Operating Instructions

Manufacturer:
DKL CHAIRS GmbH
An der Ziegelei 3
D-37124 Rosdorf
+49 (0)551-50060
info@dkl.de
www.dkl.de

L2-SUC

Form no. GEN-L2SUC
Rev. 02 / 01.08.2021

Contents

Annex

> Operating Instructions DÜRR Dental Spittoon valve 3
> Operating Instructions DÜRR Dental CAS 1 Combi-Separator
> Operating Instructions DÜRR Dental CS 1 Combi-Sepamatic
> INSTRUCTION MANUAL FARO DENTAL SYRINGE SYR3
> Use Manual Luzzani Syringe Minilight
> INSTRUCTION MANUAL FARO ALYA DENTAL LED LIGHT

Symbols in the Operating Instructions

WARNING!
(risk of injury)

CAUTION!
(to prevent damage occurring)

General explanations, without risk to persons or objects

Thermodisinfectable

Sterilisable up to the specified temperature

Call customer service!

Symbols on the unit

Observe the operating instructions!

ON / OFF

Do not dispose of with household waste.

CE-marking with identification number of the notified body

Foot controller

Type B application part

Manufacturing date

Model (designation)

Serial number

Manufacturer

Medical device

UDI - Product Identification

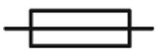
V Electrical voltage

AC Alternating current

VA Electrical power consumption

A Current intensity

Hz Frequency of alternating current



Electrical fuse

Symbols inside the Unit

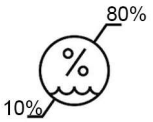
Earth conductor connection - Protective earth

Functional earth

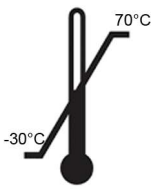
N

Connection point for neutral conductor

Symbols on the packaging



Air humidity, limitation



Permissible temperature range

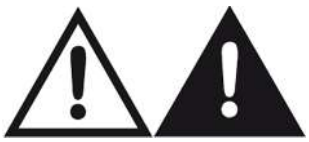
Transport upright; top

Protect from moisture!

Do not stack!

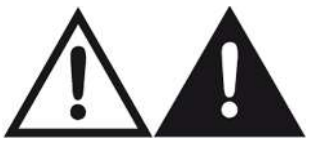
Fragile

For your safety and the safety of your patients
These operating instructions are intended to explain how to use your product. However, we must also warn of possible dangerous situations. Your safety, the safety of your team and, of course, the safety of your patients are very important to us.



Please observe the safety instructions!

Intended purpose
This treatment unit is used for the diagnosis and therapy of children and adults in the field of dentistry.

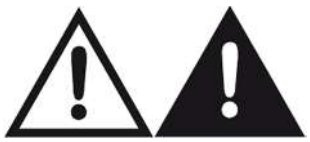


Improper use can damage the treatment unit and thus pose risks and hazards to the patient, user and third parties.

Qualification of the user
The DKL treatment unit may only be used after medically, professionally and practically trained personnel have been instructed. The development and design of the treatment unit were geared towards the target group of dentists, dental hygienists, qualified dental employees (prophylaxis) and dental assistants.

CE 0123

Production according to EU directive
The medical device complies with the provisions of Directive 93/42/EEC.



Responsibility of the manufacturer
The manufacturer can only be held responsible for the impact on the safety, reliability and performance of the treatment unit if the following instructions are observed:

> The dental unit must be used in accordance with these operating instructions.
> If assembly, additions, new settings, changes or repair work is carried out by DKL or trained technicians authorised by DKL or personnel of authorized dealers trained by DKL.
> The electrical installation of the room must comply with the regulations of the IEC 60364-7-710 standard („Erection of electrical installations in rooms used for medical purposes“) or comply with the regulations applicable in your country.
> The recommended annual maintenance is carried out and any repair work in this context meets the requirements of EN 62353.
„Repeat tests and pre-commissioning tests of medical electrical equipment and systems – general regulations“are fully complied with.
> The national legal regulations are observed when using the device, in particular the applicable health and safety regulations and accident prevention measures.

Electromagnetic Compatibility (EMC)

Medical electrical equipment is subject to special precautions with regard to EMC and must be installed and commissioned in accordance with the EMC instructions. DKL guarantees that the dental unit complies with the EMC guidelines only if original DKL accessories and spare parts are used. The use of accessories and spare parts not approved by DKL may lead to an increased emission of electromagnetic interference or to a reduced resistance to electromagnetic interference.

The EMC manufacturer declaration can be found on page 43.

HF communication equipment
Do not use portable and mobile HF-communication equipment (such as mobile telephones) during operation. These can affect medical electrical devices.

Risks due to electromagnetic fields
The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillators (ICD), can be influenced by electric, magnetic and electromagnetic fields.

> Before using the product, ask the patient and user about implanted systems and check the use.
> Perform a risk-benefit analysis.
> Do not place the product near implanted systems.
> Do not place the instruments on the patient‘s body.
> Take appropriate emergency precautions and respond immediately to health changes.
> Symptoms such as increased heart rate, irregular pulse, and dizziness may be signs of problems with a pacemaker or ICD.

Safety Instructions - General

> Before being put into initial operation, the treatment unit must be kept at room temperature for 24 hours.
> Before each application, check the treatment unit and the instruments with cables for damage and loose parts.
> Do not operate the treatment unit if it is damaged.
> Check the set parameters each time you restart the unit.
> Carry out a test run before each application.
> The application and timely shutdown of the system is the user's responsibility.
> Make sure that in the event of a device or instrument failure, the treatment can be completed safely.
> Use only original DKL fuses.
> Never touch the patient and the electrical connection at the treatment unit at the same time.
> Do not lean on the doctor‘s device, the assistant‘s device, the tray or the operating lamp.
> When moving the treatment chair, the doctor‘s device, the assistant‘s device, the tray or the operating lamp, pay attention to the patient and the practice personnel.
> Always switch off the treatment unit before leaving the practice.

Hygiene and care before using the device
> Clean and disinfect the device immediately before or after each treatment!
> Wear protective clothing.

Observe your country-specific guidelines, standards and specifications for cleaning, disinfection and sterilisation.

The treatment unit is classified as an „ordinary device“ (closed device without protection against water ingress).

The treatment unit is not suitable for use in an explosive atmosphere or in explosive mixtures of anaesthetics with oxygen or nitrous oxide.

The treatment unit is not suitable for use in rooms with an oxygen enriched atmosphere.

Safety notes – Patient chair

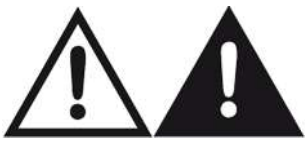
> Not suitable for patients who cannot remain in a resting position due to mental or physical disabilities.
> The patient‘s arms and legs must rest on the upholstered parts of the chair.
> Do not exceed the maximum patient weight of 150 kg.
> Do not sit on the head or foot rest of the horizontally aligned patient chair.
> Position changes must always be carried out under the surveillance of the person giving treatment.
> Watch patients while moving the treatment chair.
> Make sure that there are no objects under the treatment chair.

Safety Notes – Assistant's Device and Cuspidor

>Before putting the device into initial operation and after downtimes (weekends, (public) holidays etc.), flush the water lines intensively.
> Flush all instrument connections for 2 minutes before starting work.
> Press the glass fill button several times before starting work.
> Rinse used instruments for 20 seconds after each treatment.

Risk of injury or infection caused by instruments that are not in use:
The arrangement of the instruments may cause injury or infection to the hand and forearm when accessing the tray or the display.
Therefore, when accessing the tray or the display, pay attention to the arrangement of the instruments.

Highly immunosuppressed patients or patients with specific lung diseases should not get into contact with the water of the treatment unit.
It is recommended to use sterile solutions.



> Do not exceed the maximum permissible load of 2 kg on the Assistant's device.

Technical Specifications

The motors of the treatment unit are designed for intermittent operation in accordance with the dental treatment method.
Driving motors for patient chair and backrest: duty cycle (max. 25 s „ON“ / 400 s „OFF“)

Supply voltage	230V AC
Nominal voltage	max. 4 A
Frequency	50/60 Hz
Fuse	T 6.3 A H 250 V primary/ time-delay
Maximum power consumption	800 VA
Device class according to the 93/42/EEC Directive	IIa
Protection class	Device of protection class I
Contamination level	2
Over voltage category	II
Power cable	3x1,5 mm^2
Suction control lines to the suction device	5x1,5 mm^2
Potential equalisation	1x 4 mm^2
Relay control line optional special function	3x1,5 mm^2
Free end electrical cables above floor	500 mm
Fuse for domestic installation	Circuit breaker: 16 A medium-lag Recommendation: circuit breaker type C
Degree of protection against ingress of water	Ordinary device (without protection against water ingress)

Permanently connected device. In order to avoid the risk of electric shock, this device may only be connected to a power supply with an earth conductor.

Weight	
L2-SUC	max. 200 kg

Transport and storage conditions	
Ambient temperature	30 to +70 °C
Relative humidity	10 to 80 %
Atmospheric pressure	500 hPA to 1060 hPa

Operating conditions	
Quality and load-bearing capacity of the floor	The floor must be level and horizontal according to EN 18202. Unevenness of the floor along the total length of the chair base up to 2 mm is acceptable. The minimum load-bearing capacity of the floor must be 0.5 N/cm^2 (equivalent to approx. 500 kg/m^2).
Ambient temperature	10 to 35 °C
Relative humidity	15 to 80 %
Atmospheric pressure	700 hPA to 1060 hPa
Installation site	≤ 3,000 m above sea level The treatment unit is not suitable for operation in hazardous areas.

Media Requirements

Media water	
Water hardness	1.5 to 2.14 mmol/l
ph-value	6,5 to 8,5
Water filtration on site	≤ 100 µm
Water inflow	Pipe 10x1mm, angle valve outlet 3/8“
Water connection above floor	min. 40 mm, max. 60 mm
Water inlet pressure	2.0 to max. 6.0 bars
Water quality	Cold water in accordance with local and national drinking water regulations.
Minimum flow rate	3 l/min

- Perform the installation according to the national installation requirements (e.g. EN 1717).
- For the reduction of microorganisms in the water supply pipe, please observe the following when laying this pipe to the treatment unit:
  - Avoid long stub lines to the treatment unit.
  - Select the installation in such a way that other essential consumers (e.g. washbasin) are as far as possible behind the connection of the treatment unit can be supplied from the same pipe.
  - Avoid laying the hot water supply pipes in parallel.
- Recommendation: For the water supply of the treatment unit, install an angle valve with 2 outlets and 2 stop cocks. The second outlet allows easy sampling of water for microbiological analysis.

Connection to the public drinking water supply
The treatment unit with a water separation unit complies with the requirements of EN 1717 (free outlet with separation distance ≥ 20 mm) and the DVGW (German Technical and Scientific Association for Gas and Water). It is intrinsically safe in accordance with worksheet W540 and therefore also meets the requirements of W270 and KTW (guideline for hygienic assessment of organic materials in contact with drinking water).
When the treatment unit is equipped with a cuspidor, the bowl rinser ensures the free outlet with a separation distance ≥ 20 mm. When the treatment unit is equipped with a Bottle Care System, the spray supply of the instruments is separate from the public water supply.

Before the treatment unit is installed, the microbiologically perfect water quality of the domestic water supply should be ensured and documented in the form of a microbial count.
Sampling and microbial count should be carried out by a competent laboratory.

Media air	
Air inlet pressure	max. 7 bars
Air consumption	80 Nl/min
On-site air filtration	≤ 100 particles size 1 - 5 µm referred to one m^3 of air
Oil content	≤ 0.5mg/m^3,oil-free compressors; the compressor must suck in hygienically perfect air.
Humidity	Pressure dew point ≤ -20 °C at atmospheric pressure
Compressed air supply	Pipe 10x1 mm, angle valve outlet 3/8“
Air connection above the floor	min. 40 mm, max. 60 mm

Clean air and water pipes before installing the unit.

Chips and other foreign substances could be flushed or blown into the treatment unit.
Metal chips can interfere with the function of pneumatic components. Filters are clogged by foreign substances.
- When assembling, make sure that there are no chips or other foreign substances in the pipes.
- Flush the water pipes.
- Blow out the air ducts.
- Make sure that no further foreign substances get into the pipes and ducts after rinsing or blowing out.

Requirements for the suction system	
Vacuum at supply connection	min. 0,12 bar, max. 0,18 bar
Minimum suction power at supply connection	≥750Nl/min
Suction system	Type 1: high flow rate wet or dry suction
Diameter of suction handpieces:	small suction handpiece: 6 mm large suction handpiece: 16 mm
Suction pipe	DN40 HT-PP (polypropylene, inside diameter approx. 36.5 mm)
Water drain	DN40 HT-PP (polypropylene, inside diameter approx. 36.5 mm)
Gradient	Min. 10 mm per metre
Wastewater volume	3 l/min

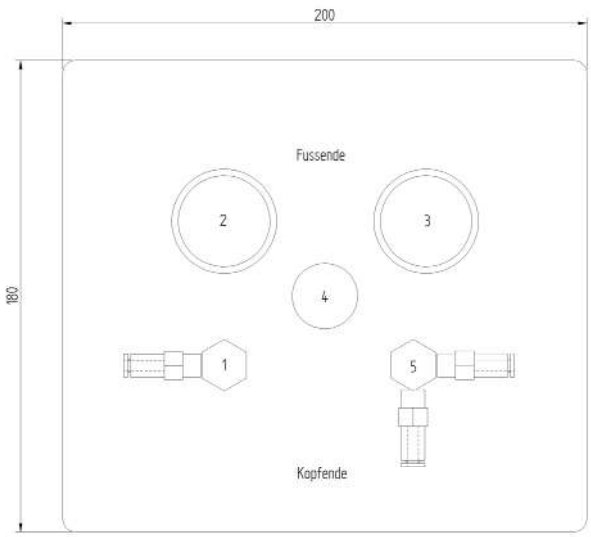
Filter in the treatment unit		maintenance interval	Article number
Particle filter water inlet	50 µm	Replace annually	210623-WBG
Particle filter compressed air inlet	50 µm	Replace annually	210623-LBG
Solid particle filter for the suction system	Mesh size 1 mm	In case of damage, replace at least annually.	514100

Typical pressure in the suction system

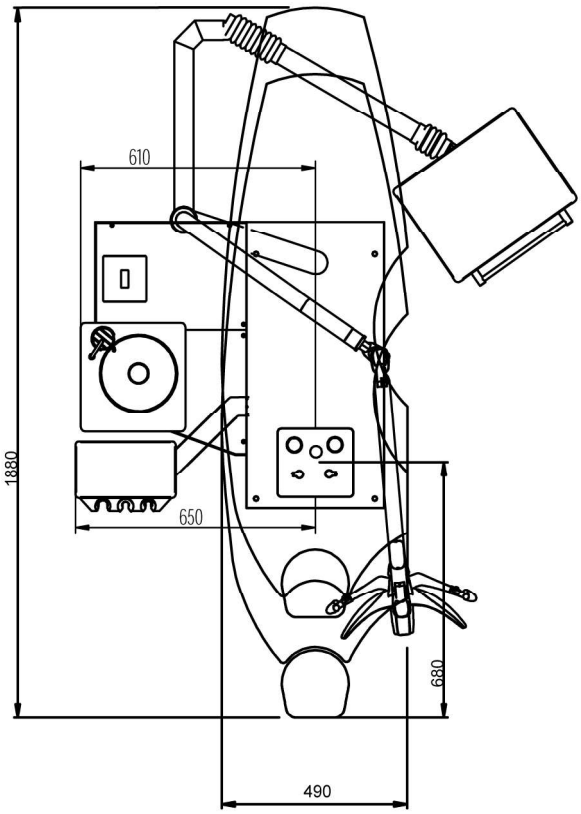
Spray mist suction	Vacuum / mbar
90 NL/min	22,6
150 NL/min	38,2
200 NL/min	60,0
250 NL/min	88,8
300 NL/min	124
316 NL/min	137
Saliva ejector	
50 NL/min	100,0
55 NL/min	120,0
60 NL/min	135,2
67 NL/min	162
80 NL/min	200

Requirements for Supply Connections

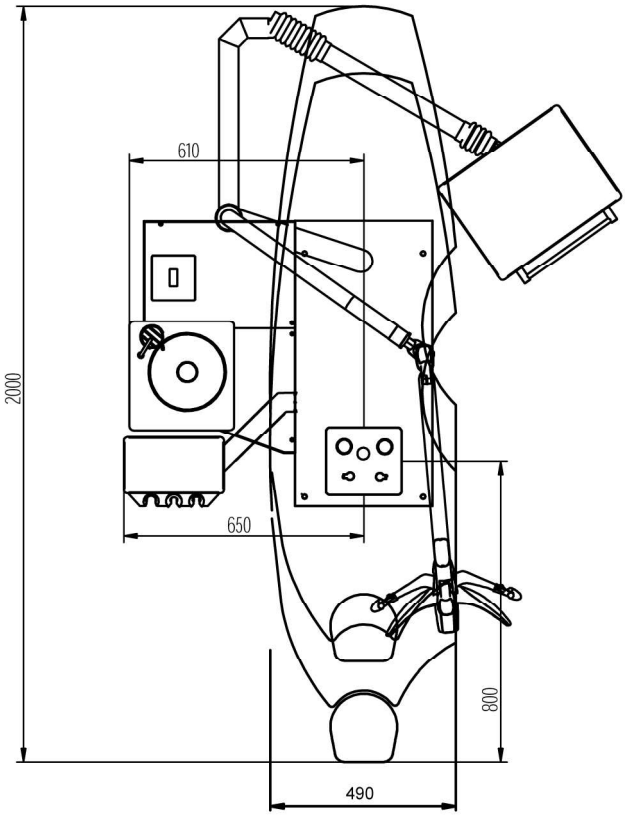
①	Air: pipe min. 10x1 mm, angle valve outlet 3/8“
②	Water drain DN40 HT-PP
③	Suction line DN40 HT-PP
④	Power cable 3x1.5 mm^2
④	Equipotential bonding 1x 4 mm^2
④	Control line to suction device 5x1.5 mm^2
⑤	Water: pipe min. 10x1 mm, angle valve outlet 3/8“ (2 outlets with 2 stopcocks)



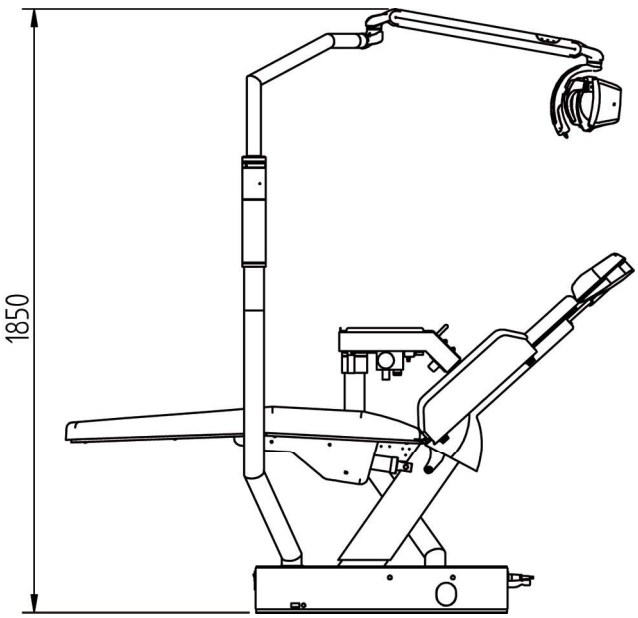
Dimensions in Millimetres



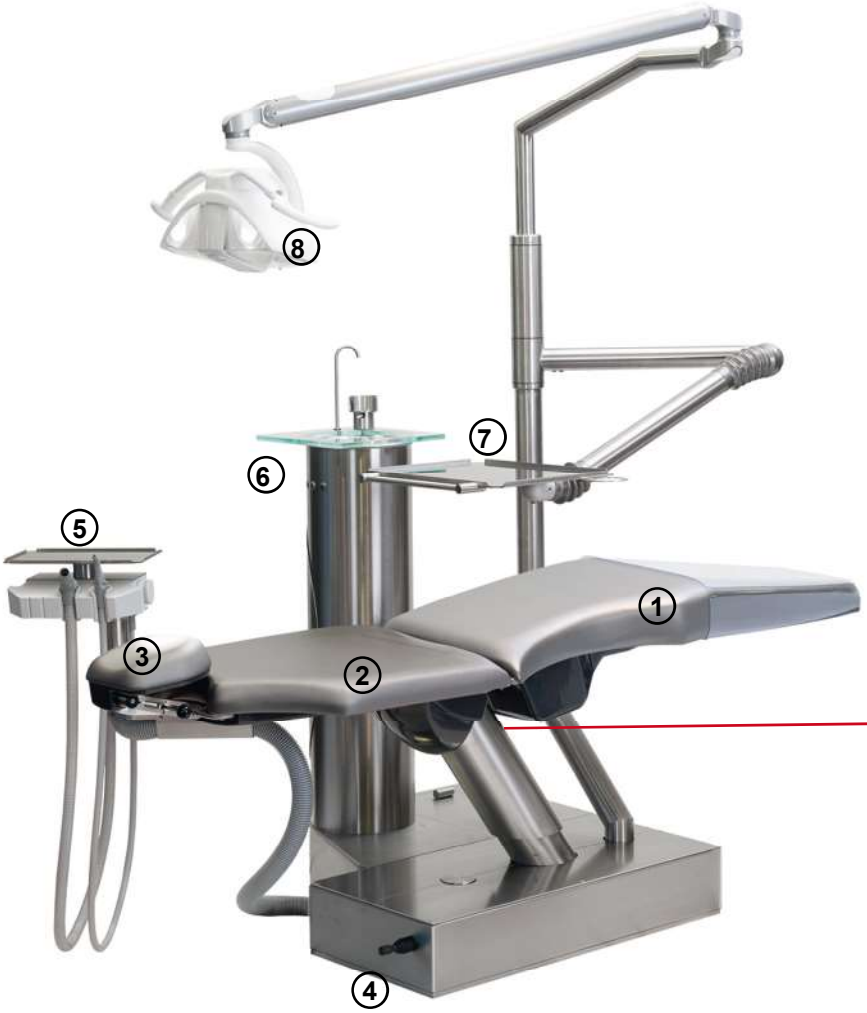
L2-SUC Version with short back rest



L2-SUC Version with long back rest

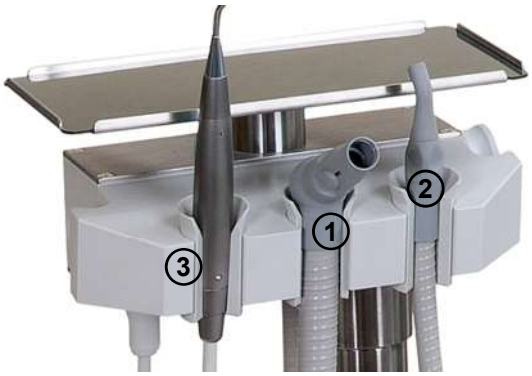


Treatment chair:
lowest position 570 mm
highest position 800 mm



①	Treatment chair, seat
②	Treatment chair, back rest
③	Treatment chair, double-jointed head rest
④	Treatment chair, joystick
⑤	Assistant’s device
⑥	Cuspidor
⑦	Tray
⑧	Operating lamp LED.light

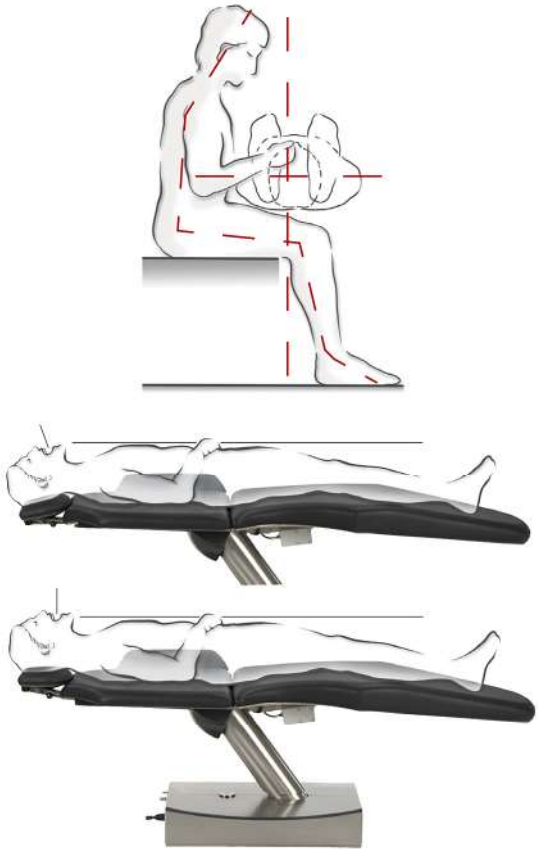
Assistant‘s device on telescopic rails with saliva ejector and spray mist suction.



①	Spray mist suction
②	Saliva ejector
③	Syringe

Connecting the instrument hoses and suction tubes.
The instrument hoses can be connected or disconnected via a plug connection under the assistant's device. Depending on the equipment of the model, the assistant's device is equipped with the following instruments (from the left): the syringe, Spray mist suction and finally the Saliva ejector. The instrument holders are marked on the back. Do not connect the tubes crosswise.

Marking	Type of holder
GS	Spray mist suction
KS	Saliva ejector
S	Syringe



Treating patients in a lying position gives you a clear view of the upper and lower jaw. This optimal working posture is ensured by sufficient legroom. During lower-jaw treatments, the patients are positioned horizontally; for treatments in the upper-jaw region the patient's head is slightly overstretched backwards. The double-jointed headrest offers stable support for the patient's head at the starting point of the neck muscles. This way the patient is relaxed and does not need to constantly correct his or her position. Treatment of patients in a lying position offers you an optimal view and, consequently, optimal results.

Moving the Treatment Chair

Joystick at the chair base


Joystick

Move the joystick downwards
>Treatment chair moves downwards.
Move the joystick upwards
>Treatment chair moves upwards.
Move the joystick to the left
>Back rest tilts backwards.
Move the joystick to the right
>Back rest moves to an upright position.

Tap the JoystickTwice
>Treatment chair moves to the entry /exit position.
Tap the joystick twice downwards
>Treatment chair moves to the treatment positionp2.
Tap the JoystickTwice to the Left
>Treatment chair moves to the rinsing position and back to the last position when tapping twice again.
Tap theJoystickTwice to the Right
>Treatment chair moves to the treatment position p1.

Programme keys at the back rest

Press “p0“
>Treatment chair moves to the position for getting on/off.
Press “p1“
>Treatment chair moves to treatment position p1.
Press “p2“
>Treatment chair moves to treatment position p2.
Press “p3“
>Treatment chair moves to treatment position p3.
Briefly press “lp“
>Treatment chair moves to the rinsing position and after renewed pressing back to the “last position”.

Saving programme keys p0 – p3

For programming the keys, move to the desired programme position manually and then keep the respective programme key pressed for about 3 seconds until you hear a signal tone. Now you have successfully saved your individual treatment position.

Saving programme key LP

Press the ”lp“ key to move the chair to the rinsing position. By pressing the key “lp” once again, the chair moves back to the previous programme position or to the manually set position. In order to programme the chair, move it manually to the desired rinsing position and then keep the key “lp” pressed for about 3 seconds until you hear a signal tone. Now you have successfully saved your rinsing position.

Emergency-Stop System
Briefly tap the joystick or any programme key at the back rest to stop the active programme immediately. For this purpose, you can also press the start button for the instruments at the foot controller.

You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2 SERIES FUNKTIONEN TREATMENT CHAIR POSITIONS

LINK: https://youtu.be/qzRuFbGAuA0

The treatment chair can optionally be equipped with arm rests. The arm rest on the assistant's side is firmly screwed on. The arm rest on the doctor's side can be removed by loosening the two knurled screws on the back of the back rest.

Pull the release lever up to freely adjust the double-jointed head rest. Press the lever down to fix the position of the double-jointed head rest. The release lever must always be pulled up completely to move the head rest.

Manually Extractable Double-Jointed Head Rest

Programme Run
Press the programme keys "0" and "Ip" simultaneously for about 3 seconds until you hear a signal tone. The treatment chair then moves the seat and the back rest into the lowest position. The motion sequence has been reset now.

Putting the Unit into Operation
Before putting your treatment unit into initial operation, an intensive flushing must be carried out [→page 36 or page 39].

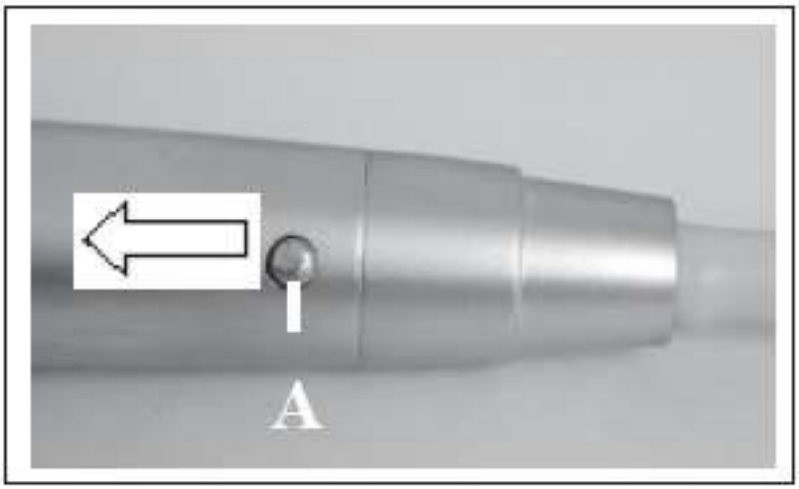
Activating / Deactivating the Treatment Unit

The treatment unit is equipped with a power switch ① on the chair base. The power switch connects the treatment unit with the power supply. In the event of longer downtimes, the treatment unit should be disconnected from the power supply. The treatment unit contains a device fuse ②. Switch on the treatment unit at the power switch.The power switch lights up green.

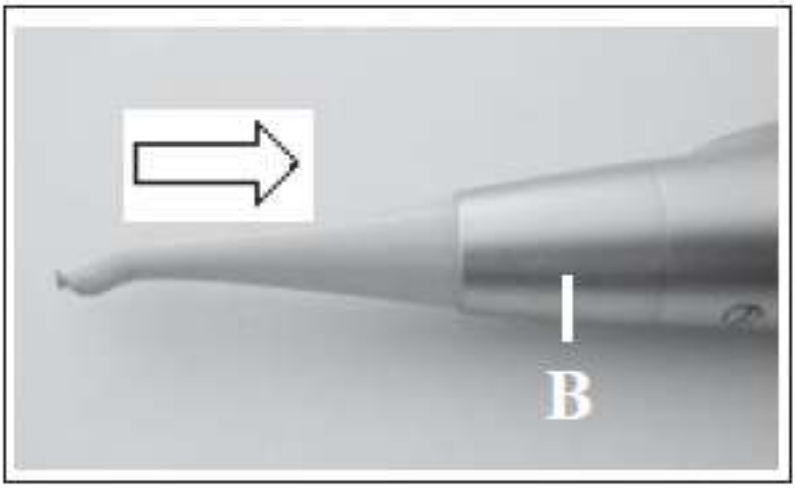
Function FARO Syringe SYR3

See also operating instructions of the FARO company for their SYR3 dental syringe!

Press the green button to release water.
Press the light blue button to release air.
Press both buttons simultaneously to release spray.



To remove the sleeve, press button „A“.
Pull out the sleeve in the direction of the arrow.



To remove the nozzle, screw off ring „B“ and pull out the nozzle in the direction of the arrow.

Before reassembling the syringe, lubricate the 2 seals on the inner body and the metal tube of the nozzle with Vaseline grease.

Cleaning the syringe
Clean the sleeve and nozzle under running water or using alcohol-based solutions.

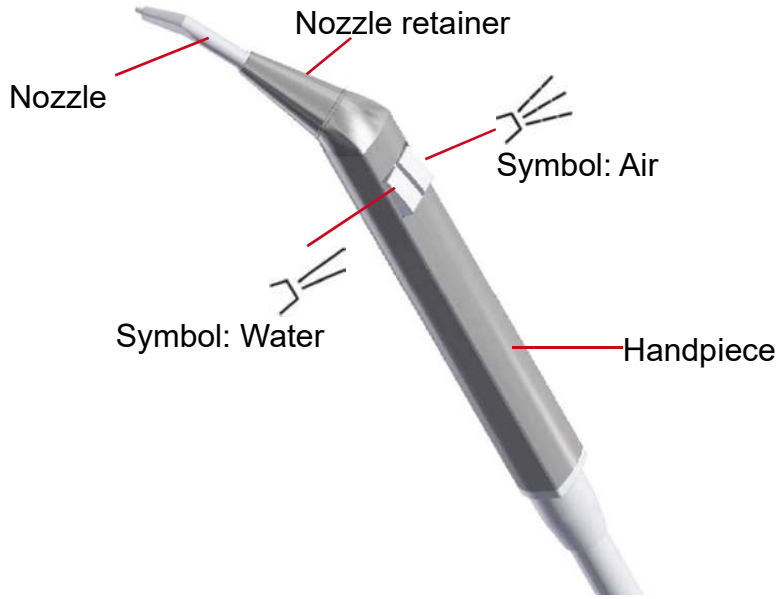
Sterilisation
- Remove the sleeve including the nozzle from the syringe body.
- Clean the sleeve and the nozzle.
- Sterilize the sleeve including the nozzle in the autoclave.

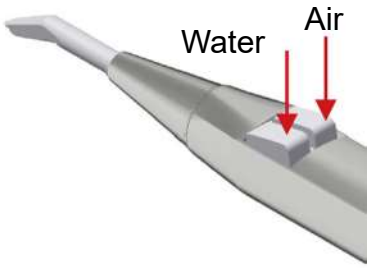
Cleaning the spouts
If the nozzle from which the water and the air come is clogged, clean it with the supplied probe.

Sleeve and spout sterilizable

Function Luzzani Syringe Minilight

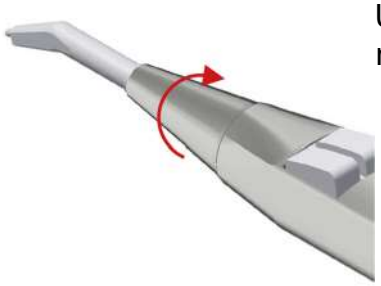
See also operating instructions of the Luzzani company for their Minilight syringe!





To blow water into the operating field, just press the left button on the handpiece, symbol: water.To insufflate air into the operating field, just press the right button on the handpiece, symbol: air. To blow a combination of air and water (spray), press both buttons on the handpiece at the same time.

After each use on a patient, the handpiece and tip of the syringe MUST be cleaned and sterilised to guarantee maximum hygiene.

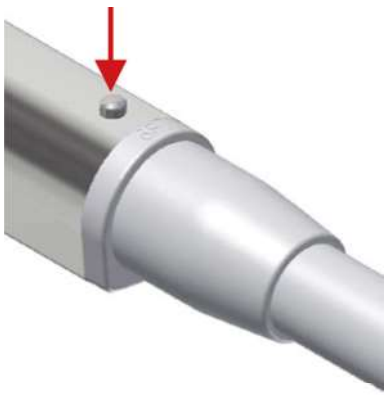


Unscrew the nozzle retainer.

You will find the sterilisation procedure 

on the handpiece.

Withdraw the nozzle retainer.



Withdraw the nozzle.

Press the pawl to release the handpiece.

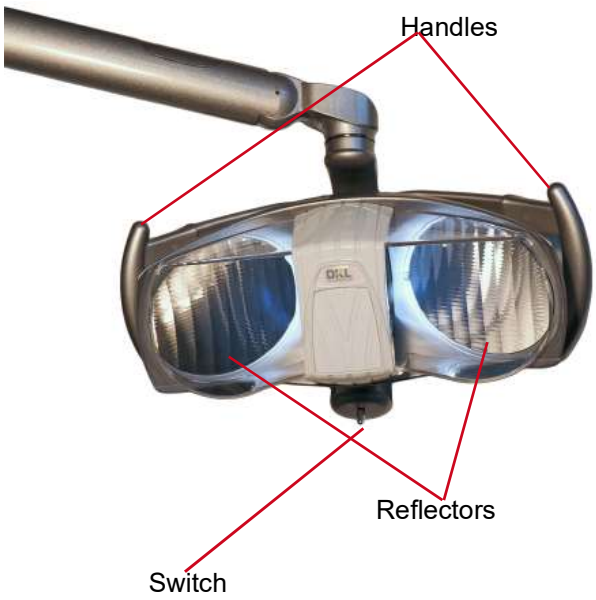
Withdraw handpiece.

LED.light Operating Lamp

When swivelling and moving the operating lamp, always make sure that no objects or persons are in the swivelling range of the arm system. Otherwise, personal injury or property damage may occur. In order to move the operating lamp only touch its handles!

Switching the Lamp on and off

The operating lamp is switched on or off by moving the microswitch to the left / right.
The intensity of the operating lamp can be adjusted from 8,000 to 50,000 LUX. Press and hold the switch to the left or right to adjust the light intensity.
If the switch is pressed backwards or forwards, the operating lamp dims to 8,000 LUX. When the switch is pressed again, the light intensity set last is selected.



Mirror

Loosen the plastic cover at the front of the protective cap by lightly pressing on its upper end. On the back of the cover there is a mirror. Attach the mirror to the plastic cover.

Optical Properties:

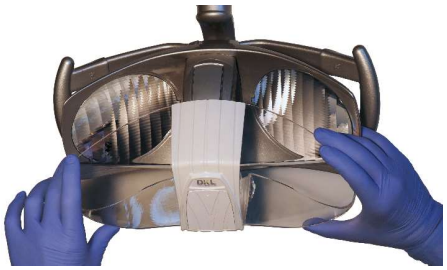
Light field	: 170 mm x 85 mm
Lux	: 8,000 to 50,000 lux at a distance of 700 mm
Colour temperature	: 5,000 K
CRI (colour rendering index)	: > 85

You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2-D2 SERIES FUNCTIONS LED.LIGHT OPERATING LAMP

LINK: https://youtu.be/OXSchFNIFXM

Cleaning and Disinfection of the LED.light Operating Lamp

Pull the protective cap towards you to remove it for cleaning.



Cleaning and care
The reflectors must be cleaned with cotton wool and ethyl alcohol. Do not use detergents that contain surfactants or water-repellent substances (staining).

Sterilisation of the handles
To remove the handles, turn the handle lock on the handles and pull off the handles. To mount the handles, reattach them and push them to the limit. Then lock the handle lock.
The handles can be sterilized 200 times with standard cycles of 121°C/134°C.

Risk of breakage of the plastic parts.
Do not use any cleaning agents or disinfectants with the following ingredients for cleaning the plastic parts:
- AMMONIUM HYDROXIDE
- SODIUM HYDROXIDE
- METHYLENE CHLORIDE
- METHYL ALCOHOL.

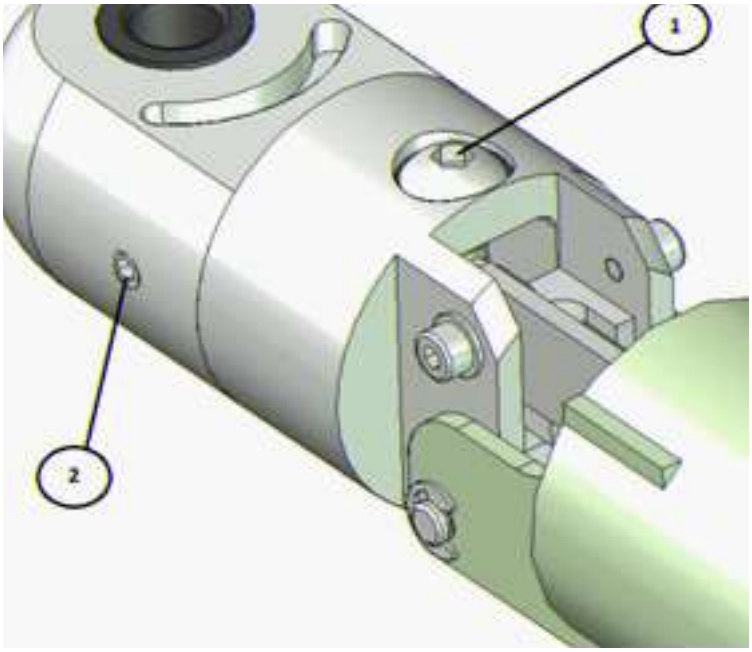
Tray

The tray should be set correctly for your standard equipment and thus remain in its desired position. The maximum load of the tray is 2 kg. Do not lean on the tray.

Pull back the bellows until the adjusting screw (1) is visible. Place your standard equipment on the tray (max. 2 kg) and move the tray into ahorizontal position.

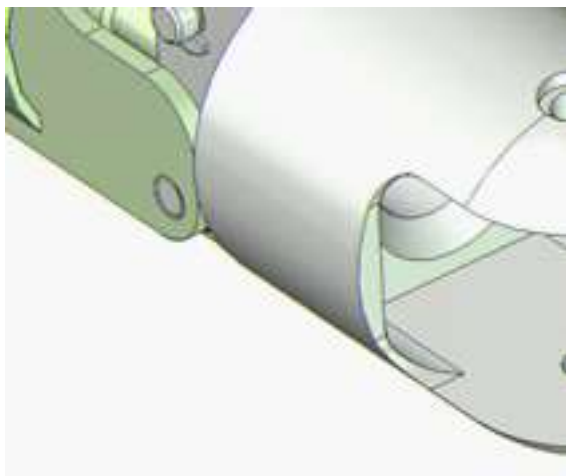
Set the adjusting screw (1) so that the arm remains in the horizontal position (with a slight upward tendency).

Turn the adjusting screw in the „ + „ direction = high weight.
Turn the adjusting screw in the „ - „ direction = low weight



Secure the 3 grub screws (2) with safety lacquer (blue).

With the adjusting screw, the tray can be aligned in its radially horizontal position.
Pull back the bellows until the adjusting screw (1) is visible. Move the tray into a horizontal position.
Secure the adjusting screw (1) for the inclination with thread locking fluid (blue).



You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2-D2-RANGE TRAY SETTINGS

LINK: https://youtu.be/r-Y14eEYtqI

Cuspidor

①	Operating status with installed water separation unit
②	Bowl rinser
③	Glass filler

The factory setting for the bowl rinser is 7 seconds.
The glass filler is factory-set to 3 seconds.

Activate the bowl rinser at the cuspidor.

Activate the cup filler at the cuspidor.

Changing the bowl rinsing time.

Keep the bowl rinser key at the cuspidor pressed. After 2 seconds, a short signal is audible. Keep the key pressed until the desired rinsing time has been reached. Successful storage is confirmed with another signal tone.
Maximum rinsing time: 25 seconds.

Changing the Filling Time for the Cup

Keep the cup filler key at the cuspidor pressed. After 2 seconds, a short signal is audible. Keep the key pressed until the desired fill level has been reached in the glass. Successful storage is confirmed with another signal tone. Maximum filling time: 10 seconds.

After switching on the treatment unit, the bowl rinsing process starts automatically for the saved duration and rinses the bowl.

You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2-D2 SERIES FUNCTIONS CUSPIDOR CUP FILLER & BOWL RINSER

LINK: https://youtu.be/SsFSKDpJI_I

Cleaning the Sieve

Clean the sieve in the cuspidor bowl once a day under running water.

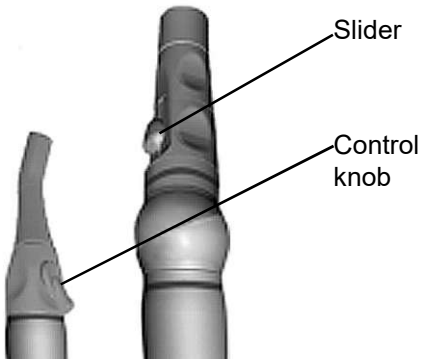
To reduce the risk of infection, liquid-tight gloves must be worn during maintenance work.

Never work without a filter, otherwise there is a risk that parts will settle in the suction system and thus impair its function.

Reflux Effect

When the suction cannula adheres to the mucous membrane of the oral cavity or to the tongue, a so-called reflux effect may occur. To prevent cross-infection among patients we recommend using suction cannulas with air-bleed openings. Here a defined bypass airstream is introduced into the suction handpiece via lateral recesses. Even if the cannula adheres to the mucous membrane of the oral cavity or to the tongue and is thus blocked, a sufficient airstream from the patient to the suction system (and not the other way round!) is maintained.

Remove the suction tube from the suction tube retainer. By opening the slider or turning the control knob, the suction power is active.



Cleaning the suction filter

To reduce the risk of infection, liquid-tight gloves must be worn during maintenance work.

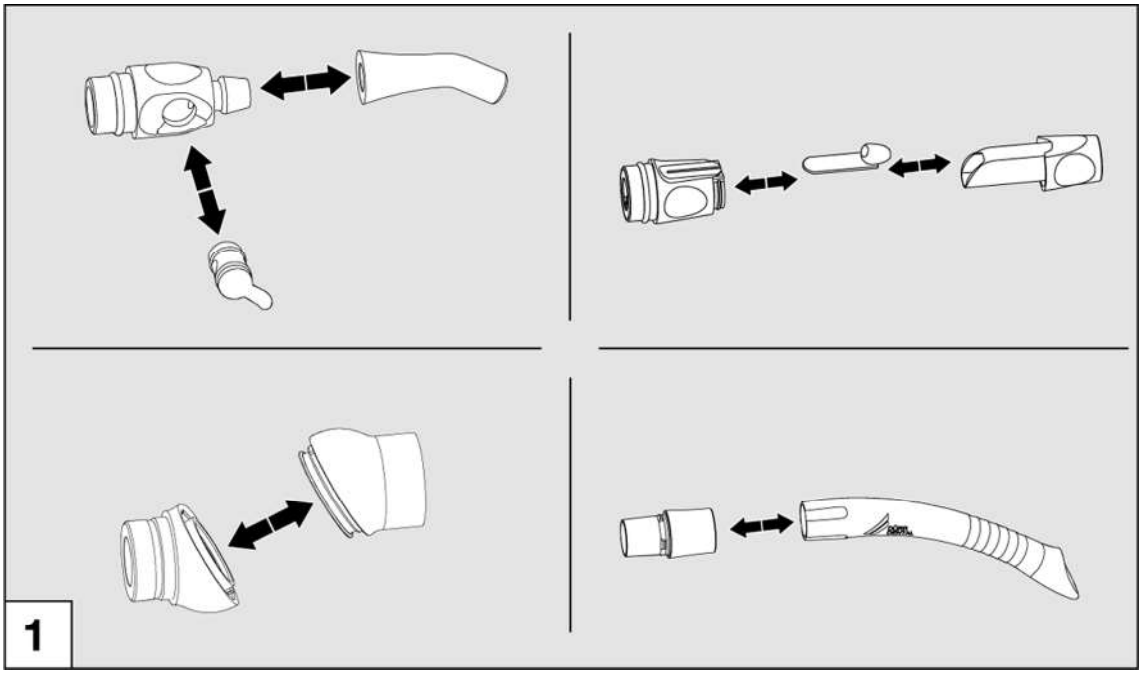
Open the lid of the filter drawer on the assistant‘s device to clean the disposable filter (daily) and replace it if damaged. The filter is designed as a disposable filter and cannot be thermally disinfected.

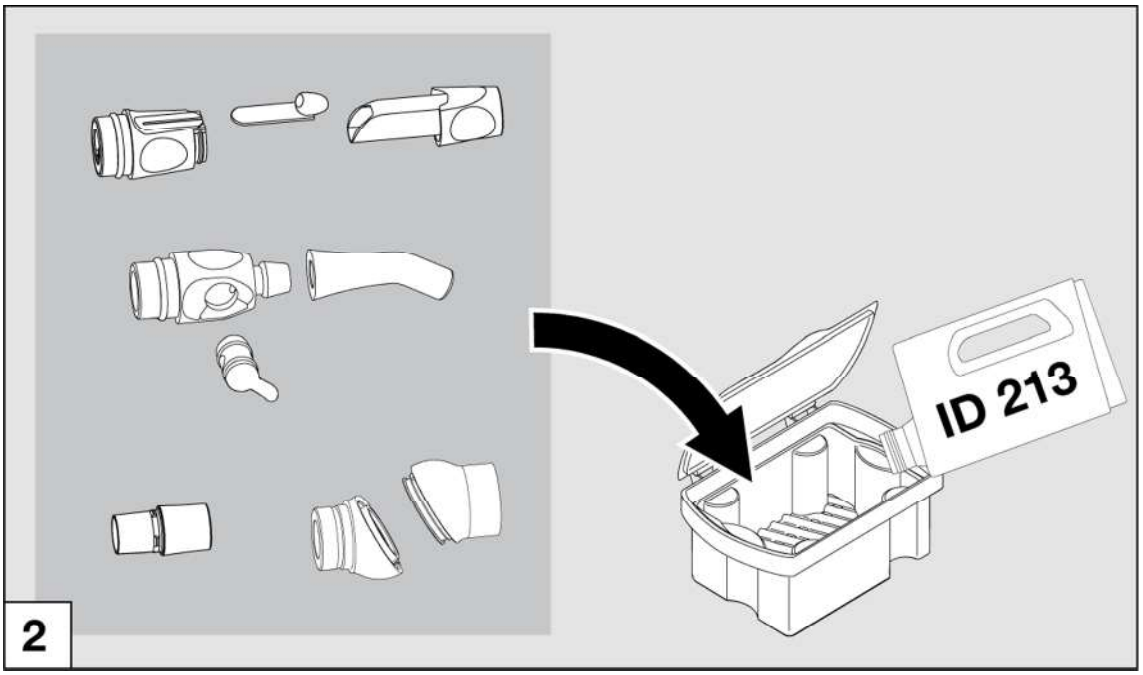
Never work without a filter; otherwise there is a risk of parts settling in the tube holder and impairing its function.

For the intended use, please observe the operating instructions issued by DÜRR Dental:
> Cuspidor valve, Version 3
> CAS 1 operating instructions issued by DÜRR Dental
> CS 1 operating instructions issued by DÜRR Dental,
depending on the equipment and design of the suction system.

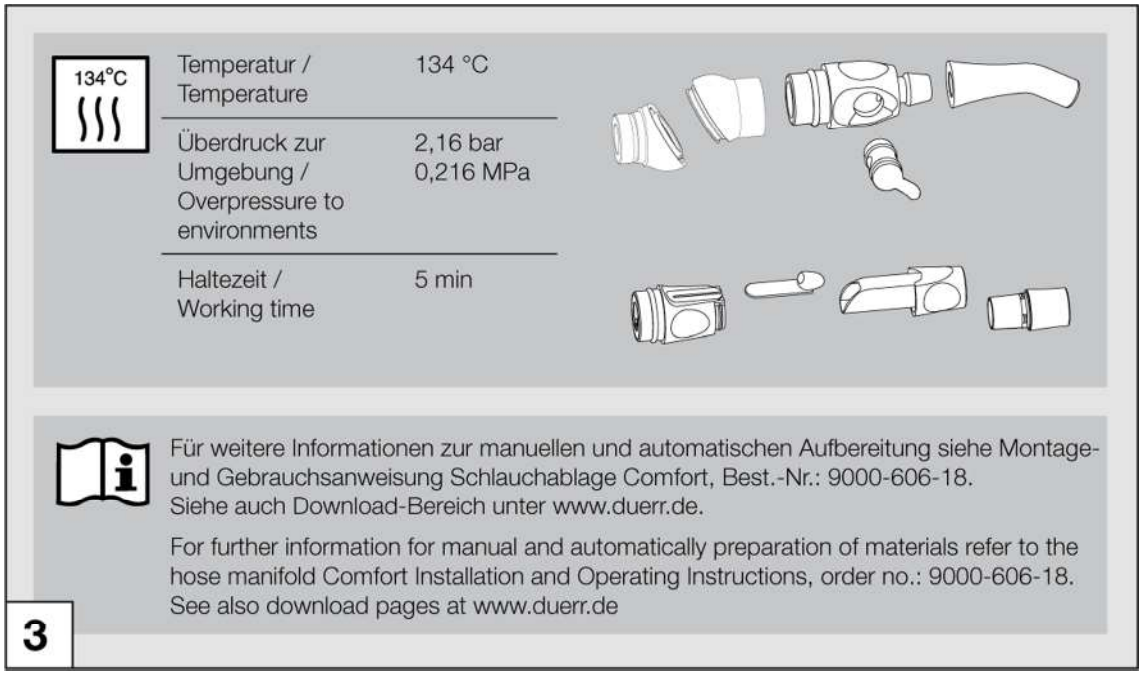
Open the door of the cuspidor fountain by pulling the handle. Depending on the equipment and design of the suction system, you will find the following in the cuspidor:
> Cuspidor valve, Version 3 (wet suction)
> CAS 1 operating instructions issued by DÜRR Dental (dry suction)
> CS 1 operating instructions issued by DÜRR Dental (dry suction)

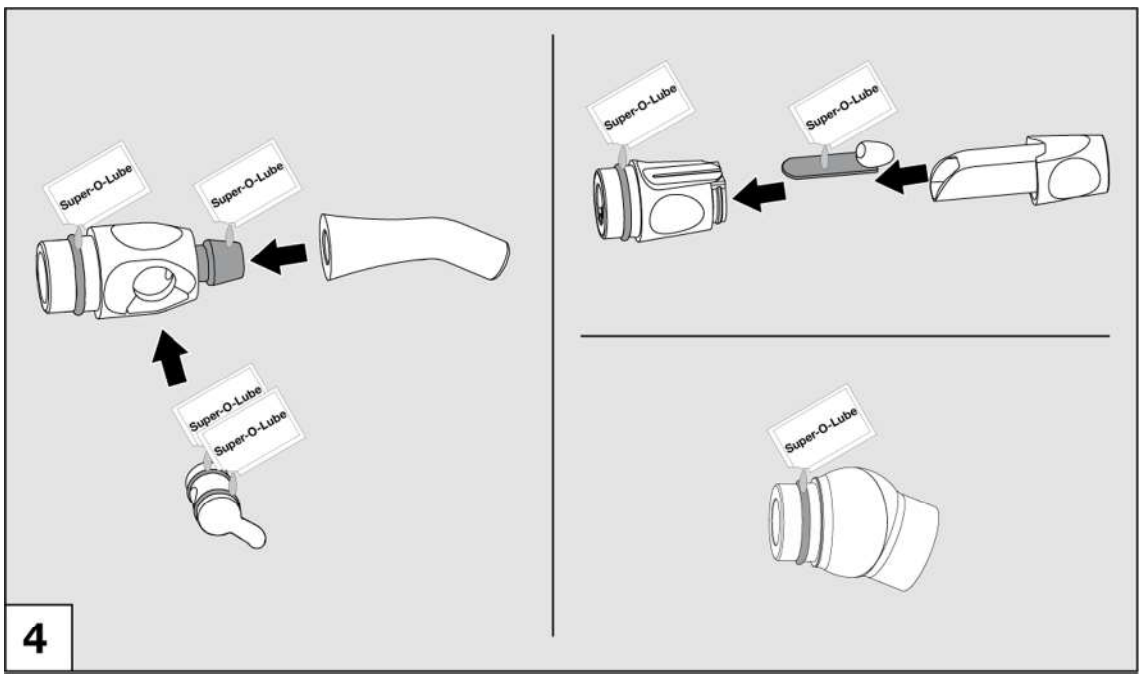
Cleaning and Disinfection of the Suction Handpieces





Cleaning and Disinfection of the Suction Handpieces





Cleaning and Disinfection of the Suction System

We recommend using the OroCup system of the DÜRR company for cleaning and disinfection.

Scope of delivery
1. OroCup, order no. 0780-350-00
2. 2 x Ø 16 mm insert (for large suction tube), (1x loose, 1x fixed)
3. 2 x Ø 6 mm insert (for the saliva ejector),
4. 1x Ø 11 mm insert (other)

Orotol® plus

MD 555 cleaner

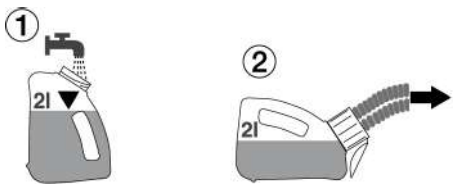
Consumables
•Orotol® plus suction unit disinfectant CDS110P6150
liquid concentrate
•MD 555 cleaner, special cleaner for suction units CCS555C6150
foam-free concentrate for dental suction units and discharge lines

Product Description
The OroCup care system is a closed dosing system for easy preparation and aspiration of disinfectants and special cleaning agents for suction system. With the OroCup, the suction systems can be equipped with all the components and the cuspidor can be cleaned and disinfected. The OroCup is suitable for standard suction tubes with different diameters. In the lid of the OroCup, there is one fixed insert for Ø 16 mm tubes. Two further inserts can be selected and used, depending on the diameter of the suction tubes. As needed, 1 - 3 suction tubes can be attached at the same time; unused connections have no influence on the function.

1. Selecting and Attaching Inserts
- Select and attach the insert according to the diameter of the suction tube (Ø 16 mm for the large suction tube, Ø 6 mm for the saliva ejector). Unused connections have no influence on the function.

2. Cleaning and Disinfecting the Suction System
Cleaning and disinfecting take place at the end of the treatment day; at higher utilisation levelstwice per day (e.g. at noon and in the evening or as needed).
• Wear personal protective equipment.

2.1 Pre-Cleaning with Water
• Aspirate 2 litres of water.



Cleaning and Disinfection of the Suction System

2.2 Preparation in the OroCup

• Depending on how much you need, prepare 1 or 2 litres of ready-to-usesolution. Observe the manufacturer‘s instructions.

• Close the lid of the OroCup and shake the OroCup.

2.3 Positioning the OroCup and Aspirating

• Open the lid of the OroCup.

• Attach the disinfected suction handpieces and aspirate the ready-to-use solution for use.

Up to 2 litres of ready-to-use solution can be prepared in the OroCup.

Position the OroCup for aspirating the ready-to-use solutionas follows:

• When aspirating the liquid, place the OroCup in a vertical position.

2.4 Cleaning and Disinfecting the Cuspidor Bowl

• Use at least 250 ml of ready-to-use solution per cuspidor bowl.

2.5 Final Rinsing

•After the exposure time has elapsed, aspirate 2 litres of water, see 2.1 (Pre-cleaning with water).

You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2-D2 SERIES CLEANING AND DISINFECTION OF THE SUCTION SYSTEM

LINK: https://youtu.be/39Lo60yeZnw

Cleaning and Disinfection of the Surfaces

Hygiene and Care of the Stainless-Steel Surfaces

The regular cleaning of stainless-steel surfaces is recommended for hygienic as well as aesthetic reasons and serves to remove grease stains or finger marks. These can be easily removed with commercially available chlorine- and acid-free stainless-steel cleaners. We recommend applying Prestan to the surface in question.
Most stainless-steel care products contain silicone oil. Using these products can make your work a lot easier. They effortlessly remove any finger marks, but do not necessarily prevent new ones. Depending on the intensity of use, the protective layer remains in place for a few days. Microfibre cloths slightly moistened with water have also provento be very effective.
Never use abrasive agents such as scouring powder, scouring milk or steel wool as these may cause scratches. Brushed surfaces must always be wiped in the direction of the finish. For this purpose, we recommend using a microfibre cloth.
After cleaning, we recommend always wiping stainless-steel surfaces dry with a lint-free cloth to remove water stains or residual cleaning agent.

Disinfection of Stainless-Steel Surfaces

Do you put emphasis on a germ-free surface? Here, too, stainless steel proves to be extremely robust. Any commercially available chlorine-free disinfectant can be used.
Tests have shown that stainless steel is considerably easier to disinfect thanother materials and even a lot less disinfectant is required in order to meet hygiene requirements.

The Most Important Facts at a Glance:

Effective and generallysafe to use on surfaces are
• Soft sponges or microfibre cloths,
• Soapy water (to remove greasy stains),
• Diluted vinegar (to remove lime),
• Sodium bicarbonate (to remove coffee stains),
• Soda (to remove tea stains),
- Alcoholic solvents (to removeglue) and
• Special stainless-steel care products (for cleaning and conservation).

Caution is called for with
- Disinfectants containing chlorine and cleaning agents containing bleach (risk of corrosion).

Never use:
- Scrubbing sponges (scratches and extraneous rust),
- Scouring powder (scratches)
- Silver polish (corrosive).

Cleaning and Disinfection of the Surfaces

DentaClean: cleaning agent for imitation leather and plastic surfaces

Properties
DentaClean gently and easily cleans soiled imitation leather and plastic surfaces.
Use
Test on a hidden area first. We recommend cleaning the chair upholstery at the end of every treatment day. This is particularly important with light colours; any visible soiling must be removed immediately. Use the provided sponge to apply DentaClean in circular motions to the surfaces to be cleaned. Then remove moisture and dirt with a soft, absorbent cloth. For a thorough cleaning, use a cleaning brush instead of the sponge twice a week. Finally, seal with DentaProtect. Upholstery that is treated regularly and properly with DentaProtect is easier to clean!

DentaProtect: Care and protection for your imitation leather upholstery

Properties
DentaProtect is a product for caring and protecting heavy-duty imitation leather upholstery. Sealing the surface, it acts as a micro-binding agent and protects the upholstery from damage due to abrasion, soiling and also discolouration by non-fixed colourants in clothes.
Application
After a thorough cleaning in the evening with a soft sponge or a brush, apply the sealant to the dry upholstery. You need 1 – 2 wipes for the complete upholstery set of your treatment chair. Close the box immediately after taking out the wipes.

proPad: Ready-to-use alcohol-free wipes for rapid disinfection of alcohol-sensitive surfaces; particularly suited for use on treatment chair upholstery.

Area of Application According to the Biocides Regulation:
Ready-to-use wipes for disinfecting alcohol-sensitive surfaces.
Particularly soft, lint-free and tear-resistant fleece. 100% PES. High absorption of the disinfectant solution. Weight: 50 g/m2. Large wipe: 28 x 30 cm. Without alcohol or perfume.
Application:
For disinfection, take the wipes out individually, wipe all over the surfaces and objects to be disinfected and allow the disinfectant to take effect. After the specified residence time, wipe the surfaces off with a clean cloth.

Cleaning and Disinfection of the Surfaces

Disinfection

proPad dispenser box incl. XL disinfectant wipes 100 wipes	Article number PP100
proPad XL Refill 300 disinfectant wipes 3 x 100 wipes	Article number PP300

Cleaning and Care

Care set 1 x DentaClean 200 ml spray foam cleaner (article DC200) 1 x DentaProtect wipe dispenser box (article DP100) 1 x cleaning brush, 3 x cleaning sponges	Article number PSET
DentaClean 1000ml Refill bottle for spray foam cleaner	Article number DC1000
DentaClean 200ml Spray foam cleaner incl. 2 x cleaning sponges	Article numberDC200
DentaProtect wipe dispenser box 100 wipes in a disposable sealing bag	Article number DP100
DentaProtect wipe dispenser set 6 wipe dispenser boxes with 100 wipes each in a disposable sealing bag	Article number DP600
Cleaning brush set, 4 pieces	Article number RB4
Cleaning sponge set, 8 pieces	Article number RS8

You can find an application film at www.youtube DKL Germany.
Video: MEDICAL UPHOLSTERY – CLEANING DISINFECTION PROTECTION

LINK: https://youtu.be/kUutWxmJI2E

Cleaning and Disinfection of the Instrument Holders

- Pull out the instrument holder
- Rinse off any soiling with water
- Remove any residual liquid (absorbent cloth; blow dry with compressed air)
- Disinfection with disinfectants; wipe disinfection is recommended.
- Observe the disinfectant manufacturer's instructions for use
- After manual cleaning and disinfection, a steam sterilization (packaged) in a steam sterilizer class B or S (in accordance with EN 13000) is necessary.
- Remove any soiling on the instrument panel with a damp cloth.
- Remove any residual liquid (absorbent cloth; blow dry with compressed air)
- Disinfection of the instrument panel with disinfectants; wipe disinfection is recommended.
- Observe the disinfectant manufacturer's instructions for use
- Put the instrument holders back into their respective positions.

Marking	Type of holder
GS	Spray mist suction
KS	Saliva ejector
S	Function syringe

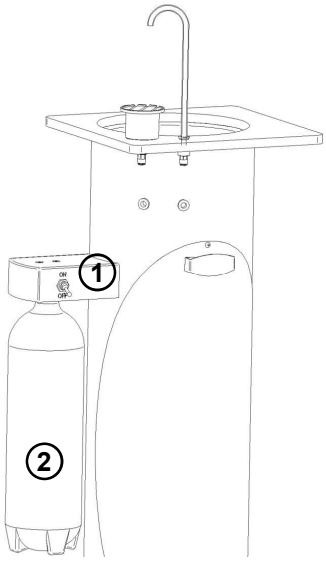
The supply tubes are not approved for mechanical cleaning (thermo washer disinfector) and sterilization. Do not twist or fold the supply tubes! Do not roll up the tubes too tightly!

Bottle Care System

The Bottle Care System is a treatment water system for the self-sufficient water supply for all the instruments and the glass filler. There is also the possibility of intensive decontamination of the service water lines in the treatment unit.

Changing the treatment water bottle on the outside of the cuspidor:

1. Set the flip switch (1) on the bottle holder to „off“. Turn the treatment water bottle (2) slightly to the left until the ventilation becomes audible.
2. Remove the treatment water bottle (2) from its holder from the left-hand side. Fill the bottle and then turn it clockwise into the bottle holder.
3. Set the flip switch (1) on the bottle holder to „on.“ The water supply is ready for operation.



Only use bottles approved by DKL.

Use the bottles before their expiration date (see bottle). Replace the bottles at the latest if they show visible damage or when they reach their expiration date – otherwise they might burst!

Empty the treatment water bottle at the end of a working day and refill the bottle at the beginning of a working day (after initial rinsing 120 sec. RKI) with fresh operating water and DK-DOX 150 Chlorine Dioxide ready-to-use solution (1 ampoule per liter).

You can find an application film at www.youtube DKL Germany.
Video: DK-DOX 150 READY-TO-USE CHLORINE DIOXIDE SOLUTION GLASS AM-POULES FOR THE BOTTLE CARE SYSTEM

LINK: https://youtu.be/Mj_y2YXAJKQ

Product number: 590013
https://dkl.de/en/DK-DOX150-Clorine-dioxide-Ready-to-use-solution/590013

To maintain the water quality in the Bottle Care System of DKL dental units.

CONTENT
- 30 x 5 ml glass ampoule of chlorine dioxide solutio
- 1 x ampoule opener

APPLICATION
Open a 5 ml glass ampoule of chlorine dioxide solution using the ampoule opener and dispense it into the bottle of the Bottle Care System per 1 litre of water.

Bottle Care System

Labelling on the bottle

REF Article number

Expiration date year-month

Bottle Disinfection
For disinfection of the inside of the bottle at regular (weekly) intervals, we recommend BC-San 100. Further product information can be obtained from ALPRO Medical GmbH at www.alpro-medical.com.

Rinsing Function with the Bottle Care System

If the device is equipped with a bottle-care system, make sure that the bottle is freshly filled with water (see Bottle Care System).

Remove the first instrument. Activate the instrument with the setting “Spray active” for 120 seconds. For this purpose, hold the instrument over the cuspidor bowl or a sink. Repeat this procedure with all the instruments. Then activate the cup filler.

Then activate the cup filler.

Carry out the initial rinse before starting work without chlorine dioxide solution.

Intensive Flushing Function with the Bottle Care System

We recommend rehabilitating the waterways after longer periods of inactivity (holidays) or at least once a year.

You can find an application film at www.youtube DKL Germany.
Video: BOTTLE CARE SYSTEM WITH TOUCH SCREEN – DISINFECTION OF THE WATER SUPPLY

LINK: https://youtu.be/1ySjnPDyuBQ

Test water quality with Bottle Care System or Water Separation Unit (WTE)

You can find an application film at www.youtube DKL Germany.
Video: DKL CHAIRS L2-D2 TEST STRIPS FOR THE DK-DOX-150 DETECTION IN THE TREATMENT WATER

LINK: https://youtu.be/3JUx-PY1xHo

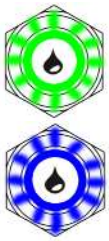
Product number: 590008 Test strips 0,1-0,4 ppm chlorine dioxide (50 pcs)
https://dkl.de/en/Test-strips-0-1-0-4-ppm-chlorine-dioxide-50-pcs/590008

Water Separation Unit (WSU)

The water separation unit meets the requirements of ISO 7494-2 and EN 1717 (free outlet with separation distance ≥ 20 mm). It is intrinsically safe in accordance with DVGW (GermanTechnical and Scientific Association for Gas and Water) worksheet 540 and also meets the requirements of W270 and KTW (guideline for hygienic assessment of organic materials in contact with drinking water). It can be directly connected to the public drinking water supply. The water separation unit is a downstream dosing unit for the maintenance of the quality of the supplied water.

The LED button for the WSU is on the cuspidor. The WSU is started automatically by the control system of the dental unit. A manual start of the WSU is only necessary when the corresponding push-button signal is received.


The push-button on the WSU flashes green = start process with start filling. The push-button of the WSU is constantly green = normal operation.
After switching on the dental unit, the water separation unit goes into normal operation after approximately 50 seconds; water release is enabled.


Intensive flushing is activated by a double click on the push-button. The WSU button lights up permanently blue during the phase of double dosage. When the rinsing is activated, the WSU button flashes green-blue. When the rinsing process is finished, the button lights up permanently green. The return to normal operation is indicated on the display.

When the push-button of the WSU flashes yellow, DK-DOX 150 must be refilled. You can continue to work without restriction and interruption until the treatment unit is restarted.


The push-button of the WSU flashes red-blue after a restart of thetreatment unit. DK-DOX 150 must be refilled!
Caution! Continued operation without DK-DOX 150 only possible after confirmationby briefly pressing the button.
If DK-DOX 150 is not refilled, the button of the WSU indicates this by flashing yellow after the start phase.


WARNING!
Push-button of the water separation unit (WSU) is flashing yellow-red. Fault in the dosing unit. WSU continues to work. Call customer service!

Push-button of the WSU is flashing red.
Call customer service immediately!

Push-button of the WSU lights up permanently red.
Immediately call customer service! Switch off the treatment unit at the main switch! The overflow sensor has tripped! There is a malfunction of the level sensor and / or the travelling valve.

Push-button of the WSU lights up permanently magenta.
Immediately call customer service! Switch off the treatment unit at the main switch!

Push-button of the WSU flashes magenta. The WSU stops! The filling process of the supplied water is too slow. Reset the WSU by keeping the button pressed for 8 seconds and restart it by pressing the button briefly. If the magenta flashes continue, call customer service!

SERVICE MODE!
Keep the push-button of the WSU pressed for 8 seconds.
The push-button of the WSU lights up white.
The mixing tank, the double-piston pump and, if necessary, all the tubing of the dental unit are pumped empty. For this purpose, the instruments and the glass filler must be activated to get the water out of the water lines.
Completion of the emptying process is indicated by a white double flashing. After that, the WSU is in standby mode. The LED-ring of the push-button is switched off.

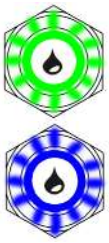

Flushing Function with the Water Separation Unit (WSU)

If the treatment unit is equipped with a water separation unit, make sure that the LED button on the cuspidor lights up green.

Remove the first instrument. Activate the instrument with the setting “Spray active” for 120 seconds. For this purpose, hold the instrument over the cuspidor bowl or a sink. Repeat this procedure with all the instruments. Then activate the cup filler.

Intensive Flushing with the Water Separation Unit (WSU)

After longer downtimes of the treatment unit, such as weekends or holidays, we recommend flushing the water lines intensively before starting work.



The push-button lights up blue: intensive flushing has started. Double click on the button of the cuspidor to activate intensive flushing. Intensive flushing is carried out in two phases. During the first phase with double dosage, the push-button of the WSU flashes blue. During the second phase, the rinsing phase, the push-button of the water separation unit flashes blue-green up to the end of the intensive flushing process.

Remove the first instrument. Activate the instrument with the setting “Spray active” for 600 seconds. For this purpose, hold the instrument over the cuspidor bowl. Repeat this procedure with all the instruments.

Once all the instruments have been flushed, activate the cup filler. Repeat this procedure until normal operation is indicated (the green push-button lights up) on the water separation unit.

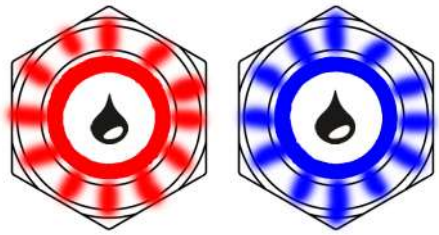
After completion of the intensive flushing, the push-button of the cuspidor lights up green to indicate normal operation.

While intensive flushing is activated (push-button lights up blue) do not work on the patient.

Filling DK-DOX 150 into the Water Separation Unit

DK-DOX 150 is used to maintain the quality of the water supplied to DKL dental units. DK-DOX 150 is a pH-neutral, chlorine-free, aqueous chlorine dioxide solution and is used in the water separation unit with a mixing ratio of 0.75mg/l. The product is not classified as a hazardous substance.

DK-DOX 150 bottle Content 250 ml Order number: 590007



Push-button flashes red/blue.
DK-DOX 150 must be refilled.

Open the cover of the storage container for the water separation unit at the base of the cuspidor.

You can find an application film at www.youtube DKL Germany. Video: DKL CHAIRS L2-D2 SERIES FILLING DK-DOX 150 WATER SEPARATION UNIT (WSU)

LINK: https://youtu.be/CObiIs6gkIQ

Do not fill any other agents into the storage container of the water separation unit. Only refill with DK-DOX150!

Open the cap of the storage container. Fill in 250 ml DK-DOX 150. Make sure that the glass bowl in the storage container does not overflow. After filling, put the cap back on the storage container and close the cover again. The water separation unit automatically returns to normal operation. The button lights up green.

Maintenance and Inspection

In order to ensure the operational and functional reliability of your treatment unit and to avoid damage due to wear and tear it is necessary to perform maintenance once a year. Maintenance is carried out by an authorised technician of your specialist dealer or a DKL CHAIRS technician.
The work steps to be performed and the parts to be replaced are specified in the document “Maintenance Log“. The tasks that were performed have to be entered in the maintenance log, which is part of the medical devices logbook.

Safety Inspections

Dental units are designed in such a way that a first fault does not present a hazard to patients, operators or third parties. Therefore, it is important to detect such faults before a second fault occurs, which may result in a hazard.
For this reason, safety inspections should be carried out every 3 years to detect electrical faults in particular (e.g. faulty electrical insulation). These checks are carried out by an authorised technician of your specialist dealer or a DKL CHAIRS technician.
The work steps to be performed are specified in the document “Safety Inspections“. The measured values have to be documented.
Safety inspections have to be carried out when putting your treatment unit into initial operation, after expansion or retrofitting activities on your treatment unit and after repair jobs.The safety inspections are carried out in accordance with DIN EN 62353.

The treatment unit may only be operated when the safety checks have been passed.

Warrantee Declaration

12 Months Warranty

This DKL medical product has been manufactured with the utmost care by highly qualified specialists. Multifarious checks and inspections ensure faultless performance. Please note that warranty claims will only be accepted if all the instructions in this operating manual have been observed.
DKL as the manufacturer shall be liable for material and manufacturing faults within a warranty period of 12 months from the date of purchase. Accessories and consumables (seals, filters, lamps and suction tubes) are excluded from this warranty.
We do not accept liability for damages caused by improper treatment or repair work carried out by third parties that are not authorised by DKL!
Any warranty claims must be filed with the supplier or an authorised DKL service partner and the sales slip must be enclosed. Any performance of this warranty does not extend the warranty period.

Waste Disposal

Make sure that the parts that are being disposed of are not contaminated.

Observe your local and national laws, guidelines, standards and regulations for disposal.
> Medical devices
> Waste electrical and electronic equipment

Further information on disposal can be found at http://dkl.de

Disposal and recycling of DKL transport packaging is carried out within the scope of the Dual System via the local waste disposal and recycling companies.
DKL transport packaging returned by customers at their own expense is supplied by DKL to the recycling companies set up for this purpose without further costs and without reimbursement.

EMC - Manufacturer‘s Declaration for the Model L2-SUC

• WARNING: The use of accessories that do not conform to the manufacturer‘s specifications may result in higher interference levels and/or lower interference immunity.
• Operate the equipment in a location as far away as possible from equipment that emits electrical and magnetic disturbances. If it is necessary to operate the device in the immediate vicinity of other devices, make sure that the system functions correctly.

BASIC SAFETY

BASIC SAFETY is ensured if it meets the safety requirements of the IEC 60601-1 standard, in particular the requirements against: electrical shock, mechanical hazards and hazards due to excessive temperatures.

ESSENTIAL PERFORMANCE

The dental unit has no direct clinical function or essential performance according to IEC 60601-1, IEC 80601-2-60, 201.4.3 ESSENTIAL PERFORMANCE.

Performance limitations are permitted according to the following criteria. This is considered in the risk analysis of the system.

Criterion A
The dental unit will withstand the test without damage or other interference. During and after the test, the device will operate perfectly within the specified limits. Basic safety is guaranteed throughout.

Criterion B
The dental unit will withstand the test without damage or other interference. After the test, the device will operate perfectly within the specified limits. Basic safety is guaranteed throughout.

Criterion C
A temporary malfunction is permitted if the function resets itself or if it can be restored by user intervention. Basic safety is guaranteed throughout.

Intended operating environment

Intended operating environments are typical professional health care facilities and areas of home health care.

Technical description

This dental unit has been tested and developed to meet the EMC behaviour in the specified environment. This includes special EMC-filters to reduce the radiation of electromagnetic waves as defined in IEC 60601-1-2.

Please read and follow all technical documentation to avoid adverse events for the patient or user.

IEC STANDARD 60601-1-2:2014, 4th Edition

This device is approved for use in a specific electromagnetic environment. The customer or user of the device must ensure that it is used in an electromagnetic environment in accordance with the description given below.

Emission Measurement	Agreement	Guidelines Regarding the Electromagnetic Environment
RF-emission according to CISPR 11	Group 1	This device uses RF-energy for internal functions only. RF-emissions are therefore very low, and it is unlikely that other nearby electronic equipment will be disturbed.
RF-emission according to CISPR 11	Class B	The device is suitable for use in all environments, including residential areas, and approved for direct connection to the public low-voltage network for residential areas.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker according to IEC 61000-3-3	met	

Interference Immunity Test	IEC 60601-test level	Compliance level	Electromagnetic Environment - Guidelinesf
Electrostatic Discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ±2, 4, 8, 15 kV air discharge	± 8 kV contact discharge ±15 kV air discharge	The floor should be wood, concrete or tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%. Criterion B
Fast transient electrical disturbances/bursts according to IEC 61000-4-4 (only for V 300/600)	± 2 kV for mains 100 kHz repeat rate	± 2 kV for mains 100 kHz repeat rate	The quality of the mains power supply should meet the requirements for a normal commercial or clinical environment. Criterion B
Surge voltages according to IEC 61000-4-5 (only for V 300/600)	± 0,5 kV , ± 1 kV L to N ± 0,5 kV , ± 1 kV ± 2 kV L to GND	± 1 kV L to N ± 2 kV L to GND	The quality of the mains power supply should meet the requirements for a normal commercial or clinical environment. Criterion B
Voltage dips, short-term interruptions and voltage fluctuations of the mains supply lines according to IEC 61000-4-11 (only for V 300/600)	0 % UT 0°,45°,90°,135°,180°,225°,270°,315° 0 % UT 0° 0% 70 % UT 0 % UT 0%	0 % UT for 1/2 Period 1 Period 25 /30 Periods (50/60Hz) 250/300 Periods (50/60Hz) for 5 s	The quality of the mains power supply should meet the requirements for a normal commercial or clinical environment. If the user of the product requires continuous operation even with interruptions of the power supply, the product should be connected to an uninterruptible power supply. Criterion A (max. mains voltage) Criterion B (min. mains voltage) Criterion A (max. mains voltage) Criterion B (min. mains voltage) Criterion A (max. mains voltage) Criterion B (min. mains voltage) Criterion A (max. mains voltage) Criterion B (min. mains voltage)
Magnetic field at the mains frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should have levels typical of an application in a commercial or clinical environment.
Note: UT is the alternating mains voltage prior to the application of the test level.			

Specifications for Enclosure Port Immunity

Immunity Test	Test condition	IEC 60601 level of conformity	Electromagnetic Environmental Recommendation
Radiated electromagnetic fields from high-frequency wireless communication devices IEC 61000-4-30-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz – 2,7 GHz	The quality of the main power supply should correspond to the one for a professional health care facility and be appropriate regarding the environment in areas of domestic health care. Criterion A
	385MHz (18Hz pulse modulation)	27 V/m	
	450MHz (FM+/-5KHz deviation 1kHz sine or 18Hz pulse modulation)	28 V/m	
	710MHz (217Hz PM)	9 V/m	
	745MHz (217Hz PM)	9 V/m	
	780MHz (217Hz PM)	28 V/m	
	810MHz (18Hz PM)	28 V/m	
	870MHz (18Hz PM)	28 V/m	
	930MHz (18Hz PM)	28 V/m	
	1720MHz (217Hz PM)	28 V/m	
	1845MHz (217Hz PM)	28 V/m	
	1970MHz (217Hz PM)	28 V/m	
	2450MHz (217Hz PM)	28 V/m	
	5240MHz (217Hz PM)	9 V/m	
	5500MHz (217Hz PM)	9 V/m	
	5785MHz (217Hz PM)	9 V/m	

Interference immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF-disturbance variables according to IEC 61000-4-6 (only for V 300/600)	3 Veff 150 kHz to 80 MHz	10 Veff	The distance between portable or mobile RF-communications equipment and parts of the product, including cables, should not be less than the recommended protective distance calculated with the equation applicable to the transmission frequency. Recommended protective distance:
Radiated RF-disturbance variables and near fields from wireless communication equipment according to IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 80 MHz to 800MHz $d = 2,3\sqrt{P}$ for 800 MHz to 2.7 GHz Here P is the maximum nominal power output of the transmitter in watts (W) according to the transmitter manufacturer‘s specifications, and d is the recommended distance in metres (m). The field strength of permanently installed RF-transmitters, which was determined by an electromagnetic location test [a] should not exceed the level [b] permitted in any frequency range. Interference may occur in the immediate vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz respectively, the larger frequency range applies.
Note 2: These guidelines may not apply to all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of structures, objects, people and animals.

[a] The field strength of permanently installed transmitters, such as base stations for radio telephony (cordless or mobile phones), mobile radio stations, amateur radio transmitters, AM and FM radio and television transmitters, cannot theoretically be calculated with absolute accuracy. To determine the electromagnetic fields generated by fixed RF-transmitters, an electromagnetic site inspection should be carried out. If the measured field strength at the location where the device is used exceeds the permissible RF-field strength specified above, the instrument should be observed. Additional measures may be necessary, e.g. reorientation or change of location of the device.

[b] In the frequency range between 150 kHz and 80 MHz, the field strength should be less than 3 V/m.

Manufacturer‘s Declaration - Electromagnetic Interference Immunity III

The device is approved for use in a specific electromagnetic environment.
The customer or user of the device must ensure that it is used in an electromagnetic environment as described below

Interference Immunity Test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidelines
Fluctuations in the mains frequency and mains voltage according to IEC 601-1, section 10.2.2. a (only for V 300/600)	Nominal frequency: up to 100 Hz: variationsof ± 1 Hz of the nominal frequency; variations of ± 10%Hz of thenominal voltage	Nennfrequenz: bis zu 100 Hz: Schwankungen von± 1 Hz der Nennfrequenz; Schwankungen von± 10%Hz der Nennspannung	The quality of the mains voltage supply should meet the requirements of a normal commercial or clinical environment.

Manufacturer‘s Declaration - Recommended Protective Distances between Portable or Mobile RF-Communication Equipment and the Device

The device is intended for use in an electromagnetic environment where the radiated RF-disturbance variables are checked. The customer or user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF-communication equipment (transmitters) and the device in accordance with the following recommendations, which are based on the maximum output power and frequency of the communication device.

Maximum nominal power of the transmitter in watts (W)	Protective distance as a function of the frequency of the transmitter in metres (m)		
	150 kHz to 80 MHz d = 1,2√P	**80 MHz to 800 MHz d = 1,2√P**	**800 MHz to 2,5 GHz d = 2,3√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 transmitters with a maximum output power not specified above, the recommended safety distance d in meters (m) can be calculated with an equation from the transmitter frequency and the maximum nominal output power P of the transmitter in watts (W) based on the transmitter manufacturer‘s specifications.
Note 1: At 80 MHz and 800 MHz respectively, the larger frequency range applies.
Note 2: These guidelines may not apply to all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of structures, objects, people and animals.

ATTENTION: The use of this device directly adjacent to or coupled to another unit should be avoided as it may lead to unintentional behaviour. However, if this arrangement is unavoidable, both devices must be observed to verify that they are functioning normally.

CAUTION: Portable RF-communication equipment (including antenna cables or external antennas) should not be closer than 30 cm to the ME-equipment or ME-system, including those cables specified by the manufacturer. Otherwise, a power limitation of the device could be caused.

Minilight

Installation and use manual

LUZZANI DENTAL

LUZZANI DENTAL S.R.L.

Via Torino, 3
20030 Senago (MI)
Italy

www.luzzani.it

E-mail: info@luzzani.it

Tel.: +39 029988433
Fax: +39 0299010379

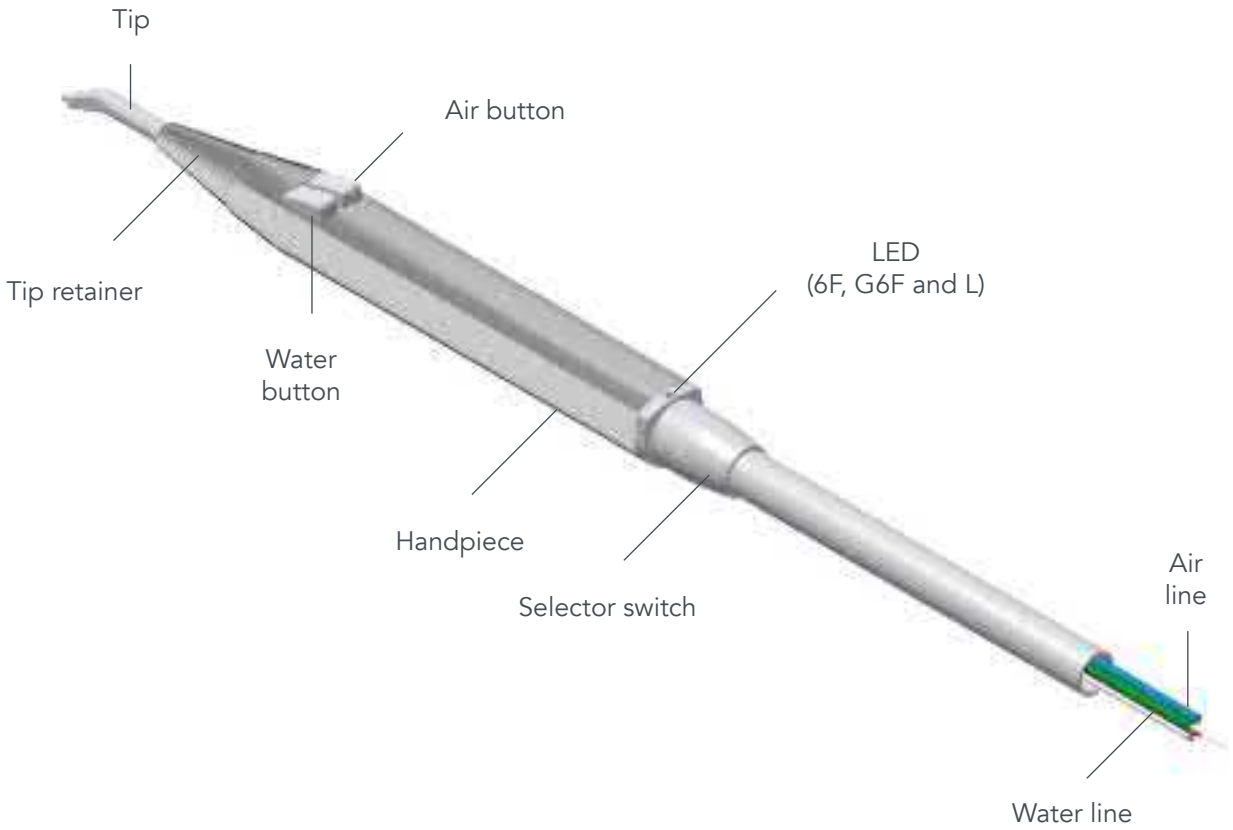
ED. 5 REV. 0

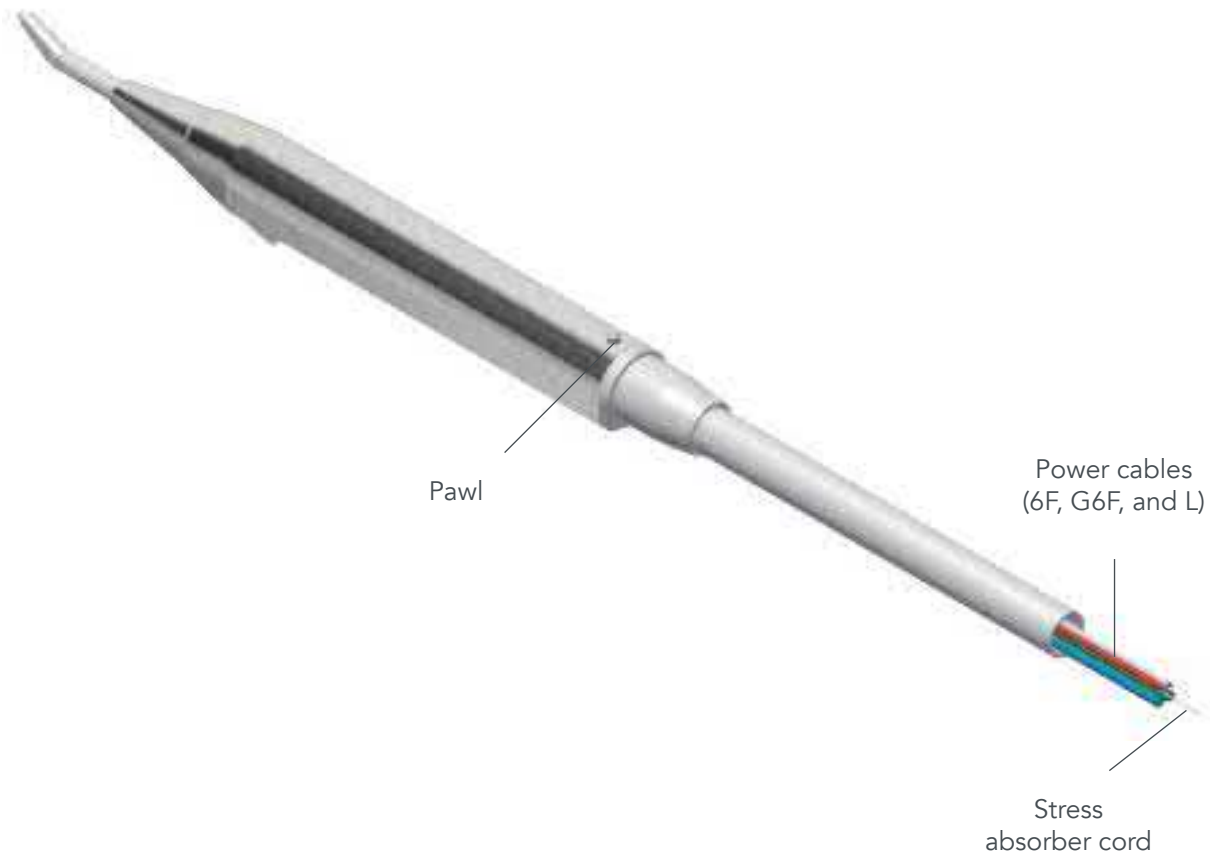
MADE IN ITALY

CE
1370

CONTENTS

0 —— SYRINGE LEGEND





1 —— WARNINGS

1.1 — Any unauthorised tampering, modification or improper use immediately terminates the warranty and exonerates our company from all liability for injury or damage to persons, animals or property that may be caused by such interference.

