

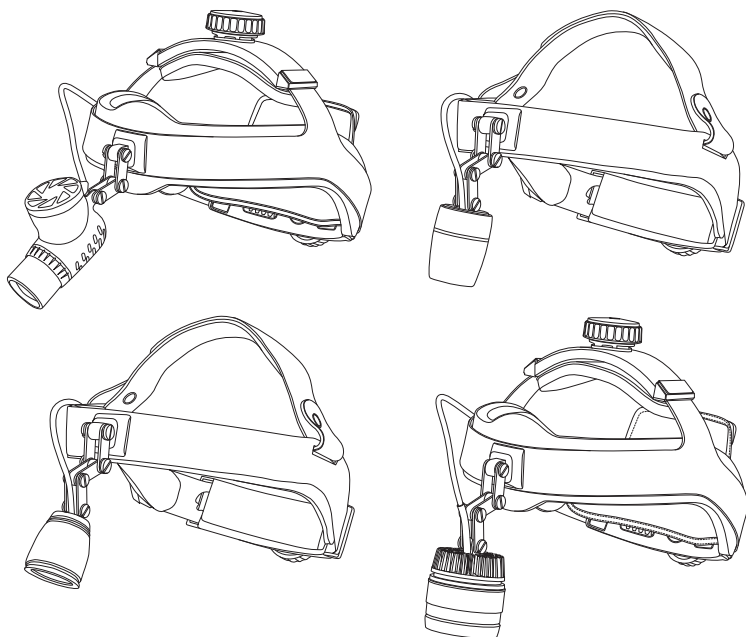


LED Surgical Headlight

Applicable Headlight Models:

Quest, Quantum Cool/Warm
Quasar Cool/Warm, Qubit Pro, Qubit Warm
XLT-225A, XLT-165A, PLT-100A, PLT-60F

Instructions For Use



Note: The image shown above is for illustration purposes only. Actual product may vary depending on model purchased.

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 in-service trainers, physicians, nurses, surgical technologists, biomedical equipment technicians, and central supply processing technicians.

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 patient and/or healthcare staff injury.
- 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 sales representative or the Enova Customer Care Team at support@goenova.com

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Indications for Use

LED Surgical Headlight Systems are adjunct light sources used for illumination during clinical or surgical procedures in a medical setting.

Contraindications

Not known.

Limitations of Use

Not known.

User / Patient Safety



WARNING:

- Prior to operation, users of Enova LED Surgical Headlight Systems should read and understand the operation manual for all equipment used in conjunction with the LED Surgical Headlight. Contact your sales representative or the Enova Customer Care Team at support@goenova.com for service and warranty information.
- Do not look directly into the LED Surgical 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 headlamp housing may become warm to the touch. This is normal and functions to dissipate heat from the LED. Always use a surgical glove or sterile cloth to adjust the angle of the lens when in use.
- **Use only Enova supplied batteries and battery charger.** The use of other batteries or battery charger may result in fire, explosion, or damage to the batteries or LED Surgical Headlight and will void the warranty. The battery must be powered off when charging. **Do not use or store battery charger in operating room or surgery suite.**
- All Enova LED Surgical Headlights are designed to be portable. **Do not use the LED Surgical Headlight while batteries are charging.**
- Do not use the LED Surgical Headlight, batteries or battery charger in explosive gas environments.
- Do not autoclave, immerse or submerge in liquid, spray with liquids or leave the LED Surgical Headlight "on" when inside the composite carrying case as it will cause damage to the LED Surgical Headlight or may cause a fire.
- Persons allergic to TPE (Thermoplastic elastomer) or PC (Polycarbonate) plastics should not use this device.
- Always consult local regulations for the disposal of electronic products.

- **Do not interchange cables to connect headlight and battery.** Use specified extension (or twist or battery) cable for correct LED Surgical Headlight, otherwise the LED Surgical Headlight will function abnormally and may damage the circuitry causing the light to fail.
- Do not insert objects, poke, or tamper with the fan mechanism or any part of the cooling apparatus.
- **Keep user's hair out of fan and away from vents in housing.** Failure to do so may result in harm to user or headlight.
- To avoid overheating, **do not cover the fan vents or otherwise impede airflow.**
- If you notice any creaking or unusual noise, vibrations, or a lack of fan movement while the LED is on, stop using the light system immediately and contact Enova customer service for assistance.

