

Instruction manual for the use of the scialytic lamp

PENTALED 30

in the following versions

Wall

Floor lamp

Ceiling Single

Ceiling Double

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Introduction

Dear user,
we ask you to read this manual carefully before using the product. By doing so you will be able to protect yourselves and all the possible future users against any damage.



This apparatus is a Class I medical device in accordance with the European Directive on medical devices (MDD) 93/42/EEC, June 1993, Appendix 9

Conformity

The manufacturer represents that this product complies with the essential requisites of the MDD Appendix 1 and proves such conformity by affixing the EC mark

Manual's validity

This instruction manual for use is valid for the following devices:

- Pentaled 30 wall version
- Pentaled 30 floor version
- Pentaled 30 ceiling single version
- Pentaled 30 ceiling double

Customer service

The customer service is at your disposal in case of any questions as to the device and its use, if you wish to order spare parts and for service and warranty reasons.

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- I-20060 Gessate -MI-
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without notice since the manufacturer is constantly searching for new solutions for the development of the products. We therefore reserve the right and duty to make changes in the devices supplied in terms of form, equipment and technology.

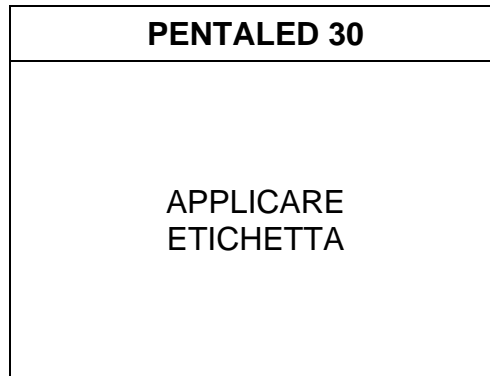
Translations

As regards the translations into languages other than Italian, the Italian version of this instruction manual shall be valid.

Manufacturer's declaration of conformity CE

The Company:

RIMSA P. LONGONI S.r.l. Via Monterosa, 18/20/22 - 20038 SEREGNO (MB) - ITALIA
declares on its own responsibility that the Medical Illumination Device for surgical and diagnostic use:



constructed by RIMSA P.LONGONI S.r.l., conforms to the Attachment VII of the 93/42 EEC Directive of June 14th 1993 and applied in Italy by the Legislative Decree N° 46 of February 24th 1997 and successive variances moreover, it is in conformity with the following safety regulation EN 60601-2-41.

Classification with reference to article 9 and Attachment IX of the 93/42/CEE Directive

DURATION: Short term (Par.1 "Definitions", art.1, paragraph 1.1, attachment IX)
DESCRIPTION : Non invasive Medical Device (Par.1 "Definition", art.1, paragraph 1.2, attachment IX)
Active Medical Device (art.1, paragraph 1.4, attachment IX)
CLASS: I (Par.3 "Classification", art.1, paragraph 1.1 Rule 1, attachment IX)

- Technical reference file Code **RIM-FT018**.
- The evaluation of conformity is developed in reference to article 11 of the 93/42 EEC Directive.
- The **RIMSA** Quality System conforms to the UNI EN ISO 9001:2000 and UNI EN ISO 13485:2004 regulations and is certified by the IMQ S.p.a. (certified CSQ n.9120.RMS1 and 9124.RMS2).

Name: Paolo Longoni
Position: Managing Director



RIMSA - P. LONGONI S.r.l.

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1 Important instructions for the user

1.1 User's qualification

Personnel	The Pentaed 30 scialytic lamp versions and these instructions for use are intended for qualified medical and technical personnel employed at hospitals and surgeries, skilled and experienced in the medical sector practices and provided with the necessary authorization, where required.
Personal safety	Importance of personal safety. Before using the device, read the safety Instructions in Paragraph 2.1, 3.4 and 3.5
Adjustments	The operations described in Chapter 6 "Adjustments" can be carried out by a technician of the service center of the device keeper provided he/she follows the safety instructions.
Cleaning	Cleaning of the device can only be carried out by duly trained personnel.
Importance of the manual	<p>This manual is an integral part of the lamp as per provisions of the European Directive 93/42/EEC and following amendments and supplements.</p> <p>Keep these instructions for use near the lamp for consultation in case of doubts about the use of the device, for safety reasons and other important information.</p> <p>Do not transfer the device to another user or site without instructions for use. This manual must always be together with the Medical Device.</p> <p>These instructions for use must always be easy of access for any user of this device.</p>

We ask you to read these instructions for use carefully before using the device. By doing so you will be able to enhance the potential of the device and protect yourselves and other people against any damage.

1.2 Instructions for a safe operation of the device

Regular installation	This instruction manual is valid only after the regular installation of the device, carried out according to the valid installation instructions, and the correct commissioning by an authorized installer. This instruction manual does not substitute the obligation to instruct the user on the important safety operations, the working, use and care of the lamp.
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Safety directions

The device is made according to the current level of technology and its working is safe, if it is used following all the instructions for use and safety.

Nevertheless, its use may cause dangers, especially if the device is handled by inadequately qualified or unskilled personnel or if it is used improperly, failing to observe the safety instructions contained in these instructions for use or to comply with the intended use.

Respect the intended use

The device is exclusively intended and suitable for the use specified in this instruction manual. Any other use may cause mortal dangers and/or dangers for the product and other material property of the keeper.

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2 Instructions for the device keeper

2.1 Technical safety characteristics

Cleaning personnel	The cleaning and disinfection operations of the scialytic lamp system described in Chapter 5 must be carried out exclusively by duly instructed cleaning personnel.
Service personnel	The control and maintenance operations described in Chapter 6 must be carried out exclusively by qualified service personnel.

2.2 Personnel instruction obligation

Instructing the users	<p>Instruct the personnel following the instructions for use as regards the lamp control, cleaning and care operations.</p> <p>Such personnel must be instructed by the keeper according to what is specified in this manual.</p>
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2.3 Warranty and responsibility

GIMA refuses all responsibility for the unreliable working of the scialytic lamps in case:

- the installation, the changes and the repairs are not carried out by a GIMA service technician or personnel authorized by GIMA,
- the device is not used in accordance to its intended use, the norms and the instructions for use.

2.4 Structural changes or variations

Arbitrary changes	For safety reasons, all structural changes or variations made in the device on one's own initiative are forbidden. In case of similar changes or transformations, the warranty of the producer for this device is annulled. This way the producer does not assure any warranty for damage or injuries caused by structural changes or variations made in the device on one's own initiative or by the use of non-original spare parts.
Use GIMA original spare parts only	Using spare parts not provided by GIMA or its representatives implies annulment of the warranty.



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2.5 Disposal after use

Life end disposal

The used device contains valuable materials which can be reused.

Dispose of the used device respecting the environment and in accordance with the national waste disposal directives in force.

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3 Importance of personal safety

3.1 Intended use

Use complying with the norms

The PENTALED 30 scialytic lamp system is used to light the area of the patient undergoing a surgical operation or being tested at a hospital or surgery.

Work field

The work field is a distance from about 70 to 140 cm from the operation point.

Single lamp:

Definition

In accordance with IEC60601-2-41, a PENTALED 30 single lamp is a secondary scialytic surgery lamp and can be used only on operations where the suspension of the lighting does not cause any risks for the patient.

Operating lamp system:

Definition

In accordance with IEC60601-2-41, a PENTALED 30 lamp system made of several lamp bodies can be used without any limitation. Furthermore, it is suitable for non-stop working.

It allows the surgeon to operate even under the most difficult conditions of visibility. It aims at making treatment and diagnosis possible and is intended for operating rooms.

Unwelcome effects of the overlapping of light fields

If the light fields of several lamp bodies are overlapped, the heat in the patient area will be increased with following dehydration of the tissues and, above all in case of sustained action and reduced blood spraying, considerable damage to the tissues.

In case of reduced blood spraying or a principle of tissue dehydration, reduce the light intensity.

