



ESU Testing (60601-2-2)

Sponsored by



Electrosurgical History & Theory

ESU Testing and Calibration Training

Focus - HF Leakage Testing



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History of Electrosurgery

Founders of modern Electrosurgery



Development of the first commercial electrosurgical device is credited to William T. Bovie, who developed the first electrosurgical device while employed at Harvard University. The first use of an electrosurgical generator in an operating room occurred on October 1, 1926 at Peter Bent Brigham Hospital in Boston, Massachusetts. The operation—removal of a mass from a patient's head—was performed by Harvey Cushing. The low powered hyfrecator for office use was introduced in 1940.

Electrosurgery

HF a.c. current applied to biological tissue



Electrosurgery is the application of a high-frequency electric current to biological tissue as a means to cut, coagulate, desiccate, or fulgurate tissue.

Electrosurgical devices are frequently used during surgical procedures because they help to prevent blood loss by sealing the tissue and blood vessels during the cutting of the tissue.

Electrosurgery can be used to achieve either the mass destruction of large volumes of tissue as in endometrial ablation, fine incision as required by the reconstructive microsurgeon, or tasks requiring both cutting and coagulation, such as incision of the skin and subcutaneous tissue with hemostasis.

Electrosurgery

Is not electrocautery or diathermy



Although **ESU** devices may be used for the **cauterization** of tissue in some applications, electrosurgery is usually used to refer to a quite different method than electro cautery.

Cautery uses heat conduction from a probe heated to a glowing temperature by a direct current (much in the manner of a soldering iron).

Electrosurgery, by contrast, uses alternating current to directly heat the tissue itself. This heat causes the destruction of small blood vessels and halting of bleeding correctly called **coagulation**

Often electrosurgery is mistakenly referred to as diathermy.

Diathermy means dielectric heating, a high-frequency electric current delivered via shortwave, microwave, or ultrasound to generate deep heat in body tissues. This effect is most widely used in microwave ovens which operate at gigahertz frequencies.

Electrosurgery

Applied EMF to biological tissue



To understand electrosurgery, it must be clear that the effects obtained are the result of heat. This heat is derived from the rapid changes in the direction (polarity) that a.c. current flow provides. There is no net transfer of electrons, and likewise, no movement of ions across cell membranes (depolarization). Part of the heat generated is from the tissue's impedance (resistance to current flow), but the majority of heat stems from the **rapid vibration of molecules** within the tissue under the effect of the changing electromagnetic field.

EMF. **E** is voltage and **H** is magnetic force in physics.

We will discuss testing for dangerous levels of **H** or **HF leakage** today.

Please ask questions now if you have forgotten your right hand rule from basic electronics or physics class.

Electrosurgery Modes

Monopolar versus bipolar

The main difference between these two modalities is that in monopolar surgery, the current goes through the patient to a return electrode (patient pad or neutral electrode) to complete the current cycle, while in bipolar surgery, the current only passes through the tissue grasped between the two electrodes of the instrument.

Electrosurgery Modes

Cut: Desiccation versus Fulgeration

- In Cut mode, tissue is vaporized as the HF current passes through the tissue and the heat of vaporization seals the tissue surrounding the cut tissue
- In Cut mode, if the electrode touches the tissue it is *desiccated*.
- If the electrode is held over the tissue and an air gap is present allowing the current to jump the gap and *fulgerate* the tissue.
- Sometimes the energy that jumps the gap is called RF Plasma energy.

Tissue Effects

•Desiccation

is the state of extreme dryness, or the process of extreme drying. A desiccant is a hygroscopic (attracts and holds water) substance that induces or sustains such a state in its local vicinity in a moderately sealed container.

Desiccation in ElctroSurgery is produced by low current and relatively higher voltage applied over a broad area, producing a low current density. In desiccation, the cells are shrunk and shriveled with elongated nuclei. Cellular detail is preserved. This effect is produced by the loss of water from the cells, without extensive coagulation of proteins.

