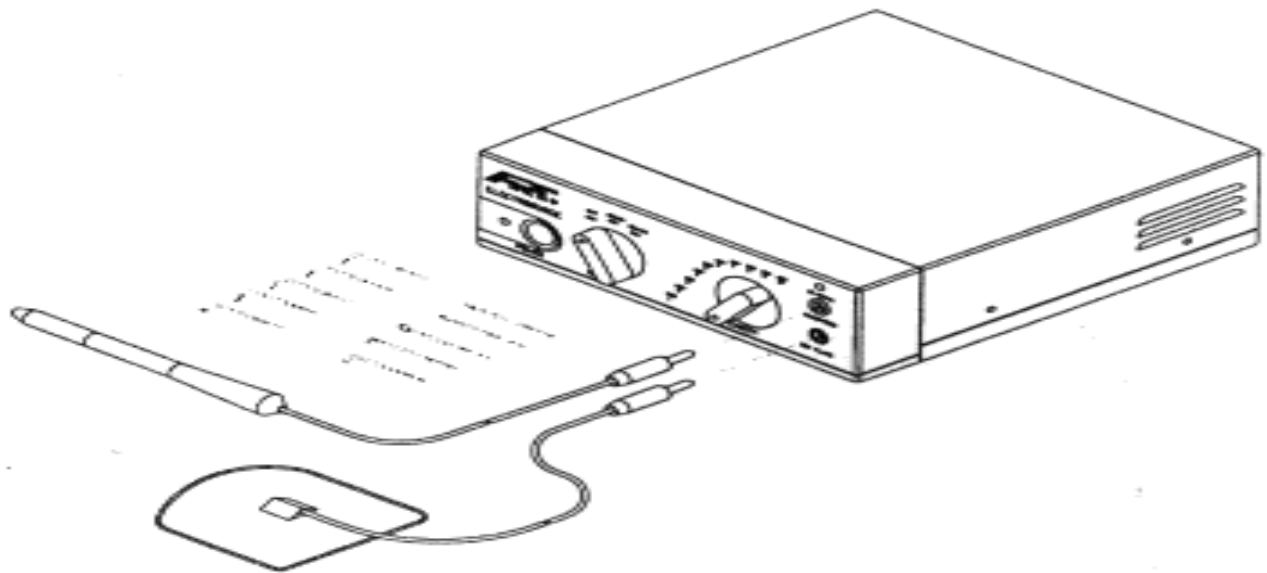


# ART - E1 ELECTROSURGERY UNIT

## USER MANUAL



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Document No. RD-E1-003

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**Warnings**

## Important Notes!

The equipment is only to be used by a qualified dentist.

A patient with a pacemaker cannot be treated with the equipment.

A shielded AC power cord must be used with this equipment.

ART-E1 should be powered from a separate wall outlet with a grounding point.

*Read this page carefully before installation and use of the instrument.*

The instrument described in this manual is designed to be used by properly trained personnel only. Only qualified personnel shall carry out adjustment, maintenance and repair of the equipment.

## **NOTE, CAUTION AND WARNING STATEMENTS**

**CAUTION:** Is used to indicate correct operating or maintenance procedures in order to prevent damage to, or destruction of the equipment or other property.

**WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

## **Symbols**



This "BF" Symbol, a caution symbol, indicates the machine was manufactured according to the degree of protection against electric shock for this type of BF equipment.



