Eagle Two

INSTRUCTION & SERVICE MANUAL

This document is a user guide for Eagle Two Electro-surgical 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 Two ESU in this document are: Generator, ESU, Machine, and Eagle Two.

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

CE 0120

ISO 13485

INDEX

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

CHAPTER 1
Introduction

***Whittemore Enterprises Inc.*,** Eagle Two Electrosurgical Generator provides necessary power for Bipolar & Sealer applications.

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 & leakage RF current.
- **Surgical Assistant:** User programmable Programs settings which covers a surgical procedures with flexibility.
- **Fully Microprocessor controlled:** To achieve high degree of clinical precision.
- **2 Bipolar Modes:** Micro & Macro Modes with high impedance bipolar output.
- **Sealer mode** with high impedance sealing operation.
- **BiCoag Alarms**: Audio feedback alarm after completion of Bipolar Coagulation reduces charring & sticking of tissue to forceps & avoids over burning of tissue.

B. MODES OF ELECTROSURGERY

Vessel Sealing System:

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

Vessel Sealing

- ***Sealer* -** Effective for standard vessel sealing and fusion.

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 implants manufacturer for instructions before performing an electrosurgical procedure. Maintain adequate distance between these implants and active electrode of the generator.

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

General Warnings & Cautions:

Warnings-

- This generator should be used by qualified medical person only.
- 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.
- Do not lean on the patient, while buzzing the hemostat, accidental and unintended burn injury may occur.

Cautions:

- 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.

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.

Bipolar

***Warnings/*Cautions:**

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

Vessel Sealing

Warnings-

- Make use of appropriate footswitch for vessel sealing operation; perform manual settings when using single paddle footswitch.
- Use appropriate power; apply adequate pressure on tissue before activating sealer.
- Completion alarm indicates the proper sealing of tissue, do not release the instrument before completion alarm sounds.

- Do not perform sealing operation in the vicinity of conductive fluids as it may cause unintended injuries to the area in vicinity of conducting fluids.
- In laparoscopic operations ensure that the direct contact with the desired tissue is established; do not activate power before proper contact as it may lead to unintended burns.
- Do not apply sealing electrode on wounded vessels as it may damage it further.
- Proper inspection of the instrument is necessary before use. If any kind of insulation failure or damages of instrument or improper assembly of instrument, do not use it on the patient as this could be dangerous for Operator and the Patient.
- Do not use Normal Saline (NS) to clean the instrument at any stage. Usage of Saline could result in failure of the instrument.
- Vessel sealing devices will not work in blood reach environment; get the tissue clean before sealing.
- Do not use vessel sealer with the tissue washed with Normal Saline (NS). Do not give saline wash till vessel sealing procedure complete. Use sterile water in case of requirement.
- Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting to blood loss during surgery.

Cautions:

- Use vessel sealing accessories provided by Whittemore Enterprises Inc.only. Making use of other instrument may not deliver optimized power or desired effects for the operation.
- Do not use saline solutions for cleaning bipolar Vessel Sealing instruments,

this may reduce working life of accessories.

Electrical Connections & Power:

Warnings-

- Make use of a dry cheesecloth between patient and ground body.
- Do not turn on the generator until
- Inspect electrode connections and contacts frequently.
- Check all the power settings & each and every connection to the generator before using the device on patient.
- Check if the earthing of power source in surgical room is proper. Make sure equipment chassis or cabinets are grounded. Never cut off or reverse the ground connection on a plug.
- Please check if power from the main line (AC) is within the specified range as required for proper functioning of the generator. Inappropriate voltage from the mains plug (AC Line) may damage the device and/or may turn out to be hazardous to patient and/or surgeon.
- Always use lowest output setting for desired surgical effect. If proper setting is unknown, set the generator at a very low setting & increase the power continuously until the desired effect is achieved.
- Take faults of the circuitry into consideration any time the surgeon continues to request a higher power. Check all the problematic extents such as: patient electrode, active electrode or ESU as excessive power may damage and/or burn the tissue.
- Simultaneously activating irrigation & electrosurgical current may result in increased arcing at electrode tip, burns to unintended tissues, shocks & burns to the surgical site.

Cautions:

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

Accessories Related:

Warnings-

- Inspect ESU unit prior to use. Remove accessories which are damaged and/or not working properly.
- Do not wrap the accessory leads around the metal objects. This may induce

currents that are dangerous to the patient.

- Do not try to increase or reduce length of cables. Excessive or improper current may unintentionally damage the tissue or skin.

Cautions:

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

Radio Frequency Burns:

Warnings-

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

Generator Placement & Environment:

Warnings-

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

Cautions:

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

Other:

Warnings-

- Check if activation, safety, warning audio & visual alarms are working properly. If found problematic; restart the generator, check it again after restarting. If problem still exists do not use the generator as it may result in erratic functioning which may lead to hazards. *Contact Whittemore Enterprises Inc. service department.*
- Always perform cleaning operation of the generator after surgery; disconnect all the electrical connections and accessories before cleaning the generator.

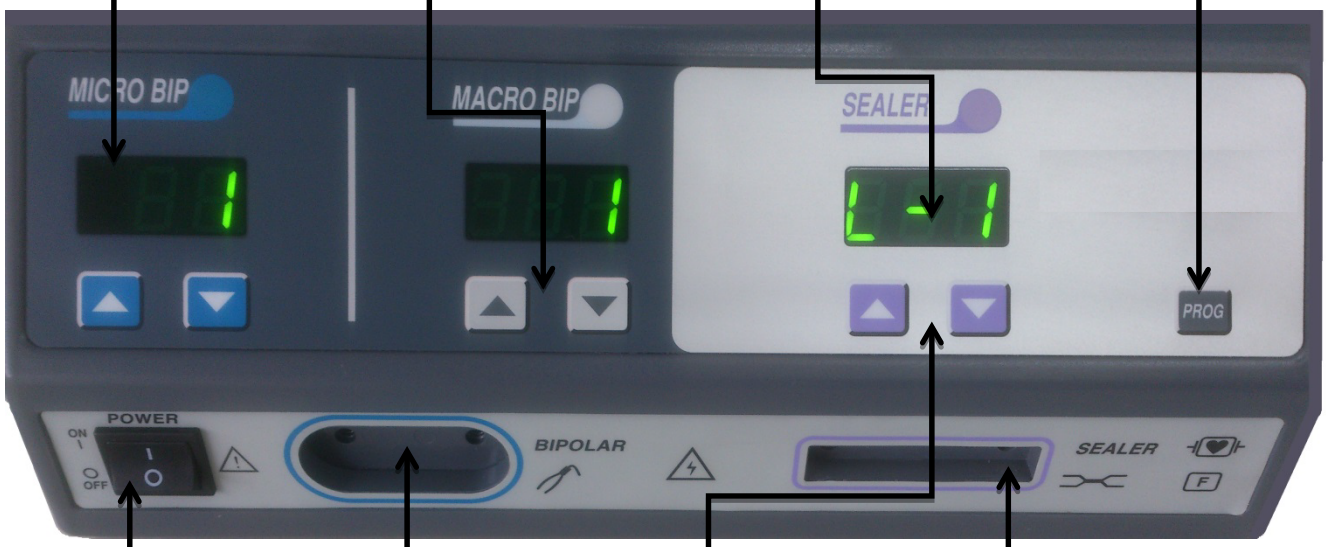
- In case if a patient is moved from one place to another recheck all the connections, as the proper contact of electrode cable with the generator is necessary.
- During procedures in small surgical field, accidental and unintended burn injury may occur.
- Shave off body hairs coming in contact with 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
Control, Indicators & Output Sockets

A. FRONT PANEL



Power Settings Display (Power in Watts)

Up/Down Keys: To Increase/ Decrease the Power

Power Settings Display: (Level 1 to 5)

Program Key: To load/ manipulate the custom program

Power ON/OFF Switch: (1) ON & (0) OFF

Bipolar Socket: Accepts 2 Pin foot switching interface

Up/Down Keys To increase/ decrease the power.

Sealer Socket: Accepts standard 4mm- two pins footswitching & hand interface cable for sealer.

B. REAR PANEL

Power Cord: To supply AC (230V / 50Hz) or (110V/ 60Hz) Power to an ESU

Volume control: To adjust activation tone volume. Alarm tone volume is not adjustable.

Sealer Footswitch: It is a single paddle footswitch

Grounding Lug: To reduce noise in other equipment. Connect it to the earthing receptacle.

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

Bipolar Footswitch: It is a Double paddle footswitch

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

CHAPTER 4
Technical Specifications

A. GENERAL SPECIFICATIONS

Output Configuration: Isolated output with cardiac defibrillator protection

Duty Cycle of Operation: At maximum rated load conditions; Bipolar- 70 watt setting at 100 Ω : the system is suitable for cycle of 10 seconds of ON time (activation time) & 30 seconds of OFF time, repeated over an hour.

Cooling by Convection: *Natural:* By side and rear panel vents.
Display: seven-segment displays, eight digits, 0.75 inch each.

Standards and IEC Classifications

ATTENTION Refer accompanying documents

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

FLOTING 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, so they don'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 Two provides a high degree of protection against electric shock. Instrument can be used for cardiac procedures due to type CF isolated (floating) output.

Drip Proof (IEC 60601-2-2)
The Eagle Two enclosure is so constructed that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely 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 to the generator, it operates without any interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

***Caution**:* Do not stack any equipment upon Eagle Two or place the generator on the top of other electrical equipment. This configuration will not allow proper cooling.

Caution: Do not place any chemical or solution in the operating room; it may spoil safety of electronic circuit by liquid spillage.

Electromagnetic compatibility (IEC 60601-1-2)
The Eagle Two fulfills the specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)
The Eagle Two operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

Defibrillator Proof
The Eagle Two meets specifications for "defibrillator proof" design.

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

Non-volatile

Audio Volume

Activation Tone:	Volume (adjustable):	40 to ≥ 65 dB
	Frequency:	Bipolar: 940 Hz

Alarm Tone:	Volume (not adjustable):	≥ 65 dB
	Frequency:	660 Hz
	Pulse:	Two Pulse 1 sec ON time, 1 sec OFF time.

High Frequency (RF) Leakage Current

Bipolar RF leakage current: < 60 mA RMS

Input Power

Mains nominal voltage:	**230 V**	**110 V**
Input mains voltage, full regulation range:	210-264 Vac	104-132 Vac
Input mains voltage, operating range:	180-264 Vac	85-135Vac
Mains current (maximum):	Idle: 0.2 A	Idle: 0.4 A
	Bipolar: 2 A	Bipolar: 4 A
Maximum VA at nominal line voltage:	Idle: 52 VA	Idle: 52 VA
	Bipolar: 528 VA	Bipolar: 528 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: 1 to 40 by step of 1, 40 to 95 by step of 5.
Macro: 1 to 40 by step of 1, 40 to 95 by step of 5.

Sealer:

L1-80W
L2-100W
L3-120W
L4-135W
L5-150W

C. OUTPUT CHARACTERISTICS

Maximum Output for Bipolar & Sealer Modes
Power readouts agree with actual power into rated load to within 20% or 10watts, whichever is greater.

