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# Operation and maintenance manual

# ORION 40
# ORION 40DS

**SECONDARY SURGICAL LAMP (TREATMENT LAMP)**

**Mobile** *(LC001LRA)*
**Wall** *(LC002LRA)*
**Single Ceiling** *(LC003LRA)*
**Double Ceiling (ORION 40+ORION 40)** *(LC004LRA)*

**ORION 40DS Wall** *(LC001LRD)*
**ORION 40DS Ceiling** *(LC002LRD)*
**ORION 40DS Mobile** *(LC003LRD)*
**Double Ceiling (ORION 40DS+ORION 40DS)** *(LC004LRD)*
**ORION 40DS Low Ceiling***(LC005LRD)*
**ORION 40DS Ceiling + TVCC Arm** *(LC006LRD)*
**ORION 40DS TVCC Ceiling** *(LC007LRD)*

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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.

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:

- ORION 40/40DS single-ceiling version
- ORION 40/40DS double-ceiling version (ORION 40/40DS+ORION 40/40DS)
- ORION 40/40DS mobile version
- ORION 40/40DS wall version

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.

- TECNO-GAZ
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Copyright

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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

**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)

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# 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** TECNO-GAZ 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.

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| | |
|---|---|
| ⚠ | **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

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### 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

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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)

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# 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

TECNO-GAZ 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:

- **mobile**
- **wall**
- **ceiling**
- **double ceiling**

See drawing 119

MOBILE version: wheel base (1), power supply unit (2), base cover (3), vertical stem (4), oscillating arm (5), fork (6), lamp cupola (7), function control keyboard (8), sterilizable handle (9), power supply plug (10), switching on base (11).

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| | |
|---|---|
| See drawing 120 | WALL version: wall plate (1), power supply unit (2), wall box (3), horizontal arm (4), oscillating arm (5), fork (6), lamp head (7), function control keyboard (8), sterilizable handle (9), power supply plug (10). |
| See drawing 121 | CEILING SINGLE version: ceiling cover (1), ceiling anchorage tube (2), power supply unit (3), horizontal arm (4), oscillating arm (5), fork (6), lamp head (7), function control keyboard (8), sterilizable handle (9). |
| See drawing 122 | CEILING DOUBLE version: ceiling cover (1), ceiling anchorage tube (2), power supply unit (3), double horizontal arm (4), oscillating arm (5), fork (6), lamp head (7), function control keyboard (8), sterilizable handle (9). |

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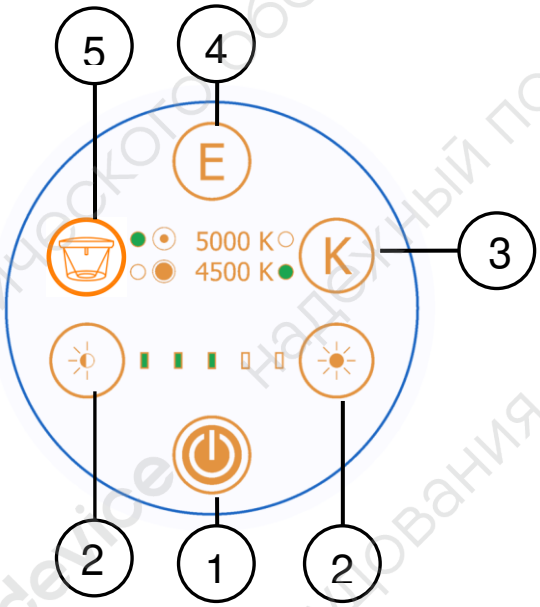


## 5.2 Description of operation

Control keyboard

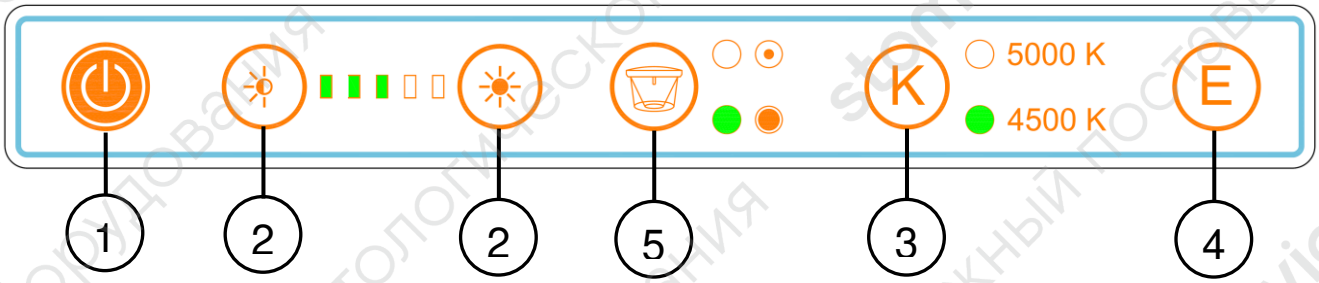
Product control is by means of the control keyboard positioned on the fork. By pressing the keys, the following functions are started:

- 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): dental care function. Function available only when the lamp is switched off
- Light field diameter selection (5), increase or decrease the light field diameter.



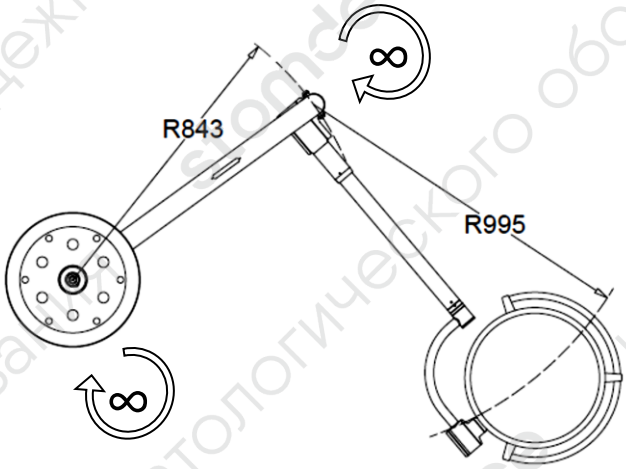

Remote control panel

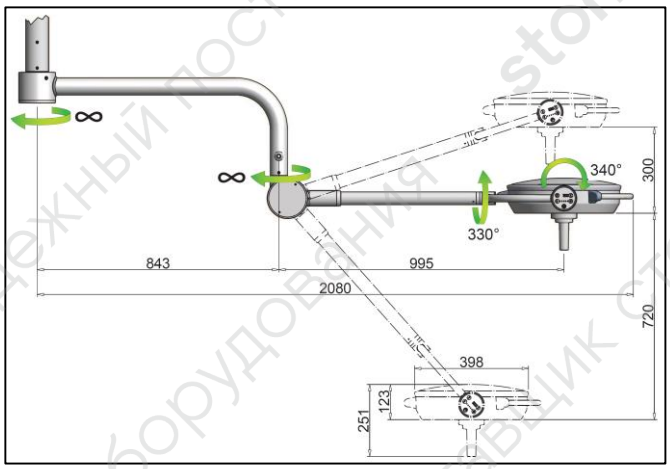
As optional, the lamp can be equipped by a wall control panel: an additional keyboard control all the functions listed above.



