

ART. **ELECTRON**TM **ELECTROSURGERY UNIT**

(ART-E1)

Directions for Use



EC REP Jorgen Kruuse A/S

Havretoften 4, DK-5550, Langeskov,
Denmark



COPYRIGHT© 2021 BONART CO., LTD.

Bonart Co., Ltd. owns all rights to this publication. This publication should be used solely as a reference for operation, maintenance, and repair of BonartTM equipment. No part of this document may be reproduced or disseminated in any forms or by any means, for any other purpose.

In the event of inadvertent or deliberate publication, Bonart Co., Ltd. intends to enforce its rights to this manual under the copyright law. Copying materials presented in this manual without the written permission from Bonart Co., Ltd. is strictly prohibited.

Product specifications, as well as information presented in this manual, are subject to change without prior notice.

**PROPERTY OF BONART CO., LTD.
ALL RIGHTS RESERVED**

ART is a registered trademark of BONART Co., Ltd. & its affiliates.
Document No. RD-02-15-02 Rev.2.0 (07/2021)
Printed in Taiwan, R.O.C.

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 to this equipment, and all repairs (internal or otherwise) must be conducted by an authorized Bonart™ technician.

If you have questions about surgical procedures, techniques and best practices, please contact doctors and universities in your area that specialize in electrosurgical procedures. Neither Bonart Co., Ltd. nor its' affiliates can offer help or advice on medical procedures of any kind.

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.

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:

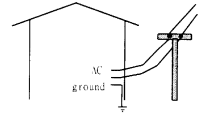
Studies have shown that electrical appliances including razors, hair dryers, microwave ovens, TV receptors, and electrical medical equipment may interfere with the normal operations of pacemakers. Therefore, **patients with pacemakers should avoid use and/or treatment with the ART-Electron™.**

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

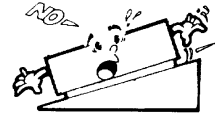
- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare
- "The Individual with a Pacemaker in the Dental Environment", Journal of the American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

NOTE (Please read prior to using):

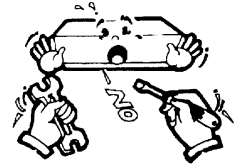
- Ensure that the ART-Electron™ is connected to a grounded outlet. Failure to meet this requirement may cause severe damage and harm to the system or user.



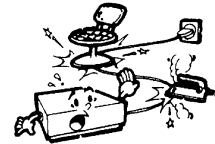
- Place the ART-Electron™ on a stable and flat platform. Tilted and unstable surfaces may degrade the performance or damage the machine.



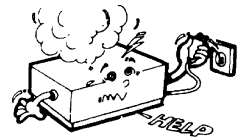
- Do not modify the ART-Electron™. Modifications may violate safety codes and cause harm to the patient and operator. Any modification will void the warranty terms.



- 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 indifferent/grounding 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 European requirements. The reviewing council classifies the ART-Electron™ in accordance with medical electrical equipment 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

Please contact any of our licensed dealers for supplies and/or replacement parts for your ART-Electron™. You can find a list of dealers for North America at www.askmagpie.com. For outside of U.S., please email to generalinquiries@bonartmed.com.

How does it work?

Energy generated within the ART-Electron™ is directed out through the handpiece and electrode and into the surgical site. The excess energy then exits the patient's body through the IND plate, cycling safely back into the unit. Improper plate contact with the patient results in all of that excess energy being funneled back through a much smaller surface area, trapping it, resulting in a conversion to heat within the plate and possible burns to the patient! Because of this, the use of conductive gel spread evenly across the plate is essential.

When using the ART-Electron™, place the IND plate as close to the surgical area as possible. The upper arm or thigh is recommended. Avoid boney or uneven areas.

WARNING: If you are experiencing a loss of power, please check the connection and placement of the IND plate first! Attempting to raise power levels when you have poor connection between the IND plate and the patient significantly increases the likelihood of plate burns.

NOTICE: Please refer to the section VI of Indifferent/IND (Grounding) Plate for more details.

Table of Contents

Copyrights	1
Operator Safety	2
Warnings	3
Preface	5
How Does It Work?	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	13
Section VII. Precautions	20
Section VIII. Techniques for Use	21
Section IX. Practice Before Using	21
Section X. Getting Started	22
Section XI. Infection Control	24
Section XII. System Maintenance	25
Section XIII. Electromagnetic Compatibility	26
Section XIV. Technical Specifications	30
Section XV. Troubleshooting	31
Section XVI. Symbols	32
Section XVII: Specifications	32
Section XVIII. Disposal	33

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.
- Warning against servicing and maintenance while the ART-Electron™ is in use.

- 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

- The indifferent plate must maintain direct contact with the patient's skin during use. Failure to maintain close, unimpeded contact can result in loss of function, as well as plate burns to the patient. Every inch of the plate's face should be flush against the patient's skin for optimum safety and efficacy.
- 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.

