Operating & Instruction Manual For The Anthony Products Electrosurgical Unit Model ES0345

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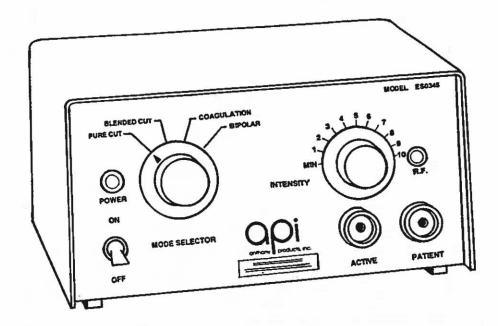
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API Electrosurgical Unit

The API Model ES0345 is a quality electrosurgery unit. Each unit has solid state circuitry and a permanently attached footswitch and line cord. It is unique in that it offers the user many options and a choice of output modes. The power on/off switch is located on the left front panel. When the unit is plugged in and the switch activated, the amber light illuminates. The red R.F. light will illuminate indicating output is present when the footswitch is activated. There are four (4) types (or modes) of output. Only one mode of output can be activated at a time. PURE-CUT is used when an incision is made but little or no hemostasis is desired, much like using a scalpel. BLENDED-CUT provides "BLOODLESS" cutting, (hemostatis is in evidence). The COAGULATION mode is used to coagulate or control the bleeding. BIPOLAR is for use with instruments that do not require patient return.

The manual that is available provides information on the care and use of our Model ES0345. A one year limited warranty for parts and labor is provided to the customer from date of shipment. API instrumentation is built to five maximum trouble free service. The need for service under normal operating conditions is almost non-existent if instructions are read, understood, and followed. If a problem should occur, call the API Customer Service Department at (317) 545-6196 or toll free (800) 428-1610.

UNPACKING AND INSPECTION

Caution should be used while unpacking the electrosurgical unit to insure that no damage occurred to the unit before it is made ready and ordered (see packing slip) are included within the carton. If any accessories are missing, please report the shortage IMMEDIATELY to the API Customer Service Department. No shortage claim will be allowed unless filed immediately upon receipt of the merchandise.

NOTES AND WARNINGS

- The safe and effective use of electrosurgery is dependent to a large extent upon factors under the control of the operator and is not entirely controllable by equipment design. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- 2. The use and proper placement of a dispersive electrode is a key element in the safe and effective use of monopolar electrosurgery, particularly in the prevention of burns. Follow directions and recommended practices for the prepartion, placement, surveillance, removal and use of any dispersive electrode used with this electrosurgical generator.
- 3. During use of electrosurgery, the patient should not be allowed to come in contact with metal parts that are grounded. It is recognized that this recommendation may not be practical during certain procedures (e.g. those in which insulated head frames are used). However, to maximize patient safety during the use of electrosurgical devices, such practices are to be minimized.
- 4. Unless the electrosurgical leads (active, bipolar, or return) are a shielded type, they should be positioned so they cannot contact the patient or other leads connected to the patient, nor should they run parallel close to other leads.
- 5. Electrodes and probes of monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if battery-powered, insulated, or isolated at 60Hz. The risk of burns can be reduced but not eliminated by placing the electrodes or probes as far away as possible from the electrosurgical site and from the dispersive electrode. Protective impedances incorporated into the monitoring leads may further reduce the risk of such burns. Needles should not be used as monitoring electrodes during such procedures.

NOTES AND WARNINGS-CONTINUED

- 6. Apparent low power output or failure of the electrosurgical equipment to function correctly at otherwise normal settings may indicate faulty application of the dispersive electrode, or failure of an electrical lead. Do not increase power output before checking for obvious defects or misapplication. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode.
- 7. Use of electrosurgery can result in electrical interference with other devices, particularly cardiac pacemakers; precautions should be taken to assure that the patient's well-being is maintained in the event of such interference.
- 8. The risk of ignition of flammable gases or other materials is an inherent hazard in the presence of electrosurgery and cannot be eliminated by devise design. Precautions must be taken to restrict flammable material from the electrosurgical site, whether they are present in the form of an anesthetic or skin preparation agent, or are generated by natural processes within body cavities, or originate from surgical drapes or other materials.
- 9. Potentially hazardous conditions may exist when accessories of similar connector types are intermixed. Be certain that accessories are appropriate for the type of generator output used.

