DI.CO.POL.21.00

UE DECLARATION OF CONFORMITY

The manufacturer G.COMM SRL with Registered Office and manufacturing site at Via XXV Aprile, 20 - 20884 Sulbiate (MB) – Italia

DECLARES

under its sole responsibility that the medical devices

ITEM NUMBER	DESCRIPTION	MD	BASIC UDI-DI	UDI-DI
86.H100.0000	DENTAL LIGHT HEAD POLARIS	(01)	805571574POL001E8	8055715740149
86.H110.0000	DENTAL LIGHT HEAD POLARIS SENSOR	(01)		8055715740156
86.H200.0000	POLARIS LIGHT HEAD 3MOV	(01)		8055715740163
86.H210.0000	LIGHT HEAD POLARIS 3RD MOV SENSOR	(01)		8055715740170
86.H301.0000	DENTAL LIGHT HEAD POLARIS NEW FRICTION 3° MOV	(01)		8055715740187
86.H301.9002	DENTAL LIGHT HEAD POLARIS NEW FRICTION 3° MOV RAL9002	(01)		8055715740194
86.H301.9016	DENTAL LIGHT HEAD POLARIS NEW FRICTION 3° MOV RAL9016	(01)		8055715740200
86.H400.9010	DENTAL LIGHT HEAD POLARIS RAL9010 3RD MOV	(01)		8055715740217
86.H600.0000	LIGHT HEAD POLARIS 3RD MOV NEW ARM	(01)		8055715740231
86.H610.0000	LIGHT HEAD POLARIS 3RD MOV SENSOR NEW ARM	(01)		8055715740248
86.H500.0000	G.O. ORTHOLUX 200 LED	(01)	805571574OTL001F7	8055715740224

comply with the requirements of the Regulation (EU) 2017/75 of the European Parliament and of the Council of 5 April 2017 on medical devices of Class I.

The intended purpose of the devices is the illumination of oral cavity for treatments of preventive care, restoration, endodontics, oral surgery, implantology and periodontology. The intended users are only medical personnel authorized to perform dentistry treatments. The devices are not intended for profan users. The devices are intended for the following types of patients: children (4-17 years), adults (18-75 years) and elderly (over 75 years), whose weight and clinical conditions to diagnose, treat and / or monitor are not relevant.

The manufacturer, fully conscious to fulfill its obligations and under its sole responsibility, declares to have realized all measures to comply with the Directive 2011/65/EU as amended in Annex II by the Delegate Directive (EU) 2015/863 for the devices listed above. The devices listed above do not contain, for the restricted substances regulated, higher concentration values in respect to those tolerated in the article 4 and in the Annex II of the Directive 2011/65/EU as amended by the Delegate Directive (EU) 2015/863.

The manufacturer also states that this Declaration of Conformity is valid only in case:

1. periodical servicing is performed only according to G.COMM's instructions and by G.COMM's authorised personnel;
2. no part of these products is replaced with spares which are not approved by G.COMM;
3. no appliance is connected to these products after their first delivery without prior G.COMM's authorisation.

Sulbiate, _____

Giaffreda Nicola

CEO

CE

INDEX

SYMBOLS USED IN THE MANUAL AND IN THE PRODUCT

 Manufacturer

 Year of Production

 Serial Number

 Reference Number

 Medical Device

 Type B applied part

 EC Marking

 Follow the instructions

 Alternating Current

 Ground

 Auxiliary Power Connector

 Light Intensity Variation

 Colour temperature Variation

 GENERAL WARNING
Read carefully and follow the instructions to avoid dangerous situations

 PROHIBITION
This should not be done to avoid damage to the medical device

 SAFE TEMPERATURE LIMITS

 On/Off

 Separate collection of electrical and electronic devices

SAFETY WARNINGS

Before using the lamp, please read the instructions contained in this manual and please pay attention to the following indications:

-The intended use is the illumination of the oral cavity in prophylaxis, restoration, endodontics, odontostomatological surgery, implantology, periodontology and oral medicine and the lamp should only be used for this purpose by a medical staff.

-The device installation must be realized only by authorized staff;

-Dental operating light must be installed on appropriate medical devices such as dental treatment unit, or supplied in conformity to electric supply specifications exposed in this manual and with wiring in conformity to laws applied for medical local;

-The lamp must be supplied with an insulated transformer which provides 2 MOPPs in accordance with EN 60601-1.

-Do not stare into beam;

-The operator should warn the patient not to fix the light beam.

-Do not realize maintenance or light cleaning during light powered on;

-Do not introduce any object in the ventilation holes that could realize a contact with in voltage point;

-Clean and disinfect the light surface according to the indications contained in this manual;

-Do not cover the ventilation light holes; clean and control periodically holes to assure a correct ventilation;

-Do not leave unguarded the light switched on for long period;

-Spray or liquid vapour entry in the light envelope has to be avoid.

INTRODUCTION

Thank you for purchasing the dental operating light "POLARIS".

"POLARIS" has been designed on 3 main basis: aesthetics, functionality and simplicity, putting particular attention to research in design and materials.

The result is a modern operating light, with a soft, fresh, pleasant design, but also very stable and functional. "POLARIS" will give you high level performances and will surely meet with any of your professional requirements. POLARIS assures an elevate light intensity, 3D light pattern (in order to emphasize the lowest details), a faithful colours' reproduction of treatment area, the possibility to regulate colour temperature, the absence of shadows and the emission of cold light.

FUNCTIONS

POLARIS is based on the innovative high performance LED (Light Emitting Diode) technology. POLARIS, through the use of a 10 low power LEDs system (1W each) and the opportune combination of the illumination flows produces an high and adjustable light intensity (from about 8.000 to 50.000 Lux).

The 10 LEDs system assures a light without shadows. In fact, the 10 LEDs reflect light on indipendent parabolas with 10 prisms each. This allows to obtain 100 individual light fields in different concentric positions and to realize a light pattern without shadows.

With this system, light remains without shadows also in case of a single LED fault or multiple LEDs fault, and this fact gives to the dentist the opportunity to end the work.

The innovative LED technology allows to have a light source with a lifetime of at least 50.000 h instead of 5.000 h of the halogen light.

LEDs have an onset time of nanoseconds and an instant light emission instead of halogen lights.

Moreover POLARIS, don't use a cooling fan and it eliminates, consequently, its noise.

POLARIS beams cold light. Cold light avoids the increase of the temperature on the treatment area and the unpleasant heating feeling by the patient.

Cold light is in fact a light without infrareds (IRs). IRs can realize the dehydration phenomenon of tissues during the surgery.

Moreover POLARIS doesn't generate UV rays. UV rays can be dangerous for biological tissues, especially for nucleic acids and proteins which are the most important absorbents of this kind of radiation.

POLARIS integrates a system, to regulate the colour temperature from about 4200K to 6000K. Recent studies demonstrate that dentist concentration increases through the rise of colour temperature with the consequent reduction of dentist eyestrain.

POLARIS allows to obtain a faithful colours' reproduction of lighted zone. Colour rendering index (CRI) represents a measure of a light source's ability to show object colours "realistically" or "naturally" compared to a familiar reference source. With its high CRI (>90), POLARIS assures a correct vision and a huge chromatic reliability.

POLARIS makes more comfortable dentist's work, especially in case of long surgeries. The region near the dentist head tends to heat, but the use of cold light reduces considerably the heating raise. POLARIS has lowered consumption (less than 20W) and an elevate reliability (LEDs have long lifetime and system don't need cooling fan) in respect to halogen light system.

Please read the following thoroughly and strictly observe the operating instructions provided.
If you're still experiencing difficulties please call our Helpline +39 039 6060420.

DEVICE DESCRIPTION

The POLARIS lamp consists of an optical unit to be used in connection with a G.COMM lamp arm (see section TECHNICAL DESCRIPTION - ACCESSORIES).

The installation activity involves the electrical and mechanical connection from the optical group to the lamp arm and from the lamp arm to the dental unit / ceiling attachment / stand / wall mount (see sections ELECTRICAL CONNECTION and INSTALLATIONS). Installation must be carried out exclusively by a technician authorized by G.COMM.

