Mano Médical

Medical equipment for veterinarians

Seal&Cut MV1

INSTRUCTION & SERVICE MANUAL

This document is a user guide for Mano Medical's Seal&Cut MV1 Electrosurgical unit. This guide is intended to be used as a reference for a qualified and trained physician, surgeon or veterinary professional. This instrument is electrically hazardous. Any user operating this generator or technician consulted for servicing should read this user manually thoroughly.

Please Note Manufacturer has every right to change specifications and/or functions of this equipment without any prior notice or announcement.

Words referring to Mano Médical Seal&Cut MV1 ESU in this document are: Generator, ESU, Machine, and Seal&Cut MV1.

Use for: This document is drafted by taking ***Seal&Cut MV1*** **ESU** into account only.

Seal&Cut MV1

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18. 29006, Málaga, Spain

Symbols used in this document

	Warning Explains the possible damage which may occur to the machine OR minor injuries to person.
	Electrical Hazard Explains the possible risk associated with personal injury or death.
	Do Not Enter Explains actions by which the possible damage which may occur to instruments associated with machine and/or others so, should be prohibited.
	Do Not Push
	Do Not Sit
	Do Not Step
	General mandatory action to be taken by user
	Refer to User Manual

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CHAPTER 1
Introduction

Mano Médical Seal&Cut MV1 Electrosurgical Generator provides necessary power for different types of surgical needs in Monopolar and Bipolar applications with multiple options of cut & coagulation effects with following features:

A. GENERAL FEATURES:

- **Smart ESU:** Surgical Monitoring and Automatic & Instant Response Technology ESU for consistent cutting & coagulation through all types of tissues.
- **6SENSE ™ Technology:** Advance feedback system which senses the change in Voltage, Current, Power, Tissue Density, Return Electrode Contact quality & leakage RF current.
- **Smart ENDO-CUT Mode:** For Endoscopic Applications.
- **Program Manager:** User programmable settings which allows surgeons to set surgical procedures.
- **Fully Microprocessor controlled:** To achieve high degree of clinical precision.
- **5" inch Touch LCD Display:** With extensive viewing angle, onscreen modes description facilitating surgeon to choose the best-suitable mode for the surgical applications.
- **4 Monopolar Cut Modes:** Low, Pure, Blend & Endo.
- **4 Monopolar Coag Modes:** Soft, Swift, Fulgurate & Spray.
- **2 Bipolar Cut:** Macro and Pulse BiCut
- **3 Bipolar Coag:** Micro, Standard, Force and Sealer.
- **Auto Bipolar mode (Optional)**
- **ARGON Beam** Coagulator upgradable.
- **Time out function (Optional):** Automatic stoppage of HF output on prolonged unintended activation.
- **Toggle Foot Switch:** To toggle between monopolar & bipolar mode using dual paddle footswitch.
- **BiCoag Alarms:** Audio feedback alarm after completion of Bipolar Coagulation reduces charring & sticking of tissue to forceps & avoids over burning of tissue.
- **Remote power setting:** Hand switch pencil can be used to control power remotely.

B. MODES OF ELECTROSURGERY

Monopolar Electrosurgery:

In Monopolar electrosurgery, only one pole, active electrode is in the surgical site. An electric current from the generator is delivered to the surgical site through an active electrode & returned to generator via patient return electrode. Monopolar electrosurgery is used for most general surgical procedures. Patient return electrode is used in these applications as the return path for RF current.

Monopolar *Cut* Modes: There are four Cut modes-

- ***Low Cut*** **-**It is used for a cut with no sparking, useful for laparoscopic surgery for precise & clean cutting of thin tissue.
- ***Pure*** **-** This is the default Monopolar cut mode it may be used for precise cutting with no hemostasis.
- ***Blend*** **-** It is used where slower cutting & moderate hemostasis is desired.
- ***Endo*** **–** It is pulsed cutting with appropriate pulse interval.

Monopolar Coag Modes: There are four Coag modes-

- ***Soft*** (Desiccate) -Desiccation dehydrates & destroys the tissues with no sparking, as the active electrode is directly in contact with the tissues, used for coagulation of soft and delicate tissues.
- ***Swift*** - Soft coagulation with larger tissue coverage.
- ***Fulgurate*** (Low)-This is the default Monopolar Coag mode. This mode is suitable for non-contact coagulation with moderate sparking in variety of applications.
- ***Randomized Spray*** (High) – This is designed for distance coagulation for large areas with minimum depth of tissue damage & necrosis.

Bipolar Electrosurgery:

In Bipolar electrosurgery, both active & return electrodes are in surgical site. Patient return electrode is not required as bipolar instrument contains an active electrode & return electrode.
An electric current flow from active electrode to the return electrode through tissue grasped by the instrument. This technique is mostly used in delicate surgeries, cosmetic surgeries & neurosurgeries.

Bipolar Cut Modes: There are two cut modes

- ***Macro*** **–** Precise bipolar cutting with hemostasis
- **Pulse BiCut** –Clean cutting with hemostasis.

Bipolar Coag Modes: There are four Coag modes

- ***Micro*** (Precise) - The voltage is kept low to avoid sparking. It is selected for delicate bipolar tissue desiccation.
- ***Standard*** - Standard bipolar coagulation for all types of tissue with moderate hemostasis.
- ***Force*** - Bipolar coagulation for thicker and high impedance tissue.
- ***Sealer*****-** Effective for standard vessel sealing and fusion.

CHAPTER 2
Safety Instructions

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

Hazardous Electrical Output: This instrument is to be used only by trained, licensed physician/surgeon.

If the patient has an internal pacemaker, an internal cardiac defibrillator, or any kind of orthopedic implant, consult the manufacturer of the pacemaker, defibrillator or orthopedic implant for instructions before performing an electrosurgical procedure. Maintain adequate distance between these implants and the active electrode of the generator.

Patient plate and patient plate cable connector should be cleaned before and after every use. Not doing so can cause risk to the patient.

General Warnings and Caution

Warnings-

- This generator should be used by qualified medical person only.
- Do not connect wet accessories to the generator.
- Use generator only if the self-test has been completed.
- Never turn the activation tone down to an inaudible level in any case.
- In any case, the patient should not touch any metal parts that are connected to earth/floor/ground. To take excessive precautions, use antistatic pads.
- Do not lean on the patient, while buzzing the hemostat, accidental and unintended burn injury may occur.
- To reduce the risk of an inadvertent burn at the electrode site due to monitoring equipment, place the electrode and / or probe as far away as possible from the electrosurgical site.

Cautions:

- Read all the Warnings & Cautions before using this generator.
- Use hand switches, Foot Switches provided by Mano Médical only.
- In case of any doubt or query contact Génia USA.
- Avoid use of needle like monitoring equipment on patient wherever possible.

Electrode & Instruments:

Warnings-

- Always ensure that instruments & electrodes are properly cleaned and dried before attaching to the generator.
- Keep the cables of electrodes as distant as possible from patient or other wires.

- Do not activate the generator, before touching the active electrode to the tissues, electrical arcs may be created.
- Do not activate the generator in an open circuit condition. Do not short Active electrode with return electrode.
- Do not activate electrodes while in contact with another instrument, an unintended tissue injury may occur.
- Do not wrap instrument cables around and/or bring into contact with any metal object as electromagnetic induction may produce hazardous electric current.
- Never use any instrument above maximum power, voltage ratings as specified by the manufacturer.
- Never use broken or damaged instruments or cord as it may harm the patient and/ or surgeon.

Cautions:

- Always use the appropriate instrument for the surgery.
- Always ensure your electrodes are properly cleaned & in good working condition.

Bipolar

Cautions:

- Bipolar accessories must be connected to the bipolar socket only.
- Bipolar mode should be utilized whenever possible.

Warnings:

- During Auto Bipolar mode, which is available on request, activation may occur with contact of any material. When not in use, place electrosurgical instruments in a safety holster or safely away from patients/user/operator and flammable materials.
- Desired clinical effects may vary depending upon the degree of cleanliness of the electrode tip. Therefore, it is always recommended to maintain a clean electrode tip to eliminate the risk of detecting wrong tissue impedance.

Cautions:

- Use vessel sealing accessories provided by Mano Médical only. Making use of other instruments may not deliver optimized power or desired effects for the operation.
- Do not use saline solutions for cleaning bipolar vessel sealing instruments; this may reduce the working life of accessories.
- Do not use vessel sealer with the tissue washed with Normal Saline (NS). Do not give saline wash till vessel sealing procedure is complete. Use sterile water in case of requirement.
- Do not use ultrasonic cleaners at high amplitudes. Product damage may otherwise result.

Electrical Connections & Power:

Warnings-

- Make use of a dry cheesecloth between patient and ground body.
- Inspect electrode connections and connections frequently.
- Check all the power settings on each connection to the generator before using the device on a patient.

- Check if the earthing of power source in surgical room is correct. Make sure equipment chassis or cabinets are grounded. Never cut off or reverse the ground connection on a plug.
- Please check if power from the main line (AC) is within the specified range as required for proper functioning of the generator. Inappropriate voltage from the main plug (AC Line) may damage the device and/or may turn out to be hazardous to patient and/or surgeon.
- Always use lowest output setting for desired surgical effect. If the correct setting is unknown, set the generator at a very low setting & increase the power continuously until the desired effect is achieved.
- Take faulty circuitry into consideration any time the surgeon needs to push a higher power. Check all the problematic extents such as: patient electrode, active electrode or ESU, as excessive power may damage and/or burn the tissue.
- Simultaneously activating irrigation & electrosurgical current may result in increased arcing at electrode tip, burns to unintended tissues, shock & burns to the surgical site.

Cautions:

- Never use power plug adaptors.
- Avoid the use of extension cords for the main power supply.
- Do not plug in or unplug power cord when the main switch &/or generator‘s switch is in the ON state.
- Never defeat the purpose of a fuse or circuit breaker. Never install a fuse of higher amperage rating than specified.
- Keep the active electrode clean. Dirty electrodes cause the reduction of output power.
- The ESU's electrical cord should be adequate in length & flexibility, to reach the electrical outlet without stress or the use of an extension cord.
- Replace defective cords and plugs. Inspect cabling for defects such as frayed wiring, loose connections, or cracked insulation.
- Check all accessories and connections to the electrosurgical generator before using. Improper connection may result in arcs, sparks.

Accessories Related:

Warnings-

- Inspect ESU unit prior to use. Remove accessories which are damaged and/or not working properly.
- Do not wrap the accessory leads around the metal objects. This may induce currents that are dangerous to the patient.
- Do not try to increase or reduce length of cables. Excessive or improper current may unintentionally damage the tissue or skin.

Cautions:

- Place foot paddles on flat, dry & clean surfaces.
- Do not reuse or resterilize accessories labeled –disposable or single use only.
- Check all accessories before using, especially if they are endoscopic accessories.

Radio Frequency Burns:

Warnings-

- Keep the monitoring equipment electrode as far away as possible from electrosurgical site to reduce the risk of inadvertent electrosurgical burn.
- Avoid skin-to-skin contact points such as fingers touching leg. Use dry cloth between contacts.
- Do not activate the electrodes for extended period of time (more than 1 minute). This may lead to excessive heating of the electrode and may burn the tissue.

Generator Placement & Environment:

Warnings-

- Never place containers of liquid on diathermy unit.
- Never use electrosurgical unit in presence of flammable anesthetic gases.
- In presence of excessive oxygen & nitrogen gases, extra measures must be taken to reduce the concentration of these gases.

Cautions:

- Do not place the generator on the top of any electrical equipment.
- Always keep as much distance as possible between monitoring equipment, video equipment and electrosurgical generator.
- Do not disconnect the generator from main line (AC) immediately after turning off. Keep it connected to the main line for at least for one minute.
- If generator is relocated from cold to warm room, keep generator ON at least for half an hour to let generator to acclimate to the room temperature.

Other:

Warnings-

- Check if activation, safety, warning audio & visual alarms are working properly. If found problematic; restart the generator, check it again after restarting. If problem still exists do not use the generator as it may result in erratic functioning, which may lead to hazards. *Contact Génia USA service department.*
- Always clean the generator after surgery; disconnect all the electrical connections and accessories before cleaning the generator.
- If a patient is moved from one place to another recheck all the connections, as proper contact of electrode cable with the generator is necessary.
- During procedures in small surgical fields, accidental and unintended burn injury may occur.
- Shave off body hairs that may come into contact with surgical site when necessary.

Cautions:

- Avoid the use of hybrid tracers that include both metal & plastic components.
- Always maintain proper ventilation in the surgical room, as surgical smoke generated during surgery is harmful to health.

Vessel Sealing:

Warnings-

- Make use of appropriate Foot Switch for vessel sealing operation; perform manual settings whenusing single paddle Foot Switch.
- Use appropriate power; apply adequate pressure on tissue before activating sealer.
- Completion alarm indicates the proper sealing of tissue, do not release the instrument before completion alarm sounds.
- Do not perform sealing operation in the vicinity of conductive fluids, as it may cause unintended injuries to the area in vicinity of conducting fluids.

- In laparoscopic operations ensure that direct contact with the desired tissue is established; do not activate power before proper contact, as it may lead to unintended burns.
- Do not apply sealing electrode on wounded vessels as it may damage it further.
- Proper inspection of the instrument is necessary before use. If there is any insulation failure or damages to instrument or improper assembly of instrument, do not use it on the patient as this could be dangerous for the operator and the patient.
- Do not use Normal Saline (NS) to clean the instrument at any stage. Usage of saline could result in failure of the instrument.
- Vessel sealing devices will not work in blood-rich environments; clean tissue before vessel sealing.
- Do not use vessel sealer with the tissue washed with Normal Saline (NS). Do not wash with saline until the vessel sealing procedure is complete. Use sterile water if required.
- Do not activate the blade without completion of sealing cycle, as this may cut live arteries resulting to blood loss during surgery.

Cautions:

- Use vessel sealing accessories provided by Mano Médical only. Using other instruments may not deliver optimized power or desired effects for the operation.

- Do not use saline solutions for cleaning bipolar vessel sealing instruments; this may reduce the working life of accessories.

Monopolar

Warnings-

- Do not connect more than one instrument at a time into a given socket.

- To avoid the electrosurgical burns beneath the patient return electrode, it is nece ow all directions on the product package for proper return electrode placement & use ent Return Electrode as close to the surgical site as possible.

Cautions:

- Use Patient Return Electrode for Monopolar modes only.

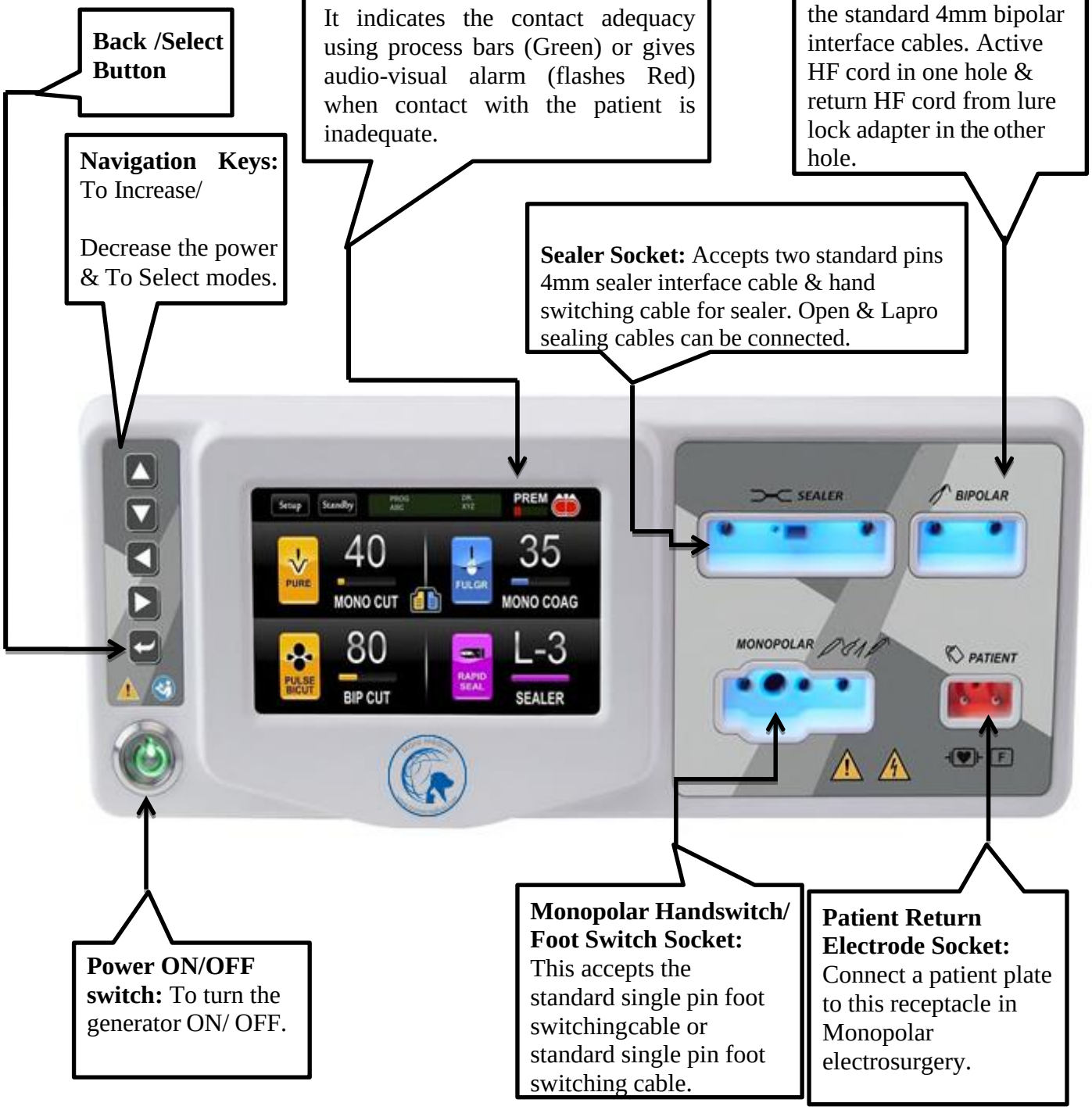
Hemostat Buzzing: -

Warnings-

- It is not recommended to use hemostat buzzing method.
- If using hemostat buzzing, firmly grip as much of the area hemostat as possible.
- Touch the active electrode on the area of hemostat, which is closest to the patient.
- Avoid leaning on the patient.
- Avoid using coagulation whenever possible, use cut instead.
- Use the lowest power setting possible for this method.
- Unintended burns may occur even after wearing the gloves due to higher current densities, which may penetrate gloves and cause current leakage resulting in shocks and burns to the surgeon.

CHAPTER 3
Controls, Indicators & Output Sockets

A. FRONT PANEL



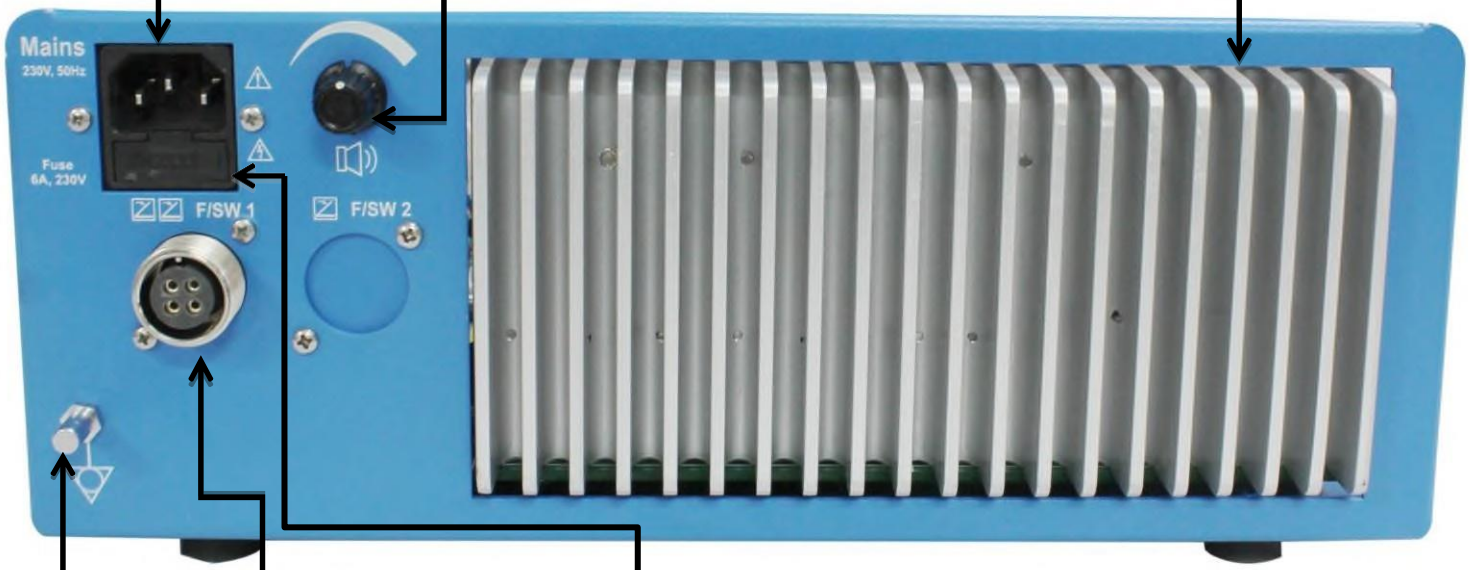
Key Symbol	Key Functions (On the Main Screen)
	• On the main screen, use the Up / Down Key to navigate vertically between modes. • When in a particular "Mode" of a surgical procedure; the Up and Down key will increase/ decrease the power of the selected mode. • Use keys relevant to desired icon.
	• On the main screen, use Right/Left Key to navigate horizontally between modes. • When selecting "Modes" of a surgical procedure use Right/Left Arrow Keys to choose desired mode. • Use keys relevant to desired icon.
	• On the main screen, use Select button to select a particular mode. • When selecting "Modes", the same button will act as a back button to return to the main screen.