Mode	**Open Circuit P-P Voltage**	**Rated Load**	**Power (max)**	**Crest Factor**
Bipolar				
Micro	360 V	100 Ω	95 W	1.5
Macro	680 V	100 Ω	95 W	1.5
Sealer	650 V	100 Ω	150 W	1.5

*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 & Sealer.

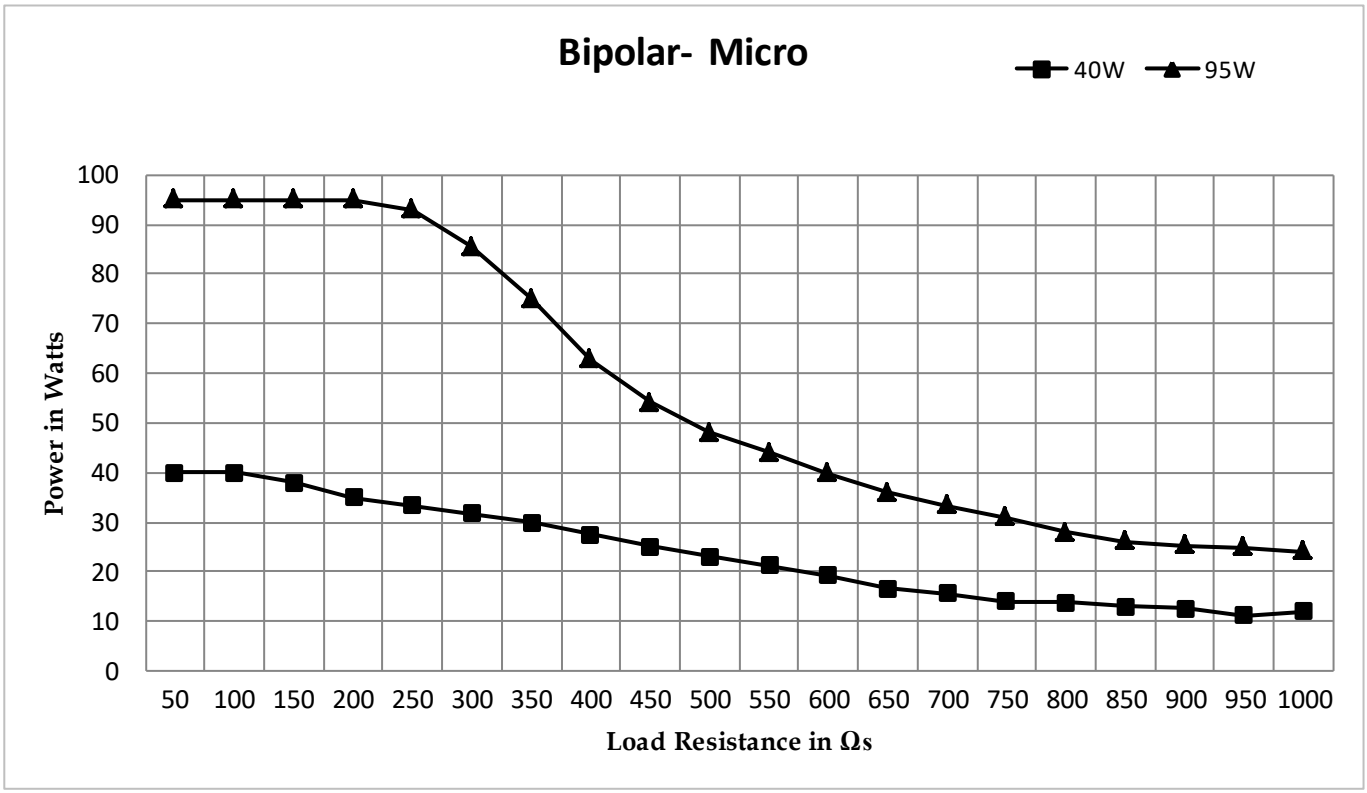
Bipolar

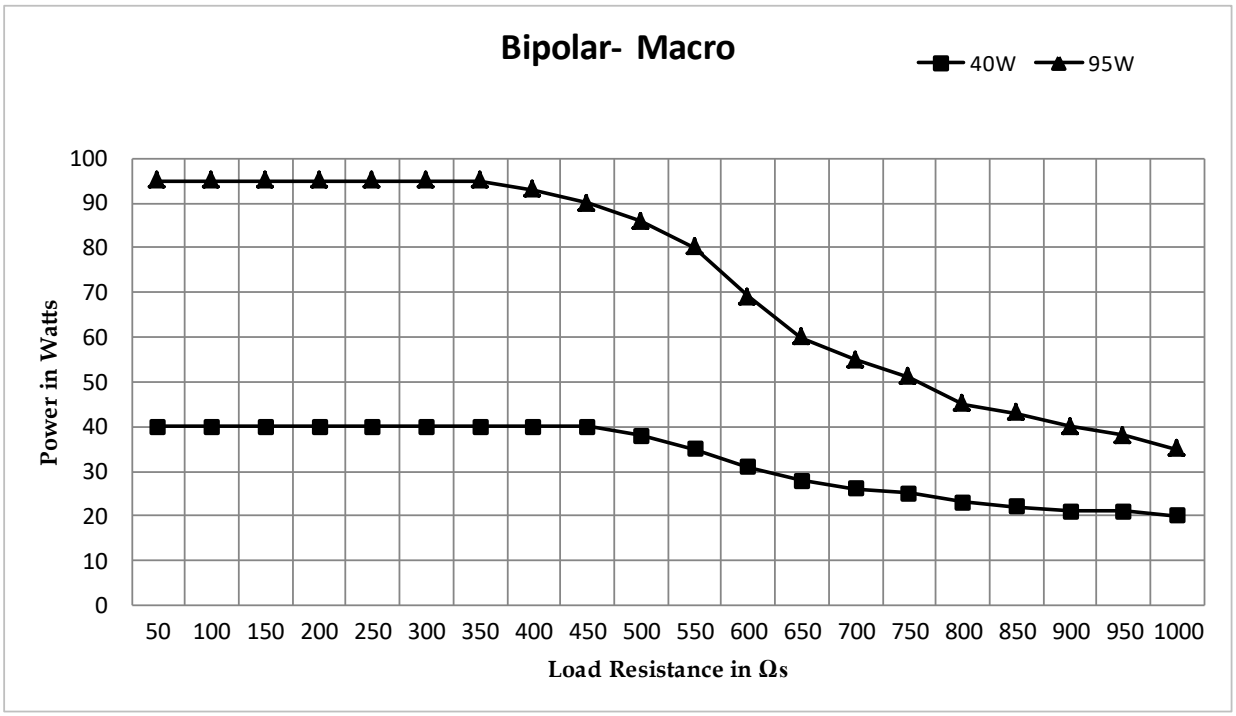
Micro 440 kHz sinusoidal
Macro 440 kHz sinusoidal
Sealer 440 kHz sinusoidal

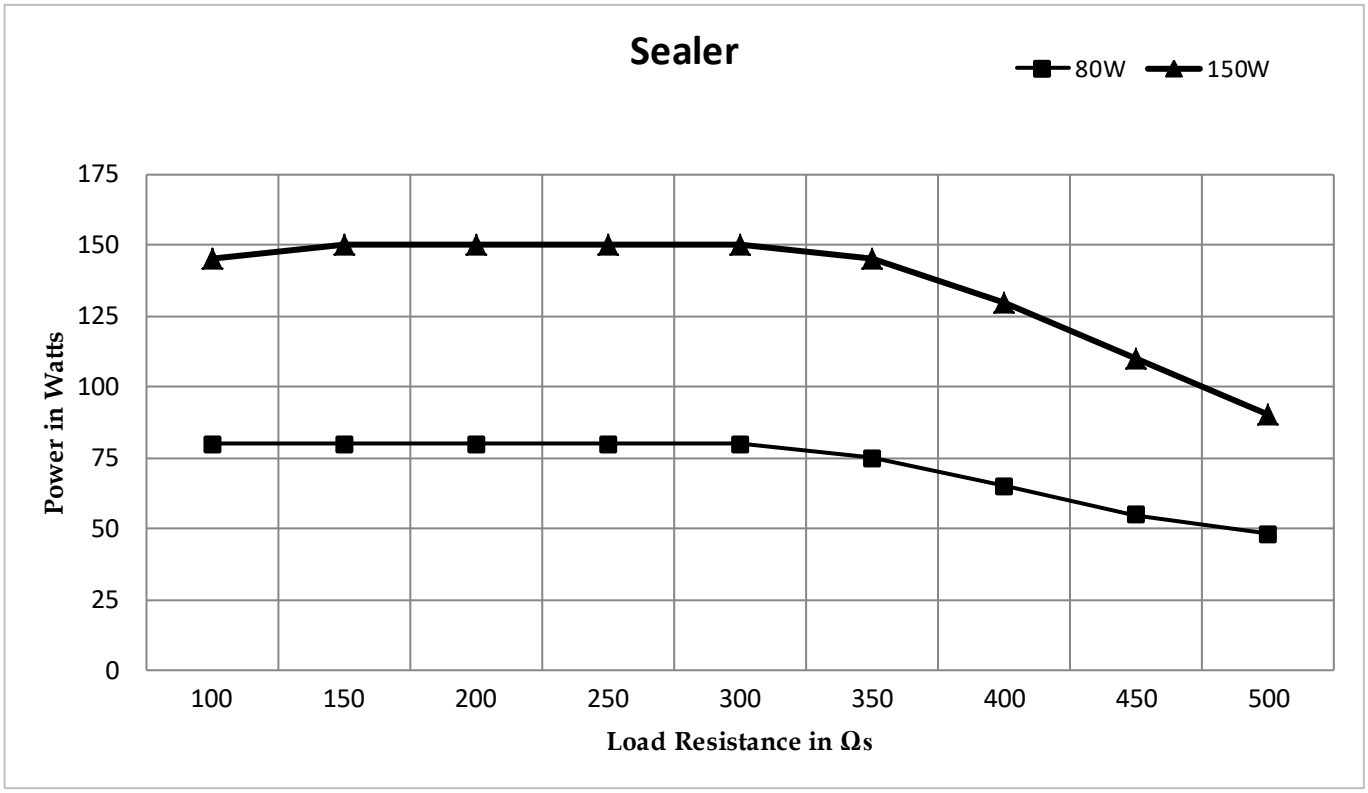
E. AREA OF APPLICATION:

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

F. OUTPUT POWER VS. LOAD GRAPHS




Bipolar- Macro
40W
95W
Power in Watts
100
90
80
70
60
50
40
30
20
10
0
50 100 150 200 250 300 350 400 450 500 550 600 650 700 750 800 850 900 950 1000
Load Resistance in Ωs


Sealer
80W
150W
Power in Watts
175
150
125
100
75
50
25
0
100 150 200 250 300 350 400 450 500
Load Resistance in Ωs

CHAPTER 5
Before Surgery

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

Before Surgery:
Caution - Read all warnings, cautions provided with this generator before using.

