Operation and maintenance manual

SERIES E/N

SECONDARY SURGICAL LAMP (TREATMENT LAMP)

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.

CE Marking

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:

- Pentaled 81 in ceiling, floor versions;
- Pentaled 63N in ceiling, floor versions;
- Pentaled 105 in ceiling version;
- Pentaled 30E in ceiling, floor and wall versions;
- Pentaled 30N 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.

List of Contents

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	Person handling the equipment (e.g., professional health personnel, non-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.
SERVICE PERSONNEL	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: ⇨ 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 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_2 (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.

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

⚠	**WARNING – 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)

⚠	**CAUTION – 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.

⚠	**CAUTION – 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.

⚠	**CAUTION – Possibility of damaging Product**

- 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_2 (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.

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.

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 for Pentaled 30E, 30N lamps**
- **floor for Pentaled 81, 63N lamps**
- **ceiling**
- **wall**
- **double ceiling**

See drawing 178

FLOOR version for 30E, 30N lamps: base with wheels (1), power plug (2), inferior stem (3), superior stem (4), swinging arm (5), lamp head (6), function control keyboard (7), sterilisable grip (8).

See drawing 179

FLOOR version for 81, 63N lamps: base with wheels (1), power plug (2), inferior stem (3), superior stem (4), swinging arm (5), lamp head

(6), function control keyboard (7), sterilisable grip (8).

See drawing 160 SINGLE CEILING version: ceiling cover (1), ceiling anchor tube (2), power supply (3), horizontal arm (4), swinging arm (5), fork (6), lamp head (7), control keyboard (8), sterilisable grip (9).

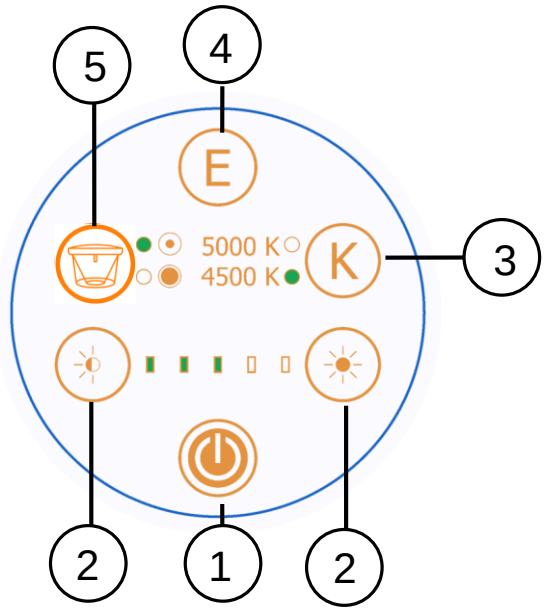
See drawing 181 WALL version: wall box (1), power plug (2), horizontal arm (3), swinging arm (4), lamp head (5), control keyboard (6, sterilisable grip (7).

See drawing 161 DOUBLE CEILING version: ceiling cover (1), ceiling anchor tube (2), power supply (3), horizontal arm (4), swinging arm (5), fork (6), lamp head (7), control keyboard (8), sterilisable grip (9).

5.2 Description of operation

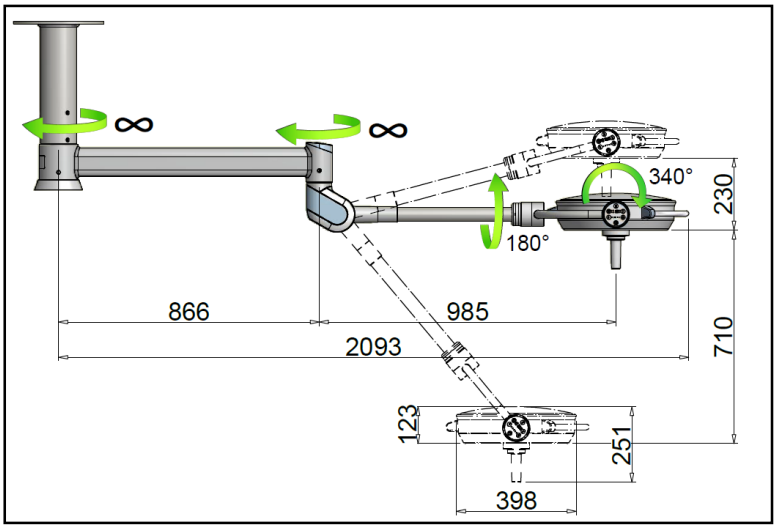
Control keyboard The membrane keyboard is located on the fork. It can control:

- On/Off button (1)
- Sun button (2): light intensity adjustment. The intensity level is indicated by 5 green microleds
- “K” button (3): color temperature selection 4.500 – 5.000K
- “E” button (4): “Endoled” function. Function available only when the lamp is switched off
- Light field diameter selection (5), increase or decrease the light field diameter.

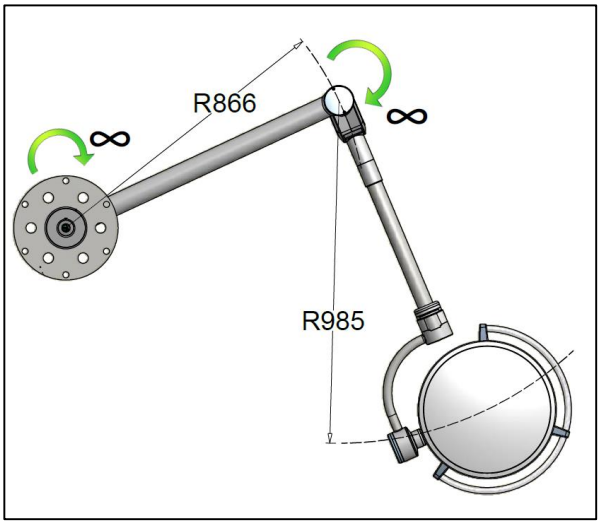


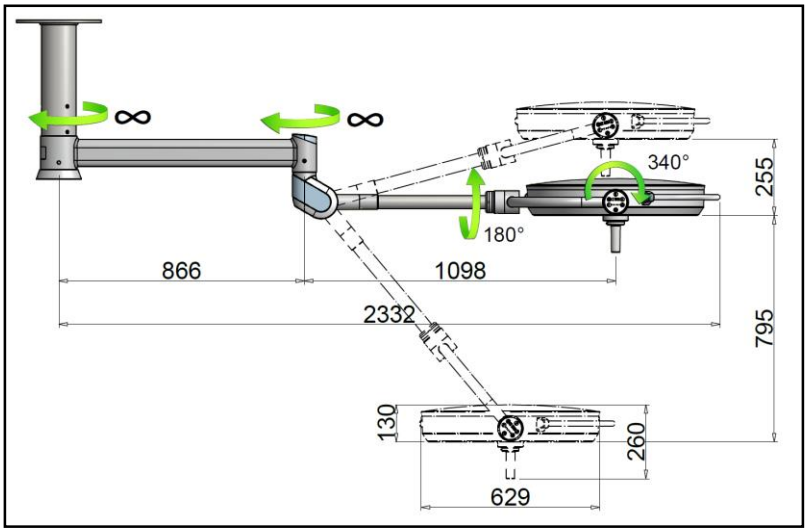
Lit-up area The Product has been designed to be able to regulate the light diameter electronically by means of the key (5) provided.