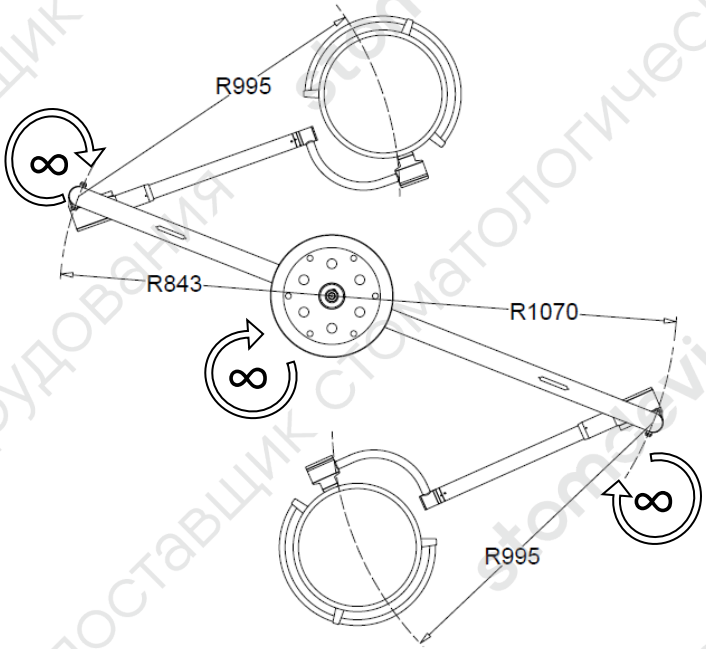
## 5.3 Product handling

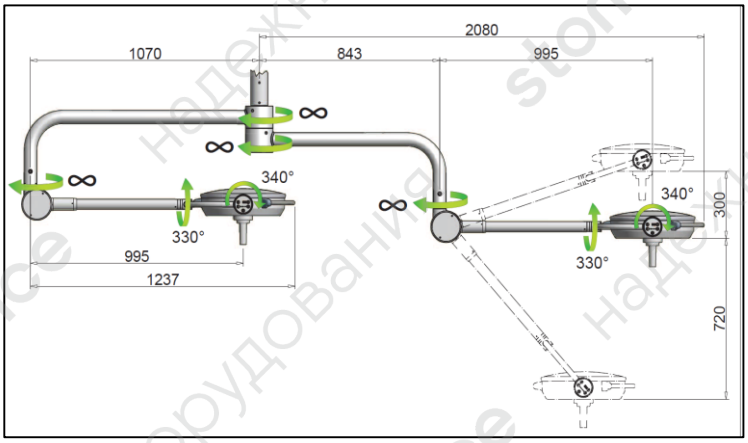
***SINGLE ceiling model***



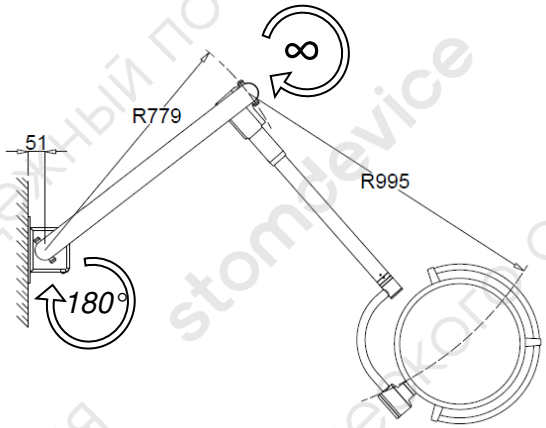

***DOUBLE ceiling model***



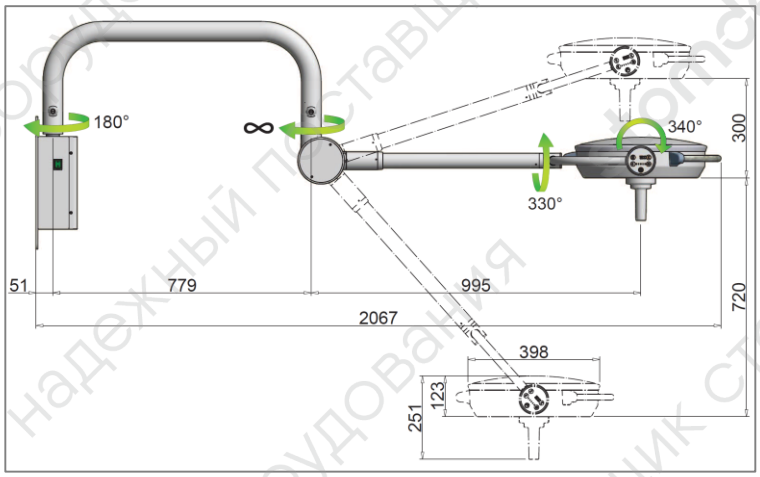



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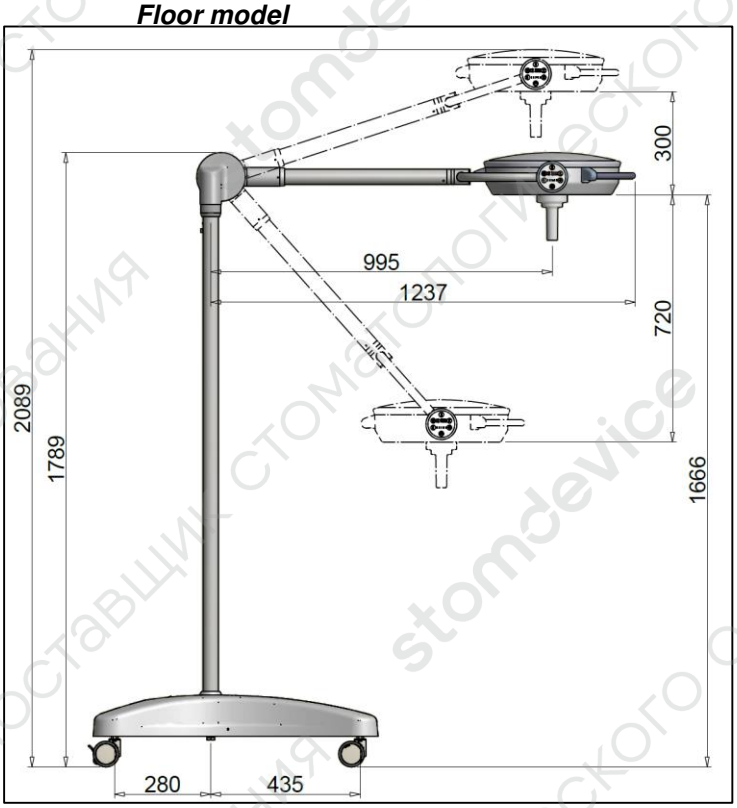


