

ART-Electron™ (E1)

Directions for Use



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Operator Safety

Please read the entire guide prior to operating the system.

The dental equipment described in this manual is designed to be used only by properly trained personnel. Only qualified personnel shall carry out any adjustments and maintenance, and all repairs (internal or otherwise) must be conducted by an authorized Bonart™ technician.

- **Notice, Caution, and Warning Statements :**

NOTICE : Indicates helpful tips and advice.

CAUTION : Indicates proper operating or maintenance procedures.

WARNING : Alerts the user of conditions that may cause severe injury when proper procedures and/or practices are not followed.

- **Symbols :**



Complies with MDD 93/42/EEC
Notified body : DNV



Indicates that the ART-Electron™ was manufactured in compliance with required standards to protect against electrical shock for BF type equipment



Indicates a grounded terminal



Requires immediate attention upon reading the instructions

Warnings

- **The ART-Electron™ and all accessories should be used solely by properly trained doctors, dentists, and any other trained personnel.**
- **The ART-Electron™ must NOT be used on patients with pacemakers.**
- **A shielded AC power cord must be used with this equipment.**
- **The power cord must be plugged into a grounded electrical outlet.**
- **The ART-Electron™ must not be immersed in or sprayed with water or liquid; it is an electrical appliance.**
- **If the patient or operator is pregnant, please consult a physician prior to operating.**



Special note for users with Cardiac Pacemakers:

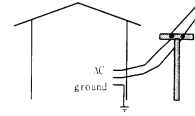
Studies have shown that electrical appliances including razors, hair dryers, microwave ovens, TV receptors, and electrical medical equipment may interfere with the normal operations of pacemakers. Therefore, **patients with pacemakers should avoid use and/or treatment with the ART-Electron™.**

For further readings on this subject, please refer to the following sources:

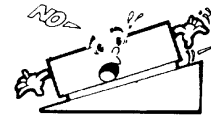
- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare
- "The Individual with a Pacemaker in the Dental Environment", Journal of the American Dental Association, Vol. 91, No. 6, pp. 1224-1229

NOTE (Please read prior to using):

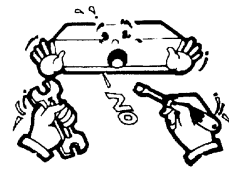
- Ensure that the ART-Electron™ is connected to a grounded outlet. Failure to meet this requirement may cause severe damage and harm to the system or user.



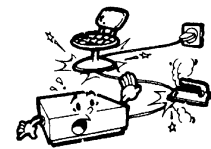
- Place the ART-Electron™ on a stable and flat platform. Tilted and unstable surfaces may degrade the performance or damage the machine.



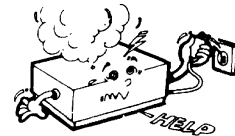
- Do not modify the ART-Electron™. Modifications may invalidate the warranty and cause harm to the patient and operator. Any modification will void the warranty terms.



- Keep the ART-Electron™ away from high sources of heat. Do not place the power cord under heavy objects, and avoid draping the cord around other objects or anywhere that could constitute a tripping hazard.



- Call Magpie Tech Corp. (the North-American distribution/repair center for Bonart™ products) if any abnormal situations arise while operating the ART-Electron™.



- Nitrous oxide-oxygen may be used in conjunction with the ART-Electron™.

- Only non-conductive plastic tools (such as saliva ejector tips, high volume evacuation tips, mouth mirrors, and tissue and tongue retractors) are recommended for use while operating the ART-Electron™.

- Keep the ECG monitoring electrode at the farthest possible distance from the electro-surgery plate and tip due to radio frequency emitted from the ART-Electron™.

Preface

ART-Electron™

The ART-Electron™ is ISO 13485 certified and CE 2460 certified in compliance with applicable requirements of the Council Directive 93/42/EEC. The reviewing council classifies the ART-Electron™ in accordance with EN60601-1, EN60601-1-2 and EN55011 safety requirements.

The ART-Electron™ transmits high frequency radio waves through a fine wire electrode, to a flat antenna on an indifferent plate placed under the subject. The high frequency radio waves pass through tissue for a clean surgical incision. The user may choose various waveforms to assist in different procedures, from cutting to hemostasis. ***The ART-Electron™ should not be confused with electro cautery systems that use thermal energy and heat to burn tissue.***

The ART-Electron™ provides several advantages. First, the system allows for fine and precise incisions with hemostasis of small “bleeders.” Second, the system provides a clearer view of the operating field with less blood obstruction, making any procedure faster and easier.

