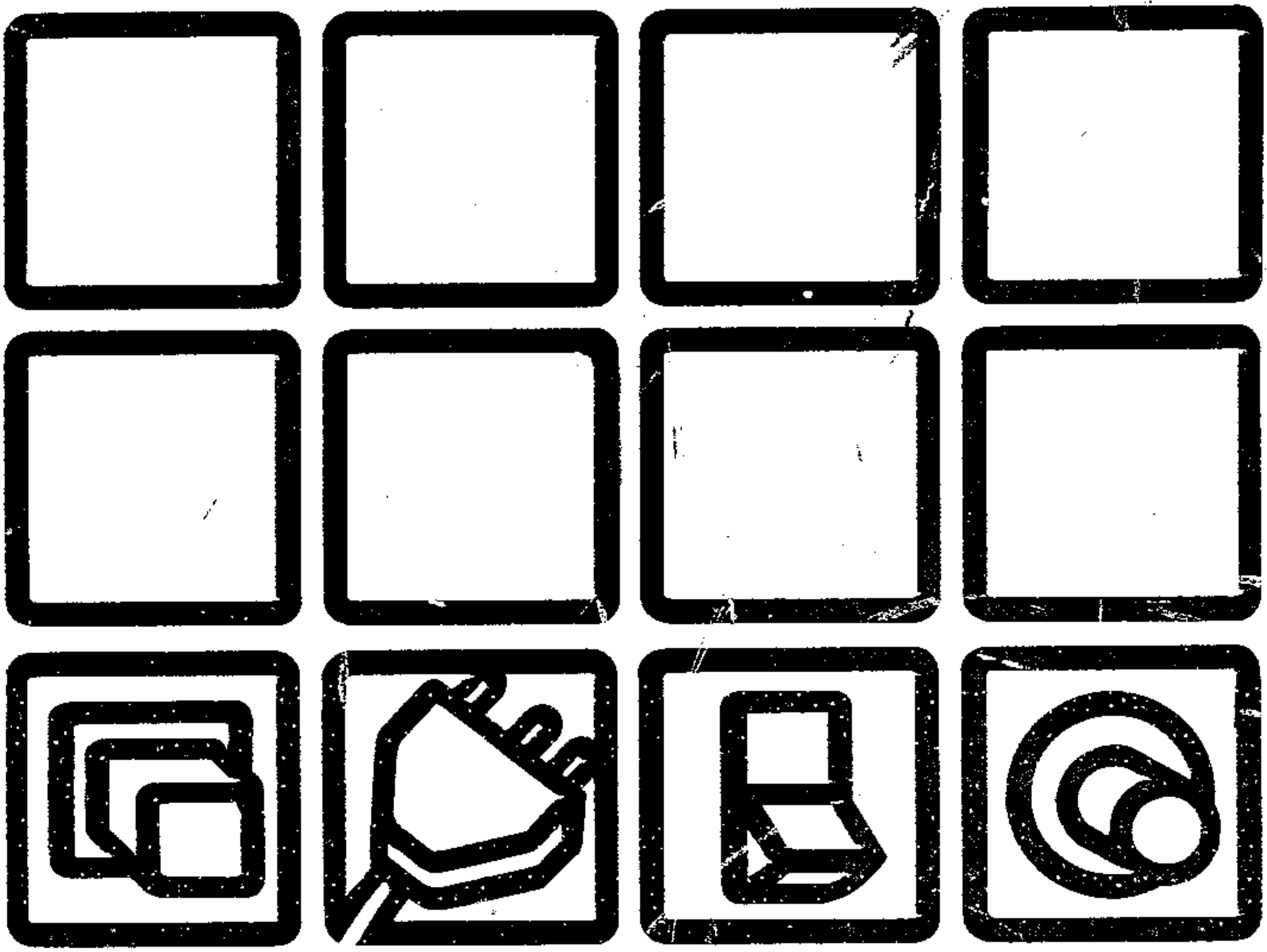

Valleylab

SSE2L
INSTRUCTION MANUAL

SSE2L INSTRUCTION MANUAL

Effectivity Date: August 1, 1984

Valleylab Part Number: A 945 110 005 H

INTENDED USES

The Model SSE2L Electrosurgical Generator is a general purpose unit intended for use in the operating room. The SSE2L 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, and COAG are intended for smooth cutting, cutting with increased degree of hemostasis, 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 designed for desiccation without cutting or fulguration. The bipolar output power may be controlled by either CUT or COAG controls. Although designed primarily for use with bipolar forceps, it is also possible to use the bipolar output with monopolar instruments. See instruction manual for details.

The SSE2L is available with a "low power option". This option consists of an additional control button on the front panel which attenuates all generator outputs so that, when the button is depressed, no more than 100 watts or 600 volts peak is available from any output receptacle. This option is intended for use in laparoscopy, neurosurgery, opthalmic surgery or any procedure where limiting power and peak voltage is critical.

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 patient return electrodes and their connections.

Electrosurgery involves electric sparking to tissue and is inherently unsafe for use with flammable anesthetics or near flammable fluids or objects.

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.

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.

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PRECAUTIONS

The surgeon should be aware that the Model SSE2L 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 generator has no way of detecting loose connections in the active or patient electrodes which may result in higher than normal low frequency components in the electro-surgical current. Low frequency currents components could cause fibrillation so the patient 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 and 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.

THE SSE2L SYSTEM

INTRODUCTION

Congratulations. Your new model SSE2L is the latest member of the famous Valleylab line of SSE2 electrosurgical generators which have become a standard in the world for performance, safety, and reliability. The first model SSE2 was introduced in 1970 and pioneered full-power, solid state electrosurgery, the isolated output, hand-switching, and numerous other features. Your SSE2 has already proven itself in literally millions of procedures and offers a wide range of surgical capabilities, safety features, and design advantages in a small and easy-to-use instrument. In addition to these time proven advantages, the SSE2L features greater safety with three electrically independent outputs for hand-switched monopolar, footswitched monopolar, and hand or foot-switched bipolar operation.

This instrumentation manual provides a great deal of information on electrosurgery, the SSE2L, and basic electricity. With the information in this manual, you should be able to understand the SSE2L well enough to use it 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 this section a surgeon should be able to decide what procedures his SSE2L 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 8 is a short primer on electricity and electronics for the electrical layman and Section 9 is a glossary of terms.

The remainder of the Instruction Manual, Sections 3 through Section 7, 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 7 as well as Sections 1 and 2.

The SSE2L Service Manual is a separate volume written for the hospital engineer. It contains routine test procedures, circuit descriptions, schematics, oscilloscope waveforms, troubleshooting procedures, and a complete replacement parts list.

If any questions arise about using your new SSE2L, 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.

SECTION 1

ELECTROSURGICAL THEORY APPLIED TO THE SSE2L

The model SSE2L is a full power, general purpose, solid state generator which can be used for nearly any procedure. Because of its wide range of capabilities it is also possible to misuse it if its operation is not well understood.

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 muscle and nerves. Putting it another way, a low frequency electric current could electrocute the patient.

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.

Typically, electrosurgical generators operate 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 the radio frequency current to wires. For these reasons the SSE2L operates at 500,000 Hz (500 KHz) which is a compromise between these two extremes.

SURGICAL EFFECTS OF ELECTROSURGERY

There are 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.*

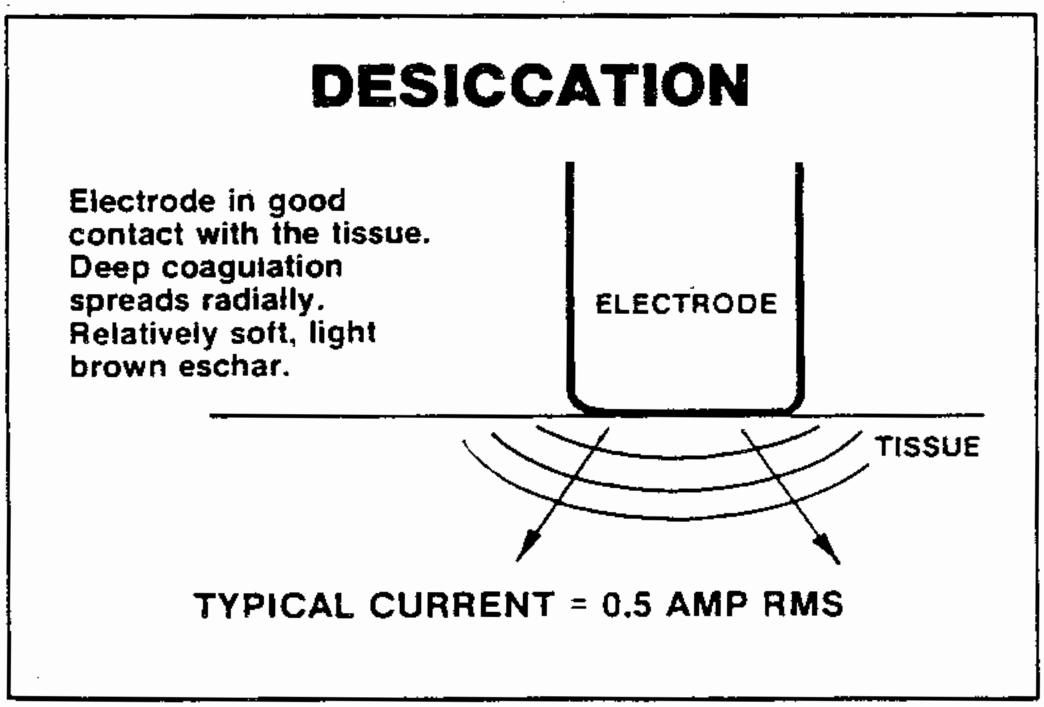
The SSE2L is optimized to perform all three of these functions.

ELECTROSURGICAL DESICCATION

Of the three, desiccation is technically the simplest because ANY waveform *(either CUT or COAG) can be used and only low power levels are required. 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 (3).*

Desiccation can be done with either the monopolar or bipolar outputs. However, the bipolar output is optimized for desiccation and will not cut or fulgurate. Even at very high settings there will be very little tendency to cut or fulgurate with the bipolar output. In contrast, the monopolar output is designed primarily for cutting and fulguration. Very low settings must be used, "2" or less, in order to confine the effect to desiccation when the monopolar output is used.

Desiccation with the SSE2L can be performed with either CUT, BLEND, or COAG waveforms. 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 waveforms are only relevant to cutting and fulguration.



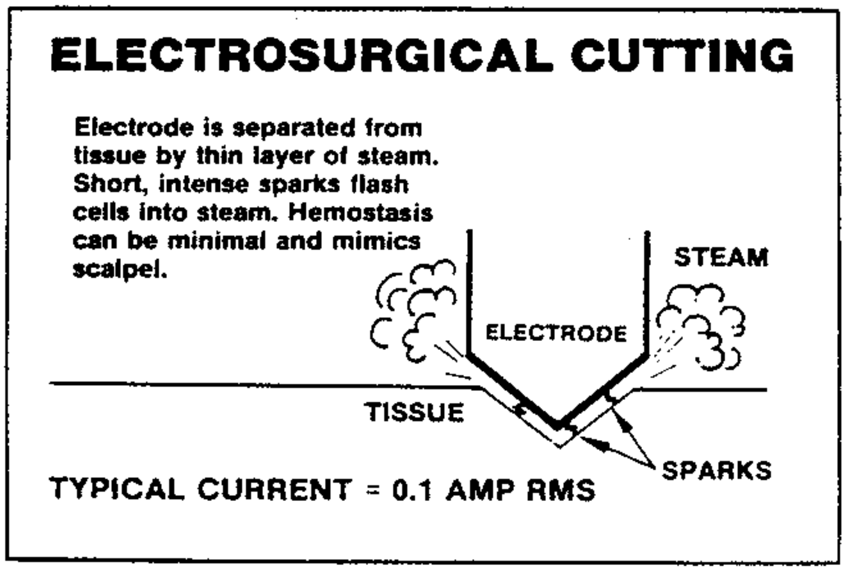
ELECTROSURGICAL CUTTING

In electrosurgical cutting the objective is to heat the tissue so rapidly that cells 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 (4). When the electrode is moved and fresh tissue is contacted, new cells are exploded and the incision is made. When the radio frequency current jumps across an air gap to tissue, the bright light in the gap is technically known as a "spark". An "arc" is a similar phenomenon which requires longer intervals to become established and probably does not play a significant role in electrosurgery.

Electrosurgical cutting involves sparking to tissue (5). It should be mentioned here that a hot cautery wire (a heated wire with no electric current passing into the tissue) can also cut tissue by the mechanism explained above.

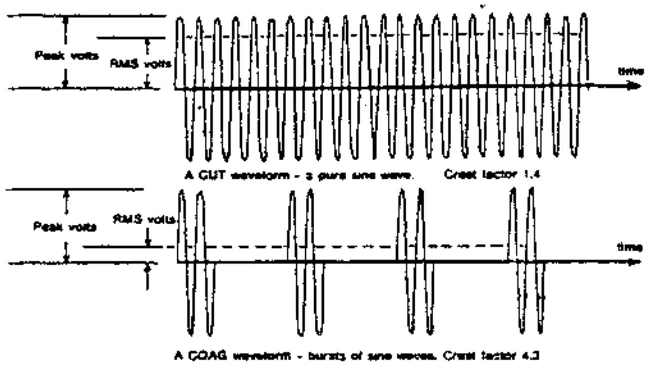
To understand the difference between the cautery wire and electrosurgical cutting, let's suppose that one tries to desiccate with a small wire electrode at a relatively high setting of CUT, say "5" on the SSE2L monopolar output. Because the power level (heat delivered per second) is high, the tissue 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. Electrons collide with the tissue as well as radiant heat from 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.



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, 500 KHz (500 kilocycles per second).

EQUAL PEAK VOLTAGE WAVEFORMS



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

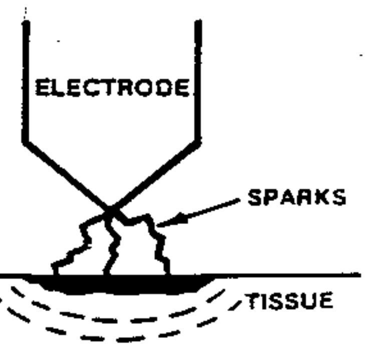
Electrosurgical Fulguration

The SSE2L COAG waveform consists of short bursts of radio frequency sinewave. The frequency of the sinewave is 450 KHz and the COAG bursts occur 20,000 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 described above. Because the voltage is the same, the sparks can jump the same distance as with 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 during the periods when the generator is on.

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.



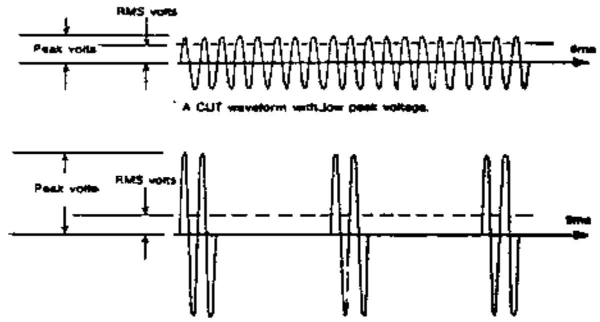
TYPICAL CURRENT = 0.1 AMP RMS

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 always produces necrosis anywhere the spark lands. 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 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.

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.

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 SSE2L COAG is 6.7 and is essentially constant over the entire control range.

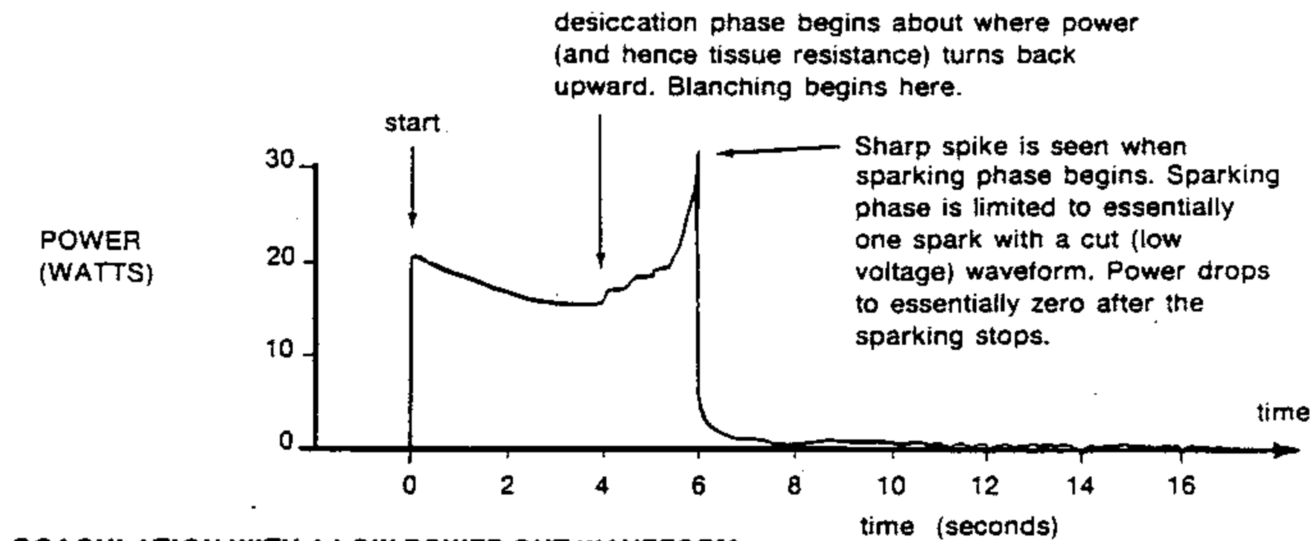
$$\text{Crest Factor} = \frac{\text{Peak Voltage}}{\text{RMS (Effective average) Voltage}}$$

__BLENDED CUT__

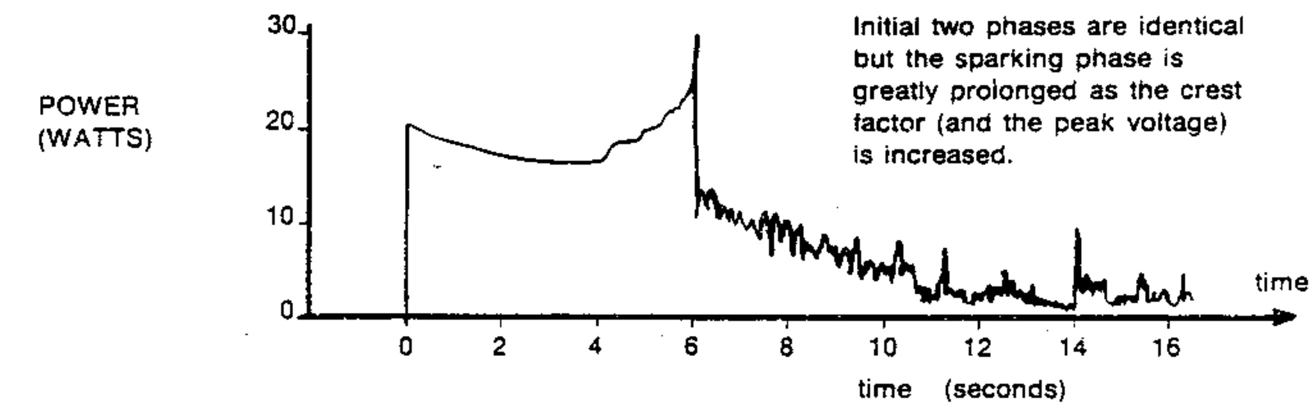
As one might expect, the BLEND is a cutting waveform with moderate hemostatic effect. That is, the walls of the incision made with the BLEND current will be well-fulgurated, depending on the fineness of the electrode. The finer the electrode, the cleaner the cut.

To obtain a BLENDED CUT with the SSE2L, the PURE/BLEND switch located at the upper right of the front panel is set to BLEND. This modified the CUT output to give it a crest factor of 2.9 which provides more hemostasis than PURE CUT, but far less than COAG. The most common misunderstanding about BLEND on all of the SSE2 models is that the BLEND is fixed and cannot be modified in any way by adjusting the COAG control. One way of looking at this is that the generator is only capable of offering two modes to the surgeon at one time. He can use COAG or PURE CUT, or he can use COAG or BLENDED CUT. When adjusting the power setting in BLENDED CUT, the surgeon uses the CUT knob.

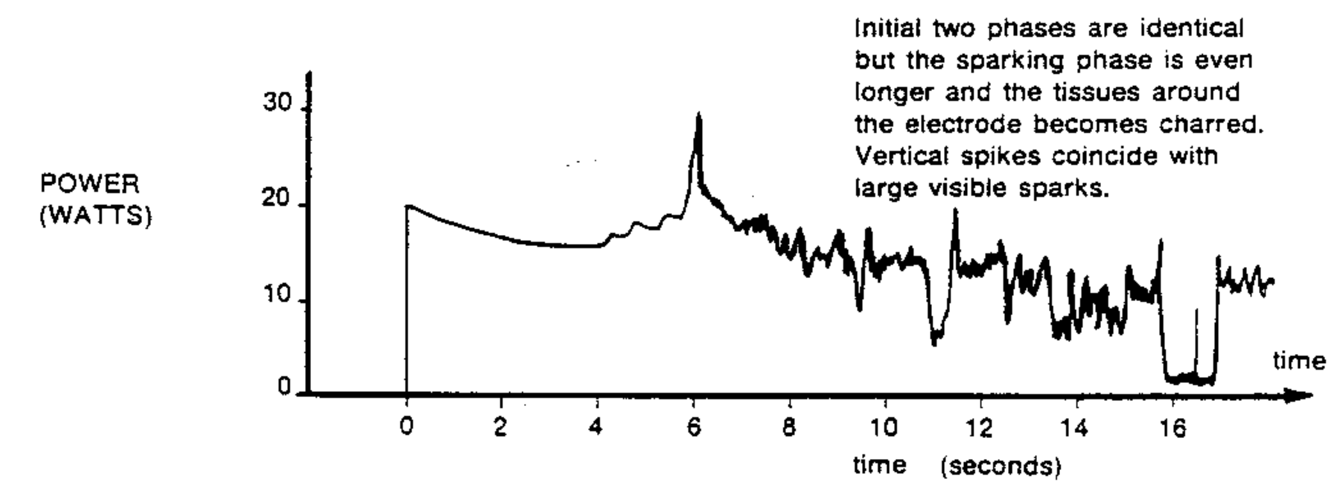
The output voltage waveforms as seen on an oscilloscope are shown on pages 92 to 94.



COAGULATION WITH A LOW POWER CUT WAVEFORM



COAGULATION WITH A LOW POWER BLEND WAVEFORM

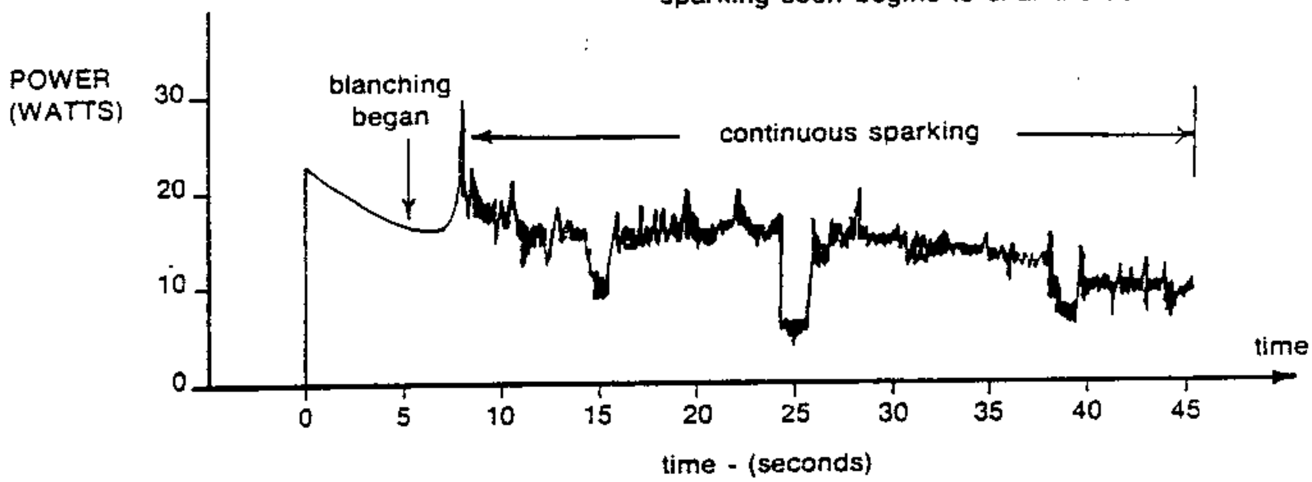


COAGULATION WITH A LOW POWER COAG WAVEFORM

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

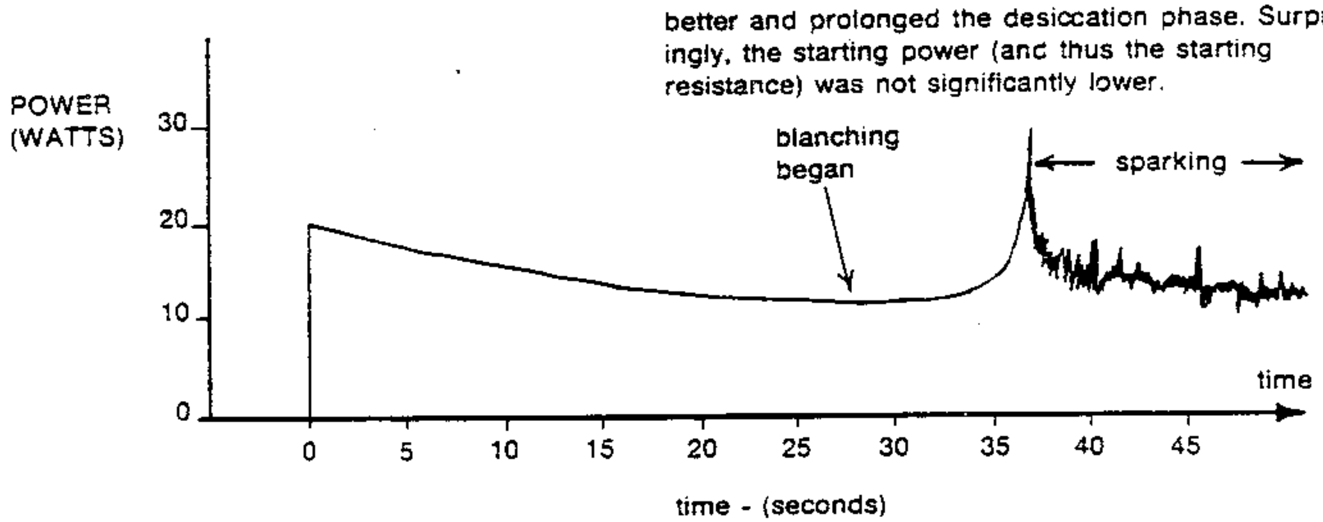
An experiment to show the effect of good physical contact between the electrode and the tissue.

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 VALLEYLAB SSE2
ELECTROSURGICAL GENERATOR

Caution is required when using the SSE2L BLEND for cutting vascular tissue. It is important to realize that the extra hemostasis will only be available WHEN THE CUTTING ELECTRODE IS MOVED SLOWLY THROUGH THE TISSUE. If one looks at the voltage waveforms for BLEND, it is clear that, unlike COAG, the voltage is never turned completely off. As a result, every voltage half cycle is available to make a spark to tissue. If the electrode is moved very rapidly, each half cycle will make a spark and the effective crest factor will not be very different than PURE-CUT.

The Valleylab model SSE2L had a crest factor of 1.4 in PURE CUT. That is, it was as "PURE" as possible. A very fine cutting loop electrode is used in transurethral resections. We found that the pure CUT is so clean that the incision bleeds excessively. For this reason subsequent SSE2 models all have a slightly higher crest factor in CUT, 1.7. This is achieved by partially defiltering the power supply and leaving a 120 Hz "ripple" on the output stage power supply. This makes the output power rise and fall 120 times per second giving some of the same on-off characteristics as COAG. This 120 Hz modulation is NOT a low frequency component which can stimulate muscles and nerves.

The relationship between CUT, BLEND and COAG can be illustrated by coagulation of liver with test electrodes in each of the three modes. This 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 sparking will continue for the longest period of time. The COAG waveform fulgurates 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.

Another way to keep the output of a generator from cutting is to use large, active electrodes so that the desiccation phase is prolonged and the electrode is prevented from sparking to tissue. Also, sparking can be prevented by pressing the active electrode firmly against the tissue.

MONOPOLAR APPLICATIONS WITH THE SSE2L

The word "monopolar" means that the active electrode (the blade, forceps, or other instrument) must be used with a patient return electrode to return the electrosurgical current to the generator and complete the circuit path. "Bipolar" means that the hand held instrument, usually forceps, contains the return path built into the instrument. When bipolar instruments are used there is no need for a patient electrode.

The SSE2L is unique in that it has two monopolar outputs which are electrically separate and can be independently activated. The hand switch monopolar output (three small holes on the lower left) are only activated ("hot") when the handswitch (on a monopolar forceps or LectroSwitch) is keyed. Similarly, the monopolar footswitch output (the square hole) is only "hot" when the footswitch is activated

and "monopolar" footswitch button on the lower left is selected. WARNING! On all previous Valleylab SSE2 and other models ALL outputs are "hot" simultaneously whenever the generator is activated by any means.
It is also possible to use the "bipolar" output with monopolar instruments and a patient electrode. However, this is only useful in rare instances and Section 2 should be carefully studied before this is attempted.

All three outputs of the SSE2L, including the two monopolar outputs, are well isolated from ground. When either of the two monopolar outputs are used, a patient return electrode must be connected to the large patient receptacle.

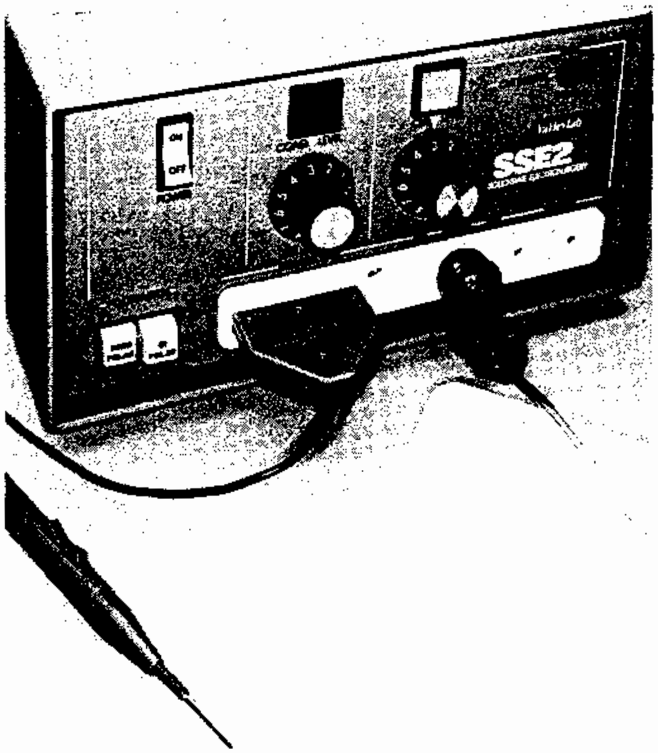
Because the SSE2L is an isolated system the circuit path from the active electrode to the patient jack must be complete in order for significant current to flow. When a break occurs in this circuit loop, the current simply stops. This protects the patient from possible burns in the event that the patient plate is not touching the patient's skin. The surgeon therefore is responsible for determining whether a break in this circuit has occurred. If the generator doesn't seem to be working. DO NOT TURN UP THE GENERATOR. CHECK THE PATIENT RETURN CIRCUIT. Also, check to see that the patient cable is plugged in, that the cable is attached to the return electrode and in good contact with the skin. If the plate is a gel pad type, remove and replace it with a fresh pad. NEVER reapply a used pad.