1.2 — To ensure maximum user and patient safety, the transformer used must be rated Safe Extra Low Voltage (SELV) with CE marking for medical use, in compliance with IEC 80.601 and IEC 60.601.

1.3 — Connection to terminals with output voltage exceeding 24 V could irreparably damage the device.

1.4 — The stress absorber cord must be anchored to the dental unit. This cord is designed to absorb any strains, thus preventing abnormal traction on the electrical or air/water line connections.

1.5 — Before use, the electric, water and air lines must be correctly connected. The syringe could be damaged if used when not connected to the water and air supplies. The lines must be connected correctly since inverting them would damage the syringe.

1.6 — To meet the requirements of Directive 93/42/EEC, the company has established a post-marketing surveillance procedure to monitor any problems generated by the use of our products. The attached form allows you to report any faults and suggest improvements which will be considered for subsequent versions of the product.

1.7 — With each syringe, the package also includes a User's manual which also includes a "Fault Report Form". Since this is required by law, the user must receive this User's manual. Therefore, the syringe installer is responsible for delivering this User's manual to the dentist. Directive 93/42/EEC requires product traceability: therefore, our customers are asked to ensure that, in case of emergency, we can identify the end customer to whom the product has been sold.

1.8 — Manufacturers and/or installers of dental units are required to comply with all the prescriptions outlined in this document.

1.9 — Use the Minilight syringe only for the applications described in the instructions for use.

1.10 — This product must only be installed by qualified persons.

1.11 — Never modify the syringe in any way. This is strictly forbidden.

1.12 — Use only original parts produced or approved by the manufacturer. If non-OEM accessories or consumables are used, the company cannot guarantee safe operation and function. No claims can be made for damages resulting from improper use.

1.13 — Disposable tip adapters are not part of the Minilight Syringe and may compromise proper functioning.

1.14 — Do not use the device in close contact with anaesthetic gases or in highly oxygenated environments (with an oxygen content >25%) or in areas where there is a risk of explosion.

1.15 — Do not perform any maintenance procedures not indicated in the manual.

1.16 — Before using the syringe, make certain that the water and air supplies have been activated.

1.17 — National regulations regarding dental unit water and air quality must be met.

1.18 — The air used must be dry, clean and free of oil.

1.19 — The Minilight syringe meets the requirements laid out in European Council Directive 93/42/EEC: Class II A

1.20 — The Minilight syringe must not be used near or set on other devices.

1.21 — Use only accessories, cables, transducers specified or supplied by Luzzani Dental.

1.22 — Do not use mobile RF communication devices within a distance less than 30 cm from the device.

2 —— PRODUCT DESCRIPTION

2.1 — GENERAL

The Minilight syringe is a medical device designed to blow air and water (separately or together, at room temperature or at body temperature) to clean and/or dry the oral cavity during any dental procedure. It has been designed for use in dentist offices and dental clinics and is built into dental unit used exclusively by dentists. Product life — under proper maintenance conditions — is 5 years.

2.2 — GENERAL CHARACTERISTICS

- The Minilight syringe is a medical device for dental use (class II a).
- Protection rating against direct contacts: B
- Temporary operation: 10 sec. ON/ 20 sec. OFF.

The Minilight syringe has been designed using the latest ergonomic concepts for easy use and immediate cleaning and sterilisation. Both the tip and handpiece can easily be removed for perfect autoclave disinfection and sterilisation at 134°C (see point 8). Several handpieces of different shape are available. Choose the shape you need: angled or stylet. The air and water can also be heated to body temperature, thus sparing the patient even the slightest discomfort induced by insufflation of products at ambient temperature.

2.3 — MODELS

The models are differentiated into versions based on the

number of functions provided:

- 3F: cold water/air/spray
- 6F: cold water/air/spray - warm water/air/spray
- G3F: cold water/air/spray (air and water inverted)
- G6F: warm water/air/spray (air and water inverted)
- A: cold water or air only
- L: cold/warm water, air and spray + light

Note:

Models 3F, G3F, 6F, G6F and L can be recognized by the printing on the back of the syringe.

Various handpieces, that differ in shape, can be mounted on all versions of the Minilight syringe.

The shape of the handpiece can be:

STYLET

ANGLED

This difference lets the dentist choose the tool ergonomically best suited for the purpose. To guarantee maximum hygiene and atoxicity, the handpieces are made of stainless steel. The devices are produced entirely in our workshop, with a tested, constantly updated work cycle using the most sophisticated machinery compliant with current quality system directives (UNI EN ISO 13485 certified).

2.4 — CONTROLS

Every syringe and all of its parts undergo duly documented, 100% complete functional and safety testing to ensure that the technical and functional design requirements are fully met.

2.5 — CE MARKING

All products bear CE marking both on syringe handpiece and inside. (batch number, autoclave symbol, Luzzani Dental logo, product name, CE marking with Notified Body number). The User's manual supplied with the product also includes details of our company, the main product characteristics and instructions for correct use and maintenance.

3 —— IDENTIFICATION DATA AND WARRANTY

3.1 — MANUFACTURING BATCH

A number, marked on the inside of each product, identifies the production batch; the number is printed on the central body of the syringe. This number uniquely identifies the production batch thus always guaranteeing traceability of the product and each of its components, with relative test sheets.

3.2 — WARRANTY

The product is guaranteed by our company for 12 months from the date of the delivery document. The warranty covers any device manufacturing defects (materials) and is limited solely to the replacement of defective parts, performed in our workshop. The product must be sent to our premises at the expense of the customer. For the warranty to be valid, the product must be returned intact, complete and showing with no signs of tampering. The syringe has no functional expiration date; its expected life span is 5 years.

4 —— PACKAGING

The product is shipped in suitable packaging to prevent problems during transport. The packaging consists of a plastic bag containing the Minilight syringe. A protective handpiece sheath and tip-saving tube protect the syringe during transport. Several bags are placed in one box. The Minilight syringe comes ready for connection to the dental unit once all packaging has been removed. For the correct use of the syringe, the protective tube must also be removed from the tip.

⚠ IMPORTANT NOTE:

With each syringe, the package also includes a User's manual which also includes a "Fault Report Form". Since this is required by law, the user must receive this User's manual. Therefore, the syringe installer is responsible for delivering these forms to the dentist. Directive 93/42/EEC requires product traceability: therefore, our customers are asked to ensure that we can identify the end customer to whom the product has been sold.

5 —— TECHNICAL CHARACTERISTICS

FUNCTIONS		6F	3F	L
Supply voltage	V~	24	***	24
LED voltage	Vdc	***	***	3,5
Max. absorbed current	A	4,3	***	4,3
Electrical power	W	103	***	103
Water supply pressure	Kpa	250	250	250
Air supply pressure	Kpa	450	450	450
Water flow rate	Cc/min	110	110	110
Air flow rate	Nl/min	10	10	10
International protection		IP40	IP40	IP40

5.1 — OPERATING CONDITIONS

Ambient temperature	10°C / +45°C
Relative air humidity	30% / 85%
Atmospheric pressure	80 Kpa - 106 Kpa

5.2 — TRANSPORT AND STORAGE CONDITIONS

Temperature	-20°C / +60°C
Relative Humidity	30% / 85%
Atmospheric Pressure	50 Kpa - 106 Kpa

6 —— INSTALLATION AND CONNECTIONS

6.1 — CONNECTION TO ELECTRICAL SYSTEM

The connection involves hooking up the two electrical terminals to the transformer, arranged to provide an output of 24 V (see wiring diagram 14.1). Model L only: voltage for LED light 3.3 Vdc: black wire (+), white wire (-)

⚠ NOTE

• The electric power supply and transformer used must be rated Safe Extra Low Voltage (SELV) for medical use, in compliance with the mandatory regulations.

• Connection to terminals with output voltage exceeding 24 V could irreparably damage the unit and compromise safety.

6.2 — CONNECTION TO HYDRAULIC SYSTEM

The syringe's green line must be hooked up to the water supply.

⚠ NOTE

- The operating pressure is 250 kPa. A slight increase in pressure would only increase the power of the jet, but would not create any problems and is not dangerous.
- The water used must be potable water, filtered (<25 µm) and free of bacteria, etc.
- For the syringe to function properly, the water pressure must not be lower than indicated.

6.2 — CONNECTION TO COMPRESSED AIR SYSTEM

The syringe's blue line must be connected to the compressed air system.

⚠ NOTE

- The recommended operating pressure is around 450 kPa.
- When using the Minilight syringe, national regulations regarding water and air quality must also be met.
- The air must be medical grade, dry and free of oil and bacteria – a 5µm air filter is recommended.

6.4 — CONNECTION OF STRESS ABSORBER CORD

The stress absorber cord must be anchored to the dental

unit. This cord is designed to absorb any strains, thus preventing abnormal traction on the electrical or air/water line connections. The manufacturer cannot be held liable for malfunctions caused by failure to anchor the stress absorber cord.

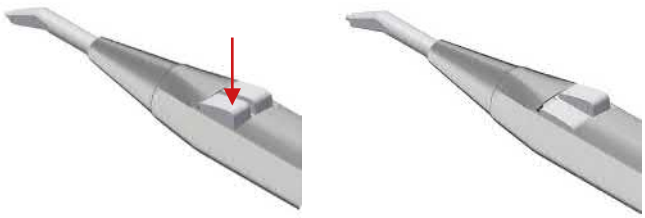
6.5 — NOTES FOR CORRECT CONNECTION

- Before carrying out functional tests, both the electric, water and air lines must be correctly connected.
- Using the syringe without connecting the water and air supplies could damage the syringe.
- The lines must be connected carefully since inverting them could damage the syringe.

7 —— NORMAL USE

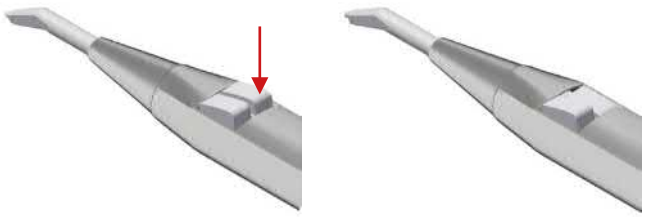
7.1 — INSUFFLATION OF COLD WATER

To blow cold water into the operating field, just press the left button on the handpiece, symbol:



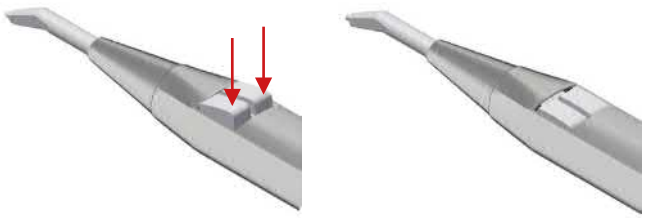
7.2 — INSUFFLATION OF COLD AIR

To insufflate cold air into the operating field, just press the right button on the handpiece, symbol:



7.3 — COMBINED INSUFFLATION OF COLD WATER AND AIR (SPRAY)

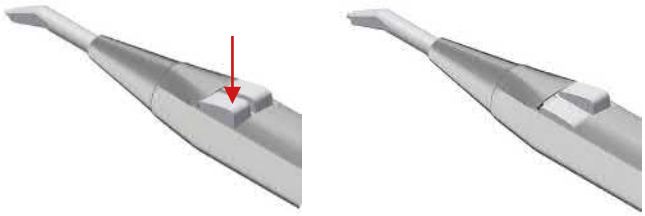
To blow a combination of cold air and water (spray), press both buttons on the handpiece at the same time:



7.4 — INSUFFLATION OF WARM WATER (present in version 6f and L)

To blow warm water into the operating field, turn the selector switch at the base of the handpiece to the right (the green LED lights up)

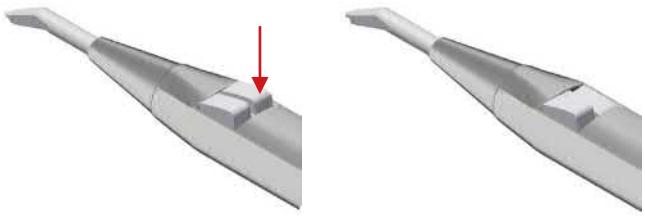
and press the left button on the handpiece:



7.5 — INSUFFLATION OF WARM AIR (present in version 6f and L)

To blow warm air into the operating field, turn the selector switch at the base of the handpiece to the right (the green LED lights up):

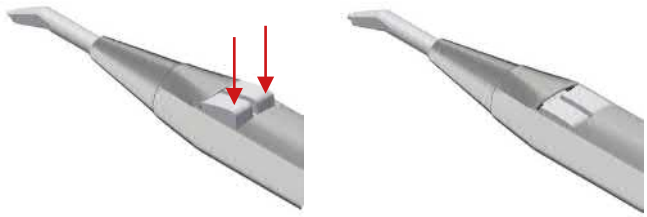
and press the right button on the handpiece:



7.6 — COMBINED INSUFFLATION OF WARM WATER AND AIR (SPRAY) (present in version 6f and L)

To blow a combination of warm air and water (spray), turn the selector switch at the base of the handpiece to the right (the green LED lights up)

and press both buttons on the handpiece at the same time:



7.7 — LIGHT FUNCTION (present in version L)

This function is present in the Minilight L version. In this model, the handpiece has an optical fibre that conducts the light generated by a LED located in the body of the syringe. We recommend using a switch to turn the LED on and off. For connections, see wiring diagram 14.2.

NOTE

- The sole function of the selector switch is to preselect warm operations. The water and/or air are only heated at the moment in which they are actually used.
- The cleaning (or line washing) procedures must always be performed in the cold position.

WARNING

Do not use the tip improperly. Remove and sterilise the tip after each patient.

IMPORTANT

Air and water must be able to flow freely from the tip. Do not rest the tip on the tooth or on an object. Do not press the tip against impression materials as they could cause obstruction

7.8 — FIRST TIME USE AND USE AFTER LONG INTERVALS

⚠ • Sterilize the handpiece and all accessories before use.

- After prolonged periods of inactivity, clean, treat and sterilise the handpiece.

⚠ BEFORE EACH PATIENT

1. Make certain the handpiece has been sterilised.
2. Adjust the supply of fluids from the dental unit (see table in point 5).
3. Press the air button and make certain that there is a clearly perceptible jet of air.
4. Check the water flow rate.
5. Use only filtered water that is free of oil and microorganisms.
6. Check the tip for any obstructions or deposits. Clean if necessary.

NOTE

- Flush out the syringe at the beginning of each work day (minimum flushing time: 2 minutes) and before each patient (minimum flushing time: 20-30 sec.).
- Immediately upstream of the syringe, install filters able to retain the microorganisms coming from the hydro-pneumatic circuit.

8 —— CLEANING AND STERILIZATION

⚠ After each use on a patient, the handpiece and tip of the syringe MUST be cleaned and sterilised to guarantee maximum hygiene.

Sterilisation symbol on the handpiece: 

To do this, proceed as follows:

Disconnect the tip by unscrewing the tip retainer

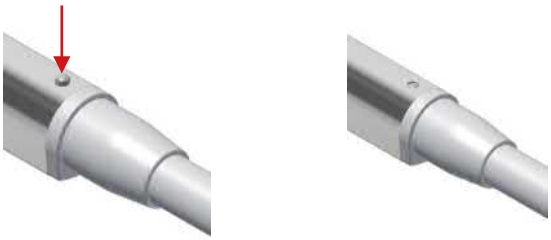
1. unscrew the tip retainer

2. withdraw the tip retainer

3. withdraw the tip

or remove the entire handpiece by pressing the button on the lower part of the handpiece and pulling upwards.

1. press the pawl to release the handpiece



2 . withdraw handpiece

wipe with a damp cloth, removing any stains. Set in a steam autoclave at 134°C for AT LEAST 3 minutes (in compliance with CEI EN 13060).

A — WARNINGS

⚠ The syringe should always be sterilised, even before using it for the first time.

- Inappropriate sterilisation is hazardous for the patient and for the operators.
- Do not perform spray disinfection.
- Do not immerse in disinfectant liquids.
- Do not perform cold or hot air chemical sterilisation.
- The personnel performing the task must be skilled and specially trained.
- Use disinfectant according to the specifications on the manufacturer label.
- Do not use chlorine-based liquids.
- When simultaneously sterilising more than one item in an autoclave, check that the load does not exceed the maximum allowed.

B — PREPARATION

Eliminate surface dirt using a disposable paper towel. Clean the inside of the lines by running air and water through the syringe for about 30 seconds. Remove the stainless-steel handpiece by pressing the button on its terminal section. Unscrew the tip retainer and remove the tip.

C — MANUAL CLEANING

Use a disposable paper towel and potable water to remove any impurities or dirt that may be present

D — AUTOMATIC CLEANING

Not envisaged

E — MANUAL DISINFECTION

Disinfect only with a disposable cloth and the permitted disinfectant (following the instructions on the label and product technical data sheet).

Recommended disinfectants:

- Incidin liquid
- FD 322 Durr
- Mikrozid AF liquid

F — AUTOMATIC DISINFECTION

Not envisaged

G — MANUAL DRYING

Dry with disposable paper towelling. Dry with clean, dry, uncontaminated compressed air, inside and out, continuing until completely dry. Do not dry with hot air.

H — AUTOMATIC DRYING

Not envisaged

I — MAINTENANCE AND CONTROL

No special maintenance is necessary. There is no objective period of time that limits the useful life of the handpiece: visually check for damage and signs of wear, and if found, replace the part.

L — PACKAGING

Use heat sealable film-paper sterilisation pouches of appropriate size.

⚠ M — STERILISATION

The handpiece and tip can be sterilised.

Sterilise in a class B steam autoclave in compliance with EN 13060 ISO 17665-1.

3-phase sterilisation with fractional vacuum system at 134°C +/- 1°C at a pressure of 2.13 bar, applying a 4-minute delay. Never exceed 134°C. The autoclave must be validated.

N — STORAGE

No particular requirements apart from storage in the sealed, sterilised pouches. Store in a suitable place that is dry, out of direct sunlight and possibly with low bioburden.

9 —— MAINTENANCE

The instrument requires no specific maintenance apart from normal cleaning and sterilisation as described in the previous paragraph.

10 —— DISPOSAL AND SCRAPPING

The product does not contain dangerous or toxic-hazardous components. Separate waste collection is required for electrical equipment. Follow the regulations in force in your country.

11 —— INFORMATION FOR THE DENTIST

The dental unit manufacturer is required to deliver the Luzzani Dental syringe User's manual to the end user.

12 —— FAULT REPORT FORM

To meet the requirements of Directive 93/42/CEE as amended, the company has established a post-marketing surveillance procedure to monitor any problems generated by the use of our products. This commitment includes the requirement that both user and manufacturer inform the competent authorities of any incident caused to patient or user by malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use. We kindly ask you to inform us of any anomalies by sending us the sheet attached to the last page of this manual.

13 —— SYMBOLS

SYMBOLS

Do not overturn

Fragile

Keep dry

Type B device

Alternating current

General warnings

Separate collection for electrical and electronic equipment

Manufacturer

Double insulation

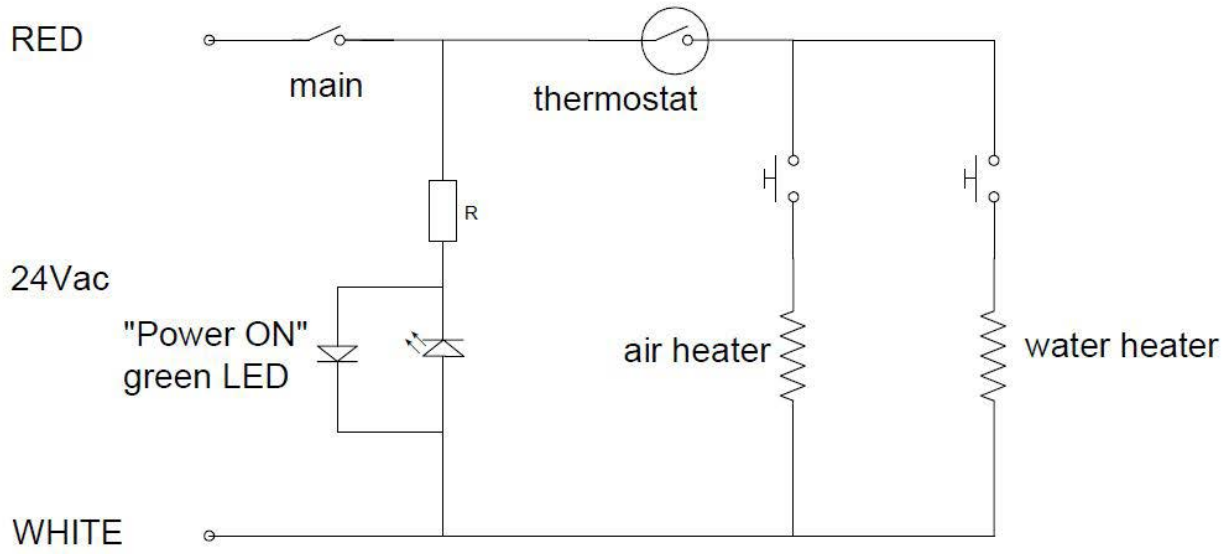
Batch number

Sterilise

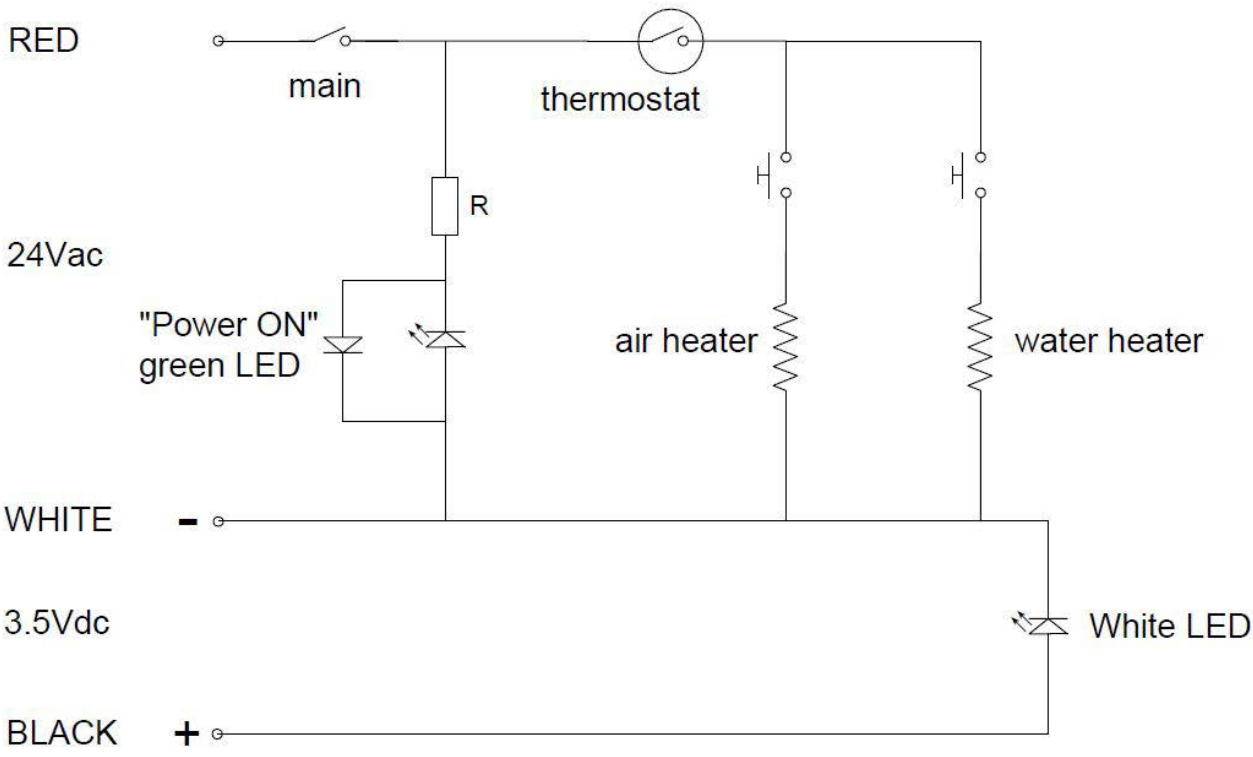
Consult User's manual

14 —— WIRING DIAGRAM

14.1 – VERSION 6F



14.2 – VERSION L



INSTRUCTIONS FOR CLEANING AND STERILIZATION OF MINILIGHT, MINIMATE, MINIBRIGHT SYRINGES IN ACCORDANCE WITH UNI EN ISO 17665 REQUIREMENTS

Warning 	• Sterilization must be performed even when using the syringe for the first time. • Inappropriate sterilization is dangerous for patients and operators. • Do not perform spray sterilization. Do not place in any disinfectant liquids. • Do not perform cold chemical or hot air sterilization. • The appointed staff must be specialized and trained. • Use the disinfectant in accordance with the specifications set by the manufacturer indicated on the label. • Do not use chlorine-based solutions. • When sterilizing more than one piece in one autoclave do not exceed its maximum load capacity.
Preparation	Remove dirt from the surface using a disposable paper tissue. Let air and water flow from the syringe for about 30 seconds in order to clean the internal channels. Press the button locateci at the bottom of the sleeve and slide the stainless steel sleeve off the syringe body. Unscrew the ferrule and remove the tip.
Manual cleansing	Wipe with a disposable paper tissue and with the aid of drinking water to remove any impurities and dirt
Automatic cleansing 	Not available
Manual disinfection	Perform disinfection only with a disposable tissue and with compatible disinfectants (in accordance with the instructions included in the product label and technical data sheet). Recommended disinfectants: • Incidin liquid • FD 322 Durr • Mikrozid AF Liquid
Automatic disinfection 	Not available
Manual drying	Dry with disposable paper tissue. Dry with dry, clean and uncontaminated compressed air both internally and externally until completely dry. Do not dry with hot air.
Automatic drying	Not available
Maintenance and checking	No particular maintenance is required. There is no objective term limiting the usage life of the sleeve: check to see if there are if any damages or signs of wear and tear, replace the part if necessary.
Packaging	Use appropriately sized sterilization packages made of thermoweldable film.
Sterilization 	The sleeve and tip are autoclavable. Sterilize using EN 13060 ISO 17665-1 compliant class-B steam autoclave. Sterilize with 3 phases fractionated vacuum 134° C +/- 1 °C with 2.13 bar pressure, 4 minutes wait. Never exceed 135° C. The autoclave must be validated.
Preservation	No particular requirements other than keeping them in their sealed and sterilized package. Keep them in an appropriate environment and out of direct sunlight and in a dry place, which should have low bioburden where possible.

FAULT REPORT FORM

PRODUCT _____

TYPE _____ BATCH _____

REPORTED BY _____

COMPANY _____

_____

_____

TYPE OF REPORT

☐ ANOMALY ☐ SUGGESTIONS ☐ _____

DESCRIPTION

_____

_____

_____

_____

_____

NOTES

_____

_____

_____

_____

_____

DATE _____ SIGNATURE _____

SEND TO:

LUZZANI DENTAL SRL
Via Torino 3 - Senago (MI) - ITALY
Tel. +39 02 99010379)

04

SYR3

SIRINGA DENTALE
DENTAL SYRINGE

MANUALE D'USO
INSTRUCTION MANUAL
MODE D'EMPLOI
GEBRAUCHSANLEITUNG
MANUAL DE USO

CE 0051 Dispositivo Medico conforme alla direttiva 93/42/CE
FARO SPA Ornago (Italy)

FARO

DAL 1948: ESPERIENZA
E RINNOVAMENTO

DICHIARAZIONE DI CONFORMITÀ CE

CE DECLARATION OF CONFORMITY

Il fabbricante FARO S.p.A.Via Faro n°15
The manufacture 20060 Ornago (Milano) ITALY
dichiara sotto la propria responsabilità, che il prodotto:
declares under it's own responsibility that the product:
Designazione del prodotto: Siringa dentale
Product's designation: Dental syringe
Modello: SYR3
Model:: SYR3
E' nuovo di fabbrica, secondo quanto previsto dall'articolo. 6 par. 2 del D.L. 626/94.
It is newly manufactured in accordance with art. 6 par. 2 of Italian law D.L. n°. 626/94.
E' conforme alle seguenti Direttive europee ed ai rispettivi recepimenti nazionali e modifiche successive.
It complies with the following European Directives and their implementations into national laws and subsequent modifications.
93/42/CEE (D.L. 24 febbraio 1997, n°46) direttiva dispositivi medici
93/42/EEC (Medical Device Directive)
Classe di appartenenza dell'apparecchio: II a

Dott. Angelo Favonio
Amministratore Delegato
Managing Director

La presente è una riproduzione conforme all'originale, che è archiviato presso il fabbricante con i relativi numeri di serie.
This is a true copy. The original is placed on manufacturer's files with the relative serial numbers.

NORME DI SICUREZZA

La siringa dentale è destinata esclusivamente ad essere utilizzata in uno studio dentistico, solo da personale medico o dall'assistente sotto responsabilità del medico, al fine di eseguire specifici interventi di pulizia e asciugatura del campo operativo.
Il dispositivo deve essere installato su uno specifico sistema di alimentazione (riunito dentale) e dovrà essere connesso ad un cordone dedicato FARO.
Il dispositivo deve essere sterilizzato in autoclave prima di utilizzarlo su un nuovo paziente.
Il dispositivo non è fornito sterile, quindi deve essere sterilizzato prima dell'utilizzo.
Eseguire solo le operazioni riportate nel seguente manuale; in qualsiasi altro caso rivolgersi all'assistenza tecnica.

INSTALLAZIONE CORDONE E SIRINGA

L'installazione deve essere eseguita solo da personale specializzato.

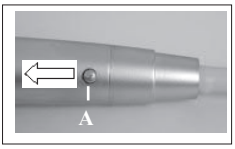
Verificare che nella confezione siano contenuti i seguenti componenti:
- Siringa dentale.
- Cordone alimentazione.
- Guarnizioni O-ring.
- Specillo.
- Manuale di istruzioni.

Collegare il tubetto AZZURRO all'entrata ARIA, quello VERDE all'entrata H2O e fissare il cordino di sicurezza.
Collegare il cordone alla siringa avvitando l'apposita ghiera. Verificare i valori di pressione di acqua e aria e accertarsi che la temperatura dei fluidi sia quella ambiente (Tmax < 41 °C).

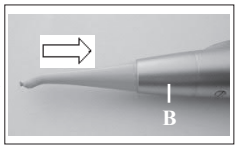
ISTRUZIONI D'USO

- Per erogare l'acqua premere il pulsante di colore verde.
- Per erogare l'aria premere il pulsante di colore azzurro.
- Per ottenere lo spray premere contemporaneamente i due pulsanti

Smontaggio del guscio e del beccuccio



- Per togliere il guscio, premere il pulsante **"A"** e sfilarlo nel senso della freccia.



Per togliere il beccuccio, svitare la ghiera **"B"** e sfilarlo nel senso della freccia.

- Prima di rimontare la siringa ingrassare con grasso di vaselina le 2 guarnizioni sul corpo interno e il tubetto metallico del beccuccio.

Pulizia del dispositivo

Pulire il guscio e il beccucccio sotto acqua corrente o utilizzando soluzioni a base di alcool.

Sterilizzazione

- Sfilare il guscio completo di beccuccio dal corpo siringa.
- Pulire il guscio e il beccuccio.
- Sterilizzare il guscio completo di beccuccio in autoclave. Il guscio incorpora una valvola che impedisce la contaminazione del corpo della siringa.

Pulizia degli ugelli

Qualora i piccoli fori del beccuccio da cui fuoriescono acqua e aria fossero ostruiti, liberare il passaggio utilizzando l'apposito specillo in dotazione.

SPECIFICHE TECNICHE

Siringa a tre funzioni SYR3

- Pressione di esercizio aria : **4 bar**
- Pressione di esercizio acqua : **2 bar**
- Portata aria : **10 l/min**
- Portata acqua : **80÷100 ml/min**
- Tubetto azzurro per passaggio : **ARIA**
- Tubetto verde per passaggio : **ACQUA**
- Peso : **100 g**
- Temperatura ACQUA-ARIA : **quella di rete**
- Immagazzinamento con imballo integro per un massimo 15 settimane con**:**
  - **Temperatura ambiente da -20°C a +70°C**
  - **Umidità relativa dal 10% al 90%**
  - **Pressione atmosferica da 500 a 1060 mBar.**

- Guscio e beccuccio sterilizzabili 

SAFETY RULES

GB

The SYR3 dental syringe is designed exclusively for use in dentistry, by dental professionals or an assistant under a dentist's supervision, in order to perform specific cleaning and drying operations on the operating area. The device must be installed on a specific supply system (dental unit) and be connected to a dedicated FARO hose. The device must be sterilised in an autoclave before it is used on another patient. The device is not supplied sterile and must therefore be sterilised prior to use. Perform only the operations contained in the following manual. In all other scases request technical assistance.

HOSE AND SYRINGE INSTALLATION

Installation must be performed by specialised personnel only.

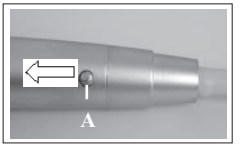
Check that the package contains the following components:
- Dental syringe.
- Supply hose.
- O-rings.
- Probe.
- Instruction manual.

Connect the BLUE tube to the AIR intake, the GREEN tube to the H_2O intake and fasten the safety cord.
Connect the hose to the syringe by tightening the ring nut. Check the water and air pressure values and make sure the fluids are at ambient temperature (Tmax < 41°C).

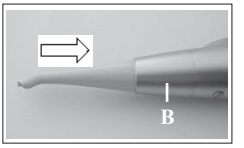
INSTRUCTIONS FOR USE

- For water, press the green button.
- For air, press the blue button.
- For spray, press both buttons simultaneously.

Disassembling sheath and nozzle



- To remove the sheath, press button **"A"** and pull off in the direction of the arrow.



- To remove the nozzle, unscrew ring **"B"** and pull off in the direction of the arrow.

- Before reassembling the syringe, grease the two seals on the inner body and the metal tube of the nozzle with petroleum jelly.

Cleaning the device

Clean the sheath and the nozzle under running water or use alcohol-based solutions.

Sterilisation
- Pull the sheath, complete with the nozzle, from the body of the syringe.
- Clean sheath and nozzle.
- Sterilise the sheath complete with the nozzle in an autoclave. The sheath has a valve that prevents contamination of the body of the syringe.

Cleaning nozzle holes
- If the tiny holes in the nozzle that the water and air come out of are plugged, free the by using the specially provided probe.

TECHNICAL SPECIFICATIONS

Three-function syringe SYR3

- Air pressure **:4 bar**
- Water pressure **:2 bar**
- Air flow **:10 l/min**
- Water flow **:80-100 ml/min**
- Blue tube for passage of **:AIR**
- Green tube for passage of **:WATER**
- Weight **:100 g**
- WATER-AIR temperature system temperature
- Storage with packaging intact for a maximum of 15 weeks with:
  - **Ambient temperature from -20°C to +70°C**
  - **Relative humidity from 10% to 90%**
  - **Atmospheric pressure from 500 to 1060 mbar.**

- Sterilisable sheath and nozzle 

NORMES DE SECURITE

F

La seringue dentaire est conçue pour être utilisée exclusivement dans un cabinet dentaire, uniquement par du personnel médical ou par l'assistant, sous la responsabilité du médecin. Elle permet d'effectuer les opérations de nettoyage et de séchage de la partie à traiter.
Le dispositif doit être installé sur un système d'alimentation spécifique (groupe dentaire) et devra être branché à un cordon dédié FARO.
Le dispositif doit être stérilisé dans un autoclave avant d'être utilisé sur un nouveau patient.
Le dispositif n'est pas fourni stérile, il doit donc être stérilisé avant l'emploi.
Effectuer uniquement les opérations indiquées dans le manuel présent. Dans tous les autres cas, s'adresser au service d'assistance technique.

INSTALLATION CORDON ET SERINGUE

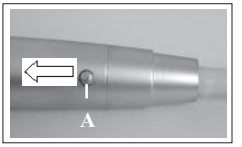
L'installation doit être effectuée uniquement par du personnel spécialisé.
S'assurer que les composants suivants sont présents dans l'emballage :
- Seringue dentaire
- Cordon d'alimentation
- Joints toriques
- Sonde
- Mode d'emploi.

Connecter le tuyau BLEU à l'arrivée d'AIR, le tuyau VERT à l'arrivée d'H2O et fixer le câble de sécurité.
Connecter le cordon à la seringue en vissant la bague prévue à cet effet. Contrôler les valeurs de pression de l'eau et de l'air et s'assurer que la température des fluides est la même que la température ambiante (T° max < 41 °C).

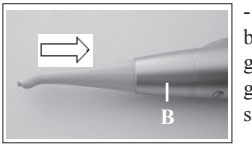
MODE D'EMPLOI

- Pour actionner l'arrivée d'eau, appuyer sur le bouton vert.
- Pour actionner l'arrivée d'air, appuyer sur le bouton bleu.
- Pour obtenir le jet, appuyer simultanément sur les deux boutons.

Démontage de la coque et de l'embout



- Pour retirer la coque, appuyer sur le bouton « **A** » et la faire glisser en suivant le sens de la flèche.



- Pour retirer l'embout, dévisser la bague « **B** » et le faire glisser en suivant le sens de la flèche.

- Avant de remonter la seringue, graisser les deux joints sur le corps interne et le tuyau métallique de l'embout à l'aide de graisse de vaseline.

Nettoyage du dispositif

- Nettoyer la coque et l'embout à l'eau courante ou à l'aide de solutions à base d'alcool.

Stérilisation

- Retirer la coque et l'embout du corps de la seringue en les faisant glisser.
- Nettoyer la coque e l'embout.
- Stériliser la coque et l'embout dans un autoclave. La coque est dotée d'une valve qui empêche la contamination du corps de la seringue.

Nettoyage des gicleurs

Si les petits trous d'où sortent l'eau et l'air sont bouchés, les nettoyer à l'aide de la sonde spéciale fournie.

DETAILS TECHNIQUES

Seringue à trois fonctions SYR3

- Pression d'exercice air : **4 bar**
- Pression d'exercice eau : **2 bar**
- Portée air : **10 l/min**
- Portée eau : **80÷100 ml/min**
- Tuyau bleu pour le passage : **AIR**
- Tuyau vert pour le passage : **EAU**
- Poids : **100 g**
- Température EAU-AIR : **celle du réseau**
- Stockage dans l'emballage intègre pendant 15 semaines maximum dans les conditions suivantes :
  - **Température ambiante de -20°C à +70°C**
  - **Humidité relative de 10% à l 90%**
  - **Pression atmosphérique de 500 à 1060 mBar.**

- Coque et embout à stériliser 

SICHERHEITSNORMEN

D

Die Dentalspritze ist ausschließlich für den Einsatz in einer Zahnarztpraxis und durch ärztliches Personal bzw. durch den zahnärztlichen Assistenten und unter der Verantwortung des Arztes vorgesehen und darf nur für spezifische Reinigungsarbeiten und das Trocknen während der Behandlungen eingesetzt werden.
Die Vorrichtung muss auf einem spezifischen Versorgungssystem (Dentaleinheit) installiert und an ein eigenes FARO-Kabel angeschlossen werden.
Die Vorrichtung ist vor der Behandlung jedes neuen Patienten im Autoklav zu sterilisieren.
Die Vorrichtung wird nicht sterilisiert geliefert und ist demzufolge vor dem Gebrauch zu sterilisieren.
Das Gerät nur für die in der Anleitung beschriebenen Anwendungszwecke einsetzen; in jedem anderen Fall den technischen Kundendienst zurate ziehen.

INSTALLATION VON KABEL UND SPRITZE

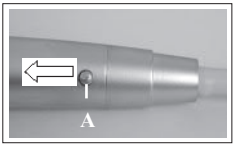
Die Installation darf ausschließlich von Fachpersonal durchgeführt werden.
Sicherstellen, dass alle folgenden Teile in der Verpackung enthalten sind:
- Dentalspritze.
- Versorgungskabel.
- O-Ring-Dichtungen.
- Sonde.
- Bedienungsanleitung

Den HELLBLAUEN Schlauch an den LUFTEINGANG, den GRÜNEN an den H_2O-Eingang anschließen und das Sicherheitskabel fixieren.
Das Kabel durch Einschrauben des dementsprechenden Rings an die Spritze anschließen. Die Wasser- und Luftdruckwerte prüfen und sicherstellen, dass die Temperatur der Flüssigkeiten bei Raumtemperatur liegt (Tmax < 41°C).

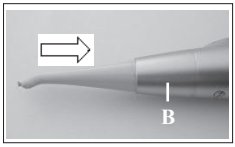
GEBRAUCHSANLEITUNG

- Zur Wasserabgabe den grünen Knopf drücken.
- Zur Luftabgabe den hellblauen Knopf drücken.
- Für den Spray beide Knöpfe gleichzeitig drücken.

Zerlegen der Hülse und der Tülle



- Zum Entfernen der Hülse den Knopf **„A“** drücken und die Hülse in Pfeilrichtung herausziehen.



- Zum Entfernen der Tülle den Ring **„B“** ausschrauben und die Tülle in Pfeilrichtung herausziehen.

- Vor dem erneuten Zusammenbau der Spritze die 2 Dichtungen am inneren Körper und das Metallrohr der Tülle mit Vaselinfett schmieren.

Reinigung der Vorrichtung

Die Hülse und die Tülle unter fließendem Wasser bzw. unter Anwendung von Lösungen auf Alkoholbasis reinigen.

Sterilisierung

- Die Hülse einschließlich der Tülle vom Spritzenkörper abziehen.
- Die Hülse und die Tülle reinigen.
- Die Hülse einschließlich der Tülle im Autoklav sterilisieren. Die Hülse beinhaltet ein Ventil, das die Kontamination des Spritzenkörpers untersagt.

Reinigung der Düsen

Bei Verstopfung der kleinen Öffnungen der Tülle, aus denen das Wasser und die Luft austreten, sind sie mit der eigens dafür mitgelieferten Sonde zu reinigen.

TECHNISCHE SPEZIFIKATIONEN

3-Funktions-Spritze SYR3

- Betriebsdruck Luft : **4 bar**
- Betriebsdruck Wasser : **2 bar**
- Luft-Fördermenge : **10 l/min**
- Wasserdurchfluss : **80-100 ml/min**
- Hellblauer Schlauch für : **LUFT**
- Grüner Schlauch für : **WASSER**
- Gewicht : **100 g**
- Temperatur WASSER/LUFT : **wie aus der Leitung**
- Lagerung mit unversehrter Verpackung höchstens 15 Wochen bei:
  - **Raumtemperatur zwischen -20°C und +70°C**
  - **Relativer Feuchtigkeit zwischen 10% und 90%**
  - **Luftdruck zwischen 500 und 1060 mbar**

- Hülse und Tülle sterilisierbar 135°C

NORMAS DE SEGURIDAD *E*

La jeringa dental está destinada exclusivamente a ser utilizada en un estudio dental, sólo por personal médico o adjunto bajo responsabilidad del médico, para ejecutar intervenciones específicas de limpieza y secado del campo operativo.
El aparato tiene que ser instalado en un sistema de alimentación específico (asociado al dental) y tendrá que ser conectado a un cable especial FARO.
El aparato tiene que ser esterilizado en autoclave antes de utilizarlo para un nuevo paciente.
El aparato no se proporciona ya esterilizado, por lo tanto tiene que ser esterilizado antes de su empleo.
Ejecutar únicamente las operaciones indicadas en el siguiente manual; en cualquier otro caso dirigirse a la asistencia técnica.

INSTALACIÓN DEL CABLE Y LA JERINGA

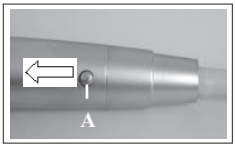
La instalación sólo debe ser realizada por personal especializado.
Comprobar que en el paquete estén contenidos los siguientes componentes:
- Jeringa dental.
- Cable de alimentación.
- Guarniciones O-ring.
- Explorador.
- Manual de instrucciones.

Conectar el tubo AZUL a la entrada AIRE, el VERDE a la entrada H2O y fijar el cordel de seguridad.
Conectar el cable a la jeringa atornillando la abrazadera apropiada. Comprobar los valores de presión de agua y aire y cerciorarse de que la temperatura de los fluidos sea la del ambiente (T. max < 41 °C).

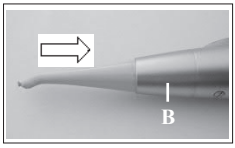
INSTRUCCIONES DE USO

- Para erogar el agua pulsar el interruptor de color verde.
- Para erogar el aire pulsar el interruptor de color azul.
- Para obtener el espray pulsar al mismo tiempo los dos interruptores

Desmontaje de la cubierta y la embocadura



- Para sacar la cubierta pulsar el interruptor **"A" y deslizarlo** en el sentido de la flecha.



Para sacar la embocadura, desatornillar la abrazadera "B" y deslizarla en el sentido de la flecha.

- Antes de reensamblar la jeringa engrasar con vaselina las 2 guarniciones del cuerpo interno y el tubo metálico de la embocadura.

-Limpieza del aparato

Limpiar la cubierta y la embocadura bajo agua corriente o utilizando soluciones a base de alcohol.

Esterilización

- Quitar la cubierta, incluyendo la embocadura, del cuerpo de la jeringa.
- Limpiar la cubierta y la embocadura.
- Esterilizar en autoclave la cubierta incluyendo la embocadura. La cubierta incorpora una válvula qué impide la contaminación del cuerpo de la jeringa.

Limpieza de los inyectores

En caso de que los pequeños agujeros de la embocadura rebosen agua y aire y estuvieran obstruidos, liberar el paso utilizando las escobillas incluidas en la dotación del aparato.

CARACTERÍSTICAS TÉCNICAS

Jeringa a tres funciones SYR3

- Presión de ejercicio aire **: 4 bares**
- Presión de ejercicio agua **: 2 bares**
- Caudal de aire **: 10 l/min**
- Caudal de agua **: 80÷100 ml/min**
- Tubo azul para paso de **: AIRE**
- Tubo verde para paso de **: AGUA**
- Peso **: 100 g**
- Temperatura AGUA-AIRE **: la de la red**
- Almacenamiento con embalaje íntegro por un máximo de 15 semanas con:
  - **Temperatura ambiente entre -20°C y +70°C**
  - **Humedad relativa del 10% al 90%**
  - **Presión atmosférica de 500 a 1060 mBar.**

- Cubierta y embocadura esterilizables

CERTIFICATO DI GARANZIA

La Faro concede al cliente finale una garanzia di **12 mesi**, dalla data della fattura di acquisto. La riparazione in garanzia dovrà essere effettuata presso **la FARO o presso un riparatore autorizzato FARO;** spese e rischi di trasporto sono a carico dell'acquirente. Il certificato di garanzia, che si trova sul risguardo del presente libretto, è ritenuto valido soltanto se sarà compilato in tutte le sue parti e recherà il timbro del rivenditore. Il certificato consentirà la riparazione in garanzia (durante il periodo di validità) soltanto se accompagnerà l'articolo da riparare insieme alla bolla o fattura di vendita. La garanzia risponde dei guasti dovuti alla cattiva qualità del materiale o a difetti di fabbricazione; in caso di reclamo fondato la garanzia consentirà la riparazione o la sostituzione gratuita. **E' esclusa la possibilità di ottenererisarcimento di danni e/o di interessi.** La garanzia non è ritenuta valida, a insindacabile giudizio della

FARO, in caso di manomissione, danneggiamento, di scorretta utilizzazione, di cattiva manutenzione o di normale usura.

GUARANTEE CERTIFICATE

FARO grants to the final customer a **12-months** guarantee starting from the date of the purchase invoice. Repairs under the guarantee shall be done at the **FARO premises or by an authorized FARO Service** person with transportation costs and risks at the expense of the purchaser. The guarantee certificate found on the endleaf of this booklet is considered valid only if it is entirely completed and bears the reseller's stamp. Repairs under guarantee (during the period of effectiveness) will be done only if the article to be repaired is accompanied by the shipping note or purchase invoice. The guarantee covers failures due to poor material quality or manufacturing detects and in case of legitimate claim the guarantee will allow repair or replacement free of charge. **No compensation for damages and/or interest will be recognized**. The guarantee is not deemed valid in the final judgement of FARO in case of tampering. damage, incorrect use, faulty maintenance or normal wear.

CERTIFICAT DE GARANTIE

FARO accorde au client final **douze mois** de garantie, à partir de la date de la facture d'achat. Les réparations couvertes par la garantie doivent être executées exclusivement chez **FARO ou par un réparateur autorisé FARO,** avec les frais et les risques du transport à charge de l'acheteur. La garantie qui se trouve sur la garde de ce livret est considerée valable seulement si celui-ci est rempli entièrement et porte le timbre du revendeur. Les réparations sous garantie (pendant la période de validité) seront effectuées seulement si l'article à reparer est accompagné du bulletin ou de la facture d'achat. La garantie répond des pannes dues à la mauvaise qualité du matériel ou à des défauts de fabrication. En cas de réclamation fondée la garantie permettra la réparation ou la substitution gratuite. **La possibilité d'obtenir le dédommagement des dommages et/ou des intérêts est exclue.** La garantie n'est pas considerée valable, au jugement sans appel de FARO, en cas de violation, d'endommagement, d'utilisation incorrecte, de mauvais entretien ou d'usure normale.

GARANTIEZERTIFIKAT

Das Haus FARO gewährt seinem Endkunden eine Garantie von **12 Monaten** ab Rechnungsdatum. Reparaturen sind durch das Haus FARO oder einen von der FARO befugten Reparaturbetrieb auszuführen. Transportenspesen und-Risiken gehen zu Lasten des Käufers. Das Garantiezertifikat im inneren Umschlagteil dieser Broschüre gilt nur dann, wenn es vollständig ausgefüllt ist und den Stempel des Wiederverkäufers trägt. Mit dem Garantiezertifikat ist eine Reparatur-während der Gültigkeitsdauer der Garantie-nur dann möglich, wenn dem Gerät der Lieferschein bzw. die Verkaufsrechnung beiliegt. Die Garantie erstreckesich auf Schäden, die durch Materialfehler bzw. Fabrikationsdefekte entstanden. Bei begründeter Beanstandung erfolgt die kostenlose Reparatur bzw. Ersatz. Einschadenersatz in Geld bzw. von Zinsen ist augeschlossen. Die Garantie ist nicht gültig, wenn der Gerät-auf unanfechtbares Urteil der Hauses FARO hin-abgeändert, beschädigt, schlecht gewartet oder unsachgemäß.

CERTIFICADO DE GARANTIA

FARO otorga al Cliente final una garantía de **12 meses** contados a partir de la fecha de la factura de compra. La reparación bajo garantía tendrá que realizarse exclusivamente en FARO o en el establecimiento del Servicio de Asistencia autorizado FARO ; los gastos y riesgos del transporte están a cargo del comprador. El certificado de garantiá que se encuentra en la anteportada del presente manual es válido sólo si está rellenado en todas sus partes y lleva el sello del revendedor. El certificado permite la reparación bajo garantiá (durante el periodo de validez) únicamente si acompaña el artículo a reparar junto con el albarán o factura de venta. La garantiá cubre las averiás debidas a la mala calidad del material o defectos de fabricación: en caso de reclamos motivados, la garantiá permitirá la reparación o reemplazo gratuitos. **Se excluye la posibilidad de obtener resarcimiento por daños y/o por intereses.** La garantiá no es válida, a completa discreción de FARO,en caso de modificaciones no autorizadas, de alteraciones, de empleo incorrecto, de mantenimiento indebidoo de desgaste normal.

12 mesi-months-mois-monaten-meses

nome-name-nom-vorname-nombre

cognome-surname-prenom-nachname-apellido

indirizzo-address-adresse-auschrift-direccion

città-town-ville-ort-ciudad

SN _____ SD _____

data d'acquisto-purchase date-date d'achat
einkaufdatum-fecha de compra

Siringa dentale SYR 3 ☐

versione-version-version-modell-versión

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

ED 12/10 COD. 988014_REV.00

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@faro-dental.de

Azienda
Certificata

CERT. 9124.FAR2

CERT. 9120.FAR1

Spittoon valve 3

EN

Installation and Operating Instructions

CE

7560100003L02

DÜRR DENTAL

1801V002

Contents

EN

Important information

Product description

Installation

Operation

Troubleshooting

Appendix

EN

1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Warning – dangerous high voltage


Biohazard warning

The warnings are structured as follows:

SIGNAL WORD
Description of the type and source of danger
Here you will find the possible consequences of ignoring the warning
› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
Immediate danger of severe injury or death
– **WARNING**
Possible danger of severe injury or death
– **CAUTION**
Risk of minor injuries
– **NOTICE**
Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.


Comply with the Operating Instructions.


Wear hand protection.


Wear protective goggles.


Use a face mask.


Refer to the accompanying electronic documents.


Cleaning button


Air


Vacuum


Manufacturer

REF Order number

SN Serial number

1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The spittoon valve is designed for installation in a treatment unit in dental surgeries or dental clinics.

The installation of the spittoon valve into a treatment unit helps to avoid suction noises emanating from the spittoon.

2.2 Intended use

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

2.4 General safety information

- When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
- Prior to each use, check condition of the device and make sure it is in perfect working order.
- Do not convert or modify the units.
- Observe the Installation and Operating Instructions.
- Make the Installation and Operating Instructions available to the person operating the device at all times.

2.5 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1 respectively).

Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

2.6 Qualified personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

- Instruct or have every user instructed in handling the unit.

Installation and repairs

- Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.7 Protection from electric shock

- When working on the units observe all the relevant electrical safety regulations.
- Never touch the patient and unshielded plug connections on the device at the same time.
- Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

- Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "13 Information about EMC in accordance with EN 60601-1-2".
- The appliance is designed for the use in health care establishments (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.

2.8 Only use genuine parts

- Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
- Only use only genuine working parts and spare parts.

2.9 Transport

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

EN

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

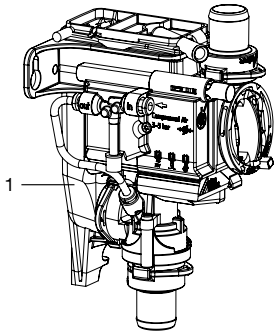
› Only transport the device in its original packaging.
› Keep the packing materials out of the reach of children.

2.10 Disposal

The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

› Decontaminate potentially contaminated parts before disposing of them.
› Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

3 Overview



1 Spittoon valve

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Spittoon valve 3 . . . . . 7560700xxx

– Spittoon valve

3.2 Special accessories

The following optional items can be used with the device:

Switch control panel 7560-520-00

3.3 Wear parts and spare parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Protective strainer 0700-702-06E

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

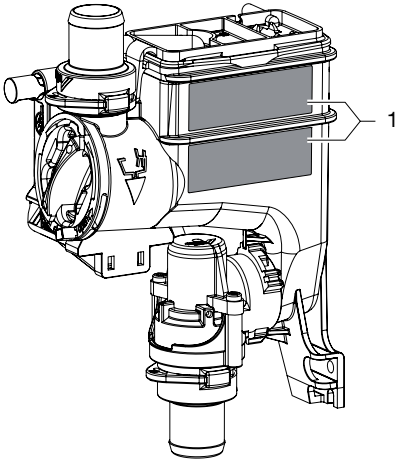
4 Technical data

EN

Electrical data		
Safety low voltage	(AC/DC)	
	V	24
Frequency	Hz	50 - 60
Nominal current	A	0.1
Rated power	W	2.4
Type of protection		IP 21
Electrical data, suction unit relay		
Switching voltage	(AC/DC)	
min.	V	5
max.	V	24
Switching current		
min.	mA	10
max.	A	2
Connections		
Supply and waste water connection		
DürrConnect	mm	∅ 20
Collection vessel vent connection	mm	∅ 9
Compressed air connection	mm	∅ 4
Media		
Compressed air		
min.	bar / MPa	3 / 0.3
max.	bar / MPa	5 / 0.5
Fluid flow rate, max.	l/min	3.5
Fluid temperature, max.	°C	35
Suction system pressure		
max.	mbar/hPa	-200
Absolute	mbar/hPa	800
General data		
Duty cycle	%	40
Medical device		Class I
Weight	g	240
Dimensions (H x W x D)	cm	143 x 75 x 110
Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	< 95
Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70
Air pressure	hPa	700 - 1060

4.1 Type plate

The type plates are located on the side of the fluid collector.



1 Type plate

4.2 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation

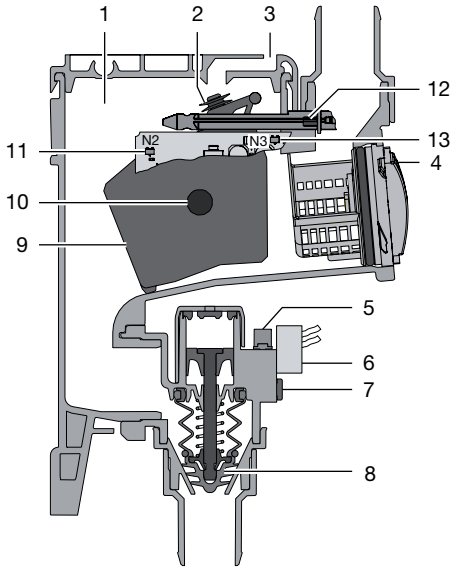


Figure 1: Idle phase

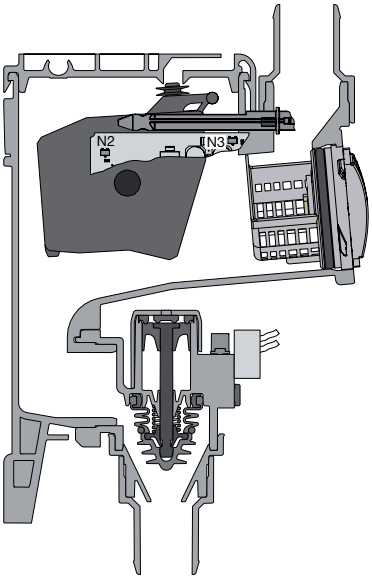


Figure 2: Operational phase

1 Fluid collector
2 Air extraction seal
3 Vent
4 Protective strainer
5 Exhaust air damper
6 Solenoid valve
7 Compressed air connection
8 Shut-off valve
9 Float sensor
10 Magnet in float sensor
11 Float sensor detection
12 Magnet in cleaning button
13 Cleaning button detection sensor

5.1 Operating function

The waste water from the spittoon flows through the coarse filter into the collector vessel. If enough fluid is present then the magnet in the float sensor is detected by the control electronics. The control electronics start up the suction unit with the suction unit relay and actuate the solenoid valve for the compressed air supply. The inflowing compressed air opens the shut-off valve via a piston. The fluid from the collector vessel is then sucked into the suction pipe. As soon as the fill level in the collector vessel has dropped, this is detected by the control electronics and the solenoid valve is switched off. While waste water continues to flow in from the spittoon the collector vessel refills and the process starts again from the beginning.

5.2 Cleaning function

The cleaning function is activated by permanent pressure on the yellow cleaning button on the spittoon valve or on the cleaning button on the switch control panel (if present). As a result the solenoid valve for the compressed air supply, and therefore the shut-off valve, is opened and the suction unit relay is actuated in order to start up the suction unit.

The cleaning and disinfection solutions can now be aspirated without hindrance through the spittoon valve into the suction pipe and into the suction unit. A suction noise can be heard at the spittoon.

6 Requirements

6.1 Setup options

– Installation in treatment units in dental surgeries or dental clinics.

6.2 Preparing for the installation

Prior to installation of the spittoon valve the following media should be checked and if necessary adjusted; refer also to "4 Technical data":

– Vacuum of the suction system
– Compressed air supply
– Water amount from the spittoon

Do not remove the gold collector or the coarse sieves from the spittoon.

6.3 Hose materials

For waste connections and suction lines only use the following hose types:

– Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
– Hoses that are resistant to dental disinfectants and chemicals

Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

– Rubber hoses
– Completely PVC hoses
– Hoses that are not sufficiently flexible

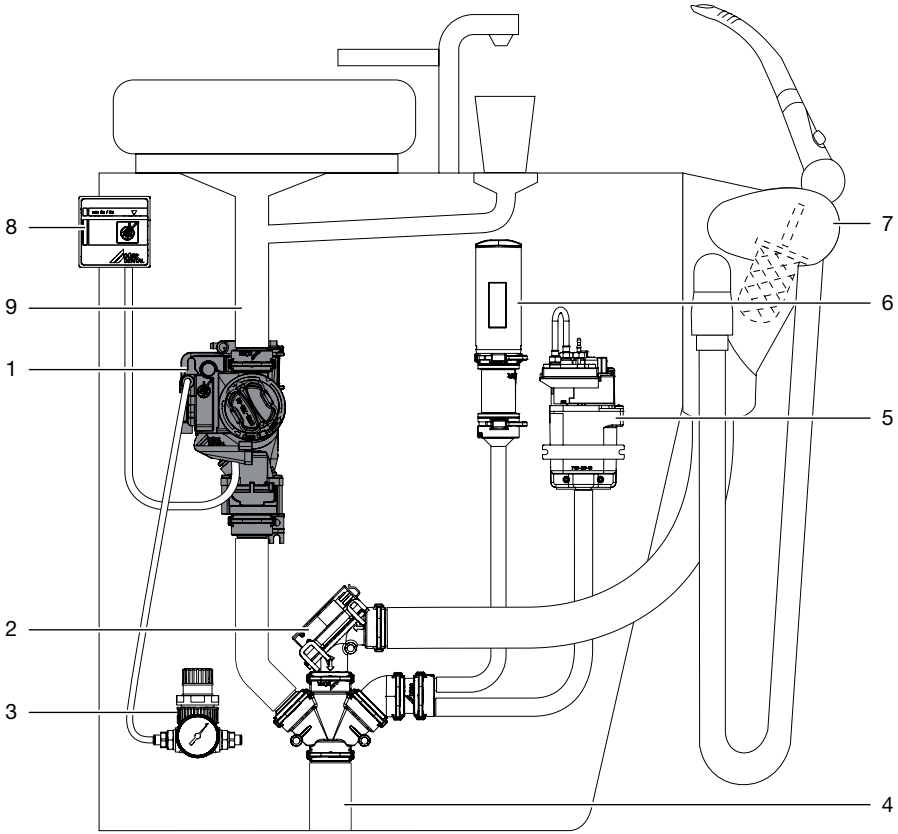
6.4 Information about electrical connections

› The supply voltage to the device must satisfy the requirements for two patient protection (MOPP) protective measures as set out in IEC 60601-1 in relation to the supply network.
› The supply voltage must satisfy the following voltage/power requirements:
24 V AC/DC, 50-60 Hz, at least 2.4 VA

7 Installation

7.1 Installation overview

EN

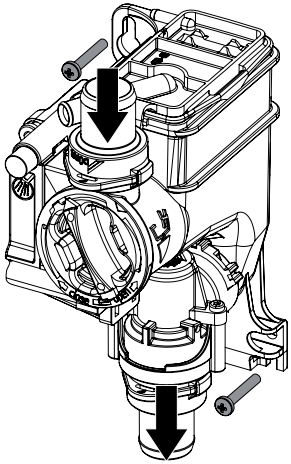


1 Spittoon valve
2 Station selection valve
3 Pressure reducer
4 Suction pipe connection
5 Rinsing unit
6 Auxiliary air nozzle
7 Hose manifold
8 Switch control panel
9 Spittoon outlet

7.2 Installation of the spittoon valve

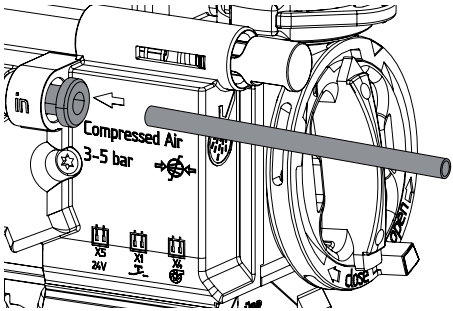
The cleaning function can be activated via the yellow button. For this reason the spittoon valve should be positioned in an easily accessible location. If this is not possible, a separate switch control panel can be used as an optional accessory.

› Disconnect the treatment unit from the power supply and secure it so that it cannot be switched back on again.
› Firmly screw the spittoon valve onto a suitable place on the treatment unit.
› Connect the drain hose from the spittoon to the inlet of the spittoon valve.
› Connect the outlet of the spittoon valve to the suction pipe.



7.3 Establishing the compressed air connection

› Disconnect a suitable compressed air line from the treatment unit.
› Install a T-piece with 4 mm branch in the compressed air line.
› Connect a compressed air hose to the T-piece.
› Route the compressed air hose to the spittoon valve, cut it off straight and insert it.



To pull off the compressed air hose from the spittoon valve, press the black sleeve on the compressed air connection inwards.

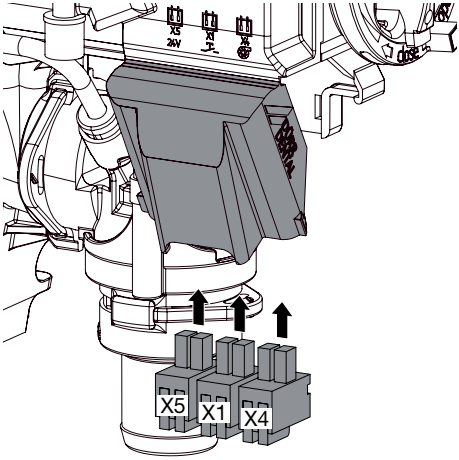
7.4 Electrical connections

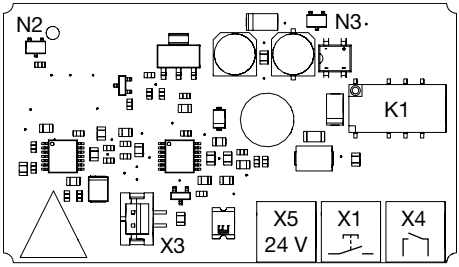
Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

The requirements of IEC 60601-1 must be satisfied during installation.

EN

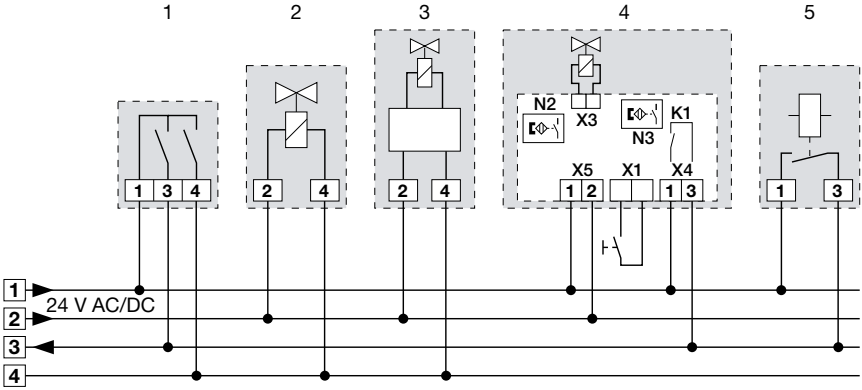
- Open the cover of the control electronics.
- Route the power supply and control line to the spittoon valve.
- Attach the connector to the connection lines.
- Plug in the connector at the corresponding positions on the control electronics.
- Secure the connection lines with cable ties to the housing.





X1 Cleaning button for switch control panel
X3 Solenoid valve
X4 Control line for suction unit
X5 Power supply
K1 Suction unit relay
N2 Float sensor detection
N3 Cleaning button detection sensor

7.5 Circuit diagram



1 Hose manifold
2 Station selection valve
3 Rinsing unit
4 Spittoon valve
X1 Cleaning button for switch control panel
X3 Solenoid valve
X4 Control line for suction unit
X5 Power supply
K1 Suction unit relay
N2 Float sensor detection
N3 Cleaning button detection sensor
5 Suction machine relay in the treatment unit

8 Commissioning and first start-up

EN

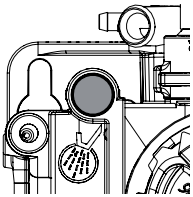
In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

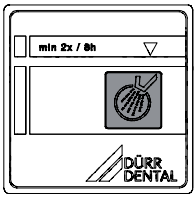
› Turn on the unit power switch or the main surgery switch.
› Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
› Carry out a functional inspection of the system and check the connections for leaks.
› Attach and screw on the covers.

9 Disinfection and cleaning

NOTICE
Device malfunctions or damage due to use of incorrect media
Guarantee claims may become invalid as a result.
› Do not use any foaming agents, e.g. household cleaning agents or instrument disinfection agents.
› Do not use abrasive cleaners.
› Do not use agents containing chlorine.
› Do not use any solvents like acetone.

9.1 Spittoon valve





› Switch on the rinsing for the spittoon.
› Keep pressing the yellow cleaning button of the spittoon valve or the cleaning button on the switch control panel (if present) until rinsing of the spittoon is finished.
› Pour disinfection solution into the spittoon and at the same time press the yellow cleaning button of the spittoon valve or the cleaning button on the switch control panel (if present) until the disinfection solution has been aspirated.

9.2 Suction system

After every treatment

› Aspirate a glass of cold water through the large and the small suction hoses. Do this even if only the small suction hose was actually used during treatment.

Suction through the large suction hose causes a large amount of air to be drawn up, thereby considerably increasing the cleaning effect.

Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:
– Material-compatible, non-foaming disinfection/cleaning agents with Dürr Dental approval, e. g. Orotol plus.
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the disinfection/cleaning agent with the care system.

Once or twice a week before the midday break

Under harsher conditions (e.g. hard water or frequent use of prophylaxis powders) 1x daily before the midday break

The following are required for cleaning:
– Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the cleaning agent with the care system.
› Rinse with ca. 2 l water after the application time.

10 Maintenance

EN

All maintenance work must be performed by a qualified expert or by one of our Service Technicians.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Maintenance interval	Maintenance work
Monthly	› Press the yellow cleaning button to empty the collection vessel. › Clean the yellow coarse filter or replace it if required.
Annually	› Check compressed air supply. * › Perform a function test.
Every 3 years	› Clean the float monitor in the collection vessel. * › Clean the seal on the float sensor for ventilation and replace if required. *

* Only by customer services service technicians.

11 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

WARNING
Infection due to contaminated unit
› Clean and disinfect the suction before working on the unit.
› Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

Fault	Probable cause	Solution
Spittoon valve not working	No power supply	› Check power supply and restore. *
	Faulty connections	› Check the plug connections. *
	Relay not switching	› Check the switching function of the relay. *
	No compressed air present	› Check the compressed air supply of the spittoon valve. *
	Sensor defective	› Check the function of the sensor with the aid of the button.
		› Check the function by manually moving the float sensor.
Suction unit does not start up or runs continuously	Float sensor does not move in its housing	› Clean the housing and float sensor. * › Insert the float sensor correctly. *
Fluid does not drain off	Drain blocked	› Clean the drain line. * › Check whether the filter is blocked, clean if necessary.

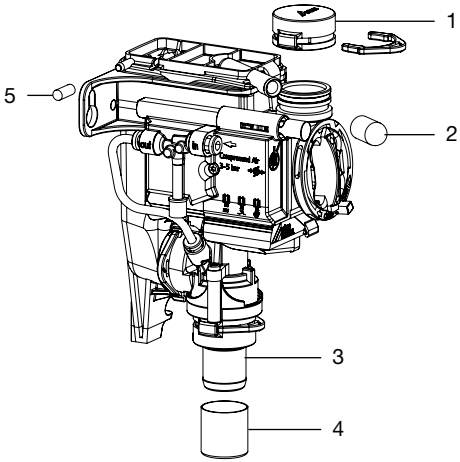
* Only by customer services service technicians.

12 Transporting the unit

WARNING
Infection due to contaminated unit
› Disinfect the unit before transport.
› Close all media connections.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

› Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
› Disinfect a defective unit using a suitable surface disinfection agent.
› Seal all connections with sealing caps.
› Pack the unit securely in preparation for transport.



1 DürrConnect dummy bushing (order no. 0700-700-10E)
2 Protective cap (order no. 9000-412-85)
3 DürrConnect hose connector socket ∅ 20 mm (order no. 0700-700-20E)
4 Protective cap (order no. 9000-412-98)
5 Sealing cap (order no. 9000-310-002)

13 Information about EMC in accordance with EN 60601-1-2

13.1 General information

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

13.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The spittoon valve uses HF energy only for its internal functions. For this reason, HF transmissions are very low and it is unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Class B	The spittoon valve is suitable for use in all facilities including those in living areas and areas that are directly connected to the public mains electricity supply that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	Not applicable	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Not applicable	

EN

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage Not applicable	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ = 10 V	$d = 0.35 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ = 10 V/m	$d = 0.35 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 0.7 \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz

Table 2: Electromagnetic interference immunity for units or systems that are operated in healthcare facilities

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a,b].

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

EN

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Keep a minimum distance of 30 cm between the device and mobile communication devices.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 0.35 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \cdot \sqrt{P}$
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.21
100	3.5	3.5	7

Table 3: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

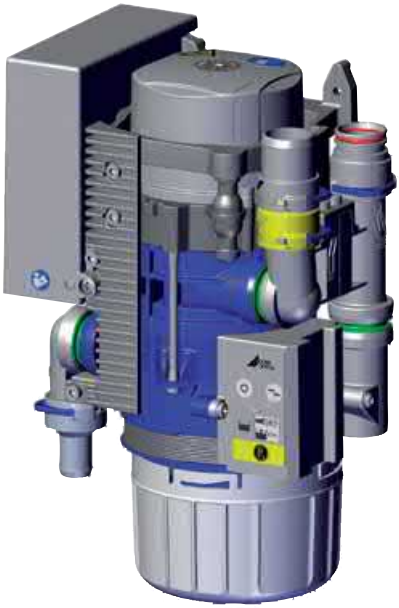
Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

Hersteller/Manufacturer:
DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL

CAS 1 Combi-Separator

EN



Installation and Operating Instructions

CE

7117100018L30

DÜRR DENTAL

1712V002

Contents

Important information

Product description

Installation

EN

Operation

Troubleshooting

Appendix

1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

General warning symbol

Biohazard warning

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
  Immediate danger of severe injury or death
– **WARNING**
  Possible danger of severe injury or death
– **CAUTION**
  Risk of minor injuries
– **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Comply with the Operating Instructions.

Wear hand protection.

Switch off and de-energise the unit (e.g. unplug from mains).

Hose manifold connection

Spittoon connections

Suction unit connection

Drain connection

Unit in operation

Unit operation interrupted

Audible signal/melody sounds

Do not reuse

CE labelling

REF Order number

SN Serial number

Manufacturer

1.2 Copyright information

EN

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The CAS 1 Combi-Separator is designed for continuous separation of liquids and air and for separation of amalgam from the entire waste water from dental treatment units.

2.2 Intended use

Installation in accordance with the requirements of the water authorities in the German Federal States or in accordance with local regulations.

In accordance with the installation regulations of DIBT Berlin.

The CAS 1 Combi-Separator is designed for the separation of liquids and air as well as for the separation of amalgam from the waste water from a single treatment unit in a dry system.

Installation in dental treatment units and in practice rooms (housing version). Positioned in the suction line after the spittoon and manifold.

The minimum volume of waste water that can be supplied to the unit is 0.1 l/min, but must not exceed 4.0 l/min. Here, a separation efficiency of at least 95% is maintained with amalgam.

A rinsing unit with fresh water can be installed in the suction line upstream of the Combi-Separator.

Installation, servicing and repairs must only be performed by qualified personnel specifically approved and authorized by Dürr Dental.

The disposable amalgam containers must only be used once.

For surgical treatments and when the Airflow is being used, the CAS 1 Combi-Separator requires a rinsing unit to be installed, which feeds a small amount of water to the device during aspiration. This thins any liquid (e.g. saliva, blood) that occurs so it can be transported more easily.

The CAS 1 Combi Separator for KaVo treatment units must be set up in a defined installation setup in order to meet the relevant safety standards. For this reason it must only be installed in the treatment units that have been designed and approved for this purpose by KaVo.

KaVo-approved treatment units:

New units delivered from 01/2016 onwards: E50, E50 Life, E70/E80, E70/E80 Vision, 1058, 1058 Life

Spare parts requirements for old units such as 1078 and 1080 among others.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

The Combi-Separator must only be used to process liquids from the oral cavity. It must not be used for the aspiration of any other substances, such as dust, sludge, plaster or similar.

Only chemicals and disinfectants that will not damage the materials, e.g. Orotol Plus or equivalent, may be used.

The unit is not suitable for installation downstream of 2 or more workplaces. The max. water volume of 4.0 l/min must not be exceeded.

The device must not be run in continuous operation; the braking process after the end of the run is required in order to keep the centrifuge drum clean.

The device must not be installed with the drain higher than the connection piece on the device.

Do not use any risers. All pipes must have a downward gradient.

Not suitable for wet rooms! Do not use this device to aspirate flammable or explosive mixtures. Do not use the unit in a potentially explosive environment!

2.4 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1 respectively).

Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

2.5 General safety information

- When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
- Prior to each use, check condition of the device and make sure it is in perfect working order.
- Do not convert or modify the units.
- Observe the Installation and Operating Instructions.
- Make the Installation and Operating Instructions available to the person operating the device at all times.

2.6 Qualified personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

- Instruct or have every user instructed in handling the unit.

Installation and repairs

- Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.7 Protection from electric shock

- When working on the units observe all the relevant electrical safety regulations.
- Never touch the patient and unshielded plug connections on the device at the same time.
- Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

- Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "17 Information about EMC in accordance with EN 60601-1-2".

2.8 Only use genuine parts

- Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
- Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.9 Transport

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

- Only transport the device in its original packaging.
- Keep the packing materials out of the reach of children.

2.10 Disposal

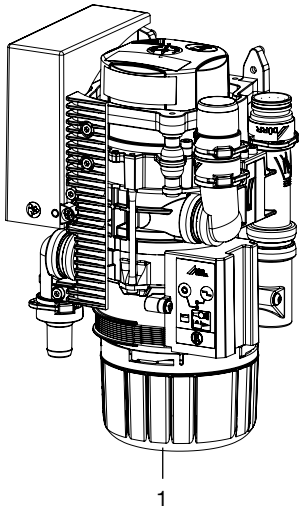
The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

- Decontaminate potentially contaminated parts before disposing of them.
- Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
- If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

EN

EN

3 Overview



1 CAS 1 Combi-Separator

3.1 Scope of delivery

The scope of delivery can vary slightly depending on the version.

The following items are included in the scope of delivery:

CAS 1 7117-100-51
– Combi-Separator
– Replacement disposable amalgam container
– Installation and operating instructions
– Operating Handbook

3.2 Special accessories

The following optional items can be used with the device:

Various installation sets are available on request.
Display panel 7805-116-00E
Cable for display panel, 1 m 9000-119-043
Cable for display panel, 3 m 9000-119-042
Station selection valve. 7560-500-60
Station selection valve for CAS 1 / CS 1. 7560-500-80
Vario rinsing unit 7100-260-50
OroCup care system. 0780-350-00
Test vessel 7117-064-00

3.3 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

Disposable amalgam container . . . 7117-033-00
DürrConnect protective strainer, 5 pieces 0700-700-18E
DürrConnect protective strainer, 5 pieces 0700-700-28E
Orotol plus (2.5 litre bottle) CDS110P6150
MD 550 spittoon bowl cleaner (750 ml bottle). CCS550C4500
MD 555 cleaner (2.5 litre bottle). CCS555C6150

3.4 Wear parts and spare parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Bellows. 7117-420-25E
Service kit (3-year interval). 7117-980-32
Service kit (5-year interval). 7117-980-30

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

4.1 CAS 1 Combi-Separator

Electrical data – centrifuge motor		
Nominal voltage	V	24 AC
Frequency	Hz	50 / 60
Rated power	VA	100

Electrical data – electronics		
Nominal voltage	V	24 AC
Nominal current	A	0.2
Signal input from the hose manifold	V	24 AC/DC

Media		
Air flow volume	l/min	≤ 300
Flow rate		high
The suction system must be suitable for a high flow rate in accordance with EN ISO 10637.		
Max. pressure	hPa/mbar	-160
Min. volume of aspiration fluid	l/min	≥ 0.1
max.	l/min	≤ 1.0
Water supply, spittoon	l/min	≤ 3
Total flow of waste liquids	l/min	≤ 4
Usable volume in amalgam collecting container	ccm	c. 90
Replacement interval		4 - 6 months

General data		
Drive motor nominal speed	rpm	2800
Operating mode		S5 95% DC*
Type of protection		IP 20
Protection class		II
Noise level ** approx.	dB(A)	56
Dimensions (H x W x D)	mm	255 x 151 x 110
Weight, approx.	kg	2.7
Separation rate	%	≥ 95
Medical device (class)		I

* DC = duty cycle

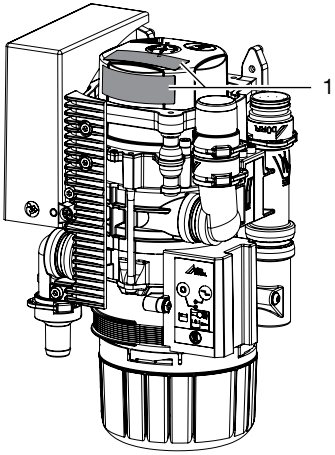
** Noise levels in acc. with EN ISO 1680 "airborne noise emissions"; measured in a sound-proofed room. The levels are average values with a tolerance of ±1.5 dB(A). Higher values may be obtained in rooms with reverberating sound characteristics.

Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	< 95

Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70

4.2 Type plate

The type plates are located on the cover of the motor.



1 Type plate

4.3 Conformity assessment

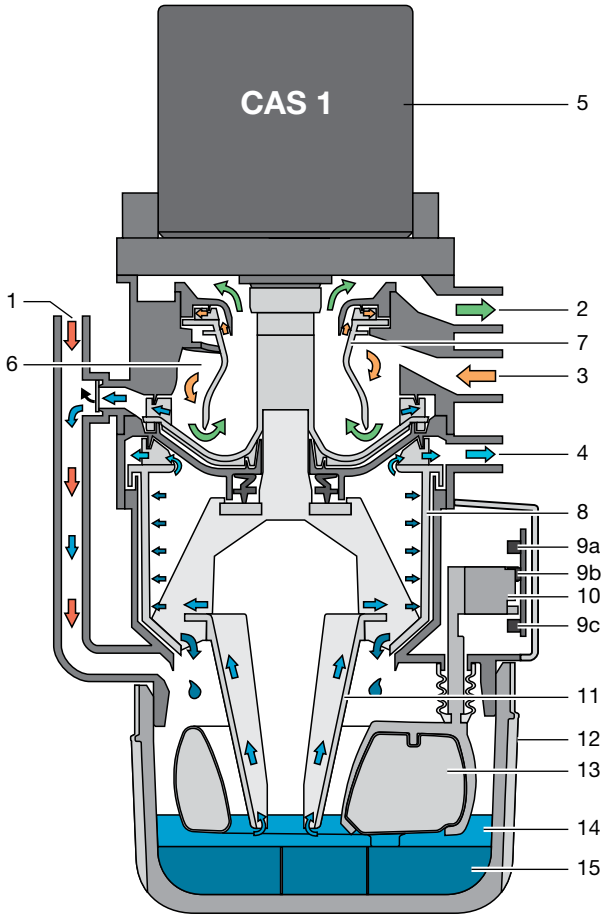
This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

4.4 Approvals

Centre of Competence in Civil Engineering, Berlin	
Test number	Z-64.1-20

Separation method compliant with standard	
ISO 11143	Type 1

5 Operation



1 Fluid intake
2 Vacuum, to suction unit
3 Aspiration input
4 Fluid output
5 Motor
6 Separation
7 Separation rotor
8 Centrifuge
9 Light barriers (3x)
10 Sensor enclosure
11 Cone pump
12 Amalgam collector vessel
13 Float sensor
14 Fluids
15 Amalgam particles

5.1 Operation

CAS 1 Combi-Separator

The task of the CAS 1 combi-separator is to provide continuous separation of secretions and air as well as the amalgam separation of all the waste water from the treatment unit.

The waste water flows through the connection (1) from the spittoon directly into the centrifuge (8) and amalgam separation.

During the suction phase the aspirated secretions are separated from the aspirated air in the separation unit (6). The secretions accumulating in the separation unit are continuously transported to the centrifuge (8), where the amalgam particles are then separated.

Underneath the centrifuge is a replaceable amalgam collector vessel (12), into which the separated amalgam particles (15) are rinsed once the centrifuge (8) is switched off. A float sensor (13) checks the level within the collector vessel and sends a signal to the display panel when it needs replacing. In combination with a light barrier (9c), this float sensor also monitors whether a collector vessel is in use.

The compact size of the CAS 1 Combi-Separator allows it to be installed in dental treatment units. This results in short secretion carrying lines. After the centrifuge is switched off, the braking cycle triggers a self-cleaning process. This self-cleaning process also leads to smooth and silent running, as well as providing a separation efficiency of more than 95%, even under heaviest loads.

5.2 Separation

At the inlet connection (3) of the CAS 1, the aspirated fluid/air mix is accelerated and set into a spiral motion in the separation unit (6). The resulting centrifugal forces sling the aspirated particles against the outer wall. The air is continuously separated from the fluid and escapes via the spinning separation rotor (7) to the suction unit.

The aspirated air is subject to high centrifugal forces by the separation rotor (7), which is driven by the motor (1), which ensures that no fluid or blood foam can be carried into the suction unit.

The spiral motion feeds the separated fluid continuously to the pump wheel, which transports the fluid into the collector vessel. The fluid is transported to the centrifuge (8) via a pump cone (11).

An external station selection valve connects the CAS 1 with the suction unit via the vacuum connection (2).

5.3 Spittoon connections

The waste water from the spittoon flows through a protective strainer on the fluid inlet (1) and into the collector vessel (12). Once sufficient fluid has been collected, the float sensor (13) activates a light barrier (9a) and (9b) via a sensor housing (10) and switches on the motor (1). The fluid is transported to the centrifuge (8) via a pump cone (11).

5.4 Station selection valve / safety valve

The station selection valve has 2 tasks:

1st task:

The station selection valve interrupts the suction flow between the hose manifold and the suction unit. As soon as a suction hose is removed from the hose manifold, a solenoid valve opens the station selection valve and suction flow is enabled.

2nd task:

The station selection valve also acts as a safety valve. If the CAS 1 is over-full or not functioning properly, the system will perform a safety shutdown. This safety shutdown prevents fluids from being drawn into the dry suction pipe.

For single station suction systems, the station selection valve takes over the function of the safety valve.

In various types, a station selection valve is already integrated in the CAS 1. The station selection valve is on the connection (2) of the CAS 1.

5.5 Amalgam separation

The switches in the hose manifold or the light barrier of the sensor system switch on the motor and the associated centrifuge (8).

The fluid containing amalgam particles flows continuously to the collector vessel (12). The fluids ejected by the centrifuge are pumped through the fluid output (4) to the central waste water system.

As soon as no further fluid is fed to the amalgam separator, e.g. when the suction hose is placed back in the hose manifold, the centrifuge drum is switched off after a short delay time. This switch-off brakes the motor, as a result of which the ring of water, which continues to rotate due to inertia, rinses the separated particles out of the centrifuge (8) downwards into the collector vessel.

The separated amalgam particles form a sediment in the replaceable collector vessel. The level of fluid in the collector is regulated by the pump cone so that the risk of fluid escaping when the collector vessel is changed can be avoided.

5.6 Sediment level measurement

The fill level in the collector vessel (12) is checked by a float sensor (13) every time the main power switch is switched on.

The centrifuge motor starts, fluid is transported via the pump cone to the centrifuge drum (8) and provides a constant level of fluid (underside of the cone pump) in the collector vessel. The float sensor sinks. Two light barriers (9a) and (9b) measure the fluid level. Once the level reaches 95% in the collector vessel, this is displayed on the display panel.

5.7 Operating problems

If the unit is not ready for operation due to a fault, this will be indicated on the display panel via illuminated LEDs and an audible signal.

