Bovie® ELECTROSURGICAL GENERATOR

USER'S GUIDE


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ELECTROSURGICAL GENERATOR
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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 Bovie® IDS-210 only.

Additional technical information is available in the *Bovie® IDS-210 Service Guide*. For the latest information and technical bulletins, visit www.boviemed.com.

Equipment Covered in this Manual

Bovie® IDS-210
Reference No.: IDS-210

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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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INTRODUCING THE BOVIE® IDS-210

This section includes the following information:

- *Indications for Use*
- *Operating Principle*
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- *Contraindications*
- *Application Specification*
- *Key Features*
- *Components and Accessories*
- *Additional Accessories*

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.

INDICATIONS FOR USE

The Bovie® IDS-210 Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue. For the latest user information and technical bulletins, visit www.boviemed.com.

OPERATING PRINCIPLE

RF energy is generated and passed through an interconnecting cable to an accessory where the energy is delivered to cut, coagulate and ablate tissue.

INTENDED USE

The Bovie® IDS-210 Electrosurgical Generator is intended for cutting, coagulation, ablation of tissue in general, gynecologic, orthopedic, ENT and urological procedures performed in an operating suite and procedure room.

NOTICE:
The Bovie® IDS-210 is not intended for Tubal Ligation.

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 Bovie® IDS-210, 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 Bovie® IDS-210 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.
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
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.
No modification of this equipment is allowed.

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.

Active cord removal during activation could result in a shock to the operator at the generator connector plug interface should activation occur by footswitch.

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.

No modification of this equipment is allowed.

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

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 of the RF Electrosurgical Generator at minimal power setting to get the expected clinical effect and for a normal clinical procedure time will not cause a surface skin temperature under the Bovie ESREC, ESRSC or ESRE patient return pads to rise above 41°C when the skin is prepared properly and the pad is attached properly. However be aware that extended surgical times particularly at high power will cause a continued temperature rise at the skin and return pad interface due to RF current return to the generator.

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings.

When HF SURGICAL EQUIPMENT and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.

Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar Instrument output jack only. Improper connection may result in inadvertent generator activation.

Avoid using power settings that would exceed the H.F. peak voltage that is acceptable for each accessory. Choose only accessories that will withstand each mode and power setting.

To avoid incompatibility and unsafe operation, use suitable cables, accessories, active and neutral electrodes, including values for the highest allowed H.F. peak voltage.

Some accessories have multiple buttons that can deliver different surgical effects. Verify accessory features and proper mode settings prior to activation.

Connected accessories need be rated for at least the maximum peak output voltage of the H.F. generator set at the intended output control setting in the intended operating mode.

Associated equipment and accessories used must be rated to withstand the combination of the maximum Vpeak rating and Crest Factor for the following RF modes: Blend, Pinpoint and Spray.

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings.

Apparent low output or failure of the IDS-210 RF to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.

When using Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1000 Vpeak max.

When using Blend mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1870 Vpeak max.

When using Coagulation mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 4000 Vpeak max.

When using Bipolar mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 600 Vpeak max.

Use electrosurgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. 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 device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.

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.

The entire area of neutral electrode should be reliably attached to patient's body and as close to operating field as possible. Refer to instructions for use.

The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.).

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.

When HF SURGICAL EQUIPMENT and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes.

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. Bovie Medical Corporation recommends the use of split return electrodes and Bovie® 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.

The PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided.

Minor neuromuscular stimulation is possible when arcs between the ACTIVE ELECTRODE and tissue occur. The generator has been designed to minimize the possibility of neuromuscular stimulation.

Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar Instrument output jack only. Improper connection may result in unsafe generator power output.

For all Monopolar modes, any associated equipment and active electrodes must be rated to with stand the combination of output voltage, vp-p and crest factor as stated in Appendix A of this manual.

The output power selected should be as low as possible for the intended purpose. Certain devices or ACCESSORIES may present an unacceptable RISK at low power settings.

Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.

Unless a compatible MONITORING NE is used with a CONTACT QUALITY MONITOR, loss of safe contact between the NE and the PATIENT will not result in an auditory alarm.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in Normal Use of the HF surgical equipment.

The generator is equipped with a return electrode sensing and contact quality monitoring system (NEM), which monitors the quality of the patient return electrode connection. When a correctly functioning single plate return electrode is connected to the generator, the NEM (contact quality monitor) verifies the connections between the generator and the single return electrode. It DOES NOT verify that a single return electrode is in contact with the patient. When using a split return electrode, the NEM (contact quality monitor) confirms the total resistance is within the preset safety range. Proper application (such as hydrating the patient's skin) and visual inspection of the patient return electrode is required for safe operation.

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.

To avoid the possibility of a burn to the patient, when using a split pad do not activate the unit if the solid pad indicator is illuminated green or the red alarm indicator remains illuminated red. This could indicate improper pad placement or a faulty NEM (contact quality monitor) circuit.

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.

CONTRAINDICATIONS

The use of the Bovie® IDS-210 is contraindicated in the presence of flammable anesthetics, oxygen-enriched or explosive atmospheres.

APPLICATION SPECIFICATION

Operating Conditions

Conditions of Visibility

RF energy is generated and passed through an interconnecting cable to an accessory where the energy is delivered to cut, coagulate and ablate tissue.

Ambient luminance range	100 lx to 1,500 lx
Viewing distance	20 cm to 200 cm
Viewing angle	normal to the display ± 30˚

Medical purpose/indication

- Cut, coagulate, and/or ablate tissue to aid surgeon, physician or clinician in performing required procedure.
- Aids healing by preventing loss of body fluids, reduces amount of open tissue surfaces susceptible to bacterial infection.

Site of Use

- Tissue

Site Condition

- Clean and protect from infection from start through completion of procedure

Patient Population – * Patient should not be user.

- Age: Infant to geriatric
- Weight: No restriction
- Patient State: Alert, relaxed, may be sedated, having had local anesthetic applied.

Intended User Profile

- Education – Trained physician, physician's assistant, nurse, nurse practitioner, clinician.
- Knowledge: No maximum
  - Minimum:

- Understands electrosurgery and electrosurgical techniques;
- Read and understands supplied User's Guide (Accompanying Document)
- Understands hygiene

- Maximum:
  - There is no maximum

- Language Understanding:
  - Languages as specified in the marketing distribution plan
- Experience:
  - Minimum:
    - Some training on techniques or training under surveillance/supervision
    - No special experience needed
  - Maximum:
    - There is no maximum
  - Permissible Impairments:
    - Mild reading / vision impairment or vision correction to 20/20
    - Impaired by 40% resulting in 60% of normal hearing at 500 Hz to 2.0 kHz.

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.

KEY FEATURES

The Bovie® IDS-210 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 Appendix A, *Technical Specifications* section of this guide.
  Cut II is a softer cut that generates constant output power with a lower voltage over a small range of impedances suggested for laparoscopic procedures. Refer to Appendix A, *Technical Specifications* section of this guide.

- **Four Levels of Blend**
  The Blend mode is a combination of cutting and hemostasis. The IDS-210 gives the surgeon freedom to adjust the desired level of hemostasis. A level setting of 1 is minimal blend with maximum cutting effect. A level setting of 4 is maximum hemostasis (blend) with minimal cutting effect. This adjustment is easily achieved by a incremental 4-level 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.

- **Three levels of coagulation: Pinpoint, Spray and Gentle Coagulation**
  – Pinpoint provides precise control of bleeding in localized areas.
  – Spray provides greater control of bleeding in highly vascular tissue over broad surface areas.
  – Gentle provides a more intense coagulation than in other modes. For instance, when Coagulation is necessary in short amounts of time, reduced electrode carbonization is provided.

- **Macro Bipolar Mode**
  The Macro Bipolar Mode provides delicate Bipolar coagulation effects to prevent tip tissue adhesion and carbonization.

