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# Operation and maintenance manual

## PENTALED12 PENTALED28

SECONDARY SURGICAL LAMP (TREATMENT LAMP)



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**Introduction** Please read this manual carefully before proceeding to correctly install the Product, so as to protect “**the Service Personnel**” and “**the Operator**” from any injury.



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.

**Conformity** The manufacturer declares that this Product is in compliance 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:

- Pentaed 12 in ceiling, floor and wall versions
- Pentaed 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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**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

<b>PRODUCT</b>	THE EM (Electro-Medical) EQUIPMENT to which this manual refers is a <b>SECONDARY SURGICAL LAMP (TREATMENT LAMP)</b> . For ease of description, in this manual this EM EQUIPMENT will be called “ <b>Product</b> ”.
<b>OPERATOR</b>	Person handling the equipment (e.g., professional health personnel, non-expert person assisting the patient).
<b>RESPONSIBLE ORGANIZATION</b>	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.
<b>SERVICE PERSONNEL</b>	<p>Individuals or entity accountable to the responsible organization that installs, assembles, maintains or repairs the equipment. In 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:</p> <p>⇒ Construction Engineer, Draughtsman, Building firm duly registered in the professional Register (for the masonry works)</p> <p>⇒ Electrical Engineer Electro-technical expert qualified to work as an electrician (for the electrical works)</p>

## 1 WARNINGS AND SAFETY NOTICES

- WARNING** 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.
- WARNING**
- The Product is not suitable for use in premises where explosion risks exist.
  - The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or NO<sub>2</sub> (laughing gas).
- WARNING** RIMSA disclaims all liability for any injury to persons or damage to things caused by the Product having been used and services by persons who are not OPERATORS or SERVICE PERSONNEL.
- WARNING** The Product is an EM electro-medical equipment and therefore falls within the field of application of the EN 62353 standard.



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

	<b>WARNING – Possibility of tissue dehydration and damage</b>
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**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)

	<b>CAUTION – Possibility of glare</b>
---	---------------------------------------

**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.

	<b>CAUTION – Do not place objects on Product</b>
---	--

**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 in the presence of inflammable mixtures of anaesthetics with air, oxygen or NO<sub>2</sub> (laughing gas).
- 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 qualification

Qualification of personnel in charge of operating on the Product

Use	OPERATOR
Cleaning	OPERATOR
Routine maintenance	SERVICE PERSONNEL
Special maintenance	SERVICE PERSONNEL
Scrapping	RESPONSIBLE ORGANIZATION and SERVICE PERSONNEL

### 3.2 Graphic symbols used in this Operation and Maintenance Manual

The following safety measures must be put in place during Product installation, use and servicing.




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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 Service Personnel must develop their capacities to upgrade and integrate them.

Indications such as DANGER, WARNING and CAUTION, preceded by the

symbol  indicate the level of “risk” to which the SERVICE PERSONNEL, the RESPONSIBLE ORGANIZATION and the PRODUCT could be exposed.

#### **DANGER**

indicates an immediately hazardous situation which could result in death or serious injuries.

#### **WARNING**

indicates a potentially hazardous situation that could result in death or serious injuries.

#### **CAUTION**

indicates a potentially hazardous situation which could result in moderate or light injuries and Product damage.



The following triangular symbol together with the explanation alongside indicates the type of hazard to be dealt with.

### 3.3 Graphic symbols used on the Product

Below are the symbols to be found on the Product:



CE mark indicating the Product conforms to directive 93/42EEC and subsequent amendments and supplements



Date of manufacture (month and year)



Manufacturer's address



Fuses used in the device



Compulsory to read the manual



Model



Serial number



Disposal (waste)

## 4 Precautions for the Product operator

### 4.1 Technical safety specifications

Cleaning personnel

The Product cleaning and disinfecting operations described in Chapter 6 must only be performed by the Operator.

Service personnel

The inspection and maintenance operations described in Chapter 7 must only be performed by the Service Personnel.

### 4.2 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.

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### 4.3 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 SERVICE PERSONNEL.

## 5 Product description and operation

### 5.1 Product description

#### Versions

The Product is available in various versions:

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

See drawing 63

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

See drawing 64

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

See drawing 75

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

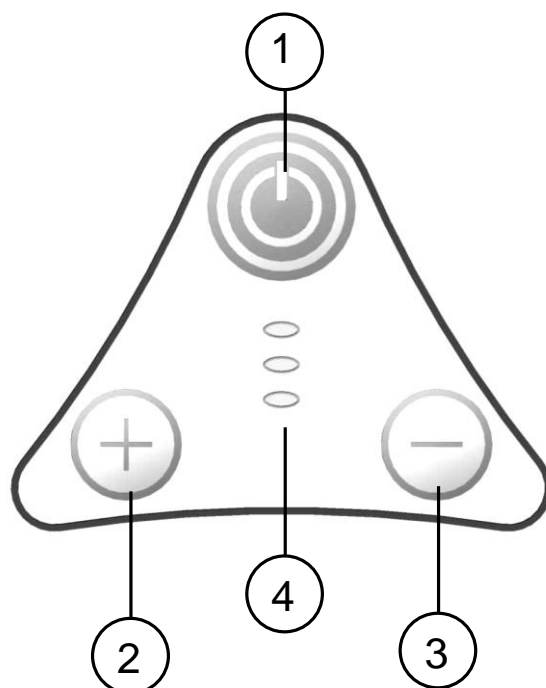
### 5.2 Description of operation

#### 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 - switches product on and off
- (key 2) increases light intensity '+'
- (key 3) reduces light intensity '-'

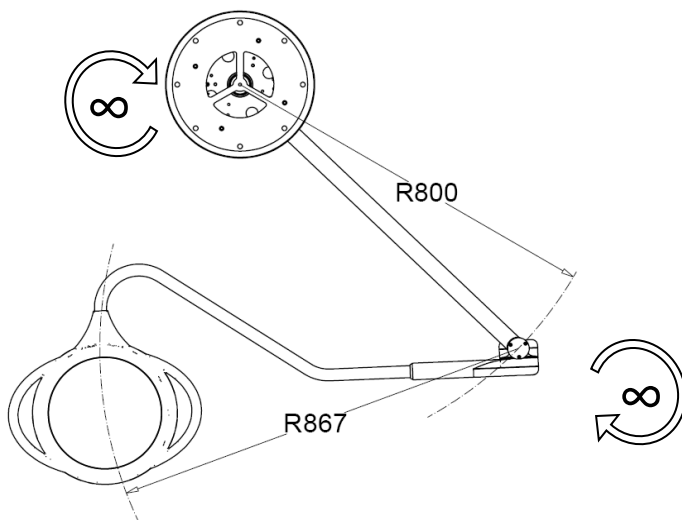
- (4) three green micro-LEDs display the selected intensity level. There are seven adjustment levels. With mains power on, a green micro-led remains on to indicate standby function.



