BENTIPS™ PIEZOSURGERY SYSTEM CONSOLIDATED INSTRUCTIONS FOR USE
V3.0 2022-04-02

BenTips™ can be contacted at
incidents@bentipsusa.com

TABLE OF CONTENTS

1 INTRODUCTION

1.1. Definitions

The following terms as used throughout these Instructions for Use mean the following:

1.1.1. "BenTips™ products" and "products" and "product" and "device" and "equipment" means all dental device products for use in periodontal and/or other dental procedures that are marketed and/or sold by the Company and branded with its BenTips™ Trademarks including but not limited to:

1.1.1.1. Consumable, single-use BenTips™ tips and shafts that are assembled by the end-user to form the CPIS Inserts;

1.1.1.2. Gold Inserts;

1.1.1.3. B1 Piezosurgery system and its components and accessories.

1.1.2. "Company" means Bennett Jacoby, DDS MS, Inc., the manufacturer of the BenTips™ products, Kailua-Kona, HI 96740 (access www.bentipsusa.com for company address); Email: incidents@bentipsusa.com; Website: ww.bentipsusa.com

1.1.3. "Practice Group" collectively refers to the individual who receives training, certification, and licenses from Company under this Agreement. The rights to use the BenTips™ products are granted to You as an individual based on your being a member of such Practice Group.

1.1.4. "You" means each individual whose signature appears on, and who receives training, certification, and licenses under the BenTips™ Group Certification, Confidentiality, and License Agreement.

1.2. Foreword

1.2.1. READ THE MANUAL: Before proceeding with the installation, use, maintenance or any other activities on the equipment, this manual must be read carefully and completely.

1.2.2. IMPORTANT: To avoid causing personal injuries or damage to property, pay special attention to all sections concerning safety requirements contained in this manual as indicated with "**DANGER**" and "**WARNING**".

1.2.3. RISK CLASSIFICATION: Depending on the level of risk involved, safety requirements are classified under the following indications:

1.2.3.1. ⚠**DANGER (ALWAYS REFERS TO PERSONAL INJURY)**

1.2.3.2. ⚠**WARNING (ALWAYS REFERS TO POSSIBLE DAMAGE TO PROPERTY)**

1.2.4. MANUAL PURPOSE: The purpose of this manual is to ensure that operators are aware of the safety requirements of the installation procedures and of

the instructions for correct use and maintenance of the equipment.

1.2.5. UNAUTHORIZED ACTS: The user is not authorized to attempt to open, disassemble or service the equipment under any circumstances, which will void the Warranty, and will release the manufacturers from any liability arising from harm or damage to persons or property.

1.2.6. INFORMATION TIMELINESS: The information and illustration contained in this manual are up-dated to the date of publication indicated on the first page.

1.2.7. PRODUCT UPDATES: BenTips™ is committed to continuous up-dating of the products, which may entail changes to components of the equipment. If there are any discrepancies between the descriptions contained in this manual and your equipment, please contact BenTips™.

1.2.8. MANUAL REPURPOSING: Using this manual for purposes other than those relating to the installation, training, use and maintenance of the equipment is strictly prohibited.

1.2.9. COMPANY CONTACT: If any problems are encountered, please contact BenTips™ at incidents@bentipsusa.com.

1.3. Product Description

With controlled three-dimensional ultrasound oscillations, the B1 heralds in a new age for osteotomy and osteoplasty in implantology, and periodontology. Its main features are:

1.3.1. Precision: Maximum surgical precision and intra-operative sensibility;

1.3.2. Selective Cutting: Maximum safety for hard and soft tissue;

1.3.3. Cavitation Effect: Maximum intra-operative visibility (bloodless field);

1.3.4. Automatic Tuning: Automatic tuning circuit that offsets wear of the tips, thus ensuring work in conditions of maximum efficiency.

1.4. Indications for Use and Intended Use

1.4.1. BenTips™ B1 Piezosurgery System Indications for Use

The BenTips™ B1 Piezosurgery System is intended for use in the following dental applications:

- Bone cutting for use in oral surgery
- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planning
- Retrograde preparation of root canals

1.4.2. BenTips™ CPIS Inserts Intended Use, Intended Users and Patient Groups

1.4.2.1. Indications For Use: BenTips™ CPIS Inserts are an accessory attachment to the BenTips™ Piezosurgery System (Model: B1). It is used by dental professionals during treatment of periodontal disease and oral surgery for the following intended uses:

- Surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.
- Soft tissue debridement and removal, particularly in intrabony lesions.
- Tooth surface debridement including removal of plaque, food, tooth debris, and other soft debris

1.4.2.2. Intended Users: The use of this device is restricted to licensed dental professionals and other persons in the Practice Group within their scope of practice.

1.4.2.3. Patient Groups and Intended Users: Patient populations with the following dental conditions or indications may be treated with BenTips:

- All stages of periodontitis
- Preprosthetic periodontal surgery procedures
- Aesthetic periodontal surgery procedures
- Surgical tooth extractions
- Dental implant site preparation
- Preprosthetic oral surgery

1.4.3. BenTips™ Gold Inserts Intended Use, Intended Users

1.4.3.1. The intended use of the BenTips™ Piezosurgery Gold Inserts is: cutting bone, the formation of bone, the collection of bone pieces, scaling and root planing, smoothing tooth surfaces.

1.4.3.2. The use of this device is restricted to licensed dental professionals and other persons in the Practice Group within their scope of practice.

1.5. Safety Requirements

1.5.1. ⚠ DANGER: USE OF THIS EQUIPMENT CONTRARY TO ANY OF THE FOLLOWING SAFETY REQUIREMENTS WILL VOID ANY WARRANTIES AND MAY RESULT IN DAMAGE TO, OR FAILURE OF, THE EQUIPMENT, SERIOUS PROPERTY DAMAGE, PERSONAL INJURY, OR DEATH. BENTIPS™ SHALL NOT BE RESPONSIBLE FOR ANY ADVERSE RESULTS THEREAFTER OCCURRING AS A RESULT OF ANY SUCH VIOLATION:

1.5.1.1. Use the equipment solely for the purpose for which it is intended (see section 1.4).

1.5.1.2. This equipment must not be used other than in accordance with all the instructions and requirements described in this manual;

1.5.1.3. This equipment must not be used in a room where the wiring system does not comply with the application standard and appropriate requirements;

1.5.1.4. No assembly operations, extensions, settings, alterations or repairs may be carried out by any personnel not authorized by BenTips™;

1.5.1.5. This equipment must be kept and stored at all times under the environmental requirements specified in this manual;

1.5.2. ⚠ DANGER: QUALIFIED AND SPECIALIZED PERSONNEL

This equipment may be used only by licensed dental professionals and other persons in the Practice Group within their scope of practice. If correctly used, this equipment will not typically give rise to adverse events. Improper use, on the other hand, will increase the risk of adverse events such as property damage, transmission of excessive heat to tissues, or other serious injury to the patient, the operator, or other persons. Do not use BenTips™ products unless and until you have been fully trained and have received BenTips™ Certification for such use and you have fully read and understand these Instructions for Use and all precautions and warnings herein.

1.5.3. ⚠ DANGER: CONTRAINDICATIONS

1.5.3.1. Do not use the equipment if the patient, the operator, or others in close proximity to the use have pace-makers or other implantable electronic devices.

1.5.3.2. Operation of electrosurgery devices in close proximity to this unit may interfere with correct functioning of this unit and thus should be avoided.

1.5.3.3. Do not use on patients with bleeding disorders such as hemophilia.

1.5.3.4. Caution must be used on patients with heart disease, pregnant women and children.

1.5.3.5. Do not use for restorative dental procedures involving condensation of amalgam.

1.5.3.6. Do not carry out this treatment on metal, ceramic or plastic dental restorations. The ultrasonic vibrations could lead to damage of these restorations.

1.5.3.7. After autoclave sterilizing of the handpiece, wait for it to cool down completely before using.

1.5.4. ⚠ DANGER: CLEANING, DISINFECTION AND STERILIZATION OF NEW OR REPAIRED PRODUCTS

All new or repaired products are delivered in non-sterile condition. Before being used for treatment, all new or repaired products must be cleaned, disinfected and sterilized per the instructions provided under Section 8.

1.5.5. ⚠ DANGER: USE ONLY ORIGINAL BENTIPS™ PRODUCTS

Using any unauthorized accessories or components with the BenTips™ piezosurgery system will void the Warranty and may result in increased risks of property damage or serious personal injury to the patient or operator. In addition, BenTips™ products are designed and tested for optimal performance with the BenTips™ Piezosurgery System (Model: B1). The safety and efficacy of using any BenTips™ products with other piezosurgery systems has not been tested, therefore BenTips™ products must not be used with any piezosurgery systems other than a BenTips™ piezosurgery system.

1.5.6. ⚠ DANGER: CHECK THE CONDITION OF THE EQUIPMENT BEFORE TREATMENT.

Always make sure that there is no water under the equipment. Before each treatment, always check that the equipment and the accessories are in good working order. Do not carry out the treatment if any problems are encountered in operating the equipment. If problems occur, contact BenTips™.

