CYNOSURE
A Hologic Company

ellman®
surgitron®

4.0 Dual RF™/90 IEC

Instruction Manual

(English-English)

NEW PRODUCT WARRANTY

New products manufactured by Cynosure, are warranted against any defects in material or workmanship for a period of one (1) year following the date of shipment to the Buyer. Cynosure, at its option, will repair or replace the same without charge, provided Buyer ships the product to Cynosure, transportation charges prepaid. Buyer must call Cynosure in advance at 888.523.2233 to request a Return Merchandise Authorization (RMA) number.

Warranty shall not apply to product that was not properly installed, maintained and operated within the limits of rated and normal usage. Warranty shall not apply to product that has been subjected to an accident, tampering, alteration, misuse, abuse, negligence, fire or water damage. Warranty does not cover defects or damage caused, directly or indirectly, as a result of service by unauthorized personnel and/or the use of unauthorized replacement parts or accessories.

Cynosure's liability under this warranty, or any other warranty, whether express or implied in law or fact, is limited to repair or replacement of defective material and workmanship, and in no event shall Cynosure be liable for consequential or indirect damages.

PATENTS

Ellman brand high frequency energy sources are covered by one or more of the following patents:

5,954,686
6,652,514
6,994,707
7,094,231
7,479,140

Caution

Federal law restricts this device to sale by or on the order of a Physician

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I. INTRODUCTION

1.0 INTRODUCTION TO RADIOSURGERY®

Radiosurgery® with Ellman's Surgitron® 4.0 Dual RF™/90 IEC system (Surgitron® Dual/EMC) is an excellent method of cutting and coagulating soft tissue. With five waveforms (4 monopolar and 1 bipolar) and a wide selection of electrode tips, the user can easily configure the system for a wide array of applications.

1.1 INTENDED USE

The intended use for the Surgitron® Dual/EMC is:

1.1.1 Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, development of skin flaps, skin tags and blepharoplasty.

1.1.2 Blended cutting and coagulation: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cysts, abscesses, and development of skin flaps.

1.1.3 Hemostasis: control of bleeding, epilation, telangiectasia.

1.1.4 Fulguration: basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis.

1.1.5 Bipolar: pinpoint precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage.

NOTE: The Surgitron® Dual/EMC generator is not designed to withstand the demands of lengthy wrinkle treatment procedures. The generator will overheat and possibly fail. Such failures will not be covered by warranty.

II. SAFETY

Improper use of this, or any high frequency surgical instrument, can result in a patient injury. Read and become familiar with all directions before using this product.

2.0 WARNINGS

2.0.1 High frequency surgical equipment should be used only by persons having adequate training and familiarity with high frequency surgical equipment and related techniques. A thorough understanding of the use of high frequency surgical equipment is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical equipment. Consult medical literature relative to related techniques, complications, and hazards prior to use of high frequency surgical equipment.

2.0.2 Never increase the power settings without first checking both the active electrode and the neutral plate.

2.0.3 Ocular Shields (plastic, non-conductive) must be used for any radiofrequency surgical procedure involving the eyelid and the immediate surrounding areas.

2.0.4 Use only with Ellman accessories including Ellman handpieces, neutral plates, cables, and electrodes.

2.0.5 When using an active electrode near a metal (conductive) accessory, ensure the electrode does not come into contact with the metal accessory.

2.0.6 Failure of high frequency surgical equipment could result in an unintended increase of output power.

2.0.7 Use a compatible neutral electrode with a contact quality monitor to ensure the auditory alarm will sound in the event of loss of safe contact between the neutral electrode and patient.

2.0.8 Risks resulting from neuromuscular stimulation can occur, especially with modes producing electrical arcs between active electrode and tissue.

2.0.9 Do not maintain or service equipment while in use. Maintaining or servicing equipment while in use may result in possible injury to the operator or patient.

2.1 PRECAUTIONS

2.1.1 General

2.1.1.1 Electrical shock hazard. Do not remove cover. Refer to authorized personnel for service.

2.1.1.2 Surgitron® Dual/EMC may present a hazard to patients with pacemakers. Consult qualified medical personnel.

2.1.1.3 The manufacturer-supplied accessories should be used to ensure the proper operation of safety monitoring circuit.

2.1.1.4 If higher than normal power settings are required, examine all cables, handpieces and the neutral plate for damage and confirm that cables are not wrapped around metal objects or touching the floor. In the event that higher power is still required, replace the neutral plate and handpieces.

2.1.1.5 WARNING: No modification of this equipment is allowed.

2.1.1.6 The patient should not come into contact with metal parts which are earthed or which have appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose.

2.1.1.7 Physician to patient skin to skin contact should be avoided. Use of insulating gloves is recommended. Patient skin-to-skin contact (eg, between the arms and body of the patient) should be avoided (eg, by insertion of dry gauze).

2.1.1.8 When used simultaneously with physiological monitoring equipment, the monitoring electrodes on the patient should be placed as far as possible from the surgical electrodes. Do not use metal needle monitoring electrodes or EKG clip electrodes as burns may occur. Monitoring systems incorporating high-frequency current-limiting devices are recommended.

2.1.1.9 The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored segregated from the patient.

2.1.1.10 The output power selected should be as low as possible for the intended purpose.

2.1.1.11 Apparent low output or failure of the surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral plate or poor contact in its connection.

2.1.1.12 Before each use inspect the accessories, electrode cables and probes for possible physical damage.

2.1.1.13 Do not obstruct air circulation vents on the rear or underside of the generator.

2.1.1.14 Surgical gloves should be worn to prevent the User from becoming a part of the RF energy return pathway.

2.1.1.15 Use caution when treating subjects with metal implants. Metal implants in the electrical pathway (between the neutral plate and electrode) have the capacity to conduct energy and/or become warm.

2.1.1.16 High frequency surgical equipment output from either active electrode may change when operating mode is changed.

2.1.1.17 Select associated equipment and active accessories that have rated accessory voltages equal to or greater than the maximum output voltage. Avoid high frequency voltage settings where maximum output voltage may exceed rated accessory voltage.

2.1.1.18 For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

2.1.1.19 Similar to all energy sources, by-products such as tissue smoke plume and aerosols, create a health concern about their carcinogenic and infectious potential. Appropriate protective measures including effective smoke evacuation should always be utilized.

2.1.2 Neutral Plate

NOTE: See Neutral Plate Instructions for Use for detailed device and use information.

2.1.2.1 The use and proper placement of the neutral plate is essential to the safe and effective use of this device in order to prevent burns from the neutral plate. The neutral plate should be reliably attached with its entire area attached to the patient's body as close as possible to the operating field. The neutral plate must make complete skin contact.

2.1.2.2 Use only Ellman supplied neutral plates.

2.1.2.3 To prevent burns at site of neutral plate, use lowest possible output settings, ensure proper patient preparation, and/or limit duration of activation.

2.1.2.4 When performing procedures requiring high power and long duration (eg, wrinkle treatment), ensure use of the largest Ellman neutral electrode available and that its entire surface area is adhered to the patient.

2.1.2.5 Ensure the neutral pad is placed in closer proximity to the patient's treatment area than any ground referenced patient contact points such as monitoring electrodes.

2.1.3 Flammable Environment

2.1.3.1 Some materials, for example cotton, wool, and gauze when saturated with oxygen may be ignited by sparks produced in normal use of the equipment.

2.1.3.2 Do not use the Surgitron® Dual/EMC in the presence of flammable anesthetics or other flammable gases, flammable liquids, or flammable objects.

2.1.3.3 Do not use this device in oxygen enriched atmospheres or in the presence of nitrous oxide (N_20).

2.1.3.4 Use only non-flammable agents for cleaning.

2.1.3.5 Flammable agents used as solvents for removing adhesives should be allowed to evaporate before powering on the Surgitron® Dual RF™. Any flammable fluid pooled under the patient or in the body depressions should be mopped up prior to using the Surgitron® Dual RF™. Attention should be called to the danger of ignition of endogenous gases.

