



Loupe Light Batteries

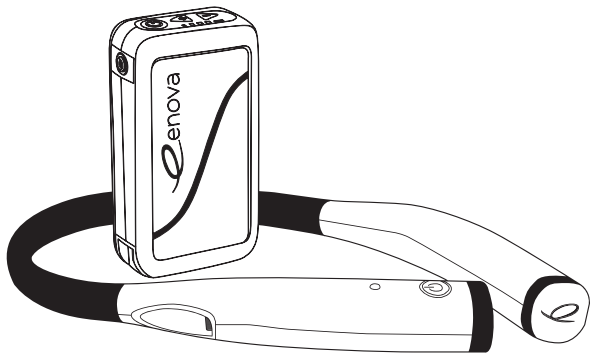
Instructions For Use

PP1.5  80203-001

Activ  80204-XXX

PP1.5 Elite  80206-001

Activ Elite  80207-XXX



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

For Use With

Approved Enova loupe lights, battery cables and accessories.

- The PP1.5 Power Pack and Activ Battery provide electrical power to ONLY the Axis LED Light.
- The PP1.5 Elite Power Pack and Activ Elite Battery provide electrical power to ONLY the Axis Elite LED Light.
- All batteries (Activ, PP1.5, Activ Elite, and PP1.5 Elite) use the PP Mobile Battery Charger.

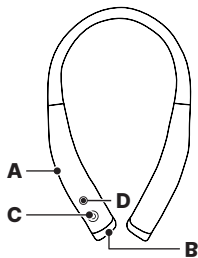
Note: The warnings and cautions in this instruction for use and product packaging meet the requirements of IEC 60601-1 and 60601-1-6. Specifically:

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

Features

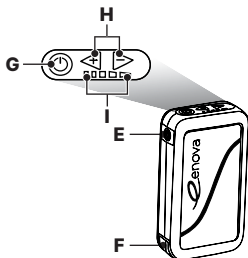
Activ / Activ Elite Battery

- A. **Output Port:**
Connection port to attach light source cable.
- B. **Charging Port:**
Port to connect mobile charging cable.
- C. **Power Button/Brightness Adjuster:**
Turn light On/Off and adjust light brightness levels.
- D. **Indicator Light:**
Indicate charging status and in use.
- Green - Fully charged or in use
 - Red - Charging or low battery



PP1.5 / PP1.5 Elite Power Pack

- E. **Output Port:**
Connection port to attach light source cable.
- F. **Charging Port:**
Port to connect mobile charging cable.
- G. **Power Button:**
Turn light On/Off.
- H. **Variable Control Buttons:**
Adjust light brightness levels.
- I. **Indicator Lights:**
Indicate charging status and remaining battery capacity.



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%

Power Pack 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

Instructions



WARNING:

- Perform recommended inspection as indicated in the [Prior To Use] section.
- Do not charge a battery that gives off an odor, generate 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 Axis LED Light with Activ Battery:

1. Wear user's loupe and Axis light, and place Activ battery on your neck.
2. Plug Axis light cable to battery output port.
3. Touch the power button to turn on the light.

To Connect Axis LED Light with PP1.5 Power Pack:

1. Wear user's loupe and Axis light, and plug the light cable to extension battery cable.
2. Plug the other end of the extension battery cable to battery output port.
3. Place PP1.5 using the battery clip and press the power button to turn on the light.



WARNING: Axis Elite Light is **ONLY** compatible with Activ Elite or PP1.5 Elite battery.

To Connect Axis Elite LED Light with Activ Elite Battery:

1. Arrange Axis Elite neck battery cable on user's loupe and wear the loupe.
2. Place Activ Elite battery on your neck.
3. Plug Axis Elite neck battery cable to battery output port.
4. Touch and hold the power button for approx. 2 seconds to turn on the light.

To Connect Axis Elite LED Light with PP1.5 Elite Power Pack:

1. Arrange Axis Elite hip extension battery cable on user's loupe and wear the loupe.
2. Plug Axis Elite hip battery extension cable to battery output port.
3. Place PP1.5 Elite using battery clip and press the power button to turn on the light.

Note: See the [Instructions] section of the Enova Axis or Axis Elite LED Light 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:

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





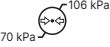
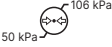
Note: Do not immerse or spray the battery or charger with disinfecting liquids or sterilizer, nor should any liquids be poured on the cable connectors.

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	PP1.5 REF 80203-001	Activ REF 80204-XXX	PP1.5 Elite REF 80206-001	Activ Elite REF 80207-XXX
Type	Rechargeable, Li-Ion Battery			
Input	10VDC, 1.4A	10VDC, 1.4A	10VDC, 1.4A	10VDC, 1.4A
Output	3.3VDC, 1.1A/0.45A	3.3-3.7VDC, 0.52A	3.4VDC, 0.44A	3.4VDC, 0.43A
Capacity	2,600mAh	2,600mAh	3,000mAh	3,000mAh
Energy	8.6Wh	10.0Wh	10.2Wh	10.2Wh
Environmental Condition	Operation		Storage and Transportation	
Temperature				
Humidity				
Atmospheric Pressure				










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"/> PP1.5		
	<input type="checkbox"/> Activ		
	<input type="checkbox"/> PP1.5 Elite		
	<input type="checkbox"/> Activ Elite		
BATTERY #2	<input type="checkbox"/> PP1.5		
	<input type="checkbox"/> Activ		
	<input type="checkbox"/> PP1.5 Elite		
	<input type="checkbox"/> Activ Elite		
OTHER			

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