Operation and Maintenance Manual

PENTALED12
PENTALED28

SECONDARY SURGICAL LAMP (TREATMENT LAMP)

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 1 medical device pursuant to European Directive on medical devices (MDD) 93/42/EEC (Annex IX) as amended and integrated.

Compliance

The manufacturer declares that this Product complies with Annex I (Essential requirements) of Directive 93/42/EEC 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 ceiling, floor and wall versions
- Pentaled 28 in ceiling, floor and wall 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.

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- Fax: +39 02 95381167
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Copyright

Translations

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

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KEY

PRODUCT THE EM (Electro-Medical) EQUIPMENT to which this manual refers is a **SECONDARY SURGICAL LAMP (TREATMENT LAMP)**. For ease of description, in this manual this EM 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 EM equipment or EM system (e.g., a hospital, an individual doctor or a non-expert person). Preparation and training are included in use.

TECHNICAL SERVICE PERSONNEL The personnel (individuals or entity accountable to the responsible organization) that installs, assembles, maintains or repairs (only fuse change) the device. Under certain circumstances, the safety of such persons depends on their knowledge and training 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 European Directive 93/42/EEC and subsequent amendments and supplements. Read and keep this Operation and Maintenance Manual close to the Product.

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

Electric shock risk

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

2 Importance of personal safety

2.1 Intended use

SECONDARY SURGICAL LAMP (TREATMENT LAMP)
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 DANGER for the PATIENT in case of a power outage.
A combination of two or more surgical lamps used in the operating theatre and required for treatment and diagnosis makes up a SURGICAL LAMP SYSTEM.

Operating field

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

Possibility of tissue dehydration and damage

Undesired effects of overlapping light fields

In the event of overlapping lamps, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.
In case of a reduction in blood flow with start of tissue dehydration, reduce light intensity.

2.2 Safety conditions (secondary effects)

Possibility of glare

Optical safety

- 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.

Do not place objects on Product

Incorrect use

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.

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 flammable mixes of anaesthetics with air, oxygen or NO_2 (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of flammable 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 GIMA or technical service personnel, the latter only for the fuse change.
Special maintenance	GIMA or authorized Dealer
Assistance 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 Graphic symbols used in this Operation and Maintenance Manual

The following safety measures must be put in place during Product use and maintenance.

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

3.3 Graphic symbols used on the Product

Below are the symbols to be found on the Product:

CE	CE marking indicating the Product conforms to directive 93/42/EEC 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
REF	Model
SN	Serial number
	Disposal
	Protection earth
'N'	Neutral lead connection point
'L'	Line lead connection point
'O'	ON
'I'	OFF
	Standby

4 Precautions for the Product operator

4.1 Personnel training obligation

Operator Instructions

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

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

4.2 Warranty and liabilities

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

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

5 Product description and operation

5.1 Product description

Versions

The Product is available in various versions:

- **floor version**
- **ceiling version**
- **wall version**
- **double ceiling version**

See drawing 63

FLOOR version (PENTALED 12 PI – PENTALED 28 PI): base with wheels (1), stem (2), stem extension (3), swinging arm (4), lamp head (5), function control keyboard (6), sterilisable grip (7), power plug (8).

See drawing 64

CEILING version (PENTALED 12 SO – PENTALED 28 SO): ceiling anchor tube (1), ceiling cover (2), horizontal arm (3), swinging arm (4), lamp head (5), control keyboard (6), sterilisable grip (7).

See drawing 74

WALL version (PENTALED 12 PA – PENTALED 28 PA): wall box (1), horizontal arm (2), swinging arm (3), lamp head (4), control keyboard (5), sterilisable grip (6).

See drawing 75

DOUBLE CEILING version (PENTALED 12 SO – PENTALED 28 SO): ceiling anchor tube (1), ceiling cover (2), horizontal arm (3), swinging arm (4), lamp head (5), control keyboard (6), sterilisable grip (7).

Separable parts

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

5.2 Description of operation

Main switch

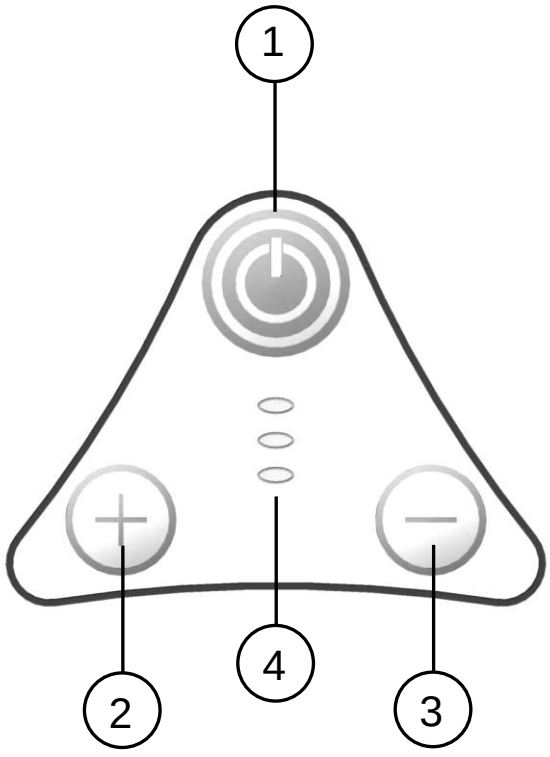
The floor and wall lamps feature a green light switch for general switch on and off.

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

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:

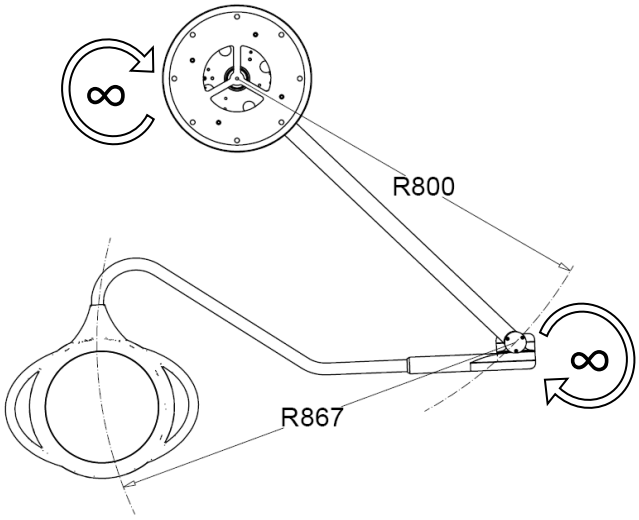
- (key 1) I/O standby switch;
- (key 2) increases light intensity '+';
- (key 3) reduces light intensity '-';
- (key 4) three green micro-LEDs display the selected intensity level. There are seven adjustment levels. With mains power on, a green micro-led remains on to indicate standby function.



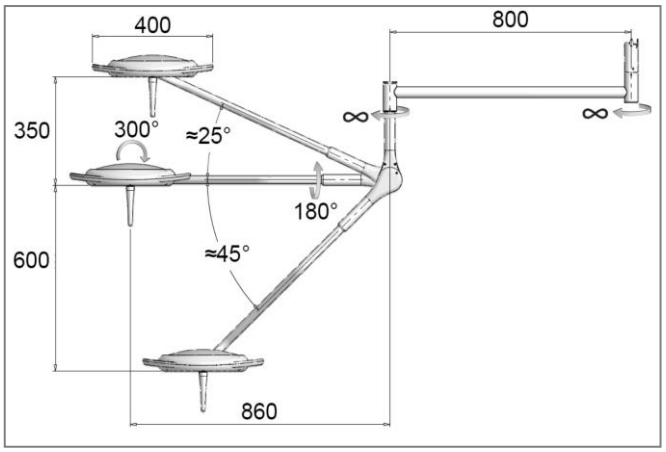
Lighted area

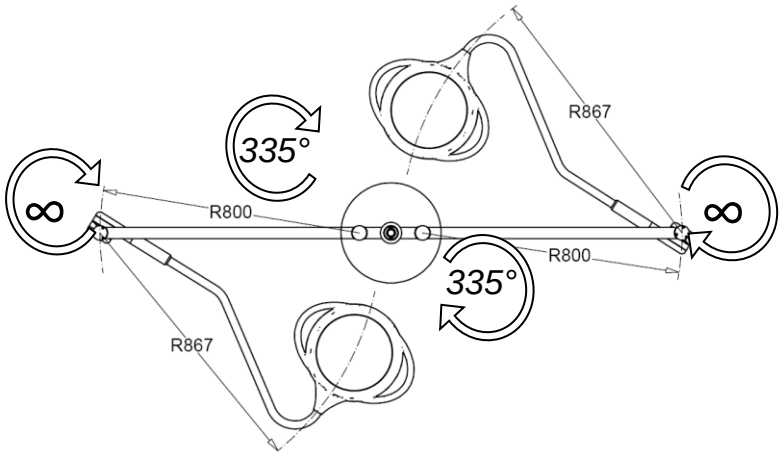
The Product has been designed to ensure a fixed light diameter without any need for adjustment.

