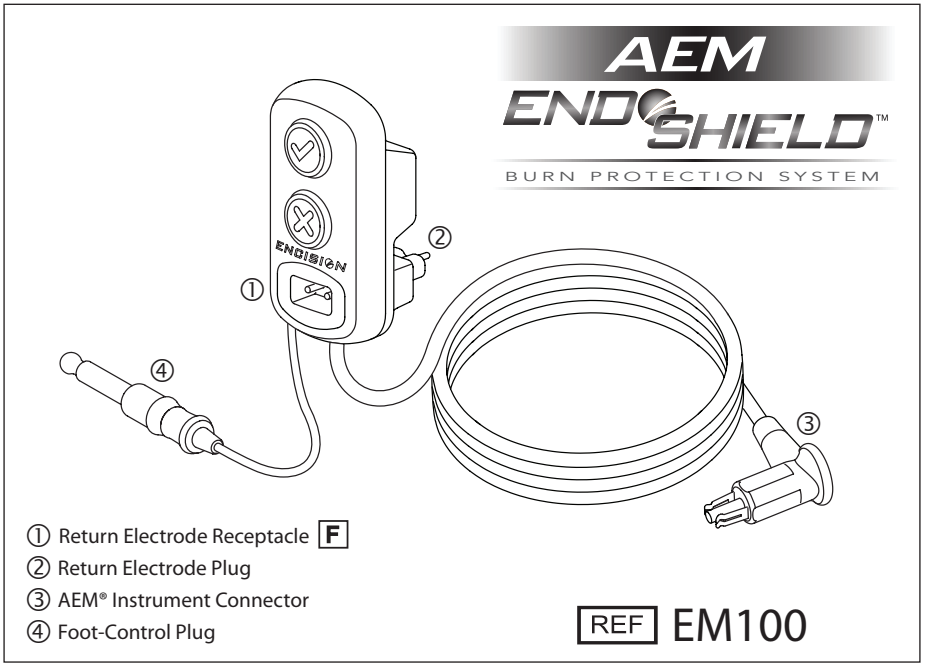
ENCISION®



Device Description

Rx ONLY STERILE EO

The AEM EndoShield Burn Protection System uses AEM® Monitoring in conjunction with AEM instruments and an electrosurgical generator to continuously monitor and dynamically manage stray energy (insulation failure and capacitive coupling) during monopolar laparoscopic electrosurgery.

AEM EndoShield is for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. These instructions are intended as a guide for the setup and operation of AEM EndoShield. They are not intended to be a general reference about the use of electrosurgery either in general application or in laparoscopic procedures.

WARNING: These devices have been specifically designed for use in electrosurgery. Do not use for other procedures.

Caution: AEM EndoShield is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling. AEM EndoShield is not intended to test for insulation damage on laparoscopic instruments. Do not attempt to use this system as an instrument inspection tool.

Prior to using the AEM EndoShield Burn Protection System, read and review these instructions, the instructions for use for the electrosurgical generator, and the instructions for use for all instruments and accessories to be used.

WARNINGS and Cautions start on page 10

Table of Contents

Indications for Use

The AEM EndoShield Burn Protection System is an accessory for use with electrosurgical generators and AEM instruments that is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling.

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.

