

OPERATION and MAINTENANCE INSTRUCTION MANUAL

ASC-12 Piezoelectric Scaler



Aseptic

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CLASSIFICATIONS:

- Internally Powered Equipment
- Class II Equipment
- Type B Equipment
- Ordinary Equipment - degree of protection against ingress of water
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

INDICATIONS FOR USE:

The ASC-12 Scaler is an ultrasonic scaling system that is used in dentistry for scaling and endodontic procedures, including:

Scaling: *Interdentium treatment, tooth neck and subgingival treatment, treatment of large dental calculi, treatment of coatings and tobacco stains, treatment of periodontal pockets, interproximal treatment, and loosening of crowns and posts.*

Endodontics: *Pulp chamber cleaning and canal filling by ultrasonic gutta-percha condensation.*



MEDICAL ELECTRIC EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1 (2nd Edition) and CAN/CSA C22.2 No. 601.1-M90

RX: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST

To prevent injury to people and damage to property, please heed relevant warnings and remarks. They are marked as follows:

WARNING: Serious injury or death may result if ignored.

CAUTION: Damage to property or the environment may result if ignored.

NOTE: Important additional information and hints.

WARNING: This device has been tested and found to comply with the emissions requirements of IEC 60601-1-2:2001-09. These requirements provide reasonable protection against harmful electromagnetic interference in a typical medical installation. However, high levels of radio-frequency (RF) emissions from electrical devices, such as cellular phones, may disrupt the performance of this device. To mitigate disruptive electromagnetic interference, position this device away from RF transmitters and other sources of electromagnetic energy.

Congratulations!

Your new Aseptico ASC-12 Amplitude™ Piezoelectric Scaler is preferred for ultrasonic scaling and endodontic treatment over older-style magnetostrictive scalers. This is because the ASC-12 uses a more precise linear scaling motion whereas magnetostrictive types provide a wider imprecise elliptical motion. The more direct linear motion also reduces the users' exposure to the bioburden carried in aerosols and allows the user to clean stains and calculus at lower power settings, which is less likely to damage tooth enamel.

PIEZOELECTRIC VS. MAGNETORESTRICTIVE SCALING



NOTE: New users of piezoelectric scalers may be inclined at first to set their ASC-12 Amplitude™ to similar power levels as those for magnetostrictive devices, however — **this is not recommended because the scaling experience between these two technologies is totally different!** It is recommended that you first try your ASC-12 at lower power levels and then adjust the power upward in order to find your ideal setting.

PACKAGE CONTENTS:

- ASC-12 Scaler Control Console
- AA-12HP Scaler Handpiece with Accessories
- AE-7PM On/Off Foot Switch
- Power Cord
- Flexible Water Hose (for connecting to water network)
- Operation & Maintenance Manual, PN: 420468

PURCHASED SEPARATELY:

- Infnitip™ Ultrasonic Piezo Tips

Infnitip™ is a trademark of American Eagle Instruments®, Inc.



SAFETY PRECAUTIONS:

Aseptico accepts no liability for direct or consequential injury or damage resulting from improper use, arising in particular through the non-observance of the operating instructions, or improper preparation and maintenance.

WARNING: Clean, disinfect, and sterilize new or repaired handpieces and instruments before first use and between each patient use. Only use sterilized handpieces and instruments during treatment. Non-sterile handpieces and instruments may cause bacterial or viral infections. Always sterilize handpieces and instruments after operation.

CAUTION: Always examine unit components for damage before commencing treatment. Damaged components must not be used and must be replaced.

WARNING: Use for intended purposes only. Failure to observe the operating instructions may result in the patient or user suffering serious injury or the product being damaged, possibly beyond repair. Before using this product, make sure that you have studied and understood the operating instructions.

WARNING: For use by qualified and trained personnel only.

WARNING: Always apply tip against tooth surfaces when scaling. Avoid unnecessary contact of tip with soft tissues, such as gingival, mucosa, or skin. Incidental contact with tissue can cause tissue burn or damage.

