MAIA

DENTAL LIGHT - DENTAL LIGHT-HEAD
INSTALLATION AND USER'S MANUAL

FARO S.p.A
Via FARO, 15
20876 Ornago (MB)
ITALY

DAL 1948: ESPERIENZA E RINNOVAMENTO

CE
Medical Device

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1 SAFETY REQUIREMENTS

Dear Customer,
FARO hopes you enjoy your work with the new high quality light. For safe work and to take full advantage of the performance of the product, read carefully this manual before using the device.
In particular, follow all the warnings and the notes given.
FARO offers the final customer a **12 month warranty** starting from the date of purchase. Repairs under guarantee must be performed at FARO; expenses and transport risks are at the risk of the purchaser. Repair under guarantee is considered valid only when all sections of the certificate have been filled in and sent in advance to FARO by Fax (+39 039 6010540) or by email: service@faro.it
The guarantee covers faults due to the bad quality of the material or manufacturing defects; in the case of valid claims, the guarantee covers free repair or replacement. Claims for damages and/or interest are excluded. The guarantee is not considered valid, at the sole discretion of FARO, if the fault is due to tampering, damage, incorrect use, improper maintenance and normal wear and tear.

1.1 SYMBOLS USED

1.1.1 Symbols used in the manual

	*WARNING*
The paragraphs marked with this symbol contain instructions that must be carefully followed to avoid damaging the device, harming the operator or the patient.	

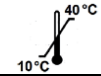
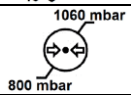
	*CAUTION*
These instructions warns you that you must pay attention to avoid situations that could damage the device.	

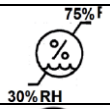
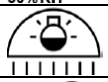
	*FORBIDDEN*
This icon highlights what you should not do to avoid damaging the device.	

	*NOTES*
This icon supplies information that allows you to use the device more efficiently.	

1.1.2 Symbols on the labels

The data plate is fixed:
• for the complete light or arms: on the rear arm
• for the head: under the heat sink cover
and outlines the following data:
Serial Number (SN): year (YY) / range of origin (LD for dental light - TE for head only) plus the progressive number (NNNNNN) e.g.: SN14LD000001 for the complete light SN 14TE000001 for the head.
The following standardized symbols are also present:

	Read the instructions use. Supplied by Electronic means.
	Manufacturer symbol according to Directive 93/42/EEC
	The instructions for use include safety warnings
	WEEE equipment according to the Directive 2012/19/EC. Dispose of the product according to this directive.
	Double insulation. Class 2 device against electrical risk
	Serial Number
	Can be sterilized with heat at 134°C
	Use the device at a temperature between 10°C and 40°C
	Use the device at pressure between 80 kPa and 106 kPa

	Use the device at relative humidity between 30 RH and 75RH
	Symbol to adjust light intensity
	Symbol to switch on/off the light

1.1.3 Symbols on the pakaging

	High
	Fragile
	Do not wet
	Do not Roll
	Do not use hooks
	Maximum stackable weight
	Storage and Trasportation temperatures
	Storage and Trasportation Relative Humidity
	Storage and Trasportation Atmospheric Pressure
	Recyclable cardboard

1.2 INTENDED USE

The device is used in dental office and is intended for illuminating the oral cavity and oral structures of patients in dentistry.
In the normal use, the device is positioned distance of 700mm from the operative area, the distance for which the lighting features were designed.
Patients can be of all ages with typical dental pathologies.

1.3 INTENDED USER

The intended users are the General Dentist, Specialized Dentist (all specializations) or Dental Nurse
To use of the light does not need any particular skill or training.

1.3.1 Professional qualification:

- Degree in Medicine with Dentistry Specialization
- Degree in Dentistry
- Degree in dental nursery

1.3.2 Minimum skills

Those planned for the professional qualification
Understanding of language: Those acquired for the professional qualification

1.3.3 Experience

Those outlined to conduct the profession

1.3.4 Possible user handicaps

For use, complete use is necessary of an upper limb.
Visual faculty compatible with the profession

1.4 GENERAL STANDARDS AND MAIN WARNINGS

- The device can be applied to the dental unit, but also be installed on specific applications to ceiling, floor or wall.
- The device can be powered both by the dental unit and by a power supply unit connected directly to the mains. See the specific installation paragraph.
- The device does not have Essential Performances for which inadequacy of the device performance does not prejudice patient safety.
- The device does not provide life support.
- The device must be clean before use (see Device Cleaning paragraph).

- The packaging of the light is suitable to adequately protect it from penetration of external agents.
- The device must never be modified without written authorization of FARO S.p.A. For maintenance only original FARO's spare parts are allowed. Fail to comply with this warning will immediately make decay the warranty and the conformity of the product to international regulations and directives on Medical Devices.

	**Warnings against electrical danger and fire**
	Do not use the light in the event parts are damaged. Installation of the device must only be carried out by qualified staff. The dental light must be installed on a specific control and power supply device, such as dental units, or with an electrical system that meets standard IEC 60364-1 and "national installation regulations for electrical systems in premises for medical use". When installed with ceiling, floor or wall applications the device must be installed with an omnipolar separation device from the mains and compliant with Standard IEC 61058-1. This separation device must be approved to withstand 4 kV of transient voltage. Installation and maintenance of device conformity with the standard IEC 60601-1 is the responsibility of the installation technician or the manufacturer of the combined units. Check the power supply voltage, indicated on the data plate, corresponds to the mains voltage. Do not carry out any maintenance on the light when the power supply is inserted: then disconnect the power supply from the mains before intervening.
	**Warning against danger of wear of the mechanical parts and falling suspended weights**
	Do not use detergents containing the following to clean plastic parts: AMMONIUM HYDROXIDE - SODIUM HYDROXIDE - METHYLENE CLORIDE – METHYL ALCOHOL. Non-compliance with this specification could cause: RISK OF WEAR ON PLASTIC OR METALLIC PARTS RESULTING IN BREAKAGE. Do not spray any kind of chemical agent directly on the light. It is also forbidden the of abrasive substances, acids, chemicals containing chlorine or phosphor.
	**Warnings for danger of suspended loads**
	Strictly comply with compliance for maximum loads planned. Do not knock against or overload the limit switches on the arms and heads. Do not position the light head directly upon the head of the patient.
	**Warnings for biological danger and glare**
	Do not fasten or focus the light strip directly in the patient's eyes, especially patients at greater risk of eye injury (e.g. children with eye diseases). In this case, always use appropriate guards and precautions. The light is classified as Class 1 from photobiological risk in compliance with IEC/EN 62471, in labelling exemption, at the distance of 200 mm. However, it cannot be excluded that particularly photo-sensitive patients or those who have taken photo-sensitising medicine can develop a rash or allergic reactions to light. In this case, suspend the treatment and use very low lighting levels. The articulated arm and the joints of the light allow correct positioning of the light spot.
	**Warning for danger of damaging the electrical parts**
	Do not overcharge the arms and the joints with end of stroke knocks. Rotation of the head and arms as well as the limit switches can damage the conductor insulations.
	**Warning for danger of explosion**
	The device is not suitable for installation in environments with the presence of inflammable gas or risks of oxygen.
	**Warning for danger of patient-patient cross contamination**
	The dentist must use disposable protection on the handles of the light and sterilize them after each patient. To disinfect the surfaces use water-alcohol mixed disinfectant (see maintenance/cleaning paragraph).
	**Warning for danger of wrong maintenance**
	Do not carry out maintenance operations or replacements of parts other than those outlined in the manual. Any intervention not indicated in the manual could compromise the safe appearance of the device. Only carry out the maintenance operations in the manual; in any other case, contact technical support.

The product is covered by WEEE Directive 2012/19/EU.
To scrap and dispose of the materials, comply with the standard in force in your country, if necessary contacting recognized and authorized specialist companies.
At the end of the life cycle, divide the materials based on their type (ferrous, rubber, plastic).
Do not leave small parts of the equipment unguarded or within reach of exposed people (children) because they are a potential sources of danger.
Other warnings are outlined in the titles of this manual.

1.5 STORAGE AND USE: ENVIRONMENTAL PROVISIONS

The appliance in the original packaging can be transported or kept in a warehouse for a period of 15 weeks if the following environmental conditions are met:
• Environmental temperature from -20°C to + 70°C
• Relative humidity from 10% to 90%
• Atmospheric pressure from 50 kPa to 106 kPa

The appliance must be used in the following environmental conditions:
• Temperature from 10° to 40°C
• Max altitude: 2000 m
• Relative humidity from 30% to 75%

1.6 REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY

REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY

This section contains specific information concerning conformity of the product with the standard IEC 60601-1-2: 2007.
The MAIA dental lamp is an electrical medical device which requires special precautions as regards: electromagnetic compatibility, and which must be installed and put into service in accordance with the electromagnetic compatibility information provided. Mobile and portable RF communication equipment (mobile phones, radio transceivers, etc.) may influence the medical system. The use of accessories, transducers and cables sold by the manufacturer of the equipment and the system as replacement parts may result in an increase in emissions or a decrease in the immunity of the equipment or systems.

Manufacturer's guidelines and statement – Electromagnetic emissions		
The lamp MAIA 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 MAIA 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 MAIA 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	

Recommended distances between portable and mobile radiocommunication devices and the dental unit			
The lamp MAIA 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.			

ELECTROMAGNETIC IMMUNITY

Manufacturer's guidelines and statement – Electromagnetic immunity		
The lamp MAIA 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 MAIA 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.

