

Bovie®



BANTAM PRO

**Electrosurgical Generator and
High-Frequency Desiccator**

User's Guide

BANTAM | PRO



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 Bantam Pro Electrosurgical Generator only.

Additional technical information is available in the Bantam Pro Service Guide.

Equipment Covered in this Manual

Bovie Bantam Pro Electrosurgical Generator:
Model No.: A952

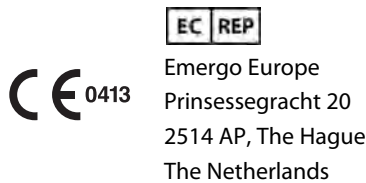
For Information Call

Bovie Medical • Clearwater, FL
www.BovieMedical.com • Sales@BovieMed.com
U.S. Phone 1 800 537 2790 • Int'l. Phone +1 727 384 2323

©2018 Bovie Medical Corporation. All rights reserved. Contents of this publication may not be reproduced without the written permission of Bovie Medical Corporation.

Bovie Part Number: MC-55-238-001 Rev. 1

Manufactured by Bovie Medical Corporation.



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.

TABLE OF CONTENTS

Equipment Covered in this Manual	iii
For Information Call	iii
Conventions Used in this Guide	iii
Introducing the Bantam Pro Electrosurgical Generator	1-1
Key Features	1-2
Components and Accessories	1-3
Safety	1-3
Contraindications	1-7
Application Specifications	1-7
Controls, Indicators, and Receptacles	2-1
Front Panel	2-2
Symbols on the Front Panel	2-3
Front Panel Controls	2-4
Indicators and Receptacles	2-5
Rear and Side Panels	2-6
Symbols on the Rear and Side Panels	2-6
Getting Started	3-1
Initial Inspection	3-2
Installing the Unit	3-2
Using the Bantam Pro	4-1
Inspecting the Generator and Accessories	4-2
Setup Safety	4-2
Setting Up	4-3
Preparing for Monopolar Surgery	4-4
Applying the Patient Return Electrode	4-4
Preparing for Bipolar Surgery	4-5
Activation Safety	4-6
Activating the Unit	4-7
Monopolar Activation	4-7
Bipolar Activation	4-7
Maintaining the Bantam Pro	5-1
Cleaning	5-2
Periodic Inspection	5-2
Fuse Replacement	5-2
Service and Repair	5-3
Troubleshooting	6-1
System Fault Code Messages	6-2
System Fatal Error Messages	6-2
Repair Policy and Procedures	7-1
Responsibility of the Manufacturer	7-2
Returning the Generator for Service	7-2
Step 1 – Obtain a Returned Goods Authorization Number	7-2
Step 2 – Clean the Generator	7-2
Step 3 – Ship the Generator	7-2

Technical Specifications	A-1
Performance Characteristics	A-2
Input Power	A-2
Duty Cycle	A-2
Dimensions and Weight.....	A-2
Operating Parameters.....	A-2
Transport	A-2
Storage	A-2
Audio Volume	A-3
Return Electrode Sensing.....	A-3
Low Frequency (50–60 Hz) Leakage Current	A-3
High Frequency (RF) Leakage Current.....	A-4
Operating Conditions	A-4
Standards and IEC Classifications	A-4
Class I Equipment (IEC 60601-1)	A-4
Type BF Equipment (IEC 60601-1)	A-4
Ingress Protection Rating (EN 60529)	A-4
Electromagnetic Interference.....	A-4
Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)	A-4
Voltage Transients (Emergency Generator Mains Transfer)	A-4
EMC Compliance.....	A-4
Output Characteristics	A-8
Maximum Output for Bipolar and Monopolar Modes.....	A-8
Output Power Curves	A-9
Warranty	B-1

LIST OF FIGURES

Figure 2 – 1	Layout of controls, indicators, and receptacles on the front panel	2-2
Figure 2 – 2	Controls and indicators for the cut, blend, coag, fulguration, bipolar, and micro bipolar modes	2-4
Figure 2 – 3	Indicators and receptacles	2-5
Figure 2 – 4	Layout of controls and indicators on the rear and side panel	2-6
Figure 4 – 1	Setup procedures.....	4-8
Figure A – 1	Output voltage (V _{peak}) versus power setting (Monopolar)	A-9
Figure A – 2	Output voltage (V _{peak}) versus power setting (Fulguration)	A-9
Figure A – 3	Output voltage (V _{peak}) versus power setting (Bipolar)	A-9
Figure A – 4	Output voltage (V _{peak}) versus power setting (Micro Bipolar)	A-9
Figure A – 5	Output power versus power setting for all modes	A-10
Figure A – 6	Output power vs impedance for Cut mode.....	A-10
Figure A – 7	Output power vs impedance for Blend mode.....	A-11
Figure A – 8	Output power versus impedance for Coagulation mode	A-11
Figure A – 9	Output power versus impedance for Fulguration mode	A-12
Figure A – 10	Output power vs impedance for Bipolar mode.....	A-12
Figure A – 11	Output power vs impedance for Micro Bipolar mode	A-13

INTRODUCING THE BANTAM PRO ELECTROSURGICAL GENERATOR

This section includes the following information:

- *Key Features*
- *Components and Accessories*
- *Safety*
- *Contraindications*
- *Application Specifications*

CAUTIONS

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

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

KEY FEATURES

The Bantam Pro Electrosurgical Generator 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. It generates constant output power over a wide range of impedances. Refer to Appendix A, *Technical Specifications* section of this guide.
- **Blend Mode**
The Blend mode is a combination of cutting and hemostasis. The Blend mode improves the rate of targeted tissue desiccation without increasing the power delivered by the generator.
- **Coagulation Mode**
Coagulation provides precise control of bleeding in localized areas.
- **Fulguration Mode**
Fulguration produces a sparking at the skin surface for more shallow tissue destruction. In the Fulguration mode, the use of a patient return electrode is optional.
- **Micro Bipolar Mode**
The Micro Bipolar Mode provides power for conventional Bipolar output.
- **Bipolar Mode**
The Standard Bipolar Mode provides precise Bipolar coagulation effects.
- **Return electrode sensing and contact quality monitoring**
The Bantam Pro 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.

- **Four Front Panel Accessory Connections**
These connectors accept a monopolar instrument, a bipolar instrument, a return patient grounding pad, and a footswitch. Refer to Section 2, Controls, Indicators, and Receptacles to learn more.
- **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® or Aaron® brand accessories supplied with your generator (Applied Parts*):

- Bantam Pro Electrosurgical Generator
- *50 sharp and 50 blunt non-sterile dermal tips
- *Five disposable electrodes (3 blades, 1 ball, 1 needle)
- *One reusable grounding cord (9.8ft (3m))
- *Five disposable grounding pads
- *A902 Handpiece (9.8ft (3m))
- Ten A910 handpiece drapes
- Hospital-grade (10ft (3.048m))
- Wall mount bracket
- User's Guide / Service Guide on CD

Additional Accessories

To avoid incompatibility and unsafe operation, we recommend using the following Bovie® or Aaron® accessories with the A952.