Active accessories:
Electric Shock Hazard
Warning - Avoid the connection of wet accessories to the generator.
Caution - Do not reuse or desterilize accessories labeled "disposable" or "single use only".

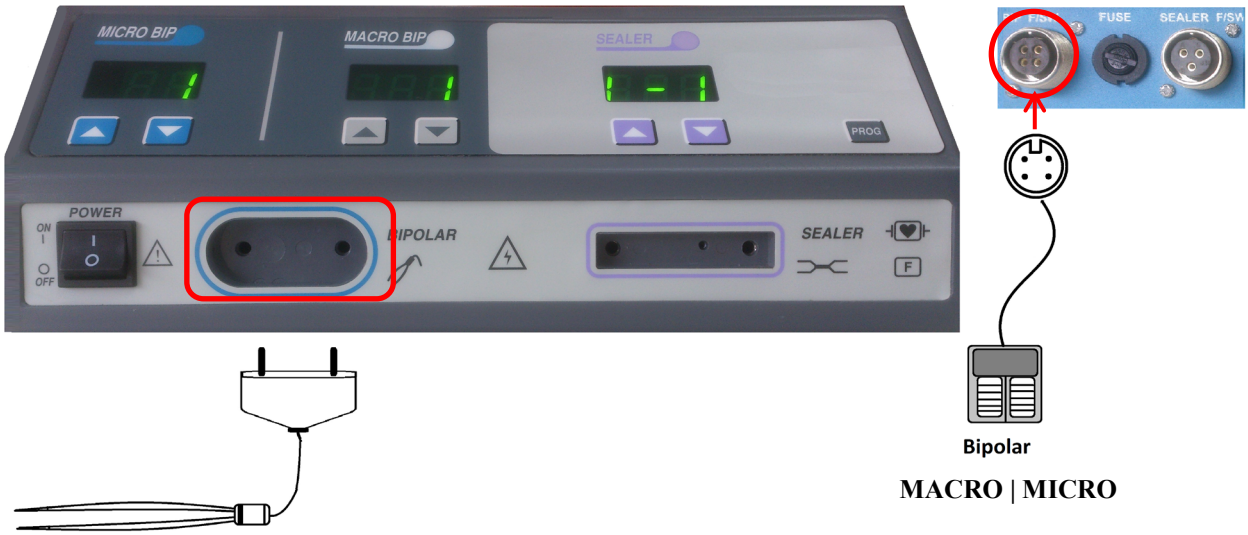
A. PREPARING THE GENERATOR

- 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.
- Verify or change the mode & power setting.
- Optional-Press the Program key on the front panel to display pre-programmed setting. Change the settings if required as surgical conditions & patient placement may require change in settings. This varies as individual skills.

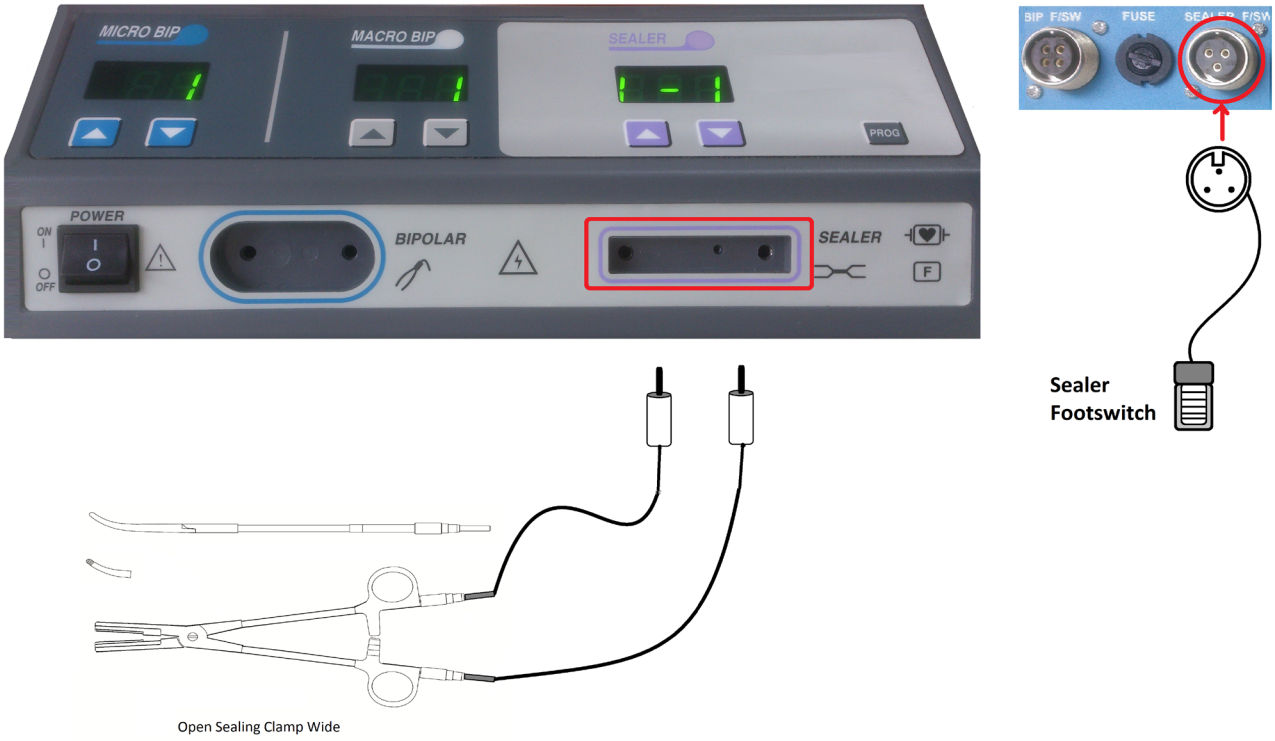
B. SETTING THE GENERATOR

1. Verify the generator is off by pressing the power switch OFF (0).
2. Place the generator on a stable flat surface, such as flat 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. Don't put generator on askew surface.
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 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:
   - Each display shows a power setting of 1 watt.
   - If the self-test is successful, connect the accessories & set the generator controls.

C. SURGERY MODES & ACCESSORY CONNECTIONS

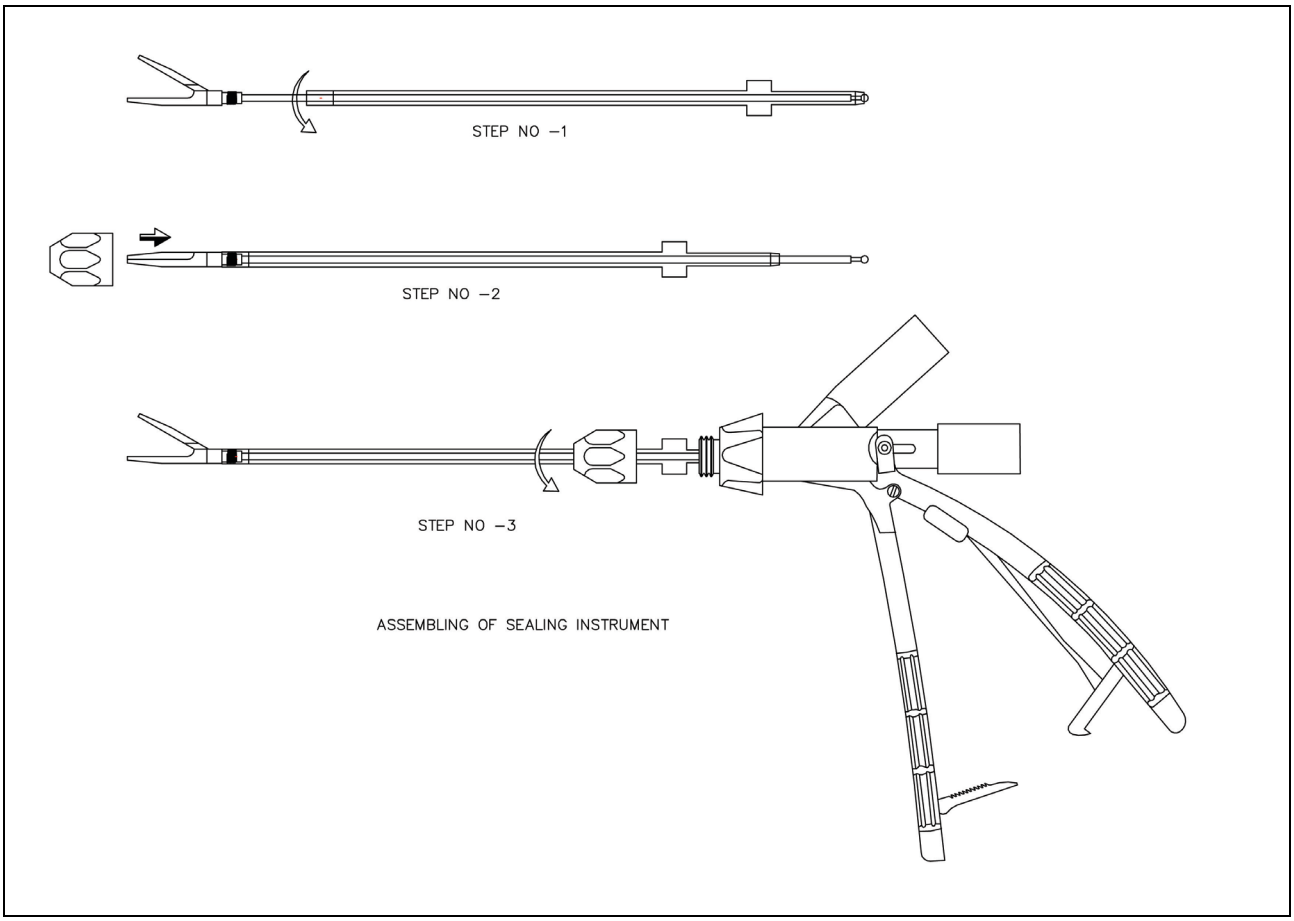


For Bipolar surgery, insert Foot switching Bipolar male connector in Bipolar rear panel socket and connect Bipolar forceps in front panel.

