Installation manual SATURNO-LED

LUMINAIRE FOR DIAGNOSIS





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Introduction

Please read this manual carefully before using the Product, so as to protect "the Technical Service Personnel" and "the Operator" from any injury.



This appliance is a Class 1 medical device pursuant to European Directive on medical devices (MDD) 93/42/EEC (Annex IX) as amended and integrated.

Compliance

The manufacturer declares that this Product complies 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:

SATURNO-LED in ceiling, floor, wall and double ceiling versions

Customer Service

The customer service is at your disposal in case of Product details, information concerning its use, identification of spare parts being required and for any other queries you might have concerning the appliance, for ordering spares and for matters relating to assistance and warranty.

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Translations

The original language of this manual is ITALIAN. For all translations, reference must be made to the original manual language.



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KEY

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

Professional medical personnel (e.g., professional health personnel, 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.

TECHNICAL SERVICE PERSONNEL

The personnel (individuals or entity accountable to the responsible organization) that installs, assembles, maintains or repairs (only fuse change) the device. The safety of such persons depends in part on their knowledge and training and ability to take appropriate precautions when gaining access to hazardous parts. 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)

For the installation phase, as regards assembly operations only, a qualified person is deemed whosoever has attended a course organized by GIMA or, alternatively, whosoever has carefully read the manual.



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1 GENERAL SAFETY INFORMATION

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 manual close to the Product.

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or N₂O (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of inflammable agents.

GIMA disclaims all liability for any injury to persons or damage to things caused by the Product having been installed by persons who are not "TECHNICAL SERVICE PERSONNEL".

The RESPONSIBLE ORGANIZATION is entirely responsible for Product installation activities; no costs or responsibilities relating to the installation and/or commissioning of the Product may therefore be traced back and/or in any case attributed to GIMA.

The ceiling or wall masonry works for Products to be installed on ceilings or walls, and the electrical works for supplying power to the Product shall be carried out in a workmanlike manner by TECHNICAL SERVICE PERSONNEL to ensure these are sturdy and safe.

The electrical system in the premises must conform to IEC:60364-7-710 standard and any national regulations. A master switch must be installed with fuse or thermal magnetic circuit breaker to be able to interrupt power to the Product.



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2 General information

2.1 Operator qualifications

Qualification of personnel in charge of operating on the Product

Installation Installer and/or qualified technician
Use Professional medical personnel

Cleaning Properly trained medical and paramedical personnel

Routine maintenance Qualified technician with required technical-professional skills

Special maintenance GIMA or technical service personnel, the latter only for the fuse change.

Assistance GIMA or authorized Dealer

Demolition Comply with applicable laws on waste disposal. This product must not be

disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through

authorized channels so as to ensure correct recycling.

2.2 Packaging, transport, storage and characteristics of installation premises

Packing Cardboard boxes containing Product. Dispose of these in compliance with

national directives applicable for waste disposal.

Transport Product transport is done by land, sea or air according to the following

characteristics:

Temperature (°C): -15 / +60

Humidity: 10 / 75 %

Atmospheric pressure (h/Pa): 500 / 1060

Storage The packaged Product must be stored (warehoused) in dry premises having

the following characteristics:

Temperature (°C): -15 / +60

Humidity: 10 / 75 %

Atmospheric pressure (h/Pa): 500 / 1060

Installation The premises where the Product is started up must have the following

premises characteristics:

Temperature (°C): +10 / +40

Humidity: 30 / 75 %

Atmospheric pressure (h/Pa): 700 / 1060



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2.3 Graphic signs and symbols used in the installation manual

The following safety measures must be put in place during Product installation.

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



General warning signal



General mandatory code of conduct signal



General prohibition signal



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2.4 Graphic symbols used on packaging

List of symbols on packaging boxes:



This side upwards



Fragile



Protect from rain



Do not stack packaging



Weight of packaging



Humidity to be complied with (max limit at top right and min limit at bottom left)



Pressure to be complied with (max limit at top right and min limit at bottom left)



Limit temperature (max limit at top right and min limit at bottom left)

2.5 Graphic symbols used on the Product

Below are the symbols to be found on the Product:



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



Date of manufacture (month and year)



Manufacturer's address



Fuses used in the device



Comply with the instructions for use



Model



Serial number



Disposal



Protection earth

الله الا

Neutral lead connection point

'L'

Line lead connection point

'O'

ON

"

OFF



Standby



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2.6 Warranty and liabilities

GIMA disclaims all liability as regards unreliable Product operation in the following cases:

- Installation, authorized modifications and repairs (only fuse change) have not been performed by TECHNICAL SERVICE PERSONNEL
- The Product has not been used for its intended purpose and in conformity with the operating instructions (see operation manual).
- The premises have not been approved for healthcare activities
- The premises are not built in conformity with the law and applicable regulations
- The electrical system in the premises is not in compliance with appropriate requirements

2.7 Structural changes or variations

CAUTION

No arbitrary structural changes or variations to the Product are admitted. Any modifications must have the prior written authorization of GIMA. In case of the Product having been tampered with, the warranty shall be invalidated and the manufacturer disclaims all liability for any injuries or damage caused to the OPERATOR, the RESPONSIBLE ORGANIZATION and the TECHNICAL SERVICE PERSONNEL.

3 Instructions on how to prepare the premises mechanically and electrically

3.1 Preparing the premises mechanically (Ceiling and wall Product version)



Carry out safe masonry works

The masonry works for preparing the ceiling to install the Product must be sturdy and safe and performed in a workmanlike manner according to applicable building regulations.

By way of example only, the professional persons charged with completing the masonry works are: Construction Engineer, Draughtsman, Building firm, duly registered in a professional register.



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Collapse of the building structure

In case of wrong perforation of the Product supporting wall (e.g., the breakage of a reinforced-concrete ceiling/wall iron) always inform the building manager as this could affect the stability of the building.



Make sure that ceiling or wall is adequate

The ceiling must be able to withstand a weight of at least 300 kg/m² and have a thickness of at least 250 mm. For the wall version, the wall must be a supporting wall and be made of solid brick. Installation on walls made of hollow bricks and plasterboard is only allowed with the fitting of another plate on the opposite side of the wall (sandwich closing).

