

# INSTRUCTIONS

for Use and Care



Orascoptic<sup>™</sup> Dragonfly<sup>™</sup> Powered Loupe

#### **Indications for Use**

This device is intended to illuminate and magnify oral structures and operating areas and is to be used by qualified health professionals including, but not limited to, dentists, dental hygienists, medical doctors and medical professionals.

This device is suitable in professional healthcare facility environments, specifically physician/dental offices and clinics, limited care facilities, freestanding surgical centers, and hospitals (emergency rooms, patient rooms, intensive care rooms, and surgery rooms), except near high frequency surgical equipment outside the radio frequency shielded room for magnetic resonance imaging (MRI).

#### **Precautions**

- 1. Before each use, ensure all screws and removable components are secured to the device.
- 2. To prolong the life of the batteries, do not store in a fully charged or discharged state.
- 3 DO NOT
  - ... disassemble or modify the device
  - ... remove the product serial number labeling
  - ... touch exposed electrical contacts
  - ... begin a procedure while the battery indicator light is flashing
  - ... hang or pull on exposed cables
  - ... spray directly onto the device
  - ... run any part of the device under water or submerge in any liquid or an ultrasonic cleaner
  - ... use an autoclave, chemiclave, glutaraldehyde, iodophor, or any other sterilization method
  - ... use a cleaner with alcohol concentration greater than 70%
  - ... use paper towel to clean the lenses

Contraindications None known. Adverse Reactions None known.

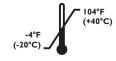
### **Disposal Instructions**



When you plan to dispose of the device, please return to Orascoptic for recycling. The European Union Waste Electrical and Electronic Equipment (WEEE) directive forbids the disposal of waste electrical and electronic equipment as unsorted municipal waste, requiring that it be collected and recycled or disposed of separately. Hazardous substances are present in electrical and electronic equipment and present potential risk to human health and environment if disposed of in municipal landfills which are not designed to prevent migration of substances into the soil and groundwater. If you need assistance when disposing the device, please call one of our Customer Care Specialists or your authorized Orascoptic distributor.

This device contains lithium-ion cells. Recycle or dispose of the batteries accordingly to national, state, and local regulations.

### **Transport and Storage**





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#### **Warnings**

- 1. The device must be used exclusively for the intended purpose described.
- 2. Do not use the device if any component is damaged, loose, detached, or missing. This includes lenses, telescopes, frame body, temple arms, nose pad, headlight, batteries, cables, and electrical contacts. Parts that are broken, missing, distorted or worn should be replaced immediately. Should such repair or replacement become necessary, ORASCOPTIC OR AN AUTHORIZED SERVICE DEALER SHOULD PERFORM ALL REPAIRS TO THIS PRODUCT.
- 3. The use of power adapters, chargers, or batteries other than those provided for use with the device may result in increased emissions or decreased immunity and may cause the system to be non-compliant with the requirements of IEC 60601-1-2. Only the power adapter, charger, and batteries that ship with the device, should be used.
- 4. This product maintains compliance with blue light testing standards for safety, set by the International Electrotechnical Commission (IEC). As with all lighting products, there are risks associated with staring directly into the light.
  - IEC 62471 Risk Group 2 CAUTION: Possibly hazardous optical radiation is emitted from this product. Do not stare at the operating lamp. May be harmful to the eyes.
- 5. Misuse of batteries may cause them to become hot, explode or ignite, and may cause serious injury. The following safety warnings must be followed:
  - · Never open or modify the frame, batteries, battery charger, or power adapter.
  - Do not use outside.
  - Protect from fluids and damp environments.
  - Maintain operational environment of 32° to 77°F (0° to 25° C).
  - Do not bring any part of the device into contact with fire or severe heat over 158°F (70°C).
  - If you determine that the device is hot, emits an odor, or changes color or shape, disconnect power immediately. The device must not be used again.
- 6. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 7. Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Orascoptic™ Dragonfly™ Powered Loupe

## **Getting Started With Your New Dragonfly Powered Loupe**

Thank you for purchasing the Dragonfly powered loupe. Please take a moment to read through these instructions to familiarize yourself with the features of this device. It is common for new users of magnification to experience some initial disorientation. This may also occur when increasing magnification from a lower power. In such cases, a two to three week acclimation period is recommended. If you initially experience dizziness, wear your Dragonfly for no more than one hour at a time and start by performing simple procedures. As your eyes adapt to a magnified field and your hand-eye coordination develops, gradually extend the time.