3.2 Environmental conditions

- The PENTALED 30 scialytic lamp system is not suitable for the use in explosion-risky areas.
- The PENTALED 30 scialytic lamp system is not suitable for the use in the presence of inflammable mixtures of anesthetics with air, oxygen or NO₂ (laughing gas).

- During working, the room temperature must be between 10°C and 40°C.
- The relevant humidity must be between 30% and 75%.
- The atmospheric pressure must be between 700 and 1060hPa.

3.3 Combinations with other medical products

- The lamp system can be equipped with devices produced by other manufacturers. Consult the instructions for use of such devices.
- Exclusively install medical devices (e.g. lcd monitor) provided with the EC mark.

3.4 Technical safety conditions

The safe use and proper working of the PENTALED 30 lamp is guaranteed if:

Safe anchorage	anchorage of the lamp to the ceiling/wall is safe from the static point of view and there is a static stability test,
Systems	the electrical systems of the sites concerned comply with the local norms in force,
Authorized personnel	changes or maintenance of the lamp are made by GIMA authorized personnel,
Proper installation and commissioning	the lamp has been installed following the currently valid installation instructions and has been commissioned regularly by the authorized installer,
Original spare parts	GIMA original parts only are used for service, repair and structural variation operations and as accessories.

3.5 Other safety conditions (secondary effects)

Dazzling	Do not look frontally inside the lamp when it is on and do not insert reflecting objects into the path of the rays. Considering the high lighting power, there is strong dazzling danger.
Improper use	Do not lay any object on the body of the lamp or hang objects on the arm or the body of the lamp, since a safe positioning is no longer ensured and such objects may fall on the operation area. The load of heavy objects (body weight of a human being) can damage the mechanics.

Cover the heads	During working the head of the lamp must not be covered since it would prevent the thermal exchange with the environment and cause overheating of the lamp.
Collisions	Collisions of the mobile arms and the lamp body must be avoided. In case of violent collision, the lamps may be damaged or pieces of paint may chip and fall on the operating field in the patient area.

3.6 Graphic symbols used in this manual

In these installation instructions and on the lamp important directions are marked by means of symbols and identifying words.

Identifying words such as **DANGER**, **WARNING** or **ATTENTION** indicate the classification of the risk of damage. This is highlighted with various symbols.

DANGER signals an immediately dangerous situation which might cause death or serious damage.

WARNING signals a potentially dangerous situation which might cause death or serious damage.

ATTENTION signals a potentially dangerous situation which might cause moderate or slight damage.

The following triangular symbol coupled with a side explanation indicates which danger is being faced:



Electric shock, Mechanical danger due to hanging masses (quick release of a suspension arm during installation)

3.7 Other graphic symbols used on the device

The symbols present on the lamp are listed below:



B-Type device. Indicates the level of protection against direct and indirect contact



Graphic symbol proving the EC marking of the product



Symbol indicating the manufacture date (month and year)



Fuses used by the device



Danger symbol: laser beam in class II

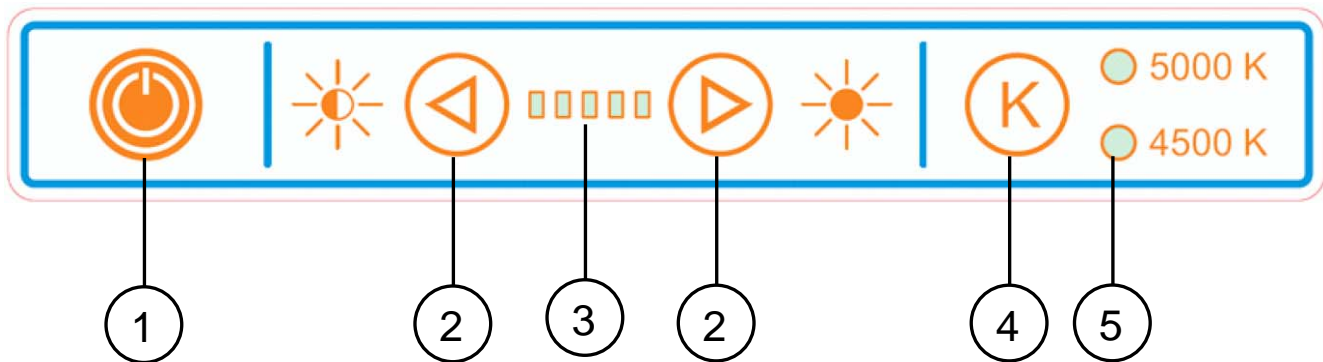
4 Lamp description and operation

4.1 Description of the device

Version	The PENTALED 30 scialytic lamp system is available in various versions: <ul style="list-style-type: none">- wall version- floor lamp version- ceiling single version- ceiling double version (scialytic lamp system)
See drawing 6	WALL version: wall anchorage plate (1), power supply box (2), horizontal arm (3), heeling arm (4), fork (5), lamp head (6), function control keyboard (7), sterilizable handle (8), power supply socket (9).
See drawing 7	FLOOR version: wheel base (1), power supply unit (2), shank (3), heeling arm (4), fork (5), lamp head (6), function control keyboard (7), sterilizable handle (8), power supply socket (9).
See drawing 8	CEILING SINGLE version: ceiling cover (1), ceiling anchorage pipe (2), horizontal arm (3), heeling arm (4), fork (5), lamp head (6), function control keyboard (7), sterilizable handle (8).
See drawing 9	CEILING DOUBLE version: ceiling cover (1), ceiling anchorage pipe (2), double horizontal arm (3), heeling arm (4), fork (5), lamp head (6), function control keyboard (7), sterilizable handle (8).

4.2 Description of the operation

Control panel	The function control keyboard is applied to the scialytic lamp head. Such keyboard allows to turn the lamp on and off by means of the membrane key I/O (1), to regulate the light intensity by pressing the keys with the triangle symbols (2) and display of the level of intensity reached through 5 green position micro-LEDs (3). Finally the choice of the color temperature between the two values 4500°K and 5000°K by pressing the key with the letter K (4) and the display of the value set by turning on one of the two green micro-LEDs (5):
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Light field

The mechanical regulation of the light field takes place through the rotation of the sterilizable handpiece. By rotating in a direction rather than the opposite one, the light field in the illuminated area (patient area) is enlarged or reduced.

5 Cleaning and disinfection

5.1 Cleaning the device



WARNING – Electric shock danger

Turn off the lamp system by the master switch of the operating room and lock it,
protect the device against water sprinkling and do not clean/disinfect it with liquids.

ATTENTION

Do not use abrasive products, petrol, paint thinners, alkaline, acidic or aldehydes;
proportion the detergents so that no liquids seep into the lamp bodies and the support arm system.
Clean the lamp with a damp but not wet cloth.

5.2 Disinfection



WARNING – Electric shock danger

Turn off the lamp system by the master switch of the operating room and lock it,
protect the device against water sprinkling and do not clean/disinfect it with liquids.

Let the lamp body cool. Disinfect the lamp body only when it is cold.

WARNING

The disinfectants may contain substances harmful to health: use disinfectants only respecting the health standards fixed by the hospital, the device keeper must respect the requisites imposed by the national competent hygiene and disinfection commission.

ATTENTION

To avoid damage to stainless steel, aluminum parts, only use disinfectants with no chlorine or halogens,
to prevent plastic parts from becoming fragile, only use low-alcohol disinfectants,
proportion the disinfectants so that no liquids seep into the lamp bodies and the support arm system.
Clean the lamp with a damp but not wet cloth.

5.3 Sterilizing the handpieces



WARNING – Danger for the patient

Replace the handpieces as soon as they show cracks or deformations, since they might fall on the area of the wound.

The lamp keeper must respect the requisites imposed by the national competent hygiene and disinfection commission.

Installation / uninstallation of the handpiece:

- press the safety key of the handpiece and extract the handpiece.
- insert the handpiece till the bottom and rotate it until it is integral with the lamp focusing movement.

