

**GIMA**

Operator's Manual

MO080-IT

12/09/2017

Rev.3

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Operator's manual for observation lamp

PRIMALED SO

**GIMA**

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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 Directive on medical devices (MDD) 93/42/EEC (Annex IX) and 2007/47/EC.

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 marking.

The Product is classified in risk group 1 according to IEC 62471 standard (Photobiological Safety of Lamps). This operator's manual is valid for the **PRIMALED SO** model.

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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The contents of this Manual may be amended by GIMA, without prior notice or any further obligations, in order to make changes and improvements. The reproduction and translation, including partial, of any part of this manual is forbidden without the written permission of GIMA.

GIMA 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 GIMA is constantly seeking new solutions which lead to product evolution. GIMA therefore reserves the right to make changes to the supplied Product in terms of shape, fittings, technology and performances.

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

1 General information

THE EM (Electro-Medical) DEVICE to which this manual refers is a LAMP for diagnosis or observation. For ease of description, in this manual this EM EQUIPMENT will be called "Product".

This manual is an integral part of the Product as indicated by European Directives 93/42/EEC and 2007/47/EC. Always keep this operator's manual close to the lamp.

GIMA 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 GIMA or, alternatively, whosoever has carefully read this installation manual. GIMA does not authorize third parties to perform special maintenance jobs. Should a problem arise, contact GIMA.

The end user 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 suitably qualified personnel to ensure these are sturdy and safe.

By way of example only, the following professional figures are deemed as suitably qualified:

⇒ 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)

In case of problematic drilling, e.g., drilling into a reinforced concrete iron rod, for safety reasons, inform the technical manager of the building inasmuch as the latter's stability could be affected.

The ceiling must be able to withstand a weight of at least 300 kg/m² and have a thickness of at least 250 mm.

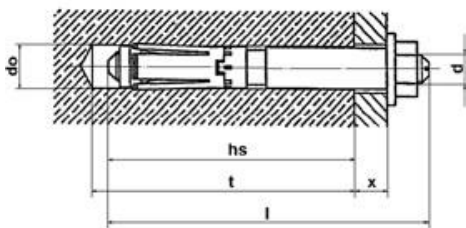
The installation premises must have building code compliance. Installation on walls made of hollow bricks and plasterboard is only allowed with the fitting of another plate on the opposite side of the wall (sandwich closing).

After making sure that the premises used for medical purposes are in conformity with the above requirements, proceed to mechanically anchor the wall plate; determine the type of wall involved and behave consequentially.

The installer takes all responsibility, technical, civil and legal, relating to the correct and suitable preparation of the product for anchoring and installation, which must be performed in a workmanlike manner. The scialytic lamp is supplied complete with ceiling coupling (Bar (Tiges) + Counter-plate). The length of the bar varies according to the height of the premises in which the lamp is installed. This is calculated to install the lamp at a height from the floor to under the light headpiece with horizontal position of the swinging arm between 19/200 cm approx., unless otherwise requested by the customer.

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

Reinforced concrete: *Mechanical anchoring* Mechanical anchoring: proceed to fasten the wall plate using the 8 x Hilti HSL-3-G M8/20 wall plugs, carefully following the indications provided by the insert manufacturers and shown below for your better information:



Anchor 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

do Nominal drill bit diameter

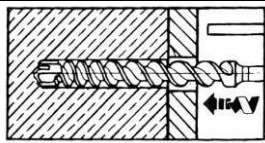
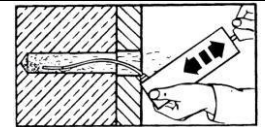
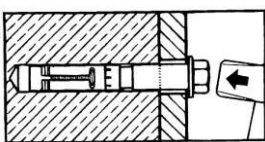
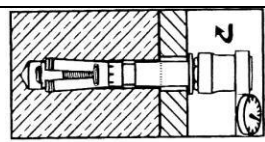
t Minimum drilling depth

hs Minimum insertion depth Anchor tie-rod length

Mt Closing bending moment

Sw Key opening

x Fastening height

1.	Using the paper template provided and attached to this manual, mark all 8 fastening holes on the chosen part of the wall.	
2.	Make the first hole in conformity with the diameter of the wall plug.	
3.	Using a small pump or vacuum cleaner with tube end, remove any dust and small drilling fragments from the hole.	
4.	The anchor tie-rod must be made to enter the hole, keeping it perpendicular and using a hammer. Attention! Take into account the insertion depth.	
5.	Using the torque metre wrench, calibrated as indicated by the wall plug manufacturer, tighten so as to open the plug. The anchor tie-rod will immediately bear the weight.	
6.	Drill the remaining holes and insert the anchor tie-rods as indicated at previous points 2– 5.	
7.	After one hour, tighten the tie-rods again using the prescribed tightening torque.	

Chemical anchoring: drill the wall using the template as indicated above. Insert the resin inside the 8 drilled holes and fill the hole, carefully following the manufacturer's instructions. GIMA recommends using HILTI HIT-HY 270 resin or similar products.

Fit 8 x M8 threaded bars into the holes. Proceed to fasten the plate with nuts and locknuts for each tie-rod and tighten using the Allen key.

Hollow-core concrete: In this case, the floor slab must be sandwich closed by means of the plate and counter-plate. The plate and counter-plate shall be jointed with M8 steel threaded bars, and clamped on the front and back ends with washers, nuts and lock nuts.

The Product is an EM electro-medical device and therefore 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 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	Installer and/or qualified technician
Use	Professional medical personnel
Routine maintenance	Qualified technician with required technical-professional skills
Special maintenance	GIMA or authorized Dealer
Assistance	GIMA or authorized Dealer
Cleaning	Properly trained medical and paramedical personnel
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.

1.2 Packaging, transport, storage and characteristics of installation premises

Boxes containing the Product together with operator's manual

Transport is made by GIMA or any road-hauler as long as in compliance with the following characteristics: Temperature (°C): -15 / +60; Humidity: 10 / 75 %; Atmospheric pressure (hPa): 500 / 1060.

The packaged Product must be stored (warehoused) in dry premises having the following characteristics:













Temperature (°C): -15 / +60; Humidity: 10 / 75 %; Atmospheric pressure (hPa): 500 / 1060.











The premises where the Product is started up must have the following characteristics:

Temperature (°C): +10 / +40; Humidity: 30 / 75 %; Atmospheric pressure (hPa): 700 / 1060.

1.3 Graphic symbols used on the Product and on packaging

Description of the symbols on plates, product and in manual:

	Graphic symbol showing product bears CE marking		RECYCLING! The Product must be recycled separately
	Symbol indicating date of manufacture (month/year)		Model
	Manual reading obligation		Serial number
	Manufacturer's address		Top side of packaging
	Humidity to be complied with (indicate max limit at top right and min limit at bottom left)		Fragile packaging
	Limit temperature (indicate max limit at top right and min limit at bottom left)		Pressure to be complied with (indicate max limit at top right and min limit at bottom left)

	Do not stack packaging		Weight of packaging
	Protect from rain		Weight of packaging
	ON power		Weight of packaging
	Stand-By		OFF power
	Line lead connection point		Neutral lead connection point

1.4 EC Declaration of Conformity of the Manufacturer

The company: **RIMSA P. LONGONI S.r.l. Via Monterosa, 18/20/22 - 20831 SEREGNO (MB) – ITALY** declares under its own responsibility that the Product (Medical device for observation and diagnosis):



made by RIMSA P.LONGONI S.r.l., complies with Annex VII of Directive 93/42/EEC dated 14/05/1993, enforced in Italy by Legislative Decree No. 46 dated 24 February 1997 and subsequent amendments (including Directive 2007/47/EC dated 05/09/2007, enforced in Italy by Legislative Decree No. 37 dated 25 January 2010) and with the following standards:

- IEC 60601-1 (Part 1: General requirements for basic safety and essential performance) (Part 1: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis)
- IEC 60601-2-41 (Part 2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)
- IEC 60601-1-2

Classification with reference to article 9 and Annex IX of Directives 93/42/EEC and 2007/47/EC

DURATION: Short term duration (Annex IX, Par.1 “Definitions”, art.1, subsection 1.1)
DESCRIPTION: Non-invasive medical device (Annex IX, Par.1 “Definitions”, art.1, subsection 1.2)
Active medical device (Annex IX, Par.1 “Definitions”, art.1, subsection 1.4)
CLASS I: (Annex IX, Par.3 “Classification”, art.3, subsection 3.3, Rule 12) and
(Annex IX Par.3 “Classification”, art.1, subsection 1.1 Rule 1)

- Reference to technical file Code RIM-FT023.
- The conformity assessment is developed with reference to article 11 of Directive 93/42/EEC and 2007/47/EC.
- The RIMSA Quality System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).
- The Medical Device to locally light up the patient's body is marketed in **NON-STERILE** form.