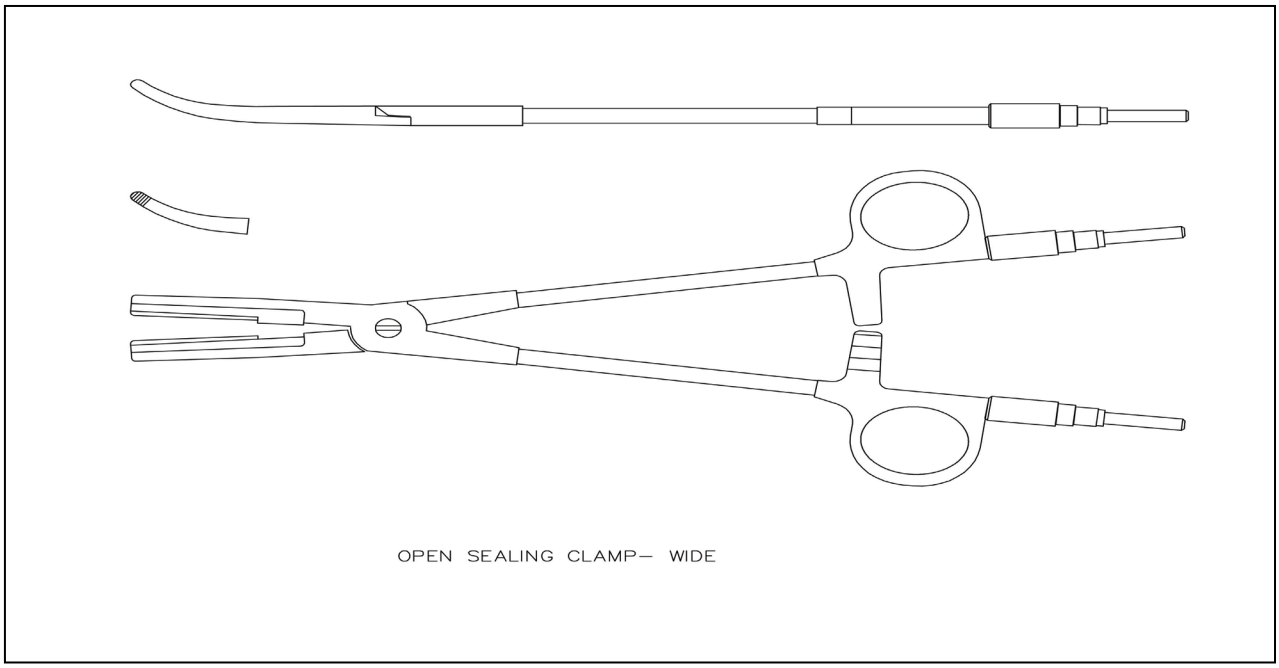


For Sealer surgery, insert Foot switching Sealer male connector in Sealer rear panel socket and connect Sealer forceps in front panel.

Sealer Instruments

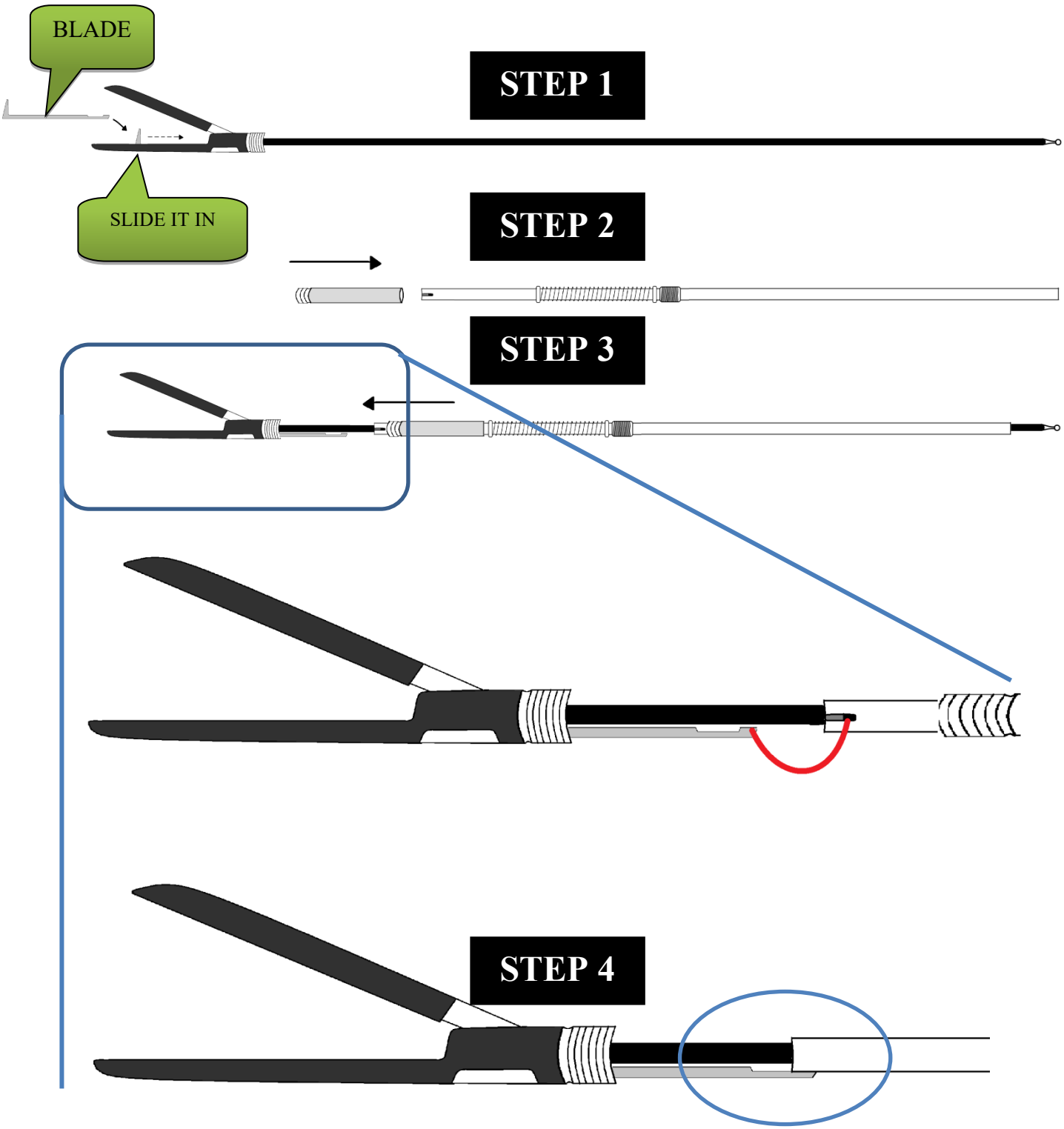


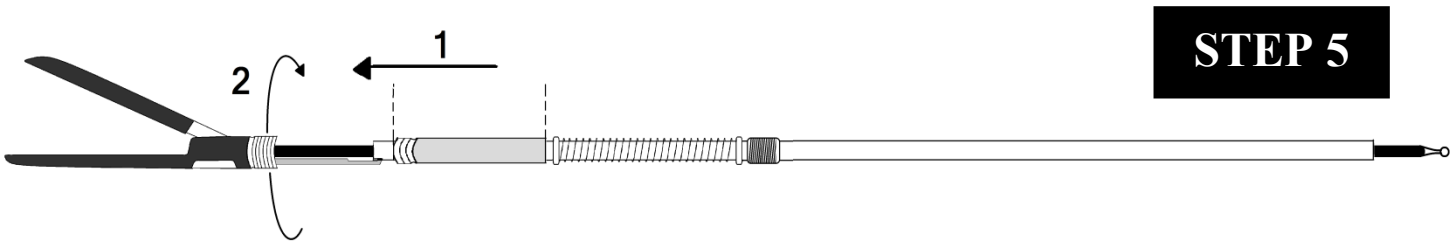
Lapro Instrument 5mm for Sealer Mode

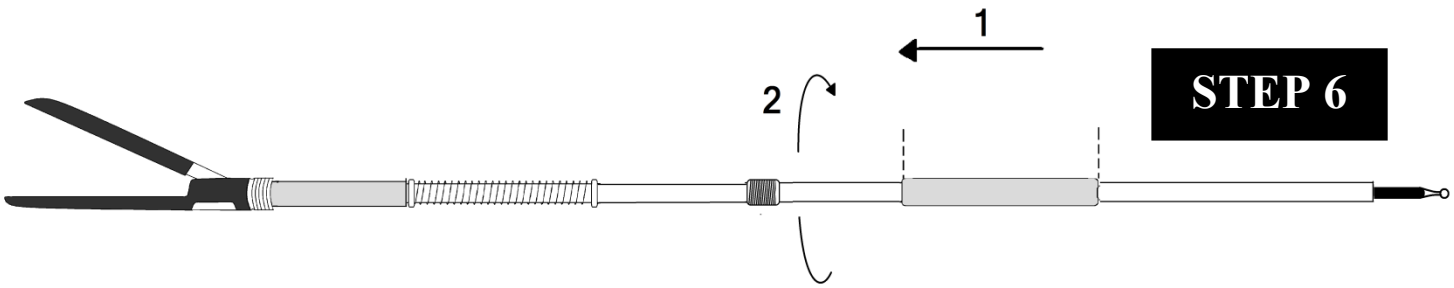


Open Clamp for Sealer Mode

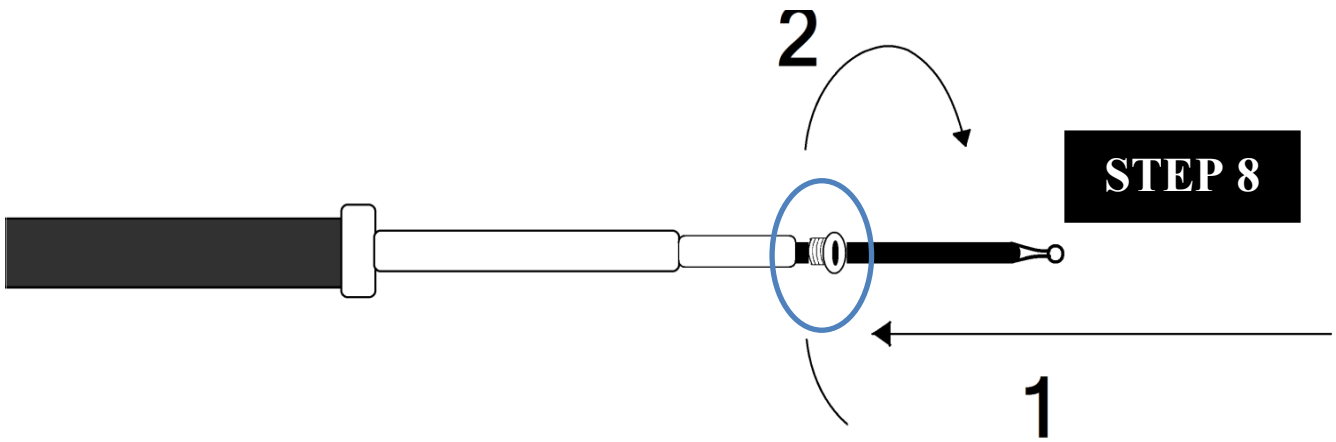
Sealer Instrument (10mm) Assembling



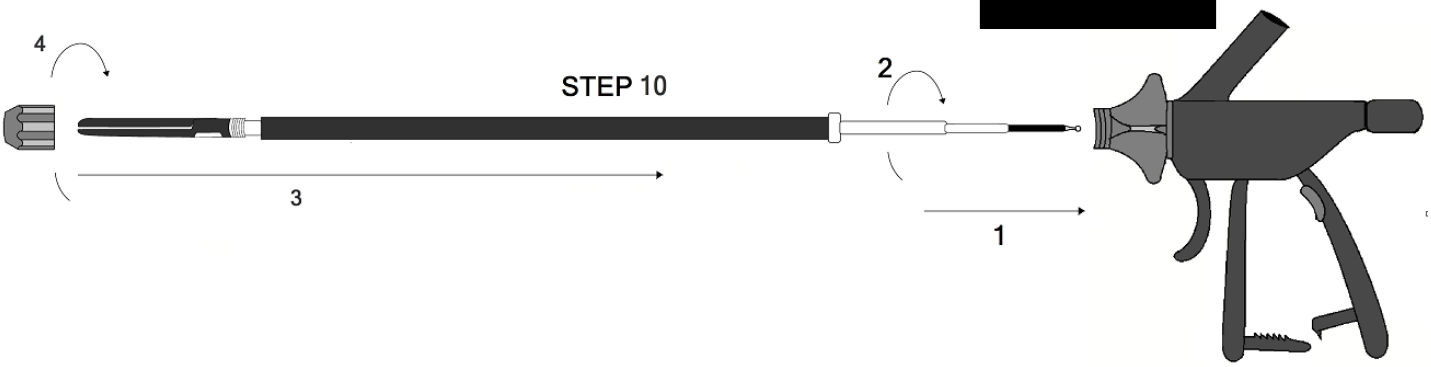

STEP 5
1
2


STEP 6
1
2


STEP 7
2
SHALYA
1


STEP 8
2
1

STEP 9



D. VESSEL SEALING INSTRUMENT GUIDELINES

BEFORE SURGERY:

- Check all parts of Outer tubing, Blade assembly, Jaws and Insert assembly and Handle for mechanical deformities and insulation breakages. Open the Outer tubing & Blade assembly to check the proper cleaning of the instrument.
- Clean the Jaws & Hinge areas by using H_2O_2 followed by any permissible disinfectant as per the operation theatres norms.
- Make sure that there is no tissue left inside the hinge areas & blades assembly tubing. This can damage the instrument during next use.
- In case of using non sterilized blades, assemble the instrument with blade earlier to packing the instrument for sterilization.
- Cover all the parts and assembly separately in the cloth as open assembly may damage the insulation of other parts during sterilization.
- Pack all covered assembly in one bunch and send it for sterilization.

DURING SURGERY:

- Blade is an incisive element. Always handle the blade cautiously.
- Do not use Normal Saline (NS) to clean the instrument at any stage. Usage of Saline could result in failure of the instrument.
- Do not activate the blade without completion of sealing cycle as this may cut the live arteries resulting to blood loss during surgery.
- Prepare the cleaning solution with 50% H_2O_2 & 50% permissible disinfectant (like Betadine) for cleaning the fat and tissue deposition on jaws during surgery.
- **DO NOT USE NORMAL SALINE (NS) FOR CLEANNING OF THE INSTRUMENT DURING THE SURGERY**
- Open the sterilized bunch of the instrument in sterilized field in OT (Operation Theatre); open the cloth cover of all the assembly.
- Inspect all assembly for physical damage and insulation failure during sterilization.
- Assemble the instrument as per the assembly instruction and check the functioning before using it in surgery.
- Do the periodic cleaning of jaws by the preparing cleaning solution 50% H_2O_2 & 50% permissible disinfectant.
- In case of incomplete sealing or alarm condition, do not activate the blade.
- Sealing instrument may not be suitable for sealing the arteries below 1mm due to functional behavior. Use other instrument in such case.
- Do not use the device in blood reach environment & do not give wash of Saline till procedure completes; as vessel sealing do not function in conductive medium.
- In case of open re-hold (OP re Hold) alarm, check instrument assembly & the cable connection, also hold the tissue properly in the device to restart the sealing cycle. If this problem persists, please call us for the technical help.
- In case of close re-hold (CL re Hold) alarm, check the instrument assembly, any metal object/ clips in the jaw during sealing or short circuit in jaws or usage of device in presence of blood reach environment or normal saline (NS). Rectify the condition & retry sealing cycle till completion alarm sounds. If this problem persists, please call us for the technical help.
- Do not hold more than 7 mm tissue chunk for sealing as this may lead to increase in sealing cycle & lateral thermal spreading.

AFTER SURGERY:

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

CHAPTER 6
During Surgery

Electric Shock Hazard:
Warning - Never remove the cover of an 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.
Warning - Never press more than one foot paddle.

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 tragic 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 any equipment on top of the generator.

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 & POWER SETTINGS

(i) Changing the Mode:

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

To reach maximum or minimum power setting for selected mode, press up & down key. Release the key when the desired setting is displayed. If you try to set power above the maximum setting or below the minimum setting for the selected mode or tone sounds.

(iii) Special Setting of the Generator:

1. *Fast Setting by Recall:* Press Prog key to select fast setting of the generator to user set default settings.

(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. 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 - 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) Lapro/Endo/GI/Ortho/Open/General Surgery-
Bipolar Micro: 20, Bipolar Macro: 30, Sealer: L-2

E. ALARM CONDITIONS

Completion Alarm:

System generates completion alarm after proper effects are accomplished in sealer & bipolar procedures.

System Alarm:

When a generator senses any problematic condition:

1. An audio-alarm is activated.
2. Output of the generator is deactivated.
3. Error number is displayed on the Sealer display

Primary measures:

1. Turn off the generator.
2. Restart & verify that if the self – test is completed successfully. If it's unable/not possible to correct the system alarm condition use standby generator to proceed with the surgery.

CHAPTER 7
After Surgery

After Surgery

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

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

Cleaning
Caution **-** Do not clean the generator with abrasive cleaner that could damage the generator.

A. PREPARING THE GENERATOR FOR REUSE

Disconnect the Accessories:

1. Turn off the generator.
2. Disconnect all other accessories from the front panel.
   - If disposable accessory, dispose it according to the procedures.
   - If the accessory is reusable, clean & resterilize it according to the manufacture's instruction.
3. Disconnect & store footswitches if used.

B. CLEANING THE GENERATOR

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

Instrument Cleaning:

- Cleaning is required for all instruments with lumens and hollow spaces.
- Abrasive materials should not be used on the any parts because they will damage the instrument's outer surface. Instead, use soft-brushes & cottons clothes.
- Use distilled de-mineralized water for the final rinse.
- Hard water (high mineral contains) should not be used, it may impact the performance of the instrument.
- Use Neutral PH enzymatic detergent for cleaning whenever possible. Alkaline detergents, if used, must be completely rinsed from the devices. Do not use corrosive fluids.
- Do not exceed 130°C during the washing and sterilization process. Cold soak sterilization is not typically recommended and, as is always necessary for all instrumentation.

After disassembly, the following manual cleaning steps are important:

1. All components should be soaked in a blood-dissolving enzymatic solution for at least five minutes with gentle agitation.
   Note: It is advisable to soak longer if protein containing material is present.
2. Soak instruments vertically which cleans instrument thoroughly.

3. Rinse it thoroughly with tap water for 5 minutes.
4. Clean all surfaces of instrument using detergent solution.
5. Brush the surfaces using soft brush. Handle cord connectors, fittings and joints with care.
6. Use the soft brushes in up and down motion to clean completely through the lumen.
7. Compressed air can be used for flushing if a precise nozzle is available and if the pressure can be controlled. Ultrasonic irrigators are also a useful way to flush instruments with lumens to remove debris from hard-to-reach areas, and they can do so in a less time than a manual cleaning process. The cycle time should be five minutes or less, and water temperature should not exceed 50°C.
8. Rinse thoroughly under running distilled water for at least five minutes.

Vessel Sealing Instrument

- Prepare the cleaning solution with 50% H_2O_2 & 50% permissible disinfectant
- Do not use normal saline for cleaning of the instrument during the surgery.
- In case of using non sterilized blades, assembled the instrument with blade earlier to pack the instrument for sterilization.
- Cover all the parts and assembly separately in the cloth as open assembly may damage insulation of other parts during sterilization.
- Pack all covered assembly in one bunch and send it for sterilization.

C. STORING THE GENERATOR:

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

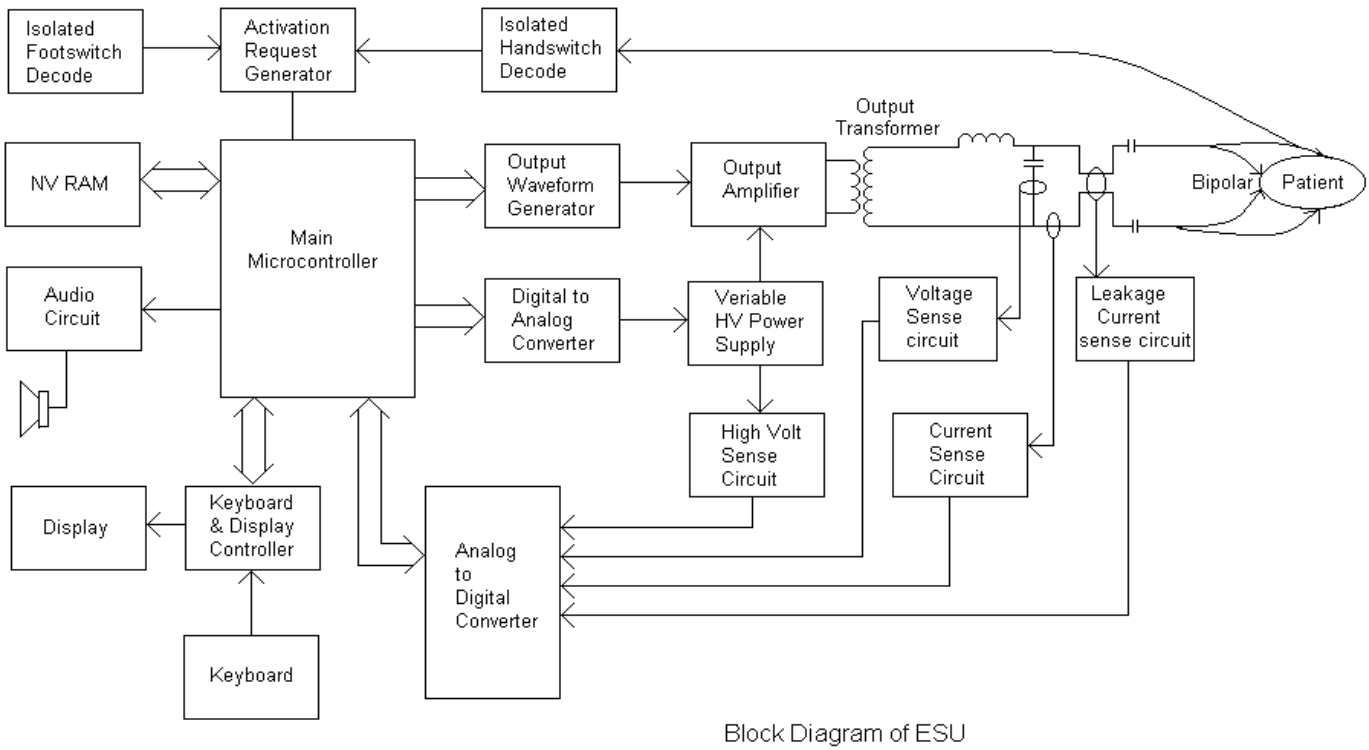
- General description
- Block diagram
- Detailed description of each board with circuit description

A. GENERAL DESCRIPTION

***6SENSE* Technology:**

This is a recent innovation in the 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 400 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.



