RIMSA società benefit Certified B Corporation

EN

PENTALED 12
PENTALED 28
SATURNO-LED

USER AND MAINTENANCE MANUAL

LUMINAIRES FOR DIAGNOSIS

15/07/2025 Rev. 10 U000004

Summary

Introduction

Please read this manual carefully and thoroughly before using the Product in order to protect the **"TECHNICAL SERVICE PERSONNEL"**and the **"OPERATOR"** from damage.

CE Marking

This device is a Class I medical device within the meaning of REGULATION (EU) 2017/745 concerning medical devices (Annex VIII) as amended and supplemented.

Compliance

The manufacturer declares that this Product is in conformity with Annex I (General Safety and Performance Requirements) of REGULATION (EU) 2017/745 as amended and supplemented by IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41 and documents this conformity by affixing the CE marking.

Manual validity

This manual is valid for the following models:

- PENTALED 12 in ceiling, wall-mounted, mobile versions, and their respective battery versions
- PENTALED 28 in ceiling, wall-mounted, mobile versions, and their respective battery versions
- SATURNO-LED in ceiling, wall-mounted, mobile versions, and their respective battery versions

Customer service

Customer service is at your disposal for clarification of the Product, its use, locating spare parts, for service and/or warranty issues, and for any other questions.

- RIMSA P. LONGONI SRL
- Via Monterosa, 18/20/22 - 20831 - Seregno (MB) - Italia
- 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 health of the patient and/or user, contact the manufacturer and the competent state authority where the event occurred.

Copyright

Translations

The original language of this manual is ITALIAN. For any translations, the original language of the manual shall prevail.

1 Legend

PRODUCT
The EM (electro-medical) EQUIPMENT to which this manual refers is a **LUMINAIRE FOR DIAGNOSIS.** For ease of description in this manual, this EM EQUIPMENT will be referred to as **"Product**.

OPERATOR
Professional medical personnel (e.g. professional health personnel, experienced patient caregiver).

RESPONSIBLE ORGANISATION
Entity responsible for the use and maintenance of EM equipment or an EM system (e.g. a hospital, an individual physician or an inexperienced person). Preparation and competence are included in the use.

TECHNICAL SERVICE PERSONNEL
Personnel (individuals or entities responsible to the RESPONSIBLE ORGANISATION) performing installation, assembly, maintenance or repair of the Product. In certain circumstances, their safety in accessing hazardous parts depends in part on their knowledge and competence to take appropriate precautions.
By way of example, but not limited to, the following professionals are considered TECHNICAL SERVICE PERSONNEL:

- Building Engineer, Surveyor, Building Contractor duly registered in the professional register (for construction work)
- Electrical Engineer, Electrical Technician qualified to practise as an electrician (for electrical works)

2 General safety information

This manual is an integral part of the Product as required by REGULATION (EU) 2017/745 as amended and supplemented. Please read and keep this manual close to the Product.

Risk of explosion.
The Product is not suitable for use in the presence of flammable anaesthetic agents.

RIMSA accepts no liability for any damage to persons or property resulting from the INSTALLATION/MANAGEMENT of the Product by anyone other than TECHNICAL SERVICE PERSONNEL or from the use of the Product by anyone other than the OPERATOR.
The installation of the Product is at the total expense and care of the RESPONSIBLE ORGANISATION; no burden or responsibility relating to the installation and/or commissioning of the Product can therefore be traced back to and/or in any way attributed to RIMSA.
The construction work to prepare the slab or wall, for Product to be installed on the ceiling or wall respectively, and the electrical work to prepare the electrical system to power the Product must be carried out in a solid and safe manner according to the rules of the art by the TECHNICAL SERVICE PERSONNEL.

Risk of electric shock.
To avoid the risk of electric shock, the Product must only be connected to a power supply network with protective ground.

Risk of electric shock.
The electrical layout of the room must comply with IEC 60364-7-710 and any national standards. A main switch with fuse protection or thermal-magnetic circuit breaker must be installed to ensure that the Product is de-energised.

3 Importance of personal safety

3.1 Intended use

LUMINAIRES FOR DIAGNOSIS
The Product is a medical device intended to be used in operating rooms within the OPERATING FIELD, with short-term duration, active, non-invasive, designed to locally illuminate the patient's body for treatments and diagnosis that can be interrupted without DANGER to the PATIENT in the event of a lack of light.
The optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as specified by the IEC 60601-2-41 standard.

FIELD OF WORK
The Product provides good light intensity between 70 and 140 cm from the operating field.

3.2 Safety conditions (side effects)

Optical security
This product emits possibly hazardous optical radiation. Do not stare at the light emitted from the surgical luminaire. Eye injury may occur.
- Do not direct the light source into the eyes of the patient and OPERATOR.
- When the use of the Product is limited to the face (e.g. maxillofacial surgery, cosmetic surgery, ENT), it is mandatory to cover the patient's eyes with appropriate protection.

Possibility of glare and injury.
Failure to do so may result in glare and damage to the retina.

Electromagnetic interference
To avoid any significant risk of mutual interference due to the presence of the Product during specific examinations or treatments, please refer to the EMC declaration section in the user and maintenance manual.

Misuse


Placing objects on the Product is prohibited.

- Do not place, hang and/or rest any objects on the Product. Failure to comply with this requirement may cause such objects to fall into the operating area.
- Do not hang on the Product with your weight. In the case of the floor-standing version, do not climb, hang, lean, push or lie on the Product. Failure to comply with this requirement may result in damage to the Product, nearby devices and personnel.
- Do not cover the Product's lighthead during operation to avoid overheating.
- Prevent Product parts from colliding with each other or with other neighbouring equipment. A collision may cause plastic or paint parts to detach from the Product and fall into the operating field.

Undesirable effects due to overlapping light fields
Overlapping the light fields of several lamp heads could lead to a temperature increase in the operating field and thus to a risk of dehydration and/or tissue damage.

Possibility of dehydration and tissue damage.
In the case of reduced blood supply with the principle of tissue dehydration, reduce the light intensity.

3.3 Environmental conditions

Risk of explosion.
The Product is not suitable for use in the presence of flammable anaesthetic 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 1060 hPa;
- the altitude must be less than or equal to 2000 m.

4 General Information

4.1 Qualification of employees

Qualification of personnel to carry out Product operations:

Installation
Qualified installer and/or technician.

Use
Professional medical staff.

Cleaning
Thoroughly trained medical and paramedical staff.

Ordinary maintenance
Qualified technician in possession of the technical-professional requirements.

Extraordinary maintenance
RIMSA or TECHNICAL SERVICE PERSONNEL.

Assistance
RIMSA or authorised dealer.

Disposal
Comply with current waste disposal regulations. This Product must not be disposed of in normal waste bins. To avoid risks to the environment and health resulting from the dispersion of pollutants into the environment, separate the various internal components (e.g. iron, aluminium, plastic and electrical material) and take them to the appropriate centres for proper recycling.

4.2 Target population and interactions

Target population
The intended use makes the Product suitable for any population without constraints of age, weight, health or medical conditions.
Patients may be awake or unconscious, under local or general anaesthesia.

The reference population can also consist of animals.

Patient interaction

An active patient can only touch the Product's lighthead and swinging/pantograph arm accidentally, whereas such contact is excluded in the case of an unconscious or incapacitated patient.

Interaction with OPERATOR

The OPERATOR necessarily touches the Product's handle and keyboard, and occasionally the frame.

4.3 Explanation of the graphic symbols used in this manual

To emphasise their importance, some safety precautions are highlighted using the graphic markers below. Safety measures must be observed during installation, use and maintenance of the Product.

General warning sign.

General mandatory behavioural signal.

Generic prohibition signal.

Follow safety precautions before using or servicing the Product. Strictly following safety precautions improves the ability to safely and properly use the Product and helps prevent improper maintenance that can be dangerous and cause damage. The safety measures are indicative but not exhaustive; the OPERATOR, the RESPONSIBLE ORGANISATION and the TECHNICAL SERVICE PERSONNEL must develop their own skills in order to improve and supplement them.

4.4 Graphic symbols used on the Product

Description of any graphic symbols on the Product:

CE marking proving Product conformity with REGULATION (EU) 2017/745 as amended and supplemented

UL Classified Mark

UL Recognized Mark

Date of manufacture (month and year)

Address manufacturer

Fuses used in the Product

	Follow the instructions for use
MD	Medical device
REF	Model Reference
SN	Serial number
UDI	Unique device identifier
ID	Device identifier
REP	Authorised national representative
	Disposal
	Protective ground
'N'	Connection point for neutral conductor
'L'	Connection point for line conductor
'I'	Accessed
'O'	Off
	Stand-by and switch-on
	No pushing, leaning or lying on Product
	No climbing on Product

5 Warnings for the Product Manager

5.1 Staff competence obligation

The RESPONSIBLE ORGANISATION must instruct the OPERATOR in the use, cleaning and maintenance of the Product. The instructions must be provided in written form on the basis of this manual.

5.2 Warranty and liability

RIMSA assumes no liability for unreliable operation of the Product if:

- The installation, authorised modifications and/or repairs are not carried out by TECHNICAL SERVICE PERSONNEL.
- The Product is not used in accordance with its intended use and with the user and maintenance manual.

- The room is not fit for use as a sanitary facility.
- The room is not constructed in accordance with the laws and/or regulations in force.
- The electrical installation of the premises does not comply with the appropriate regulations.

5.3 Checks to be carried out on Product before use

Carry out the electrical verification of the Product.
Before putting into service, carry out the electrical tests and the requirements specified in IEC 62353.

Before each use, in order to ensure Product safety and proper functionality, the OPERATOR must:
- clean/disinfect the Product in accordance with the provisions laid down by the competent national commission;
- check that the light emitted is stable and of adequate intensity;
- check that the lighthead holds its position correctly;
- check that the swinging/pantograph arm holds its position correctly;
- check that there are no pieces or fragments of paint that can detach and fall onto the operating field. If they are present, remove them manually;
- check that the light source's protective shields are not damaged.

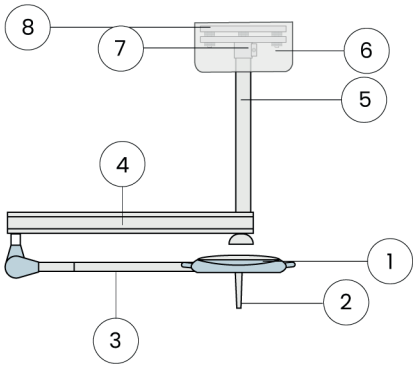
If one or more of these requirements are not met, please contact customer service.

6 Product Description and Operation

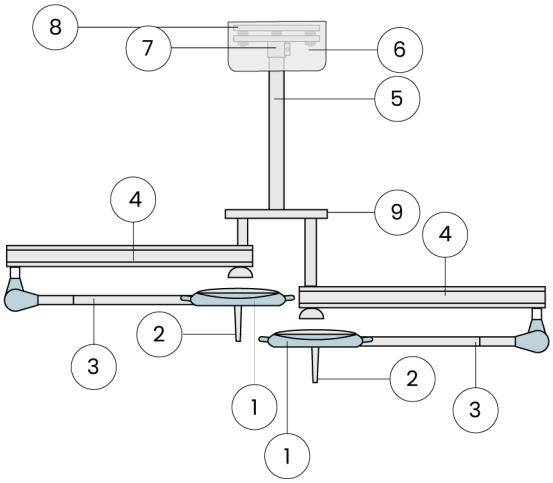
6.1 Product Description

6.1.1 Model PENTALED 12/28

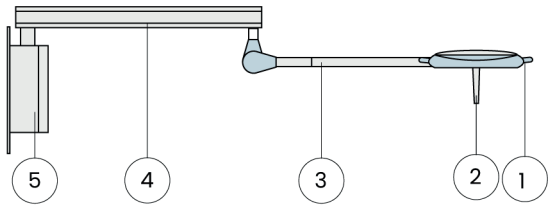
The Product PENTALED 12/28 is available in different versions:



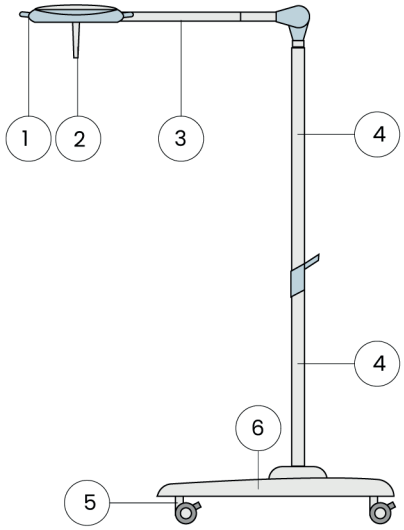
Single ceiling version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- tiges tube (5)
- tiges cover (6)
- tiges plate (7)
- counterplate (8)
- electrical panel.



Double ceiling version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- tiges tube (5)
- tiges cover (6)
- tiges plate (7)
- counterplate (8)
- joint for double attachment (9)
- electrical panel.



Wall-mounted version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- wall box (5)
- electrical panel.



Mobile version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- stems (4)
- base with wheels (5)
- base cover (6)
- electrical panel.

Separable parts

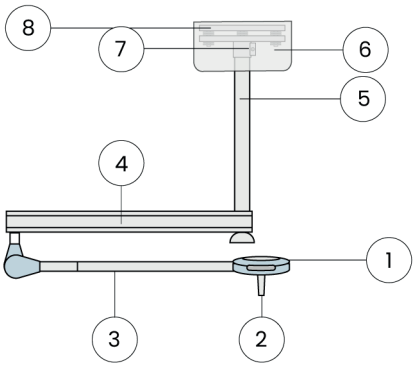
- Sterilisable handle: refer to the section on cleaning, disinfection and sterilisation of the handle for assembly/ disassembly instructions.

PENTALED 28

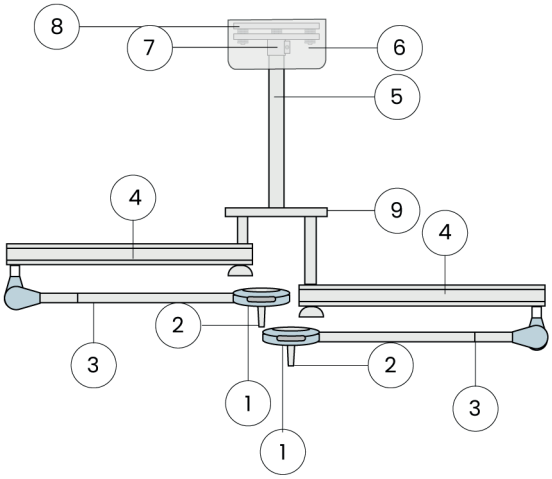
The Product PENTALED 28 originates from the lamp PENTALED 12, with the difference that a direct light system with lenses is applied using 28 LEDs and the possibility to select two color temperatures. There is also the possibility to adjust the diameter of the light field through the rotation of the appropriate handle.

