Arthrex®

AR-9600

O.P.E.S

ORTHOPAEDIC PROCEDURE ELECTROSURGICAL SYSTEM

USER'S GUIDE

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the O.P.E.S. Electrosurgical Generator only.

Additional technical information is available in the *O.P.E.S. Electrosurgical Generator Service Guide*.

Equipment Covered in this Manual

O.P.E.S. Electrosurgical Generator:
Reference No.: AR-9600
Manufactured for Arthrex, Inc. by Bovie Medical Corporation, St. Petersburg, Florida, 33710-2902, USA.

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Prior to use in a surgical procedure, carefully unpack and inspect the components for any sign of damage, which may have occurred during shipping. If shipping damage is suspected, notify Arthrex or any authorized Arthrex distributor immediately. Any such damage could compromise patient safety.

If transport or first installation damage is not reported within 7 days of receiving the product, the warranty could be rendered void.

We also refer to our general terms of business.

CONVENTIONS USED IN THIS GUIDE

WARNING:
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION:
Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE:
Indicates an operating tip, a maintenance suggestion, or a hazard that may result in product damage.

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LIST OF FIGURES

INTRODUCING THE ARTHREX O.P.E.S. ELECTROSURGICAL GENERATOR

This section includes the following information:

- *Key Features*
- *Components and Accessories*
- *Safety*

CAUTIONS:
Read all warnings, cautions, and instructions provided with this generator before using.

Read the instructions, warnings, and cautions provided with electrosurgical accessories before using. Specific instructions are not included in this manual.

KEY FEATURES

The Arthrex O.P.E.S. Electrosurgical Generator includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

- **Two Cut Modes, Cut I & Cut II**
  Two cut modes give the surgeon flexibility to cut all types of tissue without losing performance.
  Cut I generates constant output power over a wide range of impedances. Refer to Figure A-1 in the *Technical Specifications* section of this guide.
  Cut II is a softer cut that generates constant output power over a small range of impedances. Refer to Figure A-2 in the *Technical Specifications* section of this guide.

- **Blend with 10 Settings**
  The Blend mode is a combination of Cutting and Hemostasis. The Arthrex O.P.E.S. Electrosurgical Generator gives the surgeon freedom to adjust the desired level of blend. A setting of 1 is minimal hemostasis with maximum cutting effect. A setting of 10 is maximum hemostasis with minimal cutting effect. This adjustment is easily achieved by an incremental adjustment. Refer to Section 2, *Controls, Indicators, and Receptacles, Cut and Blend Controls*. The Blend mode improves the rate of targeted tissue desiccation without increasing the power delivered by the generator.

- **Presets**
  The surgeon can store 10 user-defined presets for easy recall of frequently used settings. A selection of 10 factory set presets can be reset to your preferred settings. Refer to the Preset table in Section 4 of this guide.

- **Two levels of coagulation: Pinpoint and Spray**
  Pinpoint provides precise control of bleeding in localized areas.
  Spray provides greater control of bleeding in highly vascular tissue over broad surface areas.

- **Return electrode sensing and contact quality monitoring**
  The Arthrex O.P.E.S. Electrosurgical Generator incorporates a return electrode contact quality monitoring system (Bovie NEM™). This system detects the type of return electrode: solid or split. The system also continually monitors the contact quality between the patient and the split return electrode. This feature is designed to minimize patient burns at the return electrode site.

- **FDFS™ (Fast Digital Feedback System)**
  The FDFS™ (Fast Digital Feedback System) measures voltage and current at 5,000 times a second and immediately adjusts the power to varying impedance during the electrosurgical procedure. The unit's digital technology senses and responds to changes in tissue and density. Unlike analog, this feature reduces the need to adjust power settings manually.

  NOTICE:
  The Bovie NEM™ system requires that you use a split return electrode.

- **Memory**
  The unit automatically powers up to the last selected preset settings.

- **Isolated RF output**
  This minimizes the potential of alternate site burns.

- **Standard connectors**
  These connectors accept the latest monopolar and bipolar instruments. Refer to *Section 2, Controls, Indicators, and Receptacles* to learn more.

- **Self diagnostics**
  These diagnostics continually monitor the unit to ensure proper performance. Unlike analog, this feature reduces the need to adjust power settings manually.
- **Hand/foot sensing**
  This feature automatically senses that a footswitch is being used and disengages all hand control functionality. This feature eliminates the need for non hand-controlled devices.
- **Digital vs. analog**
  The use of digital technology improves the sensing rate used by the generator compared to other electrosurgical generators on the market today.

COMPONENTS AND ACCESSORIES

You should receive the following components with your generator:

- Arthrex O.P.E.S. Electrosurgical Generator
- Hospital-grade power cord (110 VAC and 220 VAC)
- User's Guide
- Service Guide

SAFETY

The safe and effective use of electrosurgery depends to a large degree on factors solely under the control of the operator. There is no substitute for a properly trained and vigilant medical staff. It is important that they read, understand, and follow the operating instructions supplied with this electrosurgical equipment. At the customer's request, Arthrex, Inc. will be happy to provide training on how to use the O.P.E.S. Electrosurgical Generator as a normal part of product purchase.

Physicians have used electrosurgical equipment safely for many years in numerous procedures. Before starting any surgical procedure, the surgeon should be familiar with the medical literature, complications, and hazards of using electrosurgery in that procedure.

To promote the safe use of the Arthrex O.P.E.S. Electrosurgical Generator, this section presents the warnings and cautions that appear throughout this user's guide. It is important that you read, understand, and follow the instructions in these warnings and cautions so that you can operate this equipment with maximum safety. It is also important that you read, understand, and follow the instructions for use in this user's guide.

WARNINGS:
Hazardous Electrical Output - This equipment is for use only by trained, licensed physicians.
Danger: Fire / Explosion Hazard - Do not use the Arthrex O.P.E.S. Electrosurgical Generator in the presence of flammable materials.
Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room: • Flammable substances (such as alcohol based skin prepping agents and tinctures) • Naturally occurring flammable gases which may accumulate in body cavities such as the bowel • Oxygen enriched atmospheres • Oxidizing agents (such as nitrous oxide [N_20] atmospheres). The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.
Electric Shock Hazard - Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.
Electric Shock Hazard - Always turn off and unplug the generator before cleaning.
Fire Hazard - Do not use extension cords.
Patient Safety - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

WARNINGS:

Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.

The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers.

If the patient has an Implantable Cardioverter Defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICDs.

Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient.
- Place 5 to 8 cm (2 to 3 in.) of dry gauze between contact points to ensure that contact does not occur.
- Position the return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised. Arthrex recommends the use of split return electrodes and generators with a contact quality monitoring system.

Do not wrap the accessory cords or return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

CAUTIONS:
At no time should you touch the active electrode or bipolar forceps. A burn could result.

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow adequate cooling.

Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

Non-function of the generator may cause interruption of surgery. A backup generator should be available for use.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active.

When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

The use of high frequency current can interfere with the function of other electromagnetic equipment.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes. Monitoring systems incorporating high frequency current-limiting devices are recommended.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

Remove any loose fitting jewelry from the patient before activation.

Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

When not using active accessories, place them in a holster or in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.[1]

1. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser / Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September, 1996).

NOTICES:
If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

SECTION 2

CONTROLS, INDICATORS, AND RECEPTACLES

This section describes:

- *The Front and Rear Panels*
- *Controls, Indicators, Receptacles, and Ports*

FRONT PANEL

Figure 2 – 1 Layout of controls, indicators, and receptacles on the front panel

Symbols on the Front Panel

SYMBOLS	DESCRIPTION
Cut Controls	
	Cut Mode
	Blend Mode
Coag Controls	
	Pinpoint Mode
	Spray Mode
Bipolar Controls	
	Bipolar Mode
Indicators	
	Split Return Electrode
	Solid Return Electrode
Regulatory Symbology	
	Read instructions before use.
	Defibrillator Proof Type CF Equipment
	RF Isolated – patient connections are isolated from earth at high frequency.
Power Switch and Handpiece Connectors	
	Return Electrode Receptacle
	Caution High Voltage
	Cut Mode
	Coag Mode
	Monopolar Handpiece Receptacle
	Bipolar Mode
	Bipolar Handpiece Receptacle
Preset Controls	
	Recall Button
	Set Button

PRESET CONTROLS

Figure 2 – 2 Controls for setting and recalling presets

Preset Number Display
Indicates the current selection of one of the 10 presets (0-9).