For added patient safety, SSE2L model generators may be ordered with the option of having a "Return Electrode Monitoring System" (REM). This system incorporates both a visual and audio alert which enables in the event a break in the circuit path from active to the return jack has occurred.

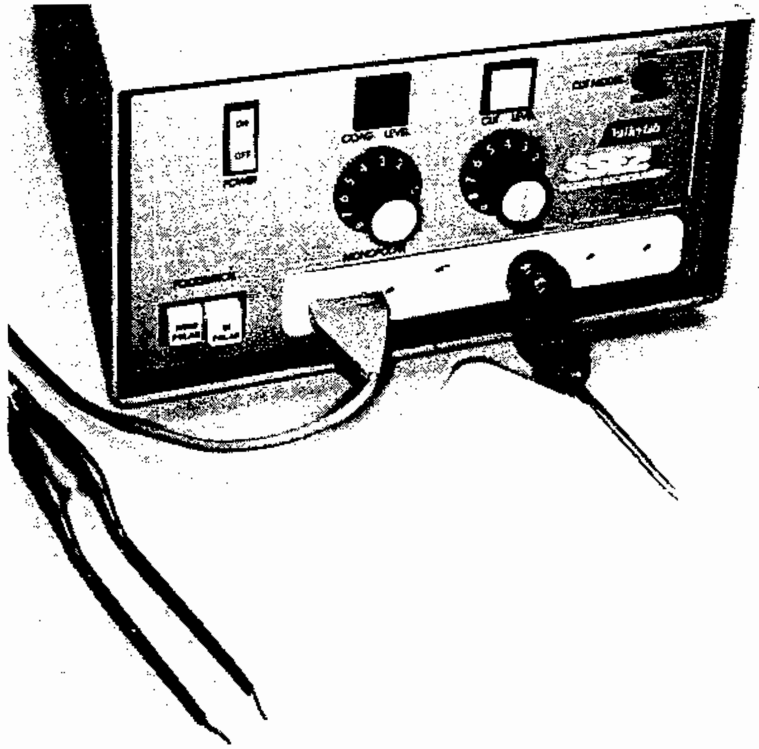
For use with the REM system, the Cohesive Return Electrode (Model E7505) has been designed. The Cohesive Return Electrode System is a dual Return Electrode, which when used with a REM equipped generator has the capability to monitor the electrical resistance between the two parts of the pad and allow operation only if the resistance is between preset limits. This instrumentation provides increased assurance that the return electrode is in good condition and properly applied to the patient's skin.

To allow compatability with previous return electrode systems, a second mode of operation having only an upper resistance limit is automatically provided if a standard electrode is connected. An adapter or special cord may be required for use with these electrodes. Note: Standard return electrodes, except the Cohesive Electrode (Model E7505) will function with the REM system and monitor cable integrity, but will not monitor patient electrode contact.

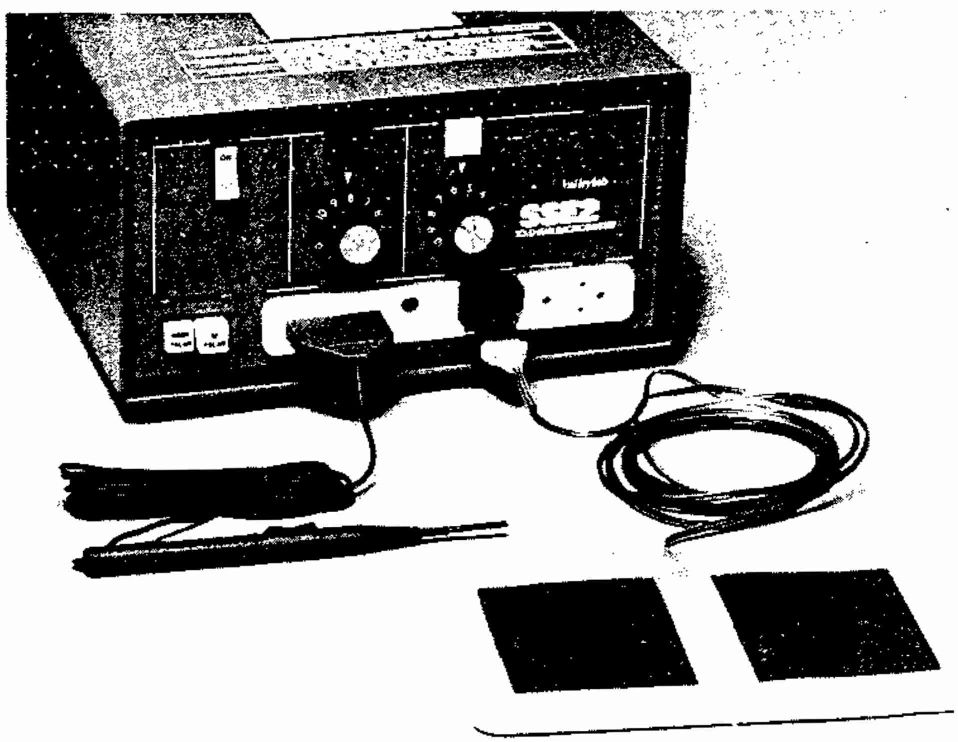
Warning: All Valleylab return electrodes and mating cables should be inspected prior to each use, for cracks or voids in the insulation and or possible loose connections. In the event a cord fault is present, the cord and/or electrode should be replaced to prevent any reduction of output power during a surgical procedure.



E0504 LectroHesive Adapter
E7503 Prep II Patient Return Electrode
E2502B LectroSwitch Pencil



E0504 LectroHesive Adapter
E7503 Prep II Patient Return Adapter
E4001 Monopolar Handswitching Coagulation Forceps



REM System Equipped Generator
E2508 Handswitching Pencil
E7505 CoHesive Patient Return Electrode*

* Use of any other patient return electrode (including Valleylab E7502, E7503, E7504) with a REM equipped generator will reduce the system to a continuity monitor only.

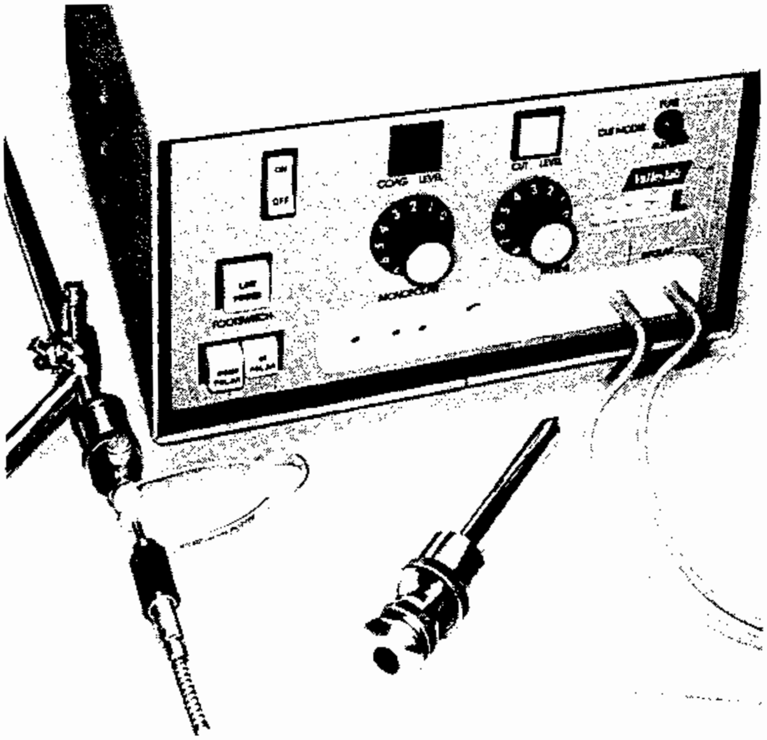
CONNECTING MONOPOLAR INSTRUMENTS
TO THE SSE2L

Suppose you check the patient plate circuit and all seems to be in order. How do you know that the generator is working? The "CUT" and "COAG" lights are activated by the presence of a radio frequency signal in the output circuit. You can demonstrate this by turning the control to zero and activating the generator. The lights should remain off until the control is advanced to about "1". When the lights are on, the generator is doing its job and the problem lies in the patient cable or possibly the active cable.

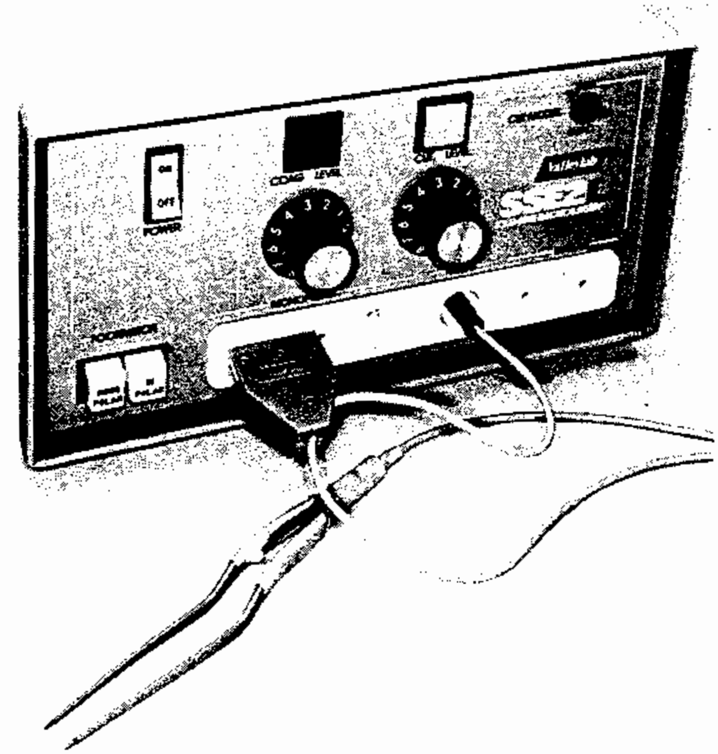
The patient plate replacement and size requirements are discussed in Section 5. In summary, we recommend using a patient electrode of about 10 square inches of skin contact area for each 100 watts of power. The return electrode should be located as close as practical to the site of the surgery. Bony prominences should be avoided and we recommend that a thin layer of good conductive gel such as "LectroGel" be replaced on the plate.

A few theoretical points about patient plate operation with the SSE2L follow: It is often noted that isolated electrosurgery cannot be perfect because the capacitance coupling to ground makes some currents flow through the ground path instead of going strictly to the patient terminal. The SSE2L has a special leakage cancelling circuit which minimizes this problem. The circuit assumes that a ten foot long active lead will be plugged into the generator. Such a lead typically has about 60 pf of capacitance between active and ground. A parallel inductor between active and ground inside the generator turns this capacitance into a resonant circuit which impedes the flow of leakage. This circuit lowers the leakage to less than 150 ma measured at maximum power, open circuit, between patient jack and ground. This is the worse case. At typical settings and with a load on the generator, the leakage will be far less than this.

Why is leakage a bad thing? Leakage could be dangerous if it entered the patient's body at some tiny grounded contact point since electrosurgery is a function of current <u>density</u>, not just current magnitude. The lesson here is that very small, grounded contact points on the patient's body should be avoided. ECG electrodes are usually grounded, at least so far as radio frequency currents are concerned. The electrodes should be as large as possible and for this reason we recommend the disposable pre-gelled type which have at least ½ square cm of area. Other electrodes such as pacemaker catheters and rectal thermometers are also a threat. All these things should (ideally) be located distally from the current path between the site of surgery and the return electrode.

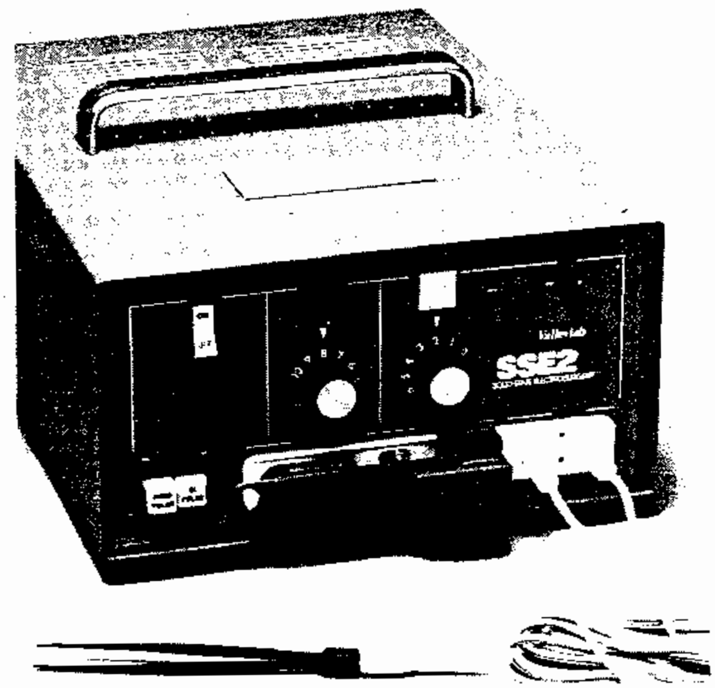


Microbipolar laparoscopy forceps attached to bipolar output receptacles. A footswitch (not shown) is required.



Use of monopolar isolated output for desiccation with handswitching macrobipolar forceps.

E0021 Adapter shown plugged into the REM patient return. This adapter allows the monopolar output to be used in a macrobipolar procedure with a REM equipped generator.



When microbipolar only is needed to perform the surgical procedure, the E0024 can be used to cover the monopolar active and patient terminals, thus eliminating the need for a patient plate with a REM equipped generator.

CONNECTING BIPOLAR INSTRUMENTS
TO THE SSE2L

BIPOLAR APPLICATIONS WITH THE SSE2L

Bipolar electrodes are simply forceps or other electrodes which have the active and return electrodes built into the same tool. No patient plate 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 most bipolar applications involve desiccation with small forceps using very low power levels, the word "bipolar" has become associated with low power levels and a desiccation-only characteristic which will desiccate without any significant tendency to cut or fulgurate. The essential requirement for bipolar operation is electrical isolation from ground. This is necessary so that the electrosurgical current will only return to the generator via the return path provided on the hand held instrument. The SSE2L bipolar output has all three of these properties; isolation, low power, and a desiccation-only characteristic.

It is also possible to cut and fulgurate with bipolar instruments, even at high power levels. For example, an experimental bipolar transurethral resectoscope has been successfully tested (2). With these applications too, the generator must be isolated from ground, but if cutting and fulgurating at high power levels are needed, then these properties must be provided. If a bipolar instrument of this type were used with the SSE2L, it would have to be used with one of the two "MONOPOLAR" outputs, because both of these outputs have the three properties required for bipolar cutting or fulgurating; namely, isolation, cutting and fulguration, and the potential for high power levels. Unfortunately, bipolar cutting and fulgurating instruments do not yet work as well as their monopolar counterparts and are not widely accepted.

Bipolar instruments have two fundamental advantages over monopolar instruments. First, the surgical effect is confined to the tissue that is in direct contact with the hand held instrument. For example, in neurosurgery, fine bipolar forceps confine the desiccation to the tissue grasped in the forceps and can minimize neural damage. Second, the bipolar instruments, together with a well isolated generator, keep the electrosurgical current from traveling any significant distance through the patient's body and eliminate the various kinds of accidents associated with patient return electrodes, current division, and other phenomena.

The illustrations on page 13 show how bipolar instruments are connected to the SSE2L. The upper two pictures show how forceps for desiccation are connected to the bipolar output. In the upper left picture, the forceps are activated by the footswitch. In order to turn on the bipolar output with a footswitch, THE "BIPOLAR" FOOTSWITCH BUTTON MUST BE DEPRESSED. Many bipolar forceps are equipped with two ordinary banana plugs. These can be plugged into the larger two holes of the four small holes on the "bipolar" receptacle. The lower two pictures illustrate proper connection of the bipolar instruments for REM system equipped generators. When a macro-bipolar application is required, the macro-bipolar forceps (SW2 series) may be used with the E0021 cord and adapter as shown in the lower left photo on page 13. For surgical procedures when micro-bipolar only is required, a cover (model E0024) should be used to cover the monopolar accessory jack as shown on lower right, page 13, to eliminate the use of a patient plate.

If the bipolar forceps are equipped for hand switch activation, a four pin plug must be used as shown in the center picture. If the bipolar instrument is designed for electrosurgical cutting and/or fulguration, it should be plugged into the "MONOPOLAR" isolated output as explained earlier. Bipolar procedures require an isolated generator such as the SSE2L. If a grounded generator 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 only the tissue which is grasped between the two electrodes is cut, desiccated, or fulgurated. 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.

Similarly, a large patient return electrode which is electrically common to the "patient" side of a bipolar instrument should not be connected to the patient's body. The large patient return electrode will present a much better path back to the generator than the small, local return electrode on the bipolar instrument. The result will be monopolar operation, not bipolar operation, and the safety of bipolar will be lost.

CONTROL TAPERS AND CALIBRATION

There are two ways to look at the SSE2L 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 voltage at a given setting are useful guides.

Power

Power is the amount of energy delivered each second. Because of differences in electrode size, this does not relate well to quantity of tissue fulgurated or cut each second. The first step in deciding what power setting you need is to have a rough idea of the demands of the procedure. Table 1 categorizes various procedures into three rough categories of low, medium and high power and gives a typical range of settings. This sounds very crude, but the differences in technique and electrodes do not make it possible to list exact settings.

The basic approach should be to start with the minimum setting, then increase it until the desired effect is achieved. Although knowing the exact maximum watts of output for a given control setting is not terribly helpful, this information is given on page 18 in the form of a graph, which shows power versus control setting.

Output Voltage

Voltage is the force which makes sparks jump to the tissue. Although the distance sparks jump depends somewhat on electrode shape, 30,000 volts can jump about an inch through air. Because COAG has higher peak voltages than CUT, it can produce longer sparks.

The peak output-voltages, measured both open circuit (with the active electrode not touching tissue) and with a 500 ohm load resistance are plotted against control setting on pages 18 and 19.

There are two common applications for this voltage information and both of them involved 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. As can be seen on page 19, COAG has higher voltages for any given control setting. The graphs on page 18 show that CUT has higher power for a given control setting. Since cutting, there is no need for either high power or high peak voltage since no sparking is required. It follows from this that a very low setting of CUT (1-2) 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, then more peak voltage is needed to overcome the resistance of the dried tissue. A good compromise between COAG and CUT is of course 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.

The SSE2L can be supplied with an optional attenuator control which reduces the power available from all three outputs to less than 100 watts and less than 600 volts peak. This option with appropriate graphs is discussed in Section 3.

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

TABLE 1

POWER LEVEL SETTINGS FOR THE SSE2L

The power levels used for various surgical procedures vary considerably with the surgeon's technique and the size of the active electrode. For example, a small needle electrode will require less power to start a spark to tissue 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 for monopolar outputs follows: (Microbipolar output may require higher settings).

1. *Low Power*
   (CUT and COAG levels 1 to 3)

   a. *neurosurgery (both bipolar and monopolar)*
   b. *laparoscopic sterilization (both bipolar and monopolar)*
   c. *vasectomies*
   d. *polypectomy*
   e. *dermatology*
   f. *oral surgery*
   g. *plastic surgery*

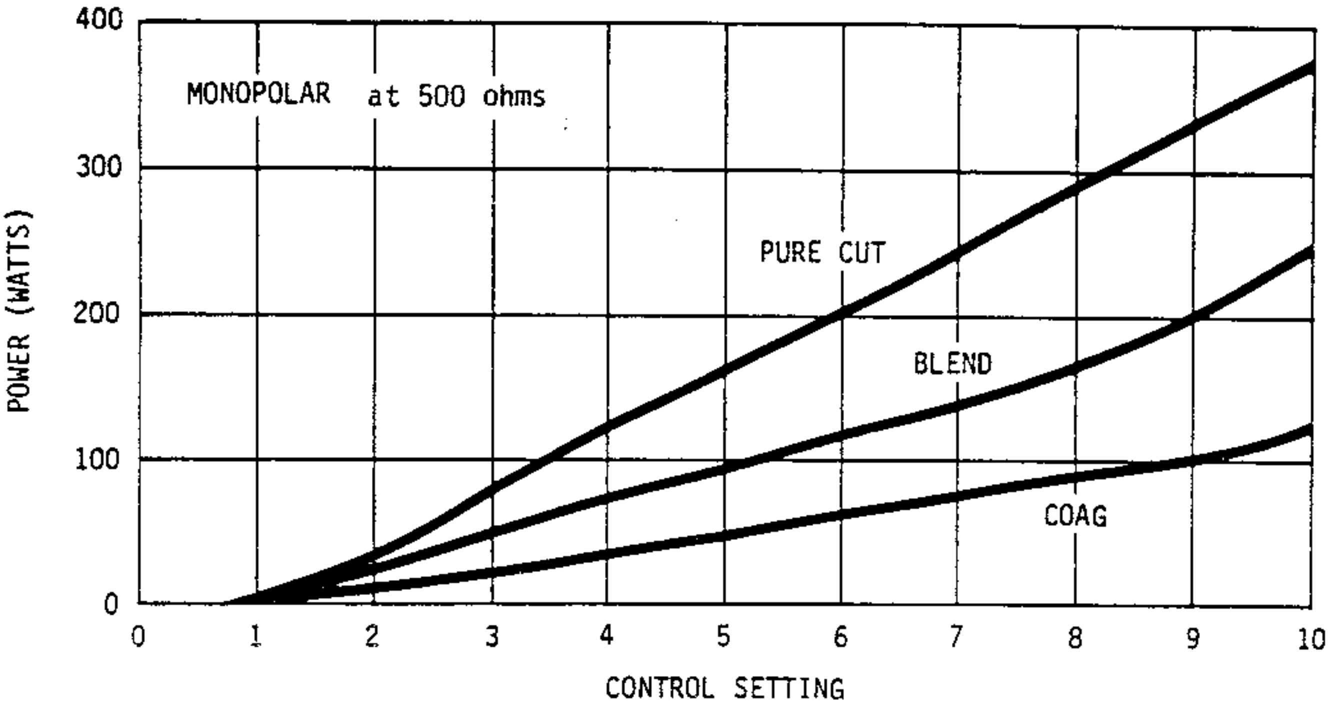
2. *Medium Power*
   (CUT and COAG levels 3 to 6)

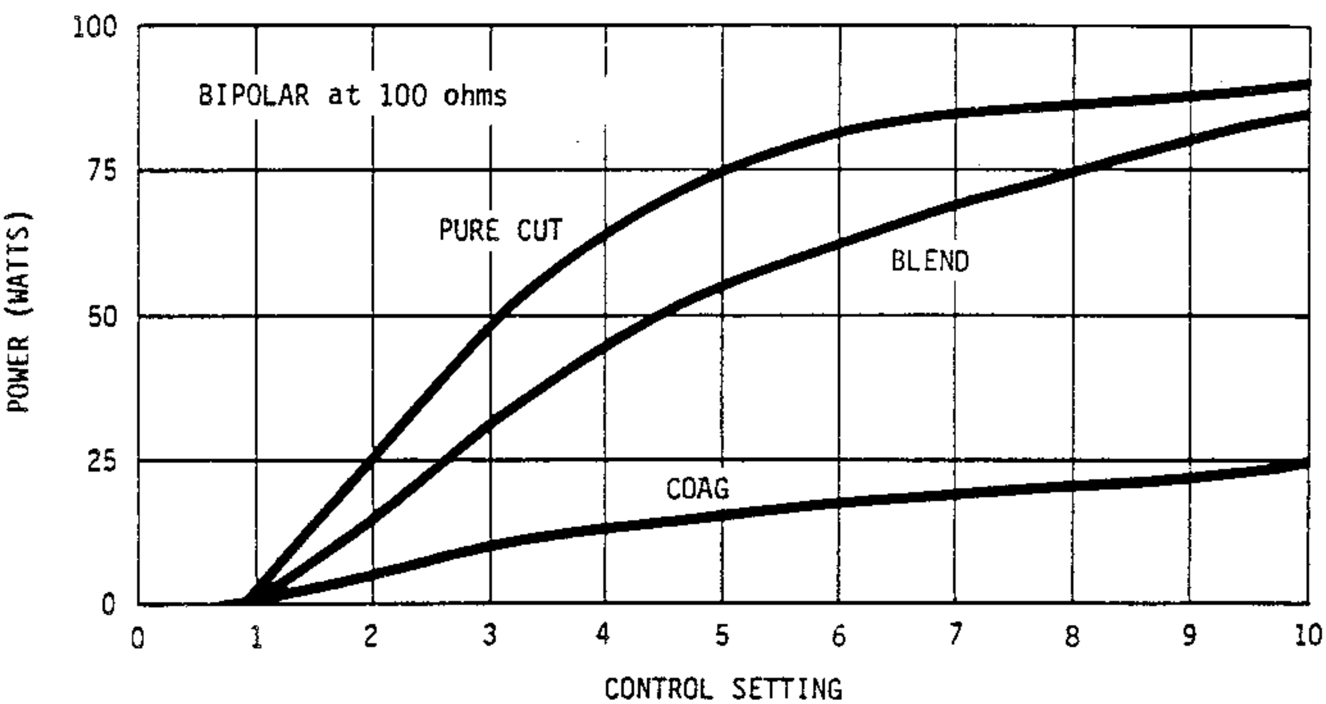
   a. *general surgery*
   b. *laparotomies*
   c. *head and neck surgery (ENT)*
   d. *major orthopedic surgery*
   e. *major vascular surgery*
   f. *routine thoracic surgery*

3. *High Power*
   (CUT and COAG levels 6 to 10)

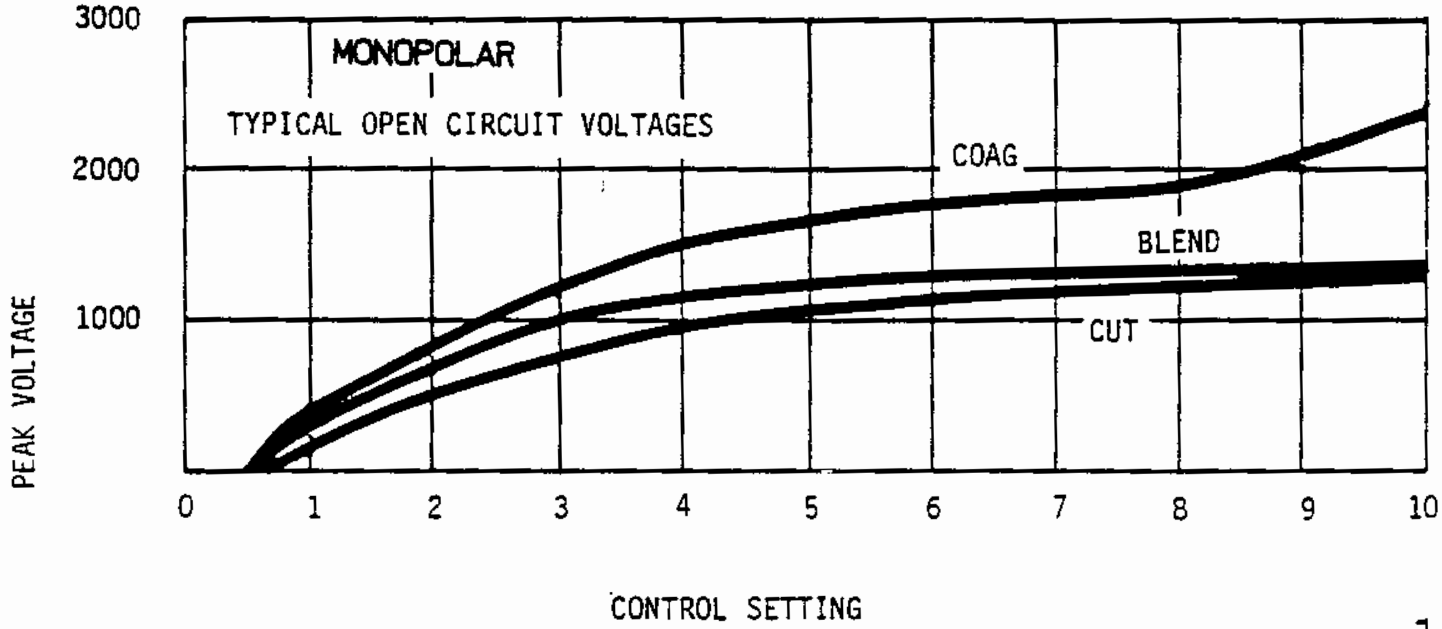
   a. *transuretral resections*
      (4 to 10 depending on the thickness of the resection loop and the technique of the surgeon)
   b. *thoracotomies*
      (heavy fulguration, 6 to 10)
   c. *ablative cancer surgery, mastectomies, etc. (6 to 10)*

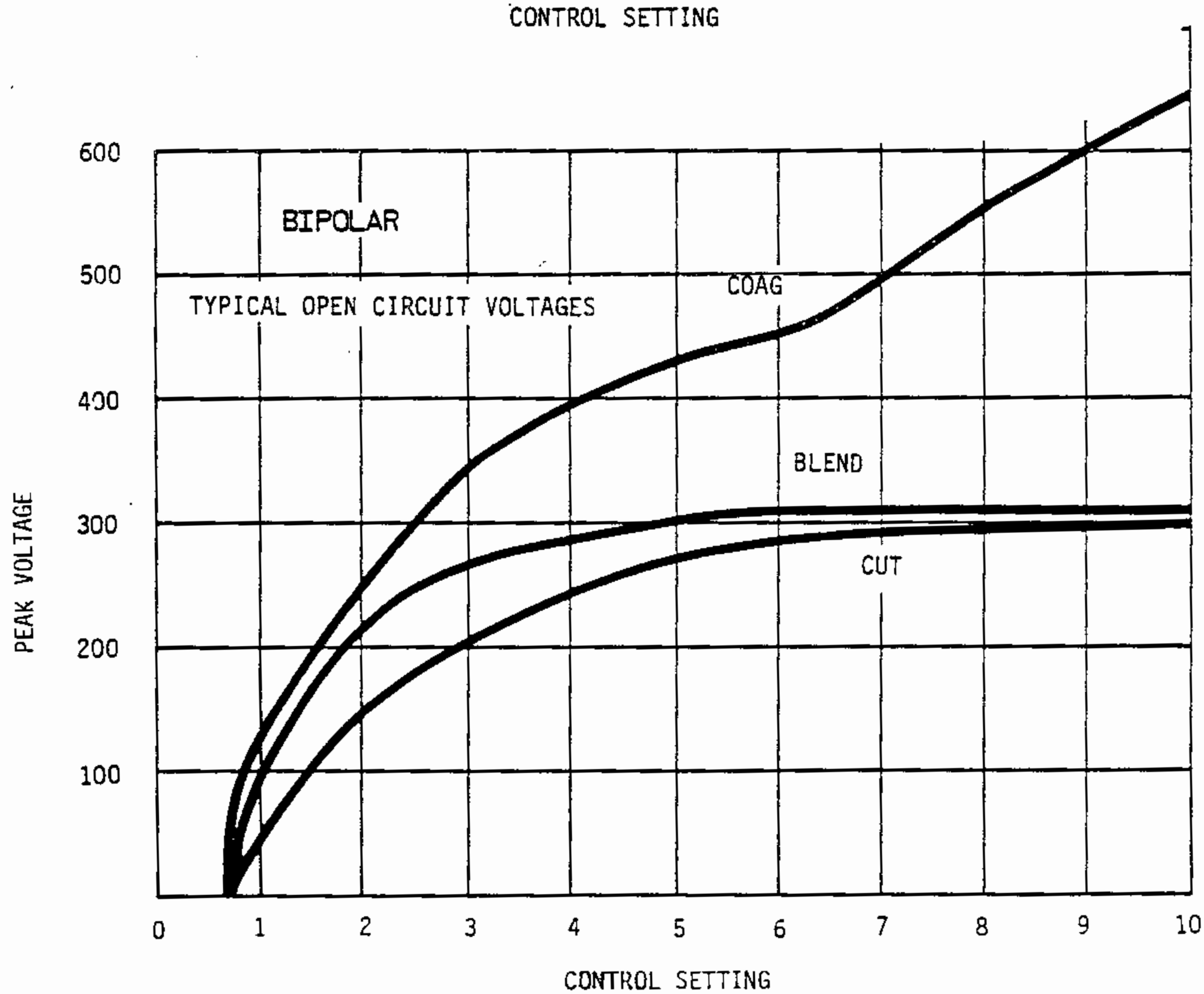
IF THE PROPER SETTING IS NOT KNOWN FROM PERSONAL EXPERIENCE, ONE SHOULD SET THE GENERATOR AT A VERY LOW SETTING (1) AND CAUTIOUSLY INCREASE IT UNTIL THE DESIRED EFFECT IS ACHIEVED





TYPICAL OUTPUT POWER VS CONTROL SETTINGS





OPEN CIRCUIT VOLTAGE CHARACTERISTICS

can cut, fulgurate, and desiccate tissue without significant differences in performance. Frequencies below 100 kilohertz can, of course, stimulate muscles and nerves and are never used in electro-surgery. (1)

Reactive Effects

The SSE2L operates at 450 KHz in COAG and 500 KHz in CUT. This small difference occurs for engineering reasons and has no clinical significance. 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 frequency is relatively low to avoid capacitive coupling which can cause leakage currents to flow in grounded objects. Thus the relatively low frequency of the SSE2L allows a high degree of isolation from ground.