6.1.2 Model SATURNO-LED

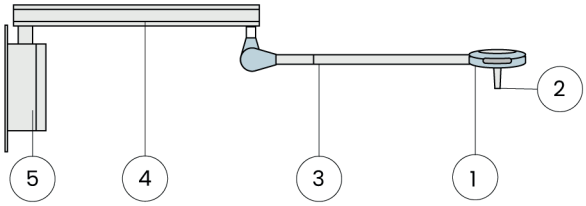
The Product SATURNO-LED is available in different versions:



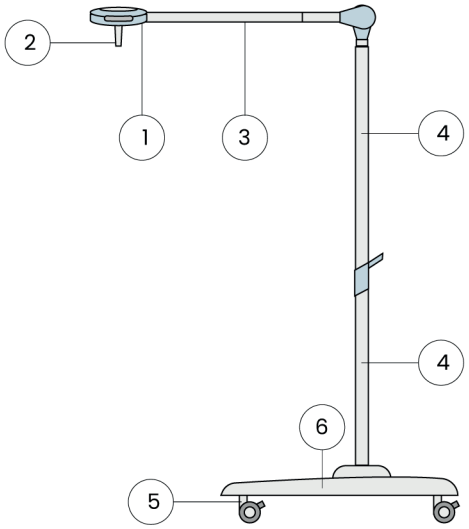
Single ceiling version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- tiges tube (5)
- tiges cover (6)
- tiges plate (7)
- counterplate (8)
- electrical panel.



Double ceiling version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- tiges tube (5)
- tiges cover (6)
- tiges plate (7)
- counterplate (8)
- joint for double attachment (9)
- electrical panel.



Wall-mounted version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- horizontal arm (4)
- wall box (5)
- electrical panel.



Mobile version:
- lighthead (1)
- sterilizable handle (2)
- swinging arm (3)
- stems (4)
- base with wheels (5)
- base cover (6)
- electrical panel.

Separable parts

- Sterilisable handle: refer to the section on cleaning, disinfection and sterilisation of the handle for assembly/disassembly instructions.

6.2 Description of Operation

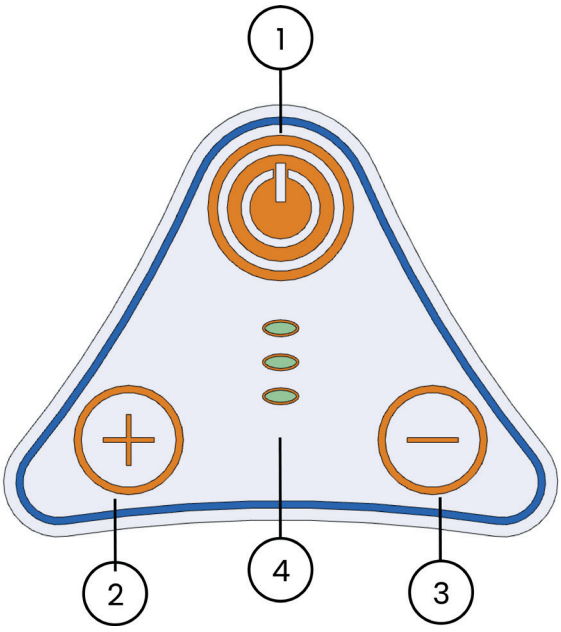
6.2.1 Main switch

For ceiling versions, plan to place the circuit breaker in an accessible place and close to the Product, so that it can be switched off if necessary.
The wall-mounted and mobile version lamps are equipped with a green light switch for general on/off.

For wall-mounted and mobile versions, position the Product in such a way that it is easy to reach and disconnect the power plug in case of emergency.

6.2.2 Control keyboard PENTALED 12

The Product is controlled via the control keyboard located on the lower part of the reflector housing.



Pressing the keys on the keyboard activates the following functions:

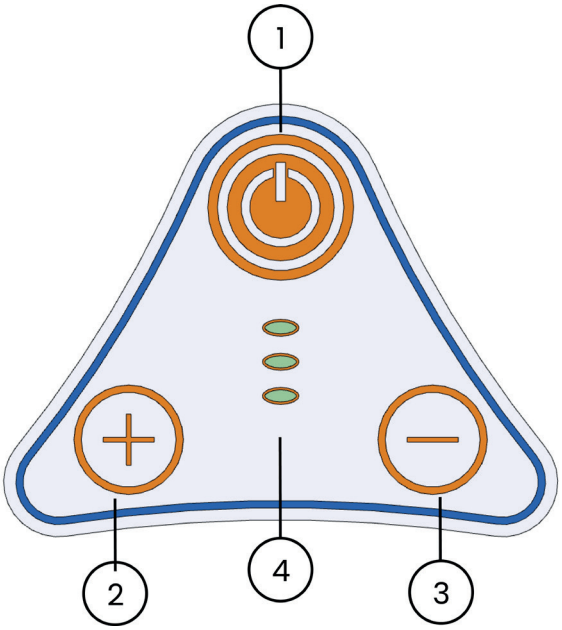
- on/off with prolonged key press (1);
- increase light intensity via key (2);
- decrease light intensity via key (3);
- three green microLEDs display the selected intensity level (4). In the presence of the network, a green microLED remains on to indicate the standby function.

Illuminated area

The Product is designed to ensure a fixed light focus without the need for adjustment.

6.2.3 Control keyboard PENTALED 28

The Product is controlled via the control keyboard located on the lower part of the reflector housing.



Pressing the keys on the keyboard activates the following functions:

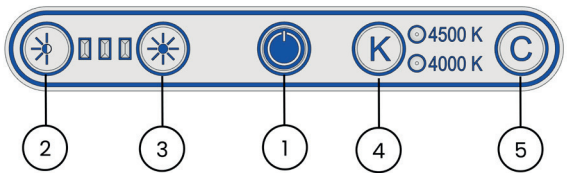
- on/off with prolonged key press (1);
- cyclic color temperature adjustment from 4500 K to 5000 K with quick key press (1);
- increase light intensity via key (2);
- decrease light intensity via key (3);
- three green microLEDs display the selected intensity level (4). In the presence of the network, a green microLED remains on to indicate the standby function.

Illuminated area

It is possible to adjust the diameter of the light field and the focus through the rotation of the central handle.

6.2.4 Control keyboard SATURNO-LED

The control of the Product is carried out via the control keyboard located on the reflector housing.



Pressing the keys on the keyboard activates the following functions:

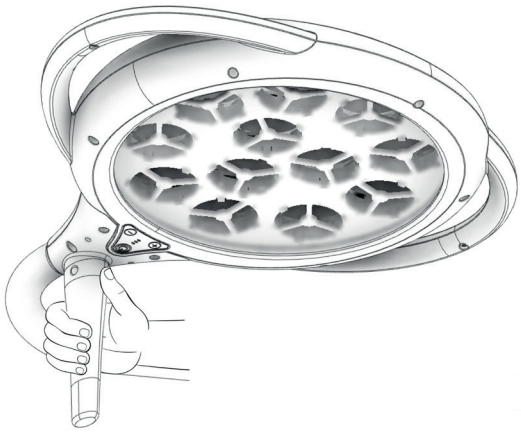
- on/off via key (1);
- increase/decrease light intensity via keys (2) and (3);
- color temperature selection via key (4);
- courtesy light selection via key (5). To select it, the lamp must be off. In courtesy mode, only the light intensity adjustment is allowed. To return to normal operating mode, it is necessary to press key (1).

Illuminated area

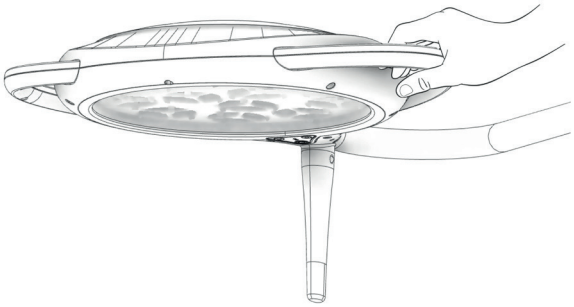
The Product is designed to ensure a fixed light focus without the need for adjustment.

6.3 Product Handling

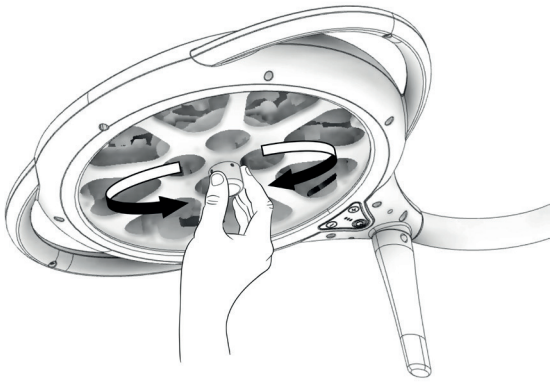
6.3.1 Movement mode



The Product can be moved using the sterilizable handle.

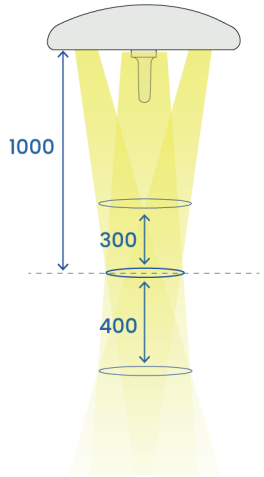


For models PENTALED 12/28, the Product can also be moved using the side handles.



For model PENTALED 28, it is possible to rotate the handle at the center of the protective screen clockwise or counterclockwise to adjust the diameter of the light field and the focus. This handle is neither removable nor sterilizable.

6.3.2 Recommended working distance



[mm]

The Product provides good light intensity at a distance of 70 cm to 140 cm from the operating field.

However, for the optimisation of light intensity, we recommend using the Product at a distance of 1 m.

6.3.3 Mobile version: handling recommendations

When it is deemed necessary to move the column, make sure to position the swinging arm downwards. If this warning is not heeded, the Product may tip over.

Possibility of Product tipping.

When handling the Product, it is recommended that the power cable be wound onto the cable reel on the vertical stem.
When positioning and using the Product, ensure that the power cable does not present a tripping hazard to the OPERATOR.

Possibility of tripping.

The mobile version is equipped with 4 wheels with foot brake to be operated to lock the Product in the desired position.
Press the brake pedal with your foot, without applying excessive force.

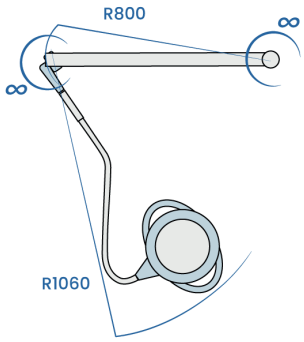
To deactivate the brake, lift the pedal with your foot.

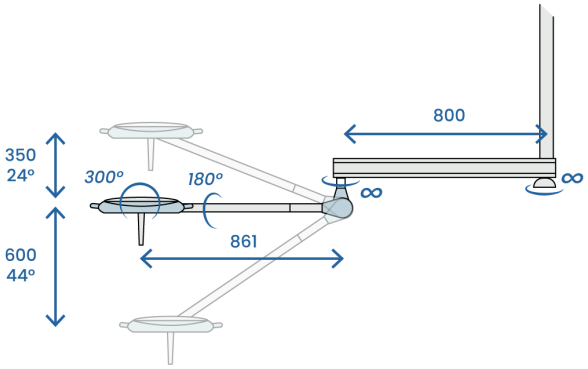
Possibility of damaging the pedal.
Do not strike or depress the brake pedal insistently once it has come to a standstill.

