

**Rx ONLY** 

## Device Description

### Monopolar ESU Adapter

The **EM3-60** Monopolar Adapter is an accessory that connects the EM3 AEM® Monitor to an electro-surgical generator (ESU) and is a required component of the AEM Monitoring System.

#### WARNING

- This product is not intended to be located in the sterile field. It is not supplied sterile.
- Steam sterilization will damage the device.

### Indications/Intended Use

The Encision AEM Monitoring System is an accessory for use with electro-surgical generators and electrodes that is designed to safely deliver electro-surgical energy and to prevent injury caused by insulation failure and capacitive coupling.

The function of the AEM Monitoring System is active electrode monitoring intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.

### Contraindications

There are no known contraindications for use of the AEM Monitor.

## Instructions For Use

### Prior to Use

Thoroughly read these instructions and the instructions in the *EM3 AEM Monitor User's Guide*.

#### WARNING

- **Explosion Hazard.** Do not use electro-surgery in the presence of flammable anesthetics.
- **Electric Shock Hazard.** Ensure that all accessories, cords, and adapters are correctly connected and that no metal is exposed.
- Good operating room practice suggests that connections of accessories to electro-surgical generators be made only while the generator is off or on standby.
- Keep electrical connections dry while in use to prevent potential conduction of HF current to the user.
- Do not attempt to connect or disconnect any cable during power activation.
- Inspect cords for breaks, cracks, nicks, or other damage before every use. Ensure 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.
- 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.

- See electro-surgical generator manual and AEM Monitor User's Guide for precautions concerning the general application of electro-surgical equipment.

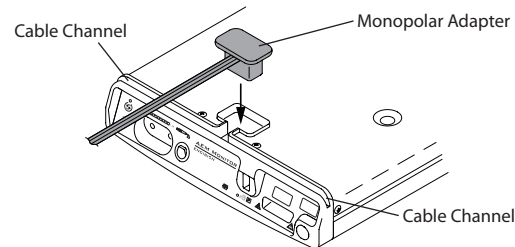
#### WARNING

- Electro-surgical generators included in the graphics below have been tested for use with the EM3 AEM Monitor. Use of an untested ESU may result in an inoperative active electrode monitoring system. Contact Encision Customer Service for more information.

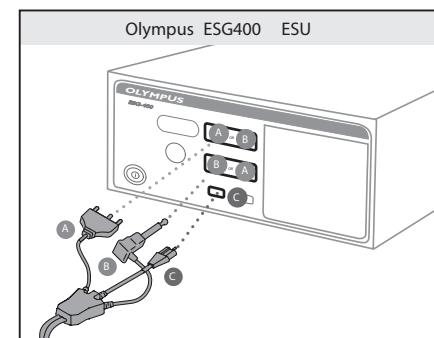
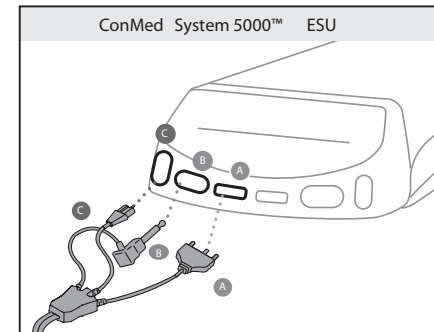
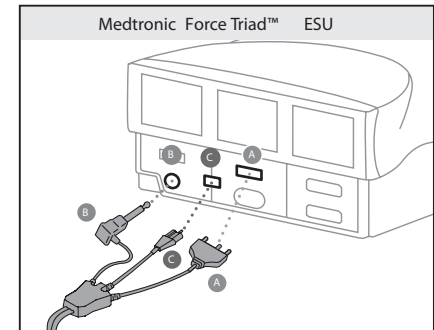
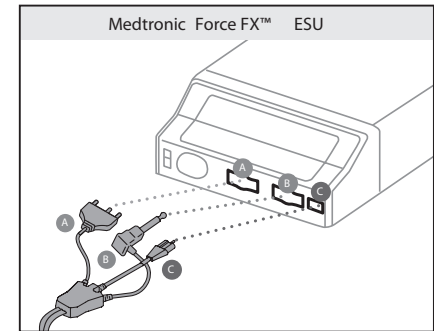
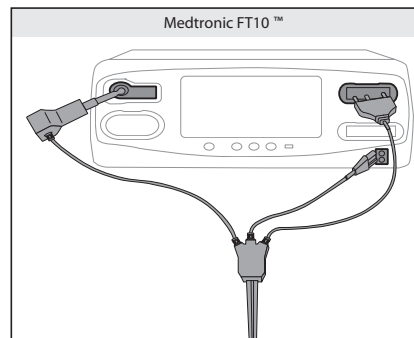
### Connecting the Monopolar Adapter

