

# Shalya Vista

## **INSTRUCTION & SERVICE MANUAL**

This document is a user guide for Shalya Vista Electrosurgical unit. Guide is intended to be referred by qualified & trained physician and surgeon. This instrument is electrically hazardous, user operating this generator / consulted technician for servicing should read this user manual 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 Shalya Vista ESU in this document are: Generator, ESU, Machine, and Vista.

**Use for:** This document is drafted by taking **Shalya Vista/Vista+ ESU** into account only, which is a product of XcelLance Medical Technologies Pvt. Ltd.

**Shalya Vista:** VSE, VSE (+), VE, VE (+), VS, SE, SE (+), V, E, E (+), S

**Registered Trademarks:**

Shalya®, Turoseal®, VesSeal®



CE  
1639

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## Conventions and Symbols used in this document

Symbol	Meaning
	<b>General warning sign</b> Explains the possible damage which may occur to the machine OR minor injuries to person.
	<b>Electrical Hazard</b> Explains the possible risk associated with personal injury or death.
	<b>Prohibition Sign</b> Explains actions by which the possible damage which may occur to instruments associated with machine and/or others so, should be prohibited.
	<b>Pushing Prohibition</b>
	<b>Sitting Prohibition</b>
	<b>Stepping Prohibition</b>
	<b>General mandatory action to be taken by user</b>
	<b>Refer Manual or Booklet</b>

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# CHAPTER 1

## Introduction

**Shalya Vista** Electrosurgical Generator – the product of *XcelLance Medical Technologies Pvt. Ltd.* provides necessary High Frequency electrical power for different types of surgical needs in advance Medical Technologies. Vessel Sealing, Saline Resection with conventional Monopolar and Bipolar Electrosurgical applications with multiple options of effects with following features:

### A. GENERAL FEATURES

#### Combo Electrosurgical Unit with following features:

- ❑ **Touch Screen LCD Interface:** 5.6” Resistive Touch Screen for user-friendly interface with on-screen modes description facilitating surgeon to choose the best-suitable mode for the surgical applications.
- ❑ **COMBO Generator Technology:** Vessel Sealing System, Saline Plasma Bipolar Resection, High Performance ESU (Diathermy) in Single Unit.
- ❑ **Smart Unit:** Surgical Monitoring and Automatic & Instant Response Technology ESU for consistent cutting & coagulation through all types of tissue.
- ❑ **6SENSE Technology:** Advance Microprocessor controlled Digital tissue impedance feedback system with sense the change in Voltage, Current, Power, Tissue Density, Return Electrode Contact quality & leakage RF current.
- ❑ **Fully Microprocessor controlled:** To achieve high degree of clinical precision.

#### SECTION 1: Electrosurgery Section:

- ❑ **PREM Safety (Patient return electrode monitoring)** – PREM – is ultimate Safety for return electrode site burns.
- ❑ **Surgical Assistant:** 500 Customizable User Programs. Recall function for fast preprogrammed case settings.
- ❑ **Bipolar/BiCoag Alarm:** Provides Audio feedback alarm after completion of Bipolar Coagulation. This reduces charring & sticking of tissue to forceps & avoids over burning of tissue. User can chose Auto BiCoag or BiCoag Alarm as per convenience.
- ❑ **Bipolar Cut:** Macro mode can be effectively used for bipolar cutting with hooks & other cutting devices in laparoscopic surgery.
- ❑ **ARGON Beam Coagulator** upgradeable.
- ❑ **Smart ENDOCUT Mode:** Pulse current for papillotomy & polypectomy Applications as option
- ❑ **Hydro Cut/ Coag:** - Helps effective cutting & Co-agulation under fluids/water.

#### SECTION 2: Vessel Sealing System:

- ❑ **Ves seal Technology** is recent innovation in field of advance feedback controlled Electro surgical Technology. System senses the tissue hold in instrument & appropriate amount of energy is delivered by continually sensing the tissue density to form the permanent seal.
- ❑ **Cool Seal** technology to seal the tissue vessel by applying calibrated pressure with RF energy. The Collagen & Elastin within the tissue in vessel walls melts & restructure to form a seal. The seal tissue appears translucent in nature & having plastic resistance property.
- ❑ Auto Stops the energy delivery with audio indication at completion of sealing.
- ❑ Tissue ReHold alarm is given if improper grasping of tissue.
- ❑ Bipolar Cut & Coag with independent Display setting with independent foot-switches.

### SECTION 3: Saline Plasma Bipolar Resection

- ❑ Electrode Disconnection / Non Saline activation Alarm.
- ❑ Regular loops can be used for saline work, hence reduces working cost.
- ❑ Regular Working Element can be used for bipolar work.

## B. MODES OF ELECTROSURGERY

### 1. Monopolar Electrosurgery:

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

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

- **Low Cut** - It is used for a cut with no sparking, useful for precise and clean cutting for thin tissue.
- **Pure** - This is the default Monopolar cut mode it may be used for precise cut with no hemostasis.
- **Blend 1** - It is used where slower cutting & moderate hemostasis is desired.
- **Blend 2** - It is used where slower cutting & extra hemostasis is desired.
- **Endo-1 Cut** - It is used for a cut with pauses & moderate pulse interval control.
- **Endo-2 Cut** - It is used for a cut with pauses & large pulse interval control.
- **Hydro Cut** - It is used for efficient cutting under bodily fluids/water.

**Monopolar Coag Modes:** There are SEVEN Coag modes-

- **Soft** - Soft coagulation with deep tissue necrosis.
- **Swift** - Low voltage non-contact coagulation
- **Desiccate** - Coagulation for soft and delicate tissues.
- **Fulgurate** - This mode is suitable for long remote/non-contact coagulation with moderate sparking in variety of application. This mode can be selected separately as and when required.
- **Spray** - This mode is suitable for long remote/non-contact coagulation with moderate coverage.
- **Hi-Spray** - Non-touch long distance coagulation with larger coverage area.
- **Hydro-Coag** - It is used for efficient coagulation under bodily fluids/water.

### 2. Bipolar Electrosurgery:

In Bipolar electrosurgery, both the 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 flows 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 Modes:** Bipolar Electrosurgery contains FIVE types of modes-

- **Micro** - The voltage is kept low to avoid sparking. It is selected for fine bipolar tissue desiccation.
- **Standard** - Standard bipolar coagulation for all type of tissue with moderate hemostatis.
- **Force** - Bipolar coagulation for thicker & high impedance tissue.
- **Macro** - Voltage in this mode is higher than other bipolar modes.
- **Bicut** - Comparatively low voltage Precious & clean bipolar cutting.

### 3. Vessel Sealing System:

In Vessel Sealing System, both the active & return electrodes are in surgical site as in bipolar. Patient return electrode is not required as Vessel Sealing instrument contains an active electrode & return electrode. Tissue vessel is sealed by applying calibrated pressure with RF energy through tissue grasped by the instrument. The Collagen & Elastin within the tissue in vessel walls melts & restructure to form a seal. The seal tissue appears translucent in nature & having plastic resistance property. This advance technique is mostly used in surgeries where larger blood vessel tissue to cut.

#### Sealer:

##### Two sealer modes:

- **Fine Seal** – Effective for delicate and thin tissue vessel sealing. (Sealing Instrument diameter less than 5mm)
- **Rapid Seal** – Effective for standard vessel sealing and fusion. (Instrument diameter between 5mm-10mm)

### 4. Saline Plasma Bipolar Resection:

In Saline Plasma Bipolar electrosurgery, both the active & return electrodes are in surgical site as in bipolar. Patient return electrode is not required as Saline plasma bipolar instrument contains an active electrode & return electrode.

The generator produces a high initial voltage spike that establishes spark in a gap between the bipolar electrodes under saline. When the activated bipolar electrode is not in contact with the tissue, the electrolyte solution in the bladder dissipates it. When the loop is sufficiently close to tissue, the high bipolar voltage spike arc between the electrodes converts the conductive sodium chloride solution into a non-equilibrium vapor layer or 'plasma' containing energy-charged sodium particles. Once formed, this plasma can be maintained at lower voltages.

With tissue contact, there is disintegration of tissue via molecular dissociation as the current flows to the nearby return electrode. Energetic species of the charged ions from the plasma result in disruption of carbon-carbon and carbon-nitrogen bonds. There is also electron impact dissociation of water molecules into excited fragments of H<sup>+</sup> and OH<sup>-</sup> ions. Bottom line is rupture of cell membranes which translates into visible cutting.

#### Saline Resection:

##### Bipolar Saline Cut:

- **Saline Cut 1** – Low intensity saline plasma cut for delicate tissues.
- **Saline Cut 2** – Medium intensity saline plasma cut for delicate tissue.
- **Saline Cut 3** – Saline plasma cut for Resection / vaporization.

##### Bipolar Saline Coag:

- **Saline Soft Coag** – Low intensity saline plasma Coag for delicate tissues.
- **Saline Standard Coag** – Medium intensity plasma coag for optimum coagulation.
- **Saline Force Coag** – Saline plasma coag for Resection / vaporization.

## C. DERIVATIVES OF SHALYA VISTA

Shalya Vista unit comes with a number of options (derivatives) to choose from which have been listed below.

Sr. No.	Derivatives	Vessel Sealer	Saline	Electrosurgery	(+) (Monopolar 1 & Monopolar 2)
1.	Shalya Vista VSE	✓	✓	✓	-
2.	Shalya Vista VSE (+)	✓	✓	✓	✓
3.	Shalya Vista SE	-	✓	✓	-
4.	Shalya Vista SE (+)	-	✓	✓	✓
5.	Shalya Vista VS	✓	✓	-	-
6.	Shalya Vista V	✓	-	-	-
7.	Shalya Vista S	-	✓	-	-
8.	Shalya Vista E	-	-	✓	-
9.	Shalya Vista E (+)	-	-	✓	✓
10.	Shalya Vista VE	✓	-	✓	-
11.	Shalya Vista VE(+)	✓	-	✓	✓

**Note:** The Instruction Manual takes into consideration all the features in Shalya Vista & its Variants, but the user should consider only the features meant for their specific Shalya Vista variant in use.



## CHAPTER 2

# Safety Instructions

***Read all the warnings, 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 and internal cardiac defibrillator or any kind of orthopedic implant, consult the pacemaker, defibrillator & orthopedic implant manufacturer for instructions before performing an electrosurgical procedure. Maintain adequate distance between these implants and 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, patient should not touch any metal parts that are connected to earth/floor/ground. Take excessive precaution 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, footswitches provided by XcelLance Medical Technologies Pvt. Ltd. only.
- In case of any doubt or query contact XcelLance Medical Technologies Pvt. Ltd.
- Avoid use of needle like monitoring equipment on patient wherever possible.



### Electrode & Instruments:

#### Warnings-

- Always ensure that instrument & electrode is properly cleaned and dried before attaching to the generator.
- Keep the cables of electrodes as distant as possible from patient 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 other instrument, an unintended tissue injury may occur.
- Do not wrap instrument cables around and/or bring in 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 cords it may turn out harmful for patient and/or surgeon.

**Cautions:**

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

**Monopolar****Warnings-**

- Do not connect more than one instrument at a time into a given socket.
- Using PREM electrode plates other than XcelLance Medical Technologies Pvt. Ltd may malfunction generator and will turn out to be hazardous for patient.
- Always ensure proper connection of PREM electrode with the patient's skin; do not apply any solution which dehydrates the skin of a patient where PREM is to be connected.
- To avoid the electrosurgical burns beneath the patient return electrode, it is necessary to follow all directions on the product package for proper return electrode placement & use. Place Patient Return Electrode as close as possible to the surgical site.

**Cautions:**

- Use Patient Return Electrode for Monopolar modes only.
- Using a patient return electrode without the PREM Safety feature, will not activate the PREM Contact Quality Monitoring System.

**Hemostat Buzzing:-****Warnings-**

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



## Bipolar

### Cautions:

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



### Warnings:

- During Auto Bipolar mode, 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.

## Vessel Sealing

### Warnings-

- Make use of appropriate footswitch for vessel sealing operation; perform manual settings when using single paddle footswitch.
- 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 the 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 vessel instrument is necessary before use. If any kind of insulation failure or damages of instrument or improper assembly of instrument occurs, do not use it on the patient as this could be dangerous for Operator and the Patient.
- Vessel sealing devices will not work in blood reach environment; get the tissue clean before sealing.
- Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting to blood loss during surgery.



### Cautions:

- Use vessel sealing accessories provided by XcelLance Medical Technologies only. Making use of other instrument 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 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 complete. Use sterile water in case of requirement.
- Do not reuse single time use instruments.
- Do not use ultrasonic cleaners at high amplitudes. Product damage may otherwise result.



## Saline Resection

### Warnings-

- Use continuous irrigation for better results.
- Do not use nonstandard saline solution.
- Use minimum possible power setting to avoid operator nerve reflection.
- Do not activate the generator without firmly engaging the loop with the tissue.
- Do not use nonconductive irrigation liquid, it may lead to alternate site injuries.



## Electrical Connections & Power:

### Warnings-

- Make use of a dry cheesecloth between patient and ground body.
- Inspect electrode connections and contacts frequently.
- Check all the power settings & each and every connection to the generator before using the device on patient.
- Check if the earthing of power source in surgical room is proper. 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 mains 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 proper setting is unknown, set the generator at a very low setting & increase the power continuously until the desired effect is achieved.
- Take faults of the circuitry into consideration any time the surgeon continues to request 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, shocks & burns to the surgical site.



### Cautions:

- Never use power plug adaptors.
- Avoid the use of “extension cord” for the mains power supply.
- Do not plug in or unplug power cord when mains 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 electrode causes 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 re-sterilize 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 distant 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) it leads 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 a 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 *XcelLance Medical Technologies Pvt. Ltd.* service department.
- Always perform cleaning operation of the generator after surgery; disconnect all the electrical connections and accessories before cleaning the generator.
- In case if a patient is moved from one place to another recheck all the connections, as the proper contact of electrode cable with the generator is necessary.
- During procedures in small surgical field, accidental and unintended burn injury may occur.
- Shave off body hairs coming in contact with surgical site whenever 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.
- 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 a 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.





## CHAPTER 3

# Controls, Indicators & Output Sockets

### A. Front Panel

#### Keypad:

This is adjunct to LCD touchscreen input.

**Arrow keys:** to select modes on the menu & to increase and/or decrease the power.

**Enter key:** to confirm any mode and setting.

#### Saline Resection/Bipolar Socket:

Accepts standard 4mm Bipolar/Saline Resection interface cables. Active HF cord in one hole & return HF cord from lure lock adapter in other hole or standard two pin bipolar resectoscope cable in Saline Resection mode.

#### Sealer Electrode Socket:

Accepts standard two pins 4mm sealer interface cable & hand switching cable for sealer.

Open & Lapro sealing cables can be connected.



#### Power ON/OFF switch:

To turn the generator ON/ OFF.

#### Touch Screen LCD:

Touch screen LCD for user friendly interface.

#### Monopolar Electrode Socket 1 & 2:

This accepts Single pin footswitching or 3-pins Hand switching Electrode cable.

Monopolar socket-2 is only provided when the request is made for such Vista variant.

#### Patient Return Electrode Socket:

This accepts PREM/ Non-PREM electrode sockets.

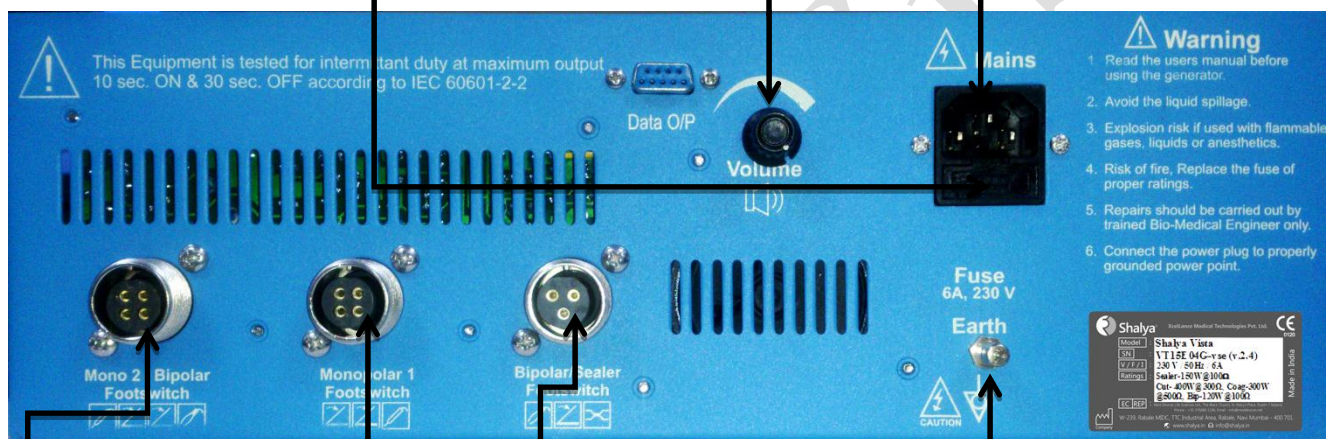
### B. Rear Panel

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

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

**Volume Control:**  
 For adjusting volume of activation tones  
**Please Note:** Alarm Volumes are not adjustable

**Speaker:**  
 Alarm speaker aperture



**Monopolar 2 / Bipolar Footswitch (double paddle footswitch):**

- ESU Mode: Sealer & Bipolar (For single monopolar variants)
- OR
- ESU Mode: (Sealer & Bipolar) / (Monopolar 2 Cut & Coagulation) depending on the selection on the main screen. (For dual monopolar variants)

**Bipolar/Sealer Footswitch: (single paddle footswitch)**

- ESU Mode: Sealer / Bipolar depending on the selection on the main screen.
- Ves seal Sealer Mode: Sealer

**Note:** Saline Resection will not work with this input.

**Equipotential Grounding Lug:**

To connect the generator to earth ground

**Monopolar1 Footswitch (double paddle footswitch):**

- ESU Mode: Monopolar Cut & Coagulation.
- Ves seal Sealer Mode: Bipolar Cut & Coagulation.
- Saline Resection Mode: Saline Cut & Coagulation

**Note:** This manual is common for both 110V/230V mains power supply.

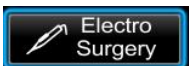
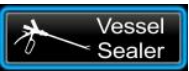


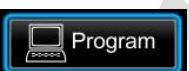
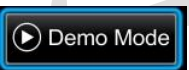

For technical specification, refer Chap 4: Technical Specification; Section: Input Power.

## C. Main Screen



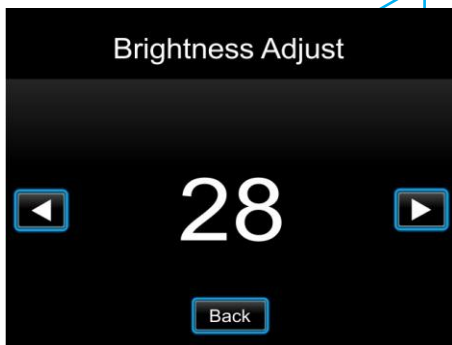
**Screen1** is the main menu screen appears once Shalya Vista has turned ON/ restarted. Touch interface and easily accessible menu makes it very user friendly. Details of symbols on the screen are given below.


**SCREEN 1**

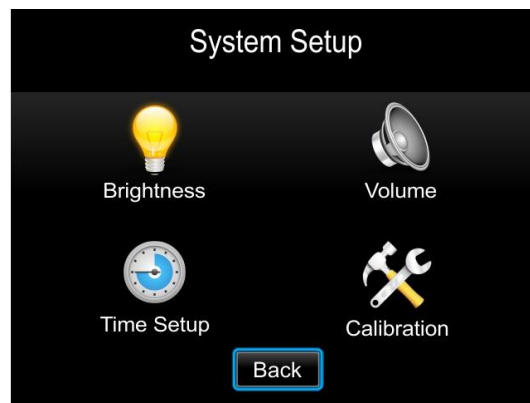
Symbols	Description
	<ul style="list-style-type: none"> <li>Every symbol on the left side forms an individual touch button.</li> <li>Touching on any of the touch button will open up the corresponding menu screen.</li> </ul>
	
	
	<ul style="list-style-type: none"> <li><b>Recall function calls up the previously used settings.</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>Program function can be used to store frequently used settings, facilitating user to store up to approx. 50+ user programs.</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>Demonstration mode.</b></li> <li><b>This mode is only provided on request. Otherwise it is provided as a deactivated option in the unit.</b></li> </ul>
	<ul style="list-style-type: none"> <li><b>Setup Function facilitates user to change system settings.</b></li> </ul>

*Please Note: Details of the modes above are explained below.*

Touch buttons to increase and/or decrease the brightness.



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



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

**Cal Default**

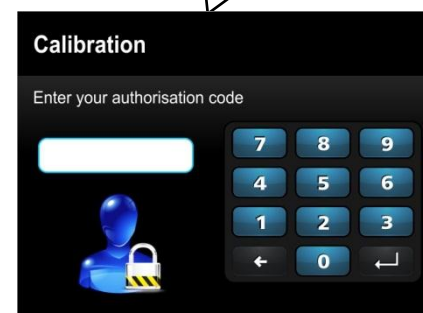
To load the default Calibration Counts.

**Test Mode**

Test mode shows the functionality of Input/output interfaces.

**Calibration**

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



## D. How to select Power &

## Mode?

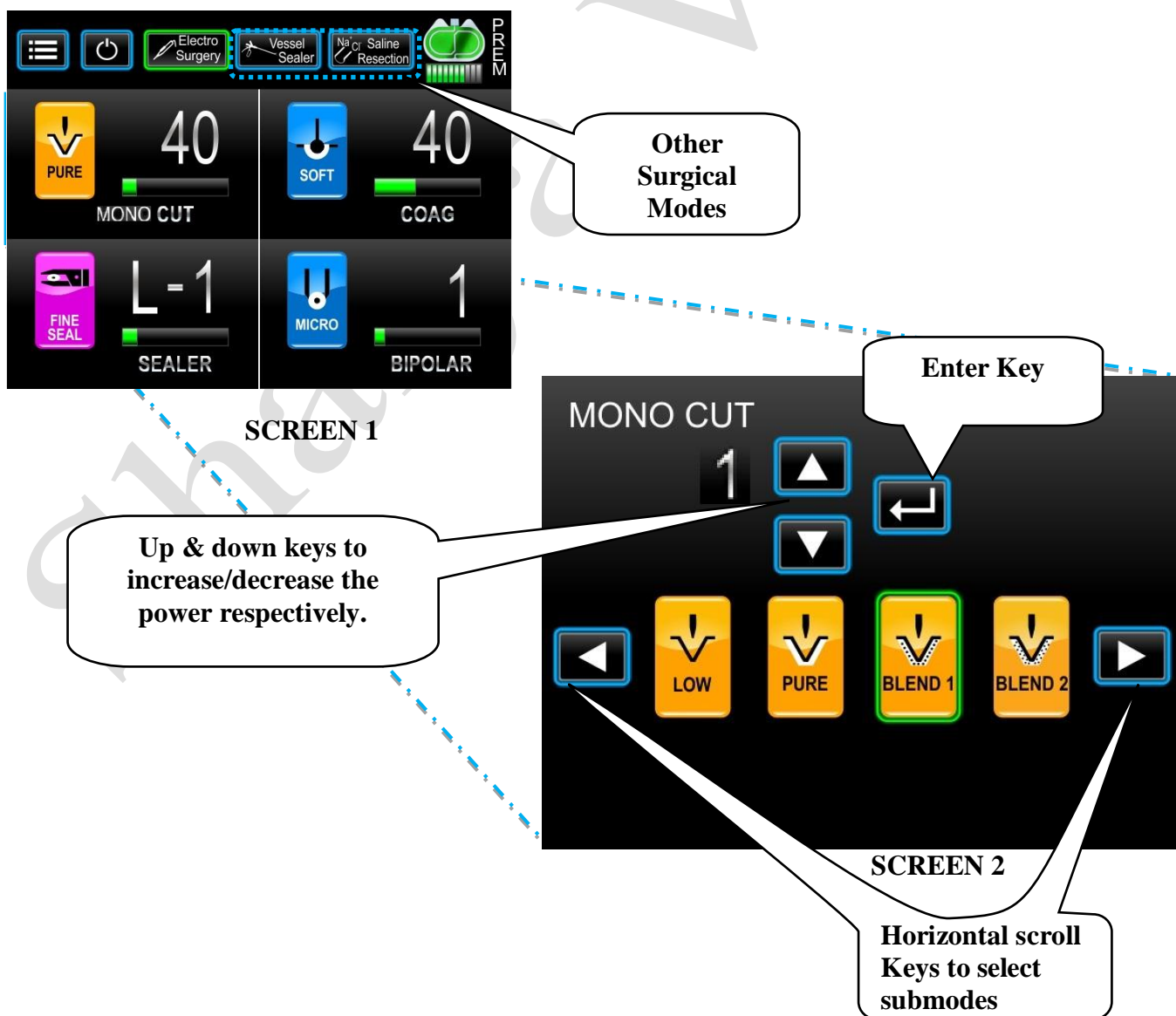
**STEP 1:-** Enter the desired surgical mode (Electro-surgery, Vessel Seal, and Saline Resection).

**STEP2:-** Select desired procedural mode just by touching relevant icon or by using Front panel Keyboard. There are four modes under *Electrosurgery* namely Monopolar Cut, Monopolar Coagulation, Sealer and Bipolar.

**STEP3:-** Enter the desired mode just by touching its icon as shown in **SCREEN 1 & 2**. Select sub-modes using Touch Selective Icons (**SCREEN2**).

**STEP4:-** Once desired sub-mode (procedure) is selected, increase/decrease the power using on-screen or front panel keypad's up/down arrow keys to.


**STEP5:-** Now once power is selected for the desired sub-mode (procedure) press Enter Key (On-screen or Keypad). Pressing appropriate foot paddle or Handswitch will make power available on relevant port. Follow the same procedure to select modes in different surgical modes viz. (Vesseeal Sealer & Saline Resection).



## E. How to set Auto Bipolar Mode?


(Only available in Vista-e Variant & optional in other Vista variants)

Select the Bipolar mode in the electrosurgery window shown in screen 1 above.

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

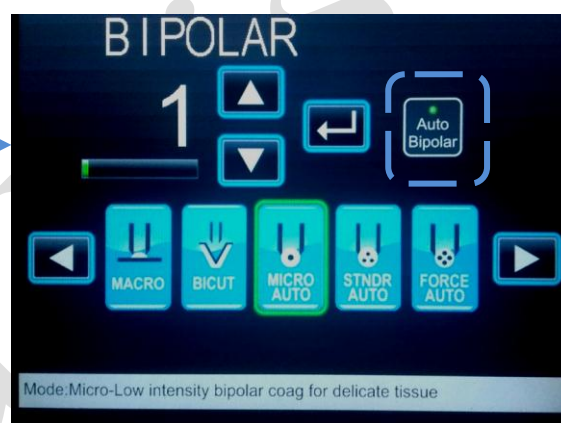
**STEP 2:-** Select sub-modes using horizontal scroll keys (Refer **Screen 3**).

**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  icon.



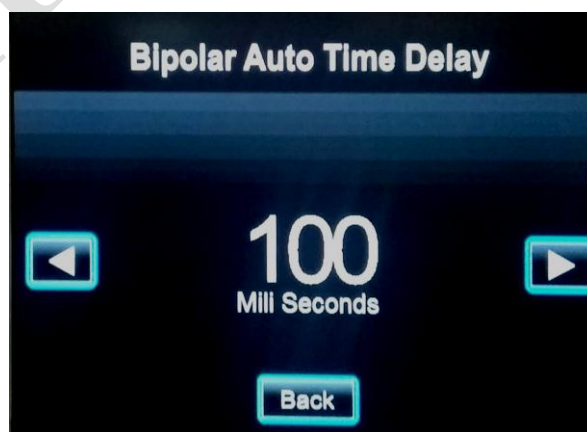
Screen 3



Screen 4

### Note:

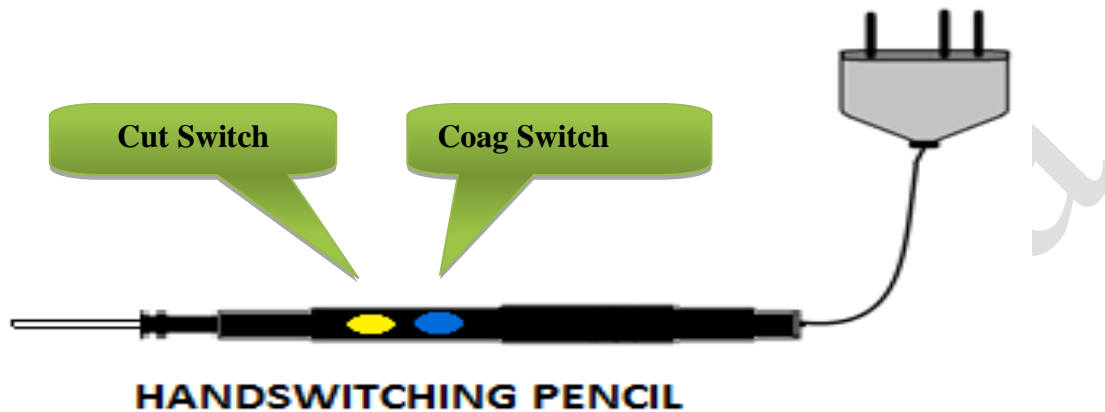
- The Auto bipolar activation delay can be set as shown in **Screen 5** by selecting the “Time Setup” tab in the “Setup” option of the main screen. (Refer Section C. Main Screen).
- Also the Time setup acts as a deactivated option in units with no auto-bipolar function since it is only used for setting the Auto bipolar activation delay & time out function.



Screen 5

## F. How To Select Power Using Handswitching Pencil?(OPTIONAL)

Shalya Vista provides remote control using handswitching electrodes. This facilitates quick remote access to manipulation of settings for very recently activated mode, during surgery.



During normal Monopolar operation, Handswitching 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 coagulation output.

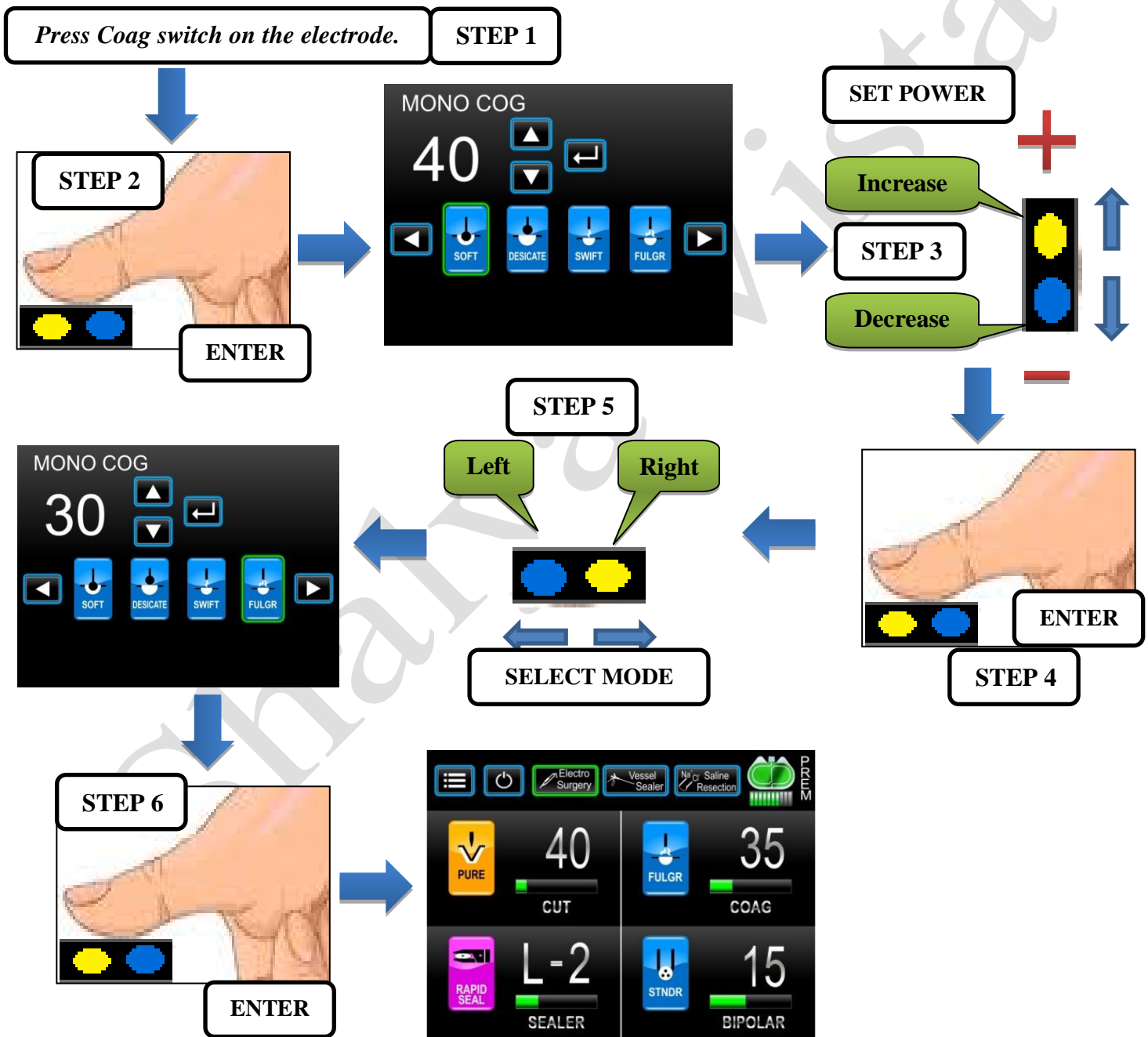
The Steps to use the handswitching pencil have been described with proper screen images in the next page.



