

Perceptive Dual LED Motor
Instructions for Use

REF 13512

RX Only

Lares Research
295 Lockheed Ave
Chico, CA 95973

Device Specifications

⚠ Caution: This device is not designed for use in an explosive atmosphere (anesthetic gas).

Identification:

Brushless electric sterilizable micromotor. Handpiece attachment per ISO 3964 with internal sprays and LED lighting.

Intended Use:

Product intended for professional use only. Use in dentistry for general dentistry work.

Any use other than that for which this device is intended is prohibited and may prove dangerous.

Classification:

Class IIa in accordance with European Medical Device Regulation. This medical device is in compliance with the legislation in force.

Electrical Safety:

According to IEC 60601-1 standard (General safety for medical Electrical Equipment), The device shall be classified as a class II type B device.

The following requirements as specified in IEC 60601-1 apply:

- Protection against electrical shock
- Ingress of liquids
- Protection against excessive temperatures and other safety hazards.

Electromagnetic Compatibility:

Corresponds to the electromagnetic compatibility in accordance with IEC 60601-2 and IEC 80601-2-60.

Motor Type:

Brushless type, 3 phase motor, synchronous with permanent magnets.

Cooling:

Cooling is conducted through compressed air from the unit. To ensure that your Contra-angle/micro motor unit functions with maximum efficiency, it must be cooled by an air supply of 8-10 standard liters per minute on the nose of the micro-motor.

Air consumption:

Less than 40 NI/MIN

Dimensions:

22 X 71.7 mm (0.87 X 2.82 inches) including the nose attachment.

Coupling:

Nose in accordance with ISO 3964, with internal spray and light.

Weight:

70.1g (2.47 oz.) without the cable.

Noise Level:

In accordance with ISO 14457, less than 53 dBA at 45 cm (17.72 inches).

Motor Rotation Speed:

From 1000 rpm to a maximum 40,000 rpm. Clockwise and anti-clockwise.

Motor Direction:

Clockwise & anti-clockwise

Fluoresce™ Technical Data:

Fluoresce HD Dual LED has a blue light (405 nm wavelength) power of 30-40 mW/cm² and white light brightness of 25k-35k lux at the end of a handpiece.

Actinic UV (200 nm - 400 nm)	Es	Exempt group
Near UV (315 nm - 400 nm)	Euva	Exempt group
Blue Light (300 nm - 700 nm)	La	Moderate, Risk group 2
Retinal Thermal (380 nm-1400nm)	La	Exempt group
IR radiation, eye (780 nm - 3000nm)	Er	Exempt group
Skin Thermal (380 nm - 3000 nm)	Er	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)).

Fluoresce HD Introduction

This motor is equipped with a Fluoresce HD enabled Dual Wavelength LED. The LED consists of a white light and a 405 nm wavelength blue light. The white/blue toggle switch in the Perceptive app is used to switch between the two light types. The Fluoresce Dual Wavelength motor 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 405 nm light (henceforth referred to as blue 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 henceforth as caries). Fluoresce blue light is used to 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 figure 1, the tooth is illuminated with a blue-violet light. 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 remain visible through the filter, so that the red-fluorescent sections of 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 blue light causes healthy enamel & dentin to fluoresce with a green color (see table 2 for examples). 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 the 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.

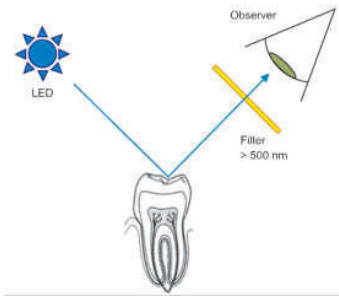


Figure 1.

