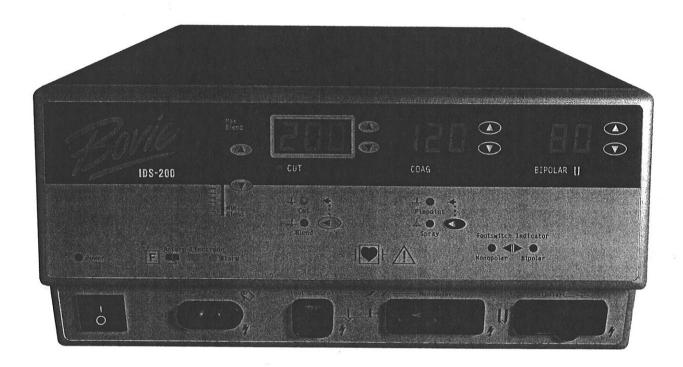


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**USER'S GUIDE** 

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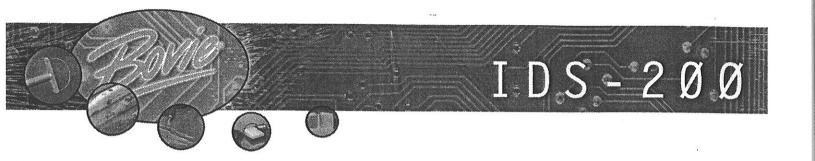
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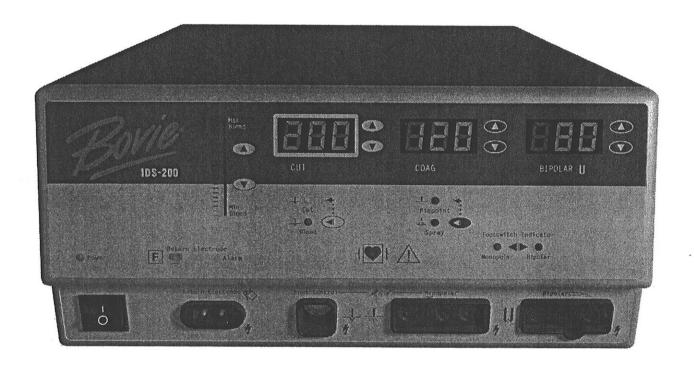
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# **USER'S GUIDE**

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-200 only.

Additional technical information is available in the Bovie IDS-200 Service Guide.

## Equipment Covered in this Manual

Bovie IDS-200:

Reference No.: IDS-200

#### For Information Contact

Bovie Medical • 7100 30th Ave. N. • St. Petersburg, FL 33710-2902 U.S. Phone 1-800-537-2790 Fax 1-800-323-1640 • International Phone +1-727-384-2323 Fax +1-727-347-9144 www.boviemedical.com • info@boviemedical.com



EC Representative: Crownhouse Hornbeam Square North Harrogate, HG2 8PB UK Phone 01423 870 998

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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 BOYIE IDS-200**

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- O Key Features
- O Components and Accessories
- Safety

#### CAUTIONS

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

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

# **KEY FEATURES**

The Bovie IDS-200 includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

#### · Cut Mode

The cut mode gives the surgeon flexibility to cut all types of tissue without losing performance.

The Cut mode generates constant output power over a wide range of impedances. Refer to Figure A-1 in the *Technical Specifications* section of this guide.

#### · Blend with 10 Settings

The Blend mode is a combination of Cutting and Hemostasis. The IDS-200 gives the surgeon freedom to adjust the desired level of hemostasis. A setting of 1 is minimal blend with maximum cutting effect. A setting of 10 is maximum hemostasis (blend) with minimal cutting effect. This adjustment is easily achieved by a incremental adjustment. Refer to Section 2, *Controls, Indicators, and Receptacles, Cut and Blend Controls.* The Blend mode improves the rate of targeted tissue desiccation without increasing the power delivered by the generator.

#### Two levels of coagulation: Pinpoint and Spray

Pinpoint provides precise control of bleeding in localized areas. Spray provides greater control of bleeding in highly vascular tissue over broad surface areas.

#### · Return electrode sensing and contact quality monitoring

The IDS-200 incorporates a return electrode contact quality monitoring system (Bovie NEM™). This system detects the type of return electrode: solid or split. The system also continually monitors the contact quality between the patient and the split return electrode. This feature is designed to minimize patient burns at the return electrode site.

#### FDFS™ (Fast Digital Feedback System)

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

#### NOTICE:

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

#### · Isolated RF output

This minimizes the potential of alternate site burns.

#### Standard connectors

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

#### Self diagnostics

These diagnostics continually monitor the unit to ensure proper performance.

# **COMPONENTS AND ACCESSORIES**

You should receive the following components with your generator:

- · Bovie IDS-200
- Hospital-grade power cord (110 VAC and 220 VAC)
- · User's Guide
- · Service Guide

## SAFETY

The safe and effective use of electrosurgery depends to a large degree on factors solely under the control of the operator. There is no substitute for a properly trained and vigilant medical staff. It is important that they read, understand, and follow the operating instructions supplied with this electrosurgical equipment.

