

*Bovie*

# AARON 1250™ ELECTROSURGICAL GENERATOR



## USER'S GUIDE



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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 Aaron 1250 Electrosurgical Generator only.

Additional technical information is available in the Aaron 1250 Electrosurgical Generator Service Manual.

### **Equipment Covered in this Manual**

Aaron 1250 Electrosurgical Generator:

110 VAC Model No.: A1250

220 VAC Model No.: A1250-220

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Bovie Aaron part number, MC-55-034-001 Rev. 7

## **CONVENTIONS USED IN THIS GUIDE**

### **WARNING**

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

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### **CAUTION**

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

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### **NOTICE**

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

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# SECTION 1

## INTRODUCING THE AARON 1250 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.  
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## KEY FEATURES

The Aaron 1250 Electrosurgical Generator includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

- **Two levels of coagulation: Pinpoint Coagulation and Fulguration**  
Pinpoint Coagulation provides precise control of bleeding in localized areas.  
Fulguration provides greater control of bleeding in highly vascular tissue over broad surface areas.
- **Return electrode sensing and contact quality monitoring**  
The Aaron 1250 incorporates a return electrode contact quality monitoring system (Bovie NEM™). This system determines the type of patient return electrode: single or split plate. The system also continually monitors the contact quality between the patient and the split-plate return electrode. This feature is designed to eliminate patient burns at the return electrode site.

### **NOTICE**

*The Bovie NEM™ system recommends that you use a split-plate patient return electrode.*

- **Memory**  
The unit automatically powers up to the last used modes and power settings.
- **Isolated RF output**  
This minimizes the potential of alternate site burns.
- **Standard connectors**  
These connectors accept the latest monopolar and bipolar instruments.
- **Self diagnostics**  
These diagnostics continually monitor the unit to ensure proper performance.

## COMPONENTS AND ACCESSORIES

To avoid incompatibility and unsafe operation, we recommend using the following Bovie brand accessories supplied with your generator:

- Aaron 1250 Electrosurgical Generator
- Hospital-grade power cord
- User's Guide
- Two disposable pencils (one standard push button)
- Three electrodes
- One reusable grounding cord
- Five disposable split grounding pads

## 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.

Physicians have used electrosurgical equipment safely 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 Aaron 1250 Electrosurgical Generator, this section presents the warnings and cautions that appear throughout this user's guide. So that you can operate this equipment with maximum safety, it is important that you read, understand, and follow the instructions in these warnings and cautions. It is also important that you read, understand, and follow the instructions for use in this user's guide.



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**WARNINGS**

**Hazardous Electrical Output** - This equipment is for use only by trained, licensed physicians.

**Danger: Fire / Explosion Hazard** - Do not use the Aaron 1250 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 which may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N<sub>2</sub>O] 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.

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 a pacemaker 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 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.

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**WARNINGS**

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 patient 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. Aaron Medical recommends the use of split patient return electrodes and Aaron Medical generators with a contact quality monitoring system.

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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.

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.....

**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.

Nonfunction 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.

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, nonconductive, 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.<sup>1</sup>

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).

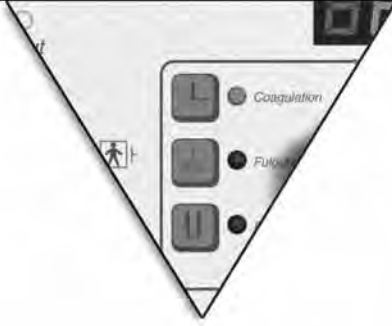
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**NOTICES**

*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.*





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# SECTION 2

## **CONTROLS, INDICATORS, AND RECEPTACLES**

This section describes:

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

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













## FRONT PANEL

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



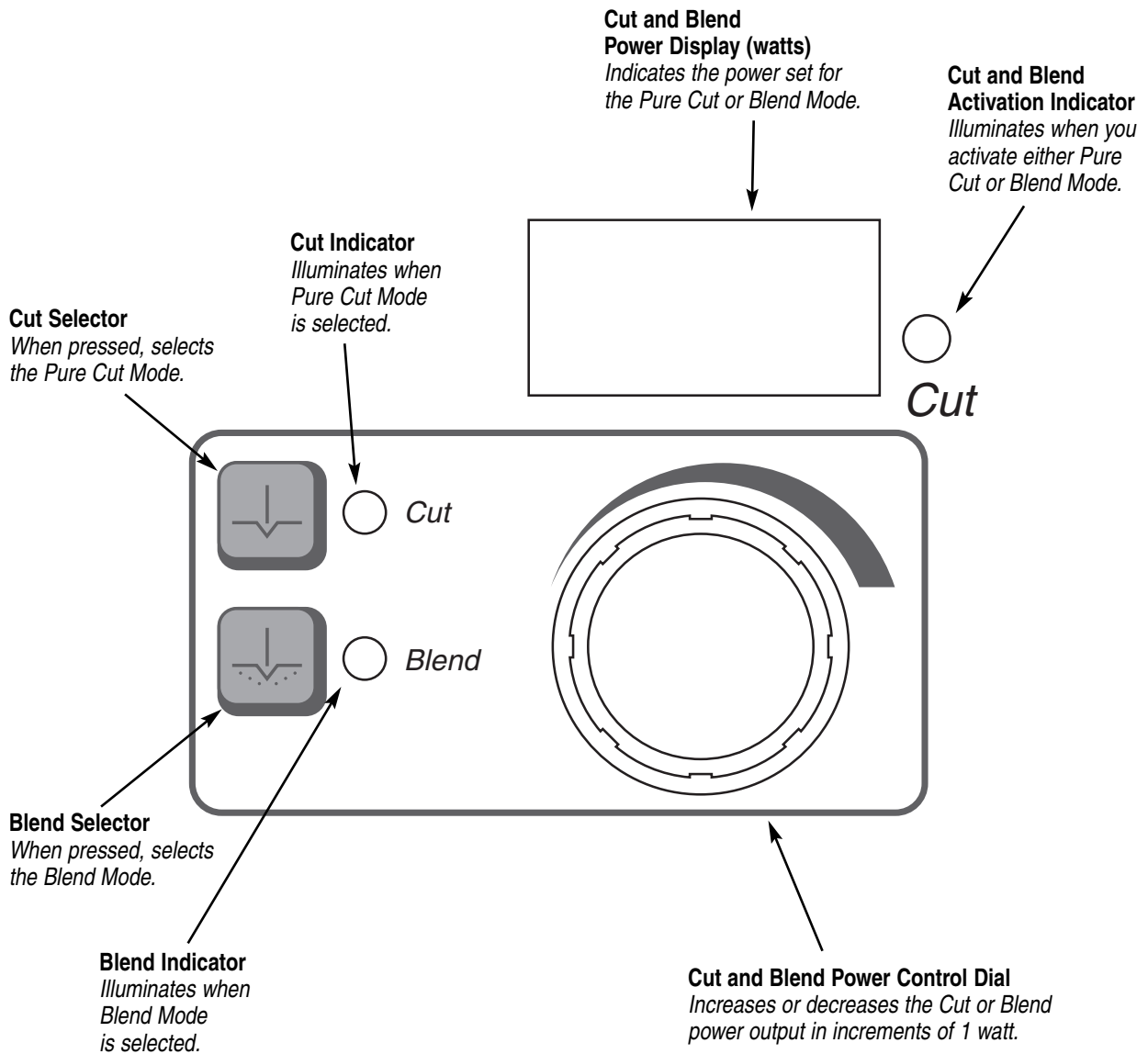
## SYMBOLS ON THE FRONT PANEL

Refer to the following table for descriptions of symbols found on the front panel of the Aaron 1250.

SYMBOLS	DESCRIPTION
<i>Cut Controls</i>	
	Cut Mode
	Blend Mode
<i>Coag Controls</i>	
	Coagulation Mode
	Fulguration Mode
<i>Bipolar Controls</i>	
	Bipolar Mode
<i>Indicators</i>	
	Split Return Electrode
	Solid Return Electrode
<i>Regulatory Symbology</i>	
	Read instructions before use.
	Defibrillator Proof Type BF Equipment
	RF Isolated – patient connections are isolated from earth at high frequency.
<i>Power Switch and Handpiece Connectors</i>	
	Patient Return Electrode
	Caution High Voltage
	Monopolar Output
	Bipolar Output

# CUT AND BLEND CONTROLS

Figure 2 – 2 Controls for the Cut and Blend Modes

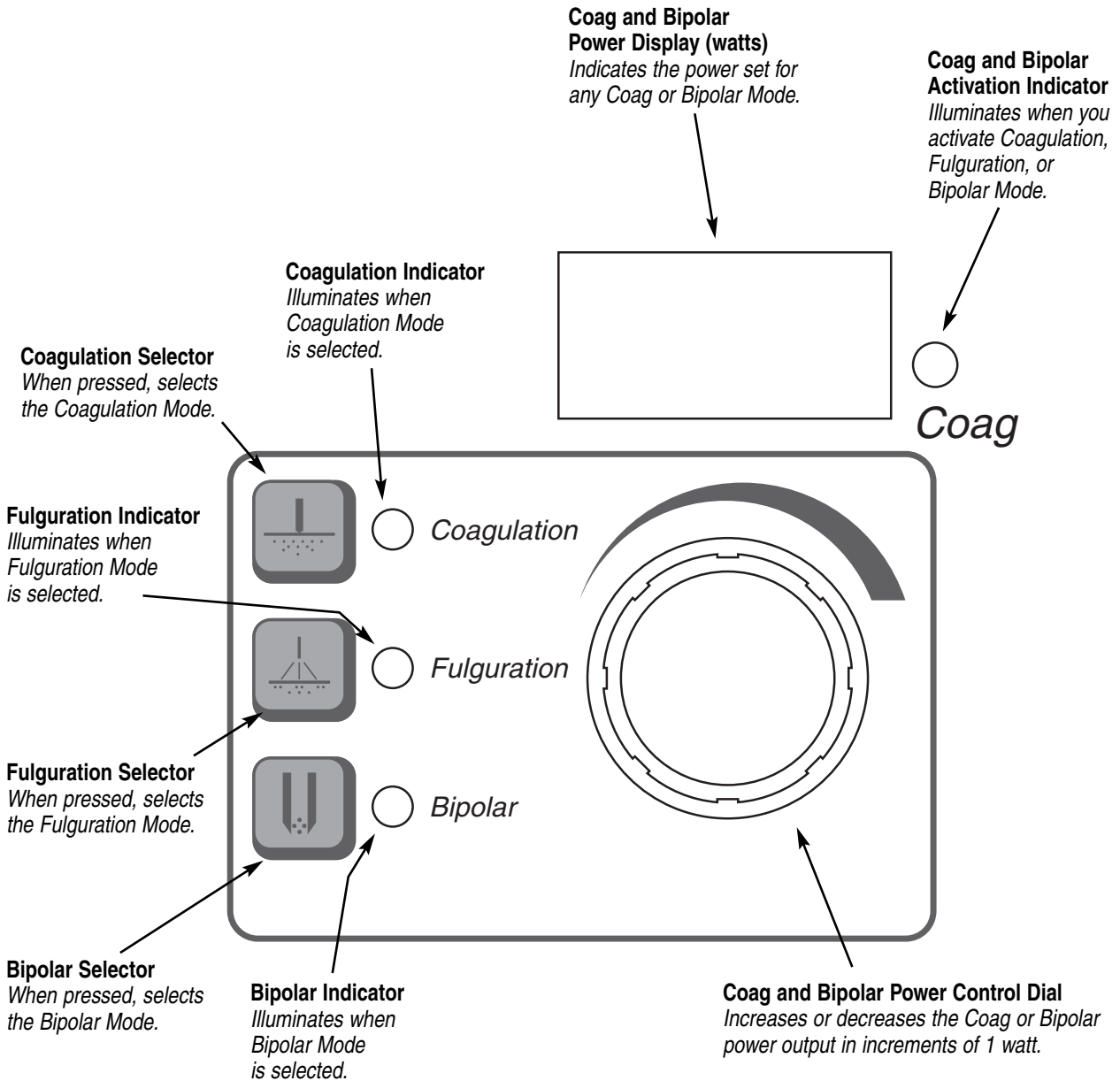


**NOTICE:**  
When selecting the Blend mode, the unit defaults to a setting of minimum blend (only the first bar is illuminated).