NOTE: To ensure safe and reliable operation, the Surgitron® Dual/EMC unit and relevant accessories should be checked for wear and tear before operation.

A maintenance contract with the manufacturer or one of its authorized service agents is recommended after the warranty period.

In the event of malfunction, the device must be returned or serviced by a Cynosure-authorized technician for repair.

III. TECHNICAL INFORMATION

3.0 PACKING LIST

3.0.1 Surgitron® Dual/90 IEC (IEC3A-S30-90/110 or IEC3A-S30-90/220)
3.0.2 IEC Power cord 12ft (IEC-PC110, IEC-PCEU, IEC-PCUK, or IEC-PCANZ)
3.0.3 Instruction Manual (DIM-50-65)

ACCESSORIES (See Catalog)

3.0.4 Disposable Neutral Plates 9.5 ft (IEC-NPD)
3.0.5 Dual Footswitch & Cable 12 ft (DF-FSC#)
3.0.6 Cart (H156 or H157)
3.0.7 IEC Foot Controlled Handpiece, 1/16 shaft 11 ft (IEC-HP1)
3.0.8 Bipolar Cable 12 ft (IEC-JX/B)
3.0.9 3-Button Fingerswitch Handpiece 12 ft (IEC-3FHPB)
3.0.10 Disposable 3-Button Fingerswitch Handpieces 12 ft (IEC-3FHPB/D)
3.0.11 Disposable Electrodes (DSEP40)
3.0.12 Electrode Set 1/16 Shaft (S10B)
3.0.13 Bipolar Forceps (J1)

3.1 SUPPLIER'S INFORMATION

Cynosure, LLC
5 Carlisle Road
Westford, MA 01886, USA
Tel: 888.523.2233 Fax: 978.349.6152/978.256.4888

Supplier will make the following available upon request; circuit diagrams, component parts list, description, calibration instructions or other information necessary to assist technical personnel. All Generators isolate their circuits electrically from the supply mains on all poles simultaneously by using an input power transformer. Dispose or recycle according to local regulations. Do not dispose of this device in the unsorted municipal waste stream.

ATTENTION: Alcohol must never be used to clean and disinfect the front panel

3.2 CLEANING, DISINFECTING AND STERILIZING THE UNIT AND ACCESSORIES

3.2.1 Cleaning and disinfecting the unit: Cleaning and disinfecting of the unit should only be done with nonflammable and nonexplosive agents. Use mild water-based detergents. Make sure that no moisture or detergents enter the unit. If cleaning or disinfecting the unit with flammable or explosive agents is unavoidable, these must be completely evaporated before the Surgitron® Dual/EMC is switched on.

3.2.2 Handpiece and Electrodes.
Always clean and disinfect the electrodes prior to sterilization.

Tissue residue can be removed from the active electrode with a sterile moist cloth, steel or copper wool. No scalpel, scissors or similar pointed objects should be used for cleaning the electrodes, since they may damage the electrode surface. Such damage increases adhesion of tissue to the surfaces of the electrodes during use.

Disinfect and sterilize handpieces and electrodes according to the directions supplied with them.

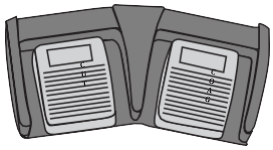
All autoclavable products should be routinely inspected for any wear, breaks, or deterioration of the insulation, and should be discarded and replaced if any of these occurrences exist.

3.2.3 The dual footswitch is a waterproof unit; it can be cleaned with regular detergent.

IV. DESCRIPTION OF CONTROL ELEMENTS

4.0 INTERFACE ACCESORIES

4.0.1 Two Pedal Footswitch



A heavy duty waterproof dual footswitch for CUT and COAG modes is supplied. The mode selectors described in 4.2 determine the cut and coag modes activated by the respective footswitch. The footswitch indicators described in 4.2, and will indicated the activated mode. The yellow footswitch indicator will be ON when the CUT footswitch is depressed. The blue footswitch indicator will be ON when the COAG footswitch is depressed. The footswitch indicators are normally OFF until one of the footswitch pedals is depressed.

The footswitch may be used with any handpiece compatible with the Surgitron® Dual/EMC.

4.0.2 Handpieces

A variety of handpieces are available for use with the Surgitron® Dual/EMC. A three-button handpiece adds convenience by enabling the user to control CUT, BLEND, and COAG modes via fingerswitch. The depressed button will control output function and disregards the front panel display setting. The fingerswitch operational features are as follows:

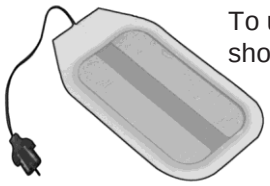
4.0.2.1 CUT button will activate CUT mode. When depressed, the Yellow Light (CUT) Indicator will be illuminated.

4.0.2.2 BLEND button will activate BLEND mode. When depressed, The Yellow Light (BLEND) Indicator will be illuminated.

4.0.2.3 HEMO button will activate COAG mode. When depressed, the Blue Light (COAG) indicator will be illuminated.

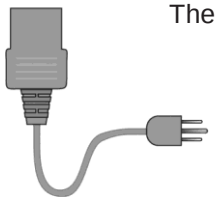
4.0.3 IEC-NPD disposable neutral plate

The IEC Neutral plate must be used with the RF Generator during activation. To use, insert the molded plug of the Neutral Plate into the RF Generator as shown in Figure 4.2.



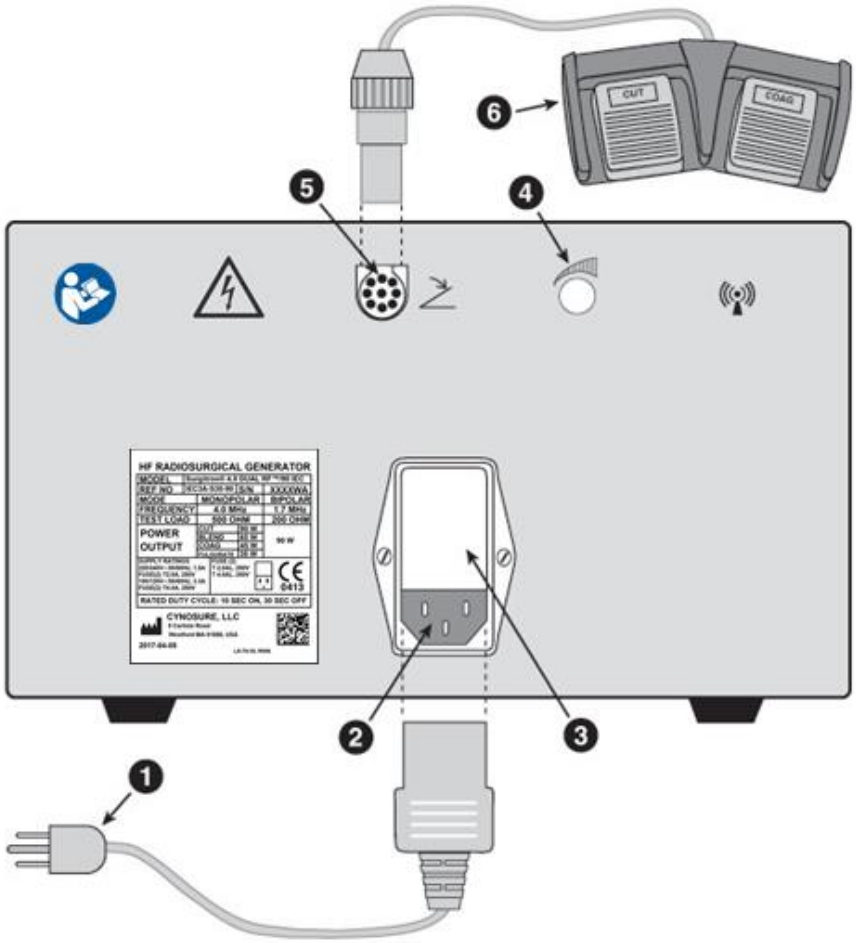
4.0.4 Power Cord

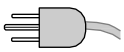
The power cord connects the RF Generator to the supply mains.



