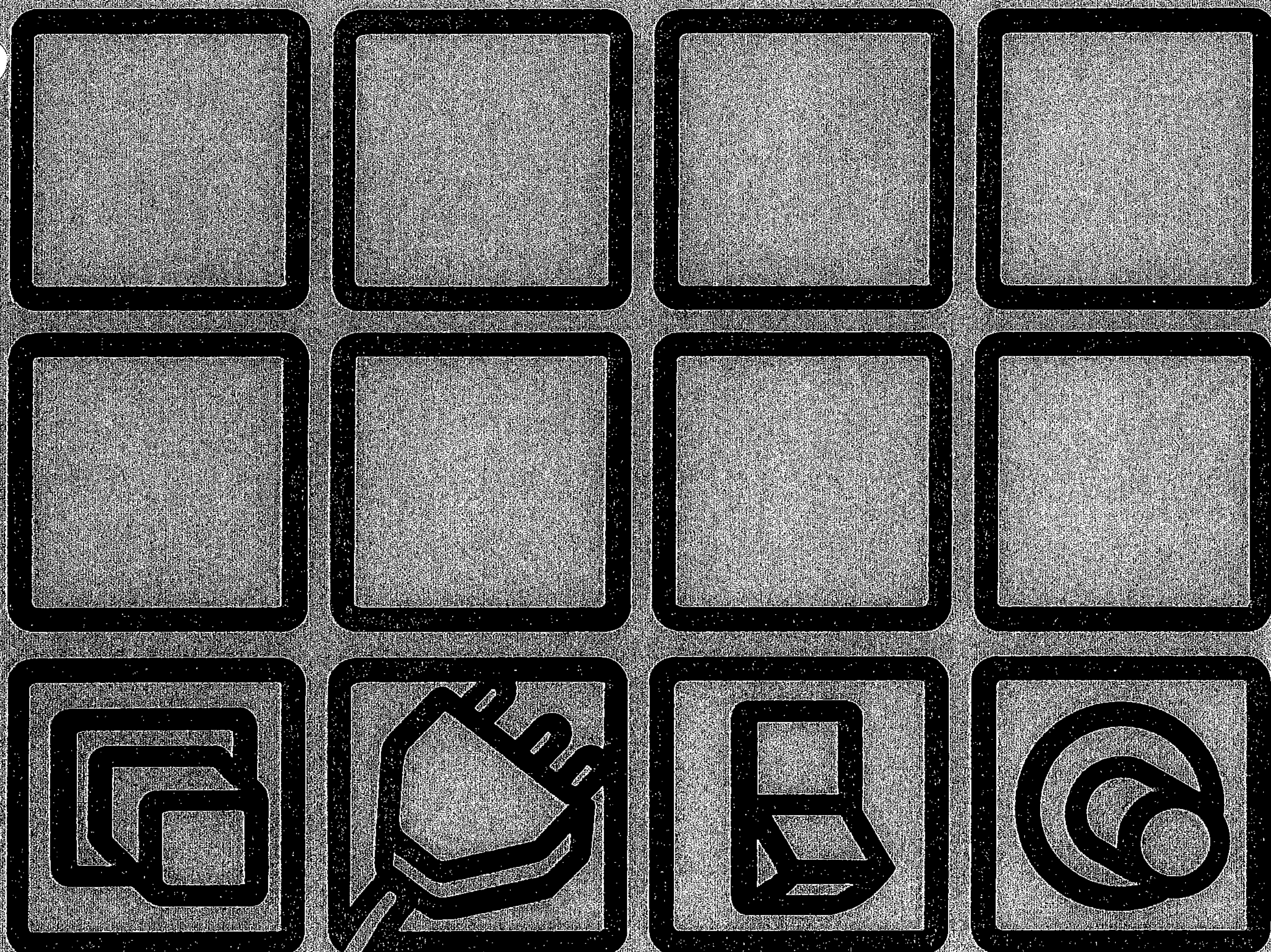

Valleylab

SSE3B INSTRUCTION MANUAL

VAL 24

1984

Valleylab

ELECTROSURGICAL SAFETY TIPS

Prior To Use

(General)

1. Know which E.S.U. will be used and how to use it. Consult the instruction manual.

2. Have all equipment and accessories available and use only accessories designed and approved for the unit.

3. Check the operation of the alarm systems. If applicable, check the operation of the return cable sentry prior to placement of the return electrode on the patient.

4. Replace all broken, bent, excessively scratched or otherwise damaged return electrodes.

5. Do not cut, crease or sharply bend a disposable return electrode.

6. Avoid the use of flammable prep solutions such as acetone, alcohol or ether.

7. Avoid the use of flammable anesthetics. (A warning to this effect should be evident on the E.S.U. cover.)

8. Always place E.C.G. electrodes as far away from the site of surgery as possible.

9. Do not use needle E.C.G. electrodes.

10. Replace uninsulated instruments with updated equipment.

11. Check the line cord and plug on the E.S.U. Extension cords should not be used.

12. Do not use any power or accessory cord that is broken, cracked, frayed or taped.

13. Use a conductive gel specifically designed for electrosurgery.

14. Have back-up equipment available.

(Patient Return Electrode Placement)

15. Always place the return electrode on the patient as close to the electrosurgical site as possible. Avoid fatty, bony, hairy, heavily scarred areas and bony protuberances.

16. Avoid placing the return electrode where fluids may pool.

17. Do not slide the return electrode under the patient. The patient should be lifted and placed on the return electrode.

18. If the patient has a pacemaker, the return electrode should be as far from it as possible.

During Use

1. Use the lowest possible power settings to achieve the desired surgical effect. The need for abnormally high settings indicates something is wrong.

2. Position cords so that they present no tripping hazard. Do not wheel equipment over electrical cords.

3. If the patient is moved or repositioned, check that the return electrode is still in good contact with the patient. (If using an adhesive electrode, make sure the gelled area is in good contact, not just the adhesive border.

4. When an active accessory is not in use, remove it from the surgical field and contact with the patient. (With most of today's generators, all outputs are "hot" when one is activated.)

5. Do not coil up active or patient cables - this will increase R.F. leakage currents and present a potential danger to the patient.

6. Do not spark the active electrode to ground to confirm operation of the unit. This may damage the unit or introduce a patient hazard.

7. Do not activate the electrosurgical unit for long lengths of time.

8. Avoid "buzzing" forceps and creating a metal to metal arc. Touch the forceps with the electrode and then activate the generator. (This will eliminate the majority of "jolts" to the surgeon.)

9. Only use endoscopes with insulated eye pieces.

10. Keep active electrodes clean. Eschar build-up will increase resistance, reduce performance, and require higher power settings.

11. Do not submerse the active accessory in liquids. This may cause the accessory to activate.

After Use

1. Turn the unit off.

2. Turn all dials to 0.

3. Disconnect all cords by grasping the plug, not the cord; disconnect the power supply cord first.

4. Coil electrical cords when storing: don't bend or kink them.

5. Do not reuse disposable accessories.

6. Routinely replace all "permanent" cables at appropriate intervals - every 3-4 months, depending upon usage rate.

7. Wash all reusable accessories with a damp cloth. Do not immerse or soak.

8. ETO sterilize accessories if possible - this will prolong their life.

SSE3B
INSTRUCTION MANUAL

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VALLEYLAB SSE3B
ELECTROSURGICAL GENERATOR PRODUCT INFORMATION

INTENDED USES

The Model SSE3B Electrosurgical Generator is a general purpose electrosurgical generator intended for use in the operating room. The SSE3B has both monopolar and bipolar output connections. The monopolar output is intended for use with a patient return electrode and is designed for electrosurgical cutting and fulguration. Its voltage waveforms, CUT, BLEND #1, BLEND #2, BLEND #3 and COAG are intended for smooth cutting, cutting with increasing degrees of hemostatis, and fulguration with a minimum of cutting, respectively. The monopolar output is powerful enough for all common procedures including transurethral resections. Desiccation with minimal cutting or fulguration using the monopolar output is practical, but low settings must be used and the surgeon is referred to the Instruction Manual for details. The bipolar output is an isolated output which is intended for desiccation without fulguration or cutting. The bipolar output power is independently controlled. Although designed primarily for use with bipolar instruments, it is also possible to use the bipolar output with monopolar instruments.

CONTRAINDICATIONS

There are no known absolute contraindications to the use of electrosurgery. The use of external or internal pacemakers, monitoring equipment, and the patient's condition may require special precautions.

WARNINGS

Never increase the power beyond the normal settings without first checking both the active and the patient return electrodes and their connections.

Burns to the surgeon's hands are possible in most clinical situations if a monopolar active electrode is touched to a metal instrument held in the surgeon's hands. Electrosurgery involves electric sparking to tissue and is inherently unsafe for use with flammable anesthetics or near flammable fluids or objects.

Electrosurgical units should be used with caution in the presence of a pacemaker because of the danger of introducing electrosurgical currents into the heart which could cause fibrillation. Also, interference from the electrosurgical current can cause a pacemaker to revert to an asynchronous mode or inhibit the pacemaker entirely.

PRECAUTIONS

The surgeon should be aware that the Model SSE3B can malfunction for reasons such as random component failure or defective active or patient electrodes. A standby generator and accessories are recommended if generator malfunction is a significant risk to the patient. The SSE3B Return Fault safety system cannot detect loose connections in the active electrode which may result in higher than normal low frequency components in the electrosurgical current. Low frequency current components could cause fibrillation, so the patient return electrode should be placed so that the electrosurgical current will not pass directly through the region of the heart.

POTENTIAL COMPLICATIONS

The most common complications associated with monopolar electrosurgery are unintended burns to the patient and surgeon caused by defective active or patient return electrodes, insufficient patient electrode contact, combinations of fault conditions, or poor surgical technique. A rare complication is the explosion of flammable bowel gas. Complications with bipolar electrosurgery are very unusual.

PREVENTATIVE MAINTENANCE

To insure safe and dependable operation, this generator should be periodically checked for wear and tear.

Of particular importance are: printed circuit board contact finger corrosion, lint and dirt build-up, power cord wear, and looseness of mechanical parts.

A thorough visual inspection of the generator should be made and appropriate steps taken to correct any and all of the above conditions. It is recommended that the generator be inspected at least twice a year and that the "Acceptance Test Procedure," outlined in the service manual, be performed at these times to insure continued efficacy and safety.

THE SSE3B SYSTEM

Congratulations. Your new SSE3B is the most versatile electrosurgical generator ever built. It offers features and performance never before available in a single generator. The SSE3B has COAG fulguration which rivals the best spark gap generators and with a minimum of cutting effect. The variable BLEND gives a wide range of hemostasis while cutting and PURE CUT is exceptionally smooth and starts promptly even in irrigated procedures. For your convenience the output is calibrated directly in watts with a large lighted, digital display. The SSE3B has a separate, isolated bipolar output which has a non-sparking (desiccation) characteristic which is ideal for neurosurgery, laparoscopy, or other applications. Hand-switch activation may be used with both monopolar and bipolar instruments as well as conventional footswitch activation. The SSE3B is equipped with the "Balanced Output" patient return electrode safety system which combines the significant advantages of isolated and grounded electrosurgery. The SSE3B may also be equipped with the Return Electrode Monitoring System (REM).

In order to instruct the user of an electrosurgical generator of the capabilities and limitations of his generator, a great deal of information must be provided. The user must be given more than just facts and specifications. Ideally, he should be given a complete understanding of his equipment so he can use the generator in new situations and recognize potential hazards before they occur.

For the surgeon the most important parts of these instructions are Sections 1 and 2. These sections contain the basic surgical capabilities and limitations of the generator. After reading these sections a surgeon should be able to decide what procedures his SSE3B can handle and how it must be used to accomplish them.

The basic problem most surgeons and nurses have in trying to understand their generator is a lack of knowledge of electricity. To fill this need, Section 9 is a short primer on electricity and electronics for the electrical layman and Section 10 is a glossary of terms.

The remainder of the Instruction Manual, Sections 3 through 8, cover technical topics which are of less concern to the surgeon but are increasingly relevant for the hospital engineer. Other OR personnel such as the circulating nurse and OR supervisor will be interested in Sections 3 through 8 as well as Sections 1 and 2.

If any questions arise about using your new SSE3B, call your local Valleylab representative. If there are questions he can't answer, do not hesitate to call or write our factory. The personnel in our Customer Service Department, Maintenance Service Department, and Engineering Department are always happy to help you with your electrosurgical problems.

CONTENTS

SECTION

SECTION 1

ELECTROSURGICAL THEORY APPLIED TO THE SSE3B

Electrosurgery can be defined as the use of a radio frequency electric current to sever tissue or achieve hemostasis. A high radio frequency is used because a low frequency, say below 100,000 Hz (cycles per second) will stimulate muscles and nerves. Putting it another way, a low frequency electric current could electrocute the patient.

Although a generator could perform electrosurgery quite well at frequencies up to 4,000,000 Hz (4 MHz), reactive phenomena, capacitance and inductance, become quite prominent at such high frequencies and it becomes difficult to confine these radio frequency currents to wires. For these reasons the SSE3B operates at 750,000 Hz (750 KHz) which is a compromise between these two extremes.

Medical diathermy is similar to electrosurgery in that radio frequency current is passed through the patient's body. Large entry and exit electrodes are used so that the current density is kept low and the resulting tissue heating is never high enough to cause necrosis. The British use the term "surgical diathermy" for electrosurgery. This is very descriptive since the major difference between these two techniques is the density of the radio frequency electric current.

There are only three surgical effects which can be achieved with electrosurgery. They are:

Electrosurgical Desiccation - Low power coagulation without sparking.

Electrosurgical Cutting - Electric sparking to tissue with a cutting effect.

Electrosurgical Fulguration - Electric sparking to tissue without significant cutting. Fulguration can coagulate large bleeders and char tissue.

The SSE3B is optimized to perform all three of these functions.

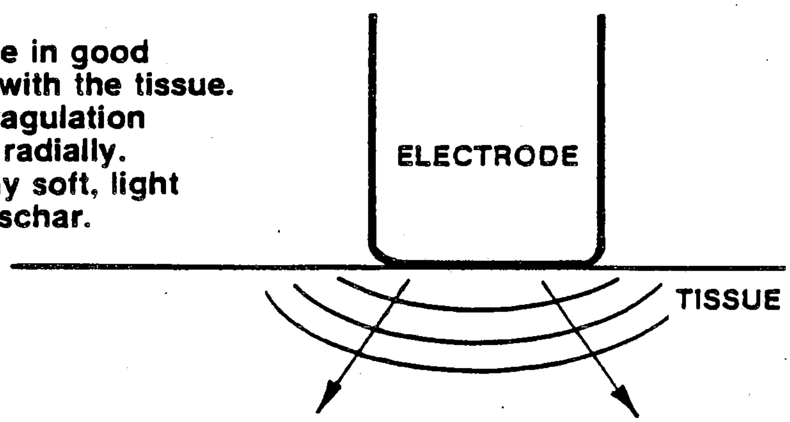
1. <u>Electrosurgical Desiccation</u>

Of the three, desiccation is technically the simplest because ANY waveform (either CUT or COAG) can be used. In desiccation, current is passed through the electrical resistance of the tissue and heat arises in the tissue. This is exactly the same phenomenon as the resistance wire in a toaster or stove which becomes hot when the current passes through it.

When the tissue becomes hot, the water is slowly driven out of the tissue and hence the name, desiccation. What one sees is that first the tissue turns a light brown color, then it steams and bubbles as the water is driven off. Since desiccation takes place with the active electrode in good electrical contact with the tissue, it is imperative that the electrode be kept clean and free of dried tissue. A dirty or charred electrode desiccates poorly. [1]

DESICCATION

Electrode in good contact with the tissue. Deep coagulation spreads radially. Relatively soft, light brown eschar.



TYPICAL CURRENT = 0.5 AMP RMS

Desiccation with the SSE3B using either of the monopolar outputs can be performed with either CUT, BLEND or COAG. The exact setting needed to desiccate depends on the area of the active electrode since the larger the electrode contact area, the more current is required to produce the same current density. Then too, the higher the control setting, the more current that is delivered and the faster the desiccation will proceed.

The bipolar output (the four receptacles at the lower right of the panel) is optimized for desiccation. This means that it is designed to deliver large currents to low resistance, moist tissue when the electrode is in firm contact with the tissue. In spite of the large currents, the maximum voltage is very low, and as will be explained shortly, the bipolar output is poor for electrosurgical cutting or fulguration.

Desiccation can also be done with the monopolar output which is the long group of five receptacles at the lower left of the panel.

The monopolar output is primarily designed for fulguration and cutting and thus very low settings (less than 30 watts) must be used to keep the surgery in the desiccation mode. As stated above, any mode, CUT, BLEND, or COAG may be used for desiccation.

2. *Electrosurgical Cutting*

In electrosurgical cutting the objective is to heat the tissue cells so rapidly that they explode into steam leaving a cavity in the cell matrix. The heat is dissipated in the steam and therefore it does not conduct through the tissue to dry out adjacent cells. When the electrode is moved and fresh tissue is contacted, new cells are exploded and the incision is made. [2]

It is also possible, and even useful, to cut mechanically with a sharp electrosurgical electrode. Moreover, desiccation softens many tissues, much the way cooking softens a tough pot roast. If a sharp electrode is pressed against tissue, the mechanical cutting may be considerably helped by electrosurgical desiccation. However, true electrosurgical cutting involves sparking to tissue. It should also be mentioned that a hot cautery wire (a heated wire with no electric current passing into the tissue) can also cut tissue by exploding cells that it contacts.

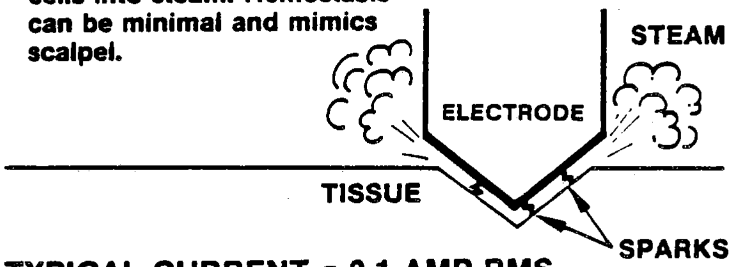
When the radio frequency current jumps across an air gap to tissue, the bright light in the air gap is technically known as an electric "spark". An "arc" is a similar phenomenon which requires longer intervals to become established and probably does not play a significant role in electrosurgery.

To understand the difference between the cautery wire and electrosurgical cutting, let's suppose that one tries to desiccate with a small wire electrode at a relatively high setting of CUT, say "7" on the SSE3B. Because the power level (heat delivered per second) is high, the tissue becomes desiccated very quickly. As the water leaves the tissue, the electrical resistance of the tissue rises. Voltage is the force that drives current through a resistance. It is also the force that drives electric sparks across an air gap. If the voltage is high enough, a spark will jump to the nearest moist tissue since air, once it is ionized, makes a better conductor than the desiccated tissue.

Once a spark to the tissue is established, the tissue heating is the result of two phenomena. The first is the tissue heating produced by the current passing through the resistance of the tissue at the point where the spark strikes the flesh. The remainder of the heating comes from energy dissipated in the spark itself. The heat originating in the spark is actually greater than that arising in the tissue. The two types of heating together are capable of exploding cells because the heating is extremely concentrated. It turns out that cutting by the desiccation phenomenon alone is practically impossible. [3]

ELECTROSURGICAL CUTTING

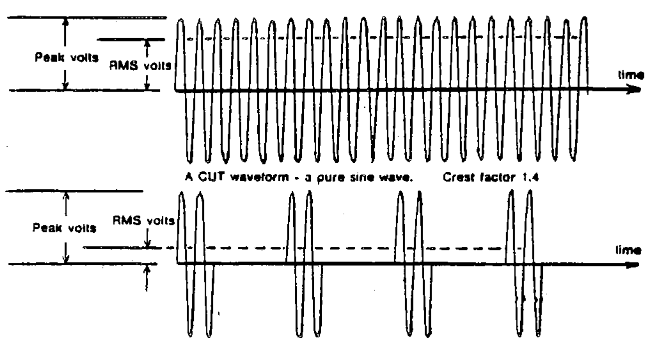
Electrode is separated from tissue by thin layer of steam. Short, intense sparks flash cells into steam. Hemostasis can be minimal and mimics scalpel.



TYPICAL CURRENT = 0.1 AMP RMS

The essential characteristic of CUT waveforms is that they are continuous sinewaves. That is, if the voltage output of the generator is plotted over time, a pure CUT waveform is a continuous sinewave alternating from positive to negative at the operating frequency of the generator, 750 KHz.

EQUAL PEAK VOLTAGE WAVEFORMS



A CUT waveform - a pure sine wave. Crest factor 1.4

A COAG waveform - bursts of sine waves. Crest factor 4.3

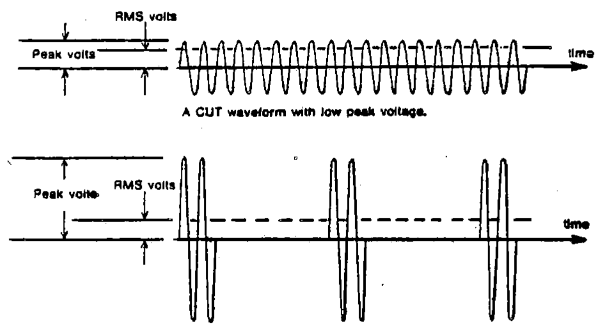
The peak voltage is the same in both of these waveforms, but the power is about 1/3 in the COAG waveform.

3. *Electrosurgical Fulguration*

The SSE3B COAG waveform consists of short bursts of radio frequency sinewaves. The frequency of the sinewave is 750 KHz and the COAG bursts occur 31,250 times/second. The important feature of the COAG waveform is the pause between each burst. Suppose that a COAG waveform had the same peak voltage as the CUT waveform, but the average power delivered (heat per second) is less because the COAG is turned off most of the time.

Now suppose that the COAG waveform had the same average voltage (RMS voltage) as the CUT waveform and thus could deliver the same heat per second. Because the COAG is turned off most of the time, it can only produce the same RMS voltage as the CUT by having very large peak voltages and currents during the periods when the generator is on.

EQUAL POWER WAVEFORMS



A COAG waveform with equal power (energy per second) to the above CUT waveform. Note that the COAG peak voltage is about three times higher in this example. Note also that the root mean square voltages are equal.

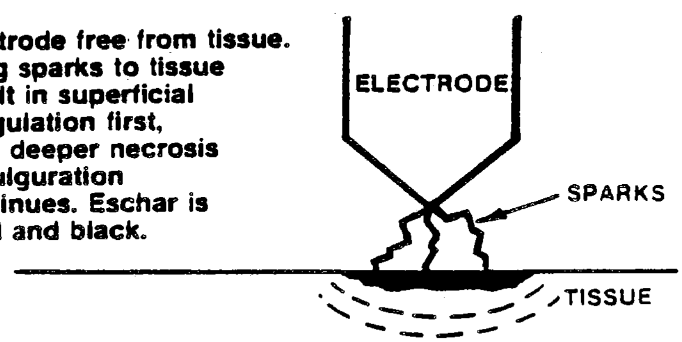
A good COAG waveform can spark to tissue without significant cutting effect because the heat is more widely dispersed by the long sparks and because the heating effect is intermittent. The temperature of the water in the cells does not get high enough to flash into steam. In this way the cells are dehydrated slowly but are not torn apart to form an incision. Because of the high peak voltage of a quality COAG waveform, it can drive a current through very high resistances. In this way it is possible to fulgurate long after the water is driven out of the tissue and actually char it to carbon. "Coagulation" is a general term which includes both desiccation and fulguration.

Fulguration can be contrasted with desiccation in several ways. First, sparking to tissue with any practical fulguration generator <u>always</u> produces necrosis anywhere the sparks land. This is not surprising when you consider that each cycle of voltage produces a new spark and each spark has an extremely high current density. In desiccation, the current is no more concentrated than the area of contact between the electrode and the tissue. As a result desiccation may or may not produce necrosis, depending on the current density. For a given level of current flow, fulguration is always more efficient at producing necrosis. In general, fulguration requires only one fifth the average current flow of desiccation.

For example, if a ball electrode is pressed against moist tissue, the electrode will begin in desiccation mode, regardless of the waveform. The initial tissue resistance is quite low and the resulting current will be high, typically 0.5 to 0.8 amperes RMS. As the tissue dries out, its resistance rises until the electrical contact is broken. Since moist tissue is no longer touching the electrode, sparks will jump to the nearest moist tissue in the fulguration mode, as long as the voltage is high enough to make a spark. [1]

FULGURATION

Electrode free from tissue. Long sparks to tissue result in superficial coagulation first, then deeper necrosis as fulguration continues. Eschar is hard and black.



TYPICAL CURRENT = 0.1 AMP RMS

The on-off characteristic of COAG waveforms can be described with a quantity called crest factor. Crest factor is defined as the ratio of peak voltage to RMS voltage. The crest factor of a pure CUT sinewave is 1.4. The crest factor of the SSE3B COAG is 10.0 and is essentially constant over the entire control range. This is the highest crest factor ever offered in a full power solid state generator. The SSE3B COAG is capable of fulgurating as well as a good spark gap type generator, but has no spark gaps and does not require routine adjustments or parts replacement.

$$\text{Crest Factor} = \frac{\text{Peak Voltage}}{\text{RMS (effective average) voltage}}$$

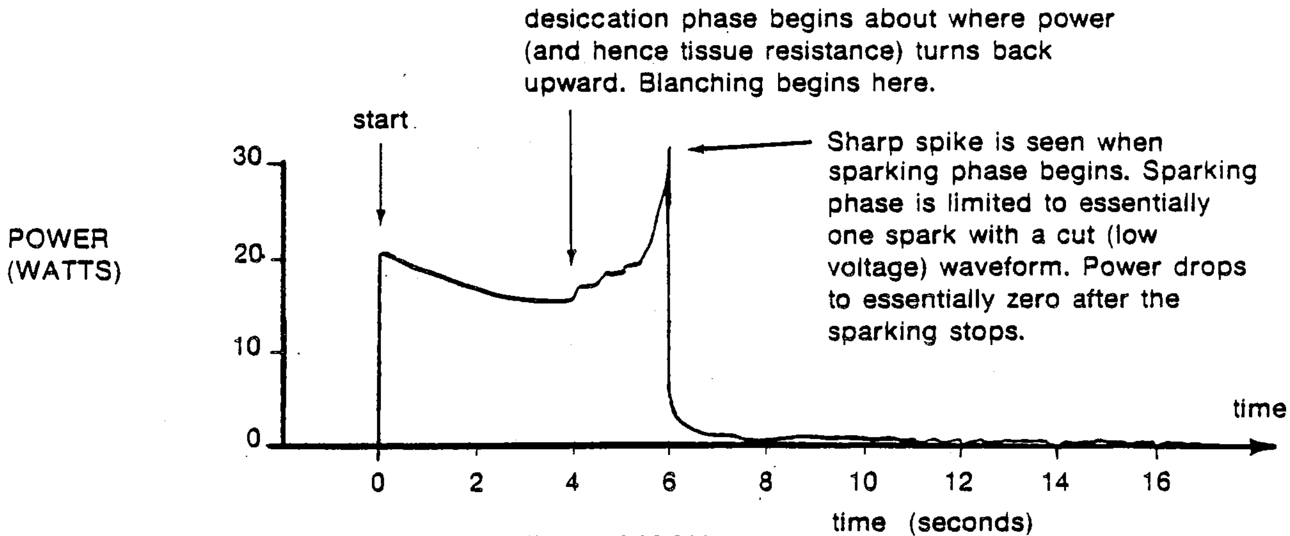
4. <u>Blended CUT</u>

As one might expect, the BLEND is a cutting waveform with moderate hemostatic effect, that is, the walls of the incision made with the BLEND current will be well fulgurated, depending on the fineness of the electrode. The finer the electrode, the cleaner the cut.

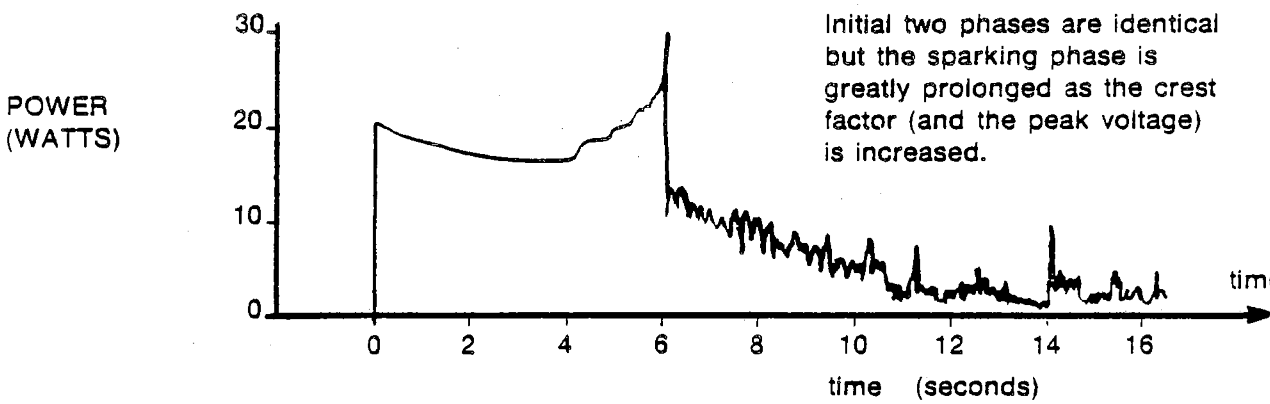
The SSE3B has a crest factor of 1.9 in CUT. A pure CUT sinewave would have a crest factor of 1.4, but many surgeons find that a pure sinewave cuts too cleanly and the incision bleeds excessively. For this reason the SSE3B CUT crest factor is slightly higher. Many urologists find that even the SSE3B CUT is too clean and prefer BLEND #1 which has a crest factor of 2.6. BLEND #2 and BLEND #3 have still higher crest factors, 3.6 and 4.4 respectively. BLEND #3 has such a high crest factor that it is equivalent to "COAG" in many competitive solid state generators. BLEND #3 is useful for cutting with a thin electrode where a maximum of hemostasis is needed. For example, many surgeons doing polypectomy through an endoscope will prefer BLEND #3 because it will allow them to cut through the pedicle in one pass without having to worry about bleeding. BLEND powers are equal for the same area of electrode as more hemostasis is added.

A common misunderstanding about American electrosurgical generators is that the degree of hemostasis (the crest factor) of the BLEND waveform can be varied by dialing in various "percentages" on both the CUT and COAG knobs. This is true of some generators made in Europe, but all Valleylab generators have fixed BLEND crest factors and the power level is controlled by the CUT knob. In other words, when a BLEND button is pushed, the CUT waveform is converted to a BLEND and the COAG is unaffected.

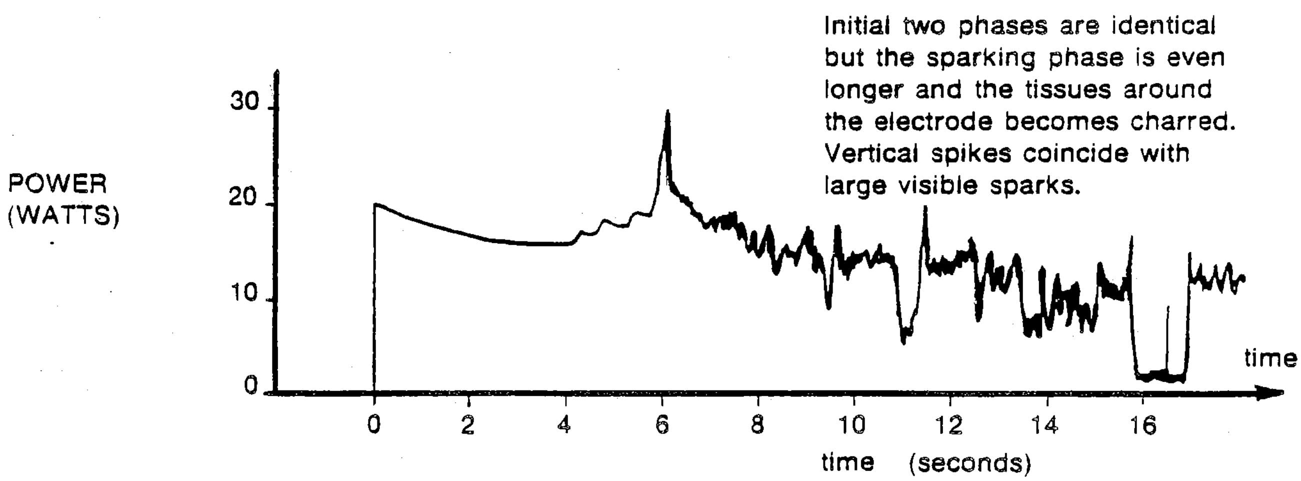
The relationship between CUT, BLEND and COAG is illustrated on the next page. Coagulation of liver with test electrodes in each of the three modes is shown as power plotted over time. The power in each mode is identical and thus each mode desiccates equally. After the tissue around the electrode becomes too dry for good electrical contact with the metal electrode, sparks begin to jump to the nearest moist tissue. Since the peak voltage of the COAG waveform is highest, it will jump sparks to more distant moist tissue and the sparking will continue for the longest period of time. The COAG waveform fulgurates



COAGULATION WITH A LOW POWER CUT WAVEFORM



COAGULATION WITH A LOW POWER BLEND WAVEFORM

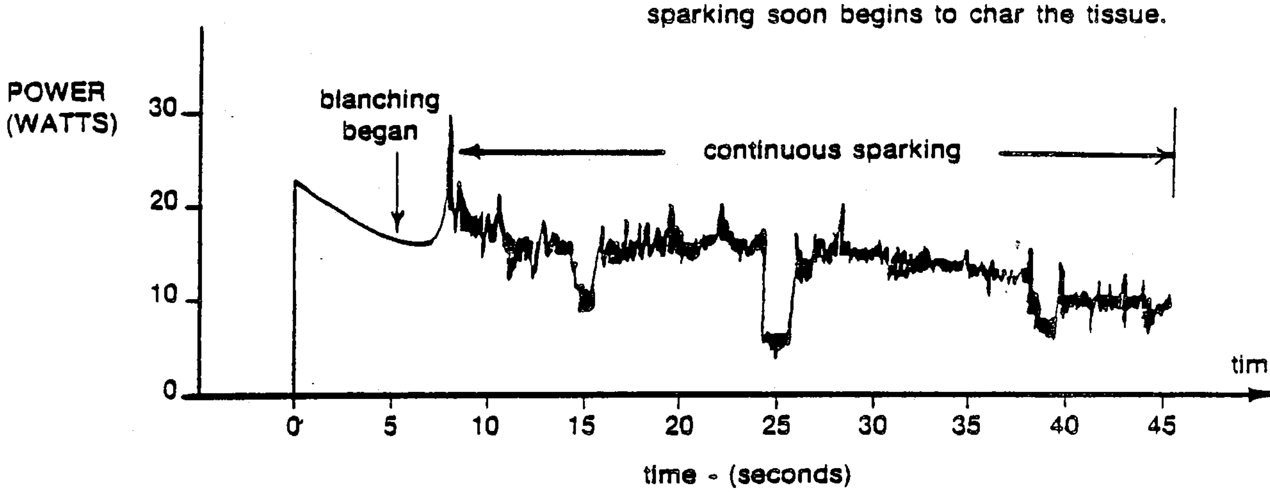


COAGULATION WITH A LOW POWER COAG WAVEFORM

COAGULATION OF LIVER SAMPLES WITH TEST ELECTRODE USING A VALLEYLAB SSE2 ELECTROSURGICAL GENERATOR

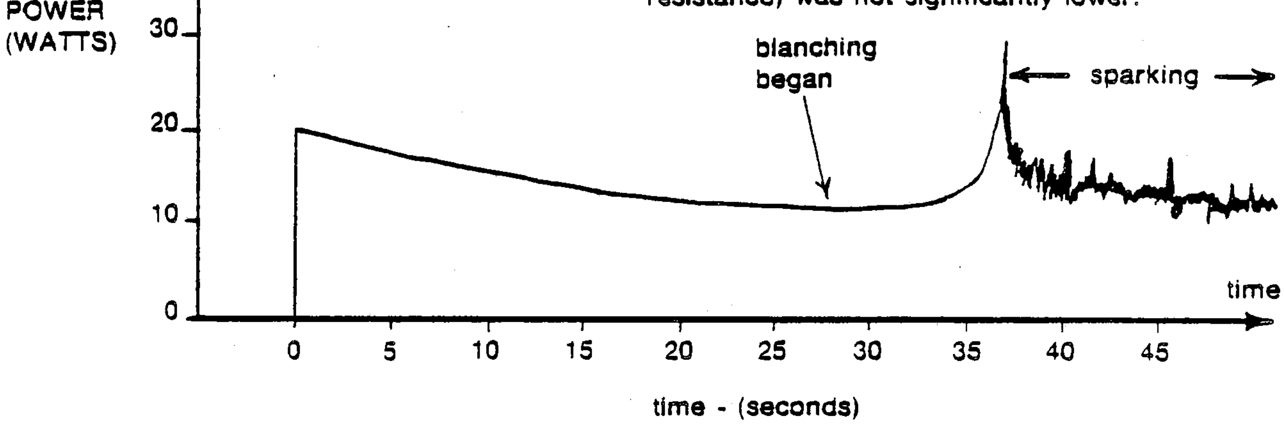
An experiment to show the effect of good physical contact between the electrode and the tissue.

With the needle loosely inserted, the "patient plate" phase and desiccation phase are short and sparking soon begins to char the tissue.



COAGULATION WITH THE NEEDLE ELECTRODE LOOSELY INSERTED INTO TWO FOLDS OF SALPINX. (COAG. WAVEFORM WAS USED)

With the tissue packed onto the needle, more tissue contacted the needle and therefore dissipated heat better and prolonged the desiccation phase. Surprisingly, the starting power (and thus the starting resistance) was not significantly lower.



COAGULATION WITH THE SALPINX TISSUE PACKED TIGHTLY ONTO THE NEEDLE ELECTRODE. (COAG. WAVEFORM WAS USED)

The lesson here is that small electrodes spark more quickly than large electrodes and tissue loosely grasped will spark more quickly than tissue which is tightly grasped.

COAGULATION OF PIG SALPINX SAMPLES WITH TEST ELECTRODE USING A VALLEYLAB SSE2 ELECTROSURGICAL GENERATOR *a wide area with a low power density while CUT has a low voltage and concentrates the power so that tissue cells are heated intensely until they explode to produce the cutting effect.*

One way to keep the output of a generator from cutting is to use large electrodes so that the desiccation phase is prolonged and the electrode is prevented from sparking to tissue. Another way to keep the electrode from sparking to tissue is to design the generator output so that it will not deliver power efficiently to those tissue resistances at which the sparking starts. The SSE3B bipolar output is designed in this way. It has a very low output impedance and less available power. It desiccates rapidly and stops abruptly when the desiccation is complete. It is comparable in performance to the small, bipolar generators designed for neurosurgery.