- A827V - Bipolar Forceps Cord (10.5ft (3.2m))
- A803 Footswitch (9.8ft (3m))

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

WARNINGS:

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

Danger: Fire / Explosion Hazard - Do not use the Bantam Pro electrosurgical generator in the presence of flammable anesthetics.

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

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N₂O] 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.

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 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 H.F. 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.

WARNINGS:

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. Disconnect power cord from power source or unplug the power cord from the unit's power inlet to isolate the internal circuits from the supply mains.

No modification of this equipment is allowed.

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location.

Electric Shock Hazard - 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. Do not use power plug adapters.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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.

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.

Failure of the HF SURGICAL 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.

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.

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 ESRS or ESRC 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.

Apparent low output or failure of the Bantam 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.

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.

WARNINGS:

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.

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

Associated equipment and accessories used must be rated to withstand the combination of the Vpeak rating and Crest Factor for all RF modes.

When using Cut mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 1600 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 2100 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 2900 Vpeak max.

When using Fulguration mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 6300 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 950 Vpeak max.

When using Micro Bipolar mode, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than 300 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 the neutral electrode should be reliably attached to the patient's body and as close to operating field as possible. Refer to NE 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.).

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.

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.

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

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

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

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.

The PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient. 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 inadvertent generator activation.

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

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.

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 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 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 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. A return electrode is not required for the fulguration mode. The patient plate alarm is not used for this mode. Procedures may be performed without the use of a return electrode.

CAUTIONS:

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

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

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

Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

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

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

When using Monopolar mode, associated equipment and active accessories should be selected that have a voltage rating of 6.3 kVp or greater.

When using Bipolar mode, associated equipment and active accessories should be selected that have a voltage rating of 1 kVp or greater.

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.

CAUTIONS:

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.

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.

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.

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

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

There are no known contraindications.

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.

APPLICATION SPECIFICATION

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.

Description

- The Bantam Pro High Frequency Electrosurgical Generators models are intended to be used for all electrosurgical cut, blend, coagulation, fulguration and bipolar procedures.

Medical Purpose / Indication

- Removal and destruction of skin lesions
- Electrosurgical cutting, blending, coagulation, fulguration and bipolar procedures of tissue to aid surgeon or physician in performing required procedures.

Site Condition

- Clean and protect from infection from start through completion of procedure.
- Note the follow Conditions of visibility for use: Site of use
- Site of use: Tissue (ligament, cartilage)

Ambient luminance range	100 lx to 1,500 lx
Viewing distance	20 cm to 200 cm
Viewing angle	normal to the display $\pm 30^\circ$

Patient population

- Age: newborn to geriatric
- Weight: >2.5 kg
- Health: no restrictions
- Nationality: no restrictions
- Patient state: alert, relaxed maybe sedated, possible local anesthesia
 - Patient should not be User

Intended User Profile

- Education: Trained physician, physicians assistance, clinicians
 - No maximum
- Knowledge:
 - Minimum:
 - o understands electrosurgery and electrosurgical techniques
 - o read and understand supplied "User's Guide" (accompanying document)
 - o understands hygiene
 - No maximum
- Experience:
 - Minimum:
 - o Some training on techniques or training under surveillance/supervision
 - o Other: no special experience needed
 - No maximum
- Permissible impairments:
 - Mild reading vision impairment or corrected vision to 20/20
 - impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz

CONTROLS, INDICATORS, AND RECEPTACLES

This section describes:

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















FRONT PANEL

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



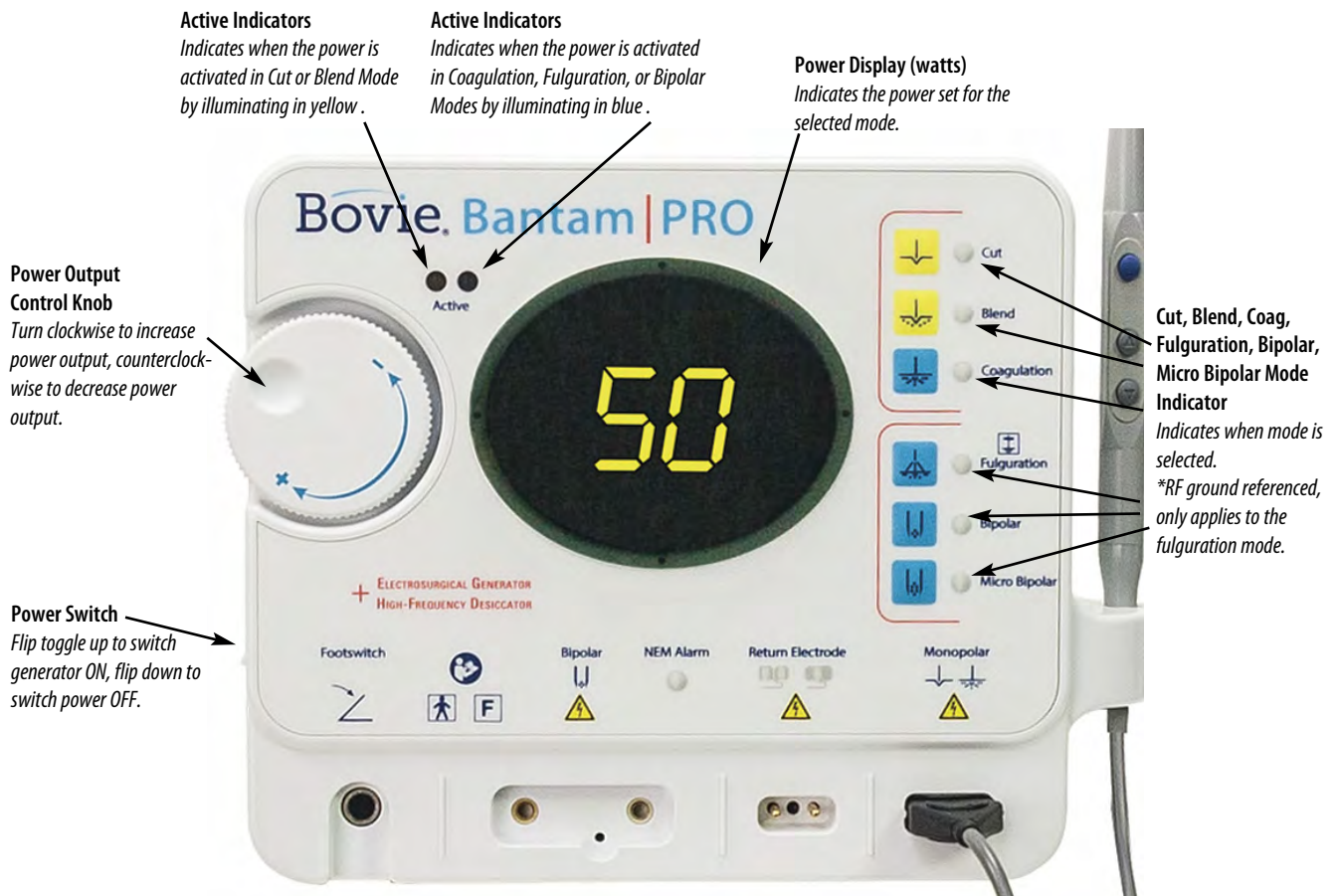
Symbols on the Front Panel

The following table lists descriptions for symbols found on the front panel of the Bantam Pro.

SYMBOLS	DESCRIPTION
<i>Generator Controls</i>	
	Cut mode
	Blend mode
	Coagulation mode
<i>High Frequency Desiccator Controls</i>	
	Bipolar mode
	Micro Bipolar mode
	Fulguration mode
<i>Indicators, Warnings</i>	
	RF ground referenced to earth
	RF Isolated – Patient connections are isolated from earth at high frequency.
	Mandatory: Refer to instruction manual / guide
	Warning - dangerous voltage
<i>Handpiece Connectors</i>	
	Monopolar handpiece
	Patient return electrode
	Footswitch
	Bipolar forceps

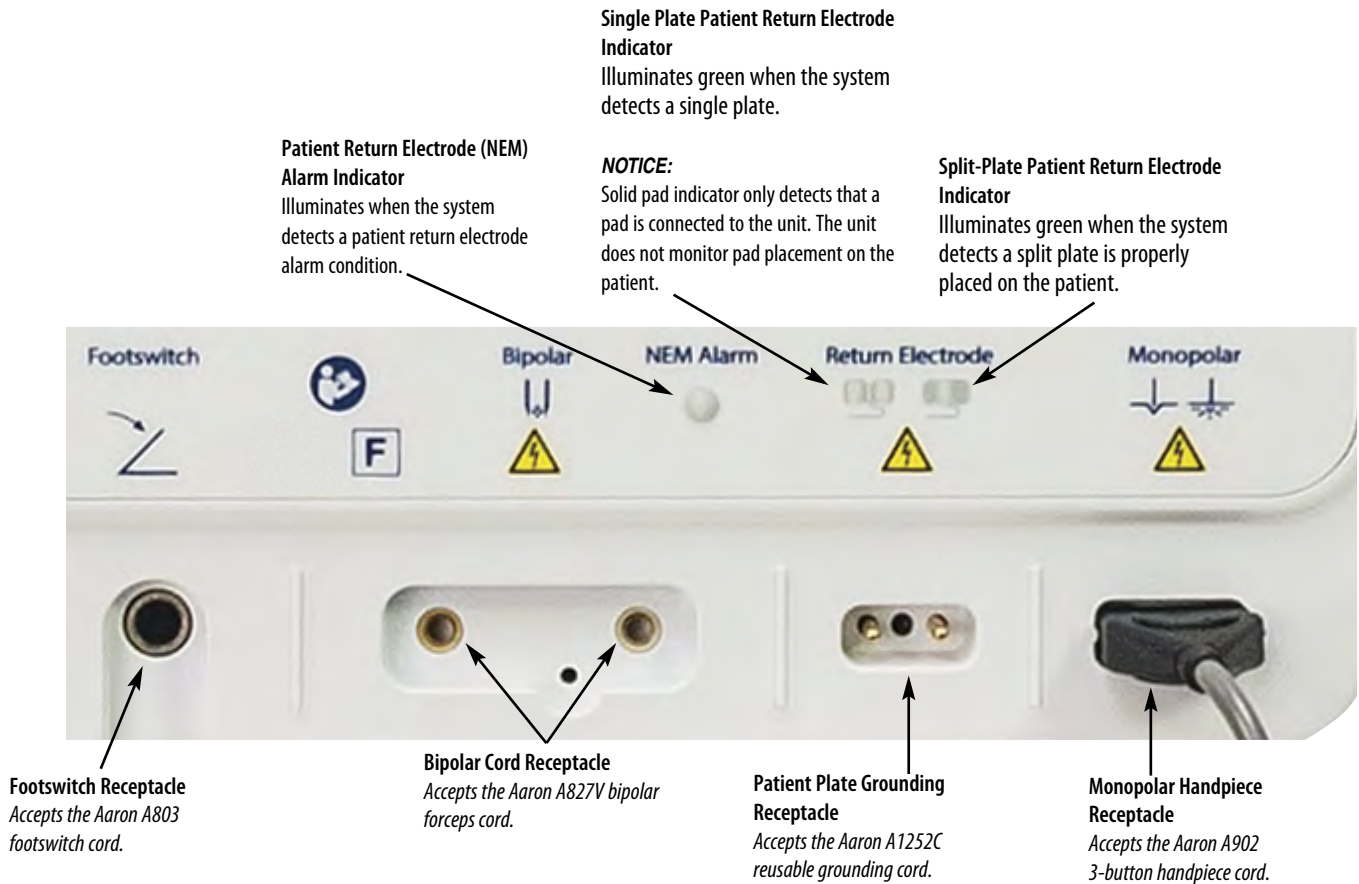
FRONT PANEL CONTROLS

Figure 2 – 2 Controls and indicators for the cut, blend, coag, fulguration, bipolar, and micro bipolar modes



INDICATORS AND RECEPTACLES

Figure 2 – 3 Indicators and receptacles



NOTICE:

A return electrode is not required for the fulguration mode. The patient plate alarm is not used for this mode. Procedures may be performed without the use of a return electrode.