Prior to use, BenTips™ tips, shafts, CPIS inserts and Gold inserts should be checked for any chips, fractures, cracks, bends, distortions or damage. If any such problems are noted, the affected item must not be used.

1.5.7. ⚠ DANGER: CHECK THE CONDITION OF THE EQUIPMENT DURING TREATMENT.

Check the tip, shaft (CPIS Insert) or Gold Insert, at frequent intervals during use for any chips, fractures, cracks, bends, distortions, damage or other indications of weakness or compromised functionality. You must immediately replace the affected item with a new item if any such indications appear.

1.5.8. ⚠ **DANGER: DO NOT INSTALL THIS EQUIPMENT ANYWHERE THERE IS A RISK OF EXPLOSION**

This equipment must not be used in the presence of flammable gases (anesthetic mixture, oxygen, etc.)

1.5.9. ⚠**DANGER: DO NOT OPERATE THE FOOT SWITCH WITH THE PUMP DOOR OPEN**

The footswitch of the B1 must not be activated when the door of the Peristaltic pump is open (Fig 5-Ref. B). Moving parts could injure the operator.

2 PRODUCT IDENTIFICATION

2.1 Product Identification Data: When contacting BenTips™ customer service, always provide the model number and serial number as shown on the data plate on the rear of the piezosurgery main unit, and on the package label of the BenTips™ tips, shafts and Gold Inserts.

2.2 Product Data Plate: Each BenTips™ piezosurgery unit has its own data plate on the rear of the unit, on which technical specifications and serial number are indicated. The remaining data is included in this manual (see section 15).

2.3 Handpiece Data Plate: The serial number of the HBPS-1 (LED) handpiece is engraved on the ring nut.

2.4 Foot Switch Data Plate: The data plate for the foot switch is located on the bottom of the foot switch.

2.5 ⚠ **WARNING. DO NOT USE ANY BENTIPS™ PRODUCT IN THE EVENT OF THE PRODUCT LABEL BEING DAMAGED/ILLEGIBLE/MISSING.**

3 DEVICE TESTING

All devices are checked and tested by BenTips™ for functionality, during intermittent operation, prior to shipping, including all accessories and components, demonstrating that all shipped units and components are free from defects and are in good working order.

4 TRANSPORTATION & DELIVERY

4.1. All BenTips™ products must be handled gently at all times during use, storage or transport. As such, the following must be avoided as they will damage the unit and void the Warranty:

4.1.1. Excessive mechanical shock, excessive vibration, shaking the unit or dropping the unit, and exposure to: direct sunlight, extraneous heat sources, rain (or other water source) and snow.

4.2. Mixing of BenTips™ products with dangerous goods.

5 LIST OF INCLUDED PARTS, ACCESSORIES AND COMPONENTS

The parts, accessories and components included with this unit may vary. For a complete list, see packing list included with the unit.

⚠ **WARNING: THE HANDPIECE AND CORD CANNOT BE DETACHED FROM EACH OTHER.**

NAME	FIG	QTY
Peristaltic pump	A	1
Main Unit	B	1
Torque wrench	C	2
HBPS-1 LED handpiece complete with cord and connector	D	2
Foot-Switch	E	1
Power-supply cable	F	1
Surgical tray	G	1
Rod for supporting irrigant bag	H	1
Support for the handpiece	I	1

Fig. A

Fig. B

Fig. C

Fig. D

Fig.E

Fig. F

Fig. G

Fig. H

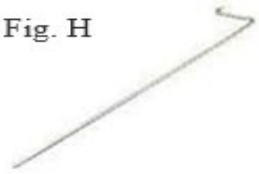
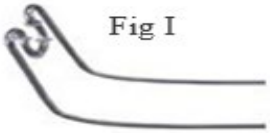


Fig I



6 INSTALLATION

6.1 Safety Requirements During Installation

6.1.1. ⚠ DANGER: THE WIRING SYSTEM OF THE PREMISES WHERE THE EQUIPMENT IS INSTALLED AND USED MUST COMPLY WITH THE APPLICABLE STANDARDS AND THE RELEVANT ELECTRICAL SAFETY REQUIREMENTS.

6.1.2. ⚠ DANGER: DO NOT INSTALL THE EQUIPMENT IN PLACES WHERE THERE IS A RISK OF EXPLOSION. THE EQUIPMENT MUST NOT BE USED IN AREAS WHERE THERE ARE FLAMMABLE GASES OR MIXTURES (ANESTHETIC, OXYGEN, ETC.)

6.1.3. ⚠ DANGER: INSTALL THE EQUIPMENT IN A PLACE WHERE IT WILL BE PROTECTED FROM PHYSICAL SHOCK AND FROM ACCIDENTAL SPRAY OF WATER OR OTHER LIQUIDS.

6.1.4. ⚠ DANGER: DO NOT INSTALL THE DEVICE ON OR IN THE VICINITY OF THE SOURCES OF HEAT. INSTALL IT IN SUCH A WAY THAT THERE IS ADEQUATE CIRCULATION OF AIR AROUND THE MAIN UNIT, ESPECIALLY FOR THE FAN ON THE REAR OF THE MAIN UNIT. (FIG. 6B)

6.1.5 ⚠ WARNING: DO NOT EXPOSE THE EQUIPMENT TO DIRECT SUNLIGHT OR TO SOURCES OF UV LIGHT.

6.1.6. ⚠ WARNING: THE EQUIPMENT IS PORTABLE, HOWEVER IT MUST BE HANDLED WITH CARE WHEN IT IS MOVED.

6.1.7. ⚠ WARNING: BEFORE CONNECTING THE POWER CORD AND HANDPIECE CORD TO THE MAIN UNIT, MAKE SURE THAT THE ELECTRICAL CONTACTS ARE COMPLETELY DRY. IF NECESSARY, DRY THEM WITH DRY COMPRESSED AIR.

6.1.8. ⚠ WARNING: TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A POWER SUPPLY THAT IS PROPERLY GROUNDED.

6.2 Initial Installation

6.2.1 To ensure proper operation of the equipment, the system must be installed per the setup instructions in this manual.

6.2.2 Carefully unpack and remove the piezosurgery main unit and all accessories from the case, and place on a stable surface in close proximity to the intended work area.

6.2.3 Install the peristaltic pump onto its mounting area on the top of the main unit, oriented such that the pump door opens to the right of the unit.

6.2.4 Refer to Section 8 CLEANING, DISINFECTION, STERILZATION AND STORAGE for

processing steps required prior to use of BenTips™ tips, shafts, Gold Inserts, handpieces, silicon handpiece supports and torque wrench.

6.2.5 Refer to Section 9 TRANSPORT, REGULAR MAINTENANCE AND STORAGE OF BENTIPS™ PRODUCTS of this manual for further important required procedures and limitations.

6.3. Connecting The Accessories

6.3.1. Insert the rod for supporting the irrigant bag into the holes provided for it. You may leave this in place or remove it, depending on your usage setup: e.g., if you are using a training bowl, you may remove this rod.

6.3.2. Connect the foot-switch to the back of the main unit by inserting the plug into the foot-switch socket and tighten the finger screws (Fig. 6B).

6.3.3. Plug the power cable into the connector on the rear of the case of the unit (Fig. 6B) and then insert the AC plug into the standard wall power outlet.

6.3.4. Insert the steel handpiece support into the two holes provided for it on the main unit, and set the silicone handpiece support cradle near the control unit. One or the other may be removed depending on the operator's preference.

6.3.5. Insert the connector of the HBPS-1 LED handpiece cord to the cord connector on the main unit front connector (Fig. 7). Note the alignment of the two red dots and the detent-enabled sleeve.

6.3.6. Put the handpiece on the support of the operator's choice.

6.3.7. Connect the flow-control system connector to the irrigant container with the appropriate liquid for the treatment.

6.3.8. Choose the appropriate BenTips™ tip and shaft, or Gold Insert, for the planned procedure.

6.3.9. Ensure that the BenTips™ products to be used are without any chips, fractures, cracks, bends, distortions, damage or other indications of weakness or compromised functionality. If any such indications are found, then the affected BenTips™ product must not be used.

6.3.10. Install the appropriate BenTips™ tip and shaft, or Gold Insert, for the planned procedure in accordance with the Instructions for Use in Section 7.5.

6.3.11. Replace the handpiece back into its support.

6.4. Irrigant Pump and Supply Set-Up:

6.4.1. Open the pump door as far as it will go.

6.4.2. Position the irrigant tube within the impeller slot (Fig.5 - Ref. B).

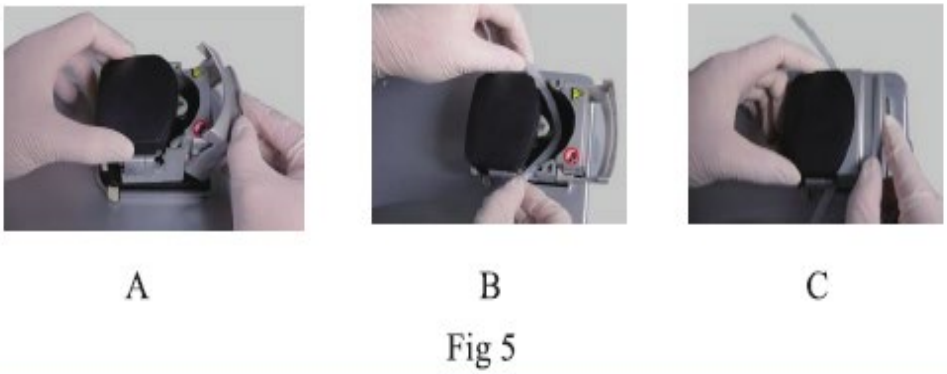
6.4.3. Close the door completely (Fig.5 - Ref. C).

