Anexa 86

Specificatie Tehnica Completata

Modelul: SATURNO-LED Mobile Stand – SATPIN LED ; Producator: RIMSA;

Tara: ITALIA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusa de către autoritatea ofertanta
Lampă pentru examinare, braț articulat (caracteristici avansate) Cod 130120 Descriere Lampă de examinare cu braț articulat pe suport mobil Alimentare 220V, 50Hz. Dimensiunea cîmpului luminous ≥ 180 mm focusabil Indexul de culoare, Ra ≥ 95 Temperatura culorii 4000 - 5500 K Ajustarea intensității luminii da Cu înălțime reglabilă 1500-1800 mm (diapazon) Distanța de lucru 800 - 1400 mm Suport cu acoperire anticorozivă reglabil pe verticala Baza cu acoperire anticorozivă, min. 5 roți Tehnologia Iluminarea bazată pe tehnologia LED Timpul de viață a LED-urilor ≥ 50 000 h Creșterea temperaturii în cîmpul luminos ≤ 1 grad Braț articulat da Nivelul de iluminare la distanță de 1 m minim 45 000 lux Mobil pe suport cu minim 5 roți da "Mîner pentru ajustarea înclinarii reflectorul lămpii" da	Lampă pentru examinare, braț articulat (caracteristici avansate) **DA** Cod 130120 Descriere Lampă de examinare cu braț articulat pe suport mobil **DA** Alimentare 220V, 50Hz. **DA** Dimensiunea cîmpului luminous 260 mm **DA** Focusabil **DA** Indexul de culoare, Ra 95 **DA** Temperatura culorii 4000 - 4500K **DA** Ajustarea intensității luminii **DA** Cu înălțime reglabilă 1100-1800 mm (diapazon) **DA** Distanța de lucru 800 - 1400 mm **DA** Suport cu acoperire anticorozivă reglabil pe vertical **DA** Baza cu acoperire anticorozivă, 4 roți **da** Tehnologia Iluminarea bazată pe tehnologia LED **DA** Timpul de viață a LED-urilor **60 000 h** DA Creșterea temperaturii în cîmpul luminos ≤ 1 grad **DA** Braț articulat **DA** Nivelul de iluminare la distanță de 1 m minim **50.000 lux** DA Mobil pe suport cu minim 4 roți **DA** "Mîner pentru ajustarea înclinarii reflectorul lămpii" **DA**

Digitally signed by Ceaicovschi Tudor
Date: 2022.09.15 16:44:23 EEST
Reason: MoldSign Signature
Location: Moldova

DICHIARAZIONE DI CONFORMITA' UE

Redatta ai sensi dell'Articolo 19 e Allegato IV del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio

Fabbricante: **RIMSA P. LONGONI S.r.l.**
Indirizzo della Sede Legale: Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) – ITALIA
Numero di registrazione unico (SRN): IT-MF-000009224

La presente dichiarazione di conformità è rilasciata secondo la responsabilità esclusiva del fabbricante.

UDI-DI di base: **++B880LUMINAIREPM**

Nome del prodotto e denominazione commerciale: **SATURNO-LED**
Riferimento di modello: SAT-LED
Configurazioni:

SATPAN-LED	LAMPADA SATURNO-LED PARETE
SATPIN-LED	LAMPADA SATURNO-LED PIANTANA
SATSON-LED	LAMPADA SATURNO-LED SOFFITTO
SATSONX2-LED	LAMPADA SATURNO-LED SOFFITTO DOPPIA

Destinazione d'uso: LAMPADA SCIALITICA SECONDARIA PER CHIRURGIA (LAMPADA DA TRATTAMENTO)

Classe di rischio del dispositivo, conformemente alle regole di cui all'Allegato VIII del REGOLAMENTO (UE) 2017/745: **CLASSE I**
Giustificazione: Durata: A breve termine (Allegato VIII, CAPO I, punto 1. DURATA DELL'USO)
Descrizione: Dispositivo medico non invasivo (Allegato VIII, CAPO III, punto 4. DISPOSITIVI NON INVASIVI, comma 4.1 Regola 1)
Dispositivo medico attivo (Allegato VIII, CAPO III, punto 6. DISPOSITIVI ATTIVI, comma 6.2 Regola 10)

Il fabbricante dichiara che il dispositivo è conforme al REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio e alle seguenti norme:

- IEC 60601-1 (Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali)
- IEC 60601-1-2 (Parte 1: Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali - Norma collaterale: Compatibilità elettromagnetica – Prescrizioni e prove)
- IEC 60601-2-41 (Parte 2: Norme particolari relative alla sicurezza fondamentale e alle prestazioni essenziali delle lampade scialitiche per uso chirurgico e per la diagnosi)

La procedura di valutazione della conformità del dispositivo è svolta secondo la premessa (60) e l'Articolo 52 del REGOLAMENTO (UE) 2017/745.

Il Sistema Qualità di RIMSA è conforme alle norme UNI EN ISO 9001 e UNI CEI EN ISO 13485 ed è certificato da CSQ (certificato CSQ n.9120.RMS1 e 9124.RMS2).

Seregno, 03/01/2022

Luogo e data

Timbro e firma del Consigliere Delegato
(Paolo Longoni)

EU DECLARATION OF CONFORMITY

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

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

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

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

Product and trade name: **SATURNO-LED**
Model reference: SAT-LED
Configurations:

SATPAN-LED	LAMP MODEL SATURNO-LED WALL
SATPIN-LED	LAMP MODEL SATURNO-LED MOBILE STAND
SATSON-LED	LAMP MODEL SATURNO-LED CEILING
SATSONX2-LED	LAMP MODEL SATURNO-LED DOUBLE CEILING

Intended purpose: MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

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

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

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

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

RIMSA Quality 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).

Seregno, 03/01/2022

Place and date

Mark and sign of Managing Director
(Paolo Longoni)

SATURNO-LED

RIMSA

Brightening Ideas

www.rimsa.it

LAMP SATURNO-LED

This is a surgical-type lamp suitable for minor surface-operation surgeries, gynaecology and first aid.
The radial pattern of the beams and the large-diameter reflector (195mm) eliminate shadows and provide three-dimensional lighting.

The reduced emission of IR rays by the LEDs together with the low power used permit obtaining a very low heat emission to the benefit of patient and doctor comfort.

The high efficiency of the LED sources and low current absorption permit obtaining a very low infra-red emission and a cold light in the operating field. Very easy handling and positioning stability.

The fact that the beams are close together means they do not have to be focused. By pressing the digital key K on the control keyboard, two different tones of white light can be selected - 4000°K and 4500°K-without altering the light intensity.

The lamp is very easy to move thanks to the lightness of the aluminium support structure.

For environments in which power supply continuity cannot be guaranteed, it is best to purchase an automatic recharge battery unit.

Class I medical device, with CE mark in compliance with the Regulation (EU) 2017/745 of the European Parliament and of the Council, of 05th April 2017.

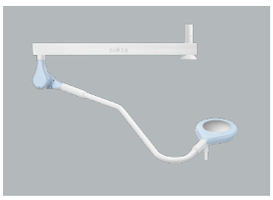
PERFORMANCES

Light intensity at 1 m distance (Ec)	Lux	50.000
Color temperature (2 selections)	K	4.000 - 4.500
Color rendering index (CRI)	Ra	95
Color rendering index (R9)	Ra	>90
d10 light field diameter where illuminance reached 10% of Ec	mm	260
Light field diameter	mm	Fixed
Depth of illumination IEC 60601-2-41 (L1+L2) at 60%	mm	1100
Depth of illumination IEC 60601-2-41 (L1+L2) at 20%	mm	1800
Total radiated energy	W/m^2	186
Ratio between radiated energy and illuminance	mW/m^2lx	3,63

ELECTRICAL DATA

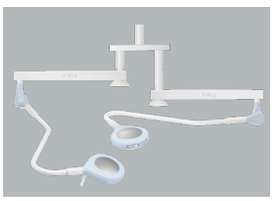
Primary alternating voltage (ac)	V	100-240
Frequency	Hz	50/60
Absorbed power	W - VA	18,5 - 37
No. of LEDs	Led	9+3 of courtesy
Average LED life	hours	> 60.000
Light head diameter	cm	19,5
Control of illuminance	%	20-100

VERSIONS AVAILABLE:



CEILING LAMP

(code **SATSON-LED**)



DOUBLE LAMP

(code **SATSONX2-LED**)

WALL MOUNTED

(code **SATPAN-LED**)

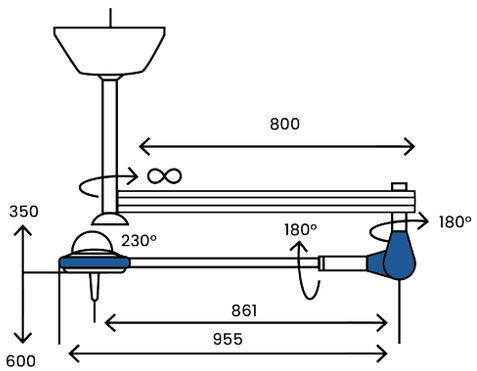
MOBILE

(code **SATPIN-LED**)

OPTIONS

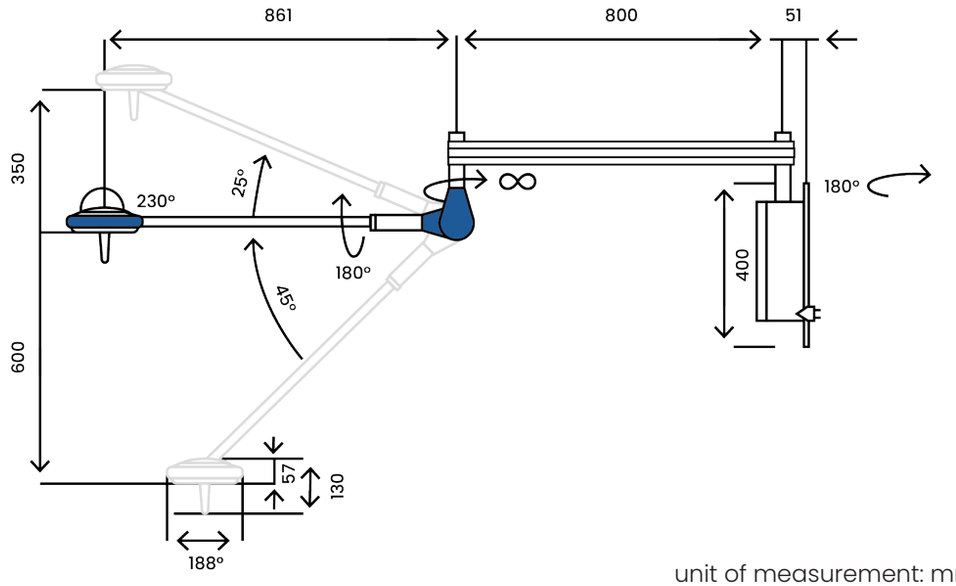
- BATTERY GROUP

SATSON-LED



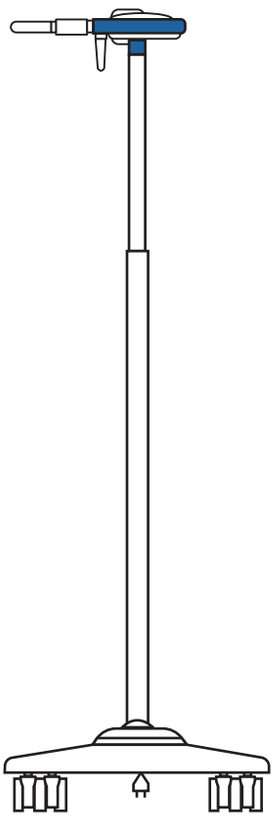
unit of measurement: mm

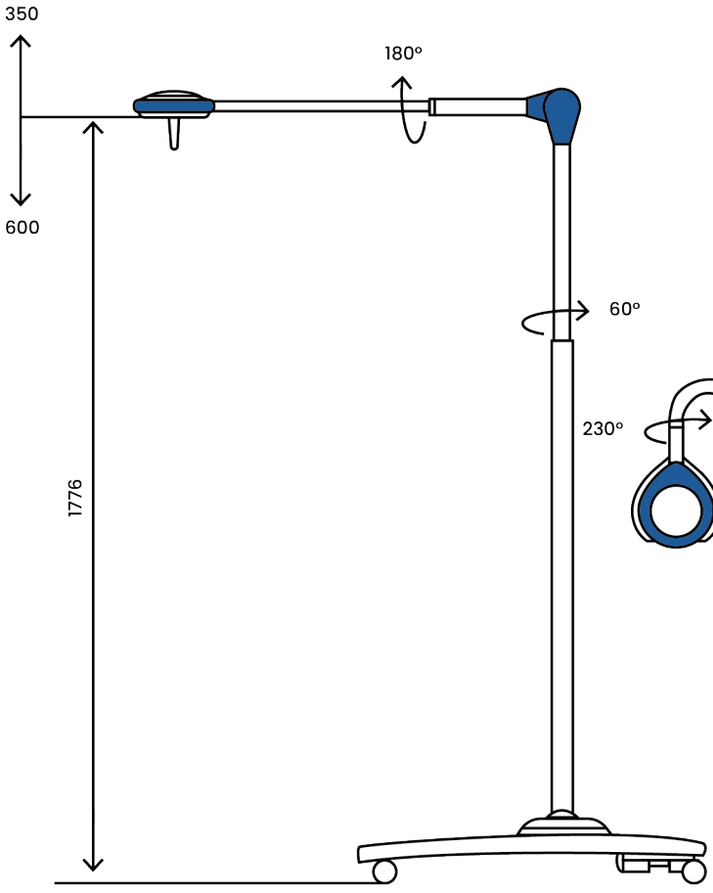
SATPAN-LED

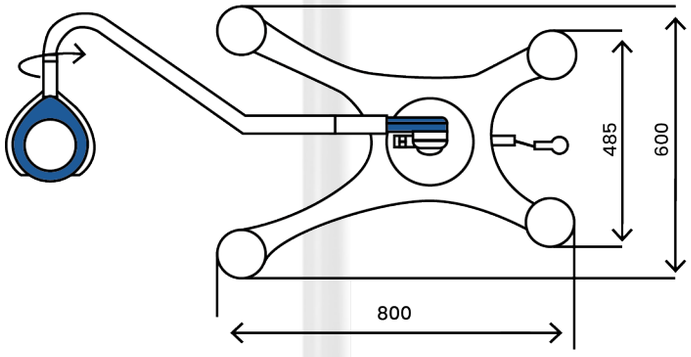


unit of measurement: mm

SATPIN-LED







unit of measurement: mm

Via Monterosa, 18 / 22 - 20831 Seregno (MB) - Italy
Ph. (+39) **0362 325709** | Fax (+39) **0362 328559** | E-mail **info@rimsa.it**
Website **www.rimsa.it**

Research & component
MADE IN ITALY

RIMSA

Brightening Ideas

www.rimsa.it

Rev: 2022, July

OPERATION AND MAINTENANCE MANUAL

PENTALED 12
PENTALED 28
QUATTROLUCI LED
SATURNO-LED

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

Introduction

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

Marking CE

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

Compliance

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

Validity of manual

This installation manual is valid for the following models:

- PENTALED 12 in single ceiling, double ceiling, wall and mobile versions;
- PENTALED 28 in single ceiling, double ceiling, wall and mobile versions;
- QUATTROLUCI LED in single ceiling, double ceiling, wall and mobile versions;
- SATURNO-LED in single ceiling, double ceiling, wall and mobile versions.

