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# Installation manual for surgical light system

## ORION 40 ORION 40DS

ORION 40 Mobile (LC001LRA)
ORION 40 Wall(LC002LRA)
ORION 40 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)



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#### Introduction

Dear user,

You are kindly invited to read this manual carefully before proceeding to use the Product in order to safeguard yourself and other people from any injuries.



This appliance is a Class 1 medical device pursuant to European Directives on medical devices (MDD) 93/42/EEC, Annex IX, and 2007/47/EC.

#### Conformity

The manufacturer declares that this product is in compliance with Annex I (essential requirements of Directive 93/42/EEC and certifies such conformity by affixing the CE mark.

The Product is classified in risk group 1 according to IEC 62471 standard (Photobiological Safety of Lamps).

#### Validity of manual

This operator's manual refers to the following products:

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

#### 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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Right to make changes TECNO-GAZ reserves the right to change, cancel or otherwise amend the data contained in this document at any time and for any reason without prior notice inasmuch as TECNO-GAZ is constantly seeking new solutions which lead to product evolution. TECNO-GAZ therefore reserves the right to make changes to the supplied Product in terms of shape, fittings, technology and performances.

**Translations** 

With regard to translations into languages other than Italian, reference shall always be made to the Italian edition of this operator's manual.

#### **IMPORTANT**

Please find attached a warranty coupon to be filled in and sent back to TECNO-GAZ. Such coupon completes:

- the traceability of the medical device as required by the MDD
- the Cover on the Product
- the confirmation of the complete reading of the manual by the installer as a necessary and sufficient clause so that he/she is declared FIT for the installation of the equipment (having all the necessary information for the installation through this manual)



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#### 1 General information

#### **IMPORTANT**

Product

The ME (Medical-Electrical) EQUIPMENT to which this manual refers is a LAMP for Operating Theatre or SYSTEM of LAMPS for Operating Theatre. For easier description such ME EQUIPMENT will be indicated in this manual with the name of "Product".

**CAUTION** 

This manual is an integral part of the Product as required by European directive 93/42/EEC and 2007/47/EC. Always keep this installation manual close to the lamp.

CAUTION

- The Product is not suitable for use in explosion-risk areas
- The Product is not suitable for use in the presence of inflammable mixtures of anaesthetics with air, oxygen or NO<sub>2</sub> (laughing gas)

CAUTION

TECNO-GAZ disclaims all liability for any injuries to persons or damage to things caused by the installation, maintenance or use of the Product by unqualified operators. By qualified operator is meant whosoever has attended a course relating to the installation, maintenance and use of the product organised by TECNO-GAZ or, alternatively, whosoever has carefully read this installation manual.

**CAUTION** 

The only party responsible for Product installation is the buyer's customer itself; no cost or responsibility relating to installation and/or commissioning of the Product shall therefore be traced back and/or in any case attributed to TECNO-GAZ.

**CAUTION** 

The masonry works involving the preparation of the ceiling or wall, for Products to be installed on the ceiling or wall respectively, and the electric works for preparing the power supply system for the Product shall be of a sturdy and safe nature and completed in a workmanlike manner by suitably trained personnel.

By way of example only, without limitation, the following professional figures are deemed adequately trained:

- ⇒ Building Engineer, Draughtsman, Building firm duly registered in the professional Register (for masonry works)
- ⇒ Electro-technician qualified to exercise the profession of electrician (for the electrical works)



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**CAUTION** Electrical installation must be made in compliance with the IEC 60364-7-710

standard and any national regulations and must contemplate protection with fuses or thermal magnetic disconnection switch and the fitting of a master switch able to ensure the complete interruption of the power supply to the

Product.

**CAUTION** The Product is a ME EQUIPMENT and consequently falls within the field of

application of the EN:62353 standard. Consequently, any operation performed on the Product must be carried out in compliance with the

EN:62353 standard, where applicable.

#### 1.1 Qualification of operators

Operator qualification This paragraph describes the requirements and qualifications which the

operators involved in the various stages of Product life and use must

possess.