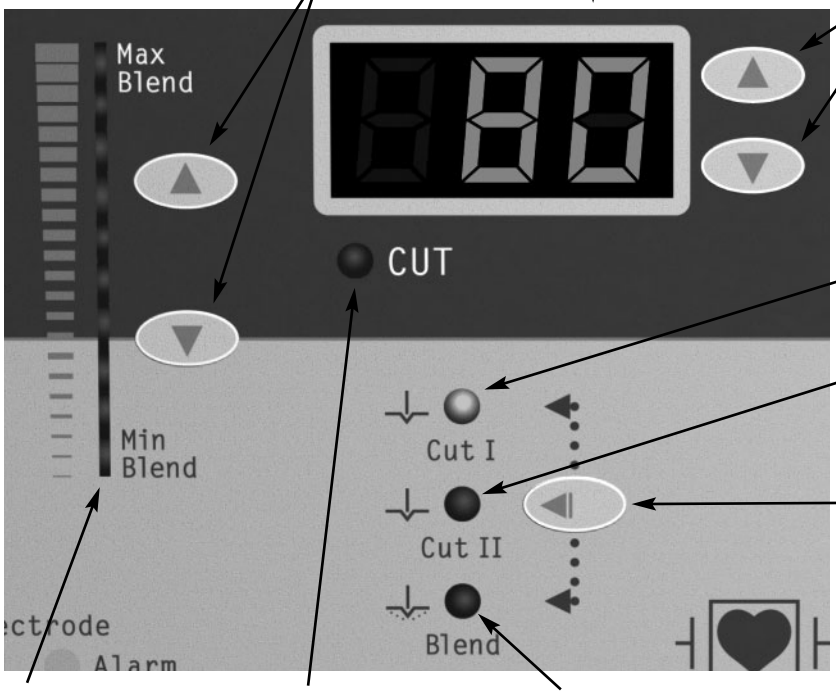
Recall Button
Toggles through the 10 presets. Stop at the desired number (0-9) illuminated in the Preset Number Display to recall a Preset.

Set Button
Sets the desired preset into one of the 10 user-defined presets. Press and hold the Set button for three seconds to save the settings.

Preset Indicator LED
Blinks in the lower right corner of the Preset display to indicate that the current setting is not one of the user-defined presets.

Cut and Blend Controls

Figure 2 – 3 Controls for the Cut and Blend modes



Blend Amount Control Buttons
Increases or decreases the amount of blend (Level 1-10) added in the Blend mode.

Cut Power Display (watts)
Indicates the power set for the Cut / Blend mode.

Cut Power Control Buttons
Increases or decreases the Cut or Blend power output in increments of 1 to 10 watts.

Cut I Mode Indicator
Indicates when the Cut I mode is selected.

Cut II Mode Indicator
Indicates when the Cut II mode is selected.

Cut and Blend Mode Selector
Toggles between Cut I, Cut II, and Blend modes.

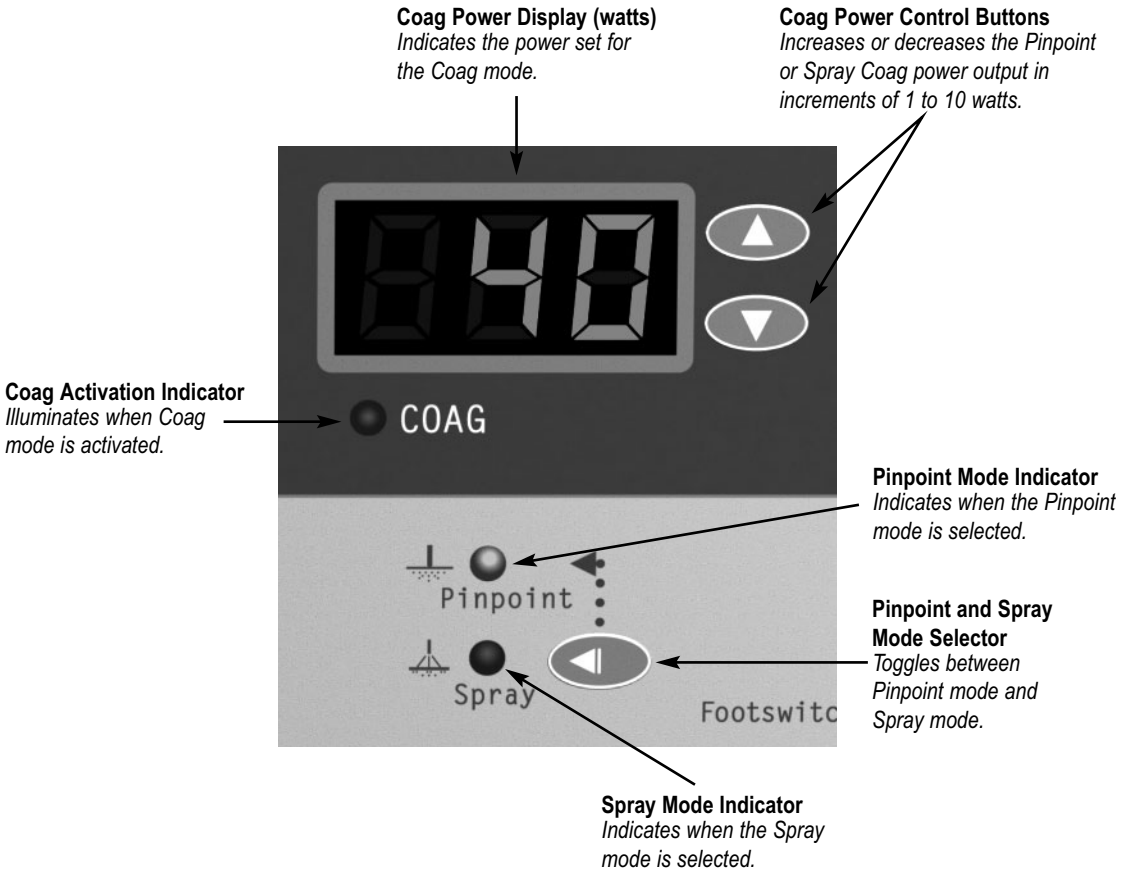
Blend Amount Indicator
Indicates the amount of blend added in the Blend mode. More bars illuminated indicates more blend, divided into 10 steps.

Cut Activation Indicator
Illuminates when Cut or Blend mode is activated.

Blend Mode Indicator
Indicates when the Blend mode is selected.

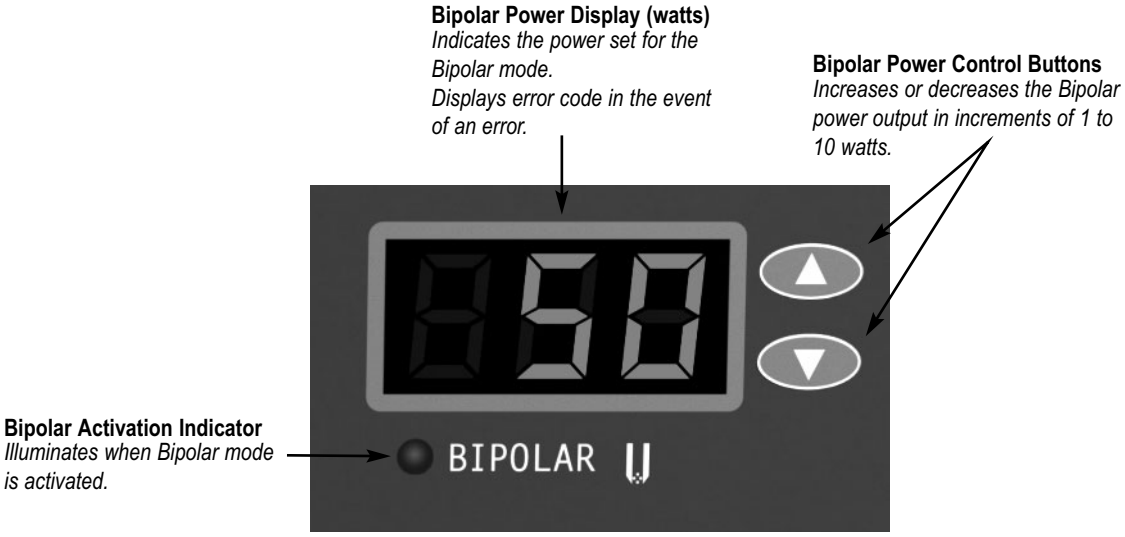
Coag Controls

Figure 2 – 4 Controls for the Coag mode



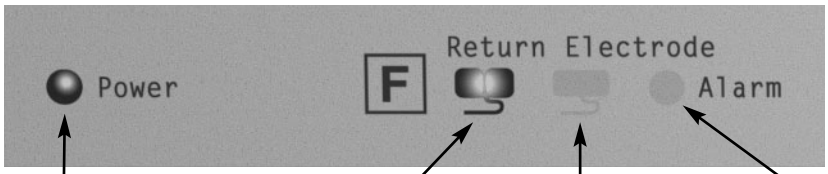
Bipolar Controls

Figure 2 – 5 Controls for the Bipolar mode



Indicators

Figure 2 – 6 Indicators for power, return electrodes, and footswitch control



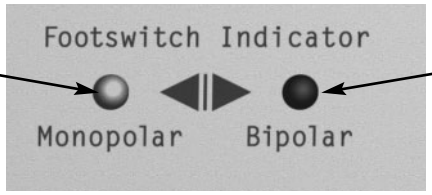
Power Indicator
Illuminates when the main power is on.

