

EAGLE

INSTRUCTION & SERVICE MANUAL

This document is a user guide for EAGLE 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 EAGLE ESU in this document are: Generator, ESU, Machine and LX.

Use for: This document is drafted by taking **EAGLE** ESU into account only, which is a product of Whittemore Enterprises Inc.

EAGLE



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Conventions and Symbols used in this document

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

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CHAPTER 1

Introduction

EAGLE Electrosurgical Generator – the product of *Whittemore Enterprises Inc.* provides necessary power for different types of surgical needs in Monopolar and Bipolar applications with multiple options of cut & coagulation effects with following features:

A. GENERAL FEATURES

- Smart ESU: Surgical Monitoring and Automatic & Instant Response Technology ESU for consistent cutting & coagulation through all types of tissues.
- 6SENSE™ Technology: advance feedback system which senses the change in Voltage, Current, Power, Tissue Density, Return Electrode Contact quality & leakage RF current.
- PREM™ Safety: Patient return electrode monitoring – PREM – is ultimate Safety for return electrode site burns.
- Surgical Assistant: User programmable Programs settings which cover most of surgical procedures with flexibility. Recall function for fast magic recall settings.
- Fully Microprocessor controlled: To achieve high degree of clinical precision.
- 3 Cut Modes: SP Cut, Pure & Blend cuts.
- 3 Coag Modes: Soft, Fulgurate & Spray Coag.
- 2 Bipolar Modes: Micro & Macro Modes with high impedance bipolar output.
- Compatible with ultrasonic surgical aspirator and smoke evacuator system
- ARGON Beam Coagulator upgradeable.

B. MODES OF ELECTROSURGERY

Monopolar Electrosurgery:

In Monopolar electrosurgery, only one 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 three Cut modes-

- ***SP Cut***- It is used for cutting tissues with no sparking. It is useful for laparoscopic surgery.
- ***Pure***-This is the default Monopolar cut mode it may be used for precise cut with no hemostasis.
- ***Blend***-It is used where slower cutting & additional haemostasis is desired.

Monopolar Coag Modes: There are three Coag modes-

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

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 two types of modes-

- **Micro** (Precise) – The voltage is kept low to avoid sparking. It is selected for fine bipolar tissue desiccation.
- **Macro** (High) - This is the default bipolar mode, Voltage is higher than other modes. Macro bipolar output can be used for wide range of tissue types & also used for bipolar CUT.

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.



General Warnings & Cautions:

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.
-
- Read all the Warnings & cautions before using this generator.
 - Use hand switches, footswitches provided by Whittemore Enterprises Inc. only.
 - In case of any doubt or query, contact Whittemore Enterprises Inc.
 - 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 or other wires.
- Do not activate the generator, before touching the active electrode to the tissues, electrical arcs may be created.
- Do not activate the generator in an open circuit condition. Do not short active electrode with return electrode.



- Do not activate electrodes while in contact with 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 Whittemore Enterprises Inc. may r 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 as possible as low power setting 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

**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 labelled “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 is 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 Whittemore Enterprises 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.



CHAPTER 3

Controls, Indicators and Output Sockets

A. FRONT PANEL

Power ON/OFF switch:
To turn the generator ON/
OFF

Patient Return Electrode Alarm Indicator: This ensures burn free electrosurgery using DUAL AREA electrode by continuously monitoring the contact quality with the patient. The PREM system gives an audio-visual alarm and stops the RF output before critical situation arises.

The indicator has three steps:

RED COLOUR: Return electrode not properly connected to the patient or the system.

NO COLOUR: Single area return electrode properly connected to the system

GREEN COLOUR: Dual area return electrode properly connected to the patient or the system.



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

Patient Return Electrode Socket: This accepts PREM/ Non-PREM electrode sockets.

Bipolar Socket:
Accepts standard 4mm Bipolar interface cables.

PROG key: This key helps in setting up the system quickly after turning ON. Ten programming setting cover most of the surgical procedures. By pressing this key, power setting display shows procedure number. After selection of required program, just press RECALL key once to set system for desired application.

RECALL key: This helps the user to restore power & mode settings of the last session after turning on the unit. It also helps to store & recall the user settable programs.

Bipolar controls

Bipolar Indicator:

Blue LED lighted up when Bipolar power is activated with an activation tone.

Bipolar Display:

Shows the power settings in watts for the selected Bipolar Mode.



MICRO Mode Lamp:

Indicates selected Mode for fine Bipolar Output with minimum sparking.

MACRO Mode Lamp:

Indicates selected Mode for Macro Bipolar which offers smart control over consistent cutting effects in variety of tissues.

Bipolar Power UP, DOWN

Keys: Press to Increase or Decrease the Power settings in selected Mode.

Bipolar MODE Key:

Press to select MICRO & MACRO Mode. Key operates in Cyclic Order.

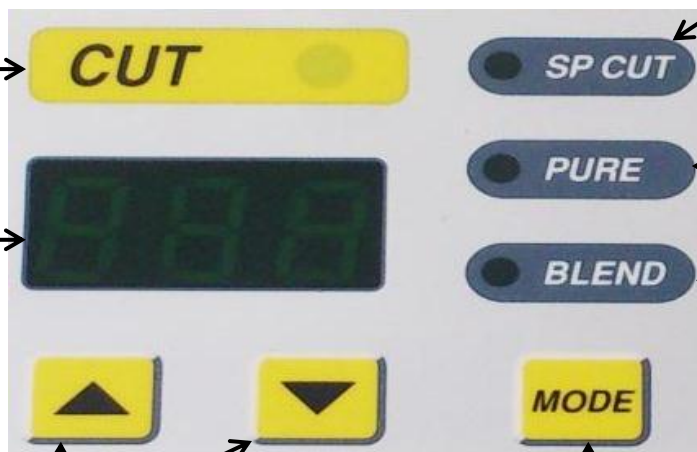
Monopolar Cut Controls:

Cut Indicator:

Yellow LED lighted up when Cut mode is activated with an activated tone.

Cut Display:

Shows the power settings in watts for the selected Cut Mode.



SP Cut Mode Lamp:

Indicates selected Mode for Cut with minimum sparking. Also indicates ENDO Cut Mode.

PURE Mode Lamp:

Indicates selected Mode for Cut with fine control over necrosis for clean and consistent cutting. This is the default Monopolar Cut Mode.

BLEND Mode Lamp:

Indicates selected Mode for Blended Cut with Additional Hemostasis.

Cut Power UP, DOWN Keys:

Press to Increase or Decrease the Power settings in selected Mode.

Cut MODE Key:

Press to select SP Cut, Pure or Blend Mode. Key operates in Cyclic Order.

Monopolar Coag Controls:

Coag Indicator:

Blue LED lighted up when Coag power is activated with an activation tone.

Coag Display:

Shows the power settings in watts, for the selected Coag Mode.



Soft Mode Lamp:

Indicates selected Mode for contact Coagulation at lower voltages.

FULGURATE Mode Lamp:

Indicates selected Mode for Non-contact Coagulation with Moderate sparking. This is the default Monopolar Coag Mode.

SPRAY Mode Lamp:

Indicates selected Mode for coagulation at larger area with minimum depth of tissue damage.

Coag Power UP, DOWN Keys:

Press to Increase or Decrease the Power settings in selected Mode.

Coag MODE Key:

Press to select Soft, Fulgurate or Spray Mode. Key operates in Cyclic Order.



RECALL Key helps the user to restore power & mode settings of the last session after turning on the unit. It also helps to store & recall the user settable programs.



PROGRAM Key helps you in setting up the system very fast after turning ON. By Pressing this key, power setting display shows program number. After selecting the desired program using Coag Up/Down keys, just once press RECALL key to set system for desired application.

Patient Return Electrode Monitoring Indicator:

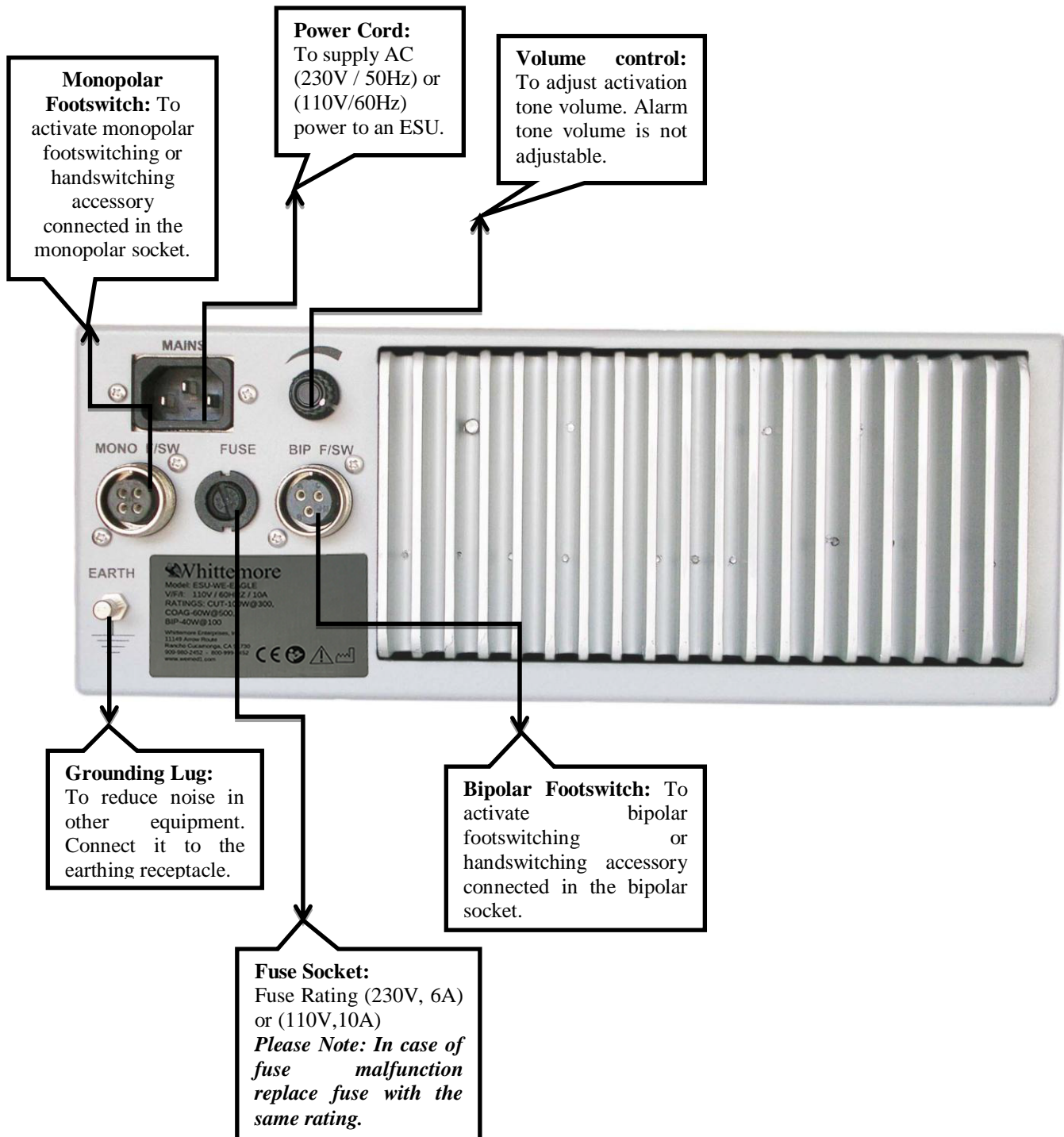
This ensures burn free electrosurgery using DUAL AREA return electrode by continuously monitoring the contact quality with the patient. PREM system gives an audio- visual alarm and stops the RF output before critical situation arises. It gives three types of indications.



Red: Return Electrode is not properly connected to the patient or the system. Return electrode may be faulty.

No Color: SINGLE AREA return electrode is connected properly to the patient and the system.

