



Surgical Headlight Batteries

Instructions For Use

PP2 REF 80200-001

PP4 REF 80201-001

PP4+ REF 80205-001



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

User / Patient Safety



WARNING:

- Upon initial receipt and before each use, inspect each component for damage.
- Do not use any equipment if damage is apparent.
- Always clean the battery before first and every use.
- Do not sterilize or immerse.
- Do not use a battery that gives off an odor, generates heat, becomes discolored, or leaks.
- Do not use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide.
- Do not short circuit, crush, incinerate or disassemble. Damage increases the risk of chemical burns from electrolyte leakage, fire or explosion.
- Do not service this equipment.
- Do not modify any component or accessory, unless otherwise specified.
- Persons allergic to TPE (Thermoplastic elastomer) or PC (Polycarbonate) plastics should not use this device.

NOTES:

- In the event the device is not used regularly, the user should charge the device every six (6) months.
- If the battery usage time has dropped by more than 20%, the user may consider replacing the unit.
- The expected service life of the battery is one (1) year.
- For additional information, especially safety information, or in-service training, contact your sales representative or Enova Customer Care Team at support@goenova.com

Intended User

Enova medical devices are intended for use by medical professionals.

For Use With

Approved Enova headlamps, battery cables, and accessories.

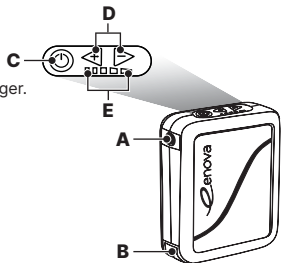
- The PP2 Power Pack provides electrical power to Enova LED Surgical Headlamps including Quasar and Qubit models.
- The PP4 Power Pack provides electrical power to Enova LED Surgical Headlamps including Quantum, Quasar and Qubit models.
- The PP4+(plus) Power Pack provides electrical power to ONLY Enova LED Surgical Headlamp Quest model.
- All batteries (PP2, PP4, and PP4+) use the PP Base Station or Single Battery Charger.

Note: The warnings and cautions in this instruction for use and product packaging meet the requirements of IEC 60601-1 and 60601-1-6. Specifically:

- Device Surface: Caution Labels
- Instruction for Use: Warning, Cautions, and Storage Requirements

Features

- A. **Output Port:**
Provides sourcing power to the headlight.
- B. **Charging Port:**
Alternative charging port for Single Battery Charger.
Use Enova-supplied charger only.
- C. **Power Button:**
Turn light On/Off .
- D. **Variable Control Buttons:**
Adjust light brightness levels.
- E. **Indicator Lights:**
Indicate charging status and remaining battery capacity.



Note: The image shown above is a sample. Actual product may vary depending on model purchased.


Power Pack Charging Status

Light Bars	Battery Charge
1 Green Light	10-19%
2 Green Lights	20-39%
3 Green Lights	40-59%
4 Green Lights	60-94%
5 Green Lights	95-99%
1 (Middle) Green Light	100%

PP2 / PP4 Low Battery Notification

Remaining Time of 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

PP4+ (plus) Low Battery Notification


Remaining Time of Battery	Audible & Visible:
20 minutes	 5 Red Lights + Beep 3 times
≤ 19 minutes	[5 Red Lights + Beep 1 time] reminder on every minute until battery is fully depleted

Instructions

 **WARNING:**

- Perform recommended inspection as indicated in the [Prior To Use] section.
- Do not charge a battery that gives off an odor, generates heat, becomes discolored, or leaks.
- Always turn the battery off before connecting/disconnecting the cable to or from the light.
- Always remove cable from battery after each use.
- Always operate the equipment within the specified environmental conditions.
- Do not cut or puncture the cables.
- Do not stretch or kink the cables. Failure to comply will damage the cable and reduce the light output permanently.

To Connect Surgical Headlight with Power Pack:

 **WARNING:** Quest Surgical Headlight is ONLY compatible with PP4+ (plus) power pack.


1. Plug headlight power cable to twist (or extension) cable and twist to lock.
2. Place headband onto user's head and adjust the headlight bracket for optimum alignment.
3. Plug the other end of twist (or extension) cable to output port on the battery.
4. Press the power button on the battery to turn the light on.
5. Use the variable controls buttons to adjust the light intensity.
6. After LED surgical headlight use, turn off battery and disconnect.

Note: See the [Instructions] section of the Enova LED Surgical Headlight IFU for battery connection to users' light.

Note: When your light starts to flash, the battery needs to be charged or replaced with other battery in approx. 5 minutes.

