

USER'S GUIDE

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Bovie Icon Gi only.

Additional technical information is available in the *Bovie Icon Gi Service Guide*.

Equipment Covered in this Manual

Bovie Icon Gi:

Reference No.: Icon Gi

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Bovie Part Number MC-55-114-001 Rev. 2

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.

TERMINOLOGY

The following terminology is used throughout this guide to describe specialized features and functionality of the Bovie Icon Gi.

Touch Screen – Touch screen located on the unit's front panel. This area is used to enter and view user selections such as modes, power setting, and presets. From each screen, the user can navigate to and from additional screens.

Pop-Up Screen – Additional input and information screens that appear on the unit's front panel. These windows display and allow input for instructions, warnings and cautions and other information about the unit and its functionality. Pop-up screens can also navigate the user to and from additional screens.

Bovie NEM™ – The contact quality monitoring system (NEM) detects the return electrode and contact quality between the return pads and the patient. This feature is designed to minimize patient burns at the return electrode site.

Graphical User Interface (GUI) – This type of interface uses symbols, images or icons along with or rather than text to make using the Icon Gi more user-friendly.

High Frequency Generator (HF Generator) – This type of equipment is used in medical procedures requiring electro surgery.

Electrosurgical Unit (ESU) – The ESU, combined with the appropriate electrosurgical accessory is used for a variety of surgical procedures.

Split Pad – With the exception of Warnings and Cautions, the term “split pad” will be used throughout this manual when discussing patient pads, return electrodes, or patient return electrodes. This accessory is used during monopolar surgery to maximize patient safety and site burns.

Cut/Blend Modes

Pure Cut – The Pure Cut mode is used when little coagulation is needed during endoscopic dissection or polypectomy.

PURE

This mode can be used for either dissection or removal of non-vascular polyps and clean dissection of non-vascular areas or areas that can be spot coagulated after dissection. It may be useful for some minimally vascular polypectomy procedures.

Safe Cut – During Safe Cut mode, the unit pulses between pure cut and gentle coag with a predetermined repetition rate.

SAFE

This mode can be used when a controlled dissection is required. It is useful for ERCP examinations when Papillotomy is performed and is also useful when piecemeal polypectomy is performed and preservation of the microscopic margins is desired.

BLEND 1

Blend 1 – This is a monopolar Cut mode that is modified to allow for minimal coagulation along the wound edges. Intended uses are for minimally vascularized polyps and areas that can be spot coagulated, post dissection. 75% duty cycle.

BLEND 2

Blend 2 – This is a monopolar Cut mode that is modified to allow for moderate coagulation along the wound edges. Intended uses are for moderately vascular polyps and areas that can be spot coagulated, post dissection. 62.5% duty cycle.

BLEND 3

Blend 3 – This is a monopolar Cut mode that is modified to allow for maximum coagulation along the wound edges. Intended uses are for vascularized polyps and areas that can be spot coagulated, post dissection. 50% duty cycle.

SMART

Smart Cut – This mode is reserved for future Gi functionality.

Continued on following page.

Coag/Bipolar Modes

PINPOINT

Pinpoint – The Pinpoint mode is most effective with the electrode tip in direct contact with the tissue at the point of bleeding. This mode will provide maximum hemostasis but may also result in some char or sticking depending on the electrode utilized. This mode may also be used to dissect tissue with hemostasis.

GENTLE

Gentle Monopolar – Using the Gentle Coagulation mode will result in minimal charring or sticking of the electrode. The electrode must be in direct contact with the tissue for positive results. It has no dissection ability.

BIPOLAR

Bipolar – Using the Bipolar mode does not require a patient return pad and is the most aggressive bipolar mode for providing hemostasis. It can also be used for bipolar cutting instruments with direct contact to tissue.

GENTL BI

Gentle Bipolar – The Gentle Bipolar mode does not require a patient return pad. This coagulation mode significantly reduces charring and sticking of the electrode.

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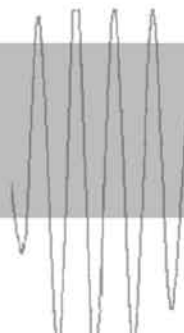
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INTRODUCING THE ICON GI

This section includes the following information:

Key Features

Components and Accessories

Safety

.....
CAUTIONS:

Read all warnings, cautions, and instructions provided with this unit 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 Icon Gi includes the latest technology. The unit utilizes a touch screen hardware interface in combination with a software graphical user interface (GUI). This allows for simple touch control features and functionality selection with unsurpassed performance, flexibility, reliability, and convenience for the user during endoscopic and laparoscopic procedures.

It includes the following features:

- **Nine Modes of Operation**

Pure Cut, Safe Cut, three levels of Blend, two levels of Coag (Pinpoint and Gentle), and two levels of Bipolar

These settings give the surgeon flexibility to cut all types of tissue without losing performance. Monopolar Pure Cut generates constant output power over a wide range of impedances. Safe Cut generates a pulsed cut followed by a controlled period of gentle coagulation. The three Blend modes generate minimal, moderate, and maximum coagulation along wound edges. The Bipolar modes require no patient return pad.

- **Touch Screen**

The Icon Gi features touch screen functionality that allows the user to interact with the generator by touching the screen. All user selections are entered on the touch screen.

- **Physician and Procedure Presets**

The Presets feature allows multiple physicians to be programmed into the generator. Each physician can program their preferred Procedure Presets, including mode and power settings for quick changeover between cases.

- **Split Pad Sensing and Contact Quality Monitoring**

The Icon Gi incorporates a split pad contact quality monitoring system (Bovie NEM™). This system detects the split pad.

The system also continually monitors the contact quality between the patient and the split pad. This feature is designed to minimize patient burns at the pad site. A split pad must be used with the Icon Gi. An alarm will sound if a solid pad is detected.

Refer to Section 3, *Getting Started* to learn more.

NOTICE:

The Icon Gi requires a split pad. Connecting a solid pad and activating a mode will cause a unit fault and trigger an alarm.

- **Isolated RF output**

This minimizes the potential of alternate site burns.

- **Lighted Connector Panel**

Illuminated panel makes connection of accessories easier to use in any surgical setting.

- **Standard Accessory Connectors**

These connectors accept the latest monopolar and bipolar instruments. Refer to Section 2, *Touch Screen and Receptacles* to learn more.

- **Multiple Communication Ports**

There are three USB connections, two on the rear and one on the front. Also, the rear panel has an ethernet and RS232 connection.

- **Data Exchange**

Used to exchange data from unit to unit.

COMPONENTS AND ACCESSORIES

You should receive the following components with your unit:

- Icon Gi Electrosurgical Generator
- 110 VAC Hospital-grade power cord
- 220 VAC Hospital-grade power cord
- Icon Gi USB Memory Stick
- User's Guide

ADDITIONAL ACCESSORIES

To avoid incompatibility and unsafe operation, we recommend using the following Bovie accessories with the Icon Gi:

- ESREC - split pad with 2.8 M cable
- BV-1253BGI - footswitch
- RHSV - **Bovie Button** - remote hand control (active)
- RHSV - **Bovie Button Laparoscopic** - remote hand control (active)
- GIACM - Gi active cord (male)
- GIACF - Gi active cord (female)
- BV-ICON-CS - Icon Gi Mobile Cart

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 Icon Gi, this section presents the warnings and cautions that appear throughout this user's guide. It is important that you read, understand, and follow the instructions in these warnings and cautions so that you can operate this equipment with maximum safety. It is also important that you read, understand, and follow the instructions for use in this user's guide.

WARNINGS:

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

Danger: Fire / Explosion Hazard - Do not use the Icon Gi in the presence of flammable materials.

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

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

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

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

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

Fire Hazard - Do not use extension cords.

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

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

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

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

WARNINGS:

Use electrosurgery with caution in the presence of internal or external 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.

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

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

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

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

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

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

Do not wrap the accessory cords or return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

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.

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 unit or place the unit 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 unit and other electronic equipment (such as monitors). An activated electrosurgical unit may cause interference with them.

Non-function of the unit may cause interruption of surgery. A backup unit 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 unit, place the smoke evacuator a distance from the unit and set the unit volume control at a level that ensures that the activation tones can be heard.

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

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

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

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

Remove any loose fitting jewelry from the patient before activation.

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

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

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

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

NOTICES:

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

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



TOUCH SCREEN AND RECEPTACLES

This section describes:

The Front and Rear Panels

Touch Screen Controls, Indicators, Receptacles, and Symbology Descriptions

NOTICE:

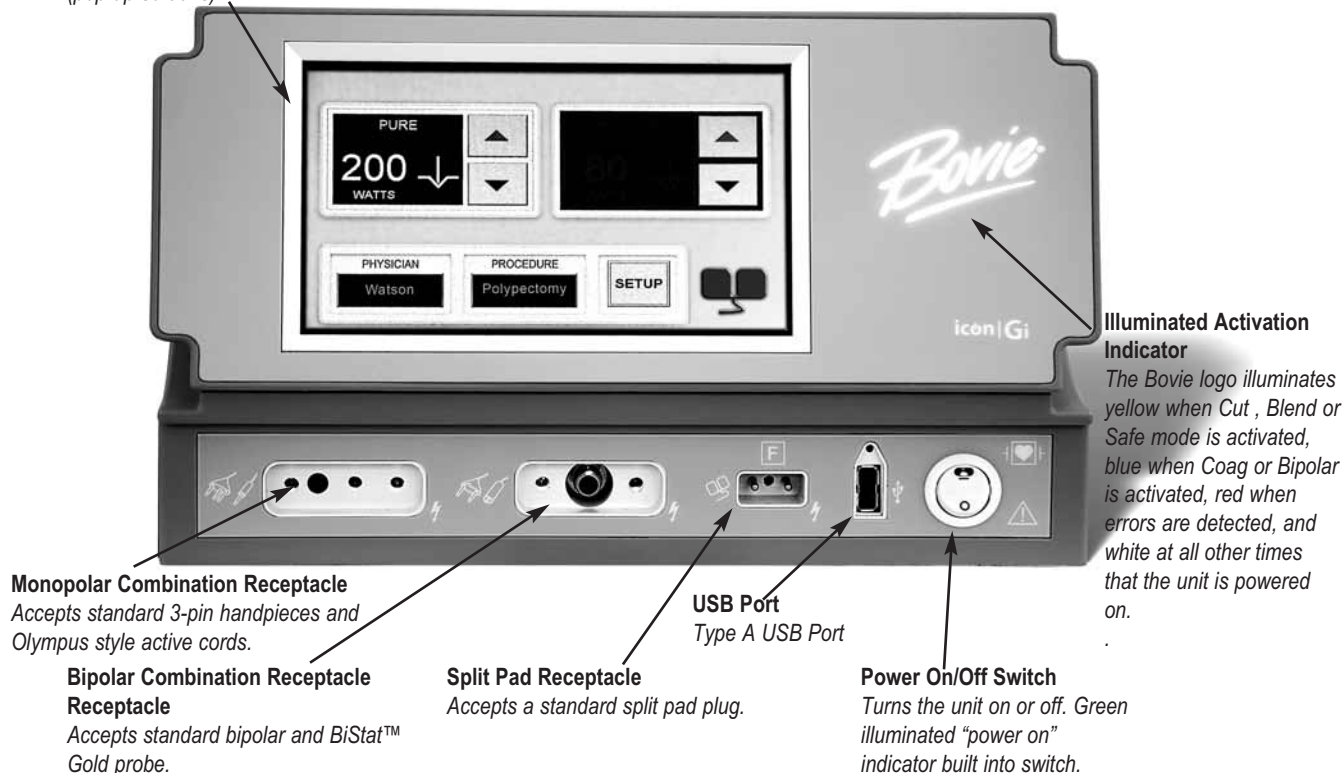
Refer to Section 4 of this guide for instructions on using the Icon Gi ESU.

FRONT PANEL

Figure 2 – 1 Layout of touch screen and receptacles on the front panel

Touch Screen

The touch screen is used to enter and view user selections such as modes, power setting, and presets. From each screen, the user can navigate to and from additional screens (pop-up screens).






















REAR PANEL

Figure 2 – 2 Layout of receptacles on the rear panel



Symbols











Table 2 – 1 Refer to the following table for descriptions of symbols found on the front of the Icon Gi.

SYMBOLS	DESCRIPTION
<i>Cut/Blend Controls</i>	
	Pure Cut Mode
	Blend Mode 1
	Blend Mode 2
	Blend Mode 3
	Safe Cut Mode
<i>Coag Controls</i>	
	Pinpoint (Coag) Mode
	Gentle Coag Mode
<i>Bipolar Controls</i>	
	Bipolar Mode
	Gentle Bipolar Mode
<i>Indicators</i>	
	Split Pad (green indicates proper placement; red indicates incorrect placement)
	Activator/Error Indicator
<i>Symbols</i>	
	Read instructions before use.
	Defibrillator Proof Type CF Equipment
	RF Isolated – patient connections are isolated from earth at high frequency.
	USB Communications
	Split Pad
	Bipolar Combination Receptacle (Standard or BiStat Gold probe)
	Monopolar Combination Receptacle (Standard 3-pin or probe)
	Caution High Voltage

Rear panel symbols on following page.

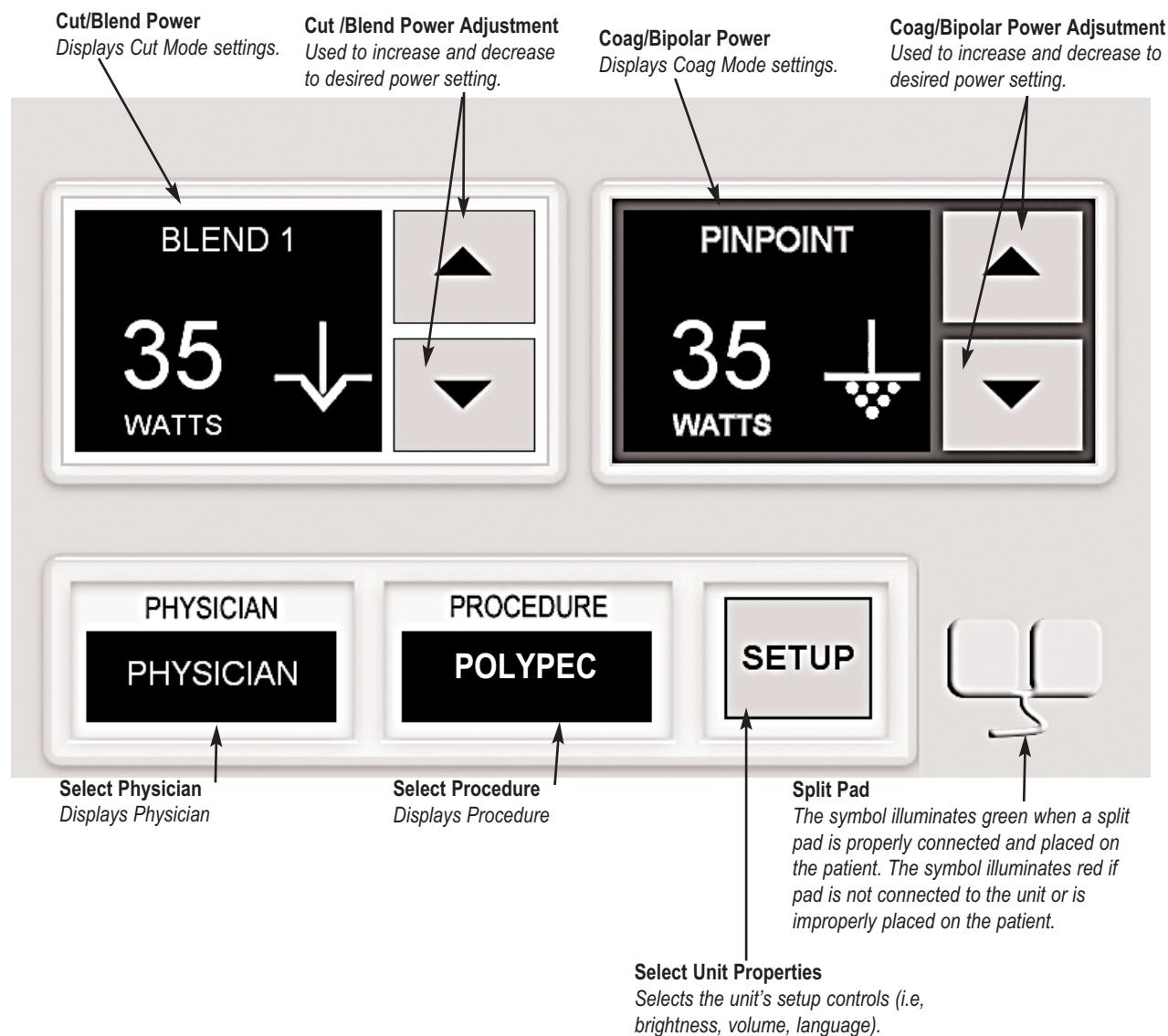
Symbols

Table 2 – 2 Refer to the following table for descriptions of symbols found on the back of the Icon Gi.

SYMBOLS	DESCRIPTION
	Equipotential Ground Stud
	Non-ionizing Radiation
	Fuse Enclosed
	Danger - Explosion Risk If Used With Flammable Anesthetics.
	Footswitch Input Jack
	Do not dispose of this device in the unsorted municipal waste stream.
	Read Instructions Before Use
	RS 232 Serial Communications
	USB Communications
	Ethernet Port

MAIN SCREEN

Figure 2 – 3 Controls for selecting and adjusting the Cut/Blend and Coagulation/Bipolar power; pre-programmed physician and procedure selections

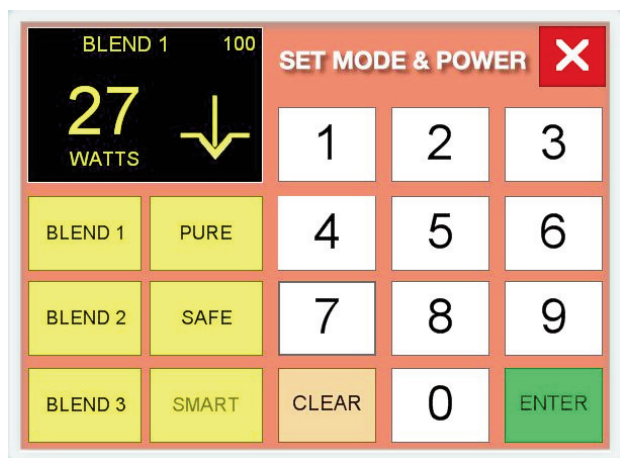


NOTICES:

Activation is only available from the Main Screen and shows the requested powers and modes. The Physician and Procedure Presets are also displayed in this screen.

CUT/BLEND AND COAG/BIPOLAR KEYPAD SCREENS

Figure 2 – 4 and 2 – 5 Controls for the Cut, Blend, Coag and Bipolar modes are selected and adjusted from these pop-up screen



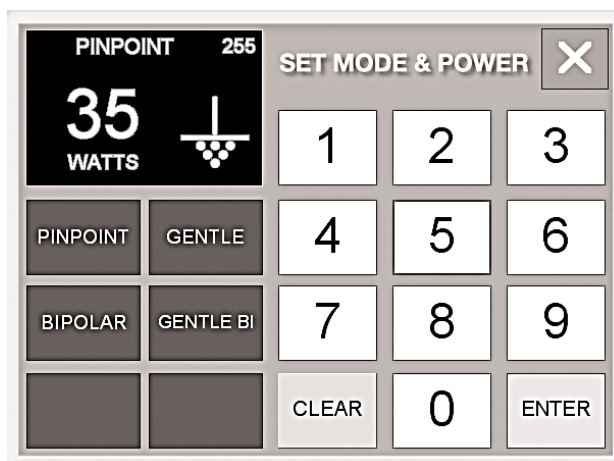
Keypad Screens

Use this screen to select (touch) modes and enter the desired power setting by touching the keypad.

Mode and power setting will be displayed (illuminated) in the upper left-hand corner of the pop-up screen.