Cleaning, disinfection and sterilization of the handpiece

the handpieces are made of plastic material resistant to heat and collisions (PPSU).

They can be cleaned with a detergent having medium alkaline level but no active chlorine.

To disinfect the handpieces we recommend to use alcohol or aldehyde-based products. The disinfectants must be approved by the manufacturer for use on the polyphenylsulfone (PPSU).

Before sterilizing, rinse the handpieces.

The handpieces can bear about 300 steam sterilization cycles if the following instructions are respected:

- steam sterilization at a121°C 1,3bar from 25 to 30 minutes,
- or
- steam sterilization at a134°C 2,3bar 4 minutes.

Put the handpieces upright with downward open side.

Do not exceed the sterilization temperature of 134°C.

Avoid contact of the handpieces with other objects when disinfecting.

Each device, in time, is subject to some wear and tear. The safety and working of the device must then be checked in the inspection and maintenance intervals.

5.4 Yearly inspections by the keeper



ATTENTION

Respect the yearly inspection intervals and check the device as follows:

- damage to the painting with danger in case of open wounds
- cracks on the plastic part
- detachment of parts

5.5 Repairs



WARNING – Non-suitable repairs

The device must only be opened and repaired by GIMA service or qualified operators.

6 Adjustments

6.1 Adjustment of the swing arm

See drawing 10

The lamp is supplied already balanced and needs no further adjustment. If, in time, the swing arm with spring balancing stiffens or loosens, it is possible to intervene mechanically adjusting the compression of the internal spring. Loosen the two locking grains (1) which lock the cover (2) and move it forward. Insert a pin (3) having maximum diameter of 7mm into the holes of the metal ring and rotate in the directions of the arrows to increase/decrease the charge of the spring.

If the heeling arm lowers, the elastic force of the spring is insufficient:

- rotate the lever downwards to charge the spring.

If the heeling arm still goes up, the elastic force of the spring is too high:

- rotate the lever upwards to discharge the spring.

At the end of the adjustment, put the cover back to its original position.

6.2 Adjustment of the braking force

See drawing 5

The brakes are set during installation. As for all the mechanic parts, brakes also are subject to wear and tear.

If the lamp body does not automatically keep the position it is put to, it is necessary to adjust the braking force by acting on the screws of the brakes.

Horizontal arm brakes

Use a cut-suitable screwdriver to increase the braking force, rotating the screws (4) and (5) of the arm brake clockwise.

Fork brakes

To increase the head braking force (6,7), rotate the two screws of the brakes clockwise with a 2 hexagonal spanner 2.

6.3 Search for failure

n	Problem	Solution
1	The lamp does not keep the position	Check the leveling of the plate installed on the wall (wall), of the shank to the base (floor), of the pipe anchored to the ceiling (ceiling) Tighten the brakes to the articulations in order to increase the frictions.
2	The lamp does not work	Check the presence of the fuses inside the terminal box, the hooking of the electrical connectors. Check the presence of voltage in the lamp head (18/26Vdc)
3	The fuse keeps burning	Check the characteristics of the fuses inserted
4	The lamp flickers	Contact the service center
5	The light beam on the operating field is not on focus (faulty meeting of the light fields through handle rotation)	Contact the service center.
6	The lamp does not turn on.	Check the power supply voltage and fuses. Electronics are damaged: contact the service center

6.4 Spare part list

Description	Order code
Sterilizable handle	Z200523
Electronic card PENTALED 30	Z300603

7 Technical data

Technical data on light	PENTALED 30 LED WALL
Reflecting mirror technology	Poly-carbonate reflectors with poly-elliptical optic curve
Color temperature [K]	4500 /5000 K ($\pm 5\%$)
Illumination E_c at a distance of 1 m (head /probe) [klx]	100
Maximum irradiation in the UV [W/m^2]	0,0015
Maximum irradiation [W/m^2]	250
Irradiation / Illumination [mW/m^2lx]	2,5
Color rendering index R_a [-]	93
Diameter of the light field d_{10} e d_{50} [mm]	$d_{10}=220$, $d_{50}=130$
Illumination depth [mm]	1050
Data on electrical connection	
Primary alternating voltage [Volt ac]	0, 230
Secondary direct voltage [Volt dc]	0, 22
frequency [Hz]	50/60
Absorbed power [W]	90
Electrical safety class	I
Protection against direct and indirect contacts	B-type device
General data	
Light source	3Watt Led diode
Led diode light source duration [h] (this datum can vary according to a power voltage higher than the specified one, voltage peaks and the frequency of use)	50.000
Dimensions	
Lamp body diameter [cm]	40