For Use With

Approved Enova battery, battery cables, and accessories. See the [Accessories] section.

- The PP2 Power Pack provides electrical power to Enova LED Surgical Headlights including Quasar Cool/Warm, Qubit Pro, PLT-100A, PLT-80F (Qubit Warm), and PLT-60F models.
- The PP4 Power Pack provides electrical power to Enova LED Surgical Headlights including Quantum Cool/Warm, Quasar Cool/Warm, Qubit Pro, XLT-225A, XLT-165A, PLT-100A, PLT-80F (Qubit Warm), and PLT-60F models.
- The PP4+ (plus) Power Pack provides electrical power to Enova LED Surgical Headlights, Quest model.

Accessories

This section describes components that may be ordered to replace original equipment that is damaged, worn, or must be replaced.



WARNING:

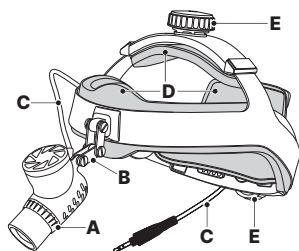
- Use only Enova-approved components and accessories, including batteries, unless otherwise specified.
- Do not modify any component or accessory, unless otherwise specified.

The following Enova-approved accessories can be sold in conjunction with the Enova LED Headlight:

DESCRIPTION	REF	DESCRIPTION	REF
PP2 Power Pack	80200-001	Power Pack Charging Base Station	80100-001
PP4 Power Pack	80201-001	NA C-13 Hospital Grade Power Cord	80150-00X
PP4+ Power Pack	80205-001	Single Battery Charger	80101-001
Black Twist Cable	80301-001	Battery Belt	80500-001
Grey Twist Cable	80302-001	Composite Carrying Case	80034-001
Black Extension Cable	80303-001	Standard Comfort Pad Set	80400-001
Quest Battery Cable	80305-001	Deluxe Elliptical Comfort Pad Set	80403-001
Quasar Yellow Filter	86004-001	Quest™ DRO Replacement Pad Set	80405-001
Yellow Filter	80060-001	Quest™ DR Replacement Pad Set	80405-002
Flip-up Filter Set for Fixed Beam Headlights	86002-001	Quest™ SRO Replacement Pad Set	80405-003
		Quest™ SR Replacement Pad Set	80405-004

Note: For a complete list of accessories, contact your sales representative or the Enova Customer Care Team at support@goenova.com

Features



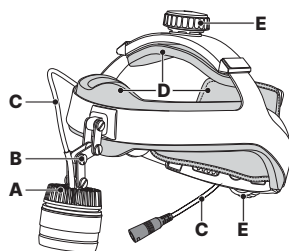
A. Spot Size Adjustment Ring:

This ring can be rotated to make the spot size smaller (2") and bigger (5").

Qubit Pro, PLT-80F (Qubit Warm) and PLT-60F models provides fixed illumination spot. These headlamps do not have spot size adjustment ring.

B. Headlight Adjustment Bracket:

This bracket is used to adjust the light beam to fit coaxially to the line of sight.



C. Headlight Power Cable:

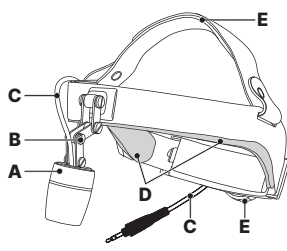
This cable routes power from the power pack to the LED Surgical Headlight.

D. Comfort Pads:

These removable pads provide a comfortable fit.

E. Headband Adjustment Strap/Knob:

Customize the fit by adjusting the strap or turning the knob clockwise to tighten and counter-clockwise to loosen the headband.



Note: The image shown above is for illustration purposes only. Actual product may vary depending on model purchased.

Instructions



WARNING:

- Perform recommended inspection as indicated in the [Prior To Use] section.
- Always operate the equipment within the specified environmental condition values. See the [Specifications] section.

