

ART-M1 Magnetostrictive Ultrasonic Scaler

Instruction Manual



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Operator Safety

Please read this manual before operating unit.

The ART-M1 magnetostrictive ultrasonic scaler should be operated, maintained and repaired by qualified and properly trained personnel.

- ***NOTE, CAUTION, AND WARNING STATEMENTS***

NOTE : Provides tips and advice

CAUTION : Provides correct operating or maintenance procedures

WARNING : Alerts users of danger that may cause severe injury when proper procedures are not followed

- ***SYMBOLS***



Compliance with MDD 93/42/EEC



BF equipment



Grounding terminal



Attention! Please read instructions

Warnings

Important!

- **Only trained and qualified doctors, dentist, and hygienists should operate the ART-M1.**
- **Patients with pacemakers cannot be treated with the ART-M1**
- **Do not immerse the ART-M1 in water!**
- **If patient or operator is pregnant, consult a physician prior to performing dental scaling for safety purposes.**
- **The ART-M1 requires a shielded AC power cord.**
- **Plug the power cord into a well-grounded outlet.**



Attention to users with cardiac pacemakers!

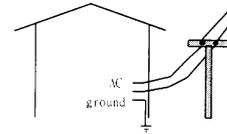
Patients with pacemakers should avoid treatment with the ART-M1. Electronic appliances including razors, hair dryers, microwave ovens, TV receptors, and other medical equipment, such as the ART-M1, may interfere with the performance of pacemakers.

For more information on this subject, please refer to the following articles:

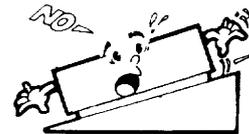
- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare
- "The Individual with a Pacemaker in the Dental Environment", Journal of the American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

Please Read Before Operating:

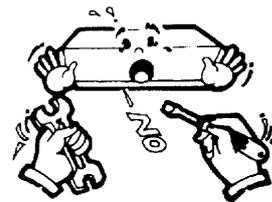
- Make sure the device is connected to a grounded outlet. Failure to meet this requirement may severely damage the user and equipment.



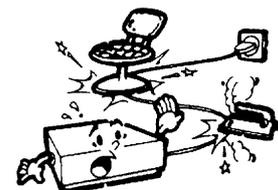
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- Place the device on a flat and stable surface. Placing the device on a tilted or unstable surface may degrade performance and also cause damage to the device.



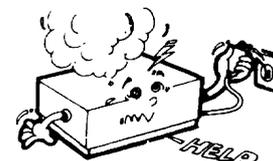
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- Do not modify this device. Modifications to the device will invalidate the safety codes and warranty while endangering the patient and operator.



-
- Do not place heavy objects on top of the power cord and keep the power cord away from intense heat.



-
- Unplug the device and call Bonart for service and instructions if you observe any abnormalities while operating the device.



Preface

About the ART-M1 Magnetostrictive Ultrasonic Scaler

The ART-M1 Magnetic Ultrasonic Scaler is manufactured by Bonart Co., Ltd., an ISO 13485:2003 company. The ART-M1 is also CE 0434 certified in compliance with the applicable requirements of the Council Directive 93/42/EEC. The reviewing council also classifies the ART-M1 in accordance with EN60601-1 and EN60601-1-2 safety requirements.

How it works

The ART-M1 consists of two parts: The main electronic system and the scaling hand piece. The main electronic system utilizes two closed loops. One loop provides automatic tuning to match the resonance of the insert. The other loop will control the tip stroke based on various working conditions.

The scaling hand piece utilizes a pulsing magnetic field. This magnetic field is applied to a metal “stack” which flexes and moves an installed scaling tip (insert) approximately 25,000-30,000+ cycles per second in an elliptical pattern based on the amount of power used. Thus, more power results in greater tip displacement, which allows for more robust scaling. However, the vibrating metal stack generates heat and requires adequate amounts of fluid to cool the hand piece and tissues during treatment.

When the two parts of the ART-M1 are placed together, the properties of the main unit and scaling hand piece enable the ART-M1 to “power away” the heaviest calculus deposits. In addition, tips may be rotated 360 degrees within the hand piece to relieve cord tension and alignment. As a result, the ART-M1 provides maximum comfort to the patient and ease of use to the operator.