B. REAR PANEL

Power Socket: To supply AC (230V / 50Hz) or (110V/60 Hz) power to ESU.

Volume Control: To adjust volume of activation tones. ***Please Note: Alarm volumes are not adjustable***

Heat Sink:
Do not place anything near heat-sink to allow proper cooling of the generator



Foot Switch: 2-paddletoggle Foot Switch for Cut & Coagulation.

Fuse Socket: Fuse Rating (230V, 6A) or (110V, 10A) ***Please Note: In case of fuse malfunction replace fuse with one of the same quality***

Grounding Lug:
Reduces noise in other equipment. Connect it to earthing receptacle.

C. WELCOME SCREEN

Once the generator is turned ON successfully, ***Screen1*** will be displayed. Select the check box after reading the instruction manual and press the **"Proceed"** button, ***Screen 2*** will appear if –Factory Reset‖ option was selected in –Startup‖ of Setup option.

SCREEN 1: WELCOME SCREEN

SCREEN 2: MAIN SCREEN

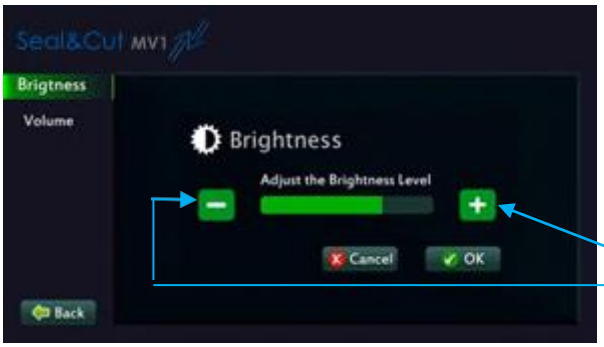
Note: While restarting the unit, if a user would like to get a previously used setting or wants unit in standby mode, refer Startup option from Section D.

D. SYSTEM SETTING

Press Setup option from Main screen to enter into System setting option. ***Screen1*** will be displayed. Select the desired option by selecting the relevant icon one the left hand side of the System setting screen.

SCREEN 1: SYSTEM SETTING

Brightness Adjustment:



SCREEN 2: BRIGHTNESS SCREEN

For Brightness adjustment, select **"System"** option from ***Screen1*** and select **"Brightness"** option, *Screen2* will be displayed.

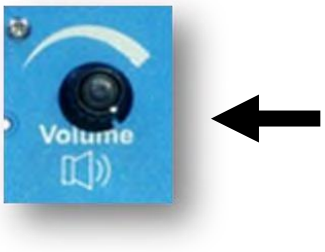
Touch buttons to increase and decrease the brightness.

Note: After setting the desired brightness press **OK** button to save the setting.

Volume Adjustment:

For volume adjustment, select **"System"** option from ***Screen1*** and select **"Volume"** option, ***Screen3*** will be displayed.

System Volume can be adjusted by turning the volume control knob on the back panel of machine.



SCREEN 3: VOLUME SCREEN

Note: After setting the desired brightness press **OK** button to save the setting.

Pulse Bi-cut Configuration:

Used for selecting the output socket for Pulse Bi Cut mode. For Pulse Bi-Cut two modes are available. SEALER/BIPOLAR. Socket Selection will be decided according to user needs. ***Screen 4*** will be displayed after pressing on Pulse BiCut from
Screen 1: System Setting.

SCREEN 4

Calibration

Warning: To be accessed only by trained professional. ***Please contact the manufacturer to obtain the Authorization code.***

SCREEN 5

After entering a valid Authorization Code, the screen will display the following options:

Calibration

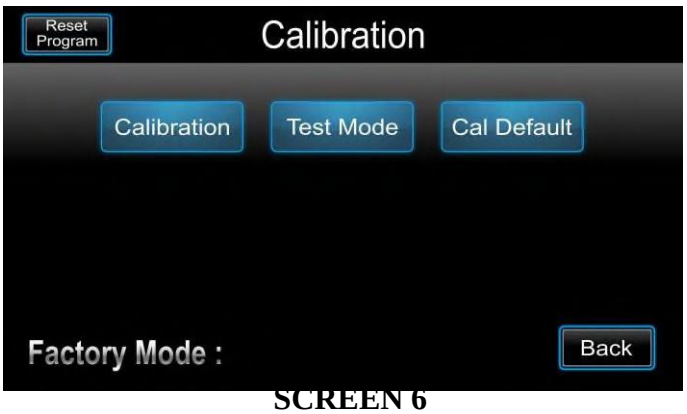
It is used to calibrate machine's sensors.
Calibration mode is explained in later chapters.

Test Mode

Test mode shows the functionality of input/output interfaces.

Cal Default

To load the default calibration counts.



SCREEN 6

Function Time Setup (optional)

User can set the time period of HF output and bipolar auto delay using Function Time Setup.

SCREEN 7

How to set Time Out Function

User may ensure that HF output is not activated unintentionally for a long period of time by using the Time Out Function. To set Time Out Function follow the steps below:

Step 1: Select –**Function Time Setup"** option from system setting screen.

Step 2: ***Screen4*** will be displayed**.** Press –Time Out Function –option.

Step 3: User can set timeout function from 10 to 90 milliseconds as per the requirement. (Refer SCREEN 8)

Use Up/Down navigation keys to increase/decrease the delay respectively.

Note: Press **OK** button to save the desired value.

SCREEN 8

How to set BIP Auto Time Delay

Step 1: To select BIP Auto Time Mode, user must select Auto bipolar key & corresponding submodes from bi-coag mode of main screen (Section F: How to set Auto Bipolar Mode)

Step 2: Select **"Function Time Setup"** option from system setting screen.

Step 2: ***Screen4*** will be displayed**.** Press BIP Auto Time Delay option.

Step 3: User can set auto bipolar delay from 0 to 900 milliseconds depending on their needs.
Use Up/Down navigation keys to increase/decrease the delay respectively. (Refer SCREEN 9)

Note: Press **OK** button to save the desired value.

SCREEN 9

Startup

Press the **Previous Activated** key on the display to get the previously used settings every time the unit starts.

Press the **"Standby"** option to disable any inputs and outputs from the generator. The generator will not respondto any sort of activation in standby mode. Generator will show ***the below screen.***
User can exit standby mode anytime by pressing the standby option again.
Entering and exiting the mode will not affect any user settings.

SCREEN 11

Note: While restarting the unit if the user wants unit in standby mode, the **"Standby"** option in the Setup setting is used. **"Standby"** option on the main screen is used during the surgery.
Press **"Factory Reset"** to restore the device to its original manufacturing settings (refer to below screen) by erasing all the earlier information stored in it.

About screen:

The screen will display the serial number and current software version of the unit.

SCREEN 12

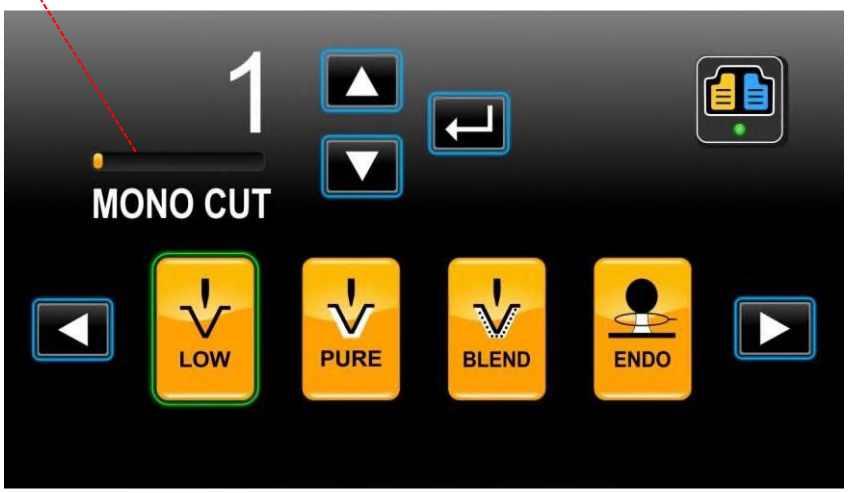
E. How to select Power & Mode

STEP 1: Enter the desired mode just by touching its icon as shown in ***SCREEN 1 & 2.*** Select sub-modes using Touch Selective Icons (***SCREEN2)***.

STEP 2: Once desired sub-mode (procedure) is selected, increase/decrease the power using on-screen or front panel keypad's up/down arrow keys to.

STEP 3: Now once power is selected for the desired sub-mode (procedure) press Enter Key (On-screen or Keypad). Pressing the appropriate foot paddle or hand switch will make power available to the relevant port.

SCREEN 1



SCREEN 2

F. How to set Auto Bipolar Mode (Optional feature)

STEP 1: Enter the Auto Bipolar mode by touching its icon as shown in ***Screen 3 & 4.***
Green light indicates activation of Auto Bipolar mode.

STEP 2: Select sub-modes using horizontal scroll keys (Refer ***Screen 3)***.

STEP 3: Once desired sub-mode (procedure) is selected, increase/decrease the power using on-screen or front panel keypad's up/down arrow keys.

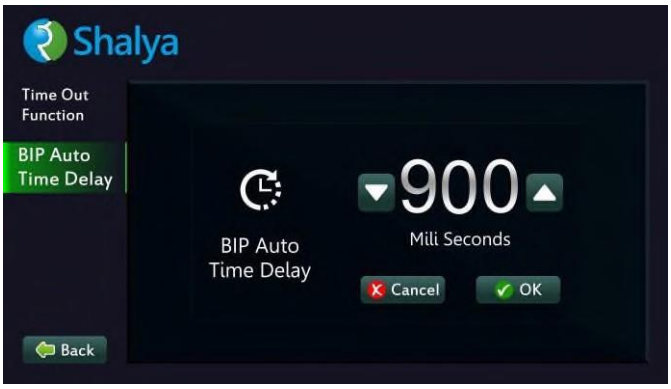
STEP 4: User can exit Auto Bipolar mode anytime by pressing Back icon.

SCREEN 3

SCREEN 4

Note:

- The Bipolar auto time delay can be set as shown in *Screen 5* by selecting the Function Time Setup tab in the Setup option of the main screen. (Refer Section C. Main Screen).
- Bipolar auto time delay is available only in Bi-coag mode.



SCREEN 5

G. Program manager

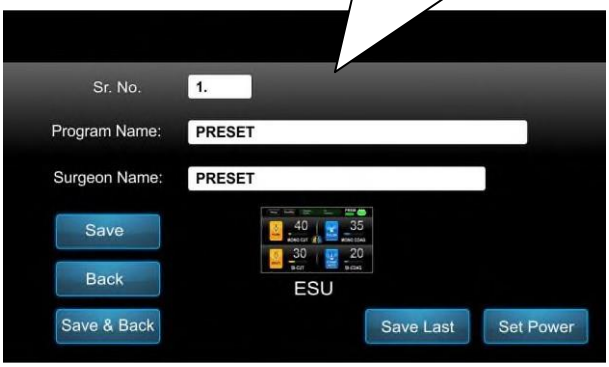
Program manager gives users the ability to edit, load & store custom user programs.

Press the tab from main screen to enter Program Manager.

SCREEN 1

User can load any program by selecting Program and pressing the **Load** button.
Use up/down navigation keys to scroll through programs.

Touching any of the text boxes will open up user friendly QWERTY on-screen keyboard.



SCREEN 2

To add a new program, follow the steps givenbelow:
New Program can be added by touching **Add New** tab on the screen. After pressing, ***Screen2*** will be displayed on the screen.
STEP1: In Program name, Surgeon Name.In Program Name enter name of surgical procedure for which setting is to be stored.
STEP2: Now, enter desired mode & set appropriate power. User can set power for multiple surgical modes as shown in the ***Screen3*.**
STEP3: Once the power, procedures & modes are selected press **Set** tab (***Screen3)***.
STEP4: Once done press Save & Back (***Screen2)***.

Note: To understand the process to select power, refer the section named "How to select power & Mode?"

SCREEN 3

H. How to set Rapid Seal mode

STEP1: Go to Main screen
STEP2: Click BIP COAG mode.
STEP3: Press RAPID SEAL mode.

Mode: Micro - Low Intensity bipolar coag for delicate tissue.

CHAPTER 4
Technical Specifications

A. GENERAL SPECIFICATIONS

Output Configuration: Isolated output with cardiac defibrillator protection.
Duty Cycle of Operation: At maximum rated load conditions, pure cut-400 watt setting at 300 Ω.
The system is suitable for activation time of 10 seconds ON, 30 seconds OFF for one hour.
Cooling: Natural by convection: By side and rear panel vents.
Display: 5 touch LCD Screen.

Standards and International Electrotechnical Commission Classifications

ATTENTION Refer accompanying documents.

SHOCK To reduce the risk of electric shock: Do not remove the cover.
For servicing consult qualified service personnel.

FLOATING The generator output is floating (isolated) with respect to ground.

DANGER Explosion risk if used with flammable anesthetics.

Class I Equipment
Accessible conductive parts are connected to the protective earth conductor, so they do not become live in the event of a basic insulation failure.

Type CF Equipment

Maximum allowable leakage current limit is as per established standards. Mano Médical Seal&Cut MV1
+V provide a high degree of protection against electric shock. Instrument can be used for cardiac procedures due to type CF isolated (floating) output.

Drip Proof
The Mano Médical Seal&Cut MV1 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.

IP Class Specification
IP Class of this equipment is rated at IP20.

Caution - Do not stack any equipment upon Mano Médical Seal&Cut MV1 or place the generator on top of other electrical equipment. This configuration does not allow proper cooling of the generator.
Caution - Do not place any chemical or solution in operating room, that may spoil safety of electronic circuit by liquid spillage.

Voltage Transients (Emergency Generator Mains Transfer)
The Mano Médical Seal&Cut MV1 operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

Defibrillator Proof
The Mano Médical Seal&Cut MV1 meets specifications for –Defibrillator proof design.

Dimensions and Weight

Length: 38.0 cm
Width: 31.5 cm
Height: 12.0 cm
Weight: < 5.0 kg

Transport and Storage

Temperature range: -40°C to 70°C
Relative humidity: 10% to 100%, condensing.

Operating Parameters

Temperature range: 10°C to 40°C
Relative humidity: 30% to 75%, noncondensing.

Warm-up time

Allow one hour for the generator to reach room temperature before use, if transported or stored at temperature outside the operating temperature range.

Internal Memory

Non-volatile

Audio Volume

***Activation Tone*:** Volume (adjustable): 40 to 65 dB
Frequency: Bip Cut: 340Hz ±5%
Bip Coag: 455Hz ±5%
Mono Cut: 580Hz ±5%
Mono Coag: 865Hz ±5%

Alarm Tone: Volume (not adjustable): 65 dB
Frequency: 865Hz ±5%
Pulse: Two 800 m sec. coag tone separated by 800msec.of silence

PREM Contact Quality Monitor

Measurement frequency**:** 80 kHz ±10 kHz
Measurement current: <10µA
Acceptable Resistance Range upto 40%
Dual Area PREM return electrode: 5 to 135 Ω
Single Area Patient return electrode: 0 to 10 Ω

Low Frequency (50 - 60 Hz) Leakage Current:

Source current, patient leads, all outputs:
Normal polarity, intact ground: <10µA
Normal polarity, ground open: <50 µA
Reverse polarity, ground open: <50µA
Enclosure source current, ground open: <300µA

High Frequency (RF) Leakage Current

Monopolar (RF) leakage current: < 150 mA rms
Bipolar RF leakage current: < 60 mA rms

Input Power 2 table

Main nominal voltage:	**230 V**	**110 V**
Input main voltage, full regulation range:	210-264 Vac	104-132 Vac
Input main voltage, operating range:	180-264 Vac	85-132Vac
Main current (maximum):	Idle: 0.2 A	Idle: 0.4 A
	Cut: 3.9A	Cut: 7.8 A
	Bipolar: 1.5 A	Bipolar :3 A
	Coag: 2.3A	Coag: 4.6 A
Maximum VA at nominal line voltage:	Idle: 52VA	Idle: 52VA
	Cut:1030 VA	Cut:1030 VA
	Bipolar: 400 VA	Bipolar: 400 VA
	Coag: 610VA	Coag: 610VA
Main line frequency range (nominal):	50 to 60 Hz	50 to 60 Hz
Fusing:	6A	10A

B. AVAILABLE POWER SETINGS (In Watts)

1. **Monopolar Cut:**
   Low: 1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 300 by step of 10.
   Pure & Endo: 1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 400 by step of 10**.**
   Blend: 1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 250 by step of 10.

2. **Monopolar Coag:**
   Soft: 1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 150 by step of 10.
   Swift, Fulgr and Spray: 1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 120 by step of 10.

3. **Bipolar Cut**
   Macro and Pulse Bicut:1 to 40 by step of 1, 40 to 100 by step of 5

4. **Bipolar Coag**
   Micro, Standard Force :1 to 40 by step of 1, 40 to 100 by step of 5
   Sealer: L1:70 watt
   L2: 85 watt
   L3:100 watt

C. OUTPUT CHARACTERISTICS

Maximum Output for Bipolar and Monopolar Modes

Power readouts reflect with actual power into rated load to within 20% or 10watts, whichever is greater.

Mode	Open Circuit P-P Voltage (In Volts)	Rated Load (in Ωs)	Power(max) (in Watts)	Crest Factor
Monopolar Cut				
Low	1200	300	300	1.5
Pure	1600	300	400	1.5
Blend	2200	300	250	2.5
Endo	1600	300	400	1.5
Monopolar Coag				
Soft	2500	500	150	4.0
Swift	4500	500	120	6.2
Fulgurate	4900	500	120	7.0
Spray	5200	500	120	8.0
Bipolar Cut				
Macro	880	100	100	1.5
Pulse BiCut	880	100	100	1.5
Bipolar Coag				
Micro	360	100	100	1.5
Standard	550	100	100	1.5
Force	880	100	100	1.5
Sealer (Rapid L3)	390	-	100	1.5

*Crest factor measured at half power condition.
*Crest factor is an indication of a waveform's ability to coagulate bleeders without a cutting effect.

D. OUTPUT FREQUENCIES

6SENSE Technology, an automatic adjustment, is applied to all bipolar modes and all cut modes. It is not applied to the Coag modes because of their non-contact capabilities.

