



The Axis™ LED Light System

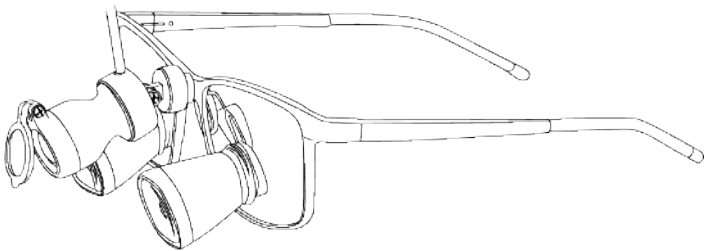
The Axis™ LED Light System
with Activ™ Neck Battery

REF 90900-001

The Axis™ LED Light System
with Hip Battery PP1.5

REF 90900-002

Instructions For Use



Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by surgeons, dentists, veterinarians, or other healthcare professionals.

Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent injury to patient, user, medical personnel, and/or other persons and animals.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information, especially safety information, or in-service training is required, contact your Enova sales representative or call Enova customer service.

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Indications for Use

The Axis Light is a clip-on headlight system designed to provide illumination during dental or minor surgical procedures. The Axis Light is part of the Enova Illumination product family.

Contraindications

None known.

Limitations of Use

None known.

For Use With

Approved battery packs, charging cables and Axis extension battery cable. See *Accessories* section.

User / Patient Safety



WARNINGS:

- Prior to operation, users should read and understand the operation manual for all equipment used in conjunction with the clip-on headlight. Contact Enova or your local distributor for service and warranty information.
- DO NOT look directly into the clip-on headlight when illuminated. DO NOT shine the light directly into the patient's eyes or face. Due to the intensity of light, eye injury may result. Patient's eyes should be appropriately protected in procedures involving the face or head.
- After a few minutes of operation, the headlight housing may become warm to the touch. This is normal and functions to dissipate heat from the LED chip. Always use a surgical glove or sterile cloth to adjust the angle of the lens when in use.
- DO NOT USE THE CLIP-ON HEADLIGHT WHILE POWER PACKS ARE CHARGING.
- Do not use any third-party chargers with Activ Neck Battery or PP1.5 battery packs, even if they look identical. Third-party chargers are not compatible with the battery packs and could damage them.
- Avoid intentional or unintentional contact of the batteries to each other or with a conductive surface. This will cause irreparable damage to the battery and is **STRONGLY DISCOURAGED**. Please make sure to keep the batteries away from each other.
- Avoid direct sunlight or heated surfaces to prevent battery packs from overheating.
- Do not use close to explosive or highly flammable materials like alcohol, methanol, acetone, etc.
- Avoid shock to product by keeping product in approved composite carrying case when not in use.
- DO NOT use the clip-on headlight, power packs or charging cables in explosive gas environments.
- DO NOT autoclave, immerse or submerge in liquid, spray with liquids or leave the clip-on headlight "on" when transporting as it will cause damage to the Axis Light or may cause a fire.
- Please consult local regulations for the disposal of electronic products.

Accessories

This section describes components that may be ordered to replace original equipment that is damaged, worn, or no longer functional.



WARNINGS:

- Use only Enova-approved components and accessories, including power packs, unless otherwise specified.
- DO NOT modify any component or accessory, unless otherwise specified.

The following Enova-approved accessories are sold with the complete Axis Wireless LED Light System:

DESCRIPTION	REF
Axis Light with Filter (or) Axis Light no Filter	800061
Activ Neck Battery	80204
PP Mobile Battery Charger	80102-001
Axis Light Accessory Kit	800050-002
Axis Extension Cable	80304-004
Enova Loupe Case	80034-006
Axis Light w/Activ Battery Combo Case	80034-008
PP1.5 Power Pack	80203-001

NOTE: For a complete list of accessories, contact your Enova sales representative or call Enova customer service.