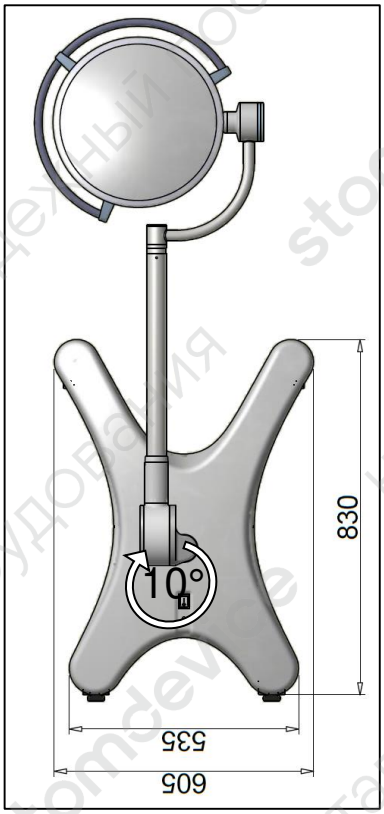



***Wall model***




***Floor model***



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



*Fig.A*

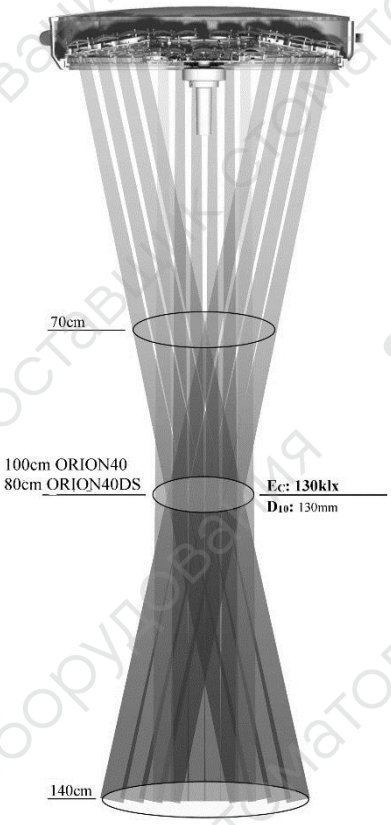


*Fig.B*

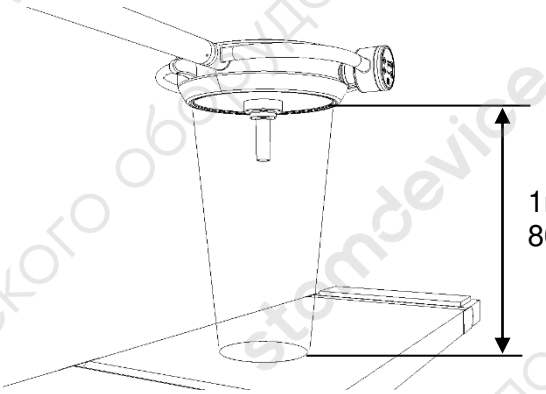
By pressing the keys on the membrane keyboard, the previously described control functions are started (fig. C)



*Fig.C*




**RECOMMENDED WORK DISTANCE**




To optimize light intensity, the product ORION40 is best used at a distance of 1 m, and the product ORION40DS at a distance of 80cm.

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

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# 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.

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## 6.2 Product disinfecting

Frequency — The Product is best disinfected daily.

| | |
|---|---|
| ⚠ | **WARNING – Electric shock hazard** |

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.

| | |
|---|---|
| ⚠ | **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.

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.

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## 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 handpiece safety key and remove the handpiece.
- insert the handpiece up fast and turn it until it fastens on and rotation is blocked.

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.

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# 7 Adjustments and maintenance

## 7.1 Setting the swinging arm

See drawing 123

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.

Loosen the two stop dowels (1) which secure the cover (2) and move this forward. Fit a pin (3) with max diameter of 7 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 swing arm drops, this means the elastic force of the spring is insufficient:

turn the lever downwards and load the spring.

If the swing arm continues to lift 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 123

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 in which it is put, 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 clockwise the screws (4) and (5) of the horizontal arm.

Fork brakes

To increase the head braking force, rotate clockwise the dowels (6 and 7) of the brake with an Allen key.

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## 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.<br>If these are not properly fastened, adequately tighten. |

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## 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 | |
|---|---|---|
| **LAMP** | **ORION40** | **ORION40DS** |
| Sterilisable grip | Z200518 | Z200518 |
| Electronic board | Z300632-PL30E | Z300632-PL81 DUAL |
| Membrane keyboard | Z300227 | Z300227 |
| 0/I switch (for floor and wall versions) | Z300016 | Z300016 |
| Switching power supply unit | Z170180 | Z170180 |

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# 8 Technical properties

| Technical details of light | ORION 40 | ORION 40DS (a 80cm) |
|---|---|---|
| Illumination $E_c$ ± 10% (5.000°K) [Lux] | 130.000 | 130.000 |
| Illumination $E_c$ ± 10% (4.500°K) [Lux] | 80.000 | 100.000 |
| Illumination $E_c$ at 80 cm ± 10% (5.000°K) [Lux] with function Dental care | N/A | 60.000 |
| Illumination $E_c$ at 80 cm ± 10% (4.500°K) [Lux] with function Dental care | N/A | 50.000 |
| Colour temperature (±5%) [K] | 4.500 / 5.000 | |
| Colour rendering index $R_a$ [-] | 96 | |
| $R_9$ | 90 | |
| Focus | Fix | |
| Light field diameter variable from - to | 16 - 28 | |
| Light range diameter $d_{50}$ [mm] | 80 | 70 |
| Light range diameter $d_{10}$ [mm] | 160 | 130 |
| Lighting depth L1+L2 [cm] | 35+18 | |
| Max irradiation [W/m$^2$] | 299 | |
| Irradiation / Illumination [mW/m$^2$lx] | 2,3 | |
| Max irradiation in UV [W/m$^2$] | 0,002 | |
| Focalization from the handling | No (electronical focusing) | |
| **Power connection details** | | |
| Primary alternate voltage [Volt ac] | 100÷240 | |
| Frequency [Hz] | 50/60 | |
| Power input [VA] | 70 | |

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| | |
|---|---|
| Light source | N°30 Led x 1.4W |
| Duration of LED diode light source [hr]<br>(this figure can vary according to power peaks and operating frequency) | 50.000 |
| Light intensity control [%] | 50 – 100 |
| **General data** | |
| Colour | RAL 9003 |
| Directive | 93/42EEC and 2007/47/EC |
| Standards | IEC 60601-2-41 |
| Classification of Medical Device | Class I |
| **Dimensions** | |
| Diameter of lamp body [cm] | 40 |
| Diameter of poly-elliptical reflectors [cm] | 5,5 |
| Light emission surface [$cm^2$] | 712 |
| Weight of floor, ceiling, wall, double ceiling surgical light [kg] | 35; 32; 27; 55 |
| **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 CE Declaration of Conformity of the Manufacturer

The company:
**TECNO-GAZ S.P.A. Strada Cavalli n. 4 - CAP 43038 - Sala Baganza – Parma – ITALY**
Declares under its own responsibility that the Product (Medical lighting device for surgical and diagnosis use):

| **ORION 40DS** |
|---|
| APPLICARE ETICHETTA |

made by TECNO-GAZ S.P.A., complies with Annex VII of Directive 93/42/EEC dated 14/05/1993, and subsequent amendments (including Directive 2007/47/EC dated 05/09/2007) and the following standards:

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

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

Name: Paolo Bertozzi
Position: Managing Director

Sala Baganza, 19-04-2012



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# 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<br>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<br>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.<br><br>**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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions<br><br>IEC 61000-3-3 | Conforming | |

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| Immunity test | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment-guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 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<br>for power supply unit<br><br>+/- 1 kV<br>for input/output lines | +/- 2 kV<br>for power supply lines<br><br>+/- 1 kV<br>for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | +/- 1 kV<br>differential mode<br><br>+/- 2 kV<br>common mode | +/- 1 kV<br>differential mode<br><br>+/- 2 kV<br>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% $U_T$<br>(>95% dip in $U_T$)<br>For 0,5 cycle<br><br>40% of $U_T$<br>(60% dip in $U_T$)<br>For 5 cycles<br><br>70% of $U_T$<br>(30% dip in $U_T$)<br>For 25 cycles<br><br><5% $U_T$<br>(>95% dip in $U_T$)<br>For 5 sec | <5% $U_T$<br>(>95% dip in $U_T$)<br>For 0,5 cycle<br><br>40% of $U_T$<br>(60% dip in $U_T$)<br>For 5 cycles<br><br>70% of $U_T$<br>(30% dip in $U_T$)<br>For 25 cycles<br><br><5% $U_T$<br>(>95% dip in $U_T$)<br>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. | | | |