Bipolar Cut

Macro 390 kHz sinusoidal
BiCut 390 kHz sinusoidal

Bipolar Coag

Micro 390 kHz sinusoidal
Standard 390 kHz sinusoidalForce
390 kHz sinusoidal
Sealer 390 kHz sinusoidal

Monopolar Cut

Low 390 kHz sinusoidal. The maximum voltage is limited to a lower value.Pure 390 kHz sinusoidal

Blend	390 kHz bursts of sinusoid, recurring at 29 kHz intervals. 55% duty cycle envelope
Endo	390 kHz sinusoid with moderate pulse interval

Monopolar Coag

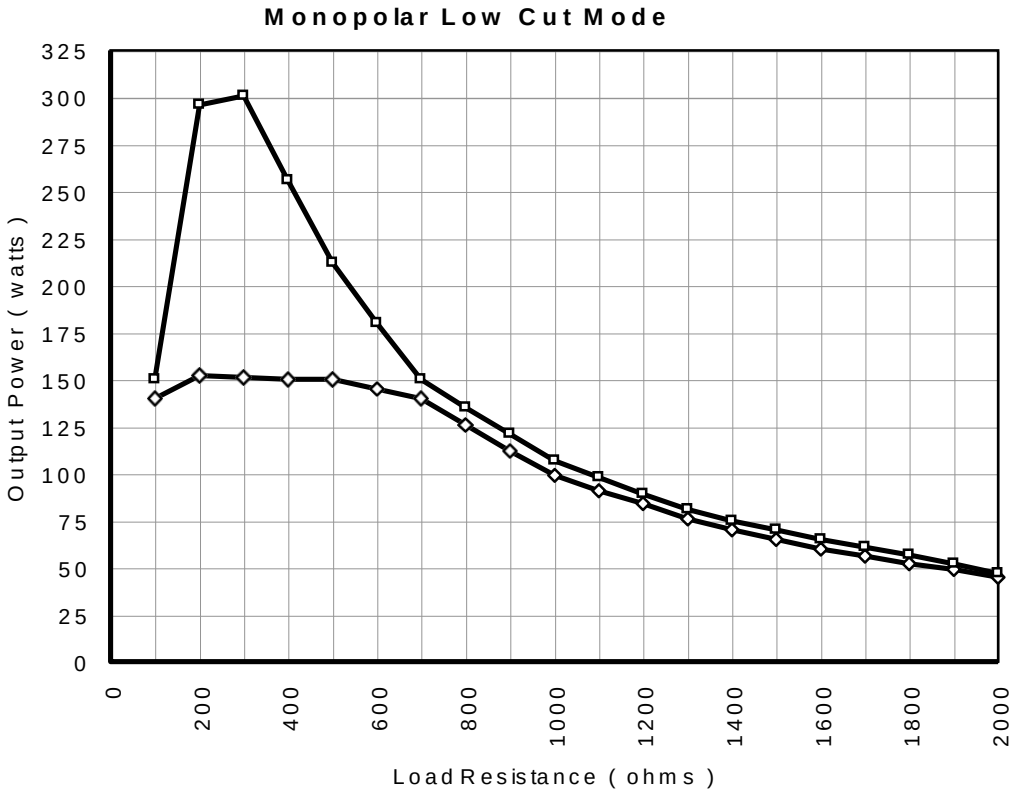
Soft	460 kHz damped sinusoid repeated at 84 kHz. 20% duty cycle
Swift	460 kHz damped sinusoidal repeating at 42 kHz
Fulgurate	460 kHz damped sinusoidal bursts repeated at 34 kHz.
Spray	460 kHz damped sinusoid repeated at randomized frequencies 34 kHz < f <50 kHz.

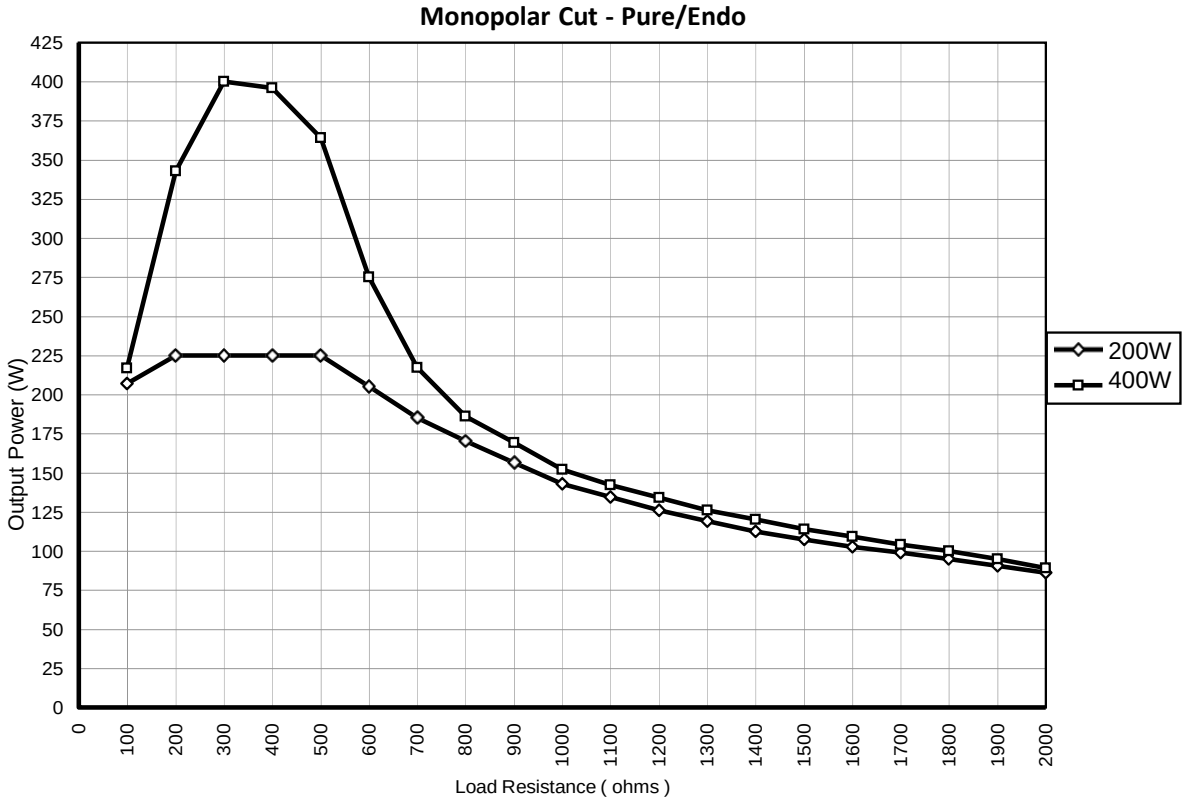
E. AREA OF APPLICATION

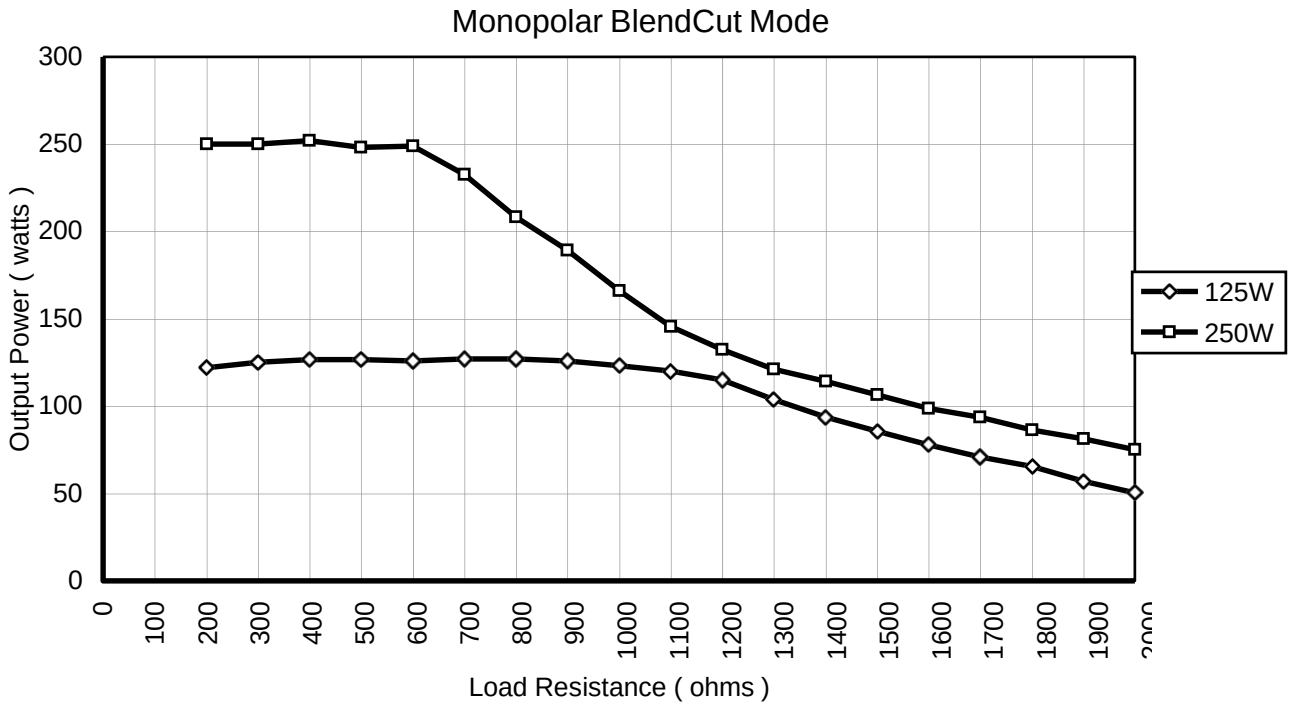
- **Applications of ESU / Diathermy Section**:
  - ✓ Gynecology
  - ✓ Urology (Resection)
  - ✓ Laparoscopic Surgeries.
  - ✓ Endoscopy (ERCP)
  - ✓ Oncosurgery
  - ✓ Heart & Chest surgery, CABG
  - ✓ Neurosurgery, Spine
  - ✓ Arthroscopy
  - ✓ All other general surgical procedures.

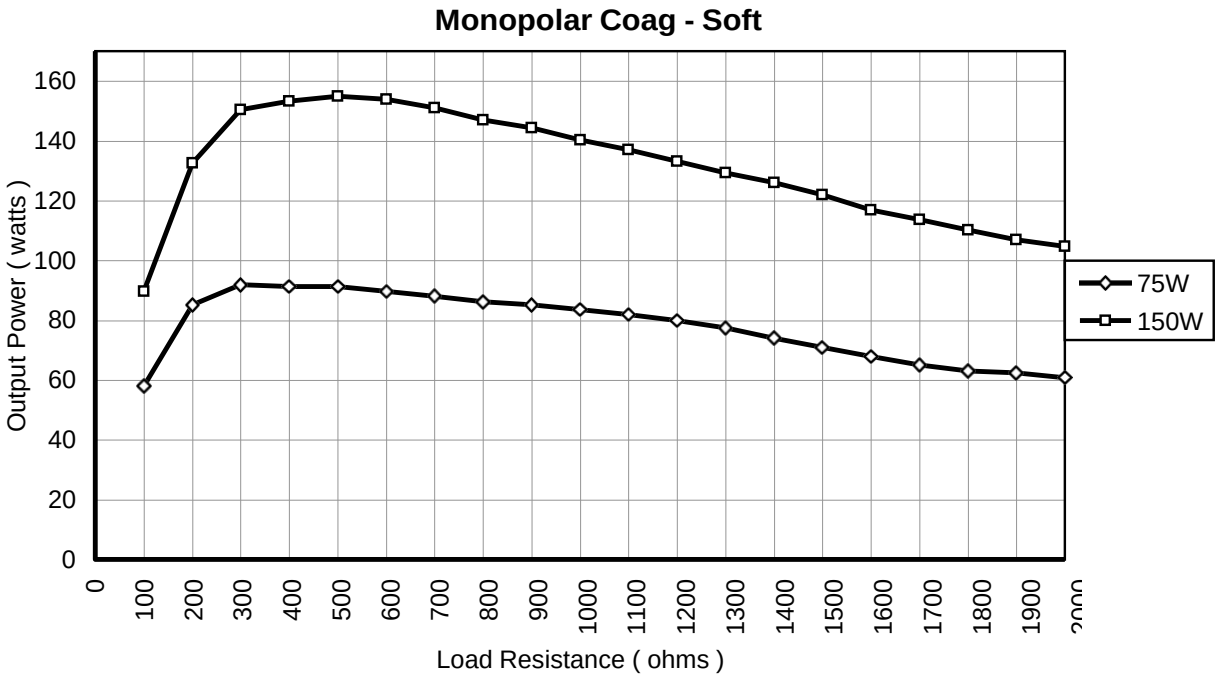
- Applications of Vessel Sealing System Section:
  - Lap-Assisted Vaginal Hysterectomy (LAVH)
  - Vaginal Hysterectomy
  - Gastrectomy
  - Gastric Bypass
  - Appendectomy
  - Colectomy
  - Nephrectomy
  - Nissen Fundoplication
  - Colon Resection
  - Cystectomy
  - Radical Hysterectomy
  - Liver Resection
  - Adenalectomy
  - Splenectomy
  - Salpingo-oophorectomy
  - Radical Prostatectomy
  - Abdominal Hysterectomy
  - Hemorhoidectomy