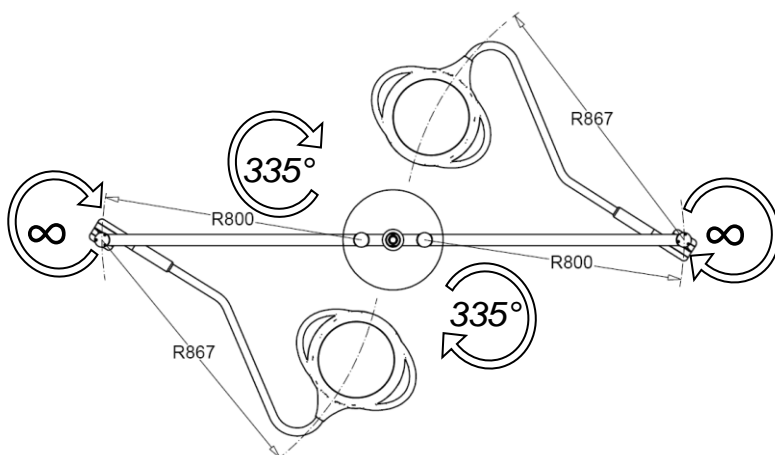
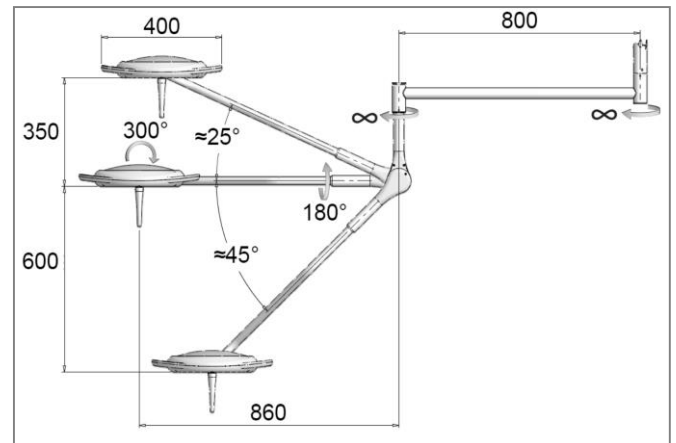
Lit-up area

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

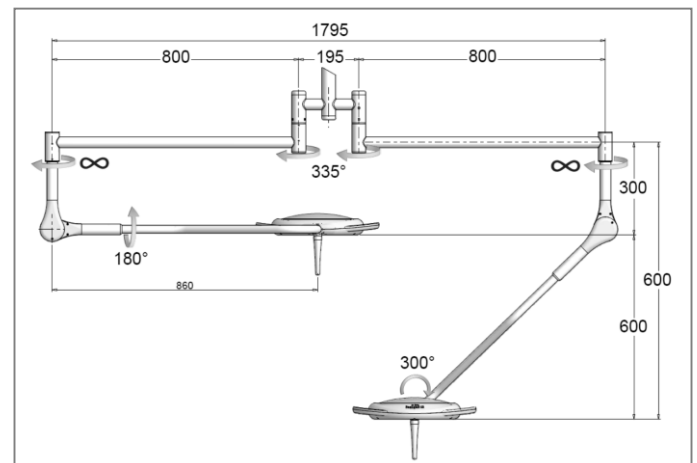
### 5.3 Product handling

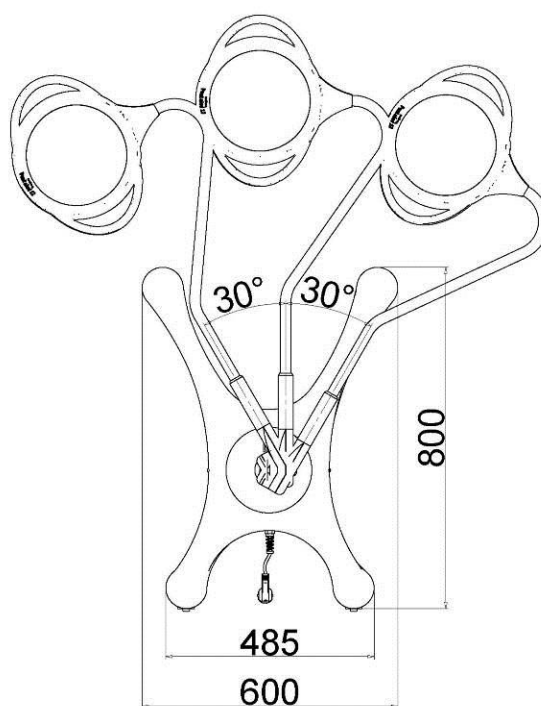


**SINGLE ceiling model**



**DOUBLE ceiling model**





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



Fig.A

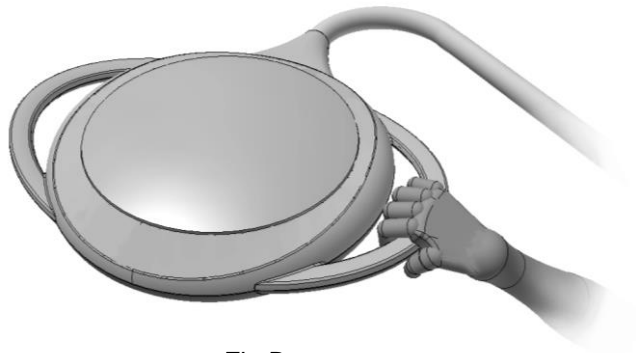
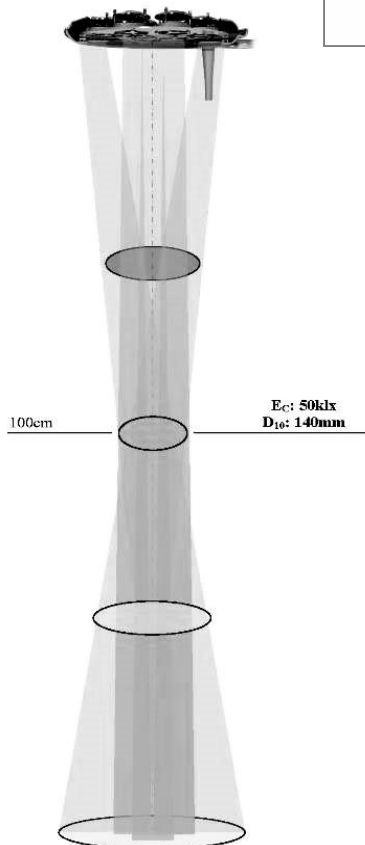


Fig.B

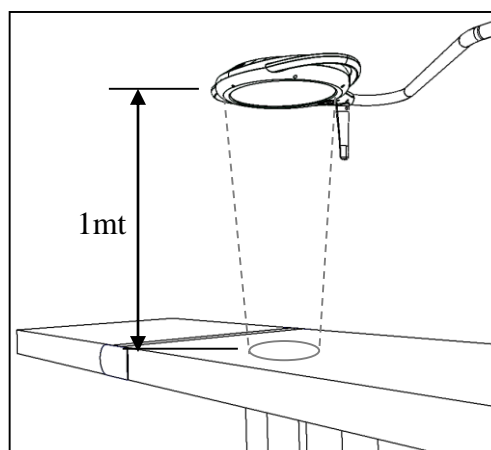
By pressing the keys on the membrane keyboard, the previously described control functions are started (fig. C)



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.

## 6 Cleaning and disinfecting

### 6.1 Cleaning the Product

Frequency

The Product is best cleaned every time before use.



#### **WARNING – Electric shock hazard**

Before cleaning 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.



#### **CAUTION – Possibility of damaging the Product**

- Do not use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.
- Do not pour liquids directly on the Product.
- Clean the Product with a damp, but not wet, cloth.
- Clean using appropriate detergents, without chlorine. 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.

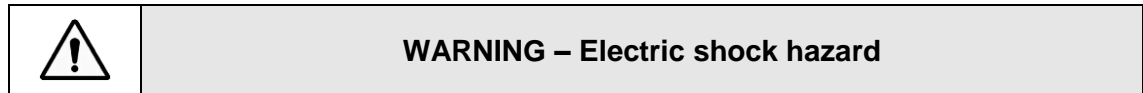
Failure to comply with the above instructions could cause the paint to come off with possible accidental dropping of such paint into the patient area, the early ageing of the plastic parts with consequent weakening and the possibility of breakages, and the tarnishing of the protection screens and glass.



## 6.2 Product disinfecting

Frequency

The Product is best disinfected daily.