The maintenance activity involves cleaning the screen and handles and sterilizing the handles; could be carried out by the operator at the end of each treatment (see section MAINTENANCE).

Extraordinary maintenance includes all the activities not provided for in the MAINTENANCE section of the device and must be carried out exclusively by a technician authorized by G.COMM (see REPAIRS section).

DEVICE DESTINATION

The intended use is to illuminate the oral cavity in prophylaxis, restoration, endodontics, odontostomatological surgery, implantology, periodontology and oral medicine.

The intended users are exclusively doctors who are authorized to perform treatments in the dental field.

The device is not intended for profan users.

The device is intended for the following types of patients: children (4-17), adults (18-75 years) and elderly (over 75 years), whose weight and clinical conditions to diagnose, treat and / or monitor are not relevant.

The lamp is expected to come into contact only with the doctor who uses it through the plastic cover of the handles.

G.COMM declines all responsibility deriving from the incorrect or improper use of the lamp.

GENERAL HYGIENE RULES

⚠ **While using this device always use individual protection devices. This device is not protected against liquid penetration.**

Clean the protection shield with a cloth and a non abrasive disinfectant or detergent. Handles can be sterilized (see instructions in the MAINTENANCE section).

DEVICE CLASSIFICATION

Device of class I with applied parts (handles and protection shield) type B (EN 60601-1).

Device of class I according to directive 93/42/CEE “Medical Devices”.

Device IPX0 not protected against liquid penetration and not suitable for use in conjuction with inflammable agents and anaesthetic mixtures with air, oxygen or nitrous oxide.

Device not suitable for use in oxygen rich environments.

Device not suitable for use in flammable enviroments.

Device for continuous work.

Risk group 1 (at 20 cm) according to EN 62471 standard.

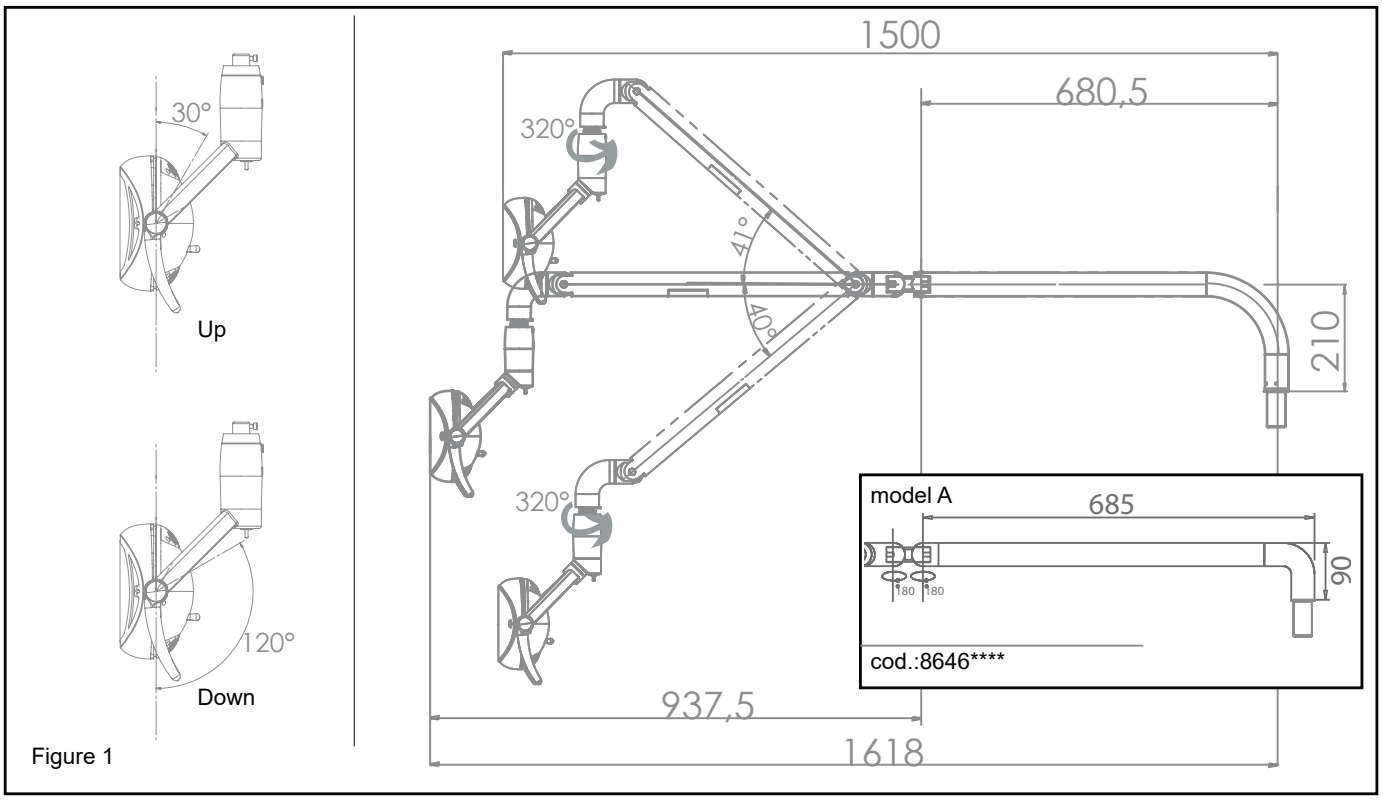


Figure 1

TECHNICAL DESCRIPTION

SPECIFICATIONS

Size and movement:	**(Fig.1)**
Light head weight:	1.900 kg
Operating light arm weight:	5.150 kg
Connection hub to light arm:	diameter 35 mm (other on request)
Power supply:	12 - 24 Vac 50/60 Hz
Maximum power consumption:	22 VA
Current consumption:	1.5 A
Fuse (with transformer):	2 x 2.5 A type F
Light pattern:	80 x 200 mm
Light intensity (adjustable):	min. 8.000Lux – max 50.000Lux (±10%)
Colour Temperature (adjustable):	from 4200 K to 6000 K
Focal distance:	70 cm
CRI:	> 90%
Light source:	10 LEDs (1 W each)
Emission spectrum:	400-700 nm
Maximum light power emitted:	10 mW
Minimum required distance from patient:	70 cm

REF:

8671xxxxx	Polaris lamp for dental unit with various arm lengths and diameter of the pivot.
8666xxxxx	Polaris lamp for ceiling mount with various arm lengths.
8668xxxxx	Polaris lamp for trolley mount with various arm lengths.
86.H100xxxxx	Polaris G.O. (lamp head only, no arm, 2 axis movement).
86.H600xxxxx	Polaris G.O. (lamp head only, no arm, 3 axis movement).

ACCESSORES:

Surgical Cart	Cod. **83040000**
Cieling mount	Cod. **82100011**
Wall Mount:	Cod. **82090000**
Trolley	Cod. **83060000**
UV Filter	Cod. **86.C102.0000**
Steel Arm:	
- Standard	Cod. **86460000/F**
- Long	Cod. **86460000/FL**
- Ceiling	Cod. **86570000/F**
Aluminum Arm:	
- Standard	Cod. **86400000**
- Long	Cod. **86400000L**
- H90 standard	Cod. **86401000I**
- H90 long	Cod. **86401000IL**
- H90 standard ceiling	Cod. **86411000I**
- H90 long ceiling	Cod. **86411000IL**
- Ceiling	Cod. **86410000**
- Trolley	Cod. **86420000**

ESSENTIAL PERFORMANCE

As defined in EN 60601-1:2006 essential performance have to be intended as device performance the absence or degradation of which would result in an unacceptable risk. Considering that no unacceptable risks for basic safety are introduced for patient and operator, minimum performance required to the device are those shown in section TECHNICAL DESCRIPTION related to emission spectrum, light intensity, colour temperature, CRI and light pattern.