5.3 Product handling

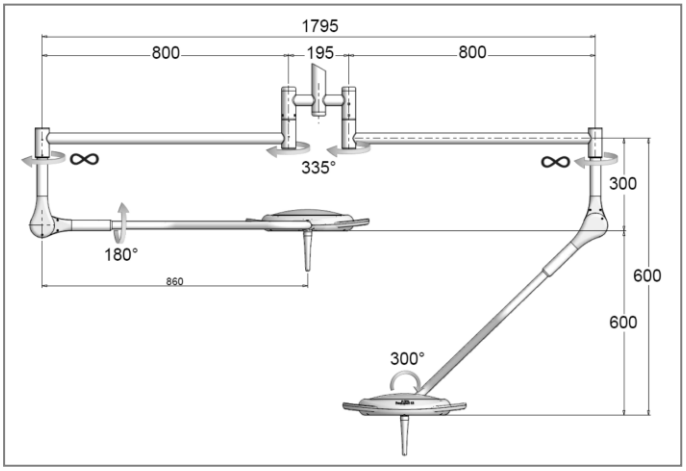


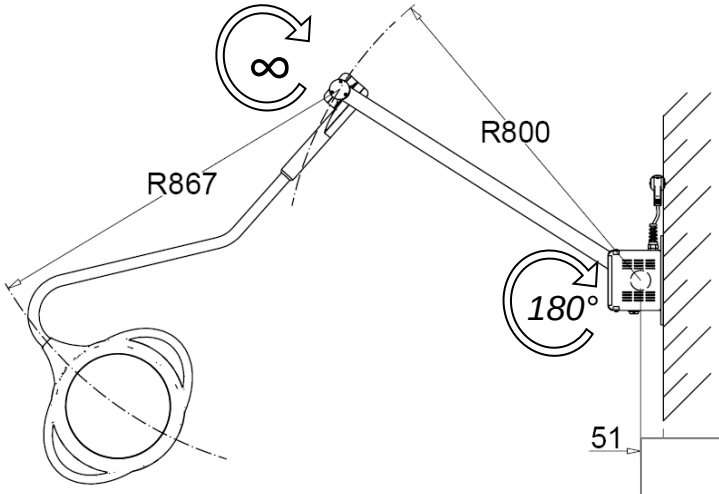
SINGLE ceiling model



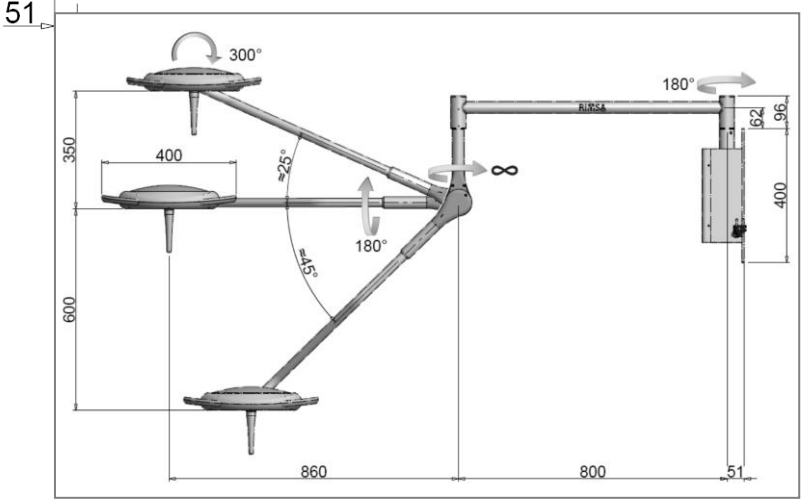


DOUBLE ceiling model

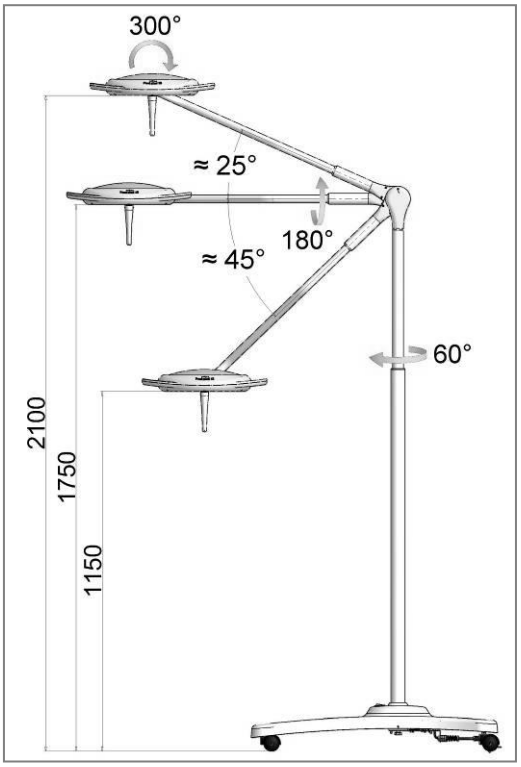


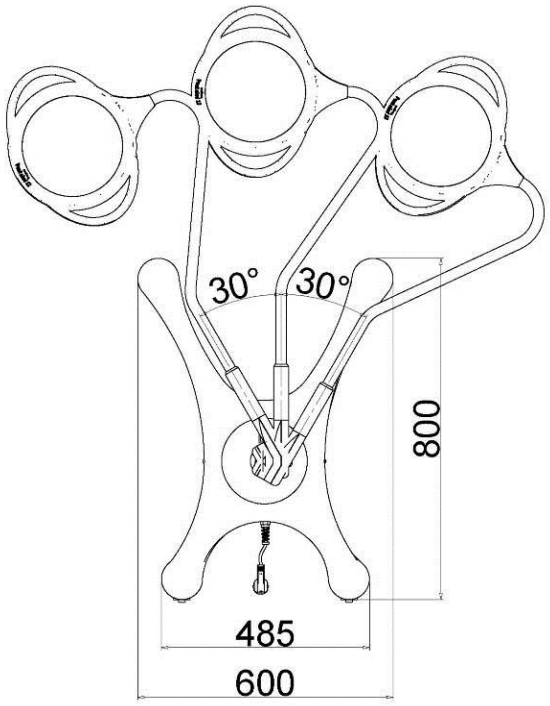


Wall model



Floor model





The Product can be moved using the sterilisable grip (fig. A) or by means of the side handles (fig. B)

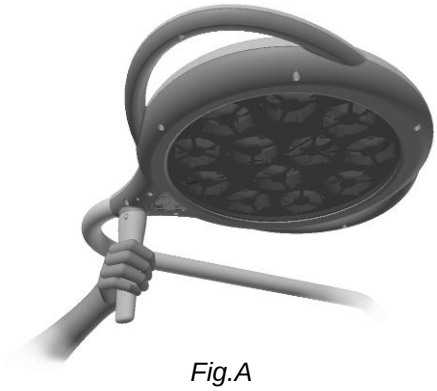


Fig.A

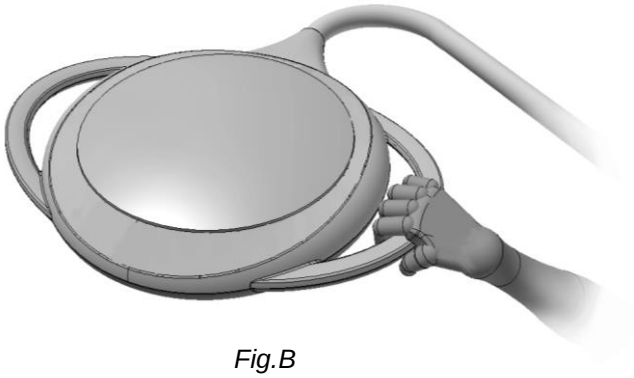


Fig.B

By pressing the keys on the membrane keyboard, the previously described control functions are started (fig. C)

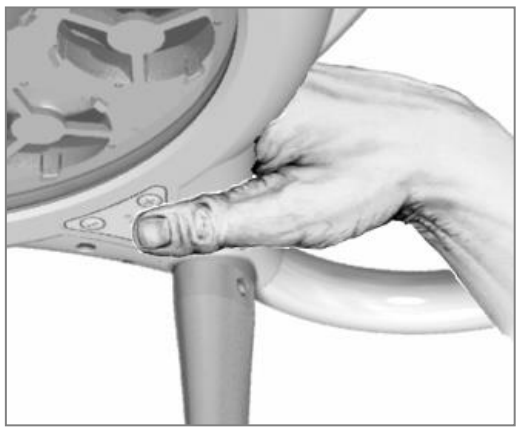
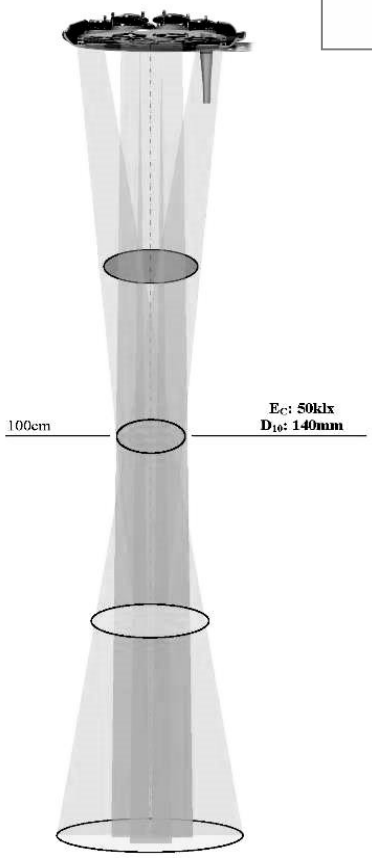
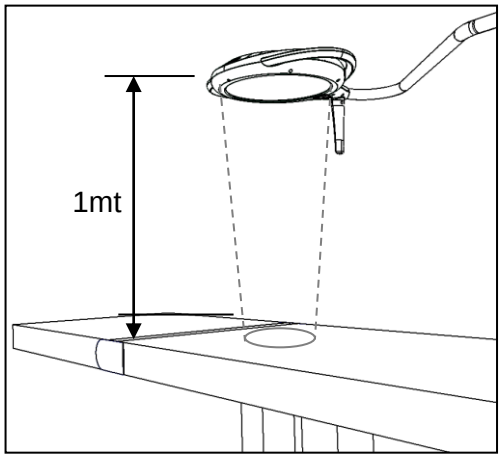


Fig. C



RECOMMENDED WORK DISTANCE



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

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

5.3.1 Brakes for floor version

The floor version features 4 castors with pedal brake to be operated to block the Product in the required position.

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

⚠	**Risk of damaging the pedal**

Do not kick the pedal or press it insistently once stop position has been reached.

To release the brake lift the pedal with your foot.

5.4 Controls to be performed every time before the lamp is used

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

- The lamp has been correctly disinfected;
- The emitted light is stable and of adequate intensity;
- The swinging arm maintains correctly its position;
- The dome maintains correctly its position.

6 Cleaning and disinfecting

6.1 Application method

	Interrupt the power supply before cleaning the Product.

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

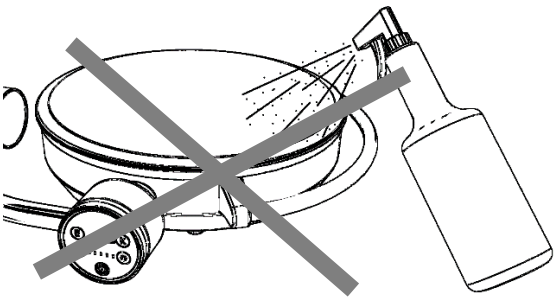
Allow the lamp to cool down and only clean it when it is cold.

Protect the Product from water spray and detergents and do not clean it in direct contact with liquids.

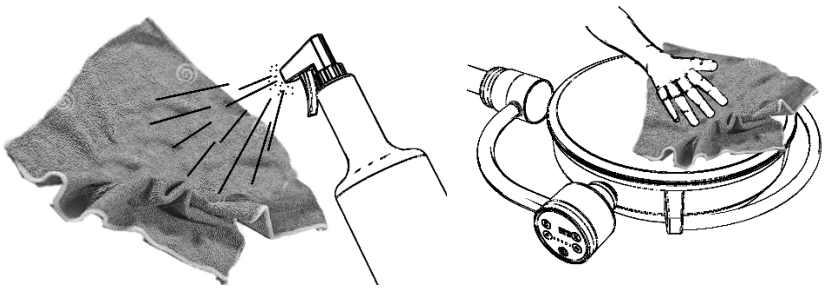
	Possibility of damaging Product

Application method

Do not spray the detergent/disinfectant directly on the Product.



Spray the detergent/disinfectant on a cloth to dampen it. Afterwards wipe the product with the cloth.



Failure to comply with the above instructions could cause:

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

6.2 Cleaning the Product

Frequency — We recommend you to clean the Product every day.

Possibility of damaging Product

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

6.3 Product disinfecting

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

Possibility of damaging Product

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

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

6.4 Handpiece sterilization

Frequency

The hand-pieces must be sterilized before use and can withstand up to 200 cycles.

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

Hazard for the patient

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

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

Hand-piece fitting / removal:

- Press the stop catches located parallel with the grip and remove this.
- Insert the grip until the catches click into and are blocked in the handpiece holes.

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 1.3 bar from 25 to 30 minutes
- steam sterilization at 134°C 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 Installation of swinging arm

See drawing 65

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

See drawing 65

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 (7) to increase the braking force, turning the dowels (6) of the arm brake clockwise.

7.3 Periodical checks to be performed on the Product

Making any changes to this device is forbidden.

Perform the electrical check on the Product

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

7.4 Routine maintenance

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	Every 6 months	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	Every 6 months	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 are tightened properly. Also check the bar horizontal arm retention screws. If these are not properly fastened, adequately tighten. See drawing 190. 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 (FLOOR AND WALL VERSIONS)	See drawing 192. Floor version: Make sure the stem retention screw (1) and the arm retention screws (2) are tightened properly. Wall version: Make sure the wall retention screws (3) and the horizontal arm retention screws (4) are tightened properly. If these are not properly fastened, adequately tighten.

7.5 Repairs

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

Interrupt the power supply before doing any maintenance jobs.

Making any changes to this device is forbidden.

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

See drawing 190

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

See drawing 191

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

In the floor version, remove the screws (3), lift the silicone ring (4) and the cover (5) along the stem.

Remove the fuse carrier (6) from the terminal board and replace the fuse (7) making sure it is replaced with another of the same type.