Block Diagram of ESU

B. BLOCK DIAGRAM & DESCRIPTION

System is divided in three basic parts:

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

Processor & Control circuitry:
This is the main control system that calculates all the system parameters as per the selected mode and monitors the overall activity of the system.

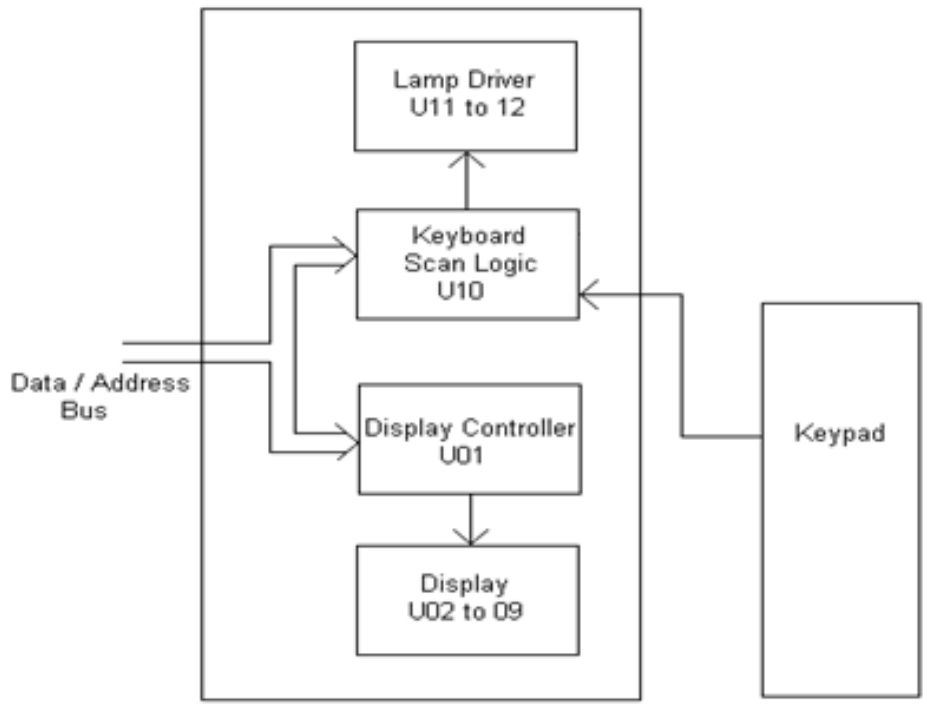
***Variable voltage power supply*:** As per the selected mode and the set power settings, power supply devices the necessary power as an input for the RF stage.

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

Circuit Board Description:

Key and Display Board:

- ***Display Circuit:*** Seven segment digital display U02 to U09 are controlled by Display controller IC U01. Mode LED's & activation bar light ups during RF power output are driven by drivers U11 & U12.

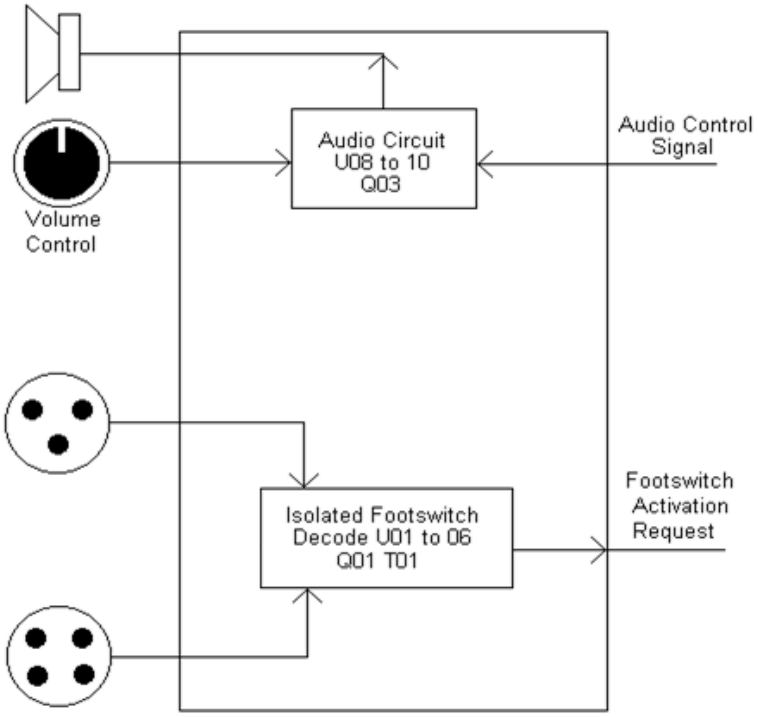


Keyboard & Display Board

- ***Keyboard Circuit:*** Front panel Key board is connected to circuit & scanned by the CPU. Pressed key is read by IC U10.

Footswitch and Audio Board:
It's divided in three sections.

- ***Isolated footswitch decode logic*:** This circuit checks the footswitch activation input with isolated supply hence provides maximum safety to user. Q01 & T01 produce necessary isolated voltages and U01 to U06 detect activation input & gives the input signal to CPU Board for activation of RF output.
- ***Audio circuit*:** Circuit generates different audio tones for cut, coag and bipolar activation. It gives two pulse outputs for ERROR conditions. Audio oscillator & driver stage comprises of U08 to U10. Signals are fed to speaker SPK 01 via driver transistor Q03 & audio volume can be controlled by control knob Kp01.



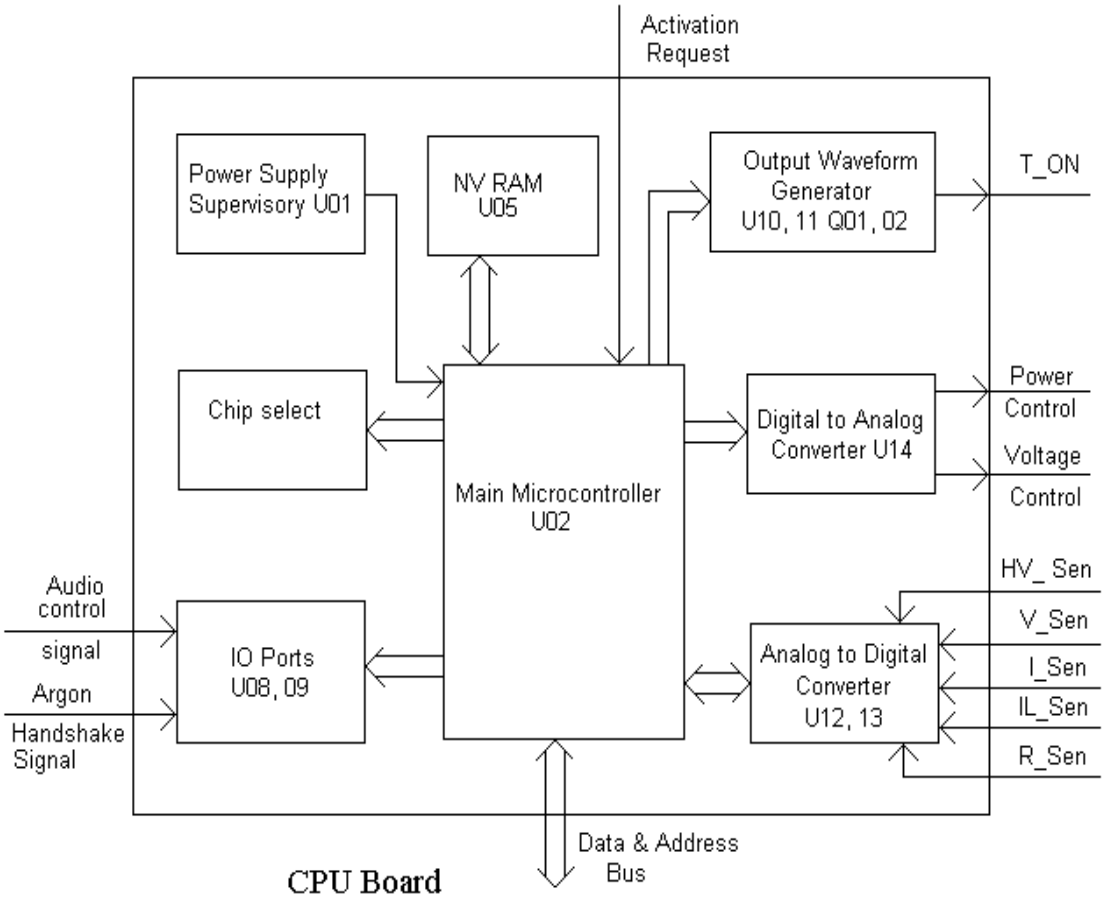
Footswitch & Audio Board

CPU Board:

Processor and control board consists of –

- ***Main microcontroller:*** IC U02 is main microcontroller and brain of system, which controls overall function of the system by I/O device. U02 has inbuilt program memory to hour the system program. All activation requests go to the system and it works accordingly by giving the I/O signals to run the task.
- ***Output waveform Generator:*** RF output waveform as per selected mode is delivered by ASIC U10, 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 U11, Q01 & Q02.
- ***Digital to Analog converter:*** Two analog control signals, Power control signal& voltage control signal are derived by IC's U12 and U13. During activation of power delivery both the control signals are changing as the change in tissue impedance.

- ***Analog to Digital converter:*** IC U14 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.
- ***I/O ports:*** Two 8 bit ports, ICs U08, U09 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.
- ***Power Supply Supervisory:*** IC U01 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.
- ***Chip Select Logic:*** IC U06 generates different chip select signals to enable the different I/Os.