Grounding Terminal



Attention! Read the Instructions

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## I. Introduction

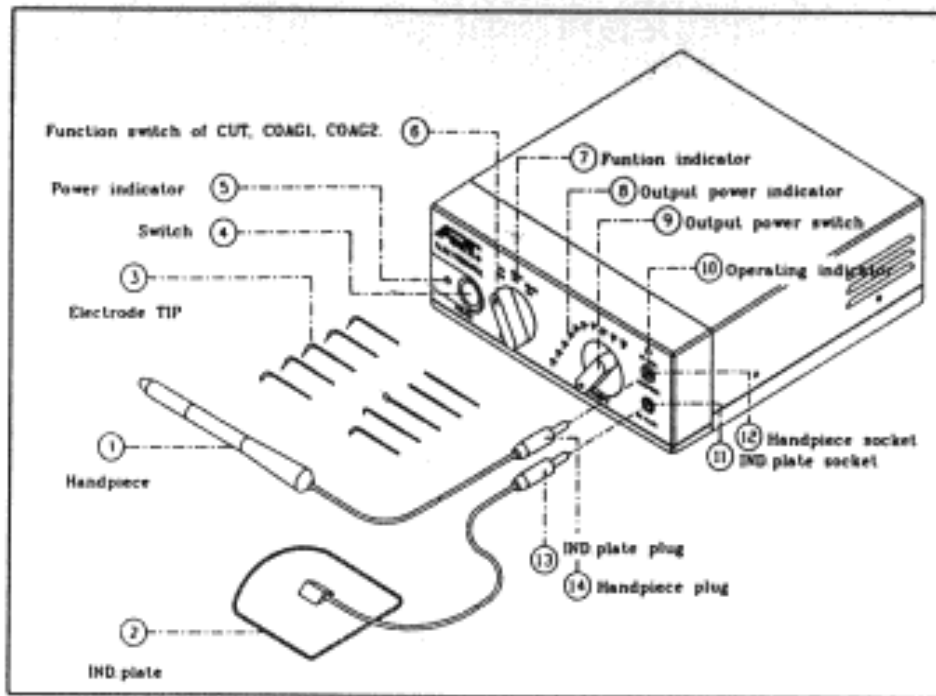


Figure 1. ART-E1 Outlook diagram(front view)

A. Configuration of ART-E1

1. Handpiece
2. IND. Plate
3. Electrode TIP
4. Switch
5. Power indicator
6. Function switch CUT, COAG1, COAG2.
7. Function indicator
8. Output power indicator
9. Output power switch
10. Operating indicator
11. IND. Plate socket
12. Handpiece socket
13. IND. Plate plug
14. Handpiece plug
15. Fans
16. Power socket
17. Pedal switch socket
18. Pedal switch

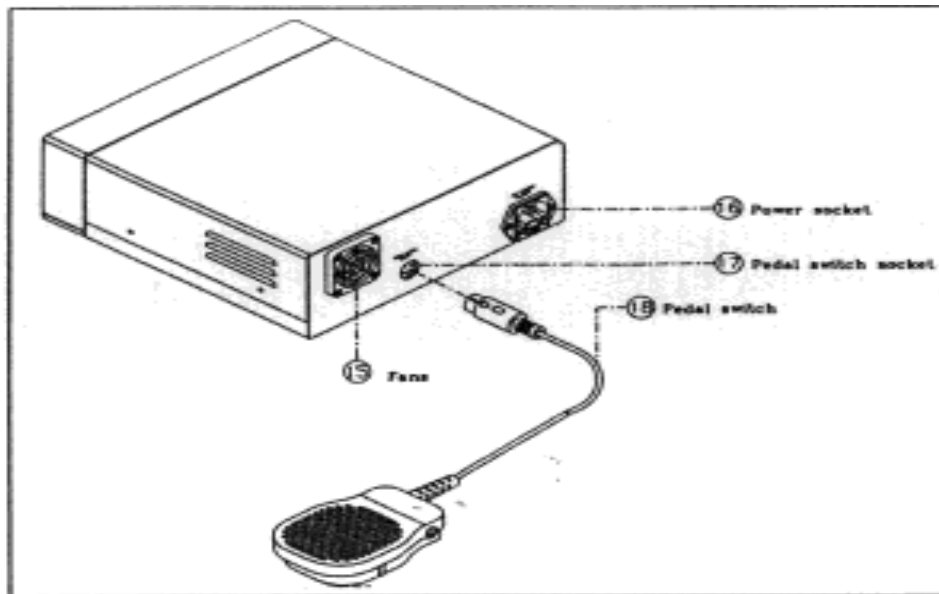


Figure 2. ART-E1 Outlook diagram(back view)