2 GENERAL FEATURES

2.1 DEVICE VARIANTS

The variants of MAIA are differentiated by:
- Type of device (complete light / head)
- Switch on and adjustment interface (mechanical switch / proximity sensor)
- Control mode (auto-on function, remote control cable)
- Type of mounting (unit, ceiling; for complete light only)
- Arms length (for complete light only)
- Power supply (with or without integrated transformer)

2.2 DESCRIPTION OF THE PRODUCT

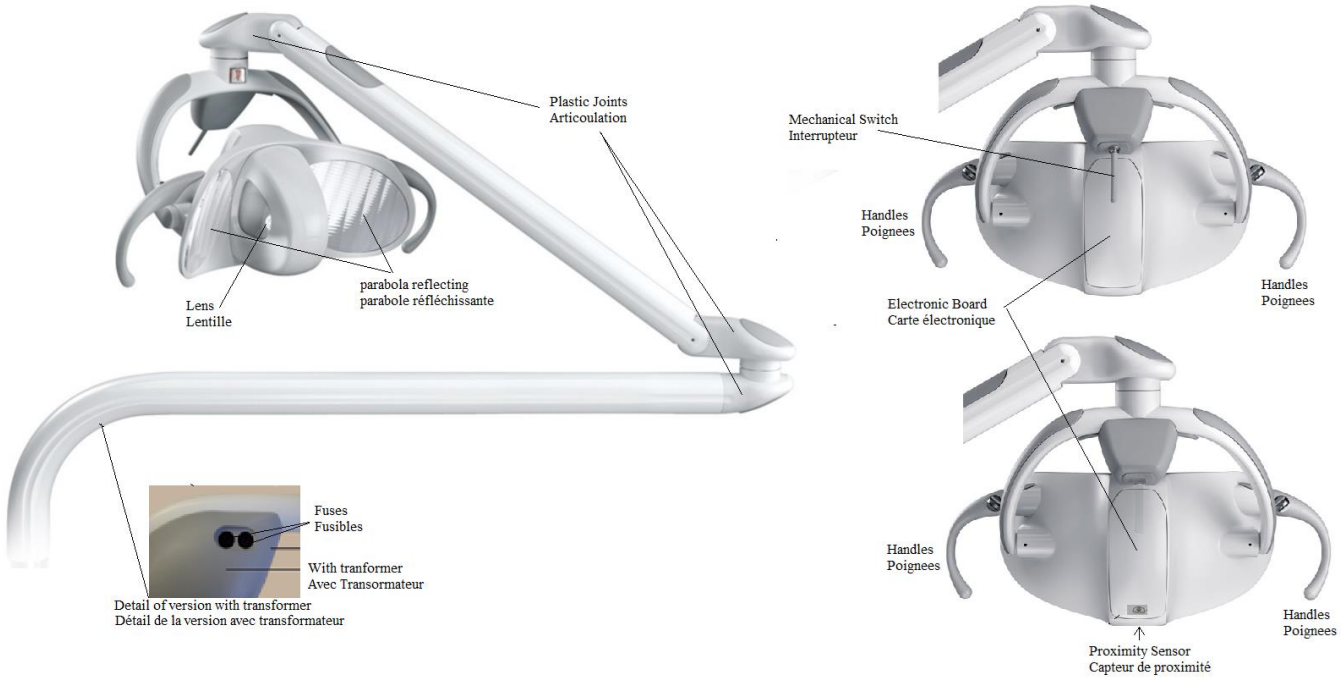
The light source on the head is composed of two LED whose light reflects against two mirrors passing through two secondary lenses.
The mirrors allow a regular and uniform spotlight to be obtained at each lighting level and to distribute the light intensity in the operative field, without creating shadows by the operator.
Adjustment of light intensity can be carried out with:

- Mechanical switch; or
- proximity sensor.

The proximity sensor switches on and off the light without having direct contact reducing the risk of cross contamination.

Maia has a function that allows its use while shooting with a camera and/or using diagnostic instruments (Diagnodent and laser, for example) without causing interference that could affect the diagnostic result. See dedicated paragraph for the activation of this function.
Maia is equipped with memorization of the last light intensity used before switching off.
The remote cable allows bringing the light commands to the combined unit. See the dedicated installation paragraph.
Maintenance is facilitated thanks to application of the new technologies which take into consideration the various needs for safety, ergonomics and hygiene.
The handles can be removed and sterilized. Comply with the specifications defined in the specific section.
For the electrical connections, comply with the instructions supplied in the installation paragraph and the wiring diagrams included in this manual.

2.3 DESCRIPTION OF THE PARTS



2.4 DEVICE IDENTIFICATION

The identification of the variant of MAIA supplied is managed through the speaking Part Number used.
The part number is made of 9 digits. In the table below is explained the meaning of the digits.

1- 2	Axis of rotation of Head	3	Mounting - Unit Control	4	Voltage input - Control	5	Arm lenght	6	Rear arm shape	7	Dental Light/Dental light Head	8 - 9	Custom
32	standard	0	Unit std	0	24 Vac – MS (*)	1	750x550	0	Curved	3	Dental Light	00	Std FARO
42	3 axis	2	Unit Auto on	1	24 Vac – PS (*)	2	900x550	9	Straigh t	0	Head of Dental Light	XX (**)	Custom
		4	Unit Remote Cable	4	230Vac – MS	9	750x855						
		5	Ceiling std	5	230 Vac - PS								
		6	Ceiling Auto On	6	120 Vac - MS								
		1	Only Head std	7	120 Vac - PS								
				8	240Vac - MS								
				9	240Vac - PS								

(*) MAIA can be supplied also with Direct Current 22 – 35 Vdc (std 24 Vdc).
(**) Customized codes include only aesthetic customization having no impact on Safety and EMC requirements

For the North American market (United States and Canada) the following variants are available:

1- 2	Axis of rotation of Head	3	Mounting - Unit Control	4	Voltage input - Control	5	Arm lenght	6	Rear arm shape	7	Dental Light/Dental light Head	8 - 9	Custom
32	standard	0	Unit std	0	24 Vac – MS	1	750x550	0	Curved	4	Dental Light	00	Std FARO
42	3 axis	2	Unit Auto on	1	24 Vac – PS	2	900x550	9	Straight			XX (**)	Custom
		5	Ceiling std			9	750x855						
		6	Ceiling Auto On										

MS: Mechanical Switch
PS: Proximity Sensor
(**) Customized codes include only aesthetic customization having no impact on Safety and EMC requirements

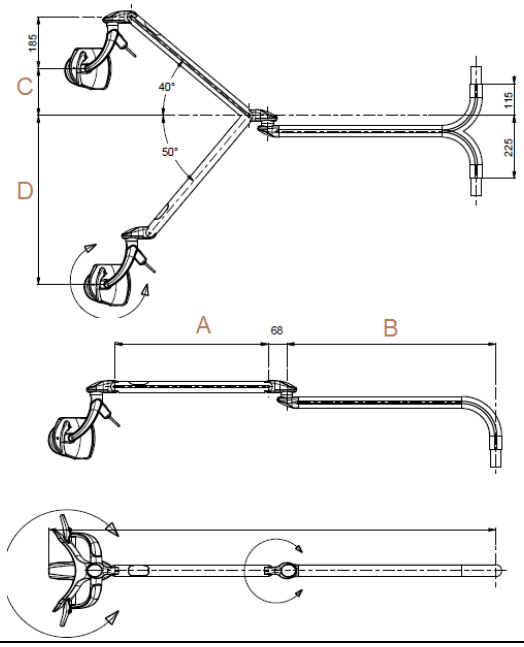
3 DEVICE INSTALLATION

	Warnings for electrical danger
	The device must be installed by specialist technicians. On installation, the power supply must always be disconnected. Refer to the wiring diagrams in the manual. Check the mainplate data before installation If the installation is not performed to dental unit it must be considerated a fixed installation. Only for US MARKET: In this case the dental light must be connected to the ground by means of a suitable ground cable and connectors.
	Note for installation
	The power supply cable on the complete light is supplied without any connector or terminal to allow connection according to the specifications of the combination or application. The functionality and safety of the light does not depend on the polarity of the power supply current. Therefore inversion of the power supply cables will not pose a risk of malfunctioning.

3.1 DIMENSIONS

Take care to leave free space around the light in order to avoid any interference with fixed obstacles.
The free space can be determined by the following dimensions:

	A	B	C	D
mm	550	830	170	605
mm	550	980	170	605
mm	855	830	360	835
mm	855	980	360	835



3.2 DENTAL LIGHT INSTALLATION

3.2.1 General Electrical requirements

The requirements for correct installation for any application (dental unit, wall, floor or ceiling) are the following:

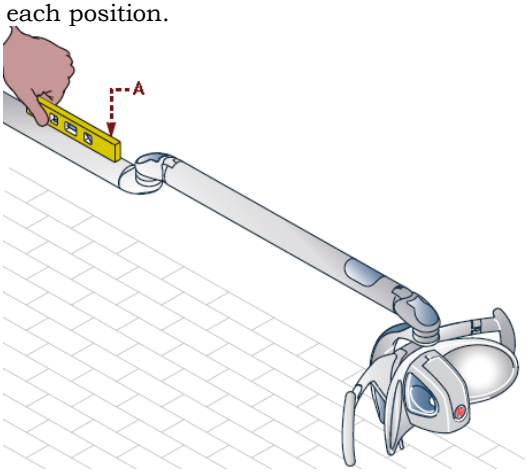
Power supply	Power cable	Type of power supply and safety requirements	Classification	Compliance with IEC 60601-1
Complete light version 17-24 Vac 50/60 Hz	2 x 0.5 mm2 300 V 105°C PVC insulation diameter insulation 1.85 mm Only use certified terminals and connectors with resistance to flame VW-1 or similar.	Transformer complies with IEC/EN 60601-1 third edition with protection of phase of secondary with appropriate fuse: • T600mAL 250V Minimum requirements: • Output: 17-24 Vac; • Power min: 9 VA; • Rigidity over 4000 V. • 2MOPP between primary and secundary • Thermal protection In case of permanent (see note 1) application add following requirements: The lamp must be installed with a multipolar device to separate it from the supply network, meeting the requirements of IEC/EN 61058 standards. This separation device must be approved to withstand 4KV of transient voltage A green status light shall be inserted to indicate that the lamp is powered.	Component built-in part of a Medical Device (Dental Unit)	The medical system must be declared compliant with IEC/EN60601-1 by the installation technician or manufacturer. Note 1: in case of fixed installation (ceiling, wall or floor) the fuse must be placed on the phase and not on the neutral. Note for the Service Eng.: assure that the combined version on which the light is installed is certified to install the complete light.
Complete light version 24 Vdc		Power supply conform to IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with one pole protected by appropriate fuse: • T600mAL250V Minimum requirements: • Output: 24 Vdc • Power: min 9 VA; • Dielectric strenght > 4000 V; • 2 MOPP between primary and sec. Continuous protection from short circuit or overcurrent		
Complete Light version 120 Vac 50/60 Hz 230 Vac 50/60 Hz 240 Vac 50/60 Hz	2x1 mm2 (blue and brown) 300-500 V 90 ° C PVC insulation diameter insulation 2.47 mm Only use certified terminals and connectors with resistance to flame VW-1 or similar	The light can be powered directly by the electricity mains corresponding to the main features outlined on the data plate or technical specifications in this manual. Ensure that the electrical system complies with IEC 60364-1 and the national standards on electrical systems in premises for medical use In case of permanent application add following requirements: The lamp must be installed with a multipolar device to separate it from the supply network, meeting the requirements of IEC/EN 61058 standards. This separation device must be approved to withstand 4KV of transient voltage A green status light shall be inserted to indicate that the lamp is powered.	Medical Electrical Equipment	//

Tab 1 – Requirements for electrical connection and compliance with IEC/EN 60601-1.

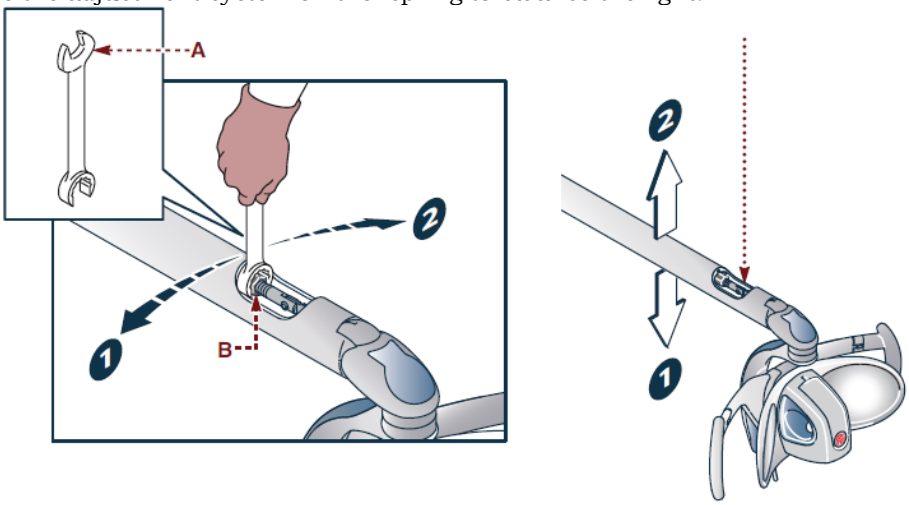
Check the packaging contains the following parts:
- Dental light / Dental Light Head (in the required version)
- Sheet to download for site instructions www.faro.it/download

3.2.2 Dental Unit Installation

With a digital level, ensure the connection element on the unit is perfectly parallel to the ground.
Install the light by inserting the light terminal pin in the specific combined compartment. Take care that the rear arm is parallel to ground in each position.



Connect the power supply cable according to the specifications outlined in Tab. 1.
Check the light stays balanced in all positions.
If necessary, use the adjustment system on the spring to balance the light.

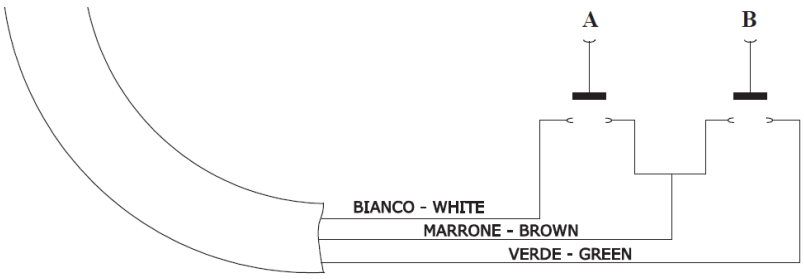


Check switch on and adjustment and (if present) the Auto-on command and the remote cable.
Following Working Loads shall be respected:

	SAFE WORKING LOAD	BREAKING LOAD
arm 855 mm	2,92 Kg	23,5 Kg.
arm 550 mm	2,56 Kg	20,5 Kg

3.2.2.1 Remote cable connection

Remote cable length 4 m
Maximum range from arm on the side of the pin: 2,5 m.
The remote cable must not be lengthened during installation. Any operation done on the remote cable could affect "EMC" performance.
Connect the cable to two buttons (A and B) with normally open contact (not supplied) according to the following diagram.



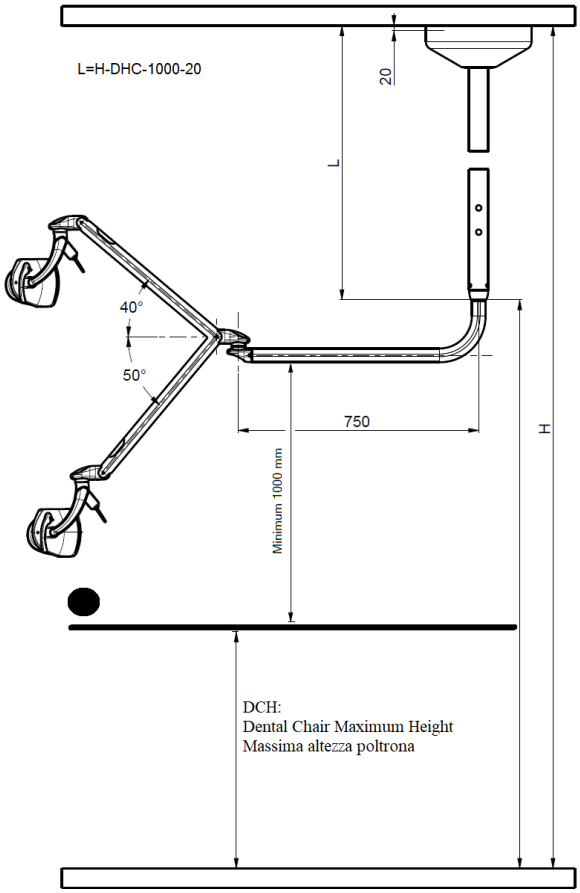
3.2.3 Complete dental light connection to the ceiling, wall or floor (permanent)

For the installation of such application please make reference to the dedicated sections of this manual.
Connect the power supply cable according to the specifications outlined in Tab. 1.
The applications are not supplied with the light

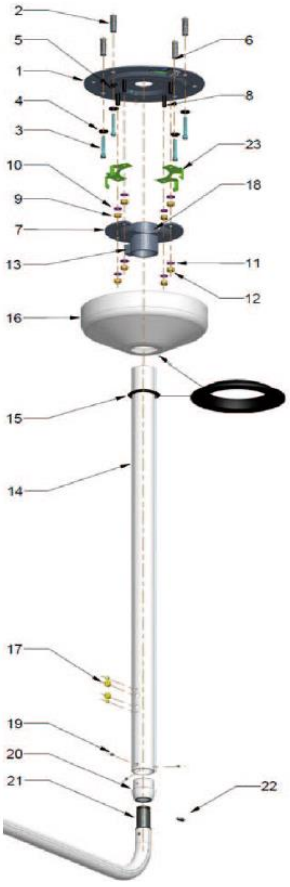
	Warnings for electrical danger and suspended masses
⚠	- The device has to be installed by specialized technicians only - The light has to be installed with FARO applications only. - The light is supplied with rotation limit switch between the fix and the mobile arm. - The switch limit must not be passed over or forced.

3.2.4 Ceiling mounting with Faro applications

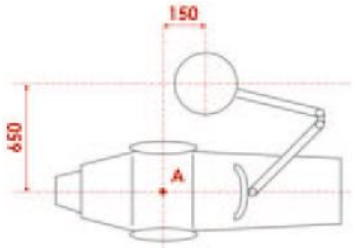
	Warnings for electrical danger and suspended masses
⚠	The device must be installed by specialized tecnicians The power supply in the room where the fitting must be installed must be always switched off. Before starting the installation take care that the ceiling is suitable to bear the load of the application and dental light. The anchor bolts provided with the application must be used only with the following base materials: concrete, natural stone. Maximum load applicable: 70 kg See §3.2.1 for the electrical requirements of the power supply. Stricly comply with the minimum heights shown below. These installations are considered Permanent. Always connect the earth cable for installations in North America.