WARNING: Do not install where there is a risk of an explosion. The ASC-12 Scaler is not intended for operation in the presence of flammable anesthetics or gases.

WARNING: **CONTRAINDICATIONS:**
The ASC-12 Scaler **MUST NOT** be used when the patient and/or operator has a cardiac pacemaker. Ultrasonic oscillations emitted by the scaler may prevent the proper function of the pacemaker.

WARNING: Instrument tips may fracture. The scaler tips oscillate at high frequency during operation. In rare cases, these oscillations may cause the tip to fracture during treatment. To prevent the patient swallowing or inhaling the fractured tip, he or she must be instructed to breathe through the nose during treatment.

CAUTION: Check for abnormal vibration of tip before using. If abnormalities are found, stop using Scaler immediately and contact Aseptico.

CAUTION: Do not allow tip to touch ceramic prosthesis during scaling. This might damage the tip.

WARNING: Do not use the ASC-12 Scaler dry. If used dry, the instrument tip will heat immediately. This may cause thermal injury to the tooth. Ensure that adequate liquid coolant is always available. Irrigate abundantly and continuously.

NOTE - Exceptions for using the ASC-12 Scaler without water coolant:

Although in almost all cases ultrasonic scalers will be used with water, piezoelectric scalers are also used without water to thermo-soften gutta percha.

CAUTION: Never use the ASC-12 Scaler on metal or porcelain restorations. The high frequency ultrasonic oscillations may loosen the restoration.

WARNING: Do not disassemble or alter the Scaler handpiece.

WARNING: Do not drop handpiece or impact it against hard surface. Damage to handpiece could result in electric shock.

CAUTION: Do not drop Scaler console or impact it against hard surface. Damage to console could result in electric shock.



DANGER

**NEVER REMOVE THE CONSOLE HOUSING FROM THE CONTROL ELECTRONICS.
DANGEROUS VOLTAGES ARE PRESENT WHEN UNIT IS OPERATING
AND CAN CAUSE FATAL INJURY IF ELECTRONICS ARE EXPOSED
AND HANDLED IMPROPERLY.**

SETTING UP THE UNIT:

NOTE: Only highly-skilled certified practitioners should operate the ASC-12 Scaler. Before using the unit the first time, connect the water accessories and activate the spray for a few minutes to rinse the internal water plumbing.

1. Unpack the ASC-12 control console. The console has dual voltage auto-detection circuitry that allows operation from either a 110-120V 60Hz or 220-250V 50 Hz power source. **NOTE:** Ensure that the correct power cord is used for each voltage source.
2. Ensure that the water coolant hose is properly connected to the back of console (see Figure 3). Connect hose quick-disconnect fitting to water supply. Check for leakage and tighten connections if necessary. **CAUTION:** Before use, ensure that clean water is running freely through device. Allow the water to flow for 30 seconds before each use.
3. Attach the power cord to the back of the console (see Figure 3) and plug into a grounded electrical outlet. Confirm that the power cord is correct for the voltage source in the country of usage and carries the proper certifications. **NOTE:** For power disconnect, the power cord must be removed. Switching the power switch to the OFF position does not disconnect the unit from the power source.
4. Attach the supplied foot switch to the connector on the back of the unit marked "Footswitch" (see Figure 3). Ensure proper alignment with keyway in connector socket.
5. Remove the ASC-12 handpiece from its packing. Wipe down handpiece with a mild disinfecting solution - do not submerge handpiece. Align socket on handpiece with receptacle in handpiece terminal and plug handpiece into terminal. Screw a sterile instrument tip into the scaler handpiece and tighten with supplied wrench. Do not overtighten. Set handpiece in holder on console.