The number in the upper right corner indicates the highest power available for that mode.

Exit Buttons
Used to exit screen and return the user to the previous screen. Any changes are discarded.



Clear Buttons

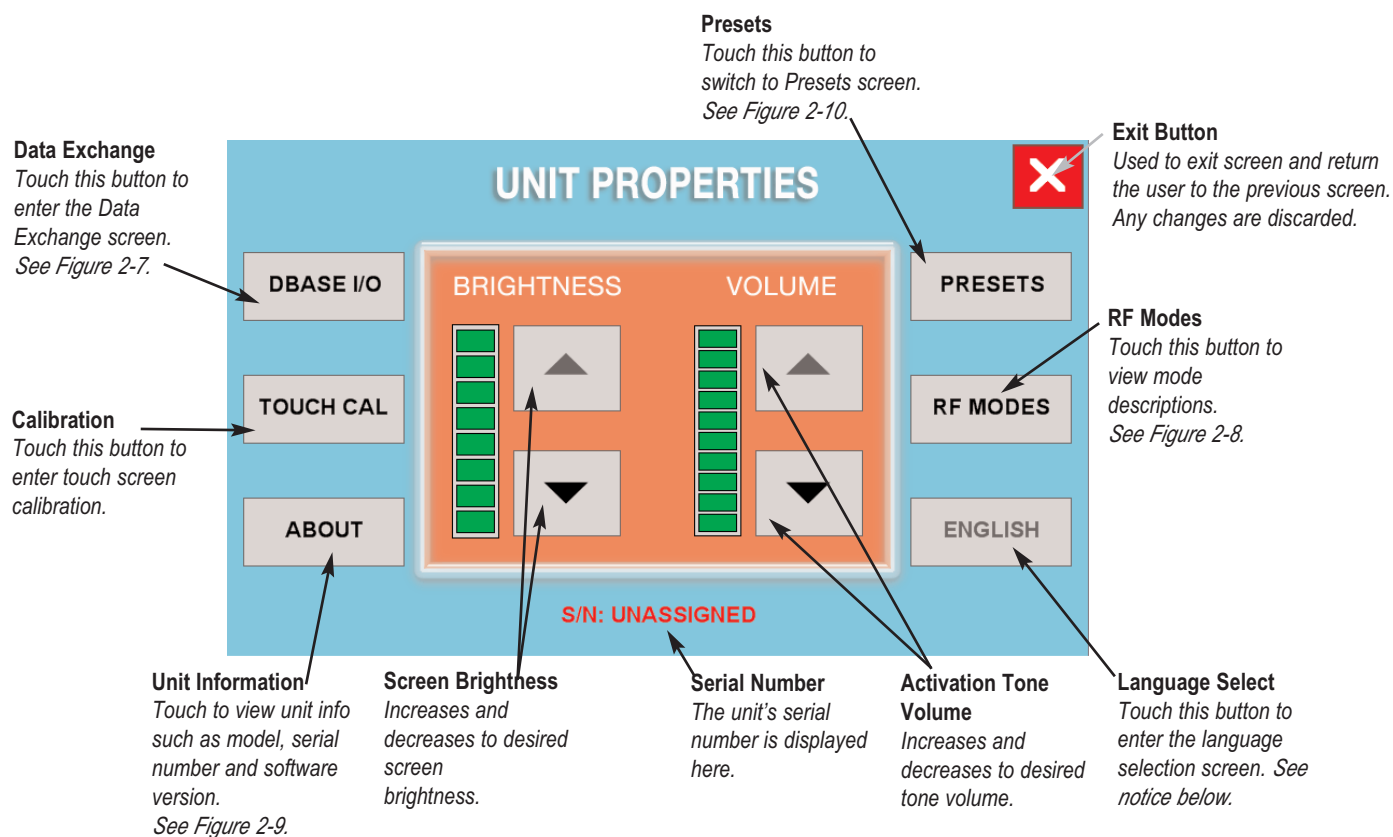
Used to reset selections so user can re-enter desired settings.

Enter Buttons

Your settings will be saved and you are returned to the previous screen.

UNIT PROPERTIES SCREEN

Figure 2 – 6 View unit properties and adjust user preferences from this pop-up screen



NOTICE:

English is the default language for the Icon Gi. Detailed directions for changing the language are provided in Section 4 of this manual.

See following page for additional Unit Properties screens.

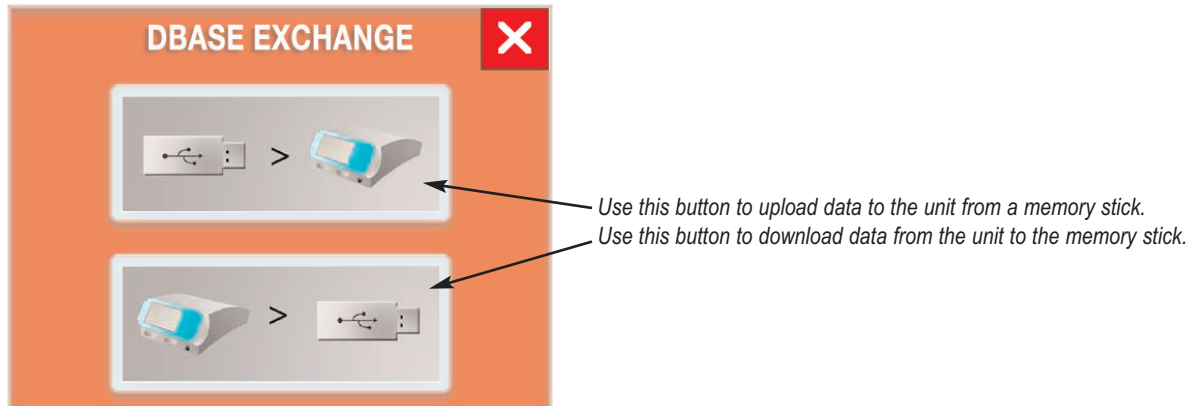
ADDITIONAL SCREENS



Exit Buttons

Used to exit screen and return the user to the previous screen. Any changes are discarded.

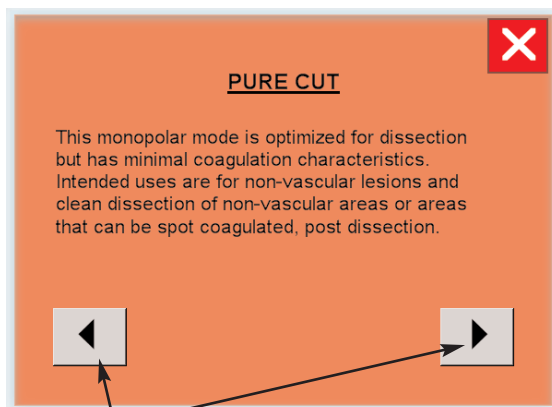
Figure 2 – 7 View and select data exchange options from this pop-up screen.



NOTICE:

Only use BV-USBGI-256 - Icon Gi USB Memory Stick with this unit.

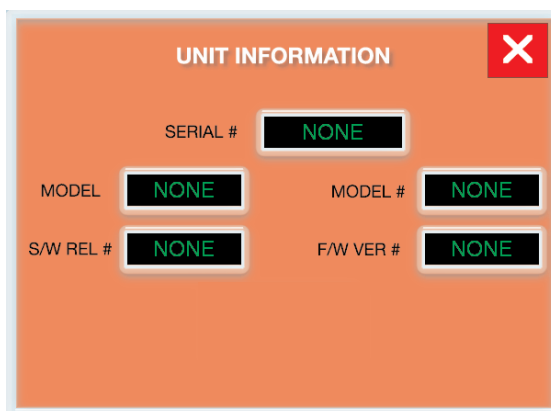
Figure 2 – 8 RF Mode example



RF Modes

Use arrows to advance through to the desired mode description by touching the arrows.

Figure 2 – 9 View unit properties from this pop-up screen.



SELECT OR EDIT PRESET SCREENS

NOTICE:

You can type up to 20 characters in the keypad screens.

Names and procedures will be displayed in alphabetical order.

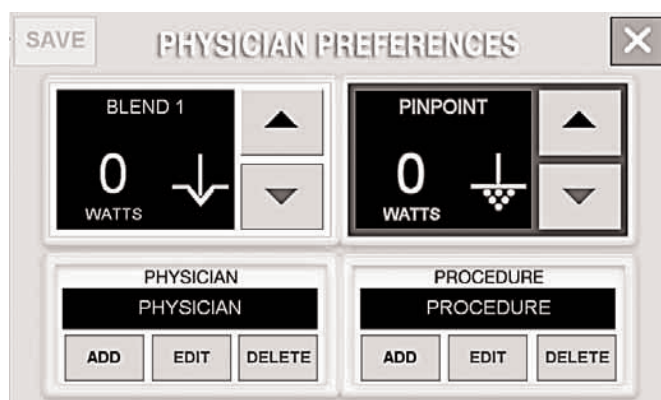
You can save up to 15 Physician names and up to 15 Procedures for each Physician.



Exit Buttons

Used to exit screen and return the user to the previous screen. Any changes are discarded.

Figure 2 – 10 View and change user presets from this pop-up screen.



Physician Preferences

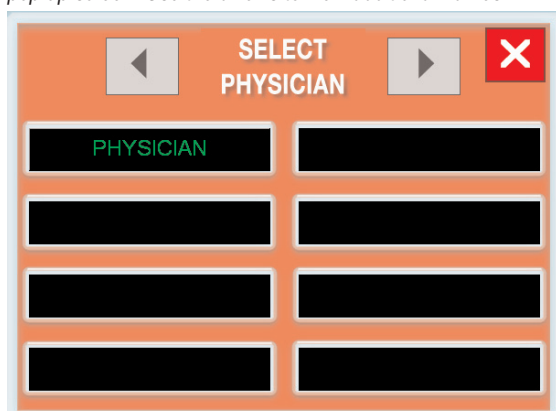
This screen is similar to the Main screen with the exception of the **Add**, **Edit** and **Delete** options.

Touching the **Save** button stores user selections to a Preset.

Use this screen to Add, Edit or Delete Physician and Procedure Presets.