#### **Accessories Included**

Power Adapter, Head Strap, Curing Filter, Side Shields, Customized Storage Case, Optical Screwdriver, Lens Cleaning Cloth, Anti-fog Cloth

Please call one of our Customer Care Specialists or your authorized Orascoptic distributor to order additional or replacement parts.

Orascoptic™ Dragonfly™ Powered Loupe

## **Cleaning and Disinfecting**

Your Dragonfly powered loupe is a precision optical-electrical instrument manufactured from high quality components. With proper care, it will provide a long and useful life. You must adhere to the following cleaning and disinfecting instructions or damage may result. Additionally, it is recommended to follow all instructions provided with your chosen cleaning/disinfecting solution.

#### **Recommended Disinfectants**

CaviCide<sup>™</sup>, CaviCide1<sup>™</sup>, CaviWipes<sup>™</sup>, or CaviWipes1<sup>™</sup>

- 1. Dampen or spray a soft cloth with your chosen cleaning/disinfecting solution, or use a disinfectant wipe. Squeeze excess fluid out of the cloth or wipe before using.
- 2. Hold the device securely while cleaning all surfaces with the damp cloth or wipe, including lenses, telescopes, temple arms, side shields, and headlight.
- 3. Discard dirty cloths or wipes and repeat the steps above until the device is clean.
- 4. If using a disinfectant, allow all surfaces to remain saturated for the proper duration (following instructions provided with your chosen disinfecting solution).
- 5. Use a clean and dry soft cloth to wipe all remaining cleaning/disinfecting solution from the surface of your device.
- 6. Dampen a lens cleaning cloth with lens cleaning solution and wipe the inside and outside of the lenses, telescopes, and side shields to remove any streaks left from the cleaning and disinfecting process.

  One lens cleaning cloth has been provided with your Dragonfly powered loupe. Please call one of our Customer Care Specialists or your authorized Orascoptic distributor to purchase additional lens cleaning cloths.

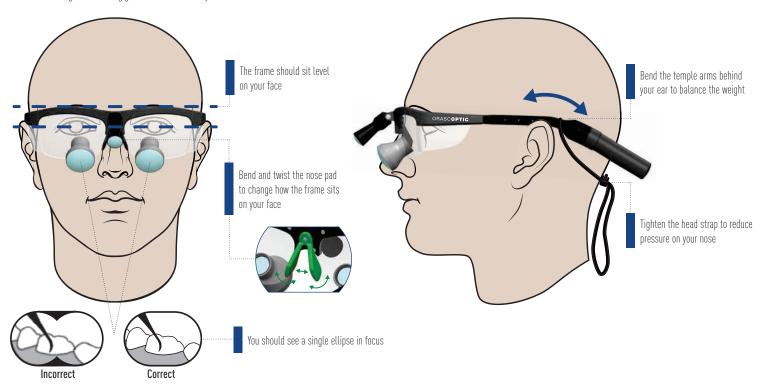
#### DO NOT

- ... spray directly onto the device
- ... hang or pull on exposed cables
- ... use paper towel to clean the lenses
- ... use a cleaning/disinfecting solution with alcohol concentration greater than 70%
- ... run any part of the device under water or submerge in any liquid or ultrasonic cleaner
- ... use an autoclave, chemiclave, glutaraldehyde, iodophor, or any other sterilization method

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## **Precision Tuning Your Dragonfly Powered Loupe**

Although your Dragonfly powered loupe has been fully tested and customized by our laboratory technicians, it may need to be initially adjusted to your individual facial geometry. Please read through the following guide to learn how to adjust this device.



Orascoptic<sup>™</sup> Dragonfly<sup>™</sup> Powered Loupe

### **Leveling the Frame**

It is important that the frame sits level on your face so your visual field is clear and in focus.