MONOPOLAR PROCEDURES WITH THE SSE3B

The SSE3B has two separate outputs. The bipolar output is the group of four pin receptacles on the lower right. The monopolar outputs are the group of five receptacle jacks on the lower left. In monopolar electrosurgery the radio frequency current travels from the active electrode, through the patient's body and returns to the generator via a patient plate or dispersive electrode which contacts a large area of the patient's skin. The SSE3B is equipped with a unique patient plate monitor system which will detect the following fault conditions during surgery:

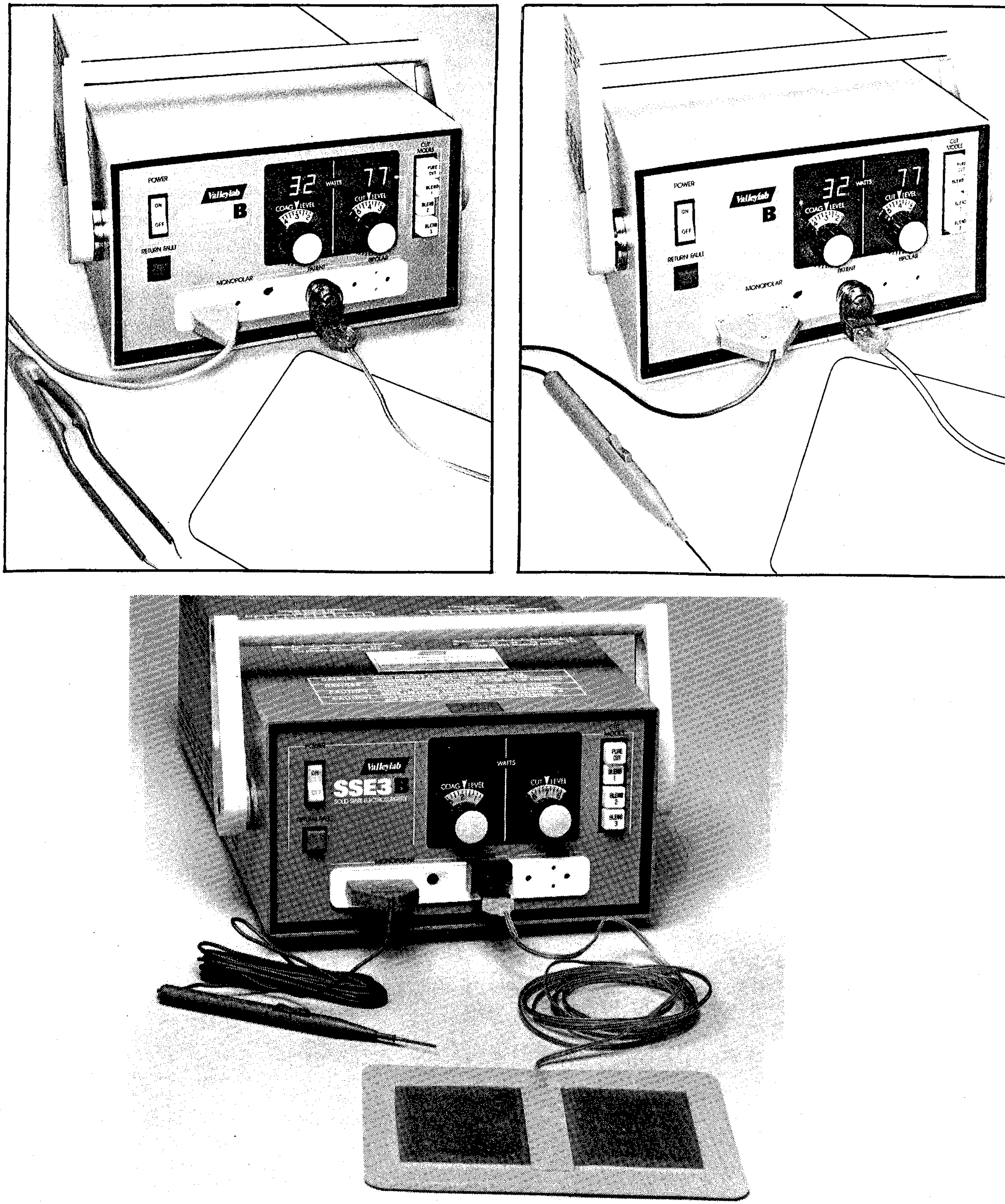
1) *Patient plate cable not plugged into generator.*
2) *Broken patient plate cable.*

If the REM System and CoHesive Return Electrode is being used, the SSE3B will also detect:

3) *Insufficient contact area of the patient plate.*
4) *Patient plate not touching patient's skin.*

In addition, the SSE3B will detect these hazards, provided that potentially dangerous ground currents actually result:

5) *Active electrode touching grounded object.*
6) *Excessive current flowing from the active electrode to ground. (Current flowing through more than 120 pf capacitance or less than 2000 ohms impedance between active and ground.)*
7) *A single area patient plate which is barely contacting the patient's skin (less than one cm2 contact area) can frequently be detected as a fault.*



CONNECTING MONOPOLAR INSTRUMENTS TO THE SSE3B

When any one of these seven faults is detected, the RETURN FAULT indicator will illuminate and the generator will not operate. To make the generator operate, the fault must be corrected and the Return Fault indicator reset by pushing the indicator button.

The CUT and COAG Lights as Safety and Check-Out Indicators

To detect a fault in the ACTIVE circuit, or to find out if the generator is actually working, the CUT and COAG indicator lights may be used. The lights will only illuminate when there is a useful radio frequency output on the output jacks. You can test this by turning either the CUT or COAG power controls to zero and keying the generator. The lights will not come on until the control is advanced to at least "1", indicating that there is no significant RF output below this setting.

Suppose the patient plate seems to be applied properly, the return fault light is OFF, but the generator does not operate. If the CUT or COAG light illuminates, you may conclude that the problem is a defective (open circuit) active cable or electrode and the current cannot complete the path from the generator to the active electrode.

Testing the Return Fault Monitor System and Electrode Area (REM) System

The RETURN FAULT monitor system can be tested by pressing the red indicator inward. The indicator should light and this verifies that the light bulb is intact. If one attempts to activate the generator while the indicator is pressed, the generator should not activate, as indicated by no audio tone and no CUT or COAG indicator lamps. This verifies that most of the RETURN FAULT circuitry is operational. The only way to test the entire return fault system is to actually simulate a fault condition. The simplest way to do this is to set either power control to any setting from 1 1/2" to 10, then touch the active electrode to a grounded object, such as the aluminum handle of the SSE3B. The indicator should light and the generator should deactivate. The RETURN FAULT indicator should stay lit until the indicator is reset by pressing it inward. Note, that the RETURN FAULT circuit only responds to actual ground current flow. It doesn't detect faults that have not yet produced excessive ground current.

The return area indicator (REM) can be tested before the return electrode is applied by noting the REM alarm even when the generator is not keyed. The return fault alarm can also be tested after placement by keying the generator and touching the electrode to the handle. Either of these conditions should disable the generator.

Dispersive electrode placement and size requirements are discussed in Section 6. In summary, we recommend using a patient plate of about 65 cm2 (10 square inches) for each 100 watts of power. The plate should be as close as possible to the site of surgery and should be in firm contact with as large an area of skin as possible.

We recommend a thin layer of good conductive gel, such as Lectrogel , be placed on the plate. If a disposable, pregelled, dispersive electrode is used, it is critical to insure that the gel pad is thoroughly wet to the touch before it is applied to the skin. Apply the return electrode to a curved or convex area of dry skin, as near as possible to the site of surgery. Avoid bony prominences and fatty tissue. Extremely hairy areas should be shaved. Position the pad carefully and apply fingertip pressure to all adhesive areas. Then press the back of the entire pad to assure firm contact of the conductive gel with the patient. Do not reuse or relocate the pad after its initial application. In case of suspected trouble with the patient cable assembly, that is, the RETURN FAULT light comes on, the adhesive pad should be removed from the skin and replaced unless the problem obviously has some other cause.

Limitations of the SSE3B Return Fault Safety System

The SSE3B RETURN FAULT system is the best monopolar safety system ever devised. However, there are certain faults it cannot detect and it is up to the operating room staff to insure that the following unsafe conditions do not occur:

1. *Insufficient Patient Electrode Area*

   A patient electrode which has only a small area (small, yet greater than 20 cm2) in good electrical contact with the patient's skin appears the same electrically as a properly applied patient electrode which should have at least 100 cm2 contact area. The patient return electrode area monitor (REM) system will detect insufficient contact area. A special dual section patient electrode (E7505) is required for units featuring REM.

2. *Careless Placement Of One (or Both) of Two Active Electrodes*

   For example, if two active electrodes are being used simultaneously, perhaps in a coronary bypass procedure, both electrodes are active ("hot") at the same time and must be guarded carefully. When one surgeon is done with an electrode, it must be returned to an insulated holster to be certain that it cannot touch the patient accidentally.

3. *Damaged Insulation on the Active Electrode or Cable*

   For example, if the active cable is frayed and bare metal is exposed, sparks can jump from that metal to the patient if the damaged cable is laid against the patient's skin.

4. *Patient Electrode Not Contacting Patient's Skin But Making Contact With Ground*

If the patient electrode falls away from the patient and makes electrical contact with a grounded object such as the operating table, the RETURN FAULT circuit will not be able to distinguish between the current flowing through the ground path and that returning via the patient electrode cable. The REM System can detect a loose electrode if the dual section pad is used.

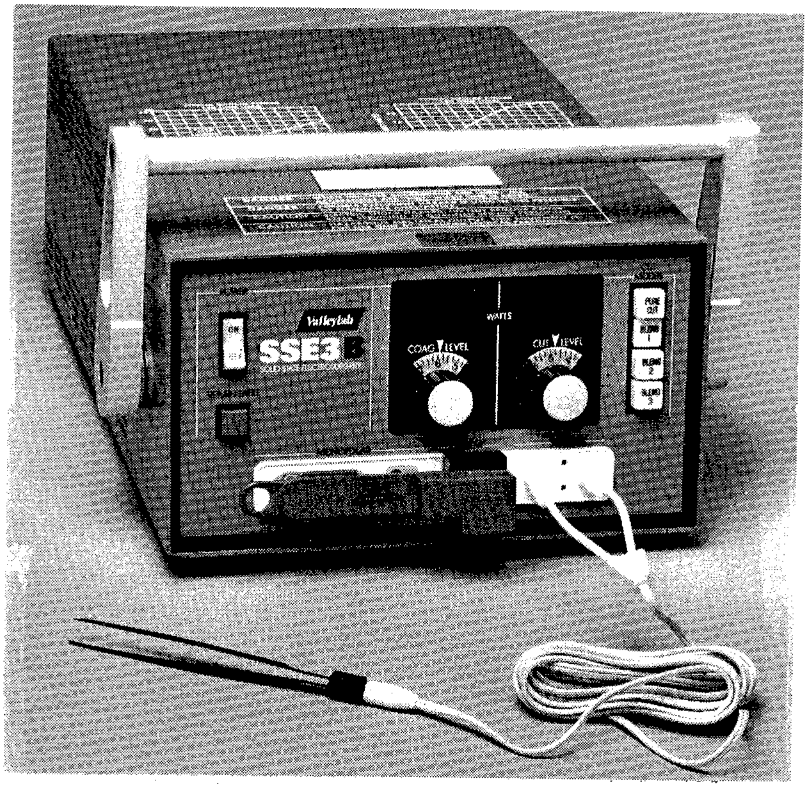
5. *Do Not Touch the Active Electrode with a Bare Finger as a Demonstration of the RETURN FAULT Circuit.*

If the impedance between the demonstrator's body and ground is less than 2000 ohms (resistive, capacitive, or inductive at 750 KHz) the RETURN FAULT detector will not allow the generator to activate. However, if the impedance to ground is MORE than 2000 ohms but less than infinite, the generator will activate and some current will flow. In the COAG mode especially, there might be a small spark to the finger which could inflict a painful burn. Fortunately, this situation is not very representative of possible fault conditions which might be encountered in surgery. The operating room situation which most closely approaches this is the practice of touching the active electrode to a bare metal hemostat held by an assistant. If the hemostat is not in good electrical contact with the patient, a spark may jump through his glove to his hand, giving him a small but painful burn.

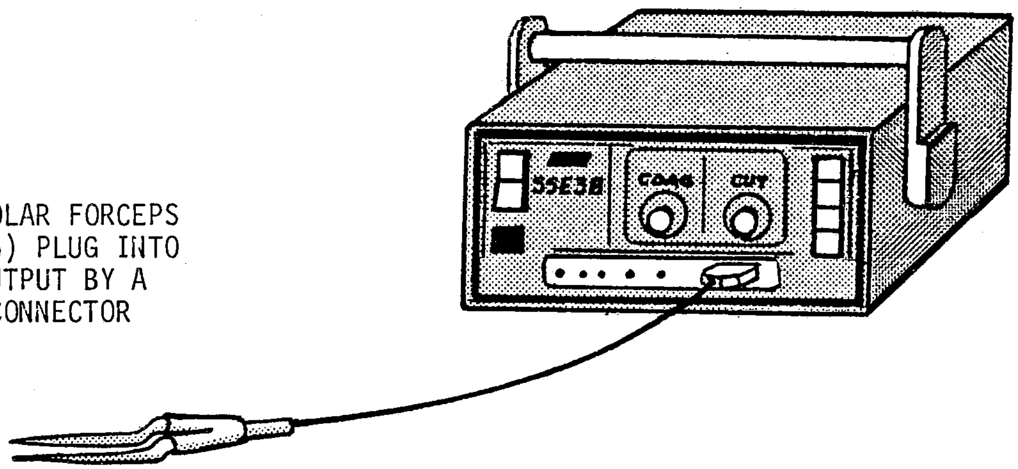
BIPOLAR PROCEDURES WITH THE SSE3B

Bipolar electrodes are simply forceps or other electrodes which have the active and return electrodes built into the same tool. No patient electrode is required. The current flows from the "active" electrode through the tissue which is grasped or touched, and returns to the "patient" electrode located on the same tool.

Because the SSE3B bipolar output is isolated from ground, it may be used for bipolar procedures.



CONVENTIONAL BIPOLAR FORCEPS (SW2 SERIES) USED IN CONJUNCTION WITH THE E0024 ADAPTER TO ELIMINATE THE NEED FOR A PATIENT PLATE IN BIPOLAR ONLY PROCEDURES



SWITCHING BIPOLAR FORCEPS (E4045 & E4506) PLUG INTO THE BIPOLAR OUTPUT BY A SINGLE 3-PIN CONNECTOR

NOTE: Bipolar instruments can only be used with the separate bipolar output. With the Valleylab SSE2 and SurgiStat models it is permissible to plug bipolar instruments directly into the same output receptacles as monopolar instruments. This is possible because those generators have a simple isolated output which does not discriminate between monopolar and bipolar operation. If one attempts to use bipolar forceps in the monopolar output of a SSE3B, the RETURN FAULT patient plate safety system may interpret a bipolar instrument as a monopolar set up with an improper patient plate. The RETURN FAULT light may come on and the generator be disabled.

CONNECTING BIPOLAR INSTRUMENTS TO THE SSE3B

Applications for the bipolar output include neurosurgery, laparoscopy, and general surgery in which desiccation is performed with forceps or other biterminal electrodes. The bipolar instrument has two basic advantages over the conventional monopolar electrode. First, the patient plate is not used and thus one of the most common sources of accidents is entirely eliminated.

Second, the local nature of the current flow means that the desiccation is extremely localized. In neurosurgery, desiccation is commonly done with very fine forceps. The advantage of the bipolar forceps is that a minimum of neural tissue is necrotized because the desiccation doesn't radiate away from the electrodes the way it does with monopolar forceps.

Biopolar procedures require an isolated output. If a grounded generator output is used and the patient's body happens to be grounded, only the electrode attached to the "active" terminal will appear to work. The electrode attached to the "patient" terminal will appear no more active than if it were made of wood. When the majority of the current is returning via some distant grounded place on the patient's body, the coagulation of the tissue will tend to spread radially away from the active electrode, just as it does with a monopolar electrode. In true bipolar operation, only the tissue which is grasped between the two electrodes is desiccated. If the coagulation spreads more than about a millimeter from the direct path between the two electrodes, current is returning to ground through some grounded contact point on the patient's skin, or, at best, it is leaving the patient's body via capacitance to ground.

It is not practical to use bipolar instruments with the SSE3B monopolar output. If this is attempted, the RETURN FAULT circuit may interpret the bipolar instrument as an inadequate patient plate connection and disable the generator. Even if the RETURN FAULT circuit does not trip, the desiccation will behave like a grounded output as described above.

Because of the inherent safety of bipolar procedures, it would be desirable if all monopolar tools could be eliminated. Unfortunately, bipolar tools cannot do all the tasks done with monopolar. While bipolar tools can be designed to fulgurate or cut, they are clumsy to use and present designs cannot compete successfully with monopolar.

To connect a bipolar instrument to the SSE3B, it is best to use the Valleylab bipolar plug which has four pins. If the special bipolar plug is not available, it is possible to use ordinary (large) banana plugs which are available universally and are commonly found on bipolar instruments. If the bipolar tool has no hand switching capability, the small jacks on the top and bottom are not needed and only the two larger jacks to the left and right are used. For REM system equipped generators used in the bipolar only mode, the E0024 adapter should be used to cover both active and patient jacks during the bipolar procedure.

As described earlier, the bipolar output differs from the monopolar output in that it desiccates well but is poor for cutting or fulgurating.

The bipolar output also has a lower output power at a given control setting and thus the power can be more finely controlled. When used with the bipolar output, the BLENDS are not very linear and are not recommended. Since ALL waveforms will desiccate, there is not need for BLENDS with the BIPOLAR output.

CONTROL TAPERS AND CALIBRATION

All Valleylab generators prior to the SSE3B were calibrated in arbitrary markings of 0 to 10 which correspond to the approximate percentage of maximum power in that mode. For example, a setting of 4 was about 40% of the power available in that mode. These arbitrary markings are still present on the knob skirts of the SSE3B and are identical to those on the Model SSE3. When used with the monopolar output the SSE3B 0 to 10 dial settings also correspond approximately to the same settings on Valleylab SSE2 models.

There are two ways to look at the SSE3B CUT and COAG control settings and the resulting output energy. Because the electrosurgical effect produced is greatly influenced by the size and configuration of the electrode, it is impossible to predict exactly what effect will be achieved by a given control setting. However, power available at the most efficient load resistance and the peak votage at a given setting are useful guides.

Power

Power is defined as the amount of energy delivered each second. Because of differences in electrode size, this does not relate well to the quantity of tissue cut or fulgurated each second. The monopolar output power for each mode selected is displayed on the front panel with the lighted numerals. These numbers are a calibration. They are not an actual measurement. In actual surgery, the impedance of the tissue, and therefore the power, varies widely from moment to moment. Consequently, the calibration is given as the maximum power which can be obtained from the generator at that setting. This maximum power occurs at about 300 ohms load impedance. The number readout at a given setting equals the amount of power in watts which would be delivered to a 300 ohm load.

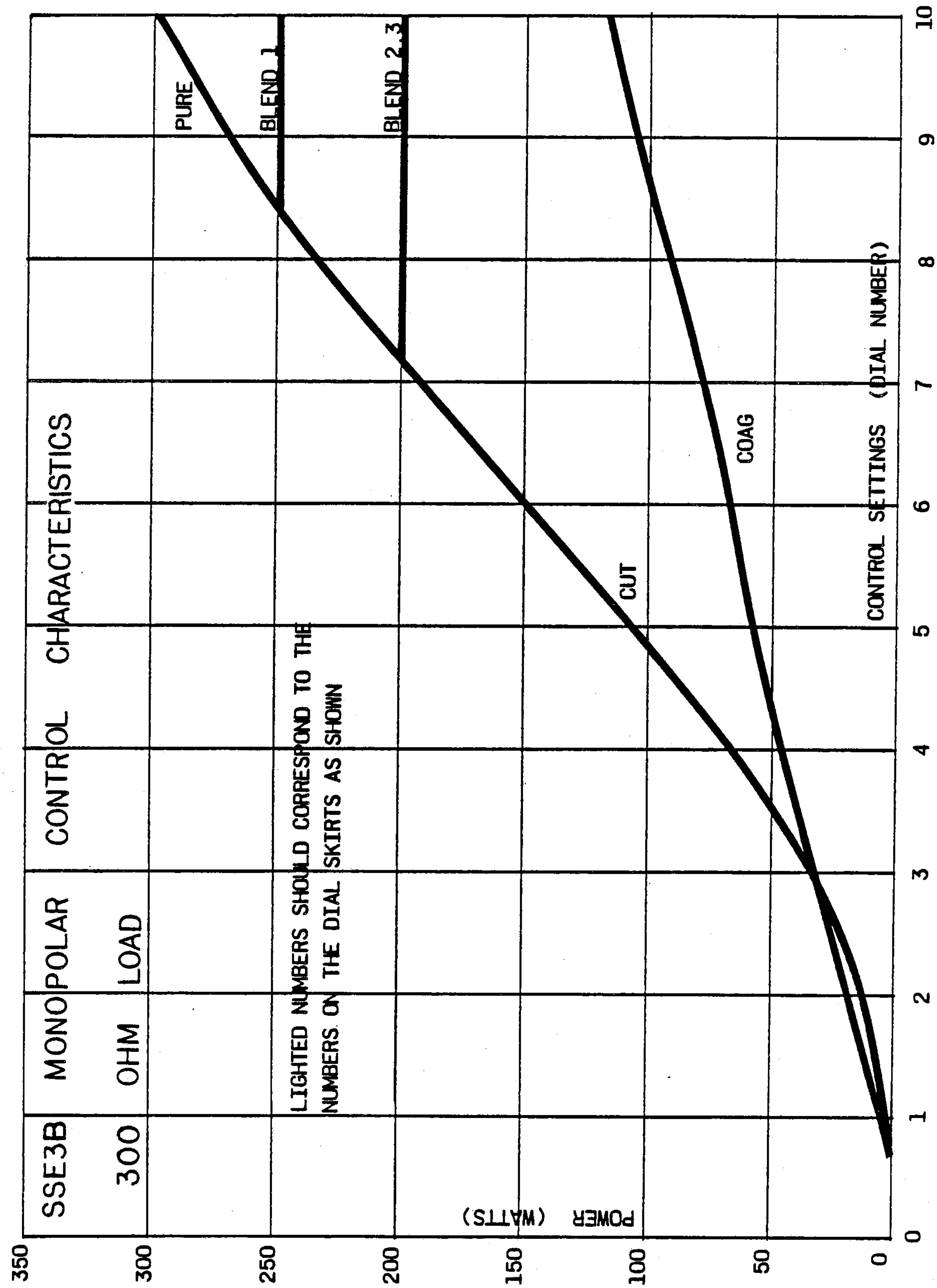
The first step in deciding what power setting you need is to have a rough idea of the demands of the procedure. Table 1 divides various procedures into three rough categories of low, medium, and high "power" and gives typical ranges of power and the 0 to 10 dial settings found on the knob skirts. Note that the actual powers in watts are generally greater for CUT modes than COAG for a given amount of knob rotation.

For example, when CUT or COAG are both set to "8", the CUT power will be about 235 watts, while the COAG power will be only be about 90 watts. Table 1 will appear very crude, but the differences in technique and electrodes make it impossible to list exact settings.

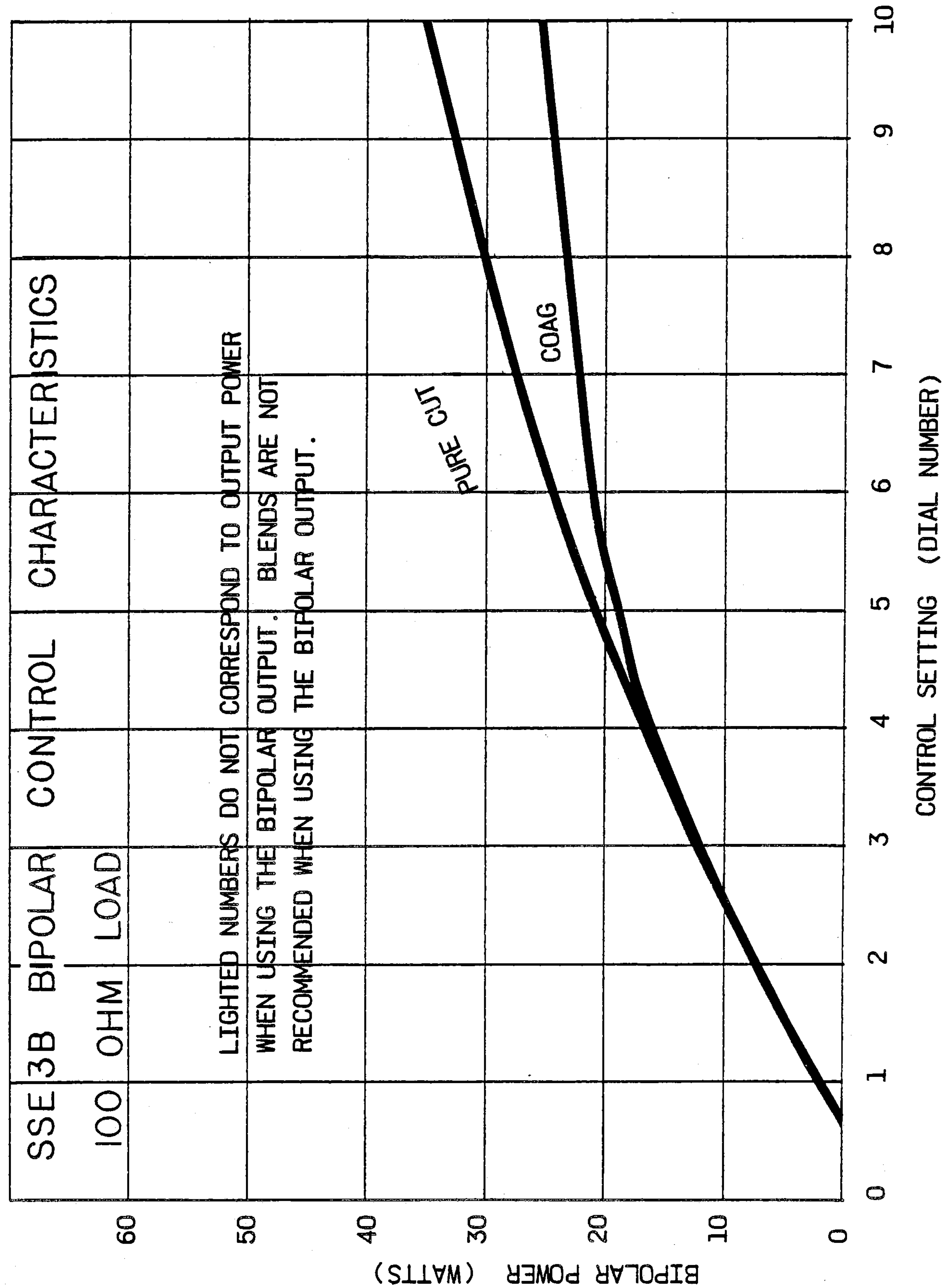
Output Voltage

Voltage is the force which makes sparks jump to the tissue. Although the distance sparks jump depends on electrode shape, 12,000 volts can jump about a centimeter through air. Because COAG has higher peak voltages than CUT, it can produce longer sparks.

The peak output voltages, measured open circuit (with the active electrode not touching tissue) are plotted against control settings for the monopolar and bipolar outputs on page 22.



SSE3B MONOPOLAR CONTROL CHARACTERISTICS



SSE3B BIPOLAR CONTROL CHARACTERISTICS
100 OHM LOAD

TABLE 1

SETTINGS FOR THE SSE3B

The power level used for various surgical procedures varies considerably with the surgeon's technique and the size of the active electrode. A needle electrode will require less power to sustain a spark than a large ball electrode. Moreover, one surgeon may perform a procedure by electrosurgically severing tissue with a cutting or blended waveform. Another surgeon might perform the same procedure by simply desiccating the tissue at a much lower power level.

A general outline of typical power settings:

1. *Lower Power - Under 30 watts (CUT and COAG levels 1 to 3)*

   a) *Neurosurgery (both bipolar and monopolar)*
   b) *Laparoscopic sterilization (both monopolar and bipolar)*
   c) *Vasectomies*
   d) *Polypectomy*
   e) *Dermatology*
   f) *Oral surgery*
   g) *Plastic surgery*

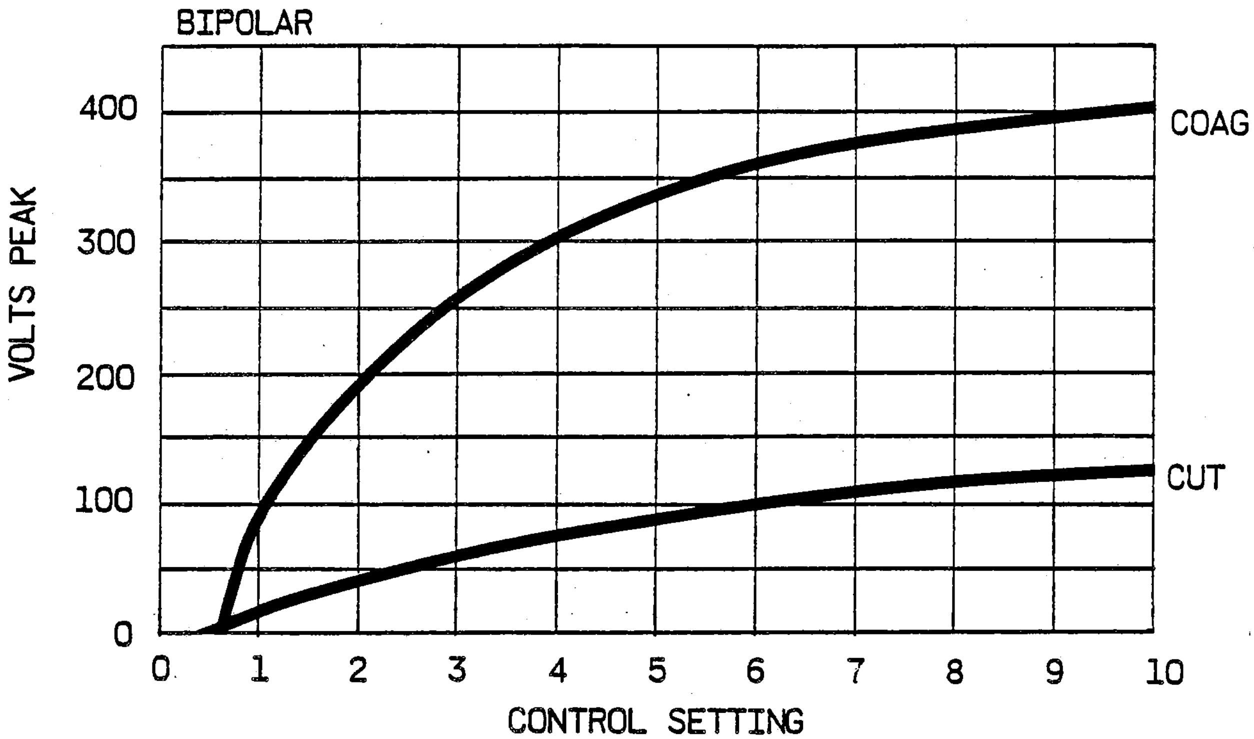
2. *Medium Power - COAG 30 to 70 watts, CUT 30 to 150 watts (CUT and COAG levels 3 to 6)*

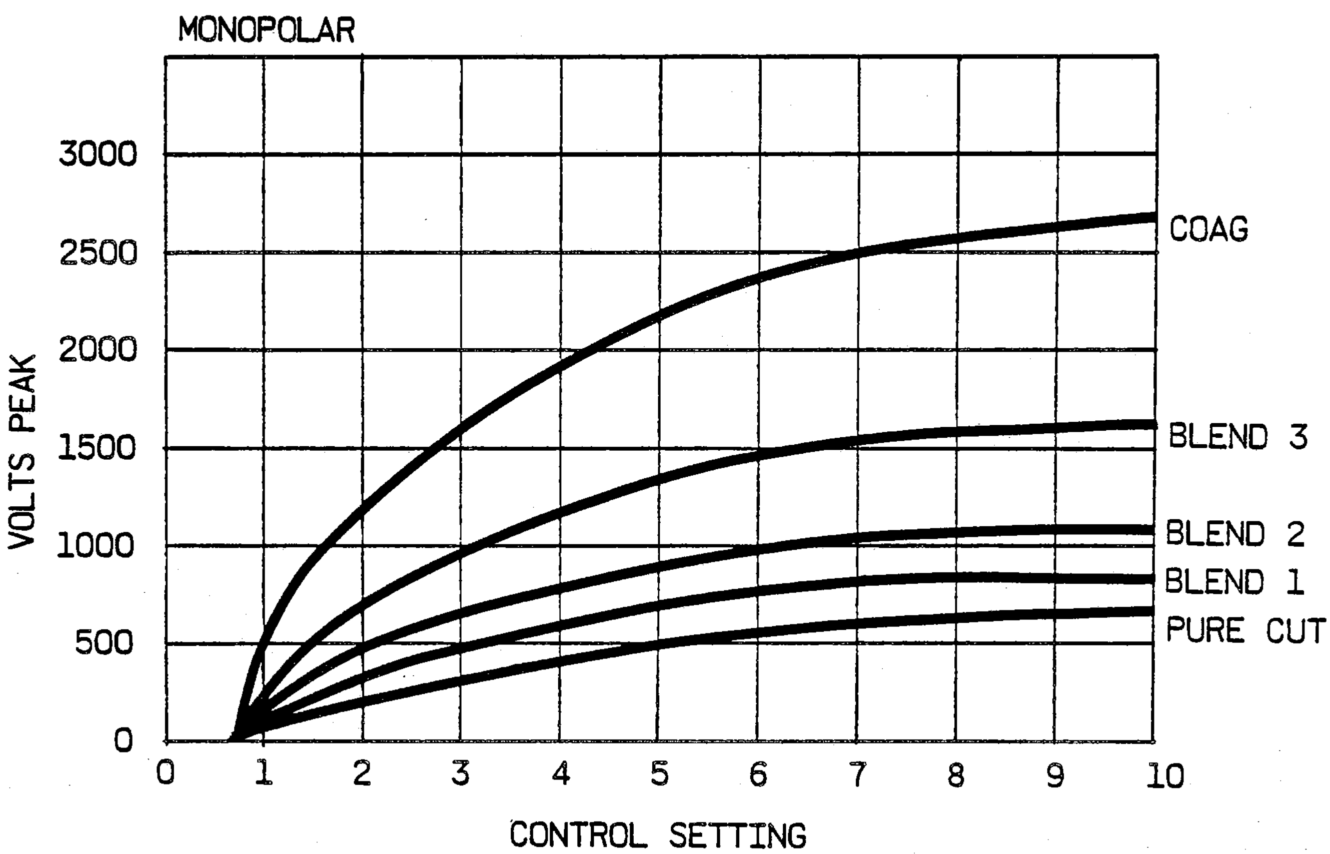
   a) *General surgery*
   b) *Laparotomies*
   c) *Head and neck surgery (ENT)*
   d) *Major orthopedic surgery*
   e) *Major vascular surgery*
   f) *Routine thoracic surgery*

3. *High Power - COAG over 70 watts, CUT over 150 watts (CUT and COAG levels 6 to 10)*

   a) *Transurethral resections*
   (CUT 120-300 watts, COAG 50-116 watts, depending on the thickness of the resection loop and the technique of the surgeon)
   b) *Thoracotomies*
   (heavy fulguration, 70 to 116 watts)
   c) *Ablative cancer surgery, mastectomies, etc.*
   (180 to 300 watts - CUT; 70 to 116 watts - COAG)

IF THE PROPER SETTING IS NOT KNOWN FROM PERSONAL EXPERIENCE, ONE SHOULD SET THE GENERATOR AT A VERY LOW SETTING (1) AND CAUTIOUSLY INCREASE POWER UNTIL THE DESIRED EFFECT IS ACHIEVED.





TYPICAL SSE3B OPEN CIRCUIT CHARACTERISTICS

There are two common applications for this voltage information and both of them involve laparoscopic sterilization. In monopolar laparoscopy it is desirable to use as low a peak voltage as possible to avoid the possibility of accidental sparking to bowel. COAG has higher voltages for any given control setting. Since most laparoscopic techniques use desiccation, there is no need for either higher power or high peak voltage since no sparking is required. It follows from this that a very low setting of CUT (10-20 watts) provides the safest possible setting for laparoscopy.

Unfortunately, this low setting of CUT may not desiccate the required length of salpinx before the tissue under the forceps becomes too dry to conduct the current. The result will be a premature end of the desiccation. The larger the contact area of the forceps, the less likely the desiccation will "stall". If it is not practical to use larger forceps, more peak voltage is needed to overcome the resistance of the dried tissue. A good compromise between COAG and CUT is a BLEND at the lowest practical setting.

Peak voltage may also be a relevant consideration for bipolar laparoscopy, but not for reasons of patient safety. Some of the forceps now on the market have internal insulation which can only tolerate a few hundred volts peak. If these voltage ratings are exceeded, the insulation will break down and the forceps will be damaged. This will not burn the patient, but the operation may be brought to a halt.

RADIO FREQUENCY AND ITS IMPLICATIONS

It might be expected that the radio frequency used in a particular generator might have a profound effect on the electrosurgical effects produced. It turns out that all frequencies between 100 kilohertz (100,000 cycles per second) and 4 Megahertz can cut, fulgurate, and desiccate tissue with no significant differences in performance. Frequencies below 100 kilohertz can of course stimulate muscles and nerves and are never used in electrosurgery. [4]

1. *Reactive Effects*

   The SSE3B operates at 750 KHz in both COAG and CUT. At radio frequencies (above 100 KHz) reactive electronic effects, capacitance and inductance, become quite significant. At frequencies above 3 or 4 megahertz, it becomes quite difficult to confine electric currents to wires since capacitive coupling and inductance can produce potentially dangerous currents in all nearby conductive objects. For this reason the SSE3B frequency is relatively low to avoid capacitive coupling which can cause leakage currents to flow in grounded objects. This relatively low frequency of the SSE3B allows isolation from ground so that nearly all current will return to the generator via the patient and the RETURN FAULT system can be made quite sensitive.

2. *Neuromuscular Stimulation*

As pointed out earlier, a radio frequency is used to prevent stimulation to muscles and nerves. Since muscles and nerves have no significant ability to respond to alternating currents at frequencies above 100 KHz, one would think that muscle stimulation could never be a problem with any generator operating above this frequency. When desiccating tissue, this is essentially true. However, when cutting or fulgurating, the spark complicates the problem by acting as a rectifier, or perhaps more accurately as an electronic noise generator. The sparking to tissue is a random process and each time the voltage rises and falls (750,000 times per second) there is the probability that the spark will not jump to the tissue. These missing sparks and differences in current through individual sparks generate low voltages at almost all frequencies in a continuous spectrum from DC up to and above the actual radio frequency. Fortunately these voltages do not cause stimulation unless currents are allowed to flow through the patient. To avoid having these low frequency currents flow through the patient, both the active and patient circuits have blocking capacitors which serve as high pass filters, that is, they only let the high frequency 750 KHz currents flow through but block the flow of low frequency components. If there is a metal-to-metal spark somewhere in the output circuit path, then large, low frequency components will be generated. This could occur when a connector is not making good contact, either in the active or patient leads, and may result in muscle twitch or even pain in an awake patient.

3. *What To Do If Neuromuscular Stimulation Is Suspected*

1) *Stop the surgery.*

2) *Before activating the generator again, check all connections to the generator, patient plate, and active electrode to look for a possible metal-to-metal spark.*

3) *If no defective connections are found, the generator should be checked for abnormal 60 Hz AC leakage currents between the metal case and ground, and between the active and patient leads and ground. Shocks due to 60 Hz power line voltage are so hazardous that this remote possibility should be taken seriously.*

4) *If the generator AC leakages are normal, the low frequency blocking capacitors in the output circuit should be checked.*

5) *Sometimes stimulation will occur in the awake patient and will seem to defy explanation. The following observations may be useful. Neuromuscular stimulation is more likely to occur in COAG mode when fulgurating than when cutting, and never occurs when desiccating. Since it is difficult to produce sparking with the bipolar output, neuromuscular stimulation is extremely unlikely when operating bipolar. A lower power setting will always produce less stimulation.*

One possible problem with the attenuator is that its impedance is added to the output impedance of the generator. This will make desiccation more difficult with the monopolar output, since it will desiccate extremely slowly. If the generator is turned up it may tend to produce cutting or fulguration, depending on the waveform. On the other hand, the attenuator is excellent for fulgurating or cutting with extremely small electrodes.

Another possible problem with the attenuator is that, if it is plugged into the patient jack, it will attenuate current returning to the generator from the patient electrode and will make the RETURN FAULT circuit more likely to trip. The way to overcome this problem is to plug it into the active side. The farthest left of the three handswitching jacks (LectroSwitch receptacle) will receive the attenuator without any modification. The active electrode must then be plugged into the attenuator by means of a single banana plug. The E0502-5 LectroActive Adapter has such a banana plug and will allow a disposable pencil, such as the E2504 LectroChuck to be used with the attenuator.