Before proceeding to clean 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.



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 any risk of damaging the surfaces.
- Do not pour disinfectant 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 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.

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

### 6.3 Sterilizing hand-pieces

#### 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.



#### **WARNING – Hazard for the patient**

The hand-pieces are made of plastic material resistant to heat and knocks (PSU – Polysulphone).

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 hand-piece holes.

#### Sterilization

Clean and disinfect the hand-pieces in the traditional way before sterilization. They can be cleaned with a mid-alkaline detergent free of active chlorine. To disinfect the hand-pieces, we suggest using alcohol or aldehyde-based products. The disinfectants must be approved by the manufacturer for use on polysulphone (PSU). After disinfecting, rinse off the detergent residues with plenty of water.

The hand-pieces fit into a suitable sterilization pack (disposable sterilization pack, e.g., plastic/paper bags; single or double pack), before being sterilized. The hand-pieces 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.

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When placing in the autoclave, make sure the open side of the hand-pieces is turned downwards. The hand-pieces must be free and not burdened by other material being sterilized.

Damaged hand-pieces must no longer be used.

## 7 Adjustments and maintenance

### 7.1 Setting the 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 lever downwards and load the spring.

If the swinging arm lifts up, this means the elastic force of the spring is too high:

- turn the lever upwards and release the spring.

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

	<b>CAUTION – Product electrical check</b>
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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

	<b>CAUTION – Interrupt the power supply before doing any maintenance jobs</b>
---	---

	<b>CAUTION – Check Product integrity</b>
---	--

No.	Period	Job
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 Service Personnel and have them replaced.
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 similar characteristics.
4	Every 6 months	If the Product fails to maintain a regular position, adjust the clutches as indicated at points <b>7.1 and 7.2 (arm and clutch adjustment)</b> .
5	Once a year	Make sure the bar retention screws are tightened properly. Also check the bar horizontal arm retention screws and the swinging arm screws. If these are not properly fastened, adequately tighten.

## 7.5 Repairs

	<b>CAUTION – Unsuitable repairs</b>
---	-------------------------------------

The Product must only be opened and repaired by the Service Personnel.

## 7.6 Disposal after use

Disposal at the end of life cycle


The used Product contains valuable materials which can be recycled. Dispose of the used Product in an environment-friendly way and in compliance with applicable national directives on waste disposal.

## 7.7 Spare parts list

Spare	Order code
Sterilisable grip	Z180045
Electronic board	Z300617
Membrane keyboard	Z300220
O/I switch (for floor and wall versions)	Z300016
Switching power supply unit	Z300700

## 8 Technical properties

Technical details of light	PENTALED 12
Illumination $E_c$ at 1 m distance $\pm 10\%$ [Lux]	50,000
Colour temperature ( $\pm 5\%$ ) [K]	4,500
Colour rendering index $R_a$ [-]	96
Light range diameter $d_{50}$ [mm]	70
Light range diameter $d_{10}$ [mm]	140
Lighting depth L1+L2 [cm]	62+25

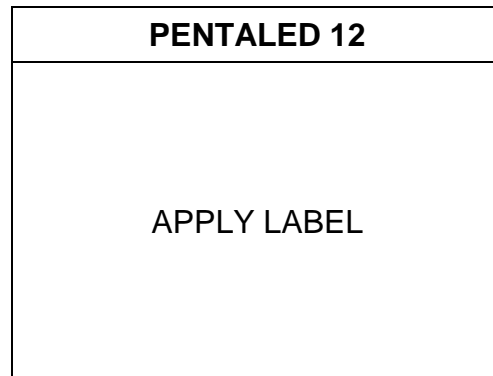
Max irradiation [W/m <sup>2</sup> ]	119
Irradiation / Illumination [mW/m <sup>2</sup> lx]	2,38
Max irradiation in UV [W/m <sup>2</sup> ]	0,001
R9	92
<b>Power connection details</b>	
Primary alternate voltage [Volt ac]	100÷240
Frequency [Hz]	50/60
Power input [VA]	40
Light source	N°12 Led x 2W
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50.000
Light intensity control [%]	20 – 100
<b>General data</b>	
Colour	RAL 9003
Directive	2007/47/EC
Standards	IEC 60601-2-41
Classification of Medical Device	Class I
<b>Dimensions</b>	
Diameter of lamp body [cm]	30
Diameter of poly-elliptical reflectors [cm]	5,5
Light emission surface [cm <sup>2</sup> ]	285
Weight of floor, ceiling, wall, double ceiling surgical light [kg]	18; 13; 12; 20
<b>Markings</b>	
	In conformity with Directive 93/42/EEC (and 2007/47/EC)
<i>All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons</i>	

## 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):



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 (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



## EMC Declaration

The Product has been tested according to EN60601-1-2 standard to ensure correct electromagnetic compatibility.

Portable and mobile communication appliances can affect the Product. Other appliances used in the proximity of the product must also be in conformity with this standard.

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.


	<b>CAUTION – Possibility of interferences with nearby appliances</b>
---	--

Immunity test	Conformity	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.  <b>Warning:</b> 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	Class A	
Voltage fluctuations/flicker emissions  IEC 61000-3-3	Conforming	



Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
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 hospital 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. main voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>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.</p> <p><b>Recommended separation distance</b></p> $d = 1,2\sqrt{P} \quad 150 \text{ KHz to } 80 \text{ MHz}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 80 \text{ MHz to } 2,5 \text{ GHz}$ <p>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).</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 

**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 $d = 1,2P$	80 MHz to 800 MHz $d = 1,2P$	800 MHz to 2.5 GHz $d = 2,3P$
<b>0.01</b>	<b>0.12</b>	<b>0.12</b>	<b>0.23</b>
<b>0.1</b>	<b>0.38</b>	<b>0.38</b>	<b>0.73</b>
<b>1</b>	<b>1.2</b>	<b>1.2</b>	<b>2.3</b>
<b>10</b>	<b>3.8</b>	<b>3.8</b>	<b>7.3</b>
<b>100</b>	<b>12</b>	<b>12</b>	<b>23</b>

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.

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## 10 Warranty Certificate

1. The appliance 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 the 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 machine is installed is not in compliance with International or local standards 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 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 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.

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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.

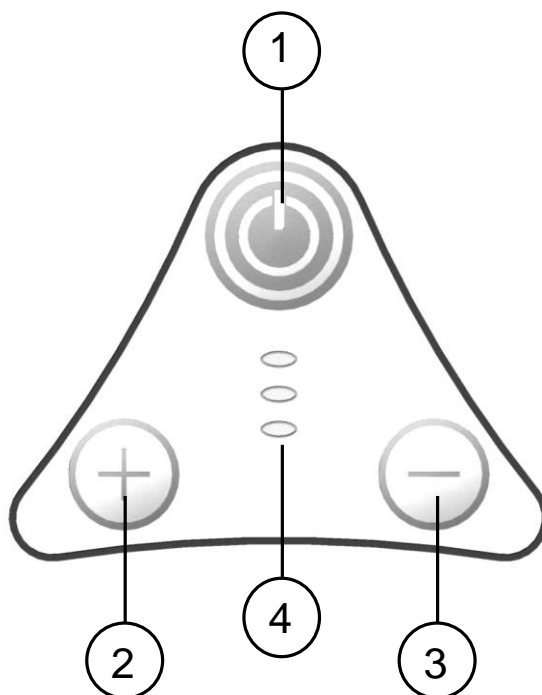
## 11 Deviation for Pentaled 28

### 11.1 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 keyboard, are selected the following functions:

- (1) I/O quick pressure turn on the product; prolonged pressure turn off the Product;
- (1) I/O quick pressure shifts colour temperature of the Product cyclically from 4500K to 5000K (switch on at 4500K)
- (2) increases light intensity '+'
- (3) reduces light intensity '-'
- (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 stand-by function.