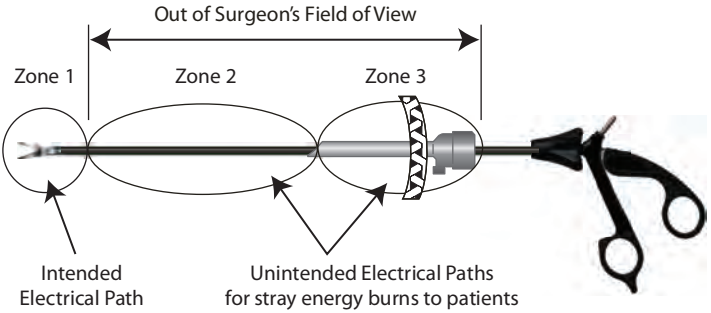
Contraindications

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

How AEM® Monitoring Works

Non-AEM Laparoscopic Instruments

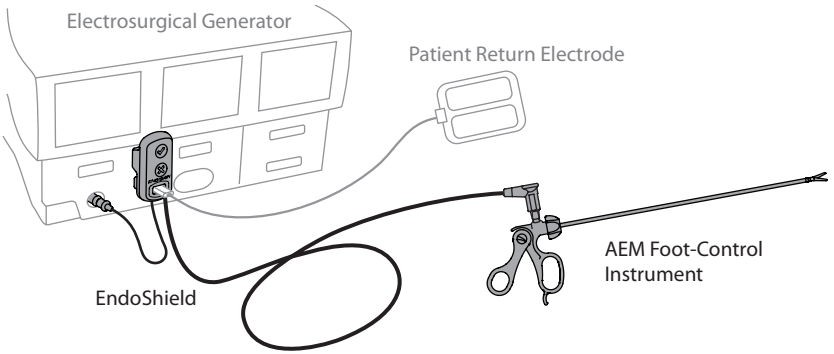
Monopolar laparoscopic instruments have an inherent problem with their design; they are prone to insulation failure and capacitive coupling, causing patient burns. These stray energy burns occur in the surgeon's blind spot. As a result, they typically go undiagnosed and further manifest into severe complications.



AEM EndoShield Burn Protection System

Encision's AEM technology eliminates stray energy burns to patients during laparoscopy by electrically shielding and monitoring our instruments.

Every AEM instrument has a protective shield that is actively monitored by the AEM EndoShield Burn Protection System throughout a procedure. This protective shield eliminates the risk of capacitive coupling to the patient by draining the energy away from the patient to the electrosurgical generator. If an insulation failure occurs, the AEM system actively drains the electrosurgical energy away from the patient through the protective shield. In addition, AEM EndoShield immediately shuts down the instrument power, similar to a circuit breaker (GFCI) in the electrical wiring of a house.



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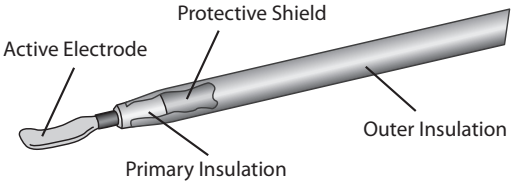
AEM Instruments

In every AEM instrument, the active electrode is surrounded by the primary insulation layer. The primary insulation layer withstands the high voltages of electrosurgery, ensuring effective use of the active electrode. The protective shield is a conductive tube that surrounds the primary insulation layer and active electrode. The shield conducts stray energy back to the electrosurgical generator, ensuring there is no chance of a stray energy burn to the patient. The outer insulation provides an additional layer of insulation for all AEM instruments.

Patients, Physicians, and Nurses can confidently use AEM monopolar energy knowing that stray energy burns to the patient have been eliminated.



WARNING: AEM shielding does not cover zone 1, the active tip of the instrument, which the surgeon should keep in view during instrument activation.

System Setup

Prior to using the AEM EndoShield Burn Protection System, read and review these instructions, the instructions for use for the electrosurgical generator, and the instructions for use for all instruments and accessories to be used.

AEM EndoShield is supplied sterile. Inspect the package and product for damage prior to use.

WARNING: The electrosurgical generators (ESUs) referenced here have been tested for use with the AEM EndoShield Burn Protection System. Use of an untested ESU may result in an inoperative active electrode monitoring system.

Caution: AEM Monitoring will not function without the use of a dual-area patient return electrode and an electrosurgical generator equipped with contact quality monitoring patient safety technology.

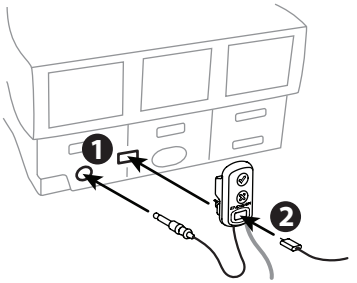
Caution: Limit electrosurgical generator power settings as noted. Higher settings may result in spurious insulation failure alarms and/or insulation breakdown.