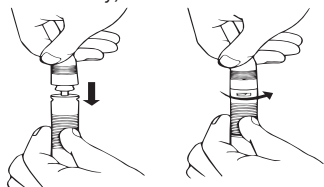
- This equipment is suitable to use in a professional healthcare facility environment.
- Do not cut or puncture the cables.
- Always turn the light source power off before connecting or disconnecting the extension (or twist or battery) cable to or from the LED Surgical Headlight.
- Always hold the strain relief near the end of the extension (or twist or battery) cable when connecting or disconnecting the extension (or twist or battery) cable from the light source (Figure 1).

CAUTIONS:

- Do not scratch the LED Surgical Headlight lens. Doing so may cause a decrease in light transmission.
- Do not stretch or kink the extension (or twist or battery) cable. Failure to comply will damage the extension (or twist or battery) cable and it will reduce the power transmission of the cable permanently.

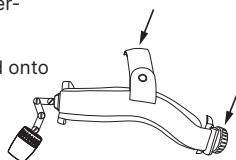
Note: Headband position will vary from person to person depending on head size and personal comfort preferences.

- 1 Plug headlight power cable to extension (or twist or battery) cable and twist to lock.



- 2-1 Detach strap to loosen headband and/or turn the knob counter-clockwise.

- 2-2 Place headband onto user's head.

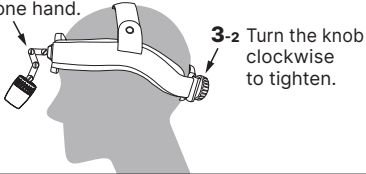


3

3-1 Hold headlight with one hand.

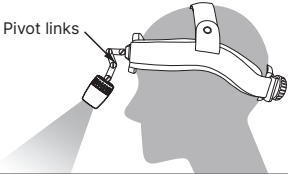
3-2 Turn the knob clockwise to tighten.

3-3 Fasten strap/knob to tighten.



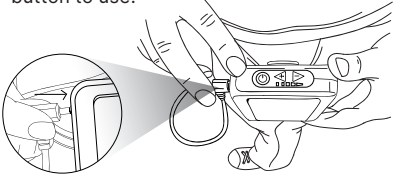
4

Adjust the headlight bracket for optimum coaxial alignment to support user's vision.



5

Plug the other end of extension (or twist or battery) cable into battery and press Power button to use.



PP2/PP4: Low Battery Notification*

Time of remaining battery	Audible: Beeping sound	Visible: Battery LEDs turn to red and flash
9 minutes	-	Flash once
7 minutes	1 beep	Flash twice
5 minutes	3 beeps	Flash 3 times
3 minutes	5 beeps	Flash 4 times
>1 minute	5 beeps	Flash 5 times

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***Note:** See the Enova Headlights Battery IFU for full Power Pack instructions.

PP4+(plus): Low Battery Notification*

Time of remaining battery	Audible Notification	Visible Notification
20 minutes	Beep three (3) times	Five (5) LEDs on battery turn to red 
Reminder	One (1) beep every minute	

To Put On an LED Surgical Headlight

CAUTIONS: Do not connect the extension (or twist or battery) cable to the battery before putting the LED Surgical Headlight.

1. Connect the LED Surgical Headlight power cable to the appropriate extension (or twist or battery) cable (Figure 1). See the [Accessories] section.

Note: To disconnect the power cable, twist the connector sleeve back before separating the connector plug and receptacle (Figure 1).

2. Loosen the headband adjustment knob on the back of the LED Surgical Headlight (Figure 2).
3. Put the LED Surgical Headlight on your head. Turn the adjustment headband knob on the back to secure the LED Surgical Headlight and adjust top headband adjustment to comfort (Figure 3). When using loupes, put them on after this step.

Note: Make sure the LED Surgical Headlight fits securely on top of your head and that the light is coaxial to your line of sight (Figure 4).

To Use an LED Surgical Headlight

1. Plug the extension (or twist or battery) cable connector into the jack on the battery (Figure 5).
2. Press the power button on top of the battery (Figure 5).
3. Press the variable control buttons (“+” and “-”) on the battery to adjust the light intensity. See the [Troubleshooting] section if required.

To Take Off an LED Surgical Headlight

1. Turn the battery off.
2. Disconnect extension (or twist or battery) cable from light/battery.
3. Loosen the headband adjustment on the top and back of the LED Surgical Headlight and remove the LED Surgical Headlight from your head.
4. Clean after each use. See the [Cleaning] section. To clean the battery, see the [Cleaning] section of Enova Power Pack IFU.