FIG. 1 - CONTROL CONSOLE DETAIL

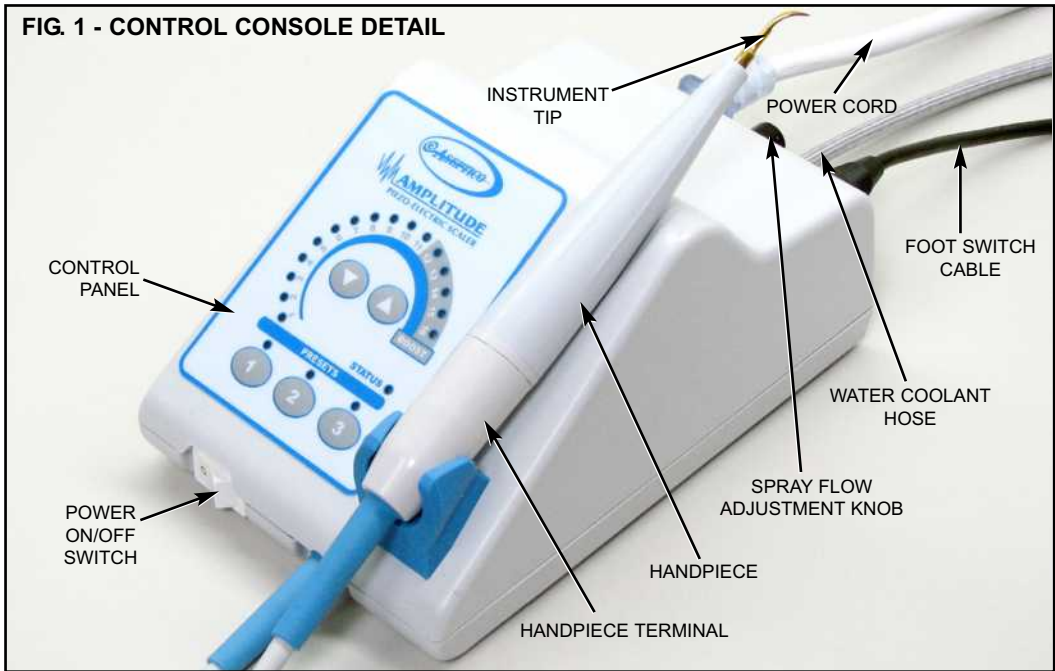


FIG. 2 - ULTRASONIC CONTROL PANEL

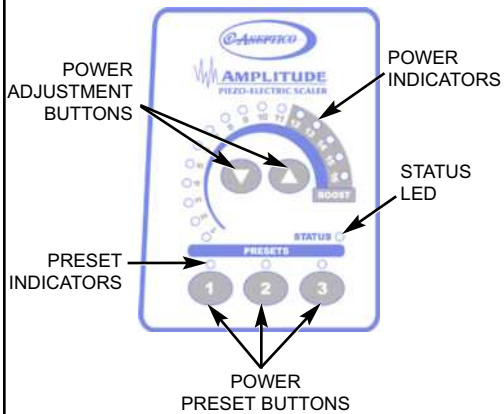
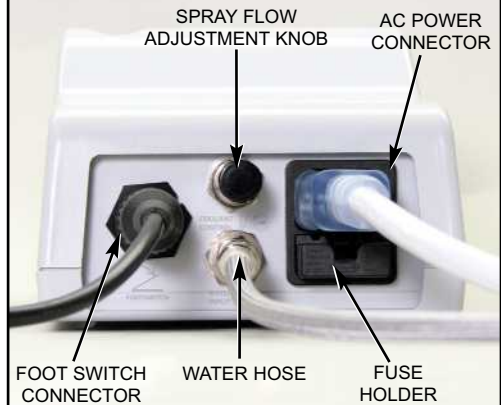


FIG. 3 - CONSOLE REAR VIEW



OPERATION FUNCTIONS:

1. Power Switch:

Controls on/off power to ASC-12 control console. When switch is turned on (I), each of the LED indicators on the console will flash once consecutively before reverting to the last used setting.

2. Control Panel:

Digital control panel with touch pad provides pressure-activated buttons for selecting and presetting ultrasonic scaling:

a) Power Selector - Two panel buttons enable precise adjustment of tip vibration through 16 different power settings with 1/2 intervals between each setting.

b) Presets - Three programmable buttons store three different power settings for quick access to preferred power level. Presets are held in memory after unit is turned off.

