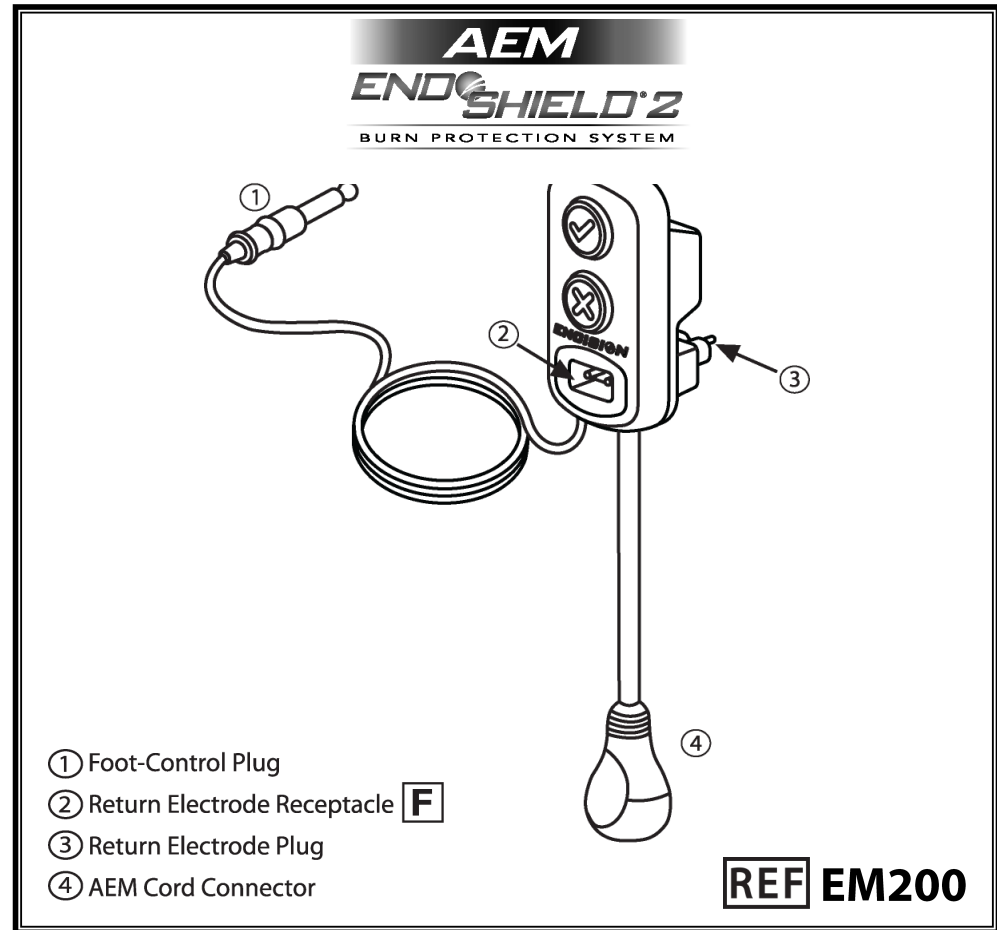


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Device Description



The AEM EndoShield® 2 Burn Protection System uses AEM® Monitoring in conjunction with AEM instruments and an electro-surgical generator to continuously monitor and dynamically manage stray energy (insulation failure and capacitive coupling) during monopolar laparoscopic electro-surgery.

The EndoShield 2 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 the EndoShield 2. They are not intended to be a general reference about the use of electro-surgery 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: The EndoShield 2 is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling. The EndoShield 2 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 EndoShield 2, 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 15

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Indications for Use

The EndoShield 2 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.

