

ART-P3II Piezoelectric Ultrasonic Scaler

Directions for Use



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Operator Safety

Please read carefully and completely before operating the unit.

ENGLISH VERSION

ART-P3II Piezoelectric Ultrasonic Scaler

The dental equipment described in this manual is designed to be used only by properly trained personnel. Only qualified personnel shall carry out any kinds of adjustment, maintenance and repair of the equipment.

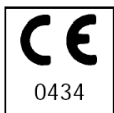
- ***NOTE, CAUTION AND WARNING STATEMENTS***

NOTE: Indicates helpful tips and advice.

CAUTION: Indicates correct operating or maintenance procedures

WARNING: Alerts the user that severe injury may occur when proper and correct procedures not followed.

- ***SYMBOLS***



Complies with MDD 93/42/EEC



Type BF equipment.



Grounding Terminal



Attention. Please read the instructions.

Warnings

Important Notes!

- **The dental equipment described in this manual shall be used solely by qualified personnel (trained doctors, trained hygienists, etc.).**
- **Patients with pacemakers should not be treated with this equipment.**
- **A shielded AC power cord must be used with this equipment.**
- **The dental equipment in this manual should be connected to a grounded electrical outlet.**
- **Do not submerge the dental device in water or liquids as it is an electronic device.**
- **If the patient or operator is pregnant, please consult a physician regarding the safety of dental scaling prior to using the equipment.**



Attention!

Special note to users with Cardiac Pacemaker:

Studies have shown that electronic appliances including razors, hair dryers, microwave ovens, TV receptors, and some electronic medical equipment, may interfere with the normal operations of pacemakers. It is suggested that patients who have pacemakers should avoid treatment with this unit. For further readings on the subject, please refer to:

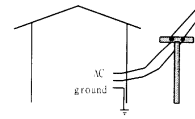
–"Advances in Cardiac Pacemaker", The New York Academy of Sciences, Vol. 167, Article 2, pp. 515-1075

–"Electromagnetic Radiation Interference with Cardiac Pacemaker", U. S. Department of Health, Education and Welfare

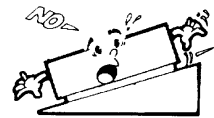
–"The Individual with a Pacemaker in the Dental Environment", Journal of the American Dental Association, Vol. 91, No. 6, pp. 1224-1229

NOTE (Please read prior to using):

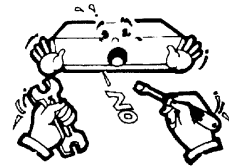
- Make sure that the Scaler System is connected to a grounded outlet. Failure to meet this requirement may cause severe damage and harm to the system or user.



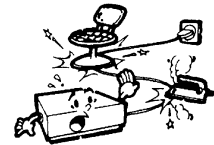
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- Place the Scaler System on a stable and flat platform. Tilted and unstable surfaces may degrade the performance or damage the machine.



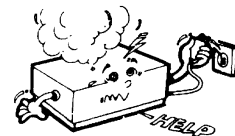
-
- Do not modify the Scaler System. Modifications may violate safety codes and cause harm to the patient and operator. Any modification will void the warranty terms.



-
- Keep the Scaler System away from high sources of heat. Do not place the power cord under heavy objects.



-
- Call Bonart if any abnormal situations arise while operating the Scaler System



Preface

ART-P3II Piezoelectric Ultrasonic Scaler

The Scaler System is ISO 13485:2003 certified and CE 0434 certified in compliance with applicable requirements of the Council Directive 93/42/EEC. The reviewing council classifies the P3II system in accordance to EN60601-1 and EN60601-1-2 safety requirements.

The ART-P3II Piezoelectric Ultrasonic Scaler utilizes 4 ceramic piezoelectric plates subject to high frequency alternating currents and a transducer that operates at a peak frequency of 29 KHz. The ceramic plates generate piezoelectric ultrasonic waves, which causes the tip to vibrate at high speed with minimal noise and heat to perform removal of tooth calculus and/or tartar using minimal water spray for cooling. The piezoelectric technology allows for more comfort and greater scaling efficiency.

