



EVA

USER MANUAL



EXPERIENCE AND INNOVATION
SINCE 1948

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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 **24 month warranty** starting from the date of installation until a maximum of 30 months from the manufacturing date.

Repairs under warranty must be performed by FARO or its approved Service network.

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.

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.

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.	
	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.	

1.2 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 heat sink cover

Serial Number description








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




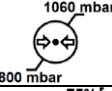














Where

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

e.g.: 2ILD000001 I the first product manufactured in 2021.

The following standardized symbols are also present:

Symbol	Description
	Mark for Conformitè Europe
	Medical Device according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,
	Read the instructions use. Supplied by Electronic means.
	Manufacturer symbol according to Regulation (EU) 2017/745
	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

Symbol	Description
	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
	Symbol to switch on/off the light on the rear arm (Alya with Theia Tech)
	High
	Fragile
	Protect the packaging from rain and high humidity
	Do not Roll
	Do not use hooks
	Maximum stackable weight
	Storage and Transportation temperatures
	Storage and Transportation Relative Humidity
	Storage and Transportation Atmospheric Pressure
	Recyclable cardboard

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.

2.1 INTENDED USER

The intended users are Dentists (all specializations) or Dental Nurse, Hygienists and Assistants

2.1.1 Professional qualification:

Degree in Medicine with Dentistry Specialization

Degree in Dentistry

Degree in dental nursery

2.1.2 Minimum skills

Those planned for the professional qualification

Understanding of language: Those acquired for the professional qualification

2.1.3 Experience

Those outlined to conduct the profession

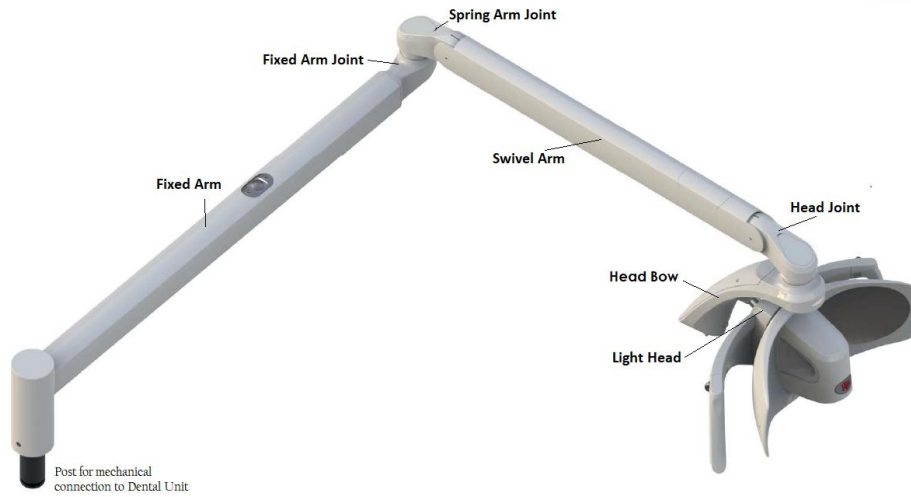
2.1.4 Possible user handicaps

For the use it is necessary at least one upper limb;

Visual faculty compatible with the profession;

The user with these characteristics does not require any special training

3 DESCRIPTION OF THE PRODUCT



Picture 1 –Dental Light – Unit Mount



Picture 2 –Dental Light – Ceiling Mount

The device is available in two main product variants:

- EVA with light source at 5000 K with “Sunlight” Spectrum
- EVA with Tunable White light source (4000 K, 5000 K, 5700 K, Composable setting (2700 K)) selectable by the operator.