Name: Paolo Longoni
Position: Managing Director



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1.5 Warranty Certificate

1. The Product is covered by an 18-month warranty, including electrical parts
2. The warranty begins on the date of product shipment from the GIMA warehouse to the buyer.
3. In case of disputes, the date indicated on the “transport document” attached to the goods shall be deemed valid.
4. The warranty only covers the sending of Product spare parts to the buyer or, in the event of GIMA considering the replacement of spare parts not feasible, the replacement of the entire product, after fabrication faults have been properly ascertained at the undisputable judgement of GIMA . The warranty does not therefore cover any other costs or expenses (including, by way of example but without limitation, labour costs, packaging costs and transport costs, etc.).
5. The guarantee does not include the components subject to normal wear, such as halogen bulbs, LEDs, fuses, relays, ball bearings, etc.)
6. The warranty does not cover:
 - malfunctions due to failure to comply with all instruction manuals;
 - malfunctions due to installation and/or maintenance errors;
 - malfunctions or faults caused by carelessness, negligence, incorrect use or other causes not attributable to GIMA;
 - malfunctions or faults due to the fact that the electrical system of the premises where the device is installed is not in compliance with CEI 64-8 standards (standards for electrical systems in premises used for medical purposes) and similar standards.
7. GIMA shall repay direct damages suffered by the buyer and which are documented as attributable to its product, caused within the warranty period, for an amount not above 40% of the net value of the product as indicated on the buyer's invoice. GIMA's liability is expressly ruled out for indirect damages or consequential damages (including cases of the lamp not being used) deriving from the supply.
8. This warranty certificate replaces legal warranties for faults and non-conformities and rules out any other possible liability of GIMA originating from the supplied products.
9. The payment of any damages to persons or things due to product malfunction or faults shall be limited to the maximum amount of GIMA's insurance coverage for civil liability.
10. The warranty shall be automatically invalidated in the event of:
 - the Product having been tampered with or modified by the buyer or third parties;
 - the Product having been repaired by the buyer or third parties, without following the instructions in the instruction manuals;
 - the Product serial number having been cancelled, defaced or removed;
 - the buyer not being up to date with payments.
11. For jobs to be done under warranty, the buyer shall contact GIMA only.
12. The component parts replaced under warranty must only be returned to GIMA, if so requested by GIMA, carriage free and suitably packed.
13. In case of failure to return a part requested by GIMA, the cost of the component part will be charged.
14. GIMA cannot accept returns from end users or in any case from parties other than the buyer.
15. Products returned to GIMA must be complete with documentation authorising such return and another document describing the malfunction.
16. For everything not indicated on this warranty certificate, reference shall be made to the laws of Italy
17. For all disputes deriving from or related to the orders to which this warranty certificate applies and which cannot be amicably settled between the parties, the only competent law court shall be that of Milan.

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2 *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 re-dispatched.

The product is supplied complete with lamp, sterilisable handpiece, bar tube 960 mm 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.

For installation, the following safety devices and tools are necessary: safety eyewear, gloves, safety footwear, drill with bit set, common manual tools and ladder, saw blade for cutting metal.

2.1 *Installation of the ceiling plate, bar, power supply and cover*

- CAUTION** If the plate is not perfectly level, an undesired spontaneous movement could occur of the horizontal arm of the lamp, moving from imbalance condition to balance condition.
- Drawing 52 Position the attached template sheet (2) on the ceiling (1) and secure with adhesive tape (3).
Make the 8 holes in accordance with the instructions in paragraph 1, depending on the type of available wall.
- Drawing 53 After drilling holes in the wall (1), fasten the counter-plate (2) to the ceiling using nuts and locknuts (3).
- Drawing 54 Secure the bar (1) to the threaded pins of the ceiling plate (2) using nut and locknut (3), making sure the bar itself is perfectly level, using a spirit level (4).
- Drawing 55 The bar tube (1) is supplied with a standard measurement of 100cm. Using the saw (2), cut the tube to the desired size in relation 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 define the correct length of the tube, use the table shown (the suggested distance between floor and lamp headpiece is 200cm).
- Drawing 56 Fit the anchor tube (1) until it is up against the hub of the ceiling plate (2) (keeping the cut side upwards); to secure the pipe, tighten the screws (3) and toothed washer (4), so the tube is well secured.
- Drawing 57 Using a drill (1), make a hole with diameter 6mm on the side of the tube where the threaded hole M8 (2) is located; now fit into the hole and tighten the tapered tip dowel M8 until this forces with the tapered tip on the hole previously obtained in the bar tube.
- Drawing 58 Make sure the mains power cable (1) can reach the lamp power board (2) without creating interferences with the bar.
Now position the cover (3) followed by the relative stop ring (4).

2.2 *Fitting the structure to the wall tube*

- Drawing 153 Fit the connection cables (7) in the anchoring tube so that they come out from the bar 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 up the connectors (1) and (2).
Insert the pin in the tube, making sure that the relative holes coincide, and fasten by screwing up the four screws (5) using an Allen key (6).

2.3 *Wiring connections*

- CAUTION** To avoid any risk of an electric shock, the Product must only be connected to power mains with an earth lead connection.
For wiring connections, use a cable suitable for at least 105°C and connect the ground lead to the terminal provided.

The Product supply unit (supporting plate, supply unit, terminal board) is integrally fastened to the bar plate.

The line power connections (L, N, PE) 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

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in the terminal marked with the ground symbol by means of the nut.

Product power protection is ensured by an input fuse (L, N) of the T1AH 250V 5X20 type, which are already connected in the switchboard.

2.4 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.

2.5 First switch-on

At this point, the Product can be switched on to make sure it works properly. Follow the instructions below:

- 1- Switch on the power to the Product by means of the master switch.
- 2- Press the I/O keyboard located on the front part of the reflector.
- 3- Make sure all LEDs and functions are working properly.

2.6 Check the result of Product installation and testing before use

The following instructions are to be deemed mandatory during the installation inspection phase, as they prove that the various jobs referred to have been correctly done. Hence each single step must be ticked.

1. Make sure the ceiling is suitable for Product installation. ☐
2. With the aid of a spirit level, make sure the bar tube is perfectly perpendicular ☐
3. Make sure the bolt is tight on the stop collar ☐
4. Make sure the hole has been drilled correctly and that the safety dowel is fitted on the bar tube ☐
5. Make sure the 4 x M4 screws which sustain the horizontal arm are tight ☐
6. Check the Product earth connection and make sure the clamps are well tightened ☐
7. Make sure movement mechanisms are working properly. ☐
8. After switch-on the Product must emit light from the headpiece ☐

Installer's stamp and signature:

3 Importance of personal safety

3.1 Intended use

The Product has been designed to light up the area of the patient undergoing observation and diagnosis and is intended for use in doctors' surgeries.

The Product correctly lights up the operating field from a minimum distance of 40 cm and a maximum distance of about 70 cm, from the point of light emission.

The Product, in conformity with the IEC 60601-2-41 standard, is defined as a lamp for diagnostics:

- A lamp for diagnostics is a lamp used to locally light up the body of a patient, in order to make diagnosis or treatment easier. These can be interrupted without any danger for the patient in case of the light going off. (The Product is not intended for use in operating theatres).

3.2 Environmental conditions

- 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 NO₂ (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.
- 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.

3.3 Safety conditions (secondary effects)

- Do not direct the light source into the patient's and/or operator's eyes.
- Obligation to adequately protect the patient's eyes.
Failure to follow such precautions could cause glare and potential damage to the retina.
- Never place and/or hang anything on the Product.
Unless this precaution is taken, positioning will not be reliable and the danger exists of such objects falling in the operating area.
- 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.
Failure to comply could prevent heat exchange with the environment and the Product could overheat.
- Avoid knocking the rocker arms and Product head.
A violent knock could damage the Product and pieces of paint could chip off and fall onto the operating field in the patient area.
- To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments, see section 9 of the manual.

3.4 Controls to be performed every time before the lamp is used

To make sure the Product is safe and provides a correct diagnosis, every time before use, the operator must check:

- The lamp has been correctly disinfected;
- The emitted light is stable and of adequate intensity;
- The flexible arm remains in the selected position, without falling.

4 Description and operation

4.1 Description

The Product locally lights up the patient's body thanks to 9 LEDs focalized by means of specific lenses. 3 non-focalized LEDs are also fitted to permit using a courtesy or reading light.

Positioning the light beam is made easy thanks to the articulated arm and is done manually. By means of the membrane keyboard on the reflector, the various product functions can be easily controlled.

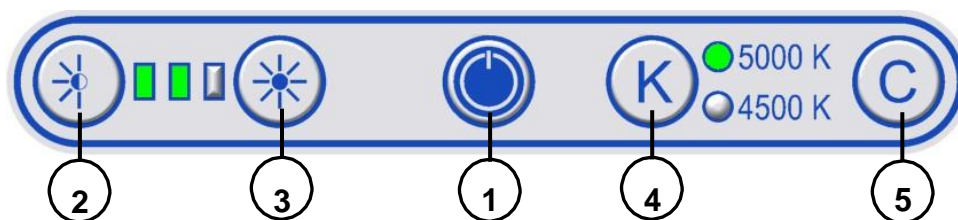
4.2 Operation

To switch on the Product, use the main switch.

IMPORTANT: do not position the device so it is hard to reach the main switch in case of an emergency.

The following functions can be controlled by means of the keyboard:

Switch the lamp on and off by means of the standby key (1), adjust light intensity by pressing keys (2) and (3), with display of the level of intensity achieved by means of 3 green positions micro-LEDs. Select the colour temperature by means of the "K" key (4) with display by means of 2 green micro-LEDs, and select the courtesy light by means of the "C" key, which permits switching on the 3 LEDs without lens, not to be used for observation (5). To select the courtesy light, the lamp must be switched off. In courtesy position, only the light intensity can be adjusted, while temperature change is not possible. To return to normal operating position, the standby key (1) must be pressed.



The light beam cannot be adjusted.

To move the lamp use the sterilisable handpiece provided. After use, to safely switch off the Product, press the main switch.

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5 *Cleaning and disinfecting*

5.1 *Cleaning the Product*

Switch off the Product by detaching the main switch and make sure it cannot be switched back on. Protect the Product from water spray and detergents and do not clean it with liquids.

Leave the lamp body to cool down. Only clean the lamp body when it is cold. Clean with suitable detergents with low alkaline content and chlorine free.