The Product installation premises must conform to local building standards. After making sure the premises used for medical purposes are in conformity with the above requirements, proceed to mechanically anchor the ceiling and wall plate, assessing the type of building and making all consequent adaptations.

The TECHNICAL SERVICE PERSONNEL has all technical, civil and legal responsibility relating to correctly and suitably performing Product anchoring and installation operations in a workmanlike manner.

3.2 Correctly wiring up the premises



Carry out safe electrical works

The premises used for medical purposes must be safely wired up in a workmanlike manner by TECHNICAL SERVICE PERSONNEL to power the Product.



Make sure that the electrical environment complies with the law



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Before installing the Product, the TECHNICAL SERVICE PERSONNEL must make sure the following conditions exist:

- The wiring system of the environment (premises) in which installation is made must be in conformity with regulations for premises used for medical purposes and with applicable national laws and/or regulations.
- The electrical system must have a certificate of conformity issued by whosoever installed it.

The earth system must be certified as required by applicable regulations. In the case of ceiling versions, position the thermal magnetic switch near the Product so that it can be switched off in case of need.

Main switch

4 Product installation

Before proceeding to install the Product, first of all check the presence of all the packaging and that this is in good condition and has not been damaged during transport.

Claims will only be taken into consideration if the seller or carrier has been immediately notified. All claims must be made in writing. Goods always travel under the responsibility and at the risk of the buyer. Keep the original packaging in case the Product has to be redispatched.

Personnel required:



Necessary protection equipment:

- Safety eyewear
- Gloves
- Accident-prevention footwear

Special equipment

- Drill (ceiling and wall version only)
- Set of hexagon spanners
- Screwdriver
- Ladder (ceiling and wall version only)
- Standard manual tools
- Saw with metal blade (ceiling version only)
- Set of drill bits (ceiling and wall version only)

After installation, the Product must be tested by Technical Service Personnel before being used.



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4.1 Parts included in the package

Ceiling version

The Product is supplied complete with lamp, sterilisable handpiece, bar tube 1100mm long, bar plate, counter-plate for fastening to the ceiling, bar cover with relative safety ring and nuts for bar fastening. GIMA does not provide any kind of anchoring for fastening the plate to the ceiling. Such equipment must all be provided by the installer.

Floor version

The Product is supplied complete with lamp, stem, wheeled base and plastic base cover with silicone ring.

Wall version

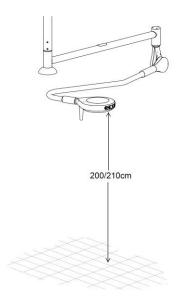
The Product is supplied complete with lamp, sterilisable handpiece, wall plate with switchboard and HAM M6x50 screw anchors.

4.2 Ceiling and wall drilling instructions

Fixing positions

For ceiling installation, the length of the bar varies according to the height of the premises in which the Product is installed.

The length of the bar is calculated to install the Product at a finished height off the floor of around 200/210 cm (as per drawing below), unless otherwise requested by the RESPONSIBLE ORGANIZATION.



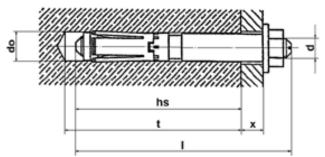
By way of example only, below is a list of some types of walls:

Reinforced concrete

Mechanical anchoring: proceed to fasten the wall plate using 8 x Hilti HSL-3-G M8/20 screw anchors (6 x HAM M6x50 anchors for the wall version) or other anchors with similar characteristics, carefully following the instructions provided by the anchor manufacturers and shown below for information purposes:



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Anchoring tie- rod	do (mm)	t (mm)	hs (mm)	l (mm)	Mt (Nm)	SW (mm)	x (mm)
HSL-3-G M 8/20	12	80	60	98	25	13	20
HAM M6x50	12	65	40	50	10	10	20

do Nominal drill bit diameter

t Minimum drilling depth

hs Minimum insertion depth

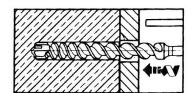
Anchoring tie-rod length

Mt Closing bending moment

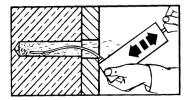
Sw Wrench opening

x Fastening height

- 1. Apply the paper template at the Product installation point and mark the fastening hole points with a pencil.
- Make the holes in the ceiling in accordance with the anchoring tie-rod manufacturer's specifications.

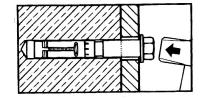


3. Using a pump or a vacuum cleaner, remove the drilling residues and dust from the hole.



4. Fasten the Bar/Plate to the ceiling/wall and, using a hammer, insert the anchoring tie-rod in the hole.

Attention! Check the fitting depth

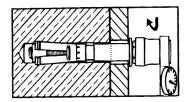




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5. Using a torque wrench, tighten the anchorage to the tightening force indicated by the screw anchor manufacturer.

The anchorage will immediately bear the weight.



- 6. Proceed in the same way for the remaining anchors.
- 7. After one hour, again tighten the tie-rods to the prescribed tightening torque.

Chemical anchoring

Hollow-core concrete

Drill the ceiling/wall using the template provided. Insert the resin inside the 8/6 drilled holes and fill the hole, carefully following the manufacturer's instructions. GIMA recommends using HILTI HIT-HI 270 resin or similar products.

Fit 8/6 x M8 threaded bars into the holes. Proceed to fasten the ceiling/wall plate with nuts and locknuts for each tie-rod and tighten using the Allen key. In this case the ceiling must be sandwich closed by means of the ceiling/wall plate and counter-plate, being careful to include at least one rafter.

The plate and counter-plate must be fastened together using suitable M8 threaded steel bars, blocked at the top and bottom ends by relative washers, nuts and locknuts.



Do not install the Product on unsuitable walls

4.3 Instructions for ceiling version of Product

4.3.1 Installation of ceiling plate, bar, switchboard and cover (single version)



Make sure the Product is stable

Make sure the Bar (anchoring tube) is perfectly level to ensure the Product is stable.