5.3 Product handling

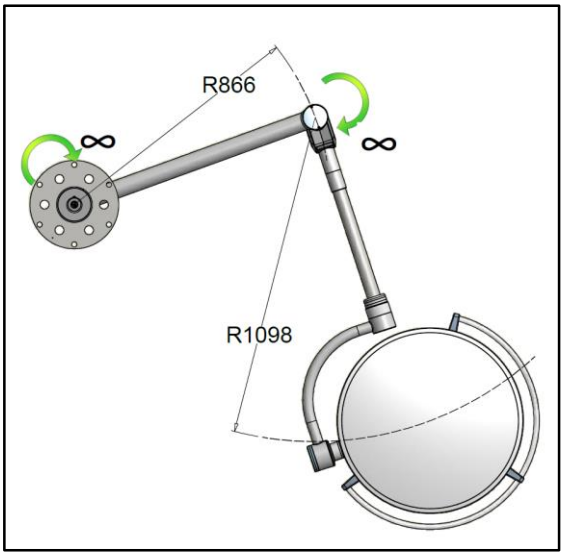


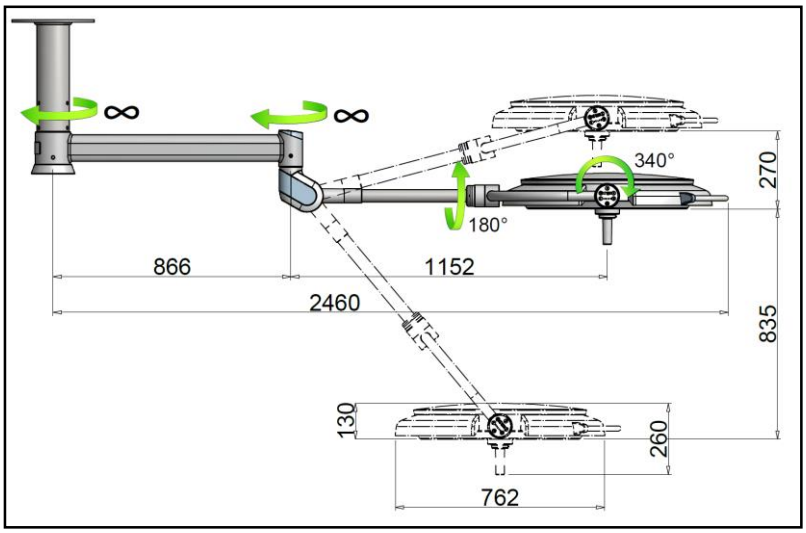
SINGLE ceiling model 30E/30N



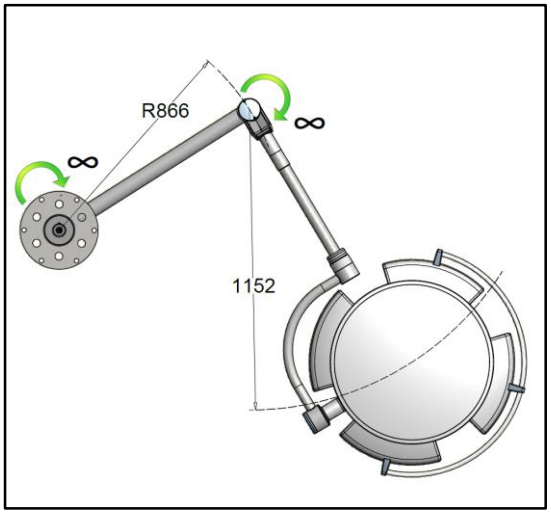


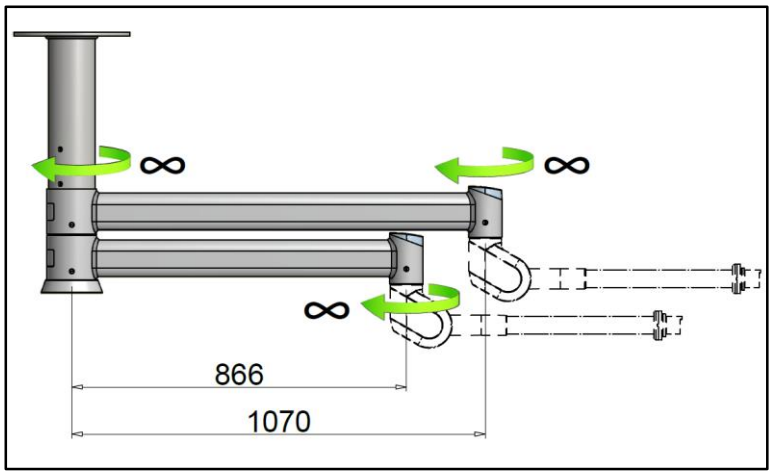
SINGLE ceiling model 81/63N



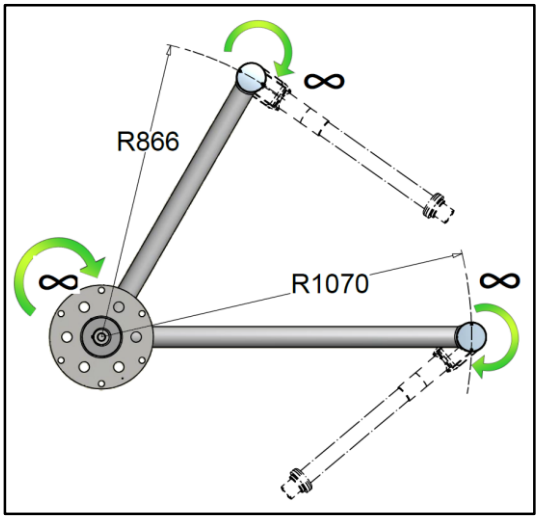


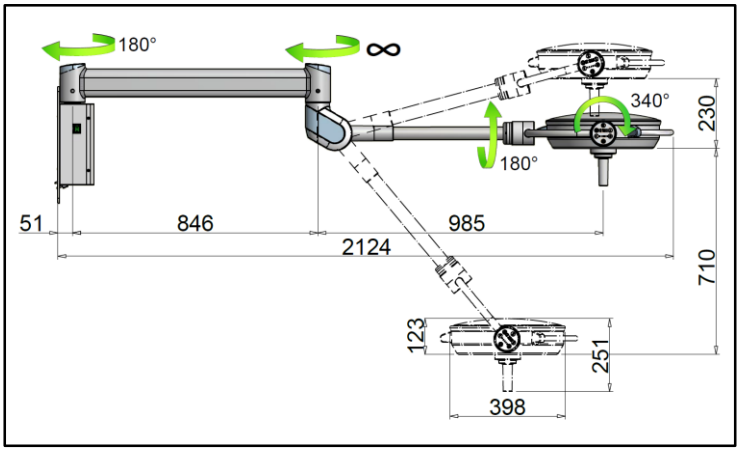
SINGLE ceiling model 105



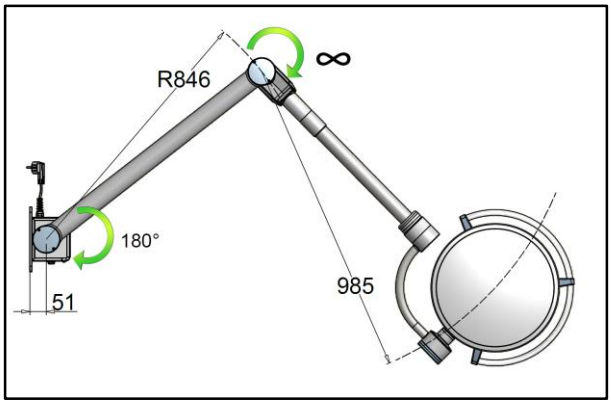


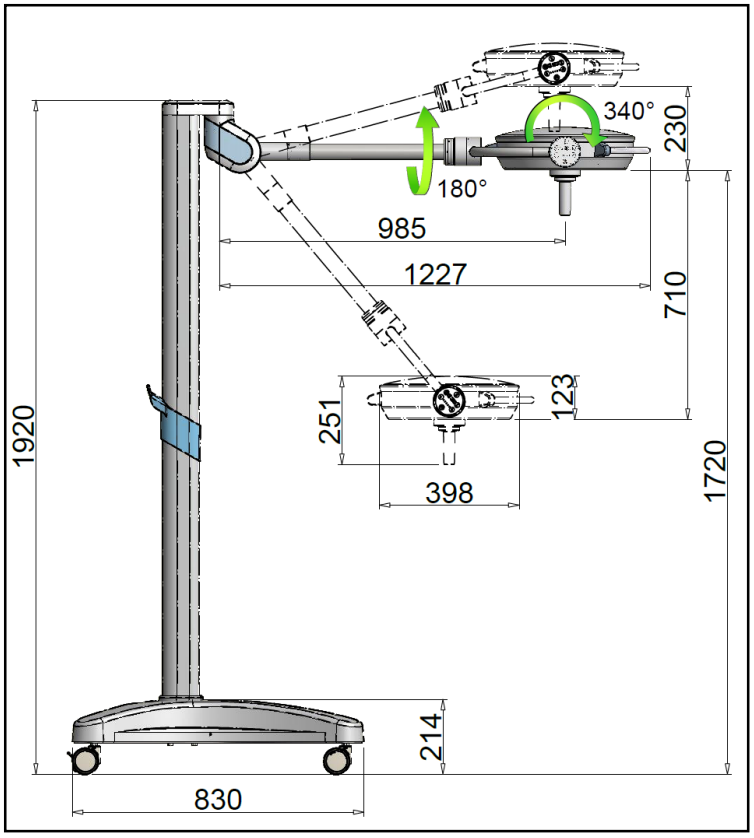
Double lamp model



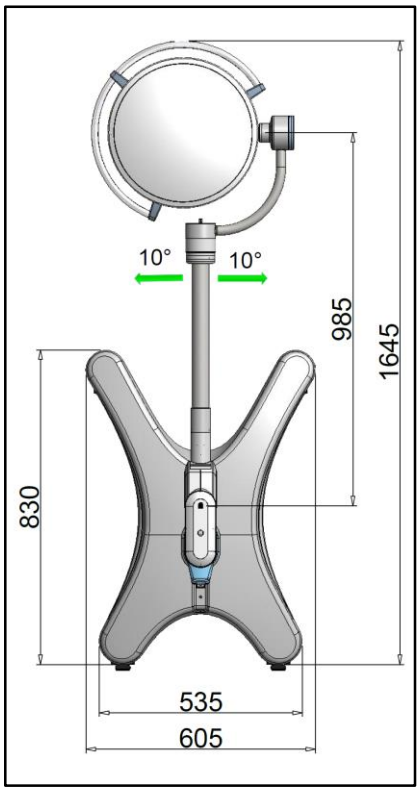


Wall model