If necessary, GIMA will provide all information needed to help the technical assistance staff to change the fuses.

All other repairs to be performed by GIMA.

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

7.6 Disposal after use

Disposal at end-of-life

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

7.7 Spare parts list

	**Only original spare parts must be used**

Description	Order code
Sterilisable grip	Z180045
Fuse T2AH 250V ‘5x20’	Z400195

8 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 [-]	96
R9	>90
Light field diameter d_{50} [mm]	95
Light field diameter d_{10} [mm]	160
Lighting depth L1+L2 [cm]	77
Max radiation [W/m^2]	366
Radiation / Illumination [mW/m^{2}lx]	3.66
Max radiance in UV [W/m^2]	0.001
Power connection details	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Absorbed power [VA]	30 (100V) – 35 (240V)
Light source	N°12 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50,000
Incorporated fuses	T2AH 250V, 5x20
General data	
Colour	RAL 9003
Directive	2007/47/EC

Standards		IEC 60601-2-41
Classification of Medical Device		Class I
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively)	
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m^2 and the total irradiance Ee in the lighted area does not exceed 1000 W/m^2 at a distance of 500 mm).	
IP degree of protection		IP20
Operating conditions		Continuous operation
Handpiece steam sterilization		121°C 1.3bar 25 to 30 minutes. 134°C 2.3bar for 4 minutes.
Mains power voltage insulation means		Outside the product (main switch) for ceiling versions Main switch for wall and floor versions
Dimensions		
Diameter of lamp body [cm]		30
Light emission surface [cm^2]		305
Weight of floor, ceiling, wall, double ceiling surgical light [kg]		21; 13; 12; 20
Markings		
CE		In conformity with Directive 93/42/EEC (and 2007/47/EC)
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons		

9 Declaration of Conformity of the Manufacturer

The company:
RIMSA P. LONGONI S.r.l. Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) – ITALY
declares under its own responsibility that the Product (Medical lighting device for surgical and diagnosis use):

PENTALED 12 / PENTALED 28
APPLY LABEL

made by RIMSA P.LONGONI S.r.l., complies with Annex VII of Directive 93/42/EEC dated 14/05/1993, enforced in Italy by Legislative Decree No. 46 dated 24 February 1997 and subsequent amendments (including Directive 2007/47/EC dated 05/09/2007, enforced in Italy by Legislative Decree No. 37 dated 25 January 2010) and with the following standards:

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

Classification with reference to article 9 and Annex IX of Directives 93/42/EEC and 2007/47/EC	
DURATION:	Short term duration (Annex IX, Par.1 “Definitions”, art.1, subsection 1.1)
DESCRIPTION:	Non-invasive medical device (Annex IX, Par.1 “Definitions”, art.1, subsection 1.2)
	Active medical device (Annex IX, Par.1 “Definitions”, art.1, subsection 1.4)
CLASS I:	(Annex IX, Par.3 “Classification”, art.3, subsection 3.3, Rule 12) and
	(Annex IX Par.3 “Classification”, art.1, subsection 1.1 Rule 1)

- Reference to technical file Code RIM-FT019.
- The conformity assessment is developed with reference to article 11 of Directive 93/42/EEC and 2007/47/EC.
- The 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

The Product has been tested according to EN60601-1-2 standard to ensure correct electromagnetic compatibility. Portable and mobile RF-communications equipment can affect the Product. The Product should not be used adjacent with other equipment and that if adjacent use is necessary the Product should be observed to verify normal operation. The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that is used in such an environment.

	**Possibility of interferences with nearby appliances**

Immunity test	**Conformity**	**Electromagnetic environment - directives**
RF Emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Product is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Product or shielding the location.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Conforming	

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply unit +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c mains voltage prior to application of the 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 2.5GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Product, 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 $d = 2,3\sqrt{P}$ 80 MHz to 2,5 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 an people.			

Recommended separation distance between portable an 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 2.5 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 an people.

11 Warranty Certificate

1. The Product is covered by an 18-month warranty, including electrical parts
2. The warranty begins on the date of product shipment from the GIMA warehouse to the buyer.
3. In case of disputes, the date indicated on the “transport document” attached to the goods shall be deemed valid.
4. The warranty only covers the sending of Product spare parts to the buyer or, in the event of GIMA considering the replacement of spare parts not feasible, the replacement of the entire product, after fabrication faults have been properly ascertained at the undisputable judgement of GIMA . The warranty does not therefore cover any other costs or expenses (including, by way of example but without limitation, labour costs, packaging costs and transport costs, etc.).
5. The guarantee does not include the components subject to normal wear, such as halogen bulbs, LEDs, fuses, relays, ball bearings, etc.)
6. The warranty does not cover:

- malfunctions due to failure to comply with all instruction manuals;
- malfunctions due to installation and/or maintenance errors;
- malfunctions or faults caused by carelessness, negligence, incorrect use or other causes not attributable to GIMA;
- malfunctions or faults due to the fact that the electrical system of the premises where the device is installed is not in compliance with CEI 64-8 standards (standards for electrical systems in premises used for medical purposes) and similar standards.

7. GIMA GIMA shall repay direct damages suffered by the buyer and which are documented as attributable to its product, caused within the warranty period, for an amount not above 40% of the net value of the product as indicated on the buyer’s invoice. GIMA’s liability is expressly ruled out for indirect damages or consequential damages (including cases of the lamp not being used) deriving from the supply.
8. This warranty certificate replaces legal warranties for faults and non-conformities and rules out any other possible liability of GIMA originating from the supplied products.
9. The payment of any damages to persons or things due to product malfunction or faults shall be limited to the maximum amount of GIMA’s insurance coverage for civil

liability.

10. The warranty shall be automatically invalidated in the event of:

- the Product having been tampered with or modified by the buyer or third parties;
- the Product having been repaired by the buyer or third parties, without following the instructions in the instruction manuals;
- the Product serial number having been cancelled, defaced or removed;
- the buyer not being up to date with payments.

11. For jobs to be done under warranty, the buyer shall contact GIMA only.
12. The component parts replaced under warranty must only be returned to GIMA, if so requested by GIMA, carriage free and suitably packed.
13. In case of failure to return a part requested by GIMA, the cost of the component part will be charged.
14. GIMA cannot accept returns from end users or in any case from parties other than the buyer.
15. Products returned to GIMA must be complete with documentation authorising such return and another document describing the malfunction.
16. For everything not indicated on this warranty certificate, reference shall be made to the laws of Italy
17. For all disputes deriving from or related to the orders to which this warranty certificate applies and which cannot be amicably settled between the parties, the only competent law court shall be that of Milan.

12 Pentaled 28 special features

12.1 Product description

The Pentaled28 lamp is the evolution of the Pentaled12 lamp, with the difference that a direct lens light system is used with 28 LEDs and the option of selecting two colour temperatures.

The diameter of the light field can also be regulated by turning the knob provided.

Separable parts

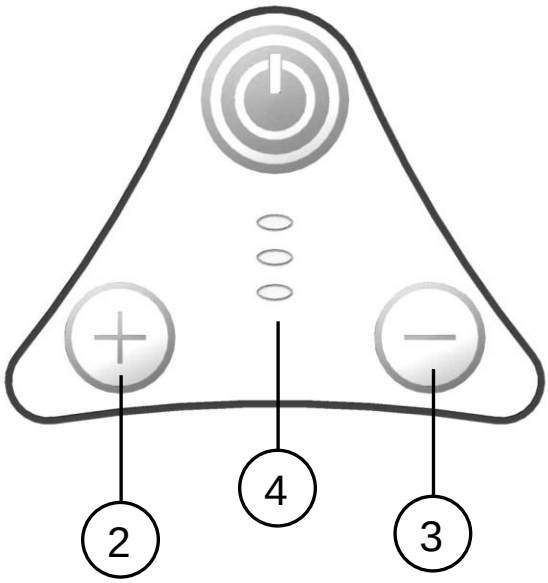
Sterilisable handpiece Refer to Section 6.4 for assembly/disassembly instructions.

12.2 Description of operation

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:

- (key 1) I/O quick press to switch on the Product; with prolonged press to place the Product in standby;
- (key 1) I/O with quick press to regulate the colour temperature of the Product cyclically from 4500K to 5000K (4500K at switch on)
- (key 2) increases light intensity '+'
- (key 3) reduces light intensity '-'
- (key 4) three green micro-LEDs display the selected intensity level. There are eleven adjustment levels. With mains power on, a green micro-led remains on to indicate standby function.

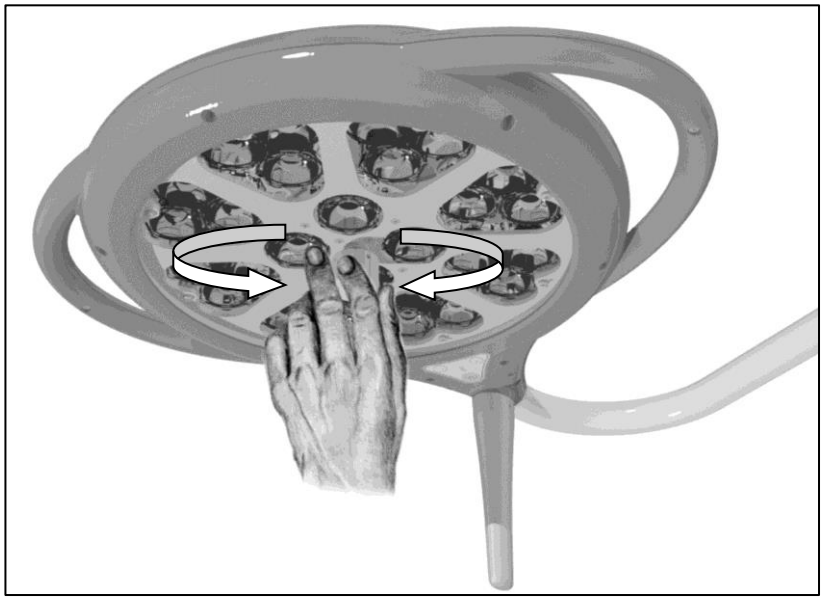


Lighted area

The diameter of the light field and focus can be regulated by turning the central wheel

12.3 Product handling

To regulate the diameter of the light field and focus, turn the wheel at the centre of the protection shield clockwise or anti-clockwise. Such wheel cannot be removed nor can it be sterilized.



