





# **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

Symmetry Surgical Inc. • 3034 Owen Drive, Antioch, TN 37013 USA Phone 1-888-364-7004 www.symmetrysurgical.com

©2024 Symmetry Surgical. All rights reserved. Contents of this publication may not be reproduced without the written permission of Symmetry Surgical.

Bovie Part Number: MC-55-238-001\_4-EN

EC REP



Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands

## CONVENTIONS USED IN THIS GUIDE

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

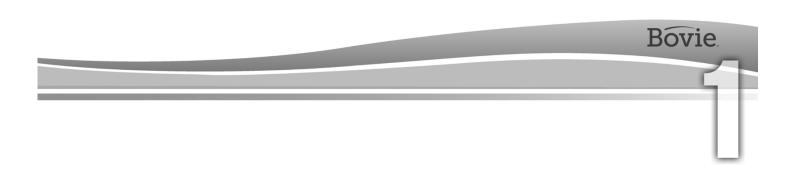
## Table of Contents

CONVENTIONS USED IN THIS GUIDEINTRODUCING THE BANTAM PRO ELECTROSURGICAL GENERATOR	. 1 2 3
	2 3
	3
KEY FEATURES	
COMPONENTS AND ACCESSORIES	. 3
SAFETY	
CONTRAINDICATIONS	7
APPLICATION SPECIFICATION	7
CONTROLS, INDICATORS, AND RECEPTACLES	. 9
FRONT PANEL	10
Symbols on the Front Panel	11
FRONT PANEL CONTROLS	12
INDICATORS AND RECEPTACLES	13
REAR AND SIDE PANELSSymbols on the Rear and Side Panels	
GETTING STARTED	15
INITIAL INSPECTION	16
INSTALLING THE UNIT	16
USING THE BANTAM PRO	17
INSPECTING THE GENERATOR AND ACCESSORIES	18
SETUP SAFETY	18
SETTING UP	19
PREPARING FOR MONOPOLAR SURGERY	20
Applying the Patient Return Electrode	
PREPARING FOR BIPOLAR SURGERY	
ACTIVATION SAFETY	22
ACTIVATING THE UNIT	
Monopolar Activation Bipolar Activation	
MAINTAINING THE BANTAM PRO	25
CLEANING	26
PERIODIC INSPECTION	26
FUSE REPLACEMENT	26
SERVICING AND REPAIR	27
TROUBLESHOOTING	28
SYSTEM FAULT CODE MESSAGES	29

SYSTEM FATAL ERROR MESSAGES	30
REPAIR POLICY AND PROCEDURES	32
RESPONSIBILITY OF THE MANUFACTURER	33
RETURNING THE GENERATOR FOR SERVICE	33
Step 1 – Obtain a Returned Materials Authorization Number	33
Step 2 – Clean the Generator	33
Step 3 – Ship the Generator	33
TECHNICAL SPECIFICATIONS	34
PERFORMANCE CHARACTERISTICS	35
Input Power	35
Duty Cycle	35
Dimensions and Weight	35
Operating Parameters	35
Transport	
Storage	
Audio Volume	
Return Electrode Sensing	
Low Frequency (50-60 Hz) Leakage Current	
High Frequency (RF) Leakage Current	
Operating Conditions	37
STANDARDS AND IEC CLASSIFICATIONS	37
Class I Equipment (IEC 60601-1)	37
Type BF Equipment (IEC 60601-1)	37
Ingress Protection Rating (EN 60529)	
Electromagnetic Interference	
Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2)	
Voltage Transients (Emergency Generator Mains Transfer)	37
EMC COMPLIANCE	38
OUTPUT CHARACTERISTICS	40
Maximum Output for Monopolar and Bipolar Modes	40
OUTPUT POWER CURVES	41
MADDANTY	4.0