Split Return Electrode Indicator
Illuminates when the system detects a split return electrode.

Solid Return Electrode Indicator
Illuminates when the system detects a solid return electrode.

Alarm Indicator
Illuminates when the system detects a return electrode alarm condition.

Monopolar Footswitch Indicator
Illuminates when monopolar footswitch control is plugged in and available.



Bipolar Footswitch Indicator
Illuminates when bipolar footswitch control is plugged in and available.

Power Switch and Receptacles

Figure 2 – 7 Location of the unit power switch and front panel receptacles

Power On/Off Switch
Turns the unit on or off.

Return Electrode Receptacle
Accepts a standard return electrode plug.

Monopolar Handswitching Receptacle
Accepts standard 3-pin handpieces. Connect handswitching accessories.

Bipolar Receptacle
Accepts standard cables for bipolar handpieces. Connect bipolar accessories.

REAR PANEL

Figure 2 – 8 Layout of connectors and controls on the rear panel

Symbols on the Rear Panel

SYMBOLS	DESCRIPTION
	Equipotential Ground Stud
	Non-ionizing Radiation
	Volume Control
	Danger - Explosion Risk If Used With Flammable Anesthetics.
	Fuse Enclosed
	Relay Connector
	Monopolar Footswitch Input Jack
	Bipolar Footswitch Input Jack
	Read Instructions Before Use

GETTING STARTED

This section includes the following information:

- *Initial Inspection*
- *Installation*
- *Function Checks*
- *Performance Checks*

INITIAL INSPECTION

When you first unpack your Arthrex O.P.E.S. Electrosurgical Generator, inspect it visually:

- Look for any signs of damage.
- Verify that the shipping package contains all items listed on the packing list.

If the unit or any accessories are damaged, notify Arthrex's Customer Service immediately.
Do not use any damaged equipment.

INSTALLATION

Place the Arthrex O.P.E.S. Electrosurgical Generator on any flat surface with a tilt angle not more than 10˚. The unit relies on natural convection cooling. Do not block its bottom or rear vents. Ensure that air flows freely on all sides of the unit.

WARNING:

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

FUNCTION CHECKS

Upon initial installation of the unit, perform the tests listed below. Refer to the figures in the previous chapter for the location of connectors and controls.

WARNING:

At no time should you touch the active electrode or bipolar forceps. A burn could result.

Setting Up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.
2. Connect a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.
3. Connect a two-button monopolar pencil to the appropriate receptacle. The use of Arthrex pencils is recommended.
4. Do not connect a patient return electrode at this time.
5. Turn the unit on by switching the power switch to the On (|)position.

Checking the Return Electrode Alarm

1. Adjust the power settings for each mode (Cut, Coag, Bipolar) to one watt.
2. Press the Coag button of the pencil. Verify that an alarm sounds for three seconds and the patient return electrode sensing alarm indicator light illuminates, indicating that no return electrode is connected to the unit.
3. Verify that adjusting the volume control on the back of the unit while the alarm is sounding does not change the alarm volume.

Confirming Modes

Confirm that you can select each mode and adjust the power up and down.

Checking Bipolar Mode (with bipolar footswitch)

1. Plug in the Bipolar footswitch. Verify that the Bipolar footswitch indicator illuminates.
2. Press the pedal on the bipolar footswitch. Verify that the Bipolar mode activation indicator illuminates and that the system generates the Bipolar activation tone.
3. While activating the Bipolar mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
4. Confirm that releasing the pedal returns the unit to an idle state.

Checking Monopolar Mode (with monopolar footswitch)

1. Plug in the Monopolar footswitch. Verify that the monopolar footswitch indicator illuminates.
2. Connect a split return electrode to the return electrode receptacle on the front of the electrosurgical generator. Attach the split electrode to a conductive media simulating patient tissue (i.e.: an orange). Verify that the green split return electrode indicator illuminates. As an alternative, connect a solid electrode to the return electrode receptacle. Verify that the green solid return electrode indicator illuminates.
3. Press the Cut pedal (yellow) on the footswitch. Verify that the Cut mode activation indicator illuminates and that the system generates the Cut activation tone.
4. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
5. Press the Coag pedal (blue) on the footswitch. Verify that the Coag mode activation indicator illuminates and that the system generates the Coag activation tone.
6. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

Checking Monopolar Mode (with handswitch)

1. Connect a handswitching handpiece to the Monopolar handpiece receptacle.
2. Connect a split return electrode to the return electrode receptacle on the front of the electrosurgical generator. Attach the split electrode to a conductive media simulating patient tissue (i.e.: an orange). Verify that the green split return electrode indicator illuminates. As an alternative, connect a solid electrode to the return electrode receptacle. Verify that the green solid return electrode indicator illuminates.
3. Activate, one at a time, the Cut and Coag handswitching controls. Verify that each control causes the correct indicator and tone to sound.

PERFORMANCE CHECKS

After the unit has passed the preliminary functional test, it is ready for performance testing. A qualified biomedical engineer who is thoroughly familiar with electrosurgical devices should conduct this testing. The testing should include checking all modes of operation for proper function and power output.

SECTION 4

USING THE ARTHREX O.P.E.S. ELECTROSURGICAL GENERATOR

This section contains the following procedures:

- *Inspecting the Generator and Accessories*
- *Setup Safety*
- *Setting Up*
- *Preparing for Monopolar Surgery*
- *Preparing for Bipolar Surgery*
- *Memory Presets and Factory Settings*
- *Blend Controls*
- *Activating the Unit*
- *Activation Safety*

CAUTIONS:
Read all warnings, cautions, and instructions provided with this generator before use.

Read the instructions, warnings, and cautions provided with electrosurgical accessories before use. Specific instructions are not included in this manual.

INSPECTING THE GENERATOR AND ACCESSORIES

Before each use of the Arthrex O.P.E.S. Electrosurgical Generator, verify that the unit and all accessories are in good working order:

- Inspect for damage to the Electrosurgical Generator and all its connections.
- Verify that the appropriate accessories and adapters are present.
- Inspect all cords and connectors for signs of wear, damage, and abrasion.
- Verify that no errors occur when you turn on the unit.

SETUP SAFETY

WARNINGS:
Hazardous Electrical Output - This equipment is for use only by trained, licensed physicians.
Electric Shock Hazard - Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.
Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.
Fire Hazard - Do not use extension cords.
Patient Safety - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.
The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.
Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.
Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.
For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.
If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICDs.
In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient return electrode that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.
To reduce the potential for alternate site burns, do one or more of the following: • Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient. • Place 5 to 8 cm (2 to 3 in.) of dry gauze between contact points to ensure that contact does not occur. • Position the return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas. • In addition, place return electrodes according to the manufacturer's instructions. Potential for alternate site burns increases if the return electrode is compromised. Arthrex recommends the use of split return electrodes and generators with a contact quality monitoring system.

CAUTIONS:
Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow adequate cooling.

Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

Non-function of the generator may cause interruption of surgery. A backup generator should be available for use.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active.