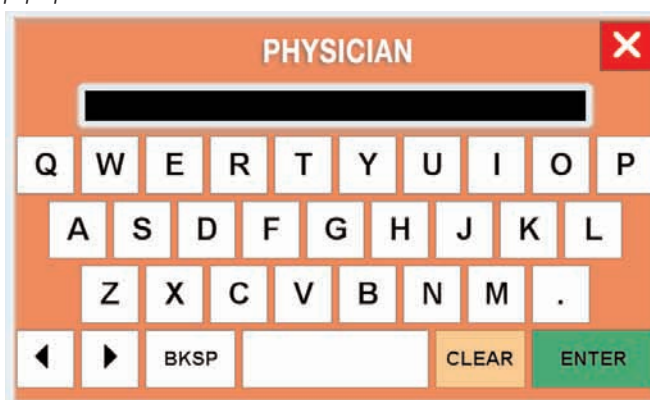
See Figures 2-11 and 2-12 for examples. The Procedure pop-ups are similar. See Section 4 for details.

Figure 2 – 11 View and select physician names from this pop-up screen. Use the arrows to view additional names.



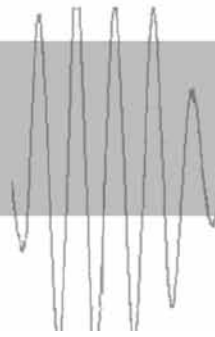
Touching a blank field brings the user back to the Physician Preferences screen.

Figure 2 – 12 Enter and modify physician names from this pop-up screen.



Add or Edit Physician or Procedure pop-up Screens

These pop-up screens allow the user to enter or edit information corresponding to the Select Physician screen or the Select Procedure screen. Touching **Clear** will reset information. Use the **Backspace** button or arrow buttons to delete characters or replace characters.



GETTING STARTED

This section includes the following information:

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

INITIAL INSPECTION

When you first unpack your Icon Gi, inspect it visually:

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

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

INSTALLATION

Place the Icon Gi on any flat surface with a tilt angle not more than 10° or on a Icon Gi mobile stand. Do not block rear fan vents. Ensure that air flows freely on all sides of the unit.

WARNING:

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

FUNCTION CHECKS

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

WARNING:

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

All accessories connected to the generator must be rated for at least the maximum peak output voltage of the Icon Gi set at the intended output control setting in the intended operating mode.

NOTICE:

The Icon Gi requires a split pad. Connecting a solid pad will cause a unit fault and trigger a fault.

Setting Up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.
2. Connect the Icon Gi power cable or a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.
3. Connect an accessory to the appropriate receptacle. The use of Bovie accessories is recommended.
4. Do not connect a split pad at this time.
5. Turn the unit on by switching the power switch to the On (I) position.

Checking the Split Pad Alarm

Proper Pad Placement

Once set up is complete and unit is powered on, you can check the unit's split pad alarm and indicator.

Connect split pad to front panel receptacle and attach securely to your bare skin.



Proper pad connection and placement is indicated by the split pad symbol in the Main screen illuminating green and an audible tone.

Improper Pad Placement

Once set up is complete and unit is powered on, you can check the unit's split pad alarm and indicator.

1. Connect split pad and an accessory such as a hand switch to front panel receptacle. Do not place the split pad to your skin.
2. Activate the accessory.

Notice the screen. A fault (F7) will display "Poor Split Pad Connection." You will also notice that the pad symbol in the screen is illuminated red and an alert tones.

Split Pad Disconnection

If the pad is removed from the patient or dislodged from the front panel receptacle after proper placement and connection, no fault error will appear but the pad symbol will change from green to red and an alert will tone.

Solid Pad Detected

If a solid pad is connected to the unit, fault code (F6) will display "Solid Pad Detected." No activation will be possible until pad is removed.

NOTICE:

A split pad is not necessary when using the Bipolar modes.

Visual and Audible Indicators

Visual

Unit activation can easily be monitored by observing the Bovie Logo located on the front of the unit.



Yellow	Cut/Blend/Safe mode is activated.
Blue	Coagulation/Bipolar mode is activated.
Red	Unit error is detected. See <i>Error Codes in Section 6</i> .
White	Unit is powered on.

Audible

Unit activation can easily be monitored by listening to the output tone.

Cut/Blend	610 Hz output tone
Safe	610 Hz pulsing tone
Coag/Bipolar	910 Hz output tone

Checking Monopolar Mode (with BV-1253BGI footswitch)

1. Plug the footswitch in the rear of the unit.
2. Select the Pure Cut mode and Pinpoint mode and set the power to one watt.
3. Connect a split pad to the split pad receptacle on the front of the unit and attach securely to your bare skin. Verify that the green split pad indicator displays (symbol illuminates green) to indicate the split pad is properly attached. You will hear a ready chime.
4. Depress the Cut pedal (yellow) on the footswitch. Verify that the Cut mode activates and that the unit sounds an activation tone and the Bovie logo illuminates yellow.
5. Depress the Coag pedal (blue) on the footswitch. Verify that the Coag mode activates and that the unit sounds an activation tone and the Bovie logo illuminates blue.

Checking Monopolar Mode (with handswitch)

1. Connect a handswitching handpiece to the Monopolar handpiece receptacle.
2. Select the Pure Cut and Pinpoint mode and set the unit to one watt from your Cut and Coag touch screens.
3. Connect split pad to front panel receptacle and attach securely to your bare skin.
Verify that the green split pad indicator displays (symbol illuminates green) to indicate the split pad is properly attached. You will hear a ready chime.
4. Depress the Cut button (yellow) on the handswitch. Verify that the Cut mode activates and that the unit sounds an activation tone and the Bovie logo illuminates yellow.
5. Confirm that releasing the pedal returns the unit to an idle state and the Bovie logo illuminates white.
6. Depress the Coag button (blue) on the handswitch. Verify that the Coag mode activates and that the unit tones an activation tone and the Bovie logo illuminates blue.
7. Confirm that releasing the pedal returns the unit to an idle state and the Bovie logo illuminates white.

Checking Bipolar Mode (with BV-1253BGI footswitch)

1. Plug the footswitch in the rear of the unit.
2. Select the Bipolar mode and set power to one watt from your Coag touch screen.
3. Depress the blue (Coag) pedal on the footswitch. Verify that the Bipolar mode activates and that the unit sounds an activation tone and the Bovie logo illuminates blue.
4. Confirm that releasing the pedal returns the unit to an idle state and the Bovie logo illuminates white.

NOTICE:

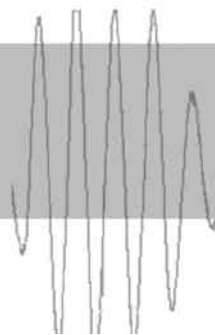
A split pad is not necessary when using the Bipolar modes.

IN-SERVICE

An initial orientation may be conducted with your Bovie representative. All of the set-up steps and function checks will be covered with your In-Service. The features and functionality of your unit will also be covered at that time.

PERFORMANCE CHECKS

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



USING THE ICON GI

This section contains the following procedures:

Inspecting the Unit and Accessories

Setup Safety

Initial Set Up

Selecting Unit Properties

Physician and Procedure Presets

Preparing for Surgery

Activating the Unit

Activation Safety

INSPECTING THE UNIT AND ACCESSORIES

Before each use of the Icon Gi, verify that the unit and all accessories are in good working order:

- Inspect for damage to the unit 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.
- Check that the display illuminates and that the Main Screen appears when you turn on the unit.
- Verify that no faults or errors display.

SETUP SAFETY

WARNINGS:

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

Electric Shock Hazard - Connect the unit 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 unit only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

The instrument receptacles on this unit 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 units.

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

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

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

CAUTIONS:

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

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

Non-function of the unit may cause interruption of surgery. A backup unit 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.

NOTICE:

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

INITIAL SET UP

1. Verify that the unit is Off by pressing the power switch Off (O).
2. Place the generator on a stable flat surface or the Icon Gi mobile stand. Do not block the two rear vents.

NOTICE:

During normal operation, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.

3. Connect the Icon Gi power cable or a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.

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.

4. Turn on the generator by pressing the power switch On (I). Verify the following:
 - The power switch illuminates green.
 - Display shows Bovie logo.
5. There will be a period while the unit boots up and completes a self-test. Once the self-test is complete, the Main Screen will appear displaying the last selected Presets settings. If the self-test is not successful, an alarm tone sounds. A message may pop up or the Bovie logo will turn red; the generator is disabled. Note the fault or error code and refer to Section 6, *Troubleshooting*.
6. Once the self-test is successful, connect additional accessories and set the generator controls.

SELECTING UNIT PROPERTIES

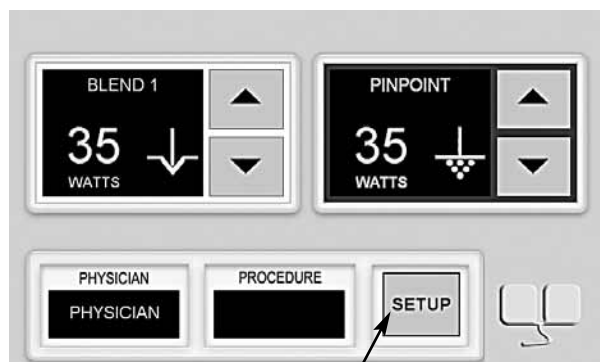


Figure 4 – 1 Main Screen

Touch Setup to access the Unit Properties screen.

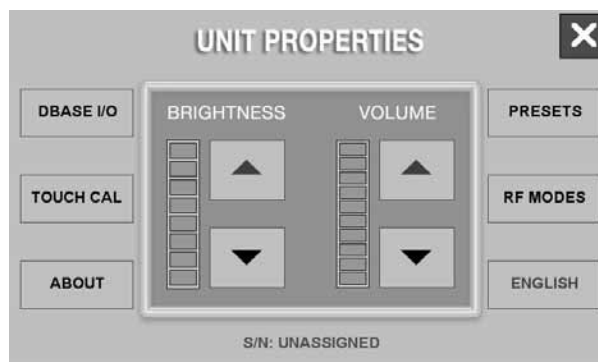


Figure 4 – 2 Unit Properties Screen

To access the Unit Properties screen, touch the Setup button at the bottom of the Main Screen display. See Figure 4-1.