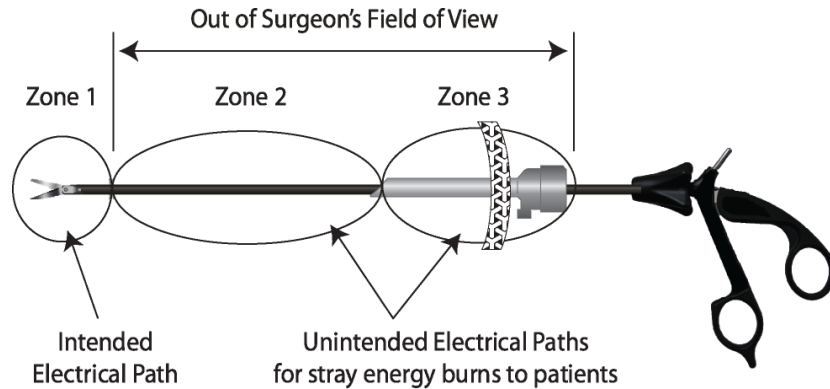
Contraindications

There are no known contraindications for the use of the EndoShield 2.

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.

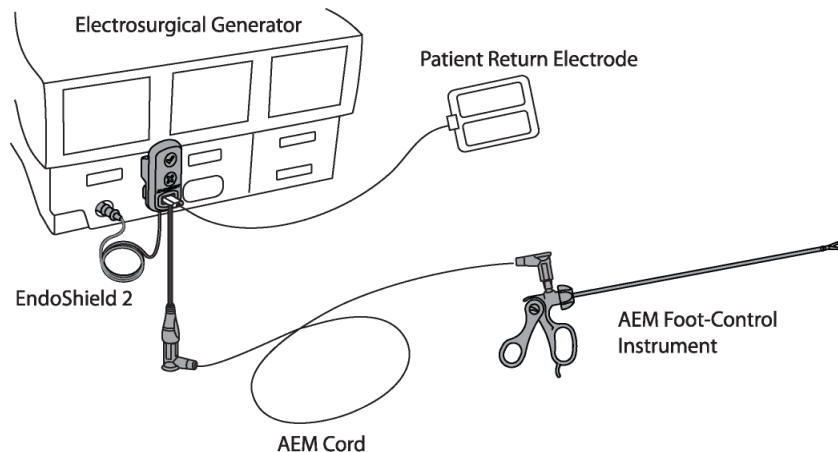


The EndoShield 2 Burn Protection System

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 EndoShield 2 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 electro-surgical generator. If an insulation failure occurs, the AEM system actively drains the electro-surgical energy away from the patient through the protective shield. In addition, the EndoShield 2 immediately shuts down the instrument power, similar to a circuit breaker (GFCI) in the electrical wiring of a house.



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; D737,981.

ENCISION®, AEM®, and AEM EndoShield® 2 are registered trademarks of ENCISION Inc.

All other referenced trademarks are owned by their respective owners.