6.4.4. Connect the distal irrigant connector to the irrigant container with the appropriate liquid for the planned procedure: i.e. bag of sterile saline or irrigant bowl with clean water for training.

6.4.5. Place a barrier over the control unit and under the handpiece.

6.4.6. ⚠**DANGER: PERSONAL INJURY**

The foot-switch of the B1 must not be activated when the door of the peristaltic pump is open (Fig. 5 – Ref. A). Moving parts could injure the operator.



A B C

Fig 5

6.4.7. Press the On/Off switch (Fig. 6A) to power the main unit. Follow these instructions below to verify proper function of the power unit and handpiece.

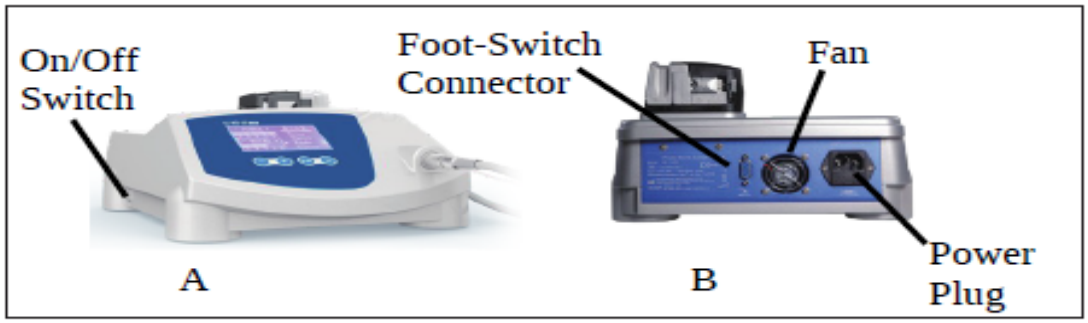


Fig 6

Fig.7

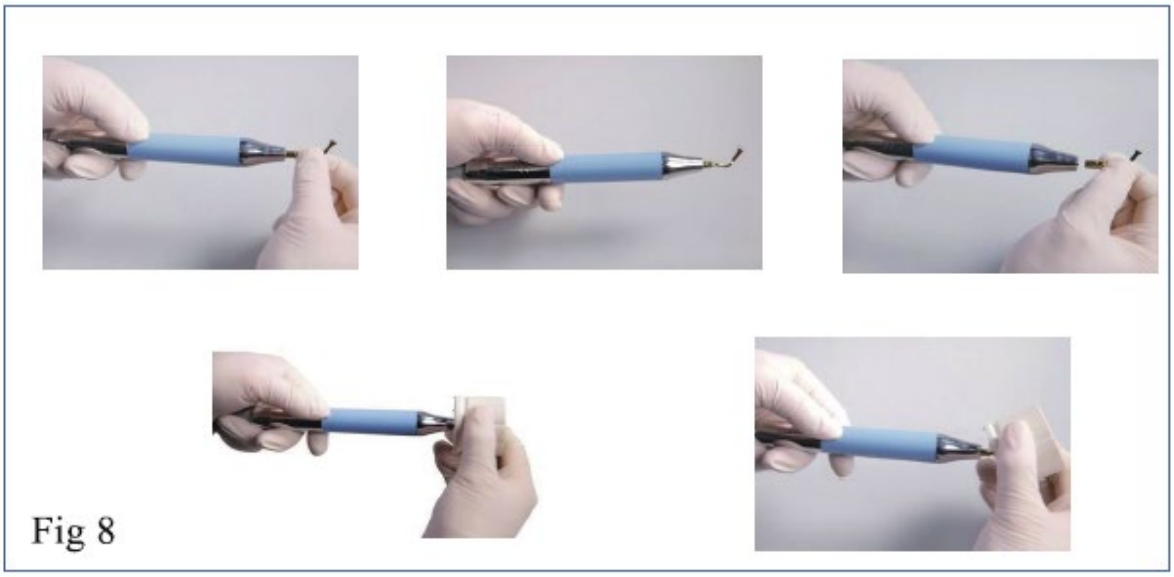


Fig 8

7 INSTRUCTIONS FOR USE

7.1 Description of The Controls

This section illustrates the parts of the front panel of the BPS-1 LED unit, enabling the controls described in this manual.