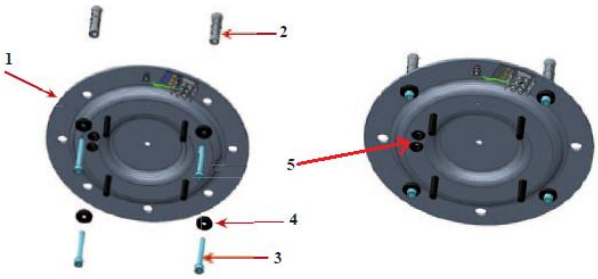
1. Ceiling flange
2. Expander
3. Screw
4. Washer
5. Cable gland
6. Terminal board
7. Flange
8. Screw
9. Nut
10. Washer
11. Washer
12. Nut
13. Screw
14. Support column
15. Ring
16. Ceiling light support
17. Plug
18. Screw
19. Screw
20. Column coupling bushing
21. Lamp pin
22. Key switch
23. Fixing guide



A After having fixed as reference point the chair centre (A). install at a distance of 650mm and 150mm, according to the directions given in the figure.
B. Unfit the flange (7) by removing the nuts (12) and washers (11).
C. By using as guide the flange (1), carry out on the ceiling 4 bores with Ø14 drill. Fit the expanders (2) in these bores.



D. Take the flange (1). Pass the power cable through the cable gland (5), then push the flange (1) against the ceiling; do not choke the cable between the flange (1) and the ceiling. Pass the screws (3) and washers (4) through the 4 bores used as reference in drilling the ceiling. Lock with the special wrench (installation accessory) the screws (3)



E. Connect the power cable to the terminal board (6) (see electrical diagrams)

F. Match the 2 fixing guides (23) to the screws (8) and fix then by means of the nuts (9) and washers (10)

G. Calculate the proper length of the column (14), according to the formula L=H-DHC-1020 mm.
Cut the exceeding column (14) part on the side were NO LATERAL BORES ARE PRESENT

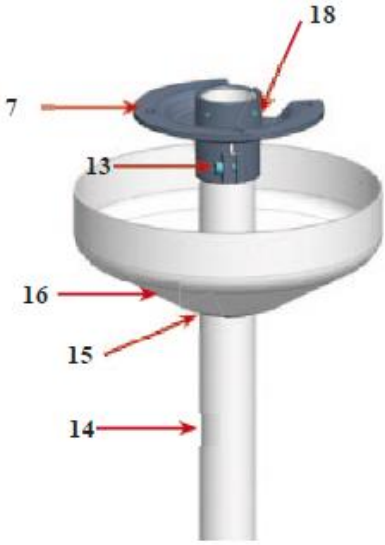
H. Insert them column (14) in the flange (7) and mark on the column (14) the position of the bores on the flange (7). Pay attention the orientation of the column in relation to the dental unit. Remove the column and carry out two Ø 8 bores at the marked points.

I. Fit on the column (14) the ring(15) at about 300mm height (it is only temporary position to allow the assembling)

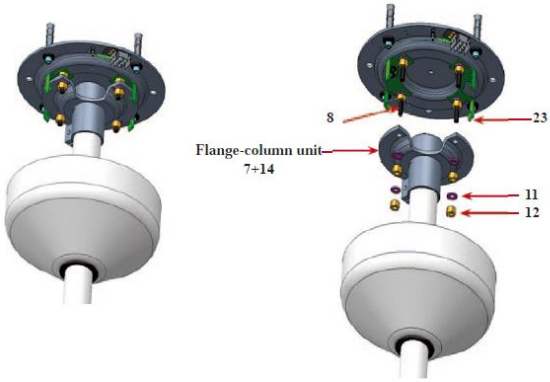
J. Insert the ceiling light support (16) on the column (14)

K. Fit the column (14) in the special bore of the column fixing flange (7)

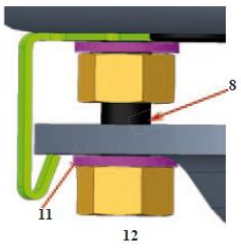
L. Lock the screw (13) and the two screws (18) with hexagonal spanners (installation accessory). Tighten sturdily the screw (13) and make sure the screws (18) have passed through the bores on the column (14)



M. Hook the unit freshly assembled (column fixing flange (7) + column (14)) to the fixing guides (23), by matching the 4 bores of the flange (7) to the screws (8) of the flanged on the ceiling (1)



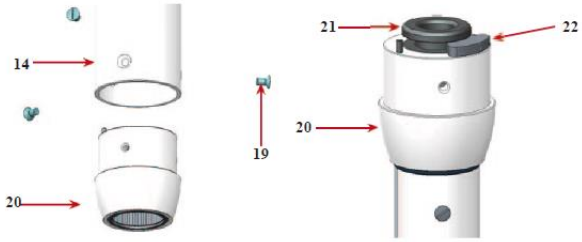
N. Screw (without locking) the nuts (12) and the remaining washers (11) on the screws (8) of the ceiling flange (1)



O. Unscrew the three screws (19) of the column (14) and remove the bushing (20)

P. Insert the bushing (20) on the lamp pin (21)

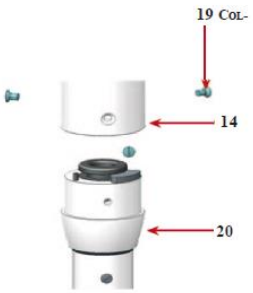
Q. Insert in the pin (21) groove the key switch (22)



R. Slip - from the top - inside the column (14) a traction cord.

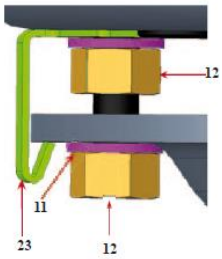
S. Connect the lamp conductor to the traction cord.

T. Fit the lamp on the column (14) and fix it with the three screws (19); make sure the bores of the bushing (20) match the screws seat on the column (14) and tighten. Simultaneously pull the traction cord to push out the conductor of the lamp from the column fixing flange (7) of about 200 mm.

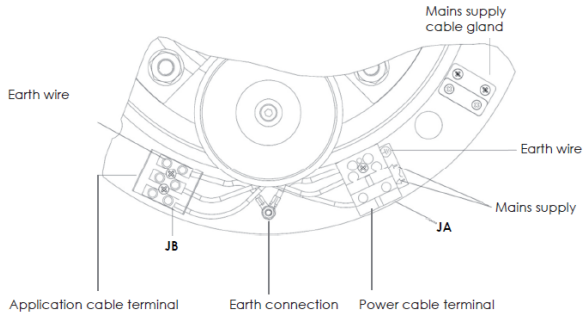


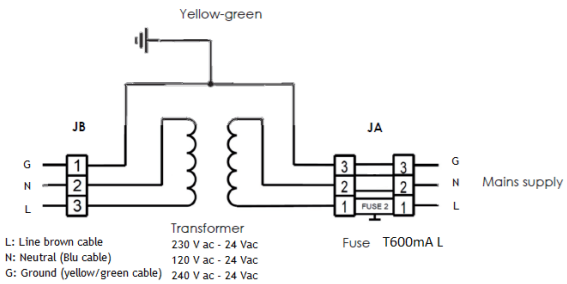
U. Connect the lamp conductor to the terminal board (6) (see electrical diagrams).

V. Check the perpendicularity of the column by acting on the nuts (9).
W. Tighten the nuts (12) and washers (11) to fix the flange (7), making it independent of the fixing rail (23).
X. Adhere the ceiling light (16) to the ceiling, pushing it against the ring (15).

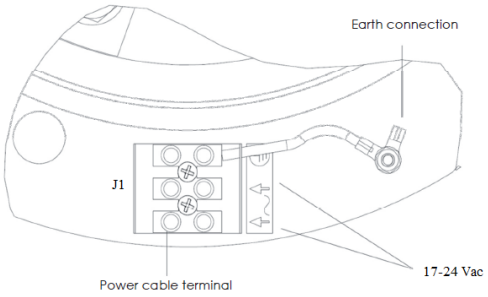


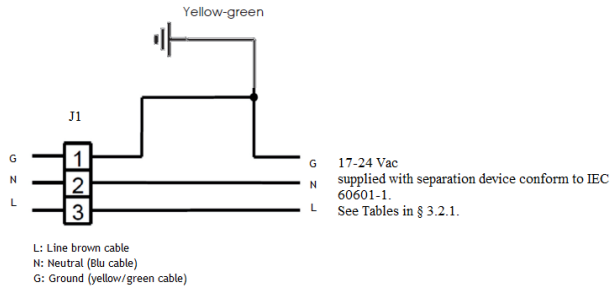
3.2.4.1 Electrical drawing – ceiling mounting with transformer





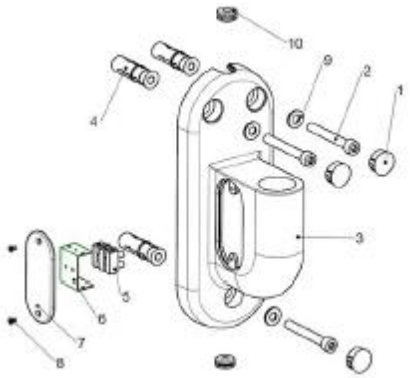
3.2.4.2 Electrical drawing – ceiling mounting without transformer