Customer Service

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

- 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.

Copyright

Translations

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

Index of contents

KEY 5
1 GENERAL SAFETY INFORMATION 6
2 Importance of personal safety 6
2.1 Intended use 6
2.2 Safety conditions (secondary effects) 7
2.3 Environmental conditions 7
3 General 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 Precautions for the Product operator 10
4.1 Personnel awareness obligation 10
4.2 Warranty and liabilities 10
5 Product description and operation 11
5.1 Product description PENTALED 12/28 11
5.2 Product description QUATTROLUCI LED 13
5.3 Product description SATURNO-LED 15
5.4 Description of operation 17
5.4.1 PENTALED 12 control keyboard 17
5.4.2 PENTALED 28 control keyboard 17
5.4.3 QUATTROLUCI LED control keyboard 18
5.4.4 SATURNO-LED control keyboard 18
5.5 Product handling 18
5.5.1 Brakes for mobile version 24
5.6 Checks to be made every time before use 25
6 Cleaning and disinfecting 25
6.1 Application method 25
6.2 Cleaning the Product 26
6.3 Product disinfecting 26
6.4 Handpiece sterilization 27
7 Adjustment and maintenance 28
7.1 Swinging arm adjustment 28
7.2 Clutch adjustment 28
7.3 Periodical checks to be performed on the Product 29
7.4 Routine maintenance 29
7.5 Repairs 31
7.6 Disposal after use 32
7.7 Spare parts list 32
8 Technical properties 33
8.1 PENTALED 12 technical properties 33
8.2 PENTALED 28 technical properties 35
8.3 QUATTROLUCI LED technical properties 37
8.4 SATURNO-LED technical properties 39
9 EU Declaration of conformity 41
10 EMC Declaration 43
11 Warranty Certificate 48

BG	За да поискате ръчник на този език, изпратете имейл на 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 ένα e-mail στη διεύθυνση info@rimsa.it.
ES	Para solicitar el manual en este idioma, envíe un correo electrónico a info@rimsa.it.
ET	Selles keeles käsiraamatu tellimiseks saatke palun e-kiri aadressile info@rimsa.it.
FI	Jos haluat käsikirjan tällä kielellä, lähetä sähköpostia osoitteeseen info@rimsa.it.
FR	Pour demander le manuel dans cette langue, veuillez envoyer un e-mail à info@rimsa.it.
GA	Chun an lámhleabhar sa teanga seo a iarraidh, seol r-phost chuig info@rimsa.it.
HR	Da biste zatražili priručnik na ovom jeziku, pošaljite e-mail na info@rimsa.it.
HU	A kézikönyv ezen a nyelven történő igényléséhez kérjük, küldjön e-mailt a info@rimsa.it címre.
LT	Norėdami prašyti vadovo šia kalba, siųskite el. laišką adresu info@rimsa.it.
LV	Lai pieprasītu rokasgrāmatu šajā valodā, lūdzu, sūtiet e-pastu uz adresi info@rimsa.it.
MT	Biex titlob il-manwal f'din il-lingwa, jekk jogħġbok ibgħat e-mail lil info@rimsa.it.
NL	Om de handleiding in deze taal aan te vragen, kunt u een e-mail sturen naar info@rimsa.it.
PL	Aby zamówić podręcznik w tym języku, należy wysłać wiadomość e-mail na adres info@rimsa.it.
PT	Para solicitar o manual nesta língua, envie por favor um e-mail para info@rimsa.it.
RO	Pentru a solicita manualul în această limbă, vă rugăm să trimiteți un e-mail la info@rimsa.it.
SK	Ak chcete požiadať o príručku v tomto jazyku, pošlite e-mail na adresu info@rimsa.it.
SL	Če želite zahtevati priročnik v tem jeziku, pošljite e-pošto na naslov info@rimsa.it.
SV	Om du vill ha handboken på detta språk skickar du ett e-postmeddelande till info@rimsa.it.

KEY

PRODUCT

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

OPERATOR

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

RESPONSIBLE ORGANIZATION

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

TECHNICAL SERVICE PERSONNEL

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

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

1 GENERAL SAFETY INFORMATION

This manual is an integral part of the Product as indicated by REGULATION (EU) 2017/745 and subsequent amendments and supplements. Read and keep this Operation and Maintenance Manual close to the Product.
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 a ME Medical Electrical equipment and therefore falls within the field of application of the IEC 62353 standard.
To avoid any risk of electric shocks, the Product must only be connected to mains supplies with earth protection.

	**Electric shock risk.**

2 Importance of personal safety

2.1 Intended use

MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)
The Product is a medical device designed for use in operating theatres within the PATIENT AREA, with short-term duration, active, non invasive, designed to locally light up the patient's body for treatments and diagnosis which can be interrupted without any HAZARD for the PATIENT in case of failure of the light.
A combination of two or more surgical luminaires used in the operating theatre and required for treatment and diagnosis makes up a SURGICAL LUMINAIRE SYSTEM.
The Product correctly lights up the operating range from a distance of about 70 – 140 cm from the patient area.
In the event of overlapping lamps, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.

Operating field

Undesired effects of overlapping light fields

	**Possibility of tissue dehydration and damage.**

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

2.2 Safety conditions (secondary effects)

Optical safety

Possibility of glare.

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

Electromagnetic disturbance

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

Incorrect use

Do not place objects on Product.

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

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

Improper use of mobile version

Pushing or resting on the product is forbidden.

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

2.3 Environmental conditions

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or N_2O (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of inflammable agents.
- During operation, the ambient temperature must be between 10°C and 40°C.
- Relative humidity must be between 30% and 75%.
- Atmospheric pressure must be between 700 and 1060hPa.

3 General information

3.1 Operator qualifications

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

3.2 Patient population and body interactions

Patient population	The intended use makes the Product suitable for all types of population without constraints of age, weight, health or medical conditions. Patients can be awake or unconscious, in local or total anaesthesia. Patient population can also be made of animals.
Patient interaction	An active patient could only accidentally touch the head and the swinging arm of the device, while this is not possible in case of unconscious or disable patients.
Operator interaction	The operator touches the device necessary on the sterilisable handpiece and function control keyboard, and occasionally on the enclosure.

3.3 Graphic symbols used in this operation and maintenance manual

The following safety measures must be put in place during Product installation, use and servicing.
To emphasize their importance, a number of safety precautions are repeated throughout the manual.
Follow the safety precautions before using or repairing the Product. Carefully abiding by the safety precautions improves the ability to use the Product safely and correctly and helps prevent incorrect maintenance which could be hazardous and cause damage. The safety measures are approximate and not exhaustive; the Operator, the Responsible Organization and the Technical Service Personnel must develop their capacities to upgrade and integrate them.

General warning signal

General mandatory code of conduct signal

General prohibition signal

3.4 Graphic symbols used on the Product

Below are the symbols to be found on the Product:

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

Date of manufacture (month and year)

Manufacturer's address

Fuses used in the device

Comply with the instructions for use

Medical Device

Model reference

Serial number

Swiss authorised representative

Disposal

Protection earth

‘N’

Neutral lead connection point

‘L’

Line lead connection point

‘I’

ON

‘O’

OFF

Standby and switch-on

No stepping on surface

4 Precautions for the Product operator

4.1 Personnel awareness obligation

Operator Instructions

The Responsible Organization must instruct the [redacted] 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.

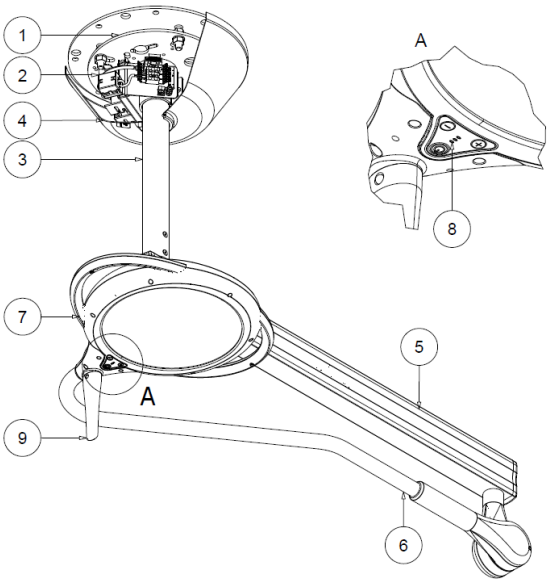
5 Product description and operation

5.1 Product description PENTALED 12/28

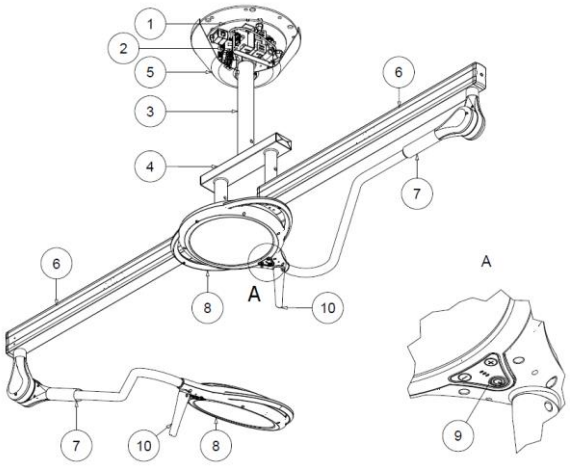
Versions

The Product is available in various versions:

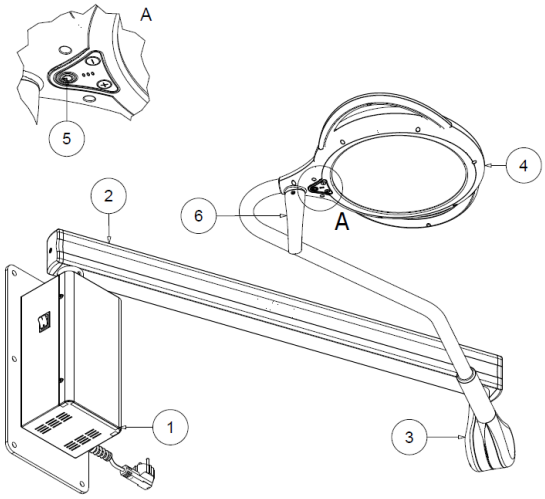
- **single ceiling version**
- **double ceiling version**
- **wall version**
- **mobile version**



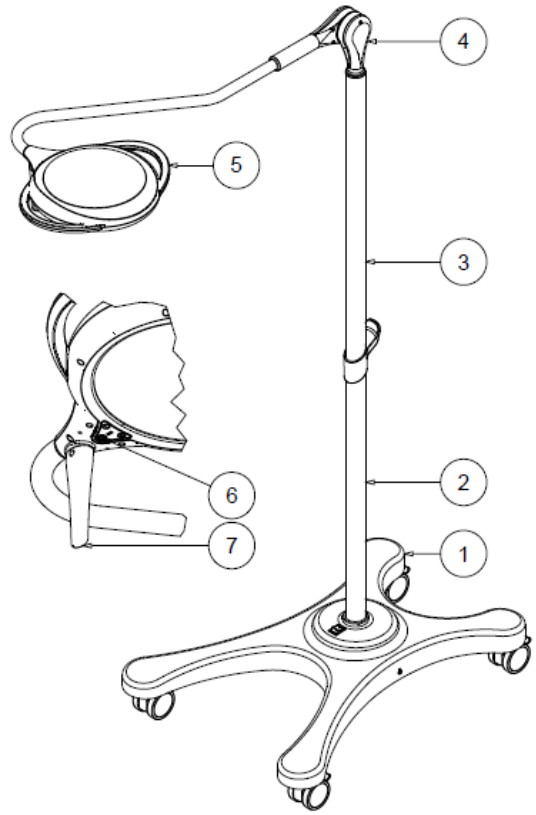
SINGLE CEILING Version: ceiling plate hub (1), switchboard (2), ceiling anchoring tube (3), ceiling cover (4), horizontal arm (5), swinging arm (6), lamp head (7), control keyboard (8), sterilisable grip (9).



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).



WALL Version: wall box (1), horizontal arm (2), swinging arm (3), lamp head (4), control keyboard (5), sterilisable grip (6).



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).

Separable parts

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

PENTALED 28

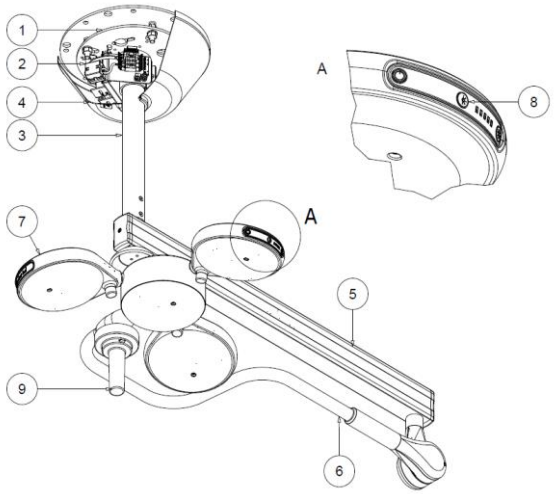
The PENTALED 28 product is based on the Pentaled12 lamp. The only difference is that it features a direct light system with lenses using 28 LEDs and the possibility of selecting two colour temperatures. The possibility also exists of regulating the diameter of the light field by rotating the handpiece provided.

