Manuale di istruzioni
Instruction manual
Manuel d'instruction
Manual de uso

V.8.00

QUADRILED OPERATING LIGHT

Installation, use and maintenance manual

CODE DE6.3020.1 // DE6.3020 // DE6.30.20S

CONTENTS

1- SYMBOLS

SN	SERIAL NUMBER SYMBOL. This symbol is placed on the product next to the serial number of the device.
CE	CE MARKING. This symbol indicates that the product has a CE marking in conformity with the provisions of Directive CEE 93/42 and subsequent amendments (Class I Devices).
	ELECTRICAL CLASS SYMBOL. Protection against electrical hazards : Class II
	INSTRUCTIONS FOR OPERATION. This symbol indicates that you need to consult the user manual before using the device.
	HAZARD SYMBOL. It indicates a dangerous situation that might result in moderate or severe/fatal injuries unless avoided.
	WARNING SYMBOL. It indicates a dangerous situation that might result in moderate or mild injuries or damage to property unless avoided.
	BILOGICAL HAZARD SYMBOL. This symbol indicates the possible presence of risks of contamination due to contact with infected biological fluids or materials.
	GENERAL INFORMATION SYMBOL. This symbol indicates a piece of information that allows you to use the device more efficiently.
	DISPOSAL SYMBOL. This symbol indicates that the product should not be disposed of like normal waste, but it should be recycled as per Directive 2002/95/ EC, 2002/96/ EC and 2003/108/ EC.
	STERILISABLE. This symbol indicates the possibility of sterilising the product in autoclave.
	DO NOT USE HOOKS SYMBOL.
	FRAGILE SYMBOL. This symbol indicates that the product inside the packaging is fragile. Avoid shocks.
	PROTECT FROM HUMIDITY SYMBOL. This symbol indicates that the product must be kept away from water and humidity.
	UP SYMBOL. Transport and store the product only in the direction indicated by the arrows.
	STACKING LIMIT BY MASS SYMBOL
	TEMPERATURE LIMIT SYMBOL. From -20 ° C to 70 ° C.
	HUMIDITY LIMIT SYMBOL. From 10 to 90%.
	ATMOSPHERIC PRESSURE LIMIT SYMBOL. From 500 to 1060 hPa.

1.1- WARNING LABELS

 It indicates a dangerous situation that might result in moderate or severe/fatal injuries unless avoided.

 It indicates a dangerous situation that might result in moderate or mild injuries or damage to property unless avoided.

 This symbol indicates the possible presence of risks of contamination due to contact with infected biological fluids or materials.

 This icon provides information that allows you to use the device more efficiently.

2- GENERAL WARNINGS

- Read this manual carefully before carrying out any operation on the product, follow the warnings contained in it and keep it for future reference.
- This manual is intended to provide the user with instructions for correct installation and use of the product.
- The product must be used in accordance with the procedures contained in the manual and never for purposes other than those provided for therein.
- The user is responsible for the installation, operation and maintenance of the device.
- The manual describes all product versions and optionals, therefore not all instructions are applicable to your product.
- The product may be equipped with additional components, which are described in this manual.
- The information, technical specifications, drawings contained in this publication are not binding.
- Tecnomed Italia s.r.l. pursues a policy of continuous product improvement and reserves the right to make changes to the product or to this manual without prior notice, **as long as said changes do not affect the safe use of the device.**
- Keep the manual within reach.
- It is also strictly forbidden any kind of reproduction or appropriation of the text and/or images in the manual; therefore, some of the instructions, specifications and images contained in this manual may differ slightly from the product purchased by you.
- All the materials contained in this manual are the property of Tecnomed Italia and/or of the companies represented by it. The images are not binding and are given for explanatory purposes only.
- This manual must be delivered together with the machine in case of resale.
- The original text of this manual is in Italian.

 **DANGER!** It is strictly forbidden to make changes to the device.
Tecnomed Italia s.r.l. assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement.

 **DANGER! Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.**

2.1 - GENERAL INSPECTION

ATTENTION! Check the package upon delivery and make sure it is intact and does not present signs of impact. Otherwise, follow the indications in paragraph 2.2 or 2.3.

2.2 - IN-TRANSIT DAMAGES FOR DELIVERIES IN ITALY

Upon delivery, if the package/parcel shows visible signs of damage, the recipient must or may sign the delivery note conditionally, reserving the right to claim for any damages. The Italian law stipulates that "the receipt of goods by paying the amount due without reserving the right to claim for any damages, renders the rights of the recipient deriving from the contract void, except in cases of willful misconduct or negligence of the carrier" (art. 1698 CC). To reserve the right to claim for any damages, fill in the dedicated fields on the delivery note handed to you by the carrier before signing it. Each carrier has his own procedure for conditional delivery, therefore you need to ask him how to proceed.

If the package presents clear signs of damage upon delivery, proceed as follows:

1. Check the appearance and the condition of the packages. Make sure they are intact and complete: if the document mentions several packages, make sure you received them all. The recipient and the carrier must sign the delivery note subject to verification after clearly writing down the reason:
   - "delivery refused/accepted subject to verification"
   - "package with packing tape pulled off, delivery refused/accepted subject to verification"
   - "package with visible signs of damage, cardboard bent, delivery refused/accepted subject to verification"
   - "package extremely damaged and/or partially open, delivery refused/accepted subject to verification"
2. Leave the product and the packaging as they are. Take a photo and/or a video of the damaged package/parcel.
3. Do not use the product.
4. Report the damages to the transport company.
5. Report the damages to Tecnomed Italy srl (produzione@dentalastec.it).
6. Do not return the product to Tecnomed Italy srl before receiving an answer and an authorisation to do so.
7. Send the signed delivery note to Tecnomed Italia srl.
8. Leave the product and the packaging as they are.
9. Do not use the product.

Note: if you suspect that the product might present hidden damages, not visible from the outside, sign the delivery note conditionally.

If the product is damaged but the packaging presents no visible signs of damage, proceed as follows:

1. Inform the transport company no later than 7 days after delivery.
2. Report the damages to Tecnomed Italy srl (produzione@dentalastec.it).
3. Leave the product and the packaging as they are.
4. Do not use the faulty product.

ATTENTION! If the recipient fails to comply with any of the aforementioned provisions, the damage shall be considered as if arising after delivery.

2.3 - IN-TRANSIT DAMAGES FOR DELIVERIES OUTSIDE ITALY

ATTENTION! Tecnomed Italy srl shall not be liable for damages occurred during transit. Check the goods as soon as you receive them!

If the package presents clear signs of damage upon delivery, proceed as follows:

1. The recipient must note down the missing parts or the damage on the delivery note. The recipient and the carrier must sign the delivery note. The recipient may claim the replacement of the product due to in-transit damages only based on such evidence.
2. Leave the product and the packaging as they are.
3. Do not use the product.

If the product is damaged but the packaging presents no visible signs of damage, proceed as follows:

1. Inform the transport company no later than 30 days after delivery.
2. Leave the product and the packaging as they are.
3. Do not use the faulty product.

ATTENTION! If the recipient fails to comply with any of the aforementioned provisions, the damage shall be considered as if arising after delivery.

2.4 - TRANSPORT AND STORAGE CONDITIONS

The packaging of the operating light is designed to suitably prevent any foreign agents from penetrating the device. If kept in its original packaging, the device can be transported of stored for up to 15 weeks in the following environmental conditions:

	Do not use hooks.
	This symbol indicates that the product inside the packaging is fragile. Avoid shocks.
	This symbol indicates that the product must be kept away from water and humidity.
	Transport and store the product only in the direction indicated by the arrows.
	Stacking limit by mass: max. 100 Kg.
	Temperature limit symbol: from -20 ° C to 70 ° C.
	Humidity limit symbol: from 10 to 90%.
	Atmospheric pressure limit symbol: from 500 to 1060 hPa.

3- SAFETY RULES FOR INSTALLATION

DANGER! Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.

ATTENTION! For safety reasons, the installation, maintenance and repair operations are to be carried out only by authorised technical staff of Tecnomed Italia s.r.l.

DANGER! In case of faults, the components are to be replaced using only original spare parts.

DANGER! Any technician not authorised by Tecnomed Italia s.r.l., who makes changes to the product replacing parts or components with spare parts different from those recommended by the manufacturer, assumes a responsibility similar to that of the manufacturer.

DANGER! It is strictly forbidden to make changes to the device. Tecnomed Italia s.r.l. assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement.