REFERENCES ON ELECTROSURGICAL THEORY

1. *Harris, F.W.; Desiccation as a Key to Understanding Electrosurgery; Paper presented to AAMI Convention, Washington, D.C., March 18, 1978.*

2. *Hoenig, W.M.; The Mechanism of Cutting in Electrosurgery; IEEE Transactions on Biomedical Engineering, pp. 58 - 62, January 1975.*

3. *Morrison, C.F.; Electrosurgical Devices Having Sesquipolar Electrode Structures Incorporated Therein; U.S. Patent 3,970,088, 20 July 1976.*

4. *Dalziel, C.F., Mansfield, T.H.; Perception of Electric Currents; Electrical Engineering 69: 794 - 800, 1950.*

SECTION 2

ELECTROSURGERY IN THE OPERATING ROOM

This chapter attempts to answer the questions that we at Valleylab hear most often about specific procedures and techniques. Electrosurgery through an endoscope produces more problems and questions than all other uses for electrosurgery. The following three sections deal with G.I. Endoscopy, Laparoscopy and Urologic surgery. The final sections cover unusual situations in open electrosurgery including hemostasis in neurosurgery, the use of two generators on the same patient, the use of two active electrodes with your SSE3B, patients with pacemakers, and the use of the bipolar output with a patient return electrode.

GASTROINTESTINAL ENDOSCOPY

1. *Polypectomy*

This procedure can be done through a colonoscope, proctoscope or sigmoidoscope. This procedure is performed with a wire snare which is looped around the polyp and closed like a noose. Electrosurgical current is applied first to desiccate the polyp, then to cut through the peduncle electrosurgically. It is also possible to make the cut mechanically by tightening the thin snare wire around the polyp stalk after the polyp blood supply has been coagulated and the tissue softened by the desiccation current. Polypectomy can also be done in one manuever by cutting with a blended current, but both approaches have their pitfalls.

Because of hydrogen gas accumulations in the bowel, some authors recommend clearing the bowel with CO_2 gas before starting the coagulation. Explosions are possible only when there is a mixture of flammable gas and oxygen, so it seems to us that one can also make a good case for not cleansing the bowel with an inert gas, so long as oxygen is not introduced into the bowel. Most authors agree that there is no need for CO_2 if the bowel has been properly evacuated.

Because the colon is electrically well connected to the body as a whole, it does not seem to be dangerous to cut and fulgurate inside the bowel. This is in contrast to monopolar laparoscopy where it is apparently risky to fulgurate in the peritoneal cavity for fear of burning bowel. The only explanation we can offer for this paradox, is that fulgurating the salpinx can isolate it electrically from the uterus, since it is basically an appendage of that organ. In the colon there is contiguous tissue in all directions from the pedicle and thus the area is unlikely to become electrically isolated.

Polypectomy - Desiccation First to Provide Hemostasis

If desiccation is done first, separate from the cutting, one can do this with COAG or a BLEND at a setting of 1 to 3. The degree of desiccation must be judged by the spread of blanching away from the snare wire. The desiccation must be just the right amount, regardless of whether the actual cut is to be made mechanically or electrosurgically. If there is too little desiccation, the stalk may bleed. If there is too much, the stalk may become too hard and dry to cut either mechanically or electrically. This may result in insufficient water in the tissue to allow the cells to explode. Water in the tissue is an essential ingredient for electrosurgical cutting and if it is not present, the snare wire may become stuck half way through the peduncle.

Fortunately, accidents in polypectomy are rare so long as the polyp is relatively small, one or two centimeters. However with a very large polyp or a sessile polyp, everything that can go wrong is most likely to do so.

While desiccating a large polyp it should be kept in mind that the generator setting will have to be higher to have the same current density along the snare wire when starting the desiccation. However the tighter one pulls the snare, the smaller the effective diameter. As the snare becomes very tight and the diameter becomes very small, the current density will rise as the inverse of the SQUARE of the diameter of the snare loop. In other words, a setting which is appropriate for a large polyp may be far too high for a small one. [1]

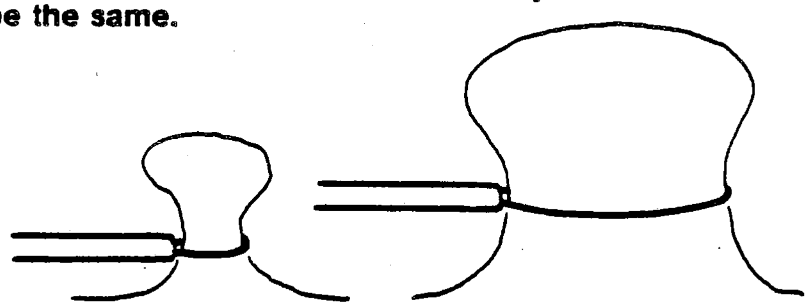
It should be remembered that the current is trying to return to the patient plate and if the stalk is well desiccated proximal to the snare wire, the current may continue to flow off the polyp to the colon wall.

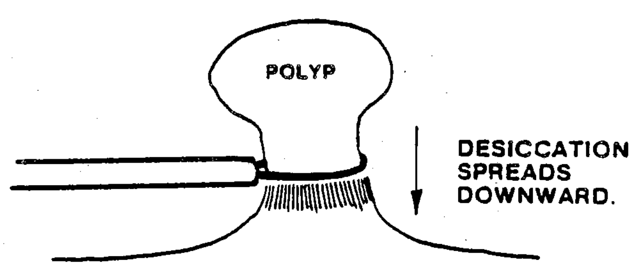
It must be understood that this procedure is an art and the only way one can learn this art is to take instruction from someone who understands the relative quantities of enough desiccation and too much desiccation. [2, 3]

POLYPECTOMY

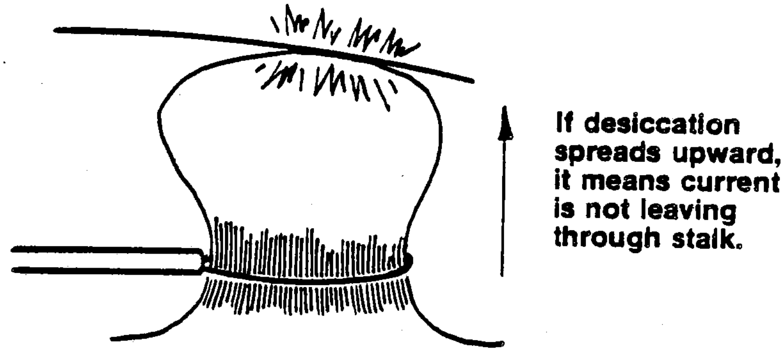
DESICCATION FOR HEMOSTASIS

Current required is proportional to the square of the polyp diameter since current density should be the same.





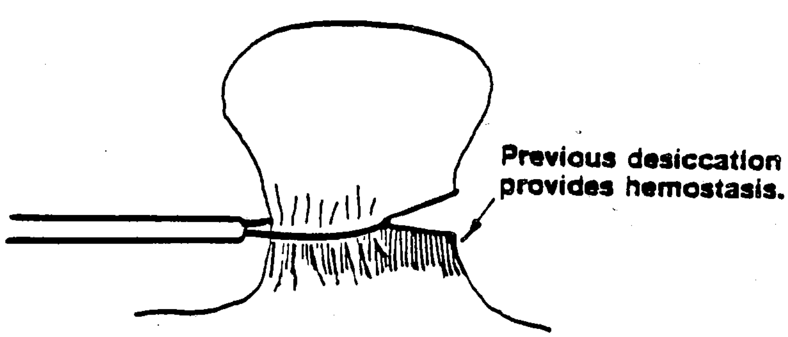
DESICCATION FIRST FOR HEMOSTASIS



Polypectomy - Mechanical Cutting After Desiccation

Cutting off the polyp after desiccation can be done mechanically by tightening the snare. There is an optimum amount of desiccation that will soften the tissue without drying it. Some surgeons recommend applying a BLEND current while pulling the snare through the polyp stalk. This has the advantage of desiccating any tissue in the center of the stalk which may have been missed. Furthermore, if sparking to tissue and electrosurgical cutting should occur, the cutting will have sufficient hemostasis. [1]

MECHANICAL CUT AFTER DESICCATION



Cutting off the polyp after desiccation can be done electrosurgically using either a CUT or BLEND. The setting will depend on the size of the polyp stalk, the degree of the desiccation, and the diameter of the snare wire, but it will be in the range of 30 to 150 watts (setting 1 to 5).

The most common misunderstanding about polypectomy technique concerns the fact that electrosurgical cutting can only occur when sparks are free to jump to the tissue. The tighter the snare is held, the less likely the cut will begin. The snare must be in POOR electrical contact with the tissue. After desiccation, it is a good idea to loosen the snare before applying the cut current.

The snare wire thickness is also important because it directly affects the area of metal in contact with the tissue. Currently available snare wires range from 0.3 to 0.8 mm. (.012" to .040") We do not recommend snare wires thicker than about 0.45 mm (.018") because of the difficulty in starting a mechanical or electrosurgical cut. Whenever the snare wire diameter is changed, generator settings must change accordingly.

The snare wire diameter also affects the degree of hemostasis. In other words, increasing the snare wire diameter could have the same affect as using BLEND #3 instead of BLEND #2. But, as explained above, the thicker wire will be harder to start. [4]

ELECTROSURGICAL CUTTING

Hold snare *loosely* to get cut started.

Fine wires (.3mm - .4mm) start better than thick wires (.45mm - .7mm).

Relatively pure cut waveforms start better than blended cut or "coag".

High settings start better than low settings.

Polypectomy - Electrosurgical Cutting in One Manuever

In this technique the polyp is severed with a Blended CUT without desiccating first. If PURE CUT were used there would be insufficient hemostasis so a BLEND is used to insure that the walls of the incision are well fulgurated.

With the Valleylab SSE2 series generators it was possible to cut electrosurgically using the COAG as a blended current and actually cut with the COAG. This was possible if the snare wire was relatively fine (0.4mm) and a high setting was used (COAG 4 to 8 on the SSE2). Because the SSE3B COAG is superior to any previous solid state generator, it is probably not practical to cut with the COAG. To duplicate this technique with the SSE3B, use BLEND #3 which has a crest factor similar to the SSE2 series COAG. A setting of about 3 to 5 should produce equivalent results.

The higher the crest factor (that is, the more hemostasis), and the thicker the snare wire, the more skill is required to cut electrosurgically. If a relatively thick wire is used (.45 mm) the polyp must be grasped extremely lightly to give a prompt start to the electrosurgical cutting.

Another advantage of grasping the polyp stalk lightly is that there is less tendency for the bowel wall to be pulled up into the snare where it could be harmed. Some surgeons use "homemade" snares to achieve this delicate feel. The "homemade" snares consist of a 0.4 mm diameter wire which is formed into a loop and passed through a plastic tube. The bare wire ends are clamped with a forceps and manipulated by a trained assistant who knows how tight to hold the wires. When the surgeon has positioned the snare, the assistant adjusts the tension and touches an electrosurgical pencil to the exposed wires. [5, 6]

If conventional commercial snares are used, the control of tension is not as precise and the surgeon may want to increase his chance of getting the cut to start promptly by using a very thin snare wire and BLEND #2. The SSE3B has a very flat power versus impedance characteristic in all monopolar modes which means that there is ample power at low tissue resistance to get the cut started.

Occasionally, with very large polyps, the electrosurgical cutting may not start promptly even though the snare is held loosely. Instead of cutting, the surgeon will see the tell-tale desiccation creeping down the polyp toward the stalk. If the desiccation has dried the tissue enough to provide the needed hemostasis, the surgeon can confidently switch to PURE CUT at an appropriate setting, 3 to 5, and usually get the cut started. A PURE CUT will "start" better than any other mode, but it has little hemostasis.

POLYPECTOMY

HEMOSTASIS WITH ELECTROSURGICAL CUTTING

Blended cut or "coag" provides the most hemostasis.

Thick wires (.45mm - .7mm) provide more hemostasis than thin wires.

Let the spark do the cutting, don't force the wire through.

In summary, all of these polypectomy techniques can be made to work successfully, but each is an art and should be learned from someone who is already successful. For the beginner, it is advisable to use the exact equipment, snare, settings and technique used by his instructor. Using one instructor's mode and power setting with another instructor's snare and technique can be a disaster.

2. *Coagulation of Intragastric Bleeding*

Recently there has been increased interest in coagulation of upper GI bleeding. This is still an experimental procedure, but the surgeons who have done the most cases [7, 8] are using desiccation with a combination electrode and irrigation probe. One of these surgeons [7] is using a Valleylab SSE2J at COAG 5 to 7. He applies the electrode to the margin of the ulcer and activates the generator in 1/2 to 2 second bursts. We believe that a setting of COAG 5 to 7 watts with the SSE3B will produce similar results.

3. *Papillotomy*

Opening the Papilla of Vater to provide relief from stones in the common bile duct is a new endoscopic electrosurgical procedure. [9] Under direct vision and fluoroscopy, a catheter is introduced into the Papilla of Vater.

A wire linkage in the catheter control handle flexes the tip of the catheter by bowing a length of electrode wire along one side of the tip. The generator is activated with a blended CUT and the sphincter is severed by the wire electrode.

Injury to the pancreas is a potentially severe complication of this procedure. To prevent this, it is essential that the electrosurgical cutting be well controlled with no starting delay or dragging during the incision. Technique is important in making the output controllable. The cutting will not occur until sparks can jump freely from the electrode to the tissue. If the electrode is pressed firmly against the tissue, the sparking will not occur until the tissue has been sufficiently desiccated to force sparks to jump across the dried tissue. Therefore, if there is a delay in starting to cut, one should apply LESS force on the electrode, not more force. If one applies more force, it will increase the delay and when the electrode finally does begin to spark, it may cut too deeply and perforate the duodenum.

Because papillotomy is potentially hazardous, we strongly recommend that the surgeon obtain first-hand training from someone already successful with the procedure and if possible, duplicate his instructor's equipment,settings, and technique as closely as possible. In papillotomy as well as any surgical procedure, it is very helpful to experiment in vitro before using any new equipment or methods which are not familiar.

4. *Leakage Bypass Cables for Colonoscopes and Gastroscopes*

Some of the longer colonoscopes have over 150 pf of capacitive coupling between the snare wire and the metal frame of the colonoscope. Since the RETURN FAULT circuit will not permit more than 120 pf coupling between active and ground, it may not be possible to activate the generator, especially if the colonoscope is grounded through the light source. Most of the metal wire framework inside the colonoscope is just underneath the black plastic covering over the flexible portion. As a result, the capacitance between the patient's body and colonoscope is frequently much greater than between the active and the colonoscope. The result is that, although the SSE3B cannot be activated with the colonoscope free of the patient, the RETURN FAULT circuit will frequently permit the surgery after the scope has been inserted half a meter or so.

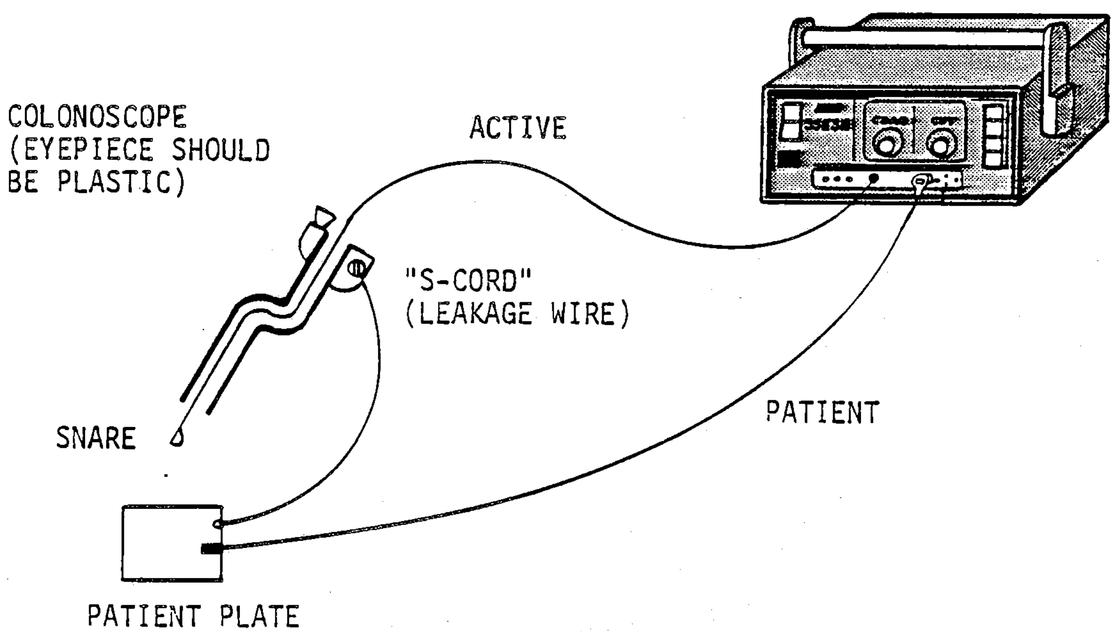
However, if the RETURN FAULT circuit continues to trigger following insertion, then the colonoscope-to-patient electrode bypass cable must be used to shunt the leakage to the patient electrode as well as ground.

Valleylab does not make a patient electrode with a second connection on it for attaching a cable from the colonoscope. Other manufacturers do make such patient electrodes and these may be used. The Valleylab E7001 permanent patient plate can easily be modified to accept a cable by drilling a small hole in the plate next to the present connector. The eyelet on the colonoscope-to-patient plate cable can then be riveted to the E7001 plate.

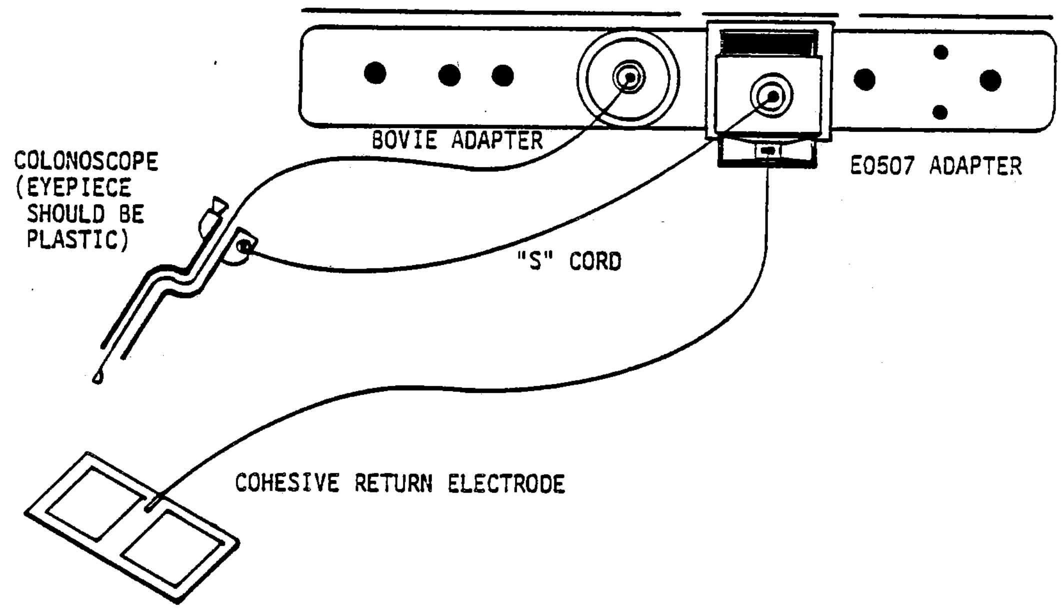
One colonoscope manufacturer has given another reason for using this cable. On some of their scopes being used in the field, the insulation separating the bowel mucosa from the colonoscope has become cracked or defective, exposing the metal wire structure of the colonoscope. If the bowel wall mucosa were to touch one of these exposed wires, all the leakage would be concentrated at this contact site. Since the current density could easily be in excess of 100 milliamperes per square centimeter for 10 seconds, a burn is possible.

In conclusion, there are two ways to handle the leakage problem with the colonoscope. First, one can use the "S-Cord" and be scrupulously careful about keeping the patient plate in good contact with the patient's skin. Alternatively, one can use a colonoscope without a colonoscope-to-patient plate cable provided that the active to ground capacitance doesn't exceed 120 pf and trigger the RETURN FAULT circuit. If the "S-Cord" is not used, the surgeon should be aware that there will always be a small voltage on the metal parts of the colonoscope that theoretically, could be a threat to him and his patient. The minimum precautions should be a plastic eyepiece to protect the surgeon's eye and a thorough examination of the colonoscope insulation before each procedure. It is also possible to perform polypectomy through a gastroscope and the same advice applies. The gastroscopes usually have only 25 pf capacitance between the active and scope, so these precautions may not be necessary.

For Valleylab electrosurgical generators equipped with the REM system, the Multiple Return/S-Cord Adapter (Model E0506) is available for use with the CoHesive Return Electrode in GI laboratory procedures where an S-Cord is needed.



CONNECTION OF THE "S-CORD" OR LEAKAGE BYPASS WIRE
(For generators not equipped with REM)



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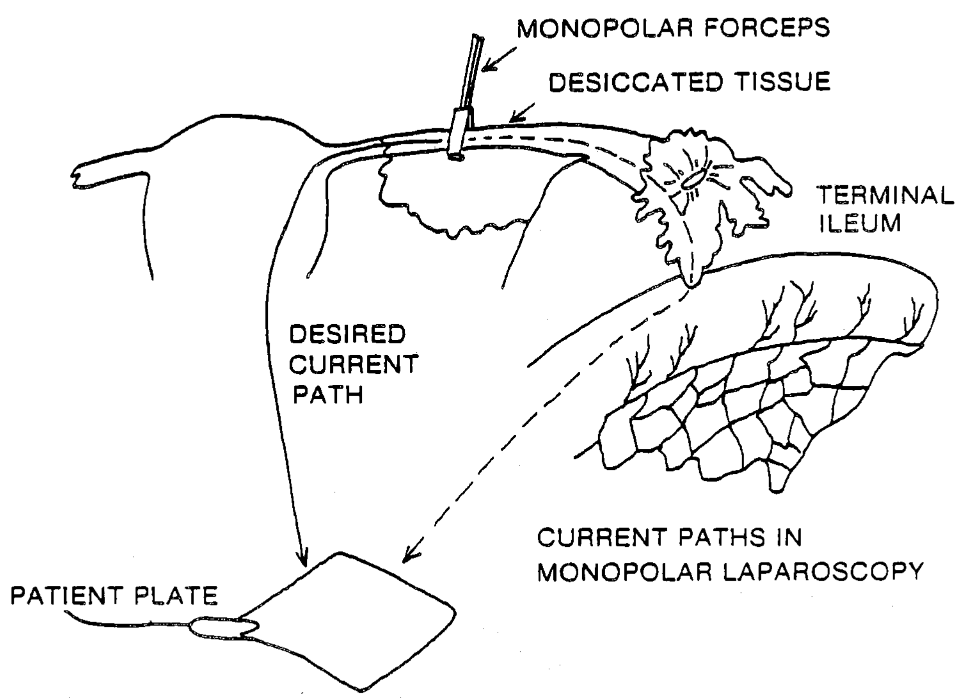
There are many different basic techniques for performing this procedure. They can be divided into monopolar techniques and bipolar techniques. Our purpose here is not to pass judgment on which exact technique is the best, but rather to help the user perform his technique with the SSE3B.

1. *Laparoscopy - Monopolar Fulguration With or Without Biopsy*

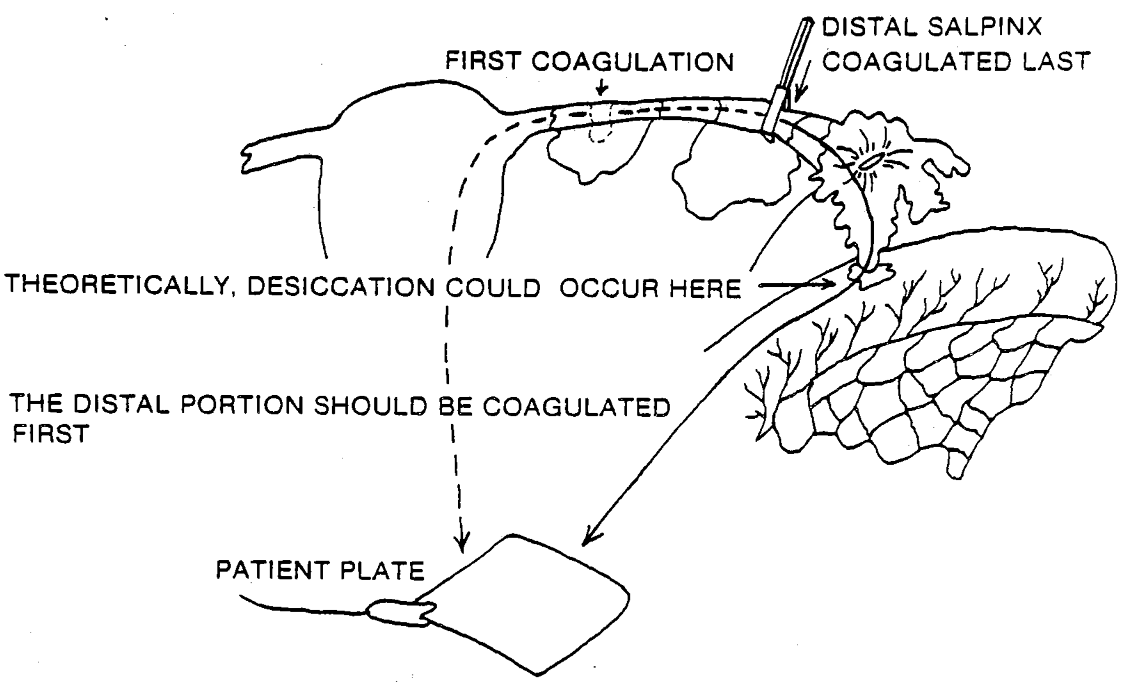
   The oldest technique uses a monopolar forceps, usually with a rotary biopsy sleeve. The tube is grasped and fulgurated. When sufficient salpinx has been fulgurated, the rotary biopsy sleeve is twisted to cut off the specimen grapsed in the forceps. This is the basic technique which all too often resulted in accidental burns to the terminal ileum. The exact reasons for these burns are not entirely clear but they seem to be related to the use of high peak voltages needed for fulguration.

MONOPOLAR LAPAROSCOPY



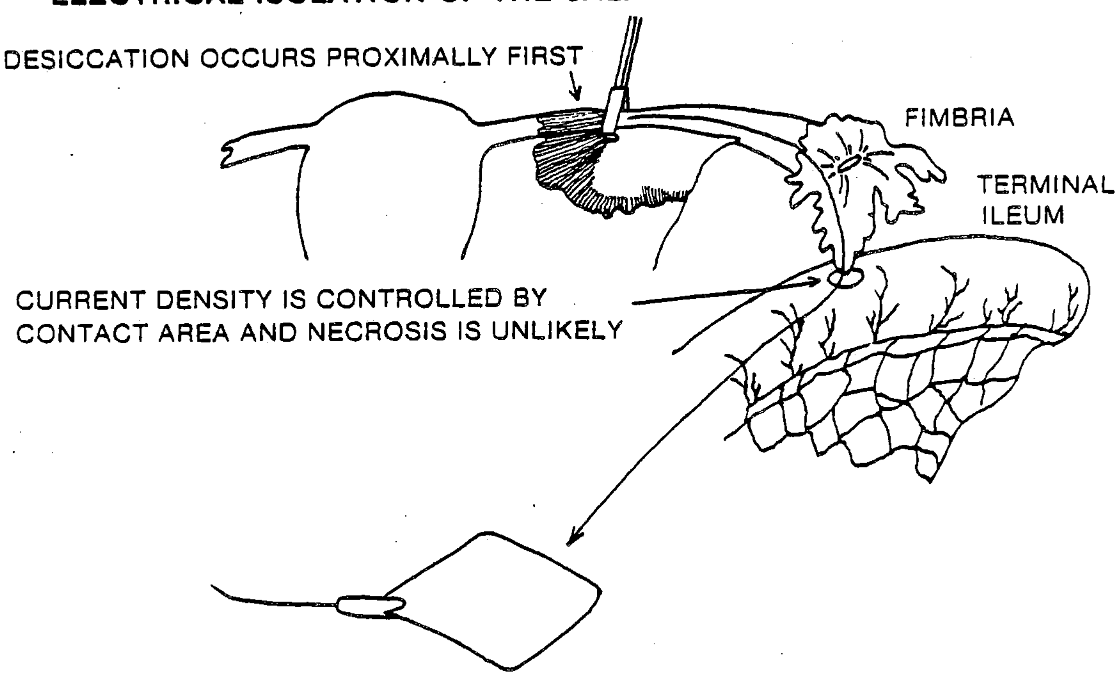
Another factor which may be very important is the rising electrical resistance of the salpinx and mesosalpinx during coagulation. The most obvious situation where this would be important is in the "two burn technique". That is, the salpinx is coagulated in two separate places. If the first coagulation is close to the uterus, the coagulated tissue will acquire a higher electrical resistance and the remainder of the salpinx will tend to become electrically isolated from the uterus. The current is trying to return to the patient plate some distance away on the skin and it will travel there primarily via those viscera which have the lowest electrical resistance. Consequently, fulgurating (or desiccating) proximally first may force current out through the fimbria and small bowel during the second coagulation. If the current were concentrated enough, it could possibly coagulate the bowel. This theory was first proposed by Loffer. [1]

THE WRONG WAY TO COAGULATE TWICE



Similarly, a single desiccation (or fulguration) can be quite erratic, in that whitening or blanching may occur much more rapidly on one side of the forceps than the other. Occasionally, a wide area will blanch first on the proximal side of the forceps before significant blanching occurs on the distal side. Conceivably, a large proportion of the current could flow out to the fimbria to some small point where it is touching the terminal ileum.

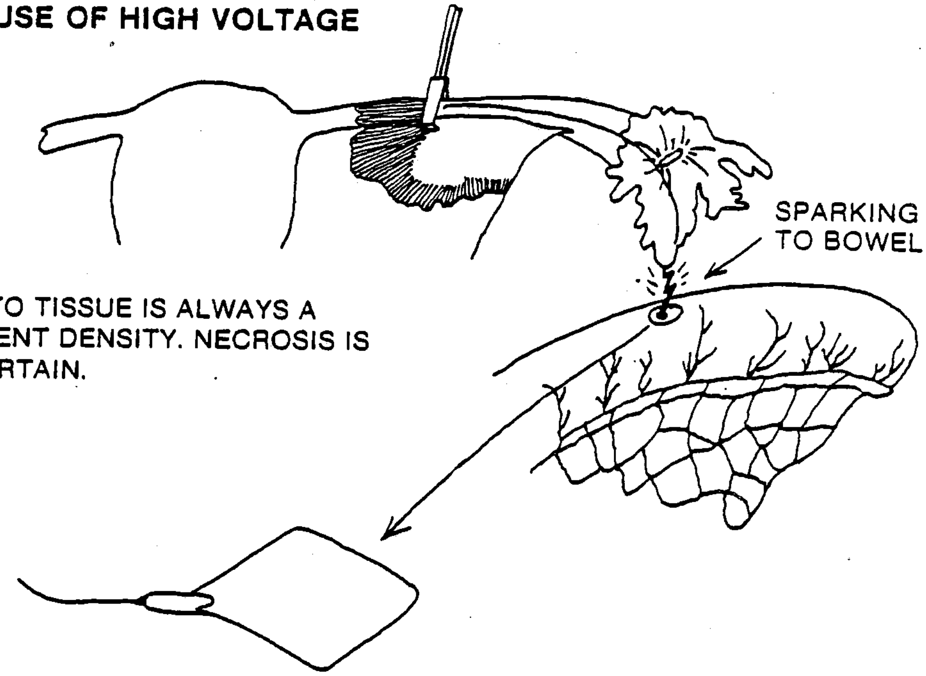
MONOPOLAR LAPAROSCOPY
ELECTRICAL ISOLATION OF THE SALPINX



Another disadvantage of fulgurating is that sparking to the metal forceps tips can heat them to temperatures as high as 500°C. Even after the generator is shut off, the forceps may require minutes to cool to ambient temperature. [2]

As explained in the discussion on fulguration in Section 1, fulguration is considerably more efficient in producing necrosis than an equal magnitude of current applied to tissue in a desiccating mode. Consequently, the current leaving the fimbria must be discouraged from sparking to bowel. The way to discourage sparking is to keep the peak voltage as low as possible. We are not aware of any advantage of fulgurating the salpinx, but if this technique is done with an SSE3B, we strongly advise against using COAG since the peak voltage is so high. Instead, use BLEND #3 at a setting no higher than 3. This will be roughly equivalent to SSE2 COAG set at 3.

ELECTRICAL ISOLATION OF THE BOWEL AND THE USE OF HIGH VOLTAGE "COAG"



2. *Laparoscopy - Monopolar Desiccation With or Without Biopsy*

The best way to avoid fulgurating bowel is to avoid fulgurating altogether. Desiccation will whiten or blanch the tissue as well as fulguration and can be done with a minimum of peak voltage. Power is highest for a given peak voltage in the CUT mode. It is possible to desiccate the salpinx using CUT at settings of 1 to 2.

It may be found that pure CUT is not very practical for desiccation because the desiccation "stalls" or ends prematurely before a sufficient length of salpinx has been desiccated. This occurs because the peak voltage (100 to 300 volts peak) is too low to force current through the dehydrated coagulum around the forceps. More peak voltage at the same power level is needed and the higher crest factor of a BLEND (#1 or #2) set at the minimum level (1 to 3) may work out to be a good compromise.

The contact area of the forceps is also very important since very small forceps jaws will dry out the tissue they contact more quickly than fatter forceps. Large forceps jaws can desiccate more area without stalling than small jaws.

When desiccating with the SSE3B monopolar output it is important to realize that desiccation requires very LOW SETTINGS to prevent entering the sparking phase, that is, to prevent either cutting or fulguration. When low settings are used, the resulting desiccation will take place SLOWLY. In fact, at first nothing seems to be happening. After a few seconds however, the salpinx will gradually begin to blanch and steam. This slow desiccation is an advantage because it means that the laparoscopist has good control over what is taking place and he can stop the desiccation any time he likes. [3]

If the SSE3B monopolar output is turned up to obtain an instant response, the desiccation may seem to "run away" and will be "hard to control" or "erratic". This may result in far more damage than was intended.

If it is necessary to have the instant starting and "automatic", self-limiting characteristic for monopolar desiccation it is possible to use the bipolar output as a monopolar output and achieve this "desiccation only" performance.

Since the bipolar output is isolated, it may be used just like any other isolated generator for monopolar applications. The standard Valleylab patient plate connector (large size banana plug) is placed in one of the bipolar jacks for the patient plate and a second large banana plug is placed in the other banana jack for the active forceps. The generator would then be controlled with the footswitch. It is even possible to use hand switching, but a special connector would have to be fashioned which would be compatible with the switching jacks on the bipolar plug. Using the bipolar output for monopolar applications is discussed in more detail at the end of this section.

3. *Laparoscopy - Monopolar Electrosurgical Cutting*

Some surgeons prefer to sever the tube electrosurgically. This requires more power than desiccation and will require a BLEND (#1 or #2) or CUT waveform.

The most common technique is to pull the forceps through the salpinx after first lightly desiccating it. The setting of CUT or BLEND needed to cut the salpinx after the desiccation will depend greatly on the size of the electrode and how dry the tube has become after the desiccation. A typical setting for the desiccation would be CUT 30 to 90 watts.

To cut the tube electrosurgically will require at least 120 watts. Cutting through the tube directly with a CUT current without first desiccating it, may lead to bleeding because the walls of the incision will not be properly desiccated (insufficient hemostasis). It is practical to cut through the salpinx with a BLEND current without first desiccating. However, it is vital that sufficient hemostasis be achieved by using as low a setting as practical and as large a cutting electrode (forceps) as possible.

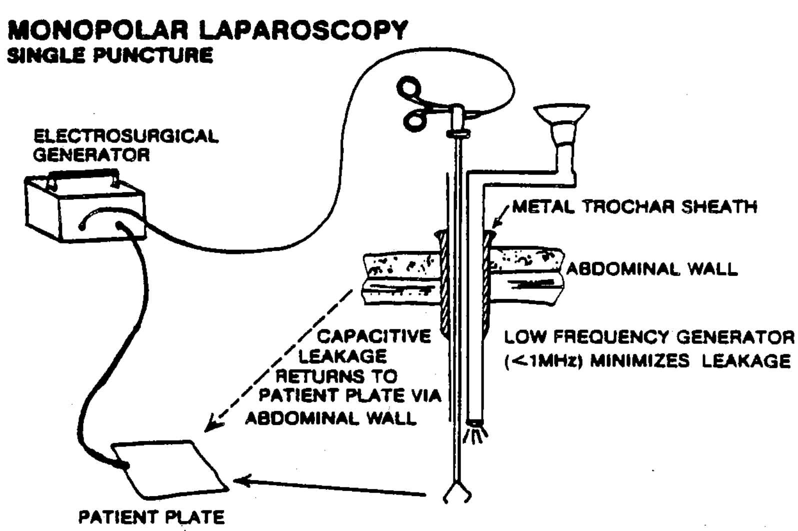
Cutting electrosurgically does not carry quite the same risk from sparking as fulguration, since the peak voltage is lower. On the other hand, cutting requires more voltage than desiccating and is therefore theoretically not as safe. Referring to the peak voltage graph, page 22, try to avoid exceeding 1000 volts peak. Although this is a purely arbitrary number, we believe it is wise to try to stay under this voltage to avoid inadvertent sparking.

4. *Monopolar Laparoscopic Sterilization With the Single Puncture Laparoscope*

Some of the single puncture laparoscopes on the market have as much as 100 pf of capacitance between the forceps and the laparoscope. For this reason, some manufacturers formerly recommended using a "common ground connector" which connects the laparoscope to the patient plate. This solution is acceptable but extra precautions must be taken to insure that the patient plate is touching the patient's skin.

When such a laparoscope is used with the SSE3B, the problem is not as severe as it is with other generators on the market because the frequency of the SSE3B is relatively low and leakage current through a capacitance is directly proportional to frequency. Moreover, the power available from such a leakage current is proportional to the square of the current. For example, a generator which operates at 3 MHz will have four times as much leakage current as the SSE3B and will produce 16 times more leakage power.

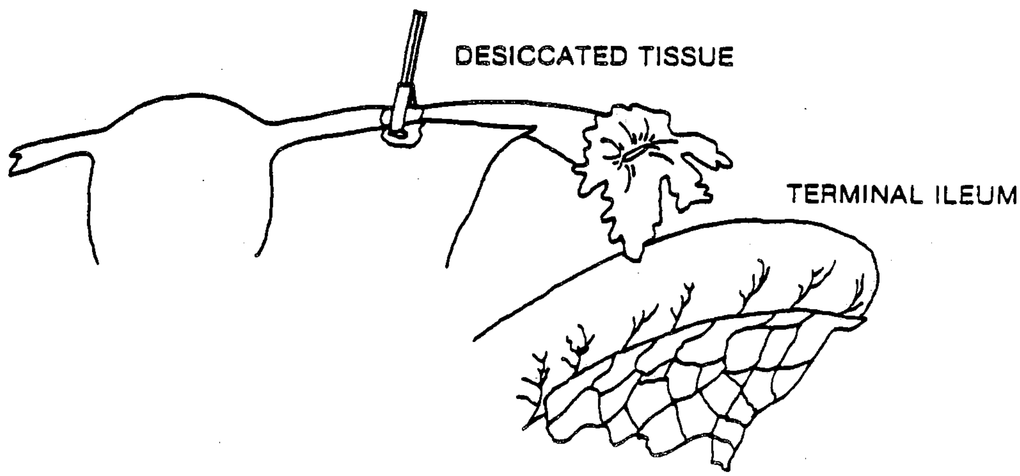
Because the problem is relatively less severe with the SSE3B, it is practical to take another approach. If a metal trochar sheath is used with the single puncture laparoscope, then the leakage current will enter the abdominal wall at the site of the incision. Since the leakage current will be less than roughly 100 ma, and because there will be at least 6 or 8 square centimeters of contact area, the current density will be well below the danger level which is roughly 100 ma per square centimeter. Even if a burn did occur at this site, there would be no risk of peritonitis, in contrast to a burn to the bowel. This solution was first proposed by Soderstrom. [4]



5. *Laparoscopy - Bipolar Desiccation*

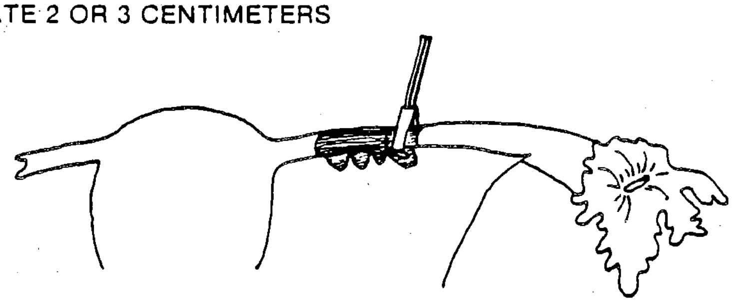
The SSE3B bipolar output is perfectly suited for bipolar laparoscopy. The simplest technique is to desiccate the salpinx in one or more places. Because so little tissue is affected with true bipolar operation, the tube must be regrasped repeatedly to necrose two or more centimeters of salpinx. One bipolar forceps on the market has a scissor type cutting surface built into the jaws, and after desiccation, the jaws are closed until the salpinx is completely severed mechanically.