Section IV: Accessories

Item No.	Description	Quantity
1	Main Unit	1
2	Foot Switch	1
3	AC Power Cord Set	1
4	Detachable Handpiece (Blue-ringed or Green-ringed)*	1
5	7pcs. Electrode set (Blue/Black or Green)*	1
6	Indifferent/IND (Grounding) Plate (Small-Style, 9.5 x 9.5 cm)**	1
7	Indifferent/IND (Grounding) Plate (Big-Style, 18 x 13 cm)**	Optional

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

* Color/type varies by region.

**Only one IND Plate will be included per unit.

NOTICE: The electrode and the IND plate are applied parts.

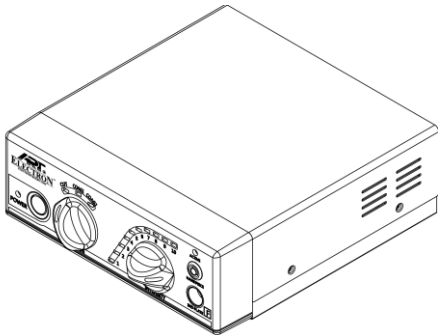


Fig.1, Main Unit

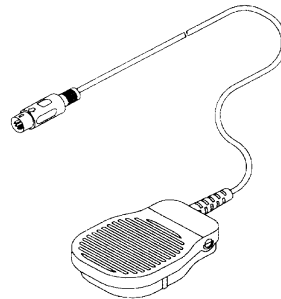


Fig.2, Foot Switch

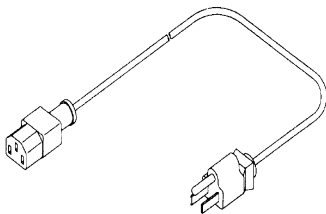


Fig.3, AC Power Cord

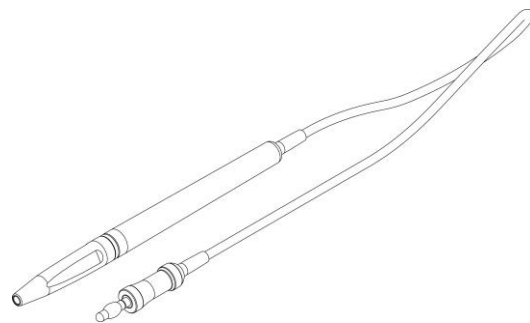
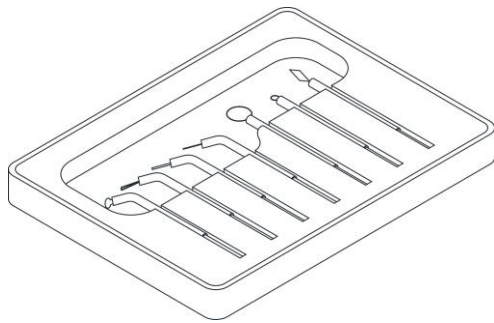
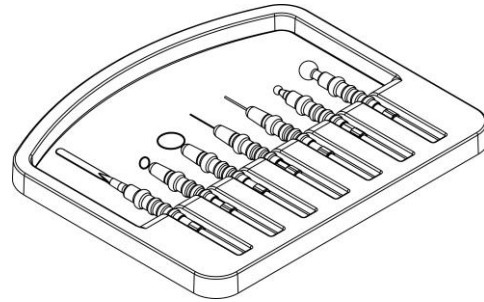


Fig.4, Detachable Handpiece (Blue-ringed or Green-ringed)

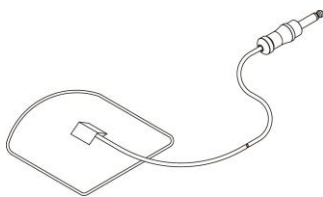


(Blue/Black, with 1/16" shaft)

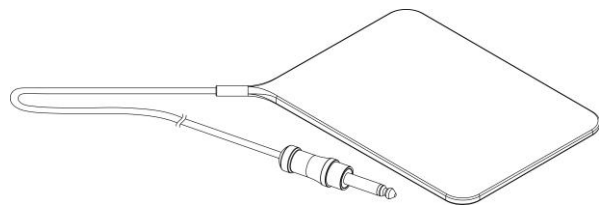


(Green, with 3/32" shaft)

Fig.5, 7pcs. Electrode set



**Fig.6, Indifferent/IND (Grounding) Plate
(Small-Style, 9.5 x 9.5 cm)**



**Fig.7, Indifferent/IND (Grounding) Plate
(Big-Style, 18 x 13 cm)**

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. Foot Switch
3. AC Power Cord
4. Detachable Hand Piece
5. 7 pcs. Electrode Set
6. Indifferent/IND (Grounding) Plate
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-pronged 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 a licensed Bonart™ representative prior to attempting to replace the fuse. Fuses blow in order to protect more expensive components, but are rarely the cause.

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: NEVER REMOVE THE IND PLATE FROM THE PROTECTIVE SLEEVE. THIS CAN BURN THE PATIENT! (Small-style IND Plate only)

5-G: Hand piece Cable Assembly Connection

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

5-H: Electrode installation

Insert the electrode gently but firmly into the cap of the hand piece.