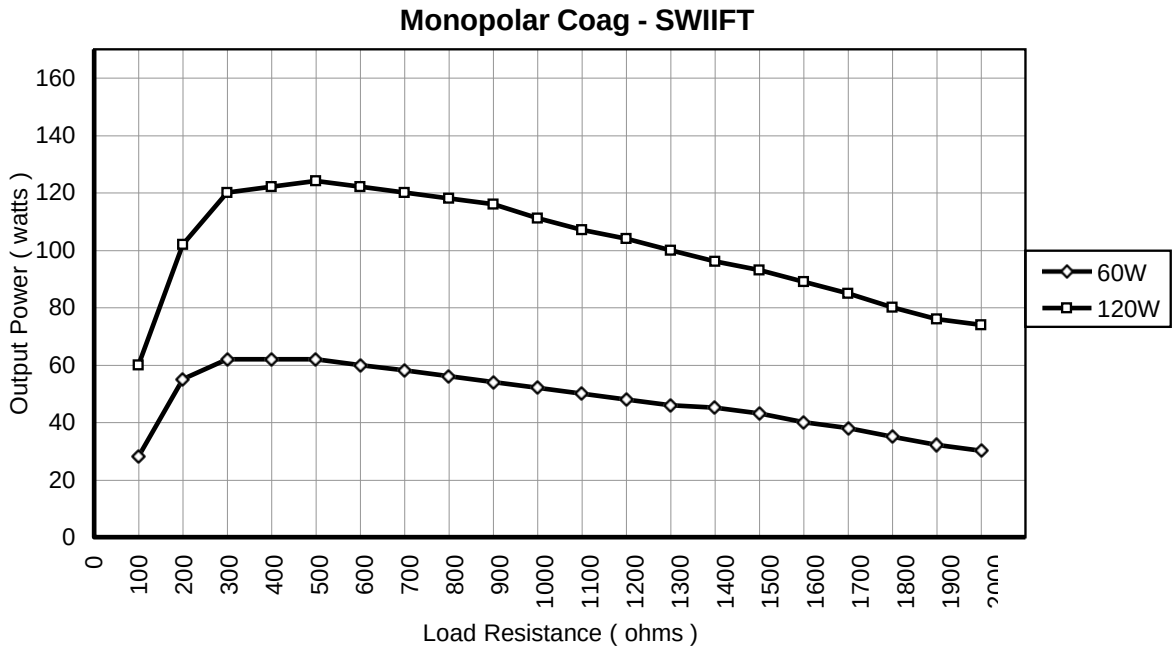
F. OUTPUT POWER VS. LOAD GRAPHS

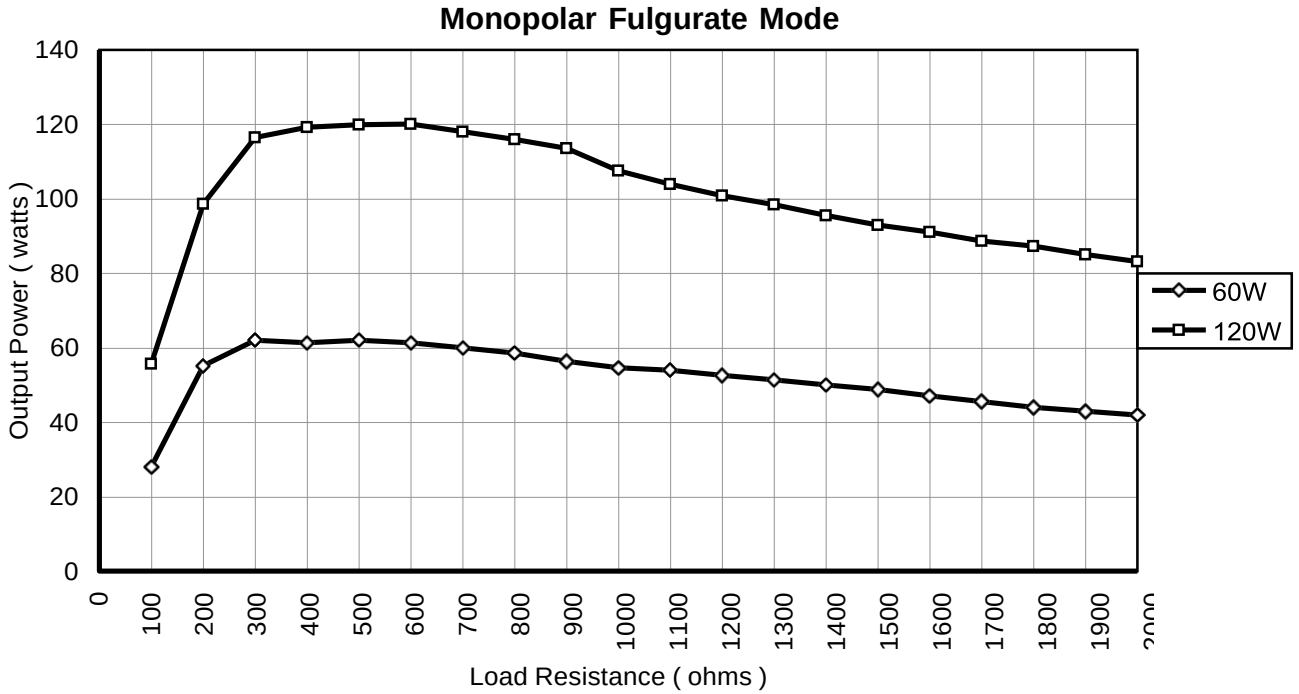


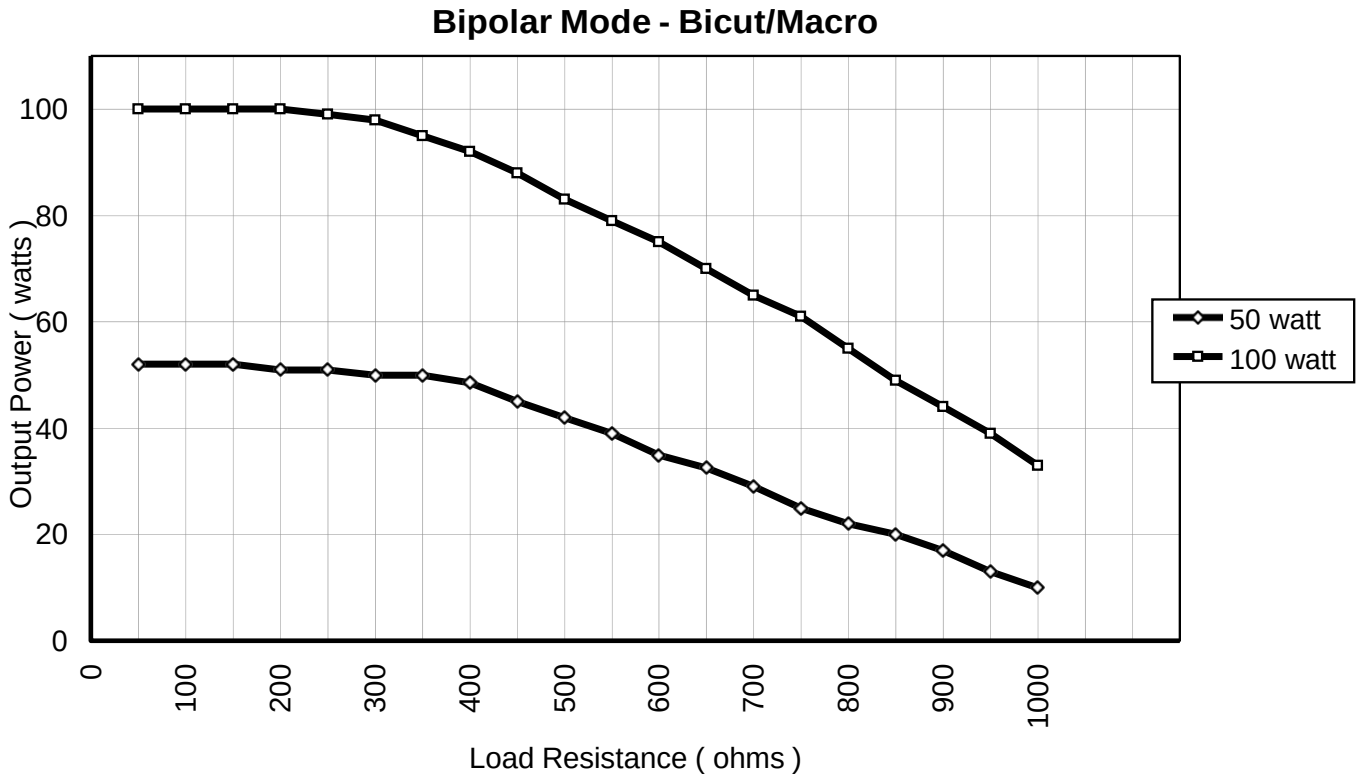


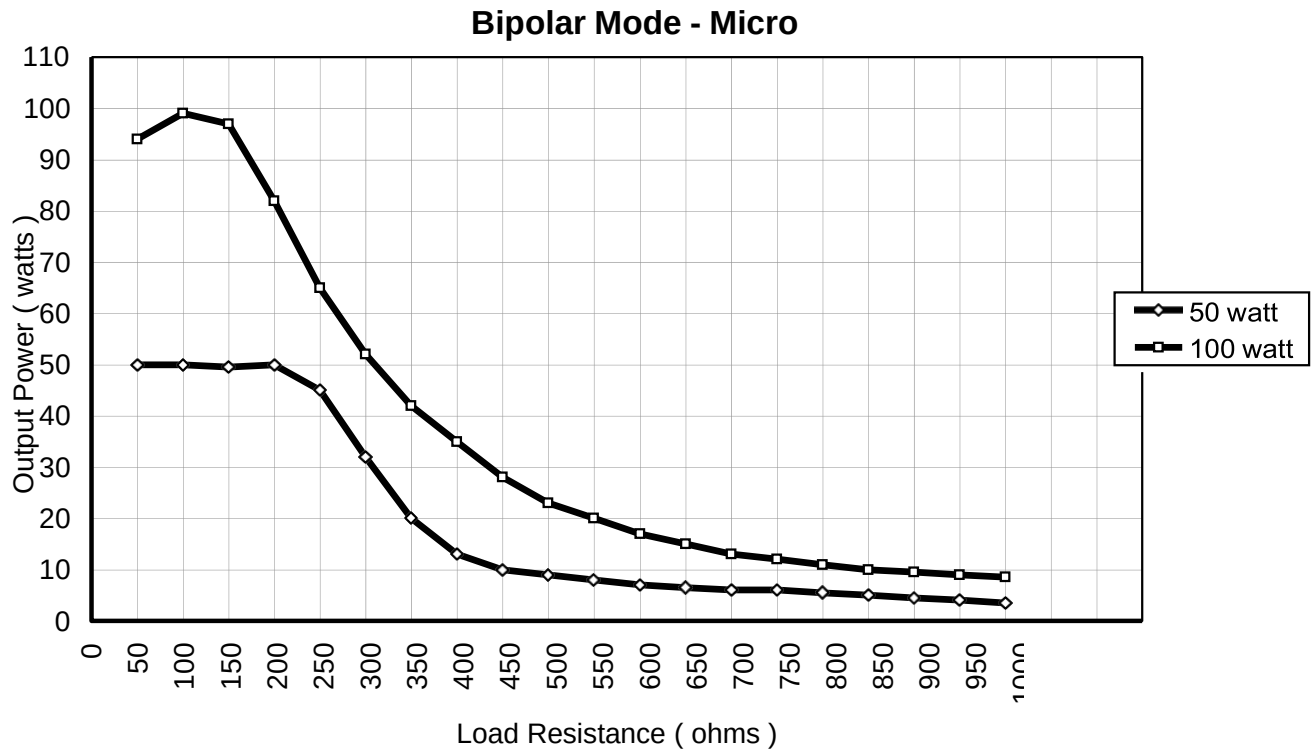

Monopolar BlendCut Mode
Output Power (watts)
300
250
200
150
100
50
0
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600
1700
1800
1900
Load Resistance (ohms)
125W
250W

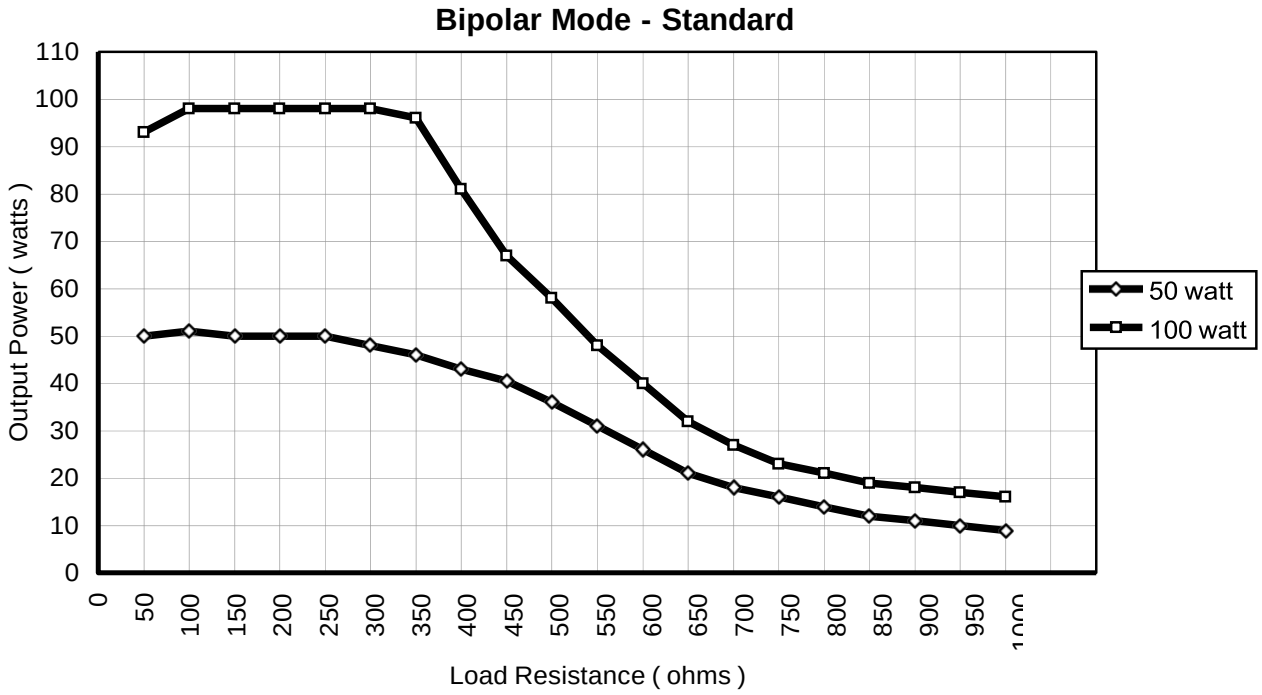

Monopolar Coag - Soft
Output Power (watts)
160
140
120
100
80
60
40
20
0
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600
1700
1800
1900
Load Resistance (ohms)
75W
150W

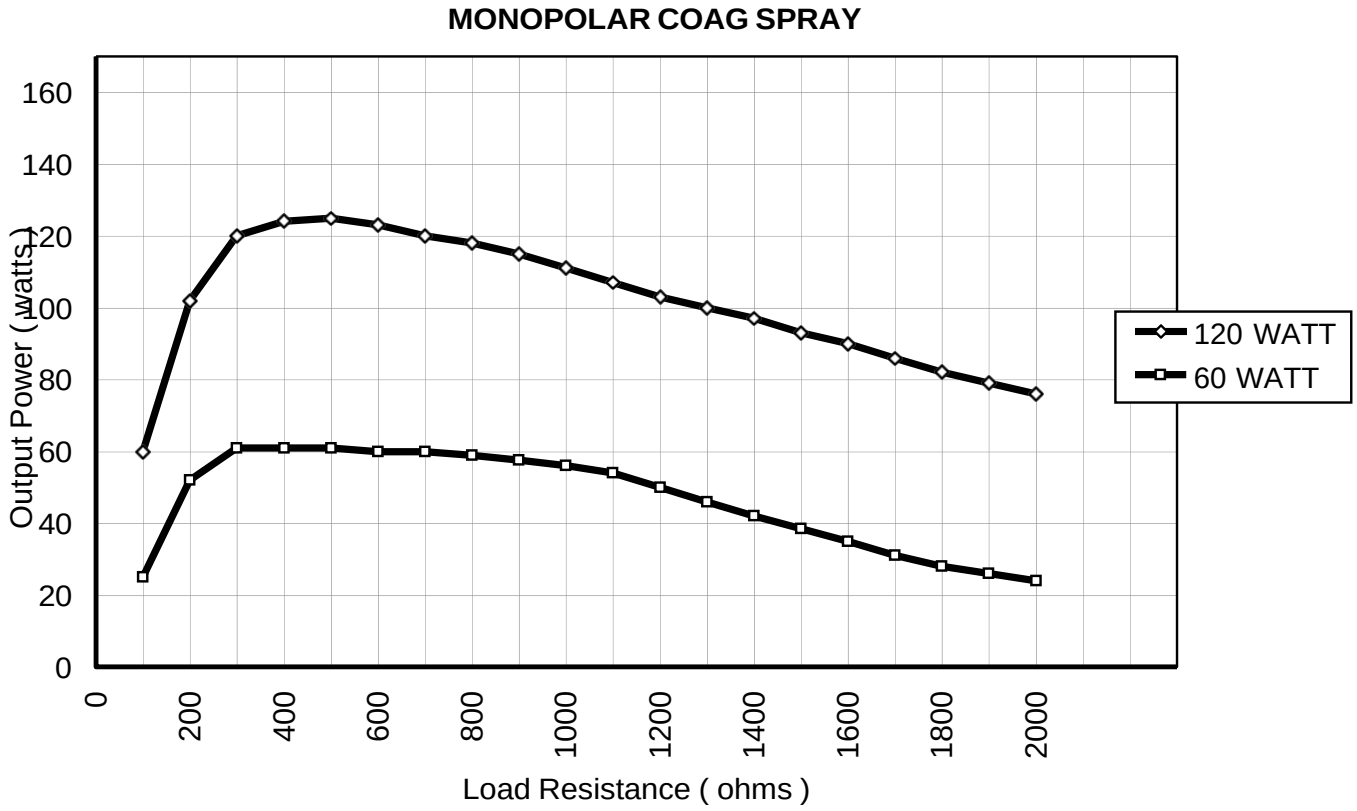

Monopolar Coag - SWIIFT
Output Power (watts)
160
140
120
100
80
60
40
20
0
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600
1700
1800
1900
2000
Load Resistance (ohms)
60W
120W

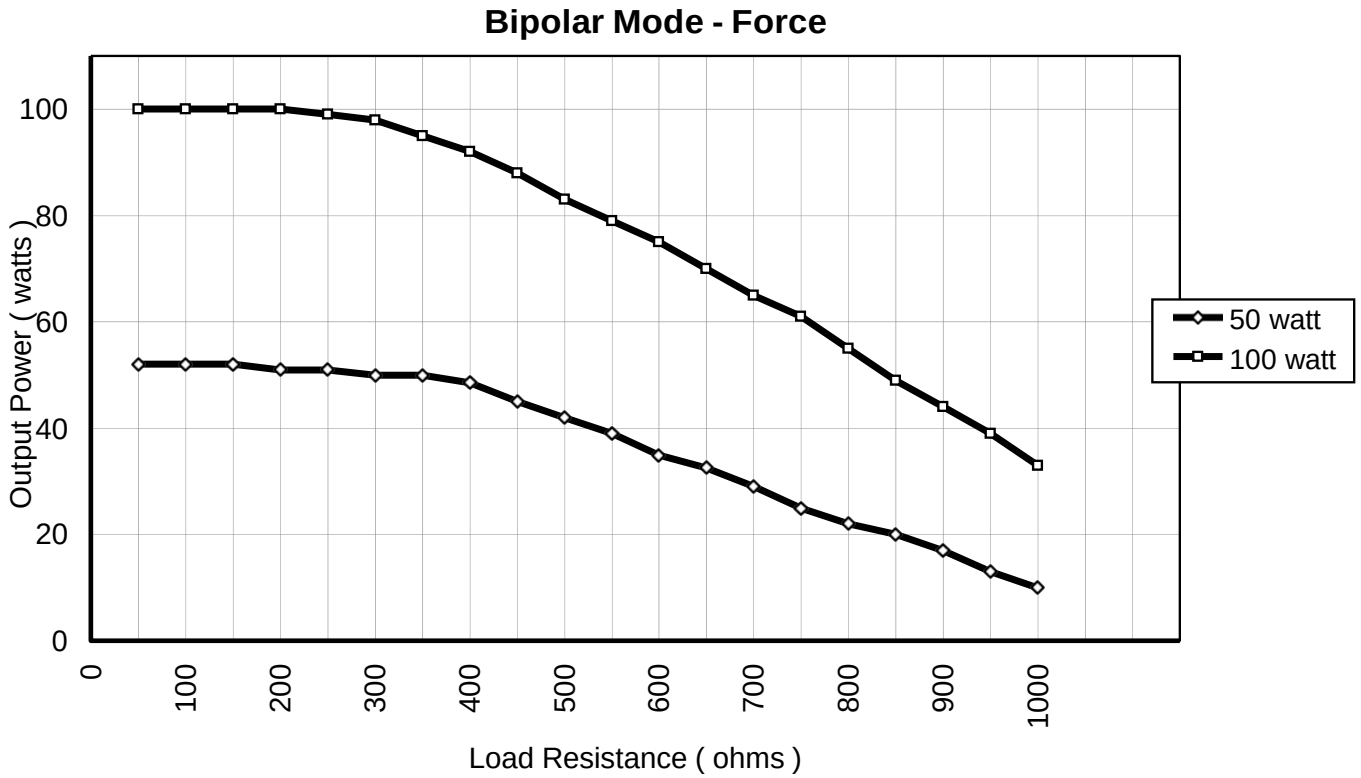

Monopolar Fulgurate Mode
Output Power (watts)
140
120
100
80
60
40
20
0
0
100
200
300
400
500
600
700
800
900
1000
1100
1200
1300
1400
1500
1600
1700
1800
1900
2000
Load Resistance (ohms)
60W
120W

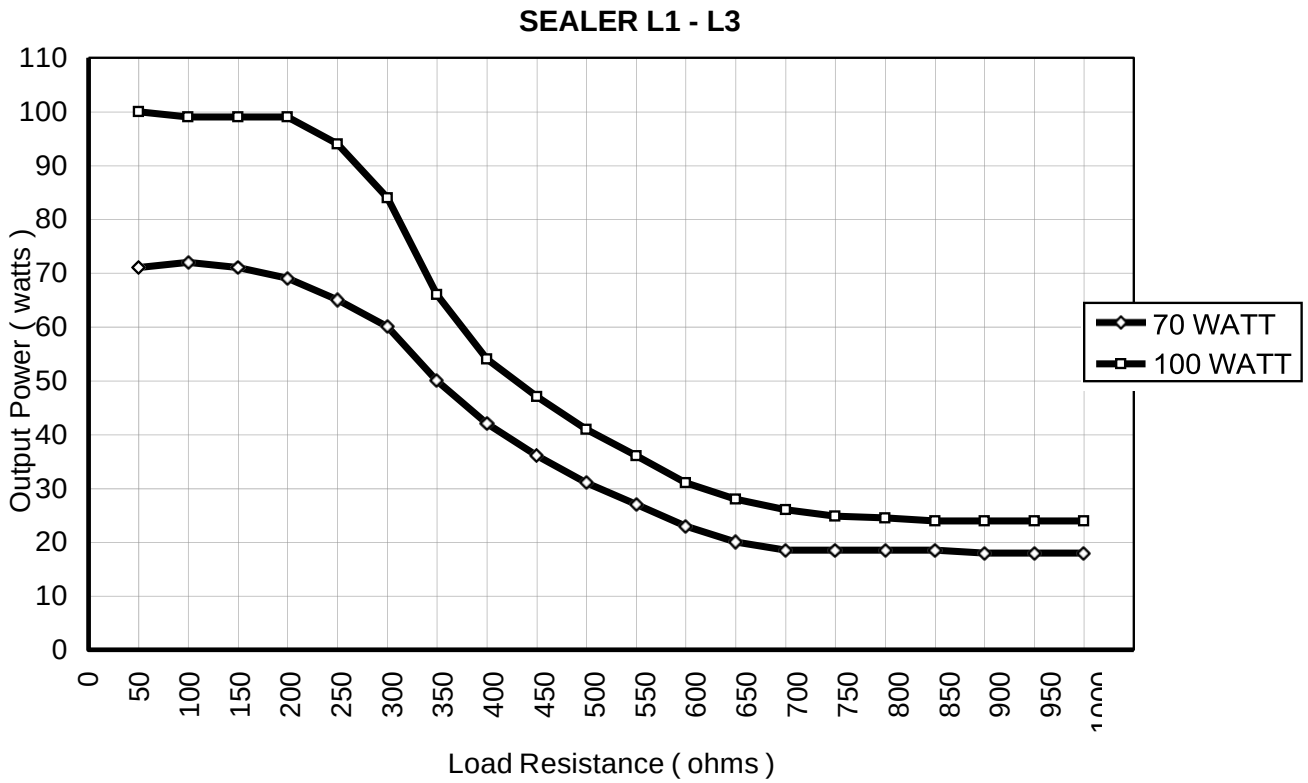

Bipolar Mode - Bicut/Macro
Output Power (watts)
0
20
40
60
80
100
0
100
200
300
400
500
600
700
800
900
1000
Load Resistance (ohms)
50 watt
100 watt


Bipolar Mode - Micro
Output Power (watts)
0
10
20
30
40
50
60
70
80
90
100
110
0
50
100
150
200
250
300
350
400
450
500
550
600
650
700
750
800
850
900
950
1000
Load Resistance (ohms)
50 watt
100 watt


Bipolar Mode - Standard
Output Power (watts)
110
100
90
80
70
60
50
40
30
20
10
0
0
50
100
150
200
250
300
350
400
450
500
550
600
650
700
750
800
850
900
950
1000
Load Resistance (ohms)
50 watt
100 watt


MONOPOLAR COAG SPRAY
Output Power (watts)
160
140
120
100
80
60
40
20
0
0
200
400
600
800
1000
1200
1400
1600
1800
2000
Load Resistance (ohms)
120 WATT
60 WATT


Bipolar Mode - Force
Output Power (watts)
0
20
40
60
80
100
0
100
200
300
400
500
600
700
800
900
1000
Load Resistance (ohms)
50 watt
100 watt


SEALER L1 - L3
Output Power (watts)
0
10
20
30
40
50
60
70
80
90
100
110
0
50
100
150
200
250
300
350
400
450
500
550
600
650
700
750
800
850
900
950
1000
Load Resistance (ohms)
70 WATT
100 WATT

CHAPTER 5
Before Surgery

Electric Shock Hazard:
Warning **-** Never remove the cover of the instrument.

Before Surgery:

Caution - Read all the Warnings, Cautions provided with this generator before using.

Active accessories:
Electric Shock Hazard:
Warning **-** Avoid connection of wet accessories to the generator.
Caution - Do not reuse or desterilize accessories labeled –disposable or –single use only.
Patient Return Electrode:
Warning **-** Do not cut patient return electrode to reduce its size, due to this, pad site burns may occur.

A. PREPARING THE GENERATOR

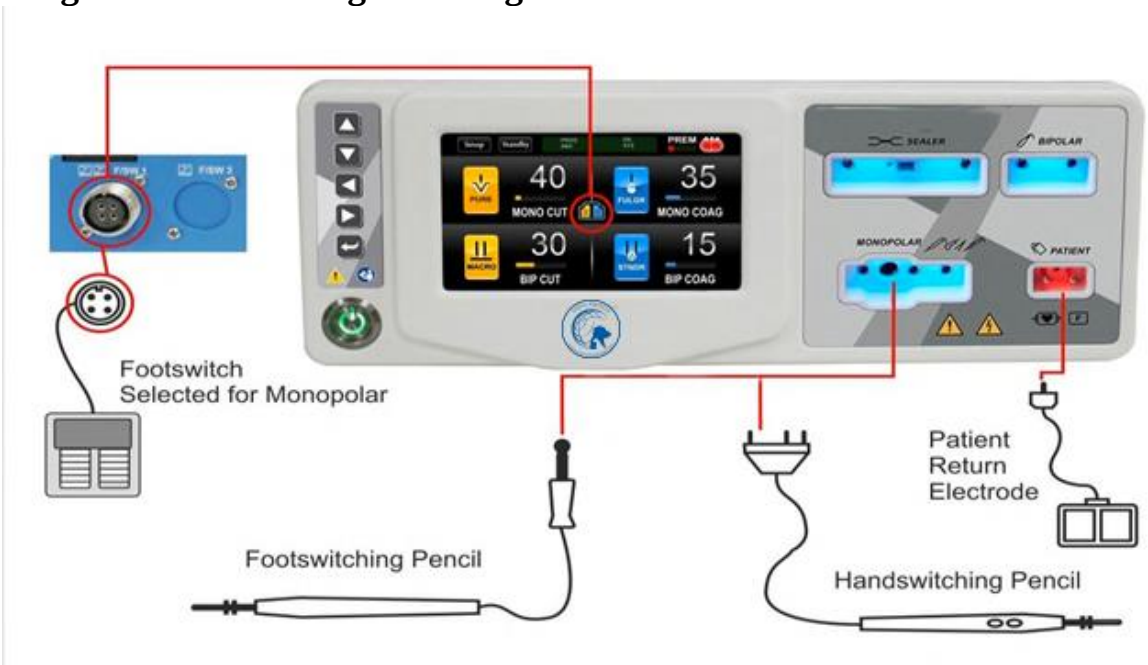
- If using a Foot Switch, connect it to the appropriate instrument socket on the rear panel.
- Connect the instrument to the appropriate instrument socket on the front panel.
- Apply patient return electrode to the patient for monopolar surgery only; connect it to the Patient Return Electrode socket on the front panel.
- Verify or change the mode & power setting.
- Optional-Press the Program key on the front panel to display pre-programmed settings. Change the mode or settings if required as surgical conditions & patient placement may require change in settings. This also varies as per individual skills.