The Unit Properties screen will appear. See Figure 4-2.

Volume

Touch the up/down arrows to increase and decrease the volume. The green illuminated bar increases and decreases as the volume is adjusted.

Brightness

Touch the up/down arrows to increase and decrease the brightness. The green illuminated bar increases and decreases as the brightness is adjusted.

Language (default English)

NOTICE:

English is the default language for the Icon Gi.

If language is changed from default, the button on the Unit Properties screen will change to display the user-set language.

To change the language from the Unit Properties screen:

1. Touch Language button.
2. Select your desired language from the list.
3. Touch the Enter button to save the selected language. The user is returned to the Unit Properties screen. The user interface will be configured for the selected language when the unit is re-started. Touching the exit button will return the user to the Unit Properties screen. No changes will be saved.

Data Exchange (DBase I/O)

The Icon Gi allows users to import and export physician and procedure information into/from the Icon Gi. To import or export physician and procedure preset information to and from the Bovie Memory Stick, touch the DBase I/O button to enter the DBase Exchange pop-up screen.

1. Plug your Bovie Memory Stick into the USB port located on the front of the unit.
2. Touch the desired exchange. A new pop-up screen appears with additional instructions. See Figure 4-3.
3. Follow the instructions. Additional selections may be necessary. The exchange takes a few moments. Wait until exchange is complete before removing the Bovie Memory Stick.
4. Touch the Exit button to return to the Unit Properties screen. New Presets information is available.



Figure 4 – 3 Data Exchange Screen

NOTICES:

When importing information from the Bovie Memory Stick, all stored Presets information will be replaced.

Use only the Bovie Memory Stick intended for the Icon Gi.

Calibrate Touchscreen (Touch Cal)

Touch the Touch Cal button to recalibrate the Touch Screen. See Section 6, *Troubleshooting* for detailed directions.

RF Modes (Modes Explanation)

Touch the RF Modes button to reference the descriptions for each RF mode available on the unit. Use the arrows at the bottom of the RF Modes screen to scroll through the list of descriptions.

About

Touch the About button to access the Unit Information pop-up screen. The Unit Information screen displays the unit's serial number, model, model number, software release number, hardware number, and firmware version number.

Presets

Touch the Presets button to select, view, add, edit, save, and delete physician and procedure presets. See Adding Physician and Procedure Presets on page 4-6 for detailed instructions.

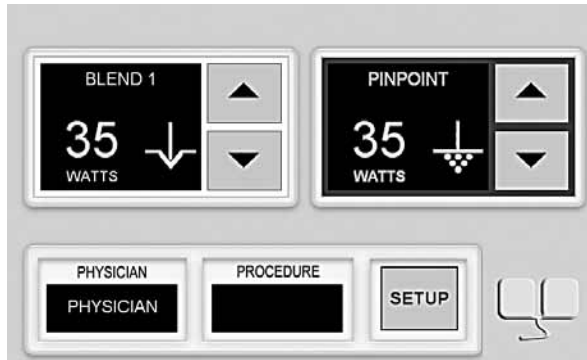


Figure 4 – 4 Main Screen

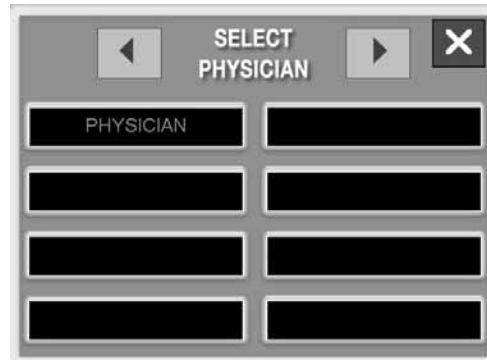


Figure 4 – 5 Select Physician Screen

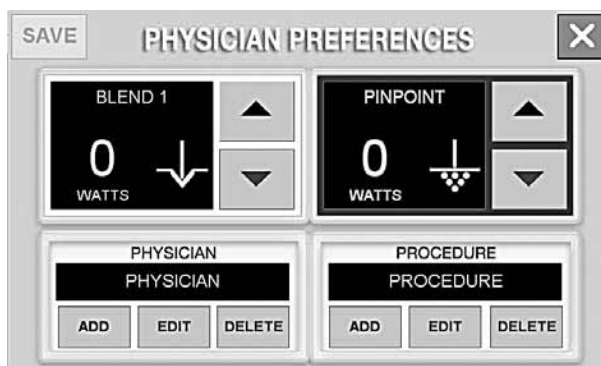


Figure 4 – 6 Physician Preferences Screen



Figure 4 – 7 Physician Keypad Screen

PHYSICIAN AND PROCEDURE PRESETS

The Icon Gi incorporates user-defined memory preset settings for easy recall of frequently used settings. Each physician (user) can enter their name and procedure mode and wattage settings. The physicians and procedures are then listed and can be quickly accessed and activated. The user can store up to 15 Physician names and each physician can store up to 15 Procedures.

Select Presets

Select Physician and Procedure

To select a physician (user) name and select a procedure associated with that physician, follow these steps:

1. Touch the Physician field on the Main Screen. See Figure 4–4. The Select Physician pop-up screen appears. See Figure 4–5.
2. Touch the name from the list on the screen. The Main Screen appears with the selected name listed in the Physician field.
3. Touch the Procedure field on the Main Screen. The Select Procedure pop-up screen appears.
4. Touch the procedure from the list on the screen. The Main Screen appears with the selected procedure listed in the Procedure field.

Add Presets

Add Physician and Procedure

To add a physician (user) name and add a procedure, follow these steps:

1. Touch the Setup button on the Main Screen. The Unit Properties screen appears.

-
2. Touch the Presets button. The Physician Preferences screen appears. See Figure 4–6.
 3. Touch Add in the Physician field. The Physician keypad screen appears. See Figure 4–7.
 4. Type in the Physician name up to 20 characters, then press Enter. The Physician Preferences screen appears.
 5. Touch Add button in the Procedure field. The Procedure keypad screen appears.
 6. Type in the Procedure name up to 20 characters, then press Enter. The Physician Preferences screen appears.
 7. Touch the Cut/Blend section of the window. The selected Set Mode & Power pop-up screen will appear.
 8. Touch the desired mode, and key in the desired power setting.
 9. Touch Enter button. The Physician Preferences screen appears.
 10. Touch the Coag/Bipolar section of the window. The selected Set Mode & Power pop-up screen will appear.
 11. Touch the desired mode, and key in the desired power setting.
 12. Touch Enter button. The Physician Preferences screen appears.
 13. Touch Save button to save the name and procedures as Presets.
 14. Touch Exit twice to return to the Main Screen.

NOTICE:

As a shortcut to add a Preset, touch the Physician or Procedure field on the Main Screen to view the Select Physician and Select Procedure pop-up screens. Then, touch a blank field in the list. Follow instructions above starting at step 3 (add physician) or step 5 (add procedure).

Edit Presets

Edit Physician and Procedure

To edit a physician (user) name, follow these steps:

1. Touch Setup button. The Unit Properties screen appears.
2. Touch Presets button. The Physician Preferences screen appears.
3. Touch the Edit button under the Physician field. The Physician keypad screen appears.
4. Edit the name.
5. Touch Enter button. The Physician Preferences screen appears.
6. Touch Edit button under the Procedure field.
7. Edit the name.
8. Touch Enter button. The Physician Preferences screen appears. Mode and power can be changed also.
9. Touch the Cut/Blend or Coag/Blend section of the window. The selected Set Mode & Power pop-up screen will appear.
10. Touch the desired mode, enter power setting and touch Enter. The Physician Preferences screen appears.

11. If necessary, touch the other mode section of the screen to make additional changes.
12. Touch Save button to save the edited name and procedure.
13. Touch Exit button twice to return to the Main Screen.

Delete Presets

Delete Physician

To remove a physician's name and the procedures associated with the physician's preset information, follow these steps:

NOTICE:

Deleting a Preset Physician name also deletes the procedures associated with that name.

1. Touch Setup button. The Unit Properties screen appears.
2. Touch Presets button. The Physician Preferences screen appears.
3. Touch the Delete button under Physician field. A Yes/No pop-up screen appears.
4. Touch Yes to delete the name or No to return to the previous screen (name will not be deleted).
5. Touch Save button.
6. Touch Exit button twice to return to the Main Screen.

Delete Procedure

1. Touch Setup button. The Unit Properties screen appears.
2. Touch Presets button. The Physician Preferences screen appears.
3. Touch the Delete button under Procedure field. A Yes/No pop-up screen appears. See Figure 4–8.
4. Touch Yes to delete the procedure or No to return to the previous screen (procedure will not be deleted).
5. Touch Save button.
6. Touch Exit button twice to return to the Main Screen.



Figure 4 – 8 Delete Procedure pop-up Screen

Cancel

The user can Cancel preset changes and return to the Main Screen at any time.

1. Touch the Exit button to exit each screen and return to the Main Screen.

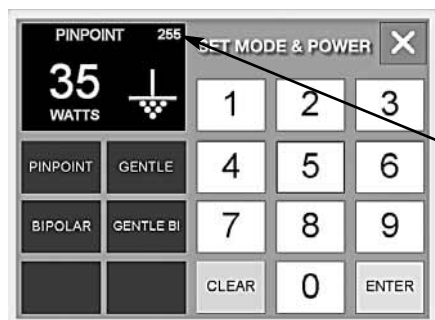


Figure 4 – 9 Max. wattage available

NOTICES:

When storing Procedure presets, be aware that the Procedure preset will be saved with the Physician name that appears in the Physician field.

The maximum wattage available for each mode will be displayed in the upper right-hand corner of the selected mode. See Figure 4-9.

Any time the Cut/Blend or Coag/Bipolar sections of the screen are visible, mode and power adjustments can be made. If adjustments are made, the Procedure field will be blank, allowing the user to activate this setting or proceed with Editing the last listed Procedure Preset with the new settings.

PREPARING FOR SURGERY

NOTICE:

Monopolar surgery requires a split pad.