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-200, 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-200 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<sub>2</sub>0] atmospheres).

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

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

**Electric Shock Hazard** - Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

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

Fire Hazard - Do not use extension cords.

**Patient Safety** - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

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

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

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

#### **WARNINGS:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Remove any loose fitting jewelry from the patient before activation.

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

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

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

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

#### **NOTICES:**

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

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

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# SECTION SECTION

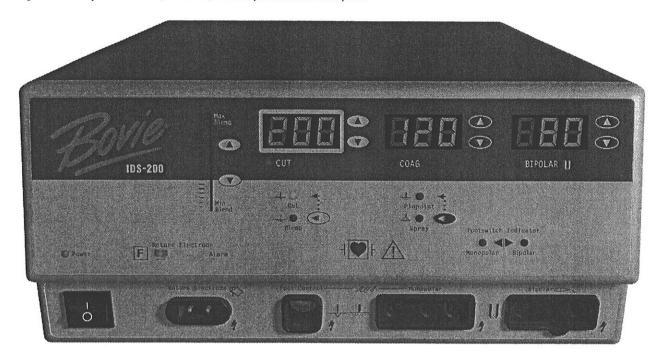
# **CONTROLS, INDICATORS, AND RECEPTACLES**

This section describes:

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

# FRONT PANEL

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



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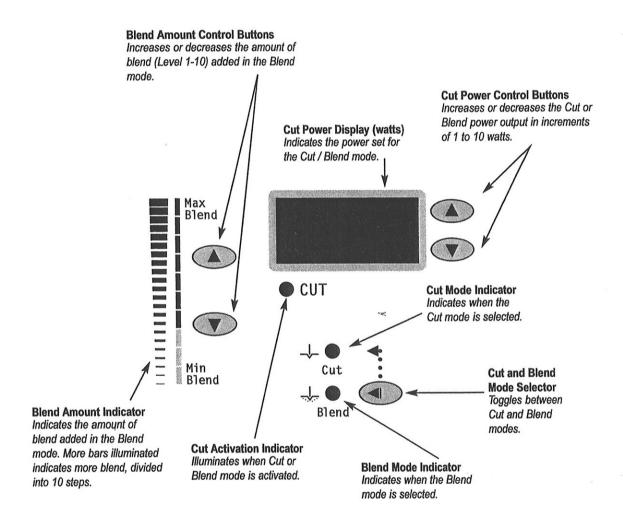
# Symbols on the Front Panel

SYMBOLS	DESCRIPTION			
Cut Controls				
<del>_</del>	Cut Mode			
	Blend Mode			
Coag Controls				
They are	Pinpoint Mode			
<del></del>	Spray Mode			
Bipolar Controls				
(,,)	Bipolar Mode			
Indicators				
	Split Return Electrode			
5	Solid Return Electrode			
Regulatory Symbo	ology			
$\triangle$	Read instructions before use.			
-  <b> </b>	Defibrillator Proof Type CF Equipment			
F	RF Isolated – patient connections are isolated from earth at high frequency.			
Power Switch and	Handpiece Connectors			
<b>(</b>	Return Electrode Receptacle			
Caution High Voltage				
Cut Mode				
Coag Mode				
RU1	Monopolar Handpiece Receptacle			
(,)	Bipolar Mode			
	Bipolar Handpiece Receptacle			

# **CUT AND BLEND CONTROLS**

Figure 2 - 2 Controls for the Cut and Blend modes



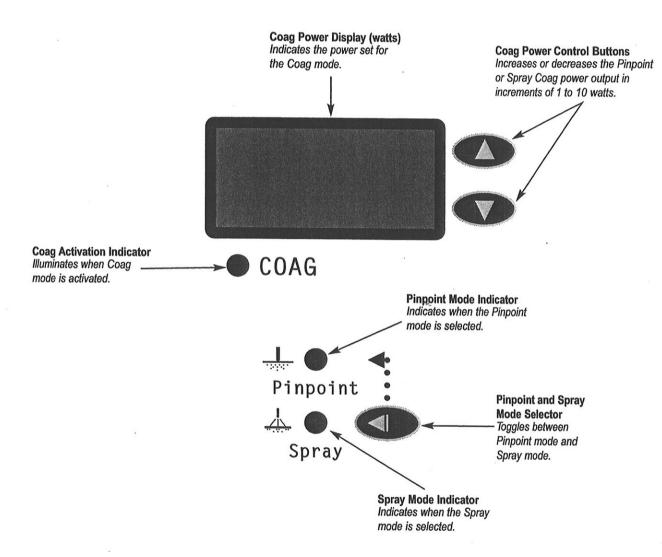


#### NOTICE:

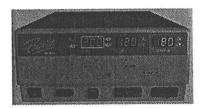
When selecting the Blend mode, the unit defaults to a setting of minimum blend (only the first bar is illuminated).