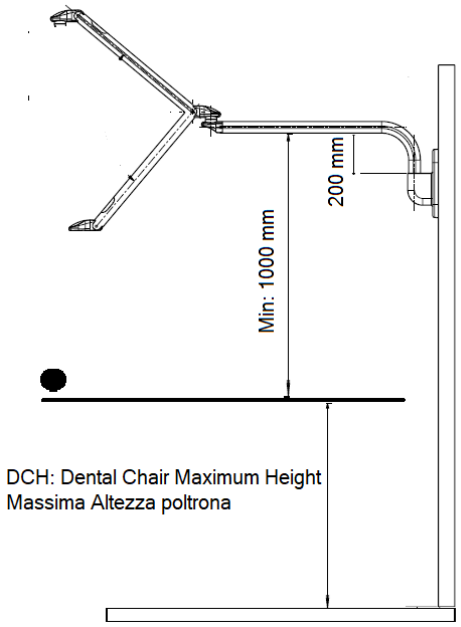


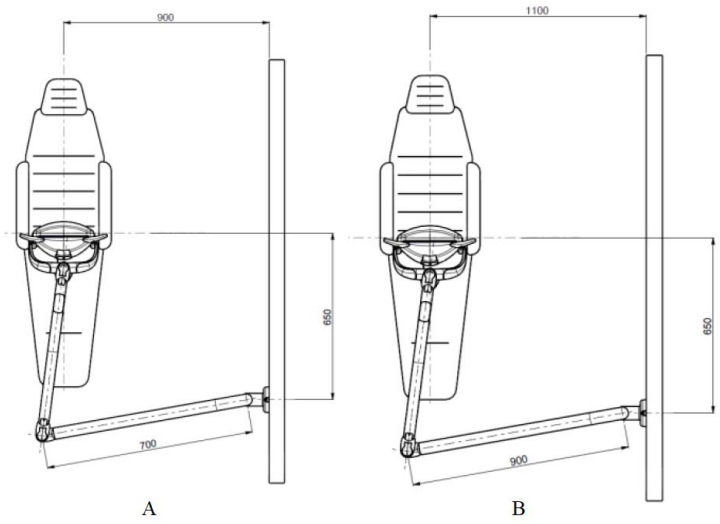


3.2.5 Wall mounting

	Warnings for electrical danger and fall of suspended masses
⚠	The device must be installed by specialized tecnicians The power supply in the room where the fitting must be installed must be always switched off. Before starting the installation take care that the ceiling is suitable to bear the load of the application and dental light. The anchor bolts provided with the application must be used only with the following base materials: concrete, natural stone. Maximum load applicable: 70 kg See §3.2.1 for the electrical requirements of the power supply. Stricly comply with the minimum heights shown below. These installations are considered permanent. Always connect the earth cable for installations in North America.

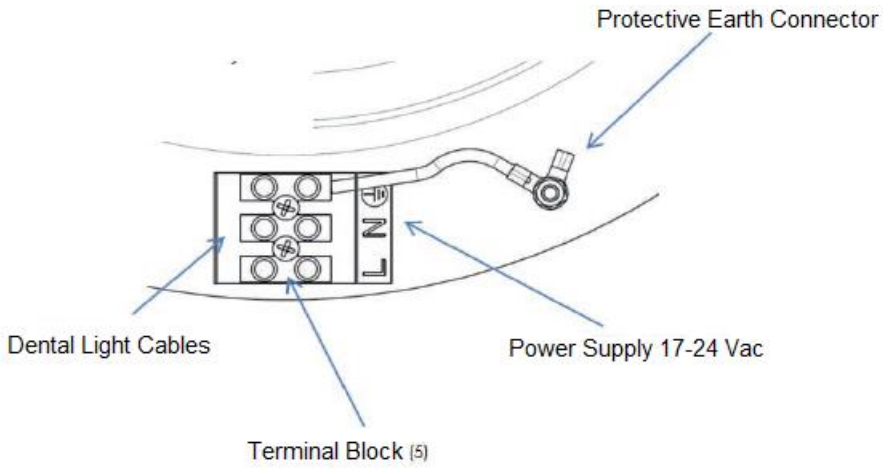
1. Cap 2. Screw 3. Wall application 4. Wall plugs 5. Electrical connector 6. Connector cover 7. Carter 8. Screws 9. Washer 10. Cable fairlead	





A. Once the fastening point has been established with reference to the center of the chair (See fig.A-B), make three holes on the wall of diameter D 14 in correspondence with the holes in the wall application (3), paying attention to the perpendicularity between hole and wall.
B. Insert the three wall plugs (12) into the holes made in A the screws (2) with the special hexagonal key (support accessories), taking care not to crush the wire between the wall application (3) and the wall itself.
C. Apply the three Caps (4) to the holes in the wall application (3).
D. Unscrew the screw (8). Remove the cover (7), insert the lamp in the ceiling application by greasing the pin.
E. Connect the lamp wires to the terminal Electrical connector (5) (see wiring diagram below) including the grounding wire.
F. Connect the wires coming out of the wall to the terminal board, in the case had been previously walled up. In the absence of this precaution, the connection it must be carried out with an external flying cable, to be introduced into the cable gland (10).
G. Mount the cover (7) using the screws (8).

3.2.5.1 Electrical drawing – wall mounting without transformer



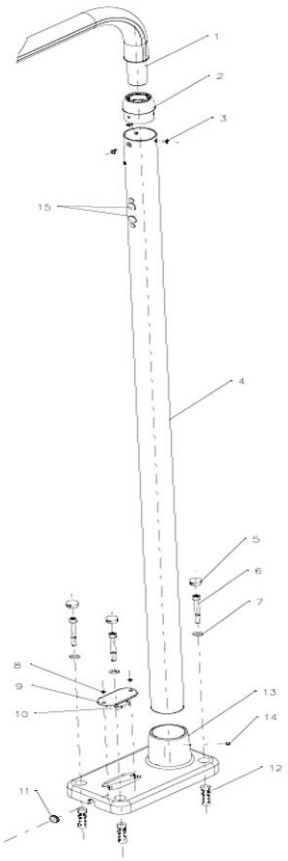
3.2.6 Floor mounting

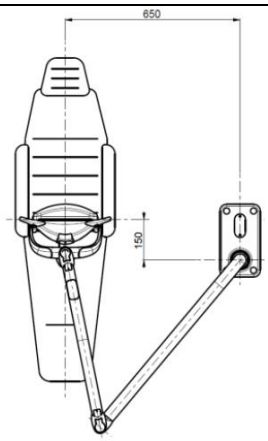
Warnings for electrical danger and suspended masses

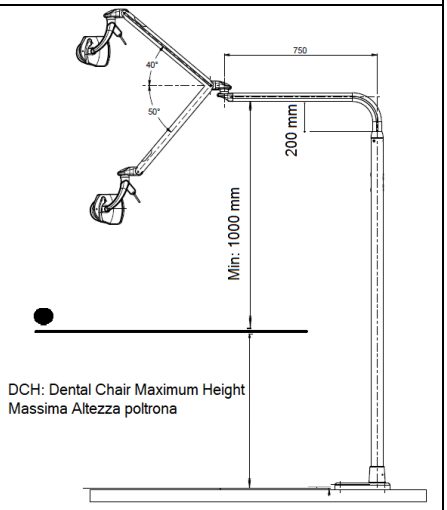
NB1. The device must be installed by specialized technicians
NB2. The power supply inside the room where the installation is carried out must always be switched off.
NB3. Before proceeding with the assembly operations it is necessary to make sure that the floor is able to support the application. The authorized materials are concrete and natural stone. The wall plugs to be used are those supplied or equivalent.
NB4. Maximum applicable load: 70 kg
NB5. Install in rooms with an electrical system that complies with the national regulations in force on medical premises (see §3.2.1 for general description)
NB6. The Dental Lights must be powered and connected according to requirements of § 3.2.1.
The resulting medical system must be declared in accordance with IEC / EN 60601-1 by the installer.

A. Once the fixing point has been established with reference (a) the center of the chair, drill four holes diameter D14 in the floor in correspondence with the holes in the floor support (13).
B. Prepare the floor support (13) by passing the washer (7) and the screw (6);
C. screw the wall plugs (12) onto the screws (6) for a few turns, pass the supply wire through the cable fairlead (11)
- Insert the four wall plugs (12) into the holes and lock the screws (6) using the appropriate hexagonal key, taking care not to damage the wire between the floor support (13) and the floor itself.
D. Apply the four caps plugs (5) to the holes in the floor support (13).
E. Unscrew the screws (8) and remove the cover plate (9)
F. Connect the power supply wire to the terminal connector (10), including the ground cable.
G. Place the column (4) to the floor support (13), during the fixing, check the perpendicularity of the column.
H. Place the bush (2) to the column (4) with the three screws (3), taking care to orient the holes in the bush (2) in correspondence with the screw housings on the column (4). Connect the lamp lead to the terminal connectors (10) including the ground cable
I. Fix the cover plate (9) to the floor support (13) with the two screws (8).