7.1.1 Diagram of “Bone” mode:

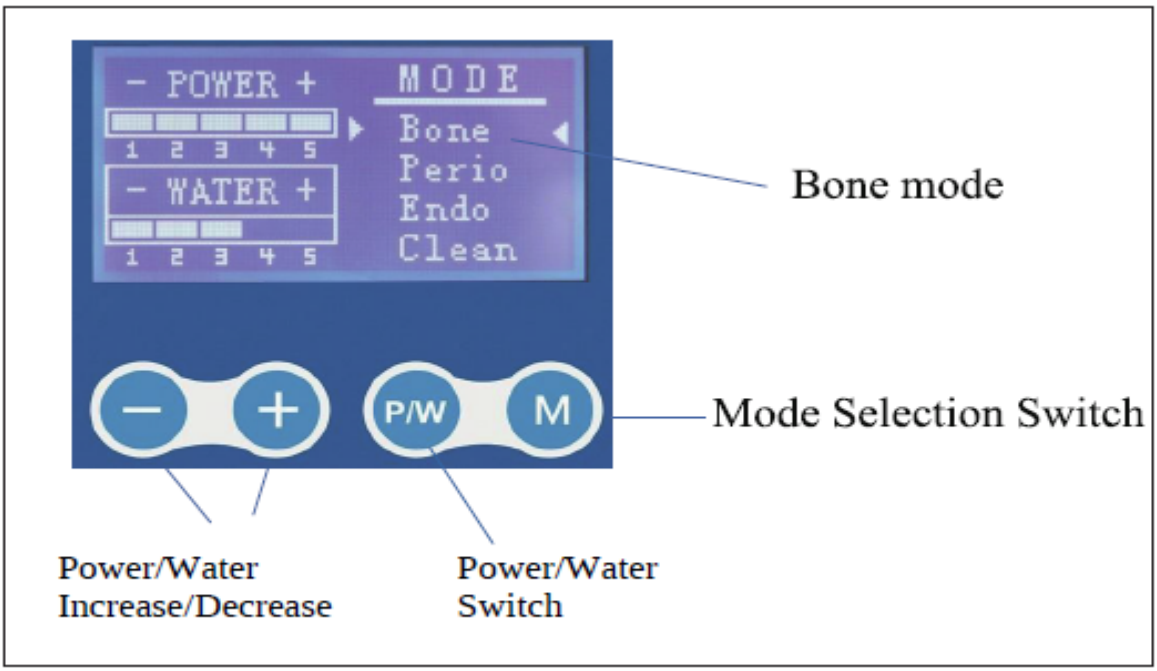


Fig.9

7.1.2 Diagram of “Perio” mode:

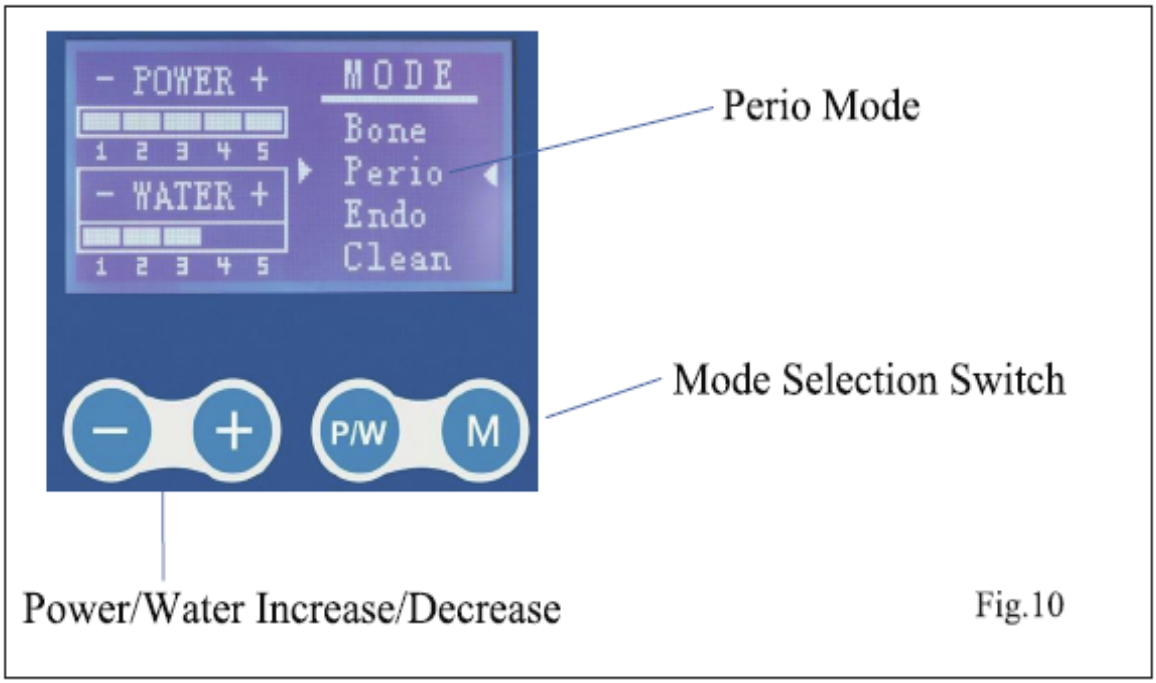


Fig.10

7.1.3 Diagram of “Clean” mode:

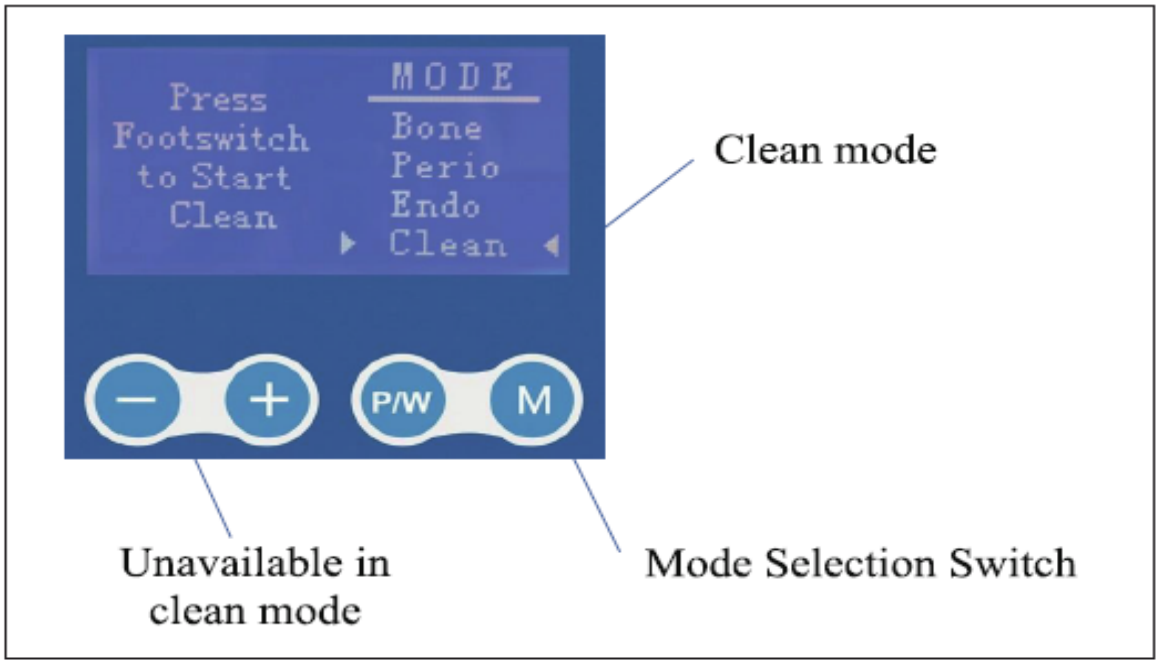


Fig.11

7.2 Description of The Display And Functions

7.2.1. There are 4 function modes available: Bone, Perio, Endo, Clean

7.2.2. Bone function mode (Fig. 9): Both power and water adjustments are available. Five power modes can be chosen from:

7.2.2.1. Power 5: Used for very high bone density and all BenTips™ soft tissue debridement modalities.

7.2.2.2. The following power levels are not often used but are available at the discretion of the operator:

- Power 4: High bone density
- Power 3: Middle bone density
- Power 2: Low bone density
- Power 1: Very low bone density

7.2.3. Perio function mode (Fig. 10): Both power and water adjustments are available. In this mode, scaling and root planing with the appropriate Gold Insert is possible.

7.2.4. Endo function mode: This is not utilized during BenTips™ procedures and is not supported.

7.2.5. Clean function mode (Fig. 11): In this function mode, press the foot-switch and hold it for 3 seconds. The unit will automatically flush the tubing with irrigant for 25 seconds without activation of the handpiece.

7.3 Safety Requirement During Use.

7.3.1. ⚠ **DANGER: CONTRAINDICATIONS**

Do not use the equipment if the patient, the operator, or others in close proximity the equipment have pace-makers or other implantable electronic devices.

7.3.2. ⚠ **DANGER: BREAKAGE AND WEAR OF THE TIPS, SHAFTS, CPIS INSERTS AND GOLD INSERTS.**

7.3.2.1. BenTips™ tips, shafts and CPIS Inserts experience more significant breakage rates than may occur with other dental instruments.

7.3.2.2. BenTips™ **tips, shafts, and CPIS Inserts** are intended for single patient use only and must not be reused.

7.3.2.3. Do not use BenTips™ tips, shafts or Gold Inserts 5 years past the manufacture date provided on the product label as the cleanliness of the product cannot be guaranteed and could result in ineffective sterilization.

7.3.2.4. BenTips™ **Gold Inserts** are resterilizable before each use, but must be discarded after a service life of 300 sterilization cycles regardless

of functionality since with every renewed preparation for use, thermal and chemical stresses will result in incremental deterioration of the Gold Inserts.

7.3.2.5. Using BenTips™ tips, shafts, CPIS Inserts or Gold Inserts with chips, fractures, cracks, bends, distortions or damage, or reuse of BenTips™ tips, shafts or CPIS Inserts, or use of BenTips™ Gold Inserts beyond the service life, significantly increases the risk of breakage of these BenTips™ products resulting in small pieces of the broken product in the mouth. Serious injury or death to the patient may occur from aspiration or swallowing of these small broken pieces. In addition, these small broken pieces may become embedded in the patient's tissues which may result in tooth movement or infection. Appropriate dental suction to immediately assist in removing these broken pieces, and throat barriers to prevent aspiration or swallowing of these pieces, must be maintained at all times while any BenTips™ products are in use, as a further precaution against these risks. The patient must also be instructed to breathe through the nose during treatment in order to assist in avoiding aspiration or ingestion of broken BenTips™ products.

7.3.2.6. After each use, BenTips™ tips, shafts and CPIS Inserts must be discarded in an FDA cleared sharps disposal container along with any BenTips™ Gold Inserts beyond their service life.

7.3.3. ⚠ DANGER: INFECTION CONTROL

For maximum safety of both the patient and the operator, clean, disinfect and sterilize the HBPS-1 LED handpiece, the tips, shafts, torque wrench and Gold Inserts prior to use. Carefully follow all Infection Control guidelines, recommendations, and regulations, as well as the specific sterilization instructions in this manual for each BenTips™ product.

7.3.4. ⚠ WARNING: CONTRAINDICATIONS

7.3.4.1. Do not use the BenTips™ products on metal or ceramic dental restorations as damage can occur.

7.3.4.2. After autoclave sterilizing of the handpiece, wait for it to cool down completely before using it.

7.3.5. ⚠ WARNING: THE ELECTRICAL CONTACTS INSIDE THE CORD CONNECTOR MUST BE DRY.

Before connecting the handpiece to the main unit, make sure the electrical contacts of the connector are completely dry, especially after the autoclave sterilization cycle. If necessary, dry the contacts by blowing air onto them with a dental air/water syringe.

7.3.6. ⚠**WARNING: TO USE THE DEVICE CORRECTLY, IT IS NECESSARY TO PRESS THE FOOT-SWITCH TO START THE HANDPIECE VIBRATIONS WITHOUT LETTING THE TIP TOUCH ANYTHING INITIALLY. THIS WILL ALLOW THE MAIN UNIT COMPUTER TO DETERMINE THE APPROPRIATE VIBRATION FREQUENCY ENABLING OPTIMUM PERFORMANCE.**

If this is not done, the main unit may shut down and return an error code.

7.3.7. ⚠**WARNING: FOR ADEQUATE IRRIGATION SPRAY DURING TREATMENT WHICH IS REQUIRED FOR PROPER COOLING OF THE HANDPIECE, SHAFT, TIP (CPIS INSERT) AND GOLD INSERT, AND THE OPERATIVE SITE, USE ONLY INSERTS AND SHAFTS THROUGH WHICH LIQUID IS PASSING FREELY.**

If it is found that water is not passing freely through the system irrigation channels and tubing to the operative site, adequate cooling of the system and the operative site may not occur.

7.3.8. ⚠**DANGER: AVOID USING EXCESS FORCE TO REDUCE THE RISK OF TIP, SHAFT AND INSERT BREAKAGE.**

7.3.9. ⚠**DANGER: NEVER OPERATE THE PIEZOSURGERY SYSTEM WITHOUT WATER FLOWING THROUGH THE HANDPIECE AND VENTING ONTO THE OPERATIVE SITE AS THIS CAN CAUSE OVERHEATING OF THE TIP, SHAFT, INSERT AND HANDPIECE WHICH CAN BURN THE PATIENT OR CLINICIAN.**

7.4 Protection Systems and Alarms

The device has a diagnostics circuit that will activate the protection system, shut down the main unit, and sound/display an alarm. These will be shown on the display, as follows:

Error Code	Reason and Remedy
Warn 01	Signal transmission problem or handpiece failure. Replace tip and shaft.
	Switch the device off and then on again, If the problem persists contact BenTips™ service center.
Warn 02	Tuning circuit not working properly. Replace tip and shaft.
	Handpiece failure. Replace handpiece.