Neuromuscular Stimulation

As explained earlier, a radio frequency is used to prevent stimulation to muscle 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 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 (500,000 times per second) there is a 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 the actual radio frequency. Fortunately these voltages do not cause stimulation unless currents are allowed to 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 500 KHz currents flow through but block the flow of these 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.

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 160 Hz AC leakage currents between the metal case and ground, and between the active and patient leads and ground. This is exceedingly unlikely, especially with the SSE2L when the Powerite circuit is being used.* However, shocks due to 60 Hz power line voltages 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 in CUT mode when cutting, and rarely occurs when desiccating. A lower power setting will always produce less stimulation.*
6. *Plastic surgery on the face is a typical situation in which neuromuscular stimulation is a problem. One solution can be the use of a capacitive attenuator, (Cat. #E0015). This attenuator decreases the available power by approximately a factor of ten, which gives a maximum of 40 watts CUT and 12 watts COAG with the monopolar output. Since the capacitor in the attenuator has extremely little conductivity at frequencies in the stimulation range, it makes an excellent stimulation filter and is sure to solve the stimulation problem. 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 than the standard SSE2L, since it will desiccate extremely slowly. If the generator is turned up to produce quicker desiccation, it will immediately begin sparking 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, either monopolar or bipolar using the monopolar output. If the attenuator is used in the bipolar output, the attenuation will be extreme and we don't know of any useful application for the configuration.*

**Powerite is explained in Section 7.*

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

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

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

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 SSE2L, patients with pacemakers, and the use of the bipolar output with a patient return electrode.

POLYPECTOMY

This procedure can be done through a colonoscope, protoscope 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 maneuver by cutting with a blended current, but both approaches have their pit falls.

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 oxygen. In the colon there is contiguous tissue in all directions from the peduncle 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 BLEND at a setting of 1 to 3 [2, 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. 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.

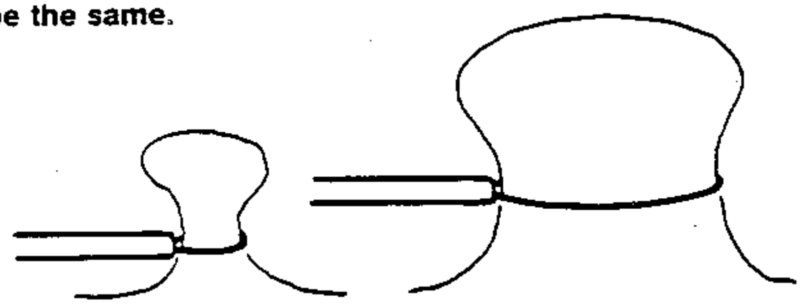
While desiccating a large polyp it should be kept in mind that the generator setting will have to be higher to have the same current density along the snare area when starting the desiccation. However, the tighter one pulls the snare, the smaller the effective diameter. As the snare becomes very tight and the diameter becomes very small, the current density will rise as the inverse of the SQUARE of the diameter of the snare loop [7]. In other words, a setting which is appropriate for a large polyp may be far too high for a small one.

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.

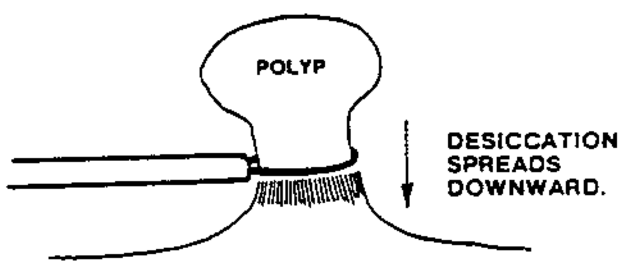
It must be understood that this procedure is an art and the only way one can learn this art is to take instruction from someone who understands the relative quantities of enough desiccation and too much desiccation.

POLYPECTOMY
DESICCATION FOR HEMOSTASIS

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

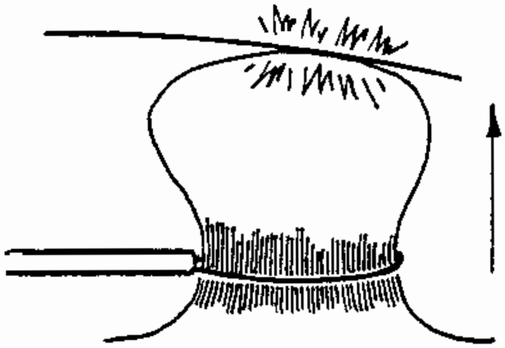


POLYPECTOMY



DESICCATION FIRST FOR HEMOSTASIS

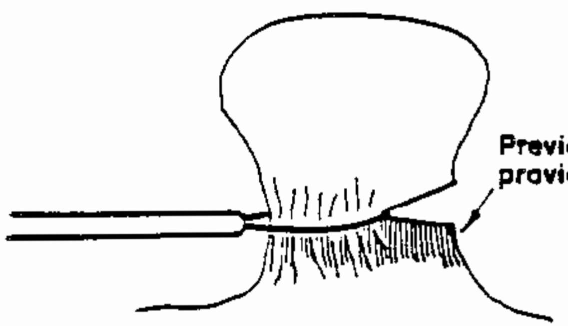
POLYPECTOMY



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 [7]. 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. Note that mechanical cutting is likely to become electrosurgical cutting with the BLEND current keyed because the electrode area touching the tissue becomes smaller and smaller as the cut proceedes.

POLYPECTOMY
MECHANICAL CUT AFTER DESICCATION



POLYPECTOMY - ELECTROSURGICAL CUTTING 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 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 effects the area of metal in contact with the tissue. Currently available snare wires range from 0.3 to 0.8 mm (0.012" to 0.040"). We do not recommend snare wires thicker than about 0.45 mm (0.025") because of the difficulty in starting a mechanical or electrosurgical cut. Whenever the snare wire diameter is changed, generator setting 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 effect as using BLEND instead of PURE. But, as explained above, the thicker wire will be harder to start [1].

POLYPECTOMY

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 MANEUVER

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. A typical setting would be BLEND 4 or 5. For small polyps and very fine snare wires, lower settings are advisable. When cutting with the BLEND with SSE2 series generators, the speed with which the electrode moves through the tissue effects the hemostasis. The faster the electrode moves, the less hemostasis. Consequently, the snare should be pulled closed very slowly to provide maximum hemostasis.

With the Valleylab SSE2 series generators it is also possible to cut electrosurgically using the COAG as a blended current and actually cut with the COAG. This is possible if the snare wire is extremely fine (.3 to .4 mm) and a high setting is used, COAG 4 to 8. 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. The forceps have been modified by wiring them to a cable that goes to the monopolar to protect the assistant. After the assistant has adjusted the tension, the footswitch is activated [8, 9].

POLYPECTOMY

HEMOSTASIS WITH ELECTROSURGICAL CUTTING

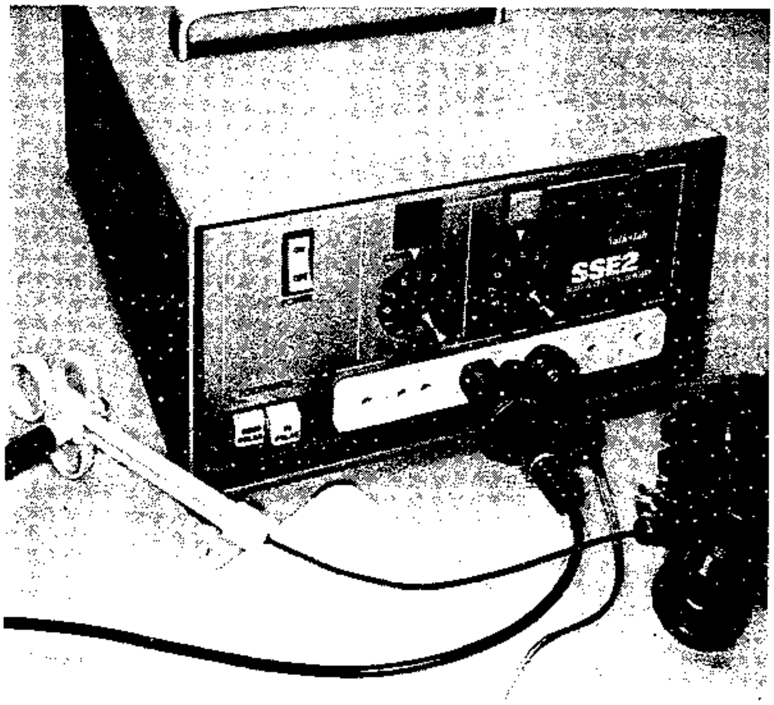
Blended cut or "coag" provides the most hemostasis.

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

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

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. The "Rapid Start" option for the SSE2L is also useful for insuring a quick start in electrosurgical cutting. This is discussed on page 65.

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 coagulated the tissue enough to provide the needed hemostasis, the surgeon can confidently switch to PURE CUT at an appropriate setting, 3-5, and usually get the cut started. A PURE CUT will "start" better than any other mode, but it has little hemostasis.



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 beginners, it is advisable to use the exact equipment, snare, settings and technique used by his instructor. Using one instructor's mode and power settings with another instructor's snare and technique can be a disaster.

COAGULATION OF G.I. BLEEDING

Recently there has been increased interest in coagulation of upper G.I. bleeding. This is still an experimental procedure, but the surgeons who have done the most cases [4, 6] are using desiccation with a combination electrode and irrigation probe. One of these surgeons [4] 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 ½ to 2 second bursts. We believe that the SSE2L will produce similar results.

PAPILLOTOMY

Opening the Papilla of Vater to provide relief from stones in the common bile duct is a new endoscopic electrosurgical procedure (10). 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. An appropriate setting with the SSE2L would be BLEND at a setting of 3 to 5.

Injury to the pancreas is a potential 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.

One way to help the problem of delay in beginning the cut in papillotomy is the "Rapid Start" option [5]. This is a modification of the standard output impedance characteristic and is explained in more detail on page 66.

Because papillotomy is potentially hazardous, we strongly recommend that the surgeon obtain first-hand training from someone who is 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.

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 endoscope. This capacitive coupling can transfer energy from the active snare to the body of the colonoscope. This energy is a potential threat to the surgeon and patient because the voltage that appears on the colonoscope metal will try to drive a current from the exposed metal parts on the colonoscope to the patient return electrode. The current may travel through unexpected paths through the surgeon or patient's body to make this journey.

Fortunately, the problem is not as severe as one would expect from 150 pf of coupling. This is because most of the metal wire framework of the colonoscope is just under the black plastic covering over the flexible portion. As a result, the metal frame makes a much greater capacitance to the patient's body than it makes to the active electrode. This second capacitance couples most of the leakage current safely back to the patient's body and patient electrode.

Prior to 1977, many colonoscopes were manufactured with the metal frame connected to ground through the light source. One might think that grounding the colonoscope frame would make any possible leakage current safe but it does not. Because the SSE2L patient circuit is isolated from ground, the leakage is only interested in returning to the patient electrode. If the leakage current is grounded, it will attempt to return to the patient electrode by entering the patient's body. Theoretically, the current could cause injury if it entered the patient's body at some small, grounded contact point.

Because the leakage current is a theoretical threat, at least two endoscope manufacturers recommend the use of leakage bypass cables. One manufacturer calls this an "S-Cord" while another calls this a "Bypass Wire". In both cases, the cables are designed to connect the metal frame of the endoscope to the patient return electrode.

These bypass cables solve one safety problem but introduce a new one. If the patient electrode looses contact with the patient's skin, then the metal frame of the endoscope will become a substitute patient electrode and all the electrosurgical currents will travel to it by all paths available. This could be worse than the original problem.

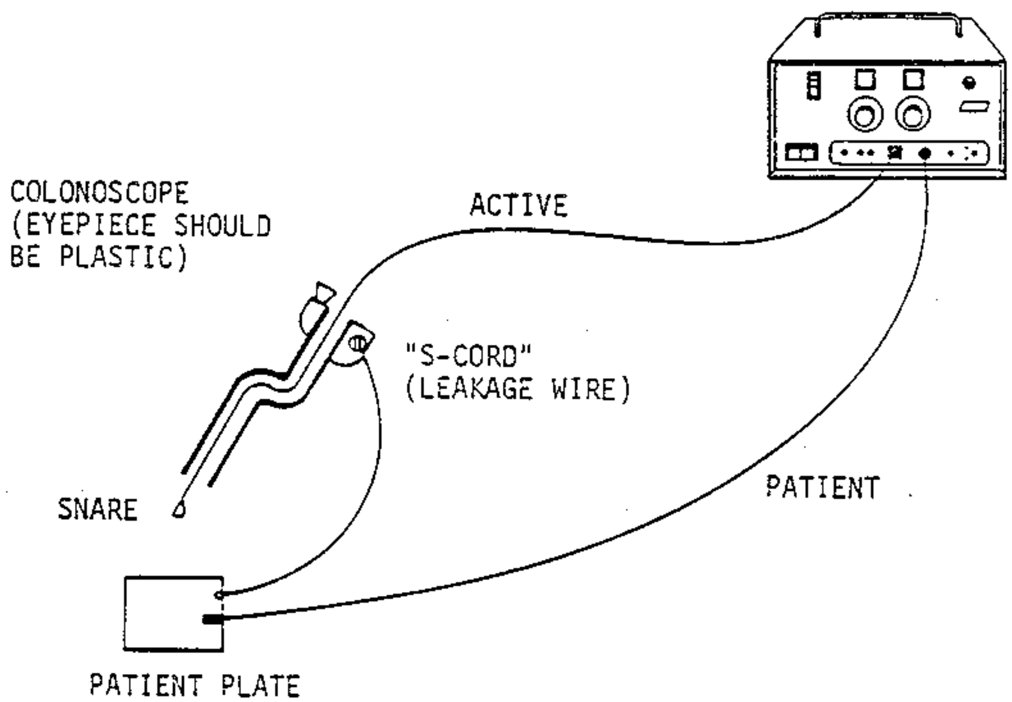
Valleylab does not make a patient electrode with a second connection on it for attaching a cable from the colonoscope. Other manufacturers do make such patient electrodes and these may be used. The Valleylab E700l permanent patient plate can easily be modified to accept a cable by drilling a small hole in the plate next to the present connector. The eyelet on the colonoscope-to-patient plate cable can then be riveted to the E700l plate.

One colonoscope manufacturer, has given another reason for using the bypass 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.

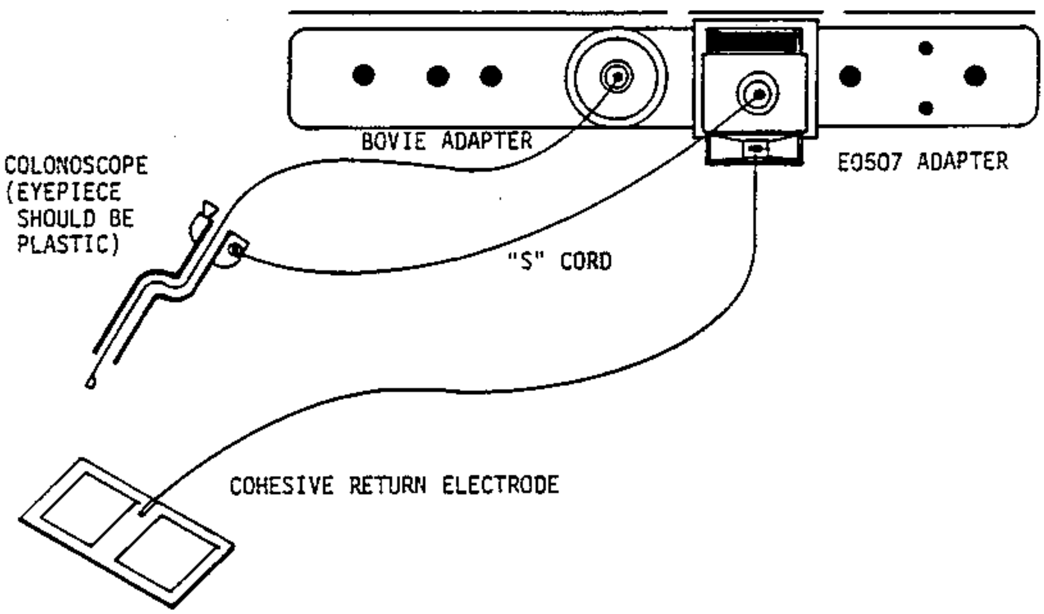
An important factor in the magnitude or risk due to leakage current is the frequency of the generator. the current that flows across a capacitor is directly proportional to the generator frequency. Moreover, the power or rate of heating caused by the leakage current is proportional to the <u>square</u> of the current. For example, a generator which operates at 2 MHz will produce four times more leakage than the SSE2L which operates at 0.5 MHz. The leakage power produced by the 2 MHz generator will be 16 times greater.

It is probably this last factor that has allowed many G.I. Endoscopists to use previous versions of the SSE2 without any leakage grounding cables and without significant problems caused by leakage currents. The SSE2L is almost identical to previous versions of the SSE2 in performance and leakage isolation, so techniques perfected with earlier SSE2's are directly applicable to the SSE2L.

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 electrode in good contact with the patient's skin. Alternatively, one can use a colonoscope without a bypass cable. 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 eye piece 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. Some gastroscopes 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"



*Multiple Return/S Cord Adapter Connection
for use with REM system generators*

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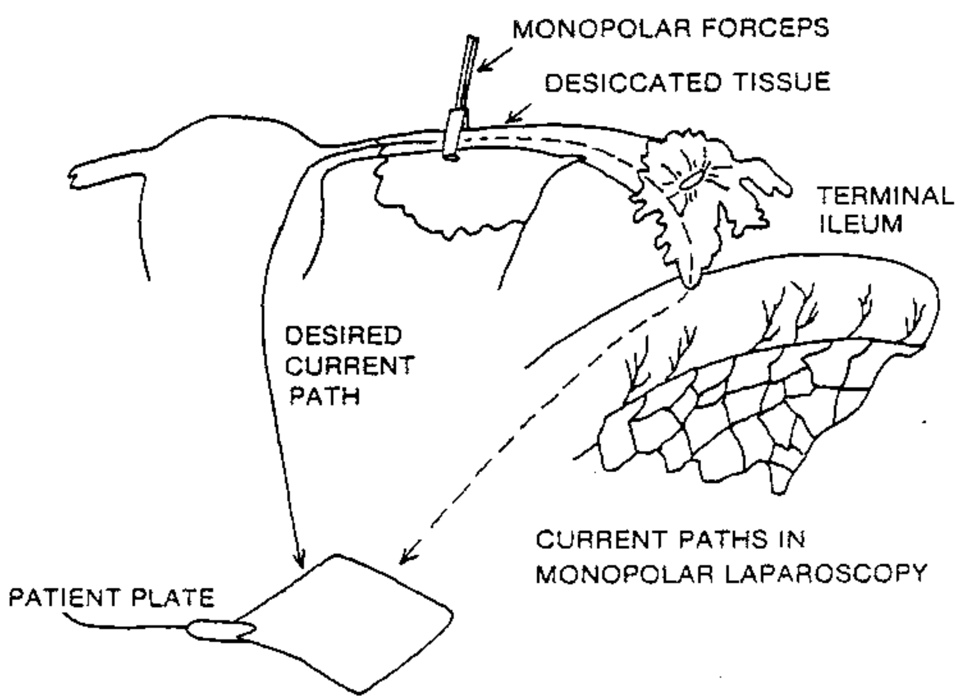
There are many different basic techniques for performing this procedure. They can be divided into monopolar techniques and bipolar techniques. Our purpose here is not to pass judgement on which exact technique is the best, but rather to help the user perform his technique with the SSE2L.

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 grasped 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

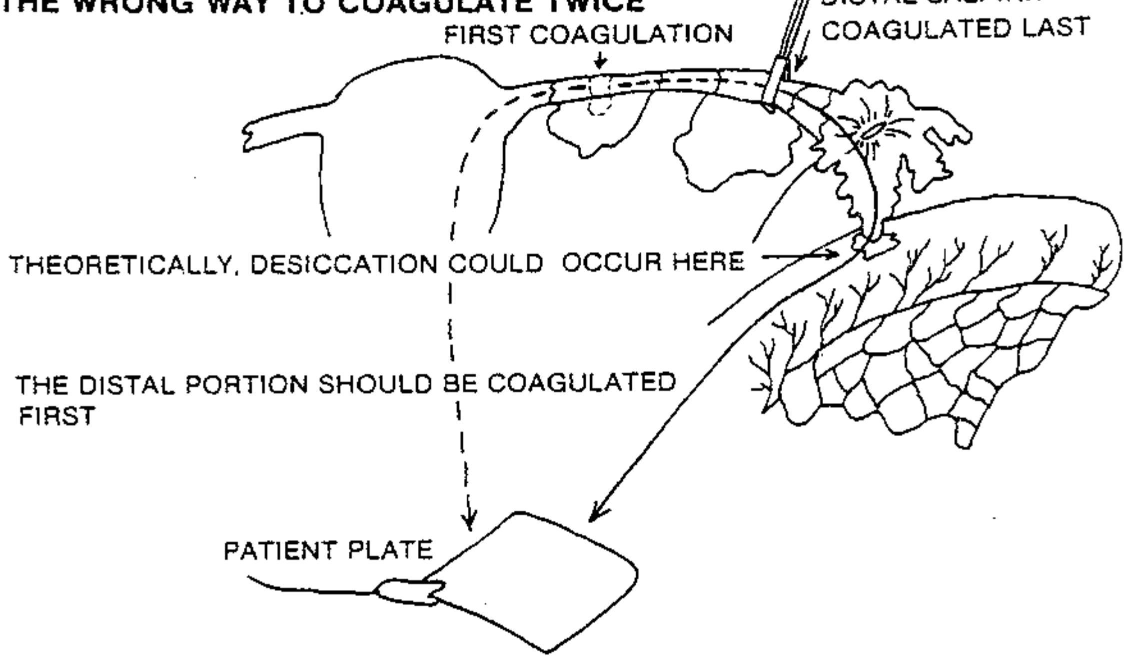


CURRENT PATHS IN MONOPOLAR LAPAROSCOPY

Another factor which may be very important is the rising electrical resistance of the salpinx and mesosalpinx during the 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 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 [3].

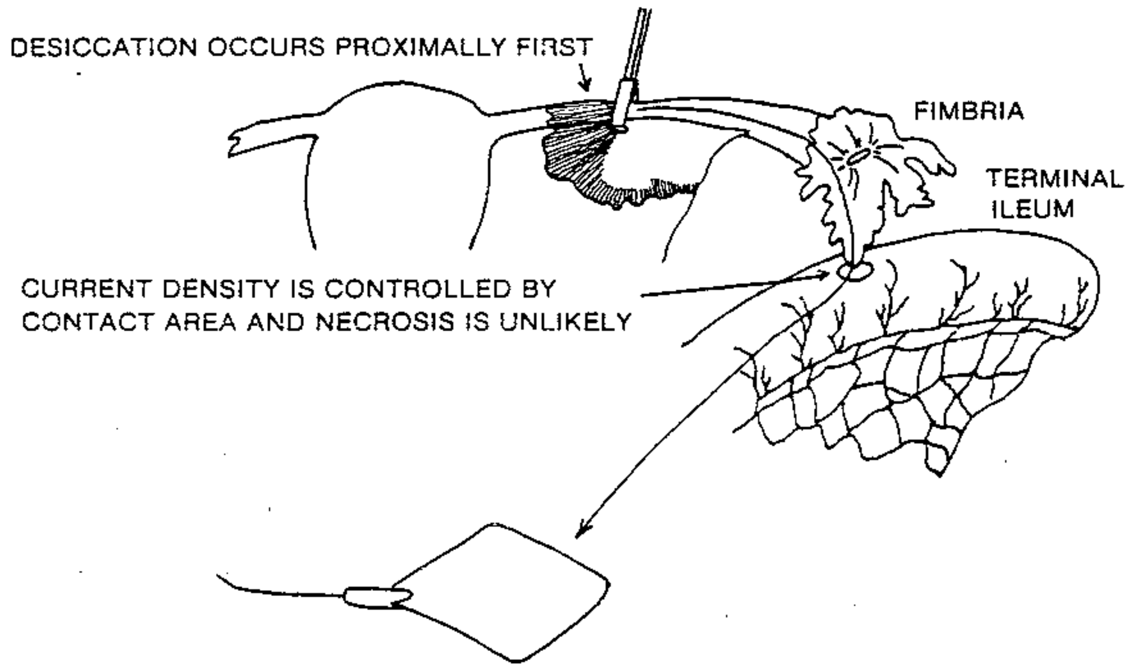
MONOPOLAR LAPAROSCOPY

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 occcurs 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.

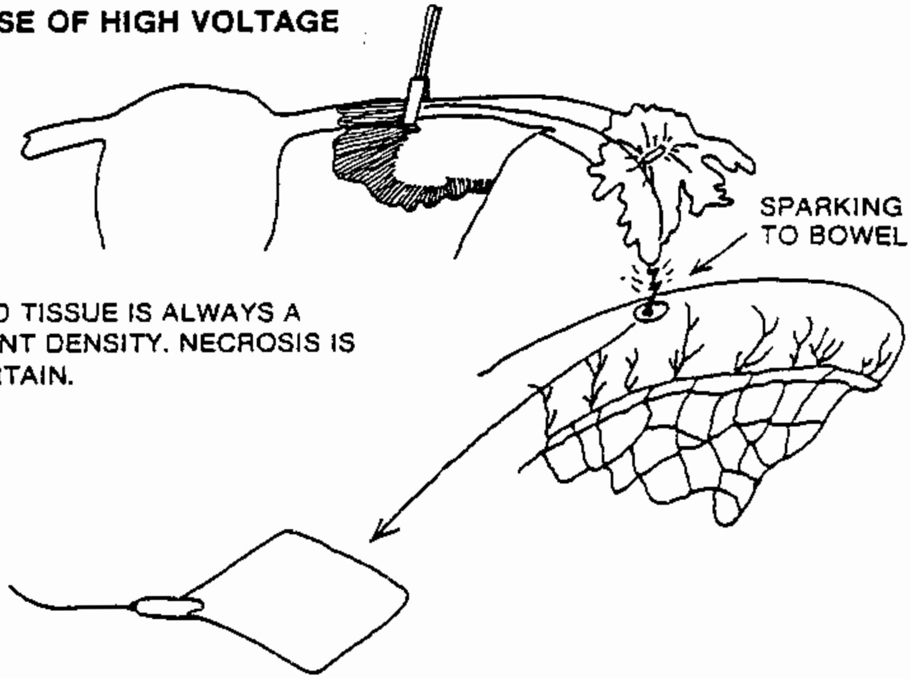
MONOPOLAR LAPAROSCOPY
ELECTRICAL ISOLATION OF THE SALPINX



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 discussed earlier in the discussion on fulguration, fulguration is considerably more efficient in producing necrosis than is an equal magnitude of current applied to tissue in a desiccating mode, that is, without sparking. 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 SSE2L, we strongly advise against using a setting higher than COAG 3.

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



SPARKING TO TISSUE IS ALWAYS A HIGH CURRENT DENSITY. NECROSIS IS ALMOST CERTAIN.

LAPAROSCOPY - MONOPOLAR DESICCATION WITH OR WITHOUT BIOPSY

The best way to avoid fulgurating bowel is to avoid fulgurating altogether. Desiccation will also whiten or blanch the tissue and can be done with a minimum of peak voltage. Notice on pages 18,19 that the power is higher for a given peak voltage in the CUT mode. It is possible to desiccate the salpinx using CUT at settings of 1 to 2½.