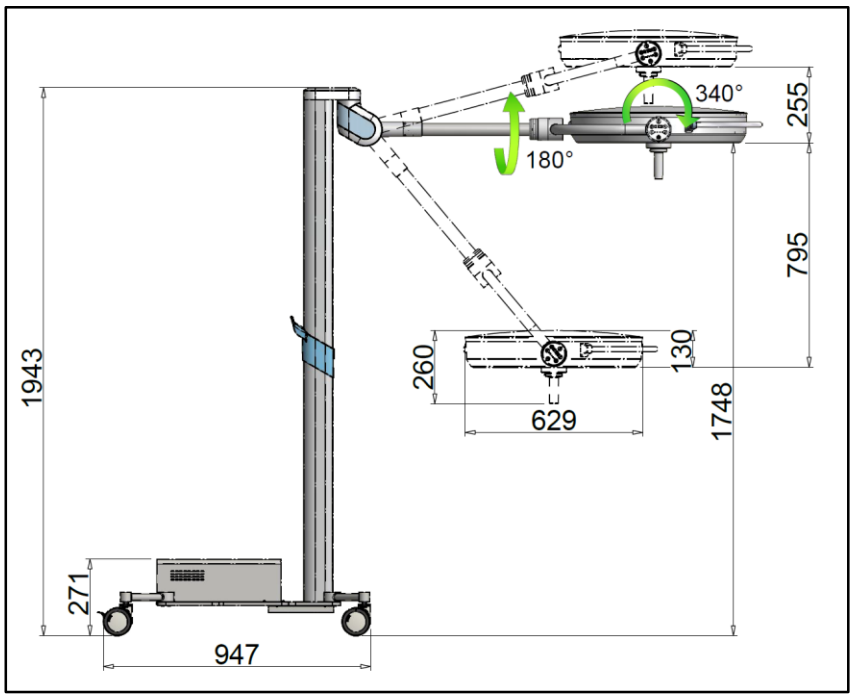


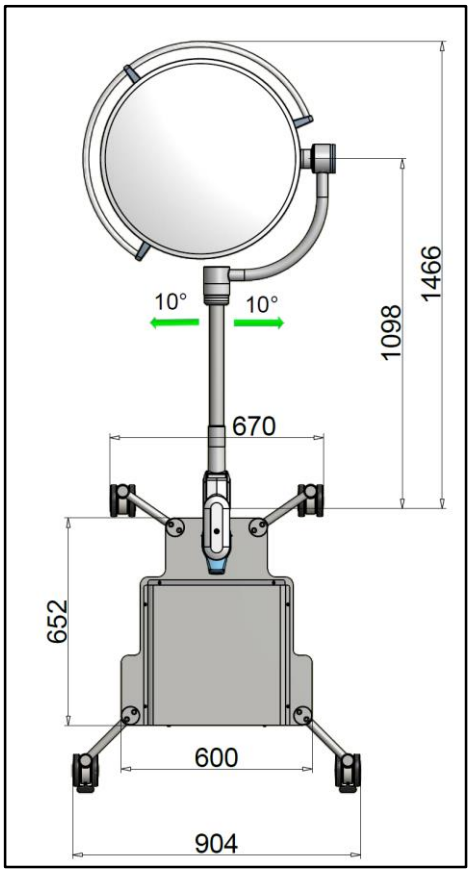


Floor model 30E, 30N



Floor model 81, 63N





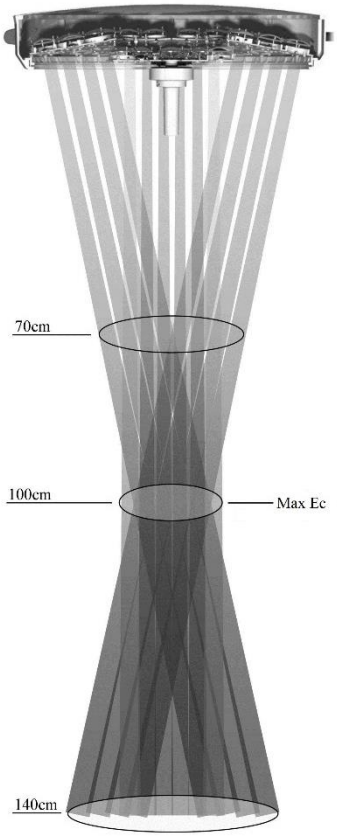
The Product can be moved using the sterilisable grip (fig. A) or by means of the side handles (fig.B)

Fig.A

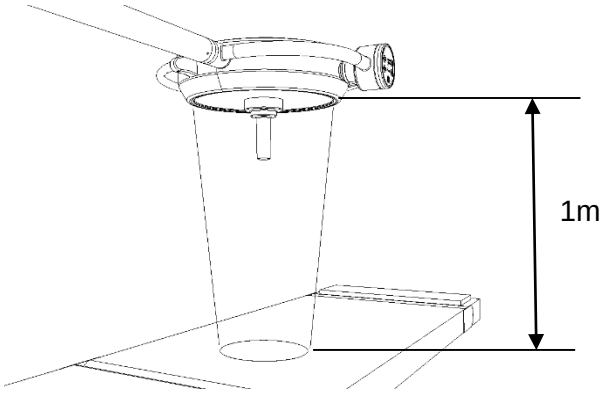
Fig.B

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 Methodology of use

⚠	**WARNING – Electric shock hazard**

Before cleaning the product, make sure it is off and cannot be switched back on.