See drawing 52

Position the template (drawing 51) (2) on the ceiling (1) and secure it with adhesive tape (3).



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Make the holes according to indications in paragraph 4.1

See drawing 53 Fasten the counter-plate (2) to the ceiling (1) using the nuts and locknuts (3).

See drawing 54 Fasten the bar (1) to the threaded pins of the ceiling counter-plate (2) using the nut and locknut (3). Using a spirit level (4), make sure the bar is correctly fastened.

See drawing 211 The bar (1) is supplied in standard length 110 cm. Using the saw (2), cut the tube to the desired size according to the height of the room (make the cut on the side of the tube (3), opposite to that bearing the fastening holes (4) of the horizontal arm).

To determine the correct length of the tube, use the chart shown (suggested installation height is 200 cm). It is not advisable to cut the bar to a length below 30 cm to avoid covering installation problems.

See drawing 56 Insert the anchoring tube (1) (with cut side upwards) tight up against the hub of the plate (2). To block the tube, tighten the bolt (3) with the toothed washer (5) and threaded hole (4). Tightened this way, the hub will ensure that the tube is sealed.



Product falling hazard

See drawing 57	Using a drill (1), make a 6 mm diameter hole on the tube where the M8 hole
	(2) is located on the plate hub. Then fit and tighten the tapered tip M8 dowel
	(3) until this presses on the previously made hole.
See drawing 58	Make sure the mains power cable (1) reaches the Product power board (2).
	Position the cover (3) and secure it with the seal (4).

4.3.2 Installation of structure to bar (single version)

See drawing 212 Fit the connection cables (7) in the anchoring tube so that they come out at the top near the plate and can be connected to the connection terminals of the switchboard.

Align the pin of the horizontal arm (3) with the bar (4).

Connect the connectors (1) and (2).

Fit the pin in the tube, making it coincide with the retention holes and, using a hexagon spanner (6) secure it with screws (5).



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4.3.3 Installation of ceiling plate, bar, switchboard and cover (double version)

0	Make sure the Product is stable
	Make sure the Bar (anchoring tube) is perfectly level to ensure the Product
	is stable.
See drawing 52	Position the template (drawing 51) (2) on the ceiling (1) and secure it with adhesive tape (3).
	Make the holes according to indications in paragraph 4.1
See drawing 53	Fasten the counter-plate (2) to the ceiling (1) using the nuts and locknuts (3).
See drawing 69	Fasten the bar (1) to the threaded pins of the ceiling counter-plate (2) using
	the nut and locknut (3). Using a spirit level (4), make sure the bar is correctly fastened.
See drawing 215	The bar (1) is supplied in standard length 115 cm. Using the saw (2), cut the
ooo aramiig 210	tube to the desired size according to the height of the room (make the cut
	on the side of the tube (3), opposite to that bearing the fastening holes (4) of the horizontal arm).
	To determine the correct length of the tube, use the chart shown (suggested
	installation height is 200 cm). It is not advisable to cut the bar to a length
	below 30 cm to avoid covering installation problems.
See drawing 71	Fit the covering of the switchboard (1) on the anchoring tube (2).
ooo aramiig	Now fit the anchoring tube (2) up tight against the ceiling plate hub. To block
	the tube, tighten the screw (3) and the toothed washer (4). Tightened this
	way, the hub will ensure that the tube is sealed.

\

Product falling hazard

See drawing 72

Using a drill (1), make a 6 mm diameter hole on the tube where the M8 hole (2) is located on the plate hub. Then fit and tighten the tapered tip M8 dowel (3) until this presses on the previously made hole.



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4.3.4 Installation of structure to bar (double version)

See drawing 216

Align the pin of the horizontal arm (1) with the hub of the anchoring tube (2). Connect the connectors (3) and (4), according to the colours.

Fit the pin in the tube, making it coincide with the retention holes and, using a hexagon spanner (6) secure it with screws (5).

Repeat the procedure for the second arm of the Product.

After completing installation, close the openings of the supporting tubes using the silicone caps (7).

4.4 Installation of Product in floor version

4.4.1 Installation of lamp base

See drawing 60 Mechanical

connection

Remove the screw (2) from the stem (1).

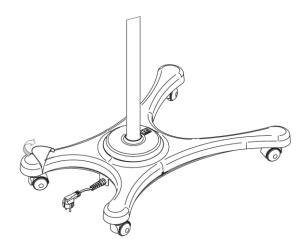
Position the stem (1) on the base (5) and fit the guide (6) in the base centring slot (7). Join the stem to the base and fasten the screw (2) tight.



Instability and overturning hazard

If the guide is not properly fitted in the base centring slot, the risk of instability could exist with possible Product overturning.

Insert the cover (3) and retaining seal (4) from the top of the stem (2). Move the cover (3) and seal (4) close to the base.



4.4.2 Installation of swinging arm and head

See drawing 213

Align the pin of the swinging arm (1) with the lamp stem (2). After connecting the electric connectors (3) (4), fit the pin of the swinging arm in the stem and



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make the holes (5) coincide with the stem holes (6), then tighten the retention screws (7).

Remove the protective film from the floor base cover.

4.5 Installation of Product in wall version

4.5.1 Installation of plate with wall switchboard



Make sure the Product is stable

Make sure the wall plate is fastened level so the Product is in stable position.

See drawing 66 Position the template sheet (2) (drawing 11) on the wall (1) and fasten it with

adhesive tape (3), with the aid of a spirit level (4) to ensure levelling. Make

the holes as indicated in paragraph 3.1

See drawing 67 Fasten the plate (2) to the wall (1) with the aid of a spirit level (3).

4.5.2 Installation of structure to plate

See drawing 214 Align the pin of the horizontal arm (1) with the box tube (2).

Connect the connectors (3) and (4).

Fit the pin in the tube, making it coincide with the holes, then using a hexagon spanner (6) secure it with screws (5).

4.6 Handpiece fitting

To fit the handpiece, turn it clockwise inside the threaded hole provided until it is up against the headpiece and rotation remains blocked.

4.7 Electrical connection of Product

CAUTION

To avoid any risk of electric shocks, the Product must only be connected to mains supplies with earth protection.