Supplies & Replacement Parts

To order supplies or replacement parts in the U.S., please contact one of our authorized distributors listed on www.askmagpie.com . For outside of U.S., please email to tammy@bonartmed.com , Bonart’s General Sales’s email.

Table of Contents

Copyrights	1
Operator Safety	2
Warnings	3
Preface	5
Contents	6
Section I. Indications	7
Section II. Contra-indications and Warnings	7
Section III. Precautions	8
Section IV. Accessories	9
Section V. Installation Instructions	10
Section VI. General Information	12
Section VII. Precautions	16
Section VIII. Techniques for Use	16
Section IX. Practice Before Using	17
Section X. Getting Started	17
Section XI. Infection Control	18
Section XII. System Maintenance	20
Section XIII. Troubleshooting	21
Section XIV. Specifications	22

Section I: Indications

Electrosurgery procedures:

- Impression-taking; gaining access to margins of prepared teeth; removing interproximal tissue.
- Extending the clinical height of a crown.
- Gingivectomy.
- Oral surgery; periodontia; endodontia; orthodontia; prosthodontia; operative crown and bridge procedures.
- Removal of pericoronal tissue on 3rd molars.
- Biopsy (bloodless).
- Reducing and removing swollen and hypertrophied gum tissue around the necks of teeth.
- Planting tissue of edentulous region prior to making impressions for prosthodontics.
- Coagulating bleeding prior to cementation procedures.
- Removing excess flabby tissue or tissue tabs.
- Incising, excising, draining, or coagulating minor periodontal conditions.
- Uncovering un-erupted teeth.
- Light surgery with antisepsis and hemostasis.

Section II: Contra-indications and Warnings

- Do not use the unit if the patient or operator is wearing a pacemaker.
- Do not immerse the unit in- or spray the unit with - water or liquid.
- Do not reach for units that have accidentally been submerged in liquid.
- Do not modify the unit. Modification will void the warranty and may cause serious harm to the patient and operator.
- Do not operate the ART-Electron™ unit if the Active indicator light remains lit even when the footswitch is not being used. This indicates that the unit is malfunctioning and should be serviced.

- Stop cutting immediately at the first sign of tissue blanching, and avoid prolonged tissue contact. Allow tissue to cool 10 seconds between cuts. Excessive exposure may retard healing and cause sloughing.
- Do not use in the presence of flammable or explosive gases.
- Do not use in any situation where the electrode will touch metal restorations, implants, bone or teeth; doing so may result in bone necrosis.
- Always operate the ART-Electron™ attentively and cautiously.

Section III: Precautions

3-A: Precautions

- The indifferent plate must maintain direct contact with the patient's skin during use. Failure to maintain close, unimpeded contact will result in an incomplete current and little or no power.
- Turn the power off before changing electrodes in order to avoid shock. After installing the electrode to the hand piece, examine carefully to assure the metal shaft is fully seated.
- Be sure the hand piece, cable and electrodes are dry before use to avoid shock.
- Do not bend the insulated portion of the electrode as this may crack the plastic sheath and lead to failure and/or shock.
- Release the footswitch before placing or removing the electrode from the patient's mouth.
- Do not allow cables to be coiled or twisted around metal objects.

IV: Accessories

Item No.	Description	Quantity
1	Main Unit	1
2	Foot Switch	1
3	AC Power Cord Set	1
4	Detachable Handpiece	1
5	Indifferent/IND (Grounding) Plate	1
6	7pcs. Electrode set	1

! Notice :
The standard set of accessories shown above is subject to change depending on region.