CAUTION: Make sure to use electrodes that are designed for the handpiece. For best results, please use Bonart™ -brand electrodes. Blue/black electrodes* are standard 1/16" style, and work with the blue-ringed handpiece*. Green electrodes* are 3/32", and work in the green-ringed handpiece*.

**Color/type varies by region.*

WARNING: Always inspect the electrode before use. Do not use the electrode if the protective sheath is damaged or cracked.

WARNING: Make sure the electrode is fully seated in the handpiece with no metal shaft exposed.

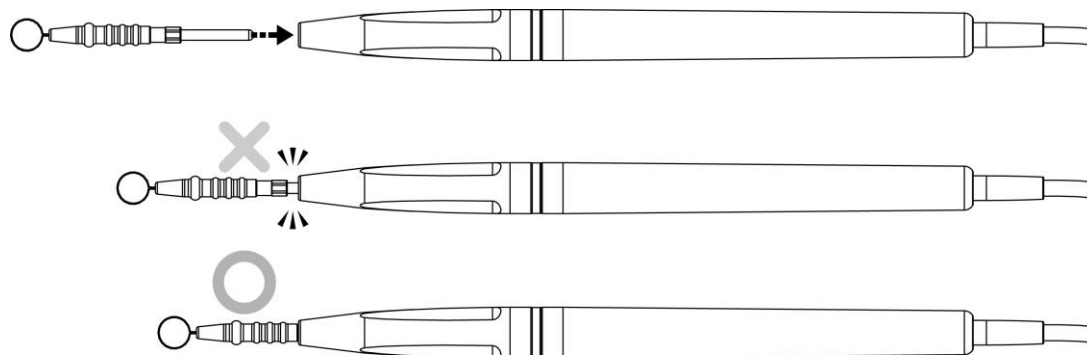


Fig.8, Electrode Installation

Section VI: General Information

ART-Electron™ Unit Diagram

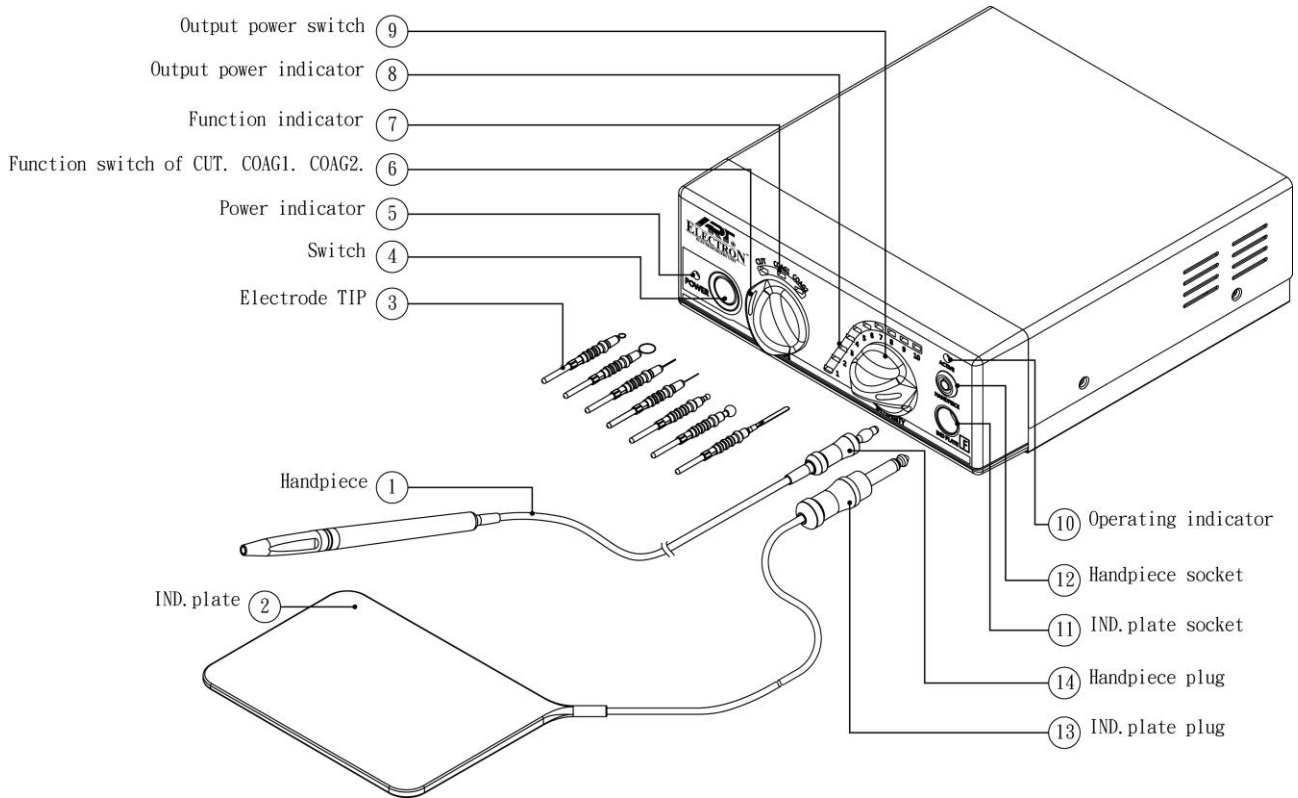


Fig.9, ART-Electron™ (front view)