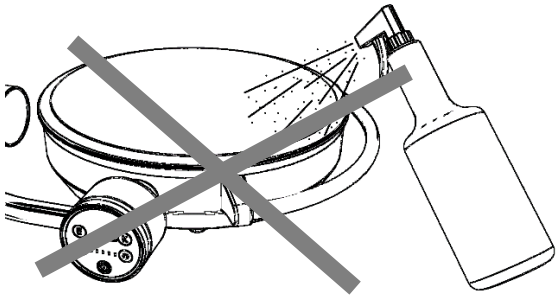
Allow the lamp to cool down and only clean it when it is cold.

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

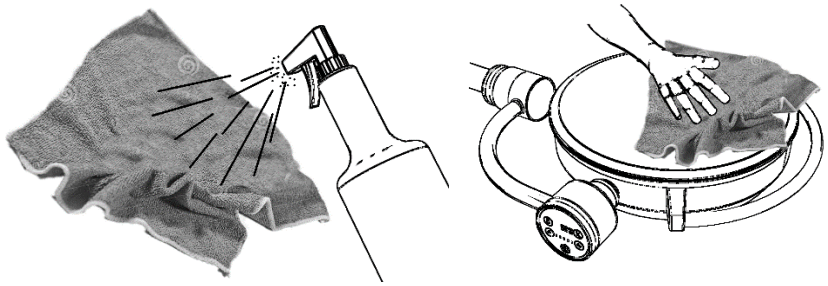
⚠	**CAUTION – Possibility of damaging the Product**

How to use

Do not spray the detergent / disinfectant directly on the Product



Spray the detergent / disinfectant on a cloth and wipe the product.



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 The Product is best cleaned daily.

⚠	**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.

6.3 Product disinfecting

Frequency The Product is best disinfected every time before use.

⚠	**CAUTION – Possibility of damaging the 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 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.

6.4 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 hand-piece release lever and remove it.
- Insert the hand-piece up tight on the support and turn it until the steel lever engages in its original place and rotation is blocked. Finally make sure the hand-piece is well secured.

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.

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 157

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.

Manually move the cover (5) forwards. Fit a pin (6) with diameter of 8 mm in the holes of the ring nut 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 upwards and release 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.

At the end of adjustment, manually reposition the cover (5) in its original position.

The swinging movement of the arm can also be adjusted upwards.

The Product is sold with maximum set swinging movement. If the swinging movement is to be reduced upwards, manually move the cover (5) forwards and insert a pin (7) with max diameter 5mm in the second ring nut. By turning the pin downwards, the swinging movement can be reduced until it is in horizontal position.

The swinging movement downwards cannot instead be changed.

At the end of adjustment, manually reposition the cover (5) in its original position.

7.2 Clutch adjustment

See drawing 157

The brakes are set during installation. Like all the other mechanical parts, the brakes are also subject to wear.

If the Product does not remain in a stable position, the braking force will have to be adjusted by means of the brake screws.

Use a flathead screwdriver to increase the braking force, turning the screws (1) and (2) of the arm brake clockwise.

To increase the braking force at the head, turn the two brake screws (3 and 4) clockwise using a flathead screwdriver.

7.3 Periodical checks to be performed on the Product

⚠	**CAUTION – Product electrical check**

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

⚠	**CAUTION – Interrupt the power supply before doing any maintenance jobs**

⚠	**CAUTION – Check Product integrity**

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 **7.1 and 7.2 (arm and clutch adjustment)**.
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

⚠	**CAUTION – Unsuitable repairs**

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	Z200518
Electronic board E and N series	Z300632
Membrane keyboard E series	Z300227
Membrane keyboard N series	Z300234
0/I switch (for floor and wall versions)	Z300016
Switching power supply unit for 30E and 30N	Z170180
Switching power supply unit for 81, 105 and 630N	Z112216

8 Technical properties

Technical details of light	PENTALED30E	PENTALED81	PENTALED105
Illumination E_c at 1 m distance ± 10% (5.000°K) [Lux]	130.000	160.000	160.000
Illumination E_c at 1 m distance ± 10% (4.500°K) [Lux]	100.000	160.000	160.000
Colour temperature double selection [K]	4.500 / 5.000		
Colour rendering index R_a [-]	96		
R_9 [-]	≥90		
Light range diameter d_{50} [mm]	80	95	100
Light range diameter d_{10} [mm]	160	190	200
Lighting depth L1+L2 [cm] at 60%	34 + 15	26 + 17	24+23
Max irradiation [W/m^2]	299	392	410
Irradiation / Illumination [mW/m^{2}lx]	2,3	2,45	2,56
Max irradiation in UV [W/m^2]	0,002		
Power connection details			
Primary alternate voltage [Volt ac]	100 - 240		
Frequency [Hz]	50 - 60		
Power input [VA]	70	145	150
Light source	n°30 LEDs	n°81 LEDs	n°105 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50.000		
Light intensity control [%]	25-100		
General data			
Colour	RAL 9003		

Directive	93/42/EEC e 2007/47/EC		
Standards	IEC 60601-2-41		
Classification of Medical Device	Classe I		
Dimensions			
Diameter of lamp body [cm]	40	63	79
Diameter of poly-elliptical reflectors [cm]	n°30x5,5	n°72x5,5 + n°9x3,2	n°96x5,5 + n°9x3,2
Light emission surface [cm^2]	712	1.782	2.352
Weight of floor, ceiling, wall, double ceiling surgical light [kg]	47, 39, 27, 63	75, 47, /, 79	79, 51, /, 87
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			

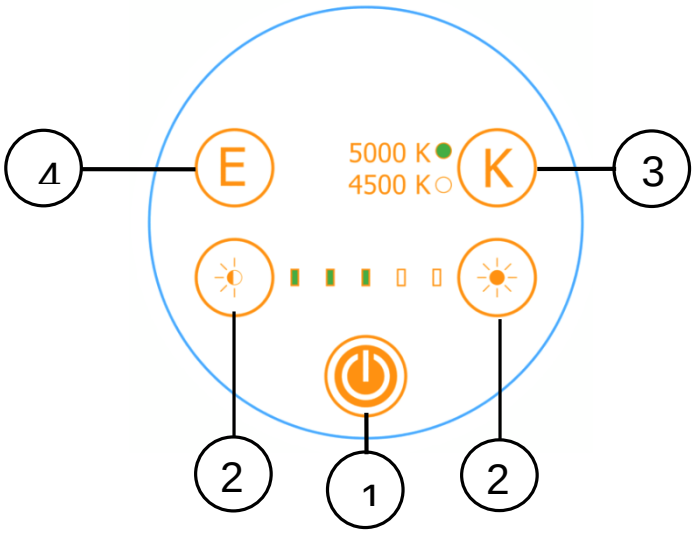
9 Deviation for N-series

9.1 Description of operation

Control keyboard

The membrane keyboard is located on the fork. It can control:

- On/Off button (1)
- Sun button (2): light intensity adjustment. The intensity level is indicated by 5 green microleds
- “K” button (3): color temperature selection 4.500 – 5.000K
- “E” button (4): “Endoled” function. Function available only when the lamp is switched off

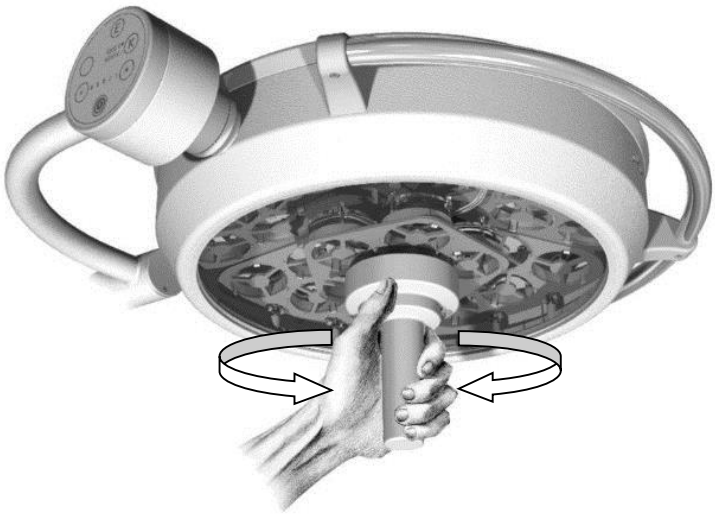


Light field adjustment

The mechanical adjustment of the light field can be performed by turning the sterilizable hand-piece. Turn clockwise to widen the light field in the lighted area (patient area) and anticlockwise to narrow it.