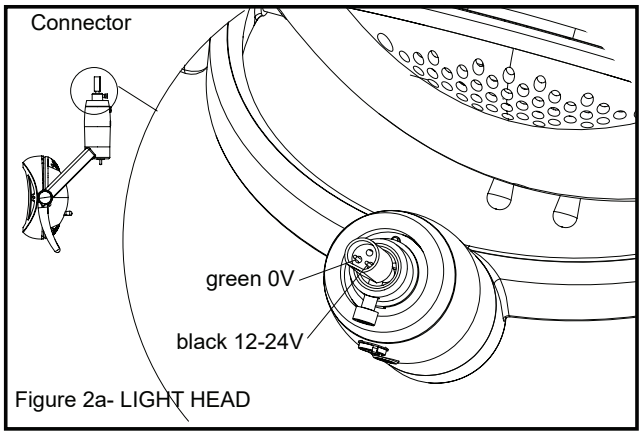


Figure 2a- LIGHT HEAD

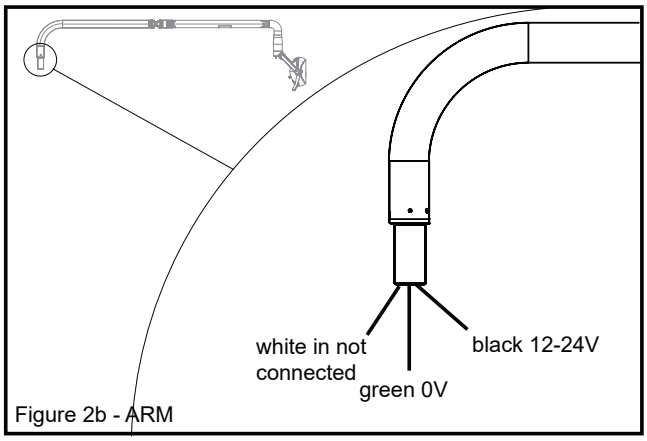


Figure 2b - ARM

ELECTRICAL CONNECTION

"POLARIS" must be electrically connected as follows (power supply intended for 50W load):

Light head (Fig.2a)

GREEN WIRE 0 Volt
BLACK WIRE 12-24 Volt ~ (alternating current)

Operating light arm (Fig.2b)

GREEN WIRE 0 Volt
BLACK WIRE 12-24 Volt ~ (alternating current)
WHITE WIRE not linked

Minimum power of the transformer for all applications related to the only optic group: 20 VA 50/60 Hz.
Minimum power of the transformer for auxiliary power supply connector: 50 VA 50/60 Hz.
It is necessary to use an insulation transformer from the net 230V 50/60Hz and with output voltage from 12 to 24Vac - 6A, that will ensure stiffened insulation according to EN60601-1. In the respect of safety regulations also make sure that, on the primary winding of the transformer, a bipolar switch would be put before in accordance with its standards with a rating of 10A–250V and that in series on the secondary windings would be put 2 rapid fuses 2.5A.

⚠ **The device must be installed only by authorized technicians.**

⚠ **Installation and all maintenance operations have to be always carried out with the lamp unplugged from the power supply (dental unit's general switch in OFF position).**

⚠ **"Lamp unplugged from the power supply" has to be always intended as the dental unit's general switch set in OFF position.**

⚠ **Dental unit general switch must have a light indication (green light indicate ON status of power supply connection).**

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

INSTALLATION

The operating light "POLARIS" is delivered as one LIGHT HEAD and one ARM packed separately.
The complete installation of the lamp requires the assembly of these two parts.

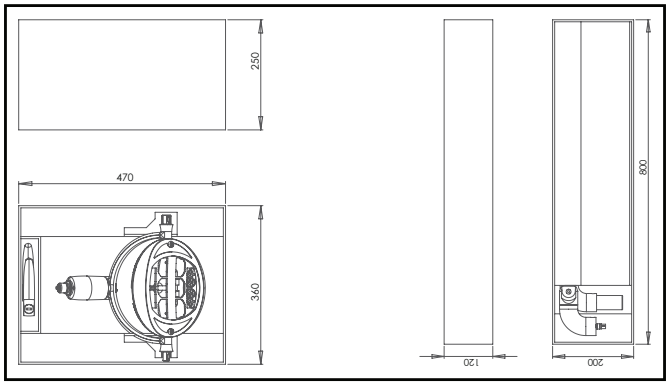


Figure 3

PACKAGING

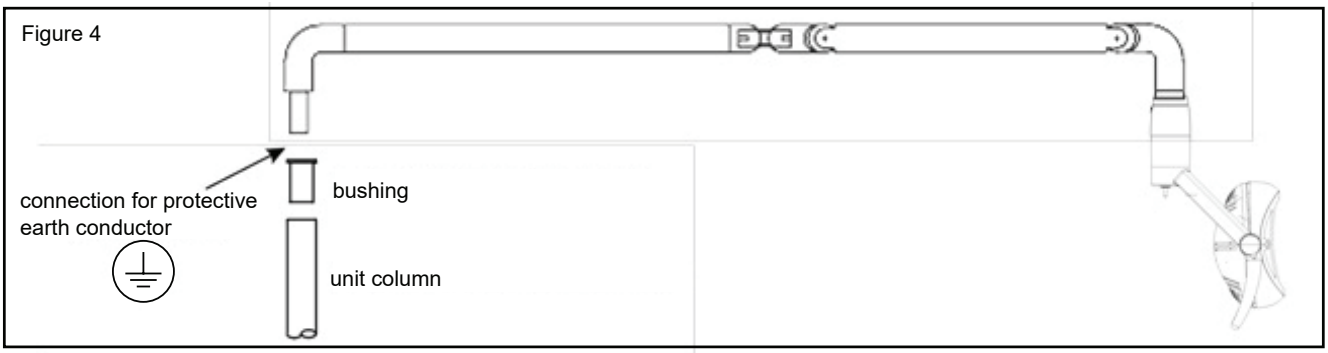
Proceed as follows:
1. Take the arm out of the box.
2. Use an eyelet to connect the ground cable at the bottom of the pivot **M3** thread **(Fig.4)**, and a yellow/green ground cable with a minimum section of **AWG 24**.
3. Connect the cable of the arm with the cable that comes out from the dental unit column. Place the arm with mounted pivot in the bushing of the column. Check the movements of the dental operating light and the stability of the entire structure (see **(Fig.4).**
4. Carefully take the "POLARIS" light head out of its protective package in order to avoid damage to glass protection or other parts.
5. (**Fig.2a/b)** connect the male connector placed in the arm to the female connector placed in the light head. Insert the light head pivot in the bend (called light head bend); make sure that the threaded hole of the pivot is in line with the small one on the arm. Place the **M5** screw supplied with the light into the hole and screw it with a tightening torque of **(6 Nm)**. Check for stability.
6.For the ground connection, connect the eyelet of the cable with the lamp pivot and connect the other side of the cable with the earthing point inside the unit.
7. Put the handles in the apposite handle holds. Handles could be installed in two configurations (lateral view):

"POLARIS" is now installed. Before switching the light ON check the electrical data with those of your transformer. Make sure the arm is properly placed and still.Rotate arm and light head in order to check proper fixation and free moviments.

⚠ **Do not modify the device and its installation system. Any modification to the installed device must be carried out exclusively by technicians authorized by G.COMM as foreseen in the REPAIRS section.**

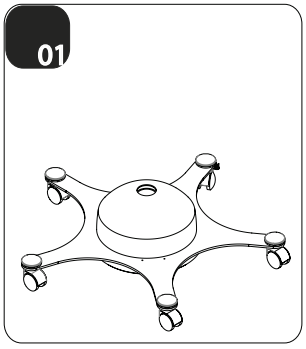
⚠ **The grounding of the lamp arm must be carried out by connecting to a ground system of a dental unit that complies with the requirements of EN 60601-1 and which provides for protection**

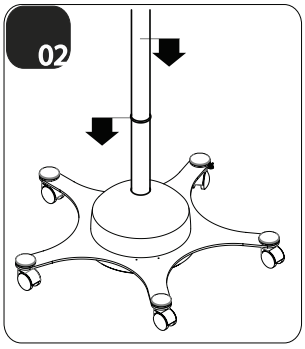
Figure 4



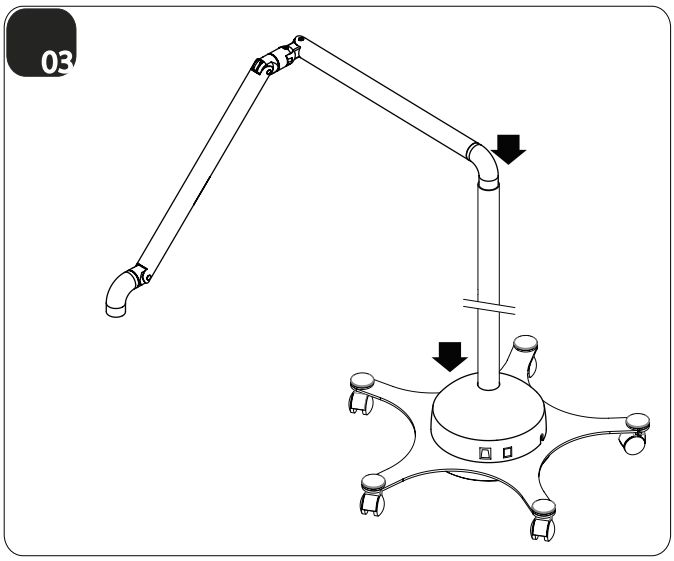
systems against involuntary loosening from the outside.