Electric shock hazard

Before making the Product power connections, make sure the mains supply line has been interrupted.

GIMA does not supply the mains supply cables.



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Mains connection to be made according to NEC (National Electrical Code) indications and CEC (Canadian Electrical Code) indications for US/CAN.

The Product supply unit (support plate, supply unit, terminal board) is fastened integral with the plate of the bar, the base or the wall plate for ceiling, floor or wall versions respectively.

Fuses

Product power protection is ensured by an input fuse (L) in the ceiling version and by two input fuses (L, N) for the wall and floor version, T1AH 250V 5x20 type, which are already connected in the switchboard.



For wiring connections in the ceiling version, use a cable suitable for at least 105°C and connect the ground lead to the terminal provided.

In the ceiling versions, the connection to the mains supply is carried out by the installer.

The line power connections (L, N) and those inside the Product (+,-, ,), must be made in compliance with the wiring diagram show in the Operation and Maintenance Manual.

Connect the line cable (L) in the screw terminal seat indicated by the label, and the neutral cable (N) in the screw terminal alongside. Crimp the faston to the ground lead with double crimping and fasten it in the terminal marked with the ground symbol by means of the nut.

See drawing 62

Floor version: join the switchboard connectors in the following order: lift the silicone seal (1) and the covering (2) by 30-40 cm to access the electrical section. Join the connectors (3) to (4) and (5) to (6). Return the cover and seal to original position and using a screwdriver (7) fasten the cover by means of the screws (8) to be fastened to the threaded bush (9).

The Product power connection is by means of a plug integrated in the supply cable supplied with the Product, placed on the box.

Wall version: The Product power connection is by means of a plug integrated in the supply cable supplied with the Product, placed on the box.

4.8 Mechanical adjustments



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The Product is supplied correctly clutched and balanced. To make movement adjustment, refer to the setting instructions shown in the operation and maintenance manual.

4.9 First switch-on

To ensure the Product operates correctly, proceed as follows:

- Make sure the power rating of the premises corresponds to that of the Product;
- 2. Fit the plug in the power socket of the premises Floor and Wall versions only;
- 3. Close the switch upstream of the system;
- Move the Product switch located on the base cover for the floor version and on the power box for the wall version respectively to position "I" (ON);
- 5. Press the **O** keyboard positioned on the Product dome.
- 6. Make sure all LEDs and functions are working properly.

At the time of commissioning, perform the electrical tests and prescriptions indicated in the IEC 62353 standard.



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4.10 Check the result of Product installation and testing before use

Ticking the requirements listed below, if applicable to the Product version, is mandatory to ensure correct installation.

1.	Make sure the ceiling/wall is suitable for Product installation.	
2.	Using a spirit level, make sure the bar is perpendicular with the ceiling	ng or
	that the wall plate is horizontal with the wall.	
3.	Make sure the bolt is tight on the plate hub to fasten the bar.	
4.	Make sure the hole has been made properly and that the safety d	owel
	has been fitted on the bar.	
5.	Make sure the screws sustaining the horizontal arm are tight (ceiling	, and
	wall versions).	
6.	Make sure the stem guide is correctly fitted in the base centring slot (floor
	version).	Ц
7.	Check the Product earth connection and make sure the clamps are	well
	tightened.	
8.	Check the correct rotation of the articulated joints and mecha-	nical
	movements.	
9.	Adjustment and rotation movements must be carefully clutched to en	sure
	the Product is stable and maintains its position.	
10.	Make sure the Product emits light.	
St	amp and signature of TECHNICAL SERVICE PERSONNEL:	