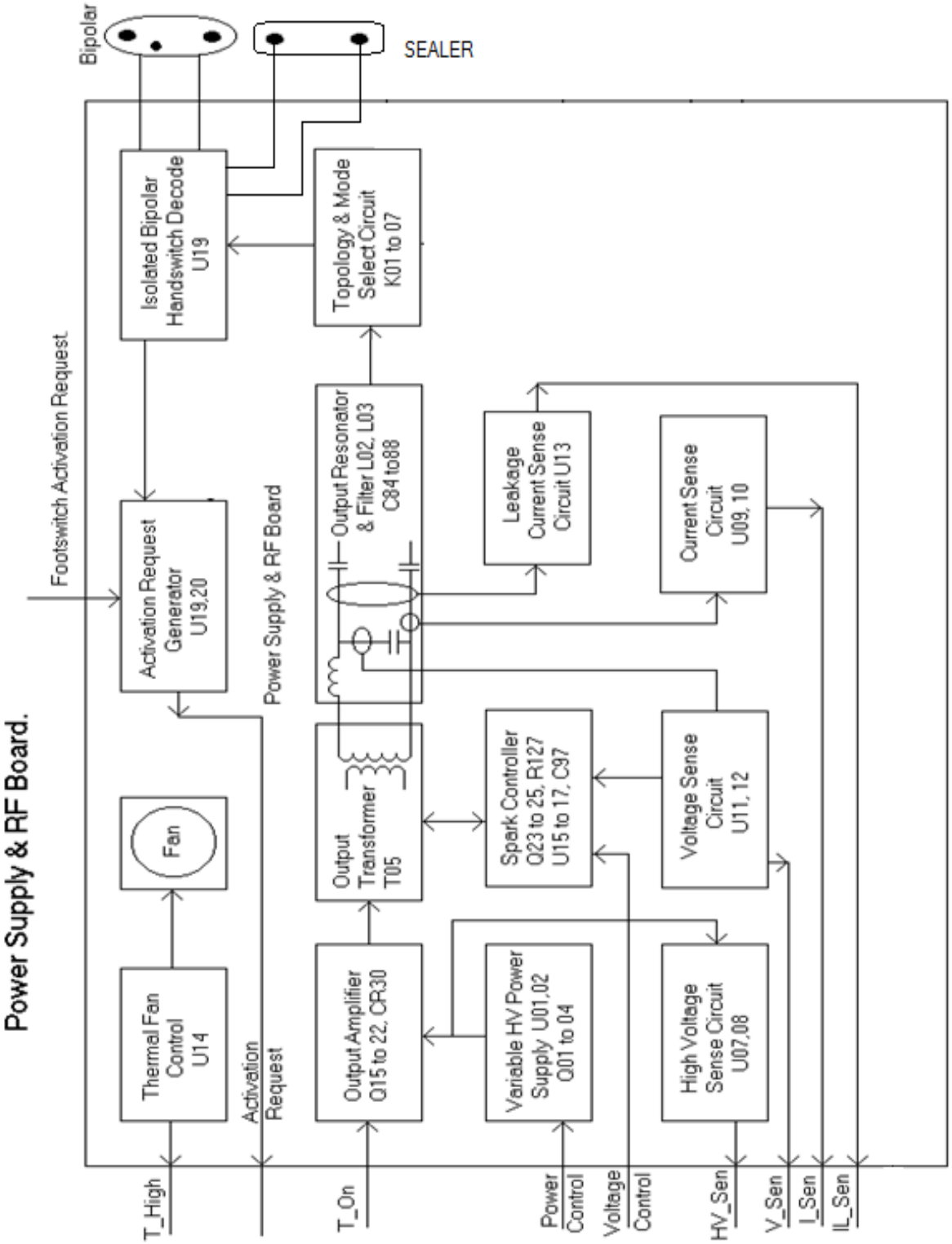
Power Supply and RF Main Board:

This board can gross by dividing in two parts, mains power supply and output RF stage. This board circuitry also supports for RF power generation & other sense circuit.

- ***Variable HV power supply:*** Supply voltage is converted in dc voltage by CR01 &C02 to C05 and again converted in Isolated DC voltage by using bridge converter. MOSFET Q01 to Q04 works in bridge configuration along with Transformer 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 & C11 to C13, 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 k09. O/P stage is driven

by switching devices Q15 to Q22 at various levels. CR30 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 C84 to C88 forms the resonator can filter circuit, which is also used to deliver the o/p in different modes of 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.
- ***Activation Request Generator:*** This circuit keeps watch on activation request from foot switch. This generates the necessary signals for CPU to start the process for RF delivery depending on the selected mode & the channel.
- ***Thermal fan control circuit:*** This circuit keeps watch on internal temperature in unit. This makes the cooling fan on & off depending on the internal temperature .If the temperature raised beyond limit; it gives the Hi- temperature alarm signal to CPU, with error code and stops RF power delivery.
- ***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. IC U13 & T08 is used to sense.
- ***RF current sense:*** Actual RF o/p current is sensed by current sense T07 and IC U09 & U10 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 U11 & U12, 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 of U15 to U17 checks the sparking condition & apply damping network R127 & C97 in primary RF circuit by switching on Q25. 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 U07&U08. Signal is sensed by CPU as Hv sense.


Power Supply & RF Board.
Bipolar
SEALER
Isolated Bipolar Handswitch Decode U19
Topology & Mode Select Circuit K01 to 07
Footswitch Activation Request
Activation Request Generator U19,20
Power Supply & RF Board
Output Resonator & Filter L02, L03 C84 to88
Leakage Current Sense Circuit U13
Current Sense Circuit U09, 10
Fan
Output Transformer T05
Spark Controller Q23 to 25, R127 U15 to 17, C97
Voltage Sense Circuit U11, 12
Thermal Fan Control U14
Activation Request
Output Amplifier Q15 to 22, CR30
Variable HV Power Supply U01,02 Q01 to 04
High Voltage Sense Circuit U07,08
T_High
T_On
Power Control
Voltage Control
HV_Sen
V_Sen
I_Sen
IL_Sen

CHAPTER 9
Testing Procedures

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

Warning- Fire Hazard - Do not use extension cords.

Caution - Do not stack equipment on top of the Eagle Two or do not place the generator on top of other electrical equipment/s. These configurations do not allow 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 both 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 plug on an equipotential grounding cable to the grounding cable the rear panel of the generator. Then, connect the cable to grounding receptacle.

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, it causes large errors when measuring high voltage RF waveforms.

Periodic Safety Check:

Perform the following safety check every two years to verify that the Eagle Two 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 apposite 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.
- ✓ Confirm outputs.
- ✓ Check leakage current and ground resistance.

Recommended Test Equipment:

- ❑ Digital voltmeter
- ❑ True RMS voltmeter
- ❑ Oscilloscope
- ❑ Leakage current tester
- ❑ Leakage table – per IEC 601-2-2,
- ❑ 100, 200, 300, 500 Ω, all 250 watt, 1% tolerance, non-inductive

Inspecting the Generator and Accessories:

Equipments

Bipolar & Sealer footswitch
Bipolar instrument cords (footswitching)
Sealer instrument cords (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 Sealer 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 & Sealer instrument socket for obstructions or damage. Insert the bipolar instrument connector into the appropriate socket to verify a secure fit. If the connection is loose, replace the front panel assembly.

Footswitches

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

Power cord

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

Inspecting the Internal Components:

Equipment: Phillips screwdriver

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

Configuration Outputs:

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

- ✓ **After calibrating the generator**
- ✓ **Every Year**

Equipment

- Two small test cables (less than 24 inches long) with banana plugs
- Current transformer
- True RMS voltmeter
- 100,300, and 500 Ω 1% no inductive power resistors
- Bipolar and Sealer 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 ± 16mA 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 Low Frequency Leakage Current and Ground Resistance

Check the frequency leakage current and ground resistance before returning the Eagle Two generator to clinical use.

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 *Whittemore Enterprises Inc.* Service center.

6. Verify single fault conditions (ground Open) the leakage current is less than or equal to300 microamps. If the leakage current is greater than 300 microamps, call the *Whittemore Enterprises Inc.* Service Centre.

Checking High Frequency Leakage Current and Ground Resistance

Check the high frequency leakage current and ground resistance before returning the Eagle Two generator to clinical use. Check the leakage current at these times, after calibrating the generator every one year.

Equipment

- 200 Ω, 250 watt, non-inductive resistor
- Current transformer
- True RMS voltmeter (Fluke 8920 or equivalent)
- Bipolar footswitch & accessories
- Leakage setup per IEC 601-2-2 clause 19.101 or 19.102

Checking Bipolar High Frequency Leakage Current

1. 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 Two

For normal running Eagle Two, 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 one year.

Steps and description:

Step 1 - Close loop current Calibration
Step 2 - Close loop voltage Calibration
Step 3 - Close loop power Calibration

Preparing for Calibration:

Equipments:

- Bipolar footswitch and Sealer footswitch.
- Small test cables with banana plugs.
- Resistor substitution box.
- Oscilloscope.
- True RMS current meter.

Entering Calibration Mode:

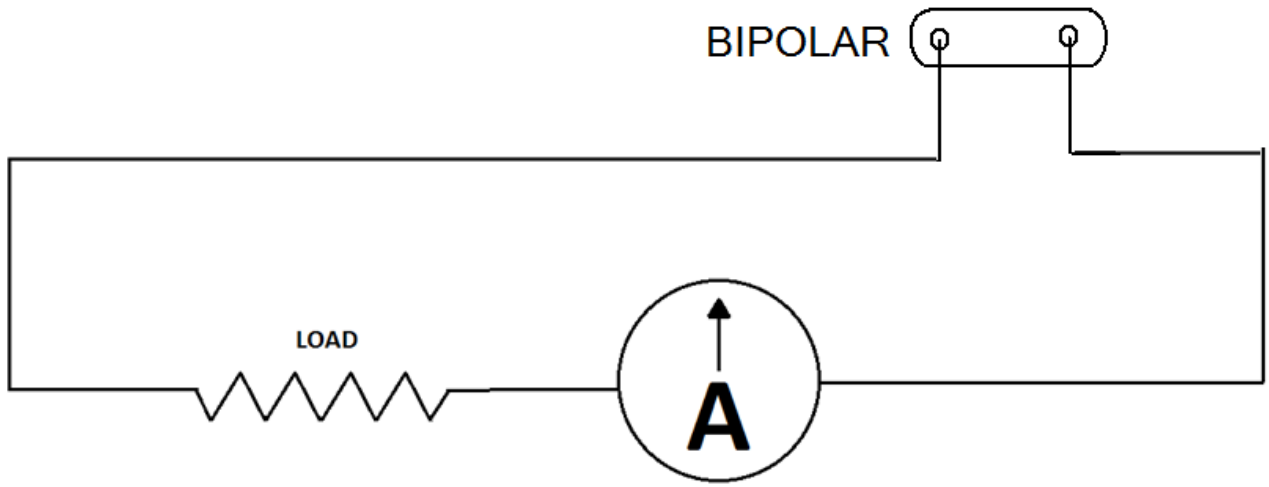
To enter in calibration mode, switch ON Eagle Two and press up & down keys of Sealer key at the same time, till display shows " 2 " in Bipolar micro , " 1 " in macro and " 50 " in Sealer display. This means system is in calibration mode. When system is in calibration mode, step no. appears in bipolar micro display and sub-step number appear in macro display, values associated with each calibration step appear in Sealer's display. You can use Sealer Up & Down keys to adjust display values. Once the count is adjusted for desired output, press the Bipolar Micro's 'UP' key to save the mode data. It will also be shown in Sealer's display & will move on to the next mode.

Exiting Calibration Mode:

One can exit calibration procedure at any time. If you want to save the values for a particular step, press the Bipolar Micro Up key, the display will indicate mode data counts. Then next step counts will be indicated in display. Switch OFF the generator to exit calibration mode. If you do not want to change mode data, just switch OFF the Eagle Two, then restart the generator to inter run mode. To jump on next Calibration step, press Bipolar Micro's 'UP' key to bypass the step. Do not press any footswitch during this process.

