electrical connection is completed, place the cover (1) against the ceiling and fix with the 3 conical-tipped screws (2).



Make sure the product is stable.



4.4 Installation of Product in wall version

4.4.1 Installation of plate with wall switchboard

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.

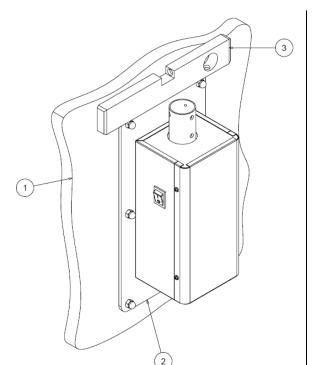
Make the holes as indicated in paragraph 4.2.

It is recommended to fix the plate at a height of about 1740 mm.

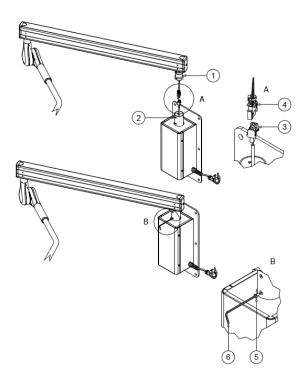
MI_027 Rev.2 08/07/2022 Page 22 of 30







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



4.4.2 Installation of structure to plate

Align the pin of the horizontal arm (1) with the box tube (2). Connect the connectors (3) and (4).

Fit the pin in the tube, making it coincide with the holes, then using a hexagon spanner (6) secure it with screws (5).

4.4.3 Electrical connection

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

MI_027 Rev.2 08/07/2022 Page 23 of 30

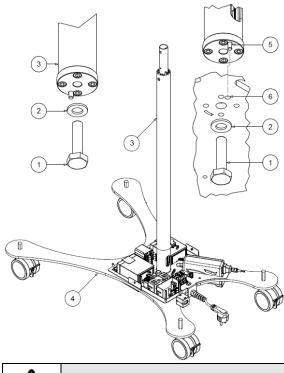


EN

4.5 Installation of Product in mobile version

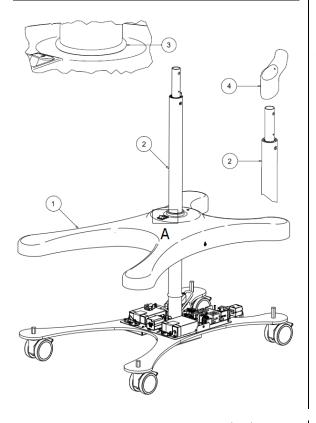
4.5.1 Installation of lamp base

Remove the screw (1) and the washer (2) from the lower stem (3). Position the lower stem (3) on the base (4), matching the centring pin (5) to the corresponding hole of the base (6); then position the washer (2) and fasten the screw (1).





Instability and overturning hazard.



If the centring pin is not properly fitted in the corresponding hole of the base, the risk of instability could exist with possible Product overturning.

Insert the cover (1) and the retaining ring (3) along the lower stem (2).

Then insert the cable reel (4) along the lower stem (2).

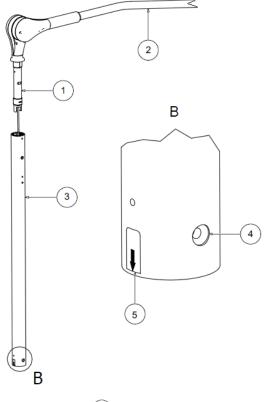
MI_027 Rev.2 08/07/2022 Page 24 of 30







Insert the connection cables and the swinging arm (1) of the lamp (2) into the upper stem (3), orientating it so that the 2 countersunk holes (4) and the label with arrow (5) are at the bottom of the stem.



Insert the swinging arm (1) completely into the upper stem (2), keeping it oriented as shown in the picture.

Assemble the parts by inserting and tightening the fixing screw (3); the screw must pass inside the rotation stop slots of the vertical tube of the swinging arm.

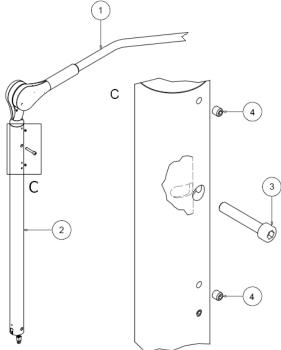


An incorrect orientation of the stem will prevent its complete insertion.

Attention!

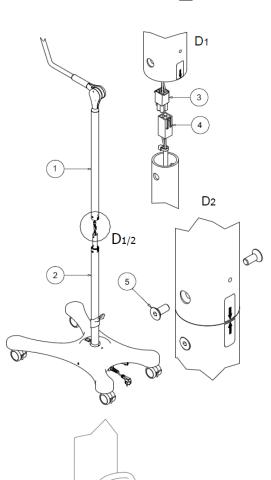
When inserting the screw, make sure not to crush the internal cables.

Then insert and lightly tighten the 2 friction dowels (4).



08/07/2022 MI_027 Rev.2 Page 25 of 30







Align the upper stem (1) and the lower stem (2) and make the electrical connections (3) and (4).

Insert the upper stem along the connection pin.

Attention!

Couple the stems by orienting them so that the labels with arrows correspond.

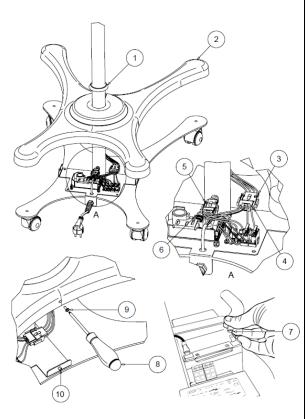
Then fasten with 2 screws (5).

Lift the cable reel (1) up to the joint between the two stems and secure it with a screw (2).

MI_027 Rev.2 08/07/2022 Page 26 of 30







4.5.3 Electrical connection

Lift the retaining ring (1) and the covering (2) by 30-40 cm to easily access the electrical section. Join the connectors (3) to (4) and (5) to (6).

For battery models connect the battery faston (7) that is disconnected

Once the electrical connection is completed, place the covering (2) in position and, using a screwdriver (8), fasten it by means of the screws (9) to be fastened to the threaded bush (10).

Finally, position the retaining ring (1) on the covering (2).

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 an input fuse (L) in the ceiling version and by two input fuses (L, N) for the wall and mobile version, T2AH 250V 5x20 type, which are already connected in the switchboard.

4.7 Handpiece fitting

Insert the handpiece up tight on the support and turn it until the steel lever engages in its original place and rotation is blocked. Finally make sure the handpiece is well secured.

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.

MI_027 Rev.2 08/07/2022 Page 27 of 30





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 wall and mobile versions only;
- 3. Close the switch upstream of the system;
- 4. Move the Product switch located on the base cover for the mobile version and on the power box for the wall version respectively to position "I" (ON);
- 5. Press the **O** keyboard positioned on the lower part of the Product cupola.
- 6. Make sure all LEDs and functions are working properly.

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

MI_027 Rev.2 08/07/2022 Page 28 of 30





4.10 Check the result of Product installation and testing before use

Ticking the requirements listed below, if applicable to the Produc	21
version, is mandatory to ensure correct installation.	

VCI	sion, is mandatory to ensure correct installation.	
1.	Make sure the ceiling/wall is suitable for Product installation.	
	the ceiling or that the wall plate is horizontal with the wall.	
3.	Make sure the bolt is tight on the plate hub to fasten the bar.	Ш
	Make sure the hole has been made properly and that the safety dowel has been fitted on the bar.	
	Make sure the screws sustaining the horizontal arm are tight (ceiling and wall versions).	
	Make sure the stem guide is correctly fitted in the base centring slot (mobile version).	
	Check the Product earth connection and make sure the clamps are well tightened.	
	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.	
Sto	amp and signature of TECHNICAL SERVICE PERSONNEL:	

MI_027 Rev.2 08/07/2022 Page 29 of 30





Possible Product damage.