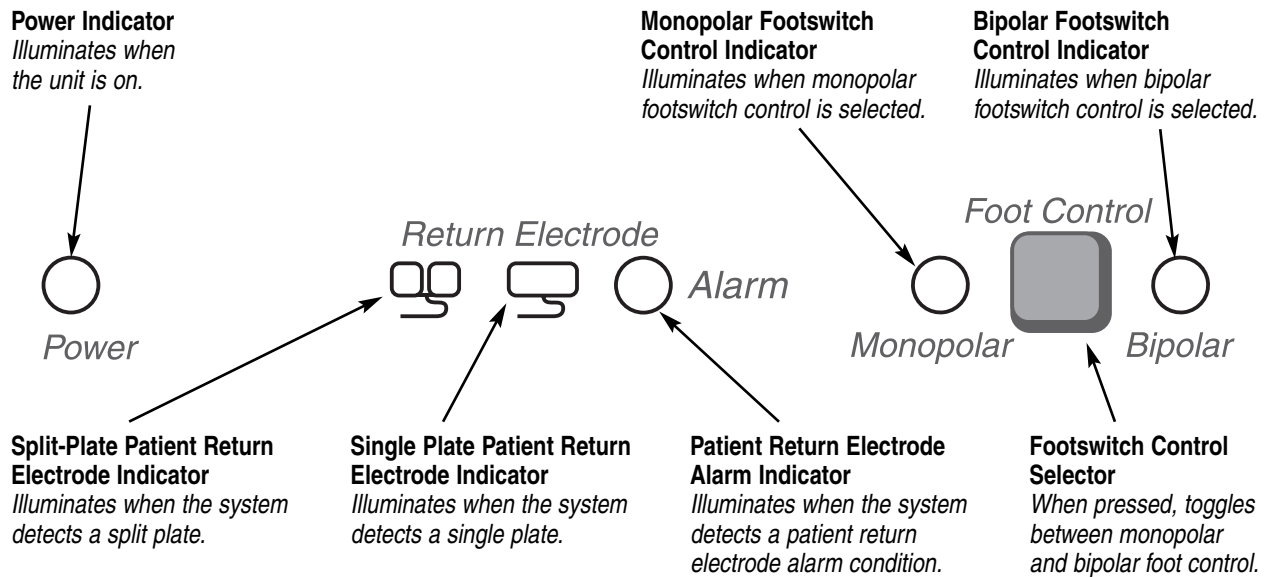
# COAG AND BIPOLAR CONTROLS

Figure 2 – 3 Controls for the Coagulation, Fulguration, and Bipolar Modes



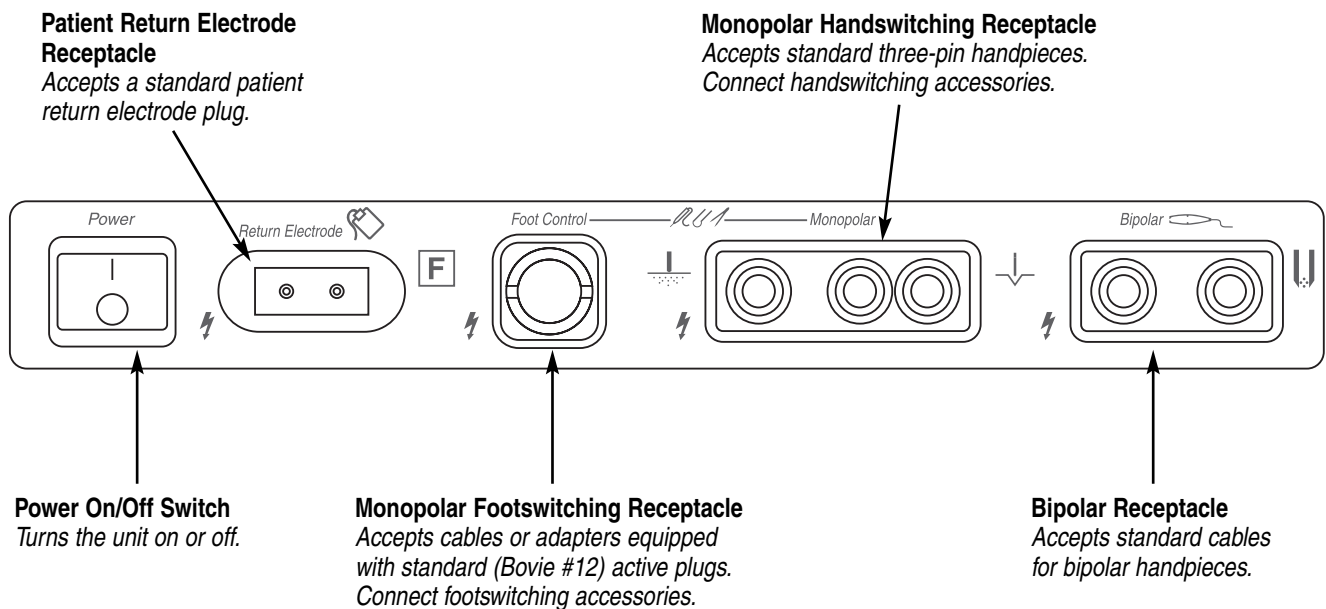
# INDICATORS

Figure 2 – 4 Indicators for power, return electrodes, and footswitch control



## POWER SWITCH AND RECEPTACLES

Figure 2 – 5 Location of the unit power switch and front panel receptacles



## REAR PANEL

Figure 2 – 6 Layout of connectors and controls on the rear panel



## SYMBOLS ON THE REAR PANEL

Refer to the following table for descriptions of symbols found on the rear panel of the Aaron 1250.

SYMBOLS	DESCRIPTION
	Equipotential Ground Stud
	Non-ionizing Radiation
	Volume Control
	<b>Danger</b> - Explosion Risk If Used With Flammable Anesthetics.
	Fuse Enclosed
	Relay Connector
	Footswitch Input Jack
	Read Instructions Before Use
	Do not dispose of this device in the unsorted municipal waste stream.