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Symbol Definitions

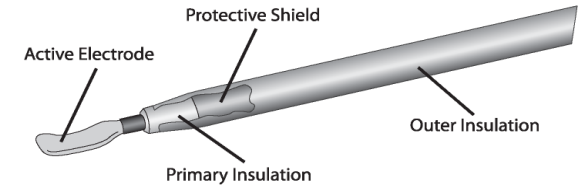
SYMBOL	MEANING	ISO 7000 REF NO.	SYMBOL	MEANING	ISO 7000 REF NO.
	Manufacturer	3082		Medical Device that has not been subjected to a sterilization process, when similar or identical products are sold Sterile.	2609
	Use by Date (Expiration Date)	2607		Consult Instructions for Use	1641
	Batch Code or Lot Code	2492		Recyclable Battery	1135
	Date of Manufacture	2497		Temperature Limits	0632
	Catalog Number/Reference	2493		Humidity Limitation	2620
SYMBOL	MEANING	REFERENCE			
	Refer to Instruction Manual	ISO 7010 Ref # M002			
	System Ready (when illuminated GREEN)	Green Check Mark – Graphical Representation of Indicator Light on Device, in ISO 7000 Ref # 1940. Equals – ISO 7000 Ref # 0652 OK – internationally recognized word meaning acceptable.			
	Check System (when illuminated RED)	Red X – Graphical Representation of Indicator Light on Device, in IEC 60417 Ref# 6335B. Equals – ISO 7000 Ref# 0652 Refer to Instruction Manual – ISO 7010 Ref# M002			
	Low Battery (When Light Flashing GREEN)	Flashing Green Check Mark – Graphical Representation of Indicator Light on Device, in ISO 7000 Ref# 1940 Equals – ISO 7000 Ref# 0652 Battery Check – IEC 60417 Ref# 5546			
	Dead Battery (When Flashing RED)	Flashing Red X - Graphical Representation of Indicator Light on Device, in IEC 60417 Ref# 6335B. Equals – ISO 7000 Ref# 0652 Battery Check – IEC 60417 Ref# 5546			
	Does not contain or no presence of natural rubber latex	ISO 15223-1 5.4.5 with negation symbol Annex B.2			
	Prescription Only	21 CFR Part 80			
	HF Isolated Patient Circuit	IEC 60601-2-2 Figure 201.102			
	WEEE Wheeled Bin. This product is to be disposed of separately from the municipal waste stream.	2002/96/EC EN50419			
	Medical Device	ISO 15223-1 5.7.7			

How AEM® Monitoring Works (continued)

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.

Hospitals, 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 EndoShield 2, 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.

The EndoShield 2 is supplied non-sterile.

WARNING: The electrosurgical generators (ESUs) referenced here have been tested for use with the EndoShield 2. 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.


System Setup (continued)

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)
Conmed System 5000™	Use Lap Specialty Mode Only: Max Power = 80
Covidien Force Triad™	All Modes: Max Power = 80
Covidien FT10™	All Modes: Max Power = 80
Covidien Force FX™ or FX-C™	Med COAG: Max Power = 75
	High COAG: Max Power = 60
	All Other Modes: Max Power = 80
Erbe VIO 300 D™	Dry Cut: Max Effect = 7, Max Power = 50
	COAG Spray Effect 2: Max Power = 25
	All Other Modes: Max Power = 50
Megadyne MegaPower™	COAG 1: Max Power = 50
	All Other Modes: Max Power = 80
Olympus ESG-400™	COAG Spray Effect 2: Max Power = 80
	All Other Modes: Max Power = 80

Whenever the patient return electrode is connected to the EndoShield 2, the device operates continuously.

1. **Connect the EndoShield 2 to the electrosurgical generator.**
2. **Connect the patient return electrode to the EndoShield 2.**

-  illuminates RED until an AEM instrument is connected.
- If no symbols illuminate, see the *Troubleshooting and System Maintenance* section.

Limited Warranty (continued)

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, notwithstanding any failure of essential purpose of any limited remedy.

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

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 Instructions for Use provided with product, or until the labeled use by date.

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.