4.1 REAR PANEL CONTROL ELEMENTS

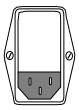
Figure 4.1 Rear Panel





1 **Power Cord:** The Surgitron® Dual/EMC unit is shipped with a hospital grade power cord. WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2 **Power Socket:** The Surgitron® Dual/EMC unit must be connected to correctly installed sockets with a grounded earth conductor using the power cord supplied by the manufacturer.



3 **Line Fuses:** The unit is protected with two line fuses. If a fuse blows, the unit should be checked for possible faults before the fuse is replaced and the unit is operated again. Always replace with a fuse of the same rating. See 4.1.1 for details.

4 **Audio Volume Control:** The volume of the acoustic signal should be set to a volume that can easily be heard by the user.

5 **Footswitch Receptacle:** The Footswitch receptacle mates with the supplied Ellman Surgitron® Dual/EMC Footswitch Pedal.

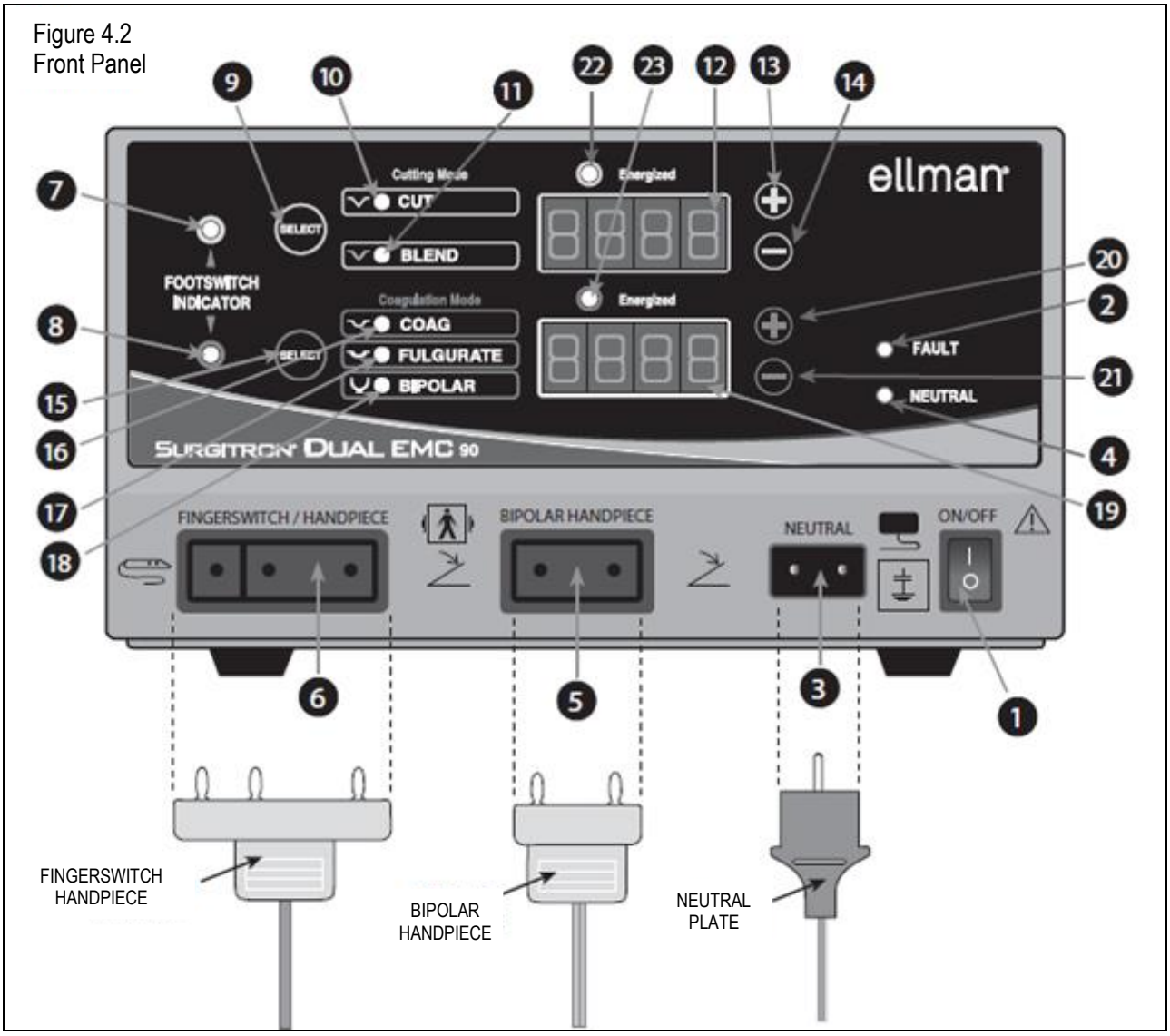
6 **Dual Footswitch Pedal:** The unit is shipped with a waterproof footswitch.

4.1.1 Line Fuse Replacement: Using a flat screwdriver, pry open the top of the line fuse door. Remove two fuse holders. Replace fuses with the same value/size fuses ONLY. The fuse holder arrows should be pointing towards the right. Snap the compartment back with the fuses inside. See Figure 4.1.1 below.

Figure 4.1.1
Fuse Replacement

4.2 FRONT PANEL CONTROL ELEMENTS

Figure 4.2
Front Panel



1 Power Switch:

When the power switch is turned on, the unit automatically performs the following functions:

- The audio signal is sounded.
- All start up sequences of tones on the front panel are activated during the functional test.
- All front panel LEDS are illuminated.
- The patient return neutral plate is tested. If the neutral plate is not properly connected to the patient and/or Surgitron® Dual/EMC, the Neutral LED Indicator will turn red and the audio alarm will sound until the patient return neutral plate is properly applied. The test is bypassed when the bipolar function is selected. All power digital indicators shall be at the default state. If any error code is shown, the error must be cleared prior to using the equipment. (For error code information, see 8.7 - Error Codes Table).

1 = ON
0 = OFF

Units are shipped from the factory with default power levels of 0 and modes of Cut and Hemo. To modify default values, simultaneously press and hold the Cutting Mode and Coagulation Mode Select buttons while turning on the unit. When CLR is displayed release the buttons and select the desired settings. Turn off power.

2 **Fault LED Indicator:**
The Fault LED Indicator will be Red if any error is detected; otherwise, it is Green.

3 **Neutral Plate Receptacle:**

The neutral plate must be applied to the patient and connected to the equipment for monopolar techniques. The Surgitron® Dual/EMC is equipped with a neutral plate safety monitor which monitors the electrical connection between the neutral plate and the unit, as well as between the neutral plate and the patient.

4 **Neutral LED Indicator:**
The indicator lights up Red and triggers an audible alarm if the neutral plate is not properly applied. The LED indicator will turn to Green when the neutral plate is correctly applied. This function is automatically bypassed if Bipolar mode is selected.

5 **Bipolar Cord Receptacle:**
Bipolar function can be activated by footswitch only.

6 **Fingerswitch/Handpiece Receptacle:**
The Fingerswitch/Handpiece Receptacle accepts any monopolar handpiece that is compatible with the Surgitron® Dual/EMC.

7 **Yellow Footswitch Indicator:** The light indicator will be ON only when the CUT control footswitch pedal is depressed in Surgitron® Dual/EMC model.

8 **Blue Footswitch Indicator:**
The light indicator will be ON only when the COAG control footswitch pedal is depressed in Surgitron® Dual/EMC model.

9 **Cutting Mode Function Select Button:** It is for selecting Cut or Blend functions.

10 **Yellow Light (Cut) Indicator:** The indicator illuminates when Cut function has been selected.

11 **Yellow Light (Blend) Indicator:** The indicator illuminates when Blend function has been selected.

12 **Output Power Intensity Indicator for Cutting Mode:** The default state is zero when On/Off power switch is turned on. The output power will remain at the selected level unless it is changed. The number displayed indicates the relative power, which will be delivered to the patient when the mode is activated. For true output power, see figures in Section 7.