Tissue Effects

•Fulguration

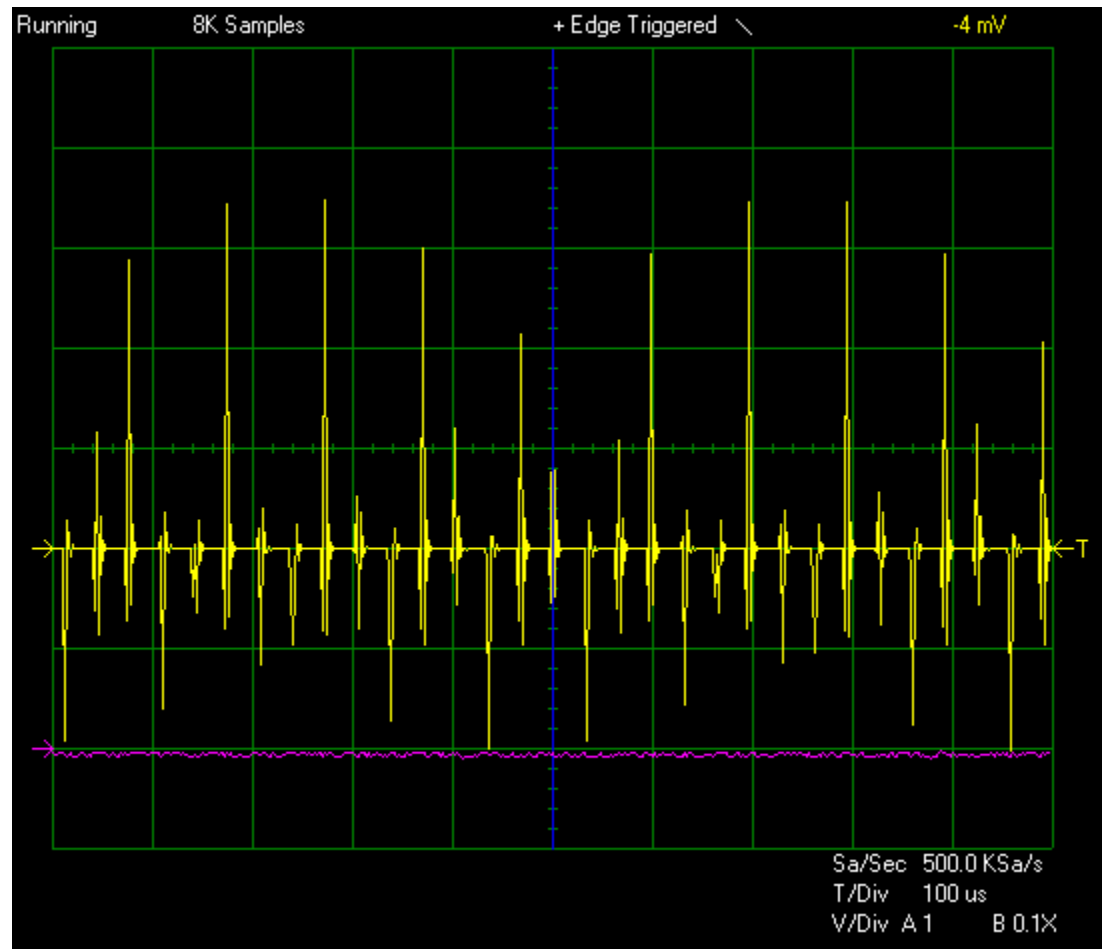
is a procedure to destroy and remove tissue (such as a malignant tumor) using a high-frequency electric current applied with a needlelike electrode.

Fulguration results from the action of electrical arcs striking the tissue at widely divergent locations, producing a localized instantaneous high current density, but a low average current density. The characteristics of fulguration are localized tissue destruction and large amounts of carbonization. Localized destruction occurs because, after the arc strikes, current is dispersed widely, causing rapid diminution of current density and little generation of heat in the deeper structures. Carbonization is due to the high temperature of the tissue at the point of the arc strike. The thin layer of carbon and the desiccated tissue beneath it form an insulating barrier, decreasing the probability of subsequent arc strikes in the same location. Fulguration requires low amperage and high voltages to overcome the resistance of the large distances between electrode and tissue.

Electrosurgery Modes

Coagulation

Coagulation mode is used to perform hemostasis and vessel sealing.



Tissue Effects

•Coagulation

is the process by which blood forms clots. It is an important part of hemostasis, the cessation of blood loss from a damaged vessel, wherein a damaged blood vessel wall is covered by a platelet and fibrin-containing clot to stop bleeding and begin repair of the damaged vessel.