ESU	***Mode and Power Limitation (Watts)***
Force Triad	All Modes: Maximum 80
Force FX or FX-C	Med Coag: Maximum 75
	High Coag: Maximum 60
	All Other Modes: Maximum 80
System 5000	Use Lap-Specialty Mode Only: Maximum 80
Excalibur	Spray Coag: Maximum 40
	All Other Modes: Maximum 80

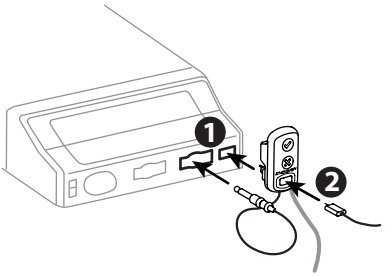
Caution: Whenever the patient return electrode is connected to AEM EndoShield, the device operates continuously.

1. **Connect AEM EndoShield to the electrosurgical generator.**
2. **Connect the patient return electrode to AEM EndoShield.**
   - (X) illuminates RED until an AEM instrument is connected.
   - If no symbols illuminate, see the *Troubleshooting* section.

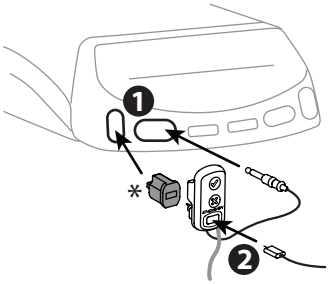
Covidien **Force Triad**™



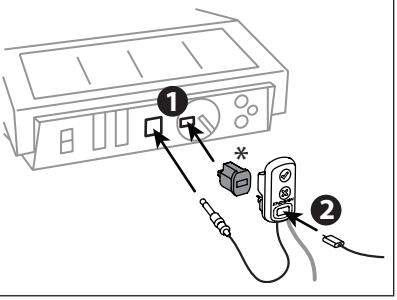
Covidien **Force FX**™ **(-C)**



Conmed **System 5000**™

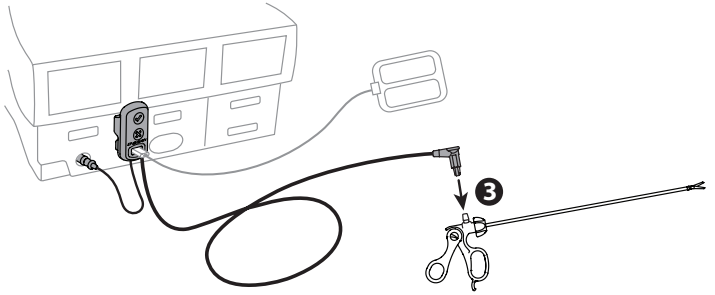


Conmed **Excalibur**™



* Reusable Encision Adapter ES9007 required to complete setup.

3. **Connect an AEM foot-control instrument to AEM EndoShield.**
   - (✓) illuminates GREEN when the AEM EndoShield Burn Protection System is fully operational.
   - If (X) illuminates RED, see the *Troubleshooting* section.



4. **Turn on the electrosurgical generator, enabling its contact quality monitoring system. It should be in its normal operating state.**

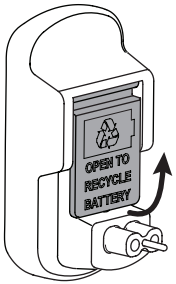
After Use

Caution: This product is supplied sterile and is not intended for use more than one time. No attempt should be made to reprocess this device.

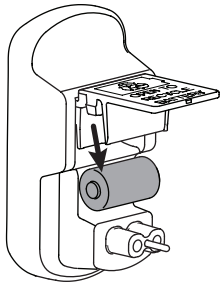
Caution: Used instruments are considered medical waste. Dispose of in accordance with local regulations.

Removing the Battery

Open the door on the back of AEM EndoShield.



Remove the battery.



AEM EndoShield contains a 3V CR2 lithium battery. The lithium battery is tested for a minimum of eight (8) hours' operating time.

WARNING: Dispose of the lithium battery in accordance with local regulations. Incineration of the device with battery may result in explosion.

Caution: The lithium battery is single use only. Do not reuse or replace the lithium battery.

End of Life Indicators

Discontinue use if any of the following are evident:

- intermittent electrical performance
- after one use of product

Reprocessing

WARNING: This product is intended for single use and shall not be reprocessed or resterilized. Resterilization may result in explosion or fire hazard. Resterilization may compromise the integrity of the device, which may result in malfunction or electrical hazard to the patient or user.

Compatible Products

For successful operation, the AEM EndoShield Burn Protection System must be used with the following compatible products.