Warn 03	Fan failure. Contact BenTips™ service center.
Warn 04	Pump failure. Replace pump.
Warn 05	Over-voltage. Verify correct input voltage.
Warn 06	Tip is not correctly secured to the handpiece or tip is worn or broken or deformed. Change the tip and shaft.
	Handpiece failure. Replace the handpiece.
Warn 07	Tuning circuit not working properly.
	Restart the device, and change the tip and shaft.

7.5 <u>Device Use</u>

7.5.1 Verify the irrigation tubing is open and unobstructed.

7.5.2 Choose the appropriate BenTips™ tip and shaft, or Gold Insert, for the planned procedure.

7.5.3 Ensure that the BenTips™ tip and shaft, or Gold Insert, are without any chips, fractures, cracks, bends, distortions, damage or other indications of weakness or compromised functionality. If any such indications are found, that tip, shaft or Gold Insert must not be used.

7.5.4 With sterile gloved hands, remove the previously sterilized tip, shaft, or Gold Insert, from the sterile autoclave pouch.

7.5.5 Gently screw the shaft or Gold Insert onto the distal end of the piezosurgery handpiece and use the torque wrench to screw the shaft or Gold Insert (Fig. 8) in a clockwise direction until two clicks of the wrench can be heard.

7.5.6 (For Tips/Shafts Only) Gently insert the proximal female threaded portion of the tip onto the male threaded distal portion of the shaft and firmly hand tighten (Fig. 8).

7.5.7 (For Tips/Shafts Only) Using the appropriate tip wrench to tighten the tip until the male threads of the shaft are covered by the tip.

7.5.8 ⚠ **WARNING: DO NOT GRIP THE DISTAL END PART OF THE HANDPIECE OR THE CORD. ONLY GRIP THE PLASTIC HANDPIECE PLASTIC AND METAL CASTINGS, AND DO NOT TURN IT WHILE FASTENING THE TIP TO THE SHAFT, OR THE SHAFT TO THE HANDPIECE OR THE GOLD INSERT TO THE HANDPIECE. MAKE SURE THAT THE HBPS-1 LED HANDPIECE IS CORRECTLY CONNECTED TO THE HANDPIECE CONNECTOR (FIG. 7).**

7.5.9. Check the display to see that the desired power, irrigation and mode have been set as desired.

7.5.9.1. For BenTips™ **CPIS Inserts**, set mode to "Bone", the power to 5 and the irrigation water flow to 3.

7.5.9.2. For BenTips™ **Gold Inserts**, set the mode to "Perio". Adjust the water flow control to a setting that provides adequate irrigation and cooling for the intended use. Adjust the power control to a setting that provides adequate but not excessive power for the intended use.

7.5.10. If the function mode required is different from the type that has been set, use key "M" (see 7.1) to switch.

7.5.11. Check the display to see the power level that has been set. If the power level required differs from the level that has been set, use the key +/- to select the desired power level.

7.5.12. Check the display to see the delivery rate of the peristaltic pump. If the delivery rate required is other than the level that has been set, use the key +/- (see 7.1) to choose the correct peristaltic pump delivery rate.

7.5.13. Please refer to the document "CPIS Inserts Product List" located at www.bentipsusa.com/members for the combinations of BenTips™ shafts and tips that are currently available to form CPIS Inserts.

7.5.14. Follow these instructions for BenTips™ **CPIS Inserts**:

7.5.14.1. Start with a light but stable intraoral or extra-oral fulcrum such as finger to tooth or hand to jaw, with the hand holding the handpiece.

7.5.14.2. Only adapt the BenTips™ CPIS Insert tip point directly onto bone or soft tissue if the most rapid and aggressive cutting action is needed, otherwise engage the side of the BenTips™ CPIS Insert tip with the tissue being treated.

7.5.14.3. Engage the tissue in the operative site with the BenTips™ tip using a light but smooth sweeping or gentle digging motion. If more rapid or aggressive cutting action is desired, then firmer pressure may be applied but this increases the risk of tip breakage.

7.5.14.4. Keep the working end of the insert in motion at all times, using overlapping horizontal, vertical, circular or oblique brush-like strokes.

7.5.14.5. The inactivated BenTips™ CPIS Insert tip can be used with a gentle "feather-light" touch to explore and evaluate root surface, bone and soft tissue consistency and surface characteristics.

7.5.14.6. ⚠ **DANGER: DURING USE, ANY CONTACT WITH THE TOOTH SURFACE WITH THE PEEK TIPS MUST BE VERY LIGHT IN PRESSURE TO REDUCE THE PROBABILITY OF TIP BREAKAGE.**

7.5.14.7. BenTips CPIS insert selection should be based on the following:

7.5.14.7.1. Patient's health status.

7.5.14.7.2. Patient's severity of disease being treated.

7.5.14.7.3. Anatomical features of the site being treated.

7.5.15. Follow these instructions for BenTips™ **Gold Inserts**:

7.5.15.1. Please refer to the document "BenTips Gold Inserts Product List" at www.bentipsusa.com/members for the list of currently available BenTips Gold Inserts and their intended use.

7.5.15.2. Start with a light but stable intraoral or extra-oral fulcrum such as finger to tooth or hand to jaw, with the hand holding the handpiece.

7.5.15.3. Adapt the Gold Insert working end to the working surface to accomplish the intended treatment.

7.5.15.4. Engage the tissue in the operative site with the distal end of the Gold Insert using a light but smooth motion. If more rapid or aggressive cutting action is desired, then firmer pressure should be applied.

7.5.15.5. Keep the Gold Insert in motion at all times, using overlapping horizontal, vertical, circular or oblique brush-like strokes.

7.5.15.6. The inactivated tip can be used with a gentle touch to explore and evaluate the tissue consistency and surface characteristics of the site being operated on.

7.6. Rules for Keeping the Device in Proper Working Order

7.6.1. Check the tip, shaft (CPIS Insert) or Gold Insert, at frequent intervals during use for any chips, fractures, cracks, bends, distortions, damage or other indications of weakness or compromised functionality. You must immediately replace the affected item with a new item if any such indications appear;

7.6.2. Avoid excess use of tips, shafts (CPIS Inserts) and Gold Inserts as this can result in wear that may lead to reduced bone removal, soft tissue debridement and scaling and root planing efficacy;

7.6.3. Do not alter the shape of the BenTips™ tips, shafts (CPIS Inserts), Gold Inserts or any other components or accessories by bending, reshaping, filing or distorting them in any way;

7.6.4. All BenTips™ products must be handled with care at all times;

7.6.5. Do not use, and promptly replace any BenTips™ tip, shaft (CPIS Insert), Gold Insert or other component or accessory which has become chipped,

fractured, cracked, bent, distorted, reshaped, damaged or which otherwise displays any signs of weakness or loss of functionality as these are subject to in-use breakage that could result in operatory harm or death;

7.6.6. Do not re-use any tip, shaft (CPIS Insert) which has been previously used;

7.6.7. Do not use BenTips™ tips, shafts or Gold Inserts 5 years past the manufacture date provided on the product label as the cleanliness of the product cannot be guaranteed and could result in ineffective sterilization. If no manufacture date is visible on the label, then do not use BenTips tips, shafts or Gold Inserts 4 years past the day you purchased the respective product.

7.6.8. Do not re-use BenTips™ **Gold Inserts** beyond its service life of 300 sterilization cycles regardless of functionality since with every renewed preparation for use, thermal and chemical stresses will result in incremental deterioration of the Gold Inserts.

7.6.9. Always make sure that any threaded parts and its contact surfaces are completely clean;

7.6.10. If any tip, shaft (CPIS Insert) or Gold Insert becomes too worn, the device will stop working. If this occurs, dispose of the affected item in an FDA cleared sharps container and use a new item.

8 CLEANING, DISINFECTION, STERILIZATION AND STORAGE

⚠ **WARNING: THE USE OF STRONG DETERGENT AND DISINFECTANT (ALKALINE PH>9 OR ACID PH <5) WILL REDUCE THE LIFE-SPAN OF ALL BENTIPS™ PRODUCTS AND MUST NEVER BE USED. USE OF SUCH AGENTS WILL VOID THE WARRANTY.**

NOTE: WATER-BASED DISINFECTING SOLUTIONS WITH A NEUTRAL PH ARE HIGHLY RECOMMENDED AS SOME ALCOHOL-BASED DISINFECTING SOLUTIONS MAY BE HARMFUL AND CAN DISCOLOR OR OTHERWISE DAMAGE THE PLASTIC MATERIALS.