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

**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.

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# 10 Warranty Certificate

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| Garanzia sul prodotto | 1. I prodotto è coperto da garanzia per un periodo di 12 mesi, incluse le parti elettriche. |
| Decorrenza garanzia | 2. La garanzia ha inizio dalla data di installazione della lampada presso il cliente solo ed esclusivamente se l'installazione è effettuata da personale TECNO-GAZ. In tutti gli altri casi la garanzia decorre dalla data di spedizione della lampada dal magazzino TECNO-GAZ al cliente. |
| Data DDT | 3. In caso di contestazione, è ritenuta valida la data indicata sul "Documento Di Trasporto" che accompagna la merce. |
| Riparazioni | 4. La riparazione o la sostituzione, in garanzia, di un particolare, è effettuata per cause ben accertate di fabbricazione e ad insindacabile giudizio della ditta TECNO-GAZ. La garanzia non comprende la trasferta del personale, le spese d'imballaggio e trasporto. |
| Usura standard | 5. Sono esclusi dalla garanzia i componenti soggetti a normale usura (a titolo esemplificativo e non esaustivo: lampadine alogene, fusibili, relè, cuscinetti, etc.) |
| Esclusioni | 6. Non sono compresi nella garanzia:<br>- avarie e difetti dovuti ad errori di installazione;<br>- avarie o vizi causati da trascuratezza, negligenza, uso anormale dell'apparecchio o altre cause non imputabili al costruttore;<br>- gli interventi per difetti presunti o verifiche di comodo. |
| Sostituzione | 7. Non è riconosciuto il diritto alla sostituzione della Lampada completa.<br>8. La garanzia non comporta alcun risarcimento danni diretti o indiretti di qualsiasi natura verso persone o cose, dovuti all'inefficienza della lampada. |
| Uso improprio | 9. TECNO-GAZ non risponde di guasti o danni causati dal prodotto usato impropriamente o sul quale non sia praticata la manutenzione ordinaria o siano trascurati gli elementari principi del buon mantenimento (negligenza). |
| Fermo d'uso | 10. Non è riconosciuto nessun risarcimento per fermo Lampada. |
| Decadimento garanzia | 11. La garanzia decade automaticamente qualora la lampada sia manomessa, riparata o modificata dall'acquirente o da terzi non autorizzati da TECNO-GAZ. |
| Interventi tecnici | 12. Per gli interventi, l'acquirente deve rivolgersi unicamente al rivenditore oppure ai centri d'assistenza indicati da TECNO-GAZ. |

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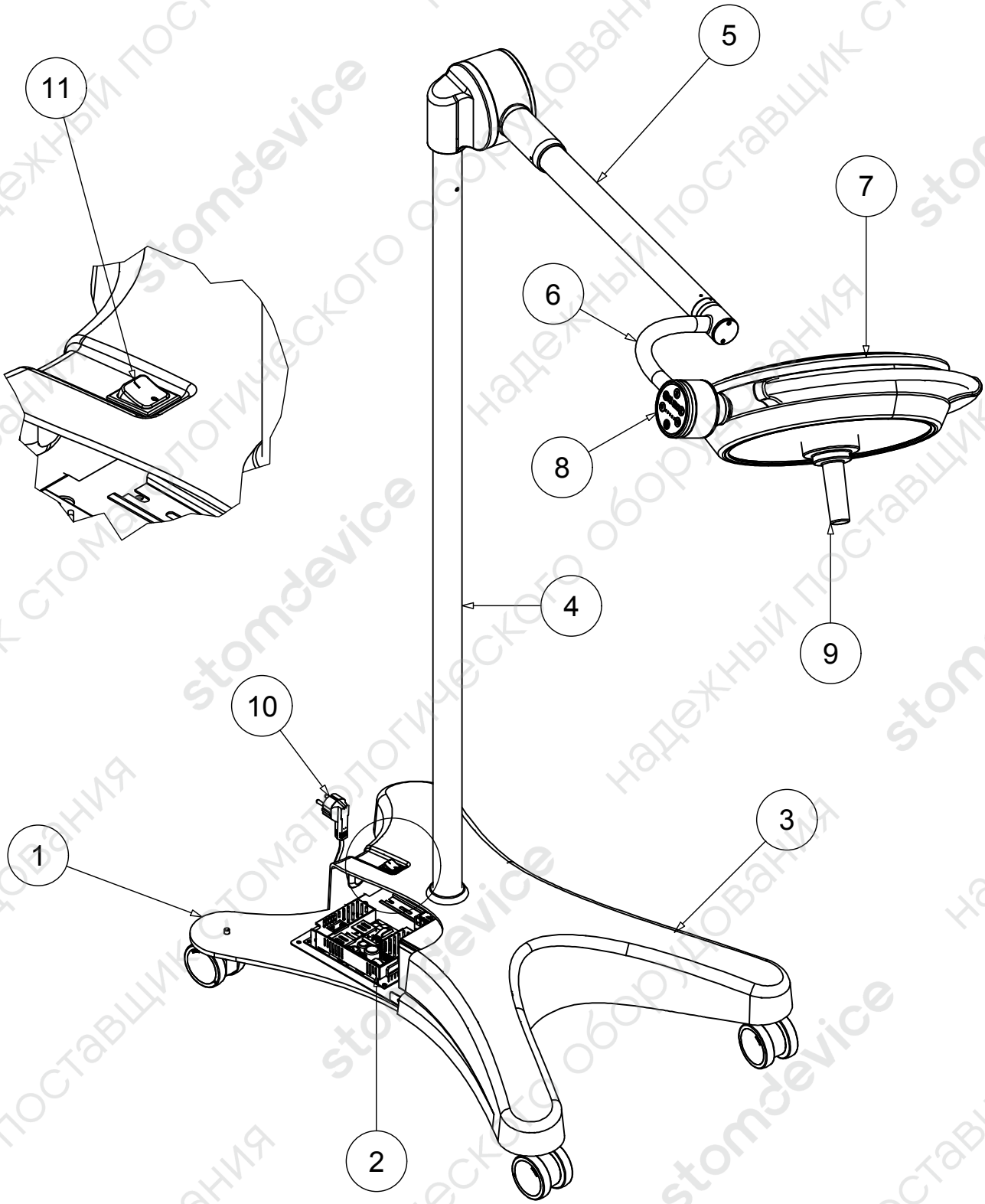


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|---|---|
| Sostituzioni comp. | 13. I componenti sostituiti in garanzia devono essere restituiti a TECNO-GAZ in porto franco. |
| | 14. La mancata restituzione comporta l'addebito del costo del particolare al richiedente. |
| Mancata restituzione | 15. La mancata restituzione comporta l'addebito del costo del particolare al richiedente. |
| Ritiri | 16. TECNO-GAZ non accetta rientri da utilizzatori finali. |
| Riparazioni | 17. Il rientro in TECNO-GAZ per riparazione, deve essere gestito dal rivenditore o dal centro d'assistenza scelto dall'utilizzatore finale in conformità allA procedurA commercialE CM-P-003 intitolata " GESTIONE DELLE RICHIESTE DI RIENTRO, RIPARAZIONE, SOSTITUZIONE DEI PRODOTTI TECNO-GAZ E RECLAMI CLIENTE". |
| Autorizzazioni al ritiro | 18. Il rientro in TECNO-GAZ deve essere documentato e autorizzato come da procedure interne. |
| Documenti tecnici | 19. I prodotti che rientrano in TECNO-GAZ, devono avere allegata la documentazione d'autorizzazione al rientro e un documento in cui sia descritto il guasto. |
| Spedizione reso | 20. Tutti i prodotti in riparazione devono essere spediti a TECNO-GAZ in porto franco e adeguatamente imballati (è obbligo utilizzare l'imballo originale). |
| Non responsabilità | 21. Il costruttore non si considera responsabile agli effetti della sicurezza, dell'affidabilità e delle prestazioni dell'apparecchio se:<br>- il montaggio, aggiunte tarature, riparazioni, non sono effettuate da persone preventivamente autorizzate dalla TECNO-GAZ;<br>- l'impianto elettrico dell'ambiente (locale) in cui è eseguita l'installazione non è conforme alle norme CEI 64-8 (norme per impianti elettrici per locali adibiti ad uso medico) e norme similari;<br>- l'apparecchiatura non è impiegata in conformità alle istruzioni d'uso. |