- **Micro Bipolar Mode**
  The Micro Bipolar Mode provides precise Bipolar coagulation effects.
- **Standard Bipolar Mode**
  The Standard Bipolar Mode provides power for conventional Bipolar output.
- **Three Bipolar Modes**
  For procedures requiring Bipolar output power, the generator offers the surgeon three Bipolar modes (Macro, Micro and Standard).
- **Presets**
  The surgeon can store 10 user-defined RF presets for easy recall of frequently used settings.
- **Return electrode sensing and contact quality monitoring**
  The IDS-210 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.

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

  Before activation, pad placement and visual verification of the split return electrode (split pad) indicator on the front panel is recommended. After connecting the split pad to the generator and placing the split pad securely to the patient, give the unit 3 seconds to recognize the split pad. The split pad indicator will illuminate green. If the split pad and cord are attached to the generator without secure contact to the patient, the alarm indicator will illuminate red.

- **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 density. Unlike analog, this feature reduces the need to adjust power settings manually with varying tissue impedance.
- **User-Friendly Design**
  Digital interface with membrane switch feature selection.
- **Three Front Panel Accessory Connections and Two Rear Panel Footswitch Connections**
  These connectors accept the latest monopolar and bipolar instruments. Refer to Section 2, Controls, Indicators, and Receptacles to learn more. Monopolar 1 connector accepts a standard 3-pin monopolar connector or adaptor (A1255A) for foot-controlled accessories. Monopolar 2 connector accepts a standard 3-pin monopolar connector for connecting standard monopolar accessories to the generator. The front panel also allows for a standard Bipolar accessory.

  The rear panel monopolar footswitch connector accepts a Bovie® Monopolar Footswitch (BV-1253B). The rear panel bipolar footswitch connector accepts a Bovie® Bipolar Footswitch (BV-1254B).
- **Memory**
  The unit automatically powers up to the last activated mode and power settings.
- **Isolated RF output**
  This minimizes the potential of alternate site burns.
- **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:

- Bovie® IDS-210
- Hospital-grade power cord (120 VAC - 09-039-001 and 240 VAC - 09-035-001)
- User's Guide - 55-231-001

ADDITIONAL ACCESSORIES

To avoid incompatibility and unsafe operation, we recommend using the following Bovie® accessories with the Bovie® IDS-210:

- BV-1253B - Monopolar Footswitch
- BV-1254B - Bipolar Footswitch
- BV-IDS-CS - Mobile Cart Stand
- A827V - Bipolar Cable
- ESP Line of Monopolar Handpieces

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

Refer to the following table for descriptions of symbols found on the front panel of the Bovie IDS-210.

SYMBOLS	DESCRIPTION
Cut Controls	
	Cut Modes (Cut I and Cut II)
	Blend Mode
Coag Controls	
	Pinpoint Mode
	Spray Mode
	Gentle Mode
Bipolar Controls	
	Macro Bipolar Mode
	Micro Bipolar Mode
	Standard Bipolar Mode

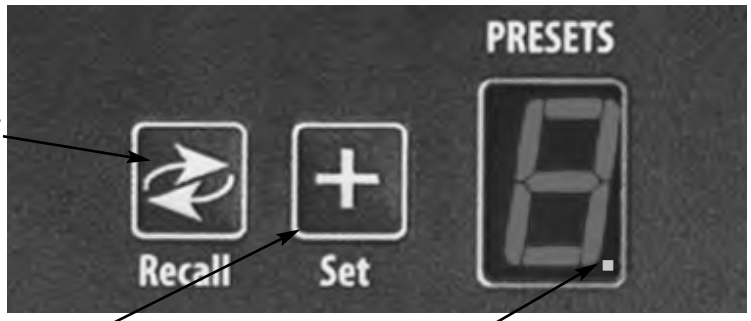
Symbols on the Front Panel Continued

Refer to the following table for descriptions of symbols found on the front panel of the Bovie IDS-210.

SYMBOLS	DESCRIPTION
Selection	
	Select / Toggle / Adjust Settings
	Recall
	Set
Indicators	
	Split Return Electrode
	Solid Return Electrode
Regulatory Symbology	
	Mandatory: Refer to instruction manual / guide
	Defibrillator Proof Type CF Equipment
	RF Isolated – patient connections are isolated from earth at high frequency.
	Warning: Dangerous voltage
Power Switch and Receptacles	
	Power OFF
	Power ON
	Return Electrode (Split)
	Return Electrode (Solid)
	Monopolar Handpiece 1 - (for 3-pin monopolar connection)
	Monopolar Handpiece 1 - (for single plug monopolar connection)
	Monopolar Handpiece 2
	Bipolar Handpiece

PRESET CONTROLS

Preset / SetUp Display
Preset indicates the current selection of one of the 10 RF presets (0-9). Also indicates a dash "–" when a Preset is not selected.



Recall Button
Toggles through the 10 RF presets.

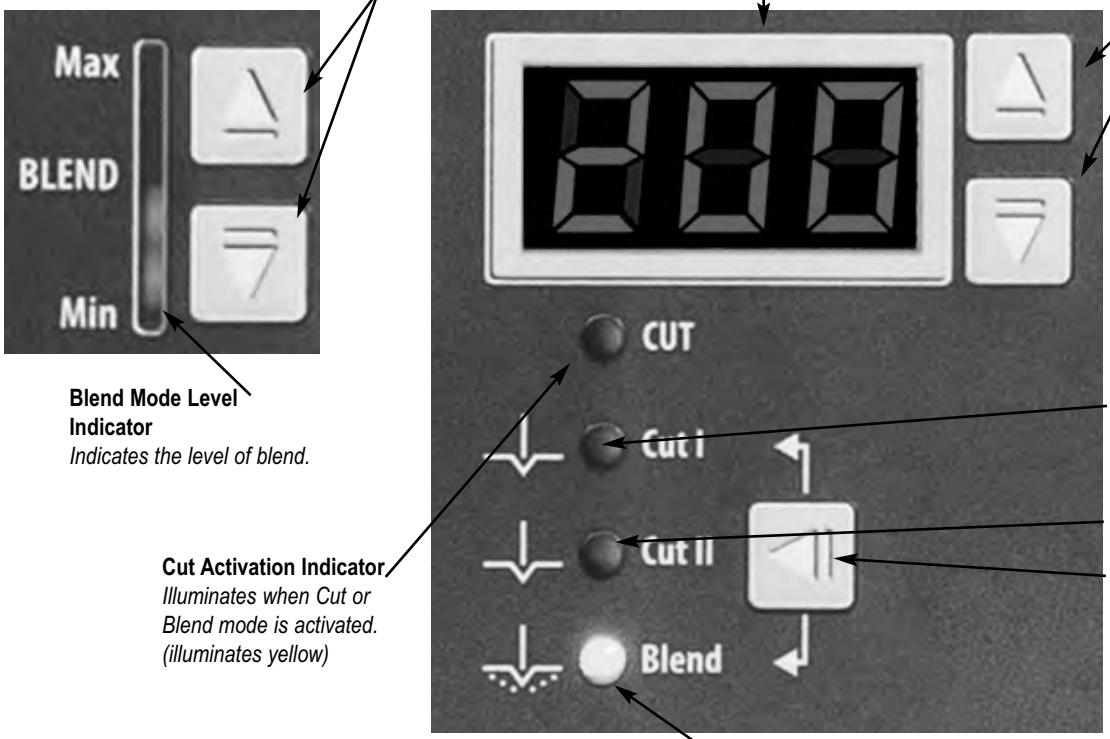
Set Button
Sets the desired preset into one of the 10 user-defined presets. Press and hold the Set button for three seconds to save the settings.

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.

NOTICES:
The Bovie® IDS-210 incorporates 10 RF presets that are factory set to zero watts and can be programmed to your preferred settings.

Set and Recall are disabled while the unit is activated.

MONOPOLAR POWER OUTPUT MODES



Monopolar Cut Power Display (watts)
Indicates the power set for the selected Cut / Blend mode. Displays error/fault code in the event of an error or fault.

Blend Level Control Buttons
Increases or decreases the blend Level (1-4) only applicable to the Blend mode.

Cut and Blend Power Control Buttons
Increases or decreases the selected Cut mode output power setting.

Blend Mode Level Indicator
Indicates the level of blend.

Cut I Mode Indicator
Illuminates green when the Cut I mode is selected.