BIPOLAR LAPAROSCOPY



CURRENT PATH IS LIMITED TO THE TISSUE DESICCATED.

THE SALPINX MUST BE GRASPED REPEATEDLY
TO DESICCATE 2 OR 3 CENTIMETERS



The use of bipolar forceps with the monopolar output is not recommended because the RETURN FAULT circuit may not permit it. Moreover, the SSE3B monopolar output is not isolated from ground and the desiccation may spread away from the forceps just as if a monopolar forceps and patient electrode were being used. If the patient's body were isolated from ground, it might work correctly, but this is not practical.

THE PROPOSED AAGL LAPAROSCOPY EQUIPMENT STANDARD

The American Association of Gynecologic Laparoscopists has drafted a standard for equipment to be used for laparoscopic sterilization. The part of this proposed standard that applies to electrosurgical generators suggests a limit of 600 volts peak and 100 watts maximum for load impedances of 200 to 500 ohms. [5] These limits are intended to prevent the problems discussed previously concerning the use of fulguration in monopolar laparoscopy.

The SSE3B bipolar output is incapable of exceeding these limits and can be used for desiccation with both monopolar or bipolar forceps. Use of the bipolar output with monopolar active electrodes is discussed at the end of this section, page 55.

If one wishes to restrict the SSE3B monopolar output to less than the AAGL guidelines, the following settings should not be exceeded:

	Dial No.	Watts
CUT	5	100
BLEND #1	3	30
BLEND #2	2	15
BLEND #3	1 3/4	10
COAG	1	5

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UROLOGIC SURGERY

Transurethral Resections

Transurethral resections are usually a high power procedure requiring 150 watts or more. The bladder and urethra are insufflated with glycine solution to provide visibility and irrigation. Glycine solutions are used because they have the proper osmolarity and are relatively poor conductors of electricity. If a hypo-osmolar solution like pure distilled water were used, large amounts of water would pass into the patient's body by osmosis. This could cause hemolysis of red blood cells and result in kidney failure. In a susceptible patient, fluid overload might also precipitate congestive heart failure.

If a good conductor of electricity like normal saline solution were used, the saline would be a short circuit on the generator and there would not be enough power left over to do the surgery. Even tap water in many places has enough salt in it to be quite conductive. So if glycine irrigating solutions are made up in the hospital pharmacy, only distilled water should be used. Note that salt is released from cells when they are cut. Consequently, the irrigation solution should be replaced frequently to keep it from becoming conductive. With the new continuous irrigation techniques, this is never a concern.

It is possible to perform TUR's with tap water conductive solutions, if the generator has 600 or more watts of power. For complete safety, 600 watts of power would require almost 390 square centimeters (60 square inches) of patient plate area in good electrical contact with the patient's skin. This is difficult to achieve with conventional patient plates. We believe that the risk to the patient of using such high power is not worth the convenience of using conductive solutions.

One problem which has haunted the solid state electrosurgery units has been the complaint of too much cut in COAG caused by the low crest factor of the COAG waveform. That is, the early solid state generators had a COAG which could have been described better as a BLEND. The SSE3B's have a high COAG crest factor, 10.0, which is equivalent to the better spark gap COAG outputs. We believe that the SSE3B's have put an end to the generalization that "solid state always cuts in COAG".

The SSE3B is also exceptional in that it produces unusually small, low frequency currents during cutting and fulguration. This results in less muscle and nerve stimulation when compared with many of the older spark gap units.

Typical settings used for the TUR are COAG 4 to 5 and CUT or BLEND #1 5 to 6 1/2. As mentioned earlier in Section 1, the SSE3B CUT has little hemostasis and many urologists prefer BLEND #1. The SSE3B CUT has approximately the same hemostasis (crest factor) as the Valleylab SSE2J and SSE2K models. Note that the effect of higher crest factor can also be achieved by increasing the resection loop wire diameter using, say 0.015" instead of 0.012". The thicker wire loop has the advantage that it is not as easily broken, but it does require slightly higher power settings to produce the same smoothness of cutting. [1]

Resectoscopes

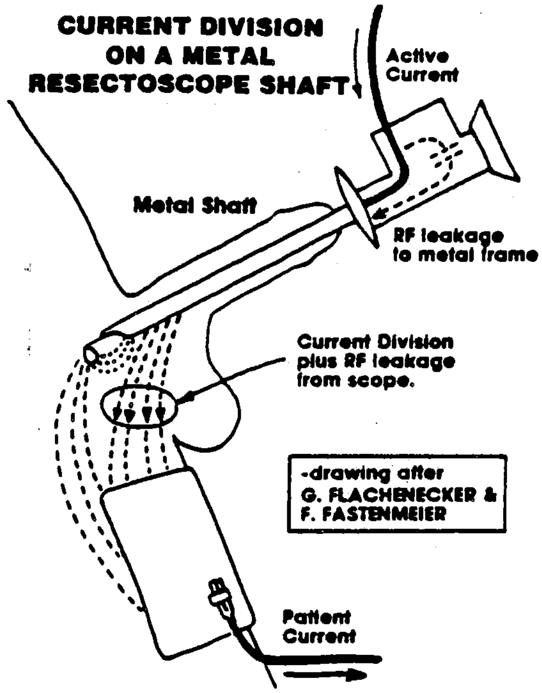
Resectoscope design can effect the safety of both the surgeon and the patient. Like other endoscopes, there is a small capacitance between the cutting loop conductor and the metal frame of the resectoscope. This small capacitance (typically 40 pf) couples a small amount of radio frequency voltage onto the metal frame of the resectoscope which will try to drive a current to the patient plate. [2]

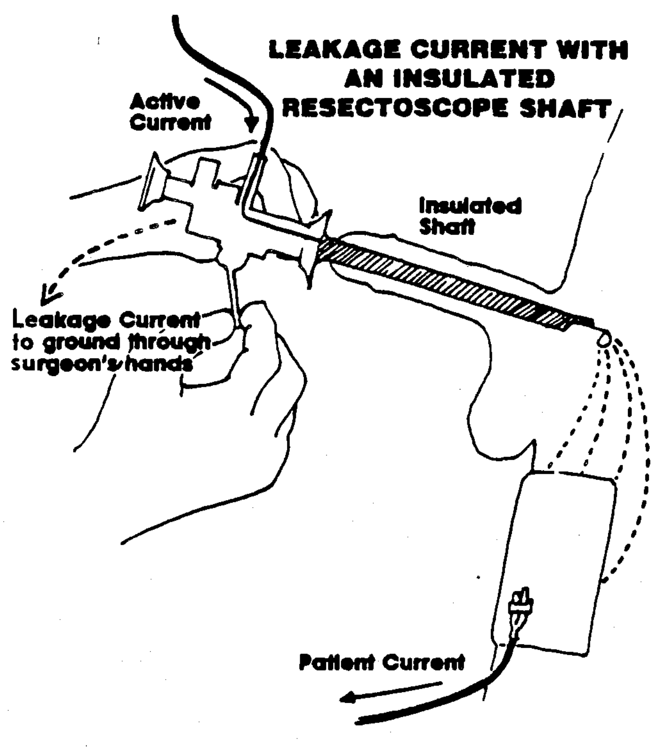
There are two different resectoscope shaft designs. In the all metal design, any RF energy on the metal resectoscope is free to enter the urethra. In the insulated design, a plastic sheath prevents such currents from entering the urethra. Both designs have their drawbacks.

The insulated shaft protects the patient, but has the drawback that the leakage current can travel into the surgeon's hands and through his body to ground. Since the SSE3B Return Fault circuit measures ground currents which are not returning to the patient plate, it is sensitive to this current and will alarm if this current is excessive. We have found that faulty insulation inside insulated-shaft type resectoscopes is a very common cause of Return Fault tripping during transurethral resection. Typically, the problem is a breakdown of the insulation which separates the active electrode from the metal frame. This insulation can become cracked, impregnated with water, or carbonized so that it gradually becomes a conductor. This results in increased leakage currents going to the surgeon or patient, depending on the type of shaft. Ideally, this insulation should be checked with a high voltage insulation tester at regular intervals.

The current to ground through the surgeon's body with an insulated shaft could be very large if the loop should break and touch the metal frame. The Return Fault circuit will prevent large currents from flowing, but it may not prevent small, low level currents from flowing to the surgeon in a fulguration mode. These currents are too small to be any threat to the hands, but if concentrated in a fulguration mode could be a threat to the eye. For this reason, endoscope eyepieces should ALWAYS be insulated. Fortunately, the thin gloves commonly used by Urologists conduct electricity quite well when wet and it is unlikely that sufficient voltage will ever build up between the resectoscope metal and the surgeon to allow fulguration to occur on the hands or eye.

Because the shaft is already insulated, it is important that the rest of the metal frame not contact the patient's body at any point. For this reason, NON-conductive lubricants such as petroleum jelly or mineral oil are recommended for insulated shaft resectoscopes. This insures that the pile up of lubricant at the proximal end of the shaft will not provide a conductive path to the glans penis.


CURRENT DIVISION ON A METAL RESECTOSCOPE SHAFT
Active Current
Metal Shaft
RF leakage to metal frame
Current Division plus RF leakage from scope.
-drawing after G. FLACHENECKER & F. FASTENMEIER
Patient Current


LEAKAGE CURRENT WITH AN INSULATED RESECTOSCOPE SHAFT
Active Current
Insulated Shaft
Leakage Current to ground through surgeon's hands
Patient Current

In the all metal design, the metal shaft during normal operation can serve as a pathway for a percentage of the current traveling between the resection loop and the patient plate. Consequently, the current densities along the metal shaft are much higher during normal operation than would be expected solely from the coupling between the active electrode cutting loop conductor inside the shaft and the outer metal shell. Because of this current density, some authors recommend that the lubricating jelly have about the same conductivity as the urethra so that the current will not concentrate at thin places in the film of lubricant. [3]

Suppose the resection loop breaks with the metal design and the broken end comes in contact with the all metal resectoscope. If this occurs, the entire generator output will be on the urethra. Fortunately, the urethra can probably stand this for several seconds and the surgeon can shut off the generator before harm occurs.

No existing resectoscope design is perfect and there probably won't be a resectoscope without potential electrical problems until there are metal free resectoscopes. To summarize, the resectoscope and active cable must be inspected regularly for any signs of deterioration. The Valleylab E0503 LectroCord is a sterile, disposable resectoscope cord which can be replaced with each use and thus insure the electrical integrity of the active cord.

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NEUROSURGERY

Hemostasis in Neural Tissue

*Hemostasis in neural tissue is an unusual problem because unlike most tissues, fulguration does not work well and the best mode of coagulation is desiccation. If one attempts to fulgurate neural tissue, a hard, superficial plaque of coagulum is formed. While the plaque is forming, virtually all the water is driven off and the plaque shrinks. As the plaque shrinks it may pull away from the normal tissue at the margin and cause new bleeding. To avoid this, only desiccation should be used.**

When neural tissue is desiccated, the coagulum remains relatively soft and does not shrink enough to provoke new bleeding. The only problem with desiccation is that the coagulum may stick to the forceps and pull away when the forceps are withdrawn. To prevent this, the electrode (or forceps) must be kept scrupulously clean so that only bright, polished metal contacts fresh tissue. Irrigation can also prevent tissue sticking. Since desiccation requires contact with moist tissue in order to pass the current, irrigating the bleeding site will insure a uniform desiccation and will prevent tissue sticking by keeping the electrode cool.

The Use of Monopolar Accessories in Neurosurgery

Neurosurgery can be divided into two separate sets of requirements; intracranial and extra-cranial. For extra-cranial work, the surgery is generally done monopolar and primarily for the purpose of stopping minor bleeding in the scalp incision or other superficial locations. A simple monopolar set-up such as a LectroSwitch (E2502B) and a CoHesive pad (E7505) would be ideal for this application.

A few neurosurgeons prefer monopolar intracranially as well. Typically, they use fine-tipped, monopolar forceps or a pencil with a needle electrode. The LectroHesive (E7503) with the Lectrode needle (E1552) can be used for this purpose.

If desiccation is performed with the monopolar output, the setting must be very low and the desiccation will proceed slowly. It is not possible to turn up the power to make the desiccation proceed faster because it will begin to spark and cut or fulgurate, depending on the waveform being used. Sparking can be avoided most easily when using the monopolar output by using the CUT waveform for desiccation. This is because for a given level of current, the CUT waveform will have the least peak voltage.

* *Petty, Peter; Unpublished study, Prince Henry's Hospital, Melbourne, Australia, 1974.*

To use the monopolar output for desiccation with a fine needle or forceps, use CUT at the lowest practical setting. The CUT light, which indicates when the generator has been activated, is useful for this purpose because it does not light until significant voltage is present at the output.

Key the generator in CUT and slowly increase the CUT setting from zero until the CUT light just comes on. This usually occurs at a setting of "1" on the knob skirt marking or about 5 watts on the CUT power calibration.

The use of the E0015 attenuator to try to achieve finer control with the monopolar output will be self defeating. Its impedance will be added to the impedance of the monopolar output and will make desiccation even more difficult to achieve without sparking.

Neurosurgical Head Frames and the Return Fault Circuit

If neurosurgical head frames are used with the monopolar output, the RETURN FAULT circuit may alarm frequently. The problem is that the metal head frame is connected to the grounded table and the metal contact points may be much closer to the site of the surgery than the patient return electrode. Too much current may flow to ground through the head frame and trip the alarm.

Since it is impossible to move the return electrode closer to the site of surgery than the shoulders, there is only one solution to this problem; isolate the head frame from ground.

Desiccating Neural Tissue With the Bipolar Forceps

The SSE3B bipolar output is ideal for desiccating with fine, bipolar forceps. It will desiccate rapidly with no tendency to spark (that is, no tendency to CUT or FULGURATE). Because the bipolar output is well isolated from ground, the current will only flow from one forceps tine to the other and the lesion will be as localized as possible.

We do not recommend using the monopolar output with bipolar forceps. The RETURN FAULT circuit may interpret the forceps as an insufficient patient return electrode and disable the generator. In addition, the monopolar output is not isolated from ground and the tissue destruction may radiate away from the forceps as if monopolar forceps were being used.

When the bipolar output was designed, it was assumed that the monopolar output would probably be used during the same case. If a monopolar accessory is plugged into the monopolar output at the same time, keep in mind that BOTH THE MONOPOLAR AND BIPOLAR OUTPUTS ARE ACTIVE ("HOT") AT THE SAME TIME.

Each accessory should be carefully guarded to prevent accidental contact with personnel or equipment. We recommend the use of the Valleylab Holster (E2400), but in the event one is not available, plastic syringe cases taped to the drapes may be used. This substitute holster may be autoclaved repeatedly. The cases must be large enough so that the forceps tips are not shorted together when the forceps are placed into the case.

A typical setting for use with a monopolar pencil for fulgurating bleeders extra-cranially would be COAG 3. It was planned so that COAG 3 would be approximately the correct setting for fine bipolar neuro-forceps used with the bipolar output. In this way, if COAG were used for desiccating, it would not be necessary to readjust the generator. CUT could also be used with the bipolar output since all the waveforms just desiccate. CUT has the advantage of having the widest power range and is the most linear. The BLENDS are not recommended with the bipolar output because they do not change linearly as the setting is varied.

When the bipolar output is being used, increasing the power setting primarily affects the speed at which the desiccation occurs. It does not greatly increase the quantity of tissue which is desiccated. For this reason, the settings used with bipolar forceps are not nearly as critical as those required to desiccate with the monopolar output.

PATIENTS WITH PACEMAKERS

It is frequently necessary to use electrosurgery on patients with pacemakers. The radio frequency current can interfere with the electronic circuitry in the pacemaker and is therefore a threat to the patient. The early, fixed rate pacemakers were prone to increase their firing rate when subjected to radio interference. This could result in rapid pacing which might lead to ventricular tachycardia and fibrillation. As far as we know, it has been several years since such pacemakers were built and there should be no more in use. Modern pacemakers are still subject to interference from electrosurgery but they are designed to be inhibited rather than to produce rapid firing. This means that the patient will return to his heart block rate for as long as the interference continues. That is, the pacemaker will be inhibited only during the few seconds the electrosurgery is activated. [1]

There is one report in the literature of electrosurgery causing a burn to the myocardium at the tip of an external pacemaker catheter. [2] Not only was the myocardium burned, but the heart fibrillated. In this case, the electrosurgery unit was a simple grounded type and the patient plate connection was broken so that the RF grounded pacemaker catheter became a substitute plate. This situation should be impossible with the SSE3B because the RETURN FAULT circuit will detect the broken patient connection. There will be current division at such a grounded catheter, so some curent will flow to ground through the catheter. Again, the RETURN FAULT circuit will be triggered if this current flow becomes excessive.

To avoid interference with the pacemaker, the electrosurgical current should not pass through the vicinity of the heart. The best way to do this is to use bipolar instruments as much as possible. When this isn't practical, the patient plate should be located as close as possible to the site of surgery and the current path between the surgery and the patient plate should be as far removed from the heart as possible. [3,4,5]

Checklist For Operating On Patients With Pacemakers

1) *Before starting surgery, double check all connections on the active and patient plate cable to be sure there will be no intermittent or metal-to-metal sparking in the connectors.*

2) *Use bipolar instruments, if possible.*

3) *If monopolar instruments must be used, place the patient plate as close as possible to the site of surgery and make sure that the current path from the site of surgery to the patient plate does not pass through the vicinity of the heart.*

4) *ALWAYS MONITOR PACEMAKER PATIENTS during surgery.*

5) *ALWAYS KEEP A DEFIBRILLATOR READY during electrosurgery on patients with pacemakers.*

REFERENCES ON ELECTROSURGERY WITH PACEMAKER PATIENTS

1. *Wajszczuk, W.J.; Mowry, F.; Dugan, N.L.: Deactivation of a Demand Pacemaker by Transurethral Electrocautery. New England J. Med. 280:34-35, 1969.*

2. *Geddes, L.A.; etal: New Electrical Hazard Associated with Electrocautery. Med Instrum 9:112-113, 1975.*

3. *Fein, R.: Transurethral Electrocautery Procedures in Patients with Cardiac Pacemakers. JAMA 202:7-9, 1967.*

4. *Fein, R.L.: Transurethral Resection of the Prostrate with An In Situ Internal Cardiac Pacemaker. J. of Urology 97:137-139, 1967.*

5. *Titel, J.H.; El Etr, A.A.: Fibrillation Resulting from Pacemaker Electrodes and Electrocautery During Surgery. Anesthesiology 29:845-846, 1968.*

Simultaneous Use of Two Active Electrodes

The SSE3B is equipped with two monopolar active terminals; one Bovie active jack and the three holes which accept the LectroSwitch and other hand switching accessories. This means that two active accessories could conceivably be plugged into the generator simultaneously. This is frequently desirable during coronary bypass procedures.

Whenever more than one active accessory is being used at one time, it must be clearly understood by everyone that ALL ELECTRODES ARE ACTIVE WHENEVER THE GENERATOR IS ACTIVATED. Therefore it is imperative that electrodes never be left unguarded. We suggest that the Valleylab Holster (E2400) be used. However, 50cc syringe cases can be used as mentioned on page 50. Discipline is needed to insure that each electrode is returned to its holster after each use.

What happens to the effective output power at each electrode when two electrodes are used simultaneously from the same generator? There is remarkably little interference between the two electrodes, if both are fulgurating or cutting simultaneously. The electrosurgical effect seems almost independent of the existance of two electrodes at once. For example, if one electrode is fulgurating at say, a setting of COAG 6, and the second electrode begins to fulgurate too, there is no noticable drop in the effective power at the first electrode. Similarly, if the first electrode stops sparking first, there is no noticable rise in power at the second electrode. The reason for this apparent paradox is that the spark is not a simple, continuous event, but rather it is a collection of many separate sparks. There can be a new spark everytime the voltage between the tissue and electrode becomes greater than zero. Since the voltage first goes positive, then goes negative, there can be two sparks for every cycle. Since there are 750,000 cycles per second, there could be 1.5 million sparks to the tissue each second. Whether or not a spark occurs depends on whether there is enough voltage developed to jump a spark to the nearest tissue. In COAG especially, the sparking is a rather random process and many of the possible sparks do not occur. With two electrodes then, there can only be one spark at one instant and it can only jump from one of the two electrodes. Perhaps the next spark will jump from the other electrode, if the distance to moist, conductive tissue is closer than from the first electrode. The two electrodes take turns sparking to the tissue, and there are enough "unused sparks" with single electrode operation, that a second may also operate without a noticable drop in electrosurgical effect.

There is definite interference between electrodes if one attempts to desiccate from one or both of the electrodes. Desiccation involves a low apparent tissue resistance. Sparking cannot occur at one electrode while the other is loaded down with a voltage-suppressing, low resistance.

If one electrode is touched down to moist tissue, while the other is fulgurating, the low resistance will extinguish the spark at the other electrode until the new electrode gets the tissue hot enough to increase its resistance, and thus change from the desiccation phase to fulguration.

In summary then, interference between electrodes can be minimized by:

1. *Using relatively high settings so that desiccation will not occur. Use CUT or COAG at 6 or above.*

2. *Both surgeons should be careful to touch the tissue LIGHTLY so that sparking will begin immediately and there will be no desiccation.*

3. *Do not attempt to desiccate with two electrodes simultaneously.*

<u>Dual Adapter Model E0012</u>

Valleylab's dual adapter allows simultaneous use of two hand-switching monopolar accessories. The adapter will accept any combination of handswitching forceps and LectroSwitch pencils. CAUTION should be exercised when using the dual adapter because current flows through ALL active electrodes when any one switch on an accessory is activated. Non-conducting holsters (E2400) should be provided for each active accessory and each tool should be returned to its holster after each use.

With the use of the dual adapter, it is possible to plug in three active electrodes simultameouly. The RETURN FAULT patient plate safety system is designed to tolerate up to 120 pf of capacitance between the active electrode and ground. A single electrode with a 3 meter long cord typically has 50 pf or more capacitance to ground. Two active electrodes will have twice as much capacitance and will produce twice as much current flowing to ground. The RETURN FAULT system will usually indicate a hazard if more than two active electrodes are used.

<u>Simultaneous Use of Two Generators</u>

Occasionally it may be desirable to use two generators simultaneously on the same patient. For example, in a coronary bypass procedure it is desirable to have one team removing the saphenous vein while the other team performs the thoracotomy. Because the two generators are not synchronized, there are frequent periods, moment to moment, when one patient plate has a high positive voltage while the other acquires an opposite negative voltage. This is especially true if one or both of the generators has an isolated output. Whenever this occurs, there will be a large potential difference between the plates and current will flow from one plate to the other. This current will cause no harm provided that it produces no sparks high current densities on the patient's body. To avoid problems, place each plate as close as possible to the respective site of surgery and make sure that there is no possibility of the two plates touching. For example, in a coronary bypass one plate can be placed under the buttocks and the other under the shoulders.

If one or both of the active electrodes are bipolar, there are no special safety precautions which need to be observed.

Simultaneous Use of Monopolar and Bipolar

As discussed above, there is no problem using monopolar and bipolar simultaneously, if separate generators are used for each tool. It is probably not practical to operate both monopolar and bipolar electrodes simultaneously with the SSE3B. The two outputs are sufficiently electrically isolated that the leakage between monopolar and bipolar circuit paths is not significant. However, because the bipolar output only desiccates and can not fulgurate, there will be some interference in electrosurgical effect between the two outputs when both outputs are supplying current to tissue simultaneously. By plugging in both monopolar and bipolar instruments simultaneously, the surgeon can use one or the other without changing the generator controls or accessory connectors. The bipolar output is designed so that typical power settings for monopolar applications will correspond to typical settings for bipolar desiccation. We believe that the surgeon will be able to find a single setting that will work with both outputs. Unfortunately, both windings are "hot" at the same time which means that each electrode must be guarded with a holster (E2400) while the other is being used.

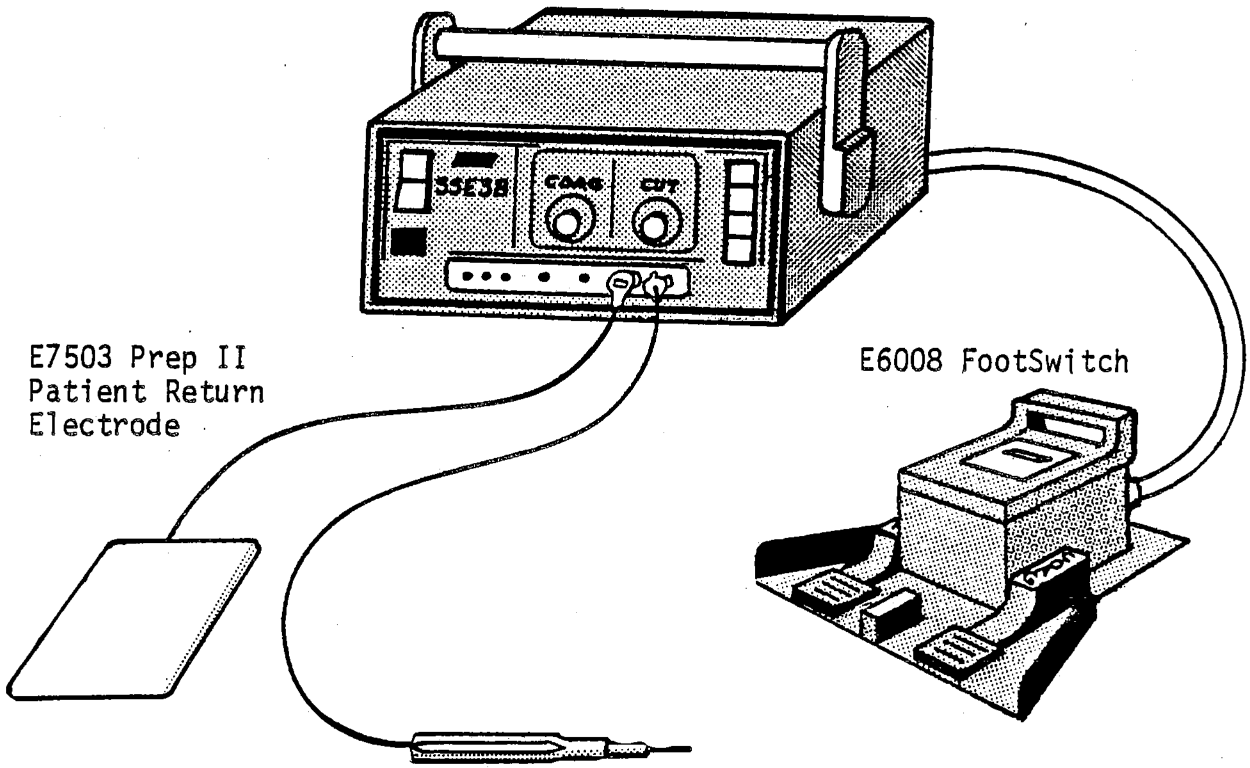
Long Active Cables

Occasionally we receive requests for extra long active cables. We generally refuse to supply long cables because they compromise the safety of isolated generators due to the increased leakage current and may trip the RETURN FAULT circuit if used with the SSE3B.

Monopolar Operation With The Bipolar Output - How to Achieve Desiccation Without Sparking with Monopolar Instruments in Neurosurgery, Laparoscopy or Other Applications.

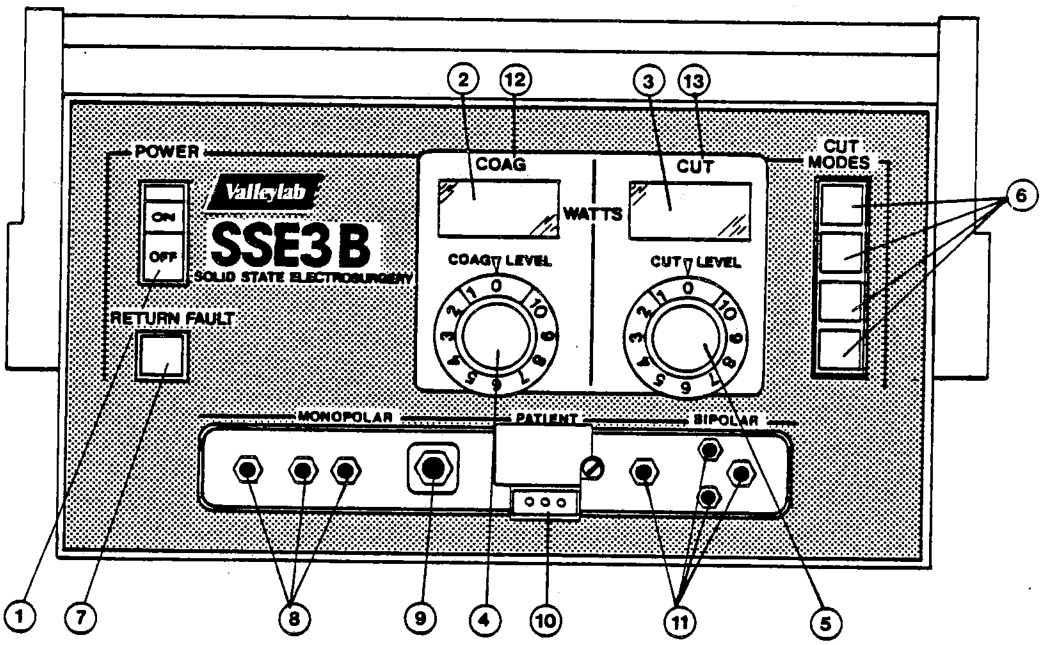
Since the SSE3B bipolar output is isolated from ground, it may be used with a patient return electrode just as the isolated output of the Valleylab SSE2 and SurgiStat models are used for Monopolar. This setup will allow the surgeon to obtain desiccation without sparking with monopolar instruments such as fine neurosurgical forceps, or monopolar laparoscopy forceps. Although this can also be done with the monopolar output, the regular monopolar is optimized for sparking, that is, fulguration and electrosurgical cutting. Consequently, if desiccation is done with the monopolar output, a very low setting and a scrupulously clean electrode are needed to prevent sparking. If a very low setting is used, the desiccation will happen slowly and the surgeon will have to stop the generator (take his foot off the footswitch) before the tissue becomes so dry that sparking begins. If the bipolar output is used, the desiccation will start promptly and end abruptly without sparking.

To use the bipolar output with a patient electrode, the patient electrode may be plugged into either the left or right large banana jacks, since these jacks are equal so far as the radio frequency output is concerned.

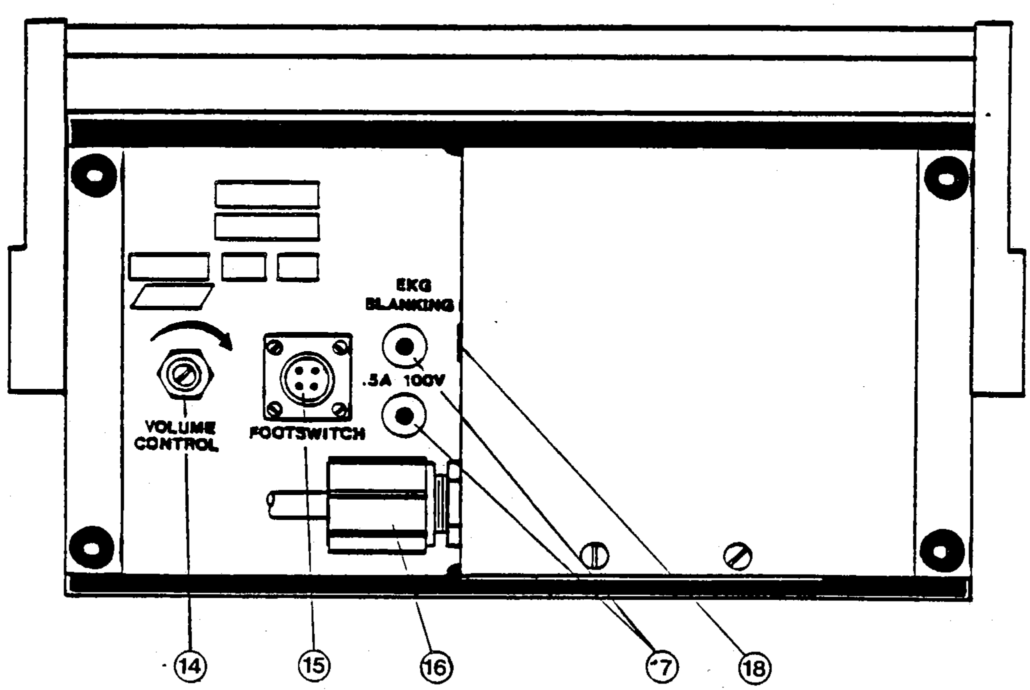


THE SSE3B BIPOLAR OUTPUT WIRED FOR MONOPOLAR OPERATION.

DESCRIPTION OF CONTROLS AND GENERATOR DESIGN



FRONT VIEW



REAR VIEW

FRONT VIEW

(1) *POWER ON/OFF SWITCH AND CIRCUIT BREAKER*

Rock switch to turn SSE3B on. Power switch illuminates when the SSE3B is on. The combination power swith and circuit breaker turns off in case of internal failure or momentary overload. Rock switch to reset.

(2) *COAG POWER READOUT*

This digital LED display is visible above the COAG level control after the generator is switched to "ON". The number displayed predicts the level of average monopolar power in watts which will be delivered to a 300 ohm resistive load when the generator is keyed in the COAG mode. (See note 1.)

(3) *CUT POWER READOUT*

This digital LED display is visible above the CUT level control after the generator is switched "ON". The number displayed predicts the level of average monopolar power in watts which will be delivered to a 300 ohm resistive load when the generator is keyed in the CUT mode. (See note 1.)

(4) *COAG LEVEL CONTROL*

This dial rotates to select coagulation current intensity. The dial is graduated from 0 to 10.

(5) *CUT LEVEL CONTROL*

This dial rotates to select cutting current intensity. The dial is graduated from 0 to 10.

(6) *CUT MODE SELECTOR BUTTONS*

The four push buttons select the type of cutting current, either PURE for minimum hemostasis or BLEND 1, 2 or 3 for increasing hemostasis while cutting. BLEND current intensity is determined solely by the CUT level setting, completely independent of COAG level setting. If none of the buttons have been pressed, BLEND #1 is automatically selected, and keying "CUT" will result in BLEND #1.

(7) *RETURN FAULT INDICATOR*

Indicator illuminates if the SSE3B is activated without a proper patient plate plate connection. The SSE3B is disabled as long as the indicator is on. After correcting the patient connection, the RETURN FAULT circuit must be reset by pushing the RETURN FAULT indicator button. See Section 6 of Service Manual for complete explanation.

Note 1: If either a return fault condition exists or the high voltage power supply disabled, the digital display of power output will blank.

(8) *MONOPOLAR SWITCHING ACTIVE RECEPTACLES*

These three position-coded receptacles located on the white plastic jack-strip accept the three-prong plug of Valleylab LectroSwitch Pencil or the two-prong plug of a switching forceps cord. CUT mode or COAG mode power may be keyed via these receptacles.

(9) *MONOPOLAR ACTIVE RECEPTACLE*

This is a rectangular receptacle located on the white plastic jackstrip which will accept most standard active accessories of other manufacturers or adapter plugs for accessories which do not fit directly.

(10) *PATIENT RECEPTACLE*

This rectangular receptacle accepts the twin-lead plugs used on the cords of dual-pad (REM) and single-pad return electrodes. The Return Electrode Monitor system is activated by the center pin on dual-pad plugs. An L.E.D. within the receptacle housing flashes in the event of a REM alert.

(11) *BIPOLAR RECEPTACLES*

These four position-coded receptacles provide an isolated bipolar power output which is electrically separate from the monopolar outputs. Output power is accessed via the horizontally aligned receptacles which accept standard banana plug connectors. The vertically aligned receptacles allow keying of generator power via the four-prong connector of Valleylab hand-switching bipolar accessories.

(12) *COAG POWER INDICATOR*

The backlighted word "COAG" will be visible above the COAG power readout when the generator is keyed in the COAG mode and usable RF power is available at the output connectors. This indicator will not be illuminated at the zero level setting. Absence of illumination of this indicator upon keying of the COAG mode at level settings greater than 1 may indicate a generator malfunction.

(13) *CUT POWER INDICATOR*

The backlighted word "CUT" will be visible above the CUT power readout when the generator is keyed in the CUT Mode and usable RF power is available at the output connectors. This indicator will not be illuminated at the zero setting. Absence of illumination of this indicator upon keying of the CUT mode at level settings greater than 1 may indicate a generator malfunction.

REAR VIEW

(14) *AUDIO VOLUME CONTROL*

This dial controls the audio volume from 0 to 72 dbA.

(15) *FOOTSWITCH CONNECTION*

This four conductor Amphenol type connector accepts the Valleylab footswitch keying accessory.

(16) *POWER CORD AND PLUG ASSEMBLY*

The low leakage type line cord is in a strain relief attached to the rear of the unit. The three-prong plug of the power cord connects to the properly grounded three-prong wall receptacle providing 110 VAC 60 Hz power. The plug is an approved hospital-grade model. Specific models of explosion-proof plugs are available through special order. Extension cords, three-prong to two-prong adapters and extra length power cords should NOT be used. For units operating from 110 VAC 50 Hz input, your Valleylab representative will install the appropriate plug.

(17) *EKG BLANKING OUTPUT*

This banana jack output can be used to turn off an electrocardiograph or cardioscope when the generator is active to prevent overload of the monitoring equipment. The two leads are switched together internally whenever the SSE3B is activated. Refer to Section 6 of the Service Manual for a complete explanation of the circuit.

(18) *Powerite Switch*

This switch is covered by a metal cap which must be snapped out to gain access to the switch. In the "ON" position, the POWERITE system continuously monitors the ground connection between the generator and the operating room's power system. The system will not function in the presence of an isolation transformer in the operating room. If isolated wiring is present, the switch should be in the "OFF" position.

Keying Systems

The SSE3B can be activated with either a footswitch or by hand held switching instruments such as forceps or the "LectroSwitch" pencil. The footswitch plugs into a four pin connector located at the rear of the generator. Monopolar handswitching instruments must be equipped with connectors which have two or three banana plugs of the proper spacing to fit the three "LectroSwitch" jack terminals at the left of the generator. Bipolar handswitching forceps must be equipped with a three or four pin bipolar plug which plugs into the bipolar output on the right of the generator.