## **LIST OF FIGURES**

igure 2 – 1.	Layout of controls, indicators, and receptacles on the front panel	10
igure 2 – 2.	Controls and indicators for the cut, blend, coag, fulguration, bipolar, and micro bipolar modes	12
igure 2 – 3.	Indicators and receptacles	13
igure 2 – 4.	Layout of controls and indicators on the rear and side panel	14
igure 4 – 1.	Setup procedures	24
igure A–1.	Output voltage (Vpeak) versus power setting (Monopolar)	41
igure A–2.	Output voltage (Vpeak) versus power setting (Fulguration)	41
igure A–3.	Output voltage (Vpeak) versus power setting (Bipolar)	41
igure A–4.	Output voltage (Vpeak) versus power setting (Micro Bipolar)	41
igure A – 5.	Output power versus power setting at rated load for all modes	42
igure A – 6.	Output power vs impedance for Cut mode	42
igure A – 7.	Output power vs impedance for Blend mode	43
igure A – 8.	Output power versus impedance for Coagulation modes	43
igure A – 9.	Output power versus impedance for Fulguration mode	44
igure A – 10	. Output power vs impedance for Bipolar mode	44
igure A – 11	. Output power vs impedance for Micro Bipolar mode	45



# INTRODUCING THE BANTAM PRO ELECTROSURGICAL GENERATOR

This section includes the following information:

- Key Features
- o 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 electrosurgical 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

## 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
- \*6 sterile and 12 non-sterile dermal tips
- \*Five disposable electrodes (3 blades, 1 ball, 1 needle)
- \*Two reusable grounding cord (9.8ft (3m))
- \*Five disposable grounding pads
- Two sterile A910ST handpiece drapes

- \*A902 Handpiece (9.8ft (3m))
- Two non-sterile A910 handpiece drapes
- Hospital-grade power cord (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 [N20] 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 if HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids pooled in these areas should be mopped up before H.F. surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases.

## **WARNINGS:**

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.

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.

For all monopolar modes, if the Generator is activated with the rated duty cycle of 10 seconds on / 30 seconds off, the surface skin temperature under the Bovie® patient return pads will not rise by more than 6°C if the skin and pad are prepared properly. However, be aware that activation times longer than the rated duty cycle of 10 seconds on / 30 seconds off, particularly at high power settings, the surface skin that is under the Bovie patient return pads may continue increasing in temperature by more than 6°C.

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. Symmetry Surgical recommends the use of split patient return electrodes and Symmetry Surgical 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  $6.3~\rm kVp$  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.<sup>1</sup>

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

## **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 ± 30°

## 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)
  - understands hygiene
  - No maximum
- Experience:
  - Minimum:
  - Some training on techniques or training under surveillance/supervision
  - 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

72

# **CONTROLS, INDICATORS, AND RECEPTACLES**

This section describes:

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

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

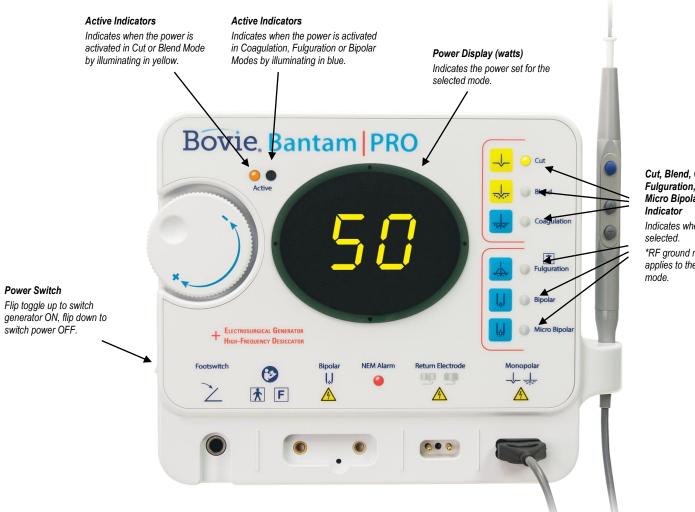


**Symbols on the Front Panel**The following table lists descriptions for symbols found on the front panel of the Bantam Pro.

