

Principles of Electrosurgery

A practical overview of RF electrosurgical generators, including safety issues, operating modes, and current modes as well as other characteristics. Covers what can be expected when power is delivered to electrodes and applied to tissue under various conditions, plus modern ESU standards and more...

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Disclaimer:

This pamphlet is only a general discussion of electrosurgical generators. Every effort has been made to ensure the accuracy of the information contained herein. However, Tektran assumes no responsibility for errors or omissions.

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INTRODUCTION

This booklet was prepared as a service to the medical profession. Its primary purpose is to provide a quick reference guide for the physician and support personnel regarding the electrical aspects of electrosurgery. Although *RF Electrosurgery* is reportedly used in over 70% of all medical procedures performed each year, it remains one of the least understood devices in the operating room. As surgery moves more and more from invasive procedures to minimally invasive procedures, knowing what to expect under various conditions is important.

Support personnel in pre-op services, the operating room, and those charged with the maintenance of ESU devices need to understand various electrical and other aspects related to their functions, so this booklet has been expanded to cover an entire spectrum of matters regarding electrosurgical generators. If those involved in sales and in-service training also find it helpful, then perhaps the booklet will serve a dual purpose and further improve understanding for all those involved.

Our appreciation to Mr. Steven W. Butts of S.B. Integrated Design for his numerous illustrations and contribution to this pamphlet.

1.1 What is Electrosurgery?

Electrosurgery employs *RF* (radio frequency) energy to both Cut and Coagulate tissue. In the *Cut Current Modes*, the tissue is literally vaporized as the electrode passes through the tissue and capillaries on either side of the incision wall are sealed as that tissue shrinks. Hence, the term "*Bloodless Surgery*". The amount of lateral *necrosis* on each wall depends upon the speed or the deliberate motion through the tissue and the type of current mode selected. In the *Coag Current Mode*, the tissue is coagulated by discharging RF either after the electrode is placed in the tissue to *desiccate* it or the electrode is held over the target site, leaving an air gap and allowing the current or RF Plasma energy to jump the gap to *fulgurate* the tissue. Post-operative healing is said to be greatly improved if the proper technique is employed.

1.2 ESU Power Classifications

ESUs (electrosurgery generators) are typically classified into *Low Power* (50-100watts), *Mid-Range Power* (100-200 watts), and *High Power* (300-400 watts) units. Units classified for *Microsurgery* typically range from 10-50 watts and may have very high operating frequencies and are highly regulated. As power and frequency increase, so does leakage. It is difficult to construct an *ESU* with 400 Watts output and still pass the qualifying standards for classification as *Isolated*. Therefore, generators at this power level are typically *Ground Reference* type. Some pre-compliance generators may employ frequencies higher than 1.0MHz, but in the standard power classifications it is not recommended. A *Mid-Range* unit will typically have adequate power for most procedures. However, for Heart Bypass and T.U.R.P. procedures a *High Power* unit may be required. Not all *Mid-Range Power* units have dual monopolar output ports. Most *High Power* units do. Typically, these dual ports work as *Discrete* output ports, meaning that they are activated with logic control on a "first come - first serve" basis. If dual ports are required, some hospitals prefer to work with two units, providing them with a backup and then using both units separately when performing other procedures.

1.3 Cautery vs. RF Electrosurgery

Electrocautery, unlike *Electrosurgery*, employs a hot thermal knife that is used to cauterize tissue. It can be used for cutting, but is generally more destructive to tissue and post-operative healing is typically longer. Hot cautery knives are still popular in low impedance fluid filled surgical sites, such as urological procedures; however, even in this practice, *Argon Coagulators* are rapidly replacing cautery knives.

1.4 Argon Coagulator

An *Argon Coagulator* is some times mistaken for a laser, but is instead a high-frequency, highly directional torch. As the inert gas *Argon* is pushed through a hollow tube under pressure, it passes through a high-voltage *RF Plasma* field and the molecular structure or free radicals are excited in such a way as to ignite the gas. The inside diameter of the tube is small and usually rifled to create a laser-like flame that extends for about 4 to 6 inches depending upon the pressure applied. The gas naturally blows the fluid away, clearing the field, allowing the beam shaped flame to cut or coagulate the tissue. Technique of use is as important as the selected settings. This is not a new concept. The use of *Argon* in this manner was first employed in the early 1950s, according to the U.S. Patent Office, and was re-introduced in the late 80s by several companies with more evolved designs.

1.5 Lasers vs. RF Electrosurgery

One area of misunderstanding in the medical field is that *Lasers* are somehow a replacement for *RF Electrosurgery*. When first introduced, *Lasers* were promoted for many applications. As papers were published regarding *Lasers*, they were later proven not ideal for many applications. Practitioners came to realize that a *Laser* is just a hot beam of concentrated light. It has its present day applications in removal of tumors and where tissue necrosis or desiccation is either desired or can be controlled by dichroic lens or other methods. *Lasers* are very destructive when used as a cutting tool compared to *RF Electrosurgery*. For cutting, excising, and even coagulating tissue, *RF Electrosurgery* is the preferred choice by many physicians. Wherever this type of concentrated light is applied to tissue, shrinkage is always a concern. This is especially critical in ophthalmic procedures. Once again, no magic - technique is as important as the science used to achieve the desired results.

2.1 Improved Standards

Many advancements have been made in *RF Electrosurgery* since the development of the earlier machines. Standards and components have also been refined to a point whereby safety issues are highly defined and now common place in the manufacturing of *ESUs (RF Electrosurgery Units)*. This subject is more extensively covered in *section 9* of this pamphlet. We think it is important for the physician to at least be made aware of these standards and recommend all hospital personnel involved in the operation and servicing of ESUs review this section.

HERE ARE IMPORTANT SAFETY CONSIDERATIONS WHEN EMPLOYING ELECTROSURGERY...

2.2 Cable Deterioration and Replacement

Prior to each use, check all Active and Return cables, probes, insulated shanks, sheaths, and electrodes for evidence of deterioration. Replace these items immediately upon evidence of deterioration.

2.3 Explosion Hazards and Flammable Anesthetics

Do not use electrosurgical devices in the presence of flammable anesthetics. This includes any oxygen rich environment or any confined area or pocket of oxygen or oxygenated gas. Even inert gases will ignite when mixed with enough oxygen. The heat from Laser beams or the high frequency from any ESU may disassociate the molecular structure and excite the free radicals causing ignition similar to an Argon Beam Coagulator.

2.4 Special Precautions During General Endoscopy Procedures

For any general endoscopy procedure, internal bodily gases should be flushed from the operating cavity prior to use of electrical currents. DO NOT operate electrosurgery in oxygen rich environments!

2.5 Preventing Patient Burns or Injury

You have heard the phrase "Dispersive Return Plate"...the key word here is dispersive, meaning plate contact with the patient should be dispersed over the entire surface area of the pad or plate. Partial contact or a high density contact could result in patient injury or burns. *Return Electrode Monitors* measure and track changes in contact density, alarm and shut down when dispersive contact is compromised. See *section 4*, titled *Patient Return Systems*.

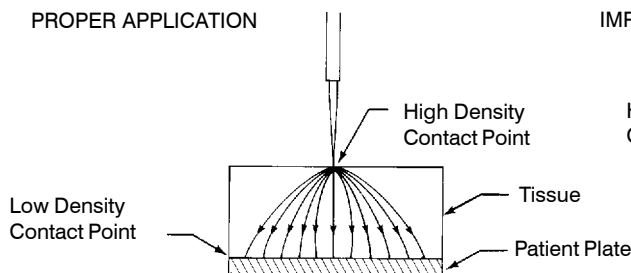


Figure 2.5-1

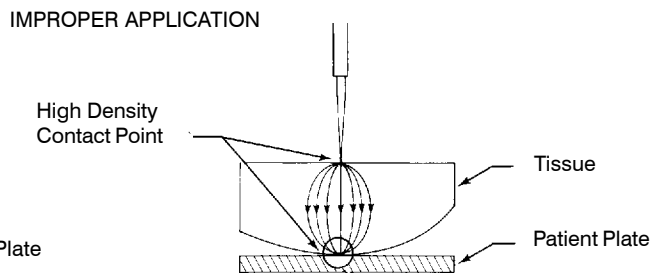


Figure 2.5-2

When is its use mandatory?

A *Return Electrode*, sometimes referred to as the *Inactive Electrode*, is required during any *Monopolar Operating Mode* procedure. For earlier ground reference generators, this is more critical as not to set up a situation where current may take an undesirable return path to ground. An earlier term used for the *Return Electrode* when employing a ground referenced generator was *Indifferent Plate*, meaning that when the plate was in contact with the patient, the current was indifferent to undesired alternative paths. For isolated units, it is important to maintain a low impedance return path back to the generator in order to achieve peak performance.

Patient Movement

Operators and operating staff should be made aware of the plate's location and keep an eye out for any movement in the patient that would cause the plate to either peel away or lift off from the skin and leave only a *High Density* contact that would otherwise result in a potential burn.

Proximity to Surgical Site

If possible, the dispersive patient return plate should be placed on the patient in an area nearest to the surgical site, but away from any other instrument cords or electrodes. For adults, recommended sites are typically the buttocks, anterior thigh, posterior thigh, abdomen, midback side, calf, and upper arm. For pediatric applications recommended sites are typically the anterior thigh, the back, or abdomen.

Reusable Patient Plate

This type of plate, often referred to as a *Butt Plate*, relies on gravity or the patient's weight to make proper full surface area contact. If these plates are uncoated, a conductive gel is recommended. Coated *Reusable Patient Plates* are also available. These work best with generators that have higher operating frequencies, 1.0 MHz and over.

Disposable Patient Plates

This type of plate is made of a microfoam backing and a layer of gel or conductive adhesive with either a single foil cell or a dual foil cell sandwiched in between. They are available corded or uncorded. Due to their thin light-weight construction, adhesion is critical to prevent burns. It is recommended that the site be prepped in accordance with the plate manufacturer's package instructions. This type of plate is a haven for bacteria and should be used once and discarded immediately, employing the hospital's protocol for waste management.

2.6 Preventing Burns Related To Active Electrodes

Usually burns are associated with improper application of return electrodes. However, *Active Electrodes* can cause burns to both patient and operating staff when exposed metal portions are not properly stored in insulating holsters or carriers during operating procedures. Also, great care should be exercised when employing electrodes activated by foot controllers. Standards now require that the generator feature a flashing light, warning the operating staff that the pedal is in the standby mode. The operator should make the staff aware of the location of the pedal or controller to prevent accidental activation.

Active Electrode Monitors

When performing a Laparoscopic procedure, typically very long shanked electrodes are employed. If the open-circuit voltages are high enough (when employing a ground referenced unit) the long insulated shank can create a low-impedance capacitive coupling to the other instruments, instead of the patient return electrode. The natural reaction to jump or move one's hand away during surgery can have worse results for the patient than the small burn to the surgeon's hand. The recent development of the *AEM** system or *Active Electrode Monitor* was introduced to monitor leakage and this capacitive coupling and shut down the current to the electrode when a fault condition occurs.

2.7 Defibrillator Discharge

ESU generators are classified based upon leakage from their *Active* and *Inactive* electrodes to earth ground as either BF or CF as a patient-connected device. BF types may not have more than 50ua leakage and CF types may not have more than 10ua leakage to indicate that CF type active electrode may touch the open heart with less odds based upon studies that it will cause fibrillation, according to the standards organizations promoting these symbols. Generators are tested by a certifying body for this qualifying classification after the unit is tested for defibrillator discharge based upon IEC 601-2-2 and either one of the following symbols must then be displayed near the patient return jack.

Indicates standard insulating design for general purpose use. Normally found on low to mid-range powered units.

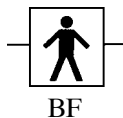


Figure 2.9-1

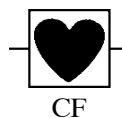


Figure 2.9-2

Indicates special insulating design for cardiac surgery. Normally found on high powered units used for heart bypass.

2.8 Color-Coded Output Jacks

Standard color codes for output ports are Yellow for CUT, Blue for COAG, Red for Active, and Black for Inactive.

2.9 When to Use the Bypass Jack?

Early style endoscopy instruments that were constructed of metal sheaths have nearly all been replaced in modern day surgery with non-conductive sheaths. However, when using an earlier model device with a metal sheath, the bypass jack must be used to prevent stray current paths. This jack is BLACK - same as Inactive.

3.1 Operating Modes

MONOPOLAR: As the illustration below displays, the RF current selected is emitted from the high-density electrode referred to as the *Active Electrode* and returns to a low density or dispersed surface area of the *Return Electrode*, also referred to as the *Inactive Electrode* which, in turn, flows back to the generator. The ideal load response curve for monopolar current modes is flat from low to high impedance reflected back to the generator.

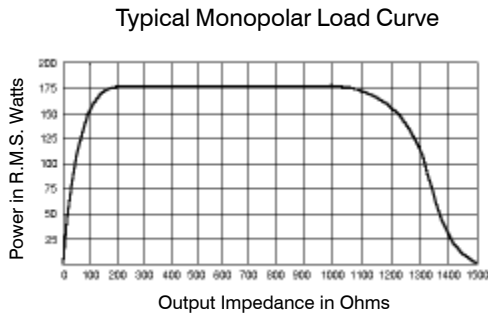
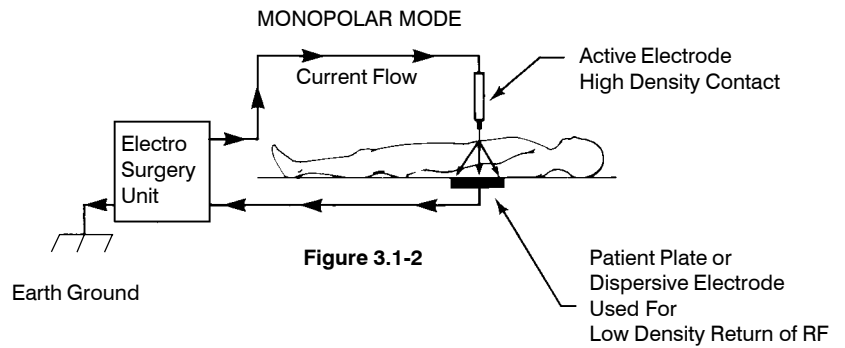


Figure 3.1-1



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

BIPOLAR: As the bipolar illustration below displays, in this operating mode, the dispersive return electrode is eliminated or switched out of the output circuit when the *Bipolar Mode* is selected. Instead, bipolar instruments typically include two poles - one is referred to as *Active* and the other is referred to as *Inactive*. The RF current is transmitted across the two poles through the tissue placed directly between the poles back to the generator. The load response curve for bipolar current mode is shaped to peak at 150 ohms and drops off quickly as reflected impedance increases.