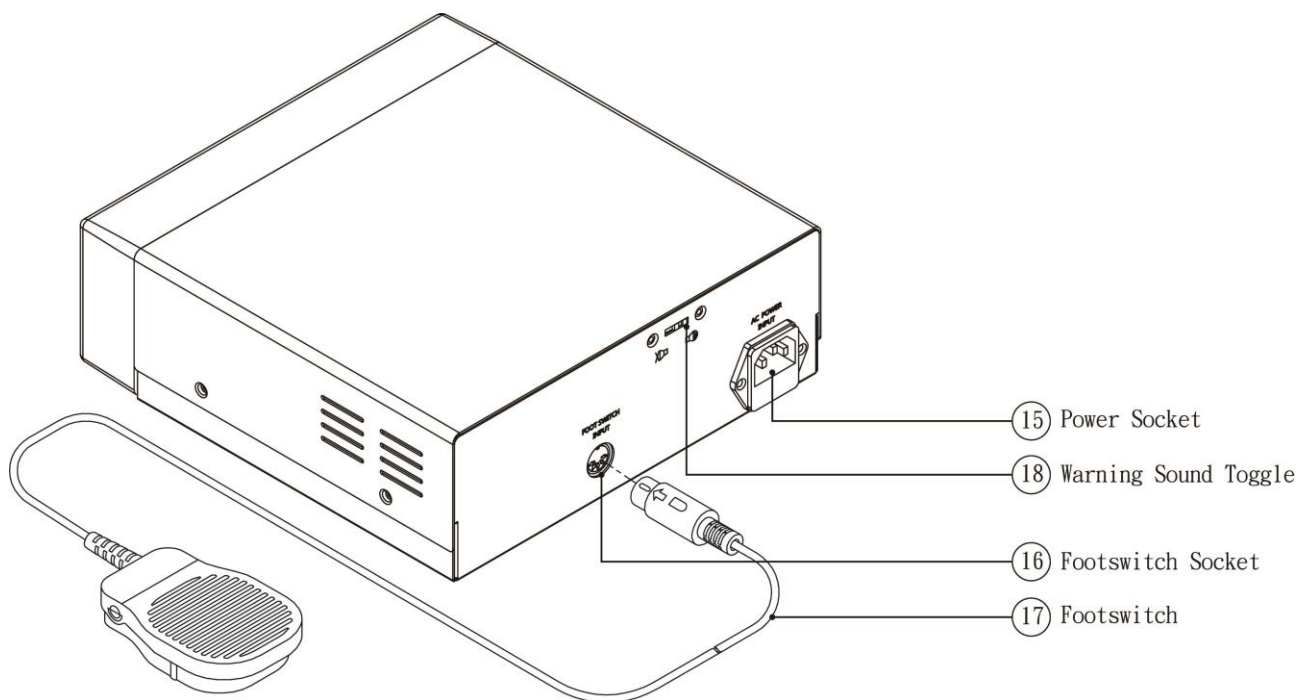


Fig.10, ART-Electron™ (back view)

1. Hand Piece

The hand piece is the housing for the electrode tips. Compatible tips should have a diameter of 1/16” for a blue-ringed/black handpiece, and a diameter of 3/32” for the green-ringed handpiece.

CAUTION: Make sure to use electrodes that are designed for the handpiece. For best results, please use Bonart™ -brand electrodes. Blue/black electrodes* are standard 1/16” style, and work with the blue-ringed handpiece*. Green electrodes* are 3/32”, and work in the green-ringed handpiece*.

**Color/type varies by region.*

CAUTION: Make sure that electrodes are fully-seated and locked in the handpiece before use.

2. Indifferent/IND (Grounding) Plate

The indifferent plate (also known by some doctors as a “return electrode”) allows the ART-Electron™ to utilize radio waves to cut and coagulate, instead of heat**. To do this, the IND plate must maintain full contact with the patient’s skin for the entire duration of the operation. This is both to ensure adequate power, and to protect the patient from plate burns. Because of this, the use of conductive gel spread evenly across the plate is essential.

When Using the IND Plate, NEVER:

- 1) **NEVER:** Ask the patient to hold it! Not only is the surface area not consistent or stable, but the patient *will* get shocked. Never, under *any* circumstances, put the plate in or on the patient’s hand!
- 2) **NEVER:** Hold it or place it on yourself and then attempt to operate on the patient! This will not work, as the circuit needs to be made with the patient!
- 3) **NEVER:** Hold it or place it on yourself and then attempt to “test” it on your fingernail/hair/skin. Not only is this incredibly dangerous, but the unit will not work at all on your fingernail or hair.
- 4) **NEVER:** Set the IND plate aside and attempt to “heat up” or test the hand piece. This will produce no function. The unit does not use heat. Without the IND plate completing a circuit with compatible flesh/tissue, you will get no response. If you have more questions about how monopolar electrosurgery works, please contact your Bonart™ representative!