5.2 Product description QUATTROLUCI LED

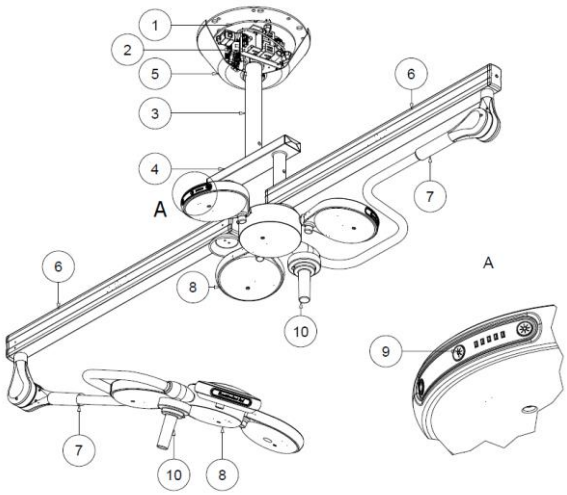
Versions

The Product is available in various versions:

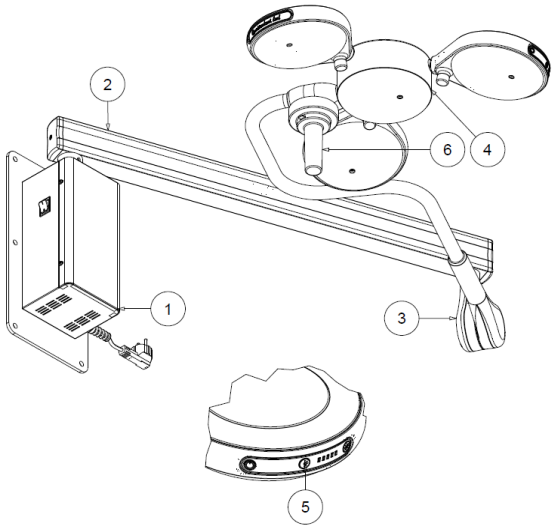
- **single ceiling version**
- **double ceiling version**
- **wall version**
- **mobile version**



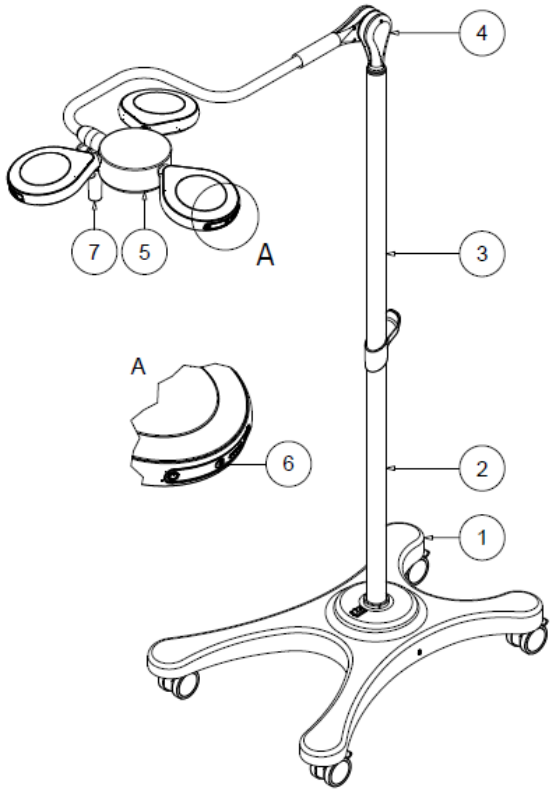
SINGLE CEILING Version: ceiling plate hub (1), switchboard (2), ceiling anchoring tube (3), ceiling cover (4), horizontal arm (5), swinging arm (6), lamp head (7), control keyboard (8), sterilisable grip (9).



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).



WALL Version: wall box (1), horizontal arm (2), swinging arm (3), lamp head (4), control keyboard (5), sterilisable grip (6).



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).

Separable parts

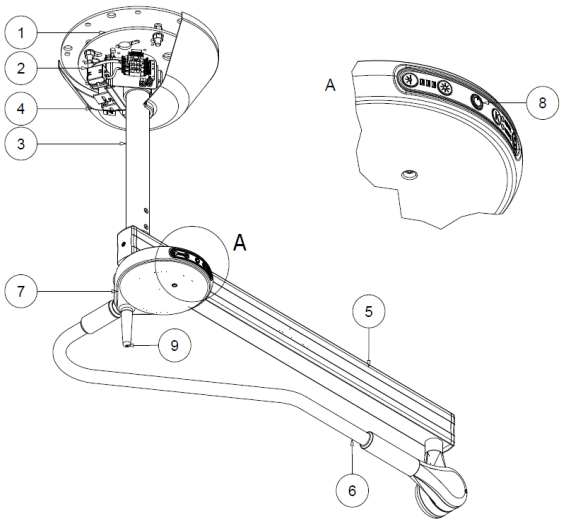
Sterilisable handpiece. Refer to Section 6.4 for assembly/disassembly instructions.

5.3 Product description SATURNO-LED

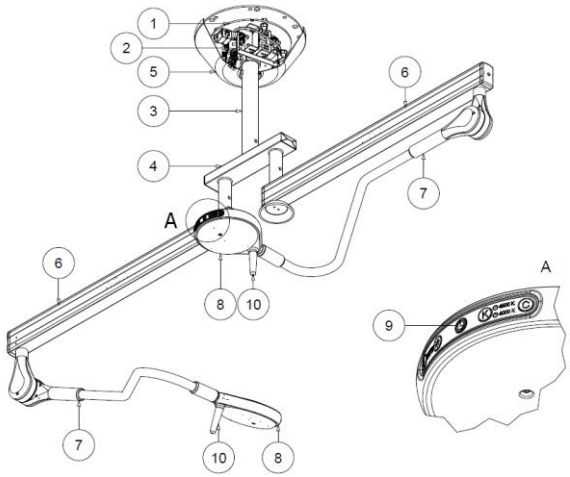
Versions

The Product is available in various versions:

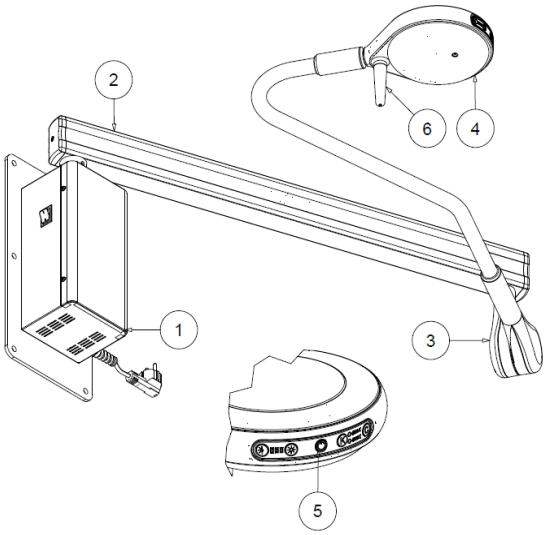
- **single ceiling version**
- **double ceiling version**
- **wall version**
- **mobile version**



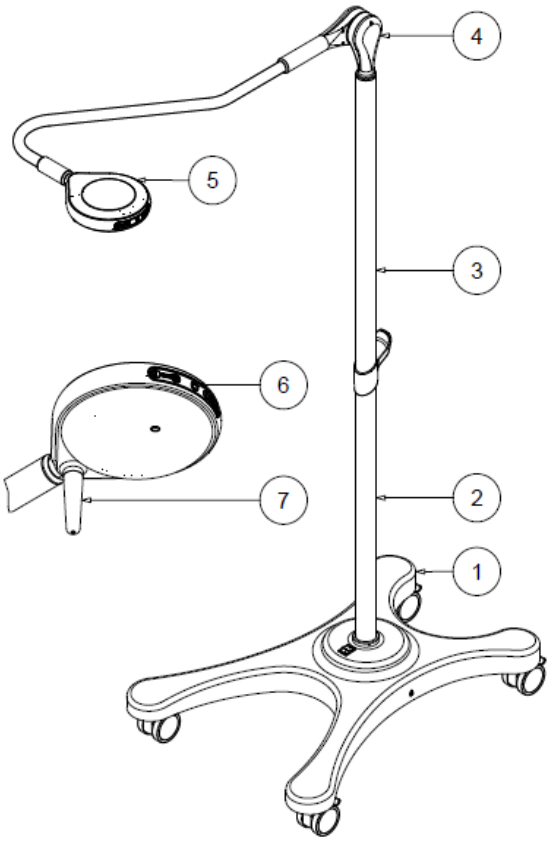
SINGLE CEILING Version: ceiling plate hub (1), switchboard (2), ceiling anchoring tube (3), ceiling cover (4), horizontal arm (5), swinging arm (6), lamp head (7), control keyboard (8), sterilisable grip (9).



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).



WALL Version: wall box (1), horizontal arm (2), swinging arm (3), lamp head (4), control keyboard (5), sterilisable grip (6).



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).

Separable parts

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

5.4 Description of operation

Main switch

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

CAUTION

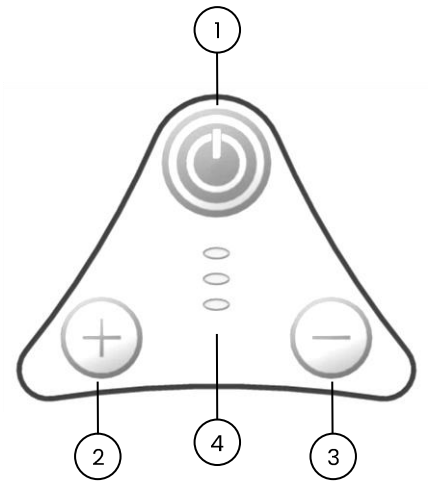
In case of wall and mobile versions do not position the device so it is hard to reach and remove the power plug in case of an emergency.

5.4.1 PENTALED 12 control keyboard

PENTALED 12 control keyboard

Product control is by means of the control keyboard positioned on the lower part of the reflector casing. By pressing the keys, the following functions are started:

- I/O long press to start/stop Product (1);
- increase light intensity '+' (2);
- reduction of light intensity '–' (3);
- three green micro-LEDs display the selected intensity level (4). With mains power on, a green micro-led remains on to indicate standby function.



Lighted area

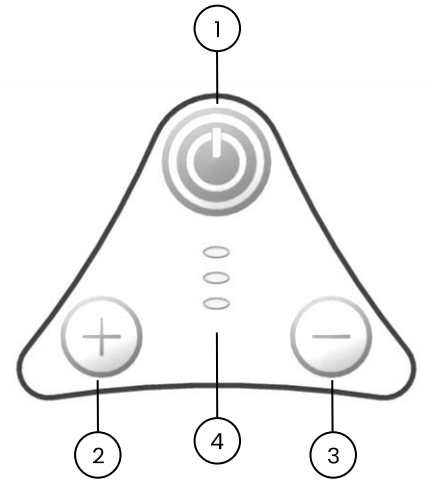
The Product has been designed to ensure a fixed light diameter without any need for adjustment.

5.4.2 PENTALED 28 control keyboard

PENTALED 28 control keyboard

Product control is by means of the control keyboard positioned on the lower part of the reflector casing. By pressing the keys, the following functions are started:

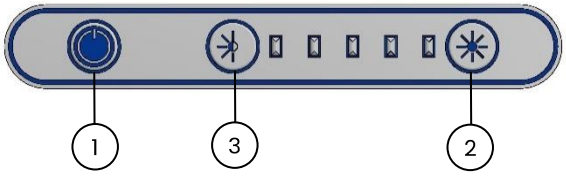
- I/O long press to start/stop Product (1);
- I/O quick press to regulate the colour temperature of the Product cyclically from 4500K to 5000K (4500K at start) (1);
- increase light intensity '+' (2);
- reduction of light intensity '–' (3);
- three green micro-LEDs display the selected intensity level (4). With mains power on, a green micro-led remains on to indicate standby function.



Lighted area

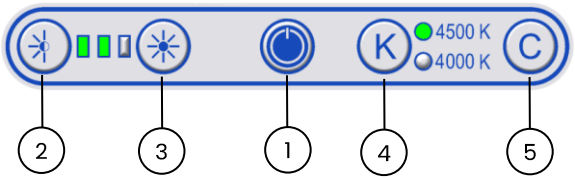
The diameter of the light field and focus can be regulated by rotating the central roller.

QUATTROLUCI LED control keyboard

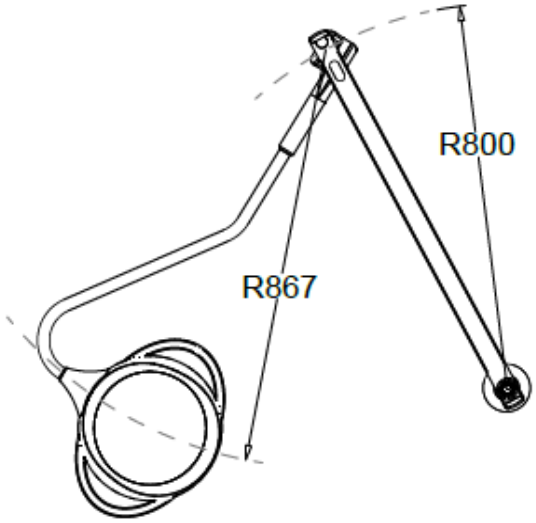


Lighted area

SATURNO-LED control keyboard



Lighted area



5.4.3 QUATTROLUCI LED control keyboard

Product control is by means of the control keyboard positioned on the reflector casing. By pressing the keys, the following functions are started:

- start/stop stand-by switch I/O (1);
- increase/reduction light intensity (2) and (3).

The light field is not adjustable.

5.4.4 SATURNO-LED control keyboard

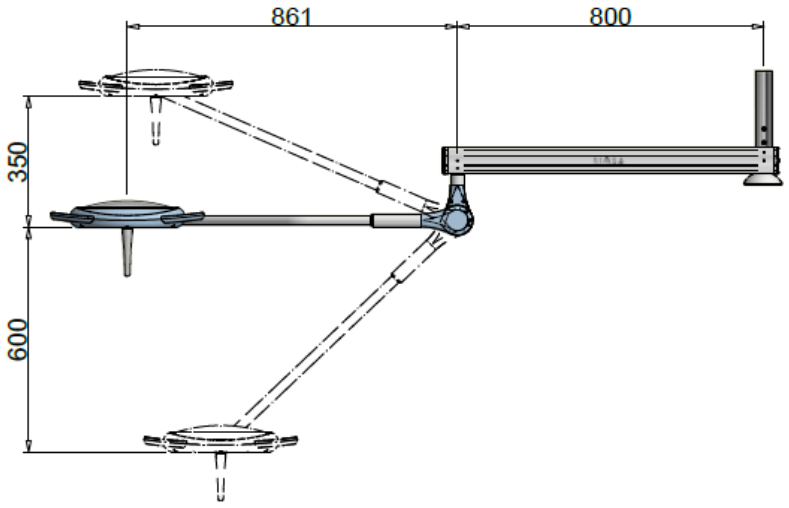
Product control is by means of the control keyboard positioned on the reflector casing. By pressing the keys, the following functions are started:

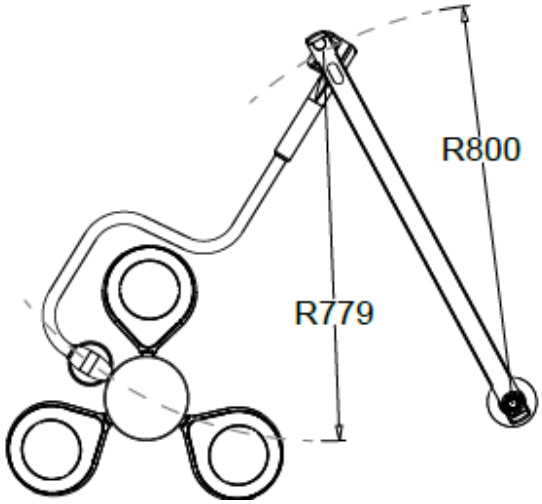
- start/stop stand-by switch I/O (1);
- increase/reduction light intensity (2) and (3);
- color temperature selection (4);
- courtesy light selection (5). To select the courtesy light, the lamp must be switched off. In courtesy position, only the light intensity can be adjusted, while temperature change is not possible. To return to normal operating position, the standby key (1) must be pressed.