6.3.4 Dimensions and handling Product

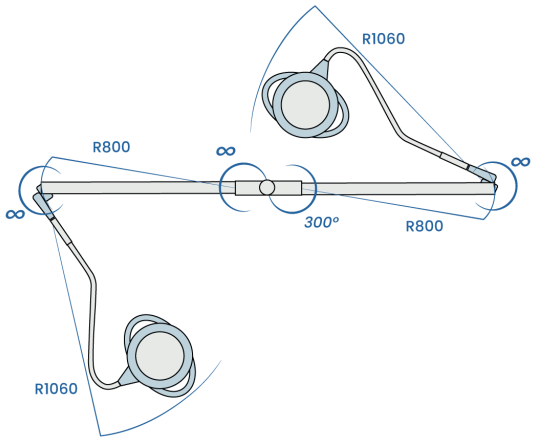
Movement PENTALED 12/28

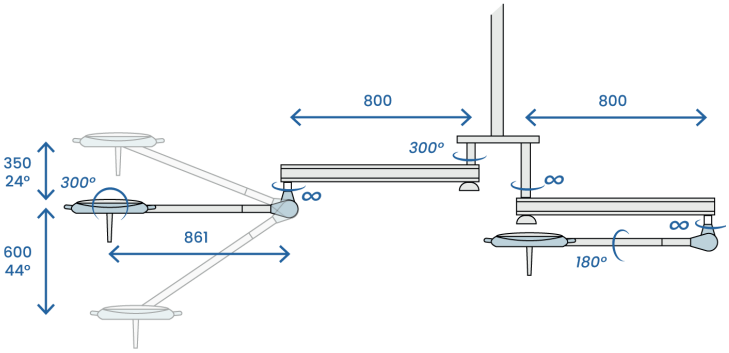
Single ceiling version



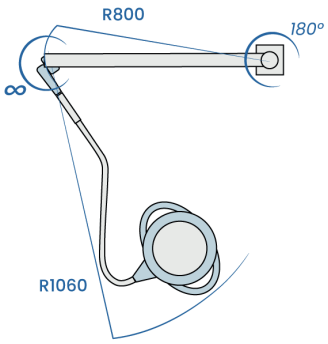


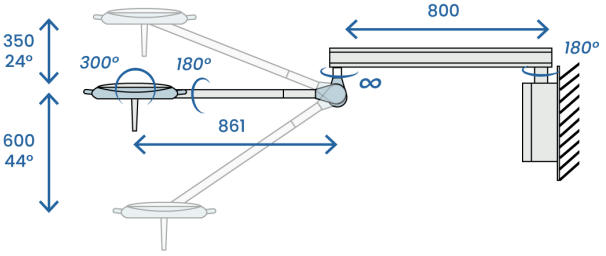
Double ceiling version



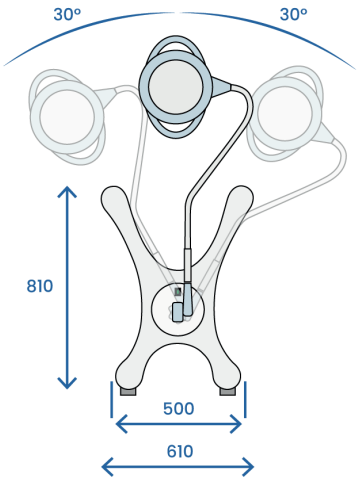


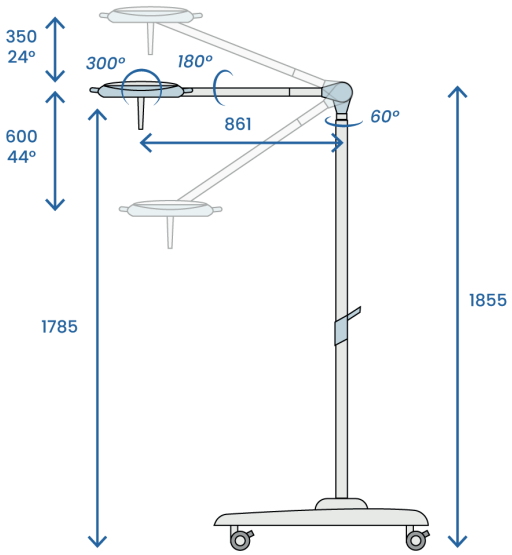
Wall-mounted version





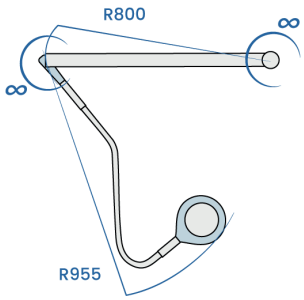
Mobile version

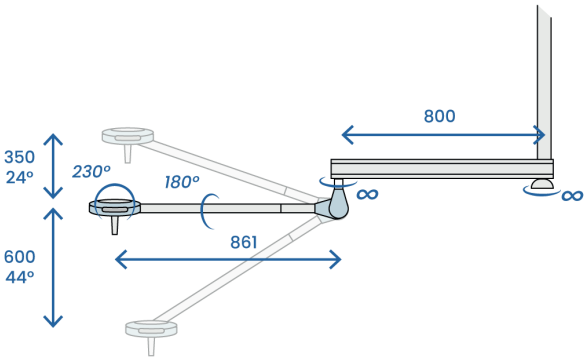




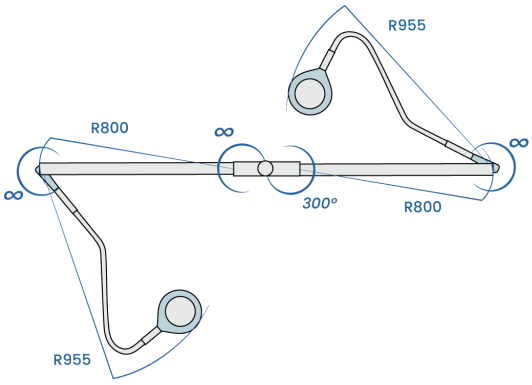
Movement SATURNO-LED

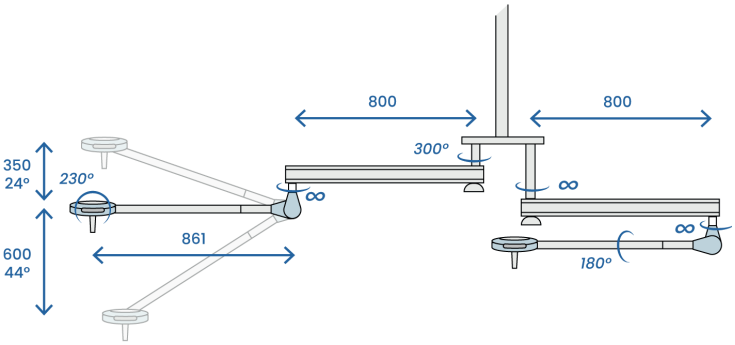
Single ceiling version



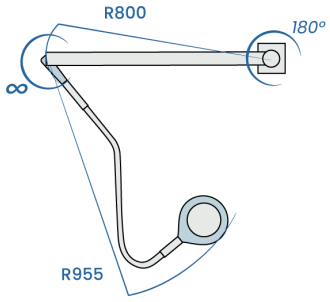


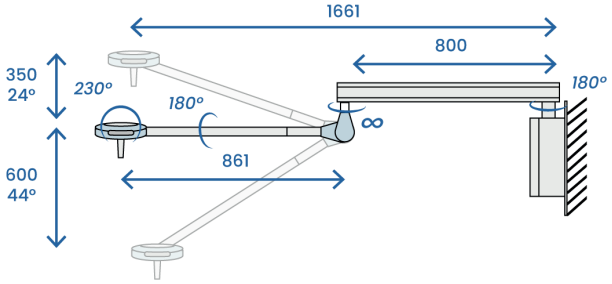
Double ceiling version



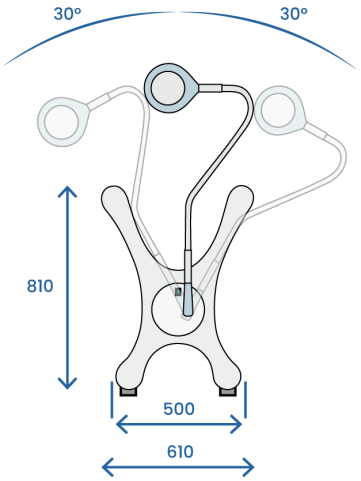


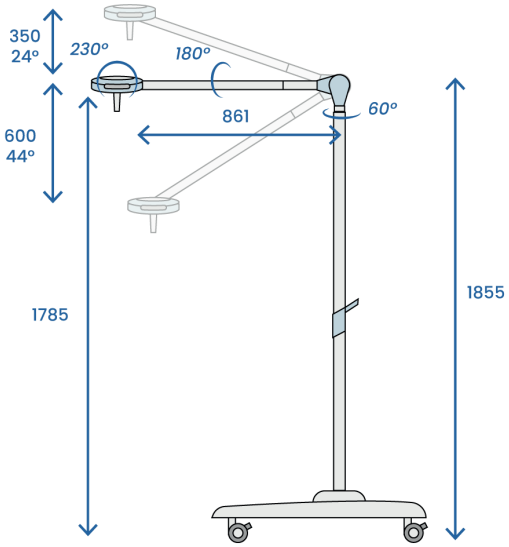
Wall-mounted version





Mobile version





6.4 Wall-mounted and mobile version: storage for non-use

If the Product is not used for a longer period of time, set the green switch to the off position (O) and disconnect the power plug from the socket, coil the cable and position it so that it does not get in the way. The environment must not be dusty, damp or exposed to the sun.

Wall-mounted version

Position the horizontal and swinging arms so as not to be in the way of personnel, if possible close to walls.

Mobile version

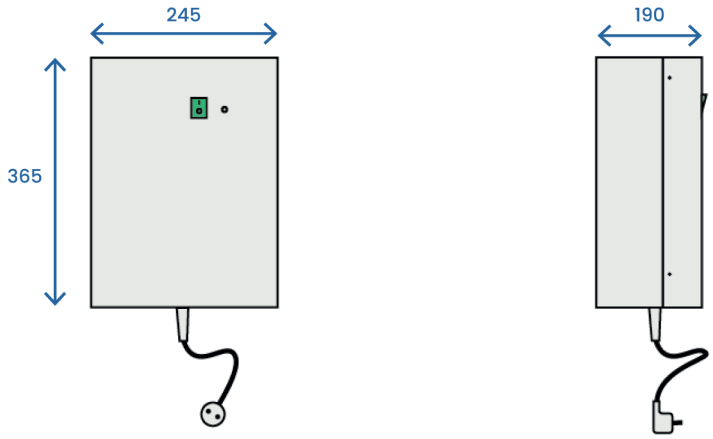
Move the swinging arm downwards, place the Product in an area that is as free of passage as possible and on a non-tilted surface, and lock the wheels.

7 Product with battery

7.1 Description

Upon request, it is possible to equip each dome with a battery pack to allow operation even in the event of a power failure on the mains line.
In the case of a ceiling or wall-mounted Product with battery, the electrical panel and battery pack are supplied together in an additional box (one box for each Product dome).
The system allows the Product to operate either from the mains (100-240 V) or, if the latter is not available, from the 24 V battery. Switching from mains to battery takes place automatically when an electrical fault occurs. To reactivate operation with the mains, the mains must be reactivated. The Product will then automatically reactivate operation with the mains.

Dimensions



[mm]

Orientation

The electrical panel with battery can be positioned in any orientation. Take care that the I/O switch is accessible.

Power

- INPUT: 100-240 Vac
- OUTPUT: 24 Vdc

Specifications

- Nominal voltage: 12 V
- Capacity: 2.7 Ah
- Maximum charging current: 0.5 A
- Weight: 0.93 kg
- Dimensions: 178x34x60 mm
- Operating range: -10 °C / + 40 °C

Storage Warnings

- Batteries are supplied charged.
- They must not be stored for longer than 6 months if stored at 20 °C, and 3 months if stored at 30 °C.
- Beyond this period they must be recharged:
  - Every 3 months when stored at a temperature of 20 °C - 30 °C
  - Every 6 months when stored at a temperature of 30 °C - 40 °C

7.2 Battery life

The estimated battery life is as follows:

Lamp model	Duration at max intensity [h]	Duration at min intensity [h]
PENTALED 12	3.5	8
PENTALED 28	2.5	6.5
SATURNO-LED	5	8.5

7.3 Charging cycle

Connect the battery pack to the mains to charge the batteries. At least 10 hours are required for a full charge.
Battery charge is indicated by a bright coloured LED:
if the light is red, it means that the battery is charging;
if the light is yellow, it means that the battery is charged between 80% and 95%;
if the light is green, the battery is fully charged.
When the battery pack is charging, the LED is lit.
If the power supply is interrupted, the LED goes out.

The number of battery life cycles depends on the charge/discharge cycle used:
- if the batteries are fully discharged, the number of theoretical life cycles is 250;
- if the batteries are discharged by 50% and subsequently recharged, the number of theoretical life cycles is 550;
- if the batteries are discharged by 30% and subsequently recharged, the number of theoretical life cycles is 1200.

7.4 Recommendations

To ensure correct operation, please follow the instructions below:
- Connect the device to the power supply regularly (e.g. once a week)
- Disconnect the batteries if you are not planning to use the device for more than three months.

It is recommended to perform a discharge/charge cycle of the batteries once a month:
- charge the batteries for at least 10 hours.
- leave the device switched on until the batteries are discharged.
- if the batteries do not meet the estimated service life, it is recommended that they be replaced.

To ensure optimal operation of the batteries, they should be replaced at least every 3 years.

If the Product is not in use and is disconnected from the power supply, set the switch to the off (O) position to prevent the batteries from being discharged.

If the Product is not used and is disconnected from the power supply for more than a month, set the switch to the off (O) position and disconnect the electrical bridge between the two batteries.

8 Cleaning and disinfection

The RESPONSIBLE ORGANISATION must comply with the prescriptions (standards and guidelines) on hygiene, disinfection and sterilisation laid down by the competent national commission.

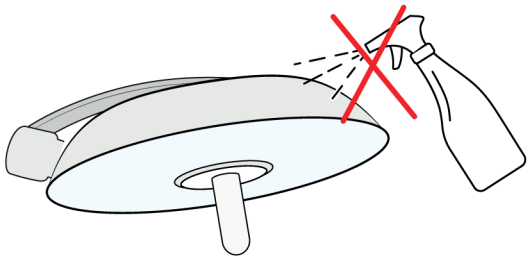
8.1 Application method

Before cleaning/disinfecting the Product, disconnect the power supply.

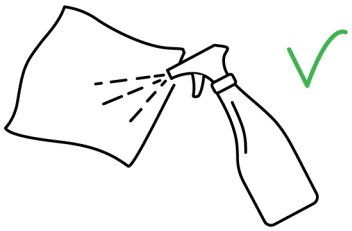
Allow the Product to cool down and only proceed with cleaning/disinfection when it is completely cold.

Possible damage to the Product.
To avoid damaging the Product, follow the instructions in this section.

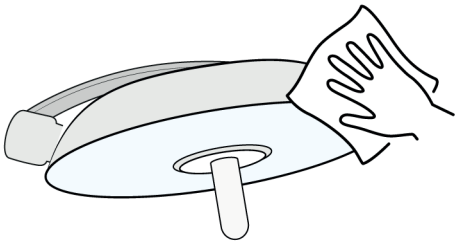
These instructions apply to the cleaning/disinfection of all Product parts.



Do not spray detergent/disinfectant or other liquids directly onto the Product.



Dampen a cloth with the cleaner/disinfectant without saturating it.
It is recommended not to use a paper cloth as, once dampened, it may crumble and some fragments may enter the device's crevices.



Wipe the cloth over the Product.

Non-compliance with the requirements described above could result in:

- the detachment of paint with the possibility of it accidentally falling into the operating field;
- the premature ageing of plastics with consequent weakening and possibility of breakage;
- the dulling of protective shields and glass panes.

8.2 Product Cleaning

Frequency

We recommend cleaning the Product daily.

Possible damage to the Product.
To avoid damaging the Product, follow the instructions in this section.

- Do not use sharp, pointed or abrasive objects to avoid the risk of damaging surfaces.
- Do not spill liquids directly onto the Product.
- Clean the Product with a damp but not wet cloth.
- Use appropriate low-alkaline and chlorine-free cleaning agents. Do not use abrasive and/or harmful products (e.g. petrol, paint thinners, alkaline, acidic or alcohol-containing cleaners or aldehydes).
- Dose the cleaning agents scrupulously observing the percentage indications in the manufacturer's technical data sheet, taking care that no liquids penetrate into the crevices of the various parts of the Product, paying particular attention to the lighthead and support structure.

8.3 Product Disinfection

Frequency

We recommend disinfecting the Product before each use.
Disinfectants may contain substances that are harmful to health; use disinfectants established by the competent national commission for hygiene and disinfection, in compliance with the hygiene standards adopted by the RESPONSIBLE ORGANISATION.

Possible damage to the Product.
To avoid damaging the Product, follow the instructions in this section.