Cut II Mode Indicator
Illuminates green when the Cut II mode is selected.

Cut Activation Indicator
Illuminates when Cut or Blend mode is activated. (illuminates yellow)

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

Blend Mode Indicator
Illuminates green when the Blend mode is selected.

COAG CONTROLS

Coag Power Display (watts)
Indicates the power set for the selected Coag mode. Displays error/fault codes in the event of an error or fault.

Coag Power Control Buttons
Increases or decreases the selected Coag mode output power setting.

Coag Activation Indicator
Illuminates when Coag mode is activated. (illuminates blue)

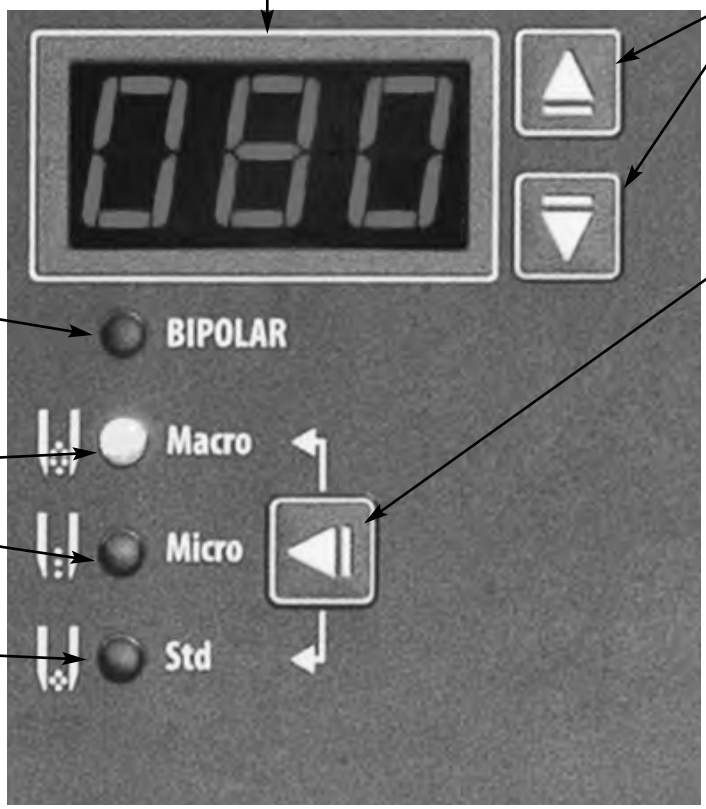
Pinpoint Mode Indicator
Illuminates green when the Pinpoint mode is selected.

Pinpoint, Spray and Gentle Mode Selector
Toggles between Pinpoint mode, Spray mode and Gentle mode.

Gentle Mode Indicator
Illuminates green when the Gentle mode is selected.

Spray Mode Indicator
Illuminates green when the Spray mode is selected.

BIPOLAR POWER OUTPUT MODES



Bipolar Power Display (watts)
Indicates the power set for the Bipolar modes.
Displays error/fault codes in the event of an error or fault.

Bipolar Power Control Buttons
Increases or decreases the output power setting for the selected Bipolar mode.

Bipolar Mode Selector
Toggles between Macro, Micro, and Standard Bipolar modes.

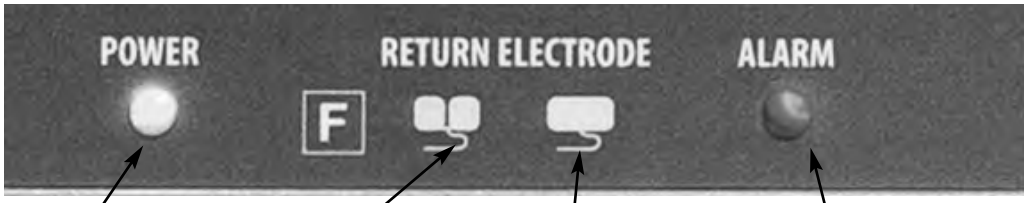
Bipolar Activation Indicator
Illuminates when the Bipolar mode is activated. (illuminates blue)

Macro Mode Indicator
Illuminates green when the Macro Bipolar mode is selected.

Micro Mode Indicator
Illuminates green when the Micro Bipolar mode is selected.

Standard (Std) Mode Indicator
Illuminates green when the Standard Bipolar mode is selected.

INDICATORS



Power Indicator
Illuminates green when the main power is on.

Split Return Electrode Indicator
Illuminates green when the system detects a split plate is properly placed on the patient.

Solid Return Electrode Indicator
Illuminates green when the system detects a single plate.

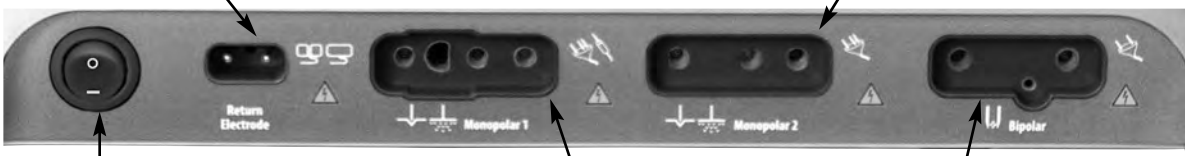
Solid pad indicator only detects that a pad is connected to the unit. The unit does not monitor pad placement on the patient.

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

POWER SWITCH AND RECEPTACLES

Return Electrode Receptacle
Accepts a standard return electrode plug.

Monopolar 2 Handswitching Receptacle
Accepts standard 3-pin handpieces. Connect handswitching accessories.



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

Monopolar 1 Handswitching/ Footswitching Receptacle
Monopolar 1 connector accepts a standard 3-pin monopolar connector or adaptor (A1255A) for foot-controlled accessories.

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

REAR PANEL

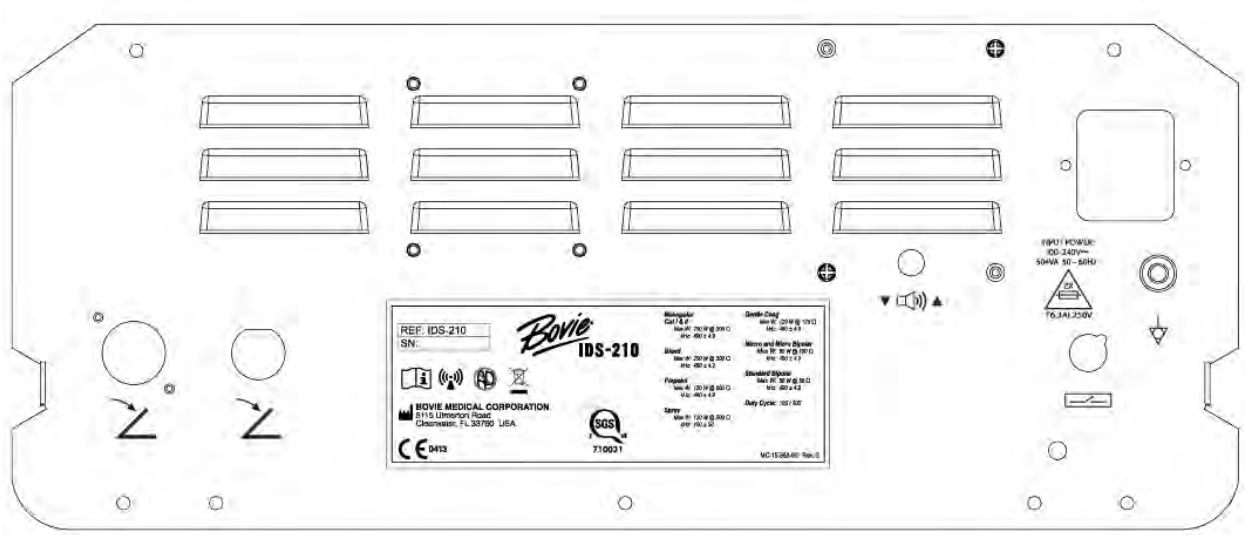


Figure 2 – 2 Layout of connectors and controls on the rear panel

Symbols on the Rear Panel

Refer to the following table for descriptions of symbols found on the rear panel of the Bovie IDS-210.