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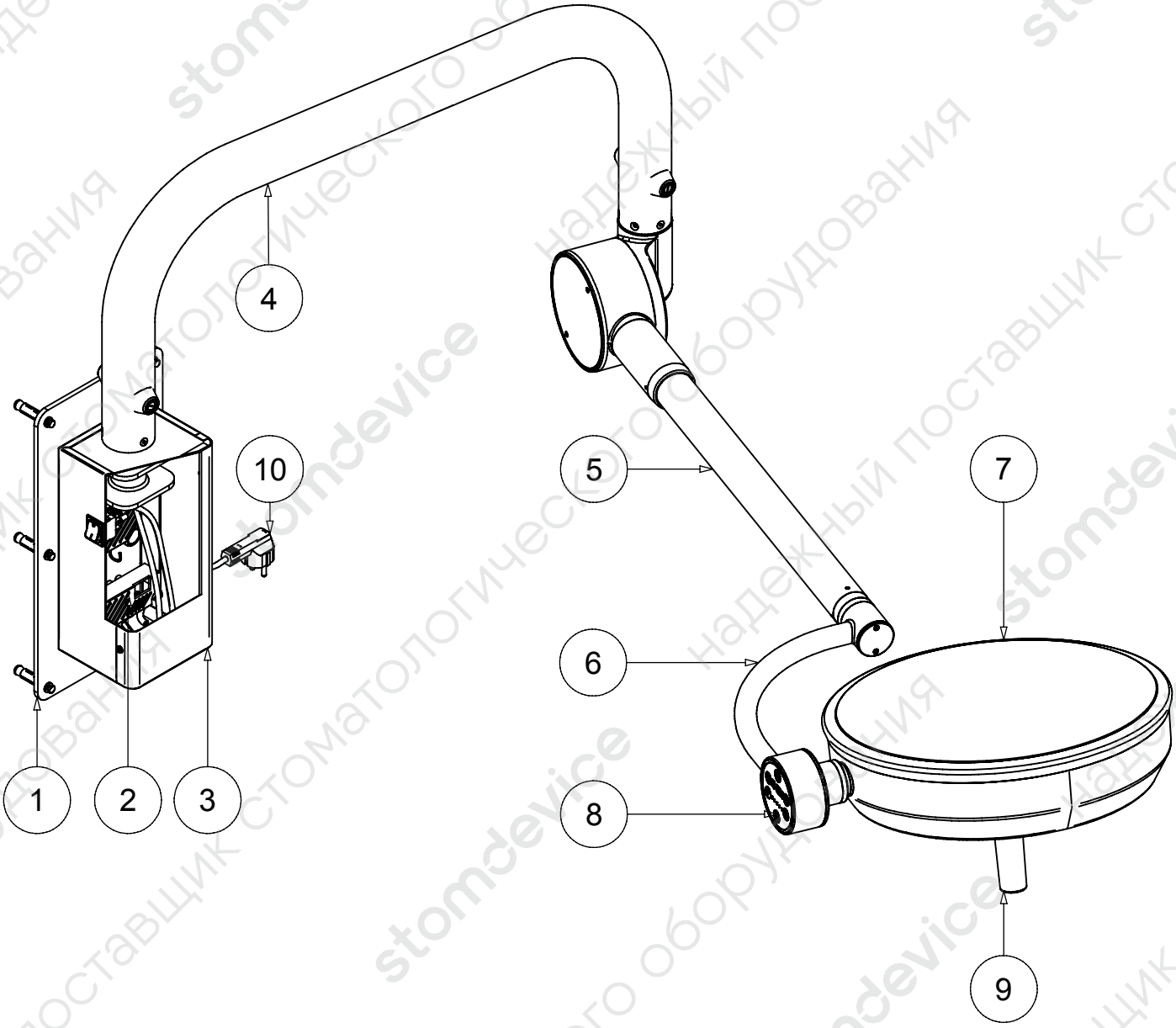