- Do not use sharp, pointed or abrasive objects to avoid the risk of damaging surfaces.
- Do not spill disinfectant liquids directly onto the Product.
- Disinfect the Product with a damp but not wet cloth.
- Use appropriate low-alcohol disinfectants.
- To avoid damage to stainless steel and aluminium parts, use only disinfectants that do not contain chlorine or halogens.
- Dilute the disinfectants scrupulously observing the percentage indications given in the manufacturer's technical data sheet, taking care that no liquid penetrates into the cracks of the various parts of the Product, paying particular attention to the lighthead and support structure.

8.4 Cleaning, disinfection and sterilisation of the handle

Frequency

The handle must be sterilised before use and can withstand about 200 sterilisation cycles.

Danger to the patient.
The OPERATOR must comply with the requirements laid down by the competent national commission for hygiene, disinfection and sterilisation.

The handle is made of polysulphone (PSU), a heat- and impact-resistant plastic material.
Replace the handle as soon as it is cracked or deformed, as it could fall into the operating field.

Mounting/dismounting the handle

PENTALED 12/28

- Assembly: press the locking pins placed parallel to the handle and insert it until the pins snap into their holes so that it remains locked.
- Disassembly: press the locking pins located parallel to the handle and remove it.

SATURNO-LED

- Assembly: rotate it clockwise into the designated threaded hole until it comes to a stop on the head and its rotation is locked.
- Disassembly: rotate the handle counterclockwise and remove it.

Cleaning

Before disinfection and sterilisation, clean the handle. It is recommended to use medium alkaline detergents free of active chlorine. Dose the detergents strictly according to the percentage specifications on the manufacturer's data sheet.
Both manual and automated cleaning are permitted.

- For manual cleaning, soak the handle in cleaning solution and clean it with a soft brush or lint-free cloth. After cleaning, rinse off the detergent residue with plenty of water.
- For automated cleaning, use a machine/scrubber that complies with the requirements of ISO 15883-1.

Disinfection

Before sterilisation, disinfect the handle It is recommended to use alcohol- or aldehyde-based products. Disinfectants must be approved by the disinfectant manufacturer for use on Polysulphone (PSU). Dilute disinfectants strictly according to the percentage specifications on the manufacturer's data sheet.
Both manual and automated disinfection are allowed.

- For manual disinfection, follow the instructions on the manufacturer's data sheet/instructions for use. After disinfection, rinse disinfectant residues thoroughly with water.
- For automated disinfection, use a washer-disinfector complying with the requirements of ISO 15883-1.

Sterilisation

Polysulphone (PSU) is tested for gamma-ray, steam and ethylene oxide (ETO) sterilisation procedures. The result of other sterilisation procedures is not guaranteed.
RIMSA, based on the design of the handle and its own experience, suggests steam sterilisation.
Before sterilising the handle, place it in a suitable sterilisation pack (e.g. plastic/paper bags; single or double pack).
When inserted into the autoclave, take care that the open side of the handle is facing downwards.
The handle must be free and must not be encumbered by other material to be sterilised.
The handle can withstand about 200 steam sterilisation cycles while respecting the following parameters:

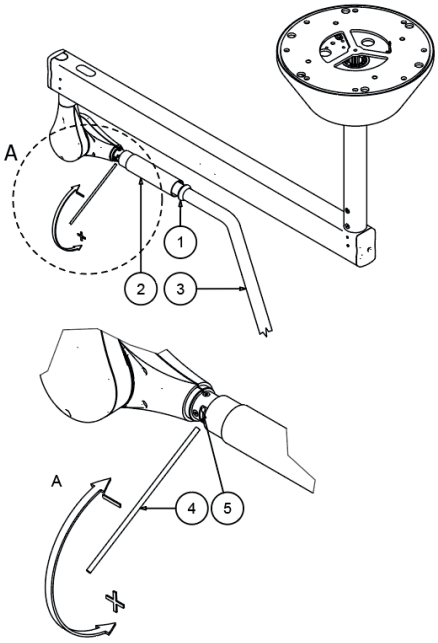
- steam sterilisation at 121 °C and 1.3 bar for 25 to 30 minutes;
- steam sterilisation at 134 °C and 2.3 bar for 4 minutes.

Danger to the patient.
Do not exceed the sterilisation temperature of 134 °C. Damaged handles must not be used. Strictly follow ISO 17665-1 and ISO 17665-2.

9 Adjustment and maintenance

9.1 Swinging arm adjustment

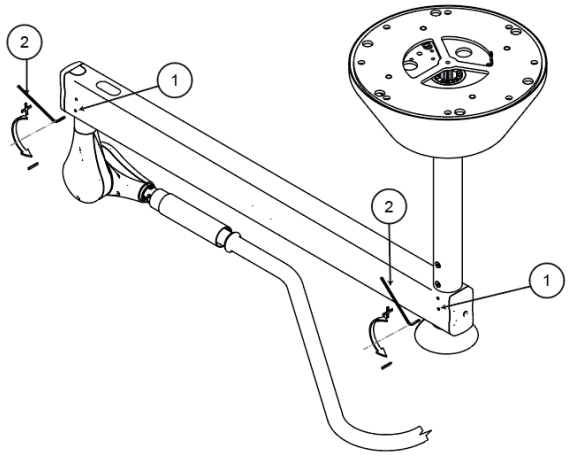
The Product is sold already balanced and requires no further calibration. Should the spring-balanced swinging arm stiffen or loosen over time, it is possible to intervene mechanically by adjusting the compression of the internal spring.



Slide the silicone seal (1) and cover (2) forward along the swinging arm (3). Insert a pin (4) with a diameter of 4 mm into the holes of the ring nut (5) and turn in the directions of the arrows to increase or decrease the spring force.
If the swinging arm goes down, the spring force is insufficient:
• turn the ring nut downwards to charge the spring.
If the swinging arm swings upwards, the spring force is too high:
• turn the ring nut upwards to relieve the spring.
When the adjustment is complete, return the cover to its original position.

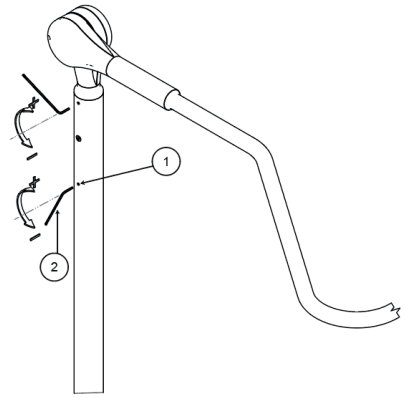
9.2 Clutch adjustment

9.2.1 Ceiling and double ceiling versions



Like all mechanical parts, clutches are also subject to wear.
If the structure does not hold its position, the clutches must be worked on.
Use a 2.5 hexagonal spanner (2) to increase the braking force by turning the grains (1) of the arm brake clockwise.

9.2.2 Mobile version



Like all mechanical parts, clutches are also subject to wear.
If the structure does not hold its position, the clutches must be worked on.
Use a 2.5 hexagonal spanner (2) to increase the braking force by turning the grains (1) of the rod brake clockwise.

9.3 Checks to be carried out on Product before use

Carry out the electrical verification of the Product.
Before putting into service, carry out the electrical tests and the requirements specified in IEC 62353.

Before each use, in order to ensure Product safety and proper functionality, the OPERATOR must:

- clean/disinfect the Product in accordance with the provisions laid down by the competent national commission;
- check that the light emitted is stable and of adequate intensity;
- check that the lighthead holds its position correctly;
- check that the swinging/pantograph arm holds its position correctly;
- check that there are no pieces or fragments of paint that can detach and fall onto the operating field. If they are present, remove them manually;
- check that the light source's protective shields are not damaged.

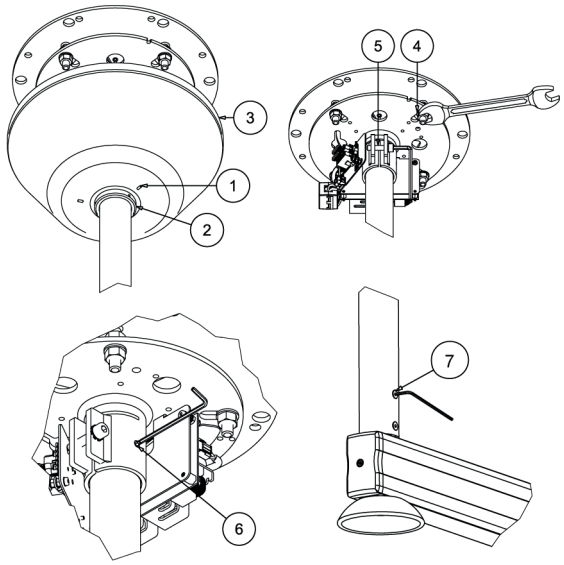
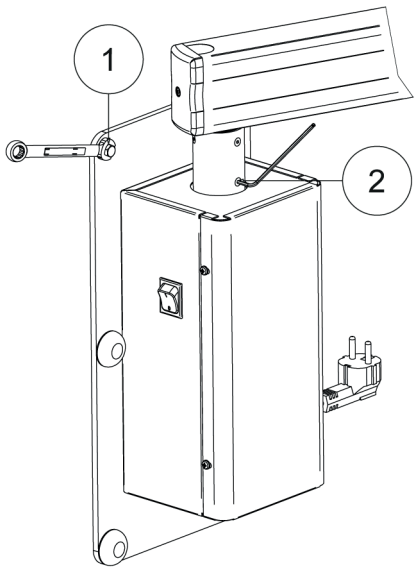
If one or more of these requirements are not met, please contact customer service.

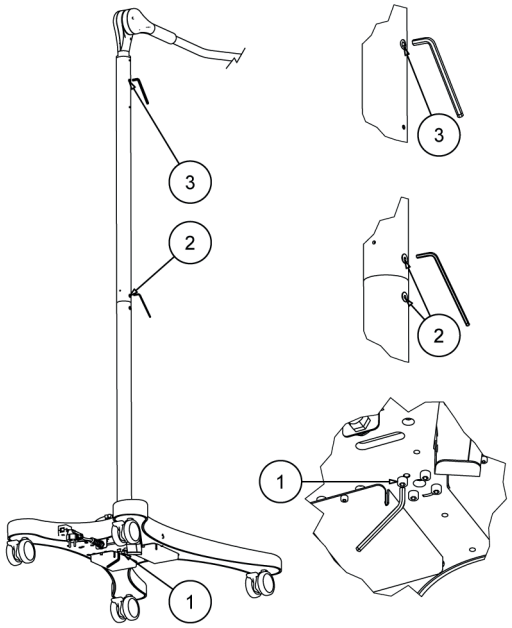
9.4 Ordinary maintenance

Disconnect the power supply before carrying out any maintenance work,

Check the integrity of the Product.

No modification of the Product is permitted.

Once a year	Carry out a complete revolution of all Product joints and check that no noises or squeaks can be heard. If this is the case, lubricate the clutches concerned with industrial grease suitable for use at a service temperature of -30 °C to +120 °C, type OKS 470 or similar.
	If the Product does not hold the position, adjust the swinging arm as indicated under Swing Arm Adjustment.
	If the Product does not hold its position, adjust the clutches as indicated under Clutch Adjustment.
Once a year (ceiling versions) 	Check that the fastening nuts on the tiges are securely tightened. Also check the anchor screws of the horizontal arm to the tiges. If they are loose, tighten them carefully. To access the screws, loosen the three grub screws (1) of the ring (2). Slide the tiges cover (3) downwards. Tighten the 4 nuts (4), the screw (5) and the grub screw (6). Also check that the screws (7) of the horizontal arm are correctly tightened.
Once a year (wall-mounted version) 	Check that the wall fastening screws (1) and the horizontal arm fastening screws (2) are properly tightened. If they are loose, tighten them appropriately.

Once a year (mobile version) 	Check that the stem fixing screw (1) and the arm fixing screws (2) are properly tightened. If they are loose, tighten them properly.

9.5 Troubleshooting

Possible damage to the Product.

Presence of dangerous voltage.

No modification of the Product is permitted.

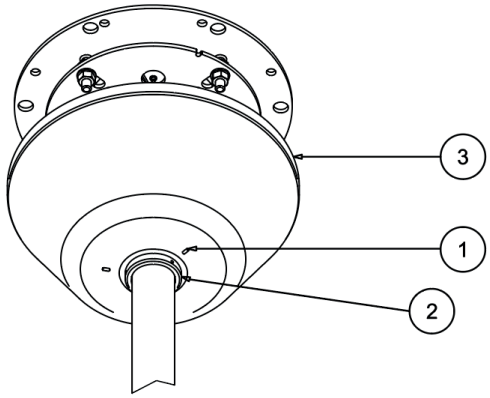
N°	Problem	Solution
1	Product does not remain in a stable position	Check whether the instructions in the installation manual have been followed. Refer to the adjustment instructions in the user and maintenance manual.
2	Light flickers or produces a stroboscopic effect	Contact customer service.
3	Product does not switch on or does not function properly	Check the supply voltage, check the presence and condition of the fuses in the electrical panel, check the connection of the electrical connectors outside and inside the Product, check the voltage continuity inside the Product. If the problem persists, contact customer service.

4	The fuse continues to burn	Check the characteristics of the inserted fuses.

Fuse Replacement

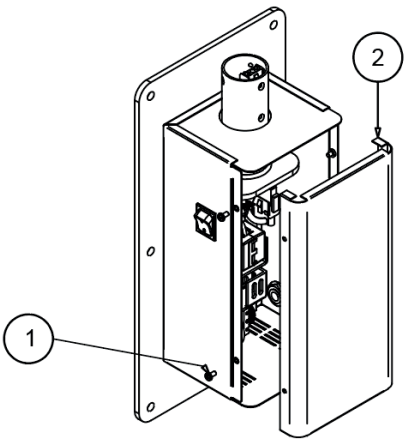
The electrical panel must be accessed for fuse replacement. Once you have identified the location of the electrical panel, follow the instructions below.

Disconnect voltage before performing any operation.



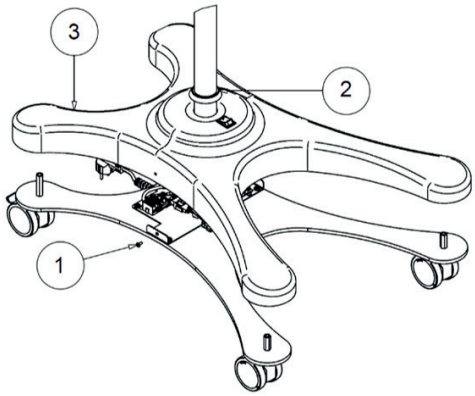
In the case of electrical panels mounted on tiges: To access the fuses in the ceiling version, loosen the 3 grub screws (1) of the ring (2). Slide the tiges cover (3) downwards.

