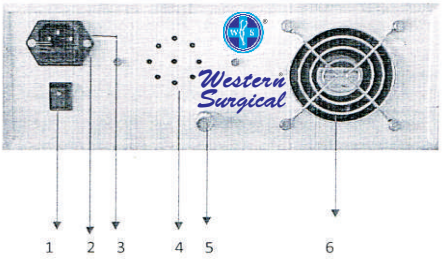

Western Surgical®

Electrosurgical Gnerator Quikseal

USER MANUAL

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INDEX

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1. GENERAL INFORMATION

1.1 Introduction

Dear Customer,
Thank you for purchasing western surgical generator:
Model – QUIKSEAL
The product you have purchased is one of the most innovative products and provides best performance of cutting, coagulation & sealing with comfort of use.
This document was compiled in order to make all information concerning the installation, handling and operation of the unit available to end users.
In order to ensure reliable operation, please take note of all the information and instructions in these operating instructions without fail.
Any enclosed documents of other vendors serve only for information.
We assume no liability whatsoever for its completeness or accuracy. If you should require information extending beyond this documentation, we will be pleased to offer you the technical advice at any time.

1.2 Proper Intended Use

The unit is intended solely for electro surgery to both cut & coagulate the tissue.

The manufacturer will not be held responsible for any damage whatsoever resulting from any unauthorized use or misuse of the equipment. The user will be solely responsible for the risk.

Observance of the operating instructions and of the inspection and maintenance condition comes under the heading of proper intended use.

1.3 KEY FEATURES

The QUIKSEAL includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

- **Four level of Cut Mode**

  The Cut mode gives the surgeon flexibility to cut all types of tissue without losing performance. The Cut mode generates constant output power over a wide range of impedances. Refer to the Technical Specifications section of this guide.

  - **PURE CUT**- A high-frequency alternating current yields smooth, rapid cuts that evoke little to no hemostasis
  - **BLEND 1** - Preset blended cut modes give the surgeon varying degrees of hemostasis in cut mode.
  - **BLEND 2** - The mode is used for the vaporization of prostatic tissue or any fat tissue. The higher output wattage gives fast cutting effect of the tissue
  - **ENDOCUT**- The mode is used to automatically control cut system to reduce the complication rate of endoscopic sphincterotomy (EST) and serum hyperamylasemia after EST compared to the conventional blended cut mode.

- **Four levels of coagulation**: Spray, Fulguration, Force, desiccation
  - **SPRAY** - spray output is made for direct coagulation at the tissue with spark. Above spark does not give any cutting effect as its CREST FACTOR is high.
  - **FORCE**- this mode is a greater degree of homeostasis and covers all demands of standard coagulation.
  - **FULGURATE**- Sparking the tissue to lead to coagulation. There is no tissue-electrode contact; rather, voltage is raised in order to incite a spark between electrodes in order to coagulate the tissue in between.
  - **DESICCATE** - Coagulation in which the active electrode is in direct contact with the tissue is referred to as desiccation and is the type of coagulation used in most surgeries It ensures pinpoint desiccation with less destruction of peripheral tissue.

- **Isolated RF output**

  This minimizes the potential of alternate site burns.

- **Standard connectors**

  These connectors accept the latest monopolar and bipolar instruments. Refer to Section 2, Controls, Indicators, and Receptacles to learn more.

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1.4 SAFETY

The safe and effective use of electrosurgery depends to a large degree on factors solely under the control of the operator. There is no substitute for a properly trained and vigilant medical staff. It is important that they read, understand, and follow the operating instructions supplied with this electrosurgical equipment.

Physicians have used electrosurgical equipment safely in numerous procedures. Before starting any surgical procedure, the surgeon should be familiar with the medical literature, complications, and hazards of using electrosurgery in that procedure.

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

WARNINGS:

- Hazardous Electrical Output - This equipment is for use only by trained, licensed physicians.
- Danger: Fire / Explosion Hazard - Do not use the in the presence of flammable materials.
- Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:
  - Flammable substances (such as alcohol based skin prepping agents and tinctures)
  - Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N20] atmospheres).
- The sparking and heating associated with electrosurgery can provide an ignition source.

  Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
- Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.
- Electric Shock Hazard
  - Connect the generator power cord to a properly grounded receptacle.
  - Do not use power plug adapters.

- Always turn off and unplug the generator before cleaning.
- Fire Hazard - Do not use extension cords.
- Patient Safety - Use the generator only if the self-test has been completed as described.
  Otherwise, inaccurate power outputs may result.
- Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.
- The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.
- Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.
- Use electro surgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.
- If the patient has an Implantable Cardioverter Defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICDs.
- Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis. For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.
- In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the return electrode that includes the skin-to-skin contact point.

Current passing through small skin-to-skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.