It may be found that CUT is not very practical for desiccation because the desiccation "stalls" or ends prematurely before a suffient length of salpinx has been desiccated. This occurs because the peak voltage (100 to 600 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 the BLEND set at the minimum level (1 to 3) may work out to be a good compromise. In other words, by using a BLEND one can always necrose the desired length of salpinx, but you may have to transfer the current across the dried coagulum by sparks toward the end of the coagulation. That is, the dessication may turn into a relatively low voltage fulguration toward the end of the coagulation.

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 SSE2L 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.

If the SSE2L 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 extremely low settings are used, it is possible to use COAG for desiccation with a fairly low peak voltage. For example, at a setting of COAG 1½, about 14 watts are delivered at 550 volts peak. This setting will blanch over one cm of salpinx on both sides of the forceps but may require 20 to 60 seconds to complete the coagulation [1].

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 handswitching, 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 on page 56.

LAPAROSCOPY - MONOPOLAR ELECTROSURGICAL CUTTING

Some surgeons prefer to sever the tube electrosurgically. This requires more power than desiccation and unless an extremely fine electrode (0.010" diameter wire snare) is used, will require a BLEND or CUT waveform.

The most common technique is to pull the forceps through the salpinx after 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 1 to 2. To cut the tube electrosurgically will require at least 3 or 4. 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 19, 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.

MONOPOLAR LAPAROSCOPIC STERILIZATION WITH THE SINGLE PUNCTURE LAPAROSCOPE

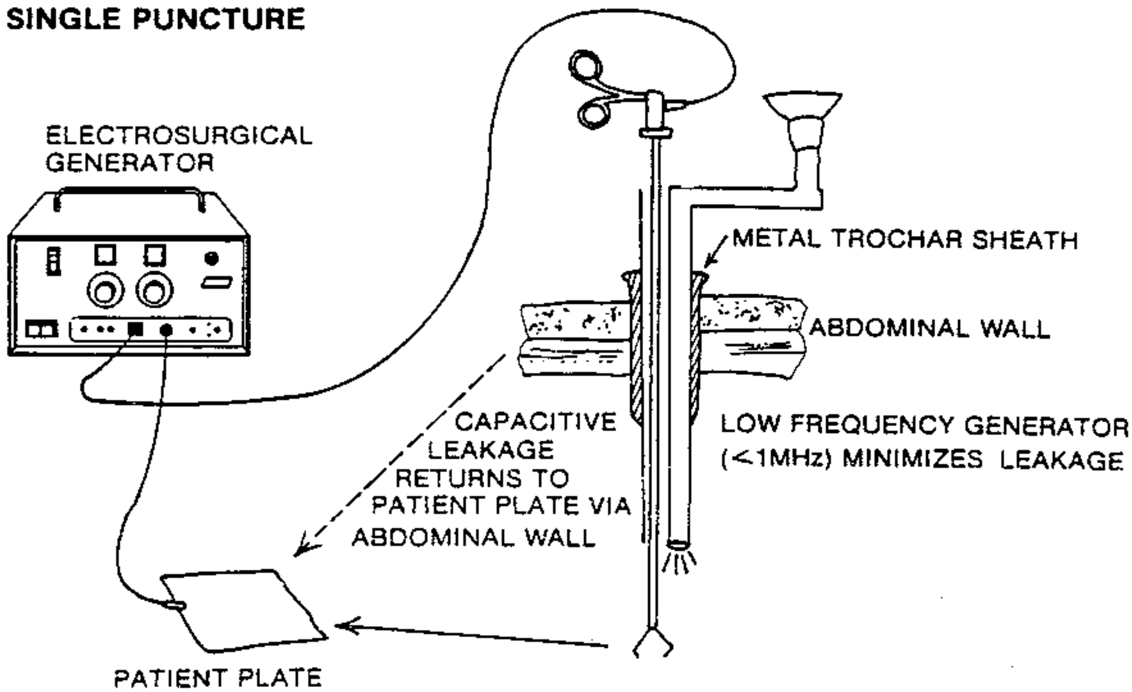
Some of the single puncture laparoscopes on the market have as much as 100 pf of capacitance between the forceps and the laparoscope. This capacitive coupling transfers energy to the metal frame of the laparoscope. Theoretically the laparoscope could behave like an active electrode and pose a threat to the patient and surgeon. there is no way to reduce this coupling but there are three methods of making it harmless. These methods are: 1) The use of a low frequency generator, such as the SSE2L; 2) A "common ground connector" which shunts the leakage current to the patient electrode; and 3) A metal trochar sleeve.

When a single puncture laparoscope is used with the SSE2L, the problem is not as severe as it is with other generators because the frequency of the SSE2L 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 six times more leakage current than the SSE2L which operates at 0.5 MHz. The 3 MHz generator will produce 36 times more leakage power.

Another solution to the problem is the "common ground connector" which is a wire that connects the metal body of the laparoscope to the patient electrode. This solution is no longer recommended, even by the firm that made the common ground connector.

The simplest solution was first proposed by Soderstrom (4). 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 with your SSE2L will be less than 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. The use of the metal trochar sleeve is recommended by the American Association of Gynecologic Laparoscopists [5].

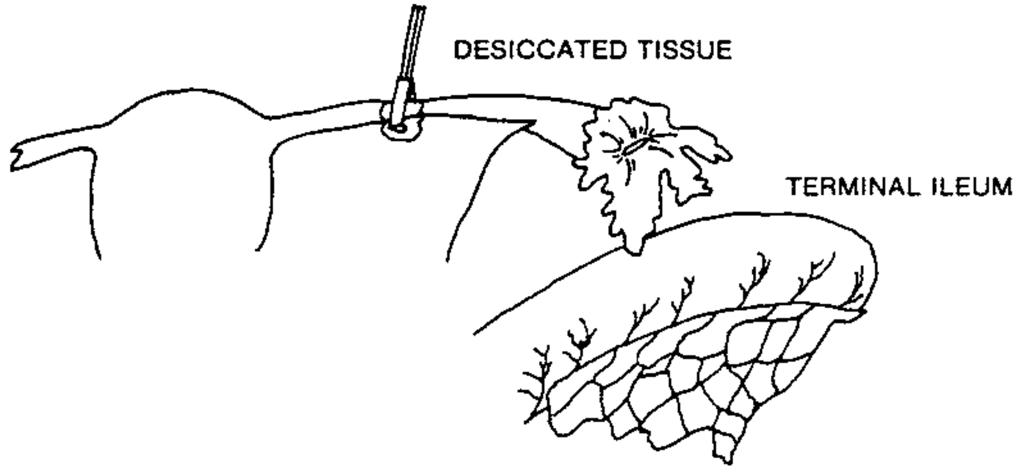
MONOPOLAR LAPAROSCOPY
SINGLE PUNCTURE



LAPAROSCOPY - BIPOLAR DESICCATION

The SSE2L 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.

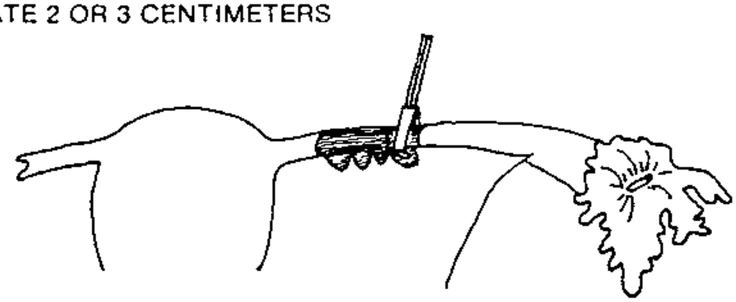
BIPOLAR LAPAROSCOPY



CURRENT PATH IS LIMITED TO THE TISSUE DESICCATED.

BIPOLAR LAPAROSCOPY

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



Settings with the bipolar output are not critical. The setting that is used will primarily effect the speed with which the desiccation takes place. Even very high settings are safe because the current path is limited. Any mode may be used since all three, CUT, BLEND, or COAG, will only desiccate when used with the bipolar output.

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 applied 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 proposed voltage and power limits do not apply to bipolar laparoscopy.

There are several ways these recommendations can be followed using the SSE2L. Using any mode or setting, the bipolar output meets the specification, although at COAG 10 with a 500 ohm load the voltage typically just reaches 600 volts peak. The bipolar output can be used with monopolar forceps as explained on page 56 at the end of this chapter.

Waveform	*Dial Setting*	*Power*	*Peak Volts*
CUT	*2*	*35*	*500*
BLEND	*1-½*	*20*	*600*
COAG	*1-½*	*5*	*600*

The SSE2L optional low power control provides still another way of meeting this recommendation. If the generator is equipped with this option, press the control button and all three of the generator outputs (both monopolar outputs and the bipolar outputs) will be attenuated to less than 100 watts and less than 600 volts peak. See page 64 for a description of this option.

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TRANSURETHRAL RESECTIONS

Transurethral resections are usually a high power procedure requiring 100 watts or more. The bladder and urethra are insufflated with glycine solution to provide visibility and irrigation. Glycine or urea 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 heat failure [1].

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.

The SSE2L has more than twice the required power for doing a transurethral resection, provided that non-conductive solutions and relatively fine resection loops are used. The resection loop wire diameter should be in the range of 0.3 mm to 0.4 mm (0.010" to 0.015"). Larger diameter wires will not cut as cleanly and will require higher power settings. Smaller diameter wire is probably too fragile to be practical.

One problem which has haunted 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 SSE2L has a COAG crest factor of 6.7 which is higher than many of the older, full power, solid state generators on the market. Because of the high crest factor, there are very few surgeons who complain about the COAG in the SSE2L. For those few surgeons who have this complaint, there are several ways of correcting this problem or at least living with it.

1) *By taking smaller pieces while cutting, large bleeders are less likely to be encountered and they are more likely to be localized. Bleeders which are well localized are easy to stop with the SSE2L.*

2) *Pressing the loop firmly against the tissue also encourages cutting.*

3) *The use of a larger resection loop wire diameter will disperse the current and decrease the cutting effect. A larger loop also requires more power for cutting, since the current is not so concentrated.*

4) *Special resection loops are available from several endoscope manufacturers which has a small sphere located half way around the loop. This sphere can serve as a coagulating ball electrode and can be used to improve the area covered during fulguration. In the event that so much bleeding is encountered that visibility is obscured, it is a good idea to have one of these ball electrodes available.*

5) *If the complaint is specifically cutting in COAG, the special Rapid Start Option discussed under the option section will probably correct this problem. However, it should be understood that the area covered by the fulguration will not be as great due to the reduced peak voltage.*

A common complaint of urologists is that there may be a delay or lag in starting when the electrode is pressed against the tissue. This can bend the electrode and is annoying as well. Several solutions follow:

1) *Quick starting and better fulguration without cutting effect can be obtained by not pressing the electrode against the tissue before starting the cut. The first thing to touch the tissue should be the spark and not the electrode, since it is the spark that does the cutting. By pressing the electrode against the tissue, a low resistance contact is achieved which puts a low resistance load on the generator. Since sparks cannot start across a low resistance, the sparking is delayed until the tissue is desiccated enough to produce a suitably high resistance.*

2) *A higher generator setting will always start more quickly.*

3) *Use a finer electrode, for example, one can use a .3 mm (0.012") diameter wire loop instead of .4 mm (0.015") wire loop. One should remember that this will tend to produce more of a cutting effect in COAG.*

4) *If all else fails, the Rapid Start Option will eliminate the lag in starting, but it will also degrade area fulguration and decrease the distance sparks will jump to the tissue.*

RESECTOSCOPE DESIGN

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.

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.

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 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 [2].

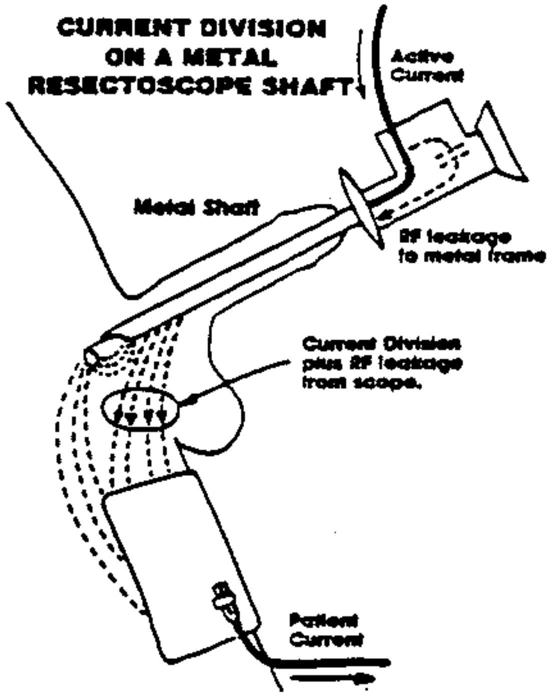
Suppose the resection loop breaks with the metal design and the broken end comes in contact with the all metal resectoscope. If this occurs, the entire generator output will be on the urethra. Fortunately, the urethra can probably stand this for several seconds and the surgeon can shut off the generator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

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. This current can be very large if the loop should break and touch the metal frame. Because of this, resectoscope eyepieces should ALWAYS be insulated to protect the surgeon's eyes.

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 (2).

Another potential problem with resectoscopes 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.

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 cable.



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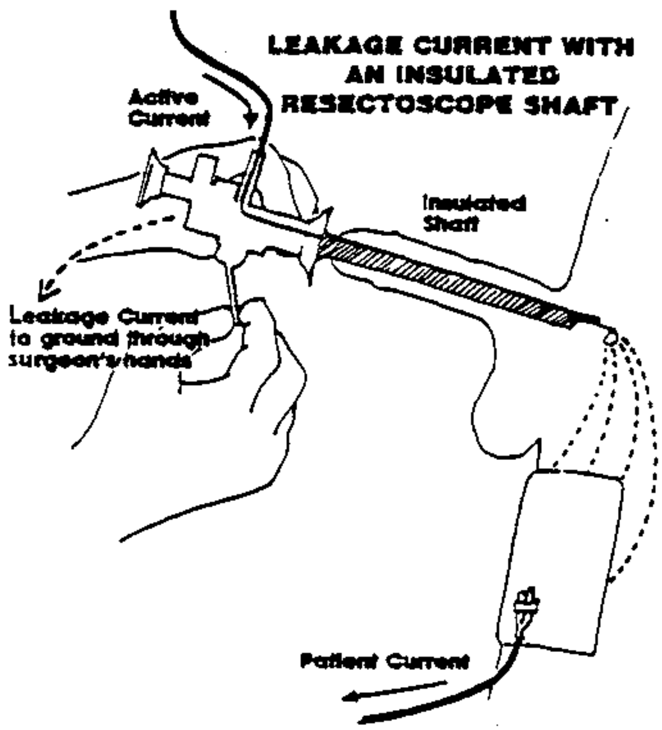
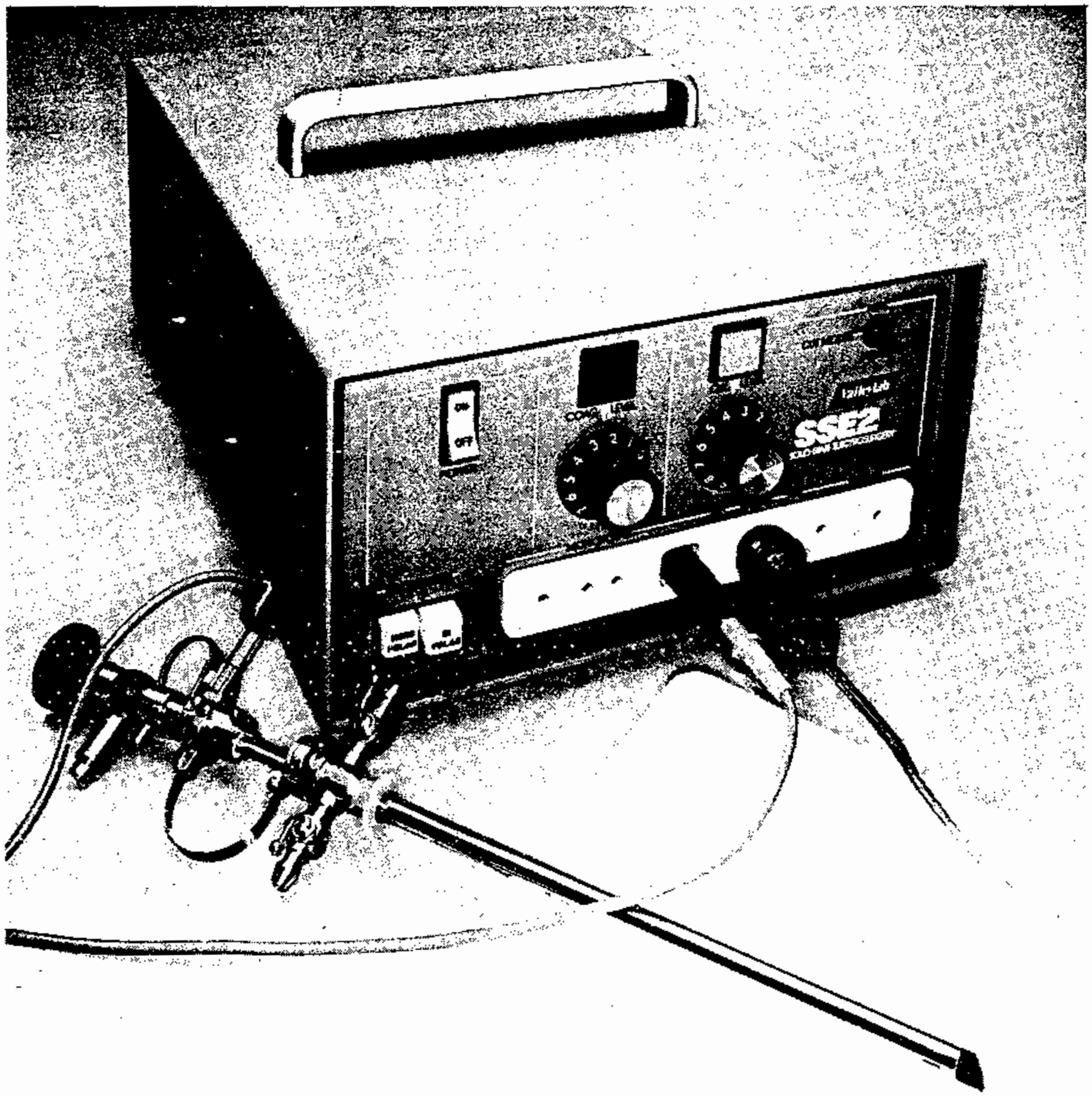
F. FASTENMEIER



RESECTOSCOPE PROCEDURE



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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 out of the tissue. 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; intra-cranial and extra-cranial. For extra-cranial work, the surgery is generally done monopolar 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 prep II Patient Return Electrode (E7503) would be ideal for this application.

A few neurosurgeons prefer monopolar intra-cranially as well. Typically, they use fine tipped, monopolar forceps or a pencil with a needle electrode. The LectroSwitch with the LectroNeedle (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.

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

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

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.

The use of the E0015 attenuator to try to achieve finer control when desiccating 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.

It is possible to achieve the desiccation-only characteristics of the bipolar output with monopolar instruments by using the bipolar output as if it were a monopolar output. This configuration is discussed on page 56.

Desiccating Neural Tissue With the Bipolar Forceps

The SSE2L bipolar output is ideal for desiccating with fine, bipolar forceps. It will desiccate rapidly with little tendency to spark (that is, little 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.

The SSE2L monopolar outputs are isolated from ground and theoretically could be used with bipolar forceps, but as explained earlier, these outputs are best for cutting and fulgurating. For extra-cranial hemostasis it is possible to fulgurate with bipolar forceps. However, the insulation on the forceps must be sufficient to withstand the high peak voltages and the insulation should be tested regularly to prevent metal-to-metal sparking between the forceps tines. Metal-to-metal sparking can result in extreme neuromuscular stimulation.

When the bipolar output was designed, it was assumed that the monopolar output would probably be used during the same 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 or BLEND could also be used with the bipolar output since ALL the waveforms desiccate when used with this output.

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.

THE LOW POWER OPTIONAL LOW POWER CONTROL IN NEUROSURGERY

The low power control option is described in detail on page 64. In brief, it reduces the maximum power available from both monopolar and bipolar outputs so that the surgeon has finer control over the lower settings. For example, when the button is pushed in, the power usually obtained at a setting of 2 is now obtained at a setting of 10.

THE SSE2L ELECTRICALLY INDEPENDENT OUTPUTS-

MULTIPLE ACTIVE ELECTRODES PLUGGED IN SIMULTANEOUSLY

In Thoracic surgery, neurosurgery, and other applications it is sometimes convenient to have two or more active electrodes plugged into the generator at the same time. The SSE2L is unique in that its three outputs, (two monopolar and one bipolar) are electrically independent and are selected by the various keying means. Earlier versions of the SSE2 and Valleylab models SSE3 and Surgistat DO NOT HAVE THIS FEATURE. Independent outputs make multiple electrodes safer because only the one which has been selected is "hot" at one time. Moreover, plugging in two or three active electrodes simultaneously will not degrade the isolation of the generator. RF leakage measurements will remain less than 150 milliamperes regardless of how many instruments are plugged into the generator.

The footswitch can activate either the monopolar accessory jack (the square hole) or the bipolar output, depending on the setting of the footswitch buttons on the front panel. The hand switching monpolar output (the three small holes at the lower left) can only be activated by keying a monopolar forceps or switching pencil plugged into that outlet. The bipolar output can be activated by either the footswitch or by a handswitch built into the bipolar instrument.

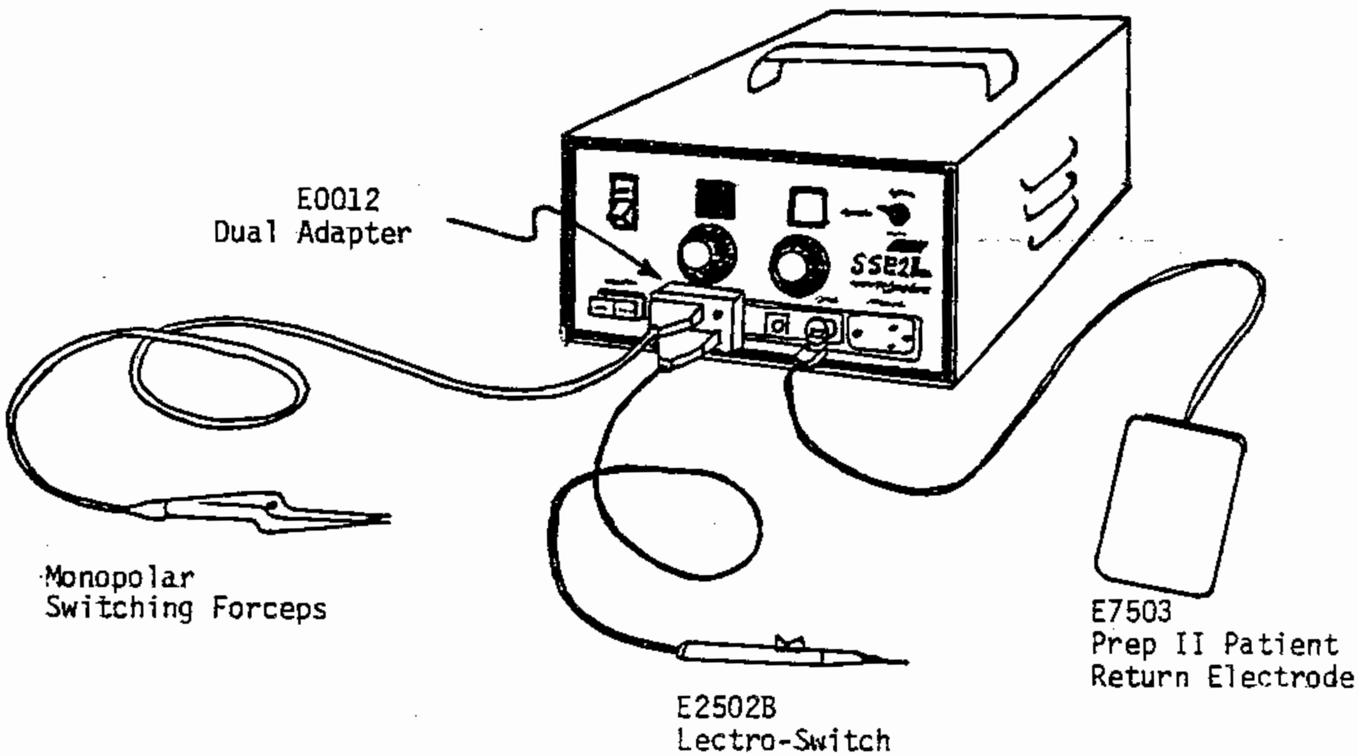
Suppose that an instrument is plugged into each of the three ouputs simultaneously. Whichever keying means is activated first controls the generator and the other two outputs are dead. There is no priority among the three outputs. Control of the output will not be released until the original switching means is released.

An obvious question is whether an unused output really is inactive or "dead" and whether it is safe to leave unused electrodes unguarded on the patient or Mayo stand? Technically, there is a small amount of leakage current available from an unused output. This leakage is about a watt in the worst case and it is difficult to produce a surgical effect with it. So from this point of view it is impossible for an unguarded electrode to cause an acident. However, it is possible that an unused electrode might become activated accidentally by having the footswitch selection button in the wrong position or by inadvertently placing a heavy object on a handswitched instrument such as a LectroSwitch. For this reason WE STRONGLY RECOMMEND THAT UNUSED ACTIVE ELECTRODES BE GUARDED AS IF THEY WERE "HOT".

Unused active electrodes can be kept in the Valleylab holster (E2400), folded between several layers of DRY toweling on the Mayo stand, or placed in holsters made of 50 cc syringe cases which may be autoclaved repeatedly and may be taped onto the drapes or Mayo stand for safe keeping. Discipline is needed to insure that each electrode is returned to its holster after each use.

DUAL ADAPTER MODEL E0012

Valleylab's dual adapter allows simultaneously use of two hand-switching monopolar accessories. The adapter will accept any combination of handswitching forceps and LectroSwitch pencils. Because the adapter merely connects the two accessories to the same, single, monopolar output jack, BOTH ACCESSORIES ARE "HOT" AT THE SAME TIME when either one of them is activated. Furthermore, the isolation of the output is degraded and RF leakage will rise above the 150 milliamperes specified for the SSE2L. If the E0012 adapter is used, non-conducting holsters (E2400) MUST be provided for each accessory, and each tool must be returned to its holster after each use.



THE SSE2L WITH MULTIPLE ACTIVE ELECTRODES

When using the Valleylab Dual Adapter (E0012), voltage is present on both electrodes simultaneously and it is possible to perform electrosurgery at two locations on the patient simultaneously. What happens to the effective output power at each electrode when two LectroSwitches are used simultaneously from the same dual adapter? 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 noticeable drop in the effective power at the first electrode. Similarly, if the first electrode stops sparking first, there is no noticeable 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 500,000 cycles per second, there could be a 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 moist 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 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 noticeable drop in the electrosurgical effect.

There is a definite interference between electrodes if one attempts to desiccate from one or both of the electrodes. Desiccation involves a low apparent tissue resistance and sparking cannot occur at one electrode if 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 dry 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.*

SIMULTANEOUS USE OF TWO GENERATORS

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 for the graft.

Because the two generators are not synchronized, there are frequent periods, moment to moment, when one patient return electrode has a high positive voltage while the other acquires an opposite negative voltage. Whenever this occurs, there will be a large potential difference between the return electrodes and current will flow from one to the other. This current will cause no harm provided that it produces no sparks or high current densities on the patient's body. To avoid problems, place each return electrode as close as possible to the respective site of surgery and make sure that there is no possibility of the two touching. For example, in a coronary bypass one Prep II Patient Return Electrode could be placed under the buttocks and another under the shoulders.

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

PATIENTS WITH PACEMAKERS

It is frequently necessary to use electrosurgery on patients with pacemakers. The radio frequency current can interface 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 product 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. [5]

There is one report in the literature of electrosurgery causing a burn to the myocardium at the tip of an external pacemaker catheter. (3) 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 SSE2L because the isolated output will prevent excessive current flow.

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. [1, 2, 4]

CHECKLIST FOR OPERATING ON PATIENTS WITH PACEMAKERS

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

2) *Use bipolar instruments, if possible.*

3) *If monopolar instruments muste 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 electrosurgery.*

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

REFERENCES ON ELECTROSURGERY WITH PACEMAKER PATIENTS

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

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

3. *Geddes, L.A.: et. al.: New Electrical Hazard Associated with Electrocautery Med. Instrumentation 9:112-113, 1975.*

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

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

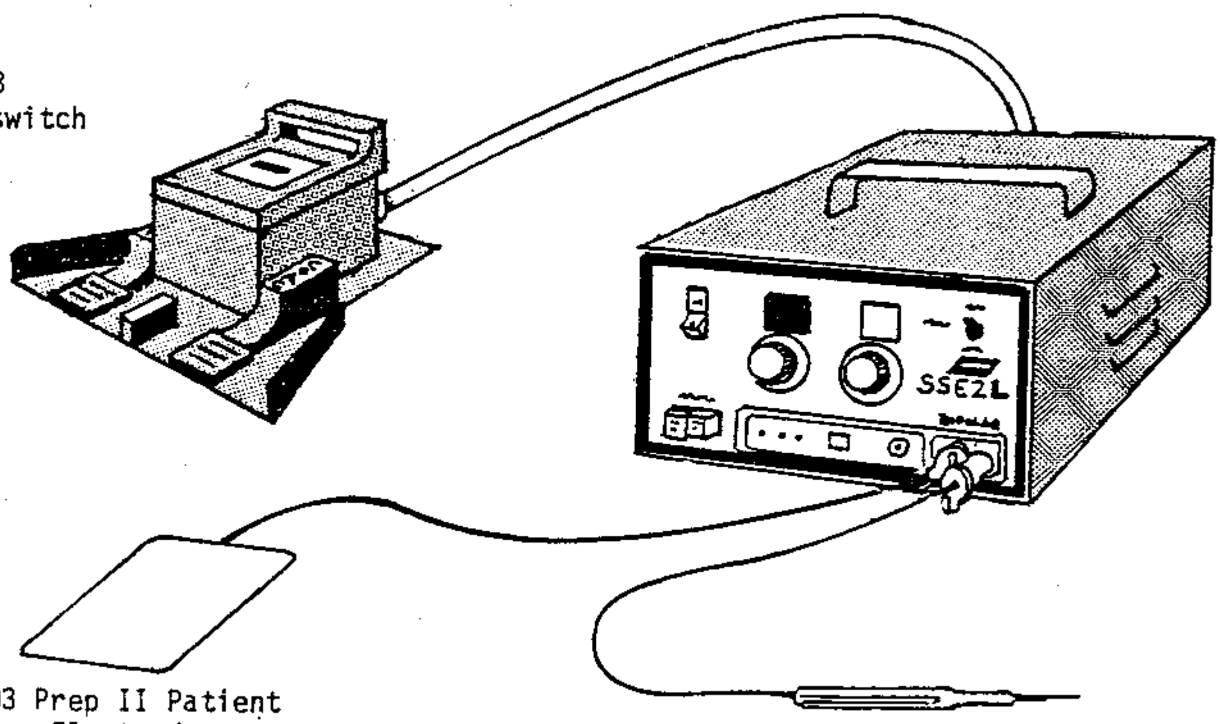
MONOPOLAR OPERATION WITH THE BIPOLAR OUTPUT

HOW TO DESICCATE WITHOUT SPARKING WITH MONOPOLAR INSTRUMENTS IN NEUROSURGERY, LAPAROSCOPY, MICROSURGERY, OR OTHER APPLICATIONS.