Let's assume if recently activated mode was **Monopolar Cut Pure** at power setting of **40Watts**.

Now if surgeon wants to change it to new mode: **Monopolar Coag Fulgar** at power settings of **30Watts**.

**FOR ENTER: Press Cut and Coag buttons simultaneously.**







## G. Programming The Generator



**SCREEN 1**

- Program function gives facility to edit, load & store custom user programs.
- User can load any program just by touching on its name and by pressing 'Load' button.
- Use up/down arrow keys to scroll through programs.
- New Program can be added by touching 'Add New' tab on the screen. After pressing, screen 2 will be displayed on the screen.
- To add new program follow the steps below.
- Follow the same procedure for editing preset programs. Select program and press 'Edit'.

**STEP1:-** Enter Program name, surgeon name. Choose desired surgical mode from Electrosurgery, Vessel Sealer or Saline Resection & Press **Set Power** tab (see **SCREEN2**).

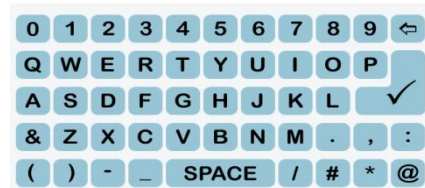
**STEP2:-** Now, Enter desired mode & set appropriate power. User can set power for multiple surgical procedures & surgical modes as shown in the **SCREEN3**.

**STEP3:-** Once the power and procedures & modes are selected press 'Set Power' tab (**SCREEN3**).

**STEP4:-** Once done press 'Save & Back'. (**SCREEN2**).

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

Input Text:

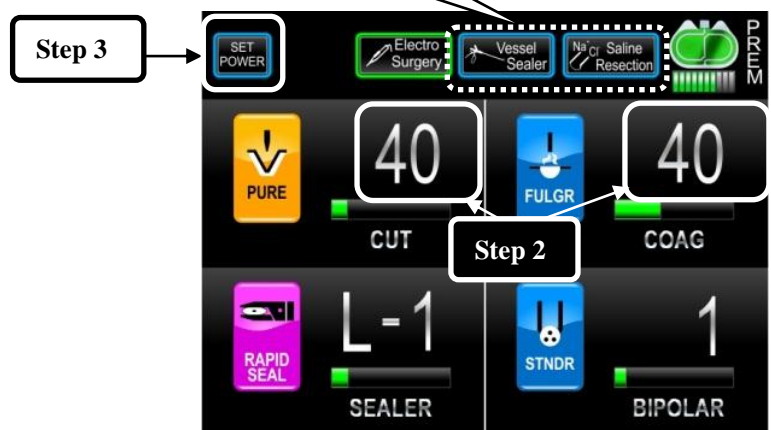


Enter name of surgical-procedure for which setting is to be stored.



**SCREEN2**

User can set powers of multiple surgical modes.



**SCREEN 3**

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

## Stand-by Mode

Pressing the stand-by option will disable any inputs to and outputs from the generator. Generator will not respond to any sort of activation in standby mode. Generator will show **the following 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 6



## CHAPTER 4

# Technical Specifications

### A. GENERAL SPECIFICATIONS

**General Output Configuration:** Isolated output with cardiac defibrillator protection.

**Duty Cycle of Operation:** At maximum rated load conditions, pure cut-400 watt setting at 300  $\Omega$  s, The system is suitable for activation time of 10 seconds ON, 30 seconds OFF for one hour.

**Cooling:** *Forced:* By temperature controlled fan airflow towards bottom.

*Natural by Convection:* By side and rear panel vents.

**Display:** 5.6" 800x480 LCD-Touch Screen Display

### Standards and IEC 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 (IEC 60601-1)

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

### Type CF Equipment (IEC 60601-1)



Maximum allowable leakage current limit is as per established standard; Shalya Vista provides a high degree of protection against electric shock. Instrument can be used for cardiac procedures due to type CF isolated (floating) output.

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

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

### IP Class Specification

IP Class of this equipment is rated at IP20 as per IEC Standard 60529.

### Electromagnetic Interference (IEC 60601-1-2)

When proper mains are connected, generator operates without interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

**Caution** Do not stack equipment upon Shalya Vista or place the generator on top of other electrical equipment. This configuration does not allow proper cooling.

**Caution** Do not place any chemical or solution in operating room, may spoil safety of electronic circuit by liquid spillage.



### Electromagnetic compatibility (IEC 60601-1-2)

The Shalya fulfills the specifications regarding electromagnetic compatibility.

### Voltage Transients (Emergency Generator Mains Transfer)

The Shalya Vista operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

### Defibrillator Proof

The Shalya Vista meets specifications for “defibrillator proof” design.

### Dimensions and Weight

Length: 42.5 cm

Width: 35.5 cm

Height: 15.5 cm

Weight: < 7.5 kg

### Transport and Storage

Temperature range: - 40° 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

EEPROM store all the user data & settings.

### Audio Volume

**Activation Tone:** Volume (adjustable): 40 to 65 dB  
 Frequency: Bipolar/Sealer: 455Hz  $\pm 5\%$   
 Cut: 580Hz  $\pm 5\%$   
 Coag: 865Hz  $\pm 5\%$

**Alarm Tone:** Volume (not adjustable): 65 dB  
 Frequency: 865Hz  $\pm 5\%$   
 Pulse: Two 800msec.coag tone separated by 800msec.of silence

- **PREM Contact Quality Monitor**

- Measurement frequency: 80 kHz  $\pm 10$  kHz
- Measurement current: <10 $\mu$ A
- Acceptable Resistance Range upto 40%

- Dual Area PREM return electrode: 5 to 135  $\Omega$  s
- Single Area Patient return electrode: 0 to 10  $\Omega$  s
- **Low Frequency (50 - 60 Hz) Leakage Current:**
  - Source current, patient leads, all outputs:
  - Normal polarity, intact ground: <10 $\mu$ A
  - Normal polarity, ground open: <50  $\mu$ A
  - Reverse polarity, ground open: <50 $\mu$ A
  - Enclosure source current, ground open: <300 $\mu$ A
- **High Frequency (RF) Leakage Current**
  - Monopolar (RF) leakage current: < 150 mA RMS
  - Bipolar RF leakage current: < 60 mA RMS

**Input Power**

Mains nominal voltage:	230 V	110 V
Input mains voltage, full regulation range:	210-260 Vac	104-132 Vac
Input mains voltage, operating range:	180-260 Vac	85-135Vac
Mains current (maximum):	Idle: 0.2 A	Idle: 0.4 A
	Cut: 3 A	Cut: 6 A
	Bipolar: 1.6 A	Bipolar :3.2 A
	Coag: 2.5 A	Coag: 5A
Maximum VA at nominal line voltage:	Idle: 52 VA	Idle: 52 VA
	Cut:792 VA	Cut:792 VA
	Bipolar: 422 VA	Bipolar: 422 VA
	Coag: 660 VA	Coag: 660 VA
Mains line frequency range (nominal):	50 to 60 Hz	50 to 60 Hz
Fusing:	6A	10A

**B. AVAILABLE POWER SETTINGS (in Watts)****Bipolar (All modes):**

1 to 40 by step of 1, 40 to 70 by step of 5, 100 to 120 by step of 10

**Monopolar Cut: Pure / Endo-1/Endo-2/Hydro**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 400 by step of 10.

**Monopolar Cut: Low**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 300 by step of 10.

**Monopolar Cut: Blend 1**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 250 by step of 10.

**Monopolar Cut: Blend 2**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 200 by step of 10.

**Monopolar Coag: Soft**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 300 by step of 10.

**Monopolar Coag: Desiccate**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 200 by step of 10.

**Monopolar Coag: Swift/Fulgar/Spray/Hydro**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 120 by step of 10.

**Monopolar Coag: Hi-Spray**

1 to 40 by step of 1, 40 to 70 by step of 10.

**Sealer:****Vesseal Sealer: Fine /Rapid**

L1-80W

L2-100W

L3-120W

L4-135W

L5-150W

**Saline Resection: Cut I/ Cut II/ Cut III**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 300 by step of 10.

**Saline Resection: Soft/Standard/Force**

1 to 40 by step of 1, 40 to 100 by step of 5, 100 to 200 by step of 10.

**C. OUTPUT CHARACTERISTICS**

Maximum Output for Bipolar and Monopolar Modes

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

Mode	Open Circuit P-P Voltage (in Volts)	Rated Load (max)	Power (max) (in Watts)	Crest Factor - (Load)
<b>Monopolar Cut</b>				<b>Load-300 Ω</b>
Low	1300	300 Ω	300	1.5
Pure	1700	300 Ω	400	1.5
Blend 1	2000	300 Ω	250	2
Blend 2	2300	300 Ω	200	2.6
Endo 1	1700	300 Ω	400	1.5
Endo 2	1700	300 Ω	400	1.5
Hydro	1700	300 Ω	400	1.5
<b>Monopolar Coag</b>				<b>Load-500 Ω</b>
Soft	1300	300 Ω	300	1.5
Desiccate	4000	500 Ω	200	5.0
Swift	4500	500 Ω	120	6.2
Fulgurate	4900	500 Ω	120	7.0
Spray	5200	500 Ω	120	8.0
Hi-Spray	6000	500 Ω	70	10.0
Hydro	4900	500 Ω	120	7.0
<b>Bipolar Coag</b>				<b>Load-100 Ω</b>
Micro	380	100 Ω	120	1.5
Standard	560	100 Ω	120	1.5
Force	700	100 Ω	120	1.5
<b>Bipolar Cut</b>				

Macro	700	100 $\Omega$	120	1.5
Bicut	700	100 $\Omega$	120	1.5
<b>Sealer</b>				<b>Load-10 <math>\Omega</math></b>
Fine Seal	560	100 $\Omega$	150	1.5
Rapid Seal	560	100 $\Omega$	150	1.5

### Saline Resection Load-100 $\Omega$

#### Saline Cut

CutI	900	100 $\Omega$	300	1.5
CutII	1020	100 $\Omega$	300	1.5
CutIII	1160	100 $\Omega$	300	1.5

#### Saline Coag

Soft	430	100 $\Omega$	200	1.5
Standard	500	100 $\Omega$	200	1.5
Force	580	100 $\Omega$	200	1.5

\*Crest factor measured at load mentioned above at half power condition.

\*Crest factor is an indication of a waveform's ability to coagulate bleeders without a cutting effect.

Maximum Output for Ultrasonic Electrosurgery Module (UEM)

*Precise Cut* and *Desiccate Coag* are the only Mono. Modes available to a connected UEM hand piece.

## 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

Micro	440 kHz sinusoid continuous.
Standard	440 kHz sinusoid continuous.
Force	440 kHz sinusoid continuous.
Macro	440 kHz sinusoid continuous.
Bicut	440 kHz sinusoid continuous.

### Monopolar Cut

Low	390 kHz sinusoid continuous. Maximum voltage is limited to a lower value.
Pure Cut	390 kHz sinusoid continuous.
Blend-1	390 kHz bursts of sinusoid, recurring at 29 kHz intervals. 50% duty cycle
Blend-2	390 kHz bursts of sinusoid, recurring at 29 kHz intervals. 50% duty cycle
Endo-1	390 kHz sinusoidal. Pulse interval controlled depends on tissue feedback
Endo-2	390 kHz sinusoidal. Pulse interval time slightly greater than Endo-1
Hydro Cut	390 kHz sinusoid continuous.

### Monopolar Coag

Soft	390 kHz Sinusoid continuous.
Desiccate	460 kHz damped sinusoidal bursts recurring at 62kHz.
Swift	460 kHz damped sinusoidal bursts recurring at 42kHz.
Fulgurate	460 kHz damped sinusoidal bursts recurring at 34kHz.
Spray	460 kHz damped sinusoidal bursts recurring at 24kHz.
Hi-Spray	460 kHz damped sinusoidal bursts recurring at 13kHz.
Hydro Coag	460 kHz damped sinusoidal bursts recurring at 34kHz.

<b>Sealer</b>	
Fine Seal	440 kHz sinusoid pulse.
Rapid Seal	440 kHz sinusoid pulse.
<b>Saline Resection</b>	
Saline Cut I	390 kHz sinusoidal
Saline Cut II	390 kHz sinusoidal
Saline Cut II	390 kHz sinusoidal
Saline Soft Coag	440 kHz sinusoidal
Saline Standard Coag	440 kHz sinusoidal
Saline Force Coag	440 kHz sinusoidal

## 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.

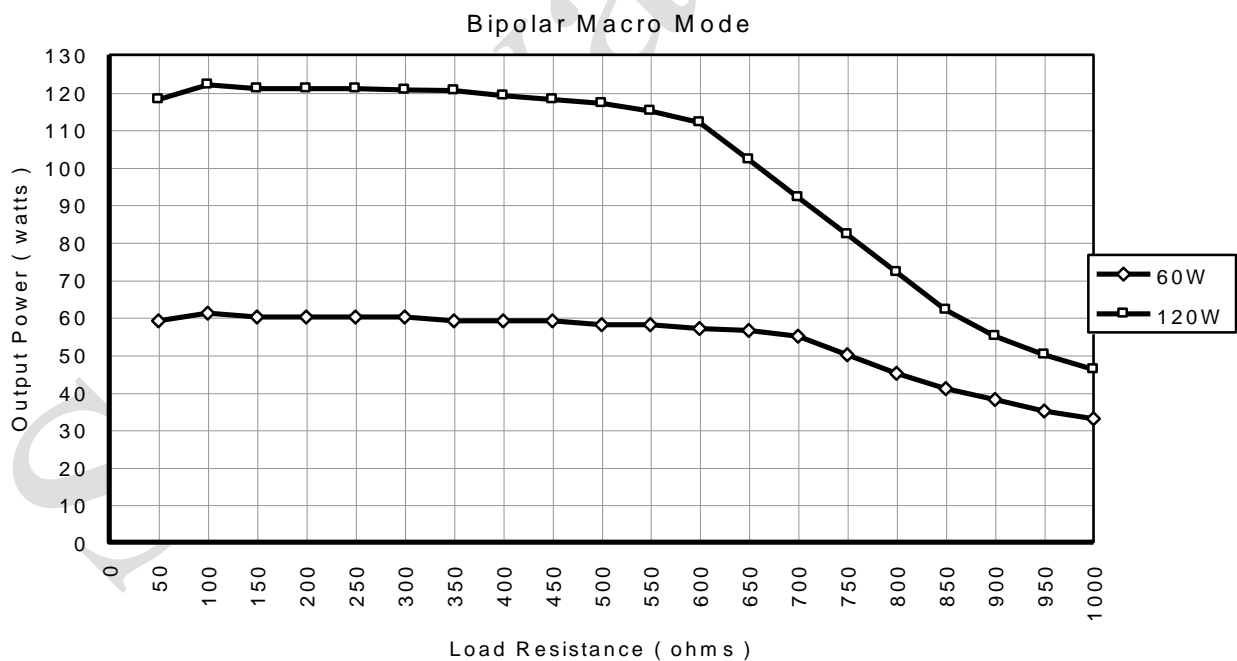
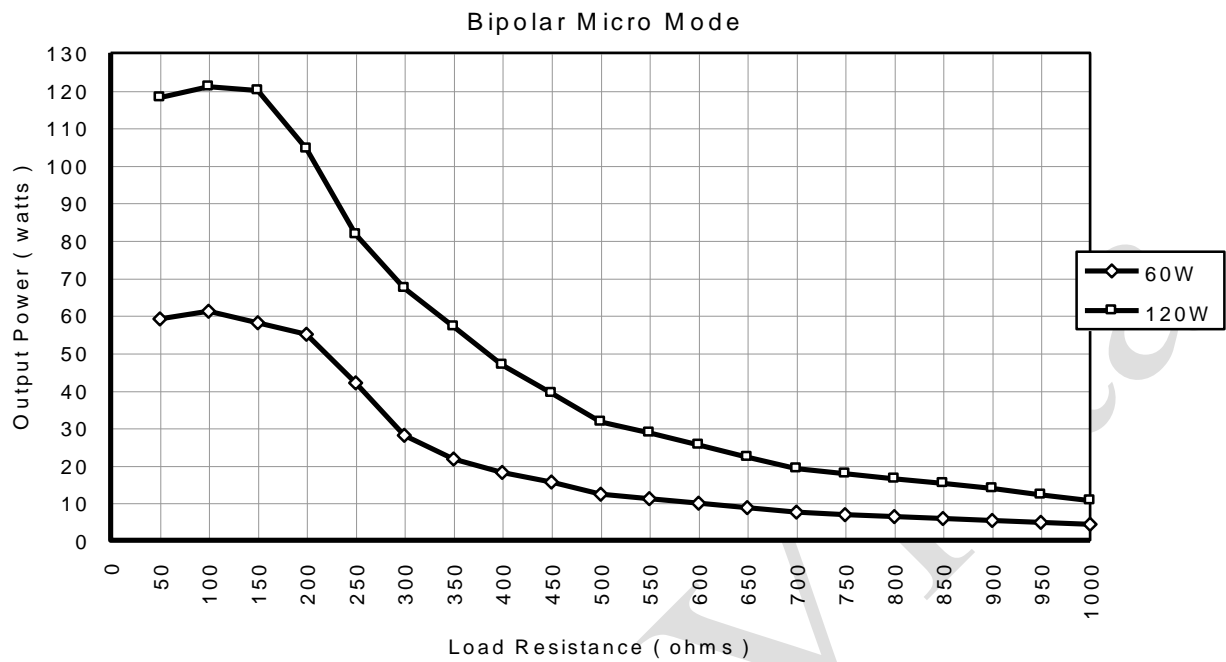
### □ Applications of Vessel Sealing System Section:

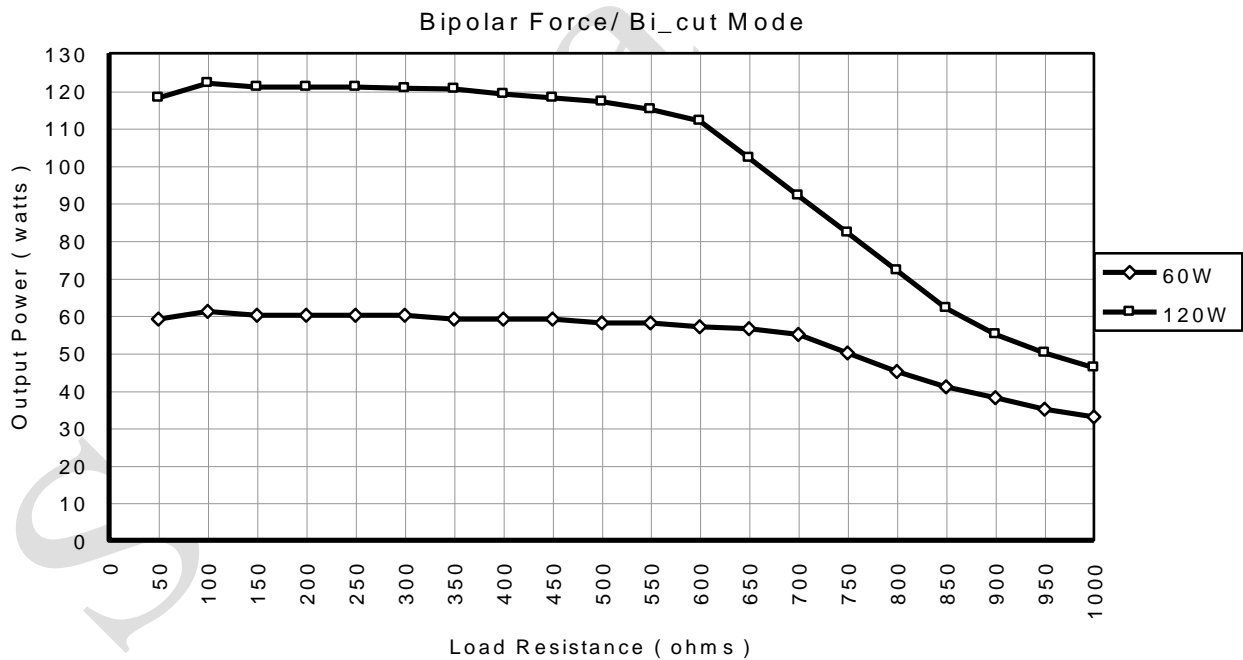
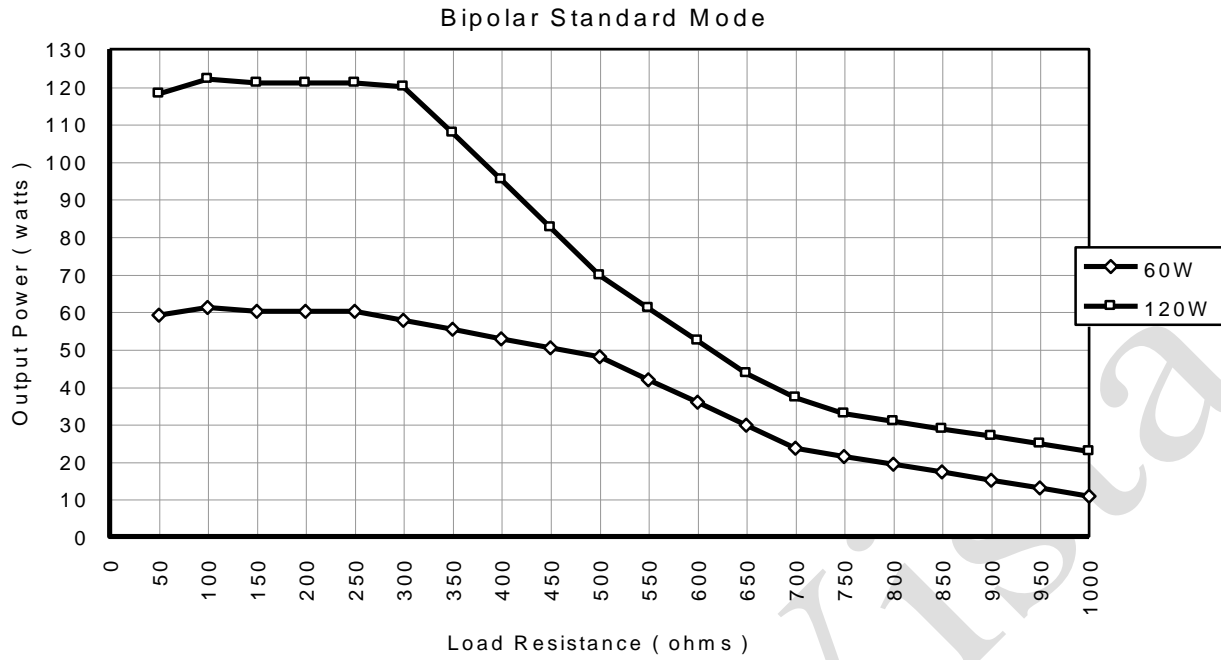
- Lap-Assisted Vaginal Hysterectomy (LAVH)
- Vaginal Hysterectomy
- Gastrectomy
- Gastric Bypass
- Appendectomy
- Colectomy
- Nephrectomy
- Nissen Fundoplication
- Colon Resection
- Cystectomy
- Radical Hysterectomy
- Liver Resection
- Adenectomy
- Splenectomy
- Salpingo-oophorectomy
- Radical Prostatectomy
- Abdominal Hysterectomy
- Hemorrhoidectomy

### □ Applications of Saline Plasma Bipolar Resection Section:

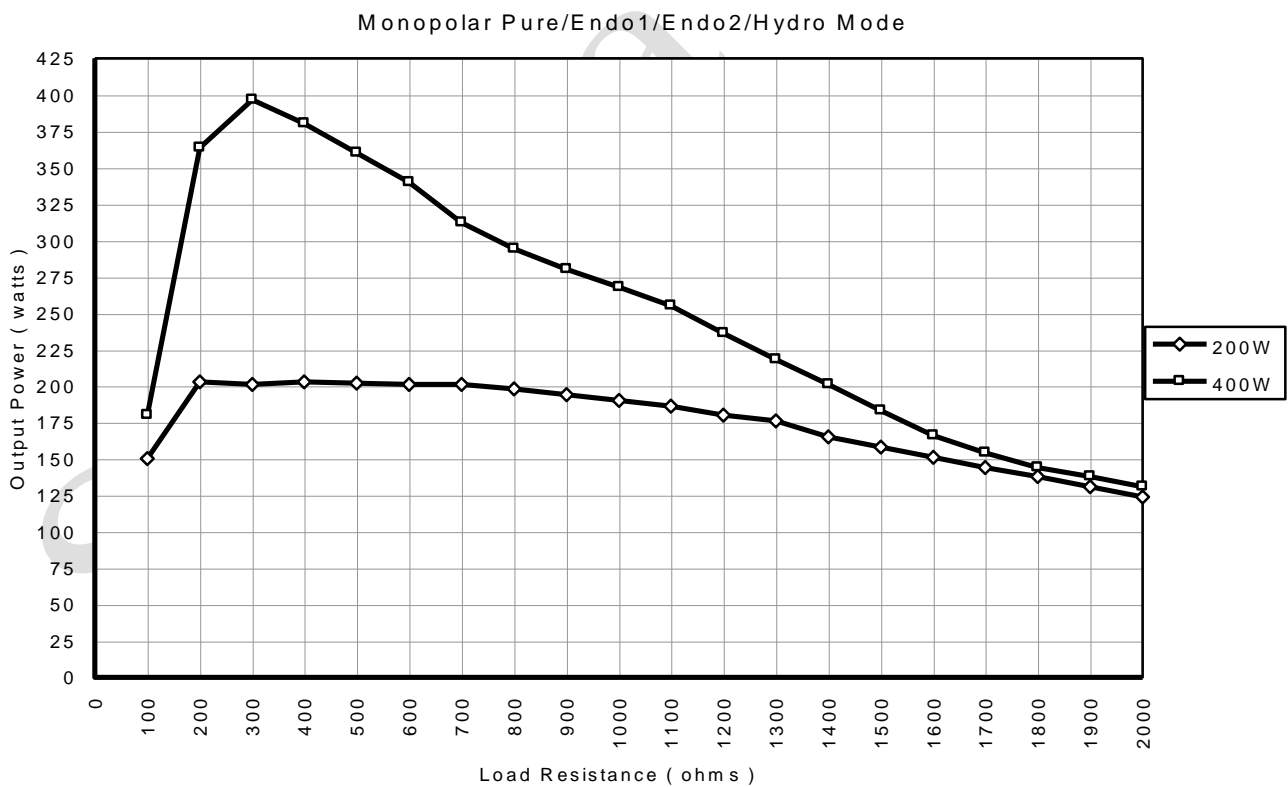
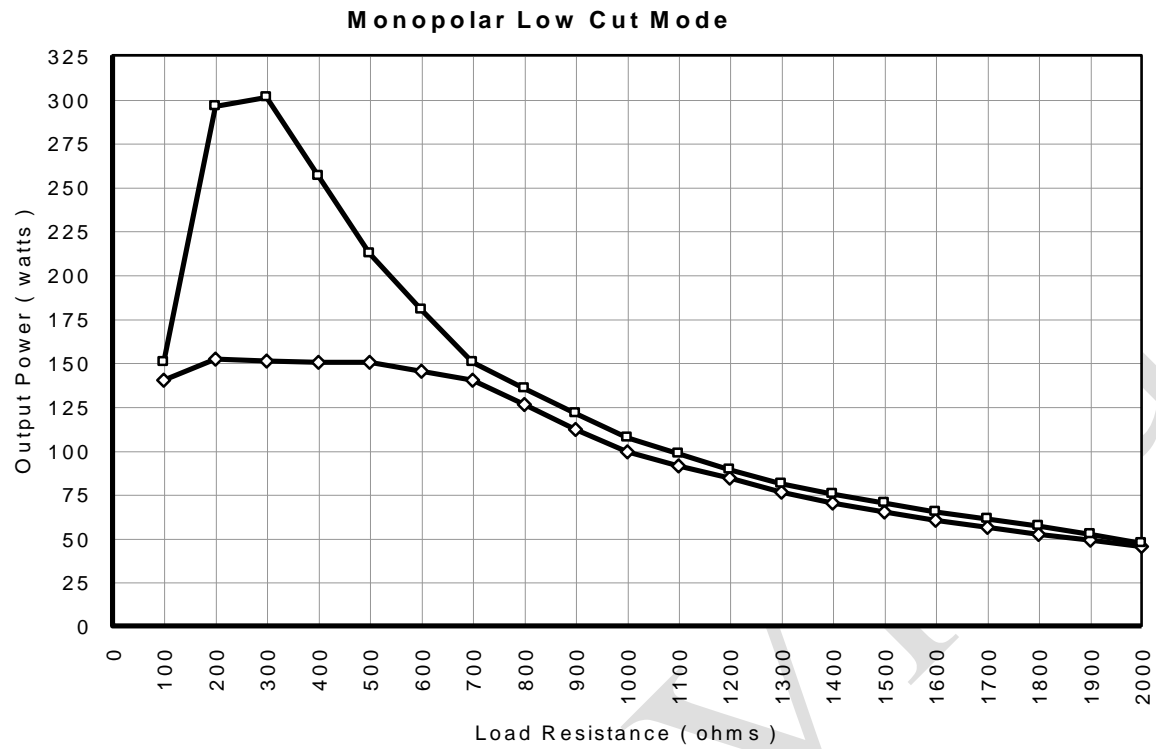
- Urology- Bipolar Saline Resection
- Gynecology- Bipolar Saline TCRE
- Arthroscopy

