



Fluoresce HD Dual LED Coupler Operator Manual Non-US Version

REF 13568



Not Sterile

Manufacturer:

Lares Research 295 Lockheed Ave, Chico, CA 95973

EU REP

MDSS Schiffgraben 41, 30175 Hannover, Germany

Lares Research hopes that you will benefit greatly from working with your new Lares Fluoresce HD Dual LED coupler. Please observe the following notes to assure continued trouble-free and safe product operation:

1.0 Technical Data



Not Sterile

Lares Fluoresce HD LED Coupler

Connection: ISO-Type 3 (6 pin)

Weight: 20-30 grams

Pressure: maximum drive air and water pressure is 40 psi (275 KPa).

Voltage: LED Lamp operating voltage: 3.4 to 3.7 volts DC

Power: Fluoresce HD Dual LED Lamp: Violet light max. 1.5 Watts.

IEC 62471 Risk Group Classifications		
Actinic UV (200 nm - 400 nm)	Es	Exempt group
Near UV (315 nm - 400 nm)	Euva	Exempt group
Blue Light (300 nm - 700 nm)	Li	Moderate, Risk group 2
Retinal Thermal (380 nm - 1400 nm)	Li	Exempt group
IR radiation, eye (780 nm - 3000 nm)	Eir	Exempt group
Skin Thermal (380 nm - 3000 nm)	Esk	Exempt group

Filter Glasses: Amber color, 99.9% UVA and UVB blockage; (alternate specification: Optical Density (OD) > 5 for 190 -410 nm wavelengths; > 50% visible light transmission (vlt)).

⚠ **Caution:** These Fluoresce HD instructions are not intended for US distributed products.

2.0 Introduction

The Fluoresce HD Dual LED coupler has white and 405nm wavelength light sources built in. The integral coupler switch can be activated to change from white light to 405nm light. The Fluoresce HD Dual LED coupler is a visualization accessory that enables the clinician to observe caries and demineralized areas under blue/violet light and observe restorative treatment under white light. The Fluoresce HD Dual LED Coupler 405nm light, together with the Fluoresce HD filter glasses, form a tool which can be used as an aid to directly visualize bacterially infected dentin (referred to below as caries). Fluoresce HD Dual LED

system 405nm light is used as an aid in the detection of caries and helps the practitioner to get a spatial map of opened tissue areas which are suspect.

As shown in the illustration figure 1, the tooth is illuminated with a blue-violet light (405 nm). Carious tooth material and healthy dentin is excited to fluorescence. The operator views the cavity through a filter. Shorter wavelengths are thereby filtered out, in particular the violet excitation light. Light with higher wavelengths remains visible through the filter, so that the red-fluorescent sections of a caries can be precisely indicated. The red-fluorescent carious tooth material can be easily indicated and compared to neighboring green-fluorescent, healthy tooth material. The 405nm light (blue-violet color) causes healthy enamel & dentin to fluoresce with a green color. The contrasting colors of the viewable prepared surfaces can be used to aid the practitioner to perform caries diagnosis. As an aid in the detection of caries, any color other than shades of green visible on the prepared tooth surface through the filter glasses should direct the dental professional to examine that area using Gold Standard techniques. Fluoresce HD Dual LED system can provide additional information to supplement the dentist's visual observations, patient history and information from other diagnostic techniques. Diagnosis subsequent to the use of Fluoresce HD Dual LED system is performed and provided by the dental practitioner.

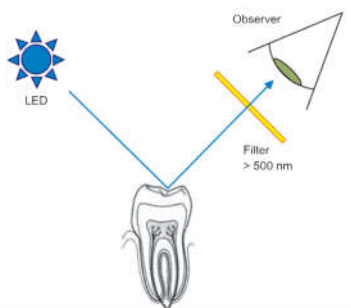


Figure 1.