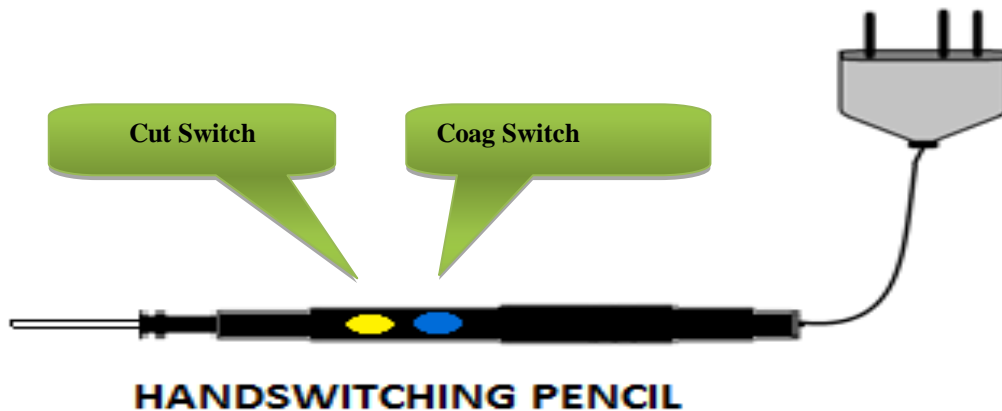
Green: DUAL AREA return electrode connected properly to the patient & the system.

B. REAR PANEL

Note: This manual is common for both 110V/230V mains power supply.
For technical specification, refer Chap 4: Technical Specification; Section: Input Power.

C. REMOTE POWER CONTROL USING HANDSWITCHING PENCIL (OPTIONAL)

EAGLE 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.

Steps to use pencil as a remote control

Please Note 1:- Power can be adjusted for recently mode.

Please Note 2:- For Enter operation: Press cut & coag keys simultaneously.

Step-I

To activate remote control press cut & coag button simultaneously.

Step-II

Activate the desired mode using the corresponding input i.e. to enter in the cut mode, press cut key (yellow). Similarly to enter coag mode, press coag key (blue).

Step-III

Press cut & coag switches simultaneously to enter the recently activated mode for which power has to be set.

Step-IV

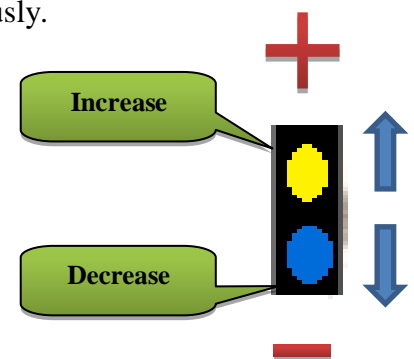
Use cut and coag buttons to increase and decrease the power respectively. And press Enter (Ref. Note2).

Step-V

Choose keys to switch between modes.

Step-VI

Once the desired mode and power is selected press enter (Ref. Note2) & activate corresponding input.



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-200 watt setting at 300 ohms, 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: seven-segment displays, six digits, 0.75 inch each.

Standards and IEC Classifications



ATTENTION Consult accompanying documents



SHOCK To reduce the risk of electric shock, do not remove the cover.
Refer servicing to 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 standard as EAGLE provides a high degree of protection against electric shock. Instrument can be used for procedures involving the heart due to type CF isolated (floating) output.

Drip Proof (IEC 60601-2-2)

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

IP Class Specification

IP Class of this equipment is rated at IP20 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 any equipment on top of the EAGLE or place the generator on top of other electrical equipment. These configurations do 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 EAGLE complies with the appropriate specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

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

Defibrillator Proof

The EAGLE meets specifications for “defibrillator proof” designation.

Dimensions and Weight

Length: 38.0 cm

Width: 30.5 cm

Height: 11.5 cm

Weight: < 5.0 kg

Transport and Storage

Temperature range: - 40°C to 70°C

Relative humidity: 10% to 100%, condensing.

Operating Parameters

Temperature range: 10°C to 40°C

Relative humidity: 30% to 75%, noncondensing.

Warm-up time

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

Internal Memory

Nonvolatile, battery-backed RAM

Audio Volume

Activation Tone:	Volume (adjustable):	40 to 65 dB
	Frequency:	Bipolar: 455Hz ±5%
		Cut: 580Hz ±5%
		Coag: 865Hz ±5%
Alarm Tone:	Volume (not adjustable):	65 dB
	Frequency:	865Hz ±5%
	Pulse:	Two 800msec.coag tone separated by 800msec.of silence

PREM Contact Quality Monitor

Measurement frequency: 80 kHz ±10 kHz

Measurement current: <10 µA

Acceptable Resistance Range upto 40%
 Dual Area PREM return electrode: 5 to 135 ohms
 Single Area Patient return electrode: 0 to 10 ohms

Low Frequency (50 - 60 Hz) Leakage Current:

Source current, patient leads, all outputs:
 Normal polarity, intact ground: <10 μ A
 Normal polarity, ground open: <50 μ A
 Reverse polarity, ground open: <50 μ A
 Enclosure source current, ground open: <300 μ 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	85-135V
Mains Current (maximum):	Idle: 0.2 A	Idle: 0.4 A
	Cut: 3 A	Cut: 4.3 A
	Bipolar: 1 A	Bipolar: 1.8 A
	Coag: 1.6 A	Coag: 3 A
Maximum VA at nominal line voltage:	Idle: 52VA	Idle: 60 VA
	Cut: 780VA	Cut: 580 VA
	Bipolar: 260VA	Bipolar: 243 VA
	Coag: 416VA	Coag: 405 VA
Mains line frequency range (nominal):	50 to 60 Hz	50 to 60 Hz
Fusing:	6A	10A

B. AVAILABLE POWER SETTINGS (In Watts)

Bipolar: Micro & Macro

1 to 40 by step of 1, 40 to 50 by step of 5

Monopolar Cut: Special and Pure

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

Monopolar Cut: Blend

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

Monopolar Coag: Soft, Fulgurate & Spray

1 to 40 by step of 1, 40 to 80 by step of 5

C. OUTPUT CHARACTERISTICS

Maximum Output for Bipolar and Monopolar Modes

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

Mode	Open Circuit P-P Voltage	Rated Load (max)	Power (max)	Crest Factor
Bipolar				
Micro	250 V	100 Ω	50 W	1.5
Macro	530 V	100 Ω	50 W	1.5
Monopolar Cut				
Sp Cut	1050 V	300 Ω	200 W	1.5
Pure	1450 V	300 Ω	200 W	1.5
Blend	1800 V	300 Ω	120 W	2.5
Monopolar Coag				
Soft	3300 V	500 Ω	80 W	5.0
Fulgurate	4600 V	500 Ω	80 W	7.0
Spray	4800 V	500 Ω	80 W	8.0

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

D. OUTPUT FREQUENCIES

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

Bipolar

Micro	390 kHz sinusoidal
Macro	390 kHz sinusoidal

Monopolar Cut

Sp Cut	390 kHz sinusoid. Maximum voltage is limited to a lower value.
Pure	390 kHz sinusoid
Blend	390 kHz bursts of sinusoid, recurring at 29 kHz intervals. 55% duty cycle envelope

Monopolar Coag

Soft	460 kHz damped sinusoid repeated at 62 kHz. 20% duty cycle
Fulgurate	460 kHz damped sinusoidal bursts repeated at 34 kHz.
Spray	460 kHz damped sinusoid repeated at randomized frequencies 34 kHz < f < 50 kHz

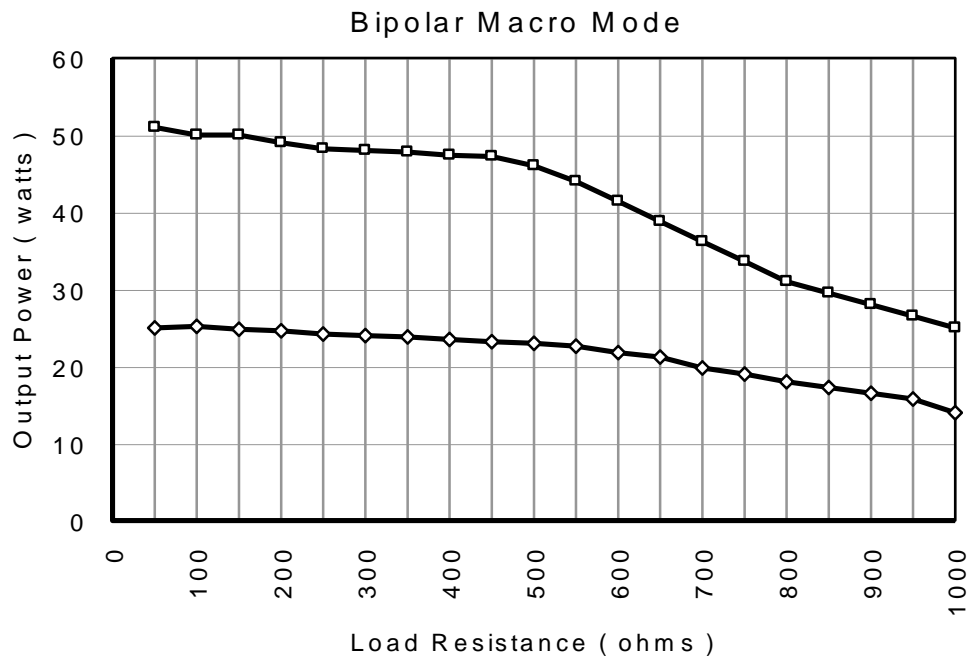
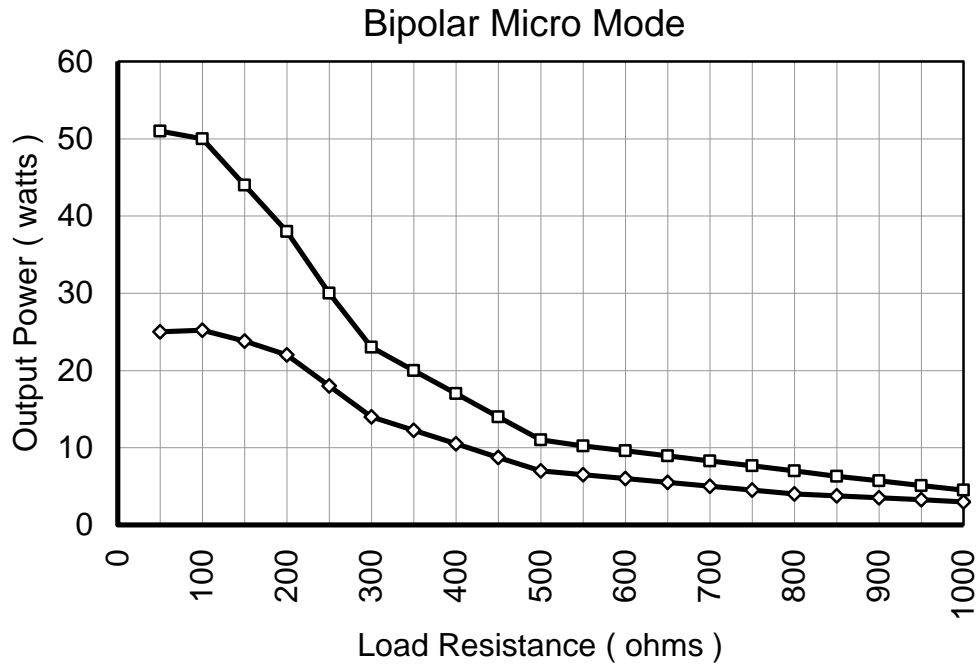
E. AREA OF APPLICATION

