MAIA

USER'S MANUAL

EXPERIENCE AND INNOVATION
SINCE 1948

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 described into the Safety Recommendations included in the Packaging.

Warranty Conditions:
FARO offers the final customer a **12 month warranty** starting from the date of installation until a maximum of 18 months from the manufacturing date.
Repairs under warranty must be performed by FARO or its approved Service partner.
Warranty is considered valid only when:

- the user sent the Certificate of Warranty duly filled out at the following email: service@faro.it
- the user registered the warranty throughout the Faro website;

The warranty covers manufacturing and engineering defects; in case of valid claims, the warranty covers free parts replacement only. Manhour work is not included in the warranty.
The warranty is not considered valid, at the sole discretion of FARO, if the fault is due to tampering, damage, unauthorized changes to the product, incorrect use, improper maintenance and normal wear and tear.
This product have a Service Life of: 10 Years.
The Product is covered by the WEEE Directive 2012/19/EU. When scrapping and disposing of materials, follow the regulations in force in your country, using recognised and authorised companies.
At the end of the life cycle, sort the materials according to their type (ferrous, rubber, plastic).

Any serious incident occurring in relation to the device should be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Table of contents

1 SYMBOLS USED

1.1 SYMBOLS USED IN THIS 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.
FORBIDDEN	This icon highlights what you should not do to avoid damaging the device.
CAUTION	These instructions warns you that you must pay attention to avoid situations that could damage the device.
NOTES	This icon supplies information that allows you to use the device more efficiently.

1.2 SYMBOLS USED IN THE LABELLING AND ON THE PACKAGING

The data plate is fixed:

- for the complete light or arms: on the rear arm
- for the head: under the switch cover

Serial Number description

- For dental light YYLDNNNNNN
- For head of dental light YYTENNNNNN

Where

- YY: last two digit of the year of manufacturing
- NNNNNN: progressive counter of the year

e.g.: 21LD000001 I the first product manufactured in 2021.

Following symbols are present also:

Symbol	Description	Symbol	Description	Symbol	Description
CE	Mark for Conformitè Europe	135°C	Can be sterilized with heat at 134°C		Fragile
MD	Medical Device according to Regulation (EU) 2017/745 on medical devices,	40 °C 10°C	Use the device at a temperature between 10°C and 40°C		Protect the packaging from rain and high humidity
	Read the instructions use. Supplied by Electronic means.	1060 mbar 800 mbar	Use the device at pressure between 800 mbar and 1060 mbar		Do not Roll
	Manufacturer symbol according to Regulation (EU) 2017/745	75% 30% RH	Use the device at relative humidity between 30 RH and 75RH		Do not use hooks
	The instructions for use include safety warnings	SN	Serial Number		Maximum stackable weight
	WEEE equipment according to the Directive 2012/19/EC.		Symbol to adjust light intensity		Storage and Trasportation temperatures
	Double insulation. Class 2 device against electrical risk	ON OFF	Symbol to switch on/off the light		Storage and Trasportation Relative Humidity
	Recyclable cardboard		High	CH REP	Swiss Authorized Rapresentative for Medical Device Regulation (MedDo)		Storage and Trasportation Atmospheric Pressure

2 INTENDED USE

The device is used in dental cabinets 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.

2.1 USER'S MINIMUM REQUIREMENTS

The user with the following characteristics does not require any special training

Intended User	Professional qualification:	Minimum skills	Experience	Possible user handicaps
The intended users are Dentists (all specializations) or Dental Nurse, Hygienists and Assistants	Degree in Medicine with Dentistry Specialization Degree in Dentistry Degree in dental nursery	Those planned for the professional qualification Understanding of language: Those acquired for the professional qualification	Those outlined to conduct the profession	For the use it is necessary at least one upper limb; Visual faculty compatible with the profession;