3.0 Indications for use

The Lares Fluoresce HD Dual LED system is intended to be used by qualified physicians in dentistry as an aid in the diagnosis of dental caries. Fluoresce HD Dual LED System is a dental device indicated to provide connection for dental handpieces and is a visualization accessory that enables the clinician to observe caries and demineralized areas under blue/violet light and observe restorative treatment under white light.

- Fluoresce HD Dual LED Coupler is a dental device intended to provide a 360-degree swivel connection for air powered dental

handpieces that are KaVo MULTiflex® compatible.

⚠ 4.0 Cautions

4.1 Regulations require that the Lares Fluoresce HD Dual LED coupler only be used by a competent person for the described application and following:

- Valid regulations on work safety.
- Valid accident prevention measures.
- These operating instructions.

4.2 The user must:

- Only use Fluoresce HD Dual LED Coupler as a visualization accessory to enable the clinician to view caries and demineralized areas. Restorative treatment must be conducted under white light.
- Not use Fluoresce HD Dual LED Coupler 405 nm light if you have red-green color vision deficiency or similar visual impairment.
- Use only devices in good working order (no damage).
- Not use parts from other sources and/or not make any type of modification. Both may result in damage or injury.
- Use only handpieces with clean undamaged optics (solid optic handpieces recommended)
- Ensure that it is used for the correct purpose.
- Protect patients and third parties from all dangers.
- Do not look directly at the lamp (light) when energized.
- Not use Fluoresce HD Dual LED Coupler in conjunction with caries detection dyes!

4.3 Caries staining materials should not be applied before using Fluoresce HD Dual LED Coupler 405nm light. The use of staining materials can negatively influence the detection of dental caries using Fluoresce HD Dual LED Coupler. The staining materials sold for the purpose of caries detection generally exhibit a strong fluorescence, and in that way distort the visual impression with Fluoresce HD Dual LED Coupler.

4.4 When the Lares Fluoresce HD Dual LED Coupler will not be used for an extended period of time it should be removed from the hose, cleaned, maintained and stored in a dry place.

4.5 Any waste, which is generated must be recycled or disposed of in a manner which is safe, both for people and for the environment. This must be done in strict compliance with all applicable national regulations. Questions on proper disposal of the Lares product can be answered by Technical Services.

4.6 In case of any malfunction or problem stop product use immediately. Contact Lares Research Technical Service or your account representative.

Toll Free 1-888-333-8440

5.0 Putting Into Operation (Installation)

5.1 Connection to hose

⚠ **Warning:** When connecting Lares Fluoresce HD Dual LED coupler make sure the power source is compliant with IEC 60601-1.

⚠ **Caution:** A supply of dry, clean, compressed and uncontaminated air must be provided.

5.1.1 Screw the Lares Fluoresce HD Dual LED coupler to the dental unit hose and tighten firmly with the enclosed wrench.

5.1.2 Lightly spray the exposed o-rings and switch seal with Lares One-Step Handpiece Conditioner. Remove excess with a towel. The coupler remains connected to the hose during normal use & maintenance.

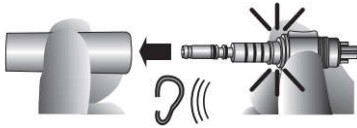
5.1.3 To remove from the hose use the wrench.

5.2 Changing the swivel handpiece

All Lares MX Swivel handpieces and Kavo MULTIFlex® connection handpieces may be connected to the Fluoresce HD Dual LED coupler.

5.2.1 Insert the Fluoresce HD Dual LED coupler into the backend of the handpiece and push until it clicks audibly into place.

5.2.2 Pull to remove.



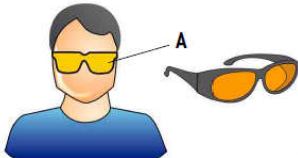
5.3 Verify LED Operation

⚠ **Caution:** Do not look directly at the Lamp (light) when energized.

- Activate lamp (depress foot switch [rheostat]).
- Activate coupler rocker switch to activate alternate wavelength LED light source.