Since the SSE2L bipolar output is isolated from ground, it may be used with a patient return electrode just as the two "monopolar" outputs are used for monopolar. This configuration 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 monopolar outputs, they are optimized for sparking, that is, fulguration and electrosurgical cutting. Consequently, if desiccation is done with a 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. At very high settings of CUT or COAG some very low level sparking is possible.

To use the bipolar output with a patient electrode, the patient electrode may be plugged into either the right or left large banana jacks, since these jacks are equal as far as the radio frequency output is concerned. The active electrode is plugged into the opposite bipolar jack by means of a banana plug. For example, the E0502-5 LectroAdapter allows a LectroChuck pencil to be plugged directly in the bipolar output. The LectroChuck will accept any of a wide variety of standard electrodes.

E6008
Footswitch



E7503 Prep II Patient
Return Electrode

E2504 LectroChuck Handle with E1552
Needle Electrode and E0502-5 Lectro-
Adapter

SECTION 3

DESCRIPTION OF CONTROLS AND GENERATOR DESIGN

FRONT VIEW

1. Power On Switch and Circuit Breaker. Rock the switch to turn SSE2-L on. Indicator illuminates when the SSE2-L is on. Transistorized circuitry eliminates the need for warmup time. The power switch also interrupts the current flow in case of internal failure or momentary overload. Rock the switch to reset. If the circuit breaker has tripped, it may be necessary to press the switch to OFF, then ON to reset it.

2. COAG Indicator. Indicator illuminates (blue)* when coagulation current is selected by depressing pencil coagulation switch, by depressing footswitch coagulation pedal, or by closing the forceps contact switch. Indicator lamps are designed to indicate the presence of a usable radio frequency output. They will NOT illuminate in the presence of zero setting or a generator malfunction. This feature can be used to give a surgeon added confidence when performing a "blind" procedure, or to isolate a problem to the generator or the accessory connected to it.

3. COAG Level Dial. Dial rotates clockwise to increase coagulation current intensity. Selector dial is graduated from 0 to 10.

4. CUT Indicator. Indicator illuminates (yellow)* when CUT (PURE or BLEND) current is selected by depressing the pencil CUT switch or by depressing the footswitch cut pedal. Indicator lamps are designed to indicate the presence of a usable radio frequency output. They will NOT illuminate in the presence of zero setting or a generator malfunction. This feature can be used to give a surgeon added confidence when performing a "blind" procedure.

5. CUT Level Dial. Dial rotates clockwise to increase CUT current intensity. Selector dial is graduated from 0 to 10.

6. Pure/Blend Selector. The two position switch selects type of cutting current, either pure for minimum hemostasis while cutting, or blend for moderate hemostasis while cutting. BLEND current intensity is determined solely by the CUT level setting, completely independent of COAG level setting.

*Blue for COAG and yellow for CUT are the new internationally recognized electrosurgery indicator colors.

7. *Footswitch Selector.* This switch selects whether the Monopolar accessory output or the Bipolar output will be activated when the footswitch is depressed. The switch is internally illuminated to indicate which output is selected.

8. *Active Switching Receptacles.* Three white position-coded receptacles accept the three-prong plug of the Valleylab LectroSwitch pencil or the two-prong plug of the switching forceps cord.

9. *Active Accessory Receptacle.* This rectangular active receptacle will accept most standard accessories of other manufacture, or will accept adapter plugs for those accessories that will not fit directly. The SSE2L is then activated by a footswitch.

10. *Patient Receptacle.* This receptacle accepts the one-prong plug of the patient plate cord.

11. *Bipolar Receptacle.* This receptacle consists of two active output connections. It will accept either two standard banana plug connectors or one Valleylab three pin connector (E4045 or E4046) for handswitching bipolar accessories. This output may be activated by either the footswitch or by a handswitching accessory.

REAR VIEW

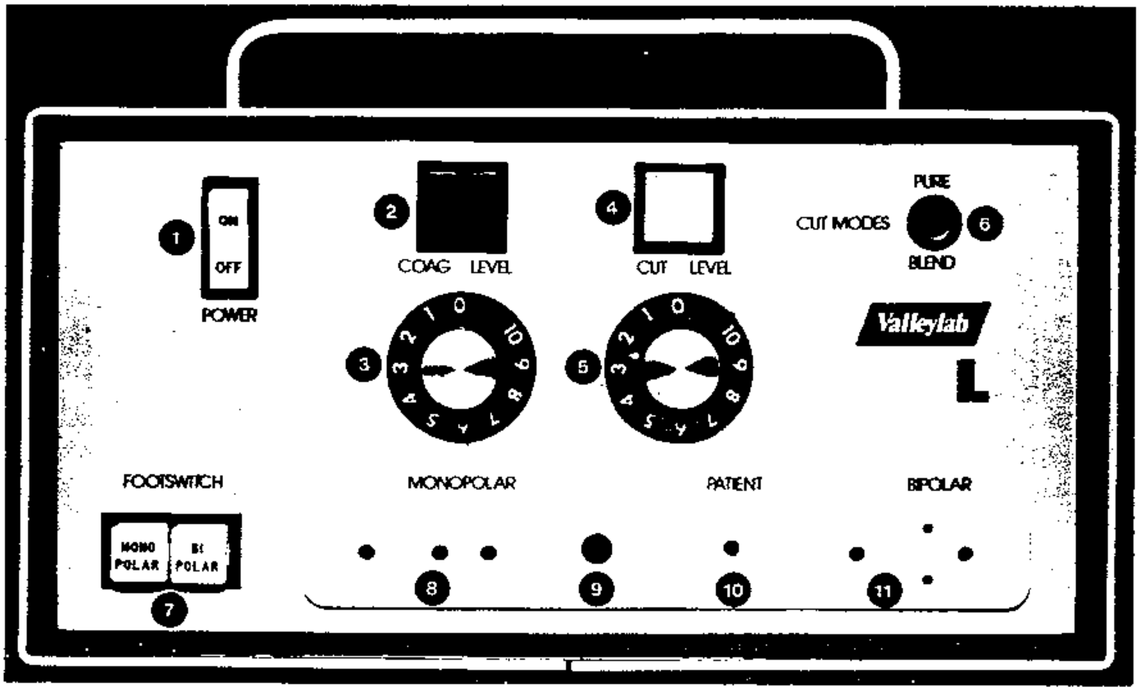
1. *Audio Volume Dial.* Dial controls the audio volume from inaudible to 65 dBA.

2. *Footswitch Connection.* The footswitch is connected to the four pin footswitch receptacle on the rear of the SSE2L.

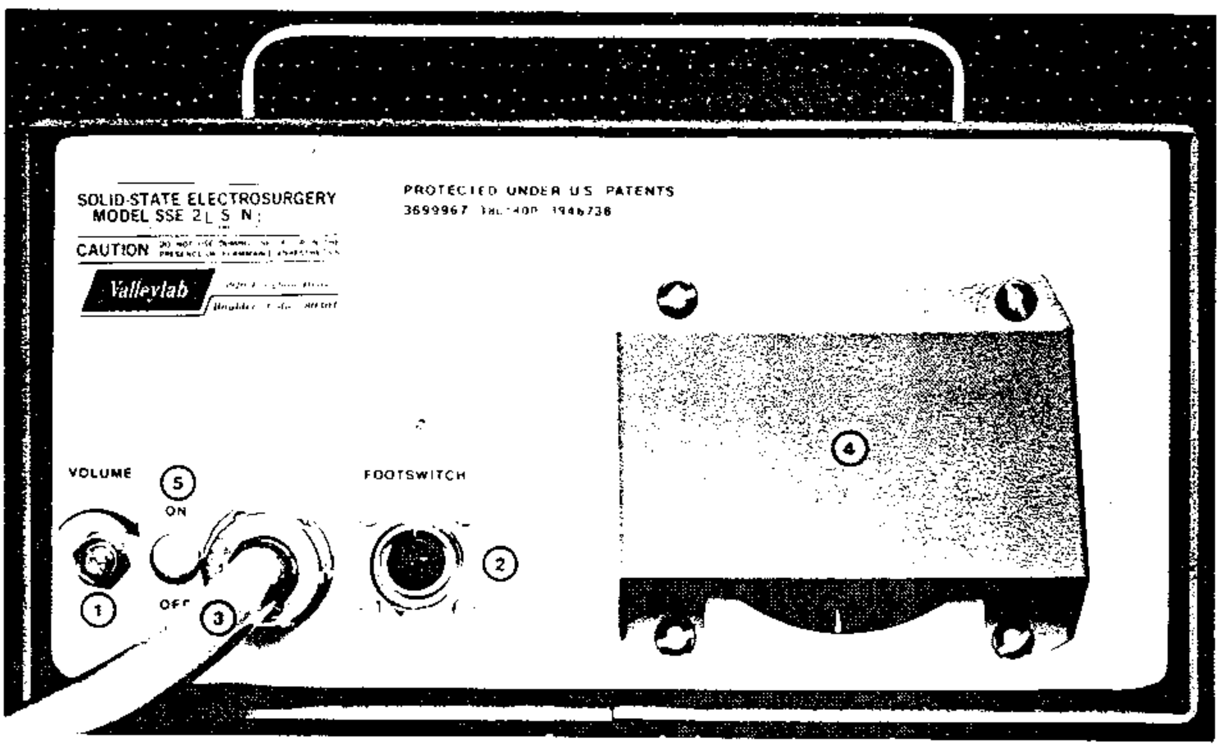
3. *Power Cord.* The three-prong plug on the power cord connects to the properly grounded three-prong wall receptacle providing 120V AC 60 Hz power. The plug is a U.L. approved hospital-grade model. Specific models of explosion-proof plugs are available through special order. Extension cords, three-prong to two-prong adapters (cheaters) and extra length power cords should NOT be used. For units operating from 220V AC input, your Valleylab representative will install the appropriate plug.

4. *Cooling Fan Shield.* The fan guard directs the air flow downward from the cooling fan and away from the sterile field.

5. *Powerite 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. The switch should also be in the "OFF" position with 220V supply in the absence of a neutral conductor at ground potential.



FRONT PANEL



REAR PANEL

KEYING SYSTEMS

The SSE2L can be activated with either a footswitch or by a hand-held switching instrument such as forceps, or the LectroSwitch pencil. The footswitch plugs into a four pin connector located at the rear of the generator. 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.

FOOTSWITCHES

The SSE2L 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.

All Valleylab footswitches have the CUT pedal on the left and the COAG pedal on the right to be consistent with other manufacturers. If both pedals are pushed simultaneously, an override circuit activates COAG, since this is the less dangerous of the two outputs.

EXPLOSION PREVENTING FOOTSWITCHES

All Valleylab generators use the "intrinsically safe" design 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. "Explosionproof" is the official test laboratory work 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 explosionproof 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 SSE2L switching current is about 1/500 of that level. The intrinsically safe design pertains as much to the generator as it does the footswitch. The E6003 and E6004 footswitches which are designed to be used with the SSE2L are rated by Canadian Standards Association as "non-incendive" footswitches suitable for location in Class I, Group C, Division II locations when used with the SSE2K and SurgiStat Generators". This official rating acknowledges that the footswitch system will not cause explosions according to the design principle described above. It is not identical to the latest C.S.A. rating of "intrisically safe" which implies that numerous simultaneous fault conditions could occur inside the generator without explosion causing energies ever becoming present inside the footswitch. Since electrosurgery almost invariable involves sparking to tissue, it is inherently unsafe for use with flammable anesthetics. Explosion preventing footswitches therefore are unnecessary.

MONOPOLAR 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) 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 plug is not critical.

The SSE2L uses only two types of connectors for the monopolar active and patient output leads. The three hand-switching jacks, the patient jack, and the two bipolar output jacks all accept the standard large size banana plugs. The banana plug is convenient because, unlike most other electrosurgical connectors, they can be purchased at any radio supply company.

The accessory active output accepts the standard "Bovie" type active plug. This plug is used with all major solid state electrosurgical generators and many of the older tube/spark-gap units.

BIPOLAR FORCEPS

Bipolar instruments need only two banana plugs to be compatible with the SSE2L. If the bipolar instrument has another type (or types) of connector(s), simply remove them and replace them with banana plugs. It isn't important which connector goes into the "active" and which goes into the "patient" unless the instruments need a special 4-pin connector available from Valleylab for this purpose.

Pictures of monopolar and bipolar accessories connected to an SSE2L are shown on pages 11, 13, of Section 1.

DESIGN FEATURES OF THE SSE2L GENERATOR

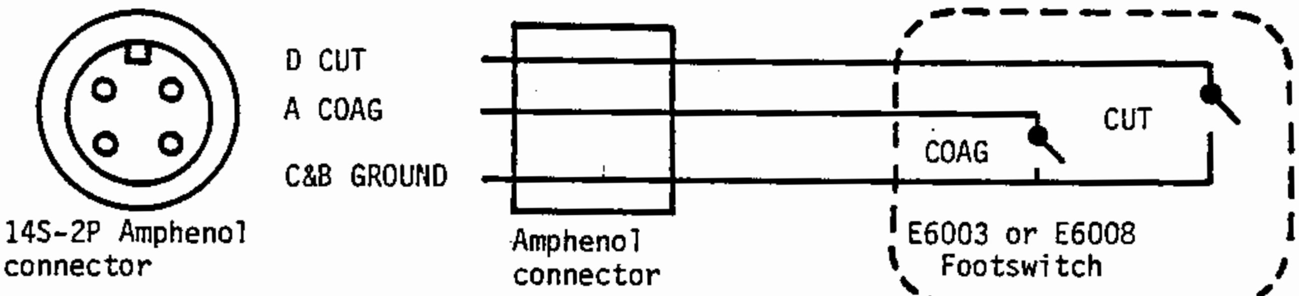
The SSE2L generator is an all solid state unit which offers the surgeon power, versatility, and reliability in a small package. There is nothing in the design of the SSE2L which could not theoretically have been accomplished with vacuum tubes and spark gaps. However, the all solid state design means that a complex design can be built in a small package with high reliability. Since there are no spark gaps or vacuum tubes with filaments these things will never burn out. 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 likely to encounter, they no longer fail. For this reason the SSE2L is cycled on a bench at maximum settings for an hour before it leaves the factory. This procedure catches nearly all of the weak transistors or other substandard components.

Because the most stressed components in the generator are the output transistors, the SSE2L is equipped with individually fused and redundant transistors. In the event that one of the seven transistors fails during a procedure, the fuses will isolate the defective transistor from the circuit and no significant power loss will occur. That is, there will be no outward sign that a failure has occurred. It is possible to lose as many as three output transistors and complete any normal procedure with somewhat reduced power. Fortunately, even the loss of one transistor is an extremely unlikely occurrence. Because this is a rare occurrence , it is appropriate to check the output transistors no more than twice a year during the normal, routine inspection.

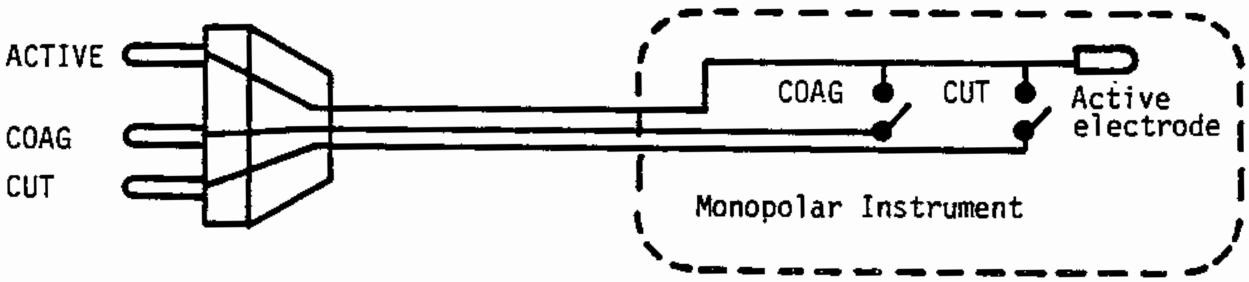
Because the SSE2L is a capable of delivering high power (400 watts), it is necessary to cool the output transistors with a fan during prolonged fulguration or cutting at very high settings. The fan is designed to be as quiet as possible and is only audible when it shifts into high speed at extreme power settings.

The SSE2L has three output receptacles, each of the which can only be activated by a specific keying means. This means that each output is only "hot" when it has been activated. This is accomplished with three separate output transformers. A relay and logic system connects the generator to the correct output transformer in response to whichever handswitch or footswitch is keyed first. For example, suppose that in a coronary bypass procedure a thoracic surgeon is using a handswitching monopolar pencil and a second surgeon is using the footswitch to control a second monopolar pencil. Whichever surgeon keys the generator has the output until he releases his foot or handswitch.

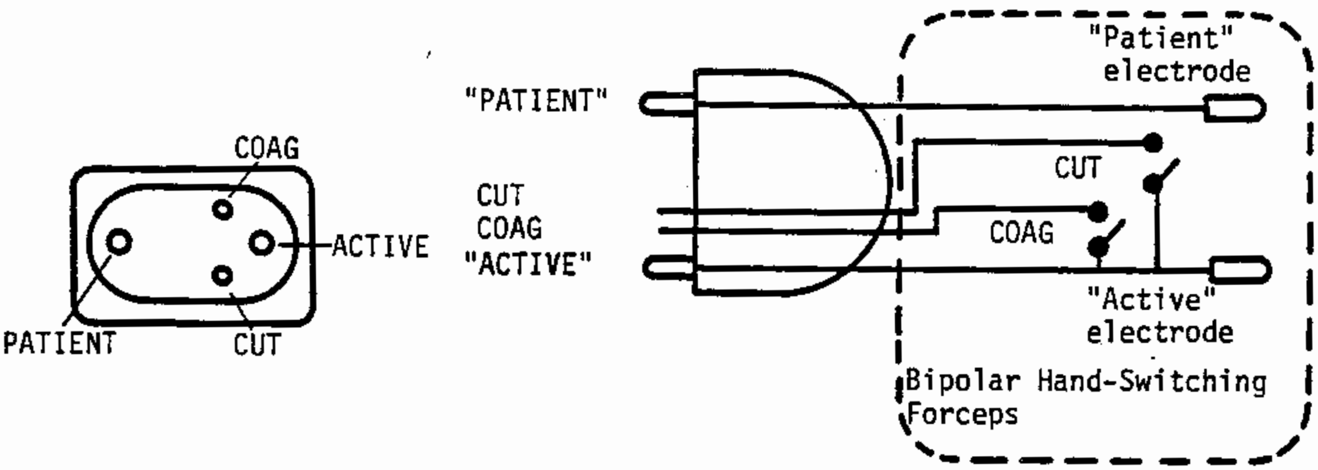
The SSE2L is equipped with an output power compensation circuit which will provide an essentially constant output power when the supply voltage varies from the usual 120 volts RMS. The actual regulation is shown in Figure 6 of the Service Manual. Although the regulation is not perfect, the change in electrosurgical effect when the input voltage varies from one extreme to the other will be negligible. This feature is useful in case of brownouts or if the generator is operated with a portable power plant.



FOOTSWITCH WIRING DIAGRAM



MONOPOLAR HAND-SWITCHING INSTRUMENT WIRING DIAGRAM

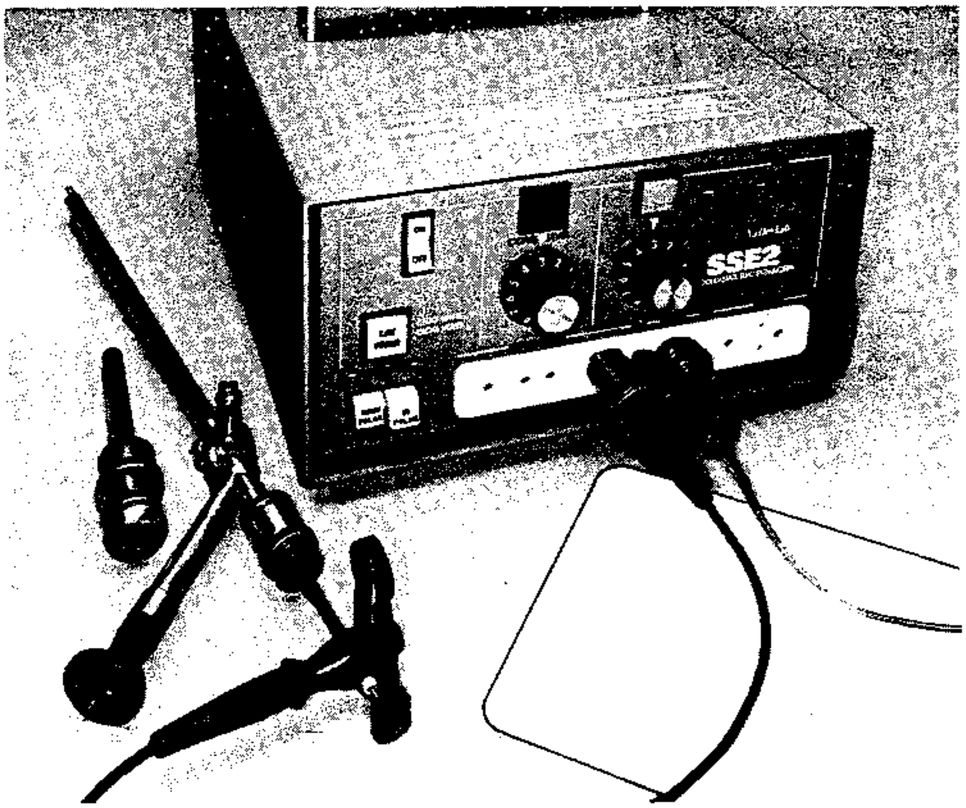


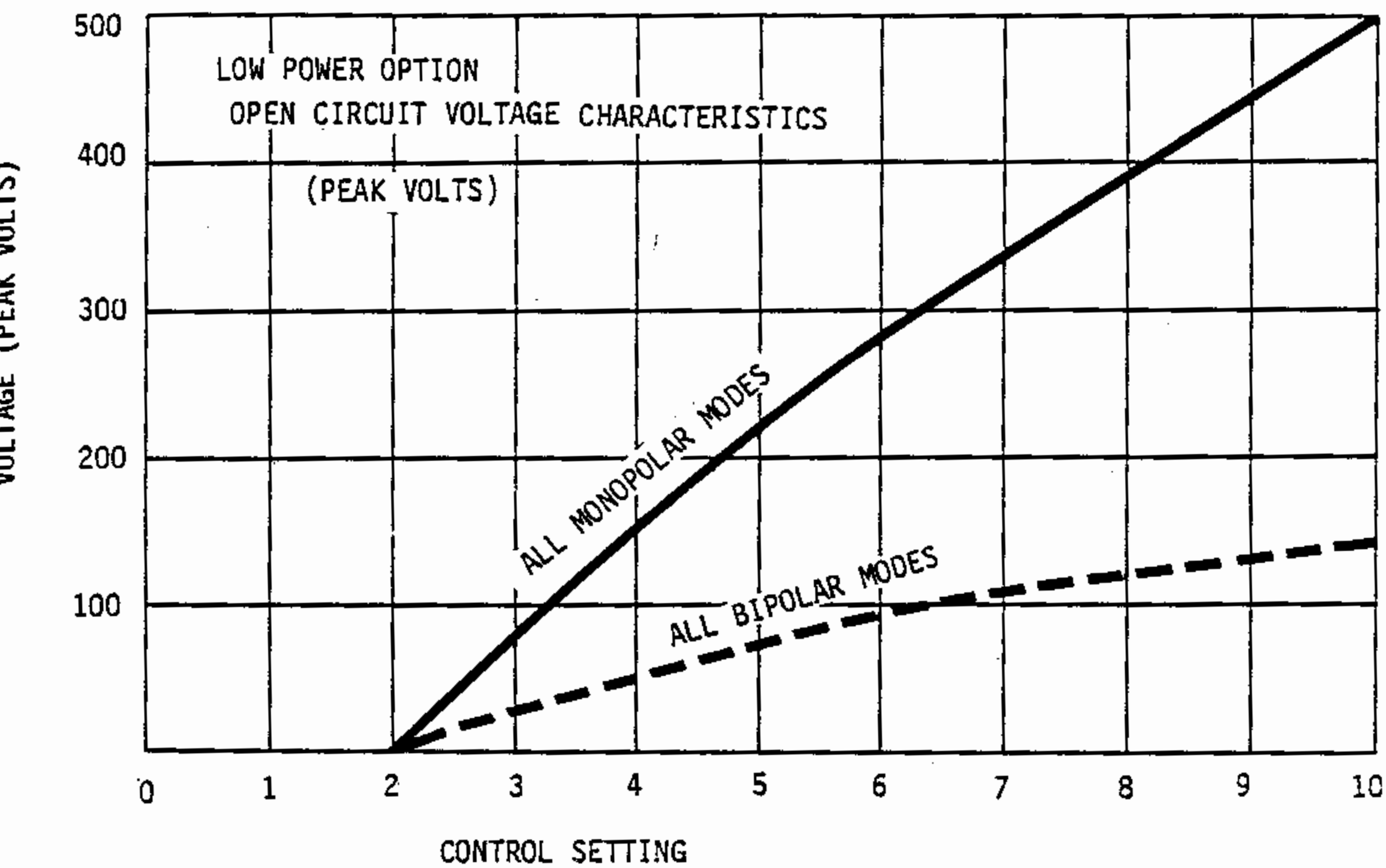
BIPOLAR HAND-SWITCHING FORCEPS WIRING DIAGRAM

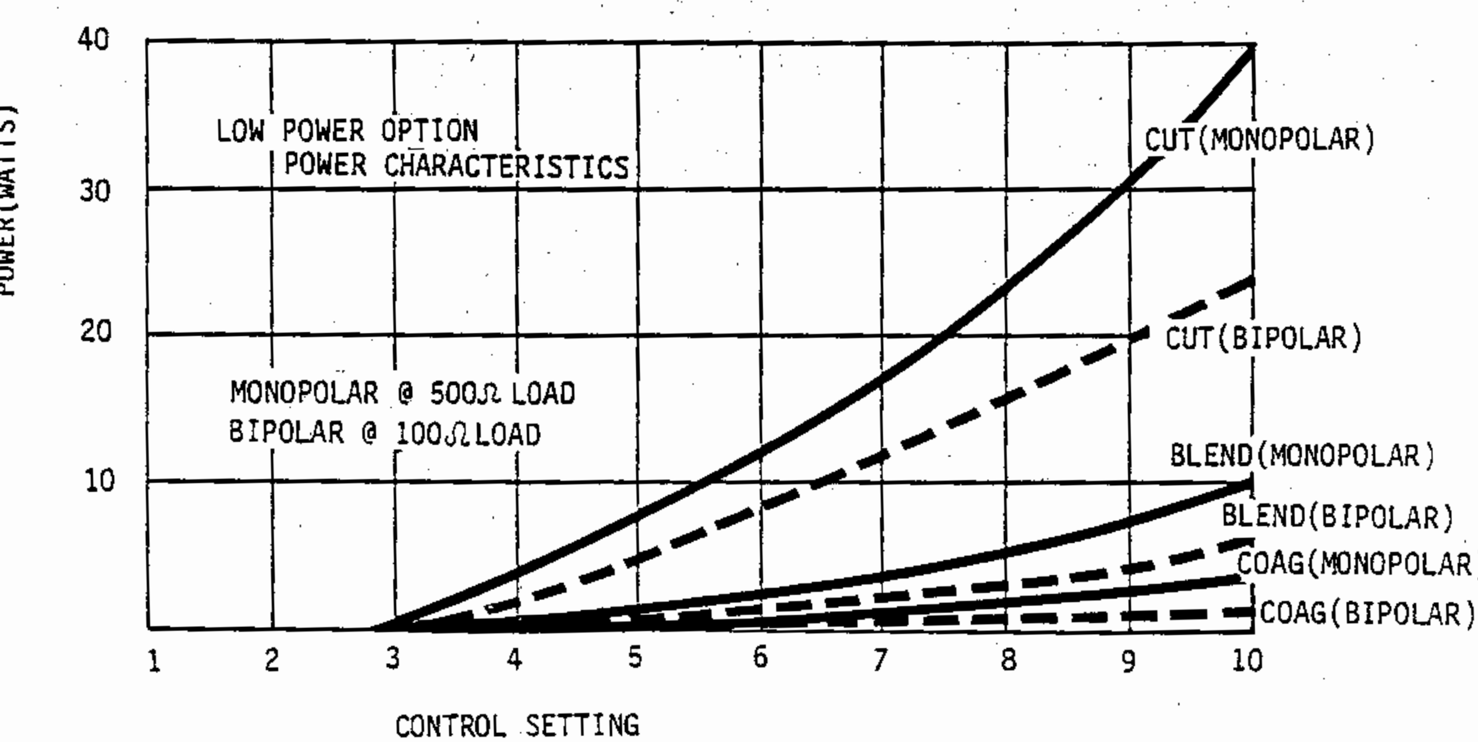
WIRING DIAGRAMS FOR FOOTSWITCHES AND HANDSWITCHING INSTRUMENTS FOR THE SSE2L

LOW POWER MODE ATTENUATOR

The SSE2L can be supplied with a low power attenuator control which limits all three generator outputs to less than 100 watts and less than 600 volts peak. The control is a white button on the front panel. When pushed inward, the button locks and illuminates. Both monopolar and bipolar outputs are attenuated uniformly. Limiting the power in this fashion is useful in monopolar laparoscopy, microsurgery and opthalmic surgery. In contrast to the use of resistive or capacitive attenuator (like catalog #0015) this attenuation system does not alter the basic output impedance characteristics of the generator. Its only effect is to "spread" the lower dial indications over the entire range of power knob rotation. Graphs showing typical power and open circuit peak voltage as a function of control knob rotation setting when using the low power mode are shown below.







TYPICAL LOW POWER OPTION CHARACTERISTICS

EXTRA LENGTH LINE CORDS

On request the SSE2L 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 SSE2L specification of 30 microamps. Because of the added leakage, the testing laboratories, C.S.A. and U.L., do not certify generators which have cords in excess of 10 feet and 15 feet, respectively.