TROLLEY APPLICATION

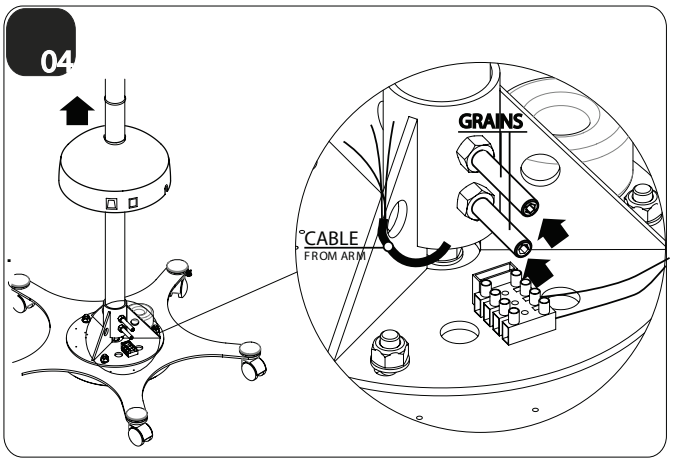




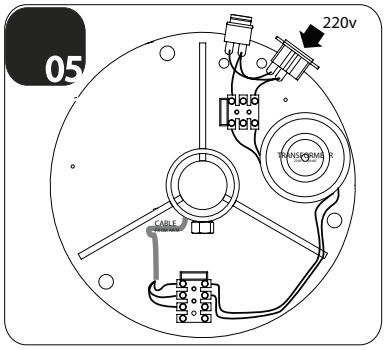
01 - Place the stand on the ground.
02 - Insert the pole into the special housing and let the transparent o-ring go down the pole.



03 - Insert the arm cable inside the pole and let the cable out of the base of the stand.



04 - Raise the dome and tighten the screws as shown in the figure.



05 - Connect the green and black cable to the power supply and leave the white cable free.

POWER SUPPLY: 12-24 Vdc
Lower the dome and then the o-ring till meeting point with the dome.

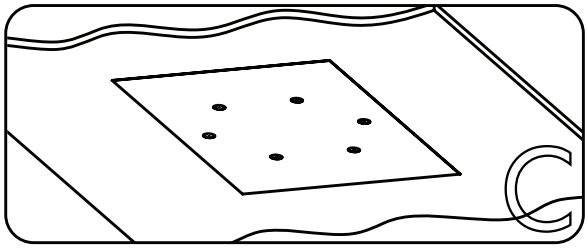
CEILING APPLICATION

⚠ **Assembly must be carried out by specialized technicians.**

⚠ **The power supply to the room, where the installation will take place, must be disconnected during the works.**

⚠ **Make an inspection of the room by evaluating the conditions of the ceiling, if it is able to withstand the weight of the application.**