# SECTION 3

## GETTING STARTED

This section includes the following information:

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

---

## **INITIAL INSPECTION**

When you first unpack your Aaron 1250, 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 Bovie Aaron Medical's Customer Service immediately. Do not use any damaged equipment.

## **INSTALLATION**

Place the Aaron 1250 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 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-pedal footswitch to the appropriate receptacle on the back of the unit. Use only Bovie Aaron Medical footswitches. Although other types of footswitches may fit, they may not be compatible.
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, Blend, Coagulation, Fulguration, and Bipolar) to one watt.
2. Press the Cut pedal of the footswitch. 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 footswitch)***

1. Select Bipolar mode by pressing the Bipolar Mode selector.
2. Select Bipolar footcontrol by pressing the Footcontrol selector.
3. Verify that the Bipolar mode indicator illuminates and that the system generates the Coag tone when you press the Coag pedal (Blue) on the footswitch.
4. While activating the Bipolar mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
5. Confirm that releasing the Coag pedal returns the unit to an idle state.

### ***Checking Monopolar Mode (with footswitch)***

1. Select monopolar footcontrol by pressing the Footswitch Control selector until the Monopolar Footswitch Control indicator illuminates.
2. Connect a single-plate return electrode to the return electrode receptacle. Verify that the green single-plate return electrode indicator illuminates.
3. Press the Cut pedal (yellow) on the footswitch. Verify that the Cut and Blend 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, Fulguration, and Bipolar 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. 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 AARON 1250

This section contains the following procedures:

- Inspecting the Generator and Accessories*
- Setup Safety*
- Setting Up*
- Preparing for Monopolar Surgery*
- Preparing for Bipolar Surgery*
- Activation Safety*
- Activating the Unit*

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**CAUTIONS:**

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

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

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## INSPECTING THE GENERATOR AND ACCESSORIES

Before each use of the Aaron 1250, 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. Bovie Aaron Medical recommends the use of split return electrodes and Aaron generators with a contact quality monitoring system.

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**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.*

*Connect the power cord to a wall outlet having the correct voltage. Otherwise, product damage may result.*

## **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 (I). 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 or Bipolar mode is selected.
  - Each display shows a power setting. The unit automatically powers up to the last used power settings.
  - 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 Cut and/or Coag 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.

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## **PREPARING FOR MONOPOLAR SURGERY**

Monopolar surgery requires a return electrode.

### **Applying the Return Electrode**

Bovie Aaron Medical recommends using return electrode contact quality monitoring system (Bovie NEM™) patient return electrodes to maximize patient safety. Using a patient return electrode without the Bovie NEM™ safety feature may result in a patient burn.

**NOTICE:**

*The Bovie NEM™ system recommends 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.

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.

### **Connecting Accessories**

1. Connect a monopolar active electrode to the unit.

**NOTICE:**

*The Bovie NEM™ system recommends that you use a split return electrode.*

<b>If you are using...</b>	<b>Connect it to...</b>
Standard 3-pin handswitching pencil	Monopolar handswitching receptacle
Footswitching pencil	Monopolar footswitching receptacle

2. If using a footswitch activated device, connect an appropriate Bovie Aaron Medical footswitch to the footswitch connecting socket on the rear of the unit.

## **PREPARING FOR BIPOLAR SURGERY**

1. Select the Bipolar Mode by pressing the Bipolar Mode selector. The Bipolar Mode indicator will illuminate.
2. Select Bipolar Foot Control by pressing the Foot Control selector.
3. Connect a Bipolar cable to the Bipolar receptacle.
4. Connect the appropriate Bovie Aaron Medical footswitch to the Footswitch receptacle on the rear of the unit.
5. Connect a forceps instrument to the Bipolar cable.

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## 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 Aaron 1250 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<sub>2</sub>O] 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.

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### 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.<sup>1</sup>

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.

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<sup>1</sup> 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.)

## ACTIVATING THE UNIT

When you turn on your unit, remember this feature:

- Aaron 1250 Electrosurgical Generator will power up to the last used modes and last used settings. For example, if you set Pure Cut mode at 50 watts when you turned the unit off, it will automatically return to Pure Cut mode at 50 watts when you turn it on again. Similarly, if you set Coagulation mode at 40 watts before you turned the unit off, it will return to Coagulation mode at 40 watts when you turn it on again.
1. Monopolar Cut - Select the mode of operation for cut: Cut or Blend, then Select the desired Cut power settings by rotating the Cut and Blend Power Control Dial.
  2. Monopolar Coag - Select the mode of operation for coagulation: Coagulation or Fulguration, then Select the coagulation power settings by rotating the Coagulation, Fulguration, and Bipolar Power Control Dial.
  3. Bipolar - Select the mode of operation for Bipolar, then select the Bipolar power settings by rotating the Coagulation, Fulguration, and Bipolar Power Control Dial.
  4. Activate the generator by pressing the appropriate button:

To Activate...	Press This...	On This Device...
Monopolar		
Cut or Blend Modes	Yellow Button Yellow Pedal	Handswitching Pencil Footswitch
Coagulation or Fulguration Modes	Blue Button Blue Pedal	Handswitching Pencil Footswitch
Bipolar		
Any Bipolar	Yellow (Cut) or Blue (Coag) Pedal	Footswitch

### NOTICES

*One footswitch activates either monopolar or bipolar footswitching accessories.*

*If the unit is in the Bipolar Mode and the Bipolar Foot Control is selected, Monopolar Modes can be activated via the 2 button handpiece. If the Cut Button is depressed, the unit will activate whichever Cut Mode is displayed, either Cut or Blend. If the Coag Button is depressed, the unit will switch to the Coagulation Mode and activate with the last used Coagulation Power Setting. To return to the Bipolar Mode the user must press the Bipolar Selector.*



# SECTION 5

## MAINTAINING THE AARON 1250

This section covers the following topics:

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

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Bovie Aaron Medical 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 Aaron 1250 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.

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.

**NOTICE:**

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

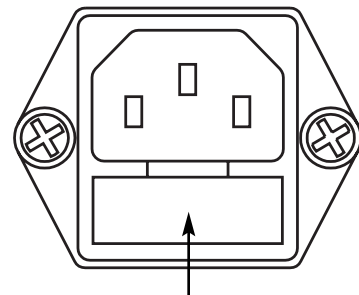


Figure 5 – 1 Fuse holder





# SECTION 6

## **TROUBLESHOOTING**

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

The Aaron 1250 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.