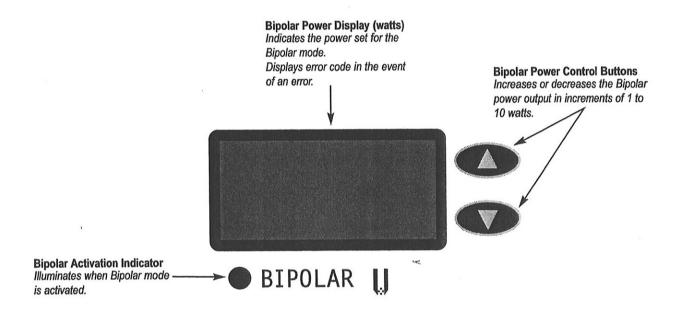
# **COAG CONTROLS**Figure 2 – 3 Controls for the Coag mode





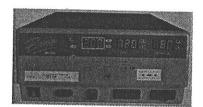
# **BIPOLAR CONTROLS**Figure 2 – 4 Controls for the Bipolar mode

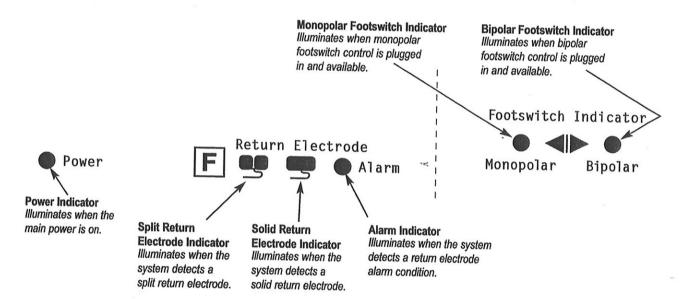




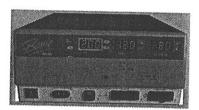
# **INDICATORS**

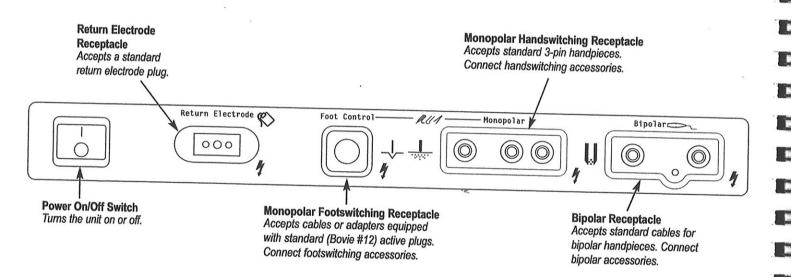
Figure 2 – 5 Indicators for power, return electrodes, and footswitch control



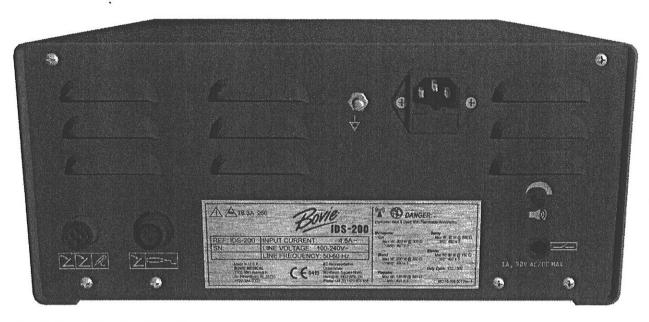


# **POWER SWITCH AND RECEPTACLES**Figure 2 – 6 Location of the unit power switch and front panel receptacles





**REAR PANEL**Figure 2 – 7 Layout of connectors and controls on the rear panel



# Symbols on the Rear Panel

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

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# **GETTING STARTED**

This section includes the following information:

- O Initial Inspection
- O Installation
- O Function Checks
- O Performance Checks

# INITIAL INSPECTION

When you first unpack your Bovie IDS-200, 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's Customer Service immediately. Do not use any damaged equipment.

# INSTALLATION

Place the Bovie IDS-200 on any flat surface with a tilt angle not more than 10°. The unit relies on natural convection cooling. Do not block its bottom or rear vents. Ensure that air flows freely on all sides of the unit.

#### WARNING:

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

# **FUNCTION CHECKS**

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

#### WARNING

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

## Setting Up the Unit

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

#### Checking the Return Electrode Alarm

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

### **Confirming Modes**

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

## Checking Bipolar Mode (with bipolar footswitch)

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

# Checking Monopolar Mode (with monopolar footswitch)

- 1. Plug in the Monopolar footswitch. Verify that the monopolar footswitch indicator illuminates.
- 2. Connect a solid return electrode to the return electrode receptacle. Verify that the green solid return electrode indicator illuminates.
- 3. Press the Cut pedal (yellow) on the footswitch. Verify that the Cut mode activation indicator illuminates and that the system generates the Cut activation tone.
- 4. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
- 5. Press the Coag pedal (blue) on the footswitch. Verify that the Coag mode activation indicator illuminates and that the system generates the Coag activation tone.
- 6. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

# Checking Monopolar Mode (with handswitch)

- 1. Connect a handswitching handpiece to the Monopolar handpiece receptacle.
- 2. Connect a 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. Verify that each control causes the correct indicator and tone to sound.

