01

MAIA

LAMPADA DENTALE A LED
DENTAL LED LIGHT
LED口腔无影灯

MANUALE D'USO
INSTRUCTION MANUAL
MODE D'EMPLOI
GEBRAUCHSANLEITUNG
MANUAL DE USO
使用说明书

CE Dispositivo Medico conforme
alla direttiva 93/42/CE
FARO SPA Ornago (Italy)
医疗器械-
符合93/42/CE标准
FARO SPA Ornago (Italy)

FARO

DAL 1948: ESPERIENZA
E RINNOVAMENTO
始于1948年　经验与创新

SYMBOLS

DANGER

Paragraphs marked with this symbol contain instructions that must be carefully followed to avoid damage to the device, the operator and even the patient.

CAUTION

These instructions warn the user that extreme caution is required to avoid situations that could damage the device.

PROHIBITION

This symbol highlights what you must not do to avoid damaging the device.

TIPS

This symbol indicates information that allows more effective use of the device.

Dispose of the device in compliance with regulations for separate refuse collection of electric material.

Class II device.

PLEASE NOTE

Refer to the enclosed documentation.

SAFETY STANDARDS

- The dental lamp MAIA is designed to light up the oral cavity of the patient during dental procedures.
- The lamp must be used by qualified personnel.
  The lamp must only be installed by specialised personnel.
  Ensure that power-line voltage indicated on the information plate corresponds to that of the supply network.
  The dental lamp must be installed on a specific control and power feed device, such as dental chairs, **or connected to a wiring system that meets IEC 364-1 standards and "national rules for installation of wiring systems in premises allocated for medical use."**
  The lamp must be installed with a multipolar device to separate it from the supply network. Said device shall meet IEC/EN 61058 standards. A green status light shall be inserted to indicate that the lamp is powered.
- Do not do any maintenance work on the lamp when the power supply is on or in the presence of the patient. Disconnect the power cable from the supply socket before starting work.
- Do not insert any objects or equipment that could come in contact with live spots into the slits of the lamp head.
- The articulated arm and hinge joints of the head allow the light beam to be correctly positioned. Do not overload the arms and hinge joints with impact at the end of stroke.
- Do not use a fixed light beam for patients at risk (e.g. children, adults with eye disorders). Always use appropriate protection devices and precautions. Faro suggests using BLUE-BAN or BABY BLUE-BAN (for children) protective eyeware.

  Faro eyeware are individual protection devices for protecting the eyes **<u>of the patient</u>** from the potential photobiological risks of light. Faro recommends using them for patients who are particularly exposed to such risks, namely children and adults with eye disorders who are taking photosensitive substances. The eyeware must be worn for the entire duration of treatment. They shall be cleaned and disinfected before and after use to prevent cross-contamination. Sterilise only at 121°C. Any scratches and/or haloes do not compromise their efficacy. Do not use in case of mechanical breakage.
- Not suitable for installation in rooms containing flammable gas.
- Do not spray detergents-disinfectants directly on the lamp head.
- The information plate with LED indications is fixed to the rear arm.
- Any inadequate performance of the device will not impair patient safety in any way.
- For cleaning plastic parts of the lamp MAIA, **DO NOT USE** detergents-disinfectants containing: **AMMONIUM HYDROXIDE SODIUM HYDROXIDE METHYLENE CHLORIDE METHYL ALCOHOL.**
  Failure to comply with this indication might cause: risk of breakage of plastic parts • risk of structural breakdown of hinge joints with potential falling of the articulated arm. In case of doubt, please contact Customer Care Faro.
- Do not perform servicing or replacement operations on parts other than those specified in the manual. Any intervention not indicated in the same might impair the safety features of the device.
- For disinfection of surfaces, use hydro-alcohol-based disinfectants.
- Do not leave small components of the device unattended or at the reach of exposed