Features

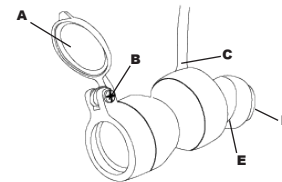


Figure 0.1

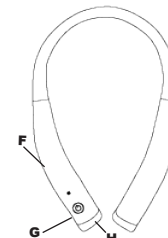


Figure 0.2

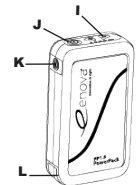


Figure 0.3

A	Optional HD Glass Composite Filter: Removes the light wavelength that speeds up the curing of composite materials.	F	OUO Port for Light Cable: Connection port to attach light source cable.	I	Variable Control Buttons: Adjust three brightness levels.
B	Filter Screw: Tightening screw for optional HD Glass Composite Filter.	G	Power/Brightness Adjuster: Provides power to light. Touch capacitive to turn light ON or OFF or adjust brightness.	J	Power Button: Turns light ON or OFF.
C	Headlight Cable: Connects the light source to the battery connection.	H	Charging Port: Port to connect mobile charging cable.	K	Port for light cable: Connection port to attach light source to battery pack.
D	Magnetic Loupe Adapter: This adapter attaches the light to the frames or loupes.			L	Charging Port: Port to connect mobile charging cable.
E	Light Adjustment Bracket: This bracket is used to adjust the light beam to fit coaxially to the line of sight.				

Instructions

- Perform recommended inspection and testing as indicated in the *Inspection and Testing* section.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section for details.
- DO NOT cut or puncture the clip-on cable.
- ALWAYS remove battery after use.

CAUTIONS:

- DO NOT scratch the clip-on headlight lens.
- DO NOT stretch or kink the cables. Failure to comply will damage the cable and reduce the light output permanently.

To Connect Axis Light to Loupes



WARNING: Do not over-loosen filter. Small internal components may be lost

ENOVA LOUPES

- Ensure that loupe has magnetic adapter secured to frame with notch of magnet pointing down.
- Ensure battery cable is at the top and gently secure the magnetic adapter to magnet on brim of the loupe frame.
- Adjust angle of Axis light source to be coaxial with eyes and illuminate the entire field of view through the loupe telescopes.
- Secure the cable to the fasteners on the temple arm of the glasses.
- If necessary, tighten hinge on filter using provided screwdriver. Be gentle as the components are very small. Tighten as you would normally a screw until filter moves up and down at your desired resistance.

UNIVERSAL CLIP

- Clip securely to frame (by pinching and then releasing the clip).
- Each frame is different and you may need to adjust a few times to find the right fit.
- Follow steps above (in "To Connect Axis Light to Loupes") to connect the Axis Light to the magnet on the adapter.

NOTE: To attach Axis light on a non-Enova loupe, please contact your Enova Representative for an approved adapter or universal clip. Adapters and universal clips are sold separately.

Battery Pack Information

The Axis Light is compatible with two Enova manufactured battery packs and offers various levels of light intensity. The Activ Battery is a neck-worn, capacitive touch battery designed to be easily activated and adjusted through gowns and without removing gloves. The Enova PP1.5 is a standard hip battery.

WITH ACTIV NECK BATTERY

The battery will not be fully charged when it arrives. Batteries will be shipped at less than or equal to 30% charge in accordance with the International Air Transport Association. It is highly recommend to charge the Activ Neck battery fully before use. The LED Indicator shows status of charge.

As battery life decreases, the LED will go through the following sequence:

- The LED flashes red while charging.
- The LED turns solid green when fully charged.
- The LED is solid green when powered on.
- The LED light flashes red and the Axis light flashes when the battery has approximately 5 minutes of power remaining.

WITH PP1.5 HIP BATTERY

The battery will not be fully charged when it arrives. Batteries will be shipped at less than or equal to 30% charge in accordance with the International Air Transport Association. It is highly recommend to charge the PP1.5 hip battery fully before use. The LED Indicator strip shows status of charge.