9.2 Product movement

To adjust the diameter of the light field and the focus, it's possible to rotate clockwise or counterclockwise the sterilisable grip.



9.3 Technical properties

Technical details of light	PENTALED30N	PENTALED63N
Illumination E_c at 1 m distance ± 10% (5.000°K) [Lux]	130.000	160.000
Illumination E_c at 1 m distance ± 10% (4.500°K) [Lux]	100.000	160.000
Colour temperature double selection [K]	4.500 / 5.000	
Colour rendering index R_a [-]	96	
R_9 [-]	≥90	
Light range diameter d_{50} [mm]	90	120
Light range diameter d_{10} [mm]	180	210
Lighting depth L1+L2 [cm] at 60%	38 + 17	24 + 22
Max irradiation [W/m^2]	263	399
Irradiation / Illumination [mW/m^2lx]	2,7	2,61

Max irradiation in UV [W/m^2]	0,001	
Power connection details		
Primary alternate voltage [Volt ac]	100 - 240	
Frequency [Hz]	50 - 60	
Power input [VA]	70	145
Light source	n°30 LEDs	n°72 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	50.000	
Light intensity control [%]	25-100	
General data		
Colour	RAL 9003	
Directive	93/42/EEC e 2007/47/EC	
Standards	IEC 60601-2-41	
Classification of Medical Device	Class I	
Dimensions		
Diameter of lamp body [cm]	40	63
Diameter of poly-elliptical reflectors [cm]	n°30x5,5	n°72x5,5
Light emission surface [cm^2]	712	1.710
Weight of floor, ceiling, wall, double ceiling surgical light [kg]	47, 39, 27, 63	75, 47, /, 79
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		

10 CE 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
APPLICARE ETICHETTA

made by RIMSA P.LONGONI S.r.l., complies with Annex VII of Directive 93/42/EEC dated 14/05/1993, (including Directive 2007/47/EC dated 05/09/2007) 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)
CLASS I:	Active medical device (Annex IX, Par.1 “Definitions”, art.1, subsection 1.4) (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)

- 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

11 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.

⚠	**CAUTION – Possibility of interferences with nearby appliances**

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. **Warning:** This Product is intended for use by professional health personnel only. This Product can cause radio-interference or disturb the operation of nearby appliances. Measures may have to be taken to reduce such disturbance, such as Product re-positioning or shielding of premises.
Harmonic emissions IEC 61000-3-2	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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5GHz	3 Vrms 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. 

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

For transmitters 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.

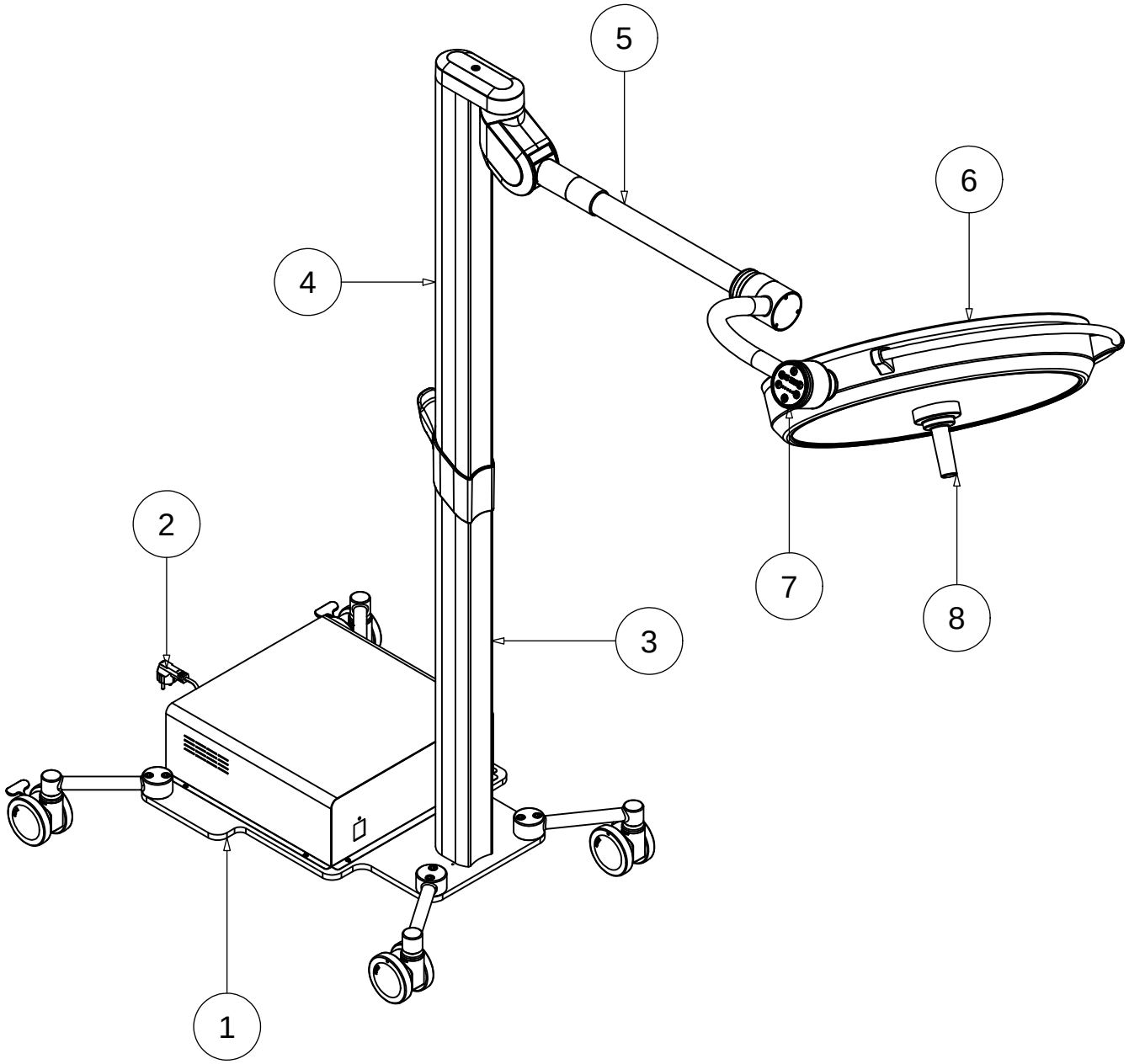
12 Warranty Certificate

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.

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.