- To reduce the potential for alternate site burns, do one or more of the following:
  - Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient.
  - Place 5 to 8 cm (2 to 3 in.) of dry gauze between contact points to ensure that contact does not occur.
  - Position the return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
  - In addition, place patient return electrodes according to the manufacturer's instructions.
- Do not wrap the accessory cords or return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

CAUTIONS:

- At no time should you touch the active electrode or bipolar forceps. A burn could result.
- Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow adequate cooling.
- Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.
- Non-function of the generator may cause interruption of surgery. A backup generator should be available for use.
- Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active.
- When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.
- The use of high frequency current can interfere with the function of other electromagnetic equipment.
- When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes. Monitoring systems incorporating high frequency current-limiting devices are recommended.

- Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.
- To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.
- Remove any loose fitting jewelry from the patient before activation.
- Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.
- When not using active accessories, place them in a holster or in a clean, dry, non-conductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.1

NOTICES:

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

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

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2. UNPACKING, HANDLING & INSTALLATION

2.1 Unpacking

The packing materials for the unit will withstand normal loads encountered during transport by road, rail or air freight. The box contains an electrosurgical generator with following accessories.

Accessories

1. Monopolar ,Bipolar & seal Footswitch.
2. Stainless steel patient plate .
3. Cord for patient plate.
4. Monopolar chuck handle.
5. Set of Reusable Electrode.
6. Bipolar Forceps with cord.
7. Disposable hand switch pencil
8. Seal forcep with cord (open/laparoscopy)

Goods Inward Control

Before commissioning electrosurgical unit, check whether the components as listed in delivery note are complete and undamaged. In the event of any discrepancy in the items supplied please contact ease customer service.

Transport Damage

The delivery company is responsible for any damage which occurs in transit. A detailed report (including a photo, if possible), describing the damage, must be submitted to the delivery company and forms the basis for any claim for damages.
We should be notified immediately of any damage to, or loss of any goods supplied. This should be confirmed by forwarding a copy of the above mentioned report.

2.2 Handling

- The electrosurgical unit may only be operated by trained personnel.
- This machine has inbuilt switch mode power supply (SMPS), so there is no need of any external power supply to be connected. Use 230v single-phase ±10% power supply.
- The unit may only be connected to an alternating current with a voltage as per specification.
- If an extension cable is used for the mains connection, it must be provided with a protective earth in accordance with regulations. Hands should always be dry when plugging the cable in.

Seal Receptacle
Accepts standard cables for seal handpieces. Connect seal accessories.

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- If the mains plug has come in to contact with a liquid, the plug must be cleaned and dried without fail before being inserted into its socket.
- The generator and the keypad must be protected against moisture and corrosive dust. No liquid must be allowed to penetrate the inside of the hosing.

2.3 Installation of the Unit

Check the plate on the back of the ESU for correct power requirements. Position your ESU within easy reach of a standard grounded electrical outlet. If your ESU does not operate correctly, first refer to the troubleshooting section for possible causes, or contact an authorized service center, for additional information.

ENVIRONMENTAL REQUIREMENTS

i. Operating room should have adequate number of air conditioning unit to ensure proper low temperature and humidity depending upon surgical specialties.
ii. If A/C units are not working, air-circulating fans should be directed towards surgical diathermy unit to dissipate the generating heat.
iii. Use only electrically conductive jelly specifically recommended for radio frequency applications. (**550K c/s** suitable for other diagnostic applications.)
iv. Periodic inspection and checking the working of patient protection circuit is recommended if provided. (Preferably after every **4 months** interval).
v. Use and avoid spilling of proper solution over and near by the patient plate.
vi. Check cable connection of metal plate with Diathermy unit every day. Loose connections if any should be tightened immediately.
vii. Refer to safety tips and preventive maintenance notes, enclosed in manual.

Cut :			
Mode	Max power	Load	Creast Factor
Pure cut	400 W	300E	1.5
Blend 1	250 W	300E	1.5
Blend 2	200 W	300E	1.5
Endocut	99 W	300E	1.5
Coag :			
Mode	Max power	Load	Creast Factor
Spray	120 W	300E	7
Force	120 W	300E	6.5
Fulgrate	150 W	300E	6
Dessicate	150 W	300E	6
Bipolar Mode :			
Mode	Max power	Load	Creast Factor
Bi-coag	80 W	100E	1.5
Bi-Cut	80 W	100E	1.5
auto	80 W	100E	1.5
Seal Mode:			
Seal	0-99 %	100E	1.5