These main variants can be supplied with:

- Different Mounting;
- Different arm length combination
- Canbus Technology
- Remote cable for bring the command to the Dental Unit’s
- Auto-on setting;
- Theia Technology (secondary light source under fixed arm);
- Integrated Camera 2K or 4K;
- RF for the connection with FARO’s room lights (Siderèa)

All variants can be ordered by dedicated product codes as reported in the table below:

Mounting		Swivel Arm		Fixed Arm		Light Source / Integrated Camera		Command / radiofrequency (RF)		Cables		Custom ⁽¹⁾	
1-2 DIGIT		3°DIGIT		4°DIGIT		5°DIGIT		6°DIGIT		7° DIGIT		8°-9° DIGIT	
5	U	0	Only Head No arms	0	Only Head No arms	0	Tunable White	0	Joystick	0	Standard	00	Std faro
5	C	1	550 mm	1	600 mm	1	Sunlight 5000K	1	Joystick RF	1	Remote Control Bus Cable	JJ	(+)
5	T	2	855 mm	2	600 mm Theia	2	Tunable White Integrated Camera	2	Sensor				
				3	820 mm	3	Sunlight 5000K Integrated Camera	3	Sensor RF				
				4	820 mm Theia	4	cNus Tunable ⁽²⁾⁽³⁾						
				5	960 mm	5	cNus Sunlight 5000K ⁽²⁾⁽³⁾						
				6	960 mm Theia								

(1) Customized codes include only aesthetic customization having no impact on Safety and EMC requirements

(2) cNus mark for North America cannot be coupled with the following variant codes:

Digit 1-2: 5T

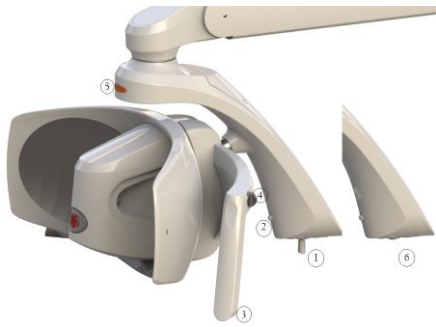
Digit 3: 0

Digit 5: 2 – 3

(3) Ceiling Mounting Versions with cNus Mark are considered Fixed Applications and must be connected to Earth Protection. These devices are Class I Insulation according to IEC 60601-1.

(4) Aesthetic branding customization not impacting on Safety and Performance requirements

3.1 DESCRIPTION OF COMMON USER'S INTERFACE



- | | |
|--|--|
| <p>1 Joystick
2 Button for pairing and Tk change
3 Sterilizable Handle</p> | <p>4 Knob of the handle
5 Indicator Strip
6 Sensor (alternative to Joystick)
7 Button for Theia Tech</p> |
|--|--|

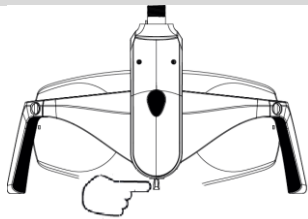
4 INSTRUCTION FOR USE

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

	<p>Caution</p> <p>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)</p>
	<p>Warning</p> <p>The Joystick must be handled with care to avoid breakages. Never move the light using the switch to grip.</p>
	<p>Note</p> <p>At the switching on the device makes a self diagnosis, and the Indicator strip starts blinking with different colours: blue, green and red. The following parameters are memorized by the lamp and made available at every switching on:</p> <ul style="list-style-type: none"> • Last light intensity setting • light colour temperature Setting (for Tunable White variant)
	<p>Warning</p> <p>Do not use the device if parts or enclosures are damaged or plays or gaps appear between:</p> <ul style="list-style-type: none"> • Head Bow / Head Joint • Fixed Arm Joint / Swivel Arm Joint
	<p>Warning</p> <p>The joystick must be handled with care to avoid breakages. Never move the light using the joystick.</p>