Technical Support

For technical support and repairs in the U.S., call 1-888-526-6278 or 626-600-5330, Monday through Friday, 9:00 AM to 5:00 PM (Pacific Time). For other areas, contact your local Bonart representative.

Supplies & Replacement Parts

To order supplies or replacement parts in the U.S., please contact one of our authorized distributors listed on our website, www.bonartmed.com.

CAUTION : Since the scaling tip (insert) is made of stainless steel, avoid direct contact with teeth. Direct contact will cause damage to teeth enamel. For optimum performance, we suggest practicing on a model or aluminum plates to become more familiar with the scaling tips before performing on patients.

Table of Contents

Copyrights	1
Operator Safety	2
Warnings	3
Preface	5
Contents	7
Section I. Indications for Use	8
Section II. Contraindications and Warnings	8
Section III. Precautions	8
Section IV. Infection Control	9
Section V. Installation	11
Section VI. General Description and Information of Parts.....		14
Section VII. Techniques	17
Section VIII. System Maintenance	18
Section IX. Troubleshooting	19
Section X. Specifications	20
Section XI. Disposal	21

Section I: Indications for Use

Ultrasonic procedures:

- Removal of calculus and plaque during dental prophylaxis.
- General supra and sub-gingival scaling applications.
- Periodontal debridement for all types of periodontal diseases.
- Endodontic procedures.

Section II: Contraindications and Warnings

- Do not use the ART-M1 for amalgam restorative dental procedures.
- Do not use the ART-M1 if the patient or operator is wearing a pacemaker.
- Do not immerse the ART-M1 in water or liquid. If the ART-M1 has water damage, return the machine to Bonart for servicing.
- Do not modify the ART-M1. Modifications will invalidate the warranty on the machine as well as invalidate safety codes and endanger the patient and operator.

Section III: Precautions

3-A: Precautions for all Ultrasonic Scaler Units and Systems

- Ensure sufficient water flow to the scaler tip during use to cool the hand piece and insert.
- Take precaution as all ultrasonic scalers produce aerosols that may transmit contagious diseases.
- Use inserts manufactured by Bonart for optimal performance and results.
- Keep the unit away from intense heat. Excessive heat may damage the electronic components.
- Switch the water valve off when the ART-M1 is not in use.
- Avoid treating patients with pacemakers due to the magnetic field produced by the ART-M1. The magnetic field may cause monitoring devices to malfunction and provide inaccurate readings.

3-B: Precautions for Ultrasonic Prophylaxis Procedures

- Scaling tips (inserts) will wear with use. Inserts with 2mm of wear will lose approximately 50% of their scaling efficiency. In general, it is recommended that inserts be discarded and replaced after 2mm of wear to maintain optimal efficiency and avoid breakage.
- Avoid direct contact of inserts with the patient's lips, cheeks and tongue.
- Do not reuse scaling tips (inserts) that are damaged, bent, or reshaped. Discard immediately.
- Use the long axis of the scaling tip (insert) to wipe accretions from the tooth. Do not gouge the tooth with the tip.

3-C: Precautions for hand-piece

In order for the system's hand-piece to function consistently and effectively, Accumulated air pressure from the handle (or hand-piece) must be released every 10 to 15 minutes on every procedure by doing the following steps:

1. Put the insert into the hand-piece and make sure it is fully seated.
2. Hold the hand-piece vertically with the insert tip on top; depress the foot Switch (control).
3. Let the water spray out for a minute or so, then start scaling procedure.

Section IV: Infection Control

4-A: General Infection Control Recommendations:

As with all dental procedures, use standard protective equipment such as face masks, eyewear, face shields, gloves and protective gowns.

To ensure safety to the operator and patient, carefully follow the Infection Control Procedures detailed in Section XII.

4-B: Water Supply Recommendations

All dental water supply systems should conform to applicable Centers for Disease Control and Prevention (CDC) and the American Dental Association (ADA) standards. These standards should apply to flushing, chemical flushing and general infection control procedures.

4-C: Cleaning and Sterilization:

Hand piece

Prior to cleaning, remove the insert from the hand piece. Next, drain any water left in the hand piece to clear the hand piece of any residue accumulated during treatment. Then, clean the surface of the hand piece with antiseptic soap or solution and rinse thoroughly with water. Afterwards, wipe or spray a chemical disinfectant on the hand piece. Please try to use a disinfectant that has a 1:6 dilute solution (ie Sporidicin Disinfectant) to avoid damaging the hand piece.