As battery life decreases, the LED will go through the following sequence:

- The green LED lights decrease from 5 to 1 and then increase as flashing red LED lights from 1 to 5 as the power is depleted.
- With 5 flashing red LED lights, the battery has about 5 minutes of power left.
- When charging, the LED lights will flash green and increase from 1 to 5 lights.
- When fully charged, the middle LED light will be solid green.

To Use Axis Light

WITH ACTIV NECK BATTERY

- Connect the Axis Light headlight cable to the Activ Battery OUD port (Figure 1).
- Turn the Axis Light ON by touching the power button (Figure 2).
- Adjust brightness level by touching the same button (Figure 3). The Axis Light has 3 brightness levels.
- Adjust angle of the light so light beam is visible through loupes or frame (Figure 4).
- Turn the light off by tapping the power button until the light turns off (Figure 5).

WITH PP 1.5 HIP BATTERY

- Connect the Axis Light to the extension battery cable (Figure 1a).
- Connect the extension battery cable to the OUD battery port (Figure 2b).
- Connect the battery cable to the PP1.5 battery pack (Figure 3c)
- Turn the Axis Light ON by pressing the power button (Figure 4d)
- Press the variable control buttons ("+" and "-") on the power pack to adjust the light intensity (Figure 5e).
- Turn the light off by pressing the power button.

NOTE: the +/- buttons can be used to increase or decrease the intensity of the light, but the LED lights on the battery in no way reflect the current output/light intensity.

To Disconnect Axis Light

- Turn off Axis Light and disconnect from power source.
- The Axis Light is held in place by a strong magnetic connection. Grip the frame and body of the light firmly and pull apart with enough force to detach the light from the magnetic adapter (Figure 6 or 6f).
- Clean after each use. See the *Cleaning* section.

NOTE: The strong magnetic connection ensures light will remain in place and will not fall off during procedures or exams.

Inspection and Testing



WARNING:

- Only individuals trained and experienced in the maintenance of medical devices should inspect and test this equipment.
- DO NOT use any equipment if damage is apparent or the inspection criteria are not met.
- DO NOT disassemble or service this equipment, unless otherwise specified.

NOTE: For service, contact your Enova sales representative or call Enova customer service.

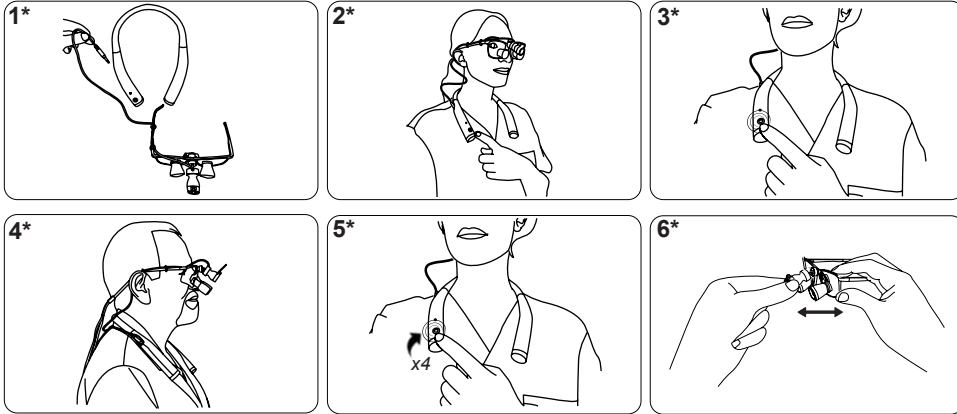
INTERVAL	INSPECTION CRITERIA	ACTION
Before Use	Inspect equipment for damage, wear, or missing components.	If damage is apparent, replace the equipment
	Inspect power cord and twist cable for cuts, punctures, or kinks.	
	Inspect headlight lens for scratches.	
	Inspect the power pack housing for cracks.	