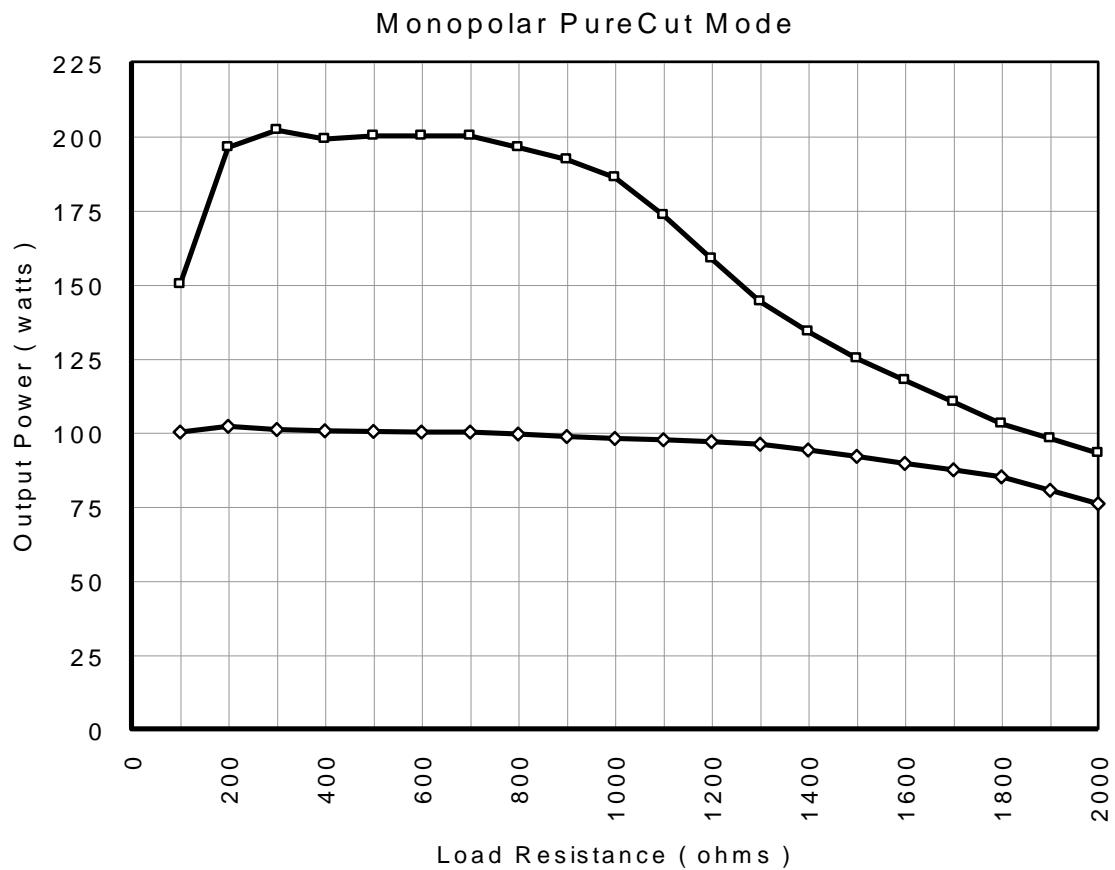
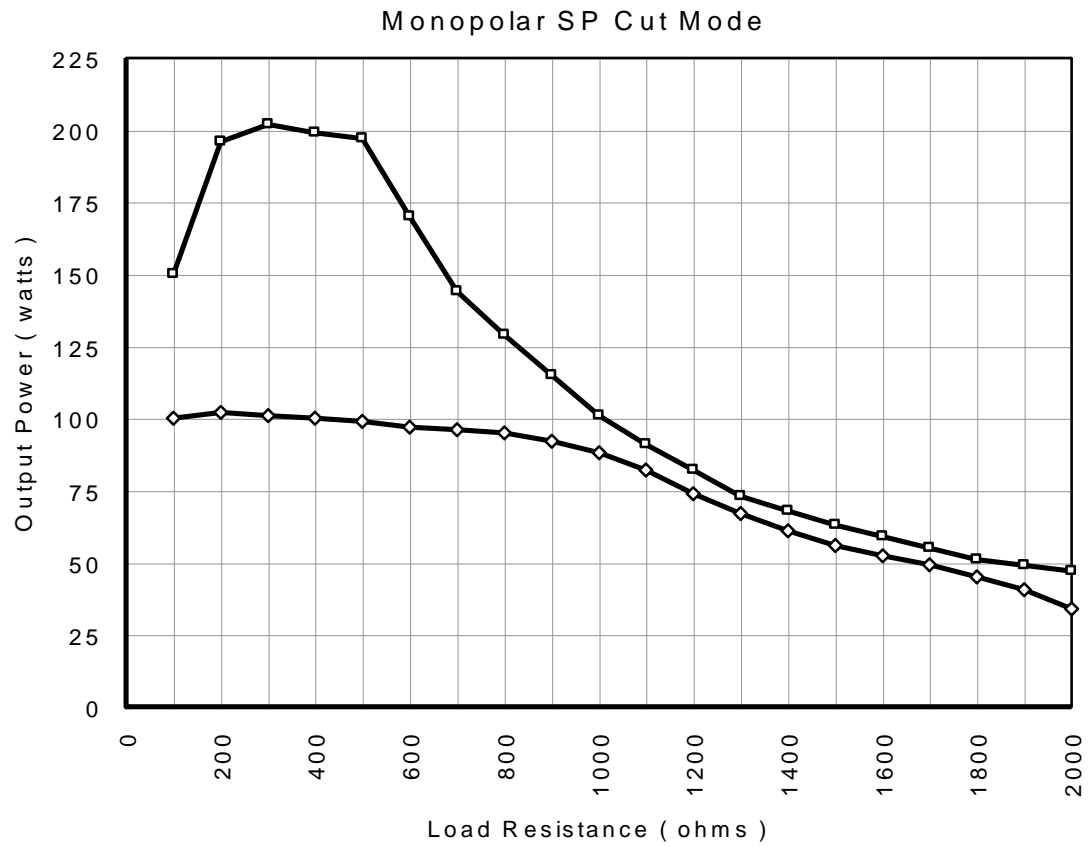
□ Applications of ESU / Diathermy Section:

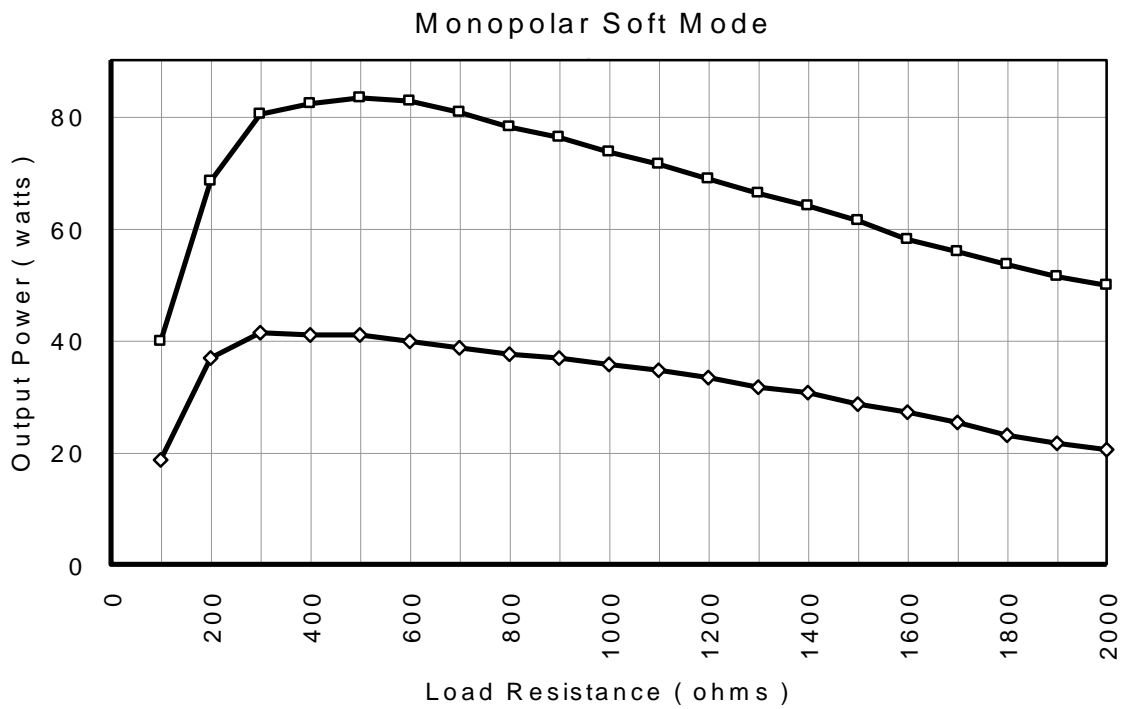
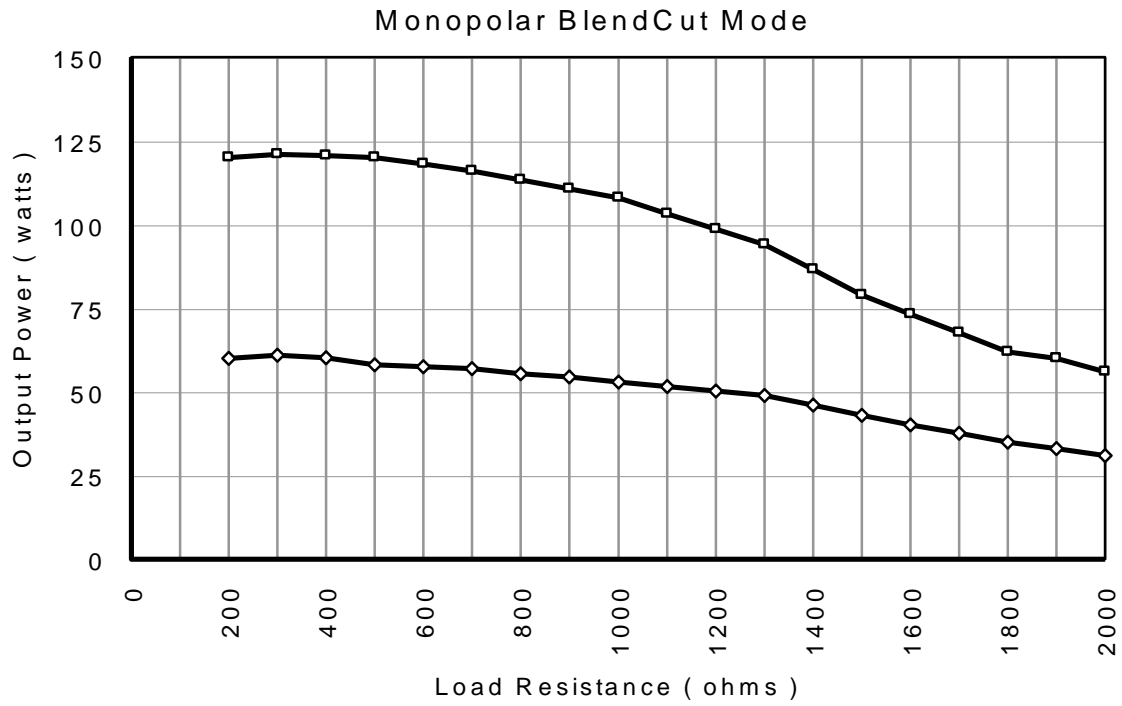
- ✓ Gynecology
- ✓ Urology (Resection)
- ✓ Laparoscopic Surgeries.
- ✓ Endoscopy (ERCP)
- ✓ Oncosurgery
- ✓ Heart & Chest surgery, CABG
- ✓ Neurosurgery, Spine