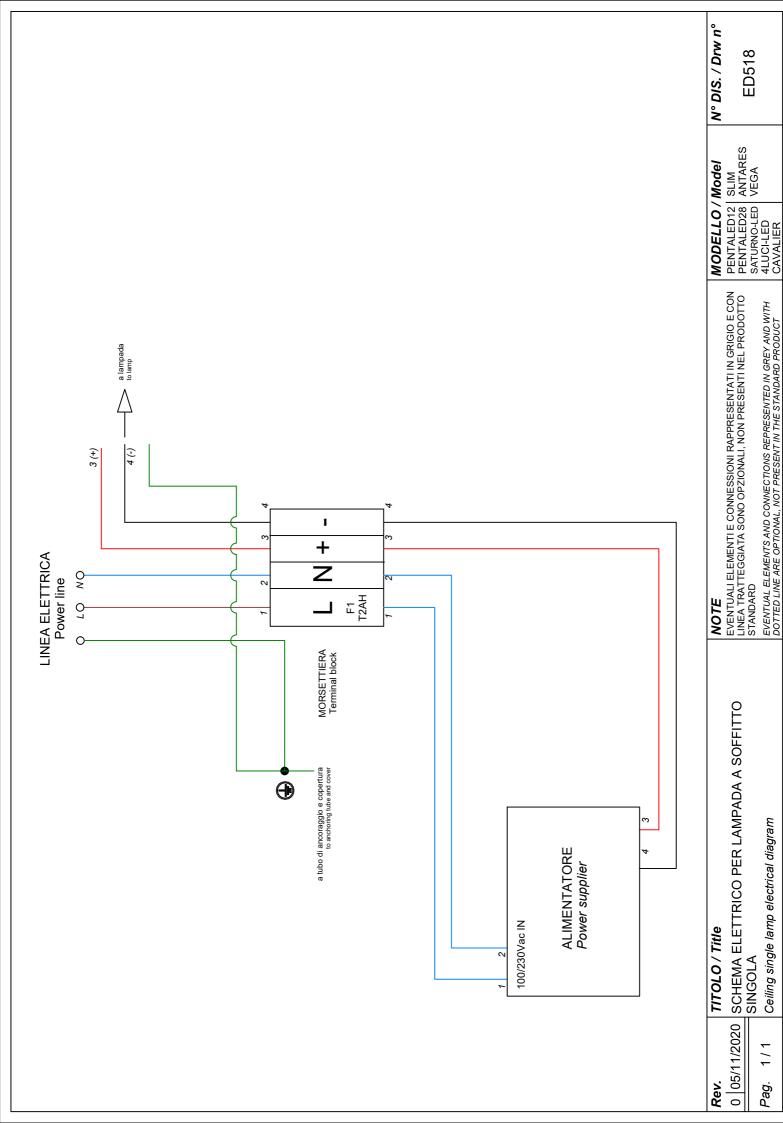


Presence of dangerous voltage.

5 Troubleshooting

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 section 7 of 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.

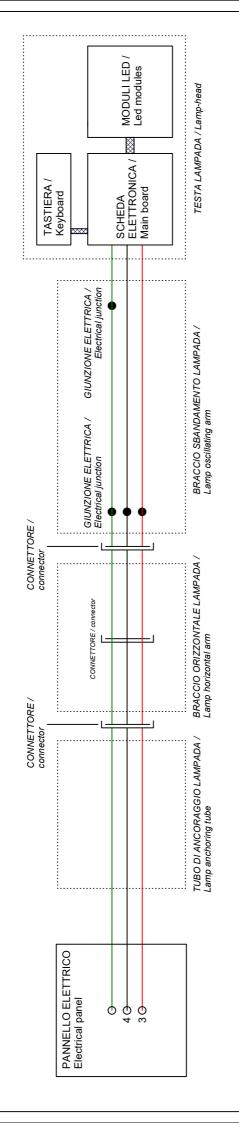
08/07/2022 Page 30 of 30 MI_027 Rev.2



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

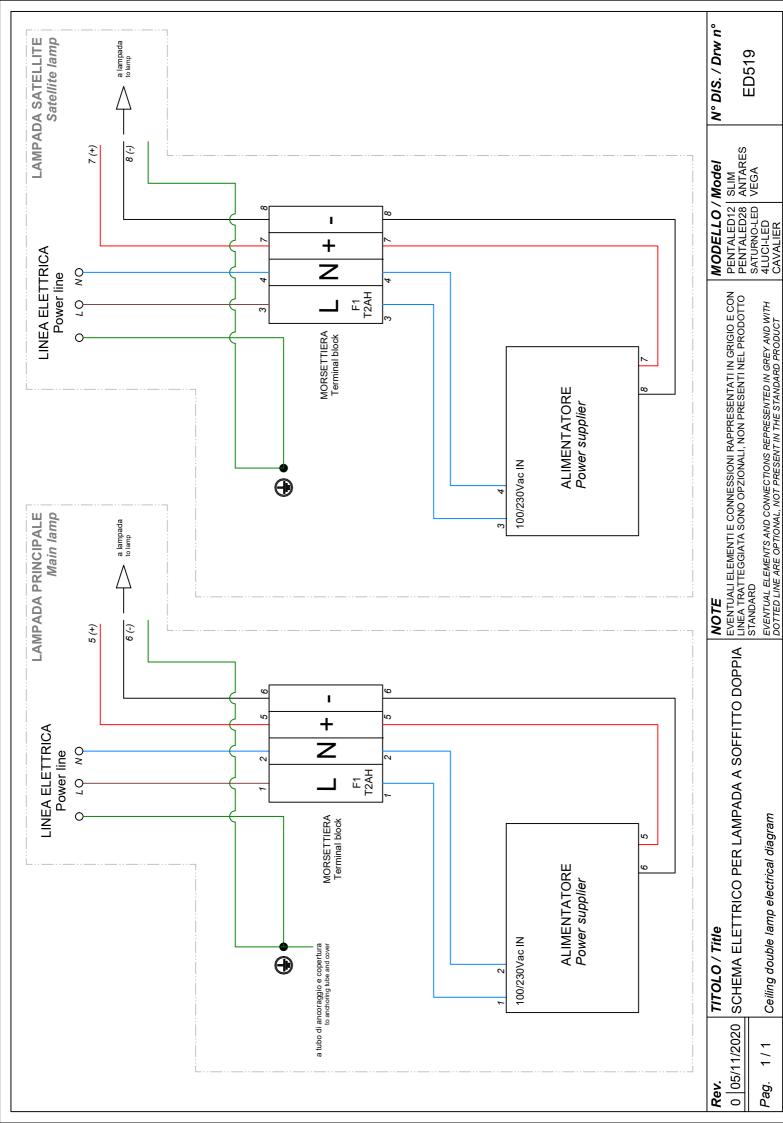
Ceiling single lamp electrical diagram

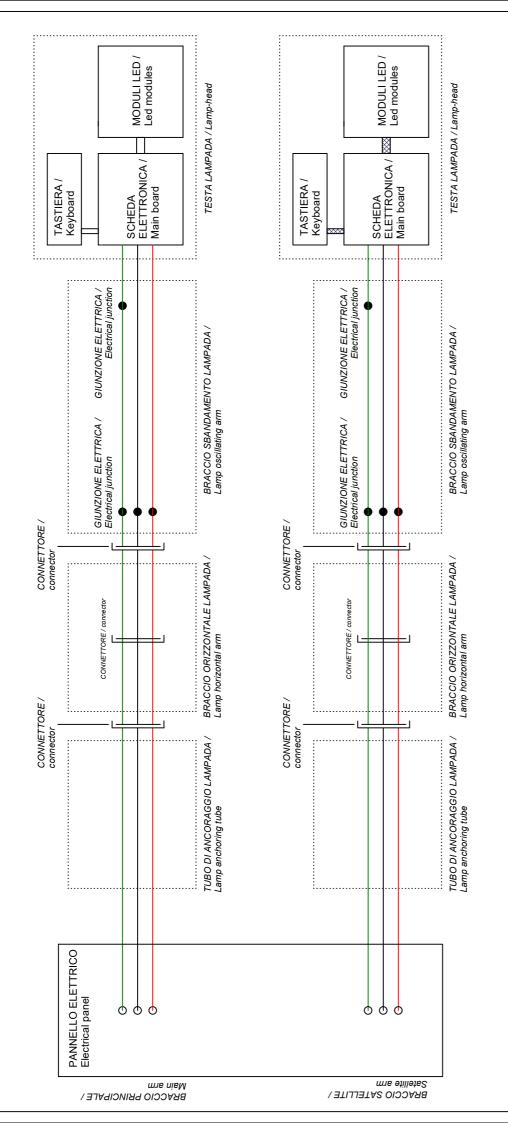
Pag. 1/1



Rev.	TITOLO / Title	NOTE	МОРЕГГО
0 07/05/2020	0 07/05/2020 SCHEMA GENERALE PER LAMPADA A SOFFITTO SINGOLA	ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON TEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO	Pentaled12 Pentaled28
		STANDARD	Saturno-led
Pag. 1/1	Ceiling single lamp general plantring diagram	EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH	SLIM
•	3	DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT	CAVALIER

N° DIS. / Drw n°





SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA Ceiling double lamp general electrical diagram TITOLO / Title

0 07/05/2020

Rev.

