

ART-M3II Magnetostrictive Ultrasonic Scaler

Instruction Manual



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Operator Safety

Please read this manual before operating unit.

The ART-M3II 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-M3II.**
- **Patients with pacemakers cannot be treated with the ART-M3II**
- **Do not immerse the ART-M3II in water!**
- **If patient or operator is pregnant, consult a physician prior to performing dental scaling for safety purposes.**
- **The ART-M3II requires a shielded AC power cord.**
- **Plug the power cord into a well-grounded outlet.**



Attention to users with cardiac pacemakers!

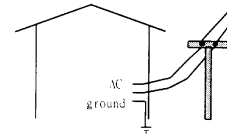
Patients with pacemakers should avoid treatment with the ART-M3II. Electronic appliances including razors, hair dryers, microwave ovens, TV receptors, and other medical equipment, such as the ART-M3II, may interfere with the performance of pacemakers.

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

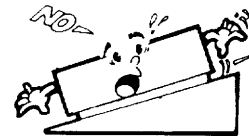
- "Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075
- "Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare
- "The Individual with a Pacemaker in the Dental Environment", Journal of the American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

Please Read Before Operating:

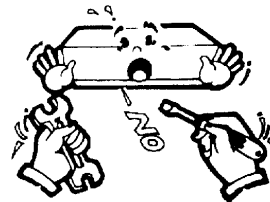
- Make sure the device is connected to a grounded outlet. Failure to meet this requirement may severely damage the user and equipment.



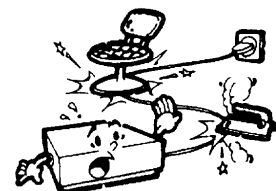
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- Place the device on a flat and stable surface. Placing the device on a tilted or unstable surface may degrade performance and also cause damage to the device.



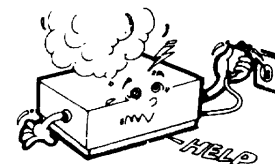
-
- Do not modify this device. Modifications to the device will invalidate the safety codes and warranty while endangering the patient and operator.



-
- 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-M3II Magnetostrictive Ultrasonic Scaler

The ART-M3II Magnetic Ultrasonic Scaler is manufactured by Bonart Co., Ltd., an ISO 13485:2003 company. The ART-M3II 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-M3II in accordance with EN60601-1 and EN60601-1-2 safety requirements.

How it works

The ART-M3II 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-M3II are placed together, the properties of the main unit and scaling hand piece enable the ART-M3II 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-M3II 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., contact your Bonart Distributor or Dealer. A list of Bonart distributors can be found on our website at 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.

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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-M3II for amalgam restorative dental procedures.
- Do not use the ART-M3II if the patient or operator is wearing a pacemaker.
- Do not immerse the ART-M3II in water or liquid. If the ART-M3II has water damage, return the machine to Bonart for servicing.
- Do not modify the ART-M3II. 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-M3II is not in use.
- Avoid treating patients with pacemakers due to the magnetic field produced by the ART-M3II. 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 personal protection gear and equipment such as facemasks, goggles, face shields, gloves and protective gowns.

Carefully follow the Infection Control Information procedures detailed in Section XIII for operator and patient safety.

4-B: Water Supply Recommendations

It is highly recommended that all dental water supply systems 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 flushing and general infection control procedures.

4-C: Cleaning and Sterilization:

Hand piece

If there is an insert in the hand piece, remove it before cleaning. Let the hand piece run for a couple of seconds to drain out the water and any possible contamination left inside the hand piece. The outer surface of the hand piece should be cleaned with an antiseptic soap or solution. Rinse with water and wipe or spray with a gentle chemical disinfectant. A sterile tip may now be re-inserted into the hand piece in preparation for the next patient.

Warning: Do not dip the hand piece and extension wire directly into sterilization fluid. Doing so will cause the unit to malfunction during normal operation.

Warning: Do not allow the disinfectant to remain on the surface longer than recommended by the manufacturer of the disinfectant to prevent damage to the hand piece.

Note: Be sure to clean the hand piece after each patient and to clean the cable at the end of the day by scrubbing with antiseptic soap or solution, and rinsing with water.

Insert

Inserts must be cleaned after each use as saliva, blood, and other debris will be left on the piezo tip. To clean tips, remove the tip from the hand piece and scrub with a brush using detergent or water, or clean with an ultrasonic cleaner. Then place the tip in a medical bag and autoclave for 30 minutes at 273°F (134°C) or as recommended by the manufacturer of your sterilization unit. We recommend using bio-indicators or chemical indicators to ensure the efficiency of the sterilization cycle.