Note: Batteries will be shipped to you at 30% charge in accordance with the International Air Transport Association. Fully charge the battery before use.

Charging Battery Using PP Base Station:

 **WARNING:** Do not touch the base station's voltage output terminals. Failure to comply may result in electronic shock.

1. Turn off the light and remove from battery. Detach all cables from their ports.
2. Connect PP base station and outlet with appropriate electrical voltage using power cord. Refer to the charger label.
3. Insert battery into the PP base station.

Charging Battery Using Single Battery Charger:

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

Prior To Use



WARNING:

- Upon initial receipt and before each use, inspect each component for damage. Do not use any equipment if damage is apparent or the inspection criteria are not met.
- Only individuals trained and experienced in the maintenance of medical devices should service this equipment.
- Do not disassemble or service this equipment, unless otherwise specified.

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

INTERVAL	INSPECTION CRITERIA	ACTION
Before use	Check equipment for damage, wear, or missing components.	If damage is apparent, replace the equipment.
	Check power cord for cuts or bent pins.	
	Check power cord receptacle or base station module for bent pins.	
	Check battery housing for cracks. A cracked battery housing has the potential to leak electrolytes and cause chemical burns.	

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.

To Clean the Battery

1. Disconnect the battery from the battery cable.
2. Dampen a gauze pad, cotton swab, or soft cloth with 70% isopropyl alcohol.
3. Wipe down the surfaces of the battery.
4. Dry the battery with a lint-free towel or medical-grade compressed air.







Note: Do not immerse or spray the battery or charger with disinfecting liquids or sterilizer, nor should any liquids be poured on the cable connectors.

Storage and Handling

CAUTION:

- Always store the equipment within the specified environmental condition values through its useful life. See the [Specifications] section.
- If storing for longer than three (3) months, it is recommended to remove the battery from the charger.
- To ensure longevity, performance and safety of this equipment, use of the original packaging material is recommended for long-term storage and/or transportation.

Specifications

Model	PP2 REF 80200-001	PP4 REF 80201-001	PP4+ REF 80205-001
Type	Rechargeable, Li-Ion Battery		
Input	10VDC, 1.4A	10VDC, 1.4A	10VDC, 1.4A
Output	3.3VDC, 0.8A/1.8A	3.3VDC, 0.8A/1.8A	6VDC, 1.65A/0.8A
Capacity	5,000mAh	5,200mAh	6,000mAh
Energy	18.5Wh	37.5Wh	43.2Wh
Environmental Condition	Operation	Storage and Transportation	
Temperature	 10°C — 30°C	 5°C — 50°C	
Humidity	 30% — 75%	 10% — 75%	
Atmospheric Pressure	 70 kPa — 106 kPa	 50 kPa — 106 kPa	










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. Always decontaminate a battery exposed to infectious material before sending it to a waste treatment facility.

To comply with Batteries Directive 2006/66/EC, the battery has been designed to be recycled at the end-of-life by the end user as a complete unit. No disassembly is required.

Symbol Definition

Symbol	Definition (Indication Color)
	General Warning Sign (Yellow) BS EN ISO 7010 Ref. W001
	Refer to Instruction Manual/Booklet (Blue) BS EN ISO 7010 Ref. M002
	Catalog Number BS EN ISO 15223-1 Ref 5.1.6
QTY	Quantity
	Batch Code BS EN ISO 15223-1 Ref 5.1.5
	Power On/Off
	Light Intensity Adjustment (Green)
	Low Battery Indicator (Red)
	ETL Certified
	Recycle: Electronic Equipment

Symbol	Definition (Indication Color)
	Temperature Limitation BS EN ISO 15223-1 Ref. 5.3.7
	Humidity Limitation BS EN ISO 15223-1 Ref 5.3.8
	Atmospheric Pressure Limitation BS EN ISO 15223-1 Ref 5.3.9
	Authorized Representative in the EU Community BS EN ISO 15223-1 Ref 5.1.2
	Manufacturer BS EN ISO 15223-1 Ref 5.1.1
	Medical Device BS EN ISO 15223-1 Ref 5.7.7
	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
	This product complies with relevant UK legislation and safety standards and has met the requirements for sale in Great Britain

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 Instructions For Use and below order detail in your records.

ORDER No.			
	Model	Serial Number	Year of Manufacture
BATTERY #1	<input type="checkbox"/> PP2		
	<input type="checkbox"/> PP4		
	<input type="checkbox"/> PP4+(Plus)		
BATTERY #2	<input type="checkbox"/> PP2		
	<input type="checkbox"/> PP4		
	<input type="checkbox"/> PP4+(Plus)		
OTHER			

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