NOTE: The ASC-12 unit is shipped from the factory with the following power settings preprogrammed into its Preset buttons:

- Preset Button 1 = Power Setting #1
- Preset Button 2 = Power Setting #6
- Preset Button 3 = Power Setting #11

These factory Presets will be erased from memory when new power levels are stored into the buttons (refer to para. 4, page 7 for more information on reprogramming Presets).

3. Ultrasonic Scaler Tips:

The scaler handpiece can accept any ultrasonic piezo tip with a 3m x 0.6 metric mounting thread size.

4. Handpiece Water Coolant:

The handpiece water flow is controlled by the spray flow adjustment knob. Turn clockwise to decrease coolant flow; turn counterclockwise to increase coolant flow.

5. Foot Switch:

The foot switch provides ON/OFF operation to the handpiece and opens flow for water spray to the scaler instrument tip.

OPERATION:

After the unit has been set up and you have made yourself familiar with the operation functions, you are ready for operation as follows:

1. Power ON:

Press the power switch on the front of the control console to the 'ON' (I) position. The last used ultrasonic settings are retained in memory and are automatically selected when the unit is switched On.

NOTE: Each of the LED indicators on the console will flash once consecutively before reverting to the last used setting.

2. Scaler Handpiece:

CAUTION: Before use, ensure that clean water is running freely through device. Rinse the water line before attaching tip. Allow the water to flow for 30 seconds.

- a) Screw a sterile instrument tip into the scaler handpiece and tighten with supplied wrench. Do not overtighten.
- b) Adjust the scaler spray flow control knob to the desired setting. The water should create a mist around the scaler tip.



WARNING:

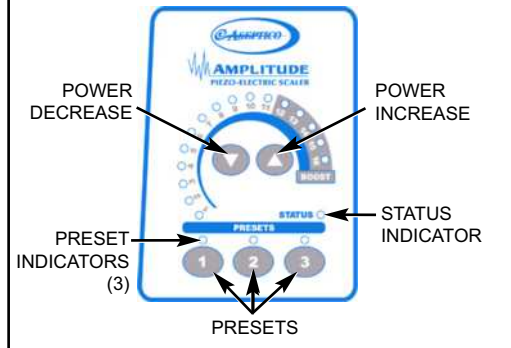
Ensure proper spray flow before using Scaler on a patient. Heat emitted by the Scaler may damage teeth if water is not atomized at the Scaler tip. Irrigate abundantly and continuously.

3. Set Power:

Press the Up/Down power adjustment buttons to the desired ultrasonic level (see Figure 4). The LEDs on the control panel will illuminate as the user steps through each level. **NOTE:** The buttons increase/ decrease power in 1/2 intervals: a single LED illuminates at each full interval, and two adjacent LEDs illuminate at each half interval.

Settings #12 through #16 indicate a "Boost" mode, which provides more aggressive tip action.

FIG. 4 - POWER CONTROLS



CAUTION: When increasing power settings, it is recommended that the user start low and gradually increase power until the desired performance is achieved.

4. Preset Buttons:

To store a desired power setting into preset memory, press and hold any one of the three preset buttons (see Figure 4) for approximately two seconds. When the button's indicator illuminates, the power setting will be programmed into that button until it is reprogrammed with a new setting. **NOTE:** Any previous Preset settings, including factory-installed Presets, will be erased when new power levels are programmed into the buttons.

5. Press the foot switch to activate the Scaler and begin operation.

6. Status Indicator:

The multi-colored LED (see Figure 4) illuminates Green when the footpedal is activated.

MAINTENANCE & STERILIZATION:

1. Control Console:

CAUTION: DO NOT IMMERSE the device in any fluid. The exterior of the console may be wiped clean with a soft cloth moistened with mild detergent or disinfecting solution.

The system allows for a disposable sanitary plastic barrier to be placed over the control console and handpiece. Replace disposable plastic barrier between each patient use.