When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

NOTICE:
If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

SETTING UP

1. Verify that the generator is Off by pressing the power switch Off (O).
2. Place the generator on a stable flat surface, such as a table, platform, or medical cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes. Provide at least 10 to 15 cm (4 to 6 in.) of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.
3. Plug the generator power cord into the AC Power Cable Receptacle on the rear panel.
4. Plug the generator power cord into a grounded receptacle.
5. Turn on the generator by pressing the power switch On (|). Verify the following:
   - All visual indicators and displays on the front panel illuminate.
   - Activation tones sound to verify that the speaker is working properly.
6. If the self-test is successful, a tone sounds. Verify the following:
   - A Cut mode is selected; a Coag mode is selected.
   - Each display shows a power setting. The unit automatically displays the last used preset setting.
   - The Patient Return Electrode Alarm Indicator illuminates red.

If the self-test is not successful, an alarm tone sounds. An error code will appear in the Bipolar display, in most cases, the generator is disabled. Note the error code and refer to *Section 6, Troubleshooting*.

Once the self-test is successful, connect the accessories and set the generator controls. Refer to *Preparing for Monopolar Surgery* or *Preparing for Bipolar Surgery* later in this section.

PREPARING FOR MONOPOLAR SURGERY

Monopolar surgery requires a return electrode.

Applying the Return Electrode

To maximize patient safety, Arthrex recommends using a split return electrode and a generator with a contact quality monitoring system (Bovie NEM™).

NOTICE:
The Bovie NEM™ system requires that you use a split return electrode.

Refer to the manufacturer's instructions for application site and placement procedures. When using metal plate return electrodes, use a conductive gel specifically designed for electrosurgery. Select a return electrode site with good blood flow. While a properly applied electrode results in minimal tissue heating beneath the electrode, a good blood flow helps carry heat away from the site.

1. Connect the cable to the Return Electrode receptacle on the front of the unit.
   The unit will automatically sense the presence of a split or solid return electrode and, if a split return electrode is used, will constantly monitor the resistance at the contact between the electrode and the patient.

2. Adjust the Blend setting to the desired amount of hemostasis (Level 1 - 10). Adjustment is preformed by pressing the up or down buttons next to the Blend setting indicator.

Select the desired power settings for Cutting. Adjustment is preformed by pressing the up or down buttons next to the Cut display. When the light above Cut I illuminates, a low Cut mode is selected. When the light above Cut II illuminates, a pure Cut mode is selected.

Select the mode of operation for Coagulation, either Pinpoint or Spray.

Select the desired power setting for Coagulation. Adjustment is preformed by pressing the up or down buttons next to the Coag display.

Connecting Accessories

1. Connect a 3-pin monopolar device into the monopolar receptacle on the front of the unit.

If footswitching control capabilities are preferred, connect the Arthrex, Inc. monopolar footswitch to the appropriate footswitch connecting socket on the rear of the unit.

If you are using…	Connect it to…
Standard 3-pin handswitching pencil	Monopolar handswitching receptacle

NOTICE:
If a monopolar footswitch device is connected to the unit, the unit cannot be activated using the handswitching pencil.

To activate the Monopolar mode, depress the cut or coag button on the monopolar handpiece or the cut or coag pedal on the monopolar footswitch.

PREPARING FOR BIPOLAR SURGERY

1. Connect a Bipolar cable to the Bipolar receptacle on the front of the unit.

2. Connect a forceps instrument to the bipolar cable.

3. Connect the bipolar footswitch to the bipolar footswitch connecting socket located on the rear of the unit.

To activate the Bipolar mode, depress the pedal on the bipolar footswitch.

MEMORY PRESETS AND FACTORY SETTINGS

Memory

The Memory feature allows the O.P.E.S. Electrosurgical Unit (unit) to display the last selected Preset when the generator is turned on. When activated by the handpiece or footswitch, the unit will operate in that particular mode and power setting.

The small red blinking dot in the lower right hand corner of the Preset display lets the user know that the Preset values have been adjusted.

All **new settings must be saved** as a Preset to be available at startup or as a Preset selection (0 through 9) when using the unit.

Memory Function Overview

- The unit powers up with the last selected preset (0-9).
- Mode (Cut and Coag) membrane switches are disabled during activation.
- Blend amount control buttons are disabled during activation.
- Recall and Set membrane switches are disabled during activation.
- During activation, the activated mode can be adjusted up and or down a maximum of four steps. Refer to the following table for power increments.

POWER SETTINGS	INCREMENTS	FOR INSTANCE...
1-50 Watts	1 Watts	*The unit is activated using the same preset values as described in Example 1 of this section.* While activated, the Cut 1 power output of 30 watts can be adjusted 4 steps down to 26 watts or 4 steps up to 34 watts. The Pinpoint and Bipolar can be adjusted to display a different setting but can not be saved during activation.
50-100 Watts	2 Watts	
100-200 Watts	5 Watts	
200-300 Watts	10 Watts	

- While operating the unit outside of a user-defined preset (small red dot will be blinking in lower right corner of the Preset display as an indicator), the unit temporarily stores the power setting for the activated mode (Cut, Coag, or Bipolar). This temporary power setting is available until either the unit is reset, a preset is selected , or the power setting for the mode in use is adjusted and the unit is again activated.
- Presets only store one Cut mode (Cut I or Cut II, or Blend) and power setting, one Blend level (if applicable), one Coag mode (Pinpoint or Spray) and power setting, and Bipolar power setting. When storing, only the information displayed in the display windows will be saved to the unit's memory.

Setting Your Presets

Select the desired preset (0-9) by pressing the recall button.

Select the desired modes to be stored by pressing the mode membrane switches (Cut and Coag).

If presetting the Blend mode, select the desired level of hemostasis (Blend Bar 1-10) by pressing the Blend amount control button.

Select the desired power (Cut, Coag, and Bipolar) to be stored by using the power output up and down membrane switches.

Once all of the settings are selected, depress and hold the Set button for three seconds. To indicate the settings have been stored, the Preset Memory Number (0-9) will blink.

To recall a Preset, repeatedly press the Recall button to toggle through all of the presets.

NOTICE:
A small red dot blinking in the lower right corner of the Preset indicator display indicates that the unit is not presently set to a user-defined preset.

Set and Recall buttons are disabled while the unit is activated.

Factory Presets

The O.P.E.S. Electrosurgical Generator incorporates 10 factory-set presets that can be reset to your preferred settings. Follow the in Setting and Recalling Memory Presets to set your user-defined presets The following table shows the preset factory settings.

NOTICE:
Presets only store one Cut mode (Cut I or Cut II or Blend) and power setting, one Blend level (if applicable), one Coag mode and power setting, and Bipolar power setting. When storing, only the information displayed in the display windows will be saved to the unit's memory.

PRESET #	CUT MODE	POWER SETTING	COAG MODE	POWER SETTING	BIPOLAR POWER SETTING
	CUT I, CUT II, or BLEND	*WATTS (if applicable, Blend %)*	*PINPOINT OR SPRAY*	*WATTS*	*WATTS*
0	CUT I	20 watts	PINPOINT	10 watts	20 watts
1	CUT II	20 watts	PINPOINT	15 watts	20 watts
2	CUT I	30 watts	PINPOINT	15 watts	20 watts
3	CUT II	30 watts	PINPOINT	40 watts	30 watts
4	CUT II	90 watts	PINPOINT	40 watts	40 watts
5	Blend 30%	100 watts	PINPOINT	40 watts	45 watts
6	CUT II	110 watts	PINPOINT	50 watts	50 watts
7	Blend 30%	120 watts	PINPOINT	50 watts	50 watts
8	Blend 30%	140 watts	PINPOINT	50 watts	50 watts
9	Blend 30%	160 watts	PINPOINT	50 watts	50 watts

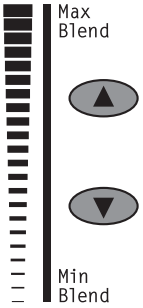
BLEND CONTROLS

In reference to Sections 2 and 4 of the User's Manual, this addendum elaborates on the functionality of the O.P.E.S.unit's Blend controls.

Blend settings can be adjusted to a desired amount of hemostasis (Level 1 - 10). The following describes how to adjust the Blend setting:

Ascending illuminated bars indicate increased hemostasis.

Increase and decrease the amount of blend added to the Blend mode by pressing the Blend amount control buttons.



NOTICE:
There are 10 levels of blend available in the Blend mode.

When selecting the Blend mode, the unit defaults to a setting of minimum blend (only the first bar is illuminated).

Memory Feature (Last Used Preset)

The Memory feature allows the unit to display the last selected power preset when the generator is turned on.