Remove the screw fuse holder from the terminal box and replace the fuse, taking care to replace it with one of the same type.



In the case of wall-mounted version: to access the fuses, remove the 4 screws (1) and the locking box (2).

Remove the screw fuse holder from the terminal box and replace the fuse, taking care to replace it with one of the same type.



In the case of the mobile version: To access the fuses in the mobile version, remove the screws (1), unscrew the 3 conical pins and lift off the locking ring (2) and the base cover (3) along the stem.

Remove the screw fuse holder from the terminal block and replace the fuse, taking care to replace it with one of the same type.

If necessary, RIMSA shall provide wiring diagrams, parts lists, descriptions, adjustment instructions, or other information to assist the TECHNICAL SERVICE PERSONNEL in repairing those parts of the Product indicated as repairable by the TECHNICAL SERVICE PERSONNEL.
If the above indications are not sufficient to solve the problem, please contact customer service.

9.6 Repair and extraordinary maintenance

The Product must only be opened and repaired by TECHNICAL SERVICE PERSONNEL.

Switch off the power supply before carrying out any repair/maintenance work.

In the event of Product malfunction or failure, contact the manufacturer's customer service department. If necessary, the manufacturer will provide wiring diagrams, parts lists, descriptions, operating instructions or other information to assist the TECHNICAL SERVICE PERSONNEL in repairing the Product.

Carry out the electrical verification of the Product.
After every repair and/or extraordinary maintenance, carry out electrical tests and the requirements specified in IEC 62353.

No modification of the Product is permitted.

9.7 Spare parts list

Use only original spare parts.

Description	Order code
Fuse T2AH 250V '5x20'	Z400195
Fuse T4AH 250V '5x20'	Z400215
Sterilizable handle PENTALED 12/28	Z180045
Sterilizable handle SATURNO-LED	Z100848

9.8 Disposal at end of use

Comply with current waste disposal regulations. This Product must not be disposed of in normal waste bins.

To avoid risks to the environment and health resulting from the dispersion of pollutants into the environment, separate the various internal components (e.g. iron, aluminium, plastic and electrical material) and take them to the appropriate centres for proper recycling.

10 Technical data

10.1 Technical data PENTALED 12

Photometric data	
Color temperature, CCT ± 10% [K]	4500
Illuminance at center $E_{C,Ref}$ ± 10% [lux]	100 000
Reference distance D_{Ref} [cm]	100
Max illuminance at center $E_{C,MI}$ ± 10% [lux]	155,000
Max illumination distance D_{MI} [cm]	71
Light field diameter d_{10} ± 10% [mm]	170
Light field diameter d_{50} ± 10% [mm]	110
d_{50} / d_{10} [%]	≥ 50
Color rendering index R_a ± 5 [-]	96
R_9 ± 5 [-]	90
Total irradiance E_{Total} (D_{Ref}) ± 10% [W/m²]	398
Total irradiance E_{Total} (D_{MI}) ± 10% [W/m²]	640
Electrical connection data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	60
Power consumption with fully discharged battery [VA]	155
Light source	n. 12 LEDs
LED light source lifespan [h] (this data may vary depending on voltage spikes and usage frequency)	60,000

General data	
Regulation	REGULATION (EU) 2017/745
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product classification Medical Device	Class I
Operating conditions	Continuous operation
Means of electrical isolation from line voltage	External main switch for ceiling versions. Main switch on the Product for mobile and wall-mounted versions.
Steam sterilization of the handle	121 °C 1.3 bar from 25 to 30 minutes. 134 °C 2.3 bar for 4 minutes.
Dimensions	
Lamp body diameter [cm]	40
Light emission surface area [cm²]	305
Product weight single ceiling - double ceiling - wall - mobile - mobile battery [kg]	15 - 25 - 20 - 21 - 23
Markings	
CE	Compliant with REGULATION (EU) 2017/745
Note 1: unless otherwise indicated, all values are to be considered with a tolerance of ± 5% due to metrological and construction reasons. *Note 2: all tests were conducted in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of the IEC 60601-2-41 standard. In particular, the Product was tested with maximum luminous intensity and color temperature of 4500K.* *Note 3: the optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as specified by the IEC 60601-2-41 standard.*	

10.2 Technical data PENTALED 28

Photometric data	
Color temperature, CCT ± 10% [K]	4500 / 5000
Illuminance at center $E_{C,Ref}$ ± 10% [lux]	120 000
Reference distance D_{Ref} [cm]	100
Max illuminance at center $E_{C,MI}$ ± 10% [lux]	155 000
Max illuminance distance D_{MI} [cm]	62
Light field diameter d_{10} ± 10% [mm]	280

Light field diameter d_{50} ± 10% [mm]	160
d_{50} / d_{10} [%]	≥ 50
Color rendering index R_a ± 5 [-]	96
R_9 ± 5 [-]	90
Total irradiance E_{Total} (D_{Ref}) ± 10% [W/m²]	456
Total irradiance E_{Total} (D_{MI}) ± 10% [W/m²]	641
Electrical connection data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	80
Power consumption with fully discharged battery [VA]	190
Light source	n. 28 LEDs
LED light source lifespan [h] (this data may vary based on the occurrence of voltage peaks and frequency of use)	60 000

General data	
Regulation	REGOLAMENTO (UE) 2017/745
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product classification Medical Device	Classe I
Operating conditions	Funzionamento continuo
Means of electrical isolation from line voltage	Interruttore generale esterno al prodotto per versioni a soffitto. Interruttore generale sul Prodotto per versioni a piantana e a parete.
Steam sterilization of the handle	121 °C 1,3 bar da 25 a 30 minuti. 134 °C 2,3 bar per 4 minuti.
Dimensions	
Diameter of light body [cm]	40
Light emission surface [cm²]	305
Product weight ceiling single - ceiling double - wall - mobile version - mobile version battery [kg]	15 - 25 - 20 - 21 - 23
Markings	
CE	Compliant with REGULATION (EU) 2017/745

Note 1: unless otherwise indicated, all values are to be considered with a tolerance of ± 5% due to metrological and construction reasons.
Note 2: all tests were conducted in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of the IEC 60601-2-41 standard. In particular, the Product was tested with maximum luminous intensity and color temperature 5000K.
Note 3: the optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as specified by the IEC 60601-2-41 standard.

10.3 Technical data SATURNO-LED

Photometric data	
Color temperature, CCT ± 10% [K]	4000 / 4500
Illuminance at center $E_{C,Ref}$ ± 10% [lux]	60,000
Reference distance D_{Ref} [cm]	100
Max illuminance at center $E_{C,MI}$ ± 10% [lux]	150,000
Max illuminance distance D_{MI} [cm]	20
Light field diameter d_{10} ± 10% [mm]	260
Light field diameter d_{50} ± 10% [mm]	160
d_{50} / d_{10} [%]	≥ 50
Color rendering index R_a ± 5 [-]	96
R_9 ± 5 [-]	90
Total irradiance E_{Total} (D_{Ref}) ± 10% [W/m²]	230
Total irradiance E_{Total} (D_{MI}) ± 10% [W/m²]	637
Electrical connection data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	60
Power consumption with fully discharged battery [VA]	150
Light source	n. 9 LEDs
LED light source lifespan [h] (this data may vary based on the occurrence of voltage spikes and frequency of use)	60,000

General data	
Regulation	REGULATION (EU) 2017/745
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product classification Medical Device	Class I
Operating conditions	Continuous operation
Means of electrical isolation from line voltage	External main switch for ceiling versions. Main switch on the Product for mobile and wall-mounted versions.
Steam sterilization of the handle	121 °C 1.3 bar for 25 to 30 minutes. 134 °C 2.3 bar for 4 minutes.
Dimensions	
Diameter of lamp body [cm]	19.5
Light emission surface area [cm²]	63
Weight Product single ceiling - double ceiling - wall - mobile - mobile battery [kg]	14 - 23 - 19 - 20 - 22
Markings	
CE	Compliant with REGULATION (EU) 2017/745

Note 1: unless otherwise indicated, all values are to be considered with a tolerance of ± 5% due to metrological and construction reasons.
Note 2: all tests have been carried out in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of the IEC 60601-2-41 standard. In particular, the Product was tested with maximum luminous intensity and color temperature 4500 K.
Note 3: the optical radiation emitted by this Product complies with the exposure limits for the reduction of photobiological risk as provided by the IEC 60601-2-41 standard.

11 EU Declaration of Conformity

Drafted pursuant to 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 SRL**
Registered Office Address: **Via Monterosa, 18/20/22 - 20831 - Seregno (MB) - Italia**
Unique Registration Number (SRN): **IT-MF-000009224**
This declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Product name and trade name: PENTALED 12
Model reference:
PENTA12SO — LAMP MODEL PENTALED 12 CEILING
PENTA12+12 — LAMP MODEL PENTALED 12 DOUBLE CEILING
PENTA12PA — LAMP MODEL PENTALED 12 WALL
PENTA12PI — LAMP MODEL PENTALED 12 MOBILE STAND
Product name and trade name: PENTALED 28
Model reference:
PENTA28SO — LAMP MODEL PENTALED 28 CEILING
PENTA28+28 — LAMP MODEL PENTALED 28 DOUBLE CEILING
PENTA28PA — LAMP MODEL PENTALED 28 WALL
PENTA28PI — LAMP MODEL PENTALED 28 MOBILE STAND
Product name and trade name: SATURNO-LED
Model reference:
SATSON-LED — LAMP MODEL SATURNO-LED CEILING
SATSONX2-LED — LAMP MODEL SATURNO-LED DOUBLE CEILING
SATPAN-LED — LAMP MODEL SATURNO-LED WALL
SATPIN-LED — LAMP MODEL SATURNO-LED MOBILE STAND
Intended use: LUMINAIRES FOR DIAGNOSIS

Device risk class, in accordance with the rules of Annex VIII of REGULATION (EU) 2017/745: **CLASS I**

Justification:	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, paragraph 4.1 Rule 1) Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, paragraph 6.2 Rule 10)

The manufacturer declares that the device complies with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, concerning 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 the following standards:

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

The conformity assessment procedure of the device is carried out according to recital (60) and Article 52 of REGULATION (EU) 2017/745.

The Quality and Environment System of RIMSA complies with UNI EN ISO 9001, UNI CEI EN ISO 13485, ISO 14001 and ISO/IEC 27001 standards and is certified by IMQ S.p.A. (certificates no. 9120.RMS1, no. 9124.RMS2, no. 0833.2023 and no. 1402.2024).

Name: Paolo Longoni
Position: CEO

12 EMC Declaration

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

Possibility of interference with neighbouring equipment
Portable and mobile communication equipment may affect the Product. The Product should not be used in the vicinity of another device and if use is necessary, the Product must be checked for functionality.

The use of accessories other than those supplied/recommended RIMSA may increase the emission level and lower the immunity level of the device.
The Product is designed for use in the electromagnetic environment described below.
It is the responsibility of the RESPONSIBLE ORGANISATION or OPERATOR to ensure that the Product is used in a compatible environment.
It may happen that the Product, when subjected to irradiation in the range 80 MHz - 1 GHz or to burst radiation, no longer responds to commands, neither for the lamp nor for the camera (if present).
In this case, essential performance will still be guaranteed, but to restore normal operation, it will be necessary to remove power from the main switch.

Immunity tests	Compliance	Electromagnetic environment - directives
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal operation. Consequently, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Product is suitable for use in all rooms except domestic rooms, and those directly connected to a low-voltage public mains supply that supplies buildings used for domestic purposes, provided the following warning is given. **Warning:**This Product is intended for use by professional medical personnel only. This Product may cause radio interference or may disturb the operation of nearby equipment. It may be necessary to take measures to mitigate such interference, such as reorienting and relocating the Product or shielding the room.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Compliant	
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

Immunity tests	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV at contact ±2, ±4, ±8 kV, ±15 kV in air	± 8 kV at contact ±2, ±4, ±8 kV, ±15 kV in air	It is preferable for the floor to be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the moisture content must be at least 30%.
Fast-pulsing electrical transients IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	A mains quality typical of a commercial or domestic environment is recommended.
Shockwaves IEC 61000-4-5	± 0.5 kV, ± 1 kV Differential mode	± 0.5 kV, ± 1 kV Differential mode	A mains quality typical of a commercial or hospital environment is recommended.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency must be at levels characteristic of a typical location in a commercial or hospital environment.
Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11	10 ms - 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms - 0% at 0° 500 ms - 70% at 0° 5 s - 0%	10 ms - 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms - 0% at 0° 500 ms - 70% at 0° 5 s - 0%	A mains power quality typical of a commercial or hospital environment is recommended. If the Product is to be used continuously even in the event of a power failure, connect the lamp to a mains supply capable of providing continuous power or to a battery.
NOTE: U_T is the AC mains voltage before application of the test level.			

Immunity tests	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment - directives
RF conducted IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 6 V ISM frequencies 3 V/m 80 MHz to 2.7 GHz	3 Veff 150 kHz to 80 MHz 6 V ISM frequencies 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communication systems must be used no closer than 30 cm (12 inches) to any part of the Product, including cables specified by the manufacturer; observe the recommended separation distance, calculated according to the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ from 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power of the transmitter in watts [W], according to the transmitter manufacturer and d is the recommended separation distance in metres [m]. Field strengths of fixed RF transmitters, as determined by an electromagnetic site survey, must be below the compliance level in each frequency range. In the vicinity of equipment marked with the following symbol, interference may occur: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Test frequency [MHz]	**Band** [a] [MHz]	**Service** [a]	**Modulation** [b]	**Maximum power** [W]	**Distance** [m]	**Immunity test level** [V/m]
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
2450	2400-2750	Bluetooth, WLAN, 02.11, b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802-11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9

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

[a] For some services only rising frequencies are included.
[b] The carrier must be modulated using a square wave signal at 50% duty cycle.
[c] As an alternative to FM modulation, a modulation of 50% of the pulse at 18 Hz may be used because, although it does not represent actual modulation, it would be the worst case.