12.4 Spare parts list

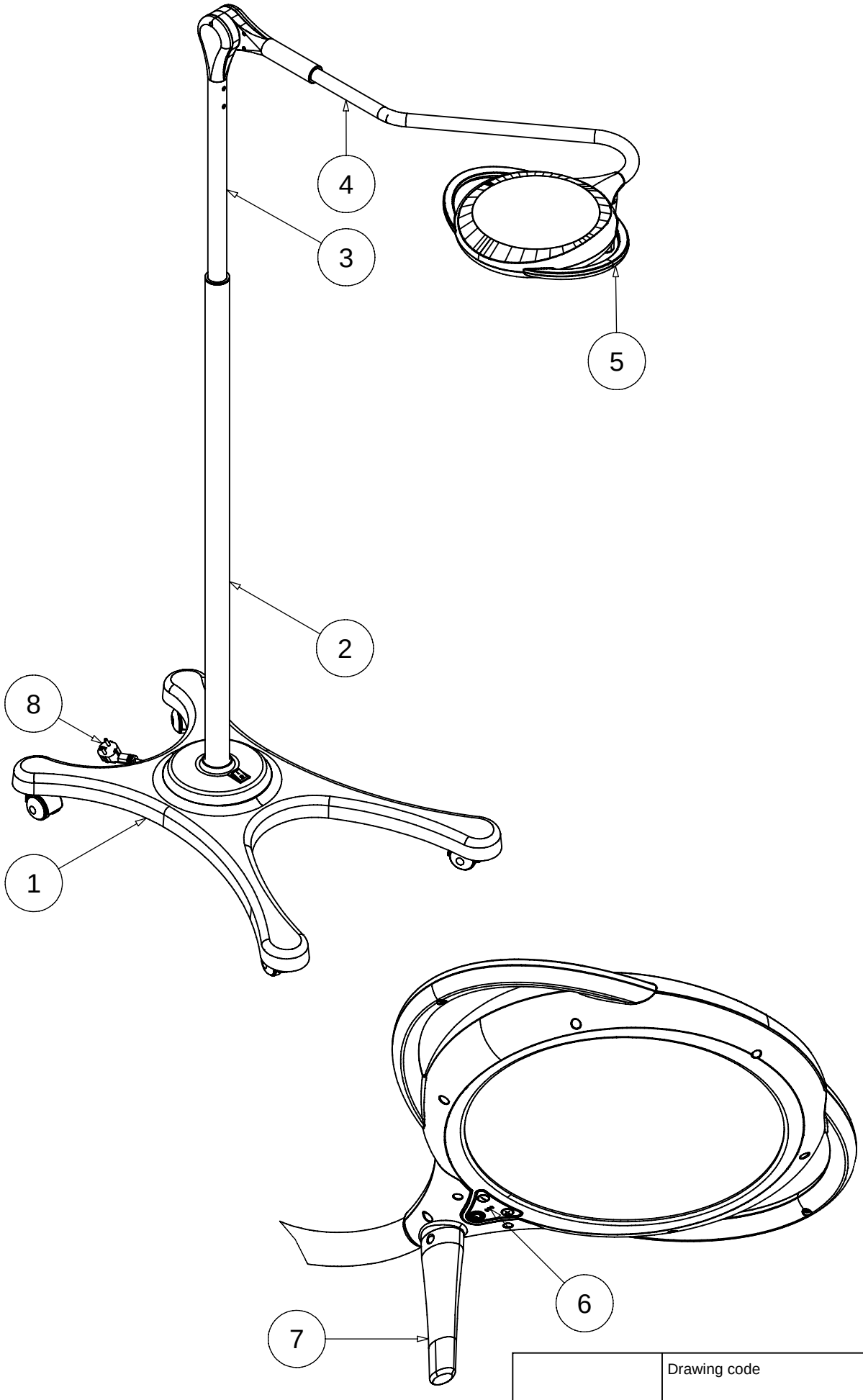
Description	Order code
Sterilisable grip	Z180045
Fuse T2AH 250V '5x20'	Z400195

12.5 Technical properties

Technical details of light	PENTALED 28
Illumination E_c at 1 m distance ± 10% [Lux] *(4500K – 5000K)*	100,000 – 120.000
Colour temperature (±5%) [K]	4,500 / 5,000
Colour rendering index R_a [-] *(4500K – 5000K)*	90 - 94
R9	>90
Light field diameter d_{50} [mm] *(4500K – 5000K)*	110 – 110
Light field diameter d_{10} [mm] *(4500K – 5000K)*	300 – 300
Lighting depth L1+L2 [cm] *(4500K – 5000K)*	88 – 74
Max radiation [W/m^2] *(4500K – 5000K)*	160 – 231
Radiation / Illumination [mW/m^{2}lx] *(4500K – 5000K)*	1.6 – 1.92
Max radiance in UV [W/m^2] *(4500K – 5000K)*	0,001
Power connection details	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Absorbed power [VA]	57 (100V) – 66 (240V)
Light source	N°28 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50,000
Light intensity control [%]	20 – 100
Incorporated fuses	T2AH 250V, 5x20

General data		
Colour		RAL 9003
Directive		2007/47/EC
Standards		IEC 60601-2-41
Classification of Medical Device		Class I
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively)	
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m^2 and the total irradiance Ee in the lighted area does not exceed 1000 W/m^2 at a distance of 500 mm).	
IP degree of protection		IP20
Operating conditions		Continuous operation
Handpiece steam sterilization		121°C 1.3bar 25 to 30 minutes. 134°C 2,3bar for 4 minutes.
Mains power voltage insulation means		Outside the product (main switch) for ceiling versions Main switch for wall and floor versions
Dimensions		
Diameter of lamp body [cm]		30
Light emission surface [cm^2] *(4500K – 5000K)*		147 – 196
Weight of floor, ceiling, wall, double ceiling surgical light [kg]		21; 13; 12; 20
Markings		
CE		In conformity with Directive 93/42/EEC (and 2007/47/EC)
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons		

Notes



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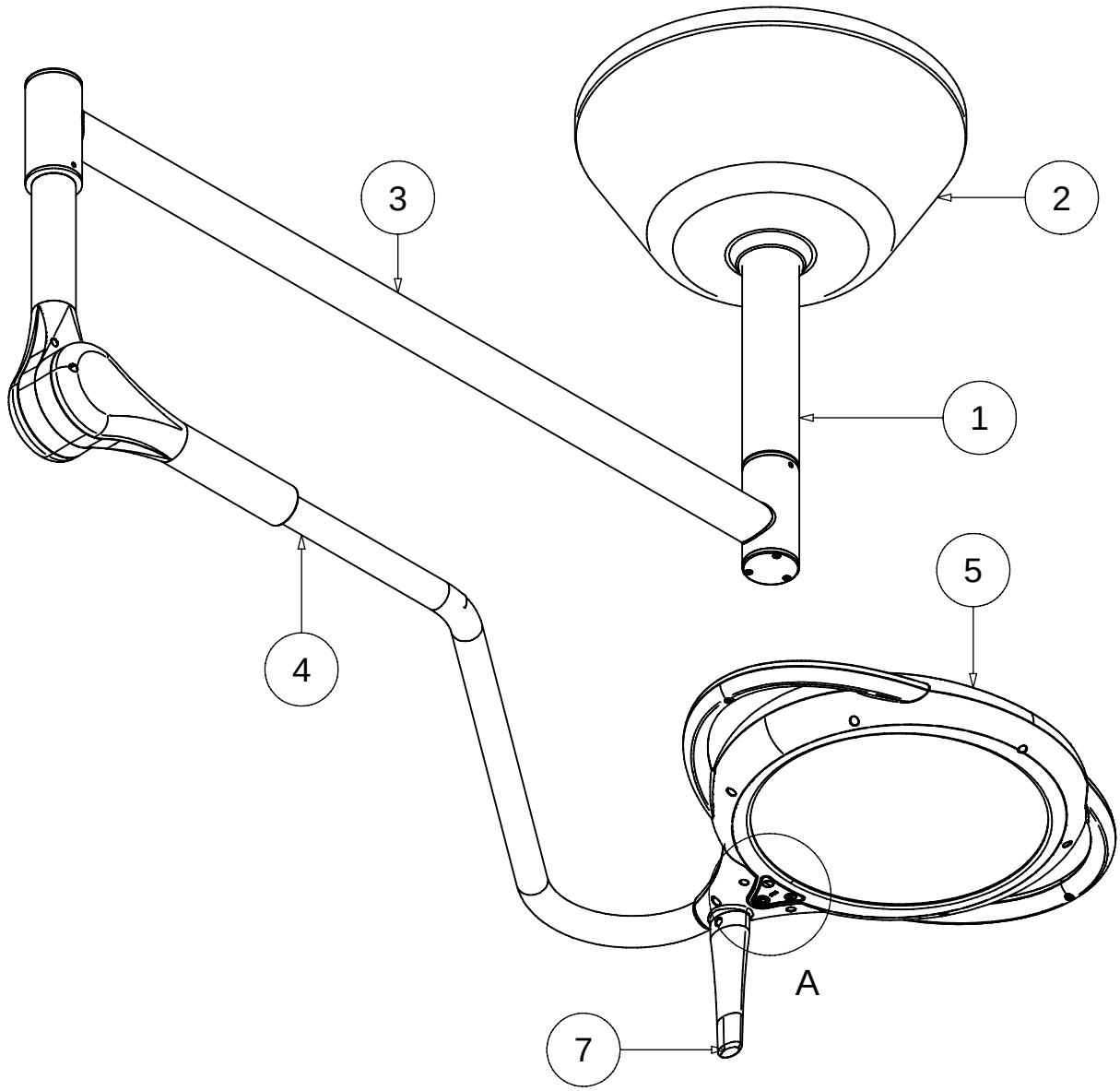