EXPLOSIONPROOF PLUGS

The SSE2L can be supplied with explosionproof 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. None of these connectors have either C.S.A. or U.L. certification and therefore no generator equipped with these connectors can bear test lab markings.

220V VOLT, 280 VOLT, AND 100 VOLT VERSIONS OF THE SSE2L

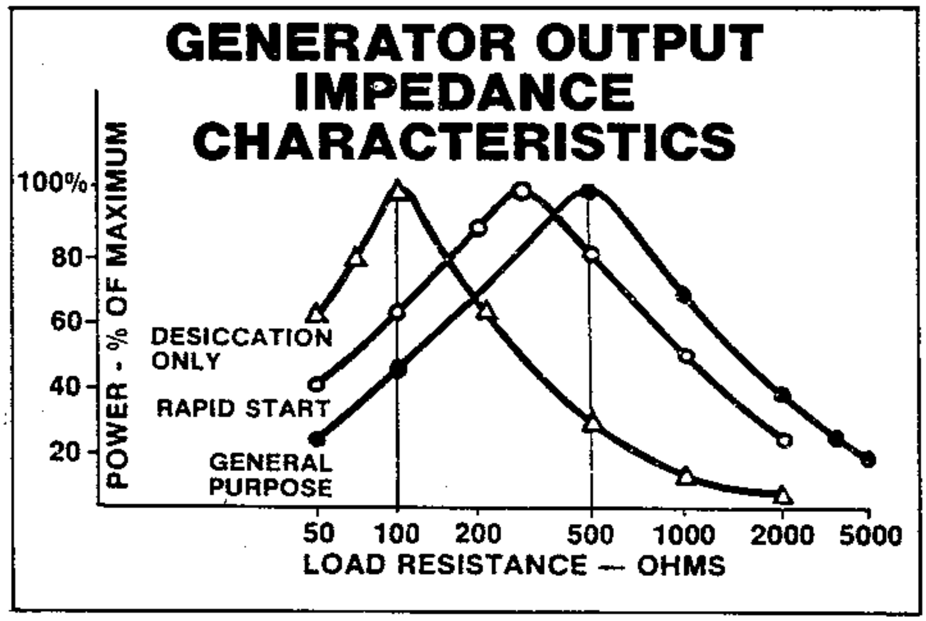
Manu customers outside the United States require input voltages different from the standard 120 volts AC. At present only the 120 volt version has U.L. certification and is shipped with the standard 120 volt power plug which is used in the United States. The plug must be converted to the proper plug for the local area.

RAPID START

This option is a reduced output impedance for the monopolar footswitched output only. It is designed for those applications which need a minimum of lag or delay when starting an electrosurgical cut or desiccation. It also has the advantage of a minimum of cutting effect during fulguration. This option is intended for transurethral resections and G.I. endoscopy, but may have other applications. The only disadvantage of this modification is that the peak voltage in COAG is reduced and it is not as acceptable for fulguration from a distance. That is, it is hard to fulgurate without actually touching the tissue with the active electrode. The maximum power of the generator is not significantly reduced by this change, but occurs at 250 ohms load instead of 500 ohms like the standard monopolar output. The power versus control setting curve is therefore the same as the regular output as shown on page 18, except that the measurement would have to be made with a 250 ohm load. If a 500 ohm wattmeter, such as the Valleylab Model E3000, were used to check the output power, the power would appear reduced to about 75% of the standard output. The open circuit voltage characteristics of the Rapid Start Output are about 70% of those shown on page 19. A comparison of the standard monopolar impedance characteristics, the Rapid Start Characteristics, and the bipolar desiccation-only characteristic are shown on the following page.

RETURN ELECTRODE MONITOR SYSTEM

The REM system will verify the electrical continuity of the patient return electrode circuit, when properly connected to any E7502, E7503 (disposable return electrodes) or an E0009-1R cable which is properly connected to a reusable return electrode (E7002). If the return electrode is not connected to the unit, the unit gives a warning signal and it is not possible to use the unit.



GENERATOR OUTPUT IMPEDANCE CHARACTERISTICS

The REM system provides additional safety when an E7505 CoHesive ™ Dual Return Electrode is connected to the generator and properly applied to the patient. The REM system continuously monitors the electrical quality of the contact between the patiend and the CoHesive ™ Dual Return Electrode. When a "poor contact" develops, the REM system will sound an alarm and disable the generator.

The REM system prevents the generator from producing RF output when the alarm is activated. If the warning signal appears during the surgical procedure, verify that the CoHesive ™ Dual Return Electrode is applied correctly, and that the cable is completely in order and connected to the generator.

SECTION 4

THE SSE2L PATIENT RETURN ELECTRODE SAFETY SYSTEM

INTRODUCTION

In monopolar electrosurgery a large patient electrode is used to disperse the RF current which returns to the generator to complete the circuit loop. In order to insure that the patient plate is properly contacting the patient's skin many clever protective systems have been devised. The goal of all these innovations is to restrict the electrosurgery to the end of the active electrode held in the surgeon's hand. Accidental patient burns at ECG electrodes or other RF (radio frequency) grounded skin contact points have plagued monopolar electrosurgery since it was first used.

The ideal situation to this problem would be a system in which 100% of the RF current flows to the return electrode and there were absolutely no stray currents available to flow through unintended ground paths.

The best existing solution is to use a bipolar instrument in which there is no patient plate at all. Bipolar instruments have two electrodes so that the return path is right along side the active electrode. In fact, electrosurgery usually occurs at both electrodes. Because of the realities of capacitive coupling at radio frequencies, even a bipolar instrument with a well-isolated (non-ground referenced) generator is not "perfect" and some small leakage to ground occurs. The biggest problem with bipolar instruments is that they cannot yet replace monopolar electrosurgery because they don't work as well in most applications.

All monopolar electrosurgery is even less ideal than bipolar because the majority of the current must pass through large portions of the patient's body before arriving at the patient plate. Because of this greater distance, there is more opportunity for "detours" in which the current takes an unwanted ground path.

GROUNDED MONOPOLAR ELECTROSURGERY

Before Valleylab's SSE2L was introduced, monpolar electrosurgical generators used ground referenced outputs. This was done by connecting the patient plate side of the output transformer secondary winding to earth ground. See Figure 1. Next Page.

There are four deficiencies of a conventional grounded electrosurgical unit. The major problem arises because most objects in the operating room are also grounded. If the active lead is touched to any grounded object the circuit will be completed and current will flow. In electrosurgery the current can be passed through tissue quite safely for indefinite periods of time, provided the current density is kept low. If one is using a setting on the generator which is capable of putting out, say 100 watts maximum, then the literature states that you need nine or ten square inches of skin contact area to pass this current safely. This can also be expressed as 1.5 watts per centimeter [5].

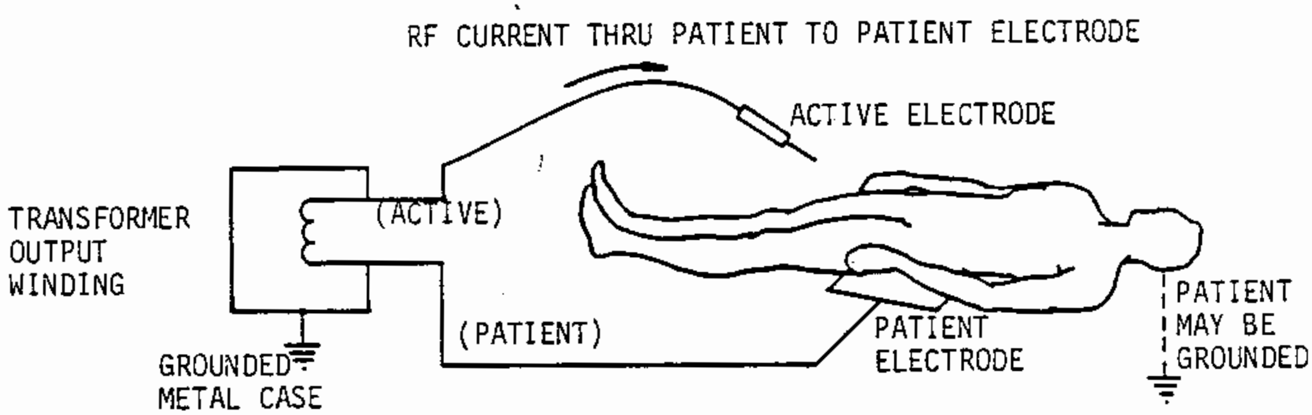


FIGURE 1
SCHEMATIC, GROUNDED ELECTROSURGICAL GENERATOR

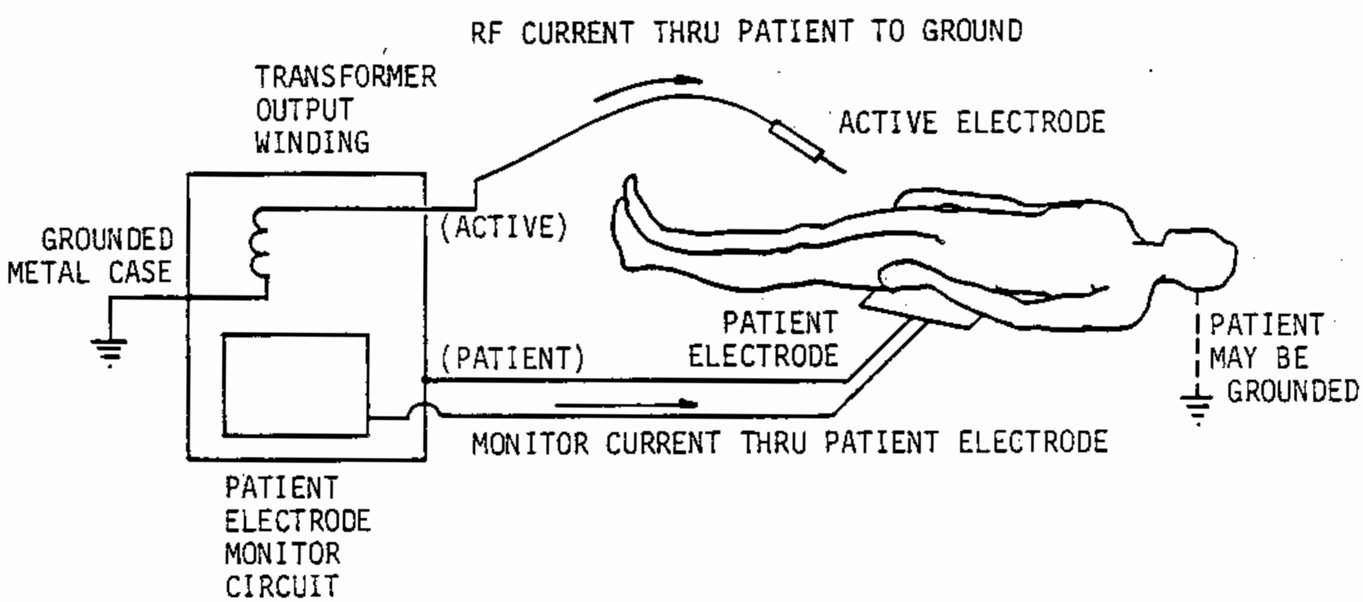


FIGURE 2
SCHEMATIC, ISOLATED ELECTROSURGICAL GENERATOR

The point of this is that if the patient plate is not securely attached to the patients'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. [1] See Figure 3, Pg. 73.

The second problem with grounded systems is that technically, the patient plate 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 plate cables are generally 10 feet long and have about 3.5u henries inductance. If the cable is wrapped into a few turns in an attempt to be "neat", the inductance can rise to 10u henries or more. At 2MHz 3.5uH 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 plate 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 plate 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 plate is securely attached to the patient's skin [2].

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 plate, which should be as close to the site of surgery as possible. Moreover, the contact points should be distal to the current path between the surgery and patient plate whenever possible.

The third problem with simple grounded systems is that the patient plate 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 plate would insure that large currents would flow through the patient and electrocute him. See Figure 4, Pg. 73.

The fourth disadvantage of grounded systems is that they perform poorly when used with bipolar accessories. Bipolar forceps cannot be used with a grounded system because there is usually a fairly low impedance between the patient and ground. 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 plate. If it is possible to isolate the patient 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 inadvertant burns due to loss of the patient plate. The most common aid is a two wire patient plate system in which a monitor current is passed out to the plate 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 plate is under the patient, and some designs don't even guarantee that the patient plate 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.

The sentry monitor circuits are of three basic types: Low frequency AC; Direct Current (DC); and High Frequency (RF) circuits. All of these are designed with high internal impedance to limit the current flow to a small safe level. The low frequency AC circuits have the disadvantage of putting a 60 cycle signal on the patients's skin which then appears as ECG interference. The DC, high impedance monitor circuits work well provided that the monitor signal is very small, in the order of 10 microamperes or less. Larger DC currents, if allowed to pass through skin, can electrolyse tissue causing a chemical burn on the skin (4). One generator on the market used a 75 KHz signal for its sentry monitor circuit. This is a high enough frequency to avoid ECG interference and significant muscle stimulation.

All sentry monitors, however, have the disadvantage that they can <u>fail</u> without the operator knowing, thus giving a false sense of security.

There is one other type of sophisticated type of patient safety device for grounded electrosurgery which is not on the market. This system passes a small DC current in the order of seven microamperes through the active lead, through the patient and through the patient plate. This current path must first be completed before the generator will activate. The patient plate 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. Similarly, contact with dry eschar or skin will have too high a resistance to allow the machine to activate. The second limitation is that it does nothing to control or limit current division through small grounded contact points during normal operation when the patient plate is properly applied.

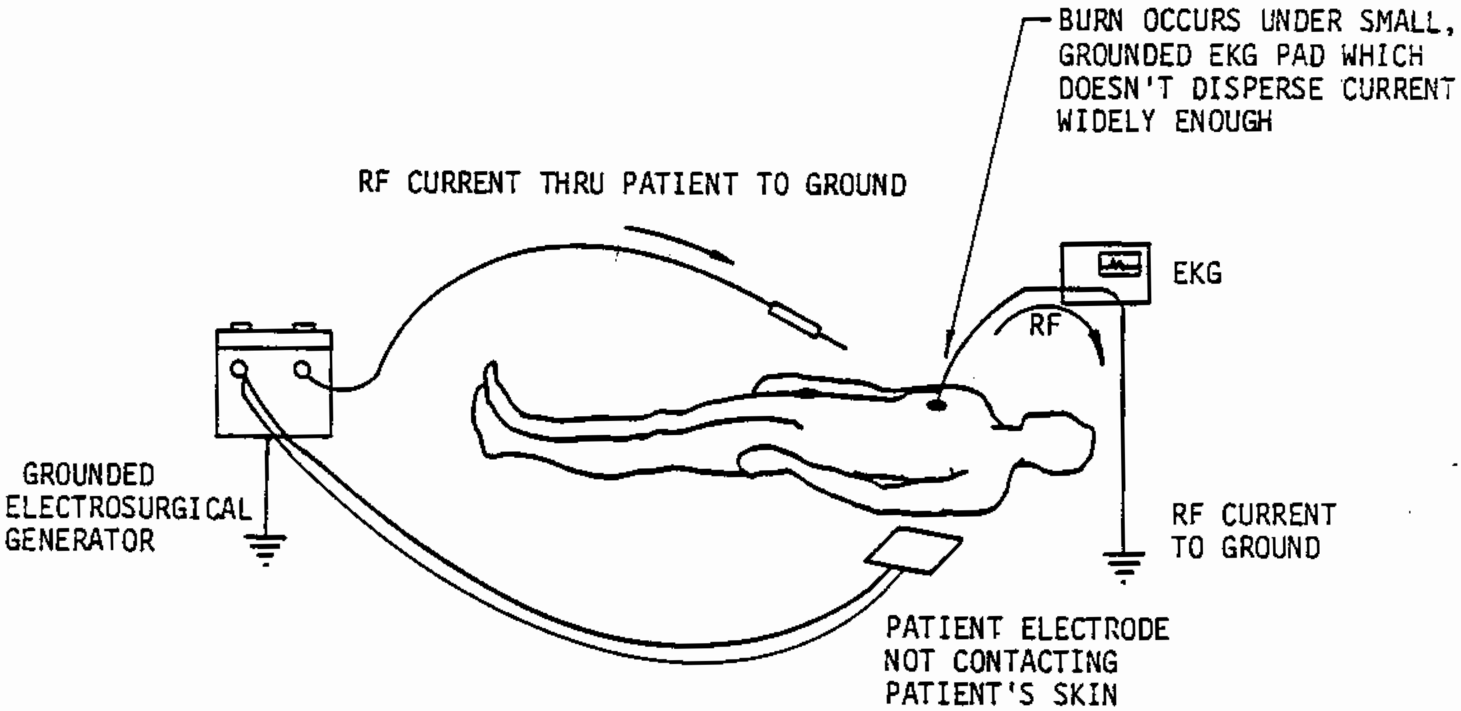


FIGURE 3

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.

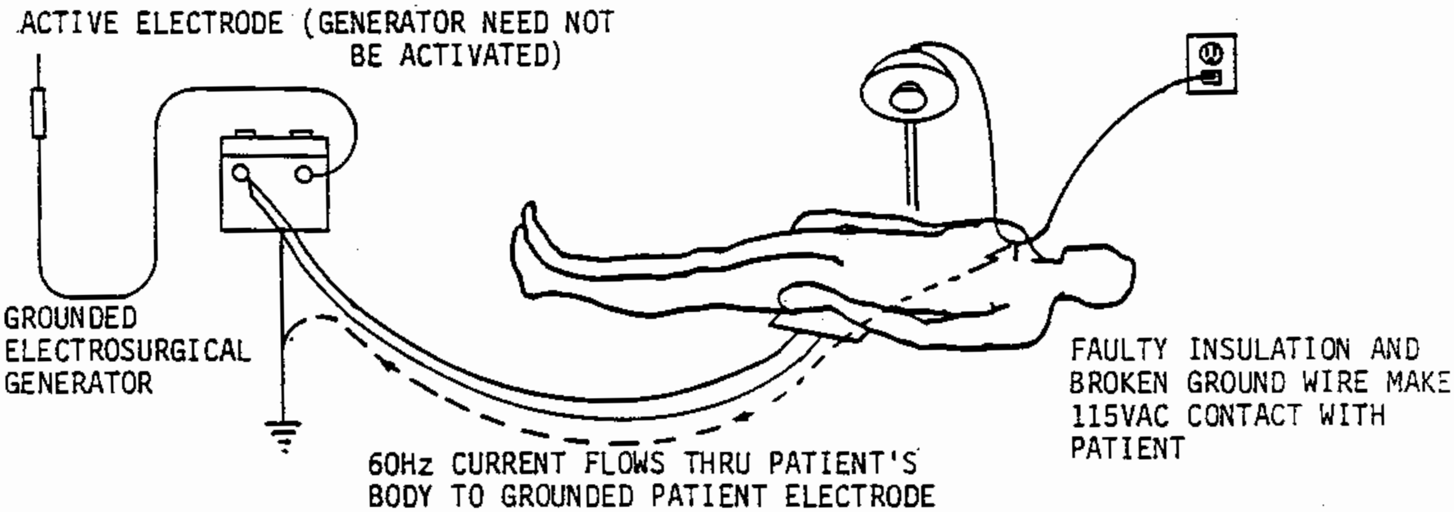


FIGURE 4

HOW A WELL GROUNDED PATIENT CAN BE ELECTROCUTED BY AN UNUSUAL FAULT IN WHICH THE 115 VOLT POWER LINE TOUCHES HIS BODY.

ISOLATED ELECTROSURGERY

One of the best available solutions to the monopolar patient plate dilemma is the isolated output which has no reference to ground . See Figure 2, Pg. 70. The isolated output 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 plate 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 plate 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 plate 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 plate safety system does not limit the surgeon's technique and finally, the isolated patient plate does not provide a 60 Hz "sink" for ground referenced power line voltages. "Current division", as described above, is not much of a problem with isolated generators because the current is trying to return to the patient plate, 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 finite 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 plate via the small grounded contact points [4].

The second limitation is that the active electrode can not be touched to ground while the patient plate is attached to the patient. If this is done, the patient plate 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, Pg. 76.

A limitation of all existing monopolar systems occurs when the patient plate falls out from under the patient and lies against a grounded object. As before, there is no patient plate to disperse the current and the current may concentrate at small, grounded skin contact points. See Figure 5, Pg. 76. 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 plate 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 plate is usually 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. 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.

RF LEAKAGE CURRENT IN ISOLATED SYSTEMS

As indicated earlier, the stray capacitance between the wire leads to ground is potentially dangerous during normal operation because this causes a leakage current that will complete its journey to the patient plate via small, grounded contact points on the patient's skin. If the wire going to the active electrode is in close proximity to ground, for example, and if it were wrapped tightly around a grounded pipe, the leakage to ground could be twice normal. A more practical example arises when electrosurgery is used to remove polyps with a colonoscope or gastroscope. Electrically the scopes are long, grounded tubes 6 feet long. The active lead is passed through the scope to a snare at the end. The active lead and the scope make a capacitor and increase the leakage to ground. Resectoscopes also have this problem but the increase in leakage is far less noticeable because the scopes are only one stitch as long. See Section 2, page 30.

Capacitance between the patient plate and ground is also potentially troublesome because this leakage can also result in current passing to the active electrode via the small, grounded contact points.

On the other hand, there is one stray capacitance which is useful. Assuming that the patient plate is firmly applied to the patient's skin, then the patient's body will be at the same potential as the plate, and since the patient is lying on a metal, grounded table, his body makes a significant capacitance to ground. The capacitance "shorts out" the RF leakage which have measured this capacitance and found it to be in the range of 200 to 600 or more picofarads. This figure varies depending on the size of the patient, how much insulation is between his body and the table, and his position on the table.

RF leakage is highest when the voltage across the output is highest. This occurs when the power controls are set to maximum and when there is no load on the output. No load means when the active electrode is not touching anything. Consequently, it is never a good idea to have a generator active when it is not actually being used. Moreover, the power settings should always be the minimum which will do the job.

The fact that some isolated generators may trip line isolation monitors in the operating room has little to do with how well they are isolated. The line isolation monitor should be looking 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.

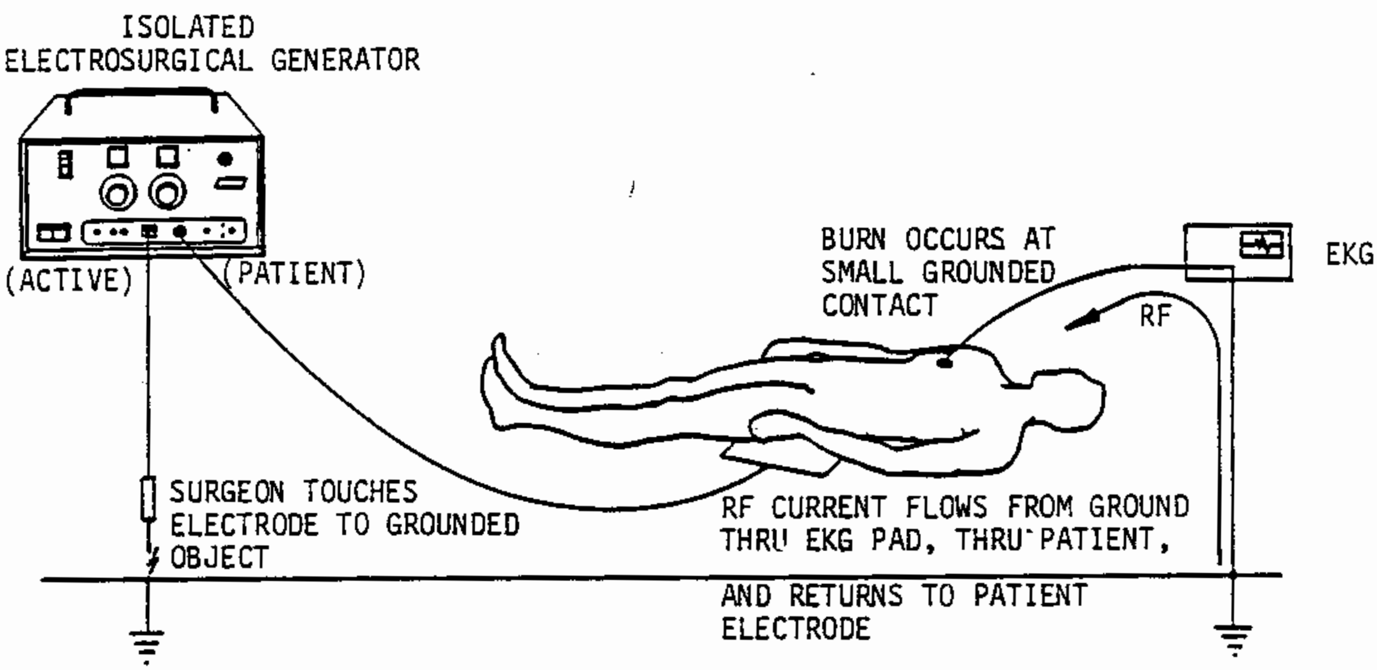


FIGURE 5

SURGEON SPARKS ELECTRODE TO GROUND WITH AN ISOLATED ELECTROSURGICAL GENERATOR. A BURN COULD POTENTIALLY OCCUR AT SMALL, GROUNDED CONTACT POINTS SUCH AS THE EKG PAD SHOWN HERE.

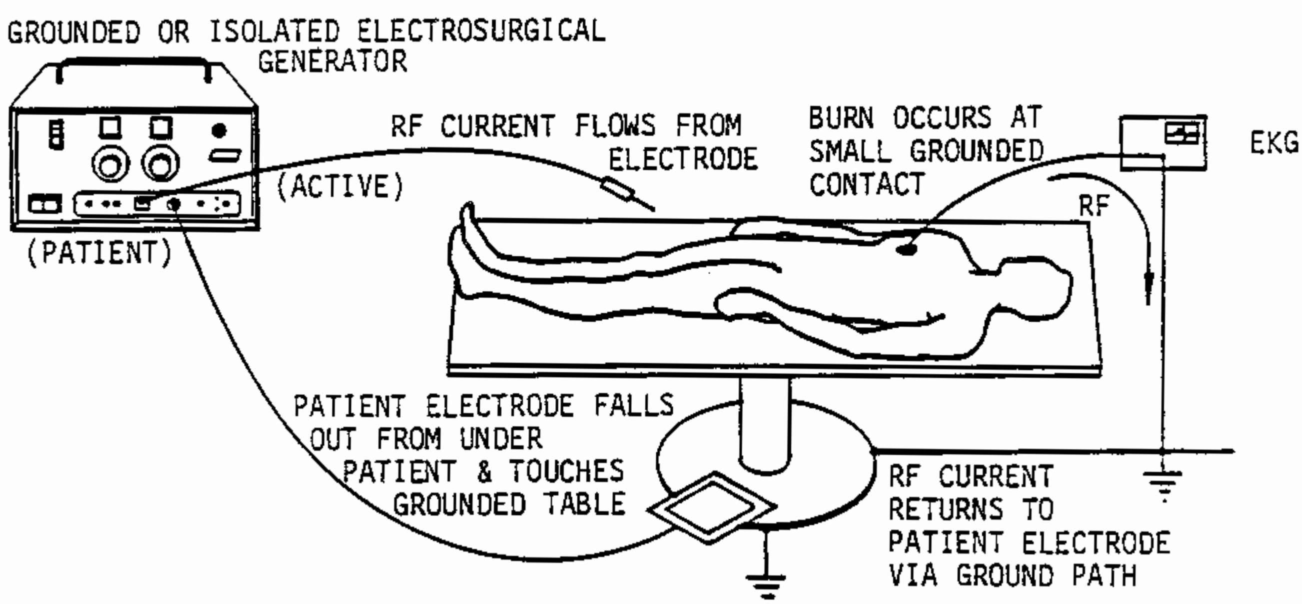


FIGURE 6

IF THE PATIENT PLATE OF ANY EXISTING ELECTROSURGICAL GENERATOR FALLS OUT FROM UNDER THE PATIENT AND MAKES CONTACT WITH A GROUNDED OBJECT SUCH AS THE TABLE PEDESTAL SHOWN HERE, A BURN CAN OCCUR AT ANY SMALL GROUNDED PATIENT CONTACT POINT.

NOTE: VALLEYLAB RETURN ELECTRODE MONITORING SYSTEM (REM) PROTECTS AGAINST THIS HAZARD.

If an isolated generator trips the isolation monitor, it may mean that the monitor is overly sensitive to RF current and that the particular combination of active and patient cables has coupled RF to ground in such a way that it must return via the monitor. The Underwriters' Standard UL544 as presently published, allows up to 10 ma of ground wire leakage. It turns out that with the patient return electrode touching ground and the generator at maximum settings, no full power generator in existence can pass this specification. In fact, grounded generators are generally worse than isolated ones in this regard.

MEASURING RADIO FREQUENCY LEAKAGE

To make a meaningful radio frequency leakage measurement it is necessary to simulate the conditions in the operating room and measure the maximum leakage current which might flow from the patient's body to ground through small, grounded contact points. The worst case occurs at maximum settings and open circuit. Open circuit occurs when the surgeon is keying the generator but not using the active electrode. The leakage current that is a thread to the patient is that current which flows out of the patient jack, over to the patient's body, and from there to ground. To measure this current a thermocouple type RF ammeter is connected between the patient jack and ground. There is no load resistance connected in series with the ammeter, so the resulting short circuit current represents the absolute maximum leakage which could never occur under any circumstance.

Other than the basic generator design, the major contributors of RF leakage are the active leads which are plugged into the generator. A single 3 meter long active cable plugged into a generator can have anywhere from 10 to 170 ph of capacitive coupling to ground. However, roughly 50 pf is typical in the ordinary operating room set up. This coupling delivers current to ground that will then try to enter the patient's body as a means of reaching the patient jack. Consquently, RF leakage measurements should be made with as many active electrodes plugged in as the surgeon's typically use.

The SSE2L is equipped with leakage cancelling circuits that resonate the active cable capacitances to ground with indicators to make the leakage with actives plugged in virtually the same as with no actives plugged in. With most generators it is possible to plug in two or more monopolar electrodes simultaneously and this can result in high leakage currents, 300 ma or more. The SSE2L electrically independent outputs minimize the leakage current because, even with electrodes plugged into all three outputs simultaneously, only one of them is active and therefore the leakage remains below 150 ma. Even small differences in leakage current can be important since the power necessary to cause harm is proportional to the square of the current. That is, a reduction in leakage current by on-half means a reduction in leakage power to $\frac{1}{4}$ the original power.

The Way <u>not</u> to measure leakage is to touch the active electrode to grounded metal and compare the length of the sparks at maximum settings. The length of the spark is proportional to the open circuit source voltage. In itself, spark length does not test the energy available to cause a burn. If fact, a long spark could mean that the COAG is superior to a generator with a shorter spark to ground.