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 (Far left)
	Bipolar Footswitch Input Jack
	Manufacturer
	Caution, Consult Accompanying Documents
	Do Not Dispose of Unit in Municipal Waste Stream.

NOTICE:
Please note that infected medical devices must be disposed of as medical/biohazard waste and cannot be included in used electronic equipment disposal/recycling programs. In addition, certain electronic products must be returned directly to Bovie Medical Corporation. Contact your Bovie® sales representative for return instructions.

GETTING STARTED

This section includes the following information:

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

INITIAL INSPECTION

When you first unpack your Bovie IDS-210, 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 Medical Corporation's Customer Service immediately. Do not use any damaged equipment.

INSTALLATION

Place the Bovie IDS-210 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.

Do not position unit so that it is difficult to disconnect the power cord from the power source.

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.

NOTICE:
The use of Bovie® accessories is recommended. Refer to accessory Instructions For Use for specific instructions concerning use and safety.

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.
3. Plug the power cable into to a properly grounded wall outlet.
4. Turn the unit on by switching the power switch to the On (—)position. Verify self-test is completed and successful by:
   - A series of test tones completes
   - All Indicators illuminate
   - All digital displays display 8's.
5. If using a footswitch, connect a monopolar footcontrol adaptor (A1255A) to the Monopolar 1 receptacle and connect a Monopolar footswitch into the receptacle located furthest left on the rear of the unit.

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.

PRELIMINARY 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.

USING THE AARON® SURGI-CENTER | PRO

This section contains the following procedures:

- *Inspecting the Generator and Accessories*
- *Setup Safety*
- *Confirming Modes*
- *Setting Up for Surgery*
- *Preparing for Monopolar Surgery*
- *Preparing for Bipolar Surgery*
- *Setting and Recalling Memory Presets*
- *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 Aaron® Surgi-Center | PRO, 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 procedure 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.
Danger: Fire / Explosion Hazard - Do not use the Aaron® Surgi-Center | PRO 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.
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
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.
Active cord removal during activation could result in a shock to the operator at the generator connector plug interface should activation occur by footswitch.
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.
No modification of this equipment is allowed.
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.
To avoid incompatibility and unsafe operation, use suitable cables, accessories, active and neutral electrodes, including values for the highest allowed H.F. peak voltage.
Connected accessories need be rated for at least the maximum peak output voltage of the H.F. generator set at the intended output control setting in the intended operating mode.
The entire area of neutral electrode should be reliably attached to patient's body and as close to operating field as possible.

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. Bovie Medical Corporation recommends the use of split return electrodes and Bovie® 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:
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.

CONFIRMING MODES

Confirm that you can select each mode and adjust the power up and down for each mode including: Cut 1, Cut II, Blend 1, Blend 2, Blend 3, Blend 4, Pinpoint Coag, Spray Coag, Gentle Coag, Macro Bipolar, Micro Bipolar, and Standard Bipolar.

Checking Bipolar Mode (with bipolar footswitch)

1. Plug in the Bipolar footswitch (BV-1254B).

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 and LED under Bipolar display illuminates (blue).

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 (BV-1253B).

2. Connect a solid return electrode to the return electrode receptacle. Verify that the green solid return electrode indicator illuminates.

3. Plug a monopolar footswitching accessory into the Monopolar 1 receptacle.

4. 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 and LED under Cut display illuminates (yellow).

5. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

6. 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.

7. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

> *NOTICES:*
> *Two monopolar handpieces can be connected to the unit at once. Only one monopolar handpiece-can be activated at a time (first come, first serve feature) in the Cut I, Cut II, Blend (1,2,3,4), Pinpoint, and Gentle modes.*
>
> *Dual activation is available ONLY in the Spray mode.*

Checking Monopolar Mode (with handpiece)

1. Connect a handswitching handpiece to the Monopolar 1 and Monopolar 2 handpiece receptacle.

2. Connect a solid return 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 for Monopolar 1 and Monopolar 2. Verify that each control causes the correct indicator and tone to sound.

SETTING UP FOR SURGERY

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:

- 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; a Bipolar mode is selected.
   - Each display shows a power setting. The unit automatically powers up to the last successfully activated mode and power setting.
   - The Patient Return Electrode Alert Indicator illuminates red.

If the self-test is not successful, an alert tone sounds. An error code will be displayed, and 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, Bovie Medical Corporation recommends using a split return electrode and a Bovie® generator with a contact quality monitoring system (Bovie NEM™).

> *NOTICE:*
> *The Bovie NEM™ system recommends that you use a split return electrode.*
>
> *Before activation, pad placement and visual verification of the split return electrode (split pad) indicator on the front panel is recommended. After connecting the split pad to the generator and placing the split pad securely to the patient, give the unit 3 seconds to recognize the split pad. The split pad indicator will illuminate green. If the split pad and cord are attached to the generator without secure contact to the patient, the alert indicator will illuminate red.*

Refer to the return electrode 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 impedance at the contact between the electrode and the patient.

Selecting and Adjusting the Power

1. Select mode for cutting (Cut I, Cut II, Blend).
2. Select the desired power settings for Cutting. Adjustment is preformed by pressing the up or down buttons to the right of the Cut power display.
3. If using Blend, adjust the Blend setting to the desired amount of hemostasis (Blend Level 1-4). Adjustment is preformed by pressing the up or down buttons to the right of the Blend setting indicator. A higher Blend number will increase tissue hemostasis effect.
4. Select the mode of operation for Coagulation (Pinpoint, Spray or Gentle).
5. Select the desired power setting for Coagulation. Adjustment is preformed by pressing the up or down buttons to the right of the

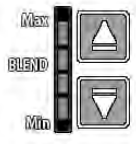
Coag display.

If you are using...	Connect it to...
Standard 3-pin handswitching pencil	Monopolar handswitching receptacle 1 or 2
Footswitching pencil	Monopolar footswitching receptacle 1 (via A1255A)

Connecting Accessories

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

If footswitching control capabilities are preferred, connect the Bovie® monopolar footswitch (BV-1253) to the appropriate monopolar footswitch connecting socket on the rear of the unit.



To activate the Monopolar mode, depress the Cut (yellow) or Coag (blue) button on the monopolar handpiece or the Cut (yellow) or Coag (blue) pedal on the monopolar footswitch.

Blend Controls

Blend settings can be adjusted to a desired amount of hemostasis (Blend Level 1-4). Ascending illuminated bars indicate increased hemostasis levels. Increase and decrease the level of Blend by pressing the Blend level control arrowed buttons.

NOTICE:
There are 4 levels of blend available in the Blend Mode.

PREPARING FOR BIPOLAR SURGERY

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

2. Connect a Bipolar instrument to the bipolar cable.

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

4. Select the mode of operation for Bipolar, either Macro, Micro, or Standard .

5. Select the desired power setting for Bipolar.

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

SETTING AND RECALLING RF MEMORY PRESETS

The Aaron® Surgi-Center | PRO incorporates 10 user-defined RF memory preset settings for easy recall of frequently used settings in all three modes.

RF Memory

The Memory feature allows the Aaron® Surgi-Center | PRO (unit) to display the last activated mode and power setting of the handpiece or footswitch, the unit will operate in that particular mode and power setting. Presets (0-9) save one Cut mode, one Coag mode, and one Bipolar mode and selected power settings.

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, but not saved. User must depress the Set Button until number blinks.

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

Memory Function Overview

- The unit powers up with the last selected preset (0-9). Number, not the Preset mode and power setting.
- Mode (Cut, Coag and Bipolar) membrane switches are disabled during activation.
- Blend level control buttons are disabled during activation.

POWER SETTINGS	INCREMENTS	Example
1-50 Watts	1 Watts	While activated, the Cut 1 power output of 30 watts can be adjusted 4 increments down to 26 watts or 4 increments up to 34 watts.
50-100 Watts	2 Watts	
100-200 Watts	5 Watts	

- 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 increments. Refer to the following table for power increments.
- 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, Spray or Gentle) and power setting, and one Bipolar (Macro, Micro, or Standard) 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 selector membrane level (Cut, Coag, and Bipolar).