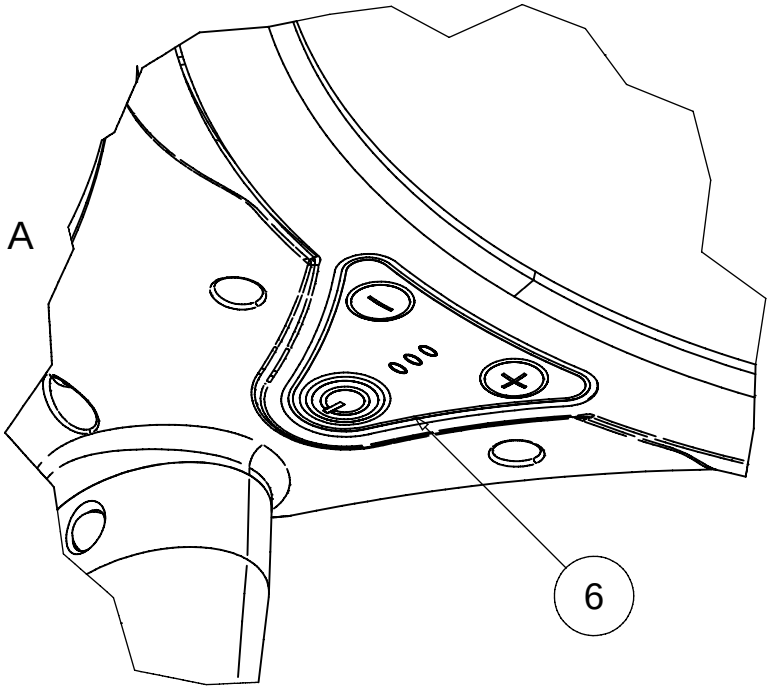

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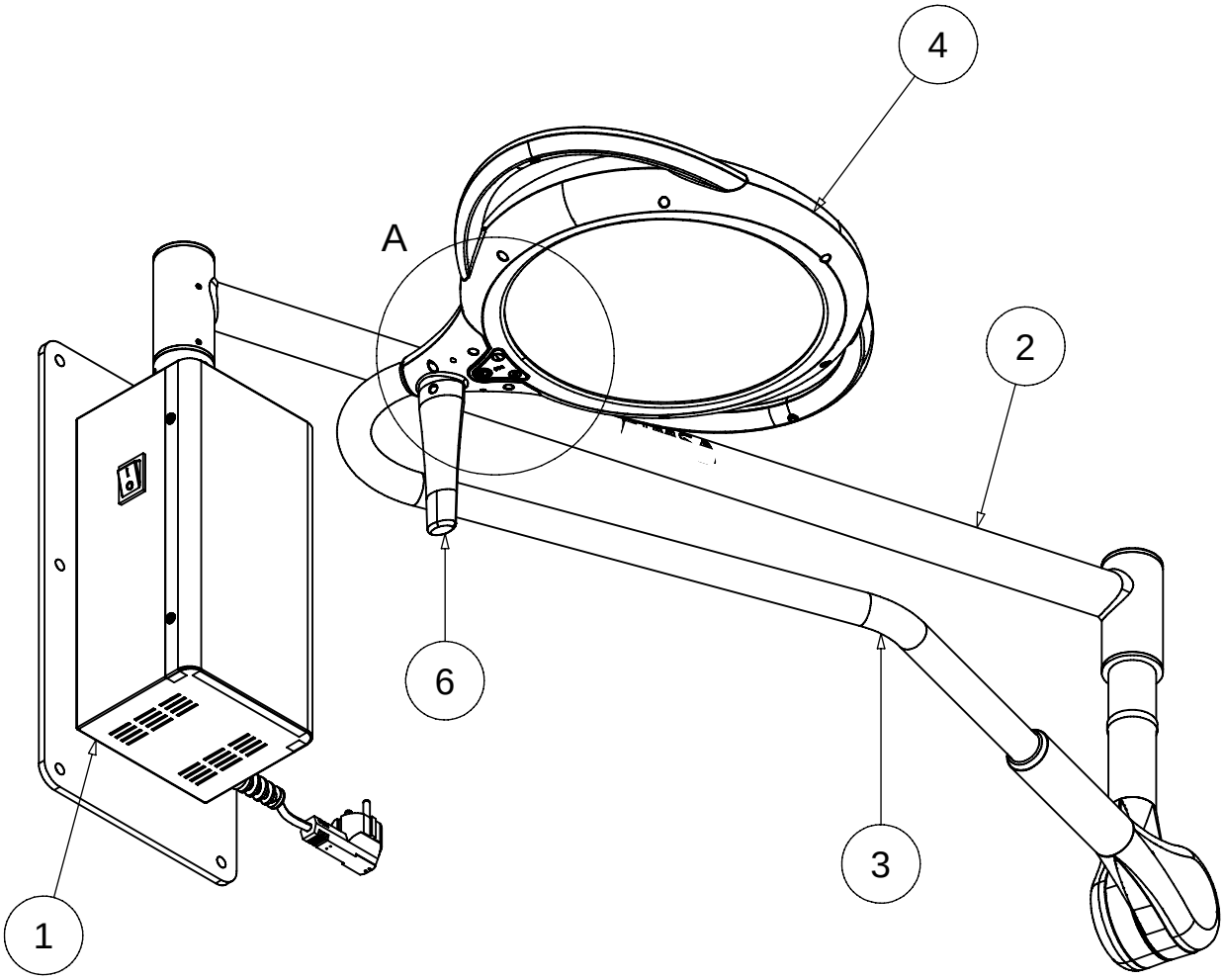

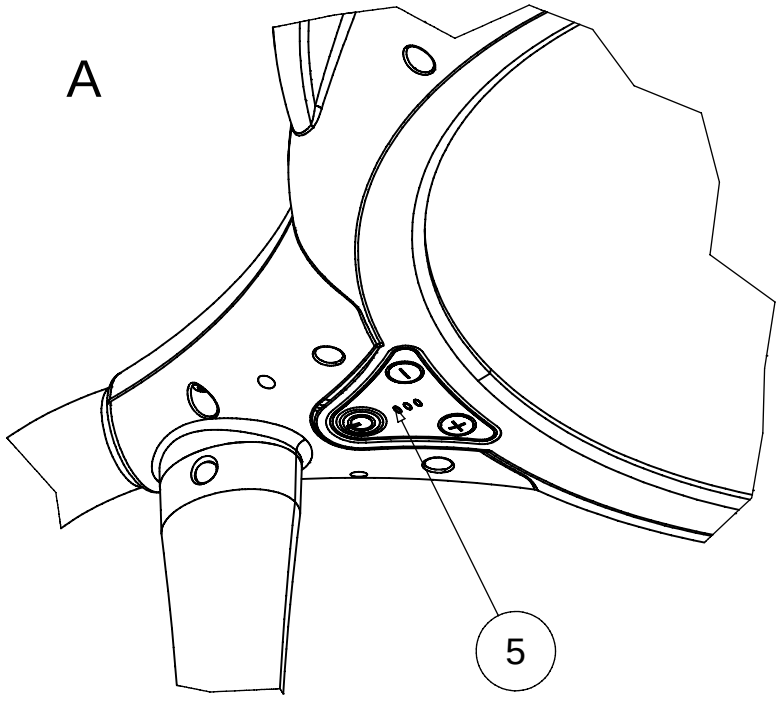

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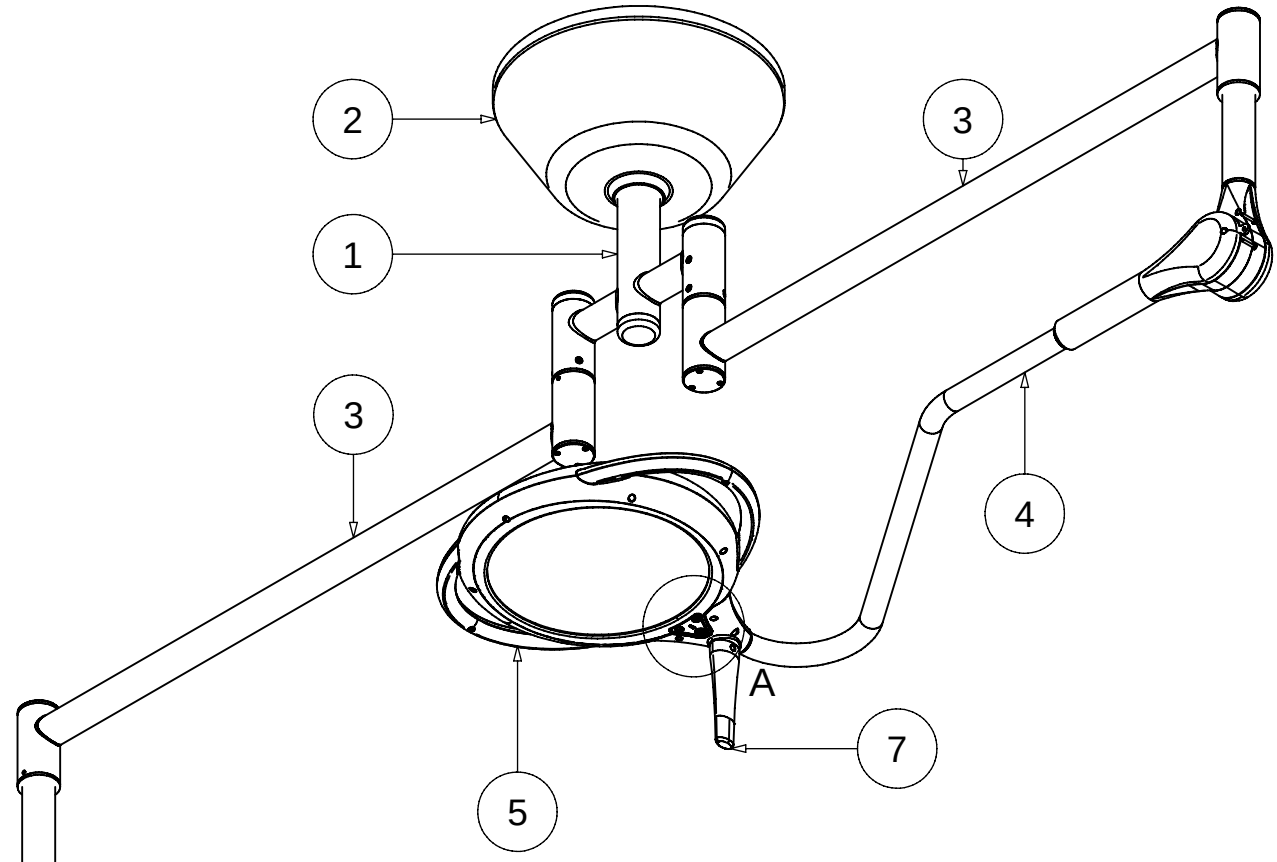

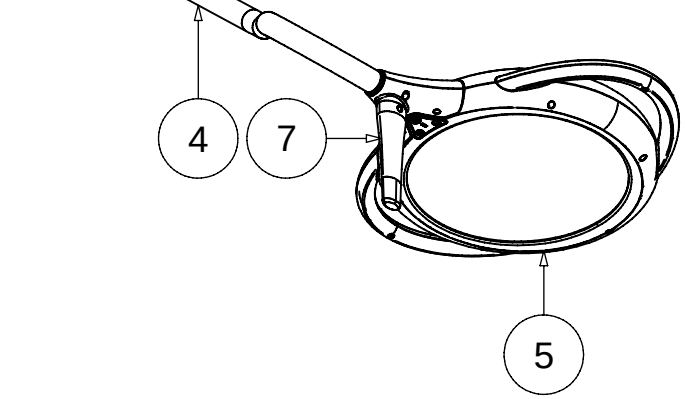

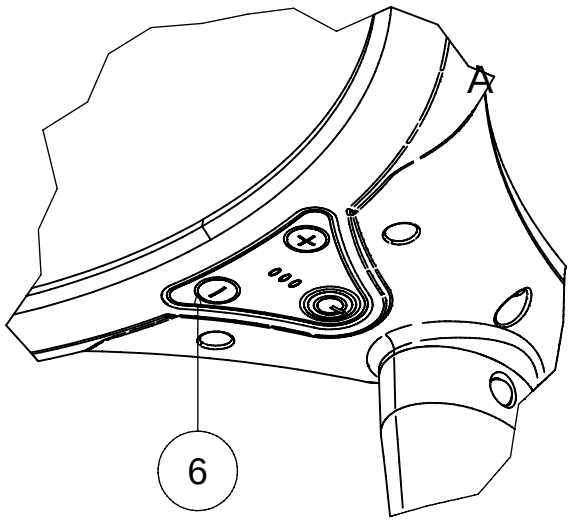

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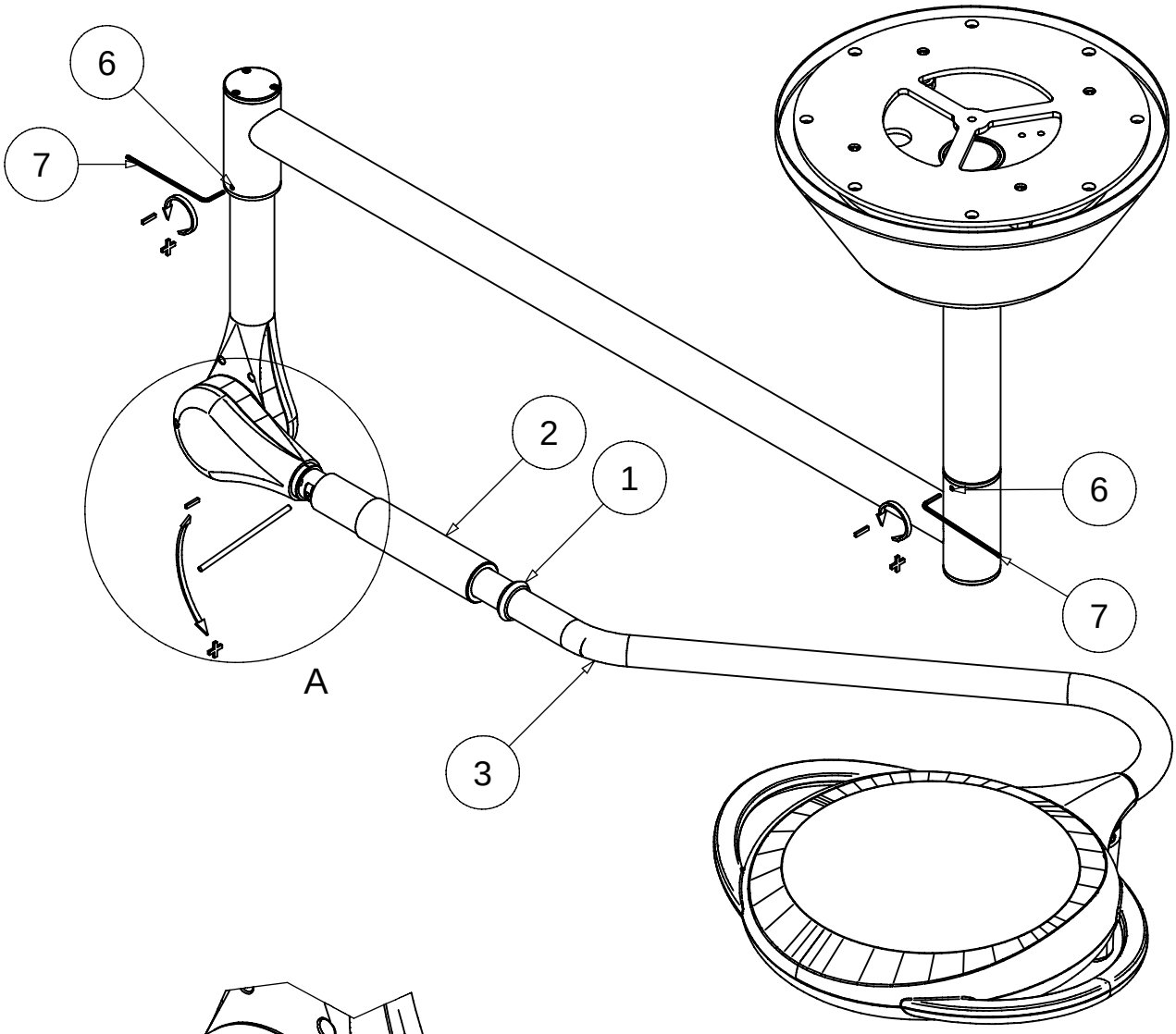