2.4 Specification of unit

2.5 QUIKSEAL PERFORMANCE RELATED TO SURGICAL SPECIALITY

	Standard Settings
CARDIOTHORACIC – Cotonary Bypass	
• Coagulation	35 watt
• Coagulation – heart surface	15 watts
• Blend cutting	60 watts
UROLOGY TURP, BLADDER TUMER	
• Pure Cut	90 watts
• Coagulation (fulgurate)	50 watts
• Coagulation to bladder neck	20-25 watts
• Blend cut for bladder tumors	90 watts
• Coagulation for bladder tumors	40 watts
NEUROSURGERY – Craniotomy, AVM, Aneurysm	
• Standard Bipolar: Desiccation	40 watts
• Standard Bipolar: Desiccation (Under magnification)	15 watts
• Cut/Blend	40 watts
• Coag	15 watts

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ENT-T&A's	
• Coagulation	30 watts
GYN – Tuboligations	
• Blend cut	40 watts
• Coagulation	35 watts
• Standard Bipolar	45 watts
TUBOPLASTY	
• Blend	35 watts
• Coag	20 watts
• Bipolar under magnification	15 watts
GASTEROINTIONALENDOSCOPY – POLYPECTOMY	
• Coag	35 watts
• Blend	40 watts
PAPILLOTOMY / SPHINCTROTOMY	
• Blend	40-45 watts
GENERAL SURGERY – GALL BLADDER	
• Pure Cut	90 watts
FULGURATE LIVER BED	
Coag	40 watts
BREAST BIOPSY	
• Coag (spray)	35 watts
MISCELLANEOUS	
• Coag	35 watts
• Blend	80 watts
ORTHOPEDICS (LATERAL RELEASE)	
• Coag	35 watts
• Blend (meniscectomy surgery)	40 watts
• Coag	35 watts
• Blend (miscellaneous)	40 watts
• Coag	35 watts
• Blend (meniscectomy surgery)	40 watts

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3. OVERVIEW

Meaning of electrosurgery:

Electrosurgery employs RF (redio frequency) energy to both cut and coagulate tissue. In the cut current modes, the tissue is literally vaporized as the electrode passes through the tissue and capillaries on either side of the incision wall are sealed as the tissue shrinks. Heance the term "bloodless surgery". The amount of lateral necrosis on each wall depends upon the speed or the deliberate motion through the tissue and the type of current mode selected.

In the coag current mode, the tissue is coagulated by discharging RF either after the electrode is placed in the tissue to desiccate it or the electrode is held over the target site, leaving an air gap and allowing the current or RF plasma energy to jump the gap to furgurate the tissue. Post operative healing is said to be greatly improved if the proper technique is employed.

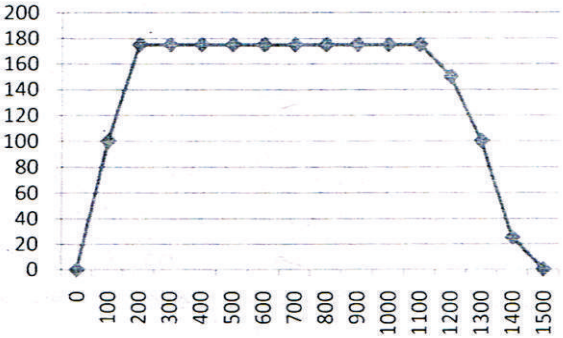
ESU power classification

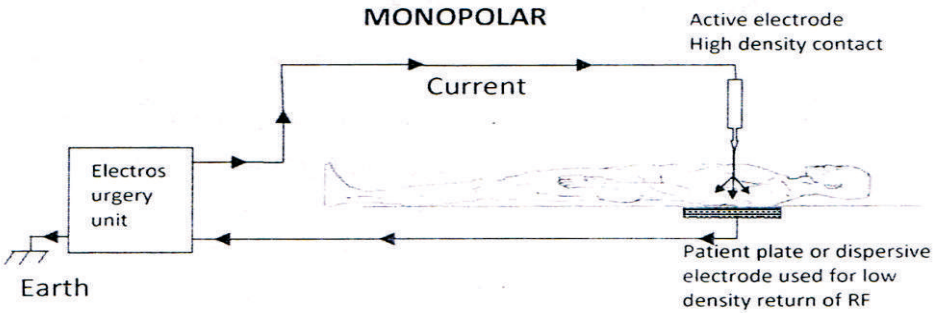
Electrosurgery generators are typically classified into low power (50 – 100watts), mid-range power (100-200watts), and high power (300-400watts) unit. Units classified for microsurgery typically range 10-50watts and many have very high operating frequencies and are highly regulated. A mid range unit will typically have adequate power for most procedures. Howe ever for heart bypass and T.U.R.P. procedures high power units do.

4. GENERAL OPERATING INFORMATION

4.1 Monopolar Operating modes:

MONOPOLAR : as the illustration below displays, the RF current selected is emitted from the high density electrode, also referred to as the inactive electrode which is turn, flows back to the generator. The ideal load response curve for monopolar current modes is flat from low to high impedance reflected back to generator.