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5 Troubleshooting

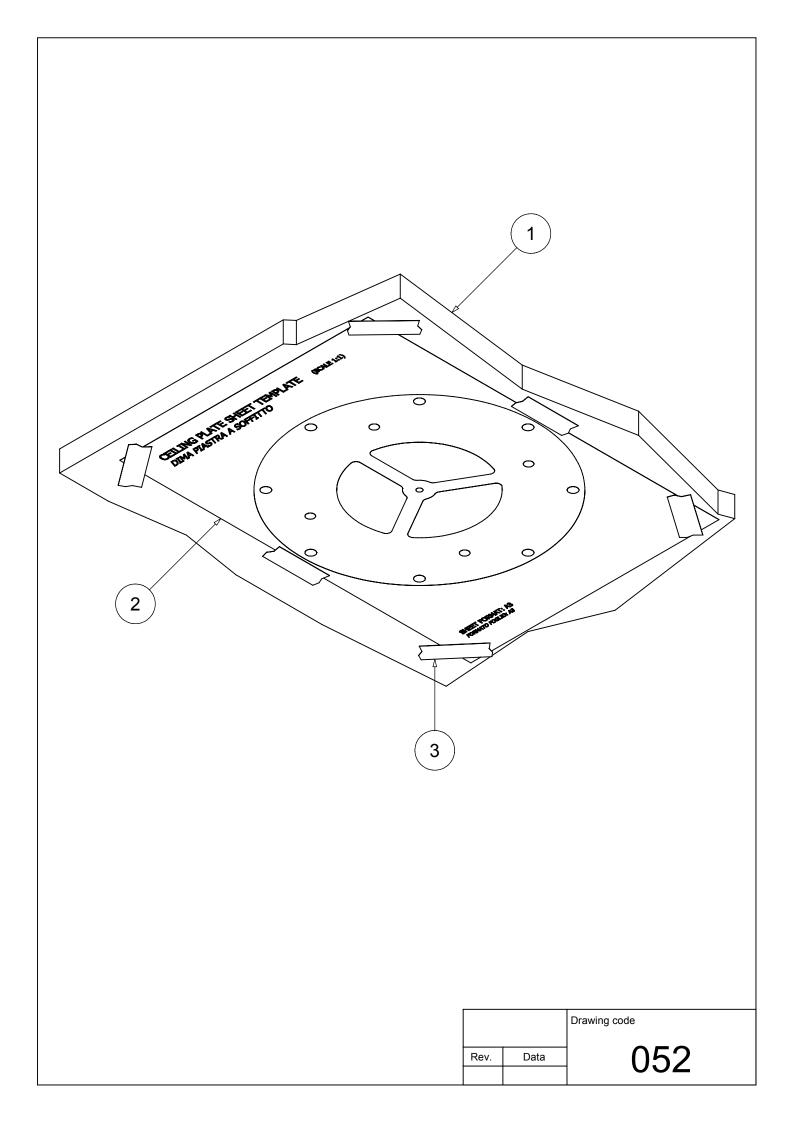


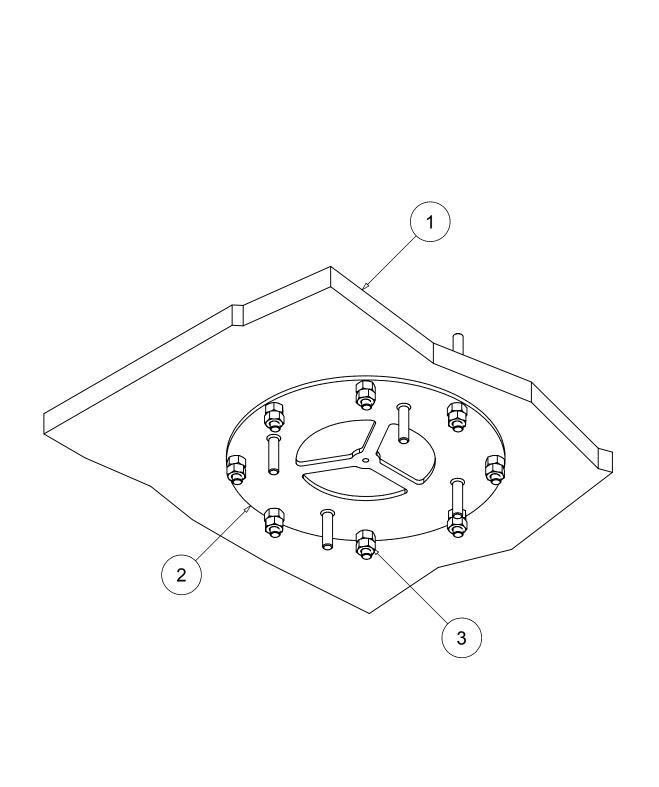
Possible Product damage



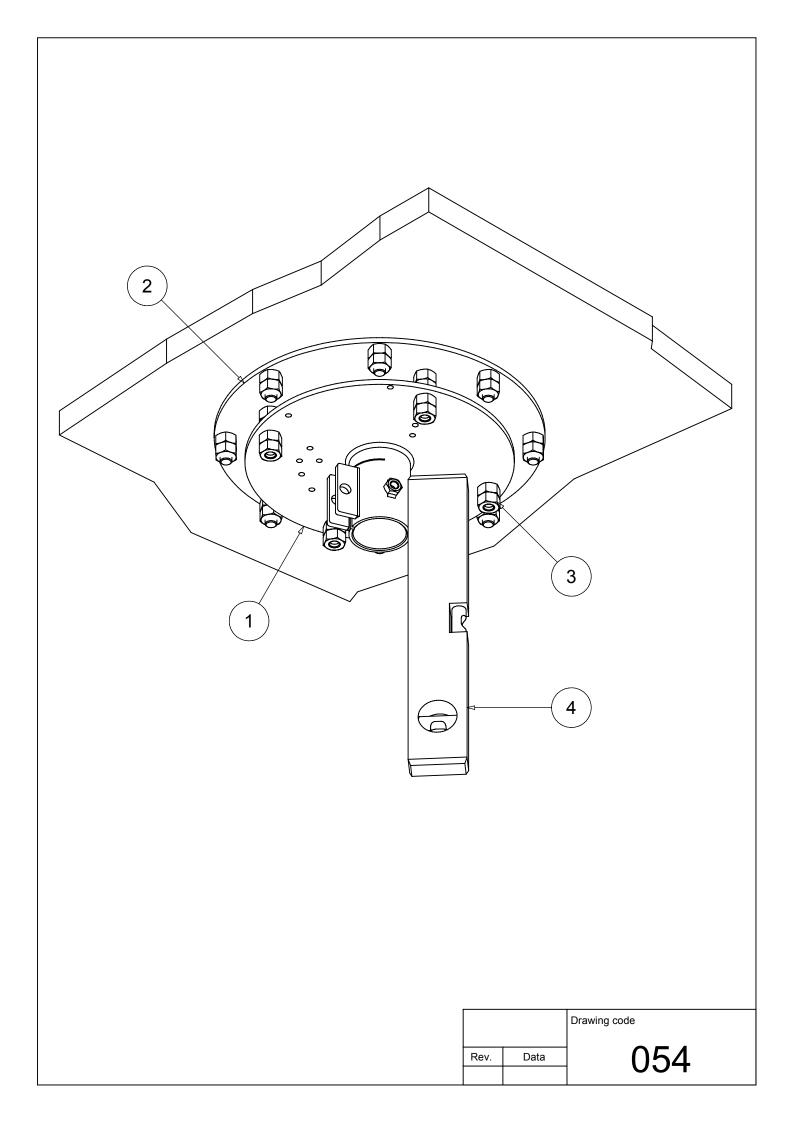
Presence of dangerous voltage

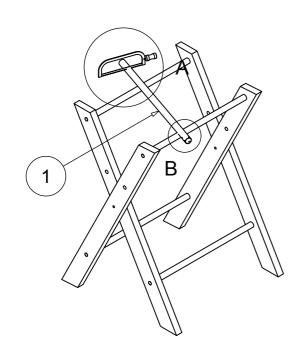
n	Problem	Solution
1	The Product fails to remain in stable position	Make sure the instructions in this manual, in the "Product installation" paragraph, have been correctly followed. Make reference to setting instructions in section 7 of the operation and maintenance manual.
2	The Product fails to work	Make sure fuses have been fitted inside the terminal board. Make sure the electrical connectors are fitted. Check if there is voltage inside the Product.
3	The fuse continues to burn out	Check the specifications of the fitted fuses.
4	The light flickers and produces a stroboscopic effect	Contact the after sales service
5	The Product does not switch on	Check the supply power voltage and check the fuses. The electronics are faulty: contact the after-sales service.