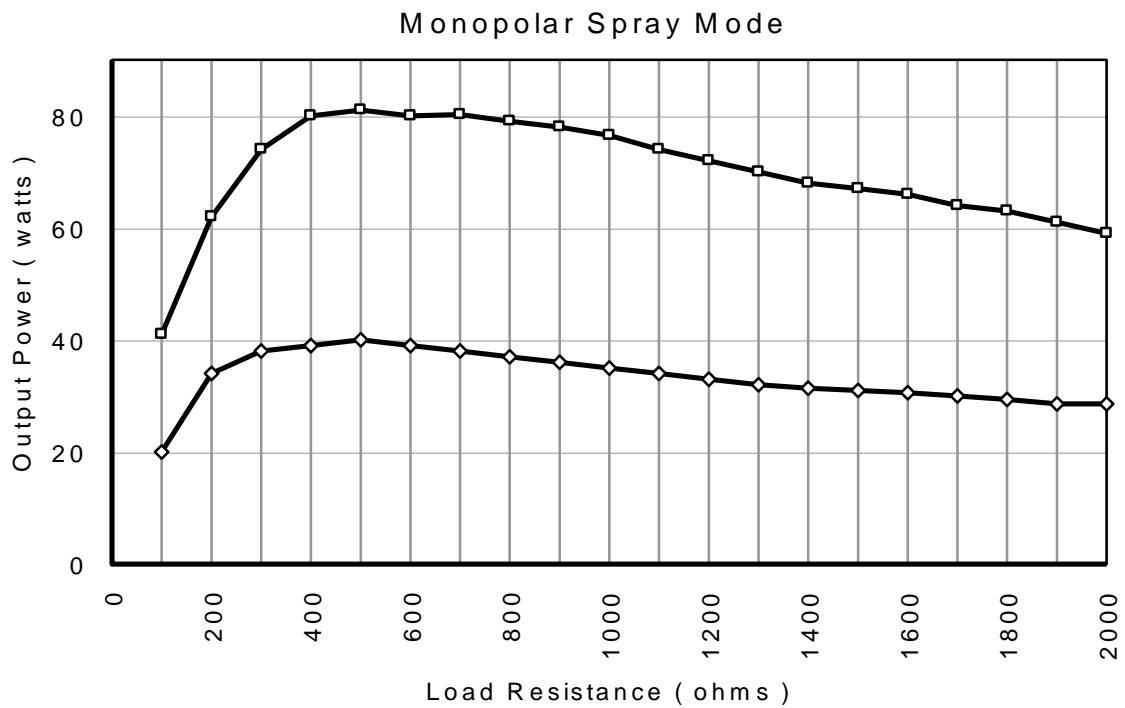
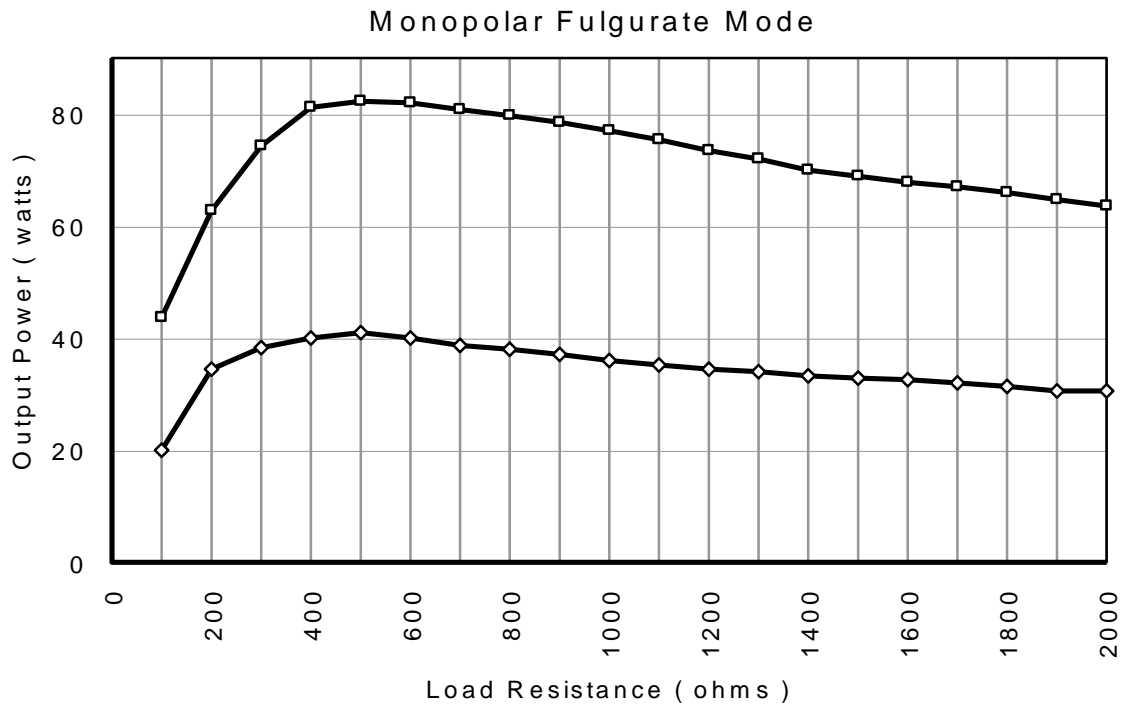
- ✓ Arthroscopy
- ✓ All other general surgical procedures.

F. OUTPUT POWER VS. LOAD GRAPHS









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 de-sterilize accessories labeled “disposable” or “single use only”.

**Patient Return Electrode:**

Warning - Do not cut patient return electrode to reduce its size, due to this, pad site burns may occur.

A. PREPARING THE GENERATOR

- If using a 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 monopolar surgery only apply patient return electrode to patient & connect it to the Patient Return Electrode socket on the front panel.
- For Bipolar surgery, press the Function key on the front panel to display “BIP” in cut display.
- Verify or change the mode & power setting.
- Optional-Press the Recall key on the front panel to display the previously used setting if required.

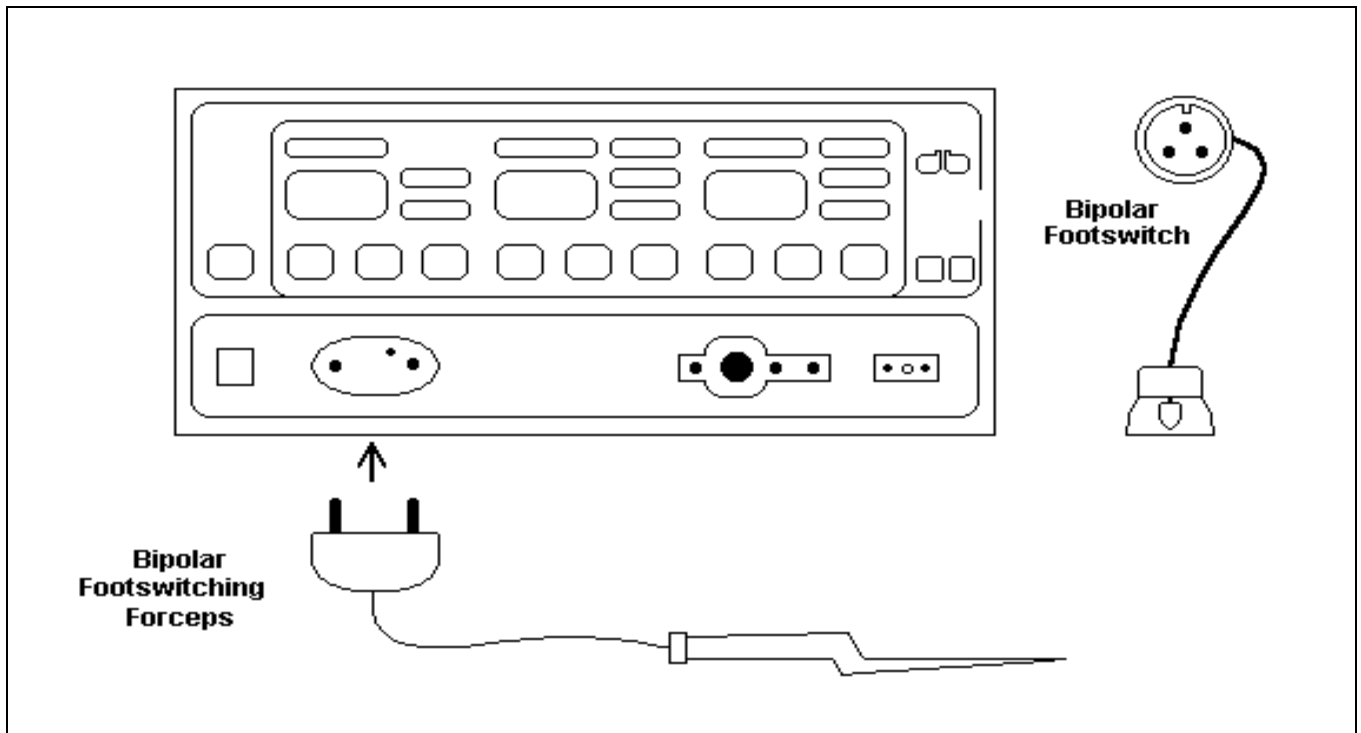
ACCESSORIES CONNECTION FOR SURGERIES:

Fig 5.1: For Bipolar surgery, insert Foot switching Bipolar male connector in Bipolar front panel socket and connect Foot switching Bipolar forceps. Also connect Footswitch in bipolar footswitch socket on rear panel.

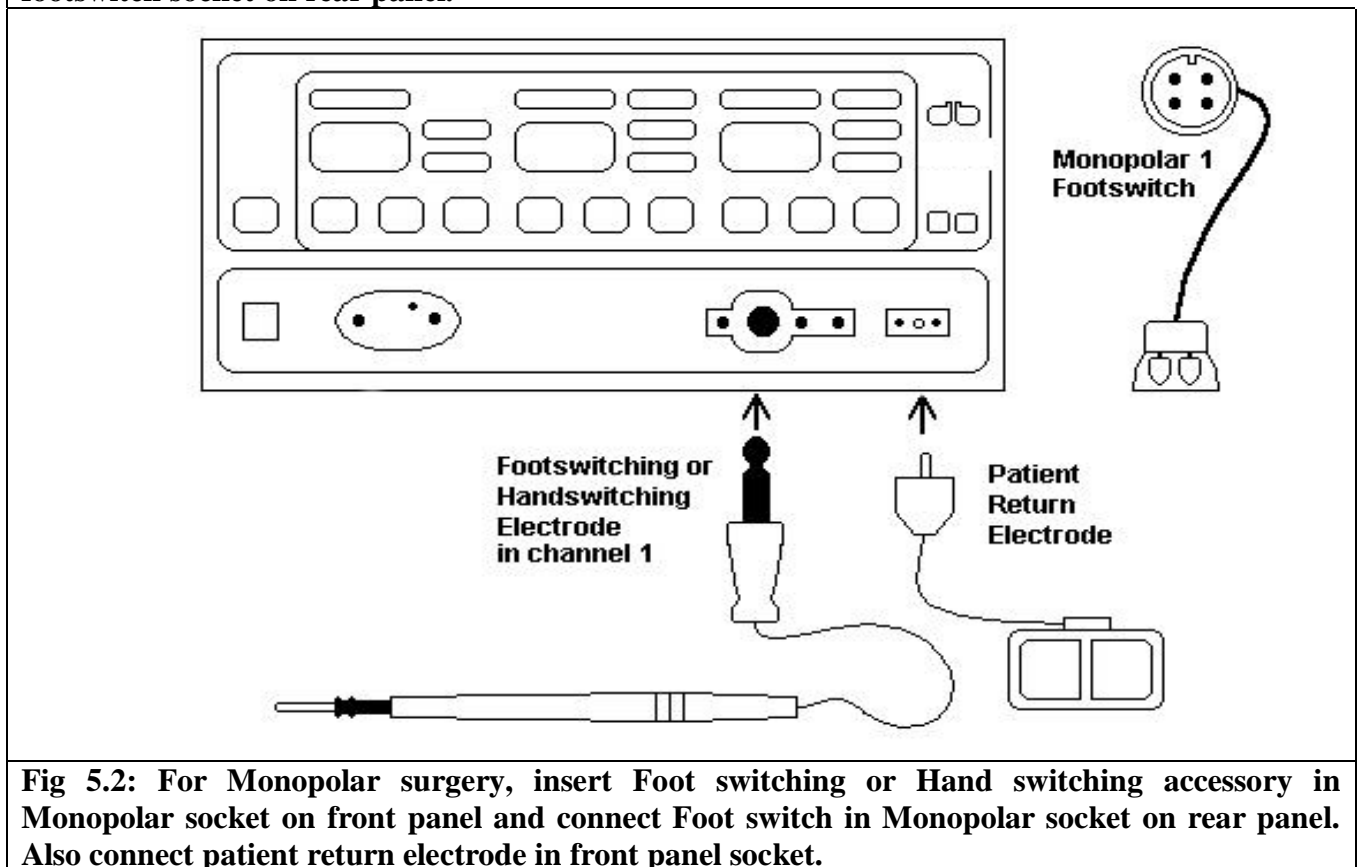


Fig 5.2: For Monopolar surgery, insert Foot switching or Hand switching accessory in Monopolar socket on front panel and connect Foot switch in Monopolar socket on rear panel. Also connect patient return electrode in front panel socket.