ATTENTION! The Quadriled operating light comes with permanent mounting.

DANGER! Comply with the conditions of use provided in the "Technical Specifications" chapter and do not exceed the recommended values.

DANGER! The electrical system available at the installation site must comply with standards CEI 64-8/7 and subsequent amendments. The device shall be installed only by technical staff authorised by Tecnomed Italia s.r.l.

ATTENTION! Make sure the mains voltage matches the power supply voltage specified on the label.

DANGER! The light is to be installed on a special power supply device, such as a dental unit, or connected to an electrical system that meets the provisions laid down in standard IEC 364-1 and in the "national regulations concerning electrical installations in medical locations".

DANGER! The device must be provided with an omnipolar cut-off switch able to cut off the power supply to the light and compliant with standard IEC / EN 61058. You must install a green indicator light to indicate when the operating light is on.

DANGER! The power supply to the location where the installation is to be carried out must be cut off.

DANGER! Before proceeding with the assembly operations, make sure the ceiling can withstand the weight of the operating light. The dowels supplied must be used ONLY on the following supports: concrete, natural stone. THEY ARE NOT SUITABLE FOR OTHER TYPES OF MATERIAL.

DANGER! Maximum applicable load: 70 Kg.

DANGER! To avoid the risk of electric shock, this device must be connected to an earthed electrical system.

DANGER! Do not install the device in environments subject to anaesthetic or flammable gases.

ATTENTION! Do not expose the device to direct sunlight or to sources of UV light.

DANGER! Install the device in a place protected against collisions or against accidental spills of water or liquids.

DANGER! Do not install the device next to heat sources. Install it so as to ensure proper ventilation inside it.

DANGER! Do not use the product with accessories not approved by Tecnomed Italia s.r.l. and without CE marking or fitted with standardised interfaces. The patient and the dentist might get injured or the device might get damaged. Install only accessories authorised by Tecnomed Italia s.r.l. **The company assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement.**

ATTENTION! In order to ensure the functionality and safety of the product and to avoid any wear-related damages, the product requires routine and extraordinary maintenance interventions (specified in this manual) that must be carried out at specified intervals by your Tecnomed Italia s.r.l. dealer. For more information, see the paragraph "Maintenance" on page 27.

DANGER! Do not disassemble the device. In case of malfunction, please contact an authorised Tecnomed Italia s.r.l. centre.

TECNOMED ITALIA S.R.L. IS RESPONSIBLE FOR THE SAFE USE OF THE PRODUCT AND GUARANTEES THE PRODUCT ONLY IF THE CONDITIONS PROVIDED IN THIS MANUAL ARE RESPECTED.

For any request, always indicate the date of purchase, the model of the device and the serial number. **For information on technical support: produzione@dentalastec.it**

3.1 - WORK ENVIRONMENT

DANGER! Before proceeding with the assembly operations, make sure the ceiling can withstand the weight of the operating light. The dowels supplied must be used ONLY on the following supports: concrete, natural stone. THEY ARE NOT SUITABLE FOR OTHER TYPES OF MATERIAL.

ENVIRONMENTAL REQUIREMENTS:

The device should be used in the following environmental conditions:
- Temperature between 10 ° C and 40 ° C
- Relative humidity between 30 and 75%.
- Atmospheric pressure between 700 and 1060Mbar

3.2 - MAXIMUM LOADS

Maximum applicable load: 70 Kg.

4- SAFETY PROVISIONS

DANGER! Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.

DANGER! The device must be used exclusively by specialised and suitably trained personnel. Use the device only for the intended use that is foreseen for it. Failure to observe this prescription may cause serious injuries to the patient, the operator, and damages to the device.

DANGER! Do not use the product with accessories not approved by Tecnomed Italia s.r.l. and without CE marking or fitted with standardised interfaces. The patient and the dentist might get injured or the device might get damaged. Use only accessories authorised by Tecnomed Italia s.r.l. **The company assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement.**

DANGER! The device and its accessories are supplied non-sterile. At the first use and after each treatment, the device and its accessories must be cleaned and/or sterilised following the instructions in paragraph "Cleaning and sterilising", on page 26.

ATTENTION! After sterilising the components in the autoclave, wait for them to cool down before using them.

CAUTION! Use only care and cleaning products authorised by Tecnomed Italia s.r.l. Inappropriate products might damage the surface of the device, affect its operation, lead to contamination or cause injuries to the patient and/or the operator. Tecnomed Italia s.r.l. assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement. For more information, see paragraph "Cleaning and sterilising", on page 26.

DANGER! Disconnect the power sources before starting maintenance or cleaning procedures.

DANGER! The electrical system available at the installation site must comply with standards CEI 64-8/7 and subsequent amendments. The device shall be installed only by technical staff authorised by Tecnomed Italia s.r.l.

DANGER! Do not use the device in environments subject to anaesthetic or flammable gases.

ATTENTION! Do not expose the device to direct sunlight or to sources of UV light.

ATTENTION! Disconnect the pneumatic, hydraulic and electrical power supply at the end of the day (if present). Tecnomed Italia s.r.l. shall not cover damages caused by failure to comply with the indications above.

DANGER! Before every treatment, always check that the device works perfectly and that the accessories are efficient. Always check that there is no water underneath the device. Do not perform the treatment if you notice any malfunctions. In case of anomalies, contact a service centre authorised by Tecnomed Italia s.r.l.

 **DANGER!** The high electromagnetic energy of the electro surgery unit can affect the functioning of the other Medical Equipment. Make reference to the instruction of the Manufacturer of such equipment for the recommended distances that must be held from other devices.

 **DANGER!** Do not address the light beam directly in the eye. Following patients can be particularly subject to photobiological risk: children and adults with eye diseases, people using photosensitive substances (drugs, cosmetics, etc) that can release phototoxic substances. These patients must not stare at the light beam and must use appropriate protection devices and precautions.

 **DANGER!** Do not leave small components of the device in unattended or within reach of people at risk (children) because they could be a source of danger.

 **DANGER!** It is strictly forbidden to make changes to the device. Tecnomed Italia s.r.l. assumes NO responsibility for personal injury and/or direct or indirect property damage resulting from non-compliance with this requirement.

 **ATTENTION!** In order to ensure the functionality and safety of the product and to avoid any wear-related damages, the product requires routine and extraordinary maintenance interventions at specified intervals (contact a service centre authorised by Tecnomed Italia s.r.l.). For more information, see the paragraph "Maintenance" on page 27.

 **DANGER!** For any malfunctions not described herein, put the device out of service and contact an authorised Tecnomed Italia s.r.l. technician.

 **DANGER!** Do not disassemble the device. In case of malfunction, please contact an authorised Tecnomed Italia s.r.l. centre.

4.1 SAFETY REQUIREMENTS

Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.

Tecnomed Italia srl cannot be held responsible, expressly or implicitly, for any type of injuries to persons and/or damages to property inflicted by the user of the product and its accessories, and which have taken place in the following cases:

- If the device is used for other purposes than those for which it is intended;
- If the device is not used in compliance with the instructions and requirements provided in this manual;
- Lack of stock materials to be used in the event of device stop due to fault or inconveniences;
- Use of accessories not authorised by Tecnomed Italia srl;
- If the electrical system available at the installation site does not comply with the application standard and the appropriate requirements;
- Assembly and/or repairs carried out by staff not authorised by Tecnomed Italia srl;
- If the storage conditions do not comply with the requirements specified in chapter "Transport and storage conditions".

5- PRODUCT DESCRIPTION

5.1 - INTENDED USE AND METHOD OF USE

The Quadriled operating light is designed to illuminate body parts and can be used in the following sectors: Dentistry, Maxillofacial surgery, Otolaryngology, Microsurgery, Podiatry, Aesthetic medicine, Dermatology, Gynaecology, Sampling, Diagnostics, Veterinary medicine. The arm and the head articulations allow to position the beam of light according to user needs.

It is the responsibility of the user to:

1- Use only EC certified devices in perfect state.
2- Protect himself, the patients and any third parties from any hazards.
3- Avoid any contamination of the product.

When using the device, follow the applicable regulations in force in the country of use, especially:

1- The provisions in force regarding safety at work.
2- The accident prevention measures in force.

 **DANGER!** The device must be used exclusively by specialised and suitably trained personnel. Use the device only for the intended use that is foreseen for it. Failure to observe this prescription may cause serious injuries to the patient, the operator, and damages to the device.