\+ 13 **Power-up Button for Cutting Mode:** A single depression of the button switch increases the power setting by one. Continuous depression gradually increases the power to maximum - 100.

\- 14 **Power-down Button for Cutting Mode:** A single depression lowers the power setting by one. Continuous depression gradually decreases the power to minimum - 0**.**

15 **Coagulation Mode Function Select Button:** It is for selecting Coag, Fulgurate, or Bipolar function.

16 **Blue Light (Coag) Indicator:** The indicator illuminates when Coag function has been selected.

17 **Blue Light (Fulgurate) Indicator:** The indicator illuminates when Fulgurate function has been selected.

18 **Blue Light (Bipolar) Indicator:** The indicator illuminates when Bipolar function has been selected.

19 **Output Power Intensity Indicator for Coagulation Mode:** The default state is zero when On/Off power switch is turned on. The output power will remain at the selected level unless it is changed. The number displayed indicates the relative power, which will be delivered to the patient when the mode is activated. For true output power, see figures in Section 7.

20 **Power-up Button for Coagulation Mode:** A single depression of the button switch increases the power setting by one. Continuous depression gradually increases the power to maximum - 100.

21 **Power-down Button for Coagulation Mode:** A single depression lowers the power setting by one. Continuous depression gradually decreases the power to minimum - 0.

22 **Yellow Energized Indicator:** The Yellow energized indicator will be ON when CUTTING MODE circuit is energized.

23 **Blue Energized Indicator:** The Blue energized indicator will be ON when COAGULATION MODE circuit is energized.

NOTE: To prevent cross-contamination, Cynosure highly recommends the use of disposable electrodes and accessories.

4.3 SYMBOL DEFINITIONS

4.3.1  Type BF defibrillator protection

4.3.2  Refer to manual

4.3.3  Protective earth connection

4.3.4  Neutral electrode referenced to ground

4.3.5  Fingerswitch control

4.3.6  Footswitch control

4.3.7  Neutral plate

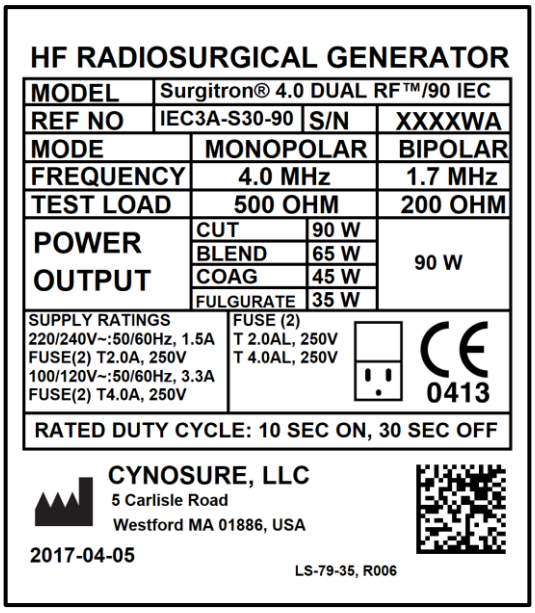
4.3.8  Non-Ionization radiation

4.3.9  Equipotential Symbol

4.3.10  Refer to instruction manual/booklet

4.3.11  Keep dry

4.3.12



Serial Number Label with Fuse and Supply Ratings

V. PREPARATION FOR USE

5.0 PREPARATION FOR USE

5.0.1 On the Surgitron® Dual/EMC check to make sure that the power switch is in the OFF position.

5.0.2 Connect the IEC power cord to a 3-wire ground AC power receptacle.

5.0.3 Insert the Neutral Plate male plug into the neutral plate receptacle on the front panel marked Neutral.

5.0.4 The Neutral Plate should be reliably attached with its entire area attached to the patient's body as close as possible to the operating field, as per the Safety Instructions specified in Section 2.1.4.

5.0.5 Select the desired electrode and handpiece and connect them as instructed by their accompanying instructions for use.

5.0.6 Plug the handpiece into the appropriate receptacle on front panel.

5.0.7 Make sure that the electrode is seated fully so that no conductive shaft is exposed.

5.1 WAVEFORM SELECTION

Reference Section 8 – Power output characteristics for more details about waveforms.

5.1.1 CUT - For micro-smooth cutting:
Select CUT by pushing SELECT button on the Cutting Mode to turn on the CUT indicator.
Push Power Up/Down Buttons on the Cutting Mode to select the desired power level. Depress the CUT Footswitch pedal or Fingerswitch CUT button to activate the output power.

The **Fully Filtered Waveform** is a pure continuous flow of high-frequency radiowaves. This filtration results in a continuous non-pulsating flow of radiowaves which provides a micro-smooth cutting flow. This wave produces the least amount of lateral heat and tissue destruction.

5.1.2 BLEND - For cutting with coagulation:

Select BLEND by pushing SELECT button on the Cutting Mode to turn on the BLEND indicator. Push Power Up/Down Buttons on the Cutting Mode to select the desired power level. Depress the CUT Footswitch pedal or Fingerswitch BLEND button to activate the output power.

The **Fully Rectified Modulated Waveform** produces a mild pulsating effect which can, under certain conditions, slightly reduce the efficiency of the cutting effect. In additional to a smooth cut, the Fully Rectified Modulated Wave is accompanied by a thin layer of coagulation on the raw cut tissue surfaces.

5.1.3 COAG -For pure Hemostasis-Coagulation to control most forms of bleeding:

Select COAG by pushing Select button of the Coagulation Mode to turn on the COAG indicator. Push Power Up/Down Buttons on the Coagulation Mode to select the desired power level. Depress the COAG Footswitch pedal or Fingerswitch HEMO button to activate the output power.

The **Partially Rectified Modulated Waveform** is an intermittent flow of the high-frequency radiowaves that produces hemostasis. The Partially Rectified Modulated Wave is also recommended for coagulating blood vessels via an indirect technique. To seal the walls of a vessel, grasp it with a hemostat and lift it free of surrounding tissues. Next contact the hemostat with the electrode, 1 to 2 inches from the hemostat's tips.

5.1.4 FULGURATION - For desiccation or fulgurate spark-gap:

Select FULGURATE by pushing SELECT button of the Coagulation Mode to turn on the FULGURATE indicator.
Push Power Up/Down Buttons on the Coagulation Mode to select the desired power level. Depress the COAG Footswitch controller to activate the output power. Note: Fulguration cannot be activated by use of the three button fingerswitch.

The **Fulguration or Spark-Gap Wave** is a waveform that has been modulated to simulate the effects of the Oudin current. The Fulguration wave produces a potent dehydration effect on tissues.

5.1.5 BIPOLAR - For precise coagulation utilizing bipolar energy:

Select BIPOLAR by pushing SELECT button of the Coagulation Mode to turn on the BIPOLAR indicator.
Depress the COAG Footswitch controller to activate the output power.

5.2 SMOKE HAZARD

By-products of high frequency surgical procedures are an occupational exposure hazard. Standards based policies and procedures must be developed in all practice settings to protect personnel from the causative factors of smoke plume and aerosols.

VI. SURGICAL DESCRIPTION AND USE

6.0 LEARNING TO USE RADIOSURGERY®

Before making contact with the tissue, the power intensity must be selected and the foot pedal or fingerswitch must be activated. During the actual cutting, it is important to use a smooth uninterrupted motion with even and light manually applied pressure. The movement should not be too slow. If it is, the build-up of lateral heat in the tissue may cause charring, followed by necrosis and sloughing (see Preoperative Cutting Practice Section 6.1). When performing a second or third cut in the same surgical site, allow approximately ten seconds for the tissue to cool between applications of the electrode to the site. Radiosurgery® should be regarded as a new technique that will require learning of new skills. All rules of good surgical technique and clinical judgment still apply.

The biggest difference to be learned is that, unlike a steel scalpel or standard electrosurgery, radiosurgery does not use manually applied pressure to cut. Therefore, a light, smooth, continuous, and brush-like stroke should be developed. Only then will the surgeon appreciate the tremendous advantages inherent in Radiosurgery®.