5.8 Service key

On the display panel there is a service key that can be used to switch off the audible signal in the event of a fill level warning or if a fault message is indicated. This button can also be used to start the device manually. To do this, press the button for longer than 2 seconds until the drive motor starts up.

6 Requirements

6.1 Installation/setup room

The room chosen for set up must fulfil the following requirements:

– Closed, dry, well-ventilated room
– Should not be a room made for another purpose (e. g. boiler room or wet cell)

EN

6.2 Setup options

CAS 1 Combi-Separator

– Directly in the treatment unit.
– In a special housing in an extension of the treatment unit.

6.3 Hose materials

For waste connections and suction lines only use the following hose types:

– Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
– Hoses that are resistant to dental disinfectants and chemicals

Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

– Rubber hoses
– Completely PVC hoses
– Hoses that are not sufficiently flexible

6.4 Installation and routeing of hoses and pipes

› Execute the on-site pipe installation in accordance with the applicable local regulations and standards.
› Lay the hose installation of the drains to or from the unit at a sufficient incline.

If incorrectly laid, the hoses can become blocked with sedimentation.

6.5 Information about electrical connections

› Ensure that electrical connections to the mains power supply are carried out in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
› Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply.
› Observe the current consumption of the devices that are to be connected.
› Install electrical lines without mechanical tension.
› Make the electrical connection via the main power switch of the treatment unit or via the main power switch of the practice.

6.6 Information about connecting cables

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Plastic sheathed cable (e.g. type NYM-J)
Flexible	– PVC flexible line (e.g. H05 VV-F) or – Rubber connection (e.g. H05 RN-F or H05 RR-F)

Control cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Shielded sheathed cable (e.g. (N)YM (St)-J)
Flexible	– PVC data cable with shielded cable sheathing, as used for telecommunications and IT processing systems (e.g. type LiYCY) or – Lightweight PVC control cable with shielded cable sheathing

Wire cross-section

Unit feed:

– 0.75 mm²

Connection external valves / units:

– 0.5 mm²

7 Installation

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

7.1 Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

› Only connect units when there can be no question of danger to operator or to patient.

› Only connect units when it is safe to do so and there is no risk of damage or harm to the surroundings.

› If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.

A copy of the system manufacturer‘s declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

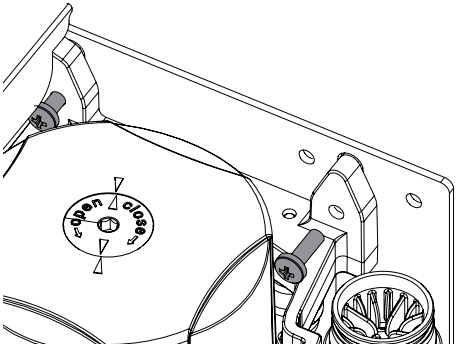
EN

7.2 Installation of the CAS 1 in treatment units

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

EN

Attach the unit vertically at a suitable position in the treatment unit.The unit is mounted on rubber pads and suspended in a metal frame. This mounting arrangement prevents the transmission of any vibrations to the treatment unit while the device is running. Vibrations may occur if the unit is not positioned vertically. A minimum distance of 3 mm must be maintained to the surroundings.



Station selection valve

In various types, the station selection valve is directly mounted on the CAS 1. The station selection valve (for separate installation) should be fitted in the suction pipe in the treatment unit, preferably near the end connection in the floor socket. In some installation setups the station selection valve also functions as a safety valve, so its actuation must be implemented via the CAS 1.

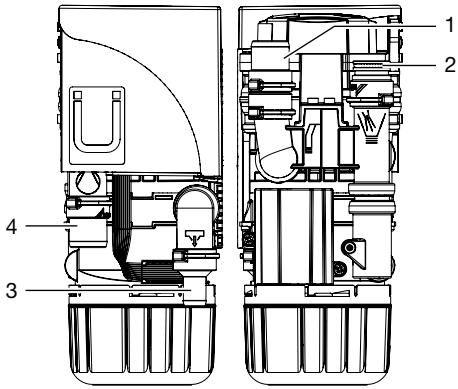
For further information, refer to the station selection valve installation and operating instructions

Inlet and outlet hoses

Connect and attach the inlet and outlet hoses with DürrConnect connectors to the relevant connections on the unit.Route the hoses at an incline.

Recommended diameter of the connection hoses: ∅ 25 mm.

The minimum nominal width for the outlet hose is 15 mm.



1 Hose manifold
2 Spittoon
3 Outlet
4 Suction unit

Spittoon connections

In some dental units it is possible that noises can be heard at the spittoon, which are amplified by the funnel shape of the spittoon itself. In this case, the outlet between spittoon and CAS 1 should be bled. A corresponding siphon trap with ventilation is available as a special accessory.

Rinsing unit

It is recommended that the suction system is equipped with a rinsing unit, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water, etc.), which can then be transported more effectively.

For further information, refer to the rinsing unit installation and operating instructions

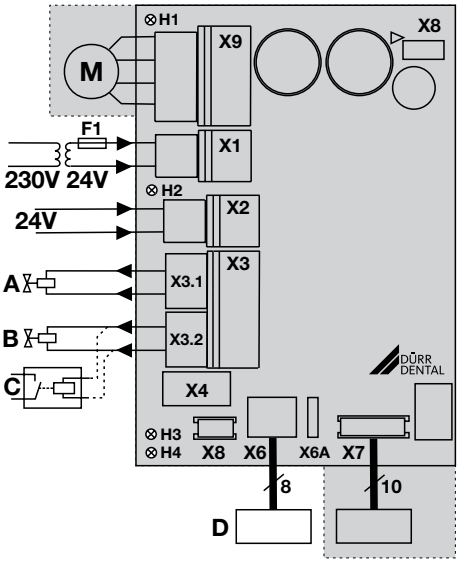
7.3 Electrical connections, controller

Power supply:

– Safety transformer order number: 9000-150-46

or

– Safety transformer 24 V AC with a with an isolator consisting of two means of patient protection (MOPP) between the mains circuit and secondary circuit, min. 100 VA, secondary fuse T 4 AH (or IEC 60127-2/V T 4 AH, 250 V)



X1 Power supply in accordance with EN 60601-1, 24 V AC

X2 Signal input 24 V AC/DC

X3.1 Place selection valve / safety valve (only CAS 1, max. output 8 W)

X3.2 Rinsing unit (CAS 1 only)

X4 CAN bus

X6 Display panel, external (X6A = connection for predecessor model)

X7 Sensor technology

X8 Production interface

X9 Motor

H1 Motor control display

H2 Manifold control display

H3 Place selection valve control display

H4 Control display, collecting container missing

A Place selection valve

B Rinsing unit

C Suction unit relay (alternative)

D Display panel, external

7.4 Electrical connections

Station selection valve / safety valve

› Connect the station selection valve / safety valve using a 2-core wire with connector to the X3 connection of the control.

Rinsing unit

› Connect the rinsing unit using a 2-core wire with connector to the X3 connection of the control.

At the connection for the rinsing unit, a suction unit relay, for example, can be connected if there is no isolation present between the suction unit signal and station selection valve in the treatment unit. Note the power consumption of the suction unit relay.

Display panel

The display panel is used to indicate messages acoustically and visually (via LEDs).

A display panel is already integrated in the unit and should be visible/audible at all times.

If the display panel is not visible/audible, fit an additional display panel in an easily visible location. The display panel is connected to the X6 socket (RJ-45 socket). An existing Dürr Dental display panel with a 6-pin connector can be connected to the X6A connector when replacing an older device.

If the installation of the amalgam separator in a neighbouring room or in the basement results in distances of more than 3 m, we recommend installing a shielded network cable with RJ-45 sockets.

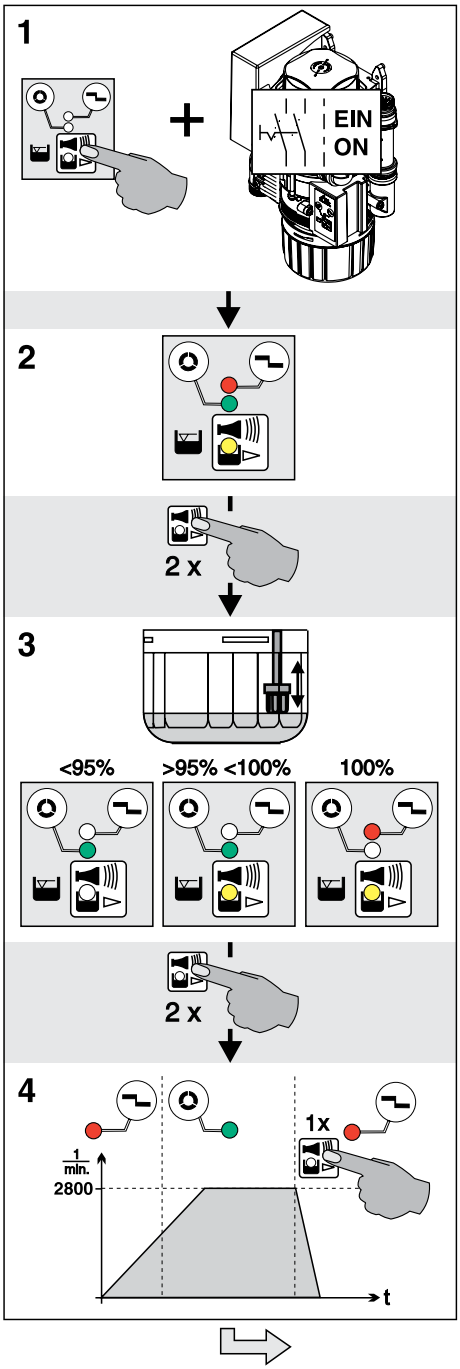
EN

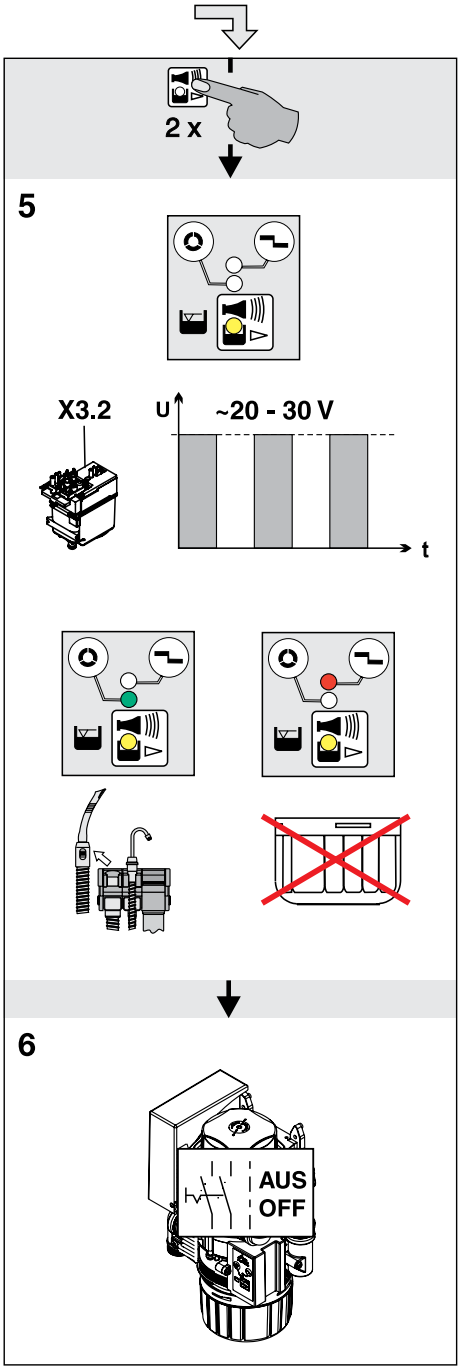
8 Commissioning and first start-up

In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

› Turn on the unit power switch or the main surgery switch.
› Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
› Check the aspiration function.
› Check the start function via the spittoon.
› Check the connections, hoses and device for leaks.

9 Service program





EN

10 Description of the service program

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

The various unit functions can be checked with the aid of the service program.

The individual program steps are:

– Display test
– Sediment level measurement
– Motor start and motor braking with rpm check
– Input and output signals

Function of the service key:

– By pressing the service key twice the next individual program step is called up.
– By pressing the service key once that program step is repeated.

A press of the service key is confirmed by an audible signal.

10.1 Service program ON/OFF

On

– Press the service key and switch on the voltage supply to the unit.
– As soon as a signal melody can be heard, release the service key.
  The green, yellow and orange LEDs on the display panel light up (display test) and the service program is activated.

Off

Switch off the main supply to the unit.

10.2 Display test

The display test is activated as soon as the service program is started.
The LEDs on the display panel are checked.
All three LEDs must come on. There is also an audible signal, which can be switched off by pressing the service button.

10.3 Sediment level measurement

While the service program is activated, the safety check for the collector vessel is deactivated.

The sediment level measurement can be used to check the function of the sediment sensor and the function of the LEDs.

Every time the service key is pressed, the sediment level is checked. If a test collector vessel is used for this, the different levels can be scanned and made visible on the display panel.

While changing the collectors (collector vessel - test collector vessel) in the service program the unit remains in the ON state.

10.4 Motor start - motor braking

The drive motor starts and, after approx. 5 seconds, braking is applied. If the service key is pressed during these 5 seconds, the motor will immediately be braked.

This procedure can be repeated by pressing the service key 1x again.

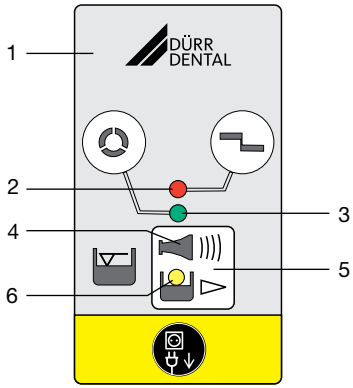
The drive motor starts up.

As a result of the rpm monitoring, the LED will change from orange to green upon start-up and from green to orange upon braking.

10.5 Input and output signals

– After this program item is activated, the yellow LED flashes and a cycled DC voltage (approx. 22-30 V) can be measured at the terminal for the rinsing unit.
– If the suction hose is lifted off the hose manifold the green LED will also come on.
– Removal of the collecting container causes the red LED to illuminate.

11 Display/handling



1 Display panel
2 RED display
3 GREEN LED
4 Audible signal/melody
5 Reset/service key
6 YELLOW LED

11.1 Ready for operation

Green LED is on

11.2 Amalgam collector vessel is 95% full

Yellow LED is on

Green LED is on

Audible signal melody sounds

– At a fill level of 95%, the signal melody can be switched off by pressing the reset button. The device is then ready for operation again.
– The yellow LED comes on as a reminder that the amalgam collector vessel is due to be changed. The level display is repeated every time the unit is switched on at the main power switch.

We recommend changing the amalgam collector vessel when it reaches 95% full.

11.3 Amalgam collector vessel is 100% full

Yellow LED is on

Red display flashes

Audible signal melody sounds

– At a fill level of 100% the signal melody can no longer be switched off by pressing the reset button.
– The collecting container needs to be replaced.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

– The separator will not be ready for operation again until the amalgam collecting container has been replaced

11.4 Amalgam collector vessel not in position

Red display flashes

Audible signal

– Press the reset button briefly to switch off the audible signal.
– Switch off the device.
– Insert the collecting container.
– Switch on the unit.
– Green LED lights up – "Ready for operation“

If this error message occurs when the collecting container is correctly inserted, this indicates that there is a technical defect – inform your Service Technician.

EN

11.5 Motor fault

Red display and

green LED flash alternately

Audible signal

– Press the reset button briefly to switch off the audible signal.
– If the reset button is pressed for longer than 2 seconds the unit can be restarted.
– Green LED lights up – "Ready for operation“

If, after pressing the reset button repeatedly, the fault report reappears again each time, this indicates a technical defect – inform your Service Technician.

EN

12 Disinfection and cleaning

NOTICE
Device malfunctions or damage due to use of incorrect media
Guarantee claims may become invalid as a result.
› Do not use any foaming agents, e.g. household cleaning agents or instrument disinfection agents.
› Do not use abrasive cleaners.
› Do not use agents containing chlorine.
› Do not use any solvents like acetone.

12.1 After every treatment

› Aspirate a glass of cold water through the large and the small suction hoses. Do this even if only the small suction hose was actually used during treatment.

Suction through the large suction hose causes a large amount of air to be drawn up, thereby considerably increasing the cleaning effect.

12.2 Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:
– Material-compatible, non-foaming disinfection/cleaning agents with Dürr Dental approval, e. g. Orotol plus.
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the disinfection/cleaning agent with the care system.

12.3 Once or twice a week before the midday break

Under harsher conditions (e.g. hard water or frequent use of prophylaxis powders) 1x daily before the midday break

The following are required for cleaning:

– Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
– Unit care system, e.g. OroCup

› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the cleaning agent with the care system.
› Rinse with ca. 2 l water after the application time.

13 Replace the amalgam collector vessel

WARNING
Risk of contamination if the amalgam collector vessel is reused since the collector vessel is not water-tight.
› Do not use the collector vessel more than once (disposable item).

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

We strongly recommend that the amalgam collector vessel should only be changed in the morning before the start of work. This will prevent fluid from dripping out of the drum while it is being changed.

› Disconnect all power from the device.
› Remove the full amalgam collecting container and from the device.
› Pour disinfectant for suction units (e.g. Orotol plus, 30 ml) into the full amalgam collector vessel.
› Close and secure the full amalgam collector vessel using the cap. Observe the markings on the cap and on the collector vessel.
› Place the securely closed amalgam collector vessel into its original packaging and seal.
› Insert a new amalgam collector vessel in the unit and clamp it in position. Only use original amalgam collector vessels.
› Switch on the power supply. The device is ready for operation again.

EN

13.1 Disposal of the collector vessel

Used amalgam collector vessels must not be sent in the post!

Dürr Dental is not a waste management company and is not allowed by law to accept any filled amalgam collector vessels.

- Arrange to have filled amalgam collector vessels collected from the surgery by a local waste management company.
- New amalgam collector vessels should be ordered from your specialist dental equipment retailer.
- Document the replacement and legally compliant disposal of the filled waste amalgam collector vessel in the Operating Handbook.

In some countries the owner is required to keep an operating handbook. This operating handbook must document all maintenance work, service work, checks and amalgam disposal.

14 Maintenance

All maintenance work must be performed by a qualified expert or by one of our Service Technicians.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

EN

Maintenance interval	Maintenance work
Dependent upon the level of usage of the device	› Replace the amalgam collecting container when a fill level of 95% or 100% is indicated on the display panel › Clean or replace protective sieves during replacement of the amalgam collecting container. At the latest, do this when the suction or draining power of the device decreases.
Annually	› Cleaning of the suction unit in accordance with the operating instructions. › Clean the float. * › Replace the bellows. *
Every 3 years	› Replace the rubber grommets on the connections. * › Replace the float. *
Every 5 years	› Replace the centrifuge drum and seal. * › Replace all O-rings (from the replacement parts kit) in the device. * › Replace the rubber grommets on the connections. * › Replace the float. *

* Only by customer services service technicians.

14.1 Tests

WARNING
Infection due to contaminated unit
› Clean and disinfect the suction before working on the unit.
› Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

EN

In some countries the owner is required to keep an operating handbook. This operating handbook must document all maintenance work, service work, checks and amalgam disposal.

Annual inspection

This inspection should only be carried out by suitably trained staff.

For inspection, the following are required:

– Test vessel

Work steps to be performed:

› General functional check (e.g. aspiration, spittoon inlet)
› Service program

The following measurement times apply to fill level measurements with a test vessel:

– For a fill level of 95%, the measurement result is displayed after approx. 30 sec, whereby the drive motor is briefly switched off during the measurement.
– At a fill level of 100% the measurement result is displayed after approx. 90 sec continuous running.

Inspection of the general operating condition every 5 years

This inspection must be carried out every 5 years (in accordance with the German Waste Water Regulations, Annex 50, Dental Treatment) by an inspector in accordance with national regulations.

For inspection, the following are required:

– Test vessel
– Measuring beaker

Work steps to be performed:

› Fill the test vessel with water and insert it into the unit.
› Start the device and wait until it switches off again.
› Once the device has switched off, remove the test vessel and measure the remaining amount of water.

The unit is working correctly if:

– there is at minimum content of 140 ml in the **test vessel**.

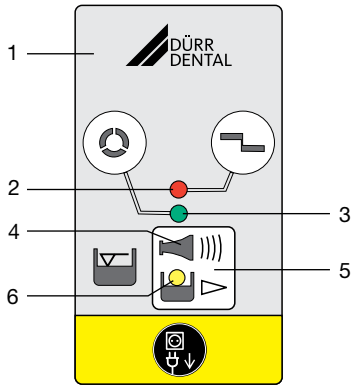
If there is less fluid, clean the centrifuge drum or check the operation of the unit.

15 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).



1 Display panel
2 RED display
3 GREEN LED
4 Audible signal/melody
5 Reset/service key
6 YELLOW LED

Fault	Probable cause	Solution
Device not "ready for operation" **No display on the display panel.**	The main power switch of the treatment unit or surgery is not switched on	› Main power switch ON
	If an external display panel is fitted: cable not correctly connected	› Check cable connections

Fault	Probable cause	Solution
Yellow display is on **GREEN LED illuminates** **Audible signal melody sounds**	Amalgam collecting container is 95% full	› Change the amalgam collecting container.
	Float sensor dirty or blocked	› If this display occurs repeatedly even when the collecting container is empty, check that the float sensor can move freely.
Yellow display is on **Red display flashes** **Audible signal melody sounds**	Amalgam collecting container is 100% full	› Change the amalgam collecting container. Audible signal can no longer be switched off.
	Float sensor dirty or blocked	› If this display occurs repeatedly even when the collecting container is empty, check that the float sensor can move freely.
	Waster water line/siphon trap dirty	› Clean the waste water line/siphon trap. *
The RED and GREEN displays flash alternately **Audible signal**	Motor is dirty or defective	› Check motor for smooth running; replace the centrifuge if necessary. * › Replace the device. *
	Contact problems at X9	› Plug in the connector correctly. * › Replace the PCB main board and connector on the motor. *
Orange LED flashes **Audible signal**		Press the service key briefly to switch off the audible signal
	Amalgam collecting container not correctly in position	› Switch OFF the device. › Insert the amalgam collecting container in the correct position. › Switch ON the device.
	Float sensor missing	› Insert the float sensor. *
Water accumulating in the spittoon	Coarse sieve in the fluid inlet blocked	› Clean the coarse sieve.
	Outlet ineffective or not vented	› Check or retrofit the ventilation. *
Suction power too weak or interrupted	Coarse sieve is blocked on the inlet of the aspiration	› Clean the coarse sieve.
	Place selection valve not or incompletely open	› Check the control voltage. * › Clean the place selection valve. *
Device running continuously	Float sensor blocked in water start position	› Clean the float. * › Free up the float sensor linkage so that it can move freely. *
	Start signal at the signal input (X2)	› Check the control voltage. *
	Waster water line/siphon trap dirty	› Clean the waste water line/siphon trap. *
Noise at the spittoon	Outlet ineffective or not vented	› Check or retrofit the ventilation. *

Fault	Probable cause	Solution
Increased vibration of the device	Pump cone dirty	› Clean or replace the pump cone. *
	Centrifuge dirty	› Clean or replace the centrifuge. *
	Water supply too low	› Introduce water into the suction pipe. › Retrofit the rinsing unit. * › Check the rinsing unit for its correct installation position. * › Check the function of the rinsing unit. *
Water cannot be pumped away or only insufficiently	Centrifuge dirty	› Clean or replace the centrifuge
	Waster water line/siphon trap dirty	› Clean the waste water line/ siphon trap

* Only by customer services service technicians.

16 Transporting the unit

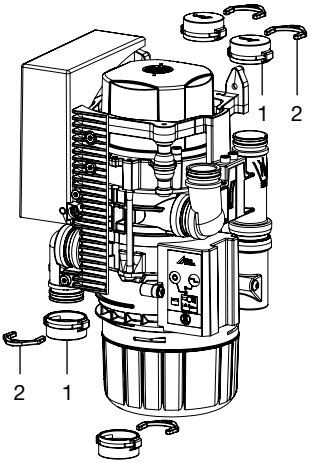
WARNING
Infection due to contaminated unit
› Disinfect the unit before transport.
› Close all media connections.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

EN

› Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
› Disinfect a defective unit using a suitable surface disinfection agent.
› Seal all connections with sealing caps.
› Pack the unit securely in preparation for transport.

16.1 Close CAS 1



1 Dummy bushing
2 Ring clamp

17 Information about EMC in accordance with EN 60601-1-2

17.1 General information

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

17.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

17.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The separator uses HF energy exclusively for internal functions. For this reason, HF emissions are very low and it is unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Class B	The separator is suitable for use in all facilities including those in living areas and areas that are directly connected to the public mains electricity supply which also supply buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Compliant	

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±8 kV contact discharge ±2; 4; 8; 15 kV air discharge	±8 kV contact discharge ±2; 4; 8; 15 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±0,5; 1 kV voltage outer conductor-outer conductor	±0.5; 1 kV symmetrical voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 1/2 period 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for 1/2 period 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at electrical frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ = 3 V	$d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 3 V/m	$d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

EN

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a,b].

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Keep a minimum distance of 30 cm between the device and mobile communication devices.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \cdot \sqrt{P}$
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

Table 2: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

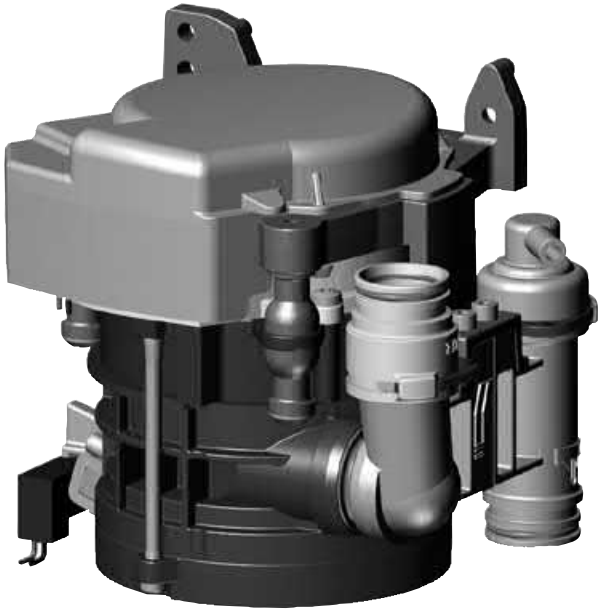
Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

Hersteller/Manufacturer:
DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL

CS 1 Combi-Sepamatic

EN



Installation and Operating Instructions

CE

9000-606-39/30

DÜRR DENTAL

1709V004

Contents

Important information

Product description

Installation

Operation

Troubleshooting

Appendix

EN

EN

1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Biohazard warning

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
  Immediate danger of severe injury or death
– **WARNING**
  Possible danger of severe injury or death
– **CAUTION**
  Risk of minor injuries
– **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.


Comply with the Operating Instructions.


Wear hand protection.


Switch off and de-energise the unit (e.g. unplug from mains).


Hose manifold connection


Suction unit connection


Drain connection


CE labelling

Order number

Serial number


Manufacturer

1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The CS 1 Combi-Sepamatic is designed for the continuous separation of liquids in the suction flow of dental treatment units in dry suction systems.

2.2 Intended use

Installation in accordance with the requirements of the water authorities in the German Federal States or in accordance with local regulations.

Installation in dental treatment units and in practice rooms (housing version).

Positioned in the suction line of a dry suction system after the spittoon and manifold.

The CS 1 Combi-Sepamatic is designed for the continuous separation of liquids in the suction flow of an individual dental treatment unit in a dry suction system.

The The CS 1 Combi-Sepamatic can be operated in continuous operation.

The permissible volume of supply water amounts to min. 0.1l/min, but must not exceed 2.0l/min.

A rinsing unit with fresh water can be installed upstream of the the CS 1 Combi-Sepamatic.

For surgical treatment and when using the Airflow, the CS 1 Combi-Sepamatic requires a rinsing unit to be installed, which feeds a small amount of water to the device during aspiration. This thins any liquid (e.g. saliva, blood) that occurs so it can be transported more easily.

Installation, servicing and repairs must only be performed by qualified personnel specifically approved and authorized by Dürr Dental.

The CS 1 Combi-Sepamatic is unable to separate amalgam. The treatment of waste water containing amalgam requires the connection of an amalgam separator to the CS 1 Combi-Sepamatic.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

The Combi-Sepamatic must only be used to process liquids emerging from the oral cavity and not any other substances such as dust, sludge, plaster or similar.

Only chemicals and disinfectants that will not damage the materials, e.g. OrotolPlus or equivalent, must be used.

The unit is not suitable for installation downstream of 2 or more workplaces. The max. water volume of 2.0l/min must not be exceeded.

The device must not be installed with the drain higher than the connection piece on the device.

Do not use any risers. All pipes must have a downward gradient.

Not suitable for wet rooms. Do not use this device to aspirate flammable or explosive mixtures. Do not use the unit in a potentially explosive environment.

2.4 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1 respectively).

Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

EN

2.5 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.6 Qualified personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

Installation and repairs

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.7 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.
› Never touch the patient and unshielded plug connections on the device at the same time.
› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "13 Information about EMC in accordance with EN 60601-1-2".

2.8 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.9 Transport

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

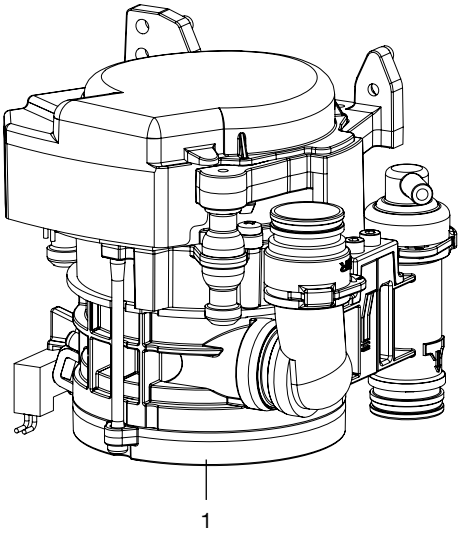
› Only transport the device in its original packaging.
› Keep the packing materials out of the reach of children.

2.10 Disposal

The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

› Decontaminate potentially contaminated parts before disposing of them.
› Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

3 Overview



1 CS 1 Combi-Sepamatic

3.1 Scope of delivery

The scope of delivery can vary slightly depending on the version.

The following items are included in the scope of delivery:

CS 1 . . . . . 7117-100-7x
or
CS 1 . . . . . 7117-100-8x

– Combi-Sepamatic
– or Combi-Sepamatic inc. station selection valve
– Rinsing unit
– Installation and Operating Instructions

3.2 Accessories

The following articles are necessary for the operation of the unit, depending on the application:

Various installation sets are available on request
Safety transformer 24 V, 100VA . . . 9000-150-46
Station selection valve for
CAS 1 / CS 1 7560-500-80

3.3 Special accessories

The following optional items can be used with the device:

Station selection valve. 7560-500-60
Rinsing unit II 7100-250-50
OroCup care system 0780-350-00

3.4 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

DürrConnect protective strainer,
5 pieces 0700-700-18E
Orotol plus
4 x 2.5 l bottles/carton CDS110P6150
MD 550 spittoon bowl cleaner
6 x 800 ml bottles / cardboard box. CCS550A4750
MD 555 cleaner
4 x 2.5 L bottle / carton CCS555C6150

3.5 Wear parts and spare parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

– Protective strainer
– Rubber grommets
– O-rings

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

EN

4 Technical data

4.1 CS 1 Combi-Sepamatic

Electrical data – centrifuge motor		
Nominal voltage	V	24 AC
Frequency	Hz	50 / 60
Rated power	VA	70

Media		
Fluid volume		
min.	l/min	≥ 0.1
max.	l/min	≤ 2.0
Air flow volume	l/min	≤ 350
Flow rate		high
The suction system must be suitable for a high flow rate in accordance with EN ISO 10637.		
Max. pressure	hPa/mbar	-160

General data		
Drive motor nominal speed	min^{-1}	2800
Operating mode		S1 100% DC*
Type of protection		IP 20
Protection class		II
Noise level ** approx.	dB(A)	49
Dimensions (H x W x D)	cm	12.5 x 15 x 12
Weight, approx.	kg	1.4
Medical device (class)		I

* DC = duty cycle

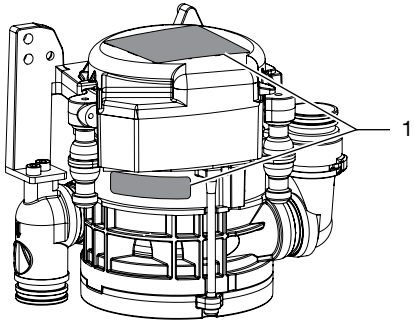
** Noise levels in acc. with EN ISO 1680 "airborne noise emissions"; measured in a sound-proofed room. The levels are average values with a tolerance of ±1.5 dB(A). Higher values may be obtained in rooms with reverberating sound characteristics.

Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	< 95

Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70

4.2 Type plate

The type plates are on the motor cover and on the motor flange.

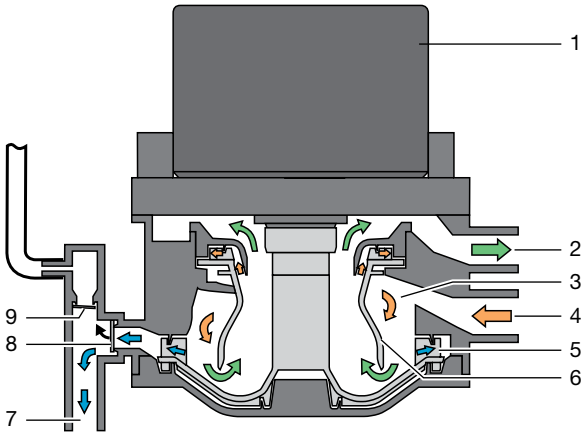


1 Type plate

4.3 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation



1 Motor
2 Vacuum, to suction unit
3 Separation
4 Aspiration input
5 Pump wheel
6 Separation rotor
7 Fluid output
8 Waste valve
9 Relief valve

5.1 Separation

Every time the suction hose is taken out of the hose manifold, the CS 1 Combi-Sepamatic and the suction unit are started.

The mixture of liquid and air drawn up is accelerated in the intake connection and then set in spiral motion in the separation. The resulting centrifugal forces sling the aspirated particles against the outer wall. The air is continuously separated from the fluid and escapes to the suction unit via the spinning separation rotor.

The aspirated air is subject to high centrifugal forces by the separation rotor, which ensures that no fluid or blood foam can be carried into the suction unit.

The spiral motion serves to continuously transport the separated liquid to the pump wheel, this then pumps the liquid into the central waste water drainage system via the waste water valve.

The air bleed is carried out via the relief valve. If fluid escapes upwards into the air bleed area following a fault, the relief valve closes automatically.

5.2 Station selection valve

The station selection valve interrupts the suction flow between the hose manifold and the suction unit. As soon as a suction hose has been removed from the hose manifold, the station selection valve is opened and suction flow is enabled.

A station selection valve is already integrated in various versions of the CS 1. An external station selection valve can be electrically controlled via the CS 1.

6 Requirements

6.1 Setup options

CS 1 Combi-Sepamatic

– Directly in the treatment unit.
– In a special housing in an extension of the treatment unit.

6.2 Hose materials

For waste connections and suction lines only use the following hose types:

– Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
– Hoses that are resistant to dental disinfectants and chemicals

Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

– Rubber hoses
– Completely PVC hoses
– Hoses that are not sufficiently flexible

6.3 Installation and routeing of hoses and pipes

› Execute the on-site pipe installation in accordance with the applicable local regulations and standards.
› Lay the hose installation of the drains to or from the unit at a sufficient incline.

If incorrectly laid, the hoses can become blocked with sedimentation.

6.4 Information about electrical connections

› Ensure that the electrical connections to the mains power supply are established in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
› Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply. It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.
› Install electrical lines without mechanical tension.
› Make the electrical connection via the main power switch of the treatment unit or via the main power switch of the practice.

6.5 Information about connecting cables

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Plastic sheathed cable (e.g. type NYM-J)
Flexible	– PVC flexible line (e.g. H05 VV-F) or – Rubber connection (e.g. H05 RN-F or H05 RR-F)

Control cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Shielded sheathed cable (e.g. (N)YM (St)-J)
Flexible	– PVC data cable with shielded cable sheathing, as used for telecommunications and IT processing systems (e.g. type LiYCY) or – Lightweight PVC control cable with shielded cable sheathing

Wire cross-section

Unit feed:
– 0.75 mm²
Connection external valves / units:
– 0.5 mm²

EN

7 Installation

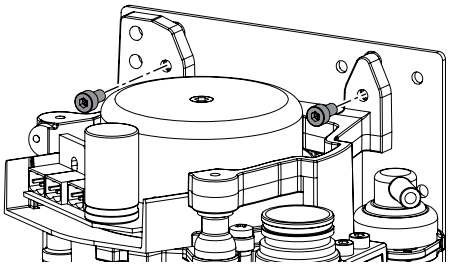
Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

7.1 Installation of the CS 1 in treatment units

WARNING
Infection due to contaminated unit

- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Attach the unit vertically at a suitable position in the treatment unit.The unit is mounted on rubber pads and suspended in a metal frame. This mounting arrangement prevents the transmission of any vibrations to the treatment unit while the device is running. Vibrations may occur if the unit is not positioned vertically. A minimum distance of 3 mm must be maintained to the surroundings.



Station selection valve

In various types, the place selection valve is directly mounted on the CS 1. The station selection valve (for separate installation) should be fitted in the suction pipe in the treatment unit, preferably near the end connection in the floor socket. The electrical connection should then also be carried out on the CS 1.

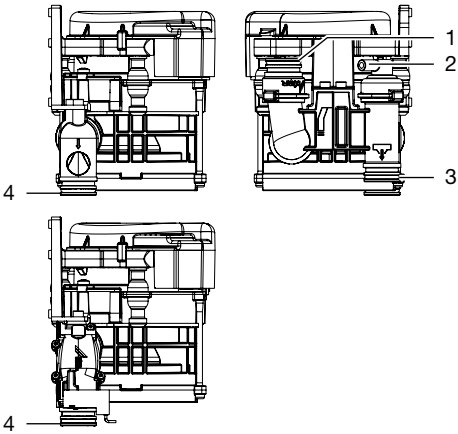
For further information, refer to the station selection valve installation and operating instructions

Inlet and outlet hoses

Connect and attach the inlet and outlet hoses with DürrConnect connectors to the relevant connections on the unit.Route the hoses at an incline.

Recommended diameter of the connection hoses: ∅ 25 mm.

The minimum nominal width for the outlet hose is 15 mm.



1 Hose manifold
2 Vent
3 Outlet
4 Suction unit

Rinsing unit

It is recommended that the suction system is equipped with a rinsing unit, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water, etc.), which can then be transported more effectively.

For further information, refer to the rinsing unit installation and operating instructions

Installation sets

Installation sets and detailed documentation for various installation situations are available from the manufacturers.

When installed in a housing, ventilation slits should be provided to avoid heat build-up in the housing.

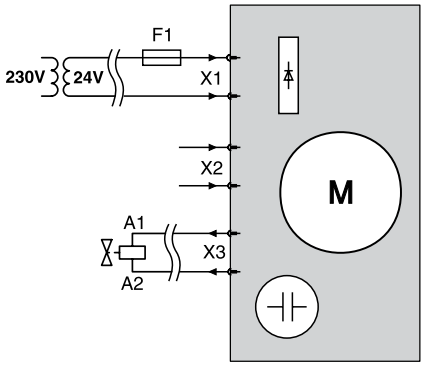
7.2 Electrical connections, controller

Power supply:

– Safety transformer order number: 9000-150-46

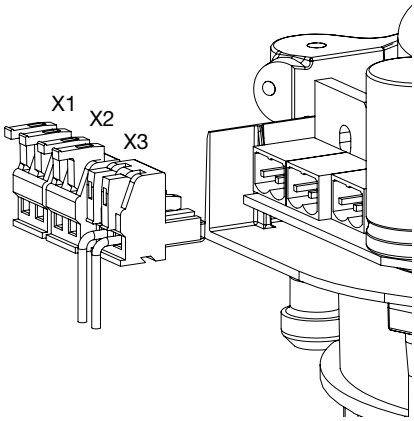
or

– Safety transformer 24 V AC with a with an isolator consisting of two means of patient protection (MOPP) between the mains circuit and secondary circuit, min. 100 VA, secondary fuse T 4 AH (or IEC 60127-2/V T 4 AH, 250 V)



X1 Power supply in accordance with EN 60601-1, 24 V AC
X2 Signal input 24 V AC/DC
X3 Place selection valve and/or rinsing unit (max output 8 W)
F1 T 4 AH, 250 V in accordance with IEC 60127-2

7.3 Electrical connections



X1 Power supply
X2 Hose manifold start signal
X3 Outgoing signal station selection valve and/or rinsing unit

› Remove the motor cover of the CS 1.
› Attach the connector to the connection lines.

To open, lift the terminal lever upwards.

› Plug the connector onto the control.
› Put the motor cover on.

EN

8 Commissioning and first start-up

In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

› Turn on the unit power switch or the main surgery switch.
› Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
› Check the aspiration function.
› Check the connections, hoses and device for leaks.

9 Disinfection and cleaning

NOTICE
Device malfunctions or damage due to use of incorrect media
Guarantee claims may become invalid as a result.
› Do not use any foaming agents, e.g. household cleaning agents or instrument disinfection agents.
› Do not use abrasive cleaners.
› Do not use agents containing chlorine.
› Do not use any solvents like acetone.

9.1 After every treatment

› Aspirate a glass of cold water through the large and the small suction hoses. Do this even if only the small suction hose was actually used during treatment.

Suction through the large suction hose causes a large amount of air to be drawn up, thereby considerably increasing the cleaning effect.

9.2 Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:
– Material-compatible, non-foaming disinfection/cleaning agents with Dürr Dental approval, e. g. Orotol plus.
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the disinfection/cleaning agent with the care system.

9.3 Once or twice a week before the midday break

Under harsher conditions (e.g. hard water or frequent use of prophylaxis powders) 1x daily before the midday break

The following are required for cleaning:
– Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the cleaning agent with the care system.
› Rinse with ca. 2 l water after the application time.

EN

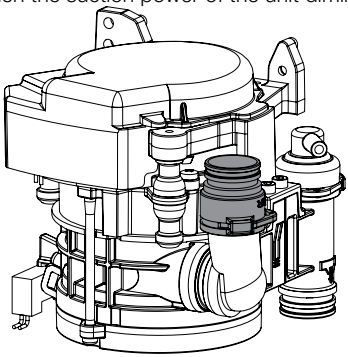
10 Maintenance

All maintenance work must be performed by a qualified expert or by one of our Service Technicians.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

EN

Maintenance interval	Maintenance work
Dependent upon the level of usage of the device	› Clean or replace the protective sieves at the aspiration inlet. At the latest, however, when the suction power of the unit diminishes. 
Annually	› Cleaning of the suction unit in accordance with the operating instructions. › Clean or replace the protective sieves at the aspiration inlet. › Where a rinsing unit is present: Clean the sieve/coarse filter in the water intake. * › Perform a function test. *
Every 3 years	› Replace the rubber grommets on the connections. *
Every 5 years	› Replace the rubber grommets on the connections. * › Replace all o-rings in the unit. *

* Only by customer services service technicians.

11 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

WARNING
Infection due to contaminated unit
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

EN

Fault	Probable cause	Solution
Device does not start	No power supply	› Check power supply. * › Check the fuses and replace if necessary. *
	No start signal	› Check the control voltage at the signal input. *
Suction power too weak or interrupted	Coarse sieve is blocked on the inlet of the aspiration	› Clean the coarse sieve.
	Place selection valve not or incompletely open	› Check the control voltage. * › Clean the place selection valve. *

* Only by customer services service technicians.

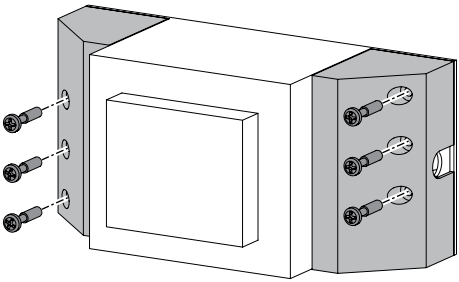
EN

11.1 Replacing the fuse

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

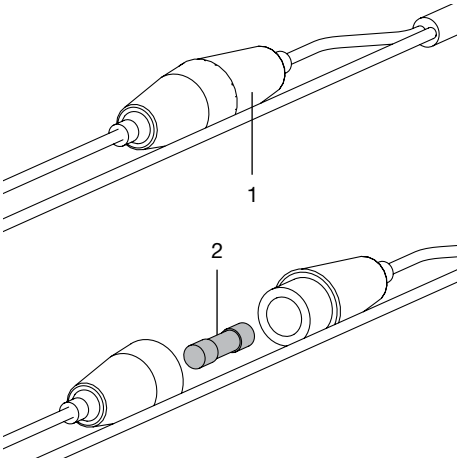
Transformer

› Unscrew and remove the safety cover.
› Replace the fuse.



Fuse housing

› Turn the fuse housing to open it.
› Replace the fuse.



1 Fuse housing
2 Fuses

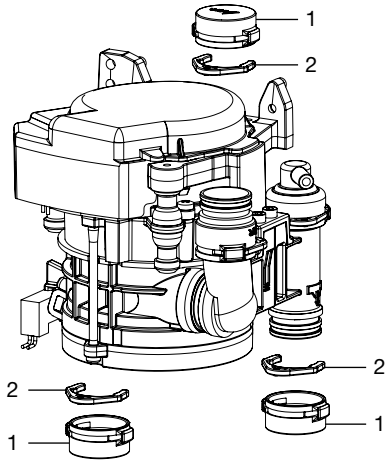
12 Transporting the unit

WARNING
Infection due to contaminated unit
› Disinfect the unit before transport.
› Close all media connections.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

› Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
› Disinfect a defective unit using a suitable surface disinfection agent.
› Seal all connections with sealing caps.
› Pack the unit securely in preparation for transport.

12.1 Close the CS 1



1 Dummy bushing
2 Ring clamp

13 Information about EMC in accordance with EN 60601-1-2

13.1 General information

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

13.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

Interference emission measurements	Compli-ance	Electromagnetic environment - guidelines
HF emissions in accord-ance with CISPR 11	Group 1	The CS 1 Combi-Sepamatic uses HF energy exclusively for internal functions. As a result, HF-transmissions are very low and it is highly unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accord-ance with CISPR 11	Class B	The CS 1 Combi-Sepamatic is suitable for use in all fa-cilities including those in living areas and areas that are directly connected to the public mains electricity supply that also supplies buildings used for residential purpos-es.
Harmonics in acc. with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Compliant	

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	$d = [3.5 / V_1] \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ V/m	$d = [3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = [7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz $d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz

Table 2: Electromagnetic interference immunity for units or systems that are operated in healthcare facilities

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a,b].

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
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

Table 3: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

13.4 Calculation table

If the measured values deviate from the standard, the values are specified in chapter "4 Technical data".

The safety distances can then be calculated in the tables shown below.

P: .....

V_1: .....

E_1: .....

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

V_1 Compliance level for the test in acc. with IEC61000-4-6

E_1 Compliance level for the test in acc. with IEC61000-4-3

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distances
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	d = [3.5 / V_1] · √P
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	d = [3.5 / E_1] · √P for 80 MHz to 800 MHz
			d = [7 / E_1] · √P for 800 MHz to 2.5 GHz

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz d = [3.5/V_1] ·√P	80 MHz to 800 MHz d = [3.5/E_1]·√P	800 MHz to 2.5 GHz d = [7 / E_1] ·√P
0.01			
0.1			
1			
10			
100			

Hersteller/Manufacturer:
DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL

01

ALYA

LAMPADA DENTALE A LED
DENTAL LED LIGHT

MANUALE D'USO
INSTRUCTION MANUAL
MODE D'EMPLOI
GEBRAUCHSANLEITUNG
MANUAL DE USO

CE Dispositivo Medico conforme
alla direttiva 93/42/CE
FARO SPA Ornago (Italy)

FARO
DAL 1948: ESPERIENZA
E RINNOVAMENTO

INDICE

1. REQUISITI DI SICUREZZA

Gentile Cliente,
FARO le augura buon lavoro con la nuova lampada di alta qualità. Per lavorare in modo sicuro e per sfruttare al massimo le performances del prodotto, legga attentamente il presente manuale prima dell'utilizzo del dispositivo. Segua in particolare tutte le avvertenze e le note riportate.

1.1 SIMBOLOGIA UTILIZZATA

1.1.1 Simbologia usata all'interno del manuale

	*AVVERTENZA*
I paragrafi contrassegnati con questo simbolo, contengono istruzioni che devono essere eseguite attentamente per evitare danni al dispositivo, all'operatore e al paziente.	

	*ATTENZIONE*
Queste istruzioni avvisano che bisogna porre molta attenzione per evitare situazioni che potrebbero danneggiare il dispositivo.	

	*DIVIETO*
Questa icona mette in evidenza cosa non si deve fare per evitare danni al dispositivo.	

	*NOTE*
Con questa icona, viene fornita un'informazione che permette di usare il dispositivo in modo più efficace.	

1.1.2 Simbologie presenti in etichettatura

La targhetta dati è fissata:

- per la lampada completa: sul braccio posteriore
- per la testata: sotto il copri-dissipatore

e riporta i seguenti dati:
Serial Number (SN): anno (AA) / famiglia di appartenenza (LD per lampada dentale - TE per la sola testata) più numero progressivo (NNNNNN) es: SN14LD000001 per la lampada completa SN 14TE000001 per la testata.
Sono inoltre presenti i seguenti simboli armonizzati:

	Leggere le istruzioni per l'uso. Fornite elettronicamente
	Simbolo di fabbricante ai sensi della Direttiva 93/42/EEC
	Le istruzioni d'uso includono avvertenze per la sicurezza
	Apparecchiatura RAEE in accordo alla direttiva 1012/19/CE. Smaltire il prodotto in accordo a questa direttiva.
	Doppio isolamento. Dispositivo di classe 2 contro il rischio elettrico
	Serial Number / Numero di Serie
	Sterilizzabile a Calore Umido a 134°C
	Utilizzare il dispositivo ad una Temperatura compresa tra 10°C e 40°C
	Utilizzare il dispositivo ad una Pressione compresa tra 800mbar e 1060mbar
	Utilizzare il dispositivo ad una Umidità Relativa compresa tra 30 RH e 75RH
	Simbolo per la regolazione dell'intensità luminosa
	Simbolo per l'accensione della lampada
	[Simbolo per l'accensione/spegnimento della luce sul braccio posteriore]

1.1.3 Simbologia presente sull'imballaggio

ALTO

FRAGILE

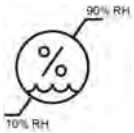
NON BAGNARE

NON ROTOLARE

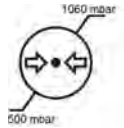
NON USARE GANCI

PESO MAX SOVRAPPONIBILE

TEMPERATURA DI IMMAGAZZINAMENTO
CONDIZIONI DI TRASPORTO



UMIDITÀ RELATIVA



PRESSIONE ATMOSFERICA

CARTONE RICICLABILE

1.2 USO PREVISTO

Il dispositivo è destinato ad essere utilizzato esclusivamente nello studio odontoiatrico da medici odontoiatri, odontostomatologi ed igienisti per l'illuminazione del sito operatorio e di intervento nel trattamento delle patologie del cavo orale e dell'apparato dentale.
Il dispositivo nel suo normale utilizzo è posizionato sopra il corpo del paziente ad una distanza di 700mm, distanza per la quale sono studiate le caratteristiche di illuminazione.
I pazienti trattati possono essere di tutte le età per patologie tipiche dell'apparato dentale.

1.3 UTILIZZATORE PREVISTO

L'utilizzatore previsto è il medico dentista, odontoiatra o l'igienista dentale.

1.3.1 Titolo di studio:

- Laurea in medicina con specializzazione in odonstomatologia
- Laurea in odontoiatria
- Laurea in Igiene dentale

1.3.2 Competenza minima

- Quelle previste dal titolo di studio
- Comprensione del linguaggio: Quelle acquisite con il titolo di studio

1.3.3 Esperienza

- Quella prevista per lo svolgimento della professione

1.3.4 Possibili handicap dell'utilizzatore

- Per l'utilizzo è necessario avere l'utilizzo di un arto superiore completo.
- Facoltà visive compatibili con la professione.

1.4 NORME GENERALI E PRINCIPALI AVVERTENZE

- Il dispositivo può essere applicato al riunito dentale, ma può anche essere installato su applicazioni dedicate. Il dispositivo può essere alimentato sia dal riunito dentale che da un alimentatore collegato direttamente alla rete. Si veda il paragrafo dedicato all'installazione
- Il dispositivo non possiede Performance Essenziali per cui l'inadeguatezza delle prestazioni del dispositivo non pregiudica la sicurezza del paziente.
- Il dispositivo non sostiene la vita.
- Il dispositivo deve essere pulito prima dell'utilizzo (vedi paragrafo "Pulizia del dispositivo").
- L'imballo della lampada è idoneo a proteggere adeguatamente la stessa dalla penetrazione di agenti esterni.

	**Avvertenza contro il pericolo elettrico o di incendio**
	Non usare la lampada in caso di danneggiamento dei suoi componenti. L'installazione del dispositivo deve essere eseguita solo da personale qualificato. La lampada dentale deve essere installata su uno specifico dispositivo di controllo e di alimentazione, come riuniti dentali, o con impianto elettrico che soddisfa la norma IEC 60364-1 e le "regole nazionali d'installazione per impianti elettrici in locali adibiti ad uso medico". L'apparecchio deve essere installato con un dispositivo di separazione dalla rete di tipo omnipolare e conforme alla Norma IEC 61058-1. L'installazione e il mantenimento della conformità del dispositivo alla norma IEC 60601-1 è a carico dell'installatore o del fabbricante di riuniti. Verificare che la tensione di alimentazione, indicata sulla targhetta dati, corrisponda a quella di rete. Non effettuare alcun intervento di manutenzione sulla lampada quando l'alimentazione è inserita: scollegare quindi il cavo di alimentazione dalla rete prima di intervenire.
	**Avvertenza contro il pericolo di degrado delle parti meccaniche e caduta di masse sospese**
	Per la pulizia delle parti in plastica non utilizzare detergenti contenenti: AMMONIUM HYDROXIDE - SODIUM HYDROXIDE - METHYLENE CLORIDE – METHYL ALCOHOL. Il mancato rispetto della prescrizione potrebbe causare: RISCHIO DI DEGRADO DELLE PARTI IN PLASTICA CON CONSEGUENTE ROTTURA. Non spruzzare alcun agente chimico direttamente sulla lampada. In particolare è vietato l'utilizzo di sostanze abrasive, acide, contenenti cloro.
	**Avvertenza per il pericolo di caduta di masse sospese**
	Attenersi scrupolosamente al rispetto dei carichi massimi previsti. Non impattare o sovraccaricare i finecorsa dei bracci e delle testate.
	**Avvertenza per il pericolo fotobiologico e di abbagliamento**
	Non fissare o puntare il fascio luminoso direttamente negli occhi del paziente soprattutto per i pazienti a maggior rischio di lesioni oculari (es. bambini con patologie agli occhi). In questo caso utilizzare sempre opportune protezioni e precauzioni. La lampada è classificata come rischio fotobiologico Exempt in accordo alla EN 62471. Tuttavia non si esclude che pazienti particolarmente fotosensibili o che abbiano assunto medicinali fotosensibilizzanti, possano avere degli eritemi o delle reazioni allergiche alla luce. In questo caso sospendere il trattamento ed utilizzare livelli di illuminamento molto bassi. Il braccio articolato e gli snodi della Lampada permettono il corretto posizionamento del fascio luminoso.
	**Avvertenza per il pericolo danneggiamento dei componenti elettrici**
	Non sovraccaricare i bracci e gli snodi con urti a fine corsa. La rotazione di testata e bracci oltre i finecorsa può danneggiare gli isolamenti dei conduttori.
	**Avvertenza per il pericolo di esplosione**
	Il dispositivo non è adatto ad essere installato in ambienti con presenza di gas infiammabile o ricchi di ossigeno.
	**Avvertenza per il pericolo di contaminazione crociata paziente-paziente**
	Il medico è tenuto ad utilizzare le protezioni monouso sulle maniglie della lampada o a sterilizzarle dopo ogni paziente. Per la disinfezione delle superfici usare disinfettanti idroalcolici (vedi paragrafo manutenzione/pulizia).
	**Avvertenza per il pericolo di manutenzione errata**
	Non eseguire operazioni di manutenzione o di sostituzioni di parti diverse da quelle riportate nel manuale. Qualsiasi intervento non indicato nello stesso potrebbe compromettere l'aspetto sicurezza previsto dal dispositivo. Eseguire solo operazioni di manutenzione riportate nel manuale; in qualsiasi altro caso rivolgersi all'assistenza tecnica.

Il Prodotto coperto dalla Direttiva RAEE 2012/19/UE
Per la rottamazione e lo smaltimento dei materiali attenersi alla normativa vigente del proprio paese, ricorrendo eventualmente a ditte specializzate riconosciute e autorizzate.
Alla fine del ciclo vita dividere i materiali in base alla loro tipologia (ferrosi, gomma, plastica).
Non lasciare piccoli componenti dell'apparecchiatura incustoditi o alla portata di persone esposte (bambini) perchè potenziali fonti di pericolo.
La società FARO non ammette alcuna modifica al prodotto che non sia espressamente autorizzata per iscritto, pena la decadenza della conformità alle norme di sicurezza e della garanzia.
Altre avvertenze sono riportate nei titoli del presente manuale.

1.5 CONSERVAZIONI ED UTILIZZO: PRESCRIZIONI AMBIENTALI

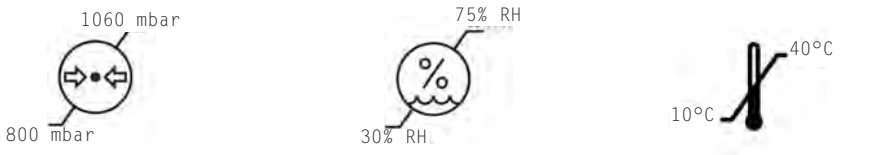
L'apparecchio nell'imballo originale può essere trasportato o tenuto in magazzino per un periodo di 15 settimane se vengono rispettate le seguenti condizioni ambientali:

- Temperatura ambiente da -20°C a + 70°C
- Umidità relativa dal 10% al 90%
- Pressione atmosferica da 800 a 1060 mbar

L'apparecchio deve essere utilizzato alle seguenti condizioni ambientali:

- Temperatura da 10°a 40°C
- Altitudine max: 2000 m
- Umidità relativa da 30 a 75%

PRESSIONE ATMOSFERICA **UMIDITÀ RELATIVA** **TEMPERATURA D'USO**



1.6 REQUISITI DI COMPATIBILITÀ ELETTROMAGNETICA

Il dispositivo medico necessita di particolari precauzioni per quanto concerne la compatibilità elettromagnetica e deve essere installatio e utilizzato secondo le informazioni fornite con i documenti di accompagnamento.

Guida e dichiarazione del costruttore - Emissioni elettromagnetiche		
La lampada ALYA è prevista per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dovrebbero assicurarsi che esso venga usato in tale ambiente		
Prova di Emissione	**Conformità**	**Ambiente Elettromagnetico - Guida**
RF Emission CISPR11 / EN 55011	Group 1	La lampada ALYA utilizza energia RF solo per il funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini.
RF Emission CISPR11 / EN 55011	Class B	La lampada ALYA è adatta per l'utilizzo in tutti gli edifici, inclusi quelli domestici e quelli direttamente collegati alla rete di alimentazione pubblica in bassa tensione che alimenta edifici per domestici.
Harmonic emission EN/IEC 61000-3-2	Class C	
Voltage fluctuations/flicker emission EN/IEC 61000-3-3	Conforme	
RF Emission CISPR11 / EN 55011	Conforme	La lampada ALYA non è adatta per essere interconnessa con altri dispositivi (versione da soffitto).

IMMUNITA' ELETTROMAGNETICA

Guida e dichiarazione del costruttore - Immunità elettromagnetica		
La lampada ALYA è prevista per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dovrebbero assicurarsi che esso venga usato in tale ambiente		
Prova di Immunità	**Conformità**	**Ambiente Elettromagnetico - Guida**
Electrostatic discharge (ESD) IEC/EN61000-4-2	± 6kV contact ± 8kV air	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno al 30%.
Electrical fast transient/burst IEC/EN61000-4-4	± 2kV power supply ± 1kV for input/output lines	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero.
Surge IEC/EN61000-4-5	± 1kV differential mode ± 2kV common mode	La qualità della tensuione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero.
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.	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore della lampada ALYA richiede unn uso continuativo anche in assenza della tensione di rete si raccomanda l'uso di un gruppo di continuità.
Power frequency magnetic field IEC/EN61000-4-8	3A/m	Livello di campo magnetico alla frequenza di rete tipico di un ambiente commerciale e ospedaliero.
Immunità Condotte IEC/EN61000-4-6	3Vrms 150kHz to 80MHz (per apparecchi che non sono life-supporting)	Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati vicino a nessuna parte dell'unità dentale, compresi i cavi, eccetto quando rispettano le distanze di separazione raccomandate calcolate dall'equazione applicabile alla frequenza del trasmettitore. Distanze di separazione raccomandate: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ da 80 Mhz a 800 MHz $d = 2,3\sqrt{P}$ da 800 MHz a 2,5 GHz Dove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e d é la distamza di separazione raccomandata in metri (m). L'intensità del campo dei trasmettitori a RF fissi, come determinato in un'indagine elettromagnetica del sito a, potrebbe essere minore del livello di conformità di ciascun intervallo di frequenza. Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo:
Immunità Condotte IEC/EN61000-4-6	3Vrms 80MHz to 2.5GHz (per apparecchi che non sono life-equipment)	
Nota: Ut è il valore della tensione di alimentazione Nota 1: A 80 MHz e 800 Mhz si applica l'intervallo della frequenza più alta. Nota 2: Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone. a) Le bande ISN (industriali, scientifiche e medicali) tra i 150kHz e 80MHz sono 6,765 MHz a 6,795MHz; 13,553 MHz a 13,567 MHz; 26,957 MHz a 27,283 MHz e 40,66 MHz a 40,70 MHz. b) I livelli di conformità nelle bande ISN tra 150kHz e 80MHz e nelle bande 80MHz a 2,5GHz sono intesi a decrescere in probabilità che un dispositivo di trasmissione portatile può causare interferenza se inavvertitamente portato nell'area paziente. Per questa ragione, un fattore addizionale di 10/3 è stato incorporato nella formula usata nel calcolo della distanza di separazione dai trasmettitori. c) Le intensità di campo per trasmettitori fissi come le stazioni di base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoreticamente e con precisione. Per stabilire un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa l'unità dentale supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale della lampada. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione della lampada. d) L'intensità di campo su un intervallo di frequenze da 150 kHz a 80 MHz dovrebbe essere minore di 3 V/m.		

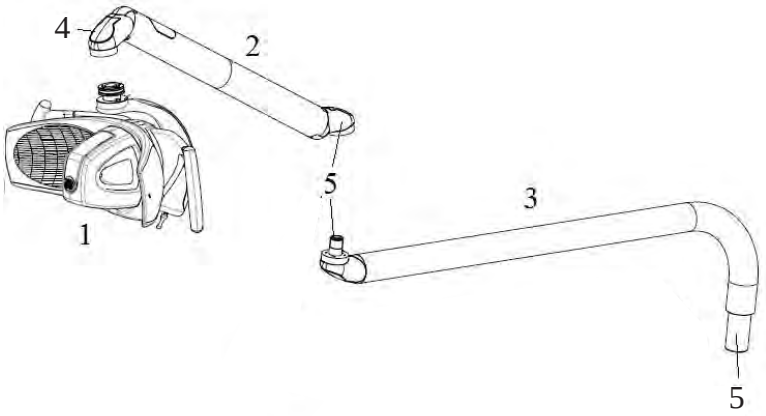
Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili e mobili e l'unità dentale			
La lampada ALYA è prevista per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore dell'unità possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e l'unità dentale, come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.			
Potenza di uscita nominale massima del trasmettitore W	**Distanza di separazione alla frequenza del trasmettitore m**		
	150 kHz a 80 MHz $d = 1,2\sqrt{P}$	80 MHz a 800 MHz $d = 1,2\sqrt{P}$	800 MHz a 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
Per i trasmettitori con potenza nominale massima di uscita sopra non riportata, la distanza di separazione raccomandata d in metri (m) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, ove P è la potenza masima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore. Note: A 80 MHz e 800 MHz si applica l'intervallo della frequenza più alta. Queste linee guida potrebbero non applicarsi inn tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.			

2. CARATTERISTICHE GENERALI

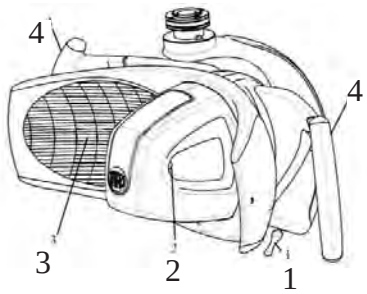
2.1 DESCRIZIONE DEL PRODOTTO

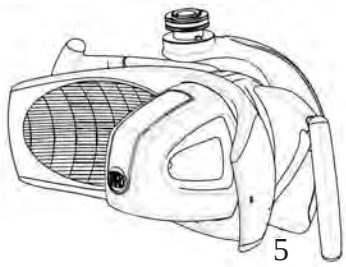
Il dispositivo serve all'utilizzatore previsto per l'illuminazione del campo operatorio nel trattamento delle patologie dell'apparato dentale.
La sorgente luminosa sita sulla testata è costituita da due LED la cui luce si riflette su due parabole passando per 2 lenti secondarie.
I riflettori permettono di ottenere uno spot di luce regolare ed uniforme ad ogni livello d'illuminamento e di distribuire uniformemente la luce nel campo operativo, senza creare ombre od oscuramenti da parte dell'operatore.
La regolazione dell'intensità luminosa può essere effettuata con un joystick o con proximity.
Il Proximity permette di accendere o spegnere la lampada senza avere un contatto diretto, eliminando così la possibilità di infezioni incrociate sul comando.
La funzione "accensione automatica" o "Auto-on" permette alla lampada di accendersi automaticamente ogni qualvolta che viene attivata l'alimentazione alla lampada.
Il cavo remoto permette di portare i comandi della lampada alla faretra del riunito. Attenersi alle istruzioni fornite nel paragrafo installazione.
Sulla testata in prossimità del joystick e/o del sensore proximity è presente un tasto che permette di attivare la funzione di sincronizzazione con la lampada ambiente prodotta da Faro. La funzione di sincronizzazione consente alla lampada Alya di comandare il livello di illuminamento della lampada ambiente al fine di garantire un livello di illuminamento più uniforme tra il campo operatorio e la zona circostante in modo da ridurre l'effetto di abbagliamento e migliorare il confort visivo.
Nella versione con la luce sul braccio posteriore denominata "Alya con Theia Tech" la sorgente luminosa è costituita da una serie di LED la cui luce passando attraverso un diffusore viene distribuita nell'ambiente sottostante.
La regolazione del livello di illuminamento avviene in sincrono con quella della testata per cui al ridurre o aumentare l'illuminamento della luce prodotta dalla testata si regola di conseguenza anche quella sul braccio.
La lampada versione "Theia Tech" avrà inoltre un comando locale destinato solo a fornire on/off sito sul braccio fisso.
Una volta accesa dal comando locale la luce si sincronizza automaticamente con il livello di intensità della testata. Se la luce della testata fosse spenta, la luce sul braccio posteriore si accenderà alla massima intensità. Alla successiva accensione della luce sulla testata la luce sul braccio si andrà a sincronizzare automaticamente.
La luce sul braccio svolge la funzione di incrementare la visibilità nella zona pre-operatoria andando a ridurre l'abbagliamento che si genera in seguito e/o successivamente alla visione del campo operatorio.
La Manutenzione è facilitata grazie all'applicazione di nuove tecnologie che tengono in considerazione le varie esigenze in fatto di sicurezza, ergonomia e igiene.
Le maniglie sono staccabili e sterilizzabili. Attenersi alle prescrizioni definite nella sezione dedicata.
Per i collegamenti elettrici attenersi alle istruzioni fornite nel paragrafo installazione e agli schemi elettrici inclusi in questo manuale.

2.2 DESCRIZIONE DELLE PARTI

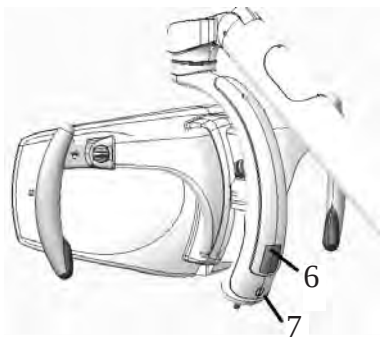


1 – Testata
2 – Braccio centrale
3 – Braccio posteriore senza trasformatore con o senza luce (Theia Tech).
4 – Snodi
5 – Perno per collegamento a riunito o ad applicazione





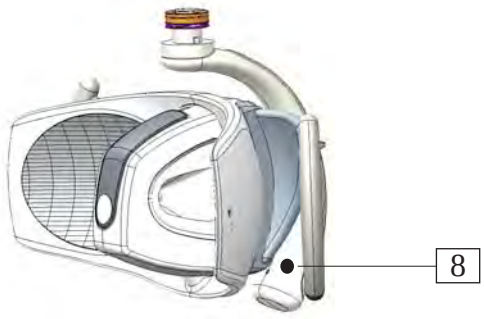
1 – Joystick
2 – Lente secondaria LED
3 – Riflettore
4 – Maniglie sterilizzabili
5 – Proximity



6 – Alloggiamento della scheda elettronica
7 – Simboli di accensione e regolazione
8 – Tasto di sincronizzazione

Versione con joystick

Versione con Proximity



2.3 IDENTIFICAZIONE DEL DISPOSITIVO

Le varianti in commercio si differenziano per:

- Tipo di dispositivo (lampada completa, lampada completa con Theia Tech o testata)
- Interfaccia di accensione e regolazione **(Joystick o Proximity; per lampada completa e testata)**
- Modalità di controllo da riunito (funzione on-off, controllo remoto; per lampada completa e testata)
- Tipo di montaggio **(riunito, soffitto, parete e pavimento; solo per lampada completa)**
- Lunghezza bracci (solo per lampada completa)
- Alimentazione

Lo sviluppo dei codici è il seguente:

ALYA – Lampada completa					
Type	3° digit Mounting e controllo da riunito	4° digit – Voltaggio e interfaccia	5° digit – braccio post x braccio centrale (mm)	6° digit Disponibile	7° 8° 9° digit Customizzazione
5 1	0 Riunito standard	0 Joystick 17-24 V AC 22-35 V DC	0 810x550	0	000 (std FARO) JJJ
	1 Soffitto	1 Proximity 17-24 V AC 22-35 V DC	1 960x550		
	2 Riunito Auto-on		9 810x 855		
	4 Riunito Cavo Rem				

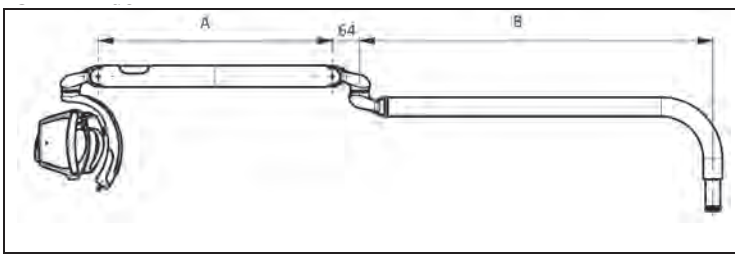
ALYA – Lampada completa con Theia Tech					
Type	3° digit Mounting e dimensioni bracci	4° digit tipo di Testata	5° digit tipo di interfaccia	6° digit Voltaggio	7° 8° 9° digit Customizzazione
52	1 Riunito 550*810	1 Standard	1 joystick	1 24Vac 50/60Hz 24 V dc	000 (std FARO) JJJ
	2 Riunito 550*960	2 Con prolunga	2 Joystick auto-on		
	3 Riunito 855*810		3 sensore		
	4 Riunito 855*960		4 Sensore auto-on		
	5 Soffitto 550*810		5 Joystick + cavo remoto		
	6 Soffitto 550*960		6 Joystick auto-on + cavo remoto		
	7 Soffitto 855*810		7 Sensore + cavo remoto		
	8 Soffitto 855*960		8 Sensore auto-on + cavo remoto		

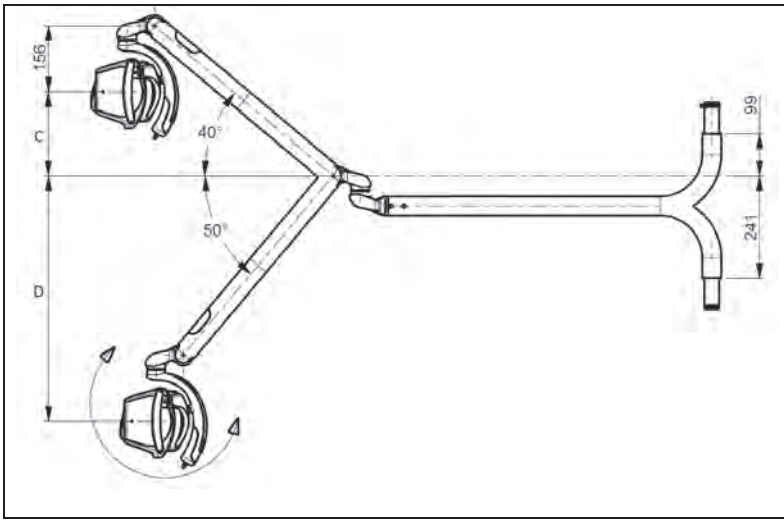
TESTATA ALYA (ALYA HEAD)					
Type	3° digit Col Temperature e controllo riunito	4° digit – Alimentazione e controllo	5° digit Available	6° digit Colors	7° 8° 9° digit Custom
3 1	5 Gruppo Ottico 5000 K	0 Joystick 17-24 V AC 22-35 V DC	0	0 White	000 Std FARO
	6 Gruppo Ottico 5000 K On/Off	1 Proximity 17-24 V AC 22-35 V DC		3 Grey	
	8 G.O. 4000 K				

3. INSTALLAZIONE DEL DISPOSITIVO

⚠	**Avvertenza per il pericolo elettrico, per lampada e testata:**
	Il dispositivo deve essere installato da tecnici specializzati. All'atto dell'installazione l'alimentazione deve sempre essere disinserita. Far riferimento agli schemi elettrici presenti nel manuale. Verificare i dati di targa prima dell'installazione
ℹ	**Nota per l'installazione**
	Il cavo di alimentazione della lampada completa è fornito senza alcun connettore o terminale per dare l'opportunità di effettuare il collegamento a seconda delle specifiche del riunito o dell'applicazione. Il funzionamento o la sicurezza della lampada non dipendono dalla polarità della corrente di alimentazione. Pertanto l'inversione dei cavi di alimentazione non comporta rischi di malfunzionamento.

3.1 INGOMBRI





	A	B	C	D
mm	550	830	265	510
mm	550	980	265	510
mm	855	830	394	706
mm	855	980	394	706

3.2 LAMPADA DENTALE COMPLETA

3.2.1 Requisiti Elettrici

I requisiti per la corretta installazione per qualsiasi applicazione (riunito, parete, pavimento o soffitto) sono i seguenti:

Alimentazione	Cavo di alimentazione	Tipo di alimentazione e requisiti di protezione	Classificaz.	Conformità alla IEC 60601-1
Versione lampada completa 17-24 Vac 50/60 Hz	2 x 0,5 mm2 300 V 105°C Isolamento PVC diametro isolamento 1,85 mm Utilizzare solo terminali e connettori certificati con resistenza alla fiamma V1 o similare.	trasformatore conforme lalla IEC/EN 60601-1 terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T1.6AL 250V Requisiti minimi: • Output: 17-24 Vac; • Power: 26 VA; • Class B; • Rigidità superiore a 4000 V. • Protezione termica	Component built-in	Il sistema medicale risultante deve essere dichiarato conforme all'IEC/EN60601-1 dall'installatore o dal fabbricante. Nota per l'installatore: assicurarsi che il riunito su cui si va ad installare la lampada sia certificato per accogliere la lampada completa.
Versione lampada completa 22-33Vdc		Alimentatore conforme alla IEC/EN 60601-1 terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T630mAL 250V Requisiti minimi: • Output: 22-33 Vdc; • Power: 14 VA; • Class B; • Rigidità superiore a 4000 V; Protezione continua da corto circuito e sovracorrenti		
Versione lampada completa con Theia Tech 24Vac 50/60Hz		trasformatore conforme alla IEC/EN 60601-1 terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T2AL 250V Requisiti minimi: • Output: 24Vac; • Power: 40VA • Class B; • Rigidità superiore a 4000 V. Protezione termica		

Alimentazione	Cavo di alimentazione	Tipo di alimentazione e requisiti di protezione	Classificaz.	Conformità alla IEC 60601-1
Versione lampada completa con Theia Tech 24Vdc	2 x 0,5 mm2 300 V 105°C Isolamento PVC diametro isolamento 1,85 mm Utilizzare solo terminali e connettori certificati con resistenza alla fiamma V1 o similare.	trasformatore conforme alla IEC/EN 60601-1 terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T2AL 250V Requisiti minimi: • Output: 24 Vdc; • Power 28 VA • Class B; • Rigidità superiore a 4000 V. Protezione termica	Component built-in	Il sistema medicale risultante deve essere dichiarato conforme all'IEC/EN60601-1 dall'installatore o dal fabbricante. Nota per l'installatore: assicurarsi che il riunito su cui si va ad installare la lampada sia certificato per accogliere la lampada completa.

Tab 1 – Requisiti per il collegamento elettrico e conformità alla IEC 60601-1.

Verificare che nella confezione siano contenuti i seguenti componenti:
- Lampada dentale / Testata (nella versione richiesta)
- Foglietto per scaricare le istruzioni dal sito www.faro.it/download

3.2.2 Carichi di sicurezza

La lampada dentale ALYA e ALYA THEIA può essere installata su varie applicazioni:
RIUNITO, SOFFITTO, PARETE, PAVIMENTO.

CARICHI DI SICUREZZA BRACCI

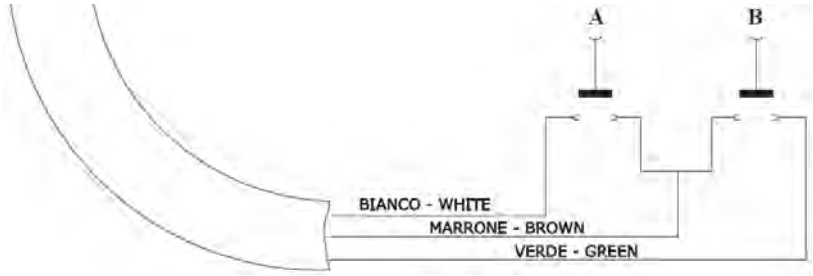
	Carico totale (SAFE WORKING LOAD)	Carico in sicurezza (MINIMUM BREAKING LOAD)
Braccio lung. 855 mm	29.2 N	235 N
Braccio lung. 550 mm	25.6 N	205 N

3.2.3 Montaggio lampada completa versione a riunito

Con una livella digitale, assicurarsi che l'elemento di connessione sia perfettamente parallelo al terreno.
Installare la lampada inserendo il perno terminale lampada nell'apposito alloggiamento del riunito.
Collegare il cavo di alimentazione secondo le specifiche riportate in tab 1.
Verificare che la lampada mantenga l'equilibrio in tutte le posizioni. Se necessario, agire sul sistema di regolazione della molla per equilibrare la lampada.
Verificare accensione e regolazione e (se presenti) comando Auto-on e cavo remoto

3.2.4 Connessione cavo remoto

collegare il cavo a due pulsanti (A e B) con contatto normalmente aperto (non forniti) secondo lo schema seguente:



3.2.5 Installazione applicazioni

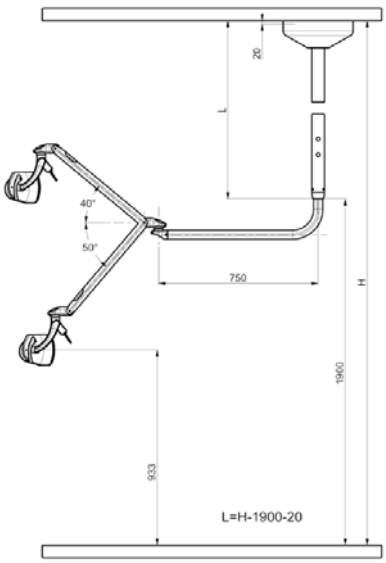
- Le applicazioni non sono fornite con la lampada
- Le applicazioni devono essere installate da tecnici specializzati

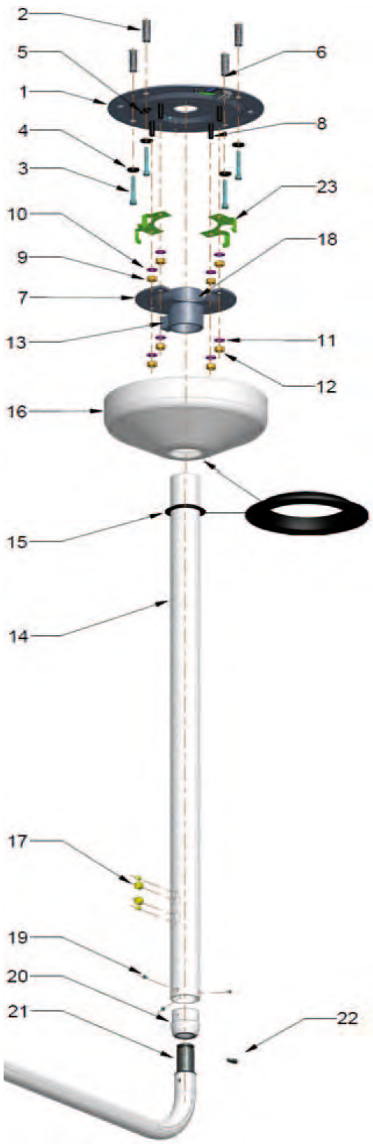
La lampada deve essere installata solo con applicazioni FARO

La lampada è dotata di un fine corsa di rotazione tra braccio fisso e braccio mobile. IL FINE CORSA NON DEVE ESSERE MAI SUPERATO O FORZATO

MONTAGGIO APPLICAZIONE A SOFFITTO

1. Flangia a soffitto
2. Espansore
3. Vite
4. Rondella
5. Passacavo
6. Morsettiera
7. Flangia
8. Vite
9. Dado
10. Rondella
11. Rondella
12. Dado
13. Vite
14. Colonna
15. Anello
16. Plafoniera
17. Tappo
18. Vite
19. Vite
20. Bussola raccordo colonna
21. Perno lampada
22. Chiavetta a settore
23. Guida di fissaggio



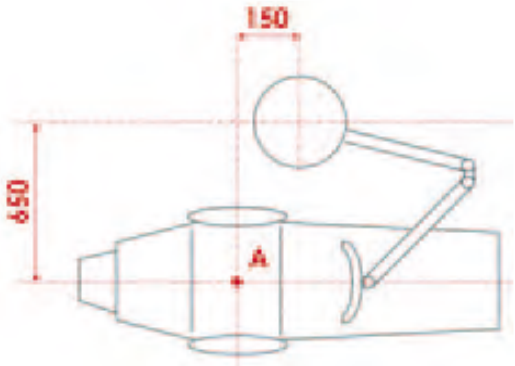


APPLICAZIONE A SOFFITTO

NB1. Il dispositivo deve essere installato da tecnici specializzati.
NB2. L'alimentazione all'interno del locale dove si esegue l'installazione deve essere sempre disinserita.
NB3. Prima di procedere con le operazioni di montaggio è necessario accertarsi che il soffitto sia in grado di reggere l'applicazione.
I materiali del soffitto autorizzati sono calcestruzzo e pietra naturale. I tasselli da utilizzare sono quelli forniti in dotazione o equivalenti.
NB4. Massimo carico applicabile: 70 kg
NB5. Installare in locali con impianto elettrico conforme alle normative nazionali vigenti sui locali medici

SEQUENZA DI INSTALLAZIONE

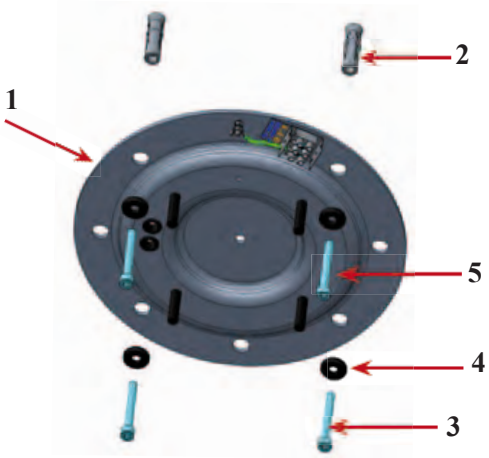
A. Stabilito come punto di riferimento il centro della poltrona (A), eseguire l'installazione a una distanza di 650mm e 150mm nelle direzioni mostrate in figura



B. Disassemblare la flangia (7) rimuovendo dadi (12) e rondelle (11).

C. Utilizzando come guida la flangia (1), effettuare nel soffitto 4 fori con la punta Ø14. In questi fori montare gli espansori (2).

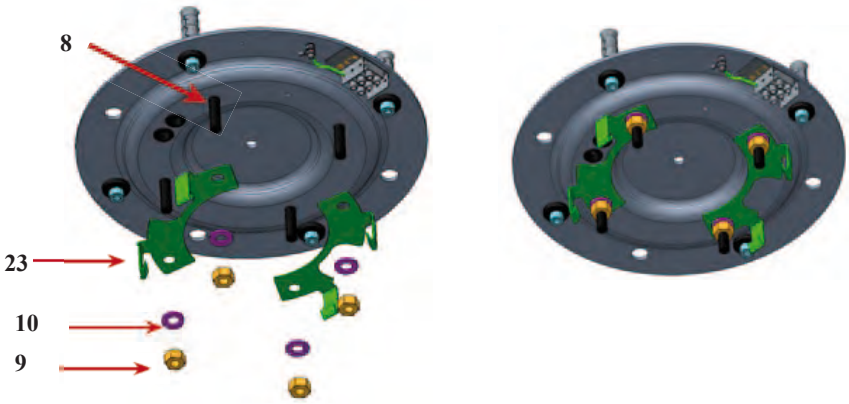
D. Prendere la flangia (1). Far passare il filo dell'alimentazione nel passacavo (5), quindi spingere contro il soffitto la flangia (1) avendo cura di non schiacciare il filo tra la flangia (1) ed il soffitto. Far passare le viti (3), unite alle rondelle (4), nei 4 fori utilizzati per fare i fori nel soffitto. Bloccare con l'apposita chiave esagonale (accessori di supporto) le viti (3).



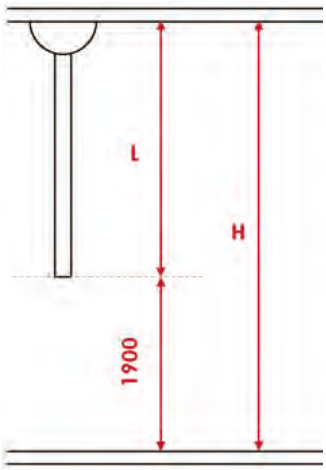
E. Collegare il filo dell'alimentazione alla morsettiera (6) (vedi schemi elettrici)

APPLICAZIONE A SOFFITTO

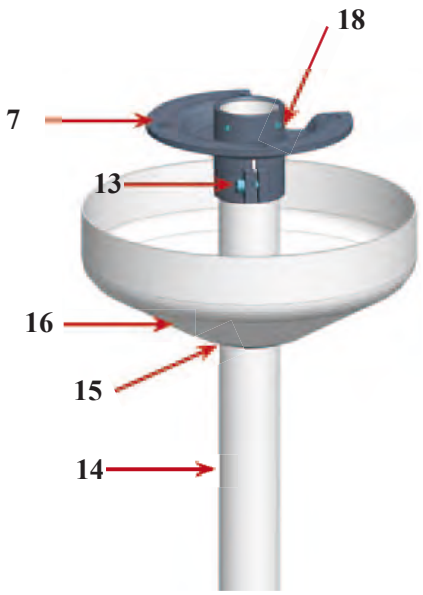
F. Calzare le 2 guide di fissaggio (23) sulle viti (8) e fissarle con dadi (9) e rondelle (10).



G. Calcolare la lunghezza giusta della colonna (14), secondo la formula L=H-1900mm. Fare attenzione di tagliare la parte eccedente della colonna (14) dal lato dove NON vi sono le forature laterali.



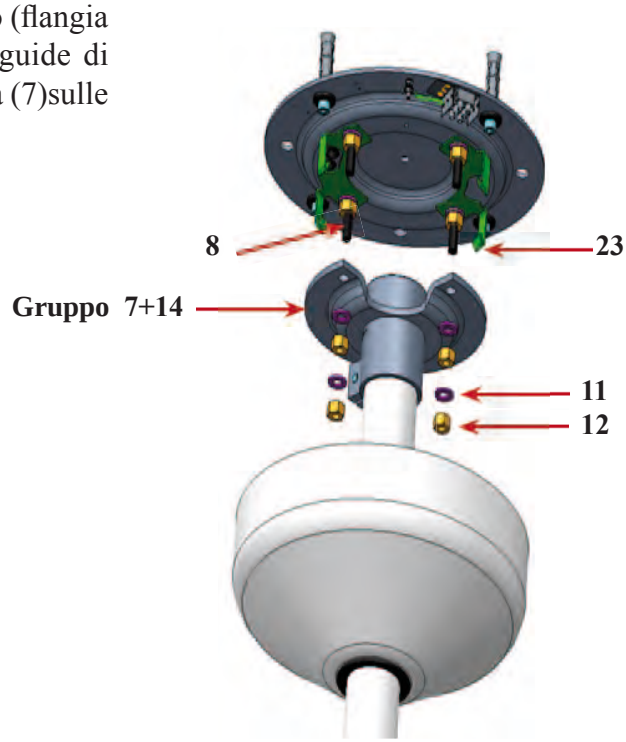
H. Infilare la colonna (14) nella flangia (7) e segnare sulla colonna (14) la posizione dei fori presenti sulla flangia (7). Prestare attenzione all'orientamento della colonna rispetto al riunito. Estrarre la colonna ed effettuare due fori passanti Ø8 in corrispondenza dei segni effettuati.