Note



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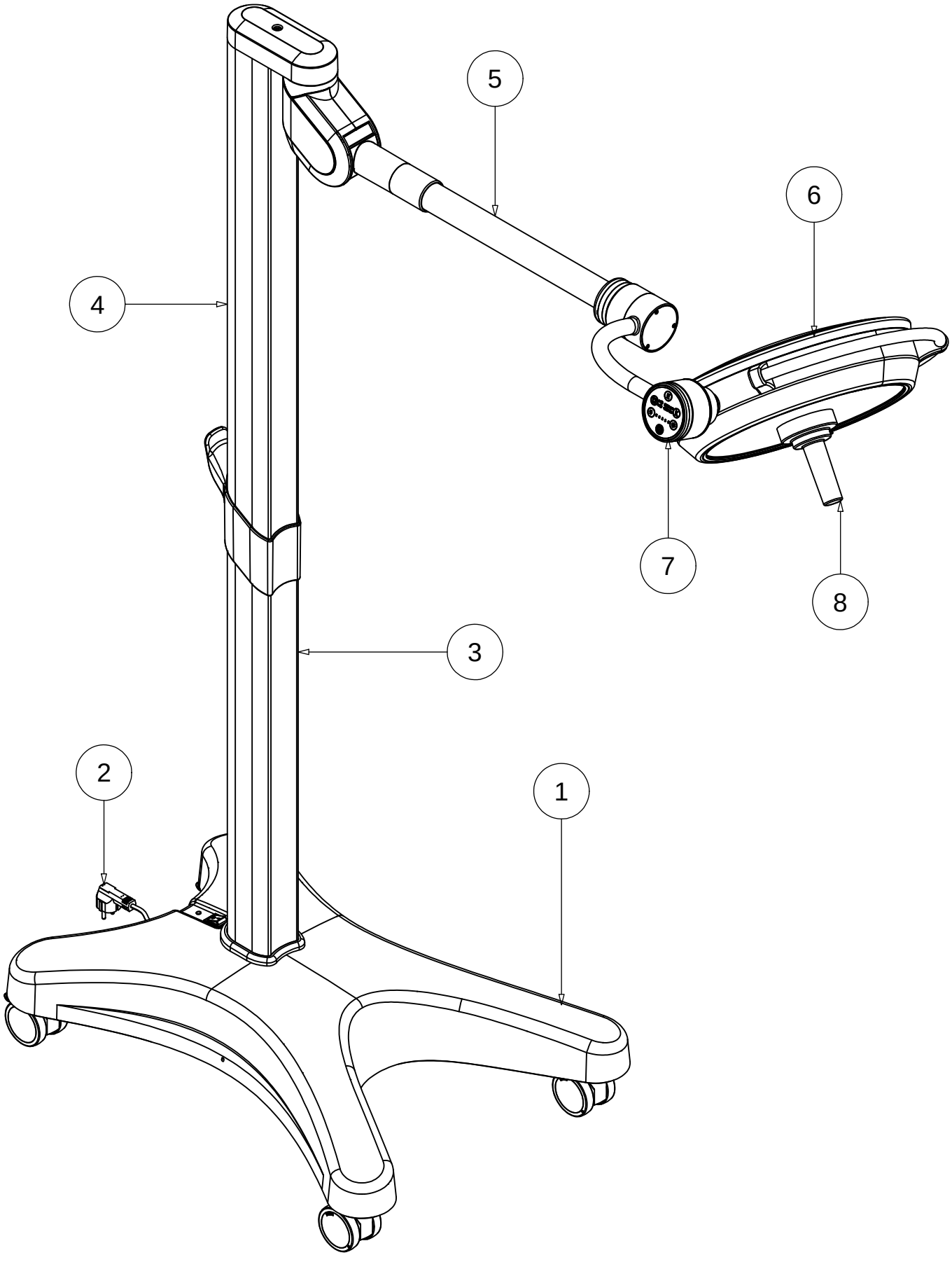

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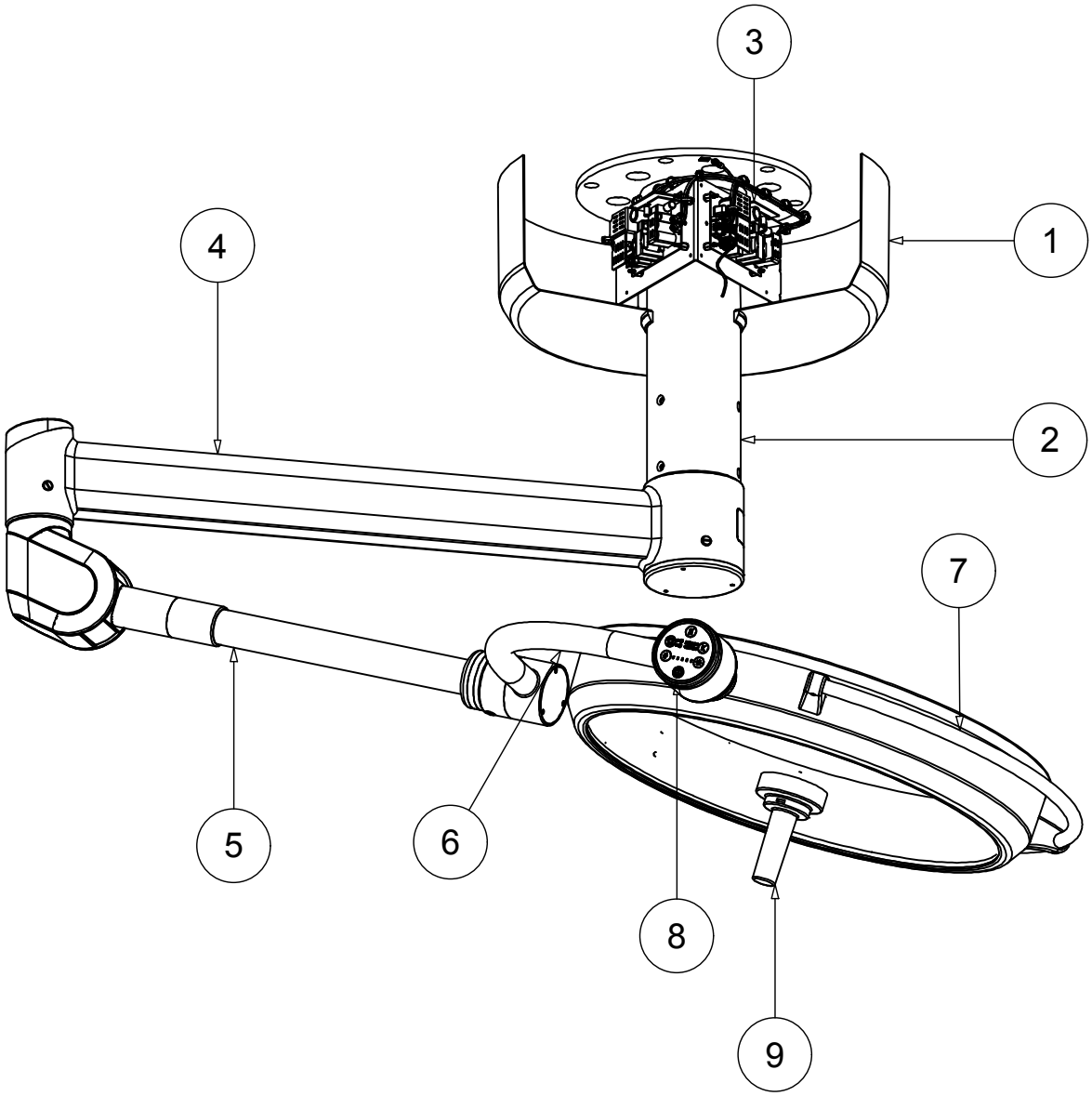