3 DESCRIPTION OF THE PRODUCT

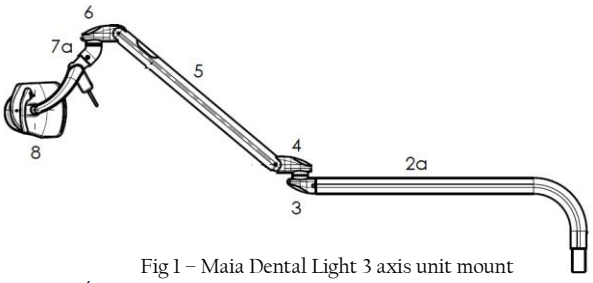


Fig 1 – Maia Dental Light 3 axis unit mount

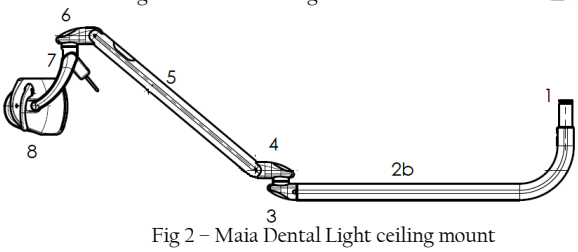


Fig 2 – Maia Dental Light ceiling mount

1 – Post for connection to unit or ceiling
2a – Fixed arm unit mount
2b – Fixed Arm Ceiling Mount
3 – Joint of the fixed arm
4 – Rear Joint of swivel arm
5 – Swivel arm
6 – Joint of the Head
7 – Joke of the Head
7a – Joke of the head with 3rd axis
8 – Head light

These main variants can be supplied with:
- Full dental light or Dental Light Head
- Command Interface: Mechanical Switch or Proximity Sensor
- Different Mounting (ceiling or dental unit)
- Different arm length combination
- Remote cable for bring the command to the Dental Unit's
- Auto-on setting;
- Power supply (with or without integrated transformer)

All variants can be ordered by dedicated product codes as reported in the table below:
32X YWZ 3NN - 42X YWZ 3NN - 32X YWZ 0NN - 42X YWZ 0NN:

	Axis of rotation	X	Mounting - Control	Y	Voltage input - Control	W	Arm lenght (mm)	Z	arm shape		Type of device	NN	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	Straight	0	Head (*)	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
(**) Custom codes

MS: Mechanical Switch PS: Proximity Sensor

For the North American market (United States and Canada) the following variants are available: 32X YWZ 4NN - 42X YWZ 4NN:

	Axis of rotation	X	Mounting - Control	Y	Voltage input - Control	W	Arm lenght (mm)	Z	arm shape		Type of device	NN	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 (**) Fixed equipments class I with earth protection connection								

4 INSTRUCTION FOR USE

4.1 DESCRIPTION OF COMMON USER'S INTERFACE

1 Mechanical Switch
2 Sterilisable Handle
3 Knob of the handle
4 Proximity Sensor
5 Mirrors
6 LED group

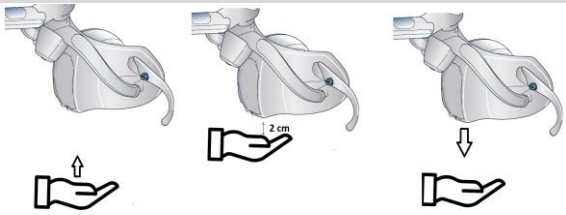
The device must be cleaned before use (see Device Cleaning paragraph).