Do not use abrasive products, petrol, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes; dose the cleaning agents so no liquids penetrate inside the lamp elements and into the support arm system.

Clean the Product with a damp, but not wet, cloth.

CAUTION: Failure to comply with the 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 glass.

The product is best cleaned at least once a day when used. To clean the lamp, the support need not be removed.

5.2 *Disinfecting*

Switch off the Product by detaching the main switch and make sure it cannot be switched back on. Protect the Product from water spray and detergents and do not clean it with liquids.

Leave the lamp body to cool down. Only disinfect the lamp body when it is cold.

Disinfectants can contain substances which are harmful for the health - only use disinfectants in accordance with the rules on hygiene established by the hospital; the Product operator must comply with the rules established by the national commission for hygiene and disinfection.

To prevent damaging parts in stainless steel or aluminium, only use disinfectants which are chlorine and halogen free; to prevent the plastic parts becoming fragile, use only disinfectants with low alcohol content; dose the disinfectants so no liquids penetrate inside the lamp elements and into the support arm system.

Clean the Product with a damp, but not wet, cloth.

The Product is best disinfected every time before use. To clean the lamp, the support need not be removed.

5.3 *Handpiece sterilization*

Replace the hand-pieces as soon as these become cracked or deformed, as these could fall in the patient area.

The Product operator must comply with the rules established by the national commission for hygiene and disinfection.

Hand-piece fitting / removal:

- turn the handpiece anti-clockwise and remove it.

- turn the handpiece clockwise until it is up against the headpiece and rotation is blocked. Cleaning, disinfection and sterilization of the hand-piece:

The hand-pieces are made of plastic material resistant to heat and knocks (PPSU - Polyphenylsulphone).

They can be cleaned with a mild or 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 polyphenylsulfone (PPSU).

Rinse the handpieces before sterilization.

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.

Position the handpieces in straight position with open side downwards. Do not exceed a sterilization temperature of 134°C.

Avoid the handpieces coming into contact with other objects during the sterilization process. Strictly keep to the ISO 17665-1 standard.

Each Product, over time, is subject to a certain amount of wear. Product safety and operation must therefore be checked during inspection and maintenance intervals.

6 Adjustments

6.1 Yearly inspections by operator

Keep to the yearly inspection schedules and inspect the product according to IEC 62353 standard.

6.2 Repairs

The Product must only be opened by technical assistance staff.

The only repair job with which the technical assistance personnel are charged is changing the fuses, as indicated in paragraph 6.6. Any other special maintenance jobs must be done by the manufacturer.

CAUTION: Interrupt the power supply before doing any maintenance jobs.

CAUTION: Making any changes to this appliance is forbidden.

6.3 Adjustments

The Product is sold already balanced and does not require further adjustment. If the Product becomes unstable over time and fails to remain in position, see section 10. If, after adjustment, the product still fails to remain in position, contact the GIMA after-sales service.

6.4 Troubleshooting

N	Problem	Solution
1	The Product fails to work	Check the integrity of the fuses. If any one of the fuses is damaged replace it as indicated in section 6.6. If the product still does not work, contact the assistance service.
2	The Product does not remain in position	See par. 10. If, after adjustment, the product still fails to remain in position, contact the GIMA after-sales service.
3	The light flickers	Contact the after sales service
4	The light beam is not focalised	Contact the after sales service

6.5 Routine maintenance

N	Period	Action
1	Once a year	Perform complete movements of all Product joints and make sure movement is smooth. If the Product fails to maintain its position or its movements are hard, see par. 10.
2	Once a year	Make sure the bar retention screws are tightened properly. Also check the bar horizontal arm retention screws. If these are not properly fastened, adequately tighten. See drawing 190. To access the screws, loosen the 3 dowels (1) of the ring (2). Remove the bar cover (3) by pulling downwards. Tighten the 4 nuts (4), the screw (5) and the safety dowel (6). Make sure the screws (7) of the horizontal arm are properly tightened.
3	Once a year	Check the condition of the Product paint. Make sure there are no paint pieces that could fall in the patient area.


6.6 Spare parts list

WARNING: only use original GIMA parts

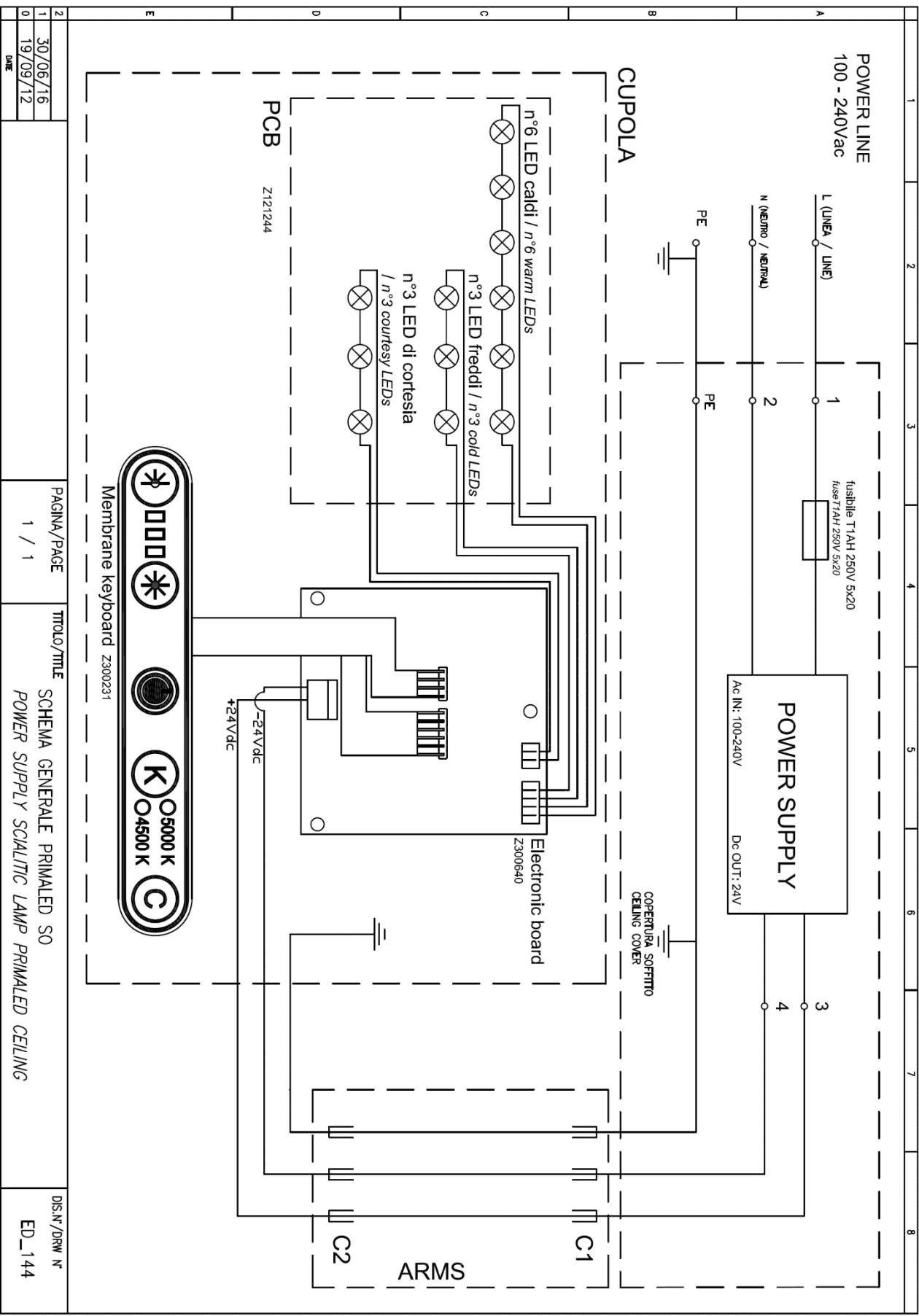
<i>Description</i>	<i>Order code</i>
Fuse T1AH 250V '5x20'	Z400208
Sterilisable grip	Z100848

- Drawing 190 To access the fuses, loosen the 3 dowels (1) of the ring (2). Remove the bar cover (3) by pulling downwards.
- Drawing 191 Remove the fuse carrier (6) from the terminal board and replace the fuse (7) making sure it is replaced with another of the same type.

7 Technical properties

Technical properties		PRIMALED/ PRIMALED-FLEX	
Illumination Ec at 50cm distance ± 10% [Lux]		95,000 / 110,000	
Colour temperature (±5%) [K]		4,000 / 4,500	
Colour rendering index Ra [-]		95	
Max irradiation [W/m2]		294	350
Irradiation / Illumination [mW/m2lx]		3.09	3.18
Max irradiation in UV [W/m2]		0.002	
Focalization from grip		No	
Power connection details			
Primary alternate voltage [Volt ac]		100-240	
Frequency [Hz]		50/60	
Power input [VA]		22 (100V) – 30 (240V)	
Light source		N°9 Led	
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)		50,000	
Light intensity control [%]		25 –100	
General data			
Colour		RAL 9003	
Directive		2007/47/EC	
Standards		IEC 60601-2-41	
Classification of Medical Device		Class I	
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3000K-6700K and 85-100, respectively)		
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance Ee in the lighted area does not exceed 1000 W/m² at a distance of 500 mm).		
IP Classification		IP20	
Operating conditions		Continuous operation	
Mains power voltage insulation means		Integrated power plug	
Integrated fuses		T1AH 250V, 5x20	
Handpiece steam sterilization		121°C 1.3 bar from 25 to 30 minutes 134°C 2.3 bar for 4 minutes.	
Dimensions			
Diameter of lamp body [cm]		19.5	
Light emission surface [cm²]		42	63
Lamp weight [Kg]		12	
Markings			
		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			

8 Wiring diagram




9 EMC Declaration

The Product has been tested according to EN60601-1-2 standard to ensure correct electromagnetic compatibility. Portable and mobile RF-communications equipment can affect the Product. The Product should not be used adjacent with other equipment and that if adjacent use is necessary the Product should be observed to verify normal operation. The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that is used in such an environment.

