

**EM3 Monopolar Adapters**

Instructions For Use/Care

EN

**Rx ONLY** 

**Device Description**

**Monopolar ESU Adapter**

The **EM3-XX Series** Monopolar Adapter connects the EM3 AEM® Monitor to an electrosurgical 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.

**CAUTION**

- Steam sterilization will damage the device.

**Indications/Intended Use**

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

The AEM Monitoring System consists of two distinct functions:

- Active electrode monitoring is intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.
- End point monitoring is intended to aid the surgeon in determining the end point of bipolar electrosurgical desiccation.

**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 electrosurgery 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 electrosurgical 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.
- Damaged external insulation AND incorrect setup of the AEM Monitor may result in a risk of unintended patient burn, shock, or fire hazard. Do not use product having damaged insulation.
- 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 electrosurgical generator manual and AEM Monitor User's Guide for precautions concerning the general application of electrosurgical equipment.

**Compatible Electrosurgical Generators**

Manufacturer / ESU Model	Monopolar Adapter
ConMed / System 5000™	EM3-40 or EM3-60
ConMed / Excalibur™	EM3-60
Covidien / Valleylab™ Force FX™	EM3-20 or EM3-60
Covidien / Force Triad™	EM3-70 or EM3-60

**WARNING**

- Electrosurgical generators included in the above list 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.

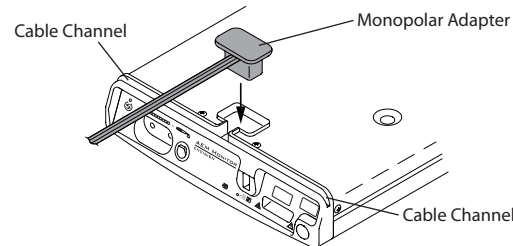
**NOTE**

- The Universal Monopolar Adapter, EM3-60, connects to all electrosurgical generators compatible with the AEM Monitor.

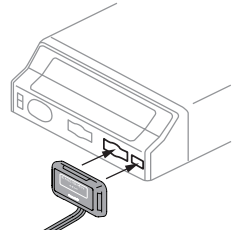
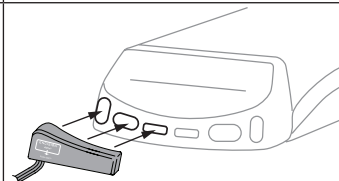
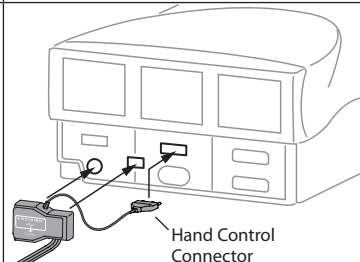
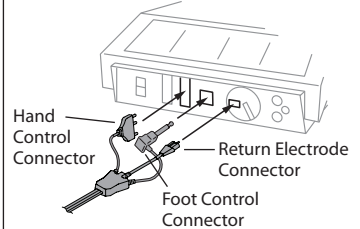
**Connecting the Monopolar Adapter**

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 top of 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 electrosurgical 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 and a hand control accessory receptacle of the ESU. For some ESUs, the adapter may also connect to a foot control accessory receptacle. After properly connecting the adapter, a secondary hand control accessory receptacle on the ESU may be accessible for use.

Covidien Valleylab Force FX ESU  with <b>EM3-20</b> Monopolar Adapter, Force FX	
Conmed System 5000 ESU  with <b>EM3-40</b> Monopolar Adapter, System 5000	
Covidien ForceTriad ESU  with <b>EM3-70</b> Monopolar Adapter, Force Triad	
ConMed Excalibur ESU  with <b>EM3-60</b> Monopolar Adapter, Universal	

**NOTE**

- When using the Force Triad ESU, the monopolar hand control connector of the adapter may be disconnected to allow usage of an instrument without AEM technology. 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 the connector body 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 surgical instrument 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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 <b>Rx ONLY</b>	Federal (USA) law restricts this device to sale by or on the order of a physician.
 <b>i</b>	Consult Instructions for Use
 <b>LATEX</b>	Latex Free

Made in USA

#### **Manufactured by**

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 **1275**

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