- The doctor shall use disposable protection devices on the handles of the lamp or guarantee its sterilisation for versions that envisage this option.
- Divide materials by type (e.g. ferrous, rubber, plastic, etc.). For scrapping and disposal of materials, comply with local regulations in force, even resorting to specialised firms that are recognised and authorised.
- The packaging of the lamp is suitable to adequately protect it from penetration of external agents.
- The lamp in its original packaging can be transported or kept in storage for a period of 15 weeks, if compliance with environmental conditions specified below is assured:
    - **Room temperature between -20° and 70°C**
    - **Relative humidity between 10% and 90%**
    - **Atmospheric pressure between 500 a 1060 mBar**
- The lamp must be used in the following environmental conditions:
    - **Temperature between 10 and 40°C**
    - **Relative humidity between 30 and 75%**
    - **Atmospheric pressure between 700 and 1060 mBar**

SAFETY STANDARDS

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.

FEATURES

Versions

The dental lamp **"Maia"** is available in the following versions:

- ***S/TS Lamp*** *(with/without transformer)* ***with switch***
- ***S/TS Lamp*** *(with/without transformer)* ***with on/off cord-pull switch***
- ***S/TS Lamp*** *(with/without transformer)* ***with proximity switch (only on request)***
- ***S/TS Lamp*** *(with/without transformer)* ***ceiling version with switch or proximity switch (only on request)***

- **Light source** including two LEDs, whose light is mirrored on two dishes.
- **Reflecting surfaces** with dishes for creation of a regular and uniform spot of light at every intensity level and for uniform distribution of the light in the operating field without operator-generated shadows or dark areas.
- **Light intensity regulation** with switch or proximity switch (only on request).
- The **Proximity Switch** allows to switch the lamp on and off without direct contact, thus eliminating potential cross-infections (only on request).
- **Servicing** is facilitated by the application of new technologies that take into account the various requirements in terms of safety, ergonomics and hygiene.
- **Detachable handles** allow sterilisation.

DESCRIPTION OF THE PARTS

Fig. 1

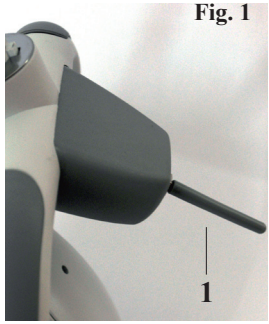
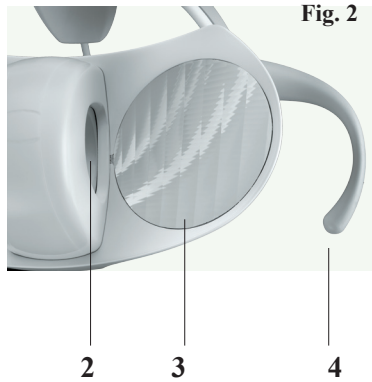


Fig. 2



1 - Switch
2 - Lens
3 - Dish
4 - Handle
5 - Proximity Switch
6 - Fuses
7 - Trasformer

Fig. 3

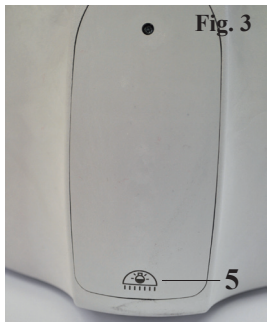
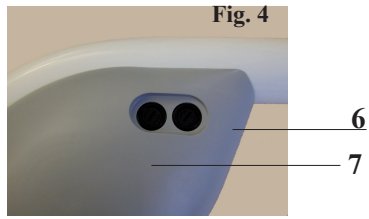


Fig. 4



INSTALLATION AND CONNECTIONS

Dental Lamp "MAIA", version S/TS

Check that the packaging contains the following components:

- Dental lamp (requested version)
- Envelope with lever + key
- Operating Manual

Clean the device before use
(see section Cleaning the device)

The device must be installed by specialised technicians.

Disconnect power supply during installation.

Lamp assembly, dental chair version

- Install the lamp by inserting the terminal lamp pin into the specific hole on the dental chair.