> ***NOTICE:***
> *To have a setting selection available at startup or to be one of the 10 user-defined presets, the adjustment to the mode and/or power settings must be saved by pressing the Set button on the Preset display panel.*

Examples

Examples 1 through 5 explain how the Memory and temporary memory features work and what happens when the power and/or mode is adjusted but not saved as one of the 10 Preset selections. Example 6 explains what happens when the power and/or mode is adjusted and saved as a new Preset setting:

#1. The physician performs a surgical procedure using Preset 2. The Preset has been stored with the following mode and power:

- The mode is set to Cut I
- The power setting for Cut I is 30 watts
- The power setting for Pinpoint is 15 watts
- The power setting for Bipolar is 20 watts.

The procedure is completed and the unit is switched off.
The next time the unit is switched on, the number 2 Preset will be displayed and available when the unit is activated. The number 2 Preset will be the same as the modes and settings indicated above.

#2. The physician performs a surgical procedure using Preset 2 (same as Example #1 Preset values).
He adjusts the power settings for each mode but does not store the new settings into the Preset.
The next time the unit is switched on, the number 2 Preset will be displayed and available when the unit is activated. The number 2 Preset will be the same as the modes and settings indicated in Example #1.

#3. The physician performs a surgical procedure using Preset 2 (same as Example #1 Preset values).
He changes the settings by selecting the Cut II mode. The displayed power will remain at 30 watts. The physician then adjusts the power to 100 watts. He resumes the procedure now using Cut II at 100 watts. He then switches the mode back to Cut I. The power output returns to 30 watts as stored in the # 2 Preset. The physician switches again to the Cut II mode and the output power returns to the temporary memory of 100 watts as previously selected. The procedure is completed without saving any modes or power settings. The next time the unit is switched on, the number 2 Preset will be displayed and available when the unit is activated. The number 2 Preset will be the same as the modes and settings indicated in Example #1.

#4. The physician performs a surgical procedure using Preset 2 (same as Example #1 Preset values.).
As required in the procedure, he selects the Blend mode (the Blend Amount Indicator illuminates to one bar indicating the Blend mode can be increased to the preferred amount of blend). He adjusts the hemostasis level up to a 30% blend but does not store the new settings into the Preset. The next time the unit is switched on, the number 2 Preset will be displayed and available when the unit is activated. The number 2 Preset will be the same as the modes and settings indicated in Example #1.

#5. The physician performs a surgical procedure using Preset 2 (same as Example #1 Preset values). He adjusts the power settings for a Cut mode, a Coag mode, and a Bipolar mode and presses the Store button for three seconds to save the new settings as Preset number 2. The next time the unit is switched on, the number 2 Preset will be displayed and available when the unit is activated. The number 2 *Preset will now be the last saved Preset settings for Preset 2.*

ACTIVATING THE UNIT

***NOTICE**:*
Review Activation Safety on page 6 of this section before activating the unit. When you turn on your unit remember the following feature:

The Arthrex O.P.E.S. Electrosurgical Generator will display the last used Preset setting.

1. Monopolar Cut - select the mode of operation for Cut: Cut I or Cut II, then select the desired Cut power settings by pressing the up and down buttons next to the Cut power output display.
2. If using Blend, vary the blend setting by pressing the up and down buttons next to the blend amount indicator graph.
3. Monopolar Coag - select the mode of operation for coagulation: Pinpoint or Spray, then select the coagulation power settings by pressing the up and down buttons next to the Coag power output display.
4. Bipolar - adjust the Bipolar power settings by pressing the up and down buttons next to the Bipolar power output display.
5. Activate the generator by pressing the appropriate button on the handpiece or pedal on the footswitch.

NOTICE:
Monopolar and bipolar footswitching operations are controlled by independent foot controls.

If a monopolar footswitch device is connected to the unit, the unit can not be activated using the handswitching pencil.

ACTIVATION SAFETY

WARNINGS:

Do not wrap the accessory cords or patient return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

Danger: Fire / Explosion Hazard - Do not use the Arthrex O.P.E.S. Electrosurgical Generator in the presence of flammable anesthetics.

Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N_2O] atmospheres).

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers.

CAUTIONS:
The use of high frequency current can interfere with the function of other electromagnetic equipment.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

Remove any jewelry from the patient before activation.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.[1]

Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

When not using active accessories, place them in a holster or in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

1. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser / Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September, 1996.)

SECTION 5

MAINTAINING THE ARTHREX O.P.E.S. ELECTROSURGICAL GENERATOR

This section covers the following topics:

- *Cleaning*
- *Periodic Inspection*
- *Fuse Replacement*

Arthrex recommends that you complete periodic inspection and performance testing. Perform inspections and performance testing every six months. A qualified biomedical technician should conduct this testing to ensure that the unit is operating effectively and safely.

CLEANING

After each use, clean the unit.

WARNING:
Electric Shock Hazard - Always turn off and unplug the generator before cleaning.

NOTICE:
Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

1. Turn off the generator, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. Do not sterilize the generator.

PERIODIC INSPECTION

Every six months, visually inspect the Arthrex O.P.E.S. Electrosurgical Generator for signs of wear or damage. In particular, look for any of the following problems:

- Damage to the power cord
- Damage to the power cable receptacle
- Obvious damage to the unit
- Damage to any receptacle
- Accumulation of lint or debris in or around the unit

FUSE REPLACEMENT

Fuses for the unit reside directly below the Power Cable Receptacle on the rear of the unit. Fuse values are indicated in Section A, *Technical Specifications* of this guide.

To replace the fuses, follow this procedure:

1. Unplug the power cord from the wall outlet.
2. Remove the power cord from the Power Cable Receptacle on the rear panel.
3. To release the fuse drawer, insert a small flathead screwdriver into the slot on the drawer below the power cord receptacle. Then, slide the drawer out.
4. Remove the two fuses and replace them with new fuses with the same values.
5. Insert the fuse holder into the Power Cable Receptacle.

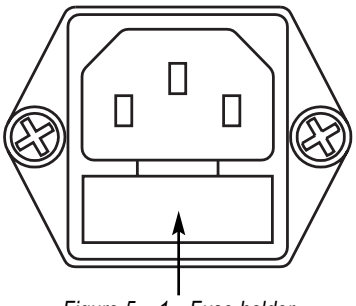


Figure 5 – 1 Fuse holder

NOTICE:
If the unit does not display an error and does not power on, check fuses.

TROUBLESHOOTING

This section includes Error Code Descriptions and actions to take to resolve them.

Error Codes and Audio Tones

The Arthrex O.P.E.S. Electrosurgical Generator includes automatic self-diagnostics. If the diagnostics detect an error, the system displays an error code, sounds an audible tone, and deactivates the unit output power. Most error codes result from faults in accessories attached to the unit. The following table lists the error codes, describes the errors, and recommends actions to take to resolve the errors. All error codes are displayed in the Bipolar display. If the unit displays any other error code, it requires service.

Error Code	Description	Recommended Action
F1	Cut handpiece button or footswitch may be stuck	1. Turn off, then turn on the generator. Do not press buttons or activate accessory devices during the self-test. 2. If the error code reappears, disconnect all accessories. Turn off, then turn on the generator again. 3. If the problem persists, replace the handpiece or footswitch and repeat the restart. 4. If the error code reappears, record the error code designation and call Arthrex Customer Service.
F2	Coag handpiece button or footswitch may be stuck	
F3	Reserved	
F4	Reserved	
F5	Bipolar footswitch pedal may be stuck	
F6	Simultaneous activation error	The Arthrex OPES Electrosurgical Generator does not allow for simultaneous activation of the Cut and Coag modes. The default activation sequence is "first come, first serve". This means that whichever mode is activated by the surgeon first will be the function dispensed by the generator. Examples of this functionality would include: A) When the handpiece Cut button is pressed, the generator is activated for Cut. If the handpiece Coag button is then pressed while still depressing the Cut button, the generator will continue to deliver Cut power. If the Cut Button is released prior to releasing the Coag button the alarm will sound and both functions will be disabled. B) When the footswitch Cut pedal is pressed, the generator is activated for Cut. If the footswitch Coag pedal is then pressed while still depressing the Cut pedal, the generator will continue to deliver Cut power. If the Cut pedal is released prior to releasing the Coag pedal the alarm will sound and both functions will be disabled. 1. Release the handpiece button or footswitch pedal activated, either Cut or Coag. 2. If the error code reappears, record the error code designation and contact Arthrex Customer Service.
E1	Output current out of specification	1. Turn the unit off. 2. Turn the unit on. 3. If the error code reappears, record the error code designation and contact Arthrex Customer Service.
E2	Output current sensors delta error	
E3	Output voltage sensors delta error	
E4	System power supply voltages error	
E5	Internal temperature of a section of the unit exceeded the limit.	1. Turn the unit off. 2. Allow the unit to cool for 20 minutes. 3. Turn the unit on. 4. If the error code reappears, record the error code designation and contact Arthrex Customer Service.
E6		
E7		
E8	NEM circuit error	1. Turn the unit off. 2. Turn the unit on. 3. If the error code reappears, record the error code designation and contact Arthrex Customer Service.