Footswitches

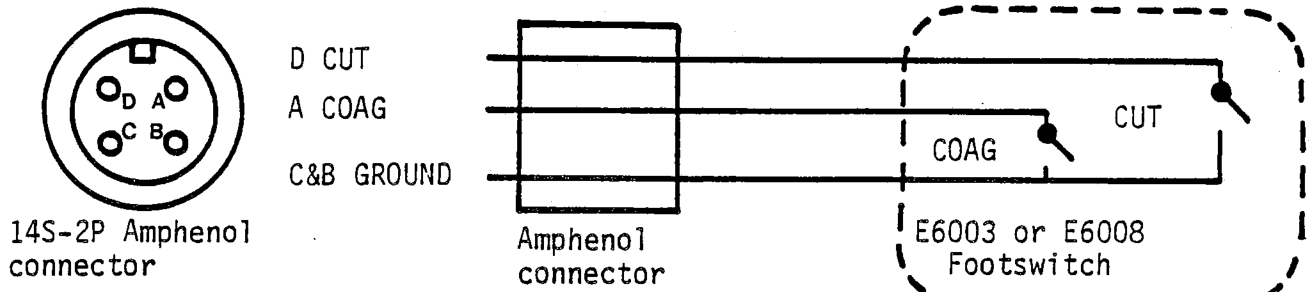
The SSE3B may be used with either the E6003, E6004 or E6008 footswitches. Other footswitches manufactured by Valleylab in the past or intended for office electrosurgery could be made to work, but are not recommended for the operating room environment. The E6004 differs from the E6003 in that it has a more rugged cast metal frame and is elevated off the floor by rubber grommets. The E6008, is also a heavy cast metal footswitch which is completely waterproof. For transurethral resections, or other procedures where the operating room floor is routinely awash with fluids, the E6004 or E6008 are preferred. The E6007 footswitch is the same as the E6008 but it has the CUT pedal on the right and the COAG pedal on the left as is preferred in some parts of Europe.

Explosion Preventing Footswitches

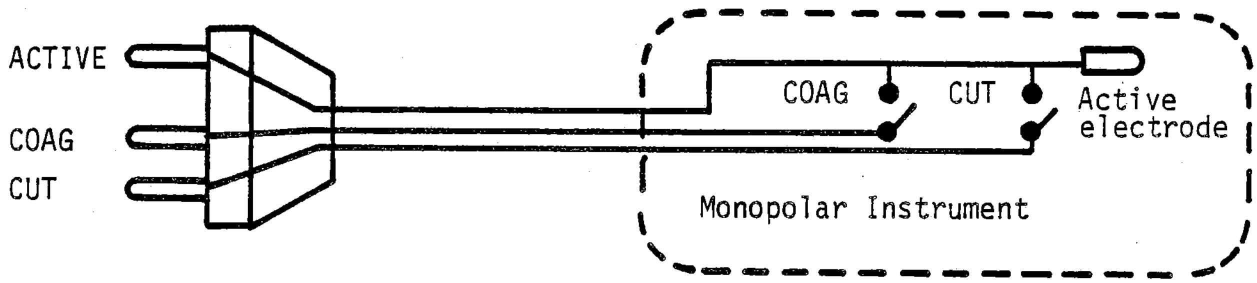
All Valleylab generators are designed to be "intrinsically safe" for explosion prevention. Explosions could be caused by the sparks which occur in the contacts of a switch if the proper mixtures of flammable gas and oxygen were present. There are two design approaches which can prevent this possibility. "Explosion-proof" is the official test laboratory word for footswitches which are designed to allow explosions to occur inside the heavy metal housing. The gases reaching the outside are cooled sufficiently to prevent the explosion from propagating to the rest of the room. This is the reason that true explosion proof footswitches are extremely heavy.

The words "intrinsically safe" mean that the switching current is too low to cause an explosion, regardless of the gas mixture. To qualify as intrinsically safe, the energy in the spark must be less than 1 millijoule. The energy available from the SSE3B switching circuit is about 1/500 of that level. The intrinsically safe rating pertains as much to the generator as it does the footswitch.

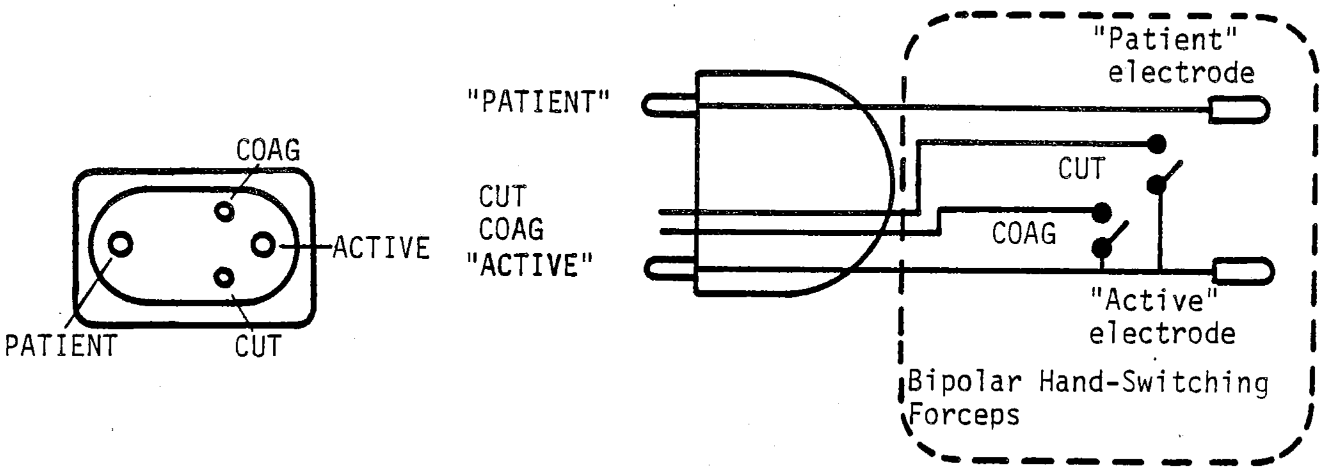
The Canadian Standards Association has another footswitch rating called "Non-incendive footswitches." This rating acknowledges that the footswitch system will cause explosions according to the intrinsically safe design principle described above. It is not identical to an official "intrinsically safe" rating because "intrinsically safe" also implies that multiple, simultaneous fault conditions can occur inside the generator without explosion-causing energies ever becoming present in the footswitch.



FOOTSWITCH WIRING DIAGRAM



MONOPOLAR HAND-SWITCHING INSTRUMENT WIRING DIAGRAM



BIPOLAR HAND-SWITCHING FORCEPS WIRING DIAGRAM

WIRING DIAGRAMS FOR FOOTSWITCHES AND HAND-SWITCHING INSTRUMENTS FOR THE SSE3B

Since electrosurgery almost invariably involves sparking to tissue, it is inherently unsafe for use with flammable anesthetics. Explosion-proof footswitches are therefore unnecessary.

Hand-Switching Forceps and Pencils

The three banana plug jacks at the left of the receptacle panel are designed to accept hand-switching tools such as the LectroSwitch pencil (E2502) and the five and seven inch monopolar switching forceps (E4001 and E4002). The banana jack at the extreme left is the active electrode terminal. The second terminal from the left carries the COAG activation signal, so that when the active pin is shorted to the second pin, COAG is activated. When the third pin is shorted to the active pin, CUT is activated. For all practical purposes, the three hand-switching jacks are all "active" with respect to the patient jack, so the orientation of the two-pin forceps is not critical. When hand-switching bipolar forceps are used, the forceps must have its switching design compatible with the SSE3B. That is, the activation must be brought about by switching one of the control leads to the active lead. The four pin bipolar connector is wired as follows: The CUT/COAG switching pins (the two small holes above and below the larger holes) are switched to the large pin on the right which can be thought of as the "active" side of the output. COAG will be activated when the upper small pin is shorted to the "active" and CUT will be activated when the lower small pin is shorted to the "active". The other large pin (the large hole on the left) can be thought of as the "patient" side of the output, although the only electrical difference between the "active" and the "patient" is the reference of the hand-switching input.

Diagrams for wiring hand-switching tools and repairing footswitch connections are shown on the opposite page. Pictures of bipolar and monopolar forceps connected to an SSE3B are shown in Section 1, pages 11 and 15.

Options

Most of the options offered with the Valleylab model SSE2K, such as the Microbipolar Output and Adjustable Blend, and EKG Blanking, are standard equipment on the SSE3B. However, extra length power cords and explosion proof plugs are available so that the SSE3B can be used with any 120 volt electric power system.

1. *220 Volt Versions*

   The SSE3B can be supplied for use with 220 volt AC line voltage. The 220 volt generator may be used with voltages ranging between 180 and 260 volts. It is supplied with the American standard 220 volt line plug. The correct plug for your area will be supplied and installed by your local representative.

2. *Extra Length Power Cords*

On request the SSE3B can be supplied with power cords up to 20 feet in length. Because the AC leakage from chassis to ground depends to some degree on the length of the line cord, the AC leakage may exceed the normal SSE3B specification of $\leq$ 50 microamps.

3. *Explosion-Proof Plugs*

The SSE3B can be supplied with explosion-proof power cord connectors of the following types: Valleylab Catalog No. E0002-1 Hubbel, E0002-2 Crouse-Hinds, E0002-3 Appleton, and E0002-4 Russel and Stoll.

Design of the SSE3B Generator

The SSE3B generator is an all solid state unit which offers the surgeon power, versatility, and reliability in a small package. There is nothing in design of the SSE3B which could not theoretically have been accomplished with vacuum tubes and spark gaps. However, all solid state construction allows a complex design to be built in a small package with high reliability, since there are no spark gaps or vacuum tubes with filaments. Transistors can fail too, but they are most likely to do so during the first few weeks of use. When they have experienced all the stresses they are ever likely to encounter, they no longer fail. For this reason the SSE3B is cycled at maximum settings before it leaves the factory. This procedure catches weak transistors or other substandard components.

The heart of the SSE3B circuitry is a computer-like control system which monitors the power requirements of the output stage and gives instructions to the power supply to provide just the right voltage and current to result in the output power requested by the power level settings on the front panel. The "computer" also monitors the electrical operating parameters of the output transistors and makes sure that they stay within their rated limits at all times. This prevents transistor failures and provides for greater power efficiency with less waste heat than ordinary generator designs. The power supply module has some intelligence of its own and, in case of a computer failure it will not supply power until the computer section has been repaired. In this way, the problem is limited to the control circuitry and can not cause damage to other components.

Other benefits of the control system are essentially perfect output regulation, less energy consumption, more precise control tapers, light weight construction, and a lower operating temperature. With respect to reliability, the main enemy of electronic components is heat. The lower operating temperature results in greater reliability than conventional designs, in spite of added complexity.

The SSE3B was designed with the bio-medical engineer in mind. Nearly all transistors, integrated circuits, and other active components are mounted on plug-in circuit boards, and in case of failure, your Valleylab representative can frequently replace the appropriate board and return the generator to service in minutes. The power supply is itself a module and can be quickly unplugged and replaced. Each output transistor is mounted on its own circuit board with a heat sink and fuses. In the unlikely event than an output transistor fails, each output transistor assembly can be unplugged and replaced in minutes. Moreover, the output transistor assembly itself is easily repaired, since the transistor and fuses plug right into the circuit board. An indicator light inside the generator allows an engineer to check out the computer control system in the field without complex test equipment.

The power supply uses high frequency AC to convert the line voltage to the required DC voltages to run the generator. This high frequency allows the SSE3B to use very small power transformers which result in an unusually light weight generator (12.8 kilograms or 28 pounds) without sacrificing the isolation and safety of a conventional, large power transformer.

Unlike the Valleylab SSE2 series generators and most competing models, the SSE3B has no fan to cool its output stage. This is another result of increasing the overall power efficiency of the unit. A conventional generator with a fan operates at 20% to 25% efficiency while the SSE3B operates at over 50% efficiency. With so much less waste heat, there is no need for forced air cooling. The advantages of not having a fan are:

1) *A fan failure cannot cause the generator to overheat.*
2) *The fan cannot bring dust and debris into the generator nor distribute dust around the room.*
3) *The fan noise cannot distract OR personnel.*

Because the SSE3B relies on convection air cooling, the grill work on the sides of the generator must be kept open so that the warm air can readily leave the cabinet. If the air vents are blocked and the generator is used at high power settings, the output stage will overheat. The SSE3B will seldom overheat if it is used on a Valleylab cart or stand and not covered with some object which might block the air circulation. The SSE3B is equipped with a fully regulated power supply which will supply a constant power output when the supply voltage varies from the usual 120 volts RMS. The regulation is essentially perfect so no detectable change in electrosurgical effect will be seen, even though the 120 volt supply voltage may vary from 90 to 140 volts AC. This feature is useful in case of brown-outs or if the generator must be operated with a portable power plant.

The point of this is that if the patient electrode is not securely attached to the patient's skin, then the circuit might be completed to the patient by some small, grounded contact point, thus producing high current densities and burning him. Such contact points might include low impedance electrocardiograph electrodes, small metal thermometers, neurosurgical head frames, or simply points where the patient is touching a grounded IV stand, stirrups, etc. [2] (See Figure 3.)

The second problem with grounded systems is that technically, the patient electrode is never really grounded. All electrosurgical generators operate at radio frequencies to avoid nerve and muscle stimulation. Full power grounded generators now on the market operate at frequencies between 1 MHz to 2 MHz. Patient electrode cables are generally 10 feet long and have about 3.5 uH inductance. If the cable is wrapped into a few turns in an attempt to be "neat", the inductance can rise to 10 uH or more. At 2 MHz a 3.5 uH inductor gives an impedance of 44 ohms. A current of 1 ampere RMS passed through such a cable will produce a voltage drop of 44 volts RMS. This means that the patient electrode is 44 volts above the metal chassis. The metal chassis, in turn is connected to "ground" via the 10 foot long power cord and the "grounded" metal cart. These paths to ground also have impedances. It is easy to see how a "grounded" patient might have 50 or more volts difference between the plate and true ground.

The RF current tries to return to the "grounded" side of the secondary winding and will go there by <u>all</u> paths available to it. The current will divide itself among these various paths in inverse proportion to the impedance of each one. For this reason it is possible for burns to occur at small, grounded contact points even though the patient electrode is securely attached to the patient's skin. [3] This phenomenon is called "current division." With a simple grounded system, the proportion of current which can flow through a contact point by means of current division is greatly dependent on the positioning of the patient electrode, which should be as close to the site of surgery as possible. Moreover, the contact points should be away from the current path between the surgery and patient electrode whenever possible.

The third problem with grounded systems is that the patient electrode is a sink for other currents resulting from ground referenced voltages which may be applied to the patient. For example, if the insulation should fail in some other apparatus and the 60 cycle line voltage were applied to the patient, the grounded patient electrode would insure that large currents would flow through the patient and electrocute him. [4] (See Figure 4.)

The fourth disadvantage of grounded systems is that they perform poorly when used with bipolar accessories. A bipolar forceps cannot be used with a grounded system because there is usually a fairly low impedance between the patient and ground.

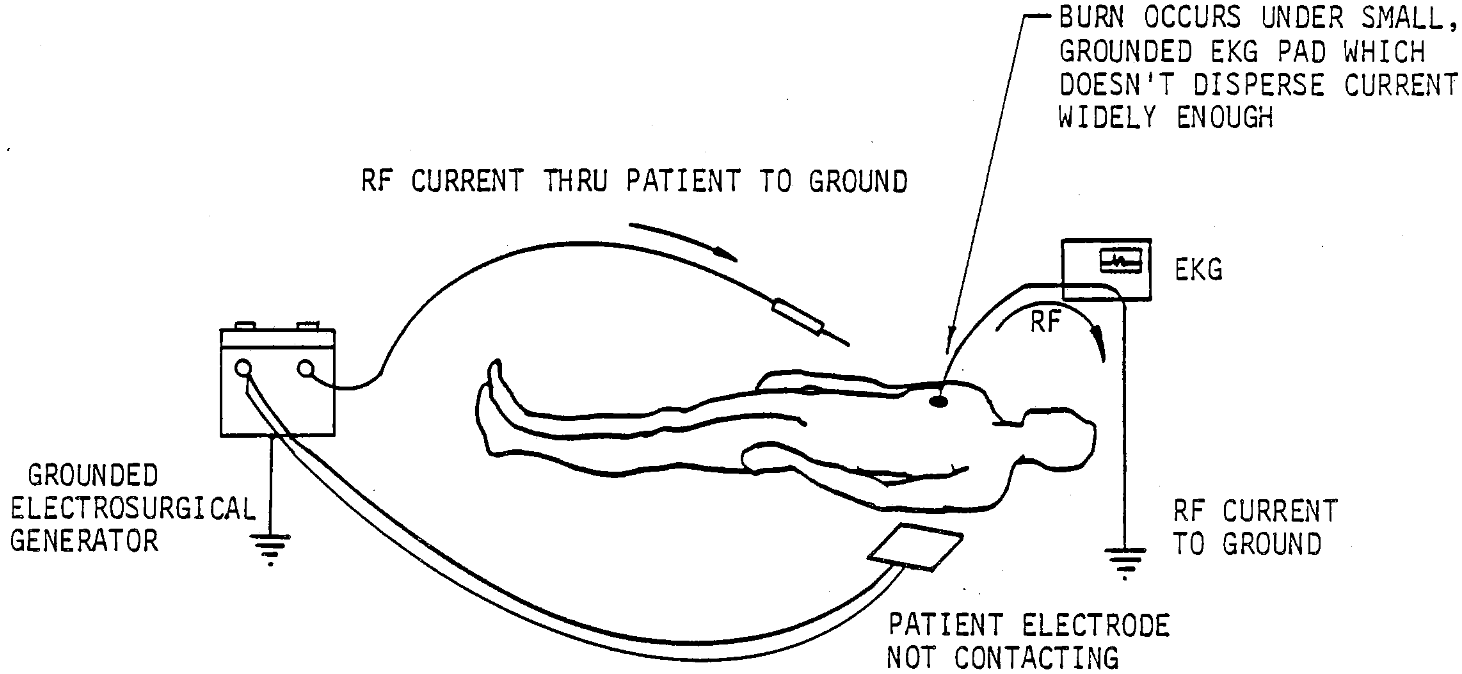


FIGURE 3

How a broken patient connection can result in a burn with a grounded electrosurgical generator. Any small, grounded patient contact (an EKG pad is shown here) can carry the RF current to ground resulting in a burn at that point.

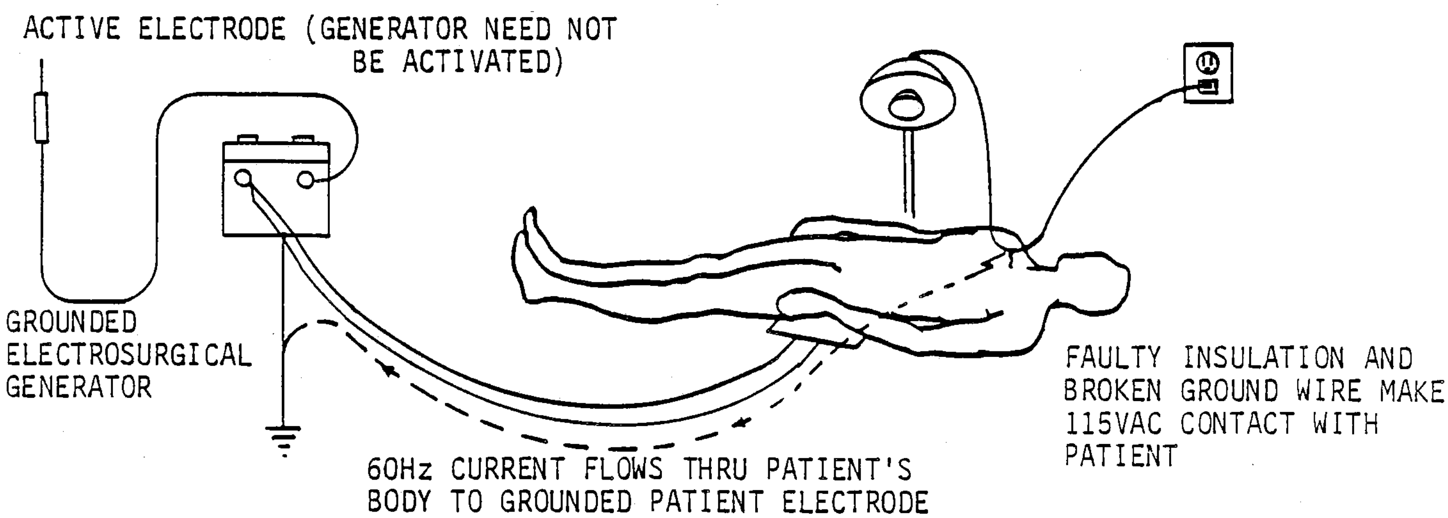


FIGURE 4

How a well-grounded patient can be electrocuted by an unusual fault in which the 115 volt power line touches his body.

This low impedance comprises not only the grounded points mentioned earlier but also the capacitive coupling between the patient's body and the grounded metal table. What one sees is that only the ungrounded tine of the forceps appears to be active. No sparking or coagulation takes place at the grounded tine and the result is inferior to using monopolar forceps with a patient electrode. If it is possible to isolate the patient's body from ground sufficiently, then of course the bipolar forceps work normally.

There is no perfect solution to the above problems encountered with grounded systems but there have been some good innovations to minimize the risk of inadvertent burns due to loss of the patient electrode. The most common aid is a two wire continuity monitor system in which a monitor current is passed out to the patient electrode and returns to the generator via the second wire. The sentry disables the generator in the event that there is a loss of continuity anywhere in the loop. The sentry does not guarantee that the patient electrode is touching the patient, and some designs don't even guarantee that the patient electrode is attached to the end of the cable. Another problem is that the two wires could conceivably be shorted together anywhere between the plate and the wiring inside the generator, thus erroneously indicating a "safe" condition. [5,6]

A more sophisticated type of patient safety device for grounded electrosurgery which is now on the market passes a small DC current of approximately seven microamperes through the active lead, through the patient's body and through the patient electrode. This current path must first be completed before the generator will activate. The patient electrode is isolated from ground by means of a large capacitor which blocks DC but keeps its RF well grounded. This ingenious system has two drawbacks. First, surgeons find that the need to touch the tissue first before the machine will activate is annoying and makes fulguration impossible without actually touching the tissue. This limitation is important in procedures where the eschar cannot be permitted to stick to the electrode. [7] The second limitation is that this DC system cannot detect or limit current division to alternate ground paths.

ISOLATED MONOPOLAR ELECTROSURGERY

One of the best available solutions to the monopolar patient return electrode dilemma is the isolated output which has no reference to ground. (See Figure 2). The isolated output for use with a patient electrode was first introduced by Valleylab in 1969. Since that time it has become the most widely accepted method of insuring patient electrode safety. It also has the unique advantage of being usable with bipolar instruments even though the patient may be grounded. The chief problem with the grounded system is that the loss of the patient electrode will allow the current to return to ground via any path available. By isolating the output, no current can flow to ground through any grounded contact point because there is no reference to ground if the patient electrode is not touching the patient. The beauty of this approach is its simplicity. No patient sentry system is needed because, if the continuity of the patient electrode lead is broken, no current will flow. In other words, the surgeon himself is the safety alarm.

When the generator will not coagulate, he knows that the patient connection may be broken. Moreover, the patient electrode safety system does not limit the surgeon's technique and finally, the isolated patient electrode does not provide a 60 Hz "sink" for ground referenced power line voltages. "Current division," as described previously, is not much of a problem with isolated generators because the current is trying to return to the patient electrode, and not to the "grounded" chassis. Therefore, the inductance of the patient cable does not contribute significantly to the ground-to-patient voltage.

In spite of these advantages, isolated electrosurgery does have two limitations. The most controversial of these is "RF leakage current." RF leakage occurs because one must use patient and active wires of a significant length. These wires form capacitors with respect to the grounded operating room, and since capacitors behave like conductors at radio frequencies, current will flow in the grounded objects and these currents could complete the path to the patient electrode via the small, grounded contact points. [8]

The second limitation is that the active electrode cannot be touched to ground while the patient electrode is attached to the patient. If this is done, the patient electrode acquires a high voltage with respect to ground, and any small, grounded skin contact point may have high density currents flowing through it. Fortunately, grounded, bare metal objects within the sterile field are very rare, so there is little opportunity for the active electrode to contact ground. We have never heard of an accident of this type and a little education can make it extremely unlikely. (See Figure 5.)

A limitation of all existing monopolar systems except those with patient electrode area monitors occurs when the patient electrode falls out from under the patient and lies against a grounded object. As before, there is no patient electrode to disperse the current and the current may concentrate at small, grounded skin contact points. See Figure 6. One possible exception is the DC test signal system described earlier, provided the patient has no DC contact with ground.

One common misconception about isolated electrosurgery is that it is the final solution for "shocks" and "burns" to surgeon's hands. If the patient or the patient electrode is well grounded, the active current can flow to any other grounded object in the room, regardless of whether the generator is isolated or grounded. It is hard to totally isolate the patient from ground because of the presence of the grounded contact points discussed earlier and the capacitive coupling to the table. Consequently the patient, and thus the patient electrode, are usually grounded even with isolated electrosurgery. Since the patient lead is grounded, the active current can flow to any other grounded object in the room. The surgeon himself is grounded by his conductive shoes, and even though they have a very high resistance (hundreds of thousands of ohms) they can pass enough current to make a mild burn or shock-like sensation. The surgeon is normally protected from this by the insulation on the electrode he is using and his rubber gloves.

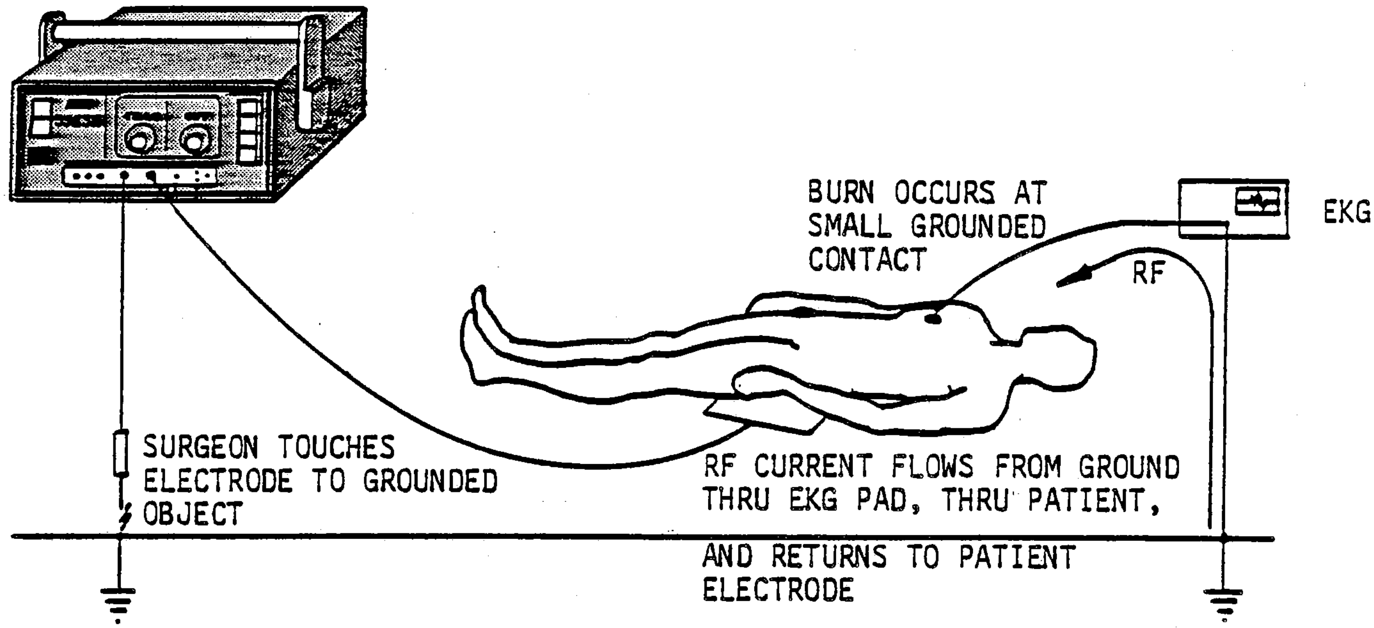


FIGURE 5

Surgeon sparks electrode to ground with an isolated electrosurgical generator. A burn could potentially occur at small, grounded contact points such as the ECG pad shown here.

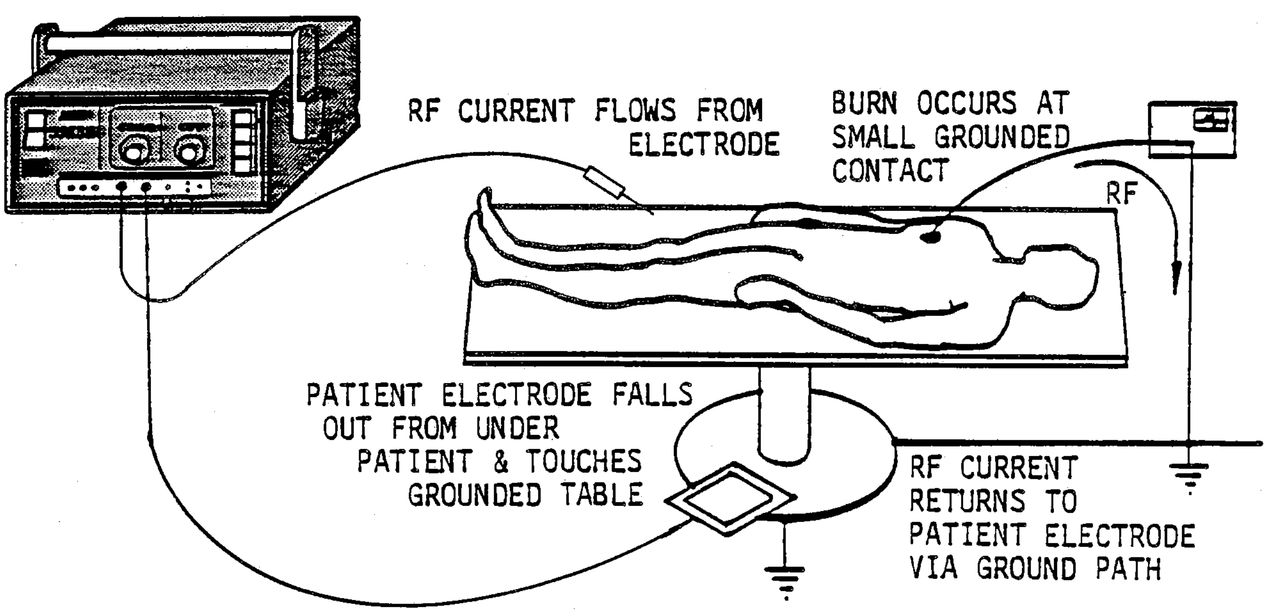


FIGURE 6

If the patient return electrode of any existing electrosurgical generator, not using a REM-CoHesive System, falls out from under the patient and makes contact with a grounded object such as the table pedestal shown here, a burn could occur at any small, grounded patient contact point (just as in Figure 3).

Unfortunately, it is an accepted procedure to hold bare metal hemostats in one's hand while an assistant touches the hemostat with the active electrode. Any small hole or weak spot in the gloves will result in a shock.

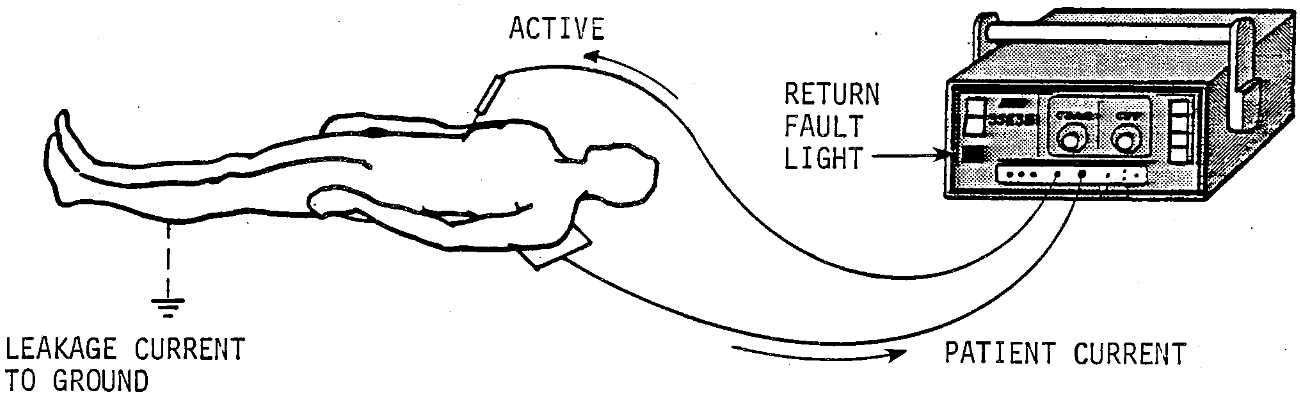
Measuring The Degree of Isolation of an Isolated Output

Since it is not possible to make a perfectly isolated generator, the quality of the isolation must be specified. Valleylab does this by measuring the maximum RF leakage current which can flow between the patient terminal and ground at maximum settings with a typical three meter long active cable plugged into the generator with no load on the generator output. That is, the active electrode is not touching any tissue or other resistive load. This simulates the worst case in the operating room. Other manufacturers measure RF leakage without plugging in an active lead which gives a proportionately lower leakage current. A well isolated generator, such as the Valleylab SSE2L, has less than 150 milliamperes RMS leakage current to ground. The isolated bipolar output of the SSE3B also has less than 150 milliamperes RMS RF leakage to ground.

THE SSE3B PATIENT ELECTRODE SAFETY SYSTEM - THE BALANCED OUTPUT

The SSE3B is equipped with a unique patient electrode monitoring system which combines the significant advantages of both the isolated and grounded systems. Technically, the patient electrode has a low impedance to ground at radio frequency, but the RETURN FAULT circuit prevents significant currents from flowing through this low impedance. It does this by measuring the current flowing from the active and comparing it with the current returning from the patient plate. If these two currents are not balanced, the RETURN FAULT circuit will conclude that significant currents are flowing in the ground path and that the patient plate is not functioning properly. The SSE3B RETURN FAULT circuit does not look for a threshold current, which it defines as "dangerous" but rather looks for a certain proportion of the current which is not accounted for in the patient plate cable. Thus the ground monitor is approximately as sensitive to a faulty patient electrode circuit at a setting of "1" as it is at maximum power.

The purpose of the balanced output is to prevent DESICCATION burns at small, grounded skin contact points. Its purpose is not to prevent electrosurgery at the active electrode, nor to detect fault conditions which MIGHT cause a burn; the system responds only to ACTUAL current flow that might be a threat and shuts off the generator before harm can occur. One fundamental assumption that the design makes is that the impedance between the patient's body and ground will be low enough to prevent FULGURATION at a small, grounded contact. In practice, this assumption has been proven valid because even with tiny infants, monitoring and anesthesia equipment as well as the surgeon's hands, keep the patient to ground impedance below roughly 1500 ohms.



RETURN FAULT MONITOR SYSTEM ON SSE3B

Although the SSE3B monopolar output is grounded at radio frequency, it is isolated at low frequencies, including DC and 60 Hz. This gives the same protection from 60 Hz shock that an isolated output offers in the event that an insulation failure in some other piece of equipment, applied an AC power line voltage onto the patient's body. The patient terminal of the SSE3B will accept less than 150 microamperes of 60 Hz current if 140 volts AC is applied to the terminal. This passive leakage current rating is called the "sink leakage". Sink leakage is a relatively unimportant safety parameter because the patient is probably grounded at some other place on his body.

Because the patient electrode is grounded by a coupling capacitor, it is tempting to call the system "grounded". However, the return fault system only allows small currents to pass through this coupling capacitor and will not allow large currents. The currents that are allowed to flow through the grounding capacitor are the same order of magnitude as the leakage currents to ground that are present with isolated electrosurgery.

Specifying the Sensitivity of the SSE3B Balanced Output

In isolated electrosurgery the RF leakage to ground is specified in an attempt to measure the degree of isolation from ground. Current is measured because the threat to the patient from RF leakage is proportional to the square of the current. This is because power (heat delivered per second) is proportional to the square of the current.

In engineering terms, the RF leakage from an isolated output behaves as a "current source."

In contrast the SSE3B monopolar output is virtually grounded. That is, the patient electrode is connected to ground with a low impedance (low resistance to RF current). By having the patient electrode grounded, the theoretical problem of RF leakage is avoided, since currents shouldn't be able to flow from one grounded object to another. Theoretically, two things that are both grounded, should have the same voltage, zero. As pointed out earlier, grounded generators aren't perfect either because technically, the patient electrode can never be perfectly grounded and there will always be some voltage difference between the patient electrode and ground. It is this voltage difference with a grounded generator that drives currents to ground through the small, grounded contact points. As explained earlier, this phenomenon is called "current division". Given even a very small voltage, the current could be huge if the resistances were very close to zero. (Ohm's Law is Voltage = Current X Resistance.) Consequently, it is not very appropriate to measure the short circuit (zero resistance) current between patient and ground because this could be quite large and still not hurt the patient. In engineering terms, the patient to ground "leakage" with a grounded generator is a "voltage source."

The threat to the patient with a grounded generator is really the patient to ground voltage, since in this case the power (heat delivered per second) will be proportional to the square of the voltage, rather than the square of the short circuit current. Therefore we specify the maximum voltage which can appear between the patient jack and ground as less than 30 volts RMS. This is the most voltage ever available to drive a current through a small grounded contact point on the patient's skin.

In normal operation currents can flow in grounded objects by another mechanism other than current division. Capacitive coupling between the active cable and ground can also cause such currents. Any time two pieces of metal are separated by insulation (plastic, air, etc.) they comprise a capacitor. The electric field between the two pieces of metal, say the active cable and the grounded table, can cause radio frequency currents to flow in the opposite metal piece. This active to ground capacitance is measured in picofarads. The RETURN FAULT circuit is set at the factory to trigger at 120 picofarads which takes into account all routine procedures. The maximum current that the RETURN FAULT circuit will allow is 250 ma at maximum settings and just under 120 picofarads capacitance. The circuit could easily be set for any capacitance, but to allow for typical active to ground capacitances seen with colonoscopes, dual pencils, or laparoscopes, this is felt to be a good compromise. This is quite comparable to the RF leakage from a well isolated generator (for example, the Valleylab SSE2K) with the same active to ground capacitance.

Since the RETURN FAULT circuit must respond to a fault condition, it must do so quickly to prevent injury. The response time is specified as less than 70 milliseconds and is typically 60 milliseconds or less. Suppose that the maximum output of the generator, 300 watts, were passed into tissue in a fault condition for 70 milliseconds in a desiccation mode. 300 watts for 70 milliseconds is 21 joules of heat energy.

The worst case would occur with a small patient with negligible capacitive coupling to ground and a single, small grounded contact point. Since there are 4.19 joules per calorie, this heat energy would raise the temperature of one gram of tissue about 5°C.

A burn would be most likely when the small grounded contact point is very small. Fortunately, the contact impedance rises as the contact area becomes smaller and smaller. A needle tip in contact with moist tissue has less than about 1400 ohms impedance and therefore such a fault can be detected by the circuit which responds to impedances less than 2000 ohms. Such high contact impedances also limit the current that can flow during the 70 milliseconds response time so that, in practice, there is typically less than about 0.5 calories of heat imparted to the tissue. This is about enough to raise a gram of tissue about 0.5°C. Because the heat is confined to the needle tip, the temperature rises enough to feel a twinge of warmth on wet skin, but no desiccation necrosis occurs.