See the *EM3 AEM Monitor User's Guide* or the *Quick Setup Guide* for complete system setup.

1. Attach the Monopolar Adapter to the AEM Monitor using the receptacle on the monitor. Route the adapter cable to either side of the monitor using the cable channel (optional).



2. Place the AEM Monitor on a cart or attach it to a boom system.
3. Place the electro-surgical generator on top of the AEM Monitor or in close proximity to the monitor to allow for connection of the Monopolar Adapter to the ESU.
4. Attach the Monopolar Adapter to the ESU. The adapter connects to the return electrode receptacle, the foot control receptacle and a hand control accessory receptacle of the ESU. After properly connecting the adapter, a secondary hand control accessory receptacle on the ESU may be accessible for use.



**NOTE**

- When using the Force Triad or FT10 ESUs the monopolar hand control connector of the adapter may be disconnected to allow usage of a monopolar pencil. The AEM foot control instrument is still available.

**Disassembly**

To remove the adapter from the AEM Monitor, pull the connector away from the monitor.

To remove the adapter from the electrosurgical generator, pull each connector away from the ESU.

**CAUTION**

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

**Reprocessing****Cleaning**

Wipe down the exterior using a mild cleaning solution or disinfectant and a damp cloth.

Use a cotton swab to clean the internal contacts of any contaminates.

**CAUTION**

- Do not steam sterilize or immerse this product in any liquid. This will damage the device.

**NOTE**

- Used instruments are considered medical waste. Dispose of in accordance with local regulations.

**Product Life**

The life of this accessory is largely dependent on the care and handling at the point of use or cleaning. For optimal instrument life, protect it from contact / impact with other instruments during decontamination. The number of uses may be reduced by improper handling.

**End of Life Indicators**

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

- Connector: Bent, broken, loose, or missing components, or corroded contacts. Damaged active contact (center post) insulation (e.g. cracks, nicks, abrasions, holes, tears, burns or melted areas).
- Cord: Damaged insulation (e.g. cracks, nicks, abrasions, holes, tears, kinks, bulges, burns or melted areas). Pay special attention to cord/connector interface. Manually flex the cable near the connector ends. Increased flexibility may indicate a conductor wire break, even without obvious insulation damage.
- Electrical: Verify proper operation with the AEM Monitor and electrosurgical generator; the adapter should be removed from service if any malfunction occurs.

**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 (including Maximum Number of Uses), whichever occurs first. Any evidence of unauthorized modification or repair of this device will void the warranty.

See AEM Monitor Operator/Service Manual 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
	Serial Number	2498
	Catalog Number/Reference	2493
	Consult Instructions for Use	1641
	CAUTION - Read Instructions for use for further details	0434A
SYMBOL	MEANING	REFERENCE
	Not made with natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
	Prescription Only	21 CFR PART 801

Made in USA

**Manufactured by**

ENCISION Inc.  
6797 Winchester Circle  
Boulder, CO 80301 USA  
Ph: 800-998-0986  
Fax: 303-444-2693  
www.encision.com  
info@encision.com

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