***The ART-Electron™ is an electrosurgery unit, not an “electrocautery” unit. Cautery units utilize heat instead of radio waves.*

When using the ART-Electron™, place the IND plate as close to the surgical area as possible. The upper arm or thigh is recommended. Avoid bony or uneven areas. If the selected area makes it difficult to apply the IND plate, rubber straps or gauze bandages may be employed to fasten it in place.

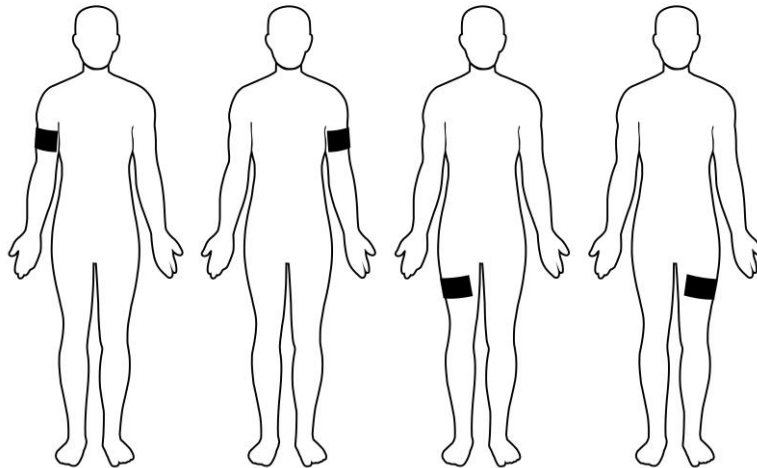


Fig.11, Application of IND Plate

CAUTION: Make sure that the IND plate maintains entire, constant contact with the patient's skin.

WARNING: If you are experiencing a loss of power, please check the connection and placement of the IND plate first! Attempting to raise power levels when you have poor connection between the IND plate and the patient significantly increases the likelihood of plate burns.

CAUTION (Small-Style IND Plates Only): The small-style indifferent plate is covered with a plastic sleeve that should never be opened or removed! Small-style IND plates can be used with conductive gel, but please ensure that you do not tear the protective sleeve while applying or removing the gel. The gel must be placed on the contact side without the warning label, on the OUTSIDE of the sleeve, not inside of it. If any gel or liquid gets inside of the protective sleeve, please replace the IND plate immediately. If the seal is torn and/or the cover opened on a small-style IND plate, dispose of it immediately and contact a Bonart™ representative for a replacement.

3. Electrodes

The ART-Electron™ comes in two different electrode sizes based on region — 1/16” and 3/32”.

- Blue/Black Electrodes

All blue/black electrodes utilize a standard 1/16” shaft and must be inserted into the Bonart™ blue-ringed handpiece.

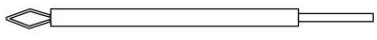
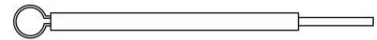
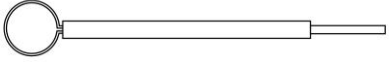
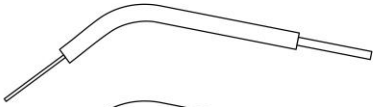
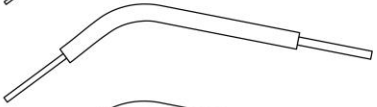


	T1: Diamond Shaped Electrode
	T2: Small Round Loop Electrode
	T3: Heavy Round Loop Electrode
	T4: Fine Wire Electrode
	T5: Heavy Wire Electrode
	T7: Fine Oval Loop Electrode
	T9: 2.5 mm Ball Electrode

Fig.12, Blue/Black Electrode set

T1, T2, T3, T7 are used for excision.

T4, T5 are used for incision.

T9 is used for fulguration and coagulation.

- Green Electrodes

All Green electrodes utilize a standard 3/32” shaft and must be inserted into the Bonart™ green-ringed handpiece.



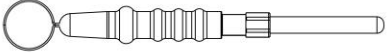


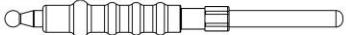

	GT1: Blade Electrode
	GT2: Small Round Loop Electrode
	GT3: Large Round Loop Electrode
	GT4: Fine Wire Electrode
	GT5: Heavy Wire Electrode
	GT8: 2.38 mm Ball Electrode
	GT9: 5 mm Ball Electrode

Fig.13, Green Electrode set

GT1 is used for incision and coagulation.

GT2, GT3 are used for excision.

GT4, GT5 are used for incision.

GT8, GT9 are used for fulguration and coagulation.

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 pressed. This will result in a red error light. Release the footswitch immediately. If the red light persists, discontinue use immediately and contact a licensed Bonart™ technician.

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.

7. Operation Mode Indicator

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

- **Cut:** Indicated with a **YELLOW** light above the knob.
- **Coag1:** Indicated with a **YELLOW** light above the knob. This mode can be considered a partial cut/partial coagulation, or “blend” mode, thus the same color as Cut.
- **Coag2:** Indicated with a **BLUE** light above the knob. This mode is not used for cutting.