 **DANGER!** Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its a

5.2 - STANDARDS/CERTIFICATIONS

The Quadriled operating light bears the CE marking.
Medical Device as per Directive 93/42/EEC
Medical class: I
Standards applied: EN 60601-1, EN 60601-1-2, EN 60825, EN 62471
Electrical class: II
Original language: Italian

5.2.1 - ELECTROMAGNETIC COMPATIBILITY

REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY

This medical device requires particular precautionary measures to ensure electromagnetic compatibility, and shall be installed and used in compliance with information provided in the accompanying documentation.

Manufacturer's guidelines and statement – Electromagnetic emissions		
The lamp MP 3020 is designed to function in the electromagnetic environment specified below. The client or user must ensure its use in the said environment.		
Emission tests	**Compliance**	**Electromagnetic environment - Guidelines**
RF Emission CISPR15	Compliant	The lamp MP 3020 uses RF energy only for its internal function. Therefore its RF emissions are very low and most likely do not cause any interference in neighbouring electronic devices.
RF Emission CISPR15	Compliant	The lamp MP 3020 is fit for use in all buildings, including domestic ones and those directly connected to the public low voltage supply network that feeds buildings for domestic use.
Harmonic emission	Class C	
Voltage fluctuations/flicker emission	Compliant	

ELECTROMAGNETIC IMMUNITY

Manufacturer's guidelines and statement – Electromagnetic immunity		
The lamp MP 3020 is designed to function in the electromagnetic environment specified below. The client or user must ensure its use in the said environment.		
Immunity test	**Compliance**	**Electromagnetic environment - Guidelines**
Electrostatic discharge (ESD) IEC/EN61000-4-2	± 6kV contact ± 8kV air	The floor must be in wood, concrete or ceramic. If the floor is covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN61000-4-4	± 2kV power supply ± 1kV for input/output lines	The quality of supply network voltage should be typical of commercial or hospital environments.
Surge IEC/EN61000-4-5	± 1kV differential mode ± 2kV common mode	The quality of supply network voltage should be typical of commercial or hospital environments.
Voltage dips, short interruption and voltage variation IEC/EN61000-4-11	< 5% Ut for 0,5 cycle 40% Ut for 05 cycle 70% Ut for 25 cycle <5% Ut for 5 sec.	The quality of supply network voltage should be typical of commercial or hospital environments. If the user of the lamp MP 3020 requires continuous use even without a supply network, use an uninterruptible power supply.
Power frequency magnetic field IEC/EN61000-4-8	3A/m	Level of magnetic field at the network frequency typical of commercial or hospital environments.
Conducted immunity IEC/EN61000-4-6	3Vrms 150kHz to 80MHz (for non life-supporting equipment)	Portable and mobile RF communication devices should not be used near any part of the dental unit, including cables, unless they comply with recommended distances calculated with the applicable equation for transmittor frequency. Recommended distances: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ from 80 Mhz to 800 MHz $d = 2.3\sqrt{P}$ from 800 Mhz to 2.5 GHz P is the maximum nominal power issued by the transmittor in Watts (W) depending on the manufacturer of the transmittor, and d is the recommended distance in metres (m). The intensity of the fixed RF transmittor field, as established in an electromagnetic investigation of site a, could be less than the compliance level of each frequency interval. There can be interference near devices marked with the following symbol:
Conducted immunity IEC/EN61000-4-6	3Vrms 80MHz to 2.5GHz (for non life-supporting equipment)	

Note: Ut is the power-line voltage
Note 1: The highest frequency interval is applied at 80 MHz and 800Mhz.
Note 2: These guidelines might not apply to all situations. Electromagnetic propagation is influenced by absorption and reflection of structures, objects and persons.
a) ISN bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.
b) Compliance levels in ISN bands between 150 kHz and 80 MHz and 80 MHz to 2.5 GHz present a decreasing probability of portable transmission devices causing interference if inadvertantly taken to the patient area.
Therefore, an additional 10/3 factor has been incorporated into the formula used to calculate the distance between transmittors.
c) Field intensities for fixed transmittors such as base stations for radiotelephones (mobiles and cordless) and cellular mobile radios on land, CB user equipment, AM and FM transmittors and TV transmittors cannot be theoretically estimated with precision. To establish an electromagnetic environment caused by fixed RF transmittors, an electromagnetic investigation of the site should be considered. If field intensity measured at the site of use of the dental unit exceeds the aforementioned applicable compliance level, normal function of the lamp should be monitored. If any abnormal performance is noticed, additional provisions such as a different orientation or position of the lamp might be necessary.
d) The field intensity in an interval of frequencies from 150 kHz to 80 MHz should be less than 3 V/m.

Recommended distances between portable and mobile radiocommunication devices and the dental unit			
The lamp MP 3020 is designed to function in an electromagnetic environment in which irradiating RF disturbances are under control. The client or operator of the unit can contribute toward preventing electromagnetic interferences by ensuring a minimum distance between mobile and portable RF communication devices (transmittors) and the dental unit, as recommended below, depending on the maximum output power of the radiocommunication devices.			
Maximum nominal output power of the transmitter W	**Distance for transmittor frequencies (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	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmittors whose maximum nominal power is not listed above, the recommended distance d in metres (m) can be calculated by using the applicable equation for the transmittor frequency, with P as maximum nominal output of the transmittor in Watts (W), depending on the manufacturer. Notes: The highest frequency interval is applied at 80 MHz and 800 Mhz. These guidelines might not apply to all situations. Electromagnetic propagation is influenced by absorption and reflection of structures, objects and persons.			

5.3 - WORK ENVIRONMENT

Model name: Quadriled
Power supply voltage: 17-24V ~ (22-35 V) ±10% - 50/60 Hz
Power absorption: 23 VA
Protection against electrical hazards: Class II
Weight (without transformer): 5 kg

- Optical performances at 1000 mm from the target
Dimensions of the spot of light: 300 mm x 200 mm (*)
Lux: 3.000 to 35.000 lux (*)
Color Temperature: 5.000 K (*)

(*)Typical value
The distance between the lamp and the target affect the optical performance.

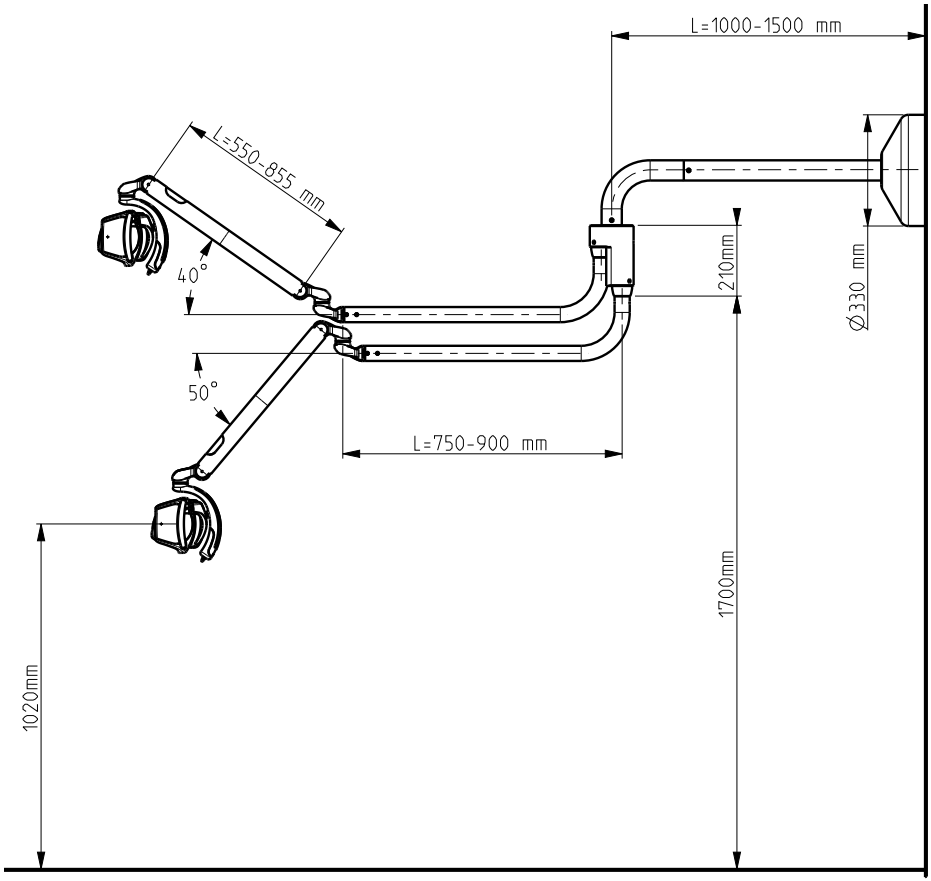
ATTENTION! The lamp is designed to have the best performance at a distance of 1000 mm.