Prior To Use



WARNING:

- Only individuals trained and experienced in the maintenance of these medical devices should inspect this equipment.
- Do not use any equipment if damage is apparent or the inspection criteria are not met.

Note: For service, contact your sales representative or the Enova Customer Care Team at support@goenova.com

INTERVAL	INSPECTION CRITERIA	ACTION
Before each use	Inspect equipment for damage, wear, or missing components.	If damage is apparent, replace the equipment.
	Inspect power cord and extension (or twist or battery) cable for cuts or punctures.	
	Inspect headlight lens for scratches.	
	Inspect the battery housing for cracks.	

Note: If any component must be discarded, see the [Disposal / Recycle] section.

Cleaning

CAUTION

- Do not use solvents, lubricants, or other chemicals, unless otherwise specified.
- Do not immerse or spray the LED Surgical Headlight, battery or battery charger with any liquids, nor should any liquids be poured on the lens, lens housing or cable connections. Make sure no liquid comes in contact with the LED Surgical Headlight, electrical connectors, base station or batteries.

To Clean the LED Surgical Headlight

1. Clean the exterior surfaces of LED Surgical Headlight, headband, and comfort pads 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. For proper hygiene, replace the comfort pads every 3-6 months. Users may order additional comfort pads from Enova or your local distributor. All comfort pads are treated with MICROBAN® Antimicrobial Technology.

Storage and Handling

CAUTION

- Always store the equipment within the specified environmental condition values throughout its useful life. See the [Specifications] section.
- 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:

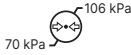
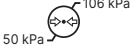
Always follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

Specifications

Model Name	Quest
Description	LED Surgical Headlight
Lamp Illumination (measured at 14")	125,000 Lux
Color Temp.	6,200K
Input	6VDC, 1.65A
Light Source	High-Powered LED

Model Name	Quantum Cool	Quantum Warm	Quasar Cool	Quasar Warm	Qubit Pro
Description	LED Surgical Headlight				
Lamp Illumination (measured at 14")	250,000 Lux	175,000 Lux	150,000 Lux	115,000 Lux	55,000 Lux
Color Temp.	6,500K	4,500K	6,500K	4,500K	6,500K
Input	3.3VDC, 1.8A	3.3VDC, 1.8A	3.3VDC, 0.8A	3.3VDC, 0.8A	3.3VDC, 0.8A
Light Source	LED Refractive Technology				

Model Name	PLT-80F (Qubit Warm)	XLT-225A	XLT-165A	PLT-100A	PLT-60F
Description	LED Surgical Headlight				
Lamp Illumination (measured at 14")	80,000 Lux	225,000 Lux	165,000 Lux	100,000 Lux	60,000 Lux
Color Temp.	4,500K	6,500K	4,500K	4,500K	4,500K
Input	3.3VDC, 0.8A	3.3VDC, 0.8A	3.3VDC, 0.8A	3.3VDC, 0.8A	3.3VDC, 0.8A
Light Source	LED Refractive Technology				

Environmental Condition	Temperature	Humidity	Atmospheric Pressure
Operation	 10°C 30°C	 30% 75%	 70 kPa 106 kPa
Storage and Transportation	 5°C 50°C	 10% 75%	 50 kPa 106 kPa

Note: See the [Specifications] section of the Enova PP2/PP4 IFU or Enova Headlights Battery IFU.

Note: The warranty period for the headlight lamp assembly is five (5) years.
The warranty period for the headband and accessories is one (1) year.