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

## FRONT PANEL CONTROLS

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



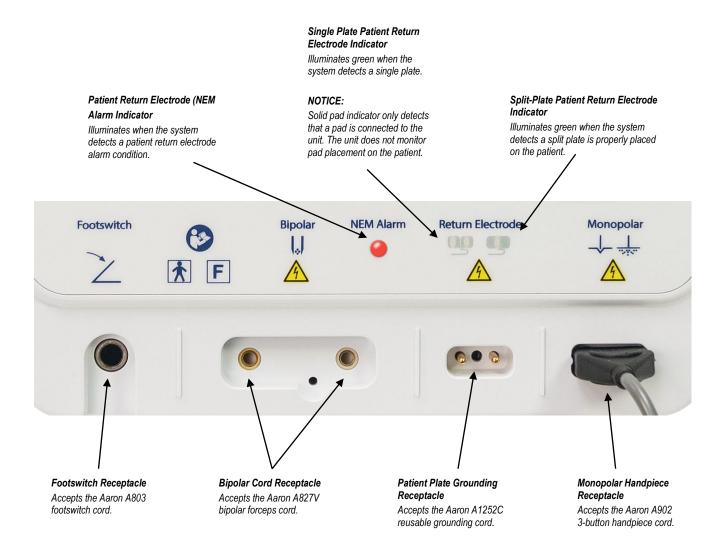
Cut, Blend, Coag, Fulguration, Bipolar, Micro Bipolar Mode

Indicates when mode 's

\*RF ground referenced only applies to the fulguration

## INDICATORS AND RECEPTACLES

Figure 2 – 3. Indicators and receptacles



## **REAR AND SIDE PANELS**

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

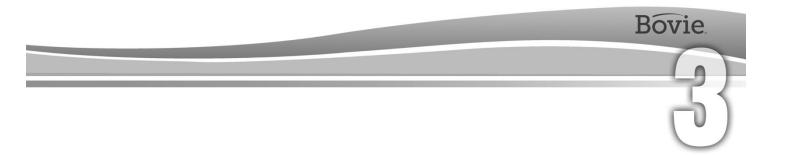




## Symbols on the Rear and Side Panels

SYMBOLS	DESCRIPTION	
0	Power Off	
	Power On	
UDI	Unique Device Identifier	
MD	Medical Device	
SN	Serial Number	
REF	Reference Number	
$\triangle$	Caution	
▼ 🗐)) 🛦	Volume Control	
X	* Do not dispose of this device in the unsorted municipal waste stream.	
(i	Caution, Consult Accompanying Documents	
	Manufacturer	
	Fuse Symbol (bottom panel, not pictured)	

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 Symmetry Surgical. 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 Symmetry Surgical'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:

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

## **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 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 (|) (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.
- 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 [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.

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.<sup>1</sup>

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

## **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.
- 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.
- 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.
- Remove the forceps from the bipolar cord and sterilize.

## NOTICE:

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

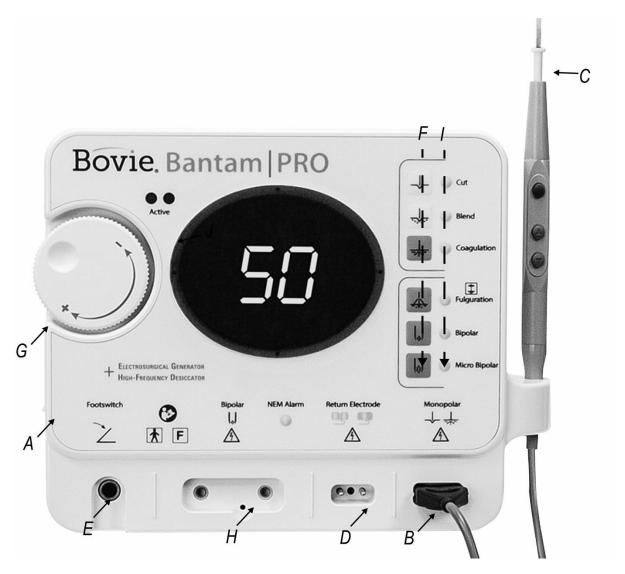
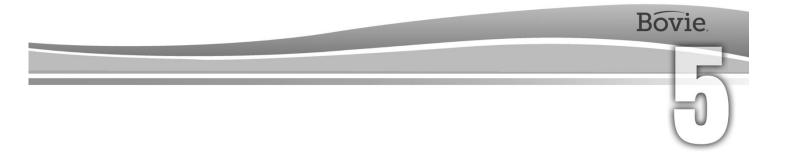


Figure 4 – 1. Setup procedures



# **MAINTAINING THE BANTAM PRO**

This section covers the following topics:

- o Cleaning
- o Periodic Inspection
- Servicing and Repair

Symmetry Surgical 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

## **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.
- 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.

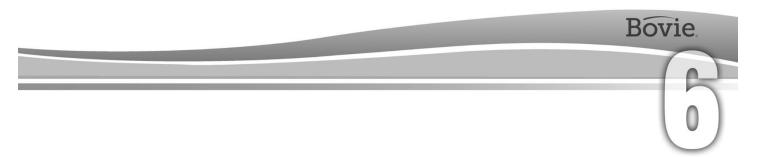
## NOTICE

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 1 800-251-3000.