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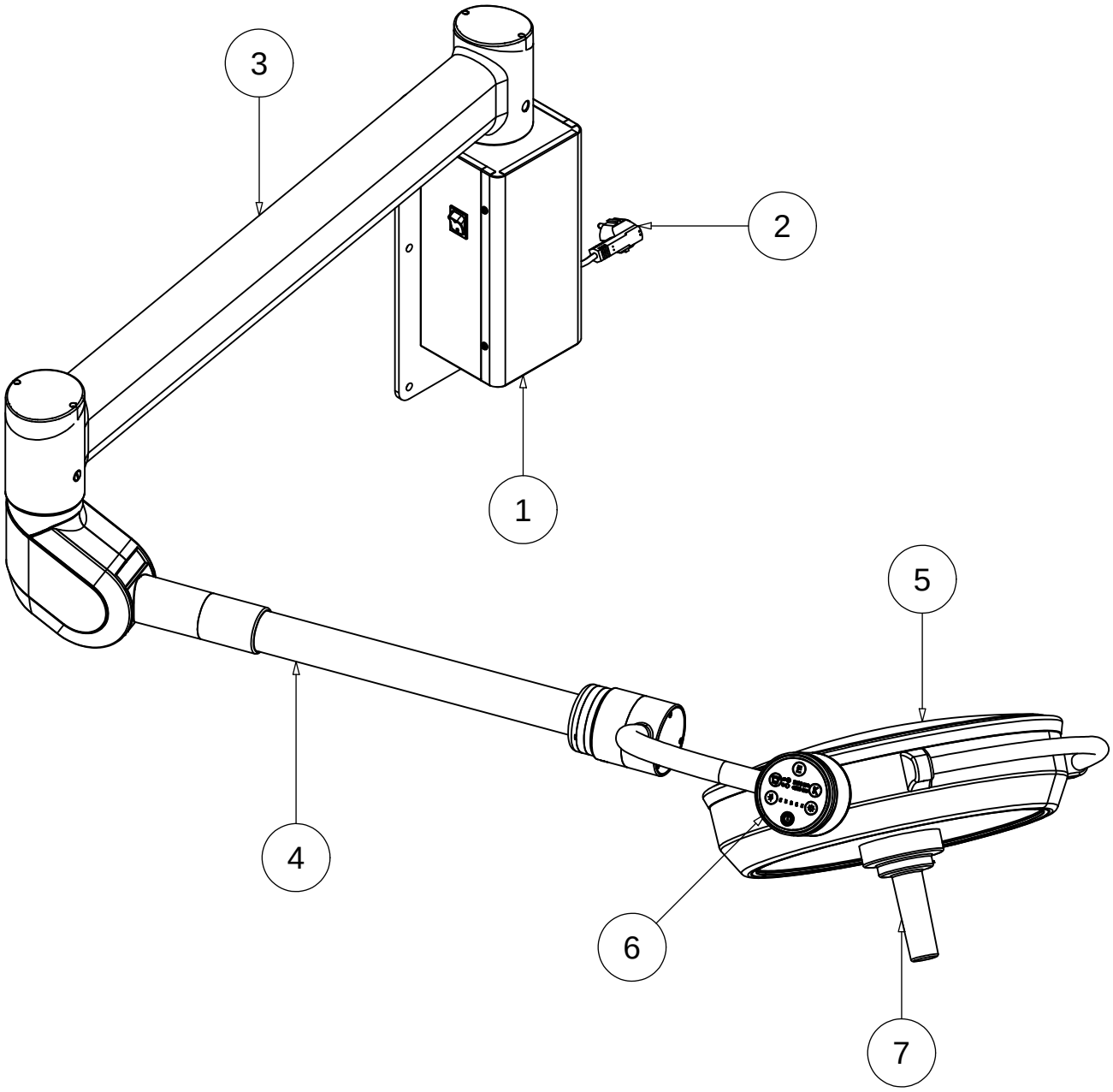

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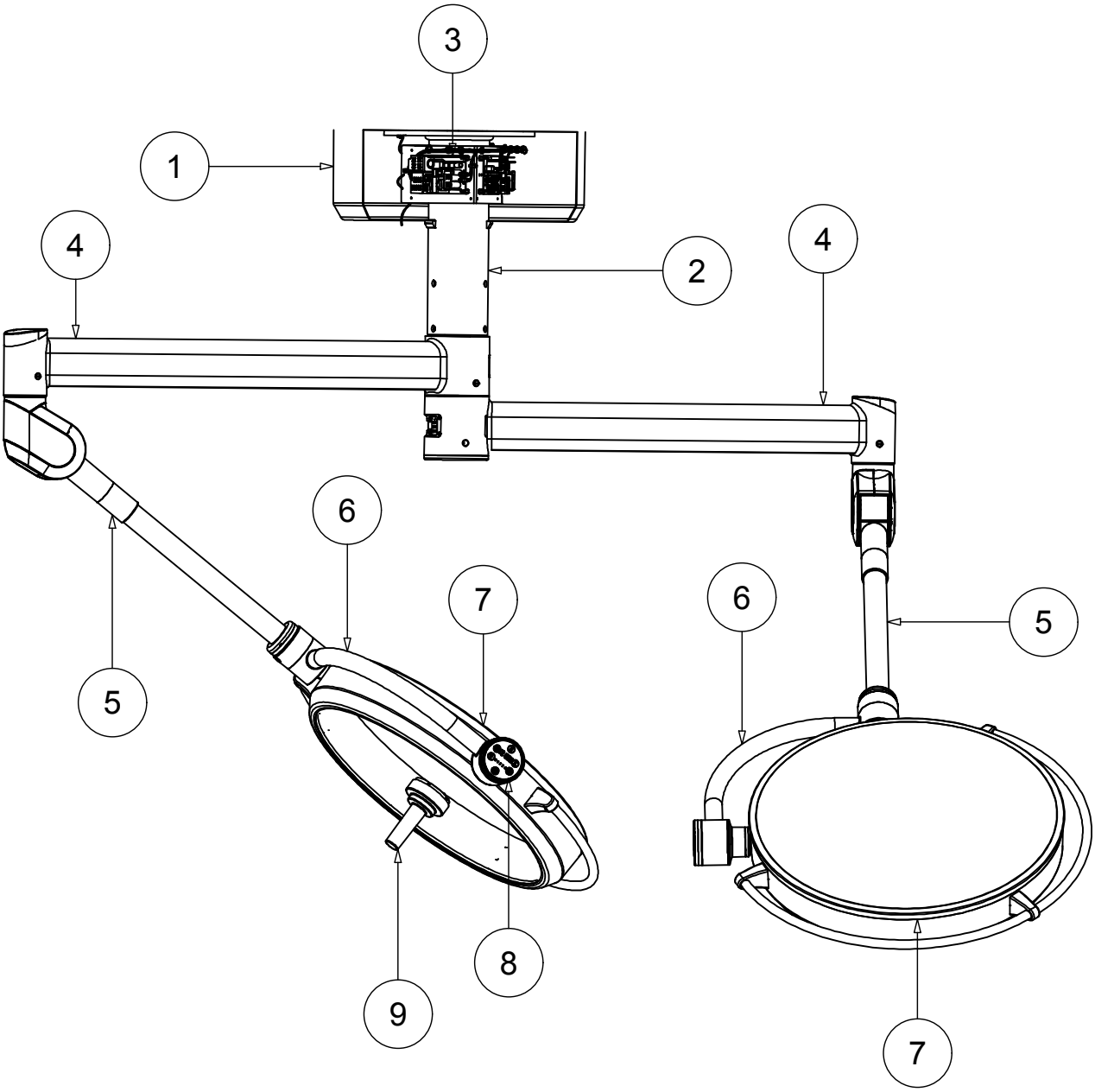