## Note




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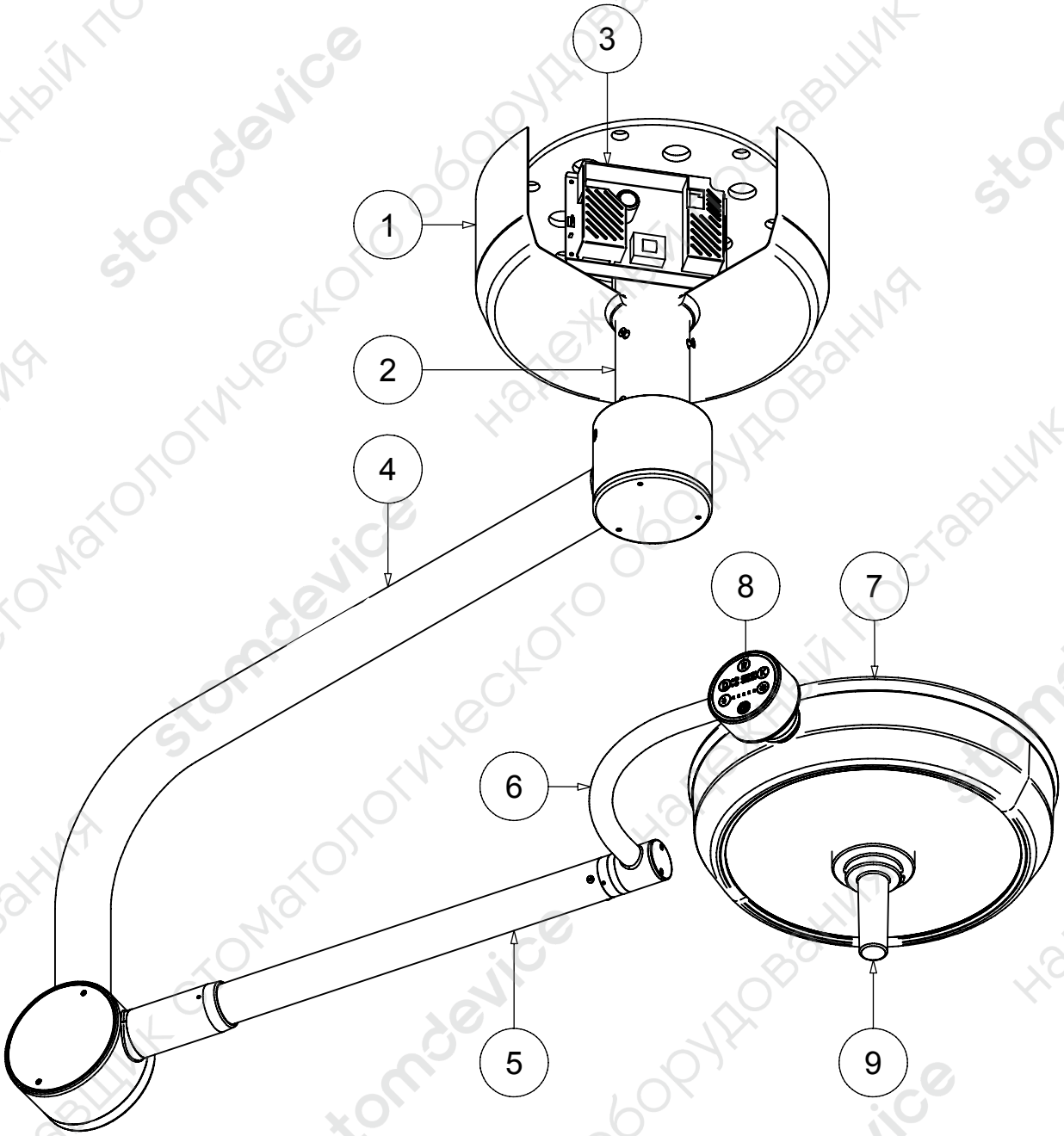
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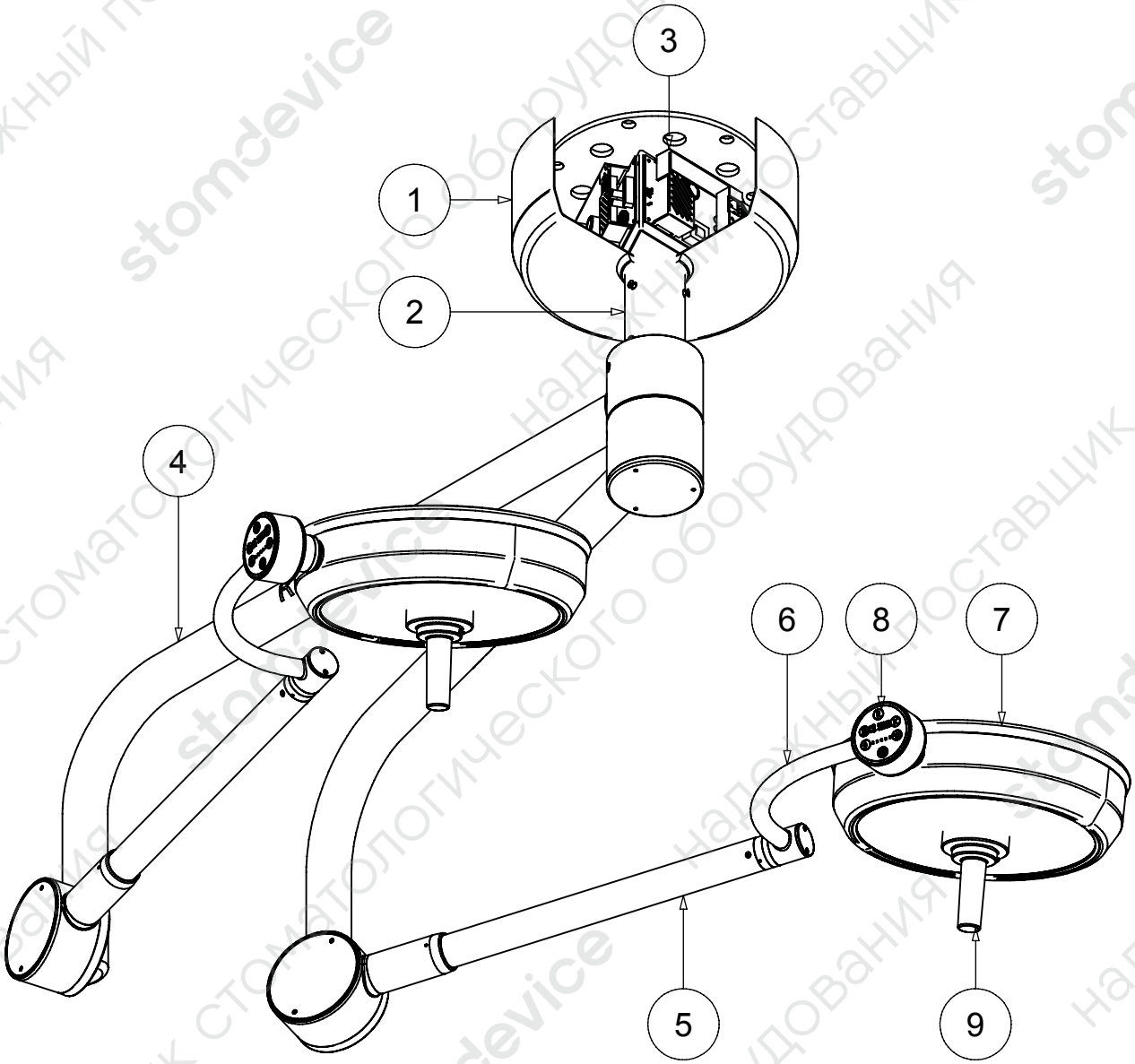