APPROACHING THE IDEAL SYSTEM

The ideal patient safety system can be closely approximated by using the SSE2L generator, and a second patient return electrode. The second patient return electrode is separated from the first and connected to ground. A 2000 pf capacitor in series with the second patient return electrode will block 60 Hz AC but will permit 500 KHz RF to pass freely. Such a system gives the theoretical advantages of both grounded and isolated systems simultaneously. The active electrode can be touched to ground without risking burns. Moreover, any RF leakage will be shunted to ground. Unfortunately, such a system adds more wires and complexity to an operating room and is especially awkward with small infants. 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 .3cm 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 out finding. Very small monitoring 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 impedance may be only a few hundred ohms [7]. As Finlay et al point out, even a few hundred ohms is better than zero ohms [5].

Rectal or esophagel 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, plathysmograph and telethermometer leads. This will convert the leads to a high impedance at RF frequencies but leave their low frequency characteristics unaltered. Finaly et al recommend RF chokes in the range of 22 to 100 mH (5). Hall et al say that 3.3 mH chokes are adequate to prevent burns (6). 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 effect the performance of an ECG, and ECG manufacturer should be contacted before attempting these modifications. Figure 7, Pg. 79 illustrates the use of a second patient plate and RF chokes in the leads.

Although current division is not as great a problem with isolated systems as with grounded ones, it doesn't hurt to take precautions to prevent its occurence. First, the patient plate 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 plate will take a larger percentage of the current than will one located distal to the main current path.

SUMMARY

There is no perfect solution to patient plate safety, but a well isolated electrosurgical generator is one of the best available systems and is certainly the least complicated. 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 plate 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 question of whether RF leakage is better than RF current division has too many variables to give an absolute answer. In either case, the use of large ECG electrodes, proper patient plate positioning, and minimum 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 plate cable is checked religiously and the patient plate is positioned properly and rechecked every time the patient is moved or the patient cable is disturbed.

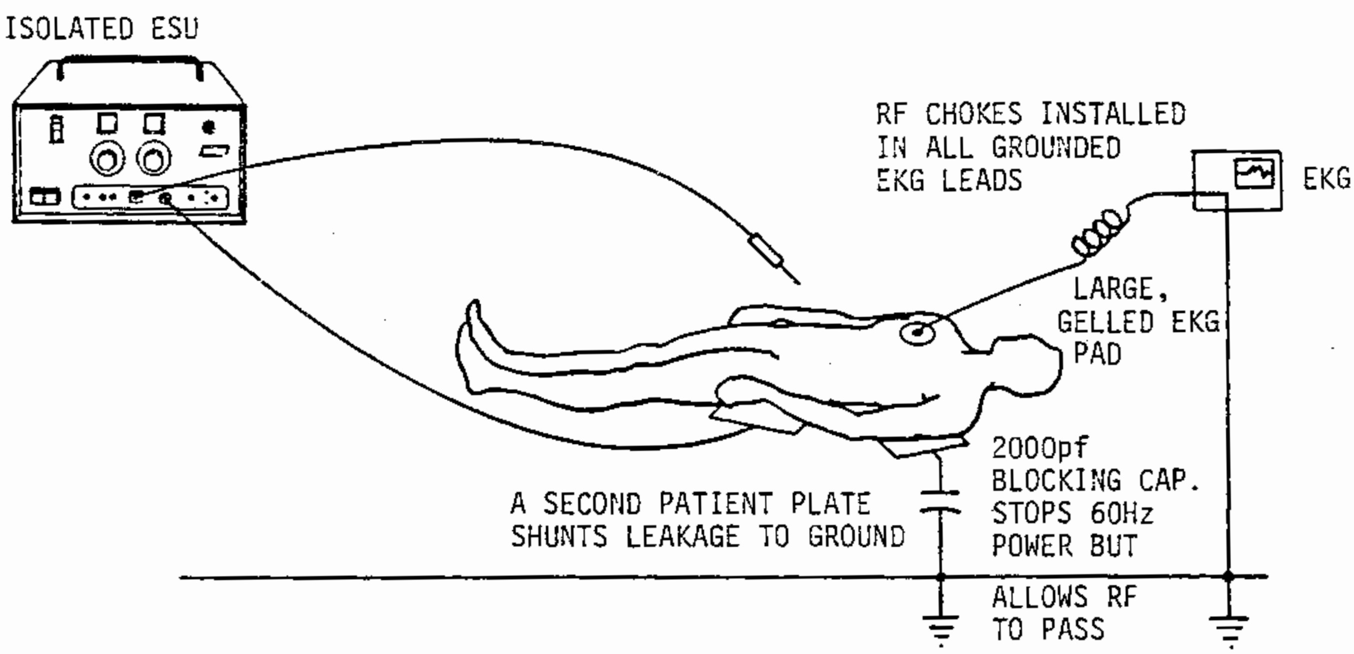


FIGURE 7

APPROACHING THE IDEAL MONOPOLAR SYSTEM WITH AN SSE2L ELECTROSURGICAL GENERATOR

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SECTION 5

PATIENT RETURN ELECTRODE RECOMMENDATIONS

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

The skin contact area required for safe patient plate orientation 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 plate. Moreover, if this guideline is followed, one need never worry about the condition of the skin under the plate, 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 plate will begin to behave like an 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 plates 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 plate in case it is improperly applied or defective in some way.

Valleylab makes patient plate systems which can be used with the SSE2L. They are:

THE E7001 PERMANENT PATIENT PLATE

This is a permanent, stainless steel plate which connects to the patient cord (E0009) with a screw-on connector mounted at the corner of the plate. The E0009 cord has a banana plug at the generator end and plugs into the patient jack. The patient jack on the SSE2L 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 is designed to go under the buttocks, thigh, shoulders or anywhere that gravity can insure an adequate contact area. It has over 80 square inches of surface area of which at least half can be touching the patient if it is applied properly.

Although it is not essential, 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 LECTROPLATE®R

The E7501 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 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 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 perfectly all right, but we recommend that the guideline of 1.5 watts per square centimeter of skin contact be followed.

THE E7503 PREP II 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 Prep II is the solution. It has a pregelled electrode with an effective area of at least 20 square inches (130 square centimeters) of contact are. The patient plate is backed with a large sheet of foam covered with adhesive so that the skin adhesion completely surrounds the patient plate. The Prep II Return Electrode is disposable and can be used for all routine procedures.

The Prep II Patient Return Electrode relies on its adhesive to hold the gelled patient plate to the patient's skin. If the pad is applied improperly, there may be insufficient area actually touching the patient. A permanent adapter (E0504-1) is needed to connect the 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 that it is wet. It should be touched with a dry finger to be absolutely certain that the gel has not dried. The Prep II 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 are contact can be assured during the procedure. For example, if the Prep II were placed on the flank and later the torso were flexed in the direction of the Prep II, the gel pad may fold away from the skin and lose much of its contact area with the skin. Note: application illustration on Prep II package.

In case of suspected patient plate circuit problem, do not assume that the gel pad is in good contact with the skin just because it looks right from the outside. Remove the Prep II from the skin and replace it with a fresh pad. NEVER re-apply a used pad.

THE E7502 LECTROHESIVE® PATIENT RETURN ELECTRODE

The Electrode works on the same principle as the Prep II with the only difference being the cord. The LectroHesive Return Electrode is designed to be used with the E0505 LectroHesive Cord. One cord comes in each case of 50 electrodes and has a recommended use of 50 times, subject to careful visual inspection prior to each use. The double-notched, pronged end of the cord, is inserted into the "locking channel" of the LectroHesive Return Electrode, making a solid mechanical and electrical connection. The LectroHesive Return Electrode requires the use of the Cord Adapter, E0504, just as the Prep II does. After removing the LectroHesive from the package, connect the semi-disposable cable to it and the generator. It is easier to attach the cable before removing the protective plastic tray.

THE E7504 PEDIATRIC PREP II

NEVER attempt to cut the Prep II or the LectroHesive Return Electrode down to a smaller size for pediatric use! The Pediatric Prep II, E7504 has been designed for low power procedures and for use with infants and small children. If the Prep II or LectroHesive Return Electrode cannot be applied on a small patient so that the gelled surface is reliably in full contact with skin surface, the Pediatric Prep II (E7504) Return Electrode is indicated. The Prep II, Pediatric Prep II and the LectroHesive Return Electrodes may be used with gravity contact and without border adhesive. 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.

THE E7505 COHESIVE RETURN ELECTRODE

The Cohesive Return Electrode is a dual return electrode, which when used with a REM equipped generator has the capability to monitor the electrical resistance between the two contact surfaces of the pad, and allow operation only if the resistance is between preset limits. The REM actually detects insufficient return electrode to patient contact while monitoring continuity of the entire patient-pad-cord circuit. In the event there is a break in the circuit path, the REM alerts the O.R. staff before injury can occur.

NOTE: Standard return electrodes, except the Cohesive Electrode will function with the REM system and monitor cable integrity, but will not monitor patient electrode contact. For this reason, we recommend using only the E7505 with a REM equipped generator.

WARNING: All Valleylab Return Electrodes and mating cables should be inspected prior to each use, for cracks or voids in the insulation and or possible loose connections. In the event a cord fault is present, the cord and/or electrode should be replaced to prevent any reduction of output power during a surgical procedure.

Lectrogel and Other Conductive Pastes

All Valleylab patient plate 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 non-drying gel because the water will evaporate out of any paste exposed to the air. Some gels contain glycerin which may look wet after hours of exposure to the air but have lost their water and are no longer conductive.

Use of the Patient Electrode as A "Ground Reference for ECG Monitors

Because the SSE2L patient electrode is not grounded, this practice is not recommended. For this reason none of the Valleyalab patient plate systems are equipped with connectors for attaching ground wires. If such a ground wire were attached to the patient's skin, the remainder of the ECG leads would probably serve as a substitute patient plate, depending on the internal impedance of the ECG unit to the 500 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 from the ECG.

When using the SSE2L 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 plate 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 grounded wires must be attached to a Valleylab patient plate, we recommend that the connection be made to the permanent patient plate (E7001) by drilling a small hole in the edge of the plate and riveting the appropriate connector to the plate. When using such a leakage shunting system, it is vital that the patient plate be securely attached to the skin. Extra precautions such as taping the plate to the skin and double checking the plate position are advisable.

SECTION 6

INTERFERENCE TO MONITORING EQUIPMENT

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 on the order of 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, Pg. 20, 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 circuitry, 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. Interferences 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 Hz. Such a ground provides a "sink" or path to ground for large 60 Hz currents as well. This could be a threat to the patient if defective insulation ever resulted in ground referenced 60 Hz voltage touching his body.

One situation in which the SSE2L could cause 60 Hz interference would be if the Powerite™ circuit were not being used and the metal chassis ground wire were 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 turned 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.) Ths 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 SSE2L ground connection. Note that the fault in the chassis ground circuit can be in the generator, the wall plug, or in the hospital wiring.

Another way the SSE2L can appear to be causing 60 Hz interference happens when an SSE2L 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 SSE2L 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 safety of the isolated system is compromised when the patient electrode is directly grounded.

What To Do If The SSE2L Appears To Be Causing ECG Interference

First, what kind of interference is it? Is it continuous or does it occur only when the SSE2L 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 or the suggestions apply.

Continuous Interference, Thickened Trace

1) *Check the ground connection on the SSE2L. 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 oeprating 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.*

*Powerite™ is explained in Section 7

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 SSE2L patient electrode.

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

6) If two generators are being used on the same patient and only one of them is the SSE2L 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 between two "grounded" objects. 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 SSE2L 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 should be looking 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 SSE2L 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 has coupled RF to ground in such a way that it must return via the monitor.

SECTION 7

TECHNICAL SPECIFICATIONS

Output Waveform (Typical)

CUT: 500 KHz ± 10 KHz sinusoid with 65% 120 Hz modulation.
COAG: Pulse modulated 450 KHz damped sinusoid.
Burst duration 7.0 usec nominally.
Burst repetition 20 KHz ± 2 KHz.
BLEND: 500 KHz sinusoid with increased amplitude bursts at 50 usec intervals.

Output Characteristics: (Typical values for control settings and load conditions specified. Power source is 120 V AC 60 Hz.)

Monopolar Output Characteristics

Mode	P-P Voltage (Open Circuit CS=10)	Power (500 ohm CS=10)	Crest Factor (500 ohm CS=5)
Pure Cut	2380 V	375 ± 25 W	2.1 ± .2
Blend	2440 V	250 ± 25 W	2.6 ± .2
Coag	4070 V	125 ± 15 W	7.6 ± .5

Bipolar Output Characteristics

Mode	P-P Voltage (Open Circuit CS=10)	Power (100 ohm CS=10)	Crest Factor (100 ohm CS=5
Pure Cut	625 V	90 + 15, - 20 W	2.1 ± .2
Blend	640 V	85 + 15, -20 W	2.2 ± .2
Coag	1100 V	25 + 5, 10 W	7.5 ± .5

Output Power Control:

CUT/BLEND and COAG output power is essentially linear with control rotation from settings of (1) to (10).

Output Interaction:

The maximum power available from any non-activated output must not exceed 20 W for MONPOLAR outputs and 3W for BIPOLAR output. Non-activated power must be measured into a 500 ohm load for MONOPOLAR outputs and a 100 ohm load for BIPOLAR output.

Output Isolation:

Line frequency source leakage current $\leq$ 0.2uA rms
Line frequency sink leakage current $\leq$ 150uA rms (1)
RF patient leakage $\leq$ 150mA rms
Line ground leakage current (50/60 Hertz)
Unit off: $\leq$ 10uA rms
Unit on: $\leq$ 30uA rms
If ground is disconnected unit automatically switches off. Reset by switching on.

Cooling:

Fan is single speed, normally off, and switches on automatically.

Indicators:

Blue coag lamp or yellow cut lamp will illuminate only when RF power is available at unit output connections. High frequency COAG tone or low frequency CUT will sound when footswitch or handswitch is depressed.

Audio Volume:

Idle: Four feet 40 dBA (approximately, fan off)
Active: 65 dBA (Volume set to maximum)

Input Power: (Control setting of 10, output short circuit)

90-135 VAC 50/60Hz	*180-270 VAC 50/60Hz*
Idle: 0.4 Amperes	*Idle: 0.2 Amperes*
Cut: 12 Amperes	*Cut: 6 Amperes*
Coag: 4 Amperes.	*Coag: 2 Amperes*

Input voltage range is selected through internal connections. Approved Hospital-Duty power plug is standard. Explosion-proof connectors can be provided if specified.

Line Regulation:

For settings used for most electrosurgical procedures, i.e., settings which produce 0-200 watts in cut and blend and 0-75 watts in coag, with line voltages varying between 100 and 130 volts, power will not vary by more than $\pm$ 25 watts in cut and blend, and $\pm$ 17 watts in coag.

Weight: *32.5 pounds (14.7 kilograms)*

Size:	*7.6 inches high*	*(19.3 centimeters high)*
	11.6 inches high	*(29.5 centimeters wide)*
	16.6 inches high	*(42.2 centimeters long)*

Note:

(1) Line frequency sink current is that current which flows from an external voltage source of 120 VAC 60 Hz applied to all front panel terminals in parallel 100 k ohms in series with 120 VAC source for safety.

Specifications subject to change without notice.

Data obtained using methods prescribed in service manual.

CAUTION: Per C.S.A. 22.2 #125, the degree of isolation of the SSE2-L is suitable for Risk Class 2 application.

REM Option Subsystem Specification:

Output Waveform: Sinusoid
Frequency 140 kHz ± 5%
Open circuit voltage 1.25 ± 10%
S.C. Current 3ma Max.

Thresholds:
Single pad mode: Alarm off, R = 20 ± 1
Cohesive mode: Low impedance alarm, 20 ± 1
High impedance alarm, 135 ± 2
Hysteresis of thresholds: This is the impedance differences between alarm and alarm silence
low impedance 3 ± 1, high impedance, 12 ± 2
Threshold shift: With the generator keyed at full output, cut or coag, into load or open circuit thresholds will shift by 5 ohm or less.

Audio Tone: 1.2 kHz intermittent
Volume level 65 dBA min. at 1 meter

LED Function: Led enables simultaneously with audible alarm.

Specifications subject to change without notice.

Data obtained using methods prescribed in service manual.

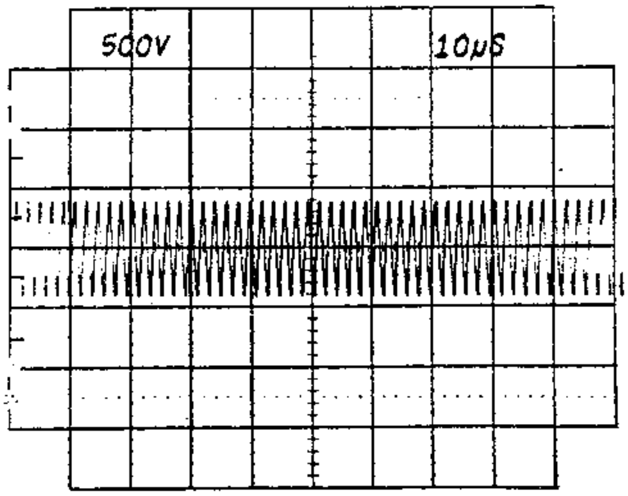
Caution: Per C.S.A. 22.2 #125, the degree of isolation of the SSE2-L is suitable for Risk Class 2 application.

Discussion of Electrical Specifications:

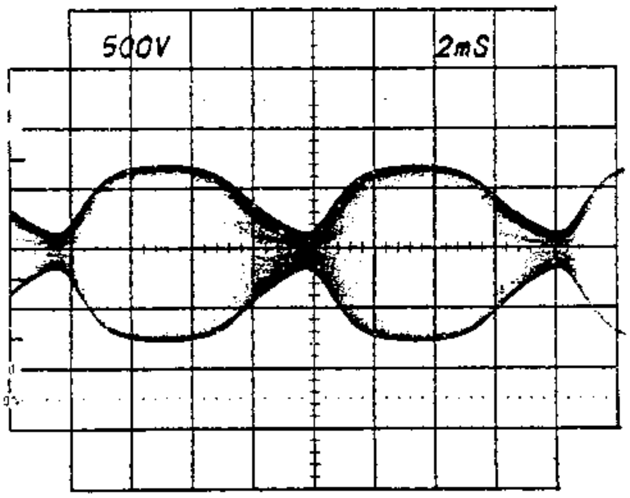
The CUT waveform

The CUT waveform is a continuous voltage sinewave with a frequency of 500 KHz (500,000 cycles per second). The sinewave has 1 120 Hz ripple or amplitude modulation which raises the crest factor from 1.4, (for a pure sinewave) to 1.7 which gives just enough fulguration on the incision margins to prevent minor bleeding. (Crest factor is a way of measuring the degree of hemostasis in an electrosurgical waveform.)

The 120 Hz modulation is NOT a 120 Hz component and therefore it cannot stimulate muscles and nerves. The ripple is roughly 65% of the maximum ripple possible. That is, 100 percent ripple would completely interrupt the waveform or turn off the radio frequency sinewave 120 times per second.



Cut Output (setting of 5)
500Ω 10μS
Keyed in Cut Mode



Cut Output (setting of 10)
500Ω 2mS
Keyed in Cut Mode

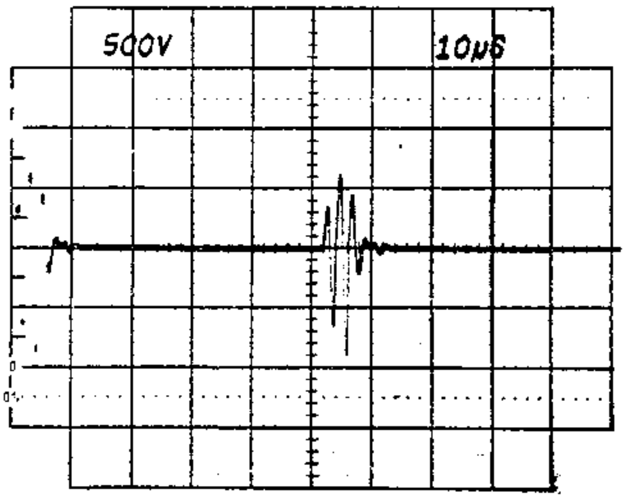
The oscilloscope pictures above show the SSE2L CUT waveform. The first picture shows a small segment of the waveform (10 microseconds per square) and the radio frequency (500 KHz) sinewave can be seen. The second picture shows a much longer segment of the waveform (2 milliseconds per square) and the 120 Hz amplitude modulation (ripple) can be seen. The vertical scale in both pictures is 500 volts per square where the horizontal center line represents the zero voltage point.

The maximum peak voltage of the CUT waveform (at CUT 10) is 1300 volts, while the peak-to-peak voltage is 2500 volts. Looking at the oscilloscope picture, the peak voltage is the voltage between the horizontal zero voltage axis and the highest voltage, either positive or negative. Peak-to-peak voltage is defined as the voltage difference between the largest positive peak and largest negative peak voltage. These peak voltages are always greatest when there is no load on the generator, that is, when the generator is activated but the electrode is not touching anything.

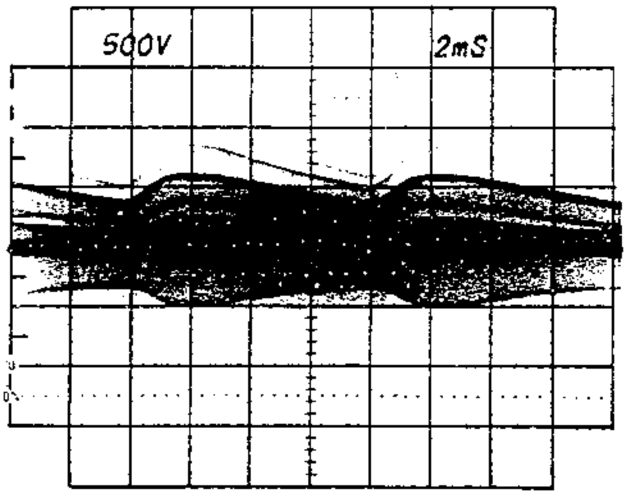
The generator delivers power optimally into a 500 ohm resistance. At CUT 10 the SSE2L will deliver a minimum of 375 watts of power into a 500 ohm test load. This means that the resistor will receive 375 joules of heat energy every second.

<u>The COAG Waveform</u>

The COAG waveform is an interrupted voltage sinewave with a frequency of 450 KHz, (450,000 cycles per second). The sinwave is turned on and off 20,000 times per second to form short "bursts" of RF voltage which are approximately 7 microseconds long.



Coag Output (setting of 5)
500Ω10μS



Coag Output (setting of 10)
500Ω2mS

The oscilloscope pictures above show the SSE2L COAG waveform. The first picture shows a small segment of the waveform (ten microseconds per square) and the radio frequency sinewave bursts can be seen to occur at 50 micro-seconds intervals. The peak voltage is measured from the center zero line to the highest point. The second picture shows a longer segment of the waveform (2 milliseconds per square) and the 120 Hz ripple of amplitude modulation can be seen. The ghost like multiple exposures result from the constantly varying peak voltage brought about by the burst.

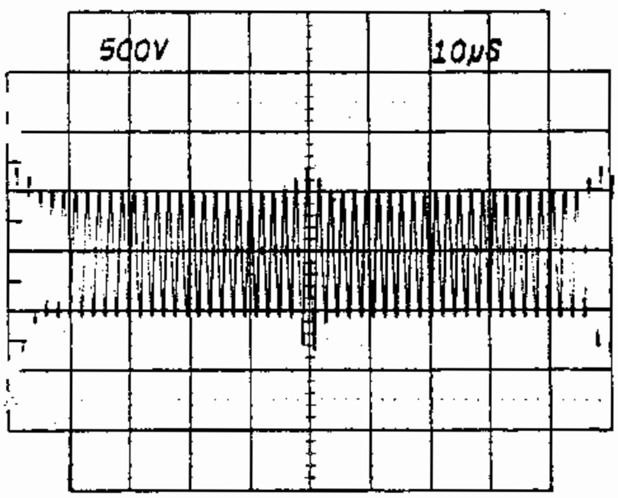
Typical peak-to-peak voltage of the COAG waveform at COAG 10 is 4000 volts with no load on the generator. As seen in the picture, at a setting of 5, the peak voltage is about 1300 volts with a 500 ohm load. The maximum COAG power output is 125 watts and occurs with a 500 ohm load.

The significance of the COAG peak voltage is that it is proportional to the maximum distance that electric sparks can jump to tissue from an electrode. Although the exact distance a spark can jump through air depends on electrode shape, a 2000 volt peak spark from the SSE2L can jump about 1.5 millimeters.

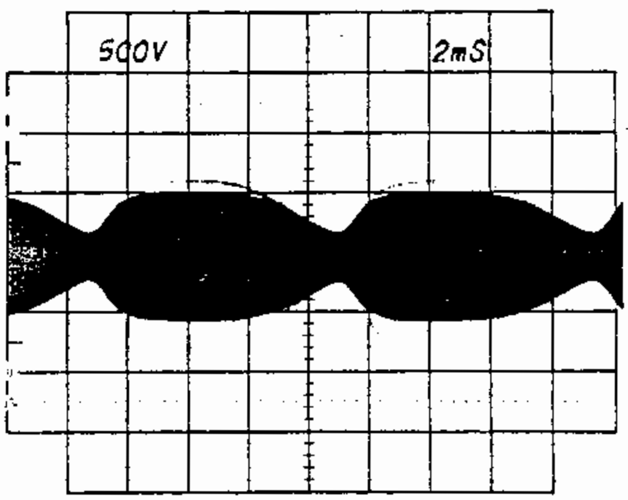
The crest factor of the COAG waveform is 6.7. Crest factor is defined as the peak voltage divided by the effective average voltage (RMS voltage). Peak voltage is defined as the maximum voltage in either the positive or negative direction from zero, whichever is greater. The effective average voltage or root mean square voltage is the average of an alternating voltage which, over a period of time, goes both positive and negative. The reader is already familiar with RMS values since house-hold power is 120 volts RMS, while the peak voltage is actually 170 volts. The relatively high crest factor of the SSE2L is to a large degree responsible for the excellent fulguration capabilities of the COAG waveform with a minimum of cutting effect. Crest factors for the bipolar output are not important because this output is not designed for sparking to tissue.

<u>The Blend Waveform</u>

The BLEND waveform is literally a combination of the CUT and COAG waveforms. More important than the shape of the BLEND waveform is the crest factor which is 2.9 and is approximately intermediate between the CUT and COAG waveforms. The BLEND is designed to cut well with a large amount of hemostasis. That is, the margins of an incision made with BLEND are well fulgurated and bleeding from the incision should not be a problem unless very large bleeders are encountered.



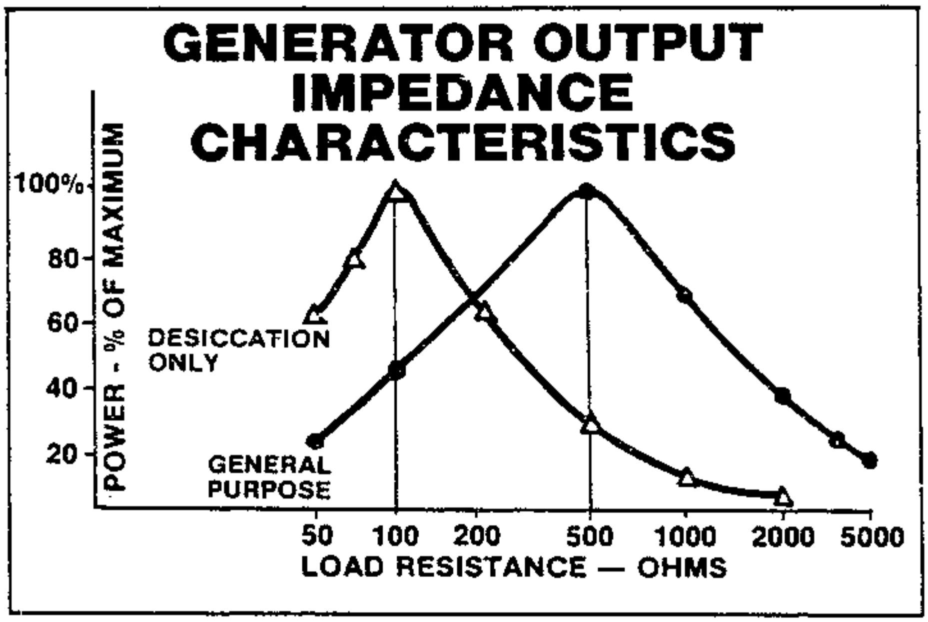
Blend Output (setting of 5)
500Ω 10μS



Blend Output (setting of 10)
500Ω 2mS

Output Impedance Characteristics

Power and crest factors are specified for particular load impedances. For the monopolar outputs, measurements to confirm these specifications would be made with a 500 ohm load. To confirm the bipolar specifications, the measurements would be made with a 100 ohm load. The amount of power that the generator can transfer into a load resistance will decide the electrosurgical performance of that output. The monopolar output is designed primarily for cutting and fulgurating. Since these modes involve sparking through steam or air to reach the tissue, high voltages are required. In contrast, the bipolar output is designed to desiccate with no appreciable cutting or fulguration. As a result, the potential energy available to break down air or steam must be severely limited. This is accomplished by moving the optimum transfer of energy from 500 ohms down to 100 ohms. Plots of power versus load impedances for the monopolar outputs and bipolar output is shown below.



Output Power Control

The CUT (BLEND) and COAG controls increase the power essentially linearly as the control is rotated from 1 to 10. The output is designed to produce signigicant power at about "1". See Section 1, page 18.

Output Interaction

The SSE2L has three separate outputs which are designed to be electrically independent. In other words, if the footswitch is activated and the "Monopolar" footswitch button has been pushed, then the monopolar hand-switched output and bipolar output should be essentially dead. Even though each of these outputs is driven by separate transformers, there is some coupling from one output to another. The maximum power available from an unactivated output under the worst conditions is 20 watts from a monopolar output and 3 watts from the bipolar output.

Low Frequency (60Hz) Output Isolation

The Line Frequency Source Leakage Current $\leq$ 0.2 microamperes, RMS.

This means that the maximum current at power line frequency (60 Hz) that can be obtained from the patient applied leads from the SSE2L is less than or equal to 0.2 microamperes RMS. When a load (presumably the patient) is connected between either one of the leads and ground with the generator operating normally and installed properly, this is the maximum current that can flow through the patient to ground. This is an extremely tiny current and is far below the threshold for any known physiological human response.

The Line Frequency Sink Leakage Current $\leq$ 150 microamperes RMS.

The sink leakage is the maximum amount of 60 Hz current that the patient leads will accept, that is, conduct to ground when 120 volts 60 Hz power is applied between the leads and ground. Notice that this "leakage" is completely passive. That is, this leakage does not represent an electrical threat to the patient unless the patient already has bare wire with 120 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 SSE2L active and patient leads as a path to ground.

Line Ground Leakage Current With the Generator OFF $\leq$ 10 microamperes RMS.