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 Instructions for the ART-M3II Magnet Ultrasonic Scaler

5-A: General Information

Be sure to observe the following requirements and recommendations if your ART-M3II system was installed by a non-Bonart representative or personnel of unauthorized distributors.

5-B: Water Line Requirements

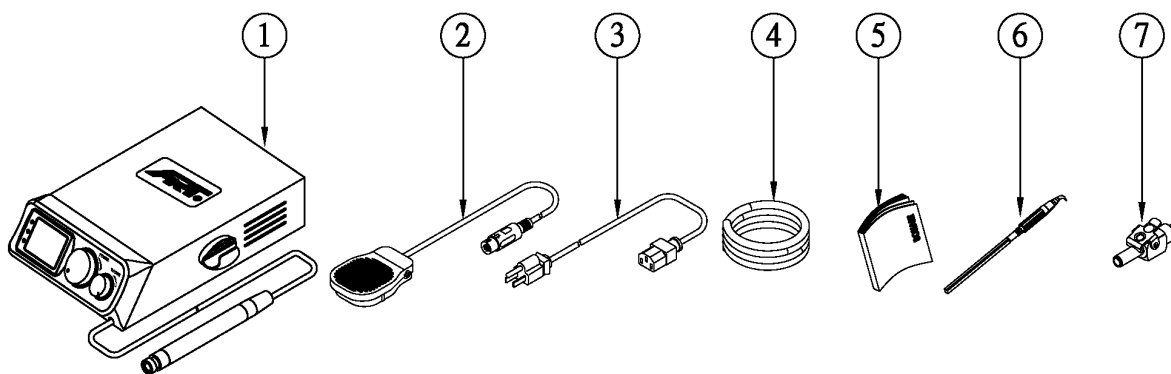
- Incoming water supply line pressure to the Scaler must be 25 psi (172 kPa minimum) to 60 psi (414Kpa maximum). If your dental water system's supply line pressure is above 60 psi, install a water regulator on the water supply line to your ART-P3II unit.
- The manual shut-off valve of the dental water system supply line should be used prior to leaving the office is unoccupied.
- After the above installations on the water supply system are completed, the water should be thoroughly flushed prior to connecting to the scaler.

5-C: Electrical Requirements

Refer to Section X: Specifications

5-D: Unpacking the Unit

Carefully unpack your ART-M3II 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.			1
ART P-10 Straight Angle Universal Metal Handle External Flow Insert.			1
(7) Water Hose/ Quick Disconnect Assembly.			1

NOTE :

While unpacking, check your ART-M3II 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-M3II 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-M3II 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-M3II hand piece, attached to the main unit, is designed only for inserts with either 25Khz or 30Khz frequency.

5-I: Assembling the Scaler Unit

1. Switch the power of the ART-M3II 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. Install an insert into the hand piece by turning the insert clockwise. Make sure that the insert is firmly seated in the hand piece. To remove the insert, turn it counter-clockwise.
4. Check the water tube connection to the water supply source and main unit.