	WARNING AGAINST HAZARD OF EXPLOSION AND ELECTROMAGNETIC MALFUNCTIONING
	Do not use the device in flammable or explosive environments Simultaneous use of the light with electro-surgical devices can cause malfunctioning (flickering, no command, etc)
	NOTE FOR POLYMERISATION OF RESTORATIVE COMPOSITES
	MAIA is not equipped with anti-polymerisation function. To minimise the risk of polymerisation: – Use the lamp at a light intensity close to the minimum; or – Use the FARO Poliblock filter
	FORBIDDEN
	The joystick must be handled with care to avoid breakages. Never move the light using the switch or parts other than the handles
	WARNING OF PHOTOBIOLOGICAL HAZARD AND GLARE
	Do not stare or aim the light beam directly into the patient's eyes, especially for patients at higher risk of eye injury (e.g. children or patient with eye diseases). In this case, always use appropriate protection and precautions. The lamp is classified as photobiological risk 1, without labelling according to IEC/EN 62471, at a distance of 200 mm. However, it cannot be excluded that particularly photosensitive individuals, or those who have taken photosensitising substances, may experience rashes or allergic reactions to light. In this case, discontinue treatment and use very low illuminance levels.
	WARNING AGAINST THE DANGER OF SUSPENDED MASSES
	Do not use the device if any parts or enclosure are damaged or if there is play or breaks between: - Head joint / Head joke - Fixed arm joint / Rear Joint of swivel arm The device is equipped with limit switches on each rotating element. Do not move the lamp by hitting the limit switches.

4.2 SWITCHING ON/ OFF

Mechanical Switch	Proximity

Push right or left and release
Acoustic signal: 1 beep

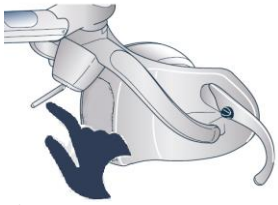


Bring the hand towards the sensor up to 2 cm and move the hand down
Acoustic signal: 1 beep

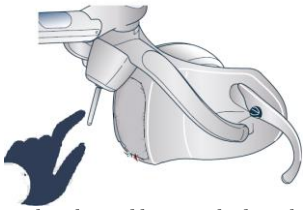
	Each time the lamp is switched on, the light intensity will set automatically on the memorized at the switch-off.

4.3 ADJUSTING THE LIGHT INSTENSITY

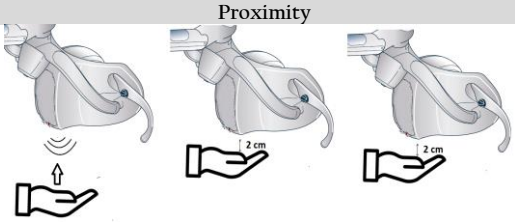
Switch – Increase Light Intensity	Switch - Decrease light intensity	Proximity



Push left and keep pushed until desired intensity is reached. Then release
Acoustic signal: 1 beep at command
Maximum intensity reached: 2 beeps



Push right and keep pushed until desired intensity is reached, then release.
Acoustic signal: 1 beep at command
Minimum intensity reached: 1 beep

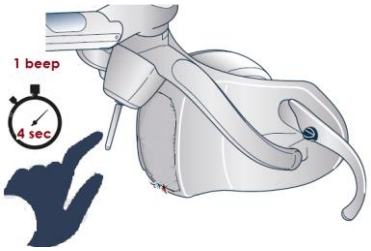


Bring the hand towards the sensor up to 2 cm and keep this distance until the desired light intensity is reached
Acoustic signal: 1 beep at command
Maximum intensity reached: 2 beeps
Minimum intensity reached: 1 beep

4.4 VIDEO RECORDING MODE

Maia is equipped with a function that allows it to be used during camera video recordings and/or the use of diagnostic instruments (e.g. Diagnodent and laser) without the risk of interference that could affect the result.
The function is only present in Mechanical Switch (MS) version and can be activated or deactivated by the user.

4.4.1 Video recording mode ON (or OFF)



1. Switch on the dental lamp
2 Act on the control to reach the minimum light intensity (1 beep at minimum).
3 Without release the MS, keep pushed for at least 4 seconds.
4. A confirmation beep is heard, the light intensity rises to the maximum level and the Video-Diagnostics function is ON (or OFF).
If the procedure does not work, repeat it from point 1.

4.4.2 Adjusting Light intensity in Video Mode

In Video-Diagnostics Mode, the light intensity adjustment changes from continuous to stepwise. Two intermediate levels of light intensity can be selected between maximum and minimum.
Procedure:
1. Switch on the Maia dental lamp using the MS (beep at the control socket).
2. Release the MS.
3. Push the MS again to reduce the light intensity and release the control at the desired intensity level.