REAR AND SIDE PANELS

Figure 2 – 4 Layout of controls and indicators on the rear and side panel



Symbols on the Rear and Side Panels

SYMBOLS	DESCRIPTION
	Power Off
	Power On
	Caution
	Volume Control
	* Do not dispose of this device in the unsorted municipal waste stream.
	Caution, Consult Accompanying Documents
	Manufacturer
	Conforms to European Union medical Directives 93/42/ECC and its revision 2007/47/EC. Compliant RoHS Directive (2011/65/EU).
	Fuse Symbol (bottom panel, not pictured)
	SGS Certification Mark; Conforms to PART 1 – ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012; CAN/CSA-C22.2 No. 60601-1:08 + C2:2011 PART 2 – AAMI 60601-2-2:2009 and CAN/CSA-C22.2 No. 60601-2-2:2009

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*
- *Installing the Unit*

INITIAL INSPECTION

When you first unpack your Bantam Pro Electrosurgical Generator, inspect it visually:

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

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

INSTALLING THE UNIT

1. Mount the Bantam Pro on the wall using the mount and screws included with the accessory kit (A837) or optional table stand (A813) using the two mounting kit screws that come with the wall mount kit. Do not position unit so that it is difficult to disconnect the power cord from the power source. Provide ample space around the generator to allow for the disconnection of the mains power source.

.....
CAUTION:

The unit is not to be utilized in the horizontal position, as liquids may easily spill into the unit. If mounting on a wall surface, a qualified individual should be consulted to avoid damage to the wall surface.
.....

2. Plug the female end of the supplied power cord into the base of the unit and the male end into a grounded wall receptacle.

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.
.....

USING THE BANTAM PRO

This section contains the following procedures:

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

CAUTIONS

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

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

INSPECTING THE GENERATOR AND ACCESSORIES

Before each use of the Bantam Pro Electrosurgical Generator, verify that the unit and all accessories are in good working order:

- Inspect for damage to the Electrosurgical Generator and all its connections.
- Verify that the appropriate accessories and adapters are present.
- Inspect all cords and connectors for signs of wear, damage, and abrasion (e.g. under magnification)
- 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 patient return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised.

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.

Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

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

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

NOTICES

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

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

SETTING UP

1. If the unit is not already installed refer to Section 3 of this manual for the installation procedure.
2. Turn on the generator by pressing the power switch ON (I) (see figure 4-1, letter A). [Figure 4-1 is located at the end of this Section].
Verify the following:
 - All visual indicators and displays on the front panel illuminate.
 - Activation tones sound to verify that the speaker is working properly.
3. If the self-test is successful, a tone sounds. Verify the following:
 - The power display will show the power level for the last used setting.
 - The mode for the last activated setting is selected.

If the self-test is not successful, an alarm tone sounds. An error code may appear on the power 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

Cut, Blend, and Coagulation modes require a patient return electrode.

NOTICE:

A return electrode is not required for the fulguration mode. The patient plate alarm is not used for this mode. Procedures may be performed without the use of a return electrode.

Applying the Patient Return Electrode

Refer to the manufacturer's instructions for application site and placement procedures. When using metal plate patient return electrodes, use a conductive gel specifically designed for electrosurgery. Select a patient 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. Plug the handpiece into the monopolar output on the lower right of the front of the unit (*see figure 4-1, letter B*).
The plug is designed to fit in only one direction. The three button handpiece is designed to give the doctor complete fingertip control of the power settings. The Aaron A902 handpiece is unique: handpieces manufactured by other manufacturers will not function with this unit. Do not use the Aaron A902 handpiece on other brand units.
2. Slide the desired active electrode into the handpiece until it is firmly seated (*see figure 4-1, letter C*). The handpiece will accept most standard 3/32" (.24 cm) electrodes.
3. Slide the handpiece from above into the holder on the right side of the unit.
4. Plug the male end of the reusable grounding cord into the Patient Plate receptacle located to the left of the monopolar output (*see figure 4-1, letter C*). Remove the disposable dispersive electrode from its pouch and attach to the snap connector on the end of the reusable grounding cord.

NOTICE:

A return electrode is not required for the fulguration mode. The patient plate alarm is not used for this mode. Procedures may be performed without the use of a return electrode.

5. An optional footswitch may be used with monopolar procedures. If the footswitch is utilized, plug the footswitch cable into the footswitch jack (*see figure 4-1, letter E*). While using a footswitch the output will be delivered via the handpiece. The activation button on the handpiece will continue to function while a footswitch is connected to the unit.
6. Choose the Monopolar mode of operation by pressing the desired membrane switch on the front panel (*see figure 4-1, letter F*). Monopolar modes include Cut, Blend, Coagulation, and Fulguration.
7. Set the output power either by using the dial on the front of the unit (*see figure 4-1, letter G*) or by the up and down buttons on the handpiece. When power level adjustment is being made by the handpiece an audible tone will sound to indicate that the power level has been changed. Depressing and holding the up or down buttons will cause the power settings to change more rapidly for quick adjustment of the output power. Power output is displayed in one watt increments for Cut, Blend, and Coagulation mode. The maximum power for each of these modes is 50 watts. Fulguration is 40 watts max. Power is displayed in ".1" watt increments below ten watts and in whole numbers from ten to 40 watts.

NOTICE:

The output settings cannot be adjusted when the unit is being activated.

8. The unit is now ready to perform surgery. Refer to *Activating the Unit* later in this section.

PREPARING FOR BIPOLAR SURGERY

1. Insert the two connectors from the bipolar cable into the bipolar cord receptacles (*see figure 4-1, letter H*).
2. Connect the desired forcep to the operating end of the bipolar cord.
3. Plug the footswitch cable into the footswitch jack (*see figure 4-1, letter E*). A footswitch is required to activate the Bipolar mode.

NOTICE:

Dispersive electrodes are not utilized during bipolar procedures.

4. Select the Bipolar mode by pressing the membrane switch on the front of the unit (*see figure 4-1, letter F*).
5. Set the output power by using the dial on the front of the unit (*see figure 4-1, letter G*). Power is displayed in “.1” watt increments below ten watts and in whole numbers from ten to 40 watts for Bipolar mode. The Micro Bipolar mode is displayed in one watt increments up to 40 watts.

NOTICE:

The output settings cannot be adjusted when the unit is being activated.

6. The unit is now ready to perform surgery. Refer to *Activating the Unit* later in this section.

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 Bantam Pro Electrosurgical Generator in the presence of flammable anesthetics.

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

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N₂O] 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.

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location.

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 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.

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. 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, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

CAUTIONS

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.
.....

ACTIVATING THE UNIT

Monopolar Activation

1. If the unit is not already set up, follow the set up procedure to prepare the unit for operation.
2. Remove the handpiece from the holder. Place the handpiece in the desired position.
3. To activate the unit, depress the activation button on the handpiece or depress the pedal on the footswitch. While the unit is activated, the appropriate audible tone is sounded and one of the activation LEDs will illuminate (see figure 4-1, letter I).
4. When the procedure is completed, turn the unit off.
5. Return the handpiece to the holder on the right side of the unit and remove the electrode. The electrode should be disposed of after each procedure. If contamination has occurred to the handpiece, the handpiece should be sterilized.