8.1 Cleaning of the Liquid Circuit

⚠ **WARNING: FAILURE TO CARRY OUT CLEANING OF THE IRRIGATION TUBES WILL LEAD TO CRYSTALLIZATION OF SALTS THAT CAN SERIOUSLY DAMAGE THE EQUIPMENT.**

⚠ **WARNING: THE HANDPIECE AND CORD CAN'T BE DETACHED FROM EACH OTHER.**

8.1.1. Change the bag containing water (demineralized water is recommended);

8.1.2. Check whether the water system is connected correctly;

8.1.3. Start the CLEAN function (Fig.11);

8.1.4. Press the foot-switch to start the cleaning cycle. As soon as the peristaltic pump starts up, a status bar will appear on the display to indicate progressively the time remaining to completion of the CLEAN cycle. The cycle

lasts for 25 seconds and cannot be stopped;

8.1.5. Once the cleaning cycle has been completed, the device exits from the CLEAN function and returns to BONE function (Fig.9);

8.1.6. On completion of the cleaning operations, empty the water tubes and dry the accessories that have been through the cleaning cycle.

8.2 Cleaning and Disinfecting the Casing of The Piezosurgery Main Unit

⚠ **DANGER: THE PIEZOSURGERY MAIN UNIT CASING IS NOT PROTECTED AGAINST THE PENETRATION OF LIQUIDS. DO NOT SPRAY LIQUIDS DIRECTLY ONTO THE SURFACE OF THE CASING.**

⚠ **DANGER: THE PIEZOSURGERY MAIN UNIT CANNOT BE STERILIZED.**

After each use carry out the following operations:

8.2.1. If BenTips™ **CPIS insert** was used; remove from the handpiece with the torque wrench and dispose of in an FDA cleared sharps container. Neither the tip nor the shaft nor the CPIS Insert is approved for reprocessing.

8.2.2. If BenTips™ **Gold insert** was used; refer to Section 8.9: Preparation, Cleaning and Sterilization of The Gold Inserts for reprocessing steps.

8.2.3. Open the pump door and remove the handpiece irrigation hose.

8.2.4. If an irrigation bag was used, disconnect this and dispose of appropriately. If a training bowl was used, pour the water from the training bowl into a sink. Rinse bowl. Autoclave.

8.2.5. Remove the handpiece proximal end plug from the control unit. Wipe down the handpiece to remove any debris. Place the clean handpiece in a sterilization pouch of appropriate size and then autoclave for reuse.

8.2.6. Clean and disinfect the surfaces of the casing, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH 7). Follow carefully the instructions given by the manufacturer of the disinfectant solution. Allow the disinfectant solution to dry in the air before using the equipment.

8.3 Sterilization Procedure

⚠ **WARNING: CARRY OUT STERILIZATION USING ONLY A STEAM AUTOCLAVE.**

8.3.1. BenTips™ tips, shafts and CPIS Inserts are single use and should be disposed of after each patient use.

8.3.2. Do not use chemical disinfectants prior to sterilization or rapid deterioration of the materials may occur.

8.3.3. Do not use other types of sterilization such as cold liquid disinfection/sterilization, chemical vapor sterilization, dry heat sterilization, radiation, ethylene oxide, gas, low temperature plasma, etc, as these methods have not been tested or validated for efficacy

8.3.4. In order to avoid bacterial or viral infection, always clean, disinfect and sterilize the following components after each use:

8.3.4.1. Handpiece (Fig. D)

8.3.4.2. Torque wrench (Fig. C)

8.3.4.3. Pump tube

8.3.4.4. Peristaltic pump tube connection

8.3.4.5. Handpiece support (Fig. I)

8.3.5. The above components are made of materials that can be sterilized for 4 minutes with 134^{O}C and 2.0bar 2.3bar (0.20MPa 0.23MPa).

8.4 Autoclave Sterilization of The Handpiece

8.4.1. ⚠ **WARNING: THE HANDPIECE AND CORD CAN NOT BE DETACHED FROM EACH OTHER;**

8.4.2. ⚠ **WARNING: DO NOT DIP THE HANDPIECE INTO DISINFECTANT SOLUTIONS OR LIQUIDS OF ANY OTHER KIND SINCE THIS COULD DAMAGE IT;**

8.4.3. ⚠ **WARNING: DO NOT STERILIZE THE HANDPIECE WITH AN INSERT OR SHAFT SCREWED INTO IT;**

8.4.4. ⚠ **WARNING: THE ELECTRIC CONTACTS OF THE CONNECTORS OF THE HANDPIECE AND OF THE CORD MUST BE DRY;**

8.4.5. ⚠ **WARNING: AFTER COMPLETING THE STERILIZATION CYCLE, ALLOW THE HANDPIECE TO DRY COMPLETELY BEFORE USING IT;**

8.4.6. ⚠ **WARNING: AT THE END OF THE STERILZATION CYCLE, AND BEFORE CONNECTING THE HANDPIECE TO THE MAIN CONTROL UNIT, MAKE SURE THAT THE ELECTRIC CONTACTS OF BOTH CONNECTORS ARE COMPLETELY DRY. IF NECESSARY, DRY THE CONTACTS BY BLOWING DRY COMPRESSED AIR ON TO THEM WITH THE DENTAL UNIT AIR-WATER SYRINGE.**

8.4.7. Clean the handpiece carefully paying special attention to the threaded distal handpiece connector onto which the tips are screwed, and to the adjacent ring-shaped cavity;

8.4.8. Disinfect the handpiece using a cloth moistened with a mild disinfectant solution having a neutral pH 7;

8.4.9. Dry the electric contacts by blowing air onto them with the syringes;

8.4.10. Seal the handpiece in an individual disposable bag (without any tips);

8.4.11. Sterilize the handpiece in the autoclave.

8.5 Autoclave Sterilization of The Torque Wrench

8.5.1. Clean the wrench;

8.5.2. Disinfect the wrench with a mild disinfectant solution having a neutral pH 7

and dry it thoroughly;

8.5.3. Seal the wrench inside an individual disposable autoclave pouch;

8.5.4. Autoclave the wrench.

8.6 <u>Autoclave Sterilization of The Peristaltic Pump Tube</u>

8.6.1. Clean the tube;

8.6.2. Disinfect with a mild disinfectant solution having a neutral pH 7 and dry it thoroughly;

8.6.3. Seal the tube inside an individual disposable bag; Autoclave the tube.

8.7 <u>Autoclave Sterilization of The Peristaltic Pump Tube Connector</u>

8.7.1. Clean the connector;

8.7.2. Disinfect with a mild disinfectant solution having a neutral pH and dry it thoroughly;

8.7.3. Seal the connector inside an individual disposable autoclave pouch;

8.7.4. Autoclave the connector.

8.8 <u>Autoclave Sterilization of the Handpiece Support</u>

8.8.1 Clean the support;

8.8.2 Disinfect with mild disinfectant solution having a neutral pH7 and dry it thoroughly;

8.8.3 Seal the support inside an individual disposable autoclave pouch;

8.8.4 Autoclave the support.

8.9. <u>Preparation, Cleaning and Sterilization of The Gold Inserts</u>

8.9.1. Initial Processing of Gold Inserts

8.9.1.1. <u>Processing principles of Gold Inserts</u>

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of inserts during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle. Please also observe the applicable legal requirements in your location as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

8.9.1.2. <u>Post-operative Preparation For Cleaning And Sterilization of Gold Inserts</u>

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation, and please note that the water for the following three steps must be pure water, distilled water or deionized water. The steps are as follows:

8.9.1.2.1. Let the piezosurgery unit works for 20- 30 seconds under Cleaning mode to flush the handpiece and insert;

8.9.1.2.2. Remove the handpiece from the piezosurgery unit, and rinse away any debris on the surface of insert with pure water (or distilled water/ deionized water);

8.9.1.2.3. Dry the insert with a clean, soft cloth and place it in a clean tray.

8.9.2. <u>Preparation Before Cleaning of Gold Inserts</u>

8.9.2.1. Gather the required tools: Torque wrench, tray, soft brush, clean and dry soft cloth

8.9.2.2. Remove the insert from the handpiece with the torque wrench.

8.9.2.3. Put the insert and wrench into a clean tray.

8.9.2.4. Then use soft cloth to dry the insert and accessories and put them into a clean tray.

8.9.3. <u>Cleaning & Disinfection of Gold Inserts</u>

8.9.3.1. Cleaning should be performed no later than 24 hours after use.

8.9.3.2. Disinfection must be performed no later than 2 hours after the cleaning phase.

8.9.3.3. It is recommended to use a washer-disinfector in accordance with EN ISO 15883.

8.9.3.4. Follow these cleaning and disinfecting steps using the washer-disinfector:

8.9.3.4.1. Carefully place the inserts into the disinfection basket. Fixation of the inserts is needed only when the inserts are removable in the device. The inserts must not be allowed to contact each other.

8.9.3.4.2. Use a suitable rinsing adaptor and connect the internal water lines to the rinsing connection of the washer-disinfector.

8.9.3.4.3. Start the program capable of the following parameters.

8.9.3.4.3.1. Cleaning:

8.9.3.4.3.1.1. The solution used can be pure water, distilled water, deionized water or multi-enzyme

solution, etc., but only freshly prepared solutions must be used.