Practical Capabilities of the SSE3B Safety System

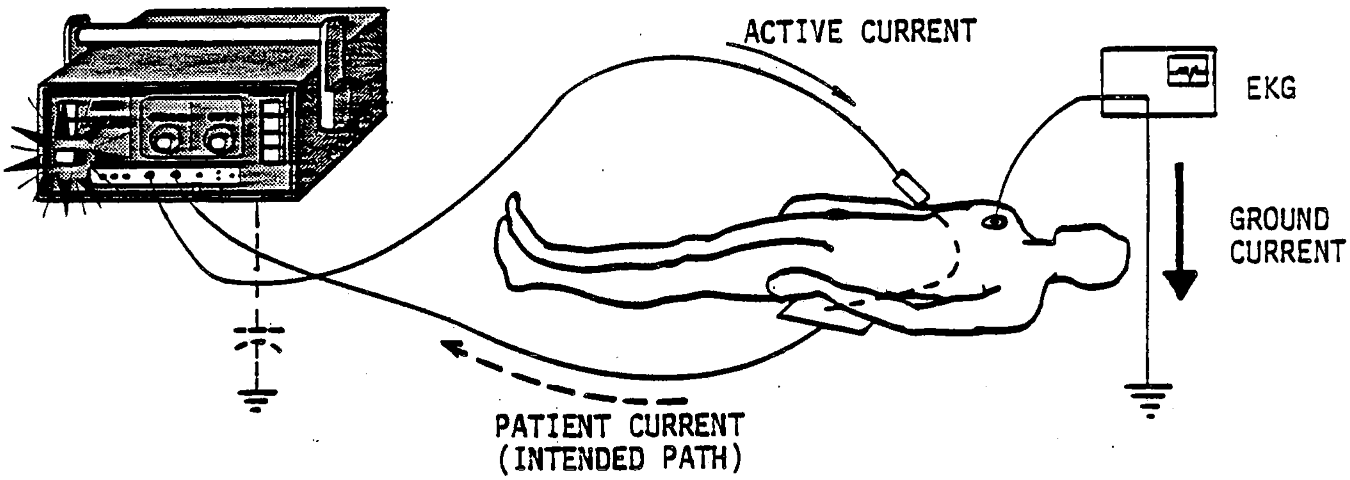
The SSE3B Balanced Output system uses the electrosurgical current to detect an improper patient electrode. When the surgeon attempts to activate the generator, the Balanced Output system will detect a problem and disable the generator before any harm can occur.

The CUT and COAG lights are also part of the SSE3B safety system since they indicate when the generator is actually putting out useful electrosurgical power. The SSE3B safety system will detect the following potentially dangerous conditions, provided that dangerous ground currents would actually result.

1) Patient electrode cable not plugged into generator.
2) Broken patient electrode cable.
3) Patient electrode not touching patient's skin.
4) Active electrode touching grounded object.
5) Excessive coupling from the active electrode to ground (in excess of 120 pf capacitance or less than 2000 ohms impedance between active and ground open circuit).
6) Excessive resistance in the patient plate circuit. More impedance (resistance to current flow) in the path between the patient's body and the "patient" connector on the SSE3B than there is between the patient's body and ground means a faulty patient connection.
7) Open circuit (broken) active cable.
8) Insufficient patient electrode area with 2 - section CoHesive electrode. (When equipped with REM.)

When any one of the first six faults causes excessive ground currents, the "Return Fault" indicator will illuminate, the digital power readout will blank, and the generator will not operate. To make the generator operate, the fault must be corrected and the RETURN FAULT indicator reset by pushing the indicator button.

BALANCED OUTPUT
DETECTION OF CURRENT DIVISION



Current will divide among all ground points touching the Patient. Excessive current may flow through small, grounded contacts close to the site of surgery.

<u>The CUT and COAG Lights as Safety and Check-Out Indicators</u>

To detect a fault in the ACTIVE circuit, or to find out if the generator is actually working, the CUT and COAG indicator lights may be used. The lights will only illuminate when there is a useful radio frequency output on the output jacks. You can test this by turning either the CUT or COAG power controls to zero and keying the generator. The lights will not come on until the control is advanced to at least "1", indicating that there is no significant RF output below this setting.

Suppose the patient electrode seems to be applied properly, the RETURN FAULT light is OFF, but the generator does not operate. If the CUT or COAG light illuminates, you may conclude that the problem is a defective (open circuit) active cable or electrode and the current cannot complete the path from the generator to the active electrode. (Fault condition #7 as listed above.)

Testing The Balance Output Safety System

The Balanced Output System can be tested by pressing the red RETURN FAULT indicator inward. The indicator should light and this verifies that the light bulb is intact. If one attempts to activate the generator while the indicator is pressed, the generator should not activate, as indicated by no audio tones and no CUT or COAG indicator lamps. This verifies that most of the Balanced Output circuitry is operational. The only way to test the entire Return Fault system is to actually simulate a fault condition. The simplest way to do this is to set either power control to any setting from 1 1/2 to 10, activate the generator, then touch the activate electrode to a grounded object, such as the aluminum handle of the SSE3B. The indicator should light, the generator should deactivate, and the RETURN FAULT indicator should stay lit until the fault is corrected and the indicator is reset by pressing it inward.

The SSE3B Balanced Output system is the best monopolar safety system ever devised. However, there are certain faults it cannot detect and it is up to the operating room staff to insure that the following unsafe conditions do not occur:

1. *INSUFFICIENT PATIENT ELECTRODE AREA*

   A patient electrode which has only a small area, say 1 to 20 cm^2, in good electrical contact with the patient's skin appears the same electrically as a properly applied patient electrode, which has at least 100 cm^2.

2. *CARELESS PLACEMENT OF ONE (OR BOTH) OF TWO ACTIVE ELECTRODES*

   For example, if two active electrodes are being used simultaneously, perhaps in a coronary bypass procedure, both electrodes must be guarded carefully. When one surgeon is done with an electrode, it must be returned to an insulated holster (E2400) to be certain that it cannot touch the patient accidentally.

3. *DAMAGED INSULATION ON THE ACTIVE ELECTRODE OR CABLE*

   For example, if the active cable has been damaged and bare metal is exposed, sparks can jump from the metal to the patient if the cable is laid against the patient's skin.

4. *PATIENT ELECTRODE NOT CONTACTING PATIENT'S SKIN BUT MAKING CONTACT WITH GROUND*

   If the patient electrode falls away from the patient's skin and makes electrical contact with a grounded object such as the operating table, the RETURN FAULT circuit will not be able to distinguish between the current flowing through the ground path and that returning via the patient electrode cable.

5. *DO NOT TOUCH THE ACTIVE ELECTRODE WITH A BARE FINGER AS A DEMONSTRATION OF THE RETURN FAULT CIRCUIT*

If the impedance between the demonstrator's body and ground is less than 2000 ohms (resistive, capacitive, or inductive at 750 KHz) the RETURN FAULT detector will not allow the generator to activate. However, if the impedance to ground is MORE than 2000 ohms but less than infinite, the generator will activate and some current will flow. In the COAG Mode especially, there might be a small spark to the finger which could inflict a painful burn. Fortunately, this situation is not representative of possible fault conditions which might be encountered in surgery. The operating room situation which most closely approaches this is the practice of touching the active electrode to a bare metal hemostat held by an assistant. If the hemostat is not in good electrical contact with the patient, a spark may jump through his glove to his hand, giving him a small but painful burn.

CONTRASTING THE SSE3B BALANCED OUTPUT WITH ISOLATED ELECTROSURGERY

Valleylab generators, before the SSE3, have had simple isolated outputs which offer excellent patient electrode protection with a minimum of electronic complexity, provided the OR staff understands how to use it. The SSE3B Balanced Output offers the following safety improvements over a simple isolated system:

Safety Improvements Over the Isolated Output

1) *ACTIVE ELECTRODE TOUCHED TO A GROUNDED OBJECT*
With a simple isolated generator, currents could flow to the patient's body through small grounded contact points, possibly causing burns. Fortunately, this situation has always been extremely unlikely, since grounded objects in the sterile field are unusual. The SSE3B RETURN FAULT system will detect this problem and prevent current from flowing.

2) *EXCESSIVE COUPLING FROM THE ACTIVE ELECTRODE TO GROUND*
With an isolated generator, using multiple active electrodes simulataneously or using a grounded colonoscope degrades the isolation by coupling RF current to ground. This current is a threat to the patient because it may enter his body via small, grounded contact points on its way to the patient plate. The SSE3B patient plate is ground referenced, so capacitively coupled current from the active is not a threat to the patient.

3) *EXCESSIVE RESISTANCE IN THE PATIENT ELECTRODE CIRCUIT*
If there is more resistance in the patient electrode circuit than there is between the patient's body and ground, the RETURN FAULT monitor will recognize this as abnormal and disable the generator. This could occur if the patient electrode were only touching the patient's body at one small point, (generally much less than 1 cm2 contact), or if a connector were defective or loose.

These faults will be detected if the impedance (resistive or capacitive) between the patient's body and ground is lower than the resistance across the loose connection in the patient circuit.

4) *METAL-TO-METAL SPARKING IN THE PATIENT CIRCUIT*
With an isolated system output there is no mechanism to guarantee that the voltage between the patient connection and the patient's body and ground is held low enough to be sure that sparking could not occur in a loose connection in the patient electrode circuit. As explained in Section 1, metal-to-metal sparking gives rise to low frequency current components which can cause neuromuscular stimulation. The balanced output patient connection is coupled to ground and it is quite unlikely that this voltage could become high enough to cause sparking and subsequent neuromuscular stimulation. The RETURN FAULT circuit will detect a loose connection as soon as current tries to flow to ground along some other path.

E. *LIMITATIONS OF THE SSE3B BALANCED OUTPUT SYSTEM IN COMPARISON WITH ISOLATED ELECTROSURGERY*

1. *The Monopolar Output Cannot be Used for Bipolar Instruments*

The RETURN FAULT system may interpret the bipolar instrument as an improper patient electrode and disable the generator. Bipolar instruments must be used with the SSE3B bipolar output which is a conventional isolated output.

2. *Do Not Touch the Active Electrode With A Bare Finger as A Demonstration of the Return Fault Circuit*

With isolated electrosurgery it is common practice to demonstrate the safety of the isolated output by first pulling out the patient electrode connection, and then activating the generator while touching the active electrode with a bare finger. Since a conventional grounded generator would burn the finger if the same demonstration were tried, the demonstration is a favorite for salesmen and hospital engineers.

With the SSE3B the demonstration will still be successful provided that the impedance between the demonstrator's body and ground is less than 2000 ohms. Moreover, it will not be necessary to remove the patient electrode from the generator before making the demonstration. However, if the impedance is over 2000 ohms but less than infinite, a small spark may fulgurate the finger tip and cause a small but painful burn. It is tempting to compare the safety of the SSE3B with that of an isolated SSE2 by measuring the maximum power available from the active electrode with the patient cables pulled out from both generators. This comparison is not valid because the purpose of the RETURN FAULT circuit is not to prevent electrosurgery at the active electrode.

The purpose is to prevent desiccation burns where small, grounded contact points are touching the patient's skin. The isolated system signals a problem in the patient circuit by not allowing electrosurgery at the active electrode. If the SSE2 patient electrode is contacting the patient's body and the patient is coupled to ground, (as he almost invariably is) then very large currents can flow from the active to ground even though the generator is well isolated. With the RETURN FAULT system, ground current flow is limited to a low level which is a function of the power settings.

TROUBLE SHOOTING A RETURN FAULT INDICATION

If the RETURN FAULT light trips during surgery and there is no obvious failure in the patient circuit, check the following items:

1) *Look for intermittent connections on the patient cable. This is most likely at the junction between the patient cable and the patient electrode. This is especially troublesome with some of the disposable stick-on patient electrodes now on the market.*

2) *If a stick-on patient electrode is used, check to see that all of it is firmly applied to the skin and not "tented" so that only the adhesive border is in good contact with skin. It is also conceivable that a dried out gel pad may have been applied to the skin. If this is suspected, replace the stick-on eléctrode. Never try to re-apply an adhesive patient electrode.*

3) *Look for excessive coupling between the active electrode and ground.*

   a) *If more than two active electrodes are plugged into the SSE3B, the RETURN FAULT will trigger.*

   b) *If the active cable is wrapped around a grounded metal object such as the SSE3B handle, this extra capacitive coupling to ground will be interpreted by the RETURN FAULT circuit as a threat to the patient or surgeon. If it is necessary to coil up extra active cable, secure the coil of wire with a rubber band and allow the coil to hang in space. In short, keep the active cable as far from grounded objects as possible.*

   c) *If the active accessory is a resectoscope, then a short circuit inside the scope could divert active current into the metal frame of the resectoscope. This current may go to ground through the surgeon's hands and body. This current has been known to burn the urologist, so the RETURN FAULT circuit is not just for protection of the patient. The solution, of course, is to have the resectosocope inspected and repaired.*

   d) *If the active accessory is a colonoscope which is grounded through the light source, it is quite likely that the RETURN FAULT circuit will not allow the generator to be activated until the colonoscope has been inserted in the patient.*

After insertion into the colon, there is usually enough coupling between the colonoscope and the patient's body to lower the ground currents so that the RETURN FAULT circuit will allow the operation to proceed. If not, the "S-Cord" discussed in Section 2 is the only solution.

4) *Look for current division as another source of ground currents which may be tripping the RETURN FAULT circuit.*

   a) *Check for current division by looking for grounded objects in contact with the patient at points closer to the site of surgery than the patient electrode. For example, if during a laparotomy the patient electrode were on the upper arm and a grounded ECG pad were on the back or shoulder, the ECG pad could be carrying as much current to ground as the patient electrode. This could be corrected by moving the patient electrode closer to the site of surgery.*

   b) *A common example of current division occurs in the use of grounded NEUROSURGICAL HEAD FRAMES. In this case it is not practical to move the patient electrode closer to the surgery. The only good solution is to modify the headframe so that it is not serving as a patient electrode. If necessary, and if everyone understands the risks, the headframe can be wired directly to the patient electrode by a shunting cable and clamp.*

5) *If the cause of the RETURN FAULT triggering cannot be found, the circuit should be checked out by the procedure outlined in the Service Manual.*

ELIMINATING THE SMALL, GROUNDED CONTACT POINTS

Another approach to the problem of patient burns is to eliminate all the small grounded points which are the focus of the problem. Large, well gelled ECG pads can be used to disperse the current. A good, gelled ECG electrode, such as the Ferris Red-Dot with an area of .3 cm2 can disperse 100 ma for at least a few seconds without causing a burn. Becker, et al, state that 100 ma/cm2 can be tolerated for about 10 seconds before a burn occurs. [3] This is in good agreement with our findings. Very small electrodes, especially needle electrodes, should never be used.

All patient monitoring equipment should be isolated from ground whenever possible. Unfortunately most "isolated" ECG instruments presently sold are well isolated only at 60 Hz. At RF frequencies the impedence may be only a few hundred ohms. [7] As Finlay, and others, point out, even a few hundred ohms is better than zero ohms. [4]

Rectal or esophageal thermometers should not have bare, grounded metal tips but should be encapsulated in plastic. It is also practical to put RF chokes in series with the ECG, plethysmograph and telethermometer leads. This will convert the leads to a high impedance at RF frequencies but leave their low frequency characteristics unaltered. Finlay, et al, recommend RF chokes in the range of 22 to 100 mH. [4]

Hall, et al, say that 3.3 mH inductance is adequate to prevent burns. [9] It is clear that any extra impedance in the grounded leads will help decrease the current and prevent burns. Finlay warns that using inductors in the leads may affect the performance of an ECG and the ECG manufacturer should be contacted before attempting these modifications.

Although current division is limited by the Balanced Output circuit, it doesn't hurt to take precautions to prevent its occurrence. First, the patient electrode should be as close to the site of the surgery as possible. A small, grounded skin contact point which is located in between the surgery and the patient electrode will take a larger percentage of the current than it will if located distal to the main current path.

SUMMARY

There is no perfect solution to patient electrode safety, but the SSE3B Balanced Output comes closer than any other system. Bipolar instruments used with a well isolated generator are the best existing solution, since the current doesn't pass through the patient and the patient electrode is eliminated. Unfortunately, bipolar instruments are only usable in a minority of procedures.

Isolated electrosurgical generators are not perfect because they can never be completely isolated. Grounded generators are not perfect because the patient plate cannot be truly grounded. the SSE3B system attempts to combine the virtues of isolated and grounded systems. With a conventional grounded generator, there is a possibility of current division causing current to pass through small, grounded contact points on the patient's body. Unlike a conventional grounded generator, the Balanced Output system limits the current which can travel to ground by current division by sensing when more current is leaving via the active lead than is returning via the patient electrode. Rather than simply limiting the ground path current to some arbitrary total amount, the Balanced Output is sensitive to the proportion of current returning through ground. Regardless of what the generator design may be, the use of large ECG electrodes, proper patient electrode positioning, and minimum power settings will prevent patient burns at small grounded skin contact points.

The best safety system is of course a well trained, vigilant OR team. Even the most primitive grounded generator can be used safely if the patient electrode cable is checked religiously and the patient electrode is positioned properly and rechecked every time the patient is moved or the patient cable is disturbed.

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SECTION 5

PATIENT RETURN ELECTRODE RECOMMENDATIONS

When using monopolar electrodes, a patient electrode is ALWAYS required. The patient electrode serves as a means for the current to leave the patient's body safely and return to the generator. The patient electrode must be considerably larger than the active electrode so that the current density is kept low and no significant heating occurs. Because the return electrode is not grounded at low frequencies, we refer to it as a "patient electrode" and not as a "ground plate". By not calling it a ground plate, we hope to avoid having people make the assumption that the patient electrode is a convenient ground for ECG's or other purposes.

The skin contact area required for safe patient electrode operation is somewhat controversial. The old (1970) NFPA Manual 76 CM recommended 1.5 watts of generator power per square centimeter of skin contact. This is admittedly quite conservative, but it is not an inordinate or totally inconvenient size for a patient electrode. Moreover, if this guideline is followed, one need never worry about the conditions of the skin under the return electrode, the blood flow through the tissue, or the length of time the current is applied. It seems to be true that if this guideline is exceeded by a factor of two and high currents are prolonged indefinitely, eventually the patient electrode will begin to behave like an active electrode and burn the patient regardless of how well it was applied, blood flow, or other factors. The main factor which is the saving grace of small patient electrodes is that the highest peak current which can be obtained at a given power setting only lasts for a second or two at the beginning of a cut or fulguration. Even though it is rational to expect these currents to drop to a safe level, it is desirable to have the extra safety of a large patient electrode in case it is improperly applied or defective in some way.

Valleylab makes three single section patient return electrode systems which can be used with the SSE3B. They are:

THE E7001-1[R] PERMANENT PATIENT PLATE

This is a permanent, stainless steel plate which connects to the patient cord with a screw-on connector mounted at the corner of the plate. The cord has a plug at the generator end and plugs into the patient jack. The patient jack on the SSE3B is recessed to provide good strain relief in case the cord is pulled inadvertently. The wire insulation is clear so it may be inspected for defects and has two conductors for extra security. The connector which fastens the cable to the patient plate has a threaded sleeve which only makes contact with the patient circuit when the plate is secure. If the connector becomes free during a procedure, the metal sleeve cannot serve as a substitute patient plate because it has no electrical connection with the wiring in the cable.

The E7001-1 is designed to go under the buttocks, thigh, shoulder or anywhere that gravity can insure an adequate contact area. It has over 516 square cm (80 square inches) of surface area of which at least half can be touching the patient if it is applied properly.

We recommend the use of LectroGel[R] or some other conductive paste to insure that the skin is wet and that the plate is in good electrical contact with the skin. Conductive gels are discussed in more detail at the end of this section.

THE E7501-1 LECTROPLATE[R]

The E7501-1 LectroPlate is a disposable patient plate, similar in size and application to the E7001 discussed above. It is made from cardboard which is covered with non-anodized aluminum foil. The cable for this disposable plate is the E0501-1 which is similar to the E0009 but has a clamp which locks the cable to the patient plate by means of large plastic teeth which go through a square hole at one end of the disposable plate.

Like the permanent patient plate, the E7501-1 is designed for use with a conductive gel such as LectroGel, E5501. Because the LectroPlate is flexible, it is possible to wrap it around a leg and tape it in place. If used with gel, this scheme is acceptable electrically, but the user should be aware of the possibility of thromboembolism due to restriction of the venous return.

The LectroPlate can be cut with scissors to provide a smaller plate of almost any size or shape desired. This is all right, but we recommend that the guideline of 1.5 watts per square centimeter of skin contact be followed and sharp, ragged foil edges be carefully removed.

THE E7502-1 LECTROHESIVE[R] PATIENT RETURN ELECTRODE

For those procedures in which the patient is likely to be moved frequently or where it is not practical to place a patient plate under the patient, the LectroHesive patient Return Electrode is the solution. It has a pregelled electrode with an effective area of at least 20 square inches (130 square centimeters) of contact area. The patient electrode is backed with a large sheet of foam covered with adhesive so that the skin adhesive completely surrounds the gelled electrode. The LectroHesive is disposable and can be used for all routine procedures.

The LectroHesive system relies on its adhesive to hold the gelled electrode to the patient's skin. If the pad is applied improperly, there may be insufficient area actually touching the patient. For example, if the LectroHesive were placed on the flank, and later the torso were flexed in the direction of the LectroHesive, the gel pad may fold away from the skin and lose much of its contact area with the skin. After removing the LectroHesive from the package, connect the semi-disposable patient cable to the LectroHesive and the generator. A permanent adapter (E0504-1) is needed to connect the semi-disposable cord to the generator.

For those who prefer, the E0504 also comes in a locking version which cannot be removed from the generator and thrown away accidentally. It is easier to attach the cable before removing the protective plastic tray. After removing the tray it is vital to inspect the gel saturated pad to be certain it is wet. It should be touched with a dry finger to be absolutely sure that the gel has not dried. The LectroHesive can be applied to any smooth, curved, hairless area of skin close to the site of surgery. This can be the arm, thigh, abdomen or anywhere good surface area contact can be assured during the procedure.

Note the application illustration on the LectroHesive package. A large wall chart is available which gives detailed advice on the use of the LectroHesive Patient Return Electrode.

In case of suspected patient circuit problems, do not assume that the gel pad is in good contact with the skin just because it looks right from the outside. Remove the LectroHesive from the skin and replace it with a fresh pad. NEVER reapply a used pad.

NEVER attempt to cut the LectroHesive down to a smaller size for pediatric use! It is possible to set small infants down on the gelled pad without trying to wrap the LectroHesive around them. If contact with the adhesive is not desired, or the infant is extremely small, cover the adhesive surfaces with towels or drapes before placing the infant on the gelled surface.

<u>LectroGel and Other Conductive Pastes</u>

All Valleylab patient electrode systems are designed for use with conductive pastes or gels. LectroGel consists of Ringer's Solution at about 9% concentration, texturizing agents, preservative and water.

In order to make a paste which is as conductive as possible, high concentrations of salt ions and water are required. All conductive gels have these ingredients. As far as we know, there is no such thing as a non-drying gel because the water will evaporate out of any paste exposed to the air. Some gels contain glycerin and may look wet after hours of exposure to the air but will have lost their water and will no longer be sufficiently conductive.

<u>Use of The Patient Electrode as "Ground Reference" for ECG Monitors</u>

Because the SSE3B patient electrode is not grounded at low frequencies, this practice is not recommended. For this reason none of the Valleylab patient electrode systems are equipped with connectors for attaching ground wires. If such a ground wire were attached to the patient electrode and the patient electrode were to come free from the patient's skin, the remainder of the ECG leads would probably serve as substitute patient electrodes, depending on the internal impedance of the ECG unit to the 750 KHz current. If such a reference is needed for the ECG, it is best to put on a separate ECG pad and keep the electrosurgical wiring separate.

When using the SSE3B with an endoscope which has a high capacitance between the active electrode and the metal body of the endoscope, it is sometimes desirable to connect the endoscope to the patient electrode to be certain that the leakage current goes to its destination safely. This is discussed in detail in Section 2. However, it is best to avoid these connections if the leakage current is small or if it can be handled in another way. If such ground wires must be attached to a Valleylab patient electrode, we recommend utilizing the E0507 Multiple Return/"S" Cord Adapter which accepts a standard male banana plug.

SECTION 6

THE SSE3B PATIENT ELECTRODE AREA MONITOR SYSTEM AND TWO-SECTION ELECTRODES

Valleylab has recently introduced an improved Return Electrode Monitor (REM™) System. This monitor employs a two section patient electrode, catalog number E7505. REM circuitry measures the impedance between the two sections of the plate and the patient's body to determine the actual contact impedance with the patient. Both sections of the electrode provide return paths for RF currents. The REM system operates in addition to the return fault monitor system to ensure that RF currents pass through an adequate surface area electrode and that little diversion to other grounded points occurs. Either system will disable the generator and signal a fault condition both audibly and visually.

The REM patient electrode is a pregelled adhesive pad with two sections 6.5 cm. by 9 cm., with 58.5 cm2 surface area for RF currents. Its site preparation and application are similar to the E7502 LectroHesive electrode discussed in the preceding section. The E7505 is supplied with a two wire cord and connector to plug into the right hand patient electrode connector. The application site should be close to the surgical area and have a minimum of adipose tissue. It should be shaved or depilitated if hairy. It should be clean and free of scaling epidermis.

The specific installation instructions pertinant to the two section pads are as follows:

1. Remove the electrode from the protective pouch leaving the tray attached to the electrode.
2. Attach the cord to the SSE3B, switch power on.
3. Verify that the REM audio and visible alarms go on. This indicates proper operation under open pad conditions.
4. Check that the electrode gel is moist.
5. With the patient in the final position for surgery, remove the tray and attach the electrode.
   a. First adhere the adhesive surrounding the cord attachment.
   b. Next adhere the borders, taking care that the conductive surfaces are in good contact with the skin and not 'tented' out of position. The REM alert should clear at this time indicating acceptable electrical conductivity thru the patient's body.
   c. Gently massage the conductive areas of the electrode to insure the best contact.

6. *Installation is now complete and the SSE3B can be switched off until needed.*

7. *Use caution when moving the patient and check the electrode after each movement.*

The SSE3B equipped with REM can be used with other patient electrodes having appropriate connectors. A pin on the connector actuates a switch within the SSE3B to inform it of the type of electrode. With a single section electrode, the REM System still monitors the pin to pin resistance at the connector and is capable of detecting broken wires or connectors in the patient electrode cable. It is not able to monitor the patient contact area in single section electrodes.

The REM System ensures adequate patient contact area by measuring the resistance between the two sections of the pad. Two limits are employed, one on the resistance value (20 to 135 ohms) and the second on the change in resistance (less than 20% increase). The SSE3B microprocessor periodically updates the REM resistance and compares the new value to the prior one. A 20% increase or a value outside the 20 to 135 ohm range will turn on the REM alert and disable the generator. If a single section patient electrode without the connector pin is used, the microprocessor checks the REM resistance for a 20 ohm value only. A pin to pin resistance above 24 ohms will trip the alarm.

The REM system complements the RF return current measurement by ensuring proper surface contact area. Both sections of the pad and both connector pins carry the RF currents. The pin to pin resistance measurement is performed continuously, even when the generator is keyed. The REM System is electrically in series with the RF return fault monitor as shown schematically in Fig. 7. The measurement uses small currents at 140 KHz and will not produce nerve stimulation or interfere with ECG monitors. The alarm levels have hysterisis so that small changes in resistance will not cause intermittent alarms.

The Valleylab REM/CoHesive™ System with return current and contact area measurement is the finest patient electrode monitor available. It will alarm under all of the following conditions:

1. *Patient electrode not plugged into generator.*

2. *Broken patient electrode cable.*

3. *Patient electrode not in contact with patient.*

4. *Reduction of patient electrode contact area due to movement, loss of adhesion or drying of contact gel.*

5. *Active electrode with excessive coupling to grounded object.*

6. *Excessive impedence in the patient electrode cable.*

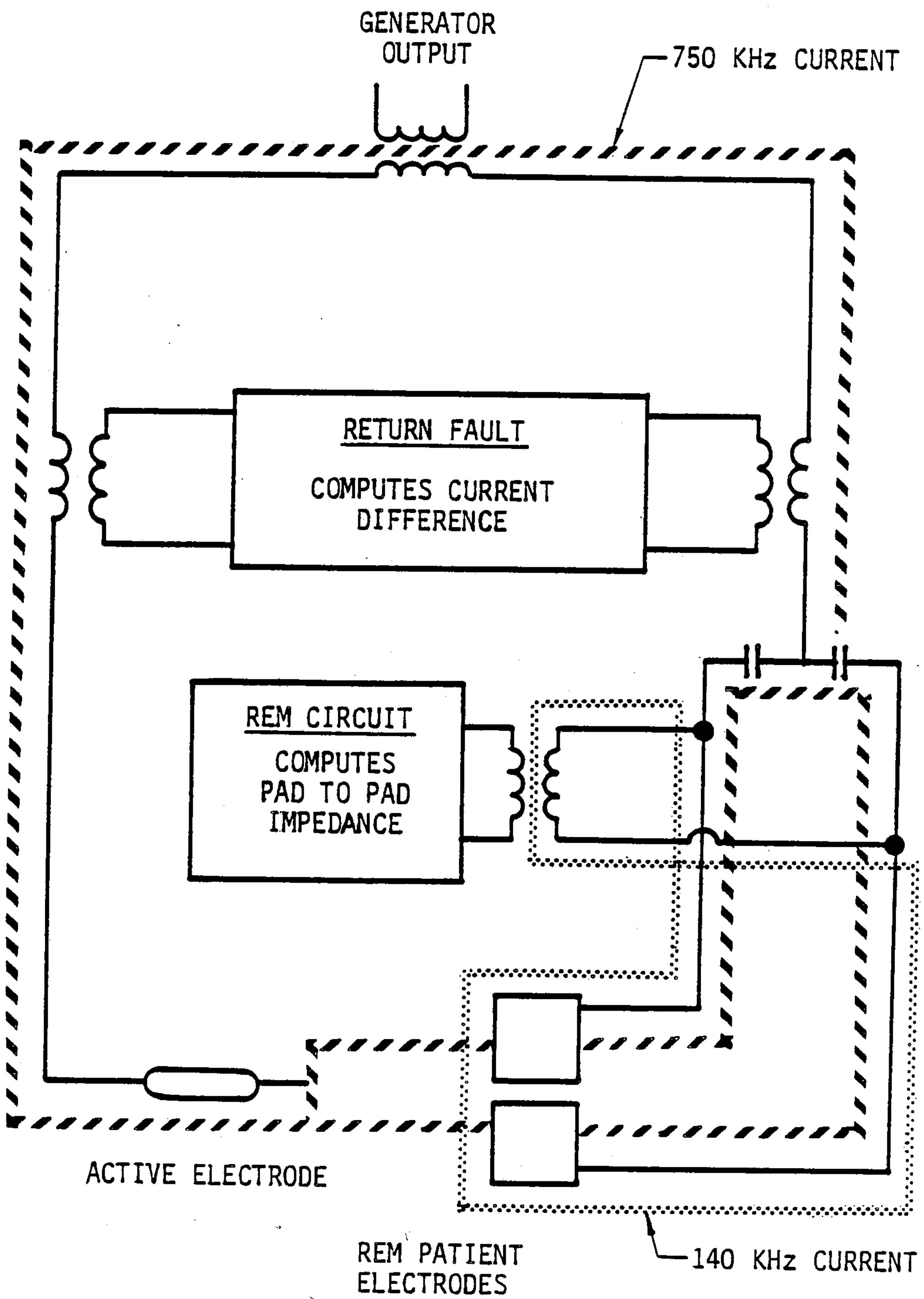


FIGURE 7
SCHEMATIC–REM/RETURN FAULT SYSTEMS

SECTION 7

INTERFERENCE TO MONITORING EQUIPMENT

Cardioscope Interference

Any time there is sparking to the tissue, either during electrosurgical cutting or fulguration, some interference with cardioscope monitors can be expected. The cardioscopes are sensitive to very low level, low frequency voltages amounting to millivolts. Electrosurgery exposes the patient to voltages thousands of times greater, but primarily at radio frequencies. In order to have a minimum of interference, first the ECG must reject all the high radio frequency components. Unfortunately, sparking produces lower frequencies as well. This was discussed in Section 1 with regard to neuromuscular stimulation. Since the ECG is designed to detect low frequencies, and since sparking in electrosurgery produces low frequencies, some ECG interference is inevitable. If there is no sparking in the circuit path, such as with desiccation, then there should be no interference. All the suggestions for eliminating neuromuscular stimulation are applicable since the cause is identical.

One of the ways that cardioscopes differ from each other is in their "common mode rejection." This refers to the ability of the ECG to reject all voltages which appear between all the ECG leads in common and ground. An ECG with good rejection will have less interference than one with poor rejection. Another difference between monitors is in their ability to recover after a low frequency, high amplitude insult. That is, if the electrosurgery produces a high level of low frequency voltage on the patient, the ECG input amplifier will be overloaded and may take many seconds to recover before a readable trace returns to the screen. A well designed monitor will recover almost instantly.

One common type of ECG interference occurs when there is a low level, 60 Hz (power line) voltage on the patient's body. This voltage is probably too low to be any danger to the patient, but may be detected by the sensitive ECG. Since the trace moves across the screen very slowly, the 60 Hz (60 cycles per second) voltage variations appear as a fine fuzz or blur on the trace. Once again, good common mode rejection in the ECG minimizes this problem because the 60 Hz voltages which appear on the patient's body are generally ground referenced. Interference of this type can be differentiated from the sparking interference discussed above in that it is continuous and not related to activating the generator. It may very well have nothing to do with the electrosurgery at all, since the 60 Hz voltage can come from many sources. A simple solution to this problem may be to ground the patient's body and thus eliminate the patient to ground voltage. Obviously the ground path needs to have a low impedance at all low frequencies, from D.C. to at least 60 Hz and preferably up to several thousand Hertz.

Every engineering decision has its trade-off. By grounding the patient electrode, ECG interference may well be reduced or eliminated in a given situation.

The trade-off is that the ground on the patient's body can serve as a "sink" for ground referenced voltages. Suppose some insulation on an electric power tool or some other appliance failed and resulted in power line voltage being applied to the patient's body. If the line voltage is ground referenced, that is, it is not an isolated power system, then currents can flow through the patient's body to ground. The currents will only harm the patient if they have a path to ground and the ground described above for the ECG can provide that path. The situation can be compared to poking one's finger into a light socket. If wearing dry tennis shoes, you may well avoid a shock. If you are standing in a flooded basement with salt water up to your knees, a serious shock is inevitable.

One situation in which the SSE3B could cause 60 Hz interference would be if the Powerite™ circuit, explained on page 104, was not being used and the metal chassis ground wire was broken. The Powerite circuit will detect a broken ground wire or improper power polarity, but can only be used with non-isolated power systems. If the ground wire is broken, the Powerite is off, and a ground referenced power source is used, then there are approximately 20 microamperes of source leakage available on the patient plate. (The U.L. and C.S.A. standards require less than 50 microamperes.) This leakage is NOT dangerous to the patient, but can produce a 60 Hz voltage which can blur the ECG trace. Obviously, the cure is to repair the SSE3B ground connection. Note that the fault in the chassis ground circuit can be in the generator, the power plug, or in the hospital wiring.

Another way the SSE3B can appear to be causing 60 Hz interference happens when an SSE3B is replacing an elderly grounded generator and a typical 60 Hz interference appears on the monitor scope. This interference is probably not caused by the SSE3B, but is the result of not having a grounded patient plate on the patient's body. With a grounded patient plate, the 60 Hz voltage between patient to ground is shorted out. This possibility can be tested by experimentally grounding the patient plate with a test wire. If the test ground eliminates the interference, ground the patient's body with a separate large, gelled ECG-type electrode. We do not recommend putting a ground wire on the patient plate because the RETURN FAULT safety system is defeated when the patient plate is grounded.

Electrocardiograph Interference

Electrocardiographs use a pen and paper chart read-out instead of the more common oscilloscope presentation. These monitors can have the same problems as the cardioscopes but the recording pens can be damaged by overloading the cardiograph. For this situation the SSE3B Blanking relay circuit provides shorting contacts whenever the generator is activated. These contacts can be used to turn off the amplifier or short out the input to the amplifier to prevent rapid pen excursions.

This circuit is usually not very successful with cardioscopes, unless the leads connecting the ECG blanking terminals on the generator are shielded and the ECG amplifier is shorted very close to its input. Longer leads act as antennae and will pick up more interference.

WHAT TO DO IF THE SSE3B APPEARS TO BE CAUSING ECG INTERFERENCE

First, what kind of interference is it? Is it continuous or does it occur only when the SSE3B is sparking to tissue? If it is continuous, does it take the form of a blurred trace or thickened trace? If it is continuous, it is probably 60 Hz interference and the following six suggestions apply. If interference only occurs when the generator is activated, the remainder of the suggestions apply.

Continuous Interference, Thickened Trace

1) *Check the chassis ground connection on the SSE3B. If the Powerite circuit is being used, it will detect any fault in the chassis ground so one can exclude a broken ground as the cause. The Powerite will also detect a defect in the hospital grounding system. If the operating room is equipped with an isolated power system, the Powerite cannot be used and the ground must be checked by other means.*

2) *Check all other electrical equipment in the operating room for defective grounds.*

3) *If the ground wires in the operating room are not electrically consistent, that is, they don't all go to the same grounded object, voltage differences can appear between two "grounded" objects. The ECG will respond to these voltages if they appear across the patient.*

4) *As a test, attempt to correct the interference by applying a test lead between the patient plate and ground. If the interference disappears, then a permanent solution to the problem can be devised by grounding the patient's body. As discussed earlier, we do not recommend grounding the SSE3B patient electrode.*

5) *Some types of ECG input amplifiers can be balanced to achieve optimum common mode rejection and will possibly correct the problem.*

6) *If two generators are being used on the same patient and only one of them is a Valleylab, it is possible that the other generator uses a 60 Hz signal in its patient plate alarm circuit. This 60 Hz signal could be the source of the interference.*

Interference Only When The Generator Is Activated

1) *Check all connections to the generator, patient plate, and active electrode to look for possible metal-to-metal sparking.*

2) *As a general rule, the interference will be greatest in fulguration with lesser amounts in cut and little or no interference during desiccation. The amount of interference can be reduced by using lower settings, but this may not be practical.*

3) *As a test, ground the patient plate with a test lead. If the interference lessens, it indicates that the ECG is responding to voltage between the patient and ground and may be improved by better common mode rejection in the ECG. Perhaps the input amplifier in the ECG can be rebalanced to lessen the interference.*

4) *When the generator is keyed but not touching the patient, there are no sparks in the circuit and there should be no low frequencies produced. Interference implies that the ECG is responding to radio frequencies.*

5) *Some manufacturers are offering RF choke filters for use in ECG leads. These filters reduce interference while the generator is activated. RF choke filters also make an electrosurgical burn at the site of the ECG electrodes extremely unlikely.*

6) *Check to be sure that the ground wires in the operating room are electrically consistent. That is, all grounded wires should go to the same grounded metal with wires that are as short as possible. If the ground wires go to different grounded objects, small voltage differences can appear. The ECG will respond to these voltages if they appear across the patient's body.*

7) *Although extremely unlikely, shorted blocking capacitors in the output circuitry of the SSE3B could result in ECG interference and neuromuscular stimulation.*

Interference To Line Isolation Monitors

The fact that some generators may trip line isolation monitors in the operating room has little to do with whether the generators are isolated or grounded. The line isolation monitor checks for excessive 60 Hz leakage between the chassis and earth ground. This current is measured in the power cord grounding wire which of course is a major path for RF current returning to the generator after being capacitively coupled to the grounded operating room environment. If the SSE3B generator trips the isolation monitor, it probably means that the monitor is overly sensitive to RF current and that the particular combination of active and patient cables had coupled RF to ground in such a way that it must return via the monitor.

Cooling

Natural convection cooled. No fan.

Indicators

The backlighted words "CUT"and "COAG" will be illuminated only when RF power is available at unit output connections.

High frequency COAG tone or low frequency CUT tone will sound when footswitch or handswitch is depressed.

Audible Mode Indicator Tones

Mode indicator tones 72 dBA at 30 cm (1 foot) maximum.
Adjustable external volume control.

Input power Source

	110V UNITS	220V UNITS
Nominal Voltage:	120 volts rms	220 volts rms
Regulation Range:	90-140 volts rms	190-280 volts rms
Operation Range:	85-140 volts rms	170-280 volts rms

Frequency 45-65 Hertz

Current		
Idle:	0.4 amperes maximum	0.2 amperes maximum
CUT:	10 amperes maximum	4.5 amperes maximum
COAG	4 amperes maximum	2.0 amperes maximum

Input Power		
Idle:	50 watts maximum	50 watts maximum
CUT:	600 watts maximum	900 watts maximum
COAG:	250 watts maximum	375 watts maximum

Line Regulation

Between 90 and 140 volts input, output power into a 300 ohm load will vary no more than 6% or 4 watts.