Installation the Product must be installed by a qualified Installer and/or Technician

Use Professional medical personnel

Routine maintenance 
Qualified technician in possession of professional technical requirements

Special maintenance Qualified technician in possession of professional technical requirements

Assistance Dealer who has attended a technical course on the Product organised by the

manufacturer

Cleaning Properly trained medical and paramedical personnel

Demolition at the end of the Product life cycle, dispose of the used Product in an

environment-friendly way and in compliance with the national directives

applicable to waste disposal

# 1.2 Packaging, transport, storage and characteristics of the installation site

Packaging Boxes containing the whole structure with installation instruction manual and

user's manual.

Transport Transport is carried out by any road haulage contractor as long as they

respect the following characteristics:

Temperature (°C): -15 / +60

Humidity: 10 / 75 %

Atmospheric pressure (h/Pa): 500 / 1060



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Storage

The devices packaged must be stored (warehoused) in a dry place and at the following temperature:

Temperature (°C): -15 / +60

Humidity: 10 / 75 %

Atmospheric pressure (h/Pa): 500 / 1060

Installation site

The site appointed for the installation of the equipment must have the following characteristics:

Temperature (°C): +10 / +40

Humidity: 30 / 75 %

Atmospheric pressure (h/Pa): 700 / 1060

#### 1.3 Graphic symbols used in the installation manual

In this installation manual and on the Product important directions are marked by means of symbols and identifying words.

Identifying words such as DANGER, WARNING or CAUTION indicate the classification of the risk of damage.

**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.

**CAUTION** 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)



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#### 1.4 Graphic symbols used on the package

The symbols present on the boxes of the packages are listed below:



High side of the package



Maximum number of packages stackable



Breakable package



Humidity-suffering package



Do not overlap packages with pallet



Weight of the package

#### 1.5 Other graphic symbols used on the Product

The symbols present on the Product are listed below:



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



Graphic symbol proving the CE marking of the product



Symbol indicating the manufacture date (month and year)



Fuses used by the device



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#### **Warranty Certificate** 1.6

Cover on the product Starting date of the

1. The product is covered for a period of 12 months, including electric parts.

warranty

2. The warranty becomes effective from the lamp installation date at the customer's premises exclusively if the installation is carried out by TECNO-GAZ personnel. In any other case the warranty becomes effective from the lamp dispatch date from TECNO-GAZ warehouse to the customer's premises.

Transport Document

Date

3. In case of contention, the date specified on the "Transport Document" given with the goods is considered valid.

Repairs

4. Repair or replacement, under guarantee, of a part is carried out for wellassessed manufacture reasons and at the unchallengeable discretion of TECNO-GAZ. The warranty includes personnel's travels, packaging and transport charges.

Standard wear

5. The warranty does not include components subject to normal wear and tear (including but not limited to: halogen lamps, fuses, relays, bearings, etc.)

Exclusion

- 6. The warranty does not include:
  - failure and faults due to improper installation;
  - failure or defects caused by carelessness, negligence, abnormal use of the device or other causes not attributable to the constructor;
  - interventions due to presumed defects or convenient inspections.

Replacement

- 7. The right to replace the whole Lamp is not acknowledged.
- 8. The warranty does not grant any indemnity for direct or indirect damage of any nature to people or things, due to the inefficiency of the lamp.

Improper use

9. TECNO-GAZ can not be held responsible for failure or damage caused by improper use of the product, non-maintenance or neglect of the basic principles of good maintenance (negligence).

Use stop

10. No indemnity is acknowledged for Lamp stop.

Loss of warranty

11. The warranty is lost automatically if the lamp is tampered with, repaired or modified by the buyer or third parties not authorized by TECNO-GAZ.

Technical interventions 12. For the interventions, the buyer must apply to the retailer only or the service centers as recommended by TECNO-GAZ.

Replacing components 13. The components replaced under guarantee must be returned to TECNO-GAZ carriage free.



Non-return

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14. The non-return implies the charge of the cost of the part to the applicant. 15. The non-return implies the charge of the cost of the part to the applicant.