If presetting the Blend mode, select the desired level of hemostasis (Blend level 1-4) by pressing the Blend level control button.

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

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 and the small red dot will stop flashing.

To recall a Preset (0-9), repeatedly press the Recall button to toggle through all of the presets until desired preset is acquired.

NOTICES:
The Aaron® Surgi-Center | PRO incorporates 10 factory-set presets that are all set to zero and can be reset to your preferred RF settings.

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.

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, Spray or Gentle) and power setting, and Bipolar (Macro, Micro, or Standard) power setting. When storing, only the information displayed in the display windows will be saved to the unit's memory.

Memory Feature (Last Selected RF Preset)

The Memory feature allows the unit to display the last activated mode and when the generator is turned on.

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

ACTIVATING THE UNIT

NOTICE:
Review Activation Safety on page 13 of this section before activating the unit. When you turn on your unit remember the following feature:

The Aaron® Surgi-Center | PRO will power up to the modes and settings displayed when the unit was last activated. For example, if you set Cut I mode at 50 watts and activate the unit, then turn the unit off, it will automatically return to Cut I mode at 50 watts when you turn it on again. Similarly, if you set Pinpoint mode at 40 watts and activate the unit before you turn it off, it will return to Pinpoint mode at 40 watts when you turn it on again.

1. Monopolar Cut - select the mode of operation for Cut: Cut I, Cut II, or Blend (level 1-4) 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 level by pressing the up and down buttons to the right of the Blend mode level indicator.
3. Monopolar Coag - select the mode of operation for coagulation: Pinpoint, Spray or Gentle, then select the coagulation power settings by pressing the up and down buttons to the right of the Coag power output display.
4. Bipolar - Select the Mode of Operation for Bipolar output (Macro, Micro, or Standard), 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.

6. After use, turn off the generator by pressing the power switch OFF (**O**).
7. Unplug the generator power cord from the grounded receptacle.

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® Surgi-Center | PRO 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 devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pace–maker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.

Avoid using power settings that would exceed the highest maximum voltage that is acceptable for each accessory. Choose only accessories that will withstand each mode and power setting.

To avoid incompatibility and unsafe operation, use suitable cables, accessories, active and neutral electrodes, including values for the highest allowed H.F. peak voltage.

Some accessories have multiple buttons that can deliver different surgical effects. Verify accessory features and proper mode settings prior to activation.

Connected accessories need be rated for at least the maximum peak output voltage of the H.F. generator set at the intended output control setting in the intended operating mode.

Associated equipment and accessories used must be rated to withstand the combination of the maximum Vpeak rating and Crest Factor for the following RF modes: Blend, Pinpoint and Spray.

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings.

Apparent low output or failure of the Aaron® Surgi-Center | PRO RF to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.

When using Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1000 Vpeak max.

When using Blend mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1870 Vpeak max.

When using Coagulation mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 4000 Vpeak max.

When using Bipolar mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 600 Vpeak max.

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.

The entire area of neutral electrode should be reliably attached to patient's body and as close to operating field as possible.

Minor neuromuscular stimulation is possible when arcs between the ACTIVE ELECTRODE and tissue occur. The generator has been designed to minimize the possibility of neuromuscular stimulation.

Accessories must be connected to the proper receptacle type. In particular, Bipolar accessories must be connected to the Bipolar Instrument output jack only. Improper connection may result in unsafe generator power output.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen

should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application if HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in Normal Use of the HF surgical equipment.

The generator is equipped with a return electrode sensing and contact quality monitoring system (NEM), which monitors the quality of the patient return electrode connection. When a correctly functioning single plate return electrode is connected to the generator, the NEM (contact quality monitor) verifies the connections between the generator and the single return electrode. It DOES NOT verify that a single return electrode is in contact with the patient. When using a split return electrode, the NEM (contact quality monitor) confirms the total resistance is within the preset safety range. Proper application and visual inspection of the patient return electrode is required for safe operation.

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.

To avoid the possibility of a burn to the patient, when using a split pad do not activate the unit if the solid pad indicator is illuminated green or the red alert indicator remains illuminated red. This could indicate improper pad placement or a faulty NEM (contact quality monitor) circuit.

Remove any 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.

MAINTAINING THE BOVIE® IDS-210

This section covers the following topics:

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

Bovie Medical Corporation 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 Bovie IDS-210 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 (T6.3AL250V) and replace them with new fuses with the same values.
5. Insert the fuse holder into the Power Cable Receptacle.

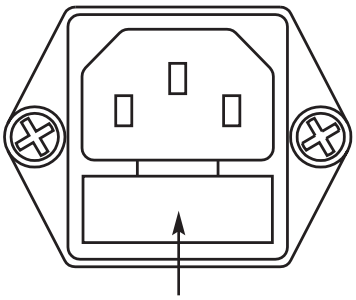


Figure 5 – 1 Fuse holder

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.

The Bovie® IDS-210 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. Power off unit and call 727-384-2323.

NOTICE:
If the unit does not power on and nothing is displayed in the Bipolar display, check fuses as described in Section 5 of this guide.

SYSTEM FAULT CODE MESSAGES

Fault messages (F) indicate improper unit setup or faulty accessories.

Fault Code	Description	Recommended Action
F1	Cut button on handpiece 1 is depressed during power up.	1. If the fault code appears, disconnect all accessories. Turn off, then turn on the generator again. 2. If the problem persists, replace the handpiece or footswitch and repeat the restart. 3. If the fault code reappears, record the number and contact Bovie® customer service at 727-384-2323.
F2	Coag button on handpiece 1 is depressed during power up.	
F3	Cut button on handpiece 2 is depressed during power up.	
F4	Coag button on handpiece 2 is depressed during power up.	
F5	Cut pedal on monopolar footswitch is depressed during power up.	
F6	Coag pedal on monopolar footswitch is depressed during power up.	
F7	Bipolar pedal on bipolar footswitch is depressed during power up.	
F8	Bipolar activation button is depressed during power up.	
F9	Simultaneous activation from a footswitch or handpiece or any combination. *This does not apply to activation of the spray mode*.	
F10	Activation request of a monopolar or bipolar footswitch when no footswitch connection or Bovie® approved footswitch is detected.	
F11	Activation request of a monopolar handpiece 1 when no monopolar footcontrolled handpiece connected to the monopolar handpiece connector 1.	

SYSTEM FATAL ERROR MESSAGES

Error messages (E) indicate internal problems with the unit.

Error Code	Description	Recommended Action
E1	Output Current out of Specification, Digital Check	1. Turn the unit off (*for Temperature Errors, let unit cool for 20 minutes*). 2. Turn the unit on. 3. If the error code reappears, record the number and contact Bovie® customer service at 727-384-2323.
E4	DC Voltage Error	
E5	Temperature Sense Error 1	
E6	Temperature Sense Error 2	
E7	NEM / Autobipolar Error	
E8	NEM Calibration Error	
E9	A/D Error	
E10	Watch Dog Error	
E11	Relay Board Cable Sense Error	
E12	Dosage Error	

REPAIR POLICY AND PROCEDURES

Refer to this section for information on:

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

RESPONSIBILITY OF THE MANUFACTURER

Bovie® 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 Medical Corporation 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 Bovie Medical Corporation instructions for use.

Please note that infected medical devices must be disposed of as medical/biohazard waste and cannot be included in used electronic equipment disposal/recycling programs. In addition, certain electronic products must be returned directly to Bovie Medical Corporation. Contact your Bovie Medical Corporation representative for return instructions.

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

RETURNING THE GENERATOR FOR SERVICE

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

Step 1 – Obtain a Returned Goods Authorization Number

Call the Bovie Medical Corporation 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 / Serial 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 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, Bovie 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 Bovie 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 Medical Corporation Service Center.

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	100-240V~ ± 10%
Mains line frequency range (nominal):	50 – 60 Hz
Power consumption:	560 VA
Fuses (two):	6.3 A (slow blow)

Duty Cycle

Under maximum power settings and rated load conditions (Cut I, 200 watt @ 300 ohm load), the generator is suitable for activation times of 10 seconds ON followed by 30 seconds OFF for 30 minutes.