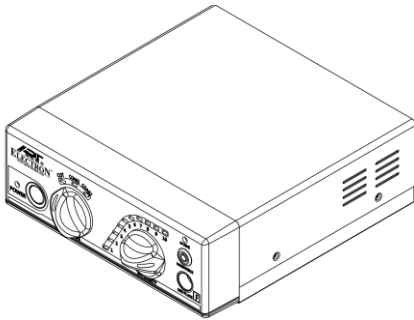


Fig.1, Main Unit

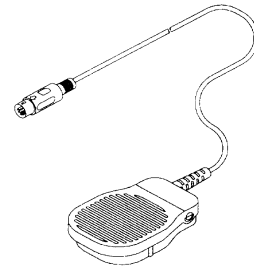


Fig.2, Foot Switch

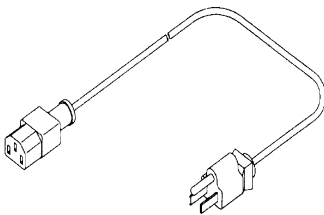


Fig.3, AC Power Cord



Fig.4, Detachable Handpiece

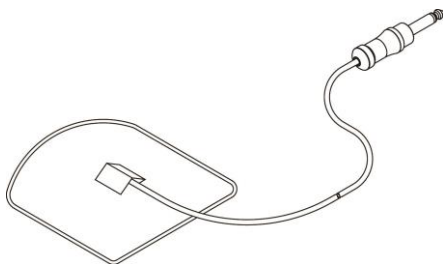


Fig.5, Indifferent/IND (Grounding) Plate



Fig.6, 7pcs. Electrode set

Section V: Installation Instructions

5-A: General Installation Information

If the installation of your ART-Electron™ system is not performed by a Bonart™ representative, please ensure that the following requirements are met :

5-B: Electrical Requirements

Refer to Section XIV: Specifications

5-C: Unpacking the Unit

Carefully unpack your ART-Electron™ unit and verify that all components and accessories are included:

1. ART-Electron™ Unit
2. AC Power Cord Set
3. Detachable Hand piece
4. Foot Switch
5. Indifferent/IND (Grounding) Plate
6. 7pcs. Electrode set
7. Literature Packet

NOTICE : While you unpack, check the ART-Electron™ for any damages. If damaged, please contact your dealer immediately.

5-D: Power Cord / Power Connection

- Verify the Power Control switch is set to the OFF position before plugging and unplugging the power cord from the unit or from the power outlet.
- Plug the detachable AC cord into the back of the unit.
- Plug the 3 prong grounded plug into a grounded outlet.



Safety Instructions

A. Grounding:

Before any connection to the output connectors is made, verify that the unit is grounded and plugged into a wall outlet.

NOTICE: Make sure the outlet and plug are easily accessible.

B. Main voltage range and fuse:

Before plugging the power cord into the power outlet, verify that the unit is compatible with the local main voltage used.

WARNING: Prior to replacing the fuse, turn the unit off and unplug the power cord from the outlet.

NOTICE: Blown fuses are often a sign of a systemic problem. Please contact the Magpie repair center prior to replacing the fuse.

The fuse holder is located on the rear panel in the input socket. To replace the fuse, follow the steps below:

1. Disconnect the unit from the power outlet.
2. Remove the cover of the fuse holder with a small screwdriver.
3. Replace with a new fuse and re-install the cover of the fuse holder. Please use a slow type of fuse, (2A/250V) .

5-E: Foot switch Cable Assembly Connection

Align the Foot switch plug with the socket on the back of the device and push firmly until seated.

5-F: IND/Indifferent Plate installation

Insert the IND plate cable directly into the red jack at the front of the unit.

WARNING: DO NOT REMOVE THE IND PLATE FROM THE PROTECTIVE SLEEVE.

5-G: Hand piece Cable Assembly Connection

Insert the hand piece cable directly into the front hand piece jack.

5-H: Electrode installation

Loosen (but do not remove) the black cap at the tip of the hand piece by turning counter-clockwise, and remove and discard the metal packing rod [First-time use only]. Insert the electrode gently but firmly into the tip of the hand piece, and tighten the black cap to secure the electrode.