Calibration Step 1 - Close Loop Current Calibration-Imax

Sub step-1 (Bipolar Micro mode)
Bipolar Connection Diagram



Equipments

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

Verify

1. The Bipolar Micro display shows calibration step – "2"
2. The Bipolar Macro display shows the sub step – "1"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 10 Ω resistor.
   b. Another test cable from bipolar socket to 10 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 Micro footswitch pedal and check the current reading equivalent to 3082 mA ± 20 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from bipolar output.**

Sub step-2 (Bipolar Macro mode)

Equipments

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

Verify

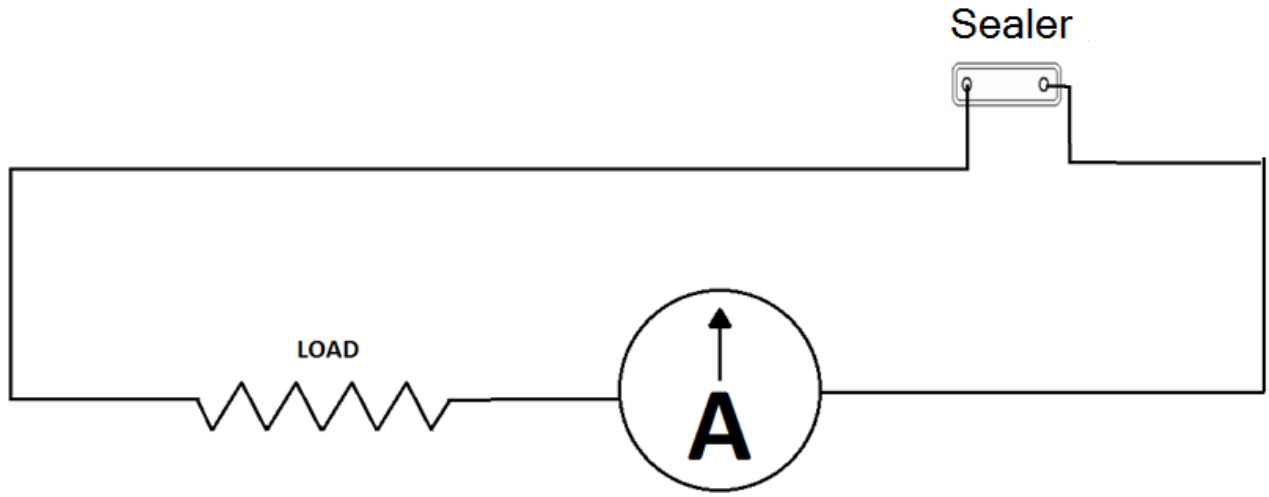
1. The Bipolar Micro display shows calibration step – "2"
2. The Bipolar Macro display shows the sub step – "2"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 10 Ω resistor.
   b. Another test cable from bipolar socket to 10 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 Macro footswitch pedal and check the current reading equivalent to 3082 mA ± 20 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from bipolar output.**

Sub step-3 (Sealer mode)

Connection Diagram



Equipments

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

Verify

1. The Bipolar Micro display shows calibration step – "2"
2. The Bipolar Macro display shows the sub step – "3"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Sealer socket passing through true RMS current meter to 10 Ω resistor.
   b. Another test cable from Sealer socket to 10 Ω resistor.

c. Sealer footswitch to the Sealer footswitch socket on the rear panel.

2. **Check and adjust the I-max for bipolar output.**
   a. Press the Sealer footswitch pedal and check the current reading equivalent to 3872 mA ± 20 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from Sealer output.**

Calibration Step 2 - Close Loop Voltage Calibration-Vmax

Sub step-1 (Bipolar Micro mode)

Equipments

- ✓ Bipolar footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 1kΩ non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "3"
2. The Bipolar Macro display shows the sub step – "1"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 1k Ω resistor.
   b. Another test cable from bipolar socket to 1k 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 Micro footswitch pedal and check if the current reading is equivalent to 200 mA ± 10 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from bipolar output.**

Sub step-2 (Bipolar Macro mode)

Equipments

- ✓ Bipolar footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 1kΩ non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "3"
2. The Bipolar Macro display shows the sub step – "2"

3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 1k Ω resistor.
   b. Another test cable from bipolar socket to 1k 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 Macro footswitch pedal and check the current reading equivalent to 200 mA ± 10 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from bipolar output.**

Sub step-3 (Sealer mode)

Equipments

- ✓ Sealer footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 1kΩ non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "3"
2. The Bipolar Macro display shows the sub step – "3"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Sealer socket passing through true RMS current meter to 1k Ω resistor.
   b. Another test cable from Sealer socket to 1k Ω resistor.
   c. Sealer footswitch to the Sealer footswitch socket on the rear panel.
2. **Check and adjust the V-max for sealer output.**
   a. Press the Sealer footswitch pedal and check the current reading equivalent to 200 mA ± 10 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from the Sealer output.**

Calibration Step 3 - Close Loop Power Calibration-Pmax

Sub step-1 (Bipolar Micro mode)

Equipments

- ✓ Bipolar footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 330Ω non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "4"
2. The Bipolar Macro display shows the sub step – "1"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 330 Ω resistor.
   b. Another test cable from bipolar socket to 330 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 Micro footswitch pedal and check if the current reading is equivalent to 348 mA ± 10 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from bipolar output.**

Sub step-2 (Bipolar Macro mode)

Equipments

- ✓ Bipolar footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 330Ω non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "4"
2. The Bipolar Macro display shows the sub step – "2"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Bipolar socket passing through true RMS current meter to 330 Ω resistor.
   b. Another test cable from bipolar socket to 330 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 Macro footswitch pedal and check the current reading equivalent to 348 mA ± 10 mA RMS.

b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
c. Repeat this step until the meter reading is not in the stated range
d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.

3. **Disconnect all of the test cables from bipolar output.**

Sub step-3 (Sealer mode)

Equipments

- ✓ Sealer footswitch.
- ✓ Small test cables with banana plugs
- ✓ True RMS current meter
- ✓ 330Ω non-inductive power resistor.

Verify

1. The Bipolar Micro display shows calibration step – "4"
2. The Bipolar Macro display shows the sub step – "3"
3. The Sealer display shows the figure – "50"

Procedure:

1. **Connect:**
   a. One test cable from Sealer socket passing through true RMS current meter to 330Ω resistor.
   b. Another test cable from Sealer socket to 330 Ω resistor.
   c. Sealer footswitch to the Sealer footswitch socket on the rear panel.
2. **Check and adjust the P-max for sealer output.**
   a. Press the Sealer footswitch pedal and check the current reading equivalent to 348 mA ± 10 mA RMS.
   b. Stop activation. If the output current is higher than desired, decrease Sealer display count using Sealer down key. If a current is lower than desired current, increase the Sealer display count using Sealer up key.
   c. Repeat this step until the meter reading is not in the stated range
   d. When reading is in stated range, then press Bipolar Micro Up key, the Sealer display will indicate data count.
3. **Disconnect all of the test cables from the Sealer 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

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.

11.1 CARE

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

11.2 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

Troubleshooting

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

- Identify and correct the miscalculations.
- If a system alarm number is displayed, take the appropriate action to correct the error.

Inspecting the Generator

If the Eagle Two 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 fuses if the generator fails the self-test or stops functioning.

A. CORRECTING MALFUNCTIONS

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct error, 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.
	Situation	**Possible Cause**
	Faulty low voltage power supply	Check the low voltage power supply.
ESU does not respond when	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.

Turned on.	Shorts or disconnects on Power Supply & RF board	Check the Power Supply & RF board for shorts or disconnects.
	Faulty mains ON-OFF switch	Replace the switch.
	Malfunctioning front panel components	Replace the front panel assembly.
Situation	**Possible Cause**	**Recommended Action**
Generator is on, but did not complete the self-test	An alarm condition exists	Check the display for an alarm number. Note the number and refer to Responding to System Alarms in this section.
	Software malfunction	Turn off and then turn on the generator.
	Loose or disconnected internal cables and/or boards.	Check and correct all internal connections. Press the connectors and boards if required.
	Faulty low voltage power supply	Check the low voltage power supply. If not working properly, replace it.
	Damaged CPU board connectors and/or malfunctioning CPU board	Remove the CPU board and inspect the connectors to the Power Supply & RF board and to the Display board for damage. Replace the CPU board if required.
	Shorts or disconnects on Power Supply & RF board	Check the Power Supply & RF board for shorts or disconnects.
	Faulty mains ON-OFF switch	Replace the switch.
	Malfunctioning front panel components	Replace the front panel assembly
Situation	**Possible Cause**	**Recommended Action**
Activation and/or alarm tones do not sound, **Speaker is malfunctioning**	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.
	Audio signal malfunction on Control board	Replace the control board.
Blank or confusing LED display	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.
	Display board malfunction	Replace the Display board.
Mode keys do	Faulty ribbon cable between CPU board and display board	Check/connect ribbon cable that the Display board to the Control board.
	Incorrect data communicated	Replace the CPU board.

not function correctly when pressed	through 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.
	Incorrect modes are being sent from the front panel	Replace the front panel.
Generator is on and accessory is activated, but generator does not deliver output	Malfunctioning footswitch instruments	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 Bipolar socket & instrument connected to Sealer instrument socket Or vice-versa	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 display for an alarm number.
	Situation	**Possible Cause**
	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.
Generator is on and accessory is activated, but generator does not deliver output	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 R112, If pulses are present, Check all MOSFET Q19 to Q22, replace with same part no. if require. • Check Diodes CR30 replace with same part no. If T_ON pulses are not present,

		• Verify T_ON pulses at TP 19, If pulses are not present, replace the CPU • Check all MOSFET Q15 to Q18, replace with same part no. If require.
Situation	**Possible Cause**	**Recommended Action**
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.
	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.
		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.
Situation	**Possible Cause**	**Recommended Action**
Abnormal neuromuscular stimulation (stop surgery immediately)	Abnormal 50-60 Hz leakage currents	Inside the generator, carefully inspect for the damage that may cause shorting between the AC line voltage and connected patient components.

B. RESPONDING TO ERROR & WARNINGS

When erroneous condition exists, an alarm tone sounds and Bipolar & sealer display indicates error code number. System will not work till the error is corrected.

Following table recommends some primary remedies to overcome the error.

Error Code No.	Description	Recommended Action
501	Bipolar Macro Footswitch may have stuck.	• Restart the generator. Do not press any activation during self-test. • If the alarm repeats, disconnect all accessories. Restart again. • If the alarm repeats, check activation request generator circuit. • Call Whittemore Enterprises Inc. service cell.
502	Bipolar Micro Footswitch may have stuck.	
503	Sealer Footswitch may have stuck.	
604	Bipolar Micro Up Key may have stuck.	• Restart the generator. Do not press any activation during self-test. • If the alarm repeats, disconnect all accessories. • Restart again. • If the alarm repeats, check activation request generator circuit. • Call Whittemore Enterprises Inc. service cell.
605	Bipolar Macro Up Key may have stuck.	
606	Sealer Up Key may have stuck.	
607	Bipolar Micro Down Key may have stuck.	
608	Bipolar Macro Down Key may have stuck.	
609	Sealer Down Key may have stuck.	
610	Prog key may have stuck.	
701	Temperature High signal.	• Restart the generator. • If the alarm repeats, check working of internal cooling fan. • Replace internal cooling fan • Call Whittemore Enterprises Inc. service cell.
702	External memory “EPROM” data loss message	• 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 Whittemore Enterprises Inc..

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

Please Note: Warranty on accessories is subject to manufacturing defect before usage & limited usage warranty as stated on packing.

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.