Applying the Split Pad

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

1. Connect the cable to the Split Pad receptacle on the front of the unit.
2. Secure split pad to patient. The unit will automatically sense the contact of the split pad and if pad is properly attached. The unit will monitor contact quality between the pad and the patient.

NOTICE:

The Split Pad symbol in the lower-right hand corner of the Main Screen illuminates green when a split pad is properly connected and placed on the patient. The symbol illuminates red if pad is not connected to the unit or is improperly placed on the patient.

Connecting Monopolar Accessories

1. Connect a monopolar cable into the monopolar receptacle on the front of the unit. The unit accepts standard 3-pin handpieces or Olympus style active cords.

NOTICE:

If using an Olympus style active cord, a footswitch is required.

2. Connect the appropriate electrode to the monopolar handpiece.
3. Connect the Bovie footswitch to the footswitch receptacle on the rear of the unit.

Connecting Bipolar Accessories

1. Connect a Bipolar cable to the Bipolar receptacle on the front of the unit. The unit accepts standard Bipolar and BiStat Gold probe accessory.
2. Connect the appropriate electrode to the Bipolar connector.
3. Connect the Bovie footswitch to the footswitch receptacle located on the rear of the unit.

Mode and Power Settings

1. Select the desired mode and power setting from the Main Screen. User Presets or Main Screen power adjustments can be used.

For user Presets and settings, follow the directions on page 4-6. For basic adjustments, Main Screen adjustments follow the directions below.

Selecting the CUT/BLEND Settings

The Icon Gi allows users to select from two Cut and three blended cut Modes and power settings. From the Main Screen, the power setting can be adjusted up and down using the Up/Down arrows.

Selecting a Cut/Blend Mode and Power Setting

1. From the Main Screen, touch yellow section of screen. The Set Mode and Power pop-up screen appears.
2. Touch the desired Mode.

-
3. Use the numeric keypad to set the power for the selected mode. The highest allowable power setting will also display in the upper right-hand corner.
 4. Touch the Enter button to save changes and return to the Main Screen. Touching Clear button will reset Power back to zero.

Canceling a Cut/Blend Mode and Power Setting

To exit without saving the settings touch the exit button.

Selecting the COAG/BIPOLAR Settings

The Icon Gi allows users to select from two Coag Modes and two Bipolar Modes and power settings. From the Main Screen, the power setting can be adjusted up and down using the Up/Down arrows.

Selecting a Coag/Bipolar Mode and Power Setting

1. From the Main Screen, touch blue section of screen. The Set Mode and Power pop-up screen appears.
2. Touch the desired Mode.
3. Use the numeric keypad to set the power for the selected mode. The highest allowable power setting will also display.
4. Touch the Enter button to save changes and return to the Main Screen. Touching Clear button will reset Power back to zero.

Canceling a Coag/Bipolar Mode and Power Setting

To exit without saving the settings touch the exit button.

ACTIVATING THE UNIT

NOTICE:

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

The Icon Gi will power up to the last selected Presets.

Once settings are selected, activate the unit by pressing the appropriate button on the handpiece or pedal on the footswitch.

NOTICE:

Footswitching operations are controlled by independent foot controls for Cut/Blend or Coag/Bipolar (blue or yellow).

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 Icon Gi 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.

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.

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

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

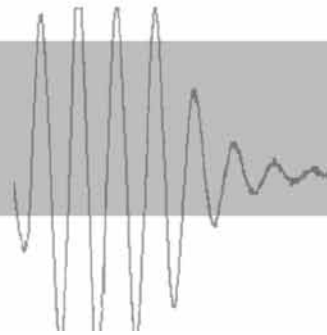
Remove any jewelry from the patient before activation.

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

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

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

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



MAINTAINING THE ICON GI

This section covers the following topics:

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

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

CLEANING

After each use, clean the unit.

WARNING:

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

NOTICE:

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

1. Turn off the unit, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the unit 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 unit.

PERIODIC INSPECTION

Every six months, visually inspect the Icon Gi for signs of wear or damage.

In particular, look for any of the following problems:

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

FUSE REPLACEMENT

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

To replace the fuses, follow this procedure:

1. Unplug the power cord from the wall outlet.
2. Remove the power cord from the Power Cable Receptacle on the rear panel.
3. To release the fuse drawer, insert a small flathead screwdriver into the slot on the drawer below the power cord receptacle. Then, slide the drawer out.
4. Remove the two fuses and replace them with new fuses with the same values.
5. Insert the fuse holder into the Power Cable Receptacle.

NOTICE:

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

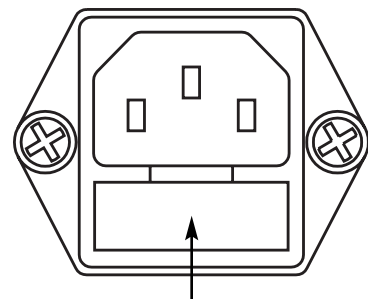
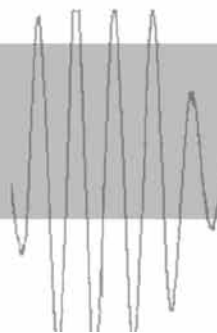


Figure 5 – 1 Fuse holder



TROUBLESHOOTING

This section includes the following information:

- *Fault Code Messages*
- *Fatal Error Messages*
- *Touch Screen Recalibration*

The Icon Gi includes automatic self-diagnostics. If the diagnostics detects a fault or error, the system displays an error message in the Warning pop-up screen, sounds an audible tone, and deactivates the unit's output power. Most fault codes result from faults in accessories attached to the unit. The following tables list the system fault codes and error codes, describes the faults, and recommends actions to take to resolve them. If the unit displays any other error code, it requires service.

SYSTEM FAULT CODE MESSAGES

Fault messages (F) indicate improper unit setup or faulty accessories. These fault messages appear in the Warning pop-up screen (red text). See Figure 6–1 below.

Fault Code	Description	Recommended Action
F1	Cut handpiece button may be stuck	<ol style="list-style-type: none"> 1. Turn off, then turn on the generator. 2. If the fault code reappears, disconnect all accessories. Turn off, then turn on the generator again. 3. If the problem persists, replace the handpiece of footswitch and repeat the restart. 4. If the fault code reappears, follow the instructions in the display, "Unit Requires Qualified Service - Power off unit and and call 727-384-2323".
F2	Coag handpiece button may be stuck	
F3	Cut footswitch pedal may be stuck	
F4	Coag footswitch pedal may be stuck	
F5	Simultaneous activation error	<p>The unit does not allow simultaneous activation of the cut and coagulation modes. The activation mode is "first come, first serve." This means that whichever mode is selected first will be the function the unit is activated to dispense. An example of this functionality includes, when the handpiece Cut button is pressed, the unit is activated for Cut. If a footswitch is simultaneously pressed for Coag, the unit will continue in the Cut mode as long as the handpiece Cut button is pressed. If the Cut button is released, the unit will sense an error and both functions will be disabled.</p> <ol style="list-style-type: none"> 1. Release either the cut or coag button on the handpiece, or the cut or coag pedal on the footswitch. 2. If the fault code reappears, follow the instructions in the display, "Unit Requires Qualified Service - Power off unit and and call 727-384-2323".
F6	Solid Pad Detected	Disconnect the solid pad accessory. Connect a split pad to the unit.
F7	Poor Spilt Pad Connection	Split pad may not be properly connected to patient or to the unit. Check placement. Use only spilt pad with the unit.



Figure 6 – 1 Warning Pop-up Screen Indicating a Fault message

SYSTEM FATAL ERROR MESSAGES

Error messages (E) indicate system errors. These error messages display in the Warning pop-up screen (red text). See Figure 6–2 below.

Error Code	Description	Recommended Action
E1	Output current too high, digital check	<ol style="list-style-type: none"> 1. Turn the unit off. 2. Turn the unit on. 3. If the error code reappears, record the number and contact Bovie customer service.
E2	Voltage Delta Error	
E3	Current Delta Error	
E4	DC Voltage Error	
E5	Temperature Sense 1	<ol style="list-style-type: none"> 1. Turn the unit off. 2. Allow the unit to cool for 20 minutes. 3. Turn the unit on. 4. If the error code reappears, record the number and contact Bovie customer service
E6	Temperature Sense 2	
E7	Temperature Sense 3	
E8	Temperature Sense 4	
E9	NEM Read Error	<ol style="list-style-type: none"> 1. Turn the unit off. 2. Turn the unit on. 3. If the error code reappears, record the number and contact Bovie customer service.
E10	NEM Calibration Error	
E11	Analog to Digital Error	



Figure 6 – 2 Warning Pop-up Screen indicating an Error message

NOTICES:

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

If a fatal error message is displayed, follow the instructions in the display, "Unit Requires Qualified Service - Power off unit and and call 727-384-2323".

All system faults and errors are recorded and stored for future diagnostic reference.

RECALIBRATION OF THE TOUCH SCREEN

Your Icon Gi is calibrated before it is packaged and shipped. If the Touch Screen is not responding properly to screen taps, recalibrate Touch Screen.

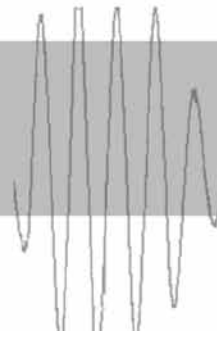
1. From the Main screen touch the Setup button. The Unit Properties screen appears.
2. Touch the Touch Cal button.
3. Touch Yes from the pop-up screen, "Do you really want to calibrate touch screen?".
4. Follow the touch screen calibration instructions on the screen using a stylus.
5. Touch the five markers.
6. When prompted, touch anywhere on the screen.

Once the screen calibrates, the unit will switch back to the Unit Properties screen.

NOTICES:

Touch screen calibration may have to be repeated if calibration is not successful.

If after several attempts calibration is not successful, unit should be return for service. Refer to Section 7, Repair Policy and Procedures.