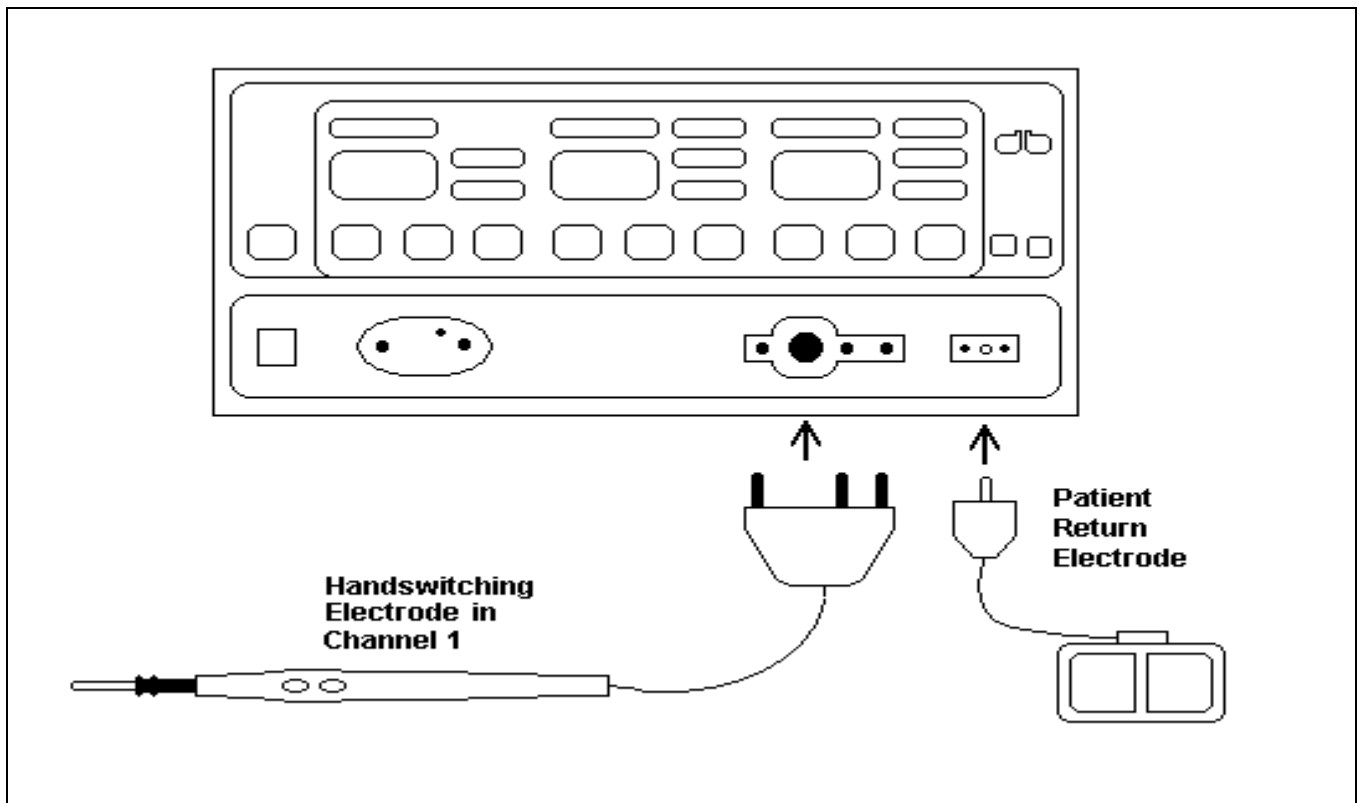


Fig 5.3: For Monopolar surgery, insert Hand switching accessory in Monopolar socket on front panel. Also connect patient return electrode in front panel socket.

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:
 - All visual indicators & displays on the front panel illuminate.
 - Activation tones sound to verify that the speaker is working properly.
6. If self-test is successful, a tone sounds. Verify the following:
 - Indicators above the default mode keys illuminate green.
 - Each display shows a power setting of 1 watt.
 - The PREM Alarm indicator illuminates red.
 - If the self-test is successful, connect the Accessories & set the generator controls.

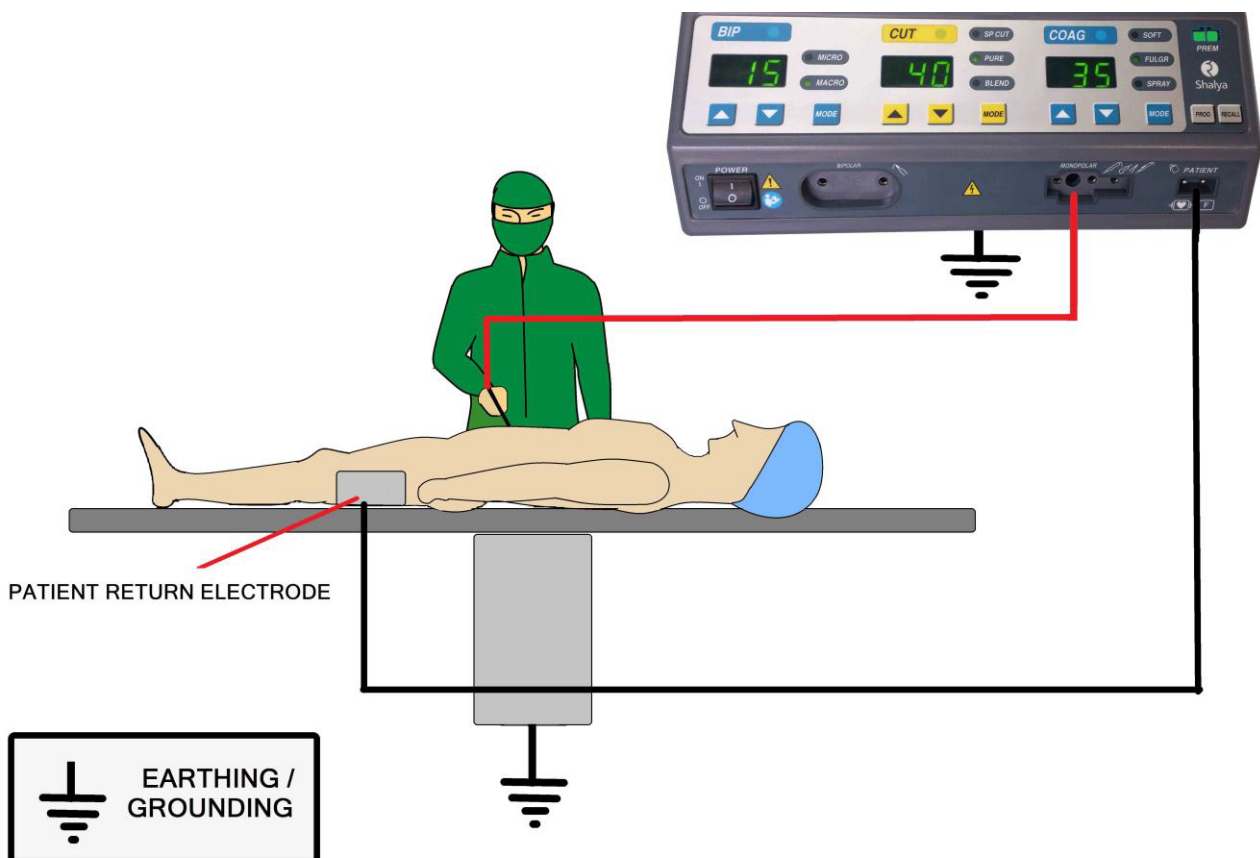
C. PROGRAMMING THE GENERATOR

Programming of User Programs: Set the ESUs mode & power, press PROG key till display shows “**r t P r g 1**”, Select program number by Coag up/down keys & press RECALL key to store the program.

To recall the program setting, press & release the PROG key, display will show “**r d P r g 1**”, Select program number by Coag up/down keys & press RECALL key to recall the respective program setting

Last Recall: Press & release the RECALL key after turning on the unit, to restore power & mode settings of the last session.

D. Patient Return Electrode Monitoring (PREM)



Connection with patient (Monopolar Mode)

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

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 ELECTRODE

Warning - Do not wrap 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.

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

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

Caution - Do not warm return electrode prior to application.

Caution - Place the return electrode after positioning the patient.

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

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

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



B. MODES AND POWER SETTINGS

(i) Changing the Mode:

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

(ii) Changing the Power Setting:

Operator should verify the power setting for the selected mode with the surgeon. One cannot change the power setting when generator is active. To increase the power, press the up arrow key for the selected mode. To decrease the power, press the down arrow key for the selected mode.

To reach maximum or minimum power setting for selected mode, press up & down key. Release the key when the desired setting is displayed. If you try to set power above the maximum setting or below the minimum setting for the selected mode, then unit will give an audio signal.

(iii) Special Setting of the Generator:

1. *Fast Setting by Recall*: Press **Recall** key to select fast setting of the generator to user set default settings.
2. *Fast Setting by Program*: Press **Prog** key and select Program No. using Coag Up/Down keys, followed by **Recall** key for fast setting of the generator.

(iv) 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 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 Fulgur: 40, Bip Macro: 1
- b) Onco/Gynac/Hernia/Fatty Tissues Surgery –
Cut Pure: 55, Coag Spray: 50, Bip Macro: 15 to 25
- c) TURP/ TCRE/under water Surgery –
Cut Pure: 90 to 120, Coag Fulgurate: 50 to 70, Bip Macro: 1

- d) ERCP/ Papillotomy/ Polypectomy Surgery-
Coag Fulgur: 20-40, Bip Macro: 1
- e) Plastic/ Neuro/ ENT/ Spine/Ophthal Surgery-
Cut Pure: 10 to 30, Coag Soft: 10 to 30, Bip Micro: 1 to 10
- f) Laparoscopic Surgery-
Cut Pure: 30 to 40, Coag Fulgur/Soft: 35 to 45, Bip Macro: 25 to 45
- g) GI/Ortho/Open/General Surgery-
Cut Pure: 30 to 45, Coag Fulgur/Soft: 30 to 50, Bip Macro: 15 to 20

E. ALARM CONDITIONS:

The following conditions can generate a PREM alarm:

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

Non - PREM Patient Return Electrode Alarm:

When a non - PREM patient return electrode is connected and generator detects a cord fault condition, the PREM Alarm indicator illuminates red. When you activate in alarm condition, the indicator blinks.

System Alarm:

1. 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.
 - Turn off the generator.
 - Turn on the generator & verify that the self – test is completed successfully.
2. If you are unable to correct the system alarm condition use standby generator to complete the surgical procedure.

F. COMPATIBILITY WITH OTHER DEVICES

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

CHAPTER 7

After Surgery

Electric Shock Hazard:

Warning - Never remove the cover of instrument.

After Surgery:

Electric Shock Hazard

Warning - Always turn off & unplug the generator before cleaning.

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 & resterilize 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.

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.

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.

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

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

1. General description
2. Block diagram
3. 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.

Randomized spray coag: In conventional spray coag, beam tends to follow the same path left by previous spark and 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.