Symbol Definition

Symbol	Definition (Indication Color)	Symbol	Definition (Indication Color)
	General Warning Sign (Yellow) BS EN ISO 7010 Ref. W001		Temperature Limitation BS EN ISO 15223-1 Ref. 5.3.7
	Instruction Manual/Booklet (Blue) BS EN ISO 7010 Ref. M002		Humidity Limitation BS EN ISO 15223-1 Ref 5.3.8
	Usage Instructions BS EN ISO 7000 Ref. 1641		Atmospheric Pressure Limitation BS EN ISO 15223-1 Ref 5.3.9
	Catalog Number BS EN ISO 15223-1 Ref 5.1.6		Authorized Representative in the EU Community BS EN ISO 15223-1 Ref 5.1.2
	Quantity		Authorized Representative in the UK Community
	Batch Code BS EN ISO 15223-1 Ref 5.1.5		Manufacturer BS EN ISO 15223-1 Ref 5.1.1
	Serial Number BS EN ISO 15223-1 Ref 5.1.7		Date of Manufacture BS EN ISO 15223-1 Ref 5.1.3
	Power On/Off		Medical Device BS EN ISO 15223-1 Ref 5.7.7
	Light Intensity Adjustment (Green)		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
	Low Battery Indicator (Red)		This product complies with relevant UK legislation and safety standards and has met the requirements for sale in Great Britain
	ETL Certified		
	Recycle: Electronic Equipment		

Troubleshooting



WARNING:

Do not service this equipment, unless otherwise specified. If you require service, contact your sales representative or the Enova Customer Care Team at support@goenova.com

PROBLEM	CAUSE	ACTION
The LED Surgical Headlight is flickering.	Extension (or twist or battery) cable may be damaged.	Try another extension (or twist or battery) cable. If flickering is resolved, dispose of original cable and replace it.
	Surgical Headlight power cable attached to headlight is damaged.	Test with other extension (or twist or battery) cable. If the headlight still won't work, send in for repair.
	The LED Surgical Headlight is damaged.	Replace the LED Surgical Headlight.
The LED Surgical Headlight does not turn on.	The battery is not charged.	Replace the battery with a fully charged one. Put the discharged battery on the battery charger.
	The extension (or twist or battery) cable is damaged.	If battery is fully charged, try another extension (or twist or battery) cable. If the headlight turns on, dispose of the original cable and replace it.
	The LED Surgical Headlight is damaged.	Replace the LED Surgical Headlight.
The LED Surgical Headlight is shorting out.	The extension (or twist or battery) cable is damaged.	Test with other extension (or twist or battery) cable. If it works, then replace the damaged extension (or twist or battery) cable.
	The LED Surgical Headlight is damaged.	Replace the LED Surgical Headlight.
Spot brightness may diminish during operation, and the headlight may become hot to the touch.	The rise in LED temperature could be attributed to an obstructed airflow.	Switch off the headlight, inspect for any obstructions in any parts of the headlight housing, and remove them. If the problem persists, contact Enova for service.
<u>Quest model only:</u> The fan is producing an unusual sound or clicking noise, or it is not spinning.	The fan might have been damaged due to impact or electrostatic discharge.	Contact Enova for service.
<u>Quest model only:</u> The fan makes excessive or unexpected noise or vibration.	The fan bearings are mis-aligned.	Power off the device, unplug the battery cable from the headlight and the battery. If the problem persists, contact Enova for service.

Note: If any component must be discarded, see the [Disposal / Recycle] section.

International Electrotechnical Commission (IEC)

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Ed: 3.2, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, Ed: 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance
IEC 62366-1:2015+AMD1:2020, Ed: 1.1, Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62133-2:2017+AMD1:2021, Ed:1.1, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)

AAMI ES60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Canadian Standards Association (CSA)

CAN/CSA C22.2 NO. 60601-1:14 + A2:22 (R2022) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
CAN/CSA C22.2 NO. 60601-1-6:11 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard:Usability

Warranty

Your Enova product is backed by an industry-leading warranty.
To review your product warranty, visit: www.goenova.com/product-support

Keep this warranty in your records.

ORDER No.			
	Model	Serial Number	Year of Manufacture
HEADLIGHT			
OTHER			

UK REP UK Responsible Person Advena UK Ltd Pure Offices Plato Close Warwick CV34 6WE United Kingdom +44 1926 800 153 info@advenamedical.com	EC REP EU Authorized Representative Advena Malta Ltd Tower Business Centre, 2nd Flr Tower Street, Swatar BKR 4013, Malta +356 2546 6689 info@advena.mt	 Manufactured by Enova Illumination, Inc. 6305 Sandburg Road, STE 100 Minneapolis, MN 55427 USA +1 651 236 8857 support@goenova.com
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