5.4 Put on Filter Glasses

- Fit the provided filter glasses on eyes (or over prescription glasses).



5.5 Operation

5.5.1 Open the previously diagnosed carious lesion in the tooth using a dental handpiece and white light.

The Fluoresce HD Dual LED coupler white light (in conjunction with a handpiece) can be used for all typical restorative procedures. Switch the Fluoresce HD Dual LED Coupler to 405nm (blue-violet) light as an aid in caries detection. It works by highlighting carious tooth material in fluorescent red/orange and healthy tooth material in fluorescent green.

⚠ **Warning:** Fluoresce HD Dual LED Coupler cannot assess initial caries. Fluoresce HD Dual LED system has not been proven to detect incipient or just beginning caries.

⚠ **Caution:** 405nm light is only used as a visualization accessory to enable the clinician to view caries and demineralized areas. Restorative treatment must be conducted under white light.

5.5.2 View the fluorescent contrast of the caries using the 405nm light source. Visualize the indicated extents of the suspect areas.

The results of Fluoresce HD Dual LED Coupler viewing provide information, which can be used for treatment. The final decision as to whether treatment is performed and how long it should last is made by the user. Fluoresce HD Dual LED system 405 nm light source helps dental practitioners to get a spatial map of areas which are suspect.

Avoid external sources of light to ensure that the distinction (contrast) between red and green fluorescence is clearly maintained. Turn the operatory or head lamp lights away from the oral cavity or switch them off while using Fluoresce HD Dual LED Coupler in 405nm mode.

5.5.3 Remove decay with typical dental instruments. Prepare the tooth restoration using a handpiece and white light.

5.5.4 While viewing a deep caries, the fluorescent light may appear brown near the pulp. In this case in particular, a further detection tool (e.g. probe) should be used to decide on the course of treatment. Fluoresce HD Dual LED system helps to check the exeresis quality of damaged tissue during or at the end of the preparation in several clinical situations common in general practice. Diagnosis subsequent to the use of Fluoresce HD Dual LED system is performed and provided by the dental practitioner. The prepared surfaces viewed through the filter glasses display colors that can be interpreted in the following table #2.

TABLE 2	Normal signal	Alert signal	
		Bright Red/Orange	Black/Brown/Dark green
Viewed color	Light green	Bright Red/Orange	Black/Brown/Dark green
Supposed state of tissue	Healthy dentin	infected dentin or affected interface	Unknown material, utilize standard methods for end of treatment diagnosis
Examine for	Healthy tooth	Infected dentin*	Presumed end of treatment*

* Diagnosis subsequent to the use of Fluoresce HD Dual LED system is performed and provided by the dental practitioner. Alert signal is only an indication, the dental practitioner is the only expert to judge and adapt the treatment options to the situation and also decide to stop treatment based on their clinical knowledge.

6.0 Troubleshooting

6.1 No Light? - Replace the Dual LED Lamp

⚠ **Caution:** Allow to cool for five (5) minutes after use before changing lamp. Sleeve and lamp may be hot!

Unscrew the lamp guard by turning it counterclockwise. Pull the lamp out of the coupler and discard. Remove any fluid or debris from the sleeve and coupler socket with gauze or cotton swab and isopropyl. Carefully insert the new Dual LED Lamp into the sleeve. Align and insert the Dual LED lamp pins into the sockets in the coupler.

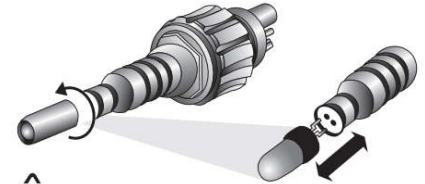


Figure 2.

Caution: Be sure that the two contact pins align with the two sockets in the coupler.

⚠ **Caution:** Do not look directly at the Lamp (Light) when energized.