Returns 16. TECNO-GAZ does not accept returns by final users.

Repairs 17. Only the retailer or the after-sales assistance centre chosen by the user

will be admitted to sent back to TECNO-GAZ the components to be repaired

according to the commercial procedure CM-P-003 called "MANAGEMENT

OF REQUEST FOR RESTITUTION, REPAIRING, REPLACEMENT OF

TECNO-GAZ EQUIPMENT AND CLIENT COMPLAINTS".

Authorization for returns 18. The returns to TECNO-GAZ must be documented and authorized as per

internal procedures.

Technical documents 19. The products returning to TECNO-GAZ must be attached with the return

authorization documents and a document describing the failure.

Return dispatch 20. All products under repair must be sent to TECNO-GAZ carriage free and

suitably packaged (it is compulsory to use the original package).

Non-responsibility 21. The constructor does not deem himself responsible for the safety,

reliability and performance of the device if:

the installation, additions, settings, repairs are not carried out by

people authorized in advance by TECNO-GAZ;

the electrical system of the installation site does not comply with the norms CEI 64-8 (norms for electrical systems in sites used as

medical premises) and similar norms;

the equipment is not used in accordance with the instructions for use.

### 2 Mechanical and electrical arrangement of the

#### site

The building and electrical arrangement works for the installation of the

product are the responsibility of the Final Customer.

#### 2.1 Mechanical arrangement of the site

The building slab arrangement works to install the product must be carried

out in a solid and safe way according to the standards by qualified

personnel.

NOTE

**DANGER** 



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By qualified personnel we mean, including but not limited to, the following professionals: Building Engineer, Surveyor, Building Contractor, duly registered with the Professional Register.

**DANGER** 

In case of improper drilling, e.g. drilling of a piece of iron of the reinforced concrete, the technician responsible for the construction will have to be informed for safety reasons, since the statics of the premises might be compromised.

**CAUTION** 

The ceiling must have a capacity of at least 300 Kg/m<sup>2</sup> and a thickness of at least 250 mm.

The installation site must be declared fit for use.

After making sure that the site used as medical premises complies with the requisites required above, proceed to the mechanical anchorage of the ceiling plate determining the type of ceiling for the anchorage and acting accordingly.

The installer assumes all responsibility, technical, civil and legal, related to the correct and suitable arrangement of the anchorage and installation of the Product, which must be carried out according to the standards.

Fixing positions

The Product is supplied complete with anchoring tube (tiges). Its length varies in relation to the height of the premises in which the Product is to be installed. The tiges is calculated to install the Product at a finished height from the floor to the cupola of the Product with the oscillating arm in a horizontal position of about 190/200 cm, save a different request from the client.

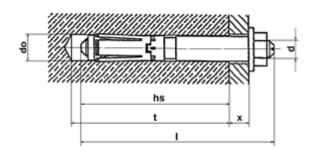
As a non-exhaustive example, we list some of the types of slab:

Reinforced concrete

Mechanical anchorage: fix the ceiling/wall plate by means of 6 screw anchors Hilti HSL-3-G M16/25 (M6/12 for wall version) following the directions given by the insert manufacturer scrupulously and listed below for information:



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Anchor tie-rod	do (mm)	t (mm)	hs (mm)	l (mm)	Mt (Nm)	SW (mm)	x (mm)
HSL-3-G M 16/25	24	125	100	163	80	24	25
HSL-3-G M 6/12	12	60	45	50	10	10	10

do Nominal diameter of the point

t Minimum depth of drilling

hs Minimum depth of insertion

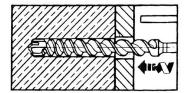
I Length of anchor tie-rods

Mt Closing torsion moment

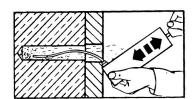
Sw Opening of the spanner

x Fixing height

- 1. Using the paper template attached to this manual, mark all the 6 fixing holes of the chosen point of the ceiling.
- 2. Make the first hole according to the safety anchor diameter.