⚠ **Refer to Fig.C and Fig.D for the positioning of the base.**
- With reference to **Fig.C** fix the drilling template to the ceiling and drill six holes in correspondence with the respective indications.
- Insert the plugs in the holes made and fix the plate (1) to the ceiling with reference to **Fig.D.**
- Insert the pole (7) in the special housing of the adjustable plate (2).
- With reference to **Fig.E** tighten the pole with the appropriate screw (12). Insert the special perforated bush into the housing and use it as a drilling guide for the pole. Perform the operation on both holes.
- Insert the screws (13) in the appropriate slots as shown in **Fig.F**
- Insert 4 flanged nuts **M8** in the appropriate threaded connections, insert the adjustable plate (2), insert 4 **M8** nuts. Referring to **Fig.G**, set the correct flatness of the two plates.
- With reference to **Fig.F** insert the transformer (5) and fix it with the appropriate nut (11) and its washer (10).
- Insert a guide cable to hook onto the arm cable (15) to be able to carry out the electrical connection at a later stage.
- Insert the dome (6) and the **O-ring** (14) to tighten everything on the pole with reference to **Fig.I**.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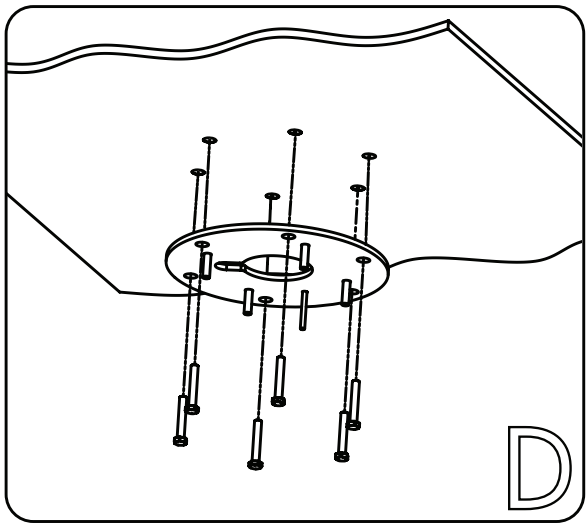
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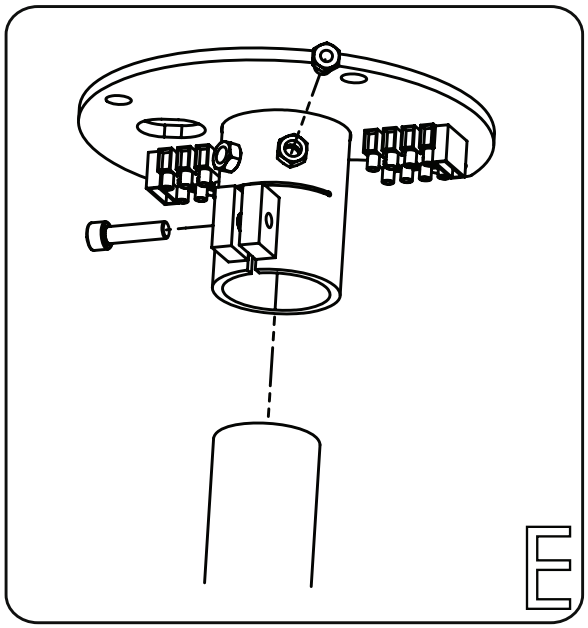
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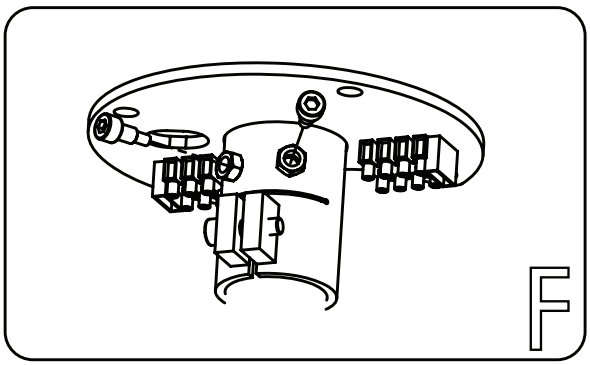
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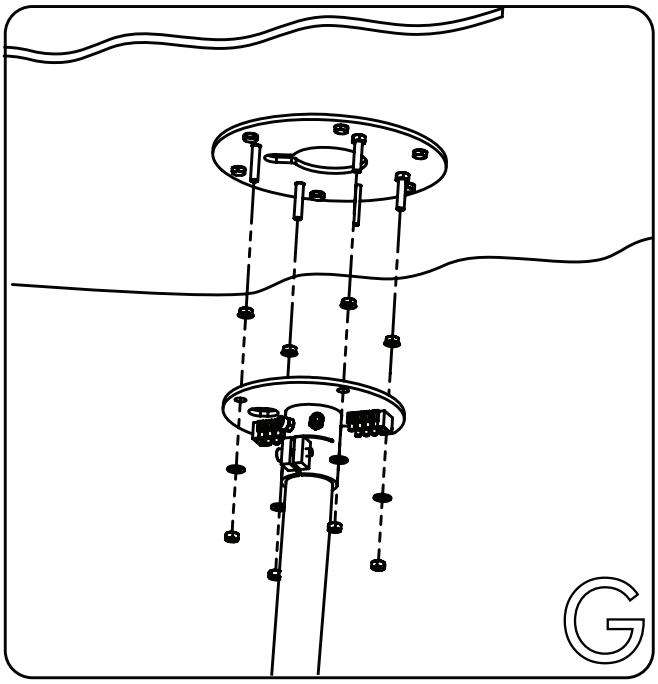
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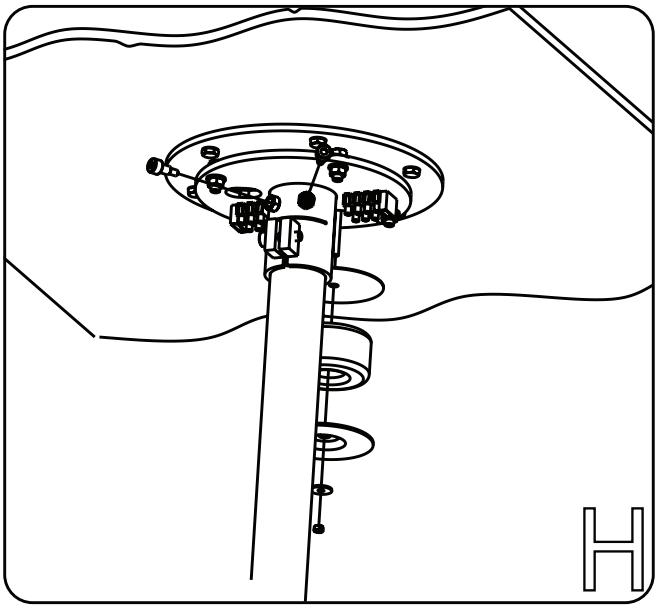
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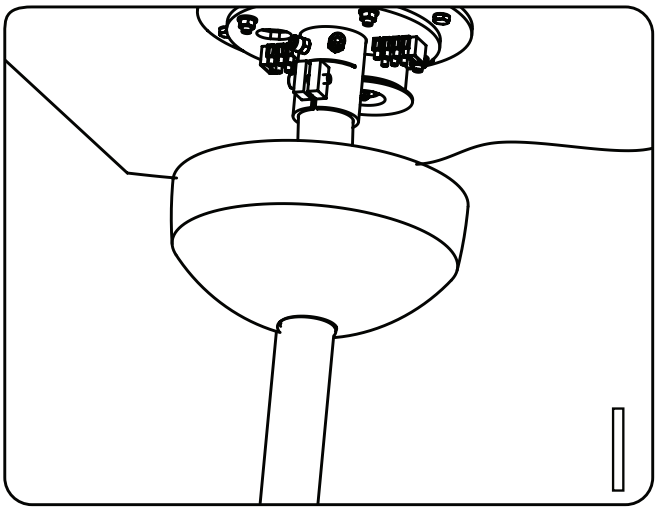
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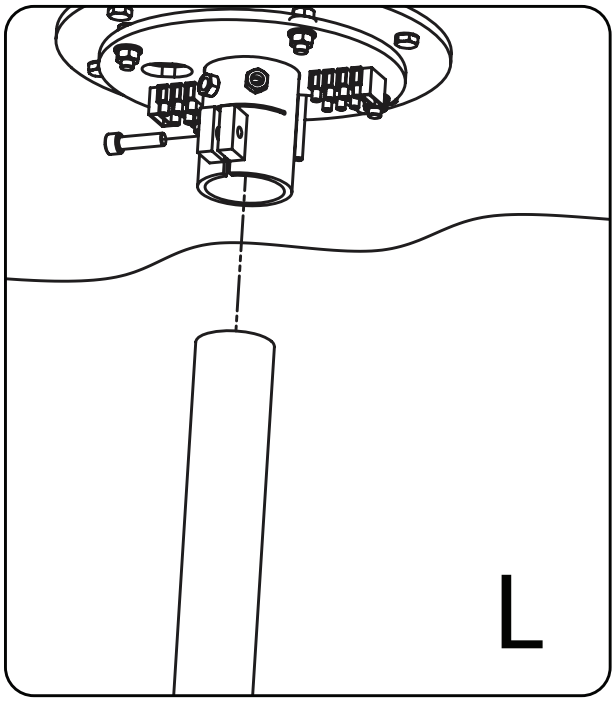
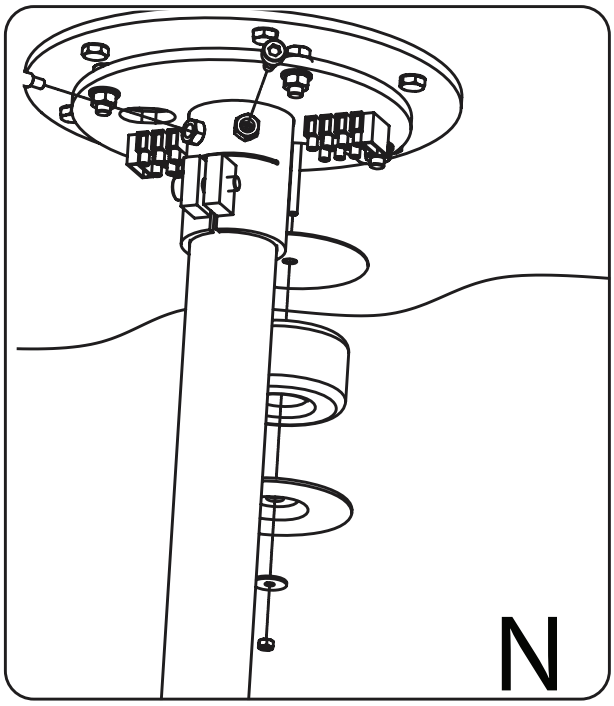
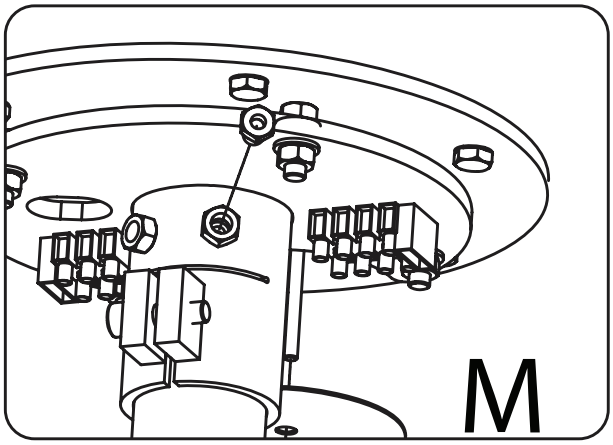
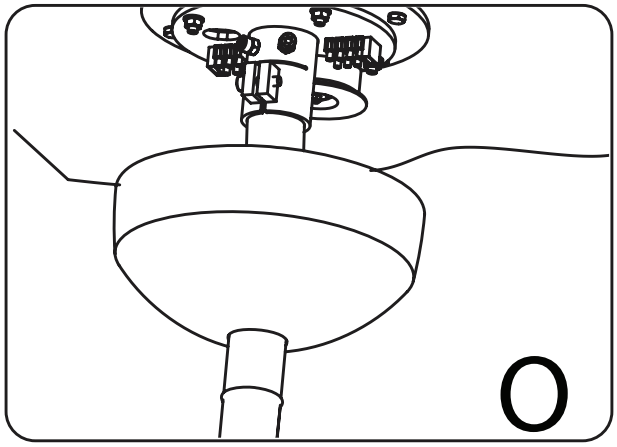








- Insert the shank of the arm (15) in the pole (7) making first attention to unscrew the screws (16) and then screw them after inserting the arm (15) for tightening.