Caution: Use of other accessories or cables may result in increased EMC emissions or decreased immunity.

Electrosurgical Generator

Electrosurgical Generator (ESU)		***Encision Adapter Required***
Manufacturer	***Model***	
Covidien	Force Triad	N/A
	Force FX	N/A
	Force FX-C	N/A
Conmed	System 5000	ES9007
	Excalibur	ES9007

WARNING: The electrosurgical generators referenced here have been tested for use with the AEM EndoShield Burn Protection System. Use of an untested ESU may result in an inoperative active electrode monitoring system.

Caution: All electrosurgical generators must have a contact quality monitoring circuit for return electrodes.

Return Electrode

The AEM EndoShield Burn Protection System requires a dual-area patient return electrode.

Active Electrode

The foot-control instrument must have patented AEM technology and be manufactured by/for Encision Inc., or licensed by Encision Inc.

Hand-control AEM instruments are not compatible with the AEM EndoShield Burn Protection System.

Encision Adapter

Some electrosurgical generators require an adapter for setup of the AEM EndoShield Burn Protection System (see the Electrosurgical Generator table above). Refer to the *Setup* section for proper connections.

Troubleshooting

Mechanical Inspection

Before use, visually inspect the following items of AEM EndoShield. Do not use if any of these items appear damaged:

- insulation of wiring and cables
- instrument receptacles and connectors

Correcting Setup Faults

Verify that the setup of the AEM EndoShield Burn Protection System is complete.

Situation	*Recommended Action*
No symbols illuminate on the front of AEM EndoShield.	Verify that a dual-area patient return electrode is connected properly and fully seated in the return electrode receptacle of AEM EndoShield. If the fault persists, replace the patient return electrode. Check the Use By date on the AEM EndoShield package. If the product is beyond the specified date, the battery life may be low or depleted, replace AEM EndoShield.
⊗ illuminates RED on AEM EndoShield, **continuous**.	Verify that the AEM instrument is properly connected to AEM EndoShield. If the fault persists, replace the AEM instrument.
No power to instrument, but the ✓ illuminates GREEN on AEM EndoShield.	Verify that both AEM EndoShield connectors to the electrosurgical generator (ESU) are properly and securely connected. Ensure that the power settings on the ESU are sufficient Verify that the foot pedal is properly connected to the ESU. Reset the ESU's pad monitoring system (applies to some ESU models). Check the return electrode application to the patient. Follow the return electrode manufacturer's instructions for proper placement. If the fault persists after performing all the previous steps, replace the AEM instrument. If the fault continues to persist, replace AEM EndoShield.

Responding to AEM EndoShield Alarms

When using AEM Monitoring, successful electrosurgery depends on an absence of critical fault conditions. Should one occur, the AEM EndoShield Burn Protection System interrupts the power delivery from the electrosurgical generator to the AEM instrument for 10 seconds.

If for any reason a fault condition persists from AEM EndoShield after following the steps described below, use a backup AEM EndoShield to complete the surgical procedure.

Situation	***Recommended Action***
⊗ illuminates RED on AEM EndoShield **for 10 seconds**. AEM EndoShield interrupts the circuit to the electrosurgical generator **for 10 seconds**.	Verify that the AEM instrument is properly connected to AEM EndoShield. Activate the instrument. If the ⊗ continues to illuminate RED, replace the instrument. If the ⊗ continues to illuminate RED after replacing the instrument, replace AEM EndoShield.
⊗ illuminates RED on the AEM EndoShield, **continuous**. AEM EndoShield interrupts the circuit to the electrosurgical generator **until the alarm condition is satisfied**.	Disconnect the AEM instrument from EndoShield. Reconnect the AEM instrument to AEM EndoShield. If the ⊗ continues to illuminate RED, replace the instrument. If the ⊗ continues to illuminate RED after replacing the instrument, replace AEM EndoShield.

WARNING: An AEM EndoShield alarm may indicate an unsafe condition. Electrosurgical energy to the AEM instrument is disabled during the alarm condition.

If other alert conditions occur during the surgical procedure, see *Correcting Setup Faults* on previous page.

Warnings and Cautions

Prior to using the AEM EndoShield Burn Protection System, read and review these instructions, the instructions for use for the electrosurgical generator, and the instructions for use for all instruments and accessories to be used.