The light field is not adjustable.

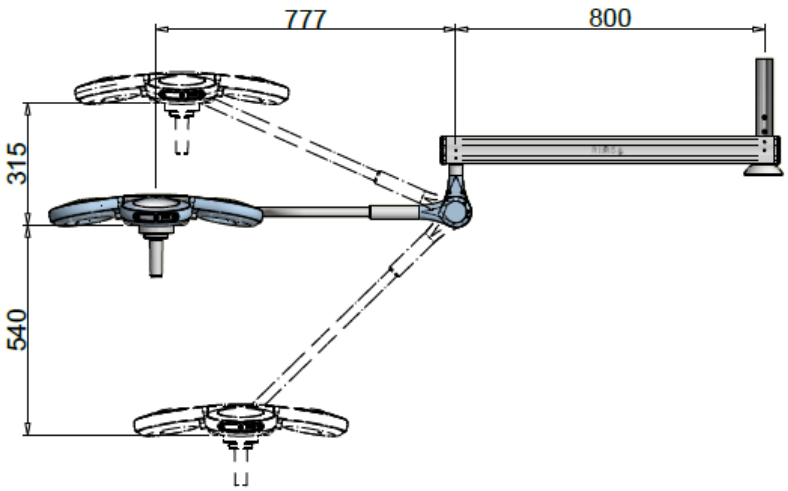
5.5 Product handling

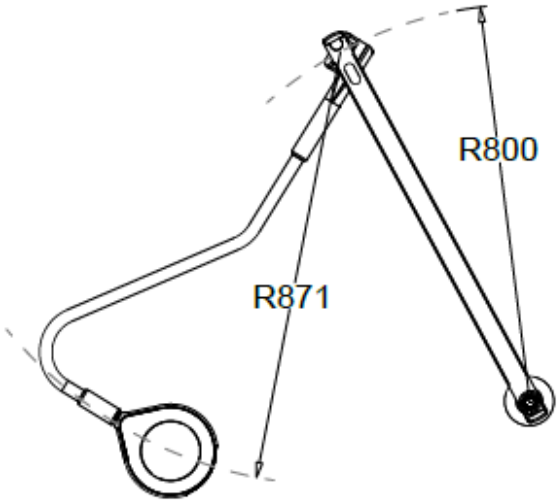
SINGLE ceiling model PENTALED 12/28



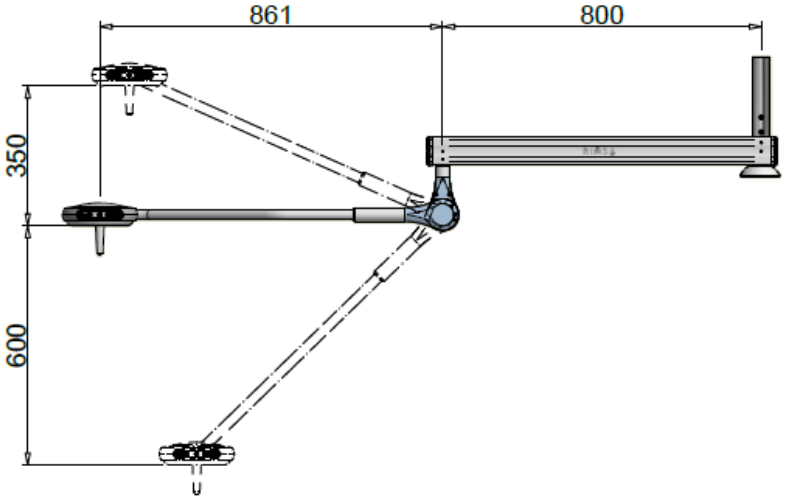


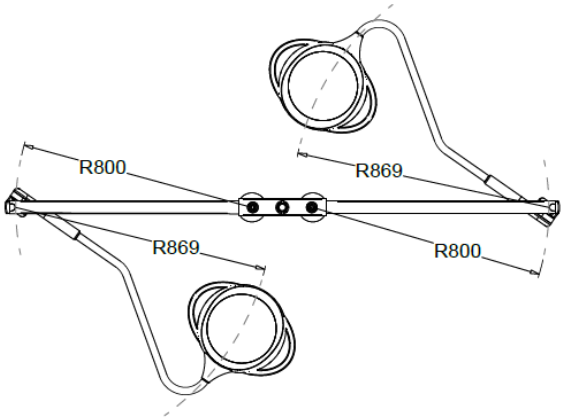
SINGLE ceiling model QUATTROLUCI LED



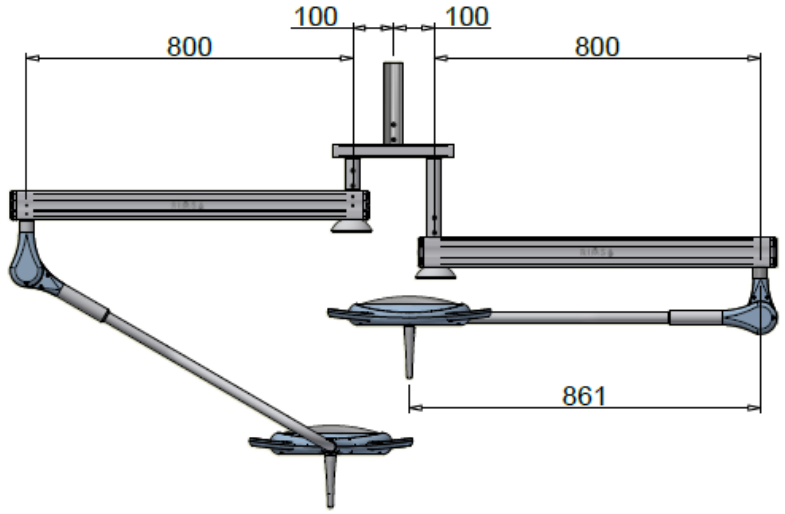


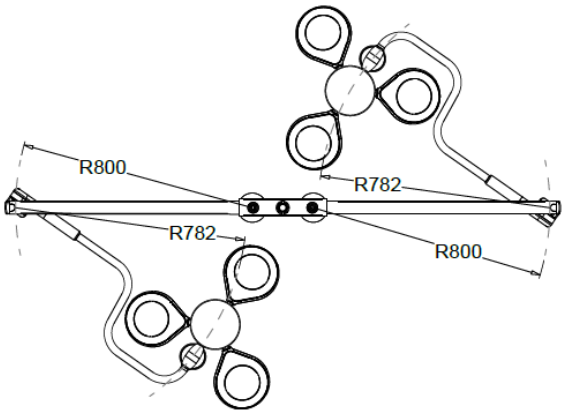
SINGLE ceiling model SATURNO-LED



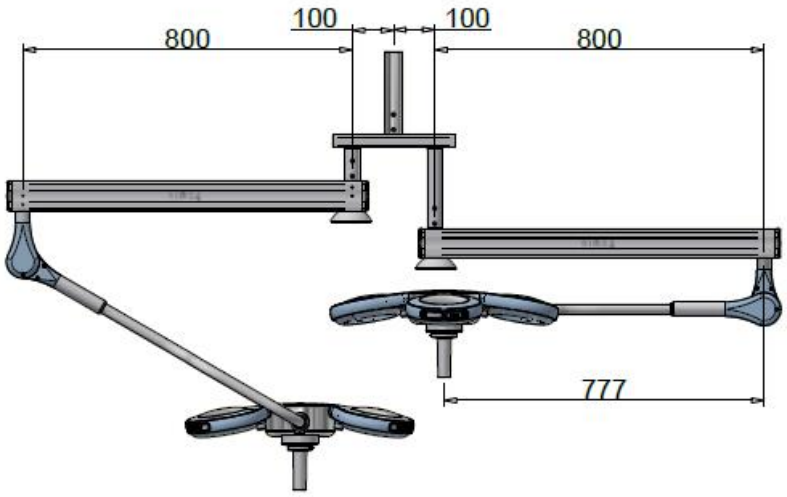


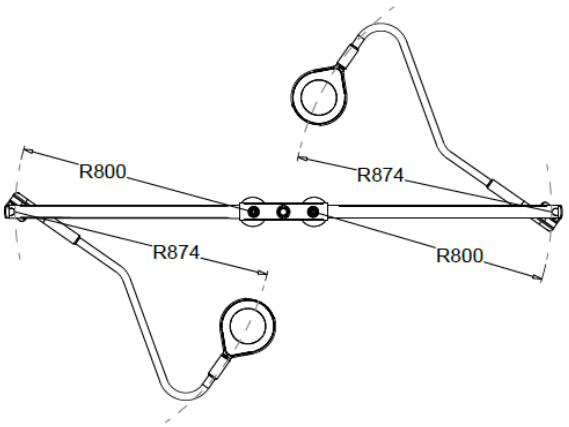
DOUBLE lamp model PENTALED 12/28



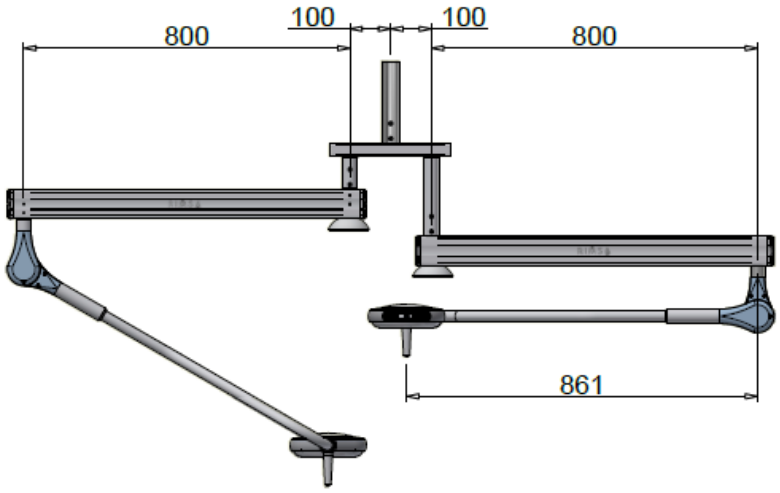


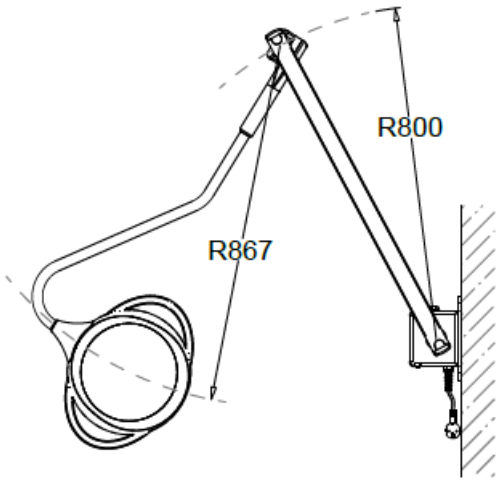
DOUBLE lamp model QUATTROLUCI LED



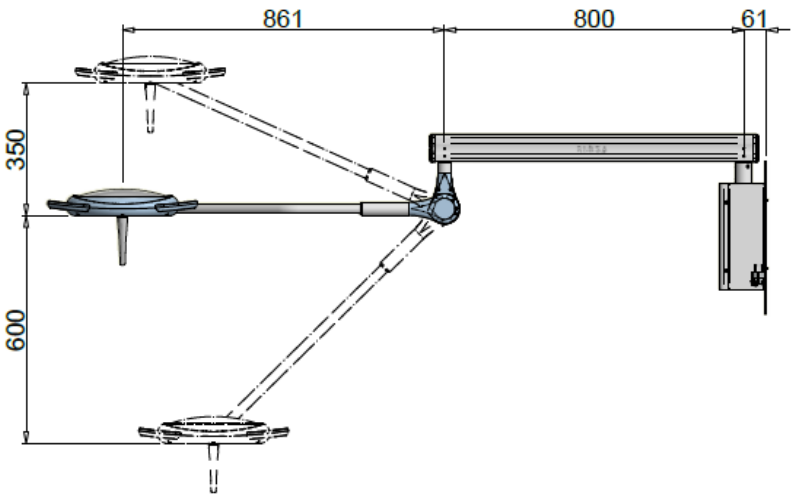


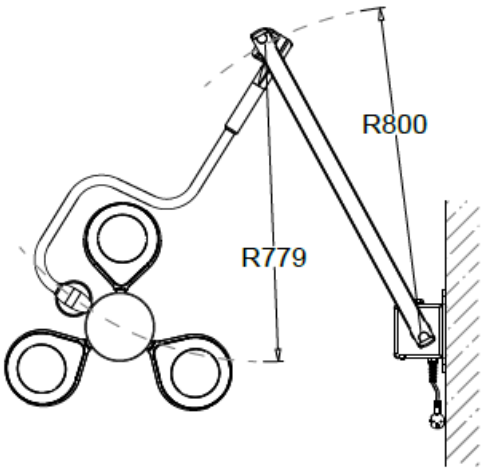
DOUBLE lamp model SATURNO-LED



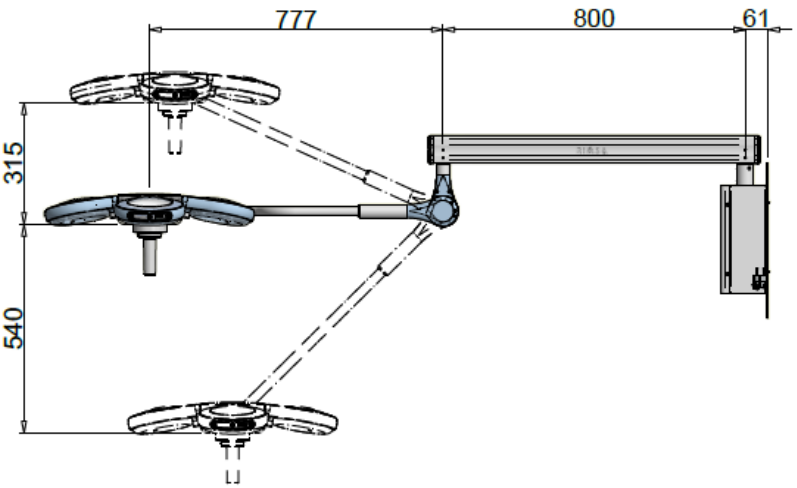


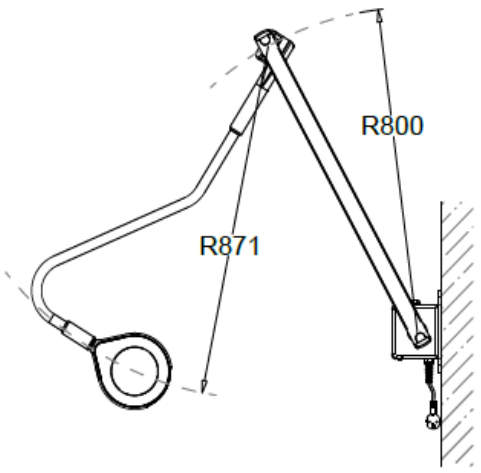
Wall model PENTALED 12/28



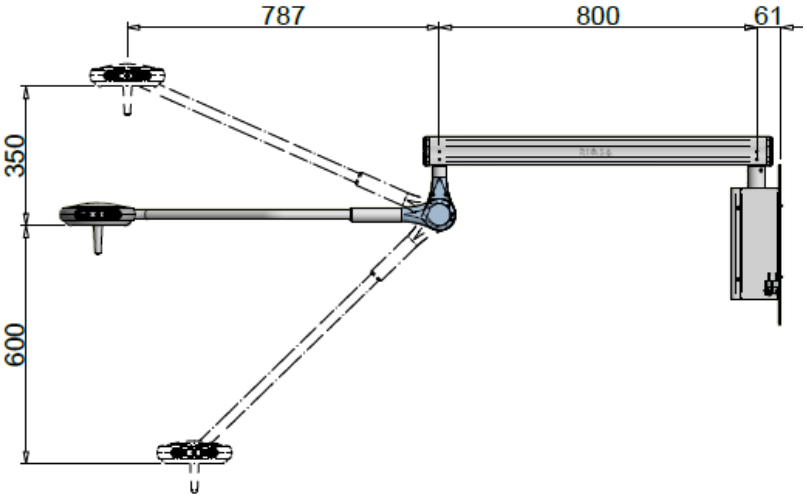


Wall model QUATTROLUCI LED

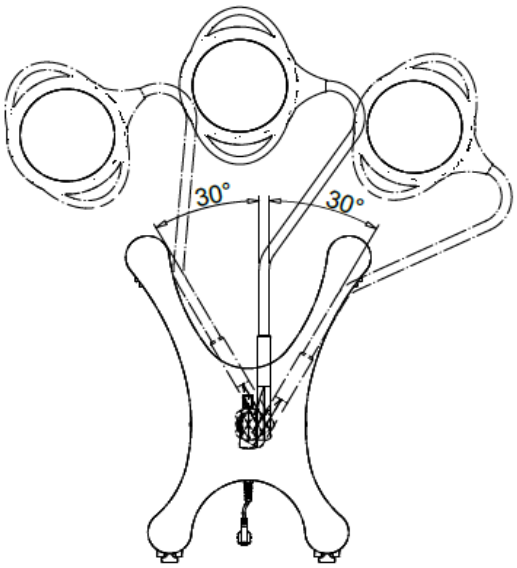


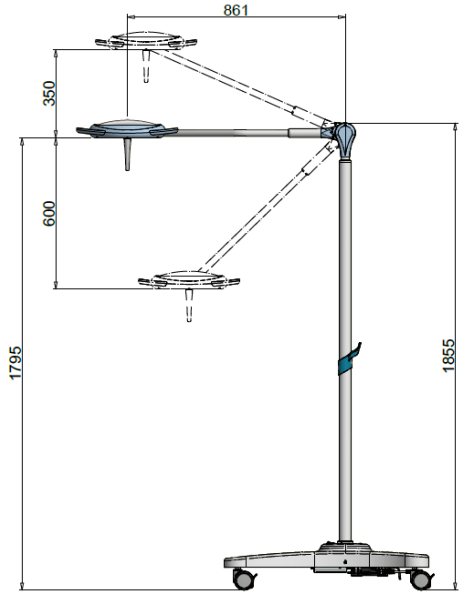


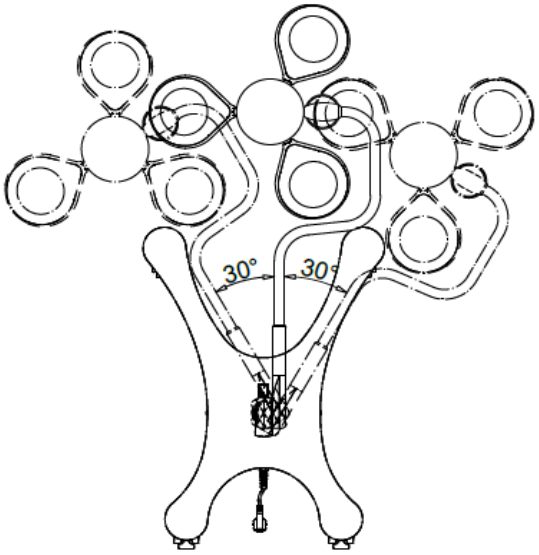
Wall model SATURNO-LED



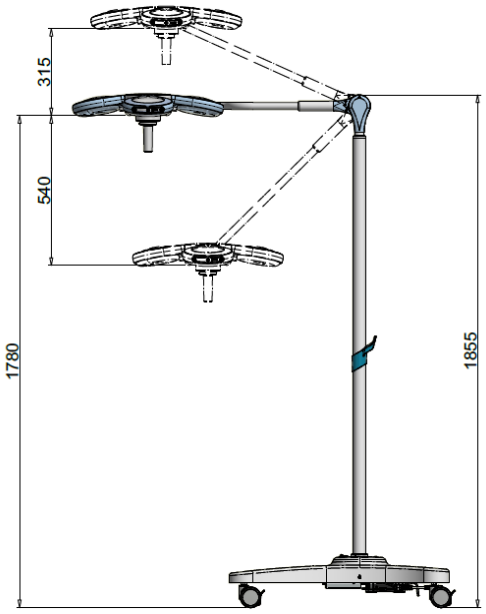
Mobile model PENTALED 12/28

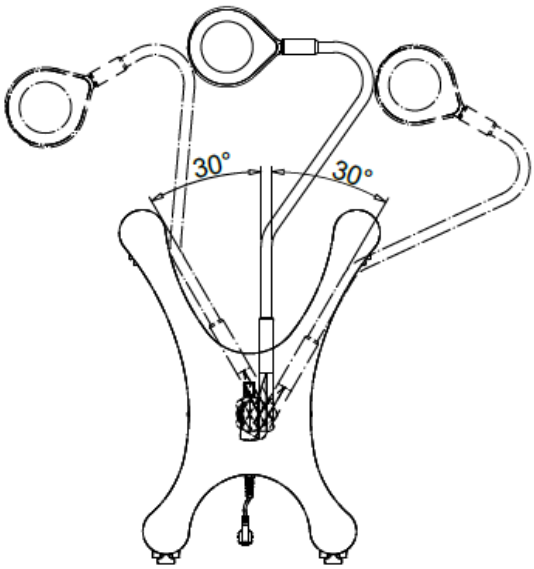




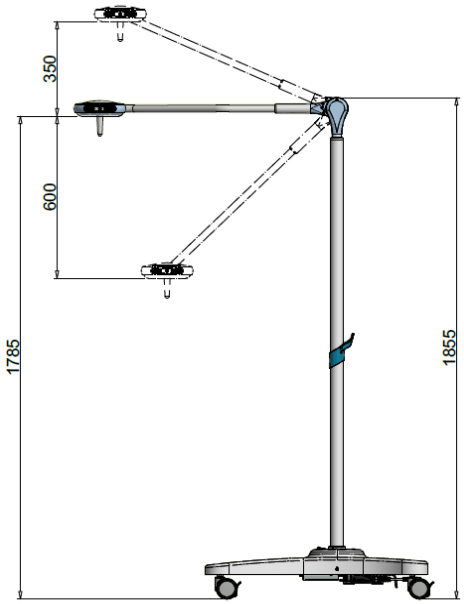


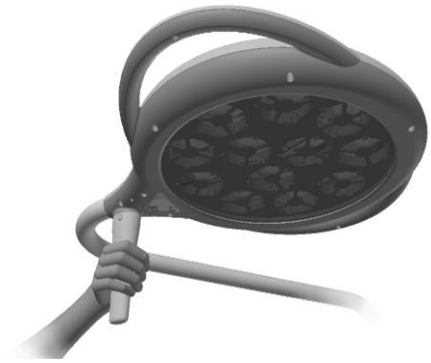
Mobile model QUATTROLUCI LED



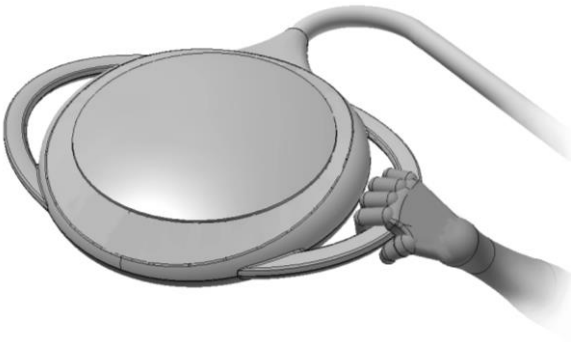


Mobile model SATURNO-LED



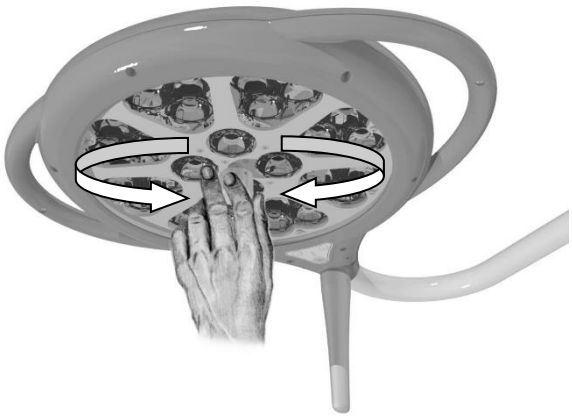


The Product can be moved using the sterilisable handpiece.

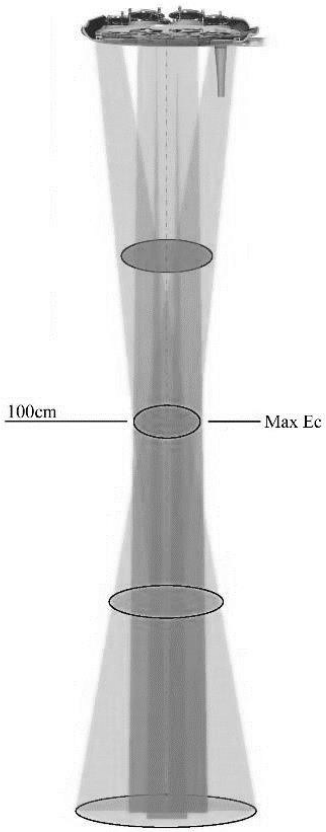


For PENTALED 12/28 models the Product can also be moved using the the side handles.

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

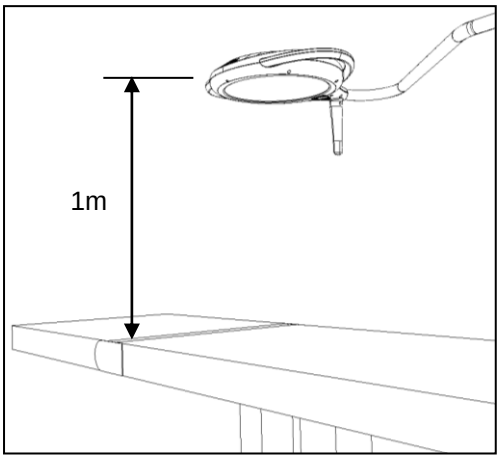