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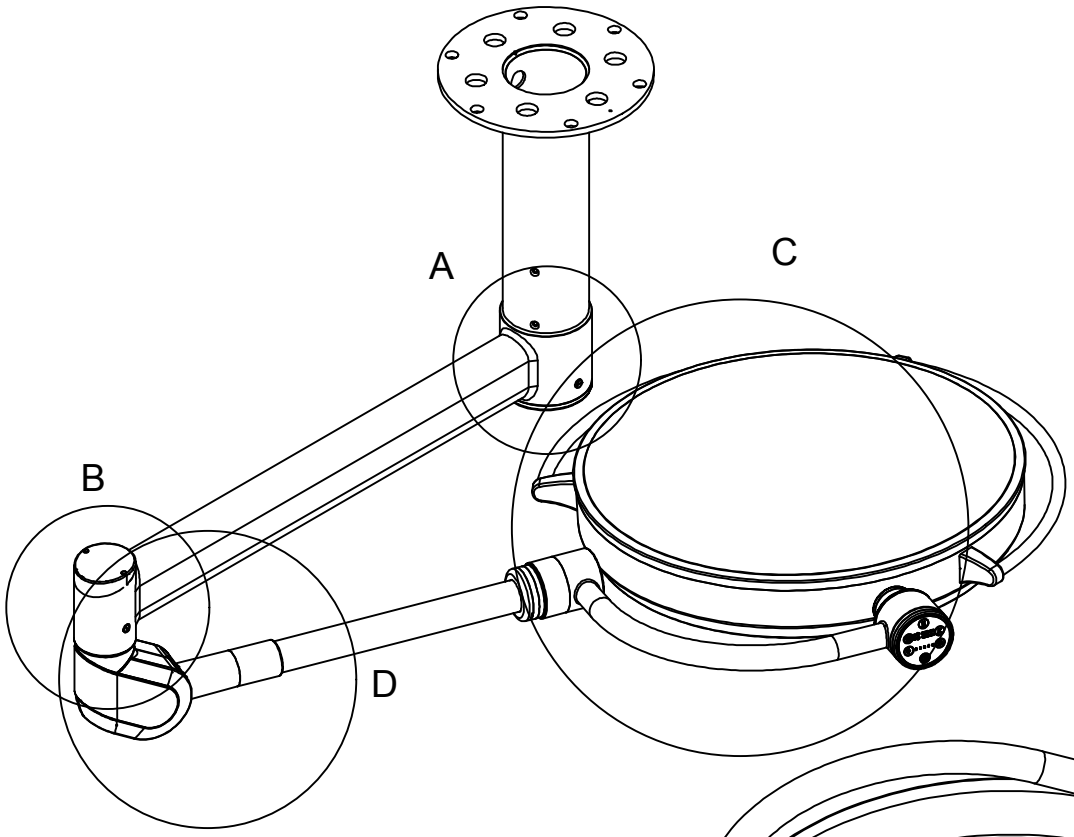

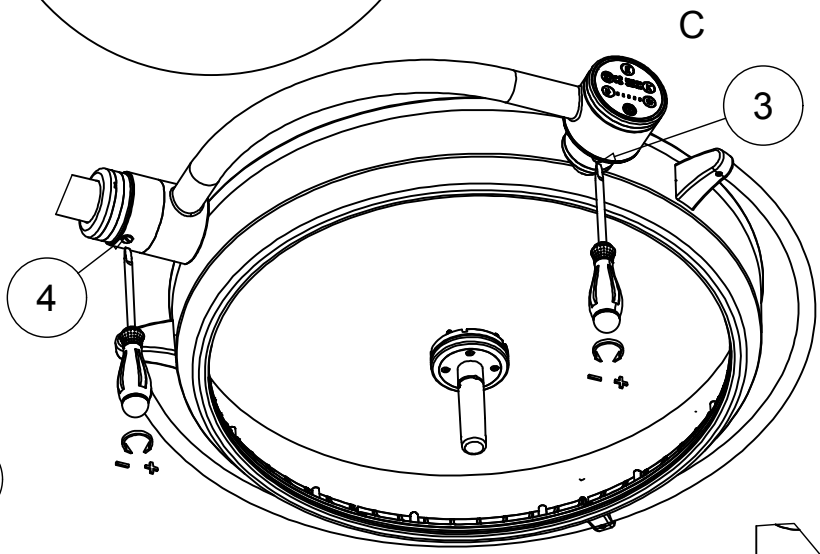

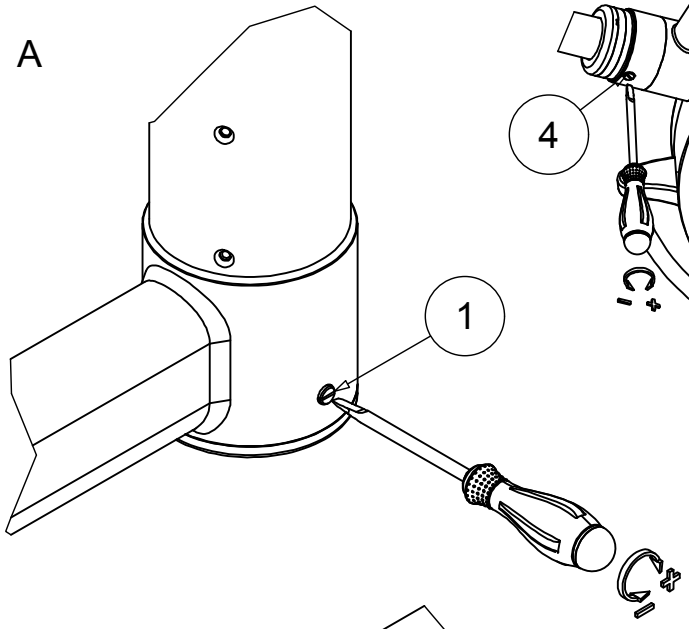

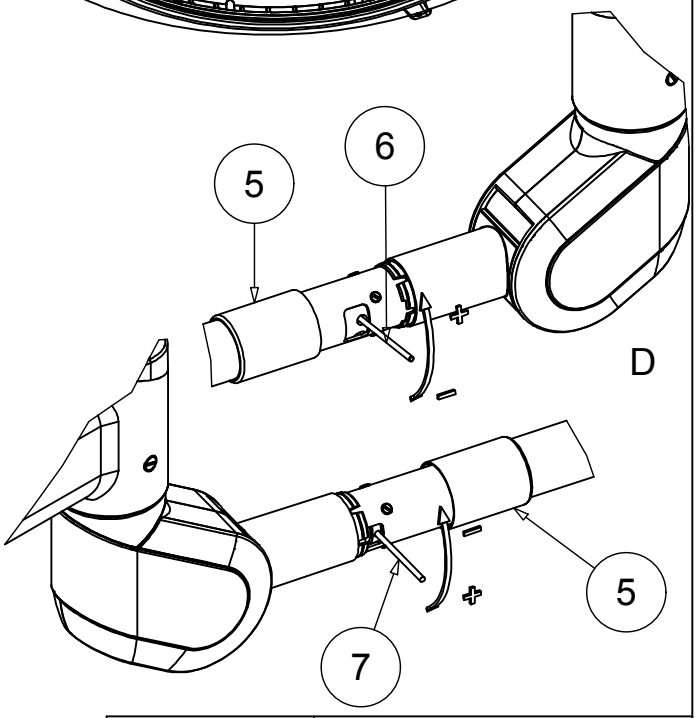

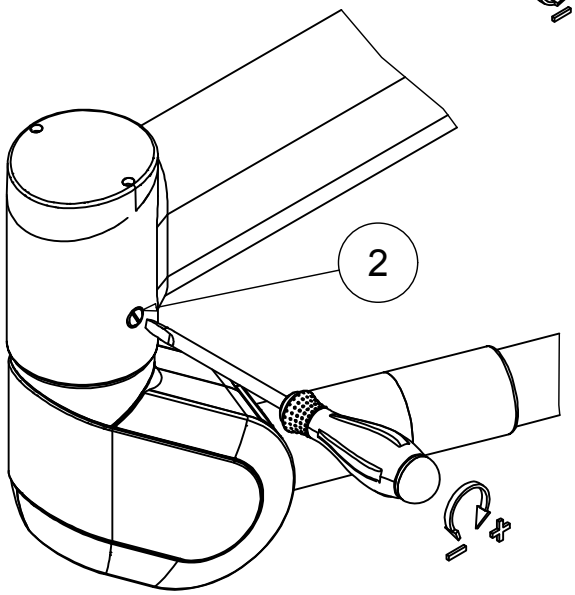

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