Pag. 1/1

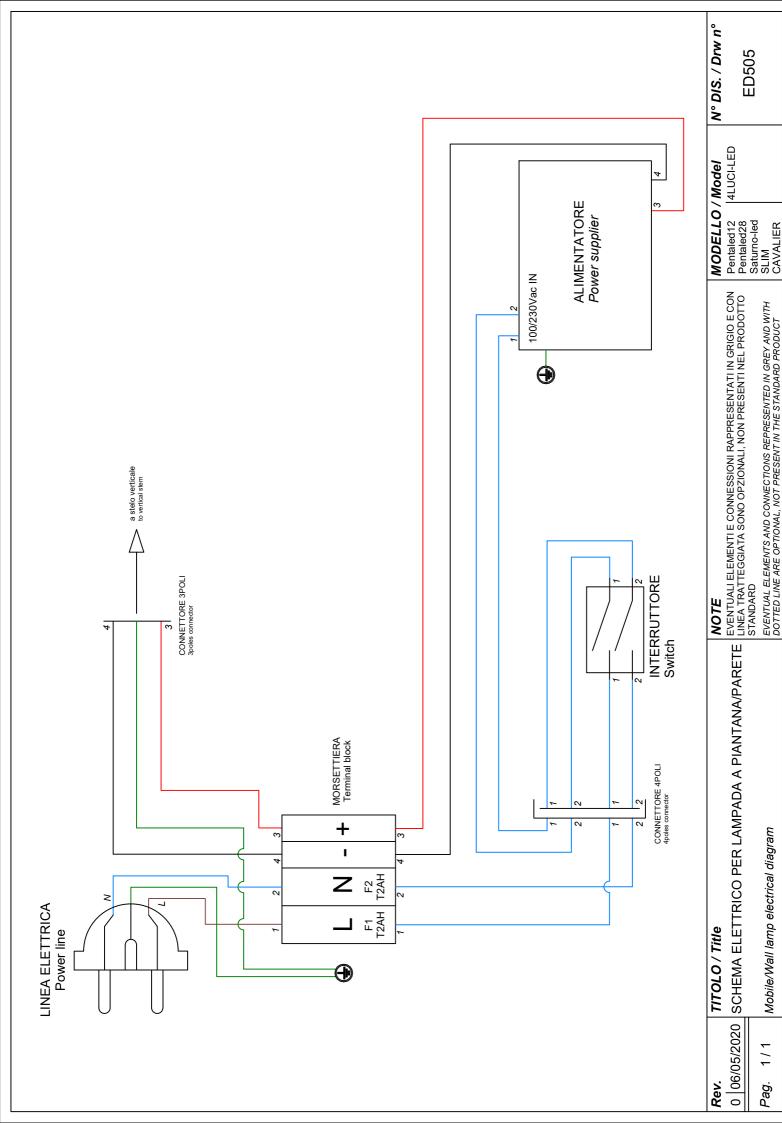
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MODELLO / Model Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER

4LUCI-LED

ED515

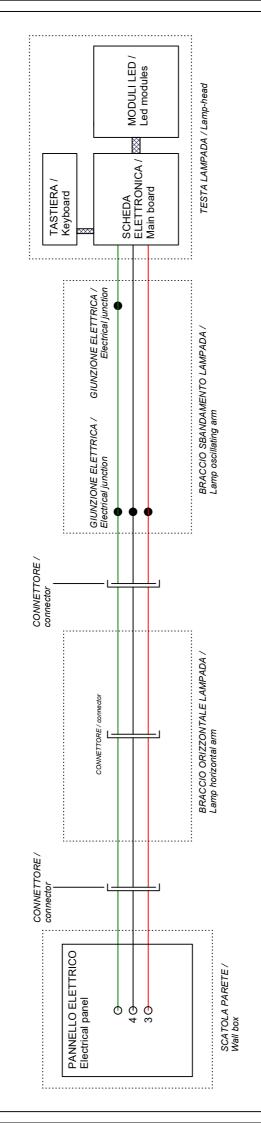
N° DIS. / Drw n°



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

Mobile/Wall lamp electrical diagram

Pag. 1/1



SCHEMA GENERALE PER LAMPADA A PARETE TITOLO / Title 0 07/05/2020 Rev.

Wall lamp general electrical diagram

Pag. 1/1

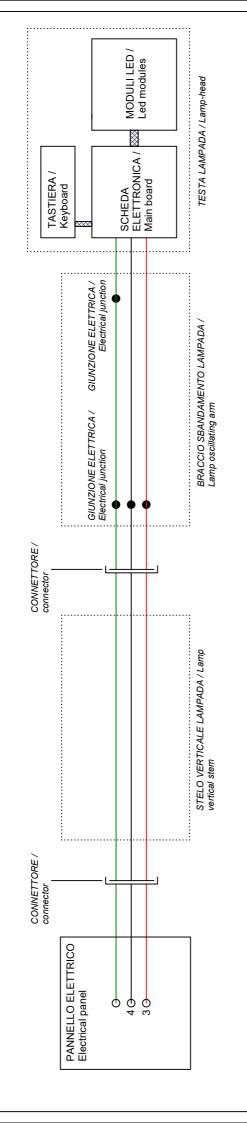
EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

MODELLO / Model Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER

4LUCI-LED

ED516

N° DIS. / Drw n°



Rev.TITOLO / Title0 | 07/05/2020SCHEMA GENERALE PER LAMPADA A PIANTANAPag. 1 / 1Mobile lamp general electrical diagram

EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD

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

MODELLO / Model
Serie UNICA CAVALIER
Pentaled 12 4 LUCI-LED
Pentaled 28 Satumo-led
SLIM

ALIER ED513





OPERATION AND MAINTENANCE MANUAL

PENTALED 30E LIGHT

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

MU_034 Rev.3 20/02/2023 Page 1 of 34





Introduction

Marking (E

Compliance

Validity of manual

Customer Service

Copyright

Translations

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

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

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

This installation manual is valid for the following models:

 PENTALED 30E LIGHT in single ceiling, double ceiling, wall and mobile versions.

The customer service is at your disposal in case of Product details, information concerning its use, identification of spare parts being required and for any other queries you might have concerning the appliance, for ordering spares and for matters relating to assistance and warranty.

- RIMSA P. LONGONI SRL
- Via Monterosa 18
- I-20831 Seregno MB
- Tel.: ++39 0362 325.709
- Fax: ++39 0362 328.559
- E-mail: info@rimsa.it

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.