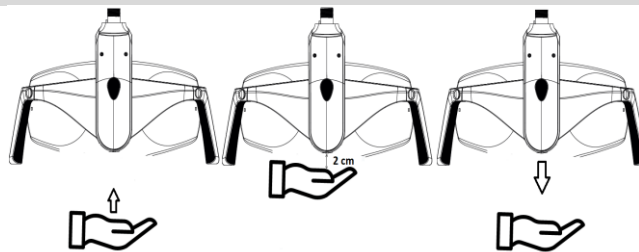
4.1 SWITCHING ON/ OFF

Joystick



Push right or left and release
Acoustic signal: 1 beep

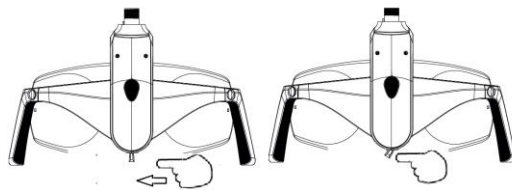
Sensor



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

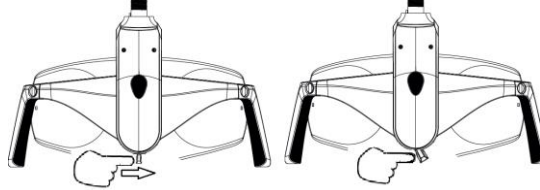
4.2 ADJUSTING THE LIGHT INSTENSITY

Joystick Increase Light Intensity



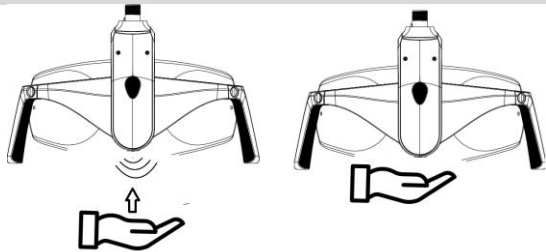
Push left and keep pushed until desired intensity is reached. Then release
Acoustic signal: 1 beep at command
Maximum intensity reached: continuous beep

Joystick Decrease light intensity



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

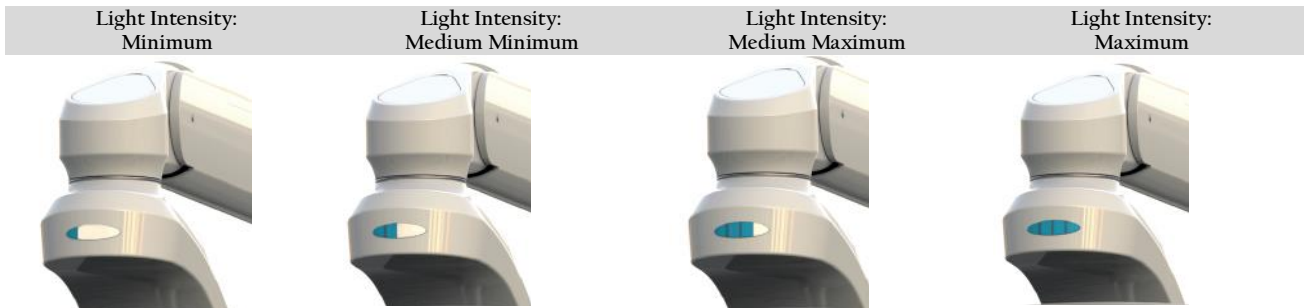
Sensor - Increase and decrease light intensity



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

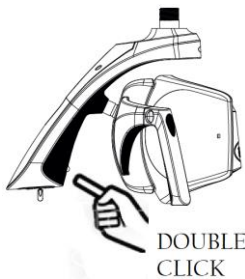
i in sensor version the light intensity changes continuously decreasing until minimum and increasing until maximum

i Note when changing the light intensity the indicator light changes according to the illuminance level, according to the images below:



4.3 CHANGING COLOR TEMPERATURE ON TUNABLE WHITE VERSION

Joystick and Sensor

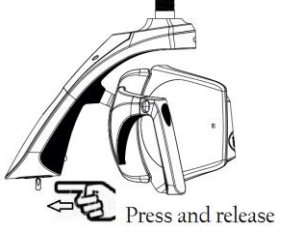
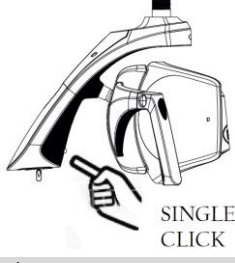

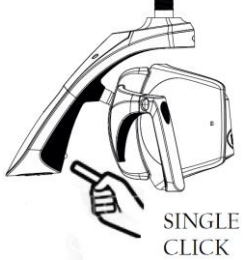



Every time a double click is performed, the Tk of the light changes. Repeat the procedure until the desired colour temperature is shown on the indicator light. 2 beeps will inform the user that Tk is changing.