SET UP

- 1. For your convenience, the line cord and footswitch are permanently attached to the unit. The male plug on the line cord is 3-wire grounded which insures proper grounding and is an important safety measure.
- 2. The FOOTSWITCH is round and should be placed on the floor with the black portion side up.
- 3. ACTIVE AND PATIENT RETURN
 - A. ACTIVE CORD

Insert male connector of the black cord into the corresponding black receptacle on the front unit panel (see number 10-figure 1). Connect the female end to the accessories to be used. The male connector is the Banana Plug.

 B. PATIENT RETURN CORD Insert male connector on the red cord into corresponding red receptacle jack on the front unit panel (see number 9 - figure 1). Connect other end (female) of red cord to patient device.

SET UP - CONTINUED

- C. Before each use check all cords for worn or broken insulation, loose plugs, etc. Almost without exception, the cause of poor performance by the unit will prove to be defective cords and/or connections. Broken wires and connections can be detected by the use of a continuity meter.
- D. ALL UNIPOLAR devices use a single cord plugged into the unit and instrument, in addition to using the patient return cord.
- E. BIPOLAR devices can be used with this unit and would have one end of cord connected to the instrument of accessory and the other end of the cord would have two (2) male plugs, one for the active jack and the other for the patient jack.

USE

- ON/OFF POWER SWITCH Turn unit on by putting the switch to the ON position (see number 1 - figure 1). The power light (amber) (see number 2 figure 1) will illuminate.
- 2. SELECTOR SWITCH

You will note there are four (4) output modes, PURE-CUT (number 3), BLENDED-CUT (number 4) COAGULATION (number 5) BIPOLAR (number 6figure 1).

- A. PURE-CUT a sharp, clean insicion is made without pressure and minimum hemostasis is produced much like using a scalpel.
- B. BLENDED-CUT provides same incision, but seals off those small vessels and provides "BLOODLESS" cutting.
- C. COAGULATION controls bleeding, provides clear operating field.
- D. BIPOLAR coagulation current when no patient return is necessary. The cord from the instrument has two (2) plugs, one into patient jack and other to active.

INTENSITY CONTROL

When any one of the above modes is chosen, make sure the intensity control is set to the desired output. The control has a range of minimum to 10 and should be set according to the procedure and conditions.

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GENERAL

Only one mode can be activated at a time. The output power should be as low as possible for the intended purpose. Apparant low output or failure of the surgical equipment to function correctly at the normal operating settings may indicate faulty application or poor contact in the connections to the patient return device. (See Maintenance: Cords & Handles).

API RETURN DEVICES

The use and proper placement of a dispersive electrode is a key element in the safe and effective use of electrosurgery, particularly in the prevention of burns. Follow directions and recommended practices for the preparation, placement, surveillance, removal and use of any dispersive electrode used with this electrosurgical unit.

Whether it be the plate or wristlet, a patient return device should be used with an electrosurgical system. The device connects with the red patient cord which plugs into the red patient jack on the front panel of the unit. (See number 9 - figure 1).

The dispersive electrode must be reliably attached with its entire area in contact with the patient's body and as close to the operating field as possible. The plate is designed to go under the buttocks, thigh, shoulder or anywhere that gravity can insure an adequate area of contact.

If the operator feels the output of power is not sufficient, he/she should first check to see that the dispersive electrode is in good contact with the patient before increasing the power setting.

A wristlet* can also be used in place of the patient return plate. It must be worn by the patient.

*WARNING - Positive contact must be made between the metal surface of the wristlet and the skin of the wearer. If the wristlet fits the wrist or ankle loosely, move the wristlet up on the forearm or calf or use tape to hold it in place and firmly against the skin

MAINTENANCE-CABINET

While the finish of the instrument cabinet will resist scuffing and the chemical attack of most acids and akalis, any liquids spilled on the cabinet should be wiper off immediately.

Occasional cleaning and protection with any good wax or equipment polish, will keep your API system looking new indefinitely.

CORDS & HANDLES

All API cords and handles can be sterilized by any conventional method. Handles must be separated from cords when sterilizing.

All handle and cord connections must be thoroughly dry before using.

To insure complete safety and trouble-free operation, a periodic inspection should be made of all cords, wires, plugs and connections. Loose wires or worn insulation should be corrected immediately.

Apparent low power output or failure of the electrosurgical equipment to function correctly at otherwise normal settings may indicate a failure of an electrical lead.

Electrical leads should be positioned so they cannot contact the patient or other leads connected to the patient, nor should they run parallel close to other leads.

ELECTRODES

Electrodes should be kept free of dried tissue and coagulum. Such materials interfere with proper cutting and coagulation and should be wiped off frequently while in use.