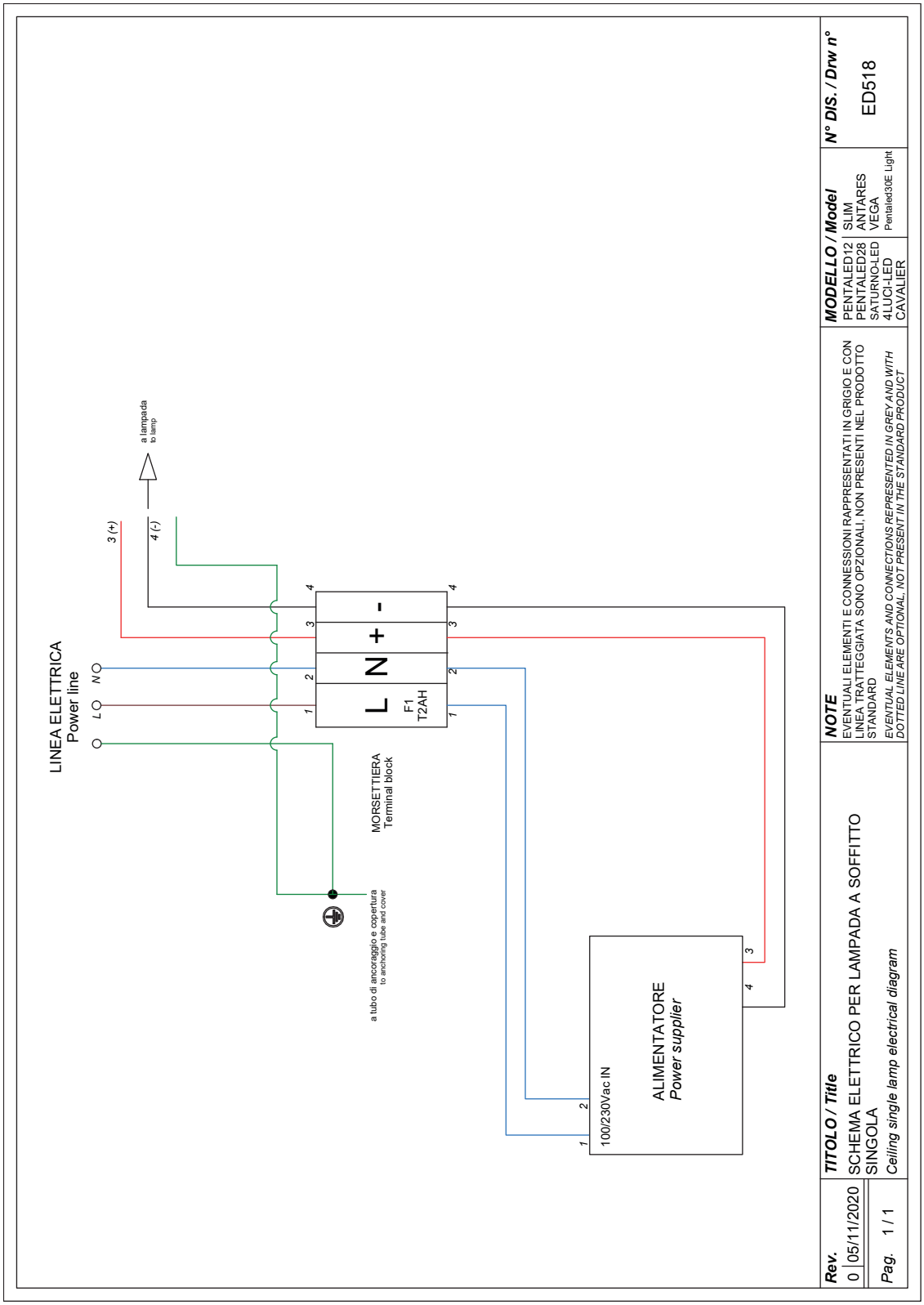
Recommended separation distance between portable and mobile RF communication equipment and the Product			
The Product is intended for use in electromagnetic environments in which radiated RF interference is controlled. The customer or the user of the Product may prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Product as specified below, according to the maximum output power of the communication equipment.			
Maximum emission power assigned to the transmitter [W]	**Separation distance as a function of transmitter frequency** [m]		
	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√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters with a maximum output power level not listed in the above table, the recommended separation distance in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts [W] in accordance with the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the upper frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from the structures of objects and people.			

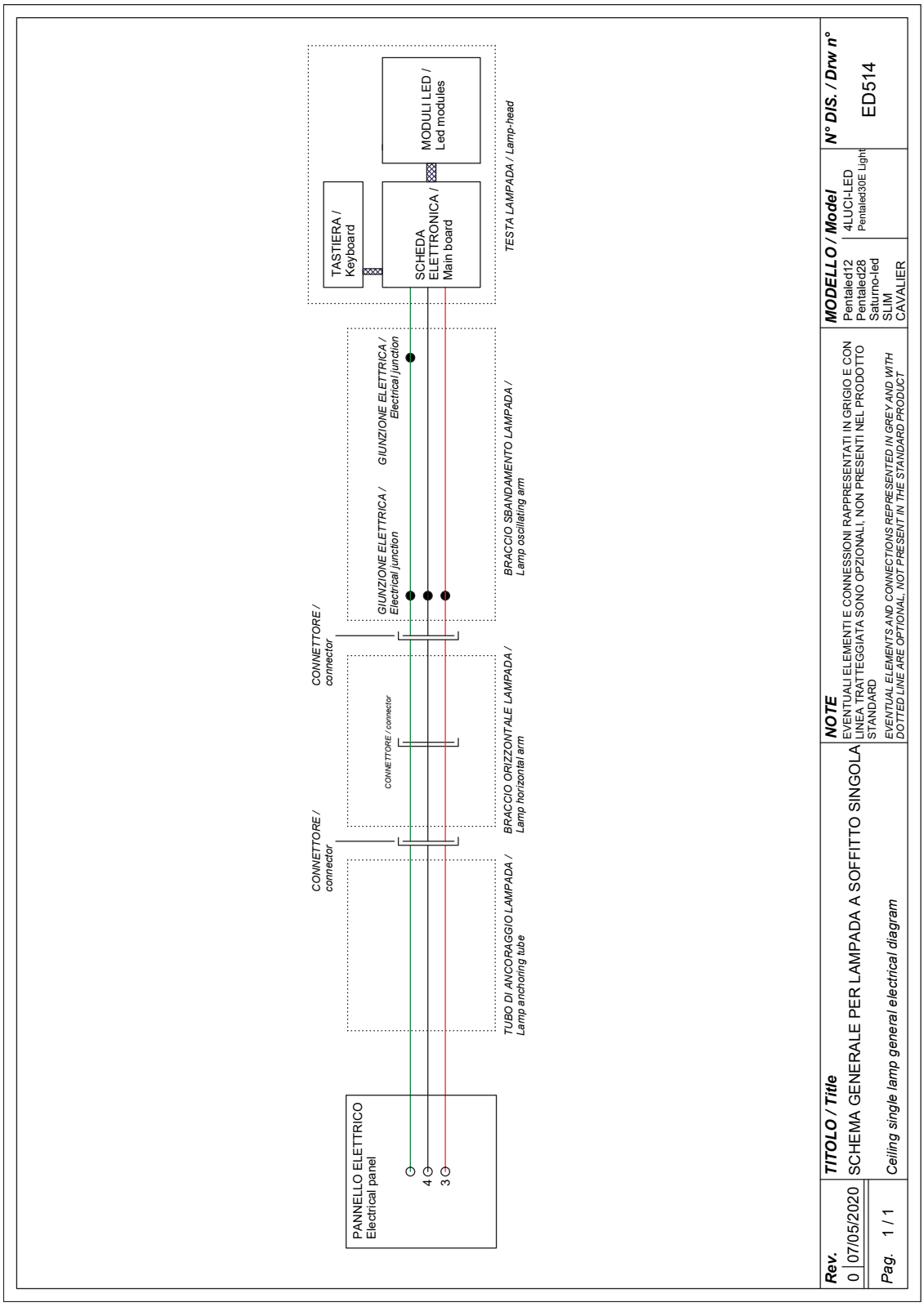
Proximity immunity to magnetic field in the frequency range 9 kHz - 13.56 MHz IEC 61000-4-39		
Magnetic fields at mains frequency must be at characteristic levels caused by radio frequency fields from devices used in close proximity.		
Test Frequency	**Modulation**	**Immunity test level** [A/m]
30 kHz [a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50 kHz	7.5 [c)]
a) This test is only applicable to ME MEDICAL DEVICES or ME SYSTEMS intended for use in a healthcare home environment. b) The vector shall be modulated using a square wave signal at 50% duty cycle. c) The mean square value shall be applied prior to modulation.		