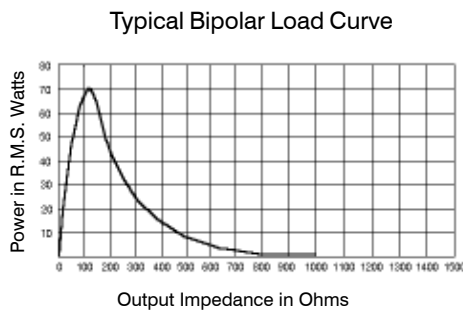
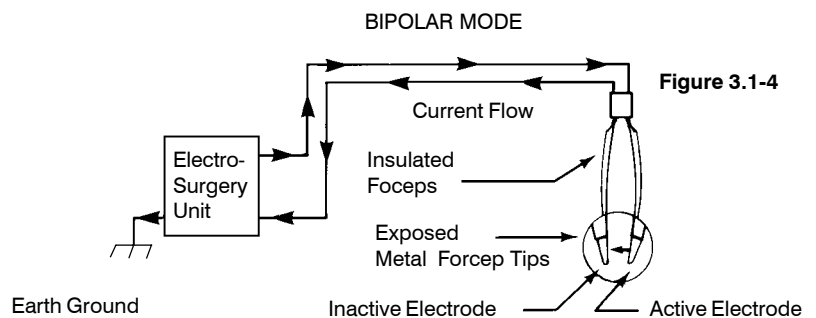


Figure 3.1-3



There are many different types of bipolar ESU instruments. Some instruments like forceps have equal size pole electrodes, some have unequal size poles, depending upon the respective purpose. See section 6.3 - page 16.

Distinctive Audible Tones: Generators usually feature LED indicators and distinctive audible tones when the generator is switched from one operating mode to the other. In the bipolar mode, the generator automatically switches the dispersive return plate out of the circuit, so it may be left on the patient when both operating modes are required during one procedure.

3.2 Electrosurgery Techniques

RF electrosurgery can be used to achieve a number of desired results. The following illustrations demonstrate various techniques associated with shaped electrodes and various current modes. As the paragraphs in each section indicate, technique has as much to do with application to the subject tissue or deliberate motion in or through subject tissue by the surgeon as it does with tissue conditions, tissue type, current mode, and shape of the electrode. *Hemostatis*, another technique not shown here, is covered in sections 5.4 and 6.2 in detail.

INCISING TISSUE

Recommended Current Mode: Pure CUT or BLEND 1

Typical Electrode: Blade Type

Effect on Tissue: Cleanest incision is with PURE CUT. Lateral necrosis on each side of incision is determined by current mode (Pure or Blend Setting) and deliberate speed or motion through tissue.

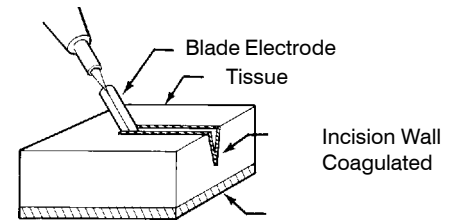


Figure 3.2-1

EXCISING TISSUE

Recommended Current Mode: Pure CUT or BLEND 1

Typical Electrode: Loop Type

Effect on Tissue: If excision is for biopsy, typically, Pure Cut or Blend 1 setting and a rapid deliberate motion through the tissue will produce a vital tissue sample for pathology. If excision is for removal of diseased tissue, then Blend 2 or 3 and a slower motion through the tissue will leave the remaining wall further coagulated. *See section 5.2*

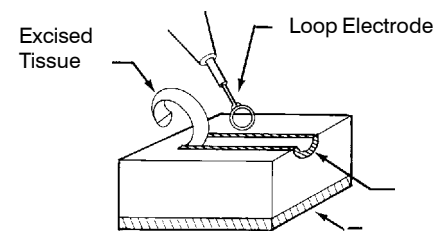


Figure 3.2-2

DESICCATION

Recommended Current Mode: BLEND 2 or BLEND 3

Typical Electrode: Blade, Blunt Needle, or Ball Type

Effect on Tissue: This is the most destructive technique, similar to desiccation by laser. Depth of lateral necrosis is determined by current mode, power level, length of penetration into tissue and stay in the wound. Bipolar desiccators are commonly used in polypectomy to desiccate the root of a polyps. Here the technique is the same, but with bipolar mode current.

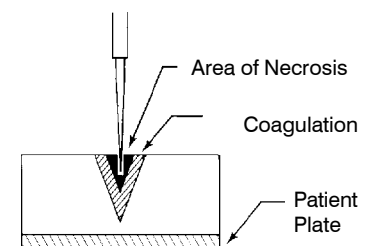


Figure 3.2-3

FULGURATION

Recommended Current Mode: COAG (Cone Spray Mode Displayed)

Typical Electrode: Blunt Needle (Pinpoint) or Ball Type (Cone Spray)

Effect on Tissue: Employed by surgeon for surface-layer hemostatis. Necrosis is determined by length of application and current mode "Crest Factor". Refer to section 3.3 covering Crest Factor and definition of "Hard" and "Soft" Coag Spray, as well as controlling target integrity of the RF plasma discharge.

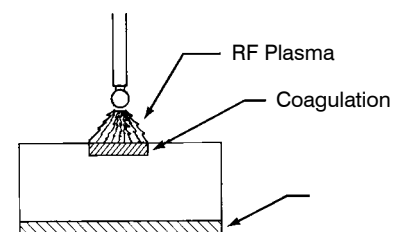


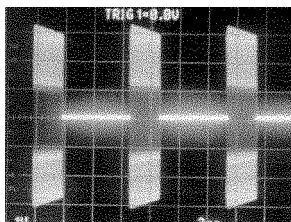
Figure 3.2-4

3.3 Crest Factor

Crest Factor is defined as a generator's ability to Coagulate without Cutting. The ideal is to slowly shrink the top layer of tissue whereby the capillaries seal off bleeding without causing any further penetration or tissue necrosis. In order to achieve this ideal, the Crest Factor measured as $CF = \text{peak volts} \div \text{rms volts}$, must be as high as possible - typically rated as a multiple of rms (i.e. $CF=7$ to 10). If CF is high enough, the power under load will ideally drop to zero before cutting. This is also proof of a *High Impedance* source.

Some manufacturers attempt to utilize the same output transformer they employ for the CUT circuit by simply switching primary winding from high to low to achieve a step-up voltage ratio. This is not ideal and at best can only simulate an inductively discharged damped waveform or *Ring Frequency* envelope. They typically modulate the carrier frequency to less than 20% duty cycle. This is similar to BLEND 3 setting in most hospital grade generators. The CUT power oscillator uses a high (μ) or permeability magnetic core in its output isolation transformer, meaning the transformer is intended to transfer maximum power at the operating frequency - ideal for cutting or creating a *Low Source Impedance* output, not *High Source Impedance* outputs. Another term used to describe this simulated COAG current is *Hard Spray*. COAG current with a high *Crest Factor* is referred to as *Soft Spray*.

Higher quality *ESUs* employ separate transformers; one to offer Low Impedance CUTTING current modes, including three BLEND modes; and the other, to offer high *Crest Factor*, true inductively discharged damped wave *Ring Frequency* envelopes. The latter uses a low (μ) magnetic core. This minimizes tissue damage during COAG modes. The difference between Low *Crest Factor* /*Hard Spray* and High *Crest Factor* /*Soft Spray* is best illustrated as follows:



Simulated Spark Gap
Hard Spray
Low Crest Factor Current

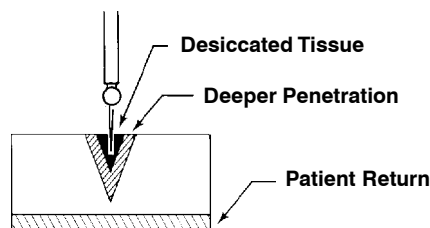
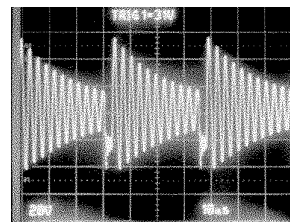


Figure 3.3-1



True Damped Wave
Soft Spray
High Crest Factor Current

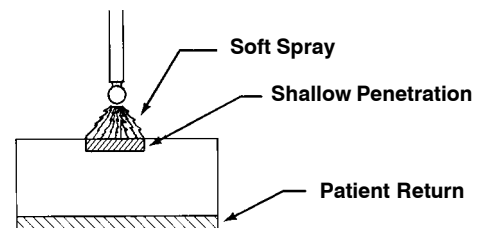


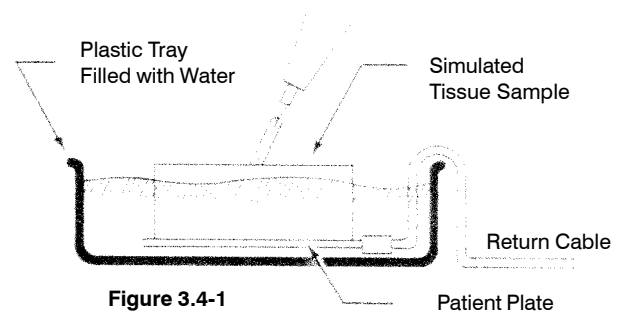
Figure 3.3-2

3.4 Conditions Affecting Impedance and Performance

When operating in either *Monopolar* or *Bipolar* modes with CUT or COAG current, the power demands will continuously change, depending upon the impedance reflected back to the generator from the load. These changes are created by a combination of factors such as wet or dry operating fields, surface density of the exposed electrode in contact with the body tissue, as well as the conductivity of various types of tissue. Fat, for example, is not a good conductor. The following page illustrates common conditions that affect reflected impedance.

Impedance and Current Demands Related to Fluids

The lowest impedance or highest current demand results when the ESU is cutting tissue in a wet or irrigated operating field. This can be simulated by filling a plastic tray with water, or worse yet, with saline solution. Regardless of regulation, the source impedance of the power oscillator and output circuit must be very low in order to continue CUTTING.



Irrigated Fields

Here is a practical application involving a fluid-filled surgical site requiring coagulation. A suction coagulator is used to first evacuate the fluid from the site and fulgurating current is applied to stop bleeding.

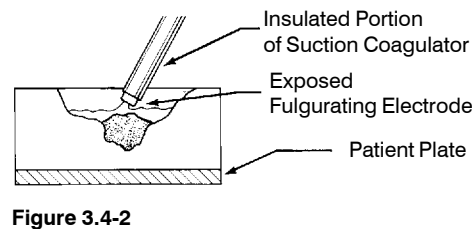


Figure 3.4-2

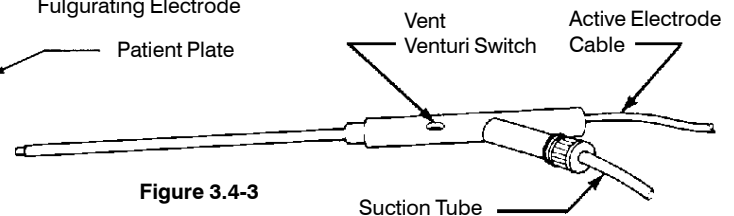


Figure 3.4-3

Impedance and Demands Related to Contact Density

The illustration here displays loop snares around the core of various size polyps. This could also be a large loop and small loop excising electrode. As contact density or more of the circumference of the loop comes in contact with the body tissue, the reflected impedance to the generator is lower and current demand increases.

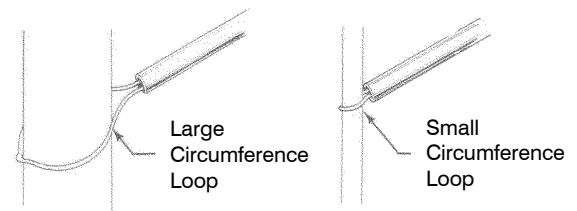


Figure 3.4-4

Low Impedance
Low Density Contact
Higher Current Demand

High Impedance
High Density Contact
Lower Current Demand

Eschar Build-up During Surgery

One factor commonly overlooked regarding performance is the carbon build-up on the exposed electrode. Until recently, most surgeons used small adhesive-backed abrasive pads to scrape it off, usually taped to the switch pen holster or surgical drape. The new PTFE coated electrodes greatly reduce *Eschar* build-up.

3.5 Impedance Matching

Those of us who have purchased a stereo set may remember how it was important to match amplifier outputs with speakers (i.e. 4 ohm or 16 ohm). When this was done, often the amplifier came with a performance chart over the audible hearing range and rated in +/- dB. A drop of 3dB is half power. Another example of impedance matching is a radio antenna. Typically, a *Smith Chart* is used by *RF* engineers to match the transmitter with the output load or antenna. When impedances are matched, power transfer to the load is maximum. An *RF Electrosurgical* generator is similar, in that power is maximum when the output or source impedance is matched to the load impedance, which in the case of electrosurgery, is made up of complex impedances across the active and inactive electrodes. These factors affecting impedance are represented mathematically in the following section.