Electrodes and other accessories can be sterilized by any conventional method. They should be thoroughly dry before using.

STERILIZATION

All accessories can be sterilized by any conventional method with temperature not to exceed 121 degrees C.

APPLICATIONS

Electrosurgery has many applications in your practice. It is excellent for initial skin incisions because it is neat and virtually "bloodless". Electrosurgery is effective at any level and for any body tissue except bone (and tooth), although it is slightly more difficult for it to cut through fat than through tissue. Coagulating blood vessels is another application where electrosurgery is most helpful. Hemostasis also may be achieved during procedures by using a hemostat and coagulating current. In addition to these applications which can aid you in many brocedures, electrosurgery is a valuable instrument for many specific procedures. As you become more and more accustomed to your system, you can perform more difficult and varied procedures with it. You probably will continue todiscover new uses for your electrosurgery system to make your practice safer, and more effective.

PRINCIPLES OF ELECTROSURGERY

Some familiarity with the basic principles of electrosurgery and how it works will help you to get the maximum usefulness and benefits from your system.

THE ADVANTAGE OF USING ELECTROSURGERY

When used properly, electrosurgery has many unique advantages that make it invaluable in your practice. It reduces operating time and produces better operative results. It reduces postoperative pain and produces virtually scar-free healing.

OTHER ADVANTAGES ARE:

Smooth, even cutting without pressure. A clean operating field, with little or no bleeding. Precise control of the incision. No tissue destruction or sloughing. No cicatrical scar tissue. Healing by the first intention is rapid and uncomplicated. No significant tissue loss after healing.

WHAT ELECTROSURGERY IS

Electrosurgery is the use of energy created by a high frequency alternating current. The resistance of the tissue to the passage of this current creates heat internally in the tissue, as in diathermy or the radar range oven. In diathermy, for example, two plates (electrodes) of approximately equal size are used, creating low current density and an even distribution of energy throughout the tissue. In electrosurgery however, we use two electrodes (an electrode and a patient return device) of greatly different sizes, resulting in greatly increased current density at the point of the smaller electrode. While the electrode itself remains cold, the highly concentrated high frequency energy creates molecular heat inside each cell. By the choice of electrodes and selection and adjustment of the current the operator controls the effect of this energy on the tissues to achieve the desired results.

CUTTING

Cutting is done, not by the electrode, but by the high frequency energy concentrated at the electrode. This high frequency energy generates molecular heat in each cell to the point where the fluids in the cell volatilize and the cell explodes.

CUTTING (Continued)

By applying this energy to individual cells in sequence, that is, by moving the electrode continuously through the tissue, the line of destruction is limited and the cutting effect is realized. At the same time the capillaries are sealed, resulting in almost bloodless cutting.

COAGULATION

Coagulation takes place when the high frequency current is applied to the tissues with a current density sufficiently concentrated to dehydrate the cells and coagulate their contents, but without penetrating deeply into the tissue.

This procedure is almost self-limiting, since the surface coagulation first created protects the underlying tissues against excessive depth of coagulation.

THE ACTIVE ELECTRODES

Be sure the electrodes are securely seated and firmly held in the handle so that the entire electrode shank is covered. In general, straight wire electrodes are used for incisions and for removing fine tissue. Loops are used for removing heavier tissue, planing, and contouring. Ball electrodes are used for coagulation.

Keep the electrode clean while operating. Tissue shreds and debris on the electrode cut down the effectiveness of the current and by impeding the passage of the electrode through the tissue, slow down the stroke. This creates unnecessary heavy coagulation which can cause sloughing and delay healing.

ANESTHESIA

Adequate anesthesia is indicated for all electrosurgical procedures. It is usually advisable to anesthetize tissue adjacent to the intended operative site, in the event it becomes necessary to extend the operative area.

Electrosurgery should not be used in the presence of flammable or explosive gases.

When using a flammable preparatory solution such as alcohol, be certain that the solution has completely evaporated before using electrosurgery.

THE TISSUES

It is preferable, whenever possible, to work on healthy tissue. With diseased tissue, it is impossible to predict the extent of the tissue loss. In these cases, it is advisable to take all possible measures to restore the tissue to health before performing any electrosurgical procedure.

The high frequency electrosurgical current will not cut hard tissue, such as bone. However, prolonged exposure to high frequency current can cause damage. It is, therefore important to develop good techniques which eliminate the danger of damage to bone. Momentary contact with bone will not cause damage.

THE POWER SETTING

The ideal power setting is the MINIMUM setting where cutting and coagulating can be accomplished.

