



ENCISION recommends placing this document with the instructions for use for your AEM® Monitor.

Device Description

Bipolar Adapter

The **BP9004** Series Bipolar Adapter connects the AEM Monitor to the Electrosurgical Unit (ESU). A Bipolar Adapter is required when using the End Point Monitoring function of the AEM Monitor.

The Bipolar Adapter consists of an insulated jacket with two insulated conductors and two plug ends

WARNING

- This product is not intended to be located in the sterile field. It is not supplied sterile.

CAUTION

- Steam sterilization will damage the device.

Use with Bipolar Surgery

In bipolar electro-surgery, the surgical instrument includes both electrodes. A patient return electrode is not used. Current flows between the two electrodes and through the tissue contacted by the instrument, heating the tissue. In bipolar electro-surgery, close control is needed to ensure the correct degree of heating.

End Point Monitoring of the bipolar instrument will assist the surgeon in confirming the end point of bipolar desiccation. This information is displayed as the bipolar current indicator bar illuminates on the AEM Monitor or the End Point Monitor Remote Display.

Intended Use

The Bipolar Adapter is intended to connect the AEM Monitor to the electrosurgical unit during bipolar electro-surgery. End point monitoring is intended to aid the surgeon in determining the end point of bipolar electro-surgical desiccation.

Contraindications

None known.

Instructions For Use

Prior to Use

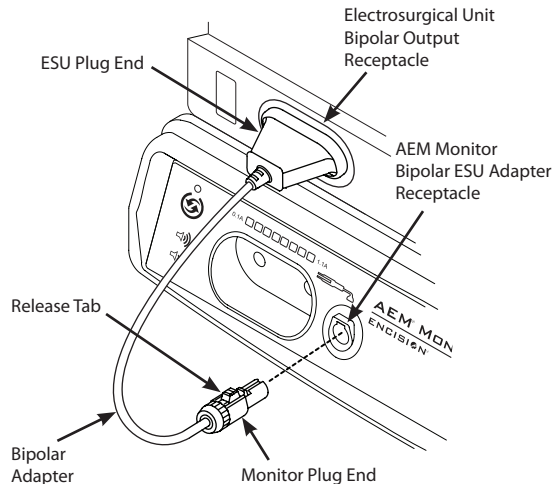
Thoroughly read these instructions and the instructions in the AEM Monitor User's Guide.

Visually inspect adapter for any potential wear or damage. See End of Life Indicators.

Bipolar Adapter Setup

See the AEM Monitor User's Guide or the Quick Setup Guide for complete setup instructions using the AEM Monitor during bipolar electro-surgery.

- Connect the monitor plug end of the Bipolar Adapter to the Bipolar ESU Adapter receptacle on the AEM Monitor. The release tab of the connector must be facing up before inserting into the receptacle.
- Connect the ESU plug end to the bipolar output receptacle of the electrosurgical unit.



WARNING

- Electric shock hazard.** Do not activate the generator bipolar output when the Bipolar Adapter is connected to the generator, but not connected to the AEM Monitor. Accessible pins of the adapter may lead to shock or burns to surgical personnel.
- Electric shock hazard.** Do not connect wet accessories to the monitor. Ensure that accessories and adapters are correctly connected and that no metal is exposed.

- Inspect accessories and cords for breaks, cracks, nicks or other damage before every use. Insure that end of life indicators are not present. If any of these are present, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating personnel.
- Do not attempt to connect or disconnect any cable during power activation.
- Pulling or tugging cords can result in breaking of internal conductors, causing sparking and burning of insulation during use. The AEM Monitor is not designed to detect or prevent an arc in the event of a broken active wire.
- Damage to connector body and/or insulation may result in shock or fire hazard.
- Keep electrical connections dry while in use to prevent potential conduction of HF current to the user.
- Good operating room practice suggests that connections of accessories to electrosurgical generators be made only while the generator is Off or on Standby.
- See electrosurgical generator manual and AEM Monitor User's Guide for precautions concerning the general application of Bipolar Surgical Equipment.

CAUTION

- If both bipolar and monopolar functions are being used, the monopolar instrument must remain connected to avoid spurious alarms.

Disassembly

To remove the monitor plug end from the AEM Monitor, depress the release tab and pull the connector away from the monitor. To remove the ESU plug end, pull the connector away from the electrosurgical unit.

CAUTION

- Always disconnect cord by pulling on connector body. Replace cord if intermittent electrical performance is observed.

Cleaning Instructions

Use a mild cleaning solution of disinfectant and a damp cloth to thoroughly wipe all surfaces of the cable and connector ends.

WARNING

- Electric shock hazard.** Always turn off and unplug the AEM Monitor and accessories before cleaning.

CAUTION

- Do not steam sterilize the Bipolar Adapter. Steam sterilization will damage the device.

Product Life

The life of this surgical instrument is largely dependent on the care of handling at the point of use or cleaning. The number of uses may be reduced by improper handling.

End of Life Indicators

Visually inspect prior to use. Discontinue use if any of the following are evident:

- Intermittent electrical performance.
- Cord: Damaged insulation (i.e. Cracks, nicks, abrasions, holes, tears, kinks, bulges, burns or melted areas). Pay special attention to cord/connector interface.
- Connector: Bent, broken, loose or missing components, or corroded contacts.

Express Warranty

ENCISION hereby warrants to Buyer that products purchased hereunder shall be free from defects in materials and workmanship under normal use and service, as specified in these Instructions for Use/Care, for the period of six months from date of purchase, or upon reaching an end of life indicator, whichever occurs first. Any evidence of repair, modification, or sterilization of this product will void this warranty.

See AEM Monitor User's Guide for details of Limitations, Disclaimer, and Exclusions.









Return of Used Product

If for any reason this product must be returned to ENCISION, a returned goods authorization is required prior to shipping. Appropriate return instructions may be obtained from ENCISION.

Product

ENCISION reserves the right to amend, modify or to change any product, to introduce new products, to withdraw products and otherwise vary product specifications at any time without notice.

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GLOSSARY OF SYMBOLS		
SYMBOL	MEANING	ISO 7000 REF NO.
	Manufacturer	3082
	Date of Manufacture	2497
	Batch Code or Lot Code	2492
	Catalog Number/Reference	2493
	Consult Instructions for Use	1641
	CAUTION - Read Instructions for use for further details	0434A
SYMBOL	MEANING	REFERENCE
	Does not contain or no presence of natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
	Prescription Only	21 CFR PART 801

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