3.6 Complex Components of Impedance

Regardless of the generator's regulating capability, which for the most part is its ability to adjust the DC supply voltage to power oscillator by means of feedback control, if the generator's output impedance is not matched to the lowest and highest possible impedance that may appear across the *Active* and *Inactive* electrode and reflected back to the generator, the current delivered may not be ideal, for example, flashing and unwanted shrinkage may occur when entering and leaving the tissue during an incision.

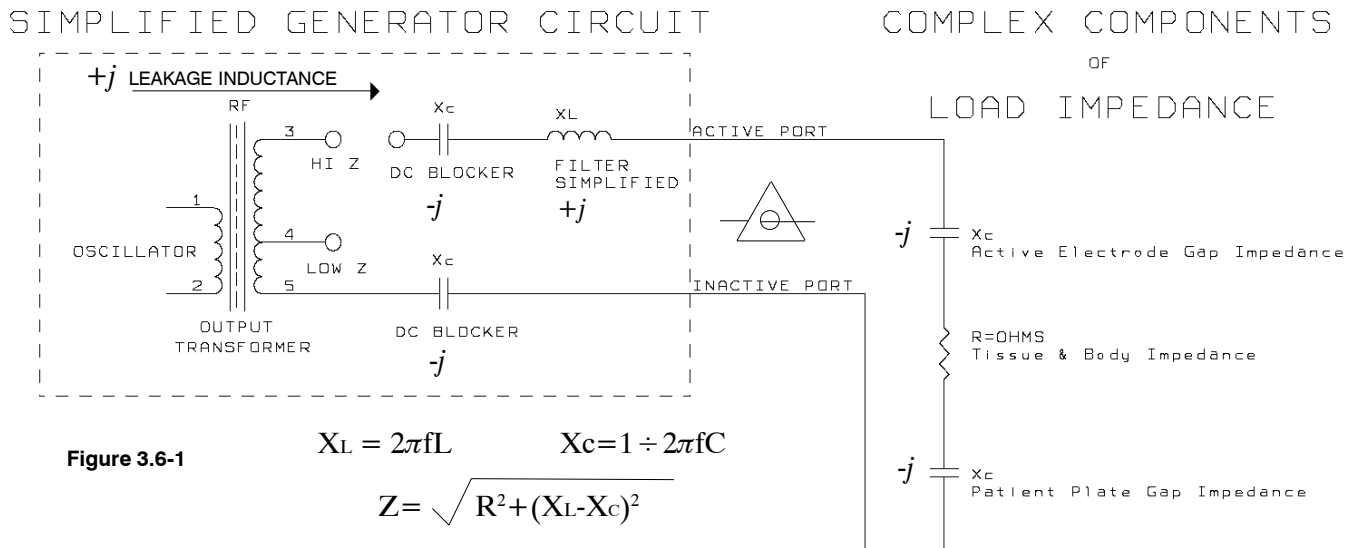


Figure 3.6-1

Resonance & Maximum Power Transfer

In electrosurgery, *Resonance* takes place when at the generator's actual output frequency, $X_L = X_c$. When these inductive and capacitive values are placed in series as shown above, as represented by the formula for (Z), resonance takes place. At that time, power transfer or power delivered to the load is maximum. To analyze this condition and the complex conjugates of *Source* and *Load* impedance, basic trigonometry or $+j$ (X_L) and $-j$ (X_c) operators are used to simplify the mathematical representation, also referred to as $+/-$ *imaginary number* units. They can be used to plot the vector or dynamic change on a *Smith Chart* in *Impedance* and *Admittance*. For example, $-j 300$ is X_c of 300 ohms. When the $(+j)$ and $(-j)$ conjugates cancel each other out (at series resonance), maximum power transfer is delivered to the load (R). The fulcrum symbol above is the electrical symbol for *Phase Shift*.

Complex Components of Load Impedance

For the most part the typical load across the output of an electrosurgical generator during operation is a combination of the capacitive reactance (X_c) and the pure resistance (R) of the body as shown. Together, when these complex components of the load impedance are computed, they are referred to as (Z) or "dynamic" AC impedance.

Complex Components of Source Impedance

It is equally important to match *Source Impedances* to *Load Impedance*. In the *Monopolar* operating mode, where typically a flat load response curve is desirable, constant power is accomplished by either lowering Q (*the peak response*), increasing power and widening the bandwidth capability of the output by means of an *Output Filter* circuit, or by means of a feedback circuit which tracks rms power over a wide range of reflected *Load Impedances* and adjusts amplitude to keep power delivered constant, often referred to as a *Square Law Detector*. In the circuit above, the *Source Impedance* is made up of the turns ratio of the output transformer, core permeability, magnetic design (*transformer series leakage inductance*), the reactance of the two DC or low-frequency blocking capacitors as well as the *Output Filter* or any other reactive elements in the path. Even connectors with poor or carbonized and galvanic contacts (*called hot spots*) or coaxial cable measured in picofarads play a part. Their effect is compared by a ratio of the *Standing Wave*. In the *Bipolar* operating mode, the load response curve is designed to peak and drop off rapidly. This is typically accomplished with a high Q filter.

4.1 Dispersive Plates and Adaptors

Dispersive return plates are available in a number of shapes, sizes, types, and configurations. There are disposable as well as reusable type plates that come in single or dual cell configurations for cable fault or *REM* systems.

Size

Disposable adhesive type dispersive plates are usually made in at least two sizes - adult and pedio sizes. These plates are normally hypoallergenic for low irritation potential which is important in pedio applications. Pedio dispersive plates are not provided in dual-cell *REM** configurations. The reason for this is that each cell would be too small to properly disperse the energy if higher power levels were used.

Corded and Uncorded

Reusable and Disposable dispersive plates are available in either *Corded* or *Uncorded* versions. *Uncorded* plates are made with either an exposed tongue for clamp mechanism similar to the illustration below or some reusable dispersive plates feature a snap that mates to an insulated snap receptacle, similar to an *EKG Tens* snap. *Corded* plates have a cable attached to a wrapped and insulated termination point on the plate. All dispersive plates should have two leads for either *Cable Fault* interruption or for *Return Electrode Monitor*. See *Different Types of Fault Circuits* in section 4.2.

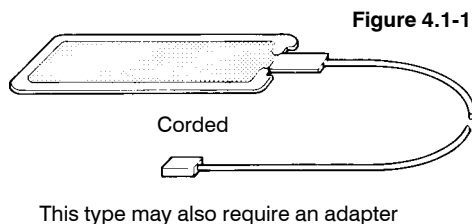


Figure 4.1-1

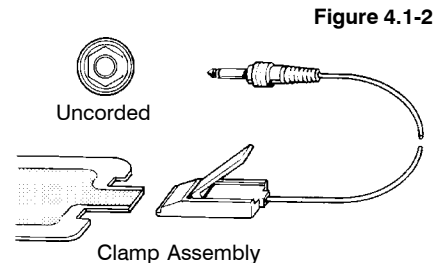


Figure 4.1-2

Patient Return Adaptors Available

A plug referred to as an IEC type is illustrated above with the *Patient Return Cable and Clamp Assembly*. This is usually supplied with each generator sold. In the world market, there are a number of different type adaptors, used by various manufacturers of generators. In addition to the IEC type which is the most common, other popular types are commonly referred to as: Valley*, Simens*, NDM*. These are also all brand names of their respective companies. The 3M* Company makes a complete line of disposable type dispersive plates and has printed an excellent color chart of connector vs. various brand generators in a publication they refer to as publication number #70-2008-6038-8.

Quality of Construction

There are a number of brands of both disposable and reusable dispersive plates. From an electrical and safety consideration, there is a difference. Here are some quality issues related to safety:

Disposable Type Plate: One gleaming difference between brands is how the foil is laid down on the microfoam substrate. A high-quality constructed plate will have the metal foil edges turned down in the substrate with sharp and clean die-cut edges. A lower quality plate often has raggedly cut edges where bits of foil appear turned up, very close to the top layer of adhesive. These unfinished edges can eventually break through and create a high density path for RF which can potentially cause burns. A quality plate is constructed as follows:

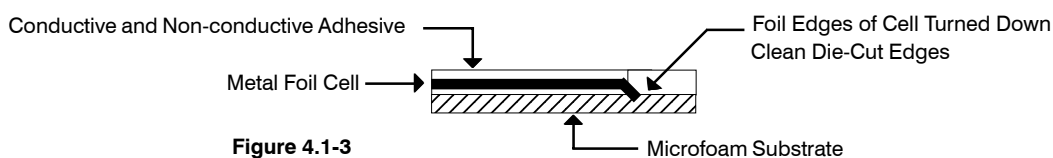


Figure 4.1-3

Reusable Type Plate: Higher quality reusable return plates usually have an insulated backing and either have the metal portion of the plate cut back so there is a perimeter of insulation or are constructed with a molded beading around the plate's perimeter. Some lower quality plates have a loose or exposed termination that potentially cause patient burns. Others offer a fully insulated reusable type dispersive plate with a tongue type portion that accepts the insulated clamp assembly above. Figures below illustrate proper construction.

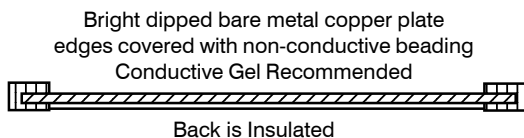


Figure 4.1-4

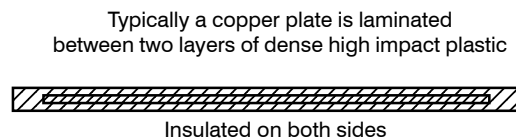


Figure 4.1-5

Single-Cell and Dual-Cell Dispersive Plates

There are basically two type of uniquely wired dispersive plates - *Single Cell* (figure 4.1-6) and *Dual Cell* (figure 4.1-7). Each type is employed with a different type of fault system as covered in section 4.2 below. The reusable type *R.E.M.* plate can be manufactured in various shapes to accommodate different generators.

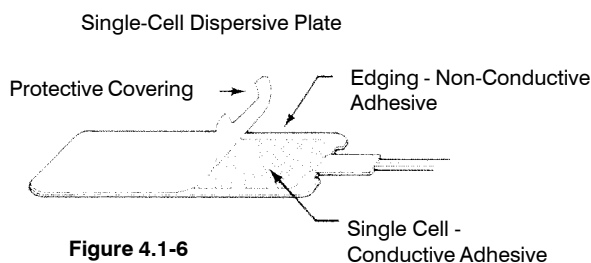


Figure 4.1-6

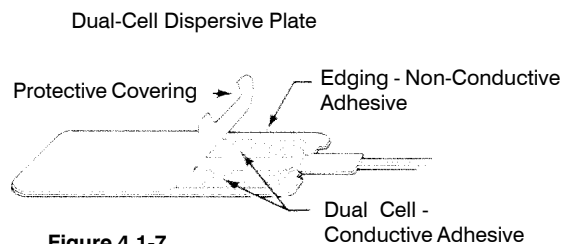


Figure 4.1-7

4.2 DIFFERENT TYPES OF FAULT CIRCUITS

There are basically two types of fault-warning systems employed in most electrosurgical generators - *Cable Fault* and *REM* (Return Electrode Monitoring). Each type, if in compliance with IEC 601 standards, offers at least three features - *Detection*, *Alarm* (Audible and Visual), and *Shut Down*.

Standard Cable Fault Warning System

As covered in proceeding sections, a reusable or disposable *Single-Cell* patient return electrode is employed with a standard *Cable-Fault* system. A *Dual Cell* type electrode will not work with a standard *Cable-Fault* system, due to the open circuit between the two separate metal foil cells. Conditions that would trip a *Cable-Fault* system are displayed below in figure 4.2-1.

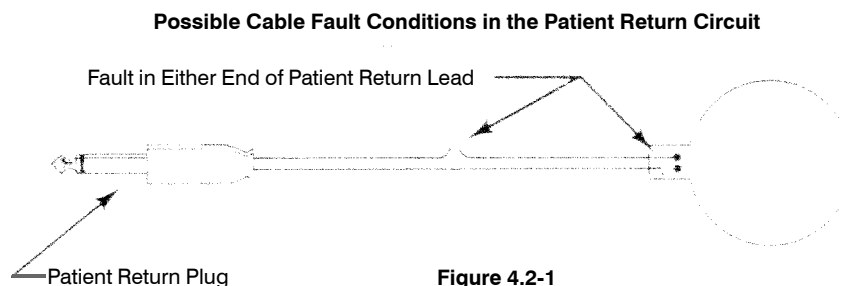
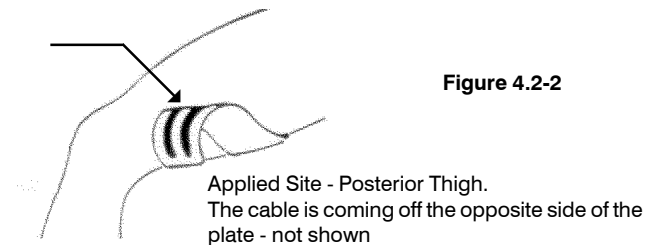


Figure 4.2-1

REM - Return Electrode Monitoring System

In addition to monitoring a break in the cable, this type of patient return system monitors the dispersive contact or *Contact Density* of the patient's body with the return electrode. This system further assures that the RF energy returning to the generator is properly dispersed over the return electrode to prevent burns or *High Density Contacts*. In order to accomplish this task, the monitoring circuit must take a measurement of the body impedance or capacitance reactance and switch to fault condition when this impedance senses an unacceptable impedance level, indicating the plate has either peeled away from contact with the patient skin or only a small portion of the plate is left in contact as illustrated in figure 4.2-2 below.