If the generator is ground referenced, the return electrode insures that current return to that path of least resistance and does not take any alternative path through operators or patients that can cause burns. This is the reson the dispersive return electrode is often referred to in electrosurgery as the indifferent plate. Meaning current is indifferent to undesired alternative paths when the return electrode is employed. If the generator output is isolated from ground, the return electrode insures maximum power and performance when activated. The dispersive return electrode should always be used while operating in the monopolar mode.

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4.1.1 MONOPOLAR MODES

1. CUT

The first clinical mode of a modern ESU is cutting. The unit offers the surgeon Three types of cutting: pure cut blended cut & endo cut. Pure cut is used for dissection only. Blended cut adds some hemostatic effect.

a. Pure Cut

In pure cut the instrument performs much like a stainless steel scalpel, in that the surgeon has little or no control over bleeding. There are, however, some notable differences. One, the cutting effect of an electrosurgical instrument results from the heat of a current passing through tissue. Thus, it is the current that parts the tissue and not the instrument. The parting of tissue actually precedes the leading edge of the active electrode by a microscopic distance. Cutting is virtually effortless, so the surgeon may direct most of his attention to guiding the instrument. He need not apply as much pressure as he must with a scalpel. Two, however sharp it may appear, a stainless steel scalpel requires pressure and some effort in making the incision. In contrast, the electrosurgical instrument makes sharply defined incisions with relative ease. By adjusting the power to the desired level, the active electrode encounters little resistance to its passage through tissue

b. Variable blend modes

In addition to the pure cut, most ESU's today offer a blended cut. The term "blended" does not refer to a blend of currents, but rather a blend of surgical effects. The blended cut permits the surgeon to cut and coagulate at the same time. In a pure cut the heat energy is so great that cells vaporize. But in a blended cut, cooling periods slow down the action to a dehydrating crawl. Cell wall explosion and vaporization are replaced by the slow dehydration of cellular fluid and protein. This stops the bleeding at the moment the cuts are actually being made. By adjusting the blend the surgeon can get varying degrees of hemostasis. A blended cut is ideal for sealing off small bleeders when cutting through soft tissue. It is also used to resect masses of tissue and to reduce and recontour redundant tissue where the cutting is continuous, but the surgeon wishes to minimize bleeding and work in a clear field.

The physician can actually feel an increase in CUT vibration as the settings are selected from BLEND 1 (DC=80%) to BLEND 2 (DC=70%) .

c. ENDO CUT MODE

Endo cut is an electrosurgical cut which is carried out in alternating intervals (fractional cut) of software controlled cutting and coagulation. The endocut function regulates cutting speed and hemostasis. This feature has increased safety and procedural outcomes in polypectomy and papillotomy significantly.

2. COAGULATION MODE

The second clinical mode of electrosurgical units is coagulation. There are three types of coagulation:

Spray Coagulation (also known as pinpoint), desiccation and Fulguration They differ primarily in how they are applied. To apply pinpoint coagulation, the surgeon holds the electrode in physical contact with or against the tissue. When fulgurating, the surgeon holds the electrode some distance away from the tissue and the RF current is delivered to tissue by way of sparks jumping cross the airspace contacting the tissue.

a. Spray mode

The spray mode (non -contact) is efficient in coagulating oozing vessel and capillaries. Tissue destruction with the use of the spray coag mode in superficial when short activations is employed. Deeper tissue damage will occur when longer, continuous activation is used or when the electrode comes in contact with the tissue. It is possible to cut with the coag mode, but it will not deliver the clean tissue effect the cut mode is capable of performing. Use spray coag for bleeding or oozing beds and for large superficial area coagulation.

b. Force mode

This mode is a greater degree of homeostasis and covers all demands of standard coagulation. This produce the fine attune waveform that creates superficial resistance in the tissue resulting in superior coagulation where the tissue destroyed by hyper evaporation This give surgeons the ability to remove surface structures without damaging deeper or peripheral tissues and to cauterize large surface areas quickly when required .

c. **Fulgurate mode**

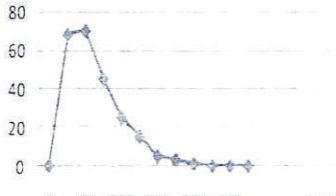
Fulguration is another type of coagulation. Fulguration can be defined as non-contact coagulation in which current sparks or jumps from the active electrode to the tissue. Not only is fulguration an important electrosurgical modality for sealing off small hidden bleeders which surgeons have difficulty locating, fulguration is especially useful for those areas with large bleeders.