B. SETTING THE GENERATOR

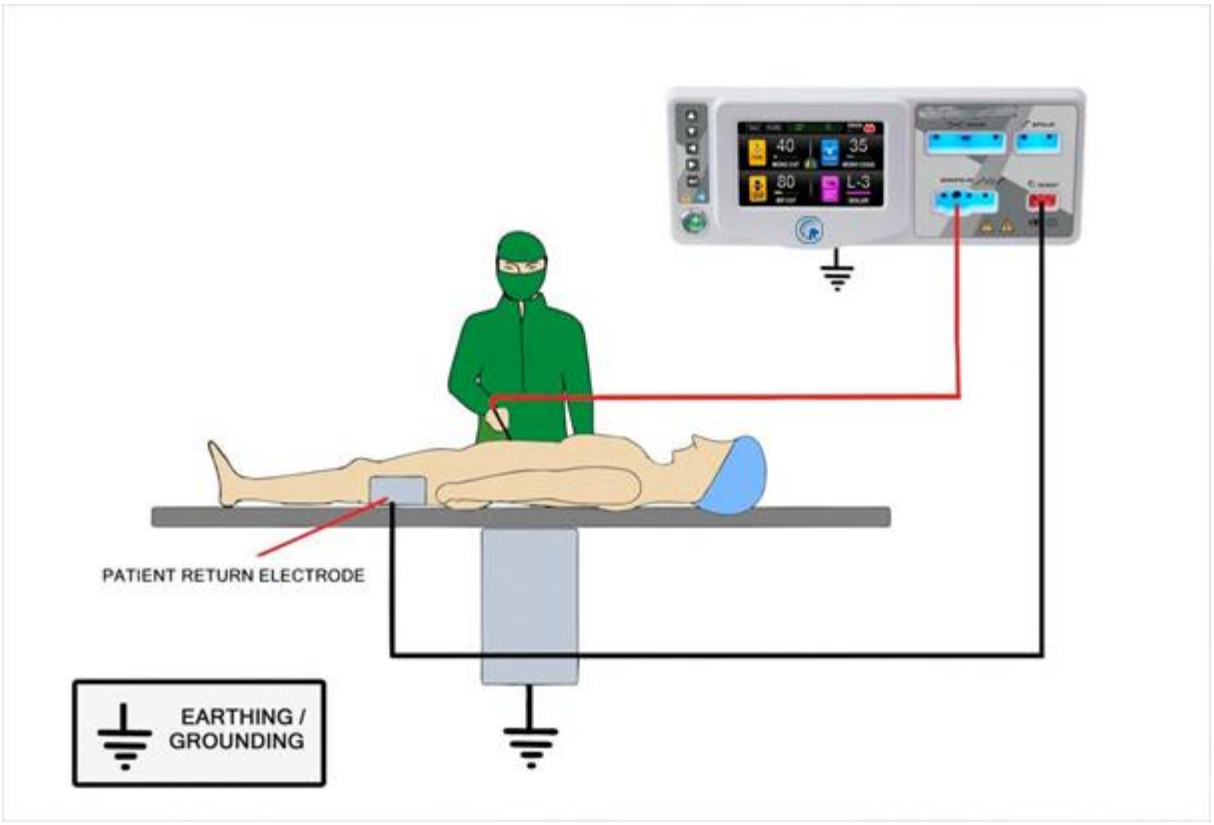
- Verify the generator is off by pressing the power switch OFF (0).
- Place the generator on a stable flat surface, such as table, provide at least 4-6 inches of space from the sides & top of the generator for cooling. Generally, the top, sides & rear panel are warm when the generator is used continuously for extended periods of time.
- Plug the generator power cable into rear panel socket.
- Plug the generator power cable into a grounded socket.
- Turn on the generator by pressing the power switch ON (1). Verify the following:
  - All visual indicators & displays on the front panel illuminate.
  - Activation tones sound to verify that the speaker is working properly.
- If self-test is successful, a tone sounds. Verify the following:
  - Each display shows a power setting of 1 watt.
  - The PREM Alarm indicator illuminates red. If the self-test is successful, connect the accessories & set the generator controls.

C. CONNECTIONS

Program Mode Settings for Surgeries:

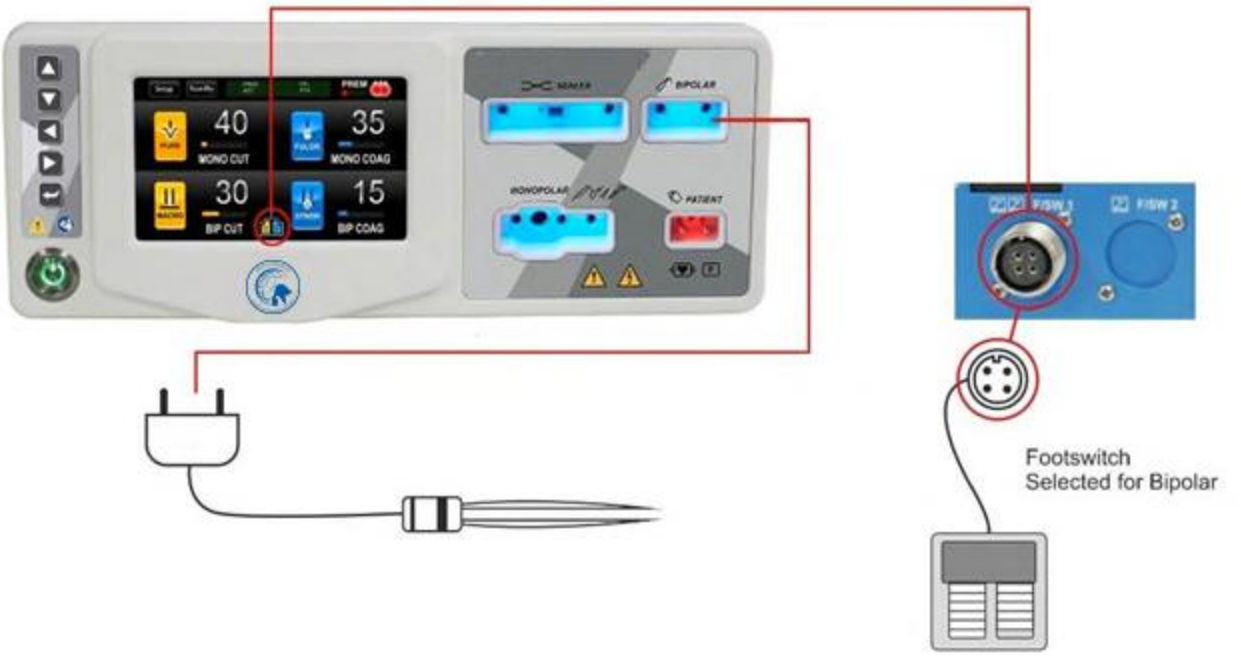


For Monopolar surgery, insert foot switching or hand switching accessory in socket on front panel and connect foot switch in Foot Switch socket on the rear panel. Also connect patient return electrode in front panel socket.



Connection with patient (Monopolar Mode)

Please Note: Patient Return Electrode is necessary for Monopolar electrosurgical modes only.

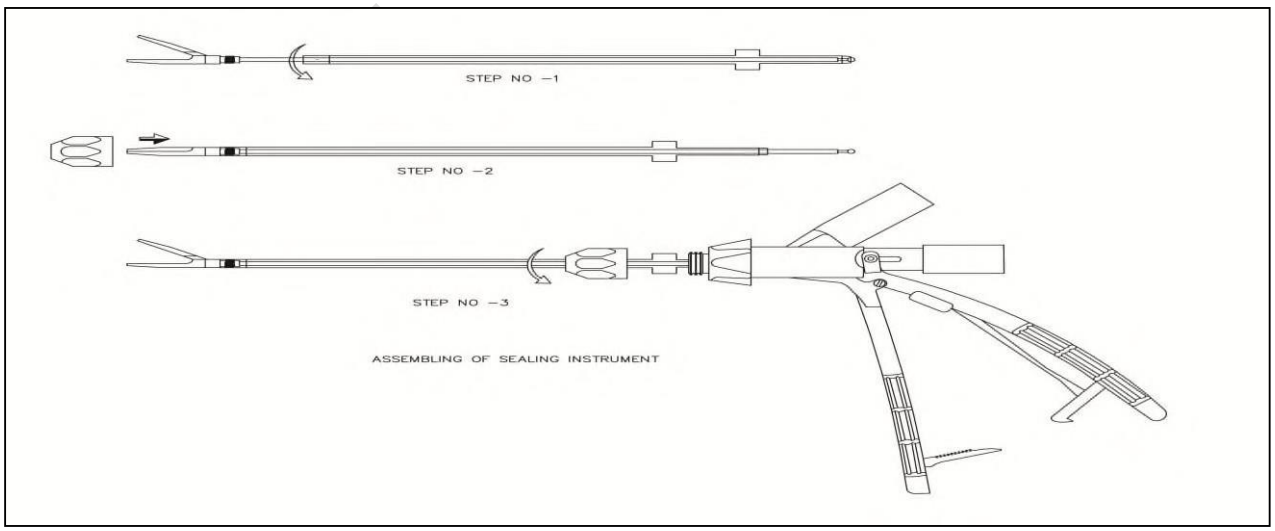


For bipolar surgery, insert bipolar instrument in bipolar front panel socket and foot switch in foot switch socket on the rear panel.

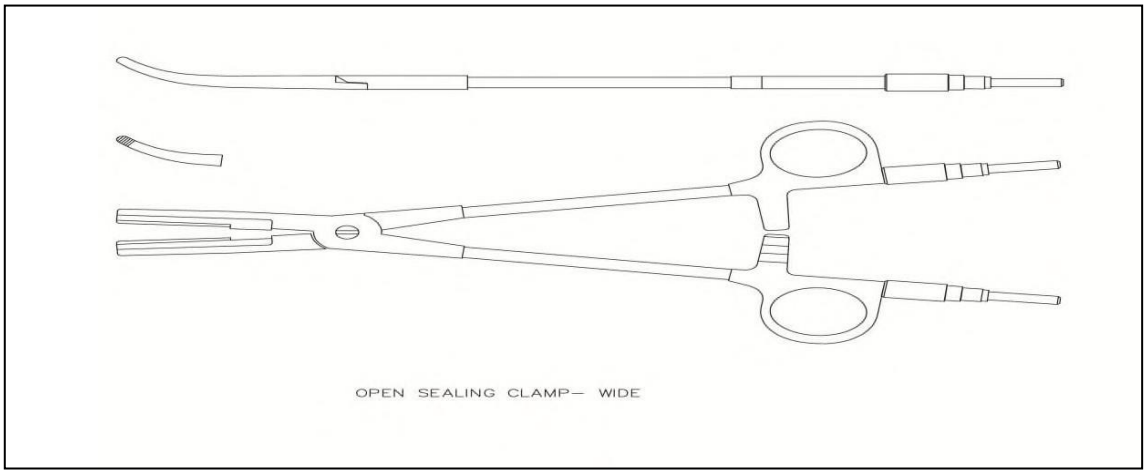
For vessel sealing surgery, insert bipolar handle or sealer handle accessory in socket on frontpanel and connect foot switch in foot switch socket on the rear panel.

For sealing and cutting, insert desiccator in the socket on front panel, connect foot switch in foot switch socket on the rear panel and select Pulse Bi-cut option in cut mode and L2/L3 in coag mode.

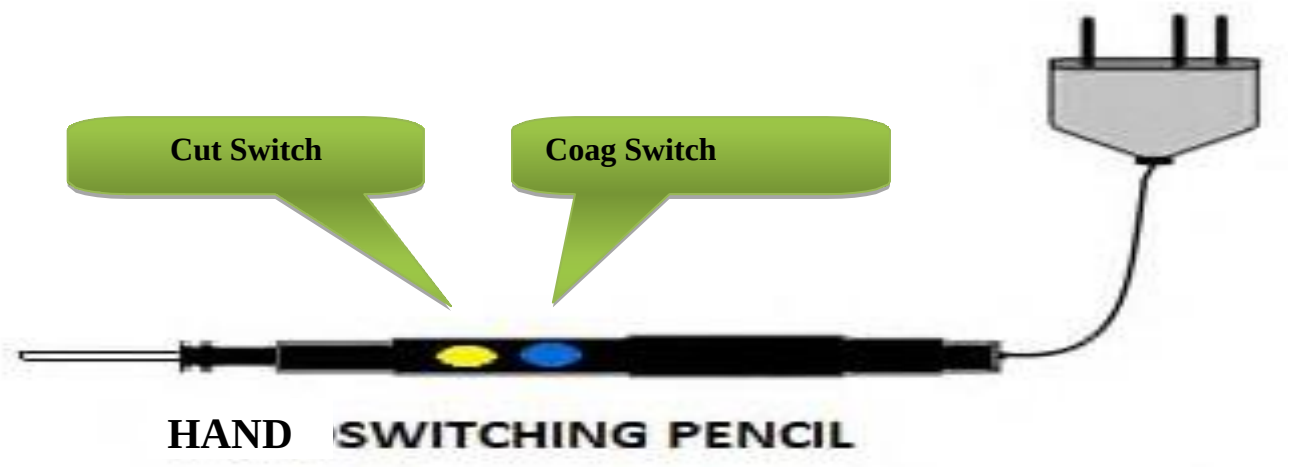
Sealer Instruments



Lapro Instrument 5mm for Sealer Mode

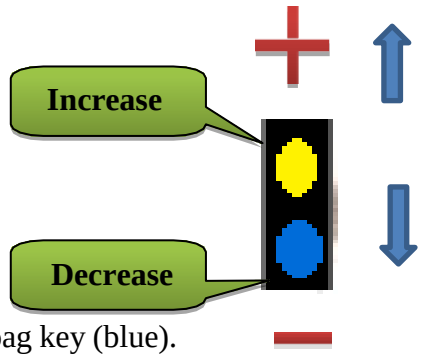


Hand Switching Pencil



During normal Monopolar operation, Hand Switching electrode (Pencil) can be used for Monopolar Cut and Monopolar Coagulation operations. Pressing yellow button will activate Monopolar Cut output and pressing blue button will activate Monopolar Coagulation output.

Steps to use pencil as a remote control



Please Note 1: - Power can be adjusted for recently activated mode.
Please Note 2: - To begin: Press cut & coag keys simultaneously.

Step-I-
To activate remote control press cut & coag button simultaneously.
Step-II
Activate the desired mode using the corresponding input i.e., to enter in the cut mode, press cut key (yellow). Similarly to enter coag mode, press coag key (blue).
Step-III
Press cut & coag switches simultaneously to enter the recently activated mode for which power has to be set.
Step-IV
Use cut and coag buttons to increase and decrease the power respectively. And press Enter (Ref. Note2).
Step-V
Choose keys to switch between modes.
Step-VI
Once the desired mode and power is selected press enter (Ref. Note 2) & activate corresponding input.

CHAPTER 6
During Surgery

Electric Shock Hazard:

Warning **-** Never remove the cover of instrument.

Generator Power Settings

Warning **-** Use lowest power setting for desired surgical effect.

Warning **-** Do not increase the power settings without first checking both active electrode & patient return electrode & their connections.

Contact with metal objects

Warning **-** Patient should not touch any metal parts that are connected to earth.

Warning **-** Contact of active electrode with any metal will increase the current flow & can result in catastrophic burn injury.

Active Accessories

Warning **-** Fire Hazard-Keep the active accessories away from flammable materials.

Warning **-** Place the active accessories in dry, clean & nonconductive area when not in use.

Using two generators simultaneously

Caution - Do not stack equipment on top of the generator. Ensure that the two patient return electrodes do not touch.

A. PREPARING THE PATIENT RETURN ELECTRODE

Warning - Do not wrap cloth over return electrode as it increases the tissue resistance, more power will be required for surgery.

Warning - Avoid bony prominences, scar tissue and skin over an implanted metal prosthesis, hairy surfaces, pressure points, and adipose tissue.

Caution - Inspect the return electrode before each use for wire breakage or fraying.

Caution - Choose a return electrode of an appropriate size for the patient.

Caution - Do not warm return electrode prior to application.

Caution - Place the return electrode after positioning the patient.

Caution - Apply the return electrode to a clean, dry skin surface, over well-vascularized, large muscle mass, and on a convex area in close proximity to the procedure site.

Caution - If necessary, shave, clean, and dry the return electrode application site.

Caution - Avoid pooling of solutions: Prep, Irrigation & Patient fluids etc.

B. MODES AND POWER SETTINGS

(i) Changing the Mode:

Operator should verify the selected mode with the surgeon. Modes may not be changed while the generator is active. To change the mode, press the mode key. The indicator for selected mode will illuminate green. You can activate only one mode at a time. When you change the modes within a function the power setting remains the same unless it exceeds maximum for the new mode. In that case, it reverts to the maximum for the new mode.

(ii) Changing the Power Setting:

Operator should verify the power setting for the selected mode with the surgeon. The power setting cannot change when the generator is activated.. To increase the power, press the up arrow key for the selected mode. To decrease the power, press the down arrow key for the selected mode.
To reach maximum or minimum power setting for selected mode, press up & down key. Release the key when the desired setting is displayed.

(iii) Technique for keeping Power Setting Low:

1. Using a small active electrode to deliver less power current is required to produce the same surgical effect.
2. Coagulate tissues by using fulguration rather than desiccation because fulguration sparks to a wider area of tissue, surface coagulation can be achieved with lower power setting using Fulgurate rather than Desiccate.
3. Hold active electrode just above the tissue & keep in motion as sparking produces continuous sparks that cut cleanly and quickly. Placing the active electrode in contact with the tissue produces desiccation that increases tissue resistance. A higher power setting may be required to overcome the increased resistance.
4. Using Bipolar Surgery - Bipolar surgery requires lower power because the amount of tissue included in electrosurgical circuit limits the tissue that is held in the bipolar instrument.

C. HELPFUL HINTS TO AVOID HEMOSTAT BURNS

***Warning*:** Hold hemostat with full grip.
Caution - Use lowest power setting possible of generator.
Caution - Activate low voltage (Sp Cut/ Desiccate) waveform.
Caution - Avoid touching the patient by other hand.
Caution - Do not activate in open circuit, touch the electrode to object & then activate the generator.
Caution - Avoid metal to metal arcing.

D. SETTINGS FOR SURGERIES:

a) Pediatric –
Cut Low: 15 to 25, Coag Soft: 15 to 20, Bipolar BiCut: 20 to 25, Bipolar Standard: 10 to 15

b) Onco /Fatty Tissues Surgery –
Cut Pure: 55, Coag Spray: 50, Bipolar BiCut: 20 to 30, Bipolar Standard: 15 to 20

c) TURP/ TCRE/Hysteroscopy –
Cut Pure: 110, Coag Fulgurate: 50

d) Plastic/ Neuro/ ENT/ Spine/Ophthal Surgery-
Cut Pure: 30, Coag Soft: 25, Bipolar BiCut: 1 to 10, Bipolar Micro: 1 to 10

e) Laparo/Gynac/Hernia-
Cut Pure: 40, Coag Fulgur: 35, Bipolar BiCut: 45 to 60, Bipolar Standard: 25 to 35

f) Ortho/Open/General Surgery-
Cut Pure: 45, Coag Fulgur: 35, Bipolar BiCut: 1 to 10, Bipolar Standard: 15 to 20

g) GI/Papillotomy/Polypectomy/ERCP—
Cut Endo: 40 to 60, Coag Soft: 35 to 45

E. ALARM CONDITIONS

The following conditions can generate a PREM alarm:

1. The patient return electrode is not connected to the generator when the generator is activated for monopolar surgery.
2. The return electrode does not have adequate contact with the patient.
3. The contact area is reduced due to movement, loss of adhesion, fluid pooling or dry contact gel.
4. The return electrode cord is damaged, causing excessive resistance.

