



Enova PP4, PP2 Power Pack

PP4 Power Pack

REF 80201-001

PP2 Power Pack

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Instructions For Use



For Use With

Enova Power Packs provide electrical power to Enova LED Surgical Headlights including Quantum, Quasar, and Qubit models. The Power Packs are charged in the Power Pack Base Station (REF 80100-001).

NOTE: The warnings and cautions in this instruction for use and product packaging meet the requirements of IEC 60601-1 and 60601-1-11.

Specifically:

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

User / Patient Safety



WARNINGS:

- Upon initial receipt and before each use, inspect each component for damage.
- DO NOT use any equipment if damage is apparent.
- ALWAYS clean the power pack before every use.
- DO NOT sterilize or immerse.
- DO NOT use a power pack 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.

NOTES:

- The On/Off tactile membrane switch is RED in color for greater visibility during any potential hazardous situation, and for easy operation to reduce any potential risk.
- In the event the device is not used regularly, the user should charge the device every six (6) months.
- If the Power Pack usage time has dropped by more than 20%, the user may consider replacing the unit with new.
- The expected service life of the Power Pack is two years.
- For additional information, especially safety information, or in-service training, contact your Enova sales representative or call Enova customer service.

Instructions

- Perform recommended inspection and testing as indicated in the *Inspection and Testing* section.
 - Don your LED surgical headlight BEFORE connecting to a Power Pack.
 - ALWAYS turn the Power Pack off before connecting or disconnecting the battery cable to or from the LED surgical headlight (Figure 1).
 - ALWAYS hold the strain relief near the end of the twist cable when connecting or disconnecting the twist cable from the light source and Power Pack.
 - Disconnect the Power Pack from your LED surgical headlight PRIOR TO doffing.
1. Connect battery cable to output power jack (Figure 2, A) on the Power Pack.
 2. Press the power button (Figure 3, C) on the Power Pack to turn it on.
 3. Use the Variable Controls (Figure 3, D) to increase or decrease light intensity.
 4. When done using the LED Headlight, turn off the Power Pack and disconnect.

NOTE: Batteries will be shipped to you at less than 30% charge in accordance with the International Air Transport Association. It is recommended to fully charge batteries prior to use. See PP4 Base Station IFU for charging instructions.

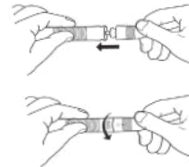


Figure 1

Features

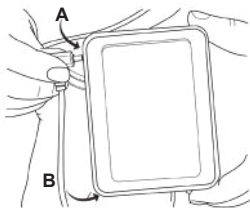


Figure 2

A	Output Power Jack: Power Source.
B	Mobile Charging Jack: Alternative charging port. Use Enova-supplied charger only.
C	Power Button: On/Off Control for Power Pack
D	Variable Controls for Light Intensity: Increases or decreases light intensity on Power Pack.
E	LED Battery Life Indicator: Displays the battery charge level.

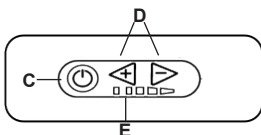


Figure 3

To Charge Power Packs



WARNINGS:

- ALWAYS make sure the power packs are dry BEFORE charging.
- DO NOT charge a power pack that gives off an odor, generates heat, becomes discolored, or leaks.
- DO NOT touch the base station's voltage output terminals. Failure to comply may result in electric shock.

Using Base Station

1. Insert a clean, dry power pack into a Power Pack Charging Base Station module. The Power Pack is properly seated in the module when the LED Battery Life Indicator lights come on and the battery beeps once.
2. Once charged, it is safe to store the power packs in the base station for up to three months. See Power Pack IFU for long-term storage instructions.

Using Single Charger

1. Plug the power cord from the charging unit into the wall outlet.
2. Plug the small charging cord that leads from the charger into the Power Pack.
3. Unplug the power pack from the single charger once fully charged.

Power Pack Charging Status

LIGHT BARS	POWER PACK CHARGE
1 Green Light	10-19%
2 Green Light	20-39%
3 Green Light	40-59%
4 Green Light	60-94%
5 Green Light	95-99%
1 Green Light in the middle	100%

Inspection and Testing



WARNINGS:

- Only individuals trained and experienced in the maintenance of these medical devices should service and test this equipment.
- 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.
- 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 Each 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 power pack housing for cracks. A cracked power pack housing has the potential to leak electrolytes and cause chemical burns.	

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

Storage and Handling

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

- Fully charged power packs can be stored on the PP4 Base Station module for up to three (3) months at a time.
- If storing for longer than three (3) months, it is recommended to remove the power pack from the base station module.
- 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.

Cleaning

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

DO NOT use disinfectants with a pH level higher than 7.5 on the power pack. See the Safety Data Sheet of the disinfectant to verify the pH range. Failure to comply may cause the power pack housing material to crack and leak.

To Clean the Power Packs

1. Disconnect the power pack from the battery cable and remove it from charger/base station.
2. Dampen a gauze pad, cotton swab, or soft cloth with 70% isopropyl alcohol or mild soap.
3. Wipe down the surfaces of the power pack. After cleaning, wipe the area with a lint-free soft cloth moistened with water to remove any residue from cleaning products.
4. Dry the power pack with a lint-free towel or medical-grade compressed air.

NOTE: DO NOT immerse or spray the battery pack or charger with disinfecting liquids or sterilizer, nor should any liquids be poured on the cable connectors.

Disposal / Recycle



WARNINGS:

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 power pack exposed to infectious material before sending it to a waste treatment facility.

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

Specifications

NOTE: Specifications are approximate.

Power Pack:	PP4 (80201-001)	PP2 (80200-001)
Electrical Output:	3.7 V ----	3.7V ----
Energy:	38Wh	19Wh
Duration: Quasar LED Surgical Headlights	10 to 24 Hours	5 to 10 hours
Duration: Quantum LED Surgical Headlights	5 to 10 Hours	Not suitable for use with Quantum Headlights

Symbol Definition

Symbol	Definition (Indication Color)	Symbol	Definition (Indication Color)
	General Warning Sign (Yellow)		Catalog number
	Power On/Off		Quantity
	Light Intensity Adjustment and Indicator		Lot number
	Recycle in Accordance with Local Laws of Li-ion batteries.		Medical Device
			Authorized Representative in European Community
			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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