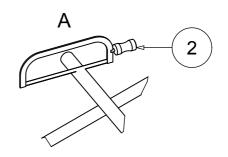


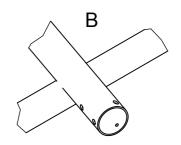


Rev. Data Drawing code



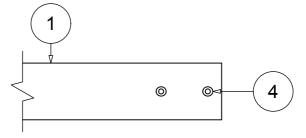


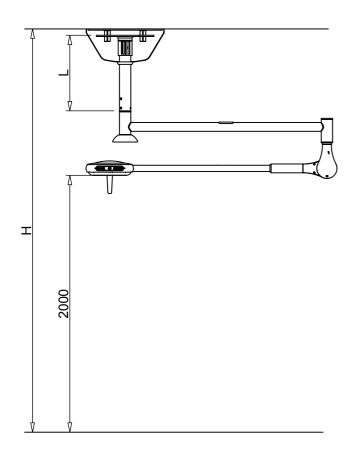




Tube length list [mm] Tabella lunghezze tubo [mm]

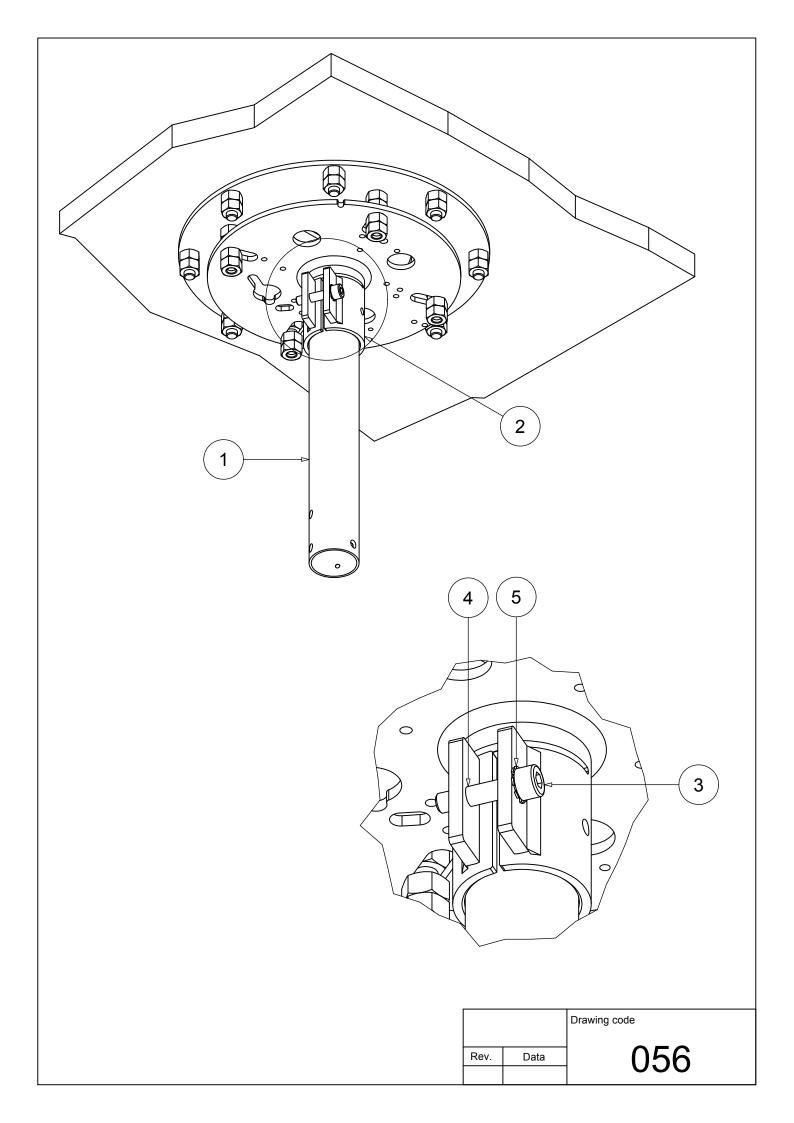