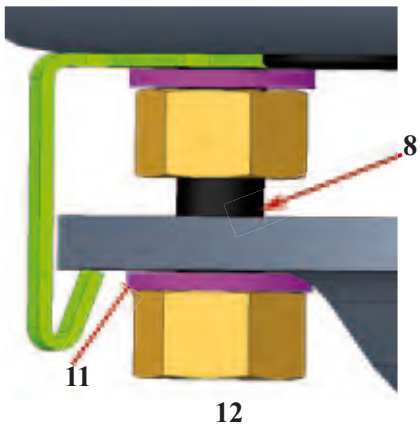
I. Infilare sulla colonna (14) l'anello (15) per circa 300 mm (non è la posizione corretta, ma è solo una posizione temporanea per permettere il montaggio).
J. Inserire la plafoniera (16) sulla colonna (14).
K. Introdurre la colonna (14), nell'apposito foro delle flangia attacco colonna (7).
L. Bloccare la vite (13) e le due viti (18) con chiavi esagonali (accessori di supporto). Serrare con forza la vite (13) e assicurarsi che le viti (18) attraversino i fori della colonna (14).

APPLICAZIONE A SOFFITTO

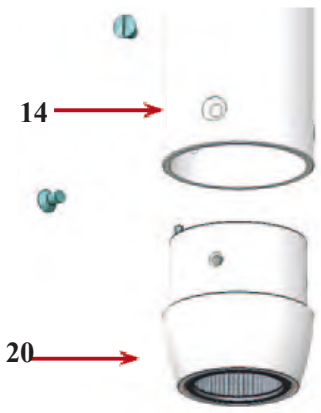
M. Agganciare il gruppo appena assemblato (flangia attacco colonna (7) + colonna (14)) alle guide di fissaggio (23), centrando i 4 fori della flangia (7)sulle viti (8) della flangia a soffitto (1).



N. Avvitare (senza bloccarli) i dadi (12) e le restanti rondelle (11) sulle viti (8) della flangia a soffitto (1).



O. Svitare le tre viti (19) della colonna (14) ed estrarre la bussola (20).
P. Infilare la bussola (20) sul perno (21) della lampada.
Q. Inserire nella scanalatura del perno (21) la chiavetta a settore (22).



APPLICAZIONE A SOFFITTO

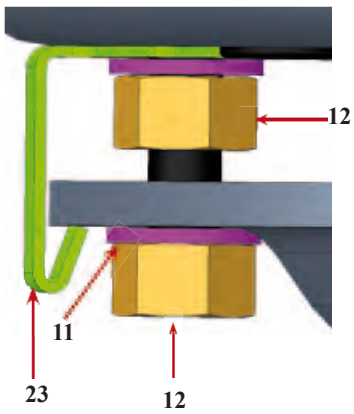
R. Infilare nella colonna (14) dall'alto un cavo di trazione.

S. Collegare il conduttore della lampada al cavo di trazione.

T. Inserire la lampada nella colonna (14) e fissarla con le tre viti (19), avendo cura di orientare i fori della bussola (20) in corrispondenza delle sedi delle viti sulla colonna (14) e avvitarle. Contemporaneamente tirare il cavo di trazione fino a far uscire il conduttore della lampada dalla flangia attacco colonna (7) per circa 200 mm.

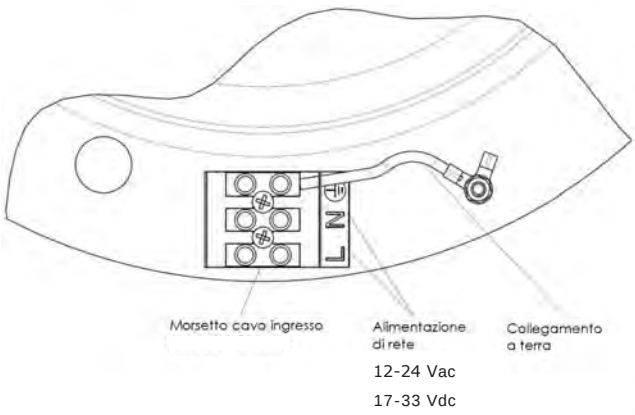
U. Collegare il conduttore della lampada alle morsettiere (6) (vedi schemi elettrici).

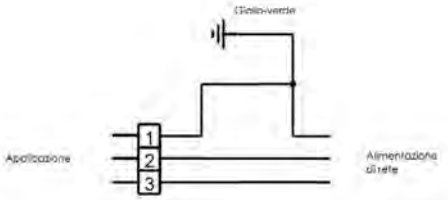
V. Verificare la perpendicolarità della colonna agendo sui dadi (9).
W. Stringere i dadi (12) e le rondelle (11) per fissare la flangia (7), rendendola indipendente dalle guide di fissaggio (23).
X. Far aderire la plafoniera (16) al soffitto, spingendovi contro l'anello (15).



SCHEMA ELETTRICO

Applicazione a soffitto SENZA trasformatore

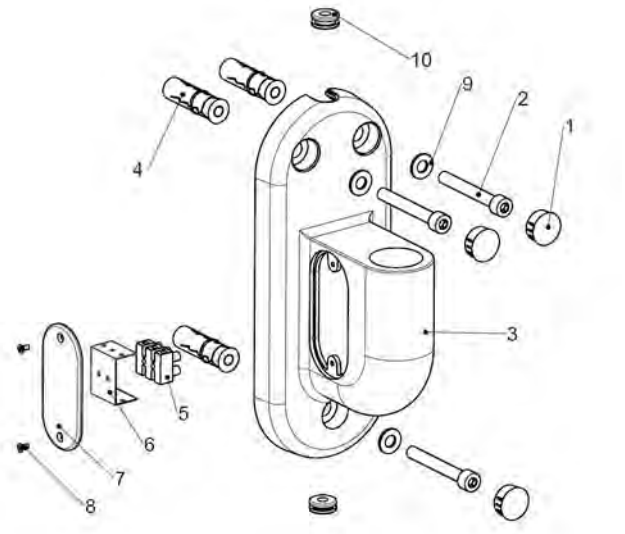


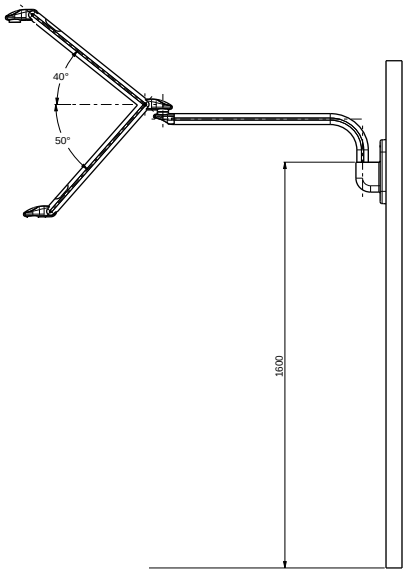


APPLICAZIONE A PARETE

MONTAGGIO LAMPADA APPLICAZIONE A PARETE

1. Tappo
2. Vite
3. Applicazione a parete
4. Espansori
5. Morsettiera
6. Copertura morsettiera
7. Copertura
8. Vite
9. Rondella
10. Passacavo





NB1. Il dispositivo deve essere installato da tecnici specializzati.
NB2. L'alimentazione all'interno del locale dove si esegue l'installazione deve essere sempre disinserita.
NB3. Prima di procedere con le operazioni di montaggio è necessario accertarsi che la parete sia in grado di reggere l'applicazione.
I materiali della parete autorizzati sono calcestruzzo e pietra naturale. I tasselli da utilizzare sono quelli forniti in dotazione o equivalenti.
NB4. Massimo carico applicabile: 70 kg.
NB5. Installare in locali con impianto elettrico conforme alle normative nazionali vigenti sui locali medici.
NB6. La lampada senza trasformatore deve essere alimentata da corrente a bassa tensione (12-24Vac o 17-33Vdc) utilizzando un trasformatore o alimentatore di sicurezza (conforme alla IEC/EN 60601-1) con protezione termica o protetto da almeno un fusibile appropriato (T500mAL250V~).
Il sistema medicale risultante deve essere dichiarato conforme alla IEC/EN 60601-1 dall'installatore.

APPLICAZIONE A PARETE

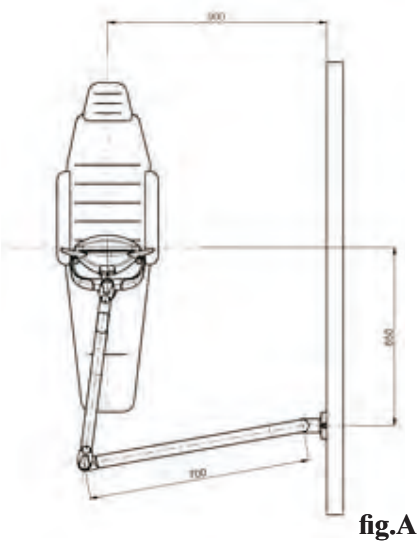


fig.A

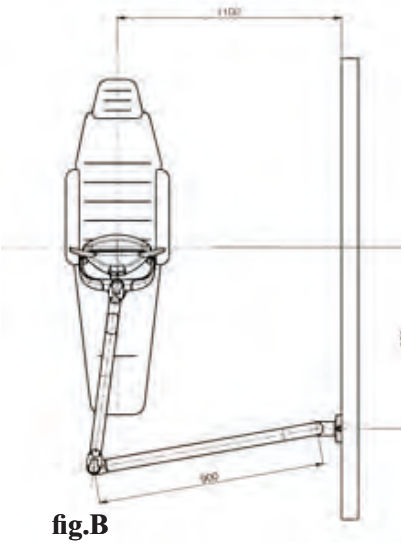
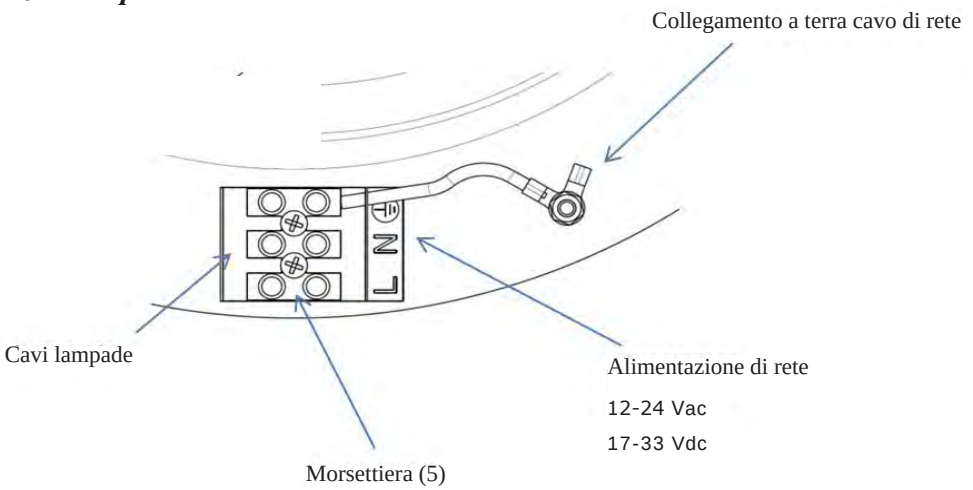


fig.B

- L'alimentazione all'interno del locale dove si esegue l'installazione, deve essere sempre disinserita.
- Stabilito il punto di fissaggio con riferimento il centro della poltrona (Vedi fig.**A-B**), eseguire sulla parete tre fori d.14 in corrispondenza dei fori dell'applicazione a parete (3), curando attentamente la perpendicolarità del foro.
- Inserire i tre espansori (12) nei fori d.14 fatti in precedenza e bloccare con l'apposita chiave esagonale (accessori di supporto) le viti 2, avendo cura di non schiacciare il filo tra l'applicazione a parete (3) e la parete stessa.
- Applicare i tre tappi (1) sui fori dell'applicazione a parete (3).
- Svitare la vite (8) Togliere la copertura (7), inserire in braccio della lampada nell'applicazione a soffitto ingrassando il perno. Collegare i fili della lampada alla morsettiera (5) (vedi sotto schema di cablaggio) compreso il filo di terra. Collegare i fili uscenti dalla parete alla morsettiera, nel caso fosse stato precedentemente murato. In mancanza di tale accorgimento, il collegamento deve essere effettuato con un cavo volante esterno, da introdurre nel passacavo (10).
- Rimontare la copertura (7) mediante le viti (8).

SCHEMA ELETTRICO

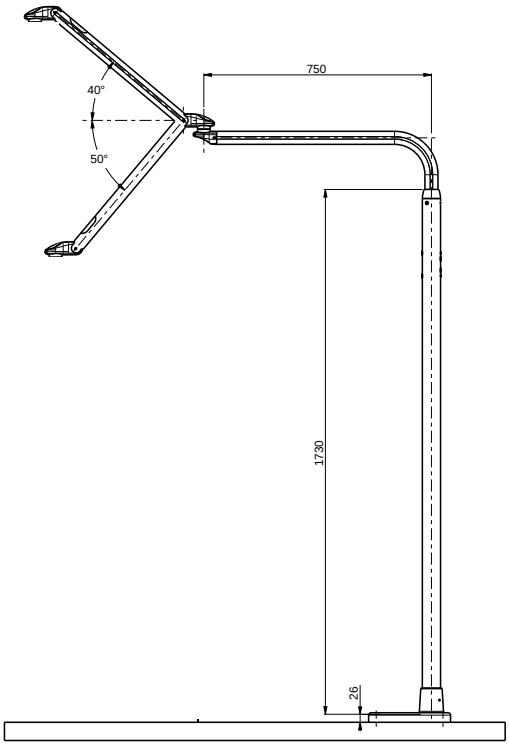
Applicazione a parete

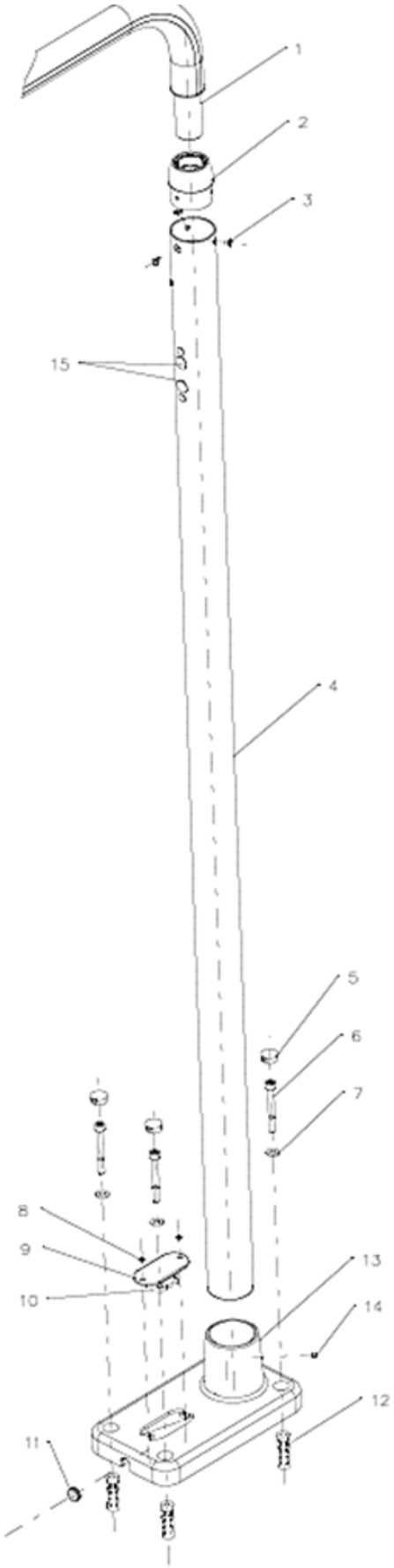


APPLICAZIONE A PAVIMENTO

MONTAGGIO APPLICAZIONE A PAVIMENTO

1. Perno
2. Bussola
3. Vite
4. Colonna
5. tappi
6. Vite
7. Rondella
8. Vite
9. Copertura
10. Morsettiera
11. Passacavo
12. Espansori
13. Supporto a Pavimento
14. Grani
15. Tappo





APPLICAZIONE A PAVIMENTO

Il dispositivo deve essere installato da tecnici specializzati

NB2. L'alimentazione all'interno del locale dove si esegue l'installazione deve essere sempre disinserita.

NB3. Prima di procedere con le operazioni di montaggio è necessario accertarsi che il pavimento sia in grado di reggere l'applicazione.

I materiali della parete autorizzati sono calcestruzzo e pietra naturale. I tasselli da utilizzare sono quelli forniti in dotazione o equivalenti.

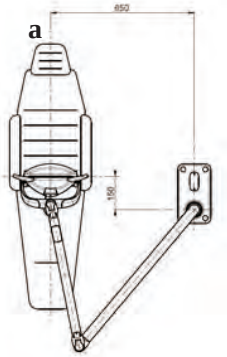
NB4. Massimo carico applicabile: 70 kg

NB5. Installare in locali con impianto elettrico conforme alle normative nazionali vigenti sui locali medici.

NB6. La lampada senza trasformatore deve essere alimentata da corrente a bassa tensione (12-24Vac o 17-33Vdc) utilizzando un trasformatore o alimentatore di sicurezza (conforme alla IEC/EN 60601-1) con protezione termica o protetto da almeno un fusibile appropriato (T500mAL250V~). Il sistema medicale risultante deve essere dichiarato conforme alla IEC/EN 60601-1 dall'installatore.

A. Stabilito come punto di riferimento il centro della poltrona "**a**", eseguire l'installazione a una distanza di 650mm e 150mm nelle direzioni mostrate in figura "**C** "

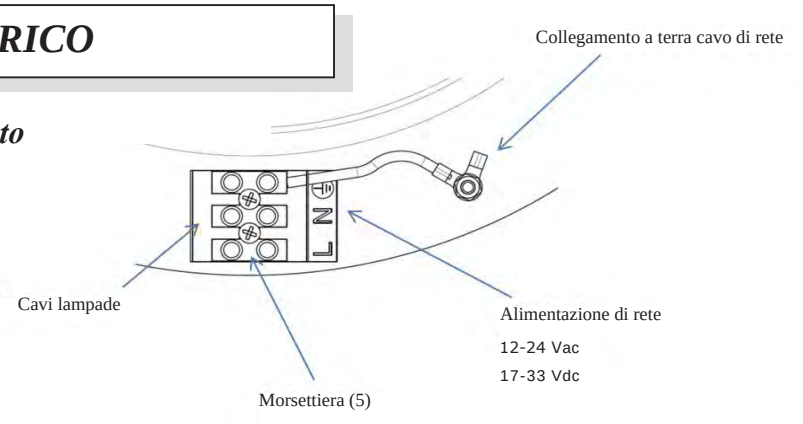
fig. C



- L'alimentazione all'interno del locale dove si esegue l'installazione, deve essere sempre disinserita.
- Stabilito il punto di fissaggio con riferimento (**a**) il centro della poltrona (Vedi fig. **C**), eseguire nel pavimento quattro fori d.14 in corrispondenza dei fori del supporto a pavimento (13).
- Preparare il supporto a pavimento (13) facendo passare la rondella (7) e la vite (6), avvitare gli espansori (12) sulle viti (6) per qualche giro, far passare il filo dell'alimentazione nel passacavo (11).
- Inserire i quattro espansori (12) nei fori d.14 fatti in precedenza e bloccare con l'apposita chiave esagonale (accessori di supporto) le viti 6, avendo cura di non schiacciare il filo tra il supporto a pavimento (13) e il pavimento stesso.
- Applicare i quattro tappi (5) sui fori del supporto a pavimento (13).
- Svitare le viti (8) e sfilare la piastrina di copertura (9) Collegare il filo dell'alimentazione nella morsettiera (10).
- Fissare la colonna (4) al supporto a pavimento (13), durante il fissaggio accertarsi della perpendicolarità della colonna.
- Fissare con le tre viti (3) la bussola (2) alla colonna (4) , avendo cura di orientare i fori della bussola (2) in corrispondenza delle sedi delle viti sulla colonna (4).
- Collegare il conduttore della lampada alla morsettiera (10).
- Fissare la piastrina di copertura (9) al supporto a pavimento (13) con le due viti (8).

SCHEMA ELETTRICO

Applicazione a pavimento



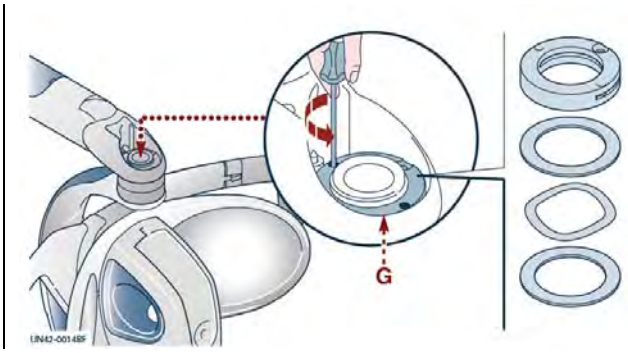
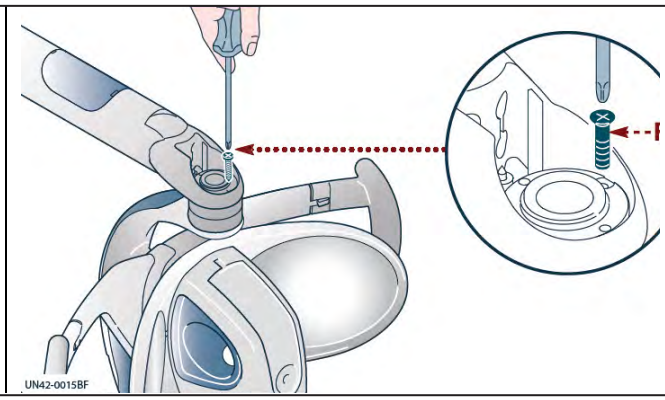
3.3 TESTATA

3.3.1 Requisiti meccanici

Per il collegamento meccanico si deve avere uno spazio adeguato all'alloggiamento del perno della testata e dei componenti di fissaggio G.
Il sistema di sostegno deve essere progettato per sostenere i seguenti carichi, moltiplicati per i fattori di sicurezza previsti dalla IEC 60601-1 o alla IEC 80601-2-60

Testata Alya	Schermo Alya
1,80 kg	0,35 kg
2,15 kg	

Per il collegamento meccanico seguire la seguente procedura:

1 - Sostenere la testata e inserire le rondelle nel perno filettato rispettando la sequenza in figura. 2 - Inserire poi la ghiera G rispettando la sequenza indicata in figura ed avvitarla con un attrezzo adeguato. La ghiera deve essere avvitata in modo da dare la giusta forza di rotazione della testata.	
3 – Avvitare le 2 viti F di sicurezza.	

⚠	**Attenzione** Il braccio centrale senza il carico della testata tende a salire in maniera repentina con il rischio di urto con parti del corpo. Durante tutta l'installazione tenere il braccio centrale in posizione e non lasciarlo fino ad installazione completata della testata.
⚠	**Avvertenza per il pericolo di caduta di masse sospese** Attenzione – Rischio di caduta della testata post installazione: - usare solo le viti fornite dalla FARO. - avvitare le viti di sicurezza a pacco.

Terminato il collegamento meccanico provvedere al cablaggio elettrico.

3.3.2 Requisiti Elettrici

I requisiti per la corretta installazione **della testata** sono i seguenti:

Alimentazione	Cavo di alimentazione	Tipo di alimentazione e requisiti di protezione	Classificaz.	Conformità alla IEC 60601-1
17-24 Vac 50/60 Hz	Cavi di alimentazione: 2 cavi unipolari rossi: UL Style 1061 300 V T 80°C 1x26 AWG VW 1 Ø max 1,02mm Connettore std: molex 51021-0300 a 3 poli	Trasformatore conforme alla IEC/EN 60601-1terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T1.6AL 250V Requisiti minimi: • Output: 17 - 24 Vac; • Power: 26 VA; • Class B; • Rigidità superiore a 4000 V. • Protezione termica	Component built-in	Il sistema medicale risultante deve essere dichiarato conforme all'IEC/EN60601-1 dall'installatore o dal fabbricante. Nota per l'installatore: assicurarsi che il riunito su cui si va ad installare la lampada sia certificato per accogliere la lampada completa.
22-33Vdc		Alimentatore conforme alla IEC/EN 60601-1 terza edizione e alla IEC/EN 60601-1-2 con protezione termica o protetto a valle da almeno un fusibile appropriato: • T630mAL 250V Requisiti minimi: • Output: 22-33 Vdc • Power: 14 VA; • Class B; • Rigidità superiore a 4000 V; • Protezione continua da corto circuito e sovracorrenti		

4. ISTRUZIONI D'USO

Leggere attentamente il paragrafo 1 per un uso sicuro del dispositivo.
Il dispositivo deve essere pulito prima dell'utilizzo (vedi paragrafo Pulizia del dispositivo).

	**Attenzione** L'uso contemporaneo della lampada con un elettrobisturi può provocare malfunzionamenti della stessa.
	**Attenzione** Il joystick di controllo deve essere maneggiato con delicatezza onde evitare rotture. Non movimentare mai la lampada usando il Joystick come appiglio.
	**Nota** Ogni volta che si accende la lampada, l'intensità luminosa sarà quella memorizzata al precedente spegnimento.
	**Avvertenza - pericolo di contatto con parti sotto tensione** non utilizzare il dispositivo se vi sono parti o involucri danneggiati.

4.1 ACCENSIONE E SPEGNIMENTO CON JOYSTICK

Si faccia riferimento al §1.1 per i simboli di accensione e regolazione.

Lampada Completa

Per l'accensione e lo spegnimento premere e rilasciare la leva joystick agendo sul lato sinistro o destro. L'intensità luminosa all'accensione sarà sempre l'ultima utilizzata prima dello spegnimento.

Lampada completa con Theia Tech

stesse operazioni della lampada completa inoltre quella sul braccio fisso si accenderà e/o spegnerà in sincrono con quella della testata.

La luce sul braccio fisso può essere accesa/spenta anche tramite il pulsante sito sul braccio. In caso di accensione a lampada accesa la luce si andrà a sincronizzare automaticamente, nel caso la luce sulla testata fosse spenta si andrà a regolare alla massima intensità.

4.1.1 Regolazione:

a) per ridurre l'intensità luminosa mantenere premuta la leva del joystick agendo sul lato sinistro (vista posteriore lampada) fino al raggiungimento dell'intensità desiderata.
Al raggiungimento della minima intensità sarà udibile una segnalazione acustica (1 beep).
b) per aumentare l'intensità luminosa mantenere premuta la leva del joystick agendo sul lato destro (vista posteriore lampada) fino al raggiungimento dell'intensità desiderata.
Al raggiungimento della massima intensità sarà udibile una segnalazione acustica (1 beep).
c) per saltare alla minima intensità premere e rilasciare la leva del joystick agendo sul lato frontale o posteriore. Ad una successiva pressione sul lato frontale o posteriore l'intensità luminosa tornerà a quella memorizzata precedentemente.
La luce sul braccio fisso si regola in sincrono con quella della testata, non può essere regolata in modo indipendente.

4.1.2 Lampada / Testata CON PROXIMITY

Accensione / Spegnimento

Lampada Completa: Per l'accensione o spegnimento avvicinarsi una volta al sensore sino ad una distanza massima di 3 cm.

Lampada completa con Theia Tech: stesse operazioni della lampada completa inoltre la luce sul braccio fisso si accenderà e/o spegnerà in sincrono con quella della testata

Regolazione

Lampada Completa: Per la regolazione dell'intensità luminosa bisogna restare fermi in prossimità del sensore sino ad ottenere l'intensità desiderata. La regolazione consente di passare dal valore massimo al minimo e dal valore minimo ancora al massimo. Al raggiungimento della massima intensità sarà udibile una segnalazione acustica (2 beep). Al raggiungimento della minima intensità sarà udibile una segnalazione acustica (1 beep).

	Nota
	Ogni volta che si accende la lampada, l'intensità luminosa sarà quella memorizzata al precedente spegnimento.

Lampada completa con Theia Tech stesse operazioni della lampada completa inoltre la luce sul braccio fisso si regolerà in sincrono con quella della testata.

4.1.3 Lampada / Lampada completa con Theia Tech / Testata "ALYA" CON COMANDO REMOTO

Accensione / Spegnimento / Regolazione
- Per l'accensione e lo spegnimento premere e rilasciare il pulsante "A".
- Regolazione:

a) per ridurre l'intensità luminosa mantenere premuto il pulsante "A" fino al raggiungimento dell'intensità desiderata.
Al raggiungimento della minima intensità sarà udibile una segnalazione acustica (1 beep).
b) per aumentare l'intensità luminosa mantenere premuto il pulsante "A" fino al raggiungimento dell'intensità desiderata.
Al raggiungimento della massima intensità sarà udibile una segnalazione acustica (2 beep).
c) per raggiungere immediatamente la minima intensità luminosa premere il pulsante "B".
Al raggiungimento della minima intensità sarà udibile una segnalazione acustica (1 beep).
Una successiva pressione del pulsante riporterà la lampada all'intensità luminosa precedentemente selezionata.

	Nota
	Ogni volta che si accende la lampada, l'intensità luminosa sarà quella memorizzata al precedente spegnimento.

4.1.4 LAMPADA / LAMPADA COMPLETA CON THEIA TECH / TESTATA "ALYA" CON COMANDO DI SINCRONIZZAZIONE

Dove previsto è possibile collegare in modalità wireless la lampada Alya alla lampada ambiente Faro, al fine di creare un sistema di illuminamento sincronizzato tra loro, denominato "**Syncro**".
La modalità "**Syncro**" è stata appositamente studiata per migliorare il confort del medico dentista/odontoiatra, al fine di ridurre l'effetto di abbagliamento che si genera quando si passa dall'osservazione di una superficie fortemente illuminata (es: cavità orale con la lampada dentale) ad una superficie poco illuminata (es: faretra dentale).
Con la modalità denominata "**Syncro**", attivabile tramite il pulsante posto sulla testata della lampada Alya, è possibile modificare in modo automatico il valore di illuminamento prodotto dalla lampada ambiente Faro in base al valore di illuminamento prodotto da Alya.
Nota: tra la lampada dentale e quella ambiente potrebbe verificarsi un piccolo ritardo nella sincronizzazione, questo è dovuto al protocollo di comunicazione, tale effetto è normale e non rappresenta un difetto.
La funzione "**Syncro**" per essere abilitata necessita di una procedura di abbinamento denominata "**Pairing**" (che dovrà essere svolta una sola volta) al fine di creare il legame tra le due lampade. Successivamente la funzione "**Syncro**" potrà essere abilitata e/o disabilitata a piacimento dell'utente tramite il pulsante posto sulla lampada dentale.

PROCEDURA DI "PAIRING"
NOTA:

- La procedura di "Pairing" è necessaria solo alla prima connessione tuttavia può essere ripetuta nel caso di sostituzione della lampada Alya o dell'elettronica di una delle due lampade collegate tra loro.

- Se nello studio dovessero essere presenti più lampade ambiente assicurarsi che le altre lampade siano spente o accese da più i 60 secondi.

Per eseguire il **“Pairing”** procedere nel seguente modo:

1. Dare tensione alla lampada ambiente Faro che si desidera accoppiare.
   La lampada ambiente si predispone al collegamento di Pairing per un tempo massimo di 60 sec.

2. Entro i 60 sec, premere sulla lampada dentale il pulsante di “**syncro**” per almeno 3 sec. ma non oltre 6 sec. altrimenti la procedura viene annullata. Al ricevimento della richiesta di “**Pairing**” da parte della lampada dentale, sulla lampada ambiente si attiva il led blu presente sul telaio di alluminio. Se il led blu non dovesse attivarsi sarà possibile (entro i 60 secondi dall’accensione) effettuare altri tentativi, superata tale tempistica bisogna ripetere la procedura a partire dal punto 1.

3. Dall’accensione del led Blu sulla lampada ambiente ci sono altri 60 secondi per confermare il “**Paring**” andando a premere il pulsante di programmazione  sito sul radiocomando della lampada ambiente. A questo punto il led blu (della lampada ambiente) fa un doppio lampeggio e poi si spegne. Se entro i 60 sec non viene premuto il tasto  sul radiocomando il led blu si spegne e la procedura deve essere ripetuta dal punto 1.

Effettuato il “**Pairing**” è ora abilitata la sincronizzazione tra le 2 lampade.

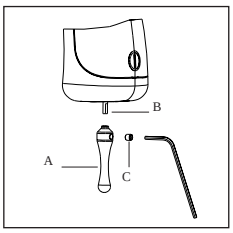
Per **ATTIVARE LA FUNZIONE DI SINCRONIZZAZIONE** bisogna procedere nel seguente modo: premere per 2 secondi il pulsante di Syncro quindi rilasciarlo.
Al rilascio si udirà un segnale sonoro (Beep) e la luce del led blu sito sulla lampada ambiente si illuminerà per indicare che la sincronizzazione è stata attivata.

Per **DISATTIVARE LA FUNZIONE DI SINCRONIZZAZIONE** bisogna procedere nel seguente modo: premere per 2 secondi il pulsante di Syncro quindi rilasciarlo.
Al rilascio si udirà un segnale sonoro (Beep) e la luce del led blu sito sulla lampada ambiente si spegnerà per indicare che la sincronizzazione è stata disabilitata

Note legate alla sincronizzazione:

- Quando la lampada ambiente Faro è in sincrono (ossia si regola in automatico) con la lampada Alya, il led blu sito sul telaio è acceso fisso, quando il led è spento la sincronizzazione è disattiva.
- Il radiocomando è sempre abilitato, quindi è possibile modificare il valore d’illuminamento, tuttavia se la lampada ambiente dovesse trovarsi nello stato di sincronizzazione (con il led blu acceso) appena si effettuerà una nuova regolazione sulla lampada Alya il valore d’illuminamento verrà immediatamente aggiornato.
- Se si dovesse spegnere la lampada Alya, la lampada ambiente resterà accesa al valore d’illuminamento in uso.
- Se si dovesse accendere la lampada Alya, la lampada ambiente si accenderà in automatico.

4.2 MONTAGGIO LEVETTA JOYSTICK ALYA



- Inserire in battuta la levetta “A”sul perno del joystick.
- Il foro della levetta “A”deve essere posizionato in corrispondenza del piano “B”.
- Avvitare completamente il grano “C” con la brugola in dotazione.

	Attenzione
	Il joystick di controllo deve essere maneggiato con delicatezza onde evitare rotture. Non movimentare mai la lampada usando il Joystick come appiglio.

5. MANUTENZIONE ORDINARIA

Non esistono operazioni di manutenzione ordinaria.

6. PULIZIA

	Avvertenza contro il pericolo di degrado e corrosione e caduta masse sospese
	Per tutte le parti della lampada in metallo o plastica è tassativamente proibito l’impiego di sostanze abrasive, acide, contenenti cloro o ioni di cloro, detergenti a base di trielina, benzina, acquaragia o similari. E’ proibito spruzzare direttamente sul dispositivo qualsiasi sostanza chimica.

6.1 PULIZIA DEI RIFLETTORI

La pulizia deve essere effettuata utilizzando un panno morbido in cotone o cotone idrofilo con alcool etilico o l’apposito detergente PERFLEX. Sono idonei disinfettanti idroalcolici con 70% di alcool isopropilico o etilico.

	Attenzione – potenziale danneggiamento o degradamento dei riflettori
	Non spruzzare mai il detergente direttamente sui riflettori. Le operazioni di pulizia dei riflettori dovrebbero essere effettuate indossando guanti, per evitare di lasciare impronte sulle superfici. Non usare detergenti contenenti tensioattivi o idrorepellenti che depositandosi possono lasciare alonature. Lievi alonature non pregiudicano la qualità della luce. Prodotti differenti da quelli suggeriti potrebbero danneggiare i riflettori. In caso di dubbio contattare il customer care FARO.

6.2 PULIZIA DELLA TESTATA

La pulizia deve essere effettuata utilizzando un panno morbido in cotone o cotone idrofilo con alcool etilico o l'apposito detergente PERFLEX. Sono idonei disinfettanti idroalcolici con 70% di alcool isopropilico o etilico.

	Avvertenza contro il pericolo di degrado delle plastiche e caduta masse sospese
	Non spruzzare mai il detergente direttamente sulla testata. Per la pulizia delle parti plastiche non utilizzare detergenti-disinfettanti contenenti: • AMMONIUM HYDROXIDE • SODIUM HYDROXIDE • METHYLENE CLORIDE • ME THYL ALCOHOL. • ACIDI DI OGNI GENERE Faro ha testato e suggerisce i seguenti disinfettanti: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

6.3 PULIZIA DEI BRACCI

Utilizzare sempre un panno inumidito con un disinfettante approvato per la disinfezione delle superfici e passarlo.

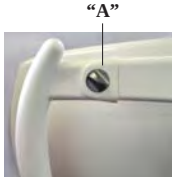
	Avvertenza contro il pericolo di corrosione e cedimento meccanico con caduta masse sospese
	Non spruzzare mai sostanze chimiche direttamente sui bracci e sugli snodi e le loro aperture.
	Avvertenza contro il pericolo di degrado delle plastiche con caduta masse sospese
	Per la pulizia delle parti plastiche non utilizzare detergenti-disinfettanti contenenti: • AMMONIUM HYDROXIDE • SODIUM HYDROXIDE • METHYLENE CLORIDE • ME THYL ALCOHOL. • ACIDI DI OGNI GENERE Faro ha testato e suggerisce i seguenti disinfettanti: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

7. STERILIZZAZIONE DELLA MANIGLIA

	Avvertenza - pericolo di contaminazione crociata
	Le maniglie non sono fornite sterili, devono quindi essere sterilizzate prima dell'utilizzo. Le maniglie devono essere sterilizzate prima di ogni paziente.

7.1 Rimozione della maniglia

Per rimuovere la maniglia svitare la manopola "A" e sfilarla dal supporto.



7.2 Decontaminazione e disinfezione

Prima della sterilizzazione le maniglie devono essere decontaminate e disinfettate.
Per la disinfezione Faro ha testato i seguenti prodotti per la disinfezione: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

	Attenzione - pericolo di rottura plastiche
	Le maniglie non possono essere disinfettate per termodisinfezione.

7.3 Sterilizzazione

Le maniglie devono essere imbustate in imballaggi conformi alla EN 868-5.
Le maniglie possono essere sterilizzate con cicli standard 121°/134° C fino a duecento (200) cicli o comunque fino alla perdita delle performance meccaniche.
I parametri del ciclo di sterilizzazione sono i seguenti:

Ciclo EN 13060	Temperatura	Pressione	Holding Time Minimo
B B	121°C 134°C	207 KPa 308 KPa	15 min 3 min

8. VERIFICHE PERIODICHE

Operazione	Frequenza	Applicabilità		Procedura	Abilitazione
		LD	TE		
Verificare assenza di gioco tra gli snodi dei bracci	Annuale	x	N/A	Verificare che la luce tra gli snodi 5 e i bracci non sia cambiata dal primo utilizzo	Utilizzatore
Verifica leggibilità dati di targa	Annuale	x	x		Utilizzatore
Verifica integrità involucri	Biennale				Service Engineer
Verifiche di sicurezza elettrica EN 62353 1. Rigidità 2. Dispersione	Annuale	x	x	Misurare rigidità dielettrica e dispersione nell'involucro. Limiti definiti nella IEC 60601-1	Service Engineer
Verifiche dei parametri di luce.	Biennale	x	x	Con uno spettroradiometro misurare i valori di: • Illuminamento massimo: >35000 lux • Decadimento del CRI: <20%. • Valore sotteso della luce Blu sullo spettro emesso misurato in: <100 W/m2	Service Engineer

Service Engineer: persona competente nella manutenzione di apparecchiature elettromeccaniche.

9. SEGNALI ACUSTICI DI ALLARME

9.1 Segnali Acustici

OpL** = Beep 30 secondi
OTP* = Beep 30 secondi

* OTP: Protezione sovratemperatura LED.
** OpL: Carico led scollegato

9.2 GUIDA AI PROBLEMI

La tabella sottostante rappresenta una guida ai potenziali difetti della lampada.
In caso il problema non si risolva chiamare l'assistenza tecnica.

Effetto	Causa	Azione (Service Engineer - SE)	Resp
La lampada non si accende	Alimentazione non inserita o inserita in maniera non corretta.	Verificare che l'alimentazione sia inserita e che il riunito sia acceso.	User
	Interferenza con elettrobisturi o strumentazione ad alta energia	Spegnere l'elettrobisturi e verificare la permanenza dell'effetto.	User
	Comando sul joystick applicato in modo errato	Per l'accensione e lo spegnimento premere e rilasciare la leva joystick agendo sul lato sinistro o destro.	User
La lampada flikera	Interferenza con elettrobisturi o strumentazione ad alta energia.	Spegnere l'elettrobisturi e verificare la permanenza dell'effetto.	User
La lampada non regola l'intensità luminosa	Comando sul joystick applicato in modo errato	Utilizzare il comando in maniera corretta come descritto nel presente manuale	User
	Interferenza con elettrobisturi o strumentazione ad alta energia.	Spegnere l'elettrobisturi e verificare la permanenza dell'effetto.	User
L'intensità luminosa si è notevolmente ridotta	Riflettori o lente secondaria sporca.	Pulire i riflettori e le lenti secondarie.	User
	Utilizzo di procedure errate	Verificare di essere alla massima regolazione con il comando	User
Sui riflettori (parabole) sono comparse delle macchie o è venuto via lo strato riflettente.	Utilizzo di prodotti non approvati.	Pulire le superfici con lo specifico prodotto "Faro Perflex". Pulire le superfici con alcool isopropilico. Per il ripristino delle superfici bisogna far sostituire il riflettore dal service.	User
La lampada non mantiene l'equilibrio e tende a scendere	Carico eccessivo sulla testata (specchietti, telecamere, etc..).	Rimuovere i carichi in eccesso.	User
La lampada non controlla la lampada ambiente.	Funzione syncro spenta.	Attivare la funzione vedi 4.1.4	User

10. CARATTERISTICHE TECNICHE

Lampada completa:
Tensione alimentazione (senza trasformatore):
- 17÷24Vac ±10% - 50/ 60Hz;
- 22÷35Vdc ±10%

Potenza assorbita :
- 26VA (versione 17÷24Vac);
- 14VA (versione 22÷35Vdc)

Fusibili consigliati:
- Versione 17÷24Vac: T1.6AL 250V
- Versione 22÷35Vdc: T630mAL 250V

Protezione contro i pericoli elettrici:
- Apparecchio di classe II

Classificazione EN 62471:
- classe Exempt

Lampada completa con Theia Tech
Tensione alimentazione (senza trasformatore):
- 24Vac ±10% - 50/ 60 Hz
- 24Vdc ±10%

Potenza assorbita :
- 40VA (versione 24Vac)
- 28VA (versione 24Vdc)

Fusibili consigliati:
- T2AL 250V

Protezione contro i pericoli elettrici:
- Apparecchio di classe II

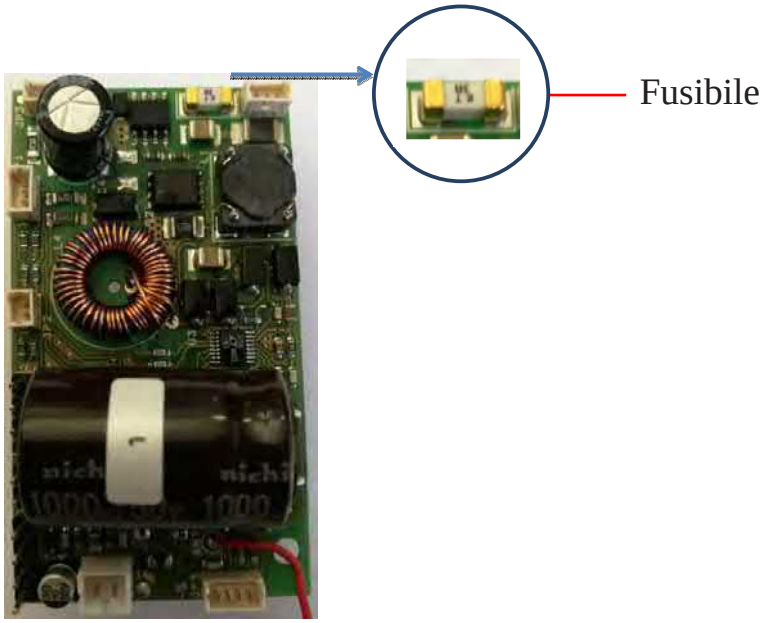
Classificazione EN 62471:
- classe Exempt

Caratteristiche ottiche della luce prodotta dalla testata in accordo alla ISO 9680
Dimensioni spot luminoso: 180 mm x 90 mm
Lux: 3.000*-50.000* lux @700mm
Temperatura di colore: 5000 K*
CRI (color rendering index): >95*

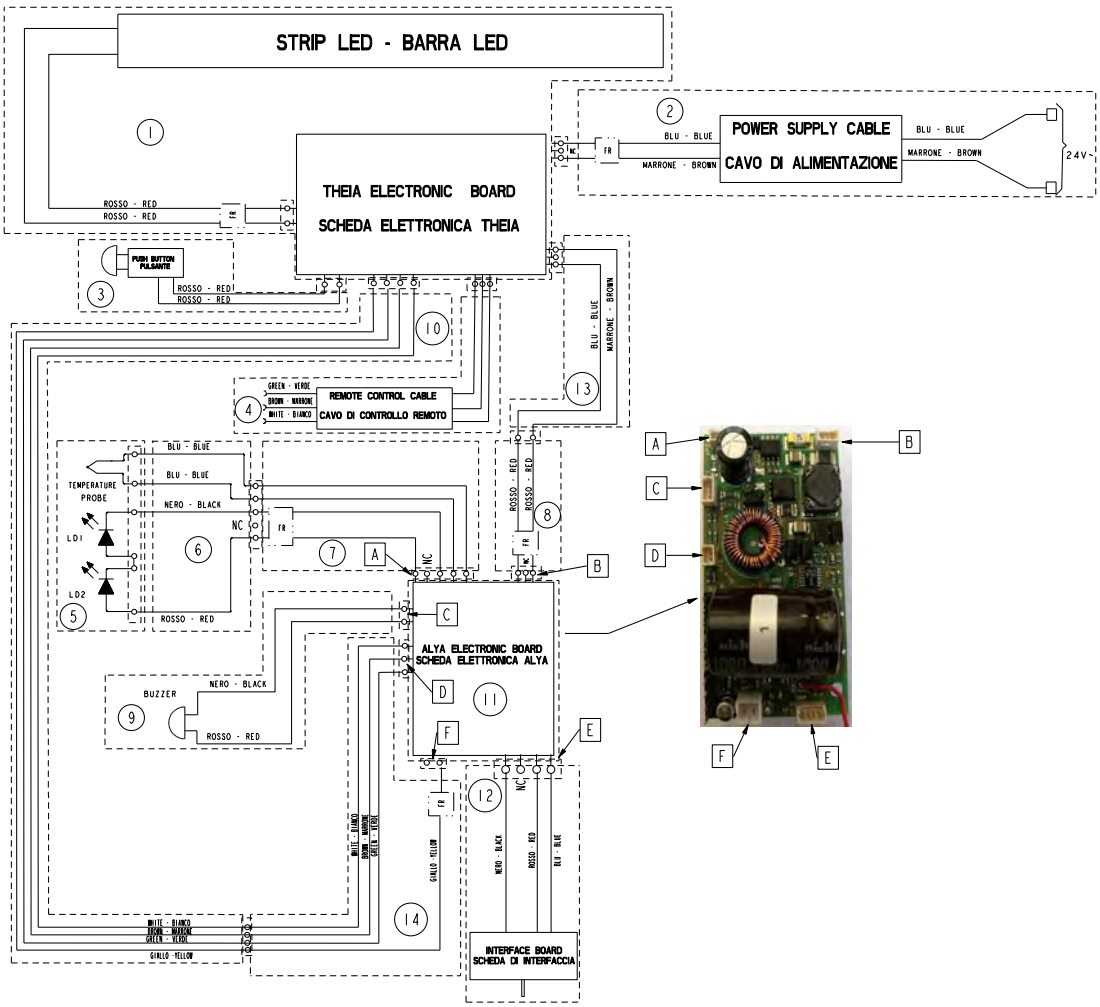
* Valori tipici soggetti a tolleranze.
Etichettatura in accordo a EN 62471: non necessaria

10.1 SCHEMI ELETTRICI

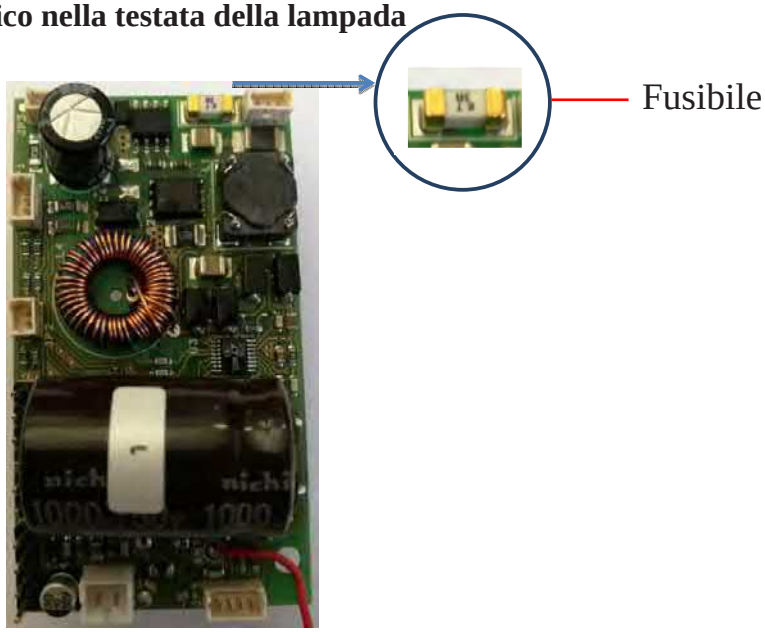
- **Lampada completa:**
  Circuito elettrico nella testata della lampada



Schema elettrico - Alya senza trasformatore

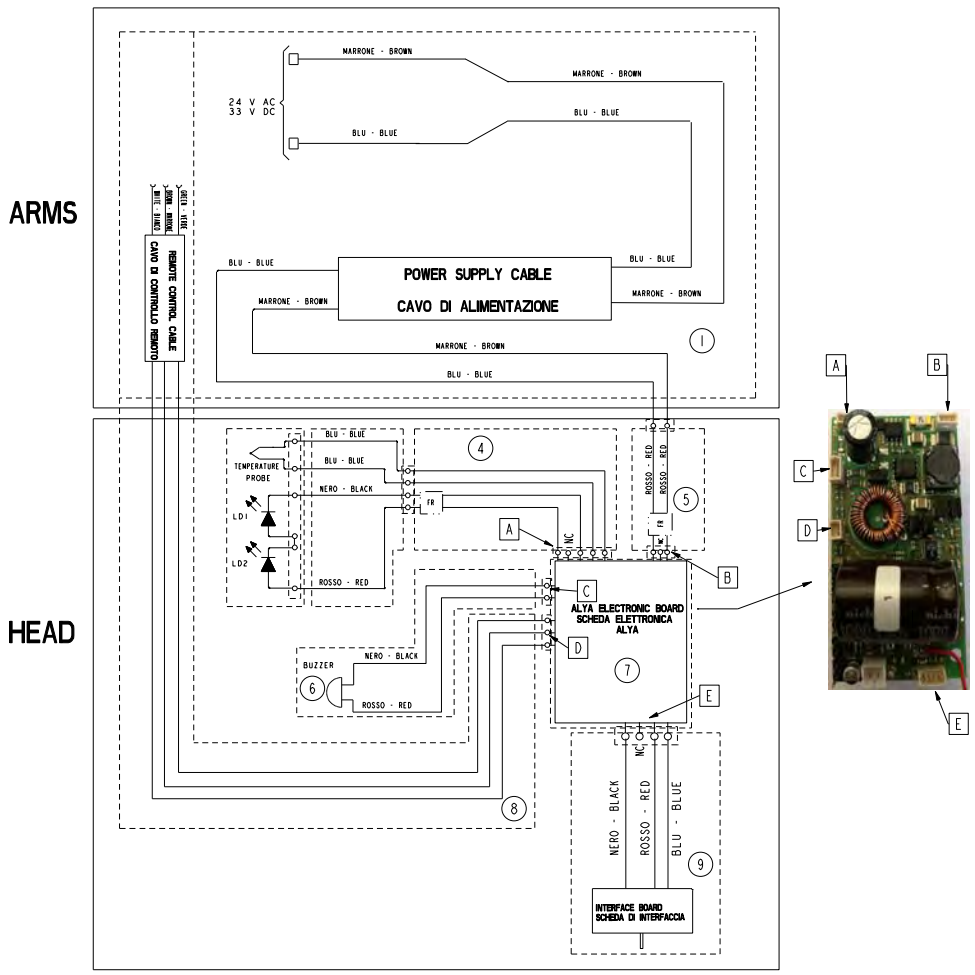


- **Lampada completa Theia Tech:**
  Circuito elettrico nella testata della lampada

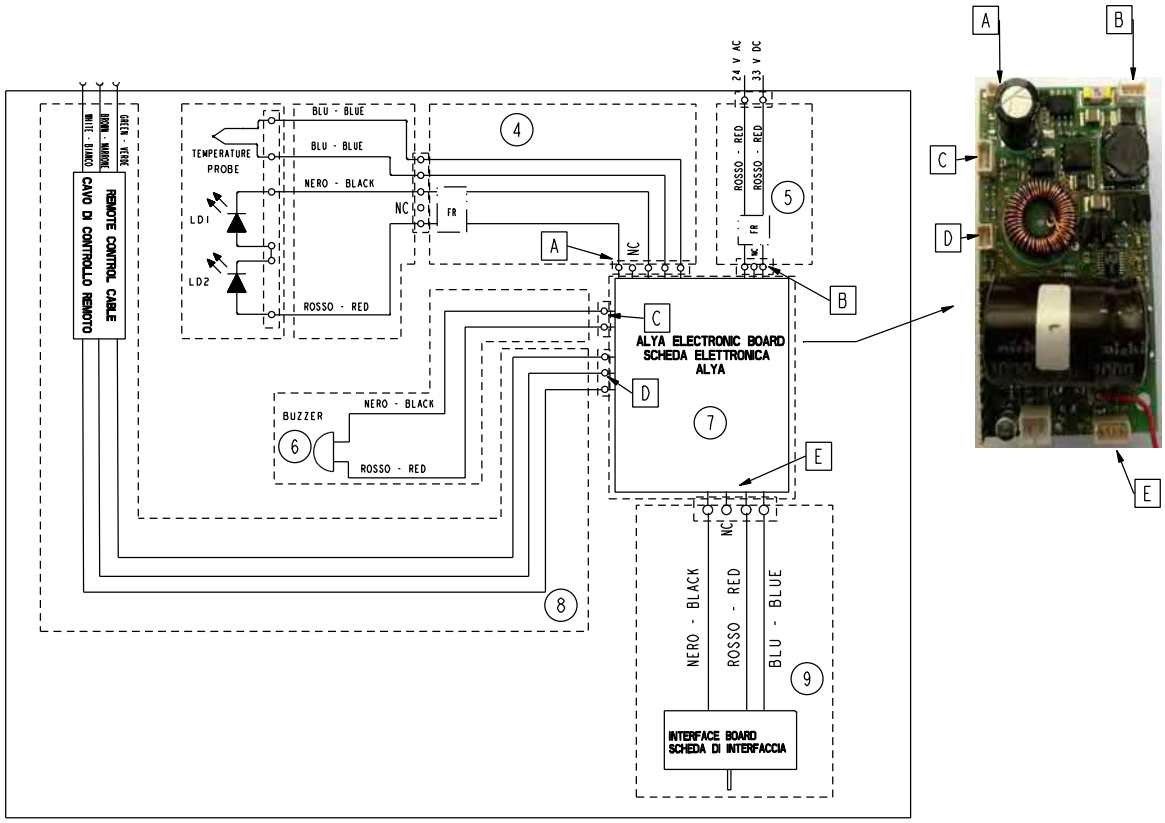


Circuito elettrico nel braccio posteriore

Schema elettrico – Alya Theia Tech.



- ***Testata:*** *Schema elettrico - Testata Alya*



CONTENT

1. SAFETY REQUIREMENTS

Dear Client,
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, carefully read this manual before using the device. In particular, follow all the warnings and the notes given.

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.	

	*WARNING*
These instructions warn 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: 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 standardised symbols are also present:

	Read the use instructions. Supply electricity
	Manufacturing symbol pursuant to Directive 93/42/EEC
	The use instructions include safety warnings
	WEEE equipment in compliance with the Directive 1012/19/EC. Dispose of he product in compliance with this directive.
	Double insulation. Class 2 device against electrical risk
	Serial Number
	Can be sterilised with humid heat at 134°C
	Use the device at a temperature between 10°C and 40°C
	Use the device at pressure between 800mbar and 1060mbar
	Use the device at relative humidity between 30 RH and 75RH
	Symbol to adjust light intensity
	Symbol to switch on the light
	[Symbol to switch on/off the light on the rear arm]

1.1.3 Symbols on the packaging

HIGH

FRAGILE

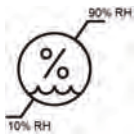
DO NOT WET

DO NOT ROLL

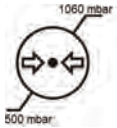
DO NOT USE HOOKS

MAXIMUM STACKABLE WEIGHT

STORAGE TEMPERATURE
TRANSPORT CONDITIONS



RELATIVE HUMIDITY



ATMOSPHERIC PRESSURE

RECYCLABLE CARDBOARD

1.2 PLANNED USE

The device is intended for use solely in dental practices by dentists and hygienists to light the operative and intervention site in the treatment of oral cavity and dental treatments.
In normal use, the device is positioned over the patient's body at a distance of 700mm, the distance for which the lighting features were designed.
The treated patients can be of all ages with typical dental pathologies.

1.3 PLANNED USER

The planned user is a dentist or dental hygienist.

1.3.1 Professional qualification:

- Degree in medicine with dentistry specialisation
- Degree in dentistry
- Degree in dental hygiene

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. 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.

	**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". The appliance must be installed with an omnipolar separation device from the mains and compliant with Standard IEC 61058-1. 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 PARTS RESULTING IN BREAKAGE. Do not spray any kind of chemical agent directly on the light. In particular, use is forbidden of abrasive substances, acids, containing chlorine.
	**Warnings for danger of suspended loads falling** Strictly comply with compliance for maximum loads planned. Do not knock against or overload the limit switches on the arms and heads.
	**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 exempt from photo-biological risk in compliance with EN 62471. 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 strip.
	**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 sterilise 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 recognised and authorised 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.
The company FARO does not allow any changes to the product not expressly authorised in writing, otherwise conformity to the safety standards and the warranty expires.
Other warnings are outlined in the titles of this manual.

1.5 STORAGE AND USE: ENVIRONMENTAL PROVISIONS

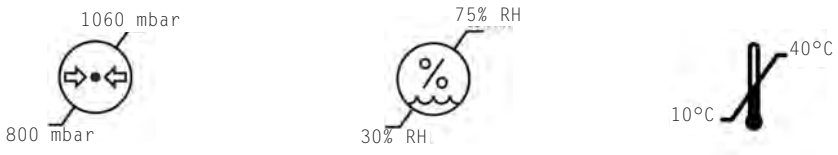
The appliance in the original packaging can be transported or kept in a warehouse for a period of 15 weeks if the following environmental conditions are met:

- Environmental temperature from -20°C to + 70°C
- Relative humidity from 10% to 90%
- Atmospheric pressure from 500 to 1060 mbar

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%

ATMOSPHERIC PRESSURE **RELATIVE HUMIDITY** **USE TEMPERATURE**



1.6 REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY

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

Manufacturer's guide and declaration – Electromagnetic emissions		
The ALYA lamp is made to function in the electromagnetic environment specified below. The client or user should make sure that it is effectively used in this environment.		
Emission tests	**Conformity**	**Guide – Electromagnetic environment**
RF Emission CISPR15	Yes	The ALYA lamp uses RF energy only for internal functioning. Therefore, its RF emissions are very low and probably do not cause any interference with other nearby electronic equipment.
RF Emission CISPR15	Yes	The ALYA lamp is suitable for use in all buildings, including domestic buildings and those connected directly to the low voltage public electricity mains that power domestic buildings.
Harmonic emission	Class C	
RF Emission CISPR11 / EN 55011	Yes	The ALYA lamp is not suitable for interconnections with other devices (ceiling model).

ELECTROMAGNETIC IMMUNITY

Manufacturer's guide and declaration – Electromagnetic immunity		
The ALYA lamp is made to function in the electromagnetic environment specified below. The client or user should make sure that it is effectively used in this environment.		
Immunity test	**Conformity**	**Guide – Electromagnetic environment**
Electrostatic discharge (ESD) IEC/EN61000-4-2	± 6kV contact ± 8kV air	Flooring must be in wood, concrete or ceramic tile. If floors are covered with synthetic material, the 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 network voltage should be equivalent to that of a typical commercial or hospital environment.
Surge IEC/EN61000-4-5	± 1kV differential mode ± 2kV common mode	The quality of network voltage should be equivalent to that of a typical commercial or hospital environment.
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 network voltage should be equivalent to that of a typical commercial or hospital environment. If the user of the ALYA lamp requires continuative use, also when electrical power is not present, it is advisable to have a UPS (uninterrupted power supply).
Power frequency magnetic field IEC/EN61000-4-8	3A/m	Level of the magnetic field at the typical power main frequency of a commercial or hospital environment.
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, except for when they comply with the recommended separation distances calculated by the equation applicable for the transmitter frequency. Recommended separation 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 Where P is the maximum nominal power emitted from the transmitter in Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in metres (m). The intensity of the fixed RF transmitter field, as determined in an electromagnetic study of the site a, could be less than the level of conformity of each frequency interval. Interference could be expe ced in proximity to devices bea-
Conducted immunity IEC/EN61000-4-6	3Vrms 80MHz to 2.5GHz (for non life-supporting equipment)	

Note: Ut is the value of the voltage.
Note 1: At 80 MHz and 800 Mhz the higher frequency interval is applied.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.
a) The ISM 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) The levels of conformity of the ISM bands between 150 kHz and 80 MHz and in the bands 80 MHz to 2.5 GHz are indicative. The probability of a portable transmitter causing interference if accidentally brought in the range of a patient decreases depending on environment conditions. This is why an additional factor of 10/3 has been incorporated into the formula used to calculate the separation distance from transmitters.
c) Field intensities for fixed transmitters like base stations for radio-telephones (cellular and cordless phones) and terrestrial transmitters, amateur radio stations, AM and FM radio transmitters and TV transmitters cannot be predicted theoretically and precisely. To establish an electromagnetic environment caused by fixed RF transmitters, an electromagnetic investigation of the site should be done. If the intensity of the field measured in the area of use of the dental unit is higher than the applicable level of conformity described above, it is necessary to monitor the lamp to check that it functions properly. If abnormal performance is detected, additional measures could prove necessary, such as a different orientation or position of the lamp.
d) The field intensity in an interval of frequencies from 150 kHz to 80 MHz should be less than 3 V/m.

Recommended separation distances between portable and mobile radio-communication devices and the dental unit

The ALYA lamp is designed to function in an electromagnetic environment in which disturbances from RF emissions are kept under control. The client or operator of the unit can contribute to preventing electromagnetic interference by assuring a minimum distance between mobile and portable RF communication devices (transmitters) and the dental unit, as recommended below, in relation to the maximum output power of the radio-communication devices.

Maximum nominal output power of the transmitter W	**Separation distance at the transmitter frequency 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

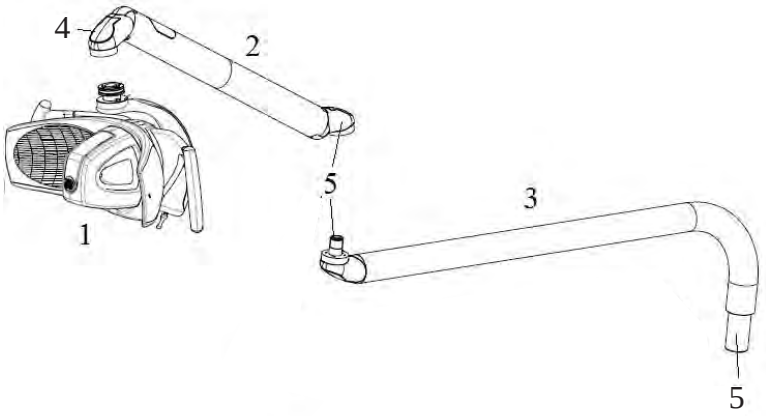
For transmitters with a maximum nominal power emission not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applied to the transmitter frequency, where P is the maximum nominal power emission of the transmitter in Watts (W) according to the manufacturer.
Note:
At 80 MHz and 800 MHz, the highest interval is applied.
These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.

2. GENERAL FEATURES

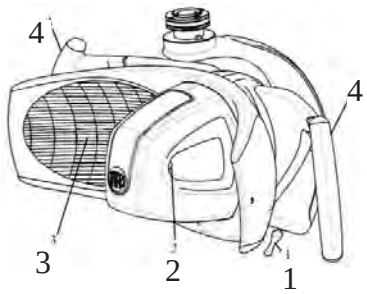
2.1 DESCRIPTION OF THE PRODUCT

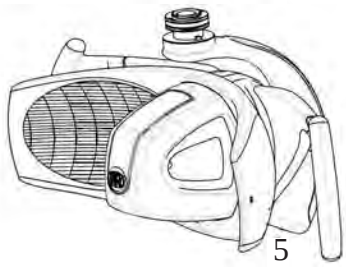
The device is used by the user to light the operative field when treating dental pathologies.
The light source on the head is composed of two LED whose light reflects against two parabolas passing through two secondary lenses.
The parabolas enable a regular and uniform spotlight to be obtained at each lighting level and to evenly distribute the light in the operative field, without creating shadows or obstruction by the operator.
Adjustment of light intensity can be carried out with a joystick or proximity sensor. The proximity sensor switches on and off the light without having direct contact, thereby eliminating the possibility of cross infection on the command.
The "automatic switch on" or "Auto-on" function allows the light to switch on automatically each time the light power supply is activated.
The remote cable allows bringing the light commands to the combined unit Comply with the instructions provided in the installation paragraph.
On the head near the joystick and/or the proximity sensor there is a button which allows for activation of the synchronization function with the environment lamp produced by Faro.
The synchronization function allows the Alya lamp to control the level of illumination of the environment lamp in order to guarantee a more uniform level of illumination between the operating area and the surrounding zone, in order to reduce the effect of glare and to improve comfort Visual.
In the version with light on the rear arm called "Alya with Theia Tech" the light source is composed of a series of LED whose light passes through a diffuser for distribution in the environment below.
Adjustment of the lighting level takes place in synchronous mode with that of the head for which on reducing or increasing lighting produced by the head, that on the arm also adjusts.
The "Theia Tech" light version also has a local command intended only to provide on/off on the fixed arm.
Once the local command is switched on, the light automatically synchronises with the level of head intensity. If the light on the head is switched off, the light on the rear arm switches on to maximum intensity. On switching on the light on the head, the light on the arm will synchronise automatically.
The light on the arm performs a visibility increase function in the pre-operative zone to reduce glare that generates following and/or after viewing the operative field.]
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 sterilised. 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

2.2 DESCRIPTION OF THE PARTS

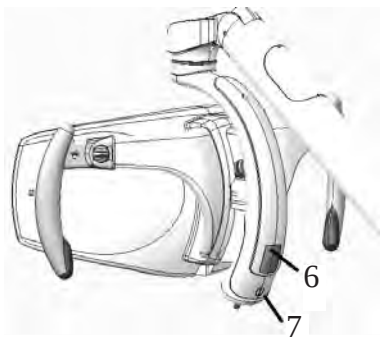


1 – Head
2 – Central arm
3 – Rear arm without transformer with or without light (Theia Tech)
4 – Joints
5 – Pin for combined or application connection





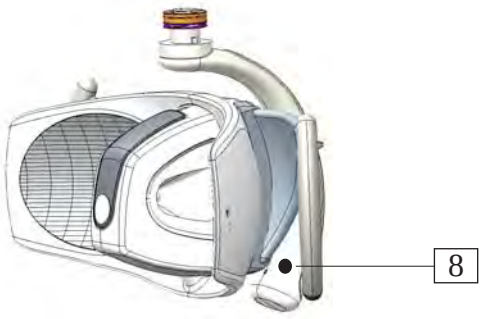
1 – Joystick
2 – LED secondary lens
3 – Parabola
4 – Sterilisable handles
5 – Proximity



6 – Electronic board slot
7 – Switch on and adjustment symbols
8 – Synchronization button

Joystick version

Sensor version



2.3 DEVICE IDENTIFICATION

The variants on the market are differentiated by:

- Type of device (complete light, complete light with Theia Tech or head)
- Switch on and adjustment interface **(Joystick or proximity sensor, for complete lights and head)**
- Combined control mode (on-off function, remote control; for complete light and head)
- Type of mount (combined, ceiling; for complete light only)
- Arms length (for complete light only)
- Power supply (with or without transformer, for complete light only)

Codes are developed as follows:

ALYA – Complete light					
Type	3° digit Mounting and combined control	4° digit – Voltage interface	5° digit – rear arm x central arm (mm)	6° digit Available	7° 8° 9° digits Customisation
5 1	0 Standard combined	0 Joystick 17-24 V AC 22-35 V DC	0 810x550	0	000 (std FARO) JJJ
	1 Ceiling	1 Proximity sensor 17-24 V AC 22-35 V DC	1 960x550		
	2 Combined Auto-on		9 810x 855		
	4 Combined Rem cable				

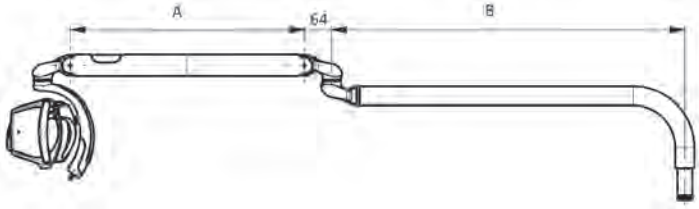
ALYA – Complete light with Theia Tech					
Type	3° digit Mounting and arm dimensions	4° digit Head type	5° digit interface type	6° digit Voltage	7° 8° 9° digits Customisation
52	1 Combined 550*810	1 Standard	1 joystick	1 24Vac 50/60Hz 24 V dc	000 (std FARO) JJJ
	2 Combined 550*960	2 With extension	2 Joystick auto-on		
	3 Combined 855*810		3 sensor		
	4 Combined 855*960		4 Auto-on sensor		
	5 Ceiling 550*810		5 Joystick + remote cable		
	6 Ceiling 550*960		6 Auto-on joystick + remote cable		
	7 Ceiling 855*810		7 Sensor + remote cable		
	8 Ceiling 855*960		8 Auto-on sensor + remote cable		

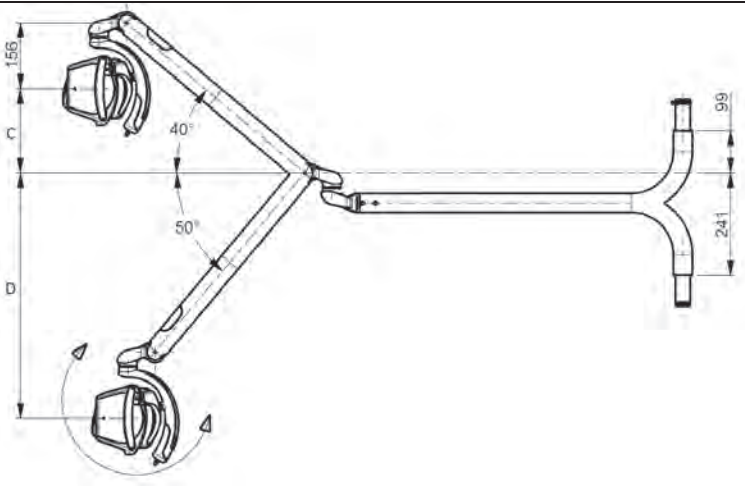
ALYA HEAD					
Type	3° digit Temperature col and combined control	4° digit – Power supply and control	5° digit Available	6° digit Colours	7° 8° 9° digits Custom
3 1	5 Optical unit 5000 K	0 Joystick 17-24 V AC 22-35 V DC	0	0 White	000 Std FARO
	6 Optical unit 5000 K On/Off	1 Proximity sensor 17-24 V AC 22-35 V DC		3 Grey	
	8 L.U. 4000 K				

3. DEVICE INSTALLATION

⚠	**Warnings for electrical danger, for the light and head:**
	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 plate data before installation
ℹ	**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





	A	B	C	D
mm	550	830	265	510
mm	550	980	265	510
mm	855	830	394	706
mm	855	980	394	706

3.2 COMPLETE DENTAL LIGHT

3.2.1 Electrical requirements

The requirements for correct installation for any application (combined, wall, floor or ceiling) are as follows:

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 V1 or similar.	transformer complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse: • T1.6AL 250V Minimum requirements: • Output: 17-24 Vac; • Power: 26 VA; • Class B; • Rigidity over 4000 V. • 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.
Complete light version 22-33Vdc		Power supply unit complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse: • T630mAL 250V Minimum requirements: • Output: 22-33 Vdc; • Power: 14 VA; • Class B; • Rigidity over 4000 V. Continuous protection from short circuit or overcurrent		
Complete light version with Theia Tech 24Vac 50/60Hz		transformer complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse: • T2AL 250V Minimum requirements: • Output: 24Vac; • Power: 40VA • Class B; • Rigidity over 4000 V. Thermal protection		

Power supply	Power cable	Type of power supply and safety requirements	Classification	Compliance with IEC 60601-1
Complete light version with Theia Tech 24Vdc	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 V1 or similar.	transformer complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse: • T2AL 250V Minimum requirements: • Output: 24 Vdc; • Power 28 VA • Class B; • Rigidity over 4000 V. 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.

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

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

3.2.2 Safe working load

The dental light EDI Led type suits various installation positions:
DENTAL UNIT, CEILING, WALL, FLOOR.

SAFE WORKING LOAD

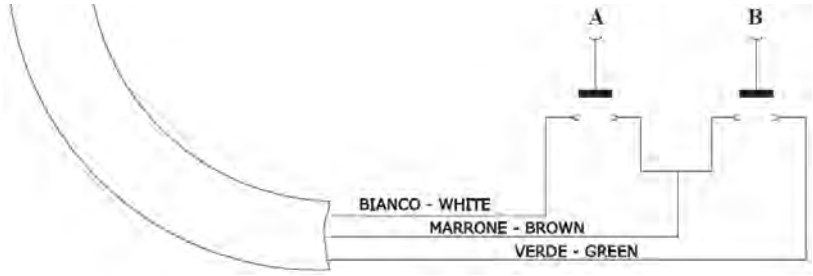
	Total load (SAFE WORKING LOAD)	Safety load (MINIMUM BREAKING LOAD)
Mobile arm 855 mm	29.2 N	235 N
Mobile arm 550 mm	25.6 N	205 N

3.2.3 Complete combined version light assembly

With a digital level, ensure the connection element is perfectly parallel to the ground.
Install the light by inserting the light terminal pin in the specific combined compartment.
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.

3.2.4 Remote cable connection

Connect the cable to the two buttons (A and B) with contact normally open (already supplied) according to the following diagram:



3.2.5 Installation applications

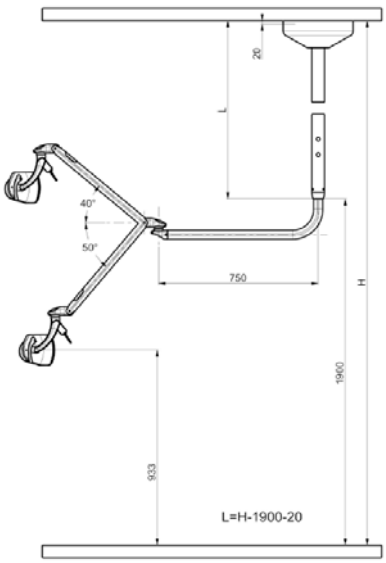
- The applications are not supplied with the light
- The device has to be installed by specialized technicians only

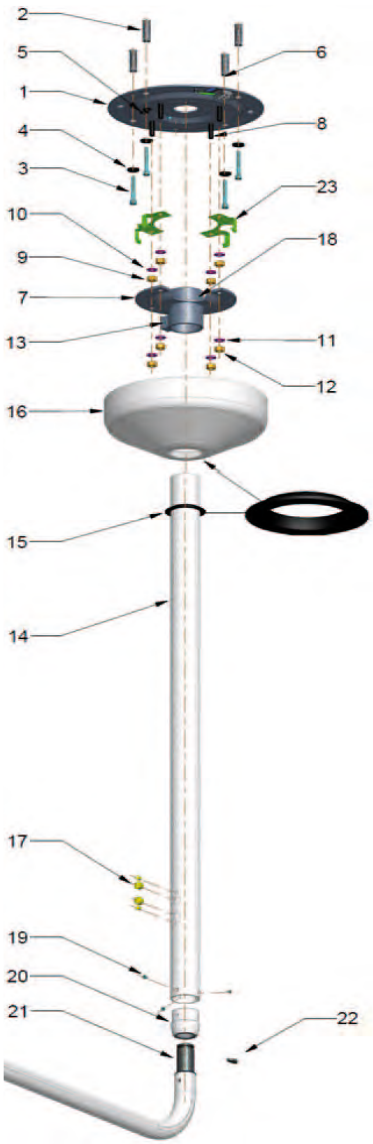
The light has to be installed with FARO applications only.

The light is supplied with rotation limit switch between the fix and the mobile arm. THE LIMIT MUST NOT BE PASSED OVER OR FORCED.

CEILING MOUNTING INSTALLATION

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



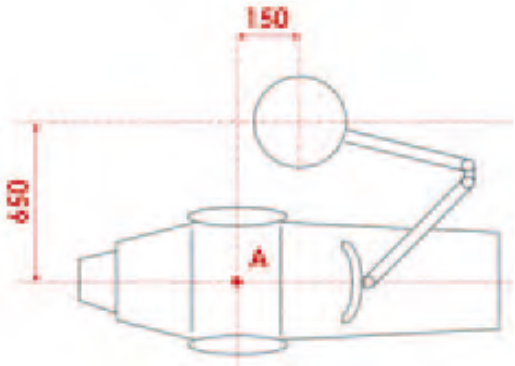


CEILING MOUNTING

NB1. The device has to be installed by specialized technicians only
NB2. Always cut off the power supply prior to installation
NB3. Before proceeding with the assembly, ensure the ceiling can bear the application.
The authorized construction materials of the ceiling are concrete and natural stone. Use the supplied fittings or equivalent ones.
NB4. Maximum applicable load: 70 kg
NB5. Installation is allowed only in spaces provided with electrical plant compliant with the national legislation in force as regards spaces for medical use
NB6. The lamp without transformer must be powered with low-voltage (12-24Vac o 17-33Vdc) using a safety transformer (according to IEC/EN 60601-1) with thermal protection or at least one suitable fuse (T500mAL250V~).

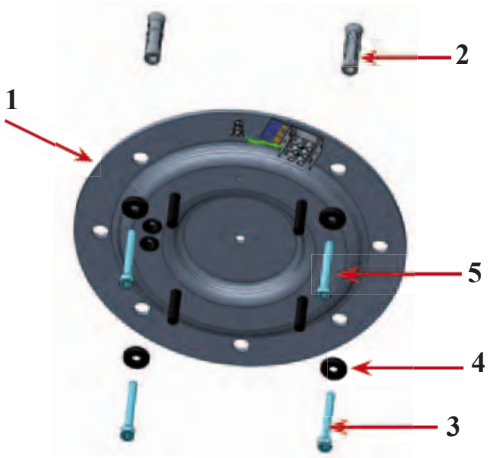
INSTALLATION STEPS

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.

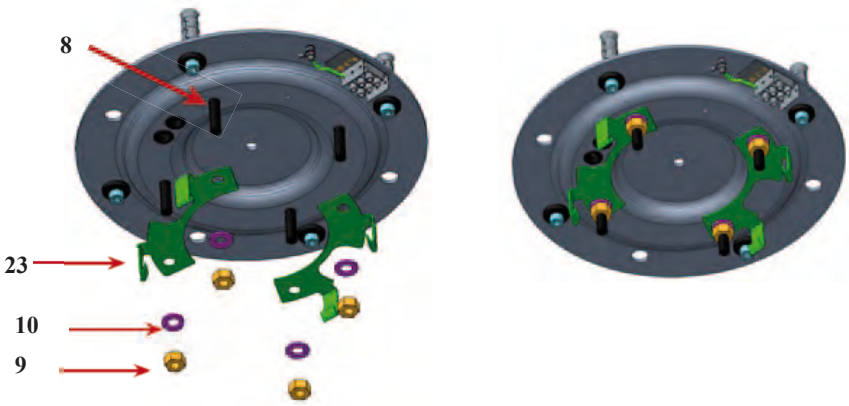
D. Take the flange (1). Pass the power cable through the cable gland (5), then push the flange (1) against the ceiling; do not choke the cable between the flange
(1) and the ceiling. Pass the screws (3) and washers (4) through the 4 bores used as reference in drilling the ceiling. Lock with the special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



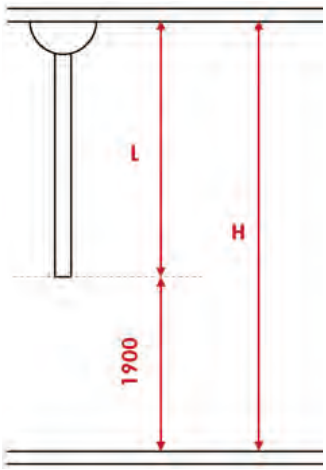
E. Connect the power cable to the terminal board (6) (see electrical diagrams)

CEILING MOUNTING

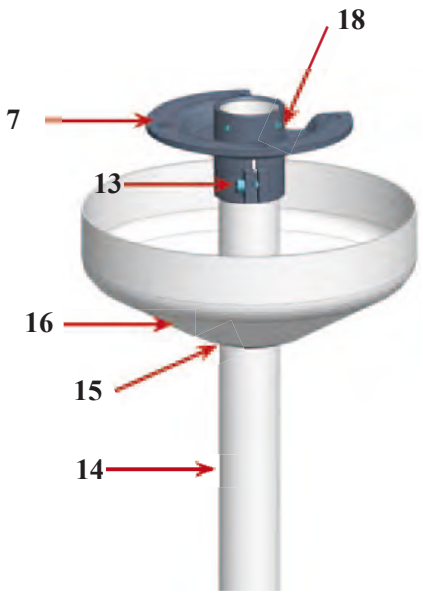
F. Match the 2 fixing guides (23) to the screws (8) and fix then by means of the nuts (9) and washers (10)



G. Calculate the proper length of the column (14), according to the formula L=H-1900mm. Cut the exceeding column (14) part on the side were NO LATERAL BORES ARE PRESENT



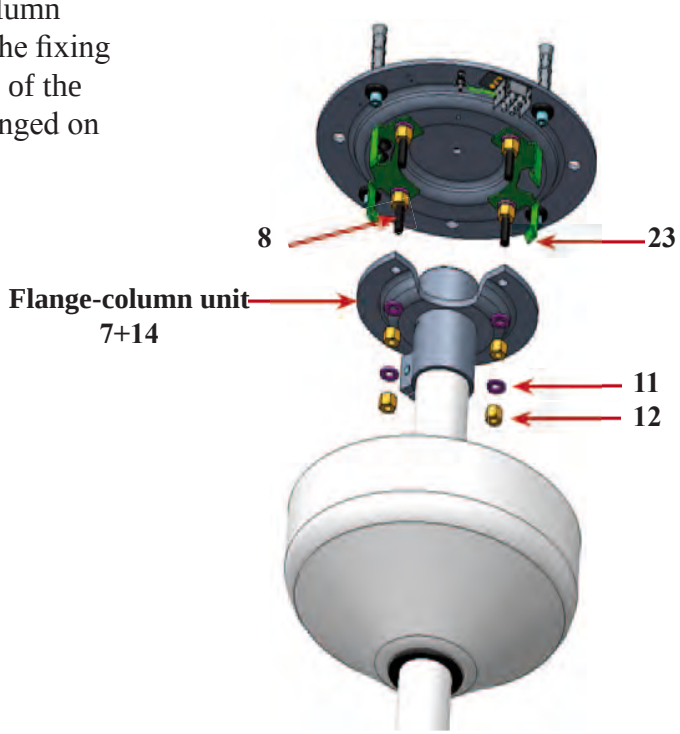
H. Insert them column (14) in the flange (7) and mark on the column (14) the position of the bores on the flange (7). Pay attention the orientation of the column in relation to the dental unit. Remove the column and carry out two Ø8 bores at the marked points



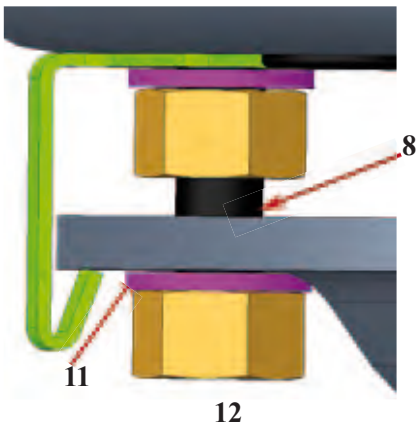
I. Fit on the column (14) the ring(15) at about 300mm height (it is only temporary position to allow the assembling)
J. Insert the ceiling light support (16) on the column (14)
K. Fit the column (14) in the special bore of the column fixing flange (7)
L. Lock the screw (13) and the two screws (18) with hexagonal spanners (installation accessory). Tighten sturdily the screw (13) and make sure the screws (18) have passed through the bores on the column (14)

CEILING MOUNTING

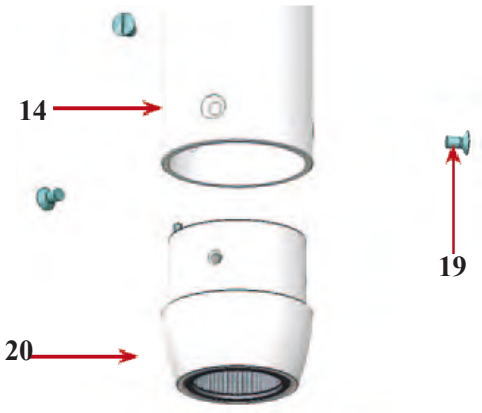
M. Hook the unit freshly assembled (column fixing flange (7) + column (14)) to the fixing guides (23), by matching the 4 bores of the flange (7) to the screws (8) of the flanged on the ceiling (1)



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)



CEILING MOUNTING

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

S. Connect the lamp conductor to the traction cord.

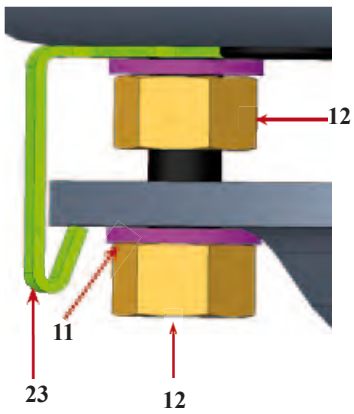
T. Fit the lamp on the column (14) and fix it with the three screws (19); make sure the bores of the bushing (20) match the screws seat on the column (14) and tighten. Simultaneously pull the traction cord to push out the conductor of the lamp from the column fixing flange (7) of about 200 mm.

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

V. Verificare la perpendicolarità della colonna agendo sui dadi (9).

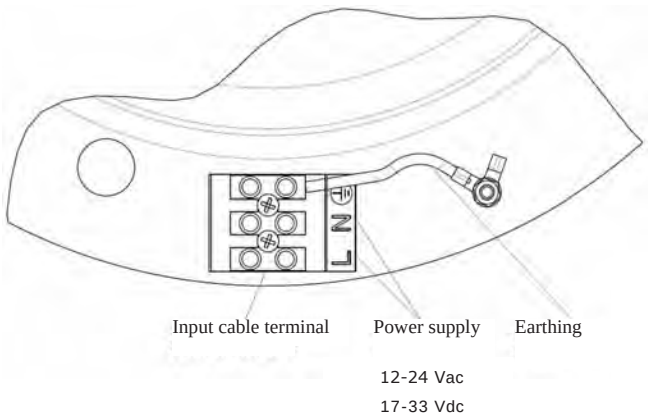
W. Stringere i dadi (12) e le rondelle (11) per fissare la flangia (7), rendendola indipendente dalle guide di fissaggio (23).

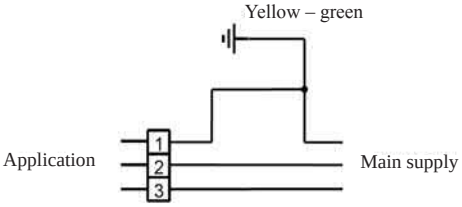
X. Far aderire la plafoniera (16) al soffitto, spingendovi contro l'anello (15).