Packing dimensions:

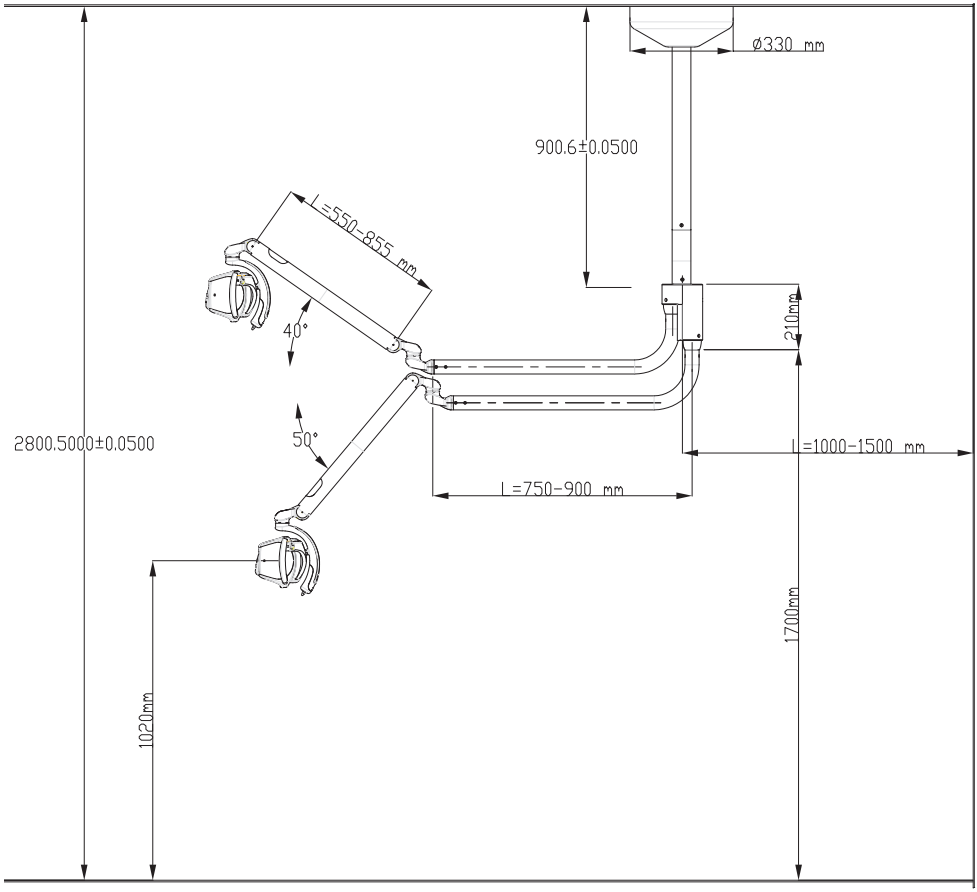
- **PARCEL 1 TECNOMED ITALIA- box with operating light**
  Dimensions 925x400x390 mm (width x depth x height). Weight 8 kg (approx).

5.3.1 - DIMENSIONS

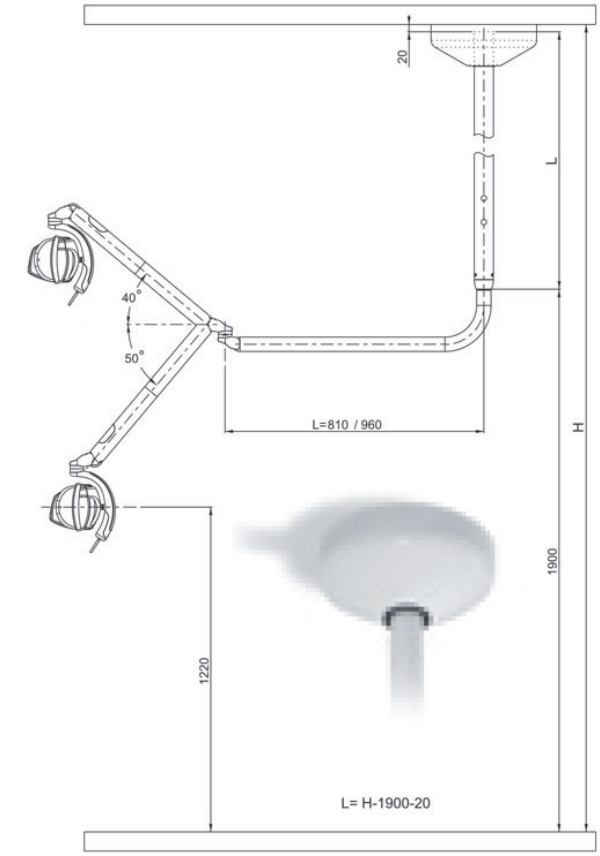
- SCIALYTIC OPERATING LIGHT QUADRILED 3020, WALL-MOUNTED DOUBLE HEAD CODE DE6.3020.1



- SCIALYTIC OPERATING LIGHT QUADRILED 3020, CEILING-MOUNTED DOUBLE HEAD CODE DE6.3020



- SCIALYTIC OPERATING LIGHT QUADRILED 3020, CEILING-MOUNTED SINGLE HEAD CODE DE6.30.20S



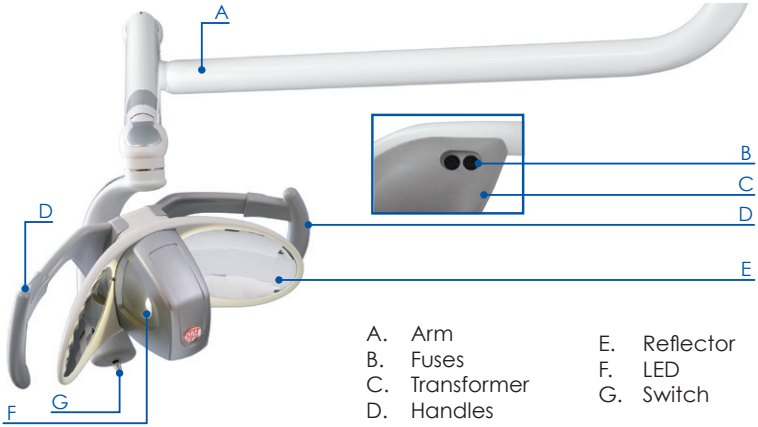
5.4 - IDENTIFICATION PLATES

The identification plate is placed on the arm of the post.

Data on the plate

- Name of the manufacturer.
- Serial number.
- Pressure limit.
- Temperature limit.
- Humidity limit.

5.5 - PRODUCT PROFILE



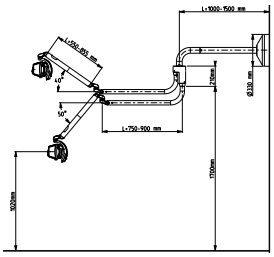
A. Arm
B. Fuses
C. Transformer
D. Handles
E. Reflector
F. LED
G. Switch

5.6 - CONFIGURATION

When placing the order, please specify the length of the post according to the tables below.

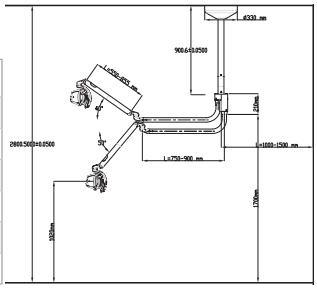
- QUADRILED 3020, WALL-MOUNTED DOUBLE HEAD CODE DE6.3020.1

The length of the post you want to order (cm)
90



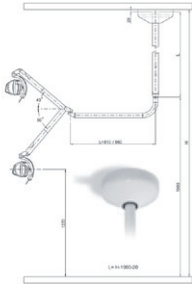
- QUADRILED 3020, CEILING-MOUNTED DOUBLE HEAD CODE DE6.3020

Room height (metres)	The length of the post you want to order (cm)
2.8	60
2.9	70
3	80
3.1	90
3.2	100
3.4	110



- QUADRILED 3020, CEILING-MOUNTED SINGLE HEAD CODE DE6.30.20S

Room height (metres)	The length of the post you want to order (cm)
2.8	90
2.9	100
3	110
3.1	120
3.2	130
3.4	140



6- INSTALLATION

6.1-PRE-ASSEMBLY

NOTE 1. The fitting must be installed by skilled technicians.