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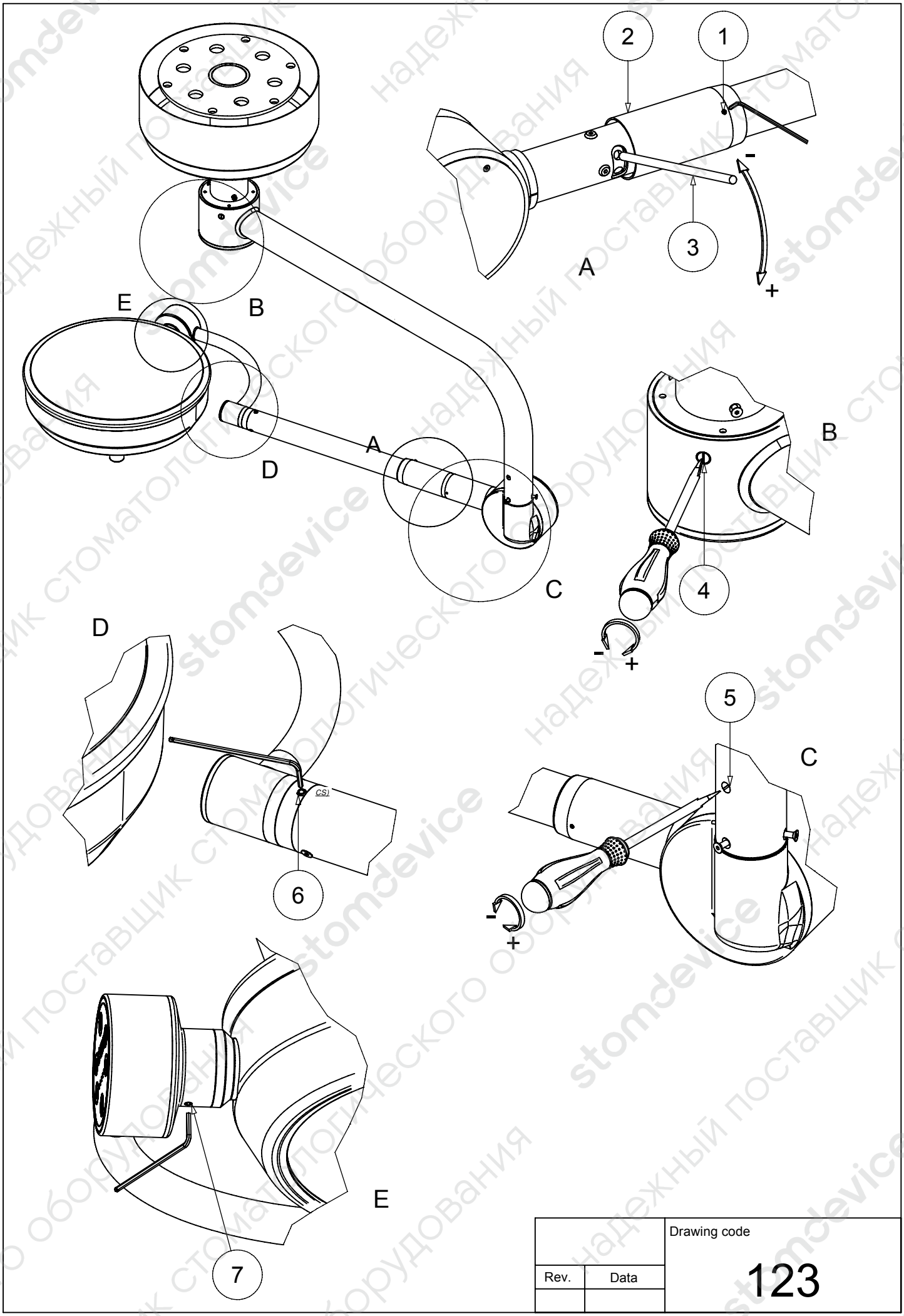
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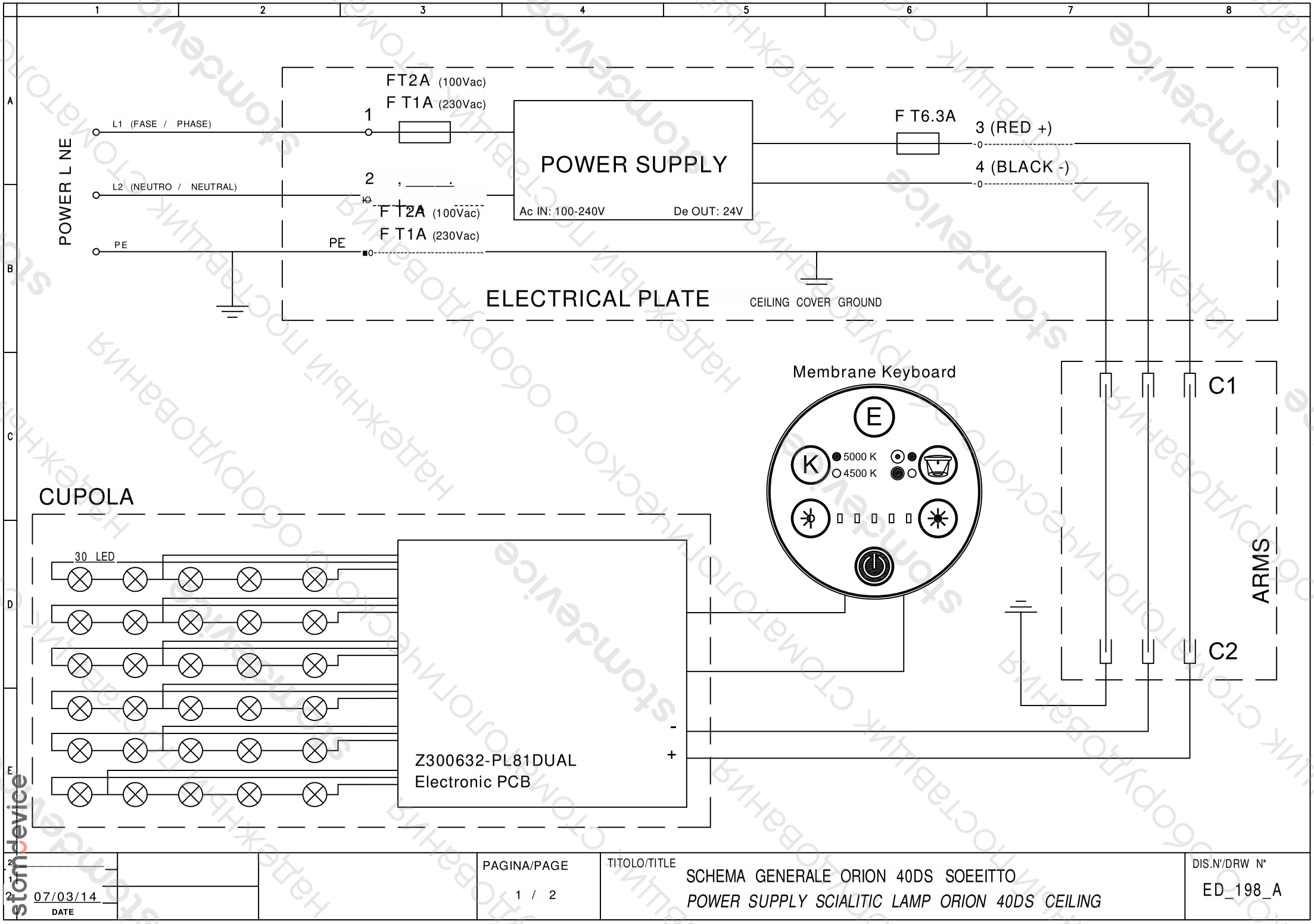