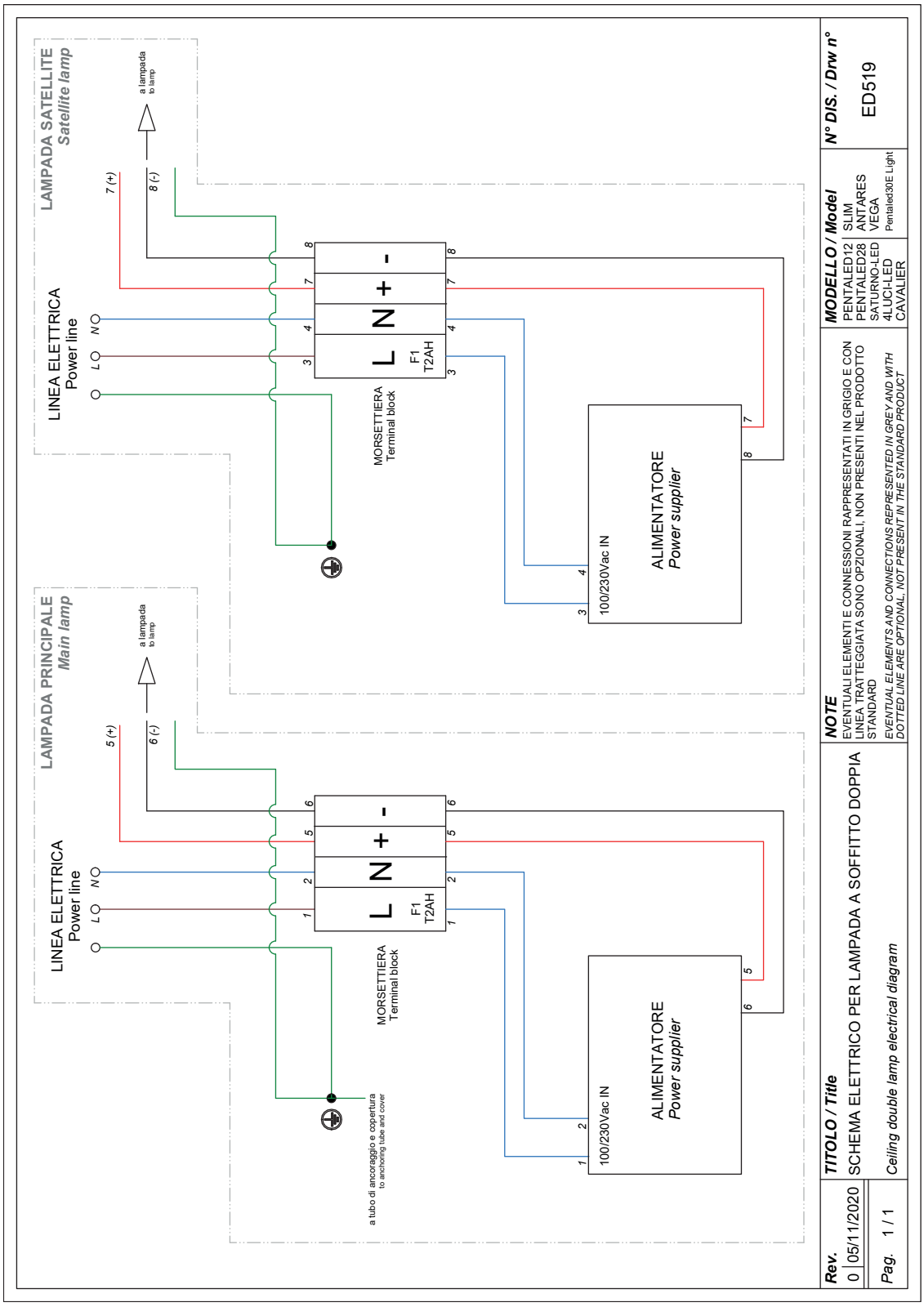
13 Certificate of Warranty

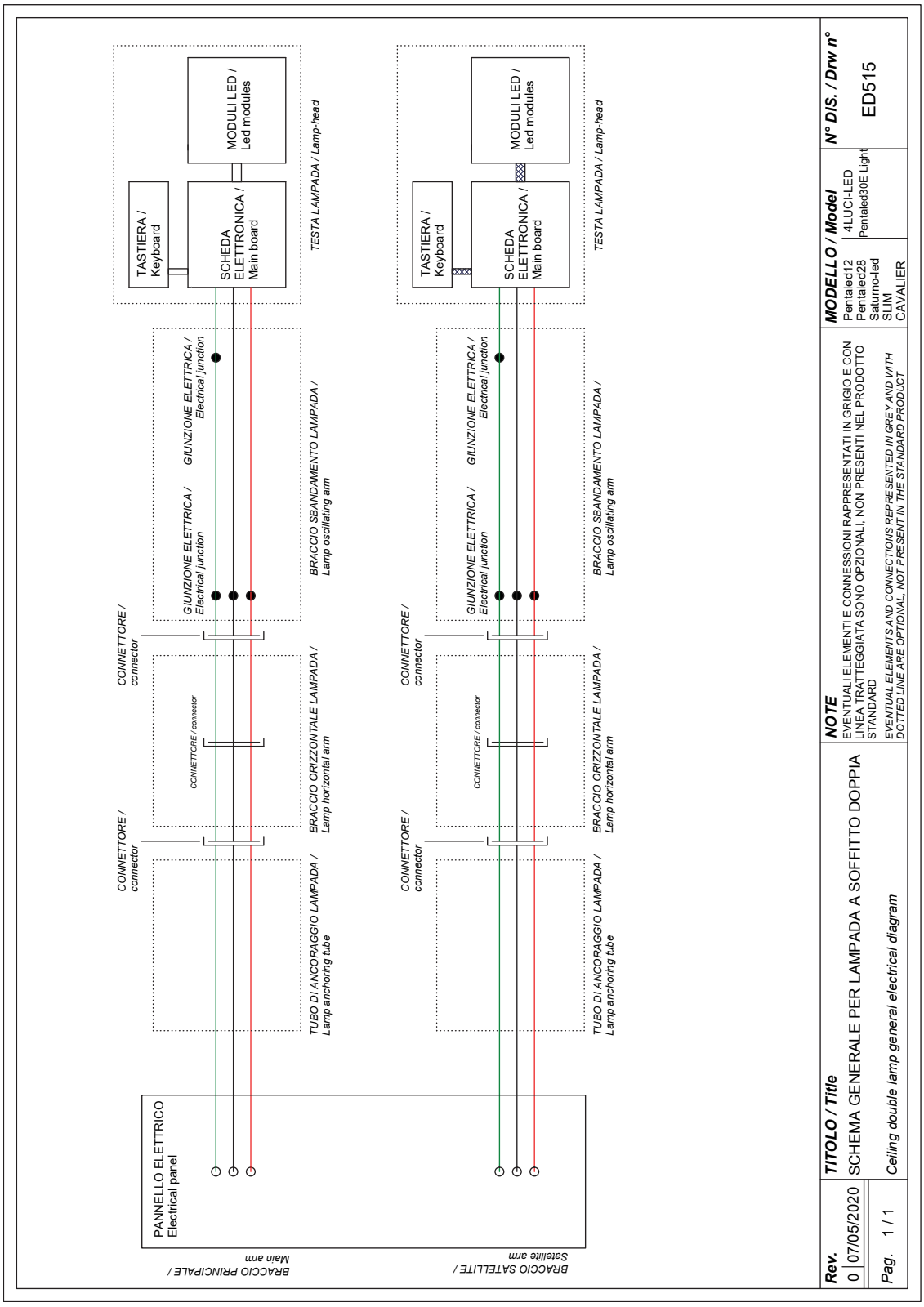
1. The Product is under warranty for a period of 18 months, including electrical parts.
2. The warranty begins on the date of dispatch of the Product from the RIMSA warehouse to the buyer.
3. In the event of a dispute, the date indicated on the 'transport document' accompanying the goods shall be deemed valid.
4. The warranty is limited to sending the buyer spare parts of the Product or, if RIMSA deems replacement of the parts to be impracticable, to replacing the entire Product, and is made for well established causes of manufacture and at RIMSA's sole discretion. The warranty does not therefore include any other costs or expenses (such as but not limited to labour costs, packaging and transport costs, etc.).
5. Excluded from the guarantee are components subject to normal wear and tear (e.g. halogen bulbs, LEDs, fuses, relays, ball bearings, etc.).
6. They are not covered by warranty:
   - malfunctions due to non-compliance with all instructions in the manuals
   - malfunctions due to installation and/or maintenance errors;
   - malfunctions or defects caused by neglect, negligence, misuse or other causes not attributable to RIMSA;
   - malfunctions or defects due to the fact that the electrical installation in the environment (room) in which the installation is carried out does not comply with IEC 60364-7-710 (standard for electrical installations for medical premises) and similar standards.
7. RIMSA shall indemnify direct damage to the buyer that is documented as being attributable to his Product, caused within the warranty period, in an amount not exceeding 40% of the net value of the Product as stated on the invoice to the buyer. RIMSA's liability for indirect or consequential damage (including loss of use of the Product) arising from the delivery is expressly excluded.
8. The guarantee in this certificate is in lieu of the legal guarantees for defects and non-conformities and excludes any other possible liability of RIMSA arising from the Products supplied.
9. Compensation for any damage to persons or property caused by the Product's malfunction or defects shall be limited to the amount of RIMSA's liability insurance coverage.
10. The purchaser automatically forfeits the guarantee if:
    - the Product has been tampered with or modified by the buyer or a third party;
    - the Product has been repaired by the Buyer or a third party without complying with the instructions contained in the Manuals
    - the serial number of the Product has been erased, blurred or removed;
    - the Buyer is not in good standing with payments.
11. For warranty work, the purchaser must only contact RIMSA.
12. Parts replaced under warranty must be returned to RIMSA, only if requested by RIMSA, carriage paid and properly packaged.
13. Failure to return the component at RIMSA's request will result in the cost of the component being charged.
14. RIMSA does not accept returns from end users or otherwise from parties other than the buyer.
15. Products returning to RIMSA must have the return authorisation documentation and a document describing the malfunction attached.
16. For anything not covered by this warranty certificate, please refer to Italian law.
17. For any dispute arising out of or in connection with orders to which this guarantee certificate applies that the parties have not been able to settle amicably, the Court of Milan shall have exclusive jurisdiction.

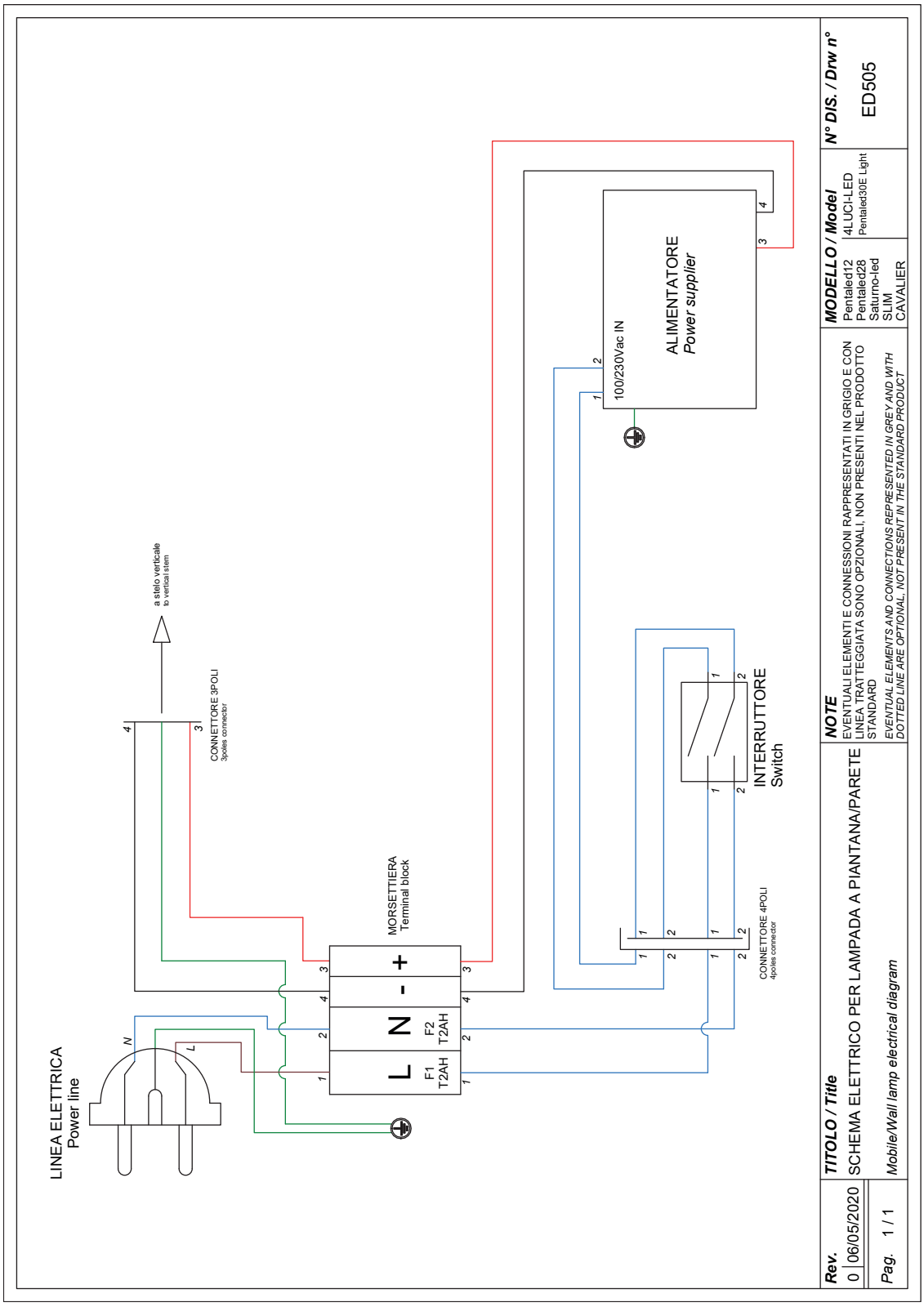
14 Electrical Schemes

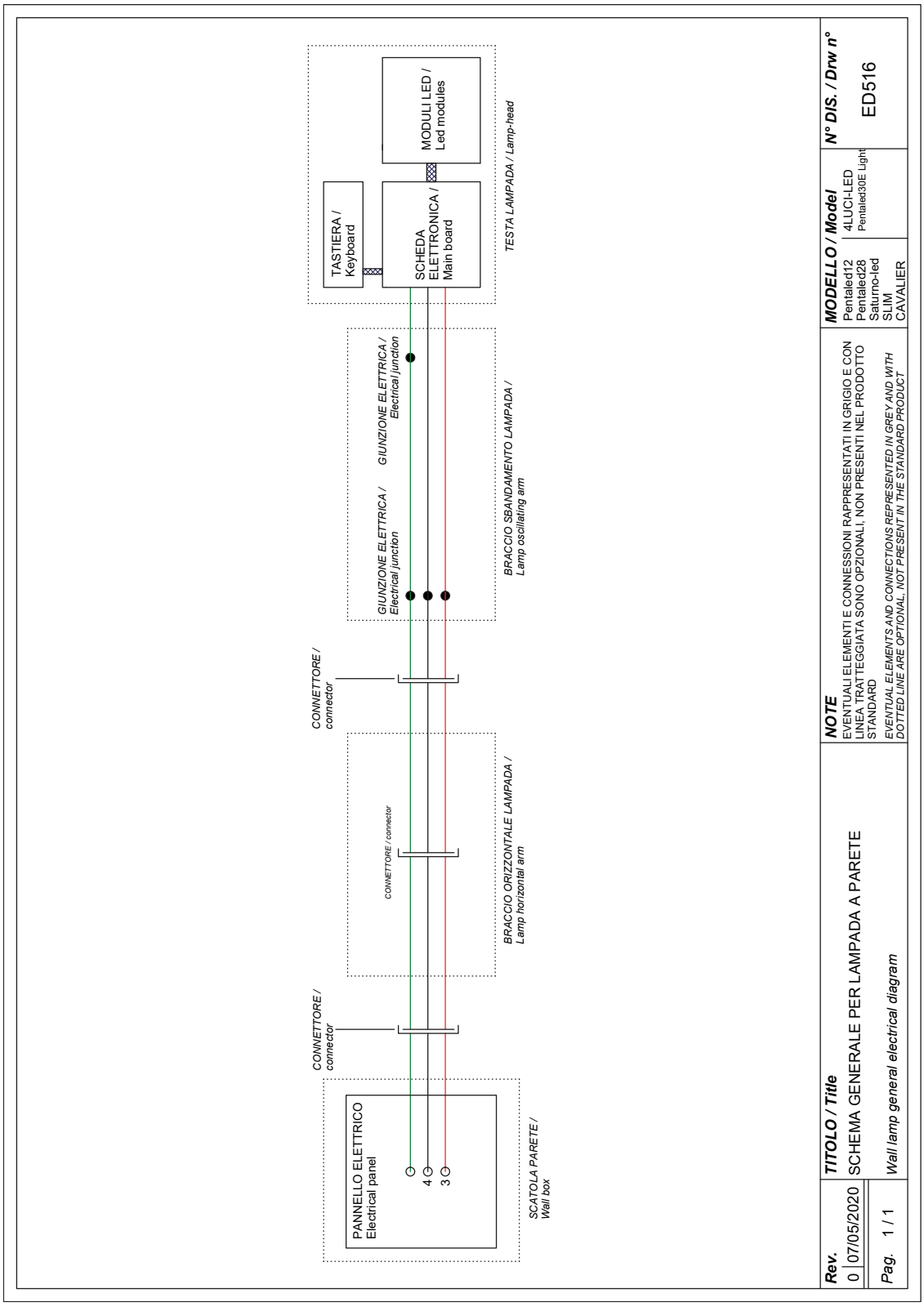


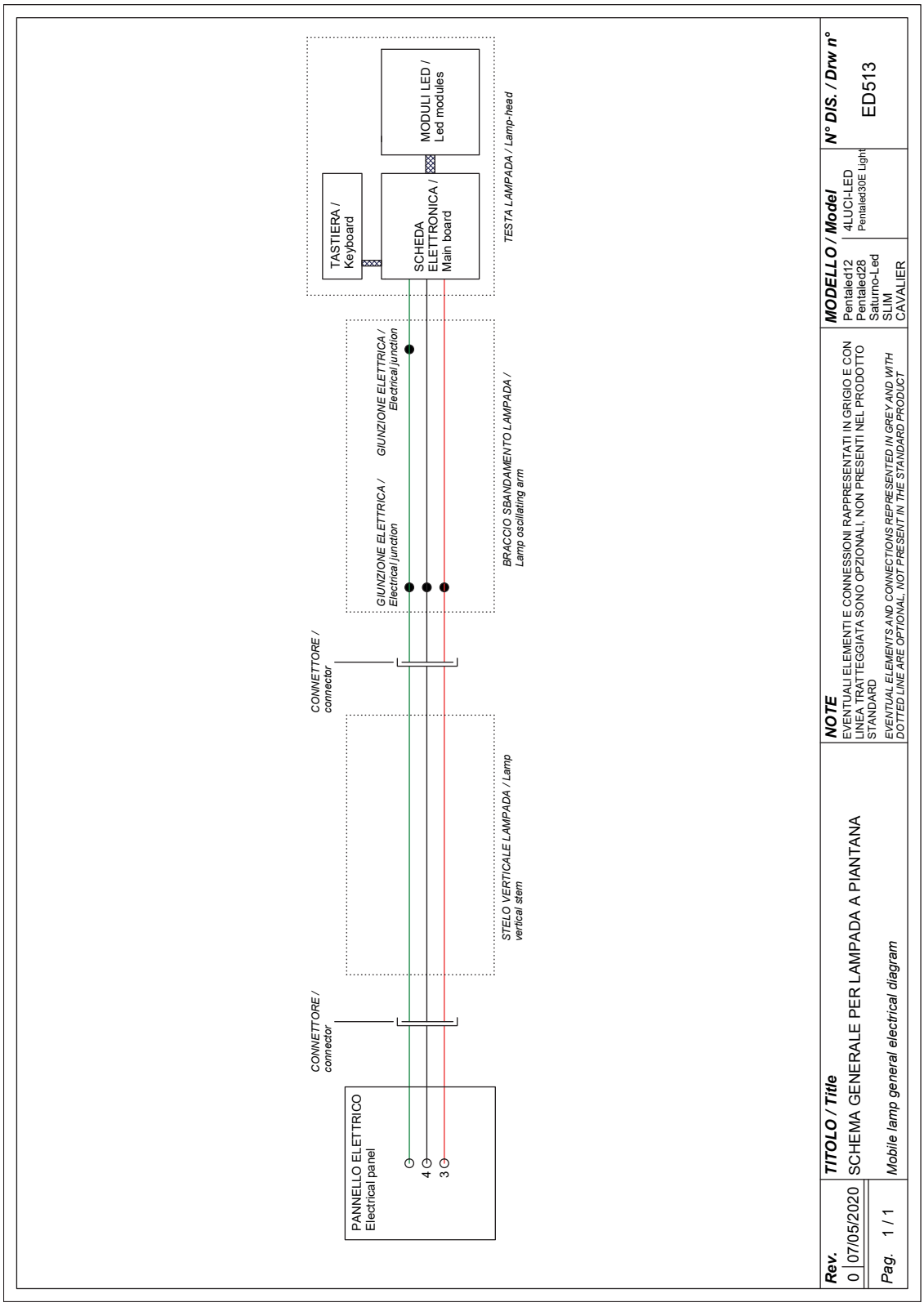

PANNELLO ELETTRICO
Electrical panel
4
3
CONNETTORE / connector
TUBO DI ANCORAGGIO LAMPADA / Lamp anchoring tube
BRACCIO ORIZZONTALE LAMPADA / Lamp horizontal arm
BRACCIO SBANDAMENTO LAMPADA / Lamp oscillating arm
GIUNZIONE ELETTRICA / Electrical junction
TESTA LAMPADA / Lamp-head
TASTIERA / Keyboard
SCHEDA ELETTRONICA / Main board
MODULI LED / Led modules
Rev.
0 07/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA GENERALE PER LAMPADA A SOFFITTO SINGOLA
Ceiling single lamp general electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED514