### 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

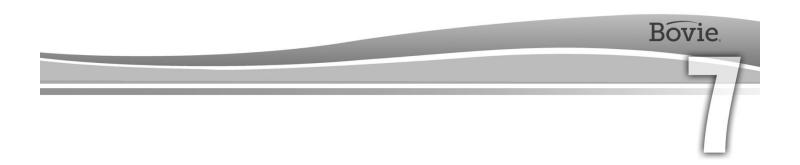
Fault messages (F) indicate improper unit setup or faulty accessories.

Fault Code	Description	Recommended Action
F1	Activation on Power-Up Fault	
F2	RF Power-Up Button on Power-Up Fault	1. If the fault code appears, disconnect all
F3	RF Power Down Button on Power-Up Fault	accessories. Turn off, then turn on the generator
F4	RF Power Down and UP Buttons Fault	again.
F5	Duty Cycle On Time Fault	If the problem persists, replace the handpiece or footswitch and repeat the restart.
F6	Monopolar Handle Not Plugged-In Fault	3. If the fault code reappears, record the number and
F7	Bipolar Cable Not Plugged-In Fault	contact Bovie® customer service at 1 800-251-3000.
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	
E1	Activation Calibration Error	
E2	DC Supply over Voltage Detection on VDD of Power Generator	
E3	Pulse Width Error	1. Turn the unit off (for Temperature Error, let unit cool for 20 minutes).
E4	DC Supply over Voltage Detection on +9VDC	2. Turn the unit on.
E5	Temperature Sense Error- Power Generator	3. If the error code reappears, record the number
E6	DC Supply over Voltage Detection on +12VDC	and contact Bovie® customer service at 1 800-251-3000.
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:

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

# RESPONSIBILITY OF THE MANUFACTURER

Symmetry Surgical 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 Symmetry Surgical 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 Symmetry Surgical instructions for use.

For warranty information, refer to Appendix B – Warranty.

# RETURNING THE GENERATOR FOR SERVICE

Before you return the generator, call your Symmetry Surgical representative for assistance. If instructed to send the generator to Symmetry Surgical, first obtain a Returned Materials Authorization Number. Then clean the Generator and ship it to Symmetry Surgical for service.

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

Call the Symmetry Surgical 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 Symmetry Surgical 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 750 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	5 0kPa 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 ± 25 Hz
	Blend: 610 Hz ± 25 Hz
	Fulguration: 910 Hz ± 25 Hz
	Micro Bipolar: 910 Hz ± 25 Hz
	Bipolar: 910 Hz ± 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: $0 \Omega$ to $8 \Omega \pm 1 \Omega$ Continuous measurement: Once the system establishes the single-plate electrode resistance, an increase of $20 \Omega \pm 2 \Omega$ in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
Split Plate	Trip resistance: $10 \Omega \pm 1 \Omega$ to $135 \Omega \pm 2 \Omega$ 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.

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

# High Frequency (RF) Leakage Current

Bipolar RF leakage current	< 44 mA ms
Monopolar RF leakage current (additional tolerance)	< 150 mA <sub>rms</sub>

### **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 Generatorcomplies 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.

### **WARNING:**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications (including peripherals such as antenna cables and extrenal antennas) should be used no closer than 30 cm (12 inches) to any part of the Bantam Pro, including cables specified by Bovie®. Otherwise, degradation of the performance of Bantam Pro could result.

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

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.

For the purposes of EN60601-1-2, the Bantam Pro has the following essential performance: There shall be no increase in HF power or change in HF operating modes.