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

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

MU_034 Rev.3 20/02/2023 Page 2 of 34





Index of contents

KEY		5
1 G	ENERAL SAFETY INFORMATION	6
2 In	nportance of personal safety	6
2.1	Intended use	6
2.2	Intended useSafety conditions (secondary effects)	
2.3	Environmental conditions	7
3 G	eneral information	8
3.1	Operator qualifications	8
3.2	Patient population and body interactions	8
3.3	Graphic symbols used in this operation and maintenance manual	9
3.4	Graphic symbols used on the Product	9
4 Pr	recautions for the Product operator	10
4.1	Personnel awareness obligation	10
4.2	Warranty and liabilities	
5 Pr	roduct description and operation	11
5.1	Product description	11
5.2	Description of operation	
5.3		14
	3.1 Brakes for mobile version	
	3.2 Moving the stand	<u>17</u>
5.4		<u>17</u>
	leaning and disinfecting	
6.1	Application method	
6.2	Cleaning the Product	
6.3	Product disinfecting	
6.4	Handpiece sterilization	19
	djustment and maintenance	
7.1	Swinging arm adjustment	
7.2	Clutch adjustment	20
7.3	Periodical checks to be performed on the Product	21
7.4	Routine maintenance	
7.5	Repairs	ZZ
7.6 7.7	Disposal after useSpare parts list	
0 T	echnical properties	24 26
8 Te	tommour properties	∠5 77
9 EL	J Declaration of conformity	21
	MC Declaration	
11 W	/arranty Certificate	33

20/02/2023





BG	За да поискате наръчника на този език, изпратете имейл на адрес info@rimsa.it.
CS	Chcete-li si vyžádat příručku v tomto jazyce, zašlete e-mail na adresu info@rimsa.it.
DA	Hvis du ønsker at få manualen på dette sprog, bedes du sende en e-mail til info@rimsa.it.
DE	Um das Handbuch in dieser Sprache anzufordern, senden Sie bitte eine E-Mail an info@rimsa.it.
EL	Για να ζητήσετε το εγχειρίδιο σε αυτή τη γλώσσα, στείλτε μήνυμα ηλεκτρονικού ταχυδρομείου στη διεύθυνση info@rimsa.it.
ES	Para solicitar el manual en este idioma, envíe un correo electrónico a info@rimsa.it.
ET	Selles keeles käsiraamatu tellimiseks saatke palun e-kiri aadressile info@rimsa.it.
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GA	Chun an lámhleabhar sa teanga seo a iarraidh, seol r-phost chuig info@rimsa.it.
HR	Da biste zatražili priručnik na ovom jeziku, pošaljite e-mail na info@rimsa.it.
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LV	Lai pieprasītu rokasgrāmatu šajā valodā, lūdzu, sūtiet e-pastu uz adresi info@rimsa.it.
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NL	Om de handleiding in deze taal aan te vragen, kunt u een e-mail sturen naar info@rimsa.it.
PL	Aby zamówić podręcznik w tym języku, należy wysłać wiadomość e-mail na adres info@rimsa.it.
PT	Para solicitar o manual nesta língua, envie por favor um e-mail para info@rimsa.it.
RO	Pentru a solicita manualul în această limbă, vă rugăm să trimiteți un e-mail la info@rimsa.it.
SK	Ak chcete požiadať o príručku v tomto jazyku, pošlite e-mail na adresu info@rimsa.it.
SL	Če želite zahtevati priročnik v tem jeziku, pošljite e-pošto na naslov info@rimsa.it.
SV	Om du vill ha handboken på detta språk skickar du ett e-postmeddelande till info@rimsa.it.

MU_034 Rev.3 20/02/2023 Page 4 of 34





PRODUCT

OPERATOR

RESPONSIBLE ORGANIZATION

TECHNICAL SERVICE PERSONNEL

KEY

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

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

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

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

- ⇒ Construction Engineer, Draughtsman, Building firm duly registered in the professional Register (for the masonry works)
- ⇒ Electrical Engineer Electro-technical expert qualified to work as an electrician (for the electrical works)

MU_034 Rev.3 20/02/2023 Page 5 of 34





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. RIMSA 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.

Importance of personal safety

2.1 Intended use

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

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

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

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

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

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

Operating field

Undesired effects of overlapping light fields



Possibility of tissue dehydration and damage.

MU_034 Rev.3 20/02/2023 Page 6 of 34





Optical safety



Possibility of glare.

Electromagnetic disturbance

Incorrect use



Do not place objects on Product.

Improper use of mobile version



Pushing or resting on the product is forbidden.

2.2 Safety conditions (secondary effects)

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

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

- Never place and/or hang anything on the Product.
 Failure to follow such precaution could result in such objects falling in the operating area.
- Never hang on the Product with the body weight of a person.
 Failure to follow such precaution could damage the Product structure.
- Never cover the head of the Product during operation to prevent overheating.
 - Avoid the Product parts colliding with one another or other nearby equipment.

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

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

2.3 Environmental conditions

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

MU_034 Rev.3 20/02/2023 Page 7 of 34





Use Cleaning Routine maintenance Special maintenance

Assistance Demolition

Patient population

Patient interaction

Operator interaction

3 General information

3.1 Operator qualifications

Qualification of personnel in charge of operating on the Product: Professional medical personnel.

Properly trained medical and paramedical personnel.

Qualified technician with required technical-professional skills.

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

RIMSA or authorized Dealer.

Comply with applicable laws on waste disposal. This product must not be disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through authorized channels so as to ensure correct recycling.

3.2 Patient population and body interactions

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

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

The operator touches the device necessary on the sterilisable handpiece and function control keyboard, and occasionally on the enclosure.

MU_034 Rev.3 20/02/2023 Page 8 of 34





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 conforms to 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





















MU_034 Rev.3 20/02/2023 Page 9 of 34





'N'

'L'

11

'O'



Operator Instructions

OPERATION AND MAINTENANCE MANUAL



Protection earth

Neutral lead connection point

Line lead connection point

ON

OFF

Standby and switch-on

No stepping on surface

4 Precautions for the Product operator

4.1 Personnel awareness obligation

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

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

4.2 Warranty and liabilities

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

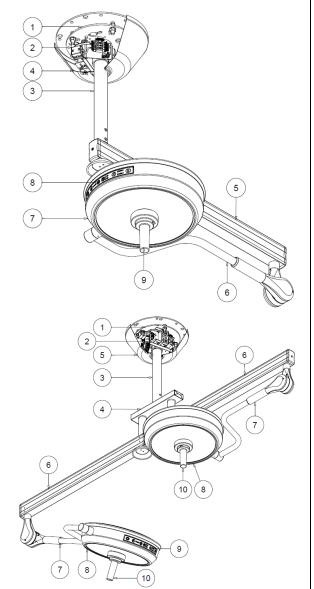
- The Product has not been used for its intended purpose and in conformity with the operating instructions.
- Authorized modifications and repairs have not been performed by TECHNICAL SERVICE PERSONNEL.

MU_034 Rev.3 20/02/2023 Page 10 of 34





Versions



5 Product description and operation

5.1 Product description

The Product is available in various versions:

- single ceiling version
- double ceiling version
- wall version
- mobile version

SINGLE CEILING Version: ceiling plate hub (1), switchboard (2), ceiling anchoring tube (3), ceiling cover (4), horizontal arm (5), swinging arm (6), lamp head (7), control keyboard (8), sterilisable grip (9).

DOUBLE CEILING Version: ceiling plate hub (1), switchboard (2), ceiling anchoring tube (3), double coupling joint (4), ceiling cover (5), horizontal arm (6), swinging arm (7), lamp head (8), control keyboard (9), sterilisable grip (10).

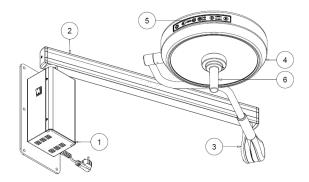
MU_034 Rev.3 20/02/2023 Page 11 of 34

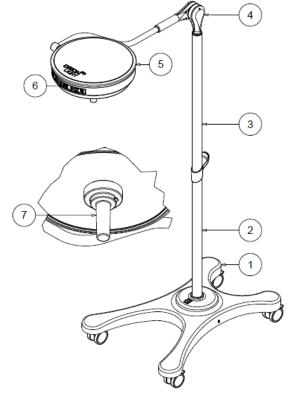




lamp head (4), control keyboard (5), sterilisable grip (6).







Separable parts

MOBILE Version: base with wheels (1), lower stem (2), upper stem (3), swinging arm (4), lamp head (5), function control keyboard (6),

sterilisable grip (7).