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.

WARNING: Always start from power level 1 and work your way up. Starting the procedure in a higher power level puts undue stress on the circuit board and transformer, which could result in premature aging of internal components.

10. Active Operating Indicator

The operating indicator shows that the foot switch is activated and radio frequency waves are being sent. The color of the Active light should match the color of the mode that the ART-Electron™ is currently in:

- **Cut: YELLOW**
- **Coag1: YELLOW**
- **Coag2: BLUE**

If a connection error has occurred (such as when the IND plate plug is only partially inserted into the socket), the Active light will turn RED. Immediately check all connections and call a licensed Bonart™ representative for troubleshooting.

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

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

14. Hand Piece Connector

The hand piece connector should be inserted 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 connector should be inserted into the footswitch socket located on the back of the ART-Electron™ unit. 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.

WARNING: The use of a conductive solution, such as saline, as an irrigation or distention medium can be a negative factor that contributes to the delivery of potentially dangerous current levels through the IND plate and back into the patient. The electrosurgical effect is rendered less effective because conductive solutions, such as saline, disperse current away from the intended surgical site, causing a dramatic reduction of efficacy. This may cause the operator to increase the output power settings on the unit, possibly overwhelming what the IND plate and patient can withstand. This can lead to plate burns and/or unit failure. Please exercise extreme caution.

- Utilizing unnecessarily-high settings may result in sparking, which can cause tissue damage.
- The smoothness and speed of the electrode passing 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. Power generated by the ART-Electron™ is dependent on proper IND plate usage, 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. 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. Work should be done in 5-10 second bursts to avoid high amounts of IND plate electrical discharge to the patient, as well as wear and tear on the unit.

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.

C. *Coagulation (Hemostasis)*

- Light bleeders may be stopped with the ART-Electron™ using either mode Coag 1 or Coag 2.
- For heavy bleeders, Coag 2 is preferred.
- Electrodes designed for coagulation are the round ball and heavy wire.

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.

WARNING!: The ART-Electron™ is intended for use by licensed medical professionals ONLY. If you have questions about surgical procedures, techniques and best practices, please contact doctors and universities in your area that specialize in electrosurgical procedures. Neither Bonart Co., LTD. nor its' affiliates can offer help or advice on medical procedures of any kind.

.....

Section IX: Practice before Using

It is highly recommended to practice using the ART-Electron™ on an apple, a bar of soap, or (optimally) a fresh piece of 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).
2. 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. Adjust the power level to 1.
6. Press the foot switch.
7. Do several incisions and observe the results. **This setting on the meat will illustrate poor cutting or extreme drag.**
8. Set the power level to 8.
9. Press the foot switch.
10. Do several incisions and observe the results. This high setting will cause sparking and may char the tissue.
11. Continue adjusting the power setting to different levels and observe the incision.
12. 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: Please refer to the section VI of Indifferent/IND (Grounding) Plate before use.

NOTICE: Monopolar systems such as the ART-Electron™ will not function without the IND 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. If you have any questions or concerns regarding proper usage of the IND plate, please contact an authorized Bonart™ representative

WARNING!: *Do not attempt to use the IND plate on yourself! Please see Page 5 for a description of how monopolar electrosurgery works to understand why you cannot use yourself as the return for the patient!*

WARNING: Please remove all jewelry and metal accessories from patients.

WARNING: Avoid placement over bony prominences or scar tissue.

WARNING: Do not apply the IND plate over the injection site.

WARNING: Please select a smooth, well-vascularized, muscular area close to the surgical site that allows the IND plate to contact the skin entirely.

WARNING: Please refer to the manufacturer's guidelines of the gel in question to determine if the gel used is appropriate for electrosurgical applications.

WARNING: Do NOT put a damp towel between the patient and the IND plate. The damp towel could shock or burn the patient. This is not an adequate replacement for jell and is very dangerous.

WARNING: Do not use alcohol between the IND plate and the patient. Alcohol is flammable and may catch fire when the electrosurgical device is activated.

G. Push the electrode into the nose/cap of the handpiece directly until it is firmly seated.

WARNING: Make sure the electrode is fully seated in the handpiece with no metal shaft exposed.

WARNING: Always inspect the electrode before use. Do not use the electrode if the protective sheath is damaged or cracked.

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 LED indicator should be lit.

K. Hold the electrode gently above 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

11-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.

11-B: Cleaning and Sterilization:

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 270°F (132°C) for 4 minutes, or as recommended by the manufacturer of your sterilization machine. Items should take approximately 30 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 270°F (132°C) for 4 minutes or as recommended by the manufacturer of your sterilization machine. Items should take approximately 30 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 the standard EN/ISO 17665-1 or ANSI/AAMI ST79.

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™ representative.

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: Never spray the unit or components directly. Liquid will short-out internal parts and components, damaging the system and potentially creating a safety hazard for users and patients.

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: Electromagnetic Compatibility

The use of accessories as replacement parts other than those specified or sold by Bonart™ may have the consequence of increasing the electromagnetic emissions or decreasing the immunity of the device.