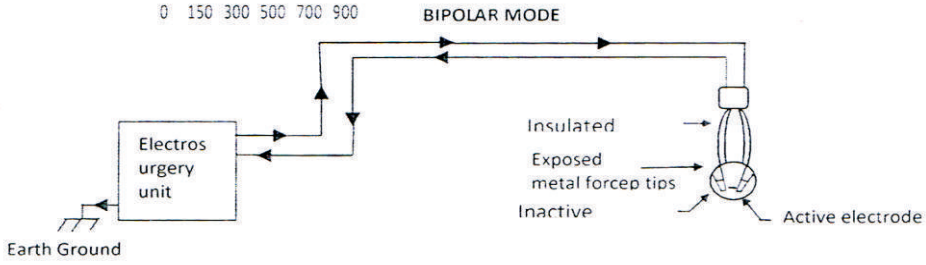
d. **Desiccate mode**

Coagulation in which the active electrode is in direct contact with the tissue is referred to as desiccation and is the type of coagulation used in most surgeries. Most surgeons will operate using coagulation current, which actually cuts and coagulates tissue. Desiccation results in hemostasis but does not always result in necrosis. Desiccation slowly drives the water content out of the cell.

4.2 BIPOLAR operating mode

As the bipolar illustration below display, in this operating mode, the dispersive return electrode is eliminated or switched out of the output circuit when the bipolar mode is selected. Instead bipolar instruments typically include two poles- one is referred to as active and the other is referred to as inactive. The RF current is transmitted across the two pole though the tissue placed directly between the pole back to generator. The load response curve for bipolar current mode is shaped to peak at 150 ohms and drop off quickly as reflected impedance increases.





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There are many different types of bipolar ESU instruments. Some instruments like forceps have equal size pole electrodes; some have unequal size poles, depending upon the respective purpose

4.2.1 BIPOLAR MODES

BIPOLAR (biterminal) is an electrosurgical technique in which the electrosurgical effect takes place between paired electrodes placed across the tissue to be treated. No patient return electrode is needed. Typically bipolar forceps are utilized for this technique.

In bipolar electrosurgery, two electrodes (generally the tips of a pair forceps or scissors) serve as the equivalent of the active and dispersive leads in the monopolar mode. Electrosurgical current in the patient is restricted to a small volume of tissue in the immediate region of application of the forceps. This affords greater control over the area to be coagulated. Damage to sensitive tissues in close proximity to the instrument can be avoided. There is less chance of current capacitively or directly arcing to surrounding structures such as the bowel. Patient burns are virtually eliminated.

a. BI-cut

The bipolar cutting system operates in quite a different manner from the familiar monopolar cutting of the present machines. While both monopolar and bipolar cutting are done with an approximately one megahertz sine wave. In monopolar cutting the power is presented to a fine tipped active electrode at a very high voltage with the return to a proportionately large indifferent or ground plate. This voltage dropped precipitously when the active electrode was brought into a firm contact with tissue or used in a bloody field or under irrigation. Customarily, for the fastest monopolar cutting, the power was turned on before the electrode contacted the tissue. A spark then jumped to the tissue as the electrode approached, the impedance remained high, and tile tissue was vaporized just prior to the contact of the electrode, so maintaining the high voltage necessary for this type of cutting.

The ease's Bipolar Cutting system was designed on the basis that there would be no spark and that the instruments would cut while in contact with the tissue whether dry or under irrigation. No indifferent plate is used. The voltage was kept quite low and the extremely low impedance of the generator minimized the voltage drop from open circuit to full load. Accordingly, this technique provides for cutting not based on vaporization by an advancing spark, but rather by a true molecular resonance by the sine wave cutting current dividing the tissue without sparking, thermal damage or current spread. Since all the current passes only between the two tips of the instruments and not to a return pad, there is no current or heat spread to adjacent

areas. The device may be used with total safety in all tissues as well as directly on bone and around crowns, fillings and metallic implants without the risk of necrosis.

b. Bi coag

Bipolar coagulation is one of the most frequently used HF surgical techniques. The high-frequency current takes a very short path through the patient's body, flowing directly from the instrument's active blade or jaw to the opposite (inactive) blade or jaw. Thus, only the treatment zone is actually affected by the electric current. Compared with the monopolar technique, the energy requirements are significantly lower and no neutral electrode is needed at all.

Ease bipolar coagulation waveform is unique in that it is totally non-rhythmic. The timing of the electrical bursts within the waveform are randomly spaced, and the waveform itself is random in timing so that it is truly aperiodic. The aperiocity of the waveform eliminates molecular resonance, rendering the coagulation waveform unable to cut, for exceptional safety.

c. Auto

Coagulation start by pressing the footswitch and stops output and audio signal automatically when the tissue is coagulated.

d. Seal

Seal mode provides unique combination of pressure and energy to create vessel fussion, leaving no foreign material behind. And no sticking and charring. Seal mode permanently fuses tissue bundles and vessels, reduce thermal spread and reduce time of surgery. The seal mode gives you something no other electrosurgical tool can - permanent vessel occlusion. The Seal mode replaces almost all other hemostatic tools because it actually fuses vessel walls to create a permanent seal.