NOTICE:
If the unit does not power on to display an error, check fuses as described in Section 5 of this guide.

REPAIR POLICY AND PROCEDURES

Refer to this section for information on:

- *Responsibility of the Manufacturer*
- *Returning the Generator for Service*

RESPONSIBILITY OF THE MANUFACTURER

Arthrex is responsible for the safety, reliability, and performance of the generator only under the following circumstances:

- The user has followed the Installation and Setup Procedures in this User's Guide.
- Persons authorized by Arthrex performed assembly operation, readjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- Equipment use is in accordance with the Arthrex instructions for use.

For warranty information, refer to *Appendix B - Warranty*.

RETURNING THE GENERATOR FOR SERVICE

Before you return the generator, call your Arthrex representative for assistance. If instructed to send the generator to Arthrex, first obtain a Returned Authorization Number. Then, clean the Generator and package securely to ensure proper protection of the unit. So as to aid in the processing of the unit, please be sure to include a reference to the Arthrex Return Authorization Number on the outside of the box and ship directly to Arthrex.

Step 1 – Obtain a Returned Authorization Number

Call the Arthrex Customer Service Center to obtain a Returned Authorization Number. Have the following information ready when you call:

- Hospital / clinic name / customer number
- Telephone number/fax number
- Department / address, city, state, and zip code
- Model number
- Description of the problem
- Type of repair to be done
- P.O. number

Step 2 – Clean the Generator

WARNING:

Electric Shock Hazard - Always turn off and unplug the generator before cleaning.

NOTICE:
Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

A. Turn off the generator, and unplug the power cord from the wall outlet.

B. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. You cannot sterilize the generator.

Step 3 – Ship the Generator

A. Attach a tag to the generator that includes the Returned Authorization Number and the information (hospital, phone number, etc.) listed in *Step 1 – Obtain a Returned Authorization Number*.

B. Be sure the generator is completely dry before you pack it for shipment. Although the preference is to have the Generator repackaged using its original packaging, Arthrex understands that this may not always be possible. If necessary, contact Customer Service for the proper packaging to ship the unit. Please be sure to include a reference of the Arthrex Return Authorization Number on the outside of the box/container.

C. Ship the generator, prepaid, to the address given to you by the Arthrex Service Center.

APPENDIX A

TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within ± 20% of a stated value at room temperature (25° C / 77° F) and a nominal input power voltage.

PERFORMANCE CHARACTERISTICS

Input Power

Input Voltage	100-240 VAC
Mains line frequency range (nominal):	50 / 60 Hz
Power consumption:	500 VA
Fuses (two):	6.3 A (slow blow)

Duty Cycle

Under maximum power settings and rated load conditions (Pure Cut, 300 watt @ 300 ohm load), the generator is suitable for activation times of 10 seconds ON followed by 30 seconds OFF for one hour.

The internal temperature of the unit is continuously monitored. If the temperature rises above 85^0 C, the alarm will sound and output power will be deactivated.

Dimensions and Weight

Width	31.1 cm (12.25 in.)	**Depth**	41.3 cm (16.25 in.)
Height	15.3 cm (6.00 in.)	**Weight**	< 8.75 kg (< 19 lbs)

Operating Parameters

Ambient temperature range	10° to 40° C (50° to 104° F)
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	700 to 1060 millibars
Warm-up time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before use.

Transport and Storage

Generator should fit on all standard Carts for monopolar generators. The device should be stored and used in a room temperature of approximately 77^0 F/25^0 C.

Ambient temperature range	-34˚ to 65˚ C (-29˚ to 149˚ F)
Relative humidity	0% to 75%, non-condensing
Atmospheric pressure	500 hPa to 1060 hPa

Audio Volume

The audio levels stated below are for activation tones (cut, coag, and bipolar) and alarm tones (return electrode and system alarms) at a distance of one meter. Alarm tones meet the requirements for IEC 60601-2-2.

Activation Tone

Volume (adjustable)	45 to 65 dB
Frequency	Cut I: 610 Hz
	Cut II: 610 Hz
	Blend: 610 Hz
	Pinpoint: 910 Hz
	Spray: 910 Hz
	Bipolar: 910 Hz
Duration	Continuous while the generator is activated

Alarm Tone

Volume (not adjustable)	70 dB ± 5dB
Frequency	2 kHz ½ seconds / 1 kHz ½ seconds
Duration	2 seconds

Return Electrode Sensing

The system presents audible and visible alarms when it senses no return electrode.

Solid	Trip resistance: 0 Ω to 5 Ω ± 3 Ω Continuous measurement: Once the system establishes the solid return electrode resistance, an increase of 20 Ω ± 5 Ω in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
Split	Trip resistance: 10 Ω ± 5 Ω to 135 Ω ± 10 Ω Continuous measurement: Once the system establishes the split return electrode resistance, an increase of 40% in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.

Low Frequency (50-60 Hz) Leakage Current

Enclosure source current, ground open	< 500 µA
Source current, patient leads, all outputs	Normal polarity, intact ground: < 10 µA Normal polarity, ground open: < 10 µA Reverse polarity, ground open: < 10 µA
Sink current at high line, all inputs	< 10 µA

High Frequency (RF) Leakage Current

Bipolar RF leakage current	< 63 $mA_{rms\ at\ 80\ watts}$
Monopolar RF leakage current (additional tolerance)	< 150 mA_{rms}

STANDARDS AND IEC CLASSIFICATIONS

Class I Equipment (IEC 60601-1)

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

Type CF Equipment (IEC 60601-1) / Defibrillator Proof

The Arthrex O.P.E.S. Electrosurgical Generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF equipment. Patient connections are isolated from earth and resist the effects of defibrillator discharge.

Drip Proof (IEC 60601-2-2)

The generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely the safety of the generator.

Electromagnetic Interference

When other equipment is placed on or beneath an Arthrex O.P.E.S. Electrosurgical Generator, the unit can be activated without interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)

The Arthrex O.P.E.S. Electrosurgical Generator complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

The Arthrex O.P.E.S. Electrosurgical Generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

OUTPUT CHARACTERISTICS

Maximum Output for Monopolar and Bipolar Modes

Power readouts agree with actual power into rated load to within 20% or 5 watts, whichever is greater.

Mode	Output Power	Output Frequency	Repetition Rate	Vp-p max	Crest Factor* (Rated Load)
Cut I	300 W @ 300 Ω	490 kHz ± 5 kHz	N / A	2500 V	1.6 ± 20%
Cut II	300 W @ 300 Ω	490 kHz ± 5 kHz	N / A	1500 V	1.6 ± 20%
Blend (Max)	200 W @ 300 Ω	490 kHz ± 5 kHz	30 kHz ± 5 kHz	3300 V	3.5 ± 20%
Pinpoint	120 W @ 500 Ω	490 kHz ± 5 kHz	30 kHz ± 5 kHz	3500 V	4.5 ± 20%
Spray	80 W @ 500 Ω	490 kHz ± 5 kHz	30 kHz ± 5 kHz	7000 V	6.5 ± 20%
Bipolar	80 W @ 150 Ω	490 kHz ± 5 kHz	30 kHz ± 5 kHz	1000 V	1.6 ± 20%

OUTPUT POWER CURVES

The curves that follow depict the changes for each mode at specific power settings.