Sunlight Version	Tunable White Version		
TK 5000 K Green Luminous Indicator Strip	TK 4000 K Yellow Luminous Indicator Strip	TK 5000 K White Luminous Indicator Strip	TK 5700 K Blue Luminous Indicator Strip

4.4 COMPOSAVE SETTING ON TUNABLE WHITE VERSION

Composave setting allow the user to work with restorative material avoiding their polymerization. Select the composave setting as described below:

Joystick version option 1	Joystick version option 2	Visual information
 <p>Press and release</p>	 <p>SINGLE CLICK</p>	
Sensor version	Visual information	
 <p>SINGLE CLICK</p>		

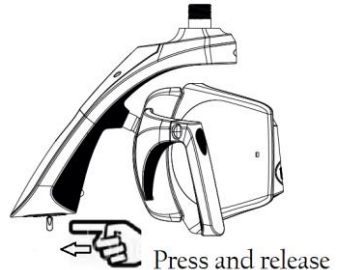
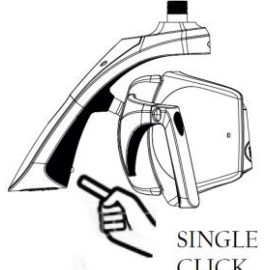
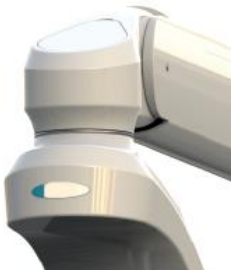


At the command selection of compo save a wigwag beep will be heard. Indicator strip changes in orange.



exit from the compo-save setting with a single click from Compo-save Setting



4.5 MINIMUM INTENSITY SETTING ON SOLAR VERSION

Joystick version	Sensor version	Visual Information
 <p>Press and release</p>	 <p>SINGLE CLICK</p>	

4.6 AUTO-ON SETTING

When the on-mode is set in on position the lamps turn on automatically (without a specific command from the user) when there is power supply.

4.7 SWITCHING ON/ OFF THEIA

	<p>The light on the fixed arm (secondary light) can be switched on/off and adjusted in synchro-mode with the operator light and its command. The secondary light can be manually operated using the button (7) on the fixed arm.</p> <p>If the secondary light is switched on after the operator light, it will be automatically synchronized.</p> <p>If the secondary light is switched on with the operator light switched off, it will be automatically settled at the maximum intensity.</p> <p> The light on the fixed arm is adjusted in synchro mode with head, it cannot be adjusted independently.</p>
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4.8 REMOTE CONTROL

Make reference to the Dental Unit's instruction for use the Dental Light from the Dental Unit's control panel

4.9 SYNCRO MODE WITH FARO ROOM LIGHT

When present, the device can be connected by Radio Frequency (RF) connection to the Faro Room Light to create a synchronized lighting system.

The procedure to create this connection is called "pairing".

If more than one Room Lights are installed in the cabinet, take care that the other Room Lights are turned off or are turned on for more than 60 seconds.

To activate the "Pairing", proceed as follows:

1. Switch on the Faro Room Light. The Room Light will start Searching an input from the dental light for 60 seconds.

2. Within the 60 seconds, press the "Pairing" button on the dental lamp between 4 and 6 seconds. But not for more than 6 seconds (otherwise the procedure will be cancelled).

The Room Light activates the blue LED on the aluminium body.