Immunity test	Conformity	Electromagnetic environment - directives
RF Emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Product is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Product or shielding the location.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Conforming	

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply unit +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c mains voltage prior to application of the test level.

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Veff 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5GHz</p>	<p>3 Veff</p> <p>3 V/m</p>	<p>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.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P} \quad 150 \text{ KHz to } 80 \text{ MHz}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 80 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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 $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.24
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.

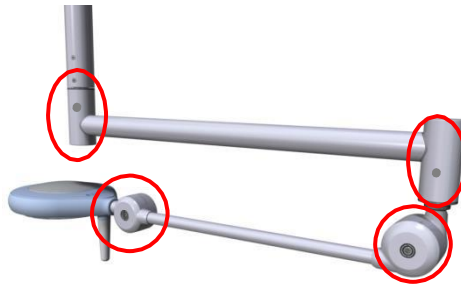
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects an people.

10 Clutch adjustment

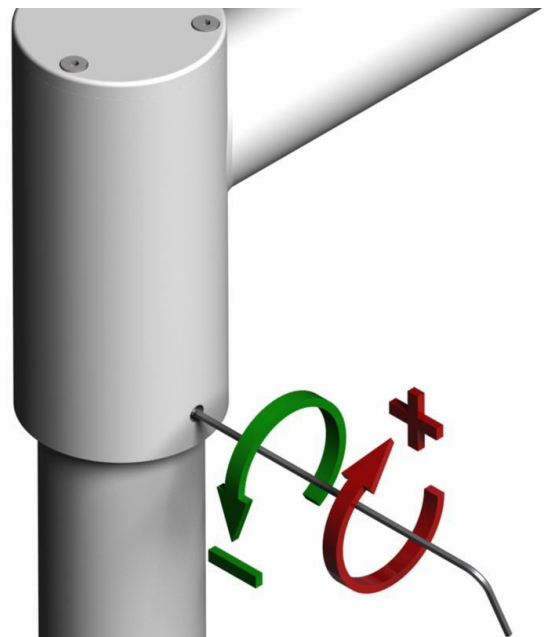
The Product is sold balanced and does not require further adjustment. Nevertheless, if the movements of the arms around the rotation joints becomes too stiff or too loose over time, such as to prevent the device remaining in position, the different clutch systems can be adjusted to restore correct stability.

Use the Allen key to adjust clutch force at the rotation joints and, therefore, the consequent movement of the small moving arms.

ROTATION JOINTS



ADJUSTMENT PROCEDURE



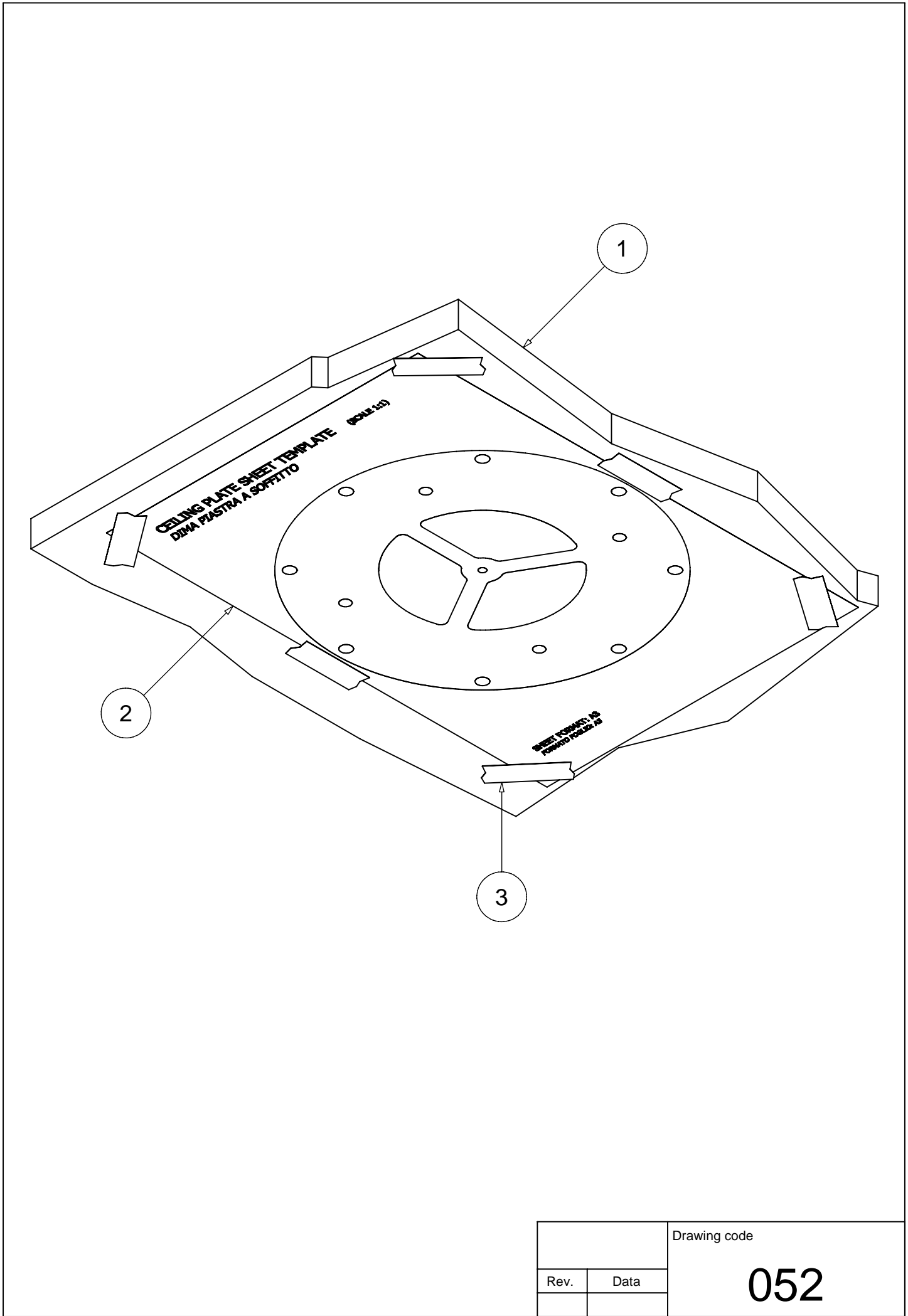
Using the Allen key, adjust the screw alongside the joint in question.

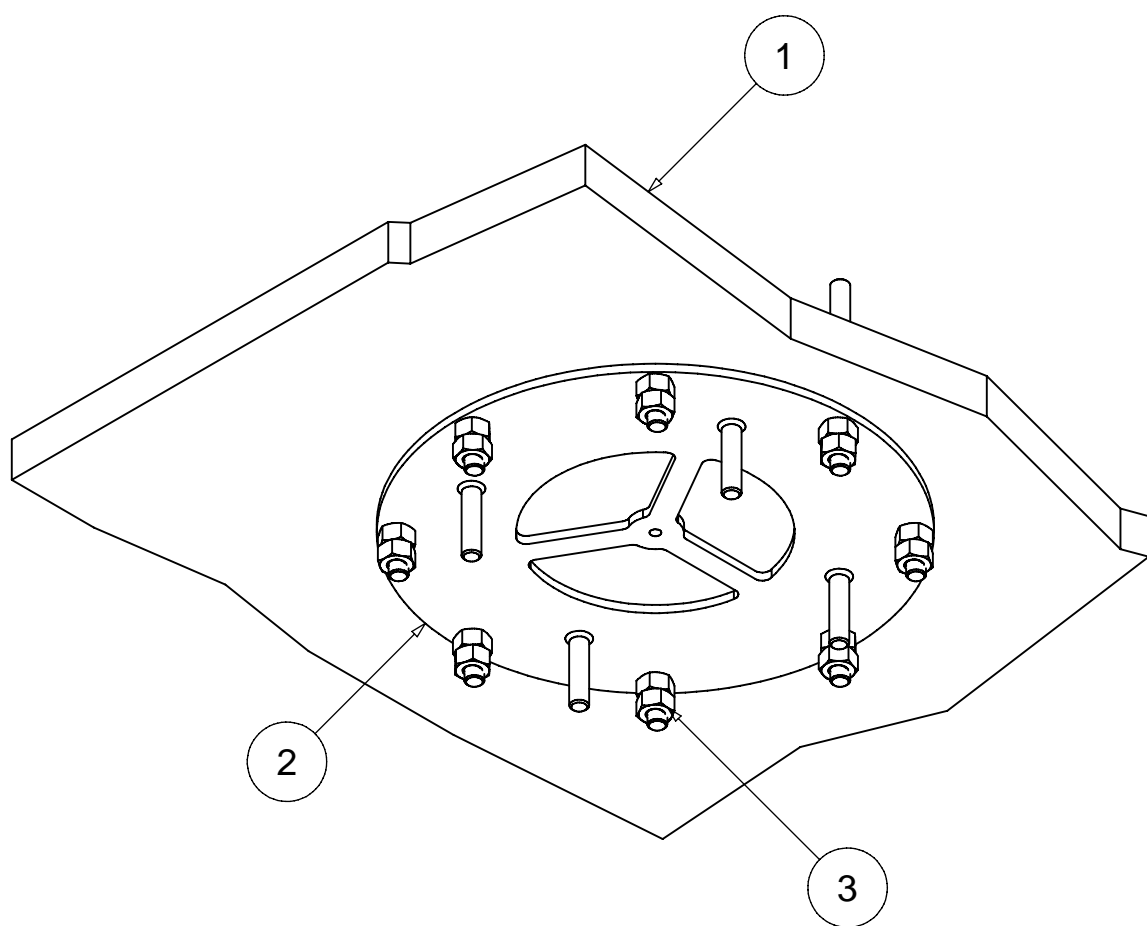
Turn clockwise to increase the force of the clutch and stiffen movement. Turn anti-clockwise to reduce the force of the clutch and loosen movement. After making adjustment, movement should be smooth and uniform.