Non - PREM Patient Return Electrode Alarm:
When a non - PREM patient return electrode is connected and generator detects a cord fault condition, the PREM Alarm indicator illuminates red. When you activate an alarm condition, the indicator blinks.

System Alarm:
When the generator senses a system alarm condition, an alarm tone sounds and the generator is deactivated. An alarm number flashes on the display.

1. Turn off the generator.
2. Turn on the generator & verify that the self – test is completed successfully.

If you are unable to correct the system alarm condition, use standby generator to complete the surgical procedure.

Vessel Sealer Completion Alarm
System generates completion alarm once tissue is adequately sealed. Do not remove sealing instrument from tissue until the completion alarm is sounded.

13 cycle Alarm:
This alarm is generated when the held tissue is too thick to seal. Please hold less tissue and then start sealing again.

Saline Resection Alarms
System generates completion alarm on open condition, when tissue is not in proper contact with the saline instrument.

F. COMPATIBILITY WITH OTHER DEVICES

1. Argon Plasma Coagulator: Unit can be combined with Argon gas delivery system to get the combined effect of argon plasma coagulation system, containing necessary hardware and software protocol for working as an APC unit.
2. Ultrasonic surgical aspirator: Unit can be attached with ultrasonic surgical aspirator such as CUSA, by connecting necessary interfacing cable. Unit works in low cut mode and soft coagulation mode during this interface other cut and coagulation modes are not available.
3. Smoke evacuator system: Surgical smoke suction system can be used with electrosurgical unit. The necessary hardware and software protocol is already build into this electrosurgical unit. This works only in monopolar surgical mode. It is recommended to go through the instruction manual of smoke evacuator system provided by the manufacturer thoroughly, prior to using for surgery.

CHAPTER 7
After Surgery

Electric Shock Hazard:
Warning **-** Never remove the cover of instrument.

After Surgery:

Electric Shock Hazard
Warning **-** Always turn off & unplug the generator before cleaning.

Caution - Do not clean the generator with abrasive cleaning that could damage the generator.

A. PREPARING THE GENERATOR FOR REUSE

Disconnect the Accessories:

1. Turn off the generator.
2. Remove the patient return electrode from the patient if used. Disconnect all other accessories from the front panel.
   - If disposable accessory, dispose of it according to the instructions.
   - If the accessory is reusable, clean & resterilize it according to the manufacture's instructions.
3. Disconnect & store Foot Switch if used.

B. CLEANING THE GENERATOR

1. Unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the generator & power cord with a mild cleaning solution or disinfectant & damp cloth. Strictly follow the procedures for cleaning as mentioned in the manual. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

C. INSTRUMENT CLEANING

- Cleaning is required for all instruments with lumens and hollow spaces.
- Abrasive materials should not be used on the any parts because they will damage the instrument's outer surface. Instead, use soft brushes & cottons cloths.
- Use distilled de-mineralized water for the final rinse.
- Hard water (water with high mineral concentration) should not be used, it may impact the performance ofthe instrument.
- Use Neutral PH enzymatic detergent for cleaning whenever possible. Alkaline detergents, if used, must be completely rinsed from the devices. Do not use corrosive fluids.
- **Recommended autoclave cycle:**
  - Sterilization temperature: 250°F, maximum time – 20 minutes
  - Drying temperature: 195°F, maximum time – 10 minutes
- After disassembly, the following manual cleaning steps are important:
  1. All components should be soaked in a blood-dissolving enzymatic solution for at least five minutes with gentle agitation.
  2. Note: It is advisable to soak longer if protein containing material is present.
  3. Soak instruments vertically which cleans instrument thoroughly.
  4. Rinse it thoroughly with tap water for 5 minutes.
  5. Clean all surfaces of instrument using detergent solution.

6. Brush the surfaces using soft brush. Handle cord connectors, fittings and joints with care.
7. Use the soft brushes in up and down motion to clean completely through the lumen.
8. Compressed air can be used for flushing if a precise nozzle is available and if the pressure can be controlled. Ultrasonic irrigators are also a useful way to flush instruments with lumens to remove debris from hard-to-reach areas, and they can do so in a less time than a manual cleaning process. The cycle time should be five minutes or less, and water temperature should not exceed 50°C.
9. Rinse thoroughly under running distilled water for at least five minutes.

D. VESSEL SEALING INSTRUMENT

1. Prepare the cleaning solution with 50% H2O& 50% permissible disinfectant
2. Do not use normal saline for cleaning of the instrument during the surgery.
3. In case of using non sterilized blades, assemble the instrument with blade earlier to packing the instrument for sterilization.
4. Cover all the parts and assembly separately in the cloth as open assembly may damage insulation of other parts during sterilization.
5. Pack all covered assembly in one bunch and send it for sterilization.

E. STORING THE GENERATOR

If the generator is stored at a temperature outside its normal operating range of 50 to 104 ^{0}F (10 to 40 ^{o}C) allow it to sit at room temperature for one hour prior to use. The generator can be stored indefinitely. You must perform a specific test procedure before use if you see it longer than one year.

CHAPTER 8
Operating Principle

Operating Principle:

This section will emphasize on the working principle of the system.

- **General description**
- **Block diagram**
- **Detailed description**

A. GENERAL DESCRIPTION

6SENSE Technology:

This is a recent innovation in field of advance feedback controlled electrosurgical technology. The system maintains the set power by sensing- voltage, current, power, tissue density, patient return electrode monitoring and leakage RF current- at 4000 times per second.

- Minimizes dragging of electrodes in different tissues.
- No need to change the power setting as the tissue changes.
- Fifty percent less thermal damage than standard ESU's which improves patient recovery time.
- Reduces the risk of collateral tissue damage.
- Reduces noise in other OT equipment.
- Reduces the risk of neuro-muscular stimulation.
- Less charring and sparking due to precise & clean cutting.

Smart ENDO Cut:

For polypectomy & papillotomy cutting is intelligently divided in cut & pause in such a way that coagulation occurs in each pause. The system changes the pause interval as tissue density changes. Hence, producing fine cutting with coagulation effect.

Smart Endo Cut: Change in cut & pause as tissue demands. d1, d2, d3 are dependent on the tissue impedance.

Randomized spray coag: In conventional spray coag, beam tends to follow the same path left by previous spark. Hence, no homogeneous coagulation over larger area occurs. By randomizing spray frequency & amplitude, spark takes multiple paths.

- Starts sparking further away from tissue.
- Uniform & homogeneous coagulation over large surface area at lower power settings.
- Less tissue necrosis & carbonization.
- Increases the speed. Reduces the output voltages.
- Drastically improves the performance when combined with Argon enhanced ESUs.

BiCoag Alarm: The system delivers an alarm after completion of coagulation in endoscopic & open surgery. This feature is very effective in endoscopic surgeries where a surgeon does not have direct contact with the tissue being coagulated. BiCoag Alarm avoids over-coagulation of tissue and reduces tissue sticking to instruments. It also reduces smoke, charring, necrosis & carbonization of tissue.

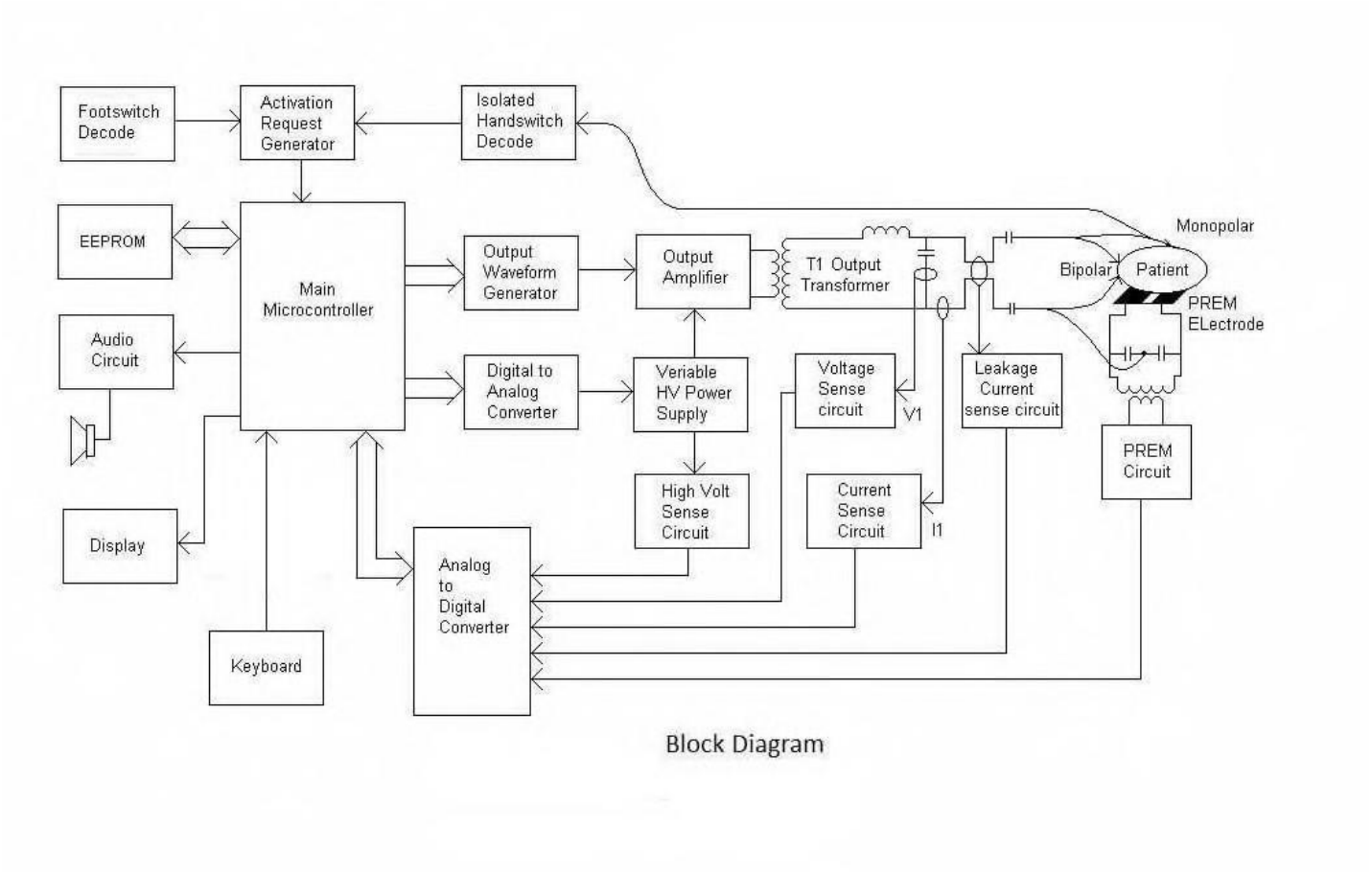
Auto Bipolar: This is the unique feature of which system can deliver automatic bipolar output by sensing the tissue & stopping the power delivery when tissue gets completely coagulated. This function canwork in all three bipolar modes. Auto start delay can also be adjusted. The steps to enable this mode are explained in Chapter 3, Section D- How to select power & mode. No foot switch is required in this modehence provide flexibility in using bipolar energy.

B. BLOCK DIAGRAM & DESCRIPTION

System is divided in three basic parts:

1) **Processor and control circuit.**
2) **Variable voltage power supply**
3) **Radio frequency output amplifier.**

Processor & Control Circuitry:
This is the main control system that calculates all the system parameters as per the selected mode and monitors the overall activity of the system.
Variable voltage power supply: As per the selected mode and the set power settings, power supply determines the necessary power as an input for the RF stage.
RF output amplifier: This converts the controlled dc voltage into radio frequency as is necessary demanded forsurgical applications.



Block Diagram

Circuit Board Description:

CPU and Display Board:
Processor and control board consists of –

1. **Main microcontroller:** IC U02 is main microcontroller and brain of the system, which controls overall function of a system using inbuilt I/O ports. U02 a built in program memory to store the system's programs. All activation requests go to the system and it works accordingly by giving I/O signals to process tasks.

2. **Digital to Analog Converter**: Two analog control signals, the power control signal & the voltage control signal are derived from ICs U03. During activation of power delivery both control signals change with change in tissue impedance.

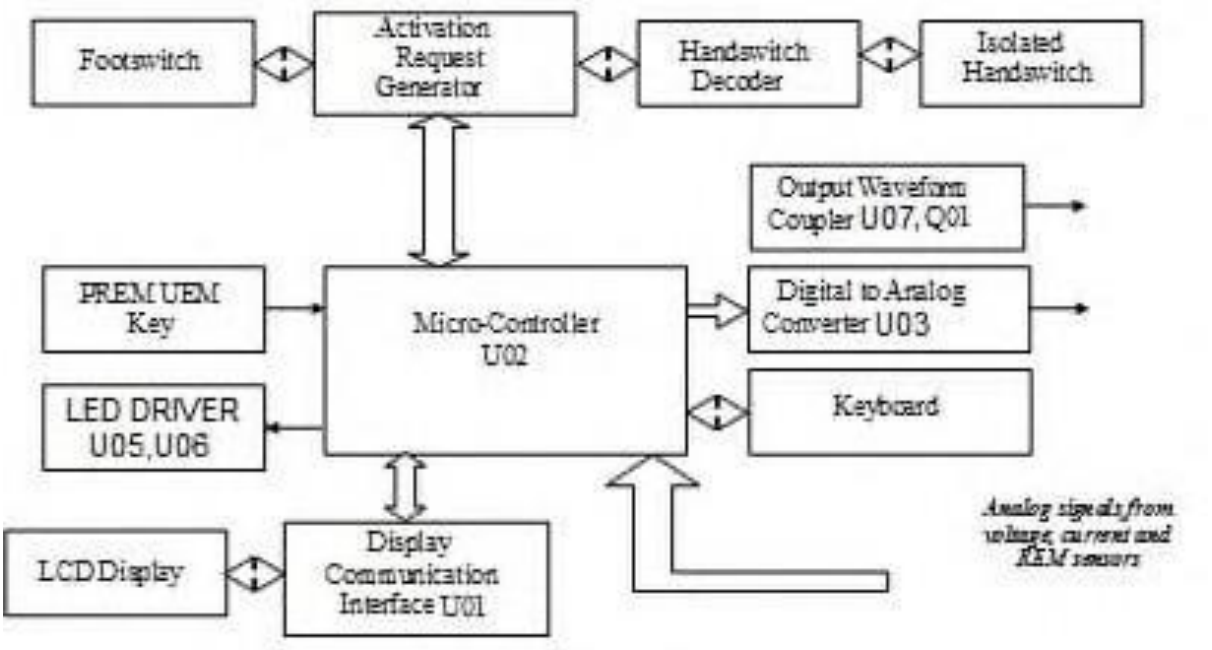
3. **Output waveform Coupler**: RF output waveform as per selected mode is delivered by the microcontroller U02. Signal conditioning is done by U07 & Q01.

4. **Analog to Digital converter**: the built in micro-controller's ADC converts all analog sense voltage in digital form to process them for monitoring the calculation in a close loop. Sensed voltage is continuously monitored by the processor for checking the contact quality of patient with return electrode.

5. **Display Circuit**: 5-inch LCD Display is interface by display communication IC U01.

6. **Keyboard Circuit:** Front panel keyboard is directly connected to the CPU. CPU continually scans for the pressed key.

7. **LED driver Circuit:** Front panel socket LEDs are driven by IC U05 & U06.

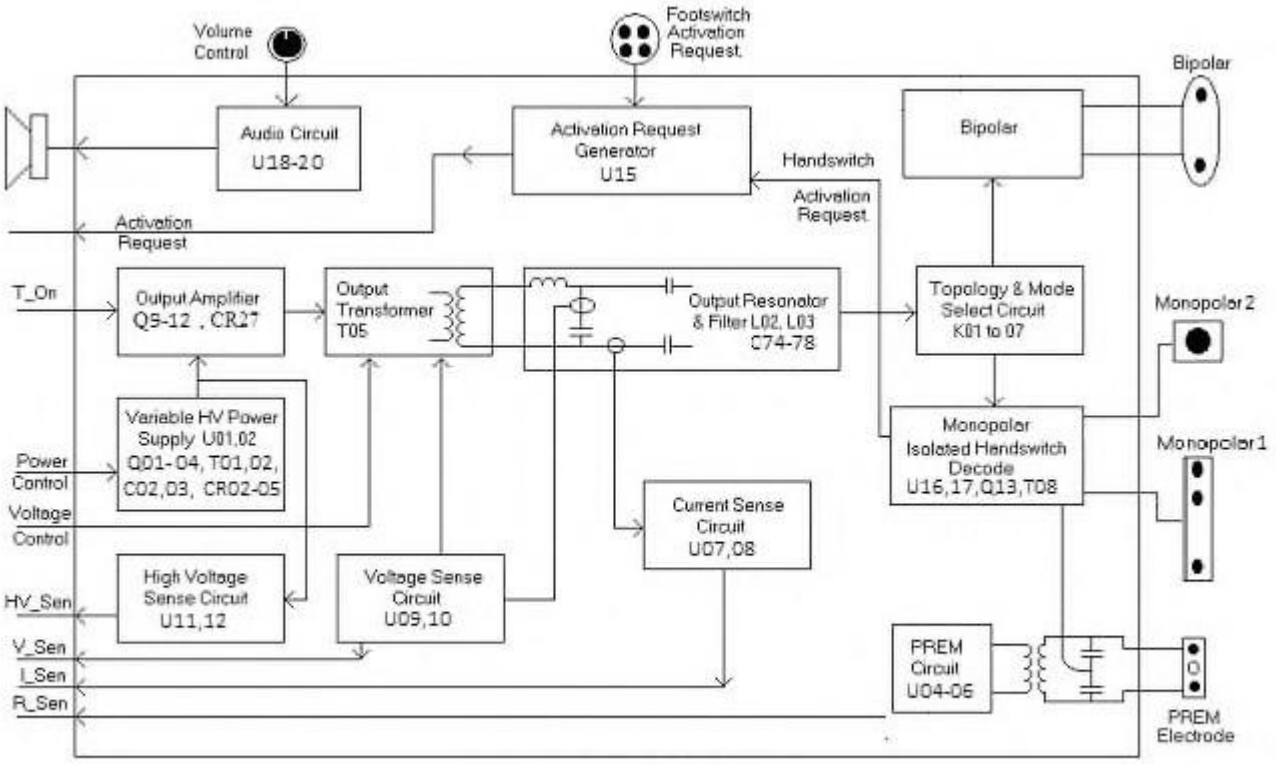


CPU and Display Board

Power Supply and RF Main Board:
This board can be divided in two parts, main power supply and output RF stage. This board circuitry also supports RF power delivery, hand switching logic, PREM and all other sense circuits.

- **Variable HV power supply:** Supply voltage is converted in dc voltage by CR01 & C02, C0 5 and again converted in Isolated DC voltage by using a bridge converter. MOSFET Q01 to Q04 works in bridge configuration along with Transformer T02 and MOSFETs are driven by T01 pulse transformer. IC's U01 & U02 controls the pulse width of ON Time depending on Error voltage between output dc voltage & set value in particular operating mode. This voltage is continuously changing during activation, hence reflecting the change in pulse width. The output of TransformerT02 is fed to the HF bridge rectifier formed of CR02 to CR05 and filtered by L01 & C08, C09, which produces pure dc voltage to drive RF stage.
- **O/P RF amplifier stage:** This stage is driven by pure controlled dc voltage from the HV power supply and control signal from waveform generator circuit on CPU board. Depending on the selected mode, the o/p transformer T05 configuration is selected by primary relay k01. O/P stage is driven by switching devices Q09 to Q12 at various levels. CR27 is also used to protect the device from reverse current.
- **O/P Resonator and filter:** RF o/p of amplifier stage is supplied to patient via resonator stage which is resonating at particular load conditions. This stage has two functions of resonator & filter for RF frequencies. Inductor L02 & L03 and capacitor C74 to C78 forms the resonator that can filter circuit, which is also used to deliver the o/p in different modes of monopolar & bipolar applications.
- **Configuration & mode selection circuit:** This circuit is used to obtain the RF o/p at the required channel. Relays k03 to k07 are used to select different o/p channel & load conditions. When power is delivered in monopolar (any of the channels), no leakage power in bipolar or other monopolar channels is present unless and until it is not operating in 2Si coag mode. In bipolar mode, return electrode circuit & both monopolar channels are isolated from RF by this circuit.
- **Monopolar & Bipolar Hand switch Decode:** Hand switch decode circuitry works on a floating principle. IC U16, U17 is used for detecting the activation request if any. This circuitry is powered by an isolated power supply separated for each channel. All activation requests pass on to activate request generator.
- **Activation Request Generator:** This circuit keeps watch on activation request from foot or hand-controlled accessories. This generates the necessary signals for CPU to start the process for RF delivery depending on the selected mode & the channel.
- **Leakage sense circuit:** Current flows from the active electrode and the return electrode is measured if difference crosses the safety limit circuit gives error voltage. The CPU as IF- sense senses this. CPU takes corrective action to reduce the current in a safe limit.
- **RF current sense:** Actual RF o/p current is sensed by current sense T07 and IC U07. U08 converts the current in average value, which is sensed by CPU as I- sense.
- **RF voltage sense:** O/P voltage is sensed by voltage sense T06 and processed by true rms converter in dc voltage by IC's U09 & U10, which is sensed by CPU as V- sense. Also, it gives the signal to spark controller.
- **High voltage sense circuit:** This circuit continuously monitors that RFHV is not crossing the limit. This senses the voltages in primary side of RF and converts in dc by True RMS detector of U11&U12. Signal is sensed by CPU as HV sense.
- **Foot Switch decode logic:** This circuit checks the foot switch activation input gives the input signal to CPU Board for activation of RF output.