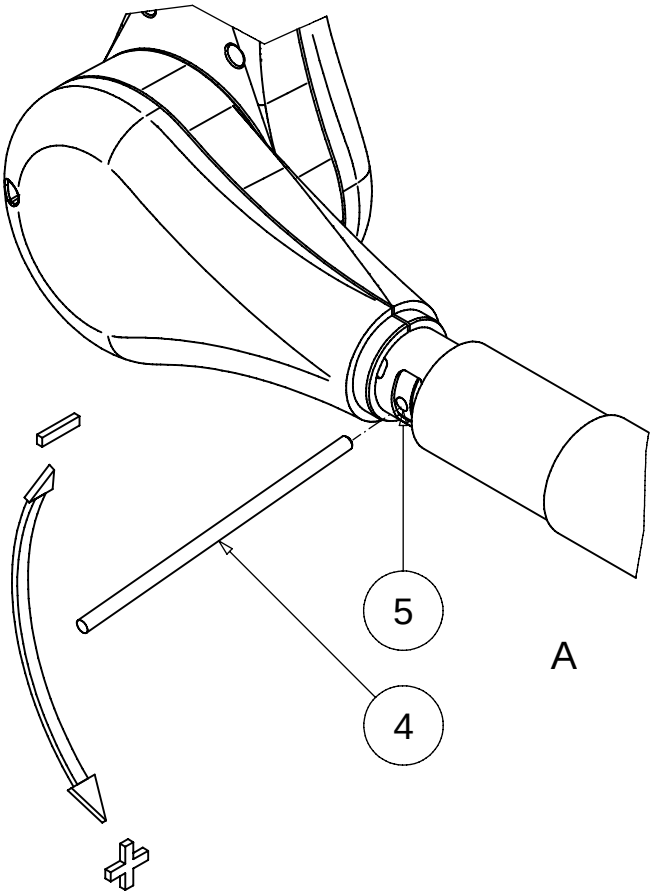

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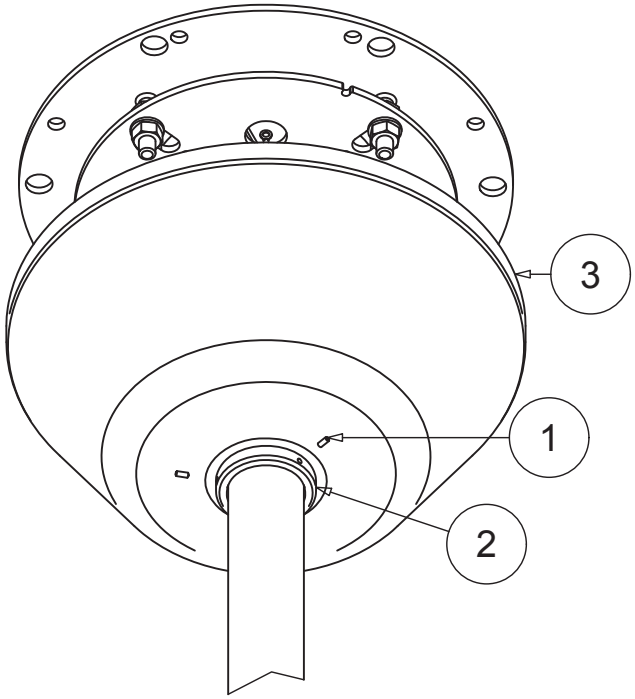

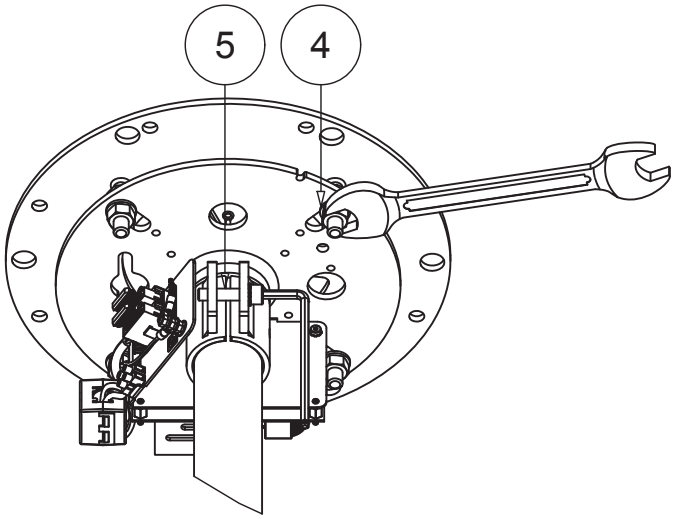

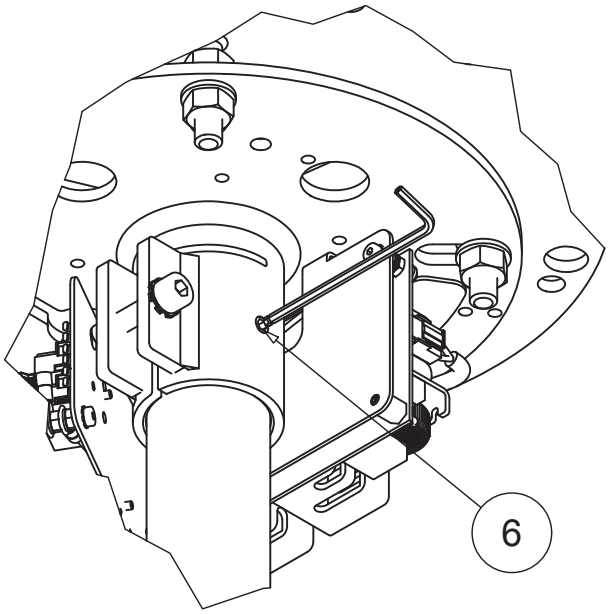

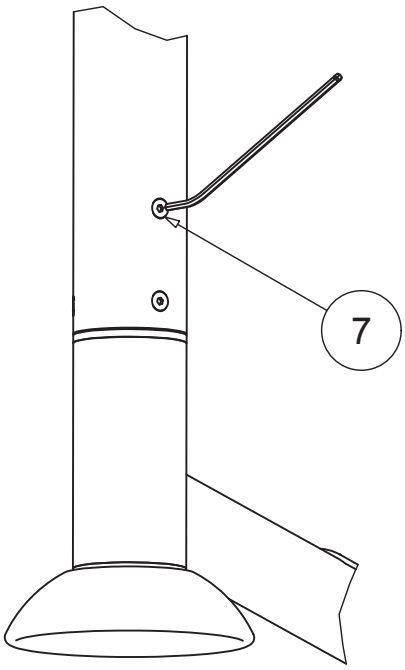

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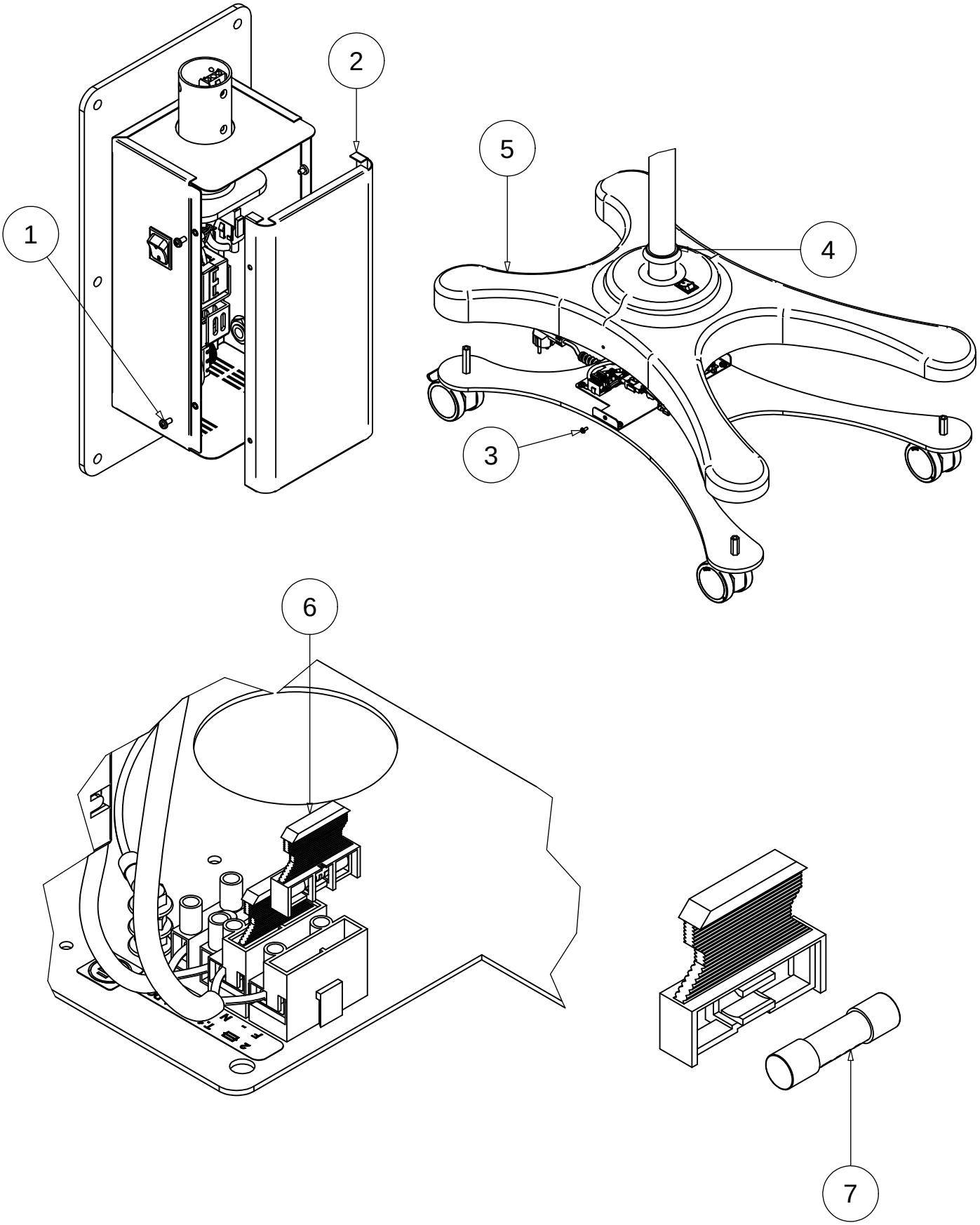