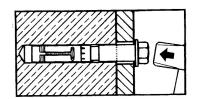


3. By means of a pump or vacuum cleaner with pipe terminal, remove the dust and the small drilling fragments from the hole.



4. The anchor tie-rod must be inserted into the hole keeping it to axis and using a hammer.

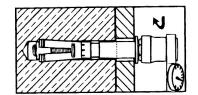
Attention! Consider the insertion depth.





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5. By the hexagonal dynamometrical spanner tighten with spanner adjusted at the value specified by the constructor of the anchors, opening the anchor.



The anchor tie-rod will immediately take the weight.

- 6. Make the remaining 5 holes and insert the anchor tie-rods as in previous points 2–5.
- 7. After one hour, tighten the anchor tie-rods again with the tightening torque prescribed.

Chemical anchorage: fix the anchoring tube with 6 chemical injection anchors mod. Hilti HIT-HY 150 with HAS following the directions given by the manufacturer Hilti scrupulously.

After arranging the chemical anchors to the CEILING/WALL, fix the anchoring tube with nuts and lock nuts for each tie-rod and tightening with the hexagonal dynamometrical spanner you will tighten with spanner adjusted at the value specified by the constructor of the anchors.

Clay-cement mix

In this case it is compulsory to enclose the slab sandwich-like by the Product plate and the counter-plate.

Plate and counter-plate must be enclosed to each other with M16 (M6 for wall version) steel threaded bars each, blocked at the upper and lower ends by respective washers, nuts and lock nuts.

#### 2.2 Electrical arrangement of the site

**DANGER** 

The electrical system arrangement works of the site used as medical premises to power the Product must be carried out in a safe way according to the standards by qualified personnel.

By qualified personnel we mean, including but not limited to, the following professionals:

Electro-technician licensed to practise as electrician

**DANGER** 

Before installing the Product check the following conditions:

the electrical system of the installation site must comply with the national laws and/or regulations in force for electrical systems in sites used as medical premises;



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the electrical system must be certified by an electrician licensed to issue the conformity certificate;

the verification of the grounding circuit must be certified as required by the norms in force.

#### 3 Product installation

Before installing the Product, make sure that all the packages are present and in good condition, without any transport-related damage, and that the contents correspond to what is specified above.

Claims will be considered only if the seller or the forwarder are informed immediately. Each claim must be in writing. Goods are always carried at the buyer's risk.

Keep the original package in case the lamp must be sent back.

#### 3.1 Ceiling version (single and double)

#### 3.1.1 Ceiling plate installation

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Incorrect levelling of the plate might cause the horizontal arm of the Product to make an unwanted move when passing from the non-balance condition to the balance one.

See drawing 13

Place the sheet template (drawing 12) (2) to the ceiling (1) fixing it with adhesive tape (3). Run the following 6 holes as prescribed in paragraph 2.1

See drawing 14

After making the holes (3) to the ceiling (1), set the plate (2) to the ceiling through the use of bolts (4) by always using the spirit-level (5).

See drawing 127

Make sure the power wires to the Product (1) reach the frame of the lamp power without creating interference with the anchoring tube.

Insert the electrical panel (2) on the Tiges tube and anchor it by tight the two M6x16 DIN912 screws (3) and relative serrated washers (4).

Place the electrical panel so that the slot (5) of the clamping frame corresponds with the M6 threaded hole (6) of the anchoring tube. Then, secure the electrical panel to the tube by tight the M6x16 DIN912 screw (7) and relative serrated washer (8).

If you need to fix the electrical panel to another location along the anchoring tube, place it at the desired position and anchor it by tight the two M6x16 DIN912 screws (3) and relative serrated washers (4); with a Ø5 drill (9), make an hole on the anchoring tube in correspondence of the slot of electrical panel clamping frame and, with an M6 tap (10), thread the hole itself.



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Finally, secure the electrical panel to the tube by tight the M6x16 DIN912 screw (7) and relative serrated washer (8).