The clutches on the horizontal arm can also be adjusted.

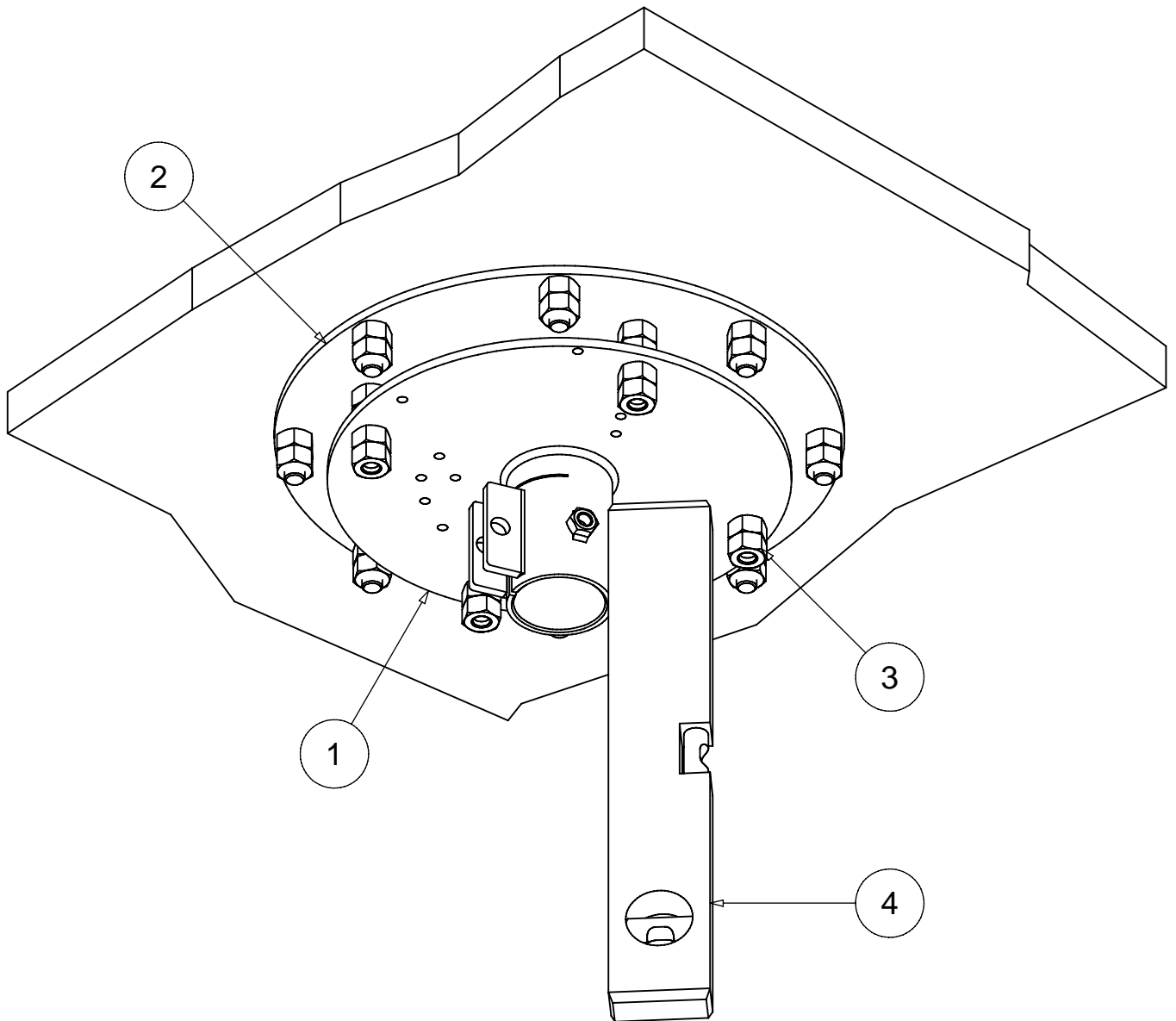
To adjust, use an Allen key and operate on the dowels on the arm hubs. To increase the force of the clutch and make movement stiffer, turn clockwise.

To reduce the braking force and loosen movement, turn the Allen key anti-clockwise. After adjustment, the rotation of both axes must be smooth and uniform.

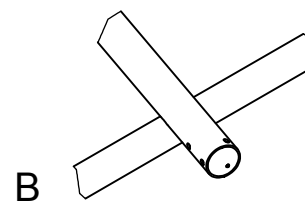
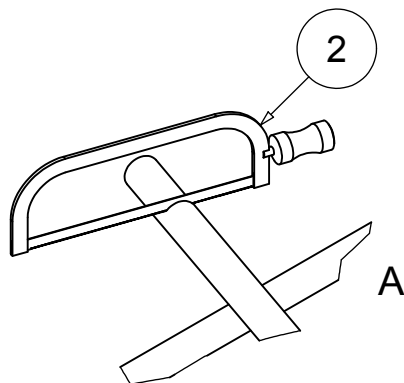
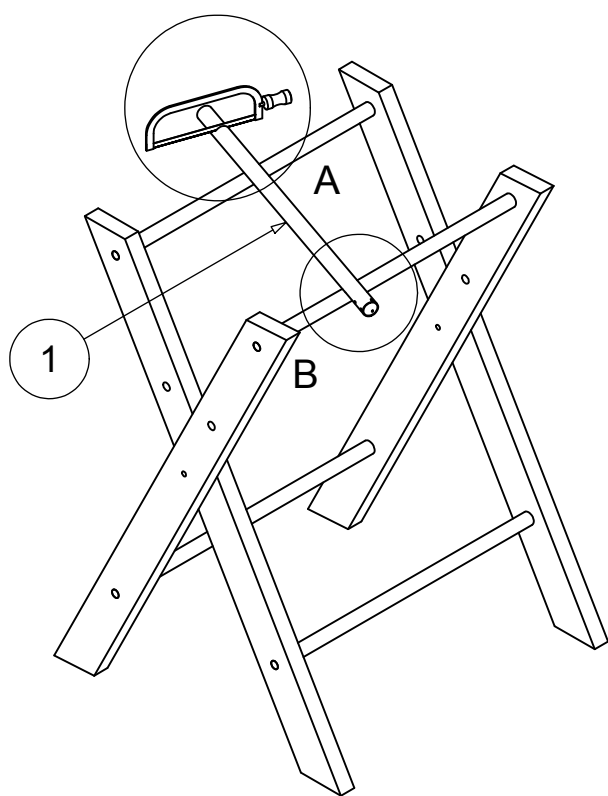




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Rev.	Data	

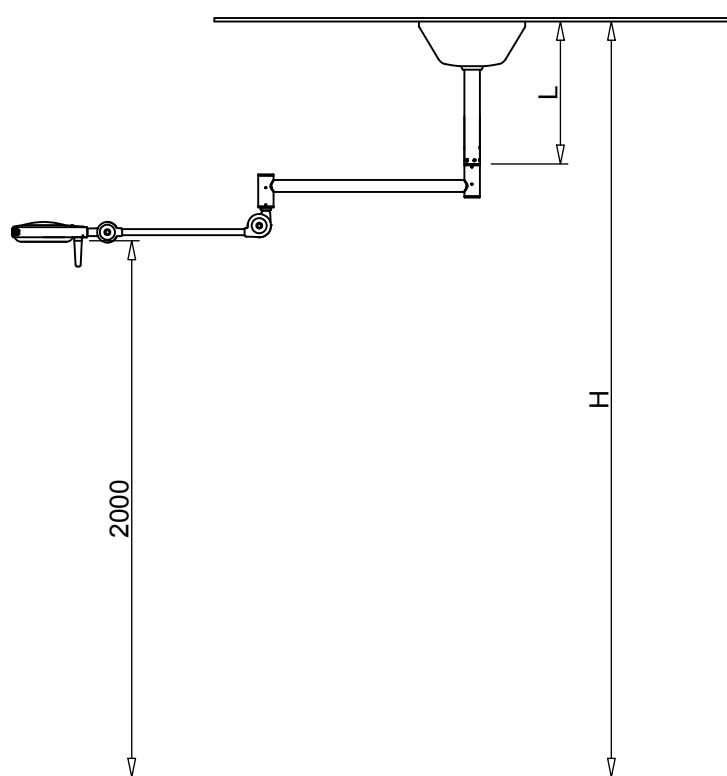
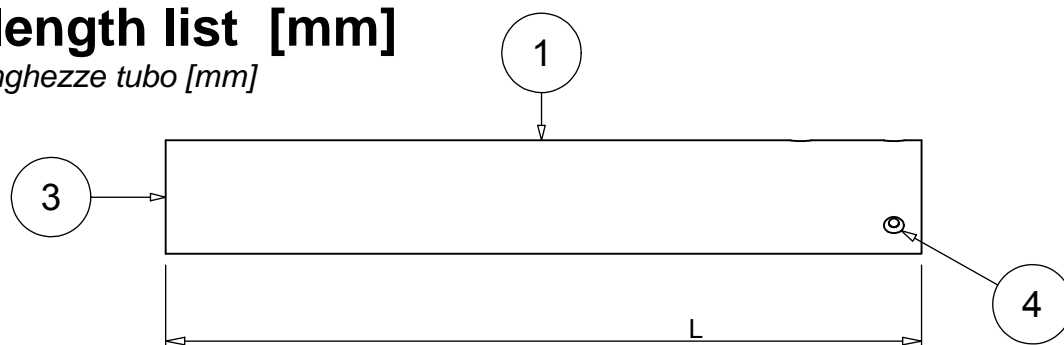