# PERFORMANCE CHECKS

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

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# **USING THE BOVIE IDS-200**

This section contains the following procedures:

- O Inspecting the Generator and Accessories
- O Setup Safety
- O Setting Up
- O Preparing for Monopolar Surgery
- O Preparing for Bipolar Surgery
- O Activating the Unit
- O 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 Bovie IDS-200, verify that the unit and all accessories are in good working order:

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

## SETUP SAFETY

#### **WARNINGS**

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

**Electric Shock Hazard** - Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

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

Fire Hazard - Do not use extension cords.

Patient Safety - Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

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

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

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

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

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

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

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

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

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

#### CAUTIONS:

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

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

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

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

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

#### NOTICE:

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

## SETTING UP

- 1. Verify that the generator is Off by pressing the power switch Off (0).
- 2. Place the generator on a stable flat surface, such as a table, platform, or medical cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes. Provide at least 10 to 15 cm (4 to 6 in.) of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.
- 3. Plug the generator power cord into the AC Power Cable Receptacle on the rear panel.
- 4. Plug the generator power cord into a grounded receptacle.
- 5. Turn on the generator by pressing the power switch On (|). Verify the following:
  - All visual indicators and displays on the front panel illuminate.
  - · Activation tones sound to verify that the speaker is working properly.
- 6. If the self-test is successful, a tone sounds. Verify the following:
  - A Cut mode is selected; a Coag mode is selected.
  - · Each display shows a power setting. The unit automatically powers up to the last used power settings.
  - · The Patient Return Electrode Alarm Indicator illuminates red.

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

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

# PREPARING FOR MONOPOLAR SURGERY

Monopolar surgery requires a return electrode.

## Applying the Return Electrode

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

#### NOTICE:

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

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

- Connect the cable to the Return Electrode receptacle on the front of the unit.
   The unit will automatically sense the presence of a split or solid return electrode and, if a split return electrode is used, will constantly monitor the resistance at the contact between the electrode and the patient.
- 2. Adjust the Blend setting to the desired amount of hemostasis (Level 1 10). Adjustment is preformed by pressing the up or down buttons next to the Blend setting indicator.

Select the desired power settings for Cutting. Adjustment is preformed by pressing the up or down buttons next to the Cut display. Select the mode of operation for Coagulation, either Pinpoint or Spray.

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

# **Connecting Accessories**

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

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

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

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

1

# PREPARING FOR BIPOLAR SURGERY

- 1. Connect a Bipolar cable to the Bipolar receptacle on the front of the unit.
- 2. Connect a forceps instrument to the bipolar cable.
- 3. Connect the bipolar footswitch to the bipolar footswitch connecting socket located on the rear of the unit.

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

## **ACTIVATING THE UNIT**

#### NOTICE:

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

The Bovie IDS-200 will power up to the settings displayed when the unit was last activated. For example, if you set the Cut mode at 50 watts and activate the unit, then turn the unit off, it will automatically return to Cut 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.

During activation, the activated mode can be adjusted up and or down a maximum of four steps. Refer to the following table for power increments.

POWER SETTINGS	INCREMENTS	FOR INSTANCE
1-50 Watts	1 Watts	
51-100 Watts	2 Watts	While activated, the Cut power output of 30 watts can be adjusted 4 steps down to 26 watts or 4 steps up to 34 watts.
101-200 Watts	5 Watts	- 4 steps down to 20 waits of 4 steps up to 34 waits.

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

#### NOTICE:

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

# **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 Bovie IDS-200 in the presence of flammable anesthetics.

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

- · Flammable substances (such as alcohol based skin prepping agents and tinctures)
- · Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
- · Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N<sub>2</sub>O] atmospheres).

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

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

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

#### CAUTIONS:

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

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

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

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

Remove any jewelry from the patient before activation.

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

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

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

 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-200**

This section covers the following topics:

- O Cleaning
- O Periodic Inspection
- O Fuse Replacement

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

## **CLEANING**

After each use, clean the unit.

#### WARNING:

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

#### NOTICE:

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

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

## PERIODIC INSPECTION

Every six months, visually inspect the Bovie IDS-200 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.
- To release the fuse drawer, insert a small flathead screwdriver into the slot on the drawer below the power cord receptacle. Then, slide the drawer out.
- 4. Remove the two fuses and replace them with new fuses with the same values.
- 5. Insert the fuse holder into the Power Cable Receptacle.