For PENTALED 28 model, it's possible to rotate clockwise or counterclockwise the sterilisable handpiece at the centre of the protection shield to adjust the diameter of the light field and the focus. This handpiece cannot be removed or sterilized.



RECOMMENDED WORK DISTANCE

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



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

5.5.1 Brakes for mobile version

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

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

⚠	**Risk of damaging pedal.**

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

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

⚠	**Risk of lamp overturning.**

5.5.2 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.

5.6 Checks to be made every time before use

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

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

6 Cleaning and disinfecting

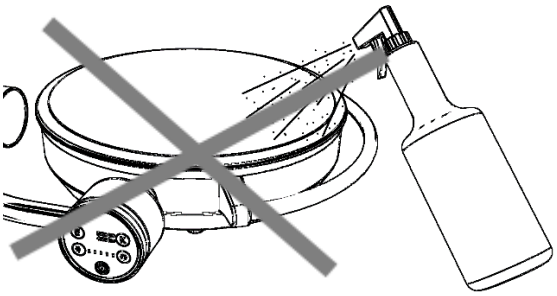
The responsible organization must comply with the rules (standards and directives) concerning hygiene, disinfection and sterilization laid down by the relevant national commission.

6.1 Application method

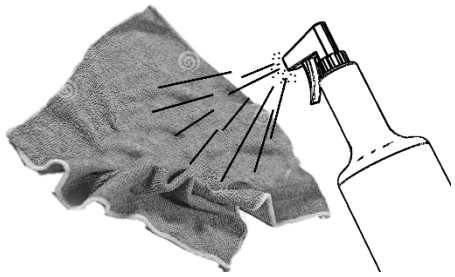
❗	**Interrupt the power supply before cleaning/disinfecting the Product.**
⚠	**Possibility of damaging the Product.**

Before proceeding to clean/disinfect the Product, make sure it is off and cannot be switched back on.
Allow the lamp to cool down and only clean it when it is cold.
Protect the Product from water spray and detergents and do not clean it in direct contact with liquids.

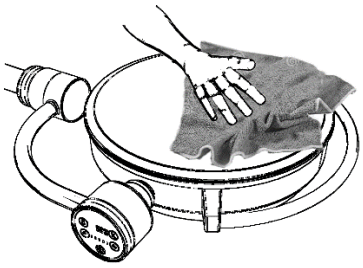
Application method



Do not spray detergent/disinfectant directly on Product.



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



Afterwards wipe the Product with the cloth.