6.2 Leaks? - Replace the o-rings

If the coupler leaks, replace the o-rings. Press the defective o-ring(s) to one side between two fingers until a loop is formed and then slide the rings to the front and remove them. Insert new o-ring(s) in the recesses and apply Lares One-Step conditioner.

⚠ **Caution:** Do not use Vaseline or any other type of grease on O-rings. It may result in handpiece or coupler damage.

6.3 Intermittent Light Operation?

If the lamp flashes or switch loses function in one position, clean the coupler in an ultrasonic cleaner in a mild cleaning solution for 5 minutes twice, once in each switch position, to remove any debris from the switch contacts. Spray the coupler with handpiece conditioner to lubricate the o-rings and preclude corrosion. Wipe the excess handpiece conditioner off with a lint free wipe.

7.0 Care Instructions

Cleaning Exterior

The Lares Fluoresce HD Dual LED coupler can be cleaned on the outside with an isopropyl alcohol solution.

7.1 Maintenance at the site of use (chair side)

⚠ WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated handpieces and accessories.

- ▶ Take suitable personal protective measures (i.e. exam gloves, eye protection, 5 µm particulate filter mask).

- ▶ Remove all residual cement, composite or blood without delay.
- ▶ Clean and maintain the coupler as soon as possible after treatment.
- ▶ Remove the coupler from the dental unit hose.
- ▶ The coupler must be dry when transported for cleaning and sterilizing.
- ▶ Do not submerge or place it in any solution.

7.2 Cleaning

7.2.1 Cleaning: Manual cleaning - external

Accessories required:

- Warm tap water 40 °C ± 5 °C (104 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush or

⚠ CAUTION

Contact corrosion due to moisture.

Leaving coupler in autoclave after cycle has finished may damage the coupler.

- ▶ Immediately remove the product from the steam sterilizer after the sterilization cycle to reduce condensation!

⚠ CAUTION

Do not use Flash Sterilization Techniques.

These techniques are not validated for efficacy and damage to the coupler may result.

comparable nylon-bristled dental instrument cleaning brush.

Manual cleaning process:

Coupler disassembly not required.

- ▶ Rinse product under warm flowing tap water to remove gross soil.
- ▶ Brush off while rinsing under flowing warm tap water for 30 to 45 seconds to remove all soil. Brush in a direction parallel to the o-ring grooves and completely around the coupler.
- ▶ Use filtered pressurized air to completely dry handpiece. If soil is still visible when dry, repeat the cleaning steps.
- ▶ Apply Lares One-Step Handpiece Conditioner to the exterior of the coupler. Spray the conditioner for two seconds over a towel or sink.

- ▶ Remove excess conditioner from the exterior of coupler with a towel.

7.2.2 Cleaning: Automated external cleaning
Not applicable.

7.2.3 Cleaning: Manual cleaning of the inside
Not applicable.

7.2.4 Cleaning: Automated internal cleaning
Not applicable.

7.3 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.

Handpiece damage may result.

- ▶ Never disinfect in a thermo-disinfectant.

7.3.1 Disinfection: Manual disinfection - external

The Lares Fluoresce HD Dual LED coupler can be disinfected on the outside with chemical disinfectants (spray disinfectant or wipe clean disinfectants). The coupler should not be immersed in any disinfecting solutions.

7.3.2 Disinfection: Manual disinfection - internal
Not Applicable

7.3.3 Disinfection: Machine disinfection - external and internal
Not Applicable

7.4 Drying

7.4.1 Manual Drying

- ▶ Blow off the outside and inside with compressed air until water drops are no longer visible.

7.4.2 Automatic Drying
Not Applicable

7.5 Care products and systems - Servicing

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- ▶ Perform proper care regularly!

Note

Lares Research only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

7.5.1 Care products and systems - Servicing:
Care with Lares One-Step Handpiece Conditioner
Lares Research recommends applying handpiece conditioner after each time it is used, i.e. after each cleaning and before each sterilization cycle.

⚠ CAUTION

Malfunctions from improper servicing and care.