NOTICE:

When sterilizing the handpiece follow the manufacturer's sterilization instructions that accompany the handpiece.

Bipolar Activation

1. If the unit is not already set up, follow the set up procedure to prepare the unit for operation.
2. Place the forceps in the desired position.
3. To activate the unit depress the footswitch pedal. While the unit is activated, an audible tone is sounded and the blue activation LED will illuminate (see figure 4-1, letter J).
4. When the procedure is completed, turn the unit off.
5. Remove the forceps from the bipolar cord and sterilize.

NOTICE:

When sterilizing the forceps follow the manufactures sterilization instructions that accompany the forceps.



Figure 4 – 1 Setup procedures

MAINTAINING THE BANTAM PRO

This section covers the following topics:

- *Cleaning*
- *Periodic Inspection*
- *Servicing and Repair*

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. 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.

NOTICE:

The A952 ESU is a programmable electrical medical system (PEMS). The firmware revision level of the ESU can be located on a label inside the unit by the responsible Service personnel.

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 Bantam Pro Electrosurgical Generator for signs of wear or damage. In particular, look for any of the following problems:

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

FUSE REPLACEMENT

Fuses for the unit reside directly below the Power Cable Receptacle on the rear of the unit.

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 (T1.25AH,250V) 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.

SERVICING AND REPAIR

It is recommended that all Bovie® parts be returned to an authorized Bovie® service center. On request, Bovie® will provide circuits diagrams, component part lists, descriptions and instructions to assist service personnel in parts repair. Refer to Service Guide (MC-55-238-002).

For warranty and repair work, please contact Bovie® and obtain a Return Materials Authorization number (RMA). Place the number so that it can be seen on the exterior of the package and ship directly to Bovie®. A return without an RMA may not be accepted.

TROUBLESHOOTING

This section includes error code descriptions and actions to take to resolve them.

The Bantam Pro 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 on the 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	Activation on Power-Up Fault	<ol style="list-style-type: none"> 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	RF Power-Up Button on Power-Up Fault	
F3	RF Power Down Button on Power-Up Fault	
F4	RF Power Down and UP Buttons Fault	
F5	Duty Cycle On Time Fault	
F6	Monopolar Handle Not Plugged-In Fault	
F7	Bipolar Cable Not Plugged-In Fault	
F8	Monopolar and Bipolar Cables Simultaneous Plugged-in Fault	

SYSTEM FATAL ERROR MESSAGES

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

Error Code	Description	Recommended Action
E0	Multiple Errors	<ol style="list-style-type: none">1. Turn the unit off (<i>for Temperature Error, let unit cool for 20 minutes</i>).2. Turn the unit on.3. If the error code reappears, record the number and contact Bovie® customer service at 727-384-2323.
E1	Activation Calibration Error	
E2	DC Supply over Voltage Detection on VDD of Power Generator	
E3	Pulse Width Error	
E4	DC Supply over Voltage Detection on +9VDC	
E5	Temperature Sense Error- Power Generator	
E6	DC Supply over Voltage Detection on +12VDC	
E7	DC Voltage Reference over Voltage Detection on +6VDC	
E8	NEM Calibration Error	
E9	Relay cable is not properly attached	

REPAIR POLICY AND PROCEDURES

Refer to this section for information on:

- The Manufacturer's Responsibility
- Returning the Generator for Service

RESPONSIBILITY OF THE MANUFACTURER

Bovie Medical Corporation 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.

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 Materials Authorization Number. Then clean the Generator and ship it to Bovie Medical Corporation for service.

Step 1 – Obtain a Returned Materials Authorization Number

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

- Hospital / clinic name / customer number
- Telephone number
- Department / address, city, state, and zip code
- Model number
- Serial number / Lot Number
- Description of the problem
- Type of repair to be done

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 Materials Authorization Number and the information (hospital, phone number, etc.) listed in Step 1 – Obtain a Returned Materials Authorization Number.
- B. Be sure the generator is completely dry before you pack it for shipment. Package it in its original shipping container, if available.
- 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 $\pm 20\%$ of a stated value at room temperature (25° C / 77° F) and a nominal input power voltage.

PERFORMANCE CHARACTERISTICS

Input Power

100 – 240 VAC
Mains line frequency range (nominal): 50 – 60 Hz
Power consumption: MAX. 1.1 A~
Fuses (two): T 1.25AH 250V 5 x 20mm (Slow Blow)

Duty Cycle

Under maximum power settings and rated load conditions (Cut, 50 watt @ 500 ohm load), the generator is suitable for activation times of 10 seconds on, 30 seconds off for one hour.

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

Dimensions and Weight

Width	228 mm (8.98 in.)	Depth	105 cm (4.13 in.)
Height	188 mm (7.40 in.)	Weight	< 2.26 kg (< 5 lbs)

Operating Parameters

Ambient temperature range	10° to 40° C (50° to 104° F)
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 (68° to 86° F)
Relative humidity	10% to 75%, non-condensing
Atmospheric pressure	50kPa to 106kPa

Audio Volume

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

Activation Tone

Volume (adjustable)	40 to ≥ 65 dB
Frequency	Cut: 610 Hz \pm 25 Hz Blend: 610 Hz \pm 25 Hz Fulguration: 910 Hz \pm 25 Hz Micro Bipolar: 910 Hz \pm 25 Hz Bipolar: 910 Hz \pm 25 Hz
Duration	Continuous while the generator is activated

Alarm Tone

Volume (not adjustable)	≥ 65 dB at a distance of one meter
Frequency	2.44 kHz / 490 ms / 1.22 kHz / 490 ms

Return Electrode Sensing

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

Single Plate	Trip resistance: 0 Ω to 8 Ω \pm 1 Ω Continuous measurement: Once the system establishes the single-plate electrode resistance, an increase of 20 Ω \pm 2 Ω in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
Split Plate	Trip resistance: 10 Ω \pm 1 Ω to 135 Ω \pm 2 Ω Continuous measurement: Once the system establishes the split-plate electrode resistance, an increase of (35 \pm 5)% in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.

NOTICE:

A return electrode is not required for the fulguration mode. The patient plate alarm is not used for this mode. Procedures may be performed without the use of a return electrode.

Low Frequency (50-60 Hz) Leakage Current

Enclosure source current, ground open	< 500 μ A 220 - 240 VAC
	< 300 μ A 90 - 120 VAC
Source current, patient leads, all outputs	Normal polarity, intact ground: < 10 μ A
	Normal polarity, ground open: < 50 μ A
	Reverse polarity, ground open: < 50 μ A
Sink current at high line, all inputs	< 50 μ A

High Frequency (RF) Leakage Current

Bipolar RF leakage current	< 44 mA _{rms}
Monopolar RF leakage current (additional tolerance)	< 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)

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

Type BF Equipment (IEC 60601-1)



The generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type BF equipment.