- 1. Place the frame on your head while in front of a mirror to level the top of the frame with the pupils of your eyes.
- If the frame is not level with your pupils, reposition the frame on your face by adjusting the nose pad and temple arms until the frame is level.
- 3. If the frame cannot be leveled with your pupils, call one of our Technical Support Specialists to assist you with properly adjusting your frame.
  - Attempting to adjust the frame beyond what is defined in these instructions without assistance may result in damage.

### **Adjusting the Nose Pad**

Adjusting the nose pad will change how the frame rests on your nose and allow you to properly see through the telescopes.

- To lower the frame on your face, spread the nose pad apart.
- To raise the frame on your face, pinch the nose pad together.
- If the frame is not centered on your face, bend one side of the nose pad or the other as needed until
  the frame is centered.
- Flatten or twist the ends of the nose pad for additional comfort.

Videos featuring helpful tips to adjust and clean Orascoptic products are available at Orascoptic.com/support/videos

#### **Adjusting the Temple Arms**

We recommend bending the temple arms to conform with the shape of your face and head, allowing the frame to fit more comfortably. While wearing your Dragonfly, bend the temple arms down behind your ears to create a secure fit and to optimally balance the weight of the frame. In rare occasions, bending the temple arms at a slightly upward angle may achieve the best balance. The temple arms will maintain your desired adjustments.

#### **Your Visual Field**

When the focus is properly adjusted, the two circles that form the field of view should appear as an ellipse and be in focus. Due to varying facial geometry, sometimes the preset convergence angle may not be aligned properly for your eyes. If your field of view is not clear, or you are experiencing double vision or eye strain, reposition the frame on your face by adjusting the nose pad and temple arms until you have a clear field of view.

### Storing your Dragonfly when not in use

Your Dragonfly is shipped in a customized storage case. We recommend always storing the device, unused batteries, and accessories in the case when not in use.



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## **Operating Your Dragonfly Powered Loupe**

The Dragonfly is powered by two specially designed Lithium-Ion batteries and is controlled with a single button on the right temple arm. Please read through the following quide to learn how to operate this device.



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### **Installing the Batteries**

The batteries are partially charged when shipped, and should be fully charged prior to use. Both batteries will deplete together. To ensure maximum run time, replace both batteries with fully charged batteries at the same time.

- Insert a fully charged battery into each battery pod. The battery contacts should be visible in the battery pod opening.
- 2. With the batteries inside, screw each battery pod clockwise onto the temple arm.
- 3. The right temple arm has a battery indicator light that blinks **SCARLET** to signify battery status:
  - When installing the first battery, the battery indicator light will blink once to signify the frame is now powered.
  - When both batteries are nearly depleted and need to be changed, the battery indicator light
    will blink every 2 seconds.

### **Operating the Headlight**

- 1. Press the control button on the right temple arm to turn the headlight on.
- 2. (PRO model only) Press the control button again to alternate the light intensity between high and low.
- 3. Press and hold the control button to turn the headlight off.
- Tilt the headlight to the appropriate angle to illuminate your visual field when looking through the telescopes.



### **Charging the Batteries**

Your Dragonfly comes with multiple rechargeable batteries, allowing two batteries to be in use while others are charging.

- 1. Plug the power adapter into an electrical outlet and into the back of the charger.
- Insert batteries into the charger bays and press down to ensure they are fully seated. The battery contacts should be inserted first and not visible while charging.
- 3. Each charging indicator light will illuminate AMBER when the battery in that bay is charging and will turn GREEN when that battery is fully charged.