The device must not be used near other equipment or placed on top of it. If this cannot be avoided, correct operation of the device in operating conditions must be checked prior to use.

• Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The user must assure that the device is used in such an environment.

Emission		
Test Item	Compliance	Electromagnetic Environment - Guidance
Conducted Disturbance CISPR 11	Class B, Group 1	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated Disturbance CISPR 11	Class B, Group 1	
Harmonic Current Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations & Flicker IEC 61000-3-3	Section 5	


• **Electromagnetic Immunity**

The device is intended for use in the electromagnetic environment specified below. The user must assure that the device is used in such an environment.

Immunity			
Test Item	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2.	± 8KV contact; ± 2KV, ±4 KV, ±8 KV, ± 15KV air	± 8KV contact; ± 2KV, ± 4KV, ± 8KV, ±15 KV air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic material (carpet, etc.), the relative humidity must be at least 30%.
Electrical fast transients IEC 61000-4-4.	±2KV for power supply lines; ±1 KV for interconnect lines	±2KV for power supply lines; ±1 KV for interconnect lines	Mains power quality should be that of a typical commercial or hospital environment (hospital, clinic).
Surges IEC 61000-4-5.	±0.5KV, ±1KV (line to line); ±0.5KV, ±1KV, ±2KV (line to earth)	±0.5KV, ±1KV (line to line); ±0.5KV, ±1KV, ±2KV (line to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11.	<ul style="list-style-type: none"> • 0% residual voltage for 0.5 cycle. • 0% residual voltage for 1 cycle. • 70% residual voltage for 25 cycles. • 0% residual voltage for 250 cycles. 	<ul style="list-style-type: none"> • 0% residual voltage for 0.5 cycle. • 0% residual voltage for 1 cycle. • 70% residual voltage for 25 cycles. • 0% residual voltage for 250 cycles. 	Mains power quality should be that of a typical commercial or hospital environment. If the use of the device requires continued operation during power mains interruption, it is recommended that the product be powered from a separate power supply (UPS, etc.).

• **Electromagnetic Immunity, Handheld Radiofrequency Equipment**

The device is designed for use in the magnetic and electromagnetic environment described in the table below. The user must ensure conformity of the electromagnetic environment.

Immunity test	Test level	Compliance Level	Electromagnetic Environment - Guidance
Portable and mobile radiofrequency communication devices must not be used near the medical device (including cables) at a distance below that recommended and calculated according to the frequency and power of the transmitter.			
Radiated radio frequency electromagnetic field (IEC61000-4-3)	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where (P) is the maximum nominal power of the transmitter in Watts (W) according to the manufacturer specifications and (d) is the minimum recommended separation distance in meters (m).
Radio frequency conducted disturbance (IEC61000-4-6)	3 V/m 150KHz to 80MHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz Recommended separation distance: $d = 1.2 \sqrt{P}$
The electromagnetic field intensity of fixed radiofrequency transmitters, as determined by an electromagnetic environment measurement (a), must be less than the conformity level for each frequency range (b). Interference may occur near equipment marked with the following symbol:			

Note 1: At 80 MHz and 800 MHz, the highest frequency range applies.

Note 2: These specifications may not be applicable in all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

(a) The electromagnetic field strengths of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular / cordless), mobile radios, amateur radio, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specification. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

(b) In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3 V/m.

• **Recommended Separation Distances**

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile FR communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter 'W'	Separation distance according to the frequency of transmitter 'm'		
	from 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	from 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	from 800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

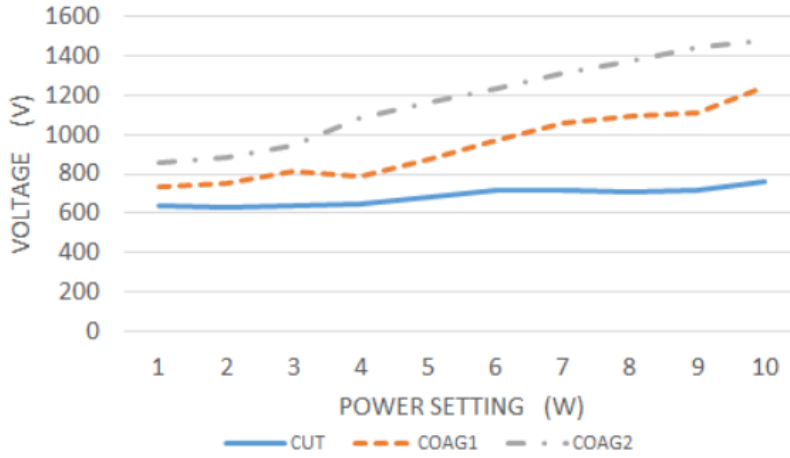
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