Failure to comply with the above instructions could cause:
- detaching of paint with possible accidental dropping of such paint into the patient area;
- early ageing of the plastic parts with consequent weakening and the possibility of breakages;
- tarnishing of the protection screens and glass.

6.2 Cleaning the Product

Frequency

⚠	**Possibility of damaging 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.

6.3 Product disinfecting

Frequency

⚠	**Possibility of damaging the Product.**

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.

6.4 Handpiece sterilization

Frequency

The handpieces must be sterilized before use and can withstand up to 200 cycles.
The Operator must comply with the rules of the national commission for hygiene, disinfection and sterilization.

	**Hazard for the patient.**

The handpieces are made of plastic material resistant to heat and knocks (PSU - Polysulfone).
Replace the handpieces as soon as these become cracked or deformed, as these could fall in the patient area.

PENTALED 12/28

Handpiece fitting / removal:
- press the stop catches located parallel with the grip and remove it.
- insert the grip until the catches click into and are blocked in the handpiece holes.

QUATTROLUCI LED

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.

SATURNO-LED

Handpiece fitting / removal:
- turn the handpiece anti-clockwise and remove it.
- turn the handpiece clockwise until it is up against the handpiece and rotation is blocked.

Sterilization

Clean and disinfect the handpieces in the traditional way before sterilization. They can be cleaned with a mid-alkaline detergent free of active chlorine. To disinfect the handpieces, we suggest using alcohol or aldehyde-based products. The disinfectants must be approved by the manufacturer for use on polylsulfone (PSU). After disinfecting, rinse off the detergent residues with plenty of water.
The handpieces fit into a suitable sterilization pack (disposable sterilization pack, e.g., plastic/paper bags; single or double pack), before being sterilized.
The handpieces can withstand about 200 steam sterilization cycles in accordance with the following parameters:
- steam sterilization at 121°C and 1.3 bar for 25 to 30 minutes
- steam sterilization at 134°C and 2.3 bar for 4 minutes

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

7 Adjustment and maintenance

7.1 Swinging arm adjustment

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

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.

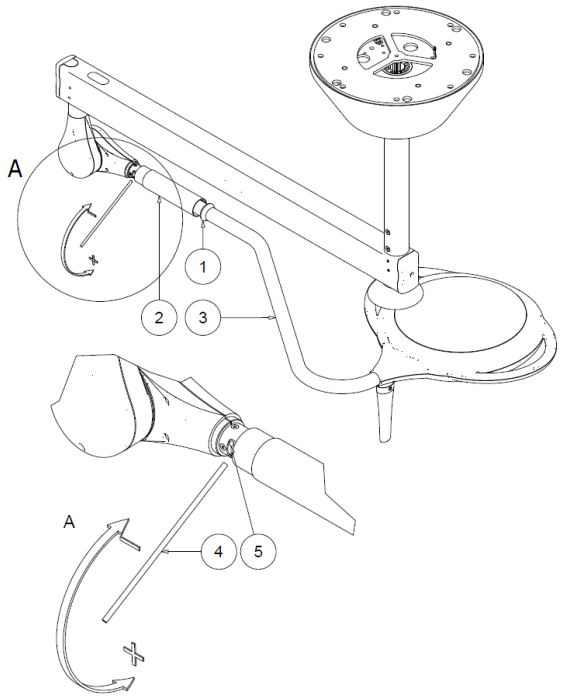
If the swinging arm drops, this means the elastic force of the spring is insufficient:

- 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.



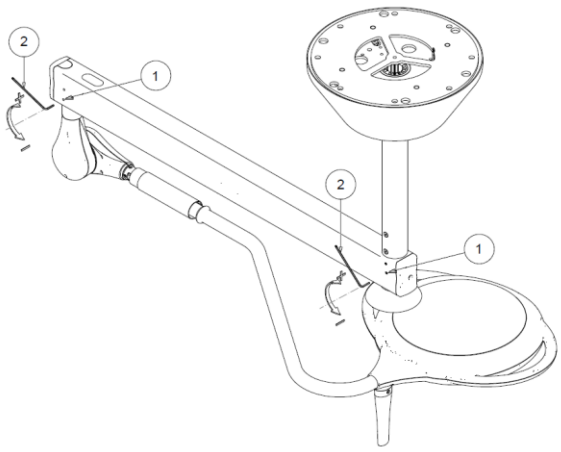
7.2 Clutch adjustment

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

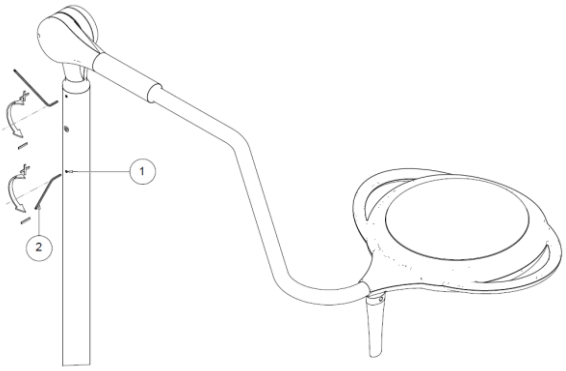
In case of the structure not maintaining the position, the clutches will have to be adjusted.

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

Ceiling version



Mobile version



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.

7.3 Periodical checks to be performed on the Product

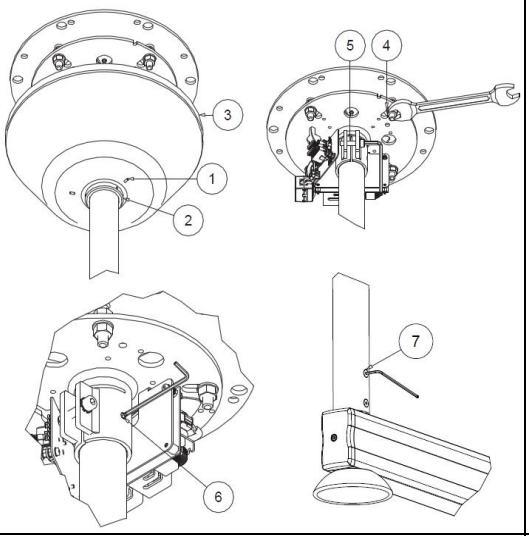
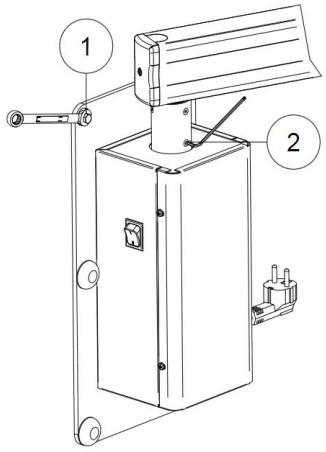
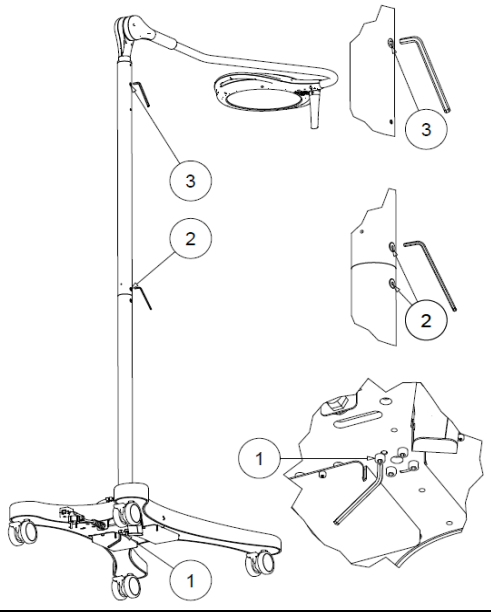
At the time of start up and after each maintenance job, perform electrical tests and jobs indicated in the IEC 62353 standard.

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

7.4 Routine maintenance

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

N.	Period	Action
1	Before using	Make sure there are no pieces or fragments of paint that could become detached and fall within the operating field. If there are any, remove them manually.
2	Before using	Make sure the light source protection screens are not damaged. If they are, contact the Customer Service.
3	Once a year	Check all the Product joints and make sure there are no noises or squeaks. If there are, lubricate the clutches involved with suitable grease for industrial use at a service temperature between -30°C and + 120°C, type OKS 470 or with similar properties.
4	Once a year	If the Product fails to maintain a regular position, adjust the clutches as indicated at points **7.1 and 7.2 (arm and clutch adjustment)**.

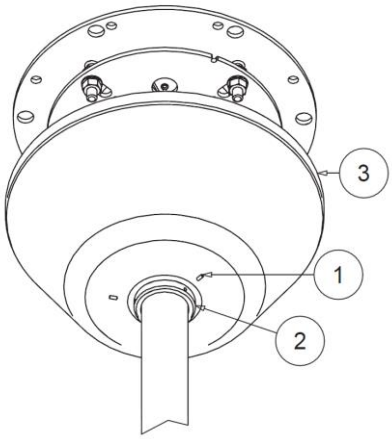
5	Once a year (CEILING VERSION) 	Make sure the bar retention screws (1) are tightened properly. Also check the bar horizontal arm retention screws (4). If these are not properly fastened, adequately tighten. To access the screws, loosen the 3 dowels (1) of the ring (2). Remove the bar cover (3) by pulling 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.
6	Once a year (WALL VERSION) 	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.
7	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.

7.5 Repairs

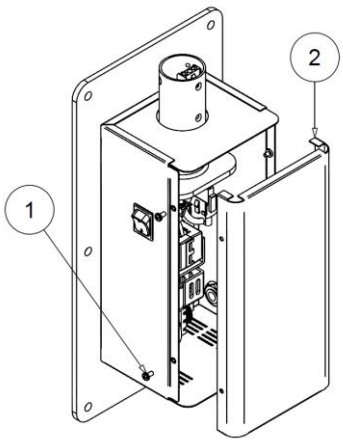
The only repair job with which the technical assistance personnel are charged is the fuse change.

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

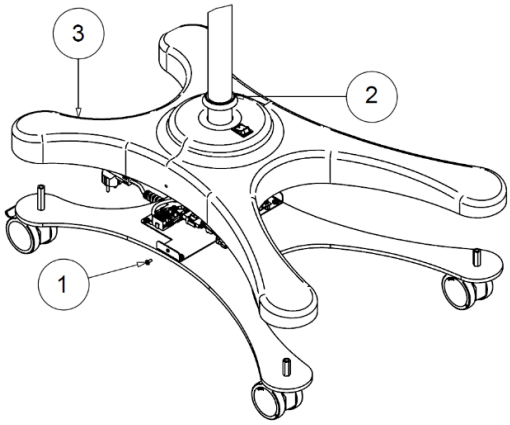
	Interrupt the power supply before doing any maintenance jobs.



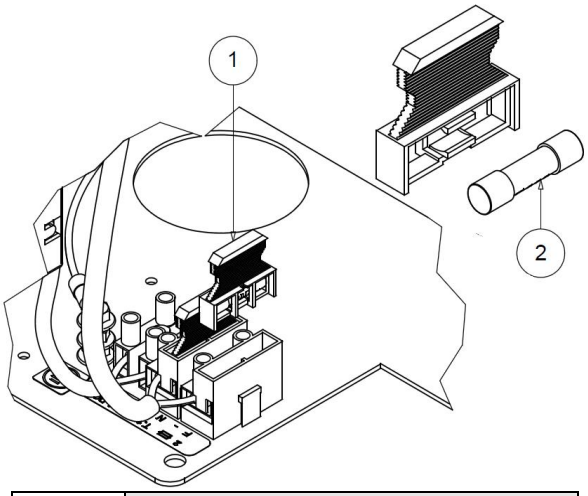
To access the fuses in the ceiling version, open the bar cover as indicated in point 5 of paragraph 7.4.



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



To access the fuses in the mobile version, 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.

Making any changes to this device is forbidden.

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

Disposal at end-of-life

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

7.7 Spare parts list

Only original spare parts must be used.

Description	Order code
Sterilisable handpiece PENTALED 12/28	Z180045
Sterilisable handpiece QUATTROLUCI LED	Z200518
Sterilisable handpiece SATURNO-LED	Z180848
Fuse T1AH 250V ‘5x20’	Z400208
Fuse T2AH 250V ‘5x20’	Z400195

8 Technical properties

8.1 PENTALED 12 technical properties

Technical details of light	PENTALED 12
Illumination E_c at 1 m distance ± 10% [Lux]	100,000
Colour temperature (±5%) [K]	4,500
Colour rendering index R_a [-]	91
R_9 [-]	> 90
Light range diameter d_{50} [mm]	98
Light range diameter d_{10} [mm]	160
Lighting depth L1+L2 [mm] at 60%	720
Lighting depth L1+L2 [mm] at 20%	1500
Max irradiation [W/m²]	370
Irradiation / Illumination [mW/m²lx]	3.7
Max irradiation in UV [W/m²]	0.001
Power connection details	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Power input [VA]	40
Light source	n°12 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
Fuses incorporated	T2AH 250V, 5x20

General data	
Regulation	REGULATION (EU) 2017/745
Classification of Medical Device	Class I
Standards	IEC 60601-2-41
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use; the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance Ee in the lighted area does not exceed 1000 W/m² at a distance of 1000 mm; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m²lx).
Colour	RAL 9003
IP degree of protection	IP20
Operating conditions	Continuous operation
Handpiece steam sterilization	121°C at 1.3bar from 25 to 30 minutes. 134°C at 2.3bar for 4 minutes.
Mains power voltage 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 surface [cm²]	305
Weight of single ceiling, double ceiling, wall, mobile, mobile battery surgical light [kg]	13, 20, 12, 21, 24
Markings	
CE	In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons	

8.2 PENTALED 28 technical properties

Technical details of light	PENTALED 28
Illumination E_c at 1 m distance ± 10% [Lux]	120,000
Colour temperature (±5%) [K]	4,500 / 5,000
Colour rendering index R_a [-] (*4500K – 5000K*)	94
R_9 [-]	> 90
Light range diameter d_{50} [mm]	160
Light range diameter d_{10} [mm]	280
Lighting depth L1+L2 [mm] at 60%	920
Lighting depth L1+L2 [mm] at 20%	1550
Max irradiation [W/m^2]	456
Irradiation / Illumination [mW/m^2lx]	3.62
Max irradiation in UV [W/m^2]	0.001
Power connection details	
Primary alternate voltage [Volt ac]	100 - 240
Frequency [Hz]	50 / 60
Power input [VA]	85
Light source	n°28 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
Fuses incorporated	T2AH 250V, 5x20