NOTE 2. The power supply in theroom where the fitting is to be installed must always be switched off.

NOTE 3. Before starting assembly, it is necessary to make sure that the ceiling is capable of bearing the weight of the fitting. The anchor bolts pro vided must be used ONLY with the following base materials: concrete, natural stone. They are not suitable for other materials.

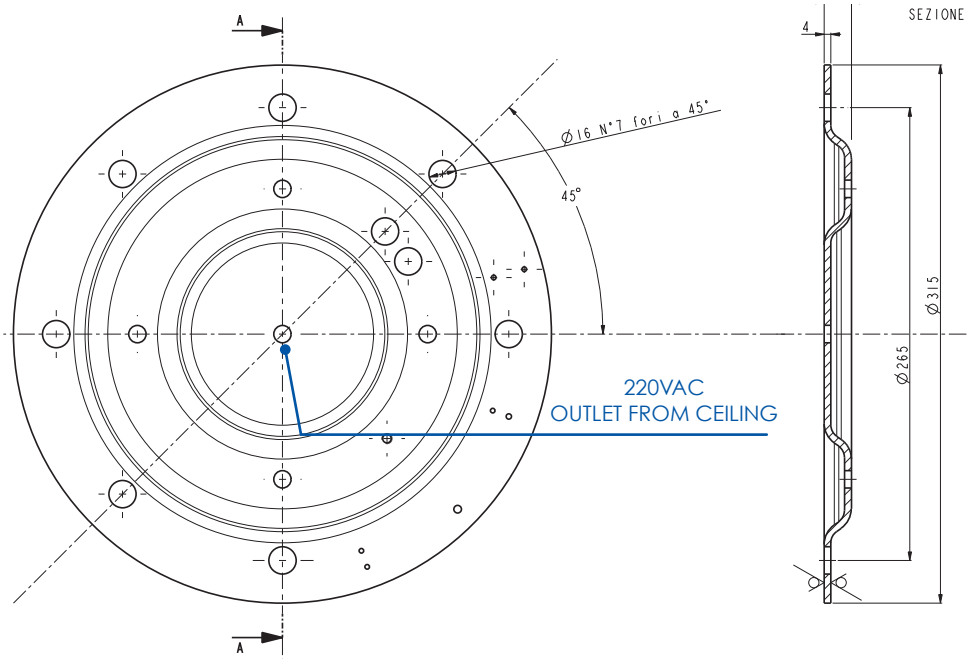
NOTE 5. Maximum load applicable: 70 kg.

NOTE 4. Install in rooms with electrical plant conforming to current national regulations for medical facilities.

DANGER! Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.

Make sure the packaging contains the following components:
- Lamp (in the version requested)
- Bag containing the lever of the switch and the wrench
- Operating Manual

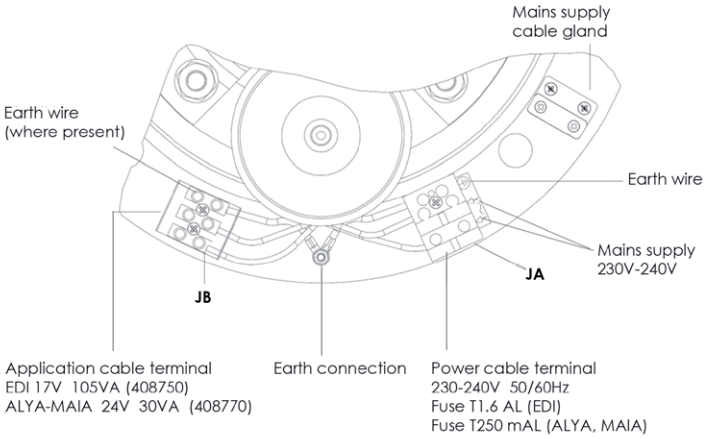
QUADRILED DRILLING FLANGE

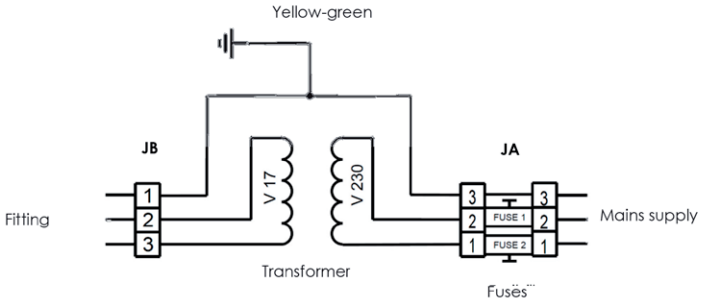


Secure the flange with 7 fisher of 16mm (10MA screw) for solid walls or 7 chemical plugs with 10mm threaded bar for hollow walls.

6.1.1 - WIRINGS DIAGRAMS

Ceiling fitting WITH transformer





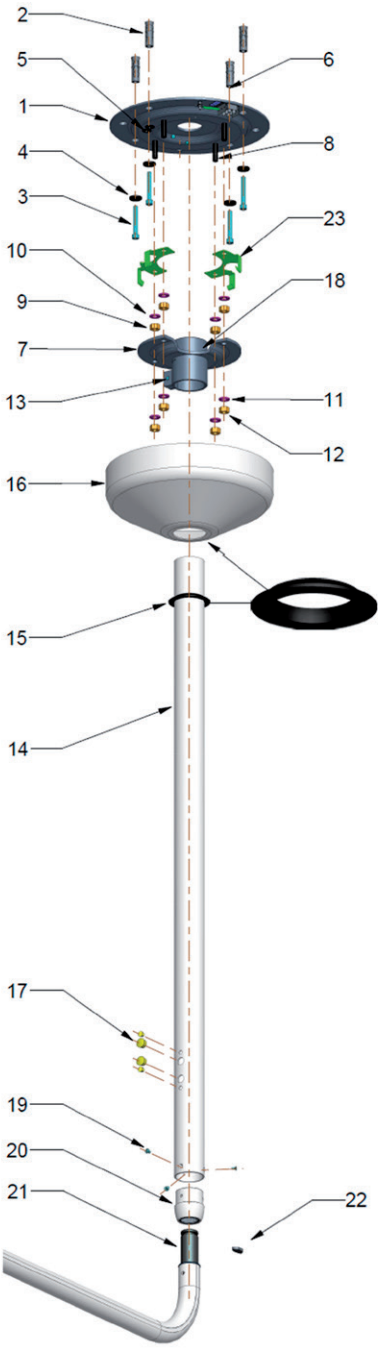
Technical specifications

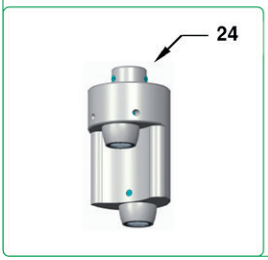
Cod. 408750
EDI Transformer – Lamp
230 – 17V 105VA

Cod. 408770
Alya Transformer – Lamp, Maia Lamp
230 – 24V 30VA

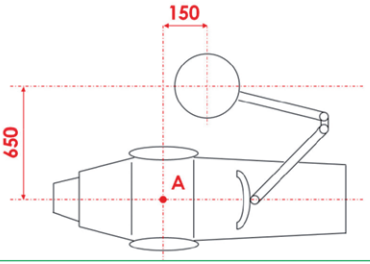
6.2- INSTALLATION

1. Ceiling flange
2. Expander
3. Screw
4. Washer
5. Cable gland
6. Terminal block
7. Flange
8. Screw
9. Nut
10. Washer
11. Washer
12. Nut
13. Screw
14. Rod
15. Ring
16. Ceiling fixture
17. Plug
18. Screw
19. Screw
20. Rod bushing
21. Lamp pin
22. Insert
23. Anchoring guide
24. DUO fitting