If an ESD event occurs the generator may fault into a safe mode and display an error code. In this event output power is disabled. To clear the error code, reset the generator by turning power off and then on.

The Bantam Pro must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

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. - electromagnetic emissions

	<u> </u>			
Emissions test	Compliance	Electromagnetic environment - guidance		
RF Emissions CISPR 11	Group 2	The Bantam Pro must emit electromagnetic energy in or to perform its intended function. Nearby electronic equipment may be affected.		
RF Emissions CISPR 11	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.		
Harmonic emissions IEC 61000-3-2	Class A			
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Complies			

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. - electromagnetic immunity

Immunity Test	Compliance Test Level		
IEC 61000-4-2, Electro-Static Discharge	±8kV Contact ±15kV Air		
IEC 61000-4-3, Radiated Immunity	10V/m 80MHz – 1000MHz 10V/m 1.4GHz – 2.7GHz(1)		
IEC 61000-4-4, Electric Fast Transients Immunity	2kV, AC Mains		
IEC 61000-4-5, Surge Immunity	1kV Line-Line 2kV Line-PE		
IEC 61000-4-6, Conducted Immunity	6Vrms, 150kHz – 80MHz		
RIEC 61000-4-8, Power Frequency Magnetic Field Immunity	30A/m, 50 and 60Hz		
IEC 61000-4-11, Voltage Dips & Interruptions	<5 % UT (>95 % dip in UT) for 0,5 cycle and 1.0 cycle  70 % UT (30 % dip in UT) for 25/30 cycles  <5 % UT (>95 % dip in UT) for 250/300 cycles		

### 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.

# **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 ± 10%	N/A	1600V	2.2 ± 20%
Blend	50 W @ 800 Ω	368 kHz ± 10%	46 kHz ± 10%	2100V	3.5 ± 20%
Coagulation	50 W @ 1000 Ω	340 kHz ± 10%	49 kHz ± 10%	2900V	5.2 ± 20%
Fulguration	40 W @ 1000 Ω	410 kHz ± 20%	21 kHz ± 10%	6300V	9.5 ± 20%
Bipolar	40 W @ 200 Ω	368 kHz ± 10%	37 kHz ± 10%	950V	5.5 ± 20%
Micro Bipolar	40 W @ 50 Ω	338 kHz ± 10%	N/A	300V	2.6 ± 20%

<sup>\*</sup> 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 (Vpeak) 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 (Vpeak) versus power setting (Monopolar)

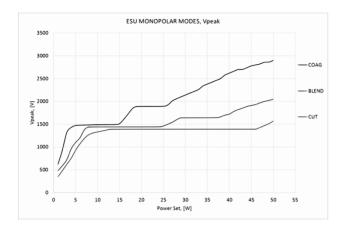


Figure A–2. Output voltage (Vpeak) versus power setting (Fulguration)

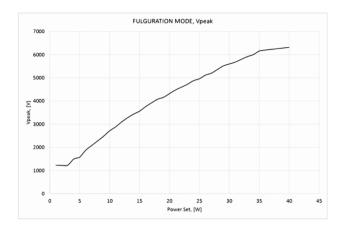


Figure A-3. Output voltage (Vpeak) versus power setting (Bipolar)

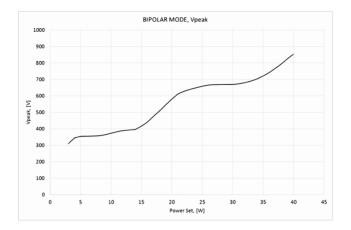


Figure A-4. Output voltage (Vpeak) versus power setting (Micro Bipolar)