General data		
Regulation		REGULATION (EU) 2017/745
Classification of Medical Device		Class I
Standards		IEC 60601-2-41
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use; the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).	
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance Ee in the lighted area does not exceed 1000 W/m² at a distance of 1000 mm; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m²lx).	
Colour		RAL 9003
IP degree of protection		IP20
Operating conditions		Continuous operation
Handpiece steam sterilization		121°C at 1.3bar from 25 to 30 minutes. 134°C at 2.3bar for 4 minutes.
Mains power voltage 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 surface [cm²]		196
Weight of single ceiling, double ceiling, wall, mobile, mobile battery surgical light [kg]		13, 20, 12, 21, 24
Markings		
CE		In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons		

8.3 QUATTROLUCI LED technical properties

Technical details of light	QUATTROLUCI LED
Illumination E_c at 1 m distance ± 10% [Lux]	160,000
Colour temperature (±5%) [K]	4,900
Colour rendering index R_a [-]	92
R_9 [-]	> 90
Light range diameter d_{50} [mm]	150
Light range diameter d_{10} [mm]	270
Lighting depth L1+L2 [mm] at 60%	1100
Lighting depth L1+L2 [mm] at 20%	1740
Max irradiation [W/m^2]	570
Irradiation / Illumination [mW/m^2lx]	3.47
Max irradiation in UV [W/m^2]	0.039
Power connection details	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Power input [VA]	95 - 120
Light source	n°36 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	15 - 100
Fuses incorporated	T2AH 250V, 5x20

General data	
Regulation	REGULATION (EU) 2017/745
Classification of Medical Device	Class I
Standards	IEC 60601-2-41
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use; the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance Ee in the lighted area does not exceed 1000 W/m² at a distance of 1000 mm; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m²lx).
Colour	RAL 9003
IP degree of protection	IP20
Operating conditions	Continuous operation
Handpiece steam sterilization	121°C at 1.3bar from 25 to 30 minutes. 134°C at 2.3bar for 4 minutes.
Mains power voltage insulation means	Outside the product (main switch) for ceiling versions. Main switch for mobile and wall versions.
Dimensions	
Diameter of lamp body [cm]	60
Light emission surface [cm²]	252
Weight of single ceiling, double ceiling, wall, mobile, mobile battery surgical light [kg]	15, 22, 14, 23, 26
Markings	
CE	In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons	

8.4 SATURNO-LED technical properties

Technical details of light	SATURNO-LED
Illumination E_c at 1 m distance ± 10% [Lux]	50,000
Colour temperature (±5%) [K]	4,000 / 4,500
Colour rendering index R_a [-]	93
R_9 [-]	> 90
Light range diameter d_{50} [mm]	160
Light range diameter d_{10} [mm]	260
Lighting depth L1+L2 [mm] at 60%	1050
Max irradiation [W/m^2]	186
Irradiation / Illumination [mW/m^{2}lx]	3.63
Max irradiation in UV [W/m^2]	0.010
Power connection details	
Primary alternate voltage [Volt ac]	100 - 240
Frequency [Hz]	50 / 60
Power input [VA]	40
Light source	n°9 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
Fuses incorporated	T1AH 250V, 5x20

General data		
Regulation		REGULATION (EU) 2017/745
Classification of Medical Device		Class I
Standards		IEC 60601-2-41
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use; the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).	
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance Ee in the lighted area does not exceed 1000 W/m² at a distance of 1000 mm; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m²lx).	
Colour		RAL 9003
IP degree of protection		IP20
Operating conditions		Continuous operation
Handpiece steam sterilization		121°C at 1.3bar from 25 to 30 minutes. 134°C at 2.3bar for 4 minutes.
Mains power voltage insulation means		Outside the product (main switch) for ceiling versions. Main switch for mobile and wall versions.
Dimensions		
Diameter of lamp body [cm]		19.5
Light emission surface [cm²]		63
Weight of single ceiling, double ceiling, wall, mobile, mobile battery surgical light [kg]		12, 19, 11, 20, 23
Markings		
CE		In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons		

9 EU Declaration of conformity

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

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

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

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

Product and trade name: **PENTALED 12, PENTALED 28, QUATTROLUCI LED, SATURNO-LED**
Model reference: PENTA12, PENTA28, QUATTRO, SAT-LED
Configurations:

PENTA12PA	LAMP MODEL PENTALED 12 WALL
PENTA12PI	LAMP MODEL PENTALED 12 MOBILE STAND
PENTA12SO	LAMP MODEL PENTALED 12 CEILING
PENTA12+12	LAMP MODEL PENTALED 12 DOUBLE CEILING
PENTA28PA	LAMP MODEL PENTALED 28 WALL
PENTA28PI	LAMP MODEL PENTALED 28 MOBILE STAND
PENTA28SO	LAMP MODEL PENTALED 28 CEILING
PENTA28+28	LAMP MODEL PENTALED 28 DOUBLE CEILING
QUATTROPA	LAMP MODEL 4LUCI-LED WALL
QUATTROPI	LAMP MODEL 4LUCI-LED MOBILE STAND
QUATTROSO	LAMP MODEL 4LUCI-LED CEILING
QUATTROSOX2	LAMP MODEL 4LUCI-LED DOUBLE CEILING
SATPAN-LED	LAMP MODEL SATURNO-LED WALL
SATPIN-LED	LAMP MODEL SATURNO-LED MOBILE STAND
SATSON-LED	LAMP MODEL SATURNO-LED CEILING
SATSONX2-LED	LAMP MODEL SATURNO-LED DOUBLE CEILING

Intended purpose: MINOR SURGICAL LUMINAIRE (TREATMENT LUMINAIRE)

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

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

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

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

RIMSA Quality 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

10 EMC Declaration

	**Possibility of interferences with nearby appliances.**

The Product has been tested according to IEC 60601-1-2 standard to ensure correct electromagnetic compatibility.
Portable and mobile communication appliances can affect the Product. The product should not be used close to another device and if this is inevitable, the product must be checked to make sure it is working properly.
The use of accessories other than those supplied/recommended by the manufacturer could increase the level of emissions and lower the level of immunity of the appliance.
The Product has been designed to be used in the electromagnetic environments described below.
The Responsible Organization or Operator is responsible for making sure the Product is used in a compatible environment.
It could occur that if the Product is affected by radiations in the range of 80 MHz – 1 GHz or bursts, it will no longer respond to the commands both as regards the lamp and the camera.
If this does occur, essential performance will in any case be ensured, but to restore normal operation it will be necessary to de-energize the master switch.

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-voltage public mains supply which supplies buildings used for domestic purposes, as long as the following precaution is followed. **Warning:** This Product is intended for use by professional health personnel only. This Product can cause radio-interference or disturb the operation of nearby appliances. Measures may have to be taken to reduce such disturbance, such as Product re-positioning or shielding of premises.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	
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 test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV at contact +/- 15 kV in air	+/- 8 kV at contact +/- 15 kV in air	Floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must at least be equal to 30%.
Rapid impulse electric transistors IEC 61000-4-4	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	Mains voltage quality should be that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	+/- 1 kV Between phases +/- 2 kV Between phases and earth	+/- 1 kV Between phases +/- 2 kV Between phases and earth	Mains voltage quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations on the power supply input lines IEC 61000-4-11	<5% U_T (drop >95% of U_T) For 0.5 cycles 40% U_T (drop = 60% of U_T) For 5 cycles 70% U_T (drop = 30% of U_T) For 25 cycles <5% U_T (drop >95% of U_T) For 5 s	<5% U_T (drop >95% of U_T) For 0.5 cycles 40% U_T (drop = 60% of U_T) For 5 cycles 70% U_T (drop = 30% of U_T) For 25 cycles <5% U_T (drop >95% of U_T) For 5 s	Mains voltage quality should be that of a typical commercial or hospital environment. If the Product user requires continued function during mains power supply interruptions, the Product should be supplied by a UPS unit or batteries.
Magnetic field at electrical mains frequency (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should have the characteristic levels of a typical locality in a commercial or hospital environment.
NOTE: U_T mains voltage in AC before application of test level.			

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Products, included cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance leave in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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

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

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

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

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

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

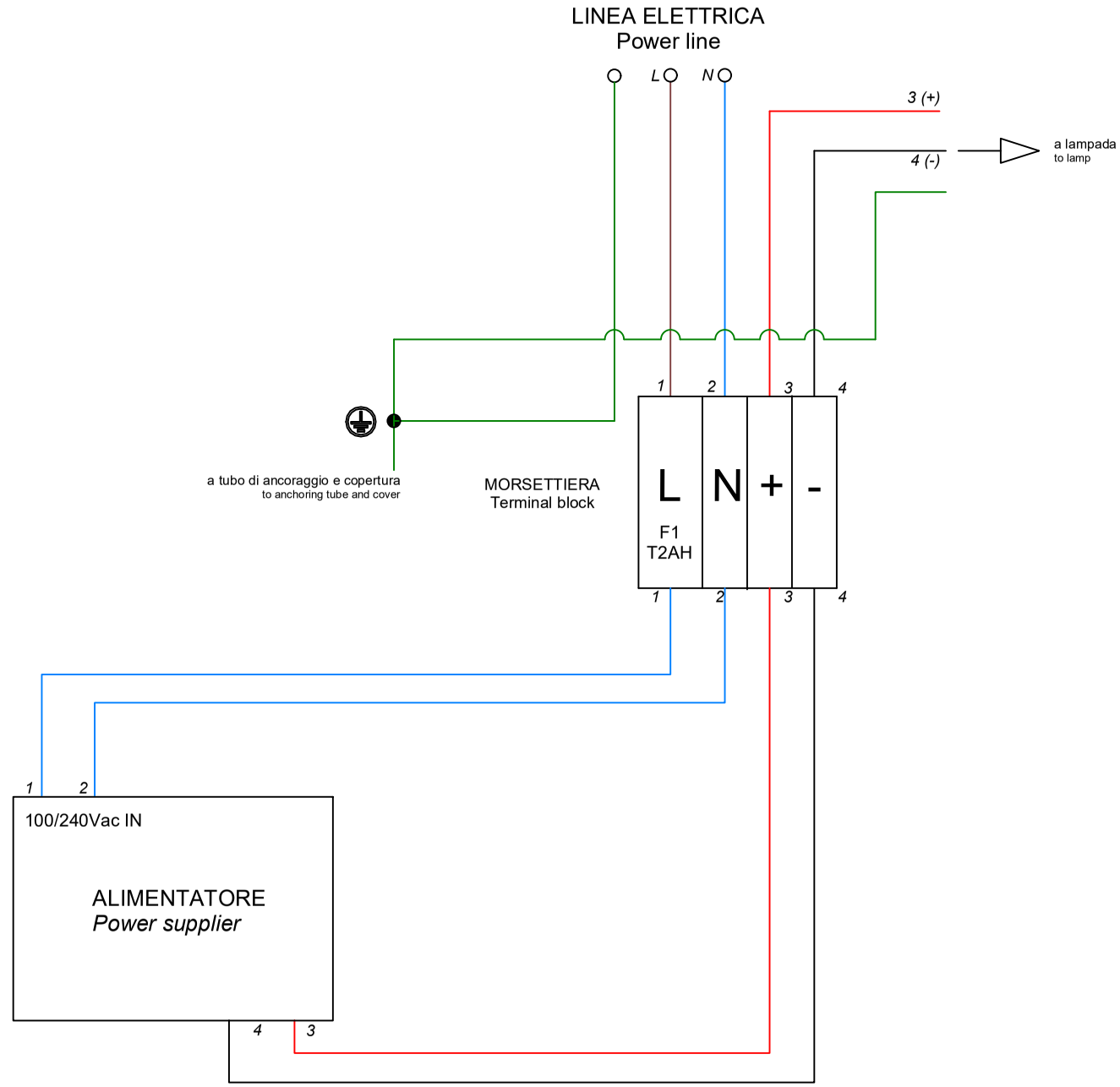
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

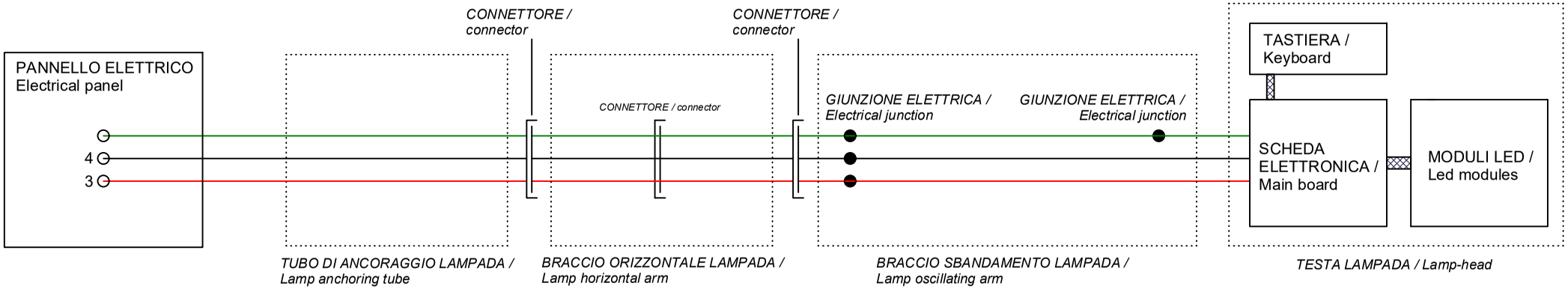
11 Warranty Certificate

1. The Product is covered by an 18-month warranty, including electrical parts.
2. The warranty begins on the date of Product shipment from the 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.