WALL Version: wall box (1), horizontal arm (2), swinging arm (3),

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

MU_034 Rev.3 20/02/2023 Page 12 of 34



EN

Main switch

CAUTION

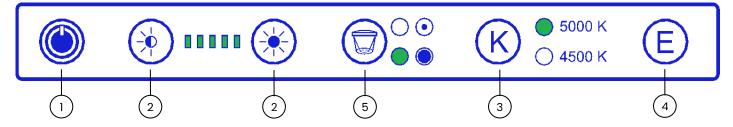
Control keyboard

5.2 Description of operation

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

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

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



Product control is by means of the control keyboard positioned on the reflector casing.

By touching on the surface of the keyboard, the following functions can be activated:

- ON and OFF I/O with green indicator LED (1).
- adjustment of light intensity by dragging your finger over the bar or touching the sun symbol keys (2). The display of the level of set intensity is indicated by 5 green LEDs.
- selection of colour temperature between 4500K and 5000K (3).
- start the "Endoled" function letter E (4). The display of the set function is indicated by the lighting up of the corresponding green LED. This function can only be used when the lamp is off.
- adjustment of the light range (5). The keys extend or reduce the lit diameter.

The Product has been designed to ensure a fixed light diameter without any need for adjustment.

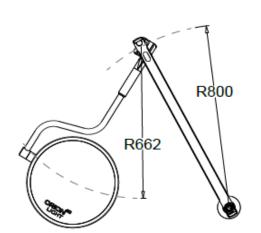
Lighted area

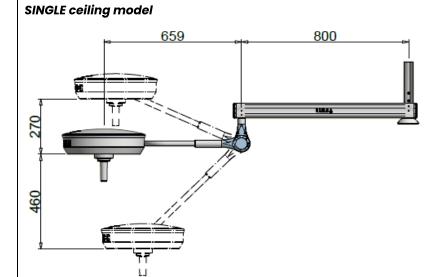
MU_034 Rev.3 20/02/2023 Page 13 of 34

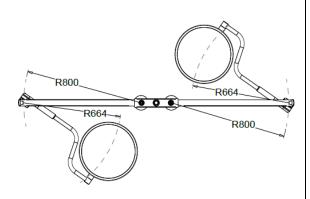




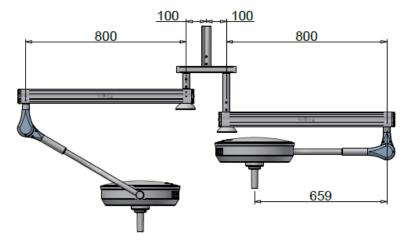


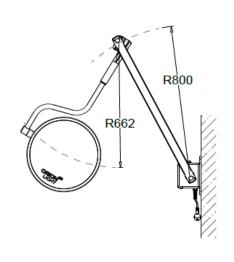




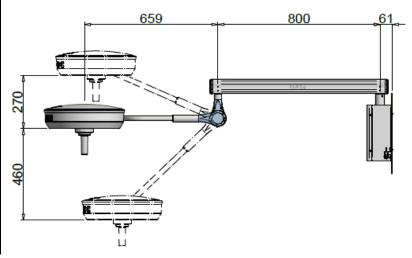






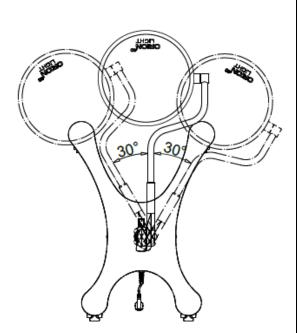




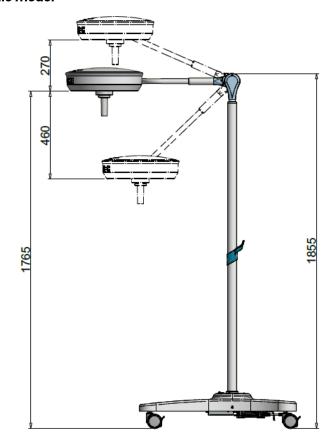








Mobile model





The Product can be moved using the sterilisable handpiece.

MU_034 Rev.3 20/02/2023 Page 15 of 34

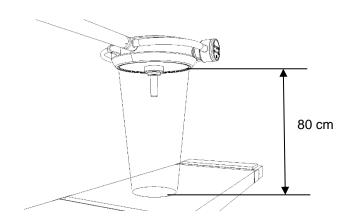








To optimize light intensity, the product is best used at a distance of 80 cm.



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

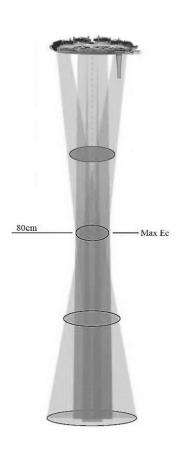
5.3.1 Brakes for mobile version

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.

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.







Risk of damaging pedal.



MU_034 Rev.3 20/02/2023 Page 16 of 34







Risk of lamp overturning.

5.3.2 Moving the stand

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

Failure to do so could cause the lamp to overturn.

5.4 Checks to be made every time before use

To make sure the Product is safe and provides a correct diagnosis, every time before use, the operator must:

- 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

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

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

Do not spray detergent / disinfectant directly on Product.

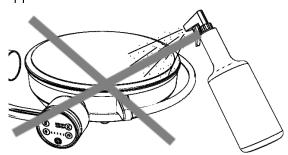


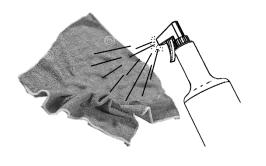
Interrupt the power supply before cleaning the Product.



Possibility of damaging the Product.

Application method





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

MU_034 Rev.3 20/02/2023 Page 17 of 34







Afterwards wipe the Product with the cloth.

Failure to comply with the above instructions could cause:

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

6.2 Cleaning the Product

We recommend you to clean the Product every day.

- Do not use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.
- Do not pour liquids directly on the Product.
- Clean the Product with a damp, but not wet, cloth.
- Clean with suitable detergents with low alkaline content and chlorine free. Do not use abrasive products, petrol, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes.
- Dose the detergents strictly according to the percentage indications shown on the manufacturer's technical sheet, being careful that no liquids penetrate into the joints of the various Product parts, with special care give to the reflector and supporting structure.

Frequency

Frequency



Possibility of damaging the Product.

Possibility of damaging the

Product.

6.3 Product disinfecting

We recommend you to disinfect the Product every time before use. Disinfectants can contain substances that are harmful for the health; use disinfectants indicated by the national commission for hygiene and disinfection, according to the hygienic standards adopted by the Responsible Organization.

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

MU_034 Rev.3 20/02/2023 Page 18 of 34





Frequency



Hazard for the patient.

Sterilization

6.4 Handpiece sterilization

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

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

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

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

Handpiece fitting / removal:

- Press the handpiece release lever and remove it.
- Insert the handpiece up tight on the support and turn it until the steel lever engages in its original place and rotation is blocked.
 Finally make sure the handpiece is well secured.

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.

MU_034 Rev.3 20/02/2023 Page 19 of 34







7.1 Swinging arm adjustment

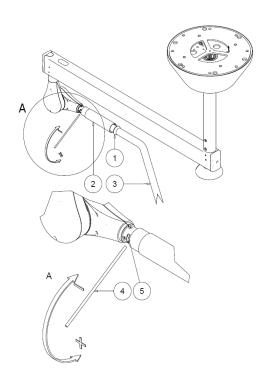
The Product is sold already balanced and does not require further adjustment. In the event of the spring swinging arm becoming stiff or loose over time, mechanical intervention is possible by regulating the compression of the internal spring.

Allow the silicone seal gasket (1) and the cover (2) to slide forwards along the swinging arm (3). Fit a pin (4) with diameter of 4mm in the holes of the ring nut (5) and turn in the direction indicated by the arrows to increase/decrease the load on the spring.

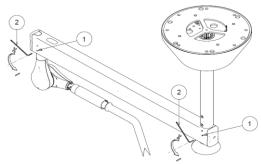
If the swinging arm drops, this means the elastic force of the spring is insufficient:

- turn the ring nut downwards and load the spring. If the swinging arm lifts up, this means the elastic force of the spring is too high:
- turn the ring nut upwards and release the spring.