This measurement represents the most 60 Hz current which can flow from the metal chassis to ground when the connection between the grounding wire in the power cord and ground is broken and the power switch is in the OFF position. This small amount of leakage results from capacitance inside the power cord between the green ground wire and the black ("hot") wire which carries the 120 volt RMS, 60 Hz voltage. The large diameter blue power cord is specially designed for low leakage and a conventional power cord would have much more leakage.

Line Ground Leakage Current With the Generator ON $\leq$ 30 microamperes RMS.

This measurement represents the most 60 Hz current that can flow from the metal chassis to ground when the ground wire in the power cord is broken. Note that this measurement only applies when operating the SSE2L with a conventional ground referenced power source with the Powerite circuit turned off. With the Powerite circuit ON, the SSE2L 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. With the power switch in the OFF position, there is still a small amount of 60 Hz leakage due to capacitive coupling to the ground wire, assuming of course that the ground wire has been disconnected for this measurement.

The Powerite^{TM} Circuit

This unique circuit is an exclusive Valleylab 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 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 between 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. This will occur whenever the grounding wire loses contact with ground, either inside the generator, inside the power cord or in the hospital wiring system.

The other fault Powerite will detect is the reversal of the black and white power cord wires. This condition could result if the hospital power receptacle were wired incorrectly or if a power plug were replaced incorrectly. This situation is detrimental because the chassis to ground leakages are higher than 30 microamperes if the ground wire should break and the wiring is incorrect.

When using an 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. Remove the silver button and turn the enclosed switch to OFF.

<u>Radio Frequency Output Isolation:</u> Patient-to-ground RF leakage current, with or without 3 meter long actives plugged into all three outputs, $\leq$ 150 ma. RMS.

The three SSE2L output circuits (2 monopolar and 1 bipolar) are 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 can be measured as the maximum current which will flow to ground through an RF ammeter from any of the active or patient terminals. It turns out that the patient leakage is always greater than the active leakage, so the larger patient leakage is specified. The three separate output transformers in the SSE2L mean that multiple actives plugged in simultaneously do not degrade the isolation.

The patient RF leakage measurement is made in the worst case situation which is as follows:

(1) No load on the generator.
(2) Ten foot long active accessories plugged into each of the three active outputs.
(3) The generator set to CUT 10.
(4) No load in series with the ammeter to product maximum current flow.

Input Power Requirements

90-135 Volts AC, 50 to 60 Hz.		*180 to 270 Volts AC, 50 to 60 Hz.*	
Idle:	*0.4 amperes*	*Idle:*	*0.2 amperes*
CUT:	*12 amperes*	*CUT:*	*6 amperes*
COAG:	*4 amperes*	*COAG:*	*2 amperes*

The SSE2L can be supplied in two standard voltage inputs, 120 volts AC and 220 volts AC nominally supply voltages. The conversion from one voltage to another is difficult in the field because the circuit breaker, power cord, and power plug, must be changed as well as intenal wiring changes. On special request the SSE2L can also be supplied specifically for 100 volt RMS and 280 volt RMS systems.

Line Regulation

The SSE2L is compensated for fluctuations in the power line voltage, between 100 and 130 volts RMS AC. In case of "brown-outs" or voltage surges, the output will remain constant enough so that the surgeon should not have to adjust his power settings.

The compensation is not perfect, but is specified as ± 20 watts for power settings between (1) and (6) in CUT. In COAG the variation is ± 12 watts for power settings between (1) and (7). At higher settings the regulation will vary from this, but the difference should not have a significant electrosurgical effect. The exact power regulation characteristic is shown in figure 6 in the Service Manual.

The techniques used for measuring all these electrical parameters are given in the Service Manual.

SECTION 8

A PRIMER ON BASIC ELECTRICITY FOR 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/second equals one watt. A "kilowatt hour" is actually a measure of energy since it means one kilowatt of power supplied for one hour.

$$1 \text{ kilowatt hour} = 1000 \times \frac{\text{joules}}{\text{seconds}} \times \text{hours} = \text{joules}$$

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 form 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. The Glen Canyon Dam is very tall, but the Colorado River is actually quite small, i.e., you can throw a rock across it. 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.

$$V = IR, \text{ so}$$
$$P = VI = (IR)I = I^2R$$
$$P = VI = V\left(\frac{V}{R}\right) = \frac{V^2}{R}$$

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 100 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)

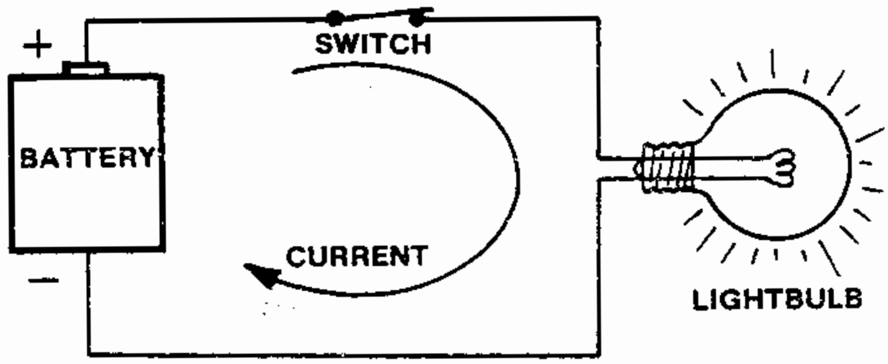
$G = mega = 10^{+9}$ (billion)

$T = tera = 10^{+12}$ (million-million, or one thousand billions)

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.

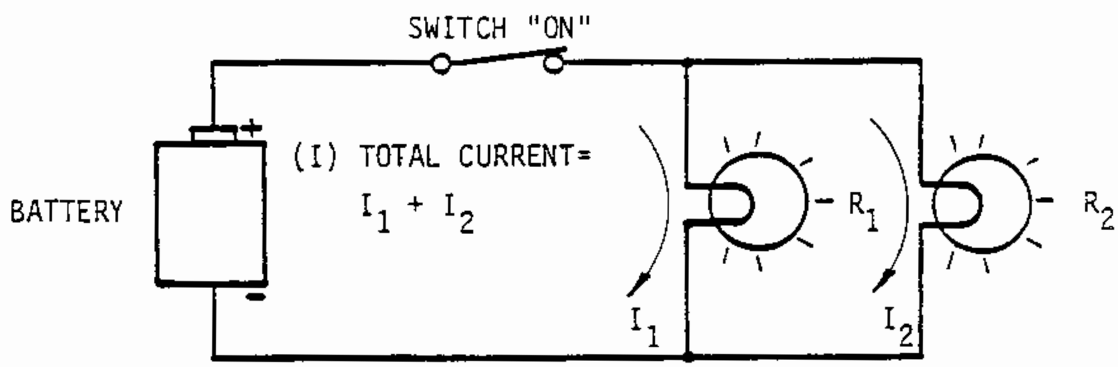
A SIMPLE CIRCUIT



Electrical current always flows in complete loops.

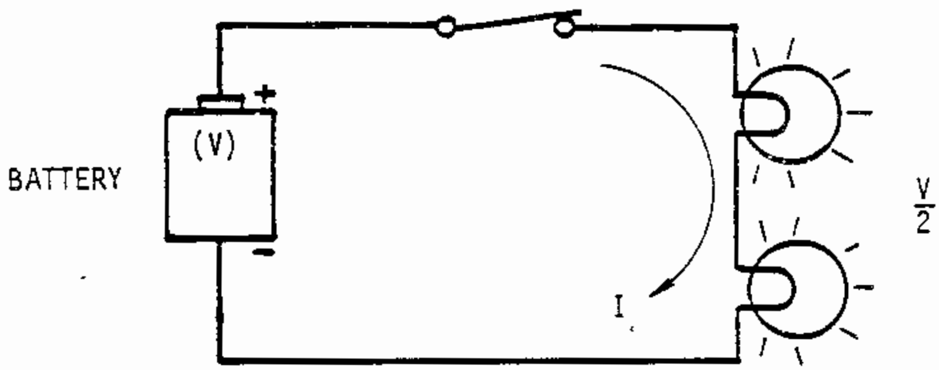
Before anyone knew any better, current flow was defined as "positive" if it flowed from plus to minus. Actually, electrons flow from minus to plus. It doesn't matter when making calculations, so current flow has never been redefined.

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.

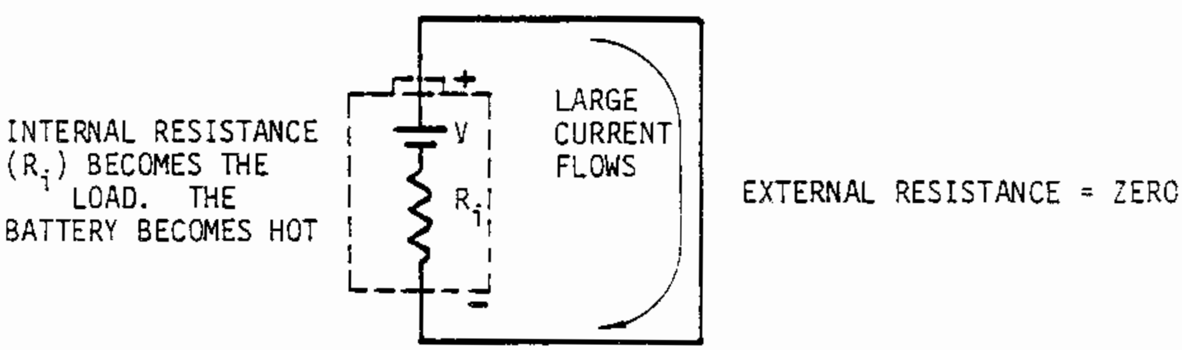


TWO LIGHT BULBS (LOADS) WIRED IN PARALLEL

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.



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



A "SHORT" CIRCUIT

According to Ohm's Law,

voltage = current x resistance,

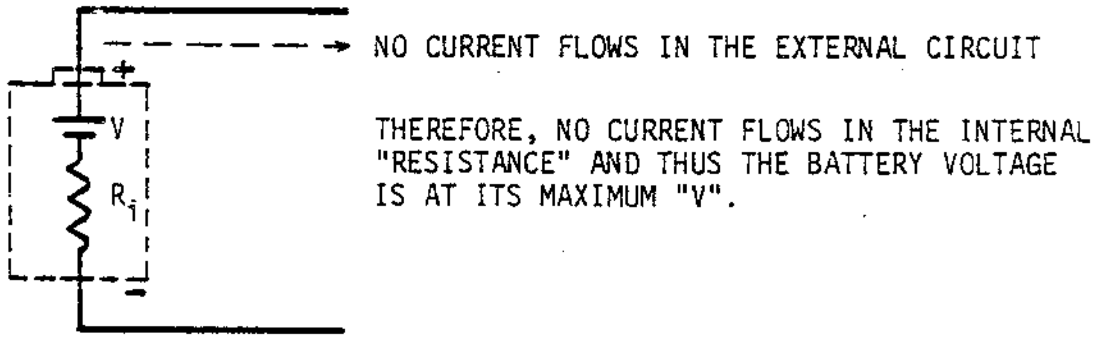
but the resistance is zero so,

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. That's like saying how much "something" do you need before "something" times nothing will equal something?

In real batteries, or any other real electrical power supply, the amount of current it can suply is limited. It is just as though there was a resistance inside 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 reisstance inside the battery. Therefore, there is no voltage drop across the imaginary resistance and, therefore, the voltage one might measure across the battery is higher 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

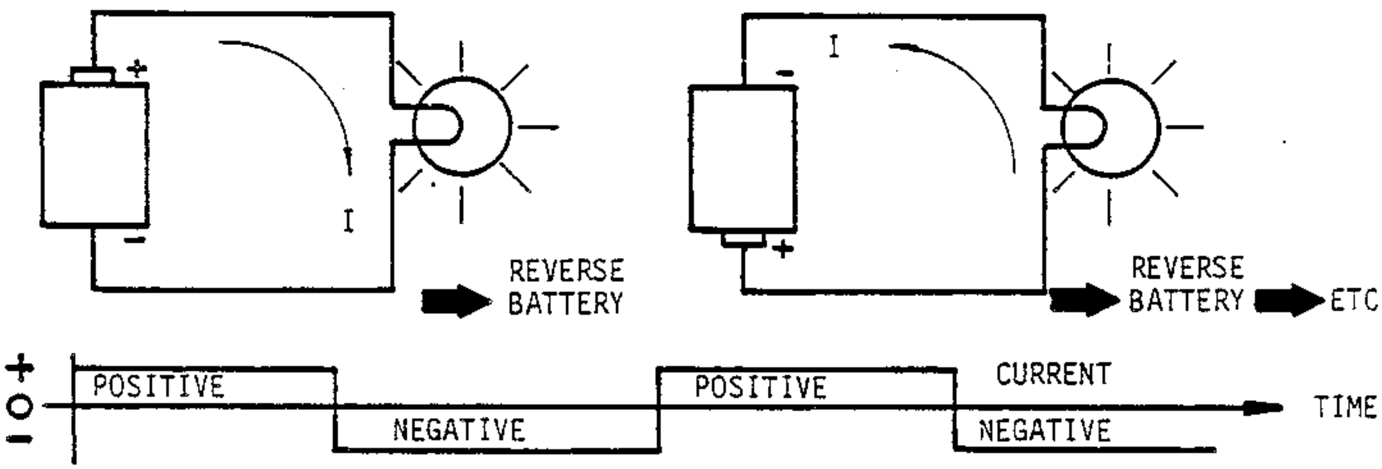
Ground is simply the earth itself. If you drove a long metal pole into the ground, you would find that there is very little resistance (about 100 ohms) between your pole and anyone else's pole, anywhere on earth.

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 and of course water pipes make excellent grounds. In a TV set, the metal chassis is "ground" and 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 betwen the two objects. 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 a person begin shocked.

ALTERNATING CURRENT (AC)

In contract 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.



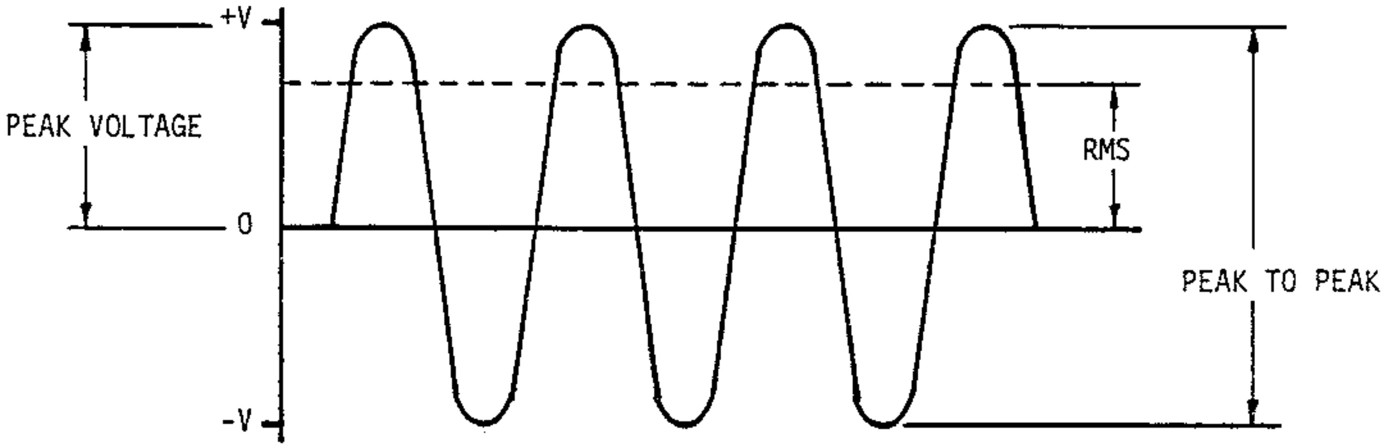
AC Frequency

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" current (RF for short) in the range of 250,000Hz to 3,000,000Hz (250KHz to 3MHz).

AC Circuits

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



An alternating voltage (sine wave) waveform

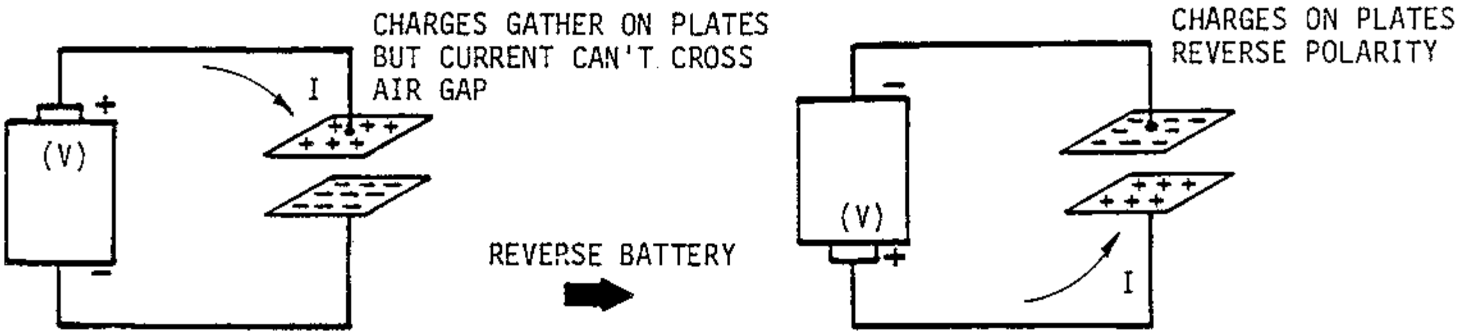
Three different types of voltages (or current) are used to describe AC electricity. "Peak-voltage" is the highest voltage away from zero, either positive or negative. "Peak-to-peak voltage" is the voltage from the lowest negative voltage to the highest positive peak. "RMS voltage" is a sort of "effective average" voltage. Voltmeters and ammeters almost always read RMS calculations and power (P=VI) calculations. The voltage that comes out of the wall is about 120 volts RMS. It could also be expresses as 170 volts peak or 340 voltas peak-to-peak.

Peak voltage is useful for getting 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 about one-half inch to tissue.

Capacitors and Inductors

Two phenomena which are seen in AC circuits but not seen in DC circuits are inductance and capacitance.

A capacitor consists of any two conducting materials and 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.

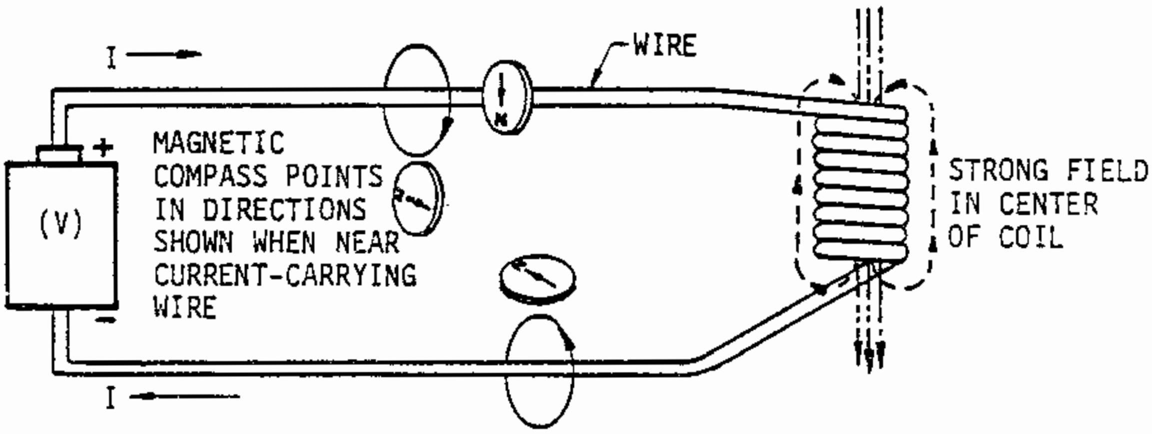
No current can flow because the air is a good insulator, and we'll assume that the voltage is too low to jump across the gap. Although no current flows, there is an attraction between the charges which gather on the plates. The positive side loses electrons and the negative plate gains electrons. The 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 or Hz). This will produce nine thousand times more of these surges per second and will cause significant alternating current. At present ther 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. This is the same kind of magnet that picks up pieces of iron, and, indeed, a tiny 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.



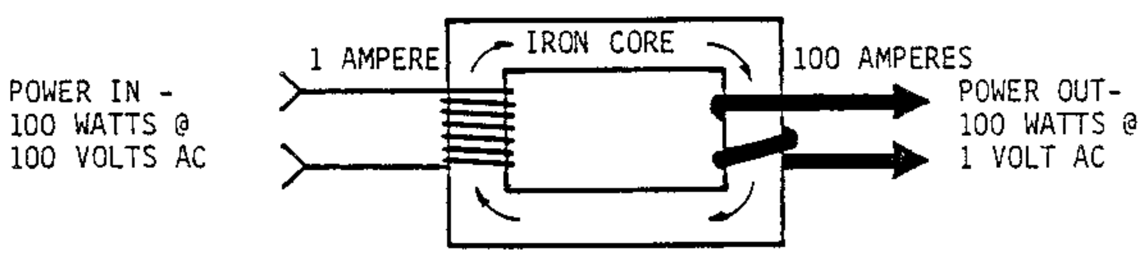
A magnetic field occurs around any wire with current passing through it. energy is stored in the field. A coil (a type of inductor) intensifies the field by taking the field from a long length of wire and gathering it together into one place.

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 just hang around waiting for the current to return. 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, and, 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 every 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, provided the winding ratios are correct.



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

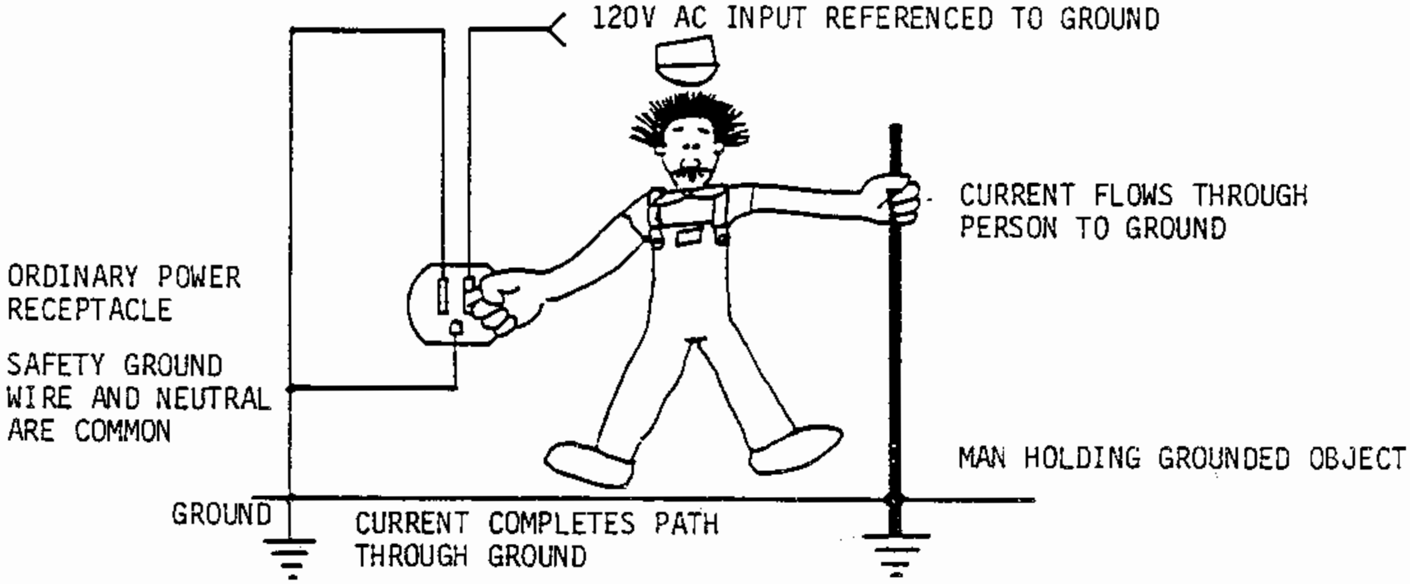
An electrosurgical generator usually has several transformers in its circuitry. generally, a large power transformer converst the 120 volt AC power to more convenient voltages for use by various internal circuits. The output transformer transforms the relatively high current, low AC voltage to the high 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. This means that it has no ground reference. Or, stating it another way, 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.

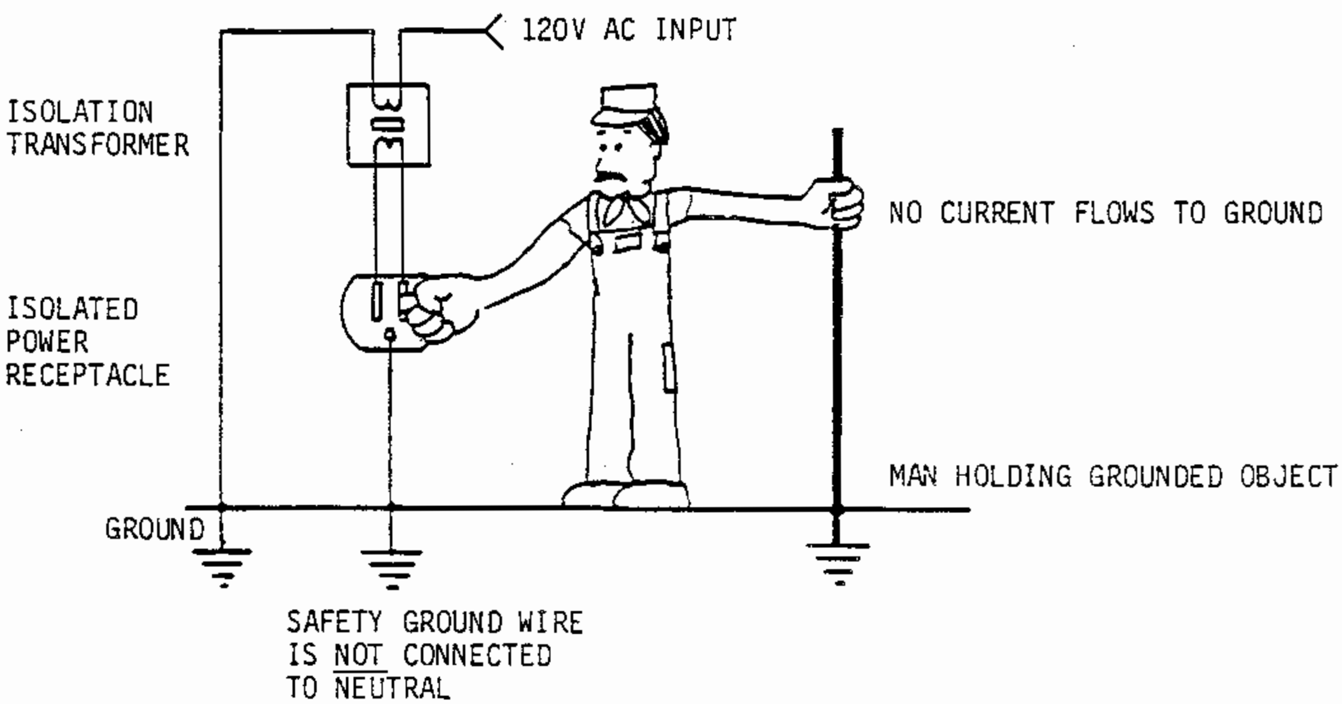
Isolated Power Systems in Operating Rooms

Another example of an 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 drill 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 posible 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 fo 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 do not have handles but instead are controlled by a small signal current. The idea is that a very small current can control a very large current. Or 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 all the in-between 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". That is, they don't contain vacuum tubes or filaments. Not only are they smaller, 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 semicondutor 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 throughly at the factory. After a few weeks fo use, the transistors usually will have seen all the kinds of electrical loads and abuse they will ever see, and, 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." In short, spark-gaps are a sort of voltage-controlled switch which can be used to run a primitive sort of radio frequency generator. Marconi's first radio transmitters used spark-gaps.

The advantage of spark-gaps for electrosurgery is that, unlike tubes and transistors, they can tolerate gigantic voltages and currents and, thus, are good for generating high peak voltage COAG waveforms. The disadvantage is that they wear out and, like spark plugs, must be replaced periodically. Typically, a large spark gap generator costs about $200 per year to keep supplied with fresh spark-gaps.

SECTION 9

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 OUPUT - A Valleylab word describing the electrosurgical output system which is used in the SSE3 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 D.C. 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.

CAUTERODYNE - A type of electrosurgical knife for bloodless surgery; a small pencil-like tube with a wire coil in place of a blade which seals minor blood vessels and is used for cancer and goiter operations.

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 electrons.

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 electrosurgical 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 wavefrm.

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 carbon dioxide 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 fine electrosurgical electrode. Electrocut. Electrocision. Electrotomy.

YCLES PER SECOND - Althernation per second of an AC current. One cycle per second equals one Hertz.

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

ENTO-ELECTRIC CAUTERY - A form of electrocautery for dental use.

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. Shortwave 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 fo 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.

ELECTROPARACENTESIS - Puncture of the eyeball with a needle, using direct current and holding the needle in position until bubbles of hydrogen appear in the aqueous humor.

ELECTROPLEXY - Electric shock.

ELECTROPUNCTURE - The introduction of direct current into tissue by means of needles placed in the patient.

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.

ELECTROTHERM - An electric appliance for heating the skin and thus relieving pain.

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 has 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.

INDUOCOAGULATION - Inductive coagulation. Induction heating arises from eddy currents and hysteresis (molecular friction) loss in an electric conductor. Metal can be heated by bringing it into an electromagnetic field produced in a coil by a high-frequency generator without direct contact between the generator and the metal. Eddy currents in the metal produce heat, which can be used to destroy surrounding tissue.

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 comporomising the safety of the isolated output. In the case of the SSE3 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. An electric 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. gnenerally, 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 resitance 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.

OHMS 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 in intended. It is uaually 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 repairable.

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 for 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 FAULT CIRCUIT - A patient circuit safety monitor unique to the Valleylab SSE3 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 work "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 out)f the chassis, patient return electrode, or active electrode when touched to a rounded object. In contrast to sink leakage, source leakage is active, that it, it)rovides a current which could flow through the patient or person touching the enerator or accessories.*

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

PARK-GAP - *A pair of electrodes mounted in a circuit and positioned so voltage 'ill cause sparks to jump across the air gap when the voltage rises to a high enough :vel. These are used in primitive electrosurgical generators as a type of voltage-ontrolled switch for the generation of COAG waveforms. In function, they are ıalogous to the breaker points in an automobile ignition.*

ARK-GAP WAVEFORM - *An electrosurgical COAG output generated by a spark-ıp electrosurgical generator.*

'ERILIZATION - *Destruction of microorganisms by (1) autoclaving—steam under essure (regular cycle is at temperature of 250°F (121°C) for 15 minutes, and ısh cycle is at 275°F (135°C) for 3 minutes); (2) ETO-Ethylene oxide gas (method which Valleylab disposables ar esterilized) over an 8-hour cycle.*

'RGICAL 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 elecatric 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

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