VARIATION POLE LENGTH PROCEDURE
- Fix the two plates to the ceiling **Fig.C and D**.
- Cut the pole to the desired length
and insert it in the housing with reference to **Fig.L** and tighten it with a suitable screw (12).
- With reference to **Fig.M** Enter the
perforated sleeve in the pole housing,
pierce the pole having as a reference the
compass.
- Take out the compass.
- Repeat steps **N** and **O** above.

AUXILIARY POWER SUPPLY OUTPUT
An auxiliary power supply connector is placed in the back of light head body. The auxiliary power supply connector has to be used only to supply G.COMM devices (for example the G.COMM bleaching dental light COREWHITE).
Maximum power supply provided: 12-24 Vac
Maximum current provided: 3A

WALL MOUNT

Assembly must be carried out by specialized technicians.

The power supply of the room, where the installation will take place, must be switched off during the work.

Make an inspection of the room assessing whether the wall is able to support the weight of the application.

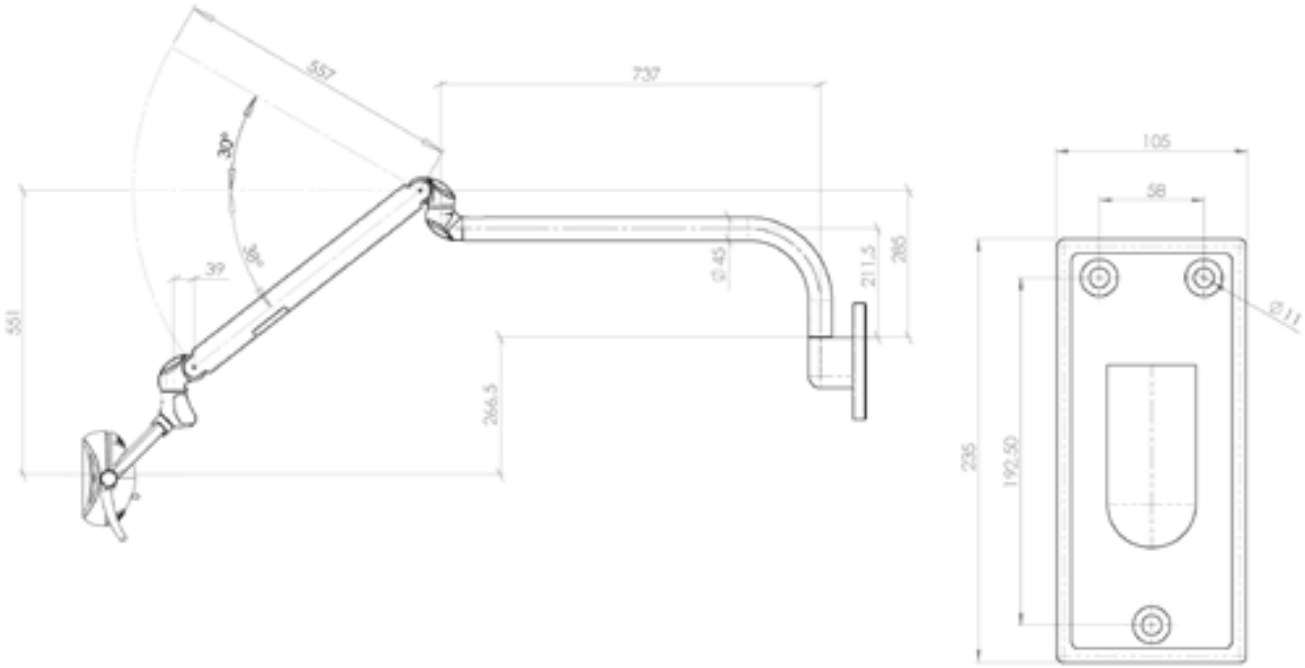
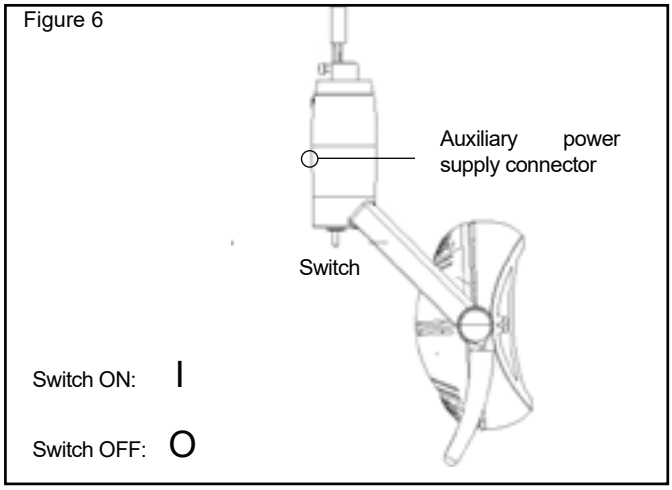


Figure 5

- With reference to **(Fig.5)** mark the center distance of the fixing holes on the wall and drill.
- Insert the dowels in the holes and fix the plate to the wall with bolts.
- Make sure the fixing is secure.
- Insert the arm coupling into the housing of the plate.
- Use a spirit level to sure that the arm is horizontal; otherwise, act by tightening the fixing bolts more tightly.
-Proceed with the assembly of the optical group.

USE

Figure 6

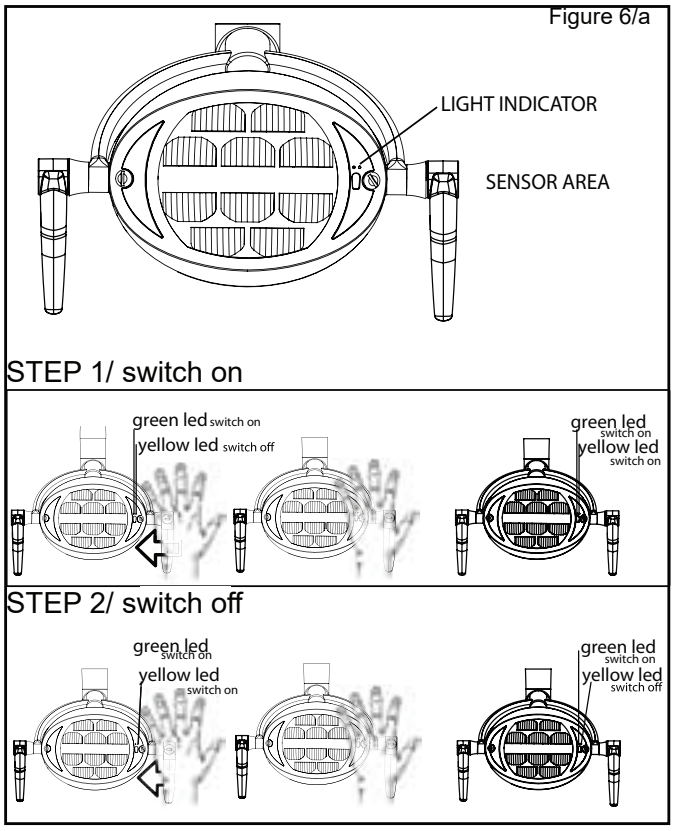


1. Switch ON / Switch OFF. Switch the operating light ON with the switch placed on the lower part of the light head **(Fig.6)**.

⚠ ATTENTION: Do not stare into beam when light is on.