Fire and Shock Hazards

WARNING:

- Explosion Hazard. Do not use electrosurgery in the presence of flammable liquids or in an oxygen enriched environment.
- Fire Hazard. Electrosurgical accessories that are activated or hot from use can cause a fire. Do not place them near or touching flammable materials (such as gauze or surgical drapes).
- Electric Shock Hazard. Ensure that all accessories, cords, and adapters are correctly connected.
- Electric Shock Hazard. Do not attempt to connect or disconnect any cable during power activation.

General

WARNING:

- Confirm proper electrosurgical power setting before proceeding with surgery. Use the lowest power setting that achieves the desired surgical effect.
- Keep electrical connections dry while in use to prevent potential conduction of High Frequency (HF) current to the user.
- Only an AEM instrument provides active electrode monitoring. Other conductive objects at or near the surgical site are not protected. Do not touch those objects with the active instrument.
- No modification of this equipment is allowed.

Caution:

- Limit electrosurgical generator power settings as noted in the *ESU Mode and Power Limitation* table in the *System Setup* section. Higher settings may result in spurious insulation failure alarms and/or insulation breakdown.

Active Accessories and the AEM EndoShield Burn Protection System

WARNING:

- Do not wrap accessory cords around metal objects. Wrapping cords around metal objects may induce currents that could lead to shocks, fires, or injury.
- The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- When not in use, place accessories in a clean, dry, nonconductive and highly visible area not touching the patient. Inadvertent contact with the patient may result in burns.
- Ensure that the insulation of conventional, nonshielded disposable and reusable laparoscopic instrumentation is intact. Compromised insulation of nonshielded instruments may lead to shocks or burns to the patient or surgical personnel.

- When using laparoscopic instrumentation with metal cannulas, the potential exists for abdominal wall burns to occur in the event of direct electrode tip contact to the cannula.
- Inspect cords for breaks, cracks, nicks. If any are present, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating personnel.
- Damaged external insulation on instruments AND incorrect setup of the AEM EndoShield Burn Protection System may result in a risk of unintended patient burn. Do not use product having damaged insulation.
- When an alert is presented by AEM EndoShield, discontinue use of the electrosurgical current immediately. Find the cause of the alert and correct it before continuing use.
- Damaged internal insulation of the instrument, or loss of shield continuity, may cause AEM EndoShield alarms. For maximum patient safety, discontinue use of the instrument if this occurs.
- A single 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.

Caution:

- Read the instructions, warnings, and cautions provided with the AEM EndoShield Burn Protection System accessories before using. Their specific instructions are not included in this manual.
- AEM Monitoring will not function without the use of a dual-area patient return electrode and an electrosurgical generator equipped with contact quality monitoring patient safety technology.
- This product is supplied sterile and is not intended for use more than one time. No attempt should be made to reprocess this device.

Electromagnetic Compatibility (EMC) Hazards

For EMC specification tables, refer to the *Technical Specifications* section.

Caution:

- Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Equipment or System as replacement parts for internal components, may result in increased Emissions or decreased Immunity of the Equipment or System.

Technical Specifications

Monopolar Operating Mode

The AEM EndoShield Burn Protection System detects improper setup conditions and detects operative faults by providing a monitored pathway for the current which is flowing from the shield to the patient return electrode. The fault condition is indicated on the front of AEM EndoShield and the flow of energy is interrupted from the electrosurgical generator to the AEM instrument.

Functional Characteristics

Monopolar Setup Fault Detection
If the return electrode is disconnected or the wrong type of return electrode is connected, no symbols illuminate on the front of AEM EndoShield.

If an AEM foot-control instrument is not connected to AEM EndoShield or not connected properly, the ⊗ illuminates RED to identify the setup fault.

Shield Cable and Return Electrode Switch Threshold
50 ohms ± 40%

Monopolar Operative Fault Detection
If there is excessive shield current or arcing between the shield and the active electrode causing an operative fault, the ⊗ illuminates RED to identify an insulation fault, and the AEM EndoShield Burn Protection System interrupts the flow of energy from the electrosurgical generator to the AEM instrument.

Radio Frequency Current Sensing
Current-sensing and spark detection are provided. Minimum electrosurgical generator output for reliable insulation fault detection: 20 Watts.