The internal temperature of the unit is continuously monitored. If the temperature rises above 75^0 C, the alert will sound and output power will be deactivated.

Dimensions and Weight

Width	37.5 cm (14.75 in.)	**Depth**	46 cm (18.1 in.)
Height	16.5 cm (6.5 in.)	**Weight**	< 9.07 kg (< 20 lbs)

Operating Parameters

Ambient temperature range	10° to 40° C
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	70kPa to 106kPa
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

Ambient temperature range	-40˚ to +70˚ C
Relative humidity	10% to 100%, including condensation
Atmospheric pressure	50kPa to 106kPa

Storage

Ambient temperature range	10˚ to 30˚ C
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	50kPa to 106kPa

The device should be stored and used in a room temperature of approximately 77^0 F/25^0 C.

Audio Volume

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

Activation Tone

Volume (adjustable)	≥ 40 dB
Frequency	All Cut Modes: 610 Hz ± 10 Hz
	All Coagulation Modes: 910 Hz ± 10 Hz
	Simultaneous Spray Mode: 1667 Hz ± 50 Hz
	All Bipolar Modes: 910 Hz ± 10 Hz
Duration	Continuous while the generator is activated

Alert Tone

Volume (not adjustable)	> 65 dB

Fault Tone

Volume (not adjustable)	> 65 dB
Audio Fault Tone	2.4 kHz 450 milliseconds / 1.2 kHz 450 milliseconds

Return Electrode Sensing

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

Solid	Trip resistance: 0 Ω to 8 Ω ± 1 Ω Continuous measurement: Once the system establishes the solid return electrode resistance, an increase to 20 Ω - 25 Ω in resistance will cause an alert. When the alert 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 alert. When the alert condition exists, the system deactivates output power.

High Frequency (RF) Leakage Current

Bipolar Micro, Macro leakage current	< 63 mA $_{rms}$
Bipolar Standard leakage current	< 50 mA $_{rms}$
Monopolar RF leakage current	< 150 mA $_{rms}$

Operating Conditions

RF energy is generated and passed through an interconnecting cable to an accessory where the energy is delivered to cut, coagulate and ablate tissue.

STANDARDS AND IEC CLASSIFICATIONS

Class I Equipment (IEC 60601-1)

Equipment protection against electric shock by (Earthed) additional protection to basic insulation through means of connecting exposed conductive parts to the protective Earth in the fixed wiring of the installation.

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

The Bovie IDS-210 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.

Spill Resistance (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 a Bovie IDS-210, 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 Bovie IDS-210 complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

The Bovie IDS-210 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	Max Power	Rated Load	Output Frequency	Repetition Rate	Duty Cycle	Vpeak max	Crest Factor* (Rated Load)
Cut I	200 W	300 Ω	490 kHz ± 4.9 kHz	N/A	N/A	1000V	1.7 ± 20%
Cut II	200 W	300 Ω	490 kHz ± 4.9 kHz	N/A	N/A	750V	1.7 ± 20%
Blend (1)	200 W	300 Ω	490 kHz ± 4.9 kHz	30 kHz ± 5 kHz	75% duty cycle	1320V	1.8 ± 20%
Blend (2)	200 W	300 Ω	490 kHz ± 4.9 kHz	30 kHz ± 5 kHz	62.5% duty cycle	1475V	2.0 ± 20%
Blend (3)	200 W	300 Ω	490 kHz ± 4.9 kHz	30 kHz ± 5 kHz	50% duty cycle	1650V	2.2 ± 20%
Blend (4)	200 W	300 Ω	490 kHz ± 4.9 kHz	30 kHz ± 5 kHz	37.5% duty cycle	1870V	2.4 ± 20%
Pinpoint Coag	120 W	500 Ω	490 kHz ± 4.9 kHz	30 kHz ± 5 kHz	25% duty cycle	1800V	3.1 ± 20%
Spray Coag	120 W	500 Ω	350 to 450 kHz	20 to 45 kHz	5.9 to 14.2% duty cycle	4000V	6.0 ± 20%
Gentle Coag	120 W	125 Ω	490 kHz ± 4.9 kHz	N/A	N/A	450V	1.6 ± 20%
Macro Bipolar	80 W	100 Ω	490 kHz ± 4.9 kHz	N/A	N/A	600V	1.5 ± 20%
Micro Bipolar	80 W	100 Ω	490 kHz ± 4.9 kHz	N/A	N/A	500V	1.5 ± 20%
Standard Bipolar	50 W	50 Ω	490 kHz ± 4.9 kHz	N/A	N/A	250V	1.5 ± 20%

• an indication of a waveform's ability to coagulate bleeders without a cutting effect.

EMC COMPLIANCE

Special precautions should be taken regarding the Bovie IDS-210. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Understand that only the Accessories supplied with or ordered from Bovie® should be used with your device. The use of accessories, transducers, and cables other than those specified, may result in increased Emissions or decreased Immunity of the IDS-210. The Bovie IDS-210 and its accessories are not suitable for interconnection with other equipment.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The Bovie IDS-210™ should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the IDS-210™ should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the IDS–210

The IDS–210 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IDS–210 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IDS–210 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
W			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The IDS–210 is intended for use in the electromagnetic environment listed below. The customer or the user of the IDS–210 should assure that is is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 2	The IDS–210 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The IDS–210 is suitable for use in all establishments other than domestic and those directly connected to the public low–voltage power supply net–work that supplies buildings used in domestic purposes.
Harmonic emissions IEC 61000–3–2	Class A	
Voltage fluctuations/flicker emissions IEC 61000–3–3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The IDS–210 is intended for use in the electromagnetic environment listed below. The customer or the user of the IDS–210 should assure that is is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000–4–2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000–4–4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000–4–5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power sup–ply input lines IEC 61000–4–11	<5 % U_t (<95 % dip in U_t) *for 0.5 cycle* <40 % U_t (<60 % dip in U_t) *for 5 cycles* 70 % U_t (<30 % dip in U_t) *for 25 cycles* <5 % U_t (>95 % dip in U_t) *for 5 sec*	<5 % U_t (<95 % dip in U_t) *for 0.5 cycle* <40 % U_t (<60 % dip in U_t) *for 5 cycles* 70 % U_t (<30 % dip in U_t) *for 25 cycles* <5 % U_t (>95 % dip in U_t) *for 5 sec*	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IDS–210 requires continued operation during power mains interruptions, it is recommended that the IDS– 210 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000–4–8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity continued...			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000–4–6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the IDS–210, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000–4–3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location which the IDS–210 is used exceeds the applicable RF compliance level above, the IDS–210 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IDS–210 . [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

OUTPUT POWER CURVES

Figures A–1 through A–9 llustrate specific output power delivered to a range of load resistances for each mode.