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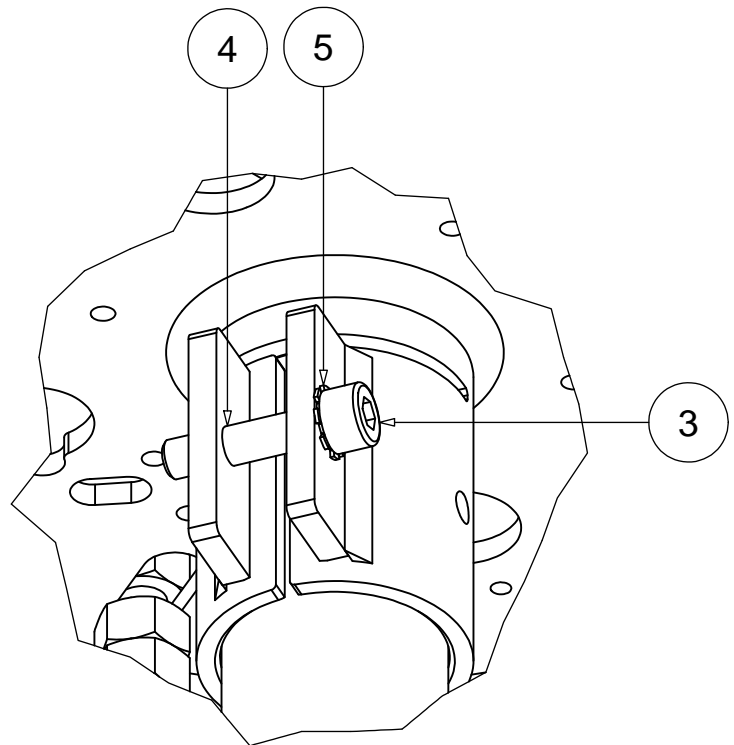
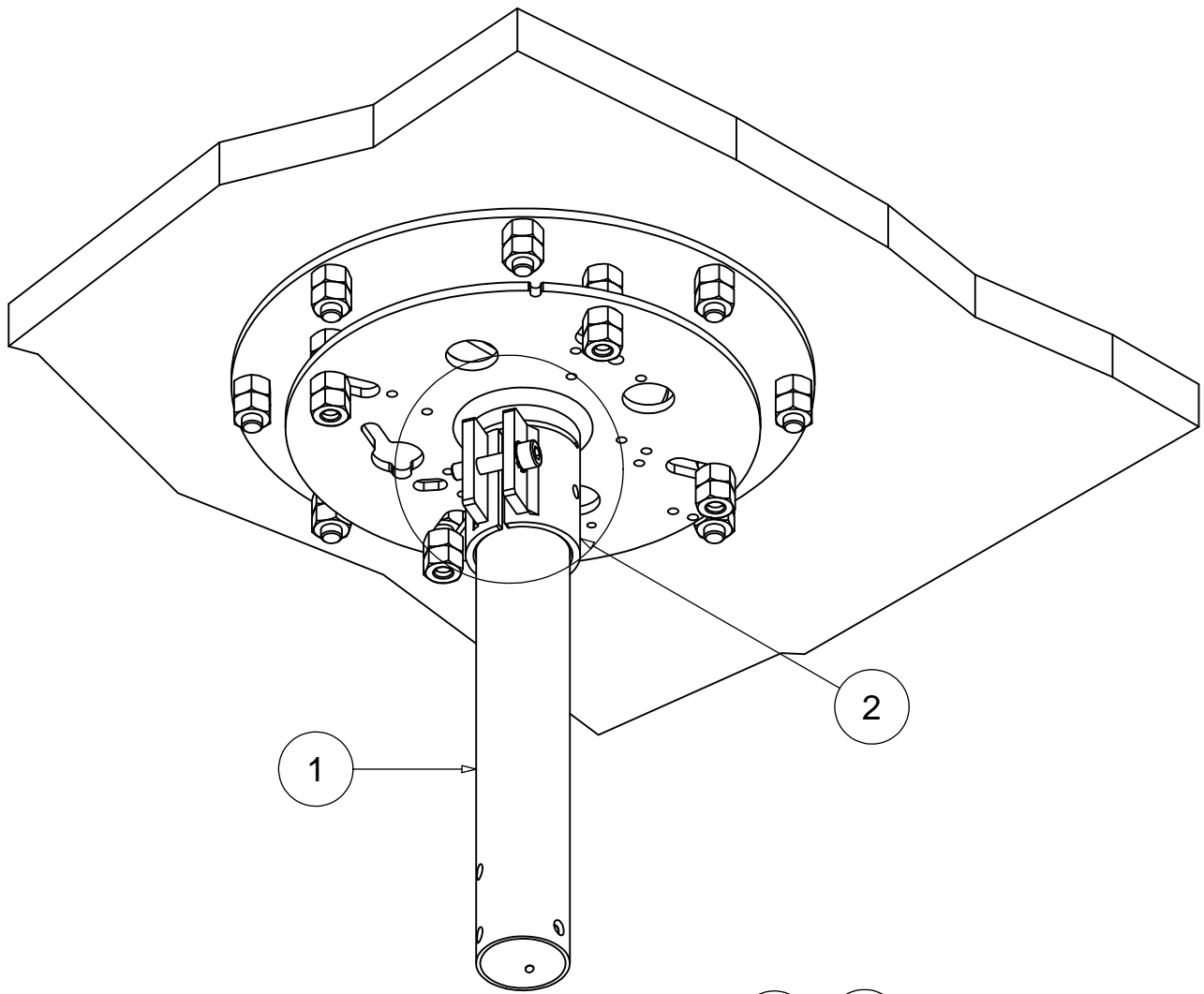
Tube length list [mm]

Tabella lunghezze tubo [mm]

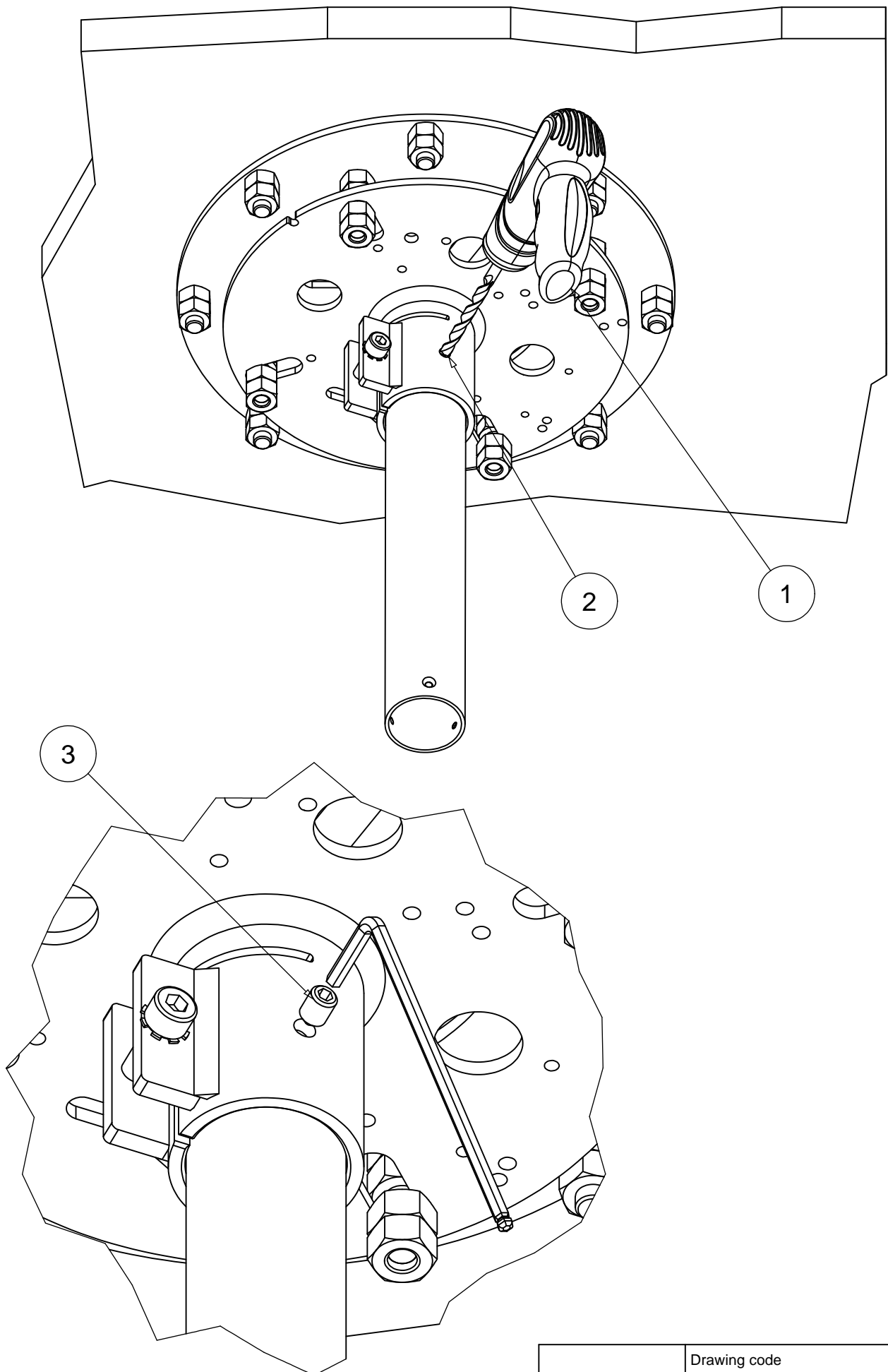


H [mm]	L [mm]
2440	200
2450	210
2500	260
2550	310
2600	360
2650	410
2700	460
2750	510
2800	560
2850	610
2900	660
2950	710
3000	760
3050	810
3100	860
3150	910
3200	960