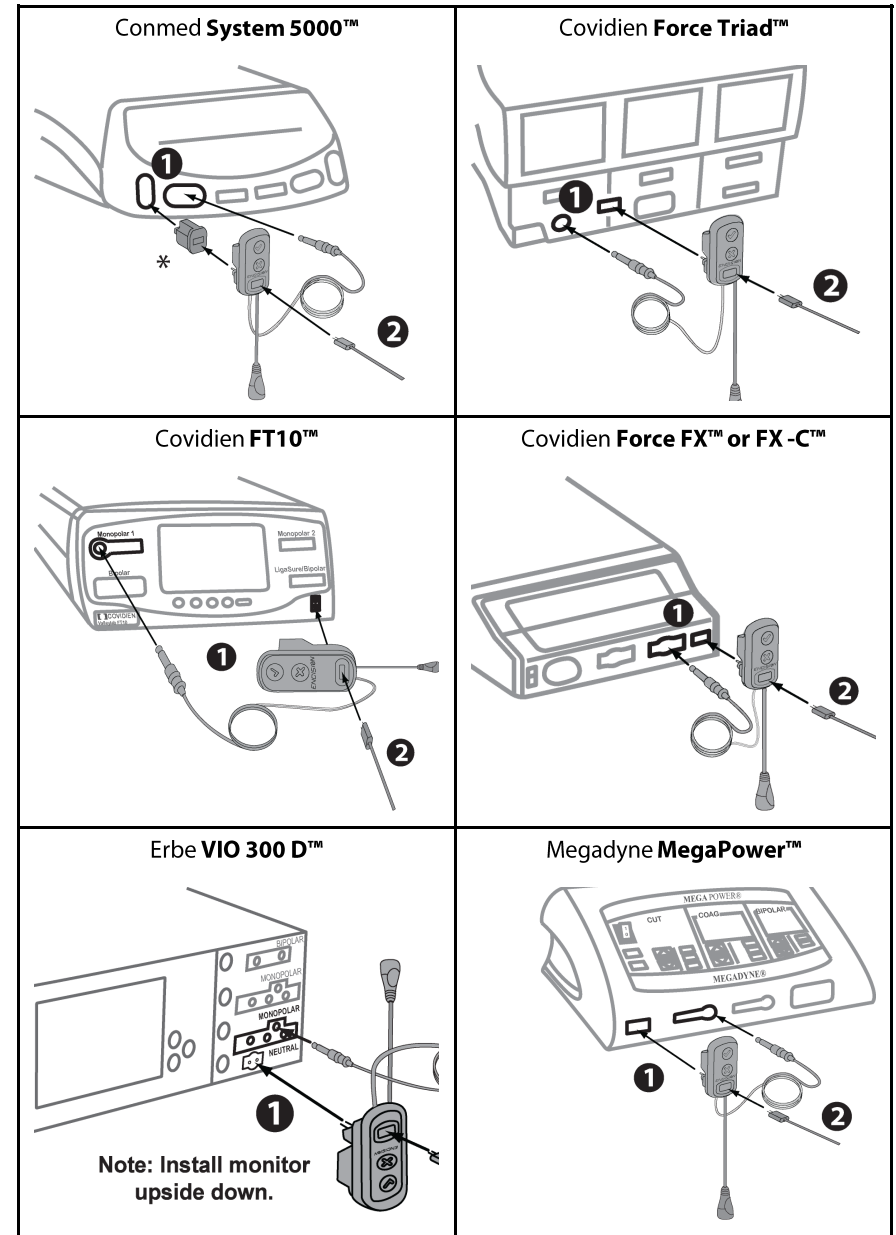
Exclusions: The express warranty set forth above specifically excludes and does not apply to defects (i) caused through no fault of ENCISION during shipment to or from Buyer, (ii) caused by modifications or alterations made to the products by Buyer or any third party (iii) caused by unauthorized repair 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.

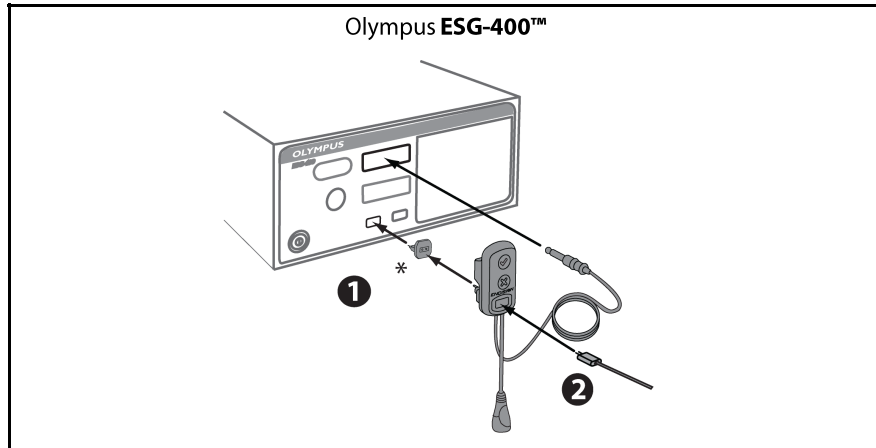
Stored Data: ENCISION shall not be liable for any loss or damage to any data stored in any product, including, without limitation, any data loss or damage resulting from any malfunction or defect or any loss or damage resulting from any inspection, repair, refurbishment, reconditioning or testing of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

System Setup (continued)



* Reusable Encision Adapter ES9007 required to complete setup.