Defining Good Technique: Tissue damage will occur if heat is allowed to accumulate to the point where excessive dehydration occurs. Preventing the accumulation of such heat is a basic objective of radiosurgical technique. The spread of lateral heat in tissue depends upon various factors as indicated in the following formula:

$$\textbf{Lateral Heat} \propto \frac{\text{Time x Power}}{\text{Frequency}}$$

Additionally the electrode type and selected waveform impact the thermal build up.

This formula may be broken down in the following manner:

A. **Time** of Electrode Contact
   a. The slower the passage of the electrode, the greater the lateral heat.
   b. The more rapid the passage of the electrode, the less the lateral heat.

B. **Power** Level
   a. If power is too high there is a high accumulation of heat.
   b. If power is set correctly, lateral heat reduced to the minimum necessary to volatize tissue cells. Smooth flow through tissue with no sparking and no resistance through tissue.
   c. If power is set too low, drag is observed causing excessive contact time and bleeding due to tissue being pulled and torn from its base.

C. **Frequency** – Tissue provides lower resistance to higher frequencies, reducing thermal build up.

D. **Electrode** Type
   a. A broader electrode tip requires more power and creates greater thermal spread.
   b. A narrower electrode tip requires less power and creates less thermal spread.

E. **Nature** of the Waveform - See Section 5.1 for details
   a. Fully Filtered (Continuous Wave - CW) - Least lateral heat.
   b. Fully Rectified - Low lateral heat.
   c. Partially Rectified - High lateral heat.
   d. Fulgurate - Highest lateral heat.

6.1 PRE-OPERATIVE CUTTING PRACTICE

Since Radiosurgery® requires very little manually applied pressure to effect a cutting action, the user may gain control by supporting his/her hand in some fashion. Gentle touch, digital dexterity, a fluid wrist action, and a feather-light touch aid in Radiosurgery®.

The tissue to be cut should be moist. If it is too dry, surface charring may occur. Excessively dry tissue can be moistened with a wet gauze.

Prior to performing an operative procedure, the area should be studied in order to select the correct electrode, waveform and power. Several practice strokes, with power off, are recommended to determine the correct length, depth, and direction of cut.

Prepare the Surgitron® Dual/EMC for operations as described in Section 5-PREPARATION FOR USE, then follow the steps below.

A. Select a piece of fresh, lean beef containing very little fat. Allow meat to reach room temperature.
   Note: Do not use veal because it does not change color when cut with an electrode.
B. Place the meat on a Neutral Plate.
C. Insert the electrode of choice (Empire, Loop, Diamond, Vari-Tip, etc.) into the handpiece.
D. Select CUT.
E. Set output power intensity to 10.
F. Depress the CUT Footswitch pedal or Fingerswitch CUT button.
G. Using a smooth, brush-like motion, make several incisions of various lengths and depths. If you notice that the electrode will not cut, cuts only with pulling and dragging, or if tissue shreds adhere to the electrode while cutting, then increase the power gradually until a smooth cut occurs.
H. If the setting is too high then you will notice sparking and discoloration along the electrode path. Reduce power and repeat the procedure as outlined above.
I. Continue to repeat the above procedure until such a point when no discoloration occurs and there is no visible sparking. The Radiosurgical tip should not encounter resistance. The cut should be micro-smooth without sparking and without any drag. Continue to practice using slow, medium, and fast strokes to acquire dexterity and confidence.

6.2 PRE-OPERATIVE COAGULATION PRACTICE

Surgitron® Dual/EMC can be used to seal off small blood vessels. Move to the COAG mode (Partially Rectified Wave). The ball electrode is normally used since it provides extended coverage of the tissue surfaces. Prior to performing coagulation, the tissue should be wiped clean of blood so that the area needing treatment can be viewed. Direct manually applied pressure will help to locate bleeders. Intermittent gentle contact with the tissue is performed until bleeding stops.

The same meat specimen used for cutting may be used for coagulating practice. Effective coagulation is achieved when the treated area appears on the meat as blanched spot of approximately 2 mm diameter with a minimum penetration into the tissue.

NOTE: Feather-light touching of the ball electrode is recommended to coagulate bleeders efficiently.

A. Select a piece of fresh, lean beef containing very little fat. Allow meat to reach room temperature.
   Note: Do not use veal because it does not change color when cut with an

electrode.

B. Place the meat on a Neutral Plate.
C. Insert a ball electrode into the Handpiece.
D. Select COAG.
E. Set the output power intensity to 10.
F. Position the ball electrode in light contact with the beef.
G. Depress the COAG Footswitch pedal or the Fingerswitch HEMO button.
H. Repeat the above procedure with power settings of 20, 30, & 40. Contact should be 2 to 3 seconds.

A wide range of coagulation or blood control can be obtained by utilizing the partially rectified modulated wave with different techniques. Bleeding should be stopped by some form of direct manually applied pressure. When bleeding has momentarily stopped, final sealing of the vessels can be accomplished by brief application of the partially rectified modulated waveform.

There are two types of hemo electrodes: ball electrodes and thick needle electrodes.

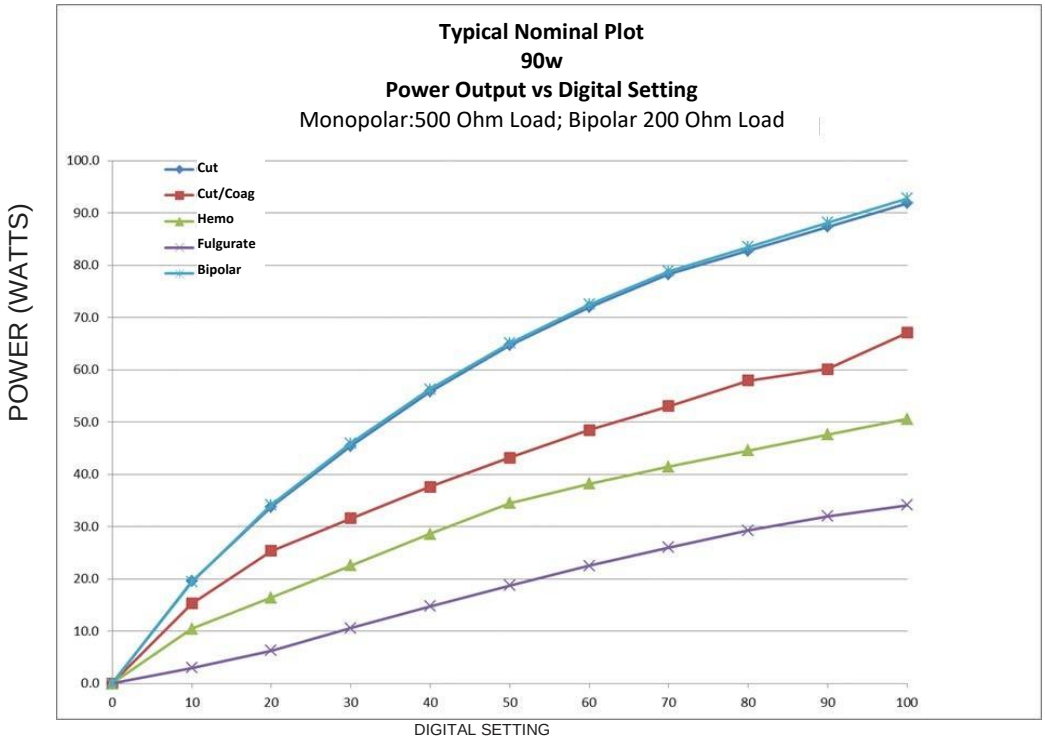
Bipolar: The Surgitron® Dual/EMC can be used for bipolar coagulation procedures. The power should be lowered to 10 or 20 depending on the procedure.

Do not attempt to operate with electrodes if the protective insulation is cracked or worn. In the event that the brass is exposed, a shock or burn may be felt by the operator or patient.