#### B. Description of function of ART-E1 panel

1. POWER: power switch. Turn on the switch, the green light will show that the power is on.
2. HANDPIECE: socket for handpiece (black). Put the handpiece plug into this black socket.
3. RF/2MHz: operating indicator. Depress the foot pedal to operate the unit, at this time, the RF/2MHz indicator is on, showing that unit is in use.
4. IND. PLATE: IND. Plate sockets (red), put the plug of IND. Plate into this red socket.
5. INTENSITY: output control switch. There are 10 levels of output intensity to be selected depending on the requirements of the desired procedure.
6. MODE: function selector. There are three modes: CUT, COAG I, and COAG2.
  - 6.1 CUT: to perform both electrosection and electrocaugulation.
  - 6.2 COAG1: perform both electrosection and electrocoagulation.
  - 6.3 COAG2: coagulation and stanches.

## C. Specifications

### Function:

Operation Modes:	Cut, Cut-Coagulation, and coagulation
Operation Frequency:	1.5 MHz
Stable and Fine Power Settings (10 steps)	
Various Electrodes Available	

### Specifications:

Dimension	24.5cm (L) x 22.5cm (W) x 8.5cm (H)
Weight	4 kg (including handpiece)

Power Supply	110-125V ~ 60 Hz 2A 220-240V ~ 50 Hz 1.2 A
Max Output Power	210 Watts (Load = 500 $\Omega$ )
Max Output Voltage	270 RMS Voltage (Load = 500 $\Omega$ )

Operation Frequency	1.4 ~ 1.7 MHz
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Handpiece Cable	180 cm
Plate Cable	200 cm

Autoclavable handpiece, electrode, plate, tip	125 C
--------------------------------------------------	-------

### Environment

Temperature:	
Operation	10C - 35C
Storage	0C - 60C

Humidity:	
Operation	20% - 80% non-condensing
Storage	10% - 90% non-condensing

Atmospheric Pressure	640 mmHg to 790 mmHg
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### Classification:

Class II, with transformer  
Type BF  
IP40

## II. Getting started

### A. Unpacking

When unpacking the box check ART-EI for any damage. If damaged, please contact your dealer or HSP immediately. Enter the unit serial number on your warranty card mail it to HSP within 10 days after setting up the machine.

#### NOTE:

The meaning of the labels printed on the outside of the package box are listed below:



**FRAGILE**



**KEEP AWAY FROM WATER**



**DO NOT HOOK**



**THIS SIDE UP**

### B. Safety Instructions

#### **Grounding**

Before any connection is made, the unit must be grounded. The main plug shall be inserted only into a wall socket provided with a protective ground.

#### **Main Voltage Range and Fuse**

Before inserting the main plug into the wall socket, make sure that the machine is compatible with the local main voltage.

**WARNING: The instrument shall be disconnected from all voltage sources when a fuse is to be replaced.**

**Note: If after replacing the fuse, the unit still does not work, return the complete Electro-Surge unit to HSP for repair or replacement.**

The main line fuseholder is located on the rear panel in the main line input socket. When the main line fuse needs replacement, proceed as follows:

- Disconnect the unit from the main line.
- Remove the cover of the fuseholder by means of a small screwdriver.
- Fit a new fuse of the correct rating and refit the cover of the fuseholder.

### C. Setting Up

1. Check ART-EI, and make sure the both power and power indicator are off when the switch is off.
2. Put the plug of ART-EI in the socket of grounded AC current.
3. Put the plug of the handpiece in the black socket labeled "HANDPIECE" on the panel.
4. Put plug of the IND. plate in the red socket labeled "IND. PLATE." The unit should be put on a secure surface near the operating site. The IND. plate must be placed on the operating table.
5. Choose the correct electrode TIP for desired procedure, and insert it into the handpiece. Make sure the insertion is complete, and the metal part is not exposed, and then close the tip of handpiece by turning clockwise.

### D. Starting ART-EI

Switch MODE to "CUT" to perform the electrosection. Switch the current dial to fully rectified (COAG1) to perform both electrocoagulation and electrosection. Switch the current dial to partially rectified (COAG 2) to perform coagulation. Then switch the INTENSITY output to a suitable intensity according to the bleeding at the surgical site.