Coagulation occurs at higher current densities than desiccation, resulting in higher tissue temperatures. The tissue fluids boil away and the proteins become denatured, forming a white coagulum similar to that produced when an egg white is boiled. There is loss of cellular definition as all tissue structures fuse into a formless, homogenous mass with a glassy or transparent appearance. This is the classic appearance of coagulation necrosis.

ESU modes and Surgical objectives

Can be confused



Surgeons have categorized ESU modes by:

- The changes to the structure of the cells

 - Desiccation

 - Coagulation

- The type of cut different waveforms produce

 - Fulgeration

 - Vaporization

Electrical engineers have categorized ESU modes by:

- The shape of the waveform

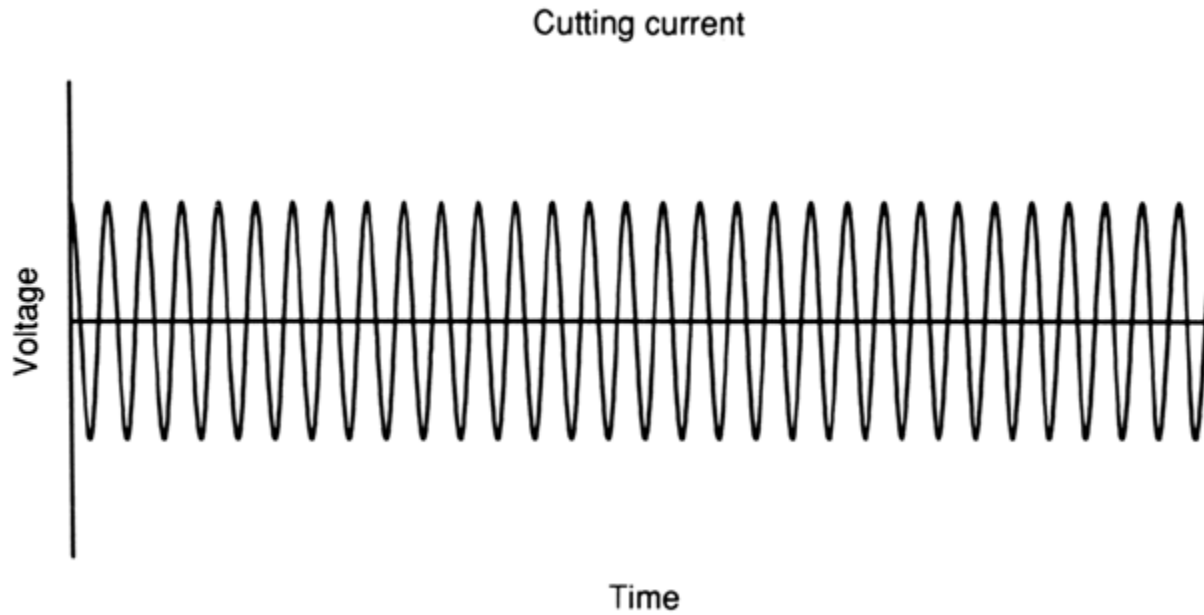