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 Part

To order supplies or replacement parts in the U.S., please contact an authorized distributor of Bonart products. To view a list of distributors authorized to carry and sell Bonart products, please visit our website at www.bonartmed.com.

Caution:

Bonart piezo tips are made of stainless steel and should avoid direct contact with teeth. If handled incorrectly, direct contact may damage the enamel of the teeth. To ensure proper utilization of functions and to obtain optimum performance, we strongly advise to practice on models and aluminum plates prior to operating on patients.

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Section I: Indications for Use

Ultrasonic procedures:

- For removal of calculus and plaque during dental prophylaxis.
- All general supra and subgingival scaling applications.
- Periodontal debridement for all types of periodontal diseases.
- Endodontic procedures.

Section II: Contraindications and Warnings

- Do not use this unit for restorative dental procedure involving the amalgam's condensation.
- Do not use this unit if the patient or operator is wearing a pacemaker.
- Do not immerse the unit in water or liquid.
- Do not modify this unit. Modification may violate safety codes and endanger patient and operator, thus voiding the warranty terms and conditions.

Section III: Precautions

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

- Ensure that an adequate amount of water flows through the piezo tip in order to cool the hand piece and tip.
- Take precaution to prevent transmission of contagious diseases as all ultrasonic scalers produce aerosols.
- Select appropriate tips for procedures to obtain optimal performance.
- Do not place the unit next to a heat source to prevent overheating and damaging of electrical components.
- Close the water valve when the unit is not in use.

3-B: Precautions for Ultrasonic Prophylaxis Procedures

- Scaler tips (piezo tips) wear out with use. Tips with just about 2mm of wear lose about 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 tips with the patient's lips, cheeks and tongue whenever it is placed in the subject's mouth.
- Scaler tips (piezo tips) that are bent, damaged or reshaped must be discarded immediately and should not be reused.
- Use the long axis of the scaler tip (piezo tip) to wipe accretions from the tooth. Do not gouge the tooth with the tip.

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 Sterilizations:

Hand piece and cable

If there is a tip 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.

Tip

Tips 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.

Warning: High room temperature conditions, improper dilution, and excessive immersion time in chemical sterilizers can damage the plastic and elastomeric materials of the tips.

Caution: Avoid use of dry heat ovens, chemical vapor type sterilizers, and quaternary ammonium compounds to prevent damaging the plastic and elastomeric materials.

Warning: Do not attempt to alter the shape of tip. Doing so will lower the power output.

Note: If the Tip is damaged or worn, replace it with a new tip.

Hand Piece and Tip Autoclave Conditions

	Temperature (Celsius)	Temperature (Fahrenheit)	Duration (minutes)
Hand piece	134	273	20 to 30
Piezo tip	134	273	20

Do NOT use ultrasonic cleaning systems.

Do NOT submerge the hand piece in disinfectant.

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-P3II Piezoelectric Ultrasonic Scaler

5-A: General Information

Be sure to observe the following requirements and recommendations if your ART-P3II 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 XI: Specifications

5-D: Unpacking the Unit

Carefully unpack your ART-P3II and verify that all components and accessories are included:

1. ART-P3II Scaler.
2. AC Power Cord Set.
3. Foot Control / Foot Switch
4. Water Hose / Quick Disconnect Assembly.
5. 2 pcs. ART-BS1 Universal Pointed Tip
6. 1 pc. ART-BS2 Chisel Head Flat Tip
7. 1 pc. ART-BS3 Round Flat Tip
8. 4 pcs. Plastic Autoclavable Wrench
9. 1 pc. Aluminum Sterilization Box
10. Literature Packet.

NOTE:

Inspect the ART-P3II unit for any damages as you unpack. If damaged, please contact your dealer immediately. Enter the unit serial number on your warranty card and mail it within 14 days from the day of the installation.

5-E: Power Cord / Power Connection

- Verify that the Power Control switch is set to OFF position before proceeding.
- Plug the detachable AC cord into the back of the unit.
- Plug the 3 prong grounded plug into a grounded outlet.