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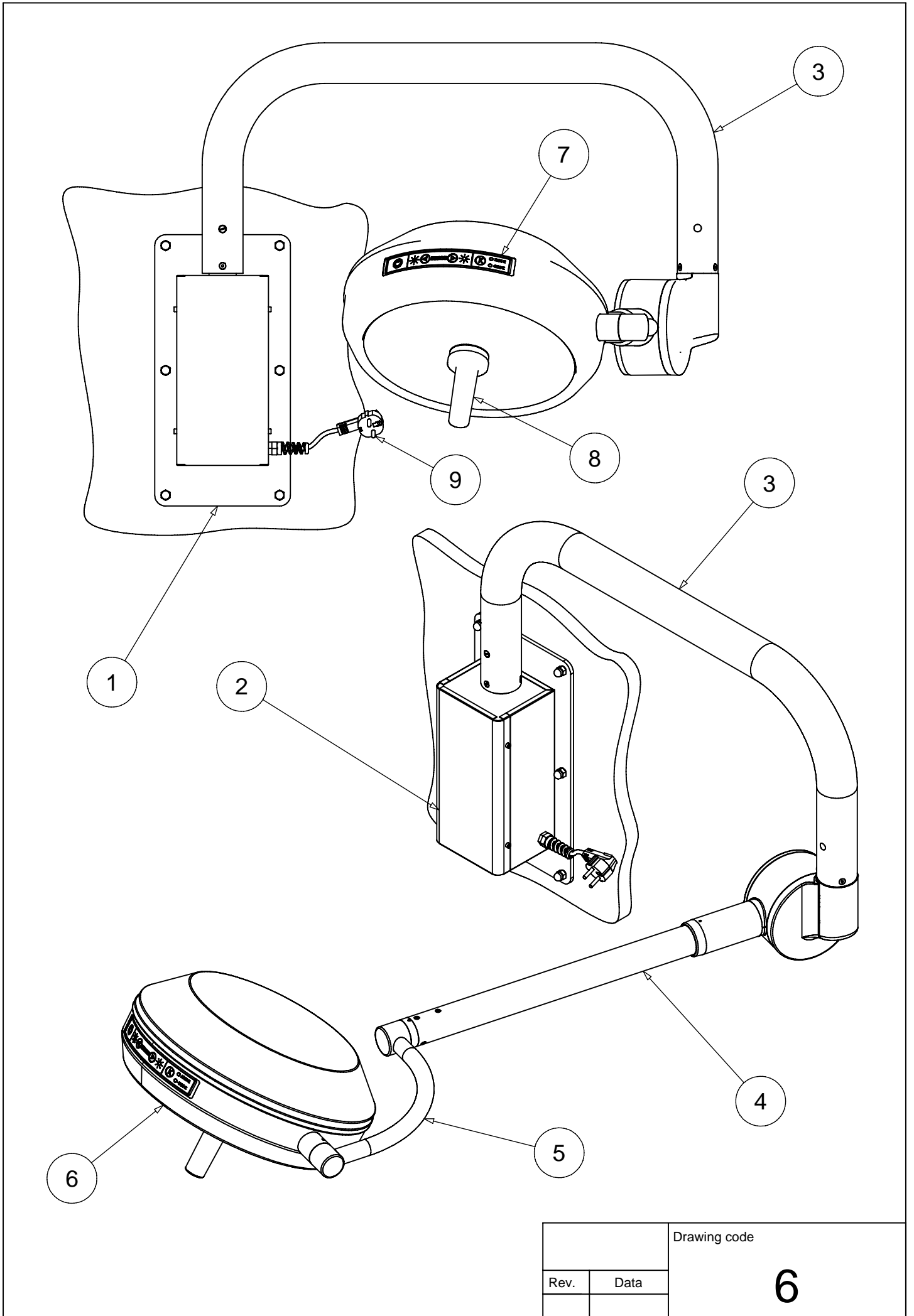
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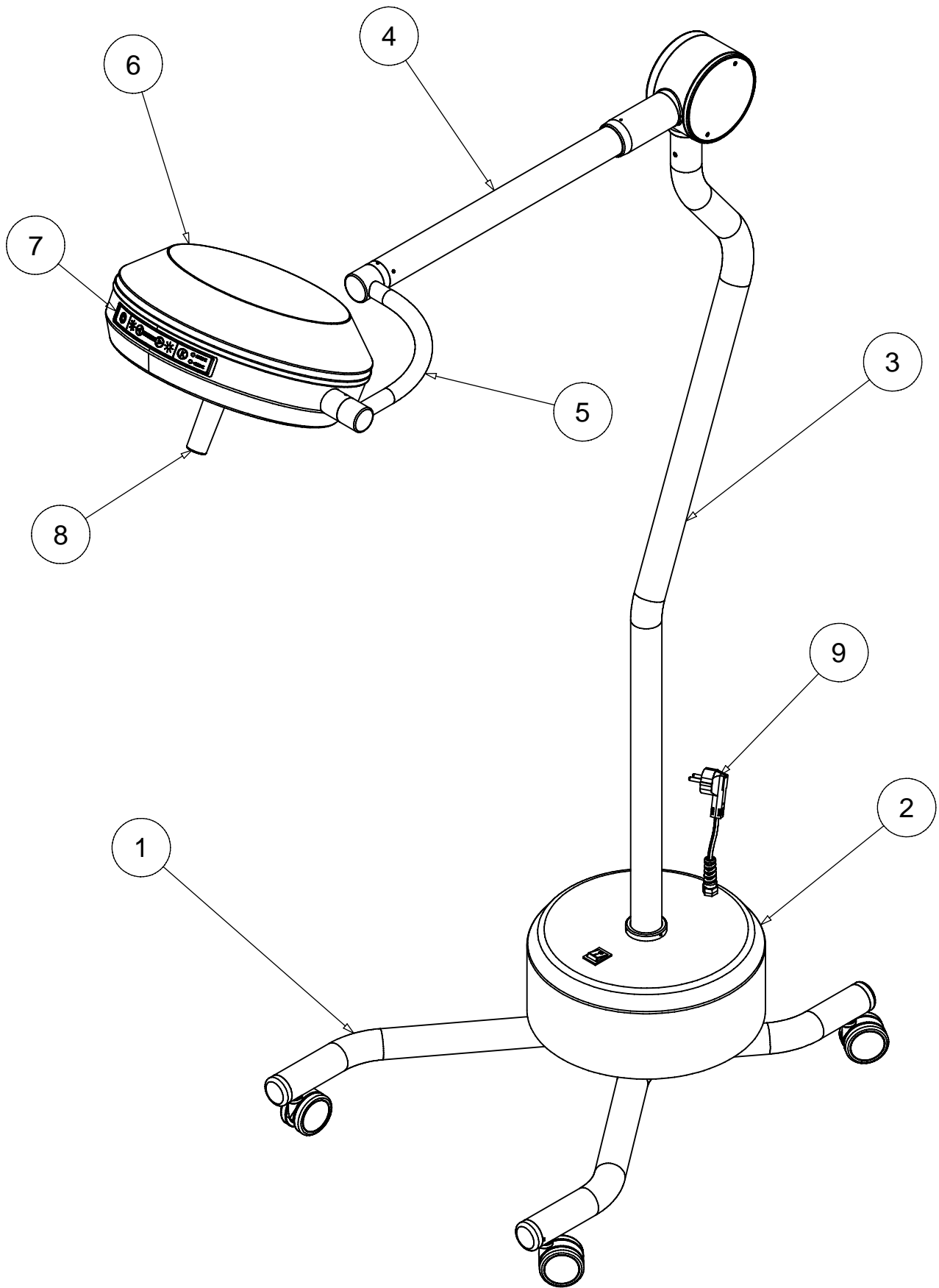
Diameter of the poly-elliptical reflectors [cm]	9
Light emission surface [cm ²]	572,2
Maximum rotation width [°]	10°
Maximum vertical head movement [cm]	135
Scialytic lamp weight [Kg]	35
Certificates	
CE	Complying with directive 93/42/EEC

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Notes



		Drawing code
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		Drawing code
Rev.	Data	7