Figure A – 1 Output power versus impedance for CUT I mode

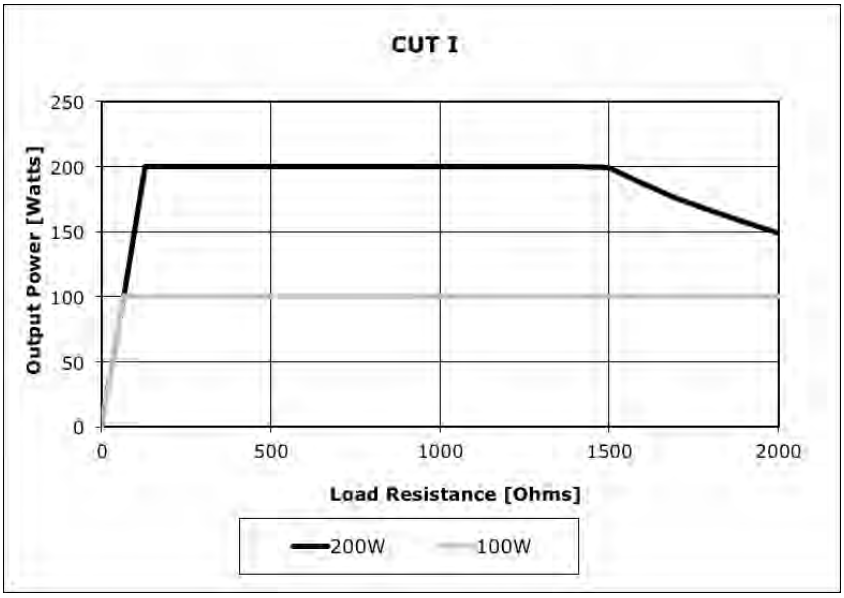


Figure A – 2 Output power versus impedance for CUT II mode

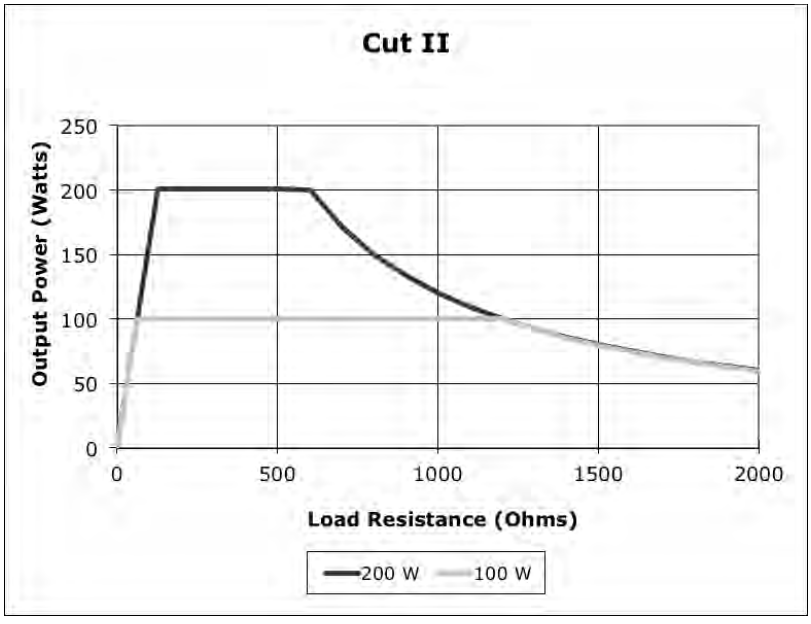


Figure A – 3 Output power versus impedance for BLEND mode (1, 2, 3, 4)