REPAIR POLICY AND PROCEDURES

Refer to this section for information on:

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

RESPONSIBILITY OF THE MANUFACTURER

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

- The user has followed the Installation and Setup Procedures in this User's Guide.
- Persons authorized by Bovie Medical performed assembly operation, readjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- Equipment use is in accordance with the Bovie Medical instructions for use.
- Equipment to be disposed/recycled.

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. Contact your Bovie Medical representative for return instructions.

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

RETURNING THE UNIT FOR SERVICE

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

Step 1 – Obtain a Returned Goods Authorization Number

Call the Bovie Medical Customer Service Center (727) 384-2323 to obtain a Returned Goods Authorization Number. Have the following information ready when you call:

- | | |
|---|------------------------------|
| • Hospital / clinic name / customer number | • Description of the problem |
| • Telephone number/fax number | • Type of repair to be done |
| • Department / address, city, state, and zip code | • P.O. number |
| • Model number | |

Step 2 – Clean the Unit

WARNING:

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

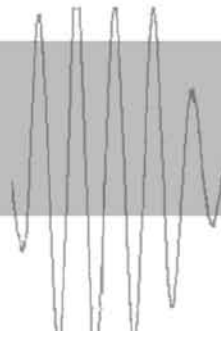
NOTICE:

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

- Turn off the unit, and unplug the power cord from the wall outlet.
- Thoroughly wipe all surfaces of the unit 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 unit.

Step 3 – Ship the Unit

- A. Attach a tag to the unit that includes the Returned Goods Authorization Number and the information (hospital, phone number, etc.) listed in *Step 1 – Obtain a Returned Goods Authorization Number*.
- B. Be sure the unit is completely dry before you pack it for shipment. Although the preference is to have the unit repackaged using its original packaging, Bovie understands that this may not always be possible. If necessary, contact Customer Service for the proper packaging to ship the unit. Please be sure to include a reference of the Bovie Return Goods Authorization Number on the outside of the box/container.
- C. Ship the unit, prepaid, to the address given to you by the Bovie Medical Service Center.



TECHNICAL SPECIFICATIONS

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

PERFORMANCE CHARACTERISTICS

Input Power

Input Voltage	100-240 VAC ~ ± 10%
Mains line frequency range (nominal):	50 – 60 Hz
Power consumption:	500 VA
Fuses (two):	3.5 A (slow blow)

Duty Cycle

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

The internal temperature of the unit is continuously monitored. If the temperature rises above 85⁰ C, the alarm will sound and output power will be deactivated.

Dimensions and Weight

Width	28.23 cm (11 in.)	Depth	44.47 cm (17.47 in.)
Height	16.87 cm (6.64 in.)	Weight	< 6.36 kg (< 14 lbs.)

Operating Parameters

Ambient temperature range	10° to 40° C (50° to 104° F)
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	700 hPa to 1060 hPa
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 and Storage

The device should be stored and used in a room temperature of approximately 77⁰ F/25⁰ C.

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

Audio Volume

The audio levels stated below are for activation tones (cut, coag, and bipolar) and alarm tones (split pad 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 Blend: 610 Hz Safe Cut: 610 Hz (lower pulsing volume) Pinpoint Coag: 910 Hz Gentle Coag: 910 Hz Bipolar: 910 Hz Gentle Bipolar: 910 Hz Note: During open circuit condition, the activation tone will pulse 20 times per second for all modes.
Duration	Continuous while the generator is activated

Alarm Tone

Volume (not adjustable)	70 dB \pm 5 dB
Frequency	2.4 kHz $\frac{1}{2}$ seconds / 1.2 kHz $\frac{1}{2}$ seconds
Duration	2 seconds

Fault Tone

Volume (adjustable)	40 – 60 dB
Frequency	1 kHz $\frac{1}{2}$ seconds / 2 kHz $\frac{1}{2}$ seconds
Duration	2 seconds

Split Pad Sensing

The system presents audible and visible alarms when it senses no split pad.

Split	The implementation of the split pad will require the generator to measure the impedance across the two contacting electrode pads. Trip resistance: 10 \pm 5 to 135 \pm 10 Continuous measurement: Once the system establishes the split pad resistance, an increase of 40% in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
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Low Frequency (50-60 Hz) Leakage Current

Enclosure source current, ground open	< 300 μ A
Source current, patient leads, all outputs	Normal polarity, intact ground: < 10 μ A Normal polarity, ground open: < 10 μ A Reverse polarity, ground open: < 10 μ A
Sink current at high line, all inputs	< 10 μ A

High Frequency (RF) Leakage Current

Bipolar RF leakage current	< 63 mA_{rms} at 80 watts
Monopolar RF leakage current (additional tolerance)	< 150 mA_{rms}

STANDARDS AND IEC CLASSIFICATIONS

Class I Equipment (IEC 60601-1)

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

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



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

Drip Proof (IEC 60601-2-2)

The Icon Gi 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 Compatibility (IEC 60601-1-2 and IEC 60601-2-2)

The Icon Gi complies with the appropriate IEC 60601-1-2 and IEC 60601-2-2 specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

The Icon Gi 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 Icon Gi. 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 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 Icon Gi. The Icon Gi and its accessories are not suitable for interconnection with other equipment.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The Icon Gi should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Icon Gi 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 Icon Gi.			
The Icon Gi is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Icon Gi can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Icon Gi 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		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{Z}{E_1} \right] \sqrt{P}$
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 Icon Gi is intended for use in the electromagnetic environment listed below. The customer or the user of the Icon Gi should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 2	The Icon Gi must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The Icon Gi 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Icon Gi is intended for use in the electromagnetic environment listed below. The customer or the user of the Icon Gi 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 Icon Gi requires continued operation during power mains interruptions, it is recommended that the Icon Gi 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Icon Gi, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{Z}{E_1} \right] \sqrt{P}$ <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 Icon Gi is used exceeds the applicable RF compliance level above, the Icon Gi should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Icon Gi.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ 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	Vp-p max	Crest Factor*
Pure Cut	200 W @ 300	492 kHz	N / A	1350 V	1.5 ± 20%
Blend I	100 W @ 300	492 kHz	30 kHz	2650 V	2.5 ± 20%
Blend II	100 W @ 300	492 kHz	30 kHz	2150 V	2.1 ± 20%
Blend III	100 W @ 300	492 kHz	30 kHz	1800 V	2.5 ± 20%
Safe Cut	200 W @ 50	492 kHz	N / A	1750 V	
Pinpoint (Coag)	80 W @ 500	492 kHz	30 kHz	3500 V	3.2 ± 20%
Gentle Coag	120 W @ 125	492 kHz	30 kHz	420 V	1.4 ± 20%
Bipolar	80 W @ 100	492 kHz	30 kHz	1000 V	3.3 ± 20%
Gentle Bipolar	50 W @ 25	492 kHz	30 kHz	220 V	1.4 ± 20%