	SAFE WORKING LOAD	MINIMUM BREAKING LOAD
Long arm 855 mm	2.92 Kg	23.5 Kg.
Long arm 550 mm	2.56 Kg	20.5 Kg

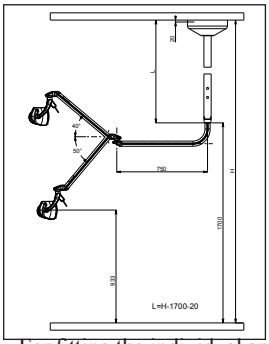
1) **POWER CORD:** in the version without transformer be sure to keep no more than the bare minimum length for the connection

- **LAMP WITH TRANSFORMER;** it must be directly powered by the power-line voltage corresponding to characteristics printed on the information plate or in the technical specifications of the manual.
- Ensure that the main switch complies with IEC/EN 61058 standards.
- **LAMP WITHOUT TRANSFORMER;** it must be powered by low voltage alternate current (17 - 24V AC) using a safety transformer that meets EN 60601-1 standards.

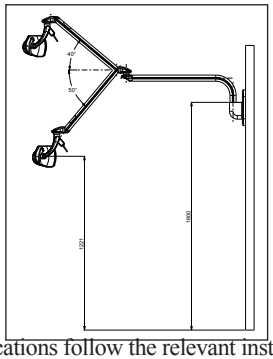
Fitting the ceiling – wall – floor light

- The applications are not supplied with the lamp.

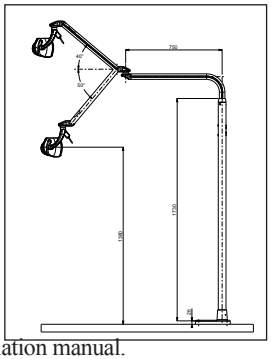
CEILING



WALL



FLOOR



- For fitting the individual applications follow the relevant installation manual.

INSTRUCTIONS FOR USE

SWITCHES SYMBOL

ON *OFF*

SWITCH ON **SWITCH OFF**

"MAIA" LAMP WITH SWITCH (see description of the parts)
On/Off/Adjustment
- To switch on or off, press and release the command lever to the left or right.
- Adjustment:

a) On command: (1 beep)
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 (1 beep).
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 (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.
The control lever must be managed very carefully to avoid breakage.

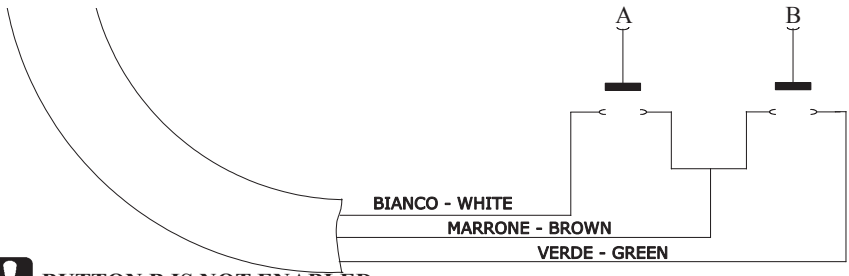
"MAIA" LAMP WITH PROXIMITY SWITCH (see description of the parts)
On/Off
- To turn the lamp on and off, place your hand close to the sensor, within a maximum distance of 3 cm. When the command is given, an acoustic signal will be heard (1 beep).
- For **light intensity** regulation, place the hand near the sensor until desired intensity is reached, from the maximum to the minimum level and from the minimum to the maximum level. On reaching maximum intensity, an acoustic signal will be heard (1 beeps); there will be 1 beep for minimum intensity.

"MAIA" LAMP WITH REMOTE CONTROL DEVICE (see description of the parts)
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 produce negative effects on the "EMC" performance.

On/Off/Adjustment
- To turn the lamp on and off, press and release button "A".
- 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.



BUTTON B IS NOT ENABLED.

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 regulation 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).