Lighted area

It is possible to adjust the diameter of the light field and the focus by turning the central wheel.

## 11.2 Product mouvement

To adjust the diameter of the light field and the focus, it's possible to rotate clockwise or counterclockwise the wheel at the center of the screen. This wheel is not removable and even sterilizable.



## 11.3 Spare parts list

Description	Order code
Sterilisable handle	Z180045
Electronic board	Z300678
Membrane keyboard	Z300220
O/I switch (for floor and wall versions)	Z300016
Switching power supply unit	Z170178

## 11.4 Technical data

Technical details of light	PENTALED 28
Light intensity $E_c$ at 1 m distance $\pm 10\%$ [Lux]	80.000 (5.000K) 50.000 (4.500K)
Colour temperature ( $\pm 5\%$ ) [K]	4.500 / 5.000
Colour rendering index $R_a$ [-]	92 (5.000K) 96 (4.500K)
Light field diameter $d_{50}$ [mm]	135
Light field diameter $d_{10}$ [mm]	270
Depth of illumination $L1+L2$ [cm] at 60%	62+25
Max radiated energy [W/m <sup>2</sup> ]	220
Ratio between radiated energy $E_e$ / illuminance $E_c$ [mW/m <sup>2</sup> .lx]	2,64
Radiated UV energy < 400nm [W/m <sup>2</sup> ]	0,001
R9	90 (5.000K) 92 (4.500K)
Power connection details	
Primary alternate voltage [Volt ac]	100÷240
Frequency [Hz]	50/60
Absorbed power [VA]	81
Light source	N°28 Led x 1.4W
Average Led light [hr] (this data can change according to power peaks and operating frequency)	50.000
Light intensity control [%]	20 – 100
General data	
Colour	RAL 9003
Directive	2007/47/EC
Standards	IEC 60601-2-41
Classification of Medical Device	Class I
Dimensions	
Diameter of lamp body [cm]	30
Diameter of poly-elliptical reflectors [cm]	5,5