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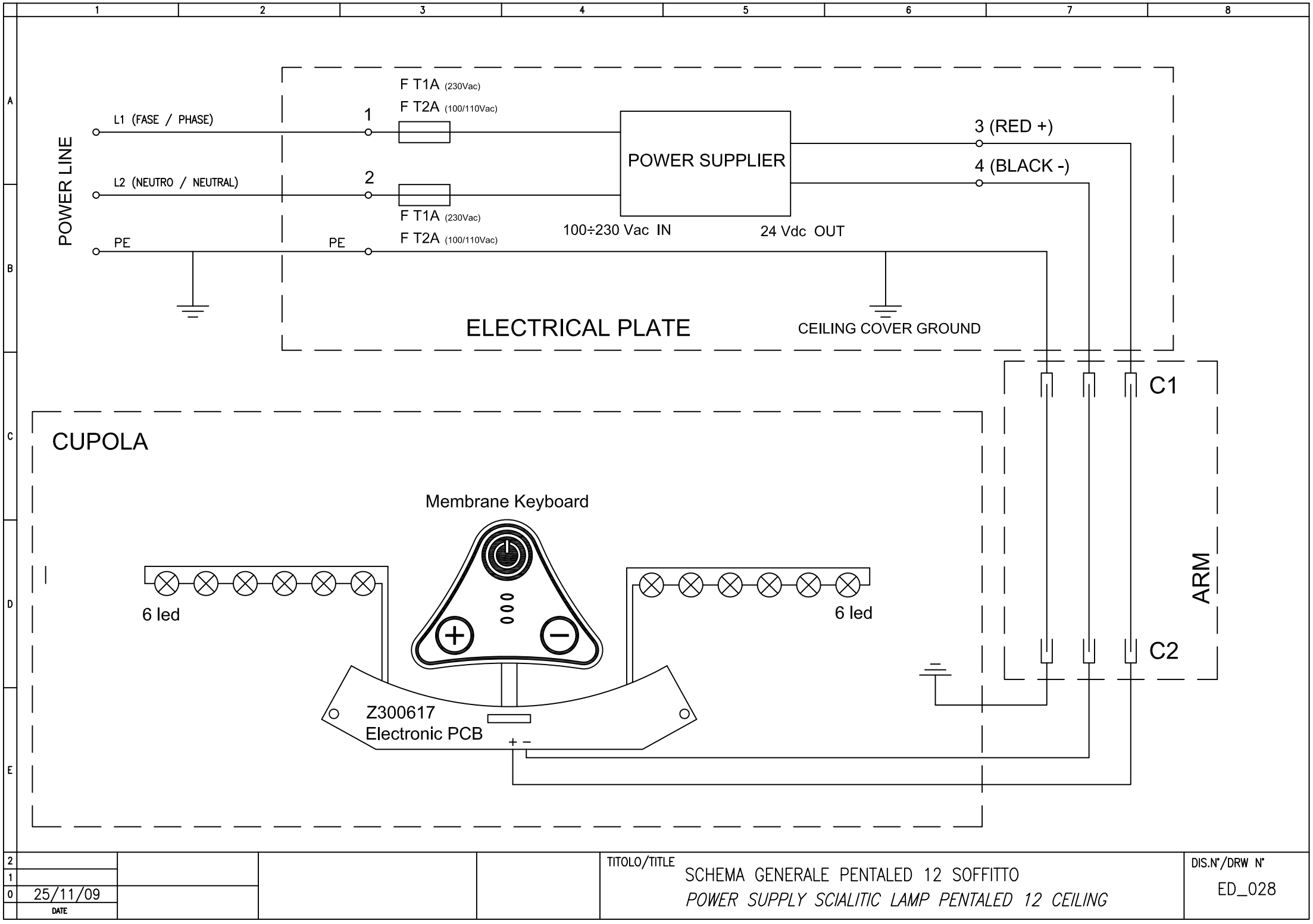

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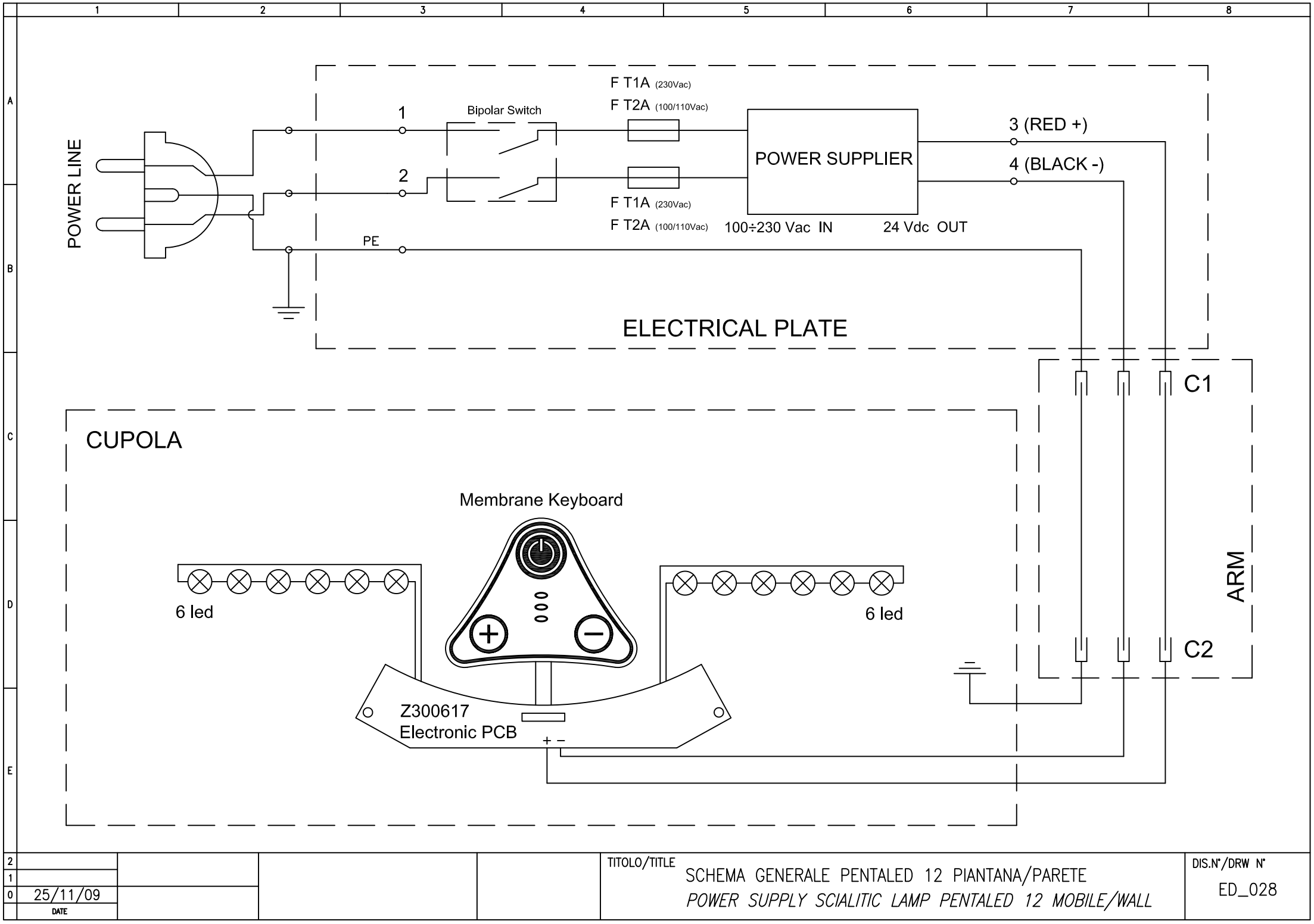
	DATE					



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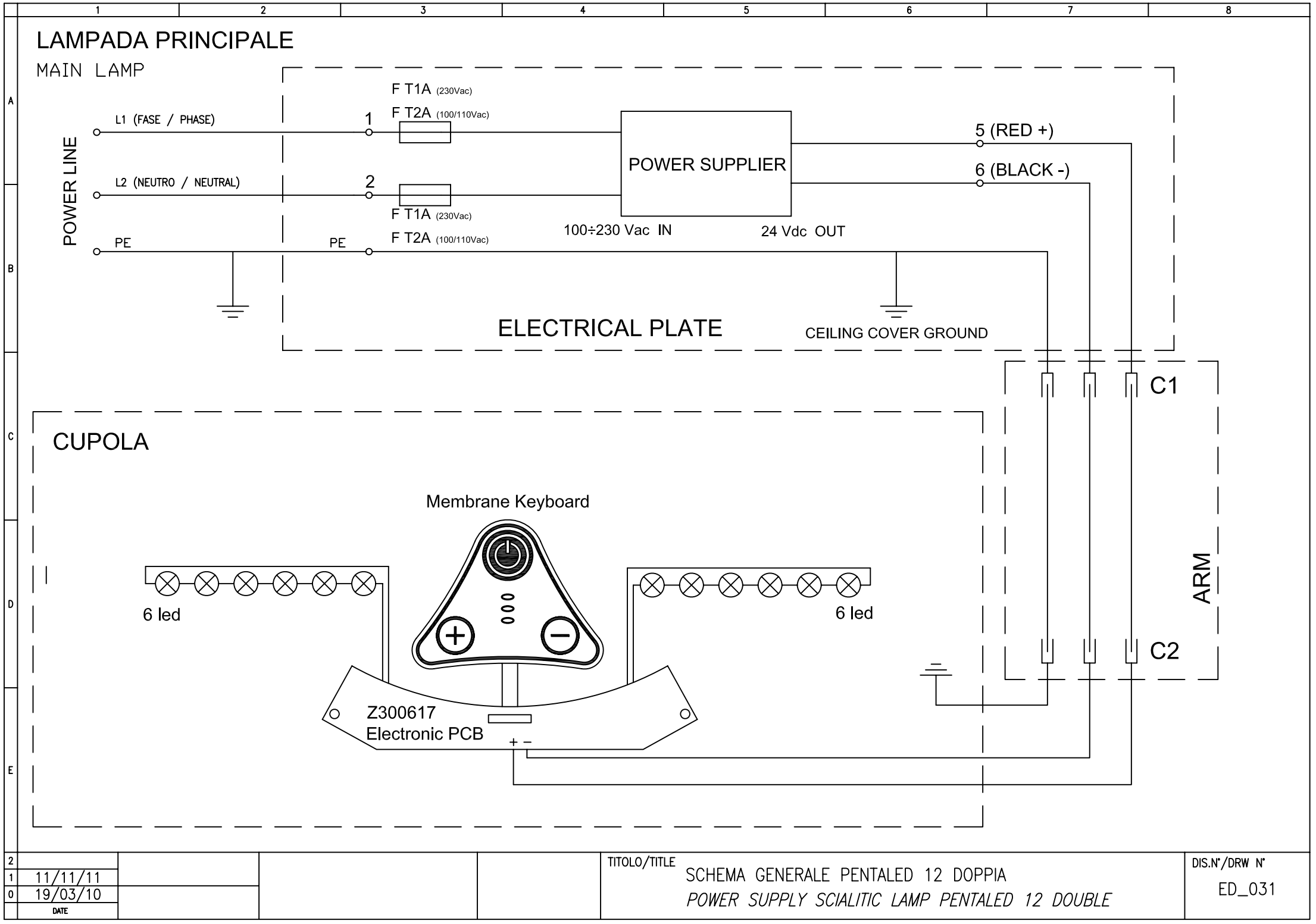