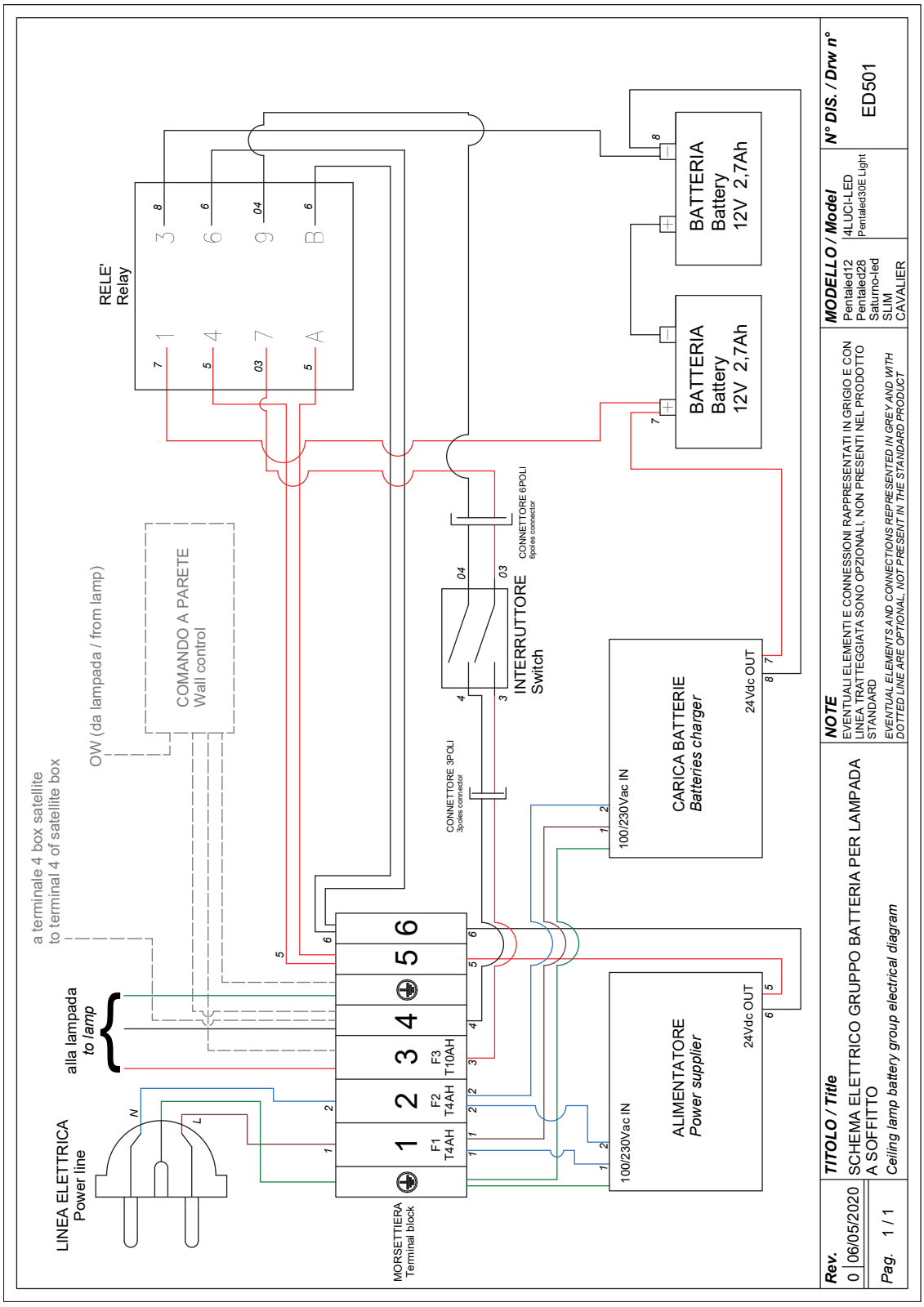

LAMPADA SATELLITE
Satellite lamp
LINEA ELETTRICA
Power line
N
L
a lampada
to lamp
7 (+)
8 (-)
MORSETTIERA
Terminal block
F1
T2AH
L
N
+
-
ALIMENTATORE
Power supplier
100/230Vac IN
LAMPADA PRINCIPALE
Main lamp
5 (+)
6 (-)
a tubo di ancoraggio e copertura
to anchoring tube and cover
Rev.
0 05/11/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA ELETTRICO PER LAMPADA A SOFFITTO DOPPIA
Ceiling double lamp electrical diagram
NOTE
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
4LUCI-LED
CAVALIER
SLIM
ANTARES
VEGA
Pentaled30E Light
N° DIS. / Drw n°
ED519

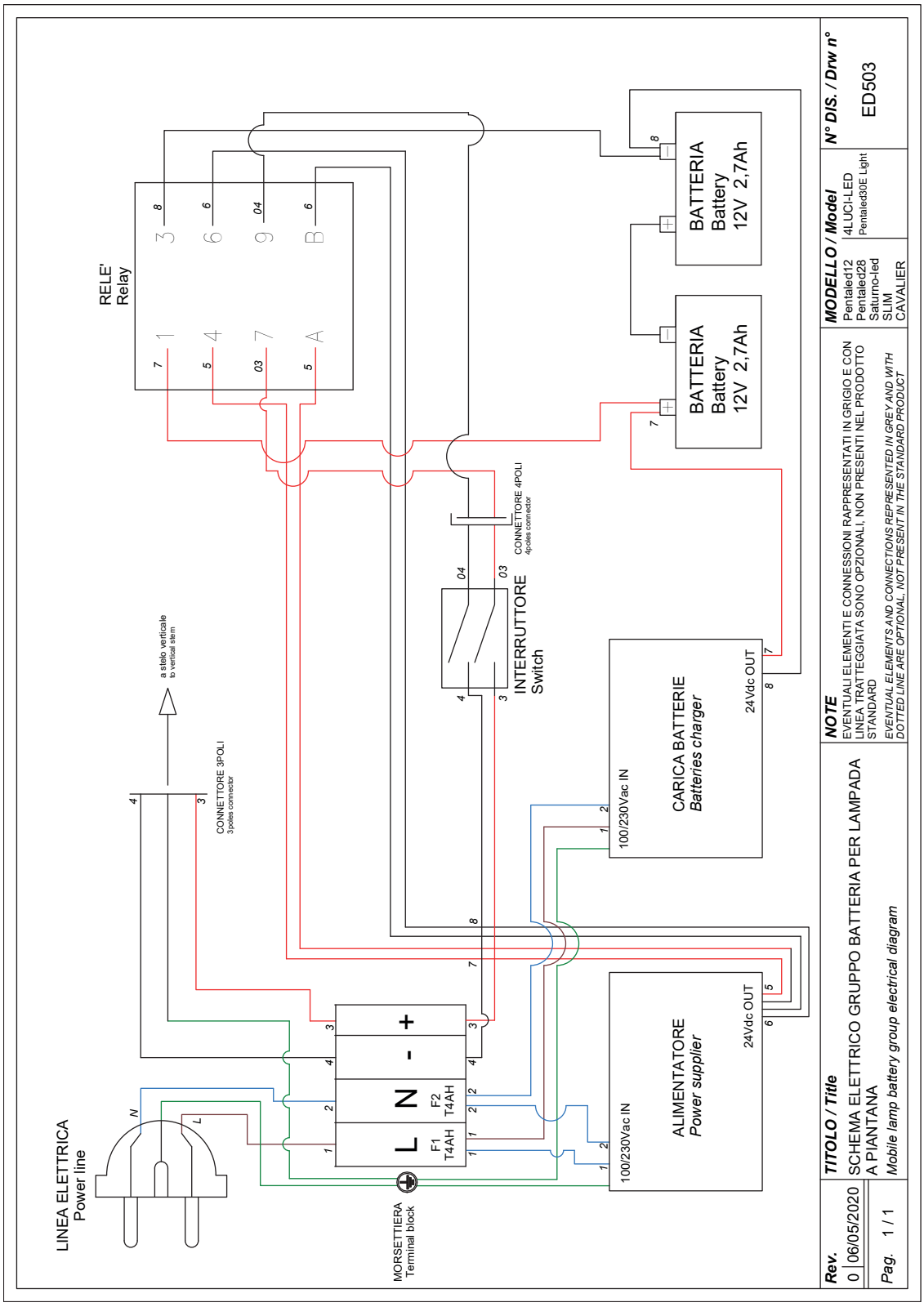

PANNELLO ELETTRICO
Electrical panel
BRACCIO PRINCIPALE / Main arm
BRACCIO SATELLITE / Satellite arm
CONNETTORE / connector
TUBO DI ANCORAGGIO LAMPADA / Lamp anchoring tube
BRACCIO ORIZZONTALE LAMPADA / Lamp horizontal arm
CONNETTORE / connector
GIUNZIONE ELETTRICA / Electrical junction
BRACCIO SBANDAMENTO LAMPADA / Lamp oscillating arm
GIUNZIONE ELETTRICA / Electrical junction
TESTA LAMPADA / Lamp-head
SCHEDA ELETTRONICA / Main board
TASTIERA / Keyboard
MODULI LED / Led modules
Rev.
0 07/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA
Ceiling double lamp general electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED515


LINEA ELETTRICA
Power line
N
L
MORSETTIERA
Terminal block
L
N
F1
T2AH
F2
T2AH
-
+
CONNETTORE 3POLI
3poles connector
a stelo verticale
to vertical stem
CONNETTORE 4POLI
4poles connector
INTERRUTTORE
Switch
ALIMENTATORE
Power supplier
100/230Vac IN
Rev.
0 06/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA ELETTRICO PER LAMPADA A PIANTANA/PARETE
Mobile/Wall lamp electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED505


TASTIERA / Keyboard
SCHEDA ELETTRONICA / Main board
MODULI LED / Led modules
TESTA LAMPADA / Lamp-head
GIUNZIONE ELETTRICA / Electrical junction
GIUNZIONE ELETTRICA / Electrical junction
BRACCIO SBANDAMENTO LAMPADA / Lamp oscillating arm
CONNETTORE / connector
CONNETTORE / connector
BRACCIO ORIZZONTALE LAMPADA / Lamp horizontal arm
CONNETTORE / connector
PANNELLO ELETTRICO Electrical panel
4
3
SCATOLA PARETE / Wall box
Rev.
0 07/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA GENERALE PER LAMPADA A PARETE
Wall lamp general electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED516


TESTA LAMPADA / Lamp-head
MODULI LED / Led modules
SCHEDA ELETTRONICA / Main board
TASTIERA / Keyboard
BRACCIO SBANDAMENTO LAMPADA / Lamp oscillating arm
GIUNZIONE ELETTRICA / Electrical junction
GIUNZIONE ELETTRICA / Electrical junction
CONNETTORE / connector
STELO VERTICALE LAMPADA / Lamp vertical stem
CONNETTORE / connector
PANNELLO ELETTRICO Electrical panel
4
3
Rev.
0 07/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA GENERALE PER LAMPADA A PIANTANA
Mobile lamp general electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED513


LINEA ELETTRICA
Power line
N
L
alla lampada
to lamp
a terminale 4 box satellite
to terminal 4 of satellite box
OW (da lampada / from lamp)
COMANDO A PARETE
Wall control
RELE'
Relay
MORSETTIERA
Terminal block
F1 T4AH
F2 T4AH
F3 T10AH
CONNETTORE 3POLI
3poles connector
CONNETTORE 6POLI
6poles connector
INTERRUTTORE
Switch
CARICA BATTERIE
Batteries charger
100/230Vac IN
24Vdc OUT
ALIMENTATORE
Power supplier
BATTERIA
Battery
12V 2,7Ah
BATTERIA
Battery
12V 2,7Ah
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED501
Rev.
0 06/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA ELETTRICO GRUPPO BATTERIA PER LAMPADA A SOFFITTO
Ceiling lamp battery group electrical diagram


RELE'
Relay
BATTERIA
Battery
12V 2,7Ah
BATTERIA
Battery
12V 2,7Ah
CONNETTORE 4POLI
4poles connector
INTERRUTTORE
Switch
a stelo verticale
to vertical stem
CONNETTORE 3POLI
3poles connector
CARICA BATTERIE
Batteries charger
100/230Vac IN
24Vdc OUT
ALIMENTATORE
Power supplier
100/230Vac IN
24Vdc OUT
LINEA ELETTRICA
Power line
MORSETTIERA
Terminal block
F1
T4AH
F2
T4AH
L
N
+
-
N
L
Rev.
0 06/05/2020
Pag. 1 / 1
TITOLO / Title
SCHEMA ELETTRICO GRUPPO BATTERIA PER LAMPADA A PIANTANA
Mobile lamp battery group electrical diagram
NOTE
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
Pentaled30E Light
N° DIS. / Drw n°
ED503

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