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I. Introduction

A. General Description

Electrosurgery is an effective method used to cut or coagulate soft tissue. Cutting tissue with electrosurgery is often called ELECTROSECTON. While electrosecting, the trauma associated with scalpel incisions is eliminated and the destruction of tissue cells is reduced. The principle of electrosurgery is to provide heat produced by current of about 2 MHz going through a resistor. The high temperature heat will dissolve, and evaporate tissue cells causing the tissue to separate as if being cut with a knife.

ELECTROCOAGULATION is the non-evaporative destruction of tissue with a high frequency current. It is convenient and helpful in healing the surgical site.

Thus, use of electrosurgery reduces post-operative pain, swelling and infection.

The ART-E1 system general diagram is shown in Fig.1. ultra high frequency radio waves are generated in the handpiece and the IND plates subjected to high frequency alternation current (about 1.5MHz), which driven by the oscillator driven circuit.

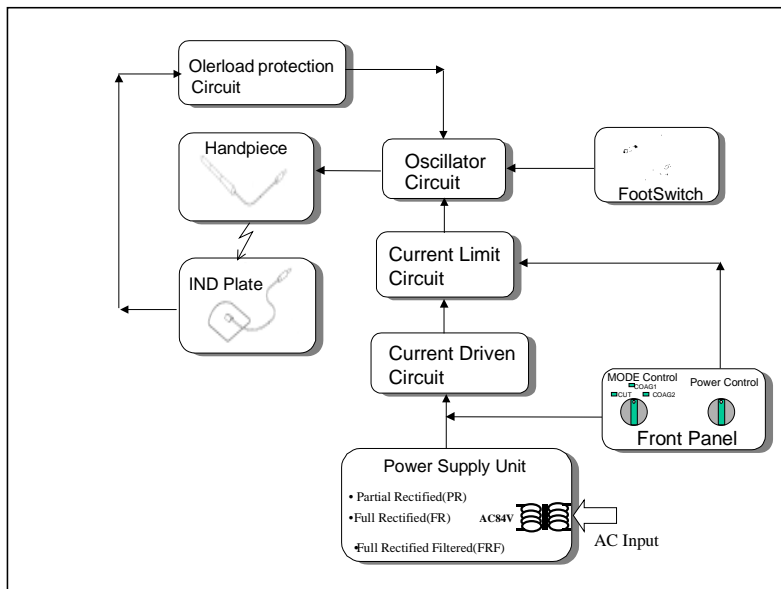


Fig.1. ART-E1 system general diagram

B.

Configuration of ART-E1

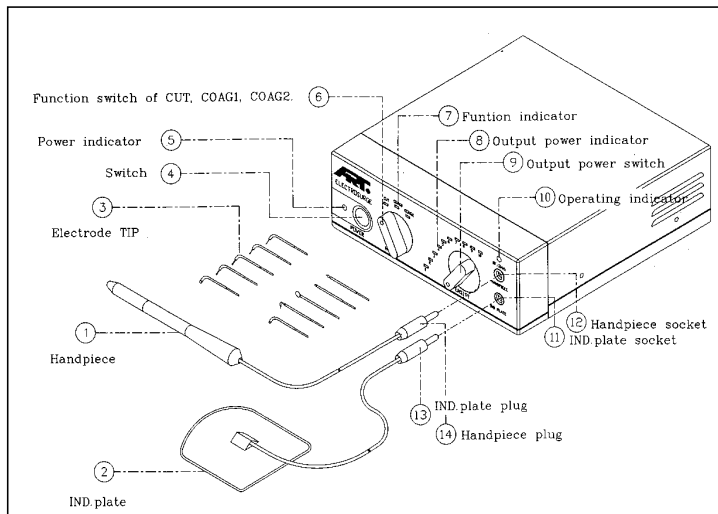


Fig. 2. ART-E1 Outlook diagram(front view)

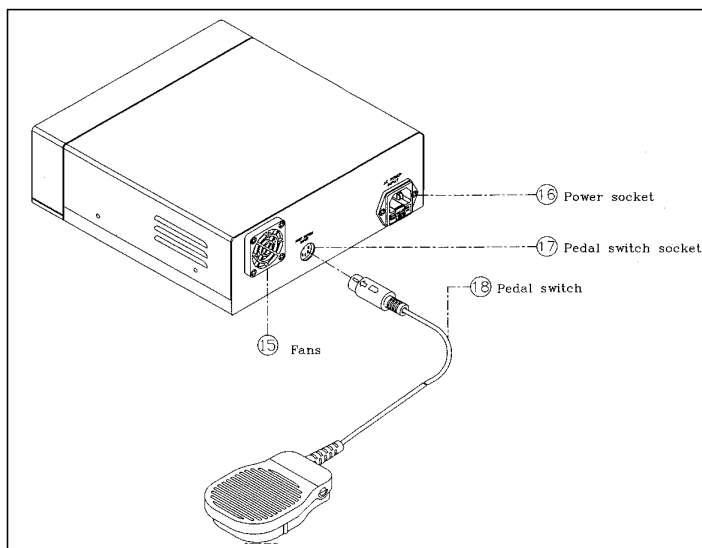


Fig. 3. ART-E1 Outlook diagram(back view)

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

C. 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.



Before turning the unit on, be sure the footswitch is in “OFF” position.