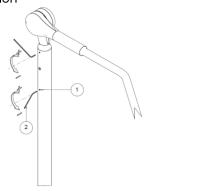
 After making adjustments, return the covering to its original position.



Ceiling version



Mobile version



7.2 Clutch adjustment

Like all the other mechanical parts, the clutches are also subject to wear.

In case of the structure not maintaining the position, the clutches will have to be adjusted.

Use a 2.5 hexagon spanner (2) to increase the braking force, turning the dowels (1) of the arm brake clockwise.

Like all the other mechanical parts, the clutches are also subject to wear.

In case of the mobile structure not maintaining the position, the clutches will have to be adjusted.

Use a 2.5 hexagon spanner (2) to increase the braking force, turning the dowels (1) of the stem brake clockwise.

MU_034 Rev.3 20/02/2023 Page 20 of 34



7.3 Periodical checks to be performed on

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



Making any changes to this device is forbidden.



7.4 Routine maintenance

the Product



Interrupt the power supply before doing any maintenance jobs.



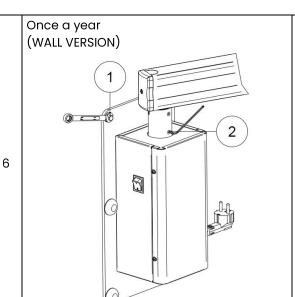
Check Product integrity.

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 screws, loosen the 3 dowels (1) of the ring (2). Remove the bar cover (3) by pulling downwards. Tighten the 4 nuts (4), the screw (5) and the safety dowel (6). Make sure the screws (7) of the horizontal arm are properly tightened.

20/02/2023 MU_034 Rev.3 Page 21 of 34



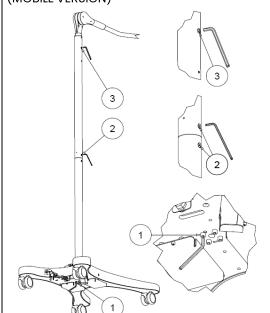




Make sure the wall retention screws (1) and the horizontal arm retention screws (2) are tightened properly.

If these are not properly fastened, adequately tighten.

Once a year (MOBILE VERSION)



Make sure the stem retention screw (1) and the arm retention screws (2) are tightened properly.

If these are not properly fastened, adequately tighten.



7

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



Interrupt the power supply before doing any maintenance jobs.

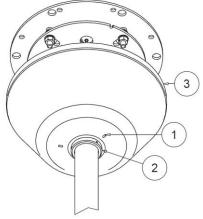
7.5 Repairs

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

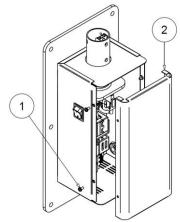
MU_034 Rev.3 20/02/2023 Page 22 of 34



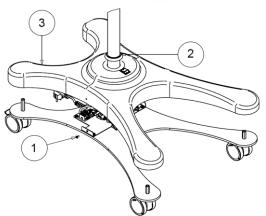




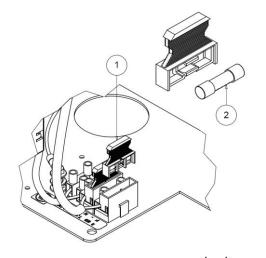
To access the fuses in the ceiling version, open the bar cover as indicated in point 5 of paragraph 7.4.



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, remove the screws (1), unscrew the 3 conical-tipped screws and lift the retaining ring (2) and the covering (3) along the stem.



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

MU_034 Rev.3 20/02/2023







Making any changes to this device is forbidden.

Disposal at end-of-life

If necessary, RIMSA will provide all necessary information to assist the technical assistance personnel in the fuse change.

All other repairs to be done by RIMSA.

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

7.6 Disposal after use

Comply with applicable laws on waste disposal. This product must not be disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through authorized channels so as to ensure correct recycling.

7.7 Spare parts list



Only original spare parts must be used.

Description	Order code
Sterilisable handpiece	Z200518
Electronic board	Z300632-PL30EL
Membrane keyboard	Z300226-B
O/I switch (for mobile and wall versions)	Z300016
Switching power supply unit	Z170178
Fuse TIAH 250V '5x20'	Z400208
Fuse T2AH 250V '5x20'	Z400195

MU_034 Rev.3 20/02/2023 Page 24 of 34





8 Technical properties

Technical details of light	PENTALED 30E LIGHT
Illumination E _c at 1 m distance ± 10% [Lux]	160,000
Colour temperature (±5%) [K]	4,500 / 5,000
Colour rendering index R _a [-]	96
R ₉ [-]	>90
Light range diameter d ₅₀ [mm]	130
Light range diameter d ₁₀ [mm]	220
Lighting depth L1+L2 [mm] at 60%	600
Lighting depth L1+L2 [mm] at 20%	950
Max irradiation [W/m²]	580
Irradiation / Illumination [mW/m²lx]	3.68
Max irradiation in UV [W/m²]	0.004
Power connection details	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Power input [VA]	65 - 85
Light source	nº30 LEDs
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

MU_034 Rev.3 20/02/2023 Page 25 of 34





	General data	
Regulation		REGULATION (EU) 2017/745
Classification of N	Medical Device	Class I
Standards		IEC 60601-2-41
Essential performance	does not vary by more than index are stable and are with Limitation of energy in the opexceed 10 W/m² and the total	nd adequate lighting (luminous flux emitted by the ME equipment n 20% during use; the colour temperature and the colour rendering thin the range 3,000K-6,700K and 85-100, respectively; Ec value shall be ≥ 40,000 lux and ≤ 160,000 lux). erating field (UV-irradiance for wavelengths below 400 nm does not all irradiance Ee in the lighted area does not exceed 1000 W/m² at a value shall be ≥ 40,000 lux and ≤ 160,000 lux; Ee/Ec ≤ 6 mV/m²lx).
Colour		RAL 9003
IP degree of prote	ection	IP20
Operating conditi	ions	Continuous operation
Handpiece steam	n sterilization	121°C at 1.3bar from 25 to 30 minutes. 134°C at 2.3bar for 4 minutes.
Mains power volto	age insulation means	Outside the product (main switch) for ceiling versions Main switch for mobile and wall versions
	Dimensions	
Diameter of lamp	body [cm]	40
Light emission su	rface [cm²] (4500K – 5000K)	483 – 762
	ceiling, double ceiling, wall, attery surgical light [kg]	15, 22, 14, 23, 26
	Markings	
C€		In conformity with REGULATION (EU) 2017/745
All technical light reasons	t measurements are to be dee	emed with a tolerance of ±6% for metrological and manufacturing

MU_034 Rev.3 20/02/2023 Page 26 of 34





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.I.

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: PENTALED 30E LIGHT

Model reference: PENTA30EL

Configurations:

PENTA30ELPA LAMP MODEL PENTALED 30E LIGHT WALL

PENTA30ELPI LAMP MODEL PENTALED 30E LIGHT MOBILE STAND

PENTA30ELSO LAMP MODEL PENTALED 30E LIGHT CEILING

PENTA30EL+30EL LAMP MODEL PENTALED 30E LIGHT 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 2: General requirements for basic safety and essential performance - Collateral Standard:

Electromagnetic disturbances - Requirements and tests)

• IEC 60601-2-41 (Part 2: Particular requirements for the safety 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 System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).

Name: Paolo Longoni

Position: Managing Director

MU_034 Rev.3 20/02/2023 Page 27 of 34







Possibility of interferences with nearby appliances.

10 EMC Declaration

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

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

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

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

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

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

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

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

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

MU_034 Rev.3 20/02/2023 Page 28 of 34





Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV at contact +/- 15 kV in air	+/- 8 kV at contact +/- 15 kV in air	Floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must at least be equal to 30%.
Rapid impulse electric transistors IEC 61000-4-4	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	Mains voltage quality should be that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	+/-1kV Between phases +/-2kV Between phases and earth	+/- 1 kV Between phases +/- 2 kV Between phases and earth	Mains voltage quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations on the power supply input lines IEC 61000-4-11	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)	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: U₁ mains voltage in AC before application of test level.		,	

MU_034 Rev.3 20/02/2023 Page 29 of 34





Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
			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:
	3 Veff 150 kHz to 80 MHz	3 Veff 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$ 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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 V ISM Frequencies	6 V ISM Frequencies	where <i>P</i> is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacture and <i>d</i> is the recommended separation distance in meters (m).
	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.