Weight 12.4 kilograms (27 lbs, 4 oz.)

Size
Height: 21.6 cm (8.5") handle up
Width: 33 cm (13.0") including handle
Length: 48.3 cm (19.0") including handle forward

Specifications subject to change without notice.

An Explanation of the Electrical Specifications

Output Waveforms:

The output waveforms differ somewhat between the monopolar and bipolar outputs but they do have several features in common. All output modes operate at a frequency of 750 KHz (750,000 cycles per second) and all are controlled by the same COAG, CUT, and BLEND controls. The bipolar output should not be thought of as a separate generator, but only as an additional circuit which modifies the basic monopolar output. Both monopolar and bipolar outputs are active ("hot") at the same time.

Monopolar Output Characteristics:

The monopolar output is optimized for sparking to tissue. In other words, the monopolar output is designed for fulguration and cutting. Since sparking from an electrode to the tissue is dependent on a large voltage between the electrode and the tissue, the peak voltages from the monopolar output are relatively high. The waveforms of the monopolar output modes are shown in Figure 8. These pictures were taken from an oscilloscope and are graphs of voltage versus time. The vertical scale of all the graphs is 500 volts/centimeter and the horizontal scale is 10 microseconds/centimeter.

In the specifications for each mode, the maximum open circuit voltages are given in peak-to-peak volts. Peak-to-peak voltage is the voltage difference between the maximum positive and the maximum negative voltage peaks. In contrast, peak voltage is simply the maximum excursion of the voltage away from the zero voltage axis in either the positive or negative direction, whichever is greater. The open circuit voltage relates to the maximum distance sparks can jump through air or across a barrier. In air, 30,000 peak volts can force a spark to jump about one inch. Unfortunately, the relationship is not simple because this distance is very dependent on electrode shape and other factors. In looking at the waveforms, especially the COAG waveform, one sees that even though the voltage is an alternating voltage, (goes both positive and negative), the waveforms are not always symmetrical about the horizontal, zero voltage axis. If the waveforms were always symmetrical, peak-to-peak voltage would always be twice the peak voltage.

Monopolar Output Power:

The specifications given for each of the five modes are measured into a 300 ohm load which is the nominal, matched load for this output. This is bound to be confusing for those accustomed to working with the Valleylab SSE2 generators which were matched to a 500 ohm load. Most SSE3B's show slightly more power into a 300 ohm load than into a 500 ohm load, so the maximum power is specified at 300 ohms. Since many hospital engineers are equipped with a 500 ohm wattmeter, these wattmeters may be used but the maximum power will be ± 10% of the 300 ohm value. The digital power calibration should be within 15% of power measurements made at 300 ohms in all five modes.

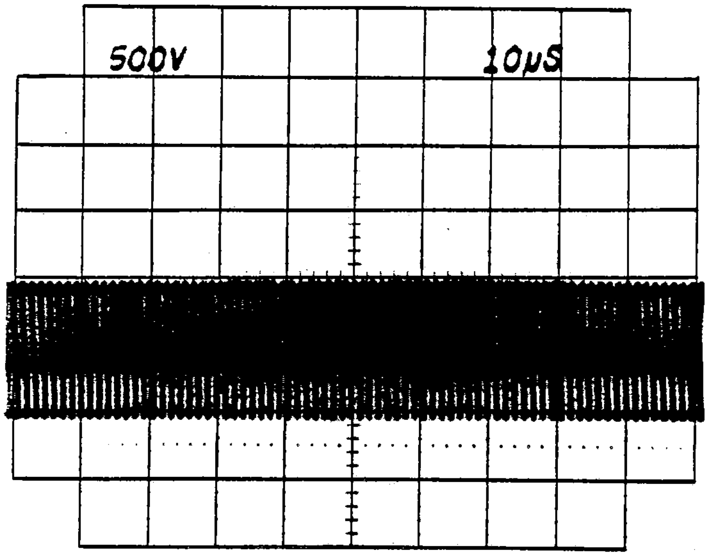
An E3002 Wattmeter is available from Valleylab which can be used to test the SSE3B and other generators at 100, 300 and 500 ohm loads.

Crest Factor:

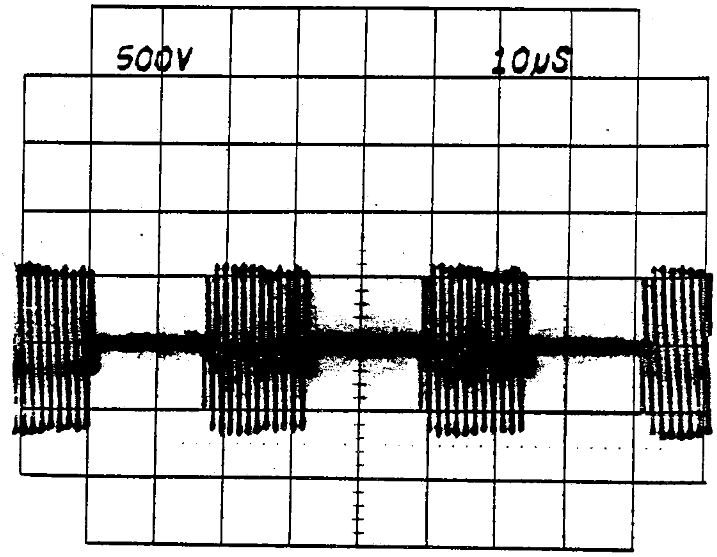
The degree of hemostasis of an electrosurgical waveform is largely dependent on the "crest factor". Crest factor is defined as the ratio of peak voltage (voltage from the horizontal, zero voltage axis to the highest peak, either positive or negative) divided by the root mean square voltage of the waveform. (Root mean square voltage is the effective average of an AC voltage over time.) The crest factors for the monopolar output modes vary from 1.9 for CUT to 15 for COAG. The SSE3B COAG crest factor is the highest ever offered in a solid state generator.

Bipolar Output Characteristics:

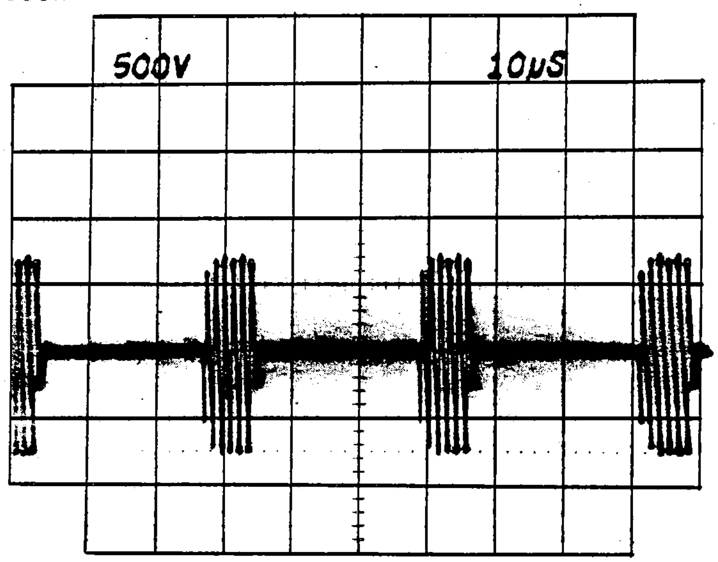
The bipolar output is designed primarily for desiccation, not fulguration or cutting. Since this output is not designed for sparking, all the voltages are considerably lower. Moreover, as explained in Section 1, any waveform can be used for desiccation since the only parameter that is important is the RMS current which passes through the tissue. Consequently, the crest factors are not very important with the bipolar output, although it is true that one can achieve electrosurgical cutting with the CUT waveform at high settings if a small electrode is used. The peak-to-peak voltages are smaller with the bipolar output which also follows from the reduced sparking capability. The bipolar output is matched to a 100 ohm load and at this resistance the maximum power is 70 watts. The bipolar output waveforms into a 100 ohm load are shown in the service manual. A graph which plots power output versus load resistance (impedance) is shown on page 102.



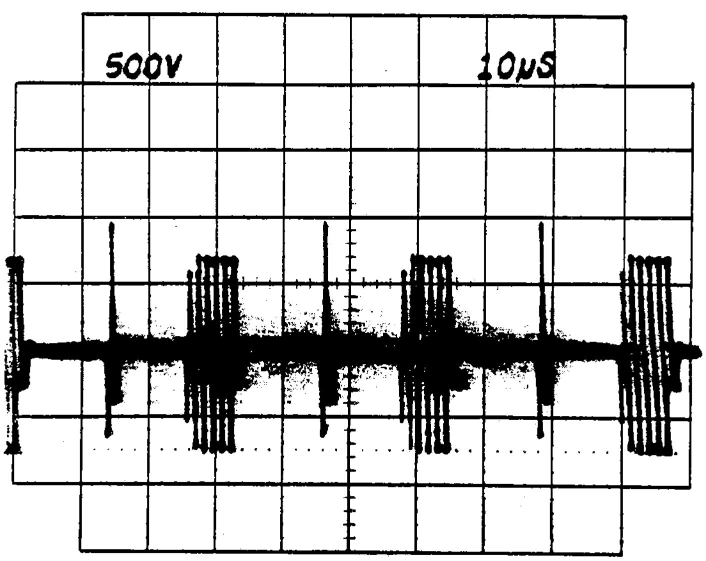
CUT @ 300W



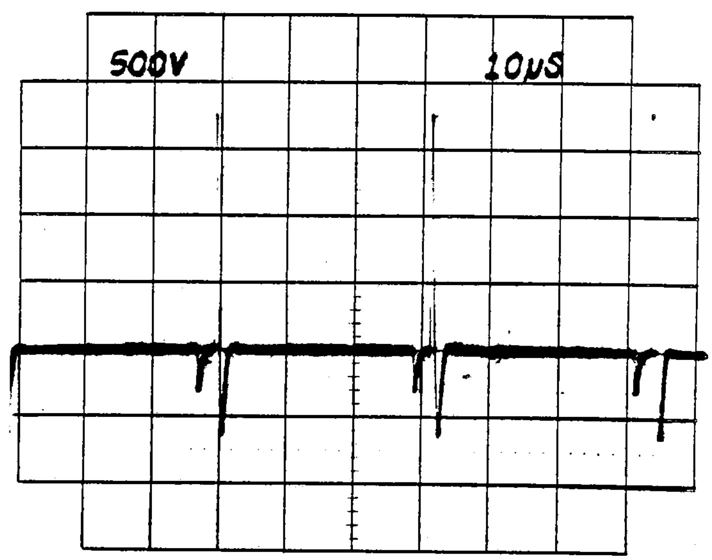
BLEND 1 @ 250W



BLEND 2 @ 200W



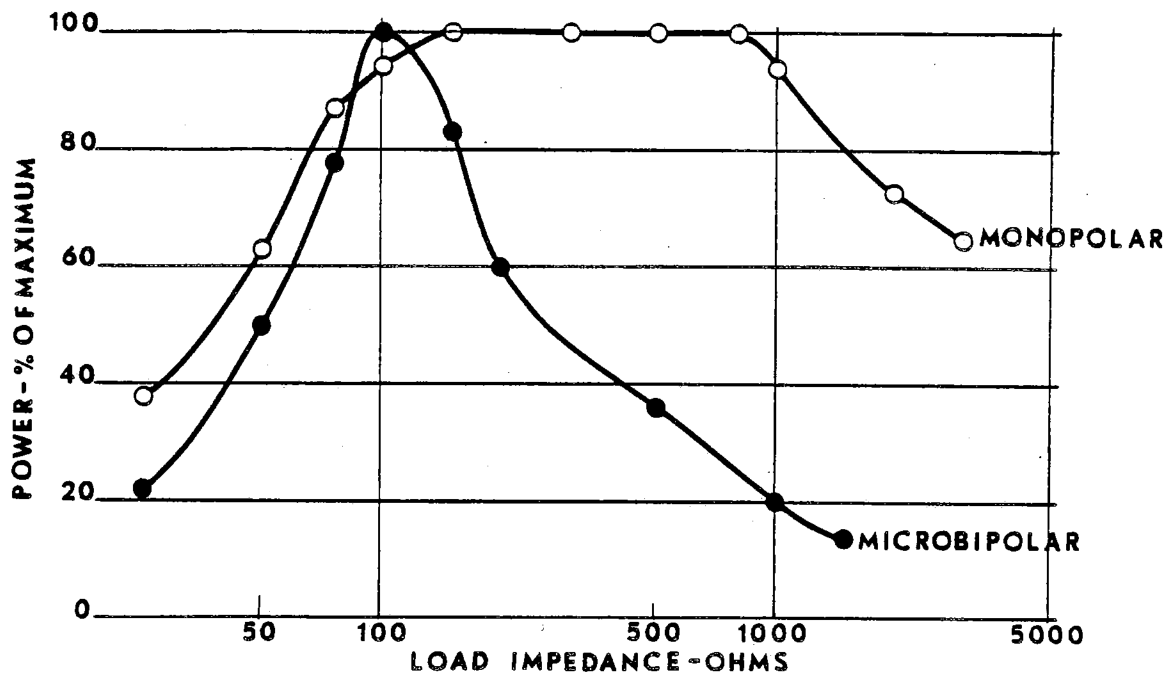
BLEND 3 @ 200W



COAG @ 116W

Vert. Scale = 500 V/CM, Horiz. Scale=10 mS/CM, Gen. Setting=10, Load = 300 ohms

FIGURE 8
MONOPOLAR OUTPUT WAVEFORMS



(Typical characteristics obtained in CUT)

SSE3B OUTPUT IMPEDANCE CHARACTERISTICS

Output Power Control

The CUT and COAG controls increase the monopolar output power essentially linearly as the control is rotated from 0 to 10. All outputs are designed to be truly zero at a setting of zero and begin to produce significant power at settings of about "1". The BLEND output power is controlled with the CUT knob. The degree of BLEND is selected with the push buttons. The COAG setting has no effect on the BLEND output. The BLEND control tapers follow the CUT power so that a setting that gives 60 watts of CUT, will also give about 60 watts of BLEND #1, BLEND #2, or BLEND #3. However, the BLENDS have less maximum power than CUT, so when the maximum power setting for each BLEND is reached, further rotation of the CUT control knob will not result in further increase in power. The monopolar control tapers are given on pages 19 and 22.

The control tapers with the bipolar output are somewhat more complex than with the monopolar output, but as pointed out earlier, the various modes of COAG, BLEND, and CUT are for the most part not relevant with the bipolar output, because all bipolar modes have the same surgical effect, desiccation. The CUT control taper with the bipolar output is essentially linear from 0 to 60 watts and can be used for nearly all applications for the bipolar output. Bipolar output control tapers are shown on pages 20 and 22.

Low Frequency Leakage (50-60 Hz)

A) Source current, patient leads, all outputs tied together.

1. *Normal polarity, intact chassis ground, $\leq$ 2.0 microamperes RMS*

   This means that the maximum current at power line frequency (60 Hz) that can be obtained from the patient applied leads is less than or equal to 2.0 microamperes RMS. When a load, (presumably the patient) is connected between any one (or all) of the leads and ground with the generator operating normally and installed properly, this is the maximum 60 Hz current that can flow through the patient to ground. This is an extremely small current and is far below the threshold for any known physiological human response.

2. *Normal polarity, ground open, $\leq$ 30uA RMS (110V), $\leq$ 60uA RMS (220V)*

   This is the maximum current at power line frequency that can flow from the patient applied leads when the generator chassis connection in the power cord becomes broken or the ground connection in the hospital wiring becomes faulty. Note that this measurement only applies when operating the SSE3B with a conventional ground referenced power source and the Powerite circuit turned off. With the Powerite circuit ON, the SSE3B will sense a break in the ground connection and turn the circuit breaker/power switch OFF, so there will be no leakage from the generator internal circuitry.

3. *Reverse polarity, ground open,* $\leq$ *30uA RMS (110V),* $\leq$ *60uA RMS (220V)*

This is the same situation as above, except that the hospital power wiring is incorrect and the neutral wire has been reversed with the line ("hot") wire. If the Powerite circuit is being used, it will detect this abnormal situation and turn the combination circuit breaker/power switch OFF.

B) *Sink current, 140 volts AC applied, all outputs,* $\leq$ *150uA (110V),* $\leq$ *300uA (220V)*

The sink leakage is the maximum amount of 60 Hz current that the patient leads will accept, that is, conduct to ground when 140 volts 60 Hz power is applied between the leads and ground. Notice that this "leakage" is completely passive. It does not represent an electrical threat to the patient unless the patient already has bare wires with 140 volts RMS referenced to ground touching his body due to some sort of serious insulation failure. If this were to occur, the patient will be shocked only if current actually flows through his body to ground.

A sink leakage current therefore expresses the maximum current that can leave the patient's body using the SSE3B active and patient leads as a path to ground. This measurement is usually made with 120 volts applied to the patient leads, since this is the nominal supply voltage. However, the SSE3B is designed to work with voltages up to 140 volts, so the sink leakage is specified for the worst case, 140 volts.

C) *Chassis, open ground* $\leq$ *100uA RMS (110V),* $\leq$ *250uA RMS (220V)*

This is the maximum 60 Hz leakage current which can flow to ground from the chassis when the chassis ground connection is broken. Since the patient does not normally come in contact with the chassis of the generator, this safety parameter primarily concerns operating room personnel who might touch the generator cabinet. 100uA is within all U.L. and C.S.A. standards for operating room equipment.

D) *The Powerite™ Circuit*

This unique circuit is a Valleylab exclusive feature. Its purpose is to detect a break in the generator grounding system or to detect an error in the hospital wiring polarity. It monitors the voltage between the metal chassis and the white (neutral) power wire. In a ground referenced power system the neutral wire is supposed to be grounded. Since the green grounding wire is also supposed to be grounded, the voltage betweeen the chassis and the white neutral wire should be zero. If the Powerite circuit detects a voltage between these two points, it turns the combination power switch and circuit breaker to OFF.

When using and isolated (non-ground referenced) power system, which many operating rooms have, the Powerite circuit will not work because there is always a voltage between the neutral and grounding wires. Moreover, the isolated power systems have a fault monitor system which in effect accomplishes the same protective function as the Powerite circuit. For this reason, the Powerite circuit must be turned OFF by means of an override switch at the rear of the generator. Merely remove the silver button and slide the enclosed switch to OFF.

<u>High Frequency Risk Parameters</u>

A) Bipolar RF leakage current, output to ground, 40 pf open output to ground, $\leq$ 150 ma RMS.

The SSE3B bipolar output circuit is designed to have as little reference to ground as possible. This means that the electrosurgical output current will not flow to grounded objects to any significant degree. The degree of isolation from ground can be measured as the maximum current which will flow to ground through an RF ammeter for either of the two active output terminals (the two large banana jacks on the bipolar output block). Since there is a long, wire cable between the output terminals and the bipolar instruments, and because this cable contributes to the RF leakage to ground, the leakage is specified with a 40 pf capacitance to ground to simulate the active cable.

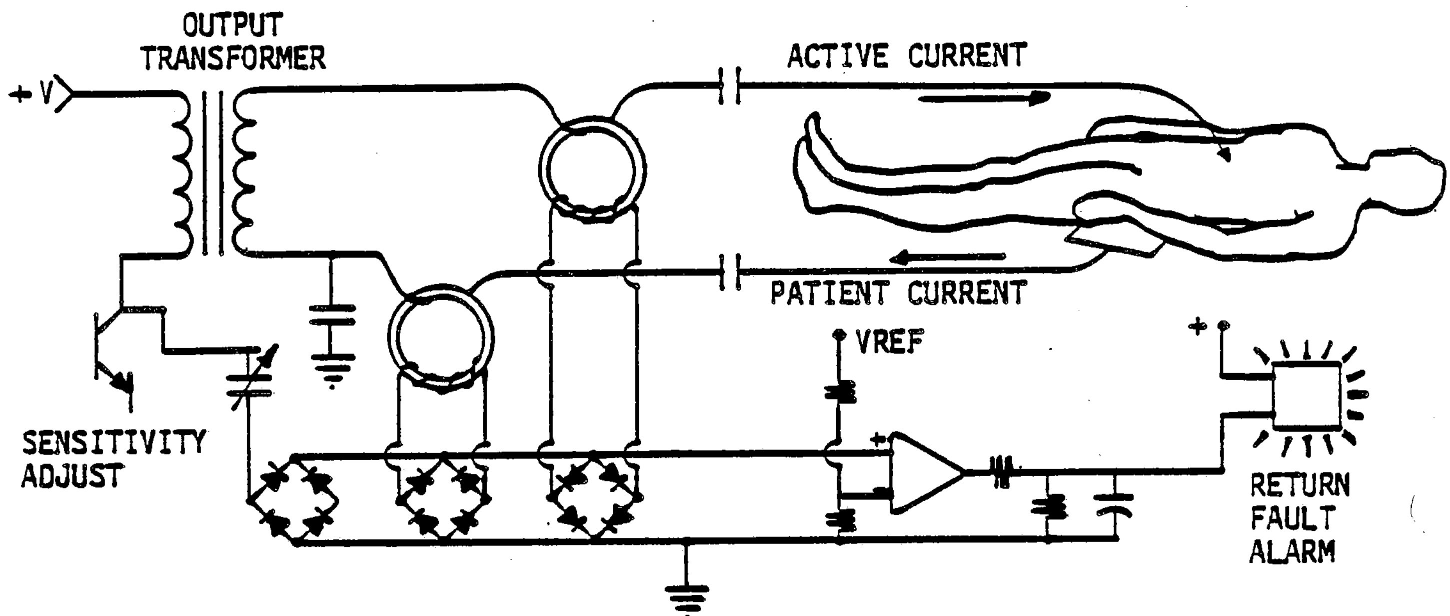
The RF leakage measurement is made in the worst case situation:

1. *No load on the bipolar output.*
2. *A three meter long active accessory plugged into the right hand, large banana jack. (Typically 40 pf to ground.)*
3. *No load in series with the ammeter to produce maximum current flow.*
4. *The ammeter connected between the left hand, large banana jack and ground.*
5. *The generator set to CUT 10 and activated.*

B) Monopolar active to ground trip capacitance = 125pf $\pm$ 25 pf in COAG,
135pf $\pm$ 5 pf in CUT.

The sensitivity of the RETURN FAULT circuit to an unsafe condition in the patient plate circuit is directly related to the amount of current that is allowed to pass from the active electrode to ground without setting off the RETURN FAULT indicator. The circuit can be made arbitrarily sensitive, but as explained above, the capacitance to ground of a typical active accessory is 40 or more pf and this capacitance conducts RF current to ground. If two electrodes are used, the capacitance can easily be over 100 pf. The circuit is adjusted at the factory to trigger at 125pf in COAG which we believe is a satisfactory compromise.

If more than 125pf capacitance to ground is placed on the active, the RETURN FAULT circuit will disable the generator until the cause of the excess current in the ground path is removed and the RETURN FAULT indicator is reset. A 125pf capacitance is equivalent to any 2000 ohm impedance (at 750 KHz) placed between the active and ground. The calibration is specified in pf because some capacitance to ground is normal, while resistance or inductance between the active and ground is not normal.



C) *Active to ground current after 40 pf capacitance, patient open, ≤ 250 ma RMS.*

This is another way of expressing the sensitivity of the RETURN FAULT circuit. This is the maximum radio frequency current which can flow from the active to ground with the patient plate unplugged from the generator. A current this large can only flow if the active to ground capacitance is just under the trip capacitance discussed above. That is, the capacitance would be slightly less than 120 pf, or just over the 2000 ohm trip point for the RETURN FAULT circuit.

D) *Patient to chassis RF voltage ≤ 30 volts RMS.*

This is the maximum voltage that can appear between the patient plate jack and ground.

It represents the maximum voltage which is available to drive currents from the patient's body to ground via small grounded contact points on the patient's body (the phenomenon of current division). In contrast to an ordinary grounded output, the RETURN FAULT circuit limits the current which can flow to ground via current division to a safe level.

E) RETURN ELECTRODE MONITOR 24-135 ohms.

This is the acceptable resistance range between the two sections of a dual electrode pad. An increase of 20% in the measured resistance will also trip the alarm. REM senses inadequate electrode contact area or drying.

F) RETURN FAULT Response time, less than 90 milliseconds.

This is the time required by the RETURN FAULT circuit to disable the generator in the event that excessive ground currents are measured.

In the worst case situation, CUT at 300 watts with a 300 ohm load between active and ground, that maximum power will be delivered to that load for about 60 milliseconds. 300 watts for 60 milliseconds is 18 watt-seconds or about 4.3 calories of heat energy. This is enough energy to raise the temperature of one gram of tissue about 4.3 degrees celsius. If the grounded contact on the patient's skin is very small, a burn might seem more likely, but in this case the impedance is very high and typically, only 0.5 calories or less is imparted before the circuit trips.

G) Input Power Source

	110V UNIT	220V UNIT
Nominal Voltage	120V RMS	120V RMS
Regulation Range	90-140 V RMS	190-280 V RMS
Operation Range	85-140 V RMS	170-280 V RMS

The SSE3B is designed to operate on 120 volts AC power, nominal. Nominal means that even though such power is called "120 volts AC", it may actually be 110, 115, 117, or 125 volts AC. The regulation range refers to the maximum range of input voltage which the SSE3B is capable of accepting without any significant change in the output power. If the 110V SSE3B is used at voltages below 90 volts, it will still operate down to 85 volts AC, although some loss of output power can be expected. Below 85 volts the functioning of the generator electronics will be impaired and this is not recommended.

Input AC Frequency

45 - 65 Hertz

The SSE3B was designed to operate from 50 to 60 Hz AC and can tolerate 5 cycle frequency shifts above and below these frequencies.

Input AC Current

	110V UNIT	*220V UNIT*
Idle:	*0.4 amperes maximum*	*0.2 amperes maximum*
CUT:	*10 amperes maximum*	*4.5 amperes maximum*
COAG:	*4 amperes maximum*	*2.0 amperes maximum*

Because of the unusual power supply design, the input current is not a simple sinewave. Instead, it is a train of short current pulses which can approach the maximum RMS values specified above. The current pulses are not sinusoidal and they are not in phase with the voltage. It is not possible to calculate the input power by multiplying the RMS current times the RMS voltage, because the maximum values of current and voltage which are given do not occur simultaneously.

Input Power

	110V UNIT	*220V UNIT*
Idle:	*50 watts maximum*	*50 watts maximum*
CUT:	*600 watts maximum*	*900 watts maximum*
COAG:	*250 watts maximum*	*375 watts maximum*

This is the actual rate of energy consumption of the generator at idle and maximum settings. It can be seen from the output power available, that the generator is about 50% efficient in the conversion of 60 Hz AC to radio frequency electrosurgical current. This compares with about 20% efficiency in an ordinary generator design.

Further help in understanding these specifications can be found in Section 1, "Electrosurgical Theory"; Section 4, "Patient Return Electrode Safety System"; Section 9, "Primer on Basic Electricity"; and Section 10, "Glossary".

SECTION 9

A PRIMER ON BASIC ELECTRICITY FOR A BETTER UNDERSTANDING OF ELECTROSURGERY

Learning electrosurgical theory and safety is difficult unless one has some understanding of basic electricity and the words used to describe it. Fortunately, the terms and concepts needed to understand your electrosurgical unit are not difficult, and this "Primer" will explain all that is relevant to a basic understanding.

The simplest, most understandable analogy to electricity is the flow of water. Quantities of water could be measured in pounds, kilograms, or buckets, and it is reasonable that the flow of a river could be expressed in buckets per second flowing past a given point. Electricity can be thought of as the movement of "charge" past a given point. Electricity can be thought of as excess electrons removed from their atoms and set into motion by an external force. The electrons flowing past a point make a "current" and electrical current is measured in amps (or amperes). To be exact, an ampere equals 6.242×10^{18} electrons going by each second.

The force that drives electrons through a conducting wire is voltage. This is analogous to gravity which drives the river down the mountain. The steeper the mountain, the faster the water flows and the better the water flow is for doing useful work such as turning a water wheel.

When water encounters an obstacle, such as a water wheel, it exerts force on the wheel and turns it. Looking at it from another viewpoint, the water wheel exerts force on the water and slows it down. In electricity, resistance to the flow of electricity is measured in ohms.

$$V = I \times R$$

$$\text{or volts} = \text{amperes} \times \text{ohms}$$

$$\text{or current} = \frac{\text{voltage}}{\text{resistance}}$$

"Power" is the energy produced or consumed over a period of time. The metric unit of energy is the "joule," although other heat energy units such as the "calorie" or the "British Thermal Unit" (BTU) could be substituted. Power can, therefore, be expressed as BTU/hour or calories/second or joules/second. One joule per second equals one watt. A "kilowatt hour" is actually a measure of energy since it means one kilowatt of power supplied for one hour.

$$1 \text{ kilowatt hour} = 1000 \times \frac{\text{joules}}{\text{seconds}} \times \text{hours} = 3{,}600{,}000 \text{ joules}$$

When hours are divided by seconds, units of time disappear from the equation, leaving simply joules of energy.

In Electricity,

Power = voltage x current

This is easily understood using the water wheel analogy. If height is equivalent to voltage, and water flow is equivalent to current, then it stands to reason that a powerful hydroelectric plant could be built if you have a lot of water falling from a great height. Suppose that the Glen Canyon Dam could put out a million watts of power and that a dam on the lower Mississippi River could put out an equal amount. Glen Canyon Dam is very tall, but the Colorado River is actually quite narrow. Even though the water flow is small, the height of drop is large. In contrast, the equivalent dam on the Mississippi has a huge water flow, but a very small drop in height.

Using Ohm's Law, $V = IR$, one can substitute into the electrical power equation.

$V = IR$, *Therefore,*
$$P = VI = (IR)I = I^2R$$
$$P = VI = V(V/R) = V^2/R$$

Using these expressions we can now express power using the electrical resistance and either the voltage or the current. The current expression is particularly useful. For example, the wattmeters used to check out an electrosurgical generator are actually ampere-meters (called ammeters) wired in series with a load resistor. The meter scale is usually calibrated in current (milliamperes) and also watts (I^2R). Notice that power delivered to tissue is equal to the square of the current. Therefore, when the current is doubled, the heat energy delivered to the tissue each second goes up four times.

When measuring very large or very small electrical quantities, they are frequently expressed with prefixes like "kilo", as in kilowatt which means 1000 watts. Other commonly used prefixes are listed below:

p = pico = 10^{-12} (one thousandth of one billionth)

n = nano = 10^{-9} (one billionth)

u = micro = 10^{-6} (one millionth)

m = milli = 10^{-3} (one thousandth)

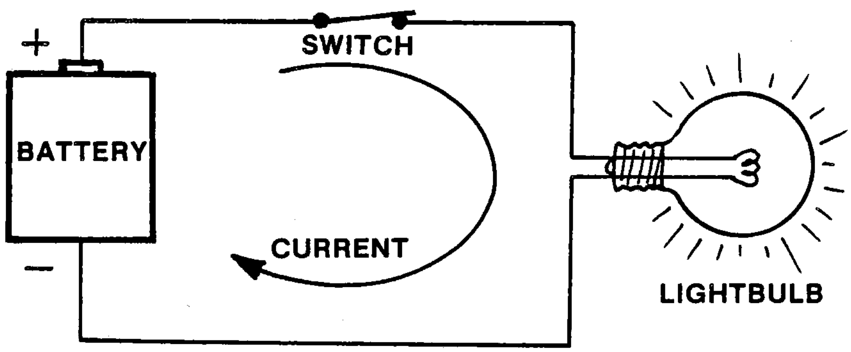
K = kilo = 10^{+3} (thousand)

M = mega = 10^{+6} (million)

Basic Direct Current Circuits

Most people who have put batteries in a flashlight are aware that the current leaves one terminal of the battery and must return to the other for the circuit to be completed. If the current is interrupted by a switch, the flow stops. In a battery, the output of the battery is direct current; that is, the electrons only flow in one direction.

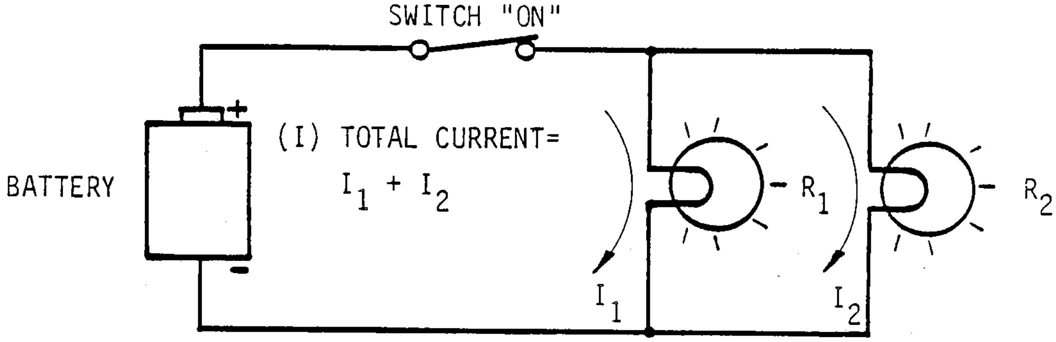
A SIMPLE CIRCUIT



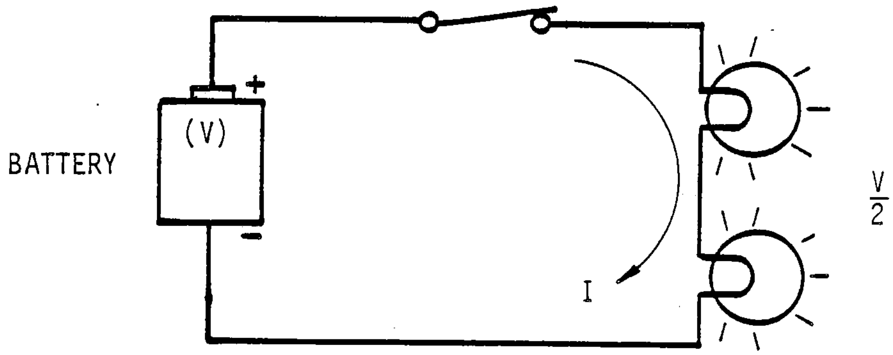
Electrical current always flows in complete loops.

For many years, current flow was defined as "positive" if it flowed from the positive pole (+) to the negative pole (-). Actually, electrons flow from negative to positive. It doesn't matter when making calculations, so current flow has never been redefined.

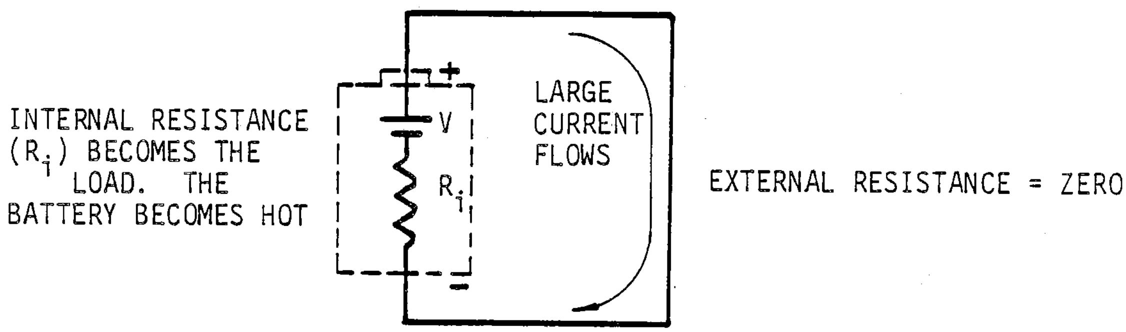
Note that in the sketch above the current flows in a single loop. If one used the battery to light two light bulbs in parallel, there would be two loops. It should be obvious that the total current supplied by the battery is the sum of the currents supplied to each of the two light bulbs.



TWO LIGHT BULBS (LOADS) WIRED IN PARALLEL



If one puts two light bulbs in __*series*__ *and uses the same battery, the bulbs will still light but they will be very dim. The voltage is now divided between the two light bulbs, and current flowing through them will be only half as much as before. Looking at it another way, the resistance to the current is* __*twice as high*__ *so only* __*half as much current*__ *will flow.*



A "SHORT" CIRCUIT

What happens when there is a "short" (no resistance) in the circuit?

According to Ohm's Law,

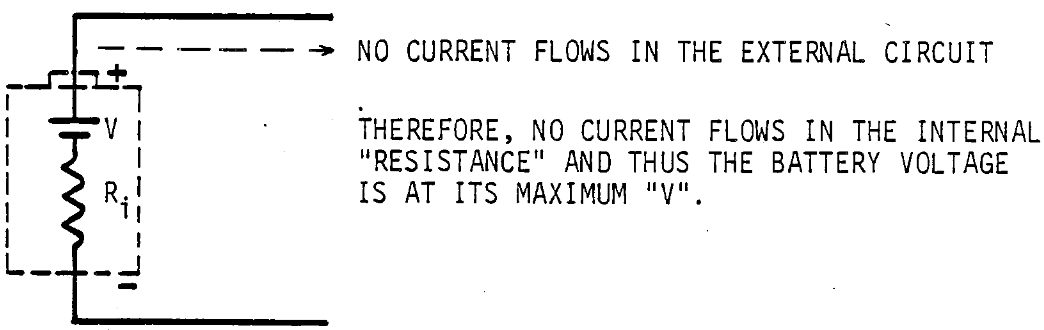
voltage = current x resistance,

but the resistance is zero so,

voltage = current x zero = zero

If the battery were "perfect," it could produce its voltage across any resistance, but that would imply that infinite current must flow.

In real batteries, or any other real electrical power supply, the amount of current it can supply is limited. It is just as though there was a resistance <u>*inside*</u> *the battery. In other words, the load resistance is now the battery itself. A battery which is connected this way is said to be "short-circuited," and if you try this, you will find that the battery becomes hot very quickly. "Short" out an electrosurgical generator and it, too, becomes hot very quickly, especially at high power settings. In the opposite situation, what happens to the voltage when the resistance is infinite? In other words, what happens when the switch is "open" or "off"?*



An "Open" circuit, or the load resistance = infinite.

Without the current flow, the voltage drop across the external load doesn't exist. Similarly, there is no current flowing through the imaginary resistance <u>*inside the battery.*</u> *Therefore, there is no voltage drop across the imaginary resistance and, therefore, the voltage one might measure across the battery is* <u>*higher*</u> *than if it were lighting a light bulb or "loaded" by some external resistance. The lesson here is that electrosurgical generators have the highest voltage across the output (patient to active) when the electrode is not touching tissue and there is no current flowing.*

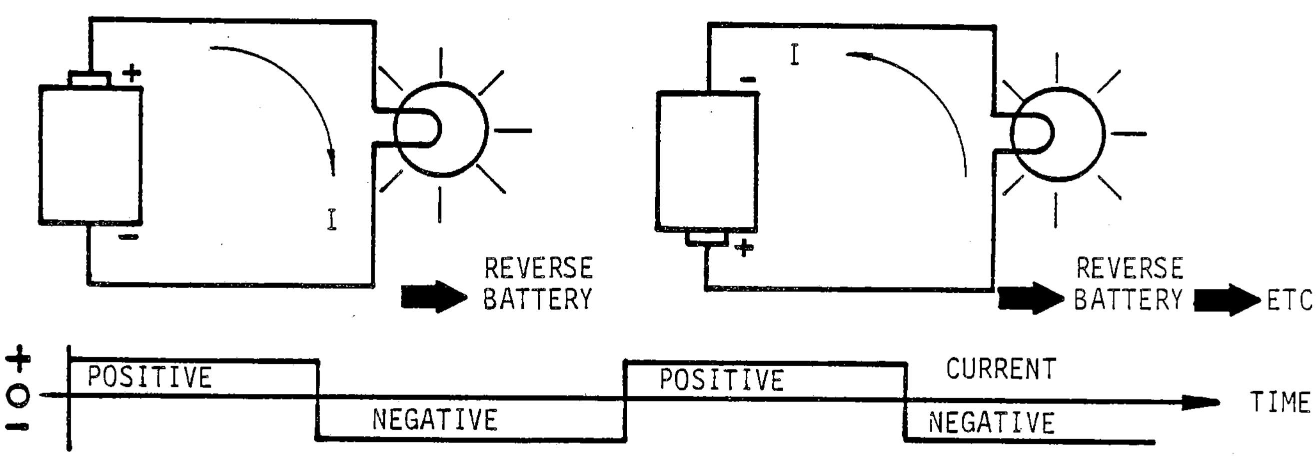
Ground

Ground is simply the earth itself. If you drove a long metal pole into the ground, you would find that there is very little resistance (about 100 ohms) between your pole and any other similar pole, anywhere on earth.