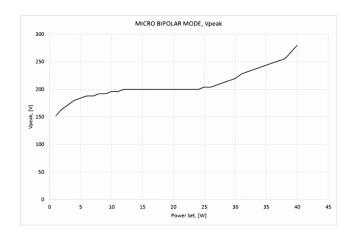


Figure A - 5. Output power versus power setting at rated load for all modes

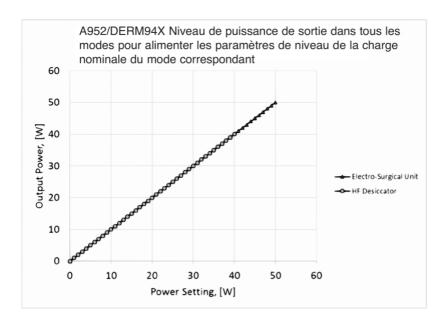


Figure A - 6. Output power vs impedance for Cut mode

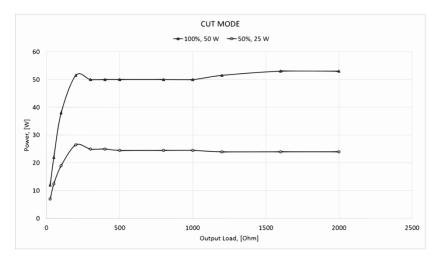


Figure A - 7. Output power vs impedance for Blend mode

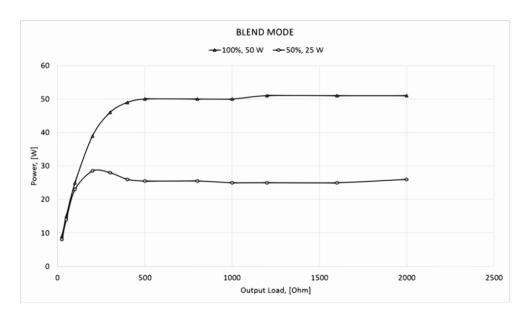


Figure A - 8. Output power versus impedance for Coagulation modes

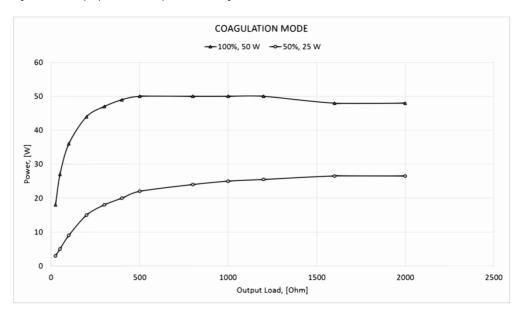


Figure A - 9. Output power versus impedance for Fulguration mode

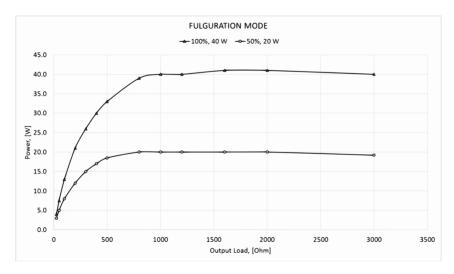


Figure A – 10. Output power vs impedance for Bipolar mode

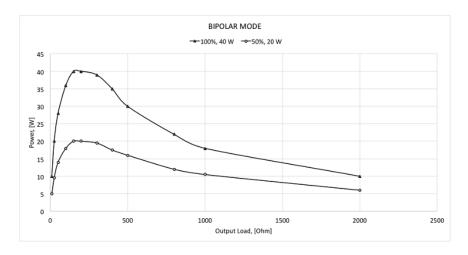
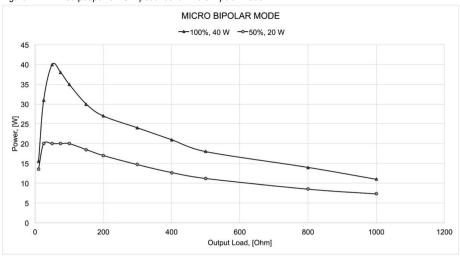


Figure A – 11. Output power vs impedance for Micro Bipolar mode



# WARRANTY

Symmetry Surgical 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.

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

The warranty periods for Symmetry Surgical 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 Symmetry Surgical.

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

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

Symmetry Surgical 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 Tennessee, 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 Davidson, State of Tennessee, USA.

Symmetry Surgical, 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.

CH REP

**MedEnvoy Switzerland Gotthardstrasse 28** 6302 Zug **Switzerland** 

**Australian Sponsor** The O R Company Pty Ltd. 4/47 Wangara Road Cheltenham, VIC 3192. Australia



Symmetry Surgical Inc. 3034 Owen Drive Antioch, TN 37013 USA 1-888-364-7004

SRN: US-MF-000024174

EC REP

**Emergo Europe** Westervoortsedijk 60 6827 AT Arnhem The Netherlands

(€2797