System Setup (continued)



* Reusable Encision Adapter ES9007 required to complete setup.

Technical Specifications (continued)

Guidance and Manufacturer's Declaration – Immunity

The EndoShield 2 is intended for use in the electromagnetic environment specified below. The customer or user of the EndoShield 2 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile communications equipment should be separated from the EndoShield 2 by no less than the distances calculated/listed below: $D=(3.5/V1)(\text{Sqrt } P)$ 150 kHz to 80 MHz $D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz $D=(7/E1)(\text{Sqrt } P)$ 800 MHz to 2.7 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.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	(E1)=3V/m	

Recommended Separation Distances for the EndoShield 2 Burn Protection System

The EndoShield 2 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the EndoShield 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the EndoShield 2 as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz $D=(3.5/V1)(\text{Sqrt } P)$	Separation (m) 80 to 800 MHz $D=(3.5/E1)(\text{Sqrt } P)$	Separation (m) 800 MHz to 2.5 GHz $D=(7/E1)(\text{Sqrt } P)$
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

Technical Specifications (continued)

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. The EndoShield 2 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 EndoShield 2 is intended for use in the electromagnetic environment specified below. The customer or user of the EndoShield 2 should ensure that it is used in such an environment.

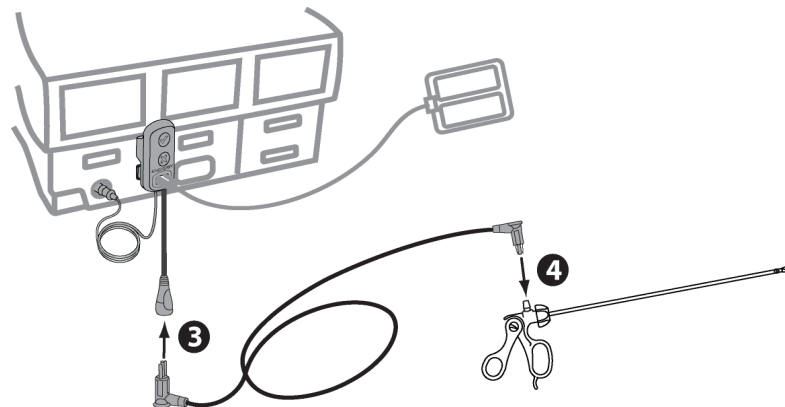
Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF emissions CISPR 11	Group 1	The EndoShield 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EndoShield 2 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	

System Setup (continued)

3. Connect an AEM cord to the EndoShield 2.

4. Connect an AEM Foot Control Instrument to the AEM Cord.


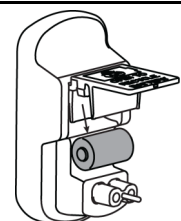
- If  illuminates GREEN, then the EndoShield 2 is fully operational.
- If  illuminates RED, see the *Troubleshooting and System Maintenance* section.
- If either  or  are flashing, see the *Troubleshooting* section.



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

At End of Life

Removing the Battery

Open the door on the back of the EndoShield 2.	Remove the battery.
	

The EndoShield 2 contains a 3V CR2 lithium battery. The lithium battery will provide approximately ten (10) hours of 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.

At End of Life (continued)

End of Life Indicators

Discontinue use if any of the following are evident:

- Intermittent electrical performance.
- The device indicates a low or dead battery condition. See the *Troubleshooting and System Maintenance* section for indications of low or dead battery.