After disinfecting the hand piece, a sterile insert may be re-inserted into the hand piece in preparation for the next patient.

At the end of the day, remove the insert from the hand piece and scrub both, the hand piece and cable, with antiseptic soap. Rinse thoroughly with water.

NOTE : Cleaning the hand piece after every patient is advised.

WARNING : Do not dip the hand piece and extension cable directly into the sterilized fluid. Doing so will cause the ART-M1 to malfunction.

WARNING : Do not leave the disinfectant on the surface of the hand piece and extension cable any longer than instructed by the manufacturer of the disinfectant.

Insert

Saliva, blood, and other debris will leave a residue on the insert after each use. Therefore, it is necessary to clean inserts after each use. Cleaning can be done manually by scrubbing the insert with a brush, water, and detergent. Be sure to rinse thoroughly after scrubbing. Let the insert dry. Then, place the insert in a bag and autoclave at 275°F (135°C) for 15 minutes (or as recommended by the manufacturer of your sterilization unit) to sterilize the insert. Bio-indicators or chemical indicators for ensuring the efficiency of the sterilization cycle are recommended.

NOTE : Routine spore testing will determine the sterile conditions of your office.

NOTE : The Sterilization Assurance Level (SAL) of steam autoclave should be 10^{-6} (According to ISO 13683: Sterilization of health Care products)

WARNING : High room temperature conditions, improper dilutions, or extended immersion time in chemical sterilizers can result in damage to the plastic and other materials of the insert/Tips.

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

Main Unit

Carefully wipe the Main Unit with absolute alcohol or an Acrylonitrile Butadiene Styrene (ABS) plastic compatible disinfectant to prevent damage to the plastic components of the casing.

Section V: Installation

5-A: General Information

If the installation of your ART-M1 system is performed by an unauthorized distributor of Bonart products, check to see that the requirements below are followed.

5-B: Water Line Requirements

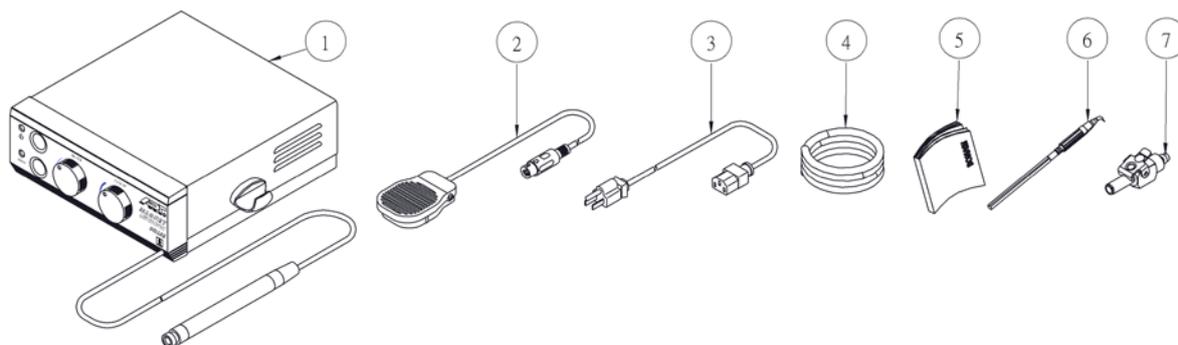
- Incoming water supply line pressure to the Scaler must be 25 psi (172 kPa minimum) to 60 psi (414Kpa maximum). If your dental water supply line pressure is above 60 psi, install a water regulator on the water supply line to your ART-M1 unit.
- After the above installation requirement is fulfilled, thoroughly flush the water prior to connecting to the scaler.
- Please use the manual shut-off valve on the dental water system supply line to shut-off water when the office is unoccupied.