Ingress Protection Rating (EN 60529)

This equipment is rated IPX0. It is protected against spillage (EN 60601-2-2), i.e the generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely the safety of the generator.

Electromagnetic Interference

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

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

The Bantam Pro Electrosurgical Generator complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

The Bantam Pro Electrosurgical Generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

EMC COMPLIANCE

Special precautions should be taken regarding the Bantam Pro. 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 Medical Corporation 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 Bantam Pro. The Bantam Pro and its accessories are not suitable for interconnection with other equipment.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The Bantam Pro should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Bantam Pro 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 Bantam Pro.			
The Bantam Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bantam Pro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Bantam Pro as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	separation distance according to frequency of transmitter in metres (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_f} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_f} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_f} \right] \sqrt{P}$
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 Bantam Pro is intended for use in the electromagnetic environment listed below. The customer or the user of the Bantam Pro should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The Bantam Pro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The Bantam Pro is a HF surgical generator which according to EN 60601-2-2 shall be tested as group 1 equipment (with the HF output not energised).
RF Emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The Bantam Pro is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used in domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTICE:

For the purposes of EN60601-1-2 the Bantam Pro has an essential performance which is that there shall be no component failure, change in operating mode or false alarm, the delivered power shall remain within +/-20% of the set power and there shall be no reset or interruption of the HF power unless this is clearly indicated on the product.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Bantam Pro is intended for use in the electromagnetic environment listed below. The customer or the user of the Bantam Pro should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±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 supply 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 Bantam Pro requires continued operation during power mains interruptions, it is recommended that the Bantam Pro 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 (V_1)	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Bantam Pro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{3} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E_1)	$d = \left[\frac{3.5}{3} \right] \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{7}{3} \right] \sqrt{P}$ <p>800 MHz to 2.5 GHz</p> <p>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)</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 Bantam Pro is used exceeds the applicable RF compliance level above, the Bantam Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Bantam Pro.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_3]$ V/m.</p>			

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	Open Circuit Vpeak max	Crest Factor* (@ 800 Ω)
Cut	50 W @ 500 Ω	343 kHz \pm 10%	N / A	1600V	2.2 \pm 20%
Blend	50 W @ 800 Ω	368 kHz \pm 10%	46 kHz \pm 10%	2100V	3.5 \pm 20%
Coagulation	50 W @ 1000 Ω	340 kHz \pm 10%	49 kHz \pm 10%	2900V	5.2 \pm 20%
Fulguration	40 W @ 1000 Ω	410 kHz \pm 20%	21 kHz \pm 10%	6300V	9.5 \pm 20%
Bipolar	40 W @ 200 Ω	368 kHz \pm 10%	37 kHz \pm 10%	950V	5.5 \pm 20%
Micro Bipolar	40 W @ 50 Ω	338 kHz \pm 10%	N / A	300V	2.6 \pm 20%

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

OUTPUT POWER CURVES

Figure A-1 through A-4 illustrates output voltage (V_{peak}) versus power setting. Figure A-5 illustrates output power versus power setting for all modes. Figures A-6 through A-11 illustrate specific output power delivered to a range of load resistances for each mode.

Figure A – 1 Output voltage (V_{peak}) versus power setting (Monopolar)

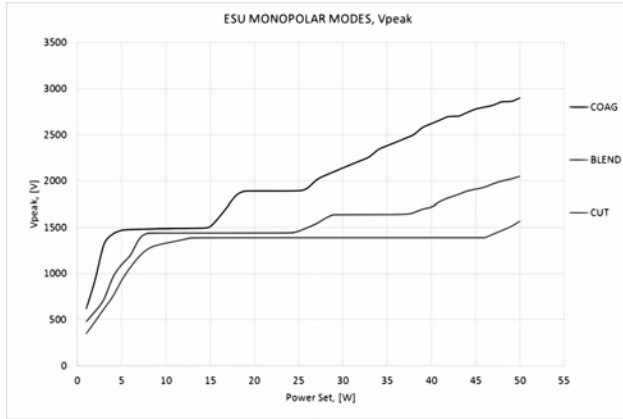


Figure A – 2 Output voltage (V_{peak}) versus power setting (Fulguration)

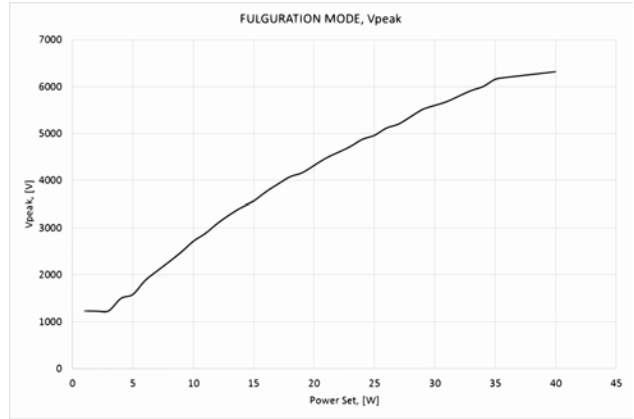


Figure A – 3 Output voltage (V_{peak}) versus power setting (Bipolar)

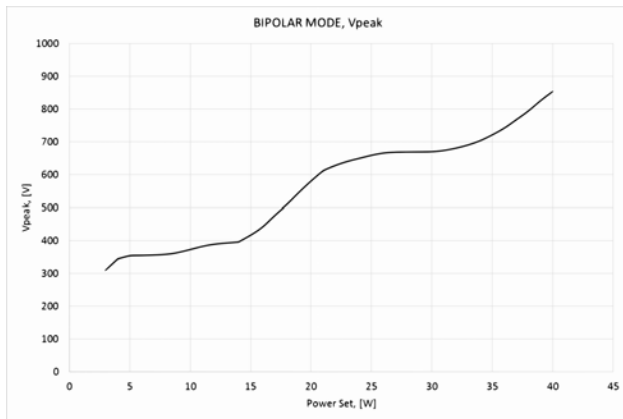


Figure A – 4 Output voltage (V_{peak}) versus power setting (Micro Bipolar)

