

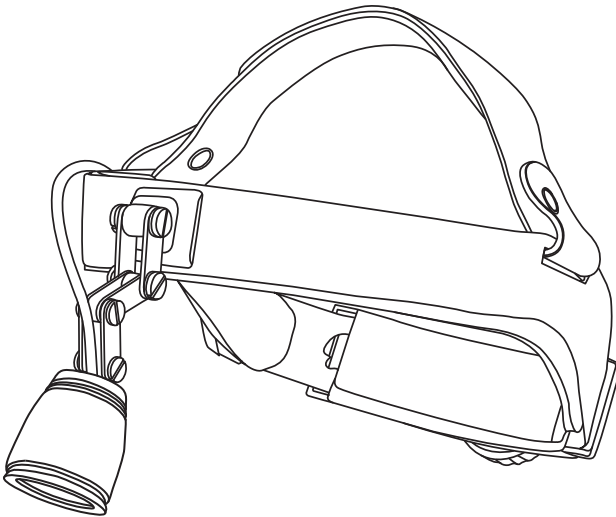


# Qubit Pro™

## LED Surgical Headlight

REF 90091-XXX

### Instructions For Use



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

## Introduction

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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](mailto:support@goenova.com)

Trademarks not the property of Enova are the property of their respective owners.

## Indications for Use

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

## Contraindications

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Not known.

## Limitations of Use

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Not known.

## User / Patient Safety

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### 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](mailto: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 Base Station and Power Packs.** The use of other base stations or batteries may result in fire, explosion, or damage to the power packs or LED Surgical Headlight and will void the warranty. The power pack must be powered off when charging. **Do not use or store base station in operating room or surgery suite.**
- All Enova LED Surgical Headlights are designed to be portable. **Do not use the LED Surgical Headlight while power packs are charging.**
- Do not use the LED Surgical Headlight, power packs or base station 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 power pack.** Use specified extension cable for correct LED Surgical Headlight, otherwise the LED Surgical Headlight will function abnormally and may damage the circuitry causing the light to fail.

## For Use With

Rechargeable PP2 and/or PP4 Power Pack and Black Extension Cable. See the [Accessories] section.

## Accessories

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



### WARNING:

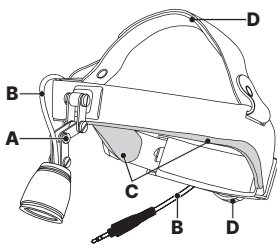
- Use only Enova-approved components and accessories, including power packs, unless otherwise specified.
- Do not modify any component or accessory, unless otherwise specified.

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

DESCRIPTION	REF	DESCRIPTION	REF
PP2 Power Pack	80200-001	Battery Belt	80500-001
PP4 Power Pack	80201-001	Composite Carrying Case	80034-001
Flip-up Filter	86002-001	Single Battery Charger	80101-001
Black Extension Cable	80303-001	Standard Comfort Pad Set	80400-001
Power Pack Charging Base Station	80100-001	Deluxe Elliptical Comfort Pad Set	80403-001
NA C-13 Hospital Grade Power Cord	80150-002		

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

## Features



### A. Headlight Adjustment Bracket:

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

### B. Headlight Power Cable:

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

### C. Comfort Pads:

These removable pads provide a comfortable fit.

### D. Headband Adjustment Strap/Knob:

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

# Instructions



## WARNING:

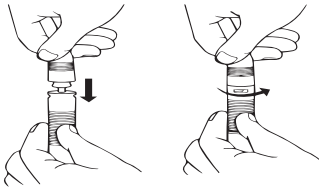
- Perform recommended inspection as indicated in the [Prior To Use] section.
- Always operate the equipment within the specified environmental condition values. See the [Specifications] section.
- This equipment is suitable to use in a professional healthcare facility environment.
- Do not cut or puncture the cables.
- Always turn the light source power off before connecting or disconnecting the extension cable to or from the LED Surgical Headlight.
- Always hold the strain relief near the end of the extension cable when connecting or disconnecting the extension 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 cable. Failure to comply will damage the extension cable and it will reduce the power transmission of the cable permanently.

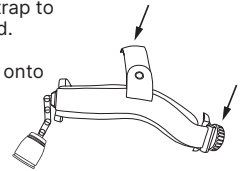
**Note:** Headband position will vary from person to person depending on head size and personal comfort preferences.

- 1** Plug headlight power cable to extension cable and twist to lock.