#### NOTICE:

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

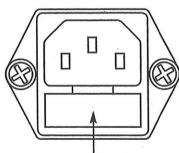
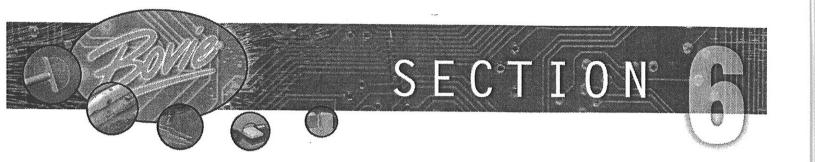


Figure 5 - 1 Fuse holder



# **TROUBLESHOOTING**

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

The Bovie IDS-200 includes automatic self-diagnostics. If the diagnostics detect an error, the system displays an error code, sounds an audible tone, and deactivates the unit output power.

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

All error codes are displayed in the Bipolar display.

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

Error Code	Description	Recommended Action	
F1	Cut handpiece button may be stuck		
F2	Coag handpiece button may be stuck	Turn off, then turn on the generator. Do not press buttons or activate accessory devices during the self-test.      If the error gode responsers discount to the control of the contr	
F3	Cut footswitch pedal may be stuck	If the error code reappears, disconnect all accessories.  Turn off, then turn on the generator again.	
F4	Coag footswitch pedal may be stuck	If the problem persists, replace the handpiece of footswitch and repeat the restart.	
F5	Bipolar footswitch pedal may be stuck	If the error code reappears, record the number and call Bovie customer service.	
F6	Simultaneous activation error	The unit does not allow simultaneous activation of the cut and coagulation modes. The activation mode is "first come, first serve."  This means that whichever mode is selected first will be the function the unit is activated to dispense. An example of this functionality includes, when the handpiece Cut button is pressed, the unit is activated for Cut. If a footswitch is simultaneously pressed for Coag, the unit we continue in the Cut mode as long as the handpiece Cut button is pressed. If the Cut button is released, the unit will sense an error and both functions will be disabled.  1. Release either the cut or coag button on the handpiece, or the cut or coag pedal on the footswitch.  2. If the error code reappears, record the number and contact Bovie customer service.	
E1	Output current out of specification	1. Turn the unit off.	
E2	Dosage voltage error	2. Turn the unit on.	
E3	Dosage current error	<ol><li>If the error code reappears, record the number and contact Bovie customer service.</li></ol>	
E4	DC power error		
E5		1. Turn the unit off.	
E6	Internal temperature of a section of the unit exceeded the limit.	Allow the unit to cool for 20 minutes.     Turn the unit on.	
E7		<ol><li>If the error code reappears, record the number and contact Bovie customer service.</li></ol>	
E8	NEM circuit error	<ol> <li>Turn the unit off.</li> <li>Turn the unit on.</li> <li>If the error code reappears, record the number and contact Bovie customer service.</li> </ol>	

#### NOTICE:

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

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# **REPAIR POLICY AND PROCEDURES**

Refer to this section for information on:

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

### RESPONSIBILITY OF THE MANUFACTURER

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

- The user has followed the Installation and Setup Procedures in this User's Guide.
- · Persons authorized by Bovie Medical 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 instructions for use.

For warranty information, refer to Appendix C - Warranty.

#### RETURNING THE GENERATOR FOR SERVICE

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

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

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

- · Hospital / clinic name / customer number
- Telephone number/fax number
- · Department / address, city, state, and zip code
- · Model number

- · Description of the problem
- · Type of repair to be done
- · P.O. number

#### Step 2 - Clean the Generator

#### WARNING:

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

#### 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 Service Center.



# **TECHNICAL SPECIFICATIONS**

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

## PERFORMANCE CHARACTERISTICS

#### Input Power

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

#### **Duty Cycle**

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

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

### **Dimensions and Weight**

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

### **Operating Parameters**

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

#### **Transport and Storage**

Generator should fit on all standard Carts for monopolar generators. The device should be stored and used in a room temperature of approximately 770 F/250 C.

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

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#### Audio Volume

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

#### **Activation Tone**

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

#### **Alarm Tone**

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

## Return Electrode Sensing

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

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

## Low Frequency (50-60 Hz) Leakage Current

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

#### High Frequency (RF) Leakage Current

Bipolar RF leakage current	< 63 mA <sub>rms at 80 watts</sub>
Monopolar RF leakage current (additional tolerance)	< 150 mA <sub>rms</sub>

#### STANDARDS AND IEC CLASSIFICATIONS

#### Class I Equipment (IEC 60601-1)

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

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



The Bovie IDS-200 provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF equipment. Patient connections are isolated from earth and resist the effects of defibrillator discharge.

