Inhibit Adapter Extension

EN Instructions For Installation and Use/Care

ENCISION

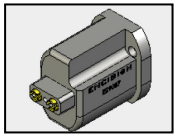
℞ ONLY LATEX

ENCISION recommends placing this document in the Instructions for Use/Care Section of your AEM® Monitor Operator/Service Manual.

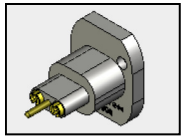
Device Description

Inhibit Adapter Extension

Inhibit Adapter Extensions are accessories designed for use with our AEM monitors and certain ESUs.



REF **ES9007** Inhibit Adapter Extension – for use with Conmed ESUs



REF **ES9008** Inhibit Adapter Extension – for use with Olympus ESUs

NOTE

- This product is rated to 4500 V peak. Limit electrosurgical generator power setting to 80 Watts or lower. Higher settings may result in spurious insulation failure alarms and/or insulation breakdown. See Encision AEM Monitor Operator/Service Manual for list of compatible electrosurgical generators.
- 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

AEM instruments for which this is an accessory incorporate the use of AEM technology and are intended for use in delivering monopolar electrosurgical energy during laparoscopic procedures only.

AEM instruments are intended for use with the AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor.

Contraindications

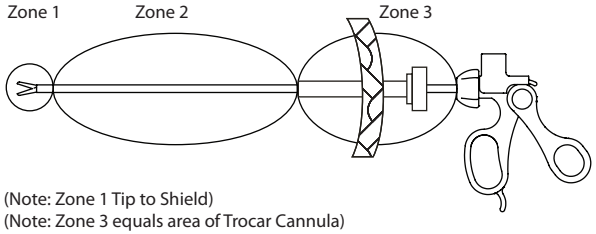
These instruments are not intended for use when laparoscopic electrosurgical techniques are contraindicated.

Laparoscopic procedures should be performed only by surgeons having adequate training and familiarity with laparoscopic techniques and who are also knowledgeable about anatomy and pathology as well as the complications, hazards, risks and benefits of the procedure.

Use with Monopolar Electrosurgery

AEM instruments, in conjunction with an AEM Monitor properly connected to the electrosurgical generator (ESU), continuously monitor and dynamically manage "stray energy" (insulation failure and capacitive coupling) in zones 2 & 3, which are likely out of the surgeon's field of view.

AEM shielding does not cover zone 1, which the surgeon should keep in view during instrument activation. As in all applications, "misapplied" electrosurgical energy remains the responsibility of the attending surgeon.



(Note: Zone 1 Tip to Shield)
(Note: Zone 3 equals area of Trocar Cannula)

WARNING

- Pulling or tugging cords can result in breaking of internal conductors, causing intermittent alarms or 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.
- 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.

CAUTION

- Good operating room practice suggests that connections of accessories to electrosurgical generators be made only while the generator is Off or on Standby.
- Keep ESU power setting as low as possible for the intended purpose to minimize unintended burns.
- A singular AEM instrument must be the sole conductor of energy to tissue. Do not conduct energy by touching an AEM instrument to a second instrument contacting tissue. The second device will not be protected from capacitive coupling and insulation failure.
- Keep electrosurgical instruments away from the patient and operative field when not in use. Accidental activation can result in unintended injury to the patient.
- Always fully connect AEM cord to instrument and adapter. Partial connections may cause arcing, which will damage the product.
- See electrosurgical generator manual and AEM Monitor Operator/Service Manual for precautions concerning the general application of electrosurgical equipment.

Instructions For Use

Prior to Use

Thoroughly read these instructions and the instructions in the AEM Monitor Operator/Service Manual.

Installation Instructions

See general illustration below. or refer to your AEM Monitor Operator/Service Manual.

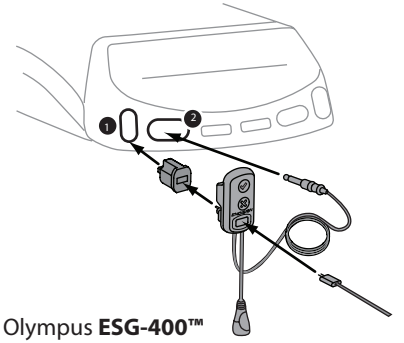
ES9007 is for use with **EM200** and **Conmed System 5000™**

1. **Connect the EM200 to the ES9007 and then into the electrosurgical generator.**
2. **Connect the patient return electrode to the EM200.**

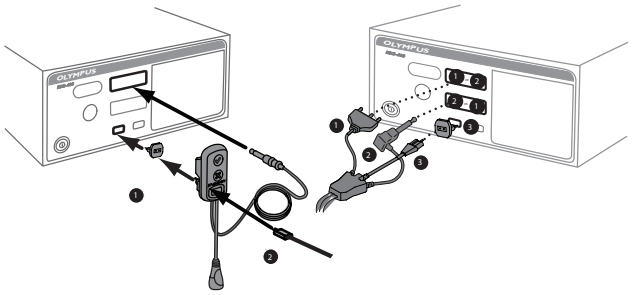
ES9008 is for use with **EM200 or the EM3** and **Olympus ESG-400™**

1. **Connect the Hand Control plug into the appropriate receptacle.**
2. **Connect the Foot Control plug into the appropriate receptacle.**
3. **Connect the Return Electrode plug into the ES9008 and then into the appropriate receptacle on the ESU.**

Conmed **System 5000™**



Olympus **ESG-400™**



Reprocessing Instructions

Manual Cleaning
Wipe down the exterior using a mild cleaning solution or disinfectant and a damp cloth to clean the adapter.

Automatic Cleaning
Do not place this product in an automatic washer or immerse this product in any liquid. This will damage the device.

Sterilization
Do not sterilize. Exposure to steam sterilization or cold soak sterilization 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 (i.e. cracks, nicks, abrasions, holes, tears, burns or melted areas).
- Electrical: Verify proper operation with the Active Electrode Monitoring System and electrosurgical generator.

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 unauthorized modification, repair or sterilization 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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System 5000 is a registered trademark of ConMed Corporation

Olympus ESG-400 Thunderbeat is a registered trademark of Olympus Corporation

GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Date of Manufacture	2497
LOT	Batch Code or Lot Code	2492
REF	Catalog Number/Reference	2493
	Consult Instructions for Use	1641
	CAUTION - Read Instructions for use for further details	0434A
SYMBOL	**MEANING**	**REFERENCE**
LATEX	Does not contain or no presense of natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
℞ ONLY	Prescription Only	21 CFR PART 801
CE	CE Mark	Medical Device Directive 93/42/EEC

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