Safety Instructions

A. Grounding:

Verify that the main unit is connected to a grounded outlet prior to connecting other parts to the main unit.

B. Main voltage range

Check the voltage of the scaler for compatibility with your local voltage before plugging the power cord into the outlet.

5-F: Foot Control Cable Assembly Connection

Align the Foot Control plug with the receptacle on the back of the device and push firmly until seated.

5-G: Water Supply Line Connection

1. Push the blue water hose over the stainless steel receptacle on the back of the main unit. Then tighten the screw over it.
2. Connect the free end with the enclosed male quick disconnect of the water tubing to the office water supply line. A female quick connector may be needed. Female quick

connectors are sold separately.

3. Inspect for leaks.

To remove the water hose from the main unit, disconnect the water supply line from the water hose, then loosen the screw from the receptacle, and gently pull the water hose off.

5-H: Hand Piece Connection and Tip Compatibility

The hand piece may be detached from the hand piece cable. **Do not twist to separate the hand piece from the cable.** Doing so will damage the hand piece connectors.

The ART-P3II is compatible with Bonart BS series tips. Other tips compatible with Satelec Acteon piezoelectric scalers may also be used.

5-I: Assembling the Scaler Unit

1. Make sure the power switch is set to the off position. The power indicator should be unlit.
2. Plug the power cord into a grounded AC power outlet.
3. Attach a tip to the hand piece using the enclosed wrench.
4. Attach the water hose to the main unit and to the water supply line.

Section VI: General Description and Information

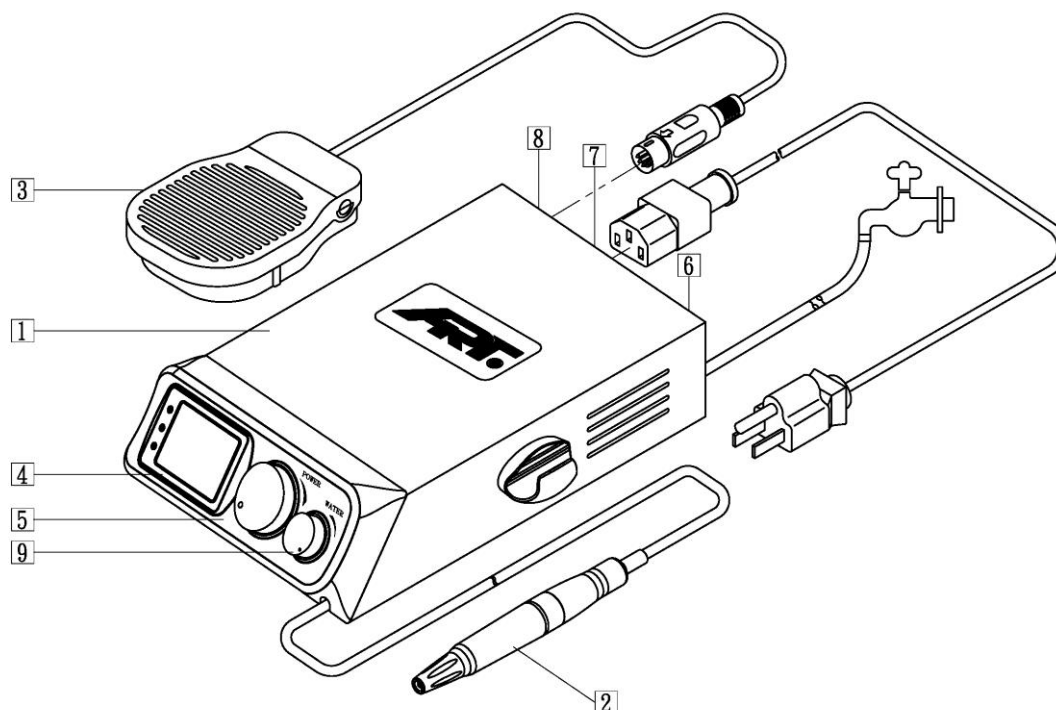


Figure 1. ART-P3II Diagram

1. Main Unit

The main unit sends a control signal to the hand piece, which allows the tip to vibrate. The hand piece then sends a signal back to the main unit which allows the unit to track pressure variation and adjust the intensity of the control signal accordingly.