Reduced product life or damaged device.!

7.5.2 Inspection and Function Testing:
Fluoresce HD Dual LED Couplers: Visually inspect for damage and wear.
Service or Discard damaged couplers.

7.6 Packaging prior to autoclaving

Note

The autoclave bag must be large enough for the coupler so that the bag is not stretched. The quality and use of the autoclave bag must satisfy applicable standards, be cleared to market and be suitable for the autoclave procedure!

- ▶ Seal each coupler individually in an autoclave bag.

7.7 Autoclaving

Process couplers in a steam sterilizer (autoclave).

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- ▶ Before each autoclave cycle, service the coupler with Lares One-Step Handpiece Conditioner.

The Lares Research Fluoresce HD Dual LED Coupler has a maximum temperature resistance up to 135 °C (275 °F).
Autoclave with gravitation process for at least 15 minutes at 132 °C ± 1 °C (270 °F ± 1.8 °F)
Drying time: 30 minutes minimum.

When autoclaving multiple couplers in one autoclave cycle ensure that the autoclave's maximum load is not exceeded. Follow the autoclave manufacturer's Instructions for Use.

7.8 Handling and storage after autoclaving

- ▶ Keep couplers in the autoclave bag until next use.

► Cleaned and autoclaved couplers should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.

Note

The reprocessing instructions provided have been validated by Lares Research as being CAPABLE of preparing a Fluoresce HD Dual LED Coupler for re-use. It remains the responsibility of the practitioner to ensure that the processing was actually performed using equipment, materials and personnel in the practitioner's facility to achieve the desired result. Use only FDA cleared equipment and materials for autoclaving and routine monitoring of the autoclaving process.

⚠ WARNING

Hazard from cross infection.

There is a risk of cross infection from patient to patient or patient to dental staff contaminated couplers.

► Do not deviate from the specified coupler reprocessing steps (i.e. cleaning, autoclaving and storage).

8.0 Accessories

Replacement Parts

Description	Part ID
Wrench	10363
Gasket	10905
Dual LED Lamp	11553
O-ring Kit	10074
Bulb Sleeve	11459
Switch Seal	11602
Handpiece Conditioner	10083

9.0 Limited Warranty:

Each Lares Fluoresce HD Dual LED Coupler (and LED lamp assembly) is warranted against defects in materials and workmanship for a period of 1 year from the date of purchase.

Any use that is not described in this manual as correct usage is considered incorrect usage. Lares Research is not to be held liable for any damage caused as a result of incorrect use. The dental practitioner bears all risks.

9.1 Additional Conditions of Warranty:

1. Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
2. The Fluoresce HD Dual LED coupler must be operated and maintained in accordance

with procedures outlined in these instructions.

3. The Fluoresce HD Dual LED coupler must not be subjected to abuse or neglect.

4. The Fluoresce HD Dual LED coupler must not be repaired or disassembled by anyone other than Lares Research or your authorized Lares distributor.

Lares Research will repair or replace, at its discretion, without charge any defective parts covered by this warranty provided the swivel coupler is returned to the factory, transportation prepaid. (Outside the US return to your authorized Lares distributor.) Lares Research makes no other warranties expressed or implied.

10.0 Patents:

This product is covered by one or more of the following patents:

US United States: 6,769,911 / 9,028,251 **AU**

Australia: 2010/300079

NZ New Zealand: 599177.

11.0 Safety note:

If a serious safety event should occur during the operation of this device it should be reported to Lares Research. It should also be reported to the regulatory authorities of the marketing region where the user/patient are established.

Disposal:

Prior to disposal this product must be reprocessed (sterilized) per this instruction.

Symbol Description	
REF Catalog Number	 Caution
SN Serial Number	 Manufacturer
EU REP EU Representative	YYYY-MM Manufacture Date
 Consult Accompanying Documents	 Steam autoclave
UDI Unique Device Identifier	 Conformity Marking