8.9.3.4.3.1.2. During the use of the cleaner, the concentration and time provided by the manufacturer must be obeyed.

8.9.3.4.3.1.3. Flush for 5-10 minutes.

8.9.3.4.3.1.4. Pre-wash for 3 minutes.

8.9.3.4.3.1.5. Wash for 5 minutes but water temperature should not exceed 45 °C (to prevent the protein solidifying which would be difficult to remove).

8.9.3.4.3.1.6. Rinse twice with each rinse lasting for 1 minute using distilled or deionized water (For example, pure water that is in accordance with the United States Pharmacopoeia).

8.9.3.4.3.2. Disinfection:

8.9.3.4.3.2.1. Temperature of 93 ° C for 2.5 minutes and A0>3000

8.9.3.4.4. After the program is finished, remove the insert from the washer-disinfector and inspect the inserts. Any inserts that are damaged, smashed, detached, corroded or bent, must not be used, and must be disposed of in an FDA cleared sharps disposal container. In addition, if the service time (number of times) of the insert reaches the specified service life of 300 sterilization cycles, then the insert must not be used, and must be disposed of in an FDA cleared sharps disposal container.

8.9.3.4.5. Dry the insert manually per section 8.9.4 below if the cleaning and disinfection equipment does not have an automatic drying function. Dry the insert repeatedly if necessary.

8.9.3.4.6. Package the insert (refer to chapter "Storage").

8.9.3.4.7. Notes:

8.9.3.4.7.1. Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

8.9.3.4.7.2. After cleaning, the chemical residue must be less than 10mg / L.

8.9.3.4.7.3. Regularly repair and inspect the disinfector.

8.9.3.4.7.4. Check the inserts for visible stains after cleaning/disinfection. If any are present, repeat the cleaning/disinfection process.

8.9.4. <u>Manual Drying of Gold Inserts</u>

8.9.4.1. Spread a clean white paper towel (or white cloth) on a flat surface, point the insert against the white paper towel (or white cloth), and then dry the insert with filtered dry compressed air (maximum pressure 3 bar), until no residual liquid is sprayed onto the white paper towel (or white cloth). At that point, the insert drying is completed.

8.9.4.2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80° C ～ 120° C and the time should be 15 ～ 40 minutes.

8.9.4.3. Notes:

8.9.4.3.1. The drying of the inserts must be performed in a clean location.

8.9.4.3.2. The drying temperature should not exceed 138°C;

8.9.4.3.3. The equipment used should be inspected and maintained regularly.

8.9.5. <u>Sterilization of Gold Inserts</u>

8.9.5.1. Use a vacuum displacement autoclave.

8.9.5.2. Package the clean, disinfected and dried inserts in an FDA cleared medical sterilization bag (or specialized holder such as a sterilization box).

8.9.5.3. Place the bagged inserts into the autoclave.

8.9.5.4. Sterilize the inserts for a minimum of 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bar.

8.9.5.5. To maintain sterility, the inserts must remain bagged until ready for use.

8.9.5.6. Notes:

8.9.5.6.1. Only inserts that have been effectively cleaned and disinfected are allowed to be sterilized;

8.9.5.6.2. The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

8.9.5.6.3. Avoid contact with parts of different metals when packaging.

8.9.5.6.4. Before using the autoclave for sterilization, read the

Instruction Manual provided by the equipment manufacturer and follow the instructions.

8.9.5.6.5. Do not use hot air sterilization or radiation sterilization as this may result in damage to the inserts;

8.9.5.6.6. The recommended sterilization procedures must be used for sterilization. It is not recommended to sterilize the inserts with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

8.10. Autoclave Sterilization of CPIS Insert Components

8.10.1. BenTipsTM components are clean but not sterile upon receipt and must be sterilized prior to use in accordance with the following instructions:

8.10.2. Use a vacuum displacement autoclave.

8.10.3. Place unassembled tip, shaft and wrench into FDA cleared sterilization pouch (1 tip, 1 shaft and 1 wrench per pouch is recommended).

8.10.4. Place the bagged device into autoclave.

8.10.5. Sterilize the device at 132°C for 4 minutes.

8.10.6. Dry for 30 minutes using the drying cycle.

8.10.7. To maintain sterility, the device should remain bagged until ready for use.

9 TRANSPORT, REGULAR MAINTENANCE AND STORAGE OF BENTIPS™ PRODUCTS

9.1. After sterilization, BenTips™ should be packaged in a FDA cleared sterilization pouch or a clean sealing container, and stored in a specialized storage cabinet. The storage time should not exceed 7 days. If it is exceeded, the BenTips™ product should be reprocessed before use. Except for the BenTips™ CPIS Inserts and their components which are single-use only and must be disposed of in an FDA cleared sharps container.

9.2. BenTips™ product storage must be batched, marked and recorded.

9.3. All BenTipsTM products must be installed and stored indoors, in a clean, dry, ventilated area, in the absence of corrosive gases, and away from sunlight or other heat sources.

9.4. The storage environment must be disinfected regularly.

9.5. Do not use or store any BenTips™ products with or near poisons, caustics, explosives or combustibles items.

9.6. BenTips™ products should be stored in a room where the relative humidity is 10% ~ 93%, the atmospheric pressure is 70kPa to l 06kPa, and the temperature is -20°C ~ +55°C.

9.7. If the BenTips™ piezosurgery main unit is not used for extended periods of time, configure the unit for typical use, including connection to a water source, and operate one time per month, for 5 minutes, then disconnect the main unit from the power outlet.

9.8. ⚠**DANGER: CHECK REGULARLY THAT THE POWER CABLE IS INTACT. IF IT IS DAMAGED, REPLACE IT WITH A BENTIPS™ REPLACEMENT POWER CORD.**

10 REPLACEMENT OF THE FUSES

10.1. ⚠ **DANGER: SWITCH OFF THE EQUIPMENT. ALWAYS TURN OFF THE MAIN UNIT BY MEANS OF THE MAIN POWER SWITCH (FIG. 6A) AND DISCONNECT IT FROM THE POWER OUTLET BEFORE CARRYING OUT THE FOLLOWING MAINTENANCE ACTIVITIES.**

10.2. Insert the flat tip of a screwdriver into the recess in the fuse compartment below the power socket and use it as a lever (Fig. 12 - Ref. A);

10.3. Pry open the fuse compartment (Fig. 12 - Ref. B);

10.4. ⚠ **DANGER: REPLACE THE FUSES USING THE SAME TYPE INDICATED ON THE IDENTIFICATION LABEL ON THE BOTTOM OF THE MAIN UNIT;**

10.5. Close the fuse compartment (Fig. 12 - Ref. B).

Fig.12

11 DISPOSAL PROCEDURES AND PRECAUTIONS

⚠ DANGER: INFECTIOUS WASTE

Treat the following items as infectious waste:

- Tips, shafts, and CPIS Inserts after each use or when worn, distorted or broken, and Gold Inserts when worn, distorted, broken or beyond their service life.
- Irrigant bag/bottle after each treatment.
- Tube of the peristaltic pump, after 8 sterilizing cycles.
- Torque wrench for tightening shafts (CPIS Inserts) and Gold Inserts, when worn or broken.

12 SYMBOLS

BenTips™ B1 Piezosurgery System Symbols

BenTips™ Gold insert Symbols

Model number

Non-sterile

Lot number

℞ Only

Prescription use only

Manufacturer

Consult the accompanying documents

BenTips™ tip, shaft (CPIS Insert) Symbols

Model number

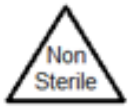
Single use only

Lot number

℞ Only

Prescription use only

Manufacturer



Non-sterile

Consult the accompanying documents

13 TROUBLESHOOTING

If the device does not seem to be working properly, read the instructions again and then check the following table:

Problem	Possible cause	Solution
The device is switched on but will not work, the message WARN appears on the display.	Cord not connected to the device.	Connect the cord to the device.
	Lack of continuity of a lead in the cord.	Contact the BenTips™ service center.
	Handpiece failure.	Contact the BenTips™ service center.
	Malfunctioning of the tuning circuit.	Contact the BenTips™ service center.
No liquid comes out of the tip during operation.	The tip is of the type with no through-flow of liquid.	Use a tip of the type with through-flow of liquid.
	The bag of liquid is empty.	Replace the bag with a full one.
	The cover of pump that connected with the water tube is open.	Close the cover.
	The tubes of the drip system and of the pump have not been correctly installed.	Check the connections of the tubes.
	The tip is clogged.	Unclog the passage in the tip through which the water passes.

Problem	Possible cause	Solution
No liquid comes out of the tip during operation.	The handpiece is clogged.	Contact the BenTips™ service center.
The device is working properly, but the pump is loud or laboring.	Too much pressure by the impeller on the tube in the peristaltic pump.	Check that the tube in the peristaltic pump has been correctly inserted.
The pump is running correctly but when it stops, liquid comes out of the handpiece.	The door of the peristaltic pump is not closed correctly.	Make sure that the door of the peristaltic pump is properly closed.
Insufficient power.	The tip /shaft/Gold Insert is not correctly fitted to the handpiece (the message WARN appears on the display).	Unscrew the tip/shaft/Gold Insert and screw it back into place correctly.
	The tip is worn, broken or deformed (the message WARN appears on the display).	Replace the tip.
LCD screen mess or incomplete display.	Voltage interference.	Stop any operation, change the mode then return to the original mode or restart the machine.