5-C: Electrical Requirements

Refer to Section X: Specifications

5-D: Unpacking the Unit

Carefully unpack your ART-M1 unit and verify that all components and accessories are included:



(Figure 1) All components and accessories

Item	Quantity	Item	Quantity
(1) Main Unit	1	(2) Foot Control / Foot Switch	1
(3) AC Power Cord Set.	1	(4) PU Water Tubing	1
(5) User Manual & Literature Packet			1
(6)			
ART IF-50 Streamline Universal Plastic Handle Internal Flow Insert.			Optional
ART P-10 Straight Angle Universal Metal Handle External Flow Insert.			Optional
(7) Water Hose/ Quick Disconnect Assembly.			Optional

NOTE :

While unpacking, check your ART-M1 unit for any damages. If any damages are found, please contact your dealer immediately. Enter the unit serial number on your warranty card and mail it within 14 days from the date of purchase.

5-E: Power Cord / Power Connection

- Always make sure that the power switch is set to the OFF position before performing the following tasks:
 - Plug the detachable AC cord into the back of the unit.
 - Plug the 3-prong plug into a grounded outlet.



Safety Instructions

A. Grounding:

Prior to connecting accessories to the unit, check that the main unit is plugged into a grounded wall outlet.

B. Main voltage range and fuse:

Prior to plugging the AC adapter into the power outlet, check that the voltage is supported.

5-F: Foot Control Cable Assembly Connection

Align the pins of the foot control plug with the receptacle on the back of the device and push in until the plug is firmly seated.

5-G: Water Supply Line Connection

Push the blue water tube (hose) into the stainless steel receptacle until the hose cannot be pushed any further. Then tighten the screw.

Connect the quick connect to the water supply line. The ART-M1 should be prepackaged with a male quick connect. If a female quick connect is necessary, please contact a Bonart distributor to purchase the part.

Inspect all connections for leaks.

To remove the water line from the ART-M1 scaler, first, turn off the water supply or disconnect the water supply line. Then loosen the screw on the water tube from the receptacle of the unit and gently pull the water hose out.

5-H: Hand piece Cable Assembly Connection

The ART-M1 hand piece, attached to the main unit, is designed only for inserts with a frequency of 25khz. The ART-M1 is not available in 30khz so please do not try using a 30khz insert with the ART-M1.

5-I: Assembling the Scaler Unit

1. Switch the power of the ART-M1 off. The power indicator should not be lit if the machine is off.
2. Plug the power cord of the main unit into a grounded AC power outlet.
3. Push the insert firmly into the hand piece. If installed properly, the insert band should be flush against the top of the hand piece. To remove the insert, pull the insert at the grip. Be careful not to cut your hand while removing the insert.
4. Check the water tube connection to the water supply source and main unit.

Section VI: General Description and Information of Parts

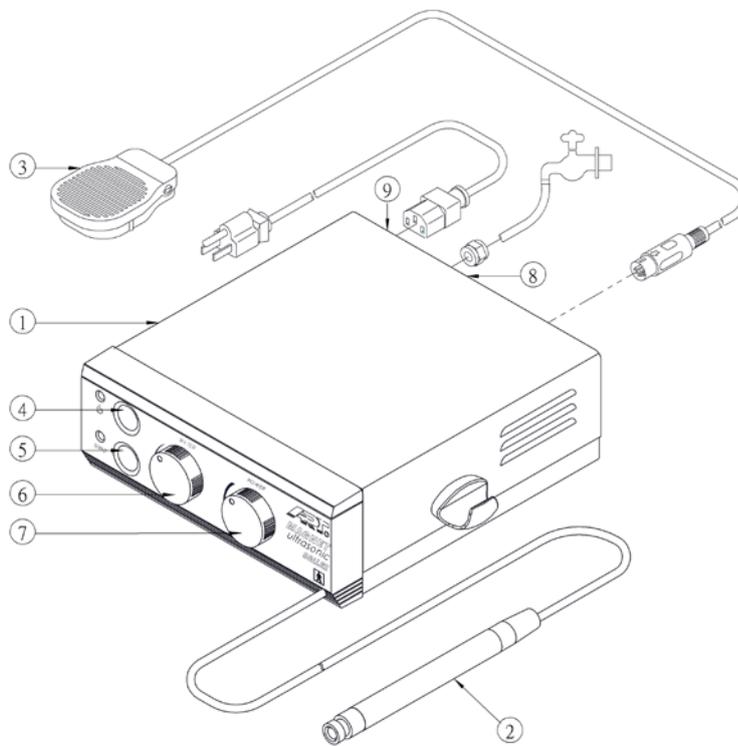


Figure 2. ART-M1 Outlook diagram

1. Main Unit

The main unit generates power and produces a signal that is passed to the hand piece. The hand piece is then powered up and vibrates the installed insert.