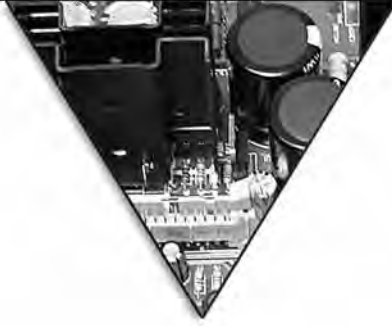
Most error codes result from faults in accessories attached to the unit. The following table lists the error codes, describes the errors, and recommends actions to take to resolve the errors.

If the unit displays any other error code, it requires service.

Error Code	Description	Recommended Action
<b>F1 (on the Cut / Blend display)</b>	Handswitch or monopolar footswitch cut pedal may be stuck.	<ol style="list-style-type: none"> <li>1. Turn off, then turn on the generator. Do not press buttons or activate accessory devices during the self-test.</li> <li>2. If the error code reappears, disconnect all accessories. Turn off, then turn on the generator again.</li> <li>3. If the problem persists, replace the handpiece or footswitch and repeat the restart.</li> <li>4. If the error code reappears, record the number and call Bovie Aaron customer service.</li> </ol>
<b>F1 (on the Coagulation / Fulguration Bipolar display)</b>	Handswitch or monopolar footswitch coag pedal may be stuck.	
<b>F2</b>	Cut and Coag buttons activated simultaneously (pencil or footswitch)	The unit does not allow simultaneous activation of the cut and coagulation modes. Release either the cut or coag button on the handpiece, or the cut or coag pedal on the footswitch.
<b>F3</b>	Footswitch Cut or Coag pedal pressed while in Bipolar Foot Control and the unit is not in Bipolar Mode.	The unit will not allow the footswitch to activate the unit if Bipolar footcontrol is selected, but the Bipolar Mode is not selected.
<b>F4</b>	Line voltage error (Line voltage too high)	<ol style="list-style-type: none"> <li>1. Turn the unit off.</li> <li>2. Verify that the unit is connected to the line voltage.</li> <li>3. If the error code reappears, record the number and contact Bovie Aaron customer service.</li> </ol>
<b>E7</b>	Internal temperature of a section of the unit exceeded the limit.	<ol style="list-style-type: none"> <li>1. Turn the unit off.</li> <li>2. Allow the unit to cool for 20 minutes.</li> <li>3. Turn the unit on.</li> <li>4. If the error code reappears, record the number and contact Bovie Aaron customer service.</li> </ol>

**NOTICE:**

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



# SECTION 7

## **REPAIR POLICY AND PROCEDURES**

Refer to this section for information on:

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

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## **RESPONSIBILITY OF THE MANUFACTURER**

Bovie Aaron Medical 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 Bovie Aaron Medical performed assembly operation, readjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements.
- Equipment use is in accordance with the Bovie Aaron Medical instructions for use.

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

## **RETURNING THE GENERATOR FOR SERVICE**

Before you return the generator, call your Bovie Aaron Medical representative for assistance. If instructed to send the generator to Bovie Aaron Medical, first obtain a Returned Goods 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 Aaron Return Goods Authorization Number on the outside of the box and ship directly to Bovie Aaron Medical.

### **Step 1 – Obtain a Returned Goods Authorization Number**

Call the Bovie Aaron Medical Customer Service Center to obtain a Returned Goods 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.

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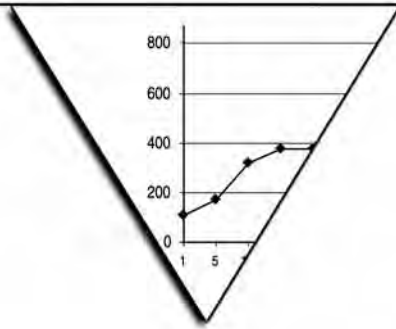
**NOTICE:**

*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 Goods Authorization Number and the information (hospital, phone number, etc.) listed in *Step 1 – Obtain a Returned Goods 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, Aaron 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 Aaron Return Goods Authorization Number on the outside of the box/container.
- C. Ship the generator, prepaid, to the address given to you by the Bovie Aaron Medical Service Center.



# APPENDIX A

## TECHNICAL SPECIFICATIONS

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

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## **PERFORMANCE CHARACTERISTICS**

### **Input Power**

<b>120 VAC ± 10%</b>	<b>240 VAC ± 10%</b>
Mains line frequency range (nominal): 50 – 60 Hz	Mains line frequency range (nominal): 50 – 60 Hz
Power consumption: 540 VA	Power consumption: 540 VA
Fuses (two): 5A (Slow Blow)	Fuses (two): 3.15A (Slow Blow)

### **Duty Cycle**

Under maximum power settings and rated load conditions (Pure Cut, 120 watt @ 500 ohm load), the generator is suitable for activation times of 10 seconds on, 30 seconds off for one hour.

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

### **Dimensions and Weight**

<b>Width</b>	26 cm (10.25 in.)	<b>Depth</b>	30.5 cm (12 in.)
<b>Height</b>	15.2 cm (6 in.)	<b>Weight</b>	< 6.5 kg (< 14 lbs)

### **Operating Parameters**

<b>Ambient temperature range</b>	10° to 40° C (50° to 104° F)
<b>Relative humidity</b>	30% to 75%, non-condensing
<b>Atmospheric pressure</b>	700 hPa to 1060 hPa
<b>Warm-up time</b>	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**

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

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### **Audio Volume**

The audio levels stated below are for activation tones (bipolar, cut and coag) 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

<b>Volume (adjustable)</b>	45 to 65 dB
<b>Frequency</b>	Cut I: 1 kHz Blend: 1 kHz Pinpoint: 2 kHz Spray: 2 kHz Bipolar: 2 kHz
<b>Duration</b>	Continuous while the generator is activated

#### Alarm Tone

<b>Volume (not adjustable)</b>	70 dB $\pm$ 5 dB
<b>Frequency</b>	2 kHz $\frac{1}{2}$ seconds / 1 kHz $\frac{1}{2}$ seconds
<b>Duration</b>	2 s