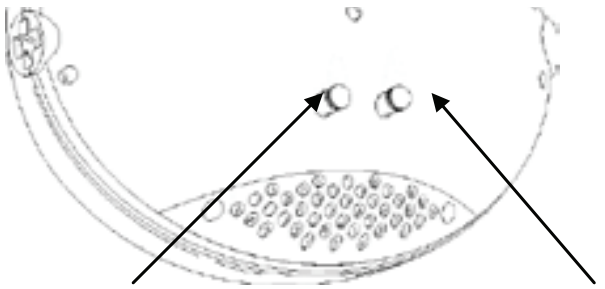
Sensor version. (Fig6/a) In the SENSOR version, the lamp is turned on / off not by means of a switch but by means of a sensor.
The connection of the lamp to the power supply is

Figure 6/a



signaled by the lighting up of the green status LED. Moving the hand in front of the sensor at a maximum distance of 5-6 cm from it, the lamp lights up and with it the yellow status LED. An acoustic signal is emitted. By moving again the hand in front of the sensor with the lamp ON at a maximum distance of 5-6 cm, the

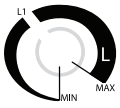
Figure 7



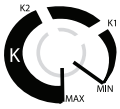
lamp switches OFF and with it the yellow status LED. An acoustic signal is emitted again.

2. Auxiliary power supply connector. The light head includes an auxiliary power supply connector at the same power supply voltage **(Fig.6)**.

3. Light intensity and colour temperature adjustment. In the back shield of light head there are two potentiometers **(Fig.7)**.



• Potentiometer **L** (lux) allows to regulate light intensity (to increase the light inten sity rotate in clockwise sense the poten tiometer).



• Potentiometer **K** (Kelvin) allows to regulate colour temperature.

	Toothmatching	*Surgery*
Potentiometer L Potentiometer K	max max-K1-K2 (suggested K1)	max K2-min to enhance soft tissues contrast

LUX adjustment (L potentiometer)	
min	minimum illumination level
L1	medium illumination level
max	maximum illumination level

COLOUR TEMPERATURE adjustment (K potentiometer)	
min	minimum colour temperature
K1-K2	medium colour temperature
max	maximum colour temperature

⚠ ATTENTION

The above mentioned potentiometer position are only suggested. The ability to perceive colour differences is subjective and the required values for a smooth perception could be different from above mentioned and from person to person.

4. Handles. Move the operating light only by holding the handles of the light head. This guarantees perfect working conditions of the dental light.

To ensure good operating light conditions avoid any scratch on the protection shield and always keep it clean.

To take out the protection shield go to section “MAINTENANCE”.

⚠ Contact technical support if it is not possible to change the illumination levels of the lamp.

⚠ Report any serious incident with the device to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

⚠ It is recommended to keep all the original packaging and to repack the device every time you need to make a significant move in order to avoid damage to the paint and external shells (for small movements, handle the instrument carefully, avoiding bumps and falls).

ELECTROMAGNETIC COMPATIBILITY WARNINGS

The POLARIS dental lamp is a electro-medical device. Special precautions regarding electromagnetic compatibility (EMC) are required and the devide must be installed and put into service in accordance with EMC information contained in the following manual.

⚠ The correct functioning of the Polaris dental lamp can be influenced by portable and mobile radio communication devices.

In the presence of particular diagnostic or therapeutic devices the functionality of the lamp may not be guaranteed.

⚠ In order to assure the good working of the device, please use only the wires and cables shown in the following table. (TABLE 01)

⚠ The use of cables other than those for which the Polaris dental lamp was designed, with the exception of the cables sold by G.COMM as spare parts for internal components, can lead to a significant degradation of performance causing an increase in emissions and / or decreased immunity.

TABLE 01

Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments
1	Optic group connector	AC	13 cm	NO	Cables used to link optic group connector to internal interface electronic board
2	Power supply cables	AC	50 cm	NO	Cables used to connect the internal interface electronic board to the power supply electronic board
3	ON/OFF switch	I/O	8 cm	NO	Switch used to turn ON/OFF the lamp
4	Potentiometers	I/O	12 cm	NO	Input signal used to drive LED sources
5	LEMO connector	AC	55 cm	NO	Power supply cables between internal electronic board and LEMO connector for bleaching lamp COREWHITE

*Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical
I/O = Signal Input or Output Port (Not Involved in Process Control)
TP = Telecommunication Ports

TABLE 02

Electromagnetic Emission		
POLARIS is intended for use in the electromagnetic enviroment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	***Compliance***	***Electromagnetic environment***
RF emissions CISPR 11	Group 1	POLARIS 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	POLARIS 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: **ATTENTION** This equipment/system is intended for use by healthcare professionals only. This device 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 device or shielding the location.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TABLE 03	**Electromagnetic immunity**		
POLARIS is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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 %.
Transient or electrostatic trains IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for imput/output lines	± 2 kV for power supply lines ±1 kV for imput/output lines	Mains power quality should be that of a typical commercial or hospital environment.
High energy pulses 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 % UT (>95 % drop UT) for 0.5 cycles (at phase angle: 0,45,90,135,180,225 e 360°) **<5 % UT** (>95 % drop UT) for 1 cycle (at phase angle 0°) **70 % UT** (30 % drop UT) for 25/30 cycles (at phase angle 0°) **<5 % UT** (>95 % drop UT) for 250/300 cycles (at phase angle 0°)	<5 % UT (>95 % drop UT) for 0.5 cycles (at phase angle: 0,45,90,135,180,225 e 360°) **<5 % UT** (>95 % drop UT) for 1 cycle (at phase angle 0°) **70 % UT** (30 % drop UT) for 25/30 cycles (at phase angle 0°) **<5 % UT** (>95 % drop UT) for 250/300 cycles (at phase angle 0°)	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that POLARIS is powered from an uninterruptible power supply or a battery.
Mains frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 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.			

TABLE 04

Electromagnetic immunity			
POLARIS is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment**
Conducted RF IEC 61000-4-6	3 V rms from 150 kHz to 80 MHz out of ISM radio bands and radio amateurs.	3 V	Portable and mobile RF communications equipment should be used no closer to any part of POLARIS including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$
	6 V rms from 150 kHz to 80 MHz in ISM radio band e amateur Radio	6 V	$d = 0.58\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz	3 V/m	$d = 1.17\sqrt{P}$ from 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ from 800 MHz to 2,7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1. At 80 MHz and 800 MHz, 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 and people.			

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which POLARIS is used exceeds the applicable RF compliance level above, POLARIS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the lamp.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 05

Recommended separation distances between portable and mobile RF communications equipment and Polaris

POLARIS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **POLARIS** 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 $d = 1.17\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.17\sqrt{P}$	***800 MHz to 2,7 GHz*** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 and people.

Do not use cables and transducers other than those specified in this manual.

The EMISSION features of device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environments (for which CISPR 11 class B is normally required), the device may not offer adequate protection from radiofrequency communication services. The user may need to take mitigation measures, such as relocation or re-orientation of the device. "

The Polaris dental lamp should not be used near or superimposed on others appliances; however if use near other equipment is necessary, check normal operation in the configuration in which the device is used.

MAINTENANCE

"POLARIS" has been designed to allow easy disinfection, with particular attention to hygiene. The following advices will simplify the cleaning process on your dental operating light.

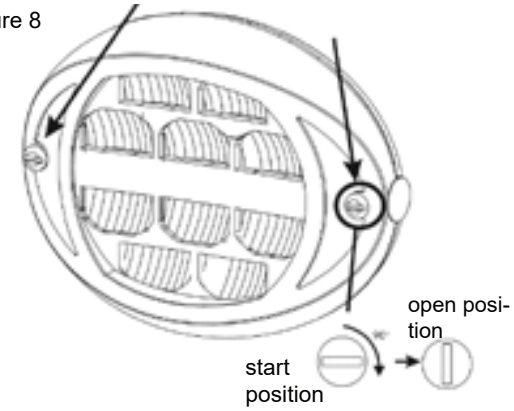
Before performing any treatment, it is recommended to clean and disinfect the device and disinfect / sterilize the handles according to the procedure described below.

USE ONLY WATER. DO NOT USE ABRASIVE SUBSTANCES AND/OR MATERIALS, especially alcohol,
trichloroethylene, gas, turpentine and similar .
Do not spray or spill liquids on the light.
Please put particular care while cleaning protection shield and handles. Please read as follows:
• **protection shield:** use a very soft cloth soaked with distillated water, with very soft movements. Dry with a soft cloth. To remove protection shield, please read as follows:
1. pay attention to the plastic knob placed on the protection shield; **(Fig.8)**
2. rotate the plastic knob for 90° in a clockwise sense **(Fig.8)** and take it out.