	When the minimum intensity is reached, a beep sounds. When it is switched on again, the dental lamp will return to full brightness (beep at the control socket).

4.5 REMOTE CABLE

Make reference to the Dental Unit's instruction for use the Dental Light from the Dental Unit's control panel.
In case remote cable is managed in installation, ask the Installator.
Commands from remote cable are managed by a Push Button,

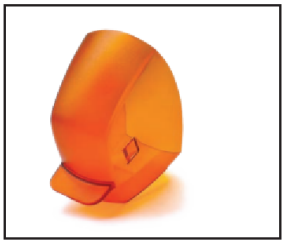
Function	Button	Command
On – Off	A	Press and Release
Adjustment	A	Press and keep pushed

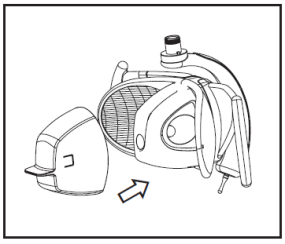
4.6 AUTO-ON MODE

When the Auto On mode is on, the lamps switch on automatically (without a specific command from the user) when there is power from the dental unit.
To change the Auto On setting, contact a Service Engineer.

4.7 USING THE POLIBLOCK FILTER

The anti-polymerisation filter "POLIBLOCK" modifies the light spectrum, avoiding the activation of the composite up to 520 nm wavelength. The device can be applied to MAIA directly by the end user during dentistry procedures.
Insert the POLIBLOCK filter, checking that it well secured to the LED group.
The light emitted by the lamp with the "POLIBLOCK" turns to a red colour, cutting the blue frequencies.
Use the POLIBLOCK only for the time necessary to the composite to be modelled to the final shape.





5 CLEANING, DISINFECTION AND STERILIZATION

	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, phosphorous or phosphorous ions, - detergents with Trilene base, petrol, white spirit, chlorine or similar. It is forbidden to directly spray any chemical substance on the device.	Do not use detergents-disinfectants containing the following substances to clean plastic parts: - Ammonium Hydroxide - Sodium Hydroxide - Hydrogen peroxide - Ammonium Chloride - Methylene chloride - Methyl alcohol - Acids and corrosive substances of all kinds. It is forbidden the use of wet wipes without rinsing.
	Faro tested and suggests the use of the following disinfectants, for plastic parts and metal parts: - Durr FD366 Sensitive - Water-alcohol based disinfectants with 70% isopropyl alcohol or ethanol are suitable.	

5.1 CLEANING OF THE MIRRORS

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

	Caution - potential damage or wear on the mirrors
	Never spray detergent directly on the mirrors. Cleaning operations 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 mirrors. If in doubt, contact FARO customer care.

5.2 CLEANING AND DISINFECTION OF THE HEAD

Cleaning must be carried out using a soft cloth in cotton wetted with disinfectant solution.
Always squeeze the cloth to remove all the liquid in excess.

5.3 CLEANING AND DISINFECTION OF ARMS

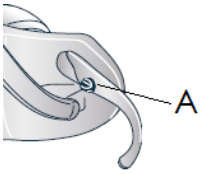
Always use a cloth soaked in disinfectant approved to disinfect the surfaces and pass it over.
Always squeeze the cloth to remove all the liquid in excess.

5.4 DECONTAMINATION AND STERILIZATION OF PARTS

Handles and PolIblock can be sterilized according to the requirements described below.

	WARNING – CROSS CONTAMINATION
	The handles and Poliblock are not supplied sterile, they must therefore be sterilised before use. The handles and Poliblock must be sterilised before each patient.

5.4.1 Decontamination And Disinfection Of The Handles



To remove the handle, unscrew knob "A" and remove it from the support.
To disinfect, Faro has tested the following products for disinfection:

- Durr FD366 Sensitive

	WARNING - danger of plastic breaking
	The handles cannot be disinfected by thermo-disinfection.