VII. POWER OUTPUT CHARACTERISTICS

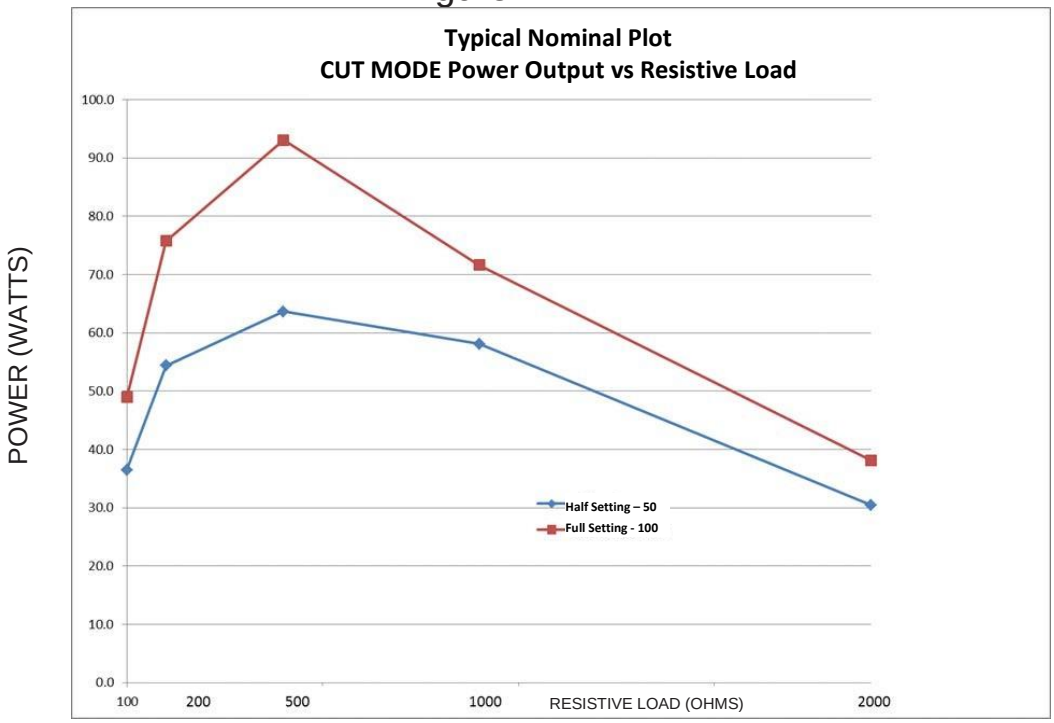
Surgitron® Dual/EMC MONOPOLAR AND BIOPOLAR MODES