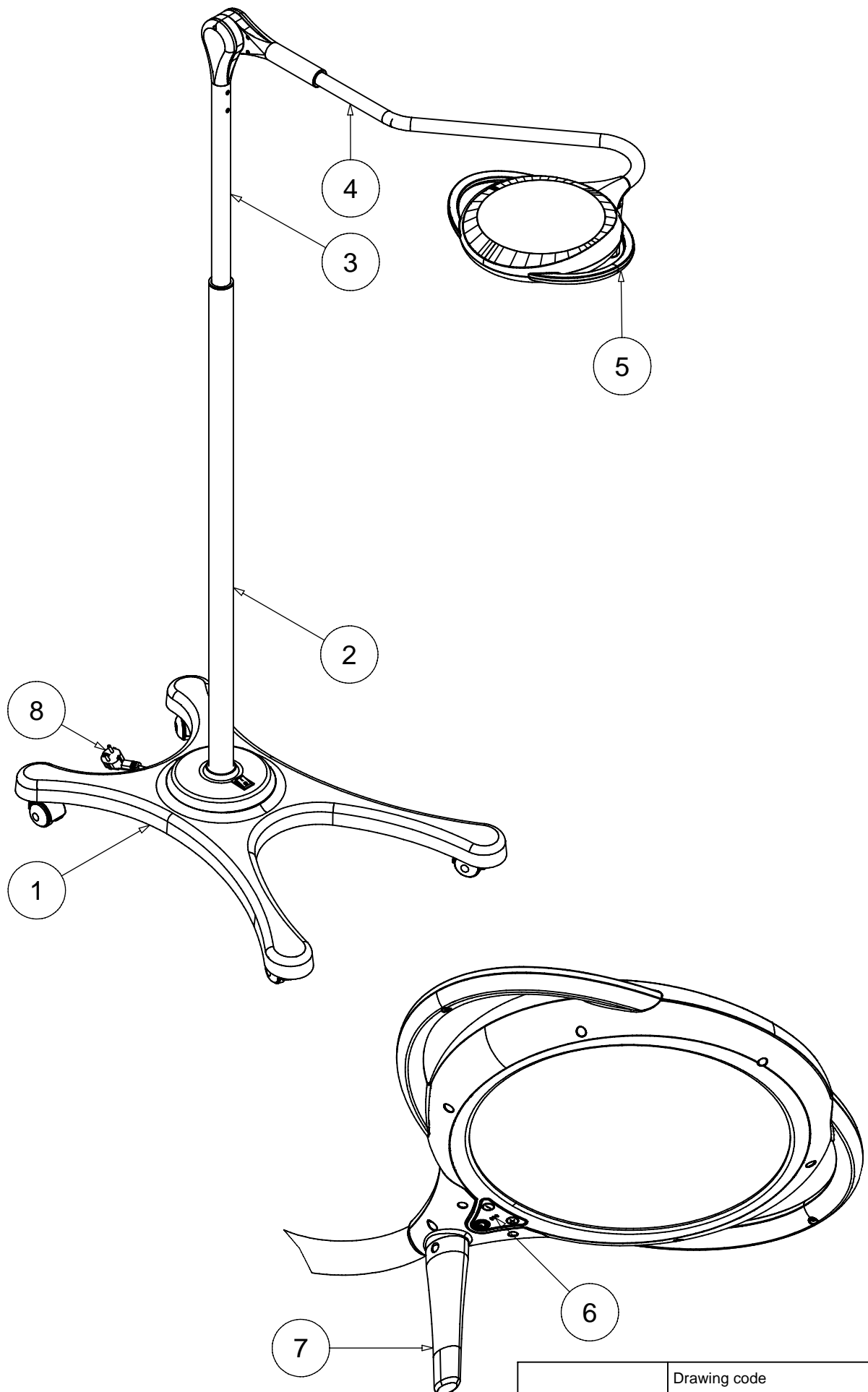


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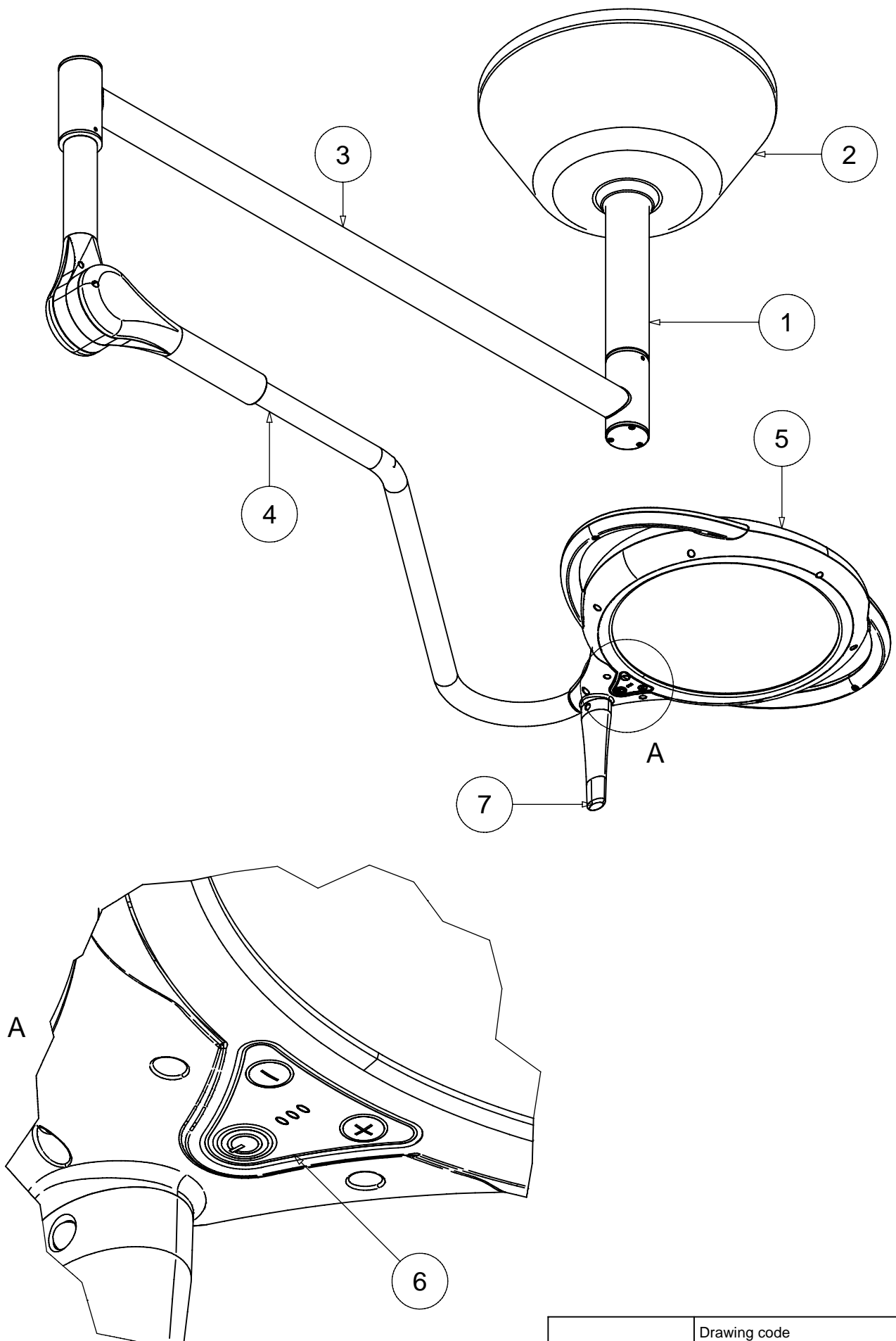
Light emission surface [cm <sup>2</sup> ]	285
Weight of mobile, ceiling, wall, double ceiling versions [kg]	18; 13; 12; 20
<b>Markings</b>	
<b>CE</b>	In conformity with Directive 93/42/EEC (and 2007/47/EC)
<i>All lighting values are subjected to a tolerance of <math>\pm 6\%</math> due to metrological and manufacturing reasons</i>	

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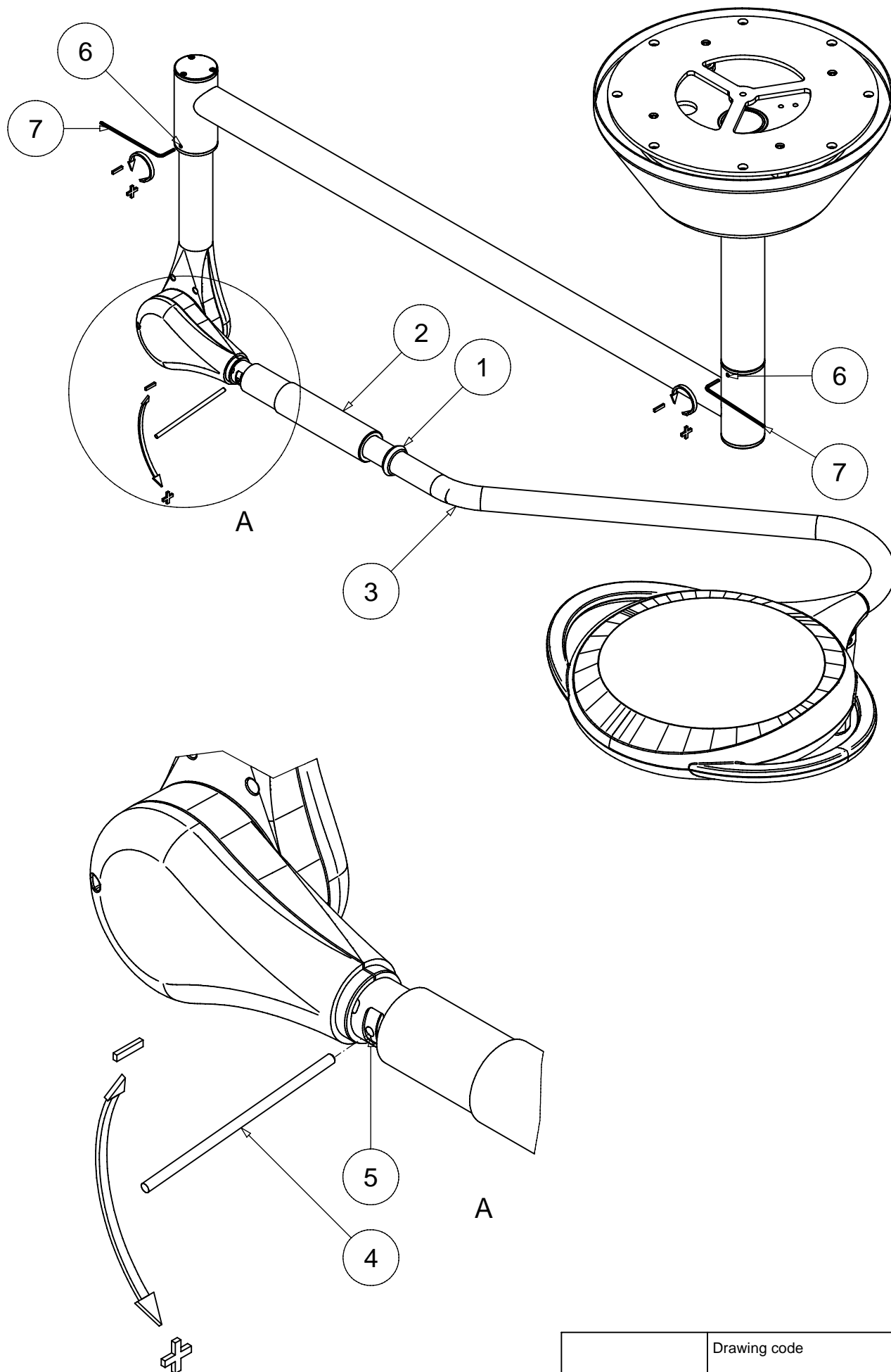
## Notes