5.4.2 Sterilization Of The Handles

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

Number of cycles validated for maintaining mechanical integrity: 200

5.4.3 Decontamination And Disinfection Of Poliblock

Before sterilisation, the Polyblock must be cleaned and decontaminated.
Faro has tested the following products for disinfection:

- Durr FD366 Sensitive

Follow the instructions of the manufacturer of the disinfectant for the correct procedure.

	WARNING – DANGER OF FALL OF SUSPENDED MASSES
	Poliblock cannot be disinfected by thermo-disinfectors.

5.4.4 Sterilization Of Poliblock

	WARNING – DANGER OF FALL OF SUSPENDED MASSES
	Poliblock cannot be sterilized at 134°C. Do not Exceed the number of steriliation cycles

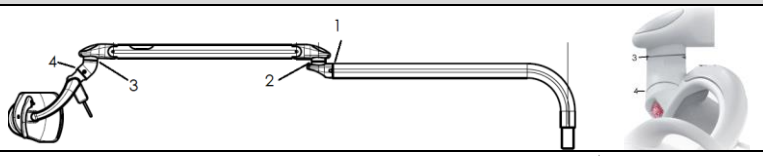
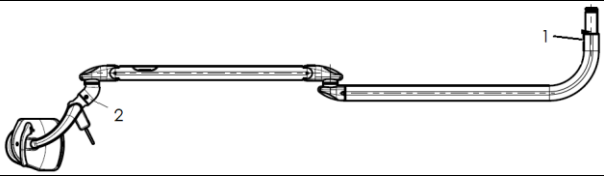
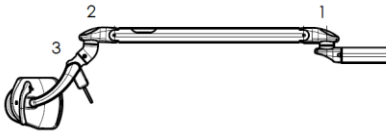
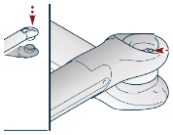
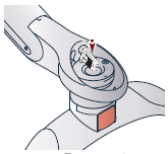
Poliblock must be packaged in compliance with EN 868-5.
Poliblock can be sterilised with standard cycles 121° C up to forty (40) cycles or however up to loss of the mechanical performance.
The parameters of the sterilisation cycle are as follows:

Cycle EN 13060	Temperature	Pressure	Holding Time Minimum
B	121°C	207 KPa	15 min

Number of cycles validated for maintaining mechanical integrity: 40

6 PREVENTIVE MAINTENANCE AND ROUTINE CHECKS

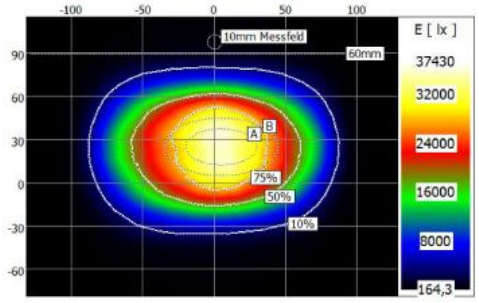
Only Service Engineer are allowed to perform corrective Maintenance and replacement of any part of the device, according to Manufacturer's Service Manual.

Check	Freq	Procedure	Resp.
No plays or space gaps between the junction points (points 1, 2, 3, 4)	Yearly		Service Engineer
Screws of connection points must be tightened and integer: • screws 1 • Screw 2 (both sides)	Yearly		Service Engineer
The nuts of connection points under carter 1, 2 must be well secured and safety screws intact. The screws under carter 3 must be well secured.	Yearly	  Carter 1  Carter 2  3 axis joint	Service Engineer
Check the absence of any oxidation into joints, arms or plastic parts.	Yearly	Visual inspection	Service Engineer
Check the main plate can be read	Yearly	Visual inspection	Service Engineer
Check of damages on enclosure and plastic joints integrity.	Yearly	Visual inspection	Service Engineer
Electrical Safety according EN 62353 1. Dielectric strength 2. Current Leakage	24 months	Use the parameters defined into IEC 60601-1	Service Engineer
Light checks	24 months	With a spectroradiometer check the values for: Max Luminance: ›30000 lux CRI › 85 Radial power on blue light: ‹100 W/m2	Service Engineer