The ART-P3II scaler features an Auto Gain Control (AGC) chip to help stabilize power settings and prevent stalling during use.

2. Hand piece

The hand piece contains a vibrator that is made of 4 piezoelectric plates. The plates are displaced by an electrical signal from the main unit which causes the tip to vibrate. The hand piece then sends a feedback signal to the main unit.

Due to the vibration of the tip, the tip will generate heat. An adequate stream of water is necessary to cool the tip during use.

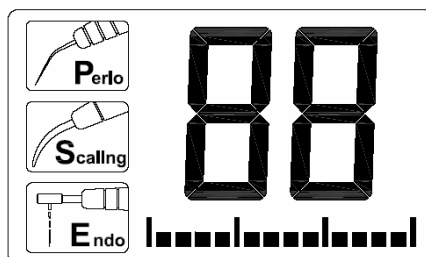
Caution: Make sure the tip is installed properly. The tip will not vibrate if installed incorrectly.

3. Foot switch

The foot switch allows the user to operate the ART-P3II while using both hands during the cleaning process.

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 tip 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.

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.

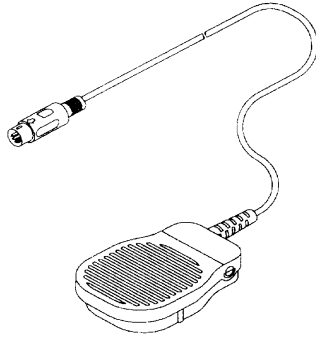


When using the system for the first time, water knob is securely turned off by the manufacturer. Please turn it on by following the directions mentioned above.

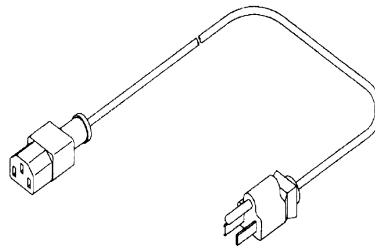
Section: VII. Accessories

7-A: Accessories included:

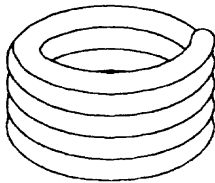
(1) Foot switch x1



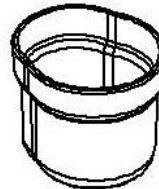
(2) AC Power Line x1



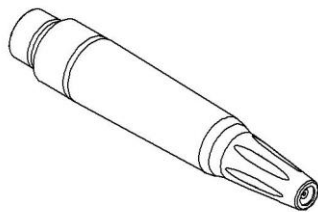
(3) Water Hose x1



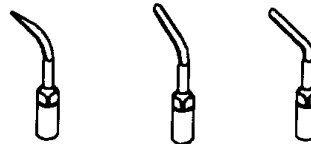
(4) Plastic Wrench Set x1



(5) Piezo Hand piece x1



(6) BS1 Tip x2 / BS2 Tip x1 / BS3 Tip x1



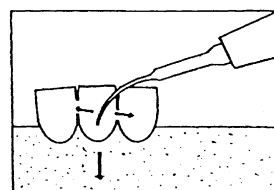
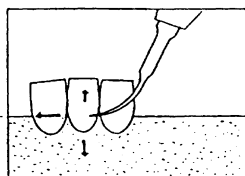
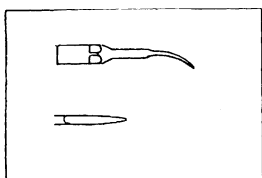
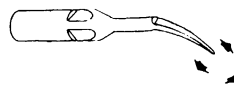
(7) Aluminum Steel Sterilization Box x1

Note: Other piezo tips are available and can be purchased separately. Included parts shown above are subject to change depending on region.