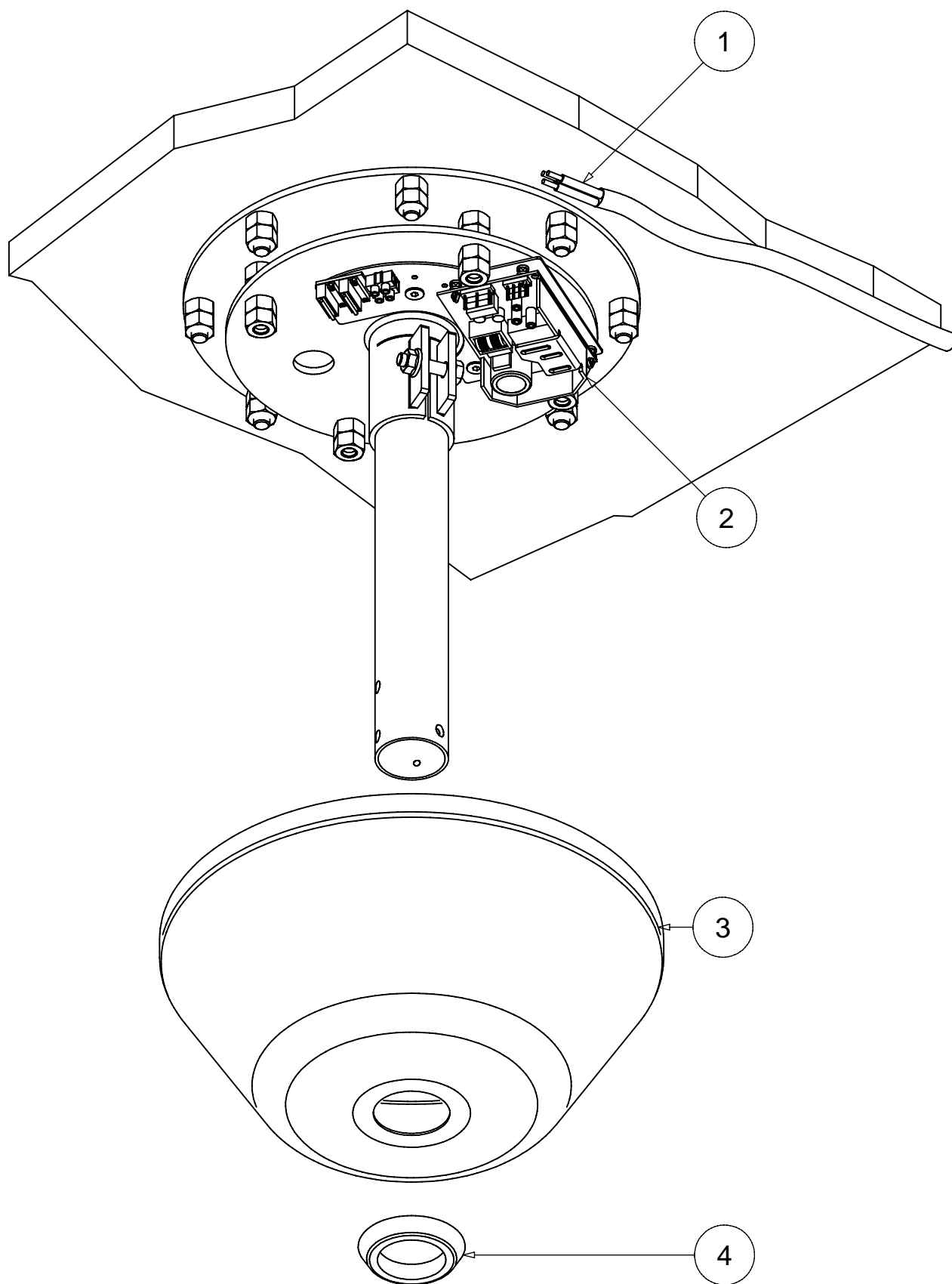
Rev.		Data	Drawing code
			055



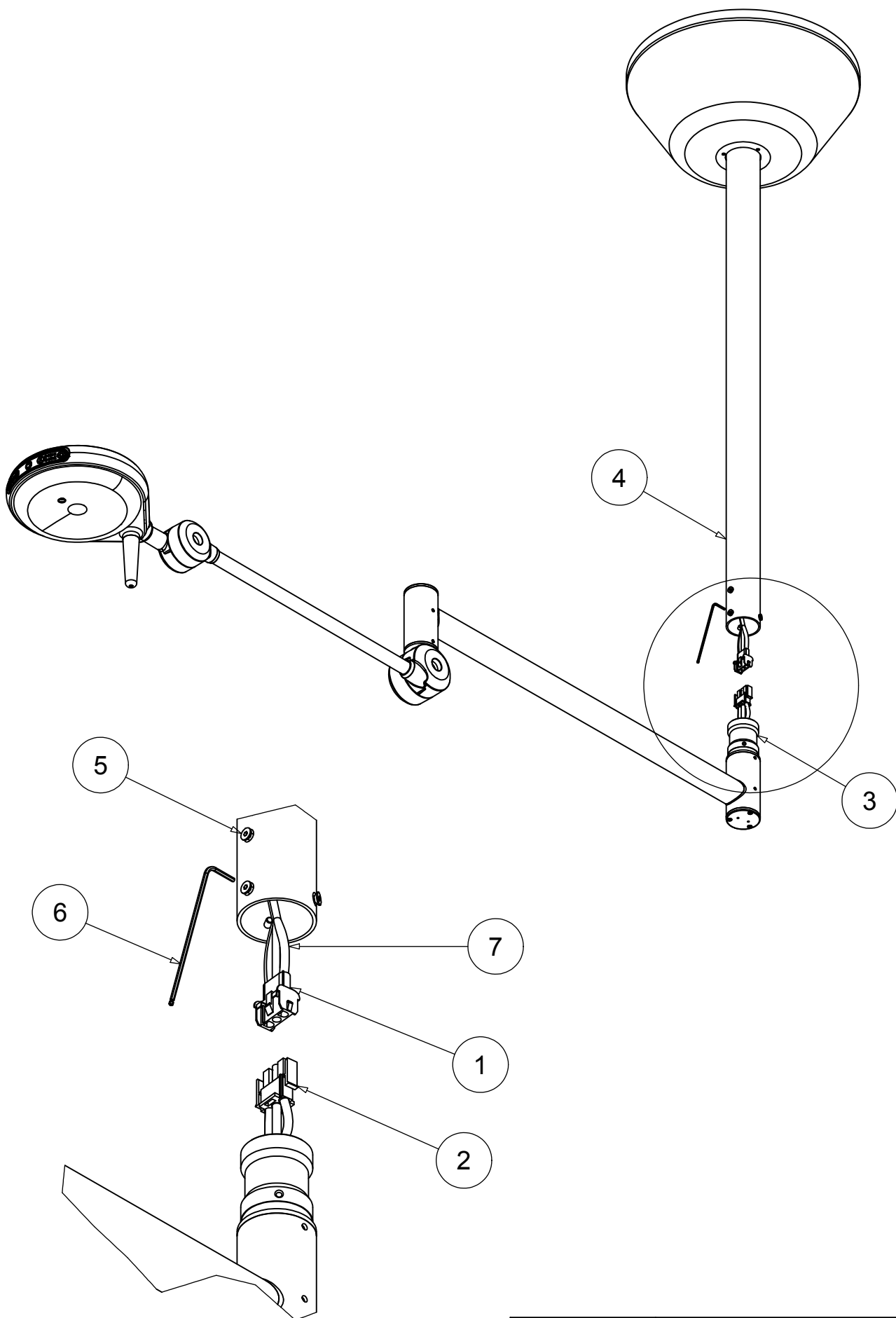
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Rev.	Data	