2. HANDPIECE: Socket for handpiece(black).Put the handpiece plug into **the** black socket.

Warning : Don't put the handpiece in the IND. PLATE socket(code red color)

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.

Warning : When the RF/2MHz LED still lit up, the unit was in overload condition.

4. IND. PLATE: IND. Plate sockets (red), put the plug of IND. Plate into this red socket.

Warning : Don't put the IND. PLATE in the HANDPIECE socket(code black color).

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, COAG1, and COAG2.

- 6.1 CUT: to perform both electrosection and **electrocoagulation**.
- 6.2 COAG1: perform both electrosection and electrocoagulation.
- 6.3 COAG2: coagulation and stanches.

II. Getting start

A. Unpacking

When unpacking the box, check ART-E1 for any **damages**. If damaged, please contact your dealer immediately. Enter the unit serial number on your warranty card mail it within 10 days after setting up the machine.

B. Storage

Environment:

The unit should be stored in a clean, dry environment. The following environmental limitations apply to both storage and shipment:

Temperature: 0. to 60.

Humidity : 10%~90% (at 40.)

Atmospheric pressure: 860~1060 hPa

Labels:

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



FRAGILE



KEEP AWAY FROM WATER



DON'T HOOK



THIS SIDE UP

C. Safety Instruction

Grounding:

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

Note : The unit must be positioned so that the plug is accessible.

Main voltage range and fuse:

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

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

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

- Disconnect the unit from the 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. The fuse will be 2A/250V fast action type.

D. Setting up

1. Check ART-E1 and make sure the both power and power indicator are off when the switch is off.
2. Plug the **power cord** into a grounded AC power outlet.
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 secured 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 it** clockwise.

E. Starting ART-E1

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 (COAG2) to perform coagulation. **Then** switch the INTENSITY output to a suitable intensity according to the bleeding at the surgical site.

III. Description

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 **electro-surgical** 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, the higher the operating power will be.
2. The smaller the tip, the lower the operating power will be.

D. Electrosection waves

Electrocoagulation has practical applications in surgery. ART-E1 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 led to a sustaining non-oscillating current. This non-oscillating current provides the required current for the operation, and is most beneficial condition for most clinical applications. Heat and tissue destruction is minimal.

2. FULLY rectified current(COAG1)

Fully rectified currents produce short but visible oscillating effects. In some circumstance, 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 small range on clinical operation but is effective. 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 hemostasis, especially for wounds of 1.6mm diameter. Partially rectified current may provide another indirect technique for coagulation. Coagulate the vessel 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-E1 is use for electrosection, electrosection/electrocoagulation and electrocoagulation for serious 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 in 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 electrode 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 depth 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 a 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 on sparking and changes in color of the beef. The electrosection should be smooth, without any difficulty. No pulling or tearing usually occurs between #5 and #6 power setting and make a special remark to denote this suitable intensity. Then practice cutting with different speeds and different power settings until proper clinical technique is achieved.

D. Explanation before coagulation

ART-E1 can be used to coagulate the capillaries. Switch the current dial to partially rectified current. 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 mote clearly. Pressing the wound indirectly is helpful to find the source of the bleeding. Touch the tissue with 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 is necessary. If NITROUS OXIDE ANALGESIA is used, the local anesthesia is necessary.

V. Maintenance

V.1. Daily Start-up

When starting the unit at the beginning of the day:

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

Note : If the power LED does not light, please check AC line or contact local authorized agent.

*Put the correct plug of the handpiece into the socket.

*Choose the correct electrode TIP.

*If the output power is weak, check the electrode TIP otherwise contact local authorized agent.

V.2. Daily Shut-off

When stopping the unit at the end of the day:

*Push the POWER SWITCH to turn the unit off.

*Cleaning the handpiece and electrode TIP.

*Sterilize the electrode TIP.

V.3. Preparing to treat a patient

*Make sure the handpiece and electrode TIP has been sterilized.

V.4. 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; otherwise, patients and/or doctors may have the possibility of getting infection. **It is mandatory that clinicians wear sterile gloves during these procedures at all time to avoid any possibilities of incomplete sterilization and/or infection.** Below we detail the procedures for the Handpiece, the electrode TIP, and the Main Unit, respectively.

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

● Handpiece

Before cleaning, remove the electrode TIP from the Handpiece. Carefully swab the Handpiece thoroughly using sterilized fluid and then rinse with distilled water. Note not to put the Handpiece and the extension wire directly into the sterilized fluid. Any left such fluid inside the machine will interfere with the normal operation of the system.