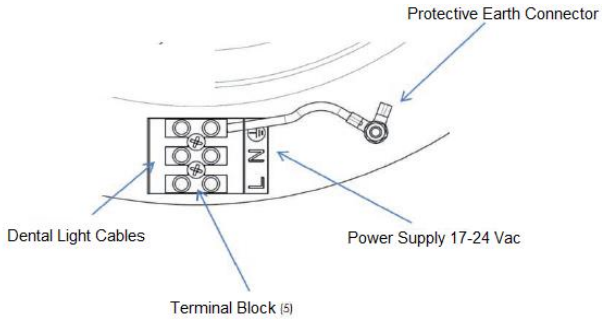
1. Pin
2. Bush
3. Screw
4. Column
5. Caps
6. Screws
7. Nut
8. Screw
9. Cover
10. Terminal connector
11. Cable Fairlead
12. Wall plugs
13. Wall suport
14. Grani
15. Caps







3.2.6.1 Electrical drawing – floor mounting without transformer



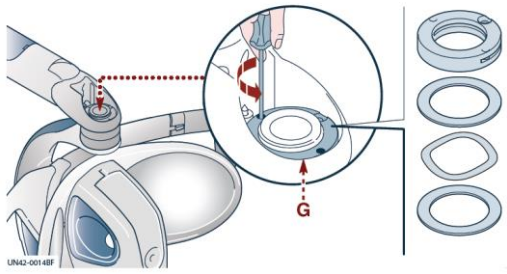
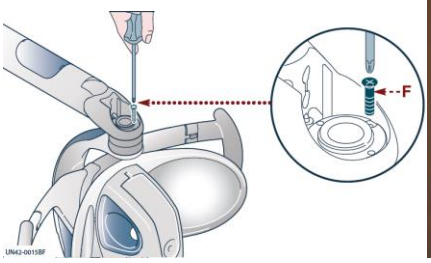
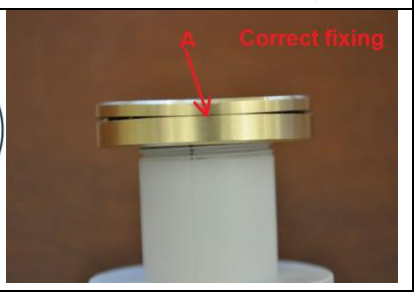
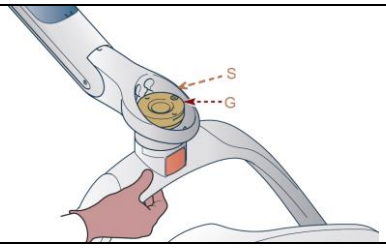
3.3 HEADLIGHT INSTALLATION

3.3.1 Mechanical Requirements

For mechanical connection an adequate space for the pin in the head and the nut identified as G. The support system must be designed to support the following loads, multiplied by the safety factors outlined by IEC/EN 60601-1 and IEC/EN 80601-2-60.

MAIA HEAD
1,7 kg

For the mechanical connection apply the following procedure:

⚠	**Warning for danger of falling of suspended mass.** **Strictly Follow the instruction to avoid the head to detach from the support.**
1 -Support the head and insert the washers in the threaded pin according to the sequence in the figure. 2 - Insert ring nut G according to the sequence indicated in the picture and screw in with adequate equipment. The ring nut must be screwed in to give the correct rotational force to the head.	
3 – Screw the safety screws F until the cut (A) into the brass nut is completely closed.	 
4 – take care to leave free space around the nut G and the support S, to avoid any friction when the head is rotating. **Fail to comply with this procedure could lead in falling of the headlight.**	
⚠	**Caution** The central arm without the head load tends to rise in a sudden manner with the risk of knocking against parts of the body. During the entire installation, keep the central arm in position and do not release it until head installation is complete.
⚠	**Warning for danger of suspended mass falling** Only use screws supplied by FARO. Screw in the safety screws together. Before removing the nut (G) **ALWAYS** remove the safety screw F. **NEVER** unscrew the nut (G) with the screws F mounted. Fail to comply with this procedure could damage the plastic threated PIN of the headlight with possible detach of the headlight.

Once mechanical connection is complete, complete electrical wiring.

3.3.2 Electrical Requirements

The requirements for correct installation of the head are as follows:

Power Supply	Supply cables	Power Supply requirements	Type of Device	Conformity to IEC 60601-1
17-24 Vac 50/60 Hz	Cable: 2 cables UL Style 1061 300 V T 80°C 1x26 AWG VW 1 Ø max 1,02mm Connector: Molex 51021-0300 3 poles	Transformer complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection Protection on secondary circuit with at least one appropriate fuse: T600mAL250V Minimum requirements: • Output: 17 - 24 Vac; • Minimum Power: 9 VA; • Dielectric strenght > 4000 V; • 2 MOPP between primary and sec. • Thermal Protection	Component built-in	The medical system must be declared compliant with IEC/EN60601-1 by the installation technician or manufacturer. Note for the installation technician: ensure the combined version on which the light is installed is certified to host the complete light.
24 Vdc		Power supply conform to IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with one pole protected by appropriate fuse: T600mAL250V Minimum requirements: • Output: 24 Vdc • Power: min 9 VA max 15 VA; • Dielectric strenght > 4000 V; • 2 MOPP between primary and sec. • Continuous protection from short circuit or overcurrent	Component built-in	

4 INSTRUCTION FOR USE

Read paragraph 1 carefully for safe use of the device.
The device must be clean before use (see Device Cleaning paragraph).

	**Caution**
	Simultaneous use of the light with electro-surgical scalpels can cause its malfunctioning.
	**Warning**
	The control switch must be handled with care to avoid breakages. Never move the light using the switch to grip.
	**Note**
	Each time you switch on the light, the light intensity will be saved on previous switch off.
	**Warning - danger of contact with powered parts**
	do not use the device if parts or enclosures are damaged.

4.1 DENTAL LIGHT OR DENTAL LIGHT HEAD WITH MECHANICAL SWITCH

Make reference to 1.1 for the symbols.
To switch on or off, press and release the command lever to the left or right.

4.1.1 Adjustment

a) On command: acoustic signal

b) To reduce light intensity, hold the command lever (on rear of lamp) to the left until the desired intensity is reached. When the minimum intensity is reached you will hear an acoustic signal..

c) To increase light intensity, hold the command lever (on rear of lamp) to the right until the desired intensity is reached. When the maximum intensity is reached you will hear an acoustic signal.

	Note
	Each time you switch on the light, the light intensity will be saved on previous switch off. The mechanical switch must be handled with care to avoid breakage.

4.1.2 Video Diagnostic Function

The Maia lamp has a function that enables it to be used when filming with a television camera and/or using diagnostic instruments (Diagnodent and laser, for example) without causing interference that could alter the diagnostic result.
This function is only in manual switch equipped versions.

Activation of the Video-Diagnostic function:
1. Switch on the Maia dental lamp (a beep will be heard when the control is used).
2. Release the control.
3. Use the control again to reach the minimum light intensity (a beep will be heard when minimum intensity is reached) then without releasing the control keep it active for at least 4 seconds.
4. A beep is emitted as confirmation, the light intensity rises to the maximum level and the Video-Diagnostic function is ACTIVE.

If the lamp does not react as described in point 4 above, repeat the whole procedure from point 1.

Deactivation of the Video-Diagnostic function:
1. Switch on the Maia dental lamp (a beep will be heard when the control is used).
2. Release the control.
3. Use the control again to reach the minimum light intensity (a beep will be heard when minimum intensity is reached) then without releasing the control keep it active for at least 4 seconds.
4. A beep is emitted as confirmation, the light intensity rises to the maximum level and the Video-Diagnostic function is DEACTIVATED.

If the lamp does not react as described in point 4 above, repeat the whole procedure from point 1.

Dimming of the light intensity with the Video-Diagnostic function ACTIVATED:
With the Video-Diagnostic function activated, the adjustment of the light intensity is modified from a continuous variation to a stepwise variation.
Two intermediate levels of light intensity can be chosen between the maximum and minimum.
Procedure:
1. Switch on the Maia dental lamp (a beep will be heard when the control is used)
2. Release the control.
3. Use the control again to reduce the light intensity and release the control at the intensity desired.

	Note
	• On reaching minimum intensity, a beep will be heard. • When the dental lamp is switched on again it will return to the maximum light intensity (a beep will be heard when the control is used).

4.2 DENTAL LIGHT OR DENTAL LIGHT HEAD WITH PROXIMITY SENSOR

To turn the lamp on and off, place your hand close to the sensor, within a maximum distance of 3 cm. When the command is given, an acoustic signal will be heard.

4.2.1 Adjustment

After the switching on, place the hand near the sensor until desired intensity is reached, from the maximum to the minimum level and from the minimum to the maximum level.
Once the desired intensity is reached, remove the hand from the position of adjustment.
On reaching maximum intensity, an acoustic signal will be heard (1 beeps); there will be 1 beep for minimum intensity.

	Note
	Each time you switch on the light, the light intensity will be saved on previous switch off.

4.3 LIGHT WITH REMOTE CABLE

To turn the light on and off, press and release button "A".

4.3.1 Adjustment:

a) to reduce the light intensity, keep button "A" pressed until the desired level of intensity is reached. When the minimum level of intensity is reached, an acoustic signal will be heard (1 beep).
When the minimum light intensity is obtained, you will hear an acoustic signal (1 beep).
b) To increase the light intensity keep the push-button "A" pressed, until the desired intensity is obtained.
When the minimum light intensity is obtained, you will hear an acoustic signal (1 beep).
Each time the lamp is turned on, the light intensity will be at the level memorised when it was turned off the time before.

5 CLEANING

	**Warning against danger of wear and corrosion and falling suspended mass**
	For all metal or plastic parts it is strictly forbidden to use substances that are abrasive, corrosive, acids, substances containing chlorine or chloride ions, phosforous or phosphorous ions Detergents with Trilene base, petrol, white spirit, clorine or similar. It is forbidden to directly spray any chemical substance on the device. It is forbidden the use of wet wipes without washing.

5.1 CLEANING OF THE REFLECTING PARABOLAS

Cleaning must be carried out using a soft cloth in cotton or absorbent cotton with ethyl alcohol or the specific PERFLEX detergent. Water-alcohol based disinfectants are suitable with 70% isopropyl alcohol or ethanol.

	**Caution - potential damage or wear on the parabolas**
	Never spray detergent directly on the parabolas. Cleaning operations on the parabolas must be carried out wearing gloves, to avoid leaving fingerprints on the surfaces. Never use detergents containing surfactants or water-repellents that depositing can leave streaks. Slight streaking will not prejudice the quality of the light. Products differing from those suggested could damage the parabolas. If in doubt, contact FARO customer care.