WIRING DIAGRAM

CEILING MOUNTING WITHOUT transformer

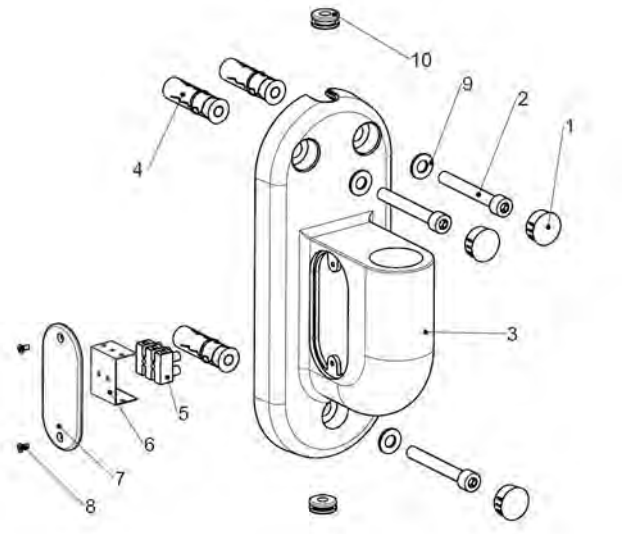


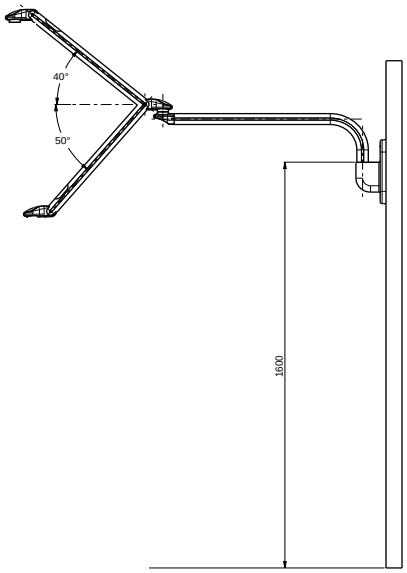


WALL MOUNTING

LIGHT MOUNTING WALL MOUNTING

1. Plug
2. Screw
3. Wall mounting
4. Expanders
5. Terminal board
6. Terminal board cover
7. Cover
8. Screw
8. Washer
8. Cable gland





NB1. The device has to be installed by specialized technicians only
NB2. Always cut off the power supply at the installation site prior to installation
NB3. Before proceeding with the assembly, ensure the wall can bear the application.
The authorized construction materials of the wall are concrete and natural stone. Use the supplied fittings or equivalent ones.
NB4. Maximum applicable load: 70 kg
NB5. Installation is allowed only in spaces provided with electrical plant compliant with the national legislation in force as regards spaces for medical use
NB6. The lamp without transformer must be powered with low-voltage (12-24Vac o 17-33Vdc) using a safety transformer (according to IEC/EN 60601-1) with thermal protection or at least one suitable fuse (T500mAL250V~).
The resulting medical system has to be declared by the installer as being compliant with IEC/EN 60601-1

WALL MOUNTING

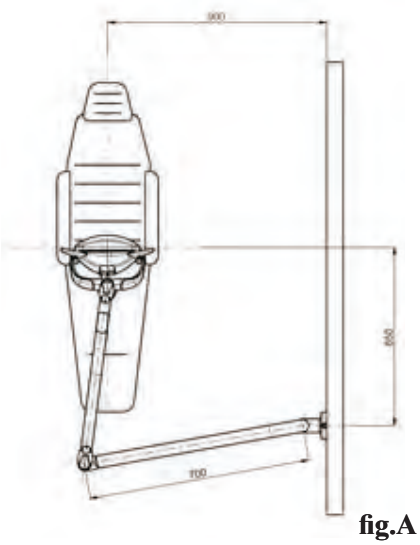


fig.A

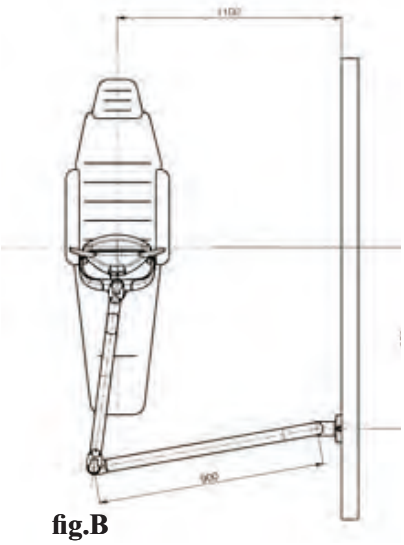
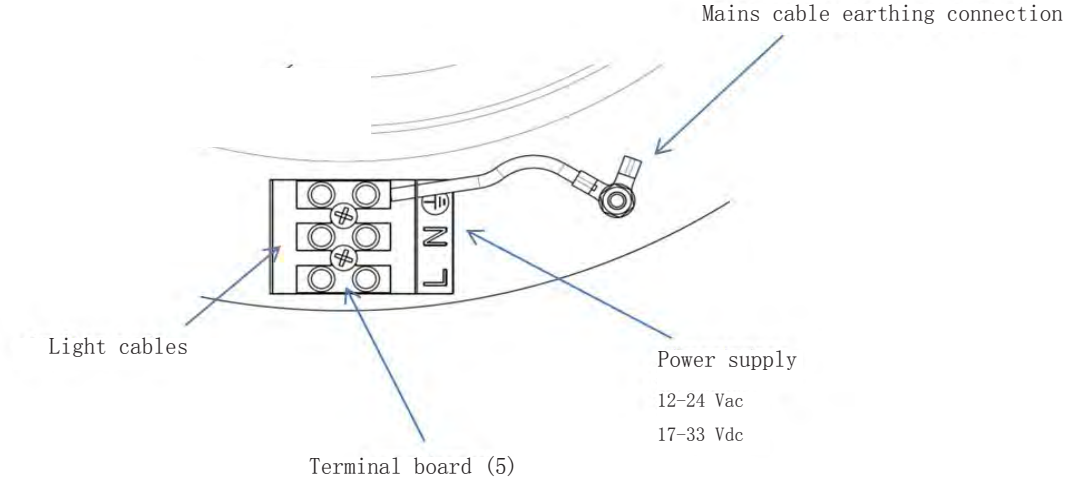


fig.B

Always cut off the power supply at the installation site prior to installation
- After having fixed as reference point the chair centre (see fig. **A-B**), carry out on the wall three d.14 bores at the bores of the wall mounting (3); pay attention the perpendicularity of the bore.
- Insert the expanders (12) in the d.14 bores previously carried out and block with the special hex spanner (installation accessory) the 2 screws; do not choke the cable between the application (3) and the wall.
- Apply three plugs (1) on the wall mounting (3) bores.
- Unscrew the screw (8) Remove the cover (7), insert the lamp arm inside the application and grease the pin. Connect the lamp cables to the terminal board (5) (see the electrical diagram below), including the earthing cable. Connect the wires which come out of the wall to the terminal board, if previously walled in. In the absence of such arrangement,
the connection as to be carried out with a movable cable, to be passed in the cable gland (10).
- Fit back the cover (7) by means of screws (8).

WIRING DIAGRAM

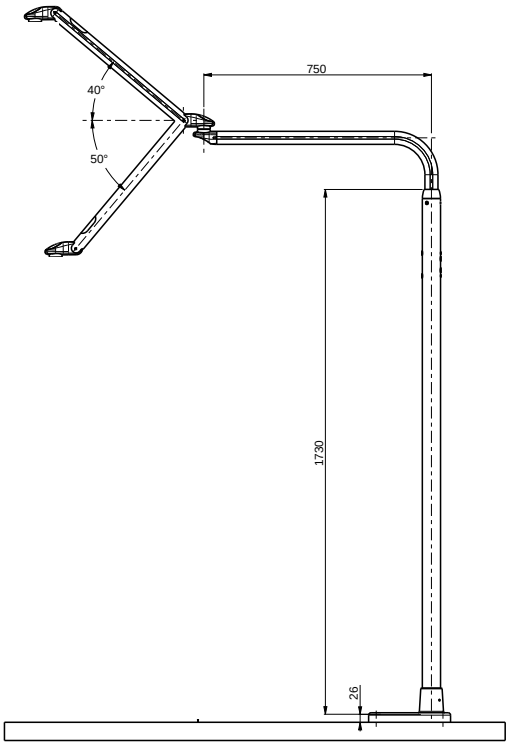
Wall mounting

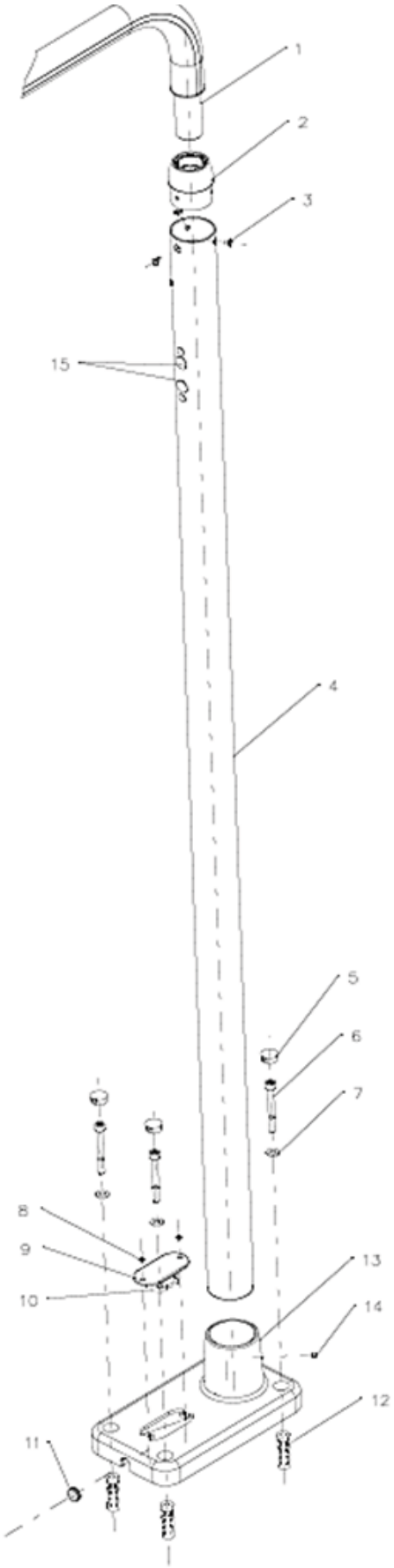


FLOOR MOUNTING

FLOOR MOUNTING

1. Pin
2. Bushing
3. Screw
4. Support column
5. plugs
6. Screw
7. Washer
8. Screw
9. Cover
10. Terminal board
11. Cable gland
12. Expanders
13. Floor support
14. Dowels
15. Plug





FLOOR MOUNTING

The device has to be installed by specialized technicians only

NB2. Always cut off the power supply prior to installation

NB3. Before proceeding with the assembly, ensure the floor can bear the application.
The authorized construction materials of the wall are concrete and natural stone. Use the supplied fitting or equivalent ones.

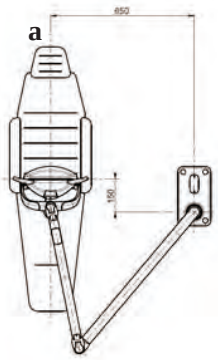
NB4. Maximum applicable load: 70 kg

NB5. Installation is allowed only in spaces provided with electrical plant compliant with the national legislation in force as regards spaces for medical use

NB6. The lamp without transformer must be powered with low-voltage (12-24Vac o 17-33Vdc) using a safety transformer (according to IEC/EN 60601-1) with thermal protection or at least one suitable fuse (T500mAL250V~). The resulting medical system has to be declared by the installer as being compliant with IEC/EN 60601-1

A. After having fixed as reference the centre of the chair "a", install at a distance 650mm and 150mm according to the directions given in figure"C "

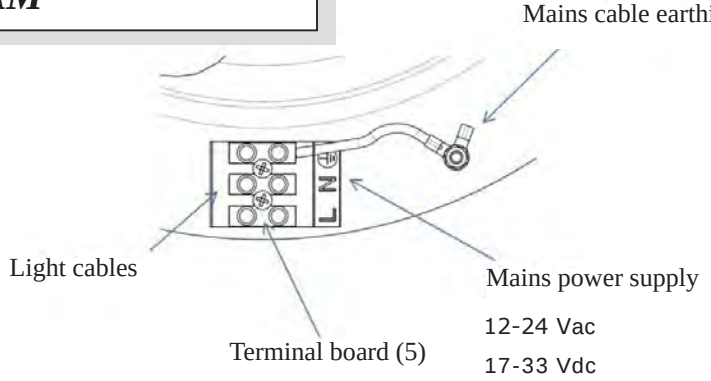
fig. C



- Always cut off the power supply at the installation site prior any operation
- After having fixed as reference point (a) the chair centre (see fig.C), drill four d.14 bores in the floor, so that they match the bores on the support (13).
- Prepare the floor support (13) by passing through the washer (7)and screw (6), then screw the expanders (12) on the screws (6) a few turns, pass the power cable through the cable gland (11).
- Insert the expanders (12) in the d.14 bores previously carried out and block with the special hex spanner (installation accessory) the 6 screws; do not choke the cable between the support (13) and the floor.
- Apply four plugs (5) on the floor support (13) bores.
- Untighten the screws (8) and remove the cover plate (9) Connect the power supply cable to the terminal board (10).
- Fix the column (4) to the floor support (13); while securing it, ensure the column is perpendicular. Secure with the three screws (3) the bushing (2) to the column (4); ensure the holes of the bushing (2) match the screws on the column (4).
- Connect the light cables to the terminal board (10).
- Fit the cover plate (9) to the floor support (13) with two screws (8).

WIRING DIAGRAM

Floor mounting



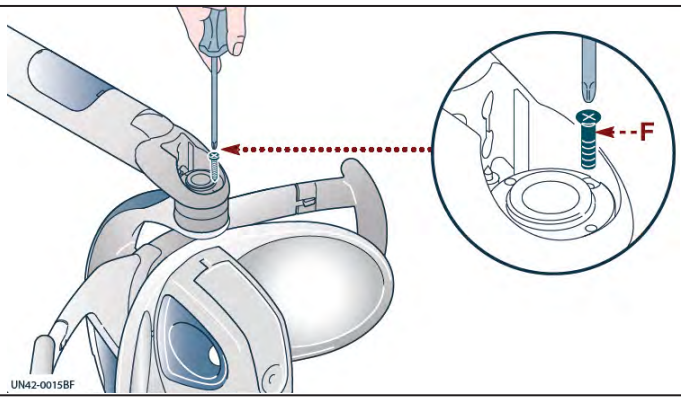
3.3 HEAD

3.3.1 Mechanical requirement

For mechanical connection you must have an adequate space for the pin in the head and the G. fastening components.
The support system must be designed to support the following loads, multiplied by the safety factors outlined by IEC 60601-1 or IEC 80601-2-60

Alya Head	Alya Screen
1,80 kg	0,35 kg
2,15 kg	

For mechanical connection, follow the procedure below:

1 - Support the head and insert the washers in the threaded pin in compliance with the sequence in the figure. 2 - Then insert ring nut G in compliance with the sequence indicated in the figure and screw in with adequate equipment. The ring nut must be screwed in to give the right rotational force to the head.	
3 – Screw in the 2 safety screws F.	

⚠	**Attention**
	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.
⚠	**Warnings for danger of suspended loads falling**
	Attention - Risk of head falling after installation: - only use screws supplied by FARO. - screw in the safety screws together.

Once mechanical connection is complete, complete electrical wiring.

3.3.2 Electrical requirements

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

<table>
<tr><th>Power supply</th><th>Power cable</th><th>Type of power supply and safety requirements</th><th>Classification</th><th>Compliance with IEC 60601-1</th></tr>
<tr><td>17-24 Vac
50/60 Hz</td><td rowspan="2">Power cable:
2 red unipolar cables:
UL Style 1061
300 V
T 80°C
1x26 AWG
VW 1
Ø max 1.02mm
Std connector:
molex 51021-0300 with 3 poles</td><td>Transformer complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse:
• T1.6AL 250V
Minimum requirements:
• Output: 17 - 24 Vac;
• Power: 26 VA;
• Class B;
• Rigidity over 4000 V.
• Thermal protection</td><td rowspan="2">Component built-in</td><td rowspan="2">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.</td></tr>
<tr><td>22-33Vdc</td><td>Power supply unit complies with IEC/EN 60601-1 third edition and IEC/EN 60601-1-2 with thermal protection or protection downstream with at least one appropriate fuse:
• T630mAL 250V
Minimum requirements:
• Output: 22-33 Vdc
• Power: 14 VA;
• Class B;
• Rigidity over 4000 V.
• Continuous protection from short circuit or overcurrent</td></tr>
</table>

4. ISTRUCTION FOR USE

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

	**Attention**
	Simultaneous use of the light with electro-surgical scalpels can cause its malfunctioning.

	**Attention**
	The control joystick must be handled with care to avoid breakages. Never move the light using the joystick 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 casing are damaged.

4.1 SWITCH ON AND OFF

Refer to §1.1 for the switch on and adjustment symbols.

Complete Light

To switch on and off the light, press and release the joystick lever using the right or left side. The light intensity on switch on will always be the last used before switch off.

Complete light with Theia Tech

Same operations of the complete light plus those on the fixed arm switch on and/or off in sync with that of the head.
The light on the fixed arm can be switched on/off even using the button on the arm. If the light is switch on, the light will be automatically synchronised, if the light on the head is off, it will be regulated to maximum intensity.

4.1.1 Adjustment:

a) to reduce light intensity keep the lever pressed on the joystick on the left side (light rear view) until the desired intensity is reached.
On reaching the minimum intensity, you will hear an acoustic signal (1 beep).
a) to increase light intensity keep the lever pressed on the joystick on the right side (light rear view) until the desired intensity is reached.
On reaching the maximum intensity, you will hear an acoustic signal (1 beep).
c) to skip to maximum intensity, press and release the joystick lever using the front or rear side. On subsequent pressing on the front or rear side, the light intensity will return to that previously saved.
The light on the fixed arm is adjusted in sync with that of the head, it cannot be adjusted independently.

4.1.2 Light / Head WITH PROXIMITY

Switch on/off

Complete Light: To switch on or off, approach the sensor once up to a maximum distance of 3 cm.

Complete light with Theia Tech: same operations of the complete light plus the light on the fixed arm switch on and/or off in sync with that of the head.

Adjustment

Complete light: To adjust light intensity, you need to stay still near the sensor until the desired intensity is obtained. Adjustment enables passage from the maximum value to the minimum value again to the maximum. On reaching the maximum intensity, you will hear an acoustic signal (2 beeps). On reaching the minimum intensity, you will hear an acoustic signal (1 beep).

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

Complete light with Theia Tech same operations of the complete light plus the light on the fixed arm will adjust in sync with that of the head.

4.1.3 Light / Complete light with Theia Tech / "ALYA" head WITH REMOTE CONTROL

Switch on / Switch off / Adjustment
- To switch on and/off press and release button "A".
- Adjustment:
a) to reduce the light intensity keep button "A" pressed until reaching the desired intensity.
On reaching the minimum intensity, you will hear an acoustic signal (1 beep).
b) to increase the light intensity keep button "A" pressed until reaching the desired intensity.
On reaching the maximum intensity, you will hear an acoustic signal (2 beeps).
c) to immediately reach the minimum light intensity, press button "B".
On reaching the minimum intensity, you will hear an acoustic signal (1 beep).
Subsequent button pressing will bring the light back to the previous light intensity selected.

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

4.1.4 LAMP / COMPLETE LAMP WITH THEIA TECH / "ALYA" HEAD WITH SYNCHRONIZATION COMMAND

Where foreseen, it is possible to connect the Alya lamp to the Faro environment lamp in wireless mode in order to turn them into a synchronized lighting system named "Synchro".
The "Synchro" mode has been purposefully designed to improve the comfort of the medical dentist/orthodontist, in order to reduce the effect of glare generated when passing from observation of a highly illuminated surface (e.g. oral cavity with a dental lamp) to a poorly lit surface (e.g. dental quiver).
With the method named "Synchro", activatable using the button situated at the head of the Alya lamp, it is possible to change the illumination produced by the Faro environment lamp automatically on the basis of the value of illumination produced by Alya.
Note: Between the dental lamp and the environmental one, a small delay in synchronization may be experienced. This is due to the communications protocol. This effect is normal and does not signify a defect.
The "Synchro" function, in order to be enabled, requires a "Pairing" process (which should only be carried out once) in order to create a link between the two lamps Subsequently, the "Synchro" function can be enabled and/or disabled as required by the user, from the button situated on the dental lamp.

"PAIRING" PROCEDURE
NOTE:
- The "Pairing" procedure is only necessary at the first connection, although it can be repeated in the event of changing the Alya lamp or the electronics of one of the two interconnected lamps.

- If there should be more environment lamps in the surgery, ensure that the other lamps are turned off or have been on for more than 60 seconds.

To carry out the **"Pairing"**, proceed as follows:

1. Apply current to the Faro environment lamp you wish to couple.
   The environment lamp prepares itself for a Pairing connection, for a maximum time of 60 seconds.

2. Within the 60 seconds, press the "synchro" button on the dental lamp for at least 3 seconds, but for no more than 6 seconds, otherwise the procedure will be cancelled.
   On receipt of the **"Pairing"** request by the dental lamp, the environment lamp activates the blue LED on the aluminium body. If the blue LED should not activate, it is possible (within 60 seconds from switching on) to carry out other attempts. Once the time has been exceeded, it is necessary to repeat the procedure from point 1.

3. From the blue LED illuminating on the environment lamp, there are 60 seconds to confirm the **"Pairing"** by pressing the programming button  situated on the remote control of the environment lamp. At this point, the blue LED (of the environment lamp) flashes at double speed and then goes out. If the button  on the remote controls is not pressed within 60 seconds, the blue LED goes out and the procedure must be repeated from point 1.

Having carried out the **"Pairing",** synchronization between the 2 lamps is now enabled.

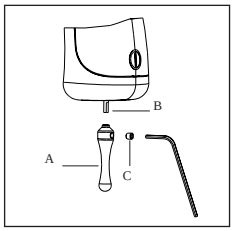
To **ACTIVATE THE SYNCHRONIZATION FUNCTION**, proceed as follows:
Press the Synchro button for 2 seconds then release it.
On release, a sound signal (Beep) will be heard and the blue LED on the environment lamp will light to indicate that synchronization has been activated.

To **DE-ACTIVATE THE SYNCHRONIZATION FUNCTION**, proceed as follows:
Press the Synchro button for 2 seconds then release it.
On release, a sound signal (Beep) will be heard and the blue LED on the environment lamp will go out to indicate that synchronization has been disabled.

Note connected with synchronization:

- When the Faro environment lamp is synchronized with the Alya lamp (or it adjusts itself automatically), the blue LED on the body is lit and steady. When the LED is off, the synchronization is not active.
- The remote control is always enabled, so it is therefore possible to change the illumination value. Nevertheless, if the environment lamp should find itself in a synchronized state (with the blue LED lit), as soon as a new adjustment is carried out on the Alya lamp, the illumination value will immediately be updated.
- If the Alya lamp should be turned off, the environment lamp will remain lit at the illumination value in use.
- If the Alya lamp should be turned on, the environment lamp will turn on automatically.

4.2 JOYSTICK ALYA JOYSTICK LEVER ASSEMBLY



- Fully insert lever “A”on the pin of the joystick.
- The hole in lever “A” must be positioned corresponding to surface “B”.
- Fully screw in grub screw “C” with the wrench supplied.

	Attention
	The control joystick must be handled with care to avoid breakages. Never move the light using the joystick to grip.

5. ORDINARY MAINTENANCE

There are no ordinary maintenance operations.

6. CLEANING

	Warning against danger of wear and corrosion and falling suspended weights
	For all metal or plastic parts of the light, it is strictly forbidden to use substances that are abrasive, acid, substances containing chlorine or chloride ions, detergents with Trilene base, petrol, white spirit or similar. It is forbidden to directly spray any chemical substance on the device.

6.1 PARABOLA CLEANING

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.

	Attention - 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.

6.2 CLEANING 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 • METHYLENE CLORIDE • ME THYL ALCOHOL. • ALL KINDS OF ACIDS Faro has tested and suggests the following disinfectants: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

6.3 ARM CLEANING

Always use a cloth soaked in disinfectant approved to disinfect the surfaces and pass it over.

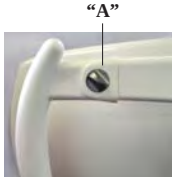
	Warning against danger of corrosion and mechanical collapse with falling suspended weights
	Never spray chemical substances directly on the arms or joints and their openings.
	Warning against danger of wear of the plastic with falling suspended weights
	Do not use detergents-disinfectants containing the following to clean plastic parts: • AMMONIUM HYDROXIDE • SODIUM HYDROXIDE • METHYLENE CLORIDE • ME THYL ALCOHOL. • ALL KINDS OF ACIDS Faro has tested and suggests the following disinfectants: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

7. STERILISING 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.

7.1 Removing the handles

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



7.2 Decontamination and disinfectant

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.

7.3 Sterilisation

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:

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

8. PERIODIC CHECKS

Operation	Frequecy	Applicability		Procedure	Enabling
		LD	TE		
Check the absence of range between the arm joints	Annual	x	N/A	Check the gap between the joints 5 and the arm has not changed since first use	User
Check data plate is legible	Annual	x	x		User
Check casing is intact	Twice-yearly				Service Engineer
Check electrical safety EN 62353 1. Rigidity 2. Dispersion	Twice-yearly	x	x	Measure dielectric rigidity and dispersion of the casing. Limits defined in IEC 60601-1	Service Engineer
Light parameter checks.	Twice-yearly	x	x	With a spectroradiometer, measure the values of: • Maximum lighting: >35000 lux • CRI decay: <20%. • Underlying value of the blue light on the spectrum emitted measured in: <100 W/m2	Service Engineer

Service Engineer: competent person in electro-mechanical equipment maintenance.

9. ACOUSTIC ALARM SIGNALS

9.1 Acoustic Signals

OpL** = Beep 30 seconds
OTP* = Beep 30 seconds

* OTP: LED overtemperature protection.
** OpL: Disconnected led load

9.2 GUIDE TO PROBLEMS

The table below represents a guide to the potential defects of the light.
If you cannot resolve the problems, call technical support

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
The lamp does not control	Synchro function off	Activate the function; see 4.1.4	User

10. TECHNICAL FEATURES

Complete light:
Power supply voltage (without transformer):
- 17÷24Vac ±10% - 50/ 60Hz;
- 22÷35Vdc ±10%

Absorbed power:
- 26VA (version 17÷24Vac);
- 14VA (version 22÷35Vdc)

Recommended fuses:
- Version 17÷24Vac: T1.6AL 250V
- Version 22÷35Vdc: T630mAL 250V

Protection against electrical danger:
- Class II device

Classification EN 62471:
- Exempt class

Complete light with Theia Tech
Power supply voltage (without transformer):
- 24Vac ±10% - 50/ 60 Hz
- 24Vdc ±10%

Absorbed power:
- 40VA (version 24Vac)
- 28VA (version 24Vdc)

Recommended fuses:
- T2AL 250V

Protection against electrical danger:
- Class II device

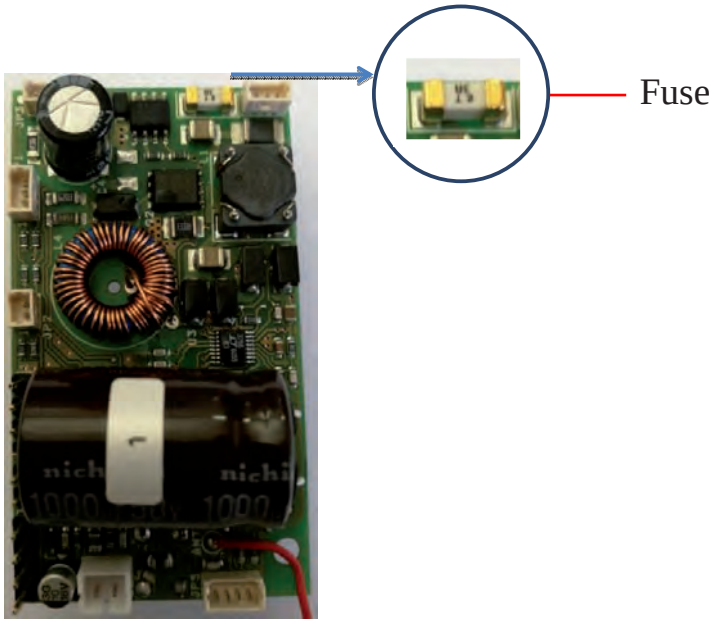
Classification EN 62471:
- Exempt class

Optical features of the light produced by the head in compliance with ISO 9680
Spot light dimensions: 180 mm x 90 mm
Lux: 3.000*-50.000* lux @700mm
Colour temperature: 5000 K*
CRI (colour rendering index): >95*

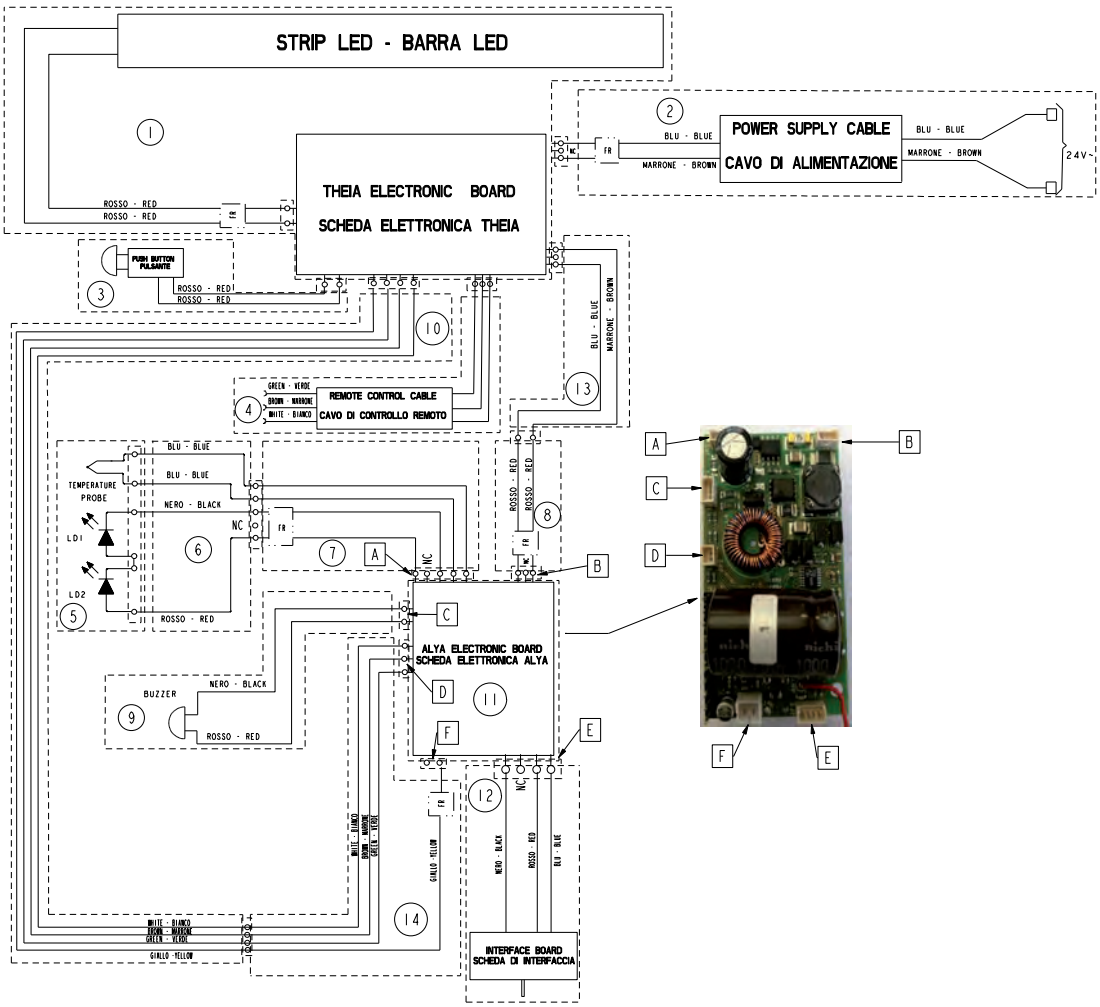
* Typical values subject to tolerances.
Labelling in compliance with EN 62471: not necessary

10.1 WIRING DIAGRAMS

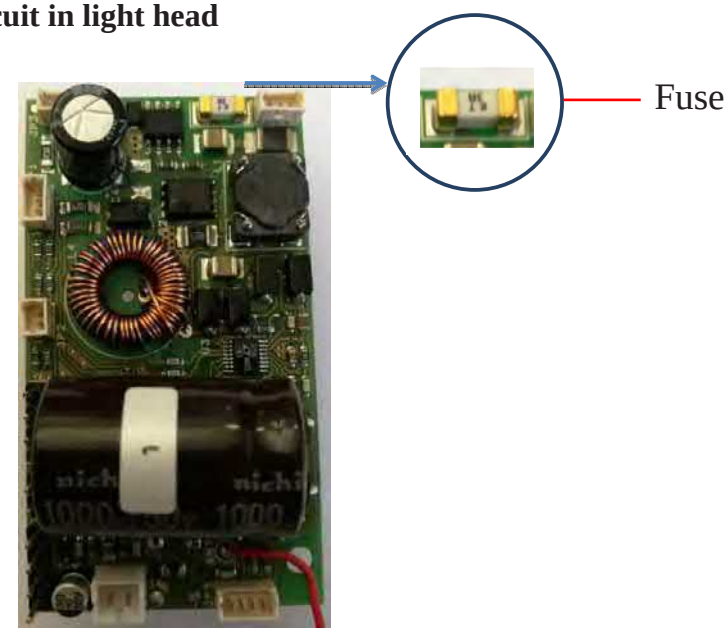
- **Complete light:**
  Electrical circuit in light head



Wiring Diagram – Alya with transformer

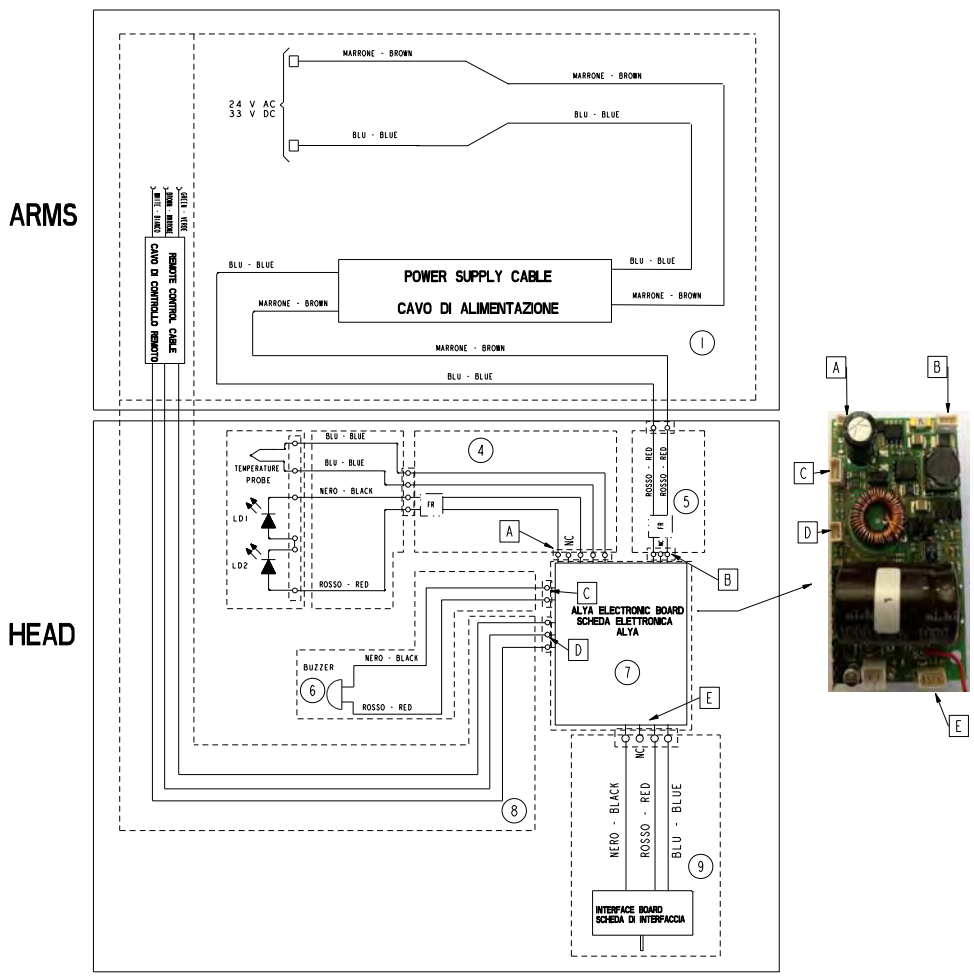


- **Complete light with Theia Tech:**
  Electrical circuit in light head

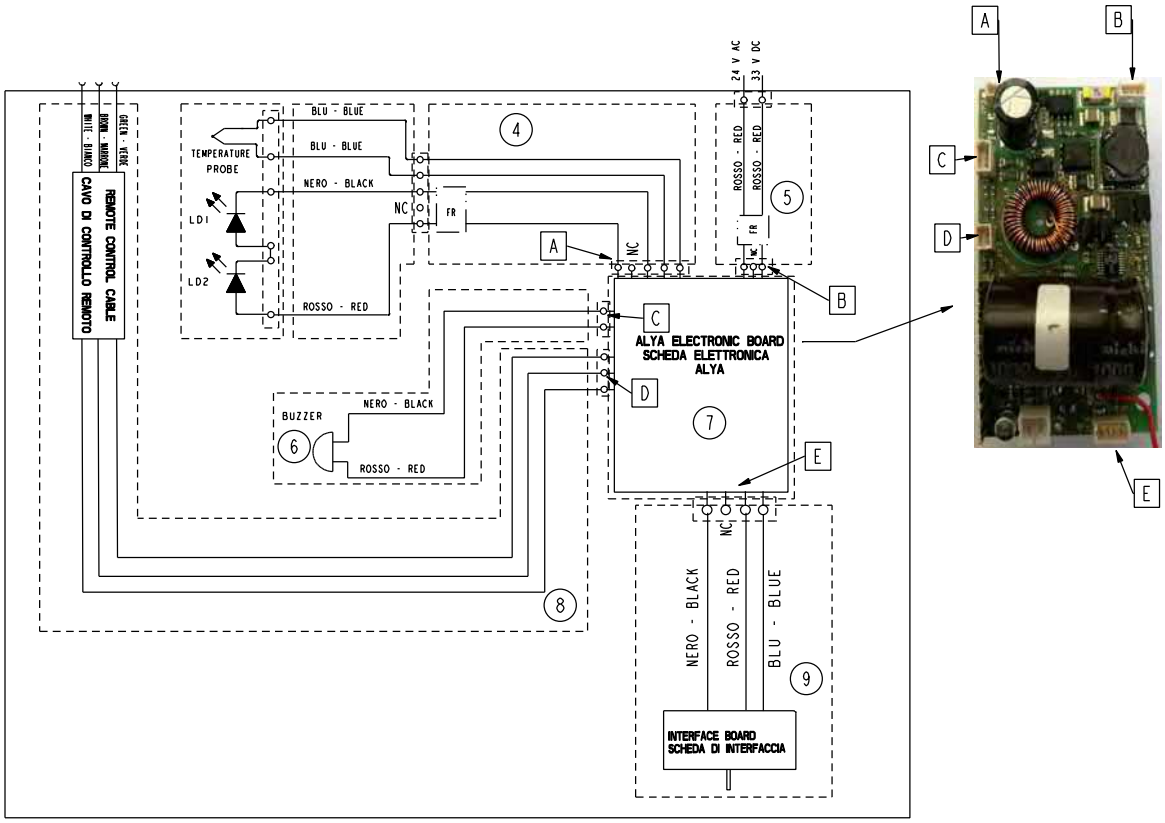


Electric circuit in rear arm

Electrical Scheme – Alya Theia Tech.



- ***Head:*** *Electrical Scheme – Alya Head*



SOMMAIRE

1. CONDITIONS DE SÉCURITÉ

Cher Client,

FARO vous souhaite bon travail avec la nouvelle lampe de haute qualité. Pour travailler de façon sûre et exploiter au maximum les performances du produit, lisez attentivement ce manuel avant l'utilisation du dispositif. Suivez en particulier toutes les mises en garde et les notes reportées.

1.1 SYMBOLES UTILISÉS

1.1.1 Symboles utilisés à l'intérieur du manuel

	*MISE EN GARDE*
Les paragraphes marqués avec ce symbole contiennent des instructions qui doivent être effectuées attentivement pour éviter des dommages sur le dispositif, l'opérateur et le patient.	

	*ATTENTION*
Ces instructions avertissement qu'il faut faire très attention pour éviter des situations dangereuses qui pourraient endommager le dispositif.	

	*INTERDICTION*
Cette icône met en évidence ce qu'il ne faut pas faire pour éviter des dommages sur le dispositif.	

	*NOTES*
Avec cette icône, on fournit une information qui permet d'utiliser le dispositif de façon plus efficace.	

1.1.2 Symboles présents en étiquetage

La plaque données est fixée:
• pour la lampe complète: sur le bras arrière
• pour la tête: sous le couvre-dissipateur
et reporte les données suivantes:
Serial Number (SN): année (AA) / famille d'appartenance (LD pour lampe dentaire - TE uniquement pour la tête) plus numéro progressif (NNNNNN) ex: SN14LD000001 pour la lampe complète SN 14TE000001 pour la tête.
Les symboles harmonisés suivants sont par ailleurs présents:

	Lire les instructions pour l'emploi. Fournies électroniquement
	Symbole de fabricant conformément à la Directive 93/42/EEC
	Le mode d'emploi comprend des mises en garde pour la sécurité
	Appareil RAEE conformément à la directive 1012/19/CE. Eliminer le produit conformément à cette directive.
	Double isolation. Dispositif de classe 2 contre le risque électrique
	Serial Number / Numéro de Série
	Stérilisable à Chaleur Humide à 134°C
	Utiliser le dispositif à une Température comprise entre 10°C et 40°C
	Utiliser le dispositif à une Pression comprise entre 800mbar et 1060mbar
	Utiliser le dispositif à une Humidité Relative comprise entre 30 RH et 75RH
	Symbole pour le réglage de l'intensité lumineuse
	Symbole pour la mise en marche de la lampe
	[Symbole pour la mise en marche/arrêt de la lumière sur le bras arrière]

1.1.3 Symboles présents sur l'emballage

HAUT

FRAGILE

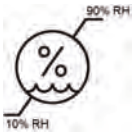
NE PAS MOUILLER

NE PAS ENROULER

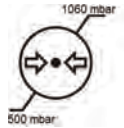
NE PAS UTILISER DE CROCHETS

POIDS MAX SUPERPOSABLE

TEMPÉRATURE DE STOCKAGE
CONDITIONS DE TRANSPORT



HUMIDITÉ RELATIVE



PRESSION ATMOSPHÉRIQUE

CARTON RECYCLABLE

1.2 USAGE PRÉVU

Le dispositif est destiné à être utilisé exclusivement dans le cabinet dentaire de médecins dentistes, chirurgiens dentaires et hygiénistes pour l'éclairage du site opératoire et d'intervention dan le traitement des pathologies de la cavité buccale et de l'appareil dentaire.
Le dispositif dans son utilisation normale est positionné au-dessus du corps du patient à une distance de 700mm, distance pour laquelle les caractéristiques d'éclairage ont été étudiées.
Les patients traités peuvent être de tous les âges pour des pathologies typiques de l'appareil dentaire.

1.3 UTILISATEUR PRÉVU

L'utilisateur prévu est le médecin dentiste, chirurgien dentaire ou l'hygiéniste dentaire.

1.3.1 Niveau d'étude:

- Diplôme en médecine avec spécialisation dentaire
- Diplôme en chirurgie dentaire
- Diplôme en Hygiène dentaire

1.3.2 Compétence minimum

- Celles prévues par le niveau d'étude
- Compréhension du langage: Celles acquises avec le niveau d'étude

1.3.3 Expérience

- Celle prévue pour le déroulement de la profession

1.3.4 Handicaps possibles de l'utilisateur

- Pour l'utilisation, il faut avoir l'utilisation d'un membre supérieur complet.
- Facultés visuelles compatibles avec la profession.

1.4 NORMES GÉNÉRALES ET MISES EN GARDE PRINCIPALES

- Le dispositif peut être appliqué à l'unité dentaire, mais il peut aussi être installé sur des applications consacrées. Le dispositif peut être alimenté aussi bien par l'unité dentaire que par un alimentateur branché directement au réseau. Voir le paragraphe consacré à l'installation
- Le dispositif ne possède pas de Performances Essentielles dont l'inaptitude des prestations du dispositif ne compromet pas la sécurité du patient.
- Le dispositif ne soutient pas la vie.
- Le dispositif doit être nettoyé avant l'utilisation (voir paragraphe "Nettoyage du dispositif").
- L'emballage de la lampe est adapté pour la protéger convenablement de la pénétration d'agents externes.

⚠	**Mise en garde contre le danger électrique ou d'incendie**
	Ne pas utiliser la lampe en cas d'endommagement de ses composants. L'installation du dispositif doit être effectuée uniquement par un personnel qualifié. La lampe dentaire doit être installée sur un dispositif de contrôle et d'alimentation spécifique, comme unités dentaires, ou avec circuit électrique qui réponde à la norme IEC 60364-1 et les "règles nationales d'installation pour circuits électriques dans des pièces prévues à usage médical". L'appareil doit être installé avec un dispositif de séparation du réseau de type omnipolaire et conforme à la Norme IEC 61058-1. L'installation et le maintien de la conformité du dispositif à la norme IEC 60601-1 est à la charge de l'installateur ou du fabricant d'unités. Vérifier que la tension d'alimentation, indiquée sur la plaque données, corresponde à celle de réseau. N'effectuer aucune intervention d'entretien sur la lampe quand l'alimentation est enclenchée: donc, débrancher le câble d'alimentation du réseau avant d'intervenir.
⚠	**Mise en garde contre le danger de dégradation des pièces mécaniques et chute de masses suspendues**
	Pour le nettoyage des pièces en plastique, ne pas utiliser de détergents contenant : HYDROXYDE D'AMMONIUM - HYDROXYDE DE SODIUM - CHLORURE DE MÉTHYLÈNE - ALCOOL MÉTHYLIQUE. Le non-respect de la prescription pourrait causer : RISQUE DE DÉGRADATION DES PIÈCES EN PLASTIQUE AVEC RUPTURE À SUIVRE. Ne vaporiser aucun agent chimique directement sur la lampe. En particulier, il est défendu d'utiliser des substances abrasives, acides, contenant du chlore.
⚠	**Mise en garde pour le danger de chute de masses suspendues**
	Respecter scrupuleusement les charges maximums prévues. Ne pas fausser ni surcharger les fins de course des bras et des têtes.
⚠	**Mise en garde pour le danger photobiologique et d'éblouissement**
	Ne pas fixer ni pointer le faisceau lumineux directement dans les yeux du patient surtout pour les patients à plus grand risque de lésions oculaires (ex. enfants avec pathologies aux yeux). Dans ce cas, toujours utiliser des protections et des précautions adaptées. La lampe est classée comme risque photobiologique Exempt conformément à l'EN 62471. On n'exclut toutefois pas que des patients particulièrement photosensibles et qui ont pris des médicaments photosensibilisants ne puissent avoir des érythèmes ou des réactions allergiques à la lumière. Dans ce cas, suspendre le traitement et utiliser des niveaux d'éclairage très bas. Le bras articulé et les articulations de la Lampe permettent le positionnement correct du faisceau lumineux.
⚠	**Mise en garde pour le danger d'endommagement des composants électriques**
	Ne pas surcharger les bras et les articulations avec des chocs en fin de course. La rotation de tête et bras au-delà des fins de course peut endommager les isolations des conducteurs.
⚠	**Mise en garde pour le danger d'explosion**
	Le dispositif n'est pas adapté pour être installé dans des milieux avec présence de gaz inflammable ou riches en oxygène.
⚠	**Mise en garde pour le danger de contamination croisée patient-patient**
	Le médecin est tenu d'utiliser les protections jetables sur les poignées de la lampe ou de les stériliser après chaque patient. Pour la désinfection des surfaces, utiliser des désinfectants hydro-alcooliques (voir paragraphe entretien/nettoyage).
⚠	**Mise en garde pour le danger d'entretien erroné**
	Ne pas effectuer d'opérations d'entretien ou de remplacements de pièces différentes de celles reportées dans le manuel. Toute intervention non indiquée dans celui-ci pourrait compromettre l'aspect sécurité du dispositif. Effectuer uniquement des opérations d'entretien reportées dans le manuel; dans tout autre cas, s'adresser à l'assistance technique.

Le Produit couvert par la Directive RAEE 2012/19/UE
Pour la mise au rebut et l'élimination des matériaux, respecter la réglementation en vigueur de son pays, en faisant éventuellement appel à des entreprises spécialisées reconnues et autorisées.
En fin du cycle de vie, diviser les matériaux en fonction de leur typologie (ferreux, caoutchouc, plastique).
Ne pas laisser de petits composants de l'appareil non surveillés ou à la portée de personnes exposées (enfants) parce que sources potentielles de danger.
La société FARO n'admet aucune modification sur le produit qui n'est pas expressément autorisée par écrit, sous peine de déchéance de la conformité aux normes de sécurité et de la garantie.
D'autres mises en garde sont reportées dans les titres de ce manuel.

1.5 CONSERVATIONS ET UTILISATION: PRESCRIPTIONS ENVIRONNEMENTALES

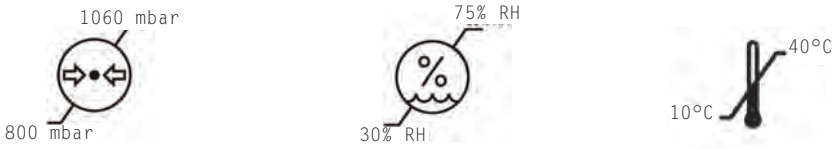
L'appareil dans l'emballage d'origine peut être transporté ou gardé en magasin pour une période de 15 semaines si les conditions environnementales suivantes sont respectées:

- Température ambiante de -20°C à + 70°C
- Humidité relative de 10% à 90%
- Pression atmosphérique de 500 à 1060 mbar

L'appareil doit être utilisé dans les conditions environnementales suivantes:

- Température de 10°à 40°C
- Altitude max : 2000 m
- Humidité relative de 30% à 75%

PRESSION ATMOSPHÉRIQUE **HUMIDITÉ RELATIVE** **TEMPÉRATURE D'UTILISATION**



1.6 CRITÈRES REQUIS POUR LA COMPATIBILITÉ ÉLECTROMAGNÉTIQUE

Le dispositif médical nécessite des précautions particulières concernant la compatibilité électromagnétique, il doit être installé et utilisé d'après les informations fournies par les documents d'accompagnement.

Guide et déclaration du fabricant – Émissions électromagnétiques		
La lampe ALYA est prévue pour fonctionner dans l'espace électromagnétique spécifié ci-dessous. Le client ou l'utilisateur devrait s'assurer qu'il est bien utilisé dans cet espace.		
Test d'émission	**Conformité**	**Espace électromagnétique - Guide**
Émission RF CISPR15	Conforme	La lampe ALYA utilise l'énergie RF seulement pour le fonctionnement interne. Ses émissions RF sont donc très basses et ne provoquent vraisemblablement aucune interférence pour les appareils électroniques proches.
Émission RF CISPR15	Conforme	La lampe ALYA s'adapte à l'utilisation dans tous les édifices, y compris ceux domestiques et ceux directement liés au réseau d'alimentation publique à basse tension qui alimente les édifices domestiques.
Émission harmonique	Classe C	
RF Emission CISPR11 / EN 55011	Conforme	La lampe ALYA n'est pas indiquée pour être interconnectée à d'autres dispositifs (version pour plafond).

IMMUNITÉ ÉLECTROMAGNÉTIQUE

Guide et déclaration du fabricant – Immunité électromagnétique		
La lampe ALYA est prévue pour fonctionner dans l'espace électromagnétique spécifié ci-dessous. Le client ou l'utilisateur devrait s'assurer qu'il est bien utilisé dans cet espace.		
Test d'immunité	**Conformité**	**Espace électromagnétique - Guide**
Décharge électrostatique (ESD) IEC/EN61000-4-2	± 6kV contact ± 8kV air	Les sols doivent être en bois, béton ou en céramique. Si les sols sont recouverts de matériau synthétique, l'humidité relative devrait être d'au moins 30 %.
Sursaut/transitoire rapide électrique IEC/EN61000-4-4	± 2kV alimentatiuon électrique ± 1kV pour lignes d'entrée/sortie	La qualité de la tension de réseau devrait être celle d'un milieu commercial ou hospitalier typique.
Surtension IEC/EN61000-4-5	± 1kV mode différentiel ± 2kV mode commun	La qualité de la tension de réseau devrait être celle d'un milieu commercial ou hospitalier typique.
Baisse de tension, courte interruption et variation de tension IEC/EN61000-4-11	< 5% Ut pour 0,5 cycle 40% Ut pour 05 cycle 70% Ut pour 25 cycle <5% Ut pendant 5 secondes	La qualité de la tension de réseau devrait être celle d'un milieu commercial ou hospitalier typique. Si l'utilisateur de la lampe ALYA requiert un usage continu même en l'absence de la tension de réseau, on recommande l'utilisation d'un groupe de continuité.
Champ magnétique de fréquence d'alimentation IEC/EN61000-4-8	3A/m	Niveau de champ magnétique à la fréquence de réseau typique d'un milieu commercial et hospitalier.
Immunités conduites IEC/EN61000-4-6	3Vrms 150kHz à 80MHz (pour les appareils qui ne sont pas "life-supporting")	Les appareils de communication à RF portables et mobiles ne devraient pas être utilisés à proximité de l'unité dentaire, y compris les câbles, excepté quand ils respectent les distances de séparation recommandées calculées par l'équation applicable à la fréquence du transmetteur. Distances de séparation recommandées: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ de 80 Mhz à 800 MHz $d = 2,3\sqrt{P}$ de 800 MHz à 2,5 GHz Où P est la puissance maximum nominale de sortie du transmetteur en Watt (W) selon le fabricant du transmetteur et d est la distance de séparation recommandée en mètres (m). L'intensité du champ des transmetteurs à RF fixes, comme déterminé par une enquête électromagnétique du site, pourrait être inférieure au niveau de conformité de chaque intervalle de fréquence. On peut vérifier l'interférence à proximité d'appareils marqués par le symbole suivant:
Immunités conduites IEC/EN61000-4-6	3Vrms 80MHz à 2.5GHz (pour les appareils qui ne sont pas "life-supporting")	

Remarque: Ut est la valeur de la tension d'alimentation
Remarque 1: A 80 MHz et 800 MHz s'applique l'intervalle de la fréquence la plus haute.
Remarque 2: Ces lignes directrices pourraient ne pas s'appliquer à toutes les situations. La propagation électromagnétique est influencée par l'absorption et par la réflexion de structures, objets et personnes.
a) Les bandes ISN (industrielles, scientifiques et médicales) entre 150kHz et 80MHz sont 6,765MHz à 6,795MHz; 13,553MHz à 13,567MHz; 26,957MHz à 27,283MHz et 40,66MHz à 40,70MHz.
b) Les niveaux de conformité dans les bandes ISN entre 150kHZ et 80MHz et dans les bandes 80MHz et 2,5GHz s'entendent à décroître selon la probabilité qu'un dispositif de transmission portable peut provoquer une interférence s'il est porté par mégarde dans la zone du patient.
C'est la raison pour laquelle un facteur additionnel de 10/3 a été incorporé dans la formule utilisée pour le calcul de la distance de séparation des transmetteurs.
c)) Les intensités de champ pour les transmetteurs fixes comme les stations de base pour radiotéléphones (portables et sans fil) et voitures-radio terrestres, appareils de radioamateurs, transmetteurs radio en AM et FM et transmetteurs TV ne peuvent être prévues théoriquement et avec précision. Afin d'établir un espace électromagnétique provoqué par des transmetteurs RF fixes, on devrait considérer une enquête électromagnétique du site. Si l'intensité de champ mesurée sur le lieu dans lequel on utilise l'unité dentaire dépasse le niveau de conformité applicable indiqué ci-dessus, on devrait placer sous observation le fonctionnement normal de la lampe. Si l'on remarque des prestations anormales, des mesures supplémentaires peuvent s'avérer nécessaires comme une orientation et une position différente de la lampe.
d) L'intensité de champ sur un intervalle de fréquences compris entre 150 kHz et 80 MHz devrait être inférieure à 3 V/m.

Distances de séparation recommandées entre les appareils de radiocommunication portables et mobiles et l'unité dentaire			
La lampe ALYA est prévue pour fonctionner dans un espace électromagnétique dans lequel les troubles irradiés RF sont sous contrôle. Le client ou l'opérateur de l'unité peuvent contribuer à prévenir les interférences électromagnétiques en assurant une distance minimum entre les appareils de communication mobiles et portables à RF (transmetteurs) et l'unité dentaire, comme recommandé ci-dessous, par référence à la puissance de sortie maximum des appareils de radiocommunication.			
Puissance de sortie nominale maximum du transmetteur W	**Distance de séparation à la fréquence du transmetteur m**		
	150 kHz à 80 MHz $d = 1,2\sqrt{P}$	80 MHz à 800 MHz $d = 1,2\sqrt{P}$	800 MHz à 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

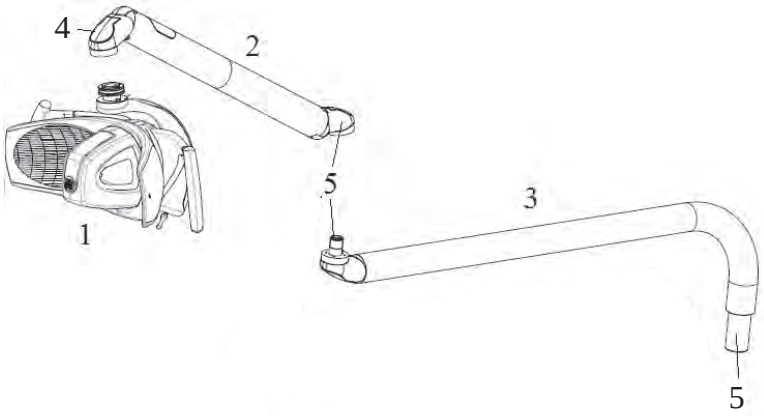
Pour les transmetteurs avec puissance nominale maximum de sortie non reportée ci-dessus, la distance de séparation recommandée d en mètres (m) peut se calculer en utilisant l'équation applicable à la fréquence du transmetteur, où P est la puissance maximum nominale de sortie du transmetteur en Watt (W) selon le fabricant du transmetteur.
Remarque:
A 80 MHz et 800 MHz s'applique l'intervalle de la fréquence la plus haute.
Ces lignes directrices pourraient ne pas s'appliquer à toutes les situations. La propagation électromagnétique est influencée par l'absorption et par la réflexion de structures, objets et personnes.

2. CARACTÉRISTIQUES GÉNÉRALES

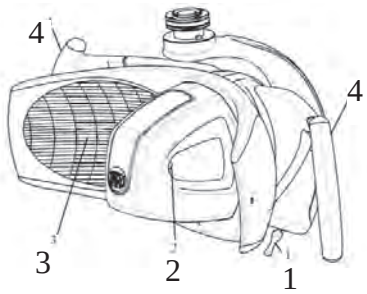
2.1 DESCRIPTION DU PRODUIT

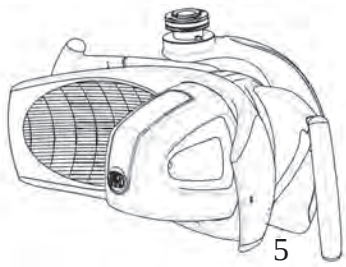
Le dispositif sert à l'utilisateur prévu pour l'éclairage du champ opératoire dans le traitement des pathologies de l'appareil dentaire.
La source lumineuse située sur la tête se compose de deux LED dont la lumière se reflète sur deux paraboles en passant par 2 lentilles secondaires.
Les réflecteurs permettent d'obtenir un spot de lumière régulier et uniforme à chaque niveau d'éclairage et de distribuer uniformément la lumière dans le champ opérationnel, sans créer d'ombres ni d'obscurcissements de la part de l'opérateur.
Le réglage de l'intensité lumineuse peut être effectué avec une manette ou avec proximity. Le Proximity permet d'allumer ou éteindre la lampe sans avoir un contact direct, pour éliminer ainsi la possibilité d'infections croisées sur la commande.
La fonction "mise en marche automatique" ou "Auto-on" permet à la lampe de s'allumer automatiquement chaque fois que l'alimentation à la lampe est activée.
Le câble à distance permet d'amener les commandes de la lampe au carquois de l'unité. Respecter les instructions fournies dans le paragraphe installation.
Un bouton qui permet d'activer la fonction de synchronisation avec la lampe d'ambiance produite par Faro se trouve sur la tête en proximité du manche à balai et/ou du capteur de proximité. La fonction de synchronisation permet à la lampe Alya de contrôler le niveau d'éclairage ambiant afin d'assurer un niveau d'illumination plus uniforme entre le champ opératoire et la zone environnante, afin de réduire l'effet d'éblouissement et d'améliorer le confort Visuel.
Dans la version avec la lumière sur le bras arrière appelée "Alya avec Theia Tech" la source lumineuse est constituée d'une série de LED dont la lumière qui passe à travers un diffuseur est distribuée dans le milieu en dessous.
Le réglage du niveau d'éclairage se fait en parallèle avec celui de la tête, donc quand on réduit ou augmente l'éclairage de la lumière produite par la tête, on règle par conséquent aussi celle sur le bras.
La lampe version "Theia Tech" a par ailleurs une commande locale destinée uniquement à fournir on/off situé sur le bras fixe.
Une fois allumée depuis la commande locale, la lumière se synchronise automatiquement avec le niveau d'intensité de la tête. Si la lumière de la tête est éteinte, la lumière sur le bras arrière s'allume à l'intensité maximum. A la mise en marche successive de la lumière sur la tête, la lumière sur le bras se synchronise automatiquement.
La lumière sur le bras a la fonction d'augmenter la visibilité dans la zone pré-opératoire en allant réduire l'éblouissement qui se génère suite et/ou après la vision du champ opératoire.]
L'Entretien est facilité grâce à l'application de nouvelles technologies qui prennent en compte les différentes exigences dans le domaine de sécurité, ergonomie et hygiène.
Les poignées détachables et stérilisables. Respecter les prescriptions définies dans la section consacrée.
Pour les branchements électriques, respecter les instructions fournies dans le paragraphe installation et les schémas électriques inclus dans ce manuel.

2.2 DESCRIPTION DES PIÈCES

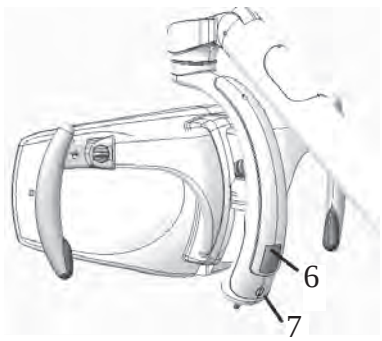


1 – Tête
2 – Bras central
3 – Bras arrière sans transformateur avec ou sans lumière (Theia Tech)
4 – Articulations
5 – Goujon pour branchement à unité ou à application



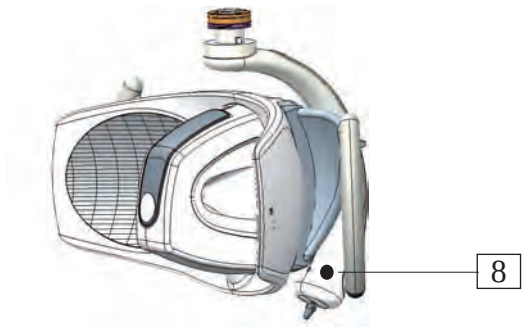


1 – Manette
2 – Lentille secondaire LED
3 – Réflecteur
4 – Poignées stérilisables
5 – Proximity

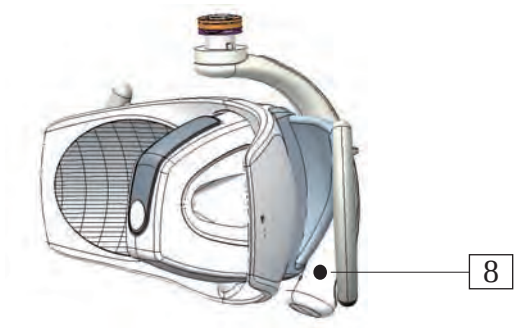


6 – Emplacement de la fiche électronique
7 – Symboles de mise en marche et réglage
8 – Touche de synchronisation

Version avec joystick



Version avec photocellule



2.3 IDENTIFICATION DU DISPOSITIF

Les variantes dans le commerce se distinguent pour:

- Type de dispositif (lampe complète, lampe complète avec Theia Tech ou tête)
- Interface de mise en marche et réglage **(Manette ou Proximity; pour lampe complète et tête)**
- Modalité de contrôle depuis unité (fonction on-off, contrôle à distance; pour lampe complète et tête)
- Type de montage **(unité, plafond, murale, sol; uniquement pour lampe complète)**
- Longueur bras (uniquement pour lampe complète)
- Alimentation (avec ou sans transformateur, uniquement pour lampe complète).

Le développement des codes est le suivant:

ALYA – Lampe complète					
Type	3° chiffres Montage et contrôle contrôle depuis unité	4° chiffres – Voltage et interface	5° chiffres – bras post pour bras central (mm)	6° chiffres Disponible	7° 8° 9° chiffres Customisation
5 1	0 Unité standard	0 Manette 17-24 V AC 22-35 V DC	0 810x550	0	000 (std FARO) JJJ
	1 Plafond	1 Proximity 17-24 V AC 22-35 V DC	1 960x550		
	2 Unité Auto-on		9 810x 855		
	4 Unité Câble Dist				

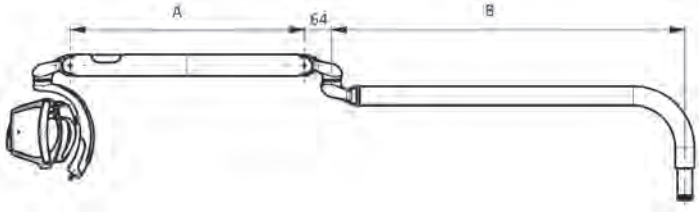
ALYA – Lampe complète avec Theia Tech					
Type	3° chiffres Montage et dimensions bras	4° chiffres type de Têt	5° chiffres type d'interface	6° chiffres Voltage	7° 8° 9° chiffres Customisation
52	1 Unité 550*810	1 Standard	1 Manette	1 24Vac 50/60Hz 24 V dc	000 (std FARO) JJJ
	2 Unité 550*960	2 Avec rallonge	2 Manette auto-on		
	3 Unité 855*810		3 Capteur		
	4 Unité 855*960		4 Capteur auto-on		
	5 Plafond 550*810		5 Manette + câble à distance		
	6 Plafond 550*960		6 Manette auto-on + câble à distance		
	7 Plafond 855*810		7 Capteur + câble à distance		
	8 Plafond 855*960		8 Capteur auto-on + câble à distance		

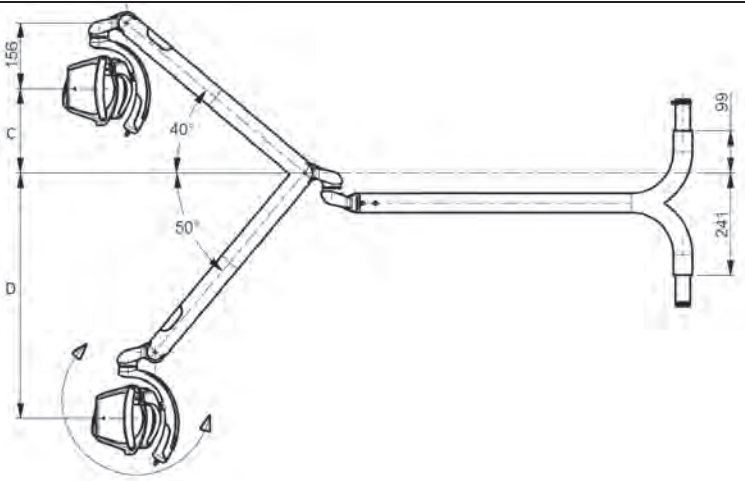
TÊTE ALYA (ALYA HEAD)					
Type	3° chiffres Avec Températures et contrôle unité	4° chiffres – Alimentation et contrôle	5° chiffres Disponible	6° chiffres Couleurs	7° 8° 9° chiffres Custom
3 1	5 Groupe Optique 5000 K	0 Manette 17-24 V AC 22-35 V DC	0	0 Blanc	000 Std FARO
	6 Groupe Optique 5000 K On/Off	1 Proximity 17-24 V AC 22-35 V DC		3 Gris	
	8 G.O. 4000 K				

3. INSTALLATION DU DISPOSITIF

⚠	**Mise en garde pour le danger électrique, pour lampe et tête:**
	Le dispositif doit être installé par des techniciens spécialisés. Au moment de l'installation, l'alimentation doit toujours être désengagée. Se reporter aux schémas électriques présents dans le manuel. Vérifier les données de plaque avant l'installation
ℹ	**Note pour l'installation**
	Le câble d'alimentation de la lampe complète est fourni sans aucun connecteur ou terminal pour permettre d'effectuer le branchement suivant les particularités de l'unité ou de l'application. Le fonctionnement ou la sécurité de la lampe ne dépendent pas de la polarité du courant d'alimentation. L'inversion des câbles d'alimentation ne comporte donc pas de risques de dysfonctionnement.

3.1 ENCOMBREMENTS





	A	B	C	D
mm	550	830	265	510
mm	550	980	265	510
mm	855	830	394	706
mm	855	980	394	706

3.2 LAMPE DENTAIRE COMPLÈTE

3.2.1 Conditions Electriques

Les conditions pour l'installation correcte pour n'importe quelle application (unité, mur, sol ou plafond) sont les suivantes:

Alimentation	Câble d'alimentation	Type d'alimentation et conditions de protection	Classification	Conformité à l'IEC 60601-1
Version lampe complète 17-24 Vac 50/60 Hz	2 x 0,5 mm2 300 V 105°C Isolation PVC diamètre isolation 1,85 mm Utiliser uniquement des terminaux et connecteurs certifiés avec résistance à la flamme V1 ou similaire.	transformateur conforme à l'IEC/EN 60601-1troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié: • T1.6AL 250V Conditions minimums: • Sortie: 17-24 Vac; • Puissance: 26 VA; • Classe B; • Rigidité supérieure à 4000 V. • Protection thermique	Composant intégré	Le système médical résultant doit être déclaré conforme à l'IEC/EN60601-1 par l'installateur ou par le fabricant. Note pour l'installateur: s'assurer que l'unité sur laquelle on va installer la lampe soit certifiée pour accueillir la lampe complète.
Version lampe complète 22-33Vdc		Alimentateur conforme à l'IEC/EN 60601-1 troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié : • T630mAL 250V Conditions minimums: • Sortie : 22-33 Vdc; • Puissance: 14 VA; • Classe B; • Rigidité supérieure à 4000 V; Protection continue contre court-circuit et surtensions		
Version lampe complète avec Theia Tech 24Vac 50/60Hz		transformateur conforme à l'IEC/EN 60601-1troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié: • T2AL 250V Conditions minimums: • Sortie: 24Vac; • Puissance: 40VA • Classe B; • Rigidité supérieure à 4000 V. Protection thermique		

Alimentation	Câble d'alimentation	Type d'alimentation et conditions de protection	Classification	Conformité à l'IEC 60601-1
Version lampe complète avec Theia Tech 24Vdc	2 x 0,5 mm2 300 V 105°C Isolation PVC diamètre isolation 1,85 mm Utiliser uniquement des terminaux et connecteurs certifiés avec résistance à la flamme V1 ou similaire.	transformateur conforme à l'IEC/EN 60601-1troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié: • T2AL 250V Conditions minimums: • Sortie : 24 Vdc; • Puissance 28 VA • Classe B; • Rigidité supérieure à 4000 V. Protection thermique	Composant intégré	Le système médical résultant doit être déclaré conforme à l'IEC/EN60601-1 par l'installateur ou par le fabricant. Note pour l'installateur: s'assurer que l'unité sur laquelle on va installer la lampe soit certifiée pour accueillir la lampe complète.

Tab 1 – conditions pour le branchement électrique et conformité à l'IEC 60601-1.

Vérifier que les composants suivants soient contenus dans l'emballage :
- Lampe dentaire / Tête (dans la version demandée)
- Feuillet pour télécharger les instructions du site www.faro.it/download

3.2.2 Charges de sécurité

La lampada dentale ALYA et ALYA THEIA peut être installée sur différents supports:
ENSEMBLE DENTAIRE, PLAFOND, MUR, SOL.

CHARGES DE SÉCURITÉ BRAS

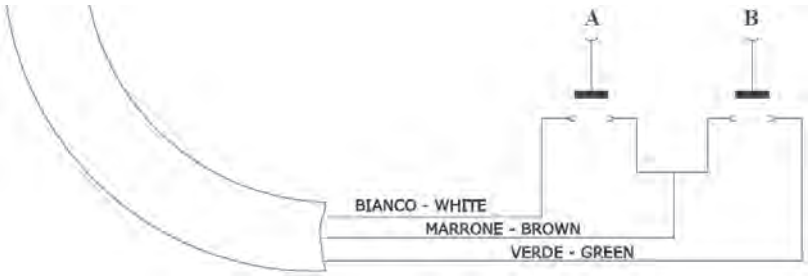
	Charge totale (SAFE WORKING LOAD)	Charge de sécurité (MINIMUM BREAKING LOAD)
Bras long 855 mm	29.2 N	235 N
Bras long 550 mm	25.6 N	205 N

3.2.3 Montage lampe complète version à unité

Avec un niveau numérique, s'assurer que l'élément de connexion soit parfaitement parallèle au sol.
Installer la lampe en introduisant le goujon terminal lampe dans l'emplacement de l'unité.
Brancher le câble d'alimentation suivant les détails reportés dans le tab 1.
Vérifier que la lampe maintienne l'équilibre dans toutes les positions. Si nécessaire, agir sur le système de réglage du ressort pour équilibrer la lampe.
Vérifier mise en marche et réglage et (si présents) commande Auto-on et câble à distance.

3.2.4 Connexion câble à distance

Brancher le câble à deux boutons (A et B) avec contact normalement ouvert (non fournis) suivant le schéma suivant :



3.2.5 Installation fixations

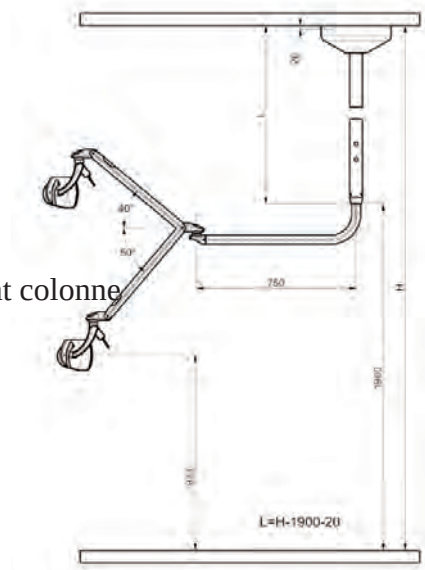
- Les fixations ne sont pas fournies avec la lampe.
- Les fixations doivent être installées par des techniciens spécialisés.

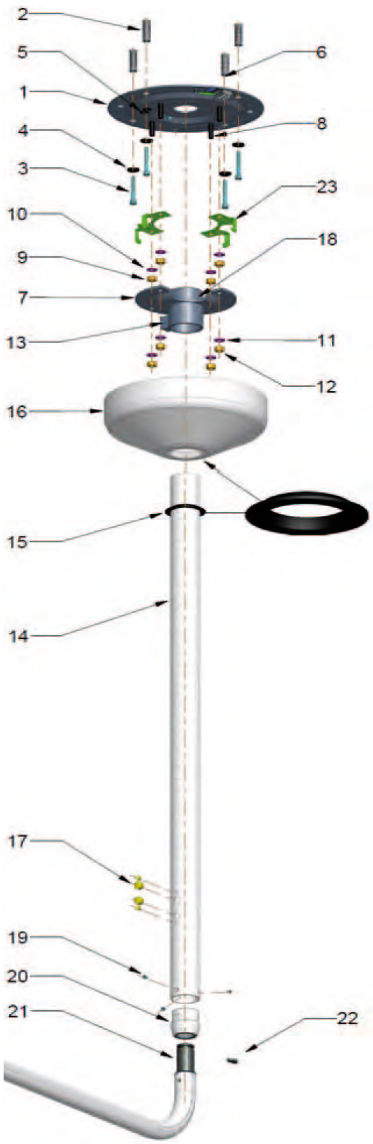
La lampe doit être installée uniquement avec les fixations FARO.

La lampe est pourvue d'un fin de course de rotation entre bras fixe et bras mobile. LE FIN DE COURSE NE DOIT JAMAIS ÊTRE DÉPASSÉ NI FORCÉ.

MONTAGE APPLICATION SUR PLAFOND

1. Bride de plafond
2. Cheville à expansion
3. Vis
4. Rondelle
5. Passe-fil
6. Bornier
7. Bride
8. Vis
9. Écrou
10. Rondelle
11. Rondelle
12. Écrou
13. Vis
14. Colonne
15. Bague
16. Rosace
17. Bouchon
18. Vis
19. Vis
20. Manchon de raccordement colonne
21. Axe lampe
22. Clavette
23. Guide de fixation



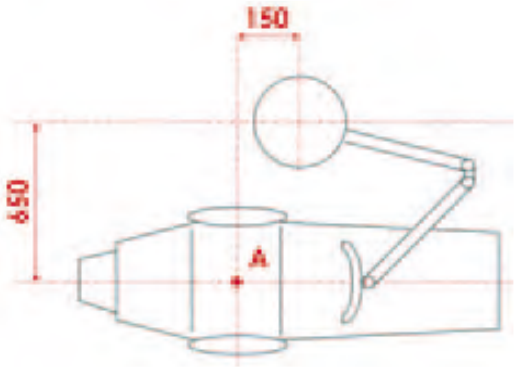


APPLICATION EN PLAFOND

NB1. Le dispositif doit être installé par des techniciens spécialisés.
NB2. L'alimentation à l'intérieur du local d'installation doit être toujours coupée.
NB3. Avant d'effectuer les opérations de montage, s'assurer que le plafond supporte l'application. Les matériaux du plafond autorisés sont le béton et la pierre naturelle. Les chevilles à utiliser sont les modèles fournis ou équivalents.
NB4. Charge max. applicable: 70 kg
NB5. Installer le dispositif dans des locaux pourvus d'une installation électrique conforme aux normes en vigueur en matière de locaux à usage médical.
NB6. La lampe sans transformateur doit être alimentée en courant à basse tension (12-24Vac ou 17-33Vdc) avec transformateur ou ballast de sécurité (conforme à la norme CEI/EN 60601-1) avec protection thermique ou protégé par au moins un fusible approprié (T500mAL250V~). Le système médical associé doit être déclaré conforme à la norme CEI/EN 60601-1 par

SÉQUENCE D'INSTALLATION

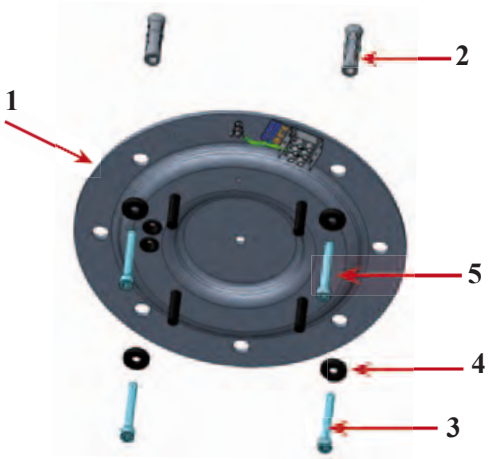
A. Après avoir pris pour point de repère le centre du fauteuil (A), procéder à l'installation à une distance de 650 mm et 150 mm dans les directions indiquées en figure.



B. Démonter la bride (7) en retirant les écrous (12) et les rondelles (11).

C. En se servant de la bride comme guide (1), pratiquer dans le plafond 4 perçages avec une mèche Ø14. Insérer les chevilles (2) dans ces trous.

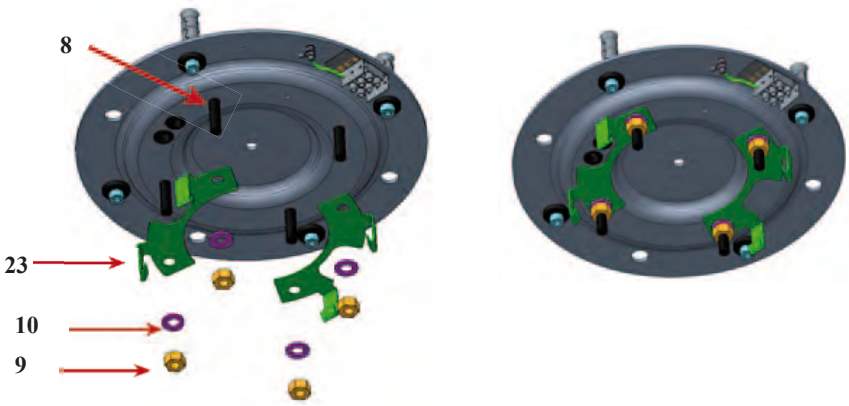
D. Prendre la bride (1). Faire passer le fil d'alimentation dans le passe-fil (5), puis appuyer sur le plafond la bride (1) en veillant à ne pas écraser le fil entre la bride (1) et le plafond. Faire passer les vis (3) assemblées aux rondelles (4) dans les 4 perçages utilisés pour percer le plafond. Serrer, avec la clé hexagonale (accessoires) les vis (3).



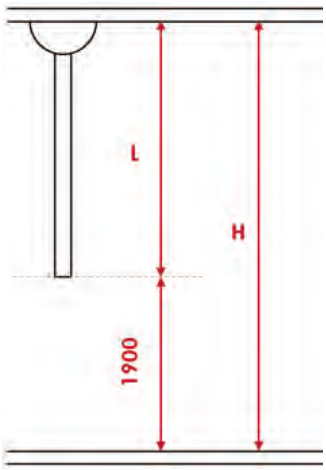
E. Brancher le fil de l'alimentation au bornier (6) (voir schémas électriques)

APPLICATION EN PLAFOND

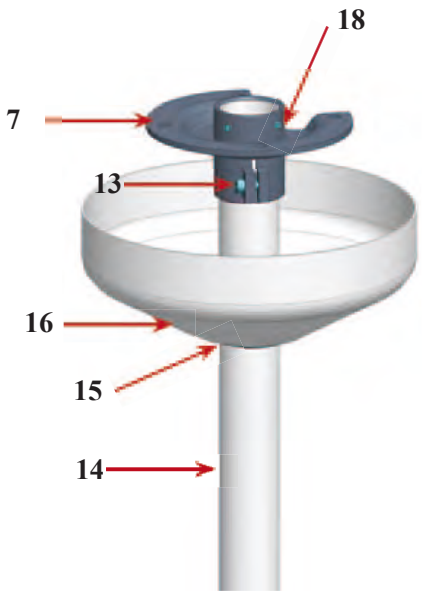
F. Enfiler les 2 guides de fixation (23) sur les vis (8) et les fixer avec des écrous (9) et rondelles (10)



G. Calculer la longueur correcte de la colonne (14), selon la formule L=H-1900mm. Veiller à couper la partie e colonne (14) en trop du côté ne présentant PAS les perçages latéraux .



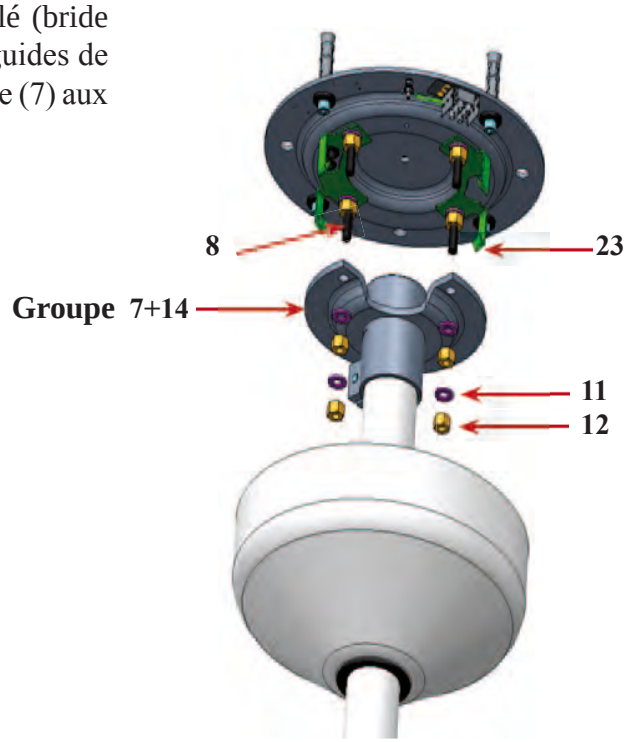
H. Enfiler la colonne (14) dans la bride (7) et marquer sur la colonne (14) la position des trous qui se trouvent surla bride (7). Faire attention à l'orientation de la colonne par rapport à l'ensemble dentaire. Extraire la colonne et pratiquer deux trous passants Ø8 au niveau des repères marqués.



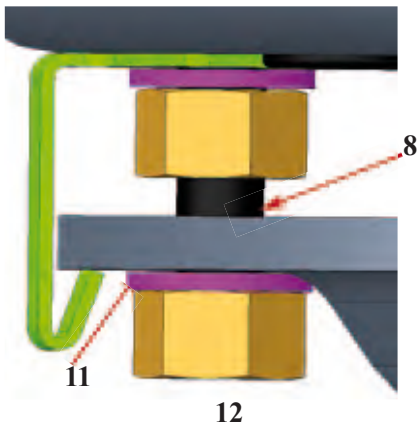
I. Enfiler sur la colonne (14) la bague (15) sur environ 300 mm (il ne s'agit pas de la bonne position, mais seulement d'une position provisoire pour le montage).
J. Insérer la rosace (16) sur la colonne (14).
K. Introduire la colonne (14) dans l'orifice de la bride de fixation de la colonne (7).
L. Serrer à fond la vis (13) et les deux vis (18) avec des clés hexagonales (accessoires). Serrer fortement la vis (13) et s'assurer que les vis (18) traversent les trous de la colonne (14).

APPLICATION EN PLAFOND

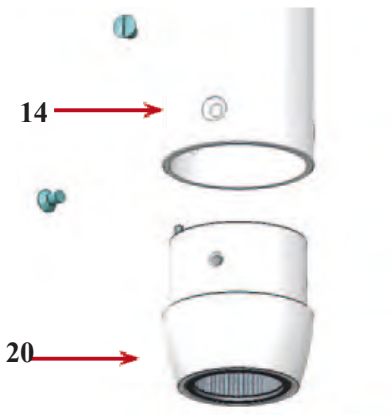
M. Accrocher le groupe tout juste assemblé (bride de fixation colonne (7) + colonne (14) aux guides de fixation (23), en centrant les 4 trous de la bride (7) aux vis (8) de la bride de plafond (1).



N. Visser (non complètement) les écrous (12) et les rondelles restantes (11) sur les vis (8) de la bride du plafond (1).



O. Dévisser les trous vis (19) de la colonne (14) et extraire la douille (20).
P. Enfiler la douille (20) sur l'axe (21) de la lampe.
Q. Insérer dans la rainure de l'axe (21) la clavette (22).



APPLICATION EN PLAFOND

R. Enfiler dans la colonne (14) par le haut un câble de traction.

S. Brancher le fil de la lampe au câble de traction.

T. Insérer la lampe dans la colonne (14) et la fixer avec les trois vis (19) en veillant à orienter les trous de la douille (20) vers les logements des vis sur la colonne (14) et les visser. En même temps, tirer le câble de traction jusqu'à faire sortir le fil de la lampe par la bride de fixation de la colonne (7) d'environ 200 mm.

U. Brancher le fil de la lampe aux borniers (6) (voir schémas électriques).

V. Vérifier que la colonne est perpendiculaire en agissant sur les écrou (9).

W. Serrer les écrous (12) et les rondelles (11) pour fixer la bride (7) en la désolidarisant des guides de fixation (23).