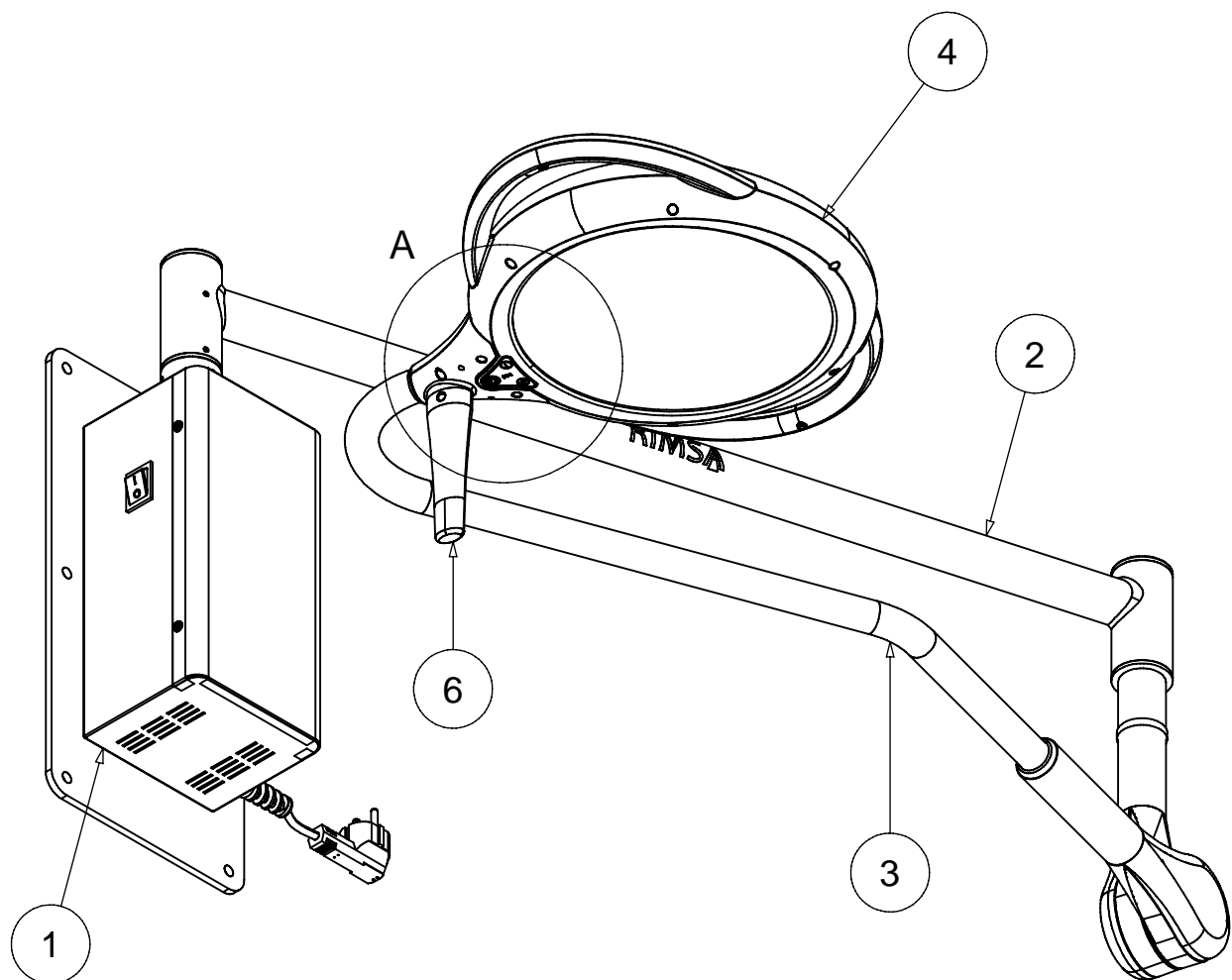
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Rev.	Data	



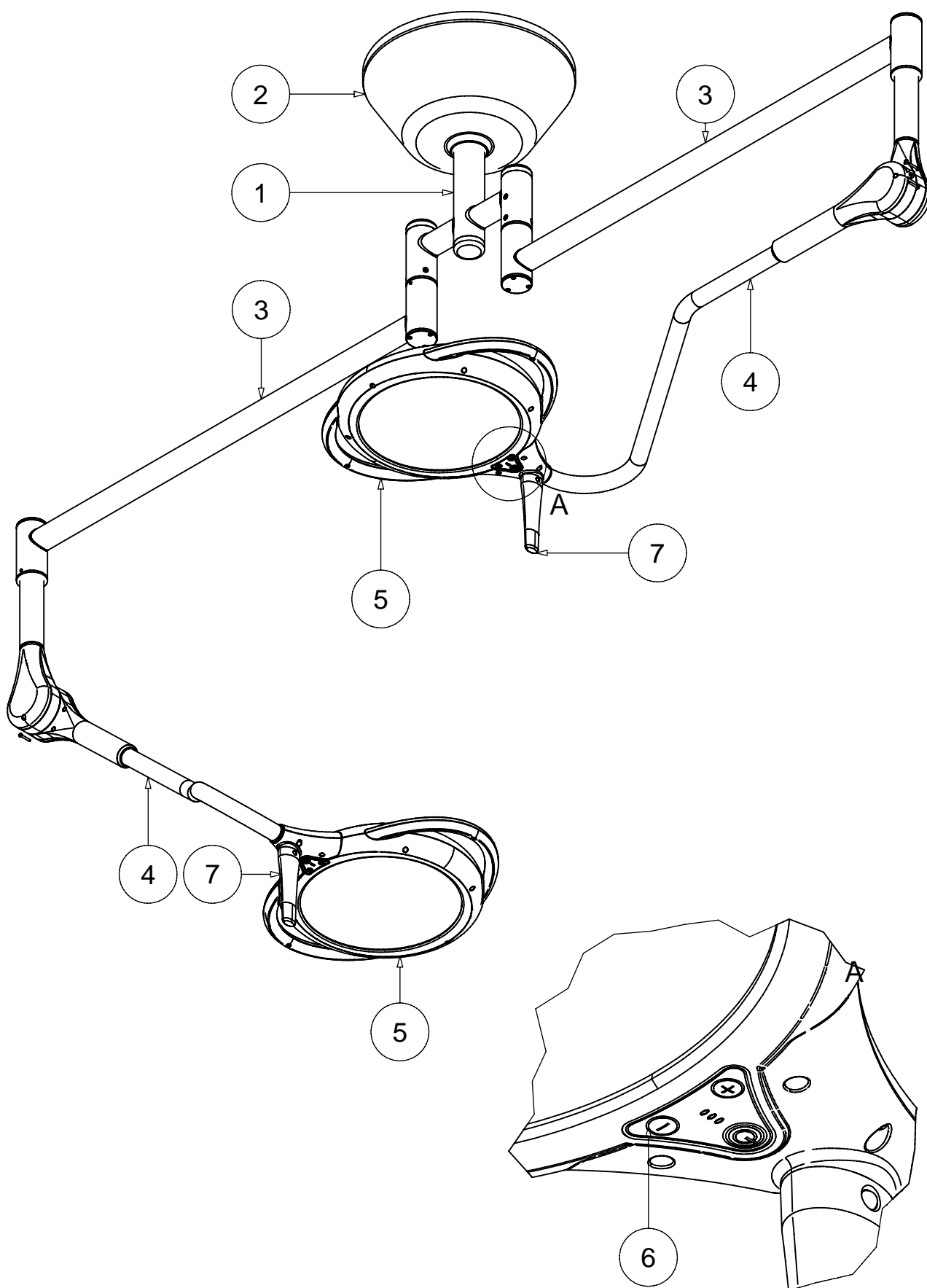
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Rev.	Data	064