Never touch LED reflectors and LEDs.If necessary clean with soft air.
· **handles:** very easy to clean; if needed the handle can be dismounted and cleaned separately. The handles plastic cover can also be sterilized in autoclave in compliance with ISO 11134 with a cycle of 15 minutes at 134°C.
For proper sterilization is recommended to seal the cover of the handles in special envelopes with "indicator correct process done" to ensure the success of the process. Please sterilize the plastic cover of handles every time it gets dirty of organic material and/or at least once per week if the lamp is used every day.
After 10 cycles of sterilization the integrity of the cover of the handles may no longer be assured. Use the second pair supplied.

To dismantle the plastic cover of handles please read the following instructions **(Fig.9):**

Figure 8



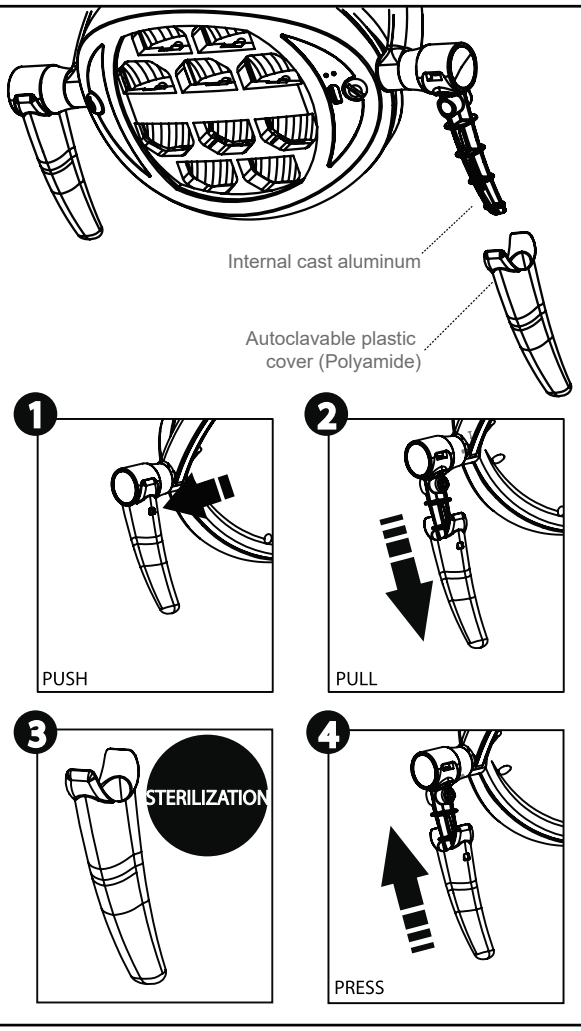


Figure 9

1. locate the unlocking button and press it;
2. remove the covers;
3. sterilizate them;
4. reinsert the covers until you ear the button click.

⚠ WARNING: if the mobile arm does not respond appropriately to the stresses of the applied load open the door on the arm and gradually tighten the compression nut of the spring placed inside checking from time to time if the compression of the spring is adequate to balance lamp's load.
The spring's stiffness verification has to be done annually by a specialized technician.

⚠ WARNING: Yearly, a qualified technician must check the grounding of the lamp arm (Fig.4).
Yearly, a qualified technician must check the correct tightening torque (6 Nm) of M5 screw (see point 5 of INSTALLATION section).

⚠ Do not perform any maintenance operations when the lamp is powered. Carry out maintenance work with the lamp switch in the OFF position.

USE CONDITIONS

Use in medical purposes rooms. Do not subject the lamp to thermal stress and do not expose it out of the following limits:
- temperature: from +10°C to +40 °C;
- relative humidity: from 0 to 75%;
- atmospheric pressure: from 800 to 1060 hPa.

TRANSPORT AND STORAGE CONDITIONS

Please keep the dental operating light POLARIS in a closed, covered and dry place.
Do not subject the lamp to thermal stress and do not expose it out of the following limits:
- temperature: from -20 to +70 °C;
- relative humidity: from 10 to 90%;
- atmospheric pressure: from 700 to 1060 hPa

REPAIRS

For any repair and / or replacement of the G.COMM light unit and / or accessories (lamp arm, stand, ceiling mount, ...) the intervention must be carried out exclusively by a technician authorized by G.COMM. Contact us directly for the addresses of distributors and authorized technicians.

G.COMM s.r.l. is in no case responsible for repairs carried out by third parties or unauthorized personnel.

G.COMM is responsable for product safety, reliability and performance only in case:
- assembly operations, extensions, adjustments, modifications or repairs made by authorized staff.
and with the use of original replacement pieces provided by G.COMM;
- electrical wiring, in which the device is installed, has to be conformed to safety laws in force;
- use of the light in accordance with the instructions given.
G.COMM will make avaible on request instructions or other information that will assist SERVICE PERSONNEL to repair those parts of POLARIS designated to be repairable by SERVICE PERSONNEL.

WARRANTY

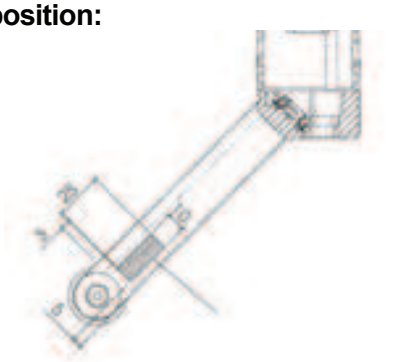
The manufacturer hereby certifies that this product has been properly manufactured in complete compliance with the european and international regulations.
The product is covered by warranty for a period of 12 months from the date of delivery to the end user. Any part to be replaced under warranty shall be returned to G.comm within 8 days. Warranty is limited to replacement or repair of the single parts or components that will result as defective.
This warranty does not include:
- labour costs, travelling expenses of the technical personnel, transport, etc.;
- any damage or defect caused by improper use or by any other use than the one for which it was originally designed;
- any damage caused by repair, alteration or disassembly of the product or part of the product carried out by the purchaser itself or by third parties not authorised by the manufacturer;
- normal wear of parts and components such as LEDs, etc.

This warranty does not cover direct or indirect damage of any kind to people and property caused by any malfunction of the product. In need of repair under warranty of the product the purchaser shall revert to the retailer, when it is officially authorised or to an authorised service centre or to the manufacturer itself.
Any defective part covered by warranty will be replaced free of charge.
This warranty does not entitle the replacement of the whole device. In case of dispute on this warranty, on the quality and efficiency of the delivered product the purchaser shall not stop or delay payment. No claim for damages shall be accepted in case the product stops working.

This warranty is not valid in case of:
- damage resulting from fall, fire, pouring of liquids, lightning, Natural calamities, or from causes other than defects in manifacturing;
- improper installation;
- incorrect connection to mains or adeguate protection devices not installed;
- serial numbers or EC mark have been removed, deleted, altered.

Any component to be replaced under warranty is to be returned to the factory that will send the spare part. If not returned, the part sent in exchange will be debited to the customer.

Serial Number S/N position:



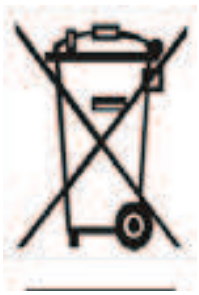
WEEE WARNING

Disposal instructions

Information to users pursuant to art. 13 of the D.Leg. of 25 July 2005, n. 151 “Implementation of the Directives 2002/95/EC and 2003/108/EC, relative to the reduction of the use of dangerous substances in electrical and electronic equipment as well to waste disposal “

The European Directives 2002/95/EC, 2002/96/EC and 2003/108/EC require that dental lamps fall into the category of electrical and electronic equipement that must be disposed of separately from the normal solid urban waste stream (WEEE).

Old appliances must be collected separately to optimize the recovery and recycling rate of the materials that make them up, to achieve significant energy savings and to prevent potential negative consequences on human health and the environment.



The consumer can deliver the disused dental lamps to the public collection service or to the areas designated by the state or local authorities.

Abusive or inadequate disposal of disused products by the holder implies the application of economic / administrative sanctions established by law.

MAN.POL.240521.REV01_ITA_ENG

We reserve the rights to modify the specifications without prior notice

G.COMM

CE

G.COMM is certified UNI CEI EN ISO 13485:2016

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