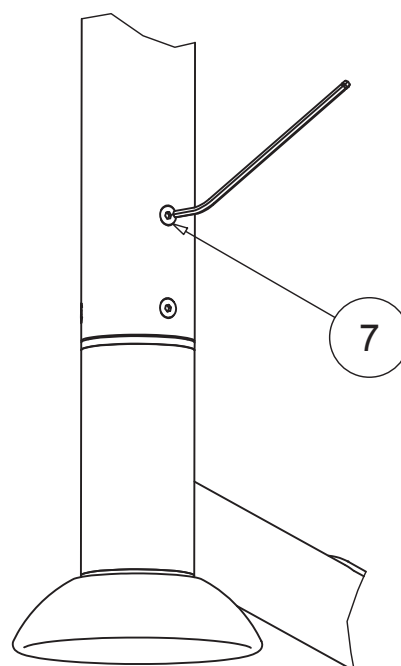
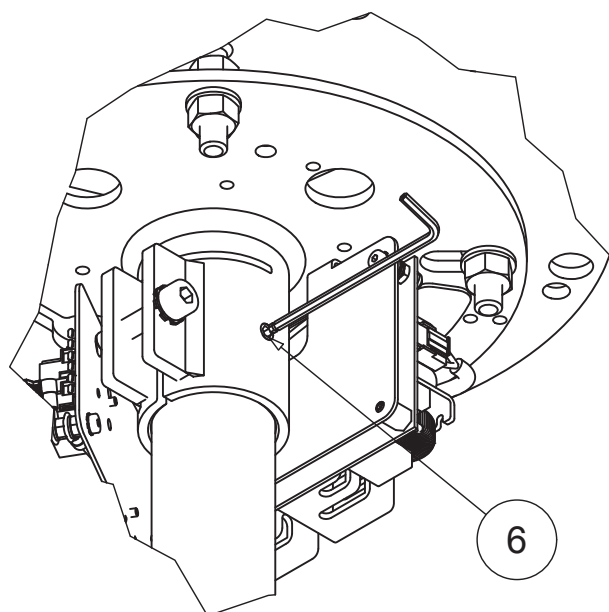
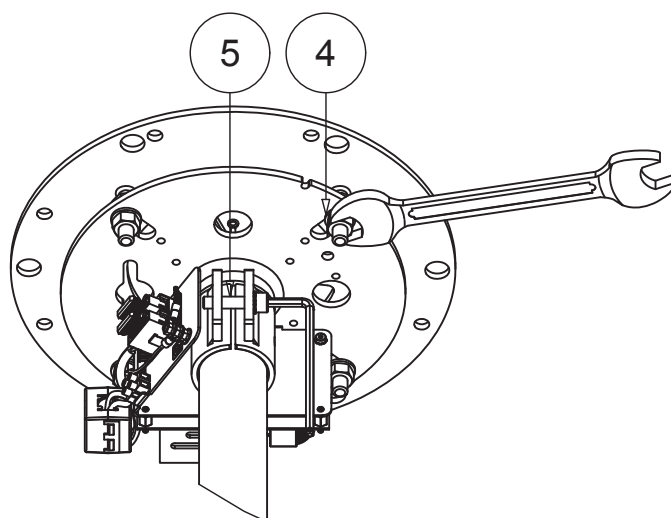
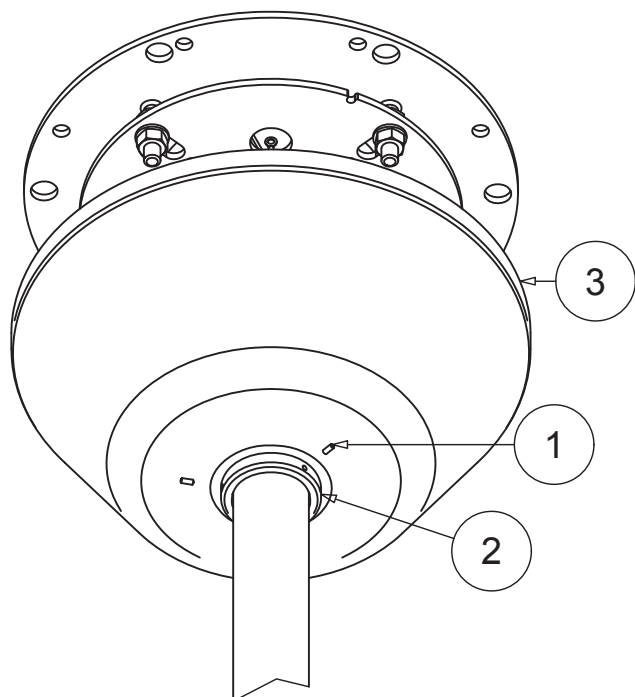
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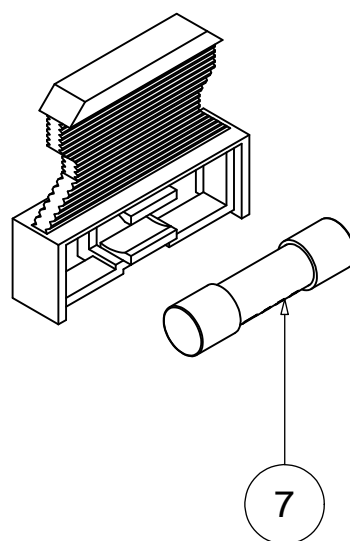
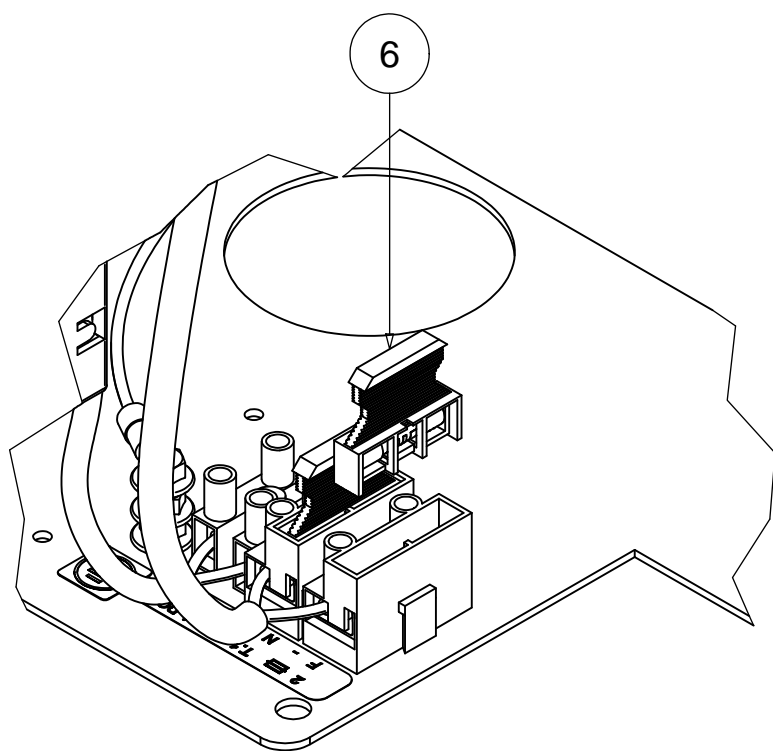
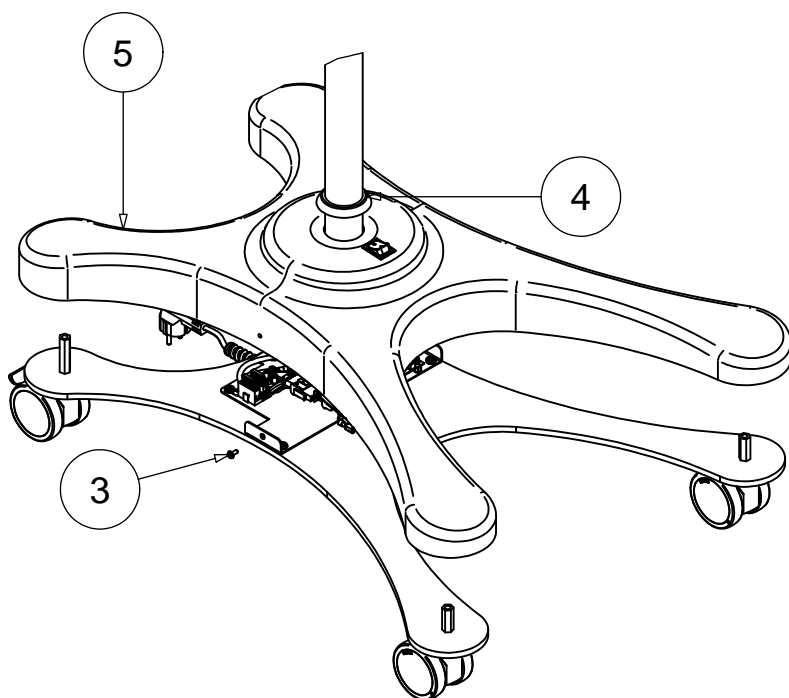
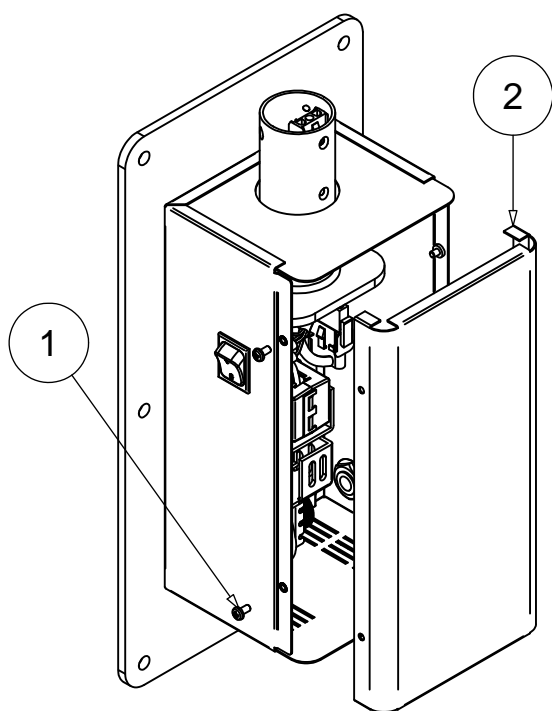
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Rev.	Data	



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Rev.	Data	



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Rev.	Data	