7 TROUBLESHHOTING

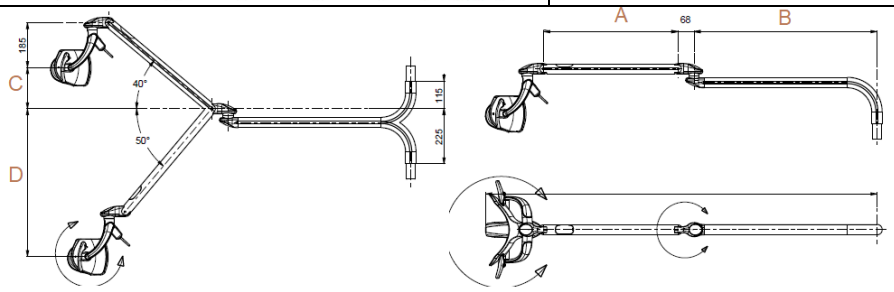
Effect	Cause	Azione (Service Engineer - SE)	Resp
The ioght does not switch on	Power supply not connected correctly	Check that power supply mains in connected and the dental uniti s switched on	User
	EM interference with electro surgical scalpels or high energy tools	Switch off the electro surgical scalpels	User
	Wrong command to the switch or proximity	See dedicated chapter	User
Flickering of the light	EM interference with electro surgical scalpels or high energy tools	Switch off the electro surgical scalpels.	User
Adjustment of the intensity not possible	Wrong command to the switch or proximity	See dedicated chapter for the correct use of commands	User
	EM interference with electro surgical scalpels or high energy tools	Switch off the electro surgical scalpels.	User
Light intensity low	Mirrors are dirty	Clean mirror and optical group	User
	Wrong command to the switch or proximity	See dedicated chapter for the correct use of commands	User
Presence of stains or halos on the mirrors. Lack of reflecting treatment on the surface of the mirrors	Use of non approved product or wrong procedure	See dedicated part of the manual on cleaning.	User
The light does not mantain the position of equilibrium	Overload due to the presence of other devices on the light (external mirrors, camera's etc.)	Remove the excessive load	User

8 TECHCNICAL SPECIFICATION

	Dental Light	Dental Light Head
Power Supply (without Transformer):	17÷24Vac ±10% 50/ 60Hz;	17÷24Vac ±10% - 50/ 60Hz; 22 – 35 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 max	
Fuses (Version with transformer):	2 x T 250mAl 250V	N/A
Reccomended fuses for installation without transformer	17÷24Vac: T600mAL	17÷24Vac: T600mAL 22 – 35 Vdc: T600mAL
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, unit, wall of floor installations)	
Classification against IEC 62471	Class 1- labelling exempt Actinic UV: EXEMPT Near UV: EXEMPT Blu Retinal: Low Risk Exposure limit for Blue : 1536 seconds	
Max illuminance (*)	From 3000 to 30.000 lux (with Poliblock › 10.000). Continuous adjustment	
Typical colour Temperature(*)	5.000 K (with Poliblock 1500 K)	
Size of light spot (*)	175 mm x 100 mm	
Hard Shadow	horizontal dimension: 5 mm / vertical dimension: 10 mm	
Camphorquinone weighted irradiance	Poliblock: 0,047 W/m^2	
Nature of the radiation	Non ionizing radiation	
Type of radiation	Visible spectrum only	
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.

Take care to leave sufficient space around the lamp to avoid any interference with fixed obstacles.
The free space can be determined from the dimensions shown below

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



Storage and transportation conditions	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
Use environmental conditions	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%

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

MAIA
Dental Operating Light
Medical Device
Class I

CE
MD

DAL 1948: ESPERIENZA E RINNOVAMENTO