Section VI: General Information

ART-Electron Unit Diagram

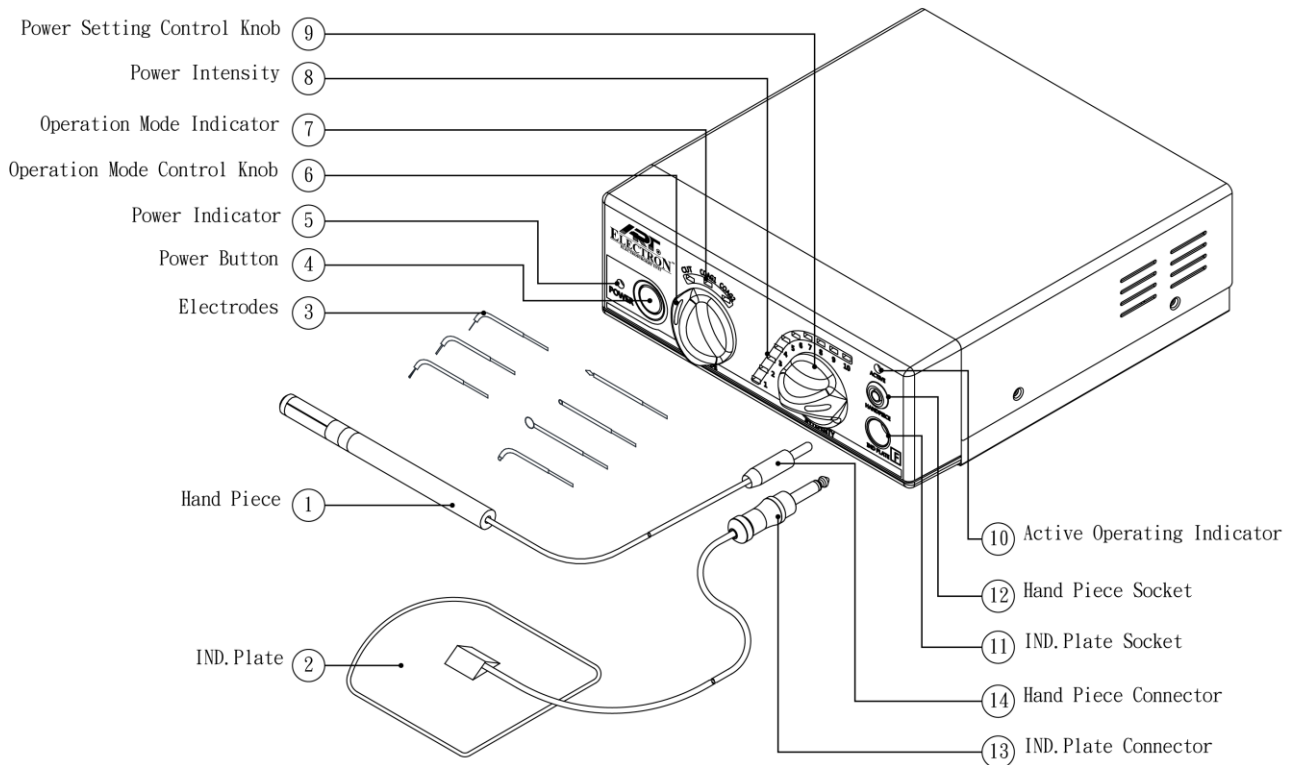


Figure 1: ART-Electron™ (front view)