### **III. Descriptions:**

#### **A. Definition of "Good Skill"**

Tissue damage may occur when the surgical site is overheated or dehydrated. Thus, it is very important to keep the surgical site irrigated and to develop proper electrosurgical technique. Two factors of proper technique are:

1. The intensity of the setting.
2. The smoothness and speed of passage of the electrode over the surgical site. These two relate to each other. Heat accumulating in the tissue is determined by many different factors, which may be summarized as follows: The heat generated by electrosurgery depends on the duration of contact between the electrode TIP and tissue, current intensity, size of TIP, and electrosection wave current.

#### **B. Intensity of Current:**

1. High intensity: The electrode will spark and may cause tissue damage.
2. Correct intensity: The heat is lowered to the threshold of evaporating the tissue cell, and the current passes through the tissue easily without any resistance or sparking.
3. Insufficient intensity: This may result in pulling, or even tearing of the tissue.

#### **C. The Size of Electrode TIP:**

1. The larger the TIP is, the higher the operating power will be.
2. The smaller the tip is, the lower the operating power will be.

#### **D. Electrosection Waves:**

Electrocoagulation has practical applications in surgery. ART-El provides hemostasis by electrocoagulation. The performance as the electrode dissects the operative site, limiting damage, and reducing trauma. About 75% of all clinical operations are performed by electrosection current waveforms.

##### **1. Fully Filtered Current (CUT)**

Fully filtered current is pure high frequency. The result of filtering leads to a sustaining non-oscillating current. This non-oscillating current provides the required current for the operation, and is the most beneficial condition for most clinical applications. Heat and tissue destruction are minimal.

##### **2. Fully rectified current (COAG1)**

Fully rectified currents produce short but visible oscillating effects. In some circumstances, this current may lessen the cutting effect slightly. Besides cutting smoothly, fully rectified current may perform some coagulation to the wound. This coagulation is of a small range on a clinical operation, but is effective homeostasis. A thin film may form at the coagulated site as the site begins to heal. The film will dissolve or fall away after the site is healed.

##### **3. Partially rectified current (COAG2)**

Partially rectified current is intermittent high frequency current. It is very effective for homeostasis, especially for wounds of 1.6mm. diameter. Partially rectified current may provide another indirect technique for coagulation. Coagulate the vessel with styptic, and take away the surrounding muscle tissue. Then contact the sphere of electrode TIP with styptic, keeping 2.5cm. to 5cm apart. When the partially rectified current is turned on, blood vessel will coagulate, which will make unnecessary coagulative contraction

#### **E. Conclusion:**

ART-El is used for electrosection, electrosection/electrocoagulation, and electrocoagulation for severe bleeding.

## **IV. Operation Guide:**

### **A. Learning how to use electrosurgery**

Before contacting the electrode with tissue, suitable power intensity should be chosen. During the operation, a smooth motion without pressure is important, even slight pressure should be avoided. The movement can't be too slow, because the heat will propagate deep into the tissue and may cause burning, resulting in necrosis. In order to cool down tissue during surgery, allow 10 second intervals between each pass of the electrode over the site. Good surgical skills apply to electrosurgery and conventional surgery. The primary difference between conventional surgery and electrosurgery is that the pressure applied when using a scalpel is not necessary in electrosurgery. A smooth cutting technique allows the operator to maximize the advantages of electrosurgery.

### **B. Explanation of Electrosection:**

The operative site should be wet. The position to be cut should be observed before surgery and the operator should select the proper tip, current and power. Turn off the power, and practice the operation with power off. Determine the length, depth and direction of the electrode movement.

### **C. Cutting Practice Before Operation:**

1. Choose a fresh beef with little fat, but not veal, which won't change color when cut with electrosurgery. The temperature of the beef should be equal to the room temperature.
2. Put the prepared beef on the IND. plate.
3. Insert the chosen tip into the handpiece.
4. Switch the power output to #10.
5. Switch the current dial to CUT.
6. Depress the foot pedal.
7. Make several incisions of different lengths and depths smoothly and quickly. You may see some sparking during cutting and the color of the tissue will change. This is a result of the power setting being too high.
8. Switching the output power to # 1, you will see the electrode can hardly work. Tissue may be pulled and torn with such low output power, and the torn tissue may stick to both sides of the electrode.
9. Repeat the previous procedure with different output power intensity until there is no sparking and changes in the color of the beef the electrosection should be smooth, without any difficulty. No pulling or tearing usually occurs between the #5 and #6 power settings. We want to make a special note of this suitable intensity. Now practice cutting with different speeds and different power settings until proper clinical technique is achieved.