NOTE: If any component must be discarded, see the *Disposal / Recycle* section.

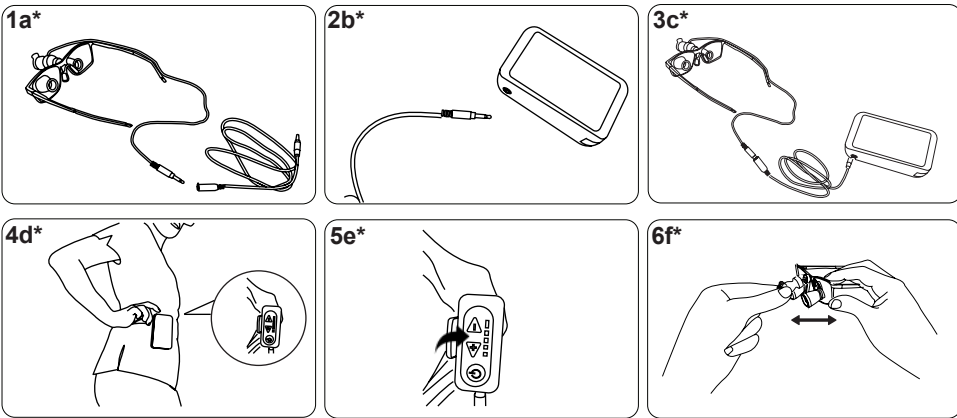
Troubleshooting

Issue	Troubleshooting
The light does not work steadily due to discharged battery	Replace battery pack. Charge the discharged battery
Battery does not function	Contact Enova representative
LED failure	
Battery overheats or produces fire during charge	
Battery leakage	
Battery swelling	

Instructions with Activ Battery



Instructions with PP1.5 Power Pack



Charging

1. Turn off Axis Light and remove from battery. Detach all cables from their ports.
2. Plug mobile charger into outlet with appropriate electrical voltage.
3. Connect mobile charger to battery's charging port.

Product Specifications

Model:	REF 800061-001
Description:	Axis LED Light
Lamp Illumination:	23,000 lux
Color Temperature:	6100K
Light Source:	LED Refractive Technology
Illumination Spot Size:	4 inches, fixed
Headlight Weight:	.88 oz (25g)
Headlight Construction:	Aluminum

Model:	REF 80204
Description:	Activ Battery
Electrical Output:	3.3 ~ 3.7 V
Energy:	10.0 Wh
Duration:	3.5 hours
Construction:	Plastic
Weight:	5oz/141g

Model:	80203-001
Description:	PP1.5 Power Pack
Electrical Output:	3.3 ~ 3.5 V
Energy:	18.5 Wh
Duration:	8 hours
Construction:	Plastic
Weight:	7oz/200g

Cleaning



WARNINGS:

CAUTION: DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

To Clean the Axis Light

NOTE: Avoid scratching or striking the front lens as a reduction in light transmission may occur.

1. Exterior surfaces of Axis Light can be cleaned using a gauze pad or cotton swab moistened with 70% isopropyl alcohol or mild soap. After cleaning, wipe the area with a lint-free soft cloth moistened with water to remove any residue from cleaning products.
2. DO NOT immerse or spray the Axis Light, battery packs or charging cables with any liquids. Make sure no liquid comes in contact with the Axis Light, electrical connectors, charging cables or battery packs.
3. To ensure a long life of the Axis Light, battery packs and charging cables, Enova recommends storing them in the supplied composite case when not in use.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life.

To ensure the longevity, performance and safety of this equipment, use of the composite carrying case or water tight packaging is recommended when storing or transporting this equipment.

Disposal / Recycle



WARNING: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

Symbol Definition

Symbol	Definition
	General Warning Sign (Yellow)
	Catalog number
QTY	Quantity
	Lot number
	Medical Device
	Recycle of Li-Ion Battery (in Accordance with Local Laws)
	Light Intensity
	CE Mark indicating that the device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

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