2. Hand piece

The hand piece is a housing for scaling inserts. Inserts are interchangeable and can be installed with a firm push. To remove the insert, pull from the grip, but be careful not to puncture or cut yourself. Aside from Bonart inserts, Dentsply/Cavitron and Hu-Friedy inserts are also compatible with the ART-M1.

When the hand piece is powered, the hand piece will begin to heat due to the power generated by the main unit. To cool the temperature of the hand piece, a stream of water is released into the hand piece and through the tip. This stream of water is also used to wash away tooth calculus and tartar.

CAUTION : Make sure that new insert is firmly seated. The insert band should be flush against the top of the hand piece

CAUTION: Do not depress the footswitch when there is no insert installed. Doing so will cause the hand piece to melt!

NOTE : The ART-M1 is a stand-alone unit and is now only available in 25Khz. Please do not use 30Khz inserts with the hand piece.

3. Footswitch

The footswitch is designed to allow the operator to use two hands while scaling.

4. Main power switch (ON/OFF)

The main power switch turns the ART-M1 unit on and off. When the power is switched on, the LED power indicator on the main unit should be lit. When the power is switched off, the LED power indicator should be unlit.



Make sure the footswitch is in the OFF position before turning on the ART-M1.

5. Turbo switch

The turbo switch allows you to switch between turbo and scaling mode. Pushing the button once during scaling mode will trigger turbo mode and light the LED mode indicator. Under turbo mode, power output increases to make cleaning easier. To return to scaling mode, push the turbo switch button again. The LED mode indicator should diminish.

6. Water control

The water control knob adjusts the amount of water flowing through the hand piece. To increase the water flow, turn the knob clockwise. To decrease the water flow, turn the knob counter-clockwise. Keep in the mind that the water level should be adjusted not only for cleaning tartar but also for cooling the hand piece during use. Increasing the water level will cool the hand piece faster.

WARNING : Do not turn the water knob counter-clockwise more than three full turns. Doing so will damage the internal water line needle.

WARNING : If needed, gently adjust the water control knob to prevent any serious damages to the water valve.



When used for the first time, turn the knob clockwise to allow water to flow through. The knob is set to the off position when assembled by the manufacturer.

7. Power control

The power control adjusts the power intensity to the desired level based on the cleaning procedure. When turned clockwise, power output increases. When turned counter-clockwise, power output decreases.

8. Water-in Connector

The water-in connector is the contact point for the water tube and the main water supply line. Use either a male or female quick connect to connect the water tube to the water supply. The ART-M1 comes with a male quick connect attached to the water tube.

9. AC Line Socket Seat

The AC line socket seat is the connection point between the power cord and the main unit.

Section VII: Techniques

7-A: Performing Ultrasonic Scaling Procedures

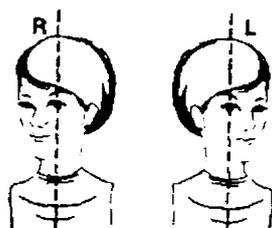
1. Use purified or distilled water to prevent infection when patients experience tissue laceration during treatment
2. Keep the power cord tidy to avoid tripping and other accidents.
3. Position the footswitch in an easily accessible spot for the user. Keep the footswitch cord tidy to avoid tripping and other accidents.
4. Hold the empty hand piece in an up right position when testing to see if the scaler is working properly. Tap the footswitch until water appears. **Do not repeatedly tap or hold the footswitch down. The empty hand piece will melt!**
5. Lubricate the rubber O-ring on the insert with water before placing it into the hand piece. To install the insert, firmly push the insert into the hand piece.
6. Hold the hand piece over a sink or drain with an insert installed. Verify that the water is reaching the tip.
7. Check your Bonart scaling inserts for wear and replace as needed.
8. Use the foot control to control the water flow to the hand piece. Hold down the foot control to allow water to flow through. Release the foot control to stop the water flow.
9. Adjust the water flow using the water control knob to the desired level of water flow and hand piece temperature. Increase the water flow by turning the water control knob clockwise. Decrease the water flow by turning the water control knob counter-clockwise.

NOTE : Increased water flow results in a cooler hand piece temperature and vice versa.