MU_034 Rev.3 20/02/2023 Page 30 of 34





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)}	1.8	0.3	27
450	430-470	GMRS 460, FRS	18 Hz FM ^{c)} ± 5kHz deviation	2	0.3	28
	100 170	460	1 kHz sine	_		
710			Pulse			
745	704-787	LTE Band 13, 17	modulation ^{b)}	0.2	0.3	9
780			217 Hz			
810		GSM800/900, TETRA 800,	Pulse			
870	800-960	iDEN 820,	modulation ^{b)}	2	0.3	28
930		CDMA 850, LTE Band 5	18 Hz			
1720		GSM 1800;	Dulas			
1845	- 1700-1990	CDMA 1900; GSM 1900;	Pulse modulation ^{b)}	2	0.3	28
1970	1700 1000	DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz	2	3.9	20
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID	Pulse modulation ^{b)}	2	0.3	28
		2450, LTE Band 7	217 Hz			
5240			Pulse			
5500	5100-5800	WLAN 802-11 a/n	modulation ^{b)}	0.2	0.3	9
5785		/	217 Hz			

NOTE: If necessary to achieve the IMMUNITY TEST 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.

MU_034 Rev.3 20/02/2023 Page 31 of 34

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 dist	tance according to frequenc m	y of transmitter
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√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.

MU_034 Rev.3 20/02/2023 Page 32 of 34





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 RIMSA 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 RIMSA 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 RIMSA. 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 RIMSA;
 - 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. RIMSA 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. RIMSA'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 RIMSA 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 RIMSA'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 RIMSA only.
- 12. The component parts replaced under warranty must only be returned to RIMSA, if so requested by RIMSA, carriage free and suitably packed.
- 13. In case of failure to return a part requested by RIMSA, the cost of the component part will be charged.
- 14. RIMSA cannot accept returns from end users or in any case from parties other than the buyer.
- 15. Products returned to RIMSA 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.