If the blue LED does not switches on, it is possible another attempt (within the 60 seconds by the firsts). If 60 seconds past from the switching on of the Room Light, it is necessary to repeat the procedure from point 1.

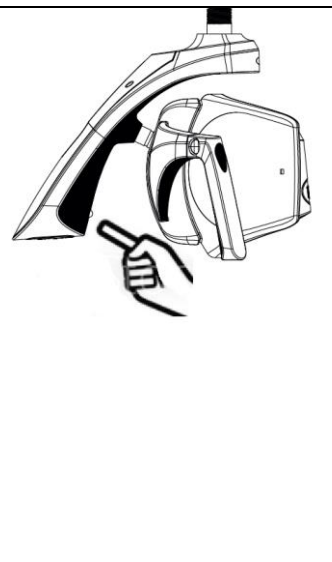
3. After the blue LED switches on the room light, there are 60 seconds to confirm the "Pairing" by pressing the programming button placed on the remote control of the Room Light. At this point, the blue LED of the Room Light blinks at double frequency and then switches off. If the button on the remote controls is not pressed within 60 seconds, the blue LED switch off and the procedure must be repeated from point 1.

After the "Pairing", synchronization between the 2 lamps (dental light and room light) is enabled.

To DE-ACTIVATE THE SYNCHRONIZATION FUNCTION, proceed as follows:

Press the Synchro button from 2 to 4 second, then release it.

On release, a sound signal (Beep) will be heard and the blue LED on the Room Light lamp will go out to indicate that synchronization has been disabled.



When the Faro Room Light is synchronized with the Dental Light the blue LED on the room light is lighted in steady mode. If the LED is off, the synchronization is not active.

The remote control is always enabled, so it is possible to change the illumination value in manual mode.

If the Dental Light is turned off, the room light will remain switched.


5 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.


Checks	Frequency	Procedure	Responsible
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: <ul style="list-style-type: none"> screws 5 Screw 6. 	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		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	//	Service Engineer
Check of damages on enclosure and plastic joints integrity.	Yearly		Service Engineer
Electrical Safety according EN 62353 1. Dielectric strength 2. Current Leakage	Every two years	Use the parameters defined into IEC 60601-1	Service Engineer
Light checks	Every two years	With a spectroradiometer check the values for: Max Luminance: >35000 lux CRI > 85 Radial power on blue light: <100 W/m ²	Service Engineer

6 CLEANING AND DISINFECTION

	<p>Warning against danger of wear and corrosion and falling suspended mass</p> <p>For all metal or plastic parts it is strictly forbidden to use substances that are</p> <ul style="list-style-type: none"> - abrasive, - corrosive, - acids, - substances containing chlorine or chloride ions, phosphorous or phosphorous ions, - detergents with Trilene base, petrol, white spirit, chlorine or similar. <p>Do not use detergents-disinfectants containing the following substances to clean plastic parts:</p> <ul style="list-style-type: none"> - Ammonium Hydroxide - Sodium Hydroxide - Hydrogen peroxide - Ammonium Chloride - Methylene chloride - Methyl alcohol - Acids and corrosive substances of all kinds. <p>It is forbidden to directly spray any chemical substance on the device. It is forbidden the use of wet wipes without rinsing.</p>
	<p>Faro tested and suggests the use of the following disinfectants, for plastic parts and metal parts:</p> <ul style="list-style-type: none"> - Durr FD366 Sensitive - Faro Perflex Advanced - Water-alcohol based disinfectants with 70% isopropyl alcohol or ethanol are suitable.

6.1 CLEANING OF THE REFLECTING PARABOLAS

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.

	<p>Caution - potential damage or wear on the parabolas</p> <p>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.</p>
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6.2 CLEANING AND DISINFECTION OF THE HEAD

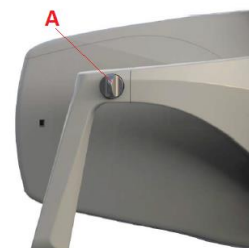
Cleaning must be carried out using a soft cloth in cotton wetted with disinfectant solution.
Always squeeze the cloth to remove all the liquid in excess.