### **Return Electrode Sensing**

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

<b>Single Plate</b>	Trip resistance: 0 $\Omega$ to 5 $\Omega$ $\pm$ 3 $\Omega$ Continuous measurement: Once the system establishes the single-plate electrode resistance, an increase of 20 $\Omega$ $\pm$ 5 $\Omega$ in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
<b>Split Plate</b>	Trip resistance: 10 $\Omega$ $\pm$ 5 $\Omega$ to 135 $\Omega$ $\pm$ 10 $\Omega$ Continuous measurement: Once the system establishes the split-plate 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**

<b>Enclosure source current, ground open</b>	< 300 $\mu$ A
<b>Source current, patient leads, all outputs</b>	Normal polarity, intact ground: < 10 $\mu$ A Normal polarity, ground open: < 50 $\mu$ A Reverse polarity, ground open: < 50 $\mu$ A
<b>Sink current at high line, all inputs</b>	< 20 $\mu$ A

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### **High Frequency (RF) Leakage Current**

Bipolar RF leakage current	< 39 mA <sub>rms</sub>
Monopolar RF leakage current (additional tolerance)	< 150 mA <sub>rms</sub>

## **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 BF Equipment (IEC 60601-1) / Defibrillator Proof**



The Aaron 1250 Electrosurgical Generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type BF 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 activated Aaron 1250 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 Aaron 1250 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 Aaron 1250 Electrosurgical Generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.



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## 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	120 W @ 500 $\Omega$	357 kHz $\pm$ 50 kHz	N / A	2.5 KV	2.9 $\pm$ 20%
Blend	90 W @ 800 $\Omega$	357 kHz $\pm$ 50 kHz	30 kHz $\pm$ 5 kHz	3.5 KV	3.3 $\pm$ 20%
Coagulation	80 W @ 1000 $\Omega$	425 kHz – 494 kHz	57 kHz $\pm$ 5 kHz	4.5 KV	5.5 $\pm$ 20%
Fulguration	40 W @ 1000 $\Omega$	410 kHz $\pm$ 50 kHz	25 kHz $\pm$ 5 kHz	6.5 KV	7.7 $\pm$ 20%
Bipolar	30 W @ 200 $\Omega$	506 kHz – 570 kHz	32 kHz $\pm$ 5 kHz	2.0 KV	6.9 $\pm$ 20%

\* an indication of a waveform's ability to coagulate bleeders without a cutting effect

## OUTPUT POWER CURVES

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

### Monopolar Cut Curves

These measurements were taken using short (< 0.5 meter) leads. For each output power vs. impedance curve, the upper curve represents readings taken at full power; the lower curve, readings taken at half power.

Figure A - 1 Output power versus impedance for Cut mode



Figure A - 2 Peak voltage vs. power setting for Cut mode

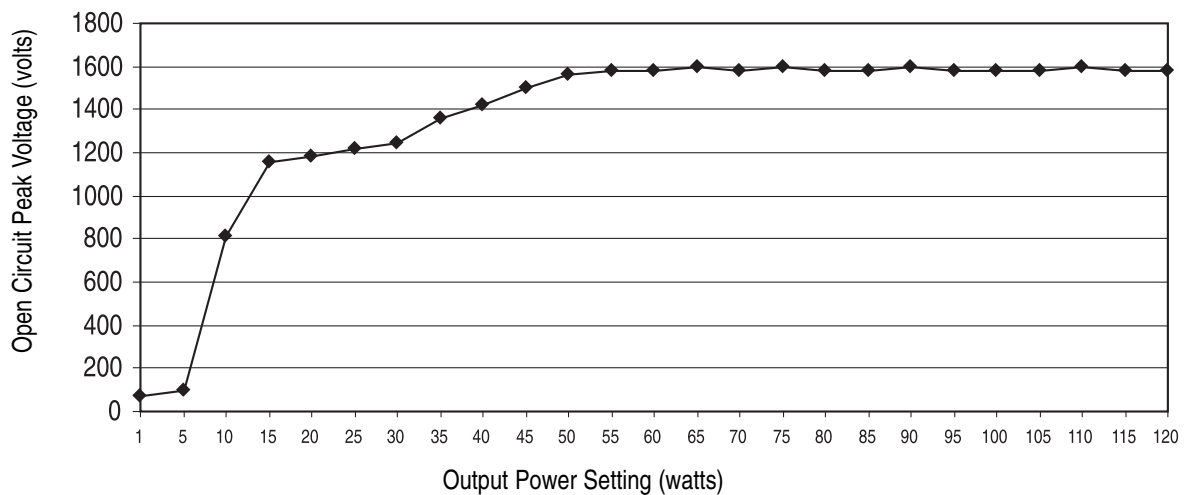
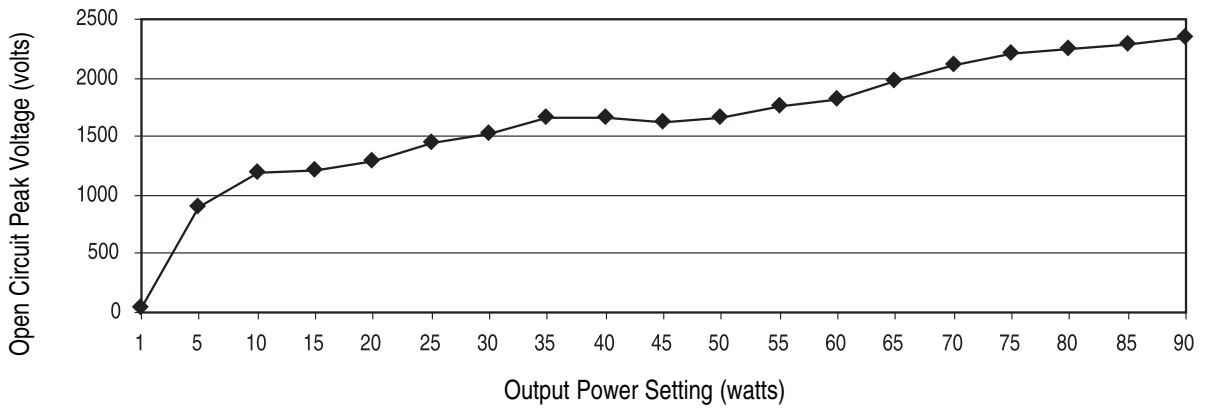


Figure A - 3 Output power versus impedance for Blend mode



Figure A - 4 Peak voltage vs. power setting for Blend mode



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## Monopolar Coag Curves

These measurements were taken using short (< 0.5 meter) leads.