Device Operation

⚠ Caution

- Never mount an instrument on a rotating motor.
- It is essential to use dry, purified compressed air to ensure the long working life of the device. Maintain the quality of the air and water by regular maintenance of the compressor and filtration systems. The use of unfiltered hard water will lead to early blockage of the tubes, connectors, and spray ports.
- Only use the Fluoresce HD Dual LED motor as a visualization accessory to enable the clinician to view caries and demineralized areas. Restorative treatment must be conducted under white light.
- Do not use the Fluoresce HD Dual LED motor 405 nm light if you have red-green color vision deficiency or similar visual impairment.
- Do not use parts from other sources and/or make any type of modification. Both may result in damage or injury.
- Only use handpieces with clean undamaged optics (solid optic handpieces recommended).
- Do not look directly at the LED bulb while energized.
- Do not use the Fluoresce HD motor 405 nm light in conjunction with caries detection dyes. The use of staining materials can negatively influence the detection of dental caries using the the Fluoresce HD motor.
- The Fluoresce HD Dual LED Motor cannot assess initial caries and this device has not been proven to detect incipient or just beginning caries.

Operating Environment:

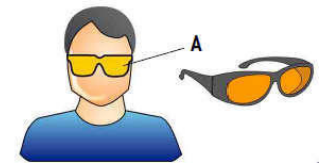
Temperature: +10 °C (50°F) to +25°C (77°F).
Relative Humidity: 20% to 90%.
Atmospheric pressure: 700 hPa to 1060 hPa. Altitude: 0 to 3048m (0 to 10,000 ft).

To Use the Motor:

1. Connect the Perceptive motor to the end of the control tubing; align the connector pins on the motor with the holes on the tubing, tighten clockwise. (Figures 4 and 5)
2. See Perceptive Motor Control Instructions for operating the motor.

To Use Fluoresce HD visual aid (405 nm light):

1. Open the previously diagnosed carious lesion in the tooth using a dental handpiece and white light. The white light (in conjunction with a handpiece) can be used for all typical restorative procedures.
2. Fit the filter glasses on eyes (or over prescription glasses).



3. View the opened area with the blue light to aid in visualizing the extent of remaining caries.
4. Remove decay with typical dental instruments. Prepare the tooth restoration using a handpiece and white light.
5. 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. The Fluoresce HD Dual LED motor 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 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.

	Normal signal	Alert signal	
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 the 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.

Device Maintenance

⚠ Caution

- The motor is delivered “non-sterile”.
- Before using for the first time and within a maximum of 30 minutes after each treatment, clean, then sterilize the motor. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
- Do not clean in a washer/disinfectant unit.
- Do not immerse in an ultra-sonic bath or any other solutions.
- Use only Lares Research provided maintenance products and parts or those recommended by Lares Research. Using other products or parts may cause operational failure and/or void the warranty.
- Do not spray any lubricant or cleaning solution into the motor.
- Wearing of personal protective equipment (gloves, goggles etc.), should be complied with by medical personnel using or performing maintenance of medical devices that are contaminated or potentially contaminated.
- Pointed and sharp instruments should be handled with great caution.

- In the event of prolonged disuse, the motor must be stored in a dry environment. Clean and sterilize the motor before reuse.
- Check that the sterilizer and the water that is used are clean. After each sterilization cycle, remove the device from the sterilizing apparatus immediately to reduce the risk of corrosion.

Clean the motor exterior:

We recommend that the motor is cleaned, disinfected, and sterilized as directed below before the initial first use and subsequently after each treatment.

The Perceptive Motor is maintenance free and does not require lubrication.

1. Remove the motor from the hose and hold the motor by the nose under warm running water 40°C ± 5°C (104°F ± 10°F).
2. With the aid of a soft brush, clean the external surface of the motor (figure 2). Avoid allowing water to enter internally into the motor either by the nose or the connector.
3. Wipe the handpiece with disinfectant wipe.
4. Dry the motor with a soft towel.
5. Visually check the cleanliness of the motor. If required, re-clean with a soft brush.

NOTE: Lares Research recommends the following disinfectant: CaviWipes® (manufactured by Metrex). After cleaning, if the moisture is present, wipe off with dry cloth or blow it off with compressed air until there is no moisture in the interior and exterior. When blowing off with compressed air, cover the handpiece with cloth to prevent scattering of water.