● Electrode TIP

After each usage, there will be tissue and/or blood left on the TIP, consequently, it is necessary to clean the electrode TIP with a cleaner first. Remember that, instead of water, use sterilized fluid in the supersonic cleaner. Wash the TIP thoroughly using mild detergent, and then rinse it (make sure no detergent left on the TIP). Dry the rinsed TIPs, and finally, put the TIPs in a bag and then put it into a medical-equipment autoclave to kill any left germs and/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 absolute alcohol calomel, and keep it away from dust. (If other disinfection is used, choose one that will have no chemical effects on the surface of the plastic case of the Main Unit. If not sure, please try it out first.)

- **Customer Service**

If service is needed, please contact local authorized agent.

V.5. 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.

V.6. Handpiece and Cable Assembly Disinfection

After treating each patient, the electrode 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, such as a 1:6 dilute solution of Sporicidin brand disinfectant. A sterile insert or nozzle is then reassembled to the handpiece in preparation for the next patient.

At the end of the day with the insert/ nozzle remove, 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 such as a 1:16 dilute solution of Sporicidin brand disinfectant and allowed to remain on the surface for the period of time recommended by the disinfectant manufacturer. The handpiece and cable area should be rinsed off with sterile water and the unit operating for a short period with water 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 entrained residue may interfere with the continuing operation of the handpiece.

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

V.7. 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 such as Sultan Orange Solvent and wiping with a dry cloth. Spray lightly or wipe with a cloth slightly dampened with a chemical disinfectant such as SPORICIDIN brand disinfectant spray, allow remaining on the surface for the manufacturers recommended period, but no longer. The wipe surface with water wet cloth and dry thoroughly including any crevices.

V.8. 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 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.(127.) for 30 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 such as Sporicidin brand disinfectant. In this method, the insert nozzle is immersed at room conditions in the disinfectant at the appropriate strength and for the recommended period by the manufacturer. **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.

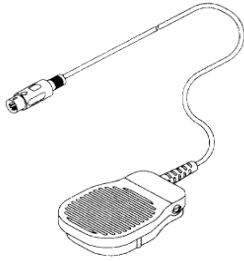
Caution : The use of a dry heat oven. Incompatible chemical vapor type sterilizers. Quaternary ammonium compounds, or alcohol- based compounds must be avoided as damage can result to the plastic and elastomeric materials.

Notes :

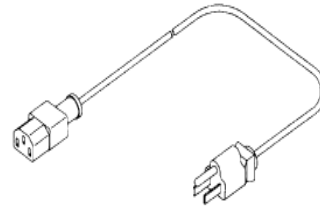
- 1.A patient with pace maker cannot be treated with electrosurgery. Please make sure the patient dose not have a pacemaker.**
- 2.Do not operate this equipment in a room with flammable and explosive liquid or gas in it.**
- 3.While replacing the ELECTRODE TIP, make sure that the foot is removed from the pedal to prevent contact of electrode TIP with the skin.**
- 4.Any parts not in use can't be put near the patient or on the towel. It may catch fire.**
- 5.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.**
- 6.Put the EKG monitor away from handpiece of electrosurgery and IND. plate as far as possible.**

VI. Accessories

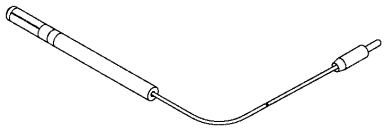
(1) Footswitch x1



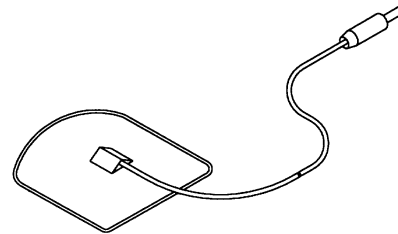
(2) AC Power Line x1



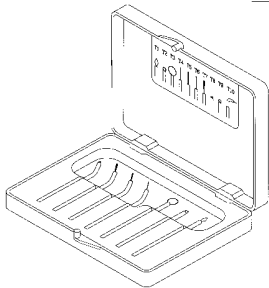
(3) Handpiece x1



(4) IND. Plate x1



(5) ELECTRODE TIP SET BOX x1



Note : The above standard outfit is subject to change depending upon country and area.

VII. Specifications

BONART ART-E1 is designed and **manufactured** to meet the most demanding environment. It's specification are **listed** below:

1. Standard lists :

Emission: EN55011 Class B	EN60555-2 Class A	EN60555-3
Immunity: IEC 1000-4-2	IEC 1000-4-4	IEC 1000-4-5
IEC 801-3	ENV50141	
Safety: EN 60601-1	EN1640	

2. Functions :

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

3. Specifications :

Power supply

115V ± 10 .	- 50/60Hz	1.8A	210VA
230V ± 10 .	- 50/60Hz	0.9A	210VA

Output power

70 Watts ± 5 .

Working frequency

1.5 – 1.7MKHz ± 5 .