Indicators and Alert Functions

GREEN ✓	Indicates that the AEM EndoShield Burn Protection System is fully operational.
RED ⊗	During setup, indicates that the AEM instrument is not properly connected. During use, indicates that the instrument in use has an unsafe operating condition. Indicates that there is excessive current or arcing between the active electrode and the shield. Once triggered in this condition, ⊗ illuminates RED for 10 seconds.

Connectors and Cables

Return Electrode Receptacle
A dual pin receptacle on the front of AEM EndoShield. Connects a dual-area patient return electrode to AEM EndoShield.

Return Electrode Plug
A single pin plug on the rear of AEM EndoShield. Connects to the electrosurgical generator's patient return electrode receptacle.

AEM Instrument Connector
Connects the AEM instrument active conductor (foot-control instrument only) to the electrosurgical generator and the shield conductors to AEM EndoShield.

Foot-Control Plug
A single active pin that connects AEM EndoShield to the electrosurgical generator's footswitch accessory receptacle.

Maximum Electrosurgical Generator Voltage

4.1 KVpeak

Electrical Characteristics

Power Source
Lithium Battery, 3V CR2

Patient Leakage Current
Source or sink leakage current is 10 µA maximum

Dimensions and Weight

External Dimensions
4" tall x 2" wide x 2.5" deep, excluding integrated cords
AEM Instrument Connector: 9' cord length
Foot-Control Plug: 6" cord length

Weight
8 oz. (227 g), excluding ESU-required adapters

Environmental Characteristics

Operating Temperature
59 to 104° F (15 to 40° C)

Storage and Transport Temperature
-13 to 140° F (-25 to 60° C)

Operating, Storage and Transport Humidity
5% to 95% relative, non-condensing

Atmospheric Pressure (Operating)
70 - 110 kPa

Standards and IEC Classifications

Internally Powered Equipment per IEC 60601-1/EN 60601-1
Equipment operates from an internal electrical power source.

Defibrillator Protected Equipment
The electrosurgical generator provides defibrillator protection. AEM Endoshield does not compromise this protection.

Caution: Ordinary equipment is not protected against the ingress of water.

Caution: Medical Electrical Equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided herein.

Caution: Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Electromagnetic emissions and immunity per IEC 60601-1-2/EN 60601-1-2

Guidance and Manufacturer's Declaration – Emissions		
The Encision AEM EndoShield Burn Protection System is intended for use in the electromagnetic environment specified below. The customer or user of AEM EndoShield should ensure that it is used in such an environment.		
Emissions Test	***Compliance***	***Electromagnetic Environment – Guidance***
RF emissions CISPR 11	Group 1	AEM EndoShield uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	AEM EndoShield is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	N/A	
Flicker IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration – Immunity			
The Encision AEM EndoShield Burn Protection System is intended for use in the electromagnetic environment specified below. The customer or user of AEM EndoShield should ensure that it is used in such an environment.			
Immunity Test	***IEC 60601 Test Level***	***Compliance Level***	***Electromagnetic Environment – Guidance***
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
Electrical Fast Transient (EFT) IEC 61000-4-4	±2kV Mains ±1kV Input/Output (I/Os)	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of AEM EndoShield requires continued operation during power mains interruptions, it is recommended that AEM EndoShield be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity			
The Encision AEM EndoShield Burn Protection System is intended for use in the electromagnetic environment specified below. The customer or user of AEM EndoShield should ensure that it is used in such an environment.			
Immunity Test	***IEC 60601 Test Level***	***Compliance Level***	***Electromagnetic Environment – Guidance***
			Portable and mobile communications equipment should be separated from AEM EndoShield by no less than the distances calculated/listed below:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separation Distances for the AEM EndoShield Burn Protection System			
The AEM EndoShield Burn Protection System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of AEM EndoShield can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and AEM EndoShield as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power *(Watts)*	***Separation (m) 150kHz to 80MHz*** D=(3.5/V1)(Sqrt P)	***Separation (m) 80 to 800 MHz*** D=(3.5/E1)(Sqrt P)	***Separation (m) 800 MHz to 2.5 GHz*** D=(7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Limited Warranty

Express Warranty: ENCISION hereby warrants to Buyer that products purchased hereunder shall be free from defects in material and workmanship under normal use and service, as specified in ENCISION's product manuals and Instructions for Use provided with such product, for the period of:

- AEM EndoShield Burn Protection System – until the labeled USE BY date, or one (1) use, whichever occurs first.
- Instruments and Accessories – as stated in the applicable Instructions for Use. This warranty shall run in favor of Buyer only, and is not enforceable by any other person or entity.