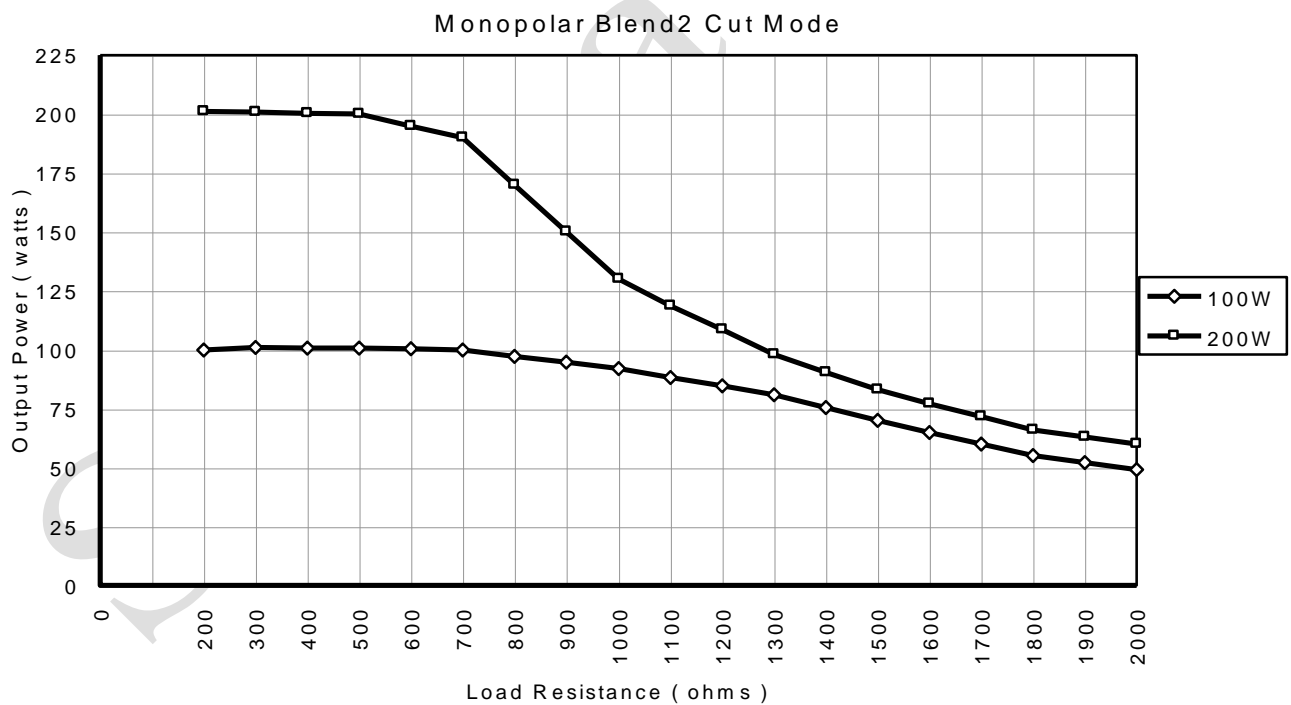
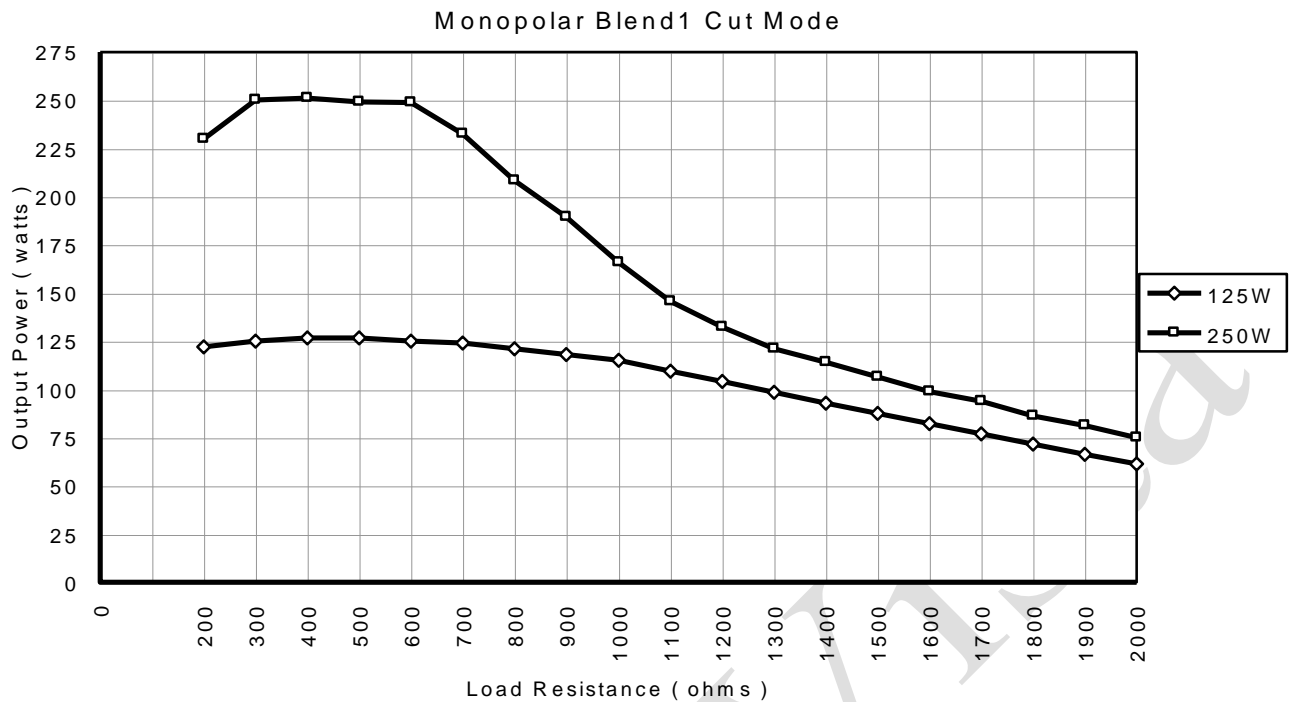
## F. OUTPUT POWER VS. LOAD GRAPHS

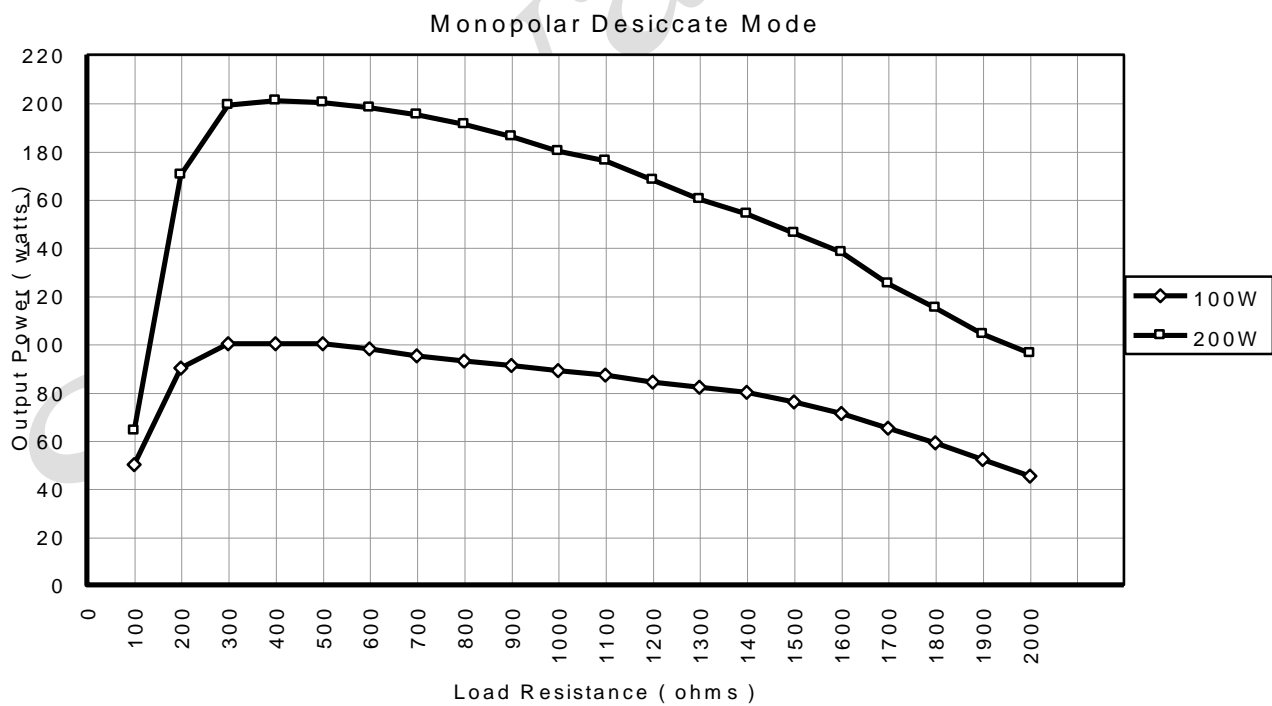
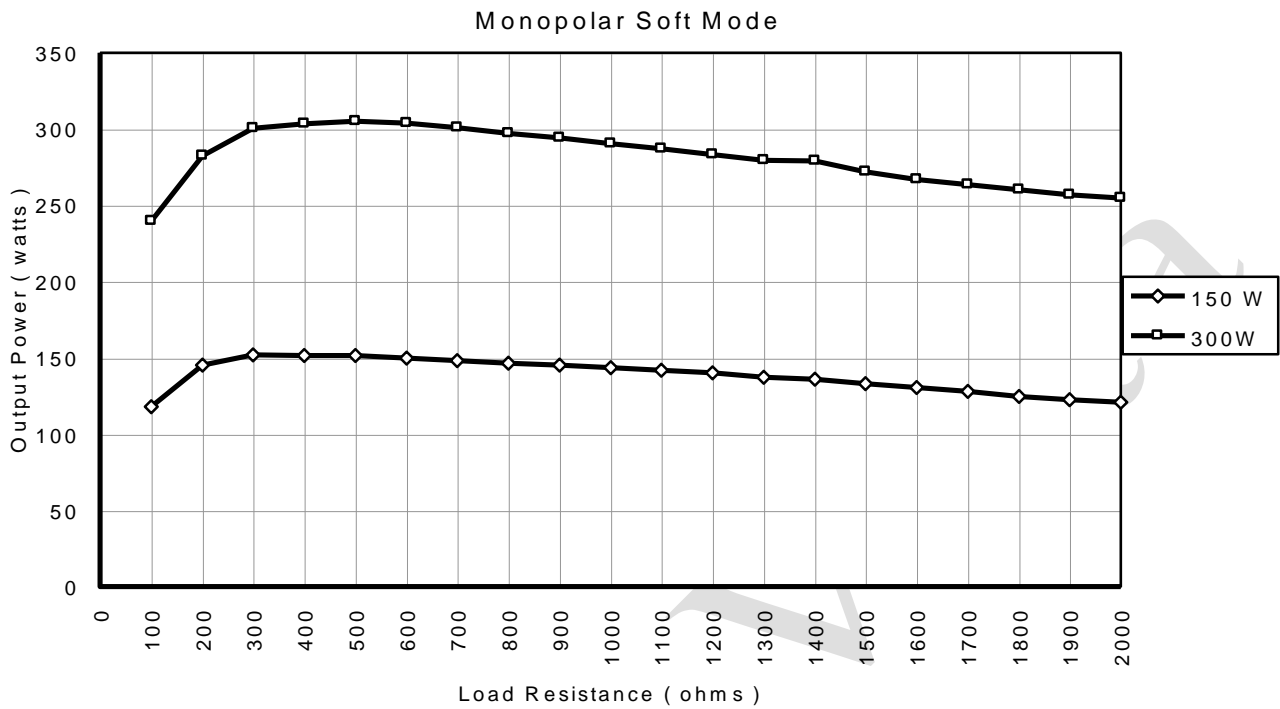


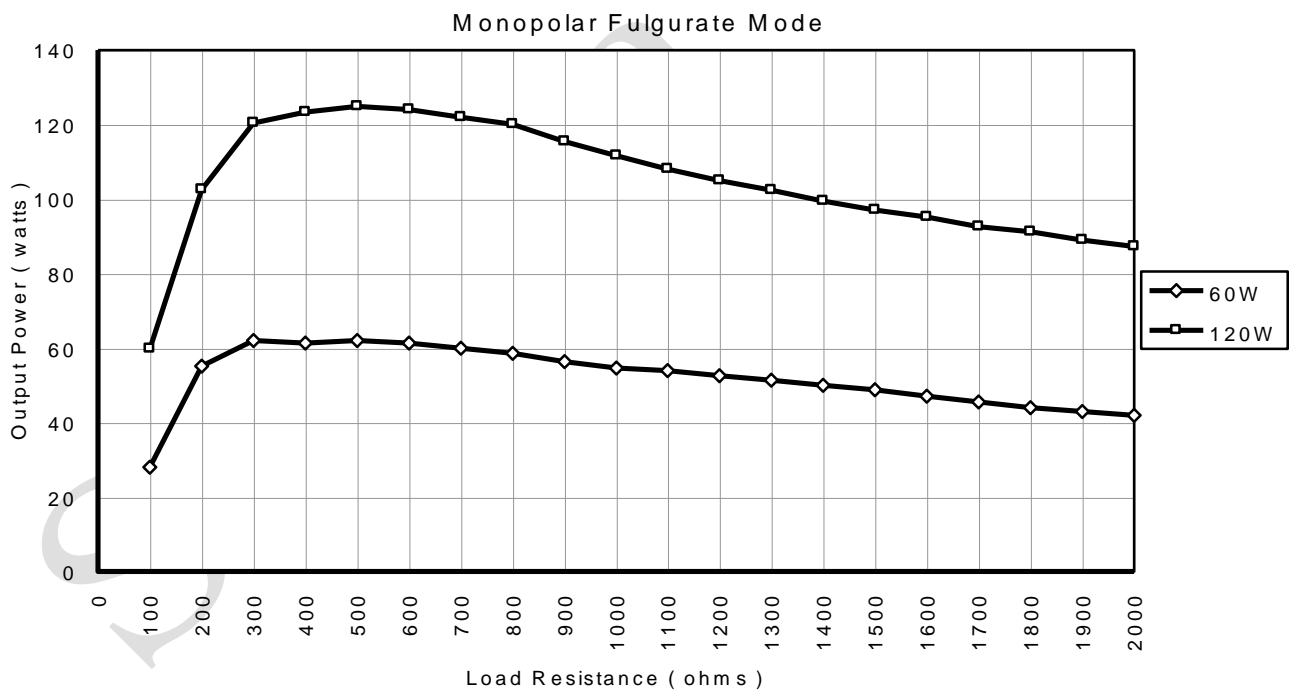
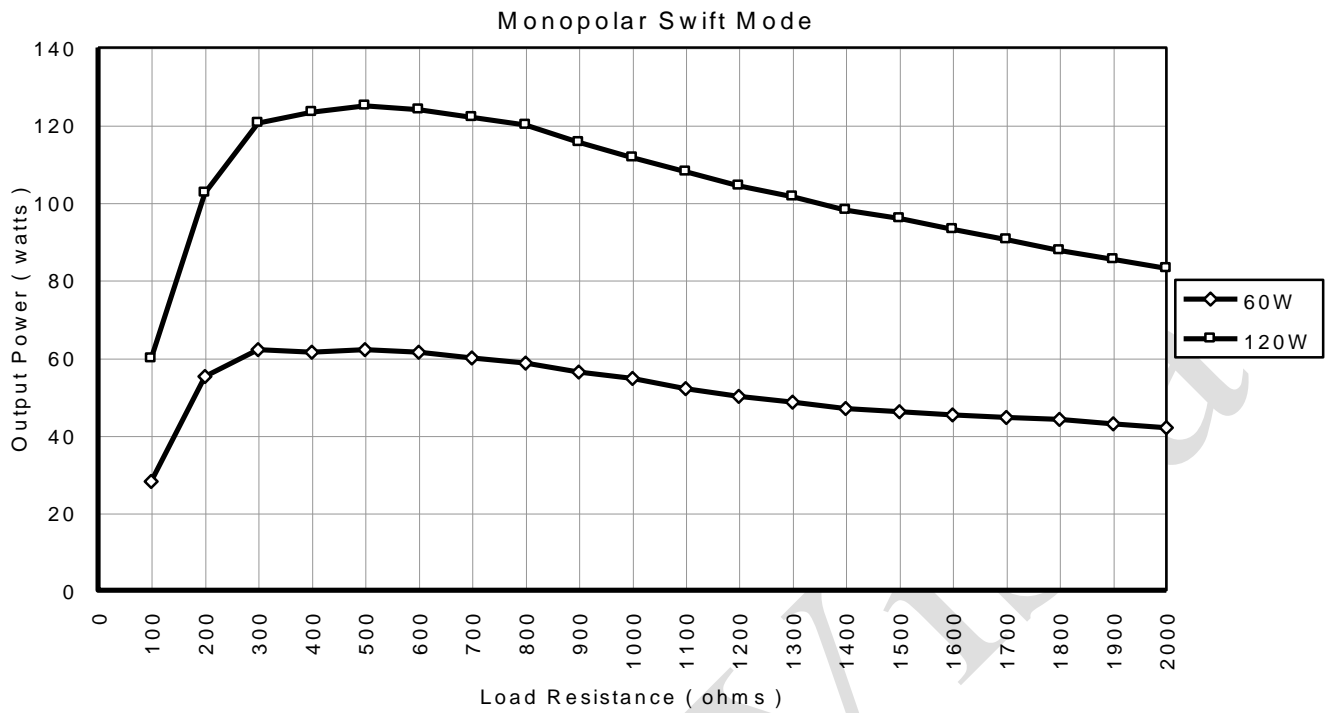


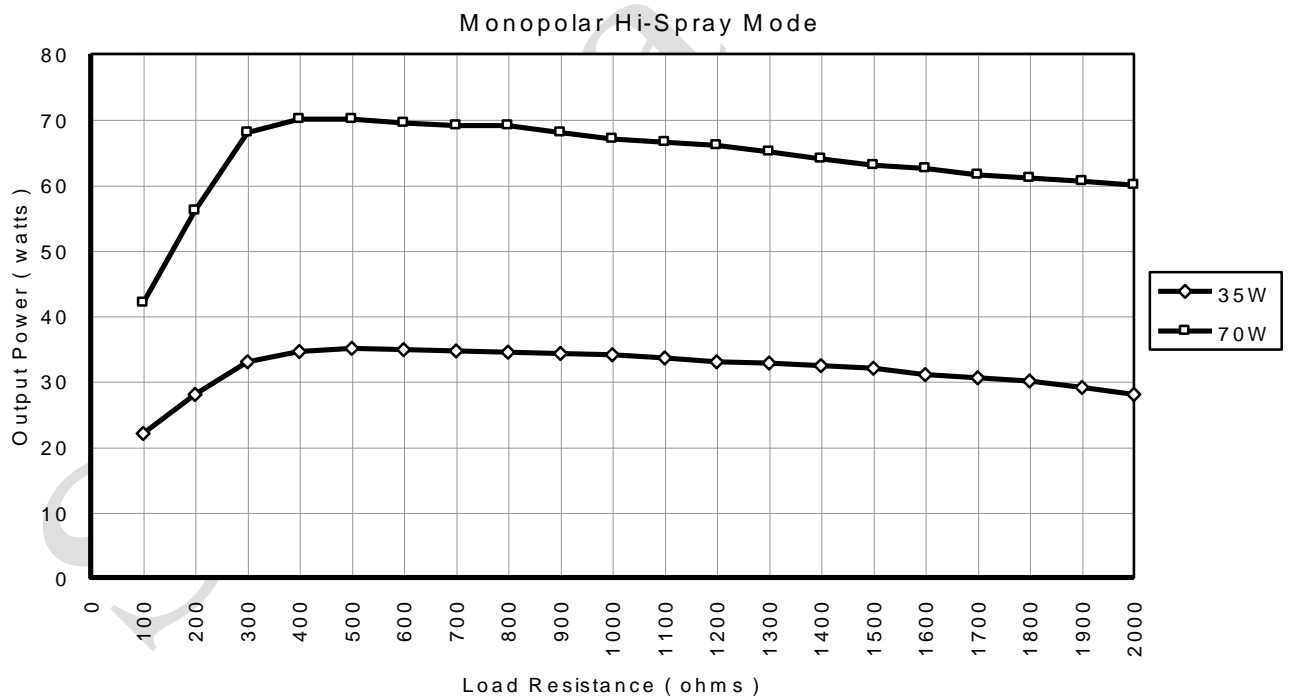
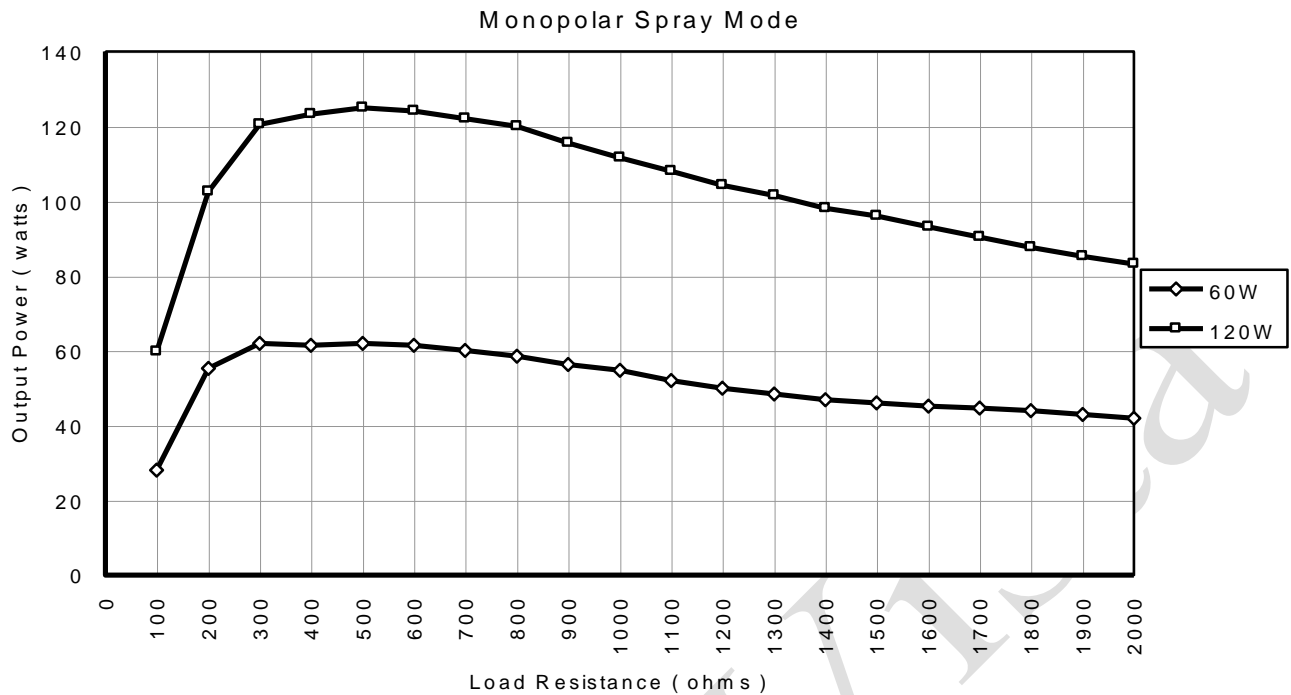


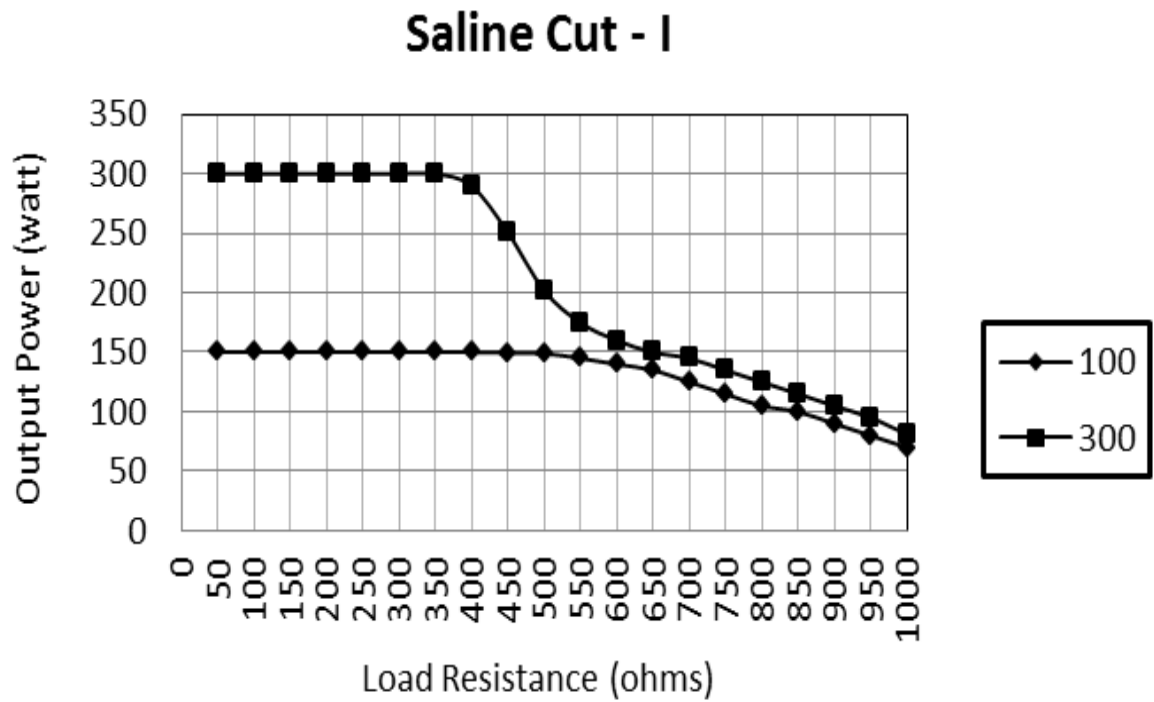
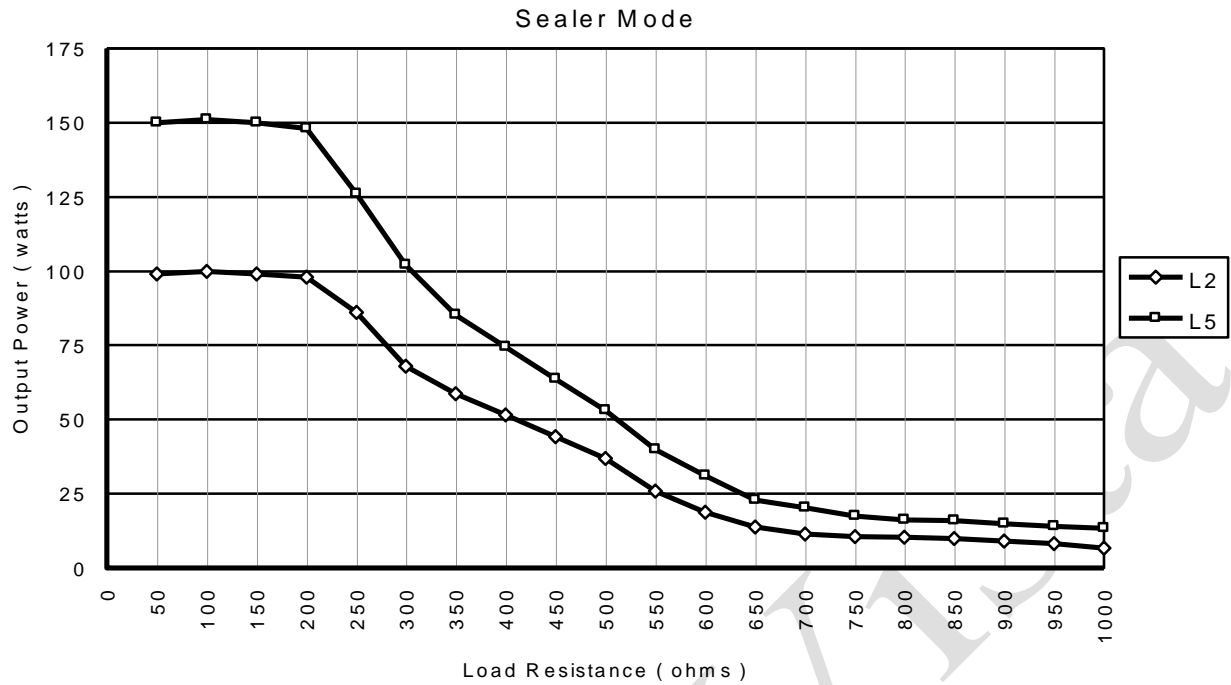