4.3 Electrosurgery techniques

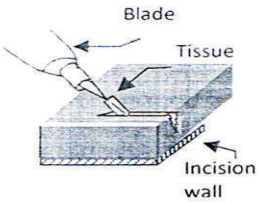
RF electrosurgery can be used to achive a number of desired results. The following illustration demonstrates various techniques associated with shaped electrodes and various current modes.

Incising Tissue

Recommended current mode : pure CUT or BLEND 1

Typical Electrode : blade type

Effect on Tissue: cleanest incision is with PURE CUT. Lateral necrosis on each side of incision is determined by current mode. (pure or blend

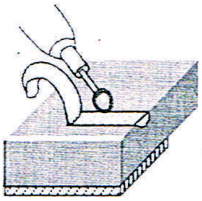


setting) and deliberate speed or motion through tissue

Excising Tissue

Recommended current mode : pure CUT or BLEND 1

Typical Electrode : loop type

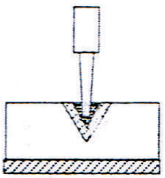


Effect on tissue : if excision is for biopsy, typically, pure Cut or Blend 1 setting and a rapid deliberate motion through the tissue will produce a vital tissue sample for pathology. If excision is for removal of diseased tissue, then Blend 2 or 3 and a slower motion throughThe tissue will leave the remaining wall further coagulated

Desiccation

Recommended current mode: BLEND 2 or Blend 3

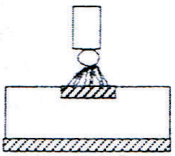
Typical Electrode: Blade, Blunt, Needle, or Ball types



Effect of Tissue: this is most destructive technique, similar to desiccation by laser.

Depth of lateral necrosis is determined by current mode, power level, length of penetration into tissue and stay in the wound. Bipolar desiccators are commonly used in polypectomy to desiccate the root of a polyp. Here the technique is the same, but with bipolar mode current.

Fulguration



Recommended current mode : COAG (Cone Spray Mode Displayed)

Typical Electrode: Blunt Needle (pinpoint), or Ball type (cone spray)

Effect of Tissue: Employed by surgeon for surface layer hemostatis. Necrosis is determined by length of application and current mode "Crest Factor".

(Crest Factor is defined as a generator's ability to coagulate without cutting. The ideal is slowly shrink the top layer of tissue whereby the capillaries seal off bleeding without causing any further penetration or tissue necrosis.)

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5. CONTROLS, INDICATORS, AND RECEPTACLES

5.1 Front Panel

Figure 2 – 1 Layout of controls, indicators, and receptacles on the front panel

Symbols on the Front Panel

Refer to the following table for descriptions of symbols found on the front panel of Quikseal

5.2 Symbols Description

	This "BF" Symbol, a caution symbol, indicates the machine was manufactured according to the degree of protection against electric shock for this type of BF equipment.
	Attention! Read the Instructions
	Monopolar Handpiece Receptacle
	Bipolar Handpiece Receptacle
	Return Electrode Receptacle
	Seal mode
	Bipolar Mode
	Foot-operated switch, the corresponding symbol on the rear panel.

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5.3 Controls and Indicators

1. Monopolar Cutting indicator Light 'CUT' - The yellow indicator light is displayed when the cutting power is activated by pressing either the yellow button of active electrode or the yellow switch of the foot padal. With these settings the unit generates monopolar cutting power.
2. Monopolar coagulation indicator light 'COAG'- the blue indicator light is displayed when the coagulation power is active by pressing either the blue button of the active electrode or the blue switch of the foot padal. With these settings the device generates monopolar coagulation power
3. Modes indicator light in 'CUT'
   a. Pure cut - The yellow indicator light is displayed when selecting pure cut mode.

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b. Blend 1 - The yellow indicator light is displayed selecting Blend 1.

c. Blend 2 - The yellow indicator light is displayed selecting Blend 2

d. Endo-cut - The yellow indicator light is displayed selecting Endo Cut.

4. Modes indicator light in 'COAG'

a. Spray - The Blue indicator light is displayed selecting Spray coagulation.

b. Fulgurate - The Blue indicator light is displayed selecting fulgurate.

c. Desiccate - The Blue indicator light is displayed selecting Desiccate.