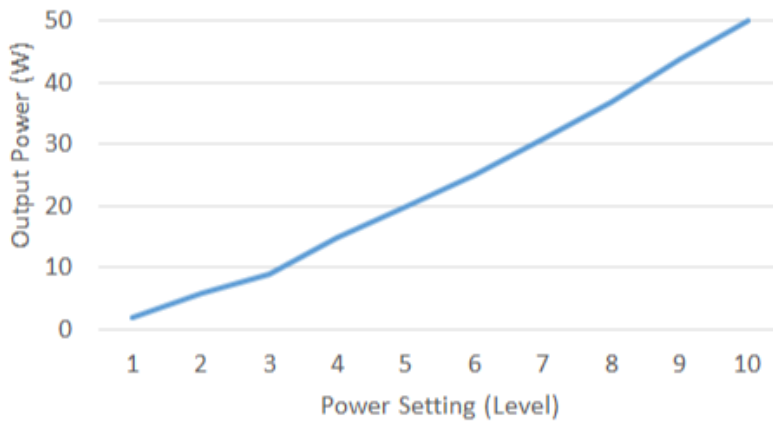
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Section XIV: Technical Specifications

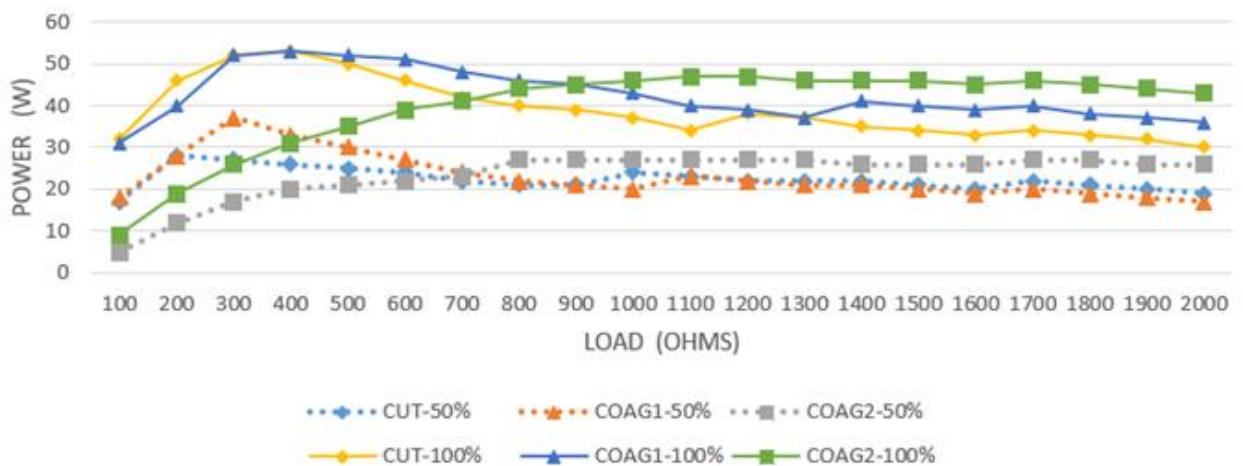
- Output voltage versus power setting (CUT, COAG1, COAG2)



- Output power versus power setting for all modes



- Output power versus impedance for all modes



Section XV: 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, complete contact with the patients' skin** (not through clothing or heavy fur). Please refer to the section VI of Indifferent/IND (Grounding) Plate for more details. **The unit will not function if this condition is not met.**
- Make sure that you are pressing the foot switch prior to attempting to cut.
- Ensure that the voltage of the wall socket matches the voltage of the unit (e.g. a 110v unit will not function in a country that utilizes 220v and vice-versa).
- 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 (footswitch, hand piece, IND plate, etc.) 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 Standard Time). For non-US territories, please contact your local Bonart™ representative.

Section XVI: Symbols

	CE Mark		Fragile; handle with care
	Manufacturer		Keep dry
	Date of manufacture		This side up
	Authorized representative in the European Community		Requires immediate attention
	Type BF equipment		Serial number
	Grounded terminal		Consult instructions for use
	With an HF isolated patient circuit		

Section XVII: Specifications

Classification

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

Standards Followed

- EN/ISO13485:** Medical devices - Quality management systems - Requirements for regulatory purposes
- EN/IEC60601-1:** Medical Electrical Equipment, General Requirement for Safety
- EN/IEC60601-1-2:** Medical Electrical Equipment, Electromagnetic Compatibility, Requirements and Tests.
- EN/IEC60601-2-2:** Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Specifications

- Power supply 115V \pm 5% \sim 50/60Hz 120VA
230V \pm 5% \sim 50/60Hz 120VA

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 357 \pm 50 kHz
- Coag 1 357 \pm 50 kHz
- Coag 2 375 \pm 50 kHz
- Dimension 22cm(L) x 25cm(W) x 8.5cm(H)
- Weight 3.2 Kg (main unit)
- Hand piece Cable 190 cm
- Plate Cable 190 cm
- Footswitch Cable 250 cm

Operation environment

- Temperature 10°C~40°C
- Relative Humidity 15% ~ 85%
- Atmospheric pressure 860~1060 hPa

Transportation and Storage conditions

- Temperature 10°C~60°C
- Relative Humidity 15% ~ 85%

Section XVIII. Disposal

Please follow all local laws and regulations for procedures on disposing of this and any medical device or accessory.