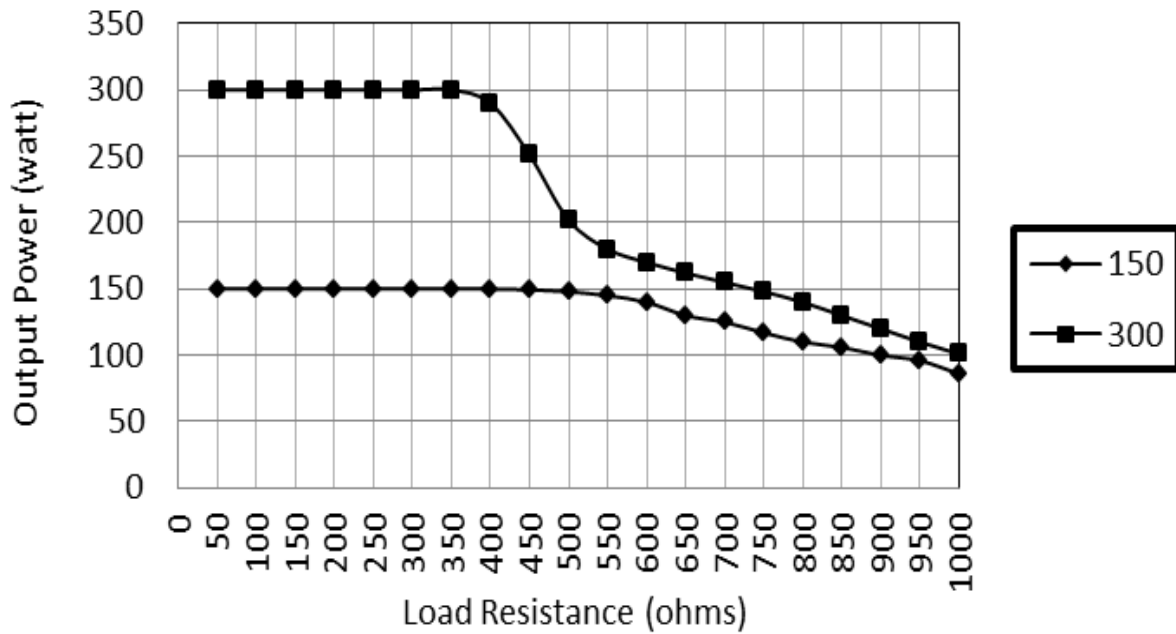




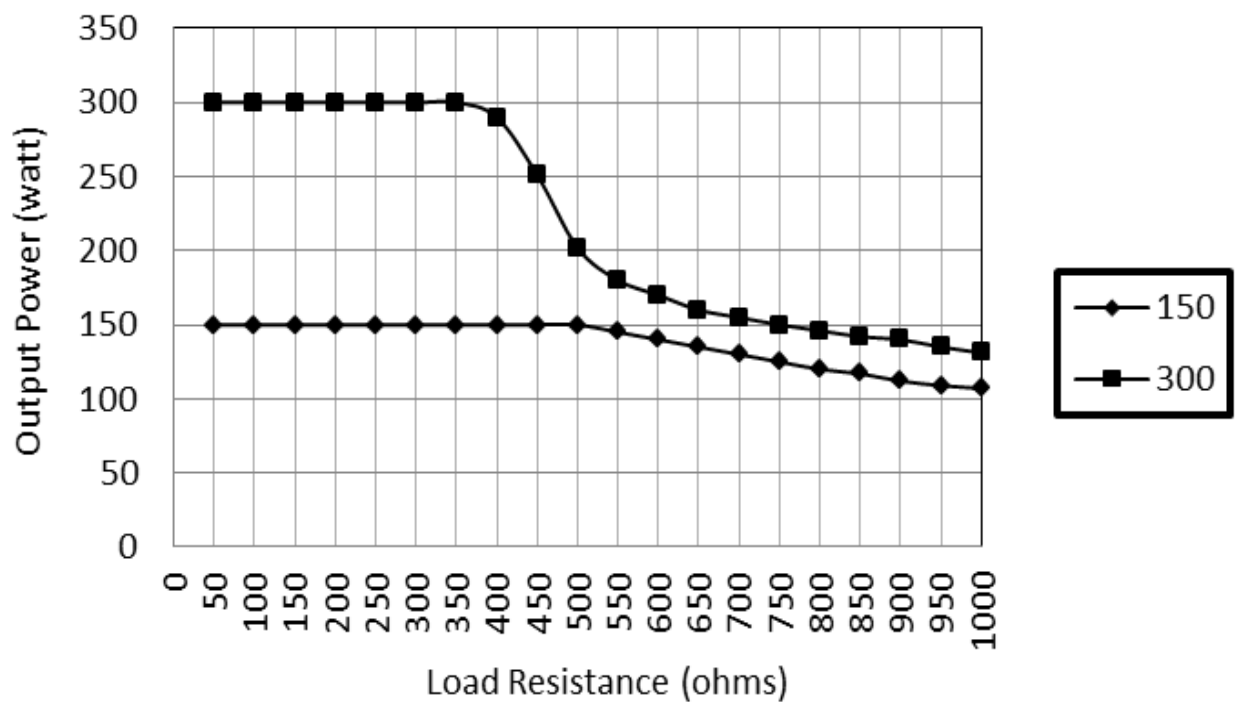




### Saline Cut - II



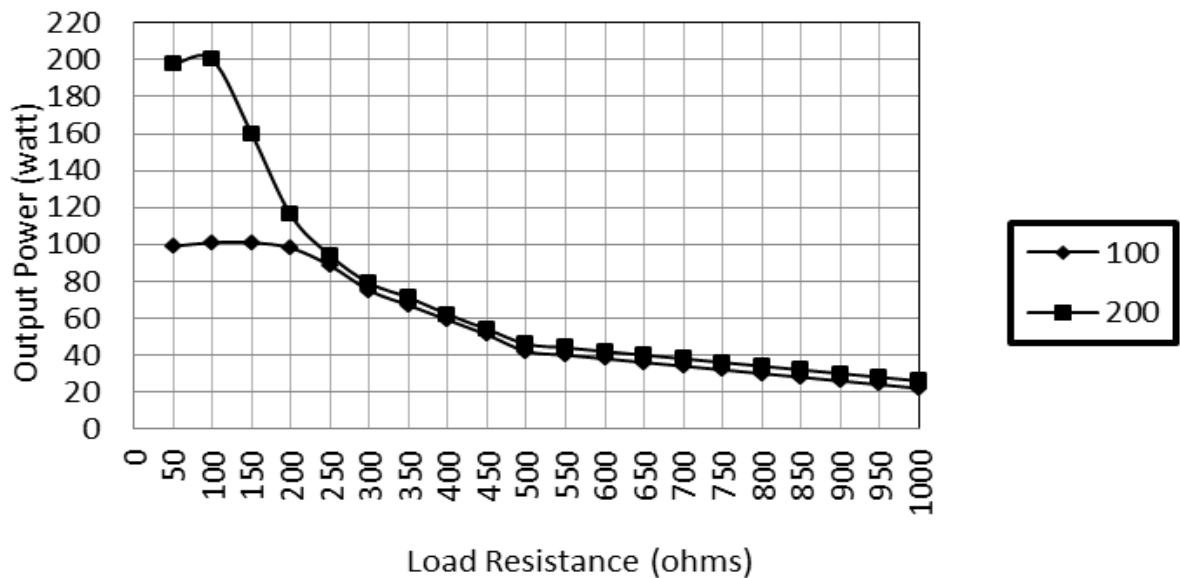
### Saline Cut - III



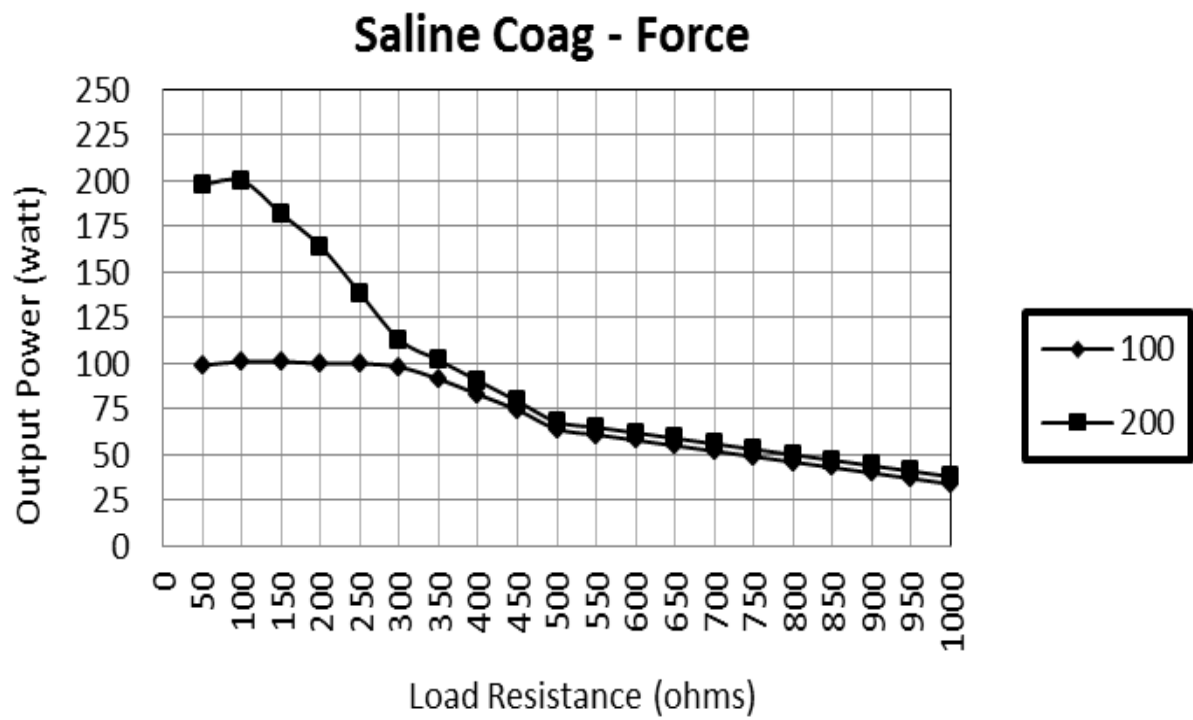
### Saline Coag - Soft



### Saline Coag - Standard







## CHAPTER 5

### Before Surgery

**Electric Shock Hazard:**

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

**Before Surgery:**

**Caution** - Read all warnings, cautions provided with this generator before using.

Active accessories:

**Electric Shock Hazard**

**Warning** - Avoid the 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, pad site burns may occur.



#### A. PREPARING THE GENERATOR

- Keep all the electrode cables untangled.
- If using a footswitch, connect it to the appropriate instrument socket on the rear panel.
- Connect the instrument to the appropriate instrument socket on the front panel.
- For simultaneous coag monopolar surgery, connect monopolar accessory to the monopolar 1 Instrument socket & Connect monopolar accessory to the monopolar 2 Instrument socket.
- For monopolar surgery only, apply the patient return electrode to patient & connect it to the Patient Return Electrode socket on the front panel.
- Verify or change the mode & power setting.
- Optional-Press the Recall key on the front panel to display previous setting if required.
- Optional-Press the Program key on main screen to display stored programs. Change the mode or settings if required as surgical conditions & patient placement may require change in settings. This also varies as individual skills, surgical conditions & patient placement may require change in settings. This also varies as individual skills.

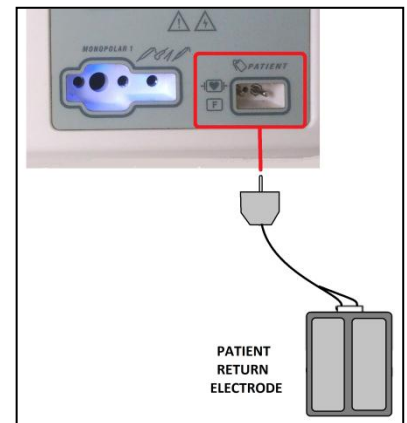
#### B. SETTING THE GENERATOR

1. Verify the generator is off by pressing the power switch OFF (0).
2. 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.
3. Plug the generator power cable into rear panel socket.
4. Plug the generator power cable into a grounded socket.
5. Turn on the generator by pressing the power switch ON (1). Verify the following:
  - a. All visual indicators & displays on the front panel illuminate.
  - b. Activation tones sound to verify that the speaker is working properly.
6. At power on, unit perform the self-tset & if self-test is successful, welcome screen appeared on the display.

## C. PATIENT RETURN ELECTRODE MONITORING (PREM)



PREM electrode is used in monopolar surgery modes. Always ensure that the contact between Patient skin & Patient Return Electrode is adequate. Bar below PREM icon indicates the contact adequacy.



Icon	Contact Quality
	<b>Excellent</b> 100% Contact with patient.
	<b>Safe</b> Contact with patient is proper and safe.
	<b>Moderate</b> Contact with patient is moderate & viable. If possible try to improve the contact, connect PREM dual area plate properly. Take appropriate measures to improve the contact quality.
	<b>Poor</b> It's not recommended to continue with the surgery; Check PREM connection or replace the PREM electrodes.
	<b>No contact</b> PREM patient plate is not connected or is damaged.

## D. SURGERY MODES & ACCESSORY CONNECTIONS

### 1. Electro Surgery Mode in Vista+

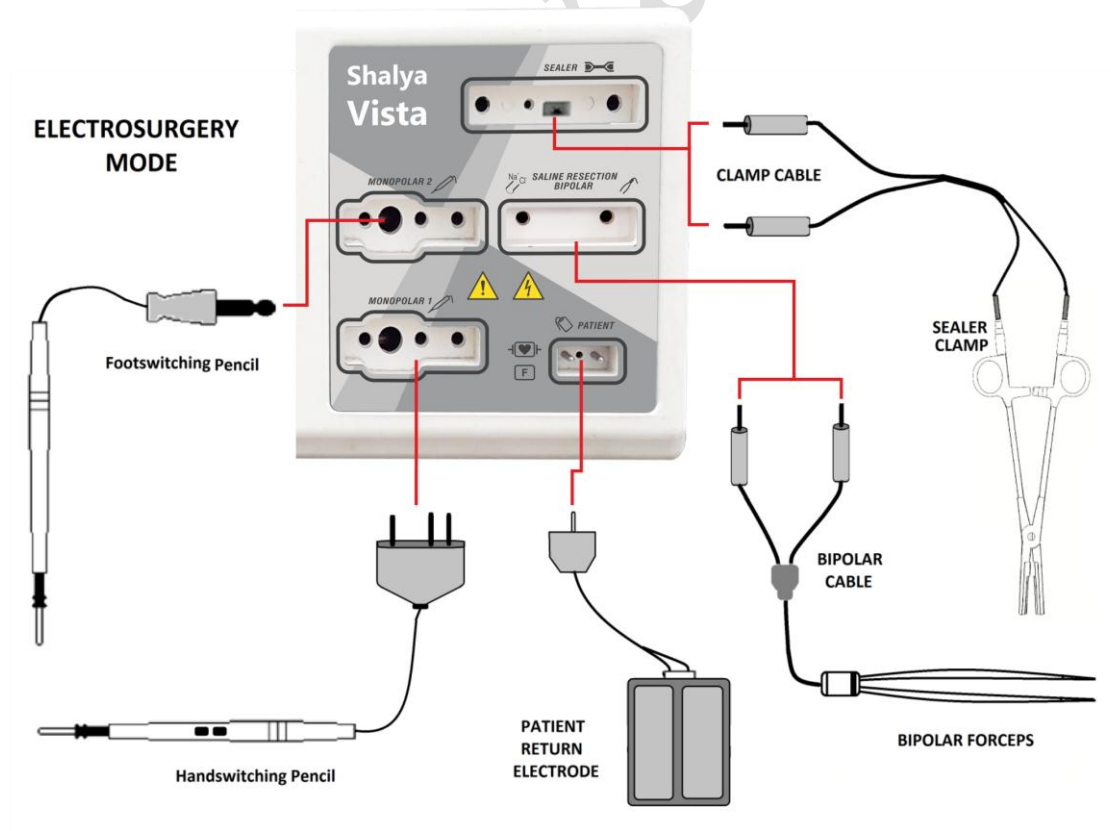


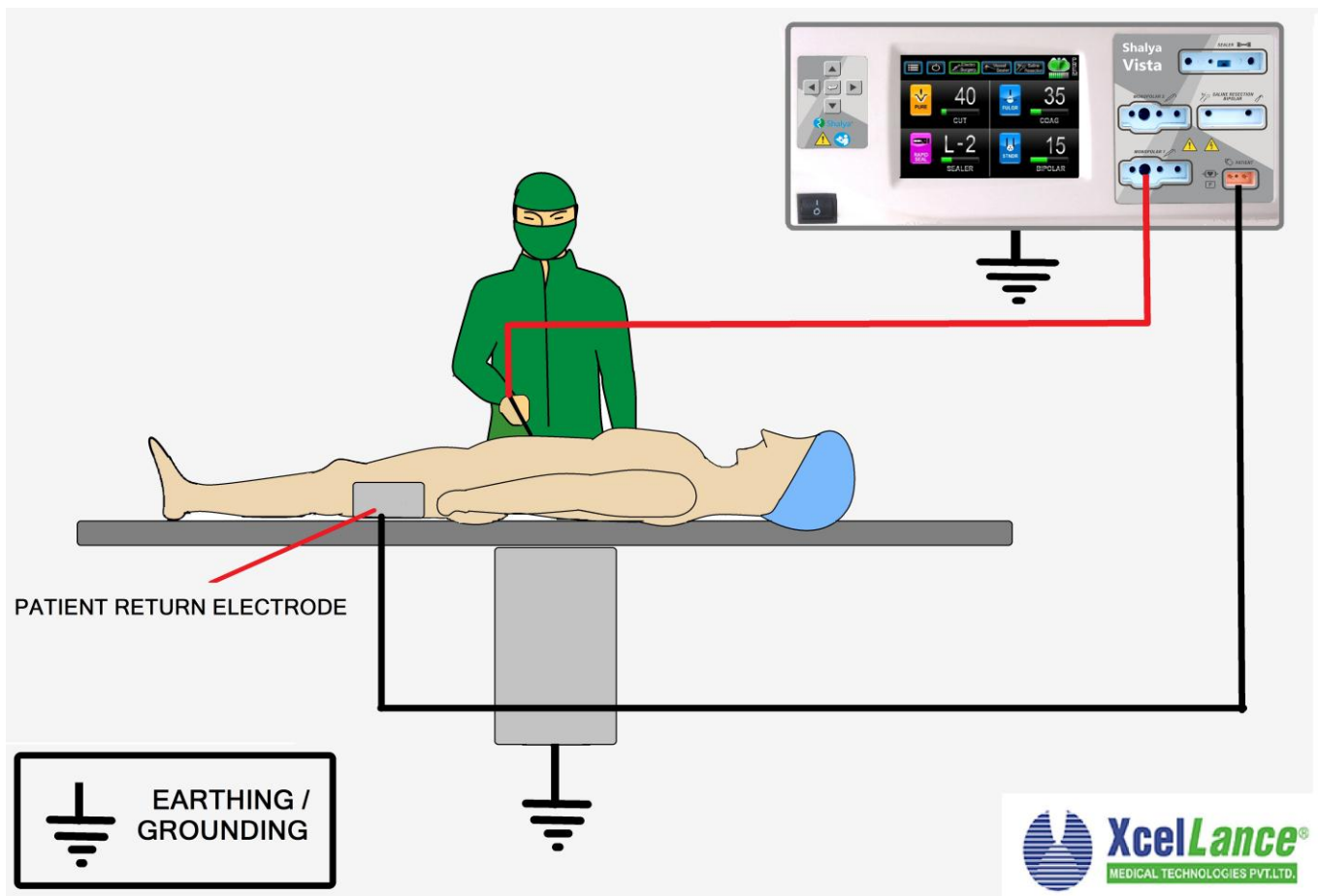
Dual-  
mono  
turned on



Vista+ involves two monopolar output sockets (Monopolar 1 & Monopolar 2 output sockets). If the user wants output from both these sockets simultaneously, there is a need to press the Dual mono option as shown in the screens above. On pressing the Dual mono option, the option turns green indicating that the unit is ready for the usage of both the Monopolar sockets together.

### Accessories connection in ESU Mode





Connection with patient (Monopolar Mode)

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

## Foot Switch Selection for Vista+:



### Default Configurations:-

Every time generator is turned ON or restarted, machine loads by default settings for footswitching sockets.

<i>For Vista+ only</i>	Modes	Monopolar 1 Footswitch	Monopolar 2 /Bipolar Footswitch	Bipolar/Sealer Footswitch
Can be Used for	Electrosurgery	Monopolar 1 Cut & Coag	Monopolar 2 Cut & Coag (By default) -----OR----- Bipolar & Sealer	Bipolar (By default) -----OR----- Sealer
	Vessel Sealer	Bipolar Cut & Coag	-	Bipolar (By default) -----OR----- Sealer
	Saline Resection	Saline Cut & Coag	-	-

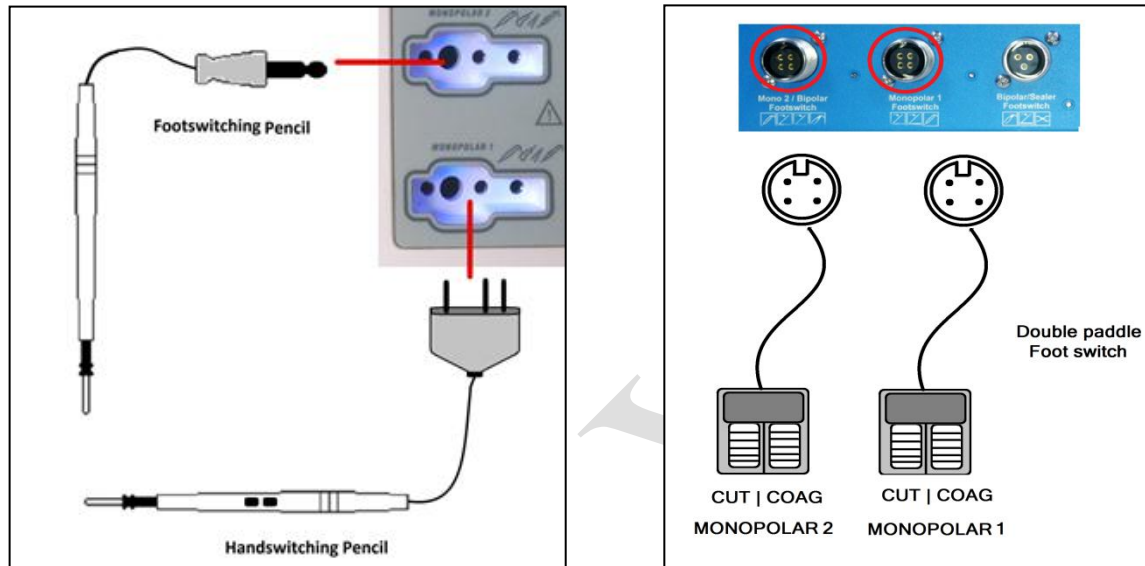
#### Please Note:

*For using these footswitching input sockets for functions other than default, user must manually configure it.*

*When using footswitching electrodes user must connect footswitches to corresponding socket on the rear panel.*

## Monopolar

As in this example if user intends to connect footswitching pencil in Monopolar -2 socket and Handswitching electrode in Monopolar-1 socket then user must connect double paddle Footswitching electrode in Monopolar-2 footswitching socket only on the rear panel, as shown in figure below.



**Please Note:** User must cautiously make selection between appropriate inputs.

## 2Si-Coag:

Vista+ supports simultaneous coagulation outputs from Monopolar modes. User can obtain simultaneous coagulation output in any of the combination below:

Sr.No.	Monopolar-1	Monopolar-2
1.	Handswitching Pencil	Handswitching Pencil
2.	Handswitching Pencil	Footswitching Pencil
3.	Footswitching Pencil	Handswitching Pencil
4.	Footswitching Pencil	Footswitching Pencil

**Please Note:** User must cautiously select appropriate footswitching or handswitching inputs.

## Footswitch Selection for Sealer & Bipolar:

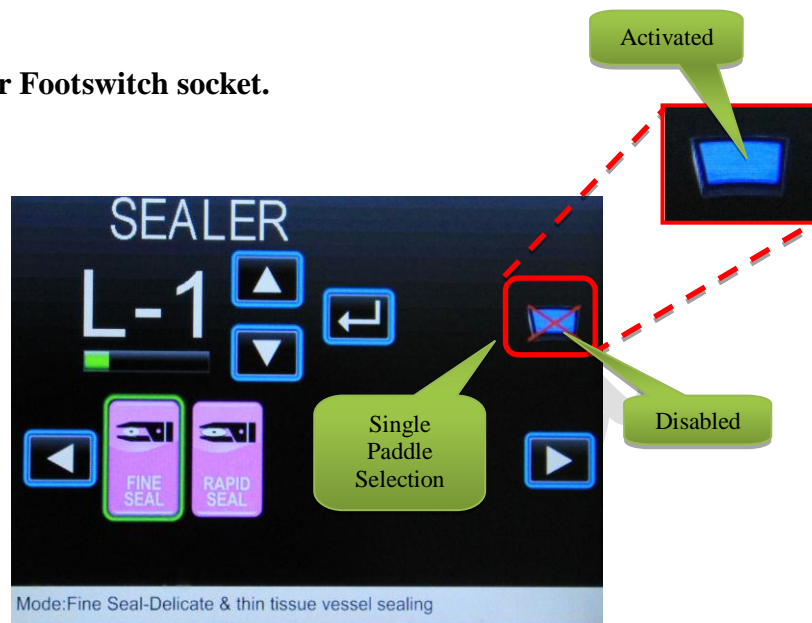
While using bipolar or sealer in Electro Surgery mode, user has two options for footswitch selection.

1. Single Paddle Footswitch in Sealer/Bipolar Footswitch socket on the rear panel.
2. Double Paddle Footswitch in Monopolar-2/ Bipolar Footswitch socket on rear panel.

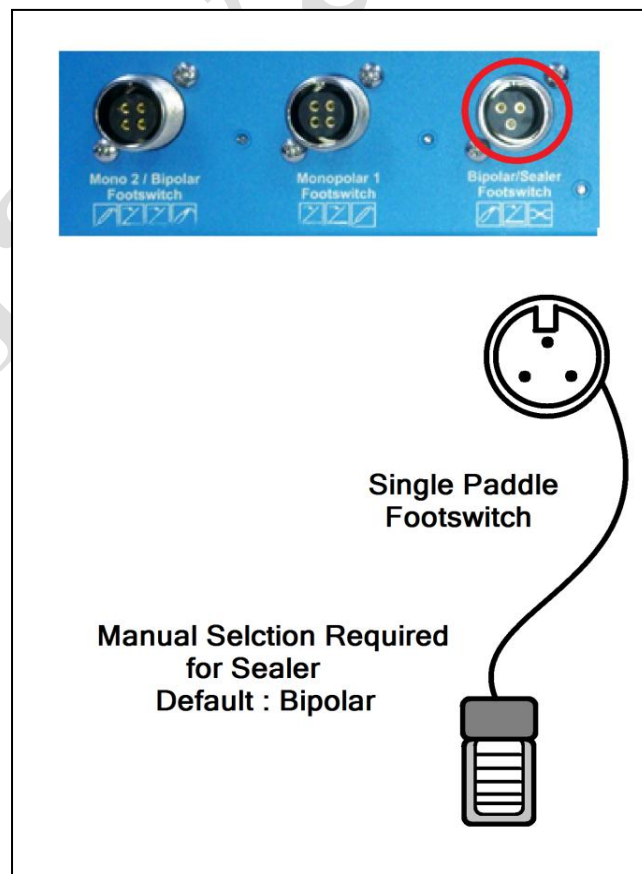


- **Single Paddle Footswitch in Sealer/Bipolar Footswitch socket.**

- After Turning on the generator, In Electro Surgery mode single paddle footswitch is configured for bipolar activations; by default.
- If user intends to use single paddle foot switch for the sealer activations, it must be configured.
- Pressing touch icon in the sealer mode will remove the cross mark from the icon, which makes the single paddle footswitch functional for sealer operations.

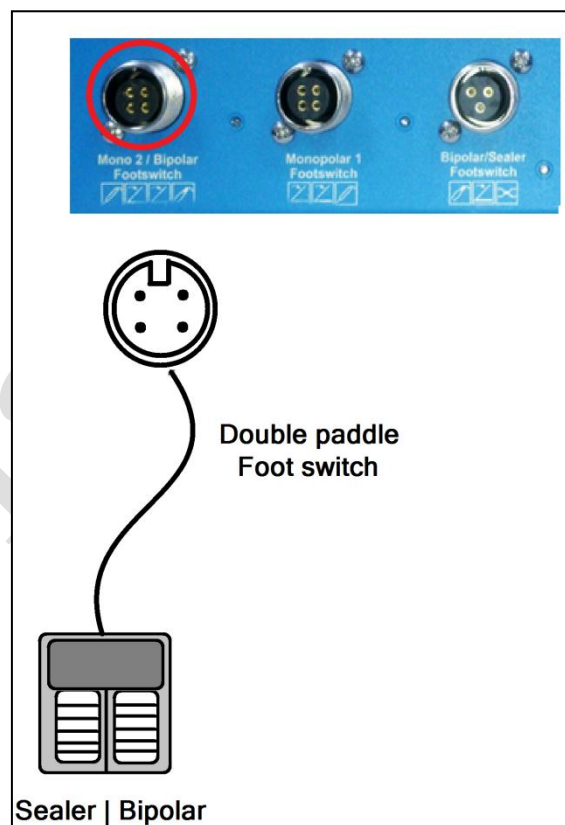
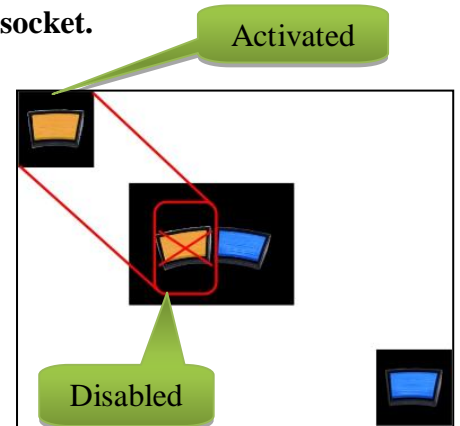


- For making it functional for bipolar again, user must configure footswitch into bipolar mode. By going into bipolar mode and removing cross mark across the blue footswitch (which is the icon of single paddle footswitch) will make it functional for bipolar mode.
- Connect footswitch as shown in figure below.



- **Double Paddle Footswitch in Monopolar-2/ Bipolar Footswitch socket.**

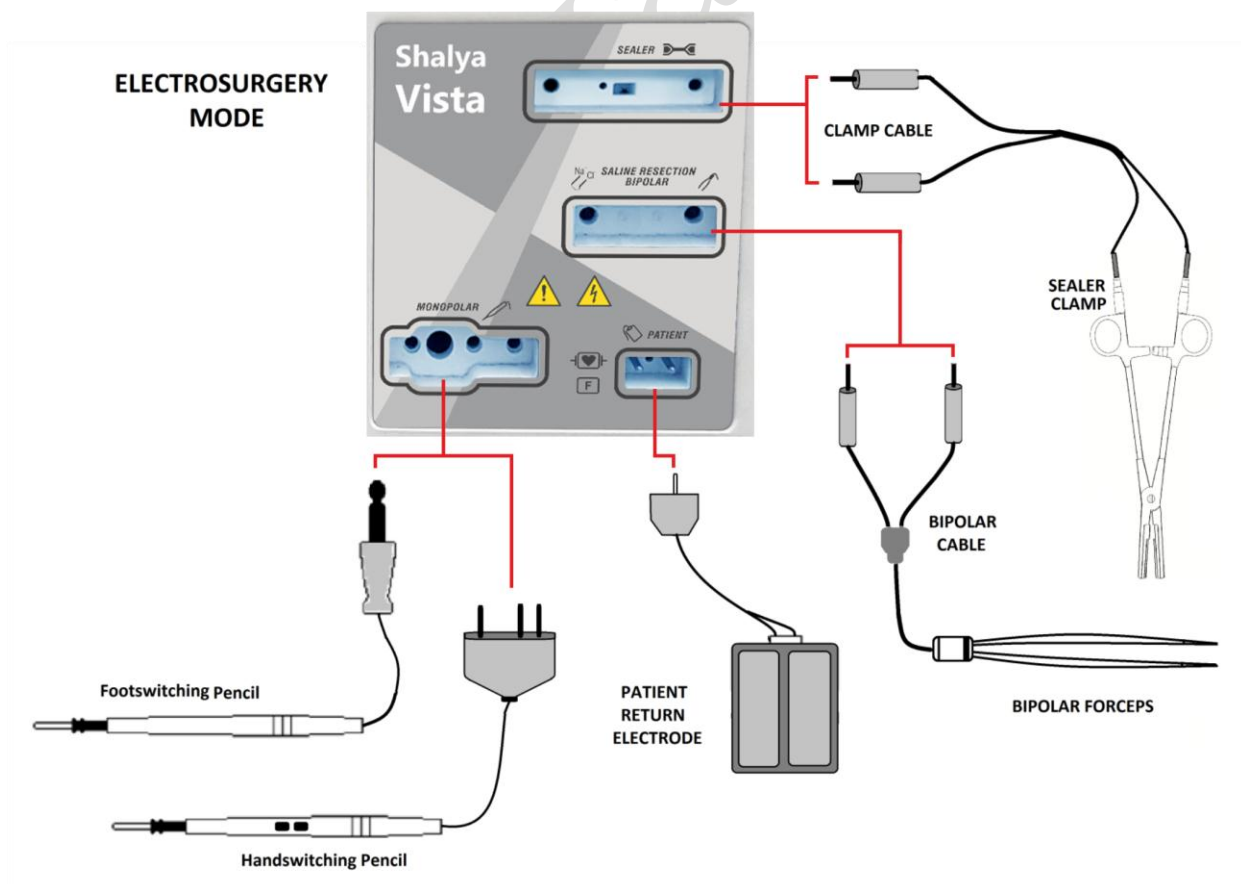
- In Vista+ double footswitch paddle is configured for monopolar 2 mode; by default, so user must make manual selection to make it functional for Bipolar-Sealer operations.
- For making double paddle footswitch functional for Sealer & Bipolar operations follow the similar procedure as described above for double paddle footswitch selection. In this case enable double paddle footswitch icon by going into Bipolar or Sealer mode.
- Connect double paddle footswitch in **Monopolar-2 / Bipolar footswitch** socket.
- Footpaddle-1 (Yellow in color) can be used for Sealer activations.
- Footpaddle-2 (Blue in color) can be used for Bipolar activations.
- Connect footswitch as shown in figure below.



## 2. Electrosurgery Mode in Vista



### Accessories connection in ESU Mode



## Foot Switch Selection for Vista:



## Default Configurations:-

Every time generator is turned ON or restarted, machine loads by default settings for footswitching sockets.

<i>For Vista only</i>	Modes	Monopolar 1 Footswitch	Monopolar 2 /Bipolar Footswitch	Bipolar/Sealer Footswitch
Can be Used for	Electrosurgery	Monopolar 1 Cut & Coag	Bipolar & Sealer (By default)	Bipolar (By default) -----OR----- Sealer
	Vessel Sealer	Bipolar Cut & Coag	-	Bipolar (By default) -----OR----- Sealer
	Saline Resection	Saline Cut & Coag	-	-

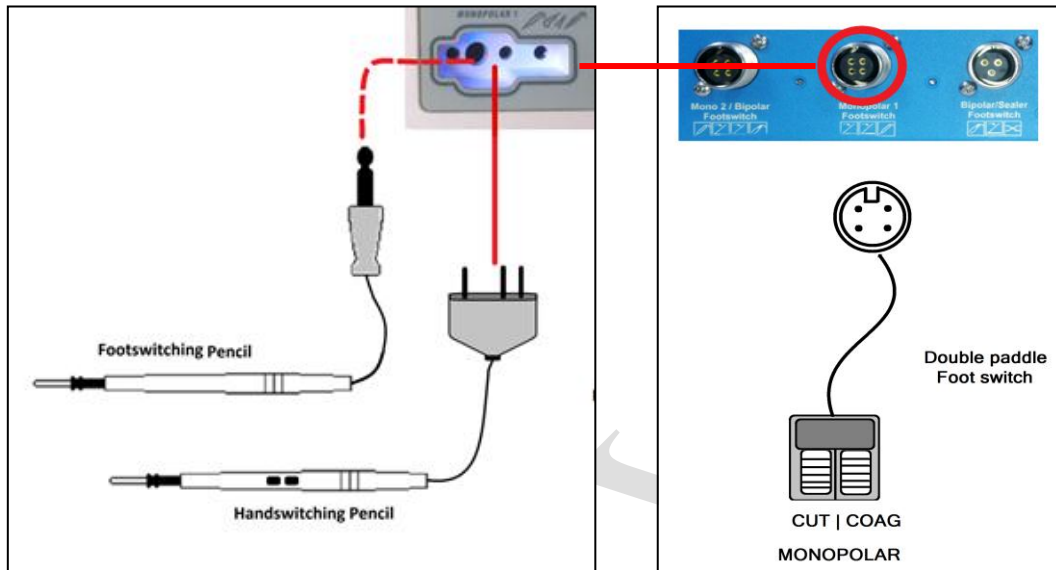
### **Please Note:**

**For using these footswitching input sockets for functions other than default, user must manually configure it.**

**When using footswitching electrodes user must connect footswitches to corresponding ports on the rear panel.**

## Monopolar

As shown in this example, user can connect either handswitching or footswitching electrodes (Pencil) in Monopolar socket. Input: footswitch is connected to the Monopolar 1 footswitching socket on the rear panel.