#### **Drip Proof (IEC 60601-2-2)**

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

#### Electromagnetic Interference

When other equipment is placed on or beneath a Bovie IDS-200, 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-200 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-200 operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

## **OUTPUT CHARACTERISTICS**

## Maximum Output for Monopolar and Bipolar Modes

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

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

## **OUTPUT POWER CURVES**

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

Figure A - 1 Output power vs impedance for Cut mode

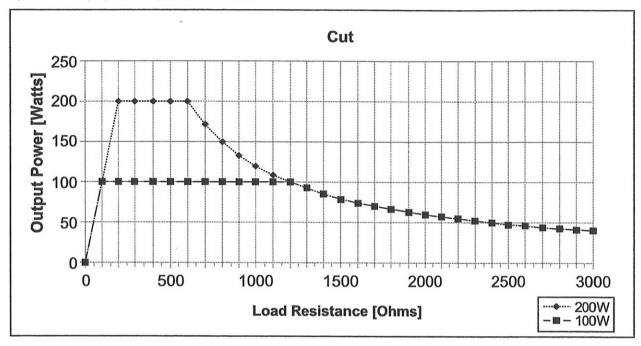


Figure A - 2 Output power versus impedance for Blend I mode

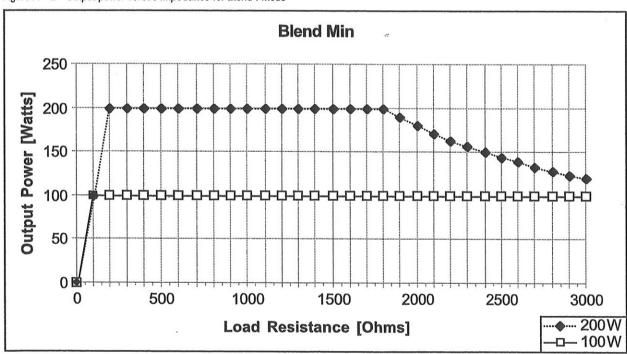


Figure A - 3 Output power versus impedance for Blend II mode

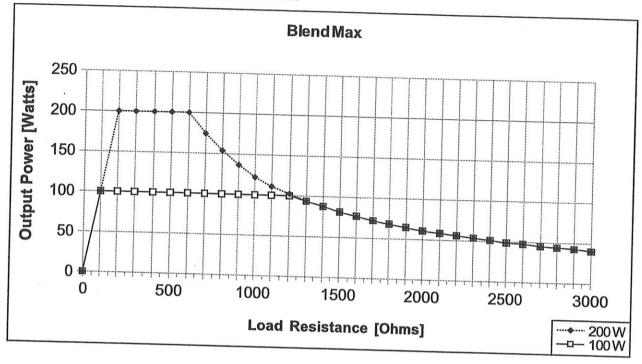


Figure A – 4 Output power vs impedance for Pinpoint mode

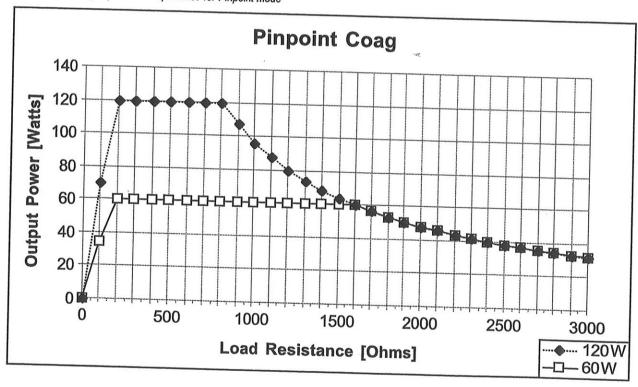


Figure A – 5 Output power vs impedance for Spray mode

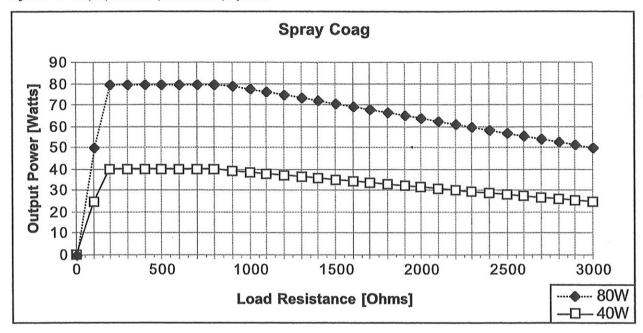
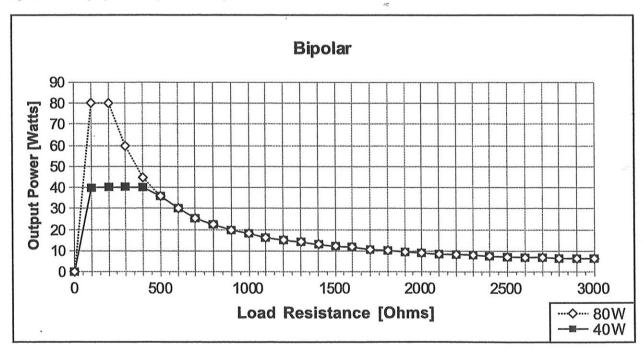


Figure A - 6 Output power vs impedance for Bipolar mode





# **ACCESSORIES**

The accessories listed in this section are recommended for use with the Bovie IDS-200. Ensure all accessories are rated for at least the maximum peak output voltage of the generator.