The metal foil strips or cells allow the generator to monitor the reflected capacitive reactance or impedance across the length of the two cells while in contact with the skin. If the system is functioning properly, fault should occur when the plate peels away, leaving only a small portion in contact. The monitor circuit is disabled when RF is activated to prevent false tripping action.

**4.3 Disposable vs. Reusable Return Electrodes**

Most hospitals in the U.S. market employ disposable type dispersive electrodes. However, a good number still use some form of reusable dispersive plate, mainly as a cost-savings measure. At first glance, it may appear that there is a cost savings; however, these healthcare facilities may find a need to look closer or recompute if a patient is seriously burned and they are required to pay out a large claim settlement. A *Return Electrode Monitor* or what is commonly referred to as a *REM** return system can further reduce the chance of patient burns as explained in the section above.

Are Burns Your Only Concern?

Of course, the argument made above is the one made by those promoting *REM** or similar contact monitoring systems as well as those promoting the disposable dual-cell dispersive plates. They are looking for the repeat business. A fact not well publicized is the problem with lesions from friction necrosis or improper removal after extended procedures. These can be much worse than a few light burns. In 1987, ECRI, an independent research and testing organization, interviewed hospitals only to find that many of the lesions first reported as burns were in fact in many cases caused from friction necrosis or improper removal of adhesive type return plates. Of course, they added the disclaimer that some sizable claims had also been reported for burns. A *REM** return system will not help you prevent this type of patient injury. In-service training may.

Reusable Return Plates

With non-adhesive type reusable return plates, friction necrosis and lesions caused from improper removal are all but eliminated. However, most reusable plates unless specially coated, require application of a conductive gel. Coated plates work best with high-frequency generators, 1.0 MHz and above. There are also coated reusable dual cell plates that work with some *Return Electrode Monitors* that may be the better of both worlds.

Our Disclaimer

After stating all the above, by no means are we recommending you stop using *REM* return systems or the disposable adhesive return plate. Hospitals are not in the business of taking risks when they can be avoided. Most hospitals will use every means at their disposal to eliminate risks, both from potential patient burns as well as lesions caused from friction necrosis or improper removal, as they should.

Need For Proper Training

Again, it comes down to proper training of the operating room staff: Those selecting or prepping the site and applying the plates, those in charge of monitoring continued dispersive contact, and those in charge of its removal as well as disposal.

4.4 GROUND REFERENCED VS. ISOLATED OUTPUTS

An electrosurgical generator with an isolated output floats the output by means of an isolation transformer. This isolates the output from earth ground. All TEKTRAN manufactured generators have isolated outputs.

The advantage over a ground-referenced generator is that the physician or a member of the operating staff can come in contact with an exposed portion of either output electrode and not be burned. This feature can be a real plus when you consider the problems associated with material coatings or insulation covering on the electrode devices and the deterioration they undergo after sterilization or handling between uses.

In order for a generator to be classified as *Isolated*, it must not permit more than 150Ma or 4.5 Watts to earth ground in accordance with IEC 601-2-2 standards. The standard requires the test be performed under ideal conditions, meaning on an isolated table, one meter from ground, with the cables separated on the table in a circular pattern. This is why most manufacturers attempt to design for well below the allowed leakage standard. In other words, during an operating procedure, the location of various devices and cables are not arranged ideally.

An isolated output that meets the standard should permit the operator to hold the flat portion of the blade electrode with two fingers at maximum power and not feel heat when the power is activated in the monopolar mode. If this test is attempted, it should be performed with the power level increased slowly and **Do Not** allow the tester's body to come either close to or in contact with the return electrode.

Isolated generators require high-frequency transformers with special construction. Special attention to creepage distances must be maintained in all output circuits and the leads as they break out of the earth ground cabinet.

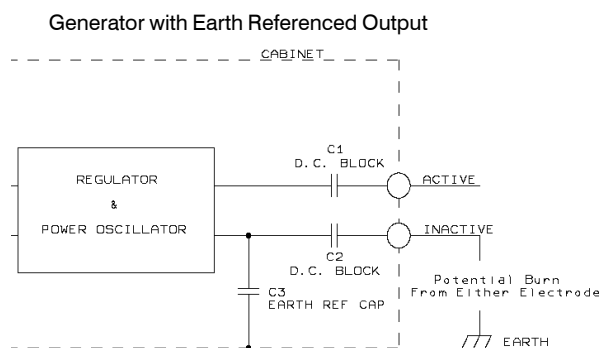


Figure 4.4-1

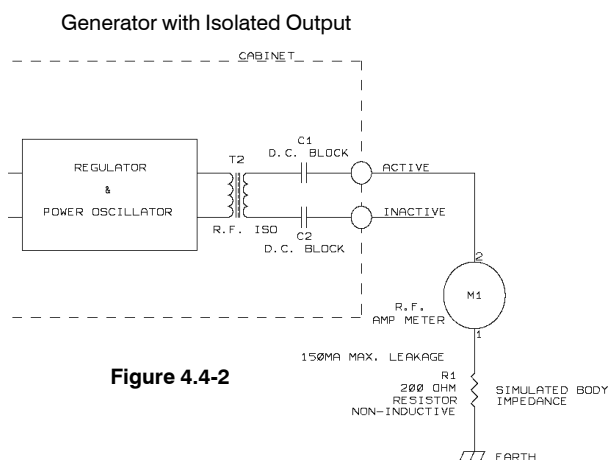


Figure 4.4-2

4.5 Neuromuscular Stimulation

Neuromuscular stimulation is said to be caused by either DC or low-frequency components reaching the patient as the circuit is completed or as the active electrode passes this current through the body to the return electrode. IEC 601-2-2 standard for high-frequency equipment requires that sufficient capacitive reactance or impedance be inserted into the patient return circuit to block these undesirable currents. Figure 4.5-1 below displays the recommended common mode connection for an isolated return circuit. C1 and C2 provide proper blocking impedance.

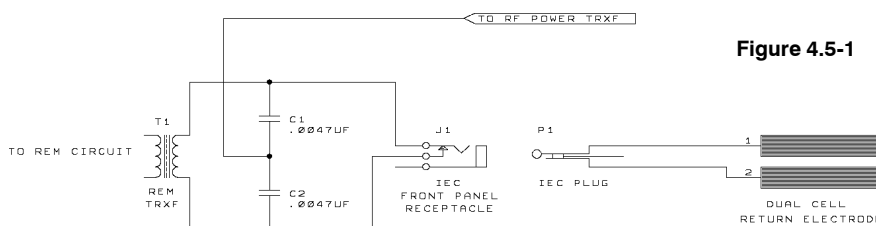


Figure 4.5-1

5.1 PURE CUT MODE

This operating mode is the most popular for incising or excising tissue when the objective is to produce the least amount of tissue necrosis on either side of the incision wall or to obtain a vital sample for biopsy. The amount of remaining necrosis will depend also upon the speed or deliberate motion through the tissue. The current mode is referred to as PURE CUT due to the fact it is pure unmodulated carrier frequency - fully rectified and filtered. The illustration and waveform demonstrate this action.

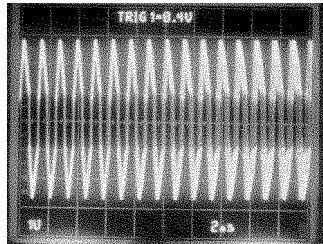


Figure 5.1-1

PURE CUT MODE
Unmodulated - 100% Duty Cycle
Operating Frequency 1MHz

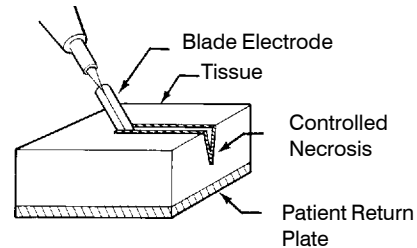
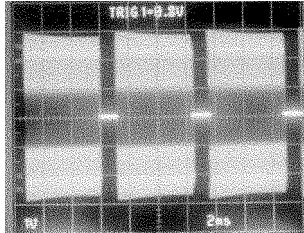


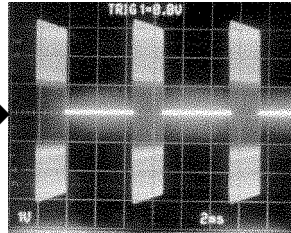
Figure 5.1-2

5.2 VARIABLE BLEND MODES

This operating mode is typically used when the subject tissue is fibrous or when an increased amount of lateral wall necrosis, shrinkage, or dehydration is desired. This is achieved by modulating the operating frequency or varying the duty cycle. The best example of this current is displayed in the output waveforms below, along with its effect on tissue as illustrated here. The physician can actually feel an increase in CUT vibration as the settings are selected from BLEND 1 to BLEND 2 and to BLEND 3. Duty cycles shown here are typical.



BLEND 1
Duty Cycle = 85%



BLEND 3
Duty Cycle = 25%

BLEND 2 - Not Shown
Duty Cycle = 50%

Figure 5.2-1

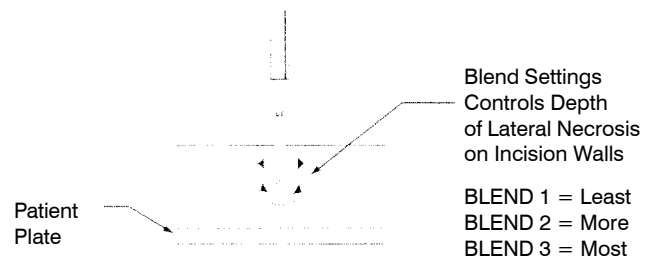


Figure 5.2-2

5.3 COAG PINPOINT & CONE SPRAY

In section 3.3, we covered the difference between *Hard Spray* and *Soft Spray* coagulating current modes. On economy model generators, some companies only offer some form of *Hard Spray*. In most high end model generators, companies offer *Soft Spray* and boast of their high *Crest Factors*. These units typically feature inductively discharged power oscillators with *True Damped Wave* outputs. The *Ring Frequency* is typically 450 kHz or higher. Figure 5.3-1 displays such waveform. Pinpoint and Cone spray are explained on the following page.

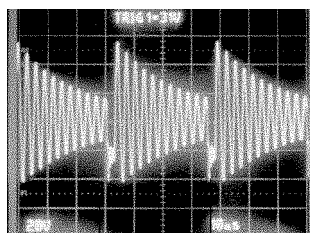


Figure 5.3-1

Burst Rate
Controls Directional
Integrity of Plasma
Discharge

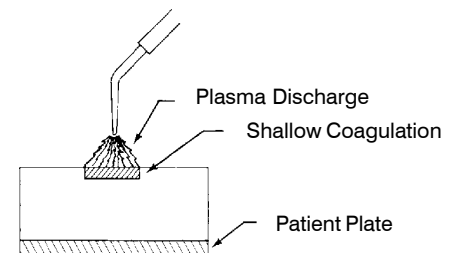


Figure 5.3-2

Pin Point Spray

The width of the spray is typically controlled by the frequency of the repetitive burst rate of each damped wave envelope as displayed in figure 5.3-1. This burst varies between manufacturers. However, it can vary typically from 5 kHz to 10 kHz or slightly higher. This lower burst rate also improves the directional integrity of the plasma discharge from the distal end of the electrode to the target site.

Cone Spray

The repetitive burst rate that creates the *Cone Spray* current mode is typically 25 kHz to 40 kHz. Directional integrity can be controlled slightly by lowering the amplitude or power setting in most cases.

Adequate Coag Power and Open Circuit Voltages

The same ECRI report mentioned earlier, also posted results after interviewing hospitals and reported that the majority of electrosurgical procedures required up to 150 watts of cutting power and rarely over 50 watts of coagulating power, unless for heart bypass, or T.U.R.P. procedures where some physicians were still using the old spark-gap units that have open-circuit voltages of up to 13 kV. Most solid state inductively discharged power oscillators have open-circuit voltages of between 6 kV and 8 kV. Of course, the higher the open circuit voltages, the greater the potential of leakage through handswitch pens to the physician's hand or some other alternative path.

5.4 USING MONOPOLAR CURRENT FOR HEMOSTASIS

Typical vascular hemostasis is associated with bipolar operating current, but often when time is critical, the surgeon may employ the metal hemostat to stop bleeding. There are a variety of monopolar forceps available that feature either foot switching or hand switching. The hand-switching monopolar forceps typically have a two-pin connector that is keyed to mate with the RED *Active* and BLUE Coagulate jacks on the hand switch output port. Typically, power is set from 0-50 watts maximum, depending upon the size of the bleeder. There are a number of issues that must be considered when employing monopolar current to hemostatically control bleeding.

When Using a Hemostat

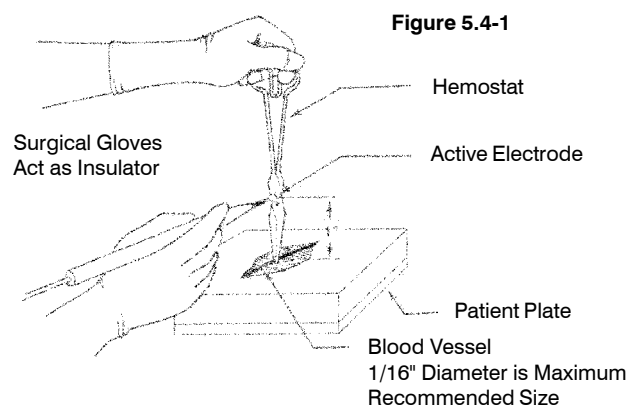
Make sure anyone participating in the surgical site or comes in contact with the hemostat during the procedure is wearing gloves. Do not activate the current until the active electrode as shown below is in contact with the metal hemostat, approximately one inch from the bleeder.