2. Handpiece:

a) Handpiece Cleaning - Thorough cleaning of the scaler handpiece after each use and before sterilization is very important to ensure proper operation and service life of the handpiece. Wipe off the handpiece, handpiece terminal, and cable with a soft cloth moistened with mild detergent solution or 45% isopropyl disinfecting solution. **CAUTION: DO NOT IMMERSE** the handpiece in any fluid, or spray any fluid directly on the handpiece. Before reinstalling the handpiece, check the water circuit O-ring for damage or wear and replace if necessary. **NOTE:** When wiping down the handpiece cable, gently wipe from the middle of the cable out to the handpiece and console. Avoid gripping the cable tightly.

IMPORTANT:

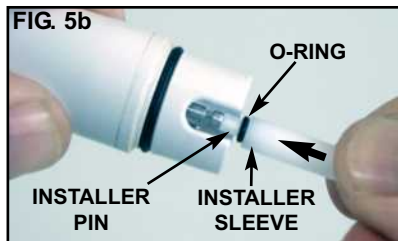
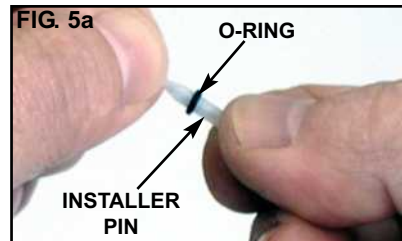
- Turn power Off before disconnecting handpiece. Never disconnect handpiece while the instrument is powered and/or the control pedal is activated.
- Always check for any handpiece damage during operation and when sterilizing.
- After each use, flush out the handpiece

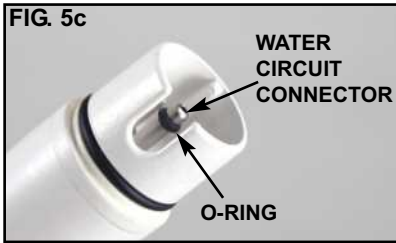
water circuit and tip with water for approximately 30 seconds.

b) Water Circuit O-Ring Replacement -

The handpiece water circuit O-ring should be replaced if damaged or worn. Use the O-ring installer pin and sleeve provided to replace O-ring:

- Remove old O-ring from handpiece water circuit connector.
- Slide new O-ring over pointed end of installer pin, onto the pin's shank (see Figure 5a).
- Insert pointed end of installer pin into open end of installer sleeve until O-ring stops against end of tool.
- Position concave end of installer pin against end of water circuit connector on handpiece (Figure 5b).
- Push installer sleeve inward, until new O-ring seats into groove on water circuit connector (Figure 5C).





NOTE: To help prolong the life of the water circuit O-ring, lubricate the O-ring with a light coat of silicone grease or pure petroleum jelly after each disassembly or sterilization.

c) Handpiece Sterilization - Sterilize handpiece between each patient use. Steam autoclave for 20 minutes at 132°C (270°F).

Sterilization Procedure:

- Separate the handpiece from its terminal.
- Use compressed air to remove any irrigation fluid in the handpiece. Shake the water out of the terminal and hose.
- The handpiece must always be sterilized without the tip installed.
- Put the handpiece in a sterilizable bag or cloth.
- Remove the handpiece from autoclave once sterilization is complete.
- Thoroughly dry the electrical contacts of the handpiece before using.
- Always check handpiece for damage after sterilization.

IMPORTANT: Never sterilize the handpiece with the tip installed.

3. TIPS:

a) Tip Installation - The scaler handpiece can accept ultrasonic piezo tips with a 3m x 0.6 metric mounting thread size. The tips must be screwed on and tightened with the wrench provided.

CAUTION: Avoid overtightening when installing tip. Overtorquing the tip beyond the thrust point may cause the tip to jam and affect performance. It is recommended that the tip be removed after each procedure to prevent jamming.

b) Tip wear - The shape of the tips should be checked regularly to maintain optimum performance. Never alter the shape of a tip by bending or filing. Check the wear of the tips against the tip card provided by the tip manufacturer. Damaged or worn tips must be replaced.

c) Tip Sterilization - The scaler tips should be sterilized between each patient use. Refer to the tip manufacturer's instructions for cleaning and sterilizing procedures.