6.3 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.

7 STERILIZATION OF THE HANDLES

	<p>Warning - danger of cross contamination</p> <p>The handles are not supplied sterile, they must therefore be sterilised before use. The handles must be sterilised before each patient.</p>
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7.1 REMOVAL OF THE HANDLES

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

7.2 DECONTAMINATION AND DISINFECTION

Before sterilising the handles, they must be decontaminated and disinfected.
To disinfect, Faro has tested the following products for disinfection:

- Faro Perflex Advance
- Durr FD366 Sensitive

	<p>WARNING - danger of plastic breaking</p> <p>The handles cannot be disinfected by thermo-disinfection.</p>
--	---

7.3 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:

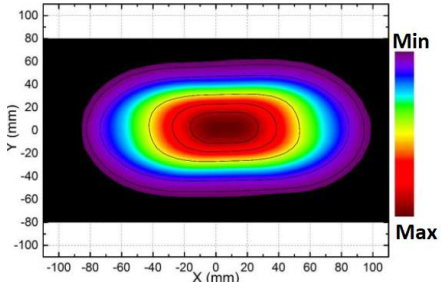
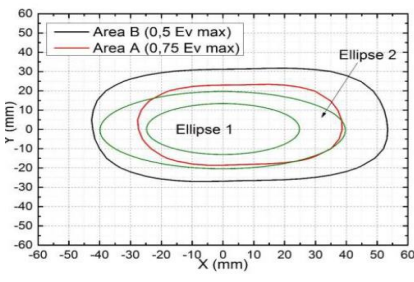
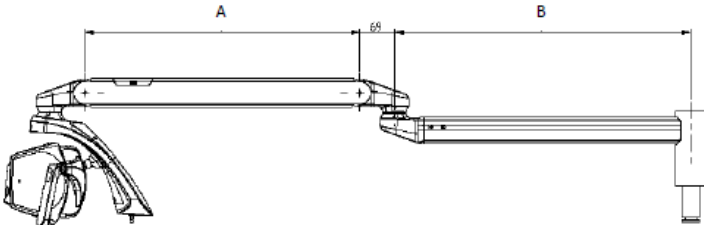
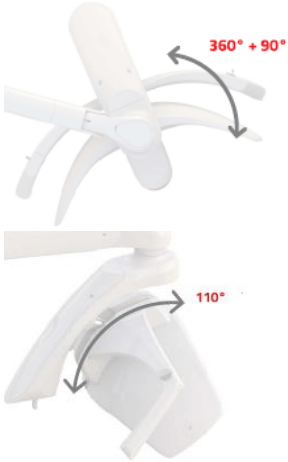
Cycle EN 13060	Temperature	Pressure	Holding Time Minimum
B	121°C	207 kPa	15 min
B	134°C	308 kPa	3 min