5. Relative power display for monopolar cutting and coagulation – The display shows the relative power used in cutting and coagulation

6. Mode setting button: The buttons are used to set the modes in monopolar cut and coag.

a. CUT : 1. Pure cut 2. Blend 1 3. Blend 2 4. Endo-cut

b. Coag : 1. Spray 2. Force. 3. Fulgurate 4. Desiccate

7. Relative Power setting button, increase & decrease. : the button are used to set relative power used in cutting and coagulation on display.

a. Pure cut - Maximum setting limit is up to 400W@480Khz

b. Blend 1 - Maximum setting limit is up to 250W@480Khz.

c. Blend 2 - Maximum setting limit is up to 200W@480Khz

d. Endo-cut - Maximum setting limit is up to 99W@480Khz

e. Spray - Maximum setting limit is up to 120W@480Khz.

f. Force - Maximum setting limit is up to 120W@480Khz.

g. Fulgurate - Maximum setting limit is up to 150W@480Khz

h. Desiccate - Maximum setting limit is up to 150W@480Khz

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1. Bipolar seal indicator light : the blue indicator light is switched on when pressing foot padal of bipolar or seal.
2. Modes indicators of bipolar- relative Blue indicator light as per mode selection.
3. Relative power display for bipolar cut and coag : the display shows the relative power used in Bi-cut and Bi-coag.
4. Mode setting button: The buttons are used to set the modes in bipolar.
   - Bi-coag - maximum setting limit is up to 80@480Khz.
   - Bi-Cut - maximum setting limit is up to 99@480Khz
   - AUTO - maximum setting limit is up to 80@480Khz.
   - Seal - maximum setting limit is up to 99%.
5. Bipolar Cut and Coag relative power setting button, increase and decrease.- the buttons are use to set relative power used in bipolar cut and Coag on display (3)

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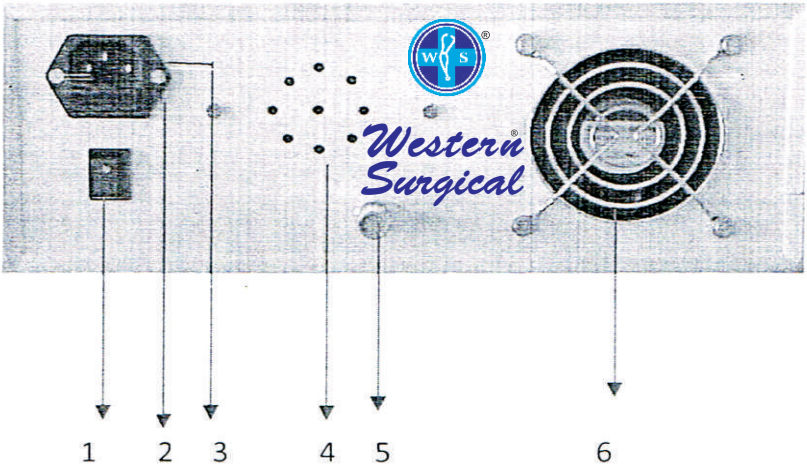
5.4 Back Panel



1. Power switch: the main power switch of the unit.
2. Mains fuse: If the fuse blows repeatedly, the unit should be serviced at an authorized service center.
3. Main connector: plug the power cord supplied with the unit into the mains connector
    a. NB! The unit must be plugged into a grounded outlet.
4. Speaker : speaker holes for audio
5. Audio Volume qdial: Dial controls the audio volume from inaudible to 65 db.
6. Cooling Fan

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6. FUNCTION CHECKS

FUNCTION CHECKS

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

WARNING:

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

Setting up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.
2. Connect a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.
3. Connect a two-button monopolar pencil to the appropriate receptacle.
4. Do not connect a patient return electrode at this time.
5. Turn the unit on by switching the power switch to the on (|) position.

Checking the Return Electrode Alarm

1. Adjust the power settings for each mode (Cut, Coag, and Bipolar) to one watt.
2. Press the Coag button of the pencil. Verify that an alarm sounds and the patient return electrode sensing alarm indicator light illuminates, indicating that no return electrode is connected to the unit.
3. Verify that adjusting the volume control on the back of the unit while the alarm is sounding does not change the alarm volume.

Confirming Modes

Confirm that you can select each mode and adjust the power up and down.

Checking Bipolar Mode (with bipolar footswitch)

1. Plug in the Bipolar footswitch. Verify that the Bipolar footswitch indicator illuminates.
2. Press the pedal on the Bipolar footswitch. Verify that the Bipolar mode activation indicator illuminates and that the system generates the Bipolar activation tone.
3. While activating the Bipolar mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
4. Confirm that releasing the pedal returns the unit to an idle state.

Checking Monopolar Mode (with monopolar footswitch)

1. Plug in the Monopolar footswitch. Verify that the monopolar footswitch indicator illuminates.
2. Connect a solid return electrode to the return electrode receptacle.
3. Press the Cut pedal (yellow) on the footswitch. Verify that the Cut mode activation indicator illuminates and that the system generates the Cut activation tone.
4. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.
5. Press the Coag pedal (blue) on the footswitch. Verify that the Coag mode activation indicator illuminates and that the system generates the Coag activation tone.
6. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

Checking Monopolar Mode (with handswitch)

1. Connect a handswitching handpiece to the Monopolar handpiece receptacle.
2. Connect a solid return electrode to the return electrode receptacle.
3. Activate, one at a time, the Cut and Coag handswitching controls. Verify that each control causes the correct indicator and tone to sound.