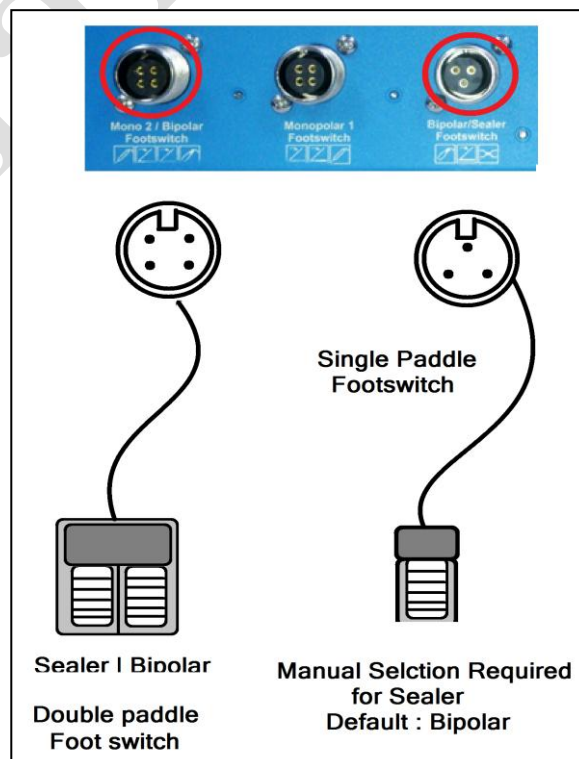


**Please Note:** User must cautiously make selection between appropriate inputs.

### Footswitch Selection for Sealer & Bipolar:

While using bipolar or sealer in Electro Surgery mode, user has two options for footswitch selection.

1. Single Paddle Footswitch in Sealer/Bipolar Footswitch socket on the rear panel.
2. Double Paddle Footswitch in Monopolar-2/ Bipolar Footswitch socket on rear panel.

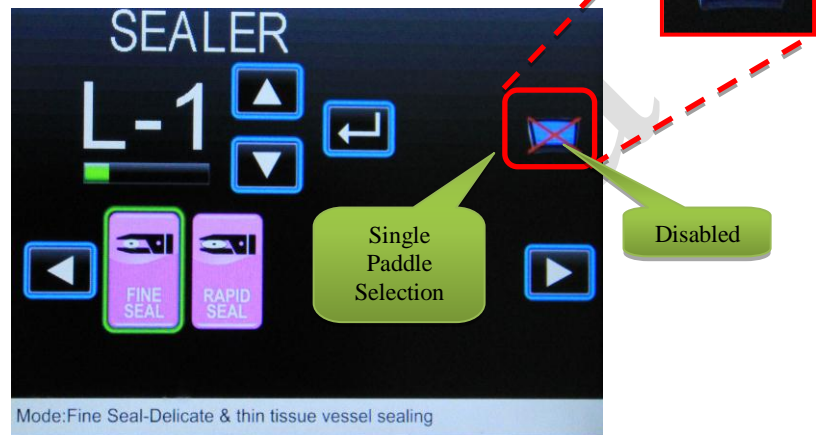


- **Single Paddle Footswitch in Sealer/Bipolar Footswitch socket.**

- After Turning on the generator, In Electro Surgery mode single paddle footswitch is configured for bipolar activations; by default.

- If user intends to use single paddle foot switch for the sealer activations, it must be configured.

- Pressing touch icon in the sealer mode will remove the cross mark from the icon, which makes the single paddle footswitch functional for sealer operations.



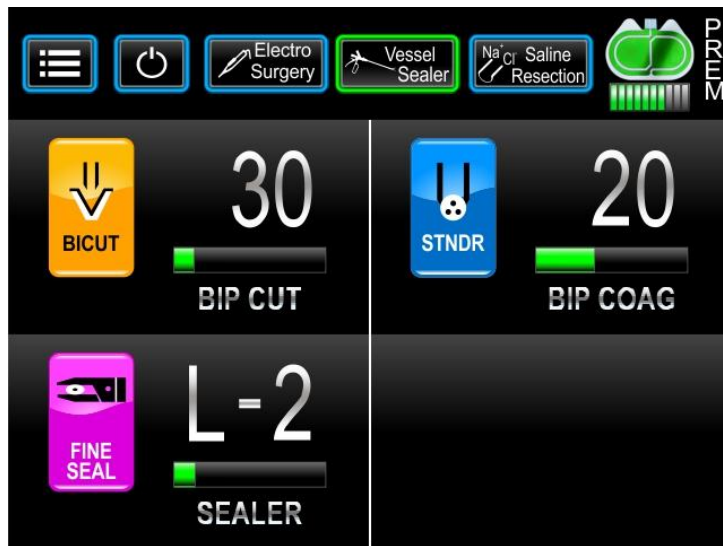
- For making it functional for bipolar again, user must configure footswitch into bipolar mode. By going into bipolar mode and removing cross mark across the blue footswitch (which is the icon of single paddle footswitch) will make it functional for bipolar mode.

- **Double Paddle Footswitch in Monopolar-2/ Bipolar Footswitch socket.**

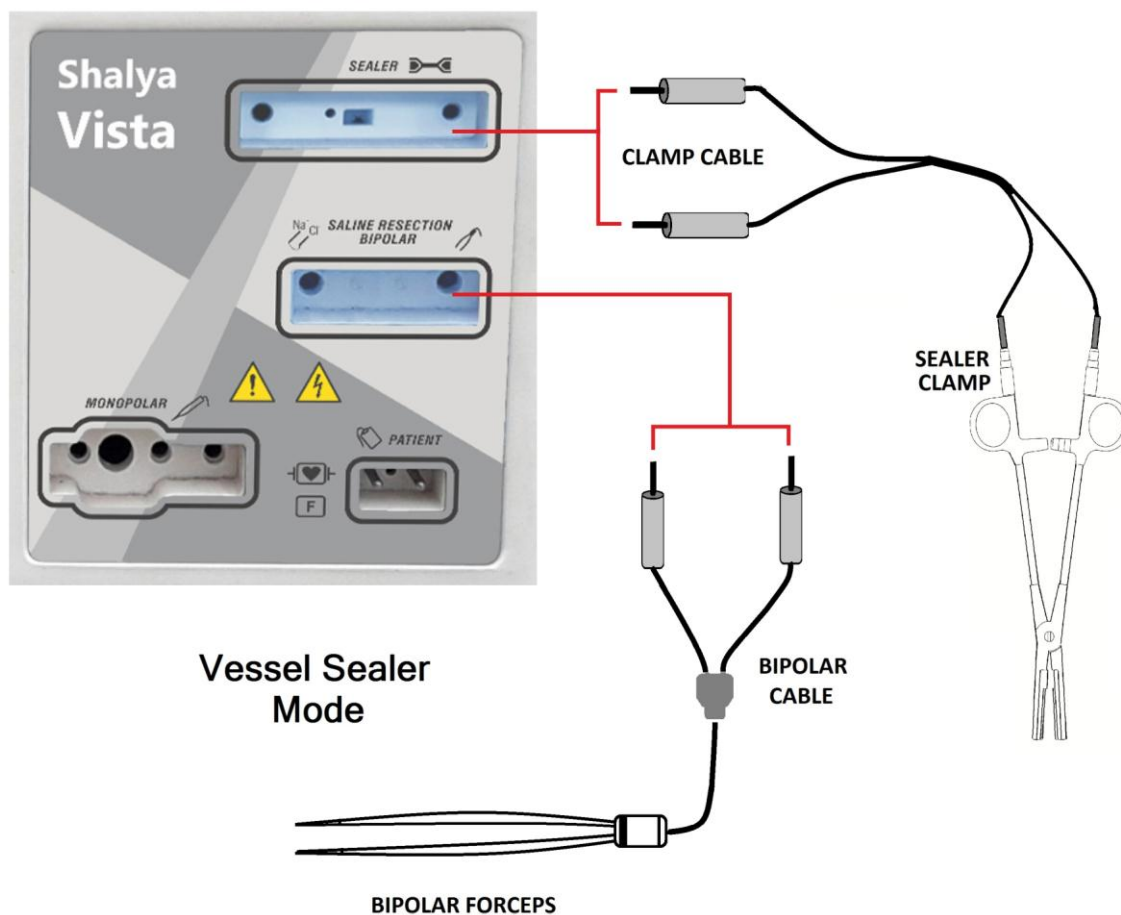
- In Vista double footswitch paddle is configured for Sealer - Bipolar; by default.
- Footswitch-1 (Yellow in color) can be used for Sealer activations.
- Footswitch-2 (Blue in color) can be used for Bipolar activations.



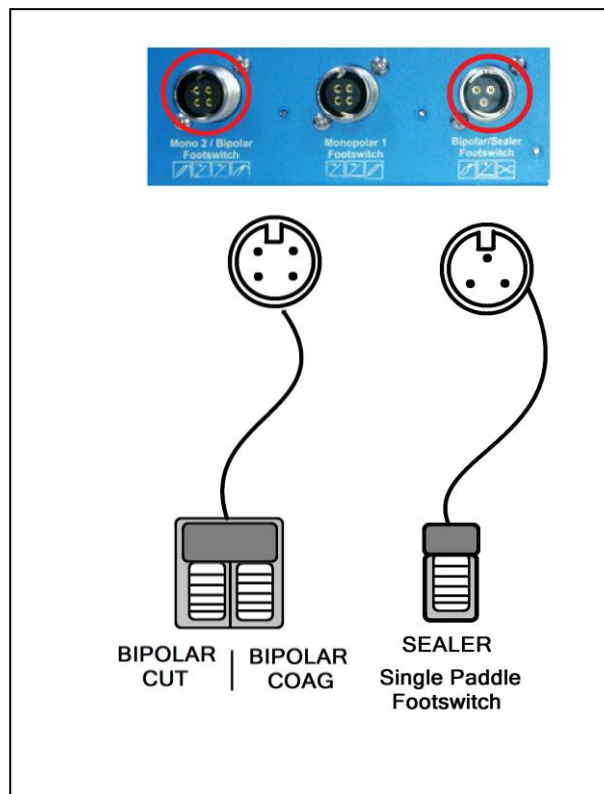
### 3. Vessel Sealer Mode in Vista/ Vista+



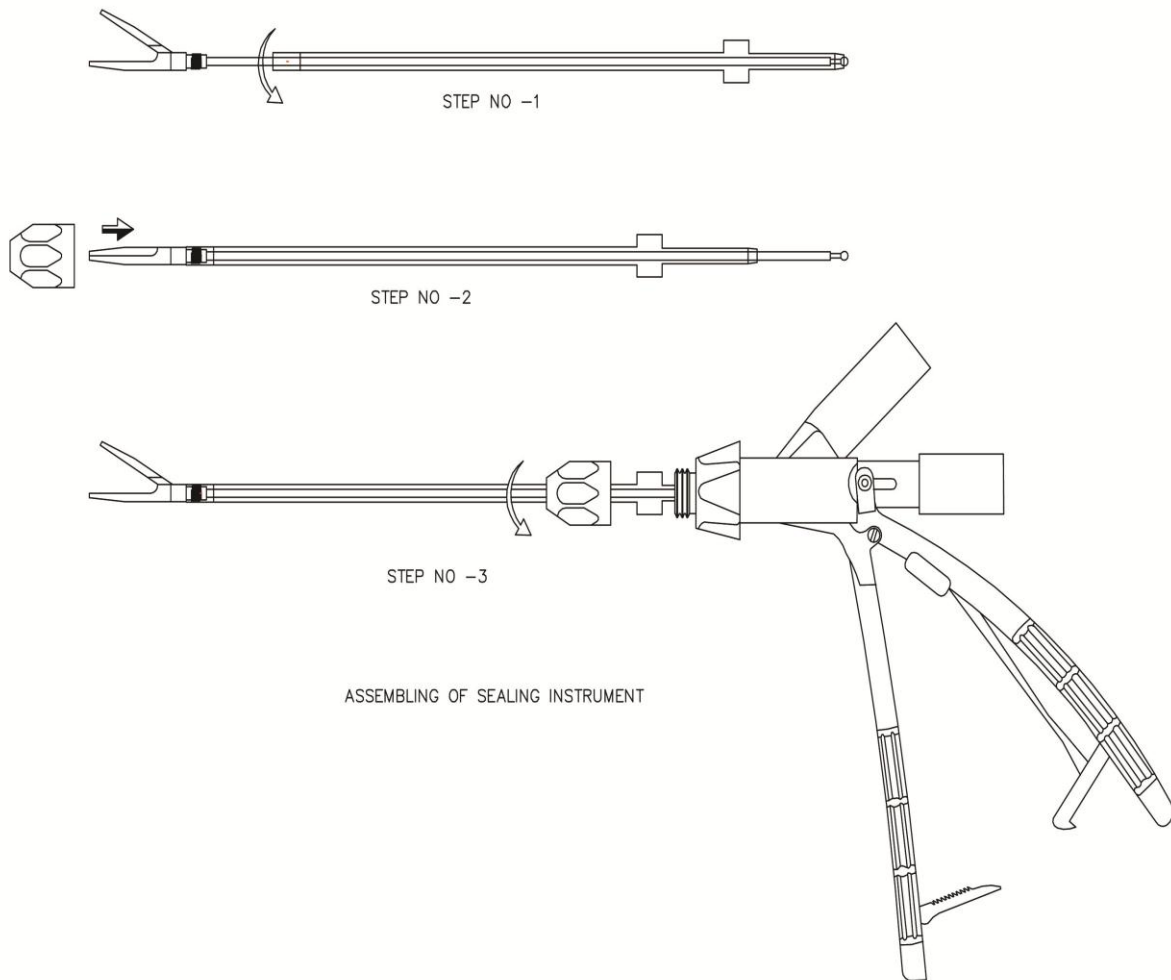
#### Accessories connection in Vessel Sealer Mode



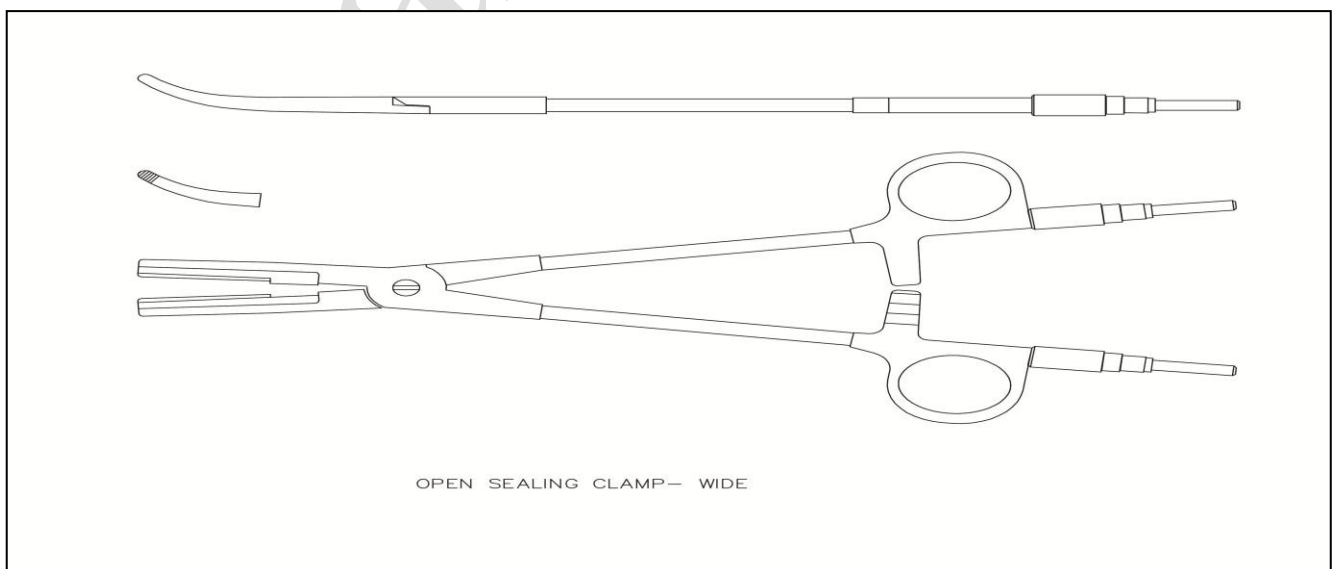
## Footswitch connection in Vessel Sealer Mode



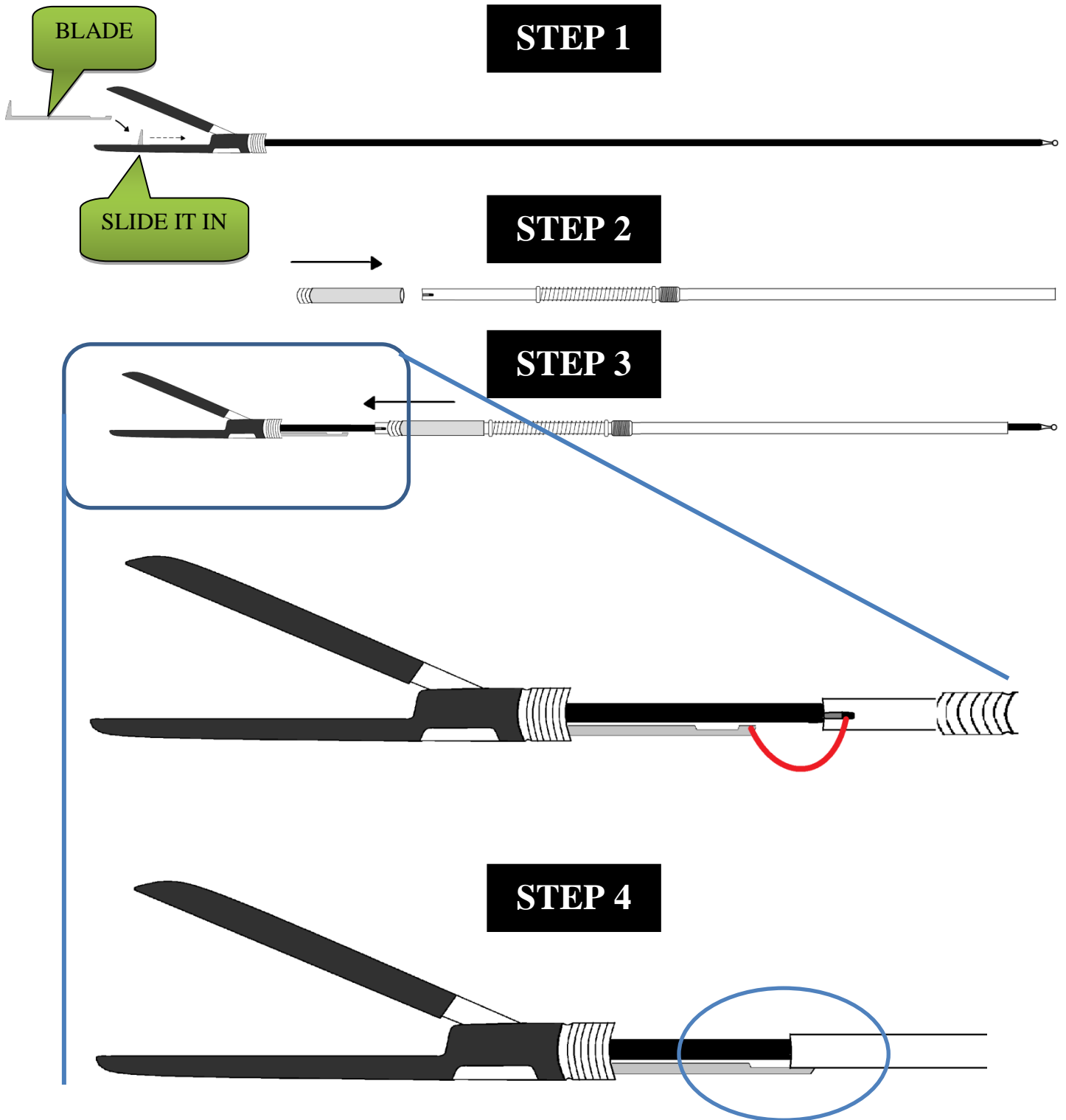


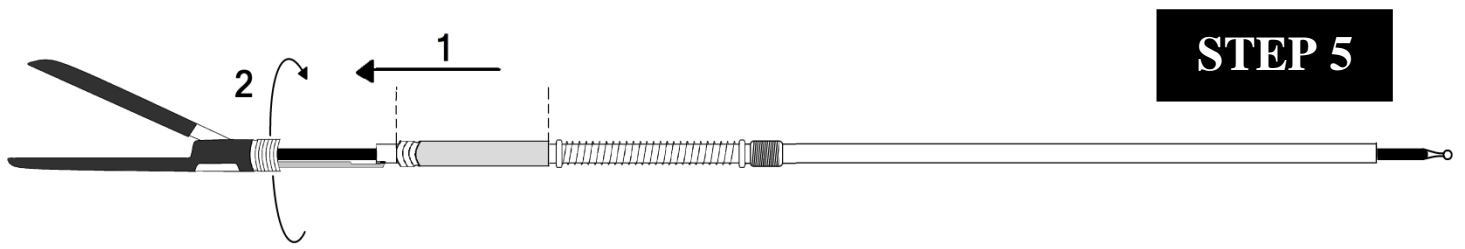


### Lapro Instrument 5mm for Sealer Mode in Vista

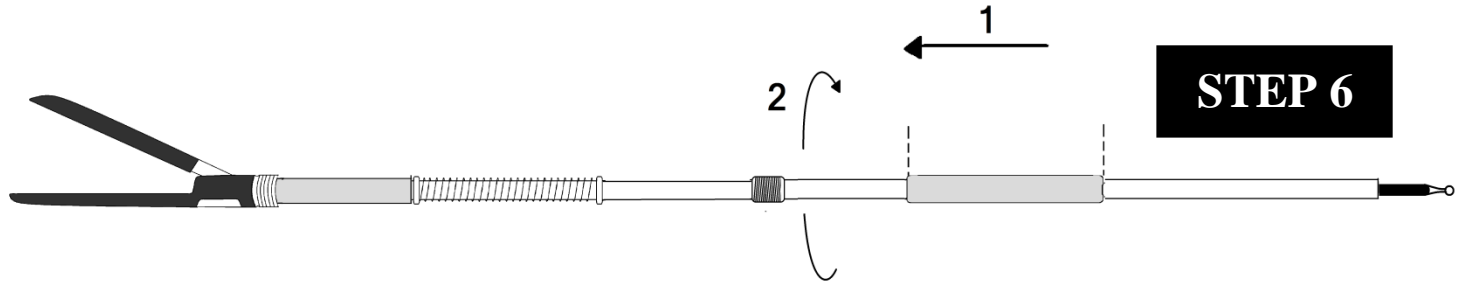


## Sealer Instrument (10mm) Assembling





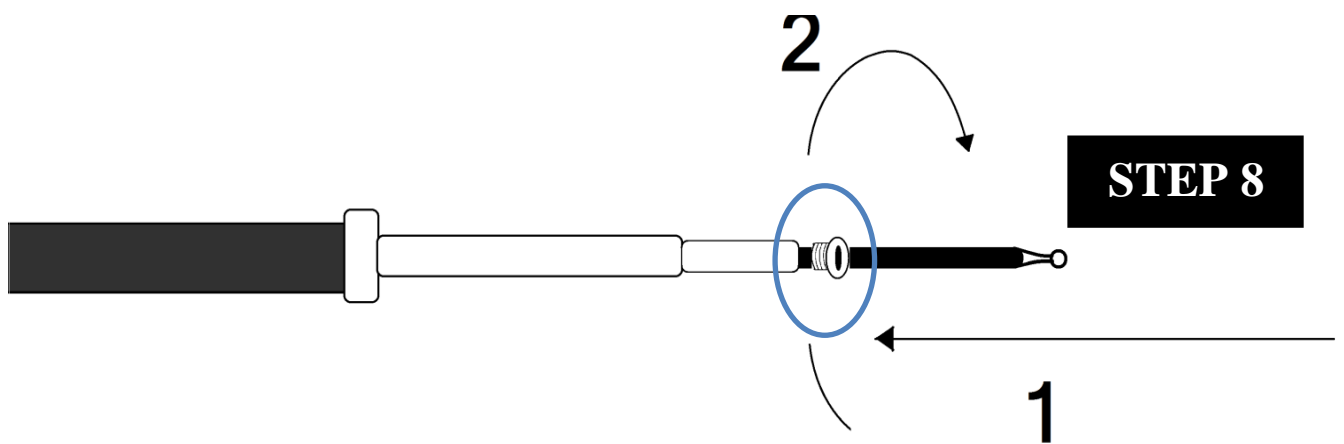
**STEP 5**



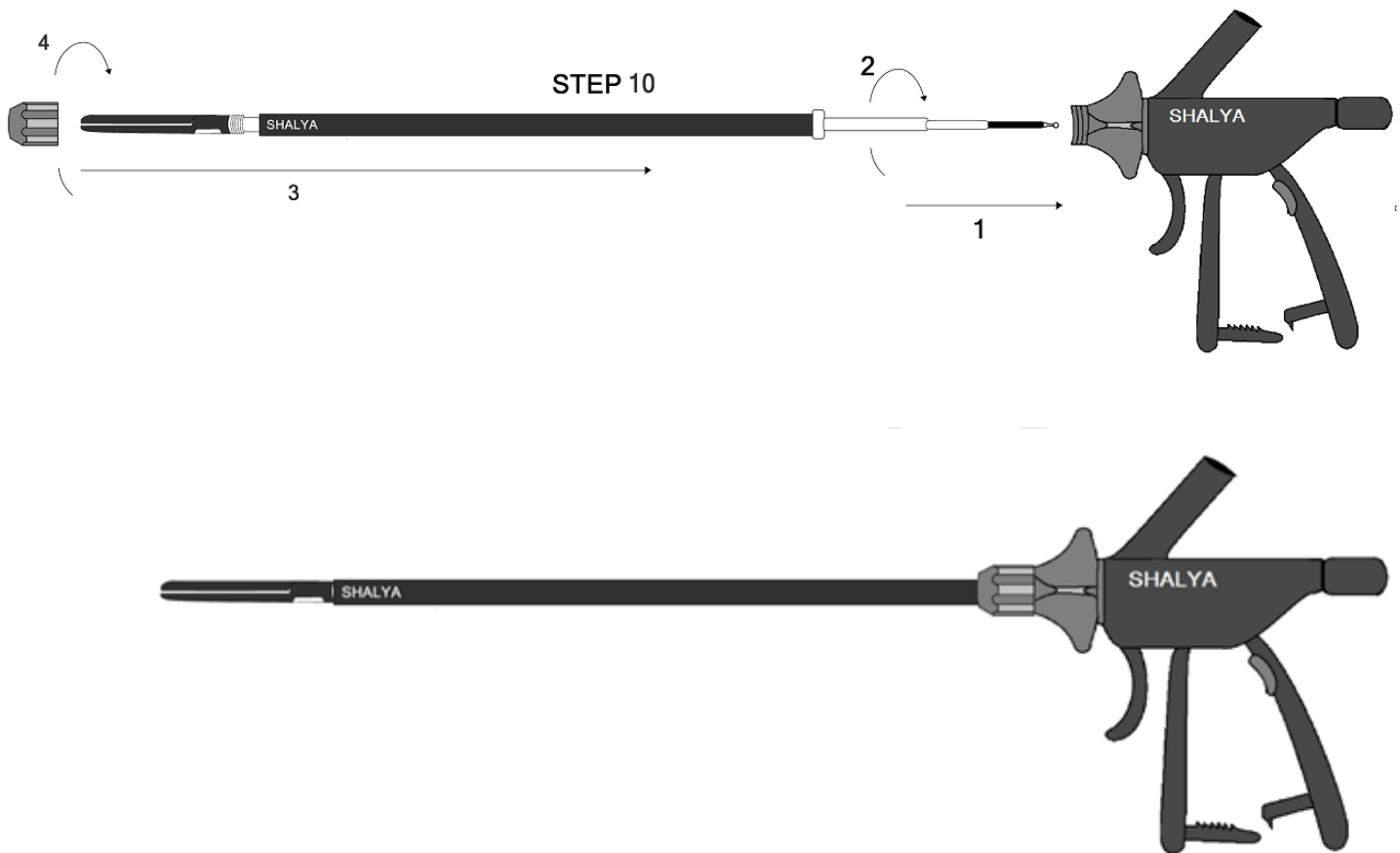
**STEP 6**



**STEP 7**



**STEP 8**

**STEP 9****Please Note:-**

- As this instrument is reusable device, the user has to always inspect the device for breakage & general tear and wear of the device before sending it for re-sterilization.
- Always check the insulation at Jaws, outer tubing insulation and inner tubing insulation for breakages and damages. Do not use the damage equipment for the further procedure.

## Vessel Sealing Instrument Guidelines

### BEFORE SURGERY:

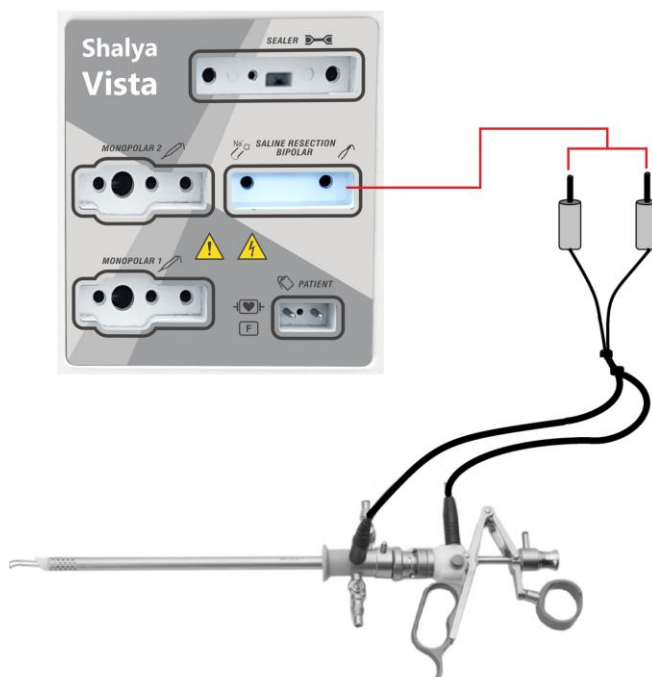
- Check all parts of Outer tubing, Blade assembly, Jaws and Insert assembly and Handle for mechanical deformities and insulation breakages. Open the Outer tubing & Blade assembly to check the proper cleaning of the instrument.
- Clean the Jaws & Hinge areas by using H<sub>2</sub>O<sub>2</sub> followed by any permissible disinfectant as per the operation theatres norms.
- Make sure that there is no tissue left inside the hinge areas & blades assembly tubing. This can damage the instrument during next use.
- In case of using non sterilized blades, assemble the instrument with blade earlier to packing the instrument for sterilization.
- Cover all the parts and assembly separately in the cloth as open assembly may damage the insulation of other parts during sterilization.
- Pack all covered assembly in one bunch and send it for sterilization.