Problem	Possible cause	Solution
The device does not turn on when the switch is positioned on ON.	The connector on the end of the power cable is plugged into the socket on the rear of the device properly.	Check that the power cable is firmly connected.
	The power cable is faulty.	Check that the power outlet is working properly. Replace the power cable.
	The fuses blew out.	Replace the fuses.
The foot-switch will not work.	The connector of the foot-switch is not properly plugged into the socket.	Insert the foot-switch connector properly
	The connector on the end of the power cable is plugged into the socket on the rear of the device properly.	Contact the nearest dealer or authorized BenTipsTM service center
A faint whistle can be heard coming from the HBPS-1 LED Handpiece during operation	The tip is not correctly tightened onto the handpiece.	Unscrew the tip and screw it back into place correctly.

14 TECHNICAL DATA

14.1. Device in accordance with Directive 93/42EEC.

14.2. According to EN60529: IPXl (device)

14.2.1. IPX8 (foot-switch)

14.2.2. Device for intermittent operation: 60s ON, 10s OFF

14.3. Power-supply voltage: - l00V-240V 50Hz/60Hz l20VA

14.4. Fuses: 2x l.6AT 250V

14.5. Working frequency: 24kHz - 36kHz

14.6. Flow: 25 - 110ml/m

14.7. Protection systems and tripping time of the APC:

14.7.1. No handpiece connected: 10ms

14.7.2. Cord interrupted: 10ms

14.7.3. Tips/Shafts/Gold Inserts broken or not correctly tightened: < 500ms

14.7.4. Protection by discharge to earth: 10ms

14.8. Alarm: Front display show the e (see section 7.3 and 14)

14.9. Operation Environment:

14.9.1. Environment temperature : +5°C - +40°C

14.9.2. Relative humidity: 30% - 75%

14.9.3. Atmosphere pressure: 70kPa - 106kPa

14.9.4. Temperature in the water inlet of water-cooling equipment is not higher than 25^0C

14.10. Delivery and storage environment: This equipment should be stored in a room where the relative humidity is 10% - 93%, atmospheric pressure is 70kPa to 106kPa, and the temperature is -20°C - +55°C.

14.11. Maximum Sterilization Cycles:

14.11.1. Pump tube: less than 8 sterilization cycles is highly recommended

14.11.2. Gold Inserts: Less than 300 sterilization cycles is required

14.11.3. CPIS Tips, Shafts and Inserts: One sterilization cycle required (single use only)

14.12. Size of main unit: 330mm x 254mm x l67mm

14.13. Weight of main unit: 3.1kg

14.14. Type of protection against electric shock: Class I equipment

14.15. Degree of protection against electric shock: Type B applied part

15 REPAIR

Contact BenTips™ customer service at incidents @bentipsusa .com to arrange repairs. BenTips™ will not be responsible for any repairs made by any other entity.

16 ENVIRONMENTAL PROTECTION

Please dispose of BenTips™ products according to applicable law.

17 MANUFACTURER'S RIGHT

We reserve the right to change the device design, operation protocols and techniques, accessories, instruction manual and the content of the original packing list at any time without notice. If any differences exist between the specification or this manual as compared to the actual equipment, please contact BenTips™ customer service.

18 DECLARATION OF CONFORMITY - EMC

18.1. The device has been tested in accordance with EN 60601-1-2 EMC. This does not guarantee in any way that this device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environments.

18.2. BenTips™ products are manufactured by Bennett Jacoby DDS MS Inc. and are warranted against defects arising from faulty materials or workmanship for ninety days from the date of purchase and only to the original purchaser.

18.3. This Warranty is subject to the following conditions:

18.3.1. This equipment has not been used for any purposes other than that for which it is intended.

18.3.2. This equipment has not been used other than in accordance with all the instructions and requirements described in this manual.

18.3.3. This equipment has not been used in a room where the wiring system does not comply with the application standard and appropriate requirements.

18.3.4. No assembly operations, extensions, settings, or alterations of this equipment have been carried out by any personnel not authorized by BenTips™.

18.3.5. This equipment has not been tampered with or repaired by any personnel not authorized by BenTips™.

18.3.6. This equipment has not been kept and stored at any time under environmental conditions which did not comply with the environmental

requirements specified in this manual.

18.3.7. Accidental damages due to transport, incorrect use or carelessness or to connection to power supplies other than as instructed in this manual, and damage to the handpiece lamps, and all accessories are also excluded from this Warranty.

18.4. To receive reimbursement for any defective BenTips™ product, you must send the defective product within the Warranty period to our warranty center. Email incidents@bentipsusa.com for further instructions and your RMA number.

18.5. OTHER THAN AS EXPRESSLY SET FORTH ABOVE, COMPANY MAKES NO OTHER REPRESENTATION, WARRANTY OR COVENANT, EXPRESS OR IMPLIED, IN ANY MANNER WHATSOEVER, UPON WHICH THE PRACTICE GROUP MAY RELY, WITH RESPECT TO THE MERCHANTABILITY, FITNESS, CONDITION, DURABILITY, OR SUITABILITY FOR THE PRACTICE GROUP'S PURPOSE, OF THE BENTIPS™ PRODUCTS, ALL OF WHICH ARE HEREBY EXPRESSLY DISCLAIMED. COMPANY NEITHER ASSUMES, NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT, ANY OTHER LIABILITY FOR ANY LOSS OR DAMAGES, INCLUDING BUT NOT LIMITED TO ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF BENTIPS™ PRODUCTS. ALL INTELLECTUAL PROPERTY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ALL WARRANTIES REGARDING THE ACCURACY, RELIABILITY, OR UTILITY OF THE INTELLECTUAL PROPERTY LICENSED TO THE PRACTICE GROUP AND THE MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USAGE OF TRADE, AND FREEDOM OF THE INTELLECTUAL PROPERTY LICENSED REGARDING BENTIPS™ PRODUCTS FROM INFRINGEMENT OF THIRD-PARTY PATENTS, OR ANY OTHER PROPRIETARY RIGHT OF ANY THIRD-PARTY ARE HEREBY EXPRESSLY DISCLAIMED. THE INTELLECTUAL PROPERTY LICENSED WITH REGARD TO THE BENTIPS™ PRODUCTS ARE PROVIDED TO THE PRACTICE GROUP ON AN "AS IS" BASIS, WITHOUT WARRANTY OF ANY KIND.

18.6. **<u>INDEMNIFICATION</u>**

You have acknowledged in the BenTips™ Group Certification, Confidentiality, and License Agreement You signed, that You understand that Company has no means of governing or controlling the use of the BenTips™ products by You or the manner in which they are used on dental patients, other than limiting the sale and use of those products to qualified and trained persons in the Practice Group as reflected in that Agreement. You represented that you have been extensively educated in the known risks in dentistry relating to small instruments, dental restorations, and other small items that could be aspirated or swallowed by a patient, or become embedded in patient's tissues, or otherwise cause patient harm, that could lead to serious damage including, but not limited to, infections, hospitalization, permanent debilitating injury, or even death. You further represented that you have had extensive training and experience in mitigating those risks. You further represented that you understand that BenTips™ tips, shafts and CPIS Inserts experience more

significant breakage rates than may occur with other dental instruments. Considering these risks in light of Your advanced training, experience, and knowledge in avoiding such risks, You have agreed to indemnify and hold harmless Company, its owners, officers, directors, agents, employees, successors, assigns and affiliates, from and against any and all claims, demands or actions whatsoever allegedly arising out of Your use of the BenTips™ products including, but not limited to, any costs of defense, judgments, settlements, expenses, attorneys' fees or any other amounts actually and reasonably incurred by Company, its owners, officers, directors, agents, employees, successors, assigns and affiliates, in connection with or arising out of any such claims, demands or actions, unless the sole cause of the alleged damage or injury was the negligence of Company, its owners, officers, directors, agents, employees, successors, assigns and affiliates. Should You become aware of any such claim, demand or action, You are required to immediately notify Company in writing by personal delivery or by certified mail, return receipt requested, addressed to Bennett Jacoby DDS MS, Inc., (access www.bentipsusa.com for company address)and by e-mail to incidents@bentipsusa.com

18.7. Reporting

Serious incidents noted while using this device should be reported to the Company who will in turn take responsibility to report the incident to the FDA or reported directly to the FDA.

19 STATEMENT

19.1. This is to certify that the B1 piezosurgery system has been tested as fully functional and is guaranteed to be fully functional upon receipt by a duly licensed and qualified end; however, it has not been tested in abnormal working environments or abnormal conditions and is not guaranteed to do so.

19.2. All rights of modifying the product are reserved by the manufacturer without further notice.

19.3. The pictures are only for reference. The final interpretation rights belong to the manufacturer.

19.4. INTELLECTUAL PROPERTY STATEMENT: BenTips™ is a trademark of Bennett Jacoby DDS MS. BenTips™ CPIS Inserts, tips, and surgical methods involving these products, are protected by USA and international patents and pending patent applications.