CLINICAL APPLICATIONS:

1. Scaling with the ASC-12 System:

- Press power switch to On (I) position. Each of the LED indicators on the console should flash once consecutively before reverting to the last used setting.
- Activate the foot control pedal.
- Adjust the spray flow (See Fig. 6).



- Operate the scaling instrument.

CAUTION: Do not press foot control pedal while switching the unit on/off.

NOTE: The scaler vibrates the tips from front to rear, along the tip axis. This straight, single-plane motion allows better, more accurate access to the tooth and gingiva. The user should consider the particular shape and vibration characteristics of each tip to achieve optimal performance.

IMPORTANT: Consult the tip manufacturer's instructions for use before performing any general scaling, periodontic, or endodontic treatments.

2. Tips:

The scaler will accept ultrasonic piezo tips with a 3m x 0.6 metric mounting thread size. **NOTE:** Compatible scaler tips, manufactured by American Eagle Instruments, Inc., are available from Aseptico. Contact Aseptico for ordering information.



WARNING:

Ensure proper spray flow before using Scaler on a patient. Heat emitted by the Scaler may damage teeth if water is not atomized at the Scaler tip. Irrigate abundantly and continuously.

REPLACING THE FUSE:

⚠ WARNING:
Turn the power off and unplug the unit before following the steps below.

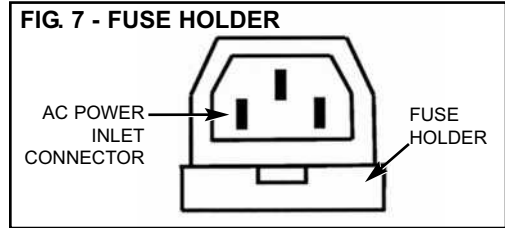
Replacement Fuse:
120V / 230V: 0.25A, 250V rated
slo-blow type (Fuse size: 5 x 20mm)

3. Replace the Fuseholder.

FUSES

NOTE: The ASC-12 is manufactured with 250V 0.25A rated fuses installed.

















1. Remove the Fuseholder from the Power Inlet connector.
2. Replace the fuses in the Fuseholder.



TROUBLESHOOTING:

| Problem: | Possible Cause: | Solution: |
|---|---|---|
| Unit does not operate when turned on. | <ul style="list-style-type: none"> - Wrong mains cord connection. - Presence of fluid or moisture between handpiece and cord. - Blown fuse. | <ul style="list-style-type: none"> - Check mains outlet. - Remove any moisture, especially on electrical contacts. - Replace fuse. |
| No spray from handpiece. | <ul style="list-style-type: none"> - Wrong water tube connection. - No water pressure. - Obstructed tip. - Wrong tip selection. - Incorrect spray adjustment. - Defective solenoid valve. | <ul style="list-style-type: none"> - Check water supply connection. - Check water supply pressure. - Remove obstruction. - Check for proper tip. - Adjust spray. - Return to Aseptico customer service. |
| Insufficient power. Low tip vibration. | <ul style="list-style-type: none"> - Worn or deformed tip. - Incorrect use: wrong angle of application or inadequate pressure on tooth. - Presence of fluid or moisture between handpiece and cord. | <ul style="list-style-type: none"> - Replace tip. - Consult tip manufacturer's instructions for use. - Wipe electrical contacts dry. |
| No piezoelectric output. | <ul style="list-style-type: none"> - Incorrect tip tightening. - Defective connector contact. - Broken wire in handpiece cord. | <ul style="list-style-type: none"> - Tighten with wrench. - Clean cord contacts. - Return to Aseptico customer service. |
| Water leak between hand-piece and cord. | <ul style="list-style-type: none"> - Worn sealing gasket (O-ring) in handpiece. | <ul style="list-style-type: none"> - Replace sealing gasket (O-ring). |