Dispersion of Energy

Unlike bipolar current that passes across the tips of the bipolar forcep, the current in this case disperses downward into the body. Therefore, it is important to sponge the area and if possible lift the vessel up away from other vital surrounding tissue before activating current to prevent alternative return paths.

Manually Controlled Duty Cycle

Again, unlike bipolar current, the monopolar mode has no timer to control duty cycle, nor does it have a shaped load response that automatically drops off as the tissue dehydrates and reflects back a higher impedance to the generator. The surgeon must control both these effects manually. The objective is to usually slowly turn the vessel white and stop. Over-heating the vessel can cause the vessel to burst on either side. Most surgeons prefer foot-switching monopolar forceps for this reason.



6.1 Overview of Bipolar Operating Techniques

One big advantage of bipolar mode current is that the return electrode or return plate is not required. In addition, the potential for RF leakage is less likely to occur. Most units with both monopolar and bipolar outputs automatically switch the return plate out of the output circuit when bipolar mode is selected.

6.2 Vascular Hemostasis

The best example of a bipolar instrument is coagulating forceps, commonly used for vascular hemostasis. In this configuration, the path is from one bayonet to the other, then back to the generator. One bayonet is referred to as the *Active* electrode and the other is still referred to as the *Inactive* electrode. Typically, this method of hemostasis is limited to vessels no greater in diameter than 1.5mm. Bipolar generators also typically feature a shaped load response curve that peak at about 100 to 200 ohms and then allow power to drop off rapidly to prevent what has been termed the *Popcorn* effect whereby the blood vessel over-heats the fluids in the vessel and causes the vessel to burst open on either side of the applied forcep tips. The illustration below demonstrates the action involved.

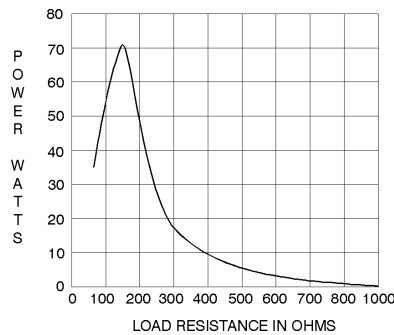


Figure 6.2-1

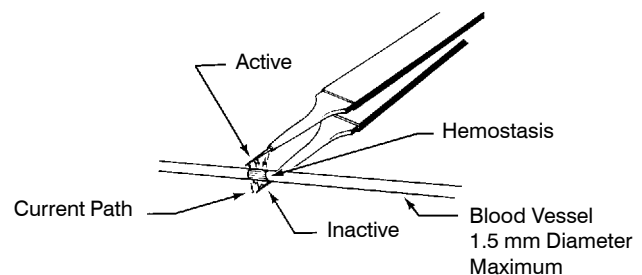


Figure 6.2-2

The Hemostatic Objective

The objective is ideally to slowly turn the vessel white, seal off the bleeder and prevent tissue from shrouding to the tips of the forceps.

Preventing Tissue Shrouding

There are factors that work against the ideal objective above that are not well understood. One is premature activation prior to the tips of the forcep being applied directly on the vessel. There have been a number of attempts to prevent this from occurring. For example, when hand-switching forceps were first introduced, they would activate prior to application on the vessel. This is caused from either improper design or distortion in the shape of the bayonets during handling. The premature plasma arc tends to weld or shroud the tissue to the tips of the forceps. This is one reason why many physicians prefer foot-controlled activation. Some physicians still prefer monopolar forceps. The inherent reason is that they can depend upon the wider dispersion of energy. Of course, care must be taken to keep the energy from taking a path to surrounding tissue. Some *ESU* generators offer a *Delayed ON* action to prevent this premature plasma arc.

Overheating The Vessel

When the vessel wall is thin, sometimes even a shaped load response curve is not enough to prevent overheating and care must be taken to turn Off the energy within a narrowed duty cycle range. One feature built into higher quality forceps is a special *Copper Tip* design to help dissipate the heat. These were first introduced by the *WECK** company. Some generators feature a duty-cycle timer to assist the physician to further prevent overheating.

6.3 Uses of Bipolar Current in Minimally Invasive Surgery

The use of bipolar mode current has found its way into many specialty fields that rely on minimally invasive or general endoscopy procedures. Again, the obvious advantage is the elimination of the return plate and the potential leakage through parts of the instruments employed. The other advantage is the use of low open circuit voltage potentials, commonly found in bipolar outputs.

Hot Biopsy Forceps

From the illustration here, you can see that this instrument is designed to pinch off a tissue sample for biopsy as the high density edges of the small shaped cups cut through the tissue trapping, the sample inside the cups for retrieval as the catheter is drawn out.

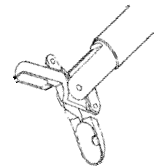


Figure 6.3-1

Polypectomy Desiccators

When polypectomy procedures were first introduced, after a loop snare was used to remove a polyp, the root of the polyp was further desiccated with a monopolar desiccator to prevent regrowth. The problem was that the typical electrosurgery generator did not feature a shaped load curve or allow its power level to drop off as the dehydrated tissue reflected back higher impedance. Of course, this increases the potential of piercing the colon wall.



Figure 6.3-2

Then later, ACMI* developed the BICAP* desiccator to take advantage of the shaped load curve on most generators with bipolar output. Here, ceramic separates copper strips of metal in a circular pattern of alternative electrical poles to desiccate the polyp's root. Both types of desiccating catheters include a hollow center to allow an irrigation pump to lavage the wound. The shaped load response curve reduces the chance of piercing the colon wall.



Figure 6.3-3

Tripolar Forceps

Here is a uniquely shaped device design for use with bipolar output, still only two electrodes, even though it is referred to as *Tripolar*. Here the *Inactive* electrode is formed into an elongated loop and the *Active* electrode is formed into a narrower elongated blade creating a scissor action. The device first clamps the tissue to coagulate the tissue on either side of the blade and then the blade cuts in a scissor action by transecting inside the loop. It is used for *Nissen Fundoplication* procedures. The device displayed here was developed by Cabot Technology Group.



Figure 6.3-4

Other Bipolar Devices

In addition to the many long shanked special shaped electrodes developed for laparoscopy, arthroscopy, and other specialty practices that are intended for monopolar operation, new instruments for use with bipolar electrosurgery are continuously being introduced as the use of minimally invasive surgery grows in popularity. A company that has made great strides in this area is Everest Medical. They have an excellent website for further investigation.

7.1 Recognized Standards

The A.O.R.N. (Association of Operating Room Nurses) publishes guidelines for hospital sterilization practices and A.A.M.I. (Association for the Advancement of Medical Instrumentation) specifically deals with sterilization use cycles and electrical breakdown tests in their standard HF-18 which is regarded as the benchmark in the industry. J.C.A.H.O. (Joint Commission on Accreditation on Healthcare Organizations) requires healthcare facilities to have policies in place regarding sterilization practices that are safe for the patient, the hospital personnel, and the surrounding environment (i.e. ventilation of EtO, waste management, etc.).

7.2 Disposable - Package Indication

Most *ESU* accessories that are packaged with this type of labeling are placed in sealed Tyvek* pouches and are pre-sterilized with gamma radiation. It is common knowledge that many physicians attempt to reuse these "For Single-Use Only" accessories. The position the A.O.R.N. takes is as follows...

"Patient safety should be the primary concern when considering reprocessing single-use medical devices. Reprocessing is not recommended unless manufacturers provide written instructions for resterilizing the single-use devices, or unless the healthcare facility can demonstrate and document that the patient's safety and the medical device's effectiveness and integrity are not compromised."

Some Reasons For Concern - Regarding Recycling "Single-Use Only" Devices

Manufacturers and distributors alike love the repeat business. With the potential for cross-contamination whether real or not, their argument is a very good one. At first glance, some physicians may feel that with an adequate sterilization protocol, why not reuse such devices if the device appears to be like new. When making this judgment regarding *ESU* accessories, there are other factors at play here that need consideration:

1. Electrical breakdown in materials due to chemical, temperature, and physical handling.
2. Oxidation inside, hidden from sight, that potentially could alter the gap impedance or creepage.
3. Accelerated galvanic reactions or shorts due to trapped moisture at various joints, etc.
4. Finally, if sterilization protocol is adjusted to protect device integrity, can you be sure it is sterile?

7.3 Reusable - Package Indication

Typically, *Reusable* *ESU* instruments come in non-sterile pouches. Insulating materials for shanks or molded parts for example, are Teflon* or Polysulfone* as opposed to PVC and any internal switches have gold-plated contacts. Cords are usually made of silicone as opposed to PVC and plug pins are stainless.

Qualifications For Reusable Markings

In order for an accessory to be approved as *Reusable*, it must pass the breakdown standard after a minimum of (20) cycles of re-sterilization at a protocol temperature, pressure and extended time in accordance with the A.A.M.I. HF-18 standard.

Reason For Higher Cost

To stamp or mold *Reusable* devices, tooled dies and molds are typically more expensive. For example, larger molding presses are normally needed to push the high-viscosity, high-temperature grade plastics through the mold and yields are normally less due to flow-rate problems. The lower temperature plastics used in *Single Use* accessories are much easier to mold and have better flow rates and are more adaptable to multiple cavity molding.

7.4 Semi-Disposable - Package Indication

A reference to "Semi-Disposable" in the AAMI/HF-18 standard could not be found. This term has come to mean that number of use cycles for the device, instead of (20) times is recommended for some other lesser use cycle as stated by the manufacturer. Devices like this may use Kynar* or some other insulating material with mid-range temperature breakdown characteristics. This type device is usually shipped sterile.

7.5 Pre-sterilization Procedures

Healthcare facilities should employ, as part of their sterilization protocol, a method to remove the shrouded tissue or eschar build-up that remains on most ESU electrodes after use. Ultrasonic baths are typically employed for invasive type electrodes. For endoscopic devices, brush-cleaning kits and soaking or for devices having lumens (hollow bores or tubes), a gravity-displacement cycle or prevacuum cycle may be recommended.

7.6 ETO - Gas Sterilization

The common recommendation for ESU devices has been EtO Gas. EtO gas is very toxic and flammable and can cause severe burns if not properly aerated. Equipment with proper ventilation is also required to protect both personnel and the environment. Healthcare facilities should follow the instructions of the EtO equipment manufacturer with respect to time cycles and aeration processes. EPA in many states now severely restricts amounts of EtO allowed into the atmosphere.

Aerating Bags

ESU electrodes and other such devices are typically placed into aerated bags with breathable Tyvek vents to speed up the gas sterilization and aeration process.

7.7 STEAM - Sterilization

A leading manufacturer of ESU accessories recommends *Steam Sterilization* at 250° F @ 20 pounds for 30 minutes. The AORN may recommend longer cycles and each case may be different.

Wrappers

Wrappers are commonly used to prevent cords and other insulating materials from coming into contact with wire cage parts, etc. that could compromise such insulation.

7.8 FLASH - Autoclaving

The same manufacturer mentioned above recommends *Flash Autoclaving* at 270°F @ 30 pounds for 4 minutes. Again each situation is different.

7.9 Chemical Disinfection

Devices soaked in glutaraldehyde must also be soaked in sterile water to remove residual amounts of the germicide which can be harmful to tissue. Devices that are heat and moisture sensitive are commonly sterilized in ethylene oxide. Devices that are heat sensitive but moisture stable are commonly sterilized in hydrogen peroxide plasma. Items that may be immersed are also commonly sterilized using peracetic acid as a liquid sterilant. Some plastics may react to chemicals and if not sure, it is advisable to check with the manufacturer of the device.

7.10 Gamma Radiation

Popular due to its penetrating sterilant. However, some plastics may experience an *Unlinking* of their bonded chains and become brittle while others will actually improve in tensile strength. Again, check with the manufacturer. This equipment is bulky and very expensive. For that reason, many healthcare facilities have turned to outside services to handle matters regarding sterilization and the tray-kit business has become very cost-effective.

7.11 Shelf Life

In addition to *Brand, Type Designation*, and *Lot Numbers*, for tracing purposes, all sterile packages must be labeled with a *Shelf Life* expiration date. Inventory control and first-in-first out practices are important to reduce cost.

7.12 Protocol & Logging

The A.O.R.N. strongly recommends a written protocol and a logging system to track sterilization for each procedure performed. J.C.A.H.O. reviews healthcare facilities to verify that these procedures are in place and followed, including pre-sterilization, post-sterilization washing, and in-transit holding practices. Also, device manufacturers' recommendations for sterilization should be kept on record and made part of the written protocol. The A.O.R.N. has guidelines regarding such practices and this, as well as other information, is available on their website <http://www.aorn.org>

8.1 Line and Load Regulation

Line Regulation

As line voltage, frequency, and output loads vary, it is important to maintain a constant $B+$ supply voltage to the power oscillators, control, and indicator circuits to insure output integrity. A regulator is employed to accomplish this task. Manufacturers rate their generators to remain stable during fluctuations in input-line voltages, typically at some \pm tolerance (at least 10%) from the nominal operating line voltages - 115/230 volts. The higher this tolerance, the greater the amount of stored energy that is dissipated to heat.

Load Regulation

Also with the input set at low end then high end from nominal line voltage, the load impedance is varied from *Full Load* (lowest expected load impedance) to *No Load* (open circuit) and the $B+$ supply voltage should not change more than 1% to 2% from these extreme loads.

8.2 Output Power Response to Load Impedance Regulation

Line and load regulation should not be confused with flat-line load response curve feedback circuits. This circuit requires an additional *Square Law Detector* or *Square Rooting Circuit* with feedback control to an error amplifier in the main regulator controlling the set point power based upon $P=I^2R$. Flat-line response is ideal only in the *Monopolar* operating mode, important when Cutting. In the bipolar operating mode, the response curve should peak and drop off rapidly with higher reflected impedance. Again, here are the two load response curves to demonstrate the ideal in each mode. In reality, most generators employ filters to shape these curves.