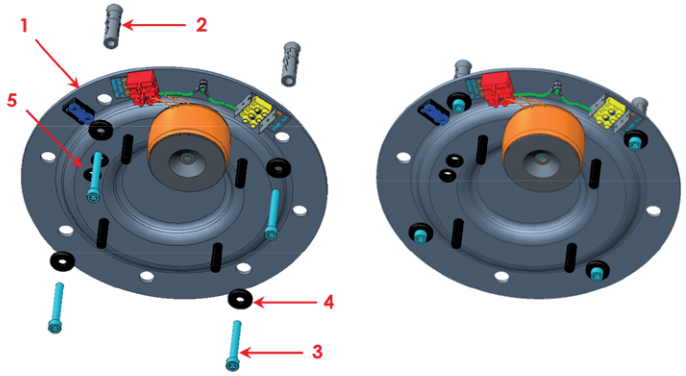
A. Using the centre of the chair as a reference point (A), install at a distance of 650mm and 150mm in the directions shown in the figure



B. Dismantle the flange (7) by removing the nuts (12) and washers (11)

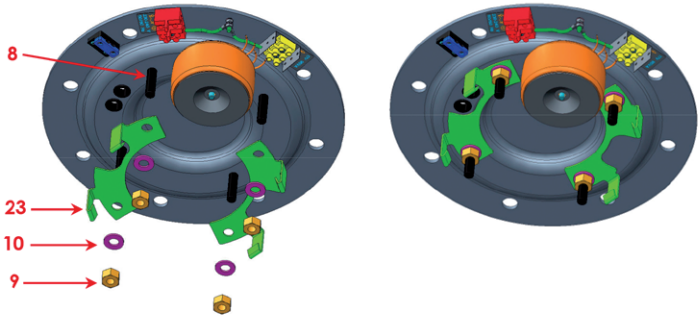
C. Using the flange (1) as a guide, drill four holes in the ceiling using a Ø14 drill bit. Place the expanders in these holes (2)

D. Pick up the flange (1). Pass the power cable through the cable gland (5), then press the flange against the ceiling (1) making sure not to crush the cable between the flange (1) and the ceiling. Put the washers (4) on the screws (3),and then fit them through the 4 holes used for making the holes in the ceiling. Tighten the screws (3) using the hexagonal spanner provided (assembly accessories)

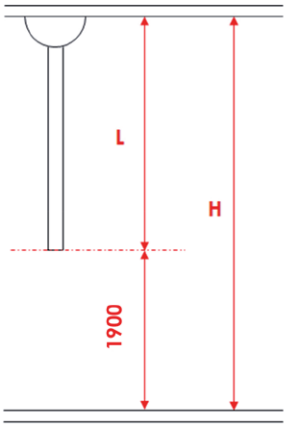


E. Connect the power cable to the terminal block (6) (see wiring diagrams page 7-8)

F. Fit the 2 anchor guides (23) onto the screws (8) and secure them with the nuts (9) and washers (10)



G. Calculatethe right length of the rod (14), using the formula L=H-1900mm. Remember to cut off the excess part of the rod (14) at the end where there are NO side holes



CODE DE6.3020

Room height (metres)	The length of the post you want to order (cm)
2.8	60
2.9	70
3	80
3.1	90
3.2	100
3.4	110

CODE DE6.30.20S

Room height (metres)	The length of the post you want to order (cm)
2.8	90
2.9	100
3	110
3.1	120
3.2	130
3.4	140

CODE DE6.3020.1

The length of the post you want to order (cm)
90

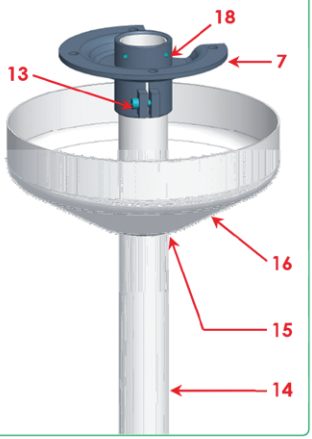
H. Insert the rod (14) into the flange (7) and mark the position of the holes in the flange (7) on the rod(14). Check the position of the rod with regard to the combined chair unit. Pull out the rod and drill two through holes Ø8 at the positions marked

I. Push the ring (15) onto the rod (14) to a distance of about 300 mm (this is not the final position but just temporary for assembling)

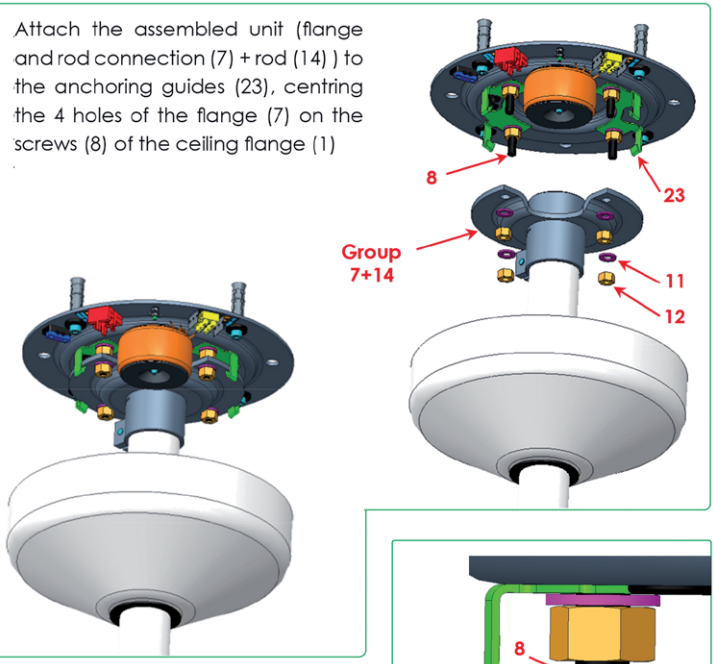
J. Fit the ceiling fitting (16) onto the rod (14)

K. Introduce the rod (14) into its hole in the rod connection flange(7)

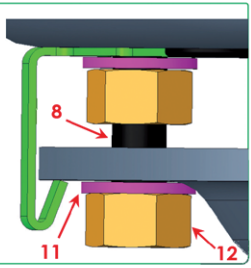
L. Secure the screw (13) and two screws (18) using the hexagonal spanners (assembly accessories).Tighten the screw (13) and make sure that the screws (18) pass through the holes in the rod (14)



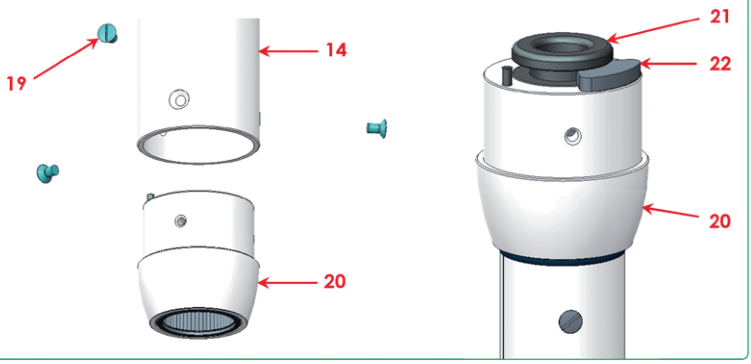
M. Attach the assembled unit (flange and rod connection (7) + rod (14)) to the anchoring guides (23), centring the 4 holes of the flange (7) on the screws (8) of the ceiling flange (1)



N. Screw on (without tightening) the nuts (12) and the remaining washers (11) on the screws (8) of the ceiling flange (1)



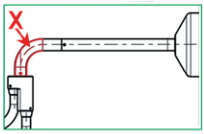
O. Unscrew the three screws (19)of the rod (14); remove the bushing (20)
P. Push the bushing (20) onto the pin(21)of the lamp
Q. Put the insert (22)into the groove of the pin (21)



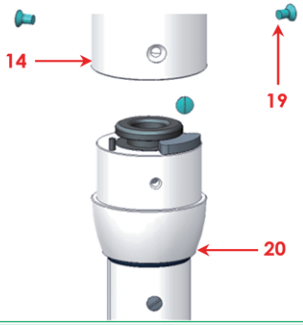
R. Insert a suspension cord into the rod (14)from above