CAUTION : During operation, a continuous flow of water is required to keep the hand piece cool.

7-B: Patient Comfort Considerations

1. Position the patient comfortably on the patient chair. Adjust the chair angle and position to access the patient's oral cavity with ease and comfort.
2. Put the saliva ejector into the patient's mouth to remove excess saliva and debris.
3. Rotate the patient's head gently so that the oral cavity can be easily accessed without causing discomfort to the patient (see figure below).



4. During treatment, try to keep the angle between the surface of the tooth and scaling insert at 15 degrees. If the patient experiences any discomfort during treatment, follow the suggestions below:
 - Increase the hand piece movement speed on the surface when treating sensitive areas.
 - Treat less sensitive area first, and then return to sensitive areas.
 - If the problem persists, reduce the power output intensity of the hand piece.

Section VIII: System Maintenance

Daily start-up

1. Open the water supply valve.
2. Turn the ART-M1 on using the main power switch. Verify that the LED power indicator (LED) is lit.
3. Set the power control knob to full power.
4. Turn the water control knob to the maximum setting.
5. Hold the empty hand piece upright over a sink or drain.
6. Depress the footswitch and flush the water line for at least 2 minutes.
7. Place a Bonart scaling insert (or a compatible insert) into the hand piece and adjust the water level as desired.

NOTE : If no water is detected, check the water supply

NOTE : If the power LED is not lit, contact a local authorized agent.

Preparations for treating each patient

1. Remove, clean, and sterilize all used ultrasonic inserts.
2. Make sure the scaling insert/tip has been sterilized before treating the next patient.
3. Clean and disinfect the surface of the power cord, hand piece, and cable assembly.

Daily shutdown

1. Use the power switch to turn the ART-M1 off.
2. Close the water supply valve.

Daily Maintenance

The suggestions below will help maximize the lifespan of the scaler.

- A. The ART-M1 should be used in a well-ventilated room
- B. Handle the ART-M1 with care when moving it.
- C. Before leaving the operation room, make sure that the ART-M1 is turned off and the water faucet is tightly closed.
- D. If you find that the power output to the hand piece is insufficient, the insert is probably worn out. Inserts should typically be replaced after six months or when worn out.
- E. If service is needed, please contact a local authorized agent for technical support.

Section IX: Troubleshooting

While Bonart offers repair service, the following trouble shooting procedures can help you save time.

9-A Troubleshooting Guide

Basic procedures:

1. Check all lines and connections to and from the system. A loose plug or connection is the most common cause of problems.
2. Check the setting of all control knobs.

System will not operate:

LED power indicator is not lit

1. Check that the power control switch is in the ON position, and that the detachable power cord is fully seated in the receptacle on back of the system.
2. Check that the three-prong power plug is fully seated in the AC receptacle on the back of the ART-M1, and that the voltage is supported.

3. Check that the power plug is plugged into the wall outlet.

LED power indicator is lit

1. Check that the footswitch connector is fully seated in the foot control receptacle on the back of the system.

System operates:

No water reaches the tip

1. Ensure that the water control knob is turned on or adjusted to allow water to flow.
2. Check that water supply control valve(s) (dental office water supply) is open.
3. Check that the external water tube is properly connected.

9-B Technical Support and Repairs

For technical support and assistance call 1-888-526-6278 or 626-600-5330 Monday through Friday, 9:00 AM to 5:00 PM (Pacific Time). For other areas, contact your local Bonart representative.

X: Specifications

Classification

- Protection against electric shock : Class I
- Degree of protection against electric shock : Type BF
- Mode of operation : Continuous
- Medical device directive : IIa

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 92VA
230V \pm 5% ~50/60Hz 92VA
- Working frequency 24.5KHz \pm 5% (for 25KHz Insert)
- Water supply 25~60 PSIG(172~414KPa)
- Dimension 24.5cm(L) x 22.5cm(W) x 8.5cm(H)
- Weight 4 Kg(include hand piece)
- Hand piece Cable 250 cm
- Footswitch Cable 250 cm

Operation environment

- Temperature 0°~60°
- Relative Humidity 10% ~ 90% (non-condensing)

Transportation and Storage conditions

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

Section XI: Disposal

Please follow county and state regulations for disposal of the ART-M1.