Disclaimer: The express warranties set forth in this agreement are in lieu of, and buyer hereby expressly waives, all other guarantees and warranties of any kind, whether express, implied or statutory including, without limitation, merchantability, fitness for particular purpose, non-infringement or by sample, and all such other warranties are hereby disclaimed and excluded by ENCISION. The sole and exclusive remedy for breach of ENCISION's warranty of the products shall be as stated herein.

Exclusions: The express warranty set forth above specifically excludes and does not apply to defects (i) caused through no fault of ENCISION during shipment to or from Buyer, (ii) caused by modifications or alterations made to the products by Buyer or any third party (iii) caused by unauthorized repair or maintenance performed on the products by Buyer or any third party, (iv) caused by the failure of Buyer to comply with any of the return procedures specified below, or (v) damaged by excessive current, temperature, physical stress or other deviation from the applicable environmental specifications.

Limitation of Remedies: ENCISION's sole obligation and Buyer's exclusive remedy for any breach of warranty is limited to the repair or replacement, at Encision's option, of any warranted product that is returned to ENCISION in its standard shipping container or properly packed in accordance with ENCISION's packing procedures, freight prepaid, where ENCISION's examination shows the product to have failed under normal use. If ENCISION's examination discloses that the returned product is not defective within the terms of this warranty, Buyer shall be subject to a $200.00 charge per individual product for testing expenses incurred by ENCISION and the product will be returned to Buyer, freight collect. Such repair or replacement and reshipment at ENCISION's expense will be Buyer's sole and exclusive remedy for such defect. ENCISION will pay shipping charges for the repaired or replaced from ENCISION's factory to Buyer's location. If, notwithstanding the foregoing, Buyer ships any product to ENCISION's factory freight collect, then ENCISION shall ship the repaired or replaced product freight collect.

Warranty Procedures: Buyer shall request authorization from ENCISION prior to the return of each defective product for repair or replacement by ENCISION. Upon such request, ENCISION shall provide the address of the facility to which such product must be returned, together with Return Material Authorization (RMA) tracer number. ENCISION may, at its sole option, employ new or used parts for products to make such repair or replacement.

Stored Data: ENCISION shall not be liable for any loss or damage to any data stored in any product, including, without limitation, any data loss or damage resulting from any malfunction or defect or any loss or damage resulting from any inspection, repair, refurbishment, reconditioning or testing of the product or incurred in connection with transportation of the product to ENCISION or ENCISION's authorized repair center.

Technical Assistance: ENCISION's warranty shall not be enlarged, and no obligation or liability shall arise out of ENCISION's rendering of technical advice or assistance in connection with the products sold hereunder.

Limitation of Liability: To the extent allowable by applicable law, in no event shall ENCISION be liable for any special, incidental or consequential damages in connection with or arising out of the sale, installation, use, operation, service or repair of any product, whether based on breach of warranty or contract, strict liability, negligence or otherwise, whether or not ENCISION shall have been advised as to the possibility or reason for any such potential loss or damage. Direct damages shall be strictly limited to the cost to Buyer of the products sold or provided to Buyer, not withstanding any failure of essential purpose of any limited remedy.

Any evidence of repair, modification, or resterilization of this product will void this warranty.

Symbol Definitions

	Do not Reuse - Single Use Only	STERILE EO	Sterilized using Ethylene Oxide
	Do not use if the product sterilization barrier or its packaging is compromised.		Recycle Battery
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.		Manufacturer
	Consult Instructions for Use		Temperature Limitation
REF	Catalog Number		Humidity Limitation
LOT	Lot Number		System Ready (when illuminated GREEN)
	Use by Date		Check System (when illuminated RED)
	Refer to Instructions for Use		Manufacture Date
F	HF Isolated Patient Circuit		

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 Changes
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.

US Patents:
5,312,401; 5,688,269; 8,007,494; 8,460,284; 8,500,728

Manufactured by:
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