Figure 7.0



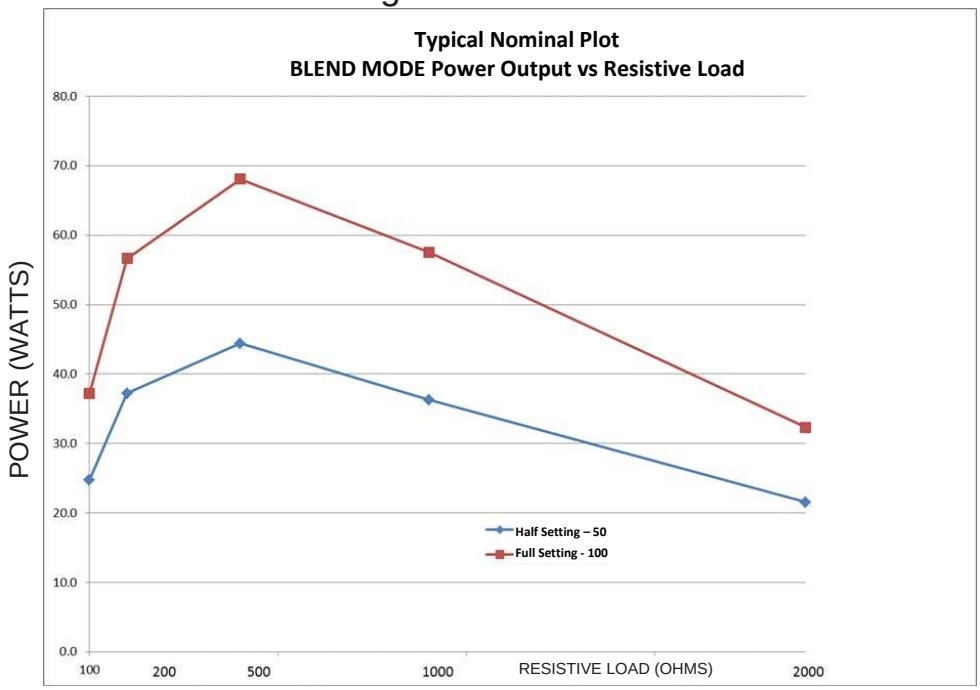
Surgitron® Dual/EMC CUT MODE

Figure 7.1



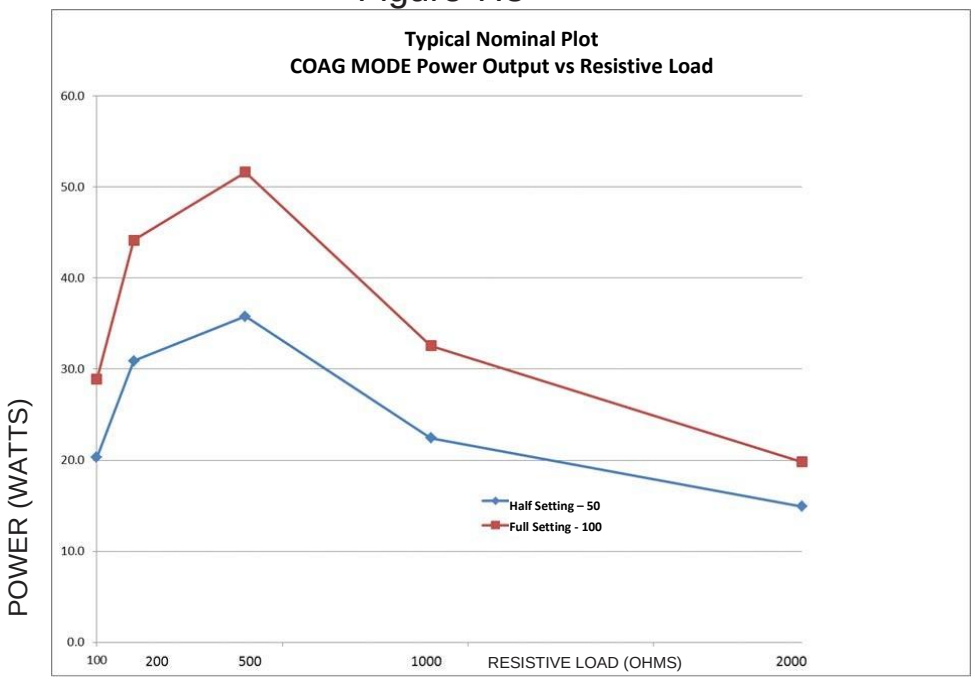
Surgitron® Dual/EMC BLEND MODE

Figure 7.2



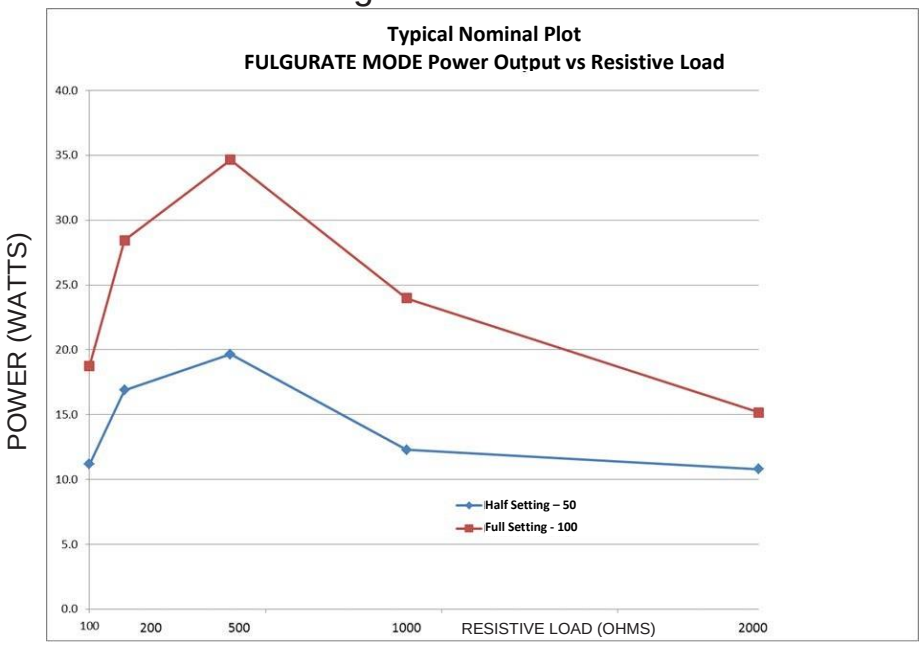
Surgitron® Dual/EMC COAG MODE

Figure 7.3



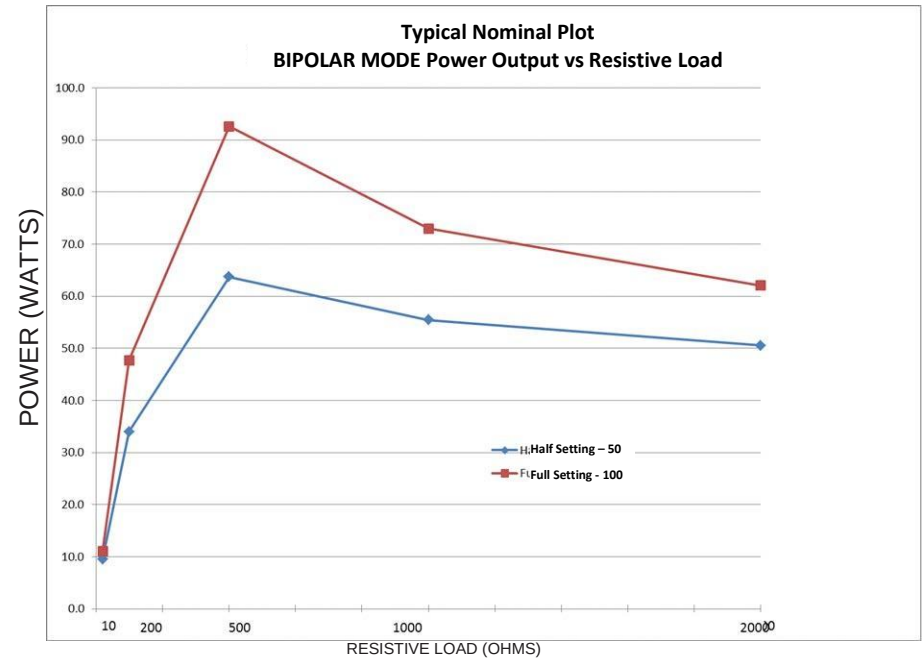
Surgitron®ᵘDual/EMC
FULGURATE MODE

Figure 7.4



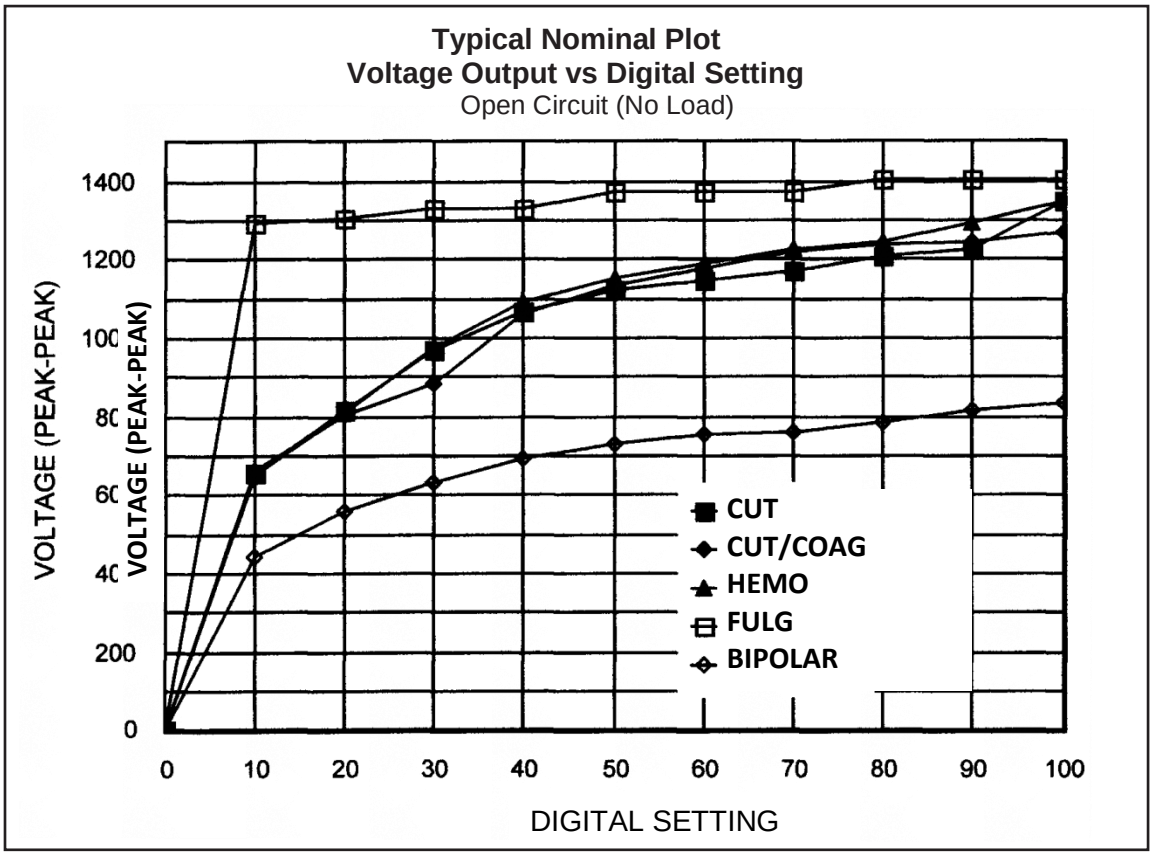
Surgitron® Dual/EMC
BIPOLAR MODE

Figure 7.5



Surgitron® Dual/EMC
MONOPOLAR/BIPOLAR
MODES

Figure 7.6



VIII. TECHNICAL SPECIFICATIONS

8.0 OUTPUT CHARACTERISTICS

Mode/ Character	Output Waveform	Maximum Output Power	Power Output vs. Setting	Power Output vs. Load Resistance	Activation
Cut	4.0 MHz sinusoid	90W @ 500 Ω	See Figure 7.0	See Figure 7.1	via footswitch or fingerswitch
Blend	4.0 MHz with fully rectified envelope	65W @ 500 Ω	See Figure 7.0	See Figure 7.2	via footswitch or fingerswitch
Coag	4.0 MHz with partially rectified envelope	45W @ 500 Ω	See Figure 7.0	See Figure 7.3	via footswitch or fingerswitch
Fulgurate	4.0 MHz with modulation	35W @ 500 Ω	See Figure 7.0	See Figure 7.4	via footswitch
Bipolar	1.7 MHz	90W @ 200 Ω	See Figure 7.0	See Figure 7.5	via footswitch

Actual output power measurements may vary with type of test equipment used and method of circuit connection.

RF Power-out is within 20% of nominal above (when greater than 10% of

maximum). RF Power-out is stable within 10% within 10 seconds after

activation.

RF output frequency is within 10% of nominal.

NOTE: The open-circuit output peak-to-peak voltage for all modes is approximately 1500 Volts.

8.1 PREVENTIVE INSPECTION AND MAINTENANCE

Regular preventive inspection should be carried out to prevent reduced safety of the unit due to aging, wear and tear, etc. The cable and electrode must be checked before each use.

The Ellman Surgitron® Dual/EMC High-Frequency Radiosurgical Generator must be inspected for technical safety at least once a year. The required technical safety inspection is detailed in the Maintenance Manual.