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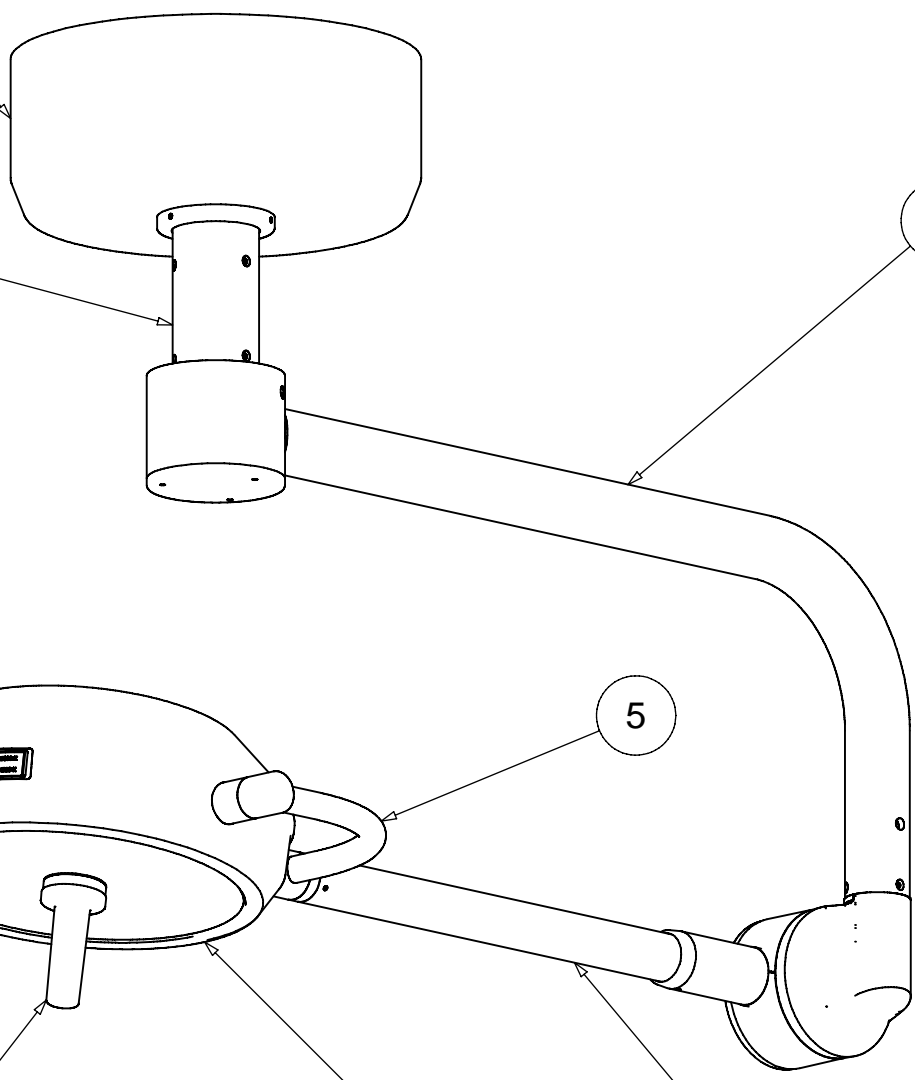
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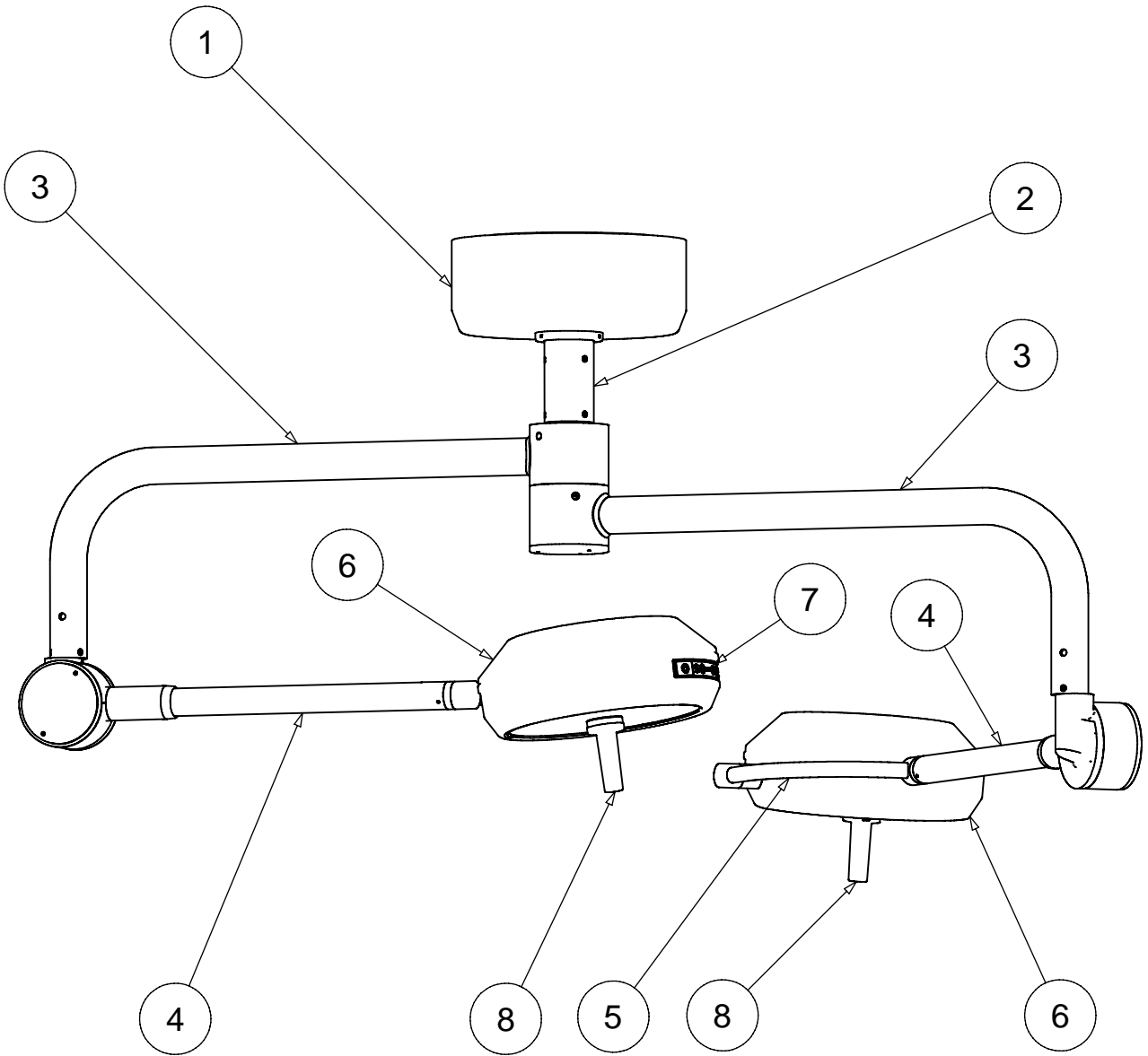
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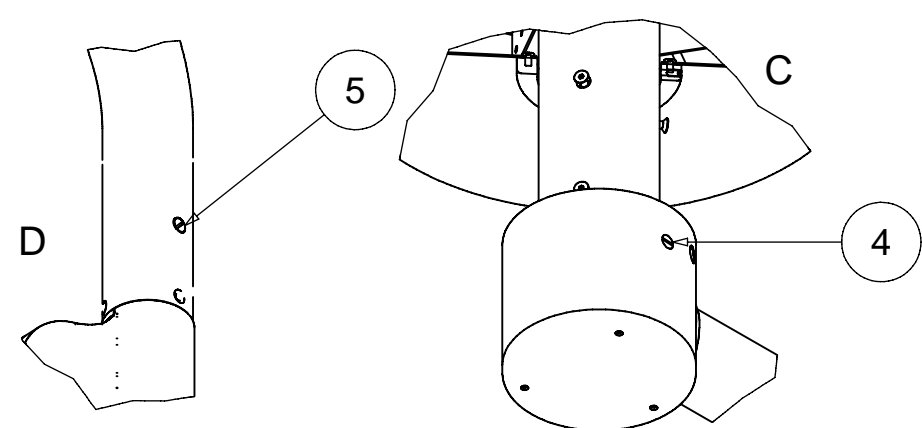
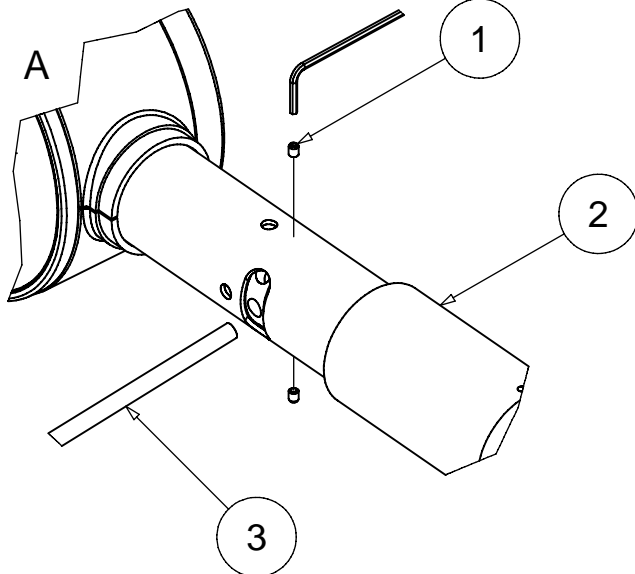
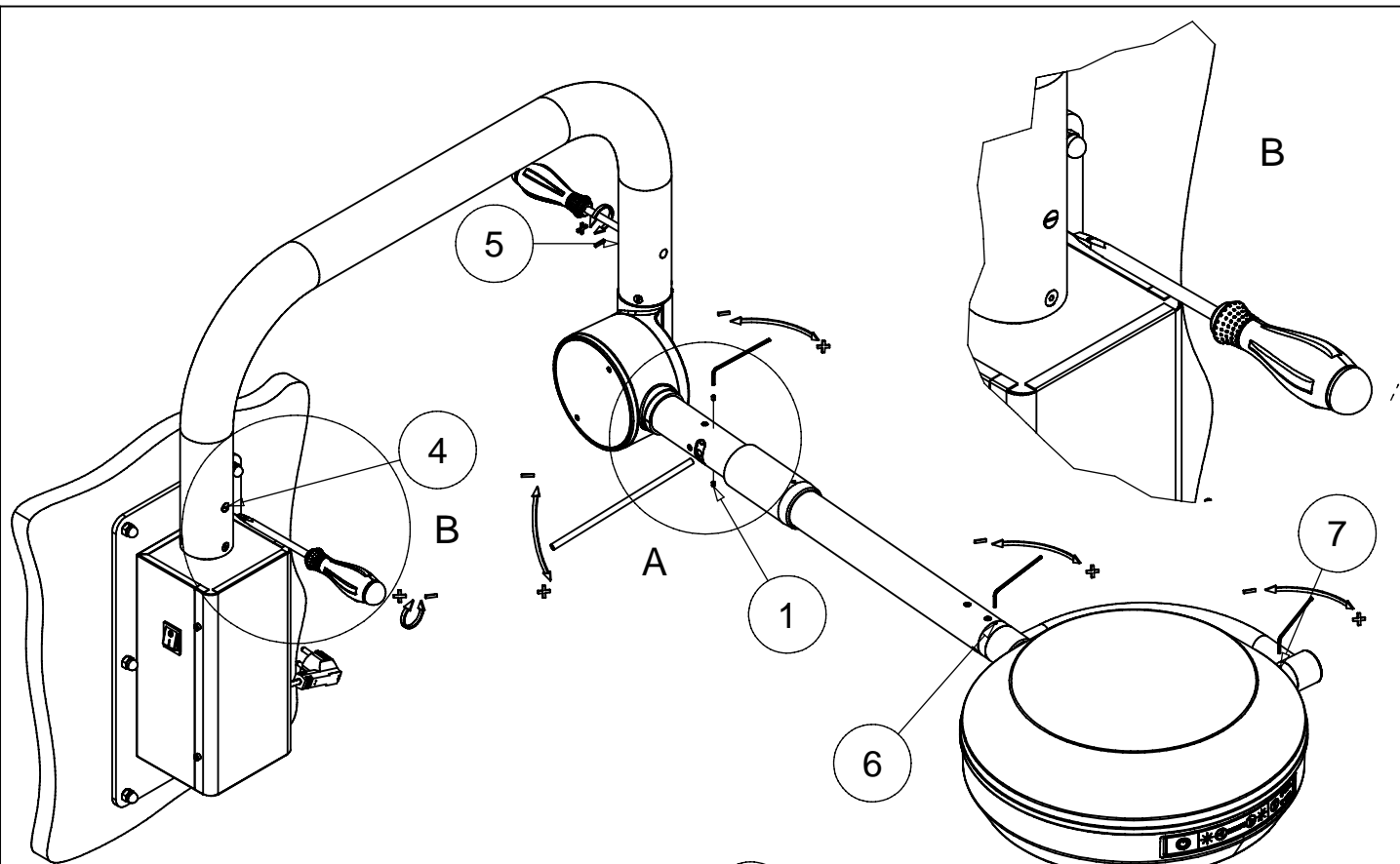
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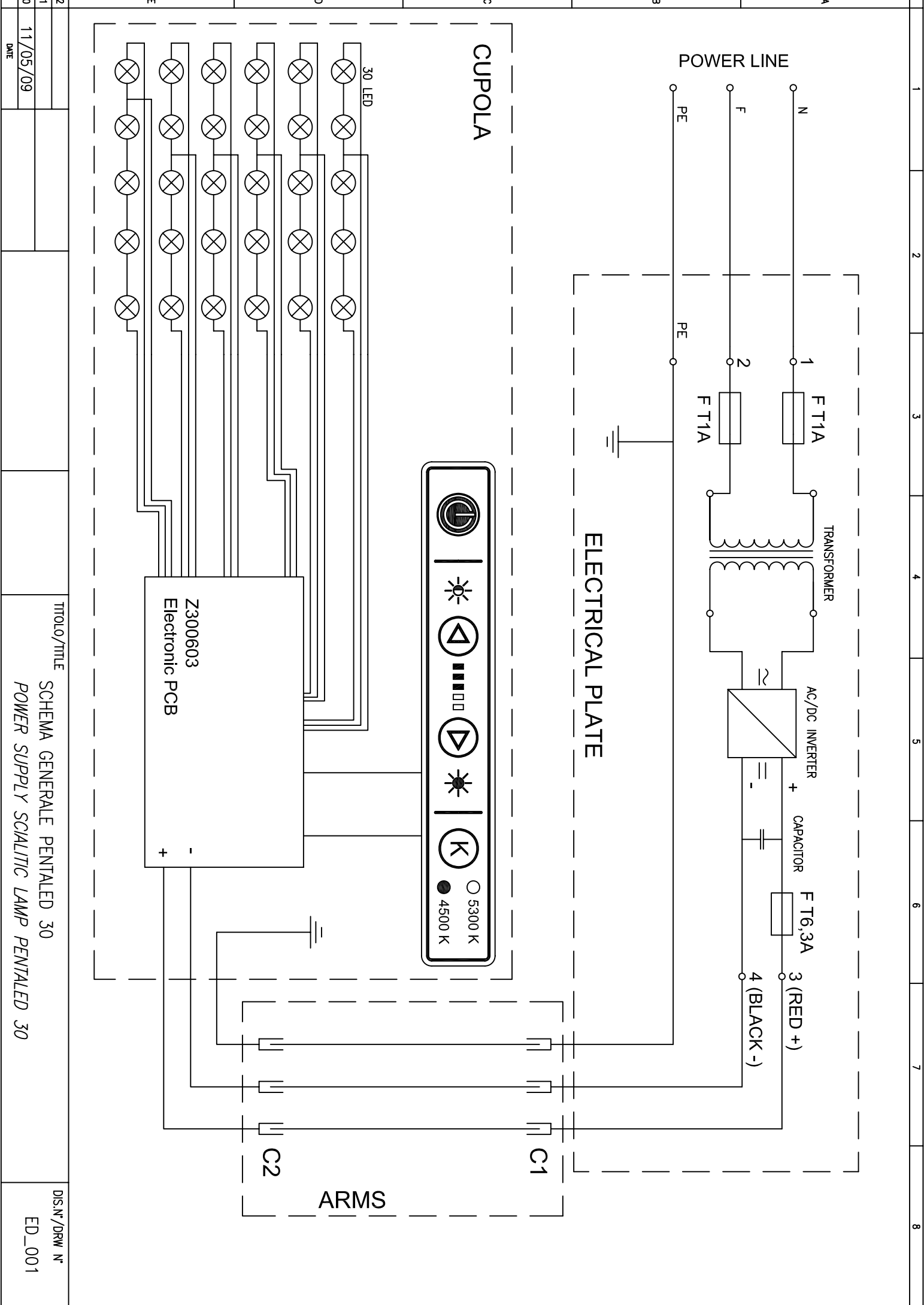
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Rev.	Data	8