5.2 CLEANING OF THE HEAD

Cleaning must be carried out using a soft cloth in cotton or absorbent cotton with ethyl alcohol or the specific PERFLEX detergent. Water-alcohol based disinfectants are suitable with 70% isopropyl alcohol or ethanol.

	**Warning against danger of wear of the plastic and falling suspended weights**
	Never spray detergent directly on the head. Do not use detergents-disinfectants containing the following to clean plastic parts: • Ammonium Hydroxide • Sodium Hydroxide • Hydrogen peroxide • Ammonium Chloride • Methylene chloride • Methyl alcohol • Acids and corrosive substances of all kinds. • Les acides et les substances corrosives de toutes sortes. Faro tested and suggests the following disinfectants: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

5.3 CLEANING OF ARMS

Always use a cloth soaked in disinfectant approved to disinfect the surfaces and pass it over. Always squeeze the cloth to remove all the liquid in excess.

.

	**Warning against danger of corrosion and mechanical collapse with falling suspended weights**
	Never spray chemical substances directly on the arms or joints and their openings. Do not use detergents-disinfectants containing the following to clean plastic parts: • Ammonium Hydroxide • Sodium Hydroxide • Hydrogen peroxide • Ammonium Chloride • Methylene chloride • Methyl alcohol • Acids and corrosive substances of all kinds. Faro tested and suggests the following disinfectants: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive In case of wrong chemicals are used,rinse the surfaces with water and contact the FARO Service.

6 STERILIZATION OF THE HANDLES

⚠	**Warning - danger of cross contamination** The handles are not supplied sterile, they must therefore be sterilised before use. The handles must be sterilised before each patient.

6.1 Removal of the handle

To remove the handle, unscrew knob "A" and remove it from the support.	

6.2 Decontamination and disinfection

Before sterilising the handles, they must be decontaminated and disinfected.
To disinfect, Faro has tested the following products for disinfection: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

⚠ ⛔	**Attention - danger of plastic breaking** The handles cannot be disinfected by thermo-disinfection.

6.3 Sterilization

The handles must be packaged in compliance with EN 868-5.
The handles can be sterilised with standard cycles 121°/134° C up to two hundred (200) cycles or however up to loss of the mechanical performance.
The parameters of the sterilisation cycle are as follows:

Cycle EN 13060	Temperature	Pressure	Holding Time Minimum
B	121°C	207 kPa	15 min
B	134°C	308 kPa	3 min

Minimum cycles of sterilisation for mechanical integrity: 200

7 MAINTENANCE

Ordinary maintenance is not foreseen for MAIA light.
Fuses replacement must be performed by Service Engineers.
Only Service Engineer are allowed to perform corrective Maintenance and replacement of any part of the device, according to Manufacturer's Service Manual.

8 PERIODIC CHECKS

Check	Frequency	Applicabilità		Procedure	Responsible
		LD	TE		
Check the absence of any play between the arm joints	Yearly	x	N/A	Verify the play between the joints	User
Check the absence of any oxidation into joints, arms or plastic parts.	Yearly	x	x	//	User
Check the main plate can be read	Yearly	x	x	//	User
Check of damages on enclosure and plastic joints integrity	Every two years			//	Service Engineer
Electrical Safety according EN 62353 1. Dielectric strenght 2. Current Leakage.	Every two years	x	x	Use the parameters defined into IEC 60601-1	Service Engineer

Check	Frequency	Applicabilità		Procedure	Responsible
		LD	TE		
Light checks	Every two years	x	x	With a spectroradiometer check the values for: • Max Luminance: >25000 lux • CRI decay: <20%. • Radial power on blue light: <100 W/m2	Service Engineer

Service Engineer: competent person qualified to mantain, check and repair powered Medical Devices and Systems.

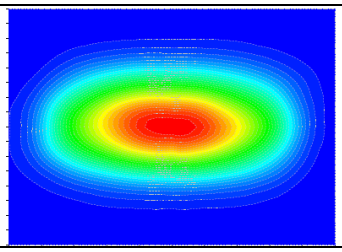
9 TROUBLESHOOTING

Effect	Cause	Action (Service Engineer - SE)	Resp
The light does not switch on	Power supply not inserted or inserted incorrectly.	Check the power supply is inserted and the combined unit is on.	User
	Interference with electro-surgical scalpels or high energy tools	Switch off the electro-surgical scalpels and check the permanence of the effect.	User
	Command on joystick applied incorrectly.	To switch on and off the light, press and release the joystick lever using the right or left side.	User
The light will flicker	Interference with electro-surgical scalpels or high energy tools.	Switch off the electro-surgical scalpels and check the permanence of the effect.	User
The light does not adjust light intensity	Command on joystick applied incorrectly.	Use the command correctly as described in this manual.	User
	Interference with electro-surgical scalpels or high energy tools.	Switch off the electro-surgical scalpels and check the permanence of the effect.	User
The light intensity is considerably reduced	Parabolas or secondary lens dirty.	Clean the parabolas and the secondary lenses.	User
	Use of wrong procedures.	Check you have maximum adjustment with the command.	User
Stains have appeared on the parabolas or the reflective layer has come away.	Use of non-approved products.	Clean the surfaces with specific "Faro Perflex" product. Clean the surfaces with isopropyl alcohol. To restore the surfaces, you need to get service to replace the parabolas.	User
The light does not stay balanced and tends to lower	Excessive load on head (small mirrors, cameras, etc..).	Remove the excess loads.	User

9.1 Acoustic signals

MIN = 1 beep
1 Beep = at commands
1 Beep = on switching on

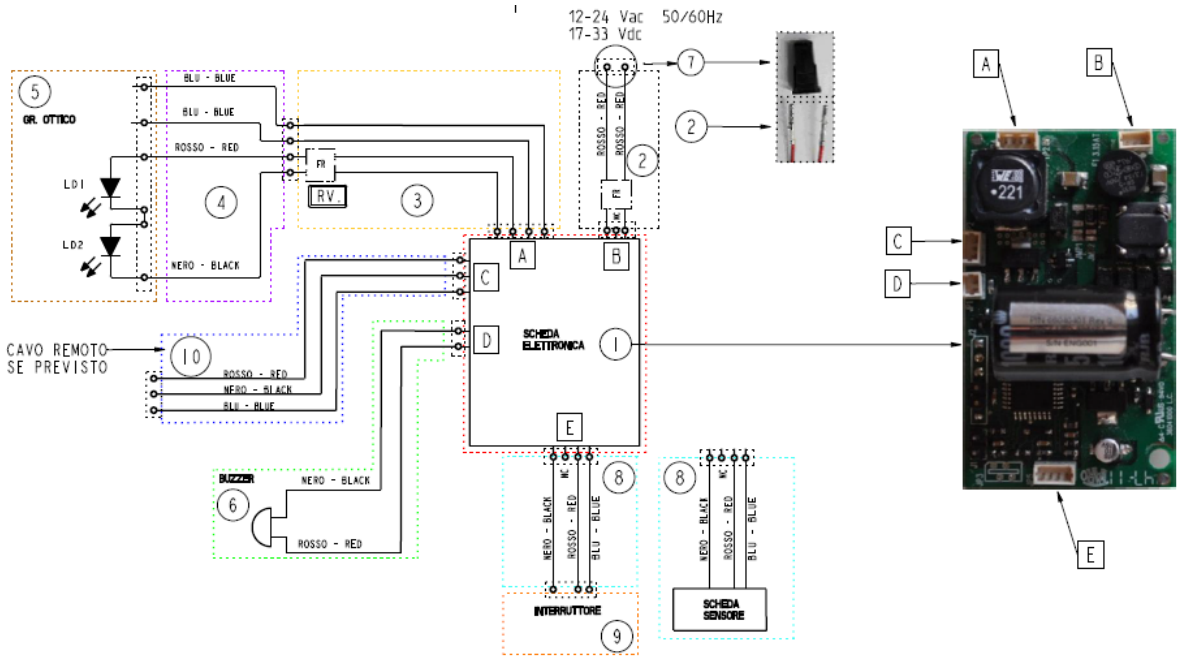
10 TECHCNICAL SPECIFICATION

	Dental Light	Dental light Head
Power Supply (without Transformer):	17÷24Vac ±10% 50/ 60Hz; 24 Vdc	17÷24Vac ±10% - 50/ 60Hz; 24 Vdc
Power supply (with transformer):	230 Vac 50/60 Hz 240 Vac 50/60 Hz 120 Vac 50/60 Hz	N/A
Max Power :	9 VA	
Fuses (Version with transformer):	2 x T 250mA1 250V	N/A
Reccomended fuses for installation without transformer (not supplied in charge to installator)	17÷24Vac: T600Mal 250V	17÷24Vac: T600mAL250V 22÷35Vdc: T600mAL250V
Protection against electrical hazad	Class II (final classification of the Protection Class of the Medical System is demanded to the installator or to the manufacturer) Only for the US Market: Class I for fixed or permanent installations (ceiling, wall of floor installations)	
Classification against IEC 62471	Class 1- Labelling Exempt	
Max illuminance (*)	> 30.000 lux	
Typical colour Temperature(*)	5.000 K	
Size of light spot (*)	175 mm x 100 mm	
Nature of the radiation	Non ionizing Radiation	
Type of radiation	Visible lights	
Typical distribution of illuminance		