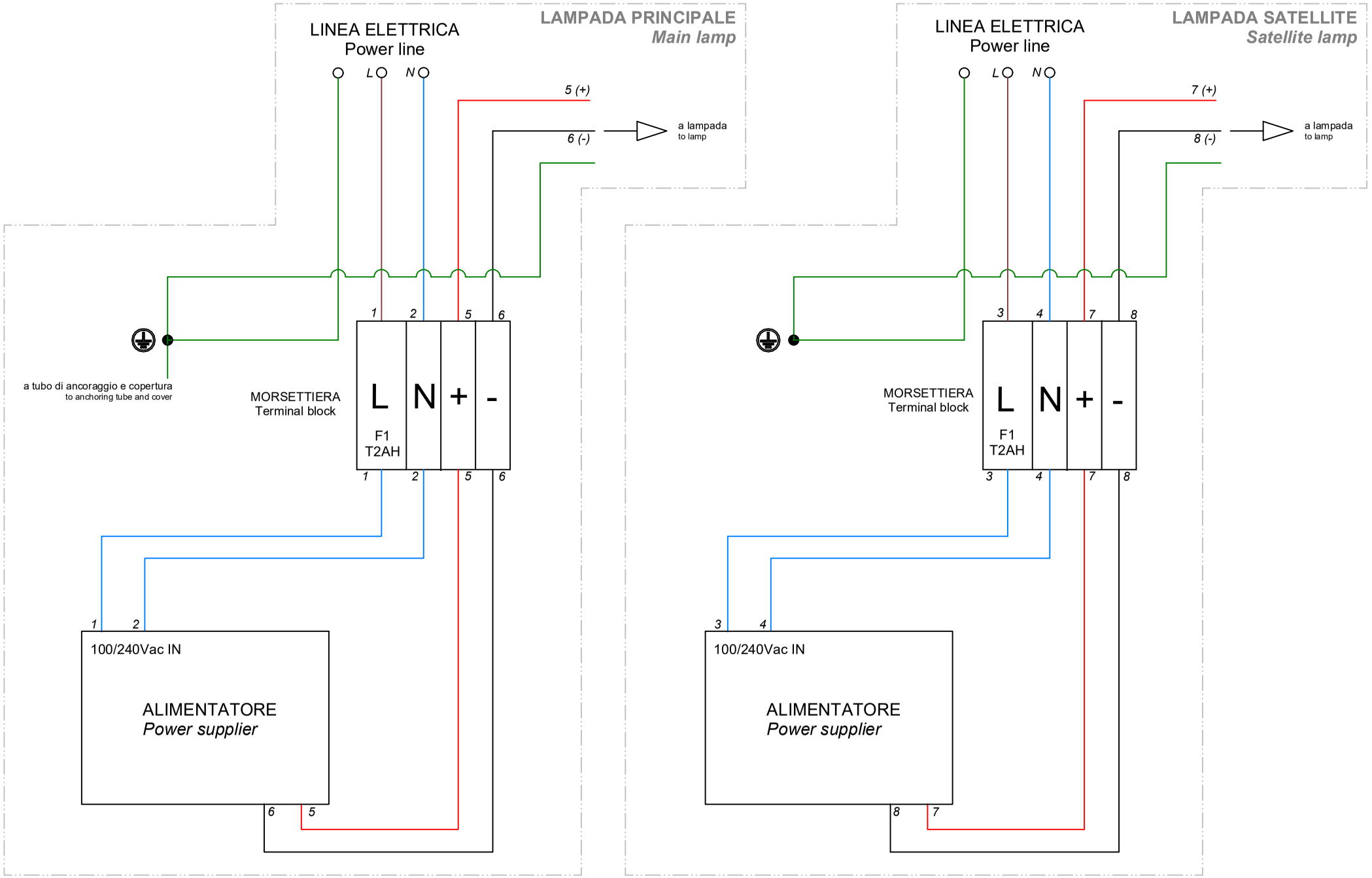
Notes



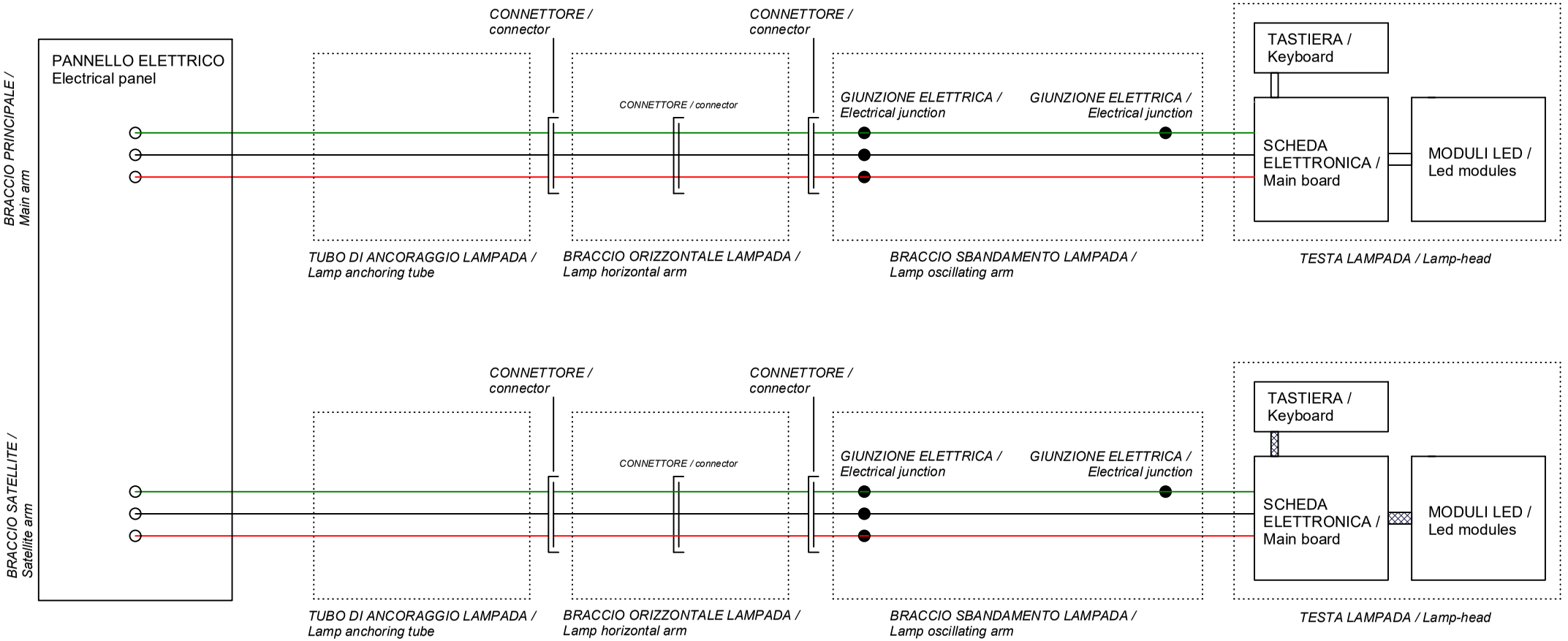
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 05/11/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO SINGOLA *Ceiling single lamp electrical diagram*	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD *EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*	PENTALED12 | SLIM PENTALED28 | ANTARES SATURNO-LED | VEGA 4LUCI-LED CAVALIER	ED518
Pag. 1 / 1				



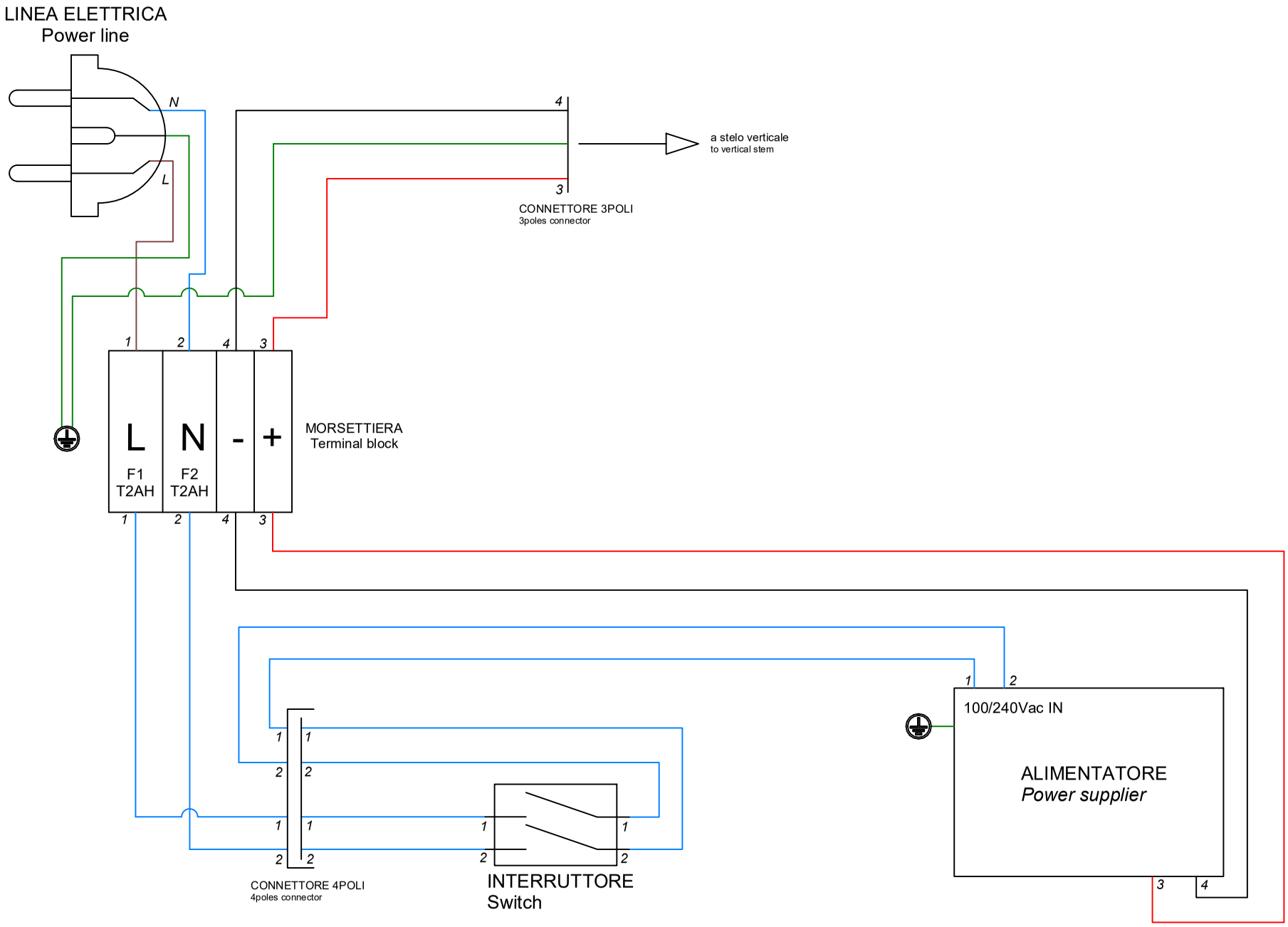
Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO SINGOLA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER	4LUCI-LED	ED514
Pag. 1 / 1	*Ceiling single lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



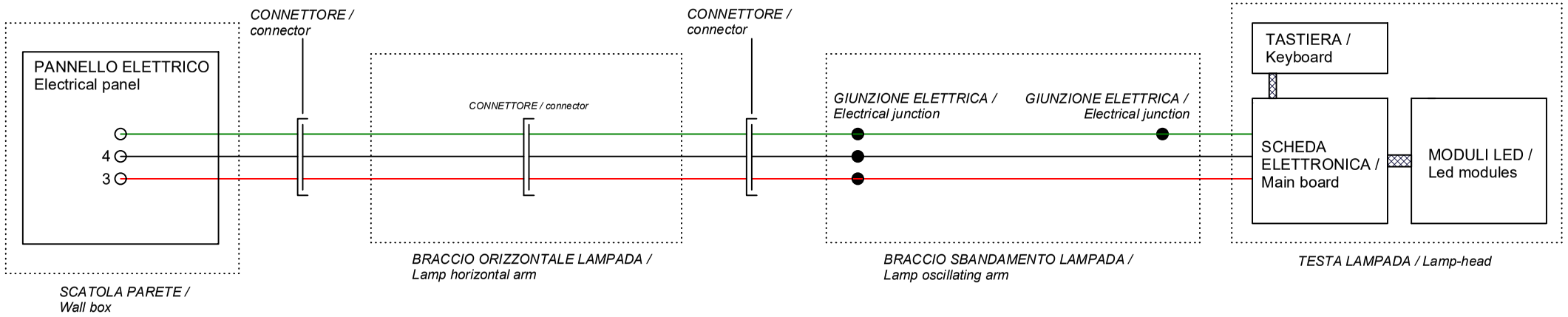
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 05/11/2020	SCHEMA ELETTRICO PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	PENTALED12 | SLIM PENTALED28 | ANTARES SATURNO-LED | VEGA 4LUCI-LED CAVALIER	ED519
Pag. 1 / 1	*Ceiling double lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



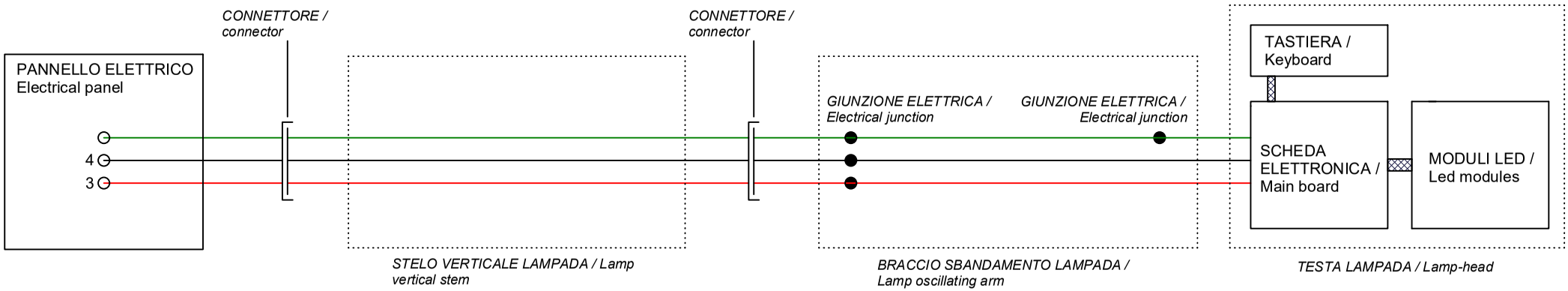
Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A SOFFITTO DOPPIA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER 4LUCI-LED	ED515
Pag. 1 / 1	*Ceiling double lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*		



Rev.	TITOLO / Title	NOTE	MODELLO / Model	N° DIS. / Drw n°
0 | 06/05/2020	SCHEMA ELETTRICO PER LAMPADA A PIANTANA/PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER	ED505
Pag. 1 / 1	*Mobile/Wall lamp electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*	4LUCI-LED	



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A PARETE	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Pentaled12 Pentaled28 Saturno-led SLIM CAVALIER	4LUCI-LED	ED516
Pag. 1 / 1	*Wall lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			



Rev.	TITOLO / Title	NOTE	MODELLO / Model		N° DIS. / Drw n°
0 | 07/05/2020	SCHEMA GENERALE PER LAMPADA A PIANTANA	EVENTUALI ELEMENTI E CONNESSIONI RAPPRESENTATI IN GRIGIO E CON LINEA TRATTEGGIATA SONO OPZIONALI, NON PRESENTI NEL PRODOTTO STANDARD	Serie UNICA Pentaled12 Pentaled28 Saturno-led SLIM	CAVALIER 4LUCI-LED	ED513
Pag. 1 / 1	*Mobile lamp general electrical diagram*	*EVENTUAL ELEMENTS AND CONNECTIONS REPRESENTED IN GREY AND WITH DOTTED LINE ARE OPTIONAL, NOT PRESENT IN THE STANDARD PRODUCT*			