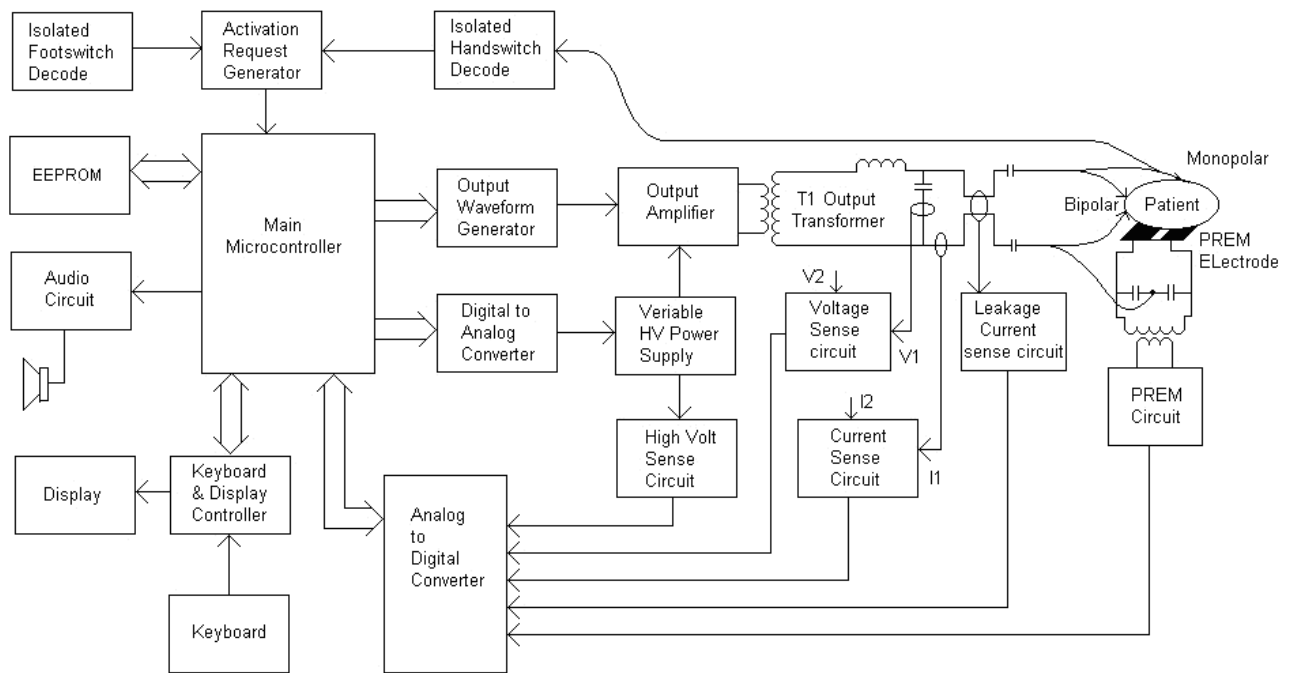
PREM – Ultimate safety from burns: Patient Return Electrode Monitoring – PREM is the care & safety against the return electrode site burns. This ensures burn free electrosurgery using DUAL AREA Return electrode by continuously monitoring the contact quality with the patient. PREM system gives an audio-visual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

B. BLOCK DIAGRAM AND DESCRIPTION

System is divided in three basic parts:

- Processor and control circuit.
- Variable voltage power supply.
- Radio frequency output amplifier.

1. **Processor & Control circuitry:** This is the main control system that calculates all the system parameters as per the selected mode and monitors the overall activity of the system.
2. **Variable voltage power supply:** As per the selected mode and the set power settings, power supply devices the necessary power as an input for the RF stage.
3. **RF output amplifier:** This converts the controlled dc voltage in Radio frequency as demanded for surgical applications.



Block Diagram of SHALYA LX

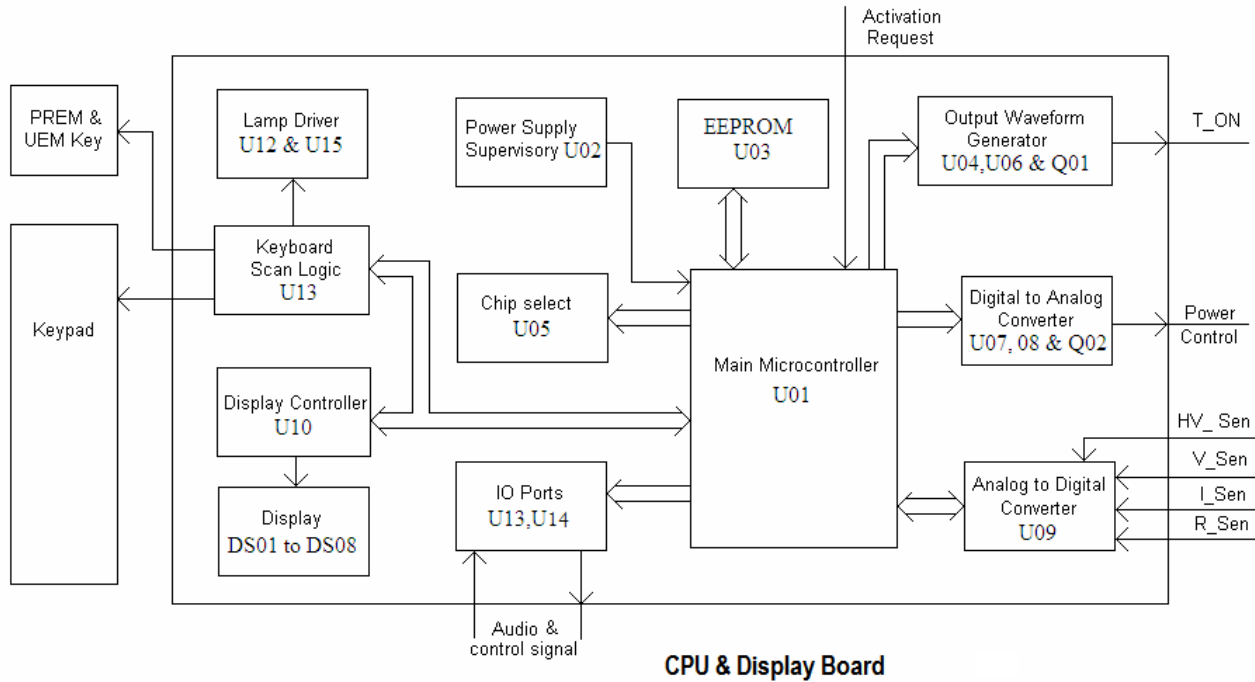
Circuit Board Description:

CPU and Display Board:

Processor and control board consists of –

1. **Main microcontroller:** IC U01 is main microcontroller and brain of system, which controls overall function of the system by I/O device. U01 has inbuilt program memory to hold the system program. All activation requests go to the system and it works accordingly by giving the I/O signals to run the task.
2. **Digital to Analog converter:** Two analog control signals, Power control signal & voltage control signal are derived by IC's U07 and U08. During activation of power delivery both the control signals are changing as the change in tissue impedance.

3. *Output waveform Generator:* RF output waveform as per selected mode is delivered by ASIC U06, which works in synchronization with main microcontroller. ASIC has inbuilt memory to develop the necessary complex waveforms for RF O/P stage. Signal conditioning is done by U04 & Q01.
4. *Analog to Digital converter:* IC U09 converts all analog sense voltage in digital form to process them for checking the calculation in close loop. Sense voltage is continuously monitored by the processor for checking the contact Quality of the patient with return electrode.



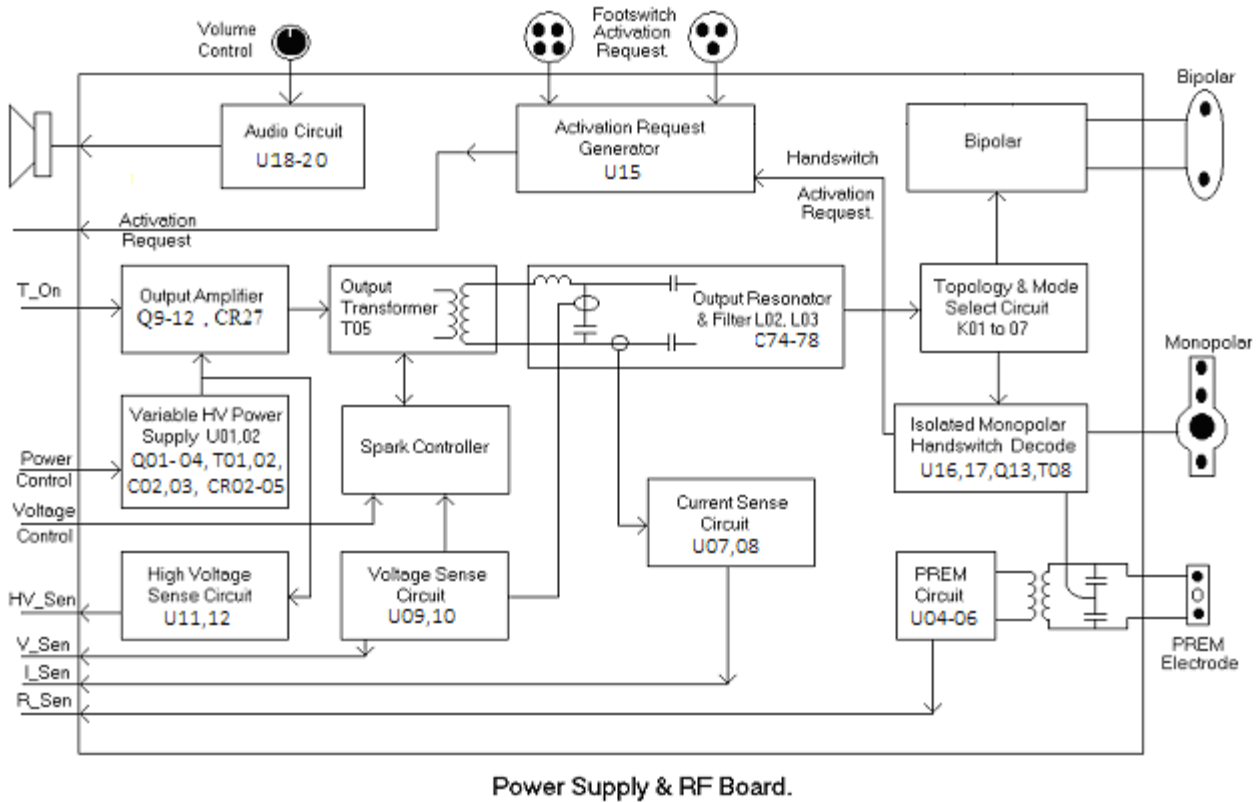
5. *I/O ports:* Two 8 bit ports, ICs U13, U14 are dedicated for I/O ports to receive or transmit digital I/O signals. CPU board controls all I/O devices activity through these ports.
6. *Power Supply Supervisory:* IC U02 circuit monitors the fluctuation in supply and at the time of turning off circuit gives the signal to microcontroller to store the necessary working data earlier to power goes off.
7. *Chip Select Logic:* IC U05 generates different chip select signals to enable the different I/Os.
8. *Display Circuit:* Seven segment digital display DS01 to DS08 are controlled by Display controller IC U10. Mode LED's & activation bar light ups during RF power output are driven by drivers U12 & U15.
9. *Keyboard Circuit:* Front panel Key board is connected to circuit & scan by CPU. Pressed key is read by IC U13.

Power Supply and RF Main Board:

This board can gross by dividing 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.

- *Variable HV power supply:* Supply voltage is converted in dc voltage by CR01, C02 & C03 and again converted in Isolated DC voltage by using bridge converter. MOSFET Q01 to Q04 works in bridge configuration along with Transformer T02 and MOSFETs are driven by T01 pulse transformer. IC's U01 & U02 controls the pulse width of ON Time depending on Error voltage between output dc voltage & set value in particular operating mode. This voltage is continuously changing during activation hence reflecting the change in pulse width. The output of Transformer T02 is fed to HF bridge rectifier formed of CR02 to CR05 and filtered by L01, C08 & C09, which produces pure dc voltage to drive RF stage.
- *O/P RF amplifier stage:* This stage is driven by pure controlled dc voltage from HV power supply and control signal from waveform generator circuit on CPU board. Depending on the selected

mode, the o/p transformer T05 configuration is selected by primary relay k01. O/P stage is driven by switching devices Q9 to Q12 at various levels. CR27 is also used to protect the device from reverse current.





- **O/P Resonator and filter:** RF o/p of amplifier stage is supplied to patient via resonator stage which is resonating at particular load conditions. This stage has two functions of resonator & filter for RF frequencies. Inductor L02 & L03 and capacitor C74 to C78 forms the resonator can filter circuit, which is also used to deliver the o/p in different modes of monopolar & bipolar applications.
- **Configuration & mode selection circuit:** This circuit is used to obtain the RF o/p at required channel. Relays k01 to k07 are used to select different o/p channel & load conditions. When power is delivered in monopolar, no leakage power in bipolar. In bipolar mode return electrode circuit & monopolar channel is isolated from RF by this circuit.
- **Monopolar Handswitch Decode:** Handswitch decode circuitry works on floating principle. IC U16 & U17 is used for detecting the activation request if any. This circuitry is powered by isolated power supply. All activation requests pass on to activate request generator.
- **Activation Request Generator:** This circuit keeps watch on activation request from foot or hand controlled accessories. This generates the necessary signals for CPU to start the process for RF delivery depending on the selected mode & the channel.
- **PREM Circuit:** Patient Return Electrode Monitoring circuit consists of IC's U04 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.
- **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.
- **RF current sense:** Actual RF o/p current is sensed by current sense T07 and IC U07 & U08 converts the current in average value, which is sensed by CPU as I-sense.