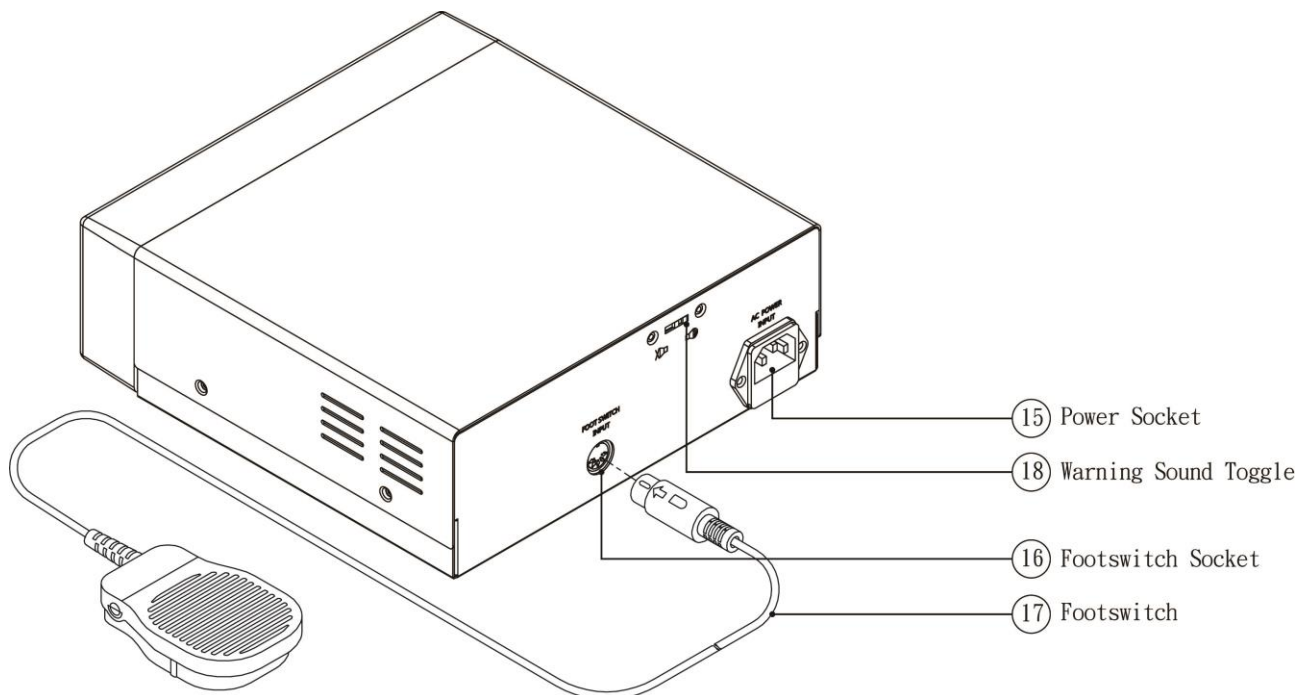


Figure 2: ART-Electron™ (back view)

1. Hand Piece

The hand piece is the housing for the electrode tips. Compatible tips should have a diameter of 1/16" (0.2cm).

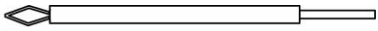

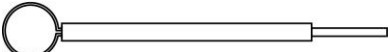
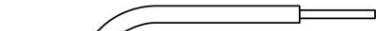
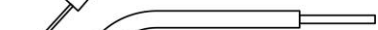


CAUTION: Make sure that electrodes are fully-seated before use.

2. Indifferent/IND (Grounding) Plate

When using the ART-Electron™, the indifferent plate must maintain contact with the patient's skin for the entire duration of the operation, lest the unit will halt function. The indifferent plate is covered with a plastic sleeve that should never be removed.

WARNING: The included indifferent plate should never be used in conjunction with gels or liquid. This can result in severe burns to the patient!

3. Electrodes

	T1 : Diamond shaped Electrode
	T3 : Large Round Loop Electrode
	T2 : Small Round Loop Electrode
	T4 : Fine Wire Electrode
	T5 : Heavy Wire Electrode
	T7 : Fine Oval Loop Electrode
	T9 : Heavy Ball Electrode

Uses and Power Settings:

T1, T2, T3: For cutting tissue with blood control and preparing for cementing.
(Start at no. 5-6 power setting)

T4: For removing gingival tissue, cutting, and changing gingival height.
(Start at no.7 power setting)

T5: For hemostasis. (Start at no. 5 power setting)

T7: For removing gingival tissue, salvaging teeth, and changing gingival height.
(Start at no. 6 power setting.)

T9: For blood control and preparation of cavities. (Start at no.3 power setting)

WARNING: Operating power is higher when using a larger tip.

CAUTION: Operating power is lower when using a smaller tip.

4. Power Button (On/Off Switch)

The power button is located on the front of the ART-Electron™ unit. Use this button to turn the unit off and on.

WARNING: Do NOT turn the unit off by unplugging the power cord.

WARNING: Do NOT turn on the ART-Electron™ unit while the foot switch is depressed.

5. Power Indicator

The power indicator is located to the left of the power button. The power indicator should be lit when the power is on and unlit when the power is off.

6. Operation Mode Control Knob

The Operation Mode Control Knob is located on the front of the ART-Electron™ unit. This knob allows you to select the following modes:

- **Cut:** Preferable for thin avian skin and incisions. This mode allows for smooth cutting by providing continuous fully-filtered high frequency waves. This mode also produces minimal lateral heat, tissue damage, and hemostasis.
- **Coag 1:** Preferable for electro-section and electrocoagulation. This mode produces a full rectified wave. While it provides less cutting power, it allows for coagulation of small capacity.
- **Coag 2:** Preferable for coagulation and stanches. This mode produces partial rectified waves and is optimized to provide more hemostasis on vessels up to 1/16” in diameter. Under this mode, the electrode is allowed to touch the hemostat near the tip and coagulate the vessel.

7. Operation Mode Indicator

The LED indicator located above each of the following modes will be lit when a mode is selected.

8. Power Intensity

There are 10 levels of output intensity, with 1 being the lowest level.

9. Power Setting Control Knob

This knob allows you to control the power intensity via levels 1 through 10. The LED indicator will be lit for the selected intensity level. When using the ART-Electron™ unit, **start at the minimum level** and slowly increase output intensity. Cutting should be smooth, without sparks.

10. Active Operating Indicator

The operating indicator shows that the foot switch is depressed and that radio frequency waves are being sent.

NOTICE: The main power must be on for the indicator to be active.

WARNING: The indicator should be unlit when the foot switch is released. If this condition is not met, stop using immediately and contact a Bonart™ representative.