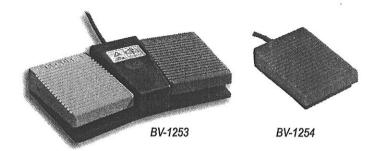
#### **FOOTSWITCHES**

BV-1253

Bovie IDS Monopolar Footswitch, Box/1

BV-1254

Bovie IDS Bipolar Footswitch, Box/1



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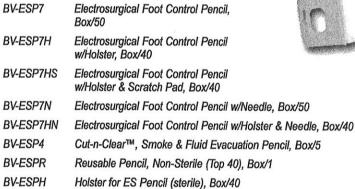
#### **ELECTROSURGICAL PENCILS**

The standard Bovie pencils feature button, rocker and foot control available with and without holster and scratch pad. Also available is the Bovie smoke evacuation pencil (BV-ESP4). All disposable pencils are packaged individually and are sterile.

Additionally, Bovie offers a reusable pencil (BV-ESPR). The pencil is validated to forty (40) autoclave cycles. The BV-ESPR is shipped non-sterile.

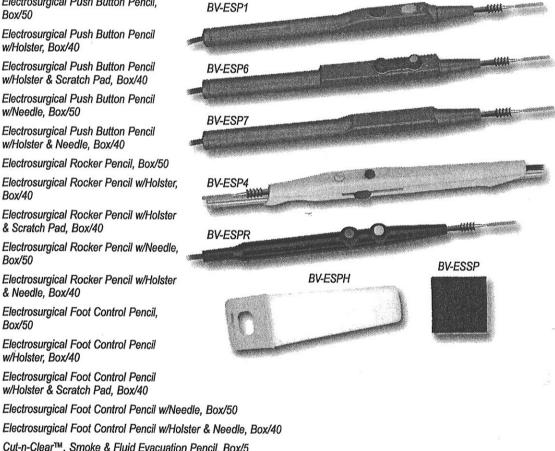
BV-ESP1 Electrosurgical Push Button Pencil, Box/50 **BV-ESP1H** Electrosurgical Push Button Pencil w/Holster, Box/40 **BV-ESP1HS** Electrosurgical Push Button Pencil w/Holster & Scratch Pad, Box/40 **BV-ESP1N** Electrosurgical Push Button Pencil w/Needle, Box/50 **BV-ESP1HN** Electrosurgical Push Button Pencil w/Holster & Needle, Box/40 **BV-ESP6** Electrosurgical Rocker Pencil, Box/50 BV-ESP6H Electrosurgical Rocker Pencil w/Holster, Box/40 **BV-ESP6HS** Electrosurgical Rocker Pencil w/Holster & Scratch Pad. Box/40 BV-ESP6N Electrosurgical Rocker Pencil w/Needle, Box/50 **BV-ESP6HN** 

& Needle, Box/40



Adapter plug for connecting footswitching pencil to the Bovie IDS Series, Box/1 (not pictured)

Scratch Pads (sterile), Box/40

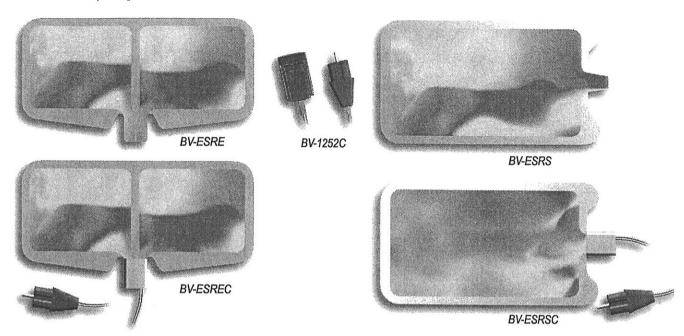


**BV-ESSP** 

BV-1255A

### RETURN ELECTRODES

Bovie disposable return electrodes with super adhesive gel are designed for single use with safety and quality built in. Where reusability is requested a reusable electrode and cable are available.



**BV-ESRE** Disposable Split Adult Return Electrode w/o Cable, Box/50 **BV-ESRS** Disposable Solid Adult Return Electrode w/o Cable, Box/50

BV-1252C Reusable Connecting Cord for ESRE & ESRS to A1250 & A2100, Box/1

**BV-ESREC** Disposable Split Adult Return Electrode w/2.8M Cable, Box/50 **BV-ESRSC** Disposable Solid Adult Return Electrode w/2.8M Cable, Box/50

## **DISPOSABLE ACTIVE ELECTRODES**

All electrodes utilize the standard 3/32" stainless steel shafts. All electrodes feature safety grip insulators combining patient and user safety with easy insertion into and removal from the surgical pencil. All disposable electrodes are manufactured to the highest standards.

They come individually packaged and sterile.