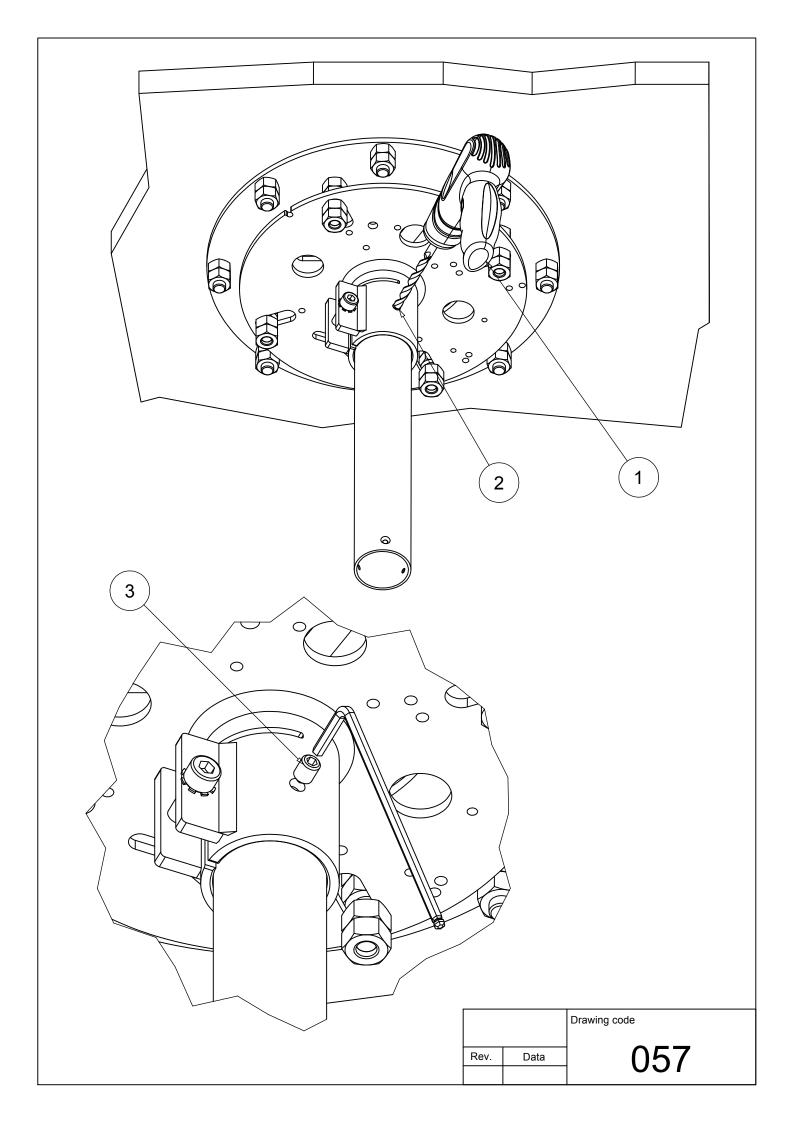


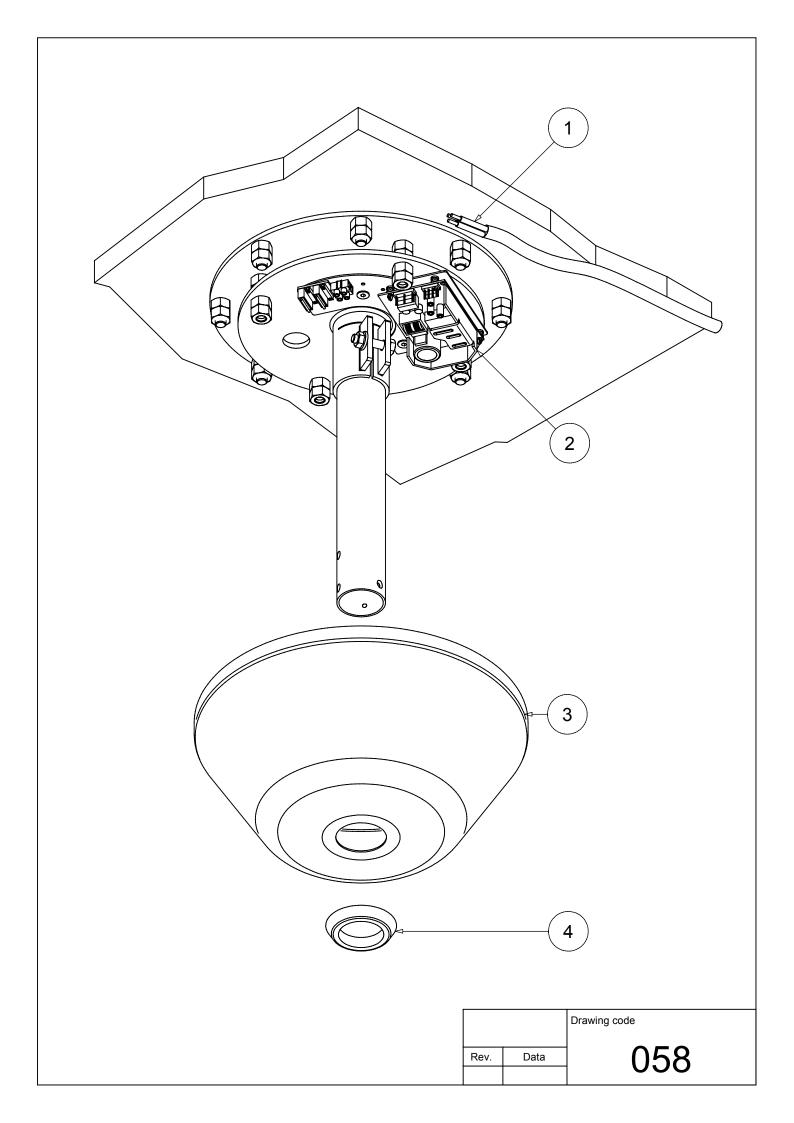


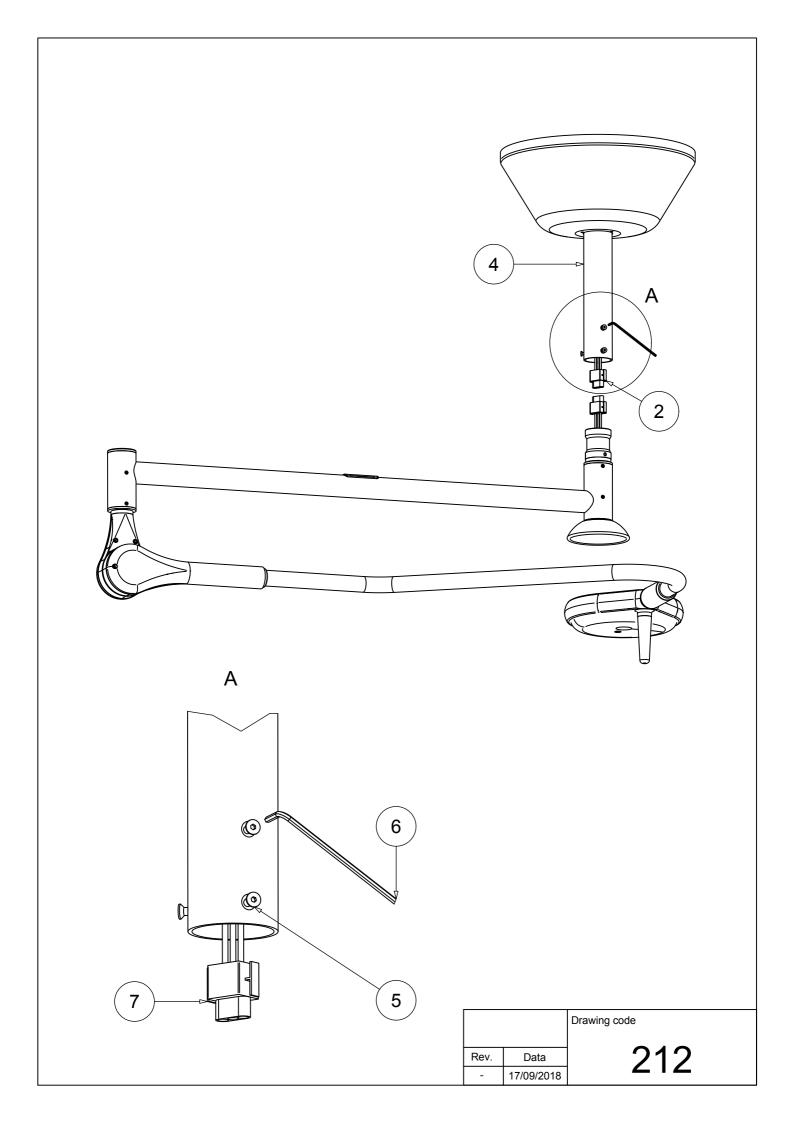
H [mm[L [mm]
2480	200
2500	220
2550	270
2600	320
2650	370
2700	420
2750	470
2800	520
2850	570
2900	620
2950	670
3000	720
3050	770
3100	820
3150	870
3200	920
3250	970
3300	1020
3350	1070
3380	1100