11. Indifferent/IND (Grounding) Plate Socket

The indifferent plate socket is located on the front of the unit below the hand piece socket. The indifferent plate connector should be inserted here.

12. Hand Piece Socket

The hand piece socket is located on the front of the unit above the indifferent plate socket. The hand piece cable connector should be inserted here.

13. Indifferent (Grounding) Plate Connector

The indifferent plate socket is located on the front of the ART-Electron™ unit below the hand piece socket. The indifferent plate connector should be inserted here.

WARNING: Do NOT connect the indifferent plate to the hand piece socket!

14. Hand Piece Connector

Plug the hand piece connector into the hand piece socket located on the front of the ART-Electron™ unit (above the indifferent plate socket).

WARNING: Do NOT connect the hand piece to the indifferent plate socket!

15. Power Socket

The power socket is located on the back of the ART-Electron™ unit. The power plug should be inserted here.

16. Footswitch Socket

The foot switch socket is located on the back of the ART-Electron™ unit. The footswitch connector should be inserted here.

17. Footswitch

The footswitch allows the user to operate the ART-Electron™ unit while leaving both hands free.

18. Warning Sound Toggle

The warning sound toggle is located on the back of the ART-Electron™ unit. You can set the toggle to the right for sound, or left for no sound.

CAUTION: THE WARNING SOUND IS THERE TO ALERT YOU THAT THE UNIT IS IN USE. PLEASE EXERCISE CAUTION IN DISABLING THE WARNING SOUND.

Section VII: Precautions

- Tissue damage may occur when the surgical site is overheated or dehydrated. Keep the surgical site irrigated.
- Utilizing unnecessarily-high settings may result in sparking, which can cause tissue damage.
- The smoothness and speed of the electrode passing through/across the surgical site should be such that there is minimal resistance and no sparking.
- Insufficient power settings can result in tissue being pulled and torn. Heat generated by the ART-Electron™ is dependent on the duration of contact between the tissue and electrode tip, as well as intensity and tip size.

Section VIII: Techniques for Use

A. Learning to use the ART- Electron™

- Prior to applying the electrode to tissue, adjust the power intensity to a proper level.
- During operation, avoid using pressure and focus on making smooth, concise motions.
- Be careful not to operate on one spot for too long, as heat may propagate deep into the tissue and cause burning and necrosis.

B. Electrosection (Cutting)

- When performing electrosection, the tissue should always be moist; cutting on dry tissue may char the surface.
- For optimal control over the hand piece, rest your hand on a sturdy surface for support.
- Avoid cutting with pressure.
- Saline solutions are recommended.

C. Coagulation (Hemostasis)

- Light bleeders may be easily stopped with the ART-Electron™ using either mode Coag 1 or Coag 2. Using a sponge or hemostat, apply direct pressure on the vessel. The vessel should be visible and not obstructed by blood.
- For heavy bleeders, Coag 2 is preferred.
- Electrodes designed for coagulation are the round ball and heavy wire.
- Another method of coagulation utilizes a hemostat and fine electrode tip. The vessel is grasped by the hemostat and the electrode is applied at about 1 inch from the end of the hemostat.

D. Bloodshed Control

- The ART-Electron™ may be used to control bloodshed through coagulation at the beginning of entering tissue. Once the bleeding begins, direct air pressure is necessary. Afterwards, Coag 2 may be used to repair the capillary or blood vessel.

E. Anesthesia

- Use general anesthesia or local anesthesia during surgery. If nitrous oxide analgesia is used, local anesthesia is necessary.

Section IX: Practice before Using

It is highly recommended to practice using the ART-Electron™ on an apple, bar of soap, or fresh meat prior to operating on actual clinical cases. Below are a few steps to help you practice:

1. Obtain a fresh lean cut of beef, such as round or sirloin steak. Use meat at room temperature (do not use frozen meat). Moisten the meat with a small amount of saline.
2. Set up the unit and place the meat **on top of** the indifferent plate. This mimics the constant contact that the indifferent plate must maintain with a live patient.
3. Insert an electrode into the hand piece.
4. Select waveform mode Coag 2.
5. Set the power level to 8.
6. Press the foot switch.
7. Do several incisions and observe the results. This high setting will cause sparking and may char the tissue.
8. Adjust the power level to 1. **This setting on the meat will illustrate poor cutting or extreme drag.**
9. Continue adjusting the power setting to different levels and observe the incision.
10. Try different waveform modes (wait 10 seconds between waveform mode adjustments). With further practice, operating on actual patients with the ART-Electron™ will become safer and easier.