PERFORMANCE CHECKS

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

7. MAINTAINING THE QUIKSEAL

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

7.1 CLEANING

After each use, clean the unit.

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

NOTICE:
Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.
1. Turn off the generator, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure.
Do not allow fluids to enter the chassis. Do not sterilize the generator.

PERIODIC INSPECTION
Every six months, visually inspect the Monoseal for signs of wear or damage.
In particular, look for any of the following problems:
- Damage to the power cord
- Damage to the power cable receptacle
- Obvious damage to the unit
- Damage to any receptacle
- Accumulation of lint or debris in or around the unit

FUSE REPLACEMENT
Fuses for the unit reside directly below the Power Cable Receptacle on the rear of the unit.
To replace the fuses, follow this procedure:
1.Unplug the power cord from the wall outlet.
2.Remove the power cord from the Power Cable Receptacle on the rear panel.

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

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

7.2 TROUBLESHOOTING

INCIDENT	Possible cause	Solution
ESU will not turn on	Disconnected or loose contact	Check connections and reconnect unit
Accessories is activated via handswitch or footswitch, but there is no ESU output	Malfunctioning instrument or accessories	Check all accessories and connections replace accessories if needed
	Incomplete or incorrect footswitch pedal connection	Reconnect footswitch pedal cable
	Possible internal malfunction	Inform Ease technical service dept.
No tissue effect	Power setting is too low	Adjust power settings
No power audio and visual alarm	Internal malfunction	Inform Ease technical service dept.
Abnormal neuromuscular stimulation (stop surgery immediately)	Demodulation due metal to metal arcing or sparking	Check all connection to the generator & accessories for loose fit or damage Ensure that the active instrument is not touching metal i.e. metal retractor
	Use of high voltage modes, such as spray or fulgurate	Use lower voltage modes such as desiccate or blend modes and lower settings, if possible
Continuous monitor interference with EKG and other vital sign monitors, i.e. EEG,Video, IV delievery systems, pulse oximeter	Faulty chassis to ground or loose connections	Check all monitor and ESU connection Re-connect or change outlets Use separate outlets for each medical device, if possible. Replace loose or damaged cords and adapters

Monitor interference occurs only when ESU is activated	Metal to metal sparking	Check all ESU, cord, adapter, instrument & monitor connections
	Cords and cables are bundled or touching, causing excessive current leakage.	Separate all cords: do not bundle for cord management Check all cords for compromised insulation Do not use any metal object for cord management
	Cord may be damaged	Replace any or all accessory cords
	Monitoring leads may be too close to electrosurgical instrument	Place monitoring equipment and leads as far away as possible from surgical site

RESPONSIBILITY OF THE MANUFACTURER

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

- The user has followed the Installation and Setup Procedures in this User's Guide.
- Persons authorized Ease systems performed assembly operation, readjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements.

For warranty information, refer to Appendix B - Warranty.

RETURNING THE GENERATOR FOR SERVICE

Before you return the generator, call your Ease systems representative for assistance. If instructed to send the generator to western surgical first obtain a Returned Goods Authorization Number. Then, clean the Generator and package securely to ensure proper protection of the unit. So as to aid in the processing of the unit, please be sure to write proper address on the outside of the box and ship directly to Ease systems.

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7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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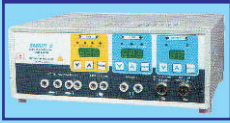
ELECTRO SURGICAL GENERATOR, ULTRASONIC SCALPEL & VESSAL SEALER ALL PRODUCT'S

LOTUS ULTRASONIC SCALPEL

VESSEL SEALER

DIGITAL ELECTRO SUR. GENER.



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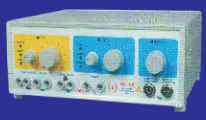


VESSEL SEALING SYSTEMS MONOSEAL

VESSEL SEALING SYSTEMS BISEAL

VESSEL SEALING SYSTEM

SSE-250

R F SURGICAL SYSTEM

BI - ECO

BI - PRO

BIPOLAR 150

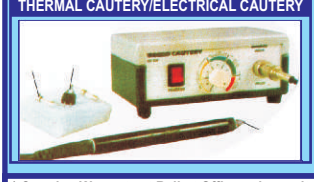
SKIN & CERVICAL CAUTRY ANALOG

400W

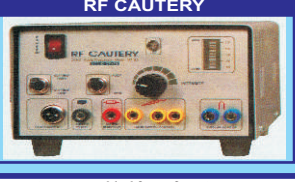
250W / 300W

LAP-BI CLAMP

THERMAL CAUTERY/ELECTRICAL CAUTERY



RF CAUTERY



CERVICAL CAUTERY ANALOG

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Western Surgical®

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