S. Connect the electrical wire of the lamp to the suspension cord

T. This step is to be done only for fitting the lamp on the wall:
First insert the curve "X" in the lamp pole.

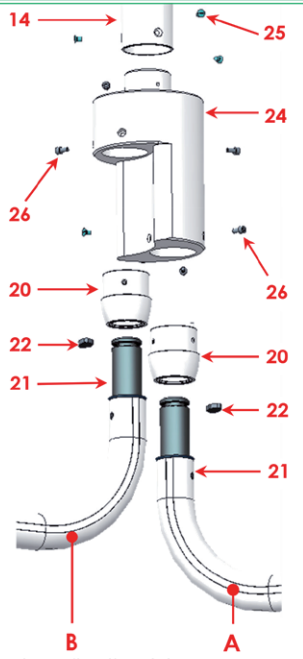


T.I. Insert the lamp into the rod (14) and secure it with the three screws (19, for the DUO fitting 26). Align the holes in the bushing (20) with thescrew holes on the rod (14),and then tighten the screws. Simultaneously, pull the suspension cord until the lamp's electrical wire comes out of the rod connection flange (7) leaving about 200mm of loose wire



If using the DUO fitting

- Unscrew the six screws (26) of the bushings of the DUO(24) and remove the two bushings (20)
- Attach the DUO (24) to the rod (14) using the three screws(25)
- Fit bushings (20) onto pins (21)
- Put the insert (22) into the grooves of the pins (21)
- Insert a suspension cord in the rod (14) from above
- Connect the electrical wire of the first application (A)to the suspension cord
- Insert the lamp in the DUO(24) and anchor it with three screws (26). Align the holes of the bushing (20) correctly and then tighten them. Simultaneously, pull the suspension cord until the lamp's electrical wire comes out of the rod connection flange (7) leaving about 200mm of loose wire
- Repeat the last three steps for the second application (B)

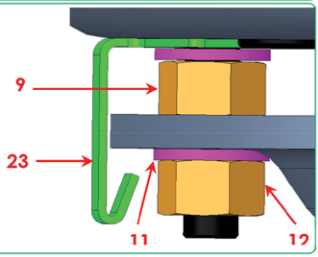


U. Connect the electrical wire of the lamp to the terminal blocks (6) (see electrical drawings page 7-8)

V. Adjust the nuts (9) so that the rod hangs perpendicular to the floor

W. Tighten nuts (12) and washers (11) to anchor the flange (7) without it resting on the anchoring guides (23)

X. Mount the ceiling fitting (16) flush with the ceiling, and push ring (15) into place



7- INSTRUCTIONS FOR USE

ATTENTION! For any malfunctions not described herein, put the device out of service and contact an authorised Tecnomed Italia s.r.l. technician.

DANGER! Before using the equipment, read the previous sections of this manual carefully, paying particular attention to paragraph "Safety provisions" on page 8.

DANGER! Do not address the light beam directly in the eye. Following patients can be particularly subject to photobiological risk: children and adults with eye diseases, people using photosensitive substances (drugs, cosmetics, etc) that can release phototoxic substances. These patients must not stare at the light beam and must use appropriate protection devices and precautions.

DANGER! Do not leave small components of the device in unattended or within reach of people at risk (children) because they could be a source of danger.

DANGER! The device and its accessories are supplied non-sterile. At the first use and after each treatment, the device and its accessories must be cleaned and/or sterilised following the instructions in paragraph "Cleaning and sterilising", on page 26.

DANGER! Maximum applicable load: 70 Kg.

DANGER! Tecnomed Italia s.r.l. declines any liability, expressed or implied, and cannot be held liable for personal injury and/or direct or indirect property damage deriving from failure to comply with the instructions in this manual and/or from incorrect installation and/or use of the device and its accessories and/or from improper and/or lack of cleaning and/or maintenance.

7.1- SWITCH-ON / SWITCH-OFF

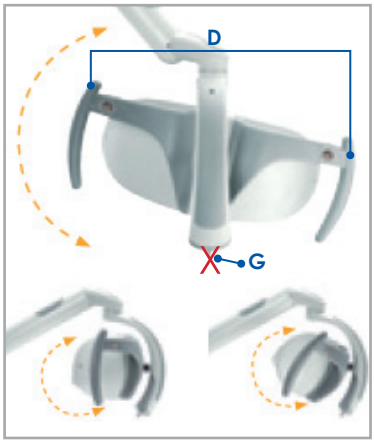
To switch the lamp on/off, move the joystick (G) to the left or to the right.

7.2- ADJUSTMENTS

- To reduce the intensity of the light, hold the joystick (G) pressed on the left side (as you look at it from the back of the light) until you obtain the desired intensity. When the light reaches the minimum intensity, it makes a beep sound.
- To increase the intensity of the light, hold the joystick (G) pressed on the right side (as you look at it from the back of the light) until you obtain the desired intensity. When the light reaches the maximum intensity, it makes a double-beep sound.
- To set the light to minimum intensity immediately, move the joystick (G) back or forth. The next time you move the joystick back or forth, the light returns to the previous light intensity setting.

The operating light stores the last light intensity setting. Each time you switch the light on, it uses the same light intensity as the last time you switched it off. The joystick must be handled carefully to avoid breaking it.
Do not use the control lever to move the whole light.

7.3- ASSEMBLY MOVEMENT



ATTENTION! Do not move the operating light using the joystick (G).
Do not move the operating light outside the limits specified in section "DIMENSIONS" paragraph 5.3.1.

7.4- ACOUSTIC WARNING SIGNALS

OTP* = Beep 30 seconds
MAX = 1 beep - 2 beep with proximity
MIN = 1 beep
1 BEEP = On the commands
1 BEEP = At start-up
OpL** = Beep 30 seconds
* OTP: Over-temperature protection
** OpL: LED charger unplugged

8 - CLEANING AND STERILISING

DANGER! Disconnect the power sources before starting maintenance or cleaning procedures.

ATTENTION! General information (in accordance with Standard DIN EN ISO 17664)
The product and all the instruments must be cleaned and disinfected before use. The staff of the practice is responsible for cleaning the product to minimise the contamination risks for patients and operators. Use authorised cleaning products and greases. Tecnomed Italia s.r.l. denies any liability, expressed or implied, and cannot be held liable for injuries to persons and/or direct or indirect damages to property, deriving from incorrect cleaning and/or use of inappropriate materials.

CAUTION! It is strictly forbidden to use abrasive substances, detergents with trichloroethylene, benzene, oil of turpentine or similar on any parts of the light. It is strictly forbidden to clean handles or other parts by ultrasonic bath.

ATTENTION! Never spray directly on the surface; the disinfectant might reach into the slots, damaging the paint and the electrical parts. Use a cloth dampened with disinfectant (it shouldn't be too wet, dripping). It is strictly forbidden to clean handles or other parts by ultrasonic bath.

CAUTION! It is strictly forbidden to use abrasive substances, detergents containing trichloroethylene, benzene, turpentine oil or other similar substances on any part of the operating light. It is strictly forbidden to use ultrasonic baths to wash any part of the operating light.

8.1- CLEANING THE MIRRORS

It is prescribed the use these products:
- Perflex FARO
- GREEN&CLEAN MK, product code 60030130: alcohol-free wipes for disinfecting surfaces that cannot be treated with alcohol. Dispenser con 70 wipes + 750 ml bottle of SK (MK START).

Use as soft cloth for the cleaning of the parts. Remove the detergent always with a soft cloth.

CAUTION! Slight halos do not compromise the quality of light.
Do not use detergents containing surfactants or water repellent agents because build-up can leave halos on the mirrors and on the screen. Do not spray any product directly on the rear of head of the lamp.

CAUTION! Follow the manufacturer's instructions for their proper use.

8.2- CLEANING OF HANDLES, ARMS AND JOINTS

To avoid damage to the product, we recommend the use of:
- GREEN&CLEAN MK, product code 60030130: alcohol-free wipes for disinfecting medical equipment surfaces that cannot be treated with alcohol. Dispenser con 70 wipes + 750 ml bottle of SK (MK START).

Use as soft cloth for the cleaning of the parts. Remove the detergent always with a soft cloth.

CAUTION! Follow the manufacturer's instructions for their proper use.

8.3- STERILIZATION OF THE HANDLES

To remove the handle, unscrew button and slip it off. To insert it, push firmly and screw on button.Handles are not provided sterile and must, therefore, be sterilised before use. Sterilize the device with standard cycles (SHPGRP) at 121°/134° C using a class B sterilizing unit. A maximum of 200 sterilization cycles is allowed.

9 - MAINTENANCE

 **DANGER!** Do not perform any maintenance operation on the lamp when it is connected to the power supply or while the patient is present.