SERVICING/CLEANING

Replacing fuses "6" in the lamp version with transformer
(see description of parts)

The lamp with transformer is supplied with two identical fuses. To replace it, proceed as described below:
- ensure that power supply is disconnected,
- unscrew caps **"6"** located on the transformer holder,
- extract the fuses. After observing the interruption, replace the fuses.

Important: the new fuses must have the characteristics indicated on the information plate and in the technical specifications.

For cleaning plastic parts of the lamp MAIA, **do not use** detergents-disinfectants containing: **AMMONIUM HYDROXIDE SODIUM HYDROXIDE METHYLENE CHLORIDE METHYL ALCOHOL**
Failure to comply with this indication might cause: risk of breakage of plastic parts • risk of structural breakdown of hinge joints with potential falling of the articulated arm. In case of doubt, please contact Customer Care Faro.

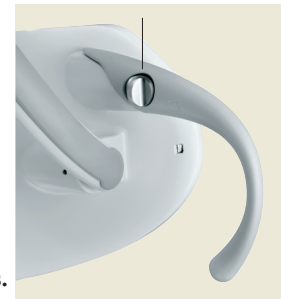
CLEANING THE DISHES "3" (see description of parts):
Clean with cotton wool and ethyl alcohol.
Do not use water-repellant or surfactant-based detergents, whose build-up can leave haloes.

Hydro-alcohol disinfectants with 70% isopropyl or ethyl alcohol are suitable.

PLEASE NOTE: other products might damage the reflectors (dishes).
In case of doubt, please contact Customer Care Faro.

Slight haloes will not impair the quality of light.

"A"



STERILIZING THE HANDLES
To remove the handle, unscrew button **"A"** and slip it off.
To insert it, push firmly and screw on **"A"**.

Handles are not provided sterile and must, therefore, be sterilised before use.

Sterilize the device with standard cycles
at 121°/134° C for a total of 200 sterilisation cycles.

OTHER PARTS OF THE LIGHT (head-articulated arm)
Clean with a soft cloth.

For all lamp parts, it is absolutely forbidden to use abrasive substances, detergents based on trichloroethylene, benzene, turpentine or the like.

TROUBLESHOOTING

The lamp will not switch on	– Check that it is connected to the power supply. – Check status of fuses. – If none of these causes applies, contact Technical Support.
Intensity has considerably diminished	– Clean the dishes. In case of failure to restore initial conditions of irradiance, contact Technical Support.
Handles will not snap on or they snap off with difficulty	– Check that the position of the locking screw on the handle is completely open.
Patches have appeared on the reflectors (dishes)	– Clean the surfaces with the specific product "Faro Perflex". – Clean the surfaces with isopropyl alcohol. – An unsuitable product for cleaning or disinfection has been used, thus damaging the surfaces. – Contact Customer Care FARO.

PERIODIC CHECKS

- Check the lack of smooth motion in hinge joints of the arms **(yearly)**
- Check readability of information on the plate **(yearly)**
- Power safety checks: **(every two years)**
  1. Rigidity
  2. Dispersion.
- Light checks: **(every five years or 10,000 hours of function)**
  1. Maximum irradiance: >35,000 lux
  2. Blue light on emitted spectrum measured in W/m^2: <100

If any anomalies occur during the periodic check, immediately contact Customer Care Faro.

ACOUSTIC SIGNALS

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

TECHNICAL SPECIFICATIONS

Power-line voltage (w/o transformer)	:	**17÷24V ac ± 10% - 50/60 Hz** **22÷35V dc**
Power-line voltage (with transformer)	:	**230 V 50/60 Hz**
Absorbed power	:	**9VA**
Fuses (version with transformer)	:	**2 x T250mA1 250V**
Protection against electrical hazards	:	**Class II device**

The label complies with EN 60825-1:94+A1:02+A2:01 standards

OPTICAL FEATURES

Size of light spot	:	**170 mm x 85mm**
Lux	:	**3000*-35000* lux @700mm**
Colour temperature	:	**5000 K**

*** Typical value**

COD.988300_REV.06

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Azienda
Certificata

CERT. 9124.FAR2

CERT. 9120.FAR1