Most wiring schemes in TV sets, electrosurgical generators, houses, etc., use "ground wires" as a common destination for current in order to reduce the number of wires needed. The ground in a house is any metal touching the earth such as water pipes. In a TV set, the metal chassis is "ground". The chassis is connected to the real earth by means of the ground wire in a three prong power plug. The purpose of grounding conductive objects is to prevent voltages from appearing between them. If all objects are wired to the same thing, ground, they will have the same voltage, and current cannot flow between them. If no current can flow, there is no danger of being shocked.

Alternating Current (AC)

In contrast to DC, alternating currents periodically switch directions of flow. We could generate an AC current by removing the battery in our DC circuit and plugging it in backwards, then pulling it out and repeating the cycle.



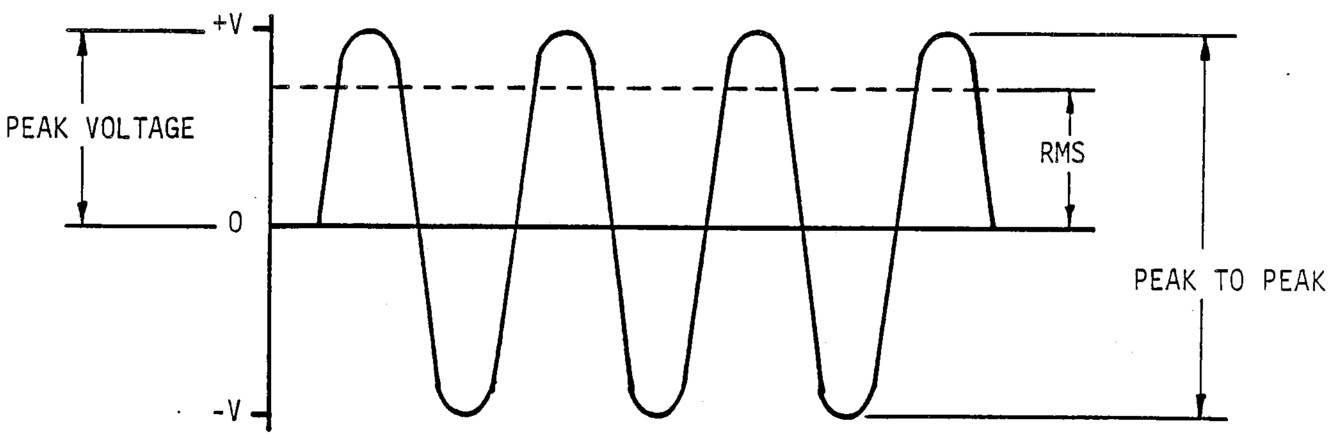
AC Frequency

The frequency of these alternations is measured in cycles per second or Hertz (Hz) (1 Hertz = 1 cycle per second).

In power lines, the current alternates 60 cycles/second or 60Hz. Radio frequencies are simply very rapid alternations. Standard AM broadcast operates at 550,000Hz to 1,600,000Hz. Television and FM are even higher, 56 to 187 megahertz (MHz). Electrosurgery uses a "radio frequency" (RF) current in the range of 250,000Hz to 3,000,000Hz (250KHz to 3MHz).

AC Circuits

Basically, AC circuits behave like DC circuits, but there are some rules that have to be followed in describing voltage and currents.



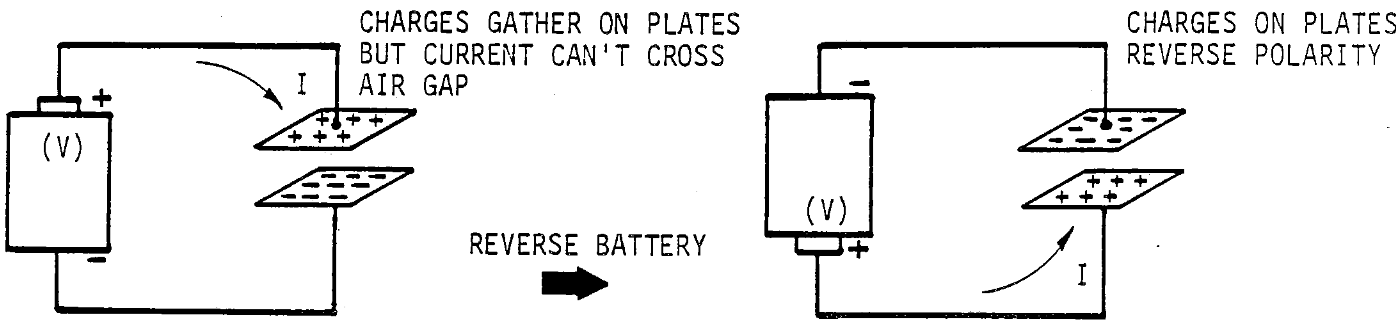
An alternating voltage (sine wave) waveform

Three different types of voltages (or current) are used to describe AC electricity. "Peak-voltage" is the highest voltage away from zero, either positive or negative. "Peak-to-peak voltage" is the voltage from the lowest negative voltage to the highest positive peak. "RMS voltage" is the "effective average" voltage. Voltmeters and ammeters almost always read RMS voltage, and RMS voltage and RMS currents work fine in Ohm's law ($V = IR$) and power ($P=VI$) calculations. Common house current is about 120 volts RMS. It could also be expressed as 170 volts peak or 340 volts peak-to-peak.

Peak voltage is useful for giving an idea how far an AC electric spark can jump through air. A 30,000 volt DC source can jump a spark one inch long through air. An elecrosurgical generator which has a 15,000 volt peak waveform can jump a spark about one-half inch to tissue.

Capacitors and Inductors

Two phenomena which are seen in AC circuits but not in DC circuits are inductance and capacitance. A capacitor consists of any two conducting materials separated in space by an insulator (a nonconductor). Suppose two metal plates were arranged with their flat surfaces parallel but not touching and connected into our DC circuit in place of the light bulb used earlier.

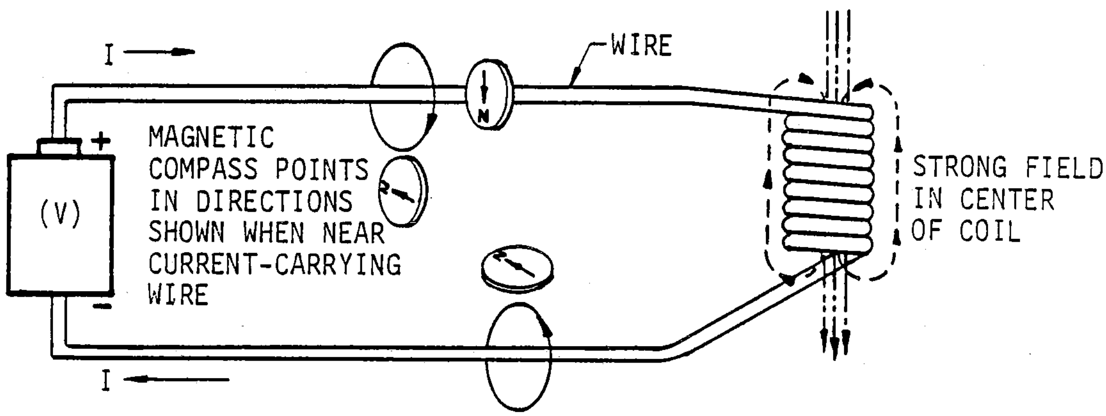


Charging a capacitor. Excess electrons gather on the "–" plate. "Positive charges" (an absence of electrons) gather on the "+" plate. Reverse polarity and the charges make a tiny current as they gather on the opposite plate.

No current can flow because the air is acting as an insulator, and we'll assume that the voltage is too low to jump across the gap. Although no current flows, there is an attraction between the charges which gather on the plates. The positive side loses electrons and the negative plate gains electrons. The larger the area of the plates and the closer they are together, the more charge can be stored on the plates. Suppose that the battery is unplugged and the polarity reversed. When this is done, the excess electrons on the lower plate are driven by the battery through the wires to gather on the upper plate. If one continues to switch the battery back and forth, that is, connects an alternating current to the capacitor, there will be a tiny surge of current each time the voltage polarity reverses. In other words, the capacitor placed across an alternating voltage source causes alternating currents to flow in the connecting wires. So even though no current actually goes through the capacitor, the capacitor acts as though it "conducts" AC currents. In the case of ten-foot-long patient return electrode and active electrode leads, these make a "small" capacitance at the power line frequency of 60 cycles per second. In other words, the sixty small surges of current each second are very difficult to measure, and the alternating current will be insignificant. On the other hand, the frequency of the electrosurgery output is roughly 500,000 Hertz (cycles/second). This will produce nine thousand times more of these surges per second and will cause significant alternating current. At present there is no way to deliver radio frequency currents to the tissue without using wires having some capacitance to ground; thus, all isolated generators have some leakage to ground. Generators equipped with grounded patient electrodes are not perfect either, and one of the reasons they are not is inductance.

One way to look at a capacitor is to say that, when charges gather on the parallel plates, energy is being stored in the electric field between the plates. An inductor is analogous to a capacitor except that the energy is stored in a magnetic field. In many ways, inductors behave like the "opposite" of capacitors, and contrasting the two is a good way to remember how they behave.

Any time a current passes through a wire, a small magnetic field appears around the wire. A compass will point in the direction shown in the drawing if it is placed close to wire carrying a large current. By wrapping the wire in a coil, the fields generated by adjacent turns of wire reinforce each other, thus making a very strong magnetic field in the center of the loops. Such a magnet can pick up iron just like a permanent, non-electric variety of magnet.



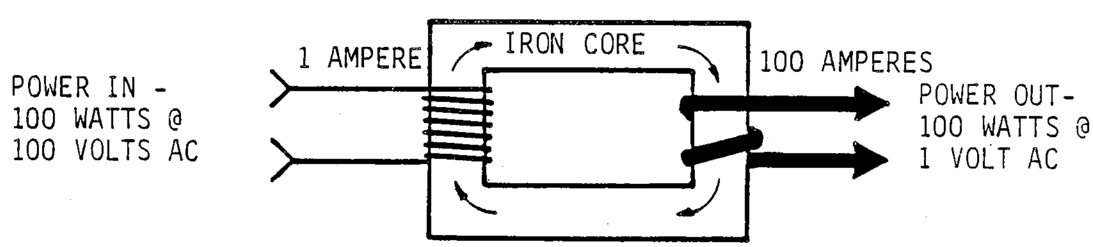
A magnetic field occurs around any wire with current passing through it. Energy is stored in the field. A coil (a type of inductor) intensifies the field by taking the field from a long length of wire and gathering it together into one place.

Now then, what happens when inductors are attached to an AC voltage source? Because the magnetic field is established in proportion to the amount of current flowing through the inductor, the current through the inductor cannot change without changing the magnetic field. When the current decreases, the energy in the field doesn't remain until the current returns. Instead, the energy returns to the wire in the form of a current going in the same direction that formed the magnetic field in the first place. If you try to increase the current through the inductor, it also seems to resist this because the magnetic energy must first be stored in the magnetic field before a current can pass through. In other words, the current through an inductor cannot change rapidly. From this, it should be clear that inductors resist alternating currents, and the faster you try to turn the current on and off, the less current will get through.

Just like capacitance, the inductance effect is not significant for 10-foot-long electrosurgical electrode leads at power line frequency, 60Hz. However, at higher frequencies, like 0.5 to 3 MHz, a ten foot wire can have significant inductance even if it isn't wrapped into a coil. The result of this is that, if the patient return electrode is grounded at the generator chassis, the patient's body is not actually grounded because the inductance of the patient return electrode wire is significant enough to produce a small voltage across the wire, hence, there is a small RF voltage between the patient's body and true ground. Therefore, even "grounded" patient return electrodes can have a leakage current to ground.

Transformers

Transformers are sophisticated inductors which "transform" the ratios of alternating voltages and currents. Transformers consist of two or more coils or windings which are positioned so that they share the same magnetic field. Iron can be used to conduct magnetic fields just the way most metals conduct electricity. By winding an inductor or transformer on an iron core, the magnetic field is more intense than it could ever be if there were only air inside the coil of wire. In most transformers, two coils are wound around an iron core and, thus, share the same magnetic field. Because the magnetic field inside the two coils is identical, the current passing through one of the windings affects the current passing through the other. In fact, if power is passed into one winding, an equal (or almost equal) amount of power may be drawn from the second winding. By adjusting the ratios of the turns of wire wrapped around the magnetic field, one can change the ratio of current to voltage which appears on the secondary. For example, if 100 volts AC at one ampere is applied to one side of a transformer, it is possible to transform this to one volt at 100 amperes.



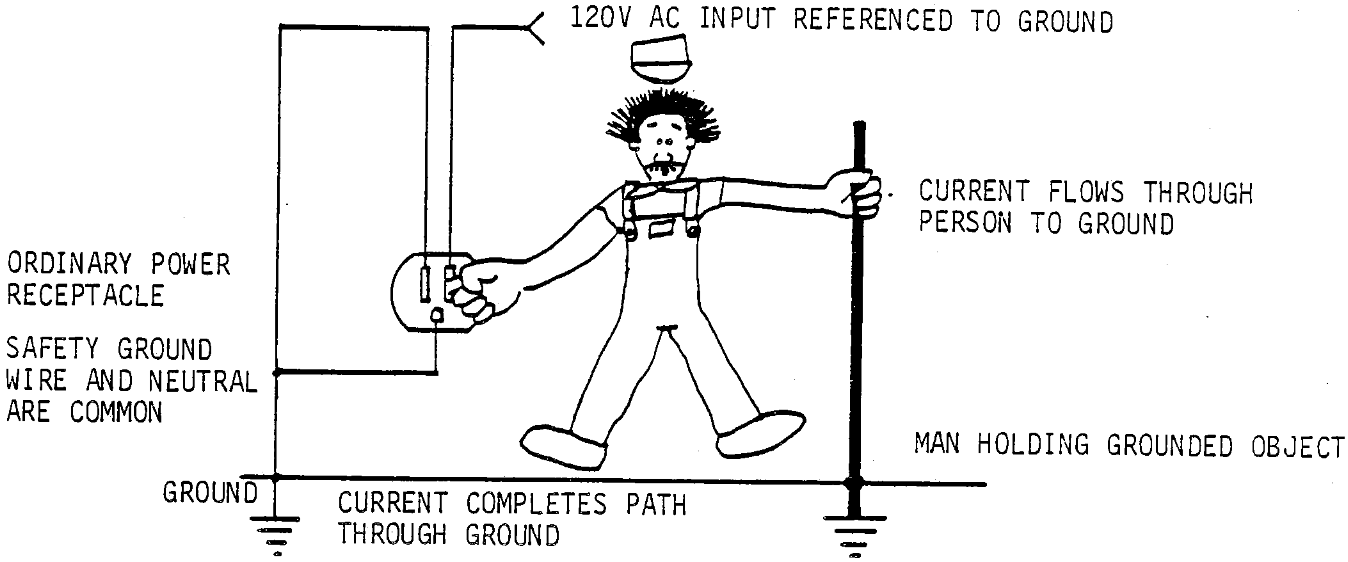
How transformers can be used to "transform" the ratio of voltage to current.

An electrosurgical generator usually has several transformers in its circuitry. Generally, a large power transformer converts the 120 volt AC power to more convenient voltages for use by various internal circuits. The output transformer transforms the relatively high current, low AC voltage to the high AC voltage with low current which is useful for electrosurgery.

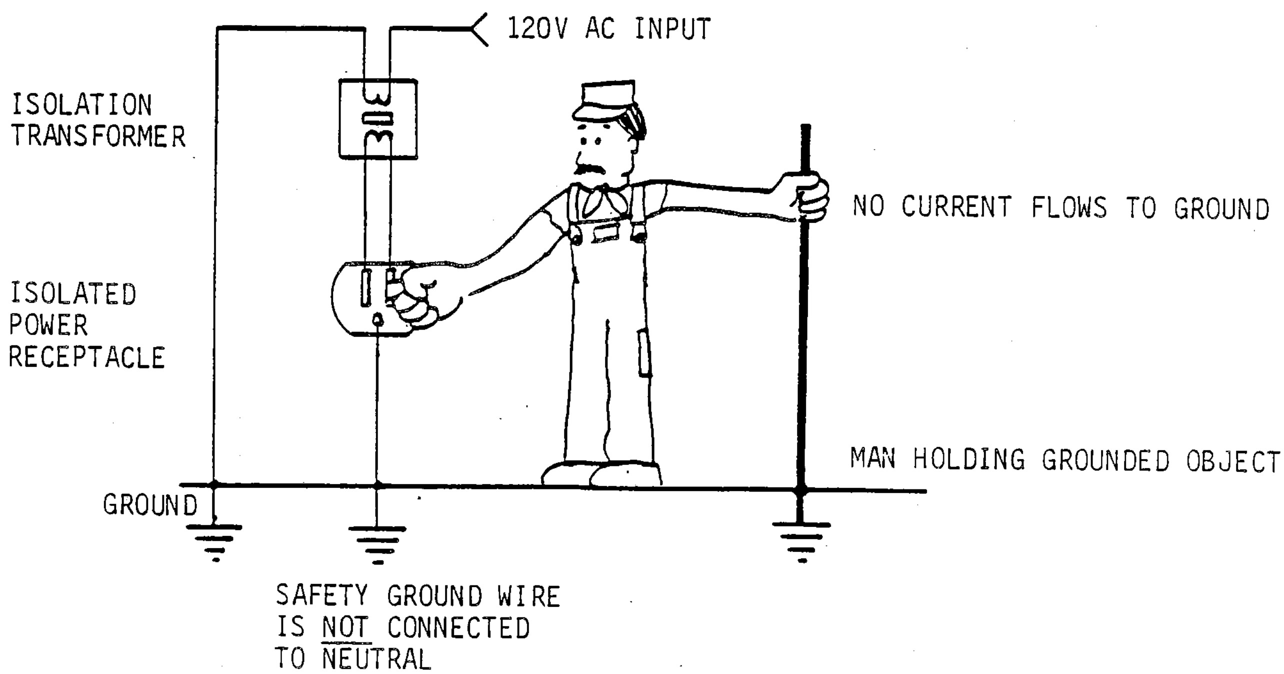
Aside from changing the ratio of voltage to current, a transformer can also isolate one circuit from another. For example, the SSE2L uses a transformer to achieve an isolated output. Neither side of the output winding of the output transformer is connected to ground. In contrast, the input side of the output transformer is effectively wired to ground through the output power transistors.

Isolated Power Systems in Operating Rooms

Another example of isolation is the isolated power system commonly found in the operating room. The ordinary 120 volt AC (or 220/240 volt AC systems outside the United States) is wired so that it is referenced to ground. That is, one of the two power wires is actually a ground wire, even though it is commonly called the "neutral" wire. If the insulation inside an electric power tool or other appliance fails, it is possible for the metal case to become "hot" with respect to ground. The third pin on the plug (the green grounding wire) is intended to be a back-up safety feature to prevent this from happening. If the ground wire were also faulty, it would still be possible for the metal case of the appliance to acquire a dangerous AC voltage with respect to ground. A person touching the metal case of such an instrument will not be harmed unless he himself is touching ground to complete the circuit. A bird sitting on a high voltage power line has nothing to fear unless he is able to complete a circuit by touching two wires at once. Touching high voltage can hurt you only if it is able to drive a current through you. By passing ground-referenced AC power through an isolation transformer, it is possible to eliminate the reference to ground. Now if the same insulation and wire breakages described above should occur, the current will not flow to ground, and the person touching the "hot" metal will not be shocked.



Why contact with ground-referenced voltages is extremely hazardous.



How an isolated power system can prevent shocks.

Vacuum Tubes and Transistors

The British call vacuum tubes "valves", and this is an excellent description of what they do. The "valve" on your water faucet allows you to adjust the water flow not only on or off (like a switch), but also to select just the right amount of flow. Tubes and transistors are controlled by a small signal current. A very small signal can make a large current follow it so that the "output" is a much larger version of the original signal. That is, tubes and transistors amplify. Note also that tubes and transistors can be used as electric switches if you don't want to use the region between full "on" and full "off."

Vacuum tubes use a filament just like light bulbs. Eventually this filament will burn out and the whole tube must be replaced after 1,000 to 20,000 hours. There are other ways tubes can fail, but filament failures are perhaps the most common.

Transistors perform the same valve function by a different principle and are solid blocks of laminated semiconductor material. Hence, they are called "solid-state". Not only are they smaller, but they do the same job with less energy and last longer. Instead of being rated in thousands of hours, they will last many, many years before various ionic migrations contaminate the semiconductor and it loses its efficiency. For all practical purposes, a transistor in an electrosurgical generator is most likely to fail the first time it is turned on, so they are tested thoroughly at the factory. After a few weeks of use, the transistors usually will have seen all the electrical loads and abuse they will ever see, thus they rarely fail after the initial break-in period.

Spark-Gaps

Spark-gaps are a primitive form of switch which consists of two small conducting metal pieces separated by an air gap. An automobile spark plug is an example of a spark-gap. When the voltage gets high enough to jump across the gap, the air ionizes or "breaks down" and the air suddenly becomes a conductor. At this point, the switch is "ON." A spark-gap is a type of voltage-controlled switch which can be used to run a primitive form of radio frequency generator.

The advantage of spark-gaps for electrosurgery is that, unlike tubes and transistors, they can tolerate gigantic voltages and currents and, are good for generating high peak voltage COAG waveforms. The disadvantage is that they wear out and, like spark plugs, must be replaced periodically.

SECTION 10

GLOSSARY

A C - Alternating Current. Electrons flowing in alternate directions around a circuit.

A C LEAKAGE CURRENT - Any 60 Hz current, including capacitively-coupled currents which may be conveyed from accessible parts of the electrosurgical generator accessories to ground or through the patient to ground.

ACTIVE CABLE - The conductor between the electrosurgical generator and the active electrode.

ACTIVE ELECTRODE - The electrode at which the electrosurgical effect is intended. It is usually a small area and provides a high current density to achieve the intended surgical effect.

AMPERES - The unit of measurement of electric current.

ARC - An electric discharge across an air gap. A true arc takes a relatively long time to become established and is probably not important in electrosurgery. The discharges seen in electrosurgery are technically known as electric "sparks."

BALANCED OUTPUT - A Valleylab word describing the electrosurgical output system which is used in the SSE3B generator. The current in the active cable is electronically compared with the current returning through the patient cable. An imbalance in these currents is used to detect an unsafe patient return electrode connection.

BIPOLAR INSTRUMENT - Forceps or other electrosurgical accessories having two electrodes, both of which are intended to be applied to the tissue undergoing electrosurgical treatment and energized by the electrosurgical generator so that the current passes between the electrodes. It is intended that a substantial portion of the total current is restricted to tissue between the electrodes.

BIPOLAR OUTPUT - An isolated generator output.

BLEND - An electrosurgical output which is intermediate in crest factor between CUT and COAG. It is best for cutting tissue while at the same time providing excellent hemostasis. BLEND can be thought of as a "mixture" of CUT and COAG.

CAPACITANCE - The property of capacitors which conducts alternating current or stores charge in DC circuits. The unit of measure of capacitance is the farad. CAPACITOR - Two pieces of electric conductor separated by an electric insulator. Capacitors can store charge in DC circuits and conduct radio frequency currents in electrosurgery.

CAUTERY - The application of a hot iron or a caustic substance as a means of stopping bleeding or killing tissue. Also see Electrocautery.

CHARGE - The absence or excess of electrons on a conductor. If two pieces of conductor are oppositely charged and brought close together, the result is a force (voltage) between the two conductors. The voltage will attempt to drive the excess electrons to the conductor with the relative deficiency of electons.

COAG - Electrocoagulation. To coagulate. The name of the voltage waveform or generator output that is optimized for the fulguration of tissue.

COAGULATE - In electrosurgery, a general term which includes the fulguration and desiccation of tissue. To cause to clot; to achieve hemostasis; to kill tissue with electrosurgery without severing it.

COLD CAUTERY - An obsolete term referring to DeForest's vacuum tube electrosurgery generator which produced a pure sine wave output and was used for cutting with no hemostasis.

COLD WAVEFORM - An obsolete term for a low crest factor CUT waveform.

COMMON GROUND CONNECTOR - A term (used by another manufacturer) for a cable which connects the metal body of a single puncture laparoscope to the patient return electrode. It is used to shunt capacitive leakage from the metal laparoscope to the patient return electrode.

CREST FACTOR - The ratio of the peak voltage to the root mean square (RMS) voltage of a periodic waveform. In electrosurgery, generally the outputs with high waveform crest factors are better for fulgurating tissue.

CRYOSURGERY - The use of freezing or very cold substances such as solid carbondioxide or liquid nitrogen to destroy tissue. Has been used in ENT and cervical cauterization.

CUT - In electrosurgery, the name of the voltage waveform or generator output which is optimized for dividing tissue with a minimium of coagulation. A generator output with a low crest factor, typically 1.4 to 2.0. Tissue division with a fineelectrosurgical electrode. Electrocut. Electrocision. Electrotomy.

CYCLES PER SECOND - Alternation per second of an AC current. One cycle per second equals one Hertz.

D C - Direct current. Electrons flowing only in one direction.

DESICCATE - The dehydration and necrosis of tissue caused by passing a radio frequency electric current through the tissue. In desiccation, the electrodes must be in good electrical contact with the tissue, and the current heats the tissue by dissipating power in the electrical resistance of the tissue. Desiccation differs from fulguration in that there is no sparking between the electrode(s) and the tissue. See Fulguration.

DIATHERMY - The generation of heat in the body tissues due to the resistance offered by the tissues to the passage of high-frequency electric currents. The therapeutic heating of the body tissues or parts without necrosis by means of an oscillating electric current of high frequency. The frequency varies from 10 million to 100 million cycles per second. Endothermy. Short wave diathermy.

DISPERSIVE ELECTRODE - See patient return electrode.

DISPERSIVE ELECTRODE CABLE MONITOR - Circuitry or device which detects an interruption in dispersive cable continuity between the electrosurgical generator and the dispersive electrode.

DUTY CYCLE - The ratio, expressed as a percentage, of the time a unit is activated to the total duration of the on-off cycle of a periodically-repeated operation.

ELECTRIC CURRENT - The flow of electrons through a conductor. Current is measured in amperes.

ELECTROANASTOMOSIS - Electrosurgical intestinal anastomosis (surgical formation of a passage between two normally distinct spaces or organs, as end-to-end union).

ELECTROAPPENDECTOMY - Electrosurgical appendectomy.

ELECTROCAUTERY - The coagulation of blood or tissue by means of a wire heated by current passing through the wire. In contrast to electrosurgery, the electric current does not pass through the tissue, but remains in the wires.

ELECTROCHOLECYSTECTOMY - Electrosurgical excision of the gallbladder.

ELECTROCHOLECYSTOCAUSIS - Electrosurgical cauterization (coagulation) of the gallbladder.

ELECTRODE - Either terminal of an electric current through which electricity is received or transmitted. In electrosurgery, it is the conductive metal or conductive pad or assembly which actually contacts the patient's body. In monitoring electrodes, the construction may be similar, but the currents are transmitted for measurement purposes. In electrosurgery, the electrodes are generally dissimilar in size, and the smaller one, the active electrode, is intended to be the site of the electrosurgery, while the larger electrode, the patient return electrode, merely completes the circuit path back to the generator.

ELECTRODIAPHAKE - An instrument for removing the lens by electrosurgery.

ELECTROENTEROSTOMY - Electrosurgical enterostomy. Surgical formation of a permanent opening into the intestine through the abdominal wall.

ELECTROGASTROENTEROSTOMY - Electrosurgical gastroenterostomy. Incision of stomach and intestine through abdominal wall.

ELECTROLITHOTRITY - The disintegration of calculi ("stone" - any abnormal concretion within the body and usually composed of mineral salts) by an electric current.

ELECTROLYSIS - Destruction by passage of a direct electric current. The breakdown of water or salts by means of a direct electric current. When direct current is passed through tissue, the water and salts in the tissue cells break down and produce acids and bases which kill and lyse cells. Surgery by this means is called galvanosurgery and is used to remove excess hair or other growths from the body. Galvanofaradization is the surgical use of simulataneous direct current and alternating current.

ELECTROPLEXY - Electric shock.

ELECTROSURGERY - The generation and delivery of a radio frequency current between an active electrode and a dispersive electrode or through a bipolar instrument for the purposes of dehydration, necrosis, cutting, coagulation or other surgical modification of tissue. In contrast to electrocautery, the electric current actually passes through the tissue.

ENERGY - The capacity for doing work and overcoming resistance. Heat, light, and electricity are examples of energy. Energy is measured in joules.

FARAD - The unit of measure of capacitance.

FULGURATE - Coagulating tissue or blood by means of radio frequency electric sparks. In contrast to desiccation, the active electrode is not in good electric contact with the tissue and sparks jump from the electrode to the tissue. fulguration is literally capable of reducing tissue to carbon.

GALVANISM - The therapeutical use of direct current. Named for and discovered by Luigi Galvani, Italian physician and physicist 1737-1798.

GALVANOCAUTERY - Cautery by a wire heated with a galvanic direct current.

GROUND - Wires and conductors connected to the earth. Grounded conductors all have the same voltage so no dangerous currents can flow between two grounded objects.

GROUNDED GENERATOR OUTPUT - An electrosurgical generator output which as the patient electrode grounded to the metal chassis of the generator. This means that current will flow from the active electrode when it touches any grounded object in the room.

GROUNDED PLATE - A patient return electrode which is connected directly to earth ground.

HENRY - The unit of measure of inductance.

HERTZ (Hz) - One Hz equals one cycle per second.

IMPEDANCE - The resistance to flow of an AC or radio frequency electric current.
The term impedance includes not only simple DC resistance, but also the resistance to flow brought about by capacitance and inductance in a circuit.

INACTIVE ELECTRODE - See patient return electrode.

INDUCTANCE - The property of a coil of wire, or even a piece of wire, in which energy is stored in a magnetic field around that wire while DC current flows in the wire. Inductors offer essentially no resistance to the flow of DC current, but offer high resistance to the flow of high frequency AC current. Inductance is measured in henries.

INDUCTOR - A circuit element consisting of a coil of wire, frequently wrapped around an iron core. Inductors have essentially no resistance to DC current, but exhibit high resistance to the flow of AC or radio frequency current.

IONTOPHORESIS APPARATUS - A low-frequency device for introducing ions into the tissue of the body for therapeutic purposes. Iontophoresis is also known as iontherapy, galvanoionization, ionic medication, and medical ionization.

ISOBLOC®- A Valleylab name for a circuit which allows hand-switching accessories to be used on isolated output electrosurgical generators without compromising the safety of the isolated output. In the case of the SSE3B monopolar output, which is not isolated, the IsoBloc circuit allows hand-switching accessories to be used without compromising the sensitivity of the RETURN FAULT circuit.

ISOLATED GENERATOR OUTPUT - A generator output which has no reference to ground. In other words, in order for current to flow there must be a complete circuit path from the active terminal all the way around to the patient terminal. Isolated outputs are required for good operation with bipolar instruments.

ISOLATED POWER SYSTEM - A large transformer assembly commonly found in operating rooms that converts conventional 120 volt AC ground-referenced power to isolated power with no voltage reference to ground.

KILO - A prefix meaning times one thousand. For example, kilowatt, kilovolt, etc..

KNIFE ELECTRODE - An electrosurgical active electrode. Electrotome. Anelectric surgical knife; radio knife; electroscalpel.

LEAKAGE CURRENT - A small current which flows along an undesired circuit path, usually to ground.

LINE ISOLATION MONITOR - A safety system used in conjunction with operating room power systems which monitors the 60 Hz AC leakage current flowing to ground through the power system ground wiring. Generally, the monitor sounds an alarm if the current becomes excessive.

LOAD - An impedance or resistance placed across a voltage source which draws current from that source. For example, the electrical resistance of the tissue grasped in the jaws of bipolar forceps is the load on the output of the electrosurgical generator.

MATCHED LOAD RESISTANCE - That load resistance for which power delivered from the electrosurgical generator is maximum.

MEASUREMENT CURRENT - A current intentionally applied to the patient's body to measure the adequacy of contact between the patient and the patient return electrode or other variables related to the function of safety features.

MEGA - A prefix meaning times one million. For example, megacycles,megahertz, megawatt, etc.

MICROBIPOLAR - A Valleylab name for an isolated generator output which has low power output and is optimized for desiccating tissue. Specifically, Microbipolar Outputs are designed for bipolar neurosurgical forceps, bipolar laparoscopic forceps, etc..

MICRO - A prefix meaning times one millionth. For example, microvolts, microamperes, etc..

MILLI - A prefix meaning times one thousandth. For example, millivolt, milliamperes, etc..

NECROSIS - Death of tissue, usually as individual cells, groups of cells, or in small localized areas.

OHMS - The unit of measurement of electrical resistance. In AC circuits, the unit of measurement of impedance.

OHM'S LAW - The relationship between voltage, current and resistance. Voltage =current x resistance. In AC (or RF) circuits, RMS voltage = RMS current X impedance.

OPEN CIRCUIT - No load or resistance connected to a voltage source. For example, if the generator is activated and the active electrode is not touching any tissue, the output of the generator is said to be open circuit.

PATIENT CABLE - *The cable or wire which connects the patient return electrode to the patient terminal on the generator.*

PATIENT CIRCUIT SAFETY MONITOR - *Any circuit in an electrosurgical unit designed to detect an unsafe condition in the output circuit and give a warning or disable the generator.*

PATIENT RETURN ELECTRODE - *The electrode at which no electrosurgical effect is intended. It is usually large in area in order to provide a low current density so that no electrosurgical effect occurs at that site. It is also known as a dispersive electrode, return electrode, inactive electrode, inert electrode, and indifferent electrode. If actually connected to earth ground, it is also appropriate to call it a "ground plate".*

PERMANENT ACCESSORY - *An electrode, switching pencil, forceps, or other accessory which is designed to be reusable.*

PHOTOCOAGULATION - *Use of concentrated light beams to destroy (coagulate) tissue (e.g., laser).*

PICOFARAD - *Micro-microfarad.* 10^{-12} *farad capacitance. A relatively small amount of capacitance appropriate for measuring capacitive coupling in electrosurgery.*

POWER - *The rate at which energy is produced or consumed. Power is equal to voltage times current or resistance times current squared. The unit of measure of power is the watt.*

POWERITE™ - *A Valleylab circuit which monitors the polarity of the electric power and the integrity of the chassis ground on the SSE2 and SSE3 Generators.*

R F - *Radio frequency. A high frequency alternating current. "Radio" generally means a frequency greater than, say, 100,000 Hz (cyles/second).*

RADIO FREQUENCY LEAKAGE CURRENT - *The maximum current which can flow to ground from an isolated generator output when one side of the output is wired directly to earth ground.*

RETURN ELECTRODE - *See patient return electrode.*

RETURN ELECTRODE MONITOR - *A subsystem available on Valleylab SSE2L and SSE3B Electrosurgical Generators, and standard on the SSE4, which continuously monitors the contact impedance of the patient return electrode and sounds an alert if the impedance rises above safe limits.*

RETURN FAULT CIRCUIT - *A patient circuit safety monitor unique to the Valleylab SSE3B and SSE4 electrosurgical generators which monitors the integrity of the patient's contact with the patient return electrode, the integrity of the patient's cable, and other safety features.*

RMS - See root mean square.

ROOT MEAN SQUARE - A mathematical method of averaging a waveform, such as an alternating current, which is symmetrical about the zero axis. The simple arithmetic average of such a waveform is zero, but root mean square averages of AC voltages or current yields numbers which may be used for calculations of power, resistance, impedance, etc..

"S-CORD" - A term used by another manufacturer for a cable which connects a patient return electrode to the metal body of a colonscope. It is used to shunt capacitive leakage from the colonoscope to the patient return electrode.

SHORT CIRCUIT - A zero impedance load connected across a voltage source. For example, if someone activates the generator and touches the metal active electrode directly to the patient return electrode, the resistance to current flow in the cables will be essentially zero and the generator is said to be operating short circuit.

SINK LEAKAGE CURRENT - The maximum current which can flow into a patient-connected lead (patient return electrode, active electrode, etc.) when 120 volts RMS 60 Hz AC is applied to that patient lead. The lead itself produces no current but passively accepts current flowing to ground when a ground-referenced power source (the line voltage) is applied to the patient by accident.

SOLID STATE - Electronic circuitry which is entirely transistorized and does not use vacuum tubes, spark gaps, or other archaic active circuit elements. The word "solid" refers to the structure of transistors which perform their electric function inside solid crystals, rather than in a vacuum, air gaps, or rarified gases.

SOURCE LEAKAGE CURRENT - The maximum 60 Hz current which will flow outof the chassis, patient return electrode, or active electrode when touched to a grounded object. In contrast to sink leakage, source leakage is active, that is, it provides a current which could flow through the patient or person touching the generator or accessories.

SPARK - An electric discharge across an air gap. In electrosurgery, it is the discharge seen at the end of an electrode when cutting or fulgurating.

SPARK-GAP - A pair of electrodes mounted in a circuit and positioned so voltage will cause sparks to jump across the air gap when the voltage rises to a high enough level. These are used in primitive electrosurgical generators as a type of voltage-controlled switch for the generation of COAG waveforms. In function, they are analogous to the breaker points in an automobile ignition.

SPARK-GAP WAVEFORM - *An electrosurgical COAG output generated by a spark-gap electrosurgical generator.*

STERILIZATION - *Destruction of microorganisms by (1) autoclaving--steam under pressure (regular cycle is at temperature of 250°F (121°C) for 15 minutes, and flash cycle is at 275°F (135°C) for 3 minutes); (2) ETO-Ethylene oxide gas (method by which Valleylab disposables are sterilized) over an 8-hour cycle.*

SURGICAL DIATHERMY - *The British term for electrosurgery.*

TRANSFORMER - *A circuit device made from two or more inductors which couples the magnetic fields from the inductors together so that currents in one inductor will induce currents in another. Transformers are used to change the ratio of voltage to current between one part of a circuit and another. For example, the output stage of an electrosurgical generator uses a transformer to convert relatively low-voltage, high-current waveforms to high-voltage, low-current waveforms useful for electrosurgery.*

VOLTAGE - *The force that drives electrons (electric current) through a circuit, wires, etc.. In electrosurgery, voltage is the force that drives electrons across an air gap to tissue to make an electric spark. The higher the voltage, the farther the spark will jump.*

VOLTS - *The unit of measure of voltage.*

WATT - *The unit of measure for power. A watt is defined as one joule of energy expended or consumed per second.*

WATTMETER - *A meter for measuring power. An RF wattmeter usually consists of an RMS ampere meter in series with a large power resistor. The meter is calibrated in the watts of power dissipated in the resistor.*

SECTION 11

WARRANTY

Valleylab, Inc. ("Manufacturer") warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service. Manufacturer's obligation under this warranty is limited to the repair or replacement, at its 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 Manufacturer'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 of Manufacturer's factory in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident.

The warranty periods for Manufacturer's products are as follows:

ELECTROSURGICAL GENERATORS	*One Year*
Mounting Fixtures (all models)	*One Year*
Footswitches (all models)	*One Year*
Return Electrodes	*Shelf life only, as stated on packaging.*
Sterile Disposables	*Sterility only, as stated on packaging.*

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF THE MANUFACTURER. Manufacturer neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Manfuacturer's products. There are no warranties which extend beyond the terms hereof. This warranty and the rights and obligations hereunder, shall be construed under and governed by the laws of the State of Colorado, U.S.A.

Valleylab, Inc., its dealers and representatives, reserve the right to make changes in equipment built and/or sold by them at anytime without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.