SYMBOL DEFINITIONS:

| | | | |
|---|---|---|------------------------------------|
|  | Type B Equipment |  | Footswitch |
|  | Class II Equipment |  | Water Input |
|  | Attention, consult accompanying documents |  | Manufacturer |
|  | Dangerous Voltage |  | Fuses |
|  | WEEE Compliant |  | Alternating current |
|  | Coolant Control | IPX1 Protect Against Dripping Water | |
|  | Temperature Limitation |  | Protective earth (ground) |
|  | Humidity Limitation |  | Authorized European Representative |
|  | Atmospheric Pressure Limitation | | |

SPECIFICATIONS:

Control Console Dimensions: 4.6" x 7.2" x 3.4"
(11.7cm x 18.3cm x 8.6cm)

Handpiece & Handpiece Terminal
Dimensions: 7.35" L x 0.84" Dia
(18.7cm x 2.1cm)

Weight: 2.1 lbs (0.95 kg)

Power Source: 120V or 230V at 50Hz/60Hz
AC Dual Voltage Auto-Switching

Fuse: 0.25A, 250V Rated, Slo-Blow Type

Current Rating: 0.25A

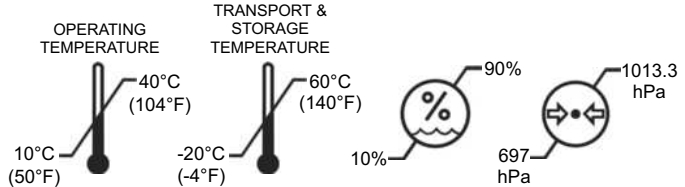
Max Power Consumption: 20W

Vibration Frequency: 25 to 32 kHz

Scaler Coolant Flow: 0ml to 150ml per minute (at 55 psi water pressure), dependent
on Tip selection.

Water Pressure: 14.5 to 73 psi (1 to 5 bar)

Environmental Conditions: Operating Temperature: 10° to 40° C (50° to 104° F)
Transport/Storage Temperature: -20° to 60° C (-4° to 140° F)
Relative Humidity: 10 to 90% non-condensing
Altitude: 0 to 3048 meters (0 to 10,000 feet)



LIABILITIES

Aseptico does not assume any liabilities arising from the misuse of its products under the following circumstances:

- Failure to follow Aseptico installation instructions.
- Maintenance or repair by persons not authorized by Aseptico.
- Use on an electrical installation that does not comply with local electrical codes or prescriptions of standards:
 - **NF— EN 60601-1 (IEC 601-1)** and
 - **NF— EN 60601-1-2 (IEC 601-1-2)**
- Uses other than those specified in this manual.

Aseptico reserves the right to modify this unit and/or operation and maintenance manual without prior notice.

WARRANTY

Aseptico warrants its products against defects in material or workmanship for a period of one (1) year, from date of original invoice. Some handpieces are warranted for one year under the same conditions. Other handpieces and expendable components, such as air turbines and light bulbs, are covered by shorter warranty periods, or have no warranty. Aseptico's sole obligation under product warranty is (at its sole option and discretion) to repair or replace any defective component or product in part or whole. Aseptico shall be the sole arbiter of such action.

In the event of alleged defect under warranty, the purchaser is to notify Aseptico's Customer Service Department promptly. Customer Service will provide instructions, usually directing that the product be returned for service. Shipment to Aseptico and the cost thereof is always the responsibility of the purchaser.

Accidental misuse, inappropriate installation, or failure to perform directed maintenance voids the warranty.

Aseptico does not assume, under this warranty, any risks or liabilities arising from the clinical use of its products, whether or not such use involves coincidental utilization of products manufactured by others.

NOTE: In the interest of serving our customers more efficiently, customers receiving service on non-warranted repairs are expected to accept charges that are less than \$250.00 without further notification.



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P/N 420468
Rev. A
ECO 11831
08/2009

Printed In The USA