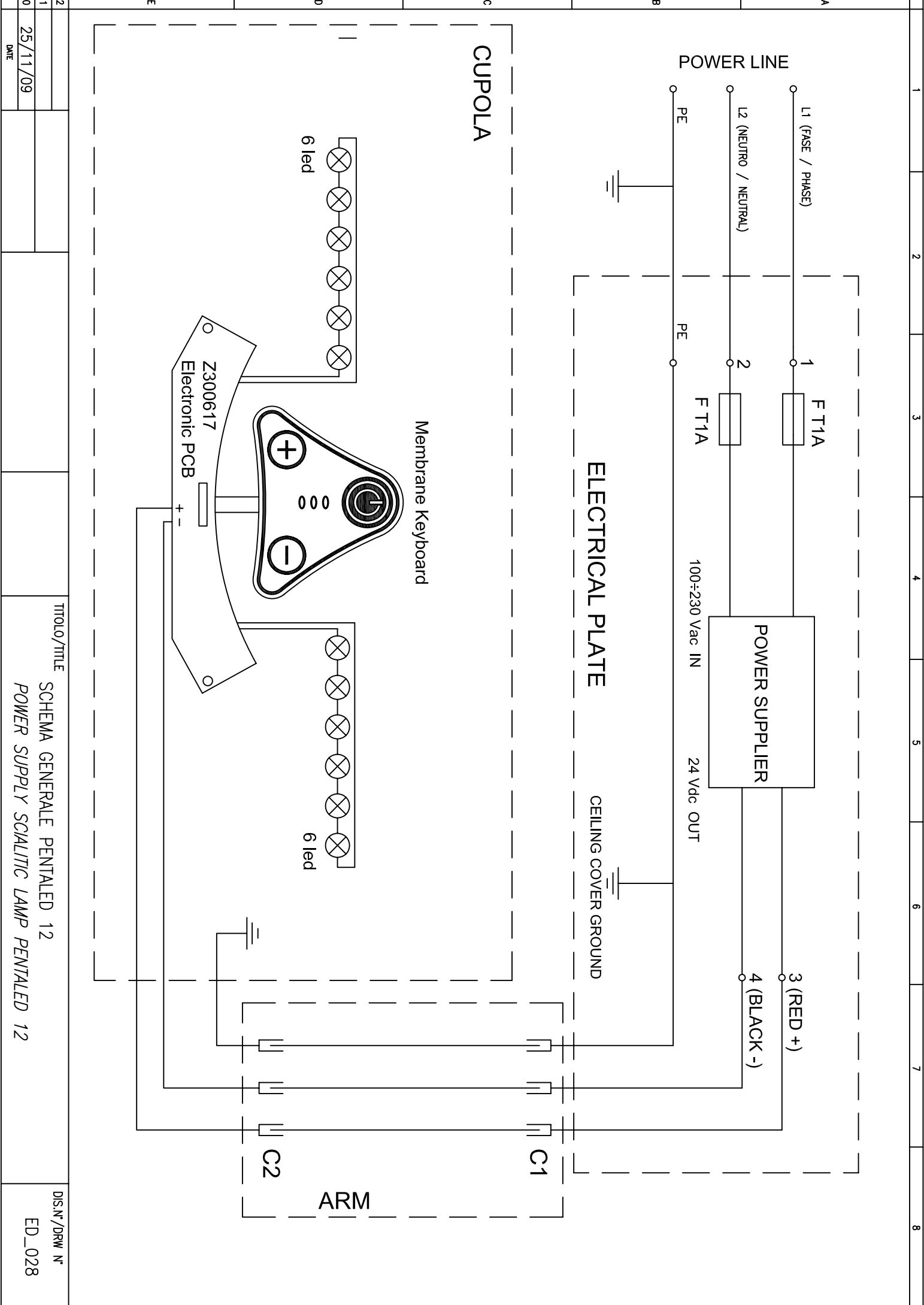
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Rev.	Data	065



		Drawing code
Rev.	Data	074



		Drawing code
Rev.	Data	075



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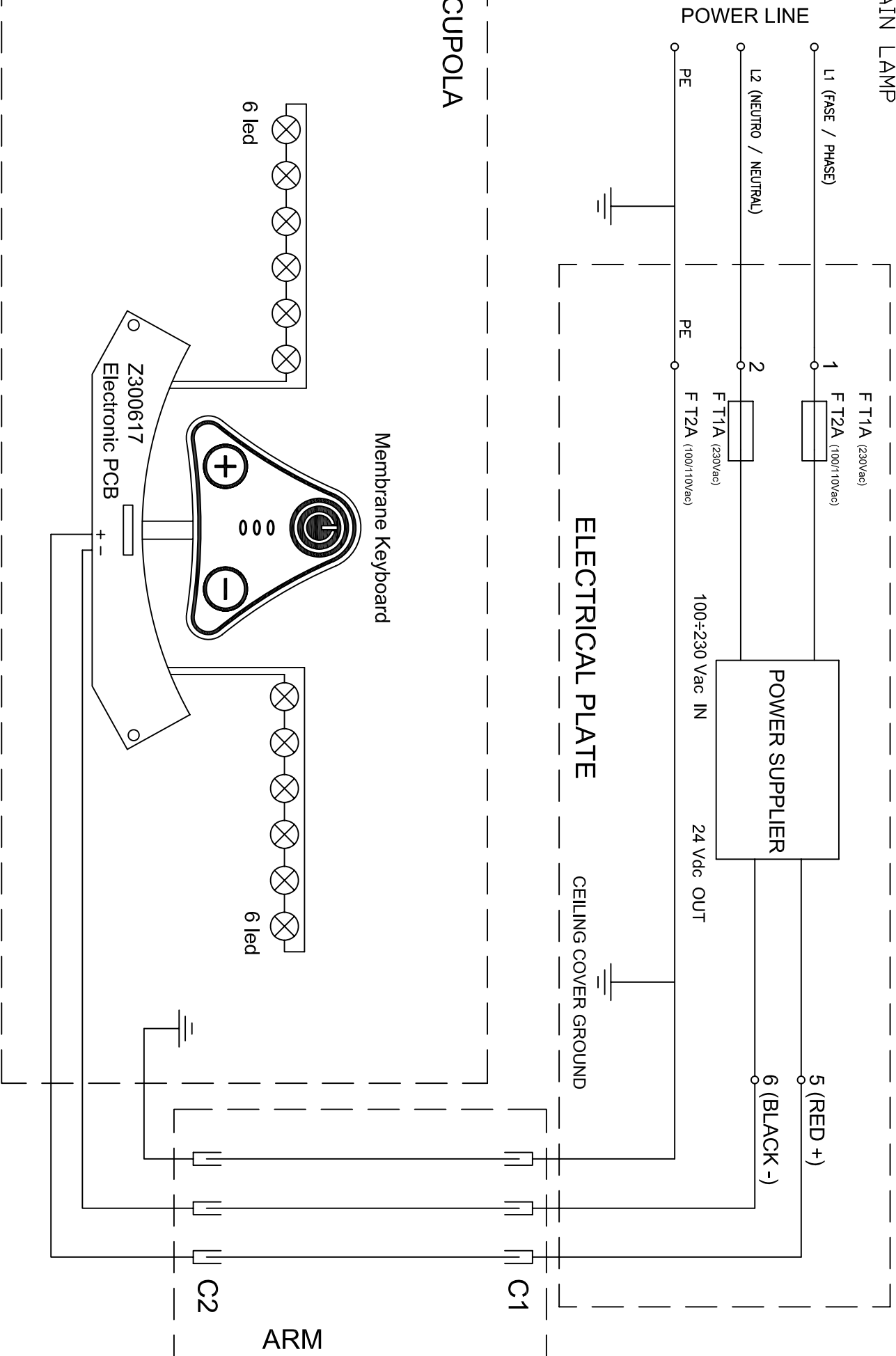
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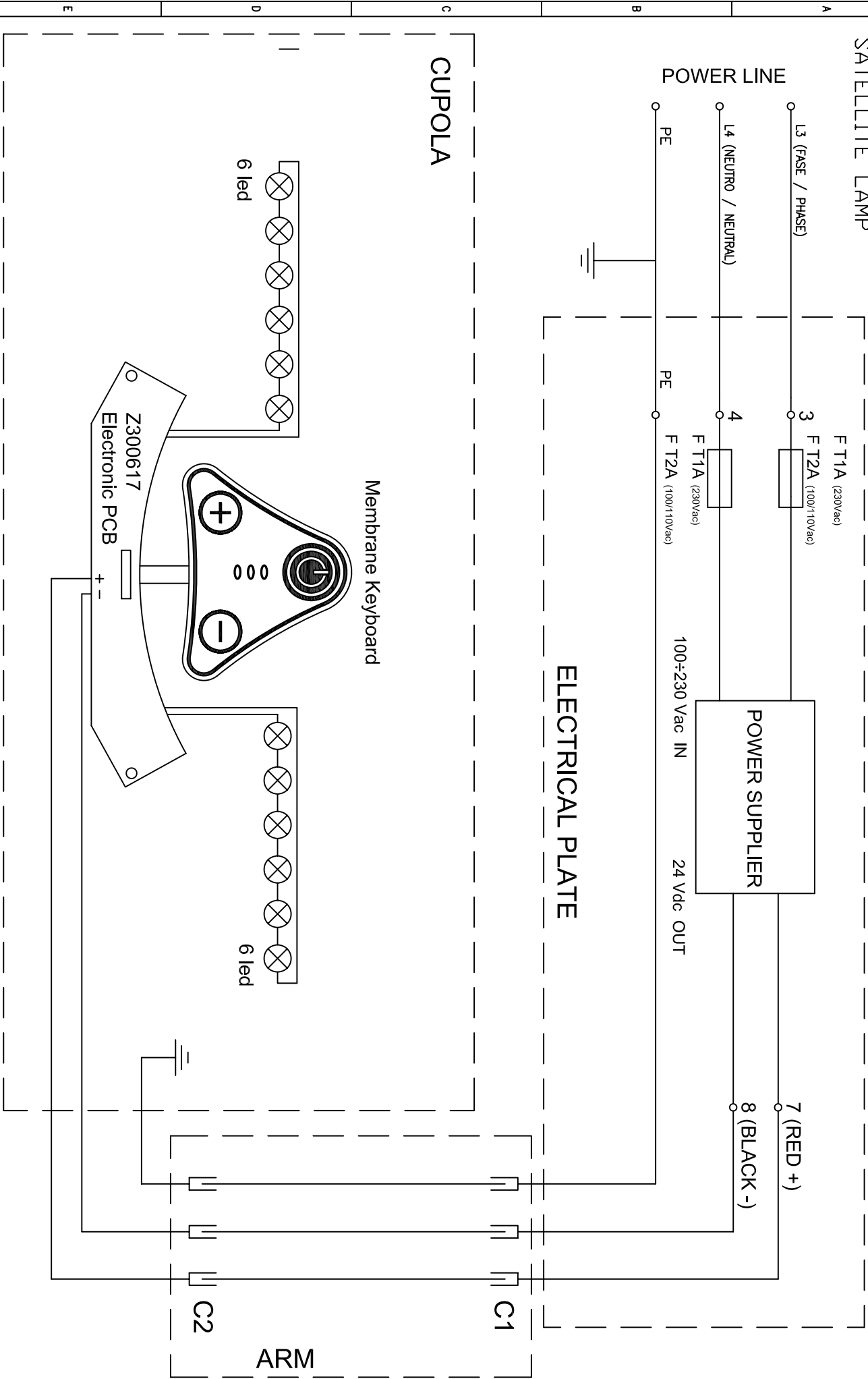
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2			TITOLO/TITLE	DIS.N°/DRW N°
1	11/11/11		SCHEMA GENERALE PENTAELED 12 DOPPIA	ED_031
0	19/03/10		POWER SUPPLY SCIALITIC LAMP PENTAELED 12 DOUBLE	
	DATE			