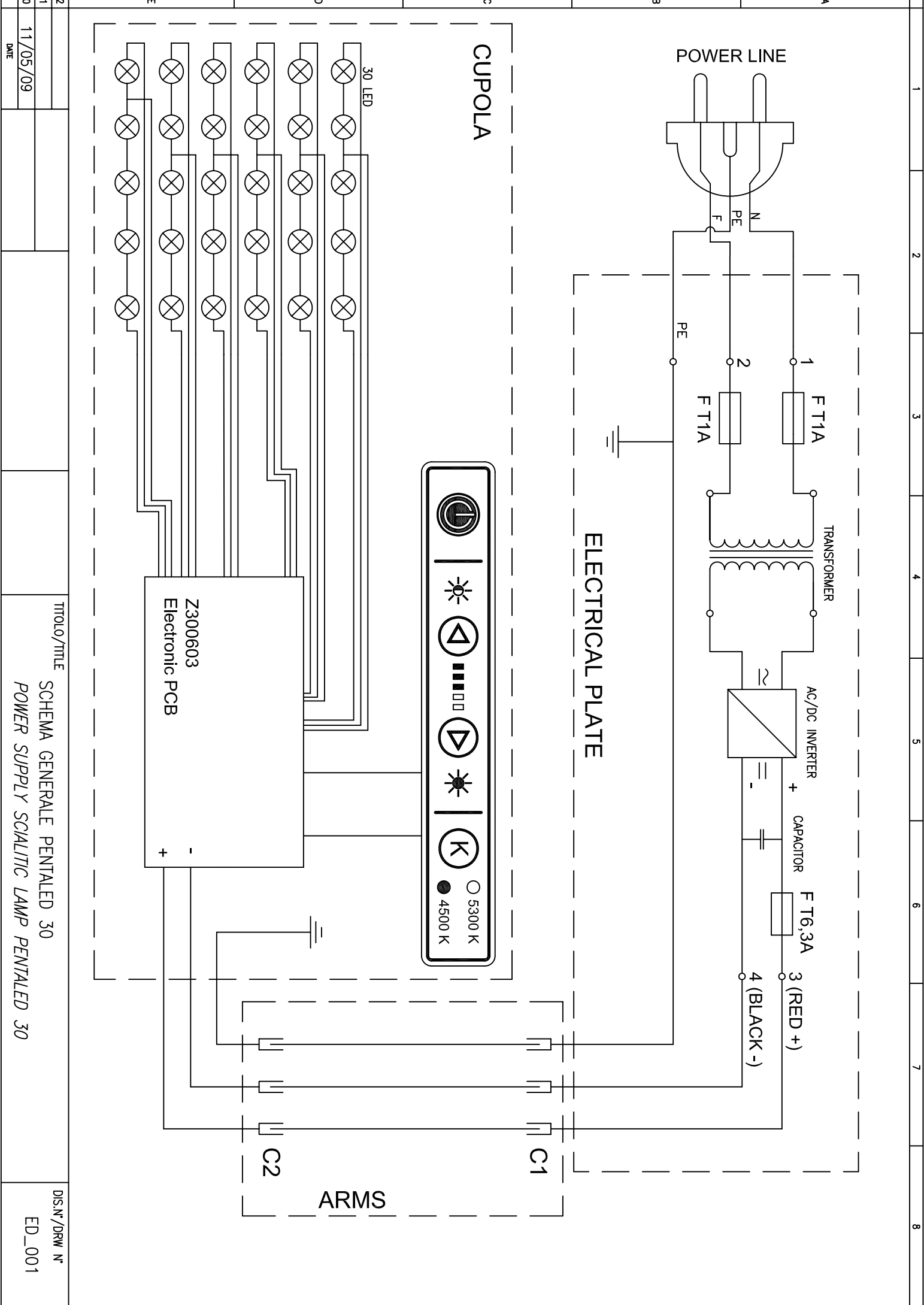
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Rev.	Data	9