### **D. Explanation Before Coagulation:**

ART-E I can be used to coagulate the capillaries. Switch the dial to partially rectified current (COAG2). Usually the electrode ball is chosen to expand the range of the covered muscle tissue. Before coagulation, wipe the blood off to see the wound more clearly. Pressing the wound indirectly is helpful to find the source of the bleeding. Touch the tissue with the electrode intermittently and gently until the bleeding stops.

## **E. Coagulation Practice Before Operation**

Practice coagulation following the same procedures as in the electrosection. When a white speckle about 2mm in diameter appear at the target position, this operation is done. It is necessary to touch the bleeding wound gently to coagulate it.

1. Put the beef on the IND. plate.
2. Put the electrode ball into the handpiece.
3. Switch the output power intensity to #1.
4. Turn the "MODE" to COAG2.
5. Touch the beef with electrode ball lightly.
6. Depress foot pedal.
7. Set the power at 2, 3, 4, repeating the previous steps, and the duration should last only 2-3 second.

## **F. Control of bloodshed**

Abnormal bleeding is not a problem for electrosurgery. With partially rectified current and different skill, the range of coagulation can be extended, and bleeding can be controlled. Coagulation can prevent the bleeding at the beginning of entering the tissue. Once the bleeding begins, it can't be stopped. Direct pressing is necessary, such as air, pressure, and styptics. When the bleeding is stopped, COAG2 can be used to repair the capillary or blood vessel.

## **G. Anesthesia**

During the surgery, local anesthesia or general anesthesia may be necessary. If a local anesthesia is preferred, nitrous oxide may be used.

## **V. Maintenance**

### **A. Daily Start Up**

When starting the unit at the beginning of the day:

Push the POWER SWITCH to light the on indicator (LED)

If no LED light, please check the AC line.

Put the correct plug of the handpiece into the socket.

Choose the correct electrode tip.

If the output power is weak, check the tips; otherwise contact your supplier.

### **B. Daily Shut Off**

When stopping the unit at the end of the day:

Push the POWER SWITCH to turn the unit off. Clean the handpiece and tips. Sterilize the tips.

### **C. Cleaning and Sterilization**

In this section we describe the procedures to clean and sterilize the unit. It is important to follow these procedures before using the machine on patients; otherwise patients and/or doctors have the possibility of infection. It is mandatory that doctors wear sterilized gloves during these procedures at all times to avoid any possibility of incomplete sterilization and/or infection. Below we detail the procedures for the handpiece, tips and the Main Unit, respectively.

When thorough cleaning is needed, or desired for the purpose of sterilization, the tips may be safely steam autoclaved,

#### **\* Handpiece**

Before cleaning, remove the tip from the handpiece. Carefully wipe the handpiece thoroughly using an approved disinfectant and then rinse with distilled water. Do not put the handpiece and the extension wire directly into the disinfectant solution. Any such fluid left inside the machine will interfere with the normal operation of the system.

#### **\* Tips**

After each use, there will be tissue and/or blood left on the tip, consequently, it is necessary to clean the tip with an ultra sonic cleaner first. Remember that, instead of water, use an approved disinfectant in the ultra sonic cleaner. Wash the tip thoroughly using mild detergent, and then rinse it (make sure no detergent is left on the tip). Dry the rinsed tips, and finally, put the tips in a bag and then into a medical equipment autoclave to kill any remaining germs or bacteria.

## \* **Main Unit**

Since the Main Unit does not have direct contact with the patients, the cleaning is simple. Just carefully wipe the Main Unit with an approved alcohol based disinfectant and keep it away from dust. (If other disinfectant is used, choose one that will have no chemical effects on the surface of the plastic case of the Main Unit. If no sure, please try it out first.)