Sterilization:

⚠ Caution

- The quality of the sterilization depends very much on the cleanliness of the device. Only perfectly clean devices may be sterilized.
- Do not use a sterilization procedure other than the one described below.

1. Install protective motor caps prior to sterilization. Figure 3
2. Insert the motor into an autoclave bag, one motor per bag.
3. Lares Research has validated a gravity type steam autoclave cycle of 132°C (270°F) for 15 minutes with a drying time of 30 minutes.

NOTE: Temperature should not exceed 275°F (135°C). Follow autoclave manufacturer's instructions.

4. After autoclave cycle is completed, remove instrument immediately and allow to dry. Remove protective caps. Allow to cool down 30 minutes prior to handling.

General Precautions

⚠ Other precautions for use

- Excess material from products used for maintenance (lubricants, cleaning products and disinfectants) originating from the motor may penetrate the electric motor and interfere with its functioning. It is essential to follow the maintenance instructions accompanying each product. Never lubricate the electric motor.

- The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order. In the event of irregular functioning, excessive vibration, abnormal heating, or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact Lares Research.
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.
- must rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.
- must use the Fluoresce blue light as a visualization accessory only, this enables the clinician to observe caries and demineralized areas under blue/violet light and observe restorative treatment under white light.

- The device must not be used in the presence of open lesions, injury to soft tissue or recent extractions. The exhaust air could propel infected material into the wounds and cause infections and risk embolism.

- The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorized and may be dangerous. The medical device meets all the current legal requirements.

Warranty and Service Servicing:

O-rings should be changed when they are damaged or the motor is leaking (figure 6 and 7).

Never disassemble the device. For any modification or repair, we recommend that you contact your account manager directly. Lares Research asks that you have the device checked or inspected every 300 sterilization cycles or once per year.

Information:

The technical specifications, illustration and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Lares Research directly at 1-888-333-8440.

Warranty:

Each Lares Perceptive Motor is warranted against defects in materials and workmanship for a period of 2 years from the date of purchase.

Additional Conditions of Warranty:

- Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
- The motor must be operated and maintained in accordance with procedures outlined in these instructions.
- The motor must not be subjected to abuse or neglect.
- The motor 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 Perceptive motor 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.

Transportation, Storage & Disposal

Transport and storage conditions:

Temperature between -25°C (-13°F) and 70°C (158°F), relative humidity between 20% and 80%, atmospheric pressure 500 hPa to 1060 hPa (7.25 to 15.37 psi).

Disposal:

This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

Serious Event Notification:

If a serious event occurs during the operation of this device it should be reported to Lares Research. In the European Union it should also be reported to the competent authority of the Member State in which the user and/or patient is established.

Replacement Parts

13191 - Replacement Sterilization Caps (2pcs.) Figure 3

13506 - Replacement O-Rings, Motor Nose Cone (3 pcs.) Figure 6

13507 - Replacement Hose Nut O-Ring Figure 7

Questions? Call 1-888-333-8440, Ext. 1

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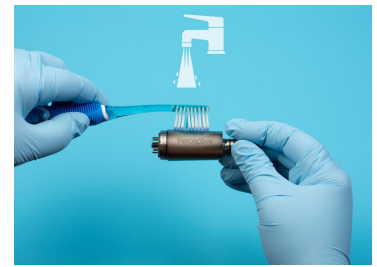


Figure 2



Figure 3

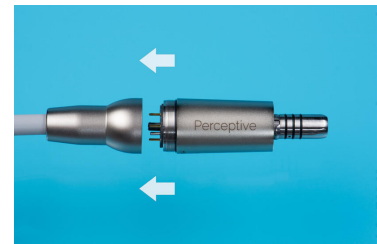


Figure 4



Figure 5



Figure 6



Figure 7

Symbol Description	
REF	Catalog Part Number
SN	Product Serial Number
EC	European Community Representative
REP	European Community Representative
CE	Conformity Marking
MAN	Manufacturer
DATE	YYYY-MM Manufacture Date
DOC	Consult Accompanying Documents
PAT	Parts Applied to Patient
AUT	Steam Autoclave