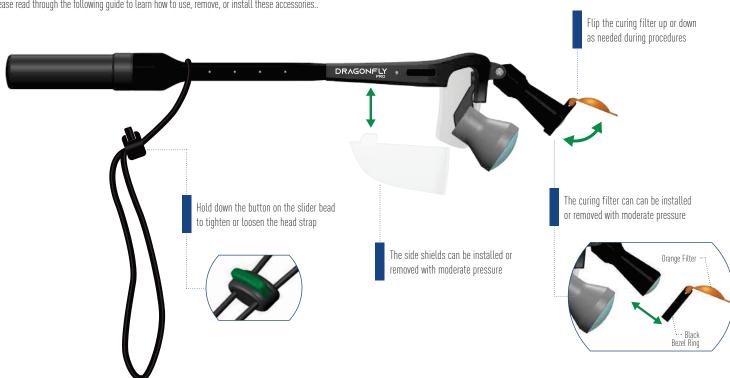
### Lithium-Ion Battery Technology

Rechargeable lithium-ion battery technology is ideal for portable devices like the Dragonfly powered loupe.

- Do not leave the batteries unused for extended periods of time, either in the device or in storage.
- Rechareable lithium-ion batteries have a limited life and will gradually lose their capacity to hold a charge, reducing the runtime of powered devices.
- If you find yourself charging batteries more often, or your device is not running as long as it should, please call our Customer Care Specialists or your authorized Orascoptic distributor to purchase replacement batteries.

## **Dragonfly Powered Loupe Accessories**

The Dragonfly includes accessory items that can be removed if not needed, or replaced if damaged. Please read through the following quide to learn how to use, remove, or install these accessories...



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### **Curing Filter**

The curing filter should be used when working with light-cured composites. When applying these materials, unfiltered light from the headlight can cause premature curing of the composite. The curing filter is made up of two components, the black bezel ring that is secured to the end of the headlight and the orange filter that can be flipped up and down as needed during procedures.

- To remove the curing filter, grasp the headlight with one hand and the black bezel ring with another and pull. It is held with a friction fit and will separate from the headlight with moderate force.
- To attach the curing filter, flip the orange filter to the UP-position and carefully press the black bezel ring onto the headlight, making sure the hinge is at the top.

Do not directly pull or press on the orange filter.

#### **Side Shields**

The side shields offer additional protection. We recommend keeping the side shields installed to maintain the device's ANSI Z87.1 certified protection, but can be removed if preferred.

- To remove the side shields, grasp the frame with one hand and the side shield with another and pull
  straight down. They are held with a friction fit and will separate from the frame with moderate force.
- To attach the side shields, align the locking tab of the side shield with the slot on the bottom of
  the frame and push straight up with moderate force, making sure the correct side shield is being
  installed on the correct temple arm. When properly installed, the front of the side shields will
  curve around the front of each lens

### **Head Strap**

We recommend tightening the head strap during use to help distribute the weight around your head instead of on your nose. The frame should fit comfortably with minimal pressure on your nose.

- While holding down the button on the slider bead, tighten or loosen the headstrap as needed.
   Release the button to lock the slider bead at the desired position.
- The head strap is made of an elastic material that can stretch over the battery pods to remove or replace if worn out.

### **Lens Cleaning Cloth**

Orascoptic lens cleaning cloths are made of high quality microfiber material to absorb and remove dust, smudges, fingerprints, or other liquid splatter. They are ideal for cleaning lenses, telescopes, and side shields without leaving streaks or scuff marks. They can be used dry or with your chosen cleaning solution as described in the **Cleaning and Disinfecting** section of these instructions.

### **Anti-Fog Cloth**

Orascoptic anti-fog cloths can be used to wipe the telescope lenses prior to use as an additional step to prevent fogging. When using anti-fog cloths, follow instructions provided with the cloth.

One lens cleaning cloth and one anti-fog cloth has been provided with your Dragonfly powered loupe. Please call our Customer Care Specialists or your authorized Orascoptic distributor to purchase additional cloths.



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## **Variable Magnification**

### **EyeZoom™ Ocular Series**

Orascoptic EyeZoom telescopes can transition between multiple magnification powers.

- To change the magnification, grasp the black ridged portion of each telescope and turn it so the arrow aligns with your preferred magnification level.
- 2. Ensure both telescopes are set to the same power.

### EyeZoom™ Mini







### **Services**

### **Loupe Prescription Service**

If your eye prescription changes, you can send your Dragonfly powered loupe into our optical laboratory to install your new prescription.