- **Audio circuit:** Circuit generates different audio tones for cut, coag and bipolar activation. It gives two pulse outputs for ERROR conditions. Audio oscillator & driver stage comprises of U18 to U20. Signals are fed to speaker SPK 01 & audio volume can be controlled by control knob kP01.



Power Supply & RF Board.

Detailed circuit diagrams & components list relevant to the purchased product will be made available to a valid customer upon request.

CHAPTER 9
Testing Procedures

Warning- Electric Shock Hazard - the generator power cord must be connected with only a properly grounded socket. Do not use power plug adaptors.

Warning- Fire Hazard - Do not use extension cords.

Caution - Do not stack equipment on top of the Mano Médical Seal&Cut MV1 or do not place the generator on top of other electrical equipment. These configurations do not allow for adequate cooling.

C**aution -** Place the generator on any stable or flat surface, such as a table or platform. Carts with conductive wheels are recommended. Refer to the procedures for your institution or to local codes for details.

Provide at least four to six inches of space from the sides and top of the generator for cooling. Normally, the top, sides and rear panel are warm when the generator is used continuously for extended period of time.

Caution - According to the procedures, connect an equipotential grounding cable to the grounding plug on the rear panel of the generator. Then, connect the cable to earth ground.

Caution - If required connect the generator to the hospital equalization connector with an equipotential cable.

Caution - Connect the power cord to a wall socket having the correct voltage. Otherwise, product damage may result.

Caution - Plug the generator power cord into a grounded socket. Grasp the plug, not the power cord. Do not pull the cord itself.

Warning- Keep test leads at a minimum length usable; lead inductance and stray capacitance can adversely affect readings. Carefully select suitable ground points to avoid ground loop error in measurements. The accuracy of most RF instruments is approximately 1-5% of full scale. Do not use uncompensated scope probe, causes large errors when measuring high voltage RF waveforms.

Periodic Safety Check:

Perform the following safety check every two years to verify that the Mano Médical Seal&Cut MV1 generator is functioning properly. Record the test results for reference in future tests. If the generator fails to meet any of the checks, refer to Chapter 10, troubleshooting.

Warning - Electric Shock Hazard - While taking measurements or troubleshooting the generator, take appropriate precautions, such as using isolated tools and equipment, using the –one hand rule, etc.

Warning - Electric Shock Hazard- do not touch any exposed wiring or conductive surfaces while the generator is disassembled and energized.

Warning - Electric Shock Hazard- Never wear a grounding strap when working on an energized generator.

Caution - The generator contains electrostatic- sensitive components. When repairing the generator, work at a static control workstation. Wear a grounding strap when handling electrostatic- sensitive components, except when working on an energized generator.

Handle circuit boards by their nonconductive edges. Use an antistatic container for transport of electrostatic-sensitive components and circuit boards.

The summary of safety checks:

Inspect the generator and accessories.
Inspect the internal components.
Test the generator.
Verify PREM Function.
Confirm outputs.
Check leakage current and ground resistance.

Recommended Test Equipment:

Digital voltmeter
True RMS voltmeter
Oscilloscope
Leakage current tester
Leakage table –
100, 200, 300, 500 ohms, all 250-watt, 1% tolerance, non-inductive

Inspecting the Generator and Accessories:

Equipment list

Dual paddle toggle (Bipolar/Monopolar)foot switch
Bipolar instrument cords (foot switching)
Monopolar instrument cords (hand switching and foot switching)

Steps for a rear-panel inspection:

Turn OFF (0) the generator by pressing the front panel power switch.
Disconnect the power cord from the wall socket.

Rear Panel Inspection

1. Check the rear panel foot switch sockets for obstructions or damage.
2. Check for a secure fit by inserting the Dual paddle toggle (Bipolar/Monopolar) foot switch connector into respective socket.
3. Remove the fuse and verify correct voltage and current rating.

Front Panel

1. Check the bipolar instrument socket for any obstructions or damage. Insert the bipolar instrument connector (foot switching) into the appropriate socket to verify a secure fit. If the connection is loose, replace the front panel assembly.
2. Check the monopolar instrument sockets for obstructions or damage. Insert the monopolar instrument connector (foot switching and hand switching) into the appropriate socket to verify a secure fit. If any of the connections are loose, replace the front panel assembly.
3. Check the patient return electrode socket for a broken pin or an obstruction. If the socket is damaged or obstructed, replace the front panel assembly.

Foot Switches and its connector

1. Remove the foot switch from the generator.
2. Disassemble the foot switches connector. Inspect the connector for damage or corrosion.

3. In case of damage or corroded foot switch connector, replace the foot switch connector. If found appropriate, reassemble the foot switches connector.
4. Inspect the foot switches for damage.
5. In case of damage foot switch, replace the Foot Switch.
   If found appropriate, reconnect the foot switches to the generator.

Power cord:

1. Remove the power cord from the unit and ensure that it is unplugged from the wall socket.
2. Visually inspect the power cord for damage.
3. Reconnect the power cord to the generator and wall socket.

Inspecting the Internal Components:
This section is only required when the system is open for troubleshooting, repair, or spare replacement.

Equipment list

- Phillips screwdriver
- Turn OFF (0) the generator by pressing the front panel power switch.
- Loosen the chassis screws. Lift the cover off the chassis. Set the cover aside for reinstallation.
- Verify that all connectors are firmly seated.
- Inspect each board for damaged components, wires, cracks, and corrosion.
- If you find evidence of damage on the Controller Board, Relay Board or Front panel, replace theboard.
- If you find evidence of damage on the Power Supply /RF Board, replace the board only if the damage is severe. Reinstall the cover on the generator. Tighten the screws that fit the cover to the chassis.

Configuration Outputs:

Use these procedures to ensure the accuracy of the generator. Always confirm the output at these times.

- After calibrating the generator
- Every year

Equipment

- Two small test cables (less than 24 inches long) with banana plugs
- Current transformer
- True RMS voltmeter
- 100,300, and 500 Ω 1% non-inductive power resistors
- Dual paddle toggle (Bipolar/monopolar foot switch)

Checking the Bipolar Output

1. Verify if the generator successfully completes the self-test.
2. Connect the test equipment for bipolar output.
3. Connect the two test cables to the bipolar socket.
4. Pass one test cable through the current transformer and connect the current transformer to the voltmeter.
5. Connect the 100 Ω power resistor across the output jacks at the end of the test cables.
6. Connect the dual paddle toggle foot switch to foot switch socket on the rear panel.

7. Set the foot switch in bipolar mode by pressing toggle switch provided on the top side off foot switch or by enabling the foot switch icon in the mode & power setting window.
   (Visible indication provided for foot switch selection on LCD display)
8. Select the Macro mode in Bipolar cut and set the bipolar power to 10.
9. Press the foot switch cut pedal and, while activating the generator, note the output on the voltmeter.
10. Test the output current for the selected bipolar mode.
11. Select other sub modes from the Bipolar cut & Bipolar coag and repeat step 4.
12. Verify that the generator output for each mode is 316 ± 16mA rms.

If the output is outside the specified range, calibrate the bipolar output as described in calibration step then repeat this procedure. If the output for one or more modes remains outside the specified range, contact Génia USA Service Center.

Checking the Monopolar Cut Output

1. Check the output for the cut modes.
2. Verify that the generator successfully completes the self-test.
3. Connect the test equipment for monopolar2 output.
4. Connect one test cable in the Monopolar2 socket. Pass the test cable through the current transformer and connect the current transformer to the voltmeter.
5. Use a test cable to short the two pins on the patient (return electrode) socket.
6. Connect the second test cable from the voltmeter to both pins of the patient (return electrode) socket.
7. Connect the 300 Ω resistor across the output jacks at the end of the test cables.
8. Connect the Dual paddle toggle foot switch to foot switch socket on the rear panel.
9. Set the foot switch in monopolar mode by pressing toggle switch provided on the top side of foot switch or by enabling the foot switch icon in the mode & power setting window.
   (Visible indication provided for foot switch selection on LCD display)
10. Select the Pure mode.
11. Press the cut up/down keys to set the cut power to 80 watts.
12. Test the monopolar2 cut output.
13. Press the foot switch cut pedal and while activating the generator, note the output on the voltmeter.
14. Release the foot switch pedal.
15. Based on the voltmeter setting and the current transformer used at the customer end, calculate and record the output current.
16. Select the Low-cut mode and repeat step 11.
17. Select the Blend mode and repeat step 11.
18. Verify that the generator output for each mode is 516 ± 26mA rms.
19. If the output is outside the specified range, calibrate the monopolar output as described in calibration steps4. 2. Then repeat this procedure. If the output for one or more cut modes remains outside the specified range, call the Génia USA Service Center.

Checking the Monopolar Coag Output

1. Check the output for the coag modes.
2. Disconnect the 300 Ω resistor and replace it with the 500 Ω resistor.
3. Select the Soft mode.
4. Press the coag Up/Down keys to set the coag power to 80 watts.
5. Test the monopolar2 coag outputs.
6. Press the foot switch coag pedal and note the output on the voltmeter while activating the generator.

7. Release the foot switch pedal.
8. Based on the voltmeter setting and the current transformer you are using calculate and record the output current.
9. Select Press the Fulgurate mode and repeat step 4.
10. Select Press the Spray mode and repeat step 4.
11. Verify that the generator output for each mode is 400 ± 20 mA rms. If the output is outside the specified range, calibrate the monopolar output as described in calibration steps 5. Then repeat this procedure. If the output for one or more coag modes remains outside the specified range, call the Génia USA Service Center.

Verifying PREM Function

Equipment list

- PREM plug
- Resistance decade box, 1 Ω resolution, 1% tolerance, 1/8 W or greater, or 50 Ω and 100 Ω 1% tolerance, non-inductive resistance loads.

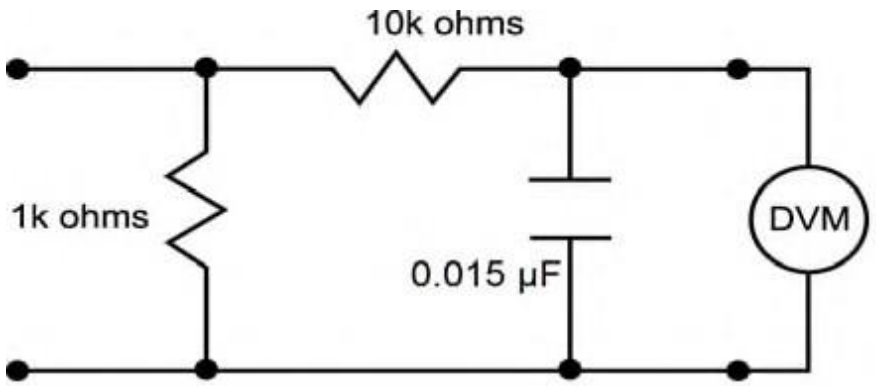
1. Remove the test cable from the Patient (return electrode) socket. Confirm the REM LED indicator light illuminates red.
2. Set the resistance decade box to 100 Ω or select a 100 Ω load. Connect the resistance box to the REM receptacle, and verify that the PREM level bar is within Level 1 to Level 3. Confirm thatthe REM LED indicator light illuminates green.
3. Decrease the resistance to 50 Ω or select a 50 Ω load and verify that the PREM level bar is within Level 4 to Level 6.
4. Decrease the resistance to 0 Ω or short the REM pins together and confirm the REM LED indicator light illuminates red with no level bar.

Checking Low Frequency Leakage Current and Ground Resistance

Check the frequency leakage current and ground resistance before returning the Mano Médical Seal&Cut MV1generator to clinical use.

Equipment

- DVM
- Leakage current tester



1 millivolt = 1 microamp

Output Socket and PREM Source Current

1. Set the DVM to AC volts (200 mV) and connect the leakage current test circuit.
2. Turn on the generator.
3. Measure between all the output sockets (including the PREM Patient Return Electrode socket) and earth ground. Record the largest reading.
4. Determine the leakage current using the conventional 1 microamp per 1 millivolt.
5. Verify under normal conditions (ground closed, normal polarity) the leakage current is less than 10 microamps. If the leakage current is greater than 10 microamps, call the Génia USA Service Centre.
6. Verify single fault conditions (ground open) the leakage current is less than or equal to 50 microamps. If the leakage current is greater than 50 microamps, call the Génia USA Service Center.

Chassis or Earth Leakage

1. Set the DVM to AC volts (200 mV) and connect the leakage current test circuit.
2. Turn on the generator.
3. Measure between the chassis and earth ground.
4. Determine the leakage current using the conventional 1 microamp per 1 millivolt.
5. Verify under normal conditions (ground closed, normal polarity) the leakage current is less than 300 microamps. If the leakage current is greater than 300 microamps, call the Génia USA Service center.
6. Verify single fault conditions (ground open) the leakage current is less than or equal to 1000 microamps. If the leakage current is greater than 1000 microamps, call the Génia USA Service Centre.

Output Socket and PREM Sink Current

1. Set the DVM to AC volts (200 mV) and connect the leakage current test circuit.
2. Turn on the generator (110 or 220 VAC) and connect the end of the leakage current test circuit to main voltage through a 120k Ω resistor.
3. Connect the other side of the INTERNATIONAL ELECTROTECHNICAL COMMISION leakage load to all the output sockets (including the PREM Patient Return Electrode Mode socket).
4. Determine the leakage current using the conventional 1 microamp per 1 mill volt.
5. Verify the leakage current is less than or equal to 50 microamps. If the leakage current is greater than 50 microamps, call the Génia USA Service Center.

Ground Continuity Testing

1. Connect the system to a ground continuity tester or a digital multimeter (DMM).
2. Test between the equipotential ground lug on the rear of the system and the supplied power cord, or directly to the middle ground pin of the inlet receptacle.
3. Initiate the test according to International Electrochemical Commission Standards.
4. Maximum permissible values are 0.3 ohms using a supplied power cord or 0.2 ohm connected directly to the middle pin of the inlet receptacle. If then specifications are not met, contact Génia USA Service Center.

Checking High Frequency Leakage Current

Check the high frequency leakage current and ground resistance before returning the Mano Médical Seal&Cut MV1generator to clinical use. Check the leakage current at these times.

- After calibrating the generator.

Equipment

- 200 Ω, 250 watt, noninductive resistor
- Current transformer
- True RMS voltmeter (Fluke 8920 or equivalent)
- Dual paddle toggle (Bipolar/monopolar) foot switches and hand switching accessories
- Leakage setup per INTERNATIONAL ELECTROTECHNICAL COMMISION 60601-2-2 clause 19.101 or 19.102

Checking Monopolar High Frequency Leakage Current

1. Connect the 200 Ω load from the monopolar active accessory through the current transformer to the equipotential ground plug on the rear of the generator.
2. Connect the current transformer to a true RMS voltmeter.
3. Connect a dual paddle foot switch to the foot switch socket at the rear panel of the generator.
4. Set the foot switch in monopolar mode
5. Activate the foot switch in each monopolar mode at the maximum control setting. Record the leakage current. It should not exceed 150 mA for any mode.
6. If the high frequency leakage exceeds 150 mA, call the Génia USA Service Center for further instructions.

Checking Patient Return High-Frequency Leakage Current

1. Connect the 200 Ω load from the PREM cable through the current transformer to the equipotential ground plug on the rear of the generator.
2. Connect the current transformer to a true RMS voltmeter.
3. Connect a dual paddle foot switch to the foot switch socket at the rear panel of the generator.
4. Set the foot switch in monopolar mode
5. Activate the foot switch in each monopolar mode at the maximum control setting. Record the leakage current. It should not exceed 150 mA for any mode.
6. If the high frequency leakage exceeds 150 mA, call the Génia USA Service Center for further instructions.

Checking Bipolar High Frequency Leakage Current

- Remove the monopolar accessories, and connect the 200 Ω load from one side of the bipolar output through the current transformer to the equipotential ground lug on the rear panel of the generator.
- Connect the current transformer to the true RMS voltmeter.
- Connect a dual paddle foot switch to foot switch socket at the rear panel of the generator.
- Set the foot switch in bipolar mode
- Activate the foot switch in each mode at maximum control setting. Record the leakage current. It should not exceed 60 mA for any mode.
- If the high frequency leakage exceeds 60 mA, call the Génia USA Service Center for further instructions.

CHAPTER 10
Calibration Procedures

Calibrating the Mano Médical Seal&Cut MV1

For normal running Mano Médical Seal&Cut MV1, program requires data constants, which are dependent on the hardware. All this data is stored in NV RAM after the calibration process is completed. Calibration is recommended after:

- Changing CPU or RF main board.

Steps and description:

Step 1 - PREM Calibration
Step 2 -Energy Calibration
A - Close loop current Calibration
B - Close loop voltage Calibration
C - Close loop power Calibration
D - Open loop power Calibration
E - Open loop voltage Calibration

Preparing for Calibration:

Equipment:

- Dual paddle toggle foot switch.
- Small test cables with banana plugs.
- PREM plug modified.
- Resistor substitution box.
- Oscilloscope.
- True RMS current meter.

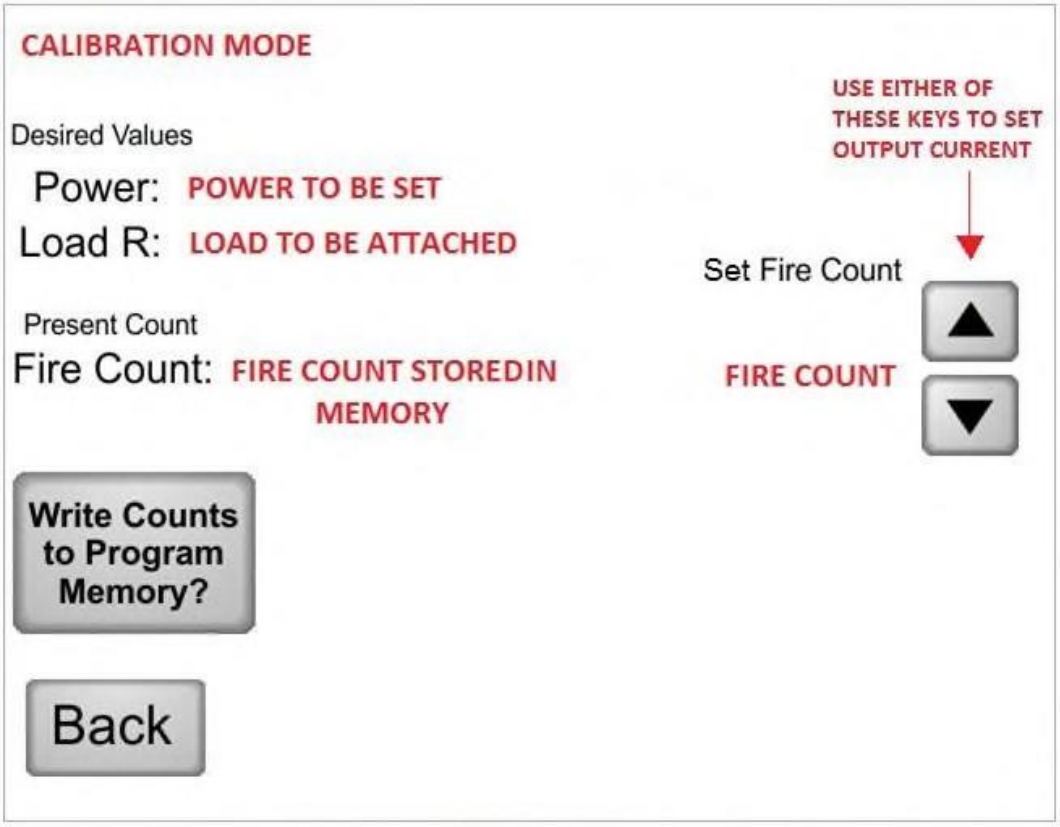
Entering Calibration Mode:

To enter in calibration mode, switch ON Mano Médical Seal&Cut MV1 and Follow following sequence:Setup Key >> Calibration (Enter Unlock key)>> Again Calibration.