The manufacturer assumes no responsibility for improper changes or repairs carried out on the unit or its accessories by unauthorized persons, and the warranty of the unit expires immediately.

8.2 SAFETY FEATURES

8.2.1	Standard Compliance	IEC60601-1 IEC60601-1-2 IEC60601-2-2 UL 2601 (USA Version) CSA 22.2601
8.2.2	Electrical Safety Electric Shock: Defibrillator Protection:	 Class I Type BF
8.2.3	Neutral Plate	earthed at HF
8.2.4	Neutral Plate monitor resistance between the 2 contact areas of a split neutral electrode	MAX 1000 ohms
8.2.5	Alarm when resistance between the contact areas of a split neutral electrode is 1000 ohms or greater	Red signal indicator and audio alarm
8.2.6	Continuous internal unit temperature monitor during operations	If temperature rises above 85° C the unit will declare an error message -error code 12
8.2.7	Continuous power test/monitor output power	Error code 13 if power test failed
8.2.8	Error indication after self check	Refer to listing of error codes in section 8.7
8.2.9	Defined duty cycle protection	10 sec. ON / 30 sec. OFF
8.2.10	Ingress of water	Ordinary equipment.

8.3 INPUT CHARACTERISTICS

8.3.1	Nominal line voltage	100 / 120 / 220 / 240 V ~ + 10%
8.3.2	Line frequency	50/60 Hz.
8.3.3	Input current at max output power	100 / 120 V: 3.3A 220 / 240 V: 1.5A
8.3.4	Rating of fuses in the main supply power	T 2.0AL, 250V, Two for 220 / 240 V T 4.0AL, 250V, Two for 100 /120 V

8.4 SIZE AND WEIGHT

8.4.1	W x H x D	9x5x13"
8.4.2	Weight	18 lbs.

8.5 OPERATING CONDITIONS

8.5.1 Ambient Temperature: +10° C - +40° C

8.5.2 Relative Humidity: 30% - 75%

8.6 TRANSPORTATION & STORAGE CONDITIONS

8.6.1 Ambient Temperature: -10° C - +50° C
8.6.2 Relative Humidity: 10% - 95%
8.6.3 Atmospheric Pressure: 500 hPa -1060 hPa

8.7 ERROR CODES TABLE

DESCRIPTION	ERROR CODE
Interface to displays failed	1
Interface to LEDS failed	2
Interface to keypad failed	3
Processor had a warm reset	4
A/D converter error	7
Foot/Fingerswitch interface failed	8
Bond sensor interface failed	9
Keypad pressed during power up protection failed	10
Foot or Fingerswitch pressed during power up protection failed	11
Temperature out of limits	12
Output power test failed	13
Measured power level does not match set power level	14
Linearization Table in Error	15
EEPROM Read	16
EEPROM Write	17

NOTE: All error messages will be reset by turning the unit off and correcting the condition.

IX. ELECTROMAGNETIC COMPATIBILITY

The information contained in this section (such as separation distances) is in general specifically written with regard to this model. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

9.0 WARNING

9.0.1 This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Surgitron® Dual/EMC or shielding the location.

9.1 PRECAUTIONS

9.1.1 Interference caused by the Surgitron® Dual/EMC could adversely affect the operation of other electrical equipment. In the event of interference, plug the unit in a separate outlet or plug the unit in another room.

9.1.2 Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use for this device.

9.1.3 Portable and mobile radio frequency RF communication equipment (including peripherals, such as antenna cables and external antennas) can affect the generator. It is recommended to keep a minimum distance of 12 inches (30 cm) from the device.

9.1.4 Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

9.1.5 Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
Emissions	***Compliance according to***	***Electromagnetic environment***
RF emissions (CISPR 11)	*Group 2*	*The Surgitron® Dual/EMC must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.*
CISPR Emissions Classification	Class A	*The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*
Harmonic emissions (IEC 61000-3-2)	*Class A*	
Voltage fluctuations / flicker (IEC 61000-3-3)	*Compliant*	

Electromagnetic Immunity			
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.			
Immunity against	***IEC 60601-1-2 test level***	***Compliance level (of this device)***	***Electromagnetic environment***
electrostatic discharge, ESD (IEC 61000-4-2)	*contact discharge: ± 8 kV* *air discharge: ± 15 kV*	*± 8 kV contact* *± 15 kV air*	*Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.*
electrical fast transients / bursts (IEC 61000-4-4)	*± 2 kV for power supply lines:* *± 1 kV for longer input / output lines*	*± 2 kV* *± 1 kV*	*Mains power quality should be that of a typical commercial or hospital environment.*
surges on AC mains lines (IEC 61000-4-5)	*Common mode: ± 2 kV* *differential mode: ± 1 kV*	*± 2 kV* *± 1 kV*	*Mains power quality should be that of a typical commercial or hospital environment.*
power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	*30 A/m*	*30 A/m*	*Equipment which emits high levels of power line magnetic fields (in excess of 30 A/m) should be kept at a distance to reduce the likelihood of interference.*
voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	***0% UT*** *(100% dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, & 315°* ***0% UT*** *(100% dip in UT) for 1 cycle at 0°* ***40% UT*** *(60% dip in UT) for 5 cycles* ***70% UT*** *(30% dip in UT) for 25/30 cycles (50/60 Hz) at 0°* ***0% UT*** *(100% dip in UT) for 250 cycles at 50 Hz and for 300 cycles at 60 Hz*	***0% UT*** *(100% dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, & 315°* ***0% UT*** *(100% dip in UT) for 1 cycle at 0°* ***40% UT*** *(60% dip in UT) for 5 cycles* ***70% UT*** *(30% dip in UT) for 25/30 cycles (50/60 Hz) at 0°* ***0% UT*** *(100% dip in UT) for 250 cycles at 50 Hz and for 300 cycles at 60 Hz*	*Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions insure that batteries are installed and charged. Insure that battery life exceeds longest anticipated power outages or provide and additional uninterruptible power source.*

This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended separation distance**
Conducted RF rf coupled into lines *(IEC 61000-4-6)*	*150 kHz to 80 MHz outside ISM bands*	*3 Vrms*	d=1.2/V1]√P
radiated rf (IEC 61000-4-3)	*80 MHz — 2.5 GHz*	*3 V/m*	c1=1.2/ √ P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Guidance and Manufacturer's Declaration—

Electromagnetic Immunity to Proximity Fields from RF Wireless Communication Equipment

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity Test Frequency (MHz)	***Service Band***	***IEC60601 test level***	***Compliance level***	***Electromagnetic Environment—Guidance***
385	*TETRA 400 (380-390 MHz)*	*27 V/m*	*27 V/m*	Unless otherwise specified, the equipment was tested at a distance of 0.3m. The equipment was tested using the IEC 61000-4-3 test method.
450	*GMRS 460, FRS 460 (430-470 MHz)*	*28 V/m*	*28 V/m*	
710 *745* *780*	*LTE Band 13, 17 (704-787 MHz)*	*9 V/m*	*9 V/m*	
810 *870* *930*	*GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 (800-960 MHz)*	*28 V/m*	*28 V/m*	
1720 *1845* *1970*	*GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Ban 1,3,4,&25, UMTS (1700-1990 MHz)*	*28 V/m*	*28 V/m*	
2450	*Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 (2400-2570 MHz)*	*28 V/m*	*28 V/m*	
5240 *5500* *5785*	*WLAN 802.11 a/n (5100-5800 MHz)*	*9 V/m*	*9 V/m*	

Recommended separation distances between portable and mobile RF communications equipment and the equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitters in meters**		
	150 kHz — 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	*0.12*	*0.12*	*0.23*
0.1	*0.38*	*0.38*	*0.73*
1	*1.2*	*1.2*	*2.3*
10	*3.8*	*3.8*	*7.3*
100	*12*	*12*	*23*

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EC REP

Hologic BVBA
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80

Cynosure, LLC, 5 Carlisle Road, Westford MA, USA
Tel: 888.523.2233 / Fax: 978.349.6152

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