Figure A - 5 Output power versus impedance for Coagulation mode



Figure A - 6 Peak voltage vs. power setting for Coagulation mode

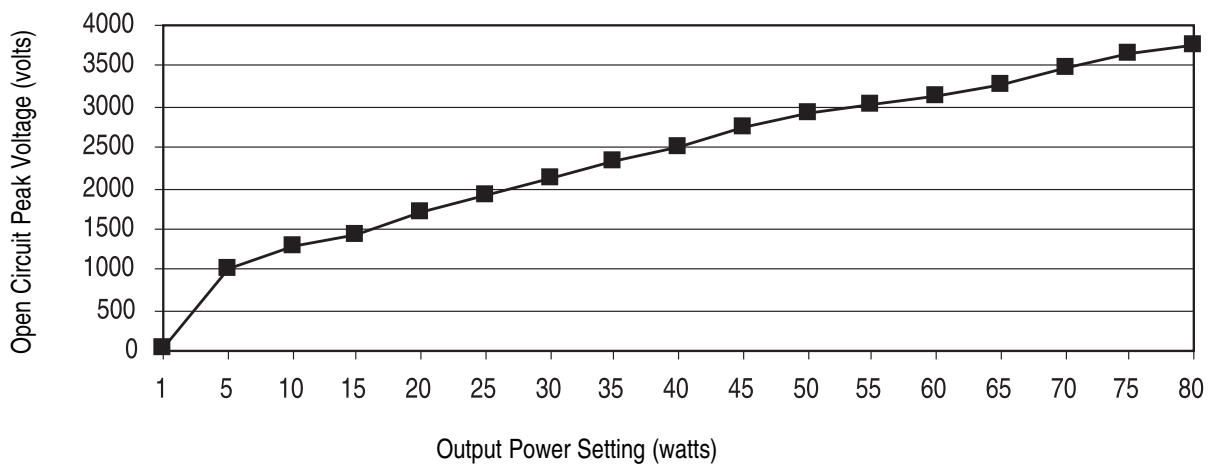


Figure A - 7 Output power versus impedance for Fulguration mode

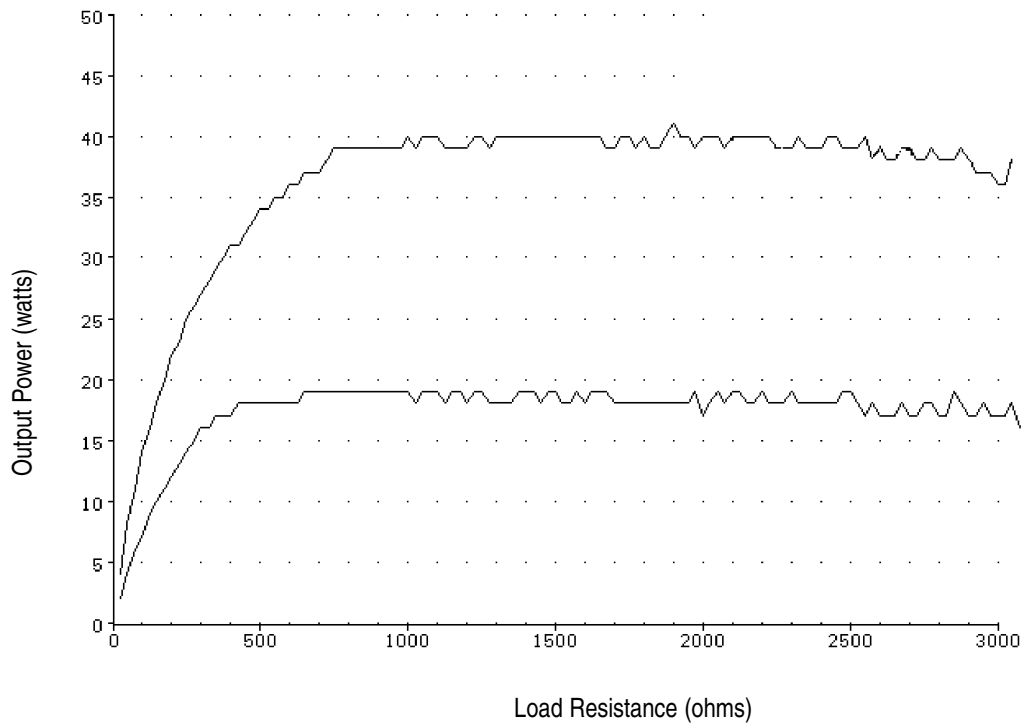
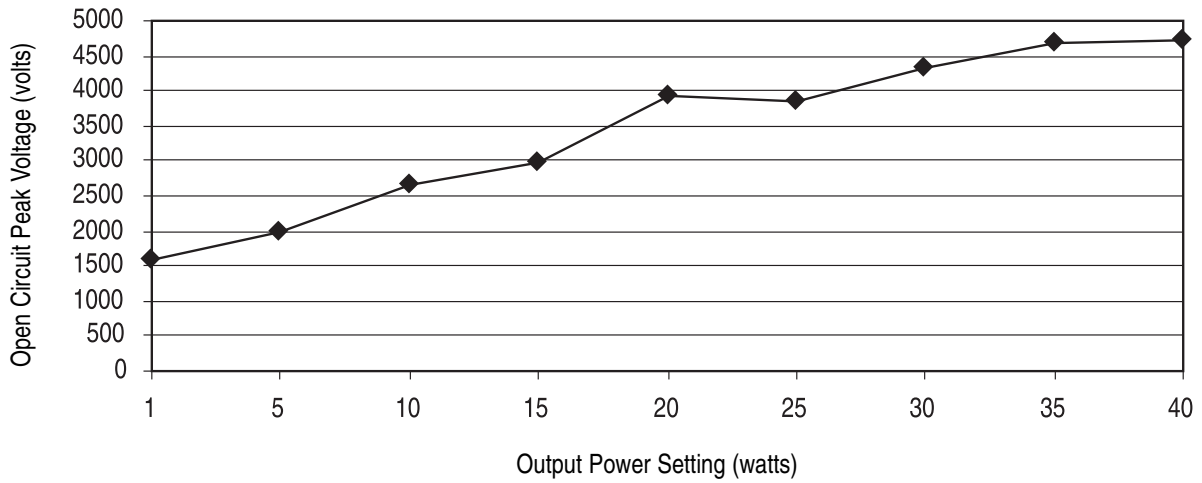