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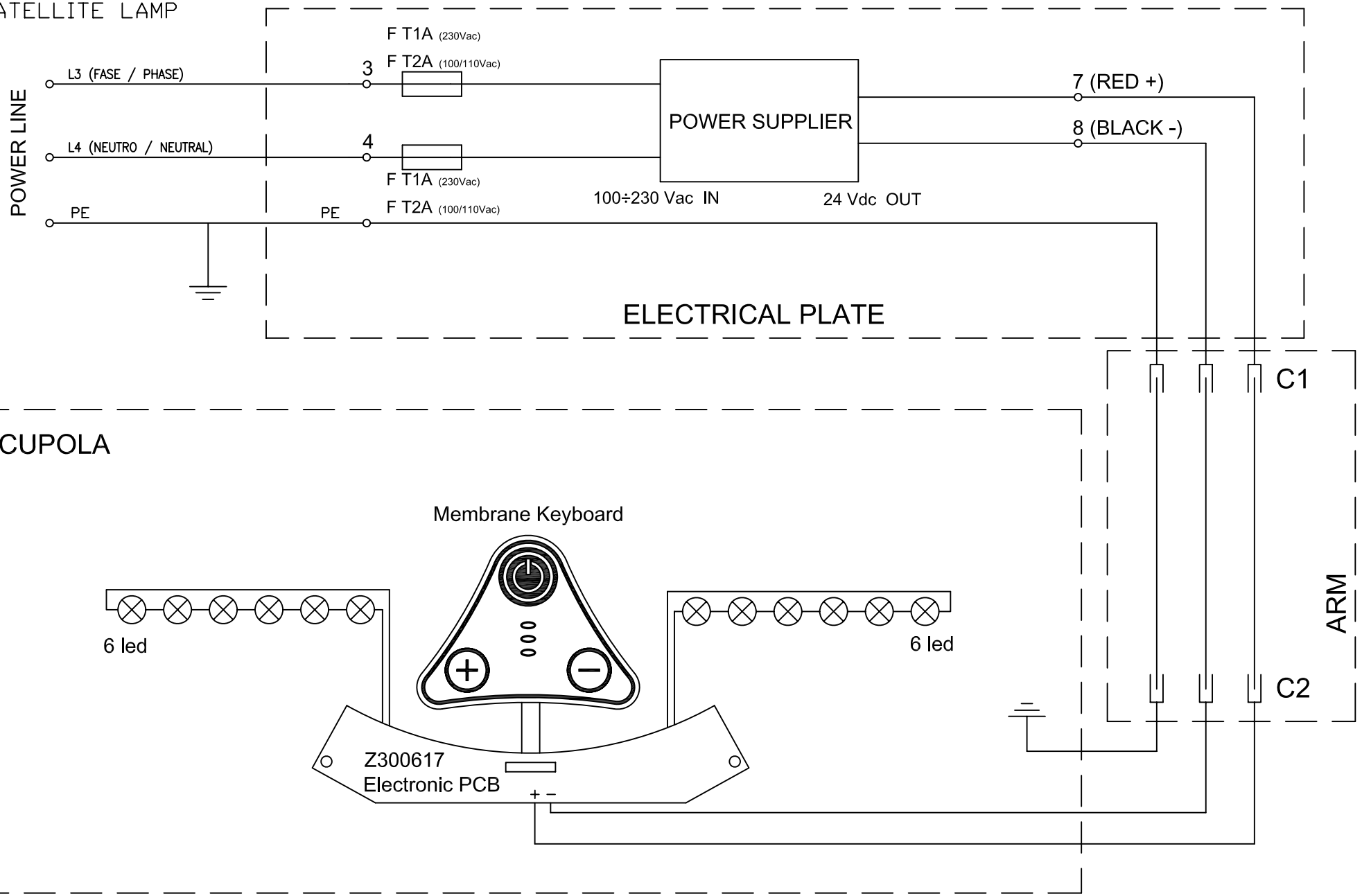
0	19/03/10			*POWER SUPPLY SCIALITIC LAMP PENTALED 12 DOUBLE*	
	DATE				

LAMPADA SATELLITE

SATELLITE LAMP



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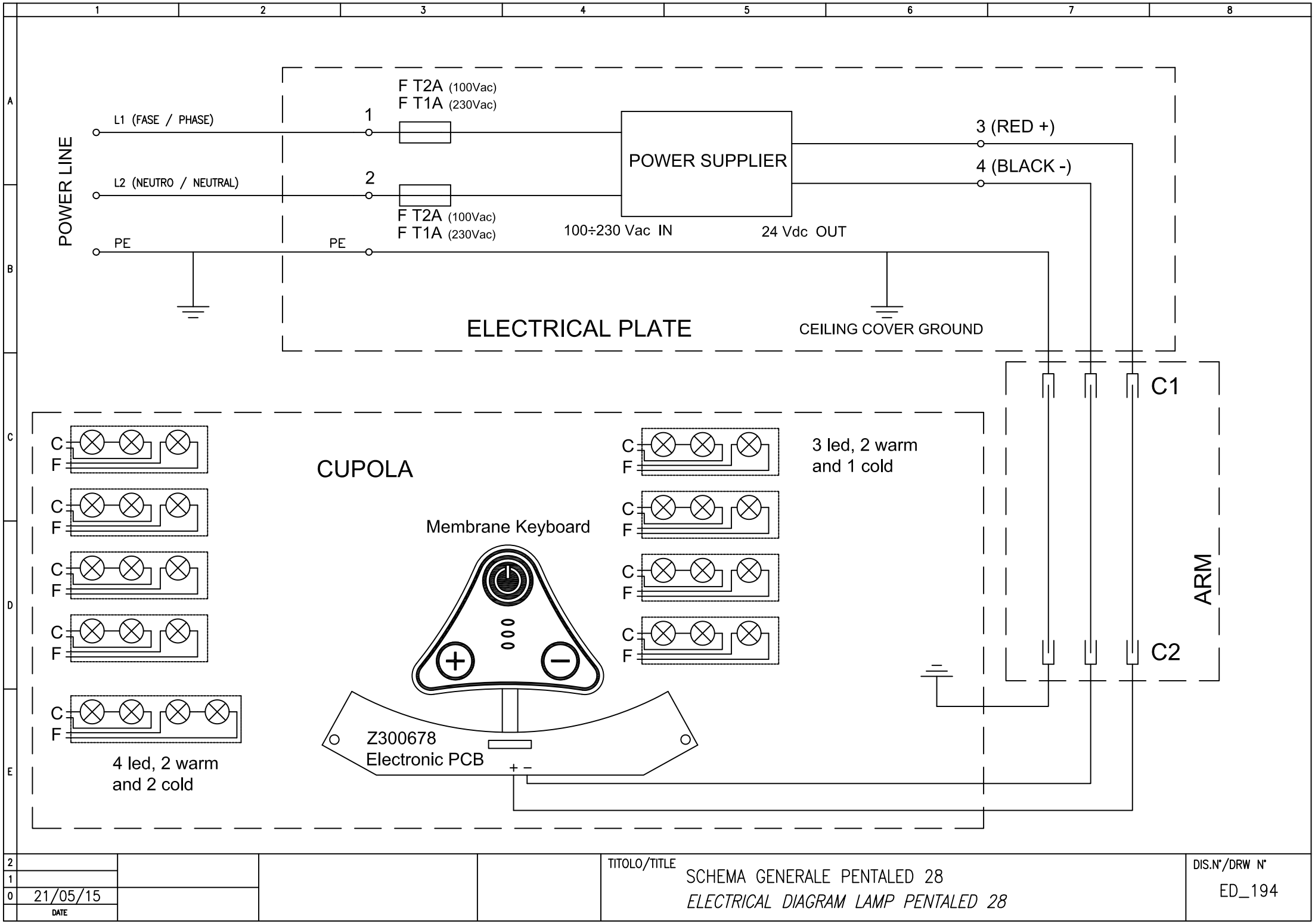

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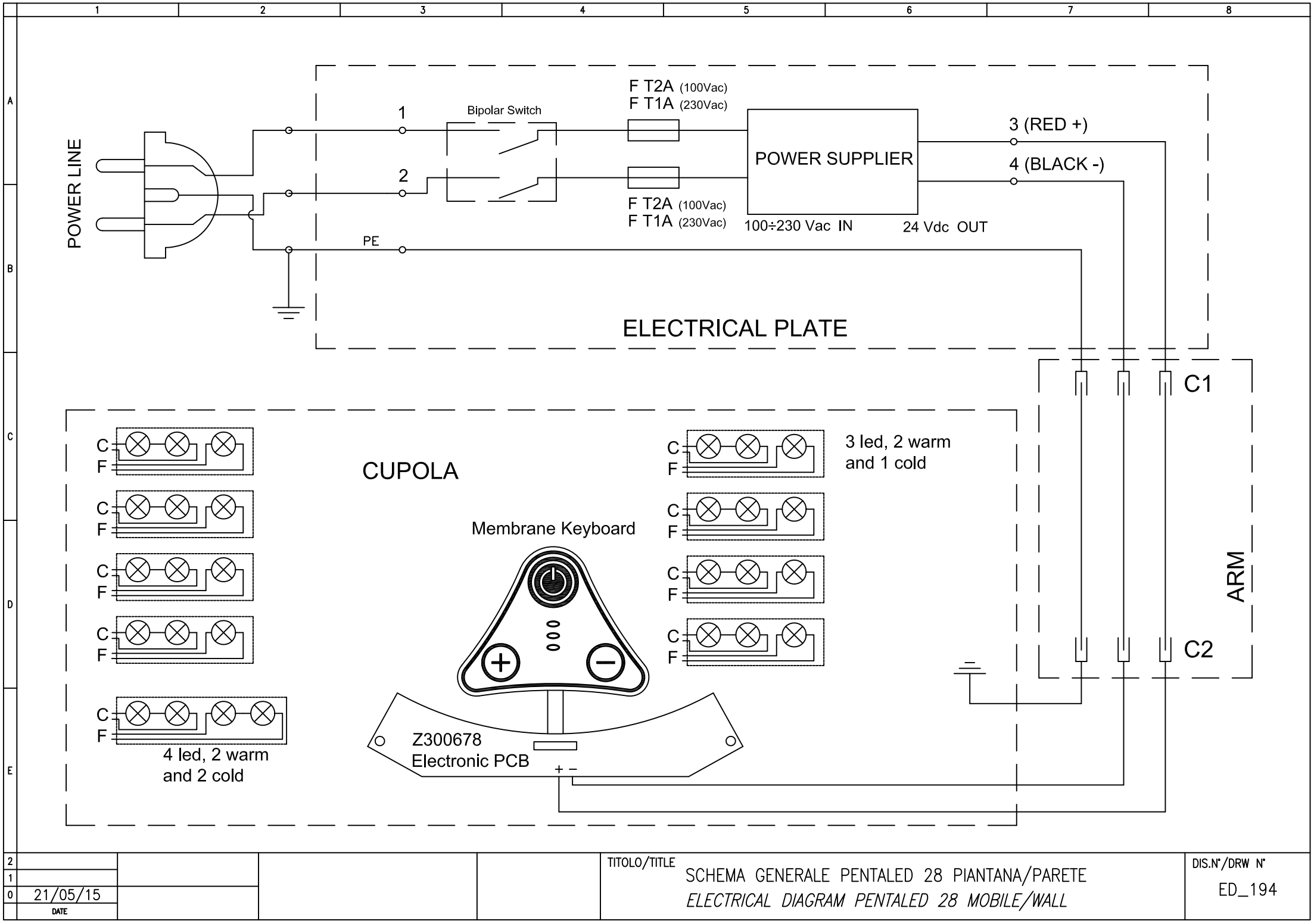

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