## \* **Customer Service**

If service is needed, please contact local authorized agent or your supplier.

## **D. Equipment Infection Control Procedures**

The primary objective of these instructions is to recommend procedures for routine care, which will reduce the possibility of cross contamination of infectious diseases to equipment. An effective equipment infection control program should follow the recommendations of the ADA and CDC. In the event of any conflict, the ADA and CDC procedures should take precedence.

## **E. Handpiece and Cable Assembly Disinfecting**

After use with each patient, the tip must be removed from the handpiece and sterilized. After removing the tip, the unit should be operated for a short period of time to expel any possible contamination from inside the handpiece. The outer surface of the handpiece should be cleaned with an antiseptic soap or solution, rinsed off with water and wiped or sprayed with a chemical disinfectant that is compatible with the handpiece material. A sterile insert or nozzle is then inserted into the handpiece in preparation for the next patient.

At the end of the day, with the insert or nozzle removed, the handpiece and cable should be scrubbed with an antiseptic soap or solution, and rinsed off with water. The handpiece should be scrubbed a second time with an antiseptic soap or solution and rinsed off with water.

The handpiece and cable are to be wiped or sprayed with a compatible chemical disinfectant which should be allowed to remain on the surface for ten minutes or the period recommended by the disinfectant manufacturer. The handpiece and cable area should be rinsed off with sterile water and the unit operated with water for a short period of time to purge the inside of the handpiece.

**Caution:** The handpiece or cable should not be directly immersed in any of the liquids mentioned above as any residue may interfere with the continuing operation on the handpiece.

The chemical disinfectant should not be allowed to remain on the surface longer than the recommended time or material damage may result.

## **F. Unit Cabinet Sanitizing**

The instrument cabinet is considered a non-critical item that needs to be sanitized at the end of the day. This consists of wiping the surface lightly with a cleansing solution and wiping with a dry cloth. Spray lightly or wipe with a cloth slightly dampened with a chemical disinfectant, allow to remain on the surface for ten minutes or manufacturer's recommended period of time, but no longer. Then wipe the surface with a damp cloth and dry thoroughly, including any crevices.

## **G. Insert or Nozzle Sterilizing**

The insert/nozzle must be cleaned free of blood, saliva or other debris prior to sterilizing. This can be done manually by scrubbing with a brush or by the use of an ultrasonic cleaner with a solution of detergent and water. After scrubbing, the insert/nozzle should be rinsed thoroughly with water to remove all detergent and then dried.

The preferred method of sterilization is to enclose the insert/nozzle in a paper bag and place it in a pressurized steam vapor type autoclave and sterilize the insert/nozzle at 260 degrees F for thirty minutes or as recommended by the manufacturer of the particular sterilizer used.

An alternative, but less desirable method of sterilization is the use of a compatible chemical sterilant. In this method, the insert/nozzle is immersed at room temperature in the disinfectant at the appropriate strength and for the recommended period of time. Then it is thoroughly rinsed with sterile water and completely dried.

**Warning:** High room temperature conditions, improper dilutions, or excessive immersion time in a chemical sterilant can result in damage to the plastic and elastomeric materials of the insert/nozzle.

**Caution:** The use of a dry heat oven, incompatible chemical vapor type sterilizers and Quaternary ammonium compounds must be avoided as damage can result to the plastic and elastomeric materials.

## **VI. Notes:**

- A. A patient with pace maker cannot be treated with electrosurgery. Please make sure the patient does not have a pacemaker.
- B. Do not operate this equipment in a room with flammable and explosive liquid or gas in it.
- C. When replacing the ELECTRODE TIP, make sure that the foot is removed from the pedal to prevent contact of electrode TIP with the skin.
- D. Any parts not in use can not be put near the patient or on the towel. It may catch fire.
- E. If the electrosurgery is not in use, or the suitable setting is not determined, operator should begin with low power, increasing it slowly and carefully until the suitable condition is determined.
- F. Put the EKG monitor away from handpiece of electrosurgery and IND. plate as far as possible.