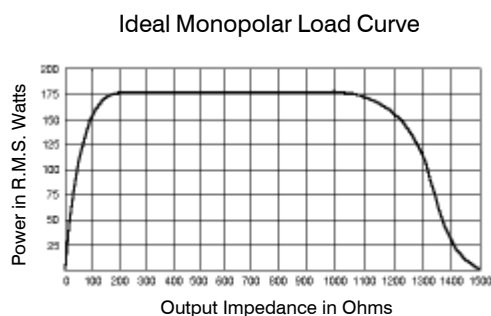


Figure 3.1-1

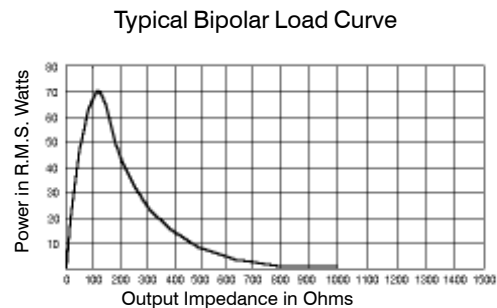


Figure 3.1-3

8.3 Dial Linearity and Tracking Tolerance

Dial Linearity Curve

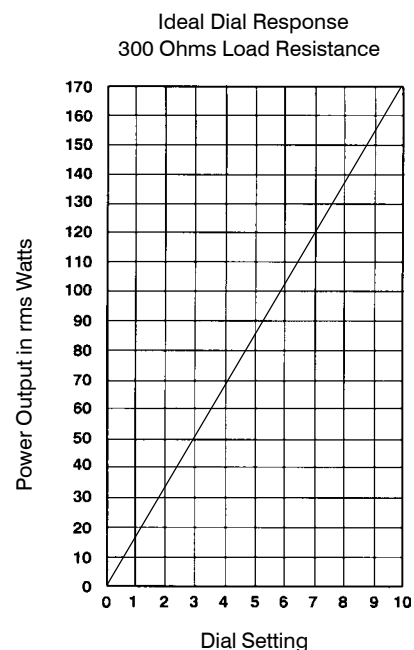
Manufacturers will typically print a *Dial Linearity Curve* that will display what the physician can expect either as a percent of dial or knob setting in rms watts at the rated load.

Digital Approximation

There seems to be a common misunderstanding in the marketplace that somehow those units with digital readout are providing the physician with the actual power output - they are not. These settings are digital approximations of power based on the rated load. If the power indicators attempted to track actual power during activation, the display would be unreadable, even with slow sampling rates. This is pointless also, since settings are read before the incision is made, not during.

Accuracy at Rated Load

IEC requires that power indications provide at least a \pm 20% accuracy in dial settings from low to high over output range.



8.4 Construction Practices

We think it is important that the biomedical engineer in the hospital is at least made aware of some of the important construction practices that are employed by most manufacturers.

Main Transformer

The main isolation transformer is probably the most important component within any *ESU*. It provides isolation from potentially harmful line frequency current. TEKTRAN employs an internationally approved bobbin set with separate winding compartments for primary and secondary windings and a shroud cover to isolate from the metal core. This design is tested to 4KV insulation. Materials are Class H temperature rating and any split windings are further insulated by PTFE* Fluorocarbon tape. Terminals are molded to the bobbins.

Output Transformer

The *RF* output transformers and insulated breakout jacks are critical to high frequency isolation from earth ground. These are typically ferrite cores with either high (μ) or low (μ) as covered earlier in this booklet. Bobbins are typically interleaved wound for best power transfer results with special *coated Foil* or *Letz* wire and all winding breakouts are insulated with special Silicone*sleeving. Toroid cores are KV coated and wound with military grade (19 stranded) Teflon* insulated wires. Terminals are either molded to the bobbin or bound by laced tape wrapping.

Fusing Techniques

It's not enough to just fuse the mains. This only allows the fuse to trip when the high impedance secondary winding is over loaded. It does nothing for low voltage or low impedance secondary overload. For example if a 115VAC primary is stepped down to a 5 volt output. The shorted 5 volt output winding would not reflect sufficient overload on the primary to trip the mains fuse. Therefore, all secondaries must have some form of fusing. TEKTRAN employs U.L. 544 approved resetting PTC* polyswitches and all low voltage regulators have current limiting as well. If the generator has dead short and transient protection built in we do not recommend the use of circuit breakers - if reset they will only further damage already damaged parts. Since manufacturers do not include backup components due to their added cost, breakers are pointless.

Thermal Protection

Main transformers should be thermally protected. TEKTRAN employs resetting thermal switches on all of its generators and in some case resetting thermal switches on key heat dissipators. Typically, these do not kick in until well after a proper duty cycle period, beyond normal service.

Overvoltage Switch

Some generators employ overvoltage switches that trip the fuse in the event that an over voltage condition appears on the input mains. For example, this may occur if the primary tap switch is set to 115 VAC and 230 VAC is applied in error. Manufacturers are required to set these switches at the factory for the international customer and indicate the setting on the unit and in the test certificate. Most include the correct power cord and plug also.

Bleeder Resistor

A bleeder resistor is employed to drain energy from the main B+ filter caps when the unit is turned Off. This should reduce dc to near zero levels with each activation.

Temperature Stability

Per IEC 601-2-2, the generator should be able to operate at full power across its rated load for 1 hour of 10 seconds On and 30 seconds Off cycles.

Dead Short and Open Circuit Stability

Per IEC 601-2-2, the generator should be able to be short circuited for 5 seconds, then open circuited for 15 seconds, then unit is switched off for 1 minute. The cycle is to be repeated 10 times. After this test the unit is required to pass dielectric and leakage standards as well as other qualifying standards.

8.5 Critical Safety Tests

Hypot Test

The generator should be able to withstand up to 3000 V rms from the earth ground stud to other parts on the cabinet enclosure without breakdown for one minute.

Earth Continuity Test

With an impedance meter, no metal part on the cabinet to earth stud should exceed 0.15 ohm. Remember to subtract the cable impedance.

AC Line Leakage Test

Line-current leakage is tested from case to earth and attached patient-connected device to earth. From Active or Inactive electrode to earth should not exceed 50uA. If it passes this standard as well as other tests, it is classified as (BF) type. If leakage does not exceed (10uA) leakage under the same conditions, then it is classified as (CF) type and is rated for cardiac related surgery. See required symbols on page 3, in section 2.7

RF Leakage Test

In order for the generator to be classified as isolated, it must not leak from either *Active* or *Return* electrode ports more than 150mA or 4.5 watts through a 200-ohm non-inductive resistor to earth. If the generator is ground referenced a 200 ohm load is to be placed across the output and the leakage is then measured on either side to earth.

Neuromuscular Stimulation Test

This condition is caused when a generator allows dc or low-frequency components to reach the patient. The common mode connected blocking caps in path with the return plate should not exceed 20 ohms of Xc impedance at the operating frequency and the blocking cap in the Active circuit should not exceed 40 ohms of Xc impedance. $X_c = 1 \div 2\pi fC$ (f=operating frequency & C=cap value in farads). To test for muscular stimulation, it requires a human volunteer. We refer you to the 1987 ECRI report on ESUs dated 9-10/87 Vol. 16, page 305.

Defibrillator Test

During surgery, if a *Return* electrode is applied to the patient and it becomes necessary to defib the patient, the ESU generator must be able to withstand at least a 2 kV discharge per IEC 601-2-2. This test is performed in accordance with paragraph 51.102 figure 109. If a generator is defibrillator proof, it is required to be so marked as either (BF) or (CF) leakage type on the ESU front panel near the patient return port. See AC Line Leakage Test above.

Power Interruption Test

Microprocessors are especially prone to failure after this test. Here the power is interrupted and quickly turned back On (10) times to examine for failure. Things to look for would be lack of function in controls and false readings that could possibly cause injury to operator or patient.

Line Transient Test

All electromedical devices that are powered by line current should include an MOV varistor or similar transient protection element sized properly for the operating current and energy dissipated during transient events.

EMI - Emission Tests

Many of the generators currently on the market at time of this printing do not comply with the most recent standards under EN55011 (A) Group 1. However, they should at least include a hash filter or some provision to reduce RFI/EMI. This is a controversial subject matter currently in review by the FDA and other regulatory agencies. The following section 9.2, titled "EMI Interference", covers this subject in some detail.

EMI-Immunity Tests

Transient immunity as well as EMC or compatibility with other O.R. equipment is covered in this part of the test. Logic, for example, should be low or high. Ground planes and perhaps multi-layer boards with signal traces on top and bottom should be used. Vcc and common planes bypassed by a layer of insulating material may help. Opto-coupler without base leads should be employed if the base lead is not required or RC filter circuits should be used. Coaxial traces on the PCB or ferrite beads may also be necessary. All these design techniques and more may be required to pass this test.

Locked Rotor Test - (i.e. fan, infusion or peristaltic pump)

Some generators employ fans or even motorized pumps. These should all be properly fused for current draw in locked rotor state. All motors should have some form of resetting thermal protection.

Splash Test - Fluid Ingress

Vent holes should never be located on top of an enclosure where fluid could fall directly on electrical circuits and vent holes should never be over 1/16 inch width. Per IEC 601-2-2 vertical splash test, a dielectric test is performed to verify if fluid ingress or moisture affects electrical circuits.

Strain Relief Tests

U.L. requires a 30-lb pull test on all cables or cord strain relieved cabinet breakouts, if any. This includes foot controllers or any combination accessory sold with the generator.

Vibration Test

All PCBs should be locked down and terminals or internal connectors should have locking rails or some other form of secure means to prevent dislodging during shipping or in-service transport. Vibration tables are available for this test which is performed in accordance with the general IEC 601 standard.

Storage Temperature Test

Environmental temperature testing is also a consideration. Operating rooms are normally kept cool, but if the unit is to be stored in a hot warehouse prior to delivery, adhesive labels should be the type that can withstand such temperatures.

Human Factors in Design

Indications should follow norms for ESU generators. All output ports should be keyed so it is not possible to reverse such connectors and cause injury or damage to devices used in combination with the generator. Output ports should be activated discretely, meaning without other ports being active at the same time. The list of requirements for audible and visual indications are too numerous to mention here.

Carton Drop Test

Generators should be packaged for shipping in some form of clam-shell insert, locking the unit in the middle, free from damage if the carton received impact. Most companies employ a drop-test of their own design to assure its safe arrival. There are also different types of recycled foam with the correct durometer ratings for size and weight.

8.6 In-service Testing

Most ESU testers designed for the bio-med department in hospitals are built to accurately measure rms generator power with an operating frequency from 500Kc to 1.0 MHz. They will normally perform all leakage, open circuit, and other tests in good order, but even though they may report true rms readings from DC to 5 MHz or higher, some also report in their manuals that power at the high end drops off (-3dB). This is half power! Unless you can secure a graph indicating where the tester starts to drop off, it is not recommended for use on generators over 1.0 MHz operating frequency. Beyond 1.0 MHz, it may be advisable to employ an RF thermal couple type ammeter and non-inductive power resistors, such as a carbon stick, Ayrton-Perry or serpentine-wound resistor.

9.1 Standards For Electrosurgical Generators

Power Source Standards

In addition to the U.L. 544, U.L. 2601-1 standards and the Canadian Standard C.S.A. 22.2 Class 125, most manufacturers now build to the international standard IEC 601-2-2 which is the particular standard for high-frequency electromedical equipment, including *Electrosurgery*. Most present day generators feature isolated outputs, reducing the risk of accidental burns sufficiently. Manufacturers are increasingly opting for certification under EN29001, EN46001, and the *MDDs* (Medical Device Directives 93/42/EEC) - the *European Norm* required before a manufacturer can apply the CE mark on its product. Most recently, concerns regarding emission of and immunity from *EMI* (Electromagnetic Interference) and *EMC* (Electromagnetic Compatibility) are under review and standards are advancing to stricter regulations. In order to give the physician and the biomedical engineer a little better insight into the importance of subject matter, we have expanded *EMI/EMC* as a separate sub section below.

Cables, Cord Sets, and Electrodes

The quality of construction and insulation of connectors, cord sets, probe, catheters, and electrodes are as important since these devices are the ones that come in contact with operating staff and the patient. Standards for these electrode devices have been greatly improved. For example, the A.A.M.I. standard HF-18 covers not only matters regarding insulation, and current leakage, but sterilization, chemical reactions, and durability with respect to use cycles.

Manufacturing - Quality Control

Manufacturing processes are regulated by the U.S. Food and Drug GMP (good manufacturing practices act) now referred to as *Quality System Regulation* /FDA 21 820.30 which has recently been updated in October of 1996 to fall more in line with the full twenty parts of ISO 9001 and the particular ISO standard for ESU manufacturing ISO 13485 which covers items related to design controls, efficacy, materials, assembly, testing, packaging, and even after-sales-service as well as documented verification. The CE mark requires compliance with both design and processing standards and regulations as covered by the *MDDs* mentioned above.

9.2 Electromagnetic Interference

As medical procedures rely more heavily on electronic devices like recording EKGs, video monitors and the like, electromagnetic interference and equipment compatibility issues become a major concern in the operating room. The earlier FCC Volume II, Part 18 standard did not address many issues and was very forgiving, given the nature of electrosurgery to emit RF energy. Most recently, standards for electromagnetic interference such as EN55011 and EN55014 which deal with RFI (radio frequency interference), EMI (electromagnetic interference), and EMC (electromagnetic compatibility) issues has been adopted.