X. Faire adhérer la rosace (16) au plafond en lui appliquant la bague (15).

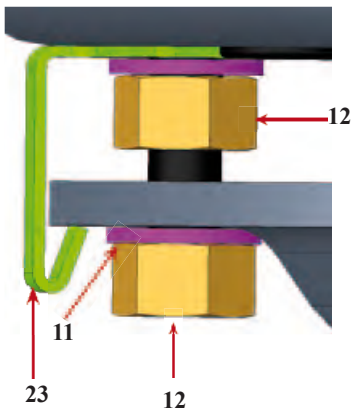
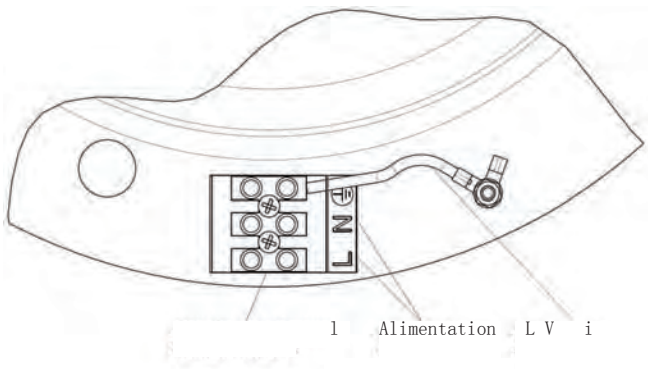


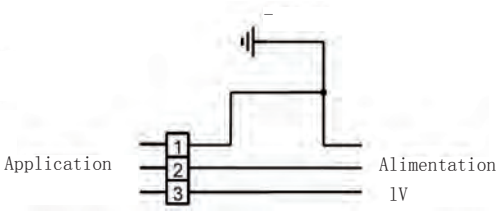
SCHÉMA ÉLECTRIQUE

Application au plafond SANS transformateur



l Alimentation L V i

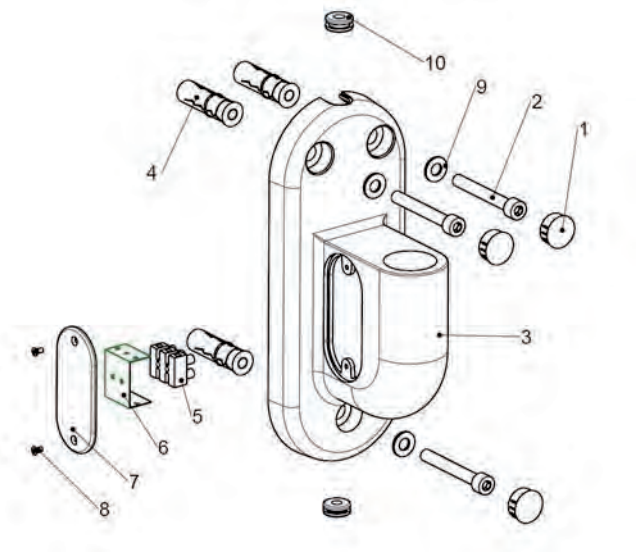
12-24 Vac
17-33 Vdc

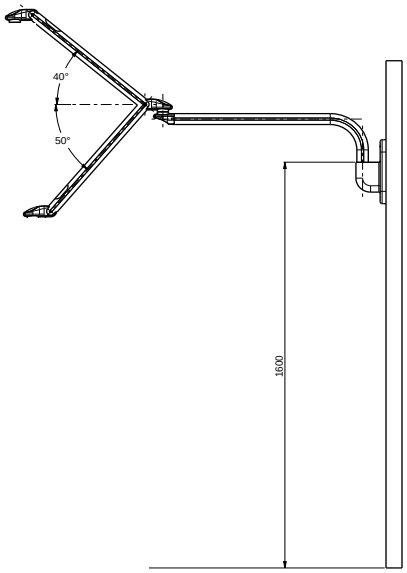


APPLICATION MURALE

MONTAGE DE LA LAMPE APPLICATION MURALE

1. Bouchon
2. Vis
3. Application murale
4. Chevilles
5. Bornier
6. Cache bornier
7. Cache
8. Vis
9. Rondelle
10. Passe-fil





NB1. Le dispositif doit être installé par des techniciens spécialisés
NB2. L'alimentation à l'intérieur du local d'installation doit être toujours coupée
NB3. Avant d'effectuer les opérations de montage, s'assurer que le mur supporte l'application. Les matériaux du mur autorisés sont le béton et la pierre naturelle. Les chevilles à utiliser sont les modèles fournis ou équivalents.
NB4. Charge max. applicable: 70 kg
NB5. Installer le dispositif dans des locaux pourvus d'une installation électrique conforme aux normes en vigueur en matière de locaux à usage médical.
NB6. La lampe sans transformateur doit être alimentée en courant à basse tension (12-24Vac ou 17-33Vdc) avec transformateur ou ballast de sécurité (conforme à la norme CEI/EN 60601-1) avec protection thermique ou protégé par au moins un fusible approprié (T500mAL250V~). Le système médical associé doit être déclaré conforme à la norme CEI/EN 60601-1 par l'installateur.

APPLICATION MURALE

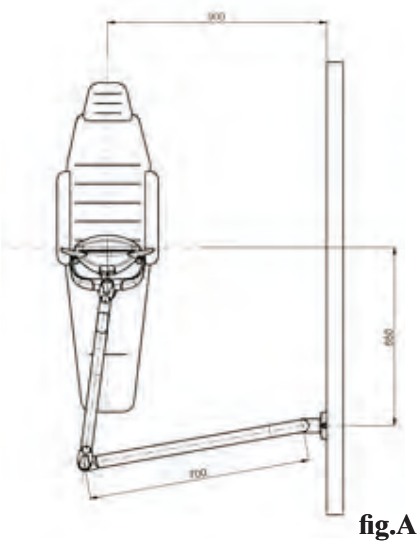


fig.A

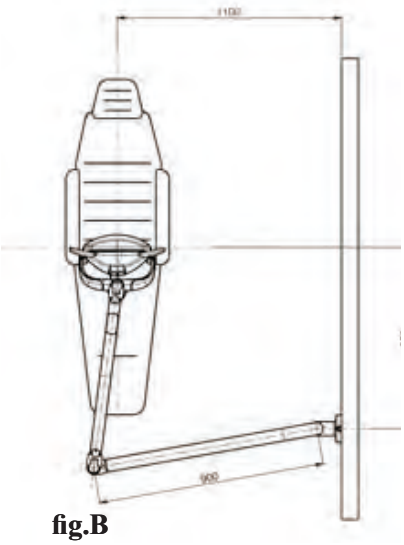
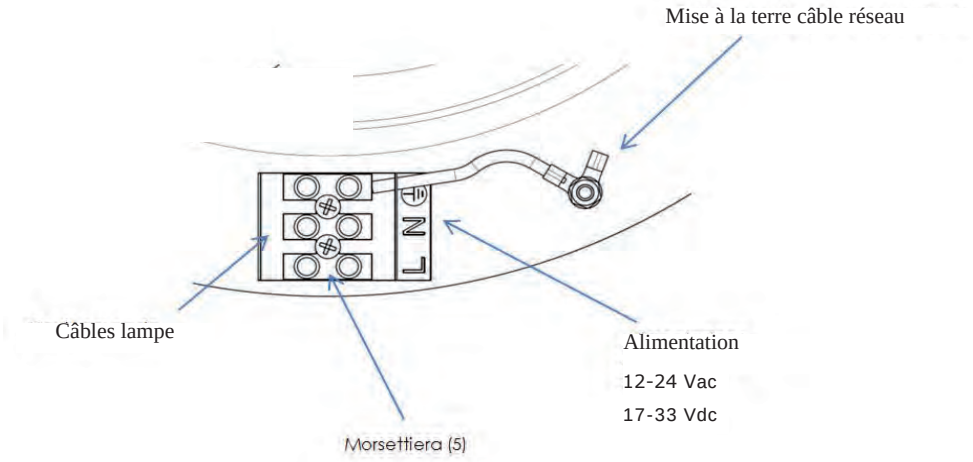


fig.B

- L'alimentation à l'intérieur du local d'installation doit toujours être coupée.
- Après avoir défini le point de fixation par rapport au centre du fauteuil (Voir fig.A-B), pratiquer sur le mur trois trous diam. 14 au niveau des orifices de la fixation murale (3), en veillant à ce que le trou soit perpendiculaire.
- Insérer les trois chevilles (12) dans les trous diam. 14 précédemment réalisés et bloquer avec la clé hexagonale (accessoires) les vis 2 en veillant à ne pas écraser le fil entre la fixation murale (3) et le mur.
- Appliquer les trois bouchons (1) sur les trous de la fixation murale (3).
- Dévisser la vis (8), ôter le cache (7), insérer le bras de la lampe dans l'application murale en graissant le pivot. Brancher les fils de la lampe au bornier (5) (voir schéma de câblage ci-dessous) y compris le fil de terre. Brancher les fils sortant du mur au bornier, s'il a été précédemment bâti. A défaut, le branchement doit être effectué avec un câble volant externe, à insérer dans le passe-fil (10).
- Remonter le cache (7) avec les vis (8).

SCHÉMA ÉLECTRIQUE

Application murale



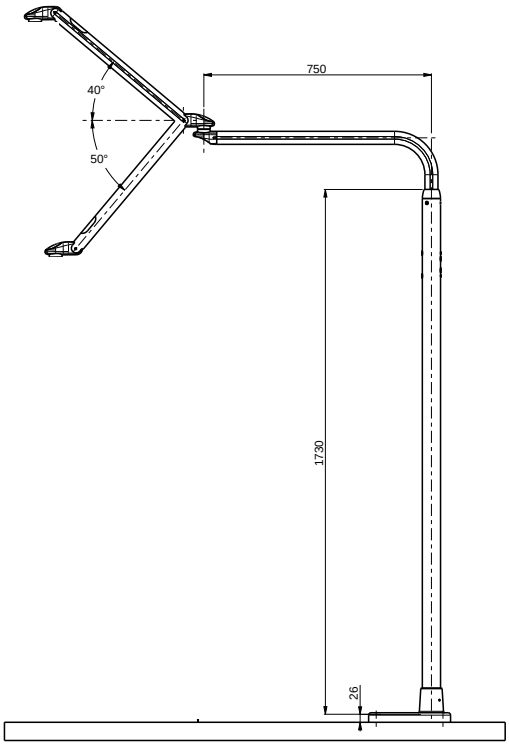
APPLICATION AU SOL

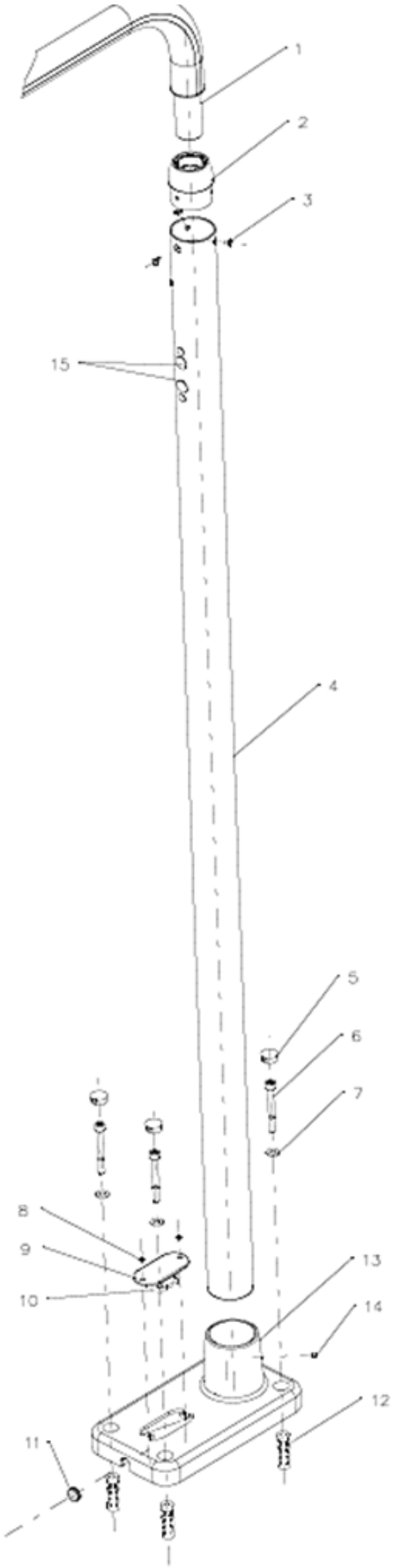
MONTAGE DE LA LAMPE APPLICATION AU SOL

1. Pivot
2. Douille
3. Vis
4. Colonne

5 bouchons

6. Vis
7. Rondelle
8. Vis
9. Cache
10. Bornier
11. Passe-fil
12. Chevilles
13. Support de sol
14. Goujons
15. Bouchon





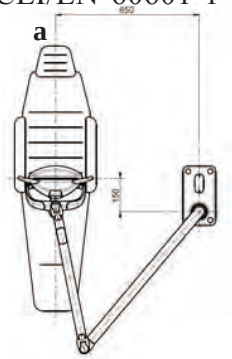
APPLICATION AU SOL

Le dispositif doit être installé par des techniciens spécialisés

NB2. L'alimentation à l'intérieur du local d'installation doit toujours être coupée
NB3. Avant d'effectuer les opérations de montage, s'assurer que le sol supporte l'application.
Les matériaux du sol autorisés sont le béton et la pierre naturelle. Les chevilles à utiliser sont les modèles fournis ou équivalents.
NB4. Charge max. applicable: 70 kg
NB5. Installer le dispositif dans des locaux pourvus d'une installation électrique conforme aux normes en vigueur en matière de locaux à usage médical.
NB6. La lampe sans transformateur doit être alimentée en courant à basse tension (12-24Vac ou 17-33Vdc) avec transformateur ou ballast de sécurité (conforme à la norme CEI/EN 60601-1) avec protection thermique ou protégé par au moins un fusible approprié (T500mAL250V~).
Le système médical associé doit être déclaré conforme à la norme CEI/EN 60601-1 par l'installateur.

A. Après avoir pris pour point de repère le centre du fauteuil **"a"**, procéder à l'installation à une distance de 650mm et 150mm dans les directions indiquées en figure **"C "**

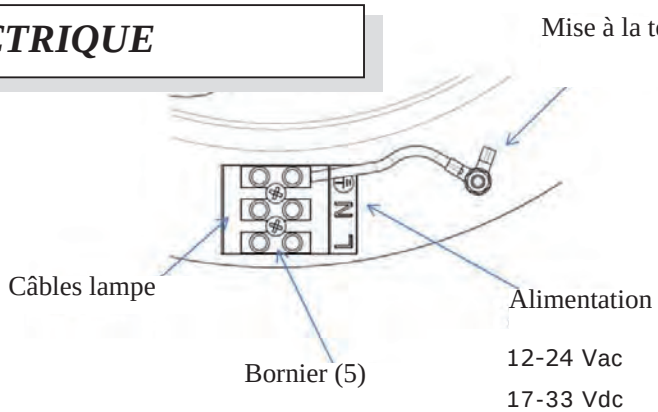
fig. C



- L'alimentation à l'intérieur du local d'installation doit toujours être coupée.
- Après avoir défini le point de fixation par rapport (**a**) au centre du fauteuil (Voir fig.**C**), pratiquer dans le sol quatre trous diam. 14 au niveau des orifices du support de sol (13).
- Préparer le support de sol (13) en faisant passer la rondelle (7) et la vis (6), visser les chevilles (12) sur les vis (6) de quelques tours, faire passer le fil d'alimentation dans le passe-fil (11).
- Insérer les quatre chevilles (12) dans les trous diam. 14 précédemment réalisés et bloquer avec la clé hexagonale (accessoires) les vis 6 en veillant à ne pas écraser le fil entre le support de sol (13) et le sol.
- Appliquer les quatre bouchons (5) sur les trous du support de sol (13).
- Dévisser les vis (8) et sortir la plaquette de couverture (9). brancher le fil d'alimentation dans le bornier (10).
- Fixer la colonne (4) au support de sol (13), lors de la fixation s'assurer que la colonne est perpendiculaire.
- Bloquer les deux goujons (14) avec les clés hexagonales (accessoires)
- Fixer avec les trois vis (3) la douille (2) à la colonne (4), en veillant à orienter les trous de la douille (2) vers les logements des vis sur la colonne (4).
- Brancher le fil de la lampe au bornier (10).
- Fixer la plaquette de couverture (9) au support de sol (13) avec les deux vis (8).

SCHÉMA ÉLECTRIQUE

Application au sol



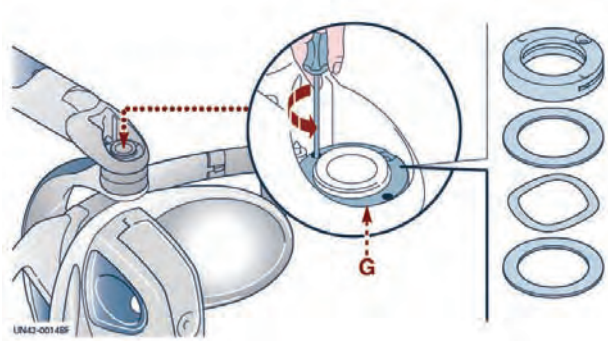
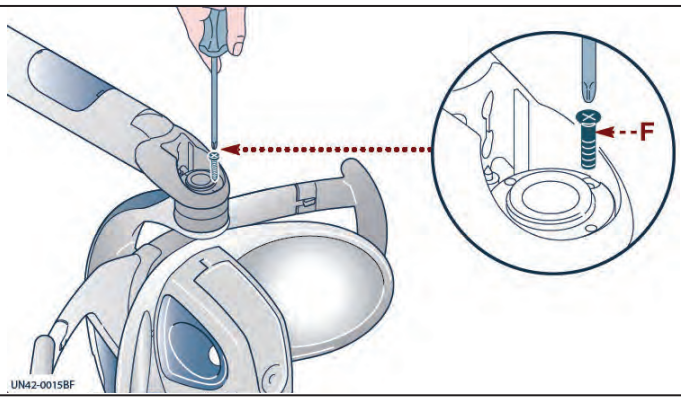
3.3 TÊTE

3.3.1 Conditions mécaniques

Pour le branchement mécanique, il faut avoir un espace adapté à l'emplacement du goujon de la tête et des composants de fixation G.
Le système de soutien doit être conçu pour soutenir les charges suivantes, multipliées par les facteurs de sécurité prévus par l'IEC 60601-1 ou l'IEC 80601-2-60

Tête Alya	Blindage Alya
1,80 kg	0,35 kg
2,15 kg	

Pour le branchement mécanique, suivre la procédure suivante:

1 - Soutenir la tête et introduire les rondelles dans le goujon fileté en respectant la séquence dans la figure. 2 - Introduire ensuite le collier de serrage G en respectant la séquence indiquée dans la figure et la visser avec un outil adapté. Le collier de serrage doit être vissé de façon à donner la force de rotation correcte de la tête.	
3 – Visser les 2 vis F de sécurité.	

⚠	**Attention** Le bras central sans le chargement de la tête tend à monter brusquement avec le risque de choc avec des parties du corps. Durant toute l'installation, tenir le bras central en position et ne pas le lâcher jusqu'à installation terminée de la tête.
⚠	**Mise en garde pour le danger de chute de masses suspendues** Attention - Risque de chute de la tête après installation: - utiliser uniquement les vis fournies par FARO. - visser les vis de sécurité à bloc.

Une fois le branchement mécanique terminé, effectuer le câblage électrique.

3.3.2 Conditions Electriques

Les conditions pour l'installation correcte **de la tête** sont les suivantes:

<table>
<tr><th>Alimentation</th><th>Câble d'alimentation</th><th>Type d'alimentation et conditions de protection</th><th>Classification</th><th>Conformité à l'IEC 60601-1</th></tr>
<tr><td>17-24 Vac
50/60 Hz</td><td rowspan="2">Câble d'alimentation:
2 câbles unipolaires rouges:
UL Style 1061
300 V
T 80°C
1x26 AWG
VW 1
Ø max 1,02mm

Connecteur std:
molex 51021-0300 à 3 pôles</td><td>Transformateur conforme à l'IEC/EN 60601-1troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié:
• T1.6AL 250V
Conditions minimums:
• Sortie: 17 - 24 Vac;
• Puissance: 26 VA;
• Classe B;
• Rigidité supérieure à 4000 V.
• Protection thermique</td><td rowspan="2">Composant intégré</td><td rowspan="2">Le système médical résultant doit être déclaré conforme à l'IEC/EN60601-1 par l'installateur ou par le fabricant.
Note pour l'installateur: s'assurer que l'unité sur laquelle on va installer la lampe soit certifiée pour accueillir la lampe complète.</td></tr>
<tr><td>22-33Vdc</td><td>Alimentateur conforme à l'IEC/EN 60601-1 troisième édition et à l'IEC/EN 60601-1-2 avec protection thermique ou protégé en aval par au moins un fusible approprié:
• T630mAL 250V
Conditions minimums:
• Sortie: 22-33 Vdc
• Puissance: 14 VA;
• Classe B;
• Rigidité supérieure à 4000 V;
• Protection continue contre court-circuit et surtensions</td></tr>
</table>

4. MODE D'EMPLOI

Lire attentivement le paragraphe 1 pour un usage sûr du dispositif.
Le dispositif doit être nettoyé avant l'utilisation (voir paragraphe "Nettoyage du dispositif").

	**Attention**
	L'utilisation simultanée de la lampe avec un bistouri électrique peut provoquer des dysfonctionnements de ce dernier.

	**Attention**
	La manette de contrôle doit être maniée avec délicatesse afin d'éviter des ruptures. Ne jamais déplacer la lampe en utilisant la Manette avec point d'appui.

	**Note**
	Chaque fois que l'on allume la lampe, l'intensité lumineuse est celle mémorisée à l'arrêt précédent.

	**Mise en garde - danger de contact avec pièces sous tension**
	Ne pas utiliser le dispositif si des parties ou enveloppes sont endommagées.

4.1 MISE EN MARCHE ET ARRÊT

Se reporter au §1.1 pour les symboles de mise en marche et réglage.

Lampe Complète

Pour la mise en marche et l'arrêt, presser et libérer le levier manette en agissant sur le côté gauche ou droit. L'intensité lumineuse à la mise en marche est toujours la dernière utilisée avant l'arrêt.

Lampe complète avec Theia Tech

Mêmes opérations que la lampe complète en plus celle sur le bras fixe s'allume et/ou s'éteint simultanément à celle de la tête.
La lumière sur le bras fixe peut être allumée/éteinte aussi avec le bouton qui se trouve sur le bras. En cas de mise en marche avec lampe allumée, la lumière se synchronise automatiquement, si la lumière sur la tête est éteinte, elle se règle à l'intensité maximum.

4.1.1 Réglage:

a) pour réduire l'intensité lumineuse, maintenir le levier de la manette enfoncé en agissant sur le côté gauche (vue arrière lampe) jusqu'à atteindre l'intensité désirée.
Une fois l'intensité minimum atteinte, on peut entendre une signalisation sonore (1 bip).
b) pour augmenter l'intensité lumineuse, maintenir le levier de la manette enfoncé en agissant sur le côté droit (vue arrière lampe) jusqu'à atteindre l'intensité désirée.
Une fois l'intensité maximum atteinte, on peut entendre une signalisation sonore (1 bip).
c) pour passer à l'intensité minimum, presser et libérer le levier de la manette en agissant sur le côté avant ou arrière. Quand on appuie à nouveau sur le côté avant ou arrière, l'intensité lumineuse repasse à celle mémorisée précédemment.
La lumière sur le bras fixe se règle en phase avec celle de la tête, elle ne peut pas être réglée de façon indépendante.

4.1.2 Lampe / Tête AVEC PROXIMITY

Mise en marche / Arrêt

Lampe Complète: Pour la mise en marche ou l'arrêt, s'approcher une fois du capteur jusqu'à une distance maximum de 3 cm.

Lampe complète avec Theia Tech: Mêmes opérations que la lampe complète en plus la lumière sur le bras fixe s'allume et/ou s'éteint simultanément à celle de la tête.

Réglage

Lampe Complète: Pour le réglage de l'intensité lumineuse, il faut rester immobiles à proximité du capteur jusqu'à obtenir l'intensité désirée. Le réglage permet de passer de la valeur maximum à la minimum et de la valeur minimum à nouveau à la maximum. Une fois l'intensité maximum atteinte, on peut entendre une signalisation sonore (2 bip). Une fois l'intensité minimum atteinte, on peut entendre une signalisation sonore (1 bip).

	Note
	Chaque fois que l'on allume la lampe, l'intensité lumineuse est celle mémorisée à l'arrêt précédent.

Lampe complète avec Theia Tech mêmes opérations que la lampe complète en plus la lumière sur le bras fixe se règle simultanément à celle de la tête.

4.1.3 Lampe / Lampe complète avec Theia Tech / Tête "ALYA" AVEC COMMANDE À DISTANCE

Mise en marche / Arrêt / Réglage
- Pour la mise en marche et l'arrêt, presser et libérer le bouton "A".
- Réglage:

a) pour réduire l'intensité lumineuse, maintenir le bouton "A" enfoncé jusqu'à atteindre l'intensité désirée.
Une fois l'intensité minimum atteinte, on peut entendre une signalisation sonore (1 bip).
a) pour augmenter l'intensité lumineuse, maintenir le bouton "A" enfoncé jusqu'à atteindre l'intensité désirée.
Une fois l'intensité maximum atteinte, on peut entendre une signalisation sonore (2 bip).
c) pour atteindre immédiatement l'intensité lumineuse minimum, appuyer sur le bouton "B".
Une fois l'intensité minimum atteinte, on peut entendre une signalisation sonore (1 bip).
Une pression successive du bouton ramène la lampe à l'intensité lumineuse précédemment sélectionnée.

	Note
	Chaque fois que l'on allume la lampe, l'intensité lumineuse est celle mémorisée à l'arrêt précédent.

4.1.4 LAMPE / LAMPE COMPLÈTE AVEC THEIA TECH / TESTÉE «ALYA» AVEC COMMANDE DE SYNCHRONISATION

Il est possible, où prévu, de brancher la lampe Alya à la lampe d'ambiante Faro, en mode sans fil, afin de créer un système d'éclairage synchronisé entre elles, dénommé «Synchro».
La modalité «Synchro» a été spécialement étudiée pour améliorer le confort du médecin-dentiste/odontologiste, afin de réduire l'effet d'aveuglement générée lorsque l'on passe de l'observation d'une surface fortement illuminée (ex : cavité orale avec la lampe dentale) à une superficie peu illuminée (ex : arc dental).
Avec la modalité dénommée «Synchro» activable au moyen de la touche de la lampe Alya, il est possible de modifier en mode automatique la valeur d'éclairage produite par la lampe ambiante Faro sur la base de la valeur d'éclairage produite par Alya.
Remarque : Entre la lampe dentale et la lampe d'ambiance un petit retard pourrait se produire dans la synchronisation, ceci est dû au protocole de communication, cet effet est normale et ne représente pas un défaut.
La fonction «Synchro» a besoin d'une procédure de couplage dénommée «Pairing» pour être activée (il suffit de l'effectuer une seule fois) pour créer le lien entre deux lampes. Par la suite, la fonction «Synchro» pourra être activée et/ou désactivée au bon vouloir de l'utilisateur au moyen de la touche placée sur la lampe dentale.

PROCÉDURE D'APPARIEMENT («PAIRING»)

Remarque :

- Cependant, la procédure de couplage «Pairing» n'est nécessaire que lors de la première connexion mais peut être répétée dans le cas de remplacement de la lampe Alya ou de l'électronique de l'une des deux lampes reliées entre elles.

- S'il devait y avoir plusieurs lampes ambiantes dans le studio, s'assurer que les autres lampes sont allumées ou éteintes pendant plus de 60 secondes.

Pour effectuer l'**appariement** procéder comme suit:

1. Mettre sous tension la lampe d'ambiance Faro que l'on souhaite associer.
   La lampe ambiante se prédispose à la connexion de couplage pendant un temps maximum de 60 secondes.

2. Dans les 60 secs, appuyez sur le bouton « **synchro** » de la lampe dentale pendant au moins 3 secs. mais pas plus de 6 secs. sinon la procédure est annulée. Lors de la réception de la demande de «**couplage**» de la part de la lampe dentale, la DEL bleue, présente sur le cadre d'aluminium s'active sur la lampe ambiante. Si la DEL bleue ne s'active pas il sera possible (dans les 60 secondes) d'effectuer d'autres tentatives, au-delà de ce délai, il faudra répéter la procédure de l'étape 1.

3. De la mise sous tension de la DEL bleue sur la lampe ambiante, il y a 60 secondes pour confirmer le «**Couplage**» en appuyant sur le bouton sur le site de programmation sur la radiocommande de la lampe ambiante. À ce stade, la DEL bleue (lumière ambiante) effectue un clignotement double puis s'éteint. Si, dans un laps de 60 secs. la touche n'est pas appuyée sur la radiocommande, la del bleue s'éteint et la procédure doit être répétée.

Une fois que le «**couplage**» est effectué, la synchronisation entre les deux lampes est maintenant activée.

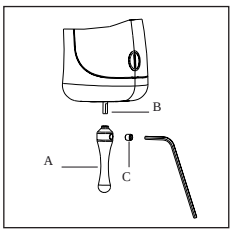
Pour **ACTIVER LA FONCTION DE SYNCHRONISATION** il faut procéder comme suit : appuyer pendant 2 secondes sur le bouton Synchro et relâcher.
Une fois que le poussoir a été libéré, un signal sonore (bip) et la lumière de la del bleue située sur la lampe ambiante s'allume pour indiquer que la synchronisation a été activée.

Pour **DÉSACTIVER LA FONCTION DE SYNCHRONISATION** il faut procéder comme suit : appuyer pendant 2 secondes sur le bouton Synchro et relâcher.
Une fois que le poussoir a été libéré, un signal sonore (bip) et la lumière de la del bleue située sur la lampe ambiante s'éteint pour indiquer que la synchronisation a été activée.

Remarques liées à la synchronisation :

- Lorsque la lampe ambiante Faro est synchrone (c'est-à-dire qu'elle se règle automatiquement) avec lampe Alya, la del bleue située sur le châssis est stable, lorsque le voyant est éteint, la synchronisation est hors tension.
- La radiocommande est toujours activée, il est donc possible de changer la valeur de l'éclairage, mais cependant, si la lampe ambiante doit se trouver dans l'état de synchronisation (avec la del bleue allumée) dès qu'un nouveau réglage s'effectue sur la lampe Alya la valeur de l'éclairage sera immédiatement mise à jour.
- Si la lampe Alya devait s'éteindre, la lampe d'ambiance reste allumée à la valeur d'éclairage en cours d'utilisation.
- Si vous deviez allumer la lampe Alya, la lumière ambiante se met en marche automatiquement.

4.2 MONTAGE LEVIER MANETTE ALYA



- Introduire dans la butée le levier “A” sur le goujon de la manette.
- Le trou du levier “A” doit être positionné au niveau du plan “B”.
- Visser complètement l’écrou “C” avec la vis à six pans creux fournie
.

	Attention
	La manette de contrôle doit être maniée avec délicatesse afin d’éviter des ruptures. Ne jamais déplacer la lampe en utilisant la Manette avec point d’appui

5. ENTRETIEN ORDINAIRE

Il n’existe pas d’opérations d’entretien ordinaire.

6. NETTOYAGE

	Mise en garde contre le danger de dégradation, corrosion et chute de masses suspendues
	Pour toutes les pièces de la lampe en métal ou plastique, il est formellement interdit d’employer des substances abrasives, acides, contenant du chlore ou des ions de chlore, détergents à base de trichloréthylène, essence, térébenthine ou similaires. Il est défendu de vaporiser directement une substance chimique quelconque sur le dispositif.

6.1 NETTOYAGE DES RÉFLECTEURS

Le nettoyage doit être effectué en utilisant un chiffon doux en coton ou coton hydrophile avec alcool éthylique ou le détergent PERFLEX. Ce sont des désinfectants hydro-alcooliques adaptés avec 70% d’alcool isopropylique ou éthylique.

	Attention - endommagement ou dégradation potentiels des réflecteurs
	Ne jamais vaporiser le détergent directement sur les réflecteurs. Les opérations de nettoyage des réflecteurs devraient être effectuées en portant des gants, pour éviter de laisser des empreintes sur les surfaces. Ne pas utiliser de détergents contenant des tensioactifs ou hydrofuges qui peuvent laisser des auréoles en se déposant. De légères auréoles ne compromettent pas la qualité de la lumière. Des produits différents de ceux suggérés pourraient endommager les réflecteurs. En cas de doute, contacter le service clients FARO.

6.2 NETTOYAGE DE LA TÊTE

Le nettoyage doit être effectué en utilisant un chiffon doux en coton ou coton hydrophile avec alcool éthylique ou le détergent PERFLEX. Ce sont des désinfectants hydro-alcooliques adaptés avec 70% d'alcool isopropylique ou éthylique.

Mise en garde contre le danger de dégradation, corrosion et chute de masses suspendues

Ne jamais vaporiser le détergent directement sur la tête. Pour le nettoyage des pièces en plastique, ne pas utiliser de détergents-désinfectants contenant:
- HYDROXYDE D'AMMONIUM
- HYDROXYDE DE SODIUM
- CHLORURE DE MÉTHYLÈNE
- ALCOOL MÉTHYLIQUE.
- ACIDES EN TOUT GENRE

Faro a testé et suggère les désinfectants suivants: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

6.3 NETTOYAGE DES BRAS

Toujours utiliser un chiffon humidifié avec un désinfectant approuvé pour la désinfection des surfaces et le passer.

Mise en garde contre le danger de corrosion et rupture mécanique avec chute de masses suspendues

Ne jamais vaporiser de substances chimiques directement sur les bras et sur les articulations et leurs ouvertures.

Mise en garde contre le danger de dégradation des plastiques avec chute de masses suspendues

Pour le nettoyage des pièces en plastique, ne pas utiliser de détergents désinfectants contenant:
- HYDROXYDE D'AMMONIUM
- HYDROXYDE DE SODIUM
- CHLORURE DE MÉTHYLÈNE
- ALCOOL MÉTHYLIQUE.
- ACIDES EN TOUT GENRE

Faro a testé et suggère les désinfectants suivants : Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366

7. STÉRILISATION DE LA POIGNÉE

Mise en garde - danger de contamination croisée

Les poignées ne sont pas fournies stériles, elles doivent donc être stérilisées avant l'utilisation. Les poignées doivent être stérilisées avant chaque patient.

7.1 Extraction de la poignée

Pour retirer la poignée, dévisser la poignée "A" et la dégager du support.

7.2 Décontamination et désinfection

Avant la stérilisation, les poignées doivent être décontaminées et désinfectées.
Pour la désinfection, Faro a testé les produits suivants pour la désinfection: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

Attention - danger de rupture plastiques

Les poignées ne peuvent pas être désinfectées par thermo-désinfection.

7.3 Stérilisation

Les poignées doivent être emballées dans des emballages conformes à l'EN 868-5.
Les poignées peuvent être stérilisées avec cycles standard 121°/134° C jusqu'à deux cents (200) cycles ou quoi qu'il en soit jusqu'à la perte des performances mécaniques.
Les paramètres du cycle de stérilisation sont les suivants:

Cycle EN 13060	Température	Pression	Holding Time Minimum
B	121°C	207 KPa	15 min
B	134°C	308 KPa	3 min

8. CONTRÔLES PÉRIODIQUES

Opération	Fréquence	Applicabilité		Procédure	Activation
		LD	TE		
Vérifier absence de jeu entre les articulations des bras	Annuel	x	N/A	Vérifier que la lumière entre les articulations 5 et les bras n'ait pas changé depuis la première utilisation	Utilisateur
Contrôle lisibilité données de plaque	Annuel	x	x		Utilisateur
Contrôle intégrité enveloppes	Tous les deux ans				Service Engineer
Contrôle de sécurité électrique EN 62353 1. Rigidité 2. Dispersion	Annuel	x	x	Mesure rigidité diélectrique et dispersion dans l'enveloppe. Limites définies dans l'IEC 60601-1	Service Engineer
Contrôle des paramètres de lumière	Tous les deux ans	x	x	Avec un spectroradiomètre, mesurer les valeurs de: • Eclairement maximum: >35000 lux • Déchéance du CRI: <20%. • Valeur sous-tendue de la lumière Bleue sur le spectre émis mesurée en: <100 W/m2	Service Engineer

9. SIGNAUX ACOUSTIQUES

9.1 Signaux Acoustiques

OpL** = Bip 30 secondes
OTP* = Bip 30 secondes

* OTP: Protection surchauffe LED.
** OpL: Charge LED débranchée

9.2 GUIDE DES PROBLÈMES

Le tableau ci-dessous représente un guide pour les défauts potentiels de la lampe.
Si le problème ne se résout pas, appeler l'assistance technique.

Effet	Cause	Action (Service Engineer - SE)	Resp
La lampe ne s'allume pas	Alimentation non enclenchée ou enclenchée incorrectement.	Vérifier que l'alimentation soit enclenchée et que l'unité soit allumée.	Utilisateur
	Interférence avec bistouris électriques ou instruments à haute énergie.	Eteindre le bistouri électrique et vérifier la permanence de l'effet.	Utilisateur
	Commande sur la manette appliquée de façon erronée	Pour la mise en marche et l'arrêt, presser et libérer le levier manette en agissant sur le côté gauche ou droit.	Utilisateur
La lampe flikera	Interférence avec bistouris électriques ou instruments à haute énergie.	Eteindre le bistouri électrique et vérifier la permanence de l'effet.	Utilisateur
La lampe ne règle pas l'intensité lumineuse	Commande sur la manette appliquée de façon erronée	Utiliser la commande correctement comme décrit dans ce manuel	Utilisateur
	Interférence avec bistouris électriques ou instruments à haute énergie.	Eteindre le bistouri électrique et vérifier la permanence de l'effet.	Utilisateur
L'intensité lumineuse est considérablement réduite	Réflecteurs ou lentille secondaire sales.	Nettoyer les réflecteurs et les lentilles secondaires.	Utilisateur
	Utilisation de procédures erronées	Vérifier qu'on est au réglage maximum avec la commande	Utilisateur
Des taches sont apparues sur les réflecteurs (parabole) ou la couche réfléchissante est partie	Utilisation de produits non approuvés.	Nettoyer les surfaces avec le produit spécifique "Faro Perflex". Nettoyer les surfaces avec de l'alcool isopropylique. Pour la réinitialisation des surfaces, il faut remplacer le réflecteur du service.	Utilisateur
La lampe ne maintient pas l'équilibre et tend à descendre	Charge excessive sur la tête (miroirs, caméras, etc...).	Retirer les charges en excès	Utilisateur
La lampe ne contrôle pas	Fonction synchro éteinte	Activer la fonction, voir 4.1.4	Utilisateur

10. CARACTÉRISTIQUES TECHNIQUES

Lampe complète:
Tension alimentation (sans transformateur):
- 17÷24Vac ±10% - 50/ 60Hz;
- 22÷35Vdc ±10%

Puissance absorbée:
- 26VA (version 17÷24Vac);
- 14VA (version 22÷35Vdc)

Fusibles conseillés :
- Version 17÷24Vac: T1.6AL 250V
- Version 22÷35Vdc: T630mAL 250V

Protection contre les dangers électriques:
- Appareil de classe II

Classification EN 62471:
- classe Exempt

Lampe complète avec Theia Tech
Tensione alimentazione (senza trasformatore):
- 24Vac ±10% - 50/ 60 Hz
- 24Vdc ±10%

Potenza assorbita:
- 40VA (versione 24Vac)
- 28VA (versione 24Vdc)

Fusibili consigliati:
- T2AL 250V

Protezione contro i pericoli elettrici:
- Apparecchio di classe II

Classificazione EN 62471:
- classe Exempt

Caractéristiques optiques de la lumière produite par la tête conformément à l'ISO 9680
Dimensions spot lumineux: 180 mm x 90 mm
Lux: 3.000*-50.000* lux @700mm
Température de couleur: 5000 K*
CRI (color rendering index): >95*

* Valeurs typiques sujettes à tolérances.
Etiquettage conformément à EN 62471: non nécessaire

10.1 SCHÉMAS ÉLECTRIQUES

- **Lampe complète:**
  Circuit électrique dans la tête de la lampe

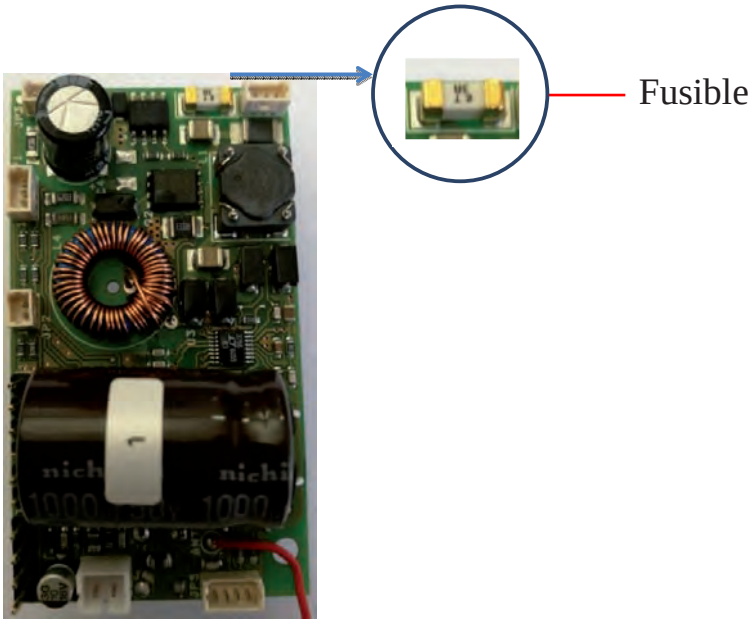
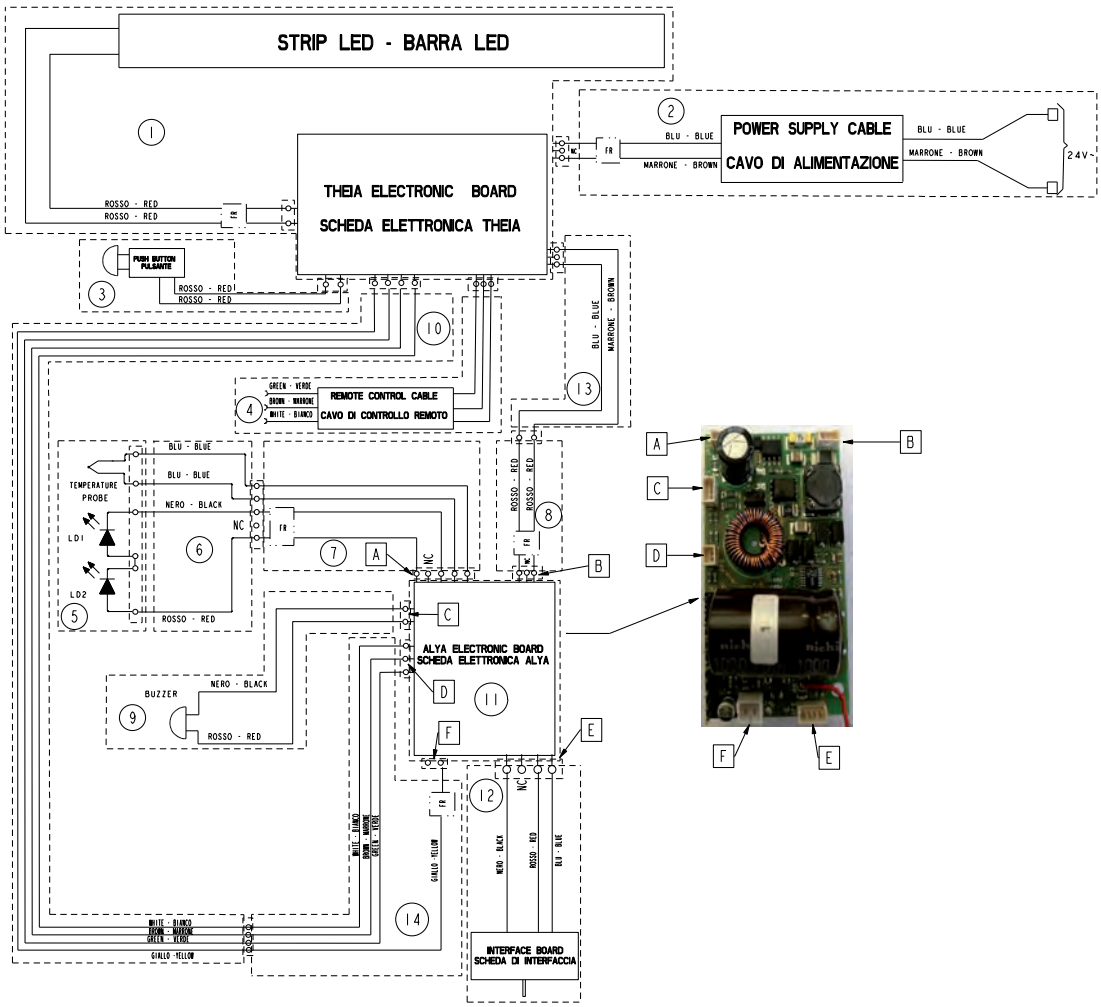
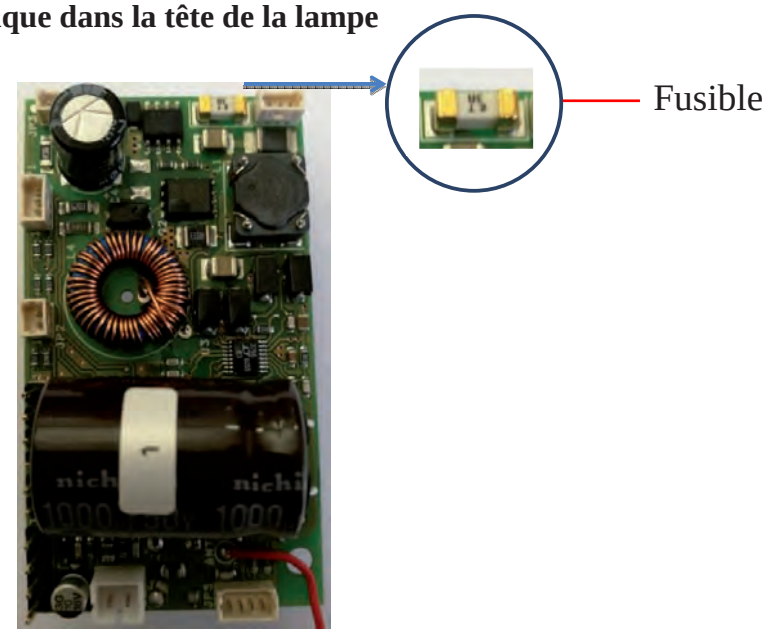


Schéma Electrique – Alya sans transformateur

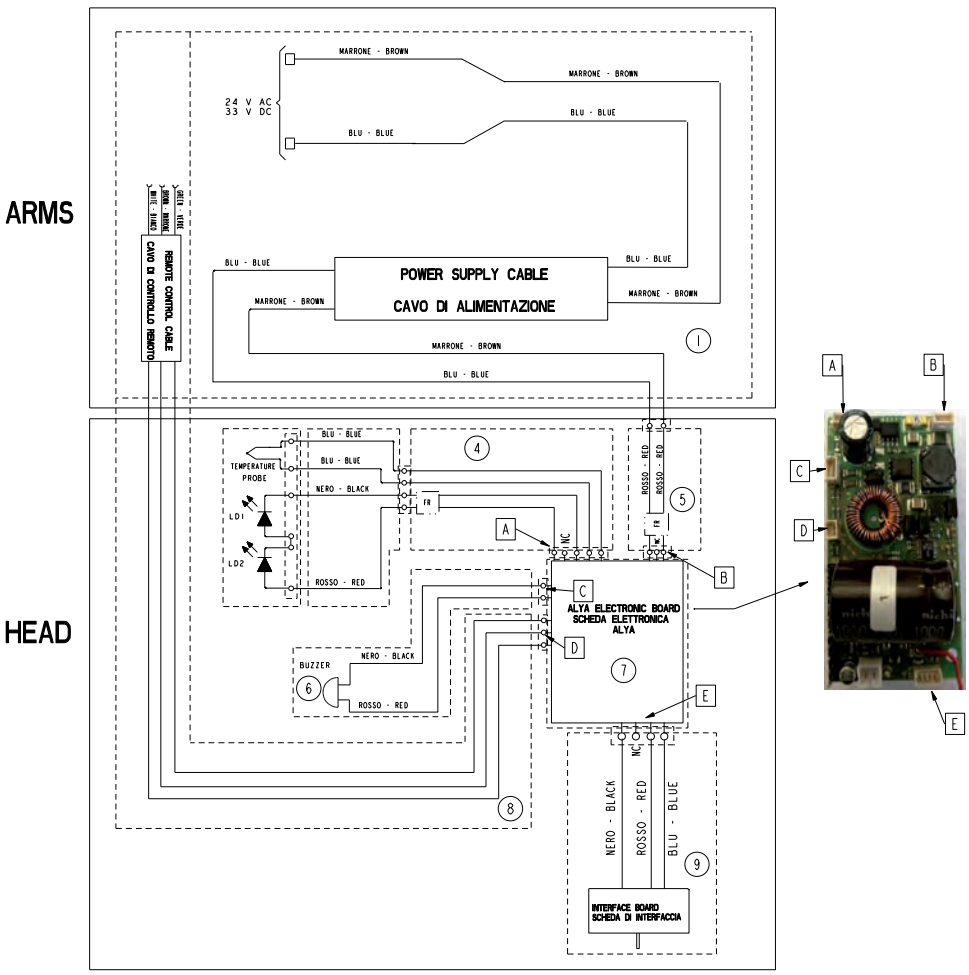


- **Lampe complète avec Theia Tech:**
  Circuit électrique dans la tête de la lampe

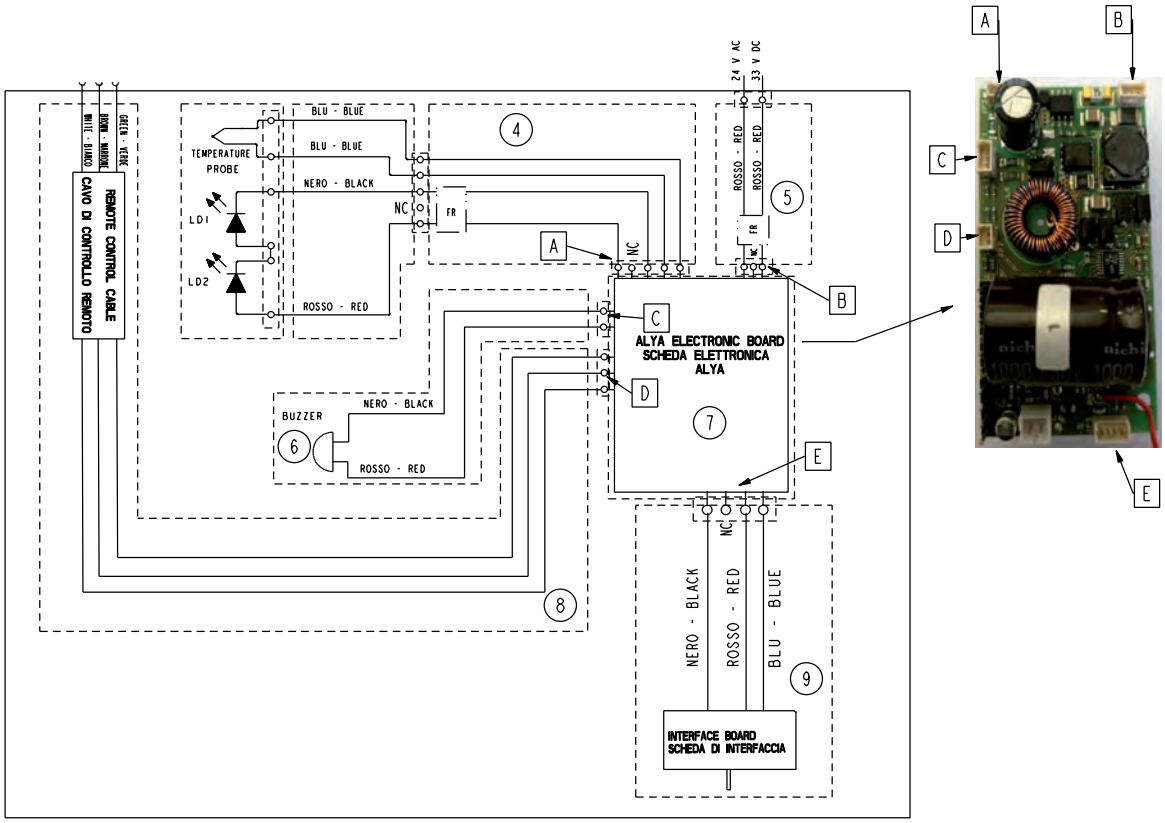


Circuit électrique dans le bras arrière

Schéma Electrique – Alya Theia Tech.



- ***Tête:*** *Schéma Electrique – Tête Alya*



INHALTSVERZEICHNIS

1. SICHERHEITSANFORDERUNGEN

Sehr geehrter Kunde,
FARO wünscht Ihnen gute Arbeit mit Ihrer neuen hochqualitativen Dentallampe. Um sicher zu arbeiten und um die Leistungen des Produkts optimal zu nutzen, lesen Sie bitte die Bedienungsanleitung sorgfältig durch, bevor Sie das Gerät benutzen.
Beachten Sie vor allem alle Warnhinweise und Hinweise.

1.1 SYMBOLE

1.1.1 Die in der Bedienungsanleitung verwendeten Symbole

	*WARNUNG*
Die Abschnitte mit diesem Symbol enthalten Anweisungen, die sorgfältig befolgt werden müssen, um Schäden am Gerät, am Bediener und am Patienten zu vermeiden.	

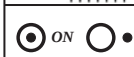
	*ACHTUNG*
Dieses Symbol weist darauf hin, dass man besonders vorsichtig vorgehen sollte, um Situationen zu vermeiden, in denen das Gerät beschädigt werden könnte.	

	*VERBOT*
Dieses Symbol weist darauf hin, was nicht gemacht werden darf, um Schäden am Gerät zu vermeiden.	

	*HINWEIS*
Dieses Symbol weist darauf hin, wie das Gerät so effizient wie möglich zu gebrauchen ist.	

1.1.2 Symbole auf den Aufklebern

Das Typenschild ist
• für die vollständige Lampe am hinteren Arm angebracht
• für den Kopf unter der Abdeckung des Kühlkörpers angebracht
und trägt die folgenden Daten:
Seriennummer (SN): Jahr (AA) / Kategorie (LD) für Dentallampen - TE nur für den Kopf) und die fortlaufende Nummer (NNNNNN) z.B.: SN14LD000001 für die komplette Dentallampe SN 14TE000001 für den Kopf.
Ferner finden Sie die folgenden harmonisierten Symbole:

	Die Bedienungsanleitungen elektronisch gelieferten lesen
	Herstellersymbol gemäß der Richtlinie 93/42/EWG
	Die Bedienungsanleitungen enthalten Sicherheitshinweise
	Gerät fällt unter die WEEE-Richtlinie 1012/19/EG. Entsorgen Sie das Altgerät gemäß dieser Richtlinie.
	Doppelte Isolierung Gerät der Schutzklasse 2 gegen Stromschlagrisiko
	Serial Number/ Seriennummer
	Mit heißem Wasserdampf bei 134°C sterilisierbar
	Das Gerät bei einer Temperatur zwischen 10°C und 40°C verwenden
	Das Gerät bei einem Druck zwischen 800 mBar und 1060 mBar verwenden
	Das Gerät bei einer relativen Luftfeuchtigkeit zwischen 30 RH und 175 RH verwenden
	Symbol für die Regulierung der Lichtstärke
	Symbol für die Einschaltung der Lampe
	[Symbol für die Einschaltung/Abschaltung des Lichts am hinteren Arm]

1.1.3 Symbole auf der Verpackung

HOCH

ZERBRECHLICH

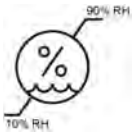
NICHT NASS MACHEN

NICHT DREHEN

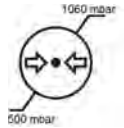
KEINE HAKEN VERWENDEN

ÜBERLAGBARES HÖCHSTGEWICHT

LAGERTEMPERATUR
TRANSPORTBEDINGUNGEN



RELATIVE LUFTFEUCHTIGKEIT



ATMOSPHÄRISCHER DRUCK

WIEDERVERTWERTBARE PAPPE

1.2 VORGESEHENER GEBRAUCH

Das Gerät ist ausschließlich für den Einsatz in Praxen für Zahnmedizin, Zahn- und Mundheilkunde und Dentalhygiene zum Beleuchten des Behandlungs- und Eingriffsraumes bei Behandlungen von Pathologien der Mundhöhle und Zähne vorgesehen.
Bei normaler Verwendung wird das Gerät über den Patienten in einer Entfernung von 700 mm, für die die Beleuchtungseigenschaften der Lampe getestet worden sind, positioniert.
Es können Patienten jeder Altersstufe für die typischen Zahnpathologien behandelt werden.

1.3 VORGESEHENER BENUTZER

Der vorgesehen Benutzer ist der Zahnarzt oder Dentalhygieniker

1.3.1 Diplom:

- Diplom in Medizin mit Spezialisierung in Zahn- und Mundheilkunde
- Diplom in Zahnmedizin
- Diplom in Dentalhygiene

1.3.2 Mindesteignung

- Die vom Diplom vorgesehenen
- Sprachkenntnisse: Die mit dem Diplom erworbenen

1.3.3 Erfahrung

- Die für die Berufsausübung vorgesehene

1.3.4 Mögliche Behinderungen

- Um das Gerät benutzen zu können, muss der Bediener einen vollständig \ funktionierenden Arm haben.
- Sehfähigkeiten, die für dem Beruf notwendig sind.

1.4 ALLGEMEINE VORSCHRIFTEN UND DIE WICHTIGSTEN WARNHINWEISE

- Das Gerät kann als Zubehör zur Dentaleinheit aber auch auf spezielle Anwendungen installiert werden. Das Gerät kann sowohl von der Dentaleinheit, als auch von einem an das Stromversorgungsnetz angeschlossenen Stromgerät versorgt werden. Bitte sehen Sie im Abschnitt zur Installation nach.
- Das Gerät wird nicht zu lebensunterstützenden Behandlungen eingesetzt, weswegen eine unzureichende Leistung des Geräts nicht die Sicherheit des Patienten beeinträchtigt.
- Es ist kein lebenserhaltenes Gerät.
- Das Gerät muss vor dem ersten Gebrauch gereinigt werden (siehe Abschnitt “Reinigung des Geräts”)
- Die Lampe ist so verpackt, dass sie angemessen gegen das Eindringen von Fremdkörpern geschützt ist.

	**Warnung vor Stromschlaggefahr und Brandgefahr** Die Lampe nicht benutzen, wenn eine ihrer Komponenten beschädigt ist. Die Lampe darf nur von qualifizierten Personen installiert werden. Die Dentallampe muss an eine spezifische Steuer- und Versorgungsgerät wie eine Dentaleinheit oder an eine elektrische Anlage, welche die Anforderungen der IEC-Norm 60364-1 und den “nationalen Vorschriften” für die Installation von elektrischen Anlagen in Räumen für den medizinischen Gebrauch” erfüllt, angeschlossen werden. Das Gerät muss mit einem allpoligen Trennschalter für das Versorgungsnetz gemäß der IEC-Norm 61058-1 installiert werden. Die Installation und das Einhalten der Bestimmungen der Norm IEC 6060-1 liegt in der Verantwortung des Installateurs oder des Herstellers der Dentaleinheit. Nachprüfen, dass die Netzspannung der auf dem Typenschild angegebenen entspricht. Keine Wartungsarbeiten an der Lampe durchführen, solange sie ans Stromnetz angeschlossen ist: Vor den Wartungsarbeiten das Stromkabel abziehen.
	**Warnung vor Beschädigungsgefahr für die mechanischen Teile und Gefahr durch Herunterfallen aufgehängter Gegenstände** Zum Reinigen der Teile aus Kunststoff keine Reiniger verwenden, die AMMONIAKWASSER - NATRIUMHYDROXID - METHYLENCHLORID - METHYLALKOHOL enthalten. Die Missachtung dieser Vorschrift kann dazu führen, dass DIE KUNSTSTOFFTEILE BESCHÄDIGT WERDEN UND KAPUTT GEHEN. Keine Chemikalien direkt auf die Lampe sprühen. Es ist vor allem verboten, Scheuermittel, säurehaltige und chlorhaltige Reinigungsmittel zu verwenden.
	**Warnung vor Gefahr durch Herunterfallen aufgehängter Gegenstände** Die vorgeschriebenen Höchstbelastungen müssen strengstens eingehalten werden. Nicht an die Endanschläge der Arme und Köpfe stoßen und sie überladen.
	**Warnung vor photobiologischer Gefahr und Blendgefahr** Der Lichtstrahl darf nicht direkt auf die Augen des Patienten gerichtet werden, vor allem bei Patienten mit höherem Risiko für Augenverletzungen (z.B. Kinder mit Augenkrankheiten). In diesen Fällen müssen immer geeignete Schutzausrüstungen verwendet und die entsprechenden Vorsichtsmaßnahmen ergriffen werden. Die Lampe ist gemäß EN 62471 für die Klasse der photobiologischen Sicherheit Exempt ausgewiesen. Es ist trotzdem nicht auszuschließen, dass besonders lichtempfindliche Patienten oder Patienten, die Medikamente eingenommen haben, welche die Lichtempfindlichkeit erhöhen, mit Hautrötungen oder allergische Reaktionen auf das Licht reagieren. In dem Fall die Behandlung abbrechen und eine niedrigere Lichtstärke einstellen. Der Gelenkarm und die Gelenke der Lampe erlauben eine korrekte Ausrichtung des Lichtbündels.
	**Warnung vor Beschädigungsgefahr für die elektrischen Komponenten** Nicht die Arme und Gelenke mit Stößen am Endanschlag überladen. Die Drehung des Kopfes und der Arme über den Endanschlag hinaus kann die Isolierungen der Leiter beschädigen.
	**Warnung vor Explosionsgefahr** Das Gerät ist nicht geeignet für den Einbau in Räumen mit entflammbaren Gas oder mit konzentriertem Sauerstoffgehalt.
	**Warnung vor der Gefahr der Kreuzkontamination von Patient zu Patient** Der Arzt ist gehalten den Einwegschutz für die Lampengriffe zu verwenden oder die Lampengriffe nach jeder Behandlung zu sterilisieren. Ausschließlich Wasser-Alkohol-Lösungen zum Desinfizieren der Oberflächen verwenden (siehe Abschnitt über Wartung / Reinigung)
	**Warnung vor Gefahr falscher Wartung** Keine anderen Wartungs- und Reparaturarbeiten als die, die in den Anleitungen beschrieben werden, vornehmen. Jeder nicht beschriebene Eingriff kann die Sicherheit des Geräts beeinträchtigen.Nur Wartungsarbeiten ausführen, die in der Bedienungs- und Wartungsanleitung beschrieben sind: Für alle anderen Arbeiten den Kundendienst rufen.

Das Produkt fällt unter die WEEE-Richtlinie 2012/19/EU
Das Altgerät muss gemäß den im Land geltenden Abfallvorschriften entsorgt und verschrottet werden und eventuell an anerkannte und autorisierte spezialisierte Unternehmen abgegeben werden. Am Ende des Lebenszyklus die Materialien nach ihren Typologien trennen (Eisen, Gummi, Kunststoff). Kleine Komponenten des Geräts nicht unbewacht oder in Nähe von Kindern liegen lassen, da sie eine potentielle Gefahrenquelle darstellen. Das Unternehmen FARO erlaubt keine Änderungen an dem Produkt, die nicht vorher schriftlich genehmigt worden sind. Nicht genehmigte Änderungen bedeuten den Verfall der Einhaltung der Sicherheitsvorschriften und der Garantie. Andere Warnhinweise sind unter den Überschriften der Bedienungs- und Wartungsanleitung angegeben.

1.5 AUFBEWAHRUNG UND GEBRAUCH VORSCHRIFTEN FÜR DIE RAUMBEDINGUNGEN

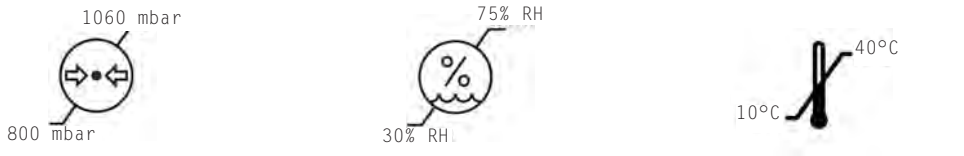
Das original verpackte Gerät kann für 15 Wochen transportiert oder gelagert werden, wenn die folgenden Raumbedingungen eingehalten werden:

- Raumtemperatur von -20°C bis + 70°C
- Relative Luftfeuchtigkeit von 10% bis 90%
- Atmosphärischer Druck von 500 bis 1060 mbar

Das Gerät darf nur unter den folgenden Raumbedingungen verwendet werden:

- Temperatur von 10°C bis 40°C
- Max. Höhe über den Meeresspiegel: 2000 m
- Relative Luftfeuchtigkeit von 30% bis 75%

ATMOSPHÄRISCHER DRUCK **RELATIVE LUFTFEUCHTIGKEIT** **GEBRAUCHSTEMPERATUR**



1.6 BEDINGUNGEN ZUR ELEKTROMAGNETISCHEN VERTRÄGLICHKEIT

Das medizinische Gerät erfordert besondere Vorsichtsmaßnahmen hinsichtlich der elektromagnetischen Verträglichkeit und muss gemäß den Hinweisen in den Unterlagen des Lieferumfangs installiert und verwendet werden.

Leitlinien und Herstellererklärung – Elektromagnetische Emissionen		
Die ALYA-Leuchte ist zum Betrieb in der unten angegeben elektromagnetischen Umgebung bestimmt. Der Kunde bzw. der Benutzer muss gewährleisten, dass sie in einer solchen Umgebung verwendet wird		
Emissionstest	**Konformität**	**Elektromagnetische Umgebung - Leitlinien**
HF-Emissionen CISPR15	Konform	Die ALYA-Leuchte nutzt HF-Energie nur für interne Funktionen. Daher sind die HF-Emissionen sehr niedrig und verursachen höchstwahrscheinlich keine Störungen an benachbarten elektronischen Geräten.
HF-Emissionen CISPR15	Konform	Die ALYA-Leuchte ist zur Verwendung in allen Gebäuden geeignet, einschließlich Wohngebäuden und solche, die direkt an das öffentliche Niederspannungsnetz zur Versorgung von Wohngebäuden angeschlossen sind
Oberschwingungen	Klasse C	
RF Emission CISPR11 / EN 55011	Konform	Die Leuchte ALYA kann nicht mit anderen Geräten verbunden werden (Deckenausführung).

ELEKTROMAGNETISCHE STÖRFESTIGKEIT

Leitlinien und Herstellererklärung – Elektromagnetische Störfestigkeit		
Die ALYA-Leuchte ist zum Betrieb in der unten angegeben elektromagnetischen Umgebung bestimmt. Der Kunde bzw. der Benutzer muss gewährleisten, dass sie in einer solchen Umgebung verwendet wird		
Störsicherheitstes	**Konformität**	**Elektromagnetische Umgebung - Leitlinien**
Elektrostatische Entladung (ESE) IEC/EN61000-4-2	± 6kV Kontakt ± 8kV Luft	Der Bodebelag sollte aus Holz, Beton oder Keramikfliesen sein. Handelt es sich beim Bodenbelag um synthetisches Material, sollte die Luftfeuchtigkeit bei mindestens 30% liegen.
Plötzlicher elektrischer Stoß/Impuls IEC/EN61000-4-4	± 2kV für Netzleitungen ± 1kV für Eingangs-/Ausgangsleitunge	Die Qualität der Netzstromversorgung sollte einer typischen Handel- oder Krankenhausumgebung entsprechen.
Stoßspannungen IEC/EN61000-4-5	± 1kV Gegentaktspannung ± 2kV Gleichtaktspannung	Die Qualität der Netzstromversorgung sollte einer typischen kommerziellen oder Krankenhausumgebung entsprechen.
Spannungseinbrüche, kurze Unterbrechungen der Stromzufuhr und Spannungsschwankungen IEC/EN61000-4-11	< 5% Ut für 0,5 Zyklen 40% Ut für 05 Zyklen 70% Ut für 25 Zyklen <5% Ut für 5 Sek.	Die Qualität der Netzstromversorgung sollte einer typischen kommerziellen oder Krankenhausumgebung entsprechen. Wenn ein Dauerbetrieb der Leuchte Alya auch bei Unterbrechung der Stromversorgung erforderlich ist, sollte das Gerät über eine unterbrechungsfreie Stromversorgung versorgt werden.
Magnetfeldeinstrahlung IEC/EN61000-4-8	3A/m	Magnetfeldeinstrahlungen sollten die typischen Werte für kommerzielle und Krankenhausumgebung aufweisen.
Leitungsgebundene HF IEC/EN61000-4-6	3Vrms 150kHz bis 80MHz (für nicht-lebenserhaltende Geräte)	Gli apparecchi di comunicazione a RF portatili e mobili non Tragbare HF-Kommunikationsgeräte dürfen nicht nahe an Teilen der Zahnarztausrüstung, einschließlich Kabeln verwendet werden, außer wenn die empfohlenen, entsprechend der Senderfrequenz berechneten Abstände, eingehalten werden. Empfohlene Abstände: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ von 80 Mhz bis 800 MHz $d = 2,3\sqrt{P}$ von 800 MHz bis 2,5 GHz Wobei P die maximale Ausgangsnennleistung des Senders in Watt (W) nach Angaben des Hersteller des Senders und d der empfohlene Abstand in Metern (m) ist. Die Feldstärke fest installierter HF-Sender, die durch eine EMV-Prüfung vor Ort ermittelt wurde, können in jedem Frequenzbereich unter der Konformitätsebene liegen. Es können Störungen bei mit folgendem Symbol ausgezeichneten Geräten auftreten:
Leitungsgebundene HF IEC/EN61000-4-6	3Vrms 80MHz bis 2.5GHz (für nicht-lebenserhaltende Geräte)	

Hinweis: Ut ist der Wert der Versorgungsspannung
Hinweis 1: Bei 80 MHz und 800 Mhz gilt der höhere Frequenzbereich.
Hinweis 2: Diese Leitlinien sind möglicherweise nicht in allen Fällen anwendbar. Die Fortpflanzung der elektromagnetischen Wellen wird auch durch Absorption und Reflexion von Bauwerken, Gegenständen und Menschen beeinflusst.
a) (Industrielle, wissenschaftliche und medizinische) ISN-Bandbreiten zwischen 150kHz und 80MHz sind 6,765 MHz bei 6,795MHz; 13,553 MHz bei 13,567 MHz; 26,957 MHz bei 27,283 MHz bei 40,66 MHz bei 40,70 MHz.
b) Die Konformitätswerte der ISN-Bandbreiten zwischen 150kHz und 80MHz und der Bandbreiten von 80MHz bis 2,5GHz sind als abnehmend hinsichtlich der Wahrscheinlichkeit des tragbaren Senders, Störungen auszulösen, falls er versehentlich in den Patientenbereich gebracht wird, anzusehen.
Aus diesem Grund wurde ein Zusatzfaktor von 10/3 in die Formel, die zur Berechnung des Abstands zu Sendern verwendet wird, eingesetzt.
c) Die Feldstärken von fest installierten Sendern wie Basisstationen für Funktelefone (Handy und kabellos) und Mobilfunk, Geräte für Amateurfunker, Kurz- und Langwellen-Radiosender sowie Fernsehsender können theoretisch nicht genau abgeschätzt werden. Um die elektromagnetische Umgebung, die durch fest installierte HF-Sender erzeugt wird, festzulegen, muss eine elektromagnetische Untersuchung vor Ort ausgeführt werden. Wenn die am Verwendungsort der zahnärztliche Ausrüstung gemessene Feldstärke die wie oben anwendbare Konformitätsebene überschreitet, muss der korrekte Betrieb der Leuchte beobachtet werden. Wenn Leistungsstörungen festgestellt werden, können Zusatzmaßnahmen wie eine Neuausrichtung oder andere Aufstellung der Leuchte notwendig sein.
d) Die Feldstärke in einem Frequenzbereich zwischen 150 kHz und 80 Mhz sollte unter 3 V/m betragen.

Empfohlene Abstände zwischen tragbaren und mobilen Funkgeräten und der Zahnarztausrüstung			
Die ALYA-Leuchte muss in einer elektromagnetischen Umgebung verwendet werden, in der HF-Störstrahlungen unter Kontrolle gehalten werden. Der Kunde oder Benutzer der Leuchte kann zur Vermeidung elektromagnetischer Störungen beitragen, indem er den Mindestabstand zwischen der zahnärztlichen Ausrüstung und tragbaren Kommunikationsgeräten sowie HF-Funkgeräten entsprechend den unten aufgeführten Empfehlungen je nach maximaler Ausgangsleistung der Funkgeräte einhält.			
Maximale Nennleistung des Senders in W	**Abstand je nach Senderfrequenz m**		
	150 kHz bis 80 MHz $d = 1,2\sqrt{P}$	80 MHz bis 800 MHz $d = 1,2\sqrt{P}$	800 MHz bis 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

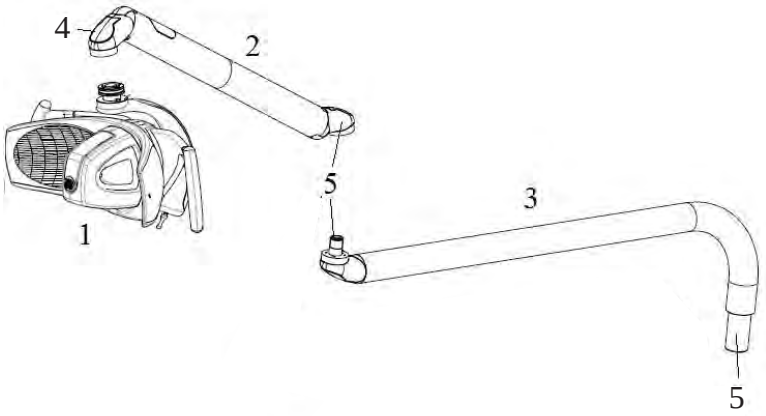
Bei Sender mit einer maximalen Nennleistung, die oben nicht aufgeführt ist, kann der empfohlene Abstand d in Metern (m) durch die der Senderfrequenz entsprechenden Formel berechnet werden, wobei P die maximale Nennleistung des Senders in W (Watt) nach Angaben des Herstellers des Senders ist.
Hinweis:
Bei 80 MHz und 800 MHz wird der höhere Frequenzbereich angewendet.
Diese Leitlinien sind möglicherweise nicht in allen Fällen anwendbar. Die Fortpflanzung der elektromagnetischen Wellen wird auch durch Absorption und Reflexion von Bauwerken, Gegenständen und Menschen beeinflusst.

2. ALLGEMEINE EIGENSCHAFTEN

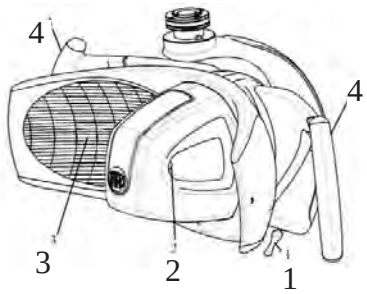
2.1 PRODUKTBESCHREIBUNG

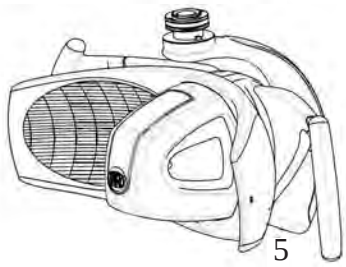
Das Gerät dient dem vorgesehenen Benutzer zum Ausleuchten des Operationsbereiches bei der Behandlung von Zahnpathologien.
Die Lichtquelle am Kopf besteht aus zwei Leuchtdioden, deren Licht von zwei Parabeln über 2 LED-Linsen reflektiert wird.
Die Reflektoren erlauben einen gleichmäßigen Lichtstrahl bei jeder Lichtstärke und die gleichmäßige Verteilung des Lichts im Operationsfeld, ohne dass Schatten oder Verdunkelungen durch den Bediener entstehen.
Die Lichtstärke kann mit einem Joystick oder einem Sensorschalter reguliert werden. Der Sensorschalter ermöglicht, die Lampe ohne direkte Berührung ein- oder abzuschalten, sodass die Möglichkeit von Kreuzinfektionen über die Bedienung ausgeschlossen ist.
Die Funktion"Automatische Einschaltung" oder "Auto-on" erlaubt der Lampe, sich jedes Mal automatisch einzuschalten, wenn die Versorgung an der Lampe eingeschaltet wird.
Das Fernsteuerkabel erlaubt, die Lampe vom Köcher der Dentaleinheit aus zu steuern. Die im Abschnitt Installation gelieferten Anweisungen befolgen.
Auf dem Kopfstück in der Nähe des Joystick und/oder des Näherungssensors befindet sich eine Taste, die es ermöglicht die Funktion der Synchronisierung mit der Raumlampe von Faro zu aktivieren.
Die Funktion der Synchronisierung ermöglicht es der Lampe Alya die Beleuchtungsstärke der Raumlampe zu steuern, um eine gleichmäßigere Beleuchtungsstärke zwischen dem Arbeitsbereich und dem umgebenden Bereich zu garantieren, um so den Effekt der Blendung zu reduzieren und die Bequemlichkeit zu verbessern.
Bei der Version "Alya mit Theia Tech" mit Licht auf dem hinteren Arm besteht die Lichtquelle aus einer Leuchtdiodenreihe, deren Licht über einen Lichtschirm in den umliegenden Raum gestreut wird.
Die Regulierung der Lichtstärke läuft synchron mit der des Kopfes, das heißt, wenn die Lichtstärke am Kopf erhöht oder vermindert wird, reguliert sich gleichermaßen die Lichtstärke am Arm.
Die Lampen haben bei der Version "Theia Tech" einen zusätzlichen On/Off- Schalter am Arm.
Sobald die Lampe vom On/Off -Schalter am Arm eingeschaltet worden ist, synchronisiert sich die Lampe auf die Lichtstärke des Kopfes. Wenn das Licht am Kopf abgeschaltet ist, schaltet sich das Licht am Arm auf die höchste Lichtstärke. Wird jetzt das Licht am Kopf eingeschaltet, wird sich das Licht am Arm automatisch synchronisieren.
Das Licht am Arm dient einer besseren Sicht im voroperativen Bereich, sodass der Benutzer weniger von dem Licht im Sichtbereich des Operationsfelds geblendet wird.
Die Wartungsarbeiten werden durch die Anwendung neuer Technologien, welche die verschiedenen Anforderungen an die Sicherheit, Ergonomie und Hygiene berücksichtigen, erleichtert.
Die Griffe sind abnehmbar und sterilisierbar. Halten Sie sich an die im entsprechenden Abschnitt beschriebenen Anweisungen.
Für die elektrischen Anschlüsse die Anleitungen im Abschnitt Installation und die Schaltpläne in der Bedienungs- und Wartungsanleitung befolgen.

2.2 BESCHREIBUNG DER TEILE

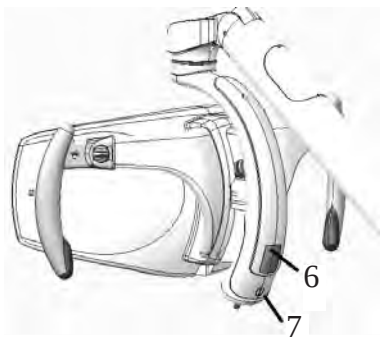


1 – Kopf
2 – Mittelarm
3 – Hinterer Arm ohne Transformator mit oder ohne Licht (Theia Tech)
4 – Gelenke
5 – Zapfen für den Anschluss an die Dentaleinheit oder Anwendung





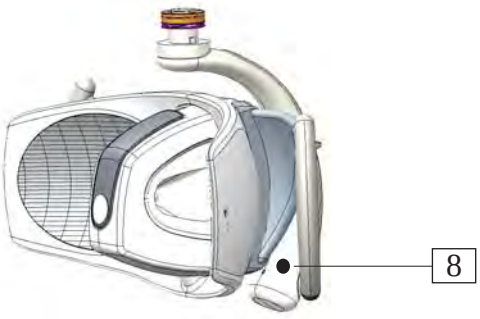
1 – Joystick
2 – LED-Linse
3 – Reflektor
4 – sterilisierbare Griffe
5 – Sensorschalter



6 – Sitz der elektronischen Karte
7 – Symbole für die Einschaltung und Regulierung
8 – Synchronisierungstaste

Version mit joystick

Version mit Bewegungssensor



2.3 GERÄTEIDENTIFIKATION

Die im Handel erhältlichen Modelle unterscheiden sich durch:

- Gerätetyp (komplette Lampe, Lampe komplett mit Theia Tech oder Kopf)
- Schnittstelle für die Einschaltung und Regulierung **(Joystick oder Näherungssensor; für komplette Lampe und Kopf)**
- Steuermodalität von der Dentaleinheit aus (On-Off-Funktion, Fernsteuerung; für komplette Lampe Und Kopf)
- Montagetyp **(Dentaleinheit, Decke, Wand, Boden; nur für komplette Lampen).**
- Länge der Arme (nur für die komplette Lampe)
- Stromversorgung (mit oder ohne Transformator, nur komplette Lampen)

Die Artikelnummern setzen sich, wie folgt, zusammen:

ALYA – komplette Lampe					
Typ	3° Digit - Montage und Steuerung von Dentaleinheit	4° Digit – Betriebsspannung und Schnittstelle	5° Digit – Arm hinten x Mittelarm (mm)	6° Digit Verfügbar	7° 8° 9° Digit Kundenspezifische Anpassung
5 1	0 Standard Dentaleinheit	0 Joystick 17-24 V AC 22-35 V DC	0 810x550	0	000 (std FARO) JJJ
	1 Decke	1 Sensorschalter 17-24 V AC 22-35 V DC	1 960x550		
	2 Dentaleinheit Auto-on	4 Joystick 230 V AC	9 810x 855		
	4 Dentaleinheit Rem cable	5 Sensorschalter 230 V AC			
		9 Joystick 240 V AC			
		8 Sensorschalter 240 V AC			

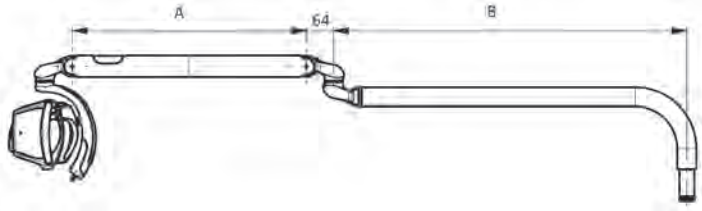
ALYA – komplette Lampe mit Theia Tech					
Typ	3° Digit Montage und Armgrößen	4° Digit Kopftyp type	5° Digit Schnittstelle	6° Digit Betriebsspannung	7° 8° 9° Digit Kundenspezifische Anp.
52	1 Dentaleinheit 550*810	1 Standard	1 joystick	1 24Vac 50/60Hz 24 V dc	000 (std FARO) JJJ
	2 Dentaleinheit 550*960	2 Mit Verlängerung	2 Joystick auto-on		
	3 Dentaleinheit 855*810		3 Sensor		
	4 Dentaleinheit 855*960		4 Auto-on Sensor		
	5 Decke 550*810		5 Joystick + Fernsteuerkabel		
	6 Decke 550*960		6 Joystick Auto-on + Fernsteuerkabel		
	7 Decke 855*810		7 Sensor + Fernsteuerkabel		
	8 Decke 855*960		8 Auto-on sensor + Fernsteuerkabel		

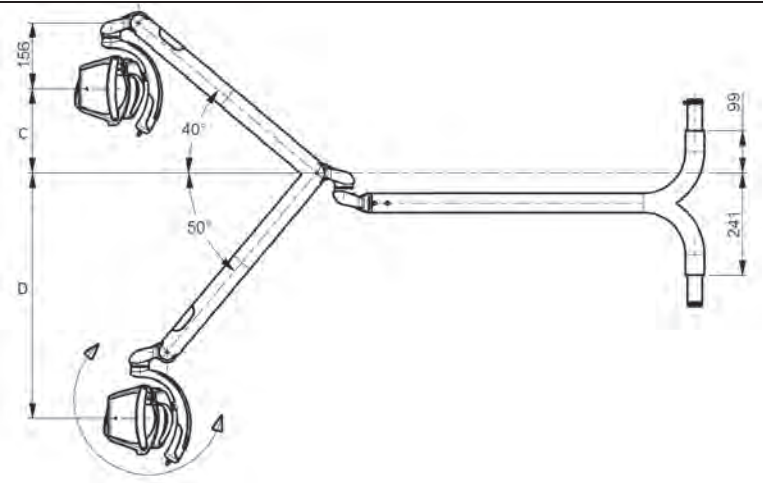
ALYA HEAD					
Type	3°-stellig Temperatur und Steuerung Dentaleinheit	4° -stellig – Stromversorgung und Steuerung	5° -stelling Verfügbar	6° -stelling Farben	7° 8° 9° -stelling Kundenspezifische Anpassung
3 1	5 Optische Gruppe 5000 K	0 Joystick 17-24 V AC 22-35 V DC	0	0 Weiß	000 Std FARO
	6 Optische Gruppe 5000 K On/Off	1 Sensorschalter 17-24 V AC 22-35 V DC		3 Grau	
	8 G.O. 4000 K				

3. GERÄTEINSTALLATION

⚠	**Warnung vor Stromschlaggefahr, bei Lampe und Kopf:**
	Das Gerät muss von Fachtechnikern installiert werden. Bei der Installation muss die Stromversorgung abgeschaltet sein. Siehe die Schaltpläne in der Bedienungsanleitung Vor der Installation die Angaben auf dem Typenschild prüfen
ℹ	**Hinweis zur Installation**
	Das Stromkabel der kompletten Lampe wird ohne Stecker oder Anschluss geliefert, damit das Gerät gemäß den Spezifikationen der Dentaleinheit oder der Anwendung angeschlossen werden kann. Der Betrieb und die Sicherheit der Lampe hängen nicht von der Polarität des Versorgungsstroms ab. Das heißt, wird das Kabel anders herum angeschlossen, kommt es nicht zu Fehlfunktionen.

3.1 ABMESSUNGEN





	A	B	C	D
mm	550	830	265	510
mm	550	980	265	510
mm	855	830	394	706
mm	855	980	394	706

3.2 KOMPLETTE DENTALLAMPE

3.2.1 Erforderliche elektrische Eigenschaften

Die Anforderungen für die korrekte Installation für jede Anwendung (Dentaleinheit, Wand, Boden, Decke) sind die folgenden:

<table>
<tr><th>Strom-versorgung</th><th>Stromkabel</th><th>Stromversorgungstyp und Schutzvorrichtungen</th><th>Klassifikat.</th><th>Konform mit IEC 60601-1</th></tr>
<tr><td>Version komplette Lampe

17-24 Vac
50/60 Hz</td><td rowspan="3">2 x 0,5 mm2
300 V
105°C
PVC-Isolierung
Durchmesser der Isolierung 1,85 mm
Nur zertifizierte Stecker und Anschlüsse mit Feuerbeständigkeit V1 oder ähnlich verwenden</td><td>Transformator konform mit IEC /EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder nach geschalteter geeigneter Sicherung:
• T1.6AL 250V
Mindestanforderungen:
• Output: 17-24 Vac;
• Spannung: 26 VA;
• Klasse B;
• Durchschlagsfestigkeit über 4000 V.
• Thermoschutz</td><td rowspan="3">Komponente eingebaut</td><td rowspan="3">Das so entstandene medizinische System muss vom Installateur oder dem Hersteller für konform mit IEC / EN60601-1 erklärt werden.
Hinweis für den Installateur: Nachprüfen, dass die Dentaleinheit, auf das die Lampe installiert wird, für die Aufnahme der kompletten Lampe zertifiziert ist.</td></tr>
<tr><td>Version komplette Lampe

22-33Vdc</td><td>Versorgungsgerät gemäß IEC / EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder mindestens mit nachgeschalteter geeigneter Sicherung:
• T630mAL 250V
Mindestanforderungen:
• Output: 22-33 Vdc;
• Spannung: 14 VA;
• Klasse B;
• Durchschlagsfestigkeit über 4000 V;
Kontinuierlicher Schutz gegen Kurzschluss und Überstrom</td></tr>
<tr><td>Version komplette Lampe mit Theia Tech

24Vac
50/60Hz</td><td>Transformator konform mit IEC /EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder nachgeschalteter geeigneter Sicherung:
• T2AL 250V
Mindestanforderungen:
• Output: 24Vac;
• Spannung: 40VA
• Klasse B;
• Durchschlagsfestigkeit über 4000 V.
Thermoschutz</td></tr>
</table>

Strom-versorgung	Stromkabel	Stromversorgungstyp und Schutzvorrichtungen	Klassifikat.	Konform mit IEC 60601-1
Version komplette Lampe mit Theia Tech 24Vdc	2 x 0,5 mm2 300 V 105°C PVC-Isolierung Durchmesser der Isolierung 1,85 mm Nur zertifizierte Stecker und Anschlüsse mit Feuerbeständigkeit V1 oder ähnlich verwenden	Transformator konform mit IEC /EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder nachgeschalteter geeigneter Sicherung: • T2AL 250V Mindestanforderungen: • Output: 24 Vdc; • Spannung 28 VA • Klasse B; • Durchschlagsfestigkeit über 4000 V. Thermoschutz	Komponente eingebaut	Das so entstandene medizinische System muss vom Installateur oder dem Hersteller für konform mit IEC / EN60601-1 erklärt werden. Hinweis für den Installateur: Nachprüfen, dass die Dentaleinheit, auf das die Lampe installiert wird, für die Aufnahme der kompletten Lampe zertifiziert ist.

Tab 1 – Anforderungen für den elektrischen Anschluss und der IEC 60601-1-Konformität.

Überprüfen, ob in der Verpackung folgende Komponenten sind:
- Dentallampe / Kopf (in der bestellten Version)
- Blatt zum Herunterladen der Anleitungen von der Webseite www.faro.it/download

3.2.2 Sicherheitshinweis: Maximalbelastung

Die Dentallampen ALYA und ALYA Theia können wie folgt installiert werden: **DENTALEINHEIT/DECKE/WAND/BODEN.**

SICHERHEITSHINWEIS: MAXIMALBELASTUNG

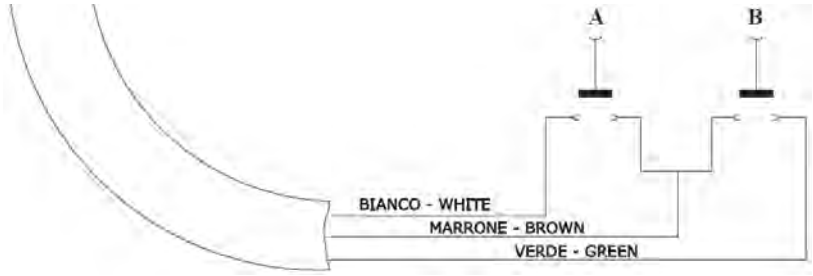
	Gesamtbelastung (SAFE WORKING LOAD)	Sicherheitslast (MINIMUM BREAKING LOAD)
Arm mit Länge 855 mm	29.2 N	235 N
Arm mit Länge 550 mm	25.6 N	205 N

3.2.3 Montage der kompletten Lampe Version Dentaleinheit

Mit einer digitalen Richtwaage nachprüfen, dass das Anschlusselement perfekt parallel zum Boden ist.
Den Anschlusszapfen der Lampe in den dafür vorgesehenen Sitz in der Dentaleinheit einstecken.
Das Stromkabel gemäß den in der Tab. 1 angegeben Spezifikationen anschließen.
Sicherstellen, dass die Lampe in keiner Position überkippt. Wenn nötig, auf die Reguliervorrichtung der Feder drücken, um die Lampe richtig einzustellen.
Die Einschaltung und Regulierung und (wenn vorhanden) den Auto-On-Schalter und das Fernsteuerkabel überprüfen.
.