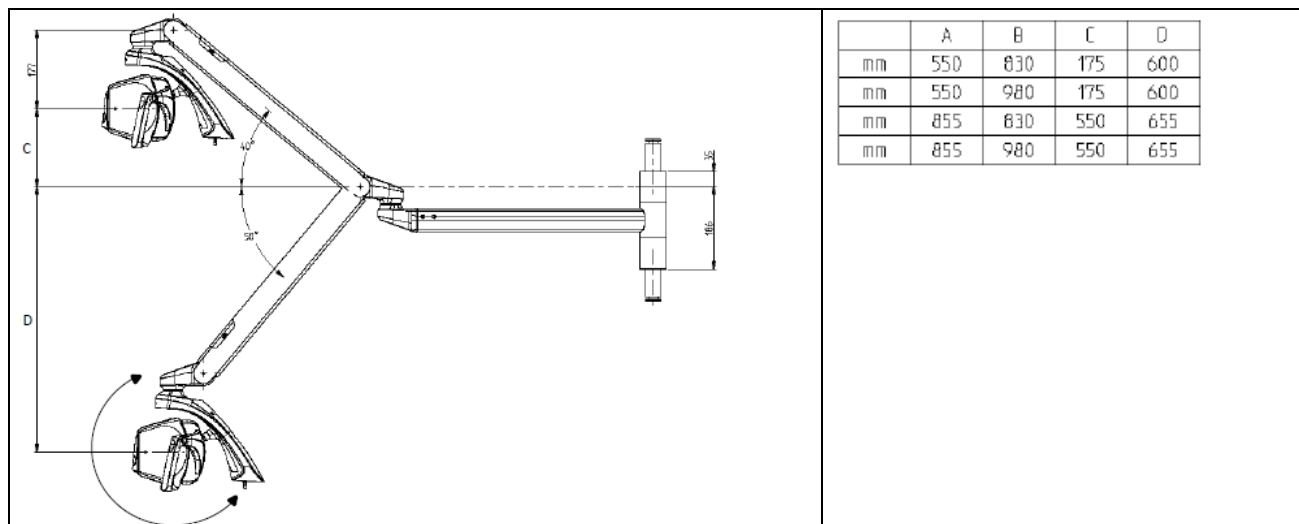
8 TROUBLESHOOTING

8.1 ERROR LIST

Error	Description	Indicator Strip	Acoustic indication
E1	Open Led channel 1	First sector blinking. Colour set-up: RED	3 short beeps repeated 3 times
E2	OPL Open Led channel 2	First and second sectors blinking Colour set-up: RED	
E3	High temperature on the Led group	No	No
E4	Low or High input voltage	All sectors blinking together. Colour set-up: RED	5 lounge beeps
E5	Over Temperature Protection active	First sector blinking. Colour set-up: PURPLE	3 lounge beeps
E6	High temperature on the board	All sectors blinking sequentially. Colour set-up: PURPLE	3 lounge beeps

9 TECHNICAL SPECIFICATIONS

	Dental Light Dental Light Head	Dental Light with Theia Tech
Power Supply	24 V ac $\pm 10\%$ 50/ 60Hz; 32 V dc $\pm 10\%$;	24V ac $\pm 10\%$ 50/60 Hz; 32 V dc $\pm 10\%$;
Max Power :	24 V ac 26 VA 32 V dc 14 VA	24 V ac: 40 VA 32 V dc: 28 VA
Recommended fuses for installation (not supplied in charge to installation)	24 V ac T1.6AL 250V 32 V dc T1.25AL 250V	24 V ac: T2AL 250V 32 V dc: T1.25AL 250V
Protection against electrical hazard	Class II Class I for Ceiling Mounting for Canada US Certification NB: final classification of the Protection Class of the Medical System is demanded to the Service Engineer in charge of installation or to the manufacturer	
Classification against IEC 62471	Class I - Labelling Exempt	
Max illuminance (*)	> 45.000 lux	
Color Rendering Index (*)	> 95	
Correlated Colour Temperature CCT (*)	Sunlight Version: 5.000 K Tunable White Versions: 4000 K – 5000 K – 5700 K Composave setting : 2700 K	
Spot Dimension (*)	180 mm x 110 mm	
Max Hard Shadow ISO 9680 (*)	10 mm x 5 mm	
Nature of the radiation	Non ionizing Radiation	
Type of radiation	Visible lights	
Typical illuminance Pattern ISO 9680	Typical illuminance Pattern ISO 9680	
		
Overall Movements	Head Rotations	
		



(*) Typical optical values subjected to tolerances

Measurement performed at 700 mm distance. Contact Faro for the correct procedure for the measurement.

9.1 STORAGE AND TRANSPORTATION: ENVIRONMENTAL CONDITIONS

The device in the original packaging can be transported and stored for a maximum 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

9.2 USE: ENVIRONMENTAL CONDITIONS

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



DAL 1948: ESPERIENZA
E RINNOVAMENTO

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EVA

Dental Operating Light

Medical Device

Class I



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