Exiting Calibration Mode:

One can exit calibration procedure at any time by pressing back keys on the screen.
Or just restart the generator by turning it off and on.
(For Calibration, follow the guide given below on the next page).

(Calibration Mode Screen)



Calibration Step1 - PREM Calibration

Equipment:

- PREM plug (modified)
- Resistor substitution box

Procedure:

1) Select mode _1:1 REM min'.
2) Connect PREM plug in the PREM socket and connect appropriate substitution resistor as indicated by _Load R', across the PREM socket.
3) Press the Coag pedal switch provided to get the fire count reading. Press _Write counts to store theacquired count.
4) Once the memory write operation is successful press Back key
5) Follow the same Steps (1 to 4) for _1:3 REM Max'

Please Note: Load R is different for both modes.

Calibration Step 2 - Energy Calibration

Mano Médical recommends that only qualified personnel calibrate the VLFT10GEN. Mano Médical defines qualified personnel as someone with experience in electrosurgical equipment repair, such as biomedical personnel, or individuals who have taken official training courses.
During calibration, the user verifies system-specific information and adjusts the information if necessary.

A - Close Loop Current Calibration

Sub step-1(BIP mode)

Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs
  b) True RMS current meter
  c) 50 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 2:1.
b) Resistor substitution box must of 50Ω.

Procedure:

1) **Connect**
   a) One test cable from Bipolar socket in series with RMS current meter to 50 Ω resistor.
   b) One test cable from Bipolar socket to 50 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the I-max for bipolar output.**
   a) Press the coag pedal & check if current reading is equivalent to 1000 mA ± 20 mA RMS.
   b) Stop activation. If the output current is high decrease Fire count by pressing down key. If low, increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from bipolar output.**

Sub step- 2 (Cut Mode)

Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 50 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 2:2.
b) Resistor substitution box must of 50Ω.

Procedure:

1) **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 50 Ω resistor.
   b) Another test cable from PREM socket to 50 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the I-max for Monopolar Cut output.**
   a) Press the cut foot switch pedal & check if current reading is equivalent to 1414 mA ± 20mA RMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.
   e) I-max for Pure Endo & Low modes are adjusted automatically.

3) **Disconnect the test cables from Monopolar output.**

Sub step- 3 (Blend Mode)
Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 50 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 2:3.
b) Resistor substitution box must of 50Ω.

Procedure:

1) **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 50 Ω resistor.
   b) Another test cable from PREM socket to 50 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the I-max for Monopolar Blend output.**
   a) Press the Cut foot switch pedal & check if current reading is equivalent to 1048 mA ± 20mA RMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from Monopolar output.**

B - Close Loop Voltage Calibration

Sub step-1(BIP mode)
Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs
  b) True RMS current meter
  c) 1000 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 3:1.
b) Resistor substitution box must of 1000Ω.

Procedure:

1) **Connect:**
   a) One test cable from Bipolar socket in series with RMS current meter to 1000 Ω resistor.
   b) One test cable from Bipolar socket to 1000 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the V-max for bipolar output.**

   a) Press the coag foot switch pedal & check if current reading is equivalent to 158 mA ± 5mA RMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press _Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from bipolar output.**

Sub step- 2 (Cut Mode)
Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 3000 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 3:2.
b) Resistor substitution box must of 3000Ω.

Procedure:

1. **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 3000 Ω resistor.
   b) Another test cable from PREM socket to 3000 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2. **Check and adjust the V-max for Monopolar Cut output.**
   a) Press the cut foot switch pedal & check if current reading is equivalent to 103 mA ± 5 mARMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.
   e) V-max for Pure Endo & Low modes is adjusted automatically.

3. **Disconnect the test cables from Monopolar output.**

Sub step- 3 (Blend Mode)
Equipment

- Monopolar foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 3000 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 3:3.
b) Resistor substitution box must of 3000Ω.

Procedure:

1) **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 3000 Ω resistor.
   b) Another test cable from PREM socket to 3000 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the V-max for Monopolar Blend output.**
   a) Press the Cut Foot Switch pedal & check if current reading is equivalent to 85 mA ± 5 mA RMS.
   b) Stop activation. If the output current is high, decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from Monopolar output.**

C - Close Loop Power Calibration

Sub step-1 (BIP mode)

Equipment

- Dual paddle toggle Foot Switch.
  a) Small test cables with banana plugs
  b) True RMS current meter
  c) 100 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 4:1.
b) Resistor substitution box must of 100Ω.

Procedure:

1) **Connect:**
   a) One test cable from Bipolar socket in series with RMS current meter to 100 Ω resistor.
   b) One test cable from Bipolar socket to 100 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the P-max for bipolar output.**
   a) Press the coag foot switch pedal & check if current reading is equivalent to 547 mA ± 10 mARMS.
   b) Stop activation. If the output current is high, decrease fire counts by pressing down key. If lowincrease it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from bipolar output.**

Sub step- 2 (Cut Mode)

Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 300 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 4:2.
b) Resistor substitution box must of 300Ω.

Procedure:

1) **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 300 Ω resistor.
   b) Another test cable from PREM socket to 300 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the P-max for Monopolar Cut output.**
   a) Press the cut foot switch pedal & check if current reading is equivalent to 365 mA ± 10 mARMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.
   e) P-max for Pure Endo & Low modes is adjusted automatically.

3) **Disconnect the test cables from Monopolar output.**

Sub step- 3 (Blend Mode)

Equipment

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs & PREM plug.
  b) True RMS current meter
  c) 300 Ω non-inductive power resistor.

Verify:

a) The display shows calibration mode 4:3.
b) Resistor substitution box must of 300Ω.

Procedure:

1) **Connect:**
   a) One test cable from Monopolar socket in series with RMS current meter to 300 Ω resistor.
   b) Another test cable from PREM socket to 500 Ω resistor.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2) **Check and adjust the P-max for Monopolar Blend output.**
   a) Press the Cut foot switch pedal & check if current reading is equivalent to 365 mA ± 10 mARMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.

d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.

3) **Disconnect the test cables from Monopolar output.**

D - Open Loop Power Calibration (Econ)

(Soft/Swift/Fulgar/Spray)

Equipment:

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs
  b) True RMS current meter
  c) 500 Ω non-inductive power resistor.
  d) PREM plug modified.

Verify:

1) Mode displayed on the screen is 5: _x'(x may be 1,2,3,4 as per chosen mode)
2) Resistance of connected resistance substitution box 500Ω

Procedure:

1. **Connect:**
   a) One test cable from socket PREM plug to 500 Ω.
   b) Another test cable from Monopolar socket passes through true RMS current meter to 500Ω.
   c) Dual paddle toggle foot switch to the foot switch socket on the rear panel.

2. **Check and adjust the Econ for Monopolar Soft output.**
   a) Press the coag foot switch pedal and check the current equivalent to 282 mA ± 10 mA RMS.
   b) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory
   .
3. **Disconnect the test cables from Monopolar output.**

Use same equipments & repeat the same procedure for calibrating VPK of different modes (Swift/Fulgr/Spray) by choosing corresponding calibration modes.

Calibration Step 6 - Open Loop Voltage Calibration

(Soft/Swift/Fulgr/Spray)

Equipment:

- Dual paddle toggle foot switch.
  a) Small test cables with banana plugs
  b) True RMS current meter
  c) 5000 Ω non-inductive power resistor.
  d) PREM plug modified.

Verify :

a) Mode displayed on the screen is 6: _x' (x may be 1,2,3,4 as per chosen mode)
b) Resistance of connected resistance substitution box 5000Ω

Procedure:

1) **Connect:**
   a) One test cable from socket PREM plug to 5000 Ω.
   b) Another test cable from Monopolar socket passes through true RMS current meter to 5000Ω.
   c) Monopolar foot switch to the Monopolar foot switch socket on the rear panel.
2) **Check and adjust the Vpk for Monopolar Soft output.**
   a) Press the coag foot switch pedal and check the current equivalent to 56 mA ± 5mA RMS.
   b) Stop activation. If the output current is high decrease fire Counts by pressing down key. If low increase it by pressing up key.
   c) Repeat step (b) until the meter reading is not in the stated range.
   d) When reading is in stated range, press Write Counts for storing corresponding fire count reading in the system memory.
3) **Disconnect the test cables from Monopolar output.**

Use same equipment & repeat the same procedure for calibrating VPK of different modes (Swift/Fulgar/Spray – Measuring current (69 mA ± 5mA RMS) by choosing corresponding calibration modes.

CHAPTER 11
Care, Storage and Disposal

After each use, perform the following cleaning procedures immediately. If cleaning is delayed, debris encrustation may become a source of infection. Encrustation may also result in electrosurgical unit malfunction.

11.1 CARE OF THE UNIT

WARNING
After cleaning the electrosurgical unit, dry it thoroughly before using it again. If it is used when wet, there is the risk of an electric shock.
Usage of Dust Cover on the unit is mandatory.

CAUTION
Never immerse the electrosurgical unit in water, clean or disinfect by immersion, gas sterilization or autoclaving. It may cause equipment damage.
Do not wipe the external surface with hard or abrasive wiping material. This will scratch the surface.
Before sending the accessories for servicing, ensure the sterilization by autoclaving from the user end.

11.2 STORAGE OF THE UNIT

1. Turn the electrosurgical unit OFF and disconnect the power cord from the receptacle (main wall outlet)
2. If the equipment is soiled with blood or other potentially infectious materials, first wipe off all the debris using neutral detergent, then wipe its surface with a lint-free cloth moistened with a surface disinfectant.
3. To remove dust, dirt and non-patient debris, wipe the electrosurgical unit and foot switch using a soft, lint-free cloth moistened with 70% ethyl or isopropyl alcohol.
4. Make sure that the electrosurgical unit and foot switch are completely dry before storage.

WARNING
Do not store these devices in humid and unventilated environment as it may encourage the growth of micro-organisms and pose an infection control risk.

CAUTION
Do not store the electrosurgical unit in a location exposed to direct sunlight, x-ray, radioactivity, liquids or strong electromagnetic radiation (e.g., near microwave medical treatment equipment, short wave medical treatment equipment, MRI equipment, radio or mobile phones). Damage to the electrosurgical unit may result.

Do not apply excessive bending, straining or squeezing force to any cords during storage. It may cause malfunction.

1. Disconnect the power cord
2. Store the equipment at room temperature in a horizontal position in a clean, dry and stable location.

11.3 CARE OF MAINS CABLE

CAUTION
The cable should not be sterilized by EtO gas or autoclaving. These methods will cause deformation and damage that will render the cable useless.

Ensure that foreign matter does not enter the main cord end connection as this will result in poor connection.

1. After each procedure, wipe with a soft, clean, lint-free cloth. If dirt persists, moisten the cloth with 70% ethyl or isopropyl alcohol and wipe again.
2. Dry thoroughly after wiping. A cable that is not completely dry may cause an electric shock.

11.4 STORAGE OF MAINS CABLE

WARNING
Never store the cable in shipping box as this may pose an infection control risk.

1. Store away from direct sunlight and source of liquids.
2. Store the cable with the clamping screw attached.

11.5 DISPOSAL

When disposing of this electrosurgical unit, accessories or any of its components (such as fuses), follow all applicable national and local laws and guidelines.

CHAPTER 12
Trouble Shooting

Trouble shooting

If the generator is not functioning properly, use the information in this section to perform the following tasks:

Identify and correct the malfunction.

If a system alarm number is displayed, take the appropriate action to correct the alarm conditions.

Inspecting the Generator

If the Mano Médical Seal&Cut MV1 generator malfunctions, check for obvious conditions that may have caused the problem:

Check the generator for visible signs of physical damage.

Verify that all accessory cords are properly connected.

Check the power cord. Replace the power cord if you find exposed wires, cracks, frayed insulation, or a damaged connector.

Open the fuse drawer and inspect the fuse housing and fuses for damage and corrosion. Verify that the fuses are firmly seated.

An internal component malfunction in the generator can damage the fuses. You may need to replace the fuses if the generator fails the self-test or stops functioning.

A. CORRECTING MALFUNCTIONS

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct malfunction, verify that the generator completes the self-test.

ESU does not respond when Turned on.	Disconnected power cord, faulty wall socket, or faulty power cord.	Check power cord connections with wall socket and ESU. Connect the power cord to a functional wall socket. If necessary, replace the power cord.
	Fuse drawer is open or fuses are blown.	Close the fuse drawer. If necessary, replace the fuse. If a problem persists, use a backup generator.
	Loose or disconnected internal cables	Check all internal connections. Press the connectors and boards if required.
	Faulty input power filter or connections	Check input power filter and its cable connections.
	Faulty low voltage power supply	Check the low voltage power supply.
	Damaged CPU board connectors and/or malfunctioning CPU board	Remove the CPU board and inspect the connectors to the Power Supply & RF board and to the Display board for damage. Replace the CPU board if required.
	Shorts or disconnects on Power Supply & RF board	Check the Power Supply & RF board for shorts or disconnects.
	Faulty mains ON-OFF switch	Replace the switch.

	`	Replace the front panel assembly.
The generator is on, but did not complete the self-test	An alarm condition exists	Check the display for an alarm number. Note the number and refer to Responding to System Alarms in this section.
	Software malfunction	Turn off and then turn on the generator.
	Loose or disconnected internal cables and/or boards.	Check and correct all internal connections. Press the connectors and boards if required.
	Faulty low voltage power supply	Check the low voltage power supply. If not working properly, replace it.
	Damaged CPU board connectors and/or malfunctioning CPU board	Remove the CPU board and inspect the connectors to the Power Supply & RF board and to the Display board for damage. Replace the CPU board if required.
	Shorts or disconnects on Power Supply & RF board	Check the Power Supply & RF board for shorts or disconnects.
	Faulty mains ON-OFF switch	Replace the switch.
	Malfunctioning front panel components	Replace the front panel assembly.
Activation and/ or alarmtones do notsound, speaker is malfunctioning	Faulty connections or speaker on main Rf board	Replace the speaker
	Audio signal malfunction on Control board	Replace the Control board.
LCD display not turning ON or malfunctioning.		
	Faulty ribbon cable between CPU and LCD Display	Check/connect ribbon cable that connects the LCD Display to the CPU board.
	Incorrect data communicated through the CPU board	Replace the CPU board.
	LCD Display malfunction	Replace the LCD Display.
Front Panel keys do not function correctly when pressed	Faulty ribbon cable between CPU board and Keypad	Check/connect ribbon cable that the keypad to the Control board.
	Incorrect data communicated through the CPU board	Replace the CPU board.
The generator is on and accessory is activated, but generator does not deliver o/p	Malfunctioning foot switch or hand switching instrument	Turn off the generator. Check and connect all accessory connections. Turn on the generator. Replace the accessory if it continues to malfunction. Connect the foot switch & the foot switching instrument to the same instrumentation socket.
	Power set too low	Increase the power setting.

The generator is on and accessory is activated, but generator does not deliver output.	Blown fuse on Main RF board	Check the high voltage power supply fuse (F02) and Replace if necessary.
	CPU board malfunction	If the indicator bar does not illuminate and the tone does not sound, replace the CPU board.
	High voltage power supply malfunction (high voltage is not present during activation)	If high voltage is not present on the Main RF board, troubleshoot the high voltage power supply Check all MOSFET Q01 to Q04, replace with same part no. if require. Check Diodes CR02 to CR05 replace with same part no. if require.
	RF output stage malfunction (high voltage is present during activation)	Troubleshoot the RF output stage as described below on the Power Supply /RF board: verify T_ON pulses at R77, if pulses are present, part no. if required. If T_ON pulses are not present, □ verify T_ON pulses at TP 16, If pulses are not present ,replace the CPU part no. if required.
Foot switch will not activate output	Malfunctioning or damaged foot switch socket	Replace the foot switch board.
	Foot switch activation signal lost on Power Supply & RF board	Replace the Power Supply & RF board.
	Foot switch activation signal lost on CPU board	Replace the CPU board.
Interference with other devices only when generator is activated	Malfunctioning monitor Metal-to-metal sparking	Replace the monitor. Check all connections to the generator, patient return electrode, and accessories.
	High settings used for fulguration	Use lower power settings for fulguration or select the Desiccate mode.
	Loose contact in ground wiring in the operating room	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continuous when the generator is activated, the monitor is responding to radiated frequencies.	Check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the generator is activated and minimizes the potential for an electrosurgical burn at the site of the electrode monitor.

Pacemaker interference	Intermittent connections or metal-to-metal sparking Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker.	Check all connections to the generator. It may be necessary to reprogram the pacemaker. Use bipolar instruments, if possible. If you must use a monopolar instrument, place the patient return electrode as close as possible to the surgical site. Make sure the current path from the surgical site to the patient return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implemented. Always monitor patients with pacemakers during surgery and keep a defibrillator available. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgery is planned on patients with cardiac pacemakers.
	Metal-to-metal sparking	Check all connections to the generator, patient return electrode, and active electrode.
Abnormal neuromuscular stimulation (stop surgery immediately)		
	Can occur during coag	Use a lower power setting for the Fulgurate and Spray modes or select the Desiccate mode.
	Abnormal 50-60 Hz leakage currents	Inside the generator, carefully inspect for the damage that may cause shorting between the AC line voltage and connected patient components.

B. RESPONDING TO ERROR CODES

When a system alarm condition exists, an alarm tone sounds and the display indicates error code number. System will not work till error condition is cleared. Alarm conditions require some action to correct it. Following screen shows the error window.

Note down the error code and type of error and take necessary measures to eliminate as described in the following table.

Error Code No.	Description	Recommended Action
501	Up Key may be Stuck	• Turn OFF and again turn ON the generator. Do not press any Key during self-test. • If the alarm repeats, disconnect all accessories. Check/connect the ribbon cable that connects the Display board to the front panel. Turn OFF and again turn ON the generator. • If the alarm repeats, replace front keypad. If the problem still persists, Call Génia USA Support.
502	Down Key may be Stuck	
503	Enter Key may be Stuck	
504	Left key may be Stuck	
505	Right Key may be Stuck	
601	Hand Switch1/Foot Switch1 Cut pedal may be stuck	• Turn OFF and again turn ON the generator. Do not press any activation during self-test. • If the alarm repeats, disconnect all accessories. Turn OFF and again turn ON the generator. • If the alarm repeats, check the activation request generator circuit.
602	Hand Switch1/Foot Switch1 Coagulation pedal may be stuck	
603	Foot Switch 2 Cut pedal may be stuck.	
604	Foot Switch 2 Coagulation pedal may be stuck.	
606	Toggle switch may be stuck	If the problem still persists, Call Génia USA Support

Warranty

Mano Médical warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period.

Mano Médical'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 company's satisfaction, that the product is defective.

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

The warranty periods for *Mano Médical* products are as follows:

Electrosurgical Generators:	One year from date of shipment
Foot switches:	One year from date of shipment
Semi-disposable instruments:	3 months from the date of shipment

Please Note: Warranty on accessories is subject to manufacturing defect before usage only.

Please Note: Mano Médical will not be liable to pay/fund any sort of penalty/due other than the aggregate purchase price of goods sold by Mano Médical, in case of any damage/injury occurs to patient/ surgeon and/or any entity.

Mano Médical neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of *Mano Médical* products.

Mano Médical reserves 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.

Disclaimer

1) Electrosurgery has been proven in surgical applications for more than 60 years. If safety instructions are not followed/ implemented, operating this equipment can be hazerdous. Risk associated with the product/procedure cannot be denied, if not used as per the user safety instructions provided in the User Instruction Manual.

2) The equipment must be used only by qualified, trained & licensed surgeon/physician.

3) Optimized & safe usage of equipment is warranted only if manufacturer's approved accessories are used along with the equipment during surgery. Company will not be responsible for any damage/injuries/complications caused to user or patient due to the use of unsafe, non-approved electrosurgical accessories.

4) Company is not responsible for any damage/ complications to patient or user due to use any equipment which has not been maintained & calibrated periodically as described in user/instruction manual.

5) The equipment maintenance has to be done by a Company trained & qualified technician/engineer. Company is not responsible for any kind of losses to equipment/ patient caused by the user due to the incorrect operation/ maintenance of the equipment by an unauthorized/ untrained person.

6) Consumables/ accessories must be used as per the instructions given in the accompanying documents. Use of expired or re-used accessories beyond the lifecycle may lead to injury/damage/complication to patient or user. Company will not be responsible for such injury/damage/complications.

7) The equipment's warranty is in lieu of all other warranties, expressed or implied, including without limitations, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of the Company. Company neither assumes nor authorizes any other person to assume for any other liability in connection with the sale or use of any of the Company products.

8) Notwithstanding any other provision herein or in any other document or communication, Company's liability of products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Company to the customer. There are no warranties which extend beyond the terms hereof. Company disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

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