#### **Blade Electrodes**

BV-ES01 Standard Blade, BV-ES01 Box/50 BV-ES37 Modified Blade, Box/25 BV-ES18 BV-ES37 BV-ES18 Angled Blade, Box/25 BV-ES04 BV-ES04 Extended Blade, Box/25 BV-ES39 Extended Modified BV-ES39 Blade, Box/25

#### **Needle Electrodes**

BV-ES17 Flexible Tip, Box/25 BV-ES17 BV-ES02 Standard Needle, Box/25 BV-ES02 BV-ES38 BV-ES38 Modified Needle. Box/25 BV-ES03 BV-ES03 Extended Needle, Box/25 BV-ES40 BV-ES40 **Extended Modified** Needle, Box/25

#### **Ball Electrodes**

BV-ES20 %" Ball, Box/25



## **LLETZ ELECTRODES**

All Bovie LLETZ Loop and Square electrodes feature tungsten wire for superior shape and integrity throughout the excision procedure. All loops are packaged with a unique protective shell to prevent damage during shipping. Ball electrodes are available in 3mm & 5mm sizes for fulguration and desiccation while the needle electrodes are available for pinpoint coagulation.

#### **Ball Electrodes**

BV-ES06 Extended 3mm Ball, Box/5

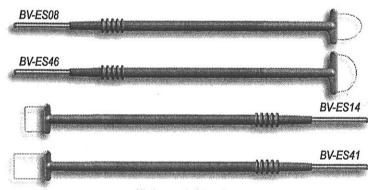
BV-ES07 Extended 5mm Ball, Box/5



#### **Loop Electrodes**

LOOP LICE	10003
BV-ES08	5mm X 5mm Loop, Box/5
BV-ES09	10mm X 10mm Loop, Box/5
BV-ES10	15mm X 8mm Loop, Box/5
BV-ES11	15mm X 10mm Loop, Box/5
BV-ES12	20mm X 8mm Loop, Box/5
BV-ES13	20mm X 15mm Loop, Box/5
BV-ES31	20mm X 20mm Loop, Box/5
BV-ES42	20mm X 12mm Loop, Box/5
BV-ES43	15mm x 15mm Loop, Box/5
BV-ES44	15mm x 5mm Loop, Box/5
BV-ES45	13mm x 13mm Loop, Box/5
BV-ES46	10mm x 5mm Loop, Box/5
BV-ES47	25mm x 10mm Loop, Box/5
BV-ES41	5mm X 10mm Square, Box/5
BV-ES14	5mm X 5 mm Square, Box/5
BV-ES15	10mm X 4mm Square, Box/5

10mm X 8mm Square, Box/5



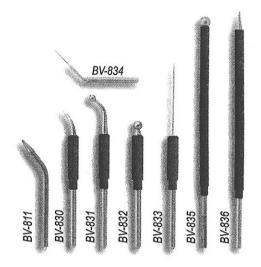
All sizes not pictured.

BV-ES16

1

## REUSABLE ACTIVE ELECTRODES

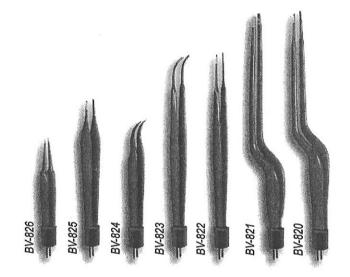
ILLOUAL	JLL AVIIVE LLLVI
BV-834	Angled, Fine Needle, Box/1
BV-811	Reusable Electrode, Box/1
BV-830	Angled, Sharp Electrode, Box/1
BV-831	Short Angled, Ball, Box/1
BV-832	Short Straight, Ball, Box/1
BV-833	Short Straight, Needle, Box/1
BV-835	Long, Straight Ball, Box/1
BV-836	Long, Straight Needle, Box/1

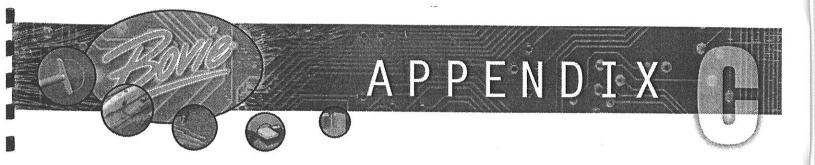


## **BIPOLAR FORCEPS (REUSABLE)**

Reusable Bipolar Forceps are available in micro, 1.0 and 2.0mm tip size and in lengths ranging from 4.5" to 8". These forceps are guaranteed for twenty (20) cycles of autoclaving. A reusable bipolar cord is also available with quality silicone construction.

BV-827	Forceps Cord, Box/1 (not pictured)
BV-826	5" Straight, Fine, Smooth, Box/1
BV-825	5 1/2" Straight, Med., Smooth, Box/1
BV-824	5" Curved, Fine, Smooth, Box/1
BV-823	7" Curved, Fine, Smooth, Box/1
BV-822	7" Straight, Fine, Smooth, Box/1
BV-821	7 1/2" Bayonet, Med., Smooth, Box/1
BV-820	7 1/2" Bayonet, Fine, Smooth, Box/1





## WARRANTY

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

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

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

The warranty periods for Bovie Medical products are as follows:

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

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.

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

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

There are no warranties which extend beyond the terms hereof.

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

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

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

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

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