Reprocessing

WARNING: This product shall not be reprocessed.

Compatible Products

For successful operation, the EndoShield 2 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)		Excision Adapter Required
Manufacturer	Model	
Conmed	System 5000	ES9007
Covidien	Force Triad	N/A
	Force FX	N/A
	Force FX-C	N/A
	FT10	N/A
Erbe	VIO 300 D	N/A
Megadyne	MegaPower	N/A
Olympus	ESG-400	ES9008

WARNING: The electrosurgical generators referenced here have been tested for use with the EndoShield 2. 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 EndoShield 2 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 EndoShield 2.

Instrument Cord

The cord connecting the foot-controlled instrument to the EndoShield 2 must have patented AEM technology and be manufactured by/for Encision Inc., or licensed by Encision Inc.

Technical Specifications (continued)

Guidance and Manufacturer's Declaration – Immunity

The EndoShield 2 is intended for use in the electromagnetic environment specified below. The customer or user of the EndoShield 2 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	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV 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	± 2 kV Mains ± 1 kV Input/Output (I/Os)	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV 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 0% Dip for 1 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EndoShield 2 requires continued operation during power mains interruptions, it is recommended that the EndoShield 2 be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Technical Specifications (continued)

Connectors and Cables

Return Electrode Receptacle:

A dual pin receptacle on the front of the EndoShield 2. The Return Electrode Receptacle connects a dual-area patient return electrode to the EndoShield 2.

Return Electrode Plug:

A single pin plug on the rear of the EndoShield 2. The Return Electrode Plug connects to the electro-surgical generator's patient return electrode receptacle.

AEM Cord Connector:

The AEM Cord Connector connects the EndoShield 2 to an AEM instrument cord.

Foot-Control Plug:

A single active pin that connects the EndoShield 2 to the electro-surgical generator's footswitch accessory receptacle.

Maximum Electro-surgical Generator Voltage

4.1 kV peak.

Electrical Characteristics

Power Source

Lithium Battery, 3V CR2.

Patient Leakage Current

Source or sink leakage current is 10 μ A maximum.

Dimensions and Weight

External Dimensions

4" tall x 2" wide x 2.5" deep, excluding integrated cords.

AEM Instrument Connector: 7 inch cord length.

Foot-Control Plug: 6 inch cord length.

Weight

140 g (5 oz).

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.

Compatible Products (continued)

Encision Adapter

Some electro-surgical generators require an adapter for setup of the EndoShield 2 (see the Electro-surgical Generator table above). Refer to the *System Setup* section for proper connections.





Mechanical Inspection

Before use, visually inspect the following items of EndoShield 2. 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 EndoShield 2 is complete.

<i>Situation</i>	<i>Recommended Action</i>
No symbols illuminate on the front of AEM EndoShield 2.	Verify that a dual-area patient return electrode is connected properly and fully seated in the return electrode receptacle of the EndoShield 2. If the fault persists, replace the patient return electrode.
 illuminates continuous RED on the EndoShield 2.	Verify that the AEM Cord is properly connected to the EndoShield 2. Verify that the AEM instrument is properly connected to the AEM Cord. If the fault persists, replace the AEM instrument and/or AEM Cord.
No power to instrument, but the  illuminates GREEN on the EndoShield 2.	Verify that both EndoShield 2 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 or instrument cord. If the fault continues to persist, replace the EndoShield 2.
Low battery condition.  illuminates flashing GREEN on the EndoShield 2.	The battery is nearing end of life. Finish existing procedure and replace the EndoShield 2.
Dead battery condition.  illuminates flashing RED on the EndoShield 2.	Replace the EndoShield 2 immediately.


Monopolar Operating Mode

The EndoShield 2 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 the EndoShield 2 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 the EndoShield 2.