- 2-1** Turn the knob counter-clockwise and/or detach strap to loosen headband.

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

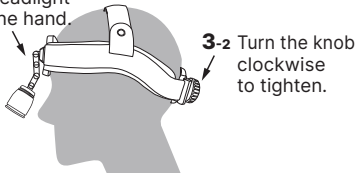


**3**

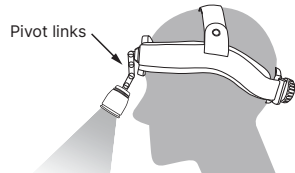
- 3-1** Hold headlight with one hand.

- 3-3** Fasten strap/knob to tighten.

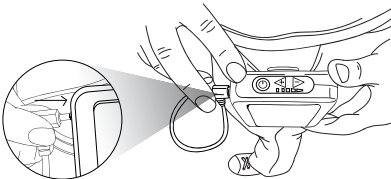
- 3-2** Turn the knob clockwise to tighten.



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



- 5** Plug the other end of extension cable into power pack and press Power button to use.



- 6** 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 minutes	5 beeps	Flash 5 times

**\*Note:** See the Enova PP2/PP4 IFU or Enova Headlights Battery IFU for full Power Pack instructions.

## To Put On an LED Surgical Headlight

**CAUTIONS:** Do not connect the extension cable to the power pack before putting the LED Surgical Headlight.

1. Connect the LED Surgical Headlight power cable to the appropriate extension 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 cable connector into the jack on the power pack (Figure 5).
2. Press the power button on top of the power pack (Figure 5).
3. Press the variable control buttons (“+” and “-”) on the power pack to adjust the light intensity. See the [Troubleshooting] section if required.

## To Take Off an LED Surgical Headlight

1. Turn the power pack off.
2. Disconnect extension 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 power pack, 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](mailto: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 cable for cuts or punctures.	
	Inspect headlight lens for scratches.	
	Inspect the power pack 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, power pack or charging base station 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 power packs.

### 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	Qubit Pro	Environmental Condition	Operation	Storage and Transportation
Description	LED Surgical Headlight	Temperature		
Lamp Illumination	55,000 Lux @ 14"	Humidity		
Color Temperature	6,500K	Atmospheric Pressure		
Input	3.3VDC, 0.8A			
Light Source	High-Powered LED			

**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
	Refer to Instruction Manual/Booklet (Blue) BS EN ISO 7010 Ref. M002		Humidity Limitation BS EN ISO 15223-1 Ref 5.3.8
	Catalog Number BS EN ISO 15223-1 Ref 5.1.6		Atmospheric Pressure Limitation BS EN ISO 15223-1 Ref 5.3.9
	Quantity		Authorized Representative in the EU Community BS EN ISO 15223-1 Ref 5.1.2
	Batch Code BS EN ISO 15223-1 Ref 5.1.5		Manufacturer BS EN ISO 15223-1 Ref 5.1.1
	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@qoenova.com](mailto:support@qoenova.com)

PROBLEM	CAUSE	ACTION
The LED Surgical Headlight is flickering.	Extension cable may be damaged.	Try another extension 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 cable. If it 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 power pack is not charged.	Replace the power pack with a fully charged one. Put the discharged power pack on the base station.
	The extension cable is damaged.	If power pack is fully charged, try another extension cable. If the LED Surgical 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 cable is damaged.	Test with other extension cable. If it works, then replace the damaged extension 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 a 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.

**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](http://www.goenova.com/product-support)

Keep this warranty in your records.

ORDER No.			
	Model	Serial Number	Year of Manufacture
<b>HEADLIGHT</b>	<b>Qubit Pro</b>		
<b>OTHER</b>			

<p><b>UK Responsible Person</b>          Advena UK Ltd          Pure Offices          Plato Close Warwick          CV34 6WE United Kingdom          +44 1926 800 153  <a href="mailto:info@advenamedical.com">info@advenamedical.com</a></p>	<p> <b>EU Authorized Representative</b>          Advena Malta Ltd          Tower Business Centre, 2nd Fir          Tower Street, Swatar          BKR 4013, Malta          +356 2546 6689  <a href="mailto:info@advena.mt">info@advena.mt</a></p>	<p> <b>Manufactured by</b>          Enova Illumination          6305 Sandburg Road, STE 100          Minneapolis, MN          55427 USA          +1 651 236 8857  <a href="mailto:support@goenova.com">support@goenova.com</a></p>
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