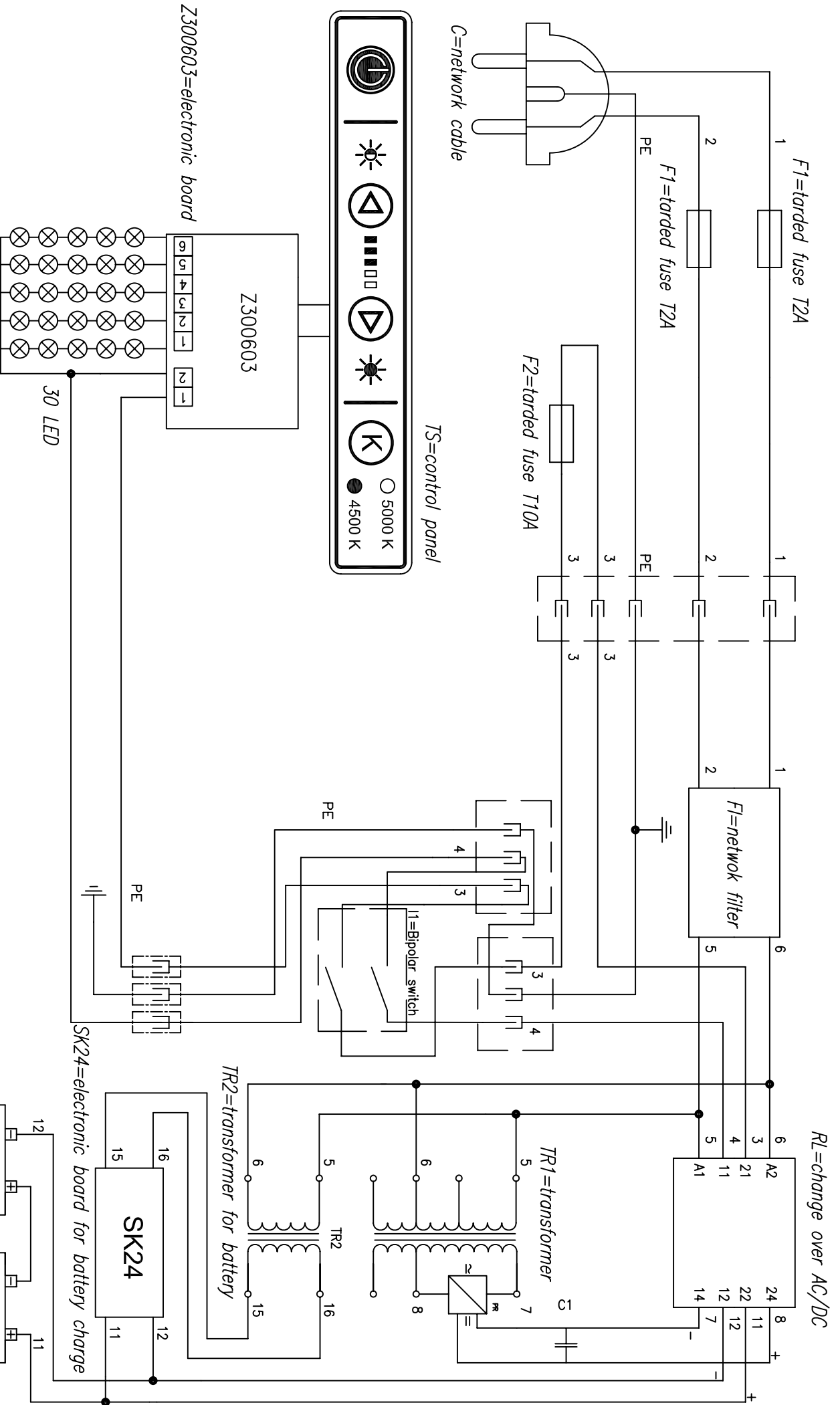
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1							
0	11/05/09						
	DATE						
TITOLO/TITLE				SCHEMA GENERALE PENTALED 30			
				POWER SUPPLY SCIALITIC LAMP PENTALED 30			
DIS.N°/DRW N°				ED_001			



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2	1	0	11/05/09	TITOLO/TITLE	SCHEMA GENERALE PENTALED 30	DIS.N°/DRW N°	ED_001
0	1	0	11/05/09	DATE	POWER SUPPLY SCIALITIC LAMP PENTALED 30		



2	DISIGNATORE/DESIGNER	RIMS	TITOLO/TITLE	SCHEMA ELETTRICO PENTALED 30 BATTERIA ELECTRIC DIAGRAM SCIALITIC LAMP PENTALED+BATTERY SYSTEM	DIS.N°/DRW N°
1	R.D.				ED_017
0	CONTROLLATO/CHECKED				
0	REVISION	S.C.			