Section VI: General Description and Information of Parts

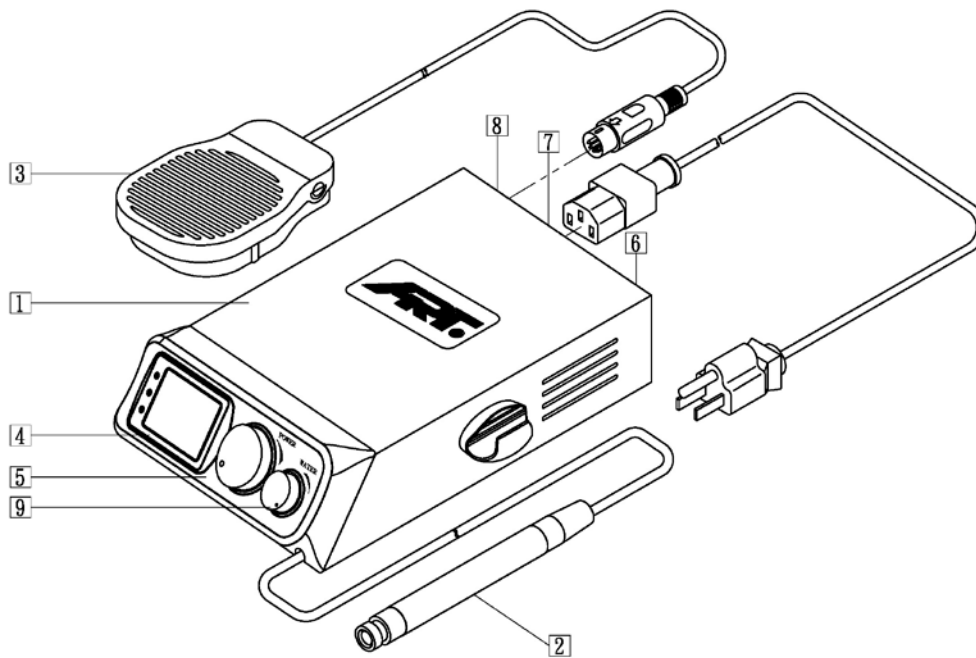


Figure 2. ART-M3II Outlook diagram

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 clockwise motion. To remove the insert, turn the insert counter-clockwise. Aside from Bonart inserts, Dentsply/Cavitron and Hu-Friedy inserts are also compatible with the ART-M3II.

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.

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

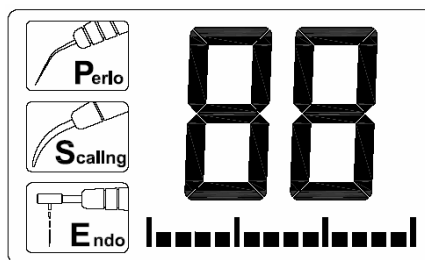
NOTE : The ART-M3II is a stand-alone unit and is now available in either a 25Khz or 30Khz vibration frequency. Please do not use 30Khz inserts with the 25Khz hand piece or vice versa.

3. Footswitch

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

4. LCD Display Screen

Power settings and operation modes are displayed on the LCD screen. Modes of operation and scale correspond to the power setting for each mode of operation. Recommended operation modes will be shown on the screen based on the current power setting. For example, if 3 modes appear on the screen after selecting a power level, the user has the option of using any of the 3 modes. Alternately, if only 2 modes are displayed, the user may only use one of the two operation modes. This function will also help the user determine which type of insert is appropriate for the procedure based on the power setting.



Caution: To prevent any damages, the user must choose an operation mode displayed on the LCD panel for the selected power setting.

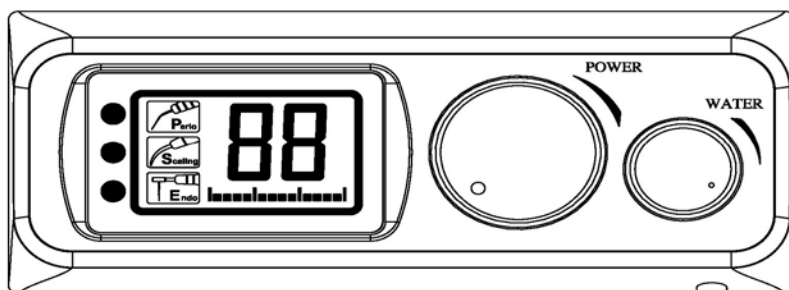


Figure 2. ART-M3II Front panel

Caution: To prevent any damages, INSERT something should go here operation has to be chosen according to the operation mode shown on the LCD display panel.

5. Power setting

The power setting can be adjusted by turning the power knob. To increase power intensity, turn clockwise. Turn counter-clockwise to decrease power intensity.

6. Water-in Connector

The water-in connector is where the water hose connects to the main unit. It is located on the back of the main unit.

7. AC Line Socket Seat

The AC line socket is where the power cord connects to the main unit.

8. Main power switch (ON/OFF)

The main power switch is used to turn the scaler on and off. When turned on, the LED power indicator should be lit.



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

9. Water control

The water flow rate can be adjusted by using the water control knob. Turn clockwise to increase the water flow rate. Turn counter-clockwise to decrease the water flow rate.

Please note that water flow is necessary for cooling the tip and hand piece. Inadequate amounts of water will result in overheating. Increasing the water flow rate will result lower the water temperature. Alternately, decreasing the water flow rate will raise the water temperature.

Warning: Do not turn the water control knob anti-clockwise over 3 full turns to prevent damaging the unit.

Warning: Increase the water flow rate using the control knob gradually to prevent damages to the water valve.



When using the sytem for the first time, water knob is securely turned off by the manufacturer. Pls. turn it on by following the directions mentioned above.