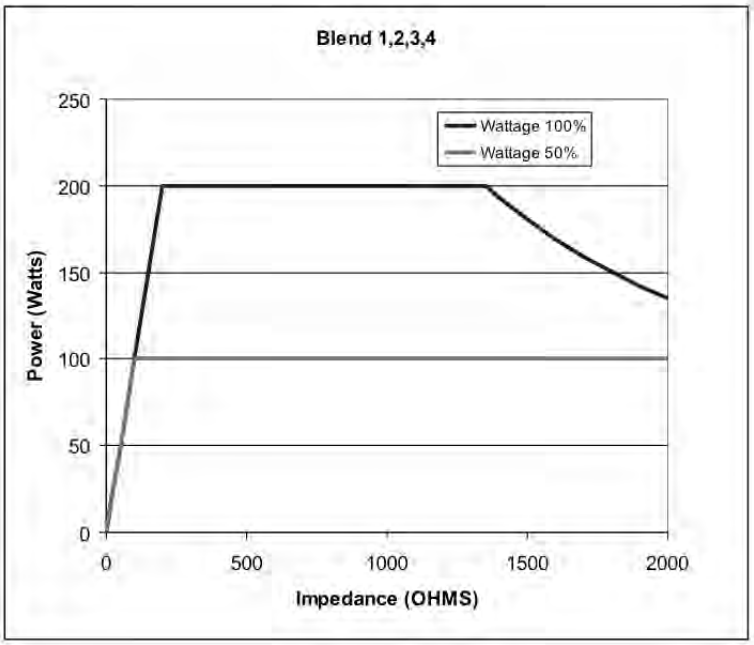


Figure A – 4 Output power versus impedance for PINPOINT COAGULATION mode

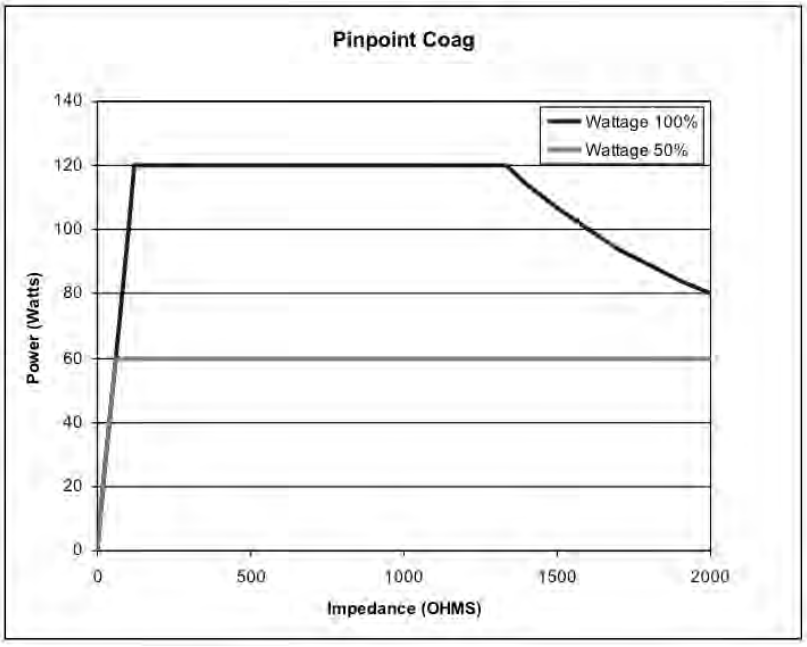


Figure A – 5 Output power versus impedance for SPRAY COAGULATION mode

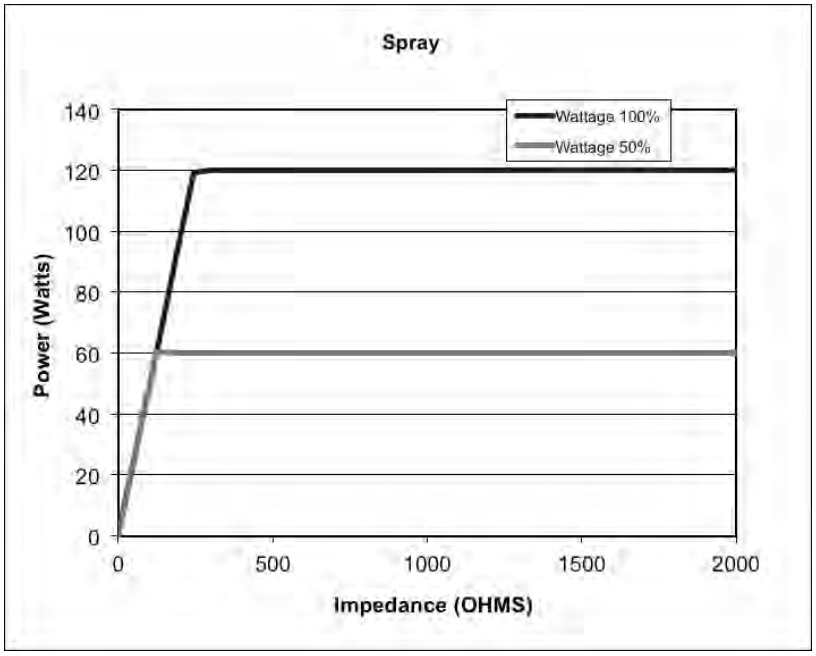


Figure A – 6 Output power versus impedance for GENTLE COAGULATION mode

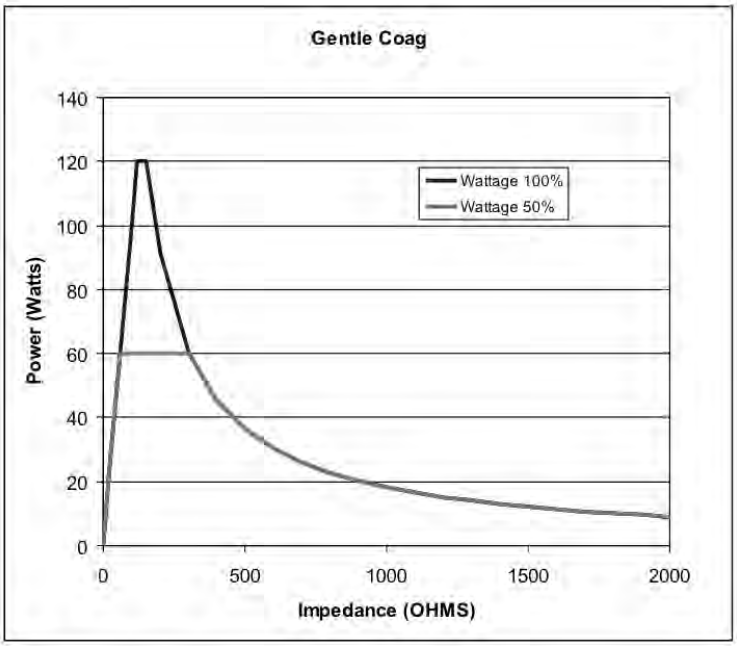


Figure A – 7 Output power versus impedance for MACRO BIPOLAR mode

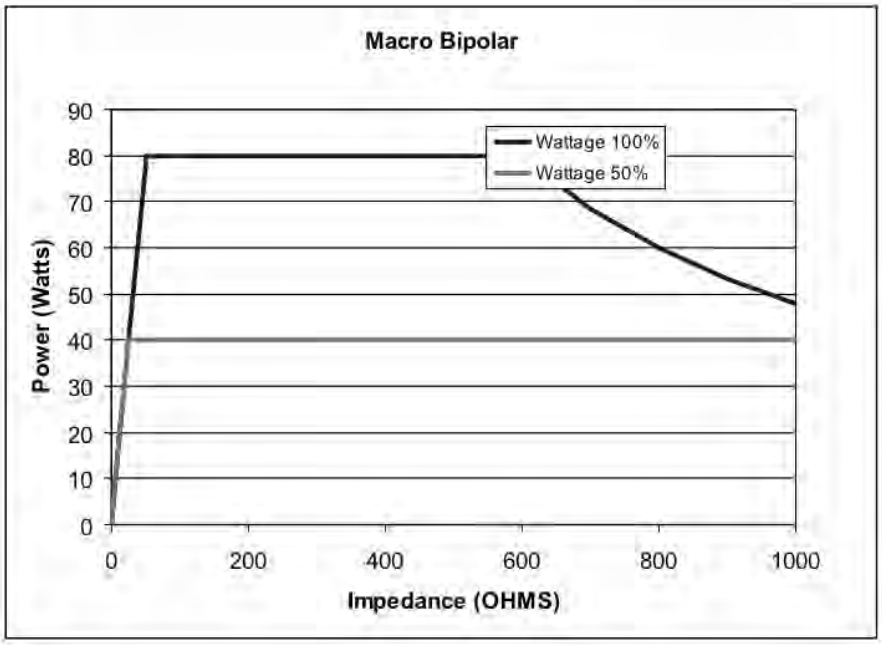


Figure A – 8 Output power versus impedance for MICRO BIPOLARmode

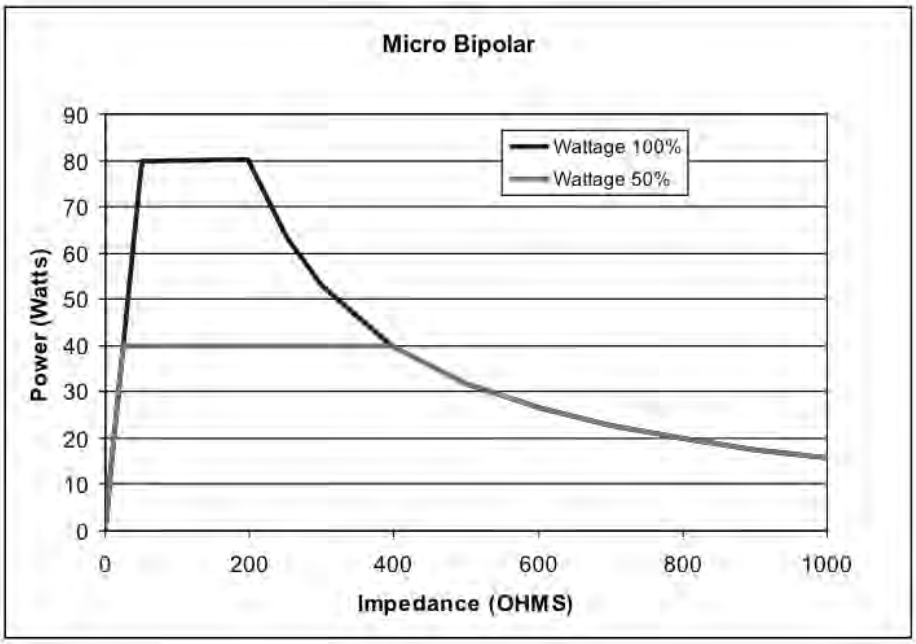
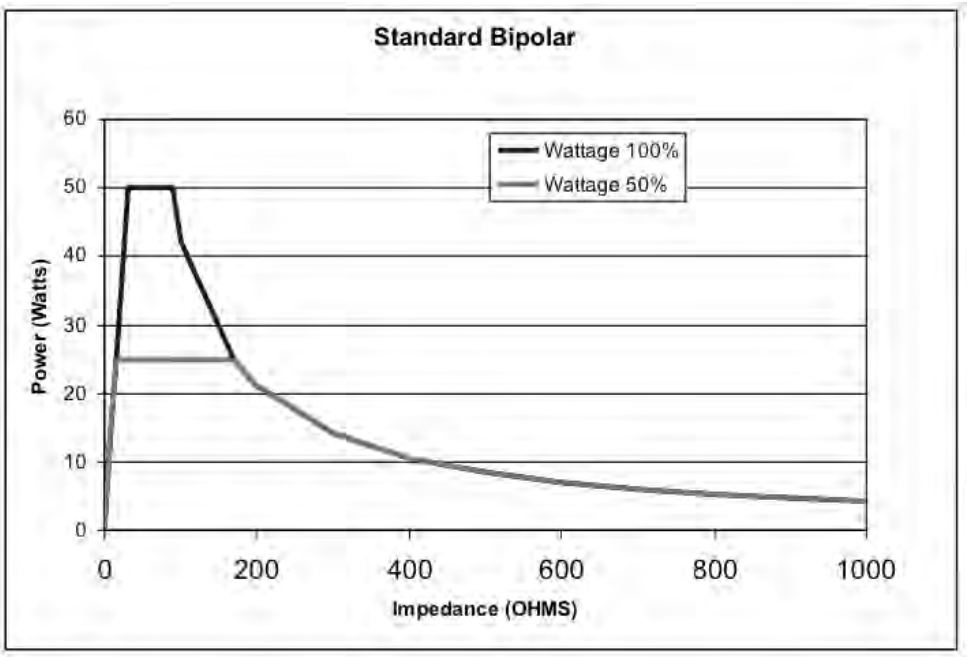


Figure A – 9 Output power versus impedance for STANDARD BIPOLAR mode



WARRANTY

Bovie Medical Corporation, 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 Medical Corporation'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 Medical Corporation'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 Medical Corporation's factory in a way so as, in Bovie Medical Corporation's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

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

- Electrosurgical Generators: Four years from date of shipment
- Mounting Fixtures (all models): Two years from date of shipment
- Footswitches (all models): One year from date of shipment
- Patient Return Electrodes: Shelf life only as stated on packaging
- Sterile Single Use Accessories: Only as stated on packaging
- Handpiece: Only as stated on packaging

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 Medical Corporation.

Bovie Medical Corporation 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 Medical Corporation's products.

Notwithstanding any other provision herein or in any other document or communication, Bovie Medical Corporation'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 Medical Corporation to the customer.

Bovie Medical Corporation 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 Medical Corporation, 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.

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