NOTICE: Cutting should be smooth with no sparks or resistance.

Section X: Getting Started

- a. Remove the unit from the box and lay it on a flat surface.
- b. Connect the power cord to the ART-Electron™ and to the power outlet.
- c. Connect the hand piece to the hand piece socket on the front panel of the ART-Electron™ unit.
- d. Connect the indifferent plate to the indifferent plate socket on the front panel of the ART-Electron™ unit.

WARNING: Never attempt to force the accessories into the sockets. Always be sure that you have matched the proper accessory to the proper socket!

- e. Connect the foot switch to the foot switch socket located on the back of the ART-Electron™ unit.
- f. Ensure that the indifferent plate has stable contact with the patient.

NOTICE: Monopolar systems such as the ART-Electron™ will not function without the IND/grounding plate maintaining constant contact with the patients' skin. Attempting to ground through clothing or heavy fur may result in loss of (or complete lack of) power. When testing on a piece of meat, fruit or a bar of soap, the item itself must be placed directly on the IND plate prior to cutting.

- g. Insert an electrode into the hand piece for operating. Follow the steps below for installing electrodes:
 1. Turn the nose/cap of the hand piece counter-clockwise to loosen the opening.
 2. Insert the selected electrode into the opening (blue side down/in).
 3. Secure the electrode by turning the nose/cap of the hand piece clockwise.

NOTICE: Do not over-tighten the nose/cap. The top portion may continue to turn even when the electrode is securely in place.

- h. Select the operating mode.
- i. Select the power intensity by turning the power control knob. Start with low intensity and slowly increase.
- j. Depress the foot switch. When depressed, the Active yellow LED indicator should be lit.
- k. Hold the electrode gently on the tissue and cut. Avoid using pressure.
- l. Keep tissue moist for cleaner incisions.

WARNING: Too much pressure on the electrodes can damage the tips.

Section XI: Infection Control

4-A: General Infection Control Recommendations:

As with all dental and medical procedures, use standard personal protection equipment such as facemasks, eyewear, face shields, gloves, and protective gowns.

To ensure the safety of operator and patient, carefully follow the Infection Control Information procedures detailed in Section XI.

It is highly recommended that all infection control procedures conform to applicable Centers for Disease Control and Prevention (CDC) and American Dental Association (ADA) standards, and that all recommendations be followed in terms of the agencies guidelines and procedures.

4-B: Cleaning and Sterilizations:

Handpiece

Always clean and sterilize the hand piece and electrodes after each patient. Remove the electrode from the hand piece prior to cleaning. The outer surface of the hand piece should be cleaned with antiseptic soap or solution; wipe with disinfectant and/or water.

Place the hand piece in a bag and steam autoclave at 275°F (135°C) for 3 minutes or as recommended by the manufacturer of your sterilization machine. Items should take approximately 15 minutes to dry.

Use bio-indicators or chemical indicators to ensure the efficiency of the sterilization cycle. Electrodes may be re-inserted into the hand piece after disinfecting, and should be run with power for several seconds to finalize sterilization.

WARNING: Steam autoclave must be used for sterilization. Do not use any other method of sterilization (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

CAUTION: Always allow accessories to dry after autoclaving and prior to use.

WARNING: Do not submerge the hand piece cable in sterilization fluid or water. Doing so may cause damage to the hand piece and system.

WARNING: When using chemical disinfectants, please follow the instructions provided by the manufacturer of the disinfectant and do not allow the chemical to remain on the surface longer than recommended.

Electrodes

Always clean and sterilize electrodes after each use to prevent spreading germs and diseases to other patients. Saliva, blood, and other debris may be left on the electrode.

To sterilize electrodes, wipe the electrode thoroughly using a mild detergent. Rinse thoroughly and dry the electrode. Place the electrode in a bag and steam autoclave at 275°F (135°C) for 3 minutes or as recommended by the manufacturer of your sterilization machine. Items should take approximately 15 minutes to dry. Use bio-indicators or chemical indicators to ensure the efficiency of the sterilization cycle.

WARNING: Steam autoclave must be used for sterilization. Do not use any other method of sterilization (dry heat, radiation, ethylene oxide, gas, low-temperature plasma, etc.).

NOTICE: Sterilization conditions in your office should be defined by the results of routine spore testing.