**CAUTION** 

Depending on the type of ceiling (with false ceiling or less), place first the flat cover (11) or high (12). If the cover is in two pieces, you can install it later, but remember to previously insert the silicone ring (13) of the ceiling cover before to proceed with the installation of the lamp structure.

#### 3.1.2 Installation horizontal arm to anchoring tube

See drawing 112

Align the pivot of the horizontal arm structure (1) with the anchoring tube (2). Insert the power cables (3) along the tube and bring them out from the hole for the connection to the source.

Insert the pin into the tube up to combine the 3+3 holes at 120° of the flanges with the 3+3 holes at 120° of the pipe.

- Point to all 6 screws DIN7991 with hexagonal key N.3
- Screw tightly ONLY two screws in a vertical side with each other (4)
- Then complete the remaining tightening. This will prevent loosening over time during the continuous rotation of the Product.

#### 3.1.3 Oscillating arm (just for double lamp)

See drawing 113

Align the oscillating arm pin (1) with the tube of horizontal arm (2).

After connecting the plugs of the electric cables (3) with (4) among each other, insert the pin of the oscillating arm into the pipe of the horizontal arm and fix it by tight the three screws M5x12 DIN7991 (5) by use of hexagon key (6) N3.

To help the insertion of connectors pull the cables from the slot located on the top of the arm. Make a "S" bend to the cables and close they inside the tube using the bent plate (7). Close it screwing the two screws (8).

#### 3.1.4 Cupola installation (satellite option)

See drawing 130

Align the oscillating arm (2) with the pin of the cupola fork (1).

After connecting the terminals of the electric cables (3) with (4) among each other insert the pin of the fork into the pipe of the arm and screw in the three screws M4x8 DIN7991 (6)

Fix the fork to oscillating arm, positioning upwards the hole (5) that houses the friction regulating dowel.

In case of double lamp with satellite, install it following the steps above.

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#### 3.2 Wall version installation

#### 3.2.1 Wall plate installation

CAUTION

Incorrect levelling of the plate might cause the horizontal arm of the Product to make an unwanted move when passing from the non-balance condition to the balance one.

See drawing 1

By means of a spirit-level (4) position the template sheet (drawing 11) (2) on the wall (1) fixing it with adhesive tape (3).

Make the 6 holes following what is specified in paragraph 2.1

See drawing 2

After making the holes (3) on the wall (1), fix the plate (2) to the wall by means of bolts (4) always using the spirit-level (5).

Make sure that the power supply socket (6) of the Product can reach a power supply point of the room without creating interferences with the movements of the same and the operators.

#### 3.2.2 Horizontal arm installation

See drawing 3

Align the arm (1) with the pin of the box (2).

Then connect the terminals of the electric cables (3) with (4) among each other, respecting the polarity.

See drawing 4

Insert the arm into the pin so as to make the 3 holes at 120° of the arm fit with the 3 holes of the pin ring nut. Screw in, one at a time, the 3 screws M5x12 DIN7991 (1) using a 3 Allen key (2).

**CAUTION** 

Tighten the clutch (3) using a screwdriver (4) taking care to maintain the clutch well aligned with the threaded hole of the tube, so that this will screw without forcing. Rotate the slot of the screw clockwise to increase the friction effect and anticlockwise to reduce it.

#### 3.2.3 Cupola installation

See drawing 114

Align the oscillating arm (1) with the pin of the head fork (2).

After connecting the terminals of the electric cables (3) with (4) among each other insert the pin of the fork into the pipe of the arm and screw in the three screws M4x8 DIN7991 (5)

**!!ATTENTION!!** 

Fix the fork to oscillating arm, positioning upwards the hole (6) that houses the friction regulating dowel.



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#### 3.3 Mobile version

#### 3.3.1 Installing pipe on mobile base

See drawing 148

Mechanical connection

Remove the bolt (2) and washer (3) from the stand bottom (1).

Position the stand (1) on the base (4) fitting and inserting its pawl (5) into the plate seat (6), use the bolt and washer previously unscrewed to join the stand to the base and tighten thoroughly.