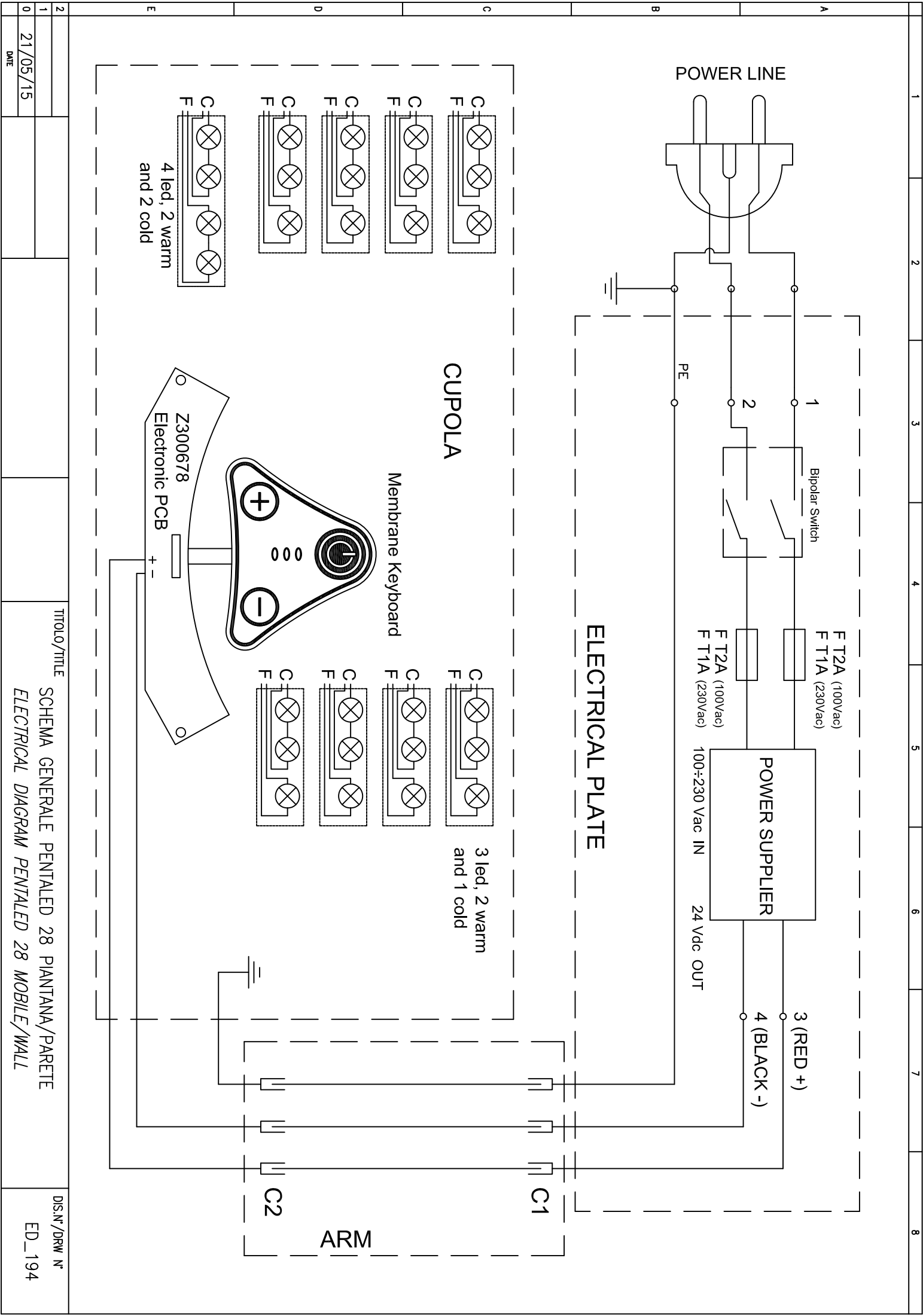
LAMPADA SATELLITE

SATELLITE LAMP



2	TITOLO/TITLE		DIS.N°/DRW N°
1	11/11/11	SCHEMA GENERALE PENTALED 12 DOPPIA	ED_031
0	19/03/10	POWER SUPPLY SCIALTIC LAMP PENTALED 12 DOUBBLE	
DATE			





2				TITOLO/TITLE	DIS.N°/DRW N°
1				SCHEMA GENERALE PENTALED 28 PIANTANA/PARETE	ED_194
0	21/05/15			ELECTRICAL DIAGRAM PENTALED 28 MOBILE/WALL	
	DATE				