If an AEM foot-control instrument is not connected to the EndoShield 2, or not connected properly, the  illuminates RED to identify the setup fault.

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 CONTINUOUS RED for 10 seconds to identify an insulation fault, and the EndoShield 2 interrupts the flow of energy from the electrosurgical generator to the AEM instrument for 10 seconds.





Radio Frequency Current Sensing

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

Shield Cable and Return Electrode Switch Threshold

50 ohms \pm 40%.

Indicators and Alarm Functions

CONTINUOUS GREEN 	Indicates that the EndoShield 2 Burn Protection System is fully operational.
CONTINUOUS 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.
FLASHING GREEN 	Indicates a low battery condition.
FLASHING RED 	Indicates a dead battery condition.

Warnings and Cautions (continued)

- 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, and/or 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 EndoShield 2 may result in a risk of unintended patient burn. Do not use product having damaged insulation.
- When an alarm is presented by the EndoShield 2, discontinue use of electrocautery immediately. Find the cause of the alarm and correct it before continuing use.
- Damaged internal insulation of the instrument, or loss of shield continuity, may activate the EndoShield 2 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 EndoShield 2 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 electrocautery generator equipped with contact quality monitoring patient safety technology.
- 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.






Troubleshooting and System Maintenance (continued)

Responding to the EndoShield 2 Alarms

When using AEM Monitoring, successful electrocautery depends on an absence of critical fault conditions. Should one occur, the EndoShield 2 interrupts the power delivery from the electrocautery generator to the AEM instrument for 10 seconds.

If for any reason a fault condition persists from the EndoShield 2 after following the steps described below, use a backup EndoShield 2 to complete the surgical procedure.

CAUTION: Always have a backup EndoShield 2 available in the event of a low or dead battery situation.

<i>Situation</i>	<i>Recommended Action</i>
 illuminates RED on the EndoShield 2 for 10 seconds. EndoShield 2 interrupts the power delivery from the electrocautery generator for 10 seconds.	Replace the instrument. If the  continues to illuminate RED for 10 seconds after replacing the instrument, replace the AEM Cord. If the  continues to illuminate RED for 10 seconds after replacing the instrument and cord, replace the EndoShield 2.
Low battery condition.  illuminates flashing GREEN on the EndoShield 2.	The battery is nearing end of life. Finish existing procedure and replace the EndoShield 2.
Dead battery condition.  illuminates flashing RED on the EndoShield 2.	Replace the EndoShield 2 immediately.

WARNING: An EndoShield 2 alarm may indicate an unsafe condition. Electrocautery energy to the AEM instrument is disabled during the alarm condition.

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

Troubleshooting and System Maintenance (continued)

Cleaning the EndoShield 2

WARNING: Electric Shock Hazard. Always unplug the EndoShield 2 before cleaning.

The EndoShield 2 may be cleaned in accordance with your facility's procedures.

1. Disconnect all accessories.
2. Follow the procedures approved by your institution, or use a validated infection control procedure.
3. Dampen a cloth with a mild cleaning solution (100:1 water to mild detergent, by mass) or disinfectant and thoroughly wipe all outside surfaces including cords.
4. Ensure unit is dry before use.

Caution:

- Do not allow fluids to enter the EndoShield 2 housing.
- Do not clean the EndoShield 2 with abrasive cleaning or disinfectant compounds, solvents, or other materials that could damage the unit.
- Do not steam sterilize the EndoShield 2.
- Do not spray the EndoShield 2 directly with cleaning solution.

Storing the EndoShield 2

The EndoShield 2 should be stored within these parameters:

- Temperature -13° to 140° F (-25° to 60° C).
- Humidity: 5% to 95% relative, non-condensing.

If you store the EndoShield 2 at a temperature that is outside its normal operating range of 59° to 104° F (15° to 40° C), allow one hour for the EndoShield 2 to reach room temperature before use.

Warnings and Cautions



Prior to using the EndoShield 2, 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 EndoShield 2 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.