B=battery 12V 12Ah

SK24=electronic board for battery charge

TR2=transformer for battery

TR1=transformer

I1=Bipolar switch

TS=control panel

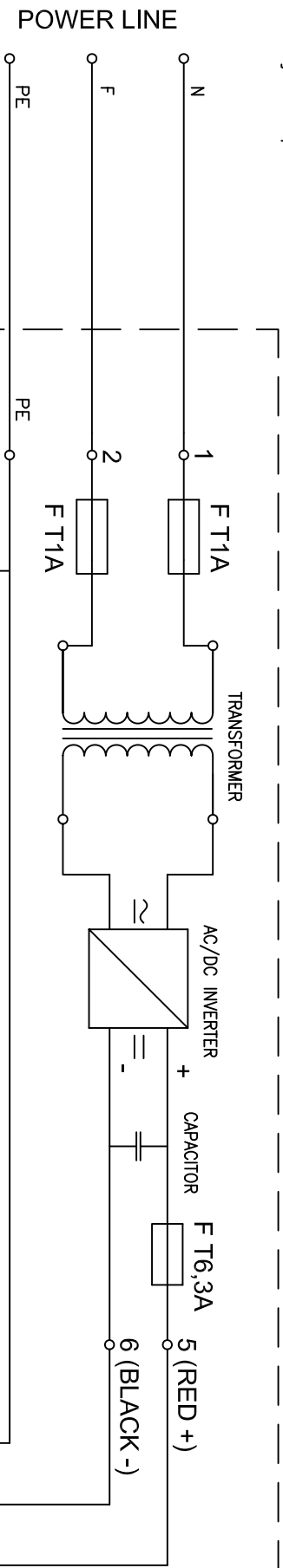
C=network cable

Z300603=electronic board

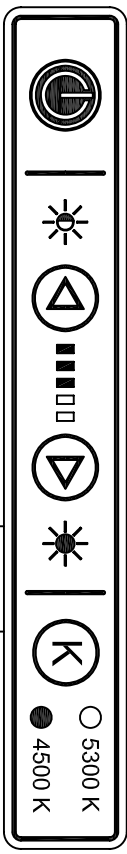
30 LED

RL=change over AC/DC

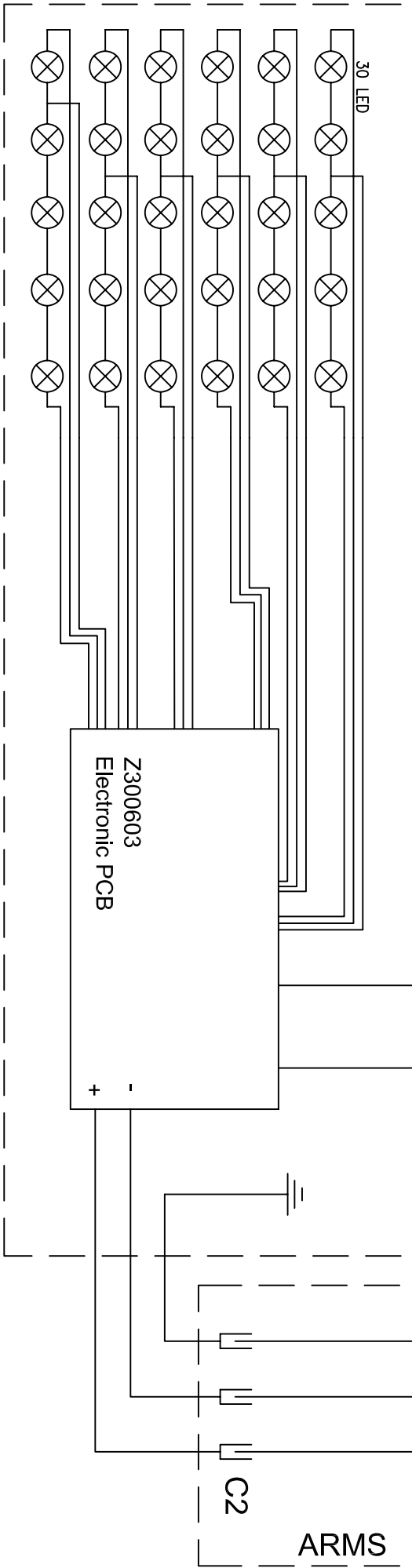
LAMPADA PRINCIPALE
Primary Lamp



ELECTRICAL PLATE

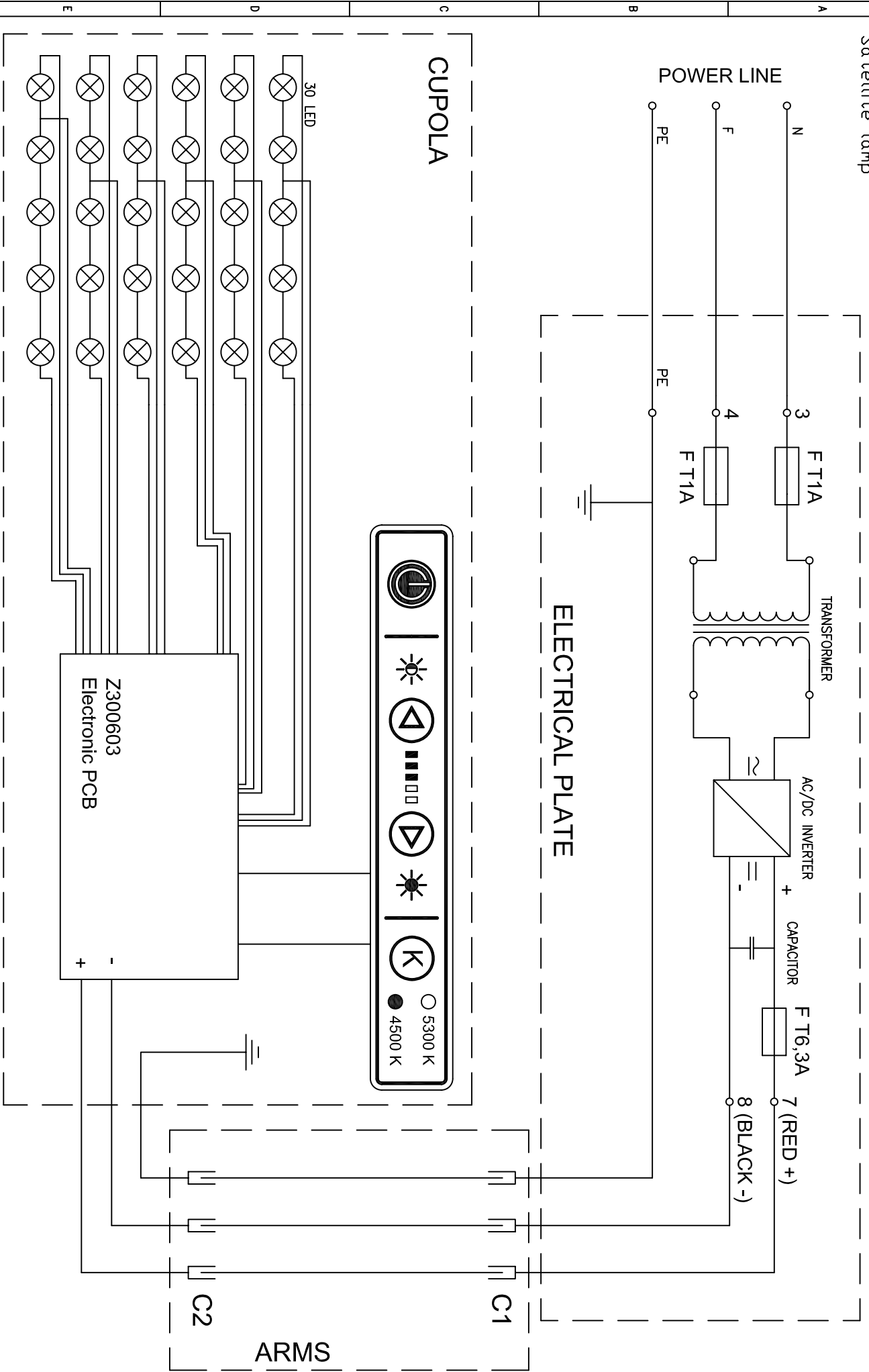


CUPOLA



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				TITOLO/TITLE	SCHEMA GENERALE PENTALED 30x2 POWER SUPPLY SCIALITIC LAMP PENTALED 30x2			DIS.N°/DRW N° ED_015

LAMPADA SATELLITE
Satellite lamp



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				TITOLO/TITLE	SCHEMA GENERALE PENTALED 30x2	DIS.N°/DRW N°		
					POWER SUPPLY SCIALITIC LAMP PENTALED 30x2	ED_015		