3.2.4 Anschluss des Fernsteuerkabels

Das Kabel mit zwei Drucktasten (A und B) mit in der Regel offenem Kontakt (nicht mitgeliefert) gemäß dem folgenden Schema verbinden:



3.2.5 Installation der Anwendungen

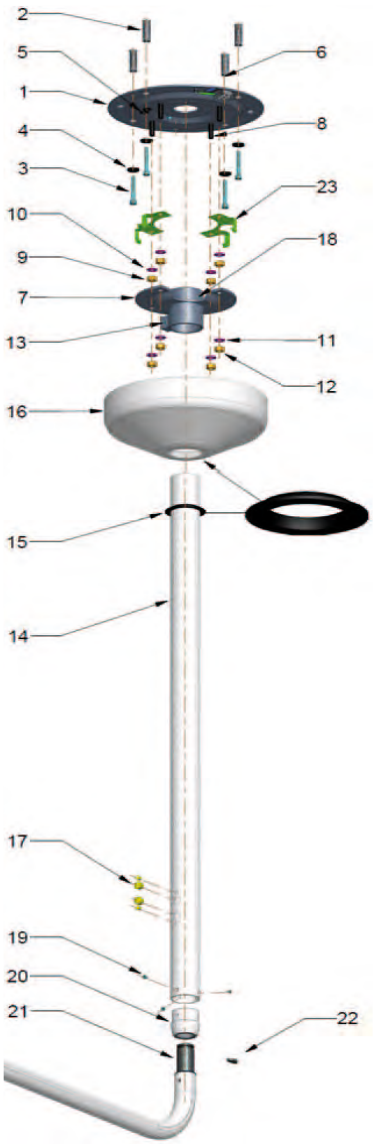
- Die Anwendungen werden nicht mit der Lampe geliefert
- Die Anwendungen müssen von Fachtechnikern installiert werden

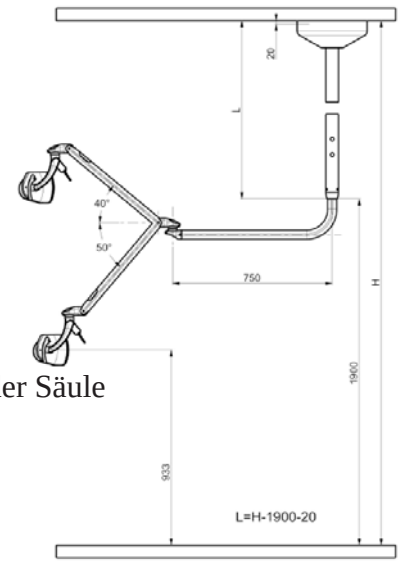
Die Lampe darf nur mit FARO Anwendungen installiert werden

Die Lampe hat einen Dreh-Endschalter zwischen dem festen Arm und dem beweglichen Arm. DER ENDSCHALTER DARF NICHT ÜBERBRÜCKT ODER ERZWUNGEN WERDEN

EINBAU DER ANWENDUNG AN DER DECKE

1. Deckenflansch
2. Expander
3. Schraube
4. Unterlegscheibe
5. Kabeldurchführung
6. Klemmleiste
7. Flansch
8. Schraube
9. Mutter
10. Unterlegscheibe
11. Unterlegscheibe
12. Mutter
13. Schraube
14. Säule
15. Ring
16. Deckenleuchte
17. Verschluss
18. Schraube
19. Schraube
20. Buchse für den Anschluss der Säule
21. Lampenstift
22. Hakenschlüssel
23. Befestigungsschiene



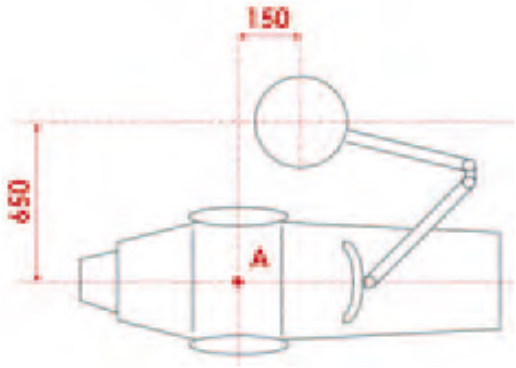


DECKENBEFESTIGUNG

HINWEIS 1. Das Gerät muss von Fachtechnikern installiert werden
HINWEIS 2. Die Stromversorgung in dem Raum, wo die Installation durchgeführt wird, muss stets ausgeschaltet sein.
HINWEIS 3. Vor den Montagearbeiten muss sichergestellt werden, dass die Decke geeignet ist, um die Anwendung zu halten.
Die zugelassenen Deckenmaterialien sind Beton und Naturstein. Die zu verwendenden Dübel sind die im Lieferumfang enthaltenen oder gleichwertige.
HINWEIS 4. Maximale Belastung: 70 kg
HINWEIS 5. In Räumen mit elektrischen Geräten in Übereinstimmung mit den geltenden nationalen Vorschriften über medizinischen Räumlichkeiten installieren

INSTALLATIONSABLAUF

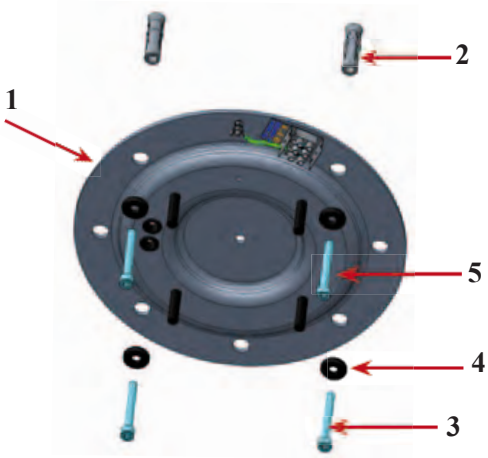
A. Die Mitte des Behandlungsstuhl (A) als Bezugspunkt bestimmen und die Installation in einem Abstand von 650mm und 150mm in den Richtungen, die in der Abbildung dargestellt sind, durchführen



B. Den Flansch (7) abnehmen durch Entfernen der Muttern (12) und Unterlegscheiben (11).

C. Den Flansch (1) als Führung verwenden und in die Decke 4 Löcher mit der Spitze Ø 14 bohren. In diese Löcher die Expander (2) montieren.

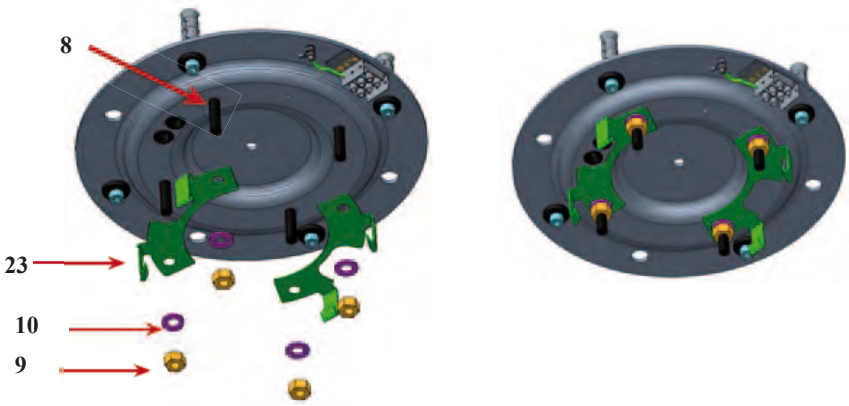
D. Den Flansch nehmen (1). Das Versorgungskabel durch die Kabelführung (5) führen, dann den Flansch (1) gegen die Decke drücken und dabei darauf achten, dass der Draht nicht zwischen dem Flansch (1) und der Decke eindrückt. Die Schrauben (3) zusammen mit den Unterlegscheiben (4) in die 4 Löcher führen, die verwendet werden, um die Löcher in der Decke zu machen. Mit einem geeigneten Sechskantschlüssel (Zubehör) die Schrauben (3) festziehen.



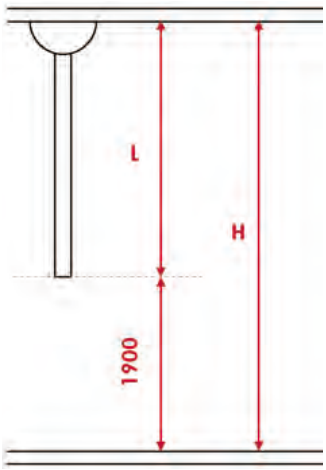
E. Das Versorgungskabel mit der Klemmleiste (6) verbinden (siehe Schaltpläne)

DECKENBEFESTIGUNG

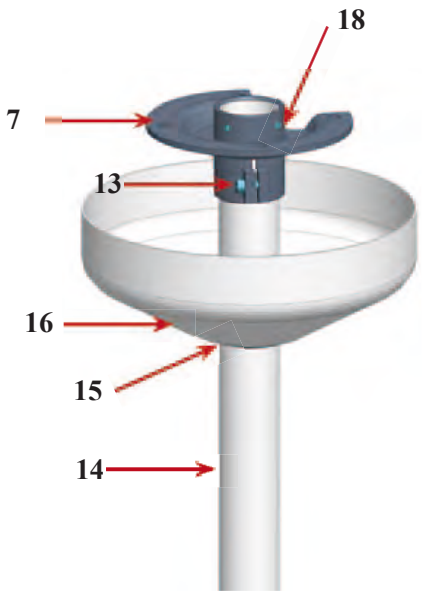
F. Die 2 Befestigungsschienen (23) an den Schrauben (8) anbringen und mit den Muttern (9) und Unterlegscheiben (10) befestigen.



G. Die genaue Länge der Säule (14), gemäß der Formel L=H-1900mm berechnen. Darauf achten den überschüssigen Teil der Säule (14) von der Seite zu schneiden, wo sich NICHT die seitlichen Bohrungen befinden.



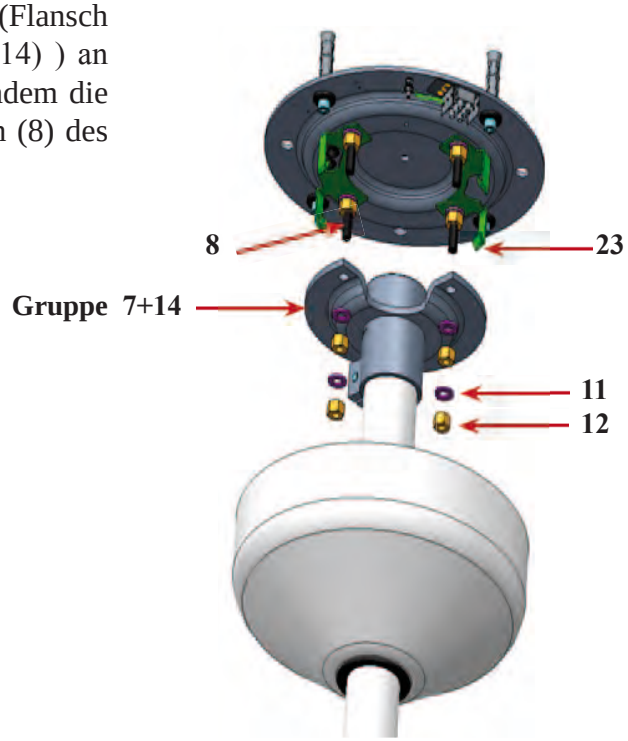
H. Die Säule (14) in den Flansch (7) einsetzen und an der Säule (14) die Position der Löcher auf dem Flansch (7) markieren. Auf die Ausrichtung der Säule zu der Behandlungseinheit achten. Die Säule entfernen und zwei Löcher von Ø 8 auf Höhe der Markierungen bohren.



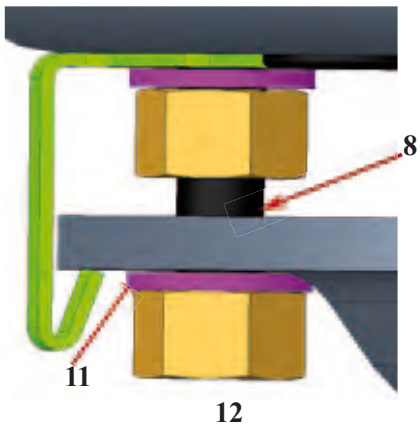
I. Auf der Säule (14) den Ring (15) etwa 300 mm einsetzen (dies ist nicht die korrekte Position, aber es handelt sich nur um eine vorübergehende Position für die Montage).
J. Die Deckenleuchte (16) auf der Säule (14) einsetzen.
K. Die Säule (14) in das entsprechende Loch des Flansch für den Anschluss der Säule (7) einsetzen.
L. Die Schraube (13) und die beiden Schrauben (18) mit Sechskantschlüssel (Zubehör) festschrauben. Die Schraube (13) kräftig anziehen und sicherstellen, dass die Schrauben (18) durch die Löcher der Säule (14) gehen.

DECKENBEFESTIGUNG

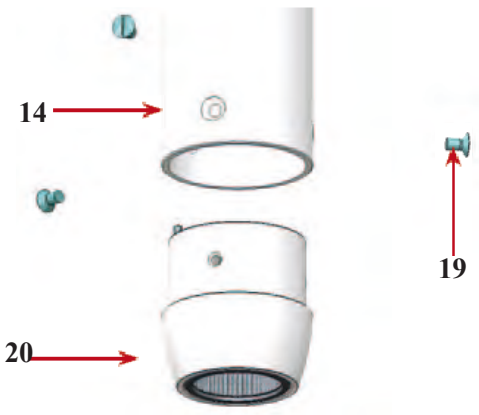
M. Die soeben zusammengebaute Einheit (Flansch zum Anschluss an die Säule (7) + Säule (14)) an den Befestigungsschienen (23) einhaken, indem die 4 Löcher des Flansch (7) an den Schrauben (8) des Flansch an der Decke (1) zentriert werden.



N. Die Muttern (12) und die verbleibenden Unterlegscheiben (11) an den Schrauben (8) des Flansch an der Decke (1) anschrauben.



O. Die drei Schrauben (19) der Säule (14) lösen und die Buchse (20) entfernen.
P. Die Buchse (20) auf dem Stift (21) der Lampe einsetzen.
Q. In die Rille des Stiftes (21) den Hakenschlüssel (22) einsetzen.



DECKENBEFESTIGUNG

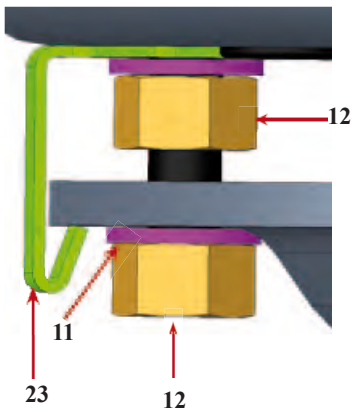
R. In die Säule (14) von oben ein Zugseil einfügen.

S. Die Leitung der Lampe mit dem Zugseil verbinden.

T. Die Lampe in die Säule (14) einsetzen und mit den drei Schrauben (19) befestigen, dabei darauf achten, die Löcher der Buchse (20) auf Höhe der Schraubensitze auf der Säule (14) auszurichten und die Schrauben anschrauben. Gleichzeitig das Zugkabel ziehen, bis die Leitung der Lampe um etwa 200 mm aus dem Flansch für den Anschluss an die Säule (7) austritt.

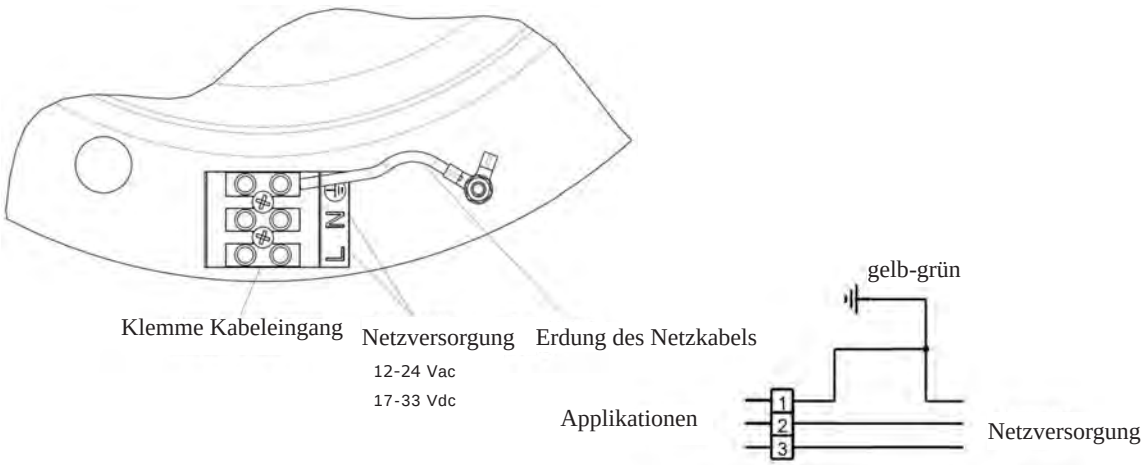
U. Die Leitung der Lampe an der Klemm¬leiste (6) anschließen (siehe Schaltpläne).

V. Die Rechtwinkligkeit der Säule prüfen durch Betätigen der Muttern (9).
W. Die Muttern (12) und die Unterlegscheiben (11) anziehen, um den Flansch (7) zu befestigen, ihn dabei unabhängig von den Befestigungsschienen (23) zu lassen.
X. Die Deckenleuchte (16) an der Decke anbringen, indem gegen¬ den Ring (15) gedrückt wird.



SCHALTPLAN

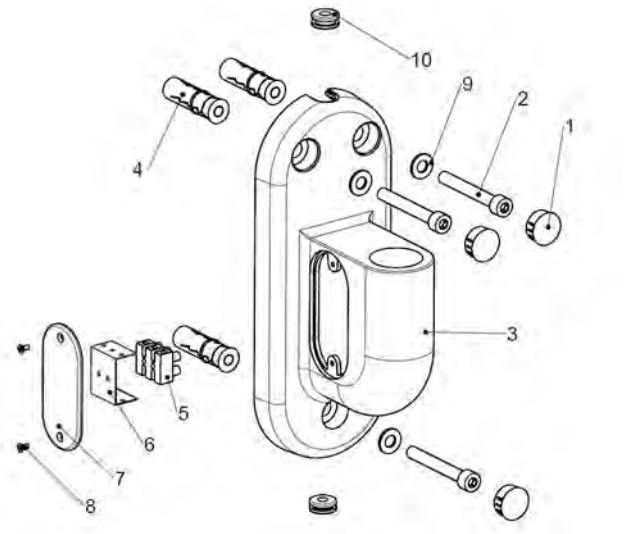
Deckenbefestigung OHNE Transformator

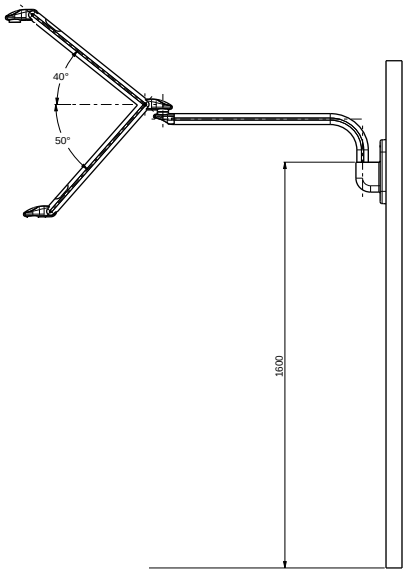


WANDBEFESTIGUNG

MONTAGE DER LAMPE MIT WANDBEFESTIGUNG

1. Verschluss
2. Schraube
3. Wandbefestigung
4. Expander
5. Klemmleiste
6. Klemmleistenabdeckung
7. Abdeckung
8. Schraube
9. Unterlegscheibe
10. Kabeldurchführung





HINWEIS 1. Das Gerät muss von Fachtechnikern installiert werden
HINWEIS 2. Die Stromversorgung in dem Raum, wo die Installation durchgeführt wird, muss stets ausgeschaltet sein.
HINWEIS 3. Vor den Montagearbeiten muss sichergestellt werden, dass die Wand geeignet ist, um die Anwendung zu halten.
Die zugelassenen Wandmaterialien sind Beton und Naturstein. Die zu verwendenden Dübel sind die im Lieferumfang enthaltenen oder gleichwertige.
HINWEIS 4. Maximale Belastung: 70 kg.
HINWEIS 5. In Räumen mit elektrischen Geräten in Übereinstimmung mit den geltenden nationalen Vorschriften über medizinischen Räumlichkeiten installieren.
HINWEIS 6. Die Lampe ohne Transformator muss durch Niederspannungsstrom (12-24Vac oder 17-33Vdc) unter Verwendung eines Transformators oder Sicherheitsnetzgerätes (in Übereinstimmung mit IEC/EN 60601-1) mit Wärmeschutz oder mit mindestens einer Sicherung geschützt (T500mAL250V~) versorgt werden.
Das entstehende medizinische System muss vom Installateur als konform mit der IEC/EN 60601-1 erkl¬ärt werden.

WANDBEFESTIGUNG

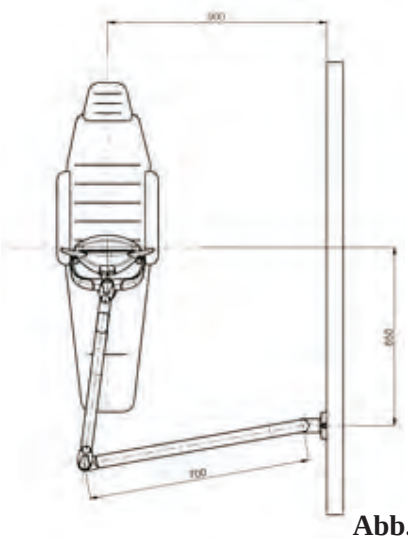


Abb. A

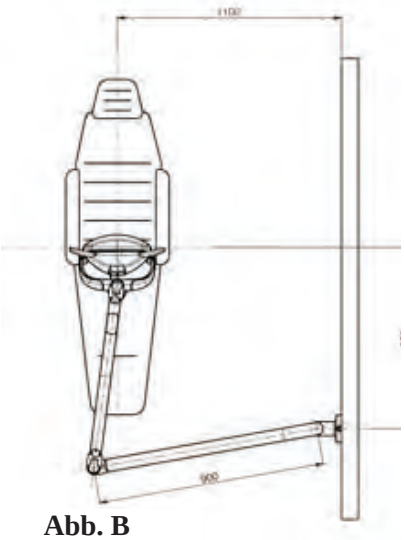
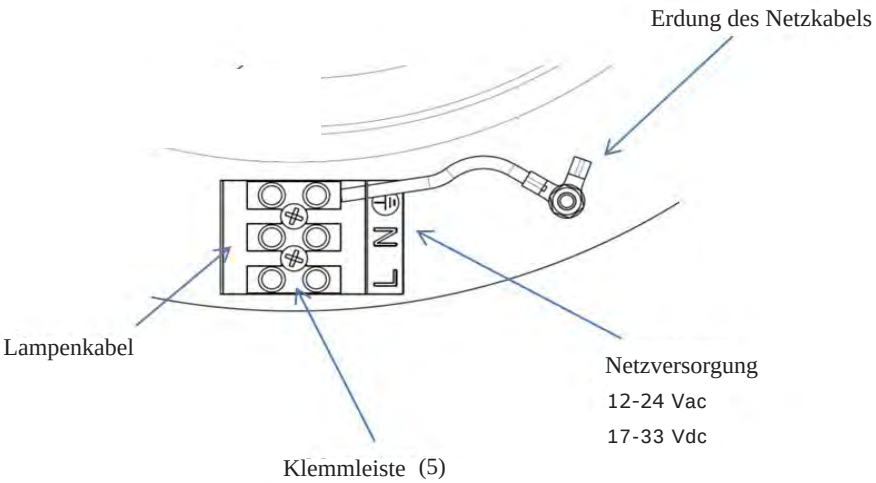


Abb. B

- Die Stromversorgung in dem Raum, wo die Installation durchgeführt wird, muss stets ausgeschaltet sein.
- Die Mitte des Behandlungsstuhl als Bezugspunkt bestimmen (siehe Abb.**A-B**) und a¬uf der Wand drei Löcher von Durchmesser 14 auf Höhe der Löcher der Wandbefestigung (3) bohren, dabei sorgfältig auf die Rechtwinkligkeit des Loches achten.
- Die drei Expander (12) in die 4 zuvor gebohrten Löcher einsetzen und mit dem entsprechenden Sechskantschlüssel (Zubehör) die 2 Schrauben fest anziehen, dabei darauf achten das Kabel nicht zwischen der Wand¬befestigung (3) und der Wand einzuquetschen.
- Die drei Verschlüsse (1) auf den Löchern der Wandbefestigung (3) anbringen.
- Die Schraube (8) lösen Die Abdeckung (7) entfernen, in den Arm der Lampe in der Deckenbefestigung einsetzen und den Stift schmieren. Die Drähte der Lampe an die Klemmleiste (5) anschließen (siehe unten Verkabelungsdiagramm) einschließlich Erdungsdrahtl. Die aus der Wand kommenden Drähte an der Klemmleiste anschließen, wenn sie zuvor gemauert wurde. Andernfalls muss der Anschluss mit einem externen abnehmbaren Kabel durchgeführt werden, das in die Kabelführung (10) eingesetzt werden muss.
- Die Abdeckung (7) wieder mit den Schrauben (8) anbringen.

SCHALTPLAN

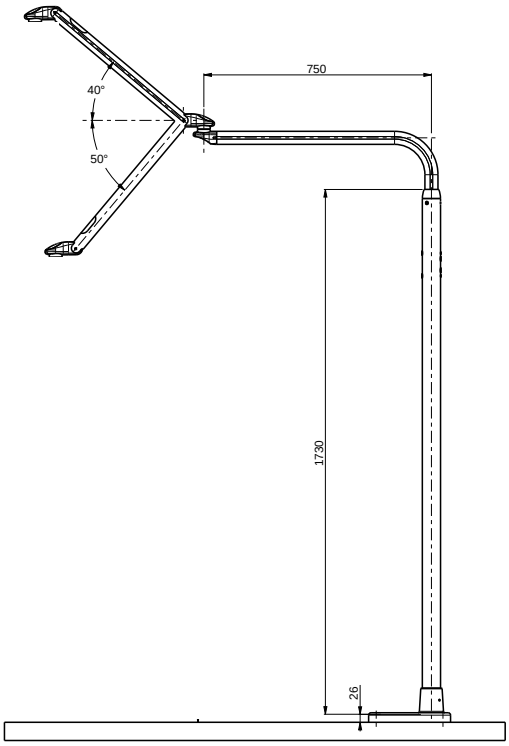
Applicazione a parete

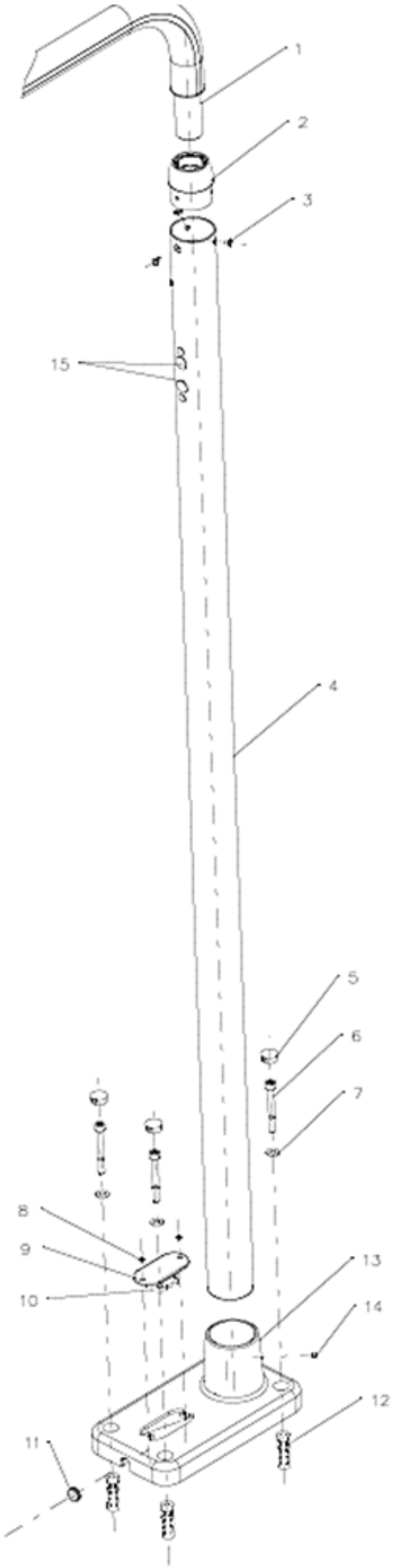


BODENBEFESTIGUNG

EINBAU DER ANWENDUNG AM BODEN

1. Stift
2. Buchse
3. Schraube
4. Säule
5. Deckel
6. Schraube
7. Unterlegscheibe
8. Schraube
9. Abdeckung
10. Klemmleiste
11. Kabeldurchführung
12. Expander
13. Bodenhalterung
14. Gewindestifte
15. Verschluss



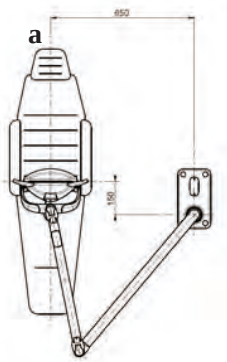


BODENBEFESTIGUNG

Das Gerät muss von Fachtechnikern installiert werden
HINWEIS 2. Die Stromversorgung in dem Raum, wo die Installation durchgeführt wird, muss stets ausgeschaltet sein.
HINWEIS 3. Vor den Montagearbeiten muss sichergestellt werden, dass der Boden geeignet ist, um die Anwendung zu halten.
Die zugelassenen Wandmaterialien sind Beton und Naturstein. Die zu verwendenden Dübel sind die im Lieferumfang enthaltenen oder gleichwertige.
HINWEIS 4. Maximale Belastung: 70 kg
HINWEIS 5. In Räumen mit elektrischen Geräten in Übereinstimmung mit den geltenden nationalen Vorschriften über medizinischen Räumlichkeiten installieren.
HINWEIS 6. Die Lampe ohne Transformator muss durch Niederspannungsstrom (12-24Vac oder 17-33Vdc) unter Verwendung eines Transformators oder Sicherheitsnetzgerätes (in Übereinstimmung mit IEC/EN 60601-1) mit Wärmeschutz oder mit mindestens einer Sicherung geschützt (T500mAL250V~) versorgt werden. Das entstehende medizinische System muss vom Installateur als konform mit der IEC/EN 60601-1 erklärt werden.

A. Die Mitte des Behandlungsstu¬hls "**a**" als Bezugspunkt bestimmen und die Installation in einem Abstand von 650mm und 150mm in den Richtungen, die in der Abbildung "**C**" dargestellt sind, durchführen

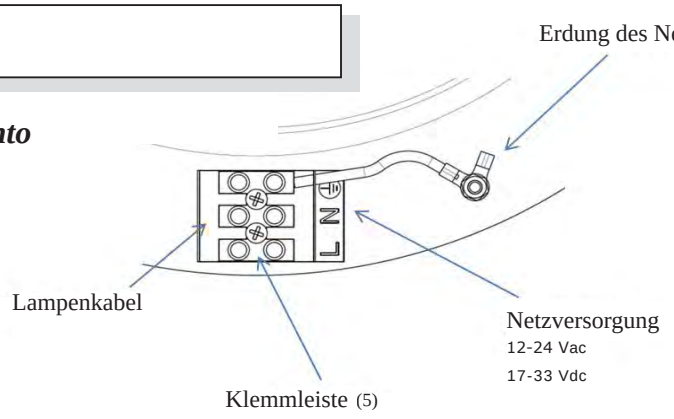
Abb. C



- Die Stromversorgung in dem Raum, wo die Installation durchgeführt wird, muss stets ausgeschaltet sein.
Die Mitte des Behandlungsstuhls (**a**) als Bezugspunkt bestimmen (siehe Abb. **C**) und in den Boden vier Löcher von Durchmesser 14 auf Höhe der Löcher der Bodenhalterung (13) bohren.
Die Bodenhalterung (13) vorbereiten, indem die Unterlegscheibe (7) und die Schraube (6) durchgeführt werden, die Expander (12) an den Schrauben (6) mit einigen Umdrehungen anschrauben, das Versorgungskabel in der Kabel¬durchführung (11) durchführen.
Die vier Expander (12) in die 14 zuvor gebohrten Löcher einsetzen und mit dem entsprechenden Sechskantschlüssel (Zubehör) die 6 Schrauben fest anziehen, dabei darauf achten das Kabel nicht zwischen der Bodenhalterung (13) und dem Boden einzuquetschen.
Die vier Verschlüsse (5) auf den Löchern der Bodenhalterung (13) anbringen.
Die Schrauben (8) lösen und die Abdeckungsplatte (9) entfernen Das Versorgungskabel in der Klemmleiste (10) anschließen.
Die Säule (4) an der Bodenhalterung (13) befestigen, während der Befestigung die Recht¬winkligkeit der Säule sicherstellen.
Die Buchse (2) mit den drei Schrauben (3) an der Säule (4) befestigen, dabei darauf achten die Löcher der Buchse (2) auf Höhe der Schraubensitze auf der Säule (4) auszurichten.
Die Leitung der Lampe an der Klemmleiste (10) anschließen.
Die Abdeckungsplatte (9) an der Bodenhalterung (13) mit den beiden Schrauben (8) befestigen.

SCHALTPLAN

Applicazione a pavimento



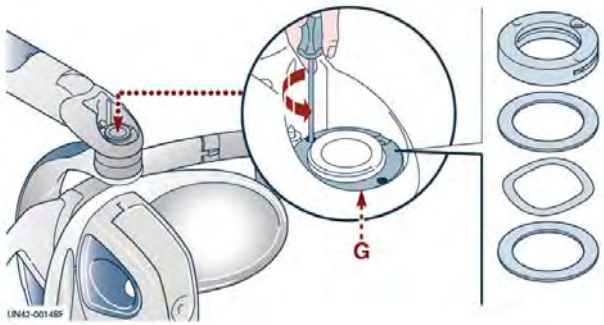
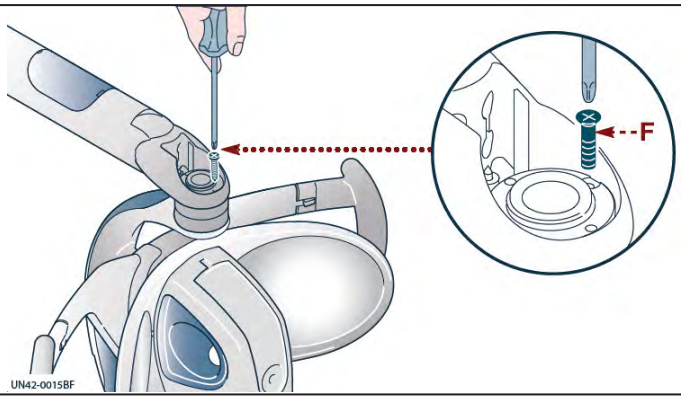
3.3 KOPF

3.3.1 Notwendig mechanische Eigenschaften

Für den mechanischen Anschluss muss genügend Raum um den Zapfen des Kopfes und den Feststellelementen G vorhanden sein. Die Halterung muss so entworfen sein, dass es die folgenden Lasten, multipliziert mit den von den Bestimmungen der IEC 606001-1 oder der IEC 80601-2-60 vorgesehenen Sicherheitsfaktoren, tragen kann

Kopf Alya	Schirm Alya
1,80 kg	0,35 kg
2,15 kg	

Für dem mechanischen Anschluss die folgenden Arbeitsschritte durchführen:

1 - Den Kopf halten und die Unterlegscheiben in den Gewindezapfen in der Reihenfolge wie in der Abbildung einsetzen. 2 - Dann den Gewindering G in der Reihenfolge wie in der Abbildung mit einem geeignetem Werkzeug eindrehen. Der Gewindering muss so eingedreht werden, dass der Kopf sich richtig drehen kann.	
3 - Die 2 Sicherheitsschrauben F eindrehen.	

⚠	**Achtung**
	Der Mittelarm neigt dazu, ohne das Gewicht des Kopfes unvermittelt nach oben zu steigen, sodass die Gefahr besteht, dass er gegen Körperteile schlägt. Der Mittelarm sollte deswegen während der Installation in seiner Position festgehalten werden, bis der Kopf fertig eingebaut ist.
⚠	**Warnung vor Gefahr durch Herunterfallen aufgehängter Gegenstände** Achtung - Es besteht die Gefahr, dass der Kopf nach der Installation herunterfällt: - Ausschließlich die von FARO mitgelieferten Schrauben verwenden. - Die im Paket gelieferten Sicherheitsschrauben anbringen.

Nach dem mechanischen Anschluss die elektrischen Kabel verlegen.

3.3.2 Erforderliche elektrische Eigenschaften

Die Anforderungen für die korrekte Installation **des Kopfes** sind::

Strom-versorgung	Stromkabel	Stromversorgungstyp und Schutzvorrichtungen	Klassifikat.	Konform mit IEC 60601-1
17-24 Vac 50/60 Hz	Stromkabel: 2 einadrige Kabel rot: UL Style 1061 300 V T 80°C 1x26 AWG VW 1 Ø max 1,02mm Stecker Standard: molex 51021-0300 3-adrig.	Transformator konform mit IEC /EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder nachgeschalteter geeigneter Sicherung: • T1.6AL 250V Mindestanforderungen: • Output: 17 - 24 Vac; • Spannung: 26 VA; • Klasse B; • Durchschlagsfestigkeit über 4000 V. • Thermoschutz	Komponente eingebaut	Das so entstandene medizinische System muss vom Installateur oder dem Hersteller für konform mit IEC / EN60601-1 erklärt werden. Hinweis für den Installateur: Nachprüfen, dass die Dentaleinheit, auf das die Lampe installiert wird, für die Aufnahme der kompletten Lampe zertifiziert ist.
22-33Vdc		Versorgungsgerät gemäß IEC /EN 60601-1 dritte Ausgabe und IEC / EN 60601-2 mit Thermoschutz oder mindestens mit nachgeschalteter geeigneter Sicherung: • T630mAL 250V Mindestanforderungen: • Output: 22-33 Vdc; • Spannung: 14 VA; • Klasse B; • Durchschlagsfestigkeit über 4000 V; • Kontinuierlicher Schutz gegen Kurzschluss und Überstrom		

4. BEDIENUNGSANWEISUNG

Aufmerksam den Absatz 1 zur sicheren Bedienung des Geräts durchlesen. Das Gerät muss vor dem ersten Gebrauch gereinigt werden (siehe Abschnitt “Reinigung des Geräts”).

	**Achtung**
	Der gleichzeitige Gebrauch von Lampe und einem Elektrokauter kann zu einer Fehlfunktion der Lampe führen.

	**Achtung**
	Der Joystick muss vorsichtig bedient werden, um Schäden zu vermeiden. Beim Bedienen den Lampe den Joystick niemals zum Festhalten benutzen.

	**Hinweis**
	Bei jedem Einschalten der Lampe schaltet sich die Lichtstärke automatisch auf die beim Abschalten gespeicherte ein.

	**Warnung - Gefahr durch unter Spannung stehende Teile**
	Niemals das Gerät verwenden, wenn Teile oder Ummantelungen beschädigt sind.

4.1 EINSCHALTEN UND AUSSCHALTEN

Siehe §1.1 für die Symbole Einschaltung und Regulierung

Komplette Lampe

Zum Einschalten und Ausschalten den Joystick nach links oder rechts drücken und loslassen. Die Lichtstärke ist immer die beim letzten Mal Abschalten gespeicherte.

Version Lampe komplett mit Theia Tech

Wie bei der kompletten Lampe, zusätzlich wird sich das Licht des feststehenden Armes synchron mit dem Kopf einschalten und/oder abschalten.

Das Licht am feststehenden Arm kann über den Schalter am Arm ein- / ausgeschaltet werden. Beim Einschalten bei eingeschalteter Lampe wird sich das Licht automatisch synchronisieren, wenn die Lampe abgeschaltet ist, stellt sich das Licht am feststehenden Arm auf die höchste Lichtstärke ein.

4.1.1 Regulierung:

a) Um die Lichtstärke zu mindern, den Joystick nach links (von hinter der Lampe aus gesehen) drücken, bis die gewünschte Lichtstärke erreicht worden ist.

Wenn die niedrigste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (1 Beep).

b) Um die Lichtstärke zu erhöhen, den Joystick nach rechts (von hinter der Lampe aus gesehen) drücken, bis die gewünschte Lichtstärke erreicht worden ist.

Wenn die höchste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (1 Beep).

c) Um auf die niedrigste Lichtstärke zu springen, vorne oder hinten auf dem Joystick drücken und loslassen. Sobald der Joystick ein weiteres Mal vorn oder hinten gedrückt wird, stellt sich die vorher gespeicherte Lichtstärke wieder ein.

Das Licht am feststehenden Arm reguliert sich synchron mit dem des Kopfes und kann nicht unabhängig reguliert werden.

4.1.2 Lampe / Kopf MIT SENSORSCHALTER

Einschalten /Ausschalten

Komplette Lampe: Sich dem Sensorschalter bis auf maximal 3 cm nähern, um die Lampe einzuschalten oder auszuschalten.

Lampe komplett mit Theia Tech Wie bei der kompletten Lampe, zusätzlich wird sich das Licht des feststehenden Armes synchron mit dem Kopf einschalten und/oder abschalten.

Regulierung

Komplette Lampe: Um die Lichtstärke zu regulieren, muss man in der Nähe des Sensorschalter stillhalten, bis die gewünschte Lichtstärke eingestellt ist. Man kann die Lichtstärke vom höchsten auf den niedrigsten und vom niedrigsten auf den höchsten Wert wechseln. Wenn die höchste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (2 Beep). Wenn die niedrigste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (1 Beep).

	Hinweis
	Bei jedem Einschalten der Lampe schaltet sich die Lichtstärke automatisch auf die beim Abschalten gespeicherte Stärke.

Komplette Lampe mit Theia Tech Wie bei der kompletten Lampe, zusätzlich wird sich das Licht des feststehenden Armes mit dem des Kopfes synchronisieren.

4.1.3 Lampe / Lampe komplett Theia Tech / Kopf“ALYA” MIT FERNBEDIENUNG

Einschalten /Ausschalten /Regulierung
- Zum Einschalten und Ausschalten den Drucktaster “A” drücken und loslassen.
- Regulierung:

a) Um die Lichtstärke zu mindern, den Drucktaster “A” gedrückt halten, bis die gewünschte Lichtstärke erreicht worden ist.
Wenn die niedrigste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (1 Beep).
b) Um die Lichtstärke zu erhöhen, den Drucktaster “A” gedrückt halten, bis die gewünschte Lichtstärke erreicht worden ist.
Wenn die höchste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (2 Beep).
c) Um sofort die niedrigste Lichtstärke zu haben, den Drucktaster “B” drücken.
Wenn die niedrigste Lichtstärke erreicht worden ist, ertönt ein akustisches Signal (1 Beep).
Mit einem weiteren Druck auf den Drucktaster stellt sich die Lampe wieder auf die vorher eingestellte Lichtstärke.

	Hinweis
	Bei jedem Einschalten der Lampe schaltet sich die Lichtstärke automatisch auf die beim Abschalten gespeicherte Stärke

4.1.4 4 LAMPE / LAMPE KOMPLETT MIT THEIA TECH / KOPFSTÜCK „ALYA” MIT SYNCHRONISATIONSBEFEHL

Wo vorgesehen, ist es möglich die Lampe Alya an die Raumlampe Faro kabellos anzuschließen, um ein synchronisiertes Beleuchtungssystem, genannt „Syncro“ zu schaffen.
Der Modus „**Syncro**” wurde speziell zur Verbesserung der Bequemlichkeit des Zahnarztes entwickelt, um den Effekt der Blendung zu reduzieren, der beim Übergang von einer Beobachtung einer stark beleuchteten Fläche (zum Beispiel Mundhöhle mit der OP-Lampe) zu einer schwach beleuchteten Fläche (zum Beispiel Köcher) entsteht.
Mit dem so genannten „**Syncro**”-Modus, der über die Taste auf dem Kopfstück der Lampe Alya aktiviert werden kann, ist es möglich die Beleuchtungsstärke durch die Raumlampe Faro automatisch basierend auf der Beleuchtungsstärke, die durch Alya produziert wird, zu ändern.
Hinweis: Zwischen der OP-Lampe und der Raumlampe kann eine kleine Verzögerung bei der Synchronisierung auftreten, dies erfolgt durch das Kommunikationsprotokoll, dieser Effekt ist normal und stellt keinen Defekt dar.
Die Funktion „**Syncro**” erfordert für ihre Aktivierung eine Paarung, genannt „**Pairing**“ (dies muss nur einmal durchgeführt werden), um die Verbindung zwischen den beiden Lampen herzustellen. Daraufhin kann die Funktion „**Syncro**” je nach Wunsch des Nutzers mit der Taste auf der OP-Lampe aktiviert und/oder deaktiviert werden.

VORGANG DES „PAIRING”

HINWEIS:

- Der Vorgang des „Pairing“ muss nur bei der ersten Verbindung durchgeführt werden. Er kann jedoch bei Austausch der Lampe Alya oder der Elektronik einer der beiden Lampen, die miteinander verbunden sind, wiederholt werden.

- Wenn in der Praxis mehrere Raumlampen vorhanden sein sollten, stellen Sie sicher, dass die anderen Lampen für mehr als 60 Sekunden eingeschaltet oder ausgeschaltet sind.

Für das „**Pairing**“ wie folgt vorgehen:

1. Die Raumlampe Faro, die sie paaren möchten, einschalten.
   Die Raumlampe bereitet sich maximal 60 Sekunden auf die Pairing-Verbindung vor.

2. Innerhalb dieser 60 Sekunden die Taste „**Syncro**“ auf der OP-Lampe mindestens 3 Sekunden, aber nicht mehr als 6 Sekunden lang drücken. Andernfalls wird der Vorgang abgebrochen. Nach Erhalt der Anforderung des „**Pairing**“ durch die OP-Lampe, aktiviert sich auf der Raumlampe die blaue LED auf dem Aluminiumrahmen. Wenn sich die blaue LED nicht aktiviert, können (innerhalb der 60 Sekunden nach dem Einschalten) weitere Versuche durchgeführt werden. Nach Ablauf dieser Zeit muss der Vorgang ab Punkt 1 wiederholt werden.

3. Ab dem Einschalten der blauen LED auf der Raumlampe gibt es weitere 60 Sekunden, um das „**Pairing**“ zu bestätigen, indem die Programmiertaste  auf der Fernsteuerung der Raumlampe gedrückt wird. Nun blinkt die blaue LED (der Raumlampe) zwei Mal und schaltet sich dann aus. Wenn innerhalb der 60 Sekunden die Taste  auf der Fernsteuerung nicht gedrückt wird, schaltet sich die blaue LED aus und der Vorgang muss ab Punkt 1 wiederholt werden.

Nach Abschluss des „**Pairing**“ ist die Synchronisierung der beiden Lampen aktiviert.

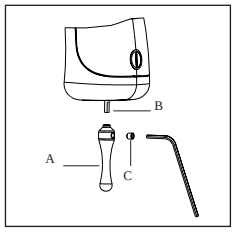
Um **DIE SYNCHRONISIERUNGSFUNKTION ZU AKTIVIEREN**, muss wie folgt vorgegangen werden: 2 Sekunden lang die Taste Syncro drücken und dann los lassen. Beim Loslassen ertönt ein Signalton (Piepton) und das Licht der blauen LED auf der Raumlampe leuchtet, um anzuzeigen, dass die Synchronisierung aktiviert wurde.

Um **DIE SYNCHRONISIERUNGSFUNKTION ZU DEAKTIVIEREN**, muss wie folgt vorgegangen werden: 2 Sekunden lang die Taste Syncro drücken und dann los lassen. Beim Loslassen ertönt ein Signalton (Piepton) und das Licht der blauen LED auf der Raumlampe schaltet sich aus, um anzuzeigen, dass die Synchronisierung deaktiviert wurde.

Hinweise bezüglich der Synchronisierung:

- Wenn die Raumlampe Faro synchronisiert ist (das heißt, sie steuert sich automatisch) mit der Lampe Alya, ist die blaue LED auf dem Rahmen fest eingeschaltet, wenn die LED ausgeschaltet ist, ist die Synchronisierung deaktiviert.
- Die Fernsteuerung ist immer aktiviert, daher ist es möglich die Beleuchtungsstärke zu ändern, aber wenn die Raumlampe sich im Synchronisierungszustand befindet (mit der blauen LED eingeschaltet), wird, sobald eine neue Einstellung an der Lampe Alya durchgeführt wird, die Beleuchtungsstärke sofort aktualisiert.
- Wenn die Lampe Alya ausgeschaltet werden muss, bleibt die Raumlampe mit der verwendeten Beleuchtungsstärke eingeschaltet.
- Wenn die Alya Lampe eingeschaltet werden muss, schaltet sich die Raumlampe automatisch ein.

.2 MONTAGE DES KIPPSCHALTERS JOYSTICKS ALYA



- Den Kippschalter “A” auf den Joystickzapfen einsetzen und einrasten lassen.
- Das Loch des Kippschalters “A” muss auf Höhe von “B” liegen.
- Die Madenschraube “C” mit dem Schraubenschlüssel bis zum Anschlag einschrauben.

	Achtung
	DDer Joystick muss vorsichtig bedient werden, um Schäden zu vermeiden. Beim Bedienen den Lampe den Joystick niemals zum Festhalten benutzen.

5. ORDENTLICHE WARTUNG

Die Lampe ist wartungsfrei.

6. REINIGUNG

	Warnung vor Gefahr durch Abnutzung und Herabfallen aufgehängter Massen
	Die Metall- und Kunststoffteile der Lampe dürfen auf keinen Fall mit Scheuermitteln, säurehaltigen, chlor- oder chlorionenhaltigen Lösungen, Reiniger auf Trichlor-, Benzin- oder Terpentinbasis oder ähnlichem gereinigt werden. Es ist verboten, Chemikalien direkt auf das Gerät zu sprühen.

6.1 REINIGUNG DER REFLEKTOREN

Die Reflektoren müssen mit einem weichen Lappen aus Baumwolle oder Watte und Ethylalkohol oder dem eigens dafür entwickelten Reiniger PERFLEX gereinigt werden. Zum Desinfizieren sind Wasser-Alkohol-Lösungen mit 70% Isopropyl- oder Ethylalkohol geeignet.

	Achtung - potenzielle Beschädigung der Reflektoren
	Niemals das Reinigungsmittel direkt auf die Reflektoren sprühen. Beim Reinigen der Reflektoren Handschuhe tragen, um keine Fingerabdrücke auf den Oberflächen zu hinterlassen. Keine Reinigungsmittel verwenden, die Tenside enthalten oder wasserabweisend sind, da diese Flecken hinterlassen können. Leichte Flecken beeinträchtigen nicht die Lichtqualität. Andere als die empfohlenen Produkte können die Reflektoren beschädigen. Bei Fragen den Kundendienst FARO kontaktieren.

6.2 REINIGUNG DES KOPFES

Die Reflektoren müssen mit einem weichen Lappen aus Baumwolle oder Watte und Ethylalkohol oder dem eigens dafür entwickelten Reiniger PERFLEX gereinigt werden. Zum Desinfizieren sind Wasser-Alkohol-Lösungen mit 70% Isopropyl- oder Ethylalkohol geeignet.

	Warnung vor Gefahr durch Beschädigung der Kunststoffteile und Herabfallen aufgehängter Massen
	Niemals das Reinigungsmittel direkt auf den Kopf sprühen. Zum Reinigen der Teile aus Kunststoff keine Reinigungs- und Desinfektionsmittel verwenden, die enthalten. • AMMONIAKWASSER • NATRIUMHYDROXID • METHYLENCHLORID • METHYLALKOHOL • SÄUREN Faro empfiehlt die folgenden in seinem Labor getesteten Desinfektionsmittel: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

6.3 REINIGUNG DER ARME

Zum Reinigen immer mit einen mit einem der empfohlenen Desinfektionsmittel angefeuchteten Lappen über die Oberflächen gehen.

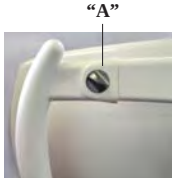
	Warnung vor Gefahr durch Rosten und mechanisches Versagen mit Herabfallen aufgehängter Massen
	Niemals Chemikalien direkt auf die Arme, die Gelenke und ihre Öffnungen sprühen.
	Warnung vor Gefahr durch Beschädigung der Kunststoffteile und Herabfallen aufgehängter Massen
	Zum Reinigen der Teile aus Kunststoff keine Reinigungs- und Desinfektionsmittel verwenden, die enthalten. • AMMONIAKWASSER • NATRIUMHYDROXID • METHYLENCHLORID • METHYLALKOHOL • SÄUREN Faro empfiehlt die folgenden in seinem Labor getesteten Desinfektionsmittel: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

7. STERILISATION DES GRIFFES

	Warnung - Gefahr der Kreuzkontamination
	Die Griffe werden nicht steril geliefert und müssen vor dem Gebrauch sterilisiert werden. Die Griffe müssen vor jedem neuen Patienten sterilisiert werden.

7.1 Abnehmen der Griffe

Um die Griffe abzunehmen, den Drehknauf “A” abdrehen und von der Halterung ziehen.



7.2 Dekontamination und Desinfektion

Vor dem Sterilisieren der Griffe müssen sie dekontaminiert und desinfiziert werden.
Faro hat die folgenden Desinfektionsmittel in seinem Labor getestet: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

	Achtung - Gefahr der Beschädigung von Plastikteilen
	Die Griffe dürfen zur Desinfektion nicht in einem Thermodesinfektor gereinigt werden.

7.3 Sterilisation

Die Griffe müssen in EN 868-5 konformen Beutel gesteckt werden. Die Griffe können mit Standardzyklen bei 121°c /134° C bis zu zweihundert (200) Mal oder in jedem Fall bis sie ihre mechanische Leistung verloren haben, sterilisiert werden. Die Zyklusparameter für die Sterilisation sind:

Zyklus EN 13060	Temperatur	Druck	Verweilzeit
B	121°C	207 KPa	15 min
B	134°C	308 KPa	3 min

8. REGELMÄSSIGE KONTROLLEN

Kontrolle	Häufigkeit	Anwendbarkeit		Verfahren	Eignung
		LD	TE		
Prüfen, dass zwischen den Armgelenken kein Spiel ist	Jährlich	x	N/A	Prüfen, dass sich das Licht zwischen den Gelenken 5 und den Armen nicht seit dem ersten Gebrauch verändert hat	Benutzer
Die Lesbarkeit des Typenschild prüfen	Jährlich	x	x		Benutzer
Die Unversehrtheit der Ummantelungen prüfen	Alle zwei Jahre				Wartungs-techniker
Die elektrischen Sicherungen nach EN 62353 prüfen: 1. Durchschlagsfestigkeit 2. Ableitstrom	Alle zwei Jahre	x	x	Die Durchschlagsfestigkeit und den Ableitstrom an der Ummantelung messen. Die Grenzwerte sind in der IEC 60601-1 festgelegt.	Wartungs-techniker
Kontrolle der Lichtparameter	Alle zwei Jahre	x	x	Mit einem Spektralradiometer die folgenden Werte messen: • Höchste Beleuchtungsstärke: >35000 lux • Abnahme des CRIs: <20%. • Öffnungswert des blauen Lichts auf dem emittierten Spektrum gemessen in: <100 W/m2	Wartungs-techniker

Wartungstechniker: Für die Wartung von elektromechanischen Geräte qualifizierte Person

9. AKUSTISCHE SIGNALE

9.1 Akustische Signale

OpL** = Beep 30 Sekunden
OTP* = Beep 30 Sekunden

* OTP: Überhitzungsschutz LED.
** OpL: Leistungsabgabe LED vom Netz getrennt
.

9.2 LEITFADEN FÜR PROBLEME

Die unten stehende Tabelle ist ein Leitfaden für potenzielle Störungen an der Lampe
Wenn das Problem nicht behoben werden kann, bitte den technischen Kundendienst rufen

Wirkung	Ursache	Behebung (Wartungstechniker - WT)	Verantw.
Die Lampe schaltet sich nicht ein	Stromversorgung nicht oder nicht korrekt eingesteckt.	Prüfen, ob die Stromversorgung eingesteckt und die Dentaleinheit eingeschaltet ist.	Benutzer
	Störung mit Elektrokauter oder Hochfrequenz-Geräten	Den Elektrokauter anstellen und prüfen, ob die Störung anhält.	Benutzer
	Der Schalter ist am Joystick falsch angebracht.	Zum Einschalten und Ausschalten den Joystick nach links oder rechts drücken und loslassen.	Benutzer
Die Lampe flimmert	Störung mit Elektrokauter oder Hochfrequenz-Geräten.	Den Elektrokauter anstellen und prüfen, ob die Störung anhält.	Benutzer
Die Lichtstärke der Lampe lässt sich nicht regulieren	Der Schalter ist am Joystick falsch angebracht.	Den Schalter gemäß der Bedienungsanleitung korrekt bedienen.	Benutzer
	Störung mit Elektrokauter oder Hochfrequenz-Geräten.	Den Elektrokauter anstellen und prüfen, ob die Störung anhält.	Benutzer
Die Lichtstärke ist merklich vermindert	Reflektoren oder LED Linsen sind schmutzig.	Die Reflektoren und die LED-Linsen reinigen.	
	Verwendung falscher Verfahren.	Prüfen, ob die Schaltung überprüfen.	Benutzer
Auf den Reflektoren (Parabeln) haben sich Flecken gebildet oder die reflektierende Schicht ist abgegangen.	Verwendung nicht empfohlener Produkte.	Die Oberflächen mit dem spezifischen Produkt “Faro Perflex” reinigen. Die Oberflächen mit Isopropylalkohol reinigen, Um die Oberflächen wieder herzustellen, muss der Reflektor vom technischen Kundendienst ersetzt werden.	Benutzer
Die Lampe kippt und neigt herunterzuklappen.	Kopf zu stark belastet (Spiegel, Videokameras usw.)	Die übermäßige Last entfernen.	Benutzer
Die Lampe steuert nicht	Funktion syncro ausgeschaltet	Die Funktion aktivieren, siehe 4.1.4	Benutzer

10. TECHNISCHE CHARAKTERISTIKEN

Komplette Lampe:
Versorgungsspannung (ohne Transformator):
- 17÷24Vac ±10% - 50/ 60Hz;
- 22÷35Vdc ±10%

Absorbierte Leistung:
- 26VA (Version 17÷24Vac);
- 14VA (Version 22÷35Vdc)

empfohlene Sicherungen:
- Version 17÷24Vac: T1.6AL 250V
- Version 22÷35Vdc: T630mAL 250V

Schutz gegen elektrische Gefahren:
- Gerät der Klasse II

Klassifizierung EN 62471
- Klasse Excempt

Version Lampe komplett mit Theia Tech
Versorgungsspannung (ohne Transformator):
- 24Vac ±10% - 50/ 60 Hz
- 24Vdc ±10%

Absorbierte Leistung:
- 40VA (Version 24Vac)
- 28VA (Version 24Vdc)

empfohlene Sicherungen:
- T2AL 250V

Schutz gegen elektrische Gefahren:
- Gerät der Klasse II

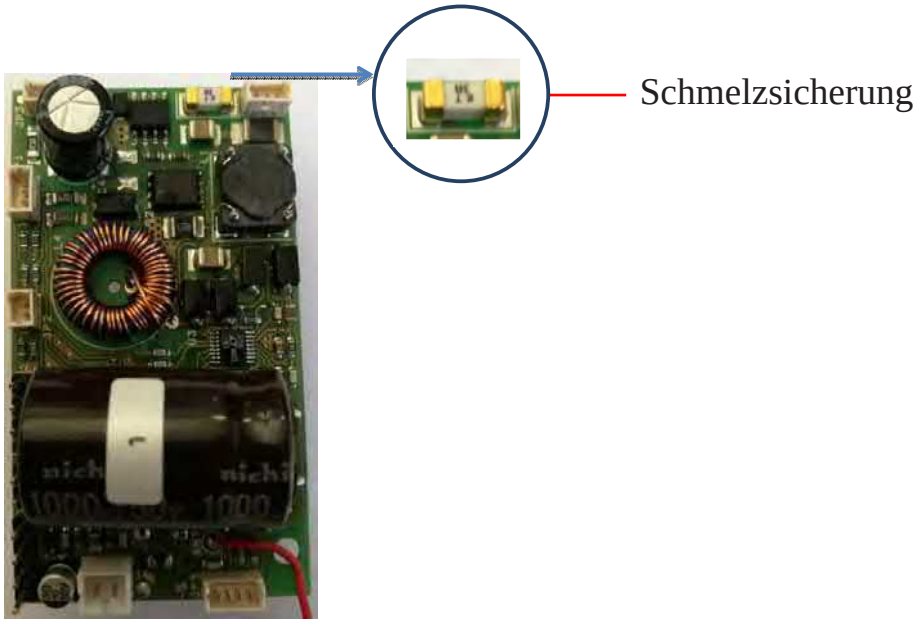
Klassifizierung EN 62471
- Klasse Excempt

Optische Eigenschaften des vom Kopf erzeugten Lichts gemäß ISO 9680
Abmessungen des Lichtstrahls 180 mm x 90 mm
Lux: 3.000*-50.000* lux @700mm
Farbtemperatur: 5000 K*
CRI (color rendering index): >95*

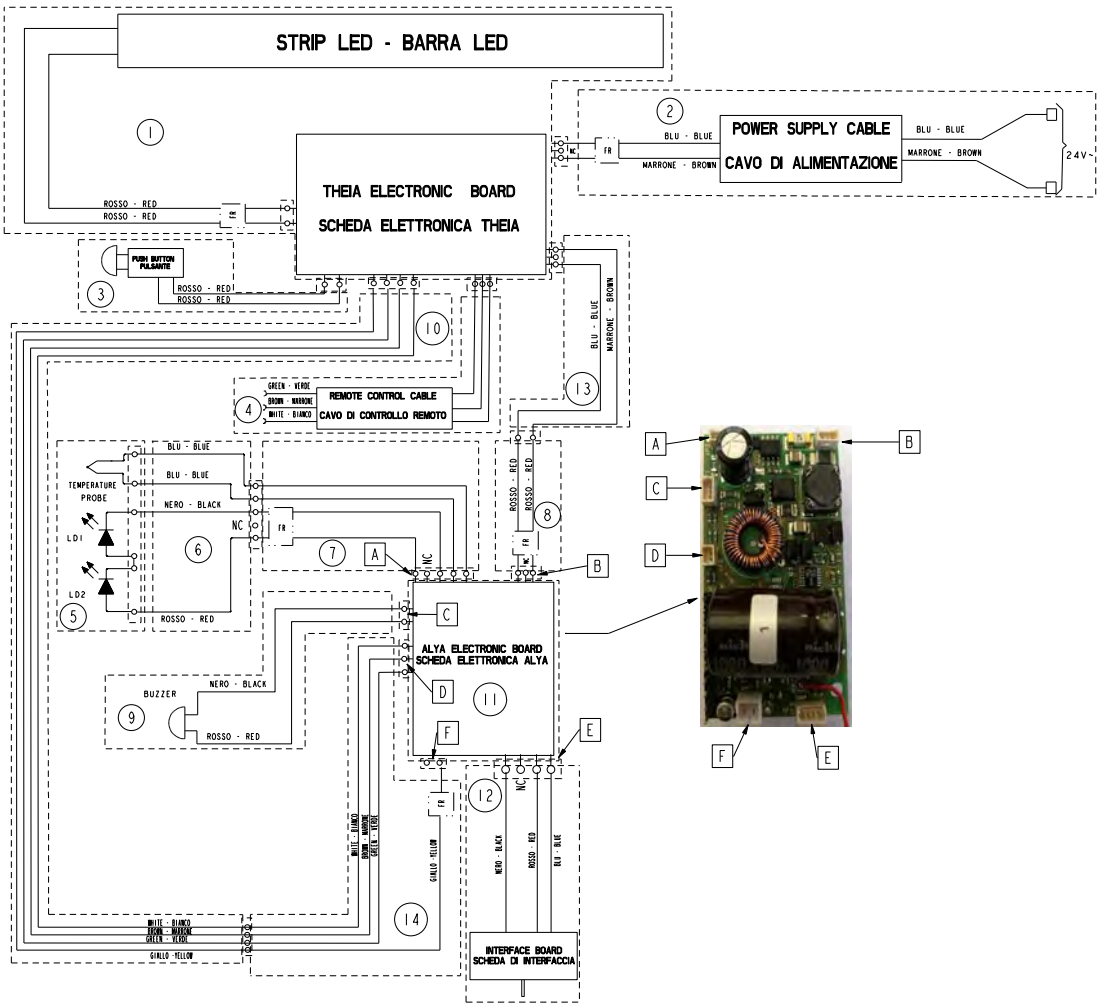
* Typische Werte mit Toleranzbereichen
Etikettierung gemäß EN 62471: nicht notwendig.

10.1 SCHALTPLÄNE

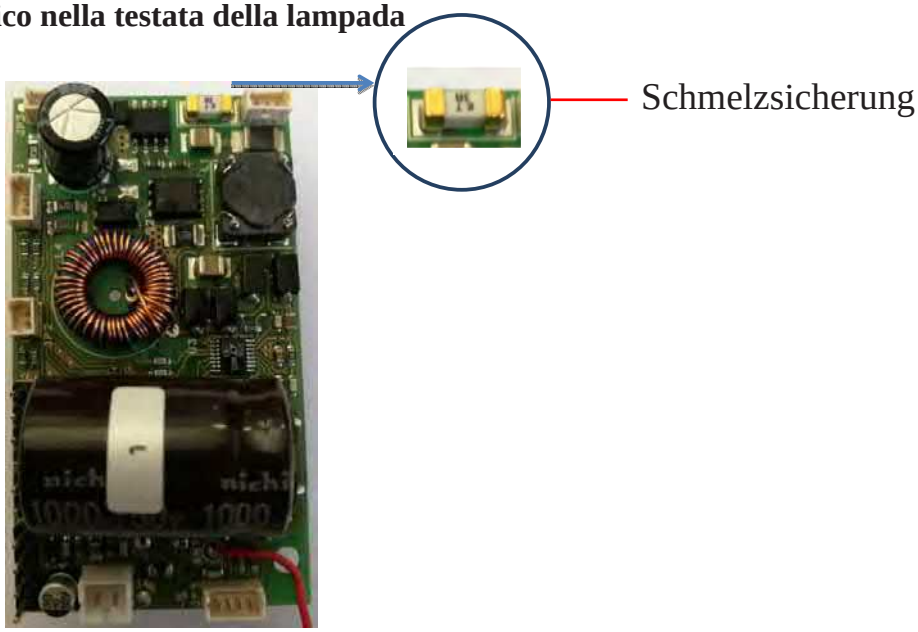
- **Komplette Lampe:**
  Stromkreislauf im Kopf der Lampe



Schaltplan - Alya ohne Transformator

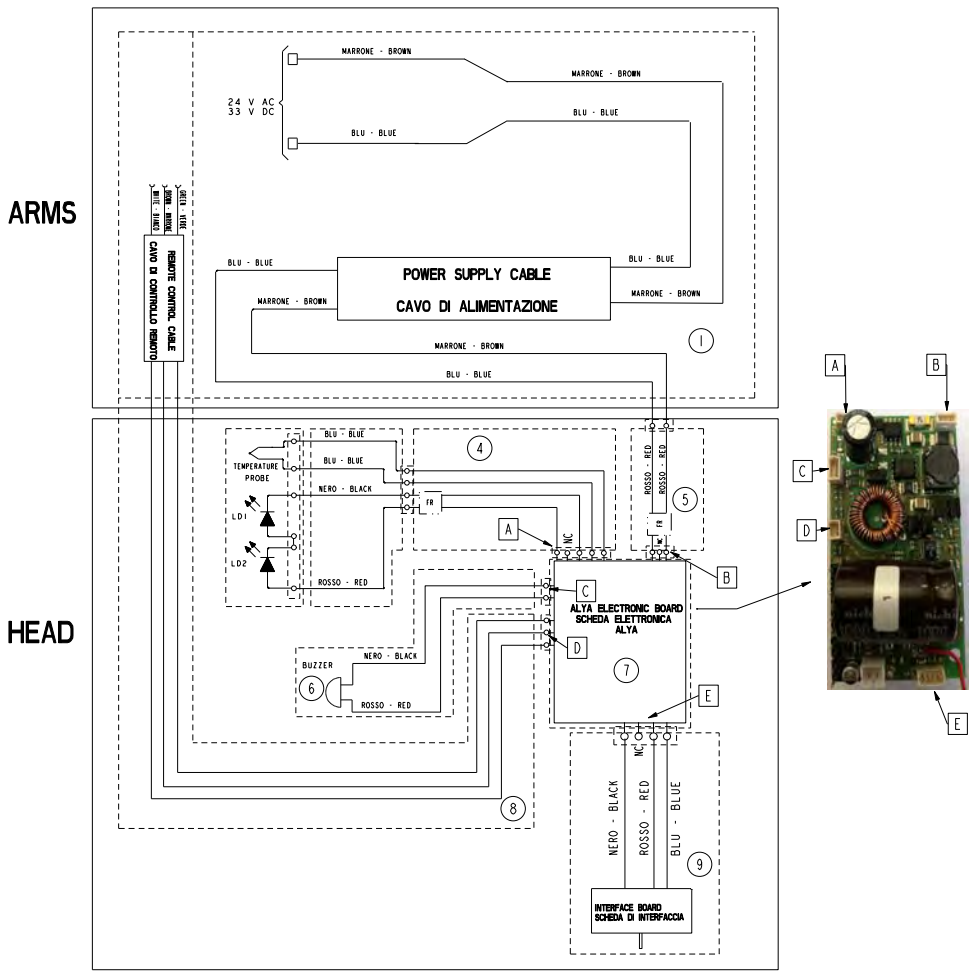


- **Lampada completa Theia Tech:**
  Circuito elettrico nella testata della lampada

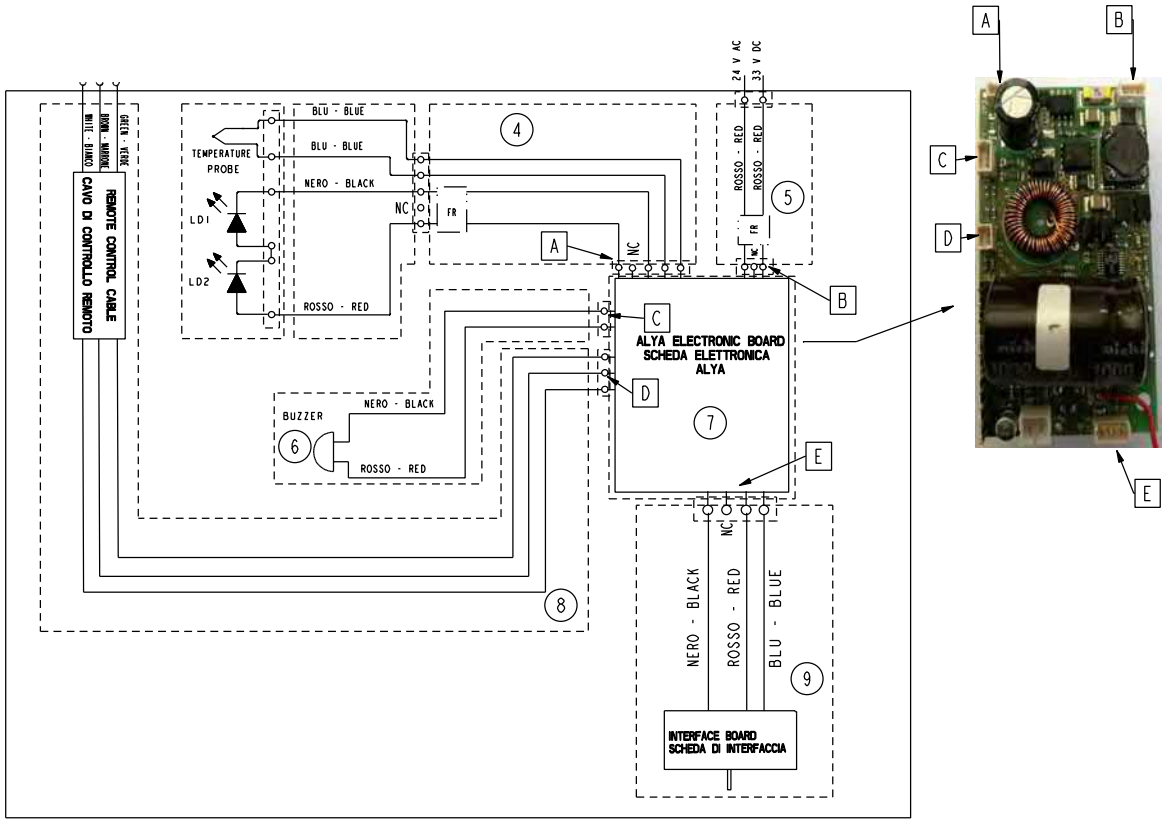


Stromkreislauf im hinteren Arm

Schaltplan – Alya Theia Tech.



- ***Kopf:*** *Schaltplan - Alya Kopf*



ÍNDICE

1. REQUISITOS DE SEGURIDAD

Estimado Cliente:
FARO le desea buen trabajo con la nueva lámpara de alta calidad. Para trabajar en modo seguro y para aprovechar al máximo las performances del producto, lea atentamente el presente manual antes del uso del dispositivo. Siga particularmente todas las advertencias y las notas indicadas.

1.1 SIMBOLOGÍA UTILIZADA

1.1.1 Simbología usada en el interior del manual

 *ADVERTENCIA*
Los párrafos que llevan este símbolo contienen instrucciones que deben ser efectuadas atentamente para evitar daños al dispositivo, al operador y al paciente.

 *ATENCIÓN*
Estas instrucciones avisan que es necesario prestar mucha atención para evitar situaciones que podrían dañar el dispositivo.

 *PROHIBICIÓN*
Este icono resalta lo que no se debe hacer para evitar daños al dispositivo.

 *NOTAS*
Con este icono, se da una información que permite usar el dispositivo en modo más eficaz.

1.1.2 Simbología presente en el etiquetad

La placa de datos está fijada:
• para la lámpara completa: en el brazo trasero
• para la cabeza: debajo del cubre-disipador e indica los siguientes datos:
Serial Number (SN): año (AA) / familia de pertenencia (LD para lámpara dental - TE solo para la cabeza) más el número progresivo (NNNNNN) ej.: SN14LD000001 para la lámpara completa SN 14TE000001 para la cabeza.
Además están presentes los siguientes símbolos armonizados:

	Lea las instrucciones para el uso suministradas electrónicamente
	Símbolo del fabricante en conformidad con la Directiva 93/42/EEC
	Las instrucciones de uso incluyen advertencias para la seguridad
	Equipo RAEE en conformidad con la directiva 1012/19/CE. Elimine el producto de acuerdo con esta directiva.
	Doble aislamiento. Dispositivo de clase 2 contra el riesgo eléctrico
	Serial Number / Número de Serie
	Esterilizable por Calor Húmedo a 134°C
	Utilice el dispositivo a una temperatura entre 10°C y 40°C
	Utilice el dispositivo a una presión entre 800 y 1060 mbar
	Utilice el dispositivo a una humedad relativa entre 30 RH y 75RH
	Símbolo para el ajuste de la intensidad luminosa
	Símbolo para el encendido de la lámpara
	[Símbolo para el encendido/apagado de la luz en el brazo trasero]

1.1.3 Simbología presente en el embalaje

ALTO

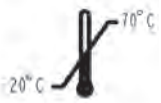
FRÁGIL

NO MOJE

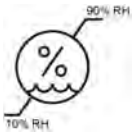
NO RUEDE

NO USE GANCHOS

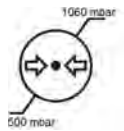
PESO MÁX SUPERPONIBLE



TEMPERATURA DE ALMACENAMIENTO
CONDICIONES DE TRANSPORTE



HUMEDAD RELATIVA



CARTÓN RECICLABLE

1.2 USO PREVISTO

El dispositivo está destinado a ser utilizado exclusivamente en el gabinete odontológico por médicos odontólogos, odontoestomatólogos e higienistas, para la iluminación del lugar operatorio y de intervención en el tratamiento de las patologías de la cavidad oral y del aparato dental.
En su uso normal, el dispositivo está colocado sobre el cuerpo del paciente a una distancia de 700 mm, para la cual están estudiadas las características de iluminación.
Los pacientes tratados pueden ser de todas las edades por patologías típicas de aparato dental.

1.3 UTILIZADOR PREVISTO

El utilizador previsto es el médico dentista, odontólogo o el higienista dental.

1.3.1 Título de estudio:

- Doctorado en medicina con especialización en odontoestomatología.
- Doctorado en odontología.
- Doctorado en higiene dental.

1.3.2 Competencia mínima

- Las previstas por el título de estudio.
- Comprensión del lenguaje: La adquirida con el título de estudio.

1.3.3 Experiencia

- La prevista para el cumplimiento de la profesión.

1.3.4 Posibles handicaps del utilizador

- Para el uso es necesario poder utilizar una extremidad superior completa.
- Facultades visivas compatibles con la profesión.

1.4 NORMAS GENERALES Y PRINCIPALES ADVERTENCIAS

- El dispositivo puede aplicarse a la unidad dental, pero también puede instalarse en aplicaciones dedicadas. El dispositivo puede ser alimentado tanto por la unidad dental como por un alimentador conectado directamente a la red. Véase el párrafo dedicado a la instalación.
- El dispositivo no tiene performances esenciales de modo que la inadecuación de sus prestaciones no perjudica la seguridad del paciente.
- El dispositivo no sostiene la vida.
- El dispositivo debe limpiarse antes del uso (véase el párrafo “Limpieza del dispositivo”).
- El embalaje de la lámpara es adecuado para protegerla de la penetración de agentes externos.

	**Advertencia contra el peligro eléctrico o de incendio**
	No use la lámpara en caso de daños de sus componentes. La instalación del dispositivo debe ser efectuada solo por personal cualificado. La lámpara dental debe ser instalada en un dispositivo específico de control y de alimentación, como unidades dentales, o con instalación eléctrica que satisfaga la norma IEC 60364-1 y las “reglas nacionales de instalación para instalaciones eléctricas en locales destinados a uso médico”. El aparato debe ser instalado con un dispositivo de separación de la red de tipo omnipolar y conforme con Norma IEC 61058-1. La instalación y el mantenimiento de la conformidad del dispositivo con norma IEC 60601-1 son a cargo del instalador o del fabricante de unidades. Controle que la tensión de alimentación, indicada en la placa de datos, corresponda con la de la red. No efectúe ninguna intervención de mantenimiento en la lámpara cuando la alimentación esté conectada: desconecte pues el cable de alimentación de la red antes de intervenir.
	**Advertencia contra el peligro de degradación de las piezas mecánicas y caída de masas suspendidas**
	Para la limpieza de las piezas de plástico, no utilice detergentes que contengan: HIDRÓXIDO AMÓNICO, HIDRÓXIDO SÓDICO, CLORURO DE METILENO, ALCOHOL METÍLICO. El incumplimiento de la prescripción puede causar: RIESGO DE DEGRADACIÓN DE LAS PIEZAS DE PLÁSTICO CON CONSIGUIENTE ROTURA. No rocíe ningún agente químico directamente en la lámpara. Particularmente, está prohibido el uso de sustancias abrasivas, ácidas, que contengan cloro.
	**Advertencia sobre el riesgo de caída de masas suspendidas**
	Aténgase escrupulosamente al respeto de las cargas máximas previstas. No impacte o sobrecargue los topes de los brazos y las cabezas.
	**Advertencia sobre el peligro fotobiológico y de deslumbramiento**
	No fije ni apunte el haz luminoso directamente en los ojos del paciente sobre todo en los pacientes de mayor riesgo de lesiones oculares (ej. niños con patologías a los ojos). En este caso utilice siempre adecuadas protecciones y precauciones. La lámpara está clasificada como de riesgo fotobiológico Exempt de acuerdo con la EN 62471. Sin embargo, no se excluye que pacientes particularmente fotosensibles o que hayan tomado medicinas fotosensibilizadoras, puedan tener eritemas o reacciones alérgicas a la luz. En este caso suspenda el tratamiento y utilice niveles de iluminación muy bajos.El brazo articulado y las articulaciones de la lámpara permiten la correcta colocación del haz luminoso.
	**Advertencia sobre el peligro de daños de los componentes eléctricos**
	No sobrecargue los brazos y las articulaciones con choques en los topes. La rotación de la cabeza y de los brazos más allá de los topes puede dañar los aislamientos de los conductores.
	**Advertencia sobre el peligro de explosión**
	El dispositivo no es adecuado para ser instalado en ambientes con presencia de gas inflamable o riesgos de oxígeno.
	**Advertencia sobre el peligro de contaminación cruzada paciente-paciente**
	El médico está obligado a usar las protecciones monouso en las manijas de la lámpara o a esterilizarlas después de cada paciente. Para la desinfección de las superficies use desinfectantes hidroalcohólicos (véase el párrafo mantenimiento/limpieza.
	**Advertencia sobre el peligro de mantenimiento errado**
	No efectúe operaciones de mantenimiento o de sustituciones de piezas distintas de las indicadas en el manual. Toda intervención no indicada en el manual puede comprometer el aspecto de seguridad previsto por el dispositivo. Efectúe solo las operaciones de mantenimiento indicadas en el manual; en todo otro caso, diríjase a la asistencia técnica.

El producto está cubierto por la Directiva RAEE 2012/19/UE
Para el desguace y la eliminación aténgase normativa vigente en su país, eventualmente dirigiéndose a empresas especializadas, reconocidas y autorizadas.
Al final del ciclo de vida divida los materiales sobre la base de su tipología (ferrosos, goma, plástico). No deje los pequeños componentes del equipo sin vigilancia o al alcance de personas expuestas (niños) porque son potenciales fuentes de peligro.
La sociedad FARO no admite ninguna modificación del producto que no haya sido expresamente autorizada por escrito bajo pena del vencimiento de la conformidad con las normas de seguridad y de la garantía.
Otras advertencias se indican en los títulos del presente manual.

1.5 CONSERVACIONES Y UTILIZACIÓN: PRESCRIPCIONES AMBIENTALES

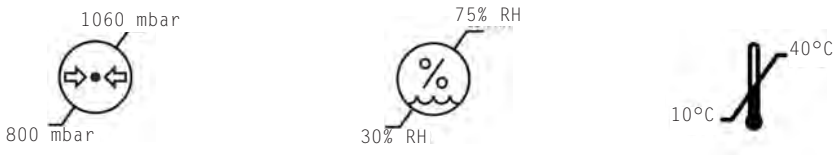
En su embalaje original, el aparato puede ser transportado o mantenido en un almacén por un período de 15 semanas si se respetan las siguientes condiciones ambientales:

- Temperatura ambiente de -20°C a + 70°C
- Humedad relativa del 10% al 90%
- Presión atmosférica de 500 a 1060 mbar

El aparato debe ser utilizado a las siguientes condiciones ambientales:

- Temperatura de 10°a 40°C
- Altura máx: 2000 m
- Humedad relativa de 30 a 75%

PRESIÓN ATMOSFÉRICA **HUMEDAD RELATIVA** **TEMPERATURA DE UTILIZO**



1.6 REQUISITOS PARA LA COMPATIBILIDAD ELECTROMAGNÉTICA

El dispositivo médico necesita precauciones especiales con respecto a la compatibilidad electromagnética, y debe ser instalado según las informaciones indicadas en los documentos que lo acompañan.

Guía y declaración del fabricante – Emisiones electromagnéticas		
La lámpara ALYA ha sido ideada para poder funcionar en el ambiente electromagnético que se especifica a continuación. El cliente o el usuario debería asegurarse de que la misma se utilice en dicho ambiente.		
Prueba di Emisión	**Conformidad**	**Ambiente Electromagnético - Guía**
RF Emission CISPR15	Conforme	La lámpara ALYA utiliza energía RF sólo para el funcionamiento interno. Por ello sus emisiones RF son muy bajas e incluso no causan ninguna interferencia a los aparatos electrónicos cercanos.
RF Emission CISPR15	Conforme	La lámpara ALYA es idónea para ser utilizada en todos los edificios, incluso los domésticos y aquellos directamente conectados a la red de alimentación pública de baja tensión que alimenta edificios para uso doméstico.
Harmonic emission	Class C	
RF Emission CISPR11 / EN 55011	Conforme	La lámpara ALYA no es adecuada para interconectarse con otros dispositivos (versión de techo).

INMUNIDAD ELECTROMAGNÉTICA

Guía y declaración del fabricante – Inmunidad electromagnética		
La lámpara ALYA ha sido ideada para poder funcionar en el ambiente electromagnético que se especifica a continuación. El cliente o el usuario debería asegurarse de que la misma se utilice en dicho ambiente.		
Prueba de Inmunidad	**Conformidad**	**Ambiente Electromagnético - Guía**
Electrostatic discharge (ESD) IEC/EN61000-4-2	± 6kV contact ± 8kV air	Los pavimentos deben ser de madera, hormigón o cerámica. Si los pavimentos están recubiertos de material sintético, la humedad relativa debería ser por lo menos del 30%
Electrical fast transient/burst IEC/EN61000-4-4	± 2kV power supply ± 1kV for input/output lines	La calidad de la tensión de red debería ser la de un típico ambiente comercial u hospitalario.
Surge IEC/EN61000-4-5	± 1kV differential mode ± 2kV common mode	La calidad de la tensión de red debería ser la de un típico ambiente comercial u hospitalario.
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.	La calidad de la tensión de red debería ser la de un típico ambiente comercial u hospitalario. Si el usuario de la lámpara ALYA necesita un uso continuado incluso en ausencia de tensión de red, se recomienda el uso de un grupo de continuidad.
Power frequency magnetic field IEC/EN61000-4-8	3A/m	Nivel de campo magnético a la frecuencia de red típico de un ambiente comercial u hospitalario.
Inmunidades Conducidas IEC/EN61000-4-6	3Vrms 150kHz to 80MHz (para aparatos que no son life-supporting)	Los aparatos de comunicación RF portátiles y móviles no deberían ser usados cerca de ninguna parte de la unidad dental, incluidos los cables, excepto cuando se respetan las distancias de separación recomendadas, calculadas a partir de la ecuación aplicable a la frecuencia del transmisor. Distancias de separación recomendadas: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ da 80 Mhz a 800 MHz $d = 2,3\sqrt{P}$ da 800 MHz a 2,5 GHz Donde P es la potencia máxima nominal de salida del transmisor en Watt (W) según el fabricante del transmisor y d es la distancia de separación recomendada en metros (m). La intensidad del campo de los transmisores RF fijos, como determinado por un estudio electromagnético del sitio a, podría ser menor del nivel de conformidad de cada intervalo de frecuencia. Pueden producirse interferencias en proximidad de aparatos marcados con el siguiente símbolo:
Inmunidades Conducidas IEC/EN61000-4-6	3Vrms 80MHz to 2.5GHz (para aparatos que no son life-supporting)	

Nota: Ut es el valor de la tensión de alimentación.
Nota 1: A 80 MHz y 800 Mhz se aplica el intervalo de la frecuencia más alta.
Nota 2: Estas directrices podrían no ser aplicadas en todas las situaciones. La propagación electromagnética se ve influenciada por la absorción y la reflexión de estructuras, objetos y personas.
a) Las bandas ISN (industriales, científicas y médicas) entre los 150kHz y los 80MHz son 6,765 MHz a 6,795MHz, 13,553 MHz a 13,567MHz, 26,957 MHz a 27,283 MHz y 40,66 MHz a 40,70 MHz.
b) Los niveles de conformidad en las bandas ISN entre 150kHz y 80MHz y en las bandas 80MHz a 2,5GHz decrecen debido a la probabilidad de que un dispositivo de transmisión portátil puede causar interferencias si en un descuido se introduce en la zona del paciente. Por esta razón, un factor adicional de 10/3 ha sido incorporado en la fórmula utilizada para el cálculo de la distancia de separación de los transmisores.
c) Las intensidades de campo para los transmisores fijos como las estaciones de base para radioteléfonos (móviles e inalámbricos) y teléfonos móviles terrestres, aparatos de radioaficionados, transmisores de radio en AM y FM y transmisores TV no pueden ser previstas teóricamente y con precisión. Para establecer un ambiente electromagnético causado por transmisores RF fijos, debería tenerse en cuenta un estudio electromagnético del sitio. Si la intensidad de campo medida en el lugar en el cual se usa la unidad dental supera el nivel de conformidad aplicable antes citado, debería someterse bajo observación el funcionamiento normal de la lámpara. Si se notan prestaciones anormales, pueden resultar necesarias medidas adicionales como una orientación o posición de la lámpara diferente.
d) La intensidad de campo en un intervalo de frecuencias de 150 kHz a 80 MHz debería ser menor que 3 V/m.