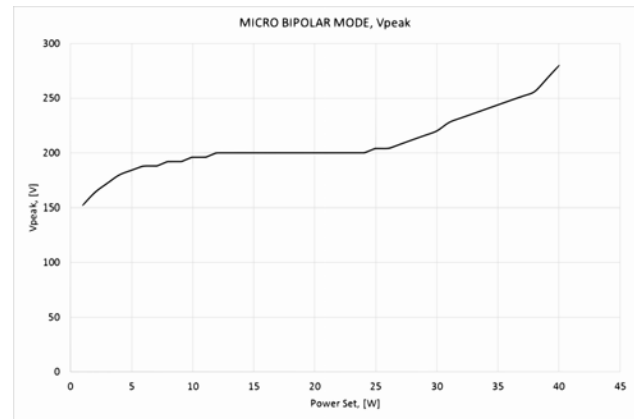


Figure A – 5 Output power versus power setting at rated load for all modes

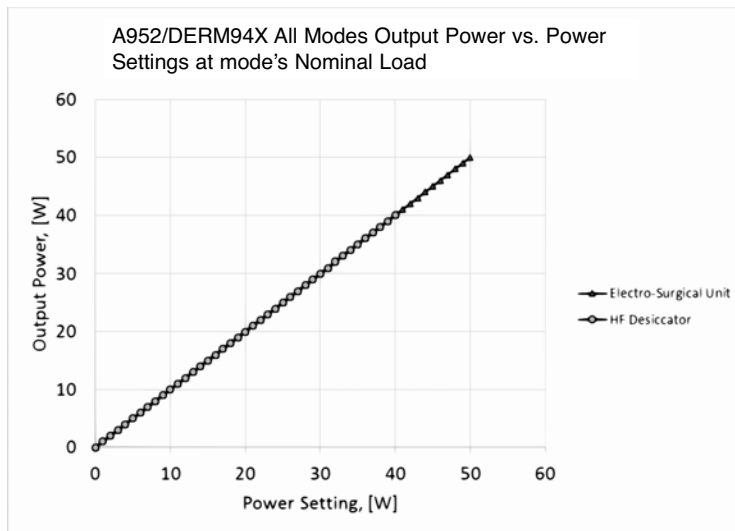


Figure A – 6 Output power vs impedance for Cut mode

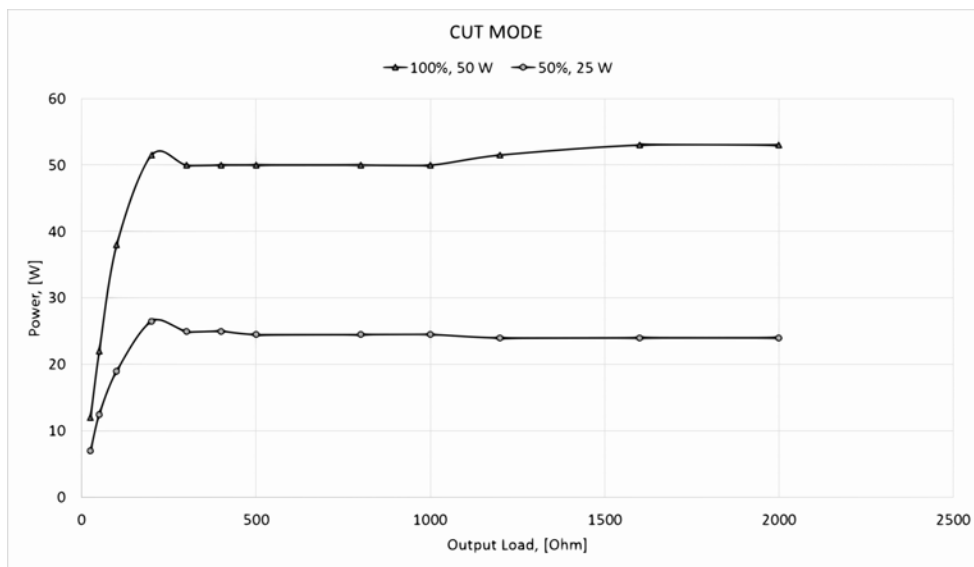


Figure A – 7 Output power vs impedance for Blend mode

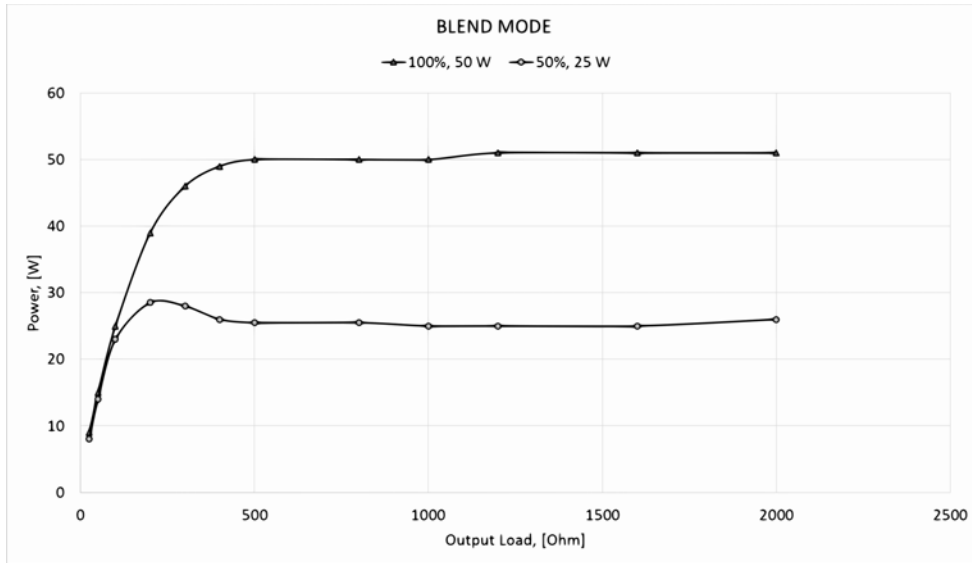


Figure A – 8 Output power versus impedance for Coagulation modes

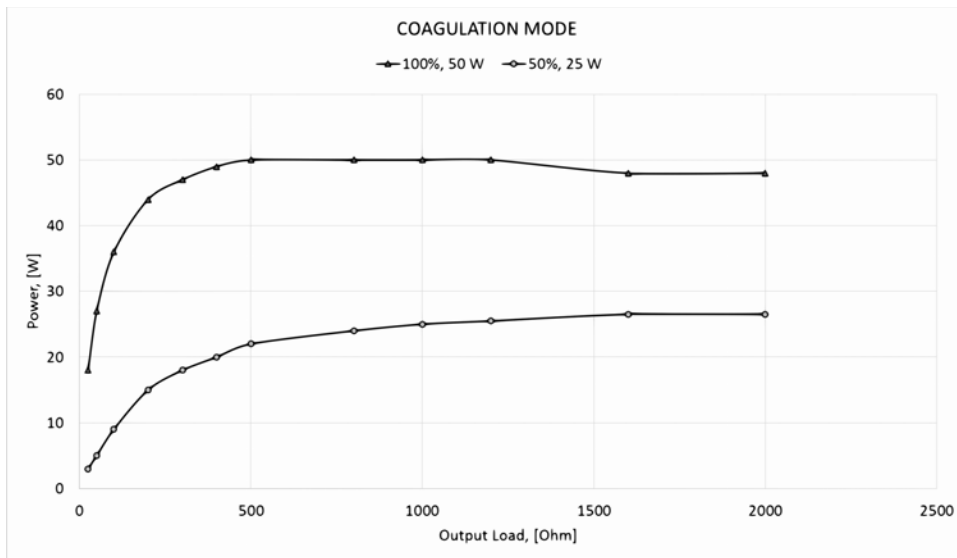


Figure A – 9 Output power versus impedance for Fulguration mode