 **DANGER!** Disconnect the power sources before starting maintenance or cleaning procedures.

 **DANGER!** The user is not allowed to perform maintenance operations not described in this manual.

 **DANGER!** Any operation not indicated in the manual can compromise the safety characteristics of the device.

 **DANGER!** For the maintenance or repair of this device use only Faro's original spare parts.

 **DANGER!** Do not insert any objects or tools which could touch parts under voltage into the slots on the lamp head.

 **ATTENTION!** The staff of the practice is responsible for making sure that the product is serviced in due time. Tecnomed Italia s.r.l. denies any liability, expressed or implied, and cannot be held liable for injuries to persons and/or direct or indirect damages to property, deriving from failure to perform the safety technical controls and maintenance operations. The product can be used only if all the technical safety controls had positive result.

 **DANGER!** The technical controls must also be carried out after making changes to the machine; for example, when installing new components to avoid any problems that might affect the electrical safety of the equipment.

The maintenance of the lamp is made up by following operations:

- Check the absence of space between joint components of the arms **(yearly)**
- Check readability of data on the information plate **(yearly)**
- Electrical safety check according to EN 62353 **(every two years)**
  - Insulation resistance
  - leakage current
- Light checks **(every five years or 10,000 hours of function)**
  - Maximum lighting intensity >35000 lux
  - CRI decay: <20% for data on the information plate.
  - Expected value of Blue light on spectrum emitted, measured in w/m2: <100.

10- TROUBLESHOOTING

PROBLEM	SOLUTION
The lamp does not switch on.	1- Check on the connected of power supply. 2- Check on the status of the fuses. 3- If none of these causes is the case contact an authorised Tecnomed Italia technician.
Light intensity is considerably low.	1- Clean the screen. 2- If the light intensity does not return to its original intensity contact an authorised Tecnomed Italia technician.
Handles will not come off or are difficult to remove	1- Check the position of the locking screws on the handle. They should be completely open.

11- RELATED ITEMS

To find all items related to this product, visit:

www.dentalastec.it

12- DISPOSAL

This equipment complies with the European Directive 2002/96/CE on waste electrical and electronic equipment (WEEE). By ensuring this product is disposed of correctly, you will help prevent potential negative consequences to the environment and human health, which could otherwise arise from improper handling of the product at the end of its service life. The symbol  indicates that the product should not be disposed of like normal waste, but it should be sent to the nearest authorised waste collection centre for electrical and electronic equipment. Disposal must be carried out in accordance with the applicable environmental regulations for waste disposal. The equipment must be properly prepared (disinfection/sterilisation) before dismantling/disposal. For more information on the treatment, recovery and recycling of this product, please contact the Ecology and Environment Department or your local waste collection service or your dental equipment distributor. Illegal dumping of the product by the user entails the administrative sanctions stated by current legislation.

13- WARRANTY

With this document, the manufacturer certifies that the product has been built correctly, in compliance with the applicable national and European regulations in force. The product is covered by a 12-month warranty from the date of purchase specified on the stamp and on the valid fiscal document issued by the seller. According to art. 1495 c.c., the person who intends to make a warranty claim, must give notice of the failure within 8 days from its discovery. The warranty claim may be refused if the invoice has been changed, deleted or made illegible after the purchase. Disconnect the pneumatic, hydraulic and electrical power supply at the end of the day (if present). Tecnomed Italia srl shall not cover damages caused by failure to comply with the indications above. Not covered by warranty:

• labour expenses, staff travel expenses, transport expenses:
• operations for the installation and connection of the machine to the various power supply sources;
• all parts subject to normal wear and tear (such as light bulbs, carbon brushes, cordon o-rings, suction tubing, etc...);
• all those parts that are faulty due to negligence or careless use and/or maintenance;
• in-transit damages;
• damages caused by limescale or dirt accumulation on hydraulic and pneumatic supply circuits (if present);
• malfunctions due to failure to respect the routine cleaning intervals of the filters (if any);
• malfunctions caused by third-party equipment (compressors, suction systems, water softeners), or other circumstances unrelated to defects in the manufacturing of the device.

The Warranty becomes void if:

- the equipment presents damages due to fall, exposure to flames, liquid spills, lightning, natural disasters, other causes not attributable to manufacturing defects;
- the installation and/or extraordinary maintenance operations and/or the technical controls have not been carried out by an authorised Tecnomed Italia s.r.l. technician;
- the power supply connection is incorrectly made or the appropriate safety devices have not been installed;
- the serial number/series or CE marking are removed, erased or tampered.

The warranty covers the replacement, free of charge, of the parts of the device resulting to be defective at the origin due to manufacturing defects.
The Customer cannot request the replacement of the entire product. In case of permanent damage or repeated failure (deriving from the same cause), the manufacturer reserves the right to decide whether the equipment will be replaced or not. The coverage for the new product provided by the warranty will remain valid until the end of the original contract.
For warranty service the purchaser should contact the reseller, the authorised service centers or Tecnomed Italy s.r.l.
This warranty does not give the Customer the right to claim for direct or indirect damages (of any nature) to persons or property resulting from machine malfunction.
Tecnomed Italia srl denies any liability, expressed or implied, and cannot be held liable for injuries to persons and/or animals and/or damages to property deriving from failure to comply with the instructions in this manual (warnings, installation safety standards, safety provisions, instructions for installation and use, information for correct cleaning and sterilisation, maintenance information, general information, technical specifications etc...). The manufacturer reserves the right to make changes or improvements without prior notice if these changes do not affect the safe use of the device. In the event of any dispute concerning the application of the warranty or the condition of the equipment delivered, the buyer may not suspend or delay the payment of the price in full or in installments. No compensation may be claimed by the buyer for equipment downtimes. If the part to be changed is not returned, it will be charged to the buyer. Also, please see page "PAYMENT TERMS AND CONDITIONS" available on our site www.dentalastec.it
Any and all disputes that may arise will be settled by the competent Court of Pesaro.

14- DECLARATION OF CONFORMITY

CERTIFIED COPY OF THE ORIGINAL
Subject: EC DECLARATION OF CONFORMITY
Distributor name: TECNOMED ITALIA SRL
Device class: I
Electrical class: II
Type/model: MP3010 (CEILING/WALL-MOUNTED OPERATING LIGHTS VERSION 1/2)
Code O&M Tecnomed Italia DE6.3020 // DE6.3020.1 // DE6.30.20S
Product description: QUADRILED OPERATING LIGHT

I, the undersigned Luca Riccardi, as administrator of TECNOMED ITALIA s.r.l., based on the certificates issued by the manufacturer and now in my possession, hereby declare that the products described above comply with the requirements of Directive 93/42/CEE (a.m.). The following standards have benn applied to ensure the conformity of the devices with said directive:

- IEC 60601-1:2005+A1:2012 (EN 60601-1:2006+A1:2013)
- IEC 60601-1-2:2007 (EN 60601-1-2:2007)
- IEC 62366:2007+A1:2014 (EN 62366:2008+A1)
- IEC 60601-1-6:2010+A1:2013
- IEC 62471:2006 (EN 62471:2008)

This compliance is expressed through the marking:

CE

TECNOMED ITALIA SRL

Luca Riccardi
Administrator

15- CERTIFICATE OF WARRANTY

The warranty on the dental unit must be registered. Failure to register the warranty invalidates it.
To register the warranty, proceed in one of the following ways:

- BY FAX
Photocopy the warranty registration card below, fill in all sections and fax it to **+39 0721 955229**, marked "**to the attention of the production manager".**

- BY E-MAIL
Send an e-mail to **produzione@dentalastec.it**, providing **all** the following details:

- BUSINESS NAME
- ADDRESS
- MODEL (SEE LABEL ON UNDERSIDE)
- SERIAL NUMBER (SEE LABEL ON UNDERSIDE)
- DATE OF PURCHASE
- NAME OF DEALER/DISTRIBUTOR

Garanzia-Guarantee-Garantie-Garantía

12
Mesi-Months-Mois-Meses

Ragione sociale studio- Business name- Raison sociale- Razón social

Indirizzo- Address- Adresse- Direccion

Etichetta prodotto - Product label - Etiquette produit - Etiqueta producto

Timbro del rivenditore-Dealer's stamp
Cachet d'achat-Sello del revendedor

Data d'acquisto-Purchase date
Date d'achat-Fecha de compra

Tecnomed Italia s.r.l. Via Salvador Allende n.2, 61040 Castelvecchio di Monte Porzio (PU) Italy
Phone +39 0721 95 51 25 Fax +39 0721 95 52 29 - www.dentalastec.it

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