Warnings:

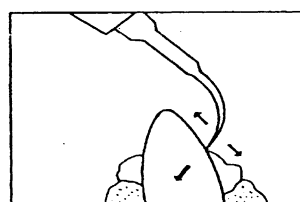
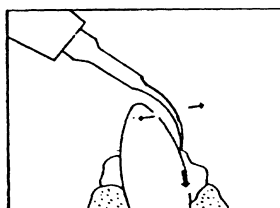
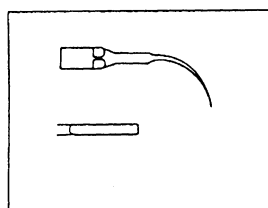
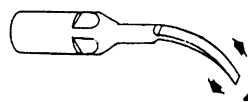
A. Tangential application (BS1 Tip)

Do not apply the BS1 tip directly against the tooth to prevent damaging the enamel.
Use slow and regular movement.



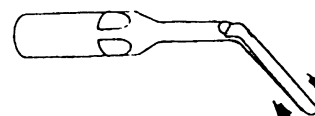
B. Frontal application (BS2 Tip)

Apply BS2 tip directly against the tartar, but not directly against the tooth. Use slight pressure.



C. Tangential Application (BS3 Tip)

Apply the BS3 tip to the enamel. Do not use pressure.



Section VIII: Techniques for Use

8-A: Performing Ultrasonic Scaling Procedures

1. Patients may experience some tissue laceration during treatment. To reduce the chances of infection, purified or distilled water should be used.
2. Keep the power cord and foot switch cable tidy to prevent accidents from occurring.
3. Position the foot switch so that it is easily accessible to the user.
4. Check the piezo tip for wear and tear. Replace if necessary.
5. Use the enclosed piezo wrench to tighten the tips onto the hand piece. Do not force or over turn the tips onto the hand piece. Doing so will break the hand piece, tip, and/or wrench.

Caution: Do not overturn the piezo wrench.

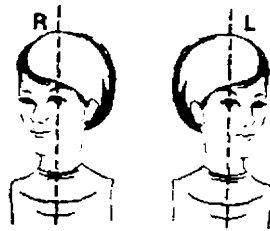
Note: The scaler will not operate if the tip is either removed from the hand piece or properly tightened onto the hand piece.

6. Turn the scaler on and hold the hand piece over a sink or drain. Depress and hold down the foot switch to allow water to flow through the tip. Check the spray temperature to verify that the water is cooling the tip. Release the foot switch to stop the hand piece and water flow.
7. Use the water control knob to adjust the water flow. Turn clockwise to increase the water flow and lower the water temperature. Turn counter-clockwise to decrease the water flow.

Caution: A continuous flow of water is required to keep the hand piece cool during operation.

8-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 IX: 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 X: Troubleshooting

Please do not attempt to perform repairs on the ART-P3II 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-P3II 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 tip 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-P3II. Tips compatible with the ART-P3II are Bonart BS series piezo tips and tips compatible with Satelec Acteon Piezoelectric Scalers.

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.

XI. Specifications

● **Classification**

- Protection against electric shock : Class I
- Degree of protection against electric shock : Type BF
- Degree of protection against the harmful ingress of water : IP40
- Mode of operation: Continuous
- Medical device directive: II A

● **Complies with the following Directive/Standards**

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

● **Specification**

- Power supply

115V \pm 5%	~50/60Hz	30VA
230V \pm 5%	~50/60Hz	30VA
- Working frequency 26KHz ~ 32KHz
- Water supply 25~60 PSIG(172~414KPa)
- Dimension 26cm(L) x 20cm(W) x 7cm(H)
- Weight 2.5 Kg(include hand piece)
- Hand piece Cable 250 cm
- Footswitch Cable 250 cm

Operation environment

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

Transport and storage conditions

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

- **PACKAGING AND STORAGE:**

A. Environment:

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

Temperature: 0°C to 60°C
Humidity: 10%~90% (at 40°C)
Atmospheric pressure: 860~1060 hPa

B. Labels:

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



FRAGILE



KEEP AWAY FROM WATER



DO NOT HOOK



THIS SIDE UP

Section XII: Disposal of Unit

- Please follow local and state laws for disposal of the unit.