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!**

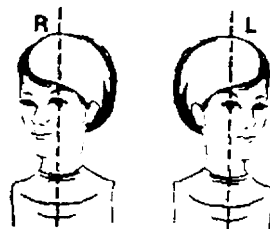
5. Lubricate the rubber O-ring on the insert with water before placing it into the hand piece. **Install the insert by gently pushing and twisting the insert clockwise. Do not force the insert in!**
6. Hold the hand piece over a sink or drain with an insert installed. Verify that the water is reaching the tip. Check your Bonart scaling inserts for wear and replace as needed.
7. 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 shut-off the water flow.
8. 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 counter-clockwise. Decrease the water flow by turning the water control knob 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. Make sure the patient is positioned comfortably on the patient chair. Adjust the chair angle and position for easy access to the patient's oral cavity.
2. Clear excessive saliva and debris from the patient's mouth with a saliva ejector.
3. Gently rotate patient's head for access to the oral cavity.



During treatment, keep the angle between the surface of the patient's tooth and the tip at 15 degrees. If the patient is experiencing discomfort, try the following steps.

- Increase the hand piece movement speed on the surface.
- Treat less sensitive areas first and return to sensitive areas later.
- If the problem persists, reduce the power intensity of the hand piece.

Section VIII: System Maintenance

Daily start-up

Starting the unit:

1. Open the water supply valve.
2. Turn scaler on using the power switch on the back of the unit. The LED power indicator should be lit.
3. Set the power control knob to full power.
4. Set the water control knob to maximum.
5. Install a sterile tip to the hand piece.
6. Hold the hand piece upright over a sink or drain.
7. Depress the footswitch and flush the water line for at least 2 minutes.
8. Set the water control knob as preferred for operating.

Note: If no water flow is detected, check the water supply.

Note: If the LED power indicator is not lit when turned on, contact local authorized agent.

Between Patients

1. Clean and sterilize all used piezo tips.
2. Clean and disinfect the surfaces of the power cord, hand piece and cable assembly.

Preparing to Treat Patients

1. Use the plastic tip wrench to tighten a piezo tip onto the hand piece. **Make sure the tip you are using has been sterilized!**

Daily shut-off

Turning off the unit:

1. Push the power switch to turn the unit off. Do not turn off by unplugging the unit from the outlet.
2. Shut the water supply valve

The following suggestions are useful for extending the life of the scaler.

- A. Place the main unit on flat surface where air can flow freely around it to prevent overheating.
- B. Handle the main unit with care. Do not throw, drop, or crush with heavy objects.

- C. Be sure to turn off the power and water valve before leaving the scaler unattended.
- D. If the power to the hand piece appears to have decreased after several months, check the tip to see if it is worn out. A replacement tip may be necessary.

Section IX: Troubleshooting

Section X: Troubleshooting

Please do not attempt to perform repairs on the ART-M3II system. Repairs performed by personnel not authorized by Bonart will invalidate the warranty. A few troubleshooting procedures listed in this section may help you determine whether your ART-M3II is in need of repair service or not.

Before you call for technical support, be sure to check all lines and connections to and from the system, a loose plug or connection will often create problems. Check the settings on the system's knobs.

10-A Troubleshooting Guide

For Systems that are not Operating:

A. The power indicator is not lit

1. Check that the power switch is set to ON
2. Check the connection between the power cord and the unit
3. Check that the 3 pronged end of the power cord is plugged all the way into the outlet

B. The power indicator is lit

1. Check the connection between the foot switch connector and the unit.

For Systems that are Operating:

A. No water flow

1. Check that the water control knob on the unit is properly adjusted
2. Check that the water supply valve is open
3. Check the connection of the external water tube to the water supply line and to the unit.

B. Hand piece is not vibrating

1. Ensure that the insert is installed correctly. For a demonstration, please see our video guide at www.bonartmed.com.
2. Ensure that the tip you are using is compatible with the ART-M3II. Tips

compatible with the ART-M3II inserts and also compatible with major brands.

10-B Technical Support and Repairs

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.

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)
27.8KHz \pm 5% (for 30KHz Insert)
- Water supply
25~60 PSIG(172~414KPa)
- Dimension
26cm(L) x 18.5cm(W) x 7cm(H)
- Weight
3.5 Kg(include hand piece)
- Hand piece Cable
250 cm
- Footswitch Cable
250 cm

Operation environment

- Temperature
0°~40°
- 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-M3II.