### DURING SURGERY:

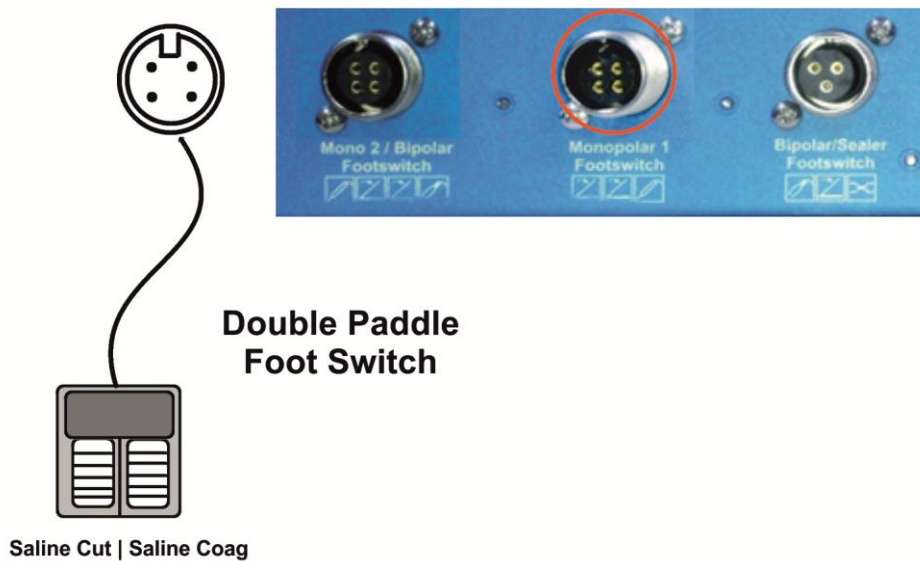
- Blade is an incisive element. Always handle the blade cautiously.
- Do not use Normal Saline (NS) to clean the instrument at any stage. Usage of Saline could result in failure of the instrument.
- Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting to blood loss during surgery.
- Prepare the cleaning solution with 50% H<sub>2</sub>O<sub>2</sub> & 50% permissible disinfectant (like Betadine) for cleaning the fat and tissue deposition on jaws during surgery.
- **DO NOT USE NORMAL SALINE (NS) FOR CLEANNING OF THE INSTRUMENT DURING THE SURGERY**
- Open the sterilized bunch of the instrument in sterilized field in OT (Operation Theatre); open the cloth cover of all the assembly.
- Inspect all assembly for physical damage and insulation failure during sterilization.
- Assemble the instrument as per the assembly instruction and check the functioning before using it in surgery.
- Do the periodic cleaning of jaws by the preparing cleaning solution 50% H<sub>2</sub>O<sub>2</sub> & 50% permissible disinfectant.
- In case of incomplete sealing or alarm condition, do not activate the blade.
- Sealing instrument may not be suitable for sealing the arteries below 1mm due to functional behavior. Use other instrument in such case.
- Do not use the device in blood reach environment & do not give wash of Saline till procedure completes; as vessel sealing do not function in conductive medium.
- In case of open re-hold (OP re Hold) alarm, check instrument assembly & the cable connection, also hold the tissue properly in the device to restart the sealing cycle. If this problem persists, please call us for the technical help.
- In case of close re-hold (CL re Hold) alarm, check the instrument assembly, any metal object/ clips in the jaw during sealing **or** short circuit in jaws **or** usage of device in presence of blood reach environment or normal saline (NS). Rectify the condition & retry sealing cycle till completion alarm sounds. If this problem persists, please call us for the technical help.
- Do not hold more than 7 mm tissue chunk for sealing as this may lead to increase in sealing cycle & lateral thermal spreading.

**AFTER SURGERY:**

- De-assemble the complete instrument, separate out the outer tubing & blade assembly, clean the jaws for internal tissue inside the hinge area, the tunings and dry the instrument by using pressurized (hot) air.
- Check the physical damages to the insulation of inner & outer tubing and also check the mechanical tear & wear at the jaws area.
- In case of any kind of damage to the device, report it to the medical engineering department for the necessary repair.
- Do not send the faulty device for next surgical use.
- Change the blade if required.
- Prepare the device for next surgery as instructed in section “Before Surgery”

**4. Saline Resection Mode in Vista/ Vista+****Accessory Connection in Saline Resection Mode**

## Footswitch Connection in Saline Resection Mode



In Saline Resection Mode, user must connect double paddle footswitch to the Monopolar 1 socket on the rear panel as shown in the figure. User can select Saline Cut III (yellow) or Saline Force (blue) depending upon the application.

## **SALINE INSTRUMENTS**

### **OPTION-I**

Luer lock adapter & conventional monopolar working element for bipolar resection

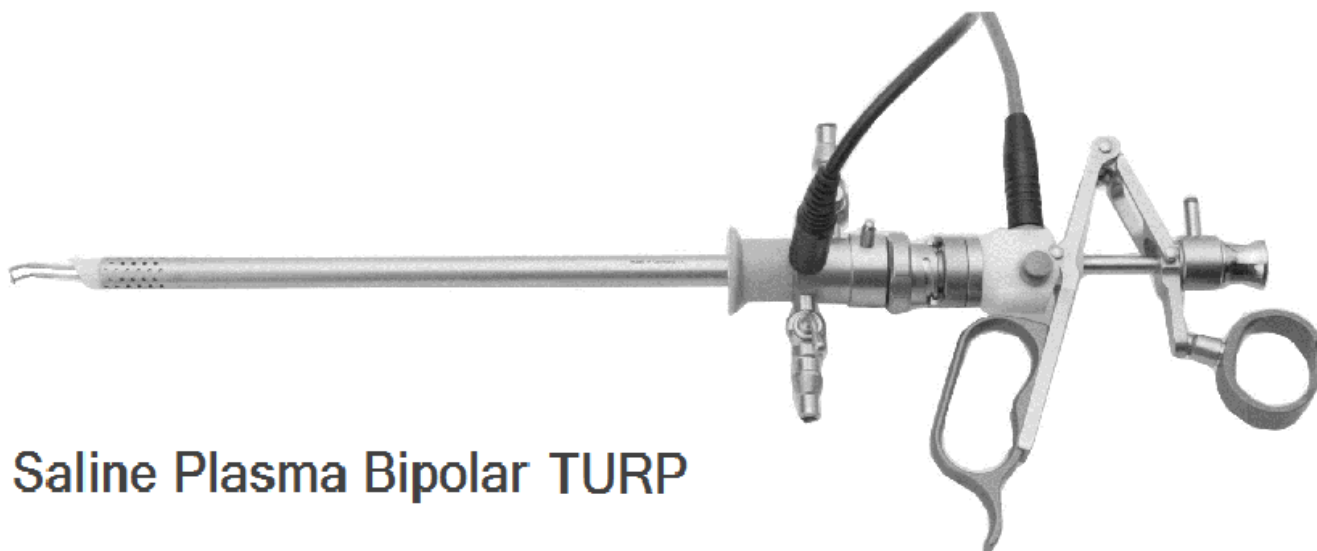


**Shalya Luer Lock Adapter**

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### **OPTION-II**

Conventional monopolar working element & isolated I/O sheath for bipolar resection



**Saline Plasma Bipolar TURP**

### **OPTION-III**

Bipolar working element with or without isolated sheath.



**BIPOLAR WORKING ELEMENT ASSEMBLING:-**

Let's divide assemblies into two:-

Assembly 1 & Assembly-2

**EQUIPMENTS**

**Active Bipolar Working Element**



**Isolated Sheath**



**Sheath Insert**

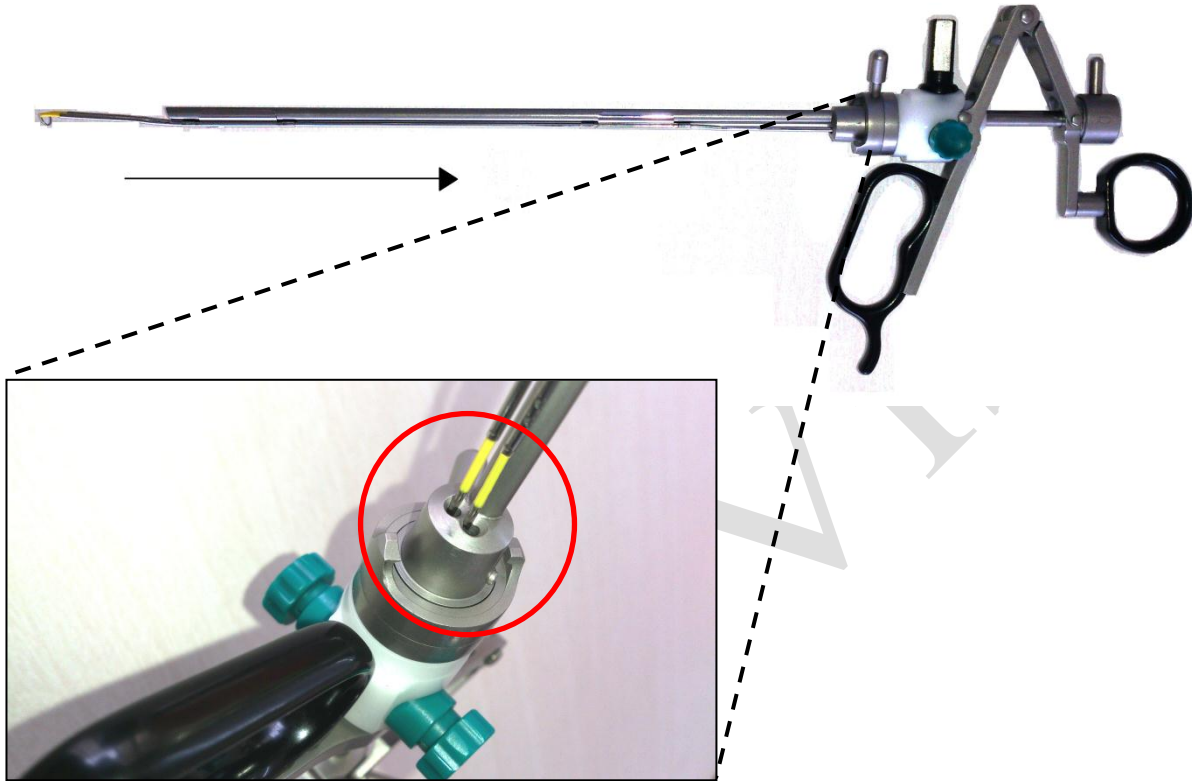


**Bipolar Loop**

## ASSEMBLY 1

### STEP-1

Attach **Bipolar loop** with **Active Bipolar working element** longitudinally as shown in the picture below. Carefully insert loop wires into respective holes & gently press it, as shown in picture.



### STEP-2

Gently press bipolar loop against working element & tighten the screws (in the direction as shown in figure beside) to firmly attach bipolar loop with the working element. While doing so do not retract the working element.

Once tightened check connection by retracting the working element. As shown in the figure beside.

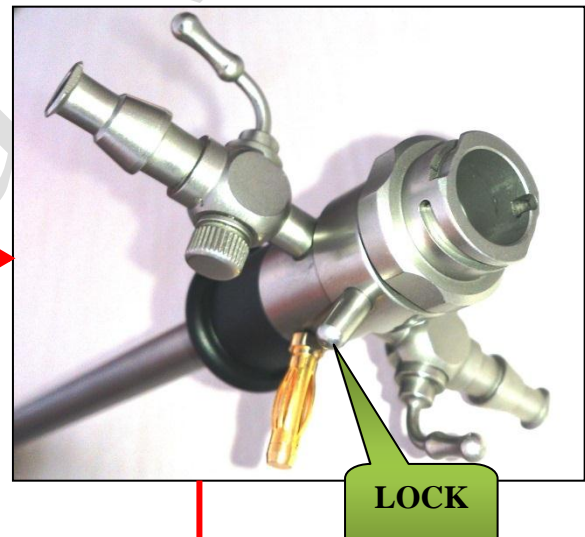
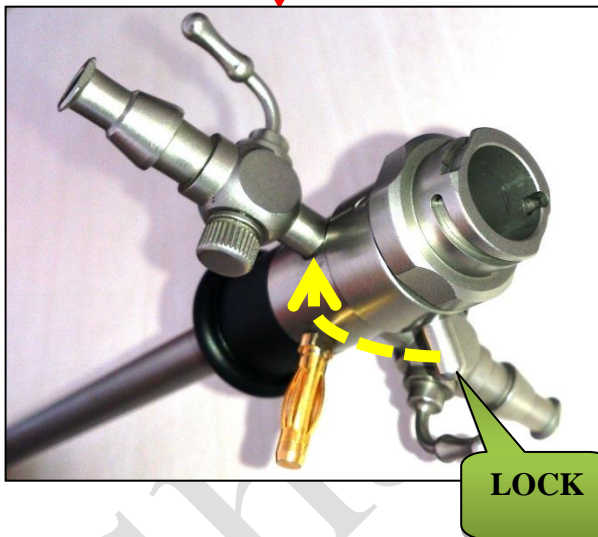
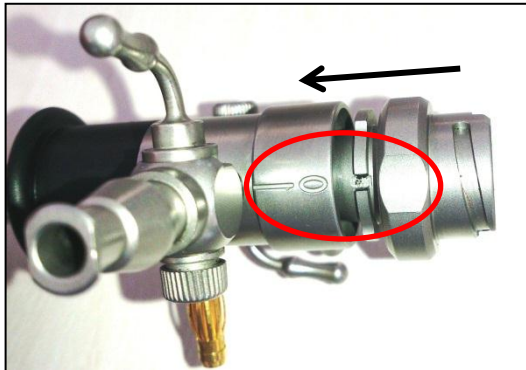


## ASSEMBLY 2

### STEP 3

Insert *Sheath insert* in *Isolated Sheath* as shown in figure.

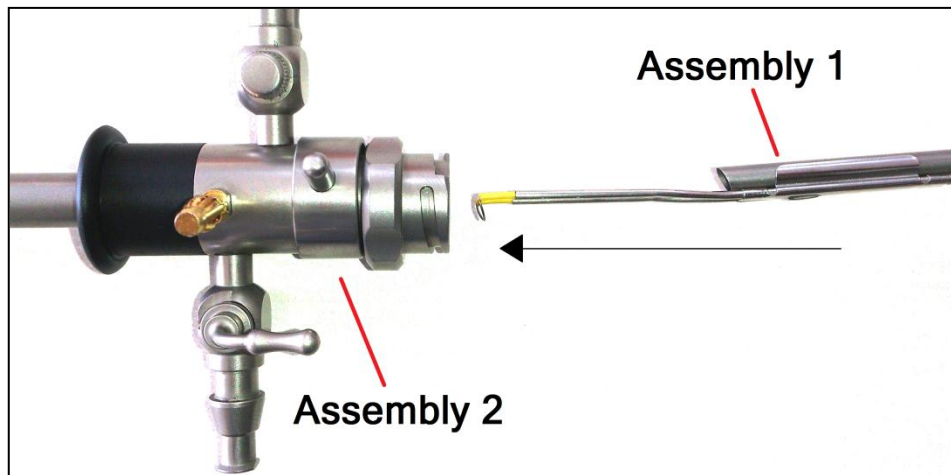
Match the '0' on *isolated sheath* with slot on the *sheath insert* then press it and lock the assembly.



## JOINING ASSEMBLY-1 & ASSEMBLY-2

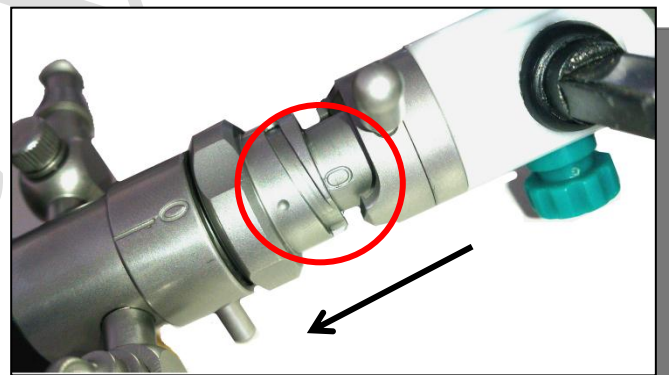
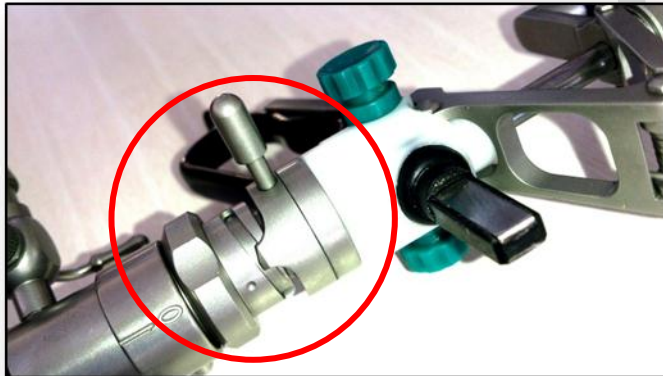
### STEP 4

Insert assembly 1 into assembly 2 carefully, as shown in figure below.



### STEP 5

Match the '0' on *Assembly 1* with the 'notch' on *Assembly 2* & insert it completely then lock it as shown in the figure below.





**Prepare the connector cable for steam sterilization according to the following cleaning procedure:**

- Remove all the residues of blood, tissue and other objects by wiping (do not use abrasive material) the Connector Cable with a cloth in a mild cleaning solution or detergent capable of removing organic deposits. Do not use reprocessing solutions.
- Rinse thoroughly in running water.
- Remove any residues further by cleaning agents with a water damp cloth.
- Dry the device thoroughly before sterilizing. Sterilize the connector cable according to the sterilization procedure.

## 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 the generator. Ensure that the two patient return electrodes do not touch.

---

## A. PREPARING THE PATIENT RETURN ELCTRODE:

**Warning** - Do not warp cloth over return electrode as it increases the tissue resistance, more power will require for surgery.

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



**Warning** - Do not stress, strain or pressurize electrode cable under any condition.

**Caution** - It is suggested/reproved that only the user of the active electrode should activate it.

**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 & POWER SETTINGS:

### Changing the Mode:

Operator should verify the selected mode with the surgeon. You cannot change mode while the generator is active. To change the mode, release the activation. 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 new mode.

### Changing the Power Setting:

Operator should verify the power setting for the selected mode with the surgeon. One cannot be change the power setting when generator is activated. To increase the power ,release the activation select the mode, 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.

### Special Setting of the Generator:

- *Fast Setting by Recall:* Press *Recall* key to load previous setting of the generator.
- *Fast Setting by Program:* Press *Program* key to select Program for fast setting of the generator.

### Technique for keeping Power Setting Low:

1. Using a small active electrode to deliver current & less power 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 c 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) **Open Heart/CABG/Thoracic Surgery –**  
Cut Pure: 1, Coag Fulgar: 40, Bip Macro: 1
- b) **Onco/Gynac /Fatty Tissues –**  
Cut Pure: 35-45, Coag Spray: 40-50, Bip Macro: 15 to 25
- c) **Resection/ TCRE/under water Surgery –**  
Cut Pure: 90-120, Coag Fulgurate: 50-70, Bip Macro: 1
- d) **ERCP/ Papillotomy/ Polypectomy Surgery-**  
EndoCut: 30-50, Coag Fulgurate: 30-50, Bip Macro: 1
- e) **Plastic/ Neuro/ ENT/ Spine/Ophthal Surgery-**  
Cut Pure: 30, Coag Soft: 30, Bip Micro: 15-25
- f) **Lapro/GI/Ortho Surgery-**  
Cut Pure: 30-40, Coag Fulgar: 35-45, Bip Macro: 25-45
- g) **Open/Hernia/General Surgery –**  
Cut Pure: 35-45, Coag Fulgurate: 35-45, Bip Macro: 15 to 25

## E. ALARM CONDITIONS:

### 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 in alarm condition, the indicator blinks. 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 with or without activation.
3. The contact area is reduced due to movement, loss of adhesion, fluid pooling or dry gel.
4. The return electrode cord is damaged, causing excessive resistance.

### System Alarm:

When the generator senses a system alarm condition, an alarm tone sounds and the generator is deactivated. An alarm number flashes in the cut display on the front panel.

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/seal in-completion Alarm:

This alarm is generated when the held tissue is too thick to seal. Please hold less tissue and then starting sealing again.

### Saline Resection Alarms

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



## 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.

**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 procedures.
  - If the accessory is reusable, clean & re-sterilize it according to the manufacture's instruction.
3. Disconnect & store footswitch 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 & a 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.
3. Use generator only after machine is completely cleaned.

**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 clothes.
- Use distilled de-mineralized water for the final rinse.
- Hard water (high mineral contains) should not be used, it may impact the performance of the 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.
- Do not exceed 130°C during the washing and sterilization process. Cold soak sterilization is not typically recommended and, as is always necessary for all instrumentation.
- 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.

**Note: It is advisable to soak longer if protein containing material is present.**

2. Soak instruments vertically which cleans instrument thoroughly.
3. Rinse it thoroughly with tap water for 5 minutes.
4. Clean all surfaces of instrument using detergent solution.
5. Brush the surfaces using soft brush. Handle cord connectors, fittings and joints with care.
6. Use the soft brushes in up and down motion to clean completely through the lumen.
7. 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.
8. Rinse thoroughly under running distilled water for at least five minutes.

### **Vessel Sealing Instrument**

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

### **C. STORING THE GENERATOR:**

If the generator is stored at a temperature outside its normal operating range of 50 to 104°F (10 to 40°C) allow it to sit at room temperature for one hour prior to use. The generator can be stored indefinitely. You must perform specific checkout 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 of each board with circuit description.**

### A. GENERAL DESCRIPTION

- **6SENSE Technology:**

This is a recent innovation in field of advance feedback controlled Electrosurgical technology. 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.
- Less thermal damage by 50% than standard ESU's hence improves the patient recovery time.
- Reduces the risk of collateral tissue damage.
- Reduces noise in other OT equipments.
- Reduces the risk of neuro-muscular stimulation.
- Less charring and sparking hence 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 is smart to change the pause interval as tissue density changes. Hence produces fine cutting with coagulation effect.

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

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

- Starts sparking more distance 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.

- **PREM** – Ultimate safety from burns: Patient Return Electrode Monitoring – PREM is the care & safety against the return electrode site burns. This ensures burn free electrosurgery using DUAL AREA Return electrode by continuously monitoring the contact quality with the patient. PREM system gives an audio-visual alarm and stops the RF output before critical situation arises.

- **Auto Bipolar:** This is the unique feature of which system can deliver automatic bipolar output by sensing the tissue & stops the power delivery when tissue gets completely coagulated. This function can work 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 footswitch is required in this mode hence provide flexibility in using bipolar energy.

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

## B. BLOCK DIAGRAM & DESCRIPTION

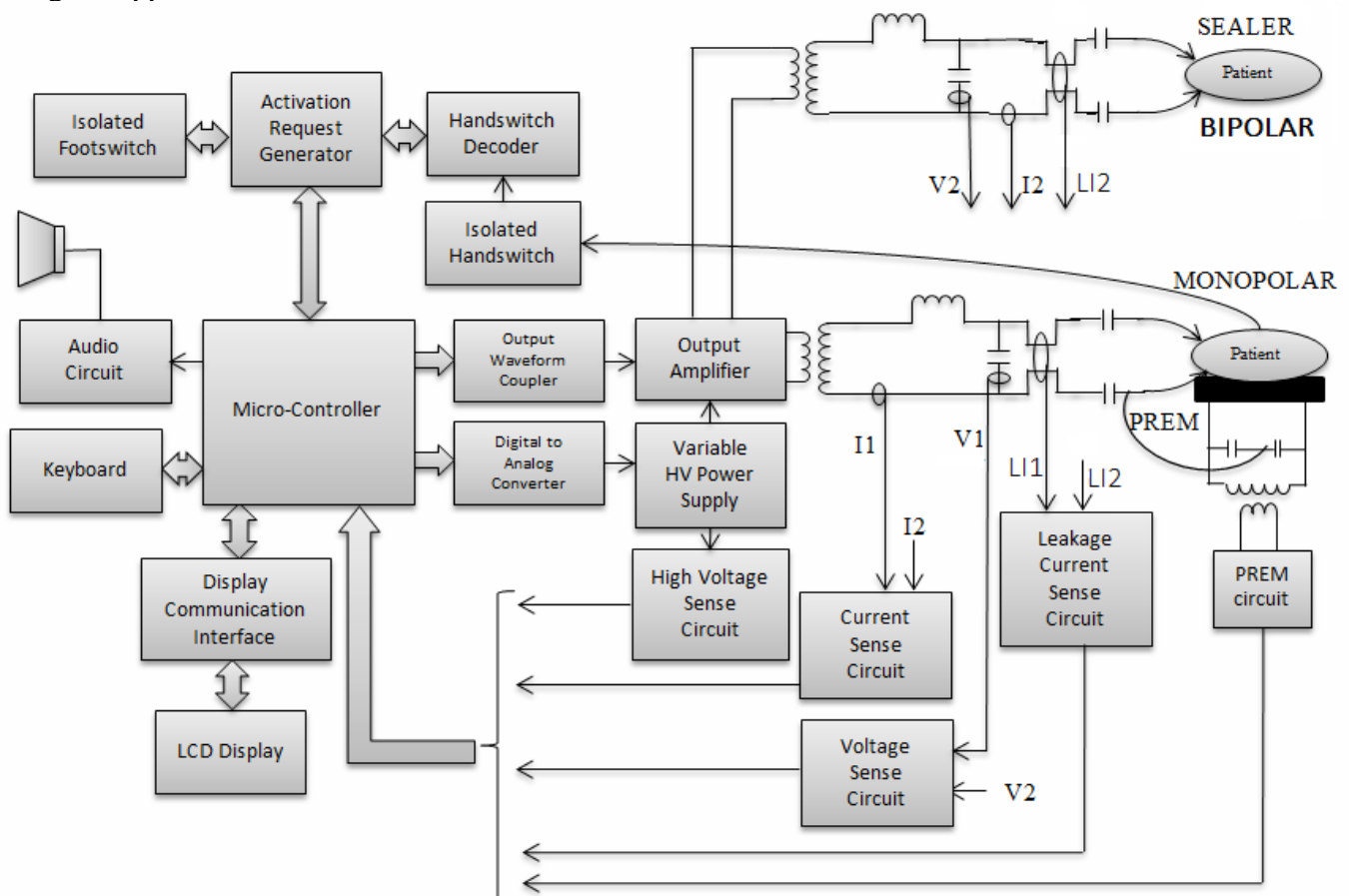
System is divided in three basic parts:

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

**Processor & Control circuit:** 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 set power settings, power supply delivers the necessary power as an input for the RF stage.

**RF output amplifier:** This converts the controlled dc voltage in Radio frequency as demanded by surgical applications.



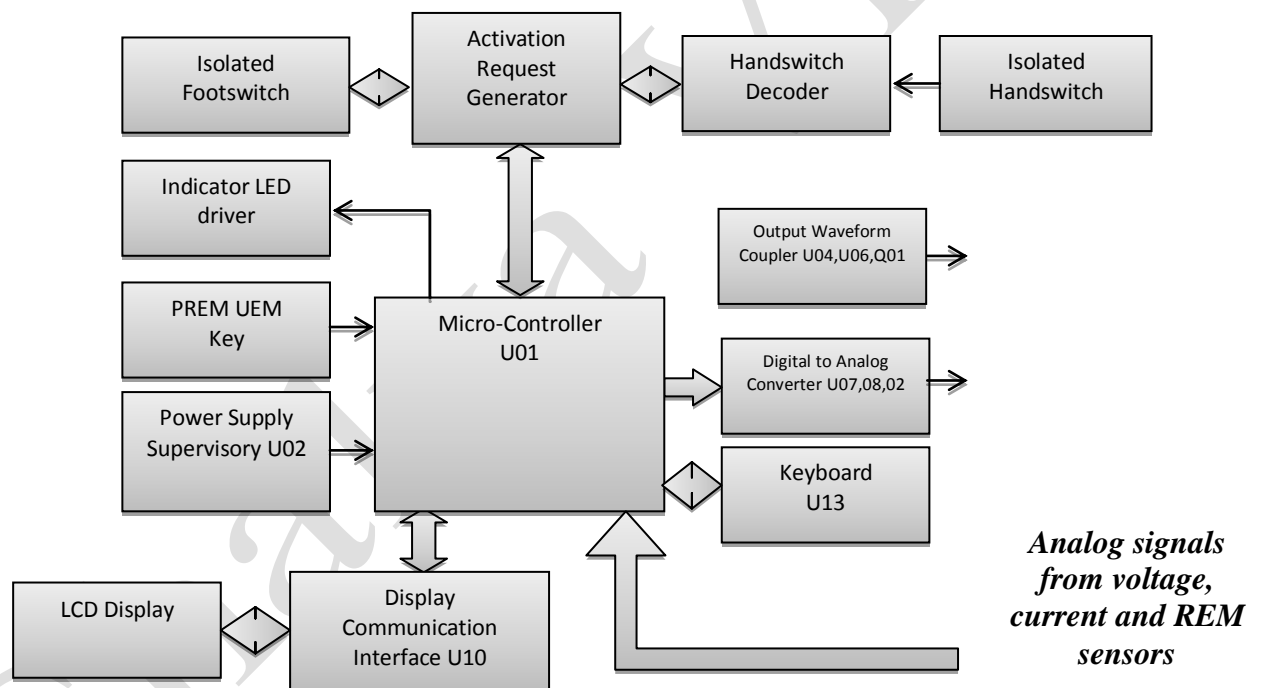
BLOCK DIAGRAM OF SHALYA VISTA

## Circuit Board Description:

### CPU and Display Board:

Processor and control board consists of –

1. **Main microcontroller:** IC U01 is main microcontroller and brain of the system, which controls overall function of a system using inbuilt I/O ports. U01 has inbuilt program memory to store the system program. 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, Power control signal & voltage control signal are derived from ICs U07 and U08. 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 main microcontroller U01. Signal conditioning is done by U04 & Q01.
4. **Analog to Digital converter:** Micro-controllers in-built 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. **Power Supply Supervisory:** IC U02 circuit monitors the fluctuation in a power supply & at the time of system shutdown it provides stand by time necessary for a system to store the crucial data.
6. **Display Circuit:** 5.6 inch touchscreen LCD Display is controlled by Display controller IC U10.
7. **Keyboard Circuit:** Front panel Key board is directly connected to the CPU. CPU continually scans for the pressed key.

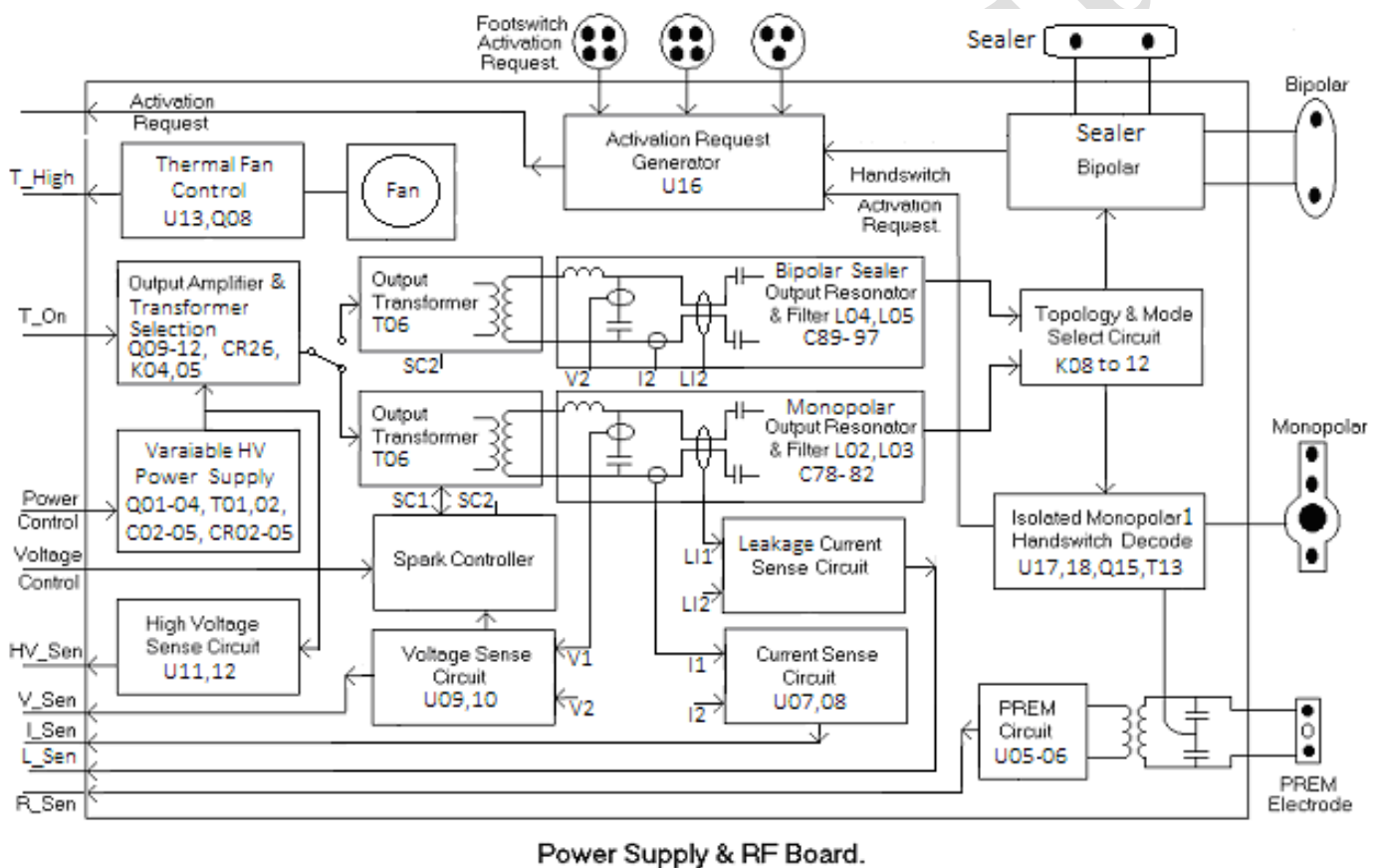
### Power Supply and RF Main Board:

This board can be divided in two parts, mains power supply and output RF stage. This board circuitry also supports for RF power delivery, handswitching logic, PREM and all other sense circuit.