OUTPUT POWER CURVES

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

Figure A – 1 Output power vs impedance for Cut (Pure) mode

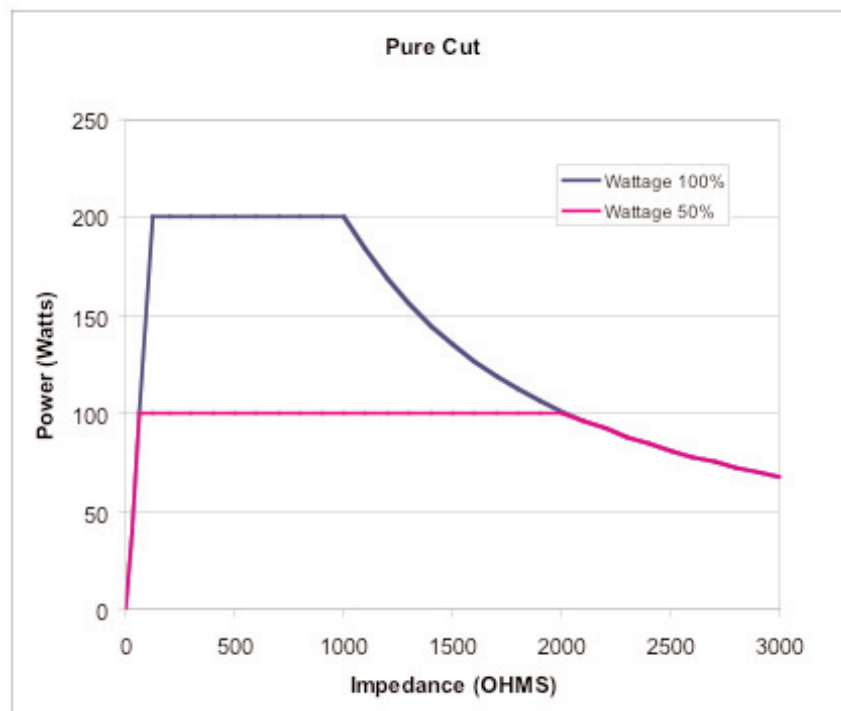


Figure A – 2 Output power vs impedance for Blend modes

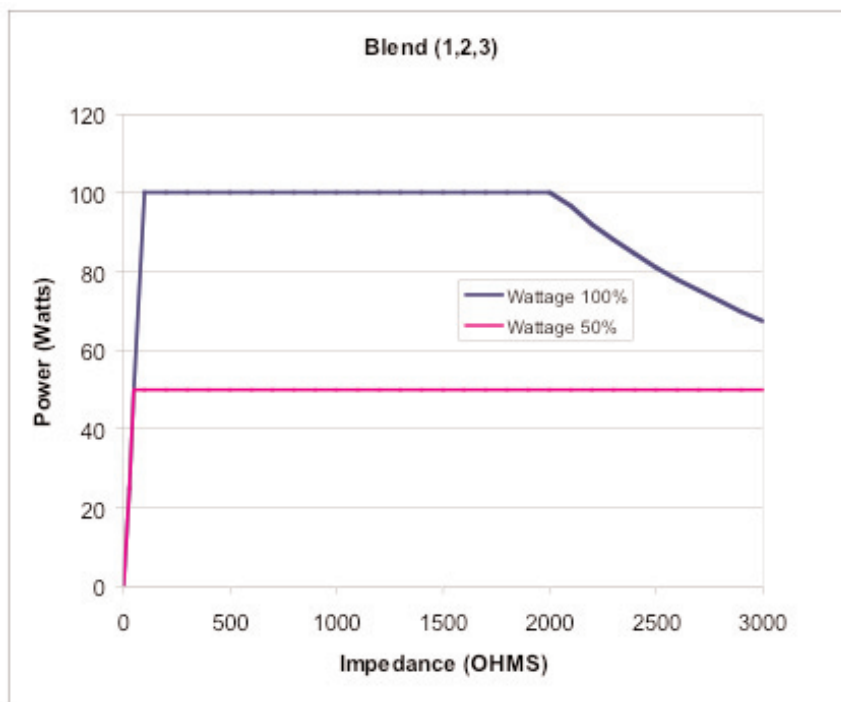


Figure A – 3 Output power versus impedance for Safe Cut mode

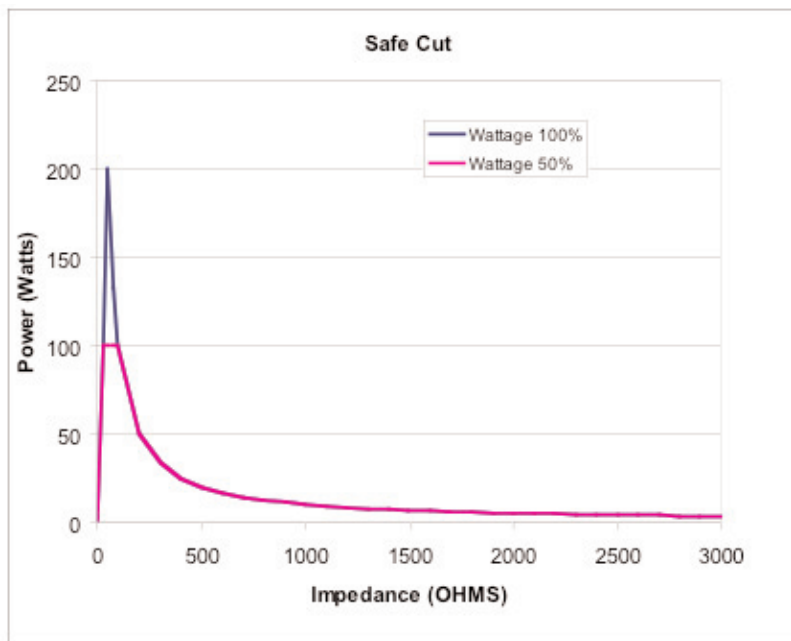


Figure A – 4 Output power versus impedance for Pinpoint mode

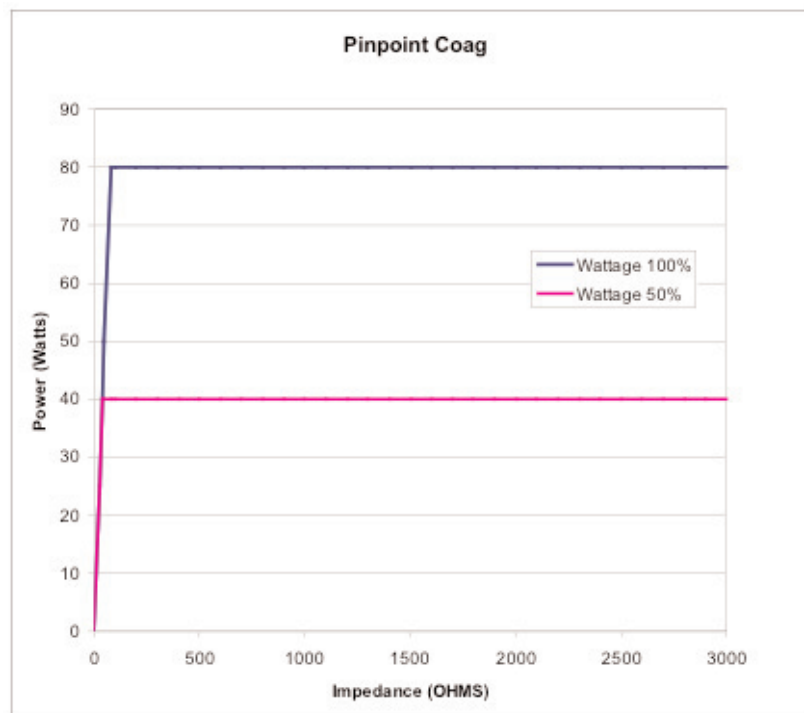


Figure A – 5 Output power vs impedance for Gentle Coag mode

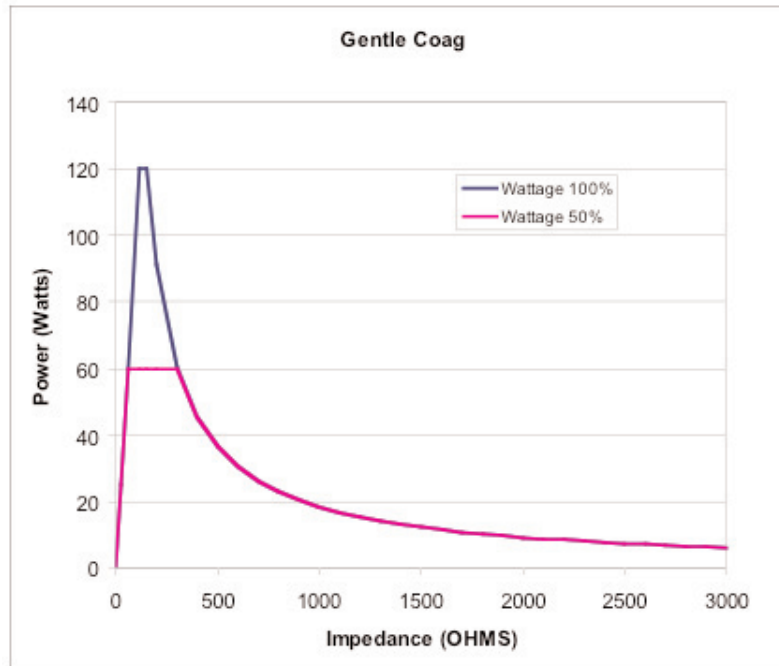


Figure A – 6 Output power vs impedance for Bipolar mode

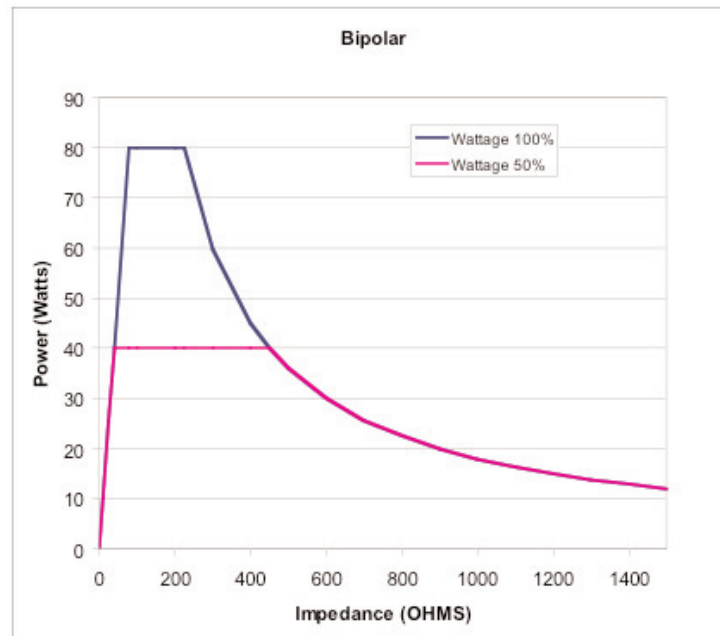
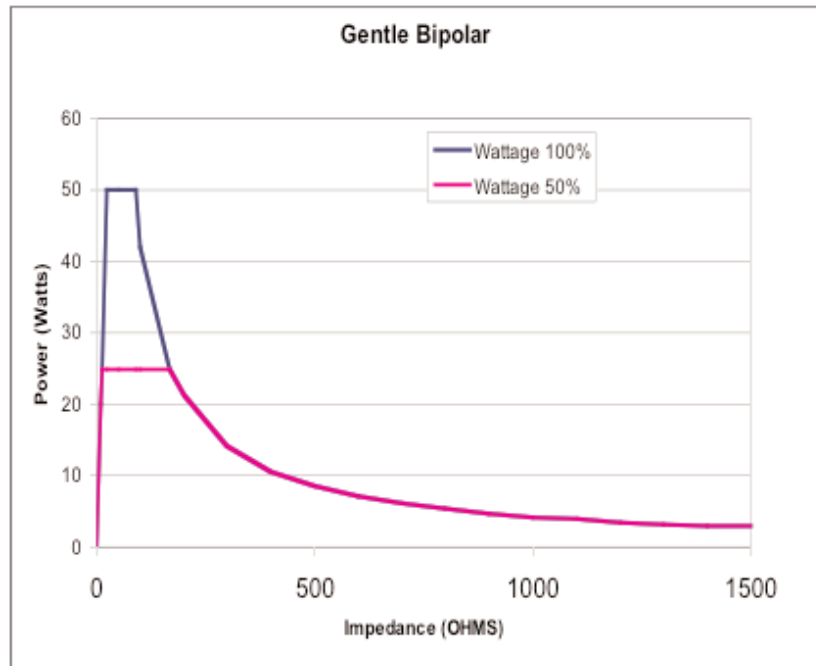
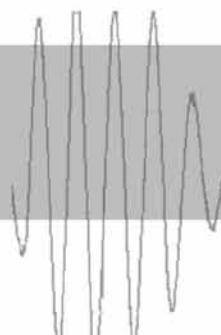


Figure A – 7 Output power vs impedance for Gentle Bipolar mode





WARRANTY

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

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

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

The warranty periods for Bovie Medical products are as follows:

- Electrosurgical Units: Two years from date of shipment
- Mounting Fixtures (all models): Two years from date of shipment
- Footswitches (all models): Ninety days from date of shipment
- Patient Return Electrodes: Shelf life only as stated on packaging
- Sterile Single Use Accessories: Only as stated on packaging.

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

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

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

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

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

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

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