- *RF voltage sense:* O/P voltage is sensed by voltage sense T06 and processed by true rms converter in dc voltage by IC's U09 & U10, which is sensed by CPU as V- sense. Also it gives the signal to spark controller.
- *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.
- *High voltage sense circuit:* This circuit continuously monitors that RFHV is not crossing the limit. This senses the voltages in primary side of RF and converts in dc by True RMS detector of U11&U12. Signal is sensed by CPU as HV sense.

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 adapters. 
- Warning -** Fire Hazard - Do not use extension cords.
- Caution -** Do not stack equipment on top of the EAGLE 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 lug 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 one year to verify that the EAGLE 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 ohm, all 250 watt, 1% tolerance, noninductive

Inspecting the Generator and Accessories:***Equipments***

- a) Bipolar & Monopolar footswitch
 - b) Bipolar instrument cords (footswitching)
 - c) 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

4. Remove the footswitches from the generator.
 1. Disassemble the footswitches connector. Inspect the connector for damage or corrosion.
 2. Reassemble the footswitches connector.
 3. Inspect the footswitches for damage.
4. 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. Inspect the power cord for damage.
3. Reconnect the power cord to the generator and wall socket.

Inspecting the Internal Components:

Equipment

- a) 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.
 5. If you find evidence of damage on the CPU Board, Display Board or Footswitch Board, replace the board.
 6. If you find evidence of damage on the Power Supply /RF Board, replace the board only if the damage is severe.
 7. Reinstall the cover on the generator. Tighten the screws that fit the cover to the chassis.

Configuration Outputs:

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

- After calibrating the generator
- Every Year

Equipment

- a) Two small test cables (less than 24 inches long) with banana plugs
- b) Current transformer
- c) True RMS voltmeter
- d) 100,300, and 500 Ω 1% no inductive power resistors
- e) 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.
3. Connect the two test cables to the bipolar socket.
4. Pass one test cable through the current transformer and connect the current transformer to the voltmeter.
5. Connect the 100 Ω power resistor across the output jacks at the end of the test cables.
6. Connect the bipolar footswitch to the Bipolar Footswitch socket on the rear panel.
7. Select the Micro mode and set the bipolar power to 10.
8. Test the output current for the selected bipolar mode.
9. Select the Macro mode and repeat step 4.
10. 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 *Whittemore Enterprises Inc.* Service Center.

Checking the Monopolar Cut Output

1. Check the output for the cut modes.
2. Verify that the generator successfully completes the self-test.
3. Connect the test equipment for monopolar output.
4. Connect one test cable to the left jack in the Monopolar socket. Pass the test cable through the current transformer and connect the current transformer to the voltmeter.

5. Use a test cable to short the two pins on the Patient (return electrode) socket.
6. Connect the second test cable from the voltmeter to both pins of the Patient (return electrode) socket.
7. Connect the 300 Ω resistor across the output jacks at the end of the test cables.
8. Connect the monopolar footswitch to the Monopolar Footswitch socket on the rear panel of the generator.
9. Select the Pure mode.
10. Press the cut up/down keys to set the cut power to 80 watts.
11. Test the monopolar cut output.
12. Press the footswitch cut pedal and, while activating the generator, note the output on the voltmeter.
13. Release the footswitch pedal.
14. Based on the voltmeter setting and the current transformer you are using calculate and record the output current.
15. Select the SP cut mode and repeat step 5.
16. Select the Blend mode and repeat step 5.
17. Verify that the generator output for each mode is 516 ± 26 mA rms.

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 Whittemore Enterprises Inc. Service Center.

Checking the Monopolar Coag Output

1. Check the output for the coag modes.
2. Disconnect the 300 Ω resistor and replace it with the 500 Ω resistor.
3. Select the Soft mode.
4. Press the coag Up/Down keys to set the coag power to 40 watts.
5. Test the monopolar coag outputs.
6. Press the footswitch coag pedal and, while activating the generator, note the output on the voltmeter.
7. Release the footswitch pedal.
8. Based on the voltmeter setting and the current transformer you are using calculate and record the output current.
9. Select Press the Fulgurate mode and repeat step 4.
10. Select Press the Spray mode and repeat step 4.
11. Verify that the generator output for each mode is 282 ± 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 Whittemore Enterprises Inc. Service Center.

Checking Low Frequency Leakage Current and Ground Resistance

1. Check the frequency leakage current and ground resistance before returning the Shalya LX generator to clinical use.

Equipment

- a) DVM
- b) Leakage current tester

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 centre.

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 Whittemore Enterprises Inc. 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 Ω 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 millivolt.
5. Verify the leakage current is less than or equal to 20 microamps. If the leakage current is greater than 20 microamps, call the Whittemore Enterprises Inc. Service Center.

Checking High Frequency Leakage Current and Ground Resistance

1. Check the high frequency leakage current and ground resistance before returning the Shalya LX generator to clinical use. Check the leakage current at these times.
 - After calibrating the generator.
 - Every one year.
- a) 200 Ω , 250 watt, noninductive resistor
- b) Current transformer
- c) True RMS voltmeter (Fluke 8920 or equivalent)
- d) Bipolar and monopolar footswitches and handswitching accessories
- e) Leakage setup per IEC 60601-2-2 clause 19.101 or 19.102

Checking Monopolar High Frequency Leakage Current

1. Connect the 200 Ω 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 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 Whittemore Enterprises Inc. Service Center for further instructions.

Checking Bipolar High Frequency Leakage Current

1. Remove the monopolar accessories, and connect the 200 Ω load from one side of the bipolar output through the current transformer to the equipotential ground lug on the rear 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 Whittemore Enterprises Inc. Service Center for further instructions.

CHAPTER 10

Calibration Procedures

Calibrating the EAGLE

For normal running EAGLE, 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 - Close loop current Calibration
- Step 3 - Close loop voltage Calibration
- Step 4 - Close loop power Calibration
- Step 5 - Open loop power Calibration
- Step 6 - 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 EAGLE and press the Coag Mode key and Function key at a time, up till display shows “11” in Cut and “10” in Coag display. This means system is in calibration mode.

When system is in calibration mode, step No and sub-step number appears in Cut display, values associated with each calibration step appear in Coag display. You can use Coag Up & Down keys to adjust display values.

Once the count is adjusted for desired output, press the Cut Up key to save the mode data. It will also be shown in Coag display.

Exiting Calibration Mode:

One can exit calibration procedure at any time.

If you want to save the values for a particular step, press the Cut Up key, the display will indicate mode data counts. Then next step counts will indicate in display. Switch OFF the generator to exit calibration mode.

If you do not want to change mode data, just switch OFF the EAGLE, then restart the generator to inter run mode.

To jump on next Calibration step, press Cut Up key to bypass the step. Do not press any footswitch in this condition.

Calibration Step1 - PREM Calibration

Equipment:

- PREM plug (modified)
- Resistor substitution box

Verify:

- The Bipolar display shows calibration step – “1”
- The Cut display shows the sub step – “1”
- The Coag display shows the number – “10”

Procedure:

1. Connect PREM plug in the power socket and connect the 10 ohm resistor from resistor substitution box across it.
2. Press the Cut up key. The data count will display and shows sub step – “2” in cut display.
3. Repeat the above procedure using 51 ohm resistor. The data counts will display and sub step “3” is displayed at cut display.
4. Repeat the above procedure using 135 ohm resistor and this will complete your PREM calibration.

Calibration Step 2 - Close Loop Current Calibration

Sub step-1 (Bipolar Macro mode)

Equipment

- Bipolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 50ohm non-inductive power resistor.

Verify

- The Bipolar display shows calibration step – “2”
- The Cut display shows the sub step – “1”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from Bipolar socket pass through true RMS current meter to 50 ohm resistor.
 - b. One test cable from Bipolar socket to 50 Ω resistor.
 - c. Bipolar footswitch to the bipolar footswitch socket on the rear panel.
2. Check and adjust the ‘I’ max for bipolar output.
 - a. Press the Bipolar footswitch pedal and check the current reading equivalent to 999 mA \pm 20 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not in the stated range
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The ‘I’ max for Micro & Standard modes are 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
- 200 Ω non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “2”
- The Cut display shows the sub step – “2”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 200 Ω One test cable from Monopolar socket pass through true RMS current meter to 200 Ω Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the ‘I’ max for Monopolar cut output.
 - a. Press the Monopolar cut footswitch pedal and check the current equivalent to 999mA \pm 20 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The ‘I’ max for low Cut mode is adjusted automatically.
3. Disconnect the test cables from Monopolar output.

Sub step- 3 (Blend Mode)**Equipment:**

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

Verify:

- The Bipolar display shows calibration step – “2”
- The Cut display shows the sub step – “3”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 200 Ω One test cable from Monopolar socket pass through true RMS current meter to 200 Ω
 - b. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the ‘I’ max for Monopolar Blend cut output.
3. Press the Monopolar footswitch pedal and check the current reading for a reading equivalent to 774 mA \pm 20 mA RMS.
4. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
5. Repeat this step until the meter reading is not within the stated range.
6. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
7. Disconnect the test cables from Monopolar output.

Calibration Step 3 - Close Loop Voltage Calibration

Sub step-1 (Bipolar Macro mode)

Equipment:

- Bipolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 1000 ohm non-inductive power resistor.

Verify:

- The Bipolar display shows calibration step – “3”
- The Cut display shows the sub step – “1”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from Bipolar socket passing through true RMS current meter to 1000 ohm resistor.
 - b. One test cable from Bipolar socket to 1000 Ω resistor.
 - c. Bipolar footswitch to the bipolar footswitch socket on the rear panel.
2. Check and adjust the V max for bipolar output.
 - a. Press the Bipolar footswitch pedal and check the current reading for a reading equivalent to $223 \text{ mA} \pm 20 \text{ mA RMS}$.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The V max for Micro& Standard modes are 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
- 1000 Ω non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “3”
- The Cut display shows the sub step – “2”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 1000 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 1000 Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the V max for Monopolar cut output.
 - a. Press the Monopolar cut footswitch pedal and check the current equivalent to $447 \text{ mA} \pm 20 \text{ mA RMS}$.

- b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The V max for low Cut mode is adjusted automatically.
3. Disconnect the test cables from Monopolar output.

Sub step- 3 (Blend Mode)**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 1000 Ω non-inductive power resistor.

Verify:

- The Bipolar display shows calibration step – “3”
- The Cut display shows the sub step – “3”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 1000 Ω one test cable from Monopolar socket passes through true RMS current meter to 1000 Ω .
 - b. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the V max for Monopolar Blend cut output.
 - a. Press the Monopolar footswitch pedal and check the current reading for a reading equivalent to 346 mA \pm 20 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Calibration Step 4 - Close Loop Power Calibration**Sub step-1 (Bipolar Macro mode)****Equipment:**

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

Verify:

- The Bipolar display shows calibration step – “4”
- The Cut display shows the sub step – “1”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from bipolar socket passes through true RMS current meter to 300 Ω resistor.
 - b. One test cable from Bipolar socket to 300 Ω resistor.

- c. Bipolar footswitch to the bipolar footswitch socket on the rear panel.
2. Check and adjust the P max for bipolar output.
 - a. Press the Bipolar footswitch pedal and check the current reading for a reading equivalent to $316 \text{ mA} \pm 20 \text{ mA RMS}$.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The P max for Micro & Standard modes are 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
- $500\text{-}\Omega$ non-inductive power resistor.
- PREM plug modified.

Verify:

1. The Bipolar display shows calibration step – “4”
2. The Cut display shows the sub step – “2”
3. The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 500Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 500Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the P max for Monopolar cut output.
 - a. Press the Monopolar cut footswitch pedal and check the current equivalent to $374 \text{ mA} \pm 20 \text{ mA RMS}$.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
 - e. The P max for low Cut mode is adjusted automatically.
3. Disconnect the test cables from Monopolar output.