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RETE ELETTRICA /
POWER LINE

L1 (FASE / PHASE)

*L2* (NEUTRO / NEUTRAL)

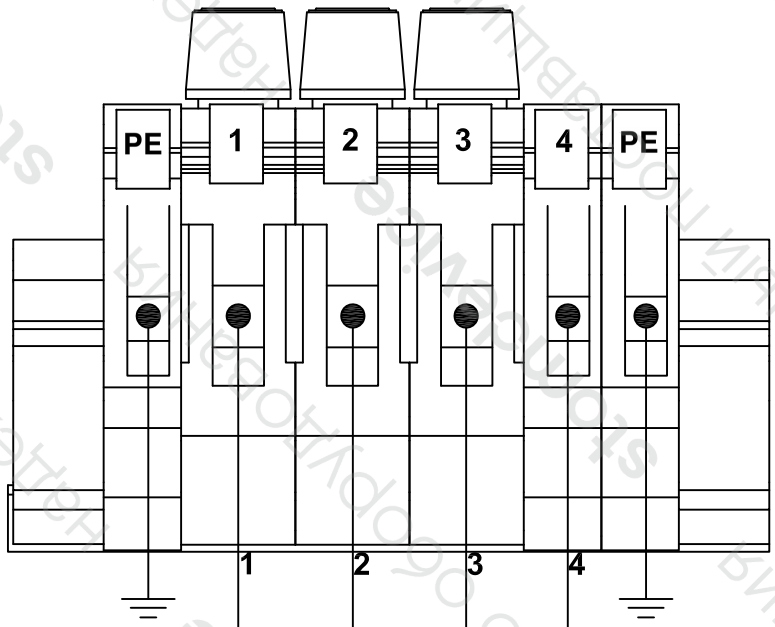
PE

STRUTTURA/ STRUCTURE

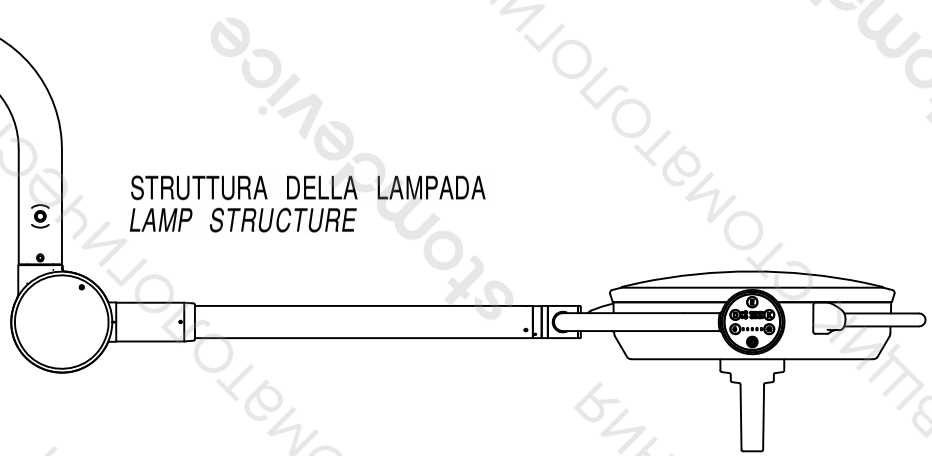
-24Vdc

+24Vdc

PE

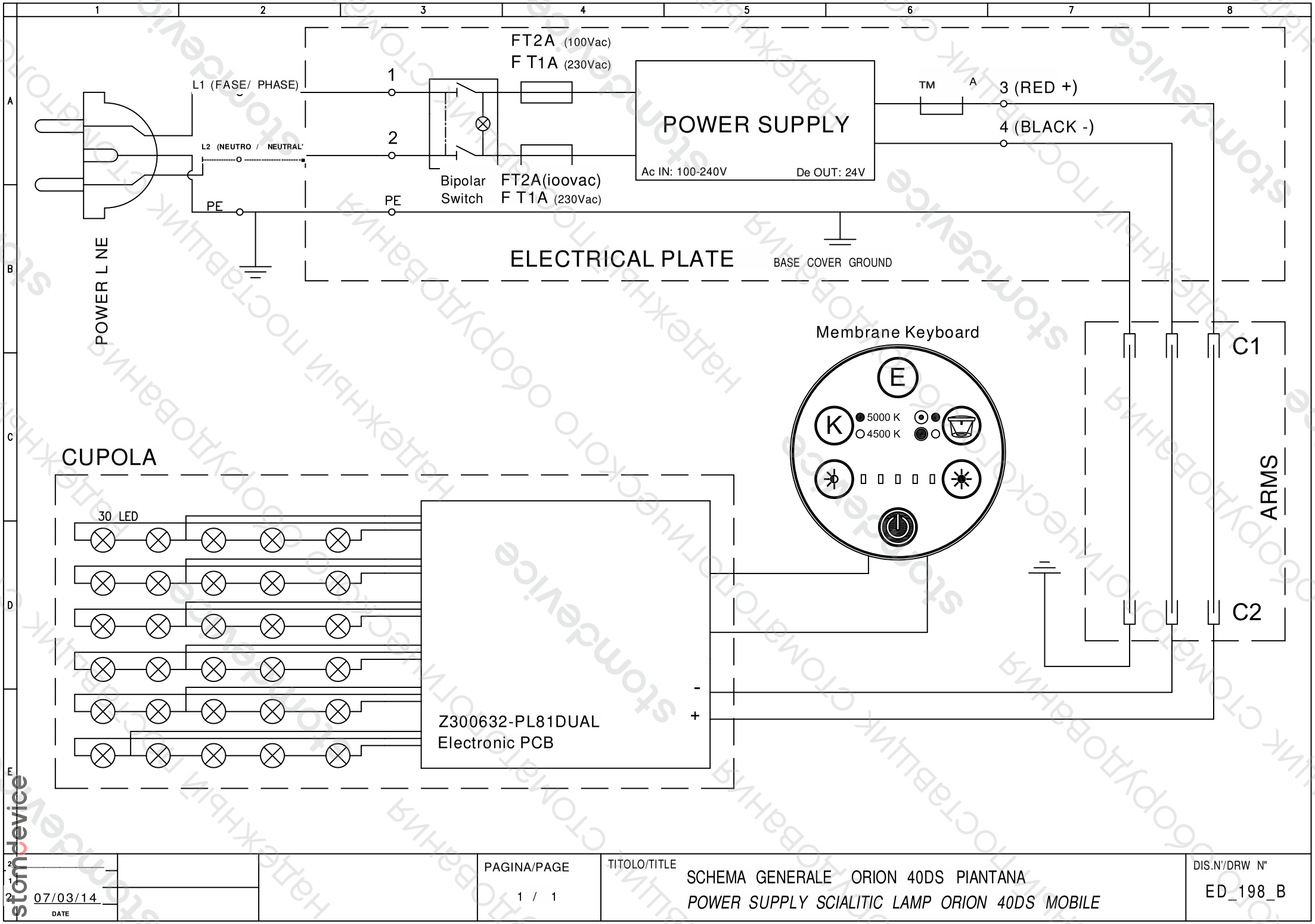



STRUTTURA DELLA LAMPADA
*LAMP STRUCTURE*



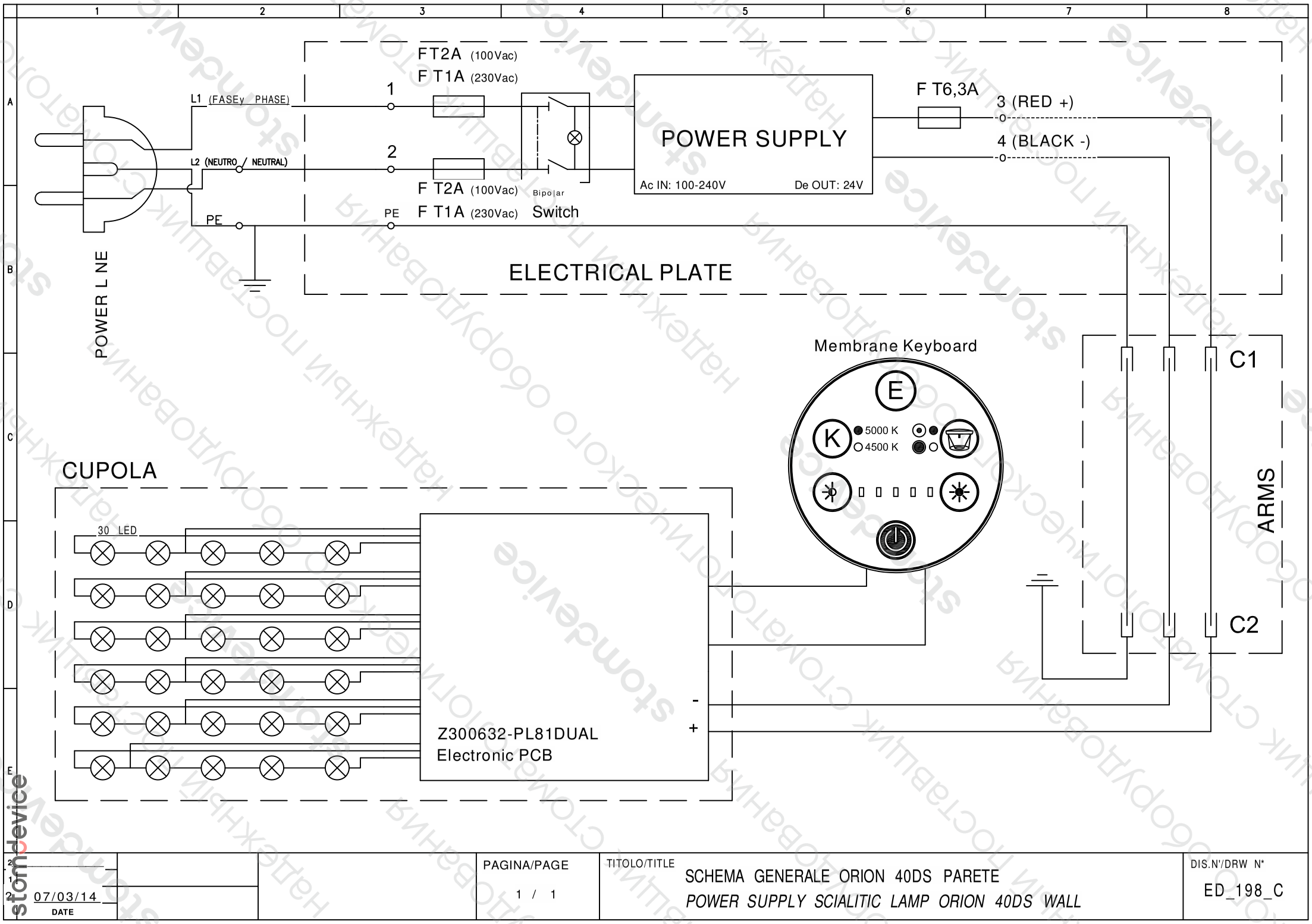
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| 07/03/14 DATE | | | PAGINA/PAGE 1 / 1 | TITOLO/TITLE SCHEMA GENERALE ORION 40DS PIANTANA *POWER SUPPLY SCIALITIC LAMP ORION 40DS MOBILE* | DIS.N°/DRW N° ED_198_B |

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| 07/03/14 DATE | | | PAGINA/PAGE 1 / 1 | TITOLO/TITLE SCHEMA GENERALE ORION 40DS PARETE *POWER SUPPLY SCIALITIC LAMP ORION 40DS WALL* | DIS.N'/DRW N* ED_198_C |

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