Insert the cover (7) from the stand top and the relevant connecting clip (8).



#### WARNING - Instability and falling danger

Failure to insert the detent into the appropriate seat present on the basement plate implies the risk of instability and the possible fall of the structure.

Joint 3-poles connector of the stem and 6-poles connector of the switch to the related connectors located on the electrical panel.

Then re-position base cover and ring and fix it tightening M4 screw located in the electrical board base.

#### 3.3.2 Installation of oscillating arm

See drawing 149

Align the pivot (2) of the oscillating arm with the hole of the tube (1) and join the electrical connectors (3) with (4) respecting the colours of the electrical cables.

Insert the pivot (2) of the arm into the hole of the stem (1) until you are able to align the hole (5) of the screw M6x45 DIN912 with the hole (6) of the pivot.

Screw down the screw (7) with a mechanical key and act on screw (8) to regulate the semi-rotation.

Place the cover (9) as showed and lock it screw down the screw (10) with a hexagon key of n.2.

#### 3.3.3 Cupola installation

See drawing 130

SEE POINT 3.1.4



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#### 3.4 Connecting to electrical plant



#### **DANGER - Danger of electric shock**

Before carrying out the electrical connections, check that the power line is NOT under tension in order to proceed with the montage safely.

The group of the Product power (support plate, transformer, terminal block) as explained above, is designed to be fixed on the anchoring tube (for the ceiling version) or it is located inside wall box (for wall version) or enclosed inside mobile base cover (for mobile version).

For *ceiling* version, to connect the line (F, N, T) to the cables of the Product (+,-, T) follow as written in the specific circuit diagram attached and as indicated from the labels placed on the electrical panel itself; in the case of *mobile* version, connect electrical cable with three pins from bent tube to base and electrical cable with six pins from cover to base, then you just need to connect the power cable plug to the network line; in the case of *wall* version you only need to connect the power cable plug to network line.



#### **CAUTION – Irreparable damage to the Product**

Fuse protection at the terminals of the electrical panel must be insert ONLY AFTER you have made all the mechanical and electrical assembly of the Product.

Any listing early can cause irreparable damage to the source of light. For long periods of non-use of the product to remove the fuses.

#### FOR MODEL ORION 40/40 DS:

n°2 T1A (primary) and n°1 T6,3A (secondary) for 230Vac supply n°2 T2A (primary) and n°1 T6,3A (secondary) for 100Vac supply

FOR MODEL ORION 40/40 DS+ORION 40/40 DS:

n°4 T1A (primary) and n°2 T6,3A (secondary) for 230Vac supply n°4 T2A (primary) and n°2 T6,3A (secondary) for 100Vac supply FOR MODEL ORION 40/40 DS BATTERY:

n°2 T2A (primary) and n°1 T10A (secondary) for both supply tensions

Fuses



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#### 3.5 First starting

#### **CAUTION**

It is now possible to power the Product to check its starting with light emission. To do so, it is necessary to:

- 1 close the circuit through the network switch upstream of the wiring (charged to the customer)
- 2 put on 'l' position the bipolar switch of the floor base cover and on the wall box (only on floor and wall versions)
- 3- press the I/O keyboard on the side of the fork

# 3.6 Installation verification and Product testing operations before use

#### **CAUTION**

The following notes are to be considered compulsory during verification of the installation, since they prove the correct verification of all the points set out. For such reason it is necessary to tick each point when it is treated.