Sub step- 3 (Blend Mode)**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- $500\text{-}\Omega$ non-inductive power resistor.

Verify:

- The Bipolar display shows calibration step – “4”
- The Cut display shows the sub step – “3”

- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 500 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 500 Ω .
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the P max for Monopolar Blend cut output.
 - a. Press the Monopolar footswitch pedal and check the current reading for a reading equivalent to 374 mA \pm 20 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Calibration Step 5 - Open Loop Power Calibration**Sub step -1 (Soft Coag)****Equipment:**

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

Verify:

- The Bipolar display shows calibration step – “5”
- The Cut display shows the sub step – “1”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 500 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 500 Ω
2. Check and adjust the P max for Monopolar Desiccate output.
 - a. Press the Monopolar coag footswitch pedal and check the current equivalent to 282 mA \pm 10 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Sub Step-2 (Fulguration Coag)**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter

- 500 Ω non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “5”
- The Cut display shows the sub step – “2”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 500 Ω .
 - b. One test cable from Monopolar socket passes through true RMS current meter to 500 Ω .
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the P max for Monopolar Fulgurate output.
 - a. Press the Monopolar coag footswitch pedal and check the current equivalent to 282 mA \pm 10 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Sub Step-3 (Spray Coag)**Equipment:**

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

Verify:

- The Bipolar display shows calibration step – “5”
- The Cut display shows the sub step – “3”
- The Coag display shows the data – “50”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 500 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 500 Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the P max for Monopolar Spray Coag output.
 - a. Press the Monopolar coag footswitch pedal and check the current equivalent to 282 mA \pm 10 mA RMS.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Calibration Step 6 - Open Loop Voltage Calibration

Sub step -1 (Soft Coag)

Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 3000 ohm non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “6”
- The Cut display shows the sub step – “1”
- The Coag display shows the data – “100”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 3000 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 3000 Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the Vmax for Monopolar Desiccate output.
 - a. Press the Monopolar coag footswitch pedal and check the current equivalent to 45 mA \pm 5%.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Sub step -2 (Fulgurate Coag)

Equipment:

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 3000 Ω non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “6”
- The Cut display shows the sub step – “2”
- The Coag display shows the data – “100”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 3000 Ω
 - b. One test cable from Monopolar socket passes through true RMS current meter to 3000 Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the V max for Monopolar Fulgurate output.
 - a. Press the Monopolar coag footswitch pedal and check the current equivalent to 50 mA \pm 5%.

- b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

Sub step -3 (Spray Coag)**Equipment:**

- Monopolar footswitch.
- Small test cables with banana plugs
- True RMS current meter
- 3000 Ω non-inductive power resistor.
- PREM plug modified.

Verify:

- The Bipolar display shows calibration step – “6”
- The Cut display shows the sub step – “3”
- The Coag display shows the data – “100”

Procedure:

1. Connect:
 - a. One test cable from socket PREM plug to 3000 Ω .
 - b. One test cable from Monopolar socket passes through true RMS current meter to 3000 Ω
 - c. Monopolar footswitch to the Monopolar footswitch socket on the rear panel.
2. Check and adjust the V max for Monopolar Spray Coag output.
 - a. Press the Monopolar coag footswitch pedal and check the current 50 mA $\pm 5\%$.
 - b. Stop activation. If the output current is high, decrease coag display count using Coag down key. If it is too low, increase the coag display count using Coag up key.
 - c. Repeat this step until the meter reading is not within the stated range.
 - d. When reading is in stated range, press bipolar Up key, the coag display will indicate data count.
3. Disconnect the test cables from Monopolar output.

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.

CAUTION

Never immerse the electrosurgical unit in water, clean or disinfect by immersion, gas sterilization or autoclaving. It may cause equipment damage.

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

11.2 STORAGE OF THE UNIT

Turn the electrosurgical unit OFF and disconnect the power cord from the receptacle (wall mains outlet)

If the equipment is soiled with blood or other potentially infectious materials, first wipe off all gross debris using neutral detergent, then wipe its surface with a lint-free cloth moistened with a surface disinfectant.

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.

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 be sterilized by EtO gas or autoclaving. These methods will cause deformation and damage that will render the cable useless.

Make sure that foreign mains cable matter does not enter the 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

Trouble shooting

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

- Identify and correct the malfunction.
- If a system alarm number displayed, take the appropriate action to correct the alarm conditions.

Inspecting the Generator

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

but did not complete the self-test		number and refer to Responding to System Alarms in this section.
	Software malfunction	Turn off and then turn on the generator.
	Loose or disconnected internal cables and/or boards.	Check and correct all internal connections. Press the connectors and boards if required.
	Faulty low voltage power supply	Check the low voltage power supply. If not working properly, replace it.
	Damaged CPU board connectors and/or malfunctioning CPU board	Remove the CPU board and inspect the connectors to the Power Supply & RF board and to the Display board for damage. Replace the CPU board if required.
	Shorts or disconnects on Power Supply & RF board	Check the Power Supply & RF board for shorts or disconnects.
	Faulty mains ON-OFF switch	Replace the switch.
Activation and/or alarm tones do not sound, speaker is malfunctioning	Malfunctioning front panel components	Replace the front panel assembly.
	Poor connection or damaged footswitch board	Check/correct connection. If indicated, replace the Footswitch board.
	Faulty connections or speaker on Footswitch board	Replace the footswitch board.
Blank or confusing LED display	Audio signal malfunction on Control board	Replace the control board.
	Faulty ribbon cable between CPU and Display board	Check/connect ribbon cable that connects the Display board to the CPU board.
	Incorrect data communicated through the CPU board	Replace the CPU board.
Mode keys do not function correctly when pressed	Display board malfunction	Replace the Display board.
	Faulty ribbon cable between CPU board and display board	Check/connect ribbon cable that the Display board to the Control board.
	Incorrect data communicated through the CPU board	Replace the CPU board.
	Faulty ribbon cable between the front panel and the Display board	Check/connect the ribbon cable that connects the Display board to the front panel.
Generator is on and accessory is activated, but generator does not deliver output	Incorrect modes are being sent from the front panel	Replace the front panel.
	Malfunctioning footswitch or handswitching instrument	Turn off the generator. Check and connect all accessory connections. Turn on the generator. Replace the accessory if it continues to malfunction.
	Footswitch connected to Monopolar socket	Connect the footswitch & the footswitching instrument to the same instrumentation socket.
	Power set too low	Increase the power setting.
	An alarm condition exists	Check the Cut & Coag display for an alarm number.

	Blown fuse on Power Supply & RF board	Check the high voltage power supply fuse (F02) and replace if necessary.
	CPU board malfunction	If the indicator bar does not illuminate and the tone does not sound, replace the CPU board.
	High voltage power supply malfunction (high voltage is not present during activation)	If high voltage is not present on the Power Supply/RF board, troubleshoot the high voltage power supply Check all MOSFET Q01 to Q04, replace with same part no. if require. Check Diodes CR02 to CR05 replace with same part no. if require.
	RF output stage malfunction (high voltage is present during activation)	Troubleshoot the RF output stage as described below on the Power Supply /RF board: Verify T_ON pulses at R77, If pulses are present, Check all MOSFET Q9 to Q12, replace with same part no. if require. <ul style="list-style-type: none"> Check Diodes CR27 replace with same part no. If T_ON pulses are not present, <ul style="list-style-type: none"> Verify T_ON pulses at TP 16, If pulses are not present, replace the CPU Check the IC U14, replace with same part no. If require.
Footswitch will not activate output	Malfunctioning or damaged footswitch socket	Replace the Footswitch board.
	Footswitch activation signal lost on Power Supply & RF board	Replace the Power Supply & RF board.
	Footswitch activation signal lost on CPU board	Replace the CPU board.
Interference with other devices only when generator is activated	Malfunctioning monitor	Replace the monitor.
	Metal-to-metal sparking	Check all connections to the generator, patient return electrode, and accessories.
	High settings used for fulguration	Use lower power settings for fulguration or select the Desiccate mode.
	Loose contact in ground wiring in the operating room	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continuous when the generator is activated, the monitor is responding to radiated frequencies.	Check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference then the generator is activated and minimizes the potential for an electrosurgical burn at the site of the monitor electrode.
Pacemaker interference	Intermittent connections or metal-to-metal sparking	Check all connections to the generator. It may be necessary to reprogram the pacemaker.
	Current traveling from active to return electrode during	Use bipolar instruments, if possible. If you must use a monopolar instrument, place the patient return electrode

	monopolar electrosurgery is passing too close to pacemaker.	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.
Abnormal neuromuscular stimulation (stop surgery immediately)	Metal-to-metal sparking	Check all connections to the generator, patient return electrode, and active electrode.
	Can occur during coag	Use a lower power setting for the Fulgurate and spray modes or select the Desiccate mode.
	Abnormal 50-60 Hz leakage currents	Inside the generator, carefully inspect for the damage that may cause shorting between the AC line voltage and connected patient components.

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 table recommends some action to overcome the error condition.

Error Code No.	Description	Recommended Action
501	Internal diagnostics. Bipolar Handswitch or Footswitch paddle stuck.	<ul style="list-style-type: none"> • Turn OFF and again turn ON the generator. Do press any activation during self-test. • If the alarm repeats, disconnect all accessories. Turn OFF and again turn ON the generator. • If the alarm repeats, check activation request generator circuit. • Call <i>Whittemore Enterprises Inc.</i> service cell. • Turn OFF and again turn ON the generator. Do press any Key during self-test. • If the alarm repeats, disconnect all accessories. Check/connect the ribbon cable that connects the Display board to the front panel. Turn OFF and again turn ON the generator. • If the alarm repeats, replace front keypad. • Call <i>Whittemore Enterprises Inc.</i> service cell.
502	Internal diagnostics. Monopolar Cut Handswitch or Footswitch paddle stuck.	
503	Internal diagnostics. Monopolar Coag Handswitch or Footswitch paddle stuck.	
601	Internal diagnostics. Bipolar Mode key stuck.	
602	Internal diagnostics. Cut Mode key stuck.	
603	Internal diagnostics. Coag Mode key stuck.	
604	Internal diagnostics. Bipolar Up key stuck.	
605	Internal diagnostics. Cut Up key stuck.	
606	Internal diagnostics. Coag Up key stuck.	

607	Internal diagnostics. Bipolar Down key stuck.	
608	Internal diagnostics. Cut Down key stuck.	
609	Internal diagnostics. Coag Down key stuck.	
610	Internal diagnostics. Recall key stuck.	
611	Internal diagnostics. Program key stuck.	
702	External memory “EPROM” data loss message	<ul style="list-style-type: none"> • Let the unit remain “ON” as it is. Do not switch “OFF”. The unit internally corrects the data loss. This may take some time. After complete data recovery, the PREM button turns green from red. Now, switch “OFF” the unit and again switch it “ON”. • If the problem persists, call <i>XcelLance Technologies</i> service cell.

Warranty

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

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

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

Whittemore Enterprises Inc. 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

- 1) 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'.
- 2) The equipment has to be strictly used only by qualified, trained & licensed surgeon/physician.
- 3) Optimized & safe usage of equipment is warranted only if manufacturer's approved accessories are used along with the equipment during surgery. Company will not be responsible for any damage/injuries/complications caused to user or patient due to the use of unsafe, non-approved electrosurgical accessories.
- 4) Company is not responsible for any damage/ complications to patient or user due to use any equipment which has not been maintained & calibrated periodically as described in user/instruction manual.
- 5) The equipment maintenance has to be done by a Company trained & qualified technician/engineer. Company is not responsible for any kind of losses to equipment/ patient/ user caused due to the incorrect operation/ maintenance of the equipment by an unauthorized/ untrained person.
- 6) 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.
- 7) The equipment's warranty is in lieu of all other warranties, expressed or implied, including without limitations, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of the Company. Company neither assumes nor authorizes any other person to assume for any other liability in connection with the sale or use of any of the Company products.
- 8) Notwithstanding any other provision herein or in any other document or communication, Company's liability of products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Company to the customer. There are no warranties which extend beyond the terms hereof. Company disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.