1. **Variable HV power supply:** Supply voltage is converted in dc voltage by CR01 & C02 to C05 and again converted in Isolated DC voltage by using bridge converter. MOSFET Q01 to Q04

works in bridge configuration along with Transformer T03 and MOSFET are driven by T01,02 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 Transformer T02 is fed to HF bridge rectifier formed of CR02 to CR05 and filtered by L01 & C10 to C12, which produces pure dc voltage to drive RF stage.

2. **O/P RF amplifier stage:** This stage is driven by pure controlled dc voltage from HV power supply and control signal from waveform generator circuit on CPU board. For the Bipolar, Sealer o/p transformer T05 is selected & for the Monopolar o/p transformer T06 is selected by transformer selection relay K04& K05. Depending on the selected mode, the o/p transformer T05 configuration is selected by primary relay K01& K02. Output stage is driven by switching devices Q09 to Q12 at various levels. CR26 is also used to protect the device from reverse current.



3. **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 C78 to C82 forms the resonator can filter circuit, which is also used to deliver the o/p in different modes of monopolar & Inductor L04 & L05 and capacitor C89 to C97 forms the resonator can filter circuit, which is also used to deliver the o/p in different modes of bipolar, sealer applications.
4. **Configuration & mode selection circuit:** This circuit is used to obtain the RF o/p at required channel. Relays K08 to K12 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. In bipolar mode return electrode circuit & monopolar channel is isolated from RF by this circuit.

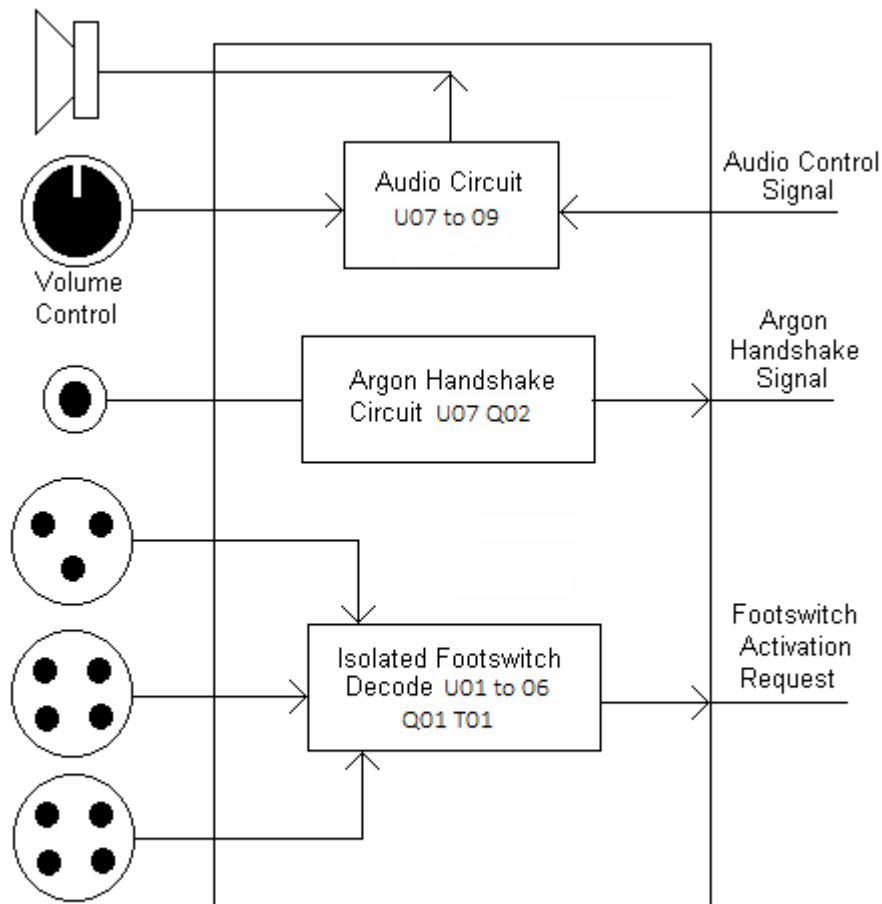


5. **Monopolar Handswitch Decode:** Handswitch decode circuitry works on floating principle. IC U17 & U18 is used for detecting the activation request if any. This circuitry is powered by isolated power supply separated for each channel. Activation requests pass on to activate request generator.
6. **Activation Request Generator:** This circuit keeps watch on activation request from foot or hand controlled accessories. IC U16 generates the necessary signals for CPU to start the process for RF delivery depending on the selected mode & the channel.
7. **Thermal fan control circuit:** This circuit keeps watch on internal temperature in unit. This makes the cooling fan on & off depending on the internal temperature .If the temperature raised beyond limit; it gives the Hi- temperature alarm signal to CPU, with error code and stops RF power delivery.
8. **PREM Circuit:** Patient Return Electrode Monitoring circuit consists of IC's U05 to U06 and series transformer T04. Contact quality resistance is reflected in the form of voltage, which is sensed by CPU. Sensing frequency is around 80 KHz & tuning can be done by adjusting preset RP01.
9. **Leakage sense circuit:** Current flows from active electrode and 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 safe limit.
10. **RF current sense:** Actual RF o/p current is sensed by current sense T08, T11 and IC U07 & U08 converts the current in average value, which is sensed by CPU as I- sense.
11. **RF voltage sense:** O/P voltage is sensed by voltage sense T07, T10 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.
12. **High voltage sense circuit:** This circuit continuously monitors that RF HV is not crossing the limit. This senses the voltages in primary side of RF and converts in dc by True RMS detector of U13 & U14. CPU sense this as HV senses signal.
13. **Spark control circuit:** When accessory is moved from high load to lighter load, it generates very high sparks. This condition is not detectable by the CPU. External hardware checks the sparking condition & apply damping network in primary RF circuit. This drastically improves the performance of the system in this transitional condition.

### Footswitch and Audio Board:

Is divided in three sections:

- **Isolated footswitch decode logic:** This circuit checks the footswitch activation input with isolated supply hence provides maximum safety to user. Q01 & T01 produce necessary isolated voltages and U01 to U06 detect 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 U07 to U09. Signals are fed to speaker SPK 01 & audio volume can be controlled by control knob Kp01.
- **Argon Handshake circuit:** This circuit of IC U07 & Q2 shares system ready status with Argon delivery can be immediately stopped if ESU gives Error signal.



### Footswitch & Audio 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 only with 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 Shalya Vista or do not place the generator on top of other electrical equipment. These configurations do not allow for adequate cooling.
- Caution -** 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 periods of time.
- Caution -** According to the procedures 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 to the 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 Shalya Vista 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 - When 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 – per IEC 60601-2-2,
- 100, 200, 300, 500  $\Omega$ , all 250 watt, 1% tolerance, non-inductive

Inspecting the Generator and Accessories:

**Equipments**

Bipolar & Monopolar footswitch

Bipolar instrument cords (footswitching)

Monopolar instrument cords (handswitching and footswitching)

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

**Rear Panel**

1. Check the rear panel footswitch sockets for obstructions or damage. Check for a secure fit by inserting the bipolar footswitch or monopolar footswitch connector into respective socket.
2. Remove the fuse and verify correct voltage and current rating.
3. If either connection is loose, replace the footswitch board.

**Front Panel**

1. Check the bipolar instrument socket for obstructions or damage. Insert the bipolar instrument connector (footswitching) 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 (footswitching and handswitching) 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.

**Footswitches**

1. Remove the footswitches from the generator.
2. Disassemble the footswitches connector. Inspect the connector for damage or corrosion.
3. Reassemble the footswitches connector.
4. Inspect the footswitches for damage.
5. Reconnect the footswitches 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

1- Phillips screwdriver

1. Turn OFF (0) the generator by pressing the front panel power switch.
2. Loosen the chassis screws. Lift the cover off the chassis. Set the cover aside for reinstallation.
3. Verify that all connectors are firmly seated.
4. Inspect each board for damaged components, wires, cracks, and corrosion.
  - If you find evidence of damage on the CPU Board, Display Board or Footswitch Board, replace the board.
  - If you find evidence of damage on the Power Supply /RF Board, replace the board only if the damage is severe.
5. 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 six months

### Equipment

- Two small test cables (less than 24 inches long) with banana plugs
- Current transformer
- True RMS voltmeter
- 100,300, and 500  $\Omega$  1% noninductive power resistors
- Bipolar and monopolar footswitches

### Checking the Bipolar Output

1. Verify that the generator successfully completes the self-test.
2. Connect the test equipment for bipolar output.
  - a. Connect the two test cables to the bipolar socket.
  - b. Pass one test cable through the current transformer and connect the current transformer to the voltmeter.
  - c. Connect the 100  $\Omega$  power resistor across the output jacks at the end of the test cables.
  - d. Connect the bipolar footswitch to the Bipolar Footswitch socket on the rear panel.
3. Select the Micro mode and set the bipolar power to 10.
4. Test the output current for the selected bipolar mode.
5. Select the Standard mode and repeat the step 4.
6. Select the Force mode and repeat step 4.
7. Select the Macro mode and repeat step 4.
8. Select the Bicut mode and repeat step 4. Follow this procedure for every mode.
9. Verify that the generator output for each mode is  $316 \pm 16\text{mA rms}$ .

If the output is outside the specified range, calibrate the bipolar output as described in calibration step 4.1. Then repeat this procedure. If the output for one or more modes remains outside the specified range, call the *XcelLance Medical Technologies Pvt. Ltd.* Service Center.

## Checking the Monopolar Cut Output

Check the output for the cut modes.

1. Verify that the generator successfully completes the self-test.
2. Connect the test equipment for monopolar output.
  - a. Connect one test cable to the left jack in the Monopolar 1/UEM socket. Pass the test cable through the current transformer and connect the current transformer to the voltmeter.
  - b. Use a test cable to short the two pins on the Patient (return electrode) socket.
  - c. Connect the second test cable from the voltmeter to both pins of the Patient (return electrode) socket.
  - d. Connect the 300  $\Omega$  resistor across the output jacks at the end of the test cables.
  - e. Connect the monopolar footswitch to the Monopolar 1 Footswitch socket on the rear panel of the generator.
3. Select the Pure mode.
4. Press the cut up/down keys to set the cut power to 80 watts.
5. Test the monopolar cut output.
  - a. Press the footswitch cut pedal and, while activating the generator, note the output on the voltmeter.
  - b. Release the footswitch pedal.
  - c. Based on the voltmeter setting and the current transformer you are using calculate and record the output current.
6. Select the Low cut mode and repeat step 5.
7. Select the Blend1, Blend2 & Hydro mode and repeat step 5. Follow this procedure for every mode.
8. Verify that the generator output for each mode is  $516 \pm 26$  mA rms.
9. If the output is outside the specified range, calibrate the monopolar output as described in calibration steps 4. 2. Then repeat this procedure. If the output for one or more cut modes remains outside the specified range, call the *XcelLance Medical Technologies Pvt. Ltd.* Service Center.

## Checking the Monopolar Coag Output

Check the output for the coag modes.

1. Disconnect the 300  $\Omega$  resistor and replace it with the 500  $\Omega$  resistor.
2. Select the Desiccate mode.
3. Press the coag Up/Down keys to set the coag power to 80 watts.
4. Test the monopolar coag outputs.
  - a. Press the footswitch coag pedal and, while activating the generator, note the output on the voltmeter.
  - b. Release the footswitch pedal.
  - c. Based on the voltmeter setting and the current transformer you are using calculate and record the output current.
5. Select Press the Fulgurate mode and repeat step 4.
6. Select Press the Swift, Spray, Hi-Spray mode and repeat step 4. Follow this procedure for every mode.
7. Verify that the generator output for each mode is  $400 \pm 20$  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 *XcelLance Medical Technologies Pvt. Ltd.* Service Center.

## Verifying PREM Function

**Equipment list**

- PREM plug
- Resistance decade box, 1  $\Omega$  resolution, 1% tolerance, 1/8 W or greater, or 50  $\Omega$  and 100  $\Omega$  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  $\Omega$  or select a 100  $\Omega$  load. Connect the resistance box to the REM receptacle, and verify that the PREM level bar is within Level 1 to Level 3. Confirm that the REM LED indicator light illuminates green.
3. Decrease the resistance to 50  $\Omega$  or select a 50  $\Omega$  load and verify that the PREM level bar is within Level 4 to Level 6.
4. Decrease the resistance to 0  $\Omega$  or short the REM pins together and confirm the REM LED indicator light illuminates red with no level bar.

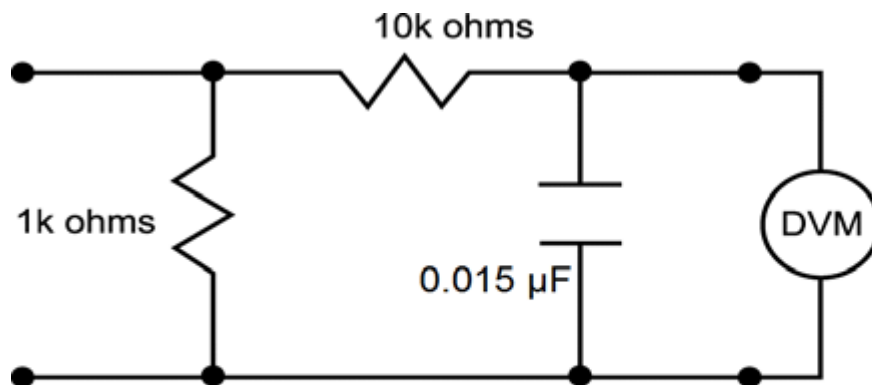
**Checking Low Frequency Leakage Current and Ground Resistance**

Check the frequency leakage current and ground resistance before returning the Shalya Vista generator 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 XcelLance Medical Technologies Pvt. Ltd. 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 XcelLance Technologies Service center. 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 XcelLance Medical *Technologies Pvt. Ltd.* 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 100 microamps. If the leakage current is greater than 100 microamps, call the XcelLance Medical *Technologies Pvt. Ltd.* Service center.
6. Verify single fault conditions (ground Open) the leakage current is less than or equal to 300 microamps. If the leakage current is greater than 300 microamps, call the XcelLance Medical *Technologies Pvt. Ltd.* 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 mains voltage through a 120k $\Omega$  resistor.
3. Connect the other side of the IEC leakage load to all the output sockets (including the PREM Patient Return Electrode 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 XcelLance Medical *Technologies Pvt. Ltd.* 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 IEC 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 XcelLance Medical *Technologies Pvt. Ltd.* Service Center.

### Checking High Frequency Leakage Current and Ground Resistance

Check the high frequency leakage current and ground resistance before returning the Shalya Vista generator to clinical use. Check the leakage current at these times.

- After calibrating the generator.
- Every six months.

### Equipment

200  $\Omega$ , 250 watt, non-inductive resistor

- Current transformer
- True RMS voltmeter (Fluke 8920 or equivalent)
- Bipolar and monopolar footswitches and handswitching accessories
- Leakage setup per IEC 60601-2-2 clause 19.101 or 19.102

### Checking Monopolar High Frequency Leakage Current

1. Connect the 200  $\Omega$  load from the 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 monopolar footswitch to the Monopolar 1 footswitch socket at the rear of the generator.
4. Activate the footswitch in each monopolar mode at the maximum control setting. Record the leakage current. It should not exceed 150 mA for any mode.
5. If the high frequency leakage exceeds 150 mA, call the *XcelLance Medical Technologies Pvt. Ltd.* Service Centre for further instructions.

**Checking Patient Return High-Frequency Leakage Current**

1. Connect the 200  $\Omega$  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 footswitch to the footswitch socket at the rear panel of the generator.
4. Set the footswitch in monopolar mode
5. Activate the footswitch in each monopolar mode at the maximum control setting. Record the leakage current. It should not exceed 150 mA for any mode.

If the high frequency leakage exceeds 150 mA, call the *XcelLance Medical Technologies Pvt. Ltd.* Service Center for further instructions.

**Checking Bipolar High Frequency Leakage Current**

1. Remove the monopolar accessories, and connect the 200  $\Omega$  load from one side of the bipolar output through the current transformer to the equipotential ground lug on the rear of the generator.
2. Connect the current transformer to the true RMS voltmeter.
3. Connect a bipolar footswitch to bipolar footswitch socket at the rear of the generator.
4. Activate the footswitch in each mode at maximum control setting. Record the leakage current. It should not exceed 60 mA for any mode.
5. If the high frequency leakage exceeds 60 mA, call the *XcelLance Medical Technologies Pvt. Ltd.* Service Centre for further instructions.

## CHAPTER 10

# Calibration Procedures

### Calibrating the Shalya Vista

For normal running Shalya Vista, program requires data constants, which are dependent on the hardware. All this data is stored in NV Ram after calibration process is completed. Calibration is recommended after:

- Changing CPU or RF main board.
- Every six months.

### 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:

#### Equipments:

- Bipolar footswitch and Monopolar footswitch.
- 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 Shalya Vista follow this procedure given below:

1. Press 'Setup' option.
2. Press the Calibration touch key to enter calibration mode.
3. Contact manufacturer for the authentication password.

After successful authentication machine will successfully enter in a calibration mode.

You can enter in calibration mode simply by pressing on the calibration touch key.

### 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).



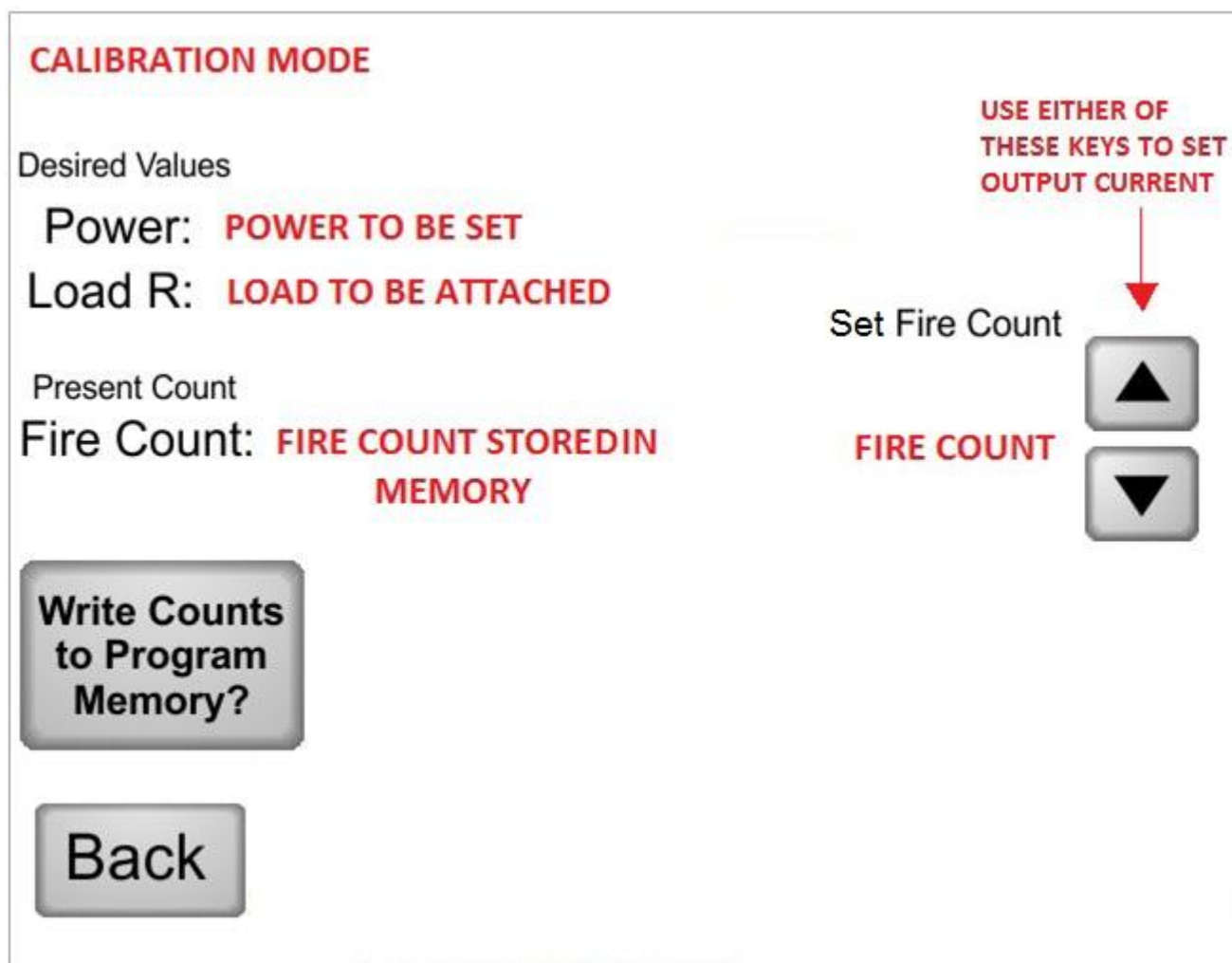


Figure 1

## 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 power socket and connect appropriate substitution resistor as indicated by 'Load R' on the screen, across the PREM socket.
- 3) Press single paddle(Bipolar/sealer) footswitch for at least 3-seconds activation to get Fire count reading, once reading is displayed on the screen press 'Write counts to program memory' to store the acquired count.
- 4) Once the memory write operation is successful press Back touch key.
- 5) Follow the same Steps (1 to 4) for '1:2 REM Max'

*Please Note: Load R is different for 1:2 mode; it will be displayed on the screen.*

## Calibration Step 2 - Energy Calibration

XcelLance Medical Technologies recommends that only qualified personnel calibrate the Shalya Vista unit. XcelLance Medical Technologies 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.

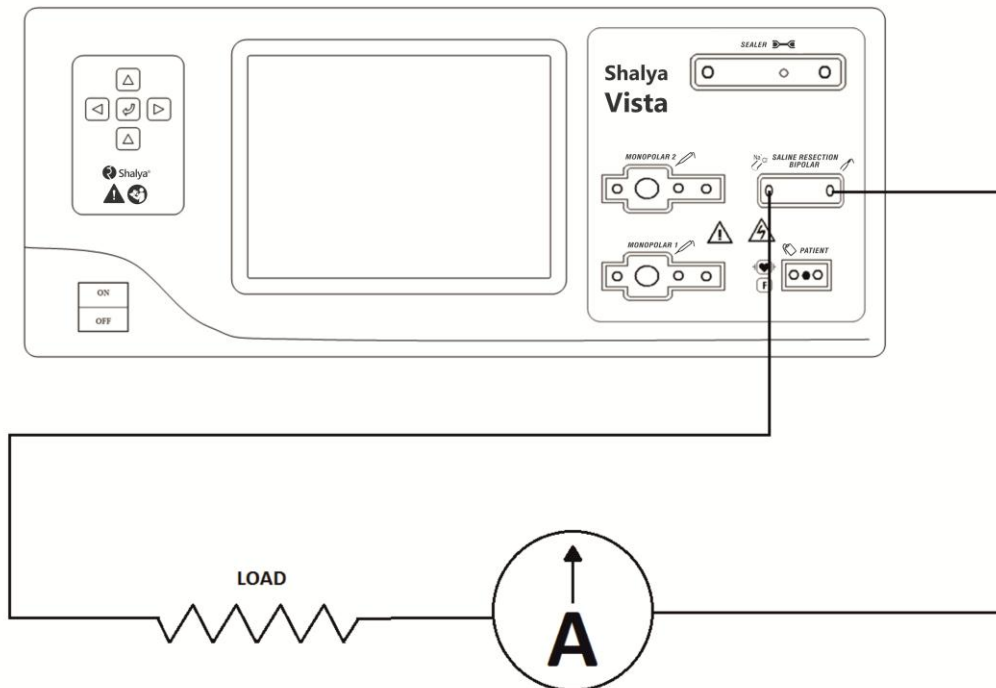
## A - Close Loop Current Calibration (I-max)

### Sub step-1(BIP mode)

#### Equipment

- Bipolar single paddle footswitch.
- Small test cables with banana plugs
- True RMS current meter.
- 10  $\Omega$  non-inductive power resistor.

#### For Bipolar



#### Verify:

- The display shows calibration mode 2:1.
- Resistor substitution box must of 10 $\Omega$ .

#### Procedure:

##### 1) Connect:

- One test cable from Bipolar socket to the RMS current meter in series with the 10  $\Omega$  resistor. (Refer the connection diagram for bipolar).
- One test cable from another Bipolar socket to a 10  $\Omega$  resistor.
- Bipolar footswitch to the bipolar/sealer single paddle footswitch socket on the rear panel.

##### 2) Check and adjust the I-max for bipolar output.

- Select mode '2:1 BIP'.
- Press the Bipolar footswitch pedal & check if current reading is equivalent to 3082 mA  $\pm$  20 mA RMS.

- c) If not then stop activation. If the output current is high decrease fire counts by pressing down touch key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) I-max for all the bipolar modes will be set automatically.

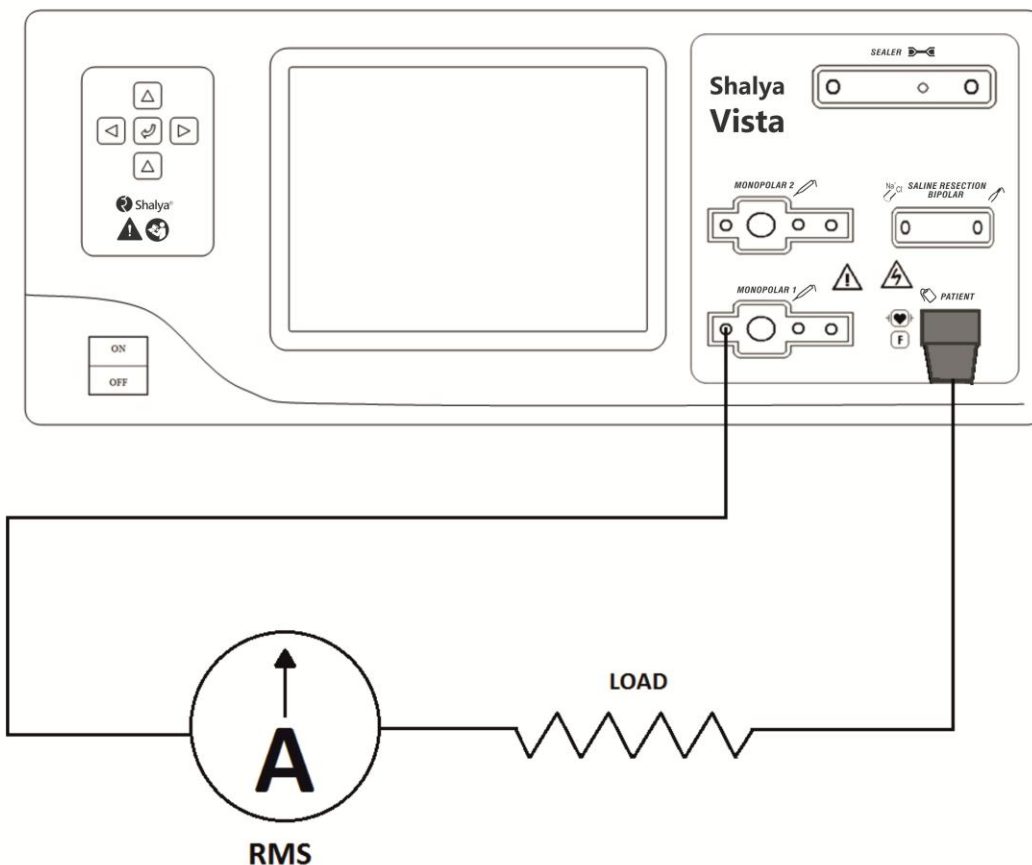
**3) Disconnect the test cables from bipolar output.**

**Sub step- 2 (Pure Cut Mode)**

**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 50  $\Omega$  non-inductive power resistor.
- PREM plug modified

**For Monopolar**



**Verify:**

- a) The display shows calibration mode 2:2.
- b) Resistor substitution box must of 50 $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from PREM socket to 50  $\Omega$  resistor. (Refer the connection diagram for Monopolar).
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with 50  $\Omega$  resistor.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the I-max for Monopolar cut output.**

- a) Select mode '2:2 Pure Cut'.
- a) Press the Monopolar footswitch pedal(yellow) and check if the current is equivalent to 1414mA  $\pm$  20 mA RMS.
- b) If not then stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up touch key.
- c) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- d) When reading is in stated range, press 'Write Counts to program memory' for storing the corresponding fire count reading in the system memory
- e) The 'I' max for Low, Hydro, Endo-1 & Endo- 2 Cut mode is set automatically.

**3) Disconnect the test cables from Monopolar output.****Sub step- 3 (Blend 1 Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 50  $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 2:3.
- b) Resistor substitution box must of 50 $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from socket PREM plug to 50  $\Omega$ . (Refer the connection diagram for Monopolar).
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with the 50 $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the I-max for Monopolar Blend 1 cut output.**

- a) Select mode '2:3 Blend 1'.
- a) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 1048 mA  $\pm$  20 mA RMS.
- b) If not then stop activation. If the output current is high decrease fire counts by pressing down touch key. If low increase it by pressing up touch key.
- c) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- d) When reading is in stated range, press 'Write Counts to program memory' for storing the corresponding fire count reading in the system memory.

**3) Disconnect the test cables from Monopolar output.****Sub step- 4 (Blend 2 Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs.

- True RMS current meter.
- 50  $\Omega$  non-inductive power resistor.

**Verify:**

- The display shows calibration mode 2:4.
- Resistor substitution box must of 50 $\Omega$ .