NOTICE: The Sterilization Assurance Level (SAL) of steam autoclave should be 10^{-6} in accordance to ISO 13683 (Sterilization of Health Care Products)

WARNING: High room temperature conditions, improper dilutions or excessive immersion time in chemicals may damage the materials of the unit.

CAUTION: Avoid using dry heat ovens, incompatible chemical vapor-type sterilizers or quaternary ammonium compounds. Doing so will damage the unit.

Main Unit

Since the main unit does not have direct contact with the patients, it can be cleaned by carefully wiping with alcohol. Avoid using disinfectants not specified for use with metal.

Section XII: System Maintenance

A. Daily Start-up

1. Make sure the ART-Electron™ is turned off prior to inserting electrodes or plugging and unplugging peripherals.
2. Plug the hand piece cable connector, foot switch and IND plate into the ART-Electron™.
3. Install an electrode to the hand piece.
4. Use the Power Switch button to turn the unit on. The power LED indicator should be lit.

NOTICE: If the power indicator is not lit when switched on, please check the power connection or contact an authorized Bonart™ agent.

B. Daily Shut-off

1. Use the Power Switch to turn the unit off.
2. Remove foot switch, IND plate and hand piece from the unit. This will prevent the cords from becoming a walking hazard.
3. Clean and sterilize the hand piece and electrode(s). Wipe the IND plate exterior with a plastics-friendly soap/cleaner.
4. Clean and disinfect the surfaces of the unit and power cord.

WARNING: Do not spray the unit or components directly. Liquid will short/damage internal parts and components.

C. Preparing to treat a patient

1. Make sure that the electrodes and hand piece have been cleaned and sterilized, and that the IND plate exterior has been cleaned.
2. Keep the operating area neat and tidy, and ensure that you have adequate reach for the hand piece cable and IND plate.

D. Between patients

Clean and sterilize all used electrodes and hand piece(s), as well as the IND plate exterior.

Section XIII: Troubleshooting

Although service and repair of the ART-Electron™ should be performed only by authorized Bonart™ personnel, the following are some basic troubleshooting procedures that will help to avoid service calls:

- Check all lines and connections to and from the system; a loose plug or connection is a common culprit.
- Check all settings on the system's knobs.
- Be sure that the IND/Indifferent plate is in **direct contact with the patients' skin** (not through clothing or heavy fur). **The unit will not function if this condition is not met.**
- Make sure that you are depressing the foot switch prior to attempting to cut.
- Ensure that the voltage of the wall socket matches the voltage of the unit. Failure to match voltages may result in blown fuses and/or damage to the circuit board.
- Ensure that electrode tips are clean and free of debris, and that they are inserted (and tightened) properly into the hand piece.

WARNING: Do not wrap the accessory cords or patient return electrode cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

Technical Support and Repair:

For technical support and mail-in repairs in the U.S., please contact Magpie Tech. Corp. at 626-600-5330, Monday through Friday, 9:00AM to 5:00PM (Pacific). For non-US territories, please contact your local Bonart™ representative.

Section XIV: Specifications

Classification

- Protection against electric shock : Class I
- Degree of protection against electric shock : Type BF
- Mode of operation : Intermittent 30s (rest) /10s (operation)
- Medical device directive : IIb

Standards Followed

ISO13485: Medical Devices, Quality Management Systems, Requirements for regulatory purposes

93/42/EEC: MDD CE Directive

EN60601-1: Medical Electrical Equipment, General Requirement for Safety

EN60601-1-2: Medical Electrical Equipment, Electromagnetic Compatibility, Requirements and Tests

Specifications

- Power supply
115V \pm 5% ~50/60Hz 210VA
230V \pm 5% ~50/60Hz 210VA

Maximum Power Output

- Cut 50 W (@500 ohm load)
- Coag 1 50 W (@800 ohm load)
- Coag 2 50 W (@1000 ohm load)

Working frequency

- Cut 357k \pm 50 kHz
- Coag 1 357k \pm 50 kHz
- Coag 2 375k \pm 50 kHz
- Dimension 23cm(L) x 22.5cm(W) x 8.5cm(H)
- Weight 3.4 Kg(include hand piece)
- Hand piece Cable 180 cm
- Plate Cable 200 cm
- Footswitch Cable 250 cm

Operation environment

- Temperature 0°C~40°C
- Relative Humidity 10% ~ 90% (non-condensing)

Transportation and Storage conditions

- Temperature 0°C~60°C
- Relative Humidity 10% ~ 90% (non-condensing)
- Atmospheric pressure 860~1060 hPa