Figure A – 1 Output power vs impedance for Cut I mode

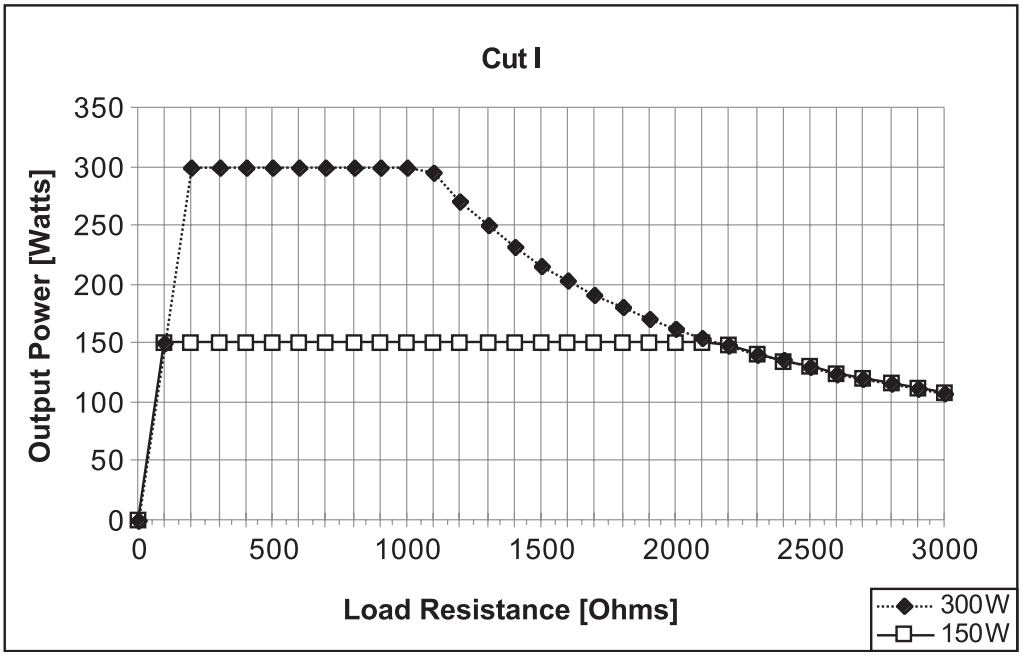


Figure A – 2 Output power vs impedance for Cut II mode

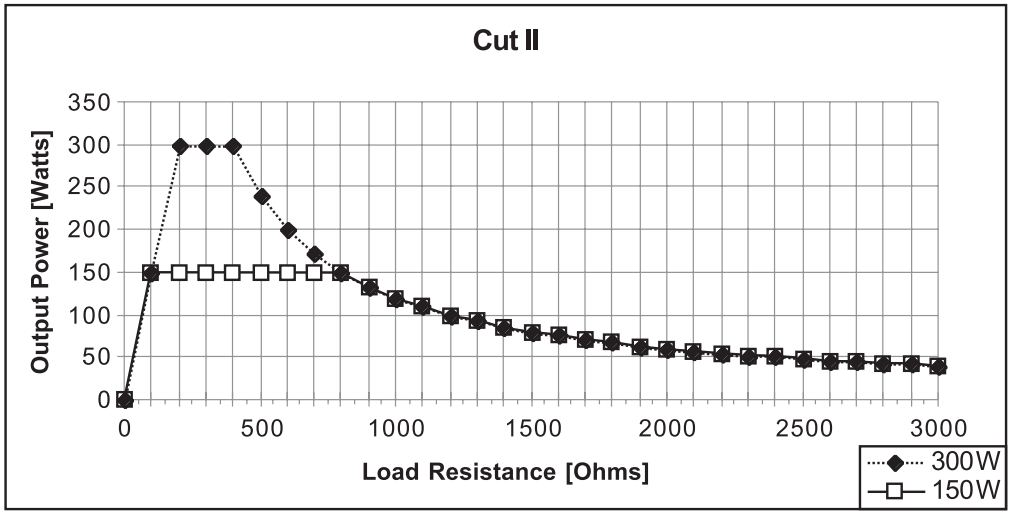


Figure A – 3 Output power versus impedance for Blend mode, set at Minimum

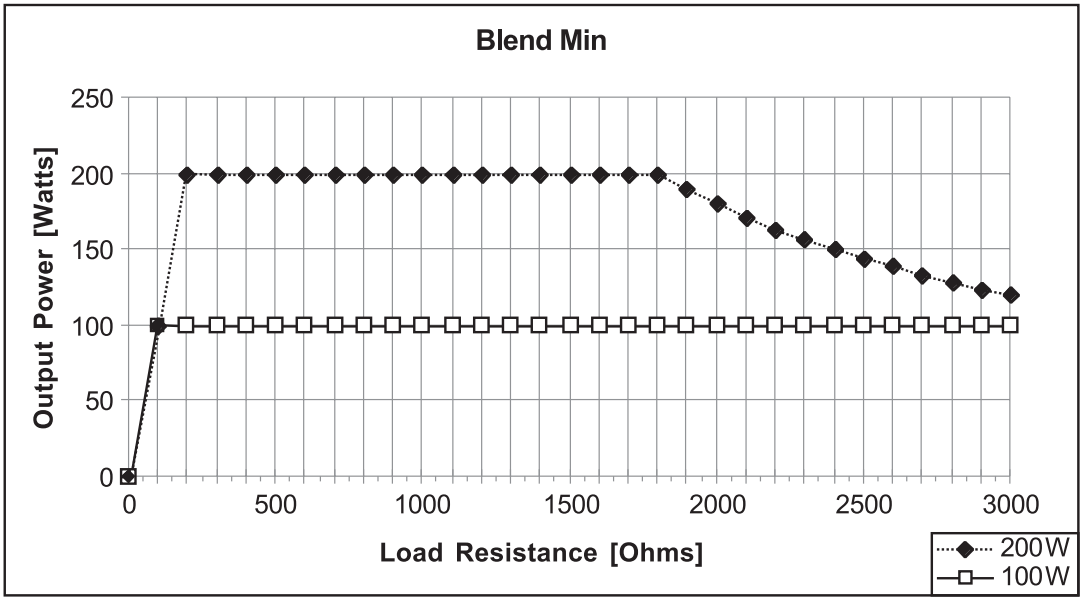


Figure A – 4 Output power versus impedance for Blend mode, set at Maximum

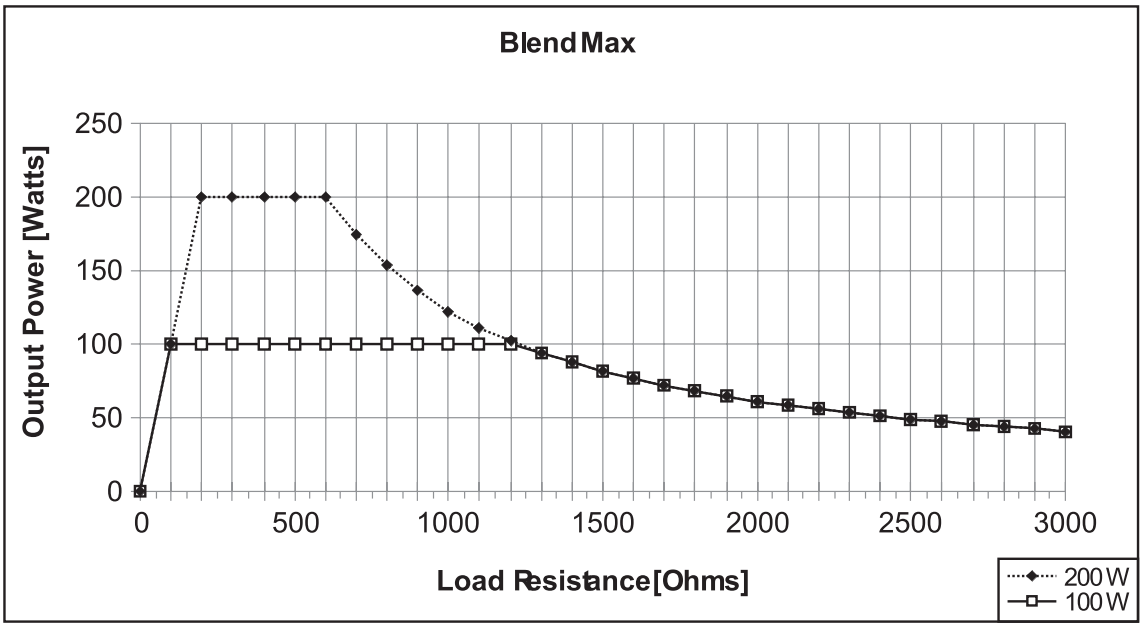


Figure A – 5 Output power vs impedance for Pinpoint mode

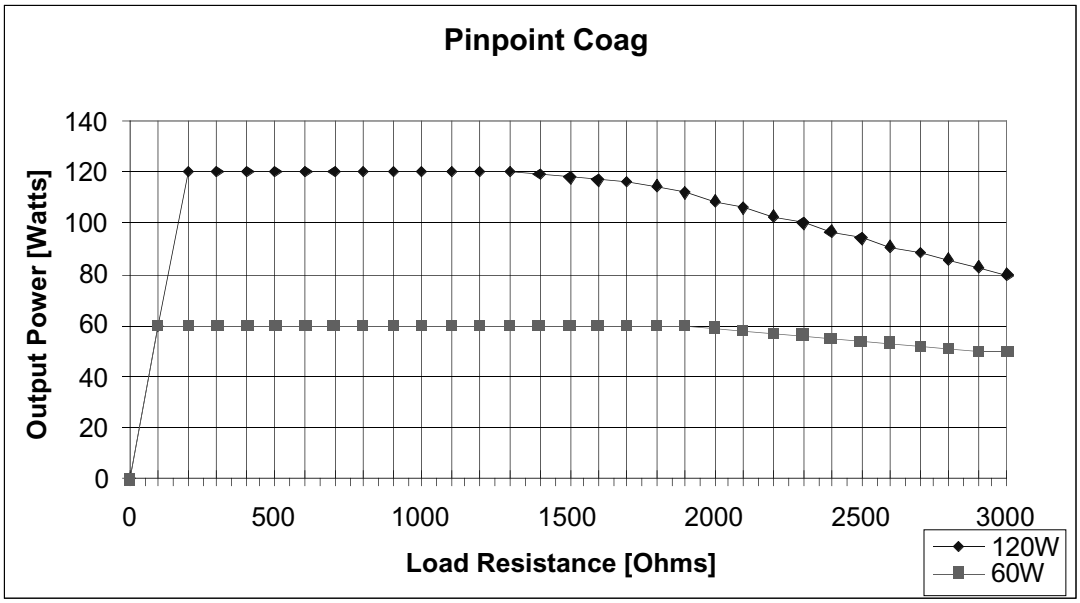


Figure A – 6 Output power vs impedance for Spray mode

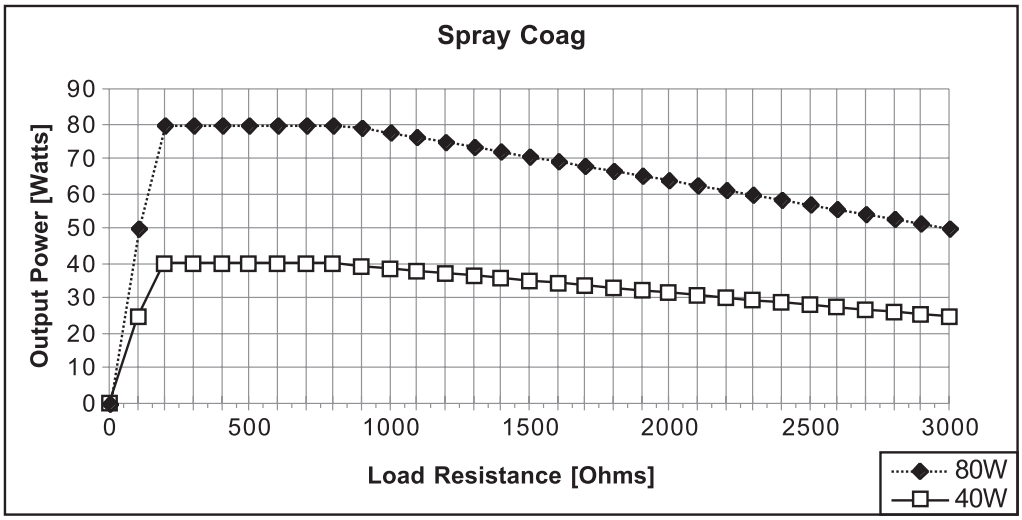
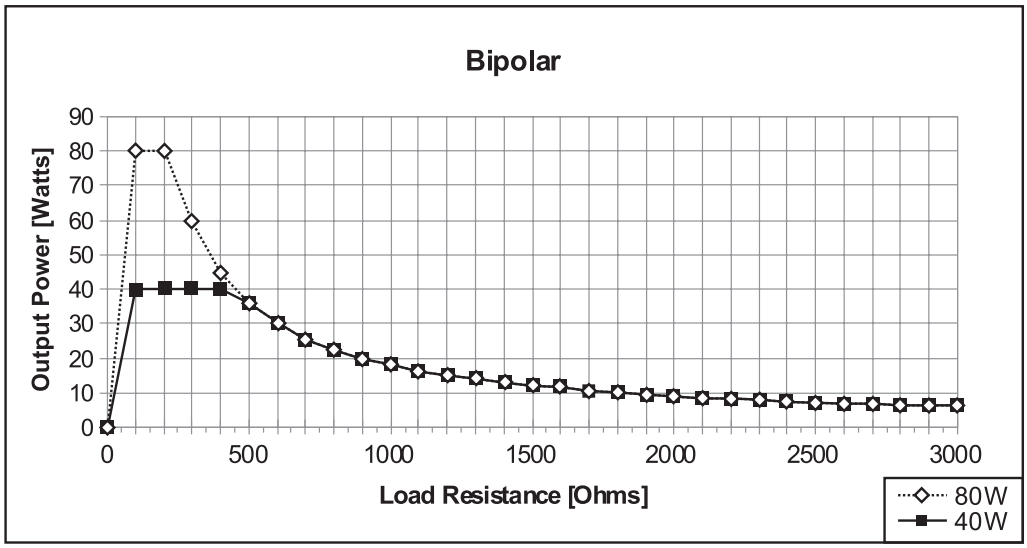


Figure A – 7 Output power vs impedance for Bipolar mode



APPENDIX B

WARRANTY

Limited Warranty. For the applicable periods as listed below, after delivery of the Equipment and subject to the terms hereof, Arthrex warrants the Equipment to be free from manufacturers' defects in material and craftsmanship under normal use and service.

The warranty periods for Arthrex, Inc. products are as follows:

• Electrosurgical Generators: One year from date of shipment.

• Mounting Fixtures (all models): One year from date of shipment.

• Footswitches (all models): Ninety days from date of shipment.

• Patient Return Electrodes: Shelf life only as stated on packaging.

• Sterile Single Use Accessories: Only as stated on packaging.

The Warranty does not apply to any Equipment that has been repaired, serviced or altered outside of the manufacturer's or Arthrex's facility or to Equipment that has been subjected to abuse, misuse, neglect, accident or negligence in use, storage or handling. Arthrex's obligation, and the Customer's sole and exclusive remedy, is limited to the replacement or repair