### **Cleaning and Repair Service**

Orascoptic offers a cleaning and repair service that is recommended every two years. Optical lab technicians will clean and disinfect your telescopes and frame, and replace worn-out screws, nose pad, side shields, and head strap.

Orascoptic continuously improves its products as a result of customer feedback. After service, products may reflect improvements in appearance and function.

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	Specifications		
Weight	2.5x Loupe: 4.53 ounces (129 grams)		
Battery type	Lithium-ion		
Light intensity modes	49 lumens on LOW setting   78 lumens on HIGH setting		
Color Rendering Index (CRI)	90+		
Correlated Color Temperature (CCT)	5700K		
Battery runtime (set of two)	Approximately 6.4 hours on LOW setting Approximately 4 hours on HIGH setting		
Charge time (set of two)	<2 hours		
Diameter of headlight	0.55 inches (14 mm)		
Electrical	Class II		
Operation mode	Continuous		
EMC standard	IEC60601-1-2, class B, EN55011		
Safety standard	IEC60601-1, IEC 62471		
Operating environment	32" to 77"F (0" to 25" C) 10% to 85% relative humidity (non-condensing) 0.5 atm to 1.0 atm (500 hPa to 1060 hPa) atmospheric pressure		

Electromagnetic Compatibility Test				
CISPR 11 Emissions: Radiated RF	Group 1, Class B			
IEC 61000-4-2 Immunity: Electrostatic Discharge	±8kV contact ±15kV air			
IEC 61000-4-3 Immunity: Radiated RF	3V/m, 80MHz – 2.7GHz, 80% 1kHz AM			
IEC 61000-4-8 Immunity: Power Frequency Magnetic Fields	30A/m, 50/60Hz			
IEC 61000-4-3 Immunity: Proximity Fields from RF Wireless Communications Equipment	IEC 60601-1-2:2014, section 8.10			

Troubleshooting					
Problem	Solution				
FRAME: Headlight does not turn on	Check that both battery pods contain a fully charged battery and both batteries are properly oriented with the battery contacts facing toward the temple arm.				
FRAME: Temple arm battery indicator light is blinking scarlet FRAME: Headlight turns on momentarily and then turns off	Indicates both batteries are nearly depleted. Replace both batteries with fully charged batteries and charge the depleted batteries.				
CHARGER: Charging indicator light does not illuminate amber or green	Check that the battery is properly oriented with the battery contacts inside the charger and not visible while charging.				
CHARGER: Charging indicator light is rapidly alternating between green and amber	The battery is not properly seated in the charging bay. Roll the battery inside the charging bay until the indicator light stops blinking.				

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Symbol Glossary								
MD	Medical Device		Order Type		Address of Distributor			
REF	Reference Number / Part Number	J	Phone Number	c Unstable Uns	Intertek Certification			
SO	Sales Order Number		Email Address		Waste Electrical and Electronic Equipment			
РО	Purchase Order Number		Website Address	-4°F (+40°C)	Temperature Limitations			
WO	Work Order Number		Engraving Content	10%	Humidity Limitations			
SN	Serial Number		Shipping Destination	0.5 atm (500 hPa)	Pressure Limitations			
LOT	Lot Number	<b>≗</b> ≡	Customer Information	$R_{\!$	Prescription Device			
UDI	Unique Device Identification	<del>[</del> ]	Consult Instructions for Use	EC REP	Authorized Representative for European Union			
	Address of Manufacturer	A	Use Caution	CH REP	Authorized Representative in Switzerland			
<b>₩</b>	Country of Manufacturer	CE	European Conformity	UK RP	Authorized Representative in United Kingdom			
~~ <b>/</b>	Date of Manufacture	CA	UK Conformity Assessed					



## **Customer Care & Technical Support**

#### **US/Canada Customer Care**

1.800.369.3698 x1 | 1.608.831.2555 x1 CustomerCare@orascoptic.com

#### **US/Canada Technical Support**

1.800.369.3698 x2 | 1.608.831.2555 x2 TechSupport@orascoptic.com



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Intertek 5024279

Conforms to AAMI Std ES60601-1 and IEC Std 60601-1-6 Certified to CSA STD C22.2# 60601-1