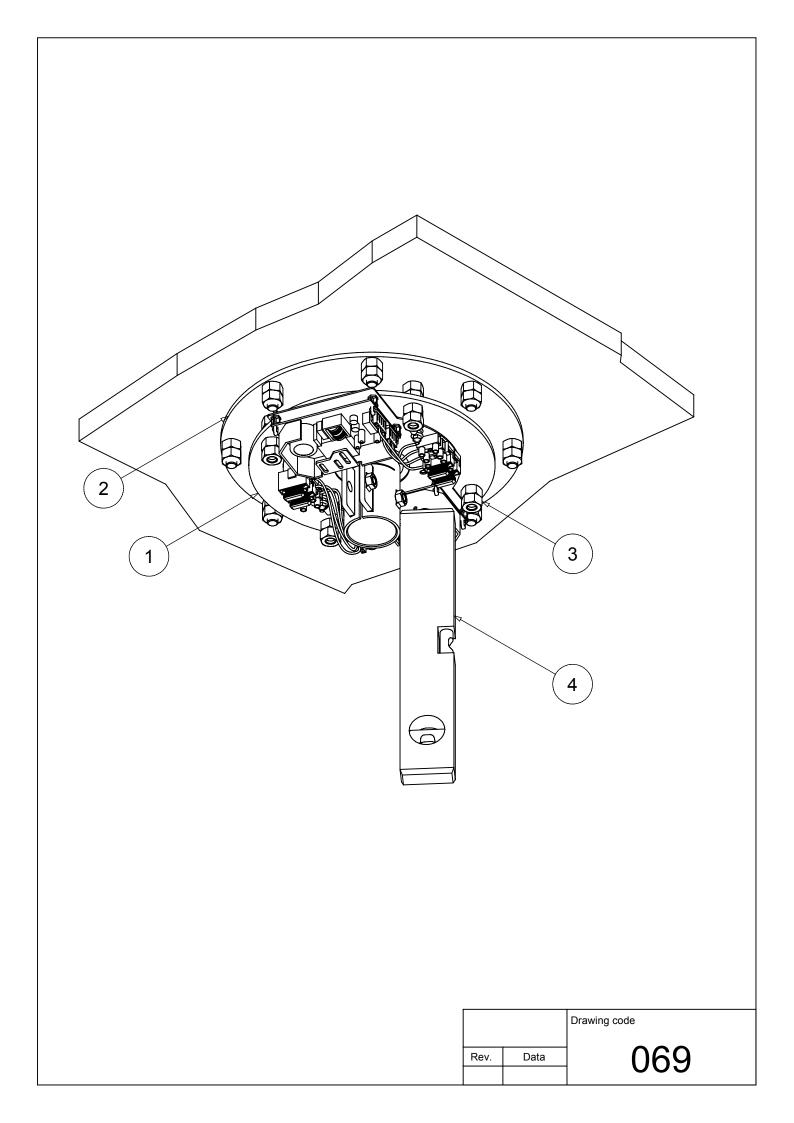
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Rev.	Data	211
-	17/09/2018	ZII

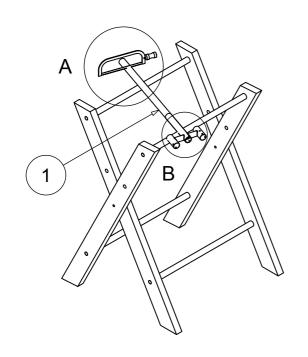


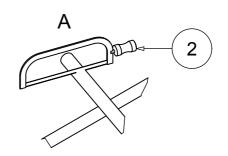


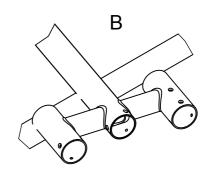


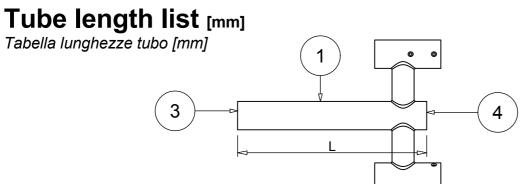


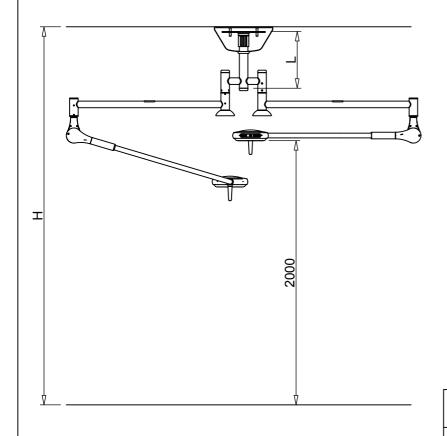












H [mm[L [mm]
2600	300
2650	350
2700	400
2750	450
2800	500
2850	550
2900	600
2950	650
3000	700
3050	750
3100	800
3150	850
3200	900
3250	950
3300	1000
3350	1050
3400	1100
3450	1150
	-

		Drawing code
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-	17/09/2018	210