Power Factor

Power Factor is defined as the phase-angle displacement of voltage and current. This is a serious problem in switching power supplies where the cosine (θ) factor is typically 0.65 or worse depending upon the ac line impedance. Even with a traditional power supply only including a rectifier and a charging filter capacitor which is typical in any *ESU* generator, the filter cap is in the order of 500uF to 1,000uF or more. Current inrush will lead voltage as the caps charge causing a phase angle shift between voltage and current. Inherent in design of most switching power supplies, this current is drawn during the peaks of the voltage sine wave. See figure 9.2-1 This is due to the charge that is maintained on the filter cap which places a back bias on the input rectifiers. Typically, these rectifiers cannot conduct current until the sinewave voltage exceeds the bias voltage of the rectifiers. Current is then drawn from the line in very high peaks. This current is rich in harmonics. The total harmonic current can equal or exceed primary current. The third harmonic alone can be as much as 85% of primary current.

Power Factor and Building Wiring Systems

Before we can discuss equipment interference, we need to know that the building is safe! With most facilities these days filled with computers and other electronic gear, most of which are regulated by high-speed switchers, power factor is a major concern for a building planner. For example, balancing loads in a three-phase 208Y/120V system will normally reduce current in the neutral leg to zero, but with harmonic distortion in phase on other legs, current can still be as much as 1.7 times the total phase currents. If the phase conductors are equal to the neutral

Biomed Department Information

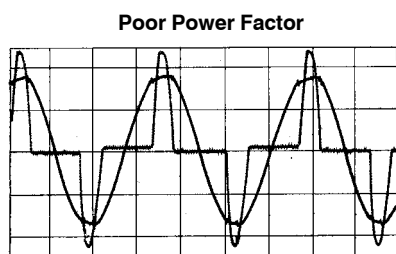
conductor, heating in the neutral conductor can be three times that of the phase conductors and fire can result. Further up the line, third and multiples of the third harmonic can circulate in the output windings of a three-phase delta-wye main transformer until the transformer fails if it is not sized to handle the volt-amperes as well as the unused volt-amperes circulating due to harmonics.

Power Factor and Equipment Interference

Harmonics circulating in the ac line system can feed through to the input line of other critical equipment causing the affected equipment to provide false readings, interrupt delivery, or fail, depending upon the AC line impedances in the AC line system.

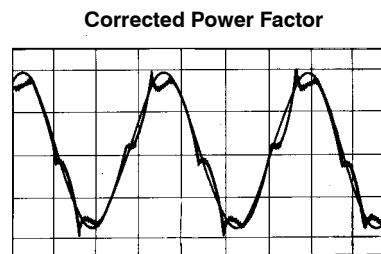
Power Factor Correction

Phase shift or poor power factor can be corrected by employing a booster or pre-regulator referred to as a *pfc* (power factor correction) circuit or in other regulators, just an inductive filter to slow the current inrush. A *Hash* filter may then take care of remaining harmonics. The waveforms below demonstrate both input with poor power factor and input after the problem is corrected:



Current is drawn only a short time during each input cycle.

Figure 9.2-1



With correction the input current becomes near sinusoidal - in phase with voltage.

Figure 9.2-2

Unique EMI Problems Related to Electrosurgical Generators

Most *ESUs* have at least two power supply circuits - a *B+* supply for *RF* power oscillators and low voltage supplies for logic control and display indicators. Typically, switching power supplies work great for regulators that are delivering low voltage from 3 to 60 volts and have high current demands. Unfortunately, *B+* power supplies in most *ESUs* must deliver 150V to 400V dc to supply their output oscillators. In these high voltage supplies, efficiencies are lost when employing switchers in snubber circuits and in the high-speed diodes during their reverse recovery period in the form of heat dissipation. For this reason, *B+* supplies will be regulated by other means, if regulated. Further, given the *EMI* problems associated with even low voltage (*Vcc*) switching supply regulators, the *ESU* designer will usually opt to use good old fashion linear regulators since average current demand is typically in the milliampere range for logic controls and indicators. Inrush currents to *B+* filter caps are handled by inductive filters in the input current path. The real *EMI* problems lay in the power output oscillators.

Class D Switchers - Charge rates and EMI- A Tradeoff

Regardless of the circuit topology employed, push-pull or full wave bridge amplifier, most modern *ESU* generators are powered by high-voltage *MosFet* switchers in *Class D* mode. The gates on these high voltage *MosFet* transistors must be switched very rapidly (within a matter of nanoseconds) in order for them to be either On or Off. When they are not either On or Off, they are said to be in their linear region and that is when they generate heat. Due to wafer size the gate to source junction capacitance in a high voltage *MosFet* is in the order of 1000 to 2500 pF. Therefore at the desired switching speeds, driving signals must be able to sink in the order of 2 to 6 amperes during the turn-On. The new *EMI* standards now come in direct conflict with what designers of these power circuits were taught to achieve efficiency. For example, as the gates of these main switching elements are turned On, typically a large overshoot transient is generated that must be clamped as well as parasitic oscillations caused by the *Miller Effect* (inductance of the leads bonded to wafer, ringing with the junction capacitance). Then upon turn Off, the stored energy in the inductive winding of the output transformer spikes on flyback and rings. The transients, parasitic oscillations, and inductive ringing all help to produce unwanted *EMI*.

Solving EMI in Class D Switchers - Reduce Slew Rates

The only obvious solution is to adjust the slew rate or to slow the rate of turn-On and turn-Off of the *MosFet* gate to reduce *EMI*. The waveforms below demonstrate how noise is nearly eliminated as the slew rate of the top switching waveform is slowed. A combination of switching elements can also be employed to achieve more efficiency. These are proprietary topologies beyond the scope of this review. However, regardless of the technique employed to reduce noise, power efficiency is a trade-off.

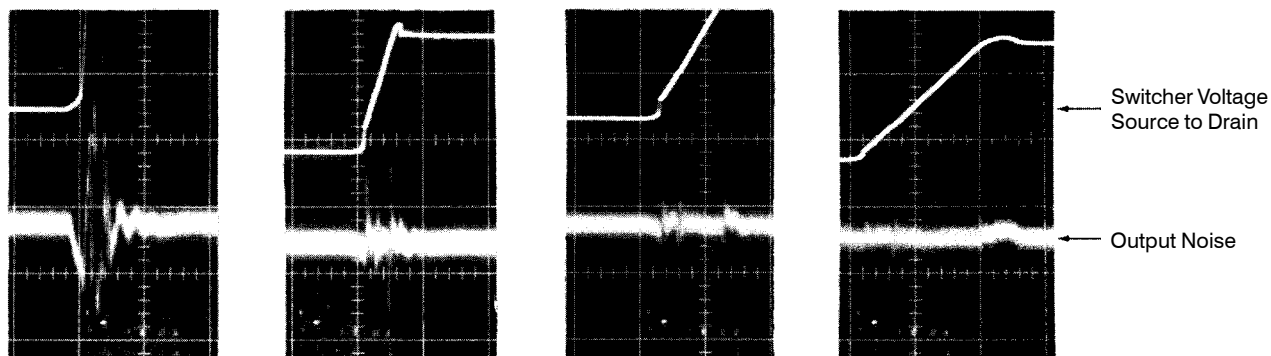


Figure 9.2-3 (Series of Four Waveforms With Progressive Improvement)

Phase-Angle Firing Interference

Another type of line disturbance is that caused by phase-angle firing circuits that employ SCRs (silicon controlled rectifiers) and TRIACs (bilateral SCRs or thyristors). These devices remain as the most efficient method of controlling line current, either as power control or static switches, especially for high-voltage/high-current applications like those found in *ESU* (B+) supplies. The *EMI* problems occur at crossover with reactive loads when line voltage and current undergo a phase shift. Two areas of concern are inrush current to charge filter caps in the supply, causing di/dt transients and false triggering caused by dv/dt (delta / phase shift at crossover).

The di/dt *EMI* problems are corrected with inductive filters, while the dv/dt problems are corrected with snubbers (RC networks) across the SCR or TRIAC as well in the bilateral trigger and opto coupler circuits. More advanced zero voltage firing circuits are also employed.

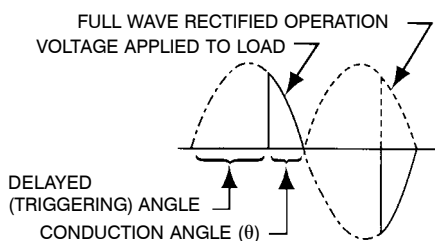


Figure 9.2-4

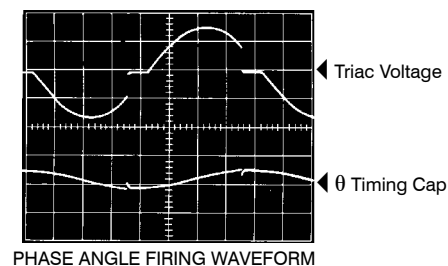


Figure 9.2-5

Testing For Harmonics

Hospitals may conduct preliminary tests for *EMI* by using a PC based spectrum analyzer. Manufacturers may use either that method for conducting preliminary *EMI* emission or immunity tests or a bench-top *G-Strip Cell*. For final compliance testing, manufacturers will turn to certified outside service firms with *Anechoic Chambers*.

Taking Measurements In an RF Rich Environment

As advances in *RF* (radio frequency) powered devices continue to play a role in modern minimally invasive surgery or therapeutic procedures and electrodes are placed into yet smaller close proximity regions where high frequency energy is emitted, new technologies will be required for accurate measurements and control. When taking temperature measurements, if the designer can overcome the cold-reference junction, special cabling, galvanic metal contacts, and linearity problems with thermocouples, it may not be so easy to overcome a bath of *RF*. One excellent example of this is with the new BPH (Benign Prostatic Hyperplasia) therapy units which must take more than one thermal measurement and report back to the high-frequency generator itself. Luxtron*, a Santa Clara, California company, is making great strides in this area with their Fluoroptic* probes which employ fluorescence of phosphors and optical signals which are immune to *RF*, microwave, and other electromagnetic fields.

Active Electrode

Employed by the physician at the surgical site to either cut or coagulate tissue. In the monopolar mode, it is also the electrode that has the highest density contact with tissue. Its output port is color-coded RED, unless the earlier style Bovie* port is employed which is normally BLACK and the largest diameter port on the front panel, located near the monopolar handswitch port.

*AEM**

This is a generic term, meaning Active Electrode Monitor. Its purpose is to detect low impedance paths to unwanted places in or around laparoscopic equipment to prevent burns or injury to patient or operators caused by the capacitive reactance of the long insulated electrode shanks used in such procedures.

Anechoic Chamber

A sound and electromagnetic proof chamber, usually located in a desolated area where RF generators are tested for high-frequency emissions that might otherwise interfere with other electrically sensitive equipment.

Argon Coagulator

A general concept developed back in the early 1950s and refined again in the late 1980s. An inert gas is pushed through a hollow tube under pressure. As it passes through the tube RF energy is induced to excite the molecular structure of the gas and a plasma flame is emitted from the tube in a short straight line similar to a laser. It clears the fluid away as the excited gas discharges and is used to cut and coagulate in a wet surgical field. Studies are still being conducted on its effect on tissue.

Bipolar Operating Mode

In this operating mode, no dispersive return electrode is applied to the patient. Instead, both Active and Inactive electrodes are applied at the surgical site. An example would be bipolar forceps used for hemostasis. The current path is between the two electrodes or exposed tips of each bayonet.

Blended Cut Current

This is when the carrier wave or RF operating frequency is modulated. Depending upon the distance between the modulated envelopes, the current is referred to as BLEND 1 (85% duty cycle), BLEND 2 (50% duty cycle), or BLEND 3 (25% duty cycle). While cutting or excising tissue the depth of lateral necrosis is controlled accordingly. See section 5.2 and figure 5.2-2

Bypass Jack

This is an additional Inactive jack used with older style endoscopes that employ metal sheaths. An insulated cord is attached from this jack to the metal portion of the scope to ensure a low impedance return path back to the generator and not through the operator to ground; especially important when using generators with ground referenced outputs.

Cable Fault Interrupter

This is a type of patient return system. It employs two lead wires to a single-cell dispersive plate and when a break is detected in either lead or connection back to the generator, it alarms and shuts the output power Off. This type of system is not capable of monitor dispersion quality or full dispersive contact with the plate.

Class-D Switcher

As opposed to class A, B, or C operation, this class of oscillator operates by switching an element On and Off at a high frequency. It is typically employed in power supplies and RF power oscillators.

Class-H Grade Materials

A recognized temperature (180°C) grade for conformal coatings, tapes, breakout sleeving, double coated magnetic wire and other insulating materials used in medical equipment and in transformers.

Coag Current

This is typically a high-impedance, high-voltage current used to stop bleeding by allowing the RF plasma discharge to jump the air gap between the Active Electrode and the tissue. Early spark-gap generators typically had output voltages as high as 13 kV. Coag voltage potentials in modern solid-state generators have outputs in the order of 6 kV to 8 kV. The purpose is to stop bleeding without cutting and to seal capillaries without penetrating further into the tissue.

Cone Spray

This is a selected Coag current mode that has a high repetitive burst rate which causes the RF plasma discharge to fan out into a cone pattern from the Active Electrode to the nearest tissue.

Crest Factor

In Electrosurgery this is said to be the ability to Coag without Cutting. It is measured by the following formula: $CF = \text{peak volts} \div \text{rms voltage}$.

Desiccate

This is a surgical technique as opposed to a current mode. It can be very destructive to tissue and surrounding tissue. It is accomplished by inserting the exposed Active Electrode into the tissue and then turning on the current. Desiccation can occur in any current mode.

Dial Linearity

This is a representation of how linear the intensity control is on an electrosurgical generator. Most manufacturers print a graph with y and x coordinates of power and dial position.

Diathermy

Electrosurgical generators are often referred to as diathermy units. A more correct example of a diathermy generator would be one that employs two dispersive pads and is used to heat muscles in a local area of the body. A common therapy for athletes.

Dielectric Hot Spot

Care must be taken when using connectors that conduct RF energy. Carbon deposits, oxidation, or loose connections can increase the chance of flame out and fire. Manufacturers of R.F. connectors rate contact impedance in pF (picofarads). X_c is AC impedance. $X_c = 1 \div 2\pi fC$ C is capacitance in farads.

Discrete Outputs

This is a term employed with respect to electrosurgical generators, referring to the generator's characteristics whereby only one port is allowed to be active at any one time. In the case of dual monopolar ports, first come / first serve logic is employed.

Dispersive Plate

This is the Inactive Electrode that allows RF current to return to the generator. It is attached to the patient's skin and it is important that its contact be fully dispersed over the entire area of the plate as not to burn the patient. Hence, the term dispersive plate.

Disposable

A term describing a type of accessory that is intended for single use and then disposed of. It typically is made of lower quality materials than that of an accessory classified as reusable and normally comes in a sterile pack.

Dual Cell Dispersive Plate

This is the type of patient electrode employed with a Return Electrode Monitor or REM*. Capacitive reactance is measured across the two cells and a sample is taken. If contact changes between samples, indicating dispersion is less than full area contact, an alarm goes off and the power to the output is interrupted to protect the patient from burns.

Dynamic Impedance

Also referred to as AC impedance, meaning in addition to pure resistance (R) in the circuit, there is also capacitive (Xc) and inductive (XL) reactance and a possible phase shift. The combination of R, Xc and XL measured in ohms make up the total impedance which is frequency dependent. $Z = \sqrt{R^2 + (X_L - X_C)^2}$

E.t.O.

A toxic and flammable gas used to sterilize medical instruments. The instruments are put into special bags to aerate the instruments so the patient or surgical staff do not receive skin burns from the residue. The process includes specially constructed chambers with proper ventilation.

ElectroCautery

A hot thermal knife as opposed to RF Electrosurgery which employs radio waves to cut or coagulate. Still used in urology and other "wet" field operations.

Excise

An electrosurgical technique as opposed to a current mode. Typically, a loop electrode is used to excise tissue for biopsy or to remove diseased tissue. Loops are available in various size diameters.

Flash Autoclave

A sterilization method often used when instruments can not withstand long periods of time under heat. Practices may vary, but typically it is performed @ 270°F under about 30 lbs of pressure for 4 minutes.

FlameOut

This is a term used in R.F. technology to describe an event when a poor connection in the path of RF energy causes a flame to literally jump across the two ends of the connection - an obvious fire hazard.

Flashing

This is a term used in electrosurgery to describe how the electrosurgical electrode flashes when entering and exiting tissue. Typically not a desirable characteristic. Also, denotes source and load impedance mismatch.

Fluoroptic Probe*

A unique method of taking temperature measurements in an R.F. rich environment or in the presence of any electromagnetic field. Employs fluorescence of phosphors and optical signals which are immune to R.F. microwave or other EM environment.

Fulgurate

A Greek term meaning lightning. An electrosurgical technique, typically employing a high-voltage, high crest factor current to create an arch of RF plasma energy across an air gap from the electrode to tissue. Used to stop bleeding without cutting or desiccating.

G-Strip Cell

A bench-top test chamber used by manufacturers to test a generator's immunity from high frequency and fast transients or what is referred to as radiated and conducted immunity tests. It can also be used for pre-compliance testing for emissions. An example of such standards are EN55011, EN55014, and EN55082.

Ground Referenced Output

This is an electrosurgical generator with an output that is referenced to earth as opposed to being isolated from earth. This type is said to be less safe than an isolated type output. Meaning, current could possibly find a path through the operator or staff to ground.

Hard Coag Spray

This is typically a low-impedance, low crest factor output that is pulsed at about 25% duty cycle or less to stimulate a spark gap generator. It has a tendency to penetrate tissue deeper than a high crest factor current which is referred to alternatively as Soft Coag Spray.

Hemostasis

A term used in electrosurgery to describe a technique or result when a hemostat or forceps is clamped on a bleeding vessel and RF energy is applied to stop the bleeding.

High Density Contact

Typically the type of contact made by the exposed portion of an Active electrode. This is what allows current to discharge across the gap impedance between the electrode and tissue to either cut or coagulate.

Inactive Electrode

This is the return electrode. It can be the dispersive electrode in the monopolar operating mode or even the return electrode, opposite the Active electrode in the bipolar operating mode device.

Incise

This is a term describing an electrosurgical technique where tissue is cut or incised. Typically it is performed with either a pure-cut or blended-cut current mode.

Indifferent Plate

An earlier term often used to refer to a dispersive electrode when employing ground referenced generators. When it is applied to the patient's skin to offer a low-impedance return path back to the generator, current is said to be indifferent to alternative paths.

Isolated Output

A term used to describe an electrosurgical generator when its output is isolated from earth making it less likely that RF current will find a path through the operator to ground. Preferred over the older ground referenced type generator.

Laser

A highly concentrated beam of nearly coherent light waves in phase with each other. There are many different types of lasers and as many uses ideally suited for each type.

Leakage Inductance

This arises when magnetic flux is lost from the core and not all linked to the windings. It is measured by shorting the secondary winding and measuring inductance across the primary winding. The effect is that a small amount of inductance is placed in series with the windings.

Letz Wire

A special coated and braided magnetic wire used in high-frequency transformers to eliminate or reduce stray capacitance that would otherwise cause losses, poor energy transfer, and result in heat.

Load Impedance

This is typically defined as the total AC impedance outside the ESU generator - all elements in the active and return circuit path, to and from the generator. It is made up of dynamic impedances of the cables, instruments, active gap impedance (X_c), body impedance (R), and dispersive plate gap impedance (X_c).

Load Response Curve

Given a constant source impedance, the actual power varies as output impedance changes. Manufacturers are required to print a graph of actual maximum power output over changes in output impedance. In the monopolar mode, this is usually 100-1500 ohms and the ideal is a flat response curve. In the bipolar mode, this is usually between 50-200 ohms and the ideal is a high Q or peak response at about 150 ohms and then a sharp drop downward as impedance increases beyond 150 ohms. This, in principle, protects from overheating tissue.

Low Density Contact

This can be a condition at either the Active or Inactive electrode. As the exposed Active electrode increases its contact with tissue, the lower the density contact. However, the term is often used to describe the dispersed contact or low-density contact (full area contact) of the patient return electrode used in the monopolar operating mode.

Monopolar Operating Mode

A mode of operation whereby current returns back to the generator by means of a dispersive electrode attached to the body, providing a low-density contact referred to as the Inactive electrode. The Active electrode is shaped as the high-density contact surgical instrument which cuts or coagulates tissue in a number of ways depending upon the *Technique* used.

MosFet

Defined as a metal oxide semiconductor field effect transistor. This device is capable of switching On and Off at very high rates of speed in the order of several nanoseconds (10^{-9}). This same device in various forms, printed on an IC chip, is what has allowed computers to operate today at clock frequencies of 200 to 400 MHz. The lower the voltage type (die or wafer size), the faster they can switch binary state from 0 to 1s without heat and noise - hence, the 3.3 volt supplies used in laptops. Unfortunately, ESUs require high voltage (large wafer size) power devices that when switched rapidly to run cool in this mode, referred to as *Class D* operation, noise or EMI is a problem. See section 9.2

Necrosis

A greek term, meaning death. In medicine, it is used to describe the state of tissue. In electrosurgery, it is used to describe the state of tissue or depth of necrosis along the lateral wall of an incision just performed by electrosurgery.

Output Filter

Usually made up of capacitive and inductive elements or more advanced feedback means. In a radio transmitter, it is used to peak the frequency response for a signal or improve its Q (bandwidth). In electrosurgery, it is used to shape the reflective load response to control power over a range of load impedance.

Patient Return System

An electronic circuit in electrosurgical generators activated in the monopolar operating mode to protect the patient and operator from burns or alternative current paths. Usually constructed in two ways as covered in section 4 of this book.

Peak Voltage

This is the amplitude of the alternating current waveform when viewing it on an oscilloscope from its common mode or zero level to the top of the positive or negative going signal. To arrive at the rms voltage, this potential must be multiplied by 0.707.

Permeability (μ)

Defined as the ability to conduct flux. A quality characteristic of a transformer's core, sometimes referred to as the B/H curve or saturation curve. Permeability (μ) = $B \div H$ In layman's terms, it simply means how well the transformer's core can be expected to allow energy to be transferred from primary to secondary at a given frequency. There are also different types of permeability, but that is beyond the scope of this book. Its importance to electrosurgery is covered in section 3.3 of this book dealing with Crest Factor.

Phase Shift

It is defined as the displacement of current and voltage. In any power generator, some displacement usually occurs at both the input and output. It is caused by reactance to less than purely resistive elements in a circuit. An inductive reactance causes current to lag voltage and a capacitive reactance causes current to lead voltage. See *Power Factor*.

Pinpoint Spray

This is a selected Coag current mode that typically employs a high-crest factor output, repetitively pulsed at a somewhat slower burst rate to increase the directional characteristics of the RF plasma as it jumps the air gap from the electrode to the target tissue.

Polypectomy

Is defined as the removal of polyps, usually on the colon wall employing a loop snare which first grasps the polyp and then separates it from the colon wall as current is activated and the snare is drawn closed. The sample is typically removed by vacuum and the root is desiccated.

Popcorn Effect

A slang term sometimes used by physicians to describe what happens if a blood vessel is over-heated causing it to burst on either end. An undesirable event during hemostasis.

Power Classification

Until recently, most generators were classified by power in low, mid-range, and high. However, many areas of medicine now employ micro-powered units operating a high frequency to perform precise results. These classifications are covered in more detail in section 2.8

Power Factor

This is defined as actual power divided by apparent power. It is presented by the cosine (θ) and when unity gain is 1.00 both current and voltage are in phase with each other, offering maximum efficiency. See *Phase Shift*.

Pure Cut Current

This is the least destructive current with respect to causing lateral necrosis along the incision wall and is often used to obtain a vital biopsy tissue sample for study. It is "pure", meaning it consists of an RF frequency without modulation, generated from a (fully rectified and fully filtered) supply current. Also referred to as 100% duty cycle current.

RMS

Is defined as Root Mean Square. When referring to power, $P=I^2R$. When unity is less than one, this is the only formula in ohm laws that will accurately provide actual power. It is also referred to as the dc equivalent when calculating rms voltage.

REM

A generic term or abbreviation, defined as Return Electrode Monitor. An advanced patient return electrical system that measures contact density or the quality of dispersion, instead of just cable impedance. A preferred method of monitoring to protect from patient burns.

Reactance

Also defined as AC impedance. It is represented in electrical terms as ohms - either X_c for capacitive reactance or X_L for inductive reactance. With pure resistance, it makes up total AC impedance of a circuit. See *Phase Shift*.

Reusable

A term describing a type of accessory that is intended for limited repetitive use and should come with sterilization procedures to assure at least 20 use cycles. Integrity of the accessory or device is regulated by the AAMI Standard HF-18. It typically comes in a non-sterile package. See section 7.3 in this booklet.

Ring Frequency

This term is used to describe the damped sinusoidal waveform that is generated by an inductively discharged power oscillator. A repetitive pulse is used to generate the number of these events over a period of time.

Semi-Disposable

A term describing the type of accessory that is intended for more than *Single Use*, but not the full 20 use cycles that a device must endure to be classified *Reusable*, based upon the AAMI standard HF-18. It typically comes in a sterile pack with instructions for sterilization. See section 7.4 in this booklet.

Single Cell Dispersive Plate

This is a type of patient electrode employed while operating in the monopolar mode with a cable interrupt type system to monitor cable impedance or a disconnect back to the generator. As opposed to a Dual Cell Dispersive Plate, it has only one large cell or foil area to disperse the RF energy and return it back to the generator.

Smith Chart

A special chart for calculating phase shift, impedance, and transfer by RF design engineers. First developed in the 1930s by Phillip H. Smith, it continues to be used in the form of slide rules or even concurrent engineering (EDA) software. The $\pm j$ operators (a symbol of trigonometry) are used to plot these qualities in a transmission line or RF output circuit. X_L is represented as $(+j)$ and X_C is represented $(-j)$.

Soft Coag Spray

This is typically a high impedance, high *Crest Factor* output that has less penetrating characteristic when applied to stop bleeding. Hence, the depth of tissue necrosis is shallow as opposed to the results after using *Hard Spray*.

Source Impedance

This can best be defined as the AC impedance in ohms looking back into the generator's output when peak output is achieved. It is empirically measured by applying a load impedance until a wattmeter peaks. In the case of R.F. output it is best to use an R.F. thermal couple type ammeter. A simple light bulb can also be used.

Square Law Detector

This is a type of feedback circuit used in RF transmitters to maintain a desired power output during operation regardless of transmission line or antenna impedance encountered.

Square Rooting Circuit

An advanced feedback circuit to accomplish the task of a *Square Law Detector*. A current mode four-quadrant multiplier or similar square rooting circuit used to provide feedback to an error or differential amplifier to control output. Typically, ESU generators do not have this built-in feature. However, generators used in microsurgery often employ such circuits to prevent flashing as the Active electrode enters and leaves the tissue.

Suction Coagulator

An accessory device used in electrosurgery to remove blood by vacuum to clear the surgical site prior to coagulating the site. The vacuum is switched On and Off by a small venturi port on the device.

Technique

The method of applying an electrode and current to the tissue, as opposed to the type of current mode. Examples are incising, excising, desiccating, fulgurating, and hemostasis. See section 3.2

True Damped Wave

This describes the appearance of an inductively discharged current that provides an initial high-voltage pulse and then tapers off to zero. In electrosurgery, it is generated at a repetitive rate to coagulate tissue. The frequency within the event is sinusoidal and its frequency is referred to as *Ring Frequency*, usually 450kc or higher.

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