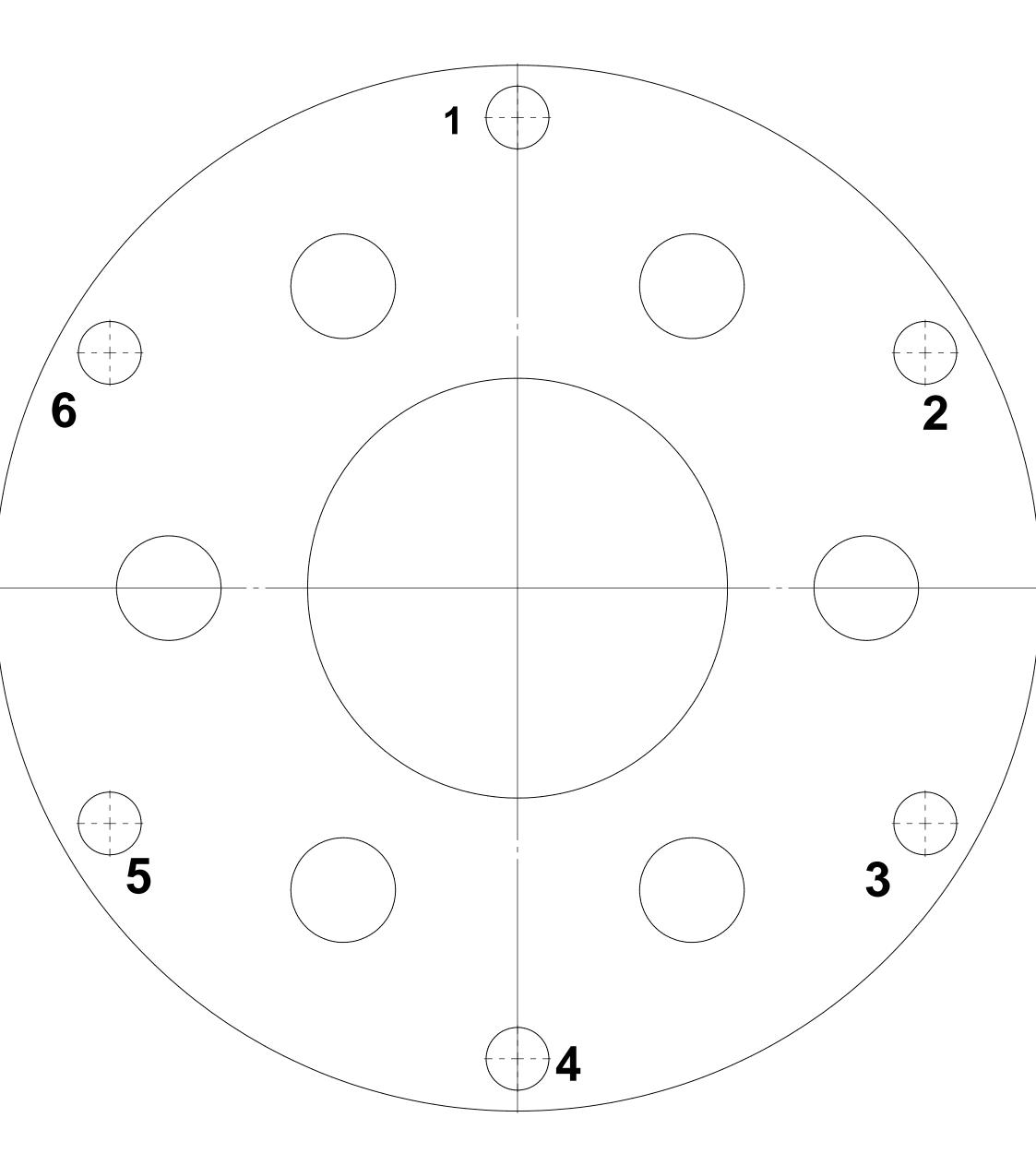
1.	Verify the suitability of the ceiling/wall on installation of the Product	
2.	By means of a spirit-level, verify the perpendicularity of the anchor	ing
	tube/wall plate	
3.	Put medium thread delay Loctite 243 on the six screws that fix	the
	Product to the anchoring tube and check the tightness as instructed.	
4.	Check the cupola light emission glass. If the light emission glass	is
	damaged or broken, glass splinters may fall. The Product must	be
	turned off immediately and no longer used until the failure is removed	.□
5.	Make sure that the movement mechanics work properly. Check	the
	mechanical working of the Product through direction and rotat	ion
	movements.	
6.	After starting, the Product must give light from the cupola	
	Seal and signature of the installer:	



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Note

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