Figure A - 8 Peak voltage vs. power setting for Fulguration mode



## Bipolar Curves

Figure A - 9 Output power versus impedance for Bipolar mode

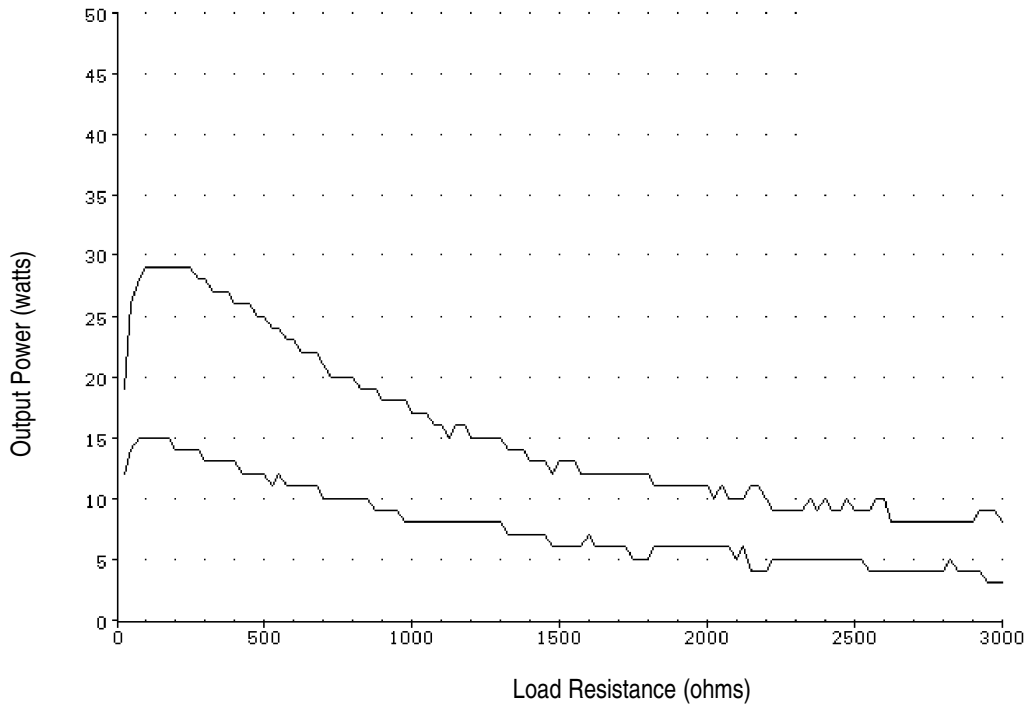
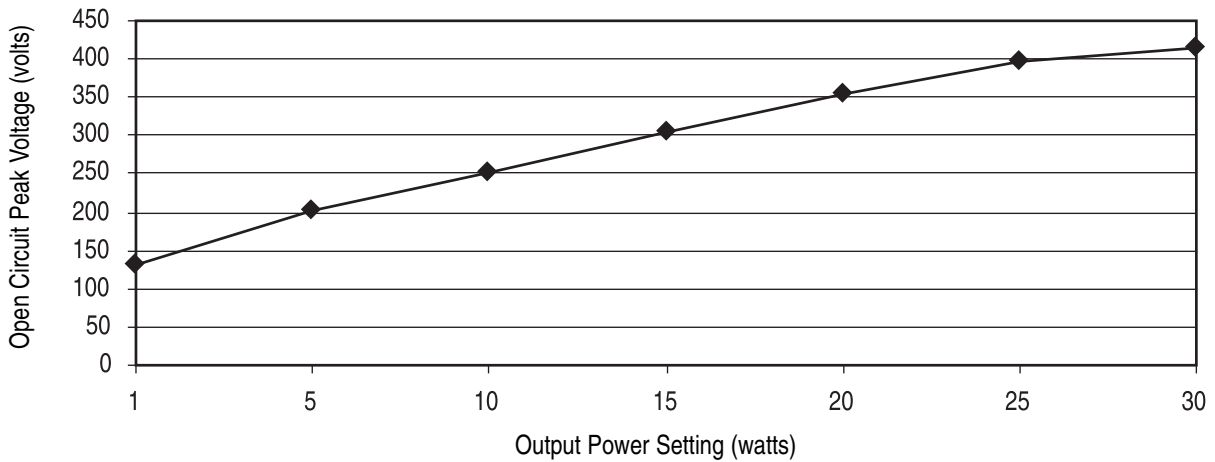


Figure A - 10 Peak voltage vs. power setting for Bipolar mode





# APPENDIX B

## WARRANTY

Bovie Aaron Medical, warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below.

Bovie Aaron Medical's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to Bovie Aaron Medical's satisfaction, that the product is indeed, defective.

This warranty does not apply to any product, or part thereof, which has been repaired or altered outside Bovie Aaron Medical's factory in a way so as, in Bovie Aaron Medical's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Bovie Aaron Medical products are as follows:

- Electrosurgical Generators: Two years from date of shipment
- Mounting Fixtures (all models): Two years 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

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This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Bovie Aaron Medical.

Bovie Aaron Medical neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Bovie Aaron Medical's products.

Notwithstanding any other provision herein or in any other document or communication, Bovie Aaron Medical's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Bovie Aaron Medical to the customer.

Bovie Aaron Medical disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Florida, USA.

The sole forum for resolving disputes arising under or relating in any way to this warranty is the District Court of the County of Pinellas, State of Florida, USA.

Bovie Aaron Medical, its dealers, and representatives reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.