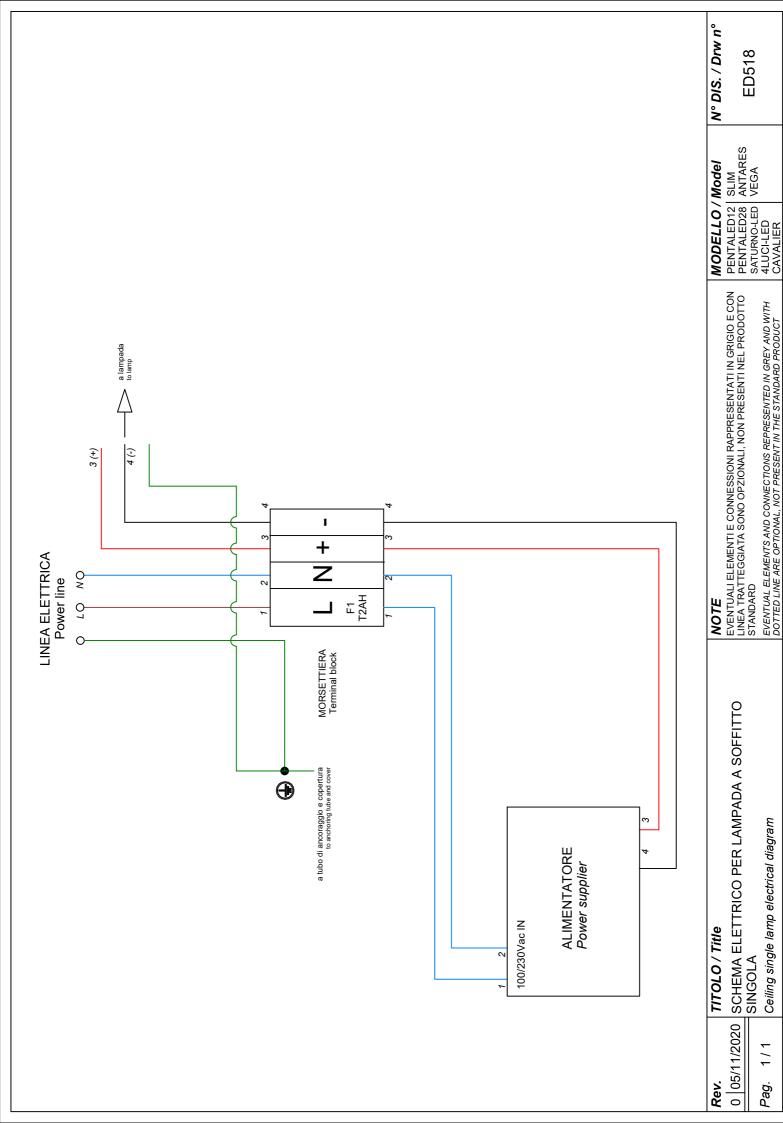
MU_034 Rev.3 20/02/2023 Page 33 of 34





Notes

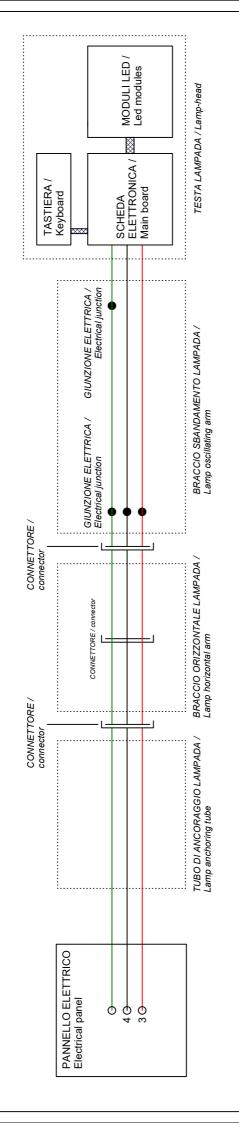
MU_034 Rev.3 20/02/2023 Page 34 of 34



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

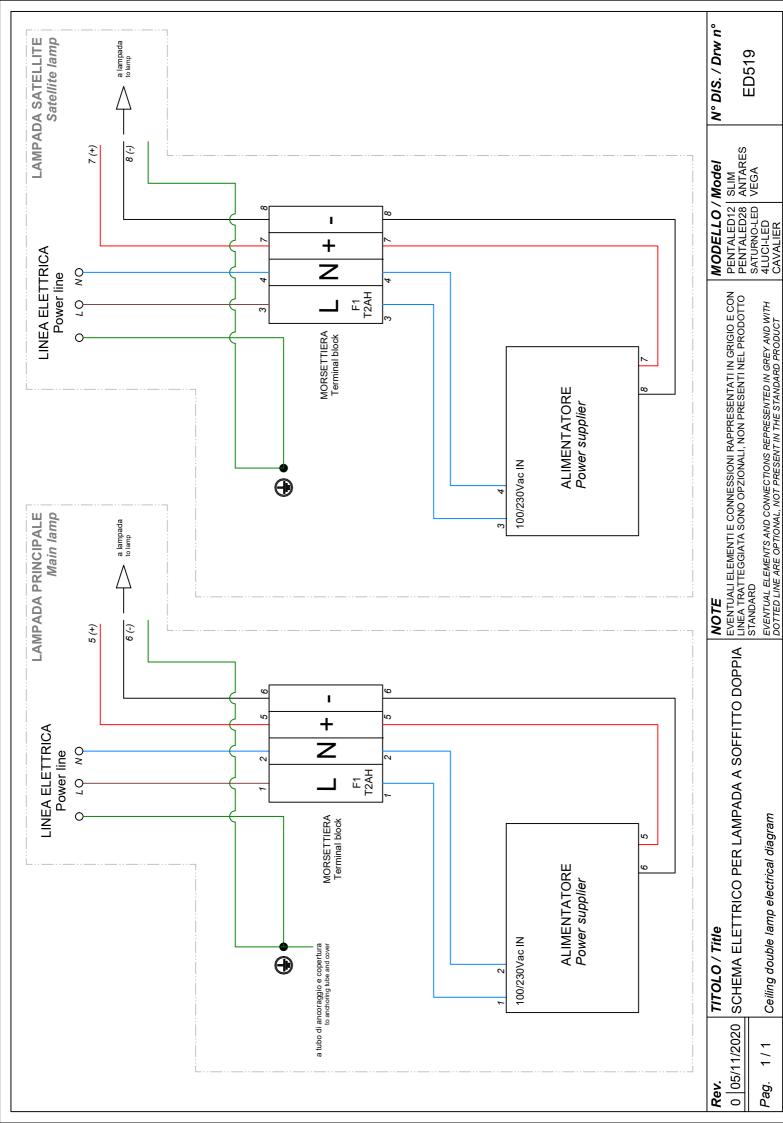
Ceiling single lamp electrical diagram

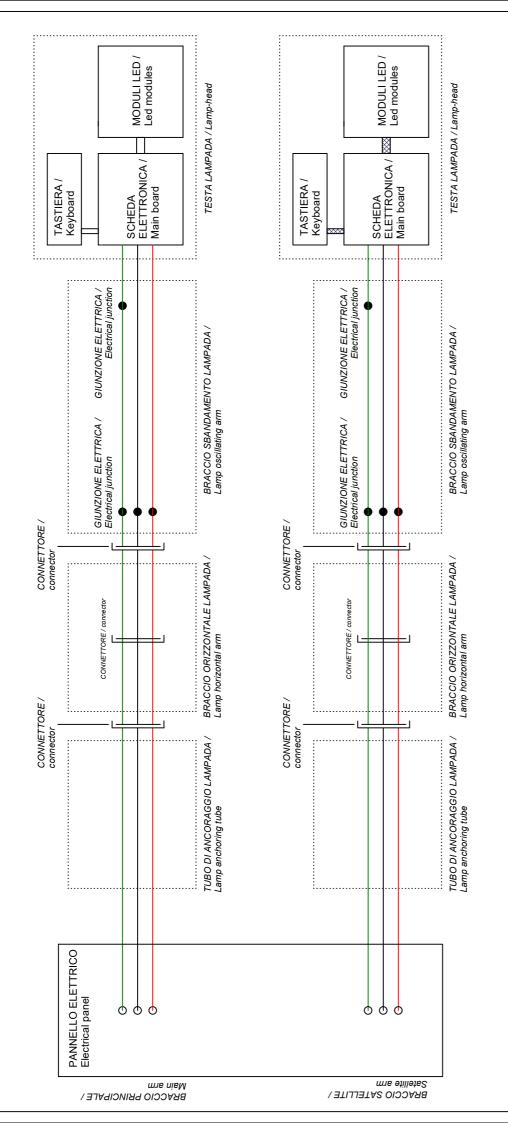
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SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA Ceiling double lamp general electrical diagram TITOLO / Title

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Rev.

Pag. 1/1

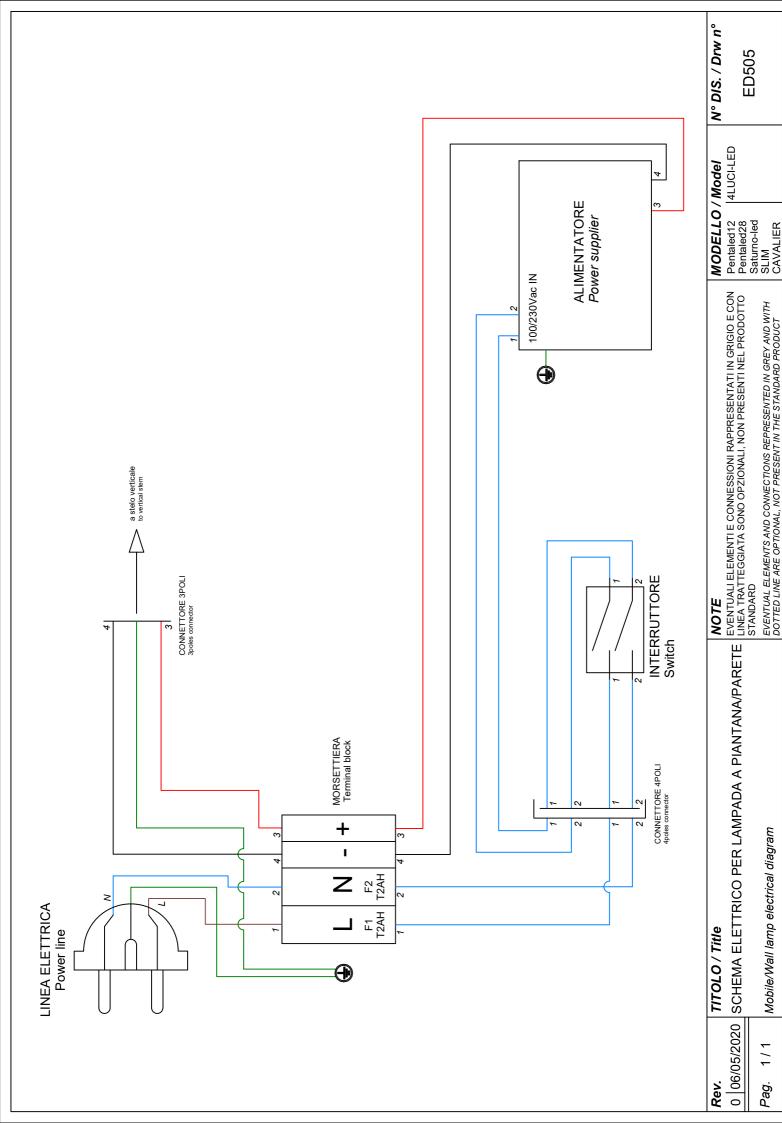
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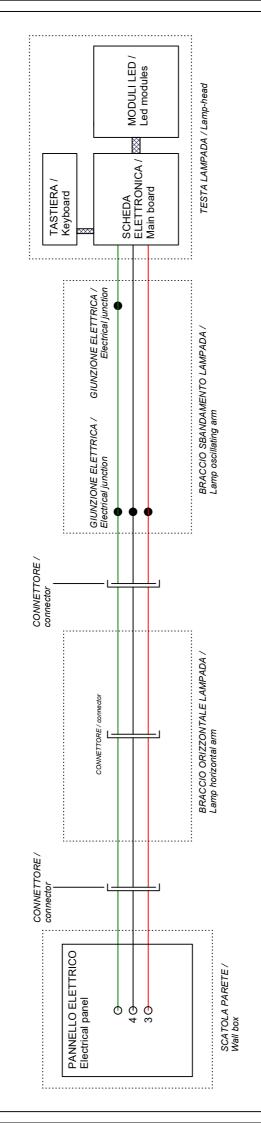
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EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT

Mobile/Wall lamp electrical diagram

Pag. 1/1



SCHEMA GENERALE PER LAMPADA A PARETE TITOLO / Title 0 07/05/2020 Rev.

Wall lamp general electrical diagram

Pag. 1/1

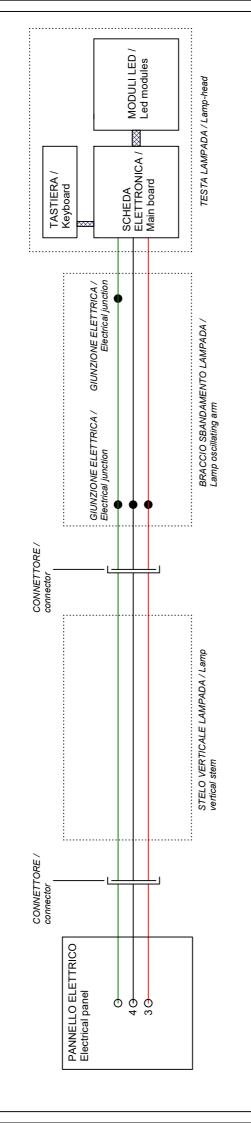
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