**Procedure:****1) Connect:**

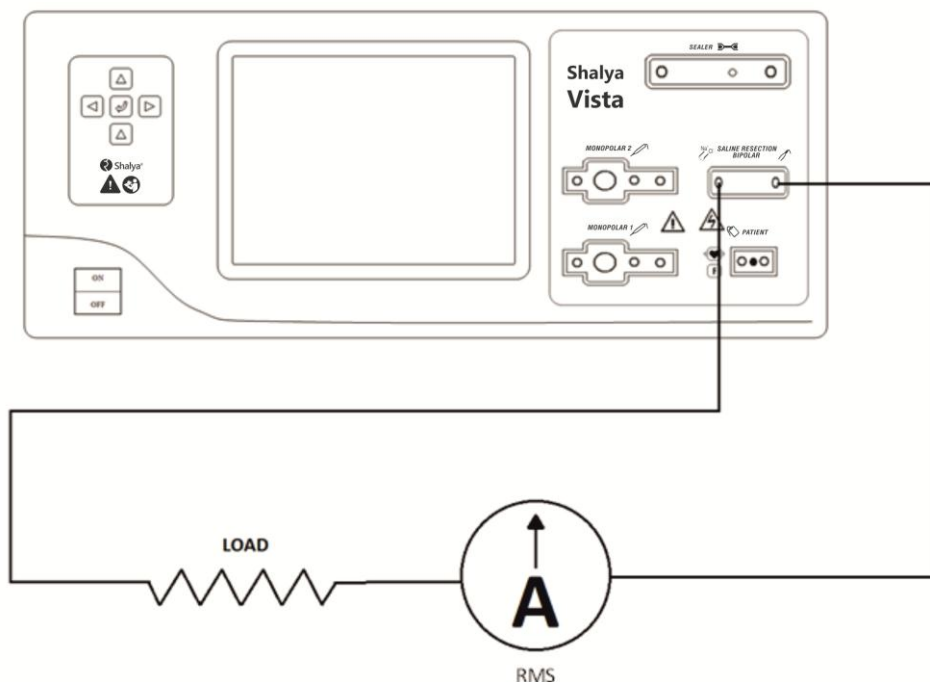
- One test cable from socket PREM plug to 50  $\Omega$  resistor. (Refer the connection diagram for Monopolar).
- One test cable from Monopolar 1 socket to true RMS current meter in series with the 50 $\Omega$  resistor.
- Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the I-max for Monopolar Blend 2 cut output.**

- Select mode '2:4 Blend 2'.
- Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 1048 mA  $\pm$  20 mA RMS.
- If not then Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

**3) Disconnect the test cables from Monopolar output.****Sub step- 5 (Saline Resection Cut III Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 300  $\Omega$  non-inductive power resistor.

**For Saline Resection**

**Verify:**

- a) The display shows calibration mode 2:5.
- b) Resistor substitution box must of 300Ω.

**Procedure:****1) Connect:**

- a) One test cable from Saline Resection plug to 300 Ω.
- b) Another test cable from Saline Resection socket to true RMS current meter in series with the 300Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the I-max for Saline Resection cut output.**

- a) Select mode '2:5 Saline Cut. (Refer the connection diagram for Saline Resection).
- a) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 816 mA  $\pm$  20 mA RMS.
- b) If not then 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) & (c) sequentially until the meter reading is not in the stated range.
- d) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- e) I-max for Saline cut I & II is adjusted automatically.

**3) Disconnect the test cables from Saline resection output.****Sub step- 6 (Saline Resection Coag Force Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 10 Ω non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 2:6.
- b) Resistor substitution box must of 10Ω.

**Procedure:****1) Connect:**

- a) One test cable from Saline Resection plug to 10 Ω. (Refer the connection diagram for Saline Resection).
- b) One test cable from Saline Resection socket to true RMS current meter in series with 10Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

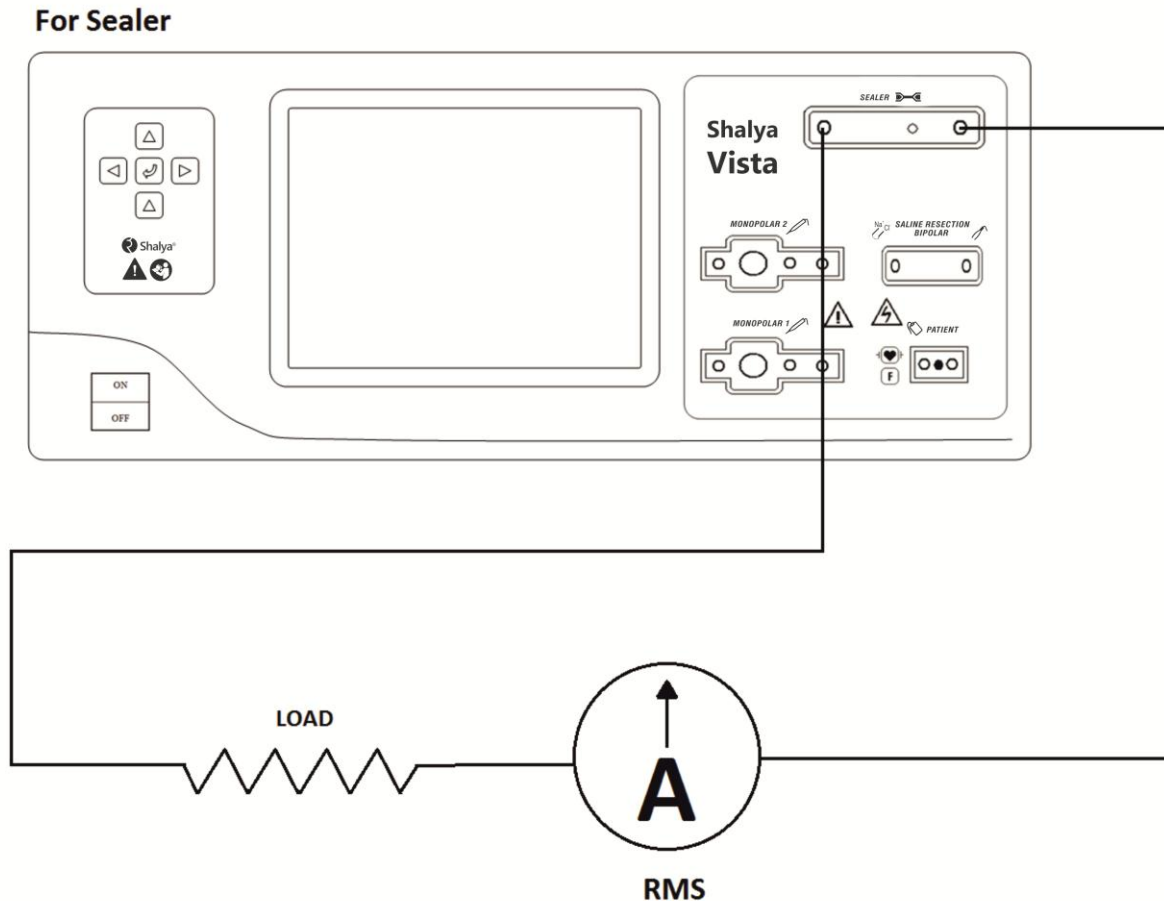
**2) Check and adjust the I-max for Saline Resection Coag output.**

- a) Select mode '2:6 BiTUR Coag.
- a) Press the Monopolar footswitch pedal(blue) and check if the current reading is equivalent to 3082 mA  $\pm$  20 mA RMS.
- b) If not then 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) & (c) sequentially until the meter reading is not in the stated range.
- d) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

e) I-max for Saline Coag Soft and Standard mode is adjusted automatically.

**3) Disconnect the test cables from saline resection output.**

**Sub step- 7 (Sealer Rapid Mode)**



**Equipment:**

- Bipolar/ Sealer footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 10  $\Omega$  non-inductive power resistor.

**Verify:**

- The display shows calibration mode 2:7.
- Resistor substitution box must of 10 $\Omega$ .

**Procedure:**

**1) Connect:**

- One test cable from Sealer socket to 10  $\Omega$ . (Refer the connection diagram for Sealer)
- Another test cable from Sealer socket to true RMS current meter in series with 10  $\Omega$ .
- Bipolar/sealer footswitch to the bipolar/sealer footswitch socket.

**2) Check and adjust the I-max for Sealer output.**

- Select mode '2:7 Seal'.



- a) Press the Bipolar/Sealer footswitch pedal and check if the current reading is to equivalent to  $3872 \text{ mA} \pm 20 \text{ mA RMS}$ .
- b) If not then 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) & (c) sequentially until the meter reading is not in the stated range.
- d) When reading is in the stated range, press 'Write Counts to program memory' for storing the corresponding fire count reading in the system memory.
- e) I-max for Sealer Fine mode is adjusted automatically.

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

### Calibration Step 3 - Close Loop Voltage Calibration (Vmax)

#### Sub step-1(BIP mode)

##### Equipment

- Bipolar/sealer footswitch.
- Small test cables with banana plugs
- True RMS current meter
- $1 \text{ k}\Omega$  non-inductive power resistor.

##### Verify:

- a) The display shows calibration mode 3:1.
- b) Resistor substitution box must of  $1 \text{ k}\Omega$ .

##### Procedure:

#### 1) Connect:

- a) One test cable from Bipolar socket to RMS current meter in series with the  $1 \text{ k}\Omega$  resistor. (Refer the connection diagram for bipolar)
- b) One test cable from Bipolar socket to  $1 \text{ k}\Omega$  resistor.
- c) Bipolar/sealer footswitch to the bipolar/sealer footswitch socket on the rear panel.

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

- a) Select mode '3:1 BIP'.
- b) Press the Bipolar/Sealer footswitch pedal & check if current reading is equivalent to  $158 \text{ mA} \pm 20 \text{ mA RMS}$ .
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) V-max for all the bipolar modes is adjusted automatically.

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

#### Sub step- 2 (Pure Cut Mode)

##### Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- $3 \text{ k}\Omega$  non-inductive power resistor.
- PREM plug modified.



**Verify:**

- a) The display shows calibration mode 3:2.
- b) Resistor substitution box must of 3k $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from socket PREM plug to 3 k $\Omega$ . (Refer the connection diagram for Monopolar)
- b) Another test cable from Monopolar 1 socket to true RMS current meter in series with the 3k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

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

- a) Select mode '3:2 Pure Cut'.
- b) Press the Monopolar footswitch pedal(yellow) and check the current equivalent to 103mA  $\pm$  5 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) The V-max for Low, Endo-1, Endo-2 & Hydro Cut mode is adjusted automatically.

**3) Disconnect the test cables from Monopolar output.****Sub step- 3 (Blend 1 Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 3 k $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 3:3.
- b) Resistor substitution box must of 3k $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from socket PREM plug to 3k $\Omega$ . (Refer the connection diagram for Monopolar)
- b) Another test cable from Monopolar 1 socket to true RMS current meter in series with the 3k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Vmax for Monopolar Blend 1 cut output.**

- a) Select mode '3:3 Blend 1'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 85 mA  $\pm$  5 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

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

**Sub step- 4 (Blend 2 Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 3k  $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 3:4.
- b) Resistor substitution box must of 3k $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from socket PREM plug to 3k  $\Omega$ . (Refer the connection diagram for Monopolar)
- b) Another test cable from Monopolar 1 socket to true RMS current meter in series with 3k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Vmax for Monopolar Blend 2 cut output.**

- a) Select mode '3:4 Blend 2'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 85 mA  $\pm$ 5 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

**3) Disconnect the test cables from Monopolar output.****Sub step- 5 (Saline Resection Cut III Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 1k  $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 3:5.
- b) Resistor substitution box must of 1k $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from Saline Resection plug to 1k  $\Omega$ . (Refer the connection diagram for Saline Resection).
- b) One test cable from Saline Resection socket passing through true RMS current meter to 1k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Vmax for Saline Resection cut output.**

- a) Select mode '3:5 BiTUR Cut'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to 273 mA  $\pm$ 5 mA RMS.

- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) V-max for Saline resection cut I & II is adjusted automatically.

**3) Disconnect the test cables from Saline resection output.**

**Sub step- 6 (Saline Resection Coag Force Mode)**

**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 1k  $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 3:6.
- b) Resistor substitution box must of 1k $\Omega$ .

**Procedure:**

**1) Connect:**

- a) One test cable from Saline Resection plug to 1k $\Omega$ . (Refer the connection diagram for Saline Resection).
- b) One test cable from Saline Resection socket passing through true RMS current meter to 1k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Vmax for Saline Resection Coag output.**

- a) Select mode '3:6 BiTUR Coag'.
- b) Press the Monopolar footswitch pedal(blue) and check if the current reading is equivalent to 200 mA  $\pm$  20 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) V-max for Saline Coag Soft and Standard mode is adjusted automatically.

**3) Disconnect the test cables from Saline resection output.**

**Sub step- 7 (Sealer Rapid Mode)**

**Equipment:**

- Bipolar/sealer footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 200  $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 3:7.
- b) Resistor substitution box must of 200 $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from Sealer socket to 200  $\Omega$  . (Refer the connection diagram for Sealer)
- b) One test cable from Sealer socket pass through true RMS current meter to 200  $\Omega$ .
- c) Bipolar/sealer footswitch to the bipolar/sealer footswitch socket.

**2) Check and adjust the Vmax for Sealer output.**

- a) Select mode '3:7 Seal'.
- b) Press the Bipolar/Sealer footswitch pedal and check if the current reading is equivalent to 866 mA  $\pm$  20 mA RMS.
- c) Stop activation. If the output current is high decrease fire Counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) V-max for Sealer Fine mode is adjusted automatically.

**3) Disconnect the test cables from Sealer output.****Calibration Step 4 - Close Loop Power Calibration (Pmax)****Sub step-1(BIP mode)****Equipment**

- Bipolar/sealer footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 100 $\Omega$  non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 4:1.
- b) Resistor substitution box must of 100 $\Omega$ .

**Procedure:****1) Connect:**

- a) One test cable from Bipolar socket to RMS current meter in series with 100  $\Omega$  resistor. (Refer the connection diagram for Bipolar)
- b) Another test cable from Bipolar socket to 100  $\Omega$  resistor.
- c) Bipolar/sealer footswitch to the bipolar/sealer footswitch socket on the rear panel.

**2) Check and adjust the Pmax for bipolar output.**

- a) Select mode '4:1 BIP'.
- b) Press the Bipolar/Sealer footswitch pedal & check if current reading is equivalent to 547 mA  $\pm$  10 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) Pmax for all the bipolar modes is adjusted automatically.

**3) Disconnect the test cables from bipolar output.****Sub step- 2 (Pure Cut Mode)****Equipment:**

- Monopolar footswitch.

- Small test cables with banana plugs
- True RMS current meter
- 300Ω non-inductive power resistor.
- PREM plug modified.

**Verify:**

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

**Procedure:****1) Connect:**

- a) One test cable from PREM plug socket to 300Ω. (Refer the connection diagram for Monopolar)
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with 300Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Pmax for Monopolar cut output.**

- a) Select mode '4:2 Pure Cut'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current is equivalent to  $365\text{mA} \pm 10\text{ mA RMS}$ .
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) The Pmax for Low, Endo-1, Endo-2 & Hydro Cut mode is adjusted automatically.

**3) Disconnect the test cables from Monopolar output.****Sub step- 3 (Blend 1 Mode)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs.
- True RMS current meter.
- 300Ω 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 socket PREM plug to 300Ω. (Refer the connection diagram for Monopolar)
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with 300Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Pmax for Monopolar Blend 1 cut output.**

- a) Select mode '4:3 Blend 1'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading for a reading equivalent to  $365\text{ mA} \pm 10\text{ mA RMS}$ .
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.

- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

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

**Sub step- 4 (Blend 2 Mode)**

**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 300Ω non-inductive power resistor.

**Verify:**

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

**Procedure:**

**1) Connect:**

- a) One test cable from socket PREM plug to 300 Ω. (Refer the connection diagram for Monopolar)
- b) One test cable from Monopolar 1 to true RMS current meter in series with 300 Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Pmax for Monopolar Blend 2 cut output.**

- a) Select mode '4:4 Blend 2'.
- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading for a reading equivalent to 365mA ±10 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

**Sub step- 5 (Saline Resection Cut III Mode)**

**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 500 Ω non-inductive power resistor.

**Verify:**

- a) The display shows calibration mode 4:5.
- b) Resistor substitution box must of 500Ω.

**Procedure:**

**1) Connect:**

- a) One test cable from Saline Resection plug to 500 Ω. (Refer the connection diagram for Saline Resection)
- b) One test cable from Saline Resection socket to true RMS current meter in series with the 500Ω.
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Pmax for Saline Resection cut output.**

- a) Select mode '4:5 Saline resection Cut'.



- b) Press the Monopolar footswitch pedal(yellow) and check if the current reading is equivalent to  $447 \text{ mA} \pm 10 \text{ mA RMS}$ .
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- f) Pmax for Saline Cut I & II is adjusted automatically.

#### Sub step- 6 (Saline Resection Coag Force Mode)

##### Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- $100 \Omega$  non-inductive power resistor.

##### Verify:

- a) The display shows calibration mode 4:6.
- b) Resistor substitution box must of  $100\Omega$ .

##### Procedure:

#### 1) Connect:

- a) One test cable from Saline Resection plug to  $100 \Omega$ . (Refer the connection diagram for Saline Resection).
- b) One test cable from Saline Resection socket to true RMS current meter in series with  $100\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

#### 2) Check and adjust the Pmax for Saline Resection Coag output.

- a) Select mode '4:6 Saline resection Coag'.
- b) Press the Monopolar footswitch pedal(blue) and check if the current reading is equivalent to  $547 \text{ mA} \pm 10 \text{ mA RMS}$ .
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- g) P-max for Saline Coag Soft and Standard mode is adjusted automatically.

#### 3) Disconnect the test cables from Saline resection output.

#### Sub step- 7 (Sealer Rapid Mode)

##### Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- $100 \Omega$  non-inductive power resistor.

##### Verify:

- a) The display shows calibration mode 4:7.
- b) Resistor substitution box must of  $100\Omega$ .



**Procedure:****1) Connect:**

- a) One test cable from Sealer socket to 100  $\Omega$ . (Refer the connection diagram for Sealer).
- b) One test cable from Sealer socket to true RMS current meter in series with 100  $\Omega$ .
- c) Bipolar/sealer footswitch to the bipolar/sealer footswitch socket.

**2) Check and adjust the Pmax for Sealer output.**

- a) Select mode '4:7 Seal'.
- b) Press the Bipolar/Sealer footswitch pedal and check if the current reading is equivalent to 1000 mA  $\pm$  20 mA RMS.
- c) Stop activation. If the output current is high decrease fire counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.
- g) P-max for Sealer Fine mode is adjusted automatically.

**4) Disconnect the test cables from Sealer output.****Calibration Step 5 - Open Loop Power Calibration (Econ)****(Desiccate/Swift/Fulgar/Spray/Hi-Spray)****Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 500  $\Omega$  non-inductive power resistor.
- PREM plug modified.

**Verify:**

- a) Mode displayed on the screen is 5:'x' ( x may be 1,2,3,4,5 as per chosen mode)
- b) Resistance of connected resistance substitution box 500 $\Omega$

**Procedure:****1) Connect:**

- a) One test cable from socket PREM plug to 500  $\Omega$ . (Refer the connection diagram for Monopolar)
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with 500  $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

**2) Check and adjust the Econ for Monopolar Desiccate output.**

- a) Select Coag mode for which Econ has to be set.
- b) Press the Monopolar footswitch pedal(blue) and check the current equivalent to 282 mA  $\pm$  10 mA RMS.
- c) Stop activation. If the output current is high decrease fire Counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

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

- 4) Use same equipments & repeat the same procedure for calibrating 'Econ' of different modes (Desiccate /Swift/Fulgar/Spray/Hi-Spray) by choosing corresponding calibration modes.

## Calibration Step 6 - Open Loop Voltage Calibration

(Desiccate/Swift/Fulgar/Spray/Hi-Spray)

### Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 5 k $\Omega$  non-inductive power resistor.
- PREM plug modified.

### Verify:

- a) Mode displayed on the screen is 6: 'x' ( x may be 1,2,3,4,5 as per chosen mode)
- b) Resistance of connected resistance substitution box 5k $\Omega$

### Procedure:

#### 1) Connect:

- a) One test cable from socket PREM plug to 5 k $\Omega$ . (Refer the connection diagram for Monopolar)
- b) One test cable from Monopolar 1 socket to true RMS current meter in series with 5k $\Omega$ .
- c) Monopolar footswitch to the Monopolar 1 footswitch socket on the rear panel.

#### 2) Check and adjust the VPK for Monopolar Desiccate output.

- a) Select Coag mode for which VPK has to be set.
- b) Press the Monopolar footswitch pedal(blue) and check the current equivalent to 56 mA  $\pm$  5 mA RMS.
- c) Stop activation. If the output current is high decrease DAC Counts by pressing down key. If low increase it by pressing up key.
- d) Repeat step (b) & (c) sequentially until the meter reading is not in the stated range.
- e) When reading is in stated range, press 'Write Counts to program memory' for storing corresponding fire count reading in the system memory.

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

- 4) Use same equipments & repeat the same procedure for calibrating 'Vpk' of different modes (Desiccate/ Swift/ Fulgar/ Spray/ Hi-Spray) 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.

Before sending the accessories for servicing, ensure the sterilization by Autoclaving from the User end.

### 11.2 STORAGE OF THE UNIT

Do not wipe the external surface with hard or abrasive wiping material. The surface will be scratched.

1. Turn the electrosurgical unit OFF and disconnect the power cord from the receptacle (wall mains 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 the 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 mains 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 under the conditions, away from direct sunlight and source of liquids.
2. Store the cable with the clamping screw attached.

### 11.5 DISPOSAL

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

## CHAPTER 12

# Troubleshooting

### Troubleshooting

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 Shalya Vista 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.

### 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.

Situation	Possible Cause	Recommended Action
<b>ESU does not respond when Turned on.</b>	Improper contact of power cord with the socket, faulty wall socket, or faulty power cord. Fuse drawer is open or fuses are blown. Loose or disconnected internal cables Faulty input power filter or connections Faulty low voltage power supply Damaged CPU board connectors and/or malfunctioning CPU board Shorts or disconnects on Power Supply & RF board Faulty mains ON-OFF switch Malfunctioning front panel	Check power cord connections with wall socket and ESU. Connect the power cord to a functional wall socket. If necessary, replace the power cord.  Close the fuse drawer. If necessary, replace the fuse. If a problem persists, use a backup generator. Check all internal connections. Press the connectors and Boards if required. Check/Change input power filter and its cable connections. Check/Change the low voltage power supply.  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. Check the Power Supply & RF board for shorts or disconnects. Replace the switch. Replace the front panel assembly.

<p><b>Generator is on, but did not complete the self-test</b></p>	<p>components</p> <p>An alarm condition exists</p> <p>Software malfunction</p> <p>Loose or disconnected internal cables and/or boards.</p> <p>Faulty low voltage power supply</p> <p>Damaged CPU board connectors and/or malfunctioning CPU board</p> <p>Shorts or disconnects on Power Supply &amp; RF board</p> <p>Faulty mains ON-OFF switch</p> <p>Malfunctioning front panel components</p>	<p>Check the display for an error code. Note the number and refer to Responding to System Alarms in this section.</p> <p>Turn off and then turn on the generator.</p> <p>Check and correct all internal connections. Press the connectors and boards if required.</p> <p>Check the low voltage power supply. If not working properly, replace it.</p> <p>Remove the CPU board and inspect the connectors to the Power Supply &amp; RF board and to the Display board for damage. Replace the CPU board if required.</p> <p>Check the Power Supply &amp; RF board for shorts or disconnects.</p> <p>Replace the switch.</p> <p>Replace the front panel assembly.</p>
<p><b>Activation and/or alarm tones do not sound, Speaker is malfunctioning</b></p>	<p>Poor connection or damaged footswitch board</p> <p>Faulty connections or speaker on Footswitch board</p> <p>Audio signal malfunction on Control board</p>	<p>Check/correct connection. If indicated, replace the Footswitch board.</p> <p>Replace the footswitch/Speaker board &amp;/or Speaker.</p> <p>Replace the control board.</p>
<p><b>Blank or confusing LEDs of Ports</b></p>	<p>Faulty ribbon cable between CPU and Display board</p> <p>Incorrect data communicated through the CPU board</p> <p>Display board malfunction</p>	<p>Check/connect ribbon cable that connects the Display board to the CPU board.</p> <p>Replace the CPU board.</p> <p>Replace the Display board.</p>
<p><b>Up/Down /Select keys do not function correctly when pressed</b></p>	<p>Faulty ribbon cable between CPU board and display board</p> <p>Incorrect data communicated through the CPU board</p> <p>Faulty ribbon cable between the front panel and the Display board</p> <p>Incorrect modes are being sent from the front panel</p>	<p>Check/connect ribbon cable that the Display board to the Control board.</p> <p>Replace the CPU board. Check Polarities.</p> <p>Check/connect the ribbon cable that connects the Display board to the front panel.</p> <p>Replace the front panel.</p>
<p><b>Generator is on and accessory is activated,</b></p>	<p>Malfunctioning footswitch or handswitching instrument</p>	<p>Turn off the generator. Check and connect all accessory connections. Turn on the generator. Replace the accessory if it continues to malfunction.</p>

<b>but generator does not deliver output</b>	<p>Footswitch connected to Monopolar 1/UEM socket &amp; instrument connected to Monopolar 2 instrument socket Or vice-versa Power set too low An alarm condition exists Blown fuse on Power Supply &amp; RF board CPU board malfunction</p> <p>High voltage power supply malfunction (high voltage is not present during activation)</p> <p>RF output stage malfunction (high voltage is present during activation)</p>	<p>Connect the footswitch &amp; the footswitching instrument to the proper instrumentation socket.</p> <p>Increase the power setting. Check the Cut &amp; Coag display for an alarm number. Check the high voltage power supply fuse (F02) and replace if necessary. If the indicator bar does not illuminate and the tone does not sound, replace the CPU board. If high voltage is not present on the Power Supply/RF board, troubleshoot the high voltage power supply</p> <ul style="list-style-type: none"> <li>• Check all MOSFET Q01 to Q04, replace with same part no. if require.</li> <li>• Check Diodes CR02 to CR05 replace with same part no. if require.</li> </ul> <p>Troubleshoot the RF output stage as described below on the Power Supply /RF board : verify T_ON pulses at R77, If pulses are present,</p> <ul style="list-style-type: none"> <li>• Check all MOSFET Q09 to Q12, replace with same part no. if require.</li> <li>• Check Diodes CR26 replace with same part no.</li> </ul> <p>If T_ON pulses are not present,</p> <ul style="list-style-type: none"> <li>• verify T_ON pulses at TP 19, If pulses are not present ,replace the CPU</li> <li>• Check IC U14, replace with same part no. if require.</li> </ul>
<b>Footswitch will not activate output</b>	<p>Malfunctioning or damaged footswitch socket</p> <p>Footswitch activation signal lost on Power Supply &amp; RF board</p> <p>Footswitch activation signal lost on CPU board</p>	<p>Replace the Footswitch board.</p> <p>Replace the Power Supply &amp; RF board.</p> <p>Replace the CPU board.</p>
<b>Interference with other devices only when generator is activated</b>	<p>Malfunctioning monitor Metal-to-metal sparking</p> <p>High settings used for fulguration Loose contact in ground wiring in the operating room If interference continuous when the generator is activated, the monitor is responding to radiated</p>	<p>Replace the monitor. Check all connections to the generator, patient return electrode, and accessories. Use lower power settings for fulguration or select the Desiccate mode. Verify that all ground wires are as short as possible and go to the same grounded metal. Check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference then the generator is activated and minimizes the potential for an</p>



	<p>frequencies.</p> <p><b>Pacemaker interference</b></p> <p>Intermittent connections or metal-to-metal sparking Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker.</p> <p><b>Abnormal neuromuscular stimulation (stop surgery immediately)</b></p> <p>Metal-to-metal sparking Can occur during coag Abnormal 50-60 Hz leakage currents</p>	<p>electrosurgical burn at the site of the monitor electrode.</p> <p>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.</p> <p>Check all connections to the generator, patient return electrode, and active electrode. Use a lower power setting for the Fulgurate and spray modes or select the Desiccate mode. Inside the generator, carefully inspect for the damage that may cause shorting between the AC line voltage and connected patient components.</p>
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### Responding to Error Codes:

When system alarm condition exists, an alarm tone sounds and cut & coag display indicates error code no. System will not work till error condition is cleared.

Alarm conditions require some action to correct it. Following screen shows the error window.



In case of keypad stuck errors user can skip errors and continue with surgery, in this case keypad will not be functional.

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 pressed	<ul style="list-style-type: none"> <li>• Turn OFF and again turn ON the generator. Do not press any activation during self-test.</li> <li>• If the alarm repeats, disconnect all accessories. Turn OFF and again turn ON the generator.</li> <li>• If the alarm repeats, check activation request generator circuit.</li> <li>• Call <i>XcelLance Medical Technologies Pvt. Ltd.</i> service cell.</li> </ul>
502	Down key pressed	
503	Enter key pressed	
504	Left key pressed	
505	Right key pressed	
601	FootSwitch1/Handswitch1: Cut activation error	<ul style="list-style-type: none"> <li>• Turn OFF and again turn ON the generator. Do not press any Key during self-test.</li> <li>• 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.</li> <li>• If the alarm repeats, replace front keypad.</li> <li>• Call <i>XcelLance Medical Technologies Pvt. Ltd.</i> service cell.</li> </ul>
602	FootSwitch1/Handswitch1 Co- agulation activation error	
603	FootSwitch2/Handswitch2 Cut activation error	
604	FootSwitch2/Handswitch2 Co- agulation activation error	
605	Single Paddle Bipolar/Sealer footswitch error	
606	Sealer Handswitch activation error.	<ul style="list-style-type: none"> <li>• Turn OFF and again turn ON the generator. If the alarm repeats, Check working of internal cooling fan.</li> <li>• Replace internal cooling fan</li> <li>• Call <i>XcelLance Medical Technologies Pvt. Ltd.</i> service cell.</li> </ul>
701	Temperature High signal.	

### Sealer Warnings:-

**WARNING !**

**Error : Sealing Open Rehold  
Incomplete Vessel Sealing**

Instrument may not closed properly  
OR connecting cable may open.

**WARNING !**

**Error : Sealing Close Rehold  
Incomplete Vessel Sealing**

Instrument may be short, metal object may  
come in instrument, Saline irrigation in surgery  
OR Saline used in instrument cleaning

**Sealer Open warnings:-****Causes:-**

- Sealer clamp is not applied / not properly applied on a vessel when sealer is activated.
- Connector is not properly connected in the sealer port.
- Sealer clamp wire breakage.

**Measures:-**

- Clean sealer clamp's head clip openings properly.
- Hold sealer clamp properly & apply adequate pressure on tissue using sealer clamp.
- Check continuity of individual clamp wire using multimeter. If it's open change sealer cables.
- In case, if problem still exists then contact XcelLance Medical Technologies Pvt. Ltd.

**Sealer Close warnings:-****Causes:-**

- Sealer clamp is activated on conducting material/ in conducting fluid.
- Connector is not properly connected in the sealer port.
- Sealer clamp cable is shorted internally.
- Sealer clamp head opening is bent or damages due to excessive external pressure from clamp head opening is not cleaned properly.

**Measures:-**

- Clean sealer clamp's head clip openings properly.
- Keep sealer clamp away from vicinity of conducting material or fluids.
- Hold sealer clamp properly & apply adequate pressure on tissue using sealer clamp.
- Check continuity between two wire using multimeter. If shorted replace the sealer cable.
- In case, if problem still exists then contact *XcelLance Medical Technologies Pvt. Ltd.*

# Warranty

*XcelLance Medical Technologies Pvt. Ltd.* warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period.

*XcelLance Medical Technologies Pvt. Ltd.* 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 *XcelLance Medical Technologies Pvt. Ltd.* 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 *XcelLance Medical Technologies Pvt. Ltd.* products are as follows:

Electrosurgical Generators:	One year from date of shipment
Trolley:	One year from date of shipment
Footswitches:	One year from date of shipment
Sterile disposables:	Shelf life only as stated on packaging
Non-Sterile Electrodes & Cables:	Warranty on manufacturing defects only
Single use patient return electrodes:	Shelf life only as stated on packaging

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

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

*XcelLance Medical Technologies Pvt. Ltd.* neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of *XcelLance Medical Technologies Pvt. Ltd.* products.

This warranty and the rights and obligations hereunder shall be construed under the governed by the laws of the Maharashtra State, India. The sole forum for resolving disputes arising under or relating in any way to this warranty is the Court of Mumbai, Maharashtra State, India.

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

## Disclaimer

- c) Electro Surgery is proven in surgical applications over more than 60 yrs. If safety instructions are not followed/ implemented, usage of this equipment in operation theatre can be hazardous. Risk associated with the product/procedure cannot be denied, if not used as per 'user & safety instructions' provided in 'User/ Instruction Manual'.
- d) The equipment has to be strictly used only by qualified, trained & licensed surgeon/physician.
- e) 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.
- f) 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.
- g) 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/ user caused due to the incorrect operation/ maintenance of the equipment by an unauthorized/ untrained person.
- h) Consumables/ accessories have to 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.
- i) 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.
- j) 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.