Distancias de separación recomendadas entre aparatos de radiocomunicación portátiles y móviles y la unidad dental			
La lámpara ALYA ha sido ideada para funcionar en un ambiente electromagnético en el cual se encuentran bajo control las interferencias irradiadas RF. El cliente o el operador de la unidad pueden contribuir a prevenir interferencias electromagnéticas asegurando una distancia mínima entre aparatos de comunicación móviles y portátiles RF (transmisores) y la unidad dental, como se recomienda a continuación, en relación con la potencia de salida máxima de los aparatos de radiocomunicación.			
Potencia de salida nominale máxima del transmisor W	**Distancia de separación a la frecuencia del transmisor m**		
	150 kHz a 80 MHz $d = 1,2\sqrt{P}$	80 MHz a 800 MHz $d = 1,2\sqrt{P}$	800 MHz a 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

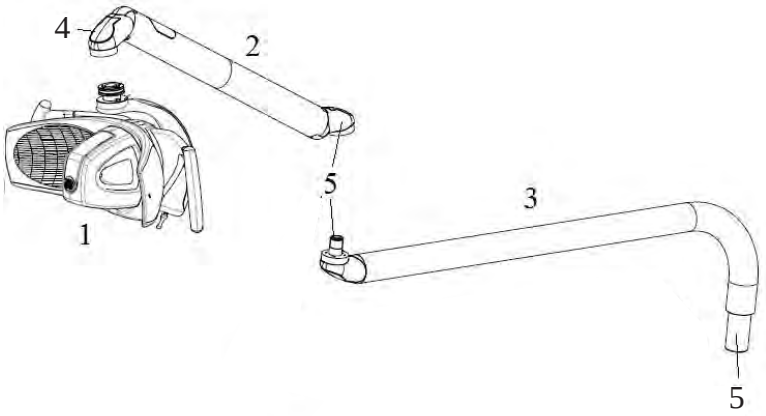
Para los transmisores con potencia nominal máxima de salida antes no indicada, la distancia de separación recomendada d en metros (m) puede ser calculada utilizando la ecuación aplicable a la frecuencia del transmisor, donde P es la potencia máxima nominal de salida del transmisor en Watt (W) según el fabricante del transmisor.
Notas:
A 80 MHz y 800 MHz se aplica el intervalo de la frecuencia más alta.
Estas directrices podrían no aplicarse en todas las situaciones. La propagación electromagnética se ve influenciada por la absorción y la reflexión de estructuras, objetos y personas.

2. CARACTERÍSTICAS GENERALES

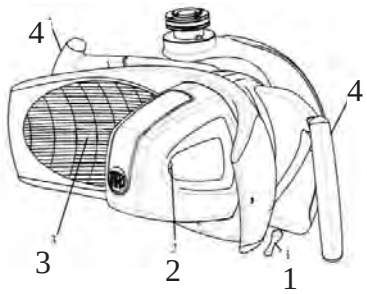
2.1 DESCRIPCIÓN DEL PRODUCTO

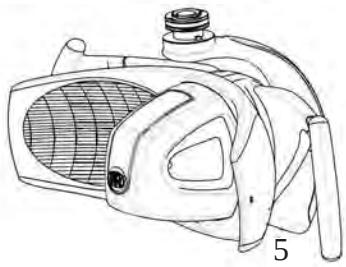
El dispositivo sirve al utilizador previsto para la iluminación del campo operatorio en el tratamiento de las patologías del aparato dental.
La fuente luminosa colocada en la cabeza se compone de dos LED cuya luz se refleja sobre dos parábolas pasando por dos lentes secundarias.
Los reflectores permiten obtener un spot de luz regular y uniforme a todo nivel de iluminación y distribuir uniformemente la luz en el campo operativo, sin crear sombras u oscurecimientos por parte del operador.
El ajuste de la intensidad luminosa puede efectuarse con un joystick o con proximity. El proximity permite encender o apagar la lámpara sin tener un contacto directo, eliminando así la posibilidad de infecciones cruzadas en el mando.
La función "encendido automático" o "Auto-on" permite a la lámpara encenderse automáticamente cada vez que se activa la alimentación de la lámpara.
El cable remoto permite poner los mandos de la lámpara en la aljaba de la unidad. Aténgase a las instrucciones dadas en el párrafo de instalación.
En la cabeza, en proximidad de la palanca de mando y/o del sensor proximity hay una tecla que permite activar la función de sincronización con la lámpara ambiente producida por Faro. La función de sincronización permite a la lámpara Alya mandar el nivel de alumbrado de la lámpara ambiente a fin de garantizar un nivel de alumbrado más uniforme entre el campo operatorio y la zona circunstante en modo de reducir el efecto de deslumbramiento y mejorar el confort visivo.
En la versión con la luz en el brazo trasero denominada "Alya con Theia Tech" la fuente luminosa se compone de una serie de LED cuya luz, al pasar a través de un difusor, es distribuida por el ambiente subestante.
[El ajuste del nivel de iluminación se efectúa en sincronía con el de la cabeza, de modo que al reducir o aumentar la iluminación de la luz producida por la cabeza, se ajusta por consiguiente también la del brazo.
La lámpara versión "Theia Tech" tendrá además un mando local destinado solo a suministrar on/off en el brazo fijo.
Una vez encendida por el mando local, la luz se sincroniza automáticamente con el nivel de intensidad de la cabeza. Si la luz de la cabeza está apagada, la luz en el brazo trasero se enciende a la máxima intensidad. Al sucesivo encendido de la luz en la cabeza, la luz en el brazo se sincroniza automáticamente.
La luz en el brazo cumple la función de incrementar la visibilidad en la zona pre-operatoria reduciendo el deslumbramiento que se genera luego y/o sucesivamente a la visión del campo operatorio.
El mantenimiento está facilitado gracias a la aplicación de nuevas tecnologías que toman en consideración las varias exigencias en cuanto a seguridad, ergonomía e higiene.
Las manijas son separables y esterilizables. Aténgase a las prescripciones definidas en la sección dedicada.
Para las conexiones eléctricas aténgase a las instrucciones dadas en el párrafo instalación y a los esquemas alámbricos incluidos en este manual.

2.2 DESCRIPCIÓN DE LAS PIEZAS

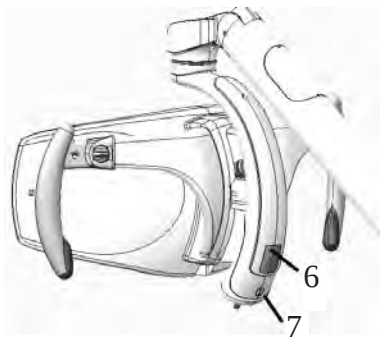


1 – Cabeza
2 – Brazo central
3 – Brazo trasero sin transformador con o sin luz (Theia Tech)
4 – Articulaciones
5 – Perno para conexión a la unidad o a la aplicación



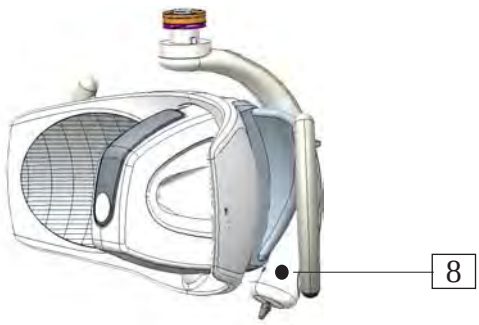


1 – Joystick
2 – Lente secundaria LED
3 – Reflector
4 – Manijas esterilizables
5 – Proximity

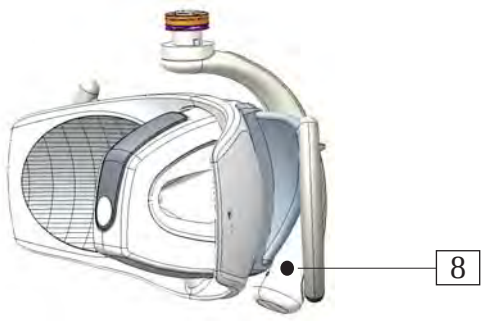


6 – Alojamiento de la tarjeta electrónica
7 – Símbolos de encendido y ajuste
8 – Tecla de sincronización

Versión con joystick



Versión con sensor de proximidad



2.3 IDENTIFICACIÓN DEL DISPOSITIVO

Las variedades en comercio se diferencian por:

- Tipo de dispositivo (lámpara completa, lámpara completa con Theia Tech o cabeza)
- Interfaz de encendido y ajuste (**Joystick o Proximity; para lámpara completa y cabeza)**
- Modalidad de control de unidad (función on-off, control remoto; para lámpara completa y cabeza)
- Tipo de montaje **(unidad, techo, pared o piso; solo para lámpara completa)**
- Longitud de los brazos (solo para lámpara completa)
- Alimentación (con o sin transformador, solo para lámpara completa)

El desarrollo de los códigos es el siguiente:

ALYA – Lámpara completa					
Type	3° digit Mounting y control de unidad	4° digit – Voltaje y interfaz	5° digit – brazo post x brazo central (mm)	6° digit Disponible	7° 8° 9° digit Adaptación al cliente
5 1	0 Unidad estándar	0 Joystick 17-24 V AC 22-35 V DC	0 810x550	0	000 (std FARO) JJJ
	1 Techo	1 Proximity 17-24 V AC 22-35 V DC	1 960x550		
	2 Unidad Auto-on	4 Joystick 230 V AC	9 810x 855		
	4 Unidad Cable Rem	5 Proximity 230 V AC			
		9 Joystick 240 V AC			
		8 Proximity 240 V AC			

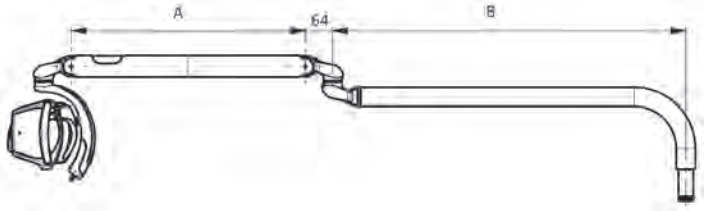
ALYA – Lámpara completa con Theia Tech					
	3° digit Mounting y dimens. de los brazos	4° digit tipo de Cabeza	5° digit tipo de interfaz	6° digit Voltaje	7° 8° 9° digit Adaptación al cliente
52	1 Unidad 550*810	1 Estándar	1 Joystick	1 24Vac 50/60Hz 24 V dc	000 (std FARO) JJJ
	2 Unidad 550*960	2 Con extensión	2 Joystick auto-on		
	3 Unidad 855*810		3 Sensor		
	4 Unidad 855*960		4 Sensor auto-on		
	5 Techo 550*810		5 Joystick + cable remoto		
	6 Techo 550*960		6 Joystick auto-on + cable remoto		
	7 Techo 855*810		7 Sensor + cable remoto		
	8 Techo 855*960		8 Sensor auto-on + cable remoto		

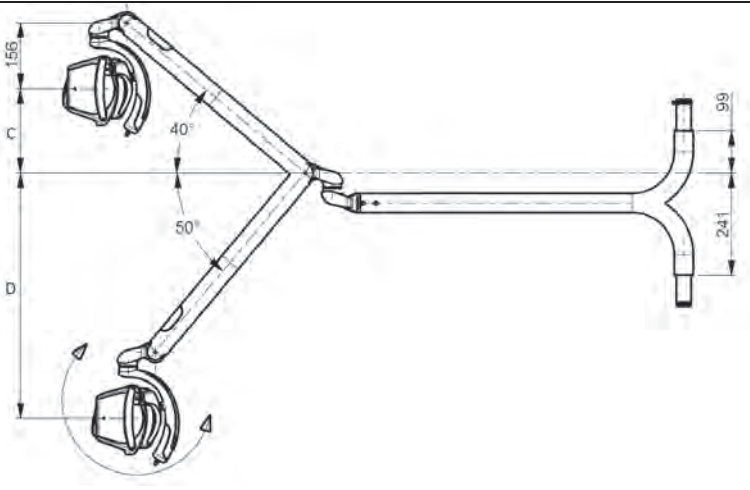
CABEZA ALYA (ALYA HEAD)					
Type	3° digit Col Temperaturas y control unidad	4° digit – Alimentación y control	5° digit Disponible	6° digit Colores	7° 8° 9° digit Custom
3 1	5 Grupo Óptico 5000 K	0 Joystick 17-24 V AC 22-35 V DC	0	0 Blanco	000 Std FARO
	6 Grupo Óptico 5000 K On/Off	1 Proximity 17-24 V AC 22-35 V DC		3 Gris	
	8 G.O. 4000 K				

3. INSTALACIÓN DEL DISPOSITIVO

⚠	**Advertencia sobre el peligro eléctrico, para lámpara y cabeza:**
	El dispositivo debe ser instalado por técnicos especializados. Al momento de la instalación la alimentación debe estar siempre desconectada. Consulte los esquemas alámbricos presentes en el manual. Controle los datos de la planta antes de la instalación
ℹ	**Nota para la instalación**
	El cable de alimentación de la lámpara completa se entrega sin ningún conector o terminal para dar la oportunidad de efectuar la conexión según las especificaciones de la unidad o de la aplicación. El funcionamiento o la seguridad de la lámpara no dependen de la polaridad de la corriente de alimentación. Por lo tanto la inversión de los cables de alimentación no implica riesgos de malfuncionamiento.

3.1 DIMENSIONES MÁXIMAS





	A	B	C	D
mm	550	830	265	510
mm	550	980	265	510
mm	855	830	394	706
mm	855	980	394	706

3.2 LÁMPARA DENTAL COMPLETA

3.2.1 Requisitos eléctricos

Los requisitos para la correcta instalación para cualquier aplicación (unidad, pared, piso o techo) son los siguientes:

Alimentación	Cable de alimentación	Tipo de alimentación y requisitos de protección	Clasificación	Conformidad con la IEC 60601-1
Versión lámpara completa 17-24 Vac 50/60 Hz	2 x 0,5 mm² 300 V 105°C Aislamiento PVC diámetro aislamiento 1,85 mm Utilice solo terminales y conectores certificados con resistencia a la llama V1 o similar.	Transformador conforme con la IEC/EN 60601-1 tercera edición y la IEC/EN 60601-1-2 con protección térmica o protección a valle por lo menos por un fusible apropiado: • T1.6AL 250V Requisitos mínimos: • Output: 17-24 Vac; • Power: 26 VA; • Class B; • Rigidez superior a 4000 V. • Protección térmica	Component built-in	El sistema medical resultado debe ser declarado conforme con la IEC/EN60601-1 por el instalador o por el fabricante. Nota para el instalador: asegúrese que la unidad donde se instalará la lámpara esté certificada para acoger la lámpara completa.
Versión lámpara completa 22-33Vdc		Alimentador conforme con la IEC/EN 60601-1 tercera edición y con la IEC/EN 60601-1-2 con protección térmica o protegido a valle por lo menos por un fusible adecuado: • T630mAL 250V Requisitos mínimos: • Output: 22-33 Vdc; • Power: 14 VA; • Class B; • Rigidez superior a 4000 V; • Protección continua contra cortocircuitos y sobrecorrientes.		
Versión lámpara completa con Theia Tech 24Vac 50/60Hz		Trasformador conforme con la IEC/EN 60601-1 tercera edición y con la IEC/EN 60601-1-2 con protección térmica o protegido a valle por lo menos por un fusible adecuado: • T2AL 250V Requisitos mínimos: • Output: 24Vac; • Power: 40VA • Class B; • Rigidez superior a 4000 V. • Protección térmica		

Alimentación	Cable de alimentación	Tipo de alimentación y requisitos de protección	Clasificación	Conformidad con la IEC 60601-1
Versión lámpara completa con Theia Tech 24Vdc	2 x 0,5 mm² 300 V 105°C Aislamiento PVC diámetro aislamiento 1,85 mm Utilice solo terminales y conectores certificados con resistencia a la llama V1 o similar.	Transformador conforme con la IEC/EN 60601-1 tercera edición y con la IEC/EN 60601-1-2 con protección térmica o protegido a valle por lo menos por un fusible adecuado: • T2AL 250V Requisitos mínimos: • Output: 24 Vdc; • Power 28 VA • Class B; • Rigidez superior a 4000 V. • Protección térmica	Component built-in	El sistema medical resultado debe ser declarado conforme con la IEC/EN60601-1 por el instalador o por el fabricante. Nota para el instalador: asegúrese que la unidad donde se instalará la lámpara esté certificada para acoger la lámpara completa.

Tab 1 – Requisitos para la conexión eléctrica y conformidad con la IEC 60601-1.

Controle que el embalaje contenga los siguientes componentes:
- Lámpara dental / Cabeza (en la versión requerida)
- Hoja para descargar las instrucciones del sitio www.faro.it/download

3.2.2 Cargas de seguridad

La lámpara dental ALYA y ALYA THEIA TECH se puede instalar en diferentes aplicaciones: **EQUIPO DENTAL- TECHO-PARED - PISO.**

CARGAS DE SEGURIDAD DE LOS BRAZOS

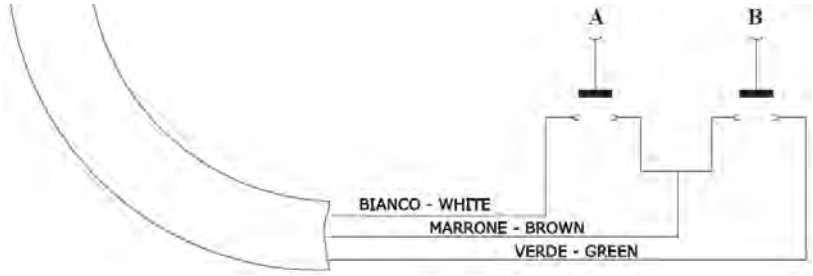
	Carga total (SAFE WORKING LOAD)	Carga útil de seguridad (MINIMUM BREAKING LOAD)
Brazo long. 855 mm	29.2 N	235 N
Brazo long. 550 mm	25.6 N	205 N

3.2.3 Montaje de la lámpara completa, versión de unidad

Con un nivel digital asegúrese que el elemento de conexión esté perfectamente paralelo al suelo.
Instale la lámpara introduciendo el perno terminal de la lámpara en el alojamiento correspondiente de la unidad.
Conecte el cable de alimentación según las especificaciones indicadas en la tabla 1.
Controle que la lámpara mantenga el equilibrio en todas las posiciones. Si es necesario, actúe en el sistema de ajuste del muelle para equilibrar la lámpara.
Controle el encendido y ajuste y, si están presentes, el mando Auto-on y el cable remoto.

3.2.4 Conexión del cable remoto

Conecte el cable de dos pulsadores (A y B) con contacto normalmente abierto (no suministrados) según el esquema siguiente:



3.2.5 Instalación de las aplicaciones

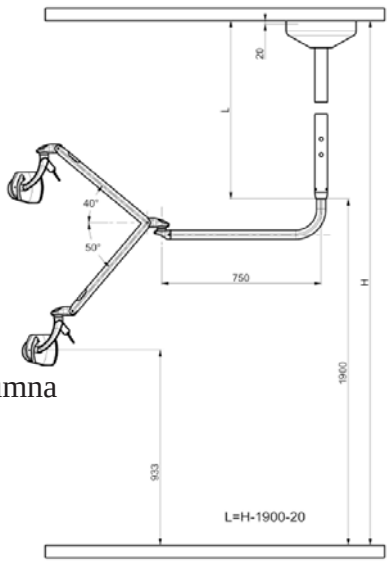
- Las aplicaciones se entregan con una lámpara
- Las aplicaciones deben ser instaladas por técnicos especializados

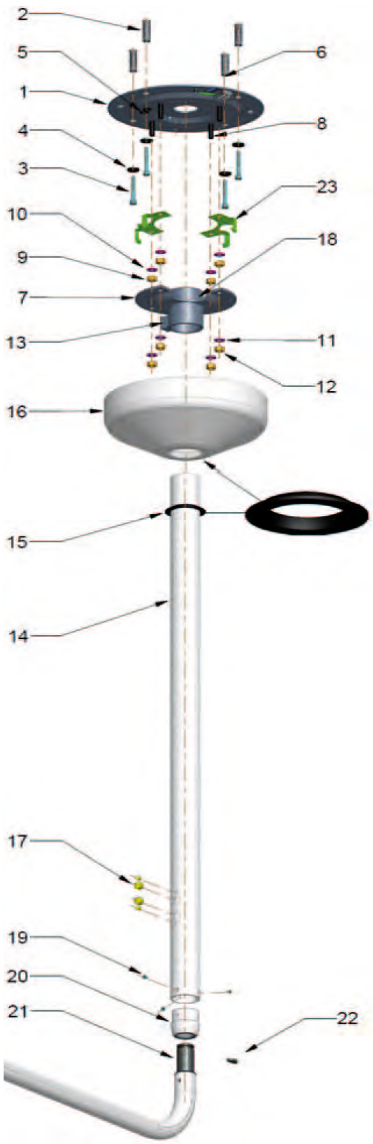
La lámpara debe ser instalada solo con aplicaciones FARO

La lámpara dispone de un microinterruptor de tope de rotación entre el brazo fijo y el brazo móvil. EL MICROINTERRUPTOR DE TOPE NO DEBE SUPERARSE NI FORZARSE NUNCA

MONTAJE DE APLICACIONES AL TECHO

1. Brida de techo
2. Expandidor
3. Tornillo
4. Arandela
5. Aislador pasapanel
6. Tablero de bornes
7. Brida
8. Tornillo
9. Tuerca
10. Arandela
11. Arandela
12. Tuerca
13. Tornillo
14. Columna
15. Anillo
16. Aplique para techo
17. Tapón
18. Tornillo
19. Tornillo
20. Casquillo de racor de la columna
21. Perno de la lámpara
22. Chaveta de sector
23. Guía de fijación



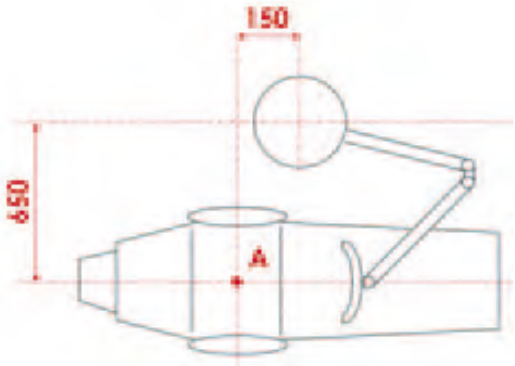


APLICACIÓN EN EL TECHO

NB1. El dispositivo debe ser instalado por técnicos especializados.
NB2. La alimentación en el interior del local donde se efectúa la instalación debe estar siempre desconectada.
NB3. Antes de proceder con las operaciones de montaje es necesario asegurarse que el techo esté en condiciones de sostener la aplicación.
Los materiales del techo autorizados son el hormigón y la piedra natural. Los tacos a utilizarse son los suministrados en dotación o equivalentes.
NB4. Máxima carga aplicable: 70 kg.
NB5. Instale en locales con instalación eléctrica conforme con las normativas vigentes en los locales médicos.

SECUENCIA DE INSTALACIÓN

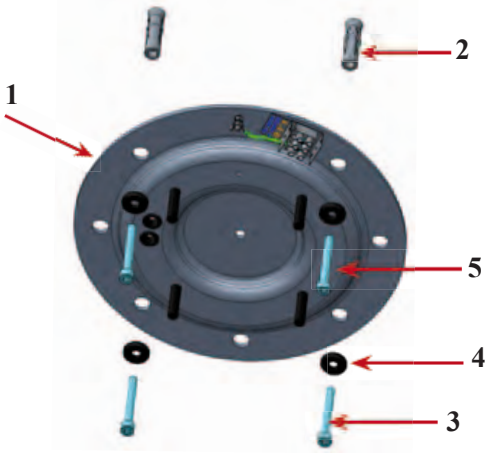
A. Establecido como punto de referencia el centro del sillón (A) efectúe la instalación a una distancia de 650 mm y 150 mm en las direcciones mostradas en la figura.



B. Desensamble la brida (7) removiendo las tuercas (12) y las arandelas (11).

C. Utilizando como guía la brida (1) efectúe en el techo 4 aguajeros con la punta Ø14. En estos agujeros monte los expandidores (2).

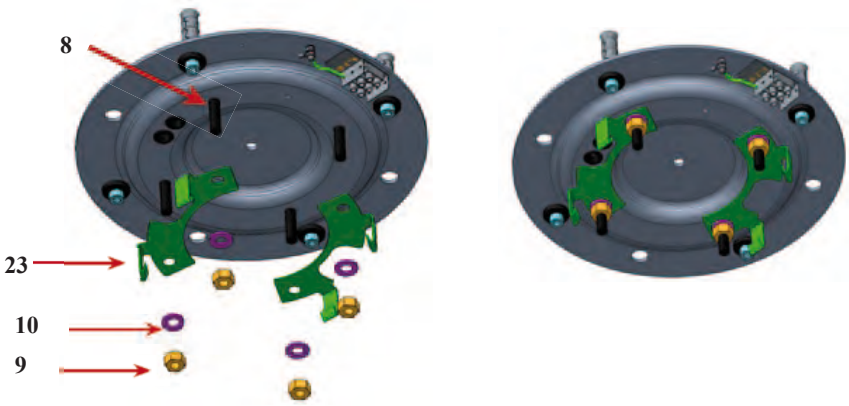
D. Tome la brida (1). Haga pasar el cable de la alimentación por el aislador pasapanel (5) luego empuje contra el techo la brida (1) teniendo cuidado de no apretar el cable entre la brida (1) y el techo. Haga pasar los tornillos (3) unidos a las arandelas (4) en los 4 agujeros utilizados para hacer los agujeros en el techo. Bloquee los tornillos (3) con la llave hexagonal correspondiente (accesorios de soporte).



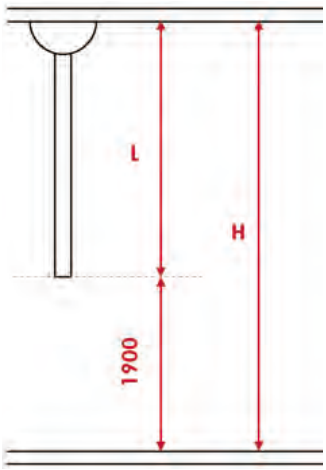
E. Conecte el cable de alimentación al tablero de bornes (6) (véanse esquemas alámbricos).

APLICACIÓN EN EL TECHO

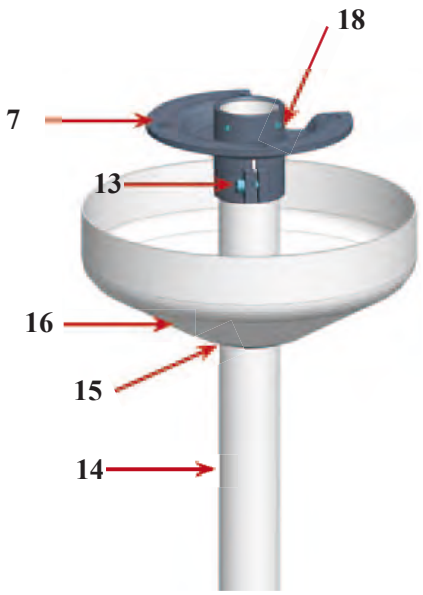
F. las 2 guías de fijación (23) en los tornillos (8) y fíjelas con las tuercas (9) y las arandelas (10).



G. Calcule la longitud justa de la columna (14) según la fórmula L=H-1900 mm. Preste atención a cortar la parte excedente de la columna (14) por el lado donde NO hay perforaciones laterales.



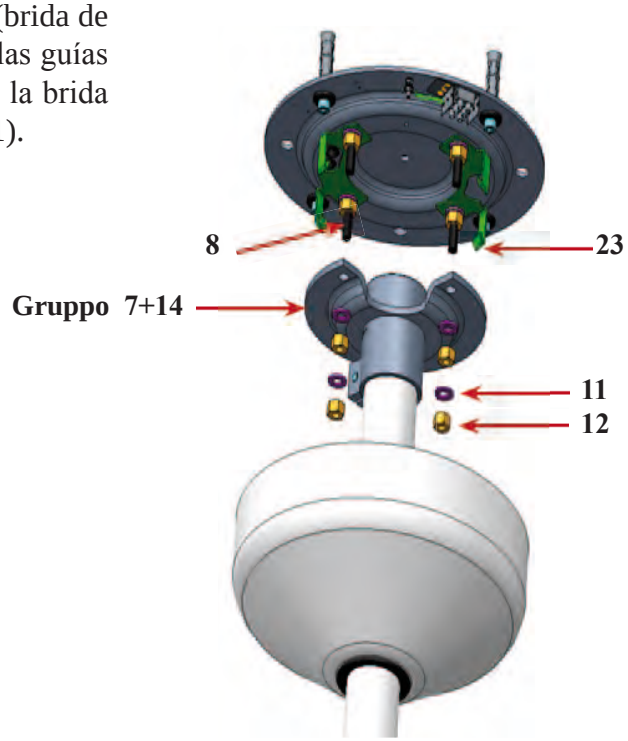
H. Introduzca la columna (14) en la brida (7) y marque en la columna (14) la posición de los agujeros presentes en la brida (7). Preste atención a la orientación de la columna respecto al equipo. Extraiga la columna y efectúe dos agujeros pasantes Ø8 en correspondencia de las marcas efectuadas.



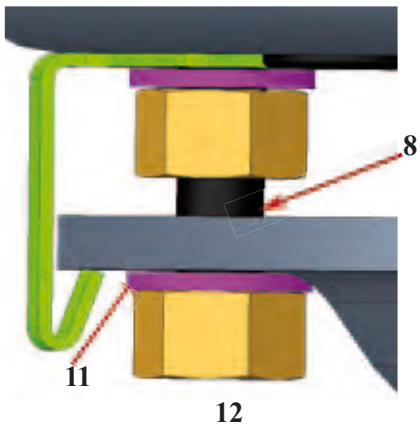
I. Introduzca en la columna (14) el anillo (15) por unos 300 mm (no es la posición correcta sino solo una posición temporal para permitir el montaje).
J. Introduzca el Aplique para techo (16) en la columna (14).
K. Introduzca la columna (14) en el agujero correspondiente de la brida de unión de la columna (7).
L. Bloquee el tornillo (13) y los dos tornillos (18) con llaves hexagonales (accesorios de soporte). Apriete con fuerza el tornillo (13) y asegúrese de que los tornillos atraviesen los agujeros de la columna (14).

APLICACIÓN EN EL TECHO

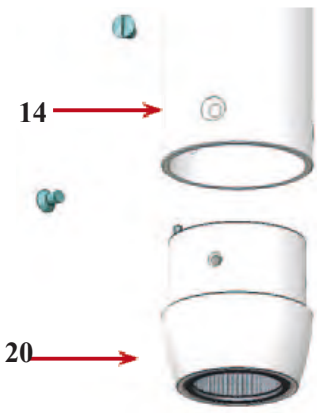
M. Enganche el grupo apenas ensamblado (brida de unión de la columna (7) + colonna (14)) a las guías de fijación (23) centrando los 4 agujeros de la brida (7) en los tornillos (8) de la brida de techo (1).



N. Entornille las tuercas (12) sin bloquearlas y las restantes arandelas (11) en los tornillos (8) de la brida de techo.



O. Destornille los tres tornillos (19) de la columna (14) y extraiga el casquillo (20).
P. Introduzca el casquillo (20) en el perno (21) de la lámpara.
Q. Introduzca la chaveta de espigón (21) en la ranura del perno (22)



APLICACIÓN EN EL TECHO

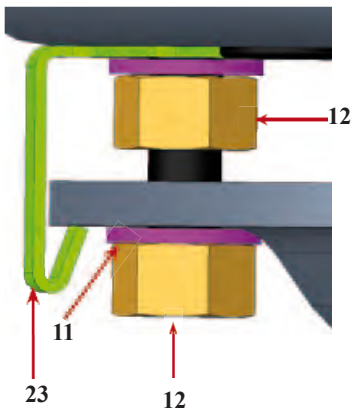
R. Introduzca desde arriba en la columna (14) un cable de tracción.

S. Conecte el conductor de la lámpara al cable de tracción.

T. Introduzca la lámpara en la columna (14) y fíjela con los tres tornillos (19) teniendo cuidado de orientar los agujeros del casquillo (20) en correspondencia de las sedes de los tornillos en la columna (14) y atorníllelos. Simultáneamente tire el cable de tracción hasta hacer salir el conductor de la lámpara de la brida de unión de la columna (7) por unos 200 mm.

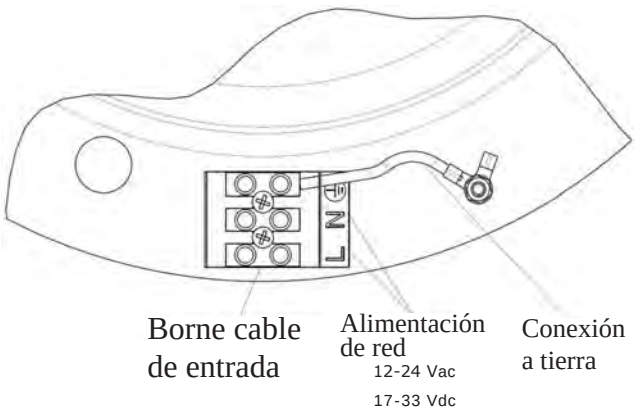
U. Conecte el conductor de la lámpara a los tableros de bornes (6) véanse esquemas alámbricos).

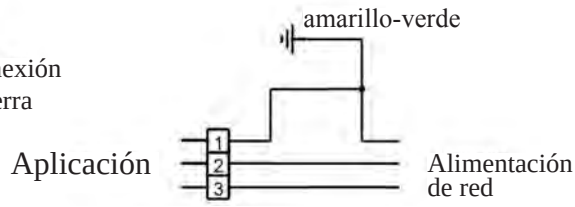
V. Controle la perpendicularidad de la columna actuando en las tuercas (9).
W. Apriete las tuercas (12) y las arandelas (11) para fijar la brida (7) haciéndola independiente de las guías de fijación (23).
X. Haga adherir el Aplique para techo (16) al techo empjando el anillo (15).



ESQUEMA ALÁMBRICO

Aplicación al techo SIN transformador

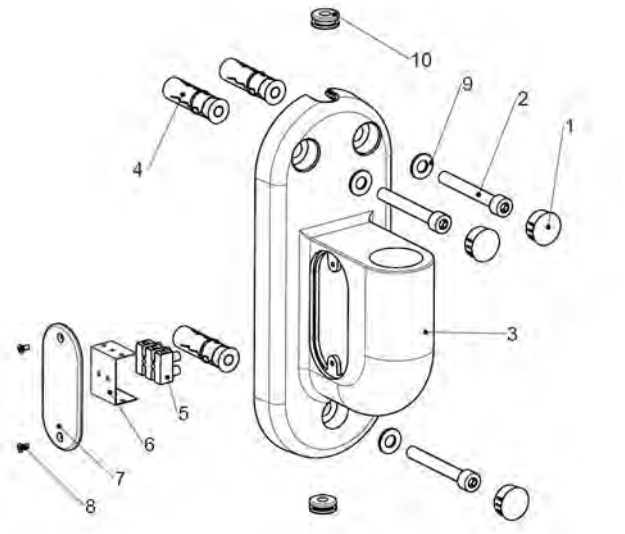


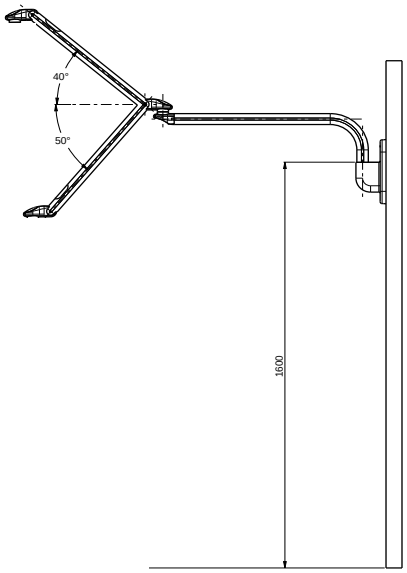


APLICACIÓN A LA PARED

MONTAJE DE LA LÁMPARA APLICACIÓN A LA PARED

1. Tapón
2. Tornillo
3. Aplicación a la pared
4. Expandidor
5. Tablero de bornes
6. Cobertura del tablero de bornes
7. Cobertura
8. Tornillo
9. Arandela
10. Aislador pasapanel





NB1. El dispositivo debe ser instalado por técnicos especializados.
NB2. La alimentación en el interior del local donde se efectúa la instalación debe estar siempre desconectada.
NB3. Antes de proceder con las operaciones de montaje es necesario asegurarse que el techo esté en condiciones de sostener la aplicación.
Los materiales del techo autorizados son el hormigón y la piedra natural. Los tacos a utilizarse son los suministrados en dotación o equivalentes.
NB4. Máxima carga aplicable: 70 kg.
NB5. Instale en locales con instalación eléctrica conforme con las normativas vigentes en los locales médicos.
NB6. La lámpara sin transformador debe ser alimentada por corriente a baja tensión (12-24Vac o 17-33Vdc) utilizando un transformador o alimentador de seguridad (conforme con la IEC/EN 60601-1) con protección térmica o protegido por lo menos por un fusible adecuado (T500mAL250V~).
El sistema médico resultado debe ser declarado por el instalador conforme con la IEC/EN 60601-1.

APLICACIÓN A LA PARED

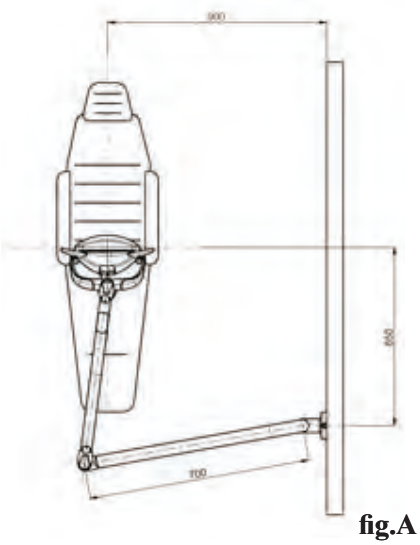


fig.A

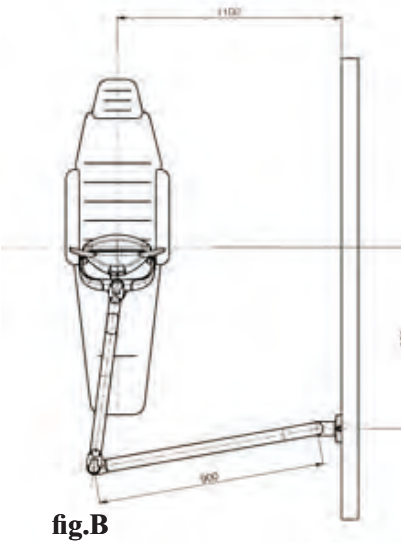
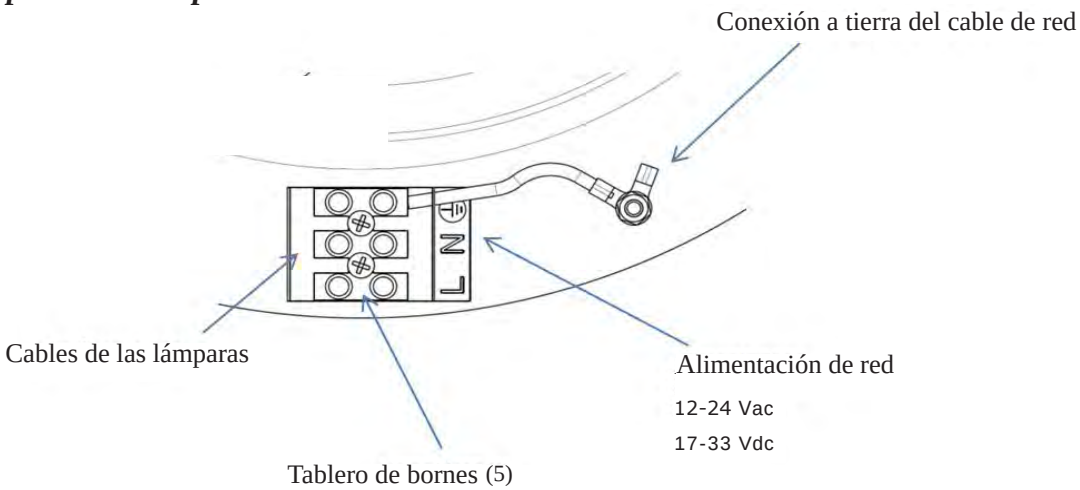


fig.B

- La alimentación en el interior del local donde se efectúa la instalación debe estar siempre desconectada.
- Establecido el punto de fijación con referencia el centro del sillón (véase fig. A-B) efectúe tres agujeros d.14 en la pared en correspondencia de los agujeros de la aplicación a la pared (3) cuidando atentamente la perpendicularidad del agujero.
- Introduzca los tres expandidores (12) en los agujeros d.14 hechos precedentemente y bloquee con la adecuada llave hexagonal (accesorios de soporte) los tornillos 2, teniendo cuidado de no aplastar el cable entre la aplicación a la pared (3) y la pared misma.
- Aplique los tres tapones (1) en los agujeros de la aplicación de pared (3).
- Destornille el tornillo (8). Saque la cubierta (7), Introduzca el brazo de la lámpara en la aplicación de techo engrasando el perno. Conecte los cables de la lámpara al tablero de bornes (5) (véase abajo el esquema de cableo) incluyendo el cable de tierra. Conecte los alambres salientes de la pared al tablero de bornes en el caso en que se hubiese tapiado precedentemente. A falta de esta medida, la conexión debe efectuarse con un cable volante externo a introducirse en el aislador pasapanel (10).
- Vuelva a montar la cobertura (7) por medio de los tornillos (8)

ESQUEMA ALÁMBRICO

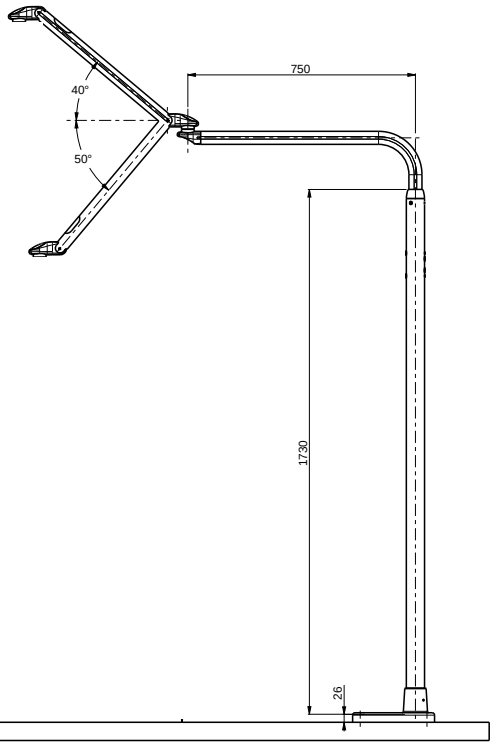
Aplicación a la pared

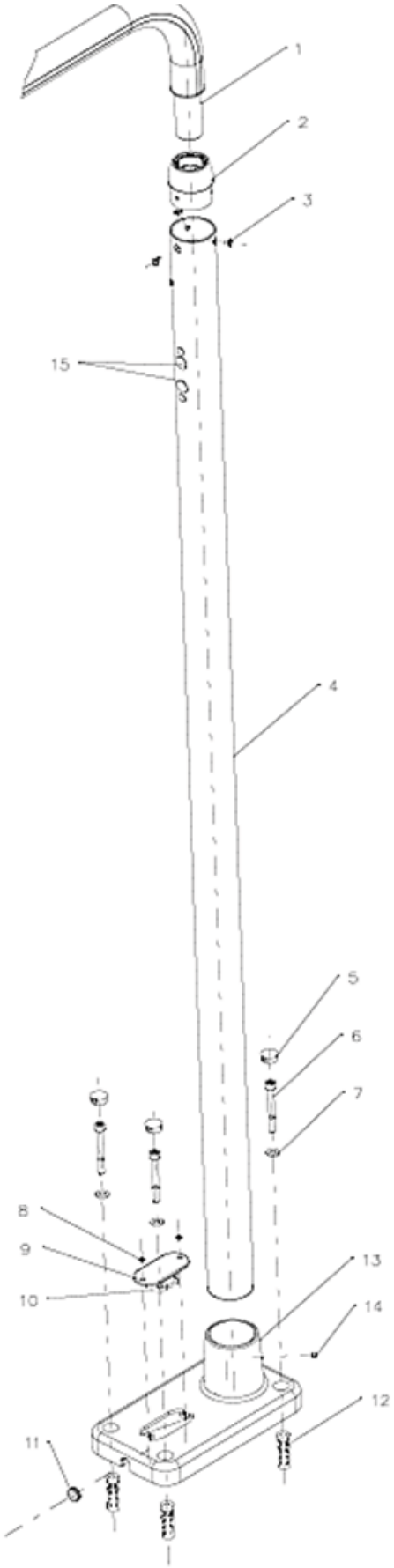


APLICACIÓN AL SUELO

MONTAJE Y APLICACIÓN AL SUELO

1. Perno
2. Casquillo
3. Tornilloe
4. Columna
5. Tapones
6. Tornillo
7. Arandela
8. Tornillo
9. Cobertura
10. Tablero de bornes
11. Aislador pasapanel
12. Expnadidors
13. Soporte de suelo
14. Tornillos sin cabeza
15. Tapón



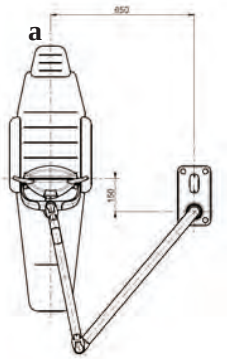


APLICACIÓN AL SUELO

El dispositivo debe ser instalado por técnicos especializados.
NB2. La alimentación en el interior del local donde se efectúa la instalación debe estar siempre desconectada.
NB3. Antes de proceder con las operaciones de montaje es necesario asegurarse que el techo esté en condiciones de sostener la aplicación.
Los materiales de la pared autorizados son el hormigón y la piedra natural. Los tacos a utilizarse son los suministrados en dotación o equivalentes.
NB4. Máxima carga aplicable: 70 kg.
NB5. Instale en locales con instalación eléctrica conforme con las normativas vigentes en los locales médicos.
NB6. La lámpara sin transformador debe ser alimentada por corriente a baja tensión (12-24Vac o 17-33Vdc) utilizando un transformador o alimentador de seguridad (conforme con la IEC/EN 60601-1) con protección térmica o protegido por lo menos por un fusible adecuado (T500mAL250V~). El sistema médico resultado debe ser declarado por el instalador conforme con la IEC/EN 60601-1.

A. Establecido como punto de referencia el centro del sillón "**a**",efectúe la instalación a una distancia de 650 mm y 150 mm en las direcciones mostradas en la figura "**C** ".

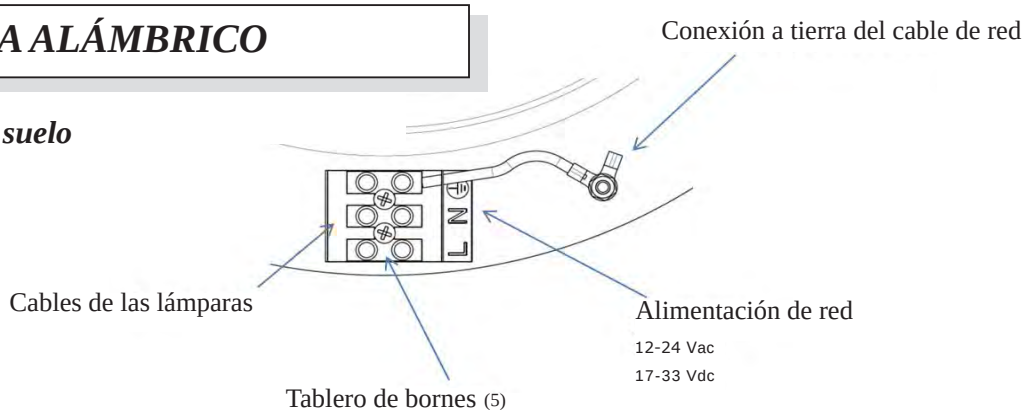
fig. C



- La alimentación en el interior del local donde se efectúa la instalación debe estar siempre desconectada.
Establecido el punto de fijación con referencia (**a**) el centro del sillón (véase fig. **C**), efectúe en el suelo cuatro agujeros de d.14 en correspondencia de los agujeros del soporte de suelo (13).
Prepare el soporte de suelo (13) haciendo pasar la arandela (7) y el tornillo (6), entornille los expandidores (12) en los tornillos (6) y de algunas vueltas, haga pasar el cable de la alimentación por el aislador pasapanel (11).
Introduzca los cuatro expandidores (12) en los agujeros d.14 hechos precedentemente y bloquee con la llave hexagonal correspondiente (accesorios de soporte) los tornillos 6, teniendo cuidado de no aplastar el cable entre el soporte de suelo (13) y el suelo mismo.
Aplique los cuatro tapones (5) en los agujeros del soporte de suelo (13).
Destornille los los tornillos (8) y extraiga la placa de cobertura (9). Conecte el cabe de alimentación al tablero de bornes (10).
Fije la columna (4) al soporte de suelo (13), durante la fijación asegúrese de la perpendicularidad de la columna.
Fije con los tres tornillos (3) el casquillo (2) a la columna (4) teniendo cuidado de orientar los agujeros del casquillo (2) en correspondencia de las sedes de los tornillos en la columna (4).
Conecte el conductor de la lámpara al tablero de bornes (10).
Fije la placa de cobertura (9) al soporte de suelo (13) con los dos tornillos (8).

ESQUEMA ALÁMBRICO

Aplicación al suelo



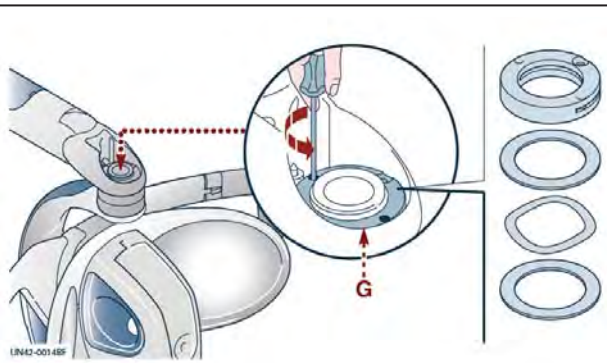
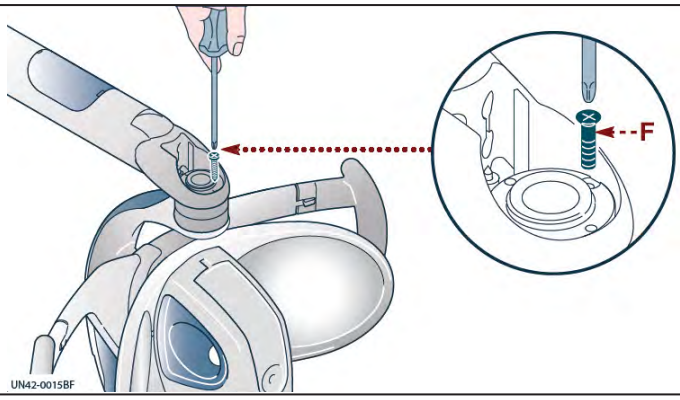
3.3 CABEZA

3.3.1 Requisitos mecánicos

Para la conexión mecánica debe haber un espacio adecuado para el alojamiento del perno de la cabeza y de los componentes de fijación G.
El sistema de sostén debe ser proyectado para sostener las siguientes cargas, multiplicadas por los factores de seguridad previstos por la IEC 60601-1 o la IEC 80601-2-60

Cabeza Alya	Pantalla Alya
1,80 kg	0,35 kg
2,15 kg	

Para la conexión mecánica siga el siguiente procedimiento:

1 – Sostenga la cabeza e introduzca las arandelas en el perno roscado respetando la secuencia en la figura. 2 – Luego introduzca la virola G respetando la secuencia indicada en la figura y atorníllela con un utensilio adecuado. La virola debe atornillarse en modo de dar la justa fuerza de rotación de la cabeza.	
3 – Atornille los dos tornillos F de seguridad.	

⚠	**Atención** El brazo central sin la carga de la cabeza tiende a subir repentinamente con el peligro de choque con piezas del cuerpo. Durante toda la instalación mantenga el brazo central en posición y no lo deje hasta haber completado la instalación de la cabeza.
⚠	**Advertencia sobre el peligro de caída de masas suspendidas** Atención – Riesgo de caída de la cabeza después de la instalación: A. – use solo los tornillos suministrados por FARO. B. – atornille los tornillos de seguridad de paquete.

Una vez terminada la conexión mecánica proceda al cableo eléctrico.

3.3.2 Requisitos eléctricos

Los requisitos para la correcta instalación **de la cabeza** son los siguientes:

<table>
<tr><th>Alimentación</th><th>Cable de alimentación</th><th>Tipo de alimentación y requisitos de protección</th><th>Clasificación</th><th>Conformidad con la IEC 60601-1</th></tr>
<tr><td>17-24 Vac
50/60 Hz</td><td rowspan="2">Cables de alimentación:
2 cables unipolares rojos:
UL Style 1061
300 V
T 80°C
1x26 AWG
VW 1
Ø máx 1,02 mm
Conector std:
molex 51021-0300 de 3 polos</td><td>Transformador conforme con la IEC/EN 60601-1 tercera edición y con la IEC/EN 60601-1-2 con protección térmica o protección a valle por lo menos por un fusible adecuado:
• T1.6AL 250V
Requisitos mínimos:
• Output: 17 - 24 Vac;
• Power: 26 VA;
• Class B;
• Rigidez superior a 4000 V.
• Protección térmica</td><td rowspan="2">Component built-in</td><td rowspan="2">El sistema medical resultado debe ser declarado conforme con la IEC/EN60601-1 por el instalador o por el fabricante.
Nota para el instalador: asegúrese de que la unidad donde se instalará la lámpara esté certificada para acoger la lámpara completa.</td></tr>
<tr><td>22-33Vdc</td><td>Alimentador conforme con la IEC/EN 60601-1 tercera edición y con la IEC/EN 60601-1-2 con protección térmica o protegido a valle por lo menos por un fusible adecuado:
• T630mAL 250V
Requisitos mínimos:
• Output: 22-33 Vdc
• Power: 14 VA;
• Class B;
• Rigidez superior a 4000 V;
• Protección continua contra cortocircuitos y sobrecorrientes</td></tr>
</table>

4. INSTRUCCIONES DE USO

Lea atentamente el párrafo 1 para un uso seguro del dispositivo.
El dispositivo debe limpiarse antes del uso (véase párrafo Limpieza del dispositivo).

	**Atención** El uso simultáneo de la lámpara con un bisturí eléctrico puede provocar malfuncionamientos de esta.
	**Atención** El joystick de control debe manejarse con cuidado para evitar roturas. Nunca desplace la lámpara usando el Joystick como punto de apoyo.
	**Nota** Cada vez que se enciende la lámpara, la intensidad luminosa es la memorizada al momento del apagado precedente.
	**Advertencia - peligro de contacto con piezas en tensión** C. No utilice el dispositivo si hay piezas o carcasas dañadas.

4.1 ENCENDIDO Y APAGADO

Consulte el §1.1 para los símbolos de encendido y ajuste.

Lámpara Completa

Para el encendido y el apagado pulse y libere la palanca joystick actuando en el lado izquierdo o derecho. La intensidad luminosa al momento del encendido es siempre la última utilizada antes del apagado.

Lámpara completa con Theia Tech

Las mismas operaciones que la lámpara completa además que la del brazo fijo se encenderá y/o se apagará en sincronía con la de la cabeza.

La luz en el brazo fijo puede encenderse/apagarse incluso por medio del pulsador colocado en el brazo. En caso de encendido con la lámpara encendida, la luz se sincronizará automáticamente, en el caso en que la luz en la cabeza estuviese apagada se ajustará a la máxima intensidad.

4.1.1 Ajuste:

a) Para reducir la intensidad luminosa mantenga pulsada la palanca del joystick actuando en el lado izquierdo (vista trasera de la lámpara) hasta alcanzar la intensidad deseada.
Al alcanzar la mínima intensidad se oirá una señal acústica (1 beep).
b) Para aumentar la intensidad luminosa mantenga pulsada la palanca del joystick actuando en el lado derecho (vista trasera de la lámpara) hasta alcanzar la intensidad deseada.
Al alcanzar la máxima intensidad se oirá una señal acústica (1 beep).
c) Para saltar a la mínima intensidad pulse y libere la palanca del joystick actuando en el lado delantero o trasero. A una sucesiva presión en el lado delantero o trasero, la intensidad luminosa volverá a ser la memorizada precedentemente.
La luz en el brazo fijo se ajusta en sincronía con la de la cabeza, no puede ajustarse en modo independiente.

4.1.2 Lámpara / Cabeza CON PROXIMITY

Encendido / Apagado

Lámpara Completa: Para el encendido o apagado acérquese una vez al sensor hasta una distancia máxima de 3 cm.

Lámpara completa con Theia Tech: Las mismas operaciones que la lámpara completa además la luz en el brazo fijo se enciende y/o se apaga en sincronía con la de la cabeza.

Ajuste de la lámpara completa: Para los ajustes de la intensidad luminosa es necesario permanecer detenidos en proximidad del sensor hasta obtener la intensidad deseada. El ajuste permite pasar del valor máximo al mínimo y del valor mínimo al máximo. Al alcanzar la máxima intensidad se oye una señal acústica (2 beep). Al alcanzar la mínima intensidad se oye una señal acústica (1 beep).

	Nota
	Cada vez que se enciende la lámpara, la intensidad luminosa es la memorizada en el apagado precedente.

Lámpara completa con Theia Tech las mismas operaciones que la lámpara completa, además la luz en el brazo fijo se ajusta en sincronía con la de la cabeza.

4.1.3 Lámpara / Lámpara completa con Theia Tech / Cabeza "ALYA" CON MANDO REMOTO

Encendido / Apagado / Ajuste
- Para el encendido y el apagado pulse y libere el pulsador "A".
- Ajuste:

a) Para reducir la intensidad luminosa mantenga pulsado el pulsador "A" hasta el alcance de la intensidad deseada.
Al alcance de la mínima intensidad se oye una señal acústica (1 beep).
b) Para aumentar la intensidad luminosa mantenga pulsado el pulsador "A" hasta el alcance de la intensidad deseada.
Al alcance de la máxima intensidad se oye una señal acústica (2 beep).
c) Para alcanzar inmediatamente la mínima intensidad luminosa pulse el pulsador "B".
Al alcance de la mínima intensidad se oye una señal acústica (1 beep).
Una sucesiva presión del pulsador regresa la lámpara a la intensidad luminosa precedentemente seleccionada.

	Nota
	Cada vez que se enciende la lámpara, la intensidad luminosa es la memorizada al momento del último apagado.

4.1.4 LÁMPARA / LÁMPARA COMPLETA CON THEIA TECH / CABEZA "ALYA" CON MANDO DE SINCRONIZACIÓN

Donde está previsto, es posible conectar en modalidad wireless la lámpara Alya a la lámpara ambiente Faro, a fin de crear un sistema de alumbrado sincronizado entre ellas denominado "**Syncro**".
La modalidad "**Syncro**" ha sido estudiada especialmente para mejorar el confort del médico dentista/odontólogo, a fin de reducir el efecto de deslubramiento que se genera cuando se pasa de la observación de una superficie fuertemente iluminada (ej.: la cavidad oral con la lámpara dental) a una superficie poco iluminada (ej.: estuche dental).
Con la modalidad denominada "**Syncro**", activable por medio del pulsador puesto en la cabeza de la lámpara Alya, es posible modificar automáticamente el valor de alumbrado producido por la lámpara ambiente Faro sobre la base del valor de alumbrado producido por Alya.
Nota: entre la lámpara dental y la ambiental puede suceder un pequeño retardo en la sincronización debido al protocolo de comunicación, este efecto es normal y no representa un defecto.
Para ser habilitada, la función "**Syncro**" necesita un procedimiento de acoplamiento llamado "**Pairing**" que deberá efectuarse una sola vez, a fin de crear la relación entre las dos lámparas.
Sucesivamente, la función "**Syncro**" podrá ser habilitada y/o deshabilitada según la necesidad del usuario, por medio del pulsador colocado en la lámpara dental.

PROCEDIMIENTO DE "PAIRING"
NOTA:

- El procedimiento de "**Pairing**" es necesario solo a la primera conexión, sin embargo puede ser repetido en caso de sustitución de la lámpara Alya o de la electrónica de una de las dos lámparas conectadas entre ellas.
- Si en el gabinete están presentes varias lámparas ambiente, asegúrese que las otras lámparas estén apagadas o encendidas desde más de 60 segundos.

Para efectuar el "**Pairing**" proceda en el modo siguiente:

1. Ponga en tensión la lámpara ambiente Faro que se desea acoplar.
   La lámpara ambiente se predispone para la conexión de "Pairing" por un tiempo máximo de 60 segundos.

2. Dentro de 60 segundos, pulse en la lámpara dental el pulsador de "**syncro**" por lo menos durante 3 segundos pero no mas de 6 segundos, de otra forma se anula el pro cedimiento. Al recibimiento del pedido de "**Pairing**" por parte de la lámpara dental, en la lámpara ambiente se activa el led azul presente en el bastidor de aluminio. Si el led azul no se activa, será posible efectuar otros intentos dentro de 60 segundos del encendido; superado este tiempo será necesario repetir el procedimiento a partir del punto 1.

3. Desde el encendido del led azul en la lámpara ambiente hay otros 60 segundos para confirmar el "**Paring**" pulsando el pulsador de programación  en el radiomando de la lámpara ambiente. A este punto el led azul de la lámpara ambiente se enciende dos veces y luego se apaga. Si dentro de 60 segundos no se pulsa el pulsador  en el radiomando, el led azul se apaga y debe repetirse el procedimiento desde el punto 1.

Una vez efectuado el "**Pairing**", está habilitada la sincronización entre las 2 lámparas..

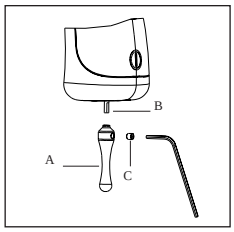
Para **ACTIVAR LA FUNCIÓN DE SINCRONIZACIÓN** es necesario proceder en el modo siguiente: pulse por 2 segundos el pulsador de Syncro y luego libérelo.
Al liberarlo se oirá una señal (beep) y la luz del led blu en la lámpara ambiente se encenderá para indicar que la sincronización ha sido activada.

Para DESACTIVAR LA FUNCIÓN DE SINCRONIZACIÓN es necesario proceder en el modo siguiente: pulse por 2 segundos el pulsador di Syncro y luego libérelo.
Al liberarlo se oirá una señal (beep) y la luz del led blu en la lámpara ambiente se apagará para indicar que la sincronización ha sido desactivada.

Notas relacionadas con la sincronización:

- Cuando la lámpara ambiente Faro está en sincrónico, es decir se regula en automático, con la lámpara Alya el led azul el bastidor en está encendido fijo; cuando el led está apagado, la sincronización está desactivada.
- El radiomando está siempre habilitado y por lo tanto es posible modificar el valor de alumbrado, sin embargo, si la lámpara ambiente se encuentra en estado de sincronización, con el led azul encendido, cuando se efectúe una nueva regulación en la lámpara Alya, el valor de alumbrado será actualizado inmediatamente.
- Si se apaga la lámpara Alya, la lámpara ambiente permanecerá encendida en el valor de alumbrado en uso.
- Si se enciende la lámpara Alya, la lámpara ambiente se encenderá automáticamente.

4.2 MONTAJE DE LA PALANCA JOYSTICK ALYA



- Introduzca en el tope la palanca “A” en el perno del joystick.
- El agujero de la palanca “A” debe ser colocado en correspondencia del plano “B”.
- Atornille completamente el tornillo sin cabeza “C” con la llave Allen en dotación.

	Atención
	El joystick de control debe ser manejado con cuidado a fin de evitar roturas. Nunca desplace la lámpara usando el Joystick como punto de apoyo.

5. MANTENIMIENTO ORDINARIO

No existen operaciones de mantenimiento ordinario.

6. LIMPIEZA

	Advertencia contra el peligro de degradación y corrosión y caída de masas suspendidas
	Para todas las piezas de la lámpara de metal o plástico, está perentoriamente prohibido el uso de sustancias abrasivas, ácidas, que contengan cloro o iones de cloro, detergentes a base de tricloroetileno, bencina, aguarrás o similares. Está prohibido rociar directamente sustancias químicas en el dispositivo.

6.1 LIMPIEZA DE LOS REFLECTORES

La limpieza debe efectuarse utilizando un paño blando de algodón o algodón hidrófilo con alcohol etílico o el detergente correspondiente PERFLEX. Son adecuados desinfectantes hidroalcohólicos con 70% de alcohol isopropílico o etílico.

	Atención – potencial daño o degradación de los reflectores
	Nunca rocíe el detergente directamente en los reflectores. Las operaciones de limpieza de los reflectores deben ser efectuadas usando guantes a fin de evitar dejar huellas en las superficies. No use detergentes que contengan tensioactivos o hidrófugos que, al depositarse, pueden dejar aureolados. Leves aureoleados no perjudican la calidad de la luz. Productos distintos de los sugeridos pueden dañar los reflectores. En caso de dudas póngase en contacto con el Customer Care de FARO.

6.2 LIMPIEZA DE LA CABEZA

La limpieza debe efectuarse utilizando un paño blando de algodón o algodón hidrófilo con alcohol etílico o el detergente adecuado PERFLEX. Son adecuados desinfectantes hidroalcohólicos con 70% de alcohol isopropílico o etílico.

	Advertencia contra el peligro de degradación de los plásticos y caída de masas suspendidas
	Nunca rocíe el detergente directamente en la cabeza. Para la limpieza de las piezas de plástico no utilice detergentes-desinfectantes que contenga: • HIDRÓXIDO AMÓNICO • HIDRÓXIDO SÓDICO • CLORURO DE METILENO • ALCOHOL METÍLICO • TODO TIPO DE ÁCIDOS Faro ha probado y sugiere los siguientes desinfectantes: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

6.3 LIMPIEZA DE LOS BRAZOS

Utilice siempre un paño humedecido en un desinfectante aprobado para la desinfección de las superficies.

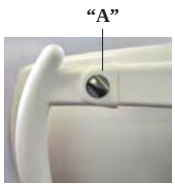
	Advertencia contra el peligro de corrosión y aflojamiento mecánico con caída de masas suspendidas
	Nunca rocíe sustancias químicas directamente en los brazos y en las articulaciones y sus aperturas.
	Advertencia contra el peligro de degradación de los plásticos con caída de masas suspendidas
	Para la limpieza de las piezas de plástico no utilice detergentes o desinfectantes que contengan: • HIDRÓXIDO AMÓNICO • HIDRÓXIDO SÓDICO • CLORURO DE METILENO • ALCOHOL METÍLICO • TODO TIPO ÁCIDOS Faro ha probado y sugiere los siguientes desinfectantes: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

7. ESTERILIZACIÓN DE LA MANIJA

	Advertencia - peligro de contaminación cruzada
	Las manijas no se entregan estériles y por lo tanto deben ser esterilizadas antes del uso. Las manijas deben ser esterilizadas antes de cada paciente.

7.1 Remoción de la manija

Para remover la manija desentornille la empuñadura “A” y extráigala del soporte.



7.2 Descontaminación y desinfección

Antes de la esterilización, las manijas deben ser descontaminadas y desinfectadas. Para la desinfección, Faro ha probado los siguientes productos para la desinfección: Eco Jet-1 (Cattani Group) / Sporekin Plus DS (Ims srl) / Zefirol Quick (Molteni Dental) / Durr FD366 Sensitive

	Atención - peligro de rotura de plásticos
	Las manijas no pueden ser desinfectadas por termodesinfección.

.3 Esterilización

Las manijas deben ser puestas en sobres y embalajes conformes con la EN 868-5.
Las manijas pueden ser esterilizadas con ciclos estándar 121°/134°C hasta doscientos (200) ciclos o en todo caso hasta la pérdida de las performances mecánicas.
Los parámetros del ciclo de esterilización son los siguientes:

Ciclo EN 13060	Température	Presión	Holding Time Mínimo
B B	121°C 134°C	207 KPa 308 KPa	15 min 3 min

8. INSPECCIONES PERIÓDICAS

Operación	Frecuencia	Aplicación		Procedimiento	Habilitación
		LD	TE		
Control de la ausencia de juego entre las articulaciones de los brazos	Cada año	x	N/A	Controle que la luz entre las articulaciones 5 y los brazos no haya cambiado desde el primer uso	Utilizador
Control de la legibilidad de los datos de la placa	Cada año	x	x		Utilizador
Control de la integridad de las envueltas	Cada dos años				Service Engineer
Control de la seguridad eléctrica EN 62353: 1. Rigidez 2. Dispersión	Cada año	x	x	Mida la rigidez dieléctrica y la dispersión en la envuelta. Límites definidos en la IEC 60601-1	Service Engineer
Controles de los parámetros de luz	Cada dos años	x	x	Con un espectrorradiómetro mida los valores de: • Intensidad de iluminación máxima: >35000 lux • Decaimiento del CRI: <20%. • Valor subyacente de la luz Azul en el espectro emitido medido en: <100 W/m²	Service Engineer

Service Engineer: persona competente en el mantenimiento de equipos electromecánicos.

9. SEÑALES ACÚSTICAS

9.1 Señales acústicas

OpL** = Beep 30 segundos
OTP* = Beep 30 segundos

* OTP: Protección exceso de temperatura LED.
** OpL: Carga de led desconectado

9.2 GUÍA A LOS PROBLEMAS

La siguiente tabla representa una guía de los potenciales defectos de la lámpara.
En el caso en que el problema no se resuelva, llame a la asistencia técnica.

Efecto	Causa	Acción (Service Engineer - SI)	Resp
La lámpara no se enciende.	Alimentación no conectada o conectada en modo no correcto.	Controle que la alimentación esté conectada y que la unidad esté encendida.	Utilizador
	Interferencia con el bisturí eléctrico o instrumentación de alta energía.	Apague el bisturí eléctrico y controle la permanencia del efecto.	Utilizador
	Mando en el joystick aplicado en modo errado.	Para el encendido y apagado pulse y libere la palanca joystick actuando en el lado izquierdo o derecho.	Utilizador
La lámpara flikera.	Interferencia con bisturí eléctrico o instrumentación de alta energía.	Apague el bisturí eléctrico y controle la permanencia del efecto.	Utilizador
La lámpara no ajusta la intensidad luminosa.	Mando en el joystick aplicado en modo errado.	Utilice correctamente el mando como se describe en el presente manual.	Utilizador
	Interferencia con bisturí eléctrico o instrumentación de alta energía.	Apague el bisturí eléctrico y controle la permanencia del efecto.	Utilizador
La intensidad luminosa se ha reducido notablemente.	Reflectores o lente secundaria sucios.	Limpie los reflectores y las lentes secundarias.	Utilizador
	Uso de procedimientos errados.	Controle que se está al máximo ajuste con el mando.	Utilizador
En los reflectores (parábolas) han aparecido manchas o ha desaparecido la capa reflectante.	Uso de productos no aprobados.	Limpie las superficies con el producto específico “Faro Perflex”. Limpie las superficies con alcohol isopropílico. Para el restablecimiento de las superficies es necesario hacer sustituir el reflector por el service.	Utilizador
La lámpara no mantiene el equilibrio y tiende a bajar.	Carga excesiva en la cabeza (espejos, telecámaras, etc.).	Saque las cargas en exceso.	Utilizador
La lámpara no controla	Función Syncro apagada	Active la función, véase 4.1.4.	Utilizador

10. CARACTERÍSTICAS TÉCNICAS

Lámpara completa:
Tensión de alimentación (sin transformador):
- 17÷24Vac ±10% - 50/ 60Hz;
- 22÷35Vdc ±10%

Potencia absorbida:
- 26VA (versión 17÷24Vac);
- 14VA (versión 22÷35Vdc)

Fusibles aconsejados:
- Versión 17÷24Vac: T1.6AL 250V
- Versión 22÷35Vdc: T630mAL 250V

Protección contra los peligros eléctricos:
- Aparato de clase II

Clasificación EN 62471:
- clase Exempt

Lámpara completa con Theia Tech
Tensión de alimentación (sin transformador):
- 24Vac ±10% - 50/ 60 Hz
- 24Vdc ±10%

Potencia absorbida:
- 40VA (versión 24Vac)
- 28VA (versión 24Vdc)

Fusibles aconsejados:
- T2AL 250V

Protección contra los peligros eléctricos:
- Aparato de clase II

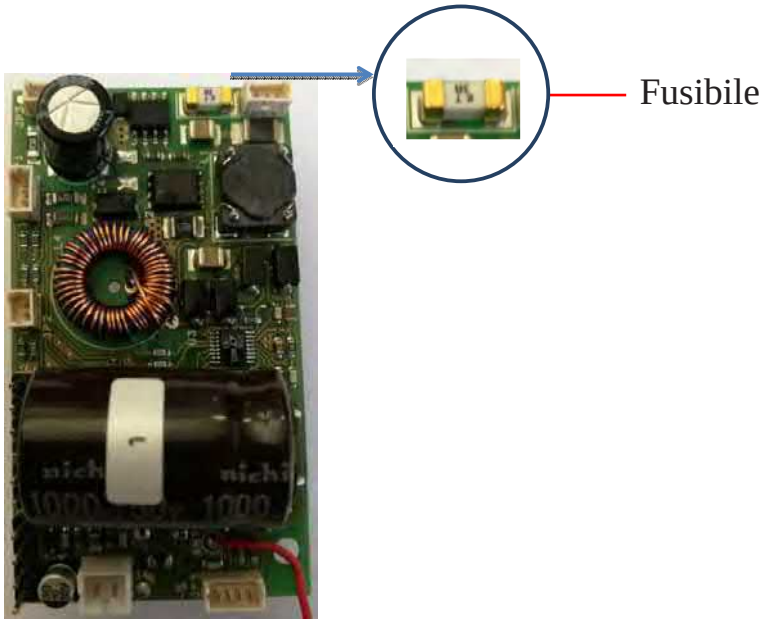
Clasificación EN 62471:
- clase Exempt

Características ópticas de la luz producida por la cabeza de acuerdo con la ISO 9680
Dimensiones spot luminoso: 180 mm x 90 mm
Lux: 3.000*-50.000* lux @700mm
Temperatura de color: 5000 K*
CRI (color rendering index): >95*

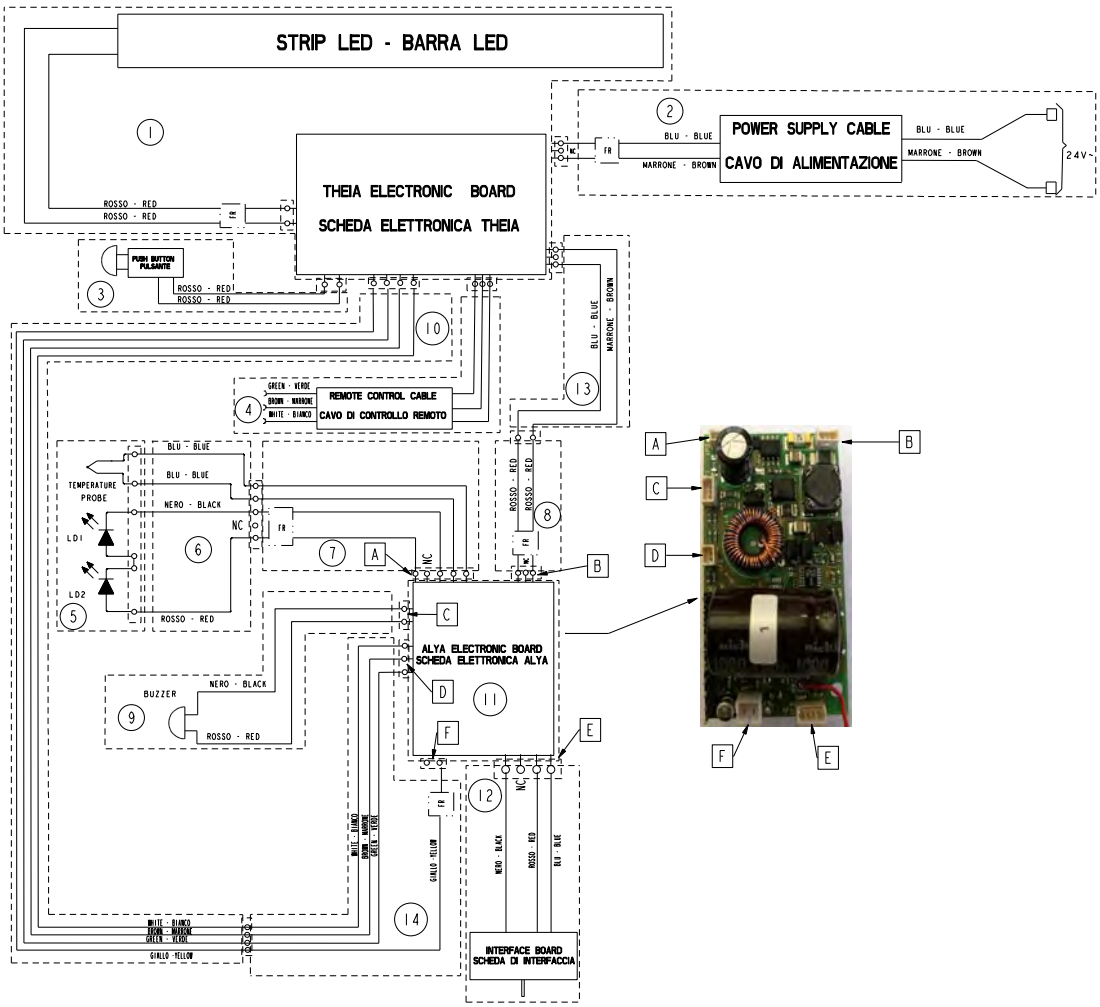
* Valores típicos sujetos a tolerancias.
Etiquetado de acuerdo a EN 62471: no necesario

10.1 ESQUEMAS ALÁMBRICOS

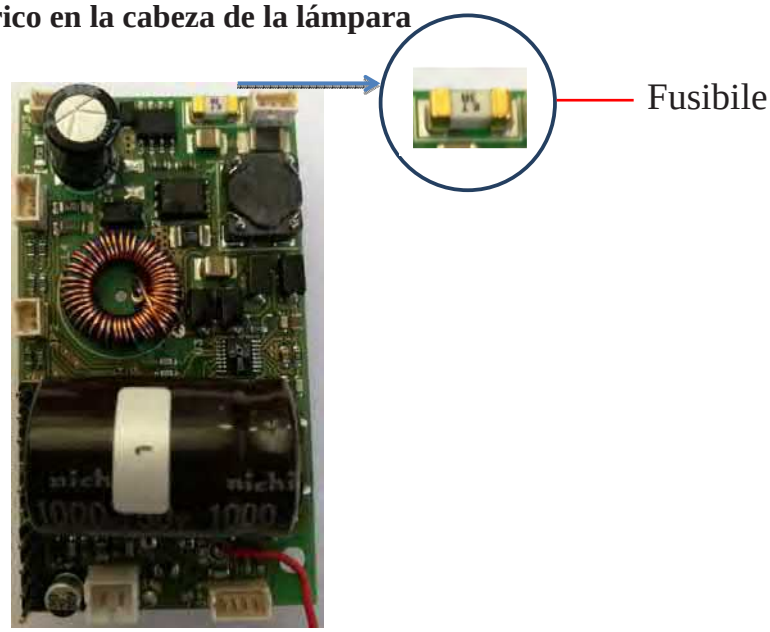
- **Lámpara completa:**
  Circuito eléctrico en la cabeza de la lámpara



Esquema alámbrico – Alya c/s transformador

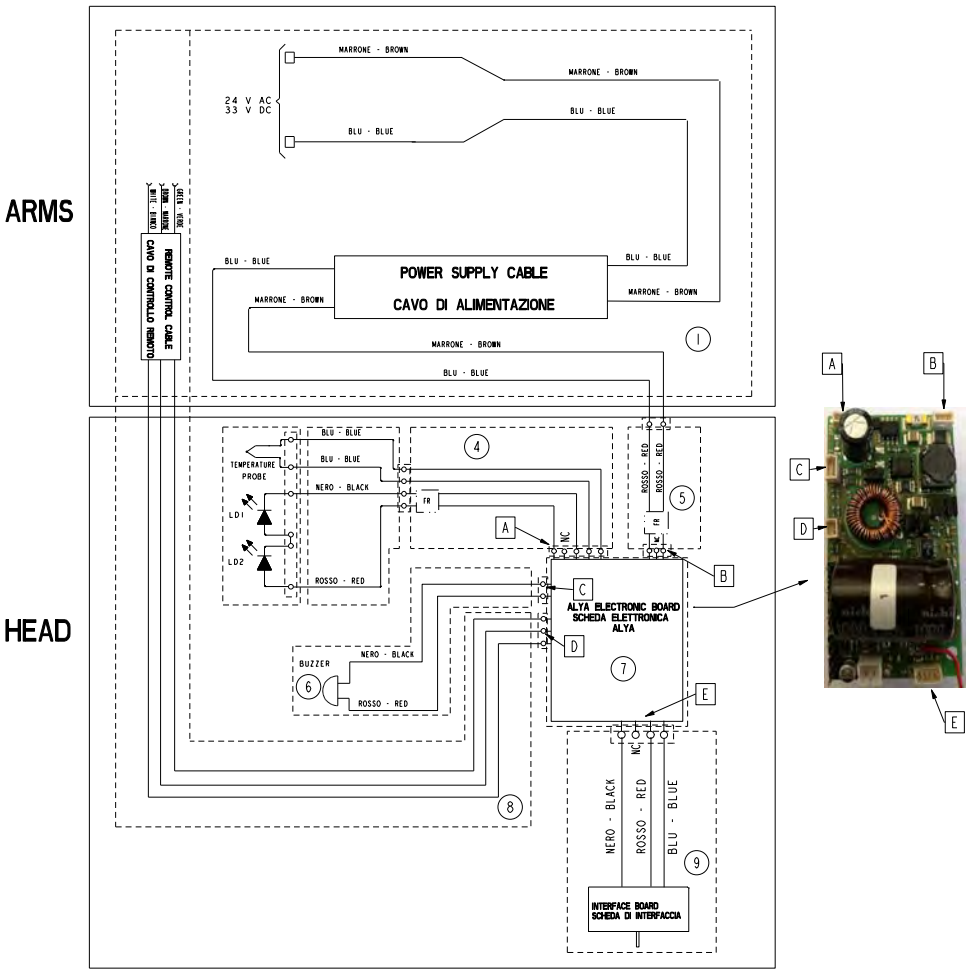


- **Lámpara completa con Theia Tech:**
  Circuito eléctrico en la cabeza de la lámpara

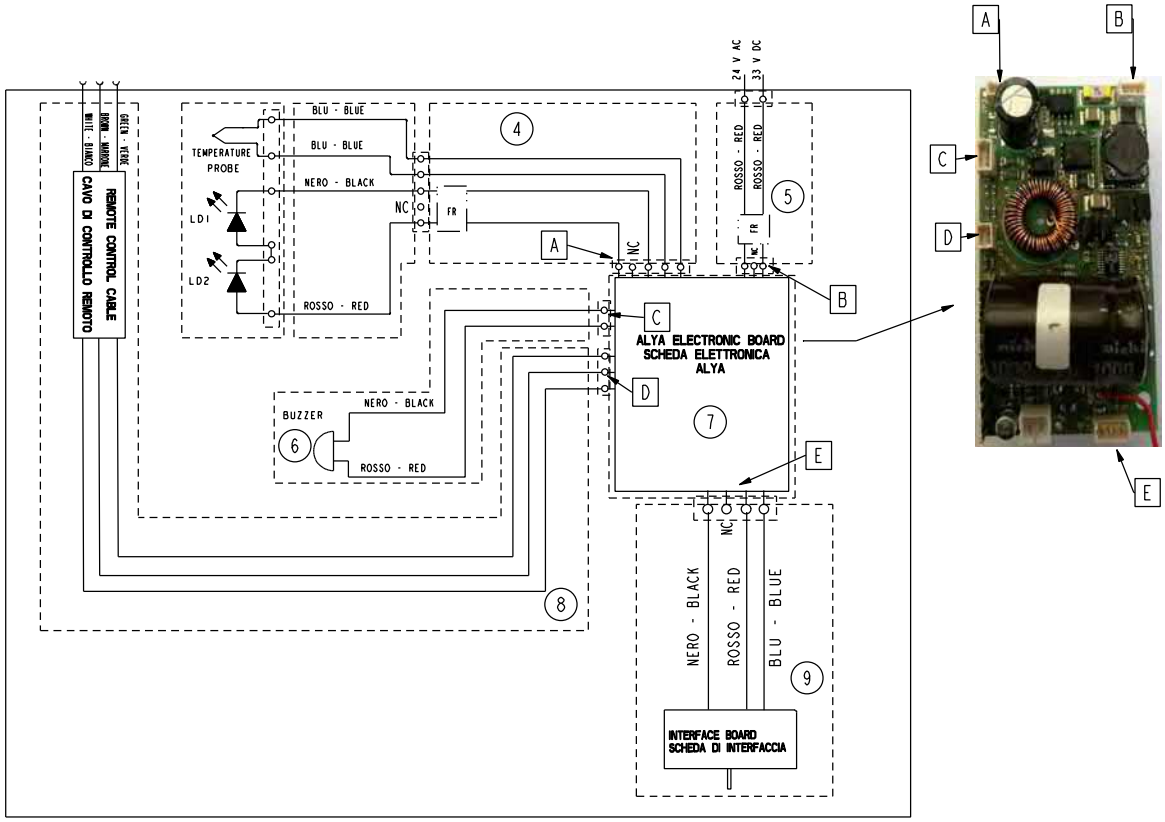


Circuito eléctrico en el brazo trasero

Esquema alámbrico – Alya Theia Tech.



- ***Cabeza:*** *Esquema alámbrico – Alya Head*



CERTIFICATO DI GARANZIA

La Faro concede al cliente finale una garanzia di **24 mesi** a partire dalla data di acquisto.
La riparazione in garanzia deve essere effettuata presso la FARO; spese e rischi di trasporto sono a rischio dell'acquirente. **La riparazione in garanzia è ritenuta valida solo quando:**

- **il certificato è stato compilato in tutte le sue parti e inviato anticipatamente alla FARO tramite Fax (039.6010540).**

La garanzia risponde dei guasti dovuti alla cattiva qualità del materiale o a difetti di fabbricazione, in caso di fondato reclamo la garanzia consente la riparazione o la sostituzione gratuita. **E' esclusa la possibilità di ottenere risarcimento di danni e/o di interessi.** La garanzia non è ritenuta valida, a insindacabilegiudizio della FARO, in caso di manomissione, danneggiamento, di scorretta utilizzazione, di cattiva manutenzione o di normaleusura

GUARANTEE CERTIFICATE

FARO offers the final customer a **24 month** guarantee 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 (039.6010540).**

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.

CERTIFICAT DE GARANTIE

FARO accorde au client final une garantie de **24 mois**, à compter de la date de l'achat.
La réparation sous garantie peut être effectuée chez FARO; les frais et les risques de transport sont aux risques de l'acheteur. **La réparation sous garantie ne peut être valable que si:**

- **Le certificat a été rempli entièrement et envoyé auparavant à FARO par Fax (039.6010540).**

La garantie est valable pour des pannes dues à la mauvaise qualité du matériau ou à des défauts de fabrication, en cas de réclamation fondée la garantie permettra la réparation ou le remplacement gratuit. **La possibilité de dédommagements ou d'indemnisation d'intérêts est exclue.** La garantie n'est pas valable, selon les décisions sans appel de FARO, en cas de modification non autorisée, endommagement, utilisation incorrecte, mauvais entretien ou usure normale.

24 mesi-months-mois-monaten-meses

nome-name-nom-vorname-nombre _____

cognome-surname-prenom-nachname-apellido _____

indirizzo-address-adresse-auschrift-direccion _____

città-town-ville-ort-ciudad _____

data d'acquisto-purchase date-date d'achat
einkaufdatum-fecha de compra _____

SN _____ LD _____

ALYA

versione-version-version-modell-versión _____

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

GARANTIEZERTIFIKAT

FARO gewährt dem Endkunden eine Garantie von **24 Monaten** ab dem Kaufsdatum.
Die Reparatur unter Garantie muss bei FARO durchgeführt werden; Transportspesen und –Risiken gehen zu Lasten des Kunden.
Die Reparatur unter Garantie wird nur dann gewährt, wenn:

- **Das Zertifikat vollständig ausgefüllt und per Fax im voraus an FARO geschickt wurde (039.6010540).**

Die Garantie gilt für Schäden, die durch Qualitätsmängel des Materials oder Herstellungsfehler entstanden sind. Im Falle einer begründeten Reklamation bietet die Garantie die kostenfreie Reparatur oder den Ersatz. **Ausgeschlossen ist die Möglichkeit, Schadenersatz und/oder Zinsvergütungen zu erhalten.**
Die Garantie wird nach unbestreitbarem Urteil von FARO als ungültig betrachtet, wenn Änderungen, Beschädigungen, nicht fachgerechter Gebrauch, schlechte Wartung oder normale Abnutzung vorliegen.

CERTIFICADO DE GARANTIA

La firma FARO concede al cliente final una garantía de **24 meses** a partir de la fecha de adquisición.
La reparación en garantía debe ser efectuada en la sede de FARO; los gastos y riesgos de transporte están a cargo del comprador.
La reparación en garantía se considera válida sólo cuando:

- **el certificado ha sido llenado en todas sus partes y enviado previamente a FARO vía Fax (039.6010540).**

La garantía cubre las averías debidas a defectos de calidad del material o defectos de fabricación; en caso de reclamo fundado la garantía permite la reparación o sustitución gratuita. **Se excluye la posibilidad de obtener una indemnización por daños y/o intereses.** La garantía no será considerada válida, a exclusiva discreción de FARO, en el caso de alteración, daños, uso incorrecto, mantenimiento inadecuado o desgaste normal.

Lampada dentale ***ALYA***

CERTIFICATO DI GARANZIA
GUARANTEE CERTIFICATE
CERTIFICAT DE GARANTIE
GARANTIEZERTIFIKAT
CERTIFICADO DE GARANTIA

DAL 1948: ESPERIENZA
E RINNOVAMENTO

COD.988280_REV.9

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