of any Equipment which Arthrex's examination shall disclose, in its sole discretion, to be defective or inoperative, and will be conditioned upon Arthrex's receiving written notice of any alleged nonconformity or defect during the applicable warranty period and the return of defective products to Arthrex, F.O.B. Arthrex's facility. If Arthrex determines that any product or service is not defective or that Arthrex is not liable for the defect, the Customer will be notified; thereafter, Arthrex will repair or replace such product upon the Customer's written consent and at prevailing prices. Arthrex may, in its discretion, provide reasonable use of loaner Equipment while repair or replacement is underway. This warranty applies only to the original Customer and is not transferable except at the discretion of Arthrex. Repairs and replacements made under this warranty are not warranted beyond the remainder of the warranty period. ARTHREX'S LIABILITY SHALL BE LIMITED SOLELY, AT ARTHREX'S OPTION, TO REPAIR OR REPLACEMENT OF THE GOODS OR COMPONENT PARTS NOT MEETING THE QUALITY AND SPECIFICATIONS WARRANTED. THERE ARE NO WARRANTIES, IMPLIED OR STATUTORY (INCLUDING THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR INTENDED USE, NON-INFRINGEMENT, OR ARISING OUT OF A COURSE OF PERFORMANCE, DEALING OR TRADE USAGE) THAT EXTEND BEYOND THIS EXPRESS WARRANTY. IN THE EVENT THAT APPLICABLE LAW PREVENTS THE DISCLAIMER OF ANY IMPLIED WARRANTIES, THEN SUCH IMPLIED WARRANTIES SHALL BE LIMITED TO THE CONTENTS AND DURATION OF THIS EXPRESS WARRANTY. This Warranty shall be governed by the laws of the State of Florida and the sole forum for resolving disputes under or relating to this Warranty shall be any state court in the County of Collier, State of Florida.