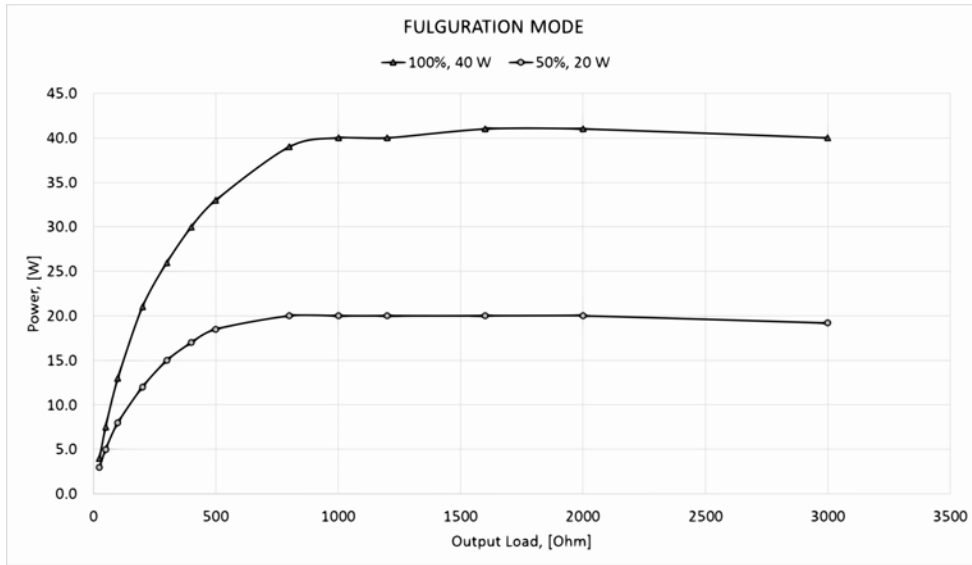


Figure A – 10 Output power vs impedance for Bipolar mode

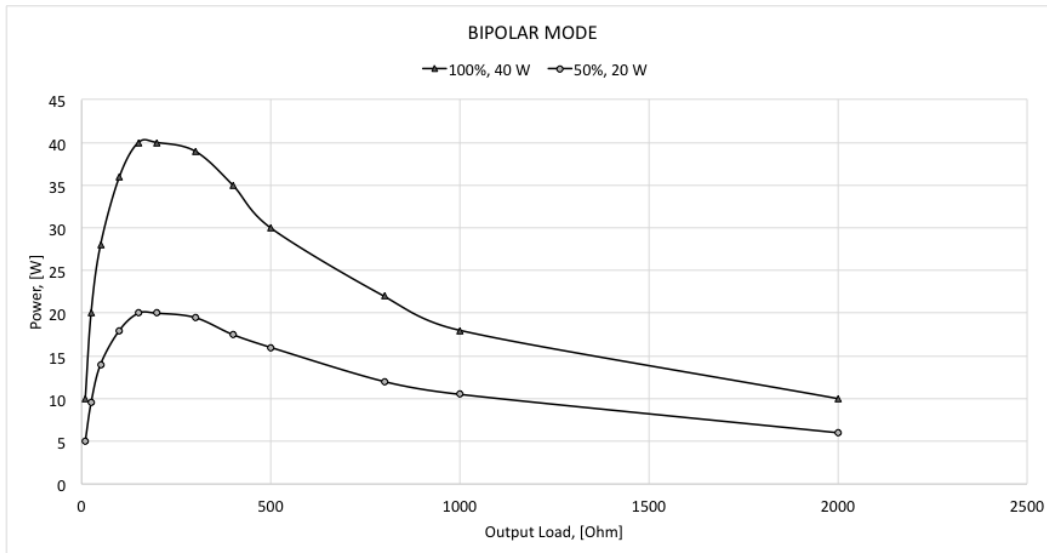
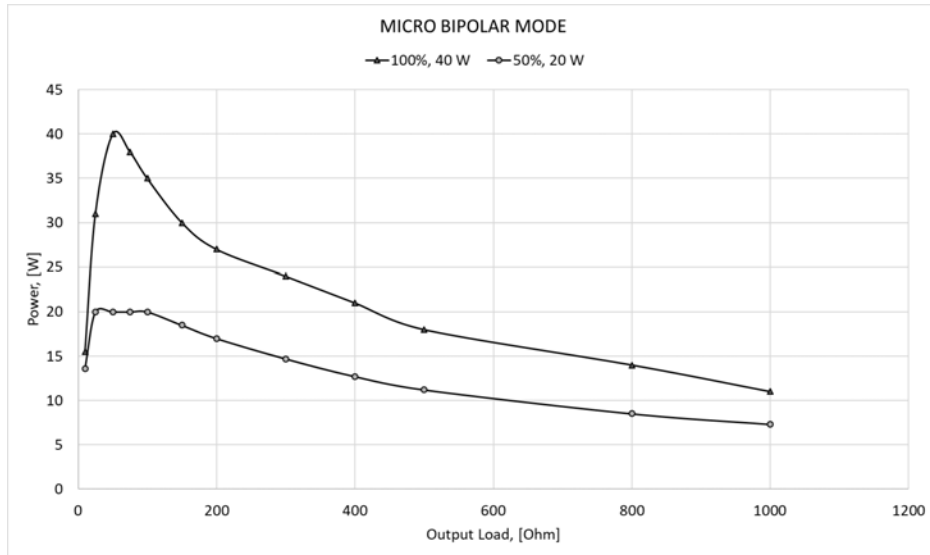


Figure A – 11 Output power vs impedance for Micro Bipolar mode



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.

Bovie®



Bovie Medical Corporation
5115 Ulmerton Road
Clearwater, FL 33760 USA

www.BovieMedical.com • Sales@BovieMed.com
U.S. Phone 1 800 537 2790 • Int'l. Phone +1 727 384 2323

MC-55-238-001 Rev. 1

2018-05-04