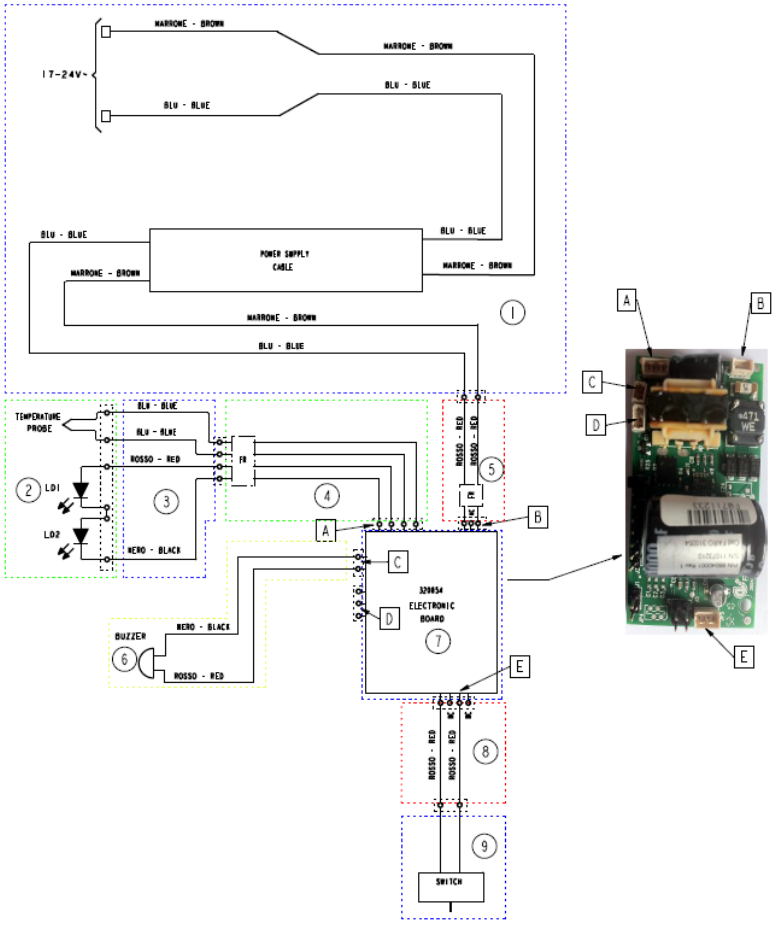
Typical optical values subjected to tolerances
Measurement performed at 700 mm distance. Contact Faro for the correct procedure for the measurement.

11 ELECTRICAL DRAWINGS

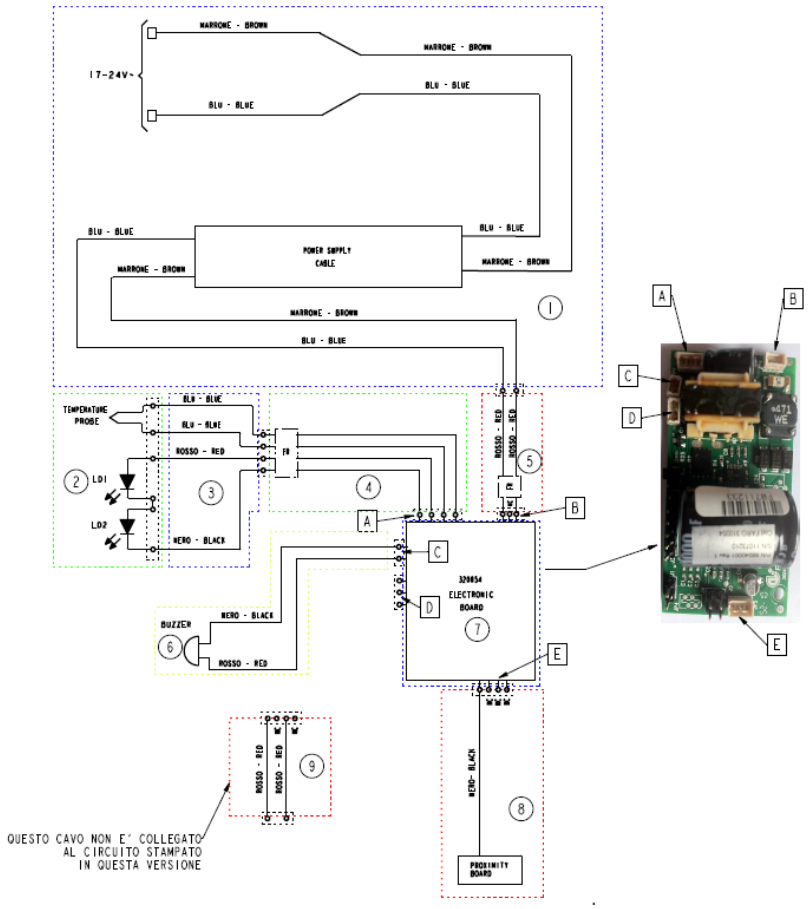
11.1 Headlight



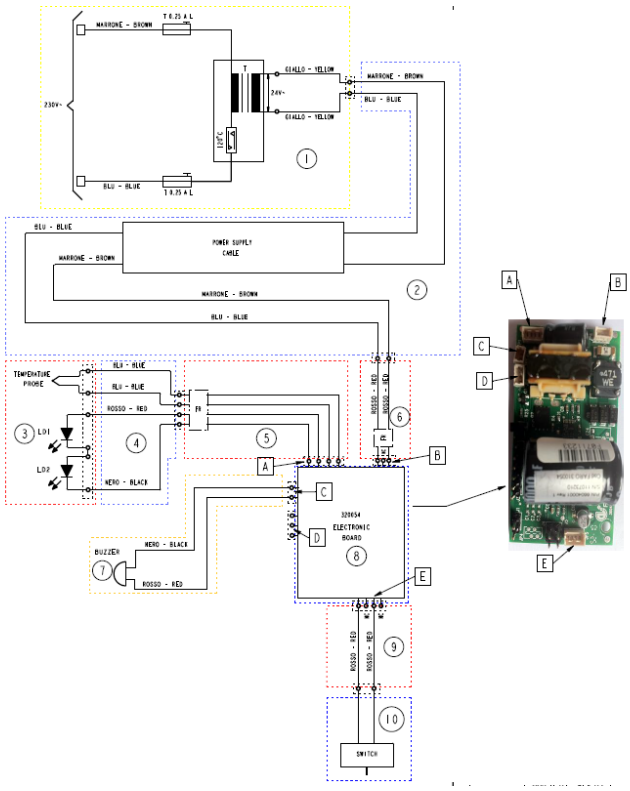
11.2 Dental Light – 17 - 24Vac with Mechanical Switch



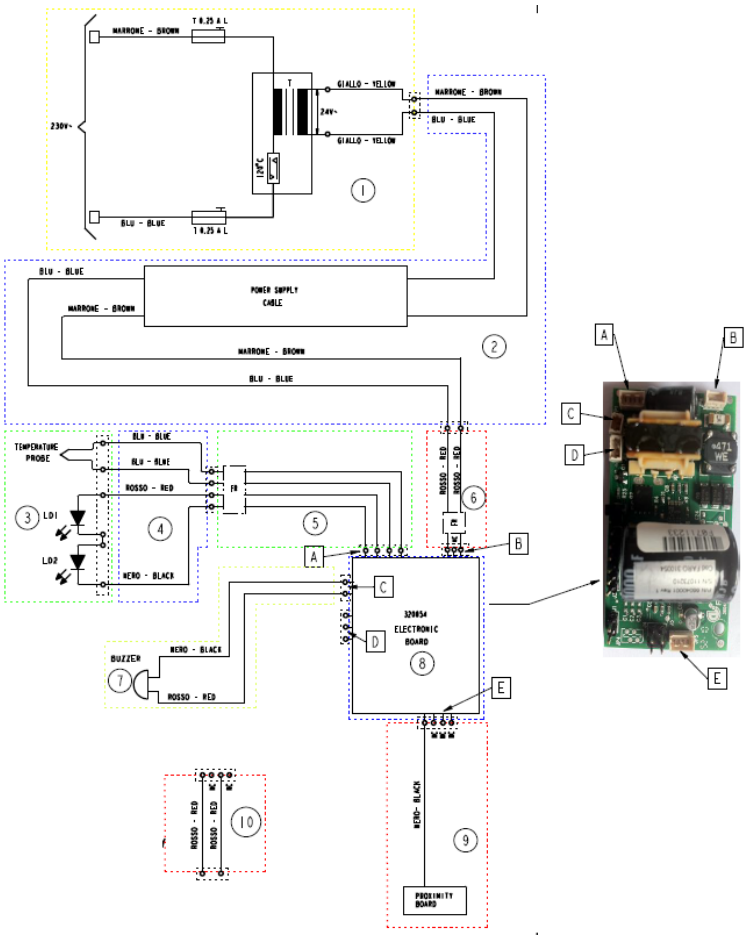
11.3 Dental Light – 17-24Vac with Proximity Sensor



11.4 Dental Light – 230Vac/240Vac/120Vac with Mechanical Switch



11.5 Dental Light – 230Vac/240Vac/120Vac with Proximity



COD. 988300

DAL 1948: ESPERIENZA
E RINNOVAMENTO

FARO S.p.A.
via Faro, 15 - 20876 Ornago (MB) - Italy
Tel. +39 039.68781 - Fax +39 039.6010540
www.faro.it - comm.italia@faro.it - export@faro.it

FARO FRANCE
Za Tgv Coriolis - 71210 Monchanin - France
Tel. +33 385.779680 - Fax +33 385.779688
www.farofrance.com - farofrance@farofrance.com

FARO DEUTSCHLAND GMBH
Gewerbepark Heideckhof Heideckstr. 179
D-47805 Krefeld - Germany
Tel. +49 2151.936921 - Fax +49 2151.936933
www.faro.it - info@farodeutschland.de

Azienda
Certificata

CERT. 9124.FAR2

CERT. 9120.FAR1