If the powe is TOO HIGH, the tissues will be discolored and there will be considerable sparking when the electrode contacts the surface.

If the power is TOO LOW, the electrode will drag through the tissue, tearing and "cooking" instead of cutting cleanly and will pick up shredded and torn tissue.

Authorities agree that it is better to err on the side of too much power rather than too little. While excessive current may slightly dehydrate the surface, it permits the electrode to move through the tissue unimpeded.

Power requirements will vary with the type and size of the electrode, the area of electrode surface in contact with the tissue, the nature of the tissue, whether cutting or coagulating, and the depth of the incision desired. Larger electrodes, deeper incisions, and tough fibrotic tissue are some indications for higher power settings.

THE CRITERIA OF GOOD CUTTING TECHNIQUE

These are three criteria of good cutting technique:

- 1. The electrode should "FLOAT" through the tissue without dragging or resistance.
- 2. There should be only very slight, if any, change in the tissue color due to dehydration or charring.
- 3. No tissue shreds should adhere to the electrode.

CUTTING TECHNIQUE

When cutting, ALWAYS activate the generator BEFORE contacting the tissue.

PLAN THE STROKE. BEFORE ACTIVATING the electrode, take one or two practice strokes to be sure you can complete the planned stroke comfortably and correctly. At this time you can evaluate the size and shape of the electrode and the speed and depth of the stroke.

MAKE THE CUT. When the practice stroke is comfortable, activate the generator and make the planned cut.

Use a smooth brushing motion without pressure. The electrode should pass through the tissue without dragging at a deliberate but NOT SLOW SPEED.

KEEP THE ELECTRODE MOVING. Prolonged contact with any one part of the tissues can create excessive coagulation.

COAGULATING

In contrast to cutting, when coagulating, the electrode should contact the tissue BEFORE activating the output.

COAGULATING PROCEDURE

Set the poser intensity control to the desired setting.

- 1. Contact the tissue with the instrument BEFORE depressing the foot switch.
- 2. Depress the footswitch pedal until the coagulation precedure is complete.

SEVERED VESSELS

Clamp the bleeder in the beaks of a hemostat.

Touch a ball electrode to any part of the hemostat.

When using foot activation instruments, depress the footswitch pedal to activate the current for several seconds. Then release the pedal and remove the electrode. Be sure the current is set high enough to achieve coagulation.

SEVERED VESSELS (Continued)

After the application of coagulating current, remove the hemostat. Bleeding should have stopped. If not, repeat the procedure.

When using electronically generated current, it is quite safe to hold the hemostat in one hand while holding the electrode handle in the other during this procedure.

Electrocoagulation forceps may be used, grasping the vessel and applying coagulation current.

BIOPSY

The use of electrosurgery for biopsy has two particular advantages. First, since electrosurgery seals the capillaries and lymphatics as it cuts, the danger of metastasis through those channels in minimized. Second, since electrosurgery does not destroy any depth of cells on the line of incision, the specimens are highly acceptable to the pathologist.

The specimen should, whenever possible, include two or three millimeters of attached normal tissue.

Small (up to one half inch) masses should be removed in one piece. Using cutting current at a relatively high setting and a needle electrode incise all around the mass in an elliptical pattern, including two or three millimeters of attached normal tissue.

Small masses may also be removed by using a suitable loop electrode, enough larger than the mass itself that it can excise two to three millimeters of attached normal tissue at the same time.

Specimens from larger masses should be taken in the form of the pie shaped wedges. Using a needle electrode and cutting current, start the apex of the wedge at the center of the suspicious mass. The base of the wedge should include two to three millimeters of attached normal tissue.

TROUBLE SHOOTING

TROUBLE	PROBABLE CAUSE	CORRECTIVE ACTION
ON/OFF switch when on does not illuminate power light.	 Unit not pluged in. Switch not working. Red light burned out. 	 Plug into wall. Replace switch. Replace lamp.
OUTPUT/YELLOW R.F. Light does not illuminate	1 Yellow Light burned out.	1 Replace lamp.
when footswitch is de- pressed	2 Footswitch not work- ing.	 Footswitch checked or replaced.
Intermittent power output or apparent low output power.	1 Faulty application or poor contact in handle.	1 Replacement of cord or spread pins to effect tighter connection.
	2 Improper placement of patient return device.	2 Place in complete contact with patient body.
	3 Worn insulation in electrical leads.	3 Replace leads.

If any of the above actions have been performed and the problem still exists, contact the Anthony Products Customer Service Department, (317) 545-6196 / (800)428-1610.