 - Cut

 - Coag

Both Cut and Coag have desiccation and fulgeration options

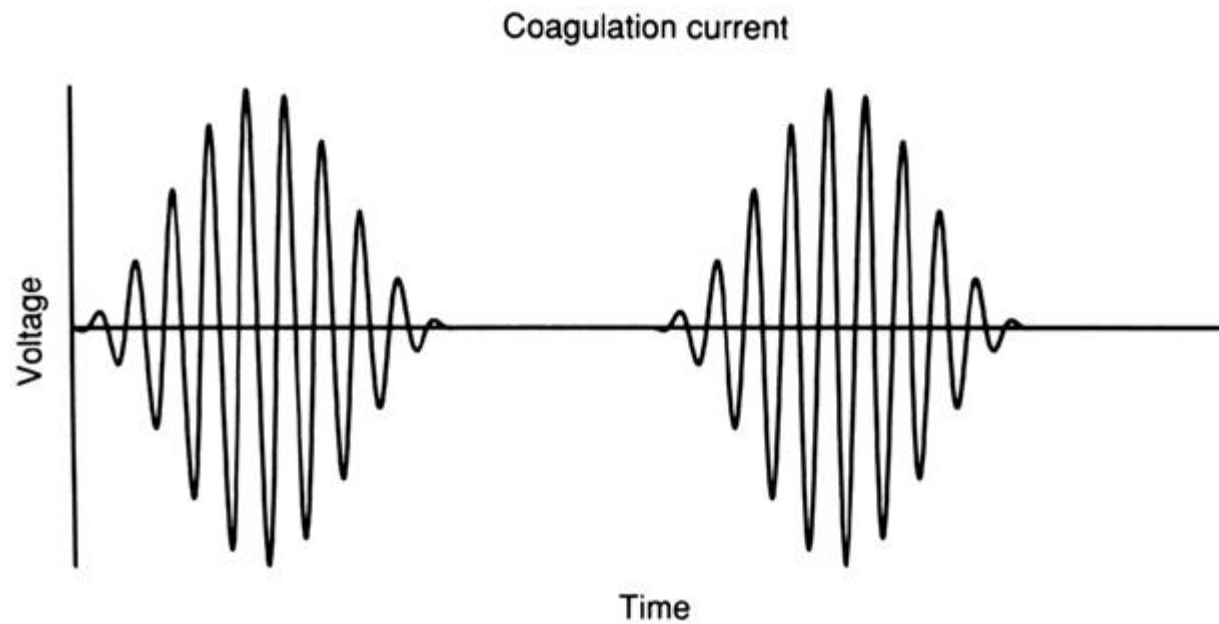
Electrosurgery

Pure sinusoidal waveform

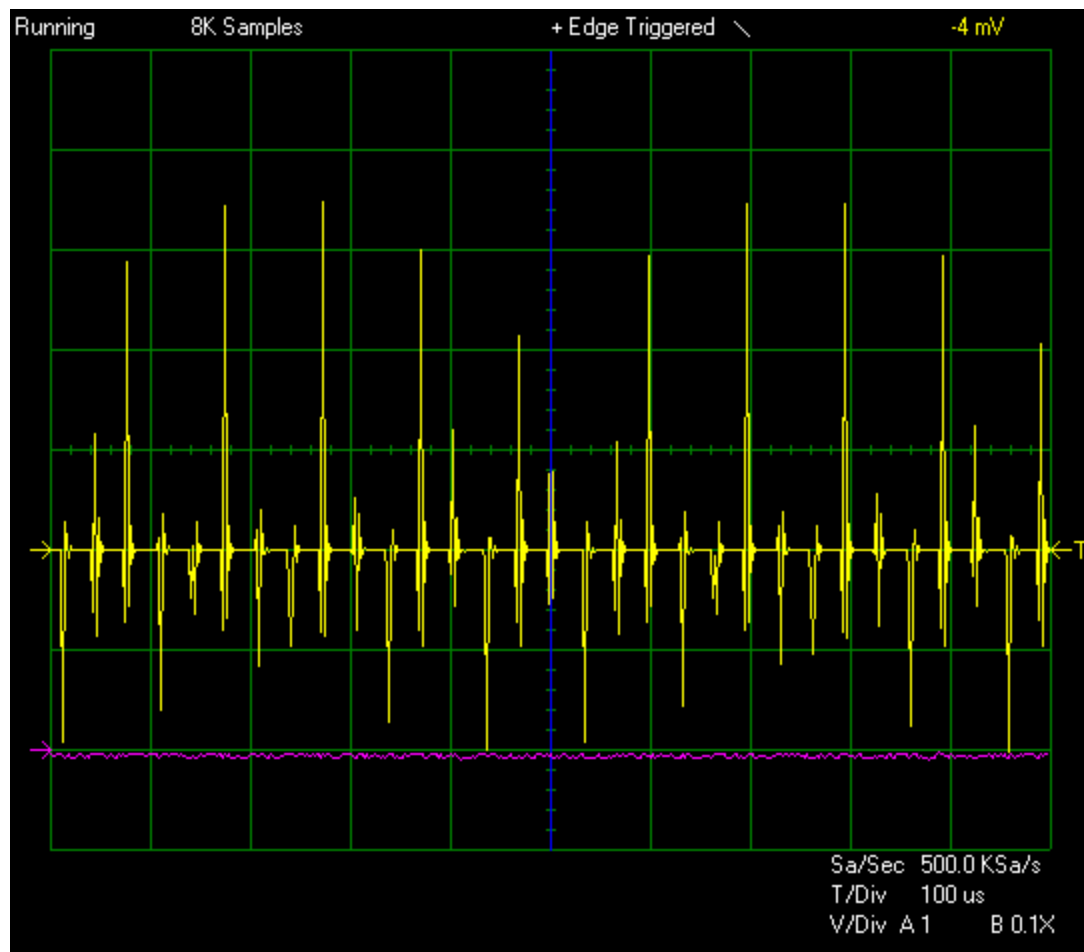


Electrosurgery

Amplitude modulated sine wave

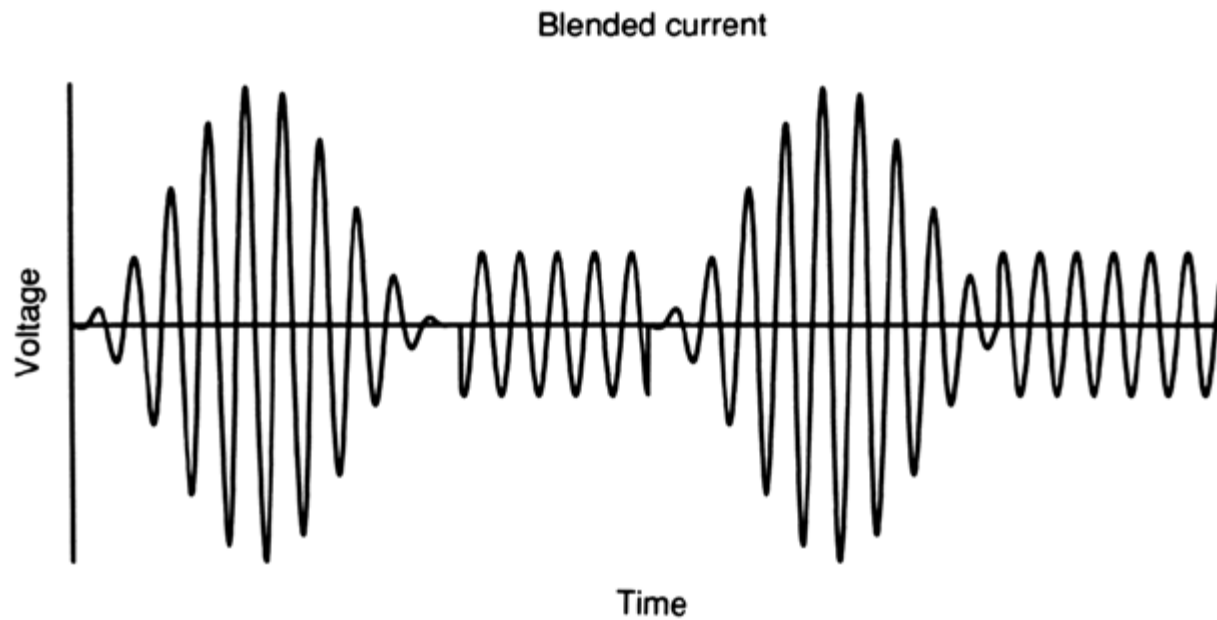


Coagulation Fulgeration waveform



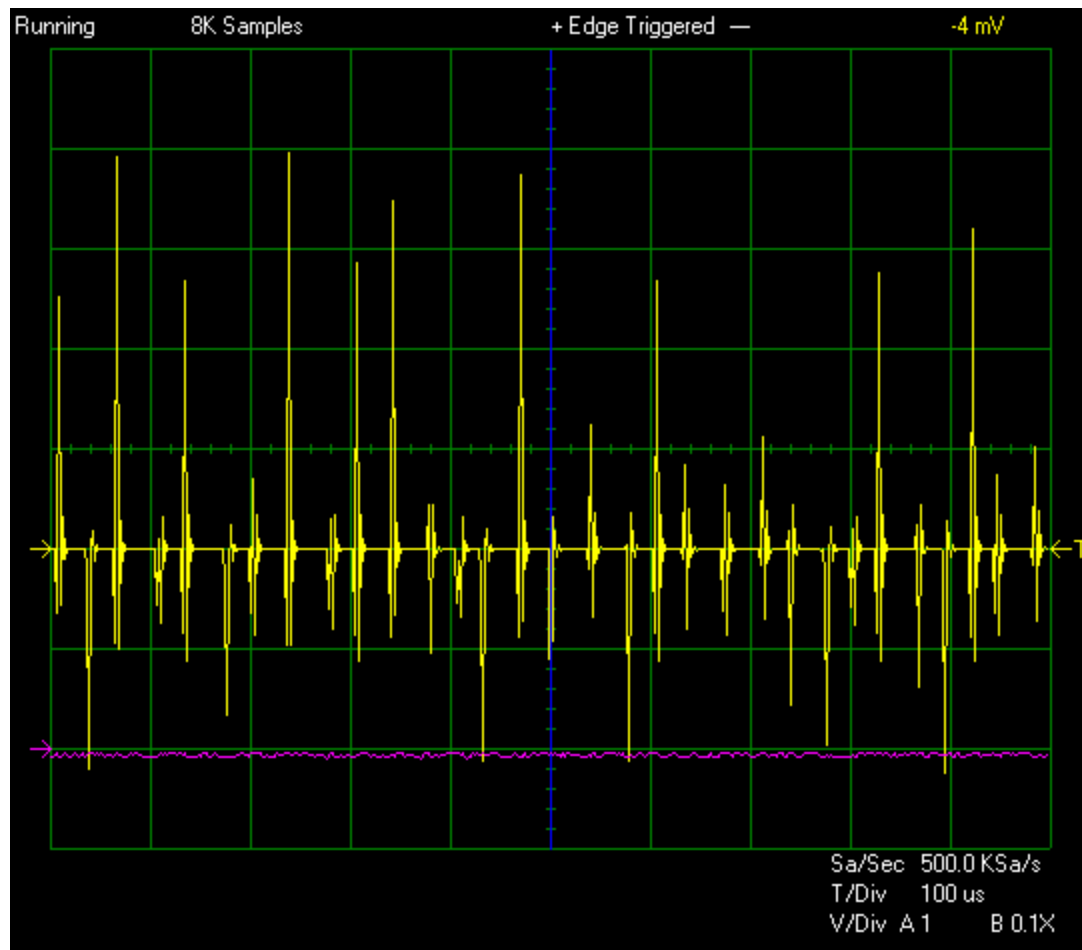
Electrosurgery

Blend waveform



Coagulation

Coag Spray waveform



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IEC 60601-2-2

AAMI/IEC 60601-2-2 specifies requirements for the safety of high frequency (HF) surgical equipment and HF surgical accessories used in medical practice. Some low-powered high frequency surgical equipment (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain requirements of this particular standard.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of high frequency surgical equipment.

Typical P.M.I. for an ESU

- Check the power output
- Current, wattage, V_{rms} & V pk-pk
- Check the return electrode monitoring circuit (the neutral or dispersive pad)
- Check the HF leakage
- Test the E.S.T., foot pedals and controls
- Always to manufacturer's guidelines

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IEC 60601-2-2

Why test ESU's for HF leakage?

- High frequency leakage test of electrosurgical generators is **required** as specified in the standard.
- *Why? It involves patient safety.*
- Insure that the ESU circuitry is properly limiting the amount of capacitive leakage of high frequency current
- At frequencies exceeding 400kHz, the electrical current has a tendency to stray
- Leading to decreased functionality and potential patient injury

Electrosurgery

19.3.101 Thermal effects of HF LEAKAGE CURRENTS

In order to prevent unintended thermal burns, HF LEAKAGE CURRENTS tested from ACTIVE and NEUTRAL ELECTRODES with PATIENT CIRCUITS activated shall, depending on their design, comply with the following requirements.

a) *HIGH FREQUENCY LEAKAGE CURRENTS*

1) *NEUTRAL ELECTRODE referenced to earth*

The PATIENT CIRCUIT is isolated from earth but the NEUTRAL ELECTRODE is referenced to earth at HIGH FREQUENCIES (see Figure 103) by components (for example a capacitor) satisfying the requirements of a TYPE BF APPLIED PART. When tested as described below, the HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE through a non-inductive 200 Ω resistor to earth shall not exceed 150 mA.

Electrosurgery

IEC 60601-2-2

Figure 105 – Measurement of HF LEAKAGE CURRENT with NEUTRAL ELECTRODE referenced to earth and load from ACTIVE ELECTRODE to earth (see test 2 of 19.3.101 a) 1))

2) NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY

The PATIENT CIRCUIT is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Compliance is checked by the following test.

The HF SURGICAL EQUIPMENT is set up as described for test 1 of 19.3.101 a) 1), the output being unloaded and loaded at the RATED LOAD. Any metal ENCLOSURES of CLASS II HF SURGICAL EQUIPMENT and INTERNALLY POWERED HF SURGICAL EQUIPMENT shall be connected to earth. HF SURGICAL EQUIPMENT having an insulating ENCLOSURE shall be positioned on earthed metal having an area at least equal to that of the base of the HF SURGICAL EQUIPMENT, during this test (see Figure 106). The HF LEAKAGE CURRENT is measured from each electrode in turn while the HF SURGICAL EQUIPMENT is operated at maximum output setting in each HF SURGICAL MODE.

IEC 60601-2-2

Why test ESU's for HF leakage?

One study.....

31 insurance companies associated through Physician Insurers Association of America (PIAA)

Data from 615 claims associated with laparoscopy procedures using electrosurgery

Found that a majority of claims resulted from

Thermal damage to unintended patient tissue.

What kind of problems?

Risk to patient

This capacitive coupling can be, in part, responsible for serious patient complications. Some methods used to minimize capacitive coupling are active electrode shielding, dispersive metal cannulas, sheathed guide wires, and bipolar active electrodes.

What kind of problems?

Decrease of functionality

- As leakage increases, the thermal density of the surrounding patient tissue increases, both at the active electrode and the dispersive electrode.
- Thermal density causes unnecessary tissue damage.

What kind of problems?

HF Interference of Other Medical Devices

- Implanted medical devices.
- Endoscopic camera images.
- In-room viewing cameras.
- ECG monitors.

What kind of problems?

Direct or indirect coupling of HF currents

- Direct
- Indirect
 - Capacitively coupled
 - Inductively coupled

Capacitively coupled currents may not be appreciated during laparoscopic and endoscopic radiofrequency electrosurgery. Two specific problems are documented and quantified: coupling of current into metal trocar cannulas during laparoscopic surgery and coupling of current into a guide wire during endoscopic surgery, which can in turn be dissipated into patient organs such as the bowel or the common bile duct.

What is tested?

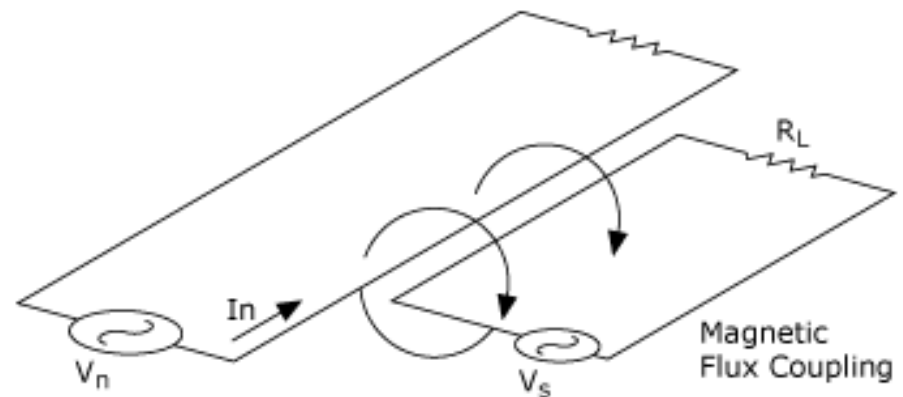
HF output current from active and dispersive electrode to earth ground

- Both active and return electrode should be tested
- The tests simulate a failure in either electrode and how well the ESU shields the resulting leakage
- Leakage should not exceed 150 milliamps or 4.5 watts to earth ground through a 200 ohm load

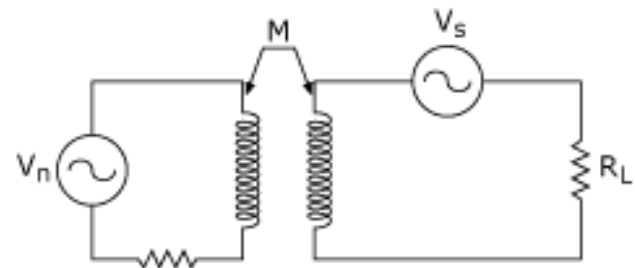
How does leakage occur?

Indirect coupling

Indirect coupling occurs when the RF energy induces a secondary, non intended current path through a conductive surface



a. Physical Representation



b. Equivalent Circuit

Direct Coupling

Unintended contact with a conductive surface

A tiny defect in the insulation of instruments in the surgical area may deliver (unobserved) a portion of the current to non-target tissue. In addition, most instruments (especially the articulating scissors and grasper-dissectors) have been designed with a significant amount of exposed metal at the distal tip. At best, the instrument may “ground out” on non-target tissue; however, it is also possible that the bowel or other structures could be burned outside the immediate view of the scope. It is also possible for the exposed metal of the active instrument to be in contact with other conductive instruments (the laparoscope or a metal clip) and a portion of the current may be conducted to tissue outside the visualized field.

How to Test?



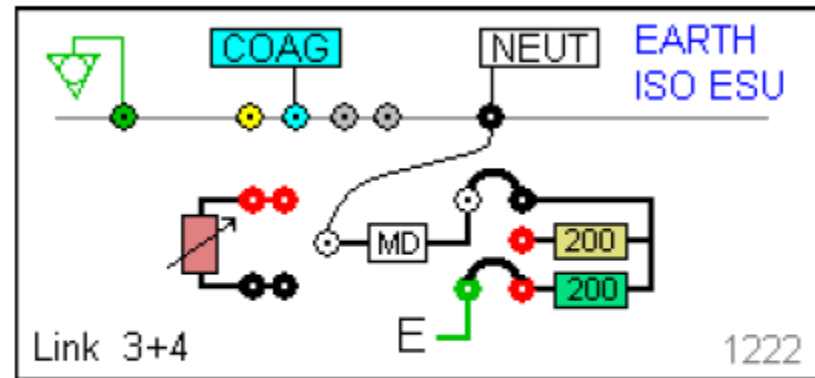
OR



How to Test?

TEST CODE 1222

IEC 601-2-2 part 1 FIGURE 103
MEASUREMENT OF H.F.
LEAKAGE CURRENT WITH
NEUTRAL ELECTRODE
ISOLATED FROM EARTH AT
HIGH FREQUENCY EARTH
ISOLATED ESU MONO-POLAR
ELECTRODE **COAG** MODE
NEUTRAL ELECTRODE



⚠ REFER TO USER MANUAL FOR LOAD PERFORMANCE

Scope
Output

MD

5-5115Ω

2

200

200



User Test

Monopolar HF leakage open ative electrode
check. Select Mono Cut. Set to 300 watts.

PASS

FAIL

Load 200 ohms

Leakage 41 mA

Limit 200 mA

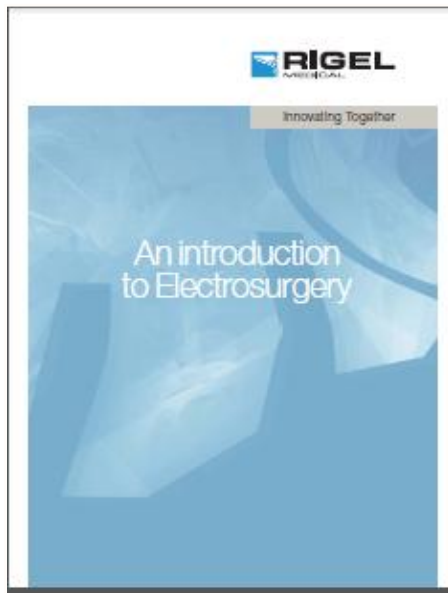
Pass